Instructions for use

Savina

WARNING
To properly use this medical device, read and comply with these instructions for use.

Ventilator Software 3.1n

Typographical conventions

1 Consecutive numbers indicate steps of action, with the numbering restarting with "1" for each new sequence of actions.

- Bullet points indicate individual actions or different options for action.

– Dashes indicate the listing of data, options, or objects.

(A) Letters in parentheses refer to elements in the related illustration.

A Letters in illustrations denote elements referred to in the text.

Any text shown on the screen and any labeling on the device are printed in bold and italics, e.g., ***PEEP***, ***O2***, or ***Audio paused 2 min.***.

The "greater than" symbol **>** indicates the navigation path in a dialog window, e.g., ***Configuration*** > ***Configuration 2/4***. In this example, ***Configuration*** represents the dialog window title and ***Configuration 2/4*** the second page of four pages in the dialog window.

Screen reproductions

Illustrations of products and screen content in this document may differ from the actual products depending on configuration and design.

Use of terms

Dräger uses the term "accessories" not only for accessories in the sense of IEC 60601-1, but also for consumables, removable parts, and attached parts.

Trademarks

Trademark	Trademark owner
Savina®	Dräger
AutoFlow®	
LPO®	
Dräger-Spirolog®	
Actichlor®	Ecolab
BruTab 6S®	Brulin
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Safety information definitions

WARNING

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

CAUTION

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

NOTE

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

Definition of target groups

For this product, users, service personnel, and experts are defined as target groups.

These target groups must have received instruction in the use of the product and must have the necessary training and knowledge to use, install, reprocess, maintain, or repair the product.

The product must be used, installed, reprocessed, maintained, or repaired exclusively by defined target groups.

Users

Users are persons who use the product in accordance with its intended use.

Service personnel

Service personnel are persons who are responsible for the maintenance of the product.

Service personnel must be trained in the maintenance of medical devices and install, reprocess, and maintain the product.

Experts

Experts are persons who perform repair or complex maintenance work on the product.

Experts must have the necessary knowledge and experience with complex maintenance work on the product.

Abbreviations and symbols

For explanations refer to sections "Abbreviations" and "Symbols" in chapter "Overview".

Contents

For your safety and that of your patients

General safety information

The following WARNING and CAUTION statements apply to general operation of the medical device.

WARNING and CAUTION statements specific to subsystems or particular features of the medical device appear in the respective sections of these instructions for use or in the instructions for use of another product being used with this medical device.

Strictly follow these instructions for use

WARNING

Risk of incorrect operation and of incorrect use

Any use of the medical device requires full understanding and strict observation of all sections of these instructions for use. The medical device must only be used for the purpose specified under "Intended use" on page 16 and in conjunction with appropriate patient monitoring (see page 10).

Strictly observe all WARNING and CAUTION statements throughout these instructions for use and all statements on medical device labels. Failure to observe these safety information statements constitutes a use of the medical device that is inconsistent with its intended use.

Maintenance

WARNING

Risk of medical device failure and of patient injury

The medical device must be inspected and serviced regularly by service personnel. Repair and complex maintenance carried out on the medical device must be performed by experts.

If the above is not complied with, medical device failure and patient injury may occur. Observe chapter "Maintenance".

Dräger recommends that a service contract is obtained with DrägerService and that all repairs are performed by DrägerService. For maintenance Dräger recommends the use of authentic Dräger repair parts.

Safety checks

The medical device must be subject to regular safety checks. See chapter "Maintenance".

Accessories

WARNING

Risk due to incompatible accessories

Dräger has tested only the compatibility of accessories listed in the current list of accessories. If other, incompatible accessories are used, there is a risk of patient injury due to medical device failure.

Dräger recommends that the medical device is only used together with accessories listed in the current list of accessories.

Not for use in areas of explosion hazard

WARNING

Risk of fire

The medical device is not approved for use in areas where combustible or explosive gas mixtures are likely to occur.

Connected devices

WARNING

Risk of electric shock and of device malfunction

Electrical connections to equipment not listed in these instructions for use or these assembly instructions must only be made when approved by each respective manufacturer.

Before operating the medical device, strictly comply with the instructions for use of all connected devices or device combinations.

Device combinations

This device can be operated in combination with other Dräger devices or devices from other manufacturers. Observe the accompanying documentation of the individual devices.

If a device combination is not approved by Dräger, the safety and the correct functioning of the individual devices can be compromised. The operating organization must ensure that the device combination complies with the applicable editions of the relevant standards for medical devices.

Savina as from serial number ASFF-1000

Device combinations approved by Dräger meet the requirements of the following standards:

- IEC 60601-1, 3rd edition (general requirements for safety, device combinations, software-controlled functions)
  - IEC 60601-1-2 (electromagnetic compatibility)
  - IEC 60601-1-8 (alarm systems)

Or:

- IEC 60601-1, 2nd edition (general requirements for safety)
  - IEC 60601-1-1 (device combinations)
  - IEC 60601-1-2 (electromagnetic compatibility)
  - IEC 60601-1-4 (software-controlled functions)
  - IEC 60601-1-8 (alarm systems)

Savina up to serial number ASFF-0999

Device combinations approved by Dräger meet the requirements of the following standards:

- IEC 60601-1, 2nd edition (general requirements for safety)
  - IEC 60601-1-1 (device combinations)
  - IEC 60601-1-2 (electromagnetic compatibility)
  - IEC 60601-1-4 (software-controlled functions)
  - IEC 60601-1-8 (alarm systems)

Patient safety

The design of the medical device, the accompanying documentation, and the labeling on the medical device are based on the assumption that the purchase and the use of the medical device are restricted to persons familiar with the most important inherent characteristics of the medical device.

Instructions and WARNING and CAUTION statements are therefore largely limited to the specifics of the Dräger medical device.

The instructions for use do not contain any information on the following points:

– Risks that are obvious to users
– Consequences of obvious improper use of the medical device
– Potentially negative effects on patients with different underlying diseases

Medical device modification or misuse can be dangerous.

CAUTION

Risk of patient injury

Do not make therapeutic decisions based solely on individual measured values and monitoring parameters.

Patient monitoring

The user of the medical device is responsible for choosing a suitable patient monitoring system that provides appropriate information on medical device performance and patient condition.

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

The responsibility for selecting the best level of patient monitoring lies solely with the user of the medical device.

Information on electromagnetic compatibility

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

Medical electrical equipment is subject to special precautionary measures concerning electromagnetic compatibility (EMC) and must be installed and put into operation in accordance with the EMC information provided on see page 180.

Portable and mobile radio frequency communication equipment can affect medical electrical equipment.

WARNING

Risk of device malfunction

Do not connect connectors with an ESD warning symbol and do not touch their pins without implementing ESD protective measures. Such protective measures can include antistatic clothing and shoes, touching a potential equalization pin before and during connection of the pins, or using electrically insulating and antistatic gloves.

All users concerned must be instructed in these ESD protective measures.

WARNING

Risk of device failure

Electromagnetic fields can compromise proper operation of the device.
Electromagnetic fields are generated by, e.g., radio frequency communication equipment such as:
- **Cellular phone**
- **Radio frequency electrosurgical equipment**
- **Defibrillators**
- **Shortwave therapy equipment**

Only use radio frequency devices at a sufficient safety distance.
See electromagnetic compatibility information on page 180.

Disposable products

WARNING

Risk of patient injury due to failure of accessories

Disposable products are developed, tested and manufactured for disposable use only. Reuse, reprocessing, or sterilization can lead to a failure of accessories and cause injury to the patient.

Do not reuse, reprocess, or sterilize disposable products.

Sterile accessories

CAUTION

Risk of medical device failure and of patient injury

Do not use sterile-packaged accessories if the packaging has been opened, is damaged, or if there are other signs of non-sterility.

Installing accessories

CAUTION

Risk of device failure

Install accessories to the basic device in accordance with the instructions for use of the basic device. Make sure that there is a safe connection to the basic device.

Strictly observe instructions for use and assembly instructions.

Storing the instructions for use

CAUTION

Risk of incorrect use

Instructions for use must be kept accessible to the user.

Product-specific safety information

WARNING

Risk of incorrect use

This medical device is only intended to be used by the target group "users".

WARNING

Failure to hear alarm signals in a loud environment

Alarm situations go unnoticed.

Adjust the volume of alarm signals so that they can be perceived.

WARNING

Risk of malfunctions

Prohibited modifications to the medical device lead to malfunctions.

This medical device must not be modified without permission from the manufacturer.

WARNING

Risk of electric shock

If the connectors of the interfaces and the patient are touched simultaneously, there is a risk of electric shock.

Do not simultaneously touch the connectors of the interfaces and the patient.

WARNING

Risk of patient injury

Penetrating liquid may cause malfunction of the device, which may endanger the patient.

Do not place any containers with liquid on or above the device.
During surface disinfection, make sure no liquids penetrate into the device.

WARNING

Risk of fire

The flow sensor can ignite medications or other substances based on highly flammable substances.

- **Do not nebulize medications or other substances that are easily flammable or spray them into the device.**
- **Do not use substances containing alcohol.**
- **Do not allow flammable or explosive substances to enter the breathing system or the breathing circuit.**

WARNING

Risk of failure of flow measurement

Deposits that were not removed during reprocessing can damage the measuring wires in the flow sensor or cause a fire.

- **Before inserting the flow sensor check for visible damage, soiling, and particles. Repeat this check regularly.**
- **Replace flow sensors when damaged, soiled, or not particlefree.**

WARNING

Risk of fire

When using O_2 pressure reducers that are not approved, excess pressure can cause a fire.

When supplying the ventilator with oxygen from a compressed gas cylinder, only use pressure reducers that comply with ISO 10524.
Open pressure reducers slowly by hand. Do not use tools.

WARNING

Risk of fire

Do not use the medical device in conjunction with flammable gases or flammable solutions that can mix with air, oxygen, nitrous oxide, or other sources of ignition since the medical device could ignite.

Do not allow the medical device to come into contact with sources of ignition.

WARNING

Risk of patient injury

Magnetic resonance imaging (MRI, NMR, NMI) may impair correct functioning of the medical device.

Do not use the medical device during magnetic resonance imaging.

WARNING

Risk of patient injury

Hyperbaric chambers may impair correct functioning of the medical device.

Do not use the medical device in hyperbaric chambers.

WARNING

Risk of electric shock

There are live components under the housing cover.

Do not remove the cover.

WARNING

Risk of fire

Due to oxygen enrichment in the ambient air and overheating, the medical device can ignite.

A distance of at least 10 cm (3.9 in) must be maintained between the rear of the medical device and walls or large-scale obstacles. Do not cover the rear during operation or standby mode so that air circulation is ensured.
Only use the medical device in adequately ventilated rooms.

CAUTION

Risk of unnoticed change in the inspiratory O_2 concentration

If an additional flow (e.g., NO, nitrous oxide) is delivered from an external flow source, the actual O_2 concentration may deviate from the displayed value.

If required, use additional monitoring, e.g., external SpO_2 monitoring.

CAUTION

Risk of overheating of the medical device

Sources of heat such as direct sunlight, heat radiators, or spotlights may cause the medical device to overheat.

Keep sources of heat away from the medical device. Only use the medical device in adequately ventilated rooms.

CAUTION

Risk of patient injury

Positive-pressure ventilation can lead to negative effects, such as barotrauma or strain on the circulatory system.

Monitor the patient's condition.

CAUTION

Risk of electric shock

If a faulty device without safety extra-low voltage (SELV) is connected to the medical device, there is a risk of electric shock when the housing is touched.

Only connect devices with safety extra-low voltage (SELV) to the connections for the serial port and the nurse call.

Functional safety

The essential performance consists in a controlled and monitored patient ventilation with user-defined settings for the monitoring functions
– minimum breathing gas flow,
– maximum airway pressure,
– minimum and maximum O_2 concentration in the breathing gas,

or, if a set limit is exceeded, an appropriate alarm.

The integrated monitoring also generates an alarm in the following situations:
– Failure of the external power supply
– Discharge of the internal battery
– Failure of the O_2 supply (HPO mode)

The medical device is equipped with basic safety features to reduce the possibility of patient injury while the cause of an alarm is remedied.

Monitoring ventilation

The following parameters are monitored by the integrated monitoring:
– Airway pressure
– Expiratory minute volume
– Respiratory rate
– Apnea
– Inspiratory O_2 concentration
– Inspiratory breathing gas temperature
– Inspiratory tidal volume

Changes in these parameters may be caused by:
– Acute changes in the patient's condition
– Incorrect settings and faulty handling
– Device malfunctions
– Failure of power and gas supplies

If the built-in monitoring fails, use substitute monitoring.

Backup ventilation with an independent manual ventilation device

WARNING

Risk of patient injury

If a fault is evident at the medical device, its life-support functions may be affected.

Ventilation of the patient using an independent ventilation device must be started without delay, if necessary with PEEP and/or an increased inspiratory O_2 concentration (e.g., with the manual resuscitator MR-100).

Application

Intended use

Savina®

Long-term ventilator for intensive care. For patients requiring a tidal volume of 50 mL and up.

Environment of use

Savina is intended for the following environments of use:

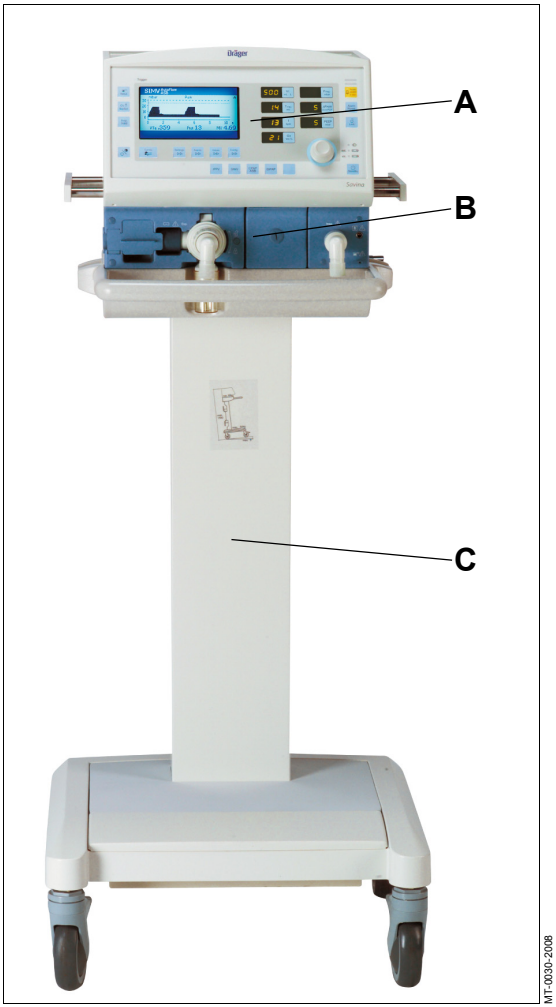
– In intensive care wards, in recovery rooms and generally for hospital use

– During the transfer of patients within the hospital

Overview

Savina

Ventilator with trolley

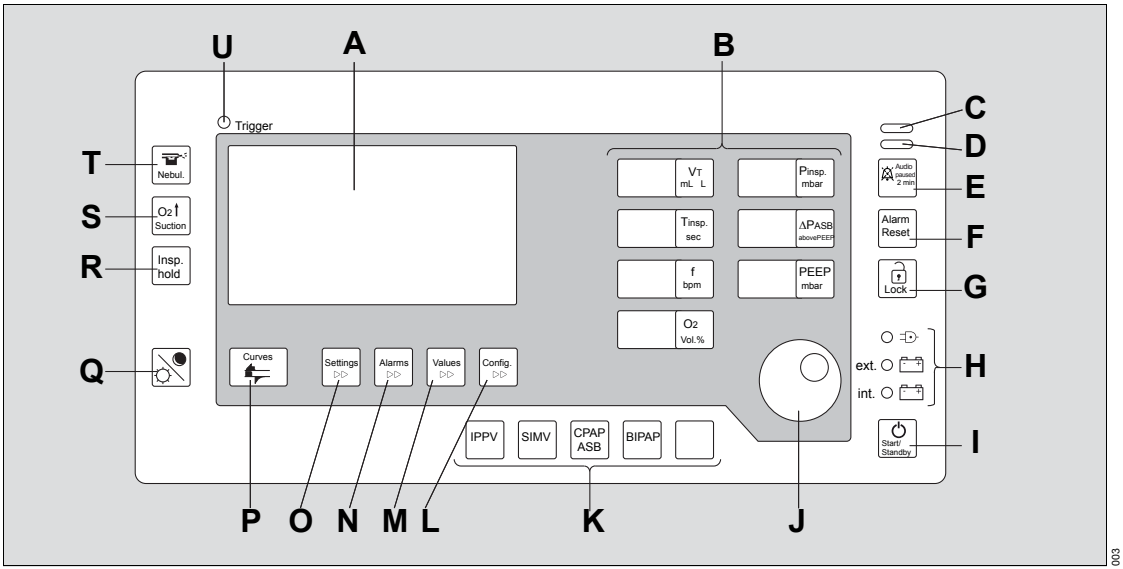


A Control and display unit

B Patient connection panel

C Trolley

Control and display unit



A Screen

B Keys for ventilation parameters ***VT***, ***Tinsp.***, ***f***, ***O2***, ***Pinsp.***, ***ΔPASB above PEEP***, ***PEEP*** with a display of the current values

C The red LED flashes for alarms with high priority

D Yellow LED:
- Flashes for alarms with medium priority
- Lights up for alarms with low priority

E ***Audio paused 2 min.*** or ***2 min*** key

F ***Alarm Reset*** key

G ***Lock*** key

H LED indicating the power supply (for more information, see page 20)

I ***Start/Standby*** or ***Standby*** key

J Rotary knob

K Keys for ventilation modes ***IPPV***, ***SIMV***, ***CPAP/ASB***, ***BIPAP***

L ***Config.*** key

M ***Values*** key

N ***Alarms*** key

O ***Settings*** key

P ***Curves*** key

Q key

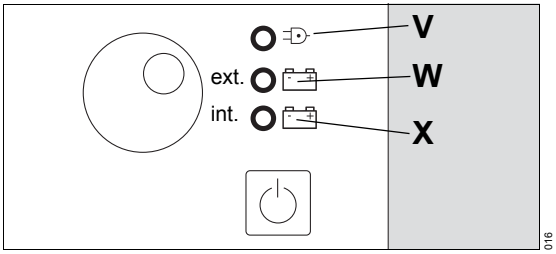
R ***Insp. hold*** key

S ***O2*** *Suction* key

T ***Nebul.*** key

U ***Trigger*** LED

Indication of power supply



V Mains power

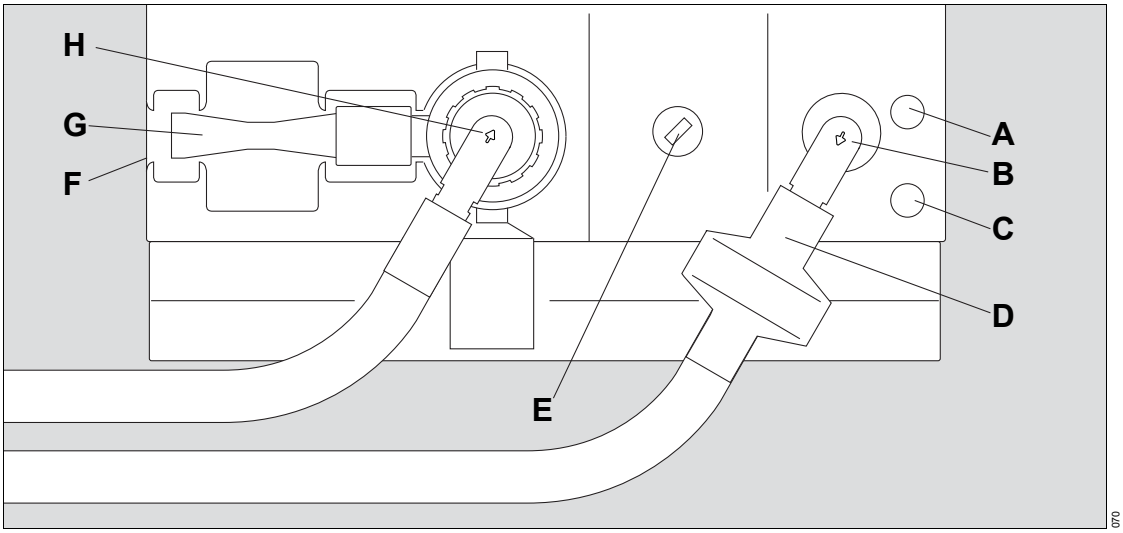
W External battery or DC on-board power supply

X Internal battery

Meaning of the LED colors:

	Each LED lights up:			
	Green	**Yellow**	**Red**	**Off**
Mains power	Present	-	-	Not present
External battery	Battery operation or fully charged	Charging	Overheated or defective	Not present
DC on-board power supply	Present	-	Overheated or defective	Not present
Internal battery	Battery operation or fully charged	Charging	Overheated or defective	Not being charged

Patient connection panel



A Socket for breathing gas temperature sensor

B Inspiratory valve with inspiratory port ***Insp.*** (GAS OUTPUT)

C Nebulizer port (nebulizer gas outlet for pneumatic medication nebulizer)

D Bacterial filter

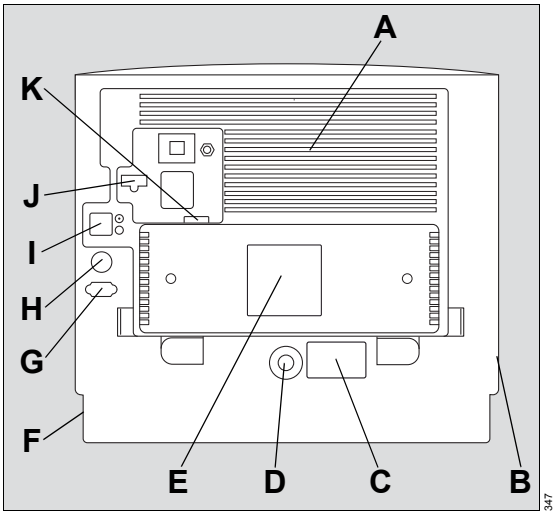
E Fastening screw for cover plate (behind cover: O_2 sensors)

F Gas outlet ***Exhaust***, non-conical connection (EXHAUST – NOT FOR SPIROMETER)

G Flow sensor

H Expiratory valve with expiratory port ***Exp.*** (GAS RETURN)

Rear of the device up to serial number ASFF-0999



A Filter cover

B On the side of the device: Labels for Options

C Rating plate

D LPO port for connecting a low-pressure oxygen source, e.g., an O_2 concentrator

E Label for LPO

F On the side of the device: HPO port for O_2 compressed gas hose ***O2***

G COM port (serial RS232 port)

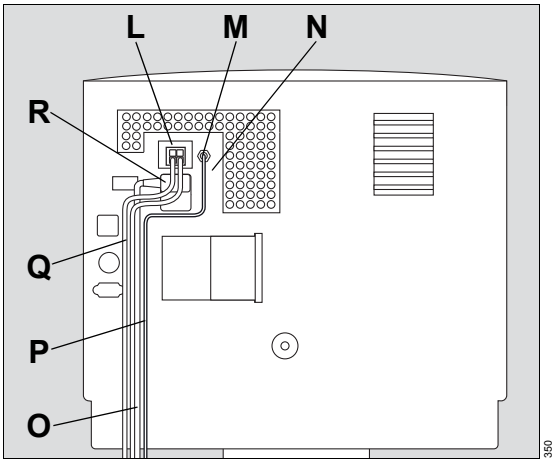
H Connection for nurse call

I Main switch for switching on ⊙ or off ⏻

J Fuse for the internal battery

K Storage recess for fuse

Rear of the device without filter cover



L Connection for external battery or DC on-board power supply

M Potential equalization pin

N Power supply unit

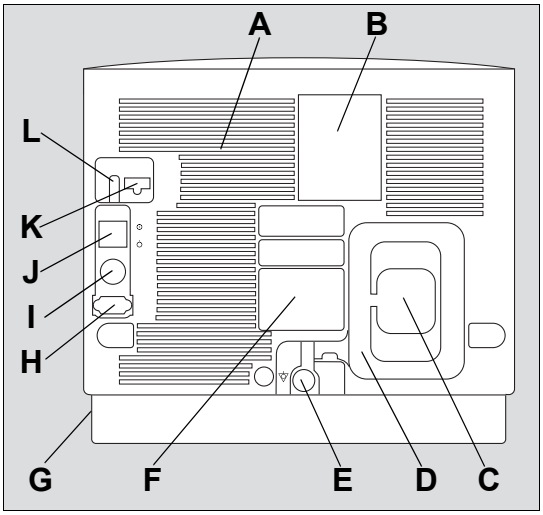
O Power cable

P Potential equalization cable

Q Cable for external battery or DC on-board power supply

R Connection for power cable, mains power fuse

Rear of the device as from serial number ASFF-1000



A Filter cover

B Labels for Options

C Rating plate

D Cable guide

E LPO port for connecting a low-pressure oxygen source, e.g., an O_2 concentrator

F Label for LPO

G On the side of the device: HPO port for O_2 compressed gas hose ***O2***

H COM port (serial RS232 port)

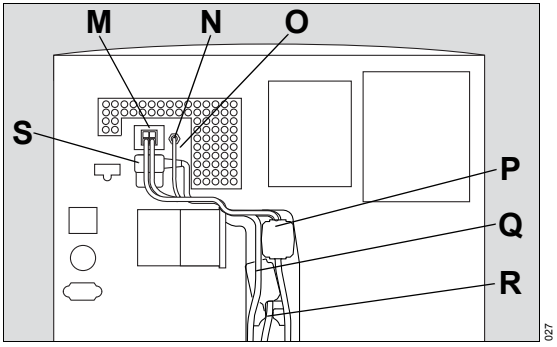
I Connection for nurse call

J Main switch for switching on ⊙ or off ⏻

K Fuse for the internal battery

L Storage recess for fuse

Rear of the device without filter cover



M Connection for external battery or DC on-board power supply

N Potential equalization pin

O Power supply unit

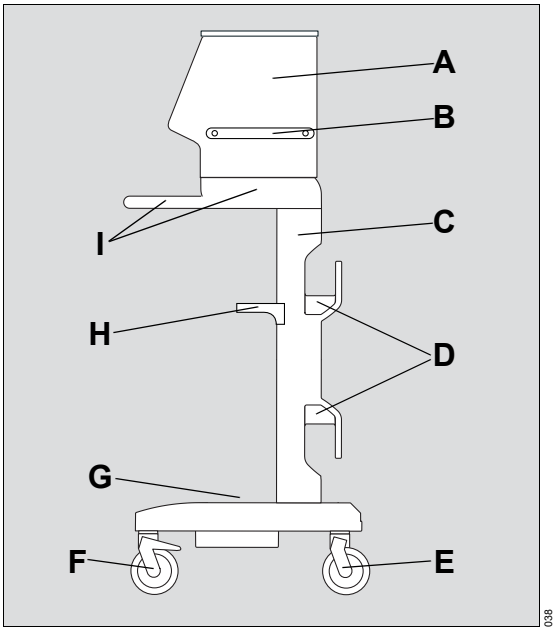
P Cable for external battery or DC on-board power supply

Q Potential equalization cable

R Power cable

S Connection for power cable, mains power fuse

Trolley



A Savina

B Lateral standard rail

C Trolley column

D Hose holder

E Castors without locking brake, set of 2

F Castors with locking brake, set of 2

G Base plate, e.g., for external battery

H Holder for breathing gas humidifier

I Mounting with handle

Range of functions

The functions described correspond to the overall functionality of Savina. Some functions are only optional and may not be included in the individual device configuration. The optional functions and the part numbers of the accessories are listed in the separate list of accessories.

Ventilation functions

For a detailed description of the ventilation modes and the additional settings, see page 187. For abbreviations, see page 26.

Application modes

– Invasive ventilation (Tube)
– Non-invasive ventilation (Mask/NIV)

Ventilation modes

Volume-controlled ventilation:
– IPPV, IPPVAssist, CPPV, IRV, PLV
– SIMV, ASB, PLV

Pressure-controlled ventilation:
– BIPAP, ASB, SB

Support of spontaneous breathing:
– CPAP, ASB, SB

Additional settings for ventilation

– Apnea ventilation
– Trigger
– Sigh
– AutoFlow

Special maneuvers

– Suction maneuver with oxygen enrichment
– Medication nebulization
– Manual inspiration – Insp. hold

Monitoring functions

Setting alarm limits for the following parameters:
– Expiratory minute volume ***MV***
– Airway pressure ***Paw***
– Inspiratory tidal volume ***V_{Ti}***
– Respiratory rate ***f_{tot}***
– Apnea alarm time ***T_{Apnoea}***
– Time until disconnection alarm ***$T_{Disconnect}$*** (during NIV)
– Inspiratory O_2 concentration ***FiO_2*** (in LPO mode)

In the HPO mode, alarm limits for the O_2 concentration ***FiO_2*** are automatically linked to the set value for ***O_2***.

During non-invasive ventilation, certain monitoring functions are switched off or can be switched off.

Displays on the screen

– Waveforms and measured values
– Alarm messages
– Information

Additional functions

– Key lock
– Change between bright and dark screen background

Power supply

Savina is supplied with mains power or with power from the internal battery.

Savina can be powered by an external battery or a DC on-board power supply.

The external battery also serves as the power supply during patient transport.

Gas supply

An internal turbine supplies Savina with ambient air.

O_2 supply

– High Pressure Oxygen (HPO) from the central gas supply system or from compressed gas cylinders

– Low Pressure Oxygen (LPO) from an external low-pressure oxygen source, e.g., O_2 concentrator

Data transfer

The COM port (serial RS232 interface) can be used for data transfer via the MEDIBUS protocol.

Medication nebulization

For medication nebulization a pneumatic medication nebulizer can be connected.

Abbreviations

Abbreviation	Explanation
Alarm Reset	Resetting or acknowledging alarm messages, stopping apnea ventilation (key on device)
Apn-Vent.	Apnea ventilation
ASB	Assisted Spontaneous Breathing, pressure-assisted spontaneous breathing
AutoFlow	Automatic optimization of inspiratory flow
BF	Insulation class Body Floating

Abbreviation	Explanation
BIPAP	Biphasic Positive Airway Pressure, spontaneous breathing under continuous positive airway pressure with 2 different pressure levels
bpm	Breaths per minute, respiratory rate per minute
BTPS	Body Temperature Pressure Saturated, measured values referring to the conditions of the patient's lungs, body temperature 37 °C (98.6 °F), plateau pressure, water-vapor-saturated gas.
C	Compliance

Abbreviation	Explanation
C hose	Compliance of the breathing circuit
CISPR	Comité International Spécial des Perturbations Radioélectriques, International special committee on radio interference
cmH_2O	Unit of measurement for pressure 1 cmH_2O = approx. 1 mbar
CPAP	Continuous Positive Airway Pressure, spontaneous breathing with continuous positive pressure level
CPPV	Continuous Positive Pressure Ventilation, ventilation with continuous positive pressure
$\Delta P_{ASB\ above\ PEEP}$	Pressure support relative (above PEEP)
ΔSigh	Additional intermittent PEEP for sigh
EMC	Electromagnetic compatibility
ESD	Electrostatic Discharge, electrostatic discharge
Exhaust	Gas outlet (EXHAUST – NOT FOR SPIROMETER)
Exp.	Label on the device, Expiratory port (GAS RETURN)
Exp.	Expiration
ext.	Label on the device, external battery or DC on-board power supply
f	Respiratory rate
f_{Apnoea}	Respiratory Rate during apnea ventilation
FiO_2	Inspiratory O_2 concentration
Flow	Flow
FlowAcc	Flow acceleration
$Flow_{peak}$	Peak flow
f_{spn}	Spontaneous breathing portion of respiratory rate

Abbreviation	Explanation
f_{tot}	Total respiratory rate
HME	Heat Moisture Exchanger, heat and moisture exchanger
hPa	Hectopascal, unit of measurement for pressure 1 hPa = 1 mbar = approx. 1 cmH_2O
HPO	High Pressure Oxygen, high-pressure O_2 supply from the central gas supply system or an O_2 compressed gas cylinder
I:E	Ratio of inspiratory time to expiratory time
Insp.	Label on the device, inspiratory port (GAS OUTPUT)
Insp.	Inspiration
Insp. hold	Manual inspiration (key on the device)
int.	Label on the device, internal battery
IPPV	Intermittent Positive Pressure Ventilation, intermittent ventilation with positive pressure
$IPPV_{Assist}$	Assisting, intermittent ventilation with positive pressure
IRV	Inversed Ratio Ventilation, ventilation with reversed ventilation time ratio
LPO	Low Pressure Oxygen, Low-pressure O_2 supply from external oxygen sources, e.g., O_2 concentrator
Mask/NIV	Application mode for non-invasive ventilation
mbar	Millibar, unit of measurement for presssure 1 mbar = approx. 1 cmH_2O
MEDIBUS	Dräger communication protocol for medical devices

Abbreviation	Explanation
MRI	Magnetic Resonance Tomography, Magnetic Resonance Imaging
MV	Overall minute volume
MV_{leak}	Leakage minute volume
MV_{spn}	Spontaneous breathing portion of minute volume
NIV	Non-Invasive Ventilation, non-invasive ventilation
NMI	Nuclear Magnetic Imaging, nuclear magnetic imaging
NMR	Nuclear Magnetic Resonance, nuclear magnetic resonance
NTPD	Normal Temperature Pressure Dry, 20 °C (68 °F), 1013 hPa, dry
O_2	Oxygen
O_2 ↑ Suction	Suction maneuver (key on the device)
OFF	Function deactivated
ON	Function activated
Paw	Airway pressure
PEEP	Positive end-expiratory pressure
$P_{insp.}$	Inspiratory pressure
Plateau	Inspiratory pause time
PLV	Pressure Limited Ventilation, Pressure-limited Ventilation
P_{max}	Maximum allowed airway pressure
P_{mean}	Mean airway pressure
P_{peak}	Peak inspiratory pressure
P_{plat}	End-inspiratory airway pressure
R	Resistance
Re	Expiratory resistance
REF	Material and revision number of the medical device
Ri	Inspiratory resistance

Abbreviation	Explanation
SB	Spontaneous Breathing, spontaneous breathing
SELV	Safety Extra-low Voltage, safety extra-low voltage
SIMV	Synchronized Intermittent Mandatory Ventilation, intermittent, triggered ventilation
SN	Device serial number
SpO_2	Peripheral O_2 saturation
T_{Apnoea}	Apnea alarm time
$T_{Disconnect}$	Time until disconnection alarm during non-invasive ventilation
Temp.	Inspiratory breathing gas temperature
T_{exp}	Expiratory time
T_{insp}	Inspiratory time
T_{plat}	Plateau time
Trigger	Trigger threshold, sensitivity
UMDNS	Universal Medical Device Nomenclature System, nomenclature for medical devices
U_N	Rated voltage
Vol%	Percentage of gas, related to the total volume
V_T	Tidal volume
VT_{Apnoea}	Tidal volume during apnea ventilation
V_{Te}	Expiratory tidal volume
V_{Ti}	Inspiratory tidal volume
V_{Tpat}	Patient's leakage-compensated tidal volume, measured on the inspiratory side (in application mode ***Mask/NIV*** only)

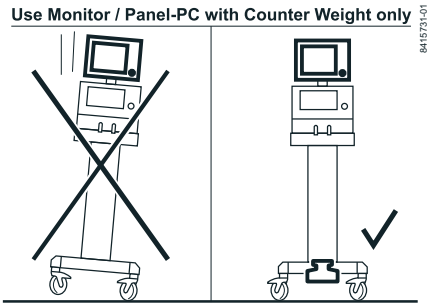
Symbols

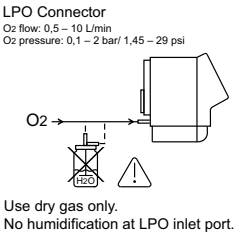
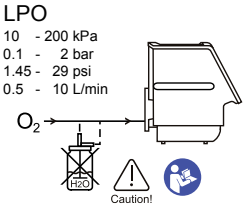
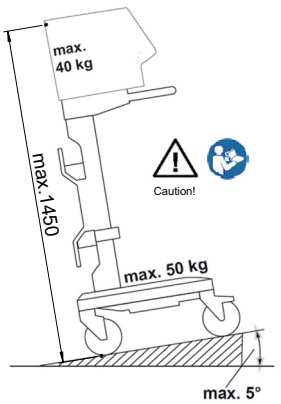
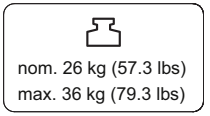
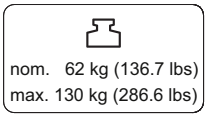
Symbol	Explanation
 	***Audio paused 2 min.*** key ***2 min*** key Suppresses the acoustic alarm for 2 minutes In this document the ***Audio paused 2 min.*** key is used.
	***Start/Standby*** key ***Standby*** key Activates standby mode or starts the therapy In this document the ***Start/Standby*** key is used.
	***Nebul.*** key Switches the medication nebulizer on or off
	***Curves*** key Switch between flow waveform and pressure waveform
	Changes between bright and dark screen background
	Opening a dialog window
	***Lock*** key Lock settings on the screen and keys against unintentional changes
	Expiratory valve unlocked
	Expiratory valve locked
	Device switched on
	Device switched off
	Lower alarm limit
	Upper alarm limit
	Upper/lower alarm limit

Symbol	Explanation
	Alarm inactive
	NIV Non-invasive ventilation
	Mains power supply (AC voltage)
	Power supply from the batteries
	Charge state of internal battery >80 %
	Charge state of internal battery ≤10 %
	Gas outlet (EXHAUST – NOT FOR SPIROMETER)
	Inserting the flow sensor
	Potential equalization connector
	Protective earth
	Nurse call
	Applied part type BF
	Applied part type B
	Caution: Observe important safety information and precautions in the instructions for use.
	Observe the instructions for use
	Warning! Strictly follow these Instructions for Use
	General mandatory action
	Marking on device surfaces where the risk of tipping over is increased when pushed, leaned against, used as a support, etc.
	Do not cover housing
	Temperature range during storage

Symbol	Explanation
	Atmospheric pressure
	Relative humidity
	Use by
	Do not reuse
	Protect from moisture
	ESD warning symbol
	ESD warning symbol on device
	Information on disposal
	Manufacturer
 XXXX	Manufacturing date

Product labels

Product label	Explanation
	Monitors may only be mounted on Savina if the counter weight is mounted in the trolley foot.
	The counter weight is mounted in the trolley foot.

Product label	**Explanation**
Devices up to serial number ASFF-0999:  	LPO connector O2 flow: 0.5 to 10 L/min O2 pressure: 0.1 to 2 bar / 1.45 to 29 psi Use only dry gas. Do not connect a humidifier to the LPO inlet.
Devices as from serial number ASFF-1000:  	
 	Maximum loads and conditions for tipping stability of Savina on the trolley
 	Nominal weight and maximum weight for the basic unit
 	Nominal weight and maximum weight for the basic unit with trolley

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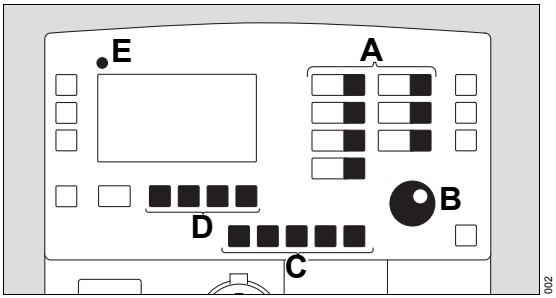
Operating concept

Control and display unit



Rotary knob

The rotary knob (B) is used to select, set and confirm parameters.

Keys to adjust ventilation

Selecting a ventilation mode

Ventilation modes (C):
– IPPV
– SIMV
– CPAP/ASB
– BIPAP

1 Press the corresponding key.

2 Press the rotary knob to confirm.

The yellow LED in the key lights up.

Setting ventilation parameters

Ventilation parameters (A):
– V_T
– $T_{insp.}$
– f
– O_2
– $P_{insp.}$
– $\Delta P_{ASB\ above\ PEEP}$
– PEEP

1 Press the corresponding key.

The yellow LED in the key lights up.

2 To make the setting, turn the rotary knob to the right or left.

3 Press the rotary knob to confirm.

The setting is accepted. The yellow LED in the key goes out.

Canceling the setting or changing process

Prerequisites: The new setting has not yet been confirmed with the rotary knob.

To cancel a change and keep the previous setting, do one of the following:

- Touch key again.
- Touch another key.
- Do not press the rotary knob. After 15 seconds, the change is reset.

Opening a dialog window

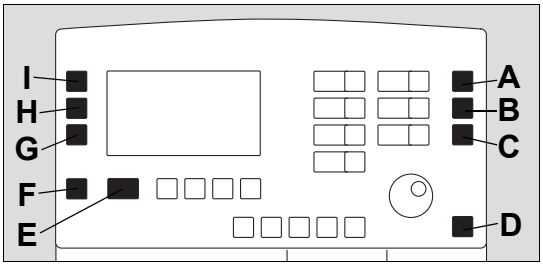
Dialog windows are opened by pressing the corresponding key (D).

Key	Dialog windows
Settings ▷▷	Settings, see page 37
Alarms ▷▷	Alarms, see page 37
Values ▷▷	Values, see page 38
Config. ▷▷	Configuration, see page 39

Trigger display

If Savina detects an inspiratory effort, the yellow LED (E) lights up.

Keys for additional functions



A	Audio paused 2 min.	Suppresses the acoustic alarm signal for 2 minutes
	2 min	
B	Alarm Reset	Resets or acknowledges an alarm message
C	Lock	Keys for setting ventilation modes and for locking and unlocking ventilation parameters
D	Start/ Standby	Activates standby mode or starts the therapy
	Standby	
E	Curves	Displays the main screen Switching between waveform displays
F		Changes between bright and dark screen background
G	Insp. hold	Starts manual inspiration
H	O_2 ↑ Suction	Starts or terminates the suction maneuver
I	Nebul.	Switches the medication nebulizer on or off

Activating a function

- Press the corresponding key.

If there is one, the yellow LED in the key lights up.

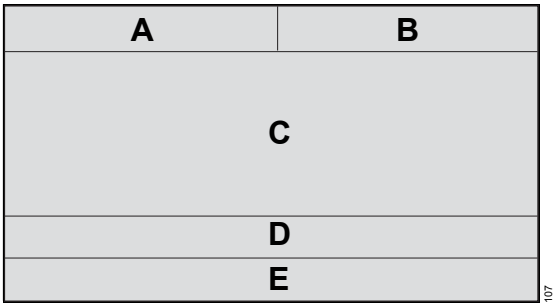
Deactivating a function

- Press the corresponding key again.

The yellow LED in the key goes out.

Dialog windows

Structure of the dialog windows



A Active ventilation mode

B Alarm message field

C Depending on the dialog window: waveforms, settings, alarm limits, measured values

D Numerical display of measured values on the main screen

E Message field for information and instructions

Opening a dialog window

Dialog windows are opened by pressing the corresponding key; see page 37. Dialog windows consist of one or more pages.

Opening a dialog window

- Press the corresponding key.

Opening other pages in the dialog window

- Press the same key again.

Overview of the dialog windows

The following tables list the keys with the resulting screens on the dialog windows.

Dialog windows *Settings*

Key	Screen	Settings for ventilation	Explanations
Settings ▷▷	Settings 1/1	Trigger	
		FlowAcc	
		AutoFlow	
		Apn-Vent.	Only if apnea ventilation is switched off
		$V_{TApnoea}$	Only if apnea ventilation is switched on
		f_{Apnoea}	
		ΔSigh	Only in ventilation mode ***IPPV***

Dialog windows *Alarms*

Key	Screen	Display	Explanations
Alarms ▷▷	Alarms 1/4	Paw	Setting of alarm limits
		MV	
		T_{Apnoea}	
		f_{tot}	
		V_{Ti}	
	Alarms 2/4	$T_{Disconnect}$	Additional alarm limit in application mode ***Mask/NIV***
		FiO_2	Additional alarm limit in LPO mode
	Alarms 3/4	Alarm history	Alarms that have been displayed in the alarm message field are listed in chronological order.
			In application mode ***Tube*** and in HPO mode the screen is displayed as ***Alarms 2/3***.
	Alarms 4/4	Inactive alarm limits	All inactive alarm limits and monitoring functions are listed.
			In application mode ***Tube*** and in HPO mode the screen is displayed as ***Alarms 3/3***.

Dialog windows *Values*

The airway pressure is displayed in a bar graph format. The other measured values are displayed numerically.

Key	Screen	Display	Explanations
Values ▷▷	Values 1/5	P_{peak}	Measured values of the active ventilation mode
		P_{plat}	
		P_{mean}	
		PEEP	
		V_{Te}	
		MV	
		MV_{spn}	
		FiO_2	
			In standby mode the screen is not displayed.
	Values 2/5	f_{tot}	
		f_{spn}	
		I:E	
		T_{plat}	Only when ventilating with plateau
		T_{insp}	Only when ventilating without plateau
		$Flow_{peak}$	
		R	
		C	
		Temp.	
			In standby mode the screen is not displayed.
	Values 3/5	f_{tot}	Additional page in application mode ***Mask/NIV***
		f_{spn}	
		PEEP	
		V_{Tpat}	
		MV	
		MV_{spn}	
		MV_{leak}	
			In standby mode the screen is not displayed.
	Values 4/5	Breathing circuit check	Results of the breathing circuit check
		Leakage	
			In standby mode the screen is displayed as ***Values 1/2***.

Key	Screen	Display	Explanations
Values ▷▷	Values 5/5	C hose	Results of the breathing circuit check
		Flow	
		Ri	
		Re	
			In standby mode the screen is displayed as ***Values 2/2***.

Dialog windows *Configuration*

Key	Screen	Functions	Explanations
Config. ▷▷	Configuration 1/4	Contrast	Screen contrast
		Volume	Volume of the alarm signal
		Meas. values	Measured values for main screen
	Configuration 2/4	O_2 calib.	Manual calibration of O_2 sensor 2
		FiO_2 monitoring	Activating or deactivating monitoring
		Flow monitoring	
		Pmax	Pressure limitation
		Plateau	Inspiratory pause time
		LPO-mode	HPO/LPO switchover
	Configuration 3/4	Language	Language of the screen texts
		dd.mm.yy	Date
		h:m	Time
		Baudrate	Interface parameters
		Parity	
		Stopbits	
	Configuration 4/4	SW	Software Version
		Working hours	Total hours of operation
		h since service	Hours of operation since the last inspection and service
		Release code	Numeric code to activate options
		Device-ID	Device identification number

Start screen

Key	Screen	Functions	Explanations
⏻ ***Start/Standby***		Breathing circuit check	Perform a breathing circuit check
		Patient Connection	Select an application mode

Main screen

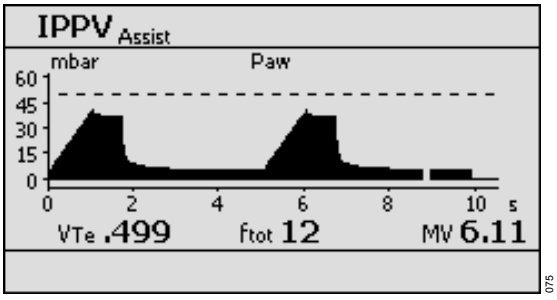
Opening the main screen

- Press the ***Curves*** key.

The following are displayed on the main screen:
– Waveform for airway pressure or flow
– 3 measured values

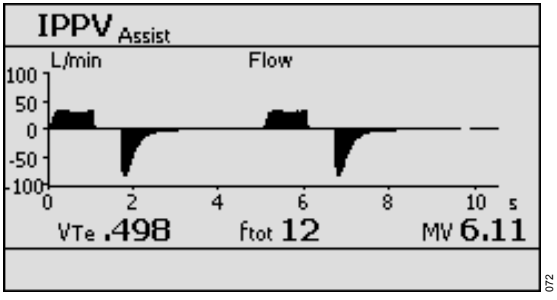
The composition of the measured values can be selected; see "Selecting measured values for the main screen" on page 110.

Waveform for airway pressure



Displayed line	Meaning
Dotted	Pressure limitation activated, set value ***Pmax***
Dashed	Alarm limit ***Paw***

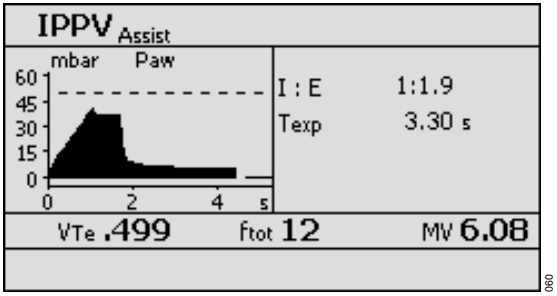
Waveform for flow



Switching the waveform display

- Press the ***Curves*** key.

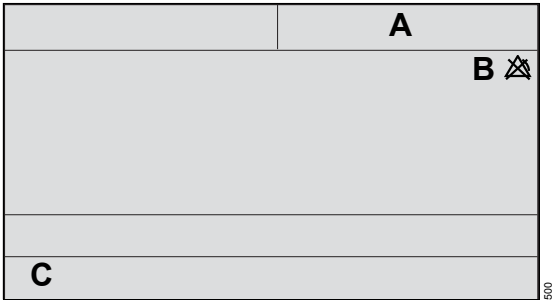
Setting assistance field



While setting a ventilation parameter, derived ventilation parameters are calculated and displayed in the setting assistance field of the main screen.

After the ventilation parameter is confirmed, the setting assistance field is no longer displayed.

Inactive alarm limits and monitoring functions



A Corresponding alarm message

B The symbol indicates that alarm limits or monitoring functions are inactive.

C Information and instructions

Assembly and preparation

Safety information

WARNING

Risk of personal injury

If medical devices are not reprocessed, there is an increased risk of infection to both hospital staff and patients.

Before each use, reprocess the device and all accessories in accordance with the instructions for use, see "Reprocessing list" on page 144. Observe the hygiene regulations of the hospital.

WARNING

Risk of personal injury and damage to the device

If the device is not securely fastened, it can fall down.

Fasten the device securely. Check for secure fit.

Preparing the trolley

Prerequisites:
– Required accessories must be mounted by service personnel.
– Assembly instructions and the maximum loads must be observed.

WARNING

Risk of personal injury due to damaged trolley

If, e.g., the double castors are faulty, then the device can move unintentionally.

Do not use the trolley if there is visible damage. Contact experts.

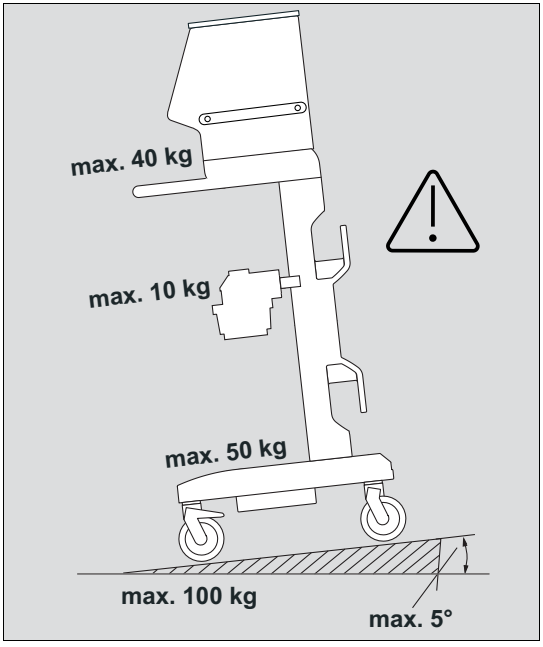
Load and tipping stability

WARNING

Risk of personal injury and damage to the device

If the device is used on a trolley at inclinations >5°, there is a risk of tipping over.

Use the device on the trolley only up to a maximum inclination of 5°.



The maximal total load of the trolley must not exceed 100 kg (220 lbs).

For the individual areas, the following load limits apply:

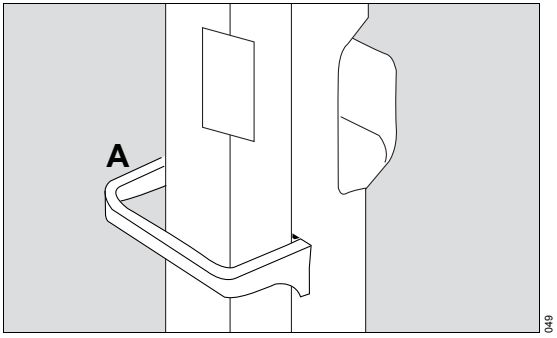
Range	Maximum load	Examples
Shelf	40 kg (88 lbs) (of which a maximum load of 5 kg (11 lbs) is allowed on each lateral standard rail)	Device, patient monitor with holder, hinged arm
Humidifier holder	10 kg (22 lbs)	Breathing gas humidifier or medication nebulizer
Base plate	50 kg (110 lbs)	Compressed gas cylinders, external battery

Also see chapter Technical data, "Maximum load" on page 175.

Attaching a humidifier holder

To attach the accessories, the humidifier holder can be mounted to the front of the trolley.

1 Screw on the humidifier holder (A).



2 Check that the humidifier holder is fastened securely.

Attaching the O_2 cylinder to the trolley

Prerequisites:

– Gas cylinder holder option is available.

– Compressed gas cylinders have the following dimensions:

Diameter	80 to 176 mm (3.15 to 6.93 in)
Length	420 to 760 mm (16.54 to 29.92 in)

WARNING

Risk of personal injury and damage to the device

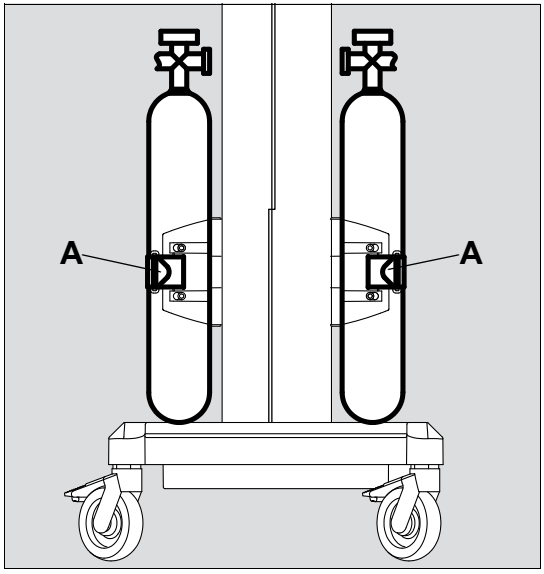
If the compressed gas cylinders are not securely fastened to the trolley, they can fall down.

Attach the compressed gas cylinders securely to the trolley using the hook-and-loop straps.

NOTE

The trolley is designed to hold a maximum of one compressed gas cylinder on each side.

Securing the compressed gas cylinders



1 Place the compressed gas cylinders into the mountings on the trolley.

2 Secure each compressed gas cylinder with one hook-and-loop strap (A). If required, have service personnel perform the following adjustments:

- Adjust the height of the gas cylinder holder to the compressed gas cylinders to be used. The height must be adjusted so that the top half of the compressed gas cylinders is held firmly in place by the cylinder holder.
- Exchange the hook-and-loop strap. The length of the hook-and-loop straps must match the circumference of the compressed gas cylinders.

3 Secure the compressed gas hose by hanging it over the hose holders.

Fastening Savina to the trolley

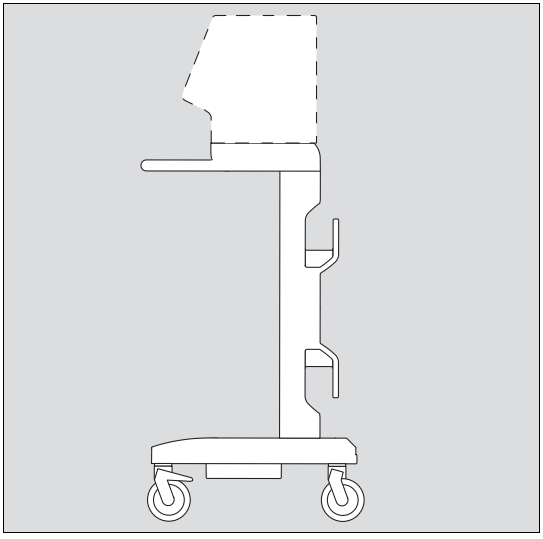
Prerequisites: Assembly instructions must be observed.

WARNING

Risk of personal injury and damage to the device

If the device is not securely fastened to the trolley, it can fall down.

Fasten the device securely. Check for secure fit.



1 Insert the device into the mounting.

2 Fasten with 2 screws (M5 x 25 with tooth lock washer) from underneath.

Parking the trolley

CAUTION

Risk of patient injury

If the brakes are not locked, the trolley can move on inclined surfaces, putting the patient at risk.

For stationary operation, lock all of the trolley's brakes and check the function of the brakes.

Parking the trolley for stationary operation:

1 Lock the brakes of the trolley.

2 Check that the brakes are functioning correctly.

Mounting an additional monitor

WARNING

Risk of patient injury due to incorrectly transmitted data

All transferred data is intended for informational purposes only and is not intended to be used as the basis for diagnostic or therapeutic decisions.

Regularly check the displays on the screen of Savina. Pay attention to the alarms directly on Savina.

Information on installation

Monitors can be mounted on the ventilator using the corresponding holder.

WARNING

Risk of tipping over

If a monitor is mounted onto Savina, there is a risk of tipping over.

The device combination is only permitted on the trolley. The counter weight provided must be mounted under the base plate of the trolley.

Infinity monitors

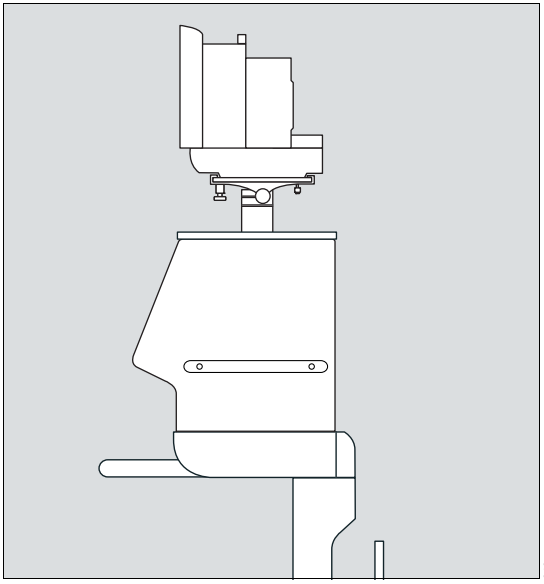
The following monitors can be mounted and connected to the MEDIBUS interface:

Infinity monitors	Mounting on Savina	Connection to MEDIBUS interface
Gamma	With docking station	Yes
Gamma XL		
Gamma XXL		
Delta	With docking station	Yes
Delta XL		

Infinity monitors	Mounting on Savina	Connection to MEDIBUS interface
Vista	Mounted directly	No
Vista XL		
Vista 120		
Kappa XLT	No	Yes

Prerequisites:
The instructions for use for the relevant monitor must be observed. In particular:
– The conditions required for operation with Savina (signal converter, cable, etc.)
– Which parameters can be displayed.

Mounting an Infinity monitor onto Savina



- Mount the Infinity monitor onto Savina using the corresponding holder.

Graphic Screen

With the Graphic Screen option and the VentView software, ventilation parameters can also be displayed graphically and numerically.

The Graphic Screen is operated using its touch screen.

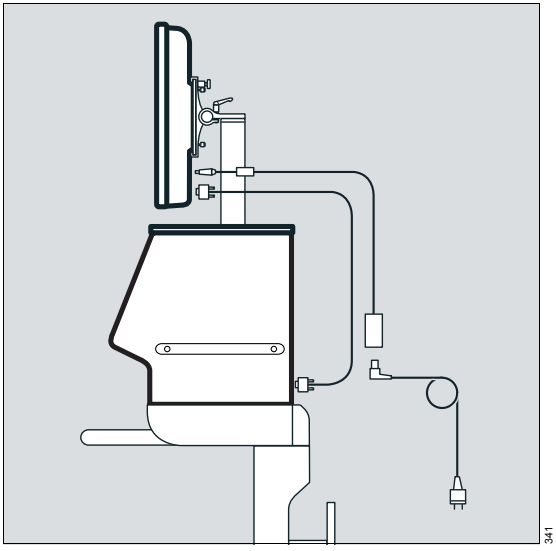
Data connection

A suitable data cable must be used for the data connection between Savina and the Graphic Screen. The data cable is connected to the COM port (serial RS232 interface).

It is also possible to connect the Graphic Screen to another PC using another data cable, e.g., to archive data.

For additional information, see instructions for use "Graphic Screen option".

Mounting the Graphic Screen onto Savina



- For more information on assembly and connection, see the instructions for use for "Graphic Screen option".

Preparing Savina

Mounting the expiratory valve

WARNING

Risk of patient injury

Expiratory valves that are damp or have not been reprocessed can impair the operation of the device and endanger the patient.

Only use properly reprocessed expiratory valves which have been sufficiently dried.

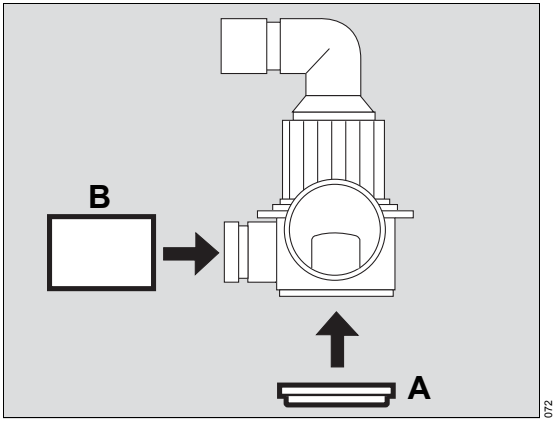
CAUTION

High airway pressures and auto-triggering

If the water trap container on the expiratory valve is missing, there is a danger of excessively high airway pressures and auto-triggering due to leakage overcompensation.

Always attach the water trap container.

Preparing the expiratory valve

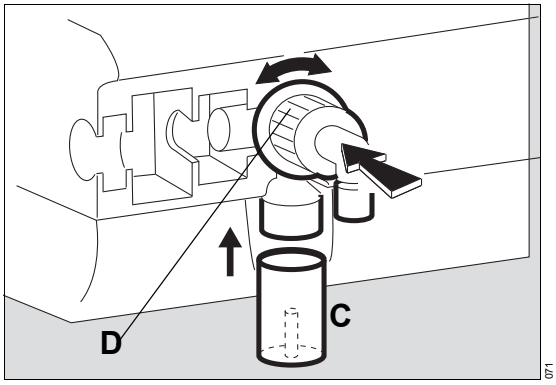


1 Fit the diaphragm (A) onto the edge of the expiratory valve housing.

2 Make sure that the diaphragm is fitted properly.

3 If the flow sensor sleeve (B) has been removed, fit the flow sensor sleeve.

Inserting the expiratory valve



1 Turn the locking ring (D) as far as possible to the left.

2 Push the expiratory valve into the fitting.

3 Turn the locking ring (D) as far as it will go to the right until it clicks audibly into place.

4 Check that it is properly secured by gently pulling on the expiratory valve.

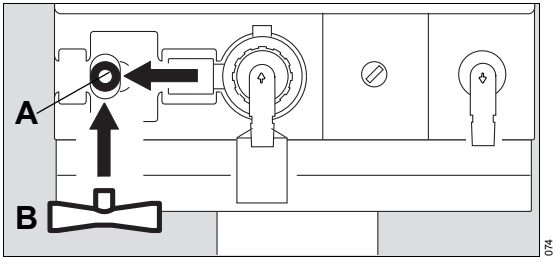
5 Attach the water trap container (C).

Fitting the flow sensor

WARNING
Risk of fire

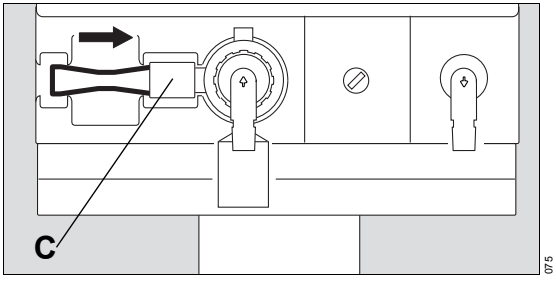
Residual vapors of easily flammable disinfectants (e.g., alcohols) and deposits that were not removed during reprocessing can ignite when the flow sensor is in use.
- **Ensure particle-free cleaning and disinfection.**
- **After disinfection, allow the flow sensor to air for at least 30 minutes.**
- **Before inserting the flow sensor check for visible damage and soiling, such as residual mucus, medication aerosols, and particles.**
- **Replace flow sensors when damaged, soiled, or not particlefree.**

Prerequisites: The flap is open.



1 Push the socket (A) as far to the left as it will go.

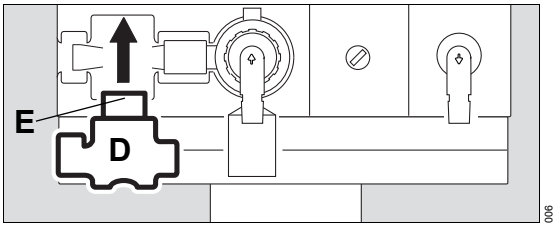
2 Insert the flow sensor (B) into the socket with the plug facing towards the device and push it into the socket as far as it will go.



3 Push the flow sensor as far to the right as it will go into the flow sensor sleeve (C) of the expiratory valve.

Fitting the flap

When the expiratory valve and the flow sensor are fitted, fit the flap.

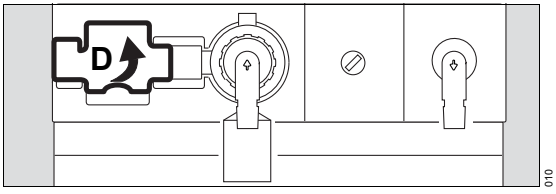


1 Push the flap (D) into the opening of the housing with the hinge (E) facing upwards.

2 Push the flap downwards until the hinge audibly clicks into place.

The flap can then be opened and closed in the installed condition. Leave the flap closed during ventilation.

Opening the flap



- Lift the flap (D) by the lower edge and pivot it upwards.

Safety information on breathing circuits and additional components

Additional components in the breathing circuit can increase the inspiratory and expiratory resistance values and exceed standard requirements.

Examples of additional components:
– Bacterial filters, inspiratory and expiratory
– HME
– CO_2 cuvette
– Coaxial hoses

CAUTION

Increased compliance or resistance

Additional components in the breathing circuit such as bacterial filters, HMEs or CO_2 cuvettes increase the dead space, compliance and resistance. Depending on the ventilation mode, either the flow or the pressure rises.

When using additional components, particular care and monitoring are required.

Using bacterial filters or HMEs

Savina is designed to minimize the patient's work of breathing. The use of bacterial filters or HMEs requires particular care and monitoring by the user. Especially during medication nebulization and humidification, the resistance of the expiratory bacterial filter may increase gradually.

CAUTION

Increased resistance

Medication nebulization and active humidification can increase the resistance of bacterial filters.

Regularly check bacterial filters for increased resistance.

Consequences of high resistance

High resistance values lead to increased work of breathing and trigger effort in assisted ventilation. Under unfavorable conditions, this can lead to an undesirable intrinsic PEEP, which can be recognized by the fact that the expiratory flow does not return to "baseline" at the end of expiration. If the PEEP is unacceptably high, this is indicated by an alarm. The measured PEEP is then approximately 8 mbar (8 cmH_2O) above the set PEEP. Check the bacterial filter and replace it if it is the cause of the PEEP alarm.

Monitoring resistance

Savina cannot directly monitor resistance in the patient connection. For this reason:

1 Check the patient’s condition.

2 Monitor the device's measured values for volume and resistance.

3 Observe the instructions for use for the HMEs, bacterial filters, and breathing circuits in use.

NOTE

Operation of the device is ensured within the specified accuracy if the use of additional components does not cause the maximum values for resistance and compliance to be exceeded. For detailed information, refer to section "Performance characteristics" on page 164.

Using coaxial hoses and extendable hoses

Coaxial hoses and extendable hoses have a higher resistance than normal double-lumen breathing hoses. If the patient therapy requires very short expiratory times, an undesirably high intrinsic PEEP may occur as a result of the increased resistance of these breathing hoses. If the PEEP values are unacceptably high, this is indicated by an alarm.

CAUTION

Undesirable intrinsic PEEP

When using coaxial hoses or extendable hoses, an undesirable intrinsic PEEP may occur with very short expiratory times (<0.75 s).

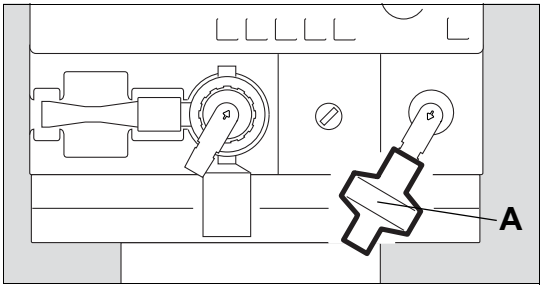
Use double-lumen breathing hoses or set the expiratory time to a value above 0.75 s if the patient therapy allows this.

Installing the bacterial filter

CAUTION
Risk of infection

If no inspiratory bacterial filter or HME is used, the patient can be infected by aspirated ambient air.

Use an inspiratory bacterial filter or HME.



- Fit the bacterial filter (A) onto the inspiratory port.

Attaching the breathing gas humidifier

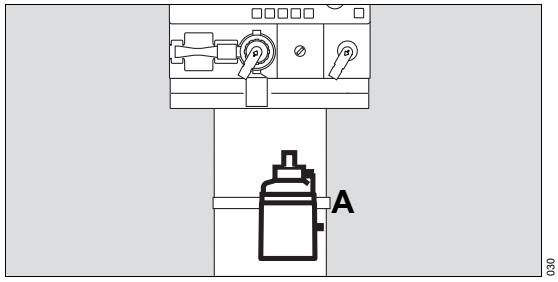
Prerequisites: The breathing gas humidifier is prepared in accordance with the corresponding instructions for use.

CAUTION
High resistance

If an HME and a breathing gas humidifier are used at the same time, resistance can increase.

Use either HME or breathing gas humidifier.

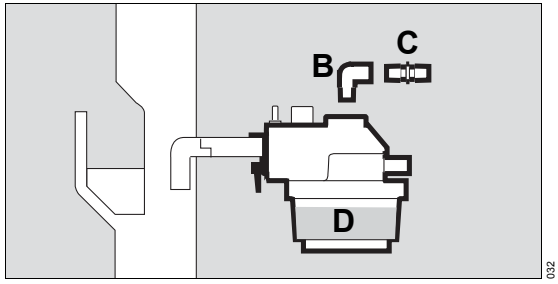
Attaching the breathing gas humidifier to the humidifier holder



- Hang the breathing gas humidifier on the humidifier holder (A) using the clamp and screw firmly into place.

Preparing the Aquapor EL breathing gas humidifier

1 Prepare the Aquapor EL in accordance with the corresponding instructions for use.



2 Insert elbow connector (B) in Aquapor EL.

3 Insert double connector (C) in the elbow connector.

4 Fill the Aquapor EL tank (D) with sterile distilled water to the upper filling mark.

Attaching breathing hoses

Prerequisites: The breathing circuit used is suitable for the respective patient.

WARNING

Risk of electric shock and of fire

The use of antistatic or conductive breathing hoses increases the risk of electric shock to the patient and the risk of fire in an oxygen-enriched environment.

Do not use antistatic or conductive breathing hoses.

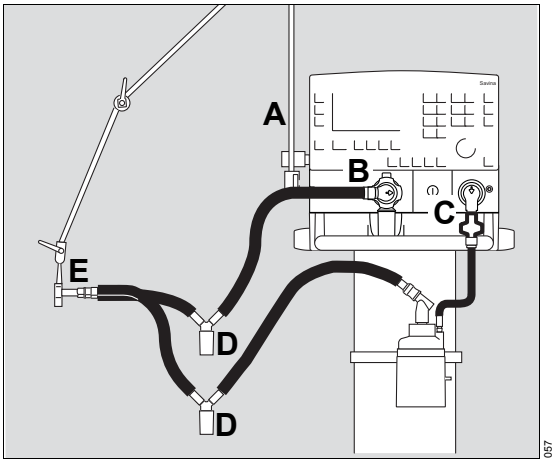
WARNING

Risk of patient injury

The inspiratory breathing gas is warmed by the turbine. If the total length of the inspiratory hoses is too short, the breathing gas temperature at the Y-piece may exceed the permissible limit.

To ensure appropriate cooling of the breathing gas, the total length of the inspiratory hoses must be at least 1.2 m (4 ft).

1 Hang the hinged arm (A) on the lateral standard rail of Savina and tighten the screws. Depending on the position of the device in relation to the bed, the hinged arm can be fitted on the right side or the left side.



2 Connect breathing hoses to the inspiratory port (C) and to the expiratory port (B).

CAUTION

If the inspiratory and expiratory ports are switched, humidification will have no effect.

Connect the breathing hoses correctly.

3 Turn the inspiratory port and expiratory port in the direction of hoses.

Depending on the breathing gas humidifier and the breathing circuit used, a water trap may be required.

4 If a water trap is required, install the water trap (D) in a vertical position.

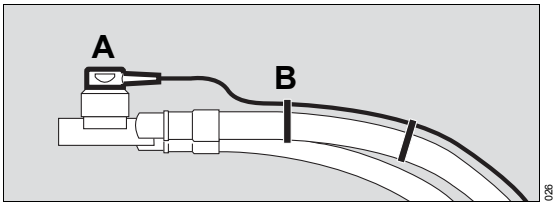
5 Connect the Y-piece (E) to the breathing hoses.

6 Insert the Y-piece or the breathing hoses in the opening of the hinged arm.

Whenever the breathing hoses or the breathing gas humidifier have been changed:

- Check the breathing circuit, see "Performing the breathing circuit check" on page 71.

Installing the breathing gas temperature sensor



1. Insert the breathing gas temperature sensor (A) into the rubber sleeve in the inspiratory part of the Y-piece as far as it will go. Position the Y-piece so that the sensor is at the top in order to prevent condensation in the sensor.
2. Fasten the sensor cable in place with hose clamps (B).
3. Insert the connector into the socket for the breathing gas temperature sensor on the patient connection panel of Savina, see page 21.

Mains power supply

Savina is designed for connection to the hospital's mains power supply.

WARNING

Risk of electric shock and of device malfunction

If the device is connected to a power socket with the wrong power voltage or without a protective ground connector, the user can be endangered and the device damaged.

The mains cable must only be connected to power sockets with a protective ground connector, see "Technical data" on page 161.

NOTE

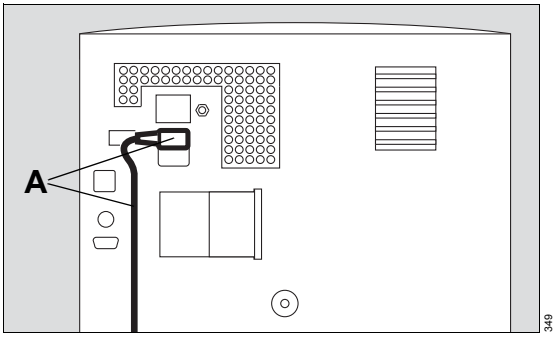
In operation, the power socket used must be readily accessible.

Connecting the mains power supply

Prerequisites:
Mains voltage: 100 V to 240 V, 50/60 Hz

On devices up to serial number ASFF-0999

1 Remove the filter cover, see page 62.



2 Connect the power cable (A) to the device.

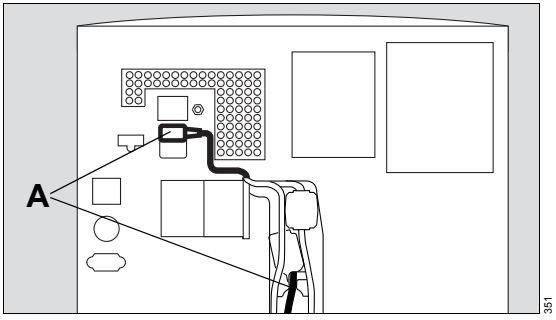
3 Fit the filter cover, see page 62. Position the power cable under the filter cover.

4 Insert the mains plug into the power socket.

The LED ⏻ lights up green.

On devices as from serial number ASFF-1000

1 Remove the filter cover, see page 63.



2 Connect the power cable (A) to the device and attach it in the cable guide.

3 Fit the filter cover, see page 63.

4 Insert the mains plug into the power socket.

The LED ⏻ lights up green.

Power supply from on-board power supply or batteries

WARNING

Risk of explosion

Electrolytic gas can occur when the batteries are charging. In a sufficient concentration, this can cause an explosion.

The device must always be placed in a well-ventilated area when connected to mains power.

Supply from a DC on-board power supply

Savina can be powered by a DC on-board power supply.

Battery supply

Savina has an internal battery included in the scope of delivery, and can additionally be powered by an external battery. For the operating time and charging times of the batteries, see "Operating data" on page 172.

Operating time of internal battery

The maximum operating time is achieved when the battery is new and fully charged. The operating time depends on the following factors:
- State of charge
- Age
- Number of charging cycles
- Speed of the turbine (for increased loads, e.g., through increases in ventilation pressure or flow acceleration, the operating time is reduced)

If Savina is powered from the internal battery, the charge state is indicated on the main screen during operation; see "Symbols" on page 29. During constant ventilation (constant turbine speed), the remaining capacity display shows a constant trend.

Charging time of internal battery

The charging time increases significantly when the battery is warm, e.g., from high ambient temperatures or after a deep discharge.

Connecting the power supply

Prerequisites:
- Mounting and connection by service personnel only.
- Both poles of the DC on-board power supply must be protected against contact.

CAUTION

Risk of patient injury

If the poles of the DC on-board power supply are not protected against contact, excessive patient leakage current can result.

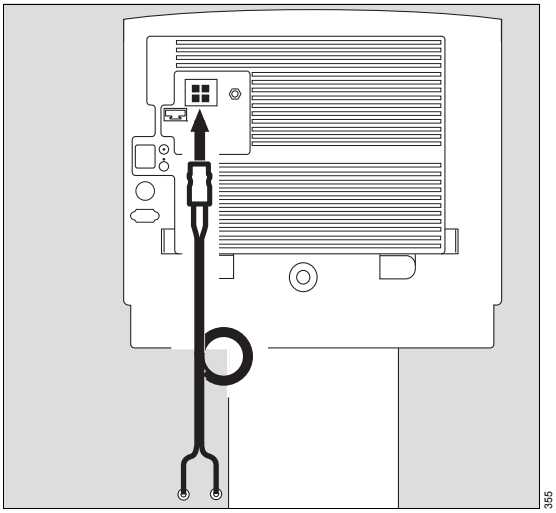
Protect both poles against contact.

CAUTION

Risk of damage to device
- Do not connect mains-operated devices to the connection for the external battery.
- Only connect external batteries which are contained in the list of accessories.
- Use only connection cables that are listed in the list of accessories.

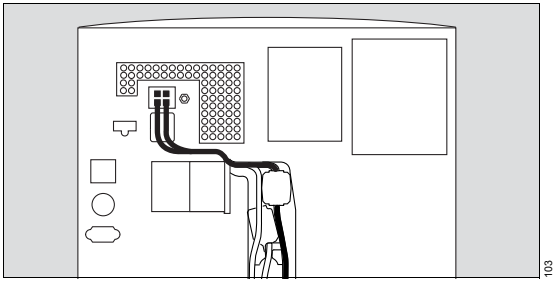
The device-side plug of the connection cable is encoded. This lets Savina detect whether an external battery or a DC on-board power supply is connected.

On devices up to serial number ASFF-0999



- Connect the external battery with the battery cable (8414092) or connect the DC on-board power supply with the on-board power cable (8414048).

On devices as from serial number ASFF-1000



1 Remove the filter cover, see page 63.

2 Connect the external battery with the battery cable (8418810) or connect the DC on-board power supply with the on-board power cable (8421403) and attach it in the cable guide.

3 Fit the filter cover, see page 63.

Using the power supply

Power is supplied according to the following rules:

Mains power	DC on-board power supply or external battery (optional)	Internal battery
Present	Not in use	Not in use
Insufficient	In use	Not in use
Insufficient	Discharged	In use

Power supply from the internal battery

If the operating time has nearly elapsed:

- Reestablish power supply from one of the following sources to avoid an interruption of ventilation:
  – Mains power supply
  – DC on-board power
  – Charged external battery

Charging the batteries

As soon as Savina is connected to the mains power supply, the batteries are charged. The voltage of the connected external battery is automatically detected.

The internal battery is also charged if Savina is supplied from the external battery or a DC on-board power supply. Savina must be turned on.

After using the batteries

- Connect the mains power supply.

It is not necessary to switch on Savina.

Additional information

Alarm messages, see "Alarm – Cause – Remedy" on page 117.

Technical Data, see "Operating data" on page 172.

Battery maintenance, see page 150.

Storing Savina, see page 94.

Gas supply

For ventilation, Savina uses ambient air supplied by an internal turbine.

The O_2 supply is provided by one of the following sources:
– Central gas supply system (HPO mode)
– Compressed gas cylinders (HPO mode)
– Low pressure oxygen source, e.g., an O_2 concentrator (LPO mode)

Connecting the O_2 supply

WARNING
Risk of explosion

Pressurized oxygen in conjunction with oil or grease may spontaneously ignite.

Do not bring any oxygen supply components into contact with oil and grease.

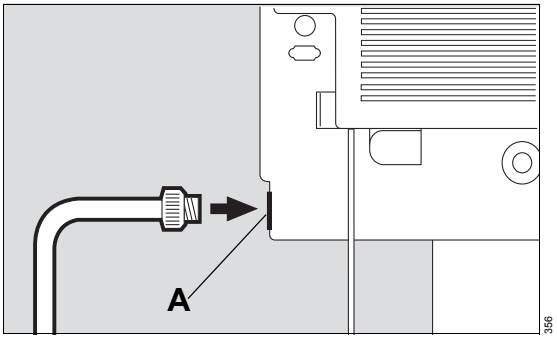
WARNING
Risk of patient injury

If compressed gases are used that are not approved for medical uses, the proper functioning of the device may be impaired.

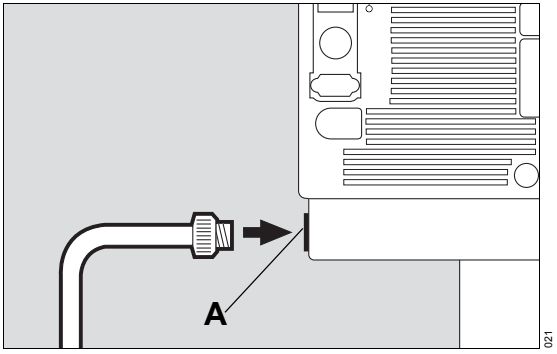
Only use compressed gases approved for medical use. The compressed gases must be free of dust and oil particles and dry.

O_2 supply from a central gas supply system

Devices up to serial number ASFF-0999:



Devices as from serial number ASFF-1000:



1 Screw the O_2 compressed gas hose to the ***O_2*** (A) connection of Savina.

2 Plug the connector into the wall terminal unit of the central gas supply system.

3 Secure the compressed gas hose by hanging it over the hose holders.

O_2 supply from compressed gas cylinders

If the central gas supply fails or is not available, O_2 can be supplied from compressed gas cylinders.

O_2 supply from a low-pressure oxygen source (LPO mode)

O_2 is supplied from an external low-pressure oxygen source, e.g., an O_2 concentrator,
see page 88.

Nurse call

Information on the nurse call

The nurse call is used for transmitting high-priority (warning) alarms to a central hospital alarm system. Medium-priority (caution) and low-priority (note) alarms are not transmitted.

If the acoustic alarm signal of the device fails, the nurse call will be activated anyway.

If, in the event of an alarm, the ***Audio paused 2 min.*** key is pressed, the acoustic alarm signal on the device and the nurse call are suppressed for 2 minutes. During this time new alarms that occur are not signaled by the nurse call.

WARNING

Risk due to limited patient monitoring

The nurse call does not forward all alarms. Do not use the nurse call as the sole source of alarm information.

Pay attention to the alarms directly on the device.

WARNING

Risk of nurse call failure

A connection failure between the device and the central hospital alarm system may interrupt the transmission of information.

Pay attention to the alarms directly on the device.

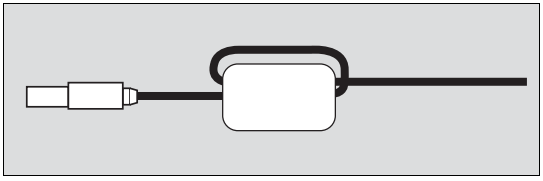
Connecting the nurse call

Connecting the nurse call to the central hospital alarm system

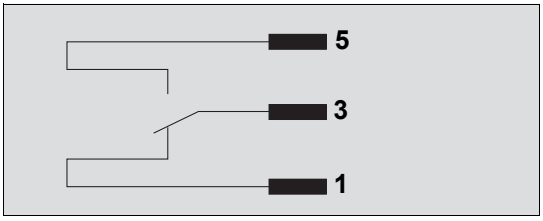
The kit must be installed by service personnel:

- Have the 6-pin circular connector (socket part) connected to the central hospital alarm system.

The connector is delivered with a ferrite core, through which the cable must be looped.



- Guide the cable, which has a shield at one end only, through the ferrite core in a loop.



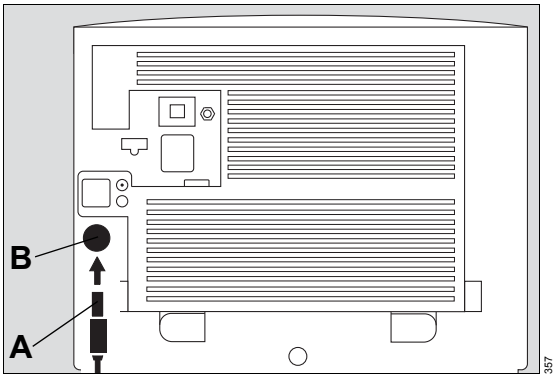
As soon as Savina signals an alarm, the connection between cable 5 and cable 3 is closed and the nurse call is activated.

The connections to the central alarm system in the hospital are typically of a single-channel design. Consequently, the electronics of the nurse call are also of a single-channel design.

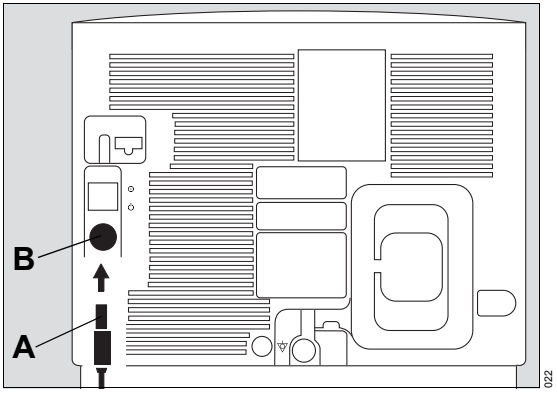
Connecting the nurse call to Savina

Prerequisites: Only connect safety extra-low voltage (SELV) devices to the connection for the nurse call.

Devices up to serial number ASFF-0999:



Devices as from serial number ASFF-1000:



1 Plug the nurse call connector (A) into the socket (B) and screw into place.

2 Check the correct operation of connected nurse call system.

MEDIBUS protocol

Information on MEDIBUS

MEDIBUS is a software protocol for the transfer of data between Savina and other medical devices (e.g., patient monitors) or other devices (e.g., computers for data management systems).

For the requirements for combining Savina and an external device, see "Device combinations" on page 9 and "Connections to IT networks" on page 185.

WARNING

Risk of patient injury due to incorrectly transmitted data

All transferred data is intended for informational purposes only and is not intended to be used as the basis for diagnostic or therapeutic decisions.

Regularly check the displays on the screen of Savina. Pay attention to the alarms directly on Savina.

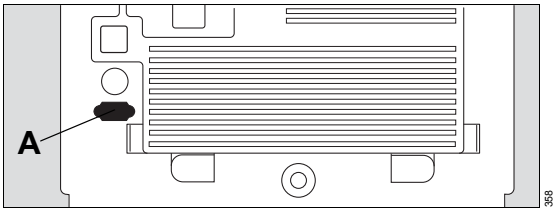
Observe the following documents:

MEDIBUS for Dräger Intensive Care Devices	9028329
Dräger RS 232 MEDIBUS, Protocol Definition	9028258

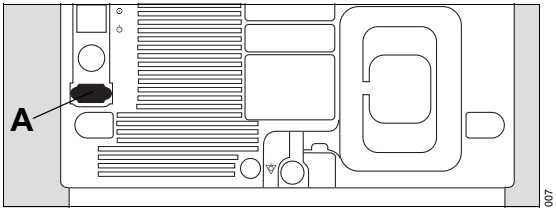
Connecting an external device for MEDIBUS

Prerequisites:
– The corresponding MEDIBUS cable is used.
– Only devices with safety extra-low voltage (SELV) are connected to the COM port (serial RS232 interface).

Devices up to serial number ASFF-0999:



Devices as from serial number ASFF-1000:



- Connect an external device to the COM port (A).

Configuring the interface

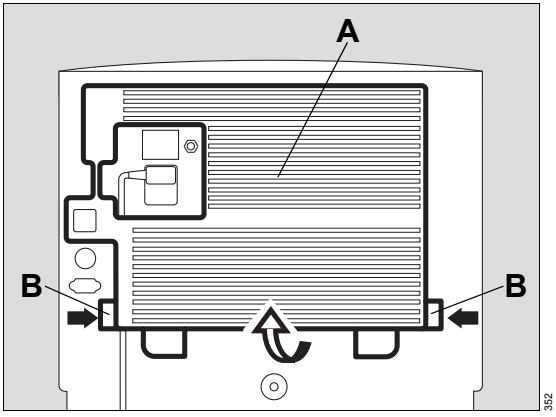
A description is given in chapter "Configuring the data interface" on page 113.

Removing and refitting the filter cover

The filter cover on the back of Savina must occasionally be removed, e.g., for the following actions:
– Connecting a potential equalization cable
– Connecting an external battery or DC on-board power supply
– Replacing the microfilter
– Replacing the dust filter set

Filter cover on devices up to serial number ASFF-0999

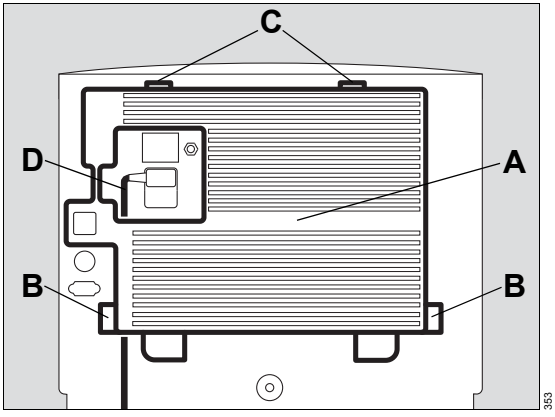
Removing the filter cover



1 Press both catches (B) inside towards each other simultaneously.

2 Detach and remove the filter cover (A).

Fitting the filter cover



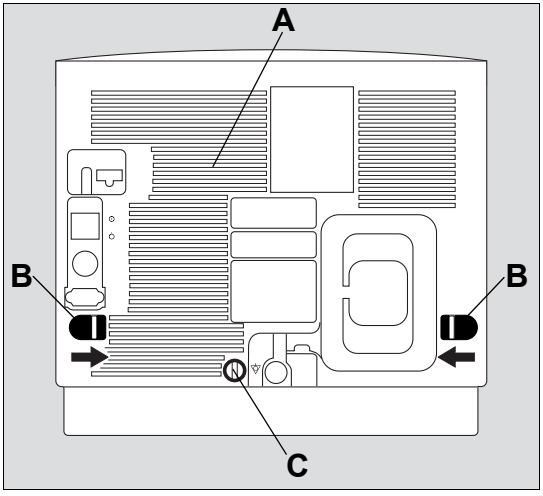
1 Insert the filter cover (A) with both holders (C) into the rear panel.

2 Position the power cable (D) under the filter cover.

3 Press the catches (B) until they engage in the recess.

Filter cover on devices as from serial number ASFF-1000

Removing the filter cover

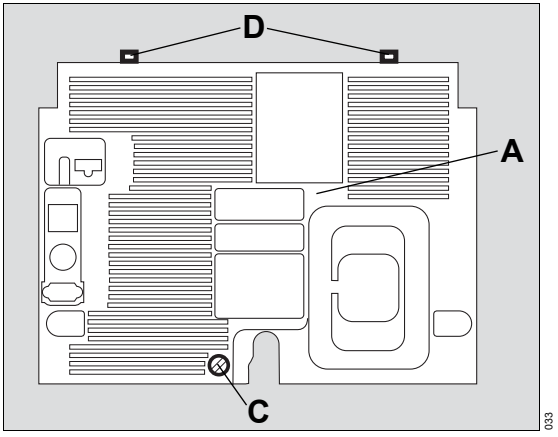


1 Use a coin to loosen the screw (C).

2 Reach into the openings (B) on both sides and press both catches inside towards each other simultaneously.

3 Detach and remove the filter cover (A).

Fitting the filter cover



1 Insert the filter cover (A) with both holders (D) into the rear panel.

2 Press the catches until they engage in the recess.

3 Use a coin to tighten the screw (C).

Connecting a potential equalization cable

Prerequisites: The potential equalization cable must only be installed by service personnel.

For more information about potential equalization pins and cable guide, see the following sections:
– "Rear of the device up to serial number ASFF-0999" on page 22.
– "Rear of the device as from serial number ASFF-1000" on page 23.

1 Remove the filter cover, see page 62.

2 Plug one end of the potential equalization cable onto the potential equalization pin of Savina as far as it will go.

3 Firmly press the potential equalization cable into the groove of the cable guide. Keep the cable as short as possible between the pin and the cable guide.

4 Fit the filter cover, see page 62.

5 Connect the other end of the potential equalization cable to the hospital's potential equalization socket.

NOTE

During operation, the hospital's potential equalization socket must be freely accessible and it must be possible to disconnect the connection without tools.

Intrahospital transport

Transport is any movement of the medical device without the patient that is not carried out for the purpose of positioning the medical device.

Increasing the tipping stability

1 Set the hinged arm to minimum deflection.

2 Drain the water container of the breathing gas humidifier.

3 Fasten the breathing gas humidifier on the humidifier holder on the front of the trolley.

4 Do not fasten additional parts to the lateral standard rails.

5 If present, turn the monitor to the middle position.

6 Grasp the handle of the trolley firmly and move the device in the longitudinal direction.

The safety information for patient transport also applies, see page 91.

Getting started

Safety information

WARNING

Risk of patient injury

Ventilation does not take place in standby mode. Patients connected to the device are endangered.

Only set the device to standby mode when no patient is connected to the device.

CAUTION

Malfunctions through condensation

When the device is moved from a cold storage location to a warm environment, condensation can form.

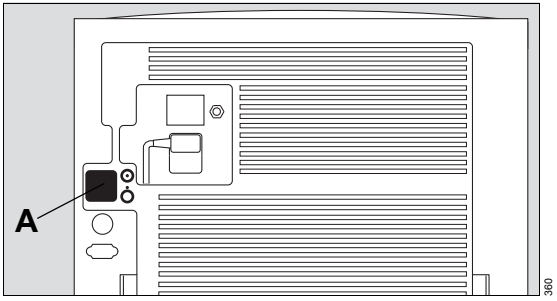
Only switch on the device when the condensation has dried.

Switching on Savina

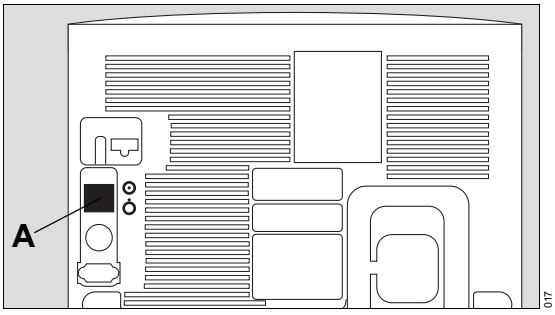
Conditions:
- Savina is reprocessed and assembled ready for operation.
- Mains power supply or power supply with a charged battery is established.
- O_2 supply is ensured.

If the internal battery is discharged, Savina does not transmit any measured FiO_2 values for the first10 to 20 minutes after it is switched on. The accuracy of the O_2 delivery is reduced during this period.

Devices up to serial number ASFF-0999:



Devices as from serial number ASFF-1000:

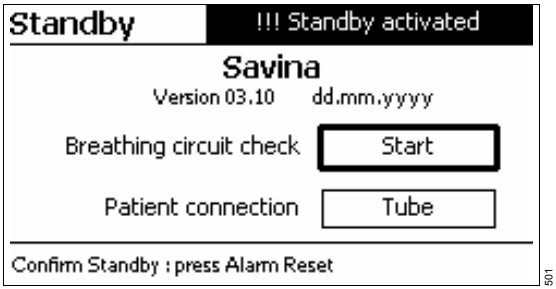


1 Set the main switch (A) to ⊙ (on).

The system start is performed.
The progress bar shows the progression of the system start.

2 Wait for the system to start (at most 20 seconds).

Savina is in standby mode. The start screen is displayed.



3 Confirm standby mode with the ***Alarm Reset*** key.

The alarm message ***Perform br. circuit check*** is displayed.

Before using the device on the patient

1 Check operational readiness, see page 70.

2 Select the application mode, see page 73.

Starting ventilation

- Press the ⏻ ***Start/Standby*** key.

Savina starts the therapy with the last set ventilation parameters and alarm limits. The main screen is displayed.

Device check after reprocessing

After every reprocessing of the device, perform the device check to confirm that Savina is functioning correctly

Prerequisites: Savina is prepared.

Connecting the test lung

- Insert the test lung into the patient connector of the Y-piece.

Checking the functioning of the LEDs and the acoustic alarm signal

Switch on Savina:

1 Set the main switch to ⊙ (on).

The LEDs in the displays and keys light up (with the exception of the LEDs of the power supply). The alarm signal sounds.

The alarm message ***!!! Standby activated*** is displayed. The red LED flashes. The alarm signal for high-priority alarms sounds.

2 Confirm the alarm message with the ***Alarm Reset*** key.

The alarm message ***!! Perform br. circuit check*** is displayed. The yellow LED flashes. The alarm signal for medium-priority alarms sounds.

3 Confirm the alarm message with the ***Alarm Reset*** key.

Checking the functioning of ventilation

1 Press the ⏻ ***Start/Standby*** key.

Savina starts ventilation.

2 Set up ventilation:

Ventilation mode	***IPPV***
VT	500 mL
Tinsp.	1.5 s
f	20 bpm
O2 (only in HPO mode)	60 Vol%
PEEP	5 mbar (5 cmH2O)
Page ***Settings 1/1***	
Trigger	OFF
FlowAcc	35 mbar/s (35 cmH2O/s)
AutoFlow	OFF
Sigh	OFF
Page ***Configuration 2/4***	
FiO2 monitoring	ON
Flow monitoring	ON
Pmax	OFF
Plateau	ON
LPO-mode	OFF
Page ***Alarms 1/4***	
Paw ⌐▲	100 mbar (100 cmH2O)

Savina ventilates the test lung with the set ventilation parameters.

3 Set further alarm limits so that ventilation is possible without triggering alarms.

4 Press the ***Values*** ▷▷ key until the screen ***Values 1/5*** is displayed.

The bar graph changes between displaying the inspiratory pressure and the final expiratory pressure, depending on whether the patient is breathing in or out.

5 The following measured values must be displayed:

PEEP	5 mbar ±2 mbar (5 cmH2O ±2 cmH2O)
MV	9.50 L/min ±1.0 L/min
FiO2 (only in HPO mode)	60 Vol% ±3 Vol%

6 Remove the test lung from the Y-piece.

The alarm message ***Airway pressure low*** is displayed. After about 45 seconds, the following measured value ***MV*** is displayed: 0 L/min +0.5 L/min

7 Fit the test lung back onto the Y-piece.

Checking the O2 alarm

In HPO mode

1 Remove the gas probe of the O2 supply from the wall terminal unit of the central gas supply system.

The alarm message ***O2 supply down*** is displayed.

2 Restore the O2 supply.

It is possible that the alarm message ***FiO2 low*** may be displayed briefly.

In LPO mode

1 Set the alarm limit ***FiO2*** ▼⌐ to 60 Vol%.

2 Disconnect O2 concentrator.

The alarm message ***FiO2 low*** is displayed.

3 Restore the O2 supply.

Check safety valve

1 Put on sterile gloves and seal the flow sensor.

The alarm message ***PEEP high*** is displayed. The red LED flashes. The alarm signal sounds.
The safety valve is opened. After about 3 seconds the airway pressure has fallen to PEEP level.

2 Set the ventilation and the alarm limits specific to the patient or hospital.

3 Press the ***Alarm Reset*** key.

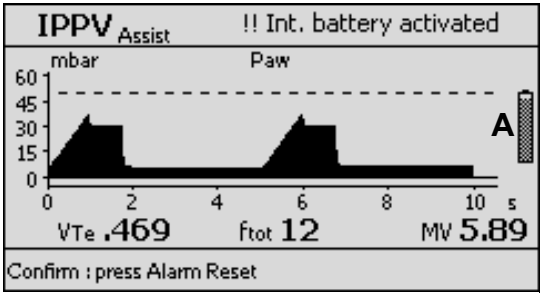
Checking switch-over to battery operation

Check that the capacity of the internal and external batteries is sufficient. Batteries can be exhausted or destroyed due to excessively long storage.

- Disconnect the mains plug.

If the external battery is connected, Savina switches over to the external battery without interruption.

If the external battery is not connected or if it is discharged, Savina switches over to the internal battery without interruption.



Wait about 30 seconds. The remaining capacity display (A) indicates the charge state of the internal battery.

If the batteries are discharged, the acoustic power supply failure alarm is triggered.

- Re-connect the mains plug.

Savina switches back to mains operation.

Additional information

"Power supply from on-board power supply or batteries" on page 55.

"Failure of the power supply" on page 116.

Checking operational readiness

WARNING

Risk of patient injury

The device's operational readiness must be checked before using the device on a patient. If a malfunction is detected during the safety-relevant test steps, the patient may be endangered.

Only start ventilation once the checks have been successfully completed.

CAUTION

Gas dosage inaccurate

For small tidal volumes, the accuracy of the gas delivery is not ensured:
– If the breathing circuit used is not suitable for the respective patient.
– If the breathing circuit check is not performed.

Use a suitable breathing circuit and perform the breathing circuit check before using the device on the patient.

The device's operational readiness is checked using the following measures:
– Checking the functioning of the LEDs and of the acoustic alarm signal
– Checking the power failure alarm
– Checking connected components
– Performing the breathing circuit check

Information on breathing circuit check

The breathing circuit check must be performed after the following actions:
– Exchange of the breathing circuit or individual components
– Exchange of the breathing gas humidifier

The following test steps are performed:
– Leakage of the breathing circuit
– Compliance of the breathing circuit
– Inspiratory resistance
– Expiratory resistance

The current leakage flow is determined and displayed. A leakage flow of up to 300 mL/min at a pressure of 60 mbar (60 cmH_2O) is acceptable.

Savina uses the compliance determined to increase the accuracy of the tidal volume delivered. Especially for small tidal volumes (VT<100 mL), an accurate delivery is required.

The values for the inspiratory and expiratory resistance must lie within the specified ranges, see Technical data, "Performance characteristics" on page 164.

Automatic cancelation

If ventilation is started or a different dialog window is opened while the breathing circuit check is being performed, the check is aborted.

Checking the functioning of the LEDs and the acoustic alarm signal

Switch on Savina:

1 Set the main switch to ⊙ (on).

The LEDs in the displays and keys light up (with the exception of the LEDs of the power supply). The alarm signal sounds.

The alarm message ***!!! Standby activated*** is displayed. The red LED flashes. The alarm signal for high-priority alarms sounds.

2 Confirm the alarm message with the ***Alarm Reset*** key.

The alarm message ***!! Perform br. circuit check*** is displayed. The yellow LED flashes. The alarm signal for medium-priority alarms sounds.

3 Confirm the alarm message with the ***Alarm Reset*** key.

Checking the power supply failure alarm

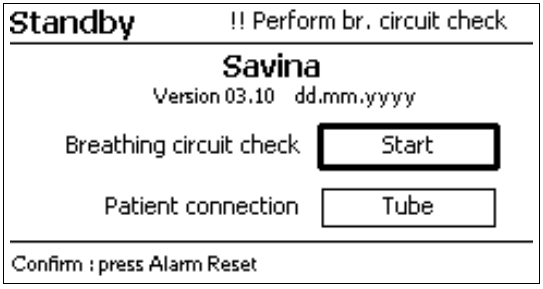
- Press the ***Alarm Reset*** key for approximately 3 seconds.

The power supply failure alarm sounds (high beeping in a quick sequence).

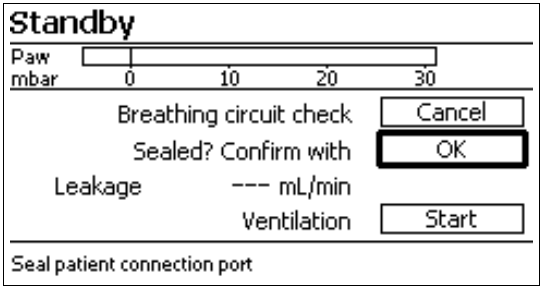
Checking connected components

- Check the correct connection of the following components:
  - Breathing circuit
  - Inspiratory bacterial filter
  - Breathing gas humidifier or HME
  - Water trap on expiratory valve
  - Test lung

Performing the breathing circuit check



1 On the ***Breathing circuit check*** line select the ***Start*** setting with the rotary knob and push to confirm.



2 When prompted by Savina, seal the patient connection port, e.g., with a sterile glove.

3 Select ***OK*** with the rotary knob and confirm.

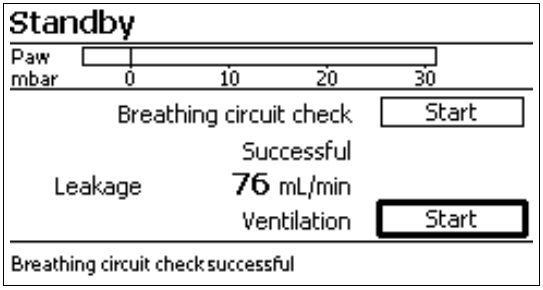
The leakage flow is displayed.

4 When requested, open the patient connection port.

5 Select ***OK*** with the rotary knob and confirm.

The breathing circuit check is continued.

After the check the check results are displayed.



After the successful breathing circuit check:
- Select the application mode, see page 73.
- Start ventilation, see page 74.

Canceling the breathing circuit check

- On the ***Breathing circuit check*** line select the ***Cancel*** setting with the rotary knob and push to confirm.

Check results

The results of the breathing circuit check will remain stored until the check is performed again, even when the device is switched off. After a restart the device prompts to perform the check again.

If a valid measurement has not yet been performed, the standard values are used but are not displayed.

Displaying check results

- Press the ***Values*** ▷▷ key until the following screens are displayed:

Screen is in standby mode	**Screen during ventilation**	**Results**
Values 1/2	Values 4/5	Breathing circuit check
		Leakage [mL/min]
Values 2/2	Values 5/5	C hose [mL/mbar]
		For a flow of 30 L/min and 60 L/min:
		Ri [mbar/L/s]
		Re [mbar/L/s]

Selecting Tube or Mask/NIV application mode

Savina can be used for the ventilation of intubated patients (application mode ***Tube***) and for non-invasive ventilation (application mode ***Mask/NIV***). After switching the device on, application mode ***Tube*** is preselected.

WARNING

Risk of patient injury

If the alarm limits and ventilation settings are not adjusted after changing from application mode *Mask/NIV* to *Tube*, Savina cannot monitor ventilation adequately.

Check alarm limits and ventilation settings and change if necessary.

CAUTION

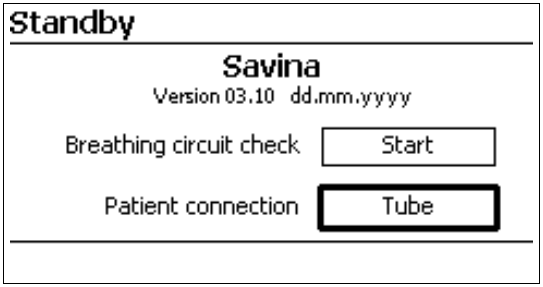
Risk of patient injury

In the ***Mask/NIV*** application mode, Savina cannot monitor intubated patients adequately.

For intubated patients, use the application mode ***Tube***.

Application mode, select

Prerequisites:
– Savina is in standby mode.
– The start screen has been opened.



1 Select the ***Patient Connection*** line with the rotary knob.

2 Press the rotary knob.

3 Select the application mode ***Mask/NIV*** or ***Tube*** with the rotary knob and confirm.

Savina displays information on changing the application mode.

In the application mode ***Mask/NIV***, the text ***NIV*** is displayed on the screen.

Additional information

For information about using the application mode ***Mask/NIV***, see "Non-Invasive Ventilation (NIV)" on page 79.

Starting therapy

Before using the device on the patient

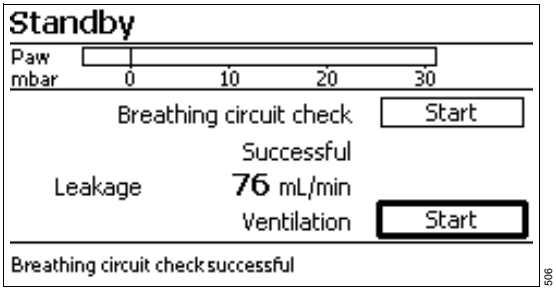
1 Check operational readiness, see page 70.

2 Select the application mode, see page 73.

3 Check the therapy settings:
- Set the ventilation mode and ventilation parameters, see page 76.
- Set the alarm limits, see page 99.

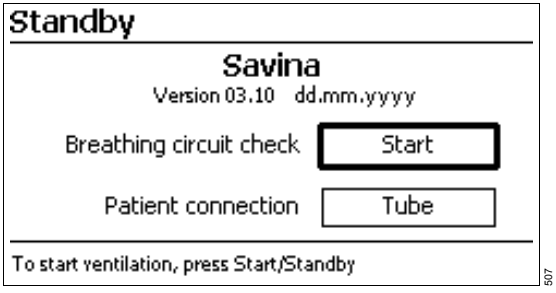
Starting ventilation

After the successful breathing circuit check:



- Select the ***Ventilation*** line with the rotary knob and confirm.

Or:



- Press the ⏻ ***Start/Standby*** key.

Savina starts the therapy with the set ventilation parameters and alarm limits. The main screen is displayed.

Operation

Setting ventilation

Ventilation is adjusted using the keys on the device and in the ***Settings*** dialog window. The settings can be changed during ventilation or in standby mode. To activate standby mode, see page 92.

A detailed description of the ventilation modes and ventilation parameters can be found in chapters "Ventilation modes" on page 188 and "Additional settings" on page 195.

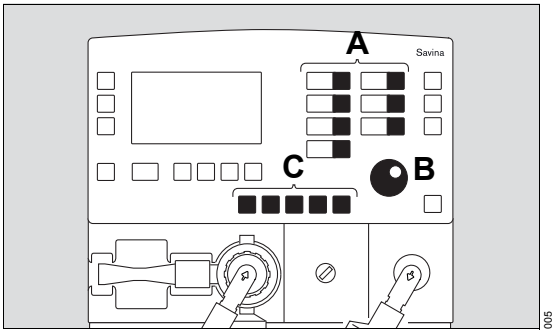
Setting ranges

Ventilation parameters	**Setting range**
V_T	0.05 to 2.0 L
$T_{insp.}$	0.2 to 10 s
f	2 to 80 bpm
O_2	21 to 100 Vol%
$P_{insp.}$	1 to 99 mbar
$\Delta P_{ASB\ above\ PEEP}$	0 to 35 mbar
PEEP	0 to 35 mbar
FlowAcc	5 to 200 mbar/s

Additional settings	**Setting range**		
Trigger	OFF	1 to 15 L/min	
AutoFlow	OFF	ON	
Apn-Vent.	OFF	f_{Apnoea}	2 to 80 bpm
		VT_{Apnoea}	0.05 to 2.0 L
ΔSigh	OFF	1 to 35 mbar	

Selecting the ventilation mode and setting ventilation parameters

Prerequisites: Savina is prepared and switched on.



Selecting a ventilation mode

1 Press the corresponding key (C).

2 Push the rotary knob (B) to confirm.

Or:

- Press the corresponding key (C) for at least 3 seconds.

The selected ventilation mode is now effective.

Setting ventilation parameters

1 Press the corresponding key (A).

The yellow LED in the key lights up.

2 Turn the rotary knob (B) to the right or left to change a setting.

The new value is displayed next to the key. Additional ventilation parameters derived from the ventilation parameter are calculated and displayed in the setting assistance field.

3 Push the rotary knob (B) to confirm.

The setting is accepted. The yellow LED in the key goes out.

Presetting ventilation parameters for another ventilation mode

1 Briefly press the appropriate ventilation mode key.

The yellow LED in the key flashes.

The LEDs flash in the keys of the ventilation parameters that are additionally required.

Ventilation parameters whose LEDs are not flashing are effective in the active ventilation mode. Any change to and confirmation of these ventilation parameters will have an immediate effect on the active ventilation mode.

2 Set the ventilation parameters.

Setting additional ventilation parameters in the dialog window

1 Press the ***Settings*** ▷▷ key.

The dialog window ***Settings 1/1*** is displayed.

2 Select the ventilation parameter with the rotary knob and confirm.

3 Set the value by turning the rotary knob and confirm.

Activating and setting additional settings

In the dialog window ***Settings 1/1***:

1 Select the corresponding line using the rotary knob and confirm.

2 Turn the rotary knob to select ***ON*** or set the value and confirm.

Exceeding the set limit of a ventilation parameter

Parameters	Adjustment limit
$P_{insp.}$	↑ 50 mbar
P_{max}	↑ 50 mbar
PEEP	↑ 20 mbar
$\Delta P_{ASB\ above\ PEEP}$ + PEEP	↑ 30 mbar
$\Delta P_{ASB\ above\ PEEP}$ + PEEP	↑ 50 mbar
ΔSigh + PEEP	↑ 20 mbar
FlowAcc	↓ 20 mbar/s
f, $T_{insp.}$ [1]	↑ I:E > 1:1
	↓ I:E < 1:3

1) f and $T_{insp.}$ are limited depending on I:E.

Once the adjustment limit for a parameter has been reached, the value flashes.

- Press the rotary knob to exceed the set limit.

The set limit can be exceeded.

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

- Press the rotary knob.

Savina takes the maximum value that can be set.

Settings for ventilation

Ventilation parameters		Ventilation mode			
Setup location		**IPPV**	**SIMV**	**CPAP/ASB**	**BIPAP**
Keys on the device	V_T	X	X		
	$T_{insp.}$	X[1)]	X[1)]	X[2)]	X
	f	X	X		X
	O_2	X[3)]	X[3)]	X[3)]	X[3)]
	$P_{insp.}$	X[4)]	X[4)]		X
	$\Delta P_{ASB\ above\ PEEP}$		X	X	X
	PEEP	X	X	X	X
Dialog window ***Settings 1/1***	Trigger	X[5)]	X	X	X
	FlowAcc	X	X	X	X
	AutoFlow	X	X		
	Apn-Vent.		X	X	X
	ΔSigh	X			
Dialog window ***Configuration 2/4***	P_{max}	X[6)]	X[6)]		

1) If ***Plateau*** or ***AutoFlow*** are activated
2) Only in application mode ***Mask/NIV***
3) If ***LPO-mode*** is deactivated
4) When ***Pmax*** is activated and ***AutoFlow*** is deactivated
5) If the ventilation parameter ***Trigger*** is activated, Savina displays the ventilation mode ***IPPV$_{Assist}$*** on the screen.
6) If ***Pmax*** is activated

CAUTION

Risk of patient injury

High trigger sensitivity may lead to auto-triggering of the ventilator.

Set the trigger threshold accordingly.

Additional information

To switch the ventilation functions ***Pmax***, ***Plateau*** and ***LPO-mode*** on or off, see "Configuring ventilation functions" on page 111.

Apnea ventilation

For a detailed description of apnea ventilation, see chapter "Apnea ventilation" on page 195.

The status of apnea ventilation is displayed for 6 seconds in the following situations:
– Another ventilation mode that also permits apnea ventilation has been selected.
– The apnea respiratory rate ***fApnoea*** was set too low in relation to the apnea alarm time ***TApnoea***.

Activating and setting apnea ventilation

In the dialog window ***Settings 1/1***:

1 Select the line ***Apn-Vent.*** with the rotary knob and confirm.

2 Use the rotary knob to set a value of at least 2 bpm.

The lines ***VTApnoea*** and ***fApnoea*** are displayed.

3 Select the respective ventilation parameter with the rotary knob and confirm.

4 Set the value by turning the rotary knob and confirm.

5 Set the alarm limit ***TApnoea***, see page 99.

Ending active apnea ventilation

- Press the ***Alarm Reset*** key.

Savina ventilates again in the previous ventilation mode.

Deactivating apnea ventilation

In the dialog window ***Settings 1/1***:

1 Select the line ***fApnoea*** with the rotary knob and confirm.

2 Use the rotary knob to set a value less than 2 bpm and confirm.

Non-Invasive Ventilation (NIV)

The use of non-invasive ventilation is described below. For a detailed description, see chapter "Non-invasive ventilation (NIV)" on page 200.

In the ***Mask/NIV*** application mode, all the ventilation modes are selectable.

Installing the NIV kit

The kit may only be installed by experts.

Safety information

WARNING
Risk of patient injury

Danger of aspiration due to high airway pressures.

Avoid high airway pressures.

WARNING
Risk of patient injury

If flow monitoring is deactivated during CPAP/ASB with a nasopharyngeal tube, Savina cannot monitor ventilation adequately.

Use a separate monitoring device.

CAUTION
Risk of patient injury

In the ***Mask/NIV*** application mode, Savina cannot monitor intubated patients adequately.

For intubated patients, use the application mode ***Tube***.

CAUTION
Risk of patient injury

Use of masks increases the dead space.

Observe the mask manufacturer's instructions.

CAUTION
Risk of patient injury

When using masks, leakages can cause the actual tidal volume to deviate from the measured value ***VTe***.

CAUTION
Risk of patient injury

The device has no integrated CO_2 monitoring.

If necessary, use external monitoring.

NOTE
Use suitable masks. Otherwise too high leakages may occur.

WARNING
Risk of patient injury

If the alarm limits and ventilation settings are not adjusted after changing from application mode *Mask/NIV* to *Tube*, Savina cannot monitor ventilation adequately.

Check alarm limits and ventilation settings and change if necessary.

Using non-invasive ventilation

1 Select application mode ***Mask/NIV***. See "Selecting Tube or Mask/NIV application mode" on page 73.

2 Select ventilation mode and set ventilation parameters. See "Setting ventilation" on page 76.

In ventilation mode ***CPAP/ASB***, the ***Tinsp.*** key can be used to limit the maximum duration of supported breaths, because the inspiratory termination criterion may be ineffective in the case of very high leakages.

3 Set the alarm limits, see page 99.

The alarm limits ***MV*** $\blacktriangledown\!\!\!/\,\overline{\ }$, ***VTi***, ***TApnoea*** can be switched off, see page 100. If required, use additional monitoring, e.g., external SpO_2 monitoring.

4 Start ventilation. See "Starting therapy" on page 74.

Suction maneuver with oxygen enrichment

For endotracheal suction, Savina offers a program for oxygen enrichment with the following phases:
– Preoxygenation to avoid any risk of hypoxia during the disconnection phase.
– Disconnection for endotracheal suction
– Postoxygenation

During suction and for 2 minutes afterwards, the lower alarm limit for the minute volume is switched off.

WARNING

Development of atelectasis

If a suction catheter is used that is too large, the air supply is impaired. Due to the negative pressure during suction, atelectasis can develop.

Select an appropriate suction catheter for suction.

WARNING

Risk to patients when using suction in a closed breathing circuit

With volume-controlled ventilation without AutoFlow and during the disconnection phase, flow delivery is limited. If suction is used in a closed breathing circuit, negative pressure is possible.

Only use suction in volume-controlled ventilation with AutoFlow or in pressure-controlled ventilation. Preoxygenation must be stopped before closed suction starts.

Performing oxygen enrichment

Prerequisites:
– O_2 supply from the central gas supply system or from an O_2 gas cylinder is ensured.
– O_2 supply pressure: 2.7 bar to 6 bar (39.2 psi to 87 psi)
– LPO mode is switched off.
– Flow sensor is functional.
– Flow monitoring is activated.

1 Press the ***O2*** ↑ *Suction* key.

The yellow LED in the key lights up.

Savina continues ventilating in the set ventilation mode at 100 Vol% O_2. So that Savina can detect later disconnection, the PEEP is increased to 4 mbar (4 cmH_2O). Any PEEP set higher is retained.

Within 180 seconds, Savina expects a disconnection for suction. In the message field, the preoxygenation phase is displayed with the remaining time.

2 Disconnect patient and perform suction maneuver.

Savina interrupts ventilation and delivers a minimal flow to detect reconnection automatically. The acoustic alarm signals are suppressed.
120 seconds are available for suctioning. In the message field, the disconnection phase is displayed with the remaining time.

3 Connect patient.

Savina continues ventilating in the set ventilation mode, except that for 120 seconds 100 Vol% O_2 is delivered for postoxygenation. In the message field, the postoxygenation phase is displayed with the remaining time.

Automatic cancelation of oxygen enrichment

Savina cancels the oxygen enrichment program in the following situations:
– The patient is not disconnected in the initial oxygen enrichment phase.
– The patient is not reconnected in the disconnection phase.

The set ventilation mode and the alarms are reactivated.

Terminating oxygen enrichment prematurely

- Press the ***O2*** *↑Suction* key.

Medication nebulization

Safety information

WARNING

Risk of fire

The flow sensor can ignite medications or other substances based on highly flammable substances.
- **Do not nebulize medications or other substances that are easily flammable or spray them into the device.**
- **Do not use substances containing alcohol.**
- **Do not allow flammable or explosive substances to enter the breathing system or the breathing circuit.**

CAUTION

Increased O_2 concentration

Savina uses for the medication nebulization 100 Vol% O_2. Therefore, the set inspiratory O_2 concentration is increased during medication nebulization.

CAUTION

Ventilation impaired

If unapproved pneumatic medication nebulizers are used, the actual tidal volume and O_2 concentration may deviate from the displayed values.

Use only medication nebulizers that are listed in the current list of accessories.

CAUTION

Ventilation impaired

If a bacterial filter is placed between the nebulizer and the tube during medication nebulization, flow resistance may increase and impair ventilation.

Place a bacterial filter between the inspiratory valve and the nebulizer.

CAUTION

Insufficient medication nebulization

If an HME is used on the Y-piece during medication nebulization, the medication will not be appropriately administered to the patient.

During medication nebulization, do not use an HME.

CAUTION

Ventilation impaired

If the nebulizer is left in the breathing circuit after use, ventilation may be impaired due to accidental medication nebulization.

Remove nebulizer after use.

CAUTION

Ventilation impaired

If medication nebulization is activated although no pneumatic medication nebulizer is connected, Savina delivers too small a tidal volume.

Deactivate medication nebulization.

NOTE

Aerosols can impair the proper functioning of the expiratory valve.

When using medication nebulization, shorten the reprocessing cycles for the expiratory valve.

Information on pneumatic medication nebulization

Medication nebulization may be used in all ventilation modes.

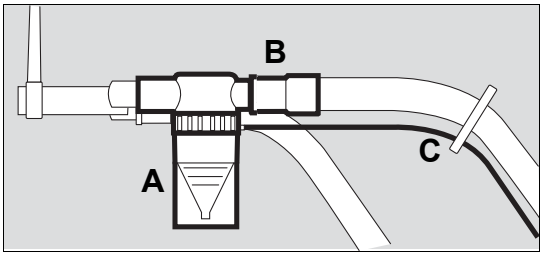
Savina applies the medication aerosol in synchronization with the inspiratory flow phase and maintains a constant minute volume.

In the case of greater deviations between the inspiratory minute volume and the expiratory minute volume, Savina performs calibration of the flow sensor during medication nebulization.

Installing the pneumatic medication nebulizer

Prerequisites:
– O_2 supply from the central gas supply system or from an O_2 gas cylinder is ensured.
– O_2 supply pressure: 2.7 bar to 6 bar (39.2 psi to 87 psi)
– Inspiratory flow: at least 18 L/min
– Medication nebulizer is prepared in accordance with the corresponding instructions for use.

When using a breathing circuit for adults



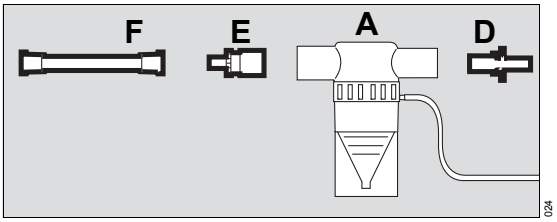
1 Connect the medication nebulizer (A) to the inspiratory side of the Y-piece.

2 Connect the inspiratory hose (B) to the medication nebulizer.

3 Place the medication nebulizer in the vertical position.

4 Using clamps, run the nebulizer hose (C) back to Savina along the inspiratory hose.

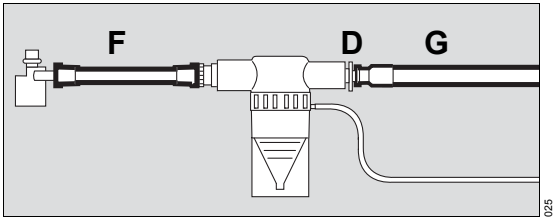
When using a breathing circuit for pediatric patients



1 Insert the catheter connector (D) into the inlet port of the medication nebulizer (A).

2 Insert the adapter (E) into the outlet port of the medication nebulizer.

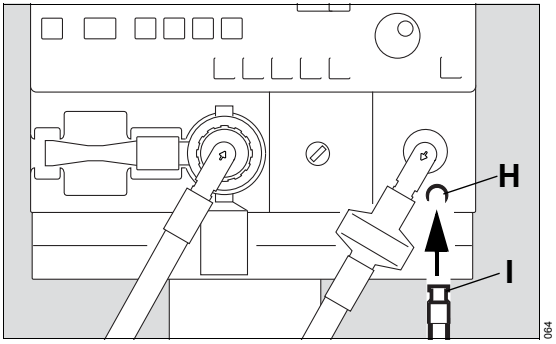
3 Connect one end of the corrugated hose (F), length 0.13 m (5.1 in), to the adapter (E).



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

5 Connect the other end of the corrugated hose (F) to the inspiratory port of the Y-piece.

Connecting the nebulizer hose



- Connect the nebulizer hose (I) onto the nebulizer port (H).

Performing pneumatic medication nebulization

Prerequisites:
– Medication nebulizer is filled in accordance with the corresponding instructions for use.
– The correct functioning of the medication nebulizer is checked.

CAUTION

Insufficient medication nebulization

A medication nebulizer malfunction is not detected by Savina.

Check the correct functioning of the medication nebulizer. Check whether aerosol is generated.

Switching on medication nebulization

- Press the ***Nebul.*** key.

The yellow LED in the key lights up.

Savina starts nebulization. The nebulization time is 30 minutes. A corresponding note appears on the screen.

Terminating medication nebulization prematurely

- Press the ***Nebul.*** key.

The yellow LED in the key goes out.

After medication nebulization

Savina automatically switches off the medication nebulizer after the nebulization time has elapsed.

Savina automatically cleans the flow sensor by heating and performs calibration following medication nebulization.

1 Remove any residual medication. Observe the instructions for use of the medication nebulizer.

2 If a bacterial filter is used to protect the expiratory valve, exchange or remove the bacterial filter.

Performing medication nebulization with the Aeroneb Pro nebulizer

- Observe the instructions for use of the Aeroneb Pro nebulizer.
- Observe the "Safety information on breathing circuits and additional components" on page 50.
- Observe the safety information on medication nebulization, see page 82.

NOTE
Do not switch on medication nebulization on Savina as the Aeroneb Pro nebulizer does not require a nebulizer flow from Savina.

After nebulization with Aeroneb Pro

- If a bacterial filter is used to protect the expiratory valve, exchange or remove the bacterial filter.

Manual inspiration – Insp. hold

The ***Insp. hold*** maneuver can be activated in all ventilation modes (except CPAP with ASB) and offers the following selections:

– Between two automatically delivered breaths, a breath can be manually started and held. The pattern of the manually started breath corresponds to the ventilation pattern of the currently active automatic ventilation mode.

– Regardless of the start time, an automatically delivered breath can be prolonged.

WARNING
Risk of patient injury due to negative pressure

If the *Insp. hold* maneuver is used during endotracheal suction, negative pressure occurs.

Do not use the *Insp. hold* maneuver during endotracheal suction.

Triggering manual inspiration

- Briefly press the ***Insp. hold*** key.

Manually extending inspiration

- Press the ***Insp. hold*** key and **hold** for the desired inspiratory time.

Savina triggers an extended breath or extends an already triggered automatic breath.

The maneuver is ended at the latest 15 seconds after pressing the ***Insp. hold*** key.

Bright and dark screen background

A bright screen background can be selected for good contrast and luminous colors, or a dark screen background with reduced screen illumination.

Changing screen backgrounds

- Press the ☼/● key.

Additional information

"Adjusting screen contrast" on page 110.

Key lock

The settings on the screen and the keys can be locked to prevent accidental changes from being made. The ***Audio paused 2 min.*** key can still be pressed.

Activating the key lock

- Press the ***Lock*** key.

The yellow LED in the key lights up.

Deactivating the key lock

- Press the ***Lock*** key.

The yellow LED in the key goes out.

Low Pressure Oxygen (LPO)

The use of the Low Pressure Oxygen (LPO) mode is described below. For a detailed description, see chapter "Low Pressure Oxygen (LPO)" on page 201.

Safety information

WARNING

Risk of patient injury

Due to faulty installation of the LPO option, proper functioning of the device may be impaired.

Only have service personnel perform installation of the LPO option.

WARNING

Risk of infection and risk of insufficient O_2 supply

If the oxygen source is not suitable for direct supply to the patient, there is a risk of infection and the LPO supply may fail.

Only connect oxygen sources that are approved for medical use and that meet the following conditions:

- **O_2 flow: 0.5 to 10 L/min**
- **O_2 pressure: 10 to 200 kPa (0.1 to 2 bar, 1.45 to 29 psi)**

WARNING

Risk of patient injury

If prohibited hoses are used between Savina and the oxygen source, the patient will be endangered.

Only use hoses approved for medical use and for use with oxygen.

CAUTION

Risk of patient injury

If a humidifier is used between Savina and the oxygen source, correct functioning of the device may be impaired or the device may be damaged, and the patient may be endangered.

Use only dry gases.

WARNING

Risk of fire

Due to oxygen enrichment in the ambient air, the medical device can ignite.

Ensure sufficient ventilation at the rear of Savina.
Do not use oxygen sources which deliver a flow exceeding 10 L/min.
Switch off the oxygen source, e.g., O_2 concentrator, when Savina is not ventilating.

WARNING

Risk of patient injury

The user is solely responsible for the ventilation and monitoring of the patient during O_2 calibration in LPO mode.

CAUTION

Insufficient O_2 supply

Patients who require an increased O_2 concentration will be endangered in the event of failure of the oxygen source.

Make sure there is an emergency oxygen supply, e.g., via O_2 compressed gas cylinder.

NOTE

In LPO mode, medication nebulization is only possible if an HPO supply is additionally connected.

NOTE

The suction maneuver with oxygen enrichment cannot be performed in LPO mode.

NOTE

In LPO mode, calibration of the O_2 sensors is performed with ambient air. The accuracy of FiO_2 measurement is therefore reduced.

If a very accurate FiO_2 measurement is required, the O_2 sensors must be calibrated in HPO mode.

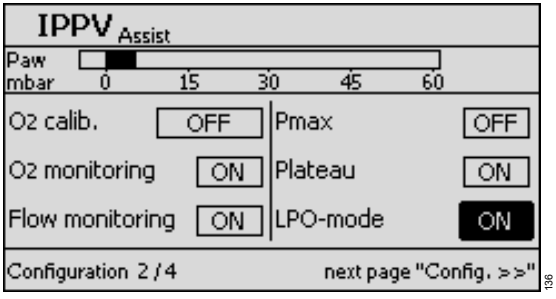
- Observe the instructions for use of the oxygen source used, e.g., O_2 concentrator.

Activating LPO mode

LPO mode can be activated during ventilation.

Prerequisites: O_2 calibration and the suction maneuver with oxygen enrichment are not active.

1 Press the ***Config.*** ▷▷ key repeatedly until the screen ***Configuration 2/4*** is displayed.



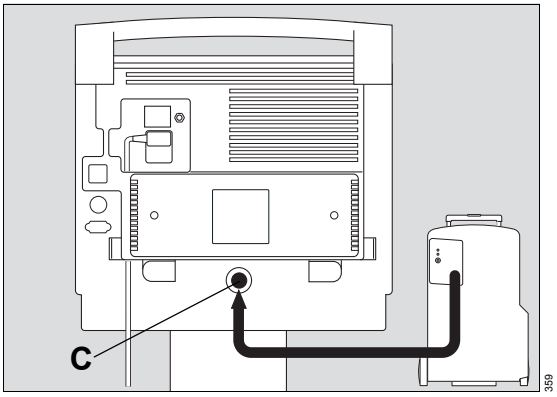
2 Select the line ***LPO-mode*** with the rotary knob and confirm.

3 Select the ***ON*** setting with the rotary knob and confirm.

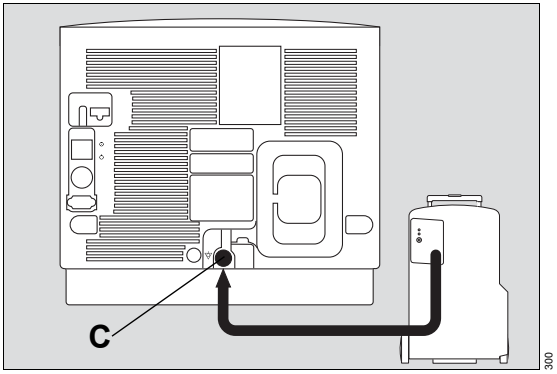
The screen displays a notice that the O_2 concentrator must be connected.

Connecting the O_2 concentrator to Savina

Devices up to serial number ASFF-0999:



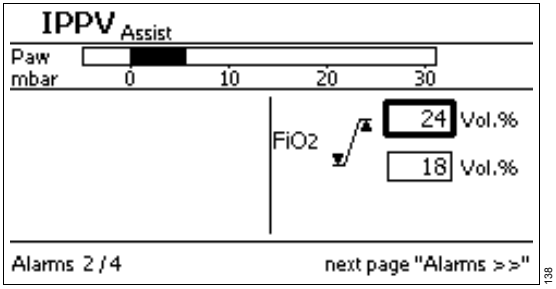
Devices as from serial number ASFF-1000:



- Connect the O_2 supply hose of the oxygen source, e.g., O_2 concentrator, to the LPO inlet for low pressure (C).

Setting the alarm limit *FiO2*

After the LPO mode is activated, Savina opens the screen ***Alarms 2/4***.



The upper and lower alarm limits for the inspiratory O2 concentration ***FiO2*** are displayed.

1 Select the alarm limit with the rotary knob and confirm.

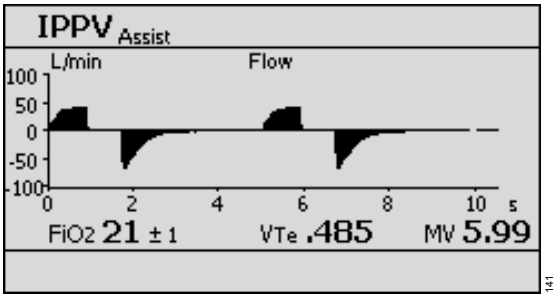
2 Set the value by turning the rotary knob and confirm.

Setting the O2 concentration

In LPO mode, the O2 concentration cannot be set on Savina. The setting is made via the flow at the O2 concentrator (LPO flow).

The O2 concentration reaching the patient is influenced by the following factors:
– The O2 concentration delivered by the O2 concentrator used
– The flow set at the O2 concentrator (LPO flow)
– The minute volume ***MV*** applied by Savina

1 Display the measured values for ***FiO2*** and ***MV***, see "Selecting measured values for the main screen" on page 110.



For ***FiO2***, both the measured value and a tolerance (±) are displayed. See page 201 for a detailed description.

2 Estimate the setting for the LPO flow, see "LPO flow setting diagram" on page 202.

3 Observe the measured values for ***FiO2*** for approximately 30 to 60 seconds and set the LPO flow accordingly:

- If ***FiO2*** is too low, set a higher value for the LPO flow.
- If ***FiO2*** is too high, set a lower value for the LPO flow.

4 Wait until the new measured value for ***FiO2*** is displayed steadily.

Additional information

To calibrate the O2 sensors, see page 105.

To switch off FiO2 monitoring, see page 106.

Deactivating LPO mode

LPO mode can be deactivated during ventilation.

1 Press the ***Config.*** ▷▷ key repeatedly until the screen ***Configuration 2/4*** is displayed.

2 Select the line ***LPO-mode*** with the rotary knob and confirm.

3 Select the ***OFF*** setting with the rotary knob and confirm.

The screen displays a notice that the O2 concentrator must be disconnected.

4 Disconnect the O2 concentrator.

5 Connect HPO supply if necessary.

6 Calibrate O2 sensor 2 manually, see "Calibrating O2 sensors" on page 105.

Transporting patients

Safety information

WARNING

Risk of patient injury

Changes to the patient's condition or damage to the device during transport endanger the patient.

The patient must be monitored continuously by users.

WARNING

Risk of tipping over, of personal injury, and of damage to the device

If the device is used at inclinations >5°, the device may tip over.

The maximum permitted inclination for using the device is 5°.
Always perform patient transport with 2 people and no faster than at a walking pace.

WARNING

Risk of personal injury and damage to the device

If Savina is placed on the bed when transporting patients, the device may fall down.

The device must not be placed on the bed when transporting patients.

CAUTION

Risk of patient injury

If the batteries are discharged, Savina cannot ventilate.

Make sure that the batteries are adequately charged both before and after patient transport.

CAUTION

Risk of patient injury

During patient transport, no breathing gas humidifier can be used and thus the patient's airways may dry out.

Use an HME on the Y-piece.

CAUTION

Flow measurement inaccurate

The accuracy of the flow measurement may be impaired due to jolts during transport.

Check the patient's condition.

Increasing the tipping stability

For the device to be used at an inclination of up to 10°, its tipping stability must be increased:

- Move accessories to the most advantageous position:
  - Set the hinged arm to minimum deflection.
  - Hoses and cables hooked as close as possible to the trolley.
  - Hang the breathing gas humidifier onto the trolley, and fold it in if necessary.

Interrupting ventilation – Standby mode

If the standby mode is activated, ventilation is interrupted. Switch to standby mode for the following actions:
– Keeping Savina ready for operation while the patient is absent
– Changing the application mode

WARNING
Risk of patient injury

Ventilation does not take place in standby mode. Patients connected to the device are endangered.

Only set the device to standby mode when no patient is connected to the device.

Activating standby mode

1 Press the ⏻ ***Start/Standby*** key for at least 3 seconds.

2 Press the ***Alarm Reset*** key.

Savina is in standby mode. ***Standby*** is shown on the display instead of the ventilation mode. Information on the last ventilation settings continues to be displayed, e.g., ***AutoFlow***.

Continuing the therapy

1 Check ventilation settings and change if necessary; see "Setting ventilation" on page 76.

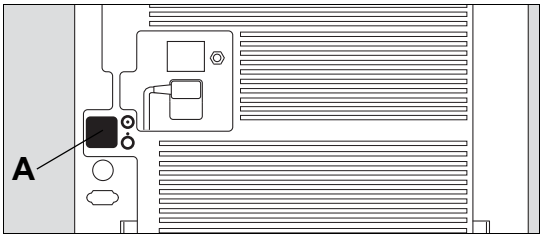
2 Press the ⏻ ***Start/Standby*** key.

The main screen is displayed, Savina continues ventilating.

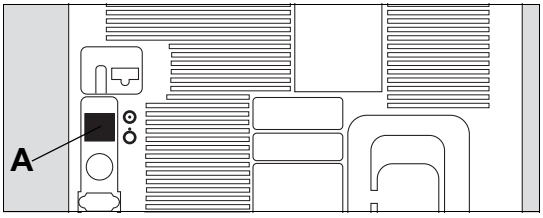
Ending operation

In standby mode

Devices up to serial number ASFF-0999:



Devices as from serial number ASFF-1000:

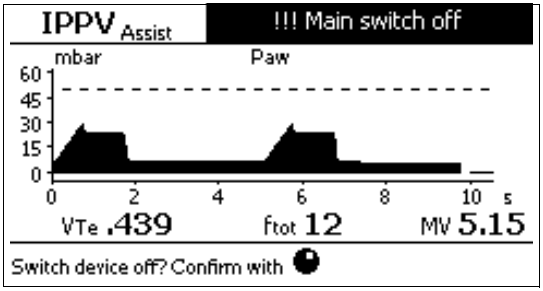


- Set the main switch (A) to ⏻ (off).

Savina ends operation.

During ventilation

1 Set the main switch (A) to ⏻ (off).



The alarm message ***Main switch off*** is displayed.

2 Confirm the alarm message with the rotary knob.

If the main switch is switched back on without confirming the alarm message, ventilation is continued. The alarm message is no longer displayed.

Interrupting gas supply

- Remove the gas probe of the O_2 supply from the wall terminal unit of the central gas supply system.

CAUTION

Risk of personal injury

When the probe is in the wall terminal unit of the central gas supply system, the compressed gas hose is under pressure and may injure the user who unscrews it from the ventilator.

Do not unscrew the compressed gas hose from the ventilator until after the probe has been removed from the wall terminal unit.

Storing Savina

Storing Savina for less than 14 days

Connect the device to the mains power supply during storage so that the internal and external batteries can be charged.

- Insert the mains plug into the power socket.

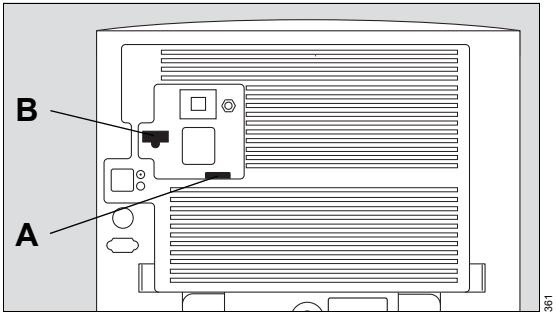
Savina can be stored.

Storing Savina for more than 14 days

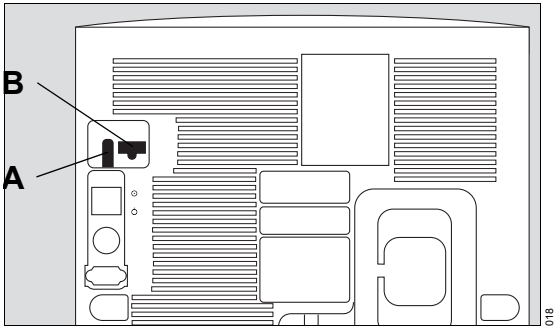
1 Insert the mains plug into the power socket.

2 When the internal battery is fully charged, pull the mains plug from the power socket.

Devices up to serial number ASFF-0999:



Devices as from serial number ASFF-1000:



3 Remove the fuse (B) for the internal battery and place it in the storage recess (A).

Savina can be stored. Even when the fuse is removed, the internal battery continues to self-discharge so that the internal battery must be recharged after 6 months at the latest.

Storage at an increased ambient temperature reduces the life span of the batteries.

Alarms

Display of alarms

Alarms are signaled optically and acoustically according to their alarm priority.

Optical alarm signals

Savina displays the following optical alarm signals:

– The relevant alarm message is displayed in the alarm message field.

– For alarms with high priority, the red LED flashes.

– For alarms with medium priority, the yellow LED flashes.

– For alarms with low priority, the yellow LED lights up.

Acoustic alarm signals

The alarm with the highest priority is signaled acoustically. The alarm signal continues to sound until either the cause for the alarm has been resolved or the alarm signal is suppressed.

The volume of the alarm signal can be adjusted, see page 111.

Failure of the acoustic alarm signal

If the loudspeaker for the alarm signal (main alarm) fails due to a defect, an intermittent tone will be generated by the loudspeaker for the auxiliary alarm.

This intermittent tone is also used for the power supply failure alarm, see page 116.

Alarm priorities

The background color of the alarm message field and the exclamation marks indicate the priority of the active alarm. If several alarms occur simultaneously, the alarm with the highest priority is displayed first. High-priority alarm messages that are no longer active are displayed in the background color of the alarm message field.

For some alarm messages, Savina displays additional information in the message field.

Color	**Priority of the alarm message**			**Action required**
Red	**Warning**	Alarm with high priority	!!!	Immediate action required to avert acute danger
Yellow	**Caution**	Alarm with medium priority	!!	Quick action required to avert danger
Yellow	**Note**	Alarm with low priority	!	Attention and action required

For a list of causes and remedies, see chapter "Alarm – Cause – Remedy" on page 117.

Suppressing the acoustic alarm signal

The acoustic alarm signal can be suppressed for a maximum of 2 minutes.

If an alarm with a higher priority occurs during this time, the alarm signal sounds once.

If the fault triggering the alarm is not eliminated after 2 minutes, the alarm signal sounds again.

- Press the ***Audio paused 2 min.*** key.

The yellow LED in the key lights up.

Reactivating the alarm signal

- Press the ***Audio paused 2 min.*** key.

The yellow LED in the key goes out.

Acknowledging an alarm message

After the fault has been eliminated, the alarm signal stops. High-priority alarm messages continue to be displayed and need to be acknowledged.

- Press the ***Alarm Reset*** key.

Setting the alarm limits

WARNING

Risk of patient injury

If the alarm limits are not adapted to the patient and the required therapy, the patient may be endangered.

Set the alarm limits accordingly.

CAUTION

Risk of patient injury due to incorrect settings

If several identical or similar devices are used in the care areas, the alarm limits of the devices can be configured differently and therefore be unsuitable for the current patient.

Check the alarm limits and adapt them to the current patient and the required therapy.
Make sure that extreme or deactivated alarm limits do not render the alarm system useless.

Opening the *Alarms* dialog window

- Press the ***Alarms*** ▷▷ key.

The set alarm limits are displayed.

Alarm limits and setting ranges

In the following table, the alarm limits are listed with the setting ranges.

Alarm limit	Setting range
Paw ⌐▲	10 to 100 mbar (10 to 100 cmH2O)
MV ⌐▲	2.0 to 41 L/min
MV ▼⌐	0.5 to 40 L/min
TApnoea[1] ⌐▲	15 to 60 s
ftot ⌐▲	10 to 120 bpm
VTi ⌐▲	0.06 to 4.0 L
TDisconnect[2]	0 to 60 s
FiO2[3] ⌐▲	21 to 99 Vol%
FiO2[3] ▼⌐	18 to 98 Vol%

1) In the ***SIMV***, ***CPAP/ASB*** and ***BIPAP*** ventilation modes
2) In application mode ***Mask/NIV*** on page ***Alarms 2/4***
3) In LPO mode on page ***Alarms 2/4***

The lower alarm limit for the airway pressure ***Paw*** is automatically linked to the set value for ***PEEP***.

In HPO mode, the alarm limits for the O2 concentration ***FiO2*** are automatically linked to the set value for ***O2***:

Set value		Alarm limit
O2 <60 Vol%	–>	FiO2 ±4 Vol%
O2 ≥60 Vol%	–>	FiO2 ±6 Vol%

Setting an alarm limit

Prerequisites: The ***Alarms*** dialog window is opened.

1. Select the alarm limit with the rotary knob and confirm.
2. Set the value by turning the rotary knob and confirm.

Deactivating alarm limits

WARNING
Risk of patient injury

If alarm limits are deactivated, Savina cannot monitor the patient.

Only deactivate alarm limits if the safety of the patient is not jeopardized by the absence of an alarm.

The following alarm limits can be deactivated:

Alarm limit	Mode
MV ▼/⌜	Only in ***Mask/NIV*** application mode
TApnoea _/▲	
VTi _/▲	
FiO2 _/▲	Only in LPO mode

How to deactivate an alarm limit

1 Select the alarm limit with the rotary knob and confirm.

2 Turn the rotary knob until ***OFF*** is displayed instead of the value. If necessary, press the rotary knob to exceed the set limit.

3 Confirm with the rotary knob.

The alarm limit is deactivated. When the ***MV*** ▼/⌜, ***VTi*** _/▲ or ***TApnoea*** _/▲ alarm limits are deactivated, Savina displays a corresponding notification in the alarm message field.

All disabled alarm limits are displayed on a separate screen, see page 101.

Response to power supply failure

Alarm limits are also retained in the event of a power supply failure, e.g., caused by a faulty internal battery.

Show alarm history

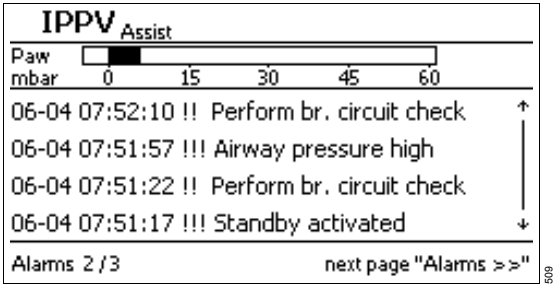
In the alarm history the occurring alarm messages are recorded in chronological order. The date (month-day) and time of each alarm message in the alarm message field is displayed. Exclamation marks indicate the priority of alarm messages. When there are no more alarm messages, **- - -** is displayed.

Starting at about 1000 alarm messages, the oldest entries are overwritten.

When the device is switched off or a power failure occurs the entries are deleted.

Opening the alarm history

- Press the ***Alarms*** ▷▷ key until the alarm history is displayed.



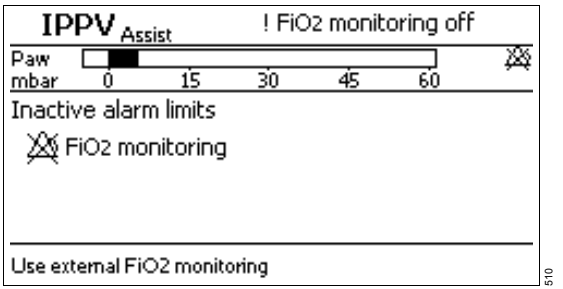
Inactive alarm limits and monitoring functions

Deactivated alarm limits and monitoring functions are displayed in a list with the symbol 🔕.

Opening the list of inactive alarm limits and monitoring functions

- Press the ***Alarms*** ▷▷ key until the list is displayed.

Example



FiO_2 monitoring is switched off.

This page has been left blank intentionally.

Monitoring

General information

Monitoring is activated at the factory. Each monitoring function can be deactivated separately.

Calibrating the sensors

Savina uses the following sensors for measurement and monitoring purposes:

sensors	Calibration Procedures
Pressure sensors	Automatic calibration
O_2 sensors	Calibration intervals, see page 104
Flow sensor	Automatic calibration

Saving calibration values

The last determined calibration values of the sensors remain stored until the next calibration, even if the device is switched off.

FiO_2 monitoring

Information on the O_2 sensors

The O_2 sensors are used in the following manner:
– O_2 sensor 1 for O_2 regulation in HPO mode and for displaying the measured value for ***FiO_2***
– O_2 sensor 2 for FiO_2 monitoring

Calibration intervals of the O_2 sensors

O_2 sensors in HPO mode

O_2 sensor 1 is automatically calibrated:
– Every 8 hours during operation
– After replacing the O2 sensors
– When the measured values of the O_2 sensors deviate from each other by more than 2 Vol%
– After a change in atmospheric pressure by more than 200 hPa
– After a change in temperature of more than 10 °C

O_2 sensor 2 must be calibrated manually:
– Every 4 weeks
– When the following alarm message is displayed: ***O_2 measurement inop.***

O_2 sensors in LPO mode

In LPO mode, no automatic calibration is performed. Both O_2 sensors must be calibrated manually every 4 weeks.

Calibrating the O_2 sensors

Prerequisites for calibration in HPO mode

CAUTION

Incorrect calibration

If the quality of the oxygen from the central gas supply system is insufficient, calibration may be incorrect.

Calibrate the O_2 sensor with calibration gas (100 % O_2).

Prerequisites for calibration in LPO mode

– After switching on Savina, wait for the ten-minute warm-up phase to complete.

– If Savina has been subjected to a significant change in temperature, wait for up to one hour. Example: after transport from a cold room to a heated room or when extreme ventilation settings were used.

FiO_2 measurement is possible during this period, provided no alarm message saying otherwise is displayed.

NOTE

In LPO mode, calibration of the O_2 sensors is performed with ambient air. The accuracy of FiO_2 measurement is therefore reduced.

If a very accurate FiO_2 measurement is required, the O_2 sensors must be calibrated in HPO mode.

For information on the accuracy of FiO2 measurement, see chapter Technical data, "Displayed measured values" on page 167.

Information on calibrating

During calibration, the alarms that would be triggered due to patient disconnection and the altered O_2 concentration are deactivated.

Automatic cancelation of calibration

If reconnection has not taken place 30 seconds after being requested to do so by Savina, the set ventilation mode and the alarms are reactivated.

If calibration was not successful

If the ***O_2 measurement inop.*** alarm message is displayed after calibration, replace the O_2 sensors, see page 154.

Starting calibration of the O_2 sensors

1 Press the ***Config.*** ▷▷ key repeatedly until the screen ***Configuration 2/4*** is displayed.

2 Select the line ***O_2 calib.*** with the rotary knob and confirm.

3 Select the ***ON*** setting with the rotary knob and confirm.

4 In LPO mode: Disconnect the O_2 concentrator when prompted to do so by Savina. Confirm with the rotary knob.

The message field indicates that the patient must be disconnected.

5 Disconnect the patient from the device within 30 seconds and continue ventilation using an independent ventilation device if necessary.

Savina calibrates the O_2 sensors. After approximately 60 seconds, it is indicated that the patient must be reconnected.

6 Reconnect the patient immediately.

7 In LPO mode: Reconnect the O_2 concentrator when prompted to do so by Savina.

Deactivating or activating FiO_2 monitoring

FiO_2 monitoring can be replaced by appropriate replacement monitoring. Set the FiO_2 alarm limits of the replacement monitoring according to the set value O_2:

Set value		Alarm limit
O_2 <60 Vol%	–>	FiO_2 ±4 Vol%
O_2 ≥60 Vol%	–>	FiO_2 ±6 Vol%

Switching off FiO_2 monitoring

1 Press the ***Config.*** ▷▷ key repeatedly until the screen ***Configuration 2/4*** is displayed.

2 Select the line ***FiO_2 monitoring*** with the rotary knob and confirm.

3 Select the ***OFF*** setting with the rotary knob and confirm.

The measured values are no longer displayed. The alarm function is deactivated. Savina displays the following alarm message: ***FiO_2 monitoring off***. Additional information is displayed in the message field.

All deactivated monitoring functions are displayed on a separate screen, see page 101.

Switching on FiO_2 monitoring

Reactivate FiO_2 monitoring as soon as possible.

- Select the ***ON*** setting with the rotary knob and confirm.

Flow monitoring

Calibration intervals of the flow sensor

Savina automatically calibrates the flow sensor:
– After the device has been switched on
– After the start of ventilation
– Every 24 hours during operation
– After replacing the flow sensor
– After and during medication nebulization
– After the oxygen enrichment program for endotracheal suction
– After changing the O_2 concentration

In certain cases, it may be necessary to calibrate the flow sensor manually, e.g., when automatic calibration has failed.

Calibrating the flow sensor

Prerequisites: Savina is switched on.

1 Remove the flow sensor.

2 Re-insert the flow sensor.

Savina uses one full inspiratory phase for calibration. Short inspiratory times are extended to approximately 1 second.

Information on calibration is displayed in the message field.

If calibration was not successful

If calibration was not successful, Savina displays a corresponding message. The expiratory portion of the flow waveform and the measured values ***V_{Te}***, ***MV***, and ***PEEP*** are not displayed.

- Replace flow sensor.

Savina automatically calibrates the new flow sensor.

Deactivating or activating flow monitoring

Flow monitoring can be switched off, e.g.:
– If the flow sensor has failed and cannot currently be replaced.
– To permit ventilation in the event of major tube leakage.

Savina cannot determine the following measured values when flow monitoring is deactivated:
– MV
– MV_{spn}
– MV_{leak}
– V_{Tpat}

Expiratory flow monitoring cannot be fully substituted via replacement monitoring. Set the minute volume alarm limits of the replacement monitoring accordingly.

WARNING
Risk of patient injury

If flow monitoring is deactivated, Savina cannot monitor the patient adequately.

Ensure that appropriate replacement monitoring is available immediately.

WARNING
Risk of patient injury

No apnea monitoring takes place when flow monitoring is deactivated.

Use independent apnea monitoring.

Deactivating flow monitoring

1 Press the ***Config.*** ▷▷ key repeatedly until the screen ***Configuration 2/4*** is displayed.

2 Select the line ***Flow monitoring*** with the rotary knob and confirm.

3 Select the ***OFF*** setting with the rotary knob and confirm.

The measured values are no longer displayed. The alarm function is deactivated. Savina displays the following alarm message: ***Flow monitoring off***. Additional information is displayed in the message field.

All deactivated monitoring functions are displayed on a separate screen, see page 101.

Activating flow monitoring

Reactivate flow monitoring after replacing the flow sensor or as soon as possible.

- Select the ***ON*** setting with the rotary knob and confirm.

Configuration

General information

The following settings can be changed in the ***Configuration*** dialog window:
– Screen contrast
– Measured values for the main screen
– Volume of the alarm signal
– Ventilation functions
– Language, date, time
– Interfaces
– Numeric code to activate options

The settings will remain stored when the device is switched off.

Additionally, information about the device is displayed.

Additional information

See page 37 for an overview of the menu structure.

The following functions are described in chapter "Monitoring".
– Calibrating the O_2 sensors
– FiO_2 and flow monitoring

Adjusting screen contrast

When equipped with the color display, the contrast setting has no effect.

1 Press the ***Config.*** ▷▷ key until the screen ***Configuration 1/4*** is displayed.

2 Select the line ***Contrast*** with the rotary knob and confirm.

3 Set the value by turning the rotary knob and confirm.

Selecting measured values for the main screen

The following combinations of measured values can be selected:

1.	V_{Te}	f_{tot}	MV
2.	FiO_2	V_{Te}	MV
3.	P_{peak}	V_{Te}	MV
4.	P_{mean}	FiO_2	MV
5.	P_{mean}	V_{Te}	MV
6.	P_{peak}	P_{mean}	V_{Te}

1 Press the ***Config.*** ▷▷ key until the screen ***Configuration 1/4*** is displayed.

2 Select the line ***Meas. values*** with the rotary knob and confirm.

3 Select the combination of measured values with the rotary knob and confirm.

Setting the volume of the alarm signal

WARNING

Failure to hear alarm signals in a loud environment

Alarm situations go unnoticed.

Adjust the volume of alarm signals so that they can be perceived.

The minimum configurable volume for the alarm signals can be configured in service mode. Contact DrägerService.

During configuration, a test signal sounds with the selected volume.

1 Press the ***Config.*** ▷▷ key until the screen ***Configuration 1/4*** is displayed.

2 Select the line ***Volume*** with the rotary knob and confirm.

3 Set the value by turning the rotary knob and confirm.

Configuring ventilation functions

The ventilation functions ***Pmax*** and ***Plateau*** can be activated or deactivated.

Pressure limitation *Pmax*

Prerequisites:
– ***Pmax*** is activated
– ***AutoFlow*** is deactivated

In the ***IPPV***, ***IPPVAssist*** and ***SIMV*** ventilation modes, the pressure is limited with ventilation parameter ***Pmax***.

Inspiratory pause time *Plateau*

Prerequisites: ***Plateau*** is activated

In the ***IPPV***, ***IPPVAssist*** and ***SIMV*** ventilation modes, the inspiratory time is set with the ***Tinsp.*** key.

Switching ventilation functions on or off

1 Press the ***Config.*** ▷▷ key repeatedly until the screen ***Configuration 2/4*** is displayed.

2 Select the corresponding line using the rotary knob and confirm.

3 Select the ***ON*** or ***OFF*** setting with the rotary knob and confirm.

Additional information

Description of the ventilation modes, see page 188.

For a description of the ventilation modes, see page 193.

Configuring country-specific settings

- Press the ***Config.*** ▷▷ key repeatedly until the screen ***Configuration 3/4*** is displayed.

Selecting the screen text language

Savina is factory-set to the customer's own language. The current language is displayed in the line ***Language***.

Selecting a different language

1 Select the line ***Language*** using the rotary knob and confirm.

2 Select the language with the rotary knob and push to confirm.

Measuring units

The measuring unit for pressure depends on the configured language:

Language	Unit of measurement for pressure
All languages except ***US-English***	mbar
US-English	cmH_2O

Setting the date and time

Savina does not change over automatically between daylight saving time and standard time. The user must change the time manually. Otherwise, the on-screen time indications will be incorrect.

Setting the date

1 Select the line ***dd.mm.yy*** using the rotary knob and confirm.

2 Select the day with the rotary knob and confirm.

Savina marks the next field.

3 Select the month with the rotary knob and confirm.

Savina marks the next field.

4 Select the year with the rotary knob and confirm.

Setting the time

1 Select the line ***h:m*** using the rotary knob and confirm.

2 Select the hour with the rotary knob and confirm.

Savina marks the next field.

3 Select the minutes with the rotary knob and confirm.

Configuring the data interface

Data exchange takes place via the RS232 serial port with MEDIBUS-capable display devices, e.g., a patient monitor or patient data management system.

- Press the ***Config.*** ▷▷ key repeatedly until the screen ***Configuration 3/4*** is displayed.

The following interface parameters can be configured:
– Baudrate
– Parity
– Stopbits

Configuring interface parameters

1 Select the corresponding line using the rotary knob and confirm.

2 Set the value by turning the rotary knob and confirm.

Displaying information about the device

- Press the ***Config.*** ▷▷ key repeatedly until the screen ***Configuration 4/4*** is displayed.

The following information about the device is displayed:
– Software version
– Identification number
– Total hours of operation
– Hours of operation since the last inspection

Enabling options

Savina can be extended with options that are enabled by entering a numerical code.

1 Press the ***Config.*** ▷▷ key repeatedly until the screen ***Configuration 4/4*** is displayed.

2 Select the line ***Release code*** with the rotary knob and confirm.

3 Select the first digit with the rotary knob and confirm.

Savina marks the next field.

4 After entering all the digits, restart Savina.

The option is enabled.

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Troubleshooting

Failure of the power supply

If the power supply fails, Savina generates a power supply failure alarm. The ventilation settings and the alarm limits remain saved even in the event of a power supply failure.

- Restore the power supply immediately, see page 54 and page 55.

Or:

- Disconnect patient from the device and continue ventilation without delay using another independent ventilator.

Power supply of the O_2 sensors

The O_2 sensors are also supplied from the internal battery of Savina when the device is switched off. This allows Savina to immediately provide valid FiO_2 measured values when it is switched on. When the internal battery is fully discharged, Savina does not display any FiO_2 measured values for the first 20 minutes after it is switched on. The accuracy of the O_2 delivery is reduced during this period.

Failure of the gas supply

If the O_2 supply fails, Savina substitutes the missing O_2 portion with ambient air and generates an alarm. The minute volume remains constant. The inspiratory O_2 concentration falls to 21 Vol%.

If the patient requires a higher O_2 concentration:

- Restore the O_2 supply immediately.

If the turbine fails, Savina can no longer continue with ventilation.

- Disconnect patient from the device and continue ventilation without delay using another independent ventilator.

High ambient temperature

To prevent the breathing gas from becoming too hot, Savina reduces the maximum speed of the turbine as the ambient temperature rises. If high inspiratory pressures are set at the same time, e.g., over 80 mbar (or hPa or cmH_2O), high flows, e.g., of 180 L/min, can no longer be achieved.

Even at slower speeds, the breathing gas delivered by the turbine is warmed. To ensure that the breathing gas temperature at the Y-piece remains under 41 °C (105.8 °F), the inspiratory hose length must be at least 1.2 m (3.9 ft) to allow the gas to cool down.

If the inspiratory breathing gas temperature is too high, Savina generates the following high-priority alarm message: ***Temperature high***

If a temperature sensor (optional) is used, Savina generates the following high-priority alarm message at temperatures above 40 °C (104 °F): ***Breathing gas temp. high***

In both cases, Savina continues ventilating the patient.

- Lower the ambient temperature.

Alarm – Cause – Remedy

Alarm messages are displayed in hierarchical order in the alarm message field; see "Display of alarms" on page 96.

Within an alarm category, alarm messages are assigned internal priorities. In the following table, internal priorities are indicated as numbers behind the exclamation marks. The alarm message with the highest priority receives number 1000. The lower the priority, the lower the number.

In general, alarms are displayed immediately after the alarm condition is detected. However, detection of the alarm condition depends on ventilation parameters and filter algorithms. Existing alarm delays are specified in the description of the alarm messages.

In the following table, the alarm messages are listed in alphabetical order. The table shows possible causes for an alarm and corresponding remedies. Causes and remedies must be worked through in the order listed until the alarm has been resolved.

Alarm priority		Alarm message	Cause	Remedy
!!!	250	Airway pressure high	Breathing hose kinked.	Check the breathing circuit. Check tube or mask.
			The upper alarm limit for the airway pressure has been exceeded. The patient is breathing against the ventilator or coughing.	Check the patient's condition. Check ventilation settings. Adjust alarm limit if necessary.
!!!	240	Airway pressure low	Leakage or disconnection.	Check connections of the breathing circuit for leakages. Make sure that the expiratory valve is properly engaged. Make sure the tube or mask is properly connected.

Alarm priority		Alarm message	Cause	Remedy
!!!	340	Ambient press. meas. inop.	Internal ambient pressure sensor failed.	Check the patient's condition. The accuracy of the measured values, which depend on atmospheric pressure, can be impaired (e.g., MV, O_2 concentration). If the incorrect values are tolerable and the alarm limit ***Paw*** is correspondingly set, ventilation can be continued with this device. Contact DrägerService.
!!!	220	Apnoea	The patient has stopped breathing.	Check the patient's condition. Apply controlled ventilation if necessary.
			Obstruction.	Check the patient's condition. Check the breathing circuit. Check tube or mask.
			Flow sensor is not calibrated or faulty.	Calibrate flow sensor and replace it if necessary.
			Apnea alarm time setting is shorter than the time for one respiratory cycle of the patient.	Extend apnea alarm time.
!	171	Apnoea Alarm off	Only in NIV application mode: The apnea alarm time was switched off.	Switch on apnea alarm time again, if necessary.
!!	360	Apnoea ventilation	Apnea was detected. Therefore, ventilator has automatically switched to apnea ventilation.	Check ventilation settings and patient condition. To return to the original ventilation mode, press the ***Alarm Reset*** key.
!!!	160	ASB > 4 s	Pressure support was terminated three times by the termination criterion.	Check connections of the breathing circuit for leakages.
!	180	ASB > 4 s	Pressure support was terminated by the termination criterion.	Check connections of the breathing circuit for leakages.

Alarm priority		Alarm message	Cause	Remedy
!	210	Atmospheric pressure high	The device is being used at an excessively high atmospheric pressure.	Use the device within the specified air pressure range.
			One of the pressure sensors is faulty.	Check the patient's condition. Due to missing measured values for ambient pressure, the device calculates values for tidal volume and minute volume based on 1013 mbar (14.7 psi). If the incorrect values are tolerable and the alarm limit ***Paw*** is correspondingly set, ventilation can be continued with this device. Contact DrägerService.
!	200	Atmospheric pressure low	The device is being used at an excessively low atmospheric pressure.	Use the device within the specified air pressure range.
			One of the pressure sensors is faulty.	Check the patient's condition. Due to missing measured values for ambient pressure, the device calculates values for tidal volume and minute volume based on 1013 mbar (14.7 psi). If the incorrect values are tolerable and the alarm limit ***Paw*** is correspondingly set, ventilation can be continued with this device. Contact DrägerService.
!!!	095	Breathing gas temp. high	Breathing gas temperature higher than 40 °C (104 °F).	Reduce the temperature of the breathing gas humidifier. Use longer inspiratory hoses.
!!	300	Check settings	Loss of saved data was detected.	Check all settings and adjust if needed. Confirm message by pressing the ***Alarm Reset*** key.

Alarm priority		Alarm message	Cause	Remedy
!!!	710	Device failure XX.YYYY	Device malfunction detected by internal safety software.	If the message is no longer displayed after the ***Alarm Reset*** key is pressed, ventilation can continue. If the message persists after the ***Alarm Reset*** key is pressed: Disconnect patient from the device and continue ventilation without delay using another independent ventilator. Contact DrägerService.
				If the device will be switched off: **1** Set the main switch to ⏻ (off). **2** Press the ⏻ ***Start/Standby*** key for 3 seconds. **3** Press the ***Alarm Reset*** key. Contact DrägerService.
!!	310	Device over temperature	The internal device temperature is too high.	Check dust filter for soiling and replace, if necessary.
!!!	280	Exp. valve inop.	Expiratory valve incorrectly connected to the port.	Insert expiratory valve correctly.
			Expiratory valve is faulty.	Replace expiratory valve.
			Flow sensor faulty.	Replace flow sensor.
!!	375	Ext. DC ?	DC on-board power supply does not correspond to specifications.	Downgrade alarm priority: Press the ***Alarm Reset*** key. When operating with DC on-board power supply, ensure that the voltage is sufficient.
			External battery is not sufficiently charged, faulty, or its voltage is too high.	Disconnect external battery from the device and connect external battery with the correct voltage.

Alarm priority		Alarm message	Cause	Remedy
!	215	Ext. DC ?	DC on-board power supply does not correspond to specifications.	When operating with DC on-board power supply, ensure that the voltage is sufficient.
			External battery is not sufficiently charged, faulty, or its voltage is too high.	Disconnect external battery from the device and connect external battery with the correct voltage.
!	110	Ext. DC supply active	Due to missing mains power supply, the device is supplied with power from DC on-board power supply or the external battery.	Reestablish mains power supply. Note the capacity of the external DC power source.
!!!	130	FiO_2 high	HPO mode: Mixer function faulty.	To continue ventilation with this device, use external O_2 monitoring and switch off integrated O_2 monitoring. Contact DrägerService.
			HPO mode: Due to a low minute volume, the mixer is not yet fully operational.	When the mixer is fully operational, the message is no longer displayed.
!!!	130	FiO_2 high	LPO mode: The upper alarm limit for the O_2 concentration was exceeded.	Check the patient's condition. Check LPO flow and ventilation settings. Adjust alarm limit if necessary.
!!!	140	FiO_2 low	HPO mode: Mixer function faulty.	To continue ventilation with this device, use external O_2 monitoring and switch off integrated O_2 monitoring. Contact DrägerService.
			HPO mode: Due to a low minute volume, the mixer is not yet fully operational.	When the mixer is fully operational, the message is no longer displayed. Check the patient's condition.

Alarm priority		Alarm message	Cause	Remedy
!!!	140	FiO2 low	LPO mode: The lower alarm limit for the O2 concentration was exceeded.	Check LPO flow and ventilation settings. Adjust alarm limit if necessary.
!!	330	FiO2 monitoring off	O2 monitoring is switched off.	Switch O2 monitoring on again or use external O2 monitoring. Downgrade alarm priority: Press the ***Alarm Reset*** key.
!	070	FiO2 monitoring off	O2 monitoring is switched off.	Switch O2 monitoring on again or use external O2 monitoring.
!!!	300	Flow measurement inop.	Water in flow sensor.	Drain water trap of breathing circuit. Dry flow sensor.
			Diaphragm inserted incorrectly in expiratory valve.	Insert diaphragm in expiratory valve correctly.
			Flow measurement is not reliable. Expiratory minute volume exceeds the minute volume delivered by the ventilator by 20 %.	Calibrate the flow sensor. To continue ventilation with this device, use external flow monitoring and switch off integrated flow monitoring. This may impair the quality of the ventilation. Contact DrägerService.
!	080	Flow monitoring off	Flow monitoring is switched off.	Switch flow monitoring on again or use external flow monitoring.
!!!	290	Flow sensor ?	Flow sensor seated incorrectly in flow sensor sleeve of expiratory valve.	Insert flow sensor correctly.
!!!	305	Flow sensor inop.	Flow sensor faulty.	Replace flow sensor.

Alarm priority		Alarm message	Cause	Remedy
!!!	170	High frequency	The patient is breathing at a high respiratory rate.	Check the patient's condition. Check ventilation settings or spontaneous respiratory rate. Adjust alarm limit if necessary.
			Auto-triggering caused by water in the breathing circuit.	Drain water trap of breathing circuit. Dry flow sensor. Check the breathing circuit.
!	290	Insp. hold interrupted	The ***Insp. hold*** key has been pressed for longer than 15 seconds.	Release the ***Insp. hold*** key.
!!!	210	Insp/Exp cycle failure	Device does not deliver any gas.	Set respiratory rate of at least 4/min.
			Apnea alarm time setting is shorter than the time for one respiratory cycle of the patient.	Extend apnea alarm time.
			Disconnection.	Connect patient.
!!!	800	Int. batt. almost discharged	The operating time with power supply from the internal battery has almost elapsed. Remaining capacity is less than 10 %. Device may fail immediately.	Immediately connect the device to the mains power supply or to an external DC power source. Charge the internal battery.
!	240	Int. batt. almost discharged	Internal battery is almost fully discharged. Mains power supply or an external DC power source is available.	Device cannot be supplied from the internal battery. Charge the internal battery.
!!	380	Int. battery activated	Due to missing mains power supply and missing or discharged DC power source, the device is supplied with power from the internal battery.	If applicable, restore mains power supply or supply from an external DC power source. Downgrade alarm priority: Press the ***Alarm Reset*** key.

Alarm priority		Alarm message	Cause	Remedy
!	220	Int. battery activated	Due to missing mains power supply and missing or discharged DC power source, the device is supplied with power from the internal battery.	If applicable, restore mains power supply or supply from an external DC power source.
!!!	810	Int. battery failed	Internal battery is faulty. In the event of mains supply failure, there is no internal battery available.	If mains power supply or supply from an external DC power source is ensured, ventilation can be continued with this device. Downgrade alarm priority: Press the ***Alarm Reset*** key. Contact DrägerService.
!	245	Int. battery failed	Internal battery is faulty. In the event of mains supply failure, there is no internal battery available.	If mains power supply or supply from an external DC power source is ensured, ventilation can be continued with this device. Contact DrägerService.
!!	390	Int. battery low	The operating time with power supply from the internal battery will soon elapse. The remaining capacity is less than 30 %.	Connect the device to the mains power supply or to an external DC power source. Downgrade alarm priority: Press the ***Alarm Reset*** key.
!	230	Int. battery low	For supply from the internal battery: Remaining capacity is less than 30 %.	Connect the device to the mains power supply or to an external DC power source.
			For mains power supply or supply from an external DC power source: Internal battery is not yet sufficiently charged.	Allow the internal battery to charge.

Alarm priority		Alarm message	Cause	Remedy
!!	221	Key xx failed	The xx key (e.g., ***Audio paused 2 min.***) was pressed for a longer period of time or it is faulty.	The ventilation functions are not impaired. Release the key. If the alarm persists, the settings can no longer be adjusted. Disconnect patient from the device and continue ventilation without delay using another independent ventilator. Contact DrägerService.
!!	220	Key xx overused	Keys were pressed very frequently within a short time (e.g., ***Audio paused 2 min.***).	Confirm message by pressing the ***Alarm Reset*** key. The function of this key is not available as long as the fault exists. If the fault cannot be eliminated, contact DrägerService.
!	100	Leakage	Only monitored in intubated patients. Leakage in the breathing circuit. The calculated leakage minute volume is greater than the minute volume measured on the expiratory side.	Check the breathing circuit for leakages. Make sure that the tube is connected correctly.
!!!	995	Main switch off	The device was switched off by the main switch on the rear of the device during ventilation.	Confirm message by pressing the rotary knob. If you want to continue ventilation, switch on the device by the main switch on the rear of the device.

Alarm priority		Alarm message	Cause	Remedy
!!	260	Main switch overused	The main switch was used very frequently within a short time.	Confirm message by pressing the ***Alarm Reset*** key. If the device is to be switched off, first switch back on at the main switch and then switch off. If this message occurs repeatedly: Ventilation with this device can be continued. If the device will be switched off: **1** Set the main switch to ⏻ (off). **2** Press the ⏻ ***Start/Standby*** key for 3 seconds. **3** Press the ***Alarm Reset*** key. Contact DrägerService.
!!!	990	Mains switch inop.	The device could not clearly detect the setting of the main switch.	Confirm message by pressing the ***Alarm Reset*** key. If the device is to be switched off, first switch back on at the main switch and then switch off. If this message occurs repeatedly: Ventilation with this device can be continued. If the device will be switched off: **1** Set the main switch to ⏻ (off). **2** Press the ⏻ ***Start/Standby*** key for 3 seconds. **3** Press the ***Alarm Reset*** key. Contact DrägerService.

Alarm priority		Alarm message	Cause	Remedy
!!!	120	Malfunction fan	Cooling fan failed.	Disconnect patient from the device and continue ventilation without delay using another independent ventilator. Contact DrägerService.
!	120	MEDIBUS COM. inop.	MEDIBUS communication failed.	Ventilation functions are not affected. Check MEDIBUS connection. Check MEDIBUS settings.
!!	110	Microfilter blocked	Microfilter is extremely soiled.	Replace microfilter.
!!!	320	Microfilter missing	Microfilter missing or incorrectly inserted.	Insert microfilter.
!!!	180	MV high	The minute volume exceeds the upper alarm limit.	Check the patient's condition. Check ventilation settings. Adjust alarm limit if necessary.
			Flow sensor faulty.	Replace flow sensor.
			Water in flow sensor.	Drain water trap of breathing circuit. Dry flow sensor.
			Device failure	Disconnect patient from the device and continue ventilation without delay using another independent ventilator. Contact DrägerService.

Alarm priority		Alarm message	Cause	Remedy
!!!	190	MV low	The minute volume has fallen below the lower alarm limit.	Check the patient's condition. Check ventilation settings. Adjust alarm limit if necessary.
			Obstruction.	Check the patient's condition. Check the breathing circuit. Check tube or mask.
			Leakage or disconnection.	Check connections of the breathing circuit for leakages. Make sure that the expiratory valve is properly engaged. Make sure the tube or mask is properly connected.
			Flow sensor faulty.	Replace flow sensor.
			Device failure	Disconnect patient from the device and continue ventilation without delay using another independent ventilator. Contact DrägerService.
!	162	MV low Alarm off	Only in NIV application mode: The lower alarm limit for minute volume was switched off.	Switch on alarm limit again, if necessary.
!	139	Nebuliser on	Medication nebulization is activated.	Wait until nebulization is finished, or terminate nebulization prematurely.

Alarm priority		Alarm message	Cause	Remedy
!!!	820	No battery charging	Due to high ambient temperatures, the batteries are not being charged.	Decrease ambient temperature. When the mains supply is secured, ventilation with this device can be continued. Downgrade alarm priority: Press the ***Alarm Reset*** key.
			Due to overvoltage in the mains power supply or the DC on-board power supply, the batteries are not being charged.	Use a mains power supply or DC on-board power supply with the correct voltage. When the mains supply or the supply via charged external battery is secured, ventilation with this device can be continued. Downgrade alarm priority: Press the ***Alarm Reset*** key. Contact DrägerService.
!	247	No battery charging	Due to high ambient temperatures, the batteries are not being charged.	Decrease ambient temperature. When the mains supply is secured, ventilation with this device can be continued.
			Due to overvoltage in the mains power supply or the DC on-board power supply, the batteries are not being charged.	Use a mains power supply or DC on-board power supply with the correct voltage. When the mains supply or the supply via charged external battery is secured, ventilation with this device can be continued. Contact DrägerService.

Alarm priority		Alarm message	Cause	Remedy
!!!	831	No int. battery	Internal battery deeply discharged.	When the mains supply is secured, ventilation with this device can be continued. Charge the internal battery.
			Internal battery is missing, faulty, or not connected or the fuse is faulty.	When the mains supply is secured, ventilation with this device can be continued. Downgrade alarm priority: Press the ***Alarm Reset*** key. Contact DrägerService.
!	250	No int. battery	Internal battery deeply discharged.	When the mains supply is secured, ventilation with this device can be continued. Charge the internal battery.
			Internal battery is missing, faulty, or not connected or the fuse is faulty.	When the mains supply is secured, ventilation with this device can be continued. Contact DrägerService.
!	255	No nebulisation	Inspiratory flow is too low, so that no nebulizer flow can be applied.	If necessary, increase ventilation parameters for flow acceleration or pressure limitation, so that a higher inspiratory flow is applied.
!!!	150	O_2 measurement inop.	O_2 measurement provides invalid values.	Calibrate O_2 sensor.
			O_2 sensor is faulty or not installed.	Install and calibrate new O_2 sensor.
			O_2 measurement faulty.	To continue ventilation with this device, use external O_2 monitoring and switch off integrated O_2 monitoring. Contact DrägerService.
!!!	310	O_2 supply down	O_2 supply pressure is too low.	Make sure that the supply pressure is greater than 2.7 bar (39.2 psi).
!	090	O_2 supply down	O_2 supply pressure is too low. If FiO_2 = 21 Vol%, the O_2 supply is not needed.	Make sure that the supply pressure is greater than 2.7 bar (39.2 psi).

Alarm priority		Alarm message	Cause	Remedy
!!	100	O_2 supply pressure high	O_2 supply pressure too high.	Make sure that the supply pressure is less than 6 bar (87 psi).
!	150	O_2 supply pressure high	O_2 supply pressure too high. If FiO_2 = 21 Vol%, the O_2 supply is not needed.	Make sure that the supply pressure is less than 6 bar (87 psi).
!!!	260	PEEP high	Expiratory valve or breathing circuit obstructed.	Check breathing circuit and expiratory valve. Check for condensate.
			Expiratory resistance increased.	Check bacterial filter. Replace, if necessary.
!!!	230	PEEP inop.	Measured PEEP is 5 mbar (5 cmH_2O) above or below set PEEP.	Check connections of the breathing circuit for leakages. Make sure that the expiratory valve is properly engaged. Contact DrägerService.
!!	77	Perform br. circuit check	The device was restarted.	Confirm message by pressing the ***Alarm Reset*** key. Perform the breathing circuit check as necessary.
!!!	270	Pressure meas. inop.	Fluid in expiratory valve.	Replace expiratory valve. Clean and dry the used valve.
			Pressure measurement failure.	Disconnect patient from the device and continue ventilation without delay using another independent ventilator. Contact DrägerService.

Alarm priority		Alarm message	Cause	Remedy
!!	251	Rotary knob failed	The rotary knob was pressed for a long period of time or it is faulty. Operation is no longer possible.	If the rotary knob is still being pressed, release the rotary knob. Otherwise, repeatedly press the rotary knob and turn it. If the alarm persists, the settings can no longer be adjusted. Disconnect patient from the device and continue ventilation without delay using another independent ventilator. Contact DrägerService.
!!	250	Rotary knob overused	The rotary knob was pressed very frequently within a short time.	Confirm message by pressing the ***Alarm Reset*** key. If the alarm persists, the settings can no longer be adjusted. Disconnect patient from the device and continue ventilation without delay using another independent ventilator. Contact DrägerService.
!!!	900	Service mode active	Device has been switched to external service mode.	Confirm external Service Mode by pressing the ***Alarm Reset*** key. If ventilation is to be continued with this device, remove cable from the serial interface. Then switch the device off and switch it on again.
!!!	1000	Standby activated	Device has been switched to standby mode.	Confirm standby mode by pressing the ***Alarm Reset*** key.
!!!	100	Temperature high	Breathing gas temperature at the inspiratory port is too high.	Decrease ambient temperature.

Alarm priority		Alarm message	Cause	Remedy
!	260	Temperature high	Due to high ambient temperatures (35 to 40 °C / 95 to 104 °F), the device achieves peak pressure, but not peak flow.	Decrease ambient temperature.
!!!	115	Temperature meas. inop.	Temperature sensor faulty.	Insert new temperature sensor.
!!!	110	Temperature sensor ?	The connector of the temperature sensor was unplugged during operation.	Plug in the connector of the temperature sensor.
			Temperature sensor cable broken.	Insert new temperature sensor.
!!!	200	Tidal volume high	The upper alarm limit of the delivered inspiratory tidal volume was exceeded by 3 breaths in succession.	Check the patient's condition. Check ventilation settings. Adjust alarm limit if necessary. Confirm message by pressing the ***Alarm Reset*** key.
			Leakage or disconnection.	Check connections of the breathing circuit for leakages.
!	280	Tidal volume high	The upper alarm limit of the delivered inspiratory tidal volume was exceeded once.	Check the patient's condition. Check ventilation settings. Adjust alarm limit if necessary.
			Leakage or disconnection.	Check connections of the breathing circuit for leakages.

Alarm priority		Alarm message	Cause	Remedy
!!	354	Tidal volume low	The lower alarm limit of the delivered inspiratory tidal volume was undershot by 4 spontaneous breaths in succession.	Check the patient's condition. Check ventilation settings. If required: – Extend the inspiratory time – Increase flow acceleration – Increase pressure limitation – Increase alarm limit ***Paw*** ⌟/▲ Confirm message by pressing the ***Alarm Reset*** key.
!	274	Tidal volume low	The lower alarm limit of the delivered inspiratory tidal volume was undershot by 2 spontaneous breaths in succession.	Check ventilation settings. If required: – Extend the inspiratory time – Increase flow acceleration – Increase pressure limitation – Increase alarm limit ***Paw*** ⌟/▲
!	135	V_{Ti} high Alarm off	Only in NIV application mode: The upper alarm limit for inspiratory tidal volume was switched off.	Switch on alarm limit again, if necessary.

Cleaning, disinfection and sterilization

Information on reprocessing

The path of the contaminated gas is shown in the pneumatic diagram (page 206). The components through which contaminated gas flows in normal operation and in the first fault event must be reprocessed.

Safety information

WARNING

Risk of infection

Reusable products must be reprocessed, otherwise there is an increased risk of infection and the correct functioning may be impaired.

- **Observe the hygiene regulations of the hospital.**
- **Use validated procedures for reprocessing.**
- **Reprocess reusable products after every use.**
- **Follow the manufacturers' instructions for cleaning agents and disinfectants**

NOTE

Do not clean or disinfect the control and display unit during ventilation. Switch off the device and disconnect the mains plug prior to cleaning or disinfection.

Safety information on the flow sensors

WARNING

Risk of fire

Residual vapors of easily flammable disinfectants (e.g., alcohols) and deposits that were not removed during reprocessing can ignite when the flow sensor is in use.

- **Ensure particle-free cleaning and disinfection.**
- **After disinfection, allow the flow sensor to air for at least 30 minutes.**
- **Before inserting the flow sensor check for visible damage and soiling, such as residual mucus, medication aerosols, and particles.**
- **Replace flow sensors when damaged, soiled, or not particlefree.**

CAUTION

Risk of failure of flow measurement

Improper reprocessing and soiling, such as deposits or particles, can damage the flow sensor:

- No machine cleaning or disinfection
- No plasma sterilization or radiation sterilization
- No water jets, compressed air, brushes or the like
- No ultrasonic bath
- No steam sterilization for the Spirolog flow sensor
- Clean and disinfect the flow sensor in accordance with the corresponding instructions for use.
- For disinfecting the flow sensor use only clean disinfectant solutions.

Disassembly

This chapter describes how to disconnect contaminated ventilation accessories and disassemble them for reprocessing.

Before disassembly

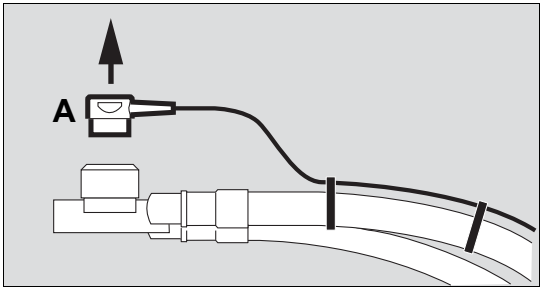
1 Switch off the device and breathing gas humidifier and remove their power plugs.

2 Drain the water traps and breathing hoses.

3 Drain the water container of the breathing gas humidifier.

Removing the breathing gas temperature sensor

1 Unplug the connector from the socket for the breathing gas temperature sensor on the patient connection panel.



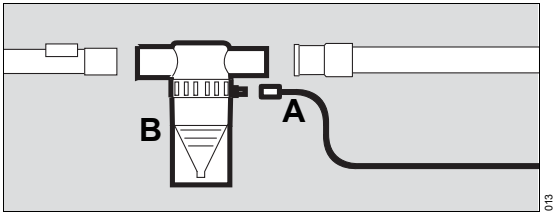
2 Remove the breathing gas temperature sensor (A) from the Y-piece or from the holder of the breathing circuit for pediatric patients. Do not pull on the cable.

Reprocessing the breathing gas temperature sensor

- Reprocess the breathing gas temperature sensor in accordance with the reprocessing list, see page 144.

Disassembling the pneumatic medication nebulizer

When using a breathing circuit for adults

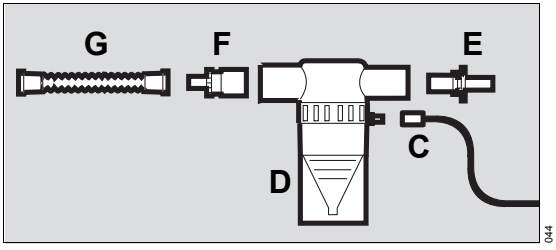


1 Remove the nebulizer hose (A) from the medication nebulizer (B) and from the nebulizer port on the device.

2 Remove the medication nebulizer (B) from the breathing circuit.

3 Disassemble the medication nebulizer in accordance with the corresponding instructions for use.

When using a breathing circuit for pediatric patients



1 Remove the nebulizer hose (C) from the medication nebulizer (D) and from the nebulizer port on the device.

2 Remove the medication nebulizer (D) from the breathing circuit.

3 Pull the catheter mount (E) out of the inlet port.

4 Pull the adapter (F) out of the outlet port.

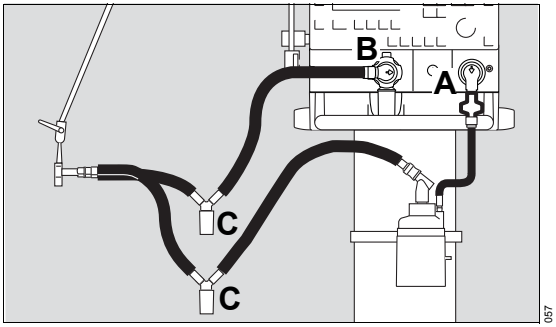
5 Remove the corrugated hose (G) from the adapter (F).

6 Disassemble the medication nebulizer in accordance with the corresponding instructions for use.

Reprocessing the medication nebulizer and parts for adapting

- Reprocess the individual parts of the medication nebulizer in accordance with the corresponding instructions for use.
- Reprocess the parts for adapting in accordance with the reprocessing list, see page 144.

Removing breathing hoses



1 Remove the breathing hoses from the inspiratory port (A) and the expiratory port (B).

CAUTION

Damage to the breathing hoses

When removing the breathing hoses, always hold them at the connection sleeve and not at the coil reinforcement.

2 If fitted: Remove the water trap (C) from the breathing hose.

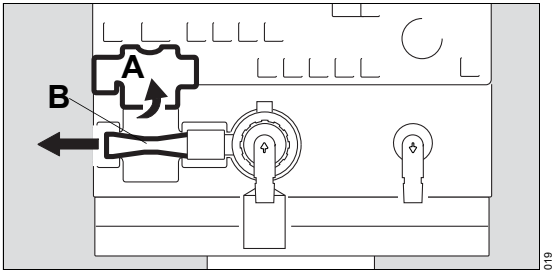
3 Remove the water trap container from the water trap and empty it.

4 Remove and dispose of the bacterial filter in accordance with the corresponding instructions for use.

Reprocessing the breathing circuit

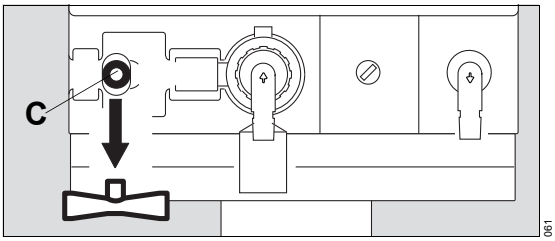
- Reprocess the breathing hoses, water trap, and water trap container and also the Y-piece in accordance with the reprocessing list, see page 144.

Removing the flow sensor



1 Lift the flap (A) by the lower edge and pivot it upwards.

2 Push the flow sensor (B) as far as it will go to the left.



3 Remove the flow sensor from the socket (C).

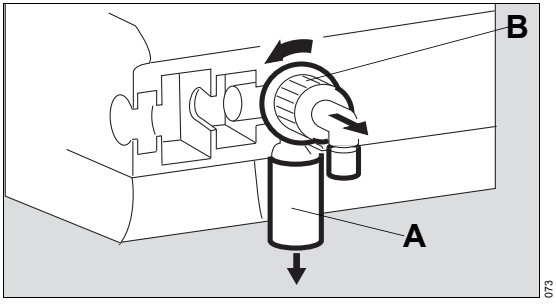
Reprocessing the flow sensor

- Reprocess the flow sensor in accordance with the corresponding instructions for use.

The flow sensor can be reused for as long as automatic calibration is successful.

Disassembling the expiratory valve

Removing the expiratory valve

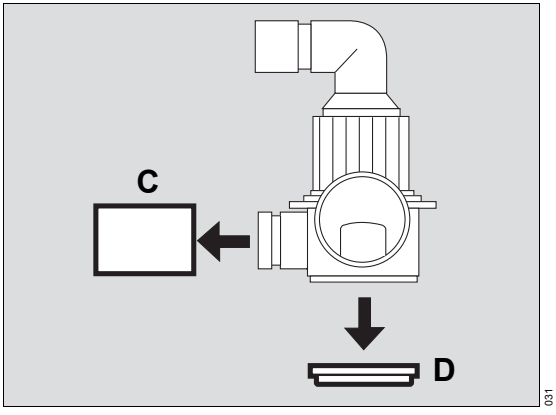


1 Remove and empty the water trap container (A).

2 Turn the locking ring (B) as far as possible to the left.

3 Remove the expiratory valve from the fitting.

Disassembling the expiratory valve



1 Pull the flow sensor sleeve (C) from the expiratory valve.

2 Remove the diaphragm (D).

Reprocessing the expiratory valve

- Reprocess the expiratory valve, diaphragm, flow sensor sleeve and the removed water trap container in accordance with the reprocessing list, see page 144.

Sterilizing the expiratory valve

NOTE

Sterilize the components of the expiratory valve (valve housing, flow sensor sleeve, diaphragm, water trap) only after disassembly.

- After cleaning and disinfecting, always dry the expiratory valve by means of hot steam sterilization at 134 °C (273.2 °F) to ensure that all remaining liquid is dried completely in the interior areas.

Reusing the expiratory valve

CAUTION

High leakage due to damaged expiratory valve

Not all damage can be detected in the device check.

Replace the expiratory valve if the following damage occurs:
– Cracking of the plastic parts
– Torn diaphragm
– Deformation or hardening of the rubber parts

Disassembling accessories

- Disassemble and reprocess the breathing gas humidifier and the Aeroneb Pro nebulizer in accordance with the corresponding instructions for use.
- Disassemble and dispose of the bacterial filter in accordance with the corresponding instructions for use.

Reprocessing methods

Classification of medical devices

For reprocessing, medical devices and their components are divided by type of application and the resulting risk:

– Uncricital medical devices: surfaces accessible to users and patients, e.g., device surfaces, cables

– Semicritical medical devices: parts conducting breathing gas, e.g. breathing hoses, masks

Testing of procedures and agents

Cleaning, disinfection, and sterilization of medical devices has been tested with the following procedures and agents. At the time of testing, the following procedures and agents showed good material compatibility and effectiveness:

Uncritical medical devices

Manual disinfection and simultaneous cleaning:
– Buraton 10F from Schülke & Mayr

Semicritical medical devices

Manual cleaning:
– Neodisher LM2 from Dr. Weigert

Manual disinfection:
– Korsolex extra from Bode Chemie

Machine cleaning:
– Neodisher MediClean from Dr. Weigert

Machine disinfection:
– Thermal, 93 °C (199.4 °F) for 10 min

Sterilization:
– Hot steam, 134 °C (273.2 °F) for 5 min

Uncritical medical devices

Surface disinfectant

Dräger recommends using a surface disinfectant from the following list. Other disinfectants are used at own risk.

Class of active ingredient	Product name	Manufacturer
Chlorine-releasing agents	Actichlor plus	Ecolab
	Klorsept 17	Medentech
	BruTab 6S	Brulin
Oxygen-releasing agents	Descogen Liquid	Antiseptica
	Descogen Liquid r.f.u.	
	Dismozon plus	Bode Chemie
	Dismozon pur	
	Oxycide	Ecolab USA
	Perform	Schülke & Mayr
	Virkon	DuPont
Quaternary ammonium compounds	Mikrozid sensitive liquid[1)]	Schülke & Mayr
	Mikrozid sensitive wipes[1)]	
Aldehydes	Buraton 10 F	Schülke & Mayr

1) Virucidal against enveloped viruses

Dräger points out that oxygen- and chlorine-releasing agents may cause color change in some materials. This is not an indication that the product is not functioning correctly.

At the time of validation, the disinfectants listed above showed material compatibility.

The manufacturers of the surface disinfectants have verified at least the following spectra of activity:
– Bactericidal
– Yeasticidal
– Virucidal or virucidal against enveloped viruses

Observe the specifications of the surface disinfectant manufacturers.

Use surface disinfectants that are nationally authorized.

Manual disinfection and simultaneous cleaning

Procedure:

1 Remove dirt immediately with a wipe soaked in disinfectant.

WARNING
Risk of patient injury

Penetrating liquid may cause malfunction of the device, which may endanger the patient.

Do not place any containers with liquid on or above the device.
During surface disinfection, make sure no liquids penetrate into the device.

2 Perform surface disinfection (scrub-and-wipe disinfection).

3 After the contact time has elapsed, remove disinfectant residues.

Semicritical medical devices

Manual cleaning

Perform manual cleaning preferably under running water and with commercially available cleaning agents (pH value ≤12).

Procedure:

1 Wash off surface dirt under running water.

2 Use cleaning agents in accordance with the manufacturer's instructions. Make sure that all surfaces and interior spaces which must be cleaned are reached. If necessary, use suitable brushes.

3 Rinse items thoroughly under running water until cleaning agent residues are no longer discernible.

4 Check parts for visible dirt and damage. If necessary, repeat manual cleaning.

Manual disinfection

Perform manual disinfection preferably with disinfectants based on aldehydes or quaternary ammonium compounds.

For choosing the appropriate disinfectant, observe country-specific lists of disinfectants. The list of the German Association for Applied Hygiene (Verbund für Angewandte Hygiene VAH) applies in German-speaking countries.

Strictly observe the manufacturer's instructions for using disinfectants. The composition of disinfectants may change.

Procedure:

1 Immerse items in disinfectant.

2 After the contact time has elapsed, rinse items thoroughly under running water until disinfectant residues are no longer discernible.

3 Check parts for visible dirt and damage. If necessary, repeat manual disinfection.

4 Thoroughly shake out residual water. Allow items to dry thoroughly.

Machine cleaning and disinfection

Perform machine cleaning and disinfection using a washer-disinfector in accordance with EN ISO 15883, preferably with a cart for anesthesia accessories and ventilation accessories.

Procedure:

1 Observe instructions for use of the washer-disinfector.

2 Securely position items in the basket. Make sure that all interior spaces and surfaces are completely flushed and that water can drain off freely.

3 Use suitable cleaning agent.

4 Select suitable program, preferably anesthesia program.
– Cleaning must be carried out at 40 °C to 60 °C (104 °F to 140 °F) for at least 5 min.

– Thermal disinfection must be carried out at 80 °C to 95 °C (176 °F to 203 °F) and with corresponding contact time.

5 Carry out final rinsing with deionized water.

6 Immediately remove items from the washer-disinfector.

7 Check parts for visible dirt and damage. If necessary, repeat program or perform manual cleaning and disinfection.

8 Allow items to dry thoroughly.

Visual inspection

- Check all items for damage and external signs of wear, such as cracking, embrittlement, or pronounced hardening, and residual dirt.

CAUTION

Risk due to faulty accessories

Even reusable accessories have a limited service life, e.g., disinfectant residues can corrode the material during autoclaving. External signs of wear can occur, e.g., cracks, deformations, discolorations, or peeling.

If there are external signs of wear, exchange affected accessories.

WARNING

Risk of fire

Deposits not removed during reprocessing can damage the heating wires in the flow sensor and lead to a fire.

Do not contaminate the flow sensor with foreign bodies in the disinfectant.
Regularly check the flow sensor for dried mucus residue, medication aerosols, lint and damage.
If deposits are present or the flow sensor is damaged after reprocessing, replace the flow sensor.

Sterilization

Sterilization frees semicritical medical devices from living microorganisms and dries residual water in the items' interior spaces.

- Only sterilize cleaned and disinfected items.

For sterilization, use a vacuum steam sterilizer (in accordance with DIN EN 285), preferably with fractionated vacuum.

CAUTION

Health hazard

Do not sterilize parts in ethylene oxide. Ethylene oxide may diffuse into the parts.

Reprocessing list

Applicable to non-infectious patients.

The reprocessing list contains approximate values only. The instructions of the hospital's infection control officer responsible have priority.

Uncritical medical devices

Items which can be reprocessed	Recommended reprocessing intervals	Manual	
		Cleaning	Disinfection
Ventilator Savina	Per patient	Outside	Outside
Trolley	Per patient	Outside	Outside
Hinged arm	Per patient	Outside	Outside
Humidifier holder	Per patient	Outside	Outside
Compressed gas hose	Per patient	Outside	Outside
Flow sensor flap	Per patient	Outside	Outside

Semicritical medical devices

Items which can be reprocessed	Recommended reprocessing intervals	Pre-cleaning	Machine cleaning and disinfection	Manual		Sterilization
				Cleaning	Disinfection	
Breathing hoses	Per patient/ weekly	Yes	Yes	According to the corresponding instructions for use		Yes
Y-piece	Per patient/ weekly	Yes	Yes	Possible	Possible	Yes
Water traps[1)]						
Water trap container						
Expiratory valve	Per patient/ weekly[2)]	Yes	Yes	Possible	Possible	Yes
Diaphragm						
Flow sensor sleeve						
Water trap container						
Breathing gas temperature sensor	Per patient/ weekly	No	No	Outside[3)]	Outside[3)]	Yes
Flow sensor	Per patient/weekly[2)]	According to the corresponding instructions for use				

Items which can be reprocessed	Recommended reprocessing intervals	Pre-cleaning	Machine cleaning and disinfection	Manual		Sterilization
				Cleaning	Disinfection	
Breathing gas humidifier	Per patient/ weekly	According to the corresponding instructions for use				
Medication nebulizer[1)]	According to the corresponding instructions for use					
Parts for adapting	Per patient/ weekly	Yes	Yes	Possible	Possible	Yes

1) Keep spring-loaded valves (water trap, pneumatic medication nebulizer) open during reprocessing.
2) Nebulization may lead to increased deposits making it necessary to exchange the parts more often.
3) For additional information, see "Reprocessing the breathing gas temperature sensor manually" on page 145.

Reprocessing the breathing gas temperature sensor manually

During manual cleaning, perform the following additional measures:

1 Immerse the breathing gas temperature sensor in the solution avoiding bubbles.

2 Before the start of contact time and after contact time, clean the sensor in the bath by means of vigorous brushing.

During manual disinfection, perform the following additional measures:

Prerequisites: Use disinfectant in accordance with manufacturer's specifications and with double contact time.

1 Immerse the breathing gas temperature sensor in the solution avoiding bubbles.

2 Before the start of contact time and after contact time, clean the sensor in the bath by means of vigorous brushing.

After reprocessing

Preparations before reuse

1 Assemble and prepare the device so that it is ready for operation, see chapter "Assembly and preparation" on page 41.

2 Perform device check, see page 67.

3 Check operational readiness, see page 70.

Maintenance

Information on maintenance

This chapter describes the maintenance measures required to maintain the proper functioning of the medical device. Maintenance measures must be performed by the personnel responsible.

WARNING

Risk of electric shock

Current-carrying components are located under the cover.

- **Do not remove the cover.**
- **Maintenance measures must be performed by the personnel responsible. Dräger recommends DrägerService to perform these measures.**

WARNING

Risk of patient injury

If maintenance measures are performed during ventilation, this endangers the patient.

Only perform maintenance measures when no patient is connected to the device.

CAUTION

Risk of electric shock

The batteries must be exchanged by service personnel or experts.

CAUTION

Risk of infection

Users and service personnel can become infected with pathogenic germs.

Disinfect and clean device or device parts before any maintenance measures and also before returning the medical device for repair.

CAUTION

Risk of medical device failure

If the safety-relevant tests are not performed on a regular basis, the proper functioning of the medical device can be compromised.

The electrical safety test and the functional tests described in the technical documentation IPM must be carried out within the specified intervals.

Definition of maintenance concepts

Concept	Definition
Maintenance	All measures (inspection, preventive maintenance, repair) intended to maintain and restore the functional condition of a medical device
Inspection	Measures intended to determine and assess the actual state of a medical device
Preventive maintenance	Recurrent specified measures intended to maintain the functional condition of a medical device
Repair	Measures intended to restore the functional condition of a medical device after a device malfunction

Inspection

Perform inspections at regular intervals and observe the following specifications.

Checks	Interval	Personnel responsible
Inspection	Must be carried out for the first time after 2 years or at the latest after 12000 operating hours, whichever occurs first. Thereafter annually or after 6000 operating hours, whichever occurs first.	Service personnel
Safety checks	Every 12 months	Service personnel

NOTE

If Savina is used in areas with extreme conditions, the intervals specified must be reduced after consulting DrägerService.

Safety checks

Safety checks are no substitute for preventive maintenance measures (including preventive replacement of wear parts) as identified by the manufacturer.

CAUTION

Risk of medical device failure

If safety checks are not performed on a regular basis, the proper operation of the medical device can be compromised.

Perform safety checks at the indicated intervals.

1 Check accompanying documents:
   – Instructions for use are available.

2 Perform a functional test of the following features according to the instructions for use:
   – All functions described in the test steps of the device check.
   – Internal and if applicable external batteries

3 Check that the device combination is in good condition:
   – All labels are complete and legible.
   – There is no visible damage.
   – Fuses which are accessible from the outside are in compliance with the specified values.

4 Using the instructions for use, check that all components and accessories needed to use the product are available.

5 Check the electrical safety according to IEC 62353.
   Any breathing gas humidifiers or power socket strips present (e.g., on the trolley) must be subjected to the above-mentioned check. The test must be carried out on individual devices and together in the system.
   – Protective conductor resistance ≤0.2 Ω
   – Substitute device leakage current ≤1 mA
   – Substitute patient leakage current ≤5 mA

6 Check safety features:
- Correct functioning of the pneumatic safety valve:
  Pressure 100 to 110 mbar (or hPa or cmH_2O)
- Correct functioning of the emergency expiratory valve:
  Pressure 5 to 10 mbar (or hPa or cmH_2O)
- Correct functioning of the non-return valve in the expiratory valve
- Correct functioning of the emergency breathing valve
- Correct functioning of the power supply failure alarm

Preventive maintenance

WARNING
Risk due to faulty components

Device failure is possible due to wear or material fatigue of the components.

To maintain the proper operation of all components, this device must undergo inspection and preventive maintenance at specified intervals.

The following table shows the preventive maintenance intervals:

Component	Interval	Measure	Personnel responsible
O_2 sensors	If the ***O_2 measurement inop.*** alarm message is displayed or if calibration is no longer possible.	Exchange, see page 154.	Users
Microfilter	Every 12 months	Exchange, see page 152.	Users
Dust filter set	Every 4 weeks	Cleaning, see page 153.	Users
	Every 12 months	Exchange, see page 153.	Users

Component	Interval	Measure	Personnel responsible
Diaphragm of the reusable expiratory valve	Every 12 months	Replace, see page 155.	Users
Internal battery	Every 12 months	Check capacity, replace battery if necessary	Service personnel
	Every 2 years	Replace battery	
External battery	Every 12 months	Check capacity, exchange battery if necessary	Service personnel[1)]
Filter in gas inlet LPO	Every 2 years	Replace	Experts
O_2 filter (in the O_2 gas inlet)	Every 6 years	Replace	Service personnel
Real-time clock	Every 6 years	Replace	Experts
Wiring harness for Spirolog flow sensor	Every 6 years	Replace	Experts
Turbine	Every 8 years	Replace	Experts

1) The capacity test for the external battery is not part of the service provided by DrägerService and is therefore the responsibility of the user.

Repair

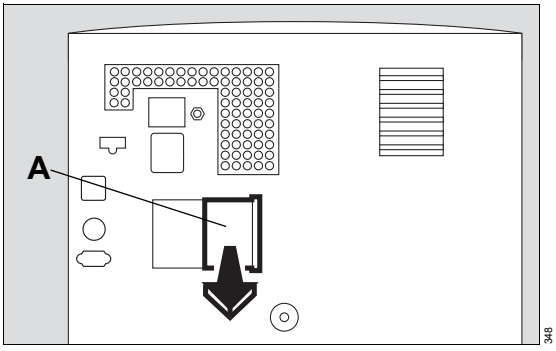
Dräger recommends that all repairs be carried out by DrägerService and that only authentic Dräger repair parts be used. Otherwise, the correct functioning of the medical device may be compromised.

Replacing the microfilter

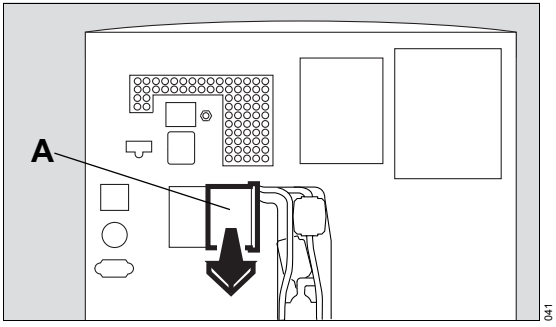
Replace the microfilter after 1 year.

1 Remove the filter cover, see page 62.

Devices up to serial number ASFF-0999:



Devices as from serial number ASFF-1000:



2 Remove the soiled microfilter (A) from the holder and dispose of it with domestic waste.

3 Push new microfilter (A) into the holder as far as it will go.

4 Fit the filter cover, see page 62.

Replacing the dust filter set

CAUTION

Risk of malfunction

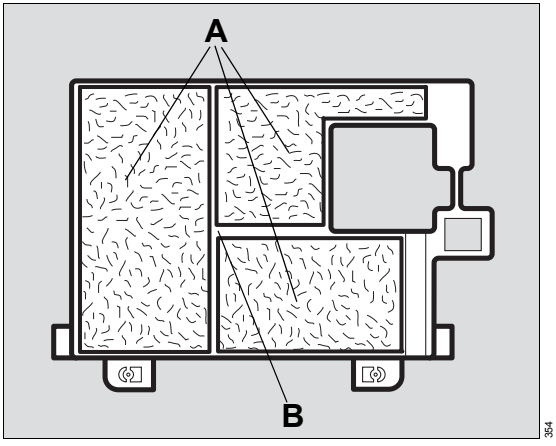
Soiled dust filters may impair the proper functioning of the device.

Replace the dust filter set at regular intervals.

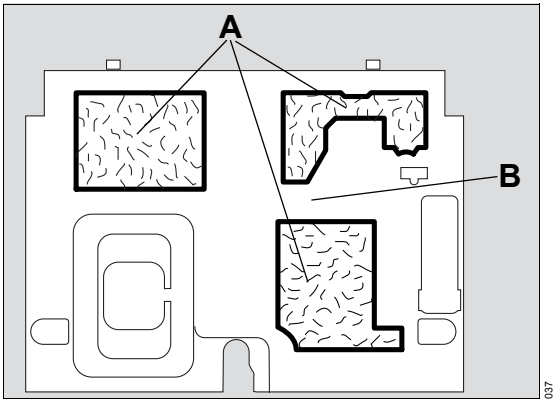
Visually check the dust filter set for soiling after 4 weeks and clean or replace as necessary. Exchange after 1 year at the latest.

1 Remove the filter cover, see page 62.

Devices up to serial number ASFF-0999:



Devices as from serial number ASFF-1000:



2 Remove the soiled dust filter set (A) from the filter cover (B) and dispose of with domestic waste.

3 Insert the new dust filter set (A).

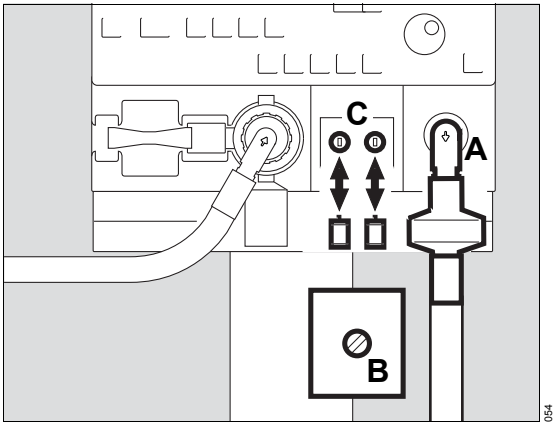
4 Fit the filter cover, see page 62.

Replacing O_2 sensors

Replace the O_2 sensors if:
– Calibration is no longer possible.
– The alarm message ***O_2 measurement inop.*** is displayed.

NOTE
Use only O_2 sensors of type Oxytrace VE (MX01049). It is possible to confuse them with the O_2 sensor Oxytrace INCU, since they are externally identical. However, their measurement processes are different.

Prerequisites: Savina is switched off.



1 Swivel the inspiratory port (A) downwards.

2 Release the screw using a coin and remove the cover plate (B).

3 Remove the old O_2 sensors from the holder (C).

4 Insert the new O_2 sensors into the correct holder (C). Note the preferred position of the plug contacts.

5 Fit the cover plate (B) again and tighten the screw using a coin.

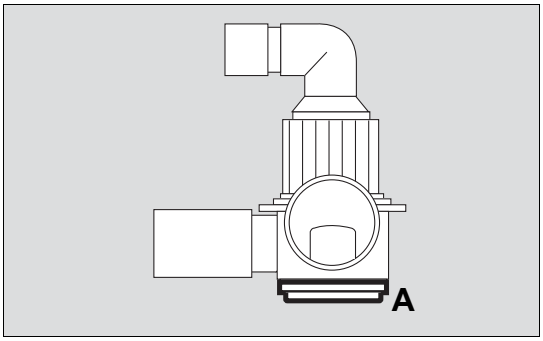
6 Switch on Savina and wait for the O_2 sensors to complete their warm-up phase (10 to 20 minutes).

7 Calibrate the O_2 sensors, see page 105.

8 Dispose of the old O_2 sensors, see page 159.

Replacing the diaphragm of the reusable expiratory valve

Prerequisites: The expiratory valve has been removed, see "Removing the expiratory valve" on page 139.



1 Remove the diaphragm (A).

2 Fit the new diaphragm onto the edge of the expiratory valve housing. Make sure that the diaphragm is fitted properly.

3 Dispose of used diaphragm with domestic waste.

4 Insert the expiratory valve, see "Inserting the expiratory valve" on page 48.

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Disposal

Safety information

CAUTION

Risk of infection

Disinfect and clean the device and its components before disposal.

For countries subject to the EU Directive 2002/96/EC

This device is subject to EU Directive 2002/96/EC (WEEE). In order to comply with its registration according to this directive, this device must not be disposed of at municipal collection points for waste electrical and electronic equipment. Dräger has authorized a company to collect and dispose of this device. To initiate collection or for further information, visit Dräger on the Internet at www.draeger.com. Use the Search function with the keyword "WEEE" to find the relevant information. If access to Dräger's website is not possible, contact the local Dräger organization.

Disposal of packaging material

Dispose of the packaging material of the device and the accessories listed in the list of accessories in accordance with the applicable laws and regulations.

Disposal of batteries

WARNING

Risk of explosion and of chemical burns

Improper handling of batteries can result in explosions and chemical burns.

Do not throw batteries into fire. Do not force batteries open.

The medical device contains batteries with toxic substances.
In the Federal Republic of Germany: The user is obliged by the law on the return and disposal of used batteries to return batteries which contain toxic substances either to the manufacturer/sales outlet or to a collection center operated by public waste disposal corporations. The battery installed in the device must therefore be removed by service personnel before disposal of the device. Observe the applicable laws and regulations for battery disposal.

Disposal of O_2 sensors

WARNING

Risk of explosion! Do not throw O_2 sensors into fire.
Risk of chemical injury! Do not open O_2 sensors using force.

O_2 sensors can be returned to Dräger.

Disposal of the medical device

At the end of its service life:

- Have the medical device appropriately disposed of in accordance with applicable laws and regulations.

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Technical data

Ambient conditions

During operation	
Temperature	5 to 40 °C (41 to 104 °F)
Atmospheric pressure	700 to 1060 hPa
Relative humidity	5 to 95 %, without condensation
During storage and transport	
Temperature	-20 to 70 °C (-4 to 158 °F)
Atmospheric pressure	600 to 1200 hPa
Relative humidity	10 to 95 %, without condensation

Ambient conditions may be restricted depending on the accessories used. Observe corresponding instructions for use.

If not explicitly specified, the tolerance specifications in the Technical data do not include the measurement uncertainty of external test equipment. The measurement uncertainties of the test equipment used are available upon request.

Setting values

Ventilation modes	IPPV, IPPV$_{Assist}$, SIMV, SIMV/ASB BIPAP, BIPAP/ASB CPAP, CPAP/ASB
Respiratory rate ***f***	2 bpm to 80 bpm
Accuracy	±1 bpm
Respiratory rate during Apnea Ventilation ***f$_{Apnoea}$***	2 bpm to 80 bpm (0 = apnea ventilation off)
Accuracy	±1 bpm
Inspiratory time ***T$_{insp.}$***	0.2 to 10 s
Accuracy	0.1 s
Tidal volume ***V$_T$***	0.05 to 2.0 L, BTPS
Tidal volume during Apnea Ventilation ***VT$_{Apnoea}$***	0.05 to 2.0 L, BTPS
Resolution	10 mL

Setting values (cont.)

Accuracy Valid for 25 °C (77 °F) ambient temperature and 50 % relative humidity, no leakage, V_T measured value valid, no pressure- or flow-related alarms. At higher humidity levels, the flow-dependent measured values are up to 8.3 % lower than the values displayed.	±10 % of the set value or ±12.5 mL, whichever is greater
O_2 concentration	21 to 100 Vol%
Accuracy Valid for 25 °C (77 °F) ambient temperature and 50 % relative humidity. At higher humidity levels, the O_2 concentration of the dry gas is up to 2.5 Vol% higher than the measured value.	±3 Vol% The accuracy of the inspiratory O_2 concentration is appreciably reduced when operating the device without O_2 sensors.
$T_{0...90}$ (VT = 500 mL, maximum values for the combination of accessories described in ISO 80601-2-12)	<60 s
$T_{0...90}$ (VT = 150 mL, breathing circuit for adults, maximum values for the combination of accessories described in ISO 80601-2-12)	<120 s
$T_{0...90}$ (VT = 150 mL, breathing circuit for pediatric patients, maximum values for the combination of accessories described in ISO 80601-2-12)	<120 s
Pressure	
Inspiratory pressure $P_{insp.}$	1 to 99 mbar (or hPa or cmH_2O) [1 mbar = 100 Pa]
Positive end-expiratory pressure PEEP or intermittent PEEP	0 to 35 mbar (or hPa or cmH_2O)
Pressure support $\Delta P_{ASB\ above\ PEEP}$	0 to 35 mbar (or hPa or cmH_2O) (relative to PEEP)
Inspiratory pressure limit P_{max}	1 to 99 mbar (or hPa or cmH_2O) [1 mbar = 100 Pa]
Sigh pressure $\Delta Sigh$	0 to 20 mbar (or hPa or cmH_2O)
Accuracy	±2 mbar (or hPa or cmH_2O)

Setting values (cont.)

Trigger sensitivity can be switched off in IPPV ventilation mode Trigger switched off = IPPV Trigger switched on = IPPV$_{Assist}$	1 to 15 L/min
Accuracy	±8 % of the set value or ±0.5 L/min, whichever is greater
Flow Acceleration ***FlowAcc***	5 to 200 mbar/s (or hPa/s or cmH_2O/s)
Accuracy	±20 % of the set value

Performance characteristics

Control principle	Time-cycled, volume-constant, pressure-controlled
Supply system for spontaneous breathing and pressure support	Turbine with quick-action pressure control valve
Maximum inspiratory flow	250 L/min, BTPS
Intermittent PEEP duration	2 cycles every 3 min
Medication nebulization (with high-pressure O_2 supply only)	For up to 30 min, in the inspiratory flow phase, 2 bar (or 200 kPa or 29 psi), at most 10 L/min, Savina takes the nebulizer flow into consideration and keeps the minute volume constant
Oxygen enrichment for endotracheal suction (with high-pressure O_2 supply only)	
Disconnection detection	automatic
Reconnection detection	automatic
Preoxygenation	up to 180 s at 100 Vol% O_2
Active suction phase	max. 120 s
Postoxygenation	up to 120 s at 100 Vol% O_2
Device compliance (with bacterial filter, 2.3 to 2.8 m (7.5 to 9.2 ft) breathing circuit for adults, breathing hoses heated or unheated, water traps and breathing gas humidifier)	
Fisher & Paykel MR 850 breathing gas humidifier with empty F&P MR 370 F humidifier chamber	≤2 mL/mbar ≤2 mL/hPa ≤2 mL/cmH_2O
Aquapor EL breathing gas humidifier with empty humidifier chamber	≤3.2 mL/mbar ≤3.2 mL/hPa ≤3.2 mL/cmH_2O

Performance characteristics (cont.)

Device compliance (with bacterial filter, 2.7 to 2.8 m (8.9 to 9.2 ft) breathing circuit for pediatric patients, Fisher & Paykel MR 850 breathing gas humidifier with empty F&P MR 340 humidifier chamber, breathing hoses heated or unheated, and water traps)	≤1 mL/mbar ≤1 mL/hPa ≤1 mL/cmH_2O
Device resistance during spontaneous breathing (if typical accessories are used)	
Inspiratory resistance (breathing circuit for adults)	≤1.0 mbar at 60 L/min ≤1.0 hPa at 60 L/min ≤1.0 cmH_2O at 60 L/min
Inspiratory resistance (breathing circuit for pediatric patients)	≤2.0 mbar at 30 L/min ≤2.0 hPa at 30 L/min ≤2.0 cmH_2O at 30 L/min
Expiratory resistance (breathing circuit for adults)	≤3.7 mbar at 60 L/min ≤3.7 hPa at 60 L/min ≤3.7 cmH_2O at 60 L/min
Expiratory resistance (breathing circuit for pediatric patients)	≤6.0 mbar at 30 L/min ≤6.0 hPa at 30 L/min ≤6.0 cmH_2O at 30 L/min
Device resistance in case of device failure in accordance with ISO 80601-2-12	
Inspiratory resistance (breathing circuit for adults)	≤6.0 mbar at 30 L/min ≤6.0 hPa at 30 L/min ≤6.0 cmH_2O at 30 L/min
Inspiratory resistance (breathing circuit for pediatric patients)	≤6.0 mbar at 15 L/min ≤6.0 hPa at 15 L/min ≤6.0 cmH_2O at 15 L/min
Expiratory resistance (breathing circuit for adults)	≤6.0 mbar at 30 L/min ≤6.0 hPa at 30 L/min ≤6.0 cmH_2O at 30 L/min
Expiratory resistance (breathing circuit for pediatric patients)	≤6.0 mbar at 15 L/min ≤6.0 hPa at 15 L/min ≤6.0 cmH_2O at 15 L/min

Performance characteristics (cont.)

Maximum values for the combination of accessories in accordance with ISO 80601-2-12 (including inspiratory bacterial filter)

Inspiratory resistance (breathing circuit for adults)	≤16.0 mbar at 60 L/min ≤16.0 hPa at 60 L/min ≤16.0 cmH_2O at 60 L/min ≤6.0 mbar at 30 L/min ≤6.0 hPa at 30 L/min ≤6.0 cmH_2O at 30 L/min
Inspiratory resistance (breathing circuit for pediatric patients)	≤25.0 mbar at 30 L/min ≤25.0 hPa at 30 L/min ≤25.0 cmH_2O at 30 L/min ≤10.0 mbar at 15 L/min ≤10.0 hPa at 15 L/min ≤10.0 cmH_2O at 15 L/min ≤0.4 mbar at 2.5 L/min ≤0.4 hPa at 2.5 L/min ≤0.4 cmH_2O at 2.5 L/min
Expiratory resistance (breathing circuit for adults)	≤10.0 mbar at 60 L/min ≤10.0 hPa at 60 L/min ≤10.0 cmH_2O at 60 L/min ≤5.0 mbar at 30 L/min ≤5.0 hPa at 30 L/min ≤5.0 cmH_2O at 30 L/min
Expiratory resistance (breathing circuit for pediatric patients)	≤22.0 mbar at 30 L/min ≤22.0 hPa at 30 L/min ≤22.0 cmH_2O at 30 L/min ≤10.0 mbar at 15 L/min ≤10.0 hPa at 15 L/min ≤10.0 cmH_2O at 15 L/min ≤0.4 mbar at 2.5 L/min ≤0.4 hPa at 2.5 L/min ≤0.4 cmH_2O at 2.5 L/min
Compliance (breathing circuit for adults)	≤3.2 mL/mbar ≤3.2 mL/hPa ≤3.2 mL/cmH_2O
Compliance (breathing circuit for pediatric patients)	≤1 mL/mbar ≤1 mL/hPa ≤1 mL/cmH_2O

Additional functions

Inspiratory relief valve	Opens breathing system in case of failure
Safety valve	Opens the breathing system at values over 100 mbar (or hPa or cmH_2O)

Displayed measured values

Airway pressure measurement (resistive relative pressure sensor)	
Peak inspiratory pressure	***P_{peak}***
Plateau pressure	***P_{plat}***
Positive end-expiratory pressure	***PEEP***
Mean airway pressure	***P_{mean}***
Range	0 to 99 mbar (or hPa or cmH_2O)
Resolution	1 mbar (or hPa or cmH_2O)
Accuracy	±2 mbar (or hPa or cmH_2O)
Inspiratory O_2 measurement (maintenance-free electrochemical sensor, ambient pressure-compensated)	
Inspiratory O_2 concentration	***FiO_2***
Range	18 to 100 Vol%
Resolution	1 Vol% O_2
Absolute accuracy with calibration in HPO mode	±3 Vol% O_2
Absolute accuracy with calibration in LPO mode	±8 Vol% O_2 (Maximum possible basic measuring error in O_2 measurement with a nominal concentration of 100 Vol% O_2 and assuming the worst-case ambient conditions in the hospital)
Drift of measurement accuracy	±1 Vol%/day
Warm-up time	10 to 20 min
Maximum response time after change from 21 Vol% to 60 Vol%	$T_{0...90}$ <20 s
Flow measurement	
Inspiratory peak flow	***$Flow_{peak}$***
Range	0 to 196 L/min
Resolution	1 L/min
Accuracy	±10 % of measured value or ±1 L/min, whichever is greater

Displayed measured values (cont.)

Minute volume measurement	
Minute volume	***MV***
Spontaneous minute volume	***MV$_{spn}$***
Range	0 to 99 L/min BTPS
Resolution	0.1 L/min
Accuracy	±12 % of measured value or ±0.6 L/min, whichever is greater
$T_{10...90}$	approx. 35 s
Leakage minute volume in relation to the inspiratory minute volume	***MV$_{leak}$***
Range	0 to 100 %
Resolution	1 % Leakages <10 % cannot be indicated with sufficient resolution. 0 % is displayed.
Accuracy	±18 % of measured value or ±0.3 L/min, whichever is greater
$T_{10...90}$	approx. 35 s
Expiratory tidal volume	***V$_{Te}$***
Range	0 to 3999 mL, BTPS
Resolution	1 mL
Accuracy	±10 % of measured value or ±11 mL, whichever is greater
Patient's leakage, compensated tidal volume, measured on the inspiratory side (only in application mode ***Mask/NIV***)	***V$_{Tpat}$***
Range	0 to 3999 mL, BTPS
Resolution	1 mL
Accuracy	±18 % of measured value or ±20 mL, whichever is greater
Respiratory rate measurement	
Spontaneous respiratory rate	***f$_{spn}$***
Total respiratory rate	***f$_{tot}$***
Range	0 to 150 bpm
Resolution	1 bpm
Accuracy	±1 bpm
$T_{10...90}$	approx. 35 s

Displayed measured values (cont.)

Ratio of inspiratory time to expiratory time	***I:E***
Range	1:150 to 150:1
Resolution	0.1
Accuracy	±6 % of measured value
Inspiratory time	T_{insp}
Range	0 to 15 s
Resolution	0.1 s
Accuracy	0.1 s
Plateau time	T_{plat}
Range	0 to 10 s
Resolution	0.1 s
Accuracy	0.1 s
Resistance	***R***
Range	3 to 100 mbar/L/s (or hPa/L/s or cmH_2O/L/s)
Resolution	1 mbar/L/s (or hPa/L/s or cmH_2O/L/s)
Accuracy	±5 mbar/L/s (or hPa/L/s or cmH_2O/L/s) or ±35 %, whichever is greater
Compliance	***C***
Range	3 to 200 mL/mbar (or mL/hPa or mL/cmH_2O)
Resolution	1 mL/mbar (or mL/hPa or mL/cmH_2O)
Accuracy (only if no leakage occurs)	±2 mL/mbar (or mL/hPa or mL/cmH_2O) or ±20 %, whichever is greater
Breathing gas temperature measurement (NTC sensor)	
Range	18 to 48 °C (64.4 to 118.4 °F)
Resolution	1 °C
Accuracy	±1 °C
Waveform displays	
Airway pressure Paw (t)	–5 to 100 mbar (or hPa or cmH_2O)
Flow (t)	–200 to 200 L/min
$T_{0...90}$	<500 ms

Monitoring

Sound pressure level L_{PA} of the alarm signals, measured according to IEC 60601-1-8 and A1:2012: Operator's position: at front of device at a distance of 1 m (39 in) and a height of 1.5 m (59 in).	
Noise pressure	
Range for high- and medium-priority alarms according to volume setting	62 dB (A) to 68 dB (A)
Range for low-priority alarms according to volume setting	63 dB (A) to 68 dB (A)
Range for the power supply failure alarm	55 dB (A) to 68 dB (A)
Expiratory minute volume	***MV***
Upper alarm limit alarm	If the upper alarm limit has been exceeded
Range	2 to 41 L/min in 0.1 L/min steps
Lower alarm limit alarm	If the value has fallen below the lower alarm limit
Range	0.5 to 40 L/min in 0.1 L/min steps
Alarm suppression	– For the first 2 min after the device is switched on – During standby mode and for 2 min after starting ventilation – When flow monitoring is deactivated and for 2 min after activation – During detected disconnection and for 2 min after reconnection
Airway pressure	***Paw***
Upper alarm limit alarm	If the upper alarm limit has been exceeded
Range	10 to 100 mbar (or hPa or cmH_2O)
Lower alarm limit alarm	When the value "PEEP + 5 mbar (or hPa or cmH_2O)" (coupled with the set value for PEEP) is not exceeded for at least 0.1 s in two successive mandatory breaths with preset PEEP+$P_{insp.}$ ≥5 mbar
Delay time ***$T_{Disconnect}$*** for alarm message ***Airway pressure low*** (only in application mode ***Mask/NIV***)	0 to 60 s

Monitoring (cont.)

Inspiratory O_2 concentration (HPO mode)	***FiO_2***
Upper alarm limit alarm	If the upper alarm limit has been exceeded for at least 20 s
Lower alarm limit alarm	If the lower alarm limit has been exceeded for at least 20 s
Setting range	Both alarm limits are automatically allocated to the set value: <60 Vol% at ±4 Vol% ≥60 Vol% at ±6 Vol%
Inspiratory O_2 concentration (LPO mode)	***FiO_2***
Alarm limits	Manual adjustment
Range of upper alarm limit	19 to 99 % in steps of 1 (100 = Off)
Range of lower alarm limit	18 to 98 %, step size 1 (18 to 99 %, if upper alarm limit is switched off)
Respiratory rate	***f_{tot}***
Alarm	If the respiratory rate (mandatory and spontaneous breaths) has been exceeded
Setting range	10 to 120 bpm
Apnea alarm time	***T_{Apnoea}***
Alarm	If no breathing activity is detected
Range	15 to 60 s adjustable in steps of 1 s
Tidal volume	***V_{Ti}***
Alarm	If the delivered tidal volume ***V_T*** exceeds the alarm limit
Range	0.06 to 4.0 L
Alarm suppression	– For the first 15 s after the device is switched on – In standby mode and for 15 s after starting ventilation – During detected disconnection and for 15 s after reconnection

Operating data

Mains power supply	
Mains power connection	100 V~ to 240 V~ 50/60 Hz
Current consumption	
At 240 V~	max. 1.3 A
At 100 V~	max. 3.4 A
Inrush current	max. 11.1 A
Device fuse	
Range 100 to 240 V~	F 5 H 250 V IEC 60127-2 5x20 (2x)
Degree of protection	
Ventilator	Class I
Breathing gas temperature sensor AWT01 (sensor fitted)	Type BF 
Expiratory valve and breathing hoses	Type BF 
Degree of protection	IP21 Protected against finger access and solid foreign bodies with a diameter of 12.5 mm (0.47 in) and wider Protected against vertically falling water drops
Battery supply	
DC fuse for internal battery	Plug-in fuse F15A32V ISO 8820-3, Type C
DC fuse for external battery	Blade fuse F25A80V UL 248, type C, standard size, arc-quenching
Supply from external battery	12 V or 24 V
Input current (DC)	
12 V battery	typically 10 A, max. 30 A
24 V battery	typically 5 A, max. 15 A
Operating time if mains power supply is not available, with a fully-charged external battery and typical ventilation (Typical ventilation, see page 176)	
Example:	
12 V battery 36 Ah	Approx. 3 hours
24 V battery 17 Ah	Approx. 4 hours (e.g., with 2 lead-gel batteries 12 V / 17 Ah)
Operating time if mains power supply is not available and no external battery is available (new and fully-charged internal battery)	Typically 60 min (±12 min) during typical ventilation (Typical ventilation, see page 176)

Operating data (cont.)

External battery	
The external battery is mounted on the trolley	
Standard rechargeable lead or lead-gel batteries can be used.	For example LC-XD1217PG (Panasonic), 2 batteries
Batteries that use other chemical systems (such as NiCd, NiMH) must **not** be used.	
Battery charge of the external battery	
Savina automatically detects the voltage of the external battery connected.	
When the battery is fully charged, the charging system switches to trickle charging.	
Trickle charging is effected by short current pulses.	
Charging time	
The charging times indicated refer to immediate charging of the external battery after discharge.	
The charging time may be longer if the batteries have partially discharged several times in succession without being fully recharged on mains power supply in the meantime.	
Type	Lead-gel batteries, maintenance-free, sealed
Minimum capacity	
12 V battery	36 Ah
24 V battery	17 Ah
Charging time	
12 V battery	<48 hours (about 20 hours for 80 % charge)
24 V battery	<24 hours (about 15 hours for 80 % charge)
Charging current	
12 V battery	2 A
24 V battery	2 A
Internal battery	
Type	Lead-gel batteries, maintenance-free, sealed
Charging time	<3 hours (about 2 hours for 80 % charge)

Operating data (cont.)

Gas supply (HPO)	
O_2 operating pressure	2.7 bar to 6 bar 270 kPa to 600 kPa 39 psi to 87 psi
O_2 input flow	up to 180 L/min
O_2 connector	NIST
Dew point	5 °C below ambient temperature
Oil concentration	<0.1 mg/m^3
Particle size	Dust-free air (filtered with pore size <1 µm)
Gas supply (LPO)	
Connecting hose	max. ø 7 mm (0.27 in)
Return valve	Resistance approx. 50 mbar (or hPa or cmH_2O) at flow of 10 L/min
O_2 operating pressure	100 mbar to max. 2 bar 100 hPa to max. 200 kPa 100 cmH_2O to max. 29 psi
O_2 flow	0.5 L/min to max. 10 L/min
O_2 humidity	without condensation
Flow for pneumatic medication nebulizer	O_2, max. 2 bar (or 200 kPa or 29 psi), max. 16 L/min
Noise emission according to ISO 80601-2-12:2011, ISO 4871:2009 and ISO 3744:2010:	
A-evaluated averaged measuring surface sound pressure level (L_{pA}) at a radius of 2 m (79 in)	39.5 dB
Uncertainty (k)	3.5 dB
A-evaluated sound power level (L_{WA})	54.5 dB
Uncertainty (k)	3.5 dB
Dimensions (W x H x D)	
Basic device	380 x 383 x ±372 ±2 mm (14.96 x 15.08 x 14.65 ±0.08 in)
Device with trolley	550 x 1347 x 559 ±5 mm (21.65 x 53.03 x 22.01 ±0.20 in)
Weight	
Basic device	approx. 24 kg (52.9 lbs) without trolley
Device outputs	
Digital output	Output and reception via an RS232 C interface for MEDIBUS protocol

Operating data (cont.)

Maximum load	
Maximum load for trolley	100 kg (220.4 lbs)
Maximum load for humidifier holder	10 kg (22.0 lbs)
Maximum load for standard rail	5 kg (11.0 lbs)
Electromagnetic compatibility EMC according to European Directive 89/336/EEC	Tested in accordance with IEC 60601-1-2
Classification according to EC Directive 93/42/EEC, Annex IX	II b
UMDNS code Universal Medical Device Nomenclature System - Nomenclature for medical devices	17-429
Materials used	
Part	Material
Breathing hose	Silicone rubber (milky, transparent)
Water trap	Polysulphone (gray, transparent)
Y-piece	Polysulphone (yellow, transparent)
Expiratory valve (housing, closure)	Polyamide (white, blue)
Inspiratory valve	Polyamide (white, blue)
Diaphragm	Silicone rubber and nickel (whitish and gray)
For nurse call (optional)	
Connection	with connecter 1846248 only
Potential-free DC contact	
Input voltage	max. 40 V =
Input current	max. 500 mA
Switching power	max. 15 W
Delay time for activation of nurse call as from alarm detection	<2.5 s
For MEDIBUS	
Delay time for sending alarms via MEDIBUS as from alarm detection	<3 s

Typical ventilation

Ventilation mode	IPPV
V_T	700 mL
O_2	21 Vol%
FlowAcc	30 mbar/s (or hPa/s or cmH_2O/s)
$T_{insp.}$	2 s
f	12 bpm
PEEP	5 mbar (or hPa or cmH_2O)
Test lung compliance	50 mL/mbar (50 mL/cmH_2O)
Test lung resistance	5.0 mbar/L/s (5.0 cmH_2O/L/s)

Factory settings

Alarm limits

Paw ⌐▲	40 mbar (or hPa or cmH_2O)
MV ⌐▲	9 L/min
MV ▼⌐	4 L/min
T_{Apnoea} ⌐▲	15 s
f_{tot} ⌐▲	35 bpm
V_{Ti} ⌐▲	0.75 L

Device and monitoring settings

Volume	100 %

Alarm system of Savina

The alarm system of Savina meets the requirements of the IEC 60601-1-8 standard and A1:2012.

The optical and acoustic alarm signals include:
– flashing LEDs
– on-screen display of alarm messages
– main acoustic alarm and auxiliary acoustic alarm (also used as power supply failure alarm).

The alarm system is designed so that the user can recognize alarm messages from a distance of 1 m (39 in). The volume of the alarm tone specified applies to a distance of 1 m (39 in) in front of the device and a height of 1.5 m (59 in). For the volumes of the main acoustic alarm with regard to the individual alarm priorities, see "Monitoring" on page 170.

The alarm system does not feature any configurable alarm presets or default alarm presets. For the "factory settings", see page 176.

Savina has two interfaces (MEDIBUS, nurse call) that can be used for a distributed alarm system. According to ICE 60601-1-8, this distributed alarm system is not suitable for the safe transmission of alarms. Data transfer via MEDIBUS or the nurse call does not replace regular checks of the monitoring on the device screen. Each device in the alarm system connected to these interfaces must be labeled with a warning that the connected device cannot guarantee the safe receipt of alarm signals.

The alarms are output acoustically and visually immediately upon detection of an alarm, without an additional delay.

NOTE
Certain alarm conditions are based on time-dependent parameters and are not detected immediately. For additional information, see chapter "Monitoring" on page 170.

According to IEC 60601-1-8, when there are multiple simultaneously active alarms with the same priority, the intelligent Savina alarm system displays the one with the highest urgency on the screen.

For a list of alarm conditions, their priorities and, where applicable for individual alarm messages, their escalation or de-escalation, refer to chapter "Alarm – Cause – Remedy" on page 117.

All the alarm limits which can be set by the user are displayed in the ***Alarms*** dialog window. For a description of alarm system operation, see chapter "Alarms" on page 95.

All the automatically set alarm limits are listed in the chapter "Automatic alarm limits" on page 178.

The acoustic alarm signal can be suppressed for a maximum of 2 minutes by pressing the ***Audio paused 2 min.*** key; see chapter "Suppressing the acoustic alarm signal" on page 98.

If a higher-priority alarm occurs during this time, the acoustic alarm signal sounds once, informing the user of the alarm.

The alarm system is activated during the Savina system start.

Following completion of the system start, Savina starts the therapy with the last set alarm limits and ventilation parameters. The main screen for ventilation is displayed.

Read chapter "Getting started" on page 65 carefully before using Savina on a patient.

During operation, all alarm limits and ventilation parameters are stored permanently and remain immediately available even after a lengthy device failure and following a restart.

Individual alarm conditions can be deactivated by the user under certain conditions. If alarm limits are deactivated, the deactivated alarm limit is permanently displayed in the dialog window. For detailed information, refer to chapter "Setting the alarm limits" on page 99.

Groups of alarm conditions can also be deactivated by the user. If monitoring functions (FiO_2, flow) are deactivated, the deactivated monitoring function is permanently displayed in the message field. For detailed information, refer to chapter "Monitoring" on page 103.

The device deviates in this respect from IEC 60601-1-8, which specifies that several simultaneously deactivated monitoring functions or alarm limits are permanently displayed by means of a symbol on the main screen.

Automatic alarm limits

The following tables describe the alarm limits which cannot be set by the user.

Pressure monitoring

Alarm message	Description/Detection
PEEP high	A too high PEEP value during ventilation is monitored. The alarm limit is always 8 mbar (8 cmH_2O) above the set PEEP.
PEEP inop.	Too low or too high a PEEP value during ventilation is monitored. The alarm limit depends on the set value of the PEEP level. The upper and lower alarm limits are 5 mbar (5 cmH_2O) lower or higher than the set PEEP.
Airway pressure low	A low airway pressure is monitored by checking whether the mean value of the lower pressure level falls below the set PEEP value. The alarm is only generated if the set PEEP is ≥3 mbar (3 cmH_2O). With NIV the alarm is delayed by the time ***$T_{Disconnect}$***.

Volume monitoring

Alarm message	Description/Detection
Tidal volume low	Volume-controlled breaths are monitored to detect whether the set volume is reached. The alarm limit corresponds to the set value V_T.

Monitoring of the breathing circuit and the patient connection

Alarm message	Description/Detection
Leakage	Leakages are monitored. The alarm limit is set at 55 % of relative leakage. Leakages during NIV are not monitored.

FiO_2 monitoring

Alarm message	Description/Detection
FiO_2 high	Too high an O_2 concentration of the applied gas is monitored.
	The alarm limit is 4 Vol% above the set value if this set value is less than or equal to 60 Vol%.
	The alarm limit is 6 Vol% above the set value if this set value is greater than 60 Vol%.
FiO_2 low	Too low an O_2 concentration of the applied gas is monitored.
	For an FiO_2 concentration of 21 Vol% the alarm limit is 18 Vol%.
	The alarm limit is 4 Vol% below the set value if this set value is greater than 21 Vol% and less than or equal to 60 Vol%.
	The alarm limit is 6 Vol% below the set value if this set value is greater than 60 Vol%.

EMC Declaration

General information

The EMC compliance of the product has been evaluated with the external cables, transducers, and accessories specified in the list of accessories. Other accessories which do not affect EMC compliance may be used if no other reasons forbid their use (see other sections of the instructions for use). The use of noncompliant accessories can result in increased emissions or decreased immunity of the medical device.

The medical device must only be used adjacent to or stacked with other devices if this configuration is approved by Dräger. If adjacent or stacked use of non-approved configurations is inevitable, verify normal operation of the medical device in the configuration in which it will be used. In any case, strictly observe the instructions for use of the other devices.

Electromagnetic emissions

When using wireless networking, be aware that the system operates at 2.4 GHz range. Other equipment, even if compliant with CISPR emission requirements, can interfere with reception of wireless data. When selecting wireless systems (wireless communication media, pager systems, etc.) for use in installations where wireless networking is used, care must always be used to ensure that operating frequencies are compatible. For example, selecting wireless communication media that operate at 2.4 GHz will likely cause difficulty with the networking components. Low-level signals such as ECG signals are particularly susceptible to interference from electromagnetic energy. Even if the equipment meets the test requirements described below, smooth operation cannot be guaranteed – the ‘quieter‘ the electrical environment the better. In general, increasing the distance between electrical devices decreases the likelihood of interference.

Detailed radio frequency characteristics

Communication devices in accordance with IEEE 802.11b:
– 2412 to 2472 MHz
– DSSS (direct-sequence spread spectrum) limited to 100 mW
– Applicable to access points and client adapters

Communication devices in accordance with IEEE 802.15.1:
– 2400 to 2485 MHz
– FHSS (frequency-hopping spread spectrum) limited to 2.5 mW

See the instructions for use of the wireless devices for further details.

Electromagnetic environment

The medical device is intended for use in an electromagnetic environment as specified below. The user must ensure that the medical device is used in such an environment.

Emissions	Compliance according to	Electromagnetic environment
Radio frequency emissions (CISPR 11)	Group 1	The medical device uses radio frequency energy only for its internal function. Therefore, its radio frequency emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	Class A	The medical device is suitable for use in all establishments other than domestic establishments and those directly connected (without transformer) 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)	Not applicable	

Electromagnetic immunity

The medical device is intended for use in an electromagnetic environment as specified below. The user must ensure that the medical device is used in such an environment.

Immunity against	IEC 60601-1-2 Test level	Compliance level (medical device)	Electromagnetic environment
Electrostatic discharge (ESD) (IEC 61000-4-2)	Contact discharge: ±6 kV	±2, 4, 6 kV	Floors should be wood, concrete, or ceramic tiles. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
	Air discharge: ±8 kV	±2, 4, 8 kV	
Electrical fast transients/bursts (IEC 61000-4-4)	Power supply lines: ±2 kV	±2 kV	Mains voltage quality should be that of a typical commercial or hospital environment.
	Longer input lines/output lines: ±1 kV	±1 kV	
Surge on AC mains lines/surges (IEC 61000-4-5)	Common mode: ±2 kV	±2 kV	Mains voltage quality should be that of a typical commercial or hospital environment.
	Differential mode: ±1 kV	±1 kV	
Power frequency magnetic field (50/60 Hz) (IEC 61000-4-8)	3 A/m	3 A/m	Devices with unusually strong line-frequency magnetic fields (transformer station, etc.) should not be operated in close vicinity to the medical device.
Voltage dips and short interruptions on AC mains input lines (IEC 61000-4-11)	Dip >95 %, 0.5 periods	>95 %, 0.5 periods	Mains voltage quality should be that of a typical commercial or hospital environment. If the user of the medical device requires continued operation during mains power supply interruptions, it is recommended that the medical device is powered from an uninterruptible power supply or a battery.
	Dip 60 %, 5 periods	60 %, 5 periods	
	Dip 30 %, 25 periods	30 %, 25 periods	
	Dip >95 %, 5 seconds	>95 %, 5 seconds	

Immunity against	IEC 60601-1-2 Test level	Compliance level (medical device)	Electromagnetic environment
Radiated radio frequency (IEC 61000-4-3)	80 MHz to 2.5 GHz: 10 V/m	20 V/m: Savina without trolley	Recommended minimum distance to portable and mobile radio frequency transmitters with transmission power PEIRP to the medical device including its lines: (1.84 m x √PEIRP)[1)]
		10 V/m: Savina with trolley in clinical application	
Conducted radio frequency (IEC 61000-4-6)	150 kHz to 80 MHz: 10 V inside ISM bands[2)]	10 V	Recommended minimum distance to portable and mobile radio frequency transmitters with transmission power PEIRP to the medical device including its lines: (1.84 m x √PEIRP)[1)]
	150 kHz to 80 MHz: 3 V outside ISM bands[2)]	3 V	

1) For PEIRP, insert the highest possible "equivalent isotropic radiated power" of the adjacent radio frequency transmitter. In the vicinity of equipment marked with the symbol ((•)), interference can occur. Field strengths from fixed, portable, or mobile radio frequency transmitters at the location of the medical device should be less than 3 V/m in the frequency range from 150 kHz to 2.5 GHz and less than 1 V/m above 2.5 GHz.

2) ISM bands in this frequency range are: 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; 40.66 MHz to 40.70 MHz.

Recommended separation distances to portable and mobile radio frequency communication devices

The following separation distances are in accordance with the specifications of IEC 60601-1-2.

Max. PEIRP (W)	150 kHz to 2.5 GHz	All other frequencies	Examples
0.03	0.32 m (1.05 ft)	0.96 m (3.15 ft)	WLAN 5250/5775 (Europe)
0.10	0.58 m (1.90 ft)	1.75 m (5.74 ft)	WLAN 2440 (Europe)
0.17	0.76 m (2.49 ft)	2.28 m (7.48 ft)	Bluetooth, RFID 2.5 GHz
0.20	0.82 m (2.69 ft)	2.47 m (8.10 ft)	WLAN 5250 (not in Europe)
0.25	0.92 m (3.02 ft)	2.76 m (9.06 ft)	UMTS mobiles
0.41	1.18 m (3.87 ft)	3.53 m (11.58 ft)	Cordless DECT devices
0.82	1.67 m (5.48 ft)	5.00 m (16.40 ft)	RFID 13.56 MHz
1.00	1.84 m (6.04 ft)	5.52 m (18.11 ft)	WLAN 5600 (not in Europe)
1.64	2.36 m (7.74 ft)	7.07 m (23.20 ft)	GSM 1800/GSM 1900
3.28	3.33 m (10.93 ft)	10.00 m (32.81 ft)	GSM 900 mobiles, RFID 868 MHz

Reduced separation distances to portable and mobile radio frequency communication devices

The following separation distances are based on additional tests performed by Dräger to determine the minimum separation distances absolutely necessary. These reduced separation distances are valid only for mobile radio frequency communication devices using the standards listed.

Mobile radio frequency communication device using ...	Separation distance
GSM 850, GSM 900, RFID 868 MHz (limited to 2 W ERP)	0.27 m (0.89 ft)
GSM 1800, GSM 1900 (limited to 1 W ERP)	0.09 m (0.30 ft)
UMTS, DECT (limited to 0.25 W ERP)	0.05 m (0.16 ft)
Bluetooth, WLAN 2450, RFID 2450 (limited to 0.1 W ERP)	0.03 m (0.10 ft)

Connections to IT networks

In an IT network, data can be exchanged by means of wired or wireless technologies. An IT network can be any data interface (e.g., RS232, LAN, USB, printer interface) that is described in standards and conventions.

During operation, this device can exchange information with other devices by means of IT networks and supports the following functions:

– Display of waveforms and parameter data
– Signaling of alarms
– Transfer of device settings and patient data
– Service mode, access to logbooks

Connecting this device to a network that incorporates other devices or making subsequent changes to that network, can lead to new risks for patients, users, and third parties. Before the device is connected to the network or the network is changed, these risks must be identified, analyzed, and evaluated, and appropriate measures taken.

Examples of subsequent changes to the network:

– Changing the network configuration
– Removing devices from the network
– Adding new devices to the network
– Performing upgrades or updates on devices that are connected to the network

Information about connecting to the network

Prerequisites

This device must only be connected to the network by service personnel. The IT representative of the hospital must be consulted in advance.

The following documents must be followed:

– Accompanying documents of this device
– Description of the network interface
– Description of the network-based alarm systems

Dräger recommends conforming to IEC 80001-1 (risk management for IT networks with medical devices).

Serial interfaces

The following interfaces are supported:

– RS232 interfaces conforming to EIA RS-232 (CCITT V.24/V.28) for the following applications:
  – MEDIBUS
  – Connections to medical devices from other manufacturers

Consequences of using an unsuitable network

If the network does not meet the requirements, dangerous situations can result. The following situations can occur with this device:

– Due to an insecure decentralized alarm system:
  – Alarms or data are transmitted at the wrong time.
  – Alarms are not transmitted.
– During an interruption of the network connection:
  – Suppressed alarms or alarm tones are not reactivated, but remain suppressed.
  – Alarms are not transmitted.
– Without firewall and antivirus software:
  – Data are not protected.
– Data are sent incomplete, sent to the wrong device, or not sent at all.
– Patient data are intercepted, falsified, or damaged.
– Data have the incorrect timestamps.

Requirements for the electrical characteristics of connected devices and networks

The serial interfaces are only suitable for the connection of devices or networks that have a rated voltage of at most 24 V DC on the network side and that meet the requirements of one of the following standards:

– IEC 60950-1: Ungrounded SELV circuits

– IEC 60601-1 (as of 2nd edition): Touchable secondary circuits

Principles of operation

Ventilation modes

IPPV/IPPVAssist/CPPV

IPPV

Intermittent Positive Pressure Ventilation

Intermittent ventilation with positive pressure

IPPVAssist

Assisting, intermittent ventilation with positive pressure

CPPV

Continuous Positive Pressure Ventilation

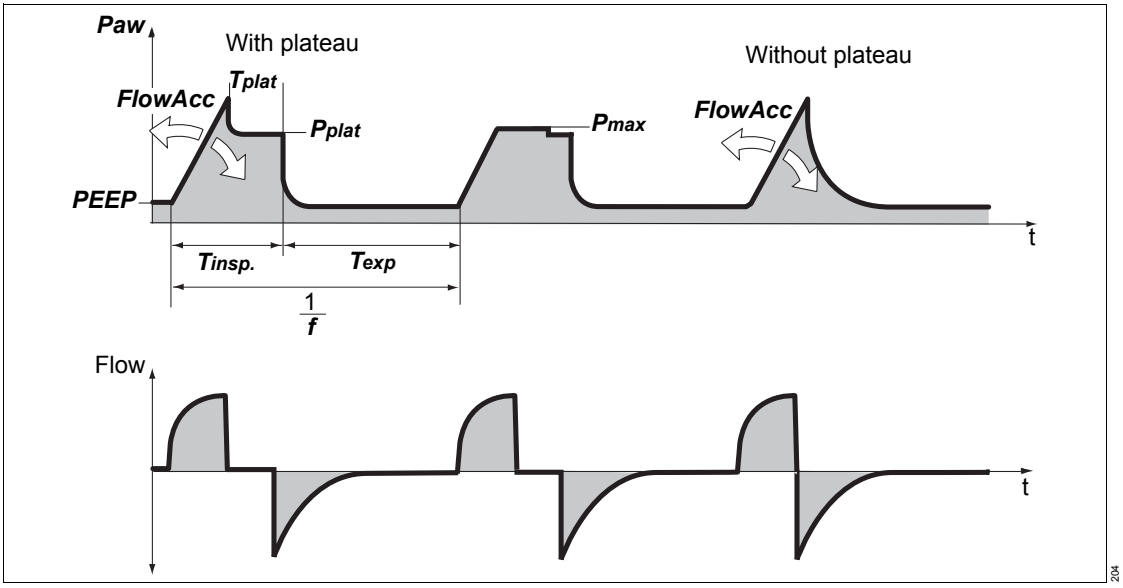
Ventilation with continuous positive pressure

This mode is not shown on the display as a ventilation mode.

IRV

Inversed Ratio Ventilation

Ventilation with reversed ventilation time ratio



Volume-controlled ventilation

The tidal volume of the mandatory breaths is determined by the volume ***VT***. The pressure rise is determined by the flow acceleration ***FlowAcc***. The mandatory breaths are time-cycled and are not triggered by the patient. The number of mandatory breaths is determined by the respiratory rate ***f***.

If the flow acceleration is so high that the set tidal volume is reached before the inspiratory time ***Tinsp.*** has fully elapsed, an inspiratory pause occurs. The inspiratory pause can be identified as the plateau ***Pplat*** in the waveform Paw (t).

If the inspiratory pause time ***Plateau*** is deactivated, Savina immediately switches to expiration as soon as the set tidal volume ***VT*** is applied.

If pressure limitation ***Pmax*** is enabled, pressure peaks are avoided.

Assisted-controlled ventilation *IPPVAssist*

Every inspiratory effort of the patient on PEEP level triggers a synchronized mandatory breath. Thus, the time and number of mandatory breaths are determined by the patient. The trigger window covers the expiratory time minus a refractory period for the previous expiration. The expiratory time is determined by the respiratory rate ***f*** and the inspiratory time ***Tinsp.***. A non-synchronized mandatory breath is triggered at the latest at the end of the expiratory time (backup respiratory rate). The minimal number of mandatory breaths is determined by the respiratory rate ***f***.

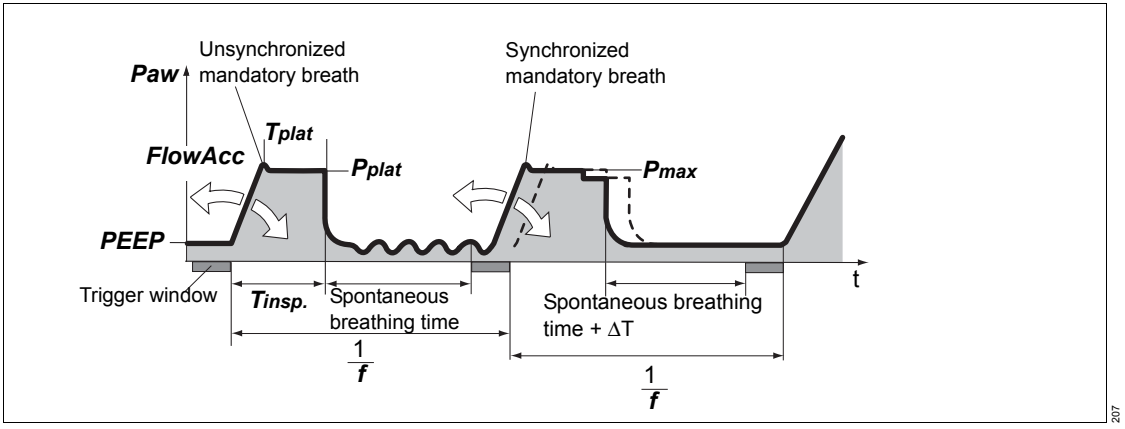
Additional information

A detailed description of the following ventilation functions can be found on page 193:
– Volume-controlled ventilation without plateau
– Flow acceleration
– Pressure limitation

SIMV

Synchronized Intermittent Mandatory Ventilation

Intermittent, triggered, ventilation, allowing spontaneous breathing during the expiratory phase



Volume-controlled ventilation

The tidal volume of the mandatory breaths is determined by the volume ***VT***. The pressure rise is determined by the flow acceleration ***FlowAcc***. The number of mandatory breaths is determined by the respiratory rate ***f***.

If the flow acceleration is so high that the set tidal volume is reached before the inspiratory time ***Tinsp.*** has fully elapsed, an inspiratory pause occurs. The inspiratory pause can be identified as the plateau ***Pplat*** in the waveform Paw (t).

If the inspiratory pause time ***Plateau*** is deactivated, Savina immediately switches to expiration as soon as the set tidal volume ***VT*** is applied.

If pressure limitation ***Pmax*** is enabled, pressure peaks are avoided.

During spontaneous breathing on PEEP level, the patient can be supported with ***ΔPASB above PEEP***.

Synchronization

The mandatory breaths can be triggered by the patient's inspiratory effort on PEEP level.

A mandatory breath can only be triggered within a "trigger window" by the flow trigger in synchrony with the patient's spontaneous inspiratory effort. This prevents the breath being applied during expiration.

The trigger window has a maximum duration of 5 seconds. For expiratory times shorter than 5 seconds, the trigger window covers the entire expiratory time minus a refractory period of 500 ms for the previous expiration.

Synchronization of the mandatory breath reduces the expiratory time. Savina prolongs the subsequent expiratory time or spontaneous breathing time by the missing time ΔT. This prevents an increase of the mandatory respiratory rate.

The number of mandatory breaths is determined by the respiratory rate ***f***.

If the patient breathes in at the beginning of the trigger window and has already inspired a significant volume, Savina takes this volume into account. During the subsequent mandatory breath, the ventilator reduces the inspiratory flow phase and the inspiratory time. The tidal volume remains constant and overinflation of the lungs is prevented.

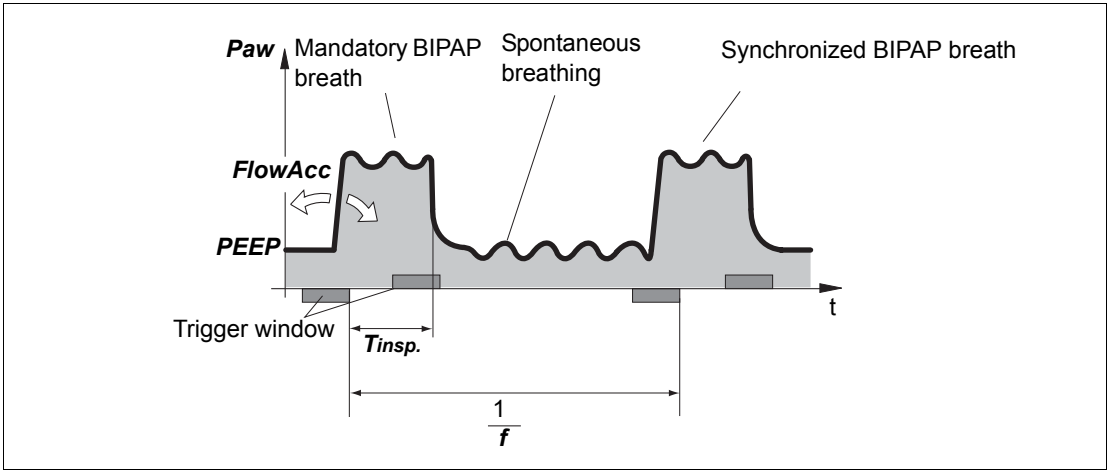
Additional information

A detailed description of the following ventilation functions can be found on page 193:
– Volume-controlled ventilation without plateau
– Flow acceleration
– Pressure limitation
– Pressure support

BIPAP

Biphasic Positive Airway Pressure

Intermittent, synchronized, pressure-controlled ventilation allowing spontaneous breathing (open system) during the entire respiratory cycle and expiratory synchronization



Pressure-controlled ventilation

The upper pressure level is determined by ***Pinsp.***. The duration of the mandatory breaths is determined by ***Tinsp.***. As in all pressure-controlled ventilation modes, the tidal volume delivered depends on the difference in pressure "Pinsp. – PEEP", the lung mechanics (resistance and compliance) and the patient's respiratory drive. The pressure rise is determined by the flow acceleration ***FlowAcc***.

The change-over from the inspiratory to the expiratory pressure level is synchronized with the patient's spontaneous breathing. Synchronization of the mandatory breath reduces the duration of the mandatory breath. Savina therefore extends the subsequent breath by the missing time. This prevents an increase in respiratory rate.

During spontaneous breathing on PEEP level, the patient can be supported with ***ΔPASB above PEEP***.

Synchronization

The mandatory breaths can be triggered by the patient's inspiratory effort on PEEP level.

A mandatory breath can only be triggered within a "trigger window" by the flow trigger in synchrony with the patient's spontaneous inspiratory effort. This prevents the breath being applied during expiration.

The trigger window has a duration of 5 seconds. For expiratory times shorter than 5 seconds, the trigger window covers the entire expiratory time minus a refractory period of 500 ms for the previous expiration.

Synchronization of the mandatory breath reduces the expiratory time. Savina therefore extends the subsequent expiratory time or spontaneous breathing time by the missing time. This prevents an increase in the mandatory respiratory rate.

The number of mandatory breaths is determined by the respiratory rate ***f***.

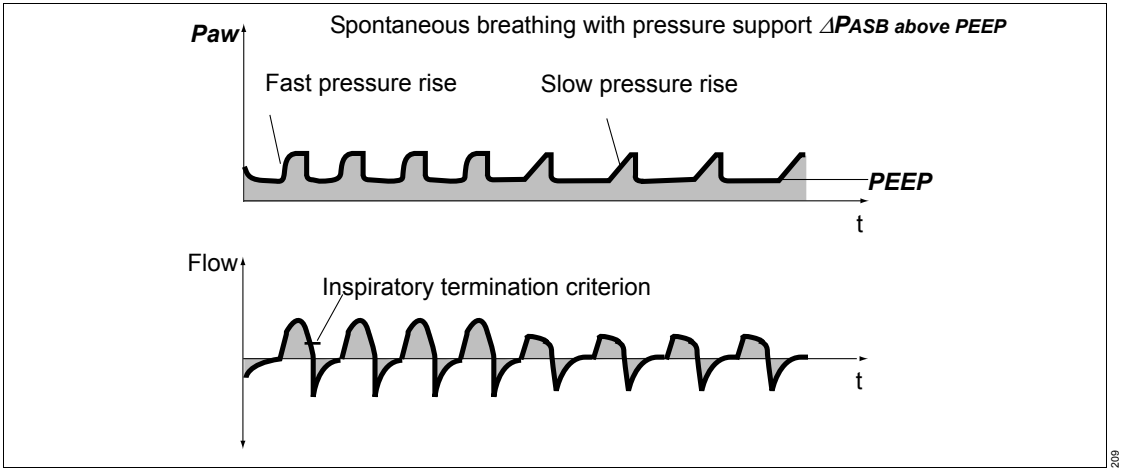
Additional information

A detailed description of the following ventilation functions can be found on page 193:
– Flow acceleration
– Pressure support

CPAP

Continuous Positive Airway Pressure

Spontaneous breathing with continuous positive pressure level



When the pressure support is not switched on, the patient's spontaneous breathing is merely supported by an increased PEEP.

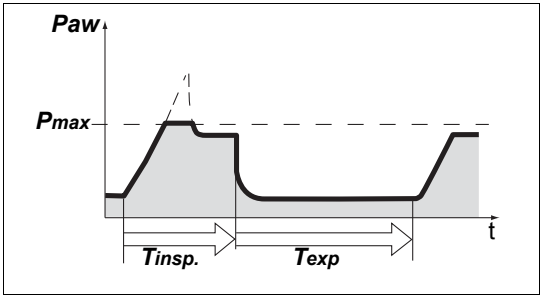
For information on pressure support, see page 193.

General ventilation functions

Flow acceleration

With the ***FlowAcc*** parameter, the pressure rise and flow increase can be modified at the start of inspiration. A greater flow acceleration results in a steeper pressure rise and flow increase. With the help of flow acceleration, the pressure waveform and the flow waveform can be adapted to the patient's needs.

Pressure limitation (PLV)



If pressure limitation ***Pmax*** is enabled, pressure peaks are avoided. Ventilation mode PLV is thus realized.

The inspiratory pressure is maintained at the level of ***Pmax*** until Savina has applied the set tidal volume ***VT*** or until the inspiratory time has fully elapsed.

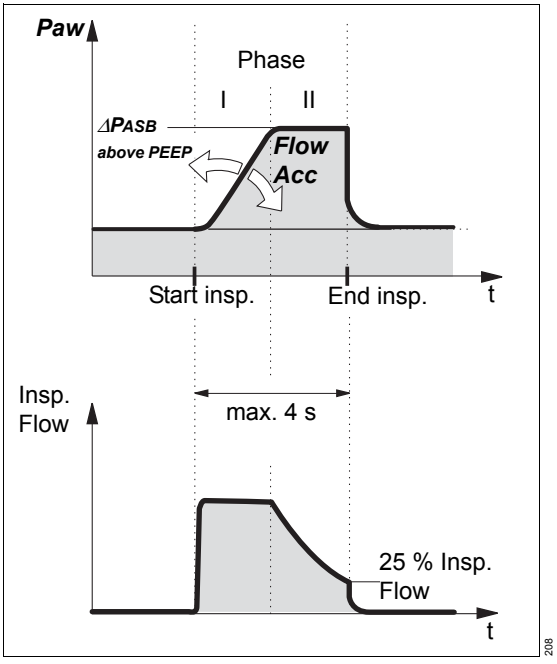
If the set tidal volume ***VT*** cannot be fully applied, an alarm message ***Tidal volume low*** is generated.

Volume-controlled ventilation without plateau

If the inspiratory pause time ***Plateau*** is deactivated, Savina immediately switches to expiration as soon as the set tidal volume ***VT*** is applied. The inspiratory time ***Tinsp*** cannot be set, but is derived from the resistance and compliance of the patient's lungs in conjunction with the set tidal volume ***VT*** and the flow acceleration ***FlowAcc***. Savina ensures a minimum expiratory time of 500 ms and limits the resulting I:E ratio to a maximum of 4:1.

Pressure support

During spontaneous breathing on PEEP level, the patient can be supported with ***ΔPASB above PEEP***. Every inspiratory effort of the patient on PEEP level that meets the trigger criteria triggers a pressure-supported breath. By setting the trigger level, the patient's inspiratory efforts are synchronized. The time, number, and duration of pressure-supported breaths is determined by the patient's spontaneous breathing.



Pressure support is initiated when the flow trigger is triggered.

As in all pressure-controlled ventilation modes, the tidal volume supplied depends on the difference in pressure, the lung mechanics (resistance and compliance) and the patient's respiratory drive. The pressure rise from the lower pressure level ***PEEP*** to the upper pressure level is determined by the ***ΔPASB above PEEP*** setting.

The inspiratory flow can be adapted to the needs of the patient with the aid of the flow acceleration ***FlowAcc***.

Pressure support is terminated:

– When the inspiratory flow returns to baseline during phase I, i.e., when the patient exhales or breathes against the ventilator.

  Or

– When the inspiratory flow falls below 25 % of the last delivered inspiratory flow in phase II (so that $\Delta P_{ASB\ above\ PEEP}$ is reached)

  Or

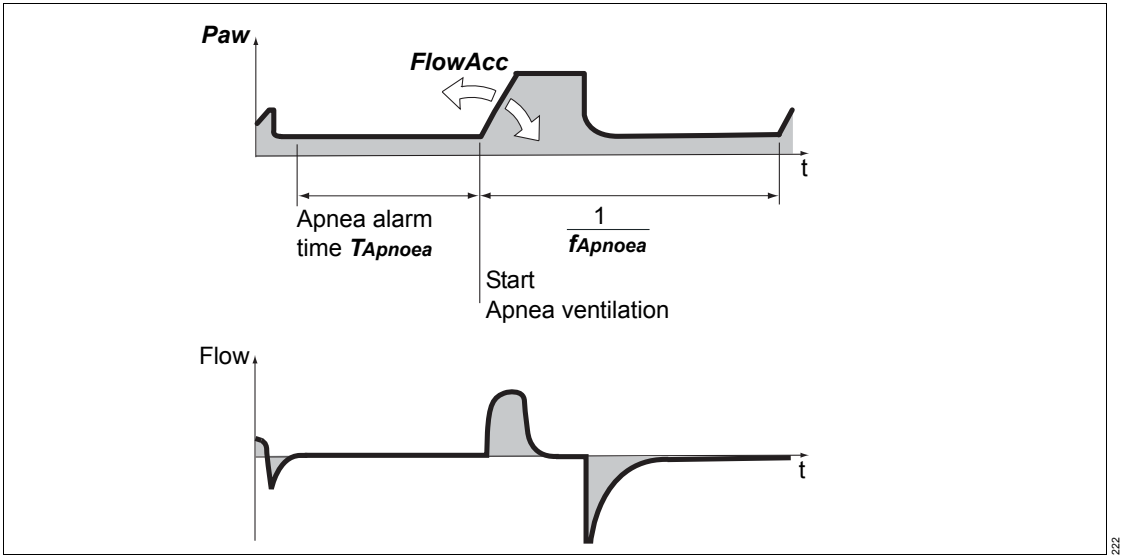
– At the latest after 4 seconds, if the two other criteria did not become effective. In this case, Savina displays the low-priority alarm message ***ASB > 4 s***. If the time is exceeded three times in succession, Savina generates the low-priority alarm message ***ASB > 4 s***.

In the application mode ***Mask/NIV***, the maximum duration of pressure support is set using the ***$T_{insp.}$*** key.

Additional settings

Apnea ventilation

For switching over automatically to volume-controlled mandatory ventilation in case of apnea



Apnea ventilation corresponds to the SIMV ventilation mode with AutoFlow.

For Savina to be able to detect apnea, flow measurement must function and the flow monitoring must be activated.

Savina detects an apnea when no expiratory flow is measured or insufficient inspiratory gas is delivered during the set apnea alarm time ***TApnoea***. When apnea ventilation is activated, volume-controlled ventilation starts with the ventilation parameters ***fApnoea*** and ***VTApnoea*** starts. The inspiratory time for apnea ventilation is determined from the set apnea respiratory rate ***fApnoea*** and a fixed I:E ratio of 1:2.

The patient can breathe spontaneously and the mandatory breaths are synchronized with the patient's spontaneous breathing. The apnea ventilation respiratory rate ***fApnoea*** remains constant. Savina provides synchronized intermittent mandatory ventilation.

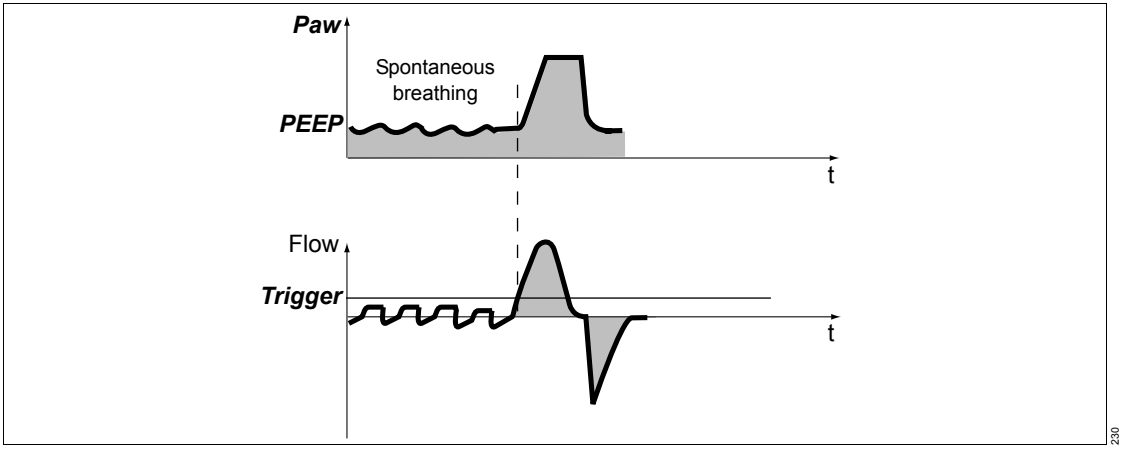
Apnea ventilation is terminated by pressing the ***Alarm Reset*** key. Savina continues ventilating in the previously set ventilation mode. Changing the ventilation mode also terminates apnea ventilation.

If an apnea situation generating an alarm occurs again during apnea ventilation, this indicates that the apnea respiratory rate ***fApnoea*** has been set too low in relation to the apnea alarm time ***TApnoea***.

Flow trigger

The flow trigger is used to synchronize mandatory breaths with spontaneous breathing. The flow trigger is also used to trigger pressure support ***ΔPASB above PEEP***.

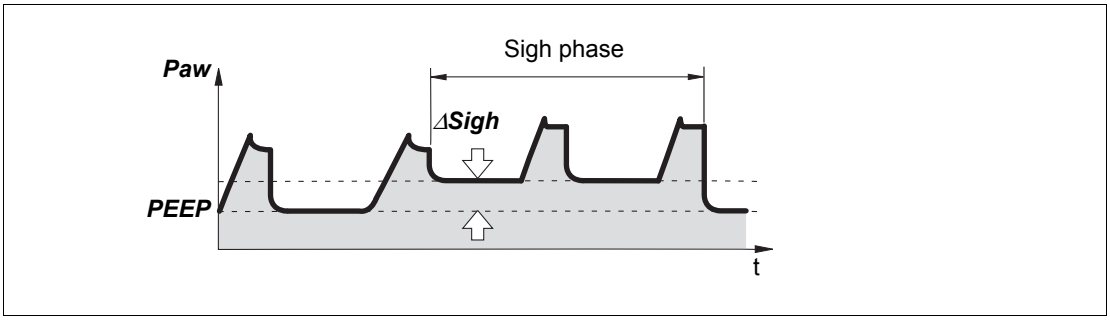
The flow trigger is triggered when the spontaneous inspiratory flow reaches the set value of the trigger threshold ***Trigger***, or when the spontaneously inspired volume exceeds 25 mL.



With the trigger threshold ***Trigger***, the mandatory breaths and pressure support ***ΔPASB above PEEP*** are synchronized with the inspiratory efforts.

Spontaneous breathing activity by the patient is indicated on the screen by the brief appearance of the symbol.

Sigh

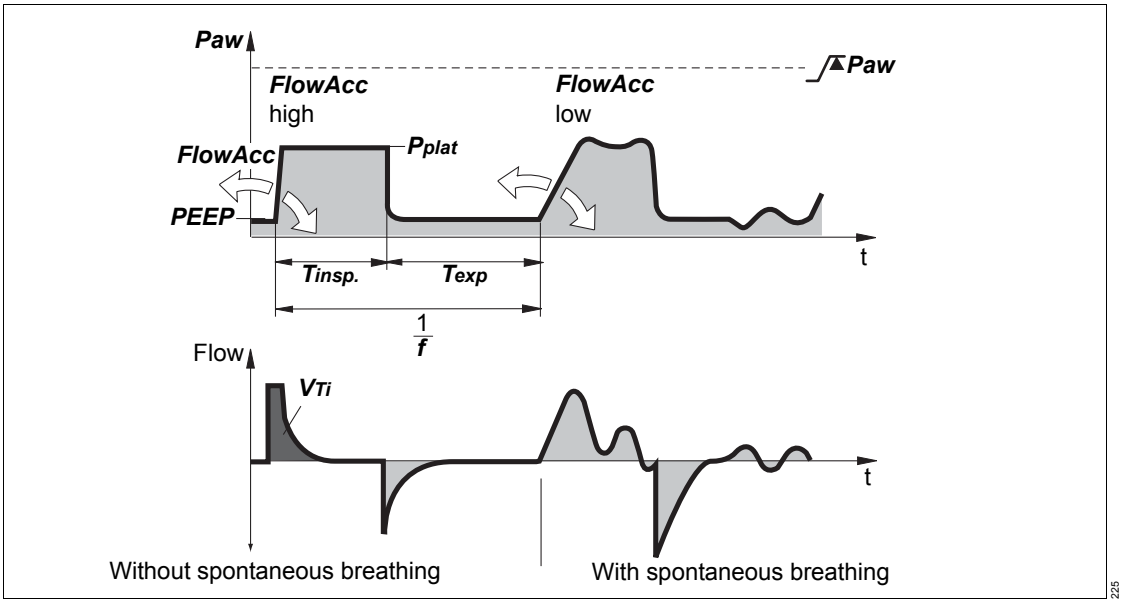


Atelectasis can be prevented by activating the sigh function and setting the sigh in the form of an intermittent PEEP. The purpose of expiratory sigh is to open collapsed areas of the lungs or to keep open slow areas of the lungs.

The sigh function can be activated in the ***IPPV/IPPV****Assist* ventilation mode. When the sigh function is activated, the end-expiratory pressure PEEP increases by the set value of the intermittent pressure ***ΔSigh*** for 2 breaths every 3 minutes.

The mean airway pressure is higher, and normally a longer filling time is available.

AutoFlow



Savina provides ventilation with AutoFlow with a decelerating flow in order to avoid pressure peaks. Savina determines the pressure required for the set tidal volume, taking into account the condition in the lungs (compliance, resistance) and the patient's spontaneous breathing demand.

When the patient breathes in, Savina delivers an additional inspiratory flow limited by the alarm limit ***VTi***. The patient can also breathe out during the inspiratory plateau phase. Set the alarm limit ***VTi*** with care in order to prevent, e.g., overinflation of the lungs following rapid changes in compliance.

The inspiratory pressure is limited by the alarm limit ***Paw***. With AutoFlow, the maximum pressure applied is limited to 5 mbar (5 cmH_2O) below the upper alarm limit ***Paw***. Always set this alarm limit in order to generate an alarm in the event of an increase in airway pressure due to reduced compliance.

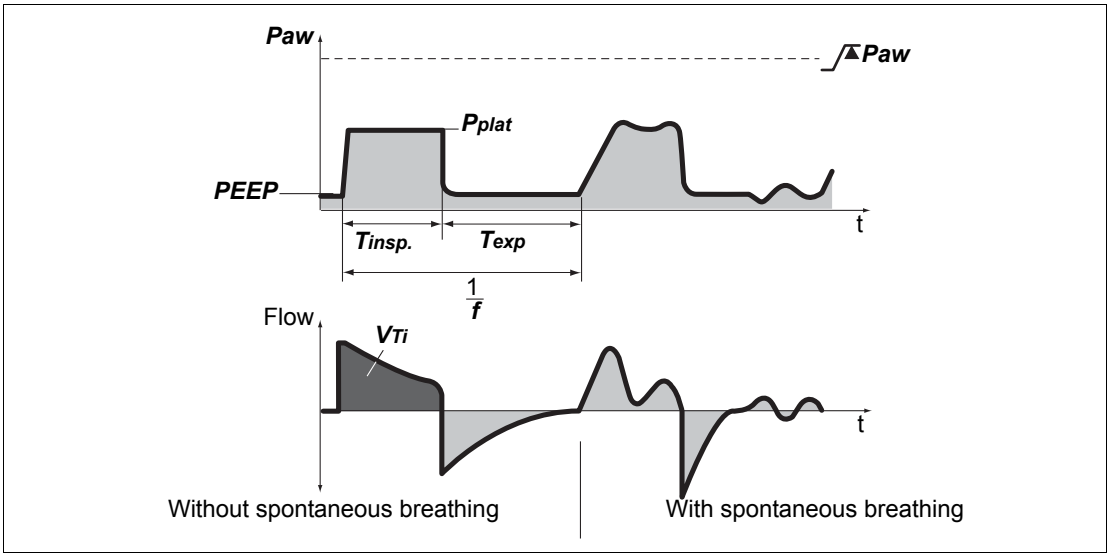
The minimum inspiratory pressure for mandatory non-triggered breaths is 5 mbar (5 cmH_2O) above PEEP; for triggered mandatory and spontaneous breaths it is 0.1 mbar (0.1 cmH_2O) above PEEP.

Typically, the selected inspiratory time ***Tinsp.*** is much longer than the lung filling time. The inspiratory pressure ***Pinsp.*** corresponds to the minimum value calculated from the tidal volume ***VT*** and compliance ***C*** of the lungs. The inspiratory flow is automatically controlled so that there is no pressure peak caused by the resistances of the tube and the airways. With AutoFlow, these fluctuations occur in increments with a maximum of 3 mbar steps (3 cmH_2O) between breaths.

If the tidal volume ***VT*** is reached (inspiratory flow = 0) before the inspiratory time ***Tinsp.*** has fully elapsed, the control system for the inspiratory and expiratory valves ensures that the patient can breathe in and out during the remaining inspiratory time, even during the constant pressure plateau ***Pplat***. If the patient breathes in or out during mandatory inspiration, the plateau pressure is not changed for the duration of this breath. Only the inspiratory and expiratory flows are adapted to the patient's demand. The applied tidal volume ***VTi*** may deviate from the set tidal volume ***VT*** in individual breaths. However, as an average over time, a constant tidal volume ***VT*** is supplied.

Exceeding the tidal volume ***VT*** can be limited by the alarm limit ***VTi***. If the set alarm limit is exceeded once, Savina generates a low-priority alarm message (!). If it is exceeded three times in succession, Savina generates a high-priority alarm message (!!!). Tidal volume is actively limited to the value of the alarm limit ***VTi*** by switching to PEEP level.

Set the alarm limits ***MV*** and ***MV*** appropriately in order to avoid insufficient or excessive ventilation caused by rapid changes in compliance. When using AutoFlow, activate flow monitoring!



A set inspiratory time ***Tinsp.*** shorter than the lung filling time can be recognized from the flow waveform. The flow at the end of the inspiratory time has not returned to baseline. In this case, it must be decided whether the current condition of the patient permits prolongation of the inspiratory time ***Tinsp.*** or an increase in flow acceleration ***FlowAcc*** in order to reduce peak pressure even further. This effect can also be caused during ventilation, e.g., due to a build-up of secretions. In this situation, the pressure is limited by Savina as described. If the set tidal volume ***VT*** can no longer be fully applied as a result, the low-priority alarm message ***Tidal volume low*** is generated.

The pressure rise from the PEEP level to the inspiratory level can be even more closely adapted to the needs of the patient in the IPPV, SIMV, BIPAP and CPAP/ASB ventilation modes via the ventilation parameter ***FlowAcc***.

Start-up procedure with AutoFlow

When ***AutoFlow*** is switched on, Savina applies the set tidal volume ***VT*** by means of a volume-controlled breath. The plateau pressure ***Pplat*** calculated for this breath serves as the start-up value for inspiratory pressure under ***AutoFlow***.

The start of mandatory inspiration can be synchronized with the patient's inspiratory efforts by means of the variable flow trigger.

The flow trigger can only be deactivated in the ***IPPV*** ventilation mode.

Non-invasive ventilation (NIV)

Non-invasive ventilation by mask for patients with spontaneous breathing

Leakages are greater with non-invasive ventilation than with invasive ventilation. Savina takes into account the leakages in the ***Mask/NIV*** application mode accordingly. The inspiratory trigger is automatically adapted to the measured leakage. This prevents auto-triggering due to a flow trigger which has been set too low and extended inspirations.

The inspiratory tidal volume is typically far higher than the patient's tidal volume. The expiratory tidal volume is slightly lower than the patient's tidal volume. The measured values for tidal volume are leakage-corrected and indicate the patient's actual tidal volume. In ventilation modes with AutoFlow, the corrected measured values are set. During volume-controlled ventilation, the inspiratory volume escaping through the leakage is additionally supplied.

Monitoring during NIV

In order to prevent artifacts in the case of very high leakages, the following alarm limits may be deactivated:

– ***$\blacktriangledown\sqrt{\ }$ MV***
– ***V_{Ti}***
– ***T_{Apnoea}***

To delay the high-priority alarm message ***Airway pressure low***, the delay time ***$T_{Disconnect}$*** can be set between 0 and 60 seconds for the lower alarm limit of the airway pressure.

The leakage minute volume ***MV_{leak}*** is displayed as a percentage of the measured minute volume in the ***Values*** dialog window. The tidal volume ***V_{Tpat}*** indicates the volume actually reaching the patient. ***V_{Tpat}*** is the delivered tidal volume minus the volume lost through leakage during inspiration.

Additional information

"Automatic leakage compensation" on page 203.

Low Pressure Oxygen (LPO)

LPO mode provides the option of supplying Savina from external low-pressure oxygen sources, such as an O_2 concentrator. Savina can thus be supplied with oxygen independently from a central gas supply system.

The O_2 flow from the O_2 concentrator is fed directly into the mixing chamber via the LPO inlet valve on the rear of Savina. In the mixing chamber, an oxygen/air mixture is formed, which is then delivered to the patient.

FiO_2 monitoring in the LPO mode

The gas mixture is drawn from the mixing chamber in synchrony with the ventilator-delivered breaths. The oxygen from the O_2 concentrator, however, is fed at a constant flow. This leads to a varying O_2 concentration in the mixing chamber, which depends on the following factors:
– Ventilation settings
– Lung parameters
– Flow from O_2 concentrator (LPO flow)

The range of variation is indicated by an additional tolerance (±) for the measured value ***FiO_2***. With small tidal volumes, the tolerance is small and with larger tidal volumes, it is correspondingly greater.

O_2 calibration in LPO mode

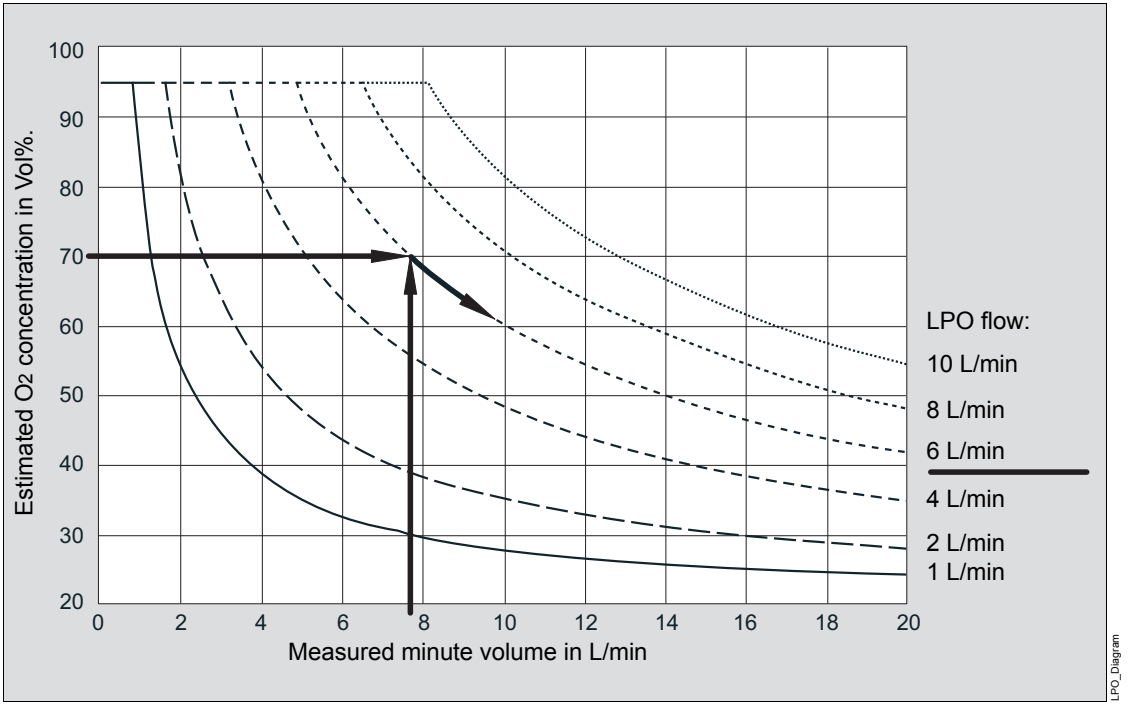
Calibration of the O_2 sensors is carried out in LPO mode in ambient air at approx. 21 Vol% O_2. This O_2 concentration depends on the humidity and temperature of the air. As Savina does not measure the humidity of the ambient air, assumptions are made for the purpose of calibration:
– Temperature = 25 °C (77 °F)
– Relative humidity 50 %

If the ambient conditions at the time of calibration differ from these figures, a calibration error occurs. This calibration error is taken into account in the FiO_2 measured value tolerance displayed.

In the case of extreme ambient conditions at the time of calibration, the calibration error may be unacceptable. Calibration must be carried out in HPO mode with 100 Vol% O_2 from the central gas supply system or an O_2 cylinder.

LPO flow setting diagram

The O_2 concentration for the patient depends on the flow of the O_2 concentrator (LPO flow) and the applied minute volume (MV). The diagram below provides a rough estimate.



Example:

What flow has to be set on the O_2 concentrator in order to attain the desired O_2 concentration (FiO_2 of 70 Vol%) at a minute volume MV of 7.8 L/min?

Read off from the diagram:

Intersection of MV = 7.8 L/min and FiO_2 = 70 Vol%

Result: LPO flow = 6 L/min

Automatic leakage compensation

The automatic leakage compensation feature of Savina ensures that ventilation is adapted to the new conditions after a few breaths in the case of leakage changes.

Mode of operation

Savina determines the difference between the delivered inspiratory flow and the measured expiratory flow. This difference provides a measure of the amount of leakage and is displayed by Savina as the leakage minute volume ***MV$_{leak}$*** in percent.

Performance characteristics of leakage compensation

- Correction of the flow trigger and the termination criterion
- Compensation of volume losses during delivery of the tidal volume ***V$_T$***
- Maintenance of the inspiratory and expiratory airway pressure during pressure-controlled ventilation and volume-controlled ventilation with AutoFlow
- Correction of the flow waveform

Flow trigger and termination criterion

The inspiratory trigger threshold and the termination criterion are continuously corrected by the determined leakage flow value. Auto-triggering is prevented and manual adjustment of the trigger threshold minimized.

Tidal volume *V$_T$*

During volume-controlled ventilation, Savina supplies additional volume in order to compensate the leakage. Unlimited volume compensation would however be inappropriate. Savina compensates for losses of up to 100 % of the set tidal volume ***V$_T$***.

Airway pressure

For pressure-controlled breaths, e.g., in BIPAP, CPAP/ASB, and AutoFlow, the flow is corrected so that the set pressure levels are maintained. Leakages are compensated up to the maximum flow the turbine can deliver.

Patient monitoring

The following measured values are displayed after correction for leakage:
- V_{Tpat}, $Flow_{peak}$
- Flow curve

The following purely expiratory measured values are displayed without correcting for leakage:
- V_{Te}, MV, MV_{spn}

Leakage compensation with and without AutoFlow in application mode *Tube*

The tidal volume ***V$_T$*** is not leakage-compensated. When AutoFlow is deactivated, volume loss due to the leakage occurs during the inspiratory pause and the plateau pressure ***P$_{plat}$*** falls as a result. When AutoFlow is activated, the plateau pressure and the delivered tidal volume ***V$_T$*** are maintained despite leakage.

Specification of compensation ranges according to ventilation mode

The following table shows the leakage compensation ranges for the individual ventilation modes.

Application mode	**Mask/NIV**	**Mask/NIV**	**Tube**
Ventilation mode	**BIPAP, CPAP/ASB**	**IPPV, IPPVAssist, SIMV**	**All**
Flow trigger and termination criterion	up to 25 L/min	up to 25 L/min	up to 10 L/min
Delivered tidal volume	-	up to 100 % of the set V_T	none
Airway pressures: – PEEP, $P_{insp.}$, $\Delta P_{ASB\ above\ PEEP}$ – $P_{insp.}/P_{plat}$ (when AutoFlow is activated)	unlimited	unlimited	unlimited
Measured values:			
– V_{Te}	not comp.	not comp.	not comp.
– MV	not comp.	not comp.	not comp.
– V_{Tpat}	compensated	compensated	not displayed
– $Flow_{peak}$	compensated	compensated	not comp.
– Flowcurve	compensated	compensated	not comp.

Monitoring of leakages

If Savina detects a significant leakage in the ***Tube*** application mode, the low-priority alarm message ***Leakage*** is displayed. In this case, the breathing circuit and the tube must be checked for leakages.

Measurements

Flow measurement

Adaptation to ambient conditions

The volume of a gas depends on the ambient conditions with regard to temperature, pressure, and humidity. In lung physiology, reference is made to the conditions inside the lung for the values of minute volume and tidal volume: 37 °C (99 °F) body temperature, pressure in the lungs, 100 % relative humidity.

Measured values for flow and volume under these conditions are characterized as BTPS. Medical gases from cylinders or from a central gas supply system are dry (approximately 0 % relative humidity) and are delivered by the ventilator at 20 °C (68 °F) and 1013 mbar (1013 cmH_2O). Measured values for flow and volume under these conditions are characterized as NTPD.

The difference between values measured as NTPD and BTPS is approximately 12 % at a pressure of 1013 mbar (1013 cmH_2O).

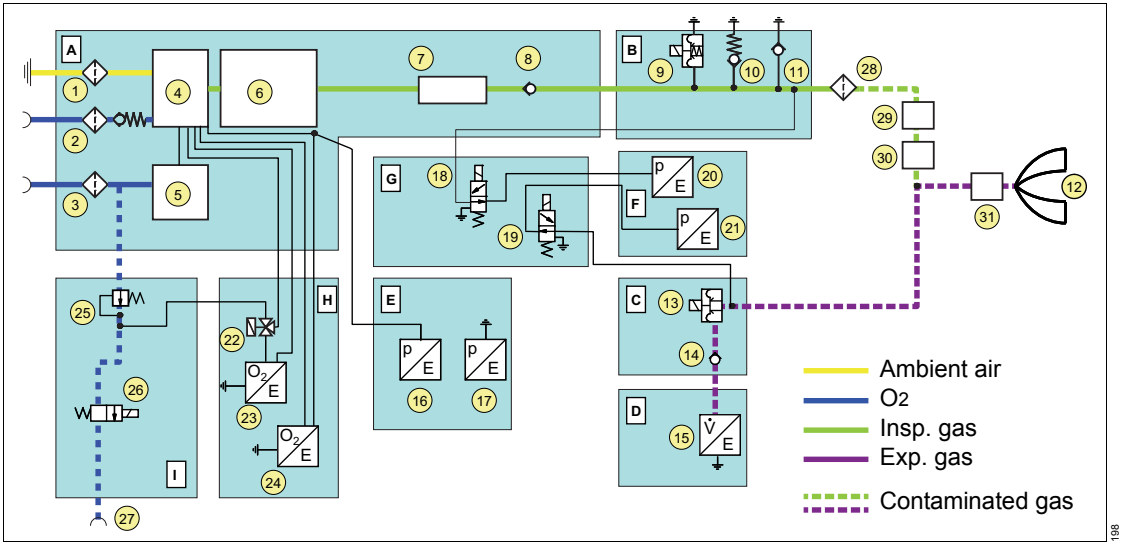
Example: 500 mL tidal volume NTPD become 564 mL BTPS when warmed to 37 °C (99 °F) and humidified to 100 % relative humidity.

Savina controls tidal volume in such a way that the set tidal volume value is applied under BTPS conditions in the lungs.

The expiratory measurement is performed on the basis of saturated gases at 30 °C (86 °F).

Pneumatic functional description

Pneumatic diagram of Savina



1 Gas inlet for ambient air with microfilter

2 Gas inlet LPO with filter and return valve

3 Gas inlet HPO with filter

4 Mixing chamber

5 O_2 metering unit

6 Turbine with flow metering

7 Flow measurement

8 Return valve

9 Safety valve

10 Pressure-Limiting Valve

11 Emergency breathing valve

12 Patient's lung

13 Expiratory valve

14 Return valve

15 Expiratory flow sensor

16 Barometric pressure sensor 1

17 Barometric pressure sensor 2

18 Calibration valve for inspiratory pressure sensor

19 Calibration valve for expiratory pressure sensor

20 Inspiratory pressure sensor

21 Expiratory pressure sensor

22 Calibration valve O_2 sensor 1

23 O_2 sensor 1

24 O_2 sensor 2

25 Pressure Regulator Assembly O_2

26 Nebulizer switching valve

27 Nebulizer outlet

28 Bacterial filter

29 Breathing gas humidifier

30 Medication nebulizer

31 CO_2 measurement (not integrated into the device)

A Gas mixing and gas delivery assembly

B Inspiratory unit assembly

C Expiratory valve assembly

D Expiratory flow sensor

E Barometric pressure measurement assembly

F Airway pressure measurement assembly

G Calibration assembly

H O_2 measurement assembly

I Medication nebulization assembly

Description of pneumatic functions

Savina consists of 9 pneumatic assemblies.

The **gas mixing and gas delivery** assembly (A) delivers a gas mixture flow that varies over time with adjustable portions of ambient air and high pressure O_2 (HPO). Oxygen from the (central) gas supply enters the device from the gas inlet connection for HPO and the subsequent filter (3) and is delivered by the O_2 delivery unit (5) in accordance with the selected concentration. Ambient air is drawn in through the microfilter (1). If a low pressure O_2 source (LPO, e.g., an O_2 concentrator) is used, the low pressure oxygen flow is directed through the filter (2) and a return valve into the device.

The gases mix in the mixing chamber (4). The turbine assembly with integrated flow metering (6) draws the gas mixture out of the mixing chamber and directs it through a flow measurement (7) with a downstream return valve (8) into the inspiratory unit (B).

The **inspiratory unit** assembly (B) consists of the safety valve (9) and two return valves, the pressure limiting valve (10) and emergency breathing valve (11). The safety valve is closed during normal operation, so that the inspiratory flow moves from the gas mixing and gas delivery assembly (A) to the patient (12). In other modes, the emergency breathing valve (11) permits spontaneous inspiration. The pressure limiting valve (10) limits the maximum airway pressure under any conditions to a maximum of 120 mbar. The safety valve (9) is opened when a detected stenosis prevents a pressure relief in the expiratory limb. In that case, the required (external) bacterial filter (28) on the inspiratory port prevents contamination of the inspiratory unit (B).

The **expiratory valve** assembly (C) consists of the expiratory valve (13) and a return valve (14). The expiratory valve is a proportional valve used to adjust the pressure in the breathing system. The return valve (14) works with the spring-loaded valve in the pressure limiting valve (10) to prevent pendulum breathing during spontaneous breathing. The **expiratory flow sensor** (D) (15) measures the expiratory flow using the metrological principle of hot wire anemometry. The measured flow is thus a mass flow (NTPD). The expiratory valve assembly and the expiratory flow sensor can be removed from Savina for cleaning.

To convert the mass flow into a volume flow (BTPS), it is necessary to know the ambient pressure. The ambient pressure is measured in the **barometric pressure measurement** assembly (E). This measurement is carried out by the independent sensors (16) and (17), with sensor (16) measuring the barometric pressure in the mixing chamber.

The pressure in the breathing system is also measured with two independent pressure sensors (20) and (21). Together, these constitute the **pressure measurement** assembly (F). The pressure sensors are zero calibrated periodically. To do this, the pressure sensors are vented to the ambient air through the two calibration valves (18) and (19). Together, they constitute the **calibration** assembly (G).

The **O_2 measurement** assembly (H) measures the inspiratory O_2 concentration using two redundant sensors (23) and (24) based on a side stream measurement principle. O_2 sensor 1 (23) with upstream calibration valve (22) permits automatic calibration to 100 % O_2 during operation. The calibration of O_2 sensor 2 (24) to 100 % O_2 must be done by manually switching to an inspiratory O_2 concentration of 100 %.

For medication nebulization a pneumatic medication nebulizer (30) can be connected to the nebulizer gas outlet (27). Savina provides a flow from the HPO supply to drive the medication nebulizer. The upstream pressure regulator (25) throttles the variable oxygen supply pressure to a constant value for delivery. The nebulizer switch valve (26) closes the nebulizer gas outlet when the nebulizer function is not activated. The pressure regulator and nebulizer switch valve constitute the **medication nebulization** assembly (I).

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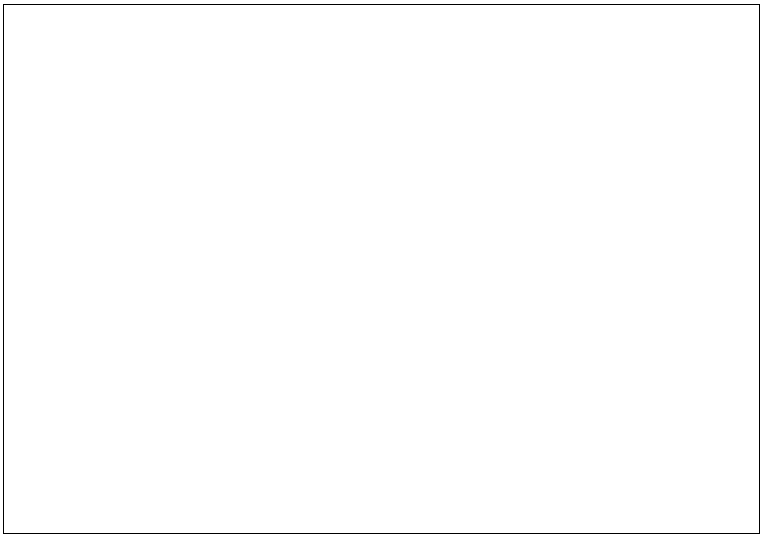

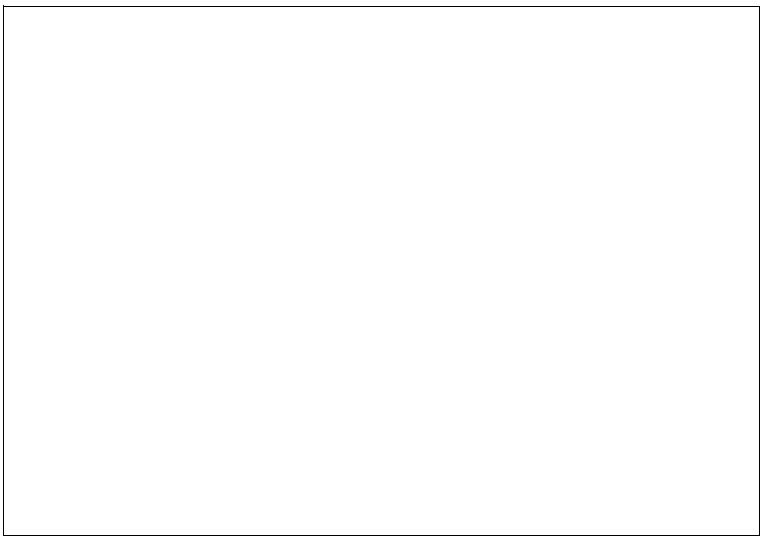

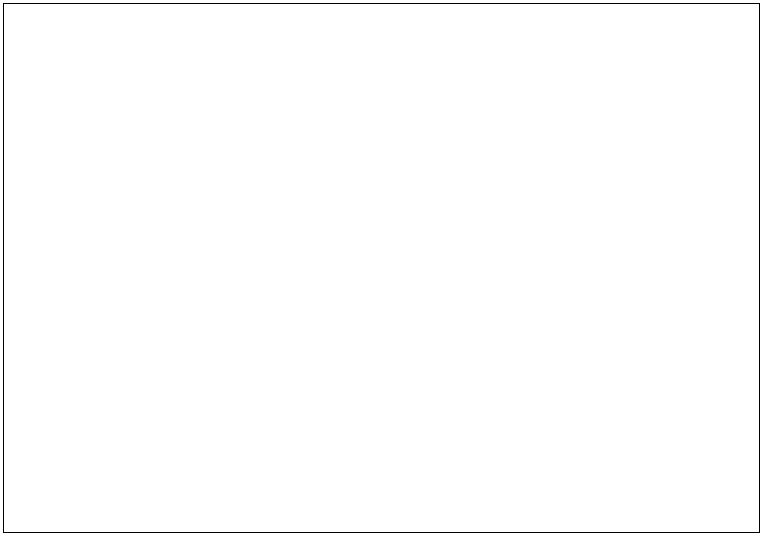

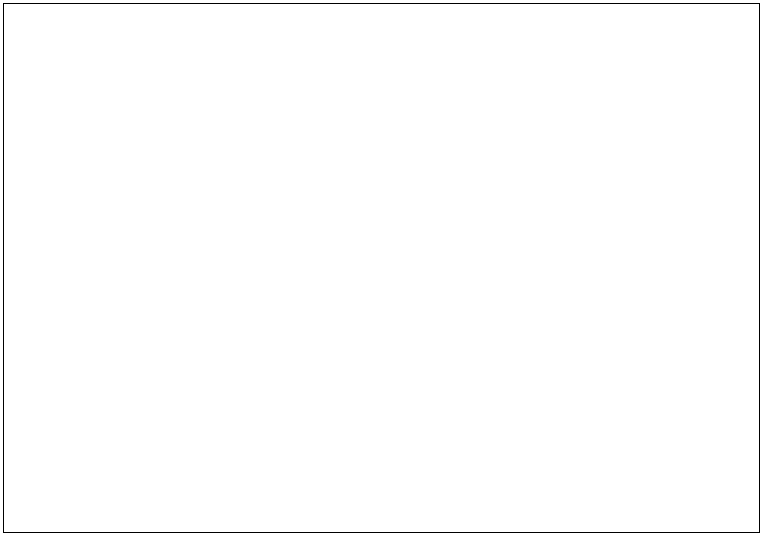

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