

NeoFlow

**Neonatal mode
Supplement to Instructions
for Use of EvitaXL
Software version 6.0 and higher**

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For Your Safety and that of Your Patients

Strictly follow the Instructions for Use

Any use of the apparatus requires full understanding and strict observation of these instructions and of the Instructions for Use of EvitaXL.

The apparatus may only be used for the purposes specified here.

Liability for proper function or damage

The liability for the proper function of the apparatus is irrevocably transferred to the owner or operator to the extent that the apparatus is serviced or repaired by personnel not employed or authorised by DrägerService or if the apparatus is used in a manner not conforming to its intended use.

Dräger cannot be held responsible for damage caused by non-compliance with the recommendations given above. The warranty and liability provisions of the terms of sale and delivery of Dräger are likewise not modified by the recommendations given above.

Dräger Medical AG & Co. KGaA

Intended Use

NeoFlow – neonatal mode with basic flow.

Extends the range of uses of EvitaXL for long-term ventilation of premature babies.

Extends paediatric flow monitoring with EvitaXL during paediatric and neonatal ventilation by means of a flow sensor positioned close to the patient and specifically for neonates.

This instruction manual also covers operation of Evita 4 and Evita 2 dura with the EvitaXL option.

Before using for the first time

Installing the NeoFlow option

Exclusively by trained personnel with corresponding installation documents.

Configuring NeoFlow

Page 19 ff.

Preparing for use

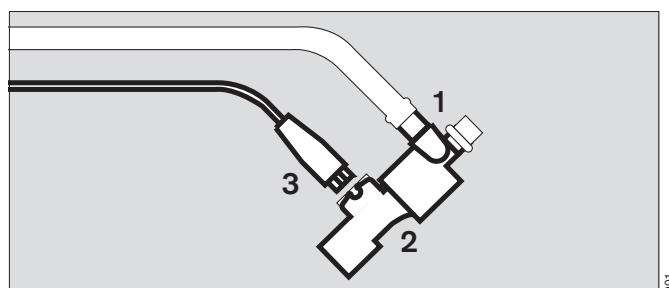
Installing the neonatal flow sensor

Prepare hose set – see chapter "Ventilating infants" in the Instructions for Use of the EvitaXL.

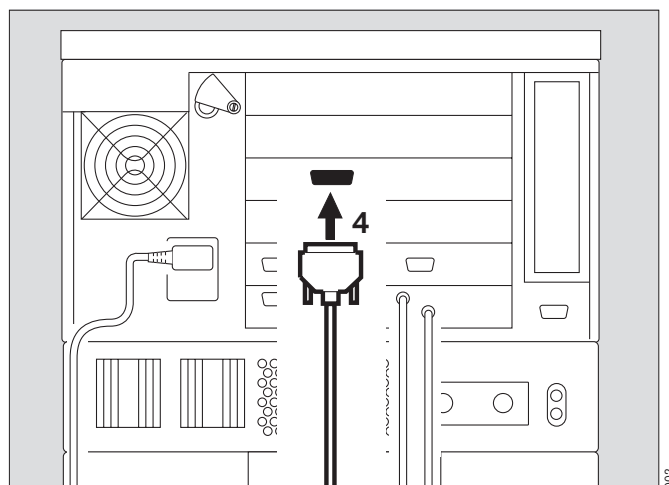
- Only the neonatal flow sensor (84 11 130) should be used.

- Do not use the Y-piece with integral flow sensor (84 10 185), as this flow sensor operates with a different characteristic curve and would give inaccurate flow measurements.

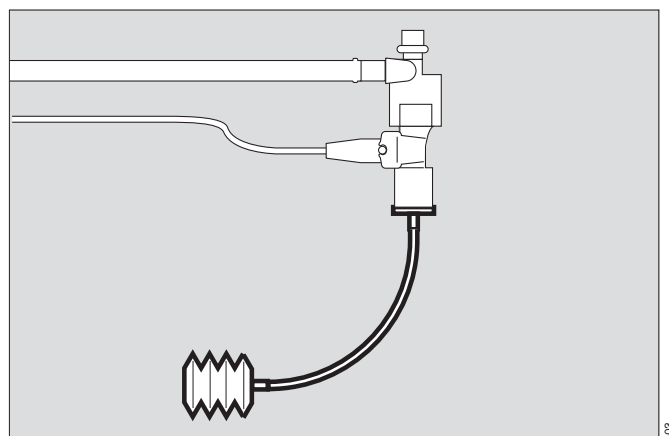
- 1 Plug the Y-piece into the ventilation hoses.
 - 2 Insert the neonatal flow sensor in the Y-piece.
 - 3 Plug the flow sensor lead into the socket.
- Route the lead along the ventilation hoses to the apparatus.



- 4 Plug the flow sensor connector into the socket at the back of the apparatus and tighten with the knurled screws.



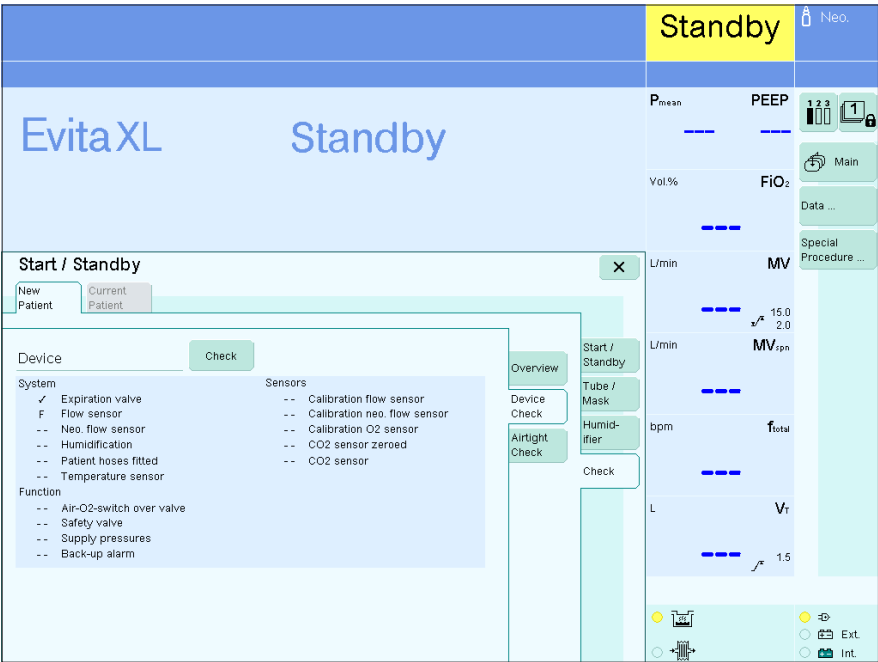
- Connect the test lung complete with tracheal tube CH 12 and connector to the patient side of the neonatal flow sensor.



Device check

The NeoFlow option expands the EvitaXL device check by the following function:

- Calibration neo. flow sensor



Calibrate the neonatal flow sensor


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

The last calibration value obtained is saved until the next calibration, even when the apparatus is switched off.

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

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

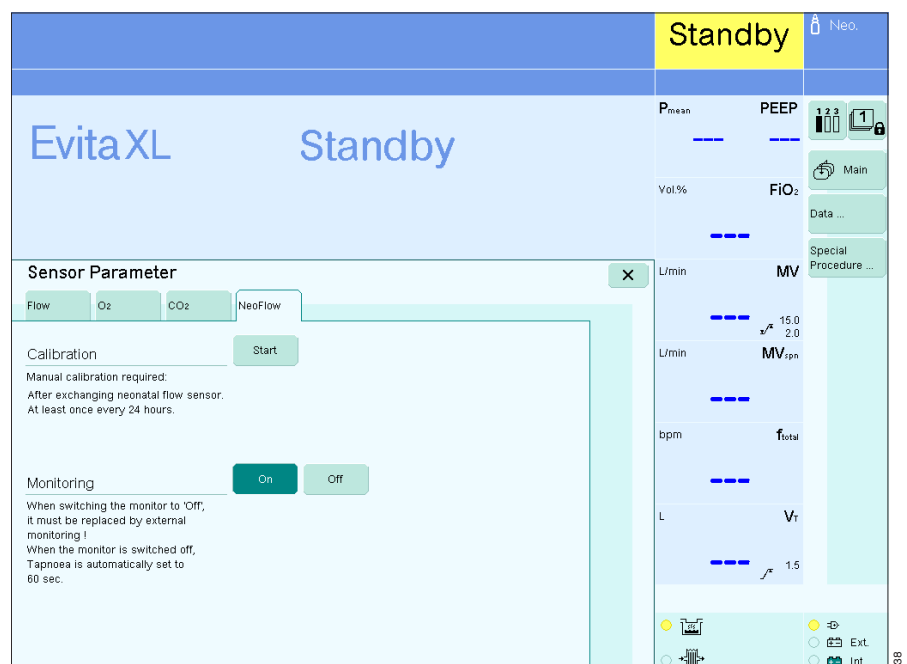
Start calibration for EvitaXL

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

Start calibration:

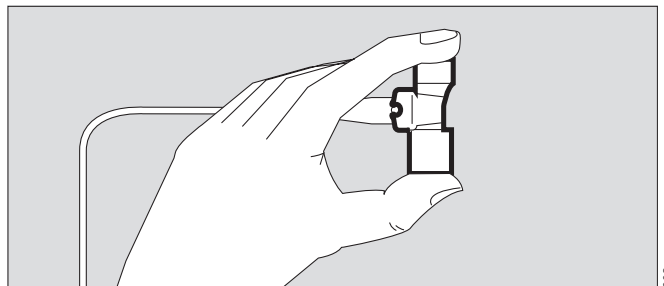
- Touch the softkey »**Start**«. The softkey turns green, the flow sensor is calibrated by the apparatus.

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



Calibrating

- Remove the tube connector,
- Remove the neonatal flow sensor from the Y-piece,
- Insert the tube connector in the Y-piece.
- Wearing a sterile glove, seal both ends of the flow sensor. This ensures flow = 0, which is required for calibration.



- Start calibration = press the rotary control. Calibration is completed after approx. 1 second.

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

- Remove the tube connector from the Y-piece. Replace the neonatal flow sensor in the Y-piece. Reconnect the tube connector.

If calibration is unsuccessful:

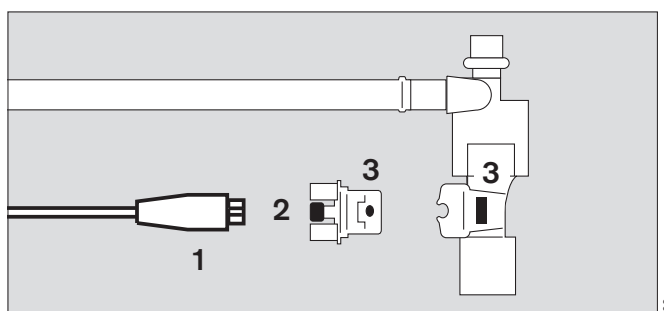
- Repeat the calibration. If necessary replace the neonatal flow sensor. Check the sensor lead.

Replacing the neonatal flow sensor

If the following error message is displayed:

Neo. flow measuring fault

- 1 Disconnect the flow sensor lead from the neonatal flow sensor.
 - 2 Press the buttons on both sides while pulling the flow sensor out of its housing. Insert new sensor until it engages. The two markings must line up.
 - 1 Reconnect the flow sensor lead.
- Calibrate the neonatal flow sensor, page 7.



Operation

Selecting neonatal mode

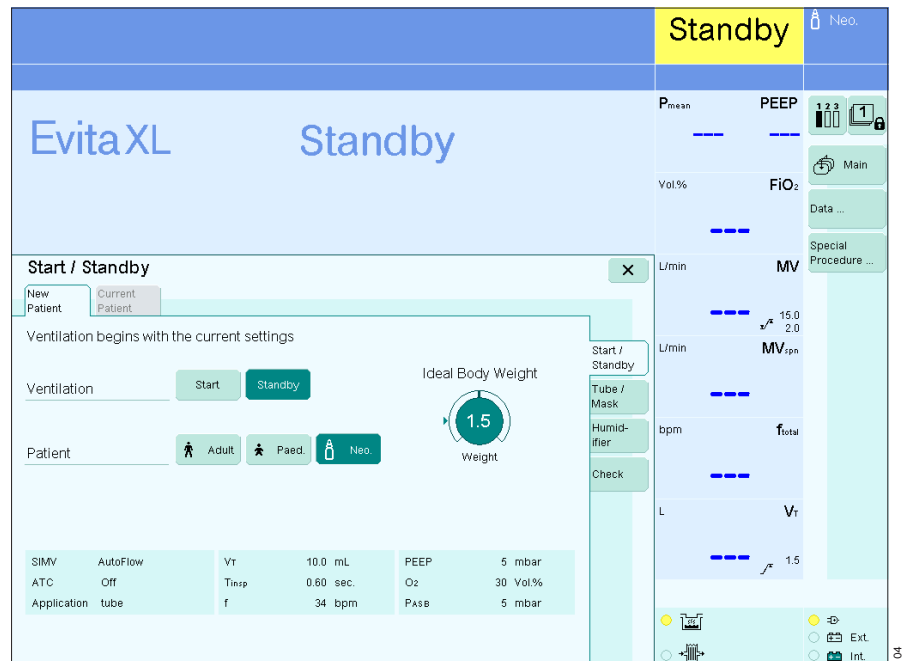
Immediately after switching on or in standby mode, the required patient mode can be selected from the EvitaXL menu:

- » **Adult** = Adults
- » **Paed.** = Paediatrics
- » **Neo.** = Neonates

The menu ranges can be configured, see "Configuring ventilation, Setting the patient mode", page 19.

- Touch the » **Neo.** softkey.

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 supplementary AutoFlow[®] function is always active with volume-controlled ventilation in neonatal mode (IPPV, SIMV, MMV).

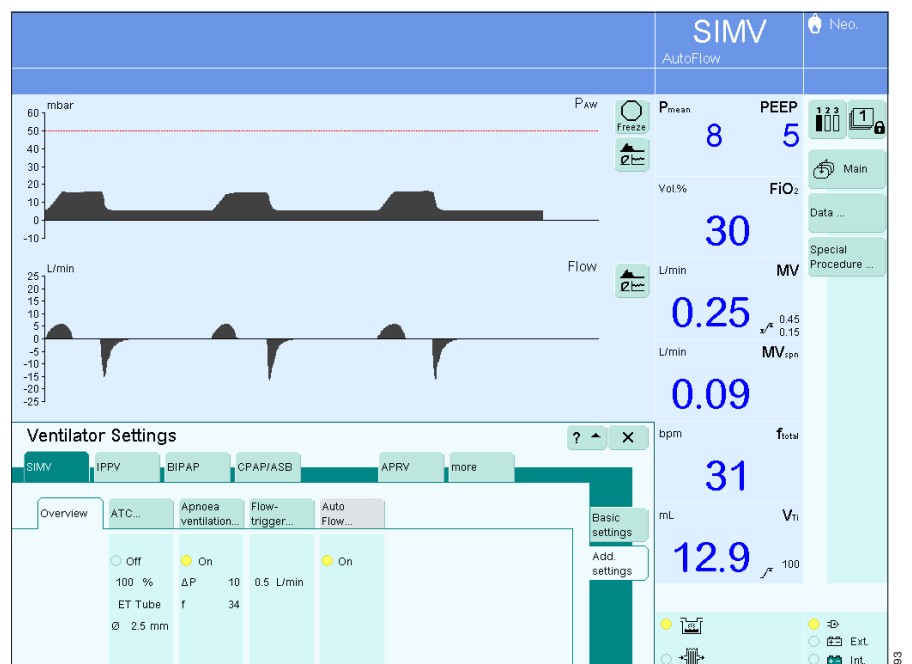
AutoFlow[®] – for automatic regulation of "Insp. Flow" and "Pinsp".

AutoFlow* is used by the EvitaXL to decelerate and regulate inspiratory flow by providing a constant pressure throughout the inspiration phase. The ventilator determines the lowest peak airway pressure for the selected VT and the 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 VTi \sqrt{f} .

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

The inspiratory pressure is limited by the alarm limit PAW \sqrt{f} .



* Refer to page 35 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 if flow monitoring is intact. If neonatal monitoring fails or has been switched off during volume-controlled ventilation, EvitaXL automatically switches over to pressure-controlled back-up ventilation.

During backup ventilation, apnoea monitoring is only partially effective. The apnoea time is 1 minute. It is recommended to monitor for apnoea independently. Should apnoea occur, apnoea ventilation might be started.

During back-up ventilation, the inspiratory pressure corresponds to the mean value of the last mandatory inspiration pressures applied while flow monitoring was still active during volume-controlled neonatal ventilation. The "T_{insp}", "f", "O₂" and "PEEP" ventilation parameters retain the same settings as before back-up ventilation.

Pressure Support/ASB

As in adult and paediatric modes, spontaneous breathing in neonatal mode can be assisted by ASB during BIPAP, SIMV and MMV ventilation. The ASB ventilation mode can be used for patients with adequate spontaneous breathing.

ASB assisted spontaneous breathing during neonatal ventilation is only possible if flow monitoring is active!

- Set the ventilation pattern for ASB assisted ventilation with the parameters:
 - Assist pressure »**ΔP_{ASB}**«
 - Pressure rise time »**Ramp**«
 - Maximum inspiration time »**T_{insp}**«

The pressure-assisted ASB ventilation stroke during neonatal ventilation is ended at the latest after the set maximum inspiration time T_{insp}.

Apnoea ventilation in neonatal mode

Unlike in adult or paediatric ventilation, if apnoea occurs in ventilation modes with activated apnoea ventilation, pressure-controlled apnoea ventilation is started after the set alarm time (T_{Apnoea}). This ventilation is adjusted by the following settings:

Frequency »f«

P_{insp} » ΔP_{Apnoea} «

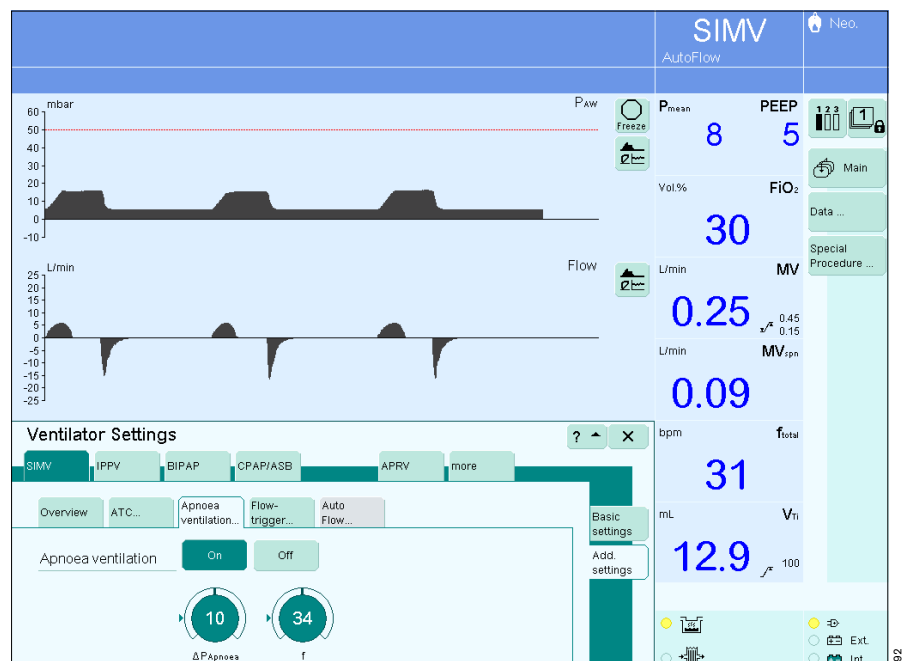
During apnoea ventilation the ratio of inspiration to expiration = 1:2. The "O₂" and "PEEP" ventilation parameters remain at the settings applied at the time apnoea ventilation is started.

Set the apnoea ventilation parameters:

- Touch the »Add. settings« softkey in the required ventilation mode. EvitaXL displays the possible extra settings.
- Touch the »Apnoea ventilation...« softkey. EvitaXL displays the menu for setting the apnoea ventilation parameters.
- Touch the screen knobs » ΔP_{Apnoea} « and »f«, set value = turn rotary control, confirm = press rotary control.

To switch on/off

- Touch the softkey »On« or »Off«, confirm = press rotary control.



NIV mask ventilation

See Instructions for Use of EvitaXL.

Set ventilation parameters

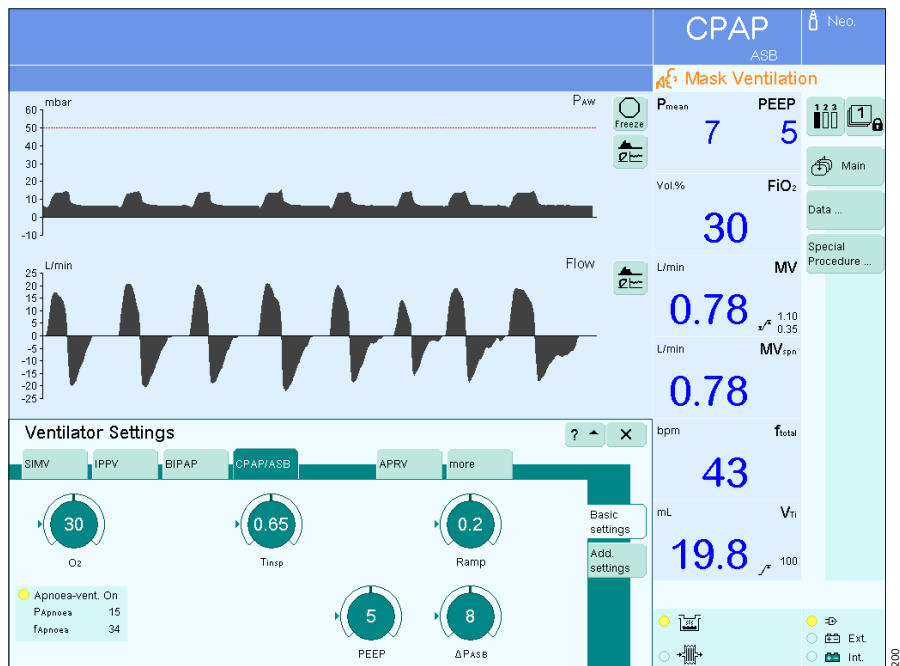
- As described for »Tube« mode.

An additional screen knob »Tinsp« is displayed for CPAP/ASB.

The apparatus limits the maximum duration of an ASB stroke to 1.5 seconds in patient mode »Paediatric« or »Neonate«.

- The maximum duration of an ASB stroke can be limited via the screen knob »Tinsp«.

»Tinsp« also limits the duration of the ASB stroke in the other ventilation modes which can be combined with ASB.



Leakage compensation in »Mask« mode

Depending on the selected patient mode, leakages up to the following values are compensated by EvitaXL in order to detect a patient trigger:

Paediatric mode: 15 L/min

Neonatal mode: 7 L/min

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

PPS

The maximum inspiration time is limited to 1.5 s (paediatric and neonatal mode). Inspiration is cancelled if the time is exceeded and the advisory message "PPS-Insp. > 1.5 s !" is displayed.

Flow monitoring during neonatal ventilation


The monitoring function of 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 major tube leakage.

When flow monitoring is deactivated, neither volume-controlled nor patient-triggered ventilation is possible.

Without Flow Sensor for neonates, the minute volume is not monitored!
Monitoring for apnoea is only partially effective. The apnoea time is 1 minute. It is recommended to monitor for apnoea independently.

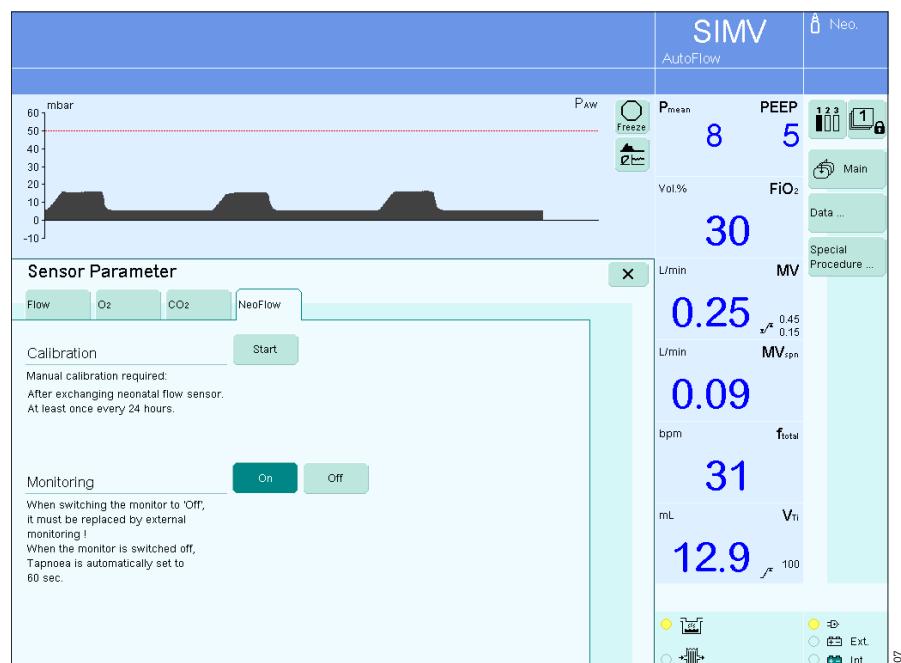
Deactivate neonatal flow monitoring

- Press the »  **Sensor Parameter**« key.
EvitaXL displays the menu »**Sensor Parameter**«.
- Touch the softkey for the sensor to be deactivated, for example »**NeoFlow**«.
- Touch the softkey »**Off**«, the softkey turns yellow.
- Confirm = press rotary control, the softkey turns green.

The values measured by the sensor concerned disappear.
The corresponding alarm function is deactivated.

After replacing the neonatal flow sensor:

- Reactivate neonatal flow monitoring and calibrate the neonatal flow sensor – see page 7.



Flow monitoring during paediatric ventilation

If the neonatal flow sensor is present and intact during paediatric ventilation it takes over the function of paediatric flow monitoring.

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 the EvitaXL. In this case, unlike in neonatal mode, volume-controlled ventilation remains possible.

For larger paediatric patients with serious infections and a severe cough:

- **Do not ventilate with the neonatal flow sensor. Instead, use the expiratory flow sensor for ventilation.** Otherwise, secretion coughed up by such patients can cause corrosion of the flow sensor.

Medicament nebulisation

In neonatal mode, medicament nebulisation is only possible with pressure-controlled ventilation.

Aerosols can clog filters and may therefore impair ventilation!

Only use the nebuliser 84 12 935 (with white middle section).

Notes for aerosol treatment

- Before medicament nebulising, remove the complete flow sensor from the Y-piece.

The wires of the flow sensor are hot. If the neonatal flow sensor is left in the ventilation system for some time during nebulising without being cleaned, deposits from the medicament sprays may build up and impair flow measurement.

In the worst case, these deposits could catch fire.

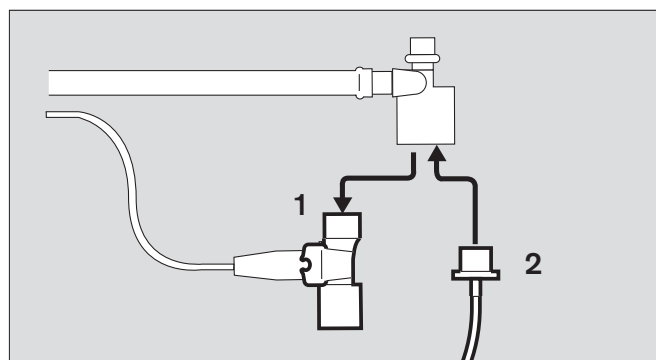
Disconnecting the flow sensor cable is not sufficient to prevent this. It is therefore important to remove the complete flow sensor before medicament nebulising.

- Calibrate the flow sensor at least once every 24 hours. See "Calibrate the neonatal flow sensor" on page 7.
- Replace/clean flow sensor if there is visible soiling (see page 24).

To remove neonatal flow sensor

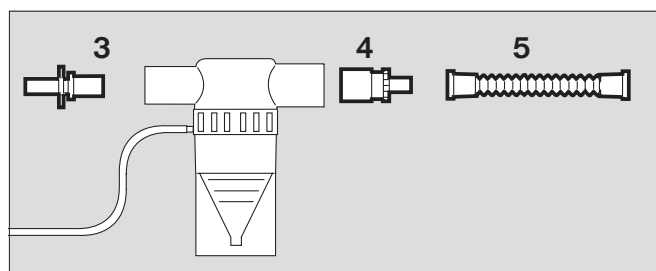
- 1 Remove complete flow sensor (housing and insert) from Y-piece.
- 2 Insert tube catheter cone into Y-piece.

The minute volume is not monitored without the neonatal flow sensor.

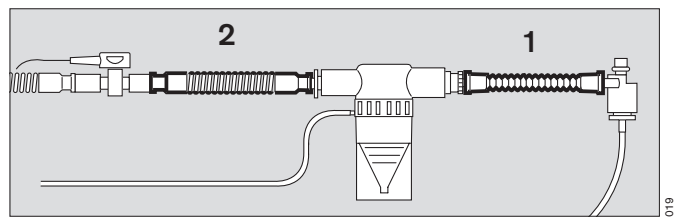


Preparation

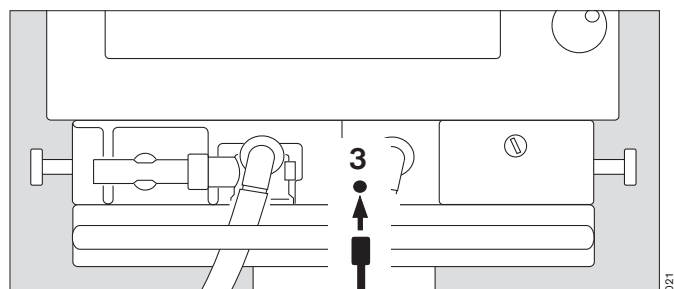
- Use only medicament nebulisers listed in the Order List.
 - Assemble the nebuliser as specified in its specific Instructions for Use.
- 3 Insert the catheter connector (ISO cone Ø15 / Ø11) in the input.
 - 4 Insert the adapter (ISO cone Ø22 / Ø11) in the outlet.
 - 5 Connect the corrugated hose (0.13 m long) to the outlet adapter.



- 1 Remove the corrugated hose of the hose set from the inspiration adapter of the Y-piece and connect it to the input adapter of the medicament nebuliser.
- 2 Connect the free end of the corrugated hose to the nebuliser with the Y-piece inspiration adapter.

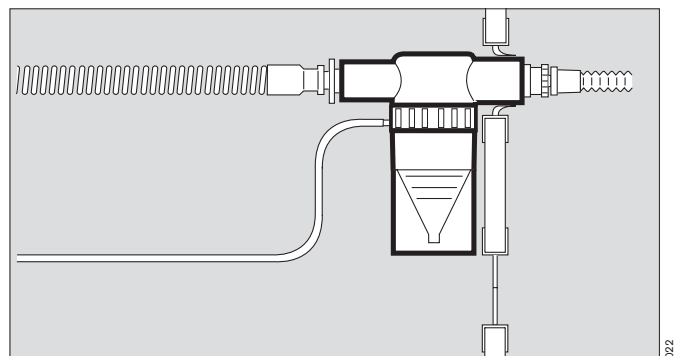


- 3 Fit the nebuliser hose to the port on the front of the EvitaXL.



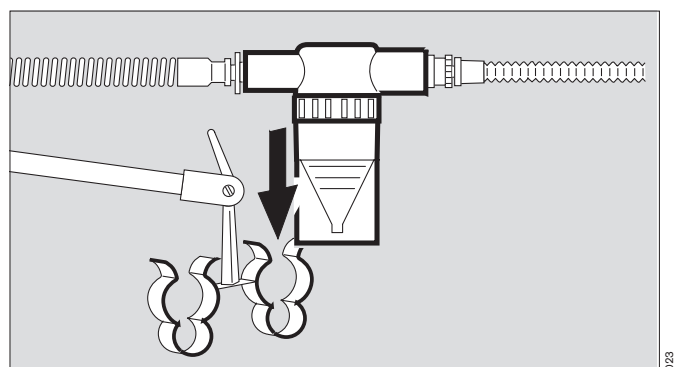
When using on the incubator

- Push the outlet adapter of the medicament nebuliser into the upper hose guide of the incubator.




When using without incubator

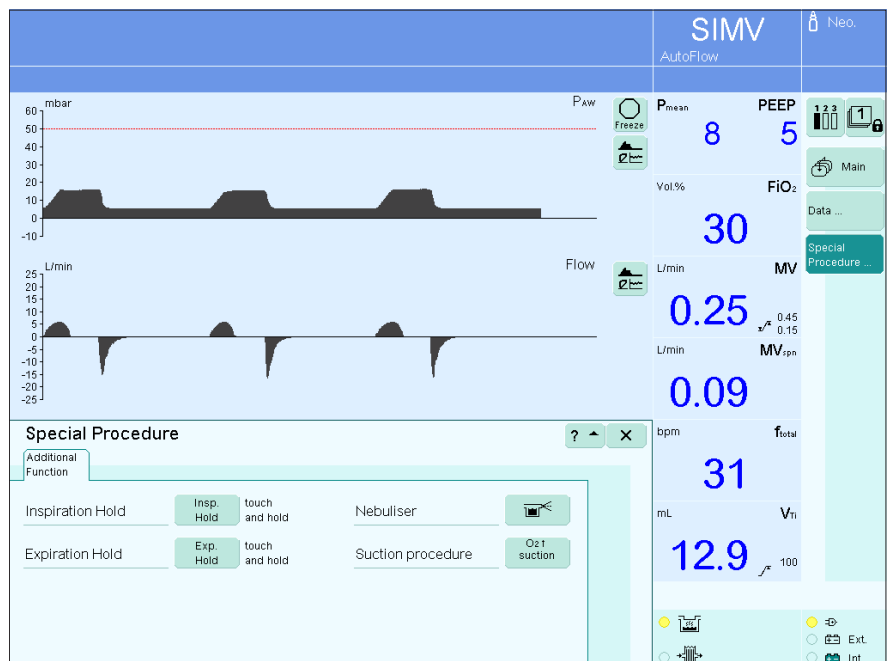
- Press the medicament nebuliser sleeve into one side of the clip and the expiration hose into the other.



- Position the nebuliser upright and fill it.

Start nebulisation

- Deactivate neonatal flow monitoring, page 13.
- Touch the screen function key »**Special Procedure...**«, EvitaXL opens the menu »**Additional Function**«.
- Touch the » **Nebuliser**« softkey, the key turns yellow.
- Confirm = press rotary control, the softkey turns green, the nebuliser is in operation.
The advisory message **Nebuliser on !** is displayed.



Ending nebulisation

- Touch the » **Nebuliser**« softkey.

Nebulisation is stopped automatically after 30 minutes.

- Remove any residual medicament from the nebuliser. Follow the Instructions for Use of the nebuliser.
- Replace the neonatal flow sensor in the Y-piece.
- Activate neonatal flow monitoring – see page 13.

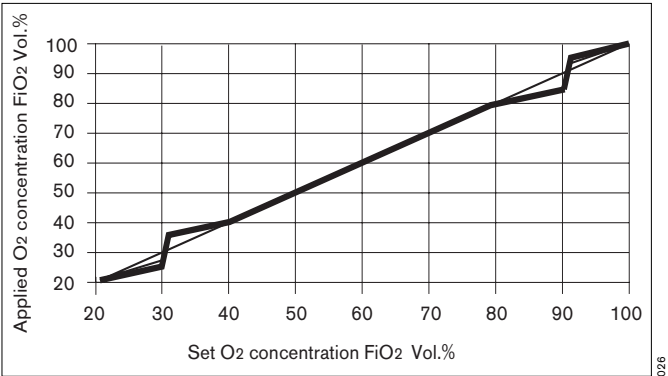
O2 concentration during nebulisation

Depending on the set O2 concentration, the medicament nebuliser is supplied with medical compressed air, O2 or a mixture of medical air and O2 in order to keep deviations in O2 concentration as low as possible.

For respiration rates greater than 12 bpm, the graph opposite applies. The maximum possible deviations are ±4 Vol.%.

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

At respiration rates below 12 bpm, the nebuliser should no longer be used.



Oxygenation for bronchial suction

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

During initial and final oxygen enrichment, however, the FiO2 concentration is increased by 25 % relative to the set FiO2 concentration.

See table:

Set FiO2 Vol.%	FiO2 for initial and final oxygen enrichment Vol.%
21	26
30	37
60	75
80	100

The current FiO2 concentration is displayed at the bottom of the screen during the oxygenation phases.

Configuration of ventilation

Setting the patient mode

Select the required patient mode from the list on the configuration page, see Instructions for Use of EvitaXL.

The following ranges are available:

Adults only


Paediatrics only

Neonates only

Adults or Paediatrics

Paediatrics or Neonates


Adults, Paediatrics or Neonates

- Press »  **System Setup**«.
- Touch the softkey »Therapy«.
- Touch the softkey »Patient Range« and enter the code 3032.
- Touch the softkey »▼« to open the selection list.
- Select the required patient mode = turn rotary control, confirm = press rotary control.



Initial values for ventilation parameters and alarm limits

The initial values for tidal volume V_T and ventilation frequency f , i.e. the values activated whenever the EvitaXL is switched on, can be defined as a function of the ideal body weight or of the patient mode.

- Press »  **System Setup**«.
- Touch the softkey »Therapy«.
- Touch the softkey »Mode & Settings« and enter the code 3032.
- Touch the softkey » V_T , f...«.

V_T , f depending on the weight:

- Touch the softkey »By Weight«.

The screen displays V_T , f and flow trigger values for various body weights.

On the line »Start-up by weight«:

- Touch the softkey »On«, confirm with rotary control.

Adjust values:

- Touch the softkeys corresponding to V_T , f and flow trigger.
- Set and confirm values with the rotary control.



V_T , f depending on the patient mode:

- Touch the softkey »By Patient«.

The screen displays V_T , f and flow trigger values for adults, children and neonates.

On the line »Start-up by patient«:

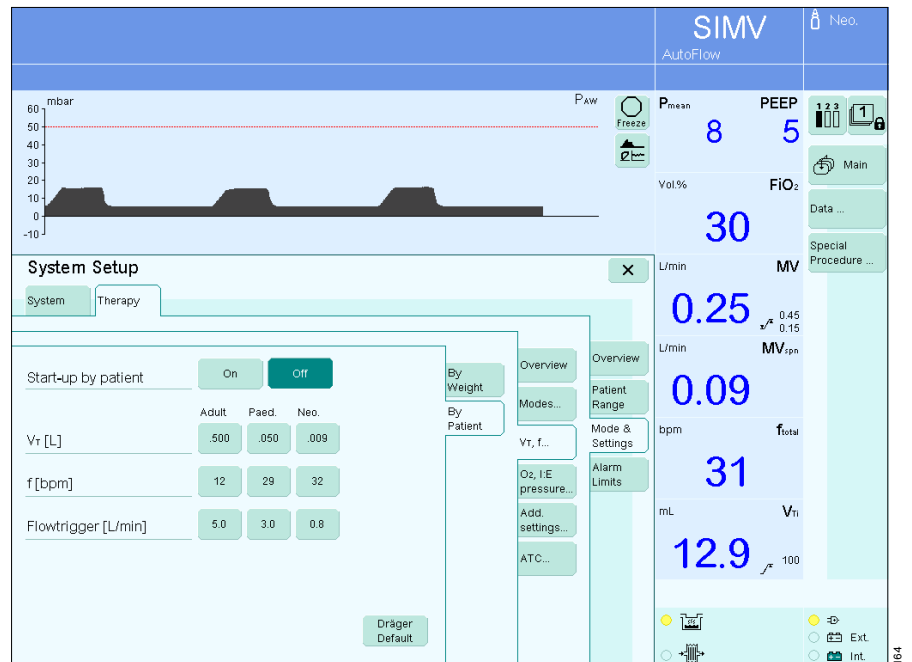
- Touch the softkey »On«, confirm with rotary control.

Adjust values:

- Touch the softkeys corresponding to V_T , f and flow trigger.
- Set and confirm values with the rotary control.

To restore the factory settings:

- Touch the corresponding softkey »Dräger Default«,
- confirm = press the rotary control.



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			Specific hospital setting		
	Tidalvolume VT mL	Ventilation frequency f 1/min	Flow Trigger L/min	Tidalvolume VT mL	Ventilation frequency f 1/min	Flow Trigger L/min
0.5	3	35	0.5
15	110	26	1
65	450	13	2
100	700	10	2

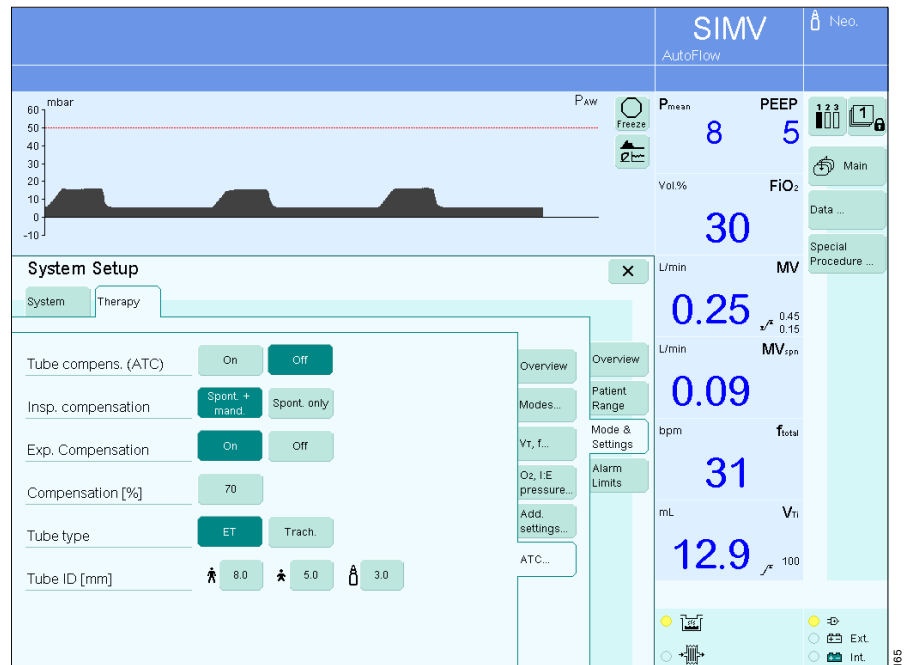
Table for selecting the initial values of VT, f and flow trigger as a function of patient mode:

Patient mode	Factory-set default			Specific hospital setting		
	Tidalvolume VT mL	Ventilation frequency f 1/min	Flow Trigger L/min	Tidalvolume VT mL	Ventilation frequency f 1/min	Flow Trigger L/min
Neo.	9	31	0.5
Paed.	50	29	1
Adults	500	12	2

The factory-set default settings can also be adopted as the hospital-specific initial settings.

Define initial values for tube compensation (ATC)

- Press »  **System Setup**«.
- Touch the softkey »**Therapy**«.
- Touch the softkey »**Mode & Settings**« and enter the code 3032.
- Touch the softkey »**ATC...**«.
- Touch the corresponding softkey to switch on or off.
- Confirm = press the rotary control.
- Touch the corresponding softkey to set the parameters for tube compensation.
- Set and confirm values with the rotary control.



The following initial values can be selected

Tube compensation (ATC):	»On« or »Off«	
Inspiratory tube compensation:	»Spont.+mand.«	(immediately effective) or
	»Spont. only«	(immediately effective)
Expiratory tube compensation:	»On« or »Off«	(immediately effective)
Degree of tube compensation:	»Compensation«	0 to 100 %
Type of tube:	»ET«	(endotracheal tube) or
	»Trach.«	(tracheostomy tube)
Inside diameter of the tube:	»Tube ID«	2.5 to 5 mm for neonates

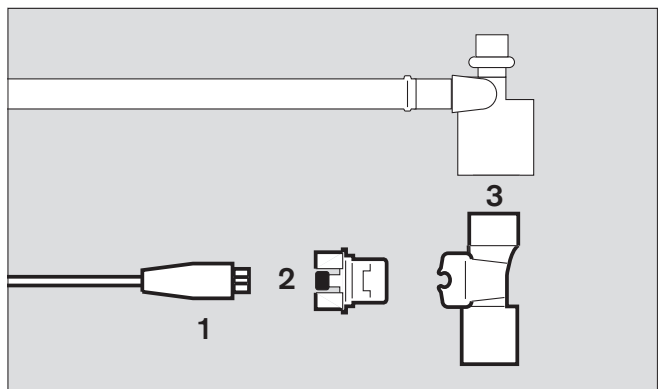
The apparatus is delivered with the following initial values

Tube compensation (ATC):	»Off«	
Inspiratory tube compensation:	»Spont. only«	(immediately effective)
Expiratory tube compensation:	»On«	(immediately effective)
Degree of tube compensation:	»Compensation«	80 %
Type of tube:	»ET«	(endotracheal tube)
Inside diameter of the tube:	»Tube ID«	3.0 mm for neonates

Care

Dismantling the neonatal flow sensor

- 1 Unplug the flow sensor lead from both the sensor and the back panel of EvitaXL.
 - 2 Remove the sensor insert:
Press the buttons on both sides while at the same time pulling the sensor out of the housing.
 - 3 Pull the housing out of the Y-piece.
- Dismantle and service the other components as described in the Instructions for Use of EvitaXL.



Disinfecting/cleaning/sterilising

Use bottled disinfectants to disinfect the apparatus.

For reasons of material compatibility, preparations based on the following active substances are suitable:

- Aldehydes
- Alcohols
- Quaternary ammonium compounds.

The following compounds are not suitable:

- Compounds containing phenol
- Strong organic compounds
- Compounds that release oxygen.

- Ethylene oxide sterilisation

For users in the Federal Republic of Germany, we recommend the use of disinfectants registered in the current list of the DGHM (DGHM: German Association for Hygiene and Microbiology). The DGHM List (published by mhp-Verlag GmbH, Wiesbaden) also specifies the active basis of each disinfectant. For countries in which the DGHM list is not known, we recommend disinfectants based on the active substances listed above.

Flow sensor lead

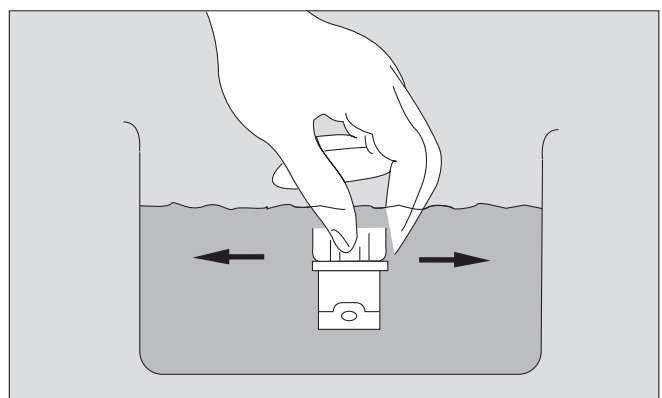
- Disinfect by wiping
Do not allow any liquid into the connector.
Note the disinfectant manufacturer's instructions.

Use of the neonatal flow sensor

⚠ Do not autoclave.
Do not clean with compressed air, water jet, brushes etc., as these processes may destroy the thin wires of the flow sensor.

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

- Immediately after use, immerse the sensor in a disinfectant bath, e. g. with Gigasept (Schülke & Mayr – Norderstedt, Germany). Note the disinfectant manufacturer's instructions.
- Then clean the sensor by stirring gently to and fro in a container of distilled water. Thoroughly shake off any residual water.
Then:
- Sterilise in hot steam at 134 °C.



Flow sensor housing

- Disinfect by high temperature wet autoclaving (93 °C/10 minutes) using **detergent only**.
- Sterilise in hot steam at 134 °C.

Fault – Cause – Remedy

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 critical fault is indicated 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, 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.

Alarm texts of the same wording as in adults/paediatrics mode can have a different cause in neonatal mode. In these cases, a specific help text is provided.

Message		Cause	Remedy
Airway obstructed ?	!!!	Neonatal flow sensor not installed in the breathing system.	Install neonatal flow sensor in the breathing system.
Apnoea	!!!	Patient's spontaneous breathing has stopped.	Check condition of patient, if necessary apply controlled ventilation.
		Neonatal flow sensor not calibrated or defective.	Calibrate the neonatal flow sensor, see page 7, replace if necessary, see page 8, recalibrate.
		Neonatal flow sensor connected but not placed in the Y-piece.	Connect neonatal flow-sensor in the Y-piece.
		Tube blocked.	Check tube.
ASB > Tinsp	!	Only in neonatal service range: The ASB phase was terminated by a time limitation.	Test ventilation system for leaks.
Back-up ventilation	!!!	Only in neonatal service 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 7, replace if necessary, see page 8, recalibrate or activate neonatal flow monitoring.
		Tube blocked.	Check tube.
Breathing cycle not detected	!!!	The device does not deliver any gas.	Check neonatal flow sensor. Increase IPPV frequency.
Neo. flow measurement inop.	!!!	Neoflow monitoring is defective or the sensor lead is not connected.	Calibrate neonatal flow sensor, see page 7. Replace if necessary, see page 8, recalibrate. Connect sensor lead. Call DrägerService.
Neo. flow measurement inop.	!	Neoflow monitoring is defective or the sensor lead is not connected.	Calibrate neonatal flow sensor, see page 7. Replace if necessary, see page 8, recalibrate. Connect sensor lead. Call DrägerService.

Message		Cause	Remedy
Neo. flow monitoring off !	!	Neoflow monitoring is defective or the sensor lead is not connected.	Calibrate the neonatal flow sensor, see page 7, replace if necessary, see page 8, and recalibrate. Connect sensor lead.
Neo. flow sensor ?	!!!	Neoflow sensor not installed in the breathing system.	Install neonatal flow sensor in the breathing system.
Neo. flow sensor ?	!	Neoflow sensor not installed in the breathing system.	Install neoflow sensor in the breathing system
PPS-Insp. > 1.5 s	!	The inspiration phase during PPS was terminated 3 consecutive times after 1.5 seconds.	Check the ventilation system for leaks.

Technical Data

for neonatal mode, supplementary to the technical data in the Instructions for Use of EvitaXL.

Neonatal settings

Tidal volume V _T		
Range	3 to 100 mL, BTPS*	
Resolution	1 mL	
Accuracy	±8 % of set value or 1 mL, whichever is greater	

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/min	10 to 150/min
Resolution	0.5/min	1/min

Inspiration time T _{insp} (CPAP, CPAP/ ASB)		
Range	0.1 to 1 sec	1 to 10 sec
Resolution	0.05 sec	0.1 sec

Set values for PPS:

Flow Assist (FlowAssist)	
Range	0 to 30 mbar/L/s
Resolution	0.5 mbar/L/s
Range	30 to 300 mbar/L/s
Resolution	5 mbar/L/s
Corresponds to a resistance compensation of	0 to 300 mbar/L/s

Volume Assist (Vol.Assist)	
Range	0 to 100 mbar/L
Resolution	1 mbar/L
Range	100 to 2000 mbar/L
Resolution	10 mbar/L
Corresponds to a compliance compensation of	infinity to 0.5 mL/mbar

Set values for ATC:

Inside diameter of the tube (Tube ID)	
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 referred to patient lung conditions:
Body temperature 37 °C, gas saturated with water vapour, ambient pressure.

Performance characteristics

Control principle	Basic flow with demand system, pressure-controlled, time-controlled	
Basic flow	6 L/min (this can be changed by DrägerService to 9 L/min)	
Basic 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 humidifier and paediatric hose system	<1 mL/mbar	
Inspiration resistance		
— during operation with Fisher & Paykel humidifier	0 mbar (basic flow) at 5 L/min	
— following device failure with Fisher & Paykel humidifier	<1.5 mbar at 5 L/min	
Expiration resistance		
— during operation	<3 mbar at 5 L/min	
— following device failure	<1.1 mbar at 5 L/min	
Deadspace volume		
Neonatal flow sensor for ISO 15 including Y-piece	<2 mL	
Measured value displays		
Flow measurement		
(with neonatal flow sensor 84 11 130)		
Range	0.25 to 30 L/min	
Minute volume MV (without leakage correction)		
Range	0 to 9.9 L/min, BTPS	10 to 99 L/min, BTPS
Resolution	0.01 L/min	0.1 L/min
Accuracy	±8 % of the measured value or 1 mL x f, whichever is greater	
To...90	approx. 35 s	
Spontaneous breathed minute volume MV _{spn} (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	±8 % of the measured value or 1 mL x f _{spn} , whichever is greater	
To...90	approx. 35 s	
Leakage minute volume MV _{leak}		
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	

Tidal volume V_{Te}

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

Tidal volume V_{Ti} , V_T

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

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 expiration valve opens when the applied tidal volume exceeds the upper alarm limit.
Range	4 to 4000 mL

Rapid shallow breathing

	when the measured spontaneous breathing rate f_{spn} exceeds the alarm limit.
Range	5 to 120 bpm

Protection class

Neonatal flow sensor (sensor inserted)	Type BF 
--	---

Materials used

Part	Appearance	Material
Neonatal flow sensor	Yellowish, transparent	Polysulphone
Neonatal flow sensor housing	Yellowish, transparent	Polysulphone
Flow sensor lead	Grey	Polyurethane

Special features of neonatal ventilation

Measurement of leakage flow

A little 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 neonatal flow sensor proximal to the patient is located upstream of the leak at the Y-piece. 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 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 leakage value, 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 measured minute volume
not corrected for leaks

MV_{leak} : Mean leakage flow

EvitaXL takes into account the calculated leakage flow in the displayed values **VT_i**, **VT_e** and **Flow**. For this purpose, the leakage flow at each instant is calculated as a function of the actual airway pressure:

$$Flow_{leak} = MV_{leak} \times P_{AW} / P_{mean}$$

$Flow_{leak}$: Actual leakage flow

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

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

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

Patient flow and tidal volume are then calculated as follows:

Inspiration:

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

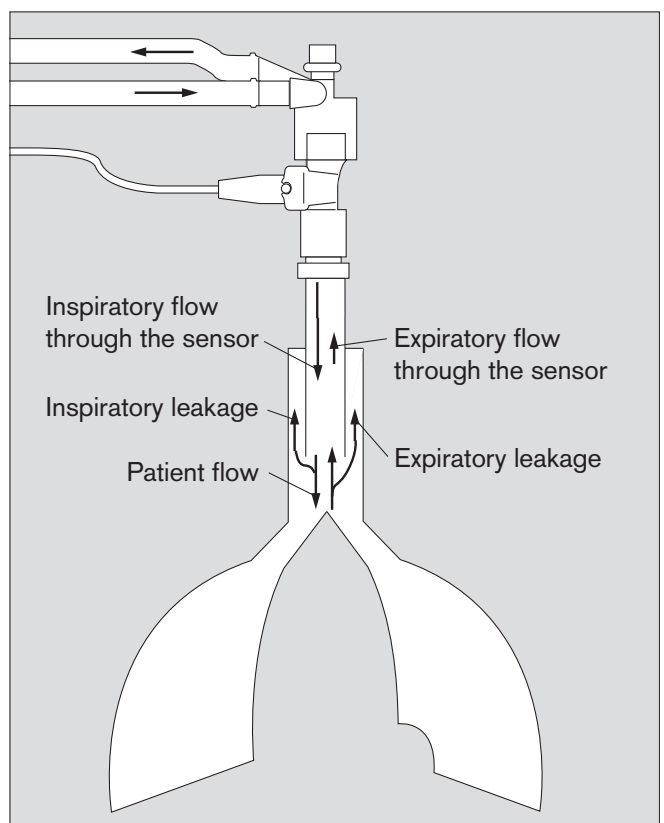
$$V_{\text{Ti}} = \int \text{Flow}_{\text{Patient, insp}} dt$$

Expiration:

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

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

- $\text{Flow}_{\text{Patient}}$: Actual patient flow, corrected for leaks
- $\text{Flow}_{\text{insp}}$: Actual inspiratory flow, not corrected for leaks
- Flow_{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_{leak} : Mean leakage flow, averaged over inspiration and expiration



Measurement of the airway pressure

EvitaXL measures the 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 apparatus. 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 during neonatal ventilation. 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 hose system.

The pressure measured by the expiratory pressure sensor is reduced by the pressure drop in the expiratory line of the hose system. These pressure differences are caused by the flow resistance of the hose system.

During expiration, the value measured at the inspiratory pressure sensor (P_{insp}) is reduced by the pressure drop caused by the basic flow (Flow_{bf}) in the inspiration line of the hose system (R_{insp}):

$$P_{\text{AW}} = P_{\text{insp}} - R_{\text{insp}} \times \text{Flow}_{\text{bf}}$$

P_{AW} : Airway pressure at the Y-piece
 P_{insp} : Airway pressure at the inspiratory sensor
 R_{insp} : Flow resistance of the inspiratory hose line
 Flow_{bf} : Basic flow

During inspiration, the value measured by the expiratory pressure sensor (P_{exp}) is raised relative to the airway pressure by the amount of the pressure drop (R_{exp}) caused by the flow (normally $\text{Flow}_{\text{out}} \leq \text{Flow}_{\text{bf}}$) through the expiratory line of the hose system:

$$P_{\text{AW}} = P_{\text{exp}} + R_{\text{exp}} \times \text{Flow}_{\text{out}}$$

P_{AW} : Airway pressure at the Y-piece
 P_{exp} : Airway pressure at the expiratory hose line
 R_{exp} : Flow resistance of the expiratory hose line
 Flow_{out} : Flow through the expiration valve during inspiration

The hose resistances are determined by EvitaXL during the device check.

Trigger response

Spontaneous breathing by the patient in neonatal mode is detected by EvitaXL by means of the flow signal from the neonatal flow sensor near the patient. When spontaneous inspiration is detected, a synchronised, mechanical pressure-controlled inspiration stroke or a pressure-assisted ASB stroke is triggered as a function of the ventilation mode.

In order to avoid incorrect triggering due to leakage flows, EvitaXL takes into account both the flow signal from the neonatal flow sensor ($Flow_{insp}$) and the calculated leakage minute volume (MV_{leak}). The leakage flow is converted to the momentary pressure level (P_{AW}):

$$Flow_{Patient, insp} = Flow_{insp} - MV_{leak} \times P_{AW} / P_{mean}$$

$Flow_{Patient}$: Patient flow

$Flow_{insp}$: Inspiratory flow, without leakage correction

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

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

P_{mean} : Average 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 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 spontaneous attempted inspiration and therefore cannot trigger a ventilation stroke.

AutoFlow®

AutoFlow is a supplementary function optimising flow control during the mandatory ventilation stroke in the constant-volume ventilation modes IPPV, SIMV and MMV.

In neonatal mode, the supplementary AutoFlow function is always activated in all volume-controlled ventilation modes (IPPV, SIMV, MMV).

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

The AutoFlow function can be activated in the »Add. settings« menu. AutoFlow takes control of »Insp Flow« and »P_{max}«. With AutoFlow activated, it is no longer possible to adjust P_{max} and Flow.

AutoFlow automatically adjusts the inspiratory flow to changes in the lung conditions (C, R) and to the patient's spontaneous demand.

Always set the alarm limit »PAW \sqrt{f} « to trigger a warning if the airway pressure increases with reduced compliance.

The maximum applied pressure is limited to 5 mbar below the upper pressure limit.

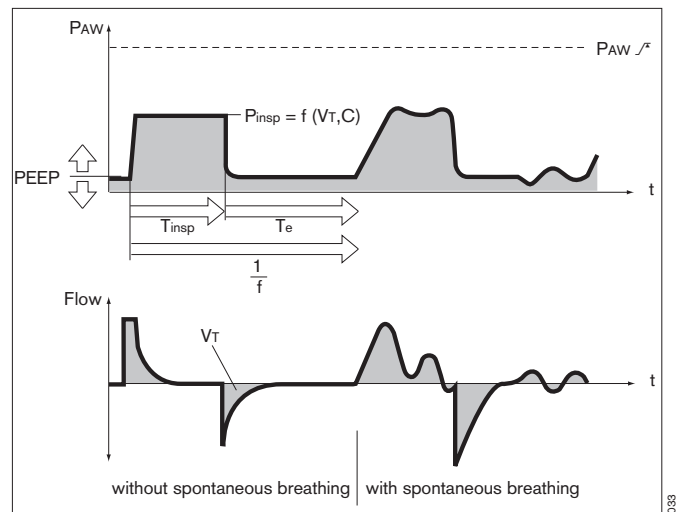
The selected inspiration time T_{insp} is typically very much longer than the time required to fill the lungs. The inspiration pressure P_{insp} corresponds to the minimum value obtained from the tidal volume V_T and lung compliance C .

The volume required to calculate the inspiration pressure is derived from the measured value V_{Te} of the neonatal flow sensor near the patient. Contamination of the neonatal flow sensor can lead to incorrect measured volumes. The airway pressure increases if the measured volume is too low.

The inspiratory flow is automatically controlled in such a way as to prevent the occurrence of a pressure peak due to the resistance of the tube and airways. As usual in constant-volume ventilation strokes, the plateau pressure P_{plat} changes as the compliance C changes. With AutoFlow, these changes are effected in increments of not more than 3 mbar from one ventilation stroke to the next.

If the tidal volume V_T (inspiratory flow = 0) is reached before expiry of the inspiration time T_{insp} , the inspiratory and expiratory valves are controlled in such a way that the patient can still breathe in and out with constant plateau pressure P_{plat} during the remaining inspiration time.

If the patient breathes in or out during mandatory inspiration, the plateau pressure P_{plat} remains unchanged in this ventilation stroke. Only the inspiratory and expiratory flow adjusts to the patient's demand. The individually applied tidal volume V_T can deviate from the set tidal volume V_T in individual ventilation strokes, but a constant tidal volume V_T is nevertheless applied on average over time.



The tidal volume V_T can be limited by the alarm limit $\text{»}V_{Ti} \text{ } \sqrt{\text{»}}$. If the set alarm limit is exceeded once, EvitaXL will output an advisory message (!). An alarm message (!!!) is output if the limit is exceeded three times in succession. If necessary, the volume is actively limited to the value of the alarm limit $\text{»}V_{Ti} \text{ } \sqrt{\text{»}}$ by switching over to the PEEP level.

- **Set alarm limits $\text{»}V_{Ti} \text{ } \sqrt{\text{»}}$ and $\text{»}V_{Ti} \text{ } \sqrt{\text{»}}$ properly to avoid over or under supply in case of abrupt changes in compliance.**

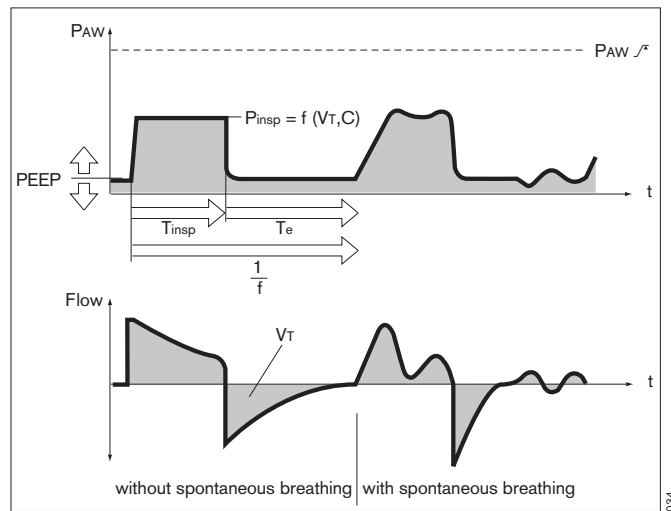
If the set inspiration time T_{insp} is shorter than the time required for the lungs to fill, this can be seen from the flow curve, for the flow will not have declined to zero at the end of the inspiration time. In such cases, it must be decided whether the patient's momentary situation will permit a longer inspiration time T_{insp} in order to reduce the peak pressure further.

This effect can also be induced during ventilation, e. g. through an accumulation of secretion. The pressure is limited by the alarm limit $\text{»}P_{AW} \text{ } \sqrt{\text{»}}$ in such a case.

The pressure rise is limited to 5 mbar below the alarm limit $\text{»}P_{AW} \text{ } \sqrt{\text{»}}$ and the alarm message $\text{»Volume not constant«}$ only appears after the set tidal volume V_T is no longer applied.

The beginning of mandatory inspiration can be synchronized with the patient's attempted inspiration with the aid of the variable flow trigger. The flow trigger can only be deactivated completely in IPPV mode (IPPVAssist \rightarrow IPPV).

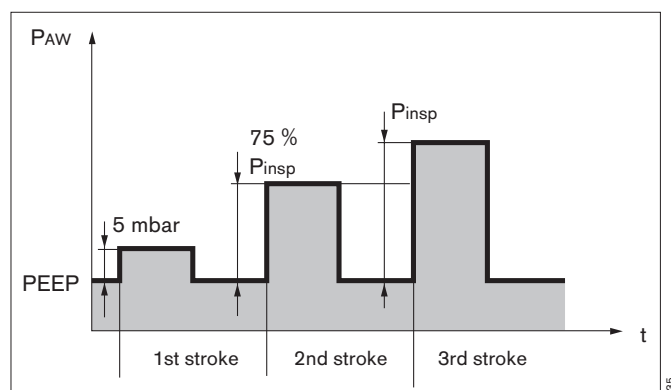
The steepness with which the pressure rises from the PEEP level to the inspiration level can also be adjusted in line with the patient's needs via the ventilation parameter pressure rise time »Ramp« in SIMV and MMV.



034

Initial response of AutoFlow in neonatal mode

When activating a volume-controlled ventilation mode, EvitaXL initially applies a test stroke with an inspiratory pressure 5 mbar greater than PEEP. This test stroke is used by EvitaXL to calculate the inspiratory stroke for the next inspiration. In the second inspiration stroke, however, EvitaXL sets only 75 % of the previously calculated inspiratory pressure in order to verify the first result and calculate a new inspiratory pressure. EvitaXL sets the inspiratory pressure as calculated from the third stroke onwards. All further adjustments of the inspiratory pressure are limited to ± 3 mbar.






035

Abbreviations

Abbreviation	Explanation
ASB	Assisted Spontaneous Breathing
BIPAP	Biphasic Positive Airway Pressure Spontaneous breathing under continuous positive airway pressure with two different pressure levels
C	Compliance
bpm	Breaths per minute
f	Mechanical ventilation frequency (setting)
f _{spn}	Spontaneous breathing rate (measured value)
Flow	Displayed real-time curve, patient flow, with leakage correction (measured value)
Flow _{out}	Flow through the expiration valve during inspiration
Flow _{Assist}	Adjustable pressure assistance in proportion to patient flow
Flow _{bf}	Basic flow (system setting), see "Technical Data" page 28
Flow _{insp}	Inspiratory flow, without leakage correction
Flow _{exp}	Expiratory flow, without leakage correction
Flow _{leak}	Actual leakage flow
Flow _{Patient}	Inspiratory/expiratory flow, with leakage correction (measured value)
IPPV	Intermittent Positive Pressure Ventilation
IPPV _{Assist}	Assisted Intermittent Positive Pressure Ventilation
MMV	Mandatory Minute Volume Ventilation
MV	Expiratory measured minute volume, without leakage correction (measured value)
MV _{leak}	Leakage minute volume – mean leakage flow, averaged over inspiration and expiration (measured value)
MV _{Patient}	Inspiratory/expiratory measured minute volume, with leakage correction
MV _{spn}	Spontaneous breathing portion of the minute volume
P _{ASB}	Set point for ASB pressure assistance
ΔP _{ASB}	Set point for P _{ASB} relative to PEEP
P _{Apnoea}	Set point for inspiratory pressure with Apnoea ventilation
ΔP _{Apnoea}	Set point for P _{Apnoea} relative to PEEP
PAW	Airway pressure at the Y-piece (measured value)
PEEP	Positive End-Expiratory Pressure
P _{exp}	Airway pressure in the expiratory hose line

Abbreviation	Explanation
P _{insp}	Set point for the upper pressure limit in BIPAP
P _{mean}	Mean airway pressure at the Y-piece (measured value)
P _{plat}	End-Expiratory Airway Pressure
R	Resistance
R _{exp}	Flow resistance of the expiratory hose system
R _{insp}	Flow resistance of the inspiratory hose system
SIMV	Synchronized Intermittent Mandatory Ventilation
T _{Apnoea}	Apnoea time (setting)
T _{insp}	Set point for inspiration time
Vol. _{Assist}	Adjustable pressure assistance in proportion to tidal volume
V _T	Tidal volume (setting)
V _{Ti}	Inspiratory tidal volume (measured value)
V _{Te}	Expiratory tidal volume (measured value)

Symbols

Symbol	Explanation
 Neo.	Neonatal patient mode
	Protection class Type BF
	Strictly follow the Instructions for Use!

Order list

Name/Description	Order No.
Kit NeoFlow SW 6.0	84 15 940
comprising:	
Extension PCB "Paediatric Flow"	
Flow sensor lead	
Neonatal flow sensor for ISO 15	
Insert for neonatal flow sensor (set of 5)	
"Water trap" kit	
Paediatric cuvette for CO2 measurement	
Corrugated hose 0.13 m	
Spare parts:	
Spare parts designed for use with the basic unit.	
Flow sensor lead	84 09 626
Neonatal flow sensor for ISO 15	84 11 130
Insert for neonatal flow sensor (set of 5)	84 10 179
"Water trap" kit	84 13 125
Paediatric cuvette for CO2 measurement	68 70 280
Corrugated hose 0.13 m	84 09 634

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These Instructions for Use apply only to
EvitaXL
with 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
machine or device.



Directive 93/42/EEC
concerning Medical Devices

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