

# NeoFlow<sup>TM</sup>

## Neonatal Patient Mode

Addendum to  
Operating Instructions  
EvitaXL\*

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\* These Operating Instructions apply also  
to Evita 4 with the XL option



## NOTICE

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## Important Safety Information

### Operator's Responsibility for Patient Safety

#### **WARNING !**

**Strictly follow this Operator's Instruction Manual**  
**Any use of the product requires full understanding and strict observation of all portions of these instructions.**  
**The equipment is only to be used for the purpose specified under "Intended Use" on page 10.**  
**Observe all WARNINGS and CAUTIONS as rendered throughout this manual and on labels on the equipment.**

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

This publication excludes references to various hazards which are obvious to a medical professional and operator of this equipment, to the consequences of product misuse, and to potentially adverse effects in patients with abnormal conditions. Product modification or misuse can be dangerous. Draeger Medical, Inc. disclaims all liability for the consequences of product alterations or modifications, as well as for the consequences which might result from the combination of this product with other products whether supplied by Draeger or by other manufacturers if such a combination is not endorsed by Draeger Medical, Inc.

#### **Patient monitoring**

The operators of the ventilator system must recognize their responsibility for choosing appropriate safety monitoring that supplies adequate information on equipment performance and patient condition. Patient safety may be achieved through a wide variety of different means ranging from electronic surveillance of equipment 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 equipment operator.

### Limitation of Liability

Draeger Medical, Inc.'s liability, whether arising out of or related to manufacture and sale of the goods, their installation, demonstration, sales representation, use, performance, or otherwise, including any liability based upon Draeger Medical, Inc.'s Product Warranty, is subject to and limited to the exclusive terms and conditions as set forth, whether based upon breach of warranty or any other cause of action whatsoever, regardless of any fault attributable to Draeger Medical, Inc. and regardless of the form of action (including, without limitation, breach of warranty, negligence, strict liability, or otherwise).

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## **Warranty**

All Draeger products are guaranteed to be free of defects for a period of one year from date of delivery.

The following are exceptions to this warranty:

1. The defect shall be a result of workmanship or material. Defects caused by misuse, mishandling, tampering, or by modifications not authorized by Draeger Medical, Inc. or its representatives are not covered.
2. Rubber and plastic components and materials are warranted to be free of defects at time of delivery.

Any product which proves to be defective in workmanship or material will be replaced, credited, or repaired with Draeger Medical, Inc. holding the option. Draeger Medical, Inc. is not responsible for deterioration, wear, or abuse. In any case, Draeger Medical, Inc. will not be liable beyond the original selling price.

Application of this warranty is subject to the following conditions:

1. Draeger Medical, Inc. or its authorized representative must be promptly notified, in writing, upon detection of the defective material or equipment.
2. Defective material or equipment must be returned, shipping prepaid, to Draeger or its authorized representative.
3. Examination by Draeger or its authorized representative must confirm that the defect is covered by the terms of this warranty.
4. Notification in writing, of defective material or equipment must be received by Draeger or its authorized representative no later than two (2) weeks following expiration of this warranty.

The above is the sole warranty provided by Draeger Medical, Inc. No other warranty expressed or implied is intended. Representatives of Draeger are not authorized to modify the terms of this warranty.

Draeger Medical, Inc., Telford, PA

## Definitions

### **WARNING !**

A **WARNING** statement refers to conditions with a possibility of personal injury if disregarded.

### **CAUTION !**

A **CAUTION** statement designates the possibility of damage to equipment if disregarded.

**NOTE:** A **NOTE** provides additional information intended to avoid inconveniences during operation.

Inspection	examination of actual condition
Service	measures to maintain specified condition
Repair	measures to restore specified condition
Maintenance	inspection, service, and repair, where necessary
Preventive Maintenance	maintenance measures at regular intervals

### Typing conventions in this manual

Controls are designated as »**Control Name**«, e.g:

»**PEEP**«

Screen pages are indicated as »Screen page«, e.g.

»Measured values«

Screen messages are printed in bold, e.g:

**Flow Calibration**

Screen messages rendered throughout the text are shown including the exclamation marks indicating their alarm level, e.g.

**Standby activated !!!**

### Abbreviations and Symbols

Please refer to "Glossary" on page 45 for explanations.

## Summary of WARNINGS and CAUTIONS

### General Precautions

#### WARNING !

Strictly follow this Operator's Instruction Manual  
Any use of the product requires full understanding and strict observation of all portions of these instructions. The equipment is only to be used for the purpose specified under "Intended Use" on page 10. Observe all WARNINGS and CAUTIONS as rendered throughout this manual and on labels on the equipment.

#### WARNING !

**DANGER**, risk of explosion if used in the presence of flammable gases or anesthetics.  
This device is neither approved nor certified for use in areas where combustible or explosive gas mixtures are likely.

#### WARNING !

Never use flammable medications (e.g. on the basis of ethanol) or other substances based on flammable solvents in the patient circuit. Fire hazard!  
Always provide adequate ventilation when using flammable substances for disinfection.

#### WARNING !

Electrical connections to equipment or components not listed in these Operating Instructions should only be made after consultation with the respective manufacturers or a qualified expert.

#### CAUTION ! Restriction of Distribution

Federal Law and Regulations in the United States and Canada restrict this device to sale by or on the order of a physician.  
Device for use in health care facilities only and exclusively by persons with specific training and experience in its use.

#### CAUTION !

##### Accessories

Use only accessories listed in the Ordering Information (page 46).

### Precautions during preparation

#### WARNING !

Installation of the NeoFlow option into EvitaXL ventilators may only be performed by factory trained and authorized service personnel. Follow installation instructions in the respective documentation.

#### WARNING !

The operator of the ventilator must still assume full responsibility for proper ventilation while flow monitoring is not available during calibration.

### Precautions during operation

#### WARNING!

The alarm limit »PAW  $\nearrow^{\text{r}}$ « must always be set so that a warning is triggered if airway pressure increases with reduced compliance or in the event of sudden changes in the size of the leak.

#### WARNING!

Minute volume during neonatal ventilation cannot be monitored without the neonatal flow sensor!  
The operator of the ventilator must still assume full responsibility for proper ventilation while flow monitoring is not available during neonatal ventilation.

## Important Safety Information

### Summary of WARNINGS and CAUTIONS

#### **WARNING!**

**Effect of aerosols on sensors, filters, and heat and moisture exchangers!**

**The measuring function of the flow sensor may be impaired.**

**The flow resistance of filters is liable to increase and may impair ventilation.**

**Do not put a bacteria filter on the nebulizer outlet when in use!**

#### **WARNING!**

**Do not use a heat/moisture exchanger simultaneously with a nebulizer or heated humidifier!**

**Risk of increased breathing resistance due to condensation.**

#### **WARNING!**

**The nebulizer function integrated in EvitaXL is designed for nebulizers with a nebulizing flow of 6 L/min at 29 psi (2 bar), for example nebulizer 84 12 935 (white central body). Other nebulizers may cause deviations in tidal volume and inspiratory O<sub>2</sub> concentration!**

#### **WARNING!**

**The wires of the flow sensor are hot. If the neonatal flow sensor is left in the patient circuit for some time during nebulizing without being cleaned, deposits from the medicated aerosols may build up and impair flow measurement.**

**In the worst case, these deposits could catch fire.**

**Disconnecting the flow sensor cable is not sufficient to prevent this.**

**It is therefore important to remove the complete flow sensor before nebulizing medications.**

#### **WARNING!**

**While flow monitoring is not available during nebulizing, the operator of the ventilator must still assume full responsibility for proper ventilation.**

#### **CAUTION !**

Do not ventilate larger pediatric patients with serious infections and a severe cough using the neonatal flow sensor. Instead, use the expiratory flow sensor for ventilation. Otherwise, coughed up secretions may cause corrosion in the neonatal flow sensor.

#### **Precautions during care procedures**

#### **WARNING !**

**Always follow accepted hospital procedures for handling equipment contaminated with body fluids.**

#### **WARNING !**

**Vent flow sensor after disinfection with ethanol for at least 30 minutes or rinse with sterile water. Otherwise, residual ethanol vapors might ignite and destroy the sensor during calibration.**

#### **CAUTION !**

Certain components of the ventilator consist of materials that are sensitive to certain organic solvents sometimes used for cleaning and disinfecting (e.g., alkylamines, phenols, halogen releasing compounds, oxygen releasing compounds, strong organic acids, etc.). Exposure to such substances may cause damage that is not always immediately recognized. Sterilization with ethylene oxide (EtO) is also not recommended.

#### **CAUTION !**

Do not allow any liquid into the connector of the flow sensor cable.

#### **CAUTION !**

Flow sensor is not compatible with parts washer equipment and may not be autoclaved or steam-sterilized. It cannot withstand high temperatures and would be destroyed.

Do not use compressed air, brushes or similar tools to clean flow sensor element as this would possibly damage the thin wires in the flow sensor.



**Precautions during maintenance**

**WARNING !**

To avoid any risk of infection, clean and disinfect ventilator and accessories before any maintenance according to established hospital procedures - this applies also when returning ventilators or parts for repair.

**WARNING !**

Preventive Maintenance work on the EvitaXL ventilators and their components may be performed by factory trained and authorized personnel only.

**WARNING !**

Never operate the ventilator if it has suffered physical damage or does not seem to operate properly.  
We recommend that you contact DraegerService for maintenance service for the EvitaXL ventilator.

**WARNING !**

When servicing the ventilator, always use replacement parts that are qualified to Draeger standards.  
Draeger cannot warrant or endorse the safe performance of third party replacement parts for use with EvitaXL ventilators.

**CAUTION !**

**Maintenance**

This device must be inspected and serviced at regular intervals. A record must be kept on this preventive maintenance. We recommend obtaining a service contract with DraegerService through your vendor.  
For repairs we recommend that you contact DraegerService.

## Intended Use

**NeoFlow** – neonatal mode with base flow.

Extends the patient range of the EvitaXL intensive care ventilator to infants and premature babies with a minimum body weight of 1.1 lbs (0.5 kg).

Extends the range of flow monitoring with EvitaXL during pediatric and neonatal ventilation employing a proximal flow sensor specifically designed for neonatal applications.

## Restrictions of Use

### **WARNING !**

**DANGER**, risk of explosion if used in the presence of flammable gases or anesthetics.

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

### **WARNING !**

Never use flammable medications (e.g. on the basis of ethanol) or other substances based on flammable solvents in the patient circuit. Fire hazard!

Always provide adequate ventilation when using flammable substances for disinfection.

### **WARNING !**

Electrical connections to equipment or components not listed in these Operating Instructions should only be made after consultation with the respective manufacturers or a qualified expert.

### **CAUTION !**

#### **Restriction of Distribution**

Federal Law and Regulations in the United States and Canada restrict this device to sale by or on the order of a physician.

Device for use in health care facilities only and exclusively by persons with specific training and experience in its use.

## **Preparation**

### **Before Using for the First Time**

Installing the NeoFlow option

#### **WARNING !**

Installation of the NeoFlow option into EvitaXL ventilators may only be performed by factory trained and authorized service personnel. Follow installation instructions in the respective documentation.

#### **Configuring NeoFlow**

Please refer to page 28 for instructions on configuring NeoFlow.

## Preparing for Use

### Installing the neonatal flow sensor

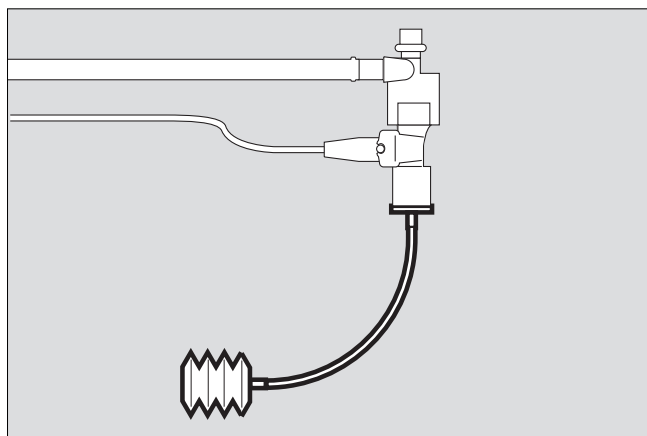
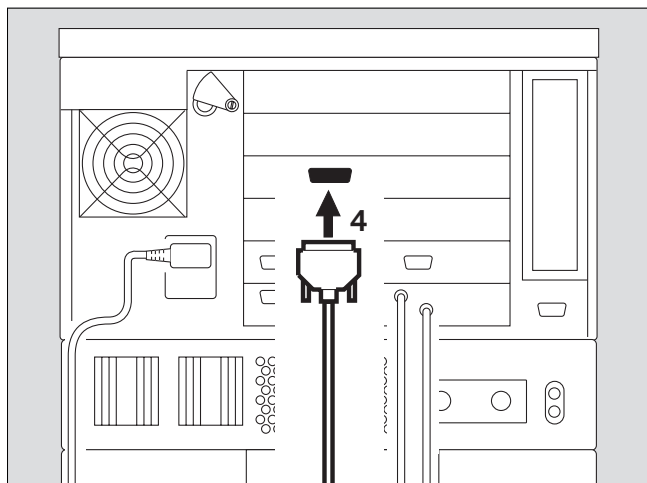
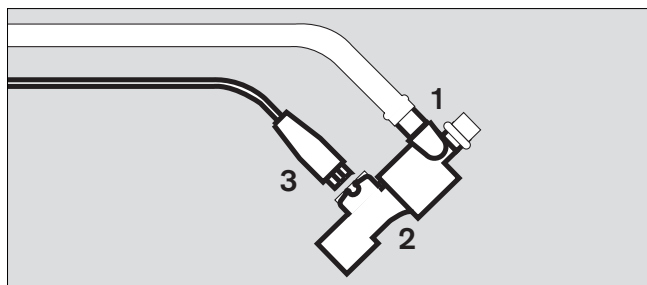
Prepare patient circuit – see chapter "Ventilating Infants" in the EvitaXL Operating Instructions.

- Only the neonatal flow sensor (84 11 130) may be used.

### WARNING !

**Do not use the Y-piece with integral flow sensor (part no. 84 10 185). This flow sensor features a different flow characteristic curve and would give inaccurate flow measurements.**

- 1 Plug the Y-piece to ventilator circuit.
  - 2 Insert neonatal flow sensor into the Y-piece.
  - 3 Plug the flow sensor cable into the socket.
- Route sensor cable to the ventilator along the patient circuit.
- 4 Plug the flow sensor connector into the socket on the back panel of the ventilator and tighten thumbscrews.
- 
- Connect test lung complete with tracheal tube CH 12 and ET-tube connector to the patient end of the neonatal flow sensor.



## Device Check

The NeoFlow option expands the EvitaXL pre-use check procedure by the following function:

- **Calibration neo. flow sensor**

The screenshot displays the EvitaXL Standby interface. The main display area shows 'EvitaXL Standby'. On the right, a vertical column of patient data fields is visible, including Pmean, PEEP, Vol%, FIO2, L/min, MV, L/min, MVspn, bpm, ftotal, L, and VT. Below the main display, a 'Start / Standby' menu is open, showing a list of checks under 'Device', 'Sensors', and 'Function'. The 'Device' section includes checks for Expiration valve, Flow sensor, Neo. flow sensor, Humidification, and Patient hoses fitted. The 'Sensors' section includes checks for Calibration flow sensor, Calibration neo. flow sensor, Calibration O2 sensor, CO2 sensor zeroed, and CO2 sensor. The 'Function' section includes checks for Air-O2-switch over valve, Safety valve, Supply pressures, and Back-up alarm. The 'Start / Standby' menu also includes options for Overview, Device Check, Airtight Check, and Check. The bottom right corner of the screen shows a small icon and the text '102276183'.

## Calibrating the Neonatal Flow Sensor


- Before use, as part of the ventilator check.
- After replacing the neonatal flow sensor.
- At least once every 24 hours.

**NOTE:** The last calibration value obtained is saved until the next calibration, even when the ventilator is switched off.

Before each calibration, the neonatal flow sensor is automatically cleaned.

**NOTE:** Recalibration is not necessary if the plug of the neonatal flow sensor has been temporarily unplugged.

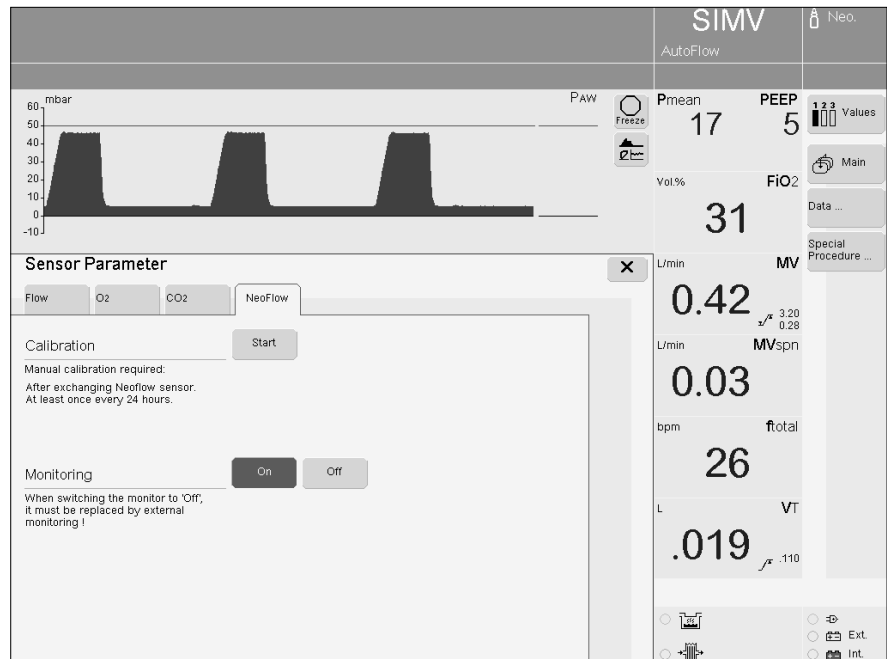
### Starting calibration for EvitaXL

- Press »  **Sensor Parameter**« key. The »**Sensor Parameter**«, menu is displayed. Select »**NeoFlow**« menu, flow monitoring is activated.

Start calibration:

- Touch »**Start**« screen key. The screen key turns green, the ventilator now calibrates the flow sensor.

The »**Start**« screen key turns pale-green when calibration is complete.



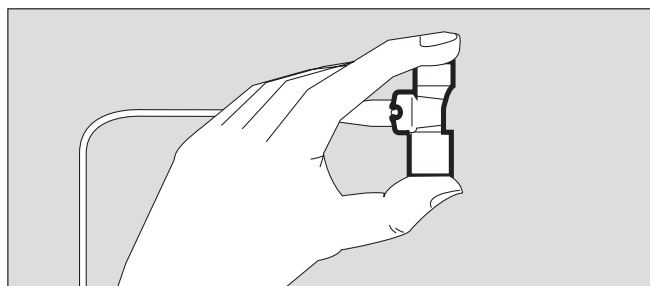
**Calibration procedure**

- Remove ET-tube connector,
- Remove neonatal flow sensor from Y-piece,
- Insert patient ET-tube connector directly into the Y-piece for the duration of the calibration.

**WARNING !**

The operator of the ventilator must still assume full responsibility for proper ventilation while flow monitoring is not available during calibration.

- Wearing a sterile glove, hold neonatal flow sensor so that both sides are sealed and flow is zero, as required for calibration.



- Start calibration = press dial knob.

Calibration is completed after approx. 1 second.

If the message **Calibration ok** is displayed:

- Remove ET-tube connector from Y-piece. Re-install neonatal flow sensor into the Y-piece. Reconnect tube connector.

If calibration is unsuccessful:

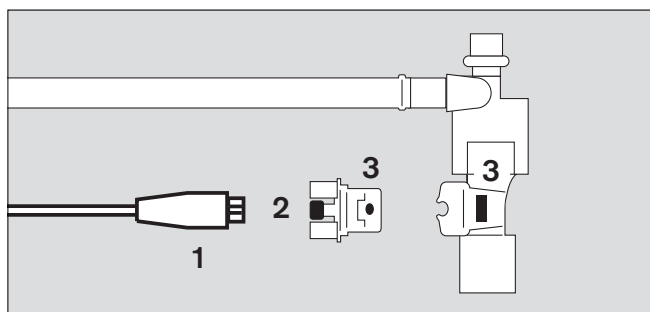
- Repeat calibration. If necessary, replace neonatal flow sensor. Check sensor cable.

**Replacing the Neonatal Flow Sensor**

If the following error message is displayed:

**Neo flow measurement inop.**

- 1 Disconnect flow sensor cable from the neonatal flow sensor.
  - 2 Press buttons on both sides while pulling the flow sensor element out of its housing. Insert new sensor until it engages.
  - 3 The two oval markings on flow sensor element and sensor housing must line up.
- 1 Reconnect flow sensor cable.
- Calibrate neonatal flow sensor, see page 14.



Operation

Selecting Neonatal Mode

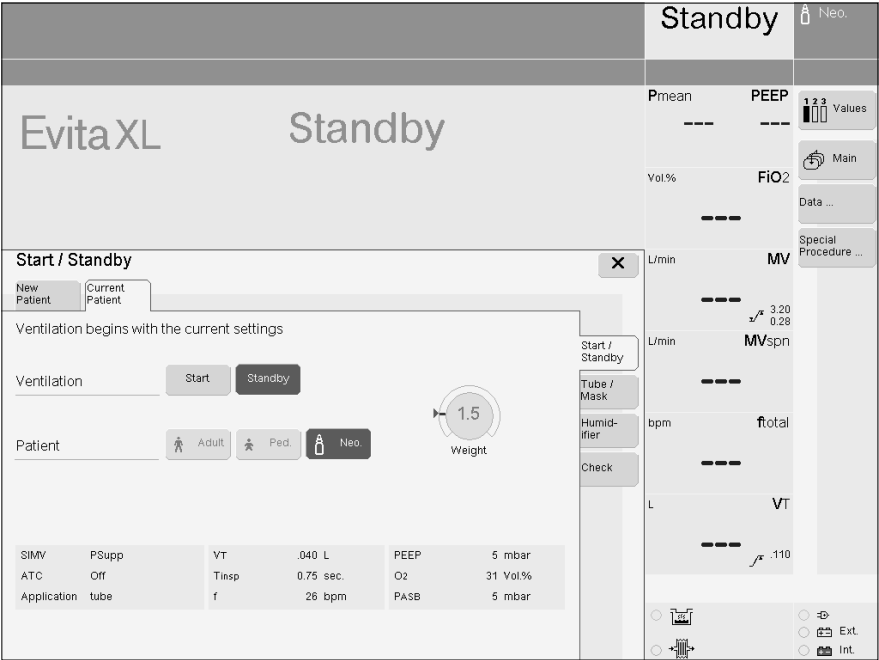
The required patient mode can be selected from the EvitaXL menu immediately after switching on or while in standby mode:

- » **Adult**« = Adult
- » **Ped.**« = Pediatric
- » **Neo.**« = Neonatal

The menu ranges can be configured, see "Configuring Ventilation, Setting the patient range", on page 28.

- Touch » **Neo.**« screen key.

Display (example for neonatal mode):  
In the top line of the screen, after the ventilation mode identifier, **Neo.** = Neonatal mode is displayed.





## Volume Controlled Ventilation in Neonatal Mode

The AutoFlow<sup>®</sup> ventilation mode supplement is always active when using volume controlled ventilation (CMV, SIMV, MMV) in neonatal mode.

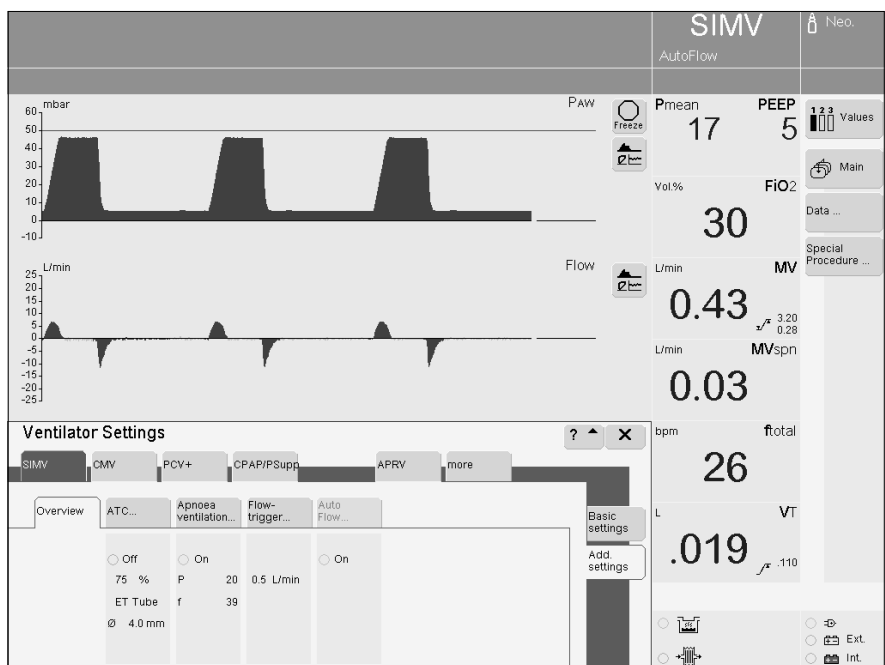
**AutoFlow<sup>®</sup>** – for automatic regulation of "Insp. Flow" and "P<sub>insp</sub>".

EvitaXL uses AutoFlow\* to decelerate and regulate inspiratory flow and providing a constant pressure throughout the inspiratory phase. The ventilator determines the lowest possible peak pressure for providing the selected V<sub>T</sub> at a given patient compliance, thereby avoiding pressure peaks.

EvitaXL delivers an additional inspiratory flow if the patient breathes in. This flow is limited by the alarm limit V<sub>Ti</sub>  $\sqrt{\wedge}$ .

The patient can also breathe out during the inspiratory plateau phase.

Inspiratory pressure is limited by the alarm limit P<sub>AW</sub>  $\sqrt{\wedge}$ .



### WARNING!

The alarm limit »P<sub>AW</sub>  $\sqrt{\wedge}$ « must always be set so that a warning is triggered if airway pressure increases with reduced compliance or in the event of sudden changes in the size of the leak.

\* Refer to page 43 for a detailed description of AutoFlow.

## Back-up Ventilation in Neonatal Mode

during volume-controlled neonatal ventilation

Volume-controlled ventilation during neonatal ventilation is only possible with intact flow monitoring. If neonatal flow monitoring fails or has been switched off during volume-controlled ventilation, EvitaXL automatically switches over to pressure-controlled back-up ventilation.

**NOTE:** Apnea monitoring continues during back-up ventilation and apnea ventilation is started if necessary.

During back-up ventilation, inspiratory pressure will correspond to the mean value of the last mandatory inspiratory pressures applied while flow monitoring was still active during volume-controlled neonatal ventilation. The "T<sub>insp</sub>", "f", "O<sub>2</sub>" and "PEEP" ventilation parameters retain the same settings as before back-up ventilation.

## Pressure Support Ventilation (PSV)

As in adult and pediatric modes, spontaneous breathing in neonatal mode can be assisted with Pressure Support during PCV+, SIMV, CPAP, and MMV ventilation. Pressure Support Ventilation may be used for patients with adequate spontaneous breathing.

**NOTE:** Pressure supported spontaneous breathing during neonatal ventilation is only possible if flow monitoring is active!

- Set the ventilation pattern for PSV ventilation with the parameters:
  - Support pressure »**PSupp.**«
  - Pressure rise time »**Slope**«
  - Maximum inspiratory time »**T<sub>insp</sub>**«

A pressure supported breath during neonatal ventilation is ended at the latest after the set maximum inspiratory time T<sub>insp</sub>.

## Apnea Ventilation in Neonatal Mode

Unlike in adult or pediatric ventilation, pressure controlled apnea ventilation is started after the set alarm time ( $T_{Apnea} \sqrt{f}$ ) if an apnea occurs in ventilation modes with activated apnea ventilation. Apnea ventilation is controlled by adjusting the following settings:

Frequency »f«

Pinsp »P<sub>Apnea</sub>«

During apnea ventilation, the ratio of inspiration to expiration is 1:2.

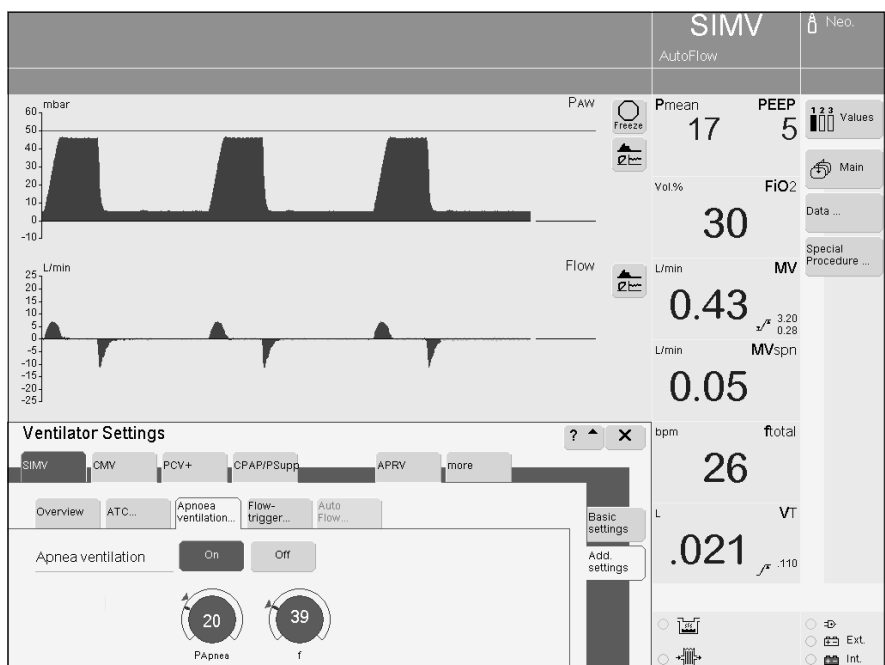
Ventilation parameters "O<sub>2</sub>" and "PEEP" remain at their respective settings in use at the time apnea ventilation is started.

### Setting apnea ventilation parameters:

- Touch »Add. settings« screen key in the desired ventilation mode. EvitaXL displays the possible additional settings.
- Touch »Apnoea ventilation...« screen key. EvitaXL displays the menu for setting apnea ventilation parameters.
- Touch »P<sub>Apnea</sub>« and »f« screen knobs. Turn dial knob to set value, press dial knob to confirm.

To switch on/off

- Touch »On« or »Off« screen key, press dial knob to confirm.



NIV (Mask Ventilation)\*

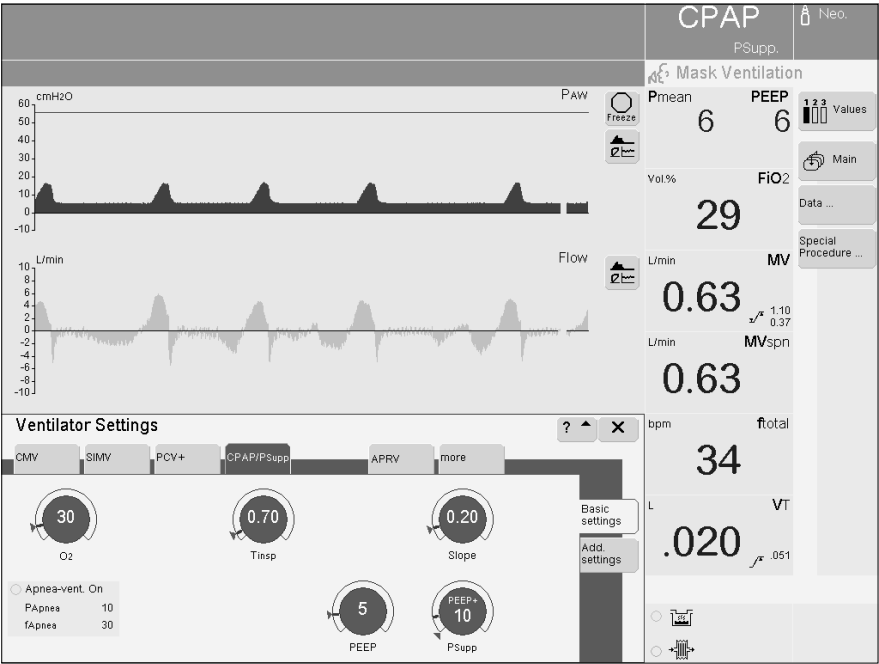
See EvitaXL Operating Instructions for details on Non Invasive Ventilation (NIV).

Set ventilation parameters

- As described for »Tube« application mode.

An additional screen knob »Tinsp« is displayed for CPAP/PSupp.  
In patient modes »Pediatric« or »Neonate«, EvitaXL limits the maximum duration of a pressure support breath to 1.5 seconds .

- The maximum duration of a pressure support breath may be further limited with the »Tinsp« screen knob.
- »Tinsp« also limits the duration of pressure supported breaths in the other ventilation modes which can be combined with PSV.



Leakage compensation in »Mask« mode

Depending on the selected patient mode, EvitaXL compensates for leaks up to the following values in order to detect a patient trigger:

- Pediatric mode: 15 L/min  
Neonatal mode: 7 L/min

EvitaXL compensates for calculated leaks up to 200 % of the set tidal volume, but not more than max. 2 L (regardless of the patient mode).

\* Available Option

## Flow Monitoring During Neonatal Ventilation

Flow monitoring with the neonatal flow sensor can be deactivated, for instance if the sensor has failed, but cannot be replaced immediately.


Flow monitoring can also be deactivated to permit ventilation in the event of a major ET-tube leak.

**NOTE:** When flow monitoring is deactivated, neither volume controlled nor patient-triggered ventilation is possible. Apnea monitoring, however, is maintained even without the neonatal flow sensor.

### WARNING!

Minute volume during neonatal ventilation cannot be monitored without the neonatal flow sensor! The operator of the ventilator must still assume full responsibility for proper ventilation while flow monitoring is not available during neonatal ventilation.

### Deactivating neonatal flow monitoring

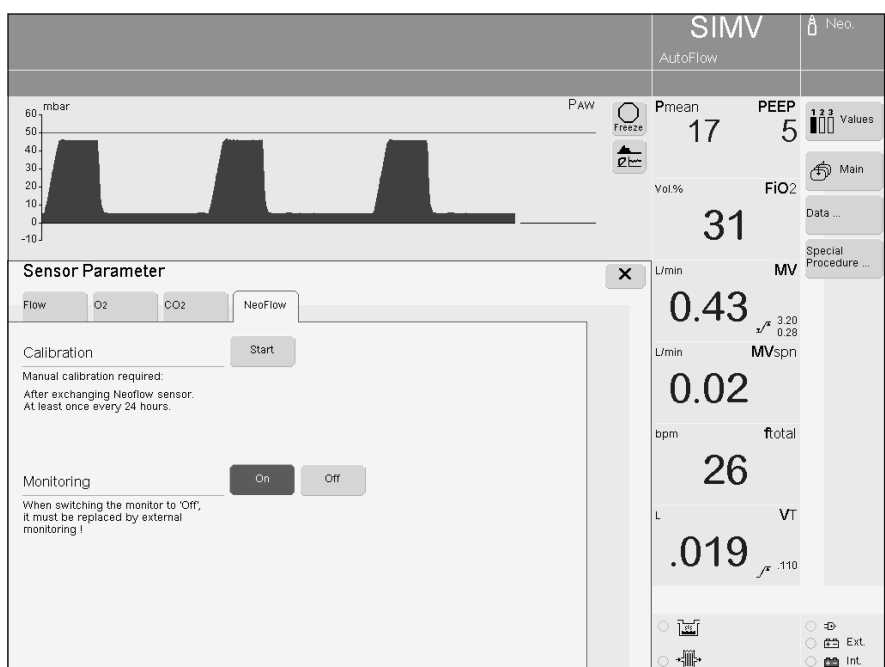
- Press the »  **Sensor Parameter**« key.
- EvitaXL displays the »**Sensor Parameter**« menu.
- Touch screen key for the sensor to be deactivated, in this case »**NeoFlow**«.
- Touch »**Off**« screen key, the screen key turns yellow.
- Press dial knob to confirm, the screen key turns green.

Neonatal flow monitoring is deactivated, and the corresponding measured values disappear from the screen.

The alarm function is deactivated.

After replacing the neonatal flow sensor:

- Reactivate neonatal flow monitoring and calibrate the neonatal flow sensor – see page 14.



#### Flow Monitoring During Pediatric Ventilation

If the neonatal flow sensor is present and intact during ventilation in pediatric patient mode, it will perform the function of pediatric flow monitoring if neonatal flow monitoring is activated.

If the neonatal flow sensor is defective or if neonatal flow monitoring is deactivated, flow monitoring is performed by the expiratory flow sensor installed in EvitaXL. In this case, unlike in neonatal patient mode, volume-controlled ventilation remains possible.

#### CAUTION !

Do not ventilate larger pediatric patients with serious infections and a severe cough using the neonatal flow sensor. Instead, use the expiratory flow sensor for ventilation. Otherwise, coughed up secretions may cause corrosion in the neonatal flow sensor.

## Nebulizing Pharmaceutical Aerosols

In neonatal mode, it is only possible to nebulize pharmaceutical aerosols during pressure controlled ventilation.

### WARNING!

**Effect of aerosols on sensors, filters, and heat and moisture exchangers!**

The measuring function of the flow sensor may be impaired.

The flow resistance of filters is liable to increase and may impair ventilation.

Do not put a bacteria filter on the nebulizer outlet when in use!

### WARNING!

Do not use a heat/moisture exchanger simultaneously with a nebulizer or heated humidifier!

Risk of increased breathing resistance due to condensation.

### WARNING!

The nebulizer function integrated in EvitaXL is designed for nebulizers with a nebulizing flow of 6 L/min at 29 psi (2 bar), for example nebulizer 84 12 935 (white central body). Other nebulizers may cause deviations in tidal volume and inspiratory O<sub>2</sub> concentration!

### WARNING!

While flow monitoring is not available during nebulizing, the operator of the ventilator must still assume full responsibility for proper ventilation.

### Notes for aerosol treatment:

- Before nebulizing medications, remove the complete flow sensor from the Y-piece.
- Calibrate flow sensor at least once every 24 hours, see "Calibrating the Neonatal Flow Sensor" on page 14.
- Replace/clean flow sensor if there is visible soiling (see page 32).

### Removing the neonatal flow sensor

#### WARNING!

The wires of the flow sensor are hot. If the neonatal flow sensor is left in the patient circuit for some time during nebulizing without being cleaned, deposits from the medicated aerosols may build up and impair flow measurement.

In the worst case, these deposits could catch fire.

Disconnecting the flow sensor cable is not sufficient to prevent this.

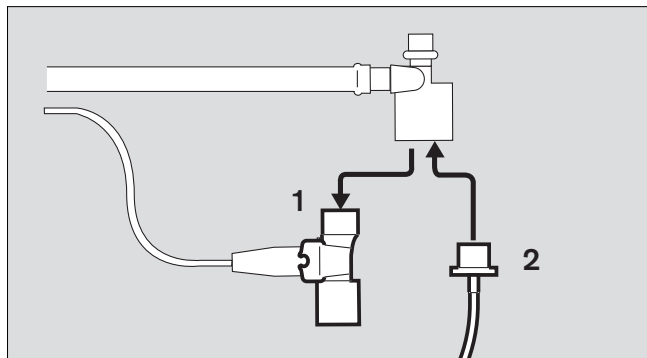
It is therefore important to remove the complete flow sensor before nebulizing medications.

- 1 Remove complete flow sensor (housing and insert) from Y-piece.
- 2 Insert ET-tube connector into Y-piece.

**NOTE:** Minute volume is not monitored without the neonatal flow sensor.

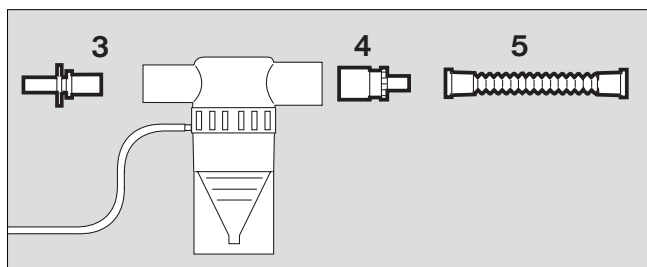
#### WARNING!

While flow monitoring is not available during nebulizing, the operator of the ventilator must still assume full responsibility for proper ventilation.



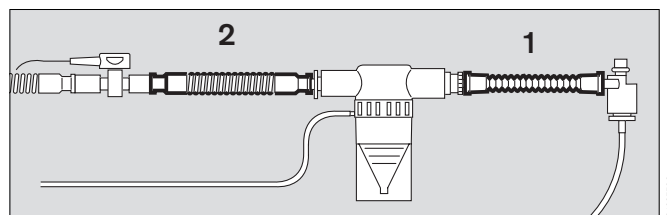
### Preparation

- Use only nebulizers with a nebulizing flow of 6 L/min at 29 psi (2 bar), for example nebulizer 84 12 935 (white central body), listed in the Ordering Information.
  - Assemble nebulizer as detailed in its specific Instructions for Use.
- 3 Insert the ET-tube connector (ISO tapered Ø15 / Ø11) into the input.
  - 4 Insert the adapter (ISO tapered Ø22 / Ø11) into the outlet.
  - 5 Connect the corrugated silicone tubing (0.13 m (5 ") long) to the outlet adapter.

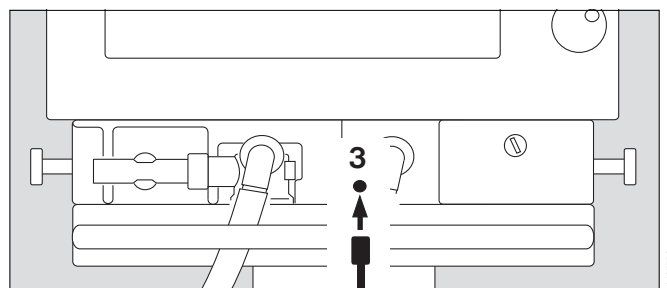




- 1 Remove corrugated silicone tubing of the patient circuit from the inspiratory adapter of the Y-piece and re-connect it to the input adapter of the nebulizer.
- 2 Using the Y-piece inspiratory adapter, connect the free end of the corrugated tubing to the nebulizer.

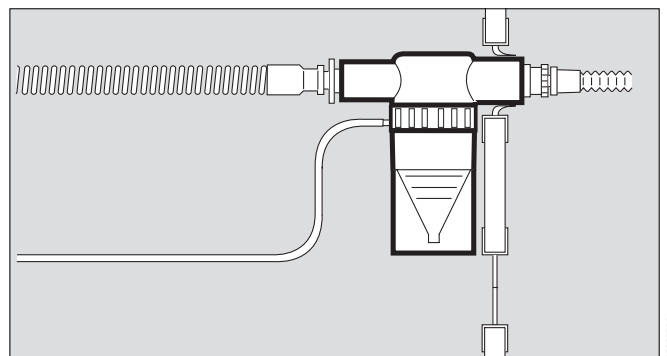


- 3 Attach the nebulizer supply line to the nipple on the front of EvitaXL.



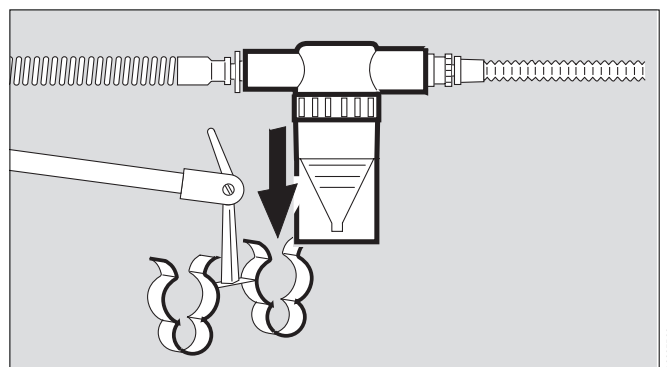
#### When using with an incubator

- Push the outlet adapter of the nebulizer into the upper access grommet in the incubator hood, if available.



#### When using without incubator

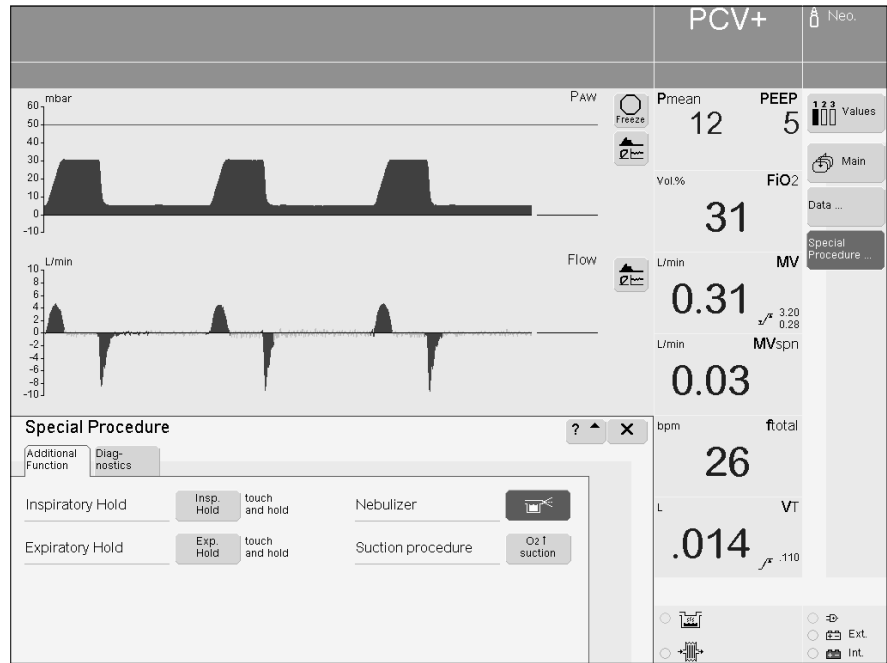
- Press the nebulizer sleeve into one side of the clip of a patient circuit support arm bracket and the expiratory circuit into the other.



- Position the nebulizer upright and fill it.

### Starting nebulization

- Deactivate neonatal flow monitoring, page 21.
- Touch »**Special Procedure...**« screen function key, EvitaXL opens the »**Additional Function**« menu.
- Touch »**Nebulizer**« screen key, the key turns yellow.
- Press dial knob to confirm, the screen key turns green. The nebulizer is in operation. The advisory message **Nebulizer on !** is displayed.



### Ending nebulization

- Touch the »**Nebulizer**« screen key.

Nebulization is stopped automatically after 30 minutes.

- Remove any residual medication from the nebulizer. Follow Instructions for Use of the nebulizer.
- Re-install neonatal flow sensor into the Y-piece.
- Activate neonatal flow monitoring – see page 21.

## O<sub>2</sub> Concentration When Using Nebulizer

The nebulizer for medication aerosols operates continuously, when activated in the neonatal range.

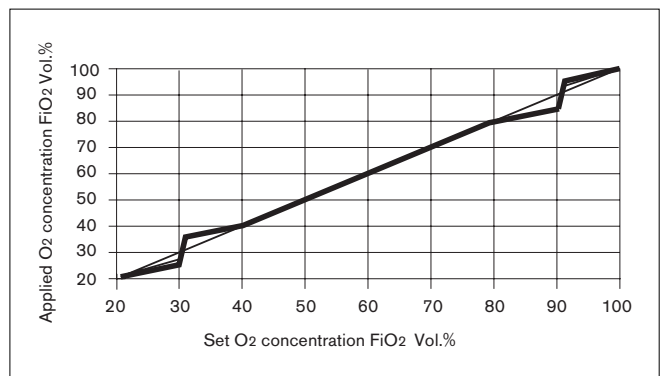
During nebulizer treatment, the base flow is increased from 6 L/min to 9 L/min.

Depending on the set O<sub>2</sub> concentration, the nebulizer is supplied with medical compressed air, oxygen, or a mixture of medical air and oxygen in order to keep deviations in O<sub>2</sub> concentration as low as possible.

For nebulizers with a nebulizing flow of 6 L/min at 29 psi (2 bar) and respiratory rates greater than 12 bpm, the graph in the side column applies. The maximum possible deviations are  $\pm 4\%$  Vol.

For respiratory rates less than 12 bpm, the deviations may be much greater in extreme cases.

We therefore recommend to discontinue use of the nebulizer if respiratory rates fall below 12 bpm.



## Oxygenation for Bronchial Suction

The timing sequence of bronchial suction in neonatal mode is the same as described for adult ventilation – see EvitaXL Operating Instructions.

However, during pre- and post-oxygenation, the FiO<sub>2</sub> concentration is increased by only 25 % – relative to the set FiO<sub>2</sub> concentration.

See table:

Set FiO <sub>2</sub> Vol.%	FiO <sub>2</sub> for pre- and post-oxygenation Vol.%
21	26
30	37
60	75
80	100

Current FiO<sub>2</sub> concentration is displayed at the bottom of the screen during the oxygenation phases.

## Configuration of Ventilation

### Setting the Patient Range

Select the required patient mode from the list on the configuration page, see EvitaXL Operating Instructions.

The following ranges are available:

**Adults only**


**Pediatrics only**

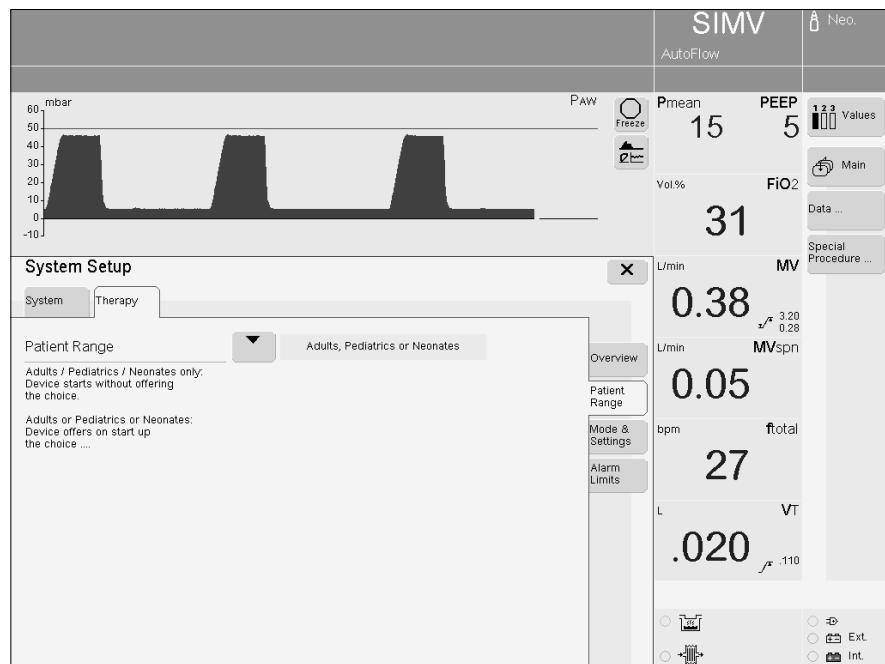
**Neonates only**

**Adults or Pediatrics**

**Pediatrics or Neonates**


**Adults, Pediatrics, or Neonates**

- Press »  **System Setup**« function key.
- Touch »**Therapy**« screen key.
- Touch »**Patient Range**« screen key and enter access code 3032.
- Touch »▼« screen key, EvitaXL displays the selection list.
- Select the desired patient mode. Turn dial knob to select, press dial knob to confirm.



## Start-up Defaults for Ventilation Parameters and Alarm Limits

Start-up default values, i.e. the values for tidal volume  $V_T$  and ventilator rate  $f$  activated whenever EvitaXL is switched on, may be defined as a function of either ideal body weight or of the patient mode.

- Press »  **System Setup**« function key.
- Touch »**Therapy**« screen key.
- Touch »**Mode & Settings**« screen key and enter access code 3032.
- Touch » **$V_T$ ,  $f$ ...**« screen key.

Change specific values as required by hospital protocol:

- Touch the corresponding screen key.
- Turn dial knob to set.
- Press dial knob to confirm.

To restore factory default settings:

- Touch »**Dräger Default**« screen key .
- Press dial knob to confirm.



## Configuration of Ventilation

### Start-up Defaults for Ventilation Parameters and Alarm Limits

To select the initial values for VT and f as a function of the ideal weight, the Radford nomogram has been extended to an ideal weight of 0.5 kg:


Weight kg	Factory-set default		Hospital-set default	
	Tidal volume VT mL	Ventilator rate f bpm	Tidal volume VT mL	Ventilator rate f bpm
0.5	3	35	.....	.....
15	110	26	.....	.....
65	450	13	.....	.....
100	700	10	.....	.....

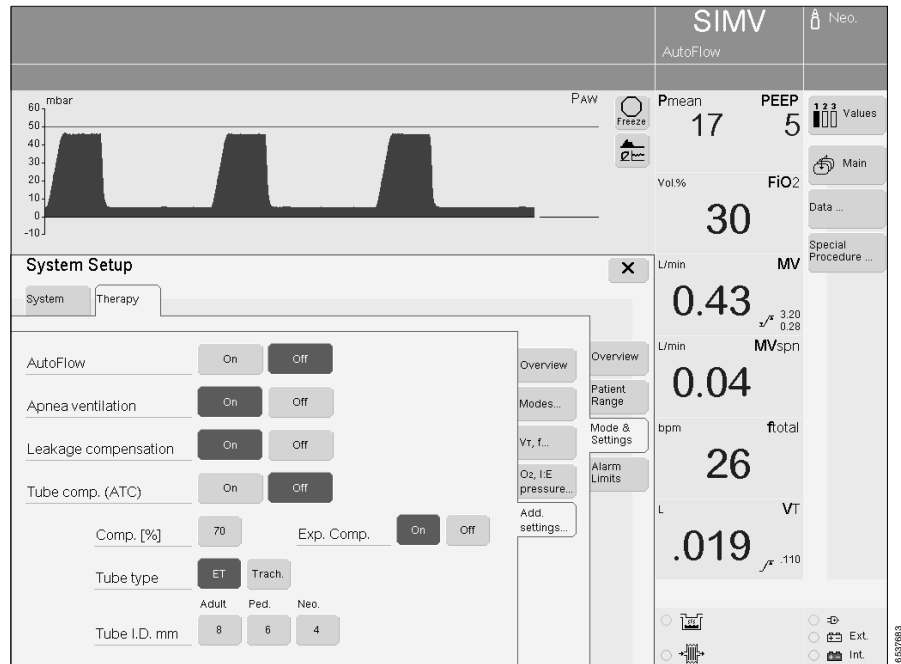
Table for selecting default values VT and f as a function of the patient mode:

Patient mode	Factory-set default		Hospital-set default	
	Tidal volume VT mL	Ventilator rate f bpm	Tidal volume VT mL	Ventilator rate f bpm
Neo.	9	31	.....	.....
Ped.	50	29	.....	.....
Adult	500	12	.....	.....

**NOTE:** Factory default settings may be adjusted to hospital-specific settings for start-up values.

## Defining Start-up Defaults for Tube Compensation (ATC)\*

- Press » **System Setup**« function key.
- Touch »**Therapy**« screen key.
- Touch »**Mode & Settings**« screen key and enter access code 3032.
- Touch »**Add. settings...**« screen key.
- Touch the respective screen key to switch ATC on or off.
- Press dial knob to confirm.
- Touch the respective screen keys to set individual tube compensation parameters.
- Set and confirm values with the dial knob.



The following start-up defaults may be selected

Tube compensation:	»On«/»Off«	
Degree of tube compensation:	»Comp.«	0 to 100 %
Expiratory tube compensation (Exp. Comp.):	»On«/»Off«	(immediately effective)
Tube type:	»ET«	(endotracheal tube) or
	»Trach.«	(tracheostomy tube)
Inside diameter of the tube:	»Tube I.D.«	2.5 to 5 mm for neonates

EvitaXL is delivered with the following start-up defaults

Tube compensation:	»Off«	
Degree of tube compensation:	»Comp.«	80 %
Expiratory tube compensation (Exp. Comp.):	»On«	(immediately effective)
Type of tube:	»ET«	(endotracheal tube)
Inside diameter of the tube:	»Tube I.D.«	3.0 mm for neonates

\* Available Option

## Care

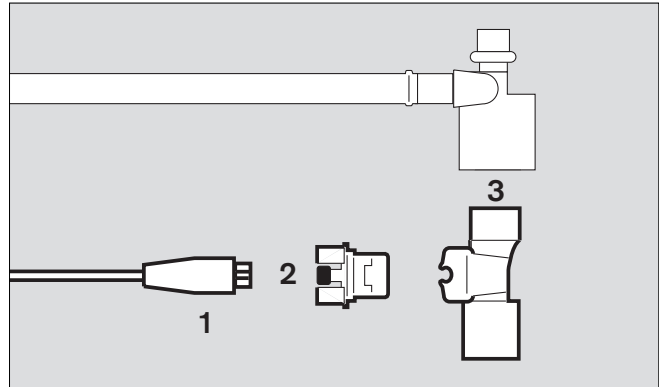
*Dismantling the Neonatal Flow Sensor*

*Disinfecting/Cleaning/Sterilizing*

## Care

### Dismantling the Neonatal Flow Sensor

- 1 Unplug flow sensor cable from both the sensor and the back panel of EvitaXL.
  - 2 Remove the sensor element:  
Press the buttons on both sides while pulling the sensor out of the housing at the same time.
  - 3 Detach sensor housing from Y-piece.
- Dismantle and process the other components as described in the EvitaXL Operating Instructions.



### Disinfecting/Cleaning/Sterilizing

#### **WARNING !**

**Always follow accepted hospital procedures for handling equipment contaminated with body fluids.**

#### **CAUTION !**

Certain components of the ventilator consist of materials that are sensitive to certain organic solvents sometimes used for cleaning and disinfecting (e.g., alkylamines, phenols, halogen releasing compounds, oxygen releasing compounds, strong organic acids, etc.). Exposure to such substances may cause damage that is not always immediately recognized. Sterilization with ethylene oxide (EtO) is also not recommended.

To prevent any damage, we recommend that only detergents and disinfectants that are compatible with the device are used for disinfection, e.g. surface disinfectants based on aldehydes or quarternary ammonium compounds.

Ensure that all disinfectants are registered with the U.S. Environmental Protection Agency for use as intended. Always follow the instruction labels specifically with respect to prescribed concentrations and the necessary exposure times.

Disinfectants often contain – in addition to their main active agents – additives that can also damage materials. When in doubt, ask the supplier/manufacturer of the disinfectant/cleaning agent.

For a list of materials used in the ventilator, please refer to EvitaXL Operating Instructions.



**Flow sensor cable**

- Disinfect by wiping with disinfectant based on the recommended active ingredients. Follow instruction labels with respect to prescribed concentrations and the necessary exposure times.

**CAUTION !**

Do not allow any liquid into the connector of the flow sensor cable.

**Neonatal flow sensor element****CAUTION !**

Flow sensor is not compatible with parts washer equipment and may not be autoclaved or steam-sterilized. It cannot withstand high temperatures and would be destroyed.

Do not use compressed air, brushes or similar tools to clean flow sensor element as this would possibly damage the thin wires in the flow sensor.

Any residue of dried mucus shortens the service life of the flow sensor. Therefore:

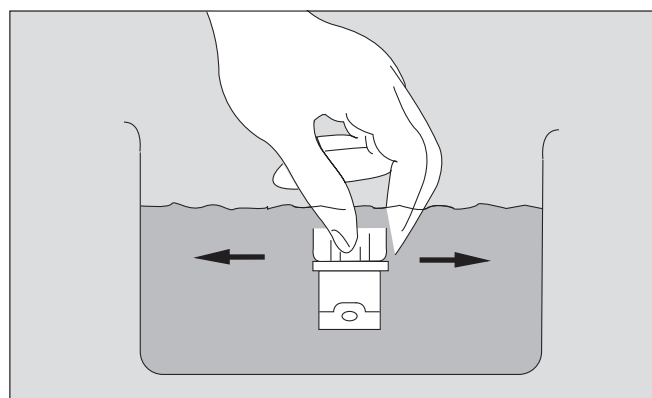
- Proceed with bath disinfection immediately after use. Use a disinfectant based on the recommended active ingredients. Follow instruction labels with respect to prescribed concentrations and the necessary exposure times.
- Then clean the sensor by gently stirring in a bath of distilled water. Thoroughly shake off any residual water.

Then:

- Steam autoclave at 134 °C (273 °F).

**WARNING !**

Vent flow sensor after disinfection with ethanol for at least 30 minutes or rinse with sterile water. Otherwise, residual ethanol vapors might ignite and destroy the sensor during calibration.

**Flow sensor housing**

- Disinfect by high temperature wet autoclaving (93 °C/200 °F, 10 minutes) using **detergent** only.
- Steam autoclave at 134 °C (273 °F).

## Maintenance

### CAUTION !

#### Maintenance

This device must be inspected and serviced at regular intervals. A record must be kept on this preventive maintenance. We recommend obtaining a service contract with DraegerService through your vendor.  
For repairs we recommend that you contact DraegerService.

### WARNING !

To avoid any risk of infection, clean and disinfect ventilator and accessories before any maintenance according to established hospital procedures - this applies also when returning ventilators or parts for repair.

### WARNING !

Preventive Maintenance work on the EvitaXL ventilators and their components may be performed by factory trained and authorized personnel only.

### WARNING !

Never operate the ventilator if it has suffered physical damage or does not seem to operate properly.  
We recommend that you contact DraegerService for maintenance service for the EvitaXL ventilator.

### WARNING !

When servicing the ventilator, always use replacement parts that are qualified to Draeger standards.  
Draeger cannot warrant or endorse the safe performance of third party replacement parts for use with EvitaXL ventilators.

## Maintenance Intervals

Preventive maintenance Every 6 months by trained and factory authorized service personnel.

The EvitaXL NeoFlow option is serviced as part of the scheduled preventive maintenance of the EvitaXL ventilator every six months.

# Troubleshooting

Alarm messages in the alarm display field are displayed in order of priority.

For example, if two faults are detected at the same time, the more urgent of the two is displayed first.

The priority of the alarm messages is indicated by exclamation marks:

Warning = top-priority message                   !!!

Caution = medium-priority message           !!

Advisory = low-priority message               !

In the table below, the additional messages specific to NeoFlow are listed in alphabetical order. The table can be used as reference for rapidly identifying and remedying the cause of any alarm.

**NOTE:** Alarm texts of the same wording as in adult/pediatric patient modes may have a different cause in neonatal mode. In these cases, a patient mode specific help text is provided.

Message		Cause	Remedy
<b>Apnea</b>	!!!	No spontaneous breathing by the patient.	Ventilate patient in a controlled mode.
		Neonatal flow sensor not calibrated or defective.	Calibrate neonatal flow sensor, see page 14. Replace if necessary, see page 15, recalibrate.
		Neonatal flow sensor connected but not in the Y-piece.	Insert neonatal flow sensor into the Y-piece.
		Tube obstructed.	Check tube.
<b>Back-up ventilation</b>	!!!	Only in neonatal patient range: In volume-controlled ventilation, a neonatal flow monitoring fault was detected or neonatal flow monitoring was switched off.	Calibrate neonatal flow sensor, see page 14. Replace if necessary, see page 15. Recalibrate or activate neonatal flow monitoring.
		Tube obstructed.	Check tube.
<b>Neo flow measurement inop.</b>	!!!	Only in neonatal patient range: Neonatal flow monitoring is defective or the sensor cable is not connected.	Calibrate neonatal flow sensor, see page 14. Replace if necessary, see page 15, recalibrate. Connect sensor cable.
			Call DraegerService.
<b>Neo flow measurement inop.</b>	!	Only in pediatric patient range: Neonatal flow monitoring is defective or the sensor cable is not connected.	Calibrate neonatal flow sensor, see page 14. Replace if necessary, see page 15, recalibrate. Connect sensor cable.
			Call DraegerService.
<b>Neo flow monitoring off</b>	!	Neonatal flow monitoring is deactivated.	Activate neonatal flow monitoring.
<b>Neo flow sensor ?</b>	!!!	Neonatal flow sensor not installed in the breathing circuit.	Install neonatal flow sensor in breathing circuit.
<b>Neo flow sensor ?</b>	!	Neonatal flow sensor not installed in the breathing circuit and flow monitoring via expiratory flow sensor switched on.	Install neonatal flow sensor in breathing circuit.
<b>Psupp. &gt; Tinsp</b>	!	Only in neonatal patient range: Pressure support phase was terminated by a time limit. <b>This message is not generated during Ventilation with Pressure support in PCV+, SIMV or MMV.</b>	

Technical Data

For neonatal mode, supplements Technical Data section in the EvitaXL Operating Instructions.

Neonatal Settings

Tidal volume VT		
Range	3 to 100 mL, BTPS*	
Resolution	1 mL	
Accuracy	greater of ±8 % of set value or 1 mL	
Trigger sensitivity		
Range	0.3 to 5 L/min	5 to 15 L/min
Resolution	0.1 L/min	0.5 L/min
Weight of patient		
Range	0.5 to 6 kg	
Resolution	0.1 kg	
Ventilation frequency f		
Range	0 to 10 bpm	10 to 150 bpm
Resolution	0.5 bpm	1 bpm
Inspiratory time T <sub>insp</sub> (CPAP, CPAP/ P <sub>supp.</sub> )		
Range	0.1 to 1 s	1 to 10 s
Resolution	0.05 s	0.1 s
Set values for ATC (with Option ATC):		
Inside diameter of the tube (Tube I.D.)		
Range	2.5 to 5 mm	
Resolution	0.5 mm	
Degree of compensation (Comp.)		
Range	0 to 100 %	
Resolution	1 %	

\* BTPS  
Body Temperature, Pressure, Saturated.  
Measured values referenced to patient lung conditions:  
Body temperature 37 °C, gas saturated with water vapor, ambient pressure.

## Performance Data

Control principle	Base flow with demand system, pressure-controlled, time-controlled	
Base flow	6 L/min (this can be changed by DraegerService to 9 L/min)	
Base flow during medicament nebulisation	9 L/min	
Insp. Flow	up to 30 L/min	
Exp. flow (measuring range)	up to 30 L/min	
Device compliance		
– (with Fisher & Paykel MR 730 humidifier and reusable silicone pediatric patient circuit)	<1 mL/cmH <sub>2</sub> O	
Inspiratory resistance		
– during operation with Fisher & Paykel humidifier	0 cmH <sub>2</sub> O (basic flow) at 5 L/min	
– following a ventilator failure while using a Fisher & Paykel humidifier	<1.5 cmH <sub>2</sub> O at 5 L/min	
Expiratory resistance		
– during operation	<3 cmH <sub>2</sub> O at 5 L/min	
– following device failure	<1.1 cmH <sub>2</sub> O at 5 L/min	
Deadspace volume		
Neonatal flow sensor ISO 15, including Y-piece	<2 mL	

## Display of Measured Values

Flow measurement (with neonatal flow sensor 84 11 130)		
Range	0.25 to 30 L/min	
Minute volume MV (without leak compensation)		
Range	0 to 9.9 L/min, BTPS	10 to 99 L/min, BTPS
Resolution	0.01 L/min	0.1 L/min
Accuracy	greater of ±8 % of the measured value or 1 mL x f	
To...90	approx. 35 s	
Spontaneous breathed minute volume MV <sub>spn</sub> (not leak compensated)		
Range	0 to 9.9 L/min, BTPS	10 to 99 L/min, BTPS
Resolution	0.01 L/min	0.1 L/min
Accuracy	greater of ±8 % of the measured value or 1 mL x f <sub>spn</sub>	
To...90	approx. 35 s	
Leakage minute volume MV <sub>Leak</sub>		
Range	0 to 9.9 L/min, BTPS	10 to 99 L/min, BTPS
Resolution	0.01 L/min	0.1 L/min
To...90	approx. 35 s	

## Technical Data

### Monitoring

#### Materials Used

#### Tidal volume $V_{Te}$

Range	0 to 999 mL, BTPS	1000 to 4000 mL, BTPS
Resolution	0.1 mL	10 mL
Accuracy	greater of $\pm 8$ % of the measured value or 1 mL	

#### Tidal volume $V_{Ti}$ , $V_T$

Range	0 to 999 mL, BTPS	1000 to 4000 mL, BTPS
Resolution	1 mL	10 mL
Accuracy	greater of $\pm 8$ % of the measured value or 1 mL	

#### Spontaneous breathing rate $f_{spn}$

Range	0 to 300 bpm
Resolution	1 bpm

## Monitoring

#### Expiratory minute volume MV

Alarm, upper alarm limit	when the upper alarm limit is exceeded.	
Range	0.1 to 0.99 L/min	1 to 41 L/min
Resolution	0.01 L/min	0.1 L/min
Alarm, lower alarm limit	when the value drops below the lower alarm limit.	
Range	0.01 to 0.99 L/min	1 to 40 L/min
Resolution	0.01 L/min	0.1 L/min

#### Volume monitoring

Alarm, upper alarm limit	Inspiration is interrupted and the expiratory valve opens when the applied tidal volume exceeds the upper alarm limit.
Range	4 to 4000 mL

#### Rapid shallow breathing

	When the measured spontaneous breath rate $f_{spn}$ exceeds the alarm limit
Range	5 to 120 bpm

## Materials Used

Part	Appearance	Material
Neonatal flow sensor	yellow, transparent	polysulphone
Neonatal flow sensor housing	yellow, transparent	polysulphone
Flow sensor cable	grey/grey	polyurethane

## Theory of Operation

### – Special Features of Neonatal Ventilation

#### Measuring Leakage Flow

A small amount of respiratory gas almost always escapes between the tracheal wall and endotracheal tubes when ventilating newborns 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 at the Y-piece upstream of the leak. During inspiration, it measures both the leakage flow and the amount of breathing gas reaching the patient's lung. During expiration, it only measures part of the gas applied during inspiration. However, assuming that another leakage flow escapes during expiration, the amount measured 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 lung and thus contributes towards ventilation. The measured value for leak displayed by EvitaXL is the mean leakage flow  $MV_{Leak}$ .

$MV_{Leak}$  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 value for leak, in combination with the expiratory minute volume  $MV$ , can therefore be used to estimate the minute volume  $MV_{Patient}$  that contributed to ventilation:

$$MV \leq MV_{Patient} \leq MV + MV_{Leak}$$

$MV_{Patient}$  : Minute volume of the patient

$MV$  : Expiratory minute volume without correction for leak

$MV_{Leak}$  : Mean leakage flow

EvitaXL 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:

$$Flow_{Leak} = MV_{Leak} * P_{AW} / P_{mean}$$

$Flow_{Leak}$  : Actual leakage flow

$MV_{Leak}$  : Leakage minute flow – mean leakage flow, averaged over inspiration and expiration

$P_{AW}$  : Airway pressure at the Y-piece

$P_{mean}$  : Mean airway pressure at the Y-piece

## Measuring Leakage Flow

Patient flow and tidal volume are then calculated as follows:

Inspiration:

$$\text{Flow}_{\text{Patient, insp}} = \text{Flow}_{\text{insp}} - \text{Flow}_{\text{Leak}}$$

$$V_{Ti} = \int \text{Flow}_{\text{Patient, insp}} dt$$

Expiration:

$$\text{Flow}_{\text{Patient, exp}} = \text{Flow}_{\text{exp}} + \text{Flow}_{\text{Leak}}$$

$$V_{Te} = \int \text{Flow}_{\text{Patient, exp}} dt$$

$\text{Flow}_{\text{Patient}}$  : Actual patient flow, corrected for leaks

$\text{Flow}_{\text{insp}}$  : Actual inspiratory flow, not corrected for leaks

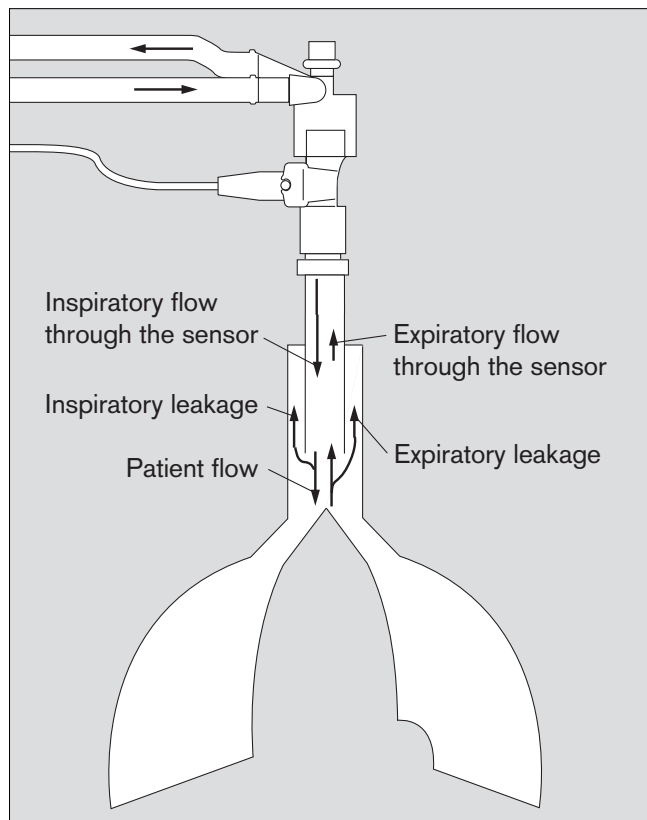
$\text{Flow}_{\text{exp}}$  : Actual expiratory flow, not corrected for leaks

$\text{Flow}_{\text{Leak}}$  : Actual leakage flow

$V_{Ti}$  : Inspiratory tidal volume

$V_{Te}$  : Expiratory tidal volume

$MV_{\text{Leak}}$  : Mean leakage flow, averaged over inspiration and expiration





## Airway Pressure Measurement

EvitaXL measures airway pressure indirectly by means of two internal pressure sensors in the apparatus. 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 ventilator. 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.

During neonatal ventilation, a continuous base flow is applied. Due to this base flow, the zero-flow condition is never met either on the inspiratory or expiratory side. The pressure measured by the inspiratory pressure sensor continues to vary with the variations in airway pressure but it is increased by the amount of the pressure drop in the inspiratory line of the patient circuit.

The pressure measured by the expiratory pressure sensor likewise is reduced by the amount of the pressure drop in the expiratory line of the patient circuit. These pressure differences are caused by the flow resistance of the patient circuit.

During expiration, the value measured at the inspiratory pressure sensor ( $P_{\text{insp}}$ ) is reduced by the pressure drop caused by the base flow ( $\text{Flow}_{\text{bf}}$ ) in the inspiratory limb of the patient circuit ( $R_{\text{insp}}$ ):

$$\text{PAW} = P_{\text{insp}} - R_{\text{insp}} * \text{Flow}_{\text{bf}}$$

PAW : Airway pressure at the Y-piece  
 $P_{\text{insp}}$  : Airway pressure at the inspiratory sensor  
 $R_{\text{insp}}$  : Flow resistance of the inspiratory limb of the patient circuit  
 $\text{Flow}_{\text{bf}}$  : Base flow

During inspiration, the value measured by the expiratory pressure sensor ( $P_{\text{exp}}$ ) is lower than the airway pressure by the amount of the pressure drop ( $R_{\text{exp}}$ ) caused by the flow (normally  $\text{Flow}_{\text{out}} \leq \text{Flow}_{\text{bf}}$ ) through the expiratory limb of the patient circuit:

$$\text{PAW} = P_{\text{exp}} + R_{\text{exp}} * \text{Flow}_{\text{out}}$$

PAW : Airway pressure at the Y-piece  
 $P_{\text{exp}}$  : Airway pressure at the expiratory limb  
 $R_{\text{exp}}$  : Flow resistance of the expiratory limb  
 $\text{Flow}_{\text{out}}$  : Flow through the expiratory valve during inspiration

EvitaXL determines patient circuit resistances during the ventilator check procedure.

## Trigger Response

In neonatal mode, EvitaXL detects a patient's spontaneous breathing using the neonatal flow sensor proximal to the patient. When spontaneous inspiration is detected, a synchronized, mechanical, and pressure controlled breath, or a pressure support breath is triggered according to the selected mode of ventilation.

In order to avoid incorrect triggering due to leak flows, EvitaXL not only takes into account the flow signal from the neonatal flow sensor ( $Flow_{insp}$ ) but also the calculated leak flow ( $MV_{Leak}$ ). For this purpose, the leak flow is referenced to the momentary pressure level (PAW):

$$Flow_{Patient, insp} = Flow_{insp} - MV_{Leak} * PAW / P_{mean}$$

$Flow_{Patient}$  : Patient flow

$Flow_{insp}$  : Inspiratory flow, without correction for leak

$MV_{Leak}$  : Leakage minute volume – mean leakage flow, averaged over inspiration and expiration

PAW : Airway pressure at the Y-piece

$P_{mean}$  : Average airway pressure at the Y-piece

Spontaneous inspiration is only detected if the corrected measured value of the neonatal flow sensor exceeds the set flow trigger threshold. The trigger threshold covers a range 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 neonatal ventilation.

The trigger threshold should be set so that self-triggering is just avoided.

If the neonatal flow sensor in neonatal mode is defective, EvitaXL can no longer detect attempts at spontaneous inspiration, and therefore cannot trigger a ventilator breath.

## AutoFlow®

AutoFlow is a ventilation mode extension that optimizes flow control during mandatory breaths in the volume constant ventilation modes CMV, SIMV, and MMV.

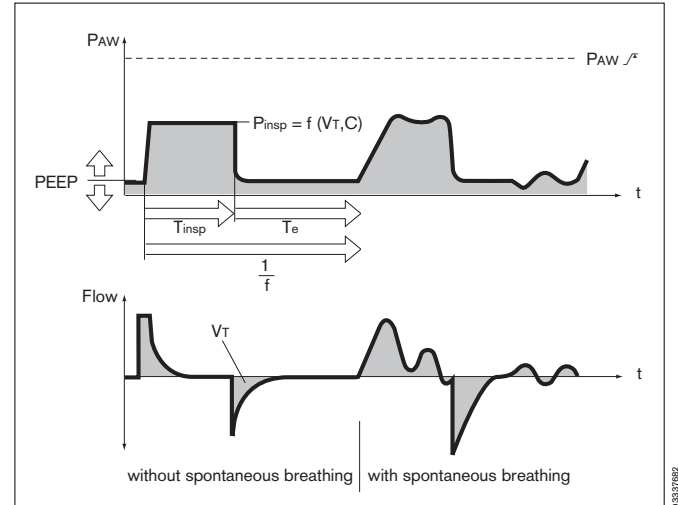
In neonatal mode, AutoFlow is always active in all volume controlled ventilation modes (CMV, SIMV, MMV).

Ventilation with AutoFlow is only possible if the neonatal flow sensor is intact.

With AutoFlow, the inspiratory flow is automatically adjusted to changes in lung conditions (C, R) and to the demands of the spontaneously breathing patient.

### WARNING!

The alarm limit »PAW  $\nearrow$ « must always be set so that a warning is triggered if airway pressure increases with reduced compliance or in the event of sudden changes in the size of the leak.



Typically, the selected inspiratory time  $T_{\text{insp}}$  is much longer than the time required to fill the lungs. Inspiratory pressure  $P_{\text{insp}}$  corresponds to the minimum value calculated from tidal volume  $V_T$  and lung compliance  $C$ .

The volume required to calculate inspiratory pressure is derived from the measured value  $V_{Te}$  of the neonatal flow sensor proximal to the patient. Contamination of the neonatal flow sensor can lead to incorrect measured volumes. Airway pressure will increase if measured volume is too low.

Inspiratory flow is automatically controlled in such a way as to prevent the occurrence of a pressure peak caused by ET-tube and airway resistance. As is common in constant-volume ventilator breaths, plateau pressure  $P_{\text{plat}}$  is allowed to fluctuate with changes in compliance  $C$ . With AutoFlow, these fluctuations occur in increments with a maximum of 3 cmH<sub>2</sub>O between ventilator breaths.

If the tidal volume  $V_T$  (inspiratory flow = 0) is reached before inspiratory time  $T_{\text{insp}}$  has elapsed, the inspiratory and expiratory valve are controlled in such a way that the patient can still breathe in and out during the remainder of inspiratory time, even while constant plateau pressure  $P_{\text{plat}}$  is applied.

If the patient breathes in or out during mandatory inspiration, the plateau pressure  $P_{\text{plat}}$  remains unchanged for the duration of this ventilator breath. Only inspiratory and expiratory flow are adapted to the patient's demand. The applied tidal volume  $V_T$  can deviate from the set tidal volume  $V_T$  in individual ventilator breaths, but as an average over time, a constant tidal volume  $V_T$  is supplied.

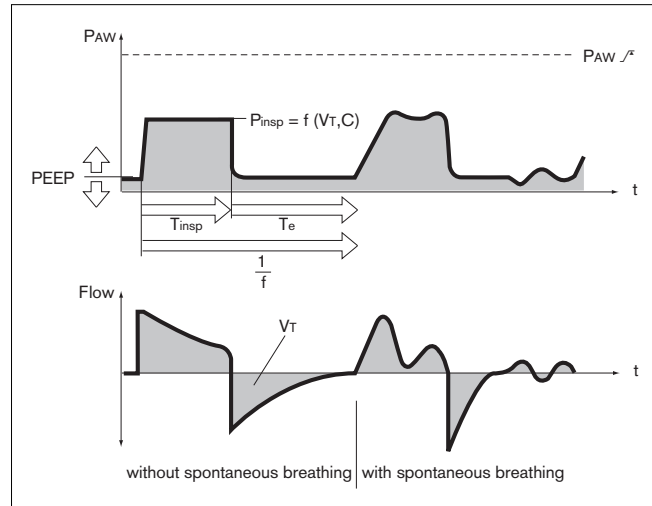
Tidal volume  $V_T$  can be limited by the alarm limit  $\gg V_{Ti} \sqrt{\text{f}} \ll$ . If the set alarm limit is exceeded once, EvitaXL will generate an advisory message (!). If the alarm limit is exceeded three times in succession, the EvitaXL will generate a warning (!!!). Tidal volume is actively limited to the value of the alarm limit  $\gg V_{Ti} \sqrt{\text{f}} \ll$  by switching to PEEP level (expiration) when necessary.

An inspiratory time  $T_{\text{insp}}$  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 dropped to zero. In such a case, it must be decided whether the patient's momentary situation will permit a longer inspiratory time  $T_{\text{insp}}$  in order to further reduce peak pressure.

The effect described can also develop in the course of ventilation, e.g. due to a buildup of secretions. In this situation, pressure is limited by the alarm limit  $\gg PAW \sqrt{\text{f}} \ll$ . The pressure rise is held to 5 cmH<sub>2</sub>O below the alarm limit  $\gg PAW \sqrt{\text{f}} \ll$ . The "Volume not constant" alarm will only become active when the set tidal volume  $V_T$  is no longer fully applied.

The beginning of a mandatory inspiration can be synchronized with a patient's attempted inspiration using the adjustable flow trigger. Only while in CMV mode can the flow trigger be completely switched off (CMVAssist → CMV).

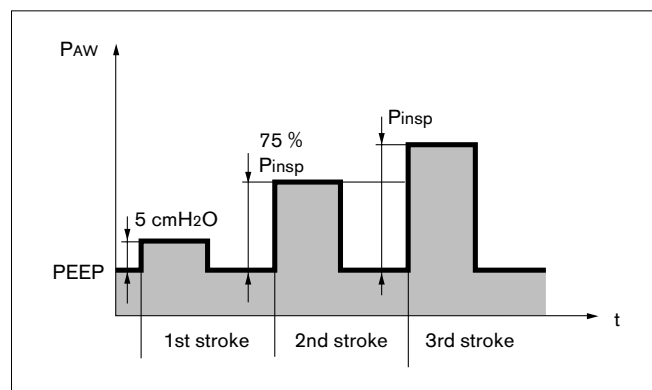
In SIMV and MMV, steepness of the pressure rise from PEEP level to the inspiratory level may be even more closely adapted to a patient's needs by adjusting pressure rise time via the ventilation parameter pressure peak rise time  $\gg \text{Slope} \ll$ .



## Initial response of AutoFlow in neonatal mode

When activating a volume-controlled ventilation mode, EvitaXL will initially apply a test breath with an inspiratory pressure 5 cmH<sub>2</sub>O greater than PEEP. This test breath is used by EvitaXL to calculate inspiratory pressure for the next inspiration.

With the inspiration of the second breath, however, EvitaXL will only set 75 % of the previously calculated inspiratory pressure in order to verify the first result and calculate a new inspiratory pressure. From the third breath on, EvitaXL sets the inspiratory pressure as calculated. All further adjustments of the inspiratory pressure are limited to  $\pm 3$  cmH<sub>2</sub>O.



## Glossary

### Abbreviations

Abbreviation	Explanation
f	Mechanical ventilation frequency (setting)
f <sub>spn</sub>	Spontaneous breathing rate (measured value)
Flow	Displayed real-time waveform, patient flow (measured value), with correction for leak
Flow <sub>out</sub>	Flow through the expiratory valve during inspiration
Flow <sub>bf</sub>	Base flow (system setting), see technical data page 36
Flow <sub>insp</sub>	Inspiratory flow, without correction for leak
Flow <sub>exp</sub>	Expiratory flow, without correction for leak
Flow <sub>Leak</sub>	Actual leakage flow
Flow <sub>Patient</sub>	Inspiratory/expiratory flow, with correction for leak (measured value)
MV	Expiratory measured minute volume, without correction for leak (measured value)
MV <sub>Leak</sub>	Leakage minute volume – mean leakage flow, averaged over inspiration and expiration (measured value)
MV <sub>Patient</sub>	Inspiratory/expiratory measured minute volume, with correction for leak
PAW	Airway pressure at the Y-piece (measured value)
P <sub>exp</sub>	Airway pressure in the expiratory limb of the patient circuit
P <sub>mean</sub>	Mean airway pressure at the Y-piece (measured value)
R <sub>exp</sub>	Flow resistance in the expiratory limb of the patient circuit
R <sub>insp</sub>	Flow resistance of the inspiratory limb of the patient circuit
T <sub>Apnea</sub>	Apnea alarm delay time (setting)
V <sub>T</sub>	Tidal volume (setting)
V <sub>Ti</sub>	Inspiratory tidal volume (measured value)
V <sub>Te</sub>	Expiratory tidal volume (measured value)

Ordering Information

Name/Description	Article No.
<b>NeoFlow kit</b>	84 13 563
consists of	
Extension PCB "Pediatric Flow"	
Neonatal flow sensor cable	
Reusable neonatal flow sensor housing ISO 15	
"Water trap" kit for expiratory valve (2x)	
Pediatric cuvette for CO2 measurement (2x)	
Corrugated patient circuit segment (reusable, silicone) 0.13 m (5") (2x)	
<b>Replacement Parts:</b>	
Replacement parts designed for use with the basic ventilator unit.	
Neonatal flow sensor cable	84 09 626
Neonatal flow sensor housing for ISO 15	84 11 130
"Water trap" kit for expiratory valve	84 13 125
Pediatric cuvette for CO2 measurement	68 70 280
Corrugated patient circuit segment (reusable, silicone) 0.13 m (5")	84 09 634

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These Instructions for Use apply only to  
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with Serial No.:

If no Serial No. has been filled in by  
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