

# MONIVENT NEO100

## USER MANUAL

### N100-SY





## Manufacturer



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## Trademark

Monivent® is a registered trademark of Monivent AB, Sweden.

## Declaration of Conformity



Monivent Neo100 conforms to European Medical Directive 93/42/EEC and meets applicable health, safety and environmental requirements. The number in conjunction with the CE-mark, is the identification number of the notified body involved in the conformity assessment procedure.

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# 1. INTRODUCTION

The Monivent Neo100 is a monitoring device designed to provide continuous, real-time feedback and guidance on several parameters, to support the gentle and effective ventilation of newborns in need of respiratory support at birth. The system shall be used to support decisions and as an adjunct to the established assessments of neonatal resuscitation.

## 1.1 INTENDED USE

The Monivent Neo100 is intended to provide guidance on expiratory tidal volume and monitoring of peak inspiratory pressure, positive end-expiratory pressure, mask leakage and ventilation rate, during treatment of newborns in need of ventilation using a bag resuscitator or T-piece resuscitator. The system is intended for use by medically qualified personnel.

## 1.2 INFORMATION FOR SAFE USE

Throughout the manual, important information for a safe use of the product is indicated with "WARNING" and "CAUTION".

**WARNING** – used to indicate a potentially hazardous situation which, if not avoided, could result in death or serious injury.

**CAUTION** – used to indicate a potentially hazardous situation which, if not avoided, could result in minor or moderate injury.

## 1.3 INFORMATION FOR EFFECTIVE USE

**NOTE** – used to indicate a point of particular interest or emphasis and intended to provide for a more efficient or convenient operation.

## 1.4 CONTRAINDICATIONS

- Monivent Neo100 is only intended for short-term use and is not intended for continuous monitoring.
- Monivent Neo100 shall not be used on patients other than newborns.

## 1.5 SYSTEM OVERVIEW

The Monivent Neo100 system comprises of a Monitor (display and charger) and Sensor Modules integrated into a single-use Sensor Mask or Mask Adapter. The system enables wireless measurement of ventilation parameters through the Sensor Mask and integrated Sensor Module.

The Monivent Neo100 system is an add-on to existing equipment used for manual ventilation and is compatible with all bag and T-piece resuscitators utilizing standard ISO 5356-1 15 mm female connection.



The Monitor displays Expiratory Tidal Volume ( $VTe$ ) graphically and numerically, and Peak Inspiratory Pressure (PIP), Positive End-Expiratory Pressure (PEEP), mask leakage (LEAK) and ventilation rate (RATE) numerically, in real time. The Monitor also incorporates the charger for the three Sensor Modules which are connected magnetically. The touch screen is operable with disposable gloves.

Sensor Masks are provided in three different sizes.

If ventilating with an endotracheal tube, supraglottic airway or with face masks other than Monivent's Sensor Masks, a Mask Adapter must be inserted between the endotracheal tube/supraglottic airway/face mask and the bag or T-piece resuscitator. The Mask Adapter is compatible with endotracheal tubes, supraglottic airways and face masks utilizing standard ISO 5356-1 15 mm male connection with a minimum inner diameter of 7 mm.



The Sensor Mask and Mask Adapter form part of the measuring unit together with the Sensor Module. The Sensor Mask and Mask Adapter are single use to ensure measurement accuracy and to avoid cross contamination. The Sensor Mask and Mask Adapter contain a filter to protect the Sensor Module from potential contaminants.

**WARNING** – Only use Monivent AB original parts or connecting parts that have been specified as compatible with the system supplied by Monivent AB.

**WARNING** – If Monivent Neo100 is to be used with a humidifier, the following conditions should be met:

- The humidification chamber temperature should be  $<38^{\circ}\text{C}$
- The humidifier should not be connected to the Sensor Mask/Mask Adapter prior to commencing ventilation
- The ambient temperature should be  $>25^{\circ}\text{C}$
- The baby should be  $\leq 32$  weeks gestation
- The humidifier should be used in accordance with the manufacturer's instructions for use to reduce condensation forming in the breathing circuit

Failure to adhere to the above conditions may affect tidal volume measurement accuracy.



## 1.6 PRINCIPLES OF OPERATION

The Sensor Mask and Mask Adapter has a fixed constriction that generates a differential pressure relative to the flow through the Sensor Mask or Mask Adapter. The Sensor Module measures the differential pressure during ventilation and converts it to flow from which the tidal volume is calculated. An algorithm detects the beginning and end of each ventilation cycle and calculates the ventilation parameter values. The displayed parameters are VTe, PIP, PEEP, LEAK and RATE. The parameters are wirelessly transmitted and displayed on the display after each ventilation cycle.

## 1.7 COMPLAINTS AND SERIOUS INCIDENT REPORTING

Medical device adverse event reporting is an essential activity for mitigating device-related risks. At Monivent we strive to provide products that are safe, compliant, easy-to-use, reliable and effective. If you have experienced a potential adverse event or suspected side effect when using our product, it is vital that you tell us about it as soon as you can. For product related complaints, please contact your local Monivent representative.

In the event of any serious incident that would occur in relation to usage of Monivent Neo100, it should be reported to Monivent and local competent authority of the Member State where you are located.

### **How to report**

For any product complaints, please contact your local Monivent representative.

For any adverse event please contact Monivent at **vigilance@monivent.se** and provide details on date of event, description of event, name of reporter and other contact details.

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## 2. SETUP

### 2.1 DELIVERY ITEMS

The Monivent Neo100 system is supplied in a box containing the following items:

- User Manual
- Monitor
- Power supply
- Sensor Modules (3 pcs)
- Mask Adapter (10 pcs)
- Screws for mounting the Monitor
- Stickers with the Sensor Modules' serial numbers  
(can be placed on charger if needed)

Ensure the outer package for the individually packed Mask Adapters is intact. Discard product if package shows signs of damage.

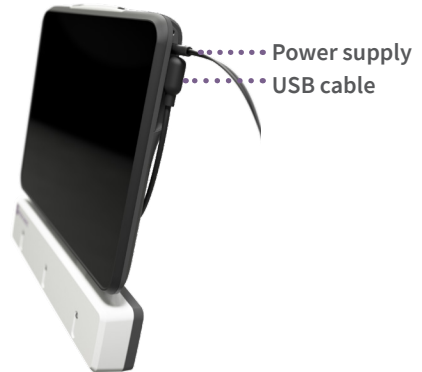
The Mask Adapter is made of polypropylene.

## 2.2 SETTING UP

- 1 The Monitor should be mounted adjacent to a resuscitation table intended for stabilization of newborns, using the standard VESA MIS-D (75 × 75 mm) mount interface. Mounting screws are provided for connector of choice.



- 2 Connect the Monitor to a power outlet using the power supply provided. Ensure the USB cable between the charger and the display is properly connected.



- 3 Switch the Monitor on by pressing the power button at the top of the display for two seconds. After a minute the configuration screen will appear.



## 2.3 CHARGING THE SENSOR MODULES

Place the Sensor Modules in the charger. Whilst the Sensor Modules are in the charger, the LED will indicate charging status:

- Charging – Pulsing red-green
- Fully charged – Steady green



Full charging takes a maximum of 3 hours. The battery life of the Sensor Module during use is at least 1 hour.

When placed in the charger the Sensor Modules may be pre-assembled with Sensor Masks.



**CAUTION** – Do not touch inside the charging slots.

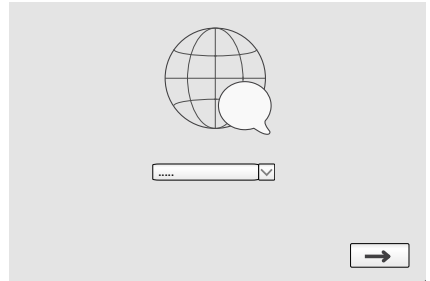
## 2.4 SYSTEM CONFIGURATION

When the Monitor is turned on for the first time the configuration view appears prompting the user to set language, region, regional format, time zone, current time and tidal volume target.

### Set language

Set the language from options in a droplist.

If language needs to be changed after the initial setup, press and hold the CONFIGURATION menu button until the language setup screen appears.



### Set region and regional format

Set the region by selecting an option in the drop-down list. The region represents where the Monivent Neo100 system is located.

Set the regional format. The regional format will control how dates and numbers are presented. An example using the set format is presented under the regional format drop-down.



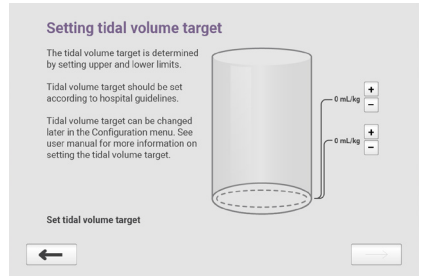
### Set date, time and time zone

Set the time zone where the Monivent Neo100 is located. Set the date and time to the current date and time.



## Set tidal volume target

Tidal volume target should be set according to hospital guidelines. Measured volumes within the target range will be indicated by a green color on the cylindrical display and green LED on the Sensor Module. The green color is used to guide the operator in delivering appropriate tidal volumes.



Set the upper and lower limits for the tidal volume target using the + and – symbol.

The upper and lower limits of the tidal volume target need to be set before proceeding to the next step in the configuration procedure.

Set tidal volume target can be changed after the initial setup in the CONFIGURATION menu.

## Pairing Sensor Modules to Monitor

The Sensor Modules need to be paired to the Monitor, to enable connection and data transmission. See further instructions on how to pair Sensor Modules in section "3.11 Configuration menu – Pair Sensor Modules".

## 2.5 FUNCTIONALITY CHECK

Complete the list in section "4.6 Functionality check" as the final step of the setup procedure for a new system.

# 3. USAGE

## 3.1 STAND-BY MODE

The Monitor should be connected to a power outlet using the power supply provided and left on at all times. One hour after last use the display will automatically turn off into stand-by mode. Press the power button swiftly to wake the display from stand-by mode.

The Sensor Modules should be placed in the charger when not used, otherwise batteries may deplete and the device may be unavailable for use. The LEDs are constantly green (fully charged) or alternating between green and red (charging) when the monitor is in stand-by mode.

**NOTE** – If the Sensor Modules are blinking blue or turned off while in the charger, assure the Monitor is powered on and connected to a power outlet.

## 3.2 CONNECTING SENSOR MODULE TO SENSOR MASK

Insert Sensor Module into Sensor Mask or Mask Adapter by holding Sensor Module with the LED facing up. Align the black markings on the Sensor Module and Sensor Mask or Mask Adapter then push the Sensor Module in and turn clockwise until it stops.

The system is designed to allow Sensor Modules and Sensor Masks or Mask Adapters to be pre-assembled prior to use, when placed in the charger.



**NOTE** – The Sensor Masks and Mask Adapter are not intended to be used without having a Sensor Module attached. Use without a Sensor Module attached will cause a minor leakage in the system.

### 3.3 START NEW FEEDBACK SESSION

To initiate a new session, follow the steps below:

- 1 Remove a Sensor Module from the charger and attach to a Sensor Mask of appropriate size.

If the Sensor Module is pre-assembled with a Sensor Mask, remove the Sensor Module and Sensor Mask assembly from the charger.

The newborn's weight can be entered before or after ventilation commences (see step 4–5).



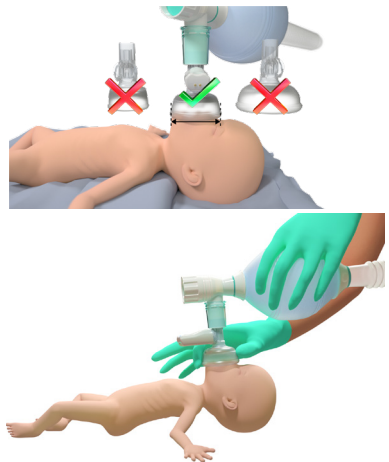
- 2 Connect the Sensor Mask and Sensor Module assembly to a bag or T-piece resuscitator.



- 3 Apply the mask, covering the nose and mouth of the newborn, without covering the eyes or overlapping the chin, to make a firm seal.

Begin ventilation in accordance to local, clinical guidelines.

If the weight has been entered before the ventilation started, the clock starts counting at the first ventilation.

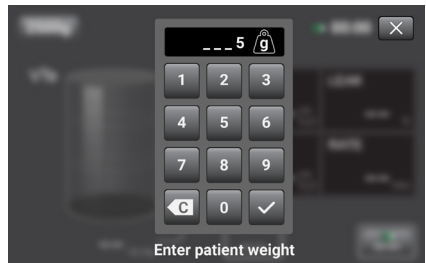




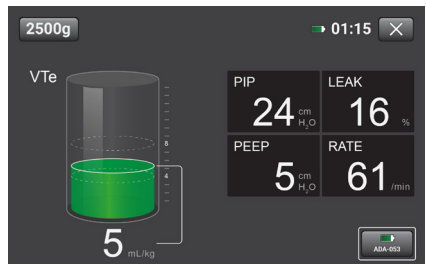
- 4 Select “GO” on the display to start a new session.



- 5 Enter estimated weight of the newborn in grams followed by “OK”.



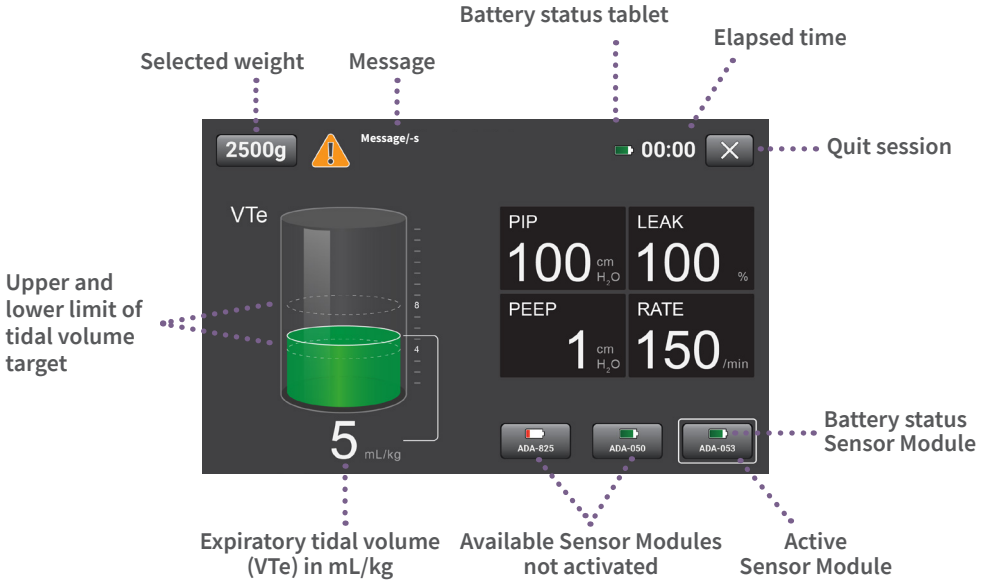
- 6 When a weight is entered, the display automatically changes to the feedback view.



**WARNING** – The Sensor Mask and Mask Adapter needs to be exchanged if there is blood, vomit or meconium in the flow path of the Sensor Mask and Mask Adapter, to reduce the risk of incorrect measurements.

**NOTE** – Monivent Neo100 is used for guidance. Clinical judgement shall be used for regular assessment of the patient's condition.

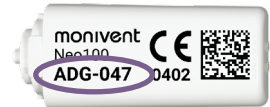
### 3.4 FEEDBACK VIEW



#### Available Sensor Modules

When a Sensor Module is removed from the charger it becomes available for use and an icon is displayed with the corresponding serial number in the lower right corner. The icon for the activated Sensor Module is highlighted with a white border. To make one of the other available Sensor Modules active, touch the corresponding icon.

The Sensor Modules are identified by their serial number.



**NOTE** – Only Sensor Modules paired to the Monitor appear as available (see section "3.11 Configuration menu – Pair Sensor Modules").

#### Change selected weight

The weight can be adjusted afterwards by touching the weight button in the upper left corner in feedback view.

## Feedback on ventilation

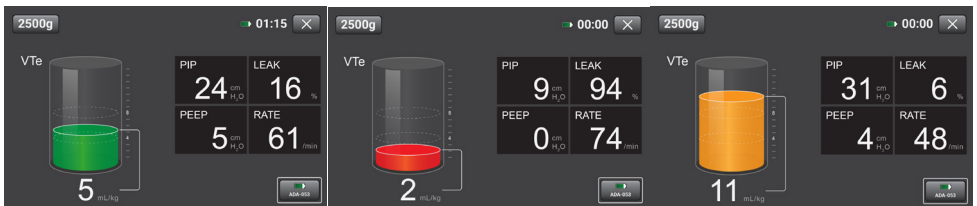
The feedback view displays the following ventilation parameters in real time.

Displayed parameter	Abbreviation	Unit
Expiratory Tidal Volume	VTe	mL/kg
Peak Inspiratory Pressure	PIP	cmH <sub>2</sub> O
Mask leakage	LEAK	Percent %
Ventilation rate	RATE	Ventilations/minute
Positive End-Expiratory Pressure	PEEP	cmH <sub>2</sub> O

All parameters are updated simultaneously on the display immediately after a ventilation cycle is registered.

## Tidal volume guidance

The expiratory tidal volume (VTe) is presented both graphically and numerically, in mL/kg based on the selected weight. The amount the cylinder fills reflects the VTe of each inflation. The color of the cylinder and the LED on the Sensor Module change to indicate how the delivered tidal volume relates to the tidal volume target. When the VTe is within the defined target range the cylinder and LED on the Sensor Module displays green. When below, they are red and when above they are orange.

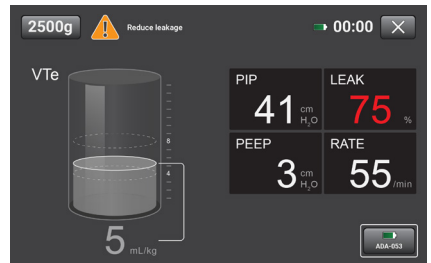


The graphical cylinder has a maximum displayed value at 2× the upper limit of the tidal volume target in mL/kg. If expiratory tidal volumes exceed this value, the tidal volume will be graphically displayed as a full cylinder.

## Too high leakage

High mask leakage may affect tidal volume measurement accuracy with an underestimation of the value. High leakage is indicated by:

- flashing leakage value in red
- tidal volume cylinder and value in gray
- LED on the Sensor Module flashing red/green/orange
- message "Reduce leakage" appearing on the display.



Adjust the mask position or change to a different mask size to reduce leakage.

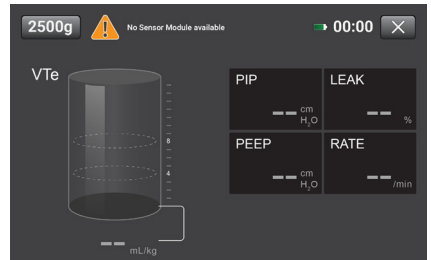
**WARNING** – High mask leakage may affect tidal volume measurement accuracy.

## 3.5 DISCONNECTION DURING PROCEDURE

If an active Sensor Module loses connection, information can no longer be updated on the display.

If the Sensor Module continues to function and change color on the LED to indicate how the tidal volume corresponds to the target, keep ventilating and connection will be re-established.

If the disconnection is permanent or the Sensor Modules is defective, replace the Sensor Module. The new Sensor Module will be activated upon the first registered ventilation.



## 3.6 LED ON SENSOR MODULE


### During ongoing session

LED on Sensor Module	Description
Flashing blue	Waiting to connect to Monitor
Steady blue	Connected, awaiting weight
Steady white	Connected and inactive (if another Sensor Module active) No new ventilation detected during the last 5 seconds
Steady green	VTe within target range
Steady red	VTe below target range
Steady orange	VTe above target range
Flashing red / green / orange	Pay attention to message on display


### While charging

LED on Sensor Module	Description
Pulsing red-green	Charging
Steady green	Fully charged
Flashing red	Error

## 3.7 QUIT FEEDBACK SESSION

To quit a session, press  button to return to the start screen. Disconnect the Sensor Module from the Sensor Mask or Mask Adaptor by turning anti-clockwise and removing. Clean Sensor Module according to instruction and return Sensor Module to the correct Monitor. Dispose of Sensor Mask or Mask Adaptor according to local guidelines.

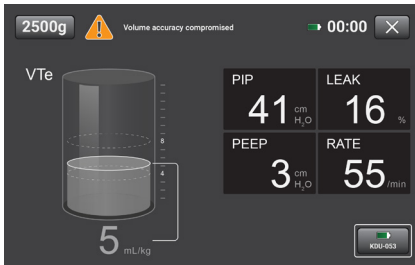
### 3.8 MESSAGES IN FEEDBACK VIEW

Messages displayed during an ongoing session appear next to the  symbol on the top of the display.

Message	LED	Description and recommended use action
Reduce leakage	Flashing red/green/orange	High leakage may cause reduced volume measurement accuracy. Reduce leakage by changing mask position or mask size.
Leakage measurement compromised	Not affected	The measured inflation flow is outside specified range of the sensor (too high flow). Leakage measurement accuracy may be compromised.
Volume accuracy compromised	Flashing red/green/orange	The measured expired flow is outside specified range of the sensor (flow too high). Measured tidal volume may be underestimated.
Pressure accuracy compromised	Not affected	The measured pressure is outside specified range of the sensor. Measured PIP and PEEP may be compromised.
Remove Sensor Module from charger	—	A Sensor Module is not yet available after the weight has been entered. Remove a Sensor Module from the charger to receive feedback on display.
No Sensor Module available	Not affected	Connection to the Sensor Module is temporarily lost. Continue ventilating as usual. The measurement functionality of the Sensor Module remain unaffected. The message disappears once the connection is re-established. If connection is not re-established within 5 seconds, replace Sensor Module.
LED defective	Disabled	LED on Sensor Module is defective and disabled. Data is transmitted and displayed on display. Replace Sensor Module to regain guiding light.

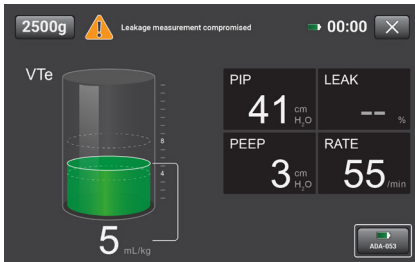
### 3.9 COMPROMISED MEASUREMENT ACCURACY

In certain situations, the accuracy of a measured parameter may be compromised. This is indicated as follows:



If measurement accuracy for tidal volume is reduced, tidal volume cylinder and value are displayed in gray.

LED flashes red/green/orange.




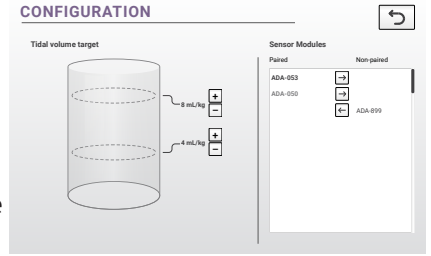
If measurement accuracy for leakage is reduced, the leakage value is replaced with --.

LED is not affected.



**NOTE** – In the absence of positive pressure ventilation patient effort and artifacts affecting patient flow or pressure, such as movement of patient tubing or mask or intermittent leakage, may cause the system to display values that shall be disregarded.

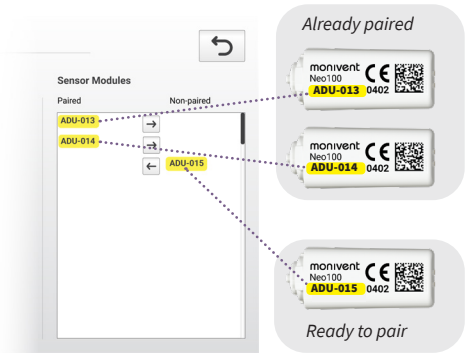
### 3.10 CONFIGURATION MENU – CHANGE TIDAL VOLUME TARGET

Go to the CONFIGURATION menu via the  symbol on the start screen. Use the + and – symbols to change the upper and lower limit of the tidal volume target. The target determines the range within which the VTe cylinder in the feedback view and the LED on the Sensor Module will be green and shall be based on applicable clinical guidelines.



### 3.11 CONFIGURATION MENU – PAIR SENSOR MODULES

Go to the CONFIGURATION menu via the  symbol on the start screen. Remove the Sensor Modules to be paired from the charger. Click on the  symbol for the corresponding serial numbers in the list of available non-paired Sensor Modules. The Sensor Module is then transferred to the list of paired Sensor Modules and connection to the Monitor is enabled.




If a defective Sensor Module needs to be replaced the new Sensor Module must be paired to the Monitor. The defective Sensor Module can be moved from *Paired* to *Non-paired*.

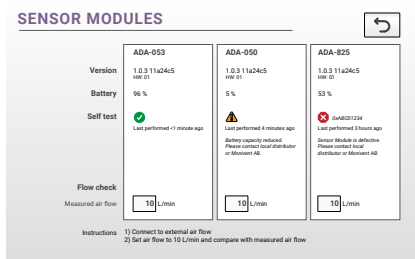
**NOTE** – The Monitor cannot receive and display data during an ongoing ventilation session from a Sensor Module which is not paired.

When using several systems in the same setting Sensor Modules could be mixed up. If needed, perform step 1 in section "4.6 Functionality check" to confirm that Sensor Modules are connected to the right monitor.




### 3.12 SENSOR MODULES MENU

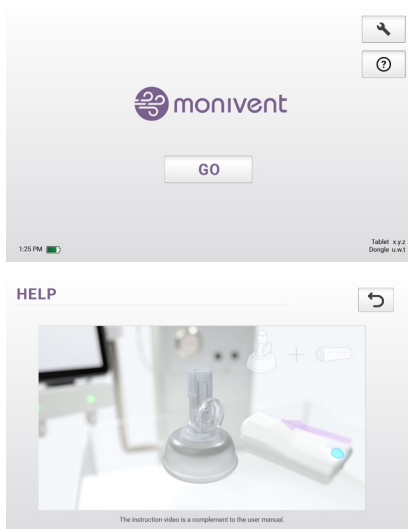
Access the SENSOR MODULES menu via the  symbol on the start screen. The Sensor Modules require no manual calibration, but an automatic zero level adjustment is performed every 5 minutes while in the charger. The system has a built-in self test performed on a regular basis, testing the sensors and battery status and ensuring that a zero-level adjustment has been performed. Sensor Module version, battery level and status of performed self test are shown in the SENSOR MODULES menu for Sensor Modules removed from charger. The flow check provides the possibility to test the flow measurement functionality (see section "4.6 Functionality check" for more detail).



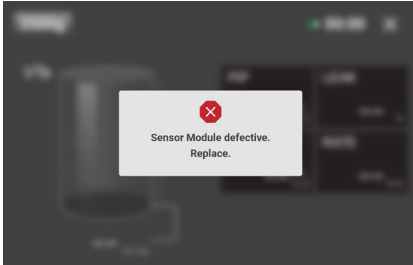
### 3.13 HELP MENU

Go to the HELP menu via the  symbol on the start screen to access a short instruction video.

The instruction video is a complement to the user manual. Consult Neo100 User Manual for more detailed instructions of use.



## 3.14 OTHER MESSAGES



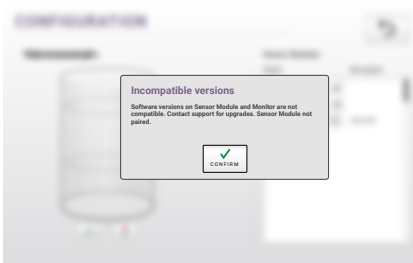
### Defective Sensor Module

The Sensor Module is defective and needs to be replaced with another Sensor Module. The message will disappear once connection is established to a new Sensor Module.



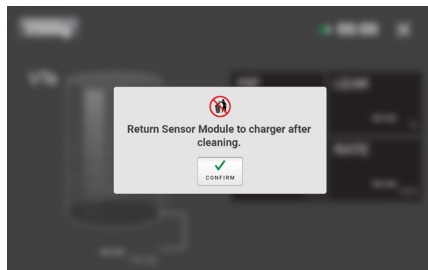
### Communication error

Ensure the USB cable is properly mounted. If issue remains, contact support.



### Incompatible versions

Software versions on Sensor Module and Monitor are not compatible. Contact support for upgrades. Sensor Module not paired.



### Return Sensor Module to charger after cleaning

Reminder to return Sensor Module to charging station after cleaning. The Sensor Modules are not disposables and should be returned to charging station after cleaning.

# 4. MAINTENANCE

## 4.1 CLEANING AND DISINFECTION

### Sensor Masks and Mask Adapters

Sensor Masks and Mask Adapters are designed for single use only. Dispose of single use items in accordance with local practices. Do not attempt to clean or reuse.

**WARNING** – Do not reuse the Sensor Mask or Mask Adapter. Cleaning and sterilizing may affect the measuring function causing measurement error.

### Sensor Modules and Monitor

The Sensor Modules shall be cleaned after each use, before returned to the charger, to prevent contamination. The Monitor should be cleaned on a regular basis in accordance with local hospital procedures.

**Cleaning agents:** Water, mild detergent, alcohol (20–70 %)

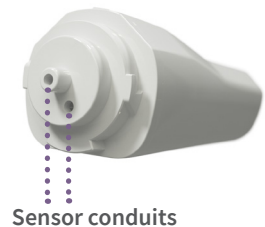
**Disinfectant:** Use 70% isopropyl alcohol or a commercial ‘70% V/V IPA disinfectant wipe’.

### Cleaning Sensor Modules

**1)** Clean all outer surfaces of the Sensor Modules with sanitizing wipes or a lightly damp cloth with cleaning agent. Care must be taken to avoid any particles or liquid entering the sensor conduits of the Sensor Module since this may damage the Sensor Module and affect the measurement accuracy.

**2)** Using disinfectant – wipe all outer surfaces of the Sensor Modules and let dry according to instructions from the manufacturer of the disinfectant.

**3)** Reassemble the system after cleaning by attaching the cleaned Sensor Modules to the correct Monitor. Charging is indicated by a pulsing red-green light.



## Cleaning Monitor

- 1) Clean all outer surfaces of the Monitor with sanitizing wipes or a lightly damp cloth with cleaning agent.
- 2) Using disinfectant – wipe all outer surfaces of the Monitor and charger and let dry according to instructions from the manufacturer of the disinfectant.
- 3) To clean inside the cavities of the charger, remove the USB cable from the display and remove the Sensor Modules. Lightly dampen a cotton swab with cleaning agent/ disinfectant and clean all surfaces inside the cavities. Re-attach USB cable.

**WARNING** – Do not autoclave, immerse or spray directly on Sensor Modules.

**NOTE** – Do not mix up Sensor Modules between systems. The Sensor Module will not be usable when it is not paired to the Monitor.

**NOTE** – When in doubt whether the Sensor Modules are connected to the right Monitor, step 1 in section "4.6 Functionality check" can be performed.

## 4.2 DISPOSAL

The single-use Sensor Mask and Mask Adapter should be disposed of according to local practices for disposal of infectious waste.

The Sensor Module and Monitor should be disposed of according to local practices for disposal of electronic waste.

## 4.3 CHARGING

The Monitor with Sensor Modules should remain on charge when not used. This ensures that the Monitor and Sensor Modules are always readily available for use. If the display is turned off the Sensor Modules will not charge. To maintain optimal performance regular restart of the Monitor every month is recommended. To maintain optimal battery capacity all Sensor Modules should be fully charged every third month.

## 4.4 STORAGE


To store the Monivent Neo100 system, turn the Monitor off and unplug the power supply. The Sensor Modules will turn off automatically. Charge the Monitor and Sensor Modules for at least one hour before use after storage.

## 4.5 PARTS AND ACCESSORIES

<b>Part</b>		<b>Reference number</b>
Neo100 Sensor Mask Starter Kit	2 × Sensor Mask 40 2 × Sensor Mask 52 2 × Sensor Mask 66 3 × Mask Adapter	N100-MA-SK
Neo100 Sensor Mask 40	× 10 pcs	N100-MA40-10
Neo100 Sensor Mask 52	× 10 pcs	N100-MA52-10
Neo100 Sensor Mask 66	× 6 pcs	N100-MA66-06
Neo100 Mask Adapter	× 10 pcs	N100-AD-10
Neo100 Sensor Module	× 1 pc	N100-SM-01
Neo100 Sensor Module	× 3 pcs	N100-SM-03

## 4.6 FUNCTIONALITY CHECK

Monivent AB recommends annual testing of the Monitor and Sensor Modules for continued suitability using the following list in line with local guidelines for maintenance of equipment used in the same environment.

<b>Steps</b>	<b>Expected Results</b>
1. Remove all Sensor Modules from the charger and go to the SENSOR MODULES menu via the  symbol on the start screen.	All Sensor Modules show up on the display with a serial number matching the serial numbers on the removed Sensor Modules.  If expected result is not achieved, check pairing described in section "3.11 Configuration menu – Pair Sensor Modules".
2. Observe the line “Self test” for each Sensor Module.	A green symbol appear for all Sensor Modules showing pass on the self test.
3. Connect each Sensor Module and Sensor Mask/Mask Adapter to a known flow (e.g. 10 L/min) and observe the line “Flow check ” for each Sensor Module.	The measured flow corresponds to the set flow.
If using a T-piece resuscitator to set the flow, make sure to cover the PEEP valve to direct the entire air flow through the Sensor Mask/MaskAdapter.	

# 5. SERVICE AND SUPPORT

## 5.1 WARRANTY

Monivent warrants the supplied product and accessories against defects in materials and workmanship for one (1) years from the date of purchase, when used and handled according to user instructions. Monivent's warranty does not cover normal wear and tear or damage caused by accident, misuse or negligence.

## 5.2 SERVICE LIFE

The Sensor Masks and Mask Adapters are single use only. The items have a shelf life of three years from date of manufacture.

Sensor Modules have an expected life time of two years.

## 5.3 SERVICE

Apart from the annual functionality test, Monivent Neo100 requires no periodic maintenance or service. For cleaning, see section 4.1. For functionality test, see section 4.6.

If any issues are experienced with the system, and the solution to the problem cannot be found in the troubleshooting guide in section 5.4, contact your local distributor or Monivent AB.

Never open any of the system parts. Any repairs must be done by the manufacturer or by authorized personnel. Failure to follow these operating instructions may void the manufacturer's warranty.

## 5.4 TROUBLESHOOTING

### Situation

### Cause and handling

The Sensor Module is not available in feedback view.

Make sure the Sensor Module is charged, removed from the charger and paired to the Monitor in the CONFIGURATION menu.

No LED on Sensor Module.

Battery discharged or Sensor Module is defective. Replace Sensor Module with new one from charger.

LED on Sensor Module is flashing in red/green/orange.

See Monitor display for additional information.

VTe cylinder and value displayed in gray.

VTe measurement accuracy may be compromised. See section "3.8 Messages in feedback view" for more information on when this can occur.

Leakage value replaced by --.

Leakage measurement accuracy may be compromised. See section "3.8 Messages in feedback view" for more info on when this can occur.

The Sensor Modules do not charge when placed in charger.

Make sure the USB cable between the display and the charger is properly attached and that the Monitor is connected to the power supply.

When attempting to pair Sensor Module to Monitor, the Sensor Module does not show up in the available list.


Make sure the Sensor Module is charged and removed from the charger to make it appear in the list of available Sensor Modules. See section "3.11 Configuration menu – Pair Sensor Modules" for more info.


Sensor Module flashing in red.


Sensor Module defective. If issue remains, contact your local distributor or Monivent AB.





## 6. SYMBOLS USED

 CE-mark and notified body identification number

 Consult instructions for use


 Number of pieces in package

 Manufacturer


 Do not re-use

 Use-by date


 Catalogue number

 Batch code

 Serial number

 Use with specified adapter


 Non-ionizing electromagnetic radiation

 Dispose of waste electrical and electronic equipment according to WEEE Directive

 Alternating current

 Direct current

 CLASS II equipment, double insulated

 Date of manufacture

 Medical Device

 Regulatory Compliance Mark (Australia and New Zealand)

# 7. SPECIFICATIONS

## Sensors

Flow sensor	Differential pressure pneumotachograph
Pressure sensor	Barometric pressure sensor

## Measured parameters

### VTe – Expiratory Tidal Volume (mL/kg)

Definition:	Expired volume, divided by weight
Accuracy:	± 1 mL or 10 % of reading

*Monivent Neo100 is calibrated on breathing gas containing 20% oxygen. Using higher concentrations of oxygen will make the system over estimate volumes up to 10%.*

### PIP – Peak Inspiratory Pressure (cmH<sub>2</sub>O)

Definition:	Maximal pressure during ventilation cycle
Accuracy:	± 1 cmH <sub>2</sub> O

### PEEP – Positive End Expiratory Pressure (cmH<sub>2</sub>O)

Definition:	Minimal pressure during ventilation cycle
Accuracy:	± 1 cmH <sub>2</sub> O

### Mask leakage (%)

Definition:	Difference between inspiratory and expiratory volumes divided by inspiratory volume
-------------	---

### Ventilation rate (ventilations / minute)

Definition:	Average rate of the ventilations during the last three seconds
-------------	--

## Monitor specification

Weight	1300 gram
Dimensions w × h	257 mm × 243 mm
Display	Medical grade 10.1" tablet with integrated battery (Onyx MD101)
Battery life	~ 8 hours
Power supply	Input: AC 100–240 V, 50–60 Hz
(ATM036T-A150)	Output: DC 15 V, 2.4 A

## Sensor Module specifications

Battery type	LiPo
Battery life	> 1 hour

## Sensor Mask / Mask Adapter specifications

Sensor Mask sizes	40 mm, 52 mm, 66 mm (outer diameter)
Flow Resistance	< 500 Pa at 250 mL/s
Connection interface	ISO 5356-1 15 mm male connection
Added deadspace	1.5 mL (Sensor Mask and Mask Adapter)

*Added deadspace in mask tube compared to other face masks, varieties in the soft part between different type of face masks disregarded.*

## Environmental specifications

Operating conditions	18–40 °C / 0–95 % Relative humidity
Storage conditions	0–45 °C / 10–95 % Relative humidity
Transportation temperature	–20–60 °C

## Regulatory

System classification	Class IIa Medical Device / MD1102
Directives	Medical Device Directive 93/42/EEC Radio Equipment Directive 2014/53/EU RoHS Directive 2011/65/EU WEEE Directive 2012/19/EU
EMC Compliance	IEC 60601-1-2 Edition 4:2014
Notified Body	RISE Research Institutes of Sweden AB (0402)

## 8. SAFETY AND COMPLIANCE

Guiding information presented by the display and the LED, consistent with measured volume and set tidal volume target, is essential performance. This is assured by the usage of disposables from Monivent together with a built-in self-test and sensor zero level adjustment.

The Monivent Neo100 is suitable for use in all establishments, including domestic establishments. The measurement performance of the device is not influenced by electromagnetic disturbances, but can degrade the radio links performance (slower updates or loss of connect).

An evaluation of the electromagnetic environment is recommended prior to use of the system. Do not use this system in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with the proper operation.

The only power supply and cable to be used with the Monivent Neo100 is the power supply manufactured by Adapter Tech (part number ATM036T-A150), supplied by Monivent AB as part of the Monivent Neo100 system.

Only the Sensor Module is intended for use in an oxygen rich environment. Do not place the Monitor in an oxygen rich environment.

**WARNING** – Verify that Monivent Neo100 is operating normally when placed in the environment where it will be used, and if changes occur in this environment.

**WARNING** – Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

**CAUTION** – Minimize wireless interference by removing other wireless devices from 30 cm vicinity of the Monivent Neo100.

## 9. TECHNICAL DESCRIPTION

<b>Guidance and manufacturer's declaration – electromagnetic emissions</b>		
The Monivent Neo100 is intended for use in the electromagnetic environment specified below. The customer or the user of the Monivent Neo100 should ensure that it is used in such an environment.		
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment – guidance</b>
RF emissions CISPR 11	Group 1	The Monivent Neo100 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Monivent Neo100 is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

<b>Wireless interface</b>	
Modulation method:	GFSK
Operating channel:	BT 2.4GHz: Ch. 0 to 39
Frequency range:	2400-2480 MHz
RF Output Power:	6.86 dBm EIRP

### Guidance and manufacturer's declaration – electromagnetic immunity


The Monivent Neo100 is intended for use in the electromagnetic environment specified below. The customer or the user of Monivent Neo100 should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2, ± 4, ± 8, ± 15 kV air	± 8 kV contact ± 2, ± 4, ± 8, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / Burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % $U_T$ (>95 % dip in $U_T$ ) for 0,5 cycle 40 % $U_T$ (60 % dip in $U_T$ ) for 5 cycles 70 % $U_T$ (30 % dip in $U_T$ ) for 25 cycles <5 % $U_T$ (>95 % dip in $U_T$ ) for 5 sec	<5 % $U_T$ (>95 % dip in $U_T$ ) for 0,5 cycle 40 % $U_T$ (60 % dip in $U_T$ ) for 5 cycles 70 % $U_T$ (30 % dip in $U_T$ ) for 25 cycles <5 % $U_T$ (>95 % dip in $U_T$ ) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Monivent Neo100 requires continued operation during power mains interruptions, it is recommended that the Monivent Neo100 be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

**NOTE**  $U_T$  is the a.c. mains voltage prior to application of the test level.

### Guidance and manufacturer's declaration – electromagnetic immunity

The Monivent Neo100 is intended for use in the electromagnetic environment specified below. The customer or the user of the Monivent Neo100 should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF	3 Vrms	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Monivent Neo100, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
IEC 61000-4-6	150 kHz to 80 MHz		<p><b>Recommended separation distance</b></p> $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2,3 \sqrt{P} \text{ 800 MHz to 2,5GHz}$
Radiated RF IEC 61000-4-3	3 V/m 80M Hz to 6 GHz	3 V/m	<p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol.</p> <div style="text-align: center;">  </div>

**NOTE 1** At 80MHz and 800MHz, the higher frequency range applies.

**NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflected from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Monivent Neo100 is used exceeds the applicable RF compliance level above, the Monivent Neo100 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Monivent Neo100.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Monivent Neo100			
The Monivent Neo100 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Monivent Neo100 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Monivent Neo100 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter  W	Separation distance according to frequency of transmitter  m		
	150 kHz to 80 MHz  $d=1,2 \sqrt{P}$	80 MHz to 800 MHz  $d=1,2 \sqrt{P}$	800 MHz to 2.5 GHz  $d=2,3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
<b>Note 1:</b> At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
<b>Note 2:</b> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			



# 10. THIRD PARTY LICENCES

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# NOTES

A series of horizontal dotted lines for writing notes.

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