NeoFlow™
Neonatal Mode
Addendum to
Operating Instructions
Evita 4 (as of software 2.n)
Evita 2 dura (as of software 3.10)
NOTICE

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## Contents

**Important Safety Information READ THIS FIRST** ........................................ 4  
Operator’s Responsibility for Patient Safety ........................................ 4  
Limitation of Liability ........................................................................ 4  
Warranty ......................................................................................... 5  
Definitions....................................................................................... 6  
General WARNINGS and CAUTIONS ................................................. 6  
Precautions During Preparation .................................................... 7  
Precautions During Operation ......................................................... 7  
Precautions During Care ............................................................... 8  
Precautions During Maintenance .................................................... 8  

**Intended Use** ................................................................................. 9  

**Preparation** .................................................................................. 10  
Installation...................................................................................... 10  
Before First Use ............................................................................. 10  
Preparing For Use ........................................................................ 10  
Ventilator Check Evita 4 ............................................................... 11  
Ventilator Check Evita 2 dura ....................................................... 11  
Calibrating the Neonatal Flow Sensor ........................................... 12  
Exchanging a Neonatal Flow Sensor Element ............................. 13  

**Operation** .................................................................................... 14  
Selecting Neonatal Mode with Evita 4 ........................................... 14  
Selecting Neonatal Mode with Evita 2 dura ............................... 14  
Volume Controlled Ventilation in Neonatal Mode ...................... 15  
Back-up Ventilation in Neonatal Mode .......................................... 16  
Pressure Support Ventilation (PSV) ............................................... 16  
Apnea Ventilation in Neonatal Mode ............................................ 17  
Flow Monitoring During Neonatal Ventilation ......................... 18  
Flow Monitoring During Pediatric Ventilation ......................... 19  
Nebulizing Medication Aerosols .................................................. 20  
O2 Concentration When Using Nebulizer .................................. 23  
Oxygenation For Bronchial Suction .............................................. 23  

**Configuration of Ventilation** ..................................................... 24  
Selecting the Patient Range .......................................................... 24  
Start-up Defaults for Ventilation Parameters and Alarm Limits With Evita 4 ................................................................. 24  
Start-up Defaults for Ventilation Parameters and Alarm Limits With Evita 2 dura ................................................................. 26  

**Care** .......................................................................................... 27  
Dismantling the Neonatal Flow Sensor ....................................... 27  
Disinfecting/Cleaning/Sterilizing .................................................. 27  
Maintenance ................................................................................... 29  

**Troubleshooting** ......................................................................... 30  

**Technical Data** ........................................................................... 31  
Performance Characteristics ...................................................... 31  
Measured Value Displays ............................................................ 31  
Monitoring ..................................................................................... 32  
Materials Used ................................................................................ 33  

**Special Features of Neonatal Ventilation** .................................. 34  
Measurement of Leak Flow .......................................................... 34  
Measurement of Airway Pressure .................................................. 36  
Trigger Response ........................................................................... 37  
AutoFlow® ....................................................................................... 38  

**Glossary** .................................................................................... 40  

**Ordering Information** ............................................................... 41  

**Index** ........................................................................................... 42
Important Safety Information

Operator's Responsibility for Patient Safety

For correct and effective use of the product and in order to avoid hazards it is mandatory to carefully read and to observe all portions of this manual.

The design of the intensive care ventilator this device is intended to be used with, 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 respiratory care equipment, to the consequences of misuse of such equipment, 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 uses of the product not covered by its intended use or 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.

The operators of ventilator systems 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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Draeger Medical, Inc. shall not be liable for, nor shall buyer be entitled to recover any special incidental, or consequential damages or for any liability incurred by buyer to any third party in any way arising out of or relating to the goods.
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.

3. Oxygen sensor capsules have a six-month limited warranty from the date 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 Medical, Inc. 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 Medical, Inc. or its authorized representative no later than two (2) weeks following expiration of this warranty.

In order to assure complete protection under this warranty, the Customer Registration Card and/or Periodic Manufacturer's Service Record (if applicable) must be returned to Draeger within ten (10) days of receipt of the equipment.

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 ("hard" keys and screen keys / fields / knobs) are designated as »Control Name«, e.g.
»Calibration«
Screen pages are indicated as »Screen page«, e.g.
»Alarm limits«
On-screen messages are printed in bold, e.g.
Calibration ok

General WARNINGS and CAUTIONS

WARNING!
Strictly follow Operator’s Instruction Manuals!
Any use of the product requires full understanding and strict observation of all portions of these instructions as well as the Operating Instructions of the Evita 4 and Evita 2 dura ventilator. The equipment is only to be used for the purpose specified under "Intended Use" (page 9). Observe all WARNINGS and CAUTIONS as rendered throughout the manuals and on labels on the equipment.

WARNING!
DANGER, risk of explosion if used in the presence of flammable anesthetics.
The equipment is neither approved nor certified for use in areas where combustible or explosive gas mixtures with air or with nitrous oxide are likely.

WARNING!
Electrical connections to equipment which is 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.

CAUTION!
Accessories
Use only accessories listed in the Ordering Information (page 41).
## Precautions During Preparation

### WARNING !
Installation of the NeoFlow option into Evita 4 or Evita 2 dura 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.

### WARNING !
The nebulizer function integrated in Evita 4 and Evita 2 dura 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 O2 concentration!

### WARNING !
Do not use a heat/moisture exchanger simultaneously with a nebulizer or heated humidifier! Risk of increased breathing resistance due to condensation.

### WARNING !
Installation of the NeoFlow option into Evita 4 or Evita 2 dura ventilators may only be performed by factory trained and authorized service personnel. Follow installation instructions in the respective documentation.

## Precautions During Operation

### WARNING !
The alarm limit »Paw« must always be set, so that a warning is triggered if the 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.

### 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 microbial filter on the nebulizer outlet when in use!

### CAUTION !
Do not ventilate with the neonatal flow sensor. Instead, use the expiratory flow sensor for ventilation. Secretion collecting in the flow sensor may cause corrosion.

### CAUTION !
The wires of the flow sensor are hot. If the neonatal flow sensor is left in the ventilation system for some time during nebulizing 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 nebulizing.
### Precautions During Care

<table>
<thead>
<tr>
<th>WARNING !</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow all accepted hospital procedures for disinfecting parts contaminated by body fluids (protective clothing, eyewear, etc.).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION !</th>
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</thead>
<tbody>
<tr>
<td>Certain components of the ventilator consist of materials that are sensitive to certain organic solvents sometimes used for cleaning and disinfecting (e.g., phenols, halogen releasing compounds, oxygen releasing compounds, strong organic acids, etc.). Exposure to such substances may cause damage that is not always immediately apparent. Sterilization with ethylene oxide (EtO) is also not recommended.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION !</th>
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<tbody>
<tr>
<td>Do not allow any liquid into the connector of the flow sensor cable.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION !</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not process flow sensor element in cleaning and disinfection equipment. 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.</td>
</tr>
</tbody>
</table>

### Precautions During Maintenance

<table>
<thead>
<tr>
<th>WARNING !</th>
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</thead>
<tbody>
<tr>
<td>To avoid any risk of infection, clean and disinfect ventilator and accessories according to established hospital procedures before any maintenance - this applies also when returning ventilators or parts for repair.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>WARNING !</th>
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</thead>
<tbody>
<tr>
<td>Preventive Maintenance work on the Evita 4 and Evita 2 dura ventilators and their components may be performed by factory trained and authorized personnel only.</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>WARNING !</th>
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</thead>
<tbody>
<tr>
<td>Never operate a ventilator if it has suffered physical damage or does not seem to operate properly. In this case always refer servicing to factory trained and authorized personnel.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION !</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance</td>
</tr>
<tr>
<td>In case of malfunction of this component, contact your local DraegerService or our Factory Authorized Technical Service Center.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION !</th>
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</thead>
<tbody>
<tr>
<td>The devices must be inspected and serviced (preventive maintenance) by factory trained and authorized technical service representatives at regular 6 month intervals. A record must be kept on this preventive maintenance. We recommend obtaining a service contract through your vendor.</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>CAUTION !</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance or repair of Evita ventilators shall be performed only by Draeger authorized technical service representatives.</td>
</tr>
</tbody>
</table>
Intended Use

NeoFlow – neonatal mode with base flow.

NeoFlow extends the patient range of Evita 4 and Evita 2 dura ventilators to infants and neonates with a minimum body weight of 1,1 lbs (0.5 kg).

A flow sensor specifically designed for neonatal applications extends the range of flow monitoring for Evita 4 and Evita 2 dura ventilators during pediatric and infant ventilation. This neonatal flow sensor is positioned at the patient wye connector.
Preparation

Installation

WARNING!
Installation of the NeoFlow option into Evita 4 or Evita 2 dura ventilators may only be performed by factory trained and authorized service personnel. Follow installation instructions in the respective documentation.

Before First Use

Please refer to page 24 for instructions on configuring NeoFlow.

Preparing For Use

Installing the neonatal flow sensor
Prepare ventilator circuit as described under "Ventilating Infants" in the Evita 4 and Evita 2 dura Operating Instructions, respectively.

1 Connect wye to ventilator circuit.
2 Insert neonatal flow sensor to the ET-tube connector end of the wye.
3 Insert flow sensor cable connector into sensor socket.
   • Route sensor cable to the ventilator along the ventilator circuit.
4 Plug flow sensor connector into the appropriate socket on the rear panel of the ventilator and tighten thumbscrews.
Connect infant test lung with tracheal tube and connector to the patient end of the neonatal flow sensor.

**Ventilator Check Evita 4**

The NeoFlow option expands the Evita 4 ventilator pre-use check procedure by the following function:

- Calibration neo. flow sensor

**Ventilator Check Evita 2 dura**

The NeoFlow option expands the Evita 2 dura ventilator pre-use check procedure by the following function:

- Calibration neo. flow sensor
Calibrating the Neonatal Flow Sensor

Calibrate 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 by superheating the hot wire in the anemometer.

NOTE: Recalibration is not necessary if the neonatal flow sensor has been temporarily disconnected.

Starting calibration with Evita 4
- Press the »Calibration« key.
- Touch »Neo. flow« screen key. The "LED" in the screen key will turn yellow.

Starting calibration with Evita 2 dura
- Press »Calib./Config.« key.
- Select screen key »Neo. flow« = turn dial knob.
- Start calibration = press dial knob.
**Calibration Procedure**

- Disconnect neonatal flow sensor at ET-tube connector and
- remove sensor from the wye.
- Connect patient ET-tube connector directly to the wye for the duration of 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 the neonatal flow sensor so that both sides are sealed and flow = 0, as required for calibration.
- Start calibration = press dial knob. Calibration is completed after approx. 1 second.

If the message *Calibration ok* is displayed:

- Disconnect ET-tube connector from wye.
- Re-install neonatal flow sensor in the wye.
- Reconnect tube connector.

If calibration is unsuccessful:

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

**Exchanging a Neonatal Flow Sensor Element**

In the event of an error message:

*Neo. flow measurement malfunction*

1. Disconnect flow sensor cable from neonatal flow sensor.
2. Press buttons on both sides while pulling flow sensor element out of its housing. Insert new sensor until it engages.
3. Be sure to line up oval markings engraved on flow sensor element and sensor housing. Do not force sensor element.

1. Reconnect flow sensor cable.
- Calibrate neonatal flow sensor, see page 12.
Operation

Selecting Neonatal Mode With Evita 4

The appropriate patient mode can be selected immediately after switching the ventilator on or while in standby mode. Mode selections from the Evita 4 menu are:

- **Adults** = Adult
- **Ped.** = Pediatric
- **Neo.** = Neonatal

The patient ranges can be configured – see "Configuring ventilation, Selecting the patient range" on page 24.

- Touch the »Neo.« screen key.

Display (example for neonatal mode):

In the top line of the screen, after the ventilation mode identifier, the letter **N = Neonatal mode** is displayed.

Selecting Neonatal Mode With Evita 2 dura

The appropriate patient mode can be selected immediately after switching the ventilator on or while in standby mode. Mode selections from the Evita 2 dura menu are:

- **Adults** = Adult
- **Ped.** = Pediatric
- **Neo.** = Neonatal

The ranges for each mode in this menu can be configured – see "Configuring Ventilation, Selecting the Patient Range" on page 24.

- Select »Neo.« screen key = turn dial knob.

Display (example for neonatal mode):

In the top line of the screen, the letter **N = Neonatal mode** is displayed.
Volume Controlled Ventilation in Neonatal Mode

NOTE: The AutoFlow® ventilation mode extension is always active when using volume controlled ventilation (CMV, SIMV, MMV) in neonatal mode. (This is also true for Evita 2 dura ventilators without Ventilation Plus option installed.)

AutoFlow® - automatically optimizes inspiratory flow. AutoFlow* controls a decelerating inspiratory flow in such a way that for a selected tidal volume VT and for the given compliance only a minimum airway pressure is used and pressure peaks are avoided. Evita 4 and Evita 2 dura deliver an additional inspiratory flow when the patient breathes in. This flow is limited by alarm limit VTi *.

Inspiratory pressure is limited by alarm limit Paw *.

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

* Refer to page 38 for a detailed description of AutoFlow
Back-up Ventilation in Neonatal Mode
during volume controlled neonatal ventilation

Volume controlled ventilation in neonatal mode is only possible with intact flow monitoring. If neonatal flow monitoring fails or has been switched off during volume controlled ventilation, Evita 4 and Evita 2 dura, respectively, will automatically switch over to pressure controlled back-up ventilation.

**NOTE:** Apnea monitoring continues during back-up ventilation and will launch apnea ventilation in case of an apnea.

During back-up ventilation, inspiratory pressure will reach the averaged value of the previous mandatory breaths applied while flow monitoring was still active during volume controlled neonatal ventilation. The \( T_{\text{insp}} \), \( f \), \( O_2 \) and \( P_{\text{EEP}} \) ventilation parameters retain the same settings as before back-up ventilation. Evita 4 and Evita 2 dura, respectively, will switch automatically back to the original volume controlled mode after re-establishing the neonatal flow monitoring.

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 can be used for patients with adequate spontaneous breathing.

Pressure Support during neonatal ventilation is only possible if flow monitoring is active!

- Set the ventilation pattern for Pressure Support Ventilation with the parameters:

  - Support pressure \( P_{\text{supp}} \)
  - Pressure rise time \( \uparrow \) or \( \text{Ramp} \) (Evita 4)
  - or \( \text{Ramp} \) (Evita 2 dura)
  - Maximum inspiratory time \( T_{\text{insp}} \)

A pressure supported breath during neonatal ventilation is ended at the latest after the set maximum inspiratory time \( T_{\text{insp}} \).
Apnea Ventilation in Neonatal Mode

In ventilation modes with apnea ventilation switched on, **pressure controlled** apnea ventilation is started after the set alarm time ($T_{\text{Tapnea}}$) if an apnea occurs while in neonatal patient mode. Apnea ventilation is controlled by adjusting the following settings:

- Frequency $f_{\text{Apnea}}$
- $P_{\text{insp}}$ $\rightarrow P_{\text{Apnea}}$

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

Ventilation parameters "$O_2"$ and "$\text{PEEP}"$ remain at their respective settings at the time apnea ventilation is started.

**Setting apnea ventilation parameters with Evita 4:**
- Touch »Extra settings« screen key.
- Touch »Apnea vent.« screen key.
- Set the desired values = touch screen key representing the appropriate "control knob", then turn and press dial knob to adjust and confirm.

**Setting apnea ventilation parameters with Evita 2 dura**
- Press »Setting« menu key
- Display:
  - Select »Apnea Vent.« screen key = turn dial knob
    Switch apnea ventilation on = press dial knob. Black indicator dot in screen key = apnea ventilation is on.
  - Select »$P_{\text{Apnea}}$« = turn dial knob, to activate, press dial knob. This Parameter is set as $P_{\text{insp}}$ above $\text{PEEP}$.
  - Set value = turn dial knob, to confirm, press dial knob.
  - Select, set, and confirm »$f_{\text{Apnea}}$« accordingly.
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 are possible. Apnea monitoring, however, is maintained even without the neonatal flow sensor.

Deactivating neonatal flow monitoring with Evita 4:

- Press »Alarm limits« key.
- Touch »Monitoring« screen key.
- Touch »Neo. flow Off« screen key.
  The screen key changes color, from green to yellow.
- To confirm deactivation of neonatal flow monitoring, press dial knob.

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 12.

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 with Evita 2 dura:

- Press »Calib./Config.« key.
- Select menu option »Sensor On/Off« using the »Sensor « key.
- Select line »NeoFlow on« = turn dial knob, confirm = press dial knob.
- Choose »Off« from the selections = turn dial knob, confirm = press dial knob.

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 12.

Flow Monitoring During Pediatric Ventilation

If a neonatal flow sensor is present and intact during pediatric ventilation, 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 the Evita 4 and Evita 2 dura ventilators. In this case, unlike in neonatal patient mode, volume controlled ventilation remains possible.

For larger pediatric patients with purulent or copious secretions:

**CAUTION !
Do not ventilate with the neonatal flow sensor. Instead, use the expiratory flow sensor for ventilation.
Secretion collecting in the flow sensor may cause corrosion.**
Nebulizing Medication Aerosols

In neonatal mode, it is only possible to nebulize medication aerosols with 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 microbial 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.

Nebulizer Preparation

**WARNING !**

The nebulizer function integrated in Evita 4 and Evita 2 dura 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 O2 concentration!

Notes for aerosol treatment:

- Before medicament nebulizing, remove the complete flow sensor from the Y-piece.
- Calibrate the flow sensor at least once every 24 hours. See "Calibrating neonatal flow sensor" on page 12.
- Replace/clean flow sensor if there is visible soiling. See "Installing neonatal flow sensor" on page 10.
Operation
Nebulizing Medication Aerosols

To remove neonatal flow sensor

1. Remove complete flow sensor (housing and insert) from Y-piece.

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

**In the worst case, these deposits could catch fire.**
Disconnected the flow sensor cable is not sufficient to prevent this.
It is therefore important to remove the complete flow sensor before medicament nebulizing.

2. Insert tube catheter cone into Y-piece.

**The 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**

- Assemble the nebuliser as specified in its specific Instructions for Use, e.g. for nebulizer 84 12 935.

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.

6. 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 nebulizer.

7. Connect the free end of the corrugated hose to the nebulizer with the Y-piece inspiration adapter.

8. Attach nebulizer pressure line to the port on the front of the Evita 4 or Evita 2 dura ventilator, respectively.
When using with an incubator
- Push the output port adapter of the nebulizer into the upper access grommet in the incubator hood, if available.

When using without an incubator
- Press the nebulizer sleeve into one side of a patient circuit support arm bracket and the expiratory hose into the other.
- Position the nebulizer upright and fill.

Start nebulization
1. Hold down key until its yellow LED lights up.

Ending nebulization
Nebulization is ended automatically after max. 30 minutes.
If you want to interrupt it earlier:
1. Press key again. The yellow LED goes out, and the nebulizer is deactivated.
- Remove any residual medication from the nebulizer. Follow the Instructions for Use of the nebulizer.
- Re-install neonatal flow sensor in the wye.
- Activate neonatal flow monitoring – see pages 18 and 19.
O2 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 O2 concentration, the nebulizer is supplied with medical compressed air, oxygen or a mixture of medical air and oxygen. This helps to keep deviations in O2 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 breath per minute, the graph in the side column applies. Maximum possible deviations to expect are ± 4 % by volume.

For respiratory rates less than 12 breaths per minute, 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 Evita 4 or Evita 2 dura Operating Instructions.

However, during pre- and post-oxygenation, the FiO2 concentration is increased by only 25 % relative to the set FiO2 concentration when in neonatal mode.

See table:

<table>
<thead>
<tr>
<th>Set FiO2 Vol.%</th>
<th>FiO2 for pre- and post-oxygenation Vol.%</th>
</tr>
</thead>
<tbody>
<tr>
<td>21</td>
<td>26</td>
</tr>
<tr>
<td>30</td>
<td>37</td>
</tr>
<tr>
<td>60</td>
<td>75</td>
</tr>
<tr>
<td>80</td>
<td>100</td>
</tr>
</tbody>
</table>

Current FiO2 concentration is continuously displayed at the bottom of the screen during the oxygenation phases.
Configuration of Ventilation

Selecting the Patient Range

with Evita 4
Select the desired patient range from the list on the configuration page – see Evita 4 Operating Instructions.

The following ranges are available:
- Adults only
- Pediatrics only
- Adults or Pediatrics
- Neonates only
- Pediatrics or Neonates
- Adult, Ped. or Neo.
  - Select the required patient range = turn dial knob.
  - Confirm = press dial knob.

With Evita 2 dura
all patient ranges are available at all times.
No configuration is possible.

Start-up Defaults for Ventilation Parameters and Alarm Limits With Evita 4

With Evita 4, start-up default values for tidal volume VT and ventilation frequency f can be defined as a function of the ideal body weight of a patient or as a function of the patient mode.

- Press »Configuration« key.
- Touch screen keys »Ventilation« and »Start-up settings«.

Enter code no. 3032
- Touch respective screen keys.

To adjust defaults to hospital-specific settings:
- Touch screen key of the parameter you wish to change.
- Change value = turn dial knob.
- Confirm new value = press dial knob.

To return to factory default settings for all start-up values:
- Touch »System Defaults« screen key and confirm = press dial knob.
To select default 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:

<table>
<thead>
<tr>
<th>Weight kg</th>
<th>Factory-set defaults</th>
<th>Hospital-set defaults</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tidal volume VT mL</td>
<td>Ventilation frequency f bpm</td>
</tr>
<tr>
<td>0.5</td>
<td>3</td>
<td>35</td>
</tr>
<tr>
<td>15</td>
<td>110</td>
<td>26</td>
</tr>
<tr>
<td>65</td>
<td>450</td>
<td>13</td>
</tr>
<tr>
<td>100</td>
<td>700</td>
<td>10</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Patient mode</th>
<th>Factory-set defaults</th>
<th>Hospital-set defaults</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tidal volume VT mL</td>
<td>Ventilation frequency f bpm</td>
</tr>
<tr>
<td>Neo.</td>
<td>9</td>
<td>31</td>
</tr>
<tr>
<td>Ped.</td>
<td>50</td>
<td>29</td>
</tr>
<tr>
<td>Adults</td>
<td>500</td>
<td>12</td>
</tr>
</tbody>
</table>

**NOTE:** Factory-set defaults may be adjusted to hospital-specific settings for start-up values.
Start-up Defaults for Ventilation Parameters and Alarm Limits With Evita 2 dura

With Evita 2 dura, start-up default values for tidal volume VT and ventilation frequency f can be defined as a function of patient mode.

- Press »Config./Calib.« menu key.
- Press »Ventilation « menu key.

Enter code no. 3032:
- Select numbers using the dial knob, press to confirm.

To adjust defaults to hospital-specific settings:
- Change value = turn dial knob.
- Confirm new value = press dial knob.

To return to factory default settings for all start-up values:
- Select »Basic settings« screen key = turn dial knob, confirm = press dial knob.

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

<table>
<thead>
<tr>
<th>Patient mode</th>
<th>Factory-set defaults</th>
<th>Hospital-set defaults</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tidal volume VT mL</td>
<td>Ventilation frequency f bpm</td>
</tr>
<tr>
<td>Neo.</td>
<td>9</td>
<td>31</td>
</tr>
<tr>
<td>Ped.</td>
<td>50</td>
<td>29</td>
</tr>
<tr>
<td>Adults</td>
<td>500</td>
<td>12</td>
</tr>
</tbody>
</table>

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

Dismantling the Neonatal Flow Sensor

1. Unplug neonatal flow sensor cable from both the sensor and the back panel of the Evita 4 or Evita 2 dura, respectively.

2. Remove the sensor element:
   Press the buttons on both sides while at the same time pulling the sensor out of the sensor housing.

3. Detach sensor housing from wye.
   Dismantle and process the other components as described in the Evita 4 and Evita 2 dura Operating Instructions, respectively.

Disinfecting/Cleaning/Sterilizing

CAUTION!
Certain components of the ventilator consist of materials that are sensitive to certain organic solvents sometimes used for cleaning and disinfecting (e.g., phenols, halogen releasing compounds, oxygen releasing compounds, strong organic acids, etc.). Exposure to such substances may cause damage that is not always immediately apparent. 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 Evita 4 and Evita 2 dura Operating Instructions.
Flow sensor cable
- Disinfection procedure: Wipe disinfection

Flow sensor element
- Disinfection procedure: Bath disinfection

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

NOTE: Any residue of dried mucus shortens life of the flow sensor, therefore:
- proceed with bath disinfection immediately after use.
- Rinse flow sensor element by gently stirring in distilled water. Thoroughly shake off residual water.
- After disinfection, the sensor element may be steam autoclaved at 134 °C (273 °F) for at least 5 min.

Flow sensor housing
- Disinfect by high temperature wet autoclaving (93 °C /200 °F 10 minutes) using detergent only.
  Or
- Steam autoclave at 134 °C (273 °F).
Maintenance

**CAUTION !**

**Maintenance**
In case of malfunction of this component, contact your local DraegerService or our Factory Authorized Technical Service Center.
The devices must be inspected and serviced (preventive maintenance) by factory trained and authorized technical service representatives at regular 6 month intervals. A record must be kept on this preventive maintenance. We recommend obtaining a service contract through your vendor.
Maintenance or repair of Evita ventilators shall be performed only by Draeger authorized technical service representatives.

**WARNING !**

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

**WARNING !**

Preventive Maintenance work on the Evita 4 and Evita 2 dura ventilators and their components shall be performed by factory trained and authorized personnel only.

**WARNING !**

Never operate a ventilator if it has suffered physical damage or does not seem to operate properly. In this case always refer servicing to factory trained and authorized personnel.

**Maintenance Intervals**

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

The Evita 4/Evita 2 dura NeoFlow option is serviced as part of the scheduled preventive maintenance of the Evita 4 and Evita 2 dura ventilators every six months.
### Troubleshooting

Alarm messages in the alarm display field are displayed in order of priority. If, for example, two faults are detected at the same time, the more urgent of the two is displayed.

The priority of alarm messages is indicated by exclamation marks:

- **Warning** = Message with top priority !!!
- **Caution** = Message with medium priority !!
- **Advisory** = Message with low priority !

The table below only lists (in alphabetical order) additional messages specific to NeoFlow. 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 mode may have a different cause in neonatal mode. In these cases, a patient mode specific help text is provided.

<table>
<thead>
<tr>
<th>Message</th>
<th>Cause</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Apnea</strong></td>
<td>No spontaneous breathing by the patient.</td>
<td>Ventilate patient in a controlled mode.</td>
</tr>
<tr>
<td></td>
<td>Neonatal flow sensor not calibrated or defective.</td>
<td>Calibrate the neonatal flow sensor, see page 12.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Replace if necessary, see page 13, recalibrate.</td>
</tr>
<tr>
<td></td>
<td>Neonatal flow sensor connected but not in the wye assembly.</td>
<td>Insert the neonatal flow sensor element into the flow sensor housing.</td>
</tr>
<tr>
<td></td>
<td>Tube obstructed.</td>
<td>Check tube.</td>
</tr>
<tr>
<td><strong>Back-up ventilation</strong></td>
<td>Only in neonatal patient range: In volume controlled ventilation, a neonatal flow monitoring fault was detected or neonatal flow monitoring was switched off.</td>
<td>Calibrate neonatal flow sensor, see page 12. Replace if necessary, see page 13, recalibrate or activate neonatal flow monitoring.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tube obstructed.</td>
<td>Check tube.</td>
</tr>
<tr>
<td><strong>Neo.flow meas. inop</strong></td>
<td>Only in neonatal patient range: Neonatal flow monitoring is defective or the sensor lead is not connected.</td>
<td>Calibrate neonatal flow sensor, see page 12. Replace if necessary, see page 13, recalibrate. Connect sensor cable</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Neo.flow monitoring off</strong></td>
<td>Neonatal flow monitoring is deactivated.</td>
<td>Activate neonatal flow monitoring.</td>
</tr>
<tr>
<td><strong>Neo.flow sensor ?</strong></td>
<td>Neonatal flow sensor not fitted in ventilation system and flow monitoring of expiratory flow sensor switched on.</td>
<td>Calibrate neonatal flow sensor, see page 12. Replace if necessary, see page 13, recalibrate. Connect sensor cable. Call DraegerService.</td>
</tr>
<tr>
<td><strong>Neo.flow sensor ?</strong></td>
<td>Neonatal flow sensor is not installed in the patient circuit.</td>
<td>Install neonatal flow sensor for ventilation in neonatal patient mode. Connect flow sensor lead cable.</td>
</tr>
<tr>
<td><strong>Psupp &gt; Tinsp</strong></td>
<td>Only in neonatal service range: The PS phase was deactivated by a time limit.</td>
<td>For all devices from SW 4.10: This message is not generated during Ventilation with Pressure support in PCV+, SIMV or MMV.</td>
</tr>
</tbody>
</table>
Technical Data

for neonatal mode, supplements technical data in the Evita 4 and Evita 2 dura Operating Instructions, respectively.

Performance Characteristics

Control principle
Base flow with demand system, pressure-controlled with or without volume guarantee, time-controlled

Base flow
- For all devices up to SW 4.0: 6 L/min
- For all devices from SW 4.10: 6 L/min (this can be changed by DrägerService to 9 L/min)

Base flow during nebulizing: 9 L/min

Insp. flow: up to 30 L/min

Exp. flow (measuring range): up to 30 L/min

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/min, 10 to 150/min
- Resolution: 0.5/min, 1/min

Inspiratory time Tinsp (CPAP, CPAP/ASB)
- Range: 0.1 to 1 sec., 1 to 10 sec.
- Resolution: 0.05 sec., 0.1 sec.

Measured Value Displays

Flow measurement (with neonatal flow sensor)
- Range: 0.25 to 30 L/min

Minute volume MV (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
- To...90 approx. 35 s

* BTPS = Body Temperature, Pressure, Saturated.

Measured values based on the conditions at the patient’s lung
Body temperature 37 °C, gas saturated with water vapor, airway pressure.
Technical Data

Monitoring

Spontaneously minute volume $MV_{spon}$

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
<th>Resolution</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>not leak compensated</td>
<td>0 to 9.9 L/min, BTPS*</td>
<td>0.01 L/min</td>
<td>greater of ±8 % of the measured value or 1 mL $f_{spon}$</td>
</tr>
<tr>
<td></td>
<td>10 to 99 L/min, BTPS*</td>
<td>0.1 L/min</td>
<td>approx. 35 s</td>
</tr>
</tbody>
</table>

Leakage flow $MV_{leak}$

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
<th>Resolution</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0 to 9.9 L/min, BTPS*</td>
<td>0.01 L/min</td>
<td>approx. 35 s</td>
</tr>
<tr>
<td></td>
<td>10 to 99 L/min, BTPS*</td>
<td>0.1 L/min</td>
<td></td>
</tr>
</tbody>
</table>

Tidal volume $V_{Te}$

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
<th>Resolution</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0 to 999 mL, BTPS*</td>
<td>0.1 mL</td>
<td>greater of ±8 % of the measured value or 1 mL</td>
</tr>
<tr>
<td></td>
<td>1000 to 4000 mL, BTPS*</td>
<td>10 mL</td>
<td></td>
</tr>
</tbody>
</table>

Tidal volume $V_{Ti}, V_T$

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
<th>Resolution</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0 to 999 mL, BTPS*</td>
<td>0.1 mL</td>
<td>±8 % of the measured value or 1 mL, whichever is greater</td>
</tr>
<tr>
<td></td>
<td>1000 to 4000 mL, BTPS*</td>
<td>10 mL</td>
<td></td>
</tr>
</tbody>
</table>

Spontaneous breathing rate $f_{spon}$

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0 to 300 bpm</td>
<td>1 bpm</td>
</tr>
</tbody>
</table>

Monitoring

Expiratory minute volume $MV$

<table>
<thead>
<tr>
<th>Alarm, upper alarm limit</th>
<th>Range</th>
<th>Resolution</th>
<th>when the upper alarm limit is exceeded.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.1 to 0.99 L/min</td>
<td>0.01 L/min</td>
<td>1 to 41 L/min</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Alarm, lower alarm limit</th>
<th>Range</th>
<th>Resolution</th>
<th>when the value drops below the lower alarm limit.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.01 to 0.99 L/min</td>
<td>0.01 L/min</td>
<td>1 to 40 L/min</td>
</tr>
</tbody>
</table>

Volume monitoring

<table>
<thead>
<tr>
<th>Alarm, upper alarm limit</th>
<th>Range</th>
<th>Inspiration is interrupted and the expiratory valve opened when the applied tidal volume exceeds the upper alarm limit.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4 to 4000 mL</td>
<td></td>
</tr>
</tbody>
</table>

Rapid shallow breathing

<table>
<thead>
<tr>
<th>Alarm</th>
<th>Range</th>
<th>When the measured spontaneous breathing rate $f_{spon}$ exceeds the alarm limit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5 to 120 bpm</td>
<td></td>
</tr>
</tbody>
</table>

* BTPS = Body Temperature, Pressure, Saturated.
Measured values based on the conditions at the patient’s lung
Body temperature 37 °C, gas saturated with water vapor, airway pressure.
## Materials Used

<table>
<thead>
<tr>
<th>Part</th>
<th>Appearance</th>
<th>Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neonatal flow sensor</td>
<td>yellowish, transparent</td>
<td>polysulphone</td>
</tr>
<tr>
<td>Neonatal flow sensor</td>
<td>yellowish, transparent</td>
<td>polysulphone</td>
</tr>
<tr>
<td>housing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neonatal flow sensor</td>
<td>gray</td>
<td>polyurethane</td>
</tr>
<tr>
<td>cable</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Special Features of Neonatal Ventilation

Measurement of Leak Flow

A small amount of respiratory gas almost always escapes between trachea wall and endotracheal tube when ventilating neonates and infants with uncuffed tubes. This flow is termed the leak flow.

Model for determining the leak flow:

The proximal (neonatal) flow sensor at the wye is located upstream of the leak. During inspiration, it measures both the leak 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 leak flow escapes during expiration, the amount measured will be 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 contributes to ventilation. The measured value for leak displayed by Evita 4 and Evita 2 dura is the mean leak 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:

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

where

- $MV_{Patient}$: Minute volume of the patient
- $MV$: Expiratory minute volume without correction for leak
- $MV_{Leak}$: Mean leak flow

Evita 4 and Evita 2 dura incorporate the calculated leak flow in the displayed values of $VTi$ and $Flow$. For this purpose, the leak flow at each moment is calculated as a function of the actual airway pressure:

$$ Flow_{Leak} = MV_{Leak} \times \frac{P_{aw}}{P_{mean}} $$

where

- $Flow_{Leak}$: Actual leak flow
- $MV_{Leak}$: Leak minute flow - mean leakage flow, averaged over inspiration and expiration
- $P_{aw}$: Airway pressure at the wye
- $P_{mean}$: Mean airway pressure at the wye
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:
\[ \text{Flow}_{\text{Patient, exp}} = \text{Flow}_{\text{exp}} \]
\[ V_{\text{Te}} = \int \text{Flow}_{\text{Patient, exp}} \, dt \]

- \text{Flow}_{\text{Patient}}: Actual patient flow, corrected for leaks
- \text{Flow}_{\text{insp}}: Actual inspiratory flow, not corrected for leaks
- \text{Flow}_{\text{exp}}: Actual expiratory flow, not corrected for leaks
- \text{Flow}_{\text{Leak}}: Actual leakage flow
- \text{V}_{\text{Ti}}: Inspiratory tidal volume
- \text{V}_{\text{Te}}: Expiratory tidal volume
- \text{MV}_{\text{Leak}}: Mean leak flow, averaged over inspiration and expiration
Measurement of Airway Pressure

Evita 4 and Evita 2 dura measure airway pressure indirectly by means of two internal pressure sensors in the ventilator. These pressure sensors are installed in the inspiratory and expiratory lines, thereby eliminating the need for an external pressure measuring line between the wye and the ventilators. As long as one side is without flow, the pressure measured by the pressure sensor in the zero-flow line corresponds to the airway pressure at the wye.

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

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

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

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

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

$P_{\text{aw}}$ : Airway pressure at the wye
$P_{\text{exp}}$ : 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.

Evita 4 and Evita 2 dura determine patient circuit resistances during the ventilator check.
Trigger Response

In neonatal mode, Evita 4 and Evita 2 dura detect 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, Evita 4 and Evita 2 dura not only take 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 (P_{aw}):

\[ \text{Flow}_{\text{Patient,insp}} = \text{Flow}_{\text{insp}} - \text{MV}_{\text{Leak}} \times \frac{\text{P}_{\text{aw}}}{\text{P}_{\text{mean}}} \]

- **Flow}_{\text{Patient,insp}}**: Patient flow
- **Flow}_{\text{insp}}**: Inspiratory flow without correction for leak
- **MV}_{\text{Leak}}**: Leak minute volume - mean leak flow, averaged over inspiration and expiration
- **P}_{\text{aw}}**: Airway pressure at the wye
- **P}_{\text{mean}}**: Average airway pressure at the wye

Spontaneous inspiration is only 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 is inoperable while in neonatal mode, Evita 4 and Evita 2 dura can no longer detect attempts of 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 with an intact neonatal flow sensor in the circuit.

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 \( \text{Paw}^\text{W} \) must always be set, so that a warning is triggered if the 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. The minimum inspiratory pressure \( P_{\text{insp}} \) corresponds to the value calculated from the tidal volume \( V_T \) and compliance \( C \) of the lung.

The volume required to calculate inspiratory pressure is derived from the measurement obtained by the neonatal flow sensor proximal to 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.

Inspiratory flow is automatically controlled so that there is no pressure peak caused by ET-tube and airway resistance. The plateau pressure \( P_{\text{plat}} \) is allowed to fluctuate with changes in compliance \( C \), as is common with all constant volume ventilator breaths. With AutoFlow, these fluctuations occur in increments with a maximum of 3 cmH₂O between ventilator breaths.

If tidal volume \( V_T \) is reached (inspiratory flow = 0) before inspiratory time \( T_{\text{insp}} \) has fully elapsed, the control system for the inspiratory and expiratory valves ensures that the patient can breathe in and out during the remaining inspiratory time, even during the constant pressure plateau \( P_{\text{plat}} \).

If the patient breathes in or out during mandatory inspiration, the plateau pressure \( P_{\text{plat}} \) is not changed for the duration of this ventilator breath: only inspiratory and expiratory flow are adapted to the patient’s demand. The applied tidal volume \( V_T \) may differ 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.
Overshoot in tidal volume VT can be limited by the alarm limit \( VT_{\text{ti}} \). If the set alarm limit is exceeded once, Evita 4 and Evita 2 dura will generate an advisory (!) message; if the limit is exceeded three times, the ventilators will generate a warning (!!!). Tidal volume is actively limited to the value of the alarm limit \( VT_{\text{ti}} \) 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 this case, it needs to be decided whether the current patient condition permits extending inspiratory time in order to reduce inspiratory pressure even further.

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 \( Paw_{\text{ti}} \). The pressure rise is held to 5 cmH2O below the alarm limit \( Paw_{\text{ti}} \). The "Volume not constant" alarm will only become active when the set tidal volume VT is no longer fully applied.

The start of a mandatory inspiration can be synchronized with a patient’s own efforts using the adjustable flow trigger. Only while in CMV mode can the flow trigger be completely switched off (CMV Assist -> CMV).

The steepness of the pressure rise from PEEP level to the inspiratory level can be even more closely adapted to the needs of the patient by adjusting pressure rise time \( \text{Ramp} \) (Evita 4) or \( \text{Ramp} \) (Evita 2 dura), respectively.

**Initial response of AutoFlow in neonatal mode**

When activating a volume controlled ventilation mode, Evita 4 and Evita 2 dura will initially apply a test breath with an inspiratory pressure 5 cmH2O greater than PEEP. This test breath is used by Evita 4 and Evita 2 dura to calculate inspiratory pressure for the next inspiration. However, with the inspiration of the second breath, Evita 4 and Evita 2 dura only apply 75 % of the previously calculated inspiratory pressure, in order to verify the first result and to calculate a new inspiratory pressure. From the third breath on, Evita 4 and Evita 2 dura set the inspiratory pressure as calculated. All further adjustments of the inspiratory pressure are limited to \( \pm 3 \text{ cmH}2\text{O} \).
### Glossary

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>f</td>
<td>Mechanical ventilator rate (setting)</td>
</tr>
<tr>
<td>fspn</td>
<td>Spontaneous breathing rate (measured value)</td>
</tr>
<tr>
<td>Flow</td>
<td>Displayed real-time waveform, patient flow (measured value), with correction for leak</td>
</tr>
<tr>
<td>Flow\textsubscript{out}</td>
<td>Flow through the expiratory valve during inspiration</td>
</tr>
<tr>
<td>Flow\textsubscript{bf}</td>
<td>Base flow 6 L/min (system setting), see technical data page 31.</td>
</tr>
<tr>
<td>Flow\textsubscript{insp}</td>
<td>Inspiratory flow, without correction for leak</td>
</tr>
<tr>
<td>Flow\textsubscript{exp}</td>
<td>Expiratory flow, without correction for leak</td>
</tr>
<tr>
<td>Flow\textsubscript{leak}</td>
<td>Actual leak flow</td>
</tr>
<tr>
<td>Flow\textsubscript{Patient}</td>
<td>Inspiratory/expiratory flow (measured value), with correction for leak</td>
</tr>
<tr>
<td>MV</td>
<td>Expiratory minute volume (measured value), without correction for leak</td>
</tr>
<tr>
<td>MV\textsubscript{leak}</td>
<td>Leak minute volume: mean leak flow, averaged over inspiration and expiration (measured value)</td>
</tr>
<tr>
<td>MV\textsubscript{Patient}</td>
<td>Expiratory measured minute volume, with correction for leak</td>
</tr>
<tr>
<td>Paw</td>
<td>Airway pressure at the wye (measured value)</td>
</tr>
<tr>
<td>P\textsubscript{exp}</td>
<td>Airway pressure in the expiratory limb of the patient circuit</td>
</tr>
<tr>
<td>P\textsubscript{mean}</td>
<td>Mean airway pressure at the wye (measured value)</td>
</tr>
<tr>
<td>R\textsubscript{exp}</td>
<td>Flow resistance of the expiratory limb of the patient circuit</td>
</tr>
<tr>
<td>R\textsubscript{insp}</td>
<td>Flow resistance of the inspiratory limb of the patient circuit</td>
</tr>
<tr>
<td>Tapnea</td>
<td>Apnea time (setting)</td>
</tr>
<tr>
<td>VT</td>
<td>Tidal volume (setting)</td>
</tr>
<tr>
<td>VT\textsubscript{i}</td>
<td>Inspiratory tidal volume (measured value)</td>
</tr>
<tr>
<td>VT\textsubscript{e}</td>
<td>Expiratory tidal volume (measured value)</td>
</tr>
</tbody>
</table>
### Ordering Information

<table>
<thead>
<tr>
<th>Item/Description</th>
<th>Part No.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Kit Option NeoFlow</strong>  for retrofitting on site</td>
<td>84 13 563</td>
</tr>
<tr>
<td>consists of:</td>
<td></td>
</tr>
<tr>
<td>&quot;Pediatric Flow&quot; extension PCB</td>
<td></td>
</tr>
<tr>
<td>Neonatal flow sensor cable</td>
<td></td>
</tr>
<tr>
<td>Reusable flow sensor housing ISO 15</td>
<td></td>
</tr>
<tr>
<td>Neonatal flow sensor element, 5 pack</td>
<td></td>
</tr>
<tr>
<td><strong>Option NeoFlow</strong>  factory installed option</td>
<td>84 13 785</td>
</tr>
<tr>
<td>consists of:</td>
<td></td>
</tr>
<tr>
<td>&quot;Pediatric Flow&quot; extension PCB</td>
<td></td>
</tr>
<tr>
<td>Neonatal flow sensor cable</td>
<td></td>
</tr>
<tr>
<td>Reusable flow sensor housing ISO 15</td>
<td></td>
</tr>
<tr>
<td>Neonatal flow sensor element, 5 pack</td>
<td></td>
</tr>
<tr>
<td><strong>Replacement Parts:</strong></td>
<td></td>
</tr>
<tr>
<td>Connecting cable for flow sensor</td>
<td>84 09 626</td>
</tr>
<tr>
<td>Neonatal flow sensor ISO 15 (sensor housing with one flow sensor element)</td>
<td>84 11 130</td>
</tr>
<tr>
<td>Neonatal flow sensor element, 5 pack</td>
<td>84 10 179</td>
</tr>
<tr>
<td>&quot;Water trap&quot; kit for expiratory valve</td>
<td>84 13 125</td>
</tr>
<tr>
<td>Pediatrics cuvette for CO₂ measurement</td>
<td>68 70 280</td>
</tr>
<tr>
<td>Corrugated patient circuit segment (reusable) 0.13 m</td>
<td>84 09 634</td>
</tr>
</tbody>
</table>
## Index

<table>
<thead>
<tr>
<th>Topic</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbreviations</td>
<td>40</td>
</tr>
<tr>
<td>Advisory message</td>
<td>30</td>
</tr>
<tr>
<td>Airway pressure</td>
<td>36</td>
</tr>
<tr>
<td>Alarm limits</td>
<td>18</td>
</tr>
<tr>
<td>Apnea ventilation</td>
<td>17</td>
</tr>
<tr>
<td>AutoFlow®</td>
<td>38</td>
</tr>
<tr>
<td>Back-up ventilation</td>
<td>16</td>
</tr>
<tr>
<td>Calibrating</td>
<td>12</td>
</tr>
<tr>
<td>Care</td>
<td>27</td>
</tr>
<tr>
<td>Caution message</td>
<td>30</td>
</tr>
<tr>
<td>Cleaning</td>
<td>27</td>
</tr>
<tr>
<td>Configuring ventilation</td>
<td>24</td>
</tr>
<tr>
<td>Default values, at start-up</td>
<td>24, 26</td>
</tr>
<tr>
<td>Disinfecting</td>
<td>27</td>
</tr>
<tr>
<td>First use</td>
<td>10</td>
</tr>
<tr>
<td>Flow monitoring</td>
<td>18, 19</td>
</tr>
<tr>
<td>Flow sensor, calibrating</td>
<td>12</td>
</tr>
<tr>
<td>Flow sensor, installing</td>
<td>10</td>
</tr>
<tr>
<td>Flow sensor element, exchanging</td>
<td>13</td>
</tr>
<tr>
<td>Glossary</td>
<td>40</td>
</tr>
<tr>
<td>Index</td>
<td>42</td>
</tr>
<tr>
<td>Intended use</td>
<td>9</td>
</tr>
<tr>
<td>Leak flow</td>
<td>34</td>
</tr>
<tr>
<td>Materials</td>
<td>33</td>
</tr>
<tr>
<td>Medication, nebulizing</td>
<td>20</td>
</tr>
<tr>
<td>Nebulizing Medication Aerosols</td>
<td>14</td>
</tr>
<tr>
<td>Neonatal mode</td>
<td>14</td>
</tr>
<tr>
<td>Neonatal ventilation</td>
<td>18, 19</td>
</tr>
<tr>
<td>Operation</td>
<td>14</td>
</tr>
<tr>
<td>Ordering information</td>
<td>41</td>
</tr>
<tr>
<td>Oxygenation for bronchial suction</td>
<td>23</td>
</tr>
<tr>
<td>Patient range</td>
<td>24</td>
</tr>
<tr>
<td>Pediatric ventilation</td>
<td>19</td>
</tr>
<tr>
<td>Preparation</td>
<td>10</td>
</tr>
<tr>
<td>Pressure Support</td>
<td>16</td>
</tr>
</tbody>
</table>

### Safety
- Sterilizing: 27

### Technical data
- Trigger response: 37
- Troubleshooting: 30

### Ventilation parameters
- Volume controlled ventilation: 15

### Warning message
- 30
These Instructions for Use apply only to Evita 4 or Evita 2 dura 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.