

## Instructions for Use Evita XL / Evita XL Neo



#### WARNING

For a full understanding of the performance characteristics of this medical device, the user should carefully read these Instructions for Use before use of the medical device. Intensive Care Ventilator Software 7.0n The **title of the main chapter** in the header line helps with orientation and navigation.

The **instructions for the user** combine text and illustrations, providing a comprehensive overview of the system. The information is presented as sequential steps of action, allowing the user to learn directly how to use the device.

The **text** provides explanations and instructs the user step-by-step in the practical use of the product, with short, clear instructions in easy-to-follow sequence.

- 1 Consecutive numbers indicate steps of action, with the numbering restarting with "1" for each new sequence of actions.
- Bullet points indicate individual actions or different options for action.
- Dashes indicate the listing of data, options or objects.
- (A) Letters in parentheses refer to elements in the relevant illustration.

The **illustrations** show the relationship between the text and the device. Elements mentioned in the text are highlighted. Unnecessary details are omitted.

Schematic renderings of screen images guide the user and allow to reconfirm actions performed. The actual screen images differ in look or in configuation.

A Letters denote elements referred to in the text.

#### Typografic conventions

Any text shown on the screen and any labeling on the device are printed in bold and italics, for example, *PEEP*, *Air* or *Apnoea ventilation*.

The "greater than" symbol > indicates the navigation path in a dialog window, for example, **System Setup** > **Therapy** > **Alarm Limits**. In this example, **System Setup** represents the dialog window title, **Therapy** represents a horizontal tab and **Alarm Limits** a vertical tab.

These Instructions for Use apply to *Evita XL* and *Evita XL Neo* as well as to Evita 4 and Evita 2 *dura* with the *Evita XL* option.

In the existing Instructions for Use, only the term "*Evita XL*" is used.

### Trademarks

- Evita  $XL^{\mathbb{R}}$
- AutoFlow<sup>®</sup>
- SmartCare<sup>®</sup>

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#### Definitions

#### WARNING

A WARNING statement provides important information about a potentially hazardous situation which, if not avoided, could result in death or serious injury.

#### CAUTION

A CAUTION statement provides important information about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or in damage to the medical device or other property.

#### NOTE

A NOTE provides additional information intended to avoid inconvenience during operation.

### **Abbreviations and Symbols**

Please refer to the sections "Abbreviations" on page 24 and "Symbols" on page 28 for explanations. This page has intentionally been left blank.

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## For Your Safety and that of Your Patients

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#### Strictly follow these Instructions for Use Accessories

#### WARNING

Any use of the medical device requires full understanding and strict observation of all portions of these Instructions for Use. The medical device is only to be used for the purpose specified under "Intended Use" on page 14 and in conjunction with appropriate patient monitoring (see page 9). Strictly observe all WARNING and CAUTION statements throughout these Instructions for Use and all statements on medical device labels.

#### Maintenance

#### WARNING

The medical device must be inspected and serviced regularly by properly trained service personnel.

Repair of the medical device may also only be carried out by properly trained service personnel.

Dräger recommends that a service contract be obtained with DrägerService and that all repairs also be carried out by them. Dräger recommends that only authentic Dräger repair parts be used for maintenance. Otherwise the correct functioning of the medical device may be compromised.

See chapter "Maintenance".

#### WARNING

Only the accessories indicated on the list of accessories 9038780 (1st edition or higher) have been tested and approved to be used with the medical device. Accordingly it is strongly recommended that only these accessories be used in conjunction with the specific medical device. Otherwise the correct functioning of the medical device may be compromised.

#### Not for use in areas of explosion hazard

#### WARNING

This medical device is neither approved nor certified for use in areas where combustible or explosive gas mixtures are likely to occur.

#### Safe connection with other electrical equipment

#### CAUTION

Danger to the patient

Electrical connections to equipment which is not listed in these Instructions for Use should only be made following consultation with the respective manufacturers.

#### Networking

Device combinations approved by Dräger (see Instructions for Use of the individual devices or units) meet the requirements set forth by the following standards:

- IEC 60601-1 (EN 60601-1) Medical electrical equipment
   Part 1: General requirements for safety
- IEC 60601-1-1 (EN 60601-1-1) Medical electrical equipment Part 1-1: General requirements for safety Collateral standard: Safety requirements for medical electrical systems
- IEC 60601-1-2 (EN 60601-1-2) Medical electrical equipment
   Part 1-2: General requirements for safety
   Collateral standard: Electromagnetic
   compatibility; Requirements and tests
- IEC 60601-1-4 (EN 60601-1-4) Medical electrical equipment
   Part 1-4: General requirements for safety
   Collateral standard: Programmable electrical medical systems

If Dräger devices or units are connected to other Dräger devices or third-party devices and the resulting combination is not approved by Dräger, the correct functioning of the devices may be compromised. The operator is responsible for ensuring that the resulting system meets the requirements set forth by the above standards.

Strictly follow Assembly Instructions and Instructions for Use for each networked device.

#### **Patient safety**

The design of the medical device, the accompanying literature, and the labeling on the medical device take into consideration that the purchase and use of the medical device are restricted to trained professionals, and that certain inherent characteristics of the medical device are known to the trained operator. Instructions, warnings and caution statements are limited, therefore, largely to the specifics of the Dräger design.

This publication excludes references to various hazards which are obvious to a medical professional and operator of this medical device, to the consequences of medical device misuse, and to potentially adverse effects in patients with abnormal conditions. Medical device modification or misuse can be dangerous.

#### CAUTION

Danger to the patient.

Individual measured values and monitoring parameters should not be used as the sole basis for therapeutic decisions.

#### **Patient monitoring**

The operators of the medical device are responsible for choosing appropriate safety monitoring that supplies adequate information on medical device performance and patient condition.

Patient safety may be achieved through a wide variety of means ranging from electronic surveillance of medical device performance and patient condition, to simple, direct observation of clinical signs.

The responsibility for the selection of the best level of patient monitoring lies solely with the medical device operator.

#### **Functional Safety**

The essential performance consists in controlled and monitored patient ventilation with user-defined settings for the monitoring functions

- minimum breathing gas flow,
- maximum airway pressure,
- minimum and maximum O2 concentration in the breathing gas,

or, if a set limit is exceeded, by an appropriate alarm. The medical device is equipped with basic safety features to reduce the possibility of patient injury while the cause of an alarm is remedied.

## **General WARNINGS and CAUTIONS**

The following WARNINGS and CAUTIONS apply to general operation of the medical device. WARNINGS and CAUTIONS specific to subsystems or particular features appear with those topics in later sections of these Instructions for Use or in the Instructions for Use of any product being used with this device.

#### WARNING

*Evita XL* must only be used under the supervision of qualified medical personnel in order to provide immediate corrective action in the case of a malfunction.

#### WARNING

Do not use the device in conjunction with flammable gases or anesthetics - fire hazard!

#### WARNING

Do not use *Evita XL* in hyperbaric chambers. Device malfunction may result, with the risk of patient injury.

#### WARNING

Do not use in conjunction with magnetic resonance imaging (MRI)! Device malfunction may result, with the risk of patient injury.

#### WARNING

Using high frequency electrosurgery equipment, defibrillators, or short-wave treatment equipment in the vicinity of the device may interfere with its operation and pose a risk of patient injury.

#### WARNING

Never use flammable medications (e.g. on the basis of isopropyl alcohol) or other substances based on flammable solvents in the breathing system. Always provide adequate ventilation when using flammable substances for disinfection. Flammable vapors may otherwise ignite when calibrating the flow sensor and destroy the flow sensor in the process. Fire hazard!

#### WARNING

Do not place any container with liquids (e.g., infusion bottle) above or on top of *Evita XL*. Any liquid getting into the device could prevent *Evita XL* from working properly or damage it and endanger the patient.

#### WARNING

When using *Evita XL* in combination with other products and when using *Evita XL* during transportation within the hospital the person responsible for operating the device must ensure that all equipment is adequately secured in accordance with the relevant basic requirements of Directive 93/42/EEC.

#### CAUTION

The touch active area of the screen has a sensitive surface. Damage to the surface will lead to malfunctions when using the touch active operating elements. Do not operate the touch active area of the screen with sharp objects. Do not damage the screen surface of *Evita XL* when cleaning or during transportation within the hospital.

#### NOTE

The risk of endangering the patient by software errors is minimized as follows:

A software development process is applied that conforms with the state-of-the-art technology and international standards for medical devices.

## Note on EMC/ESD risk for the device function

General information on electromagnetic compatibility (EMC) pursuant to international EMC standard IEC 60601-1-2:

Electromedical devices are subject to special precautionary measures concerning electromagnetic compatibility (EMC) and must be installed and put into operation in accordance with the EMC information provided on page 232.

Portable and mobile RF communications equipment can affect medical electrical equipment.

#### WARNING

Connector pins with an electrostatic discharge (ESD) warning sign should not be touched and no connections should be made between these connectors without implementing ESD protective measures. Such precautionary procedures may include antistatic clothing and shoes, the touch of a ground stud before and during connecting the pins or the use of electrically isolating and antistatic gloves. All staff involved in the above shall receive instruction in these ESD precautionary procedures.

#### **Sterile Accessories**

#### CAUTION

Do not use sterile-packaged accessories if the packaging has been opened, is damaged or there are other signs of non-sterility. Disposable articles may not be reprocessed and resterilized.

Reuse, processing or sterilization can lead to a failure of the medical devices and cause injuries to patient.

#### **Ventilation Monitoring**

The monitoring integrated in *Evita XL* monitors the following parameters:

- Airway pressure, PAW
- Expiratory minute volume, MV
- Inspiratory tidal volume, VTi
- Inspiratory O2 concentration, FiO2
- Inspiratory breathing gas temperature, T
- End-expiratory CO<sub>2</sub> concentration, etCO<sub>2</sub>
- Apnea time, TApnoea
- Respiratory rate, fspn

Changes in these parameters may be caused by:

- acute changes in the patient's condition
- incorrect settings and user error
- device fault conditions
- failure of power and gas supplies

In case of malfunction of any of the built-in monitoring, a substitute must be provided in order to maintain an adequate level of monitoring.

During O2 Therapy, the monitoring functions of *Evita XL* are restricted.

## Back-up ventilation with an independent manual ventilation device

If a fault is detected in *Evita XL*, so that its lifesupport functions are no longer assured: start ventilation using an independent ventilation device without delay – if necessary with PEEP and/or an increased inspiratory O2 concentration (e.g., with manual breathing bag MR 100).

## Application

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## Intended Use

*Evita XL* – Long-term ventilator for intensive care.

For adults, children, and neonates with a minimum body weight of 3 kg (6.6 lbs).

For premature infants with a minimum body weight of 0.5 kg (1.1 lbs) with the NeoFlow option.

*Evita XL Neo*\* – Long-term ventilator for intensive care.

For children, neonates, and premature infants with a minimum body weight of 0.5 kg (1.1 lbs).

For adults with the Adult option.

\* In some countries only available under the name *Evita XL*.

### **Environment of Use**

In the intensive care ward or in the recovery room. During transportati

During transportation of ventilated patients within the hospital.

### Scope of Delivery and Available Options

#### Evita XL without options

*Evita XL* for the Adult and Pediatric patient categories

*Evita XL Neo* for the Neonatal and Pediatric patient categories

*Evita XL* and *Evita XL Neo* can be supplemented with options, see page 16.

#### **IPPV** ventilation mode

Intermittent Positive Pressure Ventilation

Volume-controlled ventilation with fixed mandatory minute volume.

With the functions:

 CPPV (Continuous Positive Pressure Ventilation) Controlled ventilation with continuous positive airway pressure

- PLV (Pressure Limited Ventilation)
   Pressure limited constant-volume ventilation
- AutoFlow<sup>®</sup> for automatic setting of inspiratory flow and Pinsp
- IRV (Inversed Ratio Ventilation) Ventilation with inversed inspiration/expiration ratio

#### SIMV ventilation mode

Synchronized Intermittent Mandatory Ventilation

Combines mechanical (volume-controlled) ventilation with spontaneous breathing.

With the functions:

PLV (Pressure Limited Ventilation)
 Pressure limited constant-volume ventilation

 AutoFlow<sup>®</sup> for automatic setting of inspiratory flow and Pinsp

#### SB (Spontaneous Breathing)

Spontaneous breathing at ambient pressure

#### **BIPAP\*** ventilation mode

**Biphasic Positive Airway Pressure** 

Pressure-controlled ventilation combined with free spontaneous breathing during the complete breathing cycle and adjustable pressure support on CPAP level.

#### CPAP ventilation mode

Continuous Positive Airway Pressure

Spontaneous breathing with positive airway pressure.

#### ASB ventilation mode

Assisted Spontaneous Breathing

Pressure-supported spontaneous breathing.

#### **ILV** ventilation mode

Independent Lung Ventilation

Differential, synchronized ventilation with two Evita devices, independently ventilating each lung.

#### Apnoea ventilation additional setting

If apnea occurs while Apnea Ventilation is activated, the system automatically switches over to mandatory ventilation.

In the Adult and Pediatric patient categories, the device switches over to volume-controlled ventilation.

In the Neonatal patient category, the device switches over to pressure-controlled ventilation.

If apnea occurs, *Evita XL* sounds an alarm after the preset alarm period (TApnoea /<sup> $\mathbf{x}$ </sup>) and starts apnea ventilation.

#### O<sub>2</sub> Therapy

Continuous flow application with adjustable O2 concentration and flow for the O2 Therapy function for patients with independent breathing and using oxygen masks.

#### DC power pack\*\*

Integrated DC power pack supplying *Evita XL* with power from two internal 12 V lead-acid gel batteries for a maximum of 10 minutes.

For uninterrupted operation in case of mains power failure, *Evita XL* automatically switches over to the internal batteries.

#### MEDIBUS

Software protocol for the transfer of data between *Evita XL* and an external medical or non-medical device (e.g., patient monitors or computers for data management systems) via an RS 232 interface, see "MEDIBUS for Dräger Intensive Care Devices" (9028329).

#### Automatic gas switch-over

In the event of a gas failure, *Evita XL* automatically switches over to the other gas supply available.

#### Other features

- Standard display of waveforms, measured values, and PV-Loop
- Three waveforms can be displayed on-screen at the same time
- PV-Loop

Evita XL offers limited configurability.

<sup>\*</sup> Trademark Used Under Licence

<sup>\*\*</sup> Optional on Evita 4 and Evita 2 *dura* with the *Evita XL* option

### Options

*Evita XL* displays the options available in the device, see "Displaying available options" on page 158.

#### **PPS\* (Proportional Pressure Support)**

Differential proportional support of spontaneous breathing in cases of pathological compliance and/or resistance.

#### NIV – Non-Invasive Ventilation

Patients with spontaneous breathing are supported with non-invasive ventilation therapies using a nasal or face mask.

Choice between mask ventilation and ventilation of intubated patients.

#### **NIV Plus**

In addition to NIV:

- Evita XL detects the patient's inspiration and switches automatically from Standby Plus mode to non-invasive ventilation
- When the mask is removed, patient flow is reduced until the mask is put back on
- Extended leakage compensation

#### LPP\*\* (Lung Protection Package)

- Recruitment Trends
- Low Flow PV-Loop

#### Adult

Standard on Evita XL

Addition of Adult patient category to Evita XL Neo

#### ATC (Automatic Tube Compensation)

Compensation of tube resistance

Can be used with all ventilation modes.

- \* Not available for the US market
- \*\* Not available on Evita XL Neo

#### **XL Ventilation Plus**

Additional ventilation modes:

- APRV (Airway Pressure Release Ventilation) Spontaneous breathing on two independentlyadjustable pressure levels with long time ranges.
- MMV (Mandatory Minute (Volume) Ventilation) Spontaneous breathing with automatic adjustment of mandatory ventilation to the patient's minute volume requirement. With the functions:
  - PLV (Pressure Limited Ventilation) Pressure limited constant-volume ventilation.
  - AutoFlow<sup>®</sup> for automatic setting of inspiratory flow and Pinsp
- BIPAP Assist (Biphasic Positive Airway Pressure Assisted)
   Pressure-controlled, assisted ventilation

#### **XL Monitoring Plus**

Additional loops, trends, and diagnostic functions

- Intrinsic PEEP measurement
   Determination of Intrinsic PEEP and measuring trapped volume (air trapping)
- Occlusion pressure measurement Evaluation of patient's breathing drive during spontaneous breathing
- Negative Inspiratory Force NIF Measurement of the patient's maximum inspiratory effort following expiration
- RSB
   Rapid Shallow Breathing

#### **XL Configuration Plus**

Additional configuration possibilities for:

- Measured values
- Buttons in the main menu bar
- Screen configurations
- Customized values and settings

#### SmartCare / PS\*

Knowledge-based system for clinical guidelines.

For the use of SmartCare / PS the following options are additionally required:

- CapnoPlus
- ATC
- XL Monitoring Plus
- XL Configuration Plus

#### NeoFlow

Standard on Evita XL Neo

Neonatal mode with basic flow

Extends the range of uses of *Evita XL* to include long-term ventilation of premature infants through addition of the  $\triangle$  **Neo.** patient category.

In the **\****Paed.* and **<sup>A</sup>***Neo.* patient categories, a proximal neonatal flow sensor is used for flow monitoring.

#### NurseCall

- Nurse call for connection to central hospital alarm system
- Connection option for Remote Pad

#### CapnoPlus

Proximal CO2 measurement

#### Evita Link

Interface card

Output of measured values, status messages and alarm messages to connected equipment for monitoring, documentation, or further processing.

#### External battery for DC power pack

Extension of integrated DC power pack with external 12 V or 24 V lead-acid gel batteries.

For uninterrupted operation for max. 2 hours in case of mains supply failure

For supplying power during transportation within the hospital

#### **Quiet Power Failure Alarm\*\***

*Evita XL* can be equipped with a quiet version of the power failure alarm for use in particularly quiet clinical environments.

#### **Quiet loudspeaker**

*Evita XL* can be equipped with a quiet version of the alarm enunciator for use in particularly quiet clinical environments.

#### **Remote Pad**

Remote control of routine functions

#### Insp. term. PIF

Adjustable criterion for the termination of ASB breaths

<sup>\*</sup> Not available on Evita XL Neo

<sup>\*</sup> Not available for USA, Canada, Japan, China, Taiwan, Korea, and Brazil

# Monitoring in accordance with the options used

- Airway pressure, PAW
- Expiratory minute volume, MV
- Inspiratory tidal volume, VTi
- Inspiratory O2 concentration, FiO2
- Inspiratory breathing gas temperature, T
- Apnea time, TApnoea
- Respiratory rate, fspn
- End-expiratory CO2 concentration, etCO2

## System Overview

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## **Control Panel**



- A Audio paused 2 min. or Alarm Silence key for suppressing the alarm tone for two minutes
- I Touch-sensitive screen
- B **√** Alarm Limits key for setting alarm limits
- C **Wentilator Settings** key for setting ventilation mode and ventilation parameters
- D Unassigned key for future functions
- E Sensor Parameter key for calibrating sensors and for switching monitoring on or off
- F System Setup key for configuring device functions
- G () *Start/Standby* key for switching between operation and standby mode
- H Rotary knob for selecting and confirming settings

### **Front Connections**



- A ⊡ Gas exhaust port (EXHAUST – NOT FOR SPIROMETERS)
- B Flow sensor
- C Flow sensor flap
- D Expiratory valve with expiratory connector port (GAS RETURN)
- E Latch for expiratory valve
- F Nebulizer connection
- **G** Inspiratory connector port (GAS OUTPUT)

H Locking screw for protective cover (behind it: O2 sensor and ambient air filter)

## **Back Panel**



- A Power switch with protective flap
- B COM 2, COM 3 ports for RS 232, 2 CAN interfaces and analog interface (optional)
- **C** Connection [] for Remote Pad (optional)
- **D** Connection 4 for nurse call (optional)
- E Cooling-air filter
- F Connection for neonatal flow sensor (optional)
- **G** ILV socket for the connecting cable for independent lung ventilation with two ventilators
- H Connection for O2
- I Connection for medical air (Air)

- J Temp 🖈 socket for temperature sensor
- K CO2 🖈 socket for CO2 sensor (optional)
- L COM 1 RS 232C port for RS 232 interface, e.g., for printer
- M Rating plate (not visible) on the left-hand side panel
- N AC fuses
- O Connector for power cable
- P DC socket
- **Q** Fan

### Evita XL Mobil trolley



- A Evita XL
- B Handle
- C Trolley column
- D Hose hook
- E Humidifier holder (optional)
- F Alignment aid
- G Universal bracket with standard rail (optional)
- H Dual castors with locking brakes, 4 x

## Abbreviations

| Description   |
|---|
| Option for Evita XL Neo so that the device can be used for adults   |
| Display alarm causes and remedies   |
| Acknowledge alarm message   |
| Airway Pressure Release Ventilation. Spontaneous breathing at continuous positive airway pressure with short-term pressure release  |
| Assisted Spontaneous Breathing. Pressure-supported spontaneous breathing  |
| Automatic Tube Compensation   |
| Special function for automatic regulation of the inspiratory flow during volume-controlled ventilation, enables free deep breathing   |
| Biphasic Positive Airway Pressure. Ventilation mode for spontaneous breathing at<br>continuous positive airway pressure with two different pressure levels                              |
| Biphasic Positive Airway Pressure Assisted. Ventilation mode for assisted ventilation with continuous positive airway pressure with two different pressure levels                       |
| Breaths per minute  |
| Body Temperature, Pressure, Saturated<br>Measured values based on the conditions of the patient lungs: body temperature 37 °C<br>(98.6 °F), water-vapor saturated gas, ambient pressure |
| Compliance  |
| Controller Area Network   |
| Critical Closing Pressure   |
| CO2 production [L/min]  |
| Degree of tube compensation (set value)   |
| Chronic Obstructive Pulmonary Disease   |
| Continuous Positive Airway Pressure. Spontaneous breathing with positive airway pressure  |
| Spontaneous breathing with positive airway pressure and pressure support  |
| Continuous Positive Pressure Ventilation<br>Controlled ventilation with continuous positive airway pressure   |
| Static compliance   |
| Intermittent Positive End-Expiratory Pressure (expiratory sigh)   |
| Set value for PApnoea relative to PEEP  |
| Set value for PASB relative to PEEP   |
| Pressure support on the tube  |
| End-inspiratory pressure  |
| Electromagnetic compatibility   |
| End-expiratory CO2 concentration  |
|   |

| Abbreviation          | Description  |
|-----------------------|--|
| Ext. Flow             | External Flow  |
| f                     | Respiratory rate in bpm  |
| Fail to cycle         | Breathing cycle failure. Ventilator detects no inspiration   |
| fApnoea               | Respiratory rate setting for apnea ventilation   |
| FeCO2                 | Expiratory CO2 concentration   |
| FiO2                  | Inspiratory O2 concentration   |
| Flow                  | Set value of the maximum inspiratory flow<br>In the Neonatal patient category:<br>Displayed real-time waveform, patient flow, with leakage correction (measured value) |
| FlowAssist            | Adjustable pressure assistance in proportion to patient flow   |
| Flowbf                | Basic flow (system setting), see "Power Characteristics" on page 210   |
| Flowexp               | Expiratory flow, without leakage correction  |
| Flowinsp              | Inspiratory flow, without leakage correction   |
| Flowleak              | Current leakage flow   |
| Flowout               | Flow through the expiratory valve during inspiration   |
| Flowpatient           | Inspiratory/expiratory flow, with leakage correction (measured value)  |
| fmand                 | Mandatory mechanical portion of overall respiratory rate   |
| fspn                  | Spontaneous breathing portion of overall respiratory rate  |
| ftotal                | Total respiratory rate (fmand + fspn)  |
| ftrig.                | Triggered portion of overall respiratory rate  |
| I:E                   | Ratio of inspiratory : expiratory time   |
| IBW                   | Ideal Body Weight  |
| ID arnothing          | Internal tube diameter (set value)   |
| ILV                   | Independent Lung Ventilation<br>Ventilation with two ventilators, one for each lung  |
| insp. flow            | Inspiratory Flow   |
| Insp. term.<br>PIF[%] | Criterion for the termination of ASB breaths, % of maximum inspiratory flow (Peak Inspiratory Flow)  |
| IPPV                  | Intermittent Positive Pressure Ventilation<br>Intermittent ventilation with positive pressure  |
| IPPVAssist            | Trigger-assisted Intermittent Positive Pressure Ventilation  |
| IRV                   | Inversed Ratio Ventilation. Ventilation with inversed ratio of inspiration/expiration  |
| KG                    | Body weight [kg]   |
| KTube                 | Tube coefficient   |
| LIP                   | Lower Inflection Point   |
| LUST                  | List-controlled universal interface driver program   |
| MEDIBUS               | Dräger communication protocol for medical devices  |
| MMV                   | Mandatory Minute (Volume) Ventilation  |
|                       |  |

| Abbreviation | Description  |
|--------------|--|
| MV           | Minute volume, without leakage correction (measured value)   |
| MVleak       | Leakage minute volume – mean leakage flow, averaged over inspiration and expiration (measured value)                                   |
| MVPatient    | Expiratory measured minute volume, with leakage correction   |
| MVspn        | Spontaneously breathed minute volume   |
| NeoFlow      | Option for Evita XL so that the device can be used for neonates  |
| NIF          | Negative Inspiratory Force. Maximum inspiratory effort   |
| NIV          | Non-Invasive Ventilation, mask ventilation   |
| NTC          | Negative Temperature Coefficient   |
| NTPD         | Normal Temperature, Pressure, Dry  |
| O2           | Set value for inspiratory O2 concentration [Vol.%]   |
| O2↑ suction  | Oxygenation program active   |
| P0.1         | 100 ms occlusion pressure  |
| PApnoea      | Set value for inspiratory pressure with apnea ventilation  |
| Pasb         | Set value for ASB pressure support   |
| Paw          | Airway pressure at the Y-piece (measured value)  |
| PEEP         | Positive End-Expiratory Pressure   |
| PEEPi        | Intrinsic PEEP   |
| Pexp         | Airway pressure in the expiratory breathing hose   |
| Phigh        | Set value of the upper pressure level in APRV  |
| Pinsp        | Set value of the upper pressure level in BIPAP   |
| Pleth        | Plethysmogram  |
| Plimit       | Set value of maximum applied airway pressure during measuring maneuver Low Flow PV-Loop  |
| Plow         | Set value for the lower pressure level in APRV   |
| PLV          | Pressure Limited Ventilation   |
| Pmax         | Maximum airway pressure  |
| PMC          | Point of Maximum Curvature   |
| Pmean        | Mean airway pressure at the Y-piece (measured value)   |
| Pmin         | Minimum airway pressure  |
| Ppeak        | Peak pressure  |
| Pplat        | End-inspiratory airway pressure  |
| PPS          | Proportional Pressure Support. Spontaneous breathing with adjustable pressure<br>support proportional to patient flow and tidal volume |
| PS           | Pressure Support   |
| Pstart       | Initial airway pressure during measuring maneuver Low Flow PV-Loop   |
| PTrach       | Pressure in the trachea  |

| Abbreviation   | Description   |
|----------------|---|
| QRS            | Intraventricular excitation propagation in the ECG  |
| R              | Resistance  |
| Ramp           | Pressure rise time for ASB  |
| RecrTrend      | Recruitment Trend. Breath-based trend   |
| Rexp           | Flow resistance of the expiratory breathing hose  |
| Rinsp          | Flow resistance of the inspiratory breathing hose   |
| RSB            | Rapid Shallow Breathing. Quotient of spontaneous breathing rate and tidal volume  |
| SB             | Spontaneous Breathing. Spontaneous breath at ambient pressure   |
| SIMV           | Synchronized Intermittent Mandatory Ventilation   |
| SpO2           | Functional oxygen saturation  |
| т              | Inspiratory breathing gas temperature   |
| TApnoea        | Apnea alarm delay time  |
| Taue           | <ul> <li>Respiratory time constant, expiratory:</li> <li>with activated leakage compensation = leakage-compensated tidal volume / leakage-compensated maximum expiratory flow</li> <li>with deactivated leakage compensation = expiratory tidal volume / maximum expiratory flow</li> </ul> |
| Tdeconnect     | Delay time for alarm limit <b>Paw</b> $$ (airway pressure low) in Mask (NIV) application mode   |
| Te             | Expiratory time   |
| TGI            | Tracheal Gas Insufflation   |
| Thigh          | Time for the upper pressure level in APRV   |
| Ti             | Inspiratory time  |
| Ti max         | Set value of the inspiratory time with non-invasive ventilation in CPAP/ASB ventilation mode  |
| Tinsp          | Set value of the inspiratory time   |
| Tlow           | Time for the lower pressure level in APRV   |
| Tmax [SeC]     | Maximum period of measuring maneuver Low Flow PV-Loop   |
| Trigg. [L/min] | Set value for the flow trigger threshold  |
| UIP            | Upper Inflection Point  |
| UMDNS          | Universal Medical Device Nomenclature System  |
| Vds            | Serial dead space   |
| Vlimit         | Set value of maximum applied volume during measuring maneuver Low Flow PV-Loop  |
| Vol.Assist     | Adjustable pressure support in proportion to tidal volume   |
| VT             | Set value for tidal volume  |
| VTApnoea       | Set value for tidal volume of apnea ventilation   |
| VTASB          | Inspiratory tidal volume during an ASB breath   |
| VTe            | Expiratory tidal volume   |

| Abbreviation | Description   |
|--------------|---|
| VTi          | Inspiratory tidal volume  |
| Vtrap        | Volume trapped in the lung by Intrinsic PEEP and not exhaled during subsequent expiration |

## Symbols

| Symbol                          | Name                | Description   |
|---------------------------------|---------------------|---|
| A                               | Audio paused 2 min. | Suppress audible alarm for 2 minutes  |
| $\Delta$                        | Alarm Silence       | Suppress audible alarm for 2 minutes  |
| ¥/*                             | Alarm Limits        | Set alarm limits  |
| <u>}</u>                        | Ventilator Settings | Settings for ventilation  |
| ц<br>С                          | Sensor Parameter    | Sensor calibration  |
|                                 | System Setup        | Configuration   |
| $\bigcirc$                      | Start/Standby       | Ventilation/standby   |
| A                               | Main                | Back to main screen   |
|                                 |                     | Select different sets of measured values  |
| $\bigcirc$                      | Freeze              | Freeze  |
| <u></u>                         |                     | Display alarm limit in trend  |
|                                 |                     | Real-time waveforms, loops, and trends  |
|                                 |                     | Lower alarm limit   |
| _/                              |                     | Upper alarm limit   |
|                                 |                     | Nebulizer active  |
| кę.                             | Mask (NIV)          | Non-Invasive Ventilation. Mask ventilation  |
|                                 | Active Humid.       | Breathing gas humidifier  |
| -)))·                           | HME/ Filter         | Heat and Moisture Exchanger   |
| =•                              |                     | Mains supply  |
| <del>[+ -</del> ]               | Ext.                | External battery  |
| + -                             | Int.                | Internal batteries  |
| <b>↓</b> ,>))<br><b>→</b> □ □ □ |                     | Quiet power failure alarm. Alarm unit which emits a reduced-volume tone in the event of a power failure |

| Symbol              | Name    | Description  |
|---------------------|---------|--|
| <b>_</b> 4          |         | Insert flow sensor   |
| Ô                   |         | Direct access to settings, locked  |
| ப்                  |         | Direct access to settings, unlocked  |
| Exp.                |         | Expiratory outlet port (GAS RETURN)  |
| Insp.               |         | Inspiratory port (GAS OUTPUT) <sup>1)</sup>  |
| $\supseteq$         |         | Gas exhaust port (EXHAUST – NOT FOR SPIROMETER) <sup>1)</sup>  |
| *                   | Adult   | Adult patient category   |
| ¥                   | Paed.   | Pediatric patient category   |
| Â                   | Neo.    | Neonatal patient category  |
| ?*                  |         | Supplementary information  |
| Х                   |         | Close dialog window  |
| ✓                   |         | Mark for a correct result during Device Check  |
|                     |         | Caution! Observe important safety-relevant information and precautionary measures in the Instructions for Use. |
| []i]                |         | Consult Instructions for Use!  |
| $\overline{\Delta}$ |         | Protective grounding   |
| *                   |         | Protection class type B  |
| *                   |         | Protection class type BF   |
| •                   |         | Spontaneous breathing activity by the patient  |
|                     |         | Remote Pad, remote control   |
| 4                   |         | Nurse Call   |
| +                   |         | Tube compensation activated  |
|                     |         | Select screen configuration  |
| $\Rightarrow$       |         | Save screen configuration  |
| $\bigcirc$          |         | Mask out screen configuration  |
| 7                   | Country | Country-specific settings  |
| 8                   |         | Do not reprocess   |
|                     |         | ESD warning symbol   |
| X                   |         | Disposal information   |
|                     |         | Counter weight 8415824 in EvitaMobil trolley   |

| Symbol       | Name | Description   |
|--------------|------|---|
|              |      | Requirements to avoid <i>Evita XL</i> with the EvitaMobil trolley tipping over  |
|              |      | Requirements to avoid <i>Evita XL</i> with the Evita XL Mobil trolley tipping over  |
| $\bigotimes$ |      | Label to identify surfaces on the device where there is an increased risk of the device tipping over when pressing, leaning against, etc. |

1) additionally, depending on ventilator hardware version

## **Operating Concept**

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## **Control Panel**

The control panel is characterized by the small number of operating elements, its clear layout and easy operation.

Its main elements are:



- A Large screen with all the information and controls needed for ventilation.
- **B** Fixed function keys beside the screen for rapid access to major functions.
- **C** Rotary knob for selecting and confirming settings on the screen.

## **Buttons with a Fixed Function**

The following buttons are available for rapid access to important screen functions:



- A A dudio paused 2 min. or A larm Silence key for suppressing the alarm tone for two minutes
- **B √**<sup>▲</sup> **Alarm Limits** for setting the alarm limits.
- C **Ventilator Settings** for setting the ventilation mode and ventilation parameters
- D Unassigned key for future functions
- E Sensor Parameter for calibrating the sensors and for switching monitoring on or off
- F System Setup for configuring the device functions
- G () *Start/Standby* for selecting the operating mode or standby mode

#### Screen

#### Main

The Main screen displays all the most important ventilation data at a glance.

| Α               |   |                  |
|-----------------|---|------------------|
|                 |   |                  |
| P -             |   |                  |
| D               |   | С                |
|                 |   |                  |
|                 |   |                  |
| • D • • • • • • | E | <mark>،</mark> F |

- **A** Header bar with the following fields:
  - Alarms, messages, and instructions for the user, see page 120
  - Therapy status: Therapy type (ventilation or O2 Therapy), ventilation mode, and additional settings
  - Patient category, see page 75
- B Monitoring area with waveforms, loops, trends, and measured values, see "Measured Values, Graphics, and Trends" on page 125. The display can be configured, see "Selecting screen display" on page 153.
- C Main menu bar with buttons for opening dialog windows and activating functions, see page 33.
- **D** Therapy bar with therapy controls for the ventilation parameters of the active ventilation mode and its additional settings, see page 34.
- E Field for device status with type of humidification
- F Power supply display

#### Main menu bar

The main menu bar contains fixed and freely configurable buttons. Touching a button opens the corresponding dialog window or activates the corresponding function.

#### **Fixed buttons**

iiù, iiù, iiù for selecting a different set of measured values in the field for measured values.

(f) Main for selecting the main screen.

*Data ...* for displaying all measured values, the logbook, or trends on an additional card.

**Special Procedure ...** for selecting additional functions, e.g., medication nebulization or oxygenation for bronchial suctioning.

#### Freely configurable buttons

Additional buttons for directly accessing functions or dialog windows can be configured, See "Defining additional buttons in the main menu bar" on page 154.

#### **Dialog windows**

Dialog windows consist of one or several pages which are displayed by touching the corresponding horizontal or vertical tab. Dialog windows contain elements for operating the device and inform the user of current settings. Dialog windows can be opened by pressing a key or by touching a button in the main menu bar.



- A Dialog window title
- **B** Tab touch the relevant tab to open a page.
- C Setting assistance field
- **D** Button for accessing additional information (if applicable)
- **E** Button for closing the dialog window

#### Therapy bar

The therapy bar on the main screen contains the therapy controls for the active ventilation mode.



F Therapy controls

### Therapy controls

The therapy controls are used to set the ventilation parameters.

Therapy controls are contained in the therapy bar of the active ventilation mode and in the dialog window for specifying the ventilation settings.



A Therapy controls

#### Start-up settings

Arrows ( $\blacktriangleright$ ) beside the scales on the therapy controls indicate the start-up values valid when *Evita XL* is switched on. These values can be configured as required by the hospital. See "Setting start-up values for ventilation" on page 159.

#### Locking

The therapy controls in the therapy bar can be locked against the ventilation parameters being changed by accident. See "Locking therapy controls" on page 156.

#### **Controls and color scheme**

The following controls are available to the user:

- Tabs
- Therapy controls
- Buttons

The touch-sensitive screen controls are used in a similar way as real keys and rotary knobs:

- Touching these controls with a fingertip is equivalent to pressing a key or taking hold of a knob.
- Settings are made and confirmed by turning and pressing the rotary knob.

Colors are used to indicate the status of the screen controls:

| gray       | = | not available                |
|------------|---|------------------------------|
| yellow     | = | ready for use                |
| pale green | = | available, but is not active |
| dark green | = | available and is active      |

#### For buttons:



- 1 to select = touch,
- 2 the button turns yellow,
- 3 to confirm = press rotary knob,
- 4 the button turns pale green or dark green.

#### For therapy controls:



- 1 to select = touch,
- 2 the therapy control turns yellow,
- **3** to set = turn rotary knob,
- 4 to confirm = press rotary knob,
- 5 the therapy control turns pale green or dark green.

## Exceeding the limit set for a ventilation parameter

When the limit set for the parameter has been reached, *Evita XL* displays a message.

• To exceed the set limit, press the rotary knob.

The user can now exceed the set limit.

If the maximum limit set for a parameter has been reached, e. g., in relation to other parameters, it is not possible to exceed the set limit.

• Press rotary knob. *Evita XL* adopts the maximum value that can be set.

## Setting ventilation parameters on the main screen

On the main screen in the therapy bar:

**1** Touch the therapy control.

*Evita XL* opens the **Ventilator Settings** dialog window. The selected therapy control (A) is yellow and can be directly set.



- 2 To set the value, turn the rotary knob.
- **3** Press the rotary knob to confirm the value.

The color of the therapy control changes to dark green. The new setting is now effective.

### **Direct setting of ventilation parameters**

When a ventilation parameter is set directly, the changes to a setting are immediately effective. The user can see the effect of the modified setting on the patient at once. The finally chosen setting does not have to be confirmed again.

The following ventilation parameters can be set directly:

- PEEP in all ventilation modes
- Pinsp in BIPAP and BIPAP Assist
- Phigh and Plow in APRV

Direct setting can be performed in the **Ventilator Settings** dialog window.

O2 cannot be set directly.

#### Setting ventilation parameters directly

- 1 Touch the relevant therapy control.
- 2 Press the rotary knob and hold down for approx. 3 seconds.

The therapy control turns dark green with a yellow edge. The direct setting function is now active.



**3** To set a value, press and turn the rotary knob.

The set value is immediately effective.

After releasing the rotary knob, the parameter can still be set directly:

• Press and turn the rotary knob again.

## Exceeding the limit set for a parameter with direct setting

When the limit set for the parameter has been reached, *Evita XL* displays a message.

- 4 Briefly release the rotary knob.
- 5 Press and turn the rotary knob again.

The user can now exceed the set limit.
### Linked setting of ventilation parameters

Linked setting is possible for the following parameters:

- *Pinsp/PEEP* The pressure difference remains constant.
- *Phigh/Plow* The pressure difference remains constant.
- *Tinsp/f* The I:E ratio remains constant.

#### Linking Pinsp/PEEP



- 1 Touch the *Pinsp* (A) or *PEEP* (B) therapy control. The color changes to yellow.
- 2 Touch the Link Pinsp/PEEP button (C).

The therapy control of the other parameter (*Pinsp* or *PEEP*) turns yellow.

- 3 Turn the rotary knob to set the value for *Pinsp* or *PEEP*. The linked value is set correspondingly.
- 4 Press the rotary knob to confirm the value.

Both therapy controls turn dark green.

The linked setting of *Tinsp* and *f* can be performed in the same way.

• Touch the *I* : *E* constant button (D).

The linked setting of *Phigh* and *Plow* is possible in APRV and can be performed in the same way.

# Direct and linked setting of ventilation parameters

Direct and linked setting is possible for *Pinsp/PEEP* and for *Phigh/Plow*.

#### Linking and directly setting Pinsp/PEEP



- 1 Touch the *Pinsp* (E) or *PEEP* therapy control (F).
- 2 Touch the Link Pinsp/PEEP button (G).
- **3** Press the rotary knob and hold down for approx. 3 seconds.

The therapy controls turn dark green with a yellow edge. The direct setting function is now active.

4 To set a value, press and turn the rotary knob.

The linked value is set correspondingly. The values are immediately effective.

After releasing the rotary knob, the parameters can still be set directly:

• Press and turn the rotary knob again.

# Exceeding the limit set for a parameter with direct setting

When the limit set for a parameter has been reached, *Evita XL* displays a message.

- 5 Briefly release the rotary knob.
- 6 Press and turn the rotary knob again.

The user can now exceed the set limit.

Direct and linked setting of *Phigh* and *Plow* is possible in APRV and can be performed in the same way.

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# Safety Information for Preparation

#### WARNING

Before each use, reprocess the device and all the accessories according to the information in the Instructions for Use, see page 183. Hospital infection control regulations must be observed!

#### WARNING

To prevent the ventilator from tipping over, it must not be tilted more than 5°! Otherwise, high risk of the ventilator tipping over.

## Safety Information for the Trolley

#### WARNING

In the event of non-observance of the permitted loads and centers of gravity, there is a high risk of the ventilator tipping over. Observe the maximum loads and centers of gravity.

#### CAUTION

Do not use the trolley in the event of visible damage e. g., damaged castors! Call DrägerService.

#### CAUTION

Attach devices securely to the trolley. Check to make sure they are secure. Risk of damage to the device or personal injury!

#### CAUTION

Do not lean or press against surfaces identified by the label 🚯 The trolley may tip over.

#### WARNING

Do not place any container with liquids (e.g., infusion bottle) above or on top of *Evita XL*. Any liquid getting into the device could prevent *Evita XL* from working properly or damage it and endanger the patient.

#### CAUTION

Lock all the castors and check correct operation of the brakes when parking the trolley.

### Preparation of the Evita XL Mobil Trolley

The necessary accessories are to be installed by trained service personnel in accordance with the respective mounting instructions:

- Humidifier holder
- Universal bracket
- External battery
- Breathing air compressor
- Cylinder holders for compressed gas cylinders

# Requirements to avoid *Evita XL* with the Evita XL Mobil trolley tipping over:



#### WARNING

To prevent the ventilator from tipping over, it must not be tilted more than 5°! Otherwise, high risk of the ventilator tipping over.

#### WARNING

Do not move the Evita XL Mobil trolley with *Evita XL* any faster than normal walking pace. There is a higher risk of it tipping over at thresholds, on uneven floors, and on ramps. Reduce speed.

- Do not load the base plate of the Evita XL Mobil trolley with more than 60 kg (132 lbs) (e.g., with compressed gas cylinders, breathing air compressor, external battery).
- Do not load the console of the Evita XL Mobil trolley with more than 50 kg (110 lbs). E.g., through:
  - device,
  - patient monitor with monitor holder and
  - hinged arm.
- Do not load the humidifier holder (optional) or universal bracket (optional) with more than 10 kg (22 lbs), e.g., with breathing gas humidifier or medication nebulizer.

#### WARNING

The maximum total load for the trolley is 100 kg (220 lbs). Otherwise there is a higher risk of it tipping over.

# Attaching universal bracket with standard rail to trolley

The universal bracket with standard rail (optional) is attached to the trolley.



- 1 Fully unscrew clamping screw (A).
- 2 Engage right-hand side of the bracket at the right-hand side of the rail (B). Ensure that the nose of the universal bracket is located completely behind the alignment aid.
- 3 Align the bracket (C) horizontally and press the left-hand side of the bracket against the left-hand side of the column.
- 4 Tighten the clamping screw (A). Ensure that the nose of the universal bracket is located completely behind the alignment aid.
- 5 Check that the universal bracket is securely in place.

#### Adjusting height of universal bracket

- 1 Unscrew the clamping screw (A).
- 2 Adjust the height of the universal bracket (C).
- 3 Align the universal bracket horizontally.
- 4 Tighten the clamping screw (A) again.

### Attaching humidifier holder to trolley

The humidifier holder (optional) can be attached to the left- or right-hand side of the trolley column. Attachment of the humidifier holder to the righthand side is shown here.

1 Turn the clamping screw (A) counterclockwise until the humidifier holder can be inserted in the groove of the trolley column (B).



- 2 Turn the clamping screw (A) clockwise until the humidifier holder is firmly engaged in the groove.
- **3** Move the standard rail (C) to the required position.

#### Attach the accessory to the standard rail

Fasten accessory, e.g., breathing gas humidifier or medication nebulizer, to the standard rail. Observe maximum load!

# Attaching compressed gas cylinders to trolley

Only available with cylinder holder option

#### WARNING

Attach compressed gas cylinders securely to the trolley with the two Velcro straps. Otherwise, tilt stability is not assured.

#### WARNING

Have the height of the upper holder adapted to the height of the relevant compressed gas cylinders by trained service personnel. Adjust the height so that the upper halves of the compressed gas cylinders are held by the Velcro straps. Otherwise, tilt stability is not assured.

#### WARNING

The length of the Velcro straps must be appropriate for the diameter of the compressed gas cylinders in order to ensure correct fastening. If necessary, have appropriate Velcro straps fitted by trained service personnel. Otherwise, secure fastening is not assured.

Compressed gas cylinders with the following dimensions can be fitted:

Diameter: 80 to 160 mm (3.15 to 6.3 inch)

Length: 420 to 870 mm (16.54 to 34.25 inch)

#### CAUTION

Not every combination of diameter and length can be fitted.

The compressed gas cylinders with mounted pressure reducers must not touch the console of the trolley.

The max. diameter allowed is 178 mm (7.0 inch), if the foot of the compressed gas cylinder completely is seated solidly on the base plate of the lower holder or is formed as a hemisphere.

- **1** Place the cylinders in the mounts on the trolley.
- 2 Secure each cylinder with two Velcro straps (A).



#### CAUTION

Position compressed gas cylinders with pressure reducers in such a way that the pressure reducers may not be damaged during transport. The base plate of the trolley serves as impact protection. If the compressed air cylinders are too big, particular care must be taken.

### Placing the device



 Place device on the console and lock it in place, you should hear the snap of the latching device. The device must be firmly fixed on both sides of the trolley.

### Preparation of the EvitaMobil Trolley

The necessary accessories are to be installed by trained service personnel in accordance with the respective mounting instructions:

- Humidifier holder
- External battery
- DC connecting cable
- Breathing air compressor
- Cylinder holders for compressed gas cylinders
- Monitor holder with counter weight kit

#### WARNING

Monitors with monitor holders should only be installed on *Evita XL* when the EvitaMobil trolley is equipped with a counter weight mounted under the base plate or when a breathing air compressor is mounted. High risk of the ventilator tipping over!

If EvitaMobil is equipped with the counter weight, there is a label (part no. 8415824) on the front side of the base plate.



# Requirements to avoid *Evita XL* with the EvitaMobil trolley tipping over:



#### WARNING

To prevent the ventilator from tipping over, it must not be tilted more than 5°! Otherwise, high risk of the ventilator tipping over.

#### WARNING

Do not move the EvitaMobil trolley with *Evita XL* any faster than normal walking pace. There is a higher risk of it tipping over at thresholds, on uneven floors, and on ramps. Reduce speed.

- Do not load the base plate of the EvitaMobil trolley with more than 50 kg (110 lbs) (e.g., with compressed gas cylinders, breathing air compressor).
- Do not load the console of the EvitaMobil trolley with more than 40 kg (88 lbs) (e.g., with the device and hinged arm).

- When a monitor holder is fitted to *Evita XL* and a counter weight is mounted under the EvitaMobil trolley base plate or a breathing air compressor is mounted, the console of the EvitaMobil trolley may be loaded with up to 50 kg (110 lbs) (e.g., with the device, patient monitor, and hinged arm).
- Do not fix more than one breathing gas humidifier on the humidifier holder (optional).

### Placing the device



- Place device on the console and lock it in place, you should hear the snap of the latching device. The device must be firmly fixed on both sides of the trolley.
- Depending on the number of cylinder holders fitted, a maximum of 4 compressed gas cylinders can be placed on the holders and secured with Velcro straps.
- Attach the breathing gas humidifier to the humidifier holder (optional). Observe the breathing gas humidifier's Instructions for Use.

## **Positioning the Control Panel**

 Do not place control panel upright or lean against any objects, do not lay it on its front. When changing the control panel, lay it on its back.

#### Mounting the control panel to the device

 Hang control panel into its mounts on Evita XL until it clicks into position.



Tilting the control panel:

• Press segments (A) on the right and left and, at the same time, tilt control panel to the desired position.

#### Mounting the control panel to a wall rail



1 Press segments (A) on the right and left, and tilt control panel fully downwards.



- 2 Hold down release buttons (B) on the left and right and lift control panel from its mounts on *Evita XL*.
- **3** Uncoil the cable as far as necessary.
- 4 Mount the control panel to the wall rail.



5 To lock the control panel in place, pull down the latch (located beneath the bracket (C)) and turn it in the direction of the wall rail.

# Preparation of Evita XL for Ventilation

### Installing the expiratory valve



- 1 Press down the segments on the right and left and tilt the control panel (A) upwards.
- 2 Push expiratory valve (B) into the mount until it clicks into position. Check that it is properly engaged by gently pulling on the port.

#### Mounting the flow sensor



1 Push connector socket (A) all the way to the left.



- 2 Place flow sensor (B) into its mount with the connector facing towards the device and push into the socket, as far as it will go.
- 3 Push flow sensor to the right and into the rubber lip seal of the expiratory valve, as far as it will go.

#### Flow sensor flap

The flap helps to prevent the formation of condensation in the flow sensor when using an active breathing gas humidifier and when heated expiratory hoses are connected.

#### Inserting the flow sensor flap



 Slightly press together the spring-loaded arms of the flap (A) at the side and push into the mount on the device.

#### NOTE

The flow sensor flap can be removed for transport purposes.

#### NOTE

The flow sensor and the expiratory valve can only be inserted or removed when the flap is open. Keep the flap closed during ventilation.

#### Opening the flow sensor flap



The flap swivels downwards.

#### Installing an O2 sensor capsule

- When using the system for the first time
- When the display reads O2 measurement inop. !!!
- When calibration can no longer be performed
- 1 Ensure device is placed in standby mode or is switched off completely.
- 2 Press down the segments on the right and left and tilt the control panel upwards.



- **3** Turn inspiratory port (A) to the left.
- 4 Use coin to loosen screw and remove protective cover (B).
- 5 Loosen the two knurled screws and remove lid from the sensor housing (C).
- 6 Remove old sensor capsule (D) and insert new sensor capsule. The sensor end with the circular tracks must be visible.
- 7 Close the sensor housing (C) securely with the two knurled screws.
- 8 Screw protective cover (B) back in place.
- **9** Dispose of the used O2 sensor capsule, see "Disposal of O2 sensor" on page 202.

• Pull the flap forwards.

# Safety information on using HMEs, bacterial filters, and breathing circuits

The use of additional components in the breathing system can significantly increase inspiratory and expiratory breathing resistance and exceed standard requirements. Examples: Inspiratory or expiratory filters, HME (heat and moisture exchanger), coaxial hoses.

*Evita XL* is designed to minimize the patient's work of breathing. Operation does not require inspiratory or expiratory bacterial filters.

#### WARNING

The use of bacterial filters and HMEs therefore requires particular care and monitoring by the user. Especially during medication nebulization and humidifying, the resistance of an expiratory filter may increase gradually.

A higher breathing resistance leads to increased work of breathing and greater trigger effort during assisted ventilation. Under unfavorable conditions, this can lead to an undesirable intrinsic PEEP. This can be recognized by the fact that the expiratory flow does not return to zero at the end of expiration. If the PEEP is unacceptably high, this is indicated by an alarm. The measured PEEP is then approx. 8 mbar (8 cmH2O) above the set PEEP. Check and replace the bacterial filter and HME if they are the cause of the PEEP alarm.

A breathing resistance in the patient connection cannot be monitored directly by the ventilator. For this reason:

- Determine inspiratory and expiratory breathing resistance in the breathing circuit before ventilation in standby mode by means of the airtight check (see page 68).
- Check the condition of the patient and the device's measured values for volume and resistance frequently.
- Observe the Instructions for Use for the HMEs, filters and coaxial hose systems in use.

#### WARNING

Do not use an HME together with a medication nebulizer or breathing gas humidifier. This can lead to a greater breathing resistance.

### Connecting a breathing gas humidifier

 Set Evita XL to breathing gas humidifier, see "Entering the Humidification Type" on page 65.

#### WARNING

Do not use a heat and moisture exchanger simultaneously with a breathing gas humidifier as there may be a risk of increased breathing resistance due to condensation.

#### WARNING

Do not place any container with liquids (e.g., infusion bottle) above or on top of *Evita XL*. Any liquid getting into the device could prevent *Evita XL* from working properly or damage it and endanger the patient.

#### Breathing gas humidifier Aquapor EL

For ventilating adults and children in the **Adult** patient category

Upward from 100 mL tidal volume VT

1 Prepare Aquapor EL in accordance with its Instructions for Use.



- 2 Attach Aquapor EL to the humidifier holder (A) with rail clamp and tighten screws.
- 3 Insert elbow connector (B) into Aquapor EL.
- 4 Insert double connector (C) into elbow connector.
- 5 Fill the Aquapor EL tank (D) to the upper filling mark with sterile distilled water.

After changing the breathing gas humidifier:

• Perform an airtight check, see "Performing the Airtight Check" on page 68.

# Breathing gas humidifier "Fisher & Paykel MR 850"

For ventilating adults, children, and neonates

1 Prepare "Fisher & Paykel MR 850" humidifier in accordance with its Instructions for Use.



2 Attach breathing gas humidifier (E) to mount under the device with rail clamp and tighten screws.

After changing the breathing gas humidifier:

• Perform an airtight check, see "Performing the Airtight Check" on page 68.

### **Connecting breathing circuit**

#### WARNING

Do not use antistatic or conductive breathing hoses. The use of such materials increases the risk of an electric shock for the patient and the risk of fire breaking out in oxygenenriched atmospheres.

IEC 60601-2-12 Appendix AA and EN 794-1 Appendix AA: Using antistatic and/or electrically conductive materials in the breathing system of lung ventilators is not regarded as a contribution to higher safety. In fact, using such materials increases the risk of an electric shock for the patient.

Depending on the position of the device in relation to the patient bed, the hinged arm can be mounted to either side of the device.



Attachment on left-hand side:

- **1** Turn both ports (A) to the left.
- 2 Swivel breathing gas humidifier (B) to the left.

For the following descriptions it is assumed that the breathing circuit has been attached on the left-hand side.

#### Breathing circuit for adults and children

#### Adult patient category

Upward from 100 mL tidal volume VT



- 1 Attach hinged arm (A) to the rail on the left-hand side of the ventilator and tighten screws.
- 2 Connect breathing hoses of appropriate lengths to the ports (B). Observe the required hose lengths (indicated in meters).
- 3 Install water traps (C) in vertical position.
- 4 Connect Y-piece (D), with the rubber sleeve of the Y-piece on the inspiratory side.
- 5 Insert the Y-piece in the opening of the hinged arm (E).

After changing the breathing circuit:

• Perform an airtight check, see "Performing the Airtight Check" on page 68.

#### Breathing circuit for infants and neonates

Patient categories **\* Paed.** and ≜ **Neo.** Up to 300 mL tidal volume **V***T* 



- 1 Attach hinged arm (F) to the rail on the left-hand side of the ventilator with rail clamp and tighten screws.
- 2 Connect breathing hoses of appropriate lengths. Observe the required hose lengths (indicated in meters).
- **3** Install water trap (G) in vertical position.

After changing the breathing circuit:

• Perform an airtight check, see "Performing the Airtight Check" on page 68.

#### Installing a temperature sensor



- 1 Push sensor (A) as far as it will go into the rubber sleeve on the inspiratory side of the Y-piece. Align Y-piece so that the sensor is at the top, in order to avoid condensation in the sensor.
- 2 Attach sensor cable with hose clips (B).



3 Insert plug of the temperature sensor into the Temp ★ socket (C) on the back panel of the device.

#### Installing a neonatal flow sensor

Patient categories A Neo. and, if applicable, \* Paed.

- Prepare breathing circuit, see "Breathing circuit for infants and neonates" on page 53.
- Only the neonatal flow sensor (8411130) should be used.

#### WARNING

Do not use the Y-piece with integrated flow sensor (8410185), as this flow sensor operates with a different characteristic curve and would give inaccurate flow measurements.



- 1 Plug the Y-piece (A) into the breathing hoses.
- 2 Insert the neonatal flow sensor (B) in the Y-piece.
- 3 Connect the plug (C) of the flow sensor cable to the flow sensor.
- 4 Route the cable along the breathing hoses to the device.



5 Plug the flow sensor connector into the socket (D) on the back panel of the device and tighten with the knurled screws.



6 Connect the test lung (E) complete with tracheal tube CH 12 (F) and connector to the patient side of the neonatal flow sensor.

#### Replacing the insert of the neonatal flow sensor

If *Evita XL* displays the message **Neo. flow** *measurement inop. !!!* or **Neo. flow** *measurement inop. !*, the insert of the neonatal flow sensor must be replaced.



- 1 Disconnect the plug of the flow sensor cable (G) from the neonatal flow sensor.
- 2 Press the buttons (H) on both sides while pulling the flow sensor insert (J) out of its housing.
- 3 Insert new flow sensor insert (J) until it engages. The two markings (I) must line up.
- 4 Reconnect the plug of the flow sensor cable (G).

5 Calibrate the neonatal flow sensor, see page 137.

#### Installing a CO<sub>2</sub> cuvette and CO<sub>2</sub> sensor

Only available with the CapnoPlus option.

Observe "Information on cuvettes used" on page 139.



- Attach cuvette (A) to the patient connection of the Y-piece, with the cuvette windows facing to the side.
- 2 Push CO<sub>2</sub> sensor (B) onto the cuvette, with the cable towards the device.



Insert plug of the CO2 sensor into the CO2 (1)
 (C) socket on the back panel of the device.

### Connecting to the power supply

The mains voltage must correspond to the voltage range indicated on the rating plate.

Either: 220 V to 240 V

or: 100 V to 127 V

• Insert plug into the mains power socket.

For operation with DC power pack and external battery (DC power pack option):

• Connect optional external battery with cable.

#### WARNING

Observe chapter "Mains Power Supply / DC Power Supply" on page 108. Otherwise the readiness for operation of the DC power pack is not ensured.

Precautions when using a power strip for auxiliary equipment:

#### WARNING

Connecting other devices to the same extension power strip may cause the leakage current to the patient to increase beyond permissible values in the event of grounding conductor failure. In this case, the risk of electric shock cannot be safely excluded.

# Behavior of *Evita XL* in the event of temporary interruption of power supply

e. g. when hospital backup power supply is activated.

Without the optional DC power pack:

During the interruption of the power supply, *Evita XL* will emit a continuous audible alarm for at least 2 minutes (power failure alarm). If *Evita XL* has been operating for less than 15 minutes, this time might be shorter.

*Evita XL* tolerates power interruptions of less than 10 milliseconds – without affecting ventilation in any way. If power is interrupted for longer than 10 milliseconds the device will restart, performing a

brief self test of approximately 8 seconds. Ventilation is then continued with the current settings. The current settings are permanently saved.

If the lower alarm limit for minute volume has been set, the *MV low !!!* alarm will be active until the measured value has again exceeded the lower alarm threshold.

With the optional DC power pack:

 See "Mains Power Supply / DC Power Supply" on page 108.

#### WARNING

Connect other devices, e.g., a printer or a computer, to the interfaces only while *Evita XL* is properly grounded via its power cable and a grounded wall outlet or via the grounding pin on the back panel of the device. Otherwise, the risk of electric shock cannot be safely excluded.

### Connecting to the gas supply

#### Central gas supply



- Screw on the compressed air hose (A) to the Air inlet connector and the O<sub>2</sub> compressed gas hose (B) to the O<sub>2</sub> inlet connector on the back panel of *Evita XL*.
- 2 Connect the plugs to the central gas supply wall outlets.

#### WARNING

The compressed gases must be dry and free from dust and oil. Gas pressure must be 3 to 6 bar. Otherwise, the correct functioning of the device is not assured. Observe "Operating Data" on page 219.

#### WARNING

Connect the compressed gas hoses correctly at the back panel of *Evita XL*. Connect compressed air hose only to compressed air (Air) inlet and O<sub>2</sub> compressed gas hose only to oxygen (O<sub>2</sub>) inlet. Otherwise inspiratory flow delivery and flow measurement will not be accurate.

When supplying air-gas via a breathing air compressor, observe the Instructions for Use of the breathing air compressor.

Gas supply via compressed gas cylinders

#### WARNING

In the case of gas supply via compressed gas cylinders (Air and/or O<sub>2</sub>) with pressure reducers, the technical data for the gas supply shall be observed. See chapter Technical Data, "Operating Data" on page 219.

#### WARNING

In accordance with EN 794-1 and IEC 60601-2-12, pressure reducers according to EN 738 and ISO 10524 shall be used if a ventilator is supplied with medical gases from an O2 or compressed air gas cylinder. The pressure reducers have to limit the gas pressure to max. 10 bar (145 psi) in the case of a fault. Using incorrect pressure reducers will endanger the patient.

#### Changing from wall outlet to gas cylinder

If an uninterrupted change of the gas supply is required:

 First disconnect and reconnect one gas type, then disconnect and reconnect the second gas type.

If only one gas type (O2 or Air) is available:

• Connect only the available gas type at the back panel of *Evita XL*.

The inspiratory O<sub>2</sub> concentration is equivalent to the O<sub>2</sub> concentration of the gas type connected (O<sub>2</sub> or Air).

#### WARNING

When operating with only one gas type (O<sub>2</sub> or Air) the inspiratory O<sub>2</sub> concentration cannot be changed. The O<sub>2</sub> concentration is equivalent to the O<sub>2</sub> concentration of the gas type connected. If only Air is connected, the inspiratory O<sub>2</sub> concentration is 21 Vol.% O<sub>2</sub>. If only O<sub>2</sub> is connected, the inspiratory O<sub>2</sub> concentration is 100 Vol.% O<sub>2</sub>.

# **Connecting Evita Remote**

Only available with the Remote Pad option.

 Installation and activation of the Evita Remote kit should only be performed by trained service personnel.

For remote control of the device via the Remote Pad for parallel, remote operation of the following LED and key functions:



- A Red indicator light for signaling high-priority (Warning) alarm messages
- **B** Yellow indicator light for signaling mediumpriority (Caution) and low-priority (Note) alarm messages
- C A or A \* key for silencing the audible alarm for approx. 2 minutes
- D *Alarm Reset* key for acknowledging highpriority alarm messages
- E **Web.** key for starting and stopping medication nebulization

- F O2 ↑ Suction key for pre-/postoxygenation when performing bronchial suctioning
- G *Insp. hold* key for starting and holding manual insufflation
- H *Exp. hold* key for extending and holding an expiration

The function of the indicator lights and keys is equivalent to those of the respective control elements on the *Evita XL* front panel and is described in the relevant chapters of these Instructions for Use.

#### **Connecting Evita Remote**



- Insert connector of the remote control pad cable into the socket (I) on the back panel of *Evita XL*. The connector may be plugged or unplugged at any time without affecting ventilator function.
- 2 Attach Remote Pad holder to a wall rail and tighten.

<sup>\*</sup> Depending on the Remote Pad used.



3 Insert Remote Pad into its holder from the top.

#### Observe automatic check at power-up

- When connecting the remote control pad to an operating device
- When switching device on with the remote control pad connected.
- Do not press any keys on the remote control pad.

All lights in the Remote Pad will light up for 5 seconds:

- Red indicator light
- Yellow indicator light
- Yellow indicators in the keys

*Evita XL* now checks the remote control pad. In case of a fault, an alarm message will be displayed, see "Alarm – Cause – Remedy" on page 166.

# **Connecting Nurse Call**

Only available with the NurseCall option.

With the nurse call, high-priority (Warning) alarm messages are transmitted to a central hospital alarm system.

#### WARNING

Connection of the nurse call does not obviate the need to regularly check the monitoring on the device screen. Check on-screen displays regularly.

#### WARNING

A fault in any of the components in the link between nurse call and the central hospital alarm system (e.g., in the electronics for nurse call in the device, in the device's power supply, or in the enunciator of the central hospital alarm system) may result in failure of the nurse call.

 Installation of the nurse call kit should only be performed by trained service personnel. For details of the characteristics, refer to the technical data, page 222.

# Connecting nurse call to the central alarm system

• Have trained service personnel perform the installation of the round 6-pin DIN female connector to the line of the central hospital alarm system.

The hospital connections to the central alarm system typically use only one channel. The ventilator electronics for the nurse call consequently also use only one channel. Connecting nurse call to Evita XL

#### WARNING

Connect nurse call to a central hospital alarm system only while *Evita XL* is properly grounded via its power cable and a grounded mains power socket or via the grounding pin on the back panel of the device. Otherwise, the risk of electric shock cannot be safely excluded.

The nurse call is activated by closing contacts 3-5 whenever an alarm is displayed by *Evita XL*.



- Connect plug to the socket marked <sup>A</sup>
   (A) on the back panel of *Evita XL* and secure with screws.
- 2 Check correct operation of connected nurse call system.

#### Information on nurse call

High-priority (Warning) alarm messages are transmitted to a central hospital alarm system. Medium-priority (Caution) and low-priority (Note) alarm messages are not transmitted. See also "Alarm priorities" on page 120.

The nurse call is also activated when the original enunciator in the device is faulty.

If, in the case of an alarm, the  $\triangle$  **Audio paused 2** *min.*\* key is pressed, the audible alarm on the device and the nurse call are suppressed for 2 minutes.

If in the case of the alarm **Standby activated !!!** the Audio paused 2 min.\* key is pressed, the nurse call is suppressed for 2 minutes. The audible alarm on *Evita XL* continues to sound.

<sup>\*</sup> Depending on the device, the key may also be called *Alarm Silence* 

# Transportation within the hospital / Moving Evita XL with the trolley

#### WARNING

To prevent the ventilator from tipping over, it must not be tilted more than 5°! Otherwise, high risk of the ventilator tipping over. Risk of damage to the device or personal injury!

#### WARNING

In order to support tilt stability during transportation within the hospital, position the control panel on the front of *Evita XL*, see page 47. Otherwise, high risk of the ventilator tipping over. Risk of damage to the device or personal injury!

#### WARNING

Do not place the device on a patient's bed during transportation within the hospital. The device could fall or tip over. Risk of damage to the device or personal injury!

#### WARNING

Do not move the trolley any faster than normal walking pace. There is a higher risk of it tipping over at thresholds, on uneven floors, and on ramps. Reduce speed. Risk of damage to the device or personal injury!

#### WARNING

The maximum total load for the trolley is 100 kg (220 lbs). Otherwise there is a higher risk of it tipping over.

#### CAUTION

Position compressed gas cylinders with pressure reducers in such a way that the pressure reducers may not be damaged during transport. The base plate of the trolley serves as impact protection. If the compressed air cylinders are too big, particular care must be taken.

#### NOTE

When using the cylinder holder option, pay attention to the protruding hose hooks.

In order to assure stability against tipping over, optimize position of accessories:

- Adjust hinged arm to minimum reach.
- Close drawers.
- Keep hoses and cables as close to the trolley as possible.
- Attach breathing gas humidifier to the trolley, not to the device.

To move *Evita XL* mounted on the trolley:

- Release all trolley brakes.
- If nessesary, turn the castors against the direction of motion.
- Grip the handle of the trolley and move.

#### CAUTION

Lock all the castors and check correct operation of the brakes when parking the trolley.

# Starting Up

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| Entering the Humidification Type              | 65             |
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| option  | 69             |
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# Switching on Evita XL

#### WARNING

Switching on Evita XL

If condensation is visible on the device, do not switch on *Evita XL*. Operation with condensation can cause malfunction. Wait until the device has reached ambient temperature and the condensation has dried off. The waiting time is approx. 1 hour per 10 °C (18 °F) temperature rise.

# 

1 Press power switch (A) until it engages.

The protective cover pivots down over the power switch to protect against inadvertent switching off. To switch off, pivot protective cover upwards and press power switch in fully.

The Selftest screen with version no., date, and part no. of the software used is now displayed.



The Selftest is performed automatically. The progress bar indicates the elapsed time of the Selftest.

2 Wait for this test to be completed.

Evita XL then displays the "Start" screen.

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|--|--|-----|

*Evita XL* will start ventilation with the preconfigured settings unless values are changed or standby mode is activated within 30 seconds.

#### Activating standby mode

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3 Touch *Standby* button within 30 seconds and press rotary knob to confirm.

The alarm message *Standby activated !!!* is displayed in the header bar.

To acknowledge this message:

4 Touch *Alarm Reset* button to the right of the message and press rotary knob to confirm.

Evita XL is in standby mode.

#### WARNING

Ventilation does not take place in standby mode! Only switch device to standby mode when there is no patient connected to the device. Otherwise, the patient may be at risk!

# **Entering the Humidification Type**

Selecting the type of breathing gas humidification is only possible in standby or Standby Plus modes.

Prerequisite: The *Start / Standby* dialog window must be open.

1 Touch the *Humidifier* tab (A).



Evita XL offers the following selections:

Active Humid. (B)= Active breathing gas humidifier

HME/ Filter (C) = Heat and Moisture Exchanger

- 2 Touch button corresponding to the type of humidification used. The button turns yellow.
- **3** Press rotary knob to confirm. The button turns green.

*Evita XL* will take into account the selected type of humidification in its calculation of circuit compliance.

The yellow LED in front of the symbol for the selected type of humidification lights up in the status field.

After changing the type of humidification:

4 Perform Airtight Check (D), see page 68.

## **Checking Readiness for Operation**

#### WARNING

Prior to each use of the device on the patient, check readiness for operation of *Evita XL* in order to confirm correct functioning of the device. If a malfunction is detected during the check, do not operate the device! Danger to the patient!

The readiness for operation check consists of the **Device Check**, the **Airtight Check**, and the test of the DC power pack option.

The following test steps are performed:

#### During the Device Check:

- Check for completeness of ventilator assembly
- Test of the back-up alarm (power failure alarm)
- Test of the expiratory valve
- Test of the Air/O2 switchover valve
- Test of the safety valve
- Calibration of the flow sensor
- Calibration of the NeoFlow sensor (optional)
- Calibration of the O2 sensor
- Zero calibration of the CO2 sensor (optional)

#### During the Airtight Check

- Leakage test of the breathing circuit
- Determination of breathing circuit compliance and resistance

During the test of the DC power pack option:

- Changeover test to battery operation

The test results obtained from the Device Check and the calibration and zero-calibration values of the sensors remain stored until the next calibration, even if the device is switched off in the meantime.

If there are changes to the breathing circuit, type of humidification, or patient category after performing the readiness for operation check, the *Airtight Check* must be repeated before using the device.

#### Preparing the adult test lung

For testing the adult breathing circuit, the adult test lung "blue" (part no. 8403201), or the adult test lung "white" (part no. 8401892) can be used.

#### NOTE

The adult test lung "blue" (part no. 8403201) consists of a mask elbow for the Y-piece connector, a catheter connector  $\varnothing$  7 to simulate airway resistance and a 2 L breathing bag to simulate compliance.

#### CAUTION

Do not use overstretched or leaky breathing bags, or test lungs with excessively low compliance. These may generate artifacts during the Device Check.



 Only connect adult test lung with the patient connection of the Y-piece when instructed to do so by *Evita XL*.

# Preparing the pediatric test lung (part no. 8409742)

for use with the pediatric and neonatal breathing circuit

The test lung consists of a tracheal tube CH 12 to simulate airway resistance and a small bellows to simulate compliance.



• Only insert connector in the Y-piece when instructed to do so by *Evita XL*.

#### Performing the Device Check

The Device Check can only be performed in standby mode.

Prerequisite: The *Start / Standby* dialog window must be open.

Touch the *Check* tab (A).



*Evita XL* displays the date and result (B) of the last Device Check and Airtight Check.

• Touch the *Device Check* tab (C).



*Evita XL* displays a list of the individual checks (D). The scope of this list depends on the options available on the ventilator.

No Device Check is possible while the ventilator is performing an automatic calibration of the flow sensor or O<sub>2</sub> sensor.

• In this case, wait until calibration is complete and restart Device Check.

#### Starting the Device Check

• Touch the *Check* button (E).

#### Evita XL performs the following test steps:

#### System

- Fit and passability of expiratory valve
- Fit of flow sensor
- Fit of neonatal flow sensor (optional)
- Type of humidification
- Completeness of breathing circuit
- Fit of temperature sensor

#### Function

- Test of the Air/O2 switchover valve
- Test of the safety valve
- Gas supply
- Test of the back-up alarm (power failure alarm)\*

For devices with the "quiet power failure alarm" option, see "Checking the "quiet power failure alarm" option" on page 69.

#### Sensors

- Calibration of the flow sensor
- Calibration of the neonatal flow sensor (optional)
- Calibration of the O2 sensor
- Zero calibration of the CO<sub>2</sub> sensor (optional, see "Performing CO<sub>2</sub> zero calibration" on page 141)
- Position of the CO<sub>2</sub> sensor (optional)

#### **Device Check procedure**

*Evita XL* guides the user through each test step in a question-and-answer dialog format. Questions are displayed in the information field in the header bar and must be answered by touching the **Yes** or **No** buttons. The instructions for performing the test steps are displayed.

*Evita XL* indicates a correct result with a checkmark ( $\checkmark$ ). Faulty results are marked with *F*. Two dashes (- -) appear if a test step is not performed.

In the event of faulty results F:

- 1 Eliminate the cause of the problem.
- 2 Touch the Repeat button.

Test steps may be skipped by touching the *Next test* button if this is acceptable.

#### **Test results**

The test results obtained from the Device Check and the calibration and zero-calibration values of the sensors remain stored until the next calibration, even if the device is switched off in the meantime.

#### After the Device Check

- Perform an Airtight Check, see page 68.
- Test readiness for operation of DC power pack option, see page 69.

### Performing the Airtight Check

The Airtight Check must be performed after the following actions:

- Device Check
- Change of the breathing circuit
- Change of breathing gas humidification

#### WARNING

If the Airtight Check is not performed, this may lead to the following deviations:

- In the case of volume-controlled ventilation, the applied minute volume for the \*Paed. patient category may be reduced by 10 %, as compliance of the breathing circuit is not correctly taken into account. For the \*Adult patient category, the deviation is less.
- When ventilating with the NeoFlow option, the set PEEP may not be achieved because the resistance of the breathing circuit cannot be correctly taken into account. Without nebulization, the deviation may amount to up to 1 mbar (1 cmH2O). With nebulization using a pneumatic medication nebulizer, the deviation may amount to up to 2 mbar (2 cmH2O).
- Leakages in the breathing circuit are not detected.

The Airtight Check can only be performed in standby mode.

Prerequisite: The *Start / Standby* dialog window must be open.

- Touch the *Check* tab (A).
- Touch the *Airtight Check* tab (B).



#### Starting the Airtight Check

• Touch the *Check* button (C).

#### Evita XL calculates the following values (D)

- Leakage
- Compliance
- Inspiratory resistance
- Expiratory resistance

The current leakage flow is displayed continuously throughout the Airtight Check. A leakage flow of max. 300 mL/min at a pressure of 60 mbar (60 cmH2O) is acceptable.

*Evita XL* uses the calculated breathing circuit compliance to automatically correct volumecontrolled breaths, as well as values measured as part of flow monitoring, see "Flow measurement" on page 260.

When changing the patient category or type of humidification, the device automatically resets the values for circuit compliance and resistance to the default values.

#### Testing the DC power pack option

For information on the DC power pack option, see chapter "Mains Power Supply / DC Power Supply" on page 108.

#### Changeover test to battery operation

• Pull out the power plug.

If the DC power pack option is available, *Evita XL* switches over to internal or external battery mode and does not interrupt operation.

If the DC power pack option is not available, the audible power failure alarm is triggered.

• Plug in the power plug again.

The device switches to mains operation. See "Behavior of Evita XL in the event of temporary interruption of power supply" on page 55.

# Checking the "quiet power failure alarm" option

Devices with the "quiet power failure alarm" option are labeled accordingly on the control panel and on the left-hand side of the device:



Prior to use of *Evita XL*, check that the alarm tone of the quiet power failure alarm can be reliably heard in the intended environment.

The quiet power failure alarm sounds:

- during the Device Check, Back-up alarm test step
- in the event of a power failure and completely discharged internal and external batteries
- in the event of failure of the alarm loudspeaker (continuous power failure alarm tone)

 as a melody of intensive short and long tones when the device is switched on again immediately after being switched off. If there is a delay of approx. 90 seconds between switching the device off and back on again, the melody is not output.

#### WARNING

After each change of environment in which the device is used, check that the "quiet power failure alarm" can be reliably heard. Otherwise, there is a risk that device failure will not be detected in time.

#### **Checking during the Device Check**

The maximum volume of the "quiet power failure alarm" is checked. The check takes place during the Back-up alarm test step.

#### CAUTION

During a power failure, the volume of the alarm tone is reduced after approx. 90 seconds. In loud environments (ambient volume levels of approx. 55 dB(A)) the alarm tone becomes less audible after 90 seconds.

# Check before starting up for the first time and in the case of changed conditions of use

Check whether the volume of the "quiet power failure alarm" is loud enough to be reliably heard for 120 seconds in the event of a power failure. During a power failure, the volume of the alarm tone is reduced after approx. 90 seconds. In noisy environments (ambient volume levels of approx. 55 dB(A)) the alarm tone becomes less audible after 90 seconds.

Operate the device for at least 15 minutes before checking, otherwise the duration of the alarm tone may be less than 120 seconds.

#### CAUTION

Ventilation does not take place during a power failure. Only check power failure alarm when there is no patient connected to the device. For devices without the DC power pack option:

• Unplug the device from the mains power supply during operation. The "quiet power failure alarm" sounds.

For devices with the DC power pack option:

- 1 Unplug the device from the mains power supply during operation.
- 2 If present, unplug the connector for the external battery.
- 3 Wait until the internal battery has become discharged (approx. 10 to 20 minutes with fullycharged internal battery). The "quiet power failure alarm" then sounds.

The alarm tone must be audible for 120 seconds. If the alarm tone cannot be reliably heard, use the standard version of the power failure alarm.

#### WARNING

After each change of environment in which the device is used, check that the "quiet power failure alarm" can be reliably heard for at least 120 seconds. If the "quiet power failure alarm" cannot be reliably heard, there is a risk of device failure not being detected in time.

After successful checking of readiness for operation, *Evita XL* is ready for use.

## Selecting Tube or Mask (NIV) Application Mode

The Mask (NIV) application mode is only available with the NIV or NIV Plus options.

The application mode can only be changed in standby mode.

Prerequisite: The *Start / Standby* dialog window must be open.



- 1 Touch the *Tube / Mask* tab (A).
- Touch the *Tube* (B) or *κ*<sup>(2)</sup>*Mask (NIV)* button (C). The button turns yellow.
- Press rotary knob to confirm. The button turns green.

The selected application mode is now active.

If the *Mask (NIV)* application mode has been selected,

**Mask Ventilation** is displayed in the header bar. See chapter "NIV – Non-Invasive Ventilation" on page 87. This page has intentionally been left blank.
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## **Selecting the Patient**

After switching on *Evita XL*, the user can select between:

- Admitting a new patient
- Using the settings of the previous patient

#### Admitting a new patient

For a new patient, *Evita XL* determines the start-up settings for the ventilation parameters on the basis of the ideal body weight (factory setting) or on the basis of the patient category. The settings can be configured, see page 160. Only when a new patient is admitted, can the body weight or the patient category be changed.

Prerequisite: The *Start / Standby* dialog window must be open. *Evita XL* must be in standby mode.



1 Touch *New Patient* tab (A).

Depending on the patient category:

- 2 Touch *R* Adult (B), *R* Paed. (C), or A Neo. (D) button.
- 3 Touch *Ideal Body Weight* button (E).
- 4 Turn rotary knob to enter the ideal body weight [kg], press rotary knob to confirm.

*Evita XL* determines the tidal volume  $V\tau$  and respiratory rate f on the basis of the ideal body weight and displays these values in the lower part

of the dialog window (F). The other ventilation parameters displayed in the lower part of the dialog window are start-up values.

## Using the settings of the previous patient

Specific patient settings in effect before *Evita XL* was switched off may be restored, including alarm limits, application mode, and ventilator status. Monitoring is always active after the ventilator has been switched on.

Prerequisite: The *Start / Standby* dialog window must be open. *Evita XL* must be in standby mode.



 Touch *Previous Patient* tab (A) and press rotary knob to confirm.

The previous ventilation settings are again effective.

*Evita XL* will not display the *Previous Patient* tab or will not allow it to be selected following a loss of data or removal of a previously used option, therefore preventing previous settings from being restored in this case. Similarly, *Evita XL* prevents restoring previous settings if the configuration was changed before switching off the ventilator so that the previous patient category is no longer available.

## **Starting Ventilation**

#### Before using on the patient

- Check readiness for operation, see page 66.
- Check therapy settings:
  - For alarm limits, see page 123
  - For ventilation modes and ventilation parameters, see page 77

In the Start / Standby dialog window:



• Touch *Start* button (A) and press rotary knob to confirm.

## **Setting Ventilation**

#### **Opening ventilation settings**

The **Ventilator Settings** dialog window can be opened as follows:

• Press **Ventilator Settings** key.

or

• Touch a therapy control in the therapy bar.

*Evita XL* opens the **Ventilator Settings** dialog window.



The page of the active ventilation mode (A) with the **Basic settings** (B) appears by default. The corresponding therapy controls (C) are displayed. The selected therapy control is yellow and can be set. With the **Add. settings** tab (D), the active ventilation mode can be extended by additional parameters.

To select the ventilation modes for start-up, see "Selecting start-up setting of the ventilation modes" on page 159.

The following ventilation modes are factoryconfigured:

- SIMV
- IPPV
- BIPAP
- CPAP/ASB

Other ventilation modes (optional) can be selected via the *more* tab (E):

- MMV
- BIPAP Assist
- APRV
- PPS

The ventilation modes can also be supplemented with the additional settings, see "Additional settings for ventilation" on page 82.

#### Changing the ventilation mode

Prerequisite: The *Basic settings* page must be open in the *Ventilator Settings* dialog window.

1 Touch the relevant tab, e.g., *SIMV* (A). The tab turns yellow.



- 2 If necessary, set the ventilation parameters, see page 78.
- 3 Confirm the ventilation mode by pressing the rotary knob. The color of the tab changes to dark green.

The ventilation mode is active. The settings are effective for the patient.

### Setting the ventilation parameters

Prerequisite: The *Basic settings* page must be open in the *Ventilator Settings* dialog window.



- 1 Touch the relevant therapy control, e.g., (A).
- 2 Turn the rotary knob to set the value.
- 3 Press rotary knob to confirm.

Additional ventilation parameters derived from the ventilation parameter are calculated by *Evita XL* and displayed in the setting assistance field (B).

When the limit set for the parameter has been reached, *Evita XL* displays a message.

## Basic settings for ventilation

For further information on the ventilation modes, see "Ventilation Modes" on page 238.

| Ventilation mode | Ventilation<br>parameters | Dependencies, additional information               |
|------------------|---------------------------|--|
| IPPV             | Vt                        |  |
|                  | Flow                      | only available if AutoFlow is switched off         |
|                  | f                         |  |
|                  | Ramp                      | if AutoFlow is switched on                         |
|                  | Tinsp                     |  |
|                  | O2                        |  |
|                  | PEEP                      |  |
|                  | Pmax                      | if Pmax is configured and AutoFlow is switched off |
| SIMV,            | VT                        |  |
| SIMV/ASB         | Flow                      | only available if AutoFlow is switched off         |
|                  | f                         | if f = 0, the ventilation mode is CPAP/ASB         |
|                  | Tinsp                     |  |
|                  | O2                        |  |
|                  | PEEP                      |  |
|                  | Pmax                      | if Pmax is configured and AutoFlow is switched off |
|                  | ΔPASB                     | is set relative to the PEEP level                  |
|                  | Ramp                      |  |
| MMV,             | VT                        |  |
| MMV/ASB          | Flow                      | only available if AutoFlow is switched off         |
|                  | f                         |  |
|                  | Tinsp                     |  |
|                  | O2                        |  |
|                  | PEEP                      |  |
|                  | Pmax                      | if Pmax is configured and AutoFlow is switched off |
|                  | ΔPASB                     | is set relative to the PEEP level                  |
|                  | Ramp                      |  |

| Ventilation mode | Ventilation parameters | Dependencies, additional information   |
|------------------|------------------------|--|
| BIPAP, Pinsp     |                        | is set as an absolute value  |
| BIPAP/ASB        | f                      | if f = 0, the ventilation mode is CPAP/ASB                                   |
|                  | Tinsp                  |  |
|                  | O2                     |  |
|                  | PEEP                   |  |
|                  | ΔPASB                  | is set relative to the PEEP level  |
|                  | Ramp                   |  |
| BIPAP Assist     | Pinsp                  | is set as an absolute value  |
|                  | f                      |  |
|                  | Tinsp                  |  |
|                  | O2                     |  |
|                  | PEEP                   |  |
|                  | Ramp                   |  |
| APRV             | Thigh                  |  |
|                  | Tlow                   |  |
|                  | Phigh                  |  |
|                  | Plow                   |  |
|                  | O2                     |  |
|                  | Ramp                   |  |
| CPAP/ASB         | O2                     |  |
|                  | PEEP                   |  |
|                  | ΔPASB                  |  |
|                  | Timax                  | only available in the NIV application mode or in the a Neo. patient category |
|                  | Ramp                   |  |
| PPS              | FlowAssist             | Before activating PPS, set alarm limits $P_{AW}$ and $V_T$ , to              |
|                  | Vol.Assist             | protect the patient against pressure and volume trauma.                      |
|                  | PEEP                   |  |
|                  | O2                     |  |

| Ventilation<br>mode | Ventilation parameters | Dependencies, additional information   |
|---------------------|------------------------|--|
| ILVMaster           | VT                     |  |
|                     | Flow                   |  |
|                     | f                      |  |
|                     | Tinsp                  |  |
|                     | O2                     |  |
|                     | PEEP                   |  |
|                     | Pmax                   | if Pmax is configured  |
| ILVSlave            | VT                     |  |
|                     | Flow                   |  |
|                     | f                      | The $f$ setting only takes effect if the devices are inadvertently separated. In order to ensure that the two lung compartments are not ventilated at different respiratory rates in this case, set $f$ on the ILVSIave device to the same value as on the ILVMaster device. |
|                     | Tinsp                  | In slave mode <b>Asynchron</b> , is always effective. In slave modes <b>Synchron</b> and <b>Inverse</b> , only takes effect if the devices are inadvertently separated.  |
|                     | O2                     |  |
|                     | PEEP                   |  |
|                     | Pmax                   | if Pmax is configured  |

## Additional settings for ventilation

The ventilation modes can be combined with additional settings to optimize ventilation.

| Ventilation  | Additional settings |             |             |             |          |      |     |
|--------------|---------------------|-------------|-------------|-------------|----------|------|-----|
| mode         | ATC                 | Apnoea      | Flowtrigger | Inspiratory | AutoFlow | Sigh | PLV |
|              | (optional)          | ventilation |             | termination |          |      |     |
| IPPV         | Х                   |             | Х           |             | Х        | Х    | Х   |
| SIMV         | Х                   | Х           | Х           | Х           | Х        |      | Х   |
| MMV          | Х                   |             | Х           | Х           | Х        |      | Х   |
| ILVMaster    | Х                   |             | Х           |             |          | Х    | Х   |
| ILVSlave     | Х                   |             |             |             |          | Х    | Х   |
| BIPAP        | Х                   | Х           | Х           | Х           |          |      |     |
| BIPAP Assist | Х                   |             | Х           |             |          |      |     |
| APRV         | Х                   | Х           |             |             |          |      |     |
| CPAP/ASB     | Х                   | Х           | Х           | Х           |          |      |     |
| PPS          | Х                   | Х           | Х           |             |          |      |     |

#### Setting additional functions

Prerequisite: The *Ventilator Settings* dialog window must be open.

1 Touch *Add. settings* tab (A).



The additional settings of the active or selected ventilation mode are displayed.

2 Touch the tab for the relevant additional setting, e.g., (B).

The page for setting the associated parameter is displayed.



- **3** Touch therapy control (C).
- 4 Set the value using the rotary knob and confirm.

To switch on an additional setting:

**5** Touch (D) button and press rotary knob to confirm.

To switch off an additional setting:

• Touch (E) button and press rotary knob to confirm.

## Ventilation parameters of the additional settings

For further information, see "Additional Settings" on page 253.

| Additional setting       | Ventilation<br>parameters                              | Dependencies, additional information   |
|--------------------------|--|--|
| ATC                      | Tube (endotracheal<br>or tracheostomy<br>tube)<br>ID Ø |  |
| Apnoea ventilation       | f  | Patient category: <b>* Adult</b> and <b>* Paed.</b>  |
|                          | Vт   | To terminate Apnoea ventilation:   |
|                          |  | • Touch <i>Alarm Reset</i> button and press rotary knob to confirm.  |
| Apnoea ventilation       | f  | Patient category: 🖞 <b>Neo.</b>  |
|                          | $\Delta P$ Apnoea                                      | To terminate Apnoea ventilation:   |
|                          |  | • Touch <i>Alarm Reset</i> button and press rotary knob to confirm.  |
| Trigger /<br>Termination | Trigg. [L/min]   | The flow trigger can only be switched off in IPPV ventilation mode.  |
|                          | Insp. term. PIF[%]                                     | For termination criterion for ASB, see "ASB" on page 250.  |
| AutoFlow                 |  | Always active in A <b>Neo.</b> patient category.   |
|                          |  | Set the alarm limit for $V\pi i$ are fully in order to prevent, for example, overdistension of the lungs in case of rapid changes of compliance. |
| Sigh                     | ∆int.PEEP [mbar]                                       |  |
| PLV                      | Pmax   |  |
| Slave Mode               | Synchron   | Only activate ILV mode when all the parameters for   |
|                          | Asynchron  | ILVMaster and ILVSlave are set.  |
|                          | Inverse  |  |

#### ILV = Independent Lung Ventilation

Synchronized, independent ventilation of the two lung sides with two Evita ventilators that are connected via analog interfaces.

The two devices are operated in master/slave mode. The master device controls the ventilation.

For independent lung ventilation of patients with no spontaneous breathing.

Volume-controlled ventilation with fixed, mandatory minute volume MV, set with tidal volume  $V\tau$  and respiratory rate f of the master device. Activation takes place in the **Ventilator Settings** dialog window on the **Add. settings**: **Slave Mode...**.

## Preparing ILV

If a protective cover is fitted:

Pull protective cover from ILV port.

The following device combinations are possible:

- Evita XL with Evita XL
- Evita XL with Evita 4 / Evita 4 edition
- Evita XL with Evita 2 dura

Requirement for combinations:

Connecting cable part no. 8411794 must be used to connect the devices.

#### CAUTION

Connect ILV connecting cable only while ventilator is switched off.



 Connect the ILV ports of the two devices using connecting cable 8411794.

### Setting the master and slave devices

To perform independent lung ventilation:

- 1 Prepare one device for *ILVMaster* ventilation mode.
- 2 Prepare the other device for *ILVslave* ventilation mode.
- **3** To set ventilation parameters, see "Basic settings for ventilation" on page 79.
- 4 *Slave Mode...* activation, see "Setting additional functions" on page 82.

#### NOTE

Activate *Slave Mode...* only after all parameters for ILVMaster and ILVSIave have been set.

#### Master and slave synchronization

A Master device:

I: E ratio

B Slave device: Synchron

The *I*: *E* ratio of the slave device is determined by the *I*: *E* ratio of the master device. The start of inspiration is synchronized with the inspiration of the master device.

#### C Slave device: Asynchron

The start of inspiration is synchronized with the inspiration of the master device. The end of inspiration (incl. pause time) is determined by the *Tinsp* setting. The *I* : *E* ratio of the slave device is freely selectable.

D Slave device: Inverse

The start of inspiration is synchronized with the start of expiration of the master device and vice versa. The *I* : *E* ratio of the slave device is the inverse of the *I* : *E* ratio of the master device.



## NIV - Non-Invasive Ventilation

If the option NIV or NIV Plus is available, it is possible to select between the ventilation of an intubated patient (*Tube* application mode) and non-invasive ventilation (*A*{*Mask Ventilation* application mode).

In the A **Mask Ventilation** application mode, patients with spontaneous breathing are supported with non-invasive ventilation therapies via a nasal or facial mask.

In the A Mask Ventilation application mode, all ventilation modes except ILV can be selected.

#### Safety information for the use of NIV

#### WARNING

Never ventilate an intubated patient in A Mask Ventilation application mode. Otherwise, the ventilation and monitoring functions are restricted.

#### WARNING

When masks are used, dead space increases. Always follow the mask manufacturer's instructions!

#### WARNING

Apnea cannot always be detected reliably. External SpO2 monitoring must be used.

#### WARNING

After changing from A Mask Ventilation application mode to *Tube* application mode, always check and adjust alarm limits and ventilation settings if necessary to ensure that ventilation is monitored comprehensively.

#### WARNING

Avoid high airway pressures. Risk of aspiration.

#### WARNING

When *Evita XL* is supplied via a breathing air compressor, flow is limited to 30 L/min. In the case of large leakages, this may lead to the *Air supply down !!!* alarm.

If an O2 gas supply is connected, *Evita XL* will switch to this supply until the compressor has regained the required supply pressure. This may lead to an increased FiO2 concentration.

If an insufficient O2 gas supply is connected, ventilation will be interrupted until the compressor has regained the required supply pressure. During this interruption, the patient can breathe spontaneously via the emergency breathing facility.

Restore a sufficient compressed air supply immediately.

#### CAUTION

Automatic tube compensation (ATC) activated in *Tube* application mode will not be in effect in *Mask Ventilation* application mode.

#### **Selecting NIV**

The application mode can only be changed in standby mode. See "Selecting standby mode" on page 106.

Prerequisite: The *Start / Standby* dialog window must be open.

1 Touch *Tube / Mask* tab (A).



- 2 Touch A Mask (NIV) button (B).
- 3 Press rotary knob to confirm.

Evita XL displays the application mode in the header bar:

## Setting ventilation for NIV

Set ventilation mode and ventilation parameters, see "Setting Ventilation" on page 77.

In ventilation mode CPAP/ASB and other ventilation modes combined with ASB, a further therapy control appears: *Timax* (A)



*Evita XL* limits the maximum duration of an ASB breath in the

- Adult patient category to 4 seconds
- + Paed. patient category to 1.5 seconds
- A Neo. patient category to 1.5 seconds
- Set and confirm *Timax* (A) with rotary knob.

### Starting ventilation with NIV

Prerequisite: The *Start / Standby* dialog window must be open.



• Touch *Start* button (A) and press rotary knob to confirm.

## Leakage compensation during NIV

The measured values MV and VTe are not corrected for leakage and therefore read below minute and tidal volumes actually delivered to the patient in case of leakages.

Evita XL compensates leakages

- Adult patient category, up to 30 L/min
- \* Paed. patient category, up to 15 L/min
- A Neo. patient category, up to 7 L/min

It is recommended to use pressure-controlled ventilation in the presence of large leakages.

With the NIV Plus option, large leakages are compensated during pressure-controlled ventilation, see page 90.

## **Monitoring during NIV**

In order to avoid nuisance alarms and to assure proper monitoring, the following settings are required:

- Adjust upper and lower alarm limits for *MV* to the current value.
- Use additional monitoring, e.g., external SpO<sub>2</sub>, if necessary.

The following alarm limits may be deactivated in order to avoid artifacts:

- MV x/, lower alarm limit for minute volume
- VTi\_/<sup>▲</sup>, upper alarm limit for inspiratory tidal volume
- *TApnoea (*, upper alarm limit for apnea monitoring

See "Setting Alarm Limits" on page 123.

#### WARNING

Only switch off alarms if the safety of the patient will not be compromised by the absence of an alarm.

If the lower alarm limit for minute volume or the upper alarm limit for apnea monitoring is switched off, *Evita XL* displays a permanent message in the header bar.

If the upper alarm limit for inspiratory tidal volume is switched off, *Evita XL* displays a message in the header bar for 15 seconds.

A time lag *Tdeconnect* between 0 and 60 seconds can be set for the alarm limit  $PAW \sqrt{}$  (airway pressure low).

The following alarm messages are not displayed by *Evita XL* in  $A^{\text{Amask Ventilation}}$  application mode:

- ASB > 4 s !!!
- ASB > 1.5 s !
- ASB > Ti max !
- Leakage !

### Selecting Tube application mode

The application mode can only be changed in standby mode. See "Selecting standby mode" on page 106.

In the Start / Standby dialog window:

1 Touch Tube / Mask tab (A).



2 Touch Tube button (B).

3 Press rotary knob to confirm.

Evita XL is in **Tube** application mode.

The configured default alarm limits are effective again.

#### WARNING

After changing from A Mask Ventilation application mode to *Tube* application mode, always check and adjust alarm limits and ventilation settings if necessary to ensure that ventilation is monitored comprehensively.

#### **NIV Plus**

The following functions are additionally available with the NIV Plus option:

- Anti Air Shower
- Standby Plus mode
- Extended leakage compensation

#### Anti Air Shower

When the mask is removed, *Evita XL* reduces the inspiratory flow in the **Adult** and **Adult** and **Adult** and **Configured**, see "Configuring NIV" on page 163.

#### Standby Plus mode

If the device is switched from  ${}_{A} \xi Mask Ventilation$  application mode to standby mode, *Evita XL* switches to Standby Plus mode.

#### WARNING

Ventilation does not take place in standby mode! Only switch device to standby mode when there is no patient connected to the ventilator. Otherwise, the patient may be at risk!

On-screen displays:



**Standby** (A) is displayed in the header bar of the screen. **Standby Plus** (B) is also displayed on the screen.

When the mask is put back on, *Evita XL* detects the patient's inspiration and continues ventilation with the previous settings. The  $A^{\{\}$ Mask Ventilation application mode is active again.

The *k*{*Mask Ventilation* application mode can also be started manually, see "Resuming ventilation" on page 107.

#### WARNING

*Evita XL* only continues the A<sup>C</sup>Mask Ventilation application mode in Standby Plus mode, upon detection of inspiratory effort.

After connecting the patient, monitor the start of ventilation. If the patient's inspiratory effort is insufficient, *Evita XL* cannot start ventilation automatically. Ventilation must be started manually, see "Resuming ventilation" on page 107. Otherwise, the patient may be at risk!

When doing one of the following, Standby Plus mode is not available:

- During O<sub>2</sub> Therapy
- During a Device Check or Airtight Check
- After changing to the *Tube* application mode

Evita XL switches automatically to standby mode.

#### Leakage compensation with NIV Plus

With the NIV Plus option, *Evita XL* performs leakage compensation during pressure-controlled ventilation in the

- Adult patient category, up to 180 L/min
- \*Paed. patient category, up to 60 L/min
- A Neo. patient category, up to 30 L/min

#### NOTE

Large leakages result in the alarm message **Apnoea !!!**, see "Monitoring during NIV" on page 89.

## Safety information for medication nebulization

#### WARNING

Never nebulize flammable medications! Fire hazard from hot wire anemometer in the flow sensor!

#### WARNING

Consider effects of aerosols on sensors, the expiratory valve, bacteria filters, and heat and moisture exchanger (HME)!

The measuring function of the flow sensor may be impaired.

Aerosol residues can impair the function of the expiratory valve. Depending on the applied medication aerosol, the expiratory valve may have to be replaced after the nebulization. The expiratory valve is warmed by a heater. This can increase the build-up of aerosol residue.

Do not place a bacterial filter or HME on the nebulizer outlet or on the Y-piece during nebulization! Risk of increased breathing resistance!

## Pneumatic medication nebulizer 8412935

## Using the pneumatic medication nebulizer in the Adult patient category

Medication nebulization is applicable in every ventilation mode.

*Evita XL* applies medication aerosols synchronized with inspiratory flow while maintaining a constant minute volume.

Depending on the O2 concentration set, *Evita XL* supplies the nebulizer with air, O2, or a mixture of air and O2. Deviations from the set O2

concentration are thus minimized. In extreme cases (with a minimum inspiratory flow of 15 L/min), the deviations can be up to ±4 Vol.%. See diagram "Insp. O2 concentration during medication nebulization" on page 269. In order to avoid greater deviations, *Evita XL* switches off the nebulizer at inspiratory flows of less than 15 L/min.

# Using the pneumatic medication nebulizer in the Pediatric patient category (without neonatal flow sensor)

Medication nebulization is possible in pressurecontrolled ventilation modes. In volume-controlled ventilation modes, nebulization is only possible while using AutoFlow.

In contrast to nebulization in the Adult patient category, aerosol is delivered continuously in the Pediatric patient category. Aerosol generated during expiration does not, however, reach the lungs.

Depending on the O<sub>2</sub> concentration set, *Evita XL* supplies the nebulizer with air, O<sub>2</sub>, or a mixture of air and O<sub>2</sub>. Deviations from the set O<sub>2</sub> concentration are thus minimized. For respiratory rates above 12 bpm, see the diagram "Insp. O<sub>2</sub> concentration during medication nebulization" on page 269. The maximum deviation from the set O<sub>2</sub> concentration is  $\pm$ 4 Vol.%.

It is recommended not to use the nebulizer while ventilating at respiratory rates below 12 bpm.

#### WARNING

For respiratory rates below 12 bpm, deviations from the set O<sub>2</sub> concentration may be significantly higher in extreme cases. These deviations cannot be detected by the device's internal O<sub>2</sub> concentration monitoring function.

#### WARNING

On account of the nebulizer flow tolerances, the displayed minute and tidal volumes may be considerably higher or lower than the minute and tidal volumes actually delivered to the patient. Pressure-controlled ventilation is therefore recommended during nebulization.

Compare the currently measured values for minute and tidal volumes with the values measured before nebulization. If values for VT and MV appear to have changed significantly, use ventilation pressure to evaluate ventilation. A comparison of the difference between PEEP and plateau pressure before and during nebulization can be used to identify deviations of the VT and MV values.

In order to avoid nuisance alarms and to assure proper monitoring the following settings are required:

- Adjust upper and lower alarm limits for *MV* to the current value.
- Use additional monitoring, e.g., external SpO<sub>2</sub>, if necessary.

#### Using the pneumatic medication nebulizer in the Neonatal and Pediatric patient categories (with neonatal flow sensor)

In the A **Neo.** and **\*Paed.** patient categories, medication nebulization is only possible in volumecontrolled ventilation modes.

In the *APaed.* patient category, medication nebulization is also possible in volume-controlled ventilation modes in conjunction with AutoFlow.

In contrast to nebulization in the Adult patient category, aerosol is delivered continuously in the Pediatric and Neonatal patient categories. Aerosol generated during expiration does not, however, reach the lungs.

Depending on the O<sub>2</sub> concentration set, *Evita XL* supplies the nebulizer with air, O<sub>2</sub>, or a mixture of air and O<sub>2</sub>. Deviations from the set O<sub>2</sub> concentration are thus minimized.

• Before nebulization, remove the complete neonatal flow sensor from the Y-piece.

#### WARNING

The wires of the neonatal flow sensor are hot. If the flow sensor is left in the breathing circuit during nebulization without being cleaned, medication aerosol deposits may build up and impair flow measurement. In the worst case, these deposits could catch fire. Disconnecting the cable from the neonatal flow sensor is not sufficient to prevent this. Remove the neonatal flow sensor before medication nebulization. Without the neonatal flow sensor, the minute volume is not monitored and the apnea alarm function is limited! Use additional monitoring.

- Replace or clean the neonatal flow sensor if there is visible soiling, see page 185.
- Calibrate the neonatal flow sensor at least once every 24 hours, see "Neonatal Flow Sensor Calibration" on page 137.

#### Preparing the medication nebulizer

#### WARNING

Use only pneumatic medication nebulizer 8412935 (with white center section). Other pneumatic medication nebulizers may cause considerable deviations in tidal volume and inspiratory O<sub>2</sub> concentration!

 Prepare the medication nebulizer in accordance with its Instructions for Use.

## Installing medication nebulizer in the breathing circuit

For use in the **Adult** patient category:



- Connect medication nebulizer (A) to the inspiratory side (temperature sensor side) of the Y-piece.
- 2 Connect inspiratory hose (B) to the medication nebulizer.
- **3** Place the medication nebulizer in a vertical position.
- 4 Using clamps, route nebulizer hose (C) back to the device along the inspiratory hose.

For use in the **\****Paed.* and **<sup>A</sup>***Neo.* patient categories:



- 1 Insert catheter connector (D) (ISO ⊘15 / ⊘11) into the inlet of the medication nebulizer.
- 2 Insert adapter (E) (ISO Ø22/ Ø11) into the outlet of the medication nebulizer.
- 3 Connect corrugated hose (F) (length 0.13 m (5.1 inches)) to the nebulizer outlet port.



- 4 Remove corrugated hose of the breathing circuit (G) from the inspiratory port of the Y-piece and connect to the catheter connector (D).
- Connect the free end of the corrugated hose (F) to the inspiratory adapter of the Y-piece.

When using the neonatal flow sensor:



- 1 Remove the entire flow sensor (housing and insert) (H) from the Y-piece.
- 2 Insert tube catheter cone (I) into the Y-piece.

#### CAUTION

Without the neonatal flow sensor, the minute volume is not monitored in the Neonatal patient category!

#### When using on an incubator



 Push the outlet connector of the medication nebulizer into the upper hose guide of the incubator.

#### When using without incubator



- 1 Press the medication nebulizer sleeve into one side of the clip and the expiratory hose into the other.
- 2 Place the medication nebulizer in a vertical position.

#### Connecting the nebulizer hose



- 1 Connect the nebulizer hose (A) to the nebulizer port (B).
- 2 Fill the medication nebulizer in accordance with its Instructions for Use.

#### Switching on medication nebulization

In the A Neo. patient category:

- Switch off NeoFlow monitoring, see page 148.
- 1 Touch *Special Procedure ...* button in the main menu bar.



The *Additional Function* page (C) appears by default.

2 In the *Nebuliser* line (D), touch the <sup>→</sup>/<sub>2</sub> button (E) and press rotary knob to confirm.

Evita XL starts medication nebulization.

An message appears in the header bar of the screen, informing the user that nebulization is active.

#### Switching off medication nebulization

Touch the webuliser line (D).

*Evita XL* automatically switches off the medication nebulizer after 30 minutes.

#### After medication nebulization

• Remove remaining medication. Follow the Instructions for Use of the medication nebulizer.

In the **Adult** and **Adult** and **Adult** patient categories, the flow sensor is automatically cleaned and calibrated. A message appears in the header bar.

In the A Neo. patient category:

- 1 Re-insert the neonatal flow sensor in the Y-piece.
- 2 Switch on NeoFlow monitoring, see page 148.

## Active nebulizer "Aeroneb Pro" MP01010

- Follow the Instructions for Use of the "Aeroneb Pro" nebulizer.
- Observe the information on the use of filters, see "Safety information on using HMEs, bacterial filters, and breathing circuits" on page 50.
- Observe "Safety information for medication nebulization" on page 91.
- Do not switch on the Nebuliser function on *Evita XL*. Because the pneumatic nebulizer flow not used during medication nebulization is taken into account in the volume delivery, the tidal volume delivered by *Evita XL* would be too low.

#### **Before nebulization**

When using the neonatal flow sensor:

Medication nebulization is only possible in pressure-controlled ventilation modes.

- 1 Switch off NeoFlow monitoring, see page 148.
- 2 Before nebulization, remove the complete neonatal flow sensor from the Y-piece.

#### WARNING

The wires of the neonatal flow sensor are hot. If the flow sensor is left in the breathing circuit during nebulization without being cleaned, medication aerosol deposits may build up and impair flow measurement. In the worst case, these deposits could catch fire.

Disconnecting the cable from the neonatal flow sensor is not sufficient to prevent this. Remove the neonatal flow sensor before medication nebulization.

Without the neonatal flow sensor, the minute volume is not monitored and the apnea alarm function is limited! Use additional monitoring.

#### After nebulization

If a filter is used in order to protect the flow sensor or the expiratory valve:

- 1 Replace or remove the filter after medication nebulization.
- 2 Recalibrate the flow sensor, see "Flow Sensor Calibration" on page 135. Aerosols distort flow measurement!

When using the neonatal flow sensor:

- 1 Re-insert the neonatal flow sensor in the Y-piece.
- 2 Switch on NeoFlow monitoring, see page 148.

## Pre- and Postoxygenation for Bronchial Suctioning

To avoid hypoxia during bronchial suctioning, *Evita XL* offers programmed elevation of oxygenation before and after the removal of secretions.

In the **Adult** patient category, the O2 concentration is increased to 100 Vol.%. In the **Adult** And **Adult Neo.** patient categories, the O2 concentration is increased by 25 % (Example: 60 Vol.% set, applied: 75 Vol.%).

When the oxygenation procedure is started, *Evita XL* begins with preoxygenation, ventilating with the increased O<sub>2</sub> concentration in the set ventilation mode for 180 seconds.

When disconnection for suctioning occurs, *Evita XL* interrupts ventilation. During the time required for suctioning, audible alarms associated with the disconnection are silenced.

After suctioning and automatic detection of reconnection, *Evita XL* ventilates with the appropriately increased O2 concentration for 120 seconds as postoxygenation.

During suctioning and for 2 minutes afterwards, the lower alarm limit for minute volume is switched off. Other alarms are switched off during suctioning and for 15 seconds afterwards.

#### NOTE

Pre- and postoxygenation is only possible with a fully functioning flow sensor and while flow monitoring is switched on.

#### Before suctioning

1 Touch *Special Procedure ...* button in the main menu bar.



The *Additional Function* page (A) appears by default.

- 2 Touch O2 ↑ suction button (B).
- 3 Press rotary knob to confirm.

The oxygenation procedure is started.

*Evita XL* ventilates the patient in the set ventilation mode with the appropriately increased O<sub>2</sub> concentration.

If PEEP is not set to more than 4 mbar (4 cmH<sub>2</sub>O), PEEP will be applied automatically at 4 mbar (4 cmH<sub>2</sub>O). This PEEP allows *Evita XL* to detect the subsequent disconnection. The other ventilation parameters remain unaffected.

The preoxygenation phase with the remaining time in seconds is displayed continuously in the header bar.

Preoxygenation lasts for a maximum of 180 seconds. During this time, *Evita XL* waits for the disconnection necessary for suctioning. If no disconnection is detected within 180 seconds, *Evita XL* terminates the oxygenation procedure.

## **During suctioning**

After disconnection for suctioning, *Evita XL* delivers a very small flow for the duration of suctioning in order to automatically detect the end of the disconnection phase. The remaining time available for suctioning is displayed in seconds in the header bar. If suctioning is completed and the patient reconnected within the time available, *Evita XL* will end the disconnection phase.

## Automatic termination of oxygenation procedure

If there is still no reconnection after 120 seconds, the oxygenation procedure is terminated. All alarms are immediately reactivated. *Evita XL* immediately continues ventilating in the set ventilation mode.

### After suctioning

After reconnection, *Evita XL* resumes ventilation in the set ventilation mode. For postoxygenation, the O2 concentration is increased for the first 120 seconds.

The postoxygenation phase with the remaining time in seconds is displayed in the header bar.

### **Canceling oxygenation**

• Touch **O**<sub>2</sub> *isuction* button.

## **Manual Inspiration**

Manual inspiration may be activated in all ventilation modes, except in CPAP.

Regardless of the start time, a mandatory breath can be extended for up to 40 seconds.

Or:

Between two mandatory breaths, a mechanical breath may be started manually and held for max. 40 seconds.

The pattern of the manually started breath corresponds to the ventilation pattern of the currently active ventilation mode.

In CPAP/ASB a pressure-supported breath (defined by the  $\Delta$ PASB setting) is triggered.

1 Touch *Special Procedure ...* button in the main menu bar.



The *Additional Function* page (A) appears by default.

2 Touch and **hold** the *Insp. Hold* button (B) for the desired inspiratory time.

Evita XL will end inspiration after max. 40 seconds.

## **Expiratory Hold**

Manual expiration may be activated in all ventilation modes. Used for determining the measured NIF value for weaning.

1 Touch *Special Procedure ...* button in the main menu bar.



The *Additional Function* page (A) appears by default.

2 Touch and **hold** the *Exp. Hold* button (B) for the desired expiratory time.

*Evita XL* will end the expiration after max. 15 seconds.

#### Further information

To display NIF, see "Negative Inspiratory Force NIF" on page 100.

For a detailed description, see "Negative Inspiratory Force NIF" on page 267.

## Diagnostics

#### **Occlusion pressure P0.1**

Only available with the XL Monitoring Plus option.

Occlusion pressure P0.1 characterizes the negative pressure during a short occlusion (0.1 seconds) at the start of spontaneous inspiration.

Occlusion pressure P0.1 is a direct measure of a patient's neuromuscular breathing drive.

*Evita XL* displays the value for the measured pressure difference without a negative sign.

For patients with healthy lungs and regular breathing P0.1 is 3 to 4 mbar (3 to 4 cmH2O).

A high P0.1 signifies a high breathing drive, which can only be maintained for a brief period. Values over 6 mbar (6 cmH2O) for a patient with chronic obstructive pulmonary disease indicate impending exhaustion.

This measuring procedure can be used in all ventilation modes at regular intervals in order to check the breathing drive of a spontaneously breathing patient, or to assess the amount of spontaneous breathing during controlled ventilation.

#### Starting measurement

- 1 Touch *Special Procedure ...* button in the main menu bar.
- 2 Touch *Diagnostics* tab (A).



The **P0.1** page (B) appears by default.

*Evita XL* displays the P0.1 values from previous measurements (C). The value of the last measurement is shown in larger characters in the left column.

- 3 Touch Start button (D).
- 4 Press rotary knob to confirm.

Evita XL starts the P0.1 measurement.

#### Setting the interval

- 1 Touch Interval button (E).
- 2 Set the value using the rotary knob and confirm.

The time remaining until the next measurement is displayed.

It is advisable to record the measured P0.1 value as a trend, so that the progress made can be monitored, see "Displaying 1 hr trends" on page 129.

#### Aborting measurement

• Touch *Start* button (D).

### Intrinsic PEEP – PEEPi

Only available with the XL Monitoring Plus option.

Intrinsic PEEP is the actual end-expiratory pressure in the lungs.

Due to the dynamics of lung mechanics (resistance, compliance, and closing volume) and the set ventilation parameters, Intrinsic PEEP differs from PEEP in the upper airways.

This measuring procedure also measures the trapped volume resulting from this difference in PEEP values, i.e., the amount of air trapped in the lungs and therefore not taking part in the process of gas exchange.

This special measuring procedure can be performed in all ventilation modes.

#### WARNING

Patient activity during this procedure can distort the measured values.

#### Starting measurement

- 1 Touch *Special Procedure ...* button in the main menu bar.
- 2 Touch *Diagnostics* tab (A).



3 Touch PEEPi tab (B).

*Evita XL* displays the PEEPi values from the previous measurements (C). The value of the last measurement is shown in larger characters in the left column. The measured values are shown together with the set PEEP.

- 4 Touch Start button (D).
- 5 Press rotary knob to confirm.

Evita XL starts the PEEPi measurement.

#### **Further information**

For a detailed description of Intrinsic PEEP, see page 267.

#### Aborting measurement

• Touch *Start* button (D).

## **Negative Inspiratory Force NIF**

Only available with the XL Monitoring Plus option.

The Negative Inspiratory Force (NIF) measures a patient's maximum inspiratory effort after prior expiration. The breathing system is closed during measurement of NIF. The NIF value is also known as the Maximum Inspiratory Pressure (MIP). As a result of the inhalation effort during a manually extended expiration, the patient generates a negative pressure in relation to PEEP. The higher this negative pressure, the greater the likelihood of extubating a patient successfully. For patients with a NIF exceeding –30 mbar (–30 cmH2O), extubation is likely to be successful, while extubation for those with a NIF of only –20 mbar or less (–20 cmH2O) will most likely prove unsuccessful.

*Evita XL* determines the NIF value during a manually extended expiration.

#### Starting measurement

- 1 Touch *Special Procedure ...* button in the main menu bar.
- 2 Touch *Diagnostics* tab (A).



3 Touch NIF tab (B).

*Evita XL* displays the NIF values from previous measurements (C). The value of the last measurement is shown in larger characters in the left column.

• Touch and **hold** the *Exp. Hold* button (D) for the desired expiratory time.

*Evita XL* will end the expiration after max. 15 seconds.

#### **Further information**

For a detailed description of NIF, see page 267.

References [17], [18], see page 281.

## Low Flow PV-Loop

Only available with the LPP option.

*Evita XL* determines the Low Flow PV-Loop during an extended inspiration or an inspiration and expiration.

This measuring procedure can only be performed in the **†** *Adult* patient category.

The measuring procedure should only be carried out on patients with no spontaneous breathing.

- 1 Touch *Special Procedure ...* button in the main menu bar.
- 2 Touch Low Flow PV-Loop tab (A).



Observe the following information (B) before carrying out the measurement!

#### WARNING

The application of a low flow manoeuvre may decrease the patient's systemic circulatory pressure and could cause a pneumothorax. Carefully assess the patient's condition for settings.

- Applied pressure / volume must be appropriate for the patient.
- The patient must be haemodynamically stable.
- Closely monitor arterial blood pressure during the manoeuvre.
- The sudden release of high airway pressure may overload the heart and impair cardiac function.
- The calculated maximum manoeuvre time must be appropriate for the patient.
- These measurements are only valid with NO spontaneous breathing.
- These measurements are only valid with NO leakage. Volume and derived compliance values are not leakage compensated (VTi, VTe, and Cstat).
- This manoeuvre cannot be restarted within 60 seconds.
- This manoeuvre cannot be started until 60 seconds after nebulisation or suctioning.

## Starting measurement

1 Touch *Procedure* tab (A).



- 2 Touch the buttons for *Pstart* (B), *Plimit* (C), *Flow* (D), and *Vlimit* (E).
- **3** Set and confirm values with the rotary knob.

Pstart can be set at a value between 0 and PEEP.

*Plimit* and *Vlimit* are limited by the alarm limits.

• Adjust the alarm limits if necessary, see page 123.

The maximum duration of the measuring procedure *Tmax* [sec] (F) is displayed.

#### Recording inspiration and expiration

- 1 Touch Start Insp + Exp button (G).
- 2 Press rotary knob to confirm.

#### **Recording inspiration only**

- 1 Touch Start Insp only button (H).
- 2 Press rotary knob to confirm.

## **Terminating inspiration**



## During the inspiration and expiration measurement

• Touch **Stop Insp** button (A).

*Evita XL* ends inspiration, expiration takes place at the set flow.

#### During the inspiration only measurement

• Touch **Stop Insp** button (A).

*Evita XL* ends inspiration, expiration takes place at a pressure drop of max. 5 mbar/s (5 cmH2O/s).

## Quick abortion of the measurement

- 1 Touch *Abort* button (B).
- 2 Press rotary knob to confirm.

*Evita XL* ends the measurement, the pressure immediately drops to the set PEEP.

A measurement being performed is not interrupted by calling up another dialog window.

To return to the *Procedure* page:

- 1 Touch *Special Procedure ...* button in the main menu bar.
- 2 Terminate measurement with the *Stop Insp* (A) or *Abort* (B) buttons.

#### Performing a new measurement

A new measurement can only be started after 60 seconds. During this time, the buttons needed for starting a measurement are gray and cannot be activated.

#### **Measurement analysis**

After the measurement, *Evita XL* opens the *Analysis* screen (A).



#### To display a point on the waveform

- 1 Touch *Cursor* 1 (B) or *Cursor* 2 (C) button.
- 2 Turn the rotary knob to position the cross-hair cursor over the required point.

The measured values are displayed.

The light grey line connecting the two measuring points on the inspiratory or expiratory section of the waveform represents the static compliance. The values for the inspiratory and expiratory static compliance (*Cstat*), which are calculated from this, are displayed.

The measured values are not leakage-corrected.

#### **Further information**

See "Low Flow PV-Loop" on page 268.

## O<sub>2</sub> Therapy

## Safety information for O<sub>2</sub> Therapy

During O2 Therapy, only the O2 concentration FiO2 is monitored.

#### WARNING

Airway pressure and expiration-dependent ventilation parameters such as flow, minute volume, or apnea are not monitored. Use external SpO2 monitoring for patients who are dependent on an increased defined O2 concentration. Otherwise, a deterioration in the patient's condition cannot be recognized.

#### WARNING

Only use oxygen masks for O<sub>2</sub> Therapy. Do not use masks for non-invasive ventilation (NIV). The patient may be at risk if unsuitable masks are used.

## Preparing for O2 Therapy

#### Connecting breathing hoses

#### WARNING

Do not use antistatic or conductive breathing hoses. The use of such materials increases the risk of an electric shock for the patient and the risk of fire breaking out in oxygenenriched atmospheres.

IEC 60601-2-12 Appendix AA and EN 794-1 Appendix AA: Using antistatic and/or electrically conductive materials in the breathing system of the lung ventilators is not regarded as a contribution to higher safety. In fact, using such materials increases the risk of an electric shock for the patient.

## Preparing *Evita XL* with Aquapor EL breathing gas humidifier



- 1 Position the hinged arm (A) on the rail and tighten the screws. Depending on the desired position of the ventilator in relation to the bed, the hinged arm can be mounted on either side of the device.
- 2 Attach the breathing hoses for inspiration (B). Observe the required hose lengths (indicated in meters).
- **3** The expiratory ports (C) on the device and on the Y-piece remain open!
- 4 Position water trap (D) vertically.
- **5** Fit the temperature sensor, see page 53.

## Preparing *Evita XL* with Fisher & Paykel MR 850 breathing gas humidifier



- 1 Position the hinged arm (E) on the rail and tighten the screws.
- 2 Attach the breathing hoses for inspiration (F). Observe the required hose lengths (indicated in meters).
- **3** The expiratory ports (G) on the device and on the Y-piece remain open!
- 4 Fit the temperature sensor, see page 53.

## Switching on O<sub>2</sub> Therapy

- 1 Switch on *Evita XL*, see page 64.
- 2 Switch *Evita XL* to standby mode, see page 106.
- **3** Switch on O<sub>2</sub> monitoring, see page 148.

The inspiratory breathing gas temperature has a fixed upper alarm limit of 40  $^{\circ}$ C (104  $^{\circ}$ F).

The alarm limits for *etCO*2, *MV*, *fspn*, *VTi*, *PAW*, *TApnoea* are not active.

4 Touch Oxygen Therapy tab (A).



#### Setting O2 and flow for O2 Therapy

- 1 Touch the appropriate therapy control:
  - O2 (B)
    Flow (C)
  - FIOW(C)
- 2 Turn the rotary knob to set the value.
- 3 Press rotary knob to confirm.
- 4 Touch *On* button (D) and press rotary knob to confirm.

O2 Therapy is switched on. *Evita XL* displays a message in the header bar.

#### WARNING

The device must only be used under the supervision of qualified medical staff, so that help is immediately available if malfunctions occur or the patient has insufficient spontaneous breathing.

## Switching off O2 Therapy

- 1 Touch Oxygen Therapy tab (A).
- 2 Touch **Off** button (E) and press rotary knob to confirm.
- O2 Therapy is switched off.

## Standby Mode

Switch to standby mode for the following actions:

- To keep *Evita XL* ready for operation while the patient is absent
- To switch between ventilation and O<sub>2</sub> Therapy
- To change application mode
- To change between patient categories
- To perform the Device Check and Airtight Check.

#### WARNING

Ventilation does not take place in standby mode! Only switch device to standby mode when there is no patient connected to the ventilator. Otherwise, the patient may be at risk!

### Selecting standby mode

 Press and hold the <sup>()</sup> Start/Standby key for 3 seconds.

Evita XL is in standby mode.

or

• Press () Start/Standby key.

Evita XL opens the Start / Standby dialog window.



- 1 Touch *Standby* button (A).
- 2 Press rotary knob to confirm.



B

4 Press rotary knob to confirm.

*Evita XL* is in standby mode or Standby Plus mode (only with NIV Plus option, see "NIV Plus" on page 89).

On-screen displays:



**Standby** (C) is displayed in the header bar of the screen. **Standby** or **Standby Plus** is displayed on the screen (D).

If the patient category or ideal body weight is changed in standby mode, *Evita XL* will determine new start-up values for ventilation, see "Admitting a new patient" on page 75.

## **Resuming ventilation**

• Check ventilation settings (A).

|   | X   |
|---|-----|
| B |     |
| A |     |
|   |     |
|   | К7К |

- 1 Touch Start button (B).
- 2 Press rotary knob to confirm.

The main screen is displayed, *Evita XL* starts ventilation.

or

• Press <sup>()</sup> Start/Standby key.

Evita XL starts ventilation.

Terminating Standby Plus mode, see "NIV Plus" on page 89.

### **Components and definitions**

#### Mains power supply

The device is supplied with mains power via the mains power line. For voltage ranges and characteristics of the mains power, see Technical Data, "Operating Data" on page 219.

#### DC power supply

*Evita XL* contains a DC power pack\* with internal battery to ensure that operation of the device can continue for at least 10 minutes, following a power failure (provided that the battery is fully charged).

*Evita XL* may also be powered from an external battery via this DC power pack.

#### Internal battery

The DC power pack consists of two internal 12 V lead-acid gel batteries, which ensure that operation of the device can continue for at least 10 minutes (provided that the batteries are fully charged). Observe battery maintenance, see "Battery maintenance" on page 110.

#### CAUTION

The internal battery of the DC power pack will only reach its full capacity after a 24 hour charge. Charge internal battery of *Evita XL* for at least 24 hours. See "Charging batteries" on page 109.

#### \* For Evita 4 or Evita 2 dura, equipped with the Evita XL option, operation is also possible without a DC power pack.

#### WARNING

The internal battery is intended exclusively for emergency use and not for normal operation. After a switch to power from the internal battery has occurred, immediately reestablish supply with mains power or from an external battery.

#### External battery for the DC power pack option

With the DC power pack, *Evita XL* can be supplied from external rechargeable 12 V or 24 V lead-acid gel batteries. The external battery is connected to *Evita XL* via the DC socket.

The external batteries are not supplied with the DC power pack.

It is advisable to use 24 V lead-acid gel batteries (or two 12 V lead-acid gel batteries connected in series). The efficiency of the DC power pack and the resulting operating time is considerably higher than with 12 V batteries of comparable capacity. The minimum capacity must be maintained, see Technical Data, "DC Power Pack" on page 225.

The external battery comprises two 12 V lead-acid gel batteries accommodated in the base of the trolley. Refer to list of accessories for these batteries and the required connecting cable.

Otherwise, commercially available rechargeable lead-acid gel batteries can also be used. For the requirements to be met by the external batteries, see also Technical Data "DC Power Pack" on page 225.

#### WARNING

Only use rechargeable batteries! Single-use batteries may explode when being charged with the DC power pack while the device is operating on mains power.
## DC socket

Socket on the back panel of the DC power pack for connecting an external battery.

The socket is identified as follows:

DC power pack: 12 V; 24 V; VDC

### WARNING

Do not connect any mains-powered devices to the DC socket. Otherwise, the correct functioning of *Evita XL* may be impaired or *Evita XL* may get damaged.

# CAUTION

Only external batteries may be connected to the DC socket (see page 108). The connection may only be made using the connecting cables specified in the list of accessories.

# Use of the power sources

The following possibilities are available for supplying power to *Evita XL*:

- Internal battery only, with mains supply
- Internal battery and external battery, with and without mains supply

*Evita XL* draws its electric power from one of the following sources, in the order of priority listed:

- 1 Mains supply
- 2 External battery
- 3 Internal battery

The switchover between these supplies is performed without interrupting operation, according to the following rules:

- If sufficient mains power is available, the mains power source is always used.
- If sufficient mains power is not available but sufficient power is present at the DC socket, *Evita XL* will be powered by the external battery. An alarm message accompanies the switch to external battery power.

 If sufficient mains power is not available and there is also insufficient DC power available at the DC socket (e.g., with an external battery that is discharged or not connected), *Evita XL* will be powered by the internal battery.

The device can switch back from the internal battery to the external battery for a short time, if the external battery has recovered.

As soon as possible:

• The switched-on device must again be operated with mains power or a fully charged external battery again.

## CAUTION

While operating with an external battery, the internal battery is not recharged, but rather trickle charged to prevent further discharge!

# Operating time with battery

The operating time with the internal or external battery depends on the charging condition and type of batteries connected, see Technical Data "DC Power Pack" on page 225.

# **Charging batteries**

When mains power is connected and the ventilator is switched on, the internal battery is charged first, followed by the external battery.

#### WARNING

Leave the ventilator connected to mains power only in well-ventilated areas. In sufficient concentrations, the hydrogen generated when charging batteries may otherwise lead to an explosion.

## CAUTION

Ensure that *Evita XL* has been switched on. The standby mode is sufficient. Even if mains power is present, but *Evita XL* is switched off, neither the internal nor the external battery will be charged.

# Charging internal battery

The internal battery is only recharged when the device is supplied with mains power and it is switched on, see "Switching on Evita XL" on page 64.

# CAUTION

*Evita XL* must be switched on and remain connected to the mains power for at least 24 hours so that the internal battery can be fully charged. The standby mode is sufficient.

The device switches over to trickle charge when the battery is fully charged.

# **Charging external battery**

The external battery is only charged when the device is supplied with mains power and it is switched on, see "Switching on Evita XL" on page 64. The standby mode is sufficient. The internal battery must be fully charged.

The voltage of the connected external battery (12 V or 24 V) is detected automatically by the DC power pack.

# Charging times of the batteries

The specified charging times apply when batteries are recharged immediately after a full discharge.

The charging time may be significantly longer if the batteries have discharged several times in succession without being fully recharged on mains power in the meantime.

The batteries must be fully operational.

# Charge indication and charging state of the batteries

Charging of the internal and external batteries is interrupted when the charging current drops to a very low value upon reaching the end of charge. The battery is considered to be fully charged and this is indicated by a green battery symbol. The battery capacity actually available at the end of the charging process depends, among other things, on the condition of the battery and the ambient temperature. The capacity and condition of the battery cannot be detected by the DC power pack.

The green battery symbol indicates that the battery is fully charged. Even though the green symbol lights up, the capacity of old or defective batteries may be so small as to permit operation of *Evita XL* for no more than a few minutes.

# CAUTION

Sufficient battery capacity is always required. See "Battery maintenance".

# **Battery maintenance**

To ensure maximum battery life:

• Batteries should always be fully recharged and, if possible, never become totally discharged.

If the DC power pack is not used:

- Connect Evita XL to mains power after not more than 1 month and switch it on for at least 2 hours in order to recharge the internal battery.
- 2 Then fully recharge any external batteries which may be connected.

If the battery needs to be left uncharged for more than one month:

 Have the internal and/or external batteries electrically disconnected from the device by trained service personnel in order to reduce self-discharge of the batteries.

Before reconnecting internal and external batteries, check that their capacity is still adequate. The batteries may have become totally discharged or damaged as a result of prolonged storage.

• Avoid total discharge as this leads to premature wear.

# CAUTION

Batteries are wear parts. Their capacity must be checked regularly and the batteries replaced if necessary.

# Connecting an external battery

Note the requirements for external batteries, see page 108.

 Connect external battery to the connecting cable in the battery cable set (8411822). Ensure that the battery is connected with correct polarity: black to –, red to +.



2 Plug connector into DC socket (A) on the back panel of *Evita XL*.

# WARNING

Do not connect any mains-powered devices to the DC socket. Otherwise, the correct functioning of *Evita XL* may be impaired or *Evita XL* may get damaged. The device will automatically detect the voltage of the external battery (12 V or 24 V).

# Installing external battery in trolley

The battery must be installed by trained service personnel!

# Power supply displays



*Evita XL* shows the type of electrical power supplied in the device status field (A) via symbols and colored indicators:

. \_→ Mains power

**Ext.** External battery

F- Int. Internal battery

A yellow indicator next to the relevant symbol shows the source from which the device is being powered.

Green battery symbols indicate fully charged batteries.

## NOTE

Note the important information under "Charge indication and charging state of the batteries" on page 110!

# Operation with mains power

*Evita XL* switches to operation with AC power when adequate mains power is available. At the same time, *Evita XL* first charges the internal battery and then the external battery.

The indicator next to the plug symbol  $\exists \mathfrak{I}$  lights up yellow.

If the mains power supply fails, *Evita XL* will automatically switch over to the external battery.

If an external battery is not available in the event of a mains power failure, *Evita XL* switches over to the internal battery and continues operation for at least 10 minutes (provided that the internal battery was fully charged).

• The supply of mains power must be restored without delay.

To ensure that the battery is always fully charged:

1 Connect the device to the mains power supply and switch it on.

## WARNING

Leave the ventilator connected to mains power only in well-ventilated areas. In sufficient concentrations, the hydrogen generated when charging batteries may otherwise lead to an explosion.

2 Leave the device in standby mode or start ventilation.

# Operation with internal battery

*Evita XL* switches without interruption over to operation with the internal battery if the mains supply fails without an external battery being connected, or in case of a discharged external battery.

The internal battery is intended for emergency use exclusively and not for normal operation.

The indicator next to the symbol for the internal battery lights up yellow.

The green symbol for the internal battery goes out, as it is no longer fully charged.

When switching over to the internal battery, *Evita XL* displays the following medium-priority alarm message: *Int. battery activated !!*.

Acknowledge alarm message:

• Touch *Alarm Reset* button and press rotary knob to confirm.

*Evita XL* continues to display the following lowpriority alarm message: *Int. battery activated !.* 

Depending on configuration, it is possible that, when the device switches over to the internal battery, the high-priority alarm message *Int. battery activated !!!* appears instead of the medium-priority alarm message. This alarm message can also be acknowledged.

# To change the configuration so that the highpriority alarm message is displayed:

- 1 Press E System Setup key.
- 2 Touch Service tab.
- 3 Enter access code: 94999422

*Evita XL* displays *ok* on the screen. The configuration has been changed. The next time *Evita XL* switches over to the internal battery, the following alarm message is displayed: *Int. battery activated !!!*.

# To change the configuration so that the medium-priority alarm message is displayed:

- 1 Press System Setup key.
- 2 Touch Service tab.
- 3 Enter access code: 41994141

*Evita XL* displays *ok* on the screen. The configuration has been changed. The next time *Evita XL* switches over to the internal battery, the following alarm message is displayed: *Int. battery activated !!*.

#### After switching over to the internal battery

The operating time with the internal battery depends on its charge state. If the battery is fully charged, the operating time is at least 10 minutes.

After an operating time of 8 minutes, *Evita XL* displays the following medium-priority alarm message: *Int. battery only 2 minutes left !!*.

 The device must be reconnected to mains power within 2 minutes

or

 It must be connected to a fully charged external battery.

After an operating time of 10 minutes, *Evita XL* displays the following high-priority alarm message: *Int. battery discharged !!!*.

 The power supply must be restored immediately, either with mains power or from a fully charged external battery, otherwise ventilation will be interrupted.

### WARNING

If the total power supply fails, the ventilation will be interrupted. *Evita XL* switches off and the power failure alarm is immediately activated. The patient is no longer ventilated.

Restore the power supply immediately. After restoration of the power supply, *Evita XL* will restart with the previous settings. Check settings and ventilation function. Ventilation of the patient can then be continued with *Evita XL*.

If no power supply is available, immediately disconnect the patient from the device and ventilate with an independent ventilating device (e.g., with manual breathing bag MR 100).

#### After using power from the internal battery:

• Recharge the internal battery and, if available, the external battery as soon as possible, see "Charging batteries" on page 109.

# **Operation with external battery**

Only available with the external batteries option for the DC power pack

#### **Connecting external battery**

If the mains power supply fails, *Evita XL*, without interrupting operation, switches over to a connected external battery.

The indicator next to the symbol for the external battery lights up yellow.

The green symbol for the external battery goes out, as it is no longer fully charged.

When switching over to the external battery, *Evita XL* displays the following medium-priority alarm message: *Ext. battery activated !!*.

Acknowledge alarm message:

• Touch *Alarm Reset* button and press rotary knob to confirm.

*Evita XL* continues to display the following lowpriority alarm message: *Ext. battery activated !*.

Depending on configuration, it is possible that, when the device switches over to the external battery, the high-priority alarm message *Ext. battery activated !!!* appears instead of the medium-priority alarm message. This alarm message can also be acknowledged.

#### To change the configuration so that the highpriority alarm message is displayed:

- 1 Press System Setup key.
- 2 Touch Service tab.
- 3 Enter access code: 94999422

*Evita XL* displays *ok* on the screen. The configuration has been changed. The next time *Evita XL* switches over to the external battery, the following alarm message is displayed: *Ext. battery activated !!!*.

# To change the configuration so that the medium-priority alarm message is displayed:

- 1 Press System Setup key.
- 2 Touch Service tab.
- 3 Enter access code: 41994141

*Evita XL* displays *ok* on the screen. The configuration has been changed. The next time *Evita XL* switches over to the external battery, the following alarm message is displayed: *Ext. battery activated !!*.

# After switching over to the external battery

The operating time with an external battery depends on its charge state and the type of battery connected.

If the external battery is discharged, *Evita XL* automatically switches over to the internal battery and generates an alarm.

When mains power is restored, *Evita XL* automatically switches back to operation with mains power.

The internal battery is not recharged while the device is being powered by an external battery.

# After using power from the external battery

• Recharge the internal and external batteries, see "Charging batteries" on page 109.

# WARNING

Do not connect any mains-powered devices to the DC socket. Otherwise, the correct functioning of *Evita XL* may be impaired or *Evita XL* may get damaged. Only available with the Evita Link option.

In addition to the standard *COM 1* RS 232 interface, *Evita XL* has two additional serial RS 232 interfaces *COM 2* and *COM 3*, two CAN interfaces (without function), and a two-channel analog interface.

On both serial interfaces, **COM 2** and **COM 3**, the following protocols may be used:

- LUST protocol\*
- MEDIBUS protocol
- Printer protocol

The LUST protocol and printer protocol can each be used on only one serial interface at a time, whereas the MEDIBUS protocol can run on both simultaneously.

#### WARNING

Connect other devices, e.g., a printer or a computer, to the interfaces only while *Evita XL* is properly grounded via its power cable and a grounded mains power socket or via the grounding pin on the back panel of the device. Otherwise, the risk of electric shock cannot be safely excluded.

For output of measured values, status messages, and alarm messages to connected equipment for monitoring, documentation, or further processing.

Both Dräger equipment and that of other manufacturers may be connected.

# WARNING

All transferred data are for information only and should not be used as a basis for diagnostic or therapeutic decisions. Danger to the patient cannot be excluded. To protect the patient and the user against electrical hazards, it is essential that all systems consisting of medical devices as well as other electrical devices which are not restricted to computers, printers etc., are only assembled by trained personnel.

The system must meet the requirements of the IEC/EN 60601-1-1 and IEC/EN 60601-1-2 standards.

The RS 232 interfaces fulfil the requirements of the "EIA Standard RS 232 C" and "CCITT V.24" standards.

# Preparation

The interface card may only be installed by trained service personnel.

#### Connecting RS 232 interface

The following connecting cables can be used:

- Optical cable 8416900 for PC
- MEDIBUS cable 8306488 for PC
- Printer cable 8306489 for printer only
- Monitor cable 5722410 for monitor

<sup>\*</sup> For a detailed description, see Technical Data, "LUST Protocol" on page 226.



- 1 Insert connector into COM 2 (A) or COM 3 (B) port on back panel of device.
- 2 Attach other connector to device to be used.
- 3 Tighten knurled screw to secure connector.
- 4 Prepare device to be connected according to its Instructions for Use, connect and switch on.

Linked devices must operate with the same protocol and the same transmission format.

Evita XL offers the following interface protocols:

- MEDIBUS (Dräger communication protocol for medical devices, fast data, e.g., waveforms)
- LUST (list-controlled universal interface driver program, only for slow data, e.g., measured values)
- printer

# Connecting analog interface

with analog cable 8411759



- 1 Insert connector into the analog port (C) on the back panel of the device.
- 2 Prepare device to be connected according to its Instructions for Use, connect and switch on.

# Selecting MEDIBUS protocol

For use of a PC with EvitaView software or for connecting a MEDIBUS-compatible monitor.

For a detailed description of the interface protocol, see Instructions for Use "MEDIBUS for *Evita XL*" and "Dräger RS 232 MEDIBUS Protocol Definition" (9028258).

- 1 Press E System Setup key.
- 2 Touch Interface tab (A).



To connect **COM 1** (B), **COM 2** (C) or **COM 3** (D) in the **Protocol** column (E):

- 3 Touch the relevant button.
- 4 Select *Medibus* with rotary knob and press to confirm.
- 5 Set associated parameters *Baud rate* (F), *Parity* (G), *Stopbit* (H), *Interval* (I) in the same manner.

# Selecting LUST protocol

To use a monitor without real-time waveforms.

For a detailed description of this interface protocol, see Technical Data, "LUST Protocol" on page 226.

The LUST protocol cannot be configured simultaneously on *COM 2* and *COM 3*.

- 1 Press System Setup key.
- 2 Touch Interface tab (A).



To connect **COM 2** (B) or **COM 3** (C) in the **Protocol** column (D):

- 3 Touch the relevant button.
- 4 Select *LUST* with rotary knob and press to confirm.
- 5 Set associated parameters *Baud rate* (E), *Parity* (F), *Stopbit* (G), *Interval* (H) in the same manner.

# Selecting printer protocol

• See "Configuring interfaces" on page 157.

In addition to automatically generated printouts at preselectable time intervals, a printout can be started manually if the additional *Print* button has been configured in the main menu bar. See "Defining additional buttons in the main menu bar" on page 154.

# Analog interface

The *Evita XL* analog interface provides two analog channels to which signals from measured values can be freely assigned.

## **Characteristics and PIN assignment**

See Technical Data, "Device Outputs" on page 223.

External voltages must not be applied here.

# Assigning channels

• See "Configuring interfaces" on page 157.

| Measured<br>value<br>signal | Designation                       | Range/voltage level                                    |
|-----------------------------|-----------------------------------|--|
| Paw                         | Airway pressure                   | –10 to 100 mbar (–10 to 100 cmH2O)<br>0 to 4.095 V     |
| Flow                        | Expiratory and inspiratory flow   | –196 to 196 L/min<br>0 to 4.095 V                      |
| V                           | Expiratory and inspiratory volume | 0 to 2 L<br>0 to 4.095 V                               |
| MV                          | Minute volume                     | 0 to 41 L/min<br>0 to 4.095 V                          |
| f                           | Respiratory rate                  | 0 to 150 bpm<br>0 to 4.095 V                           |
| FiO2                        | Inspiratory O2 concentration      | 0 to 100 Vol.%<br>0 to 4.095 V                         |
| R                           | Resistance                        | 0 to 100 mbar/L/s (0 to 100 cmH2O/L/s)<br>0 to 4.095 V |
| С                           | Compliance                        | 0 to 250 mL/mbar (0 to 250 mL/cmH2O)<br>0 to 4.095 V   |
| CO2                         | Expiratory CO2 concentration      | 0 to 15 kPa<br>0 to 4.095 V                            |
| etCO2                       | End-expiratory CO2 concentration  | 0 to 15 kPa<br>0 to 4.095 V                            |
| NO                          | Inspiratory flow for NOdomo       | 0 to 125 L/min<br>0 to 4.095 V                         |

# Alarms

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# **On-Screen Alarm Messages**

In the event of an alarm, the relevant alarm message appears in the alarm message field (A).



# Alarm priorities

*Evita XL* assigns the alarm message its respective priority. It marks the text with exclamation marks and differently colored backgrounds. *Evita XL* generates the corresponding alarm tone sequences.

| Warning | High-priority alarm<br>message | !!! | Red background    | five-tone sequence which is sounded twice and repeated every 7 seconds. |
|---------|--------------------------------|-----|-------------------|---|
| Caution | Medium-priority alarm message  | !!  | Yellow background | three-tone sequence which is repeated every 20 seconds.                 |
| Note    | Low-priority alarm<br>message  | !   | Yellow background | two-tone sequence which is sounded once                                 |

# **Displaying Alarm Information**

 Please refer to chapter "Problem Solving" on page 165.

#### or



1 Touch *Alarm Info* button (A).

All currently active alarm messages (B) are displayed.

- 2 Using the rotary knob, select the alarm message (B).
- 3 Touch ?<sup>▲</sup> button (C).

The cause and remedy (D) of the alarm message are displayed.

Remedy the fault.

The alarm tone ceases when the fault has been remedied. Medium- and low-priority alarm messages disappear automatically. High-priority alarm messages remain displayed in the color of the header bar and must be acknowledged.

# Acknowledging alarm message

#### Acknowledging high-priority alarm messages



• Touch the *Alarm Reset* button (A) in the header bar and confirm using the rotary knob.

*Evita XL* saves the alarm message, which can be displayed in the *Data* dialog window on the *Logbook* page. See page 131.

# Acknowledging Apnoea ventilation !! alarm message

The medium-priority alarm message (Caution) *Apnoea ventilation !!* may be obscured by alarm messages of higher priority. The alarm message may therefore also be acknowledged with the *Apnoea Reset* button.



- 1 Touch *Alarm Info* button.
- 2 Touch *Apnoea Reset* button (B) and confirm using the rotary knob.

*Evita XL* continues to ventilate in the previously set ventilation mode.

# **Silencing Audible Alarms**

The audible alarm can be silenced for a maximum of 2 minutes.



# Press Audio paused 2 min. (A) or Alarm Silence (A) key.

The yellow LED in the key lights up.

The audible alarm will be silenced for 2 minutes.



If the fault that triggered the alarm is not remedied at the end of the 2 minutes, the audible alarm starts again.

If you wish to reactivate the audible alarm earlier:

Press A Audio paused 2 min. (A) or Alarm Silence (A) key again.

# **Power Failure Alarm**

If the loudspeaker for generating audible alarms fails due to a fault, a continuous tone will be generated by an auxiliary alarm.

The same continuous alarm tone also serves as a power failure alarm, see "Behavior of Evita XL in the event of temporary interruption of power supply" on page 55.

# **Quiet Power Failure Alarm\***

*Evita XL* can be equipped with a quiet version of the power failure alarm for use in particularly quiet clinical environments.

#### WARNING

Only use devices equipped with the "Quiet Power Failure Alarm" kit in quiet environments. In noisy clinical environments, there is a risk of device failure not being detected in time.

<sup>\*</sup> Not available for USA, Canada, Japan, China, Taiwan, Korea, and Brazil

# **Setting Alarm Limits**

#### WARNING

Set alarm limits according to the current patient's therapy requirements. Otherwise, the patient may be at risk!

• Press 🖌 Alarm Limits key.

Evita XL opens the Limits page (A).



The set alarm limits and the current measured value are displayed.

- (B) = Upper alarm limit
  - (C) = Current measured value
- (D) = Lower alarm limit

The values for the upper and lower alarm limit shown in the buttons are start-up values which are effective whenever the device is switched on. These start-up values can be configured to meet the hospital's requirements, see "Setting start-up values for alarm limits" on page 164.

#### Setting alarm limits

- 1 Touch the button for the respective alarm limit. The button will turn yellow.
- 2 Turn the rotary knob to set the value.
- Press rotary knob to confirm. The button turns green.

The new alarm limit is effective.

Alarm limits for the optional measured value etCO2 can be set on the *Limits* **2** page (E).

## **Deactivating alarm limits\***

- 1 Touch lower alarm limit (D).
- Reduce value using rotary knob until a message is displayed in the header bar.
- 3 Press rotary knob to confirm.
- 4 Continue turning rotary knob until the value is replaced by dashes (--) in the display (D).
- 5 Press rotary knob to confirm.

The lower alarm limit is deactivated.

optional in NIV and in the Neonatal patient category

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# Measured Values, Graphics, and Trends

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# **Displaying Graphics**

The following real-time waveforms can be displayed:

- PAW (t)
- Flow (t)
- Volume (t)
- CO2 (t)
- a real-time waveform combined with a short trend or a Recruitment Trend (breath-based trend).

# Selecting real-time waveforms

1 Touch f *Main* button in the main menu bar.



**2** Touch the relevant  $\stackrel{\bullet}{\mathbb{Z}}$  button (A).

*Evita XL* opens a dialog window, the *Curves* page (B) is selected by default.

## Selecting other real-time waveforms

- 1 Touch *Curve only* tab (C).
- 2 Touch button for the parameter (E) to be displayed as a real-time waveform.

*Evita XL* displays the real-time waveform for this parameter. The dialog window is closed automatically.

 To freeze real-time waveforms, see "Freeze" on page 127.

# Displaying real-time waveform combined with short trend

Only available with the XL Monitoring Plus option.

Prerequisite: The *Curves* page must be open.

1 Touch Curve + Shorttrend tab (D).

The respective real-time waveform may be combined with the short trend for any parameter that can be selected.

The selected real-time waveform is displayed and the button of the associated short-trend parameter appears in dark green.

2 Touch button of the parameter (E) to be displayed as a short trend.



*Evita XL* displays the associated parameter as a short trend of the last 20 minutes on the left, next to the real-time waveform (F).

The other two real-time waveforms are also automatically combined with a short trend.

If no new parameters have been selected for the short trends, *Evita XL* will display the parameters previously selected for the short trend.

# Displaying real-time waveform combined with Recruitment Trend

Only available with the LPP option.

Prerequisite: The *Curves* page must be open.

1 Touch *Curve* + *RecrTrend* tab (G).



The respective real-time waveform can be combined with the breath-based trend of the selectable parameters *EIP / PEEP*, *VTe*, and *C*.

2 Touch the button of the desired parameter (H) for the corresponding Recruitment-Trend.

To view a point on the waveform at a certain moment in time:

 Turn the rotary knob to position the cross-hair cursor (I) on the required point and the corresponding measured value is displayed above the waveform.

If the cross-hair cursor is moved out of the displayed segment, the displayed time segment is automatically shifted.

- to the right = new time segment
- to the left = old time segment

## Freeze

To freeze a current real-time waveform or loop:



• Touch  $\bigcirc$  *Freeze* button (A).

The button turns dark green with a red symbol. The momentary waveforms or loops are recorded and then stop.

To view a waveform value at a certain point in time or a pair of values in a loop:

• Turn the rotary knob to position the cross-hair cursor (B) on the desired point.

The measured value or pair of values will be displayed above or beside the waveform or loop, respectively.

Evita XL ends freeze mode automatically:

- 3 minutes after touching the button
- 3 minutes after the rotary knob was last turned.

## To view new waveforms/loops:

• Touch  $\bigcirc$  *Freeze* button again.

The current waveforms or loops are once again recorded.

# **Displaying loops**

To display two measured values which appear as a loop for each ventilation cycle, such as the PAW-V loop or the V-Flow loop.

Without the XL Monitoring Plus option, only the PAW-V loop can be displayed. The PAW-V loop is shown enlarged for the waveform in the center.

1 Touch *Main* button in the main menu bar.



**2** Touch the relevant  $\stackrel{\bullet}{\mathbb{Z}}$  button (A).

*Evita XL* opens a dialog window, the *Curves* page is selected by default.

3 Touch Loops tab (B).

*Evita XL* can display the loop in different configurations:

Two small loops, one on the left and one on the right

or

- an enlarged loop on the left.

## To display small loops:

Touch Small tab (C).

# To display a large loop:

Touch Large tab (D).

## Selecting the desired parameter combination

If two parameters should be displayed in combination:

• Touch buttons (E) for the desired parameters.

*Evita XL* records all the loops for a ventilation cycle, e.g., in SIMV mode the loops of the mandatory breaths and the loops of any spontaneous breaths.



## To display a single loop:

• Touch Single breath button (F).

Evita XL will redraw every single loop.

## To display a reference loop:

• Touch *Ref.* button (G) at the desired time to record a reference loop.

The reference loop is drawn in blue and it appears continuously in the current loop display. The time at which the reference loop was recorded appears on the left beside the *Ref.* button.

• To freeze loops, see "Freeze" on page 127.

The **Ref.** button is ineffective when the loop has been frozen using the  $\bigcirc$  **Freeze** button.

# **Displaying 1 hr trends**

Only available with the XL Monitoring Plus option.

1 Touch *Main* button in the main menu bar.



- To view a value of a trend at a certain point in time:
- Turn the rotary knob to position the cross-hair cursor (D) on the desired point.

The value is displayed at the top in the trend display (E).

The cross-hair cursor cannot be moved if the trend display has been stopped with the  $\bigcirc$  *Freeze* button.

**2** Touch the relevant  $\stackrel{\bullet}{\mathbb{Z}}$  button (A).

*Evita XL* opens a dialog window, the *Curves* page (B) is selected by default.

3 Touch Trends tab (B).

#### Selecting parameters for the trend display

4 Touch the button for the desired parameter (C).

*Evita XL* displays the trend for the selected parameter over the last one hour.



# **Displaying Measured Values**

*Evita XL* displays a preconfigured selection of measured values on the main screen together with the active alarm limits.

The three selections are factory-configured, however they may also be reconfigured to meet the hospital's requirements (only available with the XL Configuration Plus option), see "Selecting display of measured values" on page 153.

Available selections:

- <sup>1 2 3</sup>
- \_ <sup>1 2 3</sup>
- <sup>1 2 3</sup>

To change the display of measured values:

• Touch 🛍 button (A) in the main menu bar.



# Displaying all measured values and settings

To facilitate documentation, *Evita XL* displays all measured values and settings in two tables. In a third table (only available with XL Configuration Plus option), customized measured values and settings can be displayed, see "Selecting customized measured values and settings" on page 154.

• Touch *Data ...* button in the main menu bar.



*Evita XL* opens the *Data* dialog window, the *Values* page (A) is selected by default.

Customized measured values and settings are displayed on the *Custom. Table* page (B).

## To select Table 1 or Table 2:

• Touch *Table 1* (C) or *Table 2* (D) tab.

# **Displaying the Logbook**

After the initial start:

*Evita XL* records changes, events, and alarms and lists them in chronological order with the date and time of occurrence.

## NOTE

The last 1000 entries are permanently saved. Preceding entries are automatically deleted.

**Changes** are displayed with the former and new settings (example: 5 mbar -> 7 mbar (5 cmH<sub>2</sub>O -> 7 cmH<sub>2</sub>O)).

**Events** include, for instance, use of a nebulizer, flow calibration, etc.

**Alarms** are recorded in the form displayed by the device at the time of occurrence. Other alarms which are triggered with the displayed alarm, but are not themselves displayed in the field for alarm messages, are identified by an asterisk (\*) preceding their entry in the logbook.

## To display the logbook:



Touch *Data ...* button in the main menu bar.

• Touch *Logbook* tab (A).

When a time is highlighted in the trend display (see page 132), the line corresponding to that time is highlighted in the logbook.

With every recorded change in settings, *Evita XL* displays the complete list of new settings (C) for the ventilation mode effective at the time indicated in the highlighted line (B).

To view all the settings for another line entry:

• Turn the rotary knob to select the desired line (B).

# Displaying trends (1-24 h)

- Touch *Data ...* button in the main menu bar.
- Touch *Trends* tab (A).



*Evita XL* displays three trends with a common time scale (B), one below the other.

# To select a parameter or parameter combination for the trend display:

• Touch the relevant <u>button</u> (C).



Evita XL opens the selection for the trends (E).

• Touch the button for the desired parameter or parameter combination.

The trend will be displayed and the dialog window will be closed.

# To select the common time scale in increments, as 1, 3, 6, 12, 24 hr:

• Touch the relevant button for the time scale (D).

The button turns green and the selected time scale is now effective.

# To view a value of a trend at a certain point in time:

• Turn the rotary knob to position the cross-hair cursor on the desired point in time.

The value is displayed on the left, beside the  $\[box]{button}$  (F).

# Monitoring

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# Information on Sensor Calibration

*Evita XL* uses the following sensors for measuring and monitoring:

- Flow sensor
- Neonatal flow sensor (optional)
- Pressure sensors
- O2 sensor
- CO<sub>2</sub> sensor (optional)

#### CAUTION

To ensure correct operation of the sensors, they need to be calibrated regularly. Otherwise device function may be compromised.

Sensor calibration is performed at the following intervals:

| Sensor                        | Interval   |
|-------------------------------|--|
| Airway<br>pressure<br>sensors | Automatic calibration every<br>3 minutes or if deviations are<br>detected  |
| Flow sensor                   | During device check.<br>Automatic calibration once a<br>day or if deviations are<br>detected.<br>After replacing the flow<br>sensor.<br>Calibration can be performed<br>at any time, even during<br>ventilation. |
| Neonatal flow<br>sensor       | During device check.<br>At least once a day.<br>After replacing the neonatal<br>flow sensor.   |
| O2 sensor                     | Automatic calibration once a<br>day.<br>Calibration can be performed<br>at any time, even during<br>ventilation. This does not<br>affect the applied O2<br>concentration.  |
| CO2 sensor                    | Calibration can be performed<br>at any time, even during<br>ventilation.   |

The last sensor calibration values obtained are permanently saved until the sensors are calibrated again, even if the ventilator was switched off in the meantime.

# Flow Sensor Calibration

Flow sensor calibration is performed at the following intervals:

- During device check
- Automatically, at least once a day
- After replacing the flow sensor

*Evita XL* cleans the flow sensor automatically before it is calibrated.

*Evita XL* also automatically cleans and calibrates the flow sensor after medication nebulization.

# WARNING

After disinfecting with highly flammable substances, air the flow sensor for at least 30 minutes or rinse with sterile water. Otherwise, vapors could ignite during calibration. Fire hazard!

# Starting calibration of the flow sensor

1 Press *S Sensor Parameter* key.

The *Flow* page (A) appears by default. Flow monitoring is now switched on.



2 Touch Start button (B).

*Evita XL* calibrates the flow sensor. *Evita XL* uses the next inspiratory phase for calibration. Short inspiratory times are extended to approx. 1 second.

A message is displayed in the header bar.

The *Start* button turns pale green when calibration is completed.

# **External Flow Compensation**

When a constant external flow of up to 12 L/min is supplied (e.g., when using a medication nebulizer with external gas supply or when using external tracheal gas insufflation TGI), *Evita XL* is able to take this flow into account and to increase the thresholds for flow sensor monitoring. This helps to avoid the *Flow measurement inop. !!!* alarms during these applications.

*Evita XL* keeps measuring the expiratory volume. With external flow compensation activated, the values measured for VTe and MV are higher, but VTi is indicated too low. For volume-controlled ventilation, the tidal volume actually delivered to the patient is higher than the set value. It is therefore recommended to use pressure-controlled ventilation while using an external flow source.

In order to avoid nuisance alarms and to assure proper monitoring:

- Adjust upper and lower *MV* alarm limits in line with the current value.
- Use additional monitoring, e.g., external SpO<sub>2</sub>, if necessary.

## Measuring external flow

Prerequisite: The *Flow* page in the *Sensor Parameter* dialog window must be open.



• Touch *measure* button (A).

*Evita XL* measures the external flow and displays the value with date and time.

A message is displayed while measurement is in progress.

*Evita XL* aborts measurement of the external flow if it exceeds 12 L/min or if the flow measurement function is faulty.

When the external flow has been measured successfully, *Evita XL* takes it into account automatically. The **On** button (B) appears green.

If no external flow is applied:

- Touch **Off** button (C).
- Press the rotary knob to confirm.

Once *Evita XL* has calculated the external flow, it may be taken into account at any time:

- Touch **On** button (B).
- Press the rotary knob to confirm.

If the external flow changes:

• Have *Evita XL* measure the external flow again. Touch *measure* button (A).

# **Neonatal Flow Sensor Calibration**

Neonatal flow sensor calibration is performed at the following intervals:

- During device check
- At least once a day
- After replacing the neonatal flow sensor

Recalibration is not necessary if the neonatal flow sensor has been temporarily unplugged.

### WARNING

Following disinfection with highly flammable substances, air the housing and insert of the neonatal flow sensor for at least 30 minutes. Vapors could otherwise ignite when the flow sensor is connected. Fire hazard and danger to the patient!

### Starting calibration of the neonatal flow sensor

- 1 Press *S Sensor Parameter* key.
- 2 Touch *NeoFlow* tab (A).



3 Touch Start button (B).

#### Removing neonatal flow sensor

- 1 Remove the tube connector.
- 2 Remove the neonatal flow sensor from the Y-piece.
- 3 Insert the tube connector in the Y-piece.



- 4 Wearing a sterile glove,
- **5** seal both ends of the neonatal flow sensor (C).

This ensures that the requirement for calibration (flow = 0) is met.

## Performing calibration

• Press the rotary knob.

*Evita XL* calibrates the neonatal flow sensor. Calibration is completed after approx. 1 second.

The *Start* button turns pale green when calibration is completed. A message is displayed in the header bar.

# Reinserting neonatal flow sensor after calibration

- 1 Remove the tube connector from the Y-piece.
- 2 Reinsert the neonatal flow sensor in the Y-piece.
- **3** Reconnect the tube connector.

#### If calibration was unsuccessful:

• Repeat calibration.

If necessary

- Replace the neonatal flow sensor.
- Check the sensor cable.

# **O2 Sensor Calibration**

O2 sensor calibration is performed at the following intervals:

- During device check
- Automatically, at least once a day
- After replacing the O2 sensor (wait 15 minutes for the O2 sensor to warm up)
- When measured and set values diverge by more than 2 Vol.%

The O2 sensor may be calibrated during ventilation.

# Starting O2 sensor calibration

- 1 Press *Sensor Parameter* key.
- 2 Touch **O2** tab (A).



3 Touch Start button (B).

*Evita XL* calibrates the O<sub>2</sub> sensor.

A message is displayed in the header bar.

The *Start* button (B) turns pale green when calibration is completed.

# **Checking CO2 Sensor**

Only available with the CapnoPlus option.

## Information on cuvettes used

The following cuvettes may be used:

- Reusable cuvettes
- Disposable cuvettes

#### WARNING

The cuvette windows of the reusable cuvettes and the park bracket have different optical properties compared to those of the disposable cuvettes.

When using reusable cuvettes, zero calibration must only be performed on the device-side park bracket or on a clean reusable cuvette.

When using disposable cuvettes, zero calibration must only be performed on a new disposable cuvette.

Otherwise there will be a zero point deviation of up to ±1 Vol.% CO2.

# Information on checking the CO2 sensor

The following CO<sub>2</sub> sensor checks must be performed:

| Check   | Interval  |
|---|---|
| Zero point in ambient air zero is not displant air. | Perform a zero calibration if<br>zero is not displayed in<br>ambient air.                   |
|   | Before measurement and<br>when transferring the<br>CO2 sensor to another<br><i>Evita XL</i> |

| Check   | Interval   |
|---|--|
| CO2 zero<br>calibration in  | Automatically, during device check   |
| ambient air   | Manually at any time   |
|   | Before measurement and<br>when transferring the<br>CO2 sensor to another<br><i>Evita XL</i>  |
| Checking<br>calibration of<br>the CO2<br>sensor with<br>test filter     | Once a month   |
| Checking<br>calibration of<br>the CO2<br>sensor with<br>calibration gas | At least every 6 months and if<br>the check values are not met<br>on checking calibration using<br>test filter.  |
| CO2 sensor calibration  | Factory-calibrated and suitable for use with any <i>Evita XL</i>   |
|   | Recalibration of the CO2<br>sensor is only required if the<br>specified calibration values<br>are not met when testing<br>calibration with the calibration<br>gas. |

Zero calibration in ambient air, checking calibration of the CO<sub>2</sub> sensor with test filter or calibration gas and calibration of the CO<sub>2</sub> sensor may all be performed during ventilation.

# Information on checking the zero point and zero calibration

There must not be any increased CO<sub>2</sub> concentration in the measuring system when checking the zero point or performing zero calibration. Only the background concentration of approx. 0.4 Torr or 0.05 Vol.% normally found in room air will be considered.

# Information on alarm messages during CO<sub>2</sub> monitoring

# Alarm message CO2 sensor ?!!!

If the message **CO<sub>2</sub> sensor ?!!!** is displayed in spite of a connected CO<sub>2</sub> sensor and plugged cuvette, the following windows may be soiled:

- Park bracket
- Disposable cuvette
- CO2 sensor

## When using reusable cuvettes:

- 1 Clean park bracket and CO2 sensor.
- 2 Perform zero calibration. Take care not to breathe on the park bracket.

If it is not possible to remove the soiling on the park bracket:

- 1 Perform zero calibration on a clean reusable cuvette (with clean windows) in room air. Take care not to breathe on the cuvette.
- 2 Replace park bracket. Contact DrägerService.

## When using disposable cuvettes:

- 1 Clean CO2 sensor.
- 2 Perform zero calibration on a new disposable cuvette. Take care not to breathe on the cuvette.

## Alarm message CO2 zero ?!!!

If the alarm message **CO2 zero ?!!!** is displayed during measurement or if incorrect measured values are suspected, e.g., etCO2 values too low or inspiratory values too high: • Check whether cuvette windows are soiled.

If windows of the reusable cuvette are soiled:

• Clean or replace reusable cuvette.

If windows of the disposable cuvette are soiled:

• Use new disposable cuvette.

Despite design measures to minimize zero shift, major soiling of the cuvette windows, e. g. with deposits from medication nebulization, may result in a zero shift. The measured CO<sub>2</sub> values are incorrect even before the *Clean CO<sub>2</sub> cuvette !!!* message appears due to the intensity of the measuring light being too low.

In case the message **CO2 zero ?!!!** does not disappear or the measurements are still doubted, zero calibration must be performed:

### When using reusable cuvettes:

• Perform zero calibration on the clean park bracket. Take care not to breathe on the park bracket.

If the measured values are still suspect:

- 1 Perform zero calibration on a clean reusable cuvette in room air. Take care not to breathe on the cuvette.
- **2** Continue measurement with the cuvette that was used for zero calibration.

#### When using disposable cuvettes:

• Perform zero calibration on a new disposable cuvette. Take care not to breathe on the cuvette.

# Alarm message CO<sub>2</sub>-cal./-zero/-check impossible

If the message **CO2-cal./-zero/-check impossible** appears after touching the **Start**, **Filter Check** or **Gas Check** button or the **Calibration** tab, this may have the following reasons:

- The warm-up phase of the CO2 sensor was not completed.
- Wait until the warm-up phase of approx. 3 minutes has elapsed.

- CO2 sensor is not plugged in:
- Connect CO<sub>2</sub> sensor.
- CO2 sensor is defective:
- Replace CO2 sensor.
- The CO2 electronics in the device are defective.
- Contact DrägerService.

For additional information, see "Alarm – Cause – Remedy" on page 166.

# Performing CO<sub>2</sub> zero calibration

When using a reusable cuvette, only possible with a clean park bracket and a clean CO<sub>2</sub> sensor!

When using a disposable cuvette, only possible with a new disposable cuvette and a clean CO2 sensor!

1 Switch on *Evita XL* and wait at least 3 minutes for the CO<sub>2</sub> sensor to complete its warm-up.

After 3 minutes, the measured values will be within the specified tolerance range.

#### Starting CO2 zero calibration

- 2 Press *Sensor Parameter* key.
- 3 Touch CO2 tab (A).



4 Touch Start button (B).

The instruction to bring the CO<sub>2</sub> sensor in the calibration position is displayed in the header bar.



5 Remove CO2 sensor (C) from the cuvette.

#### When using reusable cuvettes:

• Place the CO2 sensor on the park bracket. Take care not to breathe on the park bracket.

#### When using disposable cuvettes:

- Fit the CO2 sensor on a new disposable cuvette, which must not be installed in the breathing circuit. It is not mandatory to perform zero calibration on the cuvette which is to be used for measuring. It is sufficient to perform zero calibration on an unused identical disposable cuvette.
- Perform calibration in ambient air, taking care not to breath on the cuvette.

# WARNING

When using disposable cuvettes, zero calibration may only be performed on a new disposable cuvette and not on the device-side park bracket. Do not breathe on the cuvette. Otherwise there will be a zero point deviation of up to 1 Vol.% CO2.

6 Press the rotary knob to confirm.

Evita XL performs CO2 zero calibration.

**CO2 zero calibration** is displayed in the header bar.

After approx. 5 seconds, *Evita XL* confirms zero calibration with the message *CO2 zero ok*.

### After CO<sub>2</sub> zero calibration

• Fit CO<sub>2</sub> sensor (C) back onto the cuvette.

# If CO2 zero calibration is faulty

The alarm message **CO2 zero ?!!!** is displayed in the header bar.

• Repeat CO2 zero calibration.

If zero calibration is again unsuccessful:

 Check whether CO<sub>2</sub> sensor or park bracket is soiled. Clean if necessary.

If the CO2 sensor is defective:

Replace CO<sub>2</sub> sensor and repeat zero calibration.

# Checking calibration of the CO<sub>2</sub> sensor with test filter

Check calibration of CO<sub>2</sub> sensors with test filter at monthly intervals.

# CAUTION

Before checking with the test filter, perform CO2 zero calibration on the park bracket or on a clean reusable cuvette and not with a disposable cuvette. The check with the test filter will otherwise be outside the specified range.



- Use test filter (A) provided on the CO<sub>2</sub> sensor cable.
- Switch on *Evita XL* and wait at least 3 minutes for the CO<sub>2</sub> sensor to complete its warm-up.
- Perform CO<sub>2</sub> zero calibration on the park bracket or a clean reusable cuvette, see page 141.

# Starting calibration check of CO2 sensor with test filter

Prerequisite: The **CO**<sup>2</sup> page (B) in the **Sensor Parameter** dialog window must be open.

Touch *Check sensor* tab (C).



- 2 Touch *Filter Check* button (D).
- 3 Insert test filter (A) into CO2 sensor.

*Evita XL* now displays the test value of the CO2 concentration FCO2. Example: *FCO2 4.1 Vol.*%

• Compare test value with the value indicated on the test filter.



This value must correspond to the value indicated (deviation of  $\pm 0.3$  Vol.% permitted).

Example:

| Test filter | Permitted range: |
|-------------|------------------|
| 4.1 Vol.%   | 3.8 to 4.4 Vol.% |

If the test value is outside the permitted tolerance, the sensor must be checked with calibration gas. If necessary, the CO<sub>2</sub> sensor has to be calibrated.

# After checking calibration of the CO<sub>2</sub> sensor with test filter

• Fit CO2 sensor back onto the cuvette.

# Checking calibration of the CO<sub>2</sub> sensor with calibration gas

Checking calibration of the CO2 sensor with calibration gas should be performed at least every 6 months and if test values are not met on checking calibration of the CO2 sensor using the test filter.

## WARNING

Do not use test gases containing N2O for testing and calibration purposes. Using test gases containing N2O can cause indication deviations of  $\pm 0.5$  Vol.% CO2.

### CAUTION

Checking calibration with calibration gas can only be performed after zero calibration has been performed on the park bracket or on a clean, reusable cuvette. After zero calibration on a disposable cuvette and subsequent checking of calibration with calibration gas with the cuvette from the calibration set, deviations of more than 2 Vol.% CO2 may occur.

- 1 Switch on *Evita XL* and wait at least 3 minutes for the CO<sub>2</sub> sensor to complete its warm-up.
- **2** Perform CO<sub>2</sub> zero calibration, see page 141.

Prerequisite: The **CO2** page (A) in the **Sensor Parameter** dialog window must be open.

3 Touch Check sensor tab (B).



## Connecting the calibration gas supply

1 Use the reusable cuvette from the calibration set!



- Connect the calibration gas cylinder (E) and cuvette (F) from the calibration set to the hose (G).
- 3 Remove CO<sub>2</sub> sensor (H) from its park bracket and fit onto the cuvette (F) from the calibration set.
- 4 Read CO<sub>2</sub> and (if it contains O<sub>2</sub>) O<sub>2</sub> concentration of the calibration gas from the calibration gas cylinder (E).

# Entering O<sub>2</sub> concentration

- 1 Touch O2 button (C).
- 2 Adjust value using the rotary knob:
- If the calibration gas contains CO<sub>2</sub>, O<sub>2</sub>, and N<sub>2</sub>:
- Enter O2 concentration read from the cylinder.

If the calibration gas contains CO2 and N2 only:

- Set O2 concentration to **0**.
- **3** Confirm value using the rotary knob.
- 4 Touch Gas Check button (D).

*Evita XL* displays the CO<sub>2</sub> concentration FCO<sub>2</sub>. Example: *FCO<sub>2</sub> 5.0 Vol.*%

After approx. 10 seconds, the FCO2 value should correspond to the CO2 content of the calibration gas read from the calibration gas cylinder (deviation of  $\pm 0.2$  Vol.% permitted).

If the value is outside the permitted tolerance, the CO<sub>2</sub> sensor must be recalibrated with calibration gas.

# After checking calibration of the CO<sub>2</sub> sensor with calibration gas

• Fit CO2 sensor back onto the cuvette.

# Calibrating CO<sub>2</sub> sensor

Calibration of the CO<sub>2</sub> sensor is required if the specified values are not met when testing calibration with calibration gas.

## WARNING

Do not use test gases containing N2O for testing and calibration purposes. Using test gases containing N2O can cause indication deviations of  $\pm 0.5$  Vol.% CO2.

### WARNING

Calibration of the CO<sub>2</sub> sensor with calibration gas can only be performed after zero calibration has been performed on the park bracket or on a clean, reusable cuvette. After zero calibration on a disposable cuvette and subsequent calibration of the CO<sub>2</sub> sensor with calibration gas using the cuvette from the calibration set, deviations of more than 2 Vol.% CO<sub>2</sub> may occur. These deviations can lead to a misinterpretation of the patient's respiratory status during ventilation.

- Switch on *Evita XL* and wait at least 3 minutes for the CO<sub>2</sub> sensor to complete its warm-up.
- 1 Perform CO<sub>2</sub> zero calibration, see page 141.

Prerequisite: The **CO**<sup>2</sup> page (A) in the **Sensor Parameter** dialog window must be open.



2 Touch *Calibration* tab (B).
#### Connecting the calibration gas supply

1 Use the reusable cuvette from the calibration set!



- 2 Connect the calibration gas cylinder (F) and cuvette (G) from the calibration set to the hose (H).
- 3 Remove CO<sub>2</sub> sensor (I) from its park bracket and fit onto the cuvette (G) from the calibration set.
- 4 Read CO<sub>2</sub> and (if it contains O<sub>2</sub>) O<sub>2</sub> concentration of the calibration gas from the calibration gas cylinder (F).

## Entering O2 and CO2 concentration

- 1 Touch the relevant button.
- 2 Adjust value using the rotary knob:

When using the standard calibration gas (5 Vol.% CO2 and 95 Vol.% N2):

- Set O2 concentration (C) to 0.
- Set CO<sub>2</sub> concentration (D) to 5.
- **3** Confirm value using the rotary knob.
- 4 Touch Start button (E).

During calibration, the message **CO<sub>2</sub> calibration**. **Please wait** is displayed.

*Evita XL* performs calibration and confirms with the message **CO2** calibration ok.

#### After calibration of the CO<sub>2</sub> sensor

• Fit CO2 sensor back onto the cuvette.

#### Procedure if calibration fails

*Evita XL* indicates failed calibration with the following messages:

#### CO2 calibration interrupted

or

#### CO2 calibration failed

Repeat calibration of the CO<sub>2</sub> sensor.

Calibration may fail for the following reasons:

- The CO<sub>2</sub> concentration value entered may not be the same as that in the calibration gas cylinder:
- Check CO2 concentration entered.
- The calibration gas cylinder is empty:
- Use a new calibration gas cylinder.
- The sensor is defective:
- Replace sensor.

## Resetting calibration of CO<sub>2</sub> sensor

If calibration was not successful or if there were problems during calibration, the sensor can be reset to the factory-set value.

Prerequisite: The **CO2** page (A) in the **Sensor** *Parameter* dialog window must be open.

1 Touch *Calibration* tab (B).



2 Touch Reset Cal. button (C).

After approx. 5 seconds, the factory-set calibration value is reactivated.

• Perform a valid calibration of the CO<sub>2</sub> sensor as soon as possible!

## Switching Monitoring Functions Off or On

## Switching flow monitoring off or on

Switch off flow monitoring only briefly if a spent flow sensor cannot be replaced immediately. Replace flow sensor as quickly as possible, calibrate flow sensor and switch on flow monitoring.

When flow monitoring is switched off, the displays for flow and the displayed values calculated on the basis of flow, such as tidal volumes and minute volume, and the monitoring of the minute volume are switched off.

The expiratory flow monitoring function cannot be fully replaced by a replacement monitoring function. The MV alarm limits of the replacement monitoring function must be set accordingly.

## WARNING

Without an expiratory flow sensor, the ventilation functions are restricted. A spent or disconnected expiratory flow sensor may lead to deviations in the minute and tidal volumes, to deviations in the *PEEP* and in the inspiratory pressure, or cause self-triggering.

Depending on the lung characteristics (resistance and compliance), a deactivated flow monitoring function may affect oxygenation of the patient and CO<sub>2</sub> elimination.

Replace a spent expiratory flow sensor immediately, calibrate the flow sensor, and reactivate the flow monitoring function.

#### WARNING

If flow monitoring is switched off despite the presence of a working and connected expiratory flow sensor, the flow sensor is still used for controlling the ventilation functions.

However, the flow sensor is not monitored and its failure will not trigger an alarm.

Switch flow monitoring on again immediately.

#### Switching flow monitoring off

1 Press *Sensor Parameter* key.

The *Flow* page (A) appears by default.



- 2 Touch Off button (B).
- **3** Press the rotary knob to confirm.

*Evita XL* displays a constant message in the header bar.

#### NOTE

The measured values disappear. The alarm function is deactivated.

#### After replacing the flow sensor

Switch monitoring function back on.

#### Switching flow monitoring on

1 Press *Sensor Parameter* key.

The *Flow* page (A) appears by default.

- 2 Touch On button (C).
- 3 Press the rotary knob to confirm.

Flow monitoring is now switched on.

## Switching NeoFlow monitoring off or on

NeoFlow monitoring can be switched off:

- If the neonatal flow sensor has failed but cannot be replaced immediately.
- Medication nebulization is to be performed.
- To permit ventilation in the event of major tube leakage.

When NeoFlow monitoring is switched off, neither volume-controlled nor patient-triggered ventilation is possible.

Without NeoFlow monitoring, the ventilation functions and ventilation monitoring are only available to a limited extent.

## WARNING

Without the neonatal flow sensor, the minute volume is not monitored! Apnea monitoring is now only effective to a limited extent. Apnea is detected if there is no notable fluctuation in the flow supply from the device over 1 minute. Independent apnea monitoring is recommended.

## Switching NeoFlow monitoring off

- 1 Press *Sensor Parameter* key.
- 2 Touch *NeoFlow* tab (A).



- 3 Touch Off button (B).
- 4 Press the rotary knob to confirm.

*Evita XL* displays a constant message in the header bar.

## NOTE

The measured values disappear. The alarm function is deactivated.

## After replacing the neonatal flow sensor

• Switch NeoFlow monitoring function back on.

## Switching NeoFlow monitoring on

- 1 Press *Sensor Parameter* key.
- 2 Touch *NeoFlow* tab (A).
- 3 Touch On button (C).
- 4 Press the rotary knob to confirm.

NeoFlow monitoring is now switched on.

## Switching O2 monitoring off or on

Switch off O2 monitoring, e.g., if a spent O2 sensor cannot be replaced immediately.

## WARNING

When O2 monitoring is switched off, provide for appropriate external replacement monitoring immediately. Otherwise, patient safety cannot be ensured.

When the O2 monitoring function is switched off, the display for the measured FiO2 value and the monitoring for inspiratory O2 concentration are switched off.

The O<sub>2</sub> monitoring function can be replaced by an appropriate external replacement monitoring function. The O<sub>2</sub> alarm limits of the replacement monitoring function must be set in accordance with the current FiO<sub>2</sub> setting:

 $FiO_2 <\!\!60 \text{ Vol.\%} \rightarrow O_2 \pm 4 \text{ Vol.\%} \\ FiO_2 \geq\!\!60 \text{ Vol.\%} \rightarrow O_2 \pm 6 \text{ Vol.\%}$ 

## Switching O2 monitoring off

- 1 Press *Sensor Parameter* key.
- 2 Touch **O2** tab (A).



- 3 Touch Off button (B).
- 4 Press the rotary knob to confirm.

*Evita XL* displays a constant message in the header bar.

## NOTE

The measured values disappear. The alarm function is deactivated.

## After replacing the sensors

• Switch monitoring function back on.

## Switching O2 monitoring on

- 1 Press *S Sensor Parameter* key.
- 2 Touch **O2** tab (A).
- 3 Touch *On* button (C).
- 4 Press the rotary knob to confirm.

O2 monitoring is now switched on.

## Switching CO2 monitoring off or on

Switch off CO2 monitoring:

- If a spent CO<sub>2</sub> sensor cannot be replaced immediately.
- When the measured CO<sub>2</sub> values are currently not required.

## Switching CO<sub>2</sub> monitoring off

- 1 Press *Sensor Parameter* key.
- 2 Touch CO2 tab (A).

| Δ | Х |
|---|---|
|   |   |
|   |   |
|   |   |
|   |   |
|   |   |
|   |   |

- 3 Touch Off button (B).
- 4 Press the rotary knob to confirm.

Evita XL displays a message in the header bar.

#### NOTE

The measured values disappear. The alarm function is deactivated.

## Switching CO2 monitoring on

- 1 Press *S Sensor Parameter* key.
- 2 Touch CO2 tab (A).
- 3 Touch On button (C).
- 4 Press the rotary knob to confirm.

CO2 monitoring is now switched on.

## **NeoFlow Monitoring**

Standard on Evita XL Neo

Only available for *Evita XL* with the NeoFlow option.

# NeoFlow monitoring in the Neonatal patient category

Measured *MV* and *VTe* values are not leakagecorrected and are therefore lower than the actual minute and tidal volumes applied to the patient in case of leakages.

*Evita XL* compensates leakages up to 100 % of the set tidal volume *Vt*. Pressure-controlled ventilation is recommended in the case of larger leakages.

In order to avoid nuisance alarms and to assure proper monitoring, the following settings are required:

- Adjust upper and lower **MV** alarm limits in line with the current value.
- Use additional monitoring, e.g., external SpO<sub>2</sub>, if necessary.

# NeoFlow monitoring in the Pediatric patient category

If the neonatal flow sensor is present and intact for the Pediatric patient category, flow monitoring is performed with this sensor.

If the neonatal flow sensor is defective or if NeoFlow monitoring is switched off, flow monitoring is performed with the expiratory flow sensor of *Evita XL*. In this case, volume-controlled ventilation remains possible.

## WARNING

The neonatal flow sensor must not be used for larger pediatric patients with serious infections and a severe cough. Secretion coughed up by patients can cause corrosion in the neonatal flow sensor. Use the expiratory flow sensor of *Evita XL* for flow monitoring.

## Configuration

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## Information on Configuration

In the **System Setup** dialog window, the user can configure settings for different applications:

- System-specific settings:
  - Alarm volume
  - Screen brightness
  - Screen display
  - Country-specific settings
  - Interfaces

- Therapy-specific settings:
- Patient ranges
- Start-up settings for ventilation
- Start-up settings for alarm limits

These customized settings become effective when the ventilator is switched on.

## **System-Specific Settings**

## Adjusting volume of the audible alarm

1 Press System Setup key.

## Selecting screen brightness



The System page (A) appears by default.

- 2 Touch Sound, Day/Night tab (B).
- **3** Touch the button in the *Alarm Volume* line (C).
- **4** Using the rotary knob, set and confirm the value.

#### WARNING

Always adjust audible alarm volume to a level that ensures the operator will be alerted when alarms occur. 1 Press System Setup key.

The **System** page (A) appears by default.



2 Touch Sound, Day/Night tab (B).

Two selections are available: **Day** (C) for strong contrast and bright colors and **Night** (D) for reduced screen brightness.

3 Touch the relevant button.

## Selecting screen display

#### Selecting display of waveforms, loops, trends

Without the XL Monitoring Plus option, only waveforms can be configured.

1 Press E System Setup key.

The System page (A) appears by default.

2 Touch Screen tab (B).



3 Touch Graphics... tab (C).

Select parameters or parameter combinations for Graphics 1, 2, and 3:

4 Touch the relevant button in the *Graphic 1* (D), *Graphic 2* (E), or *Graphic 3* (F) line.

Evita XL opens a selection list (G).

**5** Using the rotary knob, select and confirm the parameter or parameter combination.

## Selecting display of measured values

Without the XL Configuration Plus option, the measured values cannot be configured.

1 Press 🔝 System Setup key.

The **System** page (A) appears by default.

- 2 Touch Screen tab (B).
- 3 Touch *Measured Values* tab (C).



To display measured values with their effective alarm limits, the three selections can be customized specifically as required by hospital protocol. The buttons are arranged in the same order as the numerical values on the main screen.

In the **1**<sup>1</sup>/<sub>1</sub> *Group 1* (D), **1**<sup>1</sup>/<sub>1</sub> *Group 2* (E), or **1**<sup>1</sup>/<sub>1</sub> *Group 3* (F) column:

#### 4 Touch the relevant button.

#### Evita XL opens

- the choice to display one (G) or two parameters (H)
- the selection list of parameters (I)
- 5 Touch 1 Value (G) or 2 Values (H) button.
- 6 Select and confirm the parameter (I) using the rotary knob.

## Selecting measured values to be displayed as trends

1 Press E System Setup key.

The **System** page (A) appears by default.

- 2 Touch Screen tab (B).
- 3 Touch Trends... tab (C).



The measured values to be displayed as trends can be selected. Up to eight measured values can be selected, depending on the options available. Only the measured values selected are saved as a trend.

4 Touch the relevant button.

Evita XL opens the selection list (D).

 Select and confirm the measured value using the rotary knob.

## Defining additional buttons in the main menu bar

With the XL Configuration Plus option, additional buttons can be configured.

Seven additional buttons can be defined in the main menu bar for accessing a function directly.

1 Press E System Setup key.

The **System** page (A) appears by default.

- 2 Touch Screen tab (B).
- 3 Touch *Function Keys...* tab (C).



4 Touch the relevant button.

Evita XL opens the selection list (D).

5 Select and confirm the function using the rotary knob.

## Selecting customized measured values and settings

Only available with the XL Configuration Plus option.

1 Press E System Setup key.

The **System** page (A) appears by default.

- 2 Touch Screen tab (B).
- 3 Touch *Custom. Data...* tab (C).

To select customized measured values:

1 Touch *Measured Values* tab (D).



Up to 18 measured values can be compiled. The buttons (E) reflect the position and order of the measured values in the customized table.

**2** Touch the relevant button (E).

Evita XL opens the selection list.

**3** Select and confirm the measured value using the rotary knob.

To select customized settings:

1 Touch Settings tab (F).



Up to 15 settings can be compiled. The buttons (G) reflect the position and order of the settings in the customized table.

**2** Touch the relevant button (G).

Evita XL opens the selection list.

**3** Select and confirm the setting using the rotary knob.

#### Screen configurations

Only available with the XL Configuration Plus option.

6 different screen configurations are available.

For each screen configuration, the following settings are saved:

- Waveforms, loops, trends or short trends displayed on the main screen
- 3 sets of measured values
- Additional buttons in the main menu bar
- Customized data table

Changes in the configuration of the trends have an effect on the trends stored in the screen configuration.

For factory settings, see "Screen Configurations" on page 276.

#### **Displaying screen configuration**

• Touch the button (A) until the required screen configuration is displayed.

Fast switch to the required screen configuration:

 Touch the button (A) several times until the required screen configuration is displayed.

#### Setting screen configuration

1 Press E System Setup key.

The **System** page (B) appears by default.

- 2 Touch Screen tab (C).
- 3 Touch View... tab (D).



To save the current screen configuration:

- 1 Touch the  $\Rightarrow$  button (E) in the relevant line.
- 2 Press the rotary knob to confirm.

Or:

- 1 Touch the button (A) for 3 seconds, the button turns yellow.
- 2 Select and confirm a memory location using the rotary knob.

To lock the screen configuration against overwriting:

• Touch the **b** button (G) in the relevant line.

The symbol **d** (G) appears next to the display of the locked screen configuration.

To deactivate the lock:

- 1 Touch d button (F).
- 2 Enter access code: 1860

The lock is deactivated.

To hide a screen configuration:

• Touch the  $\bigcirc$  button (H) in the relevant line.

The hidden screen configuration is not displayed in the selection.

To display the factory-set screen configuration:

- 1 Touch *Dräger Default* button (I).
- 2 Press the rotary knob to confirm.
- 3 Enter access code: 1860

All screen configurations are overwritten with the factory settings, see "Screen Configurations" on page 276.

## Locking therapy controls

To prevent direct modification of the ventilation parameters, the therapy controls on the main screen can be locked.

1 Press System Setup key.

The **System** page (A) appears by default.

- 2 Touch Screen tab (B).
- 3 Touch Lock... tab (C).



To activate the lock:

4 Touch 🛱 button (D).

On the main screen in the therapy bar, the symbol **b** is displayed.

The ventilation parameters can be set in the *Ventilator Settings* dialog window.

To deactivate the lock:

● Touch d button (E).

## Selecting country-specific settings

1 Press E System Setup key.

The **System** page (A) appears by default.

2 Touch PCountry tab (B).



## Selecting the display language

*Evita XL* displays the currently-selected language in the *Language* line (C).

The device is factory-configured to the language at the customer site.

Evita XL can be set to the following languages:

| German      | Norwegian |
|-------------|-----------|
| English     | Dutch     |
| English USA | Polish    |
| French      | Hungarian |
| Spanish     | Russian   |
| Portuguese  | Chinese   |
| Italian     | Japanese  |
| Swedish     | Czech     |
| Danish      | Romanian  |

1 Touch the ▼ button in the *Language* line (C).

Evita XL opens the selection list.

2 Select and confirm language with rotary knob.

## Selecting units

Specific national units may be selected for the physical quantities pressure, temperature and CO2.

The current units are displayed in the *Units* line (D).

- **1** Touch the relevant button.
- 2 Select and confirm using the rotary knob.

## Setting the date and time

*Evita XL* displays the current date and time in the *Date* (E) and *Time* (F) lines respectively.

- 1 Touch the relevant button.
- 2 Select and confirm using the rotary knob.

## CAUTION

*Evita XL* does not have automatic summer time/winter time changeover. The adjustment must be made by the user. Otherwise the dates in the display and for stored data and actions (e.g. in the logbook) will be incorrect.

## **Configuring interfaces**

1 Press E System Setup key.

The **System** page (A) appears by default.

2 Touch Interface tab (B).



*Evita XL* displays the *COM 1* (C), *COM 2* (D), *COM* **3** (E) and *Analog* (F) interface parameters in the respective lines.

- **1** Touch the relevant button.
- 2 Select and confirm using the rotary knob.

## Displaying available options

1 Press System Setup key.

The **System** page (A) appears by default.

2 Touch Options Overview tab (B).



*Evita XL* displays an overview with patient categories and options:

- Adult
- Paediatric
- NeoFlow
- XL Configuration Plus
- XL Monitoring Plus
- XL Ventilation Plus
- ATC
- NIV
- NIV Plus
- LPP
- PPS
- CapnoPlus
- SmartCare / PS
- NurseCall
- Evita Link

The patient categories and options which are available in the device are marked with a checkmark ( $\checkmark$ ).

## Service

To display the operating status of the internal function components.

Only available to authorized personnel with the necessary access code.

## Therapy-Specific Start-Up Settings

The therapy-specific start-up settings can be configured by the user to meet the hospital's requirements.

## Setting the patient range

- 1 Press E System Setup key.
- 2 Touch *Therapy* tab (A).
- 3 Touch Patient Range tab (B).
- 4 Enter access code: 3032



*Evita XL* shows the *Patient Range* (C) that becomes effective when the device is switched on.

● Touch ▼ button.

*Evita XL* opens the selection list. The following patient ranges are available\*:

- Adults only
- Pediatrics only
- Neonates only
- Adults or Pediatrics
- Pediatrics or Neonates
- Adults, Pediatrics, or Neonates
- Select and confirm patient range with rotary knob.

## Setting start-up values for ventilation

- 1 Press E System Setup key.
- 2 Touch Therapy tab (A).
- 3 Touch Mode & Settings tab (B).
- 4 Enter access code: 3032



*Evita XL* displays an overview (C) of all configurable start-up defaults for ventilation.

## Selecting start-up setting of the ventilation modes

1 Touch *Modes...* tab (D).



<sup>\*</sup> Depending on device and available options

*Evita XL* displays the Startup and three additional ventilation modes in the *Modes* line (E). After switching on *Evita XL*, these ventilation modes will be displayed in the *Ventilator Settings* dialog window.

2 Touch the relevant button (E).

Evita XL opens the selection list.

**3** Select and confirm ventilation mode using the rotary knob.

The following ventilation modes are only available with the XL Ventilation Plus option:

- MMV
- BIPAP Assist
- APRV

## Setting start-up values for VT, f, and Flowtrigger

The start-up defaults for VT, f and Flowtrigger can be set according to the patient category or according to the weight of the patient.

Setting start-up values for VT, f, and Flowtrigger according to weight:

- 1 Touch VT, f... tab (C).
- 2 Touch By Weight tab (D).



*Evita XL* displays the start-up value for VT-, f and Flowtrigger for different weights (E).

- 3 Touch the relevant button (E).
- 4 Set and confirm start-up value using the rotary knob.

5 Touch the On button (G) in the Start-up by weight line (F) and confirm using the rotary knob.

After switching on *Evita XL*, ventilation begins with the start-up values depending on the patient weight set in the *Start / Standby* dialog window.

To restore factory settings:

Touch *Dräger Default* button (H) and confirm with rotary knob.

Setting start-up values for VT, f, and Flowtrigger according to patient category:

- 1 Touch VT, f... tab (C).
- 2 Touch By Patient tab (I).



*Evita XL* displays the start-up values for VT-, f, and Flowtrigger for different patient categories (J).

- 3 Touch the relevant button (J).
- 4 Set and confirm start-up value using the rotary knob.
- 5 Touch the *On* button (G) in the *Start-up by patient* line (K) and confirm using the rotary knob.

After switching on *Evita XL*, ventilation begins with the start-up values depending on the patient category set in the *Start / Standby* dialog window.

To restore factory settings:

Touch *Dräger Default* button (H) and confirm with rotary knob.

## Settings for VT, f, and Flowtrigger according to Radford nomogram

To select the start-up values depending on body weight, the Radford nomogram has been extended to a weight of 0.5 kg (1.1 lbs) for neonates:

|            | F                  | actory setting        | S           | Customized settings |                       |             |
|------------|--------------------|-----------------------|-------------|---------------------|-----------------------|-------------|
| Weight     | Tidal volume<br>Vт | Respiratory<br>rate f | Flowtrigger | Tidal volume<br>Vт  | Respiratory<br>rate f | Flowtrigger |
| kg (lb)    | mL                 | bpm                   | L/min       | mL                  | bpm                   | L/min       |
| 0.5 (1.1)  | 3                  | 35                    | 0.5         |                     |                       |             |
| 3.0 (6.6)  | 30                 | 35                    | 0.2         |                     |                       |             |
| 15 (33.1)  | 110                | 26                    | 1           |                     |                       |             |
| 65 (143.3) | 450                | 13                    | 2           |                     |                       |             |
| 100 (220)  | 700                | 10                    | 2           |                     |                       |             |

For selecting start-up settings depending on patient category:

|                     | F                  | actory setting        | Customized settings             |    |                       |             |
|---------------------|--------------------|-----------------------|---------------------------------|----|-----------------------|-------------|
| Patient<br>category | Tidal volume<br>VT | Respiratory<br>rate f | Respiratory Flowtrigger Trate f |    | Respiratory<br>rate f | Flowtrigger |
|                     | mL                 | bpm                   | L/min                           | mL | bpm                   | L/min       |
| Neo.                | 9                  | 31                    | 0.5                             |    |                       |             |
| Paed.               | 50                 | 29                    | 1                               |    |                       |             |
| Adult               | 500                | 12                    | 2                               |    |                       |             |

## Setting start-up values for O<sub>2</sub>, I : E, pressure...

1 Touch O2, I:E pressure... tab (C).



*Evita XL* displays the start-up values for pressure (D), Pmax (E), O2 (F), and I : E (G).

To set start-up values:

- 2 Touch the relevant button.
- **3** Set and confirm using the rotary knob.

To switch Pmax (E) on or off:

4 Touch relevant button and confirm using the rotary knob.

In addition to the ventilation parameters VT and f, the parameters inspiratory time Ti and Flow derived from the ratio of inspiratory to expiratory time I : E are displayed (H), but only if start-up values are configured **By Patient**.

To restore factory settings:

• Touch *Dräger Default* button (I) and confirm with rotary knob.

#### **Configuring additional settings**

1 Touch Add. settings... tab (C).



The following settings can be configured for the *Add. settings* page in the *Ventilator Settings* dialog window:

| AutoFlow (D)                | on or off                   |
|-----------------------------|-----------------------------|
| Apnea ventilation (E)       | on or off                   |
| Leakage compensation (F)    | on or off                   |
| Inspiratory termination (G) | Manual or Dräger<br>Default |

- 2 Touch the relevant button.
- 3 Press the rotary knob to confirm.

## Selecting start-up settings for tube compensation

1 Touch ATC... tab (C).



The following start-up settings can be selected for tube compensation:

| Tube compensation<br>(ATC) (D)     | on or off  |
|------------------------------------|--|
| Inspiratory<br>compensation (E)    | Spontaneous +<br>mandatory or<br>spontaneous only  |
| Expiratory<br>compensation (F)     | on or off  |
| Degree of tube<br>compensation (G) | 0 to 100 %   |
| Tube type (H)                      | Endotracheal tube or tracheostomy tube   |
| Inside diameter of the tube (I)    | Patient category<br>– <b>★</b> <i>Adult</i> : 5 to 12 mm<br>– <b>★</b> <i>Paed</i> .: 2.5 to 8 mm<br>– Å <i>Neo</i> .: 2.5 to 5 mm |

To switch on or off:

- 2 Touch the relevant button.
- 3 Press the rotary knob to confirm.

Set values:

- 4 Touch the relevant button.
- **5** Set and confirm using the rotary knob.

## **Configuring NIV**

Only available with the NIV Plus option.

1 Touch NIV... tab (C).



To switch on or off:

- 2 Touch the relevant button.
- **3** Press the rotary knob to confirm.

## Setting start-up values for alarm limits

- 1 Press System Setup key.
- 2 Touch *Therapy* tab (A).
- 3 Touch Alarm Limits tab (B).
- 4 Enter access code: 3032

Evita XL displays the current start-up alarm limits.

- J<sup>▲</sup> = upper alarm limit
- ✓ = lower alarm limit
- **5** Touch the relevant button.

6 Set and confirm using the rotary knob.



| Parameter               | Setting range   | Factory-set start-up value<br>(Dräger Default) | Customized start-<br>up value |
|-------------------------|---|--|-------------------------------|
| _∕ <b>▲</b> MV (C)      | 0 to 99 %   | (V⊤ x f) +50 %                                 |                               |
| ▼∕ MV (C)               | 0 to 99 %   | (V⊤ x f) –20 %                                 |                               |
| _∕ <sup>▲</sup> Paw (D) | 10 to 100 mbar<br>(10 to 100 cmH2O)                   | 50 mbar (50 cmH2O)                             |                               |
| _∕ <b>▲</b> V⊤i (E)     | 0 to 99 %   | VTi +100 %                                     |                               |
| _∕▲ fspn (F)            | 5 to 120 bpm  | 50 bpm   |                               |
| _∕▲ TApnoea (G)         | 5 to 60 seconds                                       | 15 seconds                                     |                               |
| _∕ <b>▲</b> etCO2 (H)   | 1 to 98 mmHg<br>(0.1 to 15 Vol.%,<br>0.1 to 13.2 kPa) | 60 mmHg<br>(8 Vol.%, 8 kPa)                    |                               |
| . <b>v</b> ∕¯ etCO₂ (H) | 0 to 97 mmHg<br>(0 to 14.9 Vol.%,<br>0 to 13.1 kPa)   | 30 mmHg<br>(4 Vol.%, 4 kPa)                    |                               |

The values set may be entered in the column "Customized start-up value".

To restore factory settings:

Touch *Dräger Default* button (I) and confirm with rotary knob.

## WARNING

After starting ventilation, adjust the alarm limits to the current patient. Otherwise, the patient may be at risk!

## **Problem Solving**

## Alarm – Cause – Remedy

The alarm messages are displayed in the message field of the header bar in hierarchical order.

The priority of alarm messages is indicated by exclamation marks after the message and through different background colors. These determine the priority of the corrective action required.

| Warning | !!! | Red    | High-priority alarm<br>message   | Immediate action is necessary in order to avert an acute danger |
|---------|-----|--------|----------------------------------|---|
| Caution | !!  | Yellow | Medium-priority<br>alarm message | Prompt action is necessary in order to avert a danger           |
| Note    | !   | Yellow | Low-priority alarm<br>message    | Attention is necessary, but a delayed response is sufficient    |

In order to classify the alarms within an alarm category, internal priority numbers are given after the exclamation marks in the table below. The most critical alarm is awarded the number 255. The priority of the alarm decreases the lower the number is.

If several alarms occur at the same time, the most critical alarm is displayed in the alarm message field of the header bar.

In the following table, the alarm messages are listed in alphabetical order. If an alarm occurs, the table helps to identify causes and remedies. The different causes and remedies should be worked through in the order listed until the alarm has been resolved.

| Message                        | Priority | Cause   | Remedy  |
|--------------------------------|----------|---|---|
| Air supply down !              | 250      | Air supply pressure too low. Air supply pressure not required when FiO2 = 100 Vol.%.  | Make sure supply pressure is greater than 3 bar.  |
| Air supply down !!!            | 250      | Air supply pressure too low.  | Make sure supply pressure is greater than 3 bar.  |
| Air supply pressure<br>high !  | 060      | Air supply pressure too high. Air<br>supply not required for FiO2 =<br>100 Vol.%.   | Make sure supply pressure is less than 6 bar.   |
| Air supply pressure<br>high !! | 100      | Air supply pressure too high.   | Make sure supply pressure is less than 6 bar.   |
| Airway obstructed ?!!!         | 230      | The ventilator applies only a very small volume with each mechanical stroke, e.g. because the tube is blocked.  | Check condition of patient, check tube  |
|                                |          | Patient 'fights' against the<br>mechanical strokes in pressure-<br>controlled ventilation, with the<br>result that the set inspiratory<br>pressure is reached with only a<br>very small volume. | Check condition of patient, check ventilator settings.  |
|                                |          | Neonatal flow sensor not installed in the breathing system.   | Install neonatal flow sensor in the breathing system.   |
| Airway pressure high<br>!!!    | 205      | The upper alarm limit for the<br>airway pressure has been<br>exceeded. The patient is<br>'fighting' the ventilator or<br>coughing.  | Check patient condition. Check ventilation pattern. Correct alarm limits if necessary.  |
|                                |          | Ventilation hose buckled.   | Check hose system and tube.   |
| Airway pressure low<br>!!!     | 204      | Leak or disconnection.  | Inflate cuff and check for leaks.<br>Check breathing circuit for tight<br>connections. Check that the<br>expiratory valve is properly<br>engaged. |
| Ambient pressure<br>sensor ?!! | 200      | Ambient pressure sensor faulty.   | Note:The ventilator functions<br>are not affected. Device can not<br>be used in helicopters or<br>aircraft. Call DrägerService.                   |

| Message                 | Priority | Cause   | Remedy   |
|-------------------------|----------|---|--|
| Apnoea !!!              | 181      | Patient's spontaneous breathing has stopped.  | Check condition of patient, if<br>necessary apply controlled<br>ventilation.   |
|                         |          | Stenosis  | Check condition of patient.<br>Check tube. Check breathing<br>circuit.   |
|                         |          | Flow sensor not calibrated.   | Calibrate flow sensor.   |
| Apnoea !!!              | 181      | Neonatal flow sensor not calibrated or defective.   | Calibrate the neonatal flow<br>sensor, replace if necessary,<br>recalibrate.   |
|                         |          | Neonatal flow sensor connected but not placed in the Y-piece.   | Connect neonatal flow-sensor in the Y-piece.   |
|                         |          | Tube blocked.   | Check tube.  |
| Apnoea alarm off !      | 255      | Apnoea monitoring is not active when nebulising without flow monitoring.                              | Use external monitoring or<br>switch on flow monitoring or<br>stop nebulising.   |
| Apnoea alarm off !      | 114      | Apnoea monitoring has been switched off in application mode NIV.                                      | Set the upper alarm limit for<br>apnoea monitoring to the<br>required value again.   |
| Apnoea ventilation !!   | 230      | Due to detected apnoea, the<br>system has automatically<br>switched over to mandatory<br>ventilation. | Check ventilation procedure.<br>Return to the original ventilation<br>mode by touching the 'Apnoea<br>Reset' button and confirm.<br>Check condition of patient.<br>Check tube. |
| ASB > 1.5 s !           | 180      | The ASB phase was terminated<br>3 consecutive times after<br>1.5 seconds.                             | Test ventilation system for leaks.   |
| ASB > 4 s !!!           | 148      | The ASB phase was terminated<br>3 consecutive times after<br>4 seconds.                               | Test ventilation system for leaks.   |
| ASB > Ti max !          | 180      | The ASB phase was terminated by a time limitation.  | Test ventilation system for leaks.   |
| Back-up ventilation !!! | 200      | Neonatal flow sensor not calibrated.  | Calibrate neonatal flow sensor<br>or if necessary exchange and<br>calibrate neonatal flow sensor.  |
|                         |          | Tube blocked. Neonatal flow monitoring was switched off.  | Check tube. Activate neonatal flow monitoring.   |
|                         |          | Leakage or disconnection.   | Check tightness of breathing<br>circuit. Check correct position of<br>the expiratory valve.  |

| Message                          | Priority | Cause  | Remedy   |
|----------------------------------|----------|--|--|
| Breathing cycle not detected !!! | 180      | The device does not deliver any gas.   | Set P <sub>max</sub> higher than PEEP<br>setting. Extend alarm time<br>TApnoea or increase IPPV<br>frequency.  |
|                                  |          | Device faulty.   | Disconnect patient from the<br>device and continue ventilation<br>without delay, using another<br>independent ventilator. Call<br>DrägerService.   |
| Breathing cycle not detected !!! | 180      | The device does not deliver any gas.   | Check neonatal flow sensor.<br>Increase IPPV frequency.  |
|                                  |          | Device faulty.   | Disconnect patient from the<br>device and continue ventilation<br>without delay, using another<br>independent ventilator. Call<br>DrägerService.   |
| Check frequency<br>ILVSlave !    | 020      | The frequency (breathing rate) of the master and slave device differs by more than 12 %. | Adjust the frequency of the<br>slave device to that of the<br>master device.   |
| Check settings !!                | 205      | Malfunction while setting the<br>ventilation pattern or the alarm<br>limits.             | Check ventilation pattern and<br>alarm limits. The following<br>settings are affected: O2<br>concentration 'O2', Alarm limit<br>'PAw high', 'MV low', status<br>external flow source, status<br>oxygenation for bronchial<br>suction key 'Audio paused 2<br>min' / 'Alarm Silence' screen key<br>'Alarm Reset', screen key<br>'Insp.hold' Screen key<br>'Exsp.hold', switch off O2<br>monitoring, switch off flow<br>monitoring. Confirm message<br>with 'Alarm Reset' button. |
|                                  |          | The ventilation started with the configured initial values after switching on.           | Check all therapy and alarm<br>settings and adjust them if<br>necessary. Confirm message<br>with 'Alarm Reset' button.   |
| Clean CO2 cuvette !!!            | 144      | Cuvette window for the CO2 measurement is dirty.   | Use clean reusable cuvette or take new single-use cuvette.   |
|                                  |          | Sensor window for the CO2 measurement is dirty.  | Clean CO2 sensor.  |

| Message                         | Priority | Cause  | Remedy  |
|---------------------------------|----------|--|---|
| CO2 measurement inop. !!!       | 145      | CO2 sensor faulty.   | Replace faulty CO2 sensor.  |
|                                 |          | CO2 measurement incorrect.   | The ventilator functions are not<br>affected. Ensure adequate<br>external monitoring without<br>delay. Deactivate the internal<br>CO <sub>2</sub> monitoring. Call<br>DrägerService.  |
| CO2 monitoring off !            | 092      | CO2 monitoring is switched off.  | Switch CO2 monitoring on again<br>or use adequate external<br>monitoring if necessary.  |
| CO2 sensor ?!!!                 | 146      | Probe of CO2 sensor for the CO2 measurement was removed during operation.  | Reinsert probe.   |
|                                 |          | CO2 sensor for the CO2<br>measurement not positioned on<br>cuvette.  | Place CO <sub>2</sub> sensor on cuvette.  |
|                                 |          | CO2 sensor for the CO2 measurement defective.  | Replace defective CO2 sensor.   |
| CO2 zero ?!!!                   | 142      | Zero point for the CO2<br>measurement is outside the<br>permissible tolerance.   | Perform zero calibration.   |
|                                 |          | Zero calibration for the CO2 measurement unsuccessful.   | Perform zero calibration<br>correctly.  |
|                                 |          | Cuvette window or sensor window is dirty.  | Use clean reusable cuvette or<br>take new single-use cuvette.<br>Clean CO <sub>2</sub> sensor. Perform<br>zero calibration, refer to<br>instruction for use.  |
| Device failure<br>00.00.000 !!! | 253      | Device has detected a malfunction.   | Switch the device 'off' and 'on'<br>again. If the message<br>disappears ventilation can be<br>continued. If the message does<br>not disappear, disconnect the<br>patient from the device and<br>continue ventilation immediately<br>with another independent<br>ventilator. Call DrägerService. |
| etCO2 high !!!                  | 140      | Upper alarm limit for end-<br>expiratory CO <sub>2</sub> concentration in<br>CO <sub>2</sub> measurement has been<br>exceeded. | Check condition of patient,<br>check ventilation pattern,<br>correct alarm limit if neccessary.<br>Perform CO2 zero if applicable.  |

| Message                          | Priority | Cause  | Remedy  |
|----------------------------------|----------|--|---|
| etCO2 low !!!                    | 140      | Lower alarm limit for end-<br>expiratory CO <sub>2</sub> concentration in<br>CO <sub>2</sub> measurement has been<br>exceeded. | Check condition of patient,<br>check ventilation pattern,<br>correct alarm limit if neccessary.<br>Perform CO2 zero if applicable.  |
| Evita Remote ?!                  | 010      | The remote control pad was not recognised by the device.   | Remove Remote Pad.<br>Acknowledge message by<br>touching 'Alarm Reset' button<br>and confirm. Note: The<br>ventilator functions of the device<br>are not affected. Call<br>DrägerService. |
| Evita Remote inop. !             | 010      | Key pressed on Remote Pad<br>during selftest.  | Acknowledge message by<br>touching 'Alarm Reset' button<br>and confirm. Remove Remote<br>Pad and reconnect. Ensure that<br>no key is pressed on the<br>Remote Pad during self-test.       |
|                                  |          | Remote control pad faulty.   | Acknowledge message by<br>touching 'Alarm Reset' button<br>and confirm. Remove Remote<br>Pad. The ventilator functions of<br>the device are not affected. Call<br>DrägerService.          |
| Execute device check !!          | 210      | Device check not performed.  | Perform equipment check.<br>Acknowledge message by<br>touching 'Alarm Reset' button<br>and confirm.   |
| Exp. hold interrupted !          | 230      | The 'Exp. Hold' key was activated for longer than 15 seconds.  | Release 'Exp. Hold' key.  |
| Exp. valve faulty !!!            | 220      | Expiration valve not properly<br>connected to socket.  | Push expiration valve firmly into<br>socket until it clicks into place.   |
|                                  |          | Flow sensor not calibrated or defective.   | Calibrate flow sensor, replace if necessary.  |
|                                  |          | Expiration valve faulty.   | Replace expiration valve.   |
| Ext. battery - Voltage<br>high ! | 150      | External battery has been<br>connected with excessively high<br>voltage when using DC.   | Connect a 12 V or 24 V battery.   |

| Message                          | Priority | Cause   | Remedy  |
|----------------------------------|----------|---|---|
| Ext. battery activated !         | 254      | The ventilator is being powered<br>by the external battery due to<br>the absence of mains supply.<br>With fully charged batteries in<br>the trolley the device can be<br>powered up to 120 minutes. | Connect ventilator to the mains supply.   |
| Ext. battery activated !!        | 200      | The ventilator is being powered<br>by the external battery due to<br>the absence of mains supply.<br>With fully charged batteries in<br>the trolley the device can be<br>powered up to 120 minutes. | Connect ventilator to the mains<br>supply. Acknowledge the<br>message with 'Alarm Reset'<br>button and confirm.   |
| Ext. battery activated !!!       | 160      | The ventilator is being powered<br>by the external battery due to<br>the absence of mains supply.<br>With fully charged batteries in<br>the trolley the device can be<br>powered up to 120 minutes. | Connect ventilator to the mains<br>supply. Acknowledge the<br>message with 'Alarm Reset'<br>button and confirm.   |
| Ext. battery polarity reversed ! | 150      | External battery has been<br>connected with wrong polarity<br>when using DC.  | Connect the external battery correctly.   |
| External Flow !                  | 011      | <i>Evita XL</i> monitors the externally supplied flow when external flow measurement is activated.  | Deactivate calculation of external flow.  |
| Fan failure ?!!!                 | 050      | Temperature in device is too<br>high. Fan on the back side of<br>device failed?   | Check fan function, clean or<br>replace cooling air filter. Check<br>ambient air temperature.<br>Disconnect patient from the<br>device and continue ventilation<br>immediately with another<br>independent ventilator. Call<br>DrägerService. |
| Fan malfunction !                | 016      | Temperature in device is too<br>high. Fan on the back side of<br>device failed?   | Check fan function, clean or replace cooling air filter. Check ambient air temperature.   |
|                                  |          | Cooling fan on the back side of device failed.  | Disconnect patient from the<br>device and continue ventilation<br>without delay using another<br>independent ventilator. Switch<br>off the device. Call<br>DrägerService.   |

| Message                    | Priority | Cause  | Remedy   |
|----------------------------|----------|--|--|
| FiO2 high !!!              | 130      | O2 sensor not calibrated.  | Calibrate O2 sensor.   |
|                            |          | Faulty mixer function. The<br>ventilation function may be<br>affected. This may lead to<br>deviations in the O2<br>concentration and tidal volume. | Disconnect patient from the<br>device and continue ventilation<br>immediately with another<br>independent ventilator. Call<br>DrägerService.   |
| FiO2 low !!!               | 130      | O2 sensors not calibrated.   | Calibrate O2 sensor.   |
|                            |          | Faulty mixer function. The<br>ventilation function may be<br>affected. This may lead to<br>deviations in the O2<br>concentration and tidal volume. | Disconnect patient from the<br>device and continue ventilation<br>immediately with another<br>independent ventilator. Call<br>DrägerService.   |
| Flow measurement inop. !!! | 235      | Water in flow sensor. Expiratory<br>minute volume exceeds minute<br>volume delivered by the<br>ventilation unit.                                   | Dry flow sensor or change flow sensor and perform manual calibration.  |
|                            |          | Flow sensor not calibrated or<br>faulty. Expiratory minute volume<br>exceeds minute volume<br>delivered by the ventilation unit.                   | Calibrate flow sensor, replace if necessary.   |
|                            |          | Flow measurement malfunction.  | The ventilation function of the<br>device is limited. Check patient<br>condition, check ventilation. If<br>not acceptable disconnect<br>patient from the device and<br>continue ventilation immediately<br>with another independent<br>ventilator. Call DrägerService. |
| Flow monitoring off !      | 100      | Flow monitoring is switched off.   | Immediately switch flow monitoring on.   |
| Flow sensor ?!!!           | 228      | Flow sensor not fully inserted in rubber lip of expiration valve.  | Insert flow sensor correctly.  |
| High frequency !!!         | 150      | Patient is breathing at a high spontaneous frequency.  | Check condition of patient.<br>Check pattern of ventilation or<br>spontaneaus breathing<br>frequency. Check hose system<br>for water (auto triggering).<br>Correct alarm limit if<br>neccessary.   |
| Hose kinked !!             | 205      | The pressure at the inspiratory<br>port is greater than 30 mbar,<br>e.g. due to a kinked or blocked<br>hose, or a blocked patient mask.            | Check patient hoses, check patient mask.   |

| Message                                | Priority | Cause   | Remedy   |
|--|----------|---|--|
| ILV sync. inop. !!!                    | 080      | Frequency on master device less than 4 breaths per minute.  | Set a higher frequency.  |
|  |          | Fault in communication between the units.   | The individual ventilator<br>functions are not affected. Do<br>not continue with the ventilation<br>mode ILV. Call DrägerService.  |
| Insp. hold interrupted !               | 230      | The 'Insp. Hold' key was<br>operated for longer than<br>15 seconds.   | Release 'Insp. Hold' key.  |
| Int. battery activated !               | 254      | Due to the lack of power supply<br>and absence of or discharged<br>external battery the device is<br>powered by the internal battery.<br>The maximum remaining time<br>from the internal battery is<br>10 minutes.            | Connect ventilator to the mains<br>supply or to a fully charged<br>external battery within<br>10 minutes.  |
| Int. battery activated !!              | 200      | Due to the lack of power supply<br>and absence of or discharged<br>external battery the device is<br>powered by the internal battery.<br>The maximum remaining time<br>from the internal battery is<br>10 minutes.            | Connect ventilator to the mains<br>supply or to a fully charged<br>external battery within<br>10 minutes. Acknowledge the<br>message with 'Alarm Reset'<br>button and confirm. |
| Int. battery activated !!!             | 160      | Due to the lack of power supply<br>and absence of or discharged<br>external battery the device is<br>powered by the internal battery.<br>The maximum remaining time<br>from the internal battery is<br>10 minutes.            | Connect ventilator to the mains<br>supply or to a fully charged<br>external battery within<br>10 minutes. Acknowledge the<br>message with 'Alarm Reset'<br>button and confirm. |
| Int. battery<br>discharged !!!         | 254      | Due to the lack of power supply<br>and absence of or discharged<br>external battery the device is<br>powered by the internal battery.<br>The time for operation with<br>power from the internal battery<br>has expired.       | Connect ventilator immediately<br>to the mains supply or to a fully<br>charged external battery.   |
| Int. battery only 2<br>minutes left !! | 250      | Due to the lack of power supply<br>and absence of or discharged<br>external battery the device is<br>powered by the internal battery.<br>The remaining operating time<br>from the internal battery is less<br>than 2 minutes. | Connect ventilator to the mains<br>supply or to a fully charged<br>external battery within<br>2 minutes.   |

| Message                                     | Priority | Cause  | Remedy  |
|---|----------|--|---|
| Key Exp.Hold failed !!                      | 200      | Key can no longer be pressed.                                    | Disconnect patient from device<br>and continue ventilation<br>immediately with another<br>independent ventilator. Call<br>DrägerService.  |
| Key Exp.Hold<br>overused ?!!                | 200      | Key has been pressed<br>frequently in a short period of<br>time. | Acknowledge message by<br>touching 'Alarm Reset' button<br>and confirm. If this message<br>appears repeatedly: Disconnect<br>patient from the device and<br>continue ventilation immediately<br>with another independent<br>ventilator. Call DrägerService. |
| Key 🛱 failed !!                             | 200      | Key can no longer be pressed.                                    | Disconnect patient from device<br>and continue ventilation<br>immediately with another<br>independent ventilator. Call<br>DrägerService.  |
| Key Insp.Hold failed<br>!!                  | 200      | Key can no longer be pressed.                                    | Disconnect patient from device<br>and continue ventilation<br>immediately with another<br>independent ventilator. Call<br>DrägerService.  |
| Key Insp.Hold<br>overused ?!!               | 200      | Key has been pressed<br>frequently in a short period of<br>time. | Acknowledge message by<br>touching 'Alarm Reset' button<br>and confirm. If this message<br>appears repeatedly: Disconnect<br>patient from the device and<br>continue ventilation immediately<br>with another independent<br>ventilator. Call DrägerService. |
| Key O2 <sup>↑</sup> suction<br>failed !!    | 200      | Key can no longer be operated.                                   | Disconnect patient from device<br>and continue ventilation<br>immediately with another<br>independent ventilator. Call<br>DrägerService.  |
| Key O2 <sup>↑</sup> suction<br>overused ?!! | 200      | Key has been pressed<br>frequently in a short period of<br>time. | Acknowledge message by<br>touching 'Alarm Reset' button<br>and confirm. If this message<br>appears repeatedly: Disconnect<br>patient from the device and<br>continue ventilation immediately<br>with another independent<br>ventilator. Call DrägerService. |

| Message                   | Priority | Cause  | Remedy  |
|---------------------------|----------|--|---|
| Key 🛱 overused ?!!        | 200      | Key has been pressed<br>frequently in a short period of<br>time.   | Acknowledge message by<br>touching 'Alarm Reset' button<br>and confirm. If this message<br>appears repeatedly: Disconnect<br>patient from the device and<br>continue ventilation immediately<br>with another independent<br>ventilator. Call DrägerService. |
| Key overused ?!!          | 200      | Due to frequent key use, the screen contents of the display are repeatedly redrawn.                                    | Acknowledge message by<br>touching 'Alarm Reset' button<br>and confirm.   |
|                           |          | Brief communication failure<br>between display processor and<br>main processor.  | Acknowledge message by<br>touching 'Alarm Reset' button<br>and confirm. If this message<br>appears repeatedly: Disconnect<br>patient from the device and<br>continue ventilation immediately<br>with another independent<br>ventilator. Call DrägerService. |
| Key Reset failed !!       | 200      | Key can no longer be pressed.  | Disconnect patient from device<br>and continue ventilation<br>immediately with another<br>independent ventilator. Call<br>DrägerService.  |
| Key Reset overused<br>?!! | 200      | Key has been pressed<br>frequently in a short period of<br>time.   | Acknowledge message by<br>touching 'Alarm Reset' button<br>and confirm. If this message<br>appears repeatedly: Disconnect<br>patient from the device and<br>continue ventilation immediately<br>with another independent<br>ventilator. Call DrägerService. |
| Leakage !                 | 009      | The measured minute volume<br>leak MVleak is 20 % higher than<br>the minute volume measured on<br>the expiration side. | Check that the patient hose<br>connection has no leaks. Check<br>that the tube is correctly fitted.   |

| Message                            | Priority | Cause   | Remedy  |
|------------------------------------|----------|---|---|
| Loss of data !!!                   | 252      | Lithium battery discharged or<br>device faulty.                                   | If the alarm occurs after power<br>on: Check settings. Ventilation<br>can be continued. Call<br>DrägerService. If the alarm<br>occurs during operation or<br>continuously after power on:<br>disconnect the patient from the<br>device and continue ventilation<br>immediately with another<br>independent ventilator. Call<br>DrägerService. |
| MEDIBUS COM.<br>inop. !            | 012      | The MEDIBUS cable has been<br>unplugged during operation<br>when using EvitaLink. | Plug the connector in again and<br>secure it against disconnection<br>with the two screws.  |
|                                    |          | MEDIBUS cable defective.  | Use a new MEDIBUS cable.  |
|                                    |          | Interface defective.  | Ventilation can be continued.<br>Call DrägerService.  |
| Mixer inop. !!!                    | 240      | Mixer malfunction. FiO2 and tidal volume can deviate considerably.                | Immediately disconnect the<br>patient from the device and<br>continue ventilation without<br>delay using another<br>independent ventilator. Call<br>DrägerService.  |
| Multi functional board<br>inop. !  | 010      | The multi-functional board for operating the nurse call is faulty.                | Acknowledge message by<br>touching 'Alarm Reset' button<br>and confirm. The ventilator<br>functions are not affected.<br>However, correct operation of<br>the nurse call cannot be<br>guaranteed. Disconnect nurse<br>call from multi-function board.<br>Call DrägerService.  |
| Multi functional board<br>inop. !! | 200      | The multi-functional board for operating the nurse call is faulty.                | Acknowledge message by<br>touching 'Alarm Reset' button<br>and confirm. The ventilator<br>functions are not affected.<br>However, correct operation of<br>the nurse call cannot be<br>guaranteed. Disconnect nurse<br>call from multi-function board.<br>Call DrägerService.  |

| Message                        | Priority | Cause  | Remedy   |
|--------------------------------|----------|--|--|
| MV high !!!                    | 160      | The expired minute volume has exceeded the upper alarm limit.  | Check condition of patient,<br>check pattern of ventilation,<br>adjust MV alarm limit if<br>necessary.   |
|                                |          | Flow sensor not calibrated.<br>Water in flow sensor.   | Calibrate flow sensor. Drain<br>water trap of breathing circuit.<br>Dry flow sensor or replace.  |
| MV low !!!                     | 160      | The minute volume has fallen below the lower alarm limit.  | Check condition of patient,<br>check pattern of ventilation,<br>adjust alarm limit if necessary.   |
|                                |          | Stenosis or obstruction Flow sensor not calibrated   | Check condition of patient,<br>check ventilation pattern, check<br>tube or mask. Adjust alarm limit<br>if necessary. Calibrate flow<br>sensor.   |
|                                |          | Leakage or disconnection.  | Check breathing circuit for tight<br>connections. Check whether the<br>expiratory valve is properly<br>engaged. Check whether tube<br>or mask is fitted correctly.                                       |
| MV low alarm off !             | 097      | Monitoring of the lower alarm<br>limit for minute volume has been<br>deactivated in application mode<br>NIV. | Set alarm limit MV to the required value again.  |
| Nebulisation<br>interrupted !! | 110      | Nebulisation is only possible in pressure-controlled ventilation or with AutoFlow.                           | Select an appropriate<br>ventilation mode. Restart<br>nebulisation. Acknowledge the<br>alarm with 'Alarm Reset' button<br>and confirm.   |
|                                |          | Flow sensor not ready for measurement.   | Switch on flow monitoring or<br>calibrate sensor or replace flow<br>sensor or change mode of<br>ventilation. Restart nebulisation.<br>Acknowledge the alarm with<br>'Alarm Reset' button and<br>confirm. |
| Nebulisation<br>interrupted !! | 110      | Nebulisation is only possible in pressure-controlled ventilation.  | Select an appropriate<br>ventilation mode. Restart<br>nebulisation. Acknowledge the<br>alarm with 'Alarm Reset' button<br>and confirm.   |

| Message                               | Priority | Cause  | Remedy   |
|---------------------------------------|----------|--|--|
| Nebuliser failure !!!                 | 129      | Due to the pneumatic<br>nebulisation process, FiO2<br>concentration varies at least<br>2 Vol.% of the set value. The<br>maximum variation can reach<br>30 Vol.%. | If variation of FiO2 concentration<br>is acceptable for the time of the<br>nebulisation: Acknowledge<br>message by touching 'Alarm<br>Reset' button and confirm. If<br>variation of FiO2 concentration<br>is not acceptable or if message<br>appears repeatedly: Stop<br>nebulisation process. |
| Nebuliser on !                        | 070      | The medication nebuliser is<br>switched on.  | Switch off the medication<br>nebuliser if necessary.   |
| Neo. flow<br>measurement inop. !      | 012      | NeoFlow monitoring is defective<br>or the sensor lead is not<br>connected.   | Calibrate neonatal flow sensor.<br>Replace if necessary,<br>recalibrate. Connect sensor<br>lead. Call DrägerService.   |
| Neo. flow<br>measurement inop.<br>!!! | 228      | NeoFlow monitoring is defective<br>or the sensor lead is not<br>connected.   | Calibrate neonatal flow sensor.<br>Replace if necessary,<br>recalibrate. Connect sensor<br>lead. Call DrägerService.   |
| Neo. flow monitoring off !            | 100      | NeoFlow monitoring off.  | Switch NeoFlow monitoring on again.  |
| Neo. flow sensor ?!                   | 012      | NeoFlow sensor not installed in the breathing system.  | Install NeoFlow sensor in the<br>breathing system.   |
| Neo. flow sensor ?!!!                 | 229      | NeoFlow sensor not installed in the breathing system.  | Install neonatal flow sensor in the breathing system.  |
| O2 calibration<br>overused ?!!        | 200      | Key has been pressed<br>frequently in a short period of<br>time.   | Acknowledge message by<br>touching 'Alarm Reset' button<br>and confirm. If this message<br>appears repeatedly: Disconnect<br>patient from the device and<br>continue ventilation with<br>another independent ventilator.<br>Call DrägerService.  |
| O2 measurement inop. !!!              | 132      | O2 sensor provides invalid<br>measured values.   | Calibrate O2 sensor, replace if necessary.   |
|                                       |          | O2 measurement malfunction.  | Ventilation can be continued:<br>use external O2 monitoring and<br>deactivate integrated O2<br>monitoring. Call DrägerService.   |
| O2 monitoring off !                   | 095      | O2 monitoring switched off.  | Switch internal O2 monitoring on<br>again or immediately ensure an<br>adequate external monitor<br>function.   |

| Message                       | Priority | Cause   | Remedy  |
|-------------------------------|----------|---|---|
| O2 supply down !              | 249      | O2 supply pressure too low. O2<br>supply is not required for FiO2 =<br>21 Vol.%.                | Make sure supply pressure is greater than 3 bar.  |
| O2 supply down !!!            | 249      | O2 supply pressure too low.   | Make sure supply pressure is greater than 3 bar.  |
| O2 supply pressure<br>high !  | 060      | O2 supply pressure too high. O2<br>supply is not required for FiO2 =<br>21 Vol.%.               | Make sure supply pressure is less than 6 bar.   |
| O2 supply pressure<br>high !! | 099      | O2 supply pressure too high.  | Make sure supply pressure is less than 6 bar.   |
| O2 Therapy active !           | 070      | O2 therapy is activated.  | Switch off O2 therapy. Exit Standby.  |
| PEEP high !!!                 | 216      | Expiratory system obstructed.   | Check hose system and expiration valve. Check also for condensate.  |
|                               |          | Expiratory resistance is increasing.  | Check bacterial filter. Replace if necessary.   |
|                               |          | Machine faulty.   | Disconnect patient from the<br>device and continue ventilation<br>without delay using another<br>independent ventilator. Call<br>DrägerService. |
| PEEP valve inop. !!!          | 203      | Internal PEEP valve faulty.   | Disconnect patient from the<br>device and continue ventilation<br>without delay using another<br>independent ventilator. Call<br>DrägerService. |
|                               |          | Breathing system is open.<br>PEEP pressure can not be maintained.                               | Check breathing circuit for tight<br>connections. Check whether the<br>expiratory valve is properly<br>engaged.                                 |
| PPS-insp. > 1.5 s !           | 180      | The inspiration phase during<br>PPS was terminated<br>3 consecutive times after<br>1.5 seconds. | Check the ventilation system for leaks.   |
| PPS-insp. > 4 s !!!           | 148      | The inspiration phase during<br>PPS was terminated<br>3 consecutive times after<br>4 seconds.   | Check the ventilation system for leaks.   |
| Message                       | Priority | Cause   | Remedy  |
|-------------------------------|----------|---|---|
| Pressure limited !            | 080      | Pmax pressure limit is active.  | Check the condition of the patient. Check pattern of ventilation. Correct setting if necessary.   |
| Pressure meas. inop.<br>!!!   | 170      | Fluid in expiration valve.  | Replace expiration valve, then clean and dry.   |
|                               |          | Pressure measurement malfunction.   | Disconnect patient from the<br>device and continue ventilation<br>immediately with another<br>independent ventilator. Call<br>DrägerService.  |
| Procedure overused ?!!        | 200      | Total time of procedures has<br>exceeded 15 minutes within the<br>last hour.        | Acknowledge message by<br>touching 'Alarm Reset' button<br>and confirm. If this message<br>appears repeatedly: Disconnect<br>patient from the device and<br>continue ventilation immediately<br>with another independent<br>ventilator. Call DrägerService. |
| Remote Computer<br>Control !  | 076      | This message is displayed to inform the user that Evita is being controlled via PC. | Remote control can be<br>interrupted at any time by<br>pressing the function key<br>'Remote'.   |
| Remote Control<br>aborted !!  | 111      | The device has lost the<br>connection to the remote control<br>system               | Check cable connection, restart<br>remote control system and<br>reactivate remote control mode<br>on <i>Evita XL</i> .  |
| Remote Control<br>active !    | 076      | Remote control is switched on.  | To switch remote control off,<br>press the button 'RC' and<br>confirm.  |
| Rotary knob                   | 200      | Key can no longer be operated.  | Disconnect patient from device<br>and continue ventilation<br>immediately with another<br>independent ventilator. Call<br>DrägerService.  |
| Rotary knob ⊙<br>overused ?!! | 200      | Key has been pressed<br>frequently in a short period of<br>time.                    | Acknowledge message by<br>touching 'Alarm Reset' button<br>and confirm. If this message<br>appears repeatedly: Disconnect<br>patient from the device and<br>continue ventilation immediately<br>with another independent<br>ventilator. Call DrägerService. |

| Message                                 | Priority | Cause   | Remedy  |
|---|----------|---|---|
| Standby activated !!!                   | 255      | <i>Evita XL</i> has been switched to standby.   | Acknowledge standby with<br>'Alarm Reset' button and<br>confirm.  |
| Temperature high !!!                    | 090      | Breathing gas temperature higher than 40 °C.  | Switch off humidifier.  |
| Temperature meas.<br>inop. !!!          | 091      | Temperature sensor faulty.  | Fit new temperature sensor.   |
| Temperature sensor<br>?!!!              | 090      | Temperature sensor probe has been disconnected during operation.  | Reconnect probe.  |
|   |          | Sensor cable broken.  | Fit new temperature sensor.   |
| Tidal volume high !                     | 190      | The upper alarm limit of the applied inspiratory tidal volume VTi has been exceeded.  | Check condition of patient.<br>Check pattern of ventilation.<br>Correct alarm limit if<br>neccessary.   |
|   |          | Leak or disconnection.  | Check hose system<br>connections for leakages.  |
| Tidal volume high !!!                   | 165      | The upper alarm limit of the applied inspiratory tidal volume VTi has been exceeded during three consecutive ventilation strokes. | Check condition of patient.<br>Check pattern of ventilation.<br>Correct alarm limit if<br>neccessary.   |
|   |          | Leak or disconnection.  | Check hose system connections for leakages.   |
| Vol. not const.,<br>pressure limited !! | 220      | Due to pressure limit or time<br>limit, the set tidal volume VT has<br>not been applied.  | Prolong inspiratory time 'Tinsp',<br>increase inspiratory flow 'Flow',<br>increase pressure limit 'Pmax.<br>Touch the 'Alarm Reset' button<br>and confirm to suppress the<br>visual and acoustic alarms until<br>the cause of the alarm is<br>remedied. |
| V⊤i high alarm off !                    | 085      | The upper alarm limit for the inspiratory tidal volume VTi has been deactivated in application mode NIV.                          | Set alarm limit VTi to the required value.  |

## Cleaning, Disinfection, and Sterilization

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## Safety Information for Reprocessing

#### WARNING

To avoid risks to hospital staff and patients, disinfect and clean the device after each use (wear protective clothing, eye protection, etc.).

- Always observe accepted hospital hygiene protocols!
- Reprocess the device after each patient.

## **Disassembling Components and Reprocessing**

#### Before disassembling components

- 1 Switch off both device and breathing gas humidifier, and remove their power plugs from wall outlets.
- 2 Drain water traps and breathing circuit.
- 3 Empty water container of the breathing gas humidifier.

#### CO<sub>2</sub> sensor

#### **Disassembling CO2 sensor**

1 Unplug sensor connector at the back of *Evita XL*.



- 2 Remove CO<sub>2</sub> sensor (A) from cuvette.
- 3 Remove CO2 sensor cuvette (B) from Y-piece.
- 4 Remove ET-tube connector (C) from cuvette.

#### Reprocessing CO2 sensor and test filter

- Wipe off any soiling with cotton swabs or disposable tissue, particularly on the inside and outside of the windows.
- 2 Reprocess CO<sub>2</sub> sensor and test filter in accordance with the reprocessing list, see page 192.

#### Reprocessing reusable cuvette

#### CAUTION

Only reusable cuvettes (part no. 6870279 or 6870280) can be reprocessed. The disposable cuvette is not resistant to heat and would be destroyed. Dispose of disposable cuvettes.

- Wipe off any soiling with cotton swabs or disposable tissue, particularly on the inside and outside of the windows, if necessary under running water.
- 2 Reprocess reusable cuvette in accordance with the reprocessing list, see page 192.

#### **Temperature sensor**

#### Removing temperature sensor

1 Unplug sensor connector at the back of *Evita XL*.



2 Remove temperature sensor (A) from Y-piece or from its mounting on the pediatric breathing circuit. Do not pull on cable.

#### Reprocessing temperature sensor

• Reprocess temperature sensor in accordance with the reprocessing list, see page 192.

#### CAUTION

The temperature sensor is not designed for disinfection in a washer-disinfector or for bath disinfection. Liquid can penetrate into the sensor and cause malfunction!

#### Neonatal flow sensor

#### **Disassembling neonatal flow sensor**

1 Unplug sensor connector at the back of *Evita XL*.



- 2 Disconnect the flow sensor cable (A) from the neonatal flow sensor.
- **3** Press the buttons (B) on both sides while pulling the flow sensor insert (C) out of its housing.
- 4 Pull housing (D) out of the Y-piece.

#### Reprocessing neonatal flow sensor

Regularly check flow sensor housing and flow sensor insert for damage and contamination (visual inspection).

#### WARNING

Any residue of dried mucus or medication aerosols will impair measurement accuracy. Discontinue use if there are visible deposits on the flow sensor housing or flow sensor insert.

- Reprocess the flow sensor insert immediately after each use.
- Assemble flow sensor insert as specified in its Instructions for Use.
- Reprocess housing of the neonatal flow sensor in accordance with the reprocessing list, see page 192.

 Inspect visually for residues of dried mucus, medication aerosols, or fluff, especially on the measuring wires and their pins. Install a new flow sensor insert in the event of any visible deposits that were not removed during reprocessing.

#### WARNING

Contamination may lead to deviations during flow measurement and to destruction of the flow sensor.

#### WARNING

Following disinfection with highly flammable substances, air the housing and insert of the neonatal flow sensor for at least 30 minutes. Vapors could otherwise ignite when the flow sensor is connected. Fire hazard and danger to the patient!

#### Sterilizing neonatal flow sensor

 After drying, sterilize neonatal flow sensor in hot steam (134 °C (273 °F) for at least 10 minutes).

#### CAUTION

The neonatal flow sensor is not suitable for plasma or radiation sterilization. These methods could damage the thin wires in the flow sensor.

#### Pneumatic medication nebulizer

# Disassembling medication nebulizer after use in the Adult patient category



- 1 Detach nebulizer hose (A) from the medication nebulizer (B) and from the nebulizer port on the device.
- 2 Remove medication nebulizer (B) from the breathing circuit.
- 3 Disassemble medication nebulizer in accordance with relevant Instructions for Use.

# Disassembling medication nebulizer after use in the Pediatric and Neonatal patient categories



- 1 Detach nebulizer hose (A) from the medication nebulizer (B) and from the nebulizer port on the device.
- 2 Remove medication nebulizer (B) from the breathing circuit.
- Pull catheter connector (C) (tapered ISO connector Ø15/ Ø11) from the nebulizer inlet.
- 4 Pull adapter (D) (tapered ISO connector Ø22/ Ø11) from of the nebulizer outlet.
- 5 Pull corrugated hose (E) from the adapter (D).
- 6 Disassemble medication nebulizer in accordance with relevant Instructions for Use.

#### Reprocessing medication nebulizer and adapter parts

- Reprocess the individual parts of the medication nebulizer in accordance with its Instructions for Use.
- Reprocess adapter parts in accordance with reprocessing list, see page 192.

### **Breathing circuit**

#### Removing breathing circuit



1 Remove breathing hoses from ventilator ports (A).



#### CAUTION

When removing breathing hoses, always grasp hoses by their sleeve, never by the hose itself, to avoid tearing the breathing hose at the sleeve or ripping it out of the sleeve.

- 2 Remove water traps (B) from the breathing hoses.
- 3 Remove collection containers from the water traps.

#### **Reprocessing breathing circuit**

 Reprocess breathing hoses, water traps, and associated collection containers, as well as the Y-piece in accordance with the reprocessing list, see page 192.

#### Flow sensor

#### Removing flow sensor

- 1 Tilt control panel upwards: Press down the segments on the right and left, and at the same time tilt the control panel upwards.
- 2 Open flow sensor flap.



**3** Push flow sensor (C) as far as possible to the left and remove it.

#### **Reprocessing flow sensor**

 Reprocess flow sensor as specified in its Instructions for Use.  Inspect visually for residues of dried mucus, medication aerosols, or fluff, especially on the measuring wires and their pins. Dispose of the flow sensor in the event of any visible deposits that were not removed during reprocessing.

#### WARNING

Contamination may lead to deviations during flow measurement and to destruction of the flow sensor.

#### WARNING

After disinfecting with highly flammable substances, air the flow sensor for at least 30 minutes or rinse with sterile water. Otherwise, vapors could ignite during calibration. Fire hazard!

The flow sensor may be reused as long as automatic calibration is possible.

#### **Expiratory valve**

#### Removing expiratory valve



- 1 Push the catch (A) to the right while
- 2 at the same time pulling out the expiratory valve (B).

#### CAUTION

Only the white reusable expiratory valve may be reprocessed.

Dispose of the blue disposable expiratory valve as infectious special waste.

3 If using the reusable expiratory valve, remove the optional collection container (C) from the water trap.



#### Disassembling reusable expiratory valve

Only disassemble expiratory valve if it is severely soiled.



• Unscrew cap by hand and remove together with the diaphragm assembly.

Do not disassemble expiratory valve any further.

#### Reprocessing reusable expiratory valve

 Reprocess collection containers of the water trap, expiratory valve and, if necessary, cap and diaphragm assembly in accordance with the reprocessing list, see page 192.

#### After manual disinfection

1 Thoroughly rinse reusable expiratory valve and, if necessary, its individual parts with clear water, preferably from a soft water supply.



- 2 Thoroughly shake off any residual water.
- **3** Allow parts to dry thoroughly.

#### Sterilizing reusable expiratory valve

- After drying, sterilize reusable expiratory valve in hot steam (134 °C (273 °F) for at least 10 minutes). Otherwise liquid may remain in the pressure measuring line and impair correct functioning.
- Place the open expiratory valve in the tray in such a way that it cannot be damaged by other parts.

#### Breathing gas humidifier

• Disassemble and reprocess in accordance with relevant Instructions for Use.

## **Reprocessing Procedure**

#### Machine cleaning and disinfection

Use a washer-disinfector in accordance with EN ISO 15883, preferably with a cart for anesthesia and ventilation accessories, for automatic cleaning and disinfection. Use mild alkaline or enzymatic (with neutral pH) cleaning agents. The user must strictly observe the manufacturer's information on the cleaning agent.

#### Placing parts in the washer-disinfector

- Place parts in washer-disinfector. Observe instructions for use of washer-disinfector.
- Position parts so that all interior spaces are completely flushed (e.g., hoses) and water can drain off freely.

#### **Cleaning program**

 Select suitable program (preferably anesthesia program). Cleaning is carried out at 40 to 60 °C (104 to 140 °F) for at least 5 minutes.

#### Thermal disinfection

- Thermal disinfection is carried out at 80 to 95 °C (176 to 203 °F) and with corresponding contact time.
- 2 Carry out final rinsing with deionized water.

# After completion of cleaning and disinfection program

- 1 Immediately remove parts from washerdisinfector.
- 2 Inspect parts for visible soiling and damage. If necessary, repeat cycle or clean manually.
- 3 Allow parts to dry thoroughly.

#### **Cleaning agents**

The material compatibility of reusable Dräger accessories has been tested with various mildly alkaline and enzymatic cleaning agents, and at 93 °C (199.4 °F) for 10 minutes.

The following cleaning agents showed good material compatibility at the time of the test:

- Neodisher Medizym from Dr. Weigert
- Sekumatic MultiClean from Ecolab

The user must be sure to observe the manufacturers information on the cleaning agent exactly.

#### Manual cleaning

If no washer-disinfector is available, clean parts manually under running water with commercially available cleaning agents. The user must be sure to observe the manufacturers information on the cleaning agent exactly.

- 1 Wash off soiling on surface under running water.
- 2 Use cleaning agents in accordance with manufacturers specifications. Make sure that all surfaces to be cleaned can be efficiently reached (e.g. inside hoses). Use suitable brushes if necessary.

Do not use brushes for the flow sensor. Observe the relevant instructions for use.

- Rinse parts sufficiently under running water until no cleaning agent residues can be recognized.
- 4 Check parts for visible soiling and damage. Repeat manual cleaning if necessary.

#### Manual disinfection

Manual disinfection can be carried out preferably with disinfectants based on aldehydes or quaternary ammonia compounds. The efficiency of the disinfectants used must be proven. Observe the applicable country-specific listings. The list of the Association for Applied Hygiene (VAH List) applies in German-speaking countries. The user must strictly observe the manufacturer's information on the cleaning agent.

#### Disinfectants

The material compatibility of Dräger accessories to be reprocessed has been tested with various disinfectants.

The following disinfectants showed good material compatibility at the time of the test:

Surface disinfectants (for device surfaces)

 Buraton 10 F from Schülke & Mayr, Norderstedt

Instrument disinfectants (for components or accessories):

- Gigasept FF from Schülke & Mayr, Norderstedt
- Korsolex Extra from Bode Chemie, Hamburg

The composition of the disinfectant is the responsibility of the manufacturer and can change over time.

#### **Disinfecting surfaces**

#### WARNING

Penetrating liquid may lead to failure of the device or damage to the device and endanger the patient! Only disinfect parts by wiping and make sure no liquids penetrate into the device.

- Following manual cleaning, carry out surface disinfection.
- Remove disinfectant residues.

#### **Disinfecting components or accessories**

- 1 Disinfect parts by immersing.
- 2 Sufficiently rinse parts under running water until no disinfectant residues can be recognized.
- 3 Inspect parts for visible soiling and damage. Repeat manual disinfection if necessary.
- 4 Thoroughly shake out residual water and allow parts to dry thoroughly.

#### **Visual inspection**

 Inspect all parts for damage and wear, e.g. cracking, embrittlement or major hardening and residual soiling.

#### CAUTION

Even accessories designed to be reused (e.g. after reprocessing) have a limited service life. Due to a number of factors connected with handling and reprocessing (e.g.disinfectant residues can attack the material more intensely during autoclaving), increased wear can occur and the service life can be markedly shortened. These parts must be replaced if signs of wear become visible, such as cracks, deformation, discoloration, peeling, etc.

#### Sterilization

Use a vacuum steam sterilizer (in accordance with DIN EN 285), preferably with fractional vacuum, for sterilization.

 Hot steam sterilization can be carried at 134 °C (273 °F). Observe instructions for use of device.

## Reprocessing List for Evita XL

Applicable to non-infectious patients.

#### WARNING

For infectious patients, all parts that conduct breathing gas must be additionally sterilized after disinfection and cleaning. The list is merely intended as an approximate guide. The instructions of the hospital's hygiene officer shall prevail and must be observed by the user!

| Components which  | Recommended                                | Machine                      | Manual      |                        | Sterilization |
|---|--|------------------------------|-------------|------------------------|---------------|
| can be reprocessed  | reprocessing<br>intervals                  | cleaning and<br>disinfection | Cleaning    | Disinfection           |               |
| Evita XL basic device   | after each<br>patient                      | no                           | outside     | outside                | no            |
| Trolley   | after each                                 | no                           | outside     | outside                | no            |
| Hinged arm  | patient                                    |                              |             |                        |               |
| Gas supply hose   |  |                              |             |                        |               |
| Breathing hoses   | after each                                 | yes                          | possible    | possible               | yes           |
| Y-piece   | patient/weekly                             |                              |             |                        |               |
| Water traps   |  |                              |             |                        |               |
| Collection containers   |  |                              |             |                        |               |
| Adapter parts for the medication nebulizer                    |  |                              |             |                        |               |
| Reusable expiratory valve and, if necessary, individual parts | after each<br>patient/weekly <sup>1)</sup> | yes                          | possible    | possible <sup>2)</sup> | yes           |
| Disposable expiratory valve                                   |  | Dispose of after             | each patier | nt/weekly              |               |
| Spirolog flow sensor  | daily                                      | no                           | outside     | yes <sup>3)</sup>      | no            |
| SpiroLife flow sensor   | daily                                      | no                           | outside     | yes <sup>3)</sup>      | yes           |
| Neonatal flow sensor<br>insert                                | daily                                      | no                           | outside     | yes <sup>4)</sup>      | yes           |
| Neonatal flow sensor<br>housing                               | daily                                      | yes                          | possible    | possible               | yes           |
| Temperature sensor  | daily                                      | no                           | outside     | outside <sup>5)</sup>  | yes           |
| CO2 sensor  | daily                                      | no                           | outside     | outside <sup>6)</sup>  | no            |
| Reusable cuvette of the CO2 sensor                            | daily                                      | yes                          | possible    | possible               | yes           |
| Disposable cuvette of the CO2 sensor                          |  | Dispose of after             | each patier | nt/weekly              |               |

| Components which           | Recommended  | Machine                      | Ма                    | anual        | Sterilization |
|----------------------------|--|------------------------------|-----------------------|--------------|---------------|
| can be reprocessed         | reprocessing<br>intervals  | cleaning and<br>disinfection | Cleaning              | Disinfection |               |
| Test filter for CO2 sensor | daily  | no                           | outside <sup>6)</sup> | outside      | no            |
| Breathing gas humidifier   | after each In accordance with separate Instructions for U patient/weekly |                              | is for Use            |              |               |
| Medication nebulizer       | In accordance with separate Instructions for Use                         |                              |                       |              |               |
| Bacterial filter           | In accordance with separate Instructions for Use                         |                              |                       |              |               |

Nebulizing may lead to formation of more extensive deposits requiring more frequent replacement.
Additionally treat the expiratory valve after disinfection, see page 189.

3) See page 187.

4) See page 185.

5) Do not bath-disinfect.

6) Do not bath-disinfect. Wipe-disinfect, e.g., with 70 % ethanol. For additional information, see page 184.

## **Re-assembly of Parts**

### Assembling reusable expiratory valve

- 1 The parts of the expiratory valve must be completely dry to prevent malfunctions.
- 2 The diaphragm assembly (A) consists of the diaphragm, the sealing washer, and the aluminum disk.



3 Hold cap (B) by the grip part and place diaphragm precisely on the collar of the cap. Ensure correct position of the diaphragm assembly.



4 Insert cap (B) with diaphragm assembly on top into the housing (C) from below and screw in tightly.



**5** Attach collection container (D) of water trap.

#### Assembling medication nebulizer

 Assemble medication nebulizer as specified in its Instructions for Use. For installation details, see page 93.

### Assembling breathing gas humidifier

 Assemble breathing gas humidifier as specified in its Instructions for Use. For installation details, see page 50.

## **Before Reusing on Patient**

- 1 Assemble ventilator, see "Preparation" on page 39.
- 2 Perform readiness for operation checks, "Checking Readiness for Operation" on page 66.

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## Maintenance

| Maintenance Intervals        | . 198 |
|------------------------------|-------|
| Filters                      | . 199 |
| Replacing cooling air filter | . 199 |
| intake filter                | . 199 |
| part heater                  | . 200 |
| heater                       | . 200 |

### **Maintenance Intervals**

#### CAUTION

Clean and disinfect device or device parts before each maintenance step, and also when returning for repair.

The following table provides an overview of the maintenance intervals for *Evita XL*.

| O2 sensor   | Replace when the following message is displayed:<br><b>O</b> 2 measurement inop. !!!<br>and when calibration is no longer possible           |
|---|--|
|   | For disposal see page 202.   |
| Ambient air filter,   | Clean or replace after 4 weeks, see page 199.  |
| cooling air filter, and   | Replace after 1 year.  |
|   | Disposal with normal domestic waste.   |
| Filters in the compressed gas inlets  | To be replaced after 2 years by trained service personnel.   |
| Protective grid for patient part heater   | Clean after 4 weeks.<br>Dirt blocks the air inlet and reduces the heating output.  |
| Diaphragm and sealing washer of<br>the expiratory valve (not applicable<br>for disposable expiratory valve) | To be replaced after 1 year by trained service personnel.  |
| Lithium battery for data backup   | To be replaced after 2 years by trained service personnel.   |
|   | For disposal see page 202.   |
| Internal battery of DC power pack   | Must be serviced in conjunction with half-yearly inspections.<br>To be replaced by trained service personnel after 2 years at<br>the latest. |
|   | Check battery capacity every 6 months.<br>Replace battery if necessary.  |
| External battery  | Must be serviced in conjunction with half-yearly inspections.  |
|   | Check battery capacity every 6 months.<br>Replace battery if necessary.  |
| Clock module  | To be replaced after 6 years by trained service personnel.   |
| Pressure reducer  | To be replaced after 6 years by DrägerService.   |
| Fans for cooling the electronic<br>components of the pneumatic<br>system                                    | To be replaced by trained service personnel after 6 years or after a maximum of 33000 hours of operation - whichever occurs first.           |
| Equipment inspection and service  | half-yearly by trained service personnel   |

#### Filters

#### Replacing cooling air filter

Clean if soiled or after 4 weeks at the latest. Replace after 1 year at the latest.



- 1 Remove cooling air filter (A) from its frame on the back panel of *Evita XL*.
- 2 Replace cooling air filter or clean in warm water with detergent added; dry well.
- 3 Insert cooling air filter in its frame, taking care not to crease it.
- Dispose of used cooling air filter with domestic waste.

# Removing and reinserting ambient air intake filter

Clean after 4 weeks. Replace after 1 year at the latest.



- 1 If necessary, swivel port (A) to the left.
- 2 Loosen screw (B) with a coin and remove protective cover.



- 3 Remove ambient air filter (C) from the protective cover.
- 4 Slide the cleaned or new ambient air filter under the tabs.
- 5 Fit protective cover and tighten screw with a coin.
- Dispose of used ambient air filter with domestic waste.

# Removing and reinserting filter for patient part heater

The filter is required in order to remove coarse contamination and dust particles from the ambient air.

Clean or replace if soiled, or after 4 weeks at the latest.

Replace after 1 year at the latest.



The filter (A) is located on the underside of the device next to the expiratory valve.

- **1** Remove the filter (A) from the housing.
- 2 Insert a new or cleaned filter in the housing.
- Dispose of used filter with domestic waste.

# Cleaning protective grid for patient part heater

Clean if dirty or at least after 4 weeks.

• Remove dirt on the protective grid using a disposable tissue. Do not let any moisture get into the device!

## Disposal

| Safety Information                 | 202 |
|------------------------------------|-----|
| Disposal of batteries              | 202 |
| Disposal of O2 sensor              | 202 |
| Disposal of a neonatal flow sensor | 202 |
| Disposal of the medical device     | 203 |

## **Safety Information**

## For countries subject to the EU directive 2002/96/EC

This device is subject to EU Directive 2002/96/EC (WEEE). In order to comply with its registration according to this directive, it may not be disposed of at municipal collection points for waste electrical and electronic equipment. Dräger has authorized a

company to collect and dispose of this device. To initiate take-back or for more information, please visit us on the Internet at www.draeger.com and navigate to the DrägerService area where you will find a link to "WEEE". If you have no access to our website, contact your local Dräger Medical Organization.

### **Disposal of batteries**

WARNING

Risk of explosion! Do not throw in fire. Risk of corrosion! Do not open using force.

• Do not re-charge batteries.

## **Disposal of O2 sensor**

The medical device battery contains pollutant substances.

The applicable local regulations for battery disposal must be observed in all countries.

#### WARNING

Do not throw O<sub>2</sub> sensors into a fire! Risk of explosion. Do not force O<sub>2</sub> sensors open! Danger of bodily injury. O2 sensors must be disposed of as special waste:

 Follow all local, state, and federal regulations with respect to environmental protection when disposing of waste. For information consult your local environmental agency, local government offices or appropriate waste disposal companies.

### Disposal of a neonatal flow sensor

 Should be disposed of as infectious special waste. Can be incinerated with little pollution at temperatures above 800 °C (1472 °F)

## Disposal of the medical device

When disposing of the medical device:

• Consult the relevant waste disposal company for appropriate disposal.

Observe the applicable local regulations.

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## **Technical Data**

| Environmental Conditions  |
|---|
| Settings  |
| APRV Airway Pressure Release<br>Ventilation   |
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## **Environmental Conditions**

| During operation                  |                                |
|-----------------------------------|--------------------------------|
| Temperature                       | 10 to 40 °C (50 to 104 °F)     |
| Atmospheric pressure              | 700 to 1060 hPa                |
| Rel. humidity                     | 5 to 90 % without condensation |
| During storage and transportation |                                |
| Temperature                       | –20 to 60 °C (–4 to 140 °F)    |
| Atmospheric pressure              | 500 to 1060 hPa                |
| Rel. humidity                     | 5 to 95 % without condensation |
|                                   |                                |

## Settings

| Adult and Pediatric patient categories   |  |
|--|--|
| Respiratory rate f                       | 0 to 100 bpm   |
| Inspiratory time Tinsp                   | 0.1 to 10 s  |
| Tidal volume VT                          |  |
| Pediatric patient category               | 0.02 to 0.3 L, BTPS <sup>1)</sup>                              |
| Accuracy                                 | $\pm 10$ % of set value, or $\pm 10$ mL, whichever is greater  |
| Adult patient category                   | 0.1 to 2.0 L, BTPS   |
| Accuracy                                 | $\pm 10$ % of set value, or $\pm 25$ mL, whichever is greater  |
| Inspiratory flow Flow                    |  |
| Pediatric patient category               | 6 to 30 L/min  |
| Adult patient category                   | 6 to 120 L/min   |
| Inspiratory pressure Pinsp               | 0 to 95 mbar (or hPa, or cmH2O)                                |
| Inspiratory pressure limit Pmax          | 0 to 100 mbar (or hPa, or cmH2O)                               |
| O2 concentration                         | 21 to 100 Vol.%  |
| Accuracy                                 | $\pm 5$ % of set value, or $\pm 2$ Vol.%, whichever is greater |
| Positive end-expiratory pressure PEEP or |  |
| intermittent PEEP                        | 0 to 50 mbar (or hPa, or cmH2O)                                |
| Trigger sensitivity                      | 0.3 to 15 L/min  |
| Inspiratory termination Insp. term. PIF  | 5 to 70 %, adjustable in 1 % increments                        |
| Pressure support $\triangle PASB$        | 0 to 95 mbar (or hPa, or cmH2O)                                |
|  |  |

| Rise time for pressure support          | 0 to 2 s  |
|---|---|
| Independent lung ventilation ILV        |   |
| Master                                  | with trigger/without trigger                      |
| Slave                                   | synchr. / asynchr. / inverse I : E                |
|   |   |
| Neonatal patient category               |   |
| Respiratory rate f                      |   |
| Range                                   | 0 to 10 bpm                                       |
| Resolution                              | 0.5 bpm   |
| Range                                   | 10 to 150 bpm                                     |
| Resolution                              | 1 bpm   |
| Inspiratory time Tinsp (CPAP; CPAP/ASB) |   |
| Range                                   | 0.1 to 1 s  |
| Resolution                              | 0.05 s  |
| Range                                   | 0.1 to 10 s                                       |
| Resolution                              | 0.1 s   |
| Tidal volume V⊤                         |   |
| Range                                   | 3 to 100 ml, BTPS <sup>1)</sup>                   |
| Resolution                              | 1 mL  |
| Accuracy                                | ±8 % of set value, or 15 mL, whichever is greater |
| Trigger sensitivity                     |   |
| Range                                   | 0.3 to 5 L/min                                    |
| Resolution                              | 0.1 L/min   |
| Range                                   | 5 to 15 L/min                                     |
| Resolution                              | 0.5 L/min   |
| Weight of patient                       |   |
| Range                                   | 0.5 to 6 kg (1.1 lbs to 13.2 lbs)                 |
| Resolution                              | 0.1 kg (0.2 lb)                                   |
|   |   |

 BTPS: Body Temperature, Pressure, Saturated Measured values based on the conditions of the patient lungs: body temperature 37 °C (98.6 °F), water-vapor saturated gas, ambient pressure.

## **APRV Airway Pressure Release Ventilation**

| Inspiratory time Thigh     |                                 |
|----------------------------|---------------------------------|
| Range                      | 0.1 to 10 s                     |
| Resolution                 | 0.1 s                           |
| Range                      | 10 to 30 s                      |
| Resolution                 | 1 s                             |
| Expiratory time Tlow       |                                 |
| Range                      | 0.1 to 10 s                     |
| Resolution                 | 0.05 s                          |
| Range                      | 10 to 30 s                      |
| Resolution                 | 1 s                             |
| Inspiratory pressure Phigh |                                 |
| Range                      | 0 to 95 mbar (or hPa, or cmH2O) |
| Resolution                 | 1 mbar (or hPa, or cmH2O)       |
| Expiratory pressure Plow   |                                 |
| Range                      | 0 to 50 mbar (or hPa, or cmH2O) |
| Resolution                 | 1 mbar (or hPa, or cmH2O)       |
|                            |                                 |

## **ATC Automatic Tube Compensation**

| Adult patient category                   |                                 |
|--|---------------------------------|
| Inside tube diameter (ID $\varnothing$ ) |                                 |
| Range                                    | 5 to 12 mm (0.20 to 0.47 inch)  |
| Resolution                               | 0.5 mm                          |
| Degree of compensation (Comp.)           |                                 |
| Range                                    | 0 to 100 %                      |
| Resolution                               | 1 %                             |
| Pediatric patient category               |                                 |
| Inside tube diameter (ID $\varnothing$ ) |                                 |
| Range                                    | 2.5 to 8 mm (0.08 to 0.31 inch) |
| Resolution                               | 0.5 mm                          |
| Degree of compensation (Comp.)           |                                 |

0 to 100 % 1 %

Range

Resolution

#### Neonatal patient category

| Inside tube diameter (ID $\varnothing$ ) |                                 |
|--|---------------------------------|
| Range                                    | 2.5 to 5 mm (0.08 to 0.20 inch) |
| Resolution                               | 0.5 mm                          |
| Degree of compensation (Comp.)           |                                 |
| Range                                    | 0 to 100 %                      |
| Resolution                               | 1 %                             |
|  |                                 |

## **PPS Proportional Pressure Support**

## Adult patient category

| Set values for PPS:                    |   |
|--|---|
| Flow Assist (FlowAssist)               |   |
| Range                                  | 0 to 30 mbar/L/s (0 to 30 cmH2O/L/s)          |
| Resolution                             | 0.5 mbar/L/s (0.5 cmH2O/L/s)                  |
| Corresponds to resistance compensation | 0 to 30 mbar/L/s (0 to 30 cmH2O/L/s)          |
| Volume Assist (Vol.Assist)             |   |
| Range                                  | 0 to 25 mbar/L (0 to 25 cmH2O/L)              |
| Resolution                             | 0.1 mbar/L (0.1 cmH2O/L)                      |
| Range                                  | 25 to 100 mbar/L (25 to 100 cmH2O/L)          |
| Resolution                             | 0.5 mbar/L (0.5 cmH2O/L)                      |
| Corresponds to compliance compensation | 10000 to 10 mL/mbar<br>(10000 to 10 mL/cmH2O) |
| Pediatric patient category             |   |
| Set values for PPS:                    |   |
| Flow Assist (FlowAssist)               |   |
| Range                                  | 0 to 30 mbar/L/s (0 to 30 cmH2O/L/s)          |
| Resolution                             | 0.5 mbar/L/s (0.5 cmH2O/L/s)                  |
| Range                                  | 30 to 100 mbar/L/s (30 to 100 cmH2O/L/s)      |
| Resolution                             | 5 mbar/L/s (5 cmH2O/L/s)                      |
| Corresponds to resistance compensation | 0 to 100 mbar/L/s (0 to 100 cmH2O/L/s)        |
| Volume Assist (Vol.Assist)             |   |
| Range                                  | 0 to 100 mbar/L (0 to 100 cmH2O/L)            |
| Resolution                             | 1 mbar/L (1 cmH2O/L)                          |
| Range                                  | 100 to 1000 mbar/L (100 to 1000 cmH2O/L)      |
| Resolution                             | 10 mbar/L (10 cmH2O/L)                        |
|  |   |

| Corresponds to compliance compensation | 1000 to 1 ml /mbar (1000 to 1 ml /cmH2O) |
|--|--|
|  |  |
| Neonatal patient category              |  |
| Set values for PPS:                    |  |
| Flow Assist (FlowAssist)               |  |
| Range                                  | 0 to 30 mbar/L/s (0 to 30 cmH2O/L/s)     |
| Resolution                             | 0.5 mbar/L/s (0.5 cmH2O/L/s)             |
| Range                                  | 30 to 300 mbar/L/s (30 to 300 cmH2O/L/s) |
| Resolution                             | 5 mbar/L/s (5 cmH2O/L/s)                 |
| Corresponds to resistance compensation | 0 to 300 mbar/L/s (0 to 300 cmH2O/L/s)   |
| Volume Assist (Vol.Assist)             |  |
| Range                                  | 0 to 100 mbar/L (0 to 100 cmH2O/L)       |
| Resolution                             | 1 mbar/L (1 cmH2O/L)                     |
| Range                                  | 100 to 2000 mbar/L (100 to 2000 cmH2O/L) |
| Resolution                             | 10 mbar/L (10 cmH2O/L)                   |
| Corresponds to compliance compensation | infinity to 0.5 mL/mbar (0.5 mL/cmH2O)   |
|  |  |

## O<sub>2</sub> Therapy

#### Settings

Continuous Flow O2 concentration Accuracy 2 to 50 L/min 21 to 100 Vol.% ±5 % of set value, or ±2 Vol.%, whichever is greater

## **Power Characteristics**

| Adult and Pediatric patient categories |   |
|--|---|
| Control principle                      | time-cycled, volume-constant, pressure-<br>controlled |
| Intermittent PEEP frequency            | 2 cycles every 3 minutes                              |
| Medication nebulization                | for 30 minutes  |

| Bronchial suctioning  |  |
|---|--|
| Disconnection detection   | automatic  |
| Reconnection detection  | automatic  |
| Preoxygenation  | max. 3 minutes   |
| Active suction phase  | max. 2 minutes   |
| Postoxygenation   | 2 minutes  |
| Supply system for spontaneous breathing and ASB                                   | adaptive CPAP system with high initial flow  |
| Max. inspiratory flow   | 180 L/min  |
| Device compliance   |  |
| with Aquapor EL humidifier and adult breathing circuit                            | <2.3 mL/mbar (<2.3 mL/cmH2O)   |
| with Fisher & Paykel humidifier and adult breathing circuit                       | <1.5 mL/mbar (<1.5 mL/cmH2O)   |
| Inspiratory resistance  |  |
| during operation with Aquapor EL humidifier,<br>without CO2 cuvette               | <1.5 mbar (or hPa, or cmH2O) at 60 L/min   |
| following device failure with Aquapor EL humidifier, without CO2 cuvette          | <6 mbar (or hPa, or cmH2O) at 60 L/min   |
| Expiratory resistance   |  |
| during operation without CO2 cuvette following device failure without CO2 cuvette | <4.3 mbar (or hPa, or cmH2O) at 60 L/min<br><3.7 mbar (or hPa, or cmH2O) at 60 L/min |
| Dead space volume including CO2 cuvette   | approx. 9 mL   |
|   |  |
| Control principle   | Desig flow with demond existence processor   |
|   | regulated, time-controlled   |
| Basic flow  | 6 L/min (can be changed by DrägerService to 9 L/min)                                 |
| Basic flow during medication nebulization   | 9 L/min  |
| Insp. flow  | up to 30 L/min   |
| Exp. flow (measuring range)   | up to 30 L/min   |

| Device compliance  |   |
|--|---|
| with Fisher & Paykel humidifier and pediatric<br>breathing circuit | <1 mL/mbar  |
| Inspiratory resistance   |   |
| during operation with Fisher & Paykel<br>humidifier                | 0 mbar (or hPa, or cmH2O) (basic flow) at<br>5 L/min  |
| following device failure with Fisher & Paykel humidifier           | <1.5 mbar (or hPa, or cmH2O) at 5 L/min   |
| Expiratory resistance  |   |
| during operation   | <3 mbar (or hPa, or cmH2O) at 5 L/min   |
| following device failure   | <1.1 mbar (or hPa, or cmH2O) at 5 L/min   |
| Dead space volume  |   |
| Neonatal flow sensor for ISO 15 incl. Y-piece                      | <2 mL   |
| Adult, Pediatric, and Neonatal patient categories                  |   |
| Additional Function  |   |
| Inspiratory relief valve   | opens if medical air supply fails<br>(pressure <1.2 bar (17.4 psi)),<br>enables spontaneous breathing with filtered<br>ambient air. |
| Safety valve   | opens the breathing system at 100+5 mbar (or hPa, or cmH2O)   |

## **Display of Measured Values**

| Airway pressure measurement      |                                    |
|----------------------------------|------------------------------------|
| Max. airway pressure             | Ppeak                              |
| Plateau pressure                 | Pplat                              |
| Positive End-Expiratory Pressure | PEEP                               |
| Mean airway pressure             | Pmean                              |
| Min. airway pressure             | Pmin                               |
| Range                            | –45 to 110 mbar (or hPa, or cmH2O) |
| Resolution                       | 1 mbar (or hPa, or cmH2O)          |
| Accuracy                         | 2 % (4 % when displayed in cmH2O)  |

O2 measurement in main flow (inspiratory side) Inspiratory O2 concentration FiO2

| Range   | 15 to 100 Vol.%   |
|---|---|
| Resolution  | 1 Vol.%   |
| Accuracy  | ±3 Vol.%  |
| Flow measurement with Spirolog and SpiroLife flow sensors |   |
| Minute volume MV  |   |
| Spontaneously breathed minute volume MVspn                |   |
| Range   | 0 to 120 L/min, BTPS <sup>1)</sup>                            |
| Resolution  | 0.1 L/min, or,<br>for values less than 1 L/min: 0.01 L/min    |
| Accuracy  | ±8 % of measured value  |
| T1090   | approx. 35 s  |
| Tidal volume VTe  |   |
| Spontaneously breathed tidal volume                       |   |
| Range   | 0 to 10 L, BTPS <sup>1)</sup>                                 |
| Resolution  | 1 mL  |
| Accuracy  | ±8 % of measured value  |
| Tidal volume VTASB  |   |
| Inspiratory tidal volume during an ASB breath             |   |
| Range   | 0 to 10 L, BTPS <sup>1)</sup>                                 |
| Resolution  | 1 mL  |
| Accuracy  | ±8 % of measured value  |
| Flow-measurement with neonatal flow sensor 8411130        |   |
| Range   | 0.25 to 30 L/min  |
| Minute volume MV (without leakage correction)             |   |
| Range   | 0 to 9.9 L/min, BTPS  |
| Resolution  | 0.01 L/min  |
| Range   | 10 to 99 L/min, BTPS  |
| Resolution  | 0.1 L/min   |
| Accuracy  | $\pm 8$ % of measured value or 1 mL x f, whichever is greater |
| T1090   | approx. 35 s  |
|   |   |

Spontaneous breathed minute volume MV<sub>spn</sub> (without leakage correction)

Range 0 to 9.9 L/min, BTPS Resolution 0.01 L/min 10 to 99 L/min, BTPS Range Resolution 0.1 L/min ±8 % of measured value or 1 mL x fspn, Accuracy whichever is greater T10...90 approx. 35 s Leakage minute volume MVleak Range 0 to 9.9 L/min, BTPS Resolution 0.01 L/min 10 to 99 L/min, BTPS Range 0.1 L/min Resolution T10...90 approx. 35 s Tidal volume VTe Range 0 to 999 mL, BTPS Resolution 0.1 mL Range 1000 to 4000 mL, BTPS Resolution 10 mL Accuracy ±8 % of measured value, or 1 mL, whichever is greater Tidal volume VTi, VT Range 0 to 999 mL, BTPS Resolution 1 mL Range 1000 to 4000 mL, BTPS Resolution 10 mL Accuracy ±8 % of measured value, or 1 mL, whichever is greater Respiratory rate ftotal Spontaneous respiratory rate fspn Mechanical respiratory rate fmand 0 to 300 bpm Range Resolution 1 bpm Accuracy ±1 bpm T10...90 approx. 35 s Taue 0 to 30 s Range

| Resolution                             | 0.01 s   |
|--|--|
| Accuracy                               | ±20 %  |
| Breathing gas temperature measurement  |  |
| Range                                  | 18 to 51 °C (64.5 to 123.8 °F)   |
| Resolution                             | 1 °C   |
| Accuracy                               | ±1 °C  |
| CO2 measurement in main flow           |  |
| End-expiratory CO2 concentration etCO2 |  |
| Range                                  | 0 to 100 mmHg, or<br>0 to 15 Vol.% <sup>2)</sup> , or<br>0 to 13.3 kPa |
| Resolution                             | 1 mmHg, or 0.1 Vol.%, or 0.1 kPa                                       |
| Accuracy                               |  |
| for 0 to 40 mmHg                       | ±2 mmHg  |
| for 40 to 100 mmHg                     | ±5 % of measured value   |
| T1090                                  | ≤25 ms   |
| Warm-up time                           | max. 3 minutes   |
| CO2 production VCO2                    |  |
| Range                                  | 0 to 999 mL/min, STPD <sup>3)</sup>                                    |
| Resolution                             | 1 mL/min   |
| Accuracy                               | ±9 % of measured value   |
| T1090                                  | 12 minutes   |
| Serial dead space Vds                  |  |
| Range                                  | 0 to 999 mL, BTPS <sup>1)</sup>  |
| Resolution                             | 0.1 mL   |
| Accuracy                               | ±10 % of measured value, or ±10 mL, whichever is greater               |
| Dead space ventilation Vds/VT          |  |
| Range                                  | 0 to 99 %  |
| Resolution                             | 1 %  |
| Accuracy                               | ±10 % of measured value  |
|  |  |

 BTPS: Body Temperature, Pressure, Saturated. Measured values based on the conditions of the patient lungs: body temperature 37 °C (98.6 °F), water-vapor saturated gas, ambient pressure.

2) Depending on ambient and ventilation pressure, the actual upper value, when indicated in Vol.%, can be lower than the upper value displayed.

STPD: Standard Temperature, Pressure, Dry. Measured values based on standardized physical conditions: 0 °C (32 °F), 1013 hPa, dry gas

## **Computed Value Displays**

| Compliance C                   |   |
|--------------------------------|---|
| Range                          | 0 to 300 mL/mbar (0 to 300 mL/cmH2O)                        |
| Resolution                     |   |
| Range 0 to 99.9 mL/mbar        | 0.1 mL/mbar (0.1 mL/cmH2O)                                  |
| Range 100 to 300 mL/mbar       | 1 mL/mbar (1 mL/cmH2O)                                      |
| Accuracy                       | ±20 % of measured value <sup>1)</sup>                       |
| Resistance R                   |   |
| Range                          | 0 to 600 mbar/L/s (0 to 600 cmH2O/L/s)                      |
| Resolution                     |   |
| Range 0 to 99.9 mbar/L/s       | 0.1 mbar/L/s (0.1 cmH2O/L/s)                                |
| Range 100 to 600 mbar/L/s      | 1 mbar/L/s (1 cmH2O/L/s)                                    |
| Accuracy                       | $\pm 20$ % of measured value <sup>2)</sup>                  |
| Leakage minute volume MVleak   |   |
| Range                          | 0 to 99 L/min, BTPS   |
| Resolution                     | 0.1 L/min or,<br>for values less than 0.1 L/min: 0.01 L/min |
| Accuracy                       | ±18 % of measured value                                     |
| T1090                          | approx. 35 s  |
| Rapid Shallow Breathing RSB    |   |
| Range                          | 0 to 9999 1/(min x L)                                       |
| Resolution                     | 1/(min x L)   |
| Accuracy                       | see measurement of VT and $\boldsymbol{f}$                  |
| Negative Inspiratory Force NIF |   |
| Range                          | –45 to 0 mbar (or hPa, or cmH2O)                            |
| Resolution                     | 1 mbar (or hPa, or cmH2O)                                   |
| Accuracy                       | ±2 mbar (or hPa, or cmH2O)                                  |
| Waveform displays              |   |
| Airway pressure Paw (t)        | –10 to 100 mbar (or hPa, or cmH2O)                          |
| Flow (t)                       | –200 to 200 L/min   |
| Volume V (t)                   | 0 to 2000 mL  |
| Exp. CO <sub>2</sub> concentration FCO <sub>2</sub> | 0 to 100 mmHg or                |
|---|---------------------------------|
|   | 0 to 14 kPa or                  |
|   | 0 to 15 Vol.%                   |
| Occlusion pressure P 0.1                            | 0 to 25 mbar (or hPa, or cmH2O) |

1) C values may be considerably falsified as spontaneous breathing increases. Compliance with the measuring accuracy therefore cannot be guaranteed for spontaneous breathing.

2) R values may be considerably falsified as spontaneous breathing increases. Compliance with the measuring accuracy therefore cannot be guaranteed for spontaneous breathing.

## Monitoring

| Expiratory minute volume MV       Alarm at upper alarm limit       if the upper alarm limit has been exceeded         Setting range       41 to 1 L/min, in 0.1 L/min increments         0.99 to 0.01 L/min, in 0.01 L/min increments         Setting range for NIV       60 to 1 L/min, in 0.1 L/min increments         Alarm at lower alarm limit       if the value has fallen below the lower alarm limit         Setting range       40 to 1 L/min, in 0.1 L/min increments         O.99 to 0.01 L/min, in 0.1 L/min increments       0.99 to 0.01 L/min, in 0.01 L/min increments         Alarm at lower alarm limit       if the Paw_/* value has been exceeded.         Airway pressure Paw       Alarm at upper alarm limit         Alarm at upper alarm limit       if the Paw_/* value has been exceeded.         Alarm at upper alarm limit       if the Paw_/* value has been exceeded.         Alarm at lower alarm limit       if the value "PEEP +5 mbar (or hPa, or cmH2O)" (linked to the value set for PEEP) is not exceeded for at least 96 ms in 2 successive ventilator breaths.         nsp. O2 concentration FiO2       Alarm at upper alarm limit         Alarm at lower alarm limit       if FiO2 exceeds the upper alarm limit for at least 20 seconds.         Alarm at lower alarm limit       if FiO2 falls below the lower alarm limit for at least 20 seconds.         Range       both alarm limits are automatically linked to the set value: below 60 Vol.% with ±4 Vol.%, above 60 Vol.% with ±6 Vol. |                             |   |
|---|-----------------------------|---|
| Alarm at upper alarm limit       if the upper alarm limit has been exceeded         Setting range       41 to 1 L/min, in 0.1 L/min increments         0.99 to 0.01 L/min, in 0.01 L/min increments       60 to 1 L/min, in 0.1 L/min increments         Setting range for NIV       60 to 1 L/min, in 0.1 L/min increments         Alarm at lower alarm limit       if the value has fallen below the lower alarm limit         Setting range       40 to 1 L/min, in 0.1 L/min increments         0.99 to 0.01 L/min, in 0.1 L/min increments       0.99 to 0.01 L/min, in 0.01 L/min increments         Alarm at upper alarm limit       if the PAW_/* value has been exceeded.         Alarm at upper alarm limit       if the value "PEEP +5 mbar (or hPa, or cmH2O)"         Alarm at lower alarm limit       if the value "PEEP +5 mbar (or hPa, or cmH2O)"         Alarm at upper alarm limit       if FiO2 exceeds the upper alarm limit for at least 20 seconds.         Alarm at upper alarm limit       if FiO2 exceeds the upper alarm limit for at least 20 seconds.         Alarm at lower alarm limit       if FiO2 falls below the lower alarm limit for at least 20 seconds.         Alarm at lower alarm limit       if biO2 falls below the lower alarm limit for at least 20 seconds.         Range       both alarm limits are automatically linked to the set value: below 60 Vol.% with ±4 Vol.%, above 60 Vol.% with ±6 Vol.%  | Expiratory minute volume MV |   |
| Setting range41 to 1 L/min, in 0.1 L/min increments<br>0.99 to 0.01 L/min, in 0.01 L/min incrementsSetting range for NIV60 to 1 L/min, in 0.1 L/min incrementsAlarm at lower alarm limitif the value has fallen below the lower alarm limit<br>40 to 1 L/min, in 0.1 L/min increments<br>0.99 to 0.01 L/min, in 0.1 L/min increments<br>0.99 to 0.01 L/min, in 0.01 L/min incrementsAirway pressure Paw40 to 1 L/min, in 0.01 L/min increments<br>0.99 to 0.01 L/min, in 0.01 L/min incrementsAirway pressure Pawif the Paw_/* value has been exceeded.<br>10 to 100 mbar (or hPa, or cmH2O)<br>(linked to the value set for PEEP) is not<br>exceeded for at least 96 ms in 2 successive<br>ventilator breaths.Insp. O2 concentration FiO2<br>Alarm at lower alarm limitif FiO2 exceeds the upper alarm limit for at least<br>20 seconds.Alarm at lower alarm limitif FiO2 falls below the lower alarm limit for at least<br>20 seconds.Rangeboth alarm limits are automatically linked to the<br>set value: below 60 Vol.% with ±4 Vol.%, above<br>60 Vol.% with ±6 Vol.%  | Alarm at upper alarm limit  | if the upper alarm limit has been exceeded  |
| Setting range for NIV       0.99 to 0.01 L/min, in 0.01 L/min increments         Alarm at lower alarm limit       if the value has fallen below the lower alarm limit         Setting range       40 to 1 L/min, in 0.1 L/min increments         Airway pressure Paw       0.99 to 0.01 L/min, in 0.01 L/min increments         Airway pressure Paw       if the PAW_/* value has been exceeded.         Alarm at upper alarm limit       if the PAW_/* value has been exceeded.         Setting range       10 to 100 mbar (or hPa, or cmH2O)         Alarm at lower alarm limit       if the value "PEEP +5 mbar (or hPa, or cmH2O)"         (linked to the value set for PEEP) is not exceeded for at least 96 ms in 2 successive ventilator breaths.         Insp. O2 concentration FiO2       If FiO2 exceeds the upper alarm limit for at least 20 seconds.         Alarm at lower alarm limit       if FiO2 falls below the lower alarm limit for at least 20 seconds.         Range       both alarm limits are automatically linked to the set value: below 60 Vol.% with ±4 Vol.%, above 60 Vol.% with ±6 Vol.%   | Setting range               | 41 to 1 L/min, in 0.1 L/min increments  |
| Setting range for NIV60 to 1 L/min, in 0.1 L/min incrementsAlarm at lower alarm limitif the value has fallen below the lower alarm limitSetting range40 to 1 L/min, in 0.1 L/min incrementsAirway pressure PAW  |                             | 0.99 to 0.01 L/min, in 0.01 L/min increments  |
| Alarm at lower alarm limit<br>Setting rangeif the value has fallen below the lower alarm limit<br>40 to 1 L/min, in 0.1 L/min increments<br>0.99 to 0.01 L/min, in 0.01 L/min incrementsAirway pressure PAW<br>Alarm at upper alarm limitif the PAW_/* value has been exceeded.<br>10 to 100 mbar (or hPa, or cmH2O)<br>if the value "PEEP +5 mbar (or hPa, or cmH2O)"<br>(linked to the value set for PEEP) is not<br>exceeded for at least 96 ms in 2 successive<br>ventilator breaths.nsp. O2 concentration FiO2<br>Alarm at lower alarm limitif FiO2 exceeds the upper alarm limit for at least<br>20 seconds.<br>Alarm at lower alarm limitnsp. O2 concentration FiO2<br>Alarm at lower alarm limitif FiO2 exceeds the upper alarm limit for at least<br>20 seconds.<br>both alarm limits are automatically linked to the<br>set value: below 60 Vol.% with ±4 Vol.%, above<br>60 Vol.% with ±6 Vol.%  | Setting range for NIV       | 60 to 1 L/min, in 0.1 L/min increments  |
| Setting range40 to 1 L/min, in 0.1 L/min increments<br>0.99 to 0.01 L/min, in 0.01 L/min incrementsAirway pressure PAWAlarm at upper alarm limitif the PAW_/* value has been exceeded.<br>10 to 100 mbar (or hPa, or cmH2O)Alarm at lower alarm limitif the value "PEEP +5 mbar (or hPa, or cmH2O)"<br>(linked to the value set for PEEP) is not<br>exceeded for at least 96 ms in 2 successive<br>ventilator breaths.nsp. O2 concentration FiO2<br>Alarm at upper alarm limitif FiO2 exceeds the upper alarm limit for at least<br>20 seconds.<br>Alarm at lower alarm limitAlarm at lower alarm limitif FiO2 exceeds the upper alarm limit for at least<br>20 seconds.<br>Alarm at lower alarm limitAlarm at lower alarm limitif FiO2 falls below the lower alarm limit for at<br>least 20 seconds.<br>Both alarm limits are automatically linked to the<br>set value: below 60 Vol.% with ±4 Vol.%, above<br>60 Vol.% with ±6 Vol.%  | Alarm at lower alarm limit  | if the value has fallen below the lower alarm limit   |
| Airway pressure Paw       Airm at upper alarm limit       if the Paw_/ <sup>∞</sup> value has been exceeded.         Alarm at upper alarm limit       if the Paw_/ <sup>∞</sup> value has been exceeded.         Setting range       10 to 100 mbar (or hPa, or cmH2O)         Alarm at lower alarm limit       if the value "PEEP +5 mbar (or hPa, or cmH2O)"         (linked to the value set for PEEP) is not exceeded for at least 96 ms in 2 successive ventilator breaths.         Insp. O2 concentration FiO2         Alarm at upper alarm limit         if FiO2 exceeds the upper alarm limit for at least 20 seconds.         Alarm at lower alarm limit         if FiO2 falls below the lower alarm limit for at least 20 seconds.         Range       both alarm limits are automatically linked to the set value: below 60 Vol.% with ±4 Vol.%, above 60 Vol.% with ±6 Vol.%  | Setting range               | 40 to 1 L/min, in 0.1 L/min increments  |
| Airway pressure Paw       if the Paw /* value has been exceeded.         Alarm at upper alarm limit       if the Paw /* value has been exceeded.         Setting range       10 to 100 mbar (or hPa, or cmH2O)         Alarm at lower alarm limit       if the value "PEEP +5 mbar (or hPa, or cmH2O)" (linked to the value set for PEEP) is not exceeded for at least 96 ms in 2 successive ventilator breaths.         nsp. O2 concentration FiO2       Alarm at upper alarm limit         Alarm at upper alarm limit       if FiO2 exceeds the upper alarm limit for at least 20 seconds.         Alarm at lower alarm limit       if FiO2 falls below the lower alarm limit for at least 20 seconds.         Range       both alarm limits are automatically linked to the set value: below 60 Vol.% with ±4 Vol.%, above 60 Vol.% with ±6 Vol.%  |                             | 0.99 to 0.01 L/min, in 0.01 L/min increments  |
| Alarm at upper alarm limitif the PAW_/▲ value has been exceeded.Setting range10 to 100 mbar (or hPa, or cmH2O)Alarm at lower alarm limitif the value "PEEP +5 mbar (or hPa, or cmH2O)"(linked to the value set for PEEP) is not<br>exceeded for at least 96 ms in 2 successive<br>ventilator breaths.nsp. O2 concentration FiO2If FiO2 exceeds the upper alarm limit for at least<br>20 seconds.Alarm at upper alarm limitif FiO2 falls below the lower alarm limit for at<br>least 20 seconds.Alarm at lower alarm limitif FiO2 falls below the lower alarm limit for at<br>least 20 seconds.Rangeboth alarm limits are automatically linked to the<br>set value: below 60 Vol.% with ±4 Vol.%, above<br>60 Vol.% with ±6 Vol.%  | Airway pressure Paw         |   |
| Setting range10 to 100 mbar (or hPa, or cmH2O)Alarm at lower alarm limitif the value "PEEP +5 mbar (or hPa, or cmH2O)"<br>(linked to the value set for PEEP) is not<br>exceeded for at least 96 ms in 2 successive<br>ventilator breaths.Insp. O2 concentration FiO2If FiO2 exceeds the upper alarm limit for at least<br>20 seconds.Alarm at upper alarm limitif FiO2 exceeds the upper alarm limit for at least<br>20 seconds.Alarm at lower alarm limitif FiO2 falls below the lower alarm limit for at<br>least 20 seconds.Rangeboth alarm limits are automatically linked to the<br>set value: below 60 Vol.% with ±4 Vol.%, above<br>60 Vol.% with ±6 Vol.%   | Alarm at upper alarm limit  | if the Paw_/▲ value has been exceeded.  |
| Alarm at lower alarm limitif the value "PEEP +5 mbar (or hPa, or cmH2O)"<br>(linked to the value set for PEEP) is not<br>exceeded for at least 96 ms in 2 successive<br>ventilator breaths.Insp. O2 concentration FiO2If FiO2 exceeds the upper alarm limit for at least<br>20 seconds.Alarm at upper alarm limitif FiO2 exceeds the upper alarm limit for at least<br>20 seconds.Alarm at lower alarm limitif FiO2 falls below the lower alarm limit for at<br>least 20 seconds.Rangeboth alarm limits are automatically linked to the<br>set value: below 60 Vol.% with ±4 Vol.%, above<br>60 Vol.% with ±6 Vol.%   | Setting range               | 10 to 100 mbar (or hPa, or cmH2O)   |
| nsp. O2 concentration FiO2Alarm at upper alarm limitif FiO2 exceeds the upper alarm limit for at least<br>20 seconds.Alarm at lower alarm limitif FiO2 falls below the lower alarm limit for at<br>least 20 seconds.Rangeboth alarm limits are automatically linked to the<br>set value: below 60 Vol.% with ±4 Vol.%, above<br>60 Vol.% with ±6 Vol.%  | Alarm at lower alarm limit  | if the value "PEEP +5 mbar (or hPa, or cmH2O)"<br>(linked to the value set for PEEP) is not<br>exceeded for at least 96 ms in 2 successive<br>ventilator breaths. |
| Alarm at upper alarm limitif FiO2 exceeds the upper alarm limit for at least<br>20 seconds.Alarm at lower alarm limitif FiO2 falls below the lower alarm limit for at<br>least 20 seconds.Rangeboth alarm limits are automatically linked to the<br>set value: below 60 Vol.% with ±4 Vol.%, above<br>60 Vol.% with ±6 Vol.%  | Insp. O2 concentration FiO2 |   |
| Alarm at lower alarm limitif FiO2 falls below the lower alarm limit for at<br>least 20 seconds.Rangeboth alarm limits are automatically linked to the<br>set value: below 60 Vol.% with ±4 Vol.%, above<br>60 Vol.% with ±6 Vol.%   | Alarm at upper alarm limit  | if FiO2 exceeds the upper alarm limit for at least 20 seconds.  |
| Rangeboth alarm limits are automatically linked to the<br>set value: below 60 Vol.% with ±4 Vol.%, above<br>60 Vol.% with ±6 Vol.%  | Alarm at lower alarm limit  | if FiO2 falls below the lower alarm limit for at least 20 seconds.  |
|   | Range                       | both alarm limits are automatically linked to the set value: below 60 Vol.% with $\pm$ 4 Vol.%, above 60 Vol.% with $\pm$ 6 Vol.%                                 |

| End-expiratory CO2 concentration etCO2 |   |
|--|---|
| Alarm at upper alarm limit             | if the upper alarm limit has been exceeded or if the maximum value of the measuring range has been reached  |
| Setting range                          | 1 to 98 mmHg, or<br>0.1 to 15 Vol.%, or<br>0.1 to 13.2 kPa  |
| Alarm at lower alarm limit             | if the value has fallen below the lower alarm limit   |
| Setting range                          | 0 to 97 mmHg, or<br>0 to 14.9 Vol.%, or<br>0 to 13.1 kPa  |
| Insp. breathing gas temperature        |   |
| Alarm at upper alarm limit             | if temperature reaches 40 °C (104 °F) ( <i>Evita XL</i><br>may also be used without temperature sensor if<br>the sensor is not connected on switching on) |
| Respiratory rate fspn                  |   |
| Alarm                                  | during spontaneous breathing, when the<br>spontaneous respiratory rate has been<br>exceeded.  |
| Setting range                          | 5 to 120 bpm  |
| Volume monitoring                      |   |
| Alarm at lower alarm limit             | if the set tidal volume VT (linked with the set value VT) has not been applied.   |
| Alarm at upper alarm limit             | if the applied tidal volume exceeds the value of<br>the alarm limit, inspiration is interrupted and the<br>expiratory valve is opened.                    |
| Setting range                          |   |
| Adults and pediatrics                  | 21 to 4000 mL   |
| Neonates                               | 4 to 4000 mL  |
| Apnea alarm delay time                 |   |
| Alarm                                  | if no breathing activity is detected  |
| Setting range                          | 5 to 60 seconds, adjustable in 1 second increments.   |

## **Operating Data**

Mains power connection

Current consumption Power input

Device fuses Range 100 V to 240 V 100 V to 240 V 50/60 Hz 3.2 A to 1.2 A typically approx. 125 W

F 5 H 250 V IEC 127-2 (2x), subject to technical alterations, device markings must be observed.

Protection class

Device

CO2 sensor (sensor connected) Temperature sensor (sensor connected) Expiratory valve and breathing circuit Neonatal flow sensor (sensor connected)

Gas supply O2 gage pressure

> O2 connection thread Air gage pressure

> Air connection thread Dew point Oil concentration Particle size

Gas consumption of control system Outlet for pneumatic medication nebulizer

Automatic gas switch-over

Class I Type BF

3 bar (43.5 psi) -10 % to 5.5 bar (79.8 psi) +10 % at 60 L/min (peak flow 200 L/min) M 12 x 1, female 3 bar (43.5 psi) -10 % to 5.5 bar (79.8 psi) +10 % at 60 L/min (peak flow 200 L/min) M 20 x 1.5, male 5 °C (41 °F) below ambient temperature <0.1 mg/m<sup>3</sup> Dust-free air (filtered with filter size <1 µm)

Medical air or O2 approx. 3.6 L/min Medical air or O2 max. 2 bar (29 psi), max. 10 L/min

if one gas fails (inlet pressure <1.5 bar (21.8 psi)), the device switches to the other gas.

| Sound pressure level (for free-field measurement over a reflecting surface in acc. with ISO 3744)  |  |
|--|--|
| Sound pressure level during operation  | max. 47 dB (A)                                     |
| Sound pressure level for alarm enunciator <sup>1)</sup><br>(loudspeaker)   | 60 to 85 dB(A), adjustable in 16 increments        |
| Sound pressure level for alarm enunciator <sup>1)</sup><br>with "quiet loudspeaker" option   | 50 to 70 dB(A), adjustable in 16 increments        |
| Sound pressure level for power failure alarm <sup>2)</sup>   | 70 to 85 dB(A)                                     |
| Sound pressure level for power failure alarm <sup>2)</sup><br>with "quiet power failure alarm" option (not<br>available for USA, Canada, Japan, China,<br>Taiwan, Korea, and Brazil) |  |
| at 0 s   | 69 dB(A)   |
| at 90 s  | 56 dB(A)   |
| at 120 s   | 53 dB(A)   |
| Dimensions (W x H x D)   |  |
| Basic device   | 530 x 315 x 450 mm (20.9 x 12.4 x 17.7 inches)     |
| Device with Evita XL Mobil trolley   | 580 x 1375 x 780 mm<br>(22.8 x 54.1 x 30.7 inches) |
| Device with EvitaMobil trolley   | 580 x 1370 x 660 mm<br>(22.8 x 53.9 x 26.0 inches) |
| Device with EvitaMobil trolley with column extension   | 580 x 1420 x 660 mm<br>(22.8 x 55.9 x 26.0 inches) |
| Weight   |  |
| Basic device (incl. shelf)   | approx. 29 kg (64 lbs)                             |
| Electromagnetic compatibility (EMC)  |  |
| <i>Evita XL</i> from year of manufacture 2005 <sup>3)</sup>  | IEC 60601-1-2:2004 / EN 60601-1-2:2006             |
| <i>Evita XL</i> up to and including year of manufacture 2004 <sup>3)</sup>   | IEC 60601-1-2:1993 / EN 60601-1-2:1993             |

| Alarm systems  | IEC 60601-1-8:2006 only applies to devices with the <i>Audio paused 2 min.</i> key  |
|--|---|
|  | <ul> <li>Exceptions:</li> <li>Deviations in the tone sequences can only be detected by measurement techniques.</li> <li>Start-up settings are protected by an access code against inadvertent modifications. Since the access code is indicated in these Instructions for Use, modifications are not restricted to the responsible organization.</li> </ul> |
| Classification as per EC Directive 93/42/EEC<br>Annex IX   | ll b  |
| UMDNS code<br>Universal Medical Device Nomenclature System -<br>Nomenclature for medical devices |   |
| Evita XL   | 17-429  |
| Evita XL Neo   | 14-361  |

Measured in acc. with IEC 60601-1-8 at the front at a height of 1.5 m (59.1 inch) and a distance of 1 m (39.4 inch)
 Measured in acc. with IEC 60601-1-8 at the back at a height of 1.5 m (59.1 inch) and a distance of 1 m (39.4 inch)
 From 2001 onwards, the year of manufacture is indicated on the rating plate.

### Materials Used

| Part                                     | Appearance          | Material                        |
|--|---------------------|---------------------------------|
| Breathing hose                           | milky, transparent  | silicone rubber                 |
| Water trap                               | yellow, transparent | polysulphone                    |
| Y-piece                                  | yellow, transparent | polysulphone                    |
| Connector for temperature<br>measurement | milky, transparent  | silicone rubber                 |
| Temperature sensor and cable             | milky/green or blue | silicone rubber                 |
| Expiratory valve (housing, closure)      | white               | polyamide                       |
| Diaphragm                                | whitish and gray    | silicone rubber and aluminum    |
| Reusable adult cuvette of CO2 sensor     | yellow, transparent | polysulphone with glass windows |
| Reusable pediatric cuvette of CO2 sensor | gray, transparent   | polysulphone with glass windows |
| CO2 sensor and cable                     | gray/gray           | polyurethane                    |
| Neonatal flow sensor                     | yellow, transparent | polysulphone                    |
| Neonatal flow sensor housing             | yellow, transparent | polysulphone                    |
| Flow sensor cable                        | gray                | polyurethane                    |

### For Nurse Call

| Pin assignment         |               |
|------------------------|---------------|
| 6-pin round DIN socket |               |
| Floating DC contact    | max. 40 V 5   |
| Input voltage          | max. 500 mA 3 |
| Input current          | max. 15 W     |
| Switching capacity     | <b></b> 1     |

## **Device Outputs**

## Digital outputs

COM 1 plus COM 2 and COM 3 can be configured for:

LUST protocol Baud rate: 1200, 2400, 4800, 9600, 19200 Baud Data bits: 7 Parity: even Stop bits: 1

MEDIBUS protocol Baud rate: 1200, 2400, 4800, 9600, 19200 Baud Data bits: 8 Parity: even, odd, no Stop bits: 1 or 2 (19200 Baud are required for transmitting highspeed data, e.g., for displaying flow waveforms)

Printer protocol HP Deskjet series 500 Baud rate: 1200, 2400, 4800, 9600, 19200 Baud Data bits: 8 Parity: no Stop bits: 1





Pin assignment of the MEDIBUS cable

Pin assignment of the printer cable

Cable length Load impedance Signal level (for load impedance from 3000 to  $7000 \Omega$ ) Low High Electrical isolation Up to 15 m 3000 to 7000 Ω

between 3 and 15 V between –3 and –15 V Ports COM 1, as well as COM 2 and COM 3 (optional) are electrically isolated from the device electronics. The test voltage for electrical isolation is 1500 V. Ports COM 2 and COM 3 are not electrically isolated from one another.

Digital output for Independent Lung Ventilation (ILV)

Analog interface

Voltage level Impedance of analog channels

Accuracy

Electrical isolation

Pin assignment

0 to 4.095 V

Output impedance is 200  $\Omega$ . The input impedance of connected devices should be not less than 1 M $\Omega$ , otherwise the output signal will become distorted.

0 V : 0 V to 0.005 V 4.095 V : 4.075 V to 4.115 V

The socket is electrically isolated from the device electronics. The test voltage for electrical isolation is 1500 V. The analog channels are not electrically isolated from one another.



## **DC Power Pack**

| Electrical ratings for the DC (input) socket   |  |
|--|--|
| DC input voltage   | 12 or 24 V battery                                   |
| Input current  |  |
| 12 V battery   | 13 A, max. 30 A                                      |
| 24 V battery   | 6 A, max. 15 A                                       |
| Power characteristics  |  |
| Recommended bridging times following a mains power failure (with fully operational batteries <sup>1)</sup> )                 |  |
| using fully charged internal battery   | 14 minutes; at least 10 minutes                      |
| using two fully charged external 12 V lead-acid<br>gel batteries (order no. 1843303) with a<br>capacity of 17 Ah each        | 2 hours  |
| External batteries <sup>2)</sup>   |  |
| Туре   | Lead-acid gel batteries, sealed maintenance-<br>free |
| Minimum capacity   |  |
| 12 V battery   | 30 Ah (note battery charging current)                |
| 24 V battery   | 15 Ah (note battery charging current)                |
| Maximum charging current through the DC power<br>pack (the battery used must be rated for at least<br>this charging current) |  |
| 12 V battery   | approx. 8 A  |
| 24 V battery   | approx. 4.5 A  |
| Recommended charging times <sup>3)</sup> (for 1843303), two batteries connected in series                                    |  |
| 24 V lead-acid gel battery   | 8 to 12 hours  |
| Internal batteries   |  |
| Туре   | Lead-acid gel batteries, sealed maintenance-<br>free |
| Recommended charging time  |  |
| DC power pack  | 1.5 to 2.5 hours                                     |
| Protection class   | I  |

See "Charge indication and charging state of the batteries" on page 110.
 See "Mains Power Supply / DC Power Supply" on page 108.
 See "Charging times of the batteries" on page 110.

# LUST Protocol

### LUST:

List-controlled universal interface driver program compatible with the RS 232 interface in Evita ventilators from software version 7.n upwards.

The LUST protocol consists of 4 different transmission telegrams:

- Identification telegram
- Status telegram
- Data telegram
- Alarm telegram

The first three telegrams are only sent in response to a request from the external unit. The alarm telegram is sent automatically when an alarm occurs or disappears.

## **Telegram control**

The following ASCII\* control characters are used to request the individual telegrams:

- "ACK" Request for an identification telegram
- "NAK" Request for a status telegram
- "ENQ" Request for a data telegram

Output of all telegrams can be controlled via certain control characters:

"DC1" (x-on) Enables telegram output

"DC3" (x-off) Halts output at any time

Following an enable ("DC1"), the interrupted telegram is resent without being adjusted to the current status.

Requesting a telegram overrides the effect of "DC3"; the telegram interrupted by "DC1" is lost and the requested telegram is sent.

Output of an alarm telegram can also be controlled:

"DC2" Enables output of the alarm telegrams

"DC4" Halts the output of alarm telegrams

Ongoing transmissions are not interrupted by "DC4". This is only possible with "DC3" (x-off).

A telegram request ("ACK", "ENQ", or "NAK") does not act to re-enable the output of alarm telegrams.

Following a "DC2", the last event is transmitted by the alarms in each case. If no alarm events have occurred, an alarm telegram with all active alarms is requested with each "DC2".

Unknown control characters are ignored.

### Identification telegram

The identification telegram contains the device designation and a list of all measured values sent in the data telegram. It has the following structure:

#### **Telegram header**

| "STX" | Start character       |
|-------|-----------------------|
| 050   | Identification number |

0 Channel number

#### **Telegram body**

The body of the telegram first contains the device name: "ESC *Evita XL*"

This is then followed by any number of blocks, each separated by "ESC". Each block contains all the data pertaining to a measured value, each separated by "RS".

Each block has the following structure:

- "ESC" (signal no.) "RS" (signal name, long form)
- "RS" (signal name, short form) "RS" (unit)
- "RS" (minimum) "RS" (maximum)

<sup>\*</sup> See page 284 for a list of special ASCII characters used.

The following table lists the complete identification telegram:

| Signal | Signal name,               | Short  | Unit       | Minimum | Maximum |
|--------|----------------------------|--------|------------|---------|---------|
| no.    | long form                  | form   |            | value   | value   |
| 00     | Time                       | t      | h:min      | .0.00   | 23.59   |
| 01     | Exp. tidal volume          | VTe    | L          | 0.000   | 2.000   |
| 02     | Respiratory rate           | f      | 1/min      | 0       | 240     |
| 03     | Minute Volume              | MV     | L/min      | .0.00   | 99.99   |
| 04     | Peak-pressure              | Peak   | mbar       | 0       | 120     |
| 05     | Plateau-pressure           | Plat   | mbar       | .0      | 99      |
| 06     | PEEP-pressure              | PEEP   | mbar       | .0      | 99      |
| 07     | Minimum-pressure           | Pmin   | mbar       | -20     | 99      |
| 08     | Mean-pressure              | Mean   | mbar       | .0      | 99      |
| 09     | Insp. O2 concentration     | FiO2   | %          | 15      | 99      |
| 10     | Compliance                 | С      | mL/mbar    | 0.0     | 255     |
| 11     | Resistance                 | R      | mbar/(L/s) | 0.0     | 200     |
| 12     | Spont. minute volume       | MVs    | L/min      | .0.00   | 99.99   |
| 13     | Spont. frequency           | fs     | 1/min      | 0       | 240     |
| 14     | Airway Temperature         | Temp   | deg C      | 18      | 45      |
| 15     | Intrinsic PEEP             | Pintr  | L/min      | .0.0    | 99.99   |
| 16     | Trapped Volume             | Vtrap  | mL         | 0       | 9999    |
| 17     | Occlusion Pressure         | P01    | mbar       | .0.0    | 99.9    |
| 18     | End tidal CO2 in mmHg      | CO2E1  | mmHg       | .0      | 99      |
| 19     | End tidal CO2 in kPa       | CO2E2  | kPa        | .0.0    | 99.9    |
| 20     | End tidal CO2 in %         | CO2E3  | %          | .0.0    | 99.9    |
| 21     | CO2 Production             | CO2P   | mL/min     | 0       | 999     |
| 22     | Dead Space                 | Vds    | mL         | 0       | 999     |
| 23     | Rel. Dead Space            | Vds    |            | 0       | 999     |
| 24     | SpO2                       | SpO2   | %          | 0       | 100     |
| 25     | Pulse                      | Pulse  | bpm        | 0       | 999     |
| 26     | Tidal volume ASB           | VT ASB | mL         | 0       | 9999    |
| 27     | Negative Inspiratory Force | NIF    | mbar       | -45     | .0      |
| 28     | Rapid Shallow Breathing    | RSB    | 1/L*min    | 0       | 9999    |

Leading zeroes (identified by "0.0" or "..0" in the table) are replaced by one or two blanks.

### End of telegram

"EOT"

## Status telegram

The status telegram contains all settings, alarm limits, ventilation modes, and status messages.

It has the following structure:

| "SOH" | Start character |  |
|-------|-----------------|--|
| 0011  | Otart Character |  |

050 Identification number

0 Channel number

### **Telegram body**

The body of the telegram contains any number of status messages, each separated by "GS". Each status message consists of a number and a name.

"GS" (number of the status message) (message text)

Data, such as settings and alarm limits, are enclosed between "FS" in the status message.

All status messages are listed in the following tables.

#### Settings

| 00 | date : "FS"dd"FS"-"FS"mm"FS"-"FS"yy"FS"         |
|----|---|
| 01 | O2 setting value = "FS"nnn"FS" %                |
| 02 | Max. inspiratory flow = "FS"nnn"FS" L/min       |
| 03 | Insp. tidal volume = "FS"n,nnn"FS" L            |
| 06 | I : E = "FS"nn,n"FS" : "FS"1,0"FS"              |
| 06 | I : E = "FS"1,0"FS" : "FS"nn,n"FS               |
| 07 | Max. breathing pressure = "FS"nnn"FS"           |
| 00 | $\frac{1}{100} = \frac{1}{100} = \frac{1}{100}$ |
| 00 |   |
| 09 | PEEP = "FS"nn"FS" mbar                          |
| 10 | ASB = "FS"nn"FS" mbar                           |
| 11 | Interm. PEEP = "FS"nn"FS" mbar                  |
| 12 | APRV P-low = "FS"nn"FS" mbar                    |
| 13 | APRV P-high = "FS"nn"FS" mbar                   |
| 14 | APRV T-low = "FS"nn,n"FS" s                     |
| 15 | APRV T-high = "FS"nn,n"FS" s                    |
| 16 | Apnea Time = "FS"nn"FS" s                       |
| 17 | Tachypnea warning = "FS"nnn"FS" bpm             |
| 18 | Flow Trigger = "FS"nn,n"FS" L/min               |
| 19 | Pressure increase rate = "FS"n,nn"FS" s         |
| ·  | · · · · · · · · · · · · · · · · · · ·           |

| 28 | Pinsp = "FS"nnn"FS" mbar              |
|----|---------------------------------------|
| 84 | Ti = "FS"nn,nn"FS" s                  |
| 87 | Flow Assist = "FS"nnn,n"FS" mbar*s/L  |
| 88 | Volume Assist = "FS"nnnn,n"FS" mbar/L |

#### Alarm limits

| 20 | MV low limit = "FS"nn,nn"FS" L/min       |
|----|--|
| 21 | MV high limit = "FS"nn,nn"FS" L/min      |
| 25 | CO2 upper limit = "FS"nnn"FS"mmHg        |
| 25 | CO2 upper limit = "FS"nn.n"FS"%          |
| 25 | CO2 upper limit = "FS"nn.n"FS"kPa        |
| 26 | CO2 lower limit = "FS"nnn"FS"mmHg        |
| 26 | CO2 lower limit = "FS"nn.n"FS"%          |
| 26 | CO2 lower limit = "FS"nn.n"FS"kPa        |
| 27 | PAWLimit = "FS"nnn"FS" mbar              |
| 29 | Insp. tidal volume high limit =          |
|    | "FS"n,nnn"FS" L                          |
| 71 | Tdisconnect = "FS"nn"FS" s               |
| 80 | Pulse high limit = "FS"nnn"FS" bpm       |
| 81 | Pulse low limit = "FS"nnn"FS" bpm        |
| 82 | O2 saturation high limit = "FS"nnn"FS" % |
| 83 | O2 saturation low limit = "FS"nnn"FS" %  |

#### Ventilation modes

| 30 | Mode IPPV                 |
|----|---------------------------|
| 31 | Mode IPPV/ASSIST          |
| 34 | Mode SIMV                 |
| 35 | Mode SIMV/ASB             |
| 38 | Mode CPAP                 |
| 39 | Mode CPAP/ASB             |
| 40 | Mode MMV                  |
| 41 | Mode MMV/ASB              |
| 42 | Mode APRV                 |
| 43 | Mode SYNCHRON MASTER      |
| 44 | Mode SYNCHRON SLAVE       |
| 45 | Mode Apnea ventilation    |
| 48 | Mode BIPAP                |
| 49 | Mode BIPAP/ASB            |
| 60 | Mode SIMV/AutoFlow        |
| 61 | Mode SIMV/ASB/AutoFlow    |
| 62 | Mode IPPV/AutoFlow        |
| 63 | Mode IPPV/ASSIST/AutoFlow |

| 64 | Mode MMV/AutoFlow              |
|----|--------------------------------|
| 65 | Mode MMV/ASB/AutoFlow          |
| 66 | Mode ASYNCHRON MASTER          |
| 67 | Mode CPAP/PPS                  |
| 68 | Mode BIPAP/ASSIST              |
| 69 | IV – Invasive ventilation      |
| 70 | NIV – Non-invasive ventilation |

#### Status messages

| 24 | Flow monitoring on       |
|----|--------------------------|
| 24 | Flow monitoring off      |
| 50 | Audio alarm inactive on  |
| 50 | Audio alarm inactive off |
| 51 | Nebulizer on             |
| 51 | Nebulizer off            |
| 53 | O2 calibration on        |
| 53 | O2 calibration off       |
| 54 | O2 monitoring on         |
| 54 | O2 monitoring off        |
| 55 | Suction on               |
| 55 | Suction off              |
| 56 | Flow calibration on      |
| 56 | Flow calibration off     |
| 57 | CO2 calibration on       |
| 57 | CO2 calibration off      |
| 58 | CO2 monitoring on        |
| 58 | CO2 monitoring off       |
| 85 | SpO2 monitoring on       |
| 85 | SpO2 monitoring off      |
| 97 | Neonatal                 |
| 98 | Adult                    |
| 99 | Pediatric                |
|    |                          |

#### End of telegram

"EOT"

### Data telegram

The current measured values defined by the identification telegram are transmitted in the data telegram. Invalid measured values contain dashes instead of numerical values. In addition, the data

telegram also contains all the messages in the status telegram which have changed since the last status or data telegram.

The telegram has the following structure:

#### Telegram header

| "SOH" | Start character |
|-------|-----------------|
|-------|-----------------|

| 050 Identification numbe | 050 | Identification | number |
|--------------------------|-----|----------------|--------|
|--------------------------|-----|----------------|--------|

0 Channel number

#### **Telegram body**

The body of the telegram contains all the measured values defined in the identification telegram and any number of status messages. The number of digits for the measured values is defined in the identification telegram and does not exceed five. Commas are also transmitted, leading zeroes are replaced by blanks.

- "ESC" (signal number) (measured value)
- "GS" (number of the status message) (message text)

## Alarm telegram

Alarm telegrams cannot be requested. They are transmitted automatically as soon as the alarm status changes. Automatic transmission of alarms can, however, be activated and deactivated, see "Telegram control" on page 226.

The individual messages are sent

- when an alarm occurs,
- when the alarm status is cancelled.

The alarm telegram has the following structure:

#### **Telegram header**

- "BEL" Start character
- 050 Identification number
- 0 Channel number

### Telegram body

"ESC" (warning/caution/note) (status) (alarm number) (alarm text)

The meaning of the individual fields is as follows:

| 01 | Device failure           |
|----|--------------------------|
| 02 | Air supply down          |
| 03 | O2 supply down           |
| 04 | pressure meas. inop      |
| 05 | O2 measurement inop      |
| 06 | flow measurement inop    |
| 07 | mixer inop               |
| 80 | exp. valve inop          |
| 09 | fan 1 defect             |
| 10 | Temperature meas. inop   |
| 12 | Temperature high         |
| 13 | flow sensor ?            |
| 14 | PEEP high                |
| 15 | CO2 measurement inop     |
| 16 | CO2 sensor ?             |
| 17 | clean CO2 cuvette        |
| 18 | CO2 zero ?               |
| 22 | apnea                    |
| 23 | FiO2 high                |
| 24 | FiO2 low                 |
| 25 | MV low                   |
| 26 | MV high                  |
| 27 | airway pressure low      |
| 28 | airway pressure high     |
| 29 | fail to cycle            |
| 30 | high frequency           |
| 32 | volume not constant      |
| 33 | ASB > 4 s                |
| 34 | etCO2 high               |
| 35 | etCO2 low                |
| 36 | air supply pressure high |
| 37 | air supply high          |
| 38 | apnea ventilation        |
| 39 | Insp. hold interrupted   |
| 40 | loss of data             |
| 41 | Flow monitoring off      |
| 42 | Monitoring FiO2 off      |
| 43 | Monitoring CO2 off       |

| 44 | Monitoring SpO2 off          |
|----|------------------------------|
| 45 | O2 supply high               |
| 46 | fan 2 defect                 |
| 47 | malfunction fan 2            |
| 48 | malfunction fan 1            |
| 49 | SpO2 low                     |
| 50 | SpO2 high                    |
| 51 | pulse low                    |
| 52 | pulse high                   |
| 53 | no pulse                     |
| 54 | SpO2 sensor ?                |
| 55 | SpO2 meas. inop              |
| 57 | battery not loaded           |
| 58 | battery only for 2 min.      |
| 59 | int. battery activated       |
| 60 | ext. battery wrong           |
| 61 | PEEP valve inop              |
| 62 | neo. flow meas. inop         |
| 63 | standby activated            |
| 64 | nebulizer on                 |
| 65 | Tidal volume high            |
| 67 | check Evita                  |
| 68 | frequency ILV Slave ?        |
| 69 | pressure limited             |
| 70 | ILV sync. inop               |
| 71 | MEDIBUS inop                 |
| 73 | ASB > 1.5 s                  |
| 74 | Leakage                      |
| 75 | neo.flow monitoring off      |
| 76 | neo.flowsensor unsuitable    |
| 77 | nebulizer off                |
| 78 | PPS-insp.> 1.5 s             |
| 79 | PPS-insp.> 4 s               |
| 80 | ASB > Tinsp                  |
| 81 | backup ventilation           |
| 82 | Exp. hold interrupted        |
| 83 | neo. flow?                   |
| 84 | apnea alarm off              |
| 85 | MV low alarm off             |
| 86 | VT high alarm off            |
| 87 | Evita Remote error           |
| 88 | Tube obstructed              |
| 89 | Ext. Flow compensated        |
| 90 | Error multi functional board |

91 Ambient pressure sensor?

## End of telegram

"EOT"

## **EMC** Declaration

### **General information**

The EMC declaration applies to *Evita XL* from year of manufacture 2005

The EMC conformity of medical device includes the use of the external cables and accessories (see List of Accessories 9038780).

The medical device should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is inevitable, the medical device should be observed to verify normal operation in the configuration in which it will be used. In any case observe the Instructions for Use of the other devices.

### **Electromagnetic emissions**

The medical device is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.

| Emissions                                       | Compliance according to | Electromagnetic environment  |
|---|-------------------------|--|
| Radio frequency emission<br>(CISPR 11)          | Group 1                 | The medical device uses RF energy only<br>for its internal function. Therefore, its RF<br>emissions are very low and are not likely<br>to cause any interference in nearby<br>electronic equipment.  |
|   | Class A                 | The medical device is suitable for use in<br>all establishments, including domestic<br>establishments and those directly<br>connected to the public low-voltage<br>power supply network that supplies<br>buildings used for domestic purposes. |
| Harmonic emissions<br>(IEC 61000-3-2)           | Not applicable          | Not applicable because the RF emissions comply with Class A.   |
| Voltage fluctuations/flicker<br>(IEC 61000-3-3) | Not applicable          | Not applicable because the RF emissions comply with Class A.   |

Information regarding electromagnetic emissions (IEC 60601-1-2, table 201)

## **Electromagnetic immunity**

The medical device is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.

| Immunity against   | IEC60601-1-2 test level             | Compliance level<br>(of <i>Evita XL</i> )                     | Electromagnetic<br>environment   |  |
|--|-------------------------------------|---|--|--|
| Electrostatic discharge /<br>ESD (IEC 61000-4-2)                                       | Contact discharge:<br>±6 kV         | ± 2, 4, 6 kV  | Floors should be wood, concrete or ceramic tile.   |  |
|  | Air discharge: ±8 kV                | ± 2, 4, 8 kV, except<br>interfaces bearing an<br>ESD symbol 🕹 | If floors are covered with<br>synthetic material, the<br>relative humidity should<br>be at least 30 %.   |  |
| Electrical fast transient/<br>bursts (IEC 61000-4-4)                                   | Power supply lines:<br>±2 kV        | ±2 kV   | Mains power quality should be that of a  |  |
|  | Longer input/output<br>lines: ±1 kV | ±1 kV   | typical commercial or hospital environment.  |  |
| Surge on AC mains lines  | Common mode: ±2 kV                  | ±2 kV   | Mains power quality  |  |
| (IEC 61000-4-5)  | Differential mode: ±1 kV            | ±1 kV   | should be that of a typical commercial or hospital environment.  |  |
| Power frequency mag-<br>netic field (50/60 Hz)<br>(IEC 61000-4-8)                      | 3 A/m                               | 3 A/m   | Power frequency mag-<br>netic fields should be at<br>levels characteristic of a<br>typical location in a typi-<br>cal commercial or hospi-<br>tal environment.   |  |
| Voltage dips and short<br>interruptions on AC<br>mains input lines<br>(IEC 61000-4-11) | Dip >95 %, 0.5 periods              | >95 %, 0.5 periods  | Mains power quality<br>should be that of a<br>typical commercial or<br>hospital environment. If<br>the user of the <i>Evita XL</i><br>requires continued<br>operation during power<br>mains interruptions, it is<br>recommended that the<br><i>Evita XL</i> be powered<br>from an uninterruptible<br>power supply or a<br>battery. |  |
|  | Dip 60 %, 5 periods                 | 60 %, 5 periods   |  |  |
|  | Dip 30 %, 25 periods                | 30 %, 25 periods  |  |  |
|  | Dip >95 %, 5 seconds                | >95 %, 5 seconds  |  |  |

| Immunity against               | IEC60601-1-2 test level                                   | Compliance level<br>(of <i>Evita XL</i> ) | Electromagnetic<br>environment   |
|--------------------------------|---|---|--|
| Radiated RF (IEC<br>61000-4-3) | 80 MHz to 2.5 GHz:<br>10 V/m                              | 10 V/m                                    | Recommended<br>separation distance from<br>portable and mobile RF<br>transmitters with<br>transmission power<br>PEIRP to <i>Evita XL</i><br>including its lines<br>$(1.84 \text{ m x } \sqrt{\text{PEIRP}})^{1}$ |
| Conducted RF (IEC 61000-4-6)   | 150 kHz to 80 MHz:<br>10 V within ISM bands<br>(outside)  | 10 V                                      | Recommended<br>separation distance from<br>portable and mobile RF  |
|                                | 150 kHz to 80 MHz: 3 V outside of ISM bands <sup>2)</sup> | 3 V                                       | transmitters with<br>transmission power<br>PEIRP to <i>Evita XL</i><br>including its lines   |
|                                |   |   | (1.84 m x √PEIRP) <sup>1)</sup>  |

1) For PEIRP the highest possible "equivalent isotropic radiated power" of the adjacent RF transmitter has to be inserted (value in Watt). Also in the vicinity of equipment marked with the symbol () interference may occur. Field strengths from fixed, portable or mobile RF transmitters at the location of the equipment should be less than 3 V/m in the frequency range from 150 kHz to 2.5 GHz and less than 1 V/m above 2.5 GHz.

 ISM bands in this frequency range are: 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; 40.66 MHz to 40.70 MHz.

Information regarding electromagnetic emissions (IEC 60601-1-2, table 202, 203 and 204)

| Max. PEIRP (W) | 150 kHz to 2.5 GHz | all other frequencies | Examples   |
|----------------|--------------------|-----------------------|--|
| 0.001          | 0.06 m (0.20 ft)   | 0.17 m (0.56 ft)      |  |
| 0.003          | 0.10 m (0.33 ft)   | 0.30 m (0.98 ft)      |  |
| 0.010          | 0.18 m (0.59 ft)   | 0.55 m (1.80 ft)      |  |
| 0.030          | 0.32 m (1.05 ft)   | 0.95 m (3.12 ft)      | e.g., WLAN 5250 / 5775 (Europe)  |
| 0.100          | 0.58 m (1.90 ft)   | 1.73 m (5.68 ft)      | e.g., WLAN 2440 (Europe),<br>Bluetooth   |
| 0.200          | 0.82 m (2.69 ft)   | 2.46 m (8.07 ft)      | e.g., WLAN 5250 (outside Europe)   |
| 0.250          | 0.91 m (2.99 ft)   | 2.75 m (9.02 ft)      | e.g., DECT devices   |
| 1.000          | 1.83 m (6.00 ft)   | 5.48 m (17.98 ft)     | e.g., GSM 1800- / GSM 1900- /<br>UMTS mobile telephones,<br>WLAN 5600 (outside Europe) |
| 2.000          | 2.60 m (8.53 ft)   | 7.78 m (25.52 ft)     | e.g., GSM 900 mobile telephones  |
| 3.000          | 3.16 m (10.37 ft)  | 9.49 m (31.14 ft)     |  |

## **Recommended separation distances**

Information regarding separation distances (IEC 60601-1-2, table 205 and 206)

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## **Ventilation Modes**

## Volume-controlled ventilation with PLV

#### Classic volume-constant mandatory breath



In mandatory breaths without AutoFlow, the *Flow* parameter restricts inspiratory flow. If the inspiratory flow is so high that the set tidal volume *VT* is reached before inspiratory time *Tinsp* has fully elapsed, the inspiratory valve closes and the breathing gas supply stops. The expiratory valve also remains closed until the end of the inspiratory time *Tinsp*. This phase, the inspiratory pause, can be identified in the *Paw* (t) waveform as the plateau *Pplat*.

This type of mandatory breath, which for technical reasons is found in the same form in almost all intensive care ventilators, has two serious drawbacks:

- If the lungs are non-homogeneous, pressure peaks can lead to the overdistension of specific lung areas and
- the limited inspiratory flow and closed inspiratory and expiratory valves during the inspiratory pause can cause the patient to "fight" the machine.

#### Manual pressure limiting Pmax

*Evita XL* can prevent pressure peaks, while maintaining the set tidal volume *Vt*, by means of the pressure limit *Pmax*. The tidal volume *Vt* remains constant as long as a pressure plateau *Pplat* is still detectable and the flow waveform shows a brief period of zero flow between inspiration and expiration.

*Evita XL* performs this function by reducing inspiratory flow upon reaching the set *Pmax*. If the tidal volume *VT* can no longer be applied with the selected pressure *Pmax*, due to reduced compliance, the alarm message *Vol. not const., pressure limited !!* is automatically generated.

## SIMV

Synchronized Intermittent Mandatory Ventilation

Combination of ventilation and spontaneous breathing.



SIMV enables the patient to breathe spontaneously during predefined, regular ventilation pause intervals, while mandatory mechanical breaths provide a minimum ventilation during the remaining cycle time. This minimum ventilation is controlled by the two set values of tidal volume  $V\tau$  and respiratory rate f as a result of the product  $V\tau \propto f$ .

The ventilation pattern results from setting the parameters tidal volume  $V\tau$ , insp. flow *Flow*, respiratory rate *f*, and inspiratory time *Tinsp*. The flow trigger of the ventilator ensures that a mandatory breath is triggered in synchrony with a patient's spontaneous inspiratory effort within a "trigger window". This prevents mandatory breaths from being applied during spontaneous expiration.

The duration of the trigger window is 5 seconds in **Adult** patient category and 1.5 seconds in **Adult** Patient categories. If the expiratory time is less than 5 seconds or 1.5 seconds, the trigger window covers the entire expiratory time.

Synchronization of mandatory breaths by itself reduces the effective IMV time, which would result in an undesirable increase in the effective respiratory rate. Evita XL therefore extends the subsequent time allowed for spontaneous breathing by the lost time difference  $\Delta T$  - thus preventing an increase in the SIMV rate. The mandatory respiratory rate *f*, together with tidal volume VT responsible for minimum ventilation, is kept constant. If the patient has inspired a significant volume at the beginning of the trigger window, the ventilator reduces its subsequent mandatory breath by shortening the time for the inspiratory flow phase and overall inspiratory time. Tidal volume VT remains constant and overinflation of the lungs is avoided.

During the spontaneous breathing phases, the patient can be assisted with pressure via ASB pressure support.

As part of progressive weaning, the respiratory rate *f* is further reduced, thus extending the periods of spontaneous breathing until the required minute volume is eventually supplied entirely by spontaneous breathing.

## SIMV/ASB

#### Synchronized Intermittent Mandatory Ventilation/Assisted Spontaneous Breathing



Combines mechanical (volume-controlled) ventilation with spontaneous breathing. The patient can breath spontaneously between the mandatory ventilator breaths, contributing to the total minute volume. Spontaneous inspiratory efforts can be supported with ASB. The mandatory breaths ensure minimum ventilation. This minimum ventilation is controlled by the two set values of tidal volume  $V\tau$  and respiratory rate f as a result of the product  $V\tau \times f$ .

During the weaning process, the set respiratory rate may be reduced to zero. The device will then automatically switch to CPAP or CPAP/ASB ventilation mode and it will also indicate this new ventilation mode on the screen. The *SIMV* page and the therapy controls for SIMV ventilation parameters will continue to be displayed.

### MMV

# 

#### Mandatory Minute (Volume) Ventilation



In contrast to SIMV, the MMV ventilation mode provides mandatory breathing only if spontaneous breathing is not yet sufficient and has fallen below a preselected minimum minute ventilation.

This minimum ventilation is controlled by the two set values of tidal volume  $V\tau$  and respiratory rate fas a result of the product  $V\tau \times f$ .

Unlike SIMV, mandatory breaths are not applied regularly, but only during periods of insufficient ventilation.

The respiratory rate of mandatory breaths is determined by the level of spontaneous breathing:

- If spontaneous breathing is sufficient, mandatory breaths are not applied at all.
- If spontaneous breathing is not sufficient, intermittent mandatory breaths of the set tidal volume VT are applied.
- If there is no spontaneous breathing at all, the mandatory breaths are applied at the set respiratory rate *f*.

*Evita XL* continuously balances the difference between spontaneous breathing and the set minimum ventilation. As soon as the balance becomes negative due to insufficient spontaneous breathing, *Evita XL* applies a mandatory breath at the set tidal volume  $V\tau$ , so that the balance is again positive.

Experience shows that patients breathe very irregularly. Phases of shallow breathing alternate with phases of tachypnea and large respiratory effort. In order to allow for these individual fluctuations, the balancing process also takes into account the extent to which the set minimum ventilation has been exceeded.

Within a maximum of 7.5 seconds after an apnea, *Evita XL* progressively reduces this value to zero.

In this way, the response time of *Evita XL* is automatically adapted to the preceding cycles of spontaneous breathing before activating mandatory ventilation:

- If this spontaneous breathing was close to the minimum ventilation, the device responds rapidly within the cycle time (1/f).
- However, if the patient's spontaneous breathing was much higher than the set minimum ventilation, *Evita XL* will tolerate a longer breathing pause. In extreme cases of sudden apnea after a phase of deep breathing, the response time will be approx. 7.5 seconds plus the trigger time, with a minimum of 1 cycle time (1/f).

Response times longer than 15 seconds may only occur if the minimum ventilation with a low respiratory rate f is set to correspondingly low values.

In this case, *Evita XL* will trigger an apnea alarm that will disappear again after the start of mandatory ventilator breaths. If cycle time (1/f) was set to a value greater than the alarm limit *TApnoea* \_/ and, if there is no spontaneous breathing between mandatory breaths, the apnea alarm would be triggered regularly.

Example:

f = 3/min = cycle time (1/f) = 20 seconds

TApnoea \_/▲ = 15 seconds

This system is designed to prevent mandatory ventilation being prematurely triggered in the event of irregular spontaneous breathing. However, an alarm is generated in the case of extended low ventilation levels.

Spontaneous breathing can be pressure supported with ASB.

### BIPAP

**Biphasic Positive Airway Pressure** 

The BIPAP ventilation mode is a pressure/timecycled ventilation mode in which the patient can always breathe spontaneously. BIPAP is therefore often described as a time-cycled alternation between two CPAP levels.\*

The time-cycled change of pressure provides controlled ventilation, which corresponds to pressure controlled ventilation PCV. However, the continuously available opportunity of spontaneous breathing allows the transition from controlled ventilation, to the weaning phase, and to independent spontaneous breathing to take place smoothly, without requiring any change in the mode of ventilation. In order to adapt well to the patient's spontaneous breathing pattern, both the change from expiratory to inspiratory pressure level and the change from inspiratory to expiratory pressure level are synchronized with the patient's spontaneous breathing.

The rate of the pressure level changes is kept constant, even though synchronization occurs via a trigger window with fixed time constant. The duration of the "trigger window" is 5 seconds in **★** Adult patient category and 1.5 seconds in **★** Paed. and **△** Neo. patient categories. If the expiratory time is less than 5 seconds or 1.5 seconds, the trigger window covers the entire expiratory time. At the Pinsp pressure level, the "trigger window" is 1/4 x Tinsp seconds long.

As clinical research\*\* has shown, this smooth adaptation to the patient's spontaneous breathing requires less sedation, allowing the patient to return to spontaneous breathing more rapidly.

As in all pressure-controlled ventilation modes, the patient is administered a fixed tidal volume *Vt*. The tidal volume basically results from the pressure difference between settings for PEEP and *Pinsp*.

Changes in lung compliance and airways, as well as the patient's active breathing, can lead to changes in tidal volume. This is a desired effect in this ventilation mode.

Knowing that tidal volume, and therefore minute volume, are not constant, the alarm limits for minute volume must be carefully adjusted.

The display of measured expiratory tidal volume VTe must be used to set the required difference between the two pressure levels.

Reference [8], page 281



\* References [3], [4], [7], [11], [12], page 281

As with SIMV, the time pattern is set using the basic setting parameters of respiratory rate *f* and inspiratory time *Tinsp. Evita XL* calculates the resulting inspiratory and expiratory times and displays them in the lower graphics screen field below the waveform display. The lower pressure level is set with the PEEP parameter, while the upper level is set with *Pinsp*.

When switching modes from SIMV to BIPAP, only the *Pinsp* setting needs to be changed - while maintaining the previous timing pattern.

The steepness of the increase from the lower pressure level to the upper pressure level is controlled by the rise time setting *Ramp*. The effective time for the increase in pressure cannot, however, become greater than the set inspiratory time *Tinsp*.

This precaution ensures that the upper pressure level Pinsp is reached reliably during inspiration. During weaning, the transition from controlled ventilation to fully spontaneous breathing is achieved by gradually reducing inspiratory pressure Pinsp and/or respiratory rate f.

### **BIPAP/ASB**



Biphasic Positive Airway Pressure / Assisted Spontaneous Breathing

Pressure-controlled ventilation combined with free spontaneous breathing during the complete breathing cycle and adjustable pressure assist on CPAP level. The mandatory portion of the total minute volume *MV* is set with inspiratory pressure *Pinsp* via PEEP and respiratory rate *f*.

In the course of the weaning process, the respiratory rate may be reduced to zero. The device will then automatically switch to CPAP or CPAP/ASB ventilation mode and it will also indicate this new ventilation mode. The **BIPAP** page and the therapy controls for BIPAP ventilation parameters will continue to be displayed.

## **BIPAP Assist**

Biphasic Positive Airway Pressure Assisted Pressure-controlled, assisted ventilation



Used for all patients, from those unable to breathe spontaneously to those breathing spontaneously before being weaned off the ventilator.

The inspiratory breaths are equivalent to those of BIPAP, however, the switch from *Pinsp* to *PEEP* is not synchronized with patient expiration. The duration of *Pinsp* is determined by *Tinsp*. Spontaneous breathing is possible at any time during ventilation.

Each recognized inspiratory effort at the lower pressure level by the patient will trigger a synchronized inspiratory breath.

The ventilator will start a non-synchronized inspiratory breath at the latest after the inspiratory time fixed by f and *Tinsp* has elapsed.

## APRV



Airway Pressure Release Ventilation

Spontaneous breathing under continuous positive airway pressure with brief pressure release. The patient breathes spontaneously at a high pressure level Phigh for an adjustable length of time Thigh. For very short expiratory times Tlow, *Evita XL* switches to a low pressure level Plow. The normal lung areas are emptied, but the "slow" lung areas only change volume to a lesser extent.\*

In this way, the ventilation/perfusion ratio can be improved for patients with a poor gas exchange.

The steepness of the increase from the lower pressure level to the upper pressure level is controlled by the rise time setting *Ramp*. The effective time for the increase in pressure cannot become greater than the set time Thigh.

<sup>\*</sup> References [6], [7], [8], [9], page 281

# ASB

### Assisted Spontaneous Breathing



Pressure support for insufficient spontaneous breathing.

The ventilator function for assisting insufficient spontaneous breathing is similar to that of an anesthetist manually assisting and monitoring a patient's spontaneous breathing by feeling the breathing bag.

The ventilator in part takes over the work of breathing, with the patient maintaining control of spontaneous breathing.

The CPAP system supplies the spontaneously breathing patient with breathing gas even if the inspiratory effort is weak.

ASB pressure support is started:

- when the spontaneous inspiratory flow reaches the set value of the flow trigger,
- or, at the latest, when the spontaneously inspired volume exceeds the following values:
  - 25 mL in **Adult** patient category
  - 12 mL in \* Paed. patient category

1 mL in <sup>A</sup> Neo. patient category

The ventilator then produces an increase in pressure up to the preselected ASB pressure  $\Delta$ PASB, which is adjustable to the breathing requirements of the patient.

The pressure rise time is adjustable from 64 milliseconds to 2 seconds.

With a rapid increase in pressure, *Evita XL* supports the patient's insufficient spontaneous breathing with a high peak flow.

With a slow increase in pressure, *Evita XL* begins with a low inspiratory flow. The patient has to contribute more to the work of breathing.

With the patient adjusted pressure increase and ASB pressure  $\Delta PASB$ , the patient defines the required inspiratory flow via his/her breathing, which can rise to 2 L/s in 8 ms.

ASB is terminated:

- When inspiratory flow returns to zero during phase I, i.e., when the patient exhales or fights the ventilator
- When inspiratory flow in phase II falls below a certain ratio of the maximum value previously supplied:

Without Insp. term. PIF option:

- 25 % insp. flow in all patient categories

With Insp. term. PIF option:

Therapy control Insp. term. PIF not configured:

- 25 % insp. flow in the **\*** Adult patient category
- 15 % insp. flow in the ★Paed. and A Neo.
   patient categories

Therapy control Insp. term. PIF configured:

- With therapy control *Insp. term. PIF*, alternative values between 5 % and 70 % can be set.
- If the two other criteria have not triggered, at the latest after:
  - 4 seconds in the **Adult** patient category
  - 1.5 seconds in the \* Paed. and A Neo.
     patient categories

If the time criterion is activated three times in succession, *Evita XL* will generate an alarm and will alert to the possibility of a leakage in the breathing system.

### CPAP/ASB

Continuous Positive Airway Pressure / Assisted Spontaneous Breathing\*



Spontaneous breathing at a raised pressure level in order to increase the functional residual capacity (FRC). Spontaneous breathing can be pressure supported with ASB.

## PPS

**Proportional Pressure Support** 

In **PPS** ventilation mode, the device supports the patient's spontaneous breathing proportionally to the breathing effort. If the patient breathes strongly, the device supports this effort with high pressure; shallow breathing is supported with low pressure. Mechanical support is omitted altogether if there is no spontaneous breathing. Monitoring of apnea and minute volume must therefore be set appropriately.

In PPS ventilation mode, ventilation can be compared to the power-assisted steering in a motor vehicle: every turn of the steering wheel is supported by a servo-amplifier so that less effort is required by the driver than when driving without power-assisted steering. On the other hand, there is no response from the power-assisted steering if the steering wheel is not turned at all.

The degree of support in PPS mode can be set separately according to the resistive and elastic components.



With the help of the resistive component FlowAssist, the user can determine the amount of resistive breathing effort to be undertaken by *Evita XL*. The device increases the ventilation pressure as the patient breathes in.

<sup>\*</sup> For a detailed description of CPAP/ASB, see page 281.

For a detailed description of PPS in the literature, see "Proportional Assist Ventilation", page 281 [20].

Example:

If FlowAssist is set to 5 mbar/L/s, a resistance of 5 mbar/L/s will be compensated. The resistive support pressure is calculated by *Evita XL* as follows:

 $\Delta PAW = FlowAssist x Flow$ 



With the help of the elastic component Vol.Assist, the user can determine the amount of elastic breathing effort to be undertaken by the device. This support is only effective during inspiration.

### Example:

If Vol.Assist = 10 mbar/L, the elastic work of breathing will be compensated for a compliance of 100 mL/mbar. The elastic support pressure is calculated by *Evita XL* as follows:  $\Delta$ PAW = Vol.Assist x VTi

The actual ventilation pressure is equal to the sum of the resistive and elastic components.

The airway pressure *PAw*, tidal volume *Vt*, and the inspiratory time are monitored by *Evita XL* during inspiration.

*Evita XL* limits the maximum airway pressure to  $PAW \ = 5$  mbar.

The alarm message *Pressure limited !* is displayed.

The maximum inspiratory tidal volume is limited to the upper alarm limit  $V\tau_i$ .

Inspiration is interrupted if the alarm limit is exceeded and the alarm message *Tidal volume high !!!* is displayed.

The maximum inspiratory time is limited to:

- 4 seconds in the Adult patient category
- 1.5 seconds in the **\****Paed.* and <sup>≜</sup>*Neo.* patient categories.

Inspiration is interrupted if the time is exceeded and the alarm message *PPS-insp.* > 4 s !!! or *PPS-insp.* > 1.5 s ! is displayed.
## **Additional Settings**

#### **Flow Trigger**

for synchronization with a patient's spontaneous breathing efforts

When the flow trigger is activated and a trigger level is set, mandatory breaths are synchronized with the patient's spontaneous breathing efforts. The patient's spontaneous breathing activity is indicated on the screen by the brief appearance of a lung symbol instead of the symbol for patient category.

#### **Apnea Ventilation**

# Apnea ventilation in the Adult and Pediatric patient categories

For automatically switching over to volumecontrolled mandatory ventilation if the patient stops breathing.



*Evita XL* generates an apnea alarm if either no expiratory flow is measured or insufficient inspiratory gas is delivered during the set apnea time TApnoea /\* (adjustable, see "Setting Alarm Limits" on page 123). *Evita XL* will then start volume-controlled ventilation. The ventilation

parameters  $O_2$  and *PEEP* will correspond to the settings effective at the time. Inspiratory time for apnea ventilation is determined from the set respiratory rate *f* and a fixed *I* : *E* ratio of 1:2.

As in SIMV, the patient can breathe spontaneously during apnea ventilation and mandatory breaths will be synchronized with the patient's spontaneous breathing.

Apnea respiratory rate remains constant.

# Apnea ventilation in the Neonatal patient category

If apnea occurs in the  $\triangle$  **Neo.** patient category with activated apnea ventilation, pressure-controlled apnea ventilation is started after the set alarm time (*TApnoea* /<sup>\*</sup>). Apnea ventilation is adjusted by the following parameters:

- Respiratory rate: *f*
- Pinsp: *∆PApnoea*

During apnea ventilation, the Inspiration : Expiration ratio = 1:2. The ventilation parameters *O*<sup>2</sup> and *PEEP* will correspond to the settings effective at the time.

## AutoFlow

AutoFlow is a new supplemental function that controls inspiratory flow during mandatory breaths in the volume-controlled ventilation modes IPPV, SIMV, and MMV.

AutoFlow for automatic control of inspiratory flow *Flow* and *Pmax*. Once AutoFlow has been activated, *Pmax* and *Flow* can no longer be set.

In the A **Neo.** patient category, AutoFlow is automatically activated in all volume-controlled ventilation modes (IPPV, SIMV, MMV). An intact neonatal flow sensor is required for the application.



With AutoFlow, inspiratory flow is automatically adjusted to changes in lung conditions (C, R) and to the spontaneous breathing demands of the patient.

#### WARNING

When using AutoFlow, always set the alarm limit PAw /\* in order to generate an alarm in the event of an increase in airway pressure with reduced compliance or a sudden change in the leakage. The maximum pressure which can be applied is limited to 5 mbar below the PAW /\* alarm limit. Typically, the selected inspiratory time *Tinsp* is much longer than the time required to fill the lungs. The inspiratory pressure *Pinsp* corresponds to the minimum value calculated from the tidal volume *VT* and compliance C of the lungs.

In the  $\triangle$  **Neo.** patient category, the volume required to calculate the inspiration pressure is derived from the measured value VTe of the proximal neonatal flow sensor. Contamination of the neonatal flow sensor can lead to incorrect measured volumes. The airway pressure increases if the volume is incorrectly measured as too low.

Inspiratory flow is automatically controlled so that there is no pressure peak caused by the resistances of the tube and the airways. Plateau pressure *Pplat* varies with changes in compliance *C*, as is normal in all volume-constant breaths. With AutoFlow, these fluctuations occur in increments with a maximum of 3 mbar between breaths.

If tidal volume  $V\tau$  is reached (inspiratory flow = 0) before inspiratory time *Tinsp* has fully elapsed, the control system for the inspiratory and expiratory valves ensures that the patient can breathe in and out during the remaining inspiratory time, even during the constant pressure plateau *Pplat*.

If the patient breathes in or out during mandatory inspiration, the plateau pressure *Pplat* is not changed for the duration of this mandatory breath: only inspiratory and expiratory flow are adapted to the patient's demand. The applied tidal volume VT may differ from the set tidal volume VT in individual mandatory breaths, but as an average over time, a constant tidal volume VT is supplied.

Overshoot of tidal volume  $V\tau$  can be limited by the alarm limit  $V\tau_{i}$ . If the set alarm limit is exceeded once, *Evita XL* generates a low-priority alarm message (!); if the alarm limit is exceeded three times, *Evita XL* generates a high-priority alarm message (!!). Tidal volume is actively limited to the value of the alarm limit  $V\tau_i$  /\* by switching to PEEP level when necessary.

#### WARNING

When using AutoFlow, always set the alarm limits MV / and MV / in order generate an alarm in the event of an increase in airway pressure with reduced compliance or a sudden change in leakage.

An inspiratory time *Tinsp* set to a value shorter than the time required to fill the lungs can be recognized in the flow waveform: the flow at the end of inspiration has not fallen to zero. In this situation, it must be decided whether the current patient condition permits extending inspiratory time *Tinsp* in order to reduce peak pressure even further.

This effect can also develop in the course of ventilation, e.g., due to a build-up of secretions. In this situation, pressure is limited by the alarm limit  $P_{AW}$ .

The pressure rise is held to 5 mbar below the alarm limit  $PAw_{\ \ }$ . The *Vol. not const., pressure limited !!* alarm message will only be displayed when the set tidal volume *VT* is no longer fully applied.

The start of mandatory inspiration can be synchronized with a patient's own efforts using the adjustable flow trigger. Only while in IPPV mode can the flow trigger be completely switched off (IPPVAssist -> IPPV).

The steepness of the pressure rise from PEEP level to the inspiratory level can be even more closely adapted to the needs of the patient by adjusting ventilation parameter pressure rise time *Ramp* in SIMV and MMV.



# Start-up procedure with AutoFlow in the Adult and Pediatric patient categories

When AutoFlow is switched on, *Evita XL* applies the set tidal volume *Vt* through a volume-controlled breath with minimum inspiratory flow and subsequent inspiratory pause.

The peak pressure *Pplat* calculated for this mandatory breath serves as the start-up value for inspiratory pressure for the AutoFlow function.

# Start-up procedure with AutoFlow in the Neonatal patient category



When activating a volume-controlled ventilation mode, *Evita XL* initially applies a test breath with an inspiratory pressure 5 mbar greater than PEEP. This test breath is used by *Evita XL* to calculate the inspiratory breath for the next inspiration. In the second inspiratory breath, however, *Evita XL* sets only 75 % of the previously calculated inspiratory pressure in order to verify the first result and calculate a new inspiratory pressure. *Evita XL* sets the inspiratory pressure as calculated from the third breath onwards. All further adjustments of the inspiratory pressure are limited to ±3 mbar.

### ATC

Automatic Tube Compensation Automatic compensation of the tube resistance

Please see "Tube compensation ATC" on page 264 for a detailed description

For Evita 4 or Evita 2 *dura*, equipped with the *Evita XL* option, operation is also possible without ATC.



The ventilation pressure in the breathing circuit is increased during inspiration and decreased during expiration. Airway pressure is adjusted to the tracheal level if 100 % compensation of the tube resistance has been selected. Automatic tube compensation is active during:

- spontaneous breathing
- pressure-supported breathing
- pressure-controlled mechanical ventilation
- volume-controlled mechanical ventilation with "AutoFlow" activated.

Expiratory tube compensation may be independently deactivated.

In volume-controlled ventilation modes with constant inspiratory flow (IPPV, IPPVAssist, SIMV, MMV), automatic tube compensation is only active during expiration following mechanical breaths and phases of spontaneous breathing.

*Evita XL* indicates activated tube compensation by showing a tube symbol  $\frac{1}{2}$  and the tube diameter in the status line.



When tube compensation is activated, *Evita XL* calculates the tracheal pressure on the basis of the selected tube (regardless of the selected degree of compensation). This value is then displayed as a green line in the pressure waveform together with the pressure at the Y-piece.

## Sigh

"Sigh" operates in the form of an intermittent PEEP in ventilation modes IPPV, IPPVAssist and ILV.



The purpose of expiratory sigh during ventilation is to open collapsed areas of the lung and to keep open "slow" areas of the lung.

Since atelectatic alveoli have a longer time constant – also caused by obstructed bronchioli – increased airway pressure maintained over a longer period is required to open them.

In *Evita XL* the activated sigh has an expiratory effect with an intermittent PEEP for two breaths every 3 minutes.

Mean airway pressure is higher and a longer filling time can be expected.

In order to avoid lung overinflation, pressure peaks during the sigh phase can be limited using pressure limit *Pmax* without impairing the sigh function.

During the sigh phase, the *Vol. not const., pressure limited !!* alarm message is not displayed.

#### PLV

Pressure Limited Ventilation

Please see page 239 for a detailed description.

With PLV, the limitation of pressure peaks using the *Pmax* pressure limit can be set in ventilation modes IPPV, SIMV, MMV, and ILV.

Tidal volume remains constant as long as the pressure waveform shows a plateau and the flow waveform shows a brief flow pause between inspiration and expiration.

Activate/deactivate pressure limitation *Pmax*, see "Setting start-up values for O<sub>2</sub>, I : E, pressure..." on page 162.

When pressure limitation is active, the value for *Pmax* is shown in the real-time waveform *PAW* (t) as a blue line.

The therapy control *Pmax* also appears in dialog window *Ventilator Settings*.

Volume monitoring is active. The alarm message **Vol. not const., pressure limited !!** is automatically triggered if the tidal volume **V***T* can no longer be applied. This visual and audible alarm may be muted with the **Alarm Reset** button in the header bar, after the alarm message, until the cause of the alarm is remedied.

# Trigger response in the Neonatal patient category

Spontaneous breathing by the patient in the A **Neo.** patient category is detected by *Evita XL* by means of the flow signal from the proximal neonatal flow sensor. When spontaneous inspiration is detected, a synchronized, mechanical pressure-controlled inspiratory breath or a pressure-supported ASB breath is triggered, depending on the ventilation mode set.

In order to avoid incorrect triggering due to leakage flows, *Evita XL* takes into account both the flow signal from the neonatal flow sensor (Flowinsp) and the calculated leakage minute volume (*MVleak*). The leakage flow is converted to the momentary pressure level (*Paw*):

FlowPatient, insp = Flowinsp - MVleak x PAW / Pmean

FlowPatient: Patient flow

| Flowinsp: | Inspiratory flow, without leakage |
|-----------|-----------------------------------|
|           | correction                        |

- MVleak: Leakage minute volume mean leakage flow, averaged over inspiration and expiration
- PAW: Airway pressure at the Y-piece
- Pmean: Mean airway pressure at the Y-piece

Spontaneous inspiration is detected if the corrected measured value of the neonatal flow sensor exceeds the set flow trigger threshold. The trigger threshold range extends from 0.3 L/min to 15 L/min, but only the range from 0.3 L/min to 3 L/min is recommended for the Å **Neo.** patient category. The trigger threshold should be set so that self-triggering is just avoided.

If the neonatal flow sensor is defective, *Evita XL* can no longer detect a spontaneous inspiratory effort or, consequently, a triggered mandatory breath.

## Measurements

#### **Flow measurement**

Independent of whether ventilation is volumecontrolled or pressure-controlled, positive pressures are generated in the breathing system as well as in the patient's lungs during the inspiratory phase.

Depending on the ratio of lung compliance to breathing circuit compliance, the volume delivered by the ventilator is distributed to the patient's lungs and to the breathing circuit installed between the ventilator and patient.

Resulting expiratory deviations for the measured value of flow and the calculated values of minute volume and tidal volume are minimal when ventilating adults. This is due to the relatively large lung compliance compared to the compliance of the breathing circuit.

Since only the volume actually entering and leaving the lungs is relevant for the efficiency of ventilation and, since larger deviations would be possible during ventilation of pediatric patients, *Evita XL* always compensates for the influence of breathing circuit compliance.

# Compensating for the effect of breathing circuit compliance

During the Device Check before the start of ventilation, *Evita XL* determines the compliance of the breathing circuit. It then compensates for the effect of this compliance on flow and volume measurement during ventilation.

Depending on the airway pressure, *Evita XL* increases the tidal volume by the amount that remains in the breathing circuit.

Besides the influence of breathing circuit compliance, flow/volume measurement is affected by physical parameters such as temperature and humidity, as well as by leakages in the breathing circuit. *Evita XL* takes these effects into account and corrects set and measured values accordingly.

#### Recalculating for standardized gas conditions

The volume occupied by a gas depends upon the ambient conditions, temperature, pressure and humidity. For the purposes of lung physiology, reference is made to the conditions inside the lungs for values of minute volume and tidal volume: 37 °C (98.6 °F) body temperature, pressure inside the lungs, 100 % relative humidity.

Measured values for flow and volume under these conditions are characterized as BTPS\*. Medical gases from cylinders or from a central supply are dry (approx. 0 % rel. humidity) and are delivered by the ventilator at 20 °C (68 °F). Measured values for flow and volume under these conditions are characterized as NTPD\*\*. The difference between values measured as NTPD or BTPS is typically approx. 12 %.

#### Example:

500 mL tidal volume NTPD become 564 mL BTPS when warmed to 37  $^\circ C$  (98.6  $^\circ F) and humidified to 100 <math display="inline">\%$  rel. humidity.

*Evita XL* controls tidal volume in such a way that the set value of tidal volume is applied under BTPS conditions in the lungs.

Measurement at the expiratory side is made with the assumption of saturated gas at 30 °C (86 °F).

<sup>\*</sup> BTPS = Body Temperature, Pressure, Saturated

<sup>\*\*</sup> NTPD = Normal Temperature, Pressure, Dry

# Measurement of leakage flow in the Neonatal patient category

A minimal amount of respiratory gas almost always escapes between the tracheal wall and endotracheal tubes when ventilating neonates and infants with uncuffed tubes. This flow is termed the leakage flow.

Model for determining the leakage flow:

The proximal neonatal flow sensor is located upstream of the leakage at the Y-piece. During inspiration, the flow sensor measures both the leakage flow and the amount of breathing gas reaching the patient's lungs. During expiration, it only measures part of the gas applied during inspiration. However, assuming that another leakage flow escapes during expiration, the amount measured by the flow sensor is less than the amount actually expired by the patient.

The value of greatest importance for patient monitoring is the amount of gas that actually reaches the patient's lungs and thus contributes towards ventilation. The measured value displayed by *Evita XL* is the mean leakage flow *MVIeak*. *MVIeak* corresponds to the difference averaged over time between the inspiratory and expiratory flow. (The gas which does not flow back through the sensor during expiration must have escaped through the leak).

This leakage value, in combination with the expiratory minute volume MV, can therefore be used to estimate the minute volume MVPatient that contributed to ventilation:

 $MV \le MV$ Patient  $\le MV + MV$ leak

MVPatient: Patient minute volume

- MV: Expiratory measured minute volume, without leakage correction
- MVleak: Leakage minute volume



*Evita XL* takes into account the calculated leakage flow in the displayed values VTi, VTe and flow. For this purpose, the leakage flow at each instant is calculated as a function of the actual airway pressure:

Flowleak = MVleak x PAW / Pmean

Flowleak: Actual leakage flow

- MVleak: Leakage minute volume mean leakage flow, averaged over inspiration and expiration
- Paw: Airway pressure at the Y-piece
- Pmean: Mean airway pressure at the Y-piece

Patient flow and tidal volume are then calculated as follows:

Inspiration:

FlowPatient, insp = Flowinsp - Flowleak

VTi = FlowPatient, insp dt

Expiration:

FlowPatient, exp = Flowexp + Flowleak VTe =  $\int$  FlowPatient, exp dt

- FlowPatient: Current patient flow, with leakage correction
- Flowinsp: Current inspiratory flow, without leakage correction
- Flowexp: Current expiratory flow, without leakage correction
- Flowleak: Actual leakage flow
- VTi: Inspiratory tidal volume
- VTe: Expiratory tidal volume
- MVleak: Mean leakage flow, averaged over inspiration and expiration

# Measurement of airway pressure in the Adult and Pediatric patient categories

*Evita XL* measures the airway pressure indirectly by means of two internal pressure sensors in the device. The sensors are installed in the inspiratory and expiratory lines, thereby eliminating the need for an external pressure measuring line between the Y-piece and the device. As long as one side is without flow, the measured value of the flowless pressure sensor corresponds to the airway pressure at the Y-piece.

# Measurement of airway pressure in the Neonatal patient category

*Evita XL* measures the airway pressure indirectly by means of two internal pressure sensors in the device. The sensors are installed in the inspiratory and expiratory lines, thereby eliminating the need for an external pressure measuring line between the Y-piece and the device. As long as one side is without flow, the measured value of the flowless pressure sensor corresponds to the airway pressure at the Y-piece. A constant basic flow prevails in the A **Neo.** patient category. However, due to this constant basic flow, the zero-flow condition is never attained either on the inspiratory or expiratory side. The pressure measured by the inspiratory pressure sensor varies with the variations in airway pressure but is increased by the pressure drop in the inspiratory line of the breathing circuit. The pressure measured by the expiratory pressure sensor is reduced by the pressure drop in the breathing circuit. These pressure differences are caused by the flow resistance of the breathing circuit.

During expiration, the value measured at the inspiratory pressure sensor (*Pinsp*) is reduced by the pressure drop caused by the basic flow (Flowbf) in the inspiration line of the breathing circuit (Rinsp):

PAW = Pinsp - Rinsp x Flowbf

| Paw:   | Airway pressure at the Y-piece                     |
|--------|--|
| Pinsp: | Airway pressure at the inspiratory pressure sensor |
| Rinsp: | Flow resistance of the inspiratory breathing hose  |
|        |  |

Flowbf: Basic flow

During inspiration, the value measured by the expiratory pressure sensor (Pexp) is raised relative to the airway pressure by the amount of the pressure drop caused by the flow (normally Flowout  $\leq$  Flowbf) through the expiratory line of the breathing circuit (Rexp):

PAW = Pexp + Rexp x Flowout

- PAW:
   Airway pressure at the Y-piece

   Pexp:
   Airway pressure in the expiratory breathing hose

   Rexp:
   Flow resistance of the expiratory breathing hose
- Flowout: Flow through the expiratory valve during inspiration

The hose resistances are determined by *Evita XL* during the device check.

#### Principle of measurement

#### Expiratory flow measurement

Expiratory flow is measured with a hot wire anemometer. The amount of energy required to maintain the wire at a temperature of 180  $^{\circ}$ C (356  $^{\circ}$ F) is used as a measure of the flow passing through the sensor, cooling the hot wire in the process.

#### Neonatal flow measurement

The flow is measured with a hot wire anemometer between the Y-piece and the tube. The flow direction is detected by the use of two hot wires, one of which is shielded on one side.

The amount of energy required to maintain the wire at a temperature of 400 °C (752 °F) is used as a measure of the flow passing through the sensor, cooling the hot wire in the process.

The lowest flow at which detection functions reliably is 0.2 L/min. Lower flow values are therefore suppressed and displayed as zero.

#### O2 measurement

Oxygen measurement is based on the principle of a galvanic cell. Monitored gas diffuses into the electrolyte of the sensor via a membrane. The electrolyte contains a working electrode and an opposing electrode. Oxygen is chemically reduced and the resulting current is proportional to the O2 partial pressure in the gas.

#### CO<sub>2</sub> measurement

CO2 is measured via a mainstream system based on absorption measurement. A light source generates a spectrum and two light detectors record the characteristic absorption spectrum and supply electrical signals that change with the CO2 concentration. These signals are then evaluated and displayed. Heating the CO2 sensor probe prevents condensation.

#### Automatic leakage compensation

*Evita XL* determines the difference between the delivered flow on the inspiratory side and the flow measured on the expiratory side. This difference provides a measure of the amount of leakage and is displayed by *Evita XL* as the leakage minute volume *MVleak*.

During volume-controlled ventilation, *Evita XL* can compensate for this leakage.

Example: Tidal volume setting  $V\tau$  = 500 mL, 10 % tube leakage.

#### Leakage compensation Off

*Evita XL* delivers 500 mL. This is displayed as the inspiratory tidal volume VTi. 50 mL escape as leakage during inspiration, 450 mL reach the lungs. 450 mL are also expired, of which 45 mL again escape as leakage. A tidal volume of 405 mL is measured on the expiratory side and indicated as VTe.

As a result, an inspiratory minute volume of 5.0 L/min will be delivered at a respiratory rate of 10 bpm and an expiratory minute volume of 4.05 L/min will be measured. The lungs are ventilated with an MV of 4.5 L/min

#### NOTE

Without leakage compensation, the therapy control *Vt* directly determines the volume delivered by *Evita XL*.

#### Leakage compensation On

With automatic leakage compensation, *Evita XL* will deliver a tidal volume of 550 mL on the basis of the measured leakage minute volume, instead of the 500 mL set. 500 mL enter the lungs and the displayed inspiratory tidal volume is 500 mL. This value is displayed as  $V\tau$ .

The volume of 450 mL measured on the expiratory side is displayed without compensation, even when leakage compensation is activated. The minute volume measured on the expiratory side is 4.5 L/min and is also displayed uncompensated.

Otherwise, an expiratory leakage compensation might obscure a low minute volume alarm. *Evita XL* is intended to generate an alarm in any case of low minute volume.

#### NOTE

With leakage compensation, the therapy control  $V\tau$  directly determines the volume to be delivered to the patient.

This example has been simplified:

In reality, the calculated leakage correction takes into account the pressures in the breathing circuit. A higher percentage volume is lost on the inspiratory side than on the expiratory side because the pressure during inspiration is higher.

The displayed leakage minute volume *MVleak* is based on the mean pressure *Pmean*.

Leakage minute volume *MVIeak* also takes into account inspiratory leakages. The sum of the minute volume *MV* + the leakage minute volume *MVIeak* will therefore exceed the inspiratory minute volume actually delivered to the patient.

Unlimited volume compensation would be inappropriate.

*Evita XL* compensates for losses of up to 100 % of the set tidal volume *VT*.

Due to technical tolerances, a small leakage minute volume may be displayed even for a tight breathing circuit.

# Leakage compensation in application mode *Mask (NIV)*

*Evita XL* compensates calculated leakages of up to 200 % of the set tidal volume, but not more than 2 L maximum (regardless of patient category).

Depending on the selected patient category, *Evita XL* compensates leakages (MVleak) up to the following values in order to detect a patient trigger:

- Adult patient category, up to 30 L/min
- A Paed. patient category, up to 15 L/min
- A Neo. patient category, up to 7 L/min

With the NIV Plus option, *Evita XL* compensates leakages during pressure-controlled ventilation in the

- Adult patient category, up to 180 L/min
- + Paed. patient category, up to 60 L/min
- A Neo. patient category, up to 30 L/min

#### **Tube compensation ATC**

Automatic tube compensation regulates airway pressure at the tracheal level. The ATC function calculates and displays the tracheal pressure on the basis of a mathematical tube model, the set tube type and the inside diameter of the tube.

The selected tube type and the inside diameter of the tube must correspond with the real tube for correct calculation of tracheal pressure. *Evita XL* calculates tracheal pressure on the basis of a square function of tube resistance and patient flow:

 $PTrach = PAW - KTube x Flow^2$ 

| PTrach: | Pressure in the trachea  |
|---------|--|
| Paw:    | Pressure at the Y-piece of the breathing circuit               |
| KTube:  | Tube coefficient (see table)                                   |
| Flow:   | Patient flow<br>(inspiration: Flow >0;<br>expiration: Flow <0) |

When automatic tube compensation is active, *Evita XL* controls ventilation pressure during spontaneous breathing and during pressure-controlled mechanical breathing cycles in such a way that the work of breathing required by the resistance of the tube is compensated in accordance with the selected degree of compensation.

Compensation may be independently deactivated for the expiratory breathing cycle.

Depending on the direction of the patient flow, the airway pressure is increased during inspiration or decreased during expiration. Airway pressure can be increased to not more than 5 mbar below the set upper alarm limit  $P_{AW}$  and will be reduced to a value not below 0 mbar.

The maximum airway pressure is limited to PAW / - 5 mbar.

The alarm message **Pressure limited !** is displayed.

Pressure support is calculated on the basis of a square function of tube resistance and patient flow:

 $\Delta PAW = Comp. x KTube x Flow^2$ 

- $\Delta PAW$ : Pressure support on the tube
- Comp.: Degree of compensation 0 to 100 %
- KTube: Tube coefficient (see table)
- Flow: Patient flow

#### **Tube coefficient**

The tube coefficient KTube is largely determined on the basis of the results obtained by Guttmann, Wolf et al\*.

The tube coefficient KTube for the full-length tube is always taken as the basis. The effect of reduced length is negligible.

The following tables indicate the tube coefficient values.

#### Tube coefficient for endotracheal tube:

| Inside tube diameter<br>(mm) | Tube coefficient K <sub>Tube</sub><br>(mbar/L <sup>2</sup> /s <sup>2</sup> ) |
|------------------------------|--|
| 2.50                         | 600.00   |
| 3.00                         | 340.00   |

\* Reference [19], page 281

| Inside tube diameter<br>(mm) | Tube coefficient K <sub>Tube</sub><br>(mbar/L <sup>2</sup> /s <sup>2</sup> ) |
|------------------------------|--|
| 3.50                         | 170.00   |
| 4.00                         | 100.00   |
| 4.50                         | 50.00  |
| 5.00                         | 30.96  |
| 5.50                         | 23.70  |
| 6.00                         | 17.21  |
| 6.50                         | 13.05  |
| 7.00                         | 10.56  |
| 7.50                         | 8.41   |
| 8.00                         | 6.57   |
| 8.50                         | 5.17   |
| 9.00                         | 4.29   |
| 9.50                         | 3.80   |
| 10.00                        | 3.50   |
| 10.50                        | 3.00   |
| 11.00                        | 2.50   |
| 11.50                        | 2.00   |
| 12.00                        | 1.50   |

#### Tube coefficient for tracheostomy tube:

| Inside tube diameter<br>(mm) | Tube coefficient K <sub>Tube</sub><br>(mbar/L <sup>2</sup> /s <sup>2</sup> ) |
|------------------------------|--|
| 2.50                         | 600.00   |
| 3.00                         | 340.00   |
| 3.50                         | 170.00   |
| 4.00                         | 100.00   |
| 4.50                         | 50.00  |
| 5.00                         | 30.96  |
| 5.50                         | 15.40  |
| 6.00                         | 10.00  |
| 6.50                         | 7.90   |
| 7.00                         | 6.38   |
| 7.50                         | 5.20   |

| Inside tube diameter<br>(mm) | Tube coefficient KTube<br>(mbar/L <sup>2</sup> /s <sup>2</sup> ) |
|------------------------------|--|
| 8.00                         | 4.50   |
| 8.50                         | 3.70   |
| 9.00                         | 2.95   |
| 9.50                         | 2.65   |
| 10.00                        | 2.50   |
| 10.50                        | 2.05   |
| 11.00                        | 1.65   |
| 11.50                        | 1.35   |
| 12.00                        | 1.10   |

### Weaning parameters

#### P0.1, RSB, NIF:

A physician judging the ability of a patient to be weaned off the ventilator will consider a number of criteria. Besides diagnostic and laboratory results, ventilatory parameters may be used for estimating the likelihood of successful weaning.

*Evita XL* measures or calculates the following weaning indicators:

- Occlusion pressure P0.1
- Rapid Shallow Breathing **RSB**
- Negative Inspiratory Force NIF

#### **Occlusion pressure P0.1**

Respiratory drive can be measured at the start of inspiration by measuring the mouth pressure during a short term occlusion: within the first 100 ms, the pressure is not influenced by physiological reactions that would try to compensate for the occlusion (e.g., reflexive interruption of breathing or increased respiratory drive). In principle, this pressure is also independent of the muscle strength of the diaphragm. Therefore, the negative mouth pressure **P0.1** after 0.1 seconds is a direct measure of neuromuscular breathing drive\*.

\* References [10], [15], page 281

*Evita XL* displays the value for the measured pressure difference without a negative sign.

For patients with healthy lungs and regular breathing, *P0.1* will be about 3 to 4 mbar. A high *P0.1* signifies a high breathing drive, which can only be maintained for a limited period of time. *P0.1* values beyond 6 mbar, e.g., for a COPD\*\* patient, indicate impending exhaustion (RMF – respiratory muscle fatigue).



*Evita XL* keeps the inspiratory valve closed after one expiration and measures the airway pressure produced by the patient's inspiratory effort during 100 ms (P1).

The 100 ms time interval starts when a negative pressure of -0.5 mbar below PEEP/CPAP is measured as a result of the inspiratory effort.

The second pressure value (P2) is determined after 100 ms. Simultaneously, the inspiratory valve is opened, so that the patient can breathe normally again.

The occlusion pressure **P0.1** is the difference between the pressure values P2 - P1.

#### **Rapid Shallow Breathing RSB**

The Rapid Shallow Breathing (RSB) is the quotient of spontaneous respiratory rate (spontaneously breathed breaths per minute) and tidal volume:

\*\* COPD = Chronic Obstructive Pulmonary Disease

The lower the RSB index for a patient with spontaneous breathing, the more probably he or she can be weaned successfully. The significance of the RSB index is due to the fact that patients who can be weaned successfully tend to have a lower spontaneous respiratory rate and a higher tidal volume than those who are not yet ready to be weaned.

In their 1991 study\*, Yang and Tobin showed that the RSB index is an effective instrument for predicting the success of an attempt to wean the patient. Patients with an RSB index of <100 1/(min x L) were weaned with a probability of 80 %, while 95 % of those with an RSB index of >100 1/(min x L) were not yet ready to be weaned. *Evita XL* indicates the RSB index in CPAP/ASB and PPS modes.

#### **Negative Inspiratory Force NIF**

The Negative Inspiratory Force Index (NIF)\*\* measures a patient's maximum inspiratory effort after expiration. The breathing system is closed during measurement of NIF. The NIF value is also known as the Maximum Inspiratory Pressure (MIP). As a result of the inhalation effort during a manually extended expiration, the patient generates a negative pressure in relation to PEEP. The higher this negative pressure, the greater the likelihood of extubating a patient successfully. Patients reaching a NIF< –30 mbar can in all probability be weaned successfully, while those with a NIF of less than -20 mbar will most likely prove unsuccessful. Evita XL determines the NIF value during manually extended expiration. The breathing system closes following an expiration by the patient while the Exp. Hold button is held down. Then Evita XL measures the maximum inspiratory effort made by the patient. NIF is measured as a pressure relative to PEEP. The measuring procedure is ended when the *Exp*. Hold button is released or after a maximum of 15 seconds. The last measured NIF value and the time of measurement are shown on screen in Table 2 of measured values.

#### Intrinsic PEEP – PEEPi



Intrinsic PEEP is measured in two phases: *Evita XL* keeps the inspiratory and expiratory valves closed during measuring phase 1, so that it is impossible for gas to flow into the breathing system or to escape from it. During this closed phase, pressure is equalized between the lungs and the breathing system. *Evita XL* measures the pressure over time.

Measuring phase 1 is terminated:

- when pressure changes are no longer detected, but at the earliest after 0.5 seconds,
- or at the latest after:
  - 3 seconds in the **Adult** patient category
  - 1.5 seconds in the \* Paed. patient category

The start value corresponds to PEEP, and the value at the end of the closed phase is the intrinsic PEEP.

At the end of measuring phase 1, *Evita XL* opens the expiratory valve and measures expiratory flow generated by intrinsic PEEP during a defined measuring phase 2. During this period, lung pressure is allowed to decrease to PEEP level.

Measuring phase 2 is terminated:

- when the expiratory flow has returned to 0, but after 0.5 seconds at the earliest,
- or at the latest after:
  - 7 seconds in the **Adult** patient category
  - 3.5 seconds in the \* Paed. patient category

<sup>\*</sup> Reference [16], page 281

<sup>\*\*</sup> References [17], [18], page 281

The integrated flow corresponds to the air volume trapped in the lungs Vtrap by intrinsic PEEP.

Measuring times of the measuring phase 1 for intrinsic PEEP:

- Adult patient category: max. 3 seconds
- + Paed. patient category: max. 1.5 seconds

Measuring times of the measuring phase 2 for Vtrap:

- Adult patient category: max. 7 seconds
- A Paed. patient category: max. 3.5 seconds

## Low Flow PV-Loop

The Low Flow PV-Loop\* measuring procedure records a static pressure-volume waveform, which can be used to assess the mechanical properties of the lungs.

By slowly filling the lungs with a small, constant flow, only the elasticity properties are determined in the PV-Loop. This almost static process shows a good correlation with the static Super-Syringe or Occlusion Method [27 to 29]\*\*, as long as the flow is small [22 to 26]\*\*.

There are various approaches for optimizing ventilation settings based on measurements of the lung mechanics. All approaches aim at avoiding a recurrent collapsing and re-opening of alveoli and a possible over-inflation of the lungs. A suggestion is made to set the positive end-expiratory pressure (PEEP) on the basis of the lower inflection point (LIP) and to limit the tidal volume or plateau pressure on the basis of the upper inflection point (UIP) [30 to 33]\*\*. Other research recommends taking into account the expiratory limb of the PV-Loop when determining the positive end-expiratory pressure (PEEP) required to maintain an alveolar recruitment. Characteristic points on the expiratory limb are described in this context as the critical closure pressure (CCP) or the point of maximum curvature (PMC) [22, 24, 27, 30, 34 to 40]\*\*.

To determine these points on the inspiratory/expiratory limb, two cursors can be moved over the PV-Loop. In addition, the static compliance (Cstat) can also be calculated.

Performing a low flow procedure may decrease the patient's systemic circulatory pressure and could cause a pneumothorax, for example. The condition of the patient must therefore be taken into account when making the settings.

The applied pressures and volumes must be suitable for the patient. Potentially high intrathoracic pressures can be applied over a relatively long period while performing the procedure. The patient must therefore be considered to be hemodynamically stable before starting the procedure and the vital data must be closely monitored and documented during the entire measurement. A significantly higher venous return caused by an abrupt relieving of the intrathoracic pressure can overstrain the heart under certain conditions. This is why the procedure is usually terminated, even after only an inspiratory application, with a pressure ramp of 5 mbar/s.

The procedure is similar to an apnea with a single slow breath. An acceptable procedure duration should also be estimated for the patient. To avoid longer times with a reduced gas exchange, the procedure can only be restarted 60 seconds after nebulization, suctioning, or a previous Low Flow PV-Loop.

Spontaneous breathing or leakages during the procedure distort the measured values and should be ruled out before the application.

Depending on the duration of the procedure and the metabolic turnover of the patient, the expiratory limb of a PV-Loop, in particular, can be easily influenced by the O<sub>2</sub> consumption, which is not offset by a corresponding CO<sub>2</sub> production [41, 42]\*\*\*.

<sup>\*</sup> LPP option

<sup>\*\* &</sup>quot;References" on page 281

<sup>\*\*\* &</sup>quot;References" on page 281

Insp. O2 concentration during medication nebulization

#### WARNING

Use only pneumatic medication nebulizer 8412935 (with white center section). Other pneumatic medication nebulizers may cause considerable deviations in tidal volume and inspiratory O<sub>2</sub> concentration!

To minimize the deviation from the set O2 concentration, *Evita XL* uses blended gas to drive the nebulizer.

In the **Adult** patient category, this blended gas is produced by switching between the supply gases (medical grade air and oxygen) in synchrony with inspiration.

In the  $\star$ *Paed.* and  $\triangle$ *Neo.* patient categories, the nebulizer is driven continuously with air and oxygen alternating. The driver gas of the nebulizer therefore roughly corresponds to the set FiO2.



The graph shows the possible deviations of the applied O<sub>2</sub> concentration as a function of the set FiO<sub>2</sub> with a minimal inspiratory flow (15 L/min) in the  $\clubsuit$  Adult patient category and at respiratory rates above 12 bpm in the  $\clubsuit$  Paed. and  $\triangleq$  Neo. patient categories.

## Alarm – Detection/Description

Generally, visual and audible alarms are immediately output when the alarm conditions have been detected. However, detection of the alarm conditions depends upon the ventilation parameters and filter algorithms.

Cases in which *Evita XL* alarm messages are subject to delay times are described below.

The table contains only those alarm messages which are either subject to an alarm delay time or for which detection is additionally described. The alarm messages are listed in alphabetical order.

| Message                                  | Detection/Description   |
|--|---|
| Air supply down !!!<br>Air supply down ! | The gas supply pressure at the Air inlet connector is less than:<br>- 1.2 bar (17.4 psi) for 3 seconds<br>- 2.5 bar (36.3 psi) for max. 15 seconds  |
|  | In the event of an alarm, <i>Evita XL</i> switches the gas supply over to oxygen.   |
| Air supply pressure high !!              | The gas supply pressure at the Air inlet connector is greater than 6 bar  |
| Air supply pressure high !               | (87 psi).   |
| Airway obstructed ?!!!                   | Detection in the Adult and Pediatric patient categories (without neonatal flow sensor):<br>Too little of the applied and leakage-compensated volume reaches the patient for 3 ventilation cycles.   |
|  | Detection when using a neonatal flow sensor:<br>inspiratory flow is too low for 5 ventilation cycles.   |
| Airway pressure high !!!                 | The upper alarm limit for the airway pressure has been exceeded. The device immediately reduces the airway pressure to the set PEEP. If this is not successful and the upper alarm limit is exceeded by 5 mbar, the airway pressure is reduced to ambient pressure. |
| Airway pressure low !!!                  | Only effective at a set PEEP of at least 3 mbar. The set PEEP has not been reached during expiration. The alarm delay time is dependent on the extent of the pressure difference and is not shorter than 5 seconds.   |

| Message                          | Detection/Description  |
|----------------------------------|--|
| Apnoea !!!                       | Insufficient inspiratory and expiratory breathing activity of the patient has been measured within the set TApnoea alarm limit time.   |
|                                  | The apnea measurement time of the set TApnoea alarm limit is restarted<br>by:<br>– Intrinsic PEEP measurement<br>– Expiratory Hold<br>– Manual inspiration (inspiratory hold)  |
|                                  | The alarm is delayed due to a pending <i>Airway pressure low !!!</i> alarm   |
| Apnoea ventilation !!            | The device has detected apnea and has automatically switched over to apnea ventilation.  |
|                                  | The start of apnea ventilation is delayed due to the <i>Airway pressure high !!!</i> and <i>Airway pressure low !!!</i> alarms.  |
|                                  | Apnea ventilation cannot be performed in the IPPV, ILV, MMV, and BIPAP Assist ventilation modes.   |
| Back-up ventilation !!!          | Only displayed in the Neonatal patient category, but not in the Mask (NIV) application mode.   |
|                                  | The inspiratory flow for 5 mandatory breaths is too low.   |
|                                  | Neonatal flow measurement is defective or deactivated.   |
|                                  | In case of <i>Airway pressure low !!!</i> alarm.   |
| Breathing cycle not detected !!! | No sufficient inspiratory breathing activity has been detected in the patient for 15 seconds or the set TApnoea alarm limit time (whichever is longer).  |
|                                  | <ul> <li>The detection time is restarted by:</li> <li>Intrinsic PEEP measurement</li> <li>Expiratory hold</li> <li>Manual inspiration (inspiratory hold)</li> </ul>  |
|                                  | In the Mask (NIV) application mode, with the TApnoea alarm limit deactivated, the detection time is 60 seconds.  |
| Clean CO2 cuvette !!!            | The alarm message is displayed when the intensity of the measuring<br>light is excessively low.<br>Possible causes:<br>- Cuvette or sensor windows are dirty<br>- Bulb in sensor is faulty<br>The alarm delay time is 10 seconds |
|                                  | THE diam weldy time is to seconds.   |

| Message                          | Detection/Description  |
|----------------------------------|--|
| CO2 sensor ?!!!                  | <ul> <li>Possible causes:</li> <li>The CO<sub>2</sub> sensor is not connected when CO<sub>2</sub> monitoring is activated</li> <li>The CO<sub>2</sub> sensor is not mounted on the cuvette after zero calibration</li> <li>The CO<sub>2</sub> sensor is used on a clean cuvette following zero calibration of the CO<sub>2</sub> sensor on a dirty park bracket or a cuvette with dirty windows.</li> <li>The sensor is defective</li> </ul> |
|                                  | The alarm delay time is 5 seconds.   |
| CO2 zero ?!!!                    | The measured CO <sub>2</sub> partial pressure is negative (below –3 mmHg).   |
|                                  | The alarm delay time is 20 seconds.  |
| etCO2 high !!!                   | Upper alarm limit for end-expiratory CO <sub>2</sub> concentration has been exceeded. The alarm is delayed by 15 seconds.  |
| etCO2 low !!!                    | Lower alarm limit for end-expiratory CO2 concentration has been exceeded. The alarm is delayed by 15 seconds.  |
| Execute device check !!          | When the device is switched on, the currently measured ambient pressure is compared with the stored ambient pressure measured during the last device check. The deviation is greater than 8 %.   |
| Exp. valve faulty !!!            | Only in volume-controlled ventilation modes:   |
|                                  | A high expiratory volume has been measured during three consecutive mandatory inspiratory breaths.   |
| Ext. battery - Voltage high !    | The voltage of the connected external battery is too high. The message is delayed by 48 seconds.   |
| Ext. battery polarity reversed ! | Polarity of the external battery has been reversed during connection.<br>The voltage measured is negative. The message is delayed by<br>50 seconds.  |
| Fan failure ?!!!                 | Temperature in device is too high (>70 °C (158 °F)). See also <i>Fan malfunction !</i> message.  |
| Fan malfunction !                | Temperature in device is too high (exceeds 65 °C (149 °F)). See also <b>Fan failure ?!!!</b> message.  |
| FiO2 high !!!                    | Upper alarm limit for inspiratory O2 concentration has been exceeded for at least 20 seconds.  |
|                                  | In the case of FiO2 settings up to 59 Vol.%, the permitted deviation is +4 Vol.%,  |
|                                  | In the case of FiO2 settings above 60 Vol.%, the permitted deviation is +6 Vol.%.  |
|                                  | <ul> <li>The message is suppressed for 60 seconds:</li> <li>when the device is switched on</li> <li>when the FiO2 setting is changed</li> <li>when standby mode is ended</li> <li>when O2 therapy is ended</li> </ul>  |

| Message                    | Detection/Description   |
|----------------------------|---|
| FiO2 low !!!               | Lower alarm limit for inspiratory O2 concentration has been exceeded for at least 20 seconds.   |
|                            | In the case of FiO2 settings up to 59 Vol.%, the permitted deviation is $-4$ Vol.%,   |
|                            | In the case of FiO2 settings above 60 Vol.%, the permitted deviation is –6 Vol.%.   |
|                            | <ul> <li>The message is suppressed for 60 seconds:</li> <li>when the device is switched on</li> <li>when the FiO<sub>2</sub> setting is changed</li> <li>when standby mode is ended</li> <li>when O<sub>2</sub> therapy is ended</li> </ul>                               |
| Flow measurement inop. !!! | The expiratory flow sensor cannot be calibrated.  |
|                            | Expiratory flow sensor wire is broken.  |
|                            | A flow exceeding 100 L/min has been measured for 15 seconds.  |
|                            | The measured expiratory minute volume has been 20 % higher than the delivered inspiratory minute volume for 60 seconds.   |
| Hose kinked !!             | An inspiratory pressure exceeding 30 mbar is measured for more than 30 seconds during O2 therapy.   |
| Loss of data !!!           | The stored ventilation and configuration parameters have been detected as faulty following start-up of the device. If the parameters cannot be restored, <i>Evita XL</i> starts up with the factory settings.   |
| MEDIBUS COM. inop. !       | The data connection to the COM interface has been interrupted.  |
|                            | The alarm is delayed by 120 seconds.  |
| MV high !!!                | The minute volume has exceeded the upper alarm limit.   |
|                            | <ul> <li>The message is suppressed for 120 seconds:</li> <li>when the device is switched on</li> <li>when bronchial suctioning is ended</li> <li>when standby mode or Standby Plus mode is ended</li> <li>when a Low Flow PV-Loop procedure has been performed</li> </ul> |
| MV low !!!                 | The minute volume has fallen below the lower alarm limit.   |
|                            | <ul> <li>The message is suppressed for 120 seconds:</li> <li>when the device is switched on</li> <li>when bronchial suctioning is ended</li> <li>when standby mode or Standby Plus mode is ended</li> <li>when a Low Flow PV-Loop procedure has been performed</li> </ul> |

| Message                                      | Detection/Description  |
|--|--|
| Nebuliser failure !!!                        | To minimize the deviation from the set O <sub>2</sub> concentration, blended gas consisting of Air and O <sub>2</sub> is used to drive the medication nebulizer. The time each gas is used to drive the nebulizer is monitored.<br>The O <sub>2</sub> concentration of the gas flow driving the medication nebulizer deviates from the set O <sub>2</sub> concentration by more than 5 Vol.%. In extreme cases, the medication nebulizer is driven only by O <sub>2</sub> or by Air. |
|  | <ul> <li>The total flow reaching the patient consists of:</li> <li>Inspiratory flow of min. 9 L/min, monitored by the FiO2 monitoring function</li> <li>Nebulizer flow of 6 L/min</li> </ul>   |
|  | The measuring duration of the O <sub>2</sub> concentration in the nebulizer flow is 30 seconds. Only the time the nebulizer valve is open is taken into account.   |
| Neo. flow measurement inop.                  | The neonatal flow sensor cannot be calibrated.   |
| 111  | Neonatal flow sensor wire is broken.   |
| Neo. flow measurement inop.                  | The measured expiratory minute volume has been 20 % higher than the measured inspiratory minute volume for 60 seconds.   |
| Neo. flow sensor ?!!!<br>Neo. flow sensor ?! | The neonatal flow sensor is not installed in the breathing circuit.<br>Adequate inspiratory flow and expiratory flow are not measured within<br>8 seconds.   |
|  | In the Neonatal patient category, a Warning message is displayed.<br>In the Pediatric patient category, a Note message is displayed.   |
| O2 measurement inop. !!!                     | The O2 sensor cannot be calibrated.  |
|  | The measured O2 value is lower than 15 Vol.%.  |
|  | The measured O2 value is higher than 106 Vol.%.  |
| O2 supply down !!!<br>O2 supply down !       | <ul> <li>The gas supply pressure at the O2 inlet connector is less than:</li> <li>1.2 bar (17.4 psi) for 3 seconds</li> <li>2.5 bar (36.3 psi) for max. 15 seconds</li> </ul>  |
|  | In the event of an alarm, <i>Evita XL</i> switches the gas supply over to compressed air.  |
| O2 supply pressure high !!                   | The gas supply pressure at the O <sub>2</sub> inlet connector is greater than 6 bar  |
| O2 supply pressure high !                    | (87 psi).  |
| PEEP high !!!                                | <ul> <li>The measured PEEP is higher than the set value:</li> <li>higher by 8 mbar for 2 ventilation cycles or 15 seconds</li> <li>higher by 5 mbar for 10 ventilation cycles</li> </ul>   |
| PEEP valve inop. !!!                         | The measured PEEP is 5 mbar lower than the set value for 10 ventilation cycles.  |

| Message                                 | Detection/Description   |
|---|---|
| Pressure limited !                      | The maximum airway pressure is limited to Pmax.   |
|   | In <b>ATC</b> and <b>PPS</b> application mode:<br>The resulting airway pressure has reached the pressure limit of<br>$PAW_{-} = 5$ mbar during two consecutive ventilation cycles and is<br>limited to that pressure limit. |
| Pressure meas. inop. !!!                | The internal pressure sensors cannot be automatically calibrated.   |
|   | The pressure difference between inspiratory and expiratory pressure sensors has been greater than 5 mbar for 30 seconds.  |
|   | The pressure difference between the first and second measurement channel of the inspiratory pressure sensor has been greater than 5 mbar for 30 seconds.  |
| Temperature high !!!                    | Breathing gas temperature is above 40 °C (104 °F).  |
| Temperature meas. inop. !!!             | The device has detected a short circuit in the breathing gas temperature sensor for 1 second.   |
| Temperature sensor ?!!!                 | Temperature sensor probe has been disconnected during operation.<br>The alarm remains active until the sensor is reconnected. If the sensor<br>cannot be reconnected, the device must be switched off and back on<br>again. |
| Tidal volume high !!!                   | The upper alarm limit for the applied inspiratory tidal volume $VTi$ has  |
| Tidal volume high !                     | been exceeded. If the message <i>I idal volume high !!!</i> is displayed during three consecutive mandatory breaths   |
| Vol. not const., pressure<br>limited !! | The set volume is not reached for 2 mandatory breaths.  |

# **Screen Configurations**

Screen configurations 2 to 6 are only available with the XL Configuration Plus option.

The Curve + Shorttrend display is only available with the XL Monitoring Plus option.

The table lists the settings with which the six memory locations are pre-assigned at the factory. Measured values and waveforms which are assigned to a certain option (e.g., CO<sub>2</sub>) are only available when the option is activated.

To store customized screen configurations, see "Screen configurations" on page 155.

|                       | Screen configurations |   |                          |                          |                          |                          |
|-----------------------|-----------------------|---|--------------------------|--------------------------|--------------------------|--------------------------|
|                       | 1                     | 2   | 3                        | 4                        | 5                        | 6                        |
|                       | Standard              | Mandatory<br>ventilation<br>or<br>recruitment | SmartCare                | Spontaneous<br>breathing | APRV                     | NIV                      |
| Waveform<br>display   |                       |   |                          |                          |                          |                          |
| Curve only            | Paw                   | Paw   | Paw                      | Paw                      | Paw                      | Paw                      |
|                       | Flow                  | Flow  | Flow                     | Flow                     | Flow                     | Flow                     |
|                       | Volume                | Volume  | Volume                   | Volume                   | Volume                   | Volume                   |
| Curve +<br>Shorttrend | Paw-MV                | Paw-C   | Paw-f                    | Paw-RSB                  | Paw-C                    | Paw-MV                   |
|                       | Flow-VTe              | Flow-R  | Flow-<br>Volume          | Flow-P0.1                | Flow-R                   | Flow-VTe                 |
|                       | Volume-f              | Volume-<br>∜CO2                               | Volume-<br>RSB           | Volume-<br>∜CO2          | Volume-<br>∜CO2          | Volume-f                 |
| Curve +<br>RecrTrend  | -                     | Paw-EIP /<br>PEEP                             | -                        | -                        | -                        | -                        |
|                       | -                     | Flow-VTe                                      | -                        | -                        | -                        | -                        |
|                       | -                     | Volume-C                                      | -                        | -                        | -                        | -                        |
| Loops<br>left/right   | Paw-V/<br>V-Flow      | Paw-V/<br>PTrach-V                            | Paw-V/<br>PTrach-V       | Paw-V/<br>PTrach-V       | Paw-V/<br>PTrach-V       | PAW-V/<br>PTrach-V       |
|                       | Flow-Paw/<br>Paw-V    | Flow-PAW/<br>Flow-PTrach                      | Flow-PAW/<br>Flow-PTrach | Flow-PAW/<br>Flow-PTrach | Flow-Paw/<br>Flow-PTrach | Flow-PAW/<br>Flow-PTrach |
|                       | Paw-V/<br>V-Flow      | V-Flow/<br>V-CO2                              | V-Flow/<br>V-CO2         | V-Flow/<br>V-CO2         | V-Flow/<br>V-CO2         | V-Flow/<br>V-CO2         |

|                 | Screen configurations |                                     |                 |                               |             |                   |
|-----------------|-----------------------|-------------------------------------|-----------------|-------------------------------|-------------|-------------------|
|                 | 1<br>Standard         | 2<br>Mandatory<br>ventilation<br>or | 3<br>SmartCare  | 4<br>Spontaneous<br>breathing | 5<br>APRV   | 6<br>NIV          |
|                 |                       | recruitment                         |                 |                               |             |                   |
| Trend           | MV                    | MV                                  | fspn            | MV                            | MV          | MV                |
|                 | VTe                   | VTe                                 | MV              | VTe                           | VTe         | VTe               |
|                 | f                     | ΫCO2                                | Diagnosis       | ΫCO2                          | ΰCO2        | f                 |
| Trend selection | MV                    | MV                                  | MV              | MV                            | MV          | MV                |
|                 | VTe                   | VTe                                 | VTe             | VTe                           | VTe         | VTe               |
|                 | f                     | f                                   | f               | f                             | f           | f                 |
|                 | ΫCO2                  | ΰCO2                                | ∜CO2            | ∜CO2                          | ∜CO2        | ΰCO2              |
|                 | R                     | R                                   | R               | R                             | R           | R                 |
|                 | С                     | С                                   | С               | С                             | С           | С                 |
|                 | P0.1                  | P0.1                                | P0.1            | P0.1                          | P0.1        | P0.1              |
|                 | RSB                   | RSB                                 | RSB             | RSB                           | RSB         | RSB               |
|                 | -                     | -                                   | SC-Trends       | -                             | -           | -                 |
|                 | -                     | -                                   | SC-Trends       | -                             | -           | -                 |
| Buttons in the  | -                     | O2↑ suction                         | O2↑ suction     | O2↑ suction                   | O2↑ suction | O2↑ suction       |
| main menu bar   | -                     | PEEPi                               | Diagnosis       | P0.1                          | Nebuliser   | NeoFlow<br>sensor |
|                 | -                     | Low Flow<br>PV-Loop                 | SC-<br>Overview | NIF                           | Values      | Nebuliser         |
|                 | -                     | Nebuliser                           | SC-Data         | Nebuliser                     | Logbook     | Values            |
|                 | -                     | Values                              | SC-Logbook      | Values                        | Day / Night | Logbook           |
|                 | -                     | Logbook                             | SC-Trends       | Logbook                       | -           | Diagnostics       |
|                 | -                     | Day / Night                         | Day / Night     | Day / Night                   | -           | Day / Night       |

|                    |                 | Screen configurations                              |                   |                               |             |          |
|--------------------|-----------------|--|-------------------|-------------------------------|-------------|----------|
|                    | 1<br>Standard   | 2<br>Mandatory<br>ventilation<br>or<br>recruitment | 3<br>SmartCare    | 4<br>Spontaneous<br>breathing | 5<br>APRV   | 6<br>NIV |
| Measured<br>values |                 |  |                   |                               |             |          |
| ini Group 1        | Ppeak           | FiO2   | FiO2              | FiO2                          | FiO2        | FiO2     |
|                    | Pmean           | Ppeak-Pmean  | fspn              | Ppeak-Pmean                   | Ppeak-Pmean | VTi      |
|                    | PEEP            | VT-VTe   | V⊤-etCO2          | VT-VTe                        | VT-VTe      | VTe      |
|                    | VTe             | ftotal-fspn  | SC-fspn           | ftotal-fspn                   | ftotal-fspn | MV       |
|                    | MV              | MV-MVspn   | SC-VT             | MV-MVspn                      | MV-MVspn    | MVspn    |
|                    | ftotal          | R-C  | SC-etCO2          | R-C                           | R-C         | VTASB    |
| 1ªi Group 2        | Ppeak           | Pmean  | Diagnosis         | Pmean                         | Pmean       | Pmean    |
|                    | Pmean-<br>PEEP  | Ppeak  | Phase             | Ppeak                         | Ppeak       | Ppeak    |
|                    | VTe-VTASB       | Pmin   | Duration          | Pmin                          | Pmin        | Pmin     |
|                    | MV-MVspn        | Pplat  | SC-fspn           | Pplat                         | Pplat       | Pplat    |
|                    | ftotal-fspn     | PEEP   | SC-VT             | PEEP                          | PEEP        | PEEP     |
|                    | FiO2            | MV   | SC-etCO2          | MV                            | MV          | MV       |
| iẩiํ Group 3       | Ppeak           | ΫCO2   | fspn-MV           | ∜CO2                          | ΫCO2        | RSB      |
|                    | Pmean-<br>PEEP  | Vds/VTe  | etCO2-<br>Vds/VTe | Vds/VTe                       | Vds/VTe     | R        |
|                    | VTe             | etCO2  | PEEP-Ppeak        | etCO2                         | etCO2       | С        |
|                    | etCO2-<br>V CO2 | VTe  | R                 | VTASB                         | -           | -        |
|                    | R               | Pmean  | С                 | NIF                           | -           | -        |
|                    | С               | MV   | -                 | RSB                           | -           | -        |

|            | Screen configurations |  |                |                               |           |          |
|------------|-----------------------|--|----------------|-------------------------------|-----------|----------|
|            | 1<br>Standard         | 2<br>Mandatory<br>ventilation<br>or<br>recruitment | 3<br>SmartCare | 4<br>Spontaneous<br>breathing | 5<br>APRV | 6<br>NIV |
| Customized | Mode                  | Mode   | Mode           | Mode                          | Mode      | Mode     |
| settings   | Modeext.              | Modeext.   | Modeext.       | Modeext.                      | Modeext.  | Modeext. |
|            | Flow                  | Patient  | Patient        | VT                            | f         | Patient  |
|            | Thigh                 | VT   | ATC state      | f                             | Pmax      | Vт       |
|            | Tlow                  | f  | Tube ID        | Pmax                          | O2        | f        |
|            | O2                    | O2   | O2             | O2                            | Thigh     | O2       |
|            | VT                    | Pmax   | Pasb           | Flow                          | Tlow      | Flow     |
|            | f                     | Flow   | PEEP           | Tinsp                         | Phigh     | Tinsp    |
|            | Tinsp                 | Tinsp  | Ramp           | I:E                           | Plow      | I:E      |
|            | Pmax                  | I:E  | -              | Pinsp                         | PEEP      | Pinsp    |
|            | PEEP                  | Pinsp  | -              | PEEP                          | ATC state | Pmax     |
|            | Pasb                  | PEEP   | -              | ATC state                     | Tube ID   | Pasb     |
|            | Pinsp                 | ATC state  | -              | Tube ID                       | -         | Ramp     |
|            | Phigh                 | Tube ID  | -              | Vol.Assist                    | -         | PEEP     |
|            | Plow                  | Ramp   | -              | FlowAssist                    | -         | -        |
| Customized | MV                    | FiO2   | MV             | FiO2                          | FiO2      | FiO2     |
| values     | MVspn                 | Ppeak  | MVspn          | Ppeak                         | Ppeak     | Ppeak    |
|            | Ppeak                 | Pplat  | Vt             | Pplat                         | Pplat     | Pplat    |
|            | Pplat                 | Pmean  | VTe            | Pmean                         | Pmean     | Pmean    |
|            | Pmean                 | Pmin   | R              | Pmin                          | Pmin      | Pmin     |
|            | PEEP                  | PEEP   | С              | PEEP                          | PEEP      | PEEP     |
|            | ftotal                | MV   | ftotal         | MV                            | MV        | MV       |
|            | fspn                  | MVspn  | fspn           | MVspn                         | MVspn     | MVspn    |
|            | -                     | VT   | etCO2          | VT                            | VTe       | Vт       |
|            | fspn                  | VTe  | Vds            | VTe                           | etCO2     | VTe      |
|            | -                     | etCO2  | Vds/VTe        | etCO2                         | ΰCO2      | R        |
|            | -                     | ΰCO2   | ΫCO2           | ŮCO2                          | R         | С        |
|            | VTe                   | R  | FiO2           | R                             | С         | ftotal   |
|            | VTASB                 | С  | PEEP           | С                             | ftotal    | fmand    |
|            | -                     | ftotal   | Ppeak          | ftotal                        | fmand     | fspn     |

| Screen configurations |  |                |                               |           |          |
|-----------------------|--|----------------|-------------------------------|-----------|----------|
| 1<br>Standard         | 2<br>Mandatory<br>ventilation<br>or<br>recruitment | 3<br>SmartCare | 4<br>Spontaneous<br>breathing | 5<br>APRV | 6<br>NIV |
| -                     | fmand  | Pmean          | fmand                         | fspn      | RSB      |
| R                     | fspn   | NIF            | fspn                          | -         | -        |
| С                     | RSB  | P0.1           | RSB                           | -         | -        |

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# Special ASCII Characters Used

| Character | Description            | Hexadecimal code | Control<br>characters |
|-----------|------------------------|------------------|-----------------------|
| NUL       | Zero<br>Fill character | 00               | ^@                    |
| SOH       | Start of Heading       | 01               | ^A                    |
| STX       | Start of Text          | 02               | ^B                    |
| ETX       | End of Text            | 03               | ^C                    |
| EOT       | End of Transmission    | 04               | ^D                    |
| ENQ       | Enquiry                | 05               | ^E                    |
| ACK       | Acknowledge            | 06               | ^F                    |
| BEL       | Bell                   | 07               | ^G                    |
| BS        | Backspace              | 08               | ^н                    |
| нт        | Horizontal Tabulation  | 09               | ^I                    |
| LF        | Line Feed              | 0A               | ^၂                    |
| VT        | Vertical Tabulation    | 0B               | ^К                    |
| FF        | Form Feed              | 0C               | ^L                    |
| CR        | Carriage Return        | 0D               | ^M                    |
| so        | Shift Out              | 0E               | ^N                    |
| SI        | Shift In               | 0F               | ^O                    |
| DLE       | Data Link Espace       | 10               | ^P                    |
| DC1       | Device Control 1       | 11               | ^Q                    |

| Character | Description               | Hexadecimal code | Control<br>characters |
|-----------|---------------------------|------------------|-----------------------|
| DC2       | Device Control 2          | 12               | ^R                    |
| DC3       | Device Control 3          | 13               | ^S                    |
| DC4       | Device Control 4          | 14               | ^т                    |
| NAK       | Negative Acknowledge      | 15               | ^U                    |
| SYN       | Synchronous Idle          | 16               | ^V                    |
| ЕТВ       | End of Transmission Block | 17               | ^W                    |
| CAN       | Cancel                    | 18               | ^X                    |
| EM        | End of Medium             | 19               | ^Υ                    |
| SUB       | Substitute                | 1A               | ^Z                    |
| ESC       | Escape                    | 1B               | ^[                    |
| FS        | File Separator            | 1C               | ^\                    |
| GS        | Group Separator           | 1D               | ^]                    |
| RS        | Record Separator          | 1E               | <b>^</b>              |
| US        | Unit Separator            | 1F               | ^                     |
| SP        | Space                     | 20               |                       |
| DEL       | Delete                    | 7F               |                       |

## Parts List

## For use in the Adult patient category



| ltem<br>No. | Designation/Description                     | Part No. | ltem<br>No. |
|-------------|---|----------|-------------|
| 1           | <i>Evita XL</i> or                          | 8419601  | 7a          |
|             | Evita XL                                    | 8414900  |             |
| 2           | Tray  | 8414828  | 8           |
| 3           | SpiroLife flow sensor, can be autoclaved or | MK01900  | 8a          |
|             | Spirolog flow sensor<br>(5 pcs.)            | 8403735  | 8, 8a       |
| 4           | Expiratory valve<br>(patient system) or     | 8410580  | 8b          |
|             | Disposable expiratory valve (10 pcs.)       | 8414776  | 8c          |
| 5           | Humidifier holder                           | 8411956  | 10          |
| 6           | O2 sensor capsule                           | 6850645  | 10.1        |
| 7           | Ambient air filter                          | 8412384  | 10.2        |

| ltem<br>No. | Designation/Description                                    | Part No. |
|-------------|--|----------|
| 7a          | Cooling air filter (back of <i>Evita XL</i> , not illust.) | 8412384  |
| 8           | EvitaMobil trolley (high) <sup>1)</sup>                    | 8411950  |
| 8a          | EvitaMobil trolley<br>(low) <sup>2)</sup>                  | 8411965  |
| 8, 8a       | EvitaMobil trolley with column extension <sup>3)</sup>     | 8414455  |
| 8b          | Cylinder holder set,<br>EvitaMobil (not illust.)           | 8411970  |
| 8c          | Breathing air compressor<br>(not illust.)                  | 8414350  |
| 10          | Aquapor EL   | 8414698  |
| 10.1        | Patient part for Aquapor EL                                | 8405029  |
| 10.2        | Rail clamp set   | 8403345  |

| ltem<br>No. | Designation/Description  | Part No. |
|-------------|--|----------|
| 11          | Temperature sensor   | 8405371  |
| 12-23       | Breathing circuit, adult (blue sleeve)   | 8412092  |
| 12          | Spiral hose, adult, silicone 0.6 m   | 2165627  |
| 13-<br>13.1 | Water trap   | 8404985  |
| 13.1        | Container  | 8403976  |
| 14          | Spiral hose, adult, silicone 0.35 m  | 2165619  |
| 15          | Adapter  | M25647   |
| 16          | ISO mask elbow   | M25649   |
| 17          | Y-piece, straight  | 8405435  |
| 18          | Catheter connector, straight, size 12.5 (10 pcs.)  | M23841   |
| 19          | Hose clamp   | 8403566  |
| 20          | Corrugated hose  | 8402041  |
| 21          | Catheter connector set,<br>adult Catheter connectors,<br>adult, size 6 to size 12<br>(12 pcs.) | 8403685  |
| 22          | Adapter, adult   | 8403076  |
| 23          | Cap (5 pcs.)   | 8402918  |
| 23a         | Blue adult test lung (bag)   | 8403201  |
| 23b         | White adult test lung  | 8401892  |
| 24-<br>24b  | Hinged arm<br>or   | 8409609  |
|             | Quick-fix hinged arm 2   | 2M85706  |
| 24a         | Holder   | 8409746  |
| 24b         | Hose clip  | 8409841  |
| 25          | CO2 mainstream sensor  | 6871500  |
| 26          | Reusable cuvette, adult or   | 6870279  |
|             | Disposable cuvette, adult (10 pcs.)  | MP01062  |
| 27          | Park bracket for CO2 sensor  | 8412840  |

| ltem<br>No. | Designation/Description                   | Part No. |  |  |  |
|-------------|---|----------|--|--|--|
| For Ev      | For Evita XL Mobil trolley (not illust.): |          |  |  |  |
|             | Evita XL Mobil trolley                    | G93160   |  |  |  |
|             | Universal holder with stan-<br>dard rail  | G93140   |  |  |  |
|             | Humidifier holder, variable height        | G93111   |  |  |  |
|             | Gas cylinder holder                       | G93110   |  |  |  |
|             | Set Velcro fastener                       | G93143   |  |  |  |
|             |   |          |  |  |  |

1) Not available for the US market

Not available for the US market
 Only available for the US market

# For use in the Pediatric and Neonatal patient categories



| ltem<br>No. | Designation/Description                                    | Part No. |
|-------------|--|----------|
| 1           | Evita XL / Evita XL Neo                                    | 8419601  |
|             | Evita XL Neo   | 8416950  |
| 2           | Tray   | 8414828  |
| 3           | SpiroLife flow sensor, can be autoclaved or                | MK01900  |
|             | Spirolog flow sensor<br>(5 pcs.)                           | 8403735  |
| 4           | Expiratory valve<br>(patient system)                       | 8410580  |
| 5           | Bracket  | 8411956  |
| 6           | O2 sensor capsule  | 6850645  |
| 7           | Ambient air filter   | 8412384  |
| 7a          | Cooling air filter (back of <i>Evita XL</i> , not illust.) | 8412384  |
| 8           | EvitaMobil trolley (high) <sup>1)</sup>                    | 8411950  |

| ltem<br>No. | Designation/Description                                | Part No. |
|-------------|--|----------|
| 8a          | EvitaMobil trolley (low) <sup>2)</sup>                 | 8411965  |
| 8, 8a       | EvitaMobil trolley with column extension <sup>3)</sup> | 8414455  |
| 8b          | Cylinder holder set,<br>EvitaMobil (not illust.)       | 8411970  |
| 8c          | Breathing air compressor (not illust.)                 | 8414350  |
| 24-<br>24b  | Hinged arm<br>or                                       | 8409609  |
|             | Quick-fix hinged arm 2                                 | 2M85706  |
| 24a         | Holder   | 8409746  |
| 24b         | Hose clamp   | 8409841  |
| 25-28       | Humidifier basic unit MR 850                           | 8414144  |
| 26          | Hose heater adapter                                    | 8414968  |
| ltem<br>No. | Designation/Description   | Part No. |
|-------------|---|----------|
| 27          | Mounting set (clamp for rail)   | 8411074  |
| 28          | Dual temperature sensor   | 8414989  |
| 29-30       | Humidifier chamber MR 340 incl. 100 pcs. filter paper   | 8411047  |
| 30          | Filter paper for MR 340<br>(200 pcs. not illust.  | 8411073  |
| 31          | Draw wire 1.5 m (not illust.)   | 8411050  |
| 32-43       | Dräger breathing circuit for<br>MR 850, heated on<br>inspiratory side, water trap on<br>expiratory side | 8414987  |
| 32-<br>32a  | Condensate trap for<br>expiratory side  | 8409627  |
| 32          | Container   | 8403976  |
| 33          | Double cone   | 8409897  |
| 34          | Temperature sensor holder   | 8411044  |
| 35          | Adapter K90   | 8403075  |
| 36          | Сар   | 8401645  |
| 37          | Bellows, pediatric, complete  | 8409742  |
| 38          | Corrugated hose, flex.,<br>0.13 m   | 8409634  |
| 39          | Catheter connector, size 11   | M19351   |
| 40          | Spiral hose, pediatric, silicone 22/10, 0.40 m  | 2165856  |
| 41          | Spiral hose, pediatric, silicone 22/10, 1.10 m  | 2165651  |
| 42          | Spiral hose, pediatric,<br>silicone 22/10, 0.60 m   | 2165821  |
| 43          | Spiral hose, pediatric,<br>silicone 10/10, 0.60 m   | 2165848  |
| 44          | Hose heater 1.10 m  | 8411045  |
| 45          | Bacterial filter  | MX02650  |
| 46          | CO2 mainstream sensor   | 6871500  |
| 47          | Reusable cuvette, pediatric or  | 6870280  |
|             | Disposable cuvette, pediatric (10 pcs.)   | MP01063  |

| ltem<br>No. | Designation/Description                         | Part No. |
|-------------|---|----------|
| 48          | Park bracket for CO2 sensor                     | 8412840  |
|             | Flow sensor cable                               | 8409626  |
|             | Neonatal flow sensor ISO 15                     | 8411130  |
|             | Insert for neonatal flow sensor (set of 5 pcs.) | 8410179  |
|             | "Water trap" kit                                | 8413125  |
|             | Cuvette, pediatric, for CO2 measurement         | 6870280  |
|             | Corrugated hose, 0.13 m                         | 8409634  |
| For Ev      | rita XL Mobil trolley (not illust.):            |          |
|             | Evita XL Mobil trolley                          | G93160   |
|             | Universal holder with stan-<br>dard rail        | G93140   |
|             | Humidifier holder, variable height              | G93111   |
|             | Gas cylinder holder                             | G93110   |
|             | Set Velcro fastener                             | G93143   |

1) Not available for the US market

2) Not available for the US market
 3) Only available for the US market

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These Instructions for Use only apply to *Evita XL / Evita XL Neo* SW 7.0n with the Serial No.:

If no Serial No. has been filled in by Dräger, these Instructions for Use are provided for general information only and are not intended for use with any specific device or unit. This document is provided for customer information only, and will not be updated or exchanged without customer request.

Directive 93/42/EEC concerning Medical Devices

Manufacturer:

#### Dräger Medical AG & Co. KG

- Moislinger Allee 53 55 D-23542 Lübeck Germany
- 🕾 +49 451 8 82-0
- FAX +49 451 8 82-20 80
- http://www.draeger.com

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