MEDUVENT Standard

Ventilator

Instructions for Use

Read these instructions for use before using the product.
Ignoring the instructions for use can lead to severe injury or death.

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1 Introduction

1.1 Intended purpose

MEDUVENT Standard is an emergency and transport ventilator with functions for the monitoring of respiratory values. The device can be used for invasive and non-invasive ventilation via the nose, mouth and trachea.

Patient groups

MEDUVENT Standard is used in the treatment of infants, children, and adults with a body weight of 7 kg and more where spontaneous breathing has failed or is inadequate. In the case of volume-controlled ventilation, tidal volumes of 50 ml or more are possible.

Users

Qualified medical personnel (e.g. paramedics, emergency physicians).

Intended areas of application

- Mobile use in emergency medicine or primary care at the site of the emergency, e.g. for resuscitation or to initiate and execute anesthesia (including TIVA: total intravenous anesthesia)
- During transport between hospital rooms and departments
- During transport between the hospital and other premises by ambulance, aircraft, helicopter or ship
- In hospital in the shock room or recovery room

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⚠ WARNING

Risk of injury from misuse due to disregard of the information in the instructions for use!

Intended use includes compliance with all the information in these instructions for use. Any use other than or in addition to intended use is considered misuse. Failure to comply with the information in these instructions for use might result in a misuse of the product and may cause serious or life-threatening injury to the patient, the user, or persons in the vicinity.

⇒ Use the device only for the intended purpose (see "1.1 Intended purpose", page 6).

⇒ Observe any exclusions and limitations of the intended purpose (see "1.1.1 Exclusions and limitations of the intended purpose", page 8).

⇒ Observe the safety information in the instructions for use.

⇒ Observe all the sections of the instructions for use.

Contraindications

None known to date.

Possible side effects / complications

- Unwanted influencing of the cardiovascular system (e.g. reduced cardiac output, reduced venous return)
- Drying of the airways
- Hyperinflation of lung tissue (e.g. lung rupture)
- Gastric insufflation during mask ventilation (e.g. aspiration of stomach contents)

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1.1.1 Exclusions and limitations of the intended purpose

The device has **not** been approved for the following applications:

- Operation in hyperbaric chambers
- Operation in conjunction with magnetic resonance imaging machines
- Use in sustained ventilation for longer than 24 hours

1.2 Owner/operator and user qualification

The device must only be used by persons with medical training who have received instruction in ventilation technique.

As the operator or user, you must familiarize yourself with the method of operation and use of this medical device by reference to the instructions for use before using it for the first time.

You should also get yourself trained in the operation and use of this medical device. Follow the statutory requirements for operation and use (in Germany, particularly the Medizinprodukte-Betreiberverordnung [German regulation concerning the operators of medical devices]).

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2 Safety

Read these instructions for use carefully. They form part of the devices described, and must be available at all times.

2.1 Safety information in these instructions for use

⚠ DANGER	**Danger!** DANGER indicates a dangerous situation which will result in death or serious injury if not prevented.
⚠ WARNING	**Warning!** WARNING indicates a dangerous situation which might result in death or serious injury if not prevented.
⚠ CAUTION	**Caution!** CAUTION indicates a dangerous situation which might result in minor injury if not prevented.
NOTICE	**Notice!** NOTICE indicates risks which might possibly cause damage to property or environmental damage.
i	Designates useful tips relating to a particular sequence of actions.

2.2 Using the device safely

⚠ WARNING	**Risk of injury from device being used for too long without further humidification of the respiratory gas!** If the device is used for too long, the patient might be ventilated with dry gas for too long. This might expose the patient to the risk of serious or life-threatening injury. ⇒ Do not use the device for sustained ventilation (longer than 24 hours).

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⚠ WARNING

Hazardous therapy as a result of inadequate patient monitoring!

If the patient and the device are not observed and monitored during ventilation, delayed responses by medical personnel to alarms and faults might result in serious or life-threatening injury to the patient and incorrect therapy.

⇒ Continuously observe and monitor the patient and device during ventilation.

⇒ Additionally use external monitoring (e.g. SpO_2 and/or $etCO_2$).

⚠ WARNING

Failure of therapy as a result of device malfunction or loss of pneumatic or electric power!

A device failure might result in failure of the therapy. This might expose the patient to the risk of serious or life-threatening injury.

⇒ Provide alternative ventilation option.

⚠ WARNING

Risk of injury resulting from incorrectly set limitation of maximum airway pressure!

An excessively high airway pressure might expose the patient to serious or life-threatening injury.

⇒ Always set the pressure limit pMax to suit the current patient and the current therapy.

⚠ WARNING

Risk of suffocation resulting from extubation during patient transport!

If the device falls off, or the breathing circuit detaches during patient transport, the patient might be extubated, resulting in laryngospasm. This might expose the patient to the risk of serious or life-threatening injury.

⇒ Secure the device against falling while transporting the patient on a stretcher.

⇒ Always fix the breathing circuit in place while transporting the patient.

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⚠ WARNING

Hazardous therapy due to leaks during ventilation!
The measured MVi value indicates the volume the device is administering to the patient. In the event of leaks during ventilation, the measured MVi value will not match the tidal volume actually administered. If this is not observed, the patient might suffer serious or life-threatening injury.
⇒ Do not use the measured MVi value as an adequate means of assessing ventilation.
⇒ Use external monitoring ($etCO_2$ or expiratory volume measurement).

⚠ CAUTION

Risk of infection resulting from use of a contaminated device for subsequent ventilation procedures!
If the device is used in a contaminated environment, the patient might suffer serious or life-threatening injury.
⇒ If you suspect that the interior of the device has been contaminated, take the device out of service and contact the manufacturer.

⚠ WARNING

Risk of infection resulting from failure to use hygiene filter!
If the device is used without a hygiene filter in a contaminated environment, it might draw in contaminated ambient air.
This might expose the patient and the user to the risk of serious or life-threatening injury.
⇒ Always use a hygiene filter when operating the device in a contaminated environment.

⚠ WARNING

Reduced ventilation performance resulting from increased device input resistance as a result of using the device in a very dusty atmosphere!
If the device is operated in a very dusty atmosphere, it might draw in dust and dirt from the ambient air, which might get into the patient's lungs. Ventilation performance might also be reduced by increased device input resistance. This might expose the patient to the risk of serious or life-threatening injury and damage the device.
⇒ Only operate the device with a hygiene filter.
⇒ Replace the hygiene filter after operating the device in a very dusty atmosphere.

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⚠ WARNING

Disrupted or failed therapy due to defective or non-operational device or accessories!

Using defective devices and defective accessories might result in device malfunctions. This might expose the patient and the user to the risk of serious or life-threatening injury.

⇒ Perform a complete function check prior to every use.
⇒ Only operate the device and accessories if they are externally undamaged.
⇒ Only use devices and accessories which have passed the function check.
⇒ Have defective devices repaired.
⇒ Have defective accessories repaired or replace them.
⇒ Also follow the instructions for use of the accessories.
⇒ Observe maintenance intervals.

⚠ WARNING

Disrupted or failed therapy due to inadequate protection from dust and damp!

If the interfaces for the SD card or the breathing circuit are not protected when transporting the device in a dusty or damp environment, disruption or failure of therapy might occur as a result of device failure. This might expose the patient to the risk of serious or life-threatening injury and damage the device.

⇒ Close the SD card cover to assure IP protection.
⇒ Connect the breathing circuit or close the protective caps to assure IP protection.

⚠ WARNING

Inadequate patient monitoring and device operability resulting from device being operated in an unsuitable position!

Operating the device in an unsuitable position might mean that alarm transmitters cannot be heard or the display is hard to read. This might expose the patient to the risk of serious or life-threatening injury.

⇒ Use the device only in the following positions:

- Display facing upward (when the device is standing on a table for example).
- Display facing forward (when the device is mounted on a wall by a portable system for example).

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⚠ WARNING

Risk of injury and delayed therapy due to alarm signals being unable to be heard!
Alarm signals quieter than the noise level in the environment prevent alarm situations being detected. This might result in treatment delays and thus to injury to the patient.
⇒ Always set the device volume to be louder than the ambient noise level.

⚠ WARNING

Electric shock resulting from incompatibility with other devices!
Connecting a different device or non-approved accessories might cause voltage on a part of the device which can be contacted and so lead to electric shock. This might expose the user to the risk of serious or life-threatening injury.
⇒ Use only approved accessories.

⚠ WARNING

Disrupted or failed therapy due to operation of the device and its accessories outside the specified ambient conditions!
Using the device and its accessories outside the specified ambient conditions might result in tolerances being exceeded and in device failure. This might expose the patient to the risk of serious or life-threatening injury.
⇒ Only operate the device and its accessories within the specified ambient conditions (see "15 Technical data", page 138).
⇒ Never use the device and its accessories in hyperbaric chambers.

⚠ WARNING

Risk of explosion if the device is used in hyperbaric chambers!
If the device is used in a hyperbaric chamber, this may lead to explosions.
⇒ Never use the device in hyperbaric chambers.

⚠ WARNING

Disrupted or failed therapy due to use of bubble humidifiers!
Using bubble humidifiers might cause moisture at the oxygen inlet and result in malfunctions and device failure. This might expose the patient to the risk of serious or life-threatening injury.
⇒ Do not use bubble humidifiers.

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⚠ WARNING

Risk of injury from operating the device in a toxic environment!
Operating the device in a toxic environment may cause toxic gases to reach the patient's lung, exposing him or her to the risk of serious of life-threatening injury.
⇒ Do not use device in a toxic environment.

⚠ WARNING

Disrupted or failed therapy due to lack of maintenance!
If maintenance intervals are not observed, malfunctions might occur. This might expose the patient to the risk of serious or life-threatening injury.
⇒ Observe the maintenance intervals according to the instructions for use and the displays on the device.
⇒ Also observe the maintenance intervals for devices and accessories in storage.

⚠ WARNING

Disrupted or failed therapy due to modifications to the design of the device or accessories!
Modifications to the design of the device might result in disruption or failure of therapy. This might expose the patient to the risk of serious or life-threatening injury.
⇒ Do not make any modifications to the design of the device or accessories.

⚠ WARNING

Risk of fire and explosion resulting from incorrect handling of highly compressed oxygen/oxygen cylinder!
Compressed oxygen in combination with combustible substances in an oxygen-enriched environment might cause fires and explosions. This might expose the patient, user and persons in the vicinity to the risk of serious or life-threatening injury.
⇒ Never smoke near oxygen-carrying fittings.
⇒ Keep the oxygen supply away from naked flames and other ignition sources.
⇒ Ensure adequate ventilation.
⇒ Keep the device and screw fittings free of oil and grease.
⇒ Wash your hands to remove any oil or grease before working on the oxygen supply.
⇒ Secure the oxygen cylinder against toppling over.
⇒ Tighten or loosen all screw fittings on the oxygen cylinder and on the pressure reducer by hand only.

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⚠ WARNING

Risk of fire resulting from use of the device in conjunction with anesthetics!

Flammable gases and anesthetics can cause spontaneous explosions. This might expose the patient, user and persons in the vicinity to the risk of serious or life-threatening injury, as well as damaging the device.

⇒ Do not use the device in conjunction with flammable gases or gaseous and ignitable anesthetics.

⚠ WARNING

Risk of injury resulting from incorrect handling of the rechargeable battery!

Incorrect handling of the rechargeable battery might expose the patient, user and persons in the vicinity to the risk of serious or life-threatening injury.

⇒ Do not throw the rechargeable battery into a fire, and never expose it to high temperatures.
⇒ Do not open the rechargeable battery.
⇒ Do not deform the rechargeable battery.
⇒ Do not short-circuit the rechargeable battery.
⇒ Protect the rechargeable battery from moisture.
⇒ Protect the rechargeable battery from high temperatures.
⇒ Do not subject the rechargeable battery to high pressure.
⇒ Have the rechargeable battery replaced only by trained personnel.

⚠ WARNING

Premature failure of therapy resulting from use of a rechargeable battery with a low state of charge at low temperatures!

Using a rechargeable battery with a low state of charge at low temperatures of < 0 °C might result in a much reduced device operating time and thus to premature failure of therapy. This might expose the patient to the risk of serious or life-threatening injury.

⇒ Always use a fully charged rechargeable battery at low temperatures.

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⚠ WARNING

Disrupted or failed therapy due to interaction between medical electrical devices!

Medical electrical devices which are operated directly next to or on top of each other can cause mutual interference to functionality. This might expose the patient to the risk of serious or life-threatening injury.

⇒ Do not stack the device with other medical electrical devices.

⇒ Do not operate the device in the direct vicinity of other medical electrical devices (exception: Other WEINMANN Emergency devices which have been tested to ensure that they can operate without problem alongside the device. A list of the other devices can be provided on request).

⇒ If stacking or operation in the immediate vicinity cannot be avoided: Closely monitor the functioning of all affected medical electrical devices and do not use if functions are disrupted.

⚠ WARNING

Disrupted or failed therapy due to magnetic resonance imaging machines in the immediate vicinity of the device!

The magnetic action of magnetic resonance imaging machines in the immediate vicinity of the device might throw the device around. This may lead to therapy being interrupted and expose the patient to the risk of serious or life-threatening injury.

⇒ Never operate device in conjunction with magnetic resonance imaging machines.

⚠ WARNING

Disrupted or failed therapy due to portable high-frequency communication equipment in the immediate vicinity of the device!

Portable radio-frequency communication equipment (e.g. mobile radios, antennas and antenna cables) in the immediate vicinity of the device may impair the performance characteristics of the device and injure the patient.

⇒ Keep portable high-frequency communication equipment a minimum distance of 30 cm away from the device and its accessories.

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⚠ WARNING

Fault in or failure of the device or its accessories during therapy as a result of high-frequency surgical equipment in the immediate vicinity of the device!

High-frequency surgical equipment in the immediate vicinity of the device or its accessories may lead to faults or failure of the device or its accessories. This might expose the patient to the risk of serious or life-threatening injury.

⇒ Do not use the device and its accessories in the vicinity of high-frequency surgical equipment.

⚠ WARNING

Disrupted or failed therapy due to incompatibility of the device with consumables, accessories and other medical devices!

Defective or non-approved accessories might cause malfunctions, increased electromagnetic interference or reduced electromagnetic immunity of the device, incorrect output values, and reduced ventilation performance. This might expose the patient to the risk of serious or life-threatening injury.

⇒ Use only approved accessories.

⇒ Follow the instructions for use of the accessories.

⚠ WARNING

Disrupted and failed therapy due to incorrect use of disposables!

Reusing and reprocessing disposables might induce unpredictable reactions as a result of aging, embrittlement, wear, thermal loading and chemical action. This might place the functionality and safety of the device at risk, and cause the patient or user to suffer serious or life-threatening injury.

⇒ Do not reuse disposables.

⇒ Do not subject disposables to hygienic reprocessing.

⚠ WARNING

Risk of infection and contamination from contaminated disposables!

Reused disposables may cause infections and contamination if they come into contact with airways. This might expose the patient and the user to the risk of serious or life-threatening injury.

⇒ Do not reuse disposables.

⇒ Do not subject disposables to hygienic reprocessing.

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⚠ WARNING

Risk of injury resulting from condensation in the patient valve at temperatures below 0 °C!

If patients are subjected to sustained ventilation, at temperatures below 0 °C, the exhalation moisture in the patient valve might condense and impair the function of the parts. This might expose the patient to the risk of serious or life-threatening injury.

⇒ Quickly move the patient to a warmer location.

⇒ At temperatures below 5 °C, use a breathing system filter to extend application time.

⚠ WARNING

Delayed or incorrect therapy as a result of illegible labeling on device!

Unsuitable cleaning and disinfectant products may remove the device labeling and markings and lead to material damage, with the result that the user is unable to use the device and its accessories properly in an emergency situation. This might expose the patient to the risk of serious or life-threatening injury.

⇒ Only use the recommended cleaning and disinfectant products.

⇒ Replace illegible labels.

⚠ CAUTION

Increased spontaneous breathing resistance and reduced ventilation performance resulting from blocked intake opening/hygiene filter!

A blocked intake opening/blocked hygiene filter will reduce ventilation performance in operation, and in the event of device failure will result in increased spontaneous breathing resistance. This might injure the patient.

⇒ Do not conceal or block the intake opening/hygiene filter.

⚠ CAUTION

Hazardous therapy due to lack of monitoring of the oxygen concentration administered!

The device does not monitor inspiratory oxygen concentration in the same way as an RGM (respiratory gas monitor), and has no corresponding alarm. Dispensing respiratory gas with a slightly different oxygen concentration might put the therapy at risk. This might injure the patient.

⇒ Use a separate respiratory gas monitor to monitor the oxygen concentration administered to the patient.

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⚠ CAUTION

Risk of injury resulting from temperatures on application parts and in the respiratory gas when using the device at high ambient temperatures!

Using the device at high ambient temperatures might result in the temperatures of the respiratory gas and of application parts increasing in line with the ambient temperature. Temperatures >41 °C might injure the patient if applied for a protracted period of time.

⇒ Note that all application parts can warm up to ambient temperature.

⇒ Note that the applied respiratory gas can reach a temperature above 41 °C.

⇒ Shorten the application time at high ambient temperatures >41 °C.

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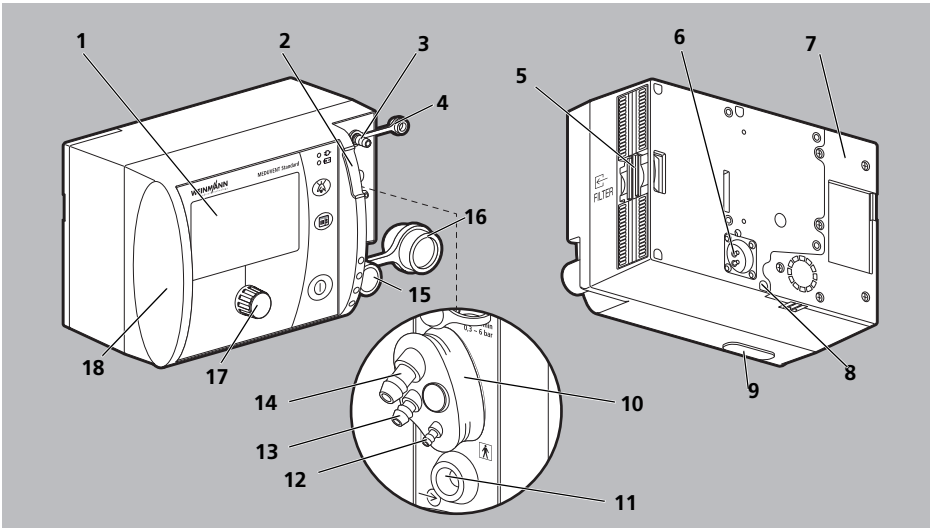
3 Description

3.1 Overview



3-1 Device overview

No.	Designation	Description
1	Display	Displays settings and current values (see "3.3 Symbols in the display", page 24).
2	Alarm light	Displays high-priority alarms visually.
3	Oxygen inlet	Used to connect the oxygen supply.
4	Protective cap for oxygen inlet	Protects the oxygen inlet when it is not in use.
5	Filter compartment	Holds the hygiene filter.
6	Power supply connection	Connects the device to the power supply.
7	Battery compartment cover	Covers the battery compartment.
8	Security seal	Indicates whether the device has been opened without authorization.
9	SD card slot with splash guard	For inserting an SD card.
10	Measuring circuit connection	Connects the device to the measuring circuit of the breathing circuit.
11	Accessories connection	Connects the device to the MEDUtrigger.

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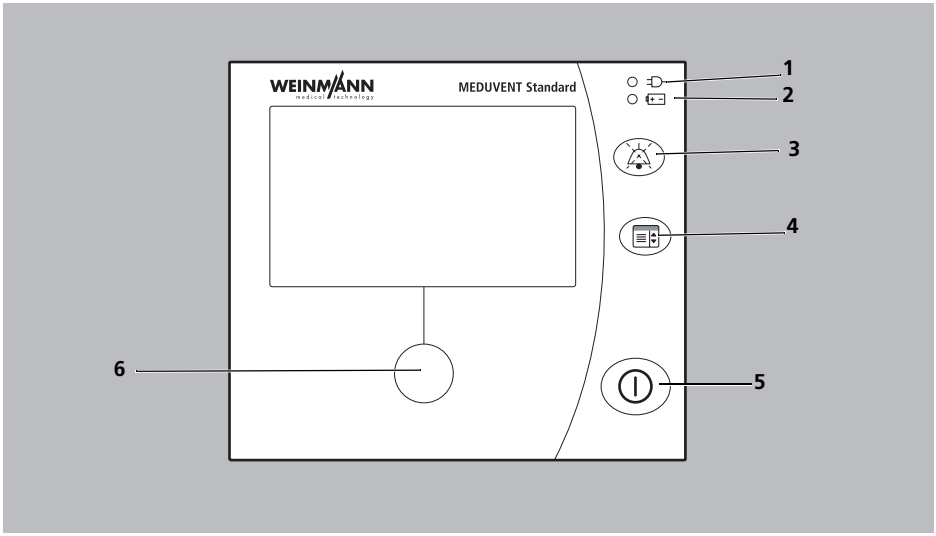
No.	Designation	Description
12	PEEP control tube connection	Connects the device to the PEEP control tube.
13	Pressure measuring tube connection	Connects the device to the pressure measuring tube.
14	Connection for flexible oxygen tube	Connects the device to the flexible oxygen tube.
15	Ventilation hose connection	Connects the device to the ventilation hose of the breathing circuit.
16	Protective cap for ventilation hose connection	Protects the ventilation hose connection when it is not in use.
17	Navigation knob	Permits navigation in the menus.
18	Loudspeaker (not seen)	Emits audio alarms.

3.2 Control panel and display

3.2.1 Control panel



3-2 Control panel

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No.	Designation	Description
1	Line power indicator	• LED showing green: Indicates that the device is connected to line power. • LED not on The device is being operated by the rechargeable battery and not by line power.
2	Battery status indicator	• LED showing green: The rechargeable battery is fully charged. • LED flashing green: The rechargeable battery is being charged. • LED showing red: The rechargeable battery is defective or not in the device. • LED not on The device is being operated by the rechargeable battery and not by line power. • LED flashing red and green alternately: The battery is outside charging temperature and cannot be charged, even though the device is being supplied by line power.
3	Alarm mute button	Mutes an alarm for 120 seconds.
4	Menu button	• In the start menu: Opens the operator menu. • During ventilation: Opens the user menu to change ventilation mode or patient group.
5	On/Off button	Switches the device on or off.
6	Navigation knob	Permits values for ventilation parameters to be selected and confirmed.

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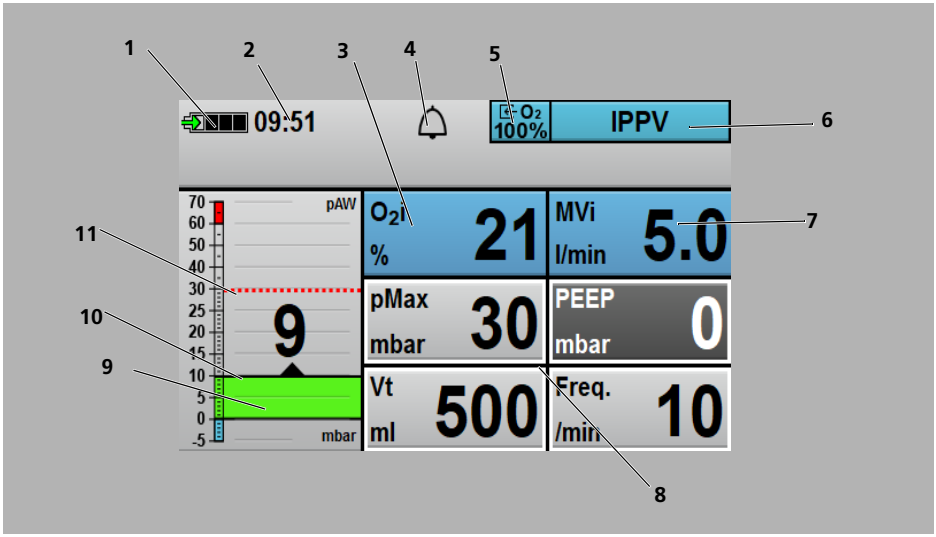
3.2.2 Display



3-3 Display (example)

No.	Designation	Description
1	Battery status	Indicates the charge level of the battery (see "3.5 Rechargeable battery and battery status indicator", page 31)
2	Time	Displays the current time.
3	O_2i	Displays the oxygen concentration delivered.
4	Alarm	Indicates whether the audio alarm output is active or muted (see "3.3 Symbols in the display", page 24).
5	Supply gas symbol	(see "3.3 Symbols in the display", page 24)
6	Ventilation mode	Indicates the ventilation mode set.
7	MVi	Indicates the minute volume delivered by the device.
8	Ventilation parameters	Ventilation parameters which can be set to control ventilation.
9	Bar graph	Indicates the level of ventilation pressure being administered.
10	Maximum value indicator	Indicates the end-expiratory ventilation pressure reached.
11	Pressure limiting	Displays the set alarm limit.

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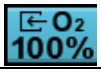
3.3 Symbols in the display

Symbol	Designation	Description
	Alarm symbol	Audio alarm output active
		Audio alarm output muted for 120 seconds
	Battery status symbol	Indicates current rechargeable battery status (see "3.5 Rechargeable battery and battery status indicator", page 31).
	Function check symbol	Fault determined during function check
		Follow instructions for use
		Servicing measure required
	Emergency mode symbol	Emergency mode Infant (up to about 1 year old)
		Emergency mode Child (between about 1 and 12 years old)
		Emergency mode Adult (from about 13 years old)
	Supply gas symbol	Operation with concentrator oxygen
		Operation with 100 % oxygen

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3.4 Accessories

The following presents an overview of accessories for the device. For a complete list, including the relevant article numbers, refer to the "Scope of supply and accessories" chapter (see "14 Scope of supply and accessories", page 133). Please refer to the instructions for use supplied with the accessories.

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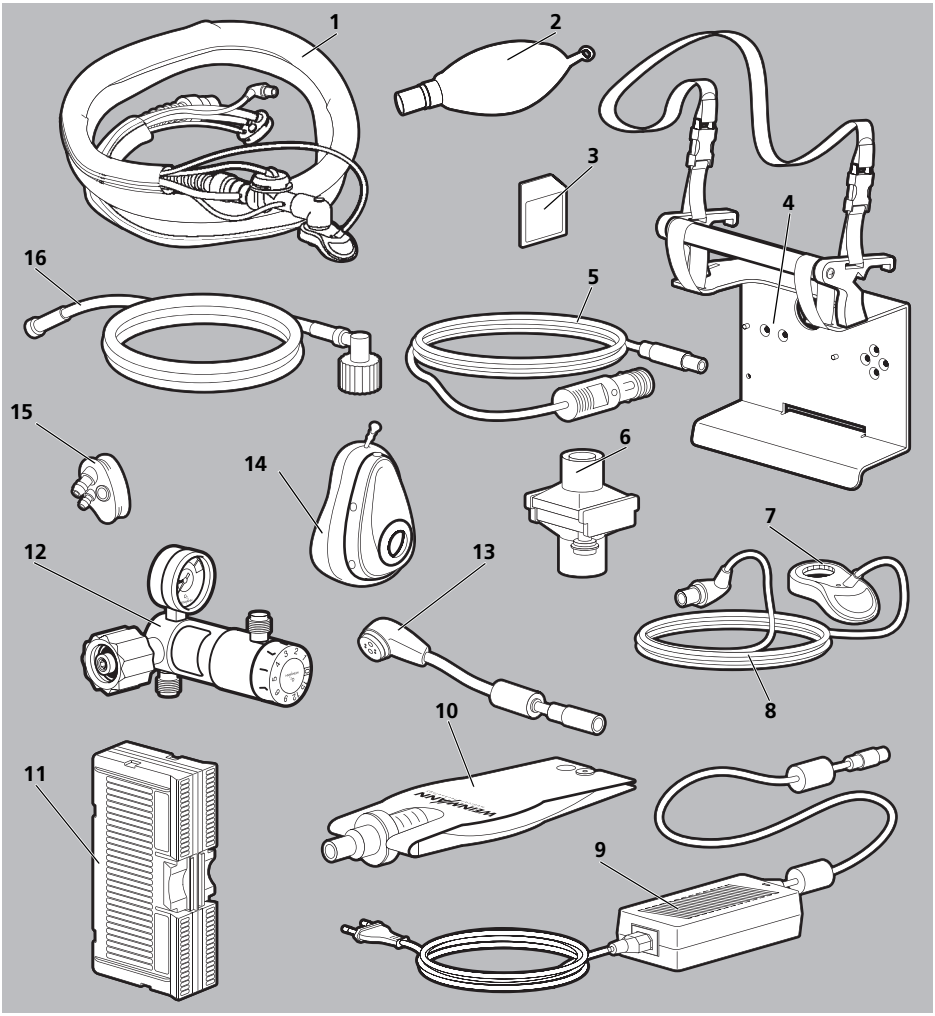
3.4.1 Overview



3-4 Accessories

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No.	Designation	Description
1	Breathing circuit	Administers the inspiratory gas to the patient via a mask or tracheal tube. There are two types of breathing circuit: • Reusable breathing circuit (see 3.4.2, p. 28) • Disposable breathing circuit (see 3.4.3, p. 30)
2	Testing bag	Simulates a ventilated patient in the function check.
3	SD card	Used to read session data and log files, and to update the device software.
4	Portable system (example)	Used to transport the device (see "3.6 Transport options", page 32).
5	12 V cable	Supplies the device with power from the vehicle's on-board power supply.
6	Breathing system filter	For filtering and humidifying respiratory air.
7	MEDUtrigger	Used to trigger mechanical breaths manually.
8	MEDUtrigger connection line	Connects the MEDUtrigger to the device.
9	Power supply unit and charger	Supplies power to the device.
10	EasyLung for WEINMANN Emergency	Simulates a ventilated patient for presentation purposes and in the function check.
11	Hygiene filter	Protects the device from viral and bacterial contamination.
12	Pressure reducer	Reduces the pressure of the oxygen from the oxygen cylinder to the operating pressure for the device.
13	Charging adapter	Connects the power supply unit and charger or the adapter cable for 12 V on-board power to the device.
14	Ventilation mask	Connects the breathing circuit to the patient.
15	Adapter for disposable breathing circuit	Permits operation of the device with a disposable breathing circuit.
16	Oxygen inlet tube	Routes the oxygen from the oxygen supply to the device.

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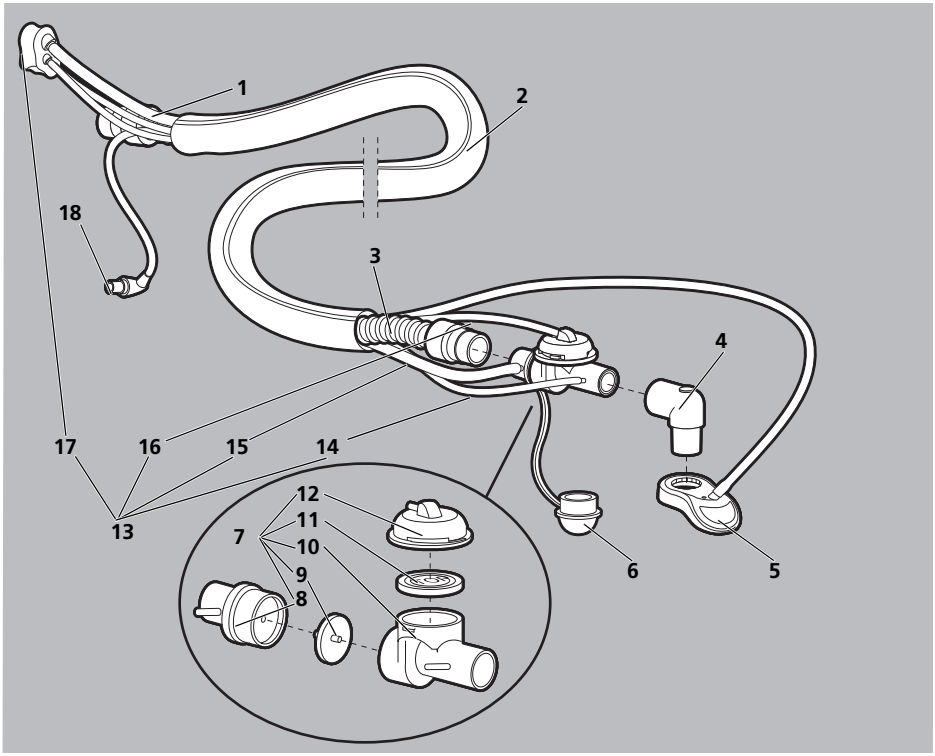
3.4.2 Reusable breathing circuit



3-5 Reusable breathing circuit

No.	Designation	Description
1	Service label (concealed)	Indicates the time of the next maintenance.
2	Protective sleeve	Protects the ventilation hose from dirt and damage.
3	Ventilation hose	The respiratory gas flows through the ventilation hose from the device to the patient valve.
4	Elbow	Connects the reusable breathing circuit to the mask or tracheal tube.
5	MEDUtrigger	Manually triggers mechanical breaths.
6	Protective cap	Protects the patient end of the breathing circuit from damage and dirt.
7	Patient valve	Switches between inspiration and expiration.

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No.	Designation	Description
Comprising:		
8	Holder for check valve diaphragm	Connects the patient valve to the ventilation hose, and includes the check valve diaphragm.
9	Check valve diaphragm	The respiratory gas flows through the check valve diaphragm only toward the patient. No rebreathing takes place.
10	Main body	Provides a connection for a mask, a tracheal tube or the elbow.
11	PEEP control diaphragm	In combination with the control cover, creates a pressure chamber for PEEP control.
12	Control cover	In combination with the PEEP control diaphragm, creates a pressure chamber for PEEP control.
13	Measuring circuit (reusable)	The device uses the measuring circuit to measure the patient's vital signs.
Comprising:		
14	Pressure measuring tube	Measures the ventilation pressure at the patient.
15	Flexible oxygen tube	Feeds the oxygen to the patient.
16	PEEP control tube	The device controls the patient valve and the PEEP by way of the PEEP control tube.
17	Measuring circuit connector	Connects the measuring circuit to the measuring circuit connection on the device.
18	MEDUtrigger connection line	Connects the MEDUtrigger to the device.

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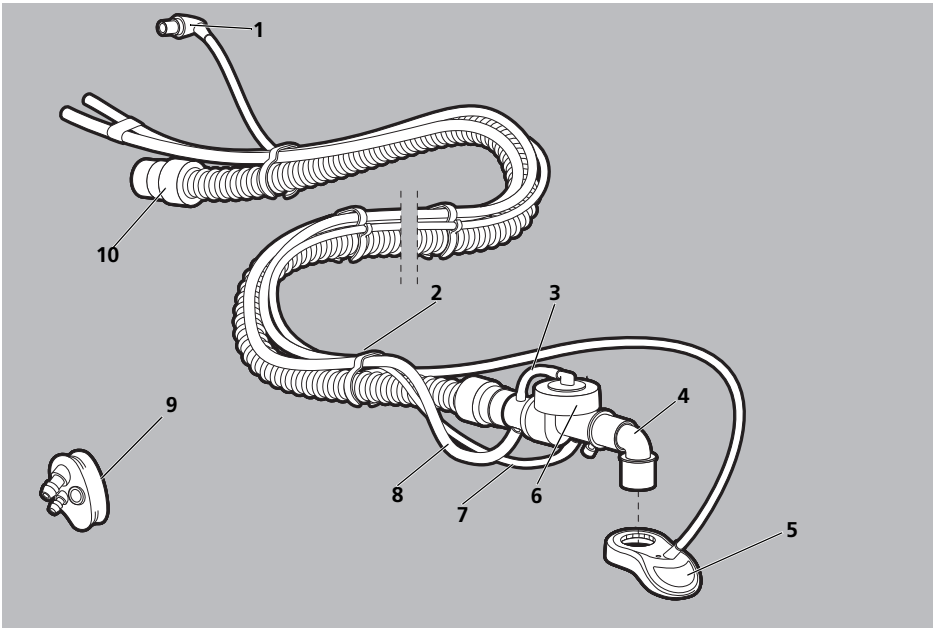
3.4.3 Disposable breathing circuit



3-6 Disposable breathing circuit

No.	Designation	Description
1	MEDUtrigger connection line	Connects the MEDUtrigger to the device.
2	Tube clip	Holds the tubes and the connecting cable of the MEDUtrigger together.
3	PEEP control tube	The device controls the patient valve and the PEEP by way of the PEEP control tube.
4	Elbow	Connects the circuit to the mask or tracheal tube.
5	MEDUtrigger	Manually triggers mechanical breaths.
6	Patient valve	Switches between inspiration and expiration.
7	Pressure measuring tube	Measures the ventilation pressure at the patient.
8	Flexible oxygen tube	Feeds the oxygen to the patient.
9	Disposable breathing circuit adapter	Connects the device to the measuring circuit of the disposable breathing circuit. The disposable breathing circuit adapter remains permanently connected to the device.
10	Ventilation hose	The respiratory gas flows through the ventilation hose from the device to the patient valve.

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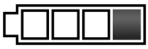
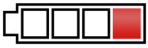
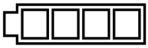
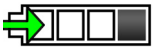
3.5 Rechargeable battery and battery status indicator

The device has an integrated rechargeable battery which may only be replaced by the operator. This rechargeable battery is automatically charged when the power supply is connected.

Symbol	Designation
	Battery status > 90 %
	Battery status approx. 60 % – 90 %
	Battery status approx. 40 % – 60 %
	Battery status approx. 10 % – 40 %
	Battery status < 10% • The last remaining segment in the battery status symbol is red. • The message **Battery weak** appears in the display.
	Rechargeable battery almost empty The message **Battery empty** appears in the display. The device can be used for at least another 5 minutes.
	• Rechargeable battery is defective. **or** • No rechargeable battery. **or** • Rechargeable battery not at suitable temperature.
	Green arrow: Rechargeable battery is charging

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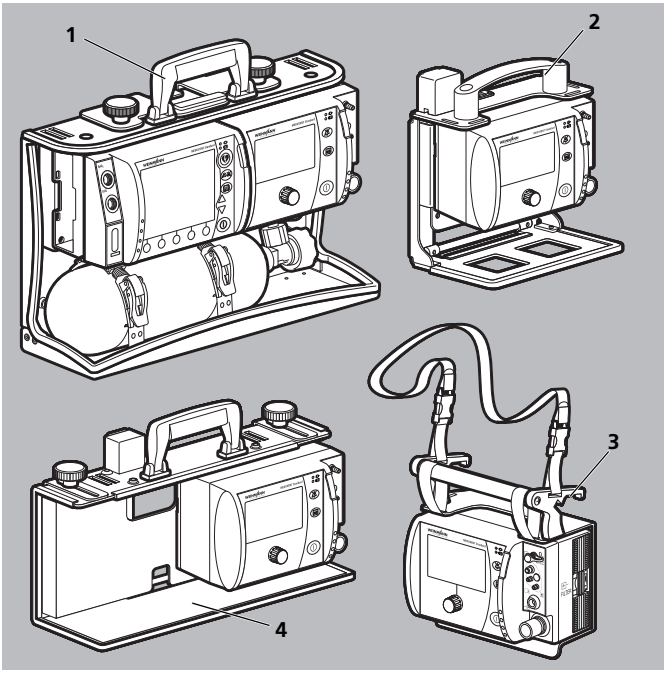
3.6 Transport options

In order to transport the device, carry accessories, provide a power supply for charging, and attach it to a wall mounting, you can mount the device on one of the following portable systems:



3-7 Transport options (examples)

No.	Designation
1	LIFE-BASE 3 NG
2	LIFE BASE 1 NG XS
3	LIFE-BASE *light* XS
4	LIFE BASE 1 NG XL

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4 Preparation

⚠ WARNING

Electric shock on touching the device!
Accessories connected to the device might create a voltage on the device. This might result in an electric shock on contact with the device, and cause the user serious or life-threatening injury.
⇒ Use only approved accessories.

⚠ WARNING

Risk of cross-contamination resulting from use of an incorrect patient valve!
Using a non-approved patient valve might cause rebreathing of the previous patient into the device, contaminating the device. This might expose the patient to the risk of serious or life-threatening injury.
⇒ Use only patient valves approved by WEINMANN Emergency.

4.1 Assembling the device

The device is mounted on a portable system as standard and is ready for use. Follow the instructions for use of the portable systems.

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4.2 Connecting a power supply

⚠ WARNING

Failure of therapy or loss of power resulting from use of an incorrect power supply unit and charger!

If you are using a portable system with the MEDUVENT Standard and MEDUCORE Standard/MEDUCORE Standard^2 device combination, the devices might lose power when using the 50 W power supply unit and charger, and the therapy might fail prematurely.

⇒ Use only the more powerful 100 W power supply unit and charger (WM 28937) for the MEDUVENT Standard and MEDUCORE Standard/MEDUCORE Standard^2 device combination.

⚠ WARNING

Failure of therapy due to defective power supply unit and charger.

A power supply unit and charger which is defective due to shock, vibration or wet is unable to charge the battery and will thus lead to failure of the therapy.

⇒ Do not use the power supply unit and charger outdoors.

⇒ Protect the power supply unit and charger from wet.

⇒ Do not use the power supply unit and charger in an emergency vehicle.

⚠ CAUTION

Risk of infection from contaminated power supply unit and charger

A contaminated power supply unit and charger can lead to infections.

⇒ Protect the power supply unit and charger from contamination.

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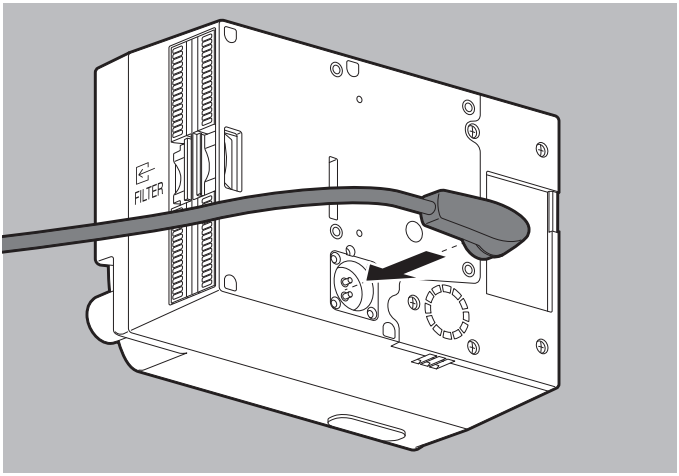

1. Connect the device to line power by its charging adapter (WM 28979) and power supply unit and charger.
   or
   When operating on the portable system: Attach the portable system to a wall mounting with a charging interface.
   or
   Connect the device to the vehicle's on-board power supply by its charging adapter (WM 28979) and 12 V cable.

Result The device has been connected to the power supply. The device automatically starts charging the rechargeable battery.

4.3 Connecting the breathing circuit

⚠ WARNING

Hypoventilation resulting from use of additional breathing system filters!

Using additional breathing system filters (breathing system filter, bacteria filter or combined breathing system/bacteria filter) increases the dead space of the overall system. An increased dead space might lead to hypoventilation. This might expose the patient to the risk of serious or life-threatening injury.

⇒ Use only approved accessories.

⇒ Pay attention to increased dead space volume when ventilating at low tidal volumes.

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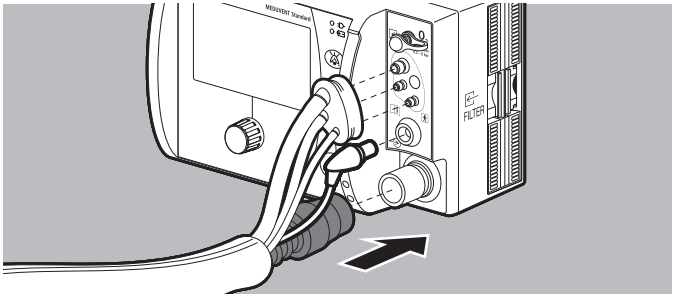
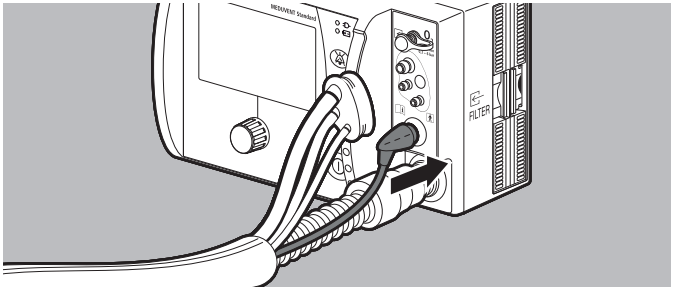
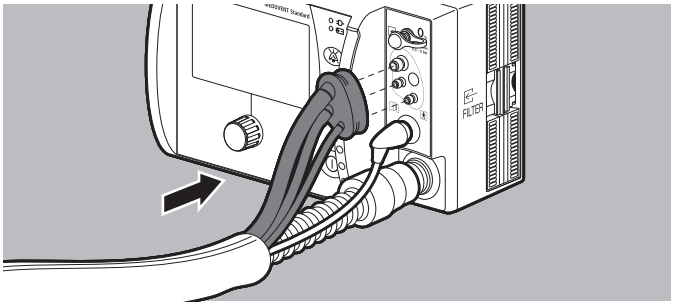
4.3.1 Connecting the reusable breathing circuit



1. Connect the ventilation hose to the ventilation hose connection.



2. If present: Connect the MEDUtrigger.



3. Attach the measuring circuit connector to the measuring circuit connection.

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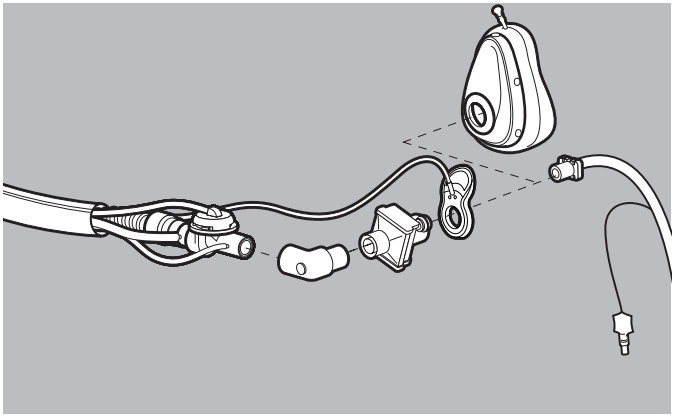

4. In the case of invasive ventilation: Connect the patient valve of the breathing circuit to the tracheal tube following intubation:
   - With/without elbow
   - With breathing system filter

   or

   For mask ventilation: Connect the ventilation mask to the patient valve of the breathing circuit:
   - With/without elbow
   - With breathing system filter

Result The reusable breathing circuit has been connected to the device and is ready for use.

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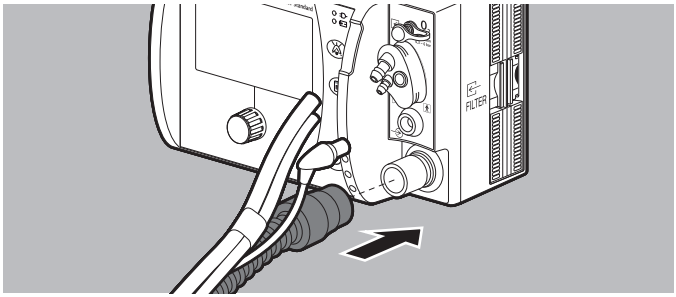
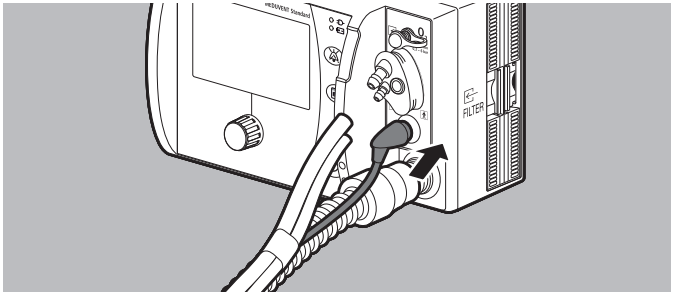
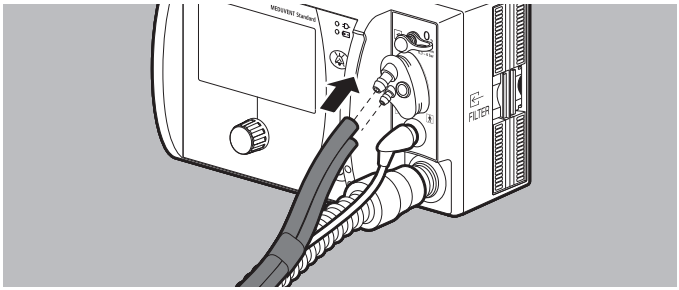
4.3.2 Connecting the disposable breathing circuit



1. Connect the ventilation hose to the ventilation hose connection.



2. If present: Connect the MEDUtrigger.



3. Connect the flexible oxygen tube and pressure measuring tube.

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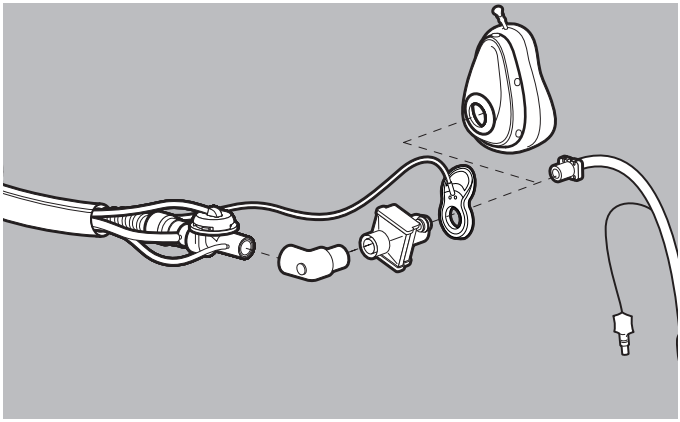

4. In the case of invasive ventilation: Connect the patient valve of the breathing circuit to the tracheal tube following intubation:
   - With/without elbow
   - With breathing system filter

   or

   For mask ventilation: Connect the ventilation mask to the patient valve of the breathing circuit:
   - With/without elbow
   - With breathing system filter

Result The disposable breathing circuit has been connected to the device and is ready for use.

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4.4 Connecting the oxygen supply

⚠ CAUTION

Hazardous therapy as a result of inadequate oxygen concentration!

If oxygen is supplied from non-approved, inadequately cleaned or damp oxygen sources, the pneumatic connections in the device may be blocked by impurities or particles. This might injure the patient.

⇒ Use only oxygen sources which conform to the specifications (see "15 Technical data", page 138).

⇒ Use only oxygen sources which are free of particles, clean and dry.

⚠ CAUTION

Falsified oxygen therapy resulting from use of unsuitable oxygen!

Unsuitable oxygen might falsify the therapy. This might expose the patient to the risk of serious or life-threatening injury.

⇒ Use only concentrator oxygen (90 % to 96 % oxygen) or medical oxygen.

⚠ CAUTION

Failure of oxygen therapy resulting from inadequate supply of oxygen!

An inadequate oxygen supply will prevent ventilation of the patient. This might injure the patient.

⇒ Check the pressure in the oxygen cylinder prior to ventilation.

Requirement The oxygen cylinder has been filled.

1. Briefly open the oxygen cylinder valve and then close it again to blow off dirt particles.

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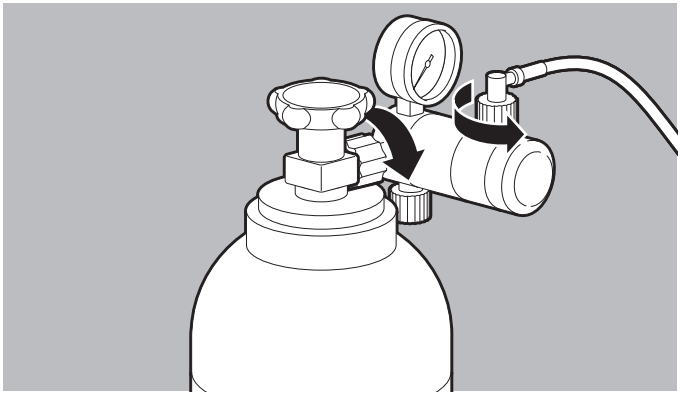
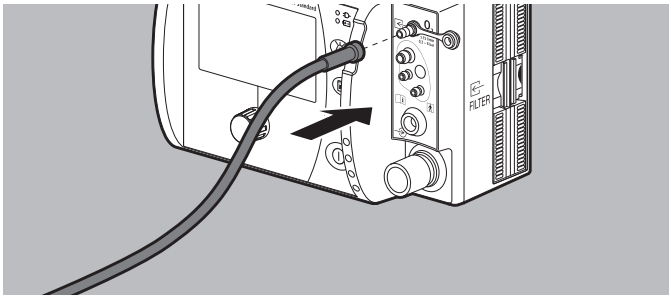


2. Connect the pressure reducer (see "14.2 Accessories and other parts", page 133) to the oxygen cylinder valve using a fluted union nut and tighten it by hand.
3. Connect the oxygen inlet tube to the outlet of the pressure reducer.



4. Connect the oxygen inlet tube to the device's oxygen inlet.

Result The device has been connected to the oxygen supply.

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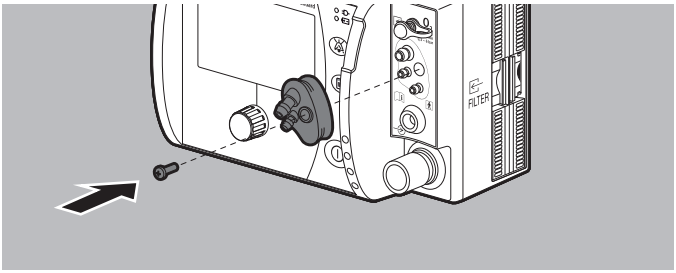
4.5 Converting the device

4.5.1 Converting the device to a disposable breathing circuit

1. Remove the protective cap from the hole on the measuring circuit connection and fit it in the disposable breathing circuit adapter.



2. Connect the disposable breathing circuit adapter to the ventilation hose connection.
3. Secure the disposable breathing circuit adapter using the screw supplied.

Result The device has been converted for use with a disposable breathing circuit. The disposable breathing circuit adapter remains permanently connected to the device.

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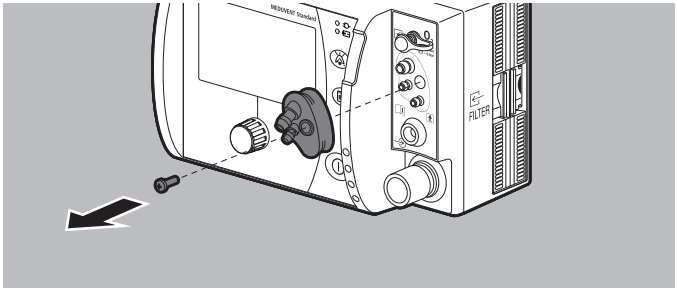
4.5.2 Converting the device to a reusable breathing circuit



1. Loosen the screw on the disposable breathing circuit adapter.
2. Remove the disposable breathing circuit adapter from the device.
3. Remove the protective cap from the disposable breathing circuit adapter.
4. Fit the protective cap over the open hole on the device.

Result The device has been converted for use with a reusable breathing circuit.

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5 Function check

⚠ WARNING

Disrupted or failed therapy due to defective or non-operational device or accessories!
Using defective devices or defective accessories may result in device malfunctions. This might expose the patient and the user to the risk of serious or life-threatening injury.
⇒ Perform a complete function check prior to every use.
⇒ Only operate the device and accessories if they are externally undamaged.
⇒ Replace illegible or damaged labels.
⇒ Only use devices and accessories which have passed the function check.
⇒ Have defective devices repaired.
⇒ Have defective accessories repaired or replace them.
⇒ Observe maintenance intervals.
⇒ Keep alternative means of ventilation at the ready.

5.1 Intervals

Perform a function check at the following intervals:

Part concerned	Interval
Device	• Before each use • After each hygienic reprocessing • After each repair
Breathing circuit (reusable breathing circuit)	• Before each use • After each hygienic reprocessing • After each disassembly

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5.2 Preparing for the function check

1. Check battery status: The rechargeable battery must be fully charged.
   If necessary: Charge rechargeable battery.
2. Check the following parts for external damage:
   - Device
   - Labels on the device
   - Connectors and cables
   - Breathing circuit
   - Accessories
3. If necessary: Replace damaged parts.
4. Check the patient valve of the reusable breathing circuit (see "5.4 Checking the reusable breathing circuit", page 52).
5. If necessary: Replace the breathing circuit.
6. Check the fill level of the oxygen cylinder.
7. If necessary: Replace the oxygen cylinder.

Result The function check has been prepared.

5.3 Performing the function check

You can perform the function check with the following test lungs:

- Testing bag WM 1453
- Testing bag WM 1454
- EasyLung for WEINMANN Emergency WM 28625

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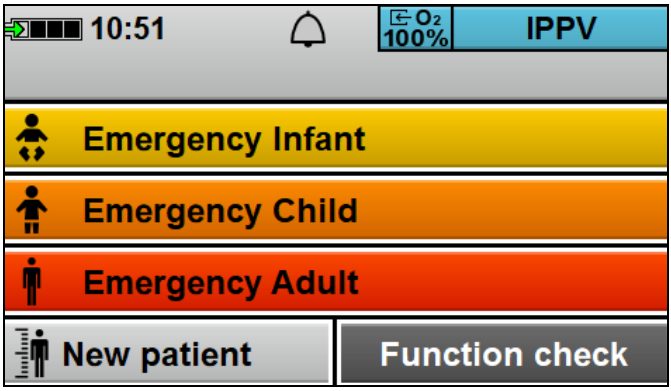
⚠ WARNING

Hazardous therapy due to connection between device and patient during function check!
A connection between the device and the patient during the function check might lead to the therapy posing a risk as a result of excessively high pressures or unsuitable ventilation volumes. This might expose the patient to the risk of serious or life-threatening injury.
⇒ Always disconnect the connection between the device and the patient for the function check.

Requirement

- The device is disconnected from the patient.
- The rechargeable battery is fully charged.
- An SD card is in the SD card slot.
- The hygiene filter is inserted in the filter compartment.
- The oxygen supply is shut off.
- The function check has been prepared (see "5.2 Preparing for the function check", page 45).
- The device is switched on (see "6.1 Switching on the device", page 54).



1. Select the **Function check** menu item.

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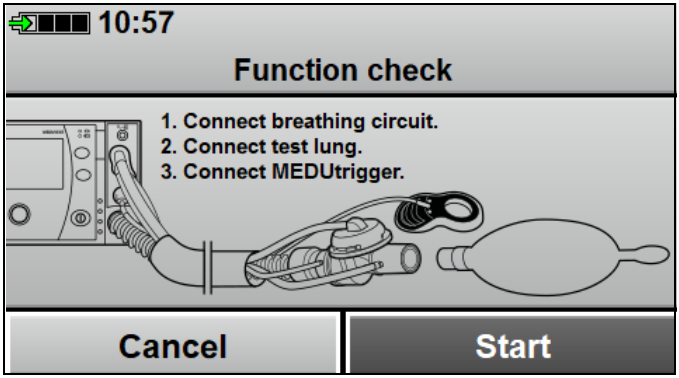
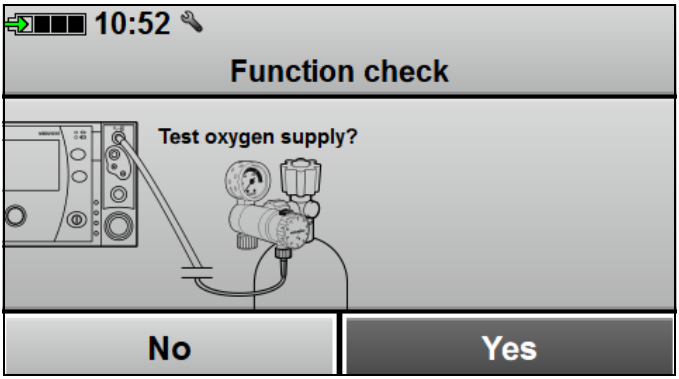


2. Prepare the device:
   - Connect the breathing circuit to the device.
   - Connect the test lung to the breathing circuit.
   - Connect the MEDUtrigger.
3. Select **Start**.



4. If you want to test the oxygen supply: Select **Yes**.

   or

   If you do not want to test the oxygen supply: Select **No**.
   The device skips the oxygen test.

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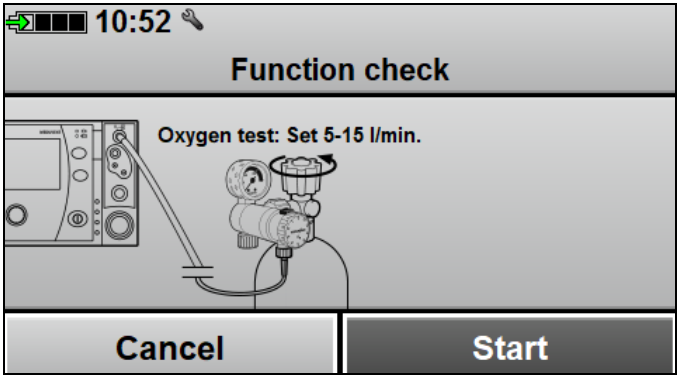
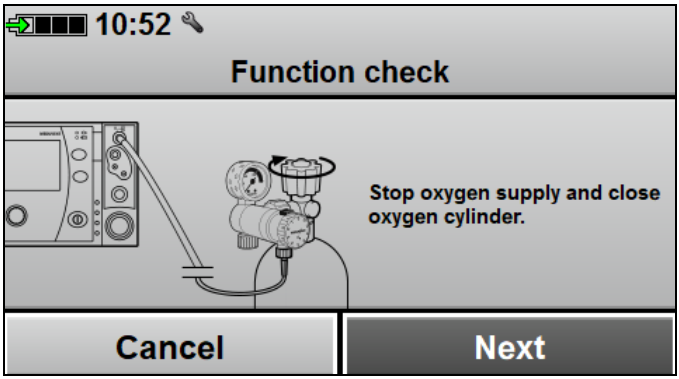


5. Set the oxygen supply rate (5-15 l/min)
(see “6.7 Introducing oxygen”, page 63).

6. Select **Start**.



7. Stop the oxygen supply and close the oxygen cylinder
(see “6.7 Introducing oxygen”, page 63).

8. Select **Next**.

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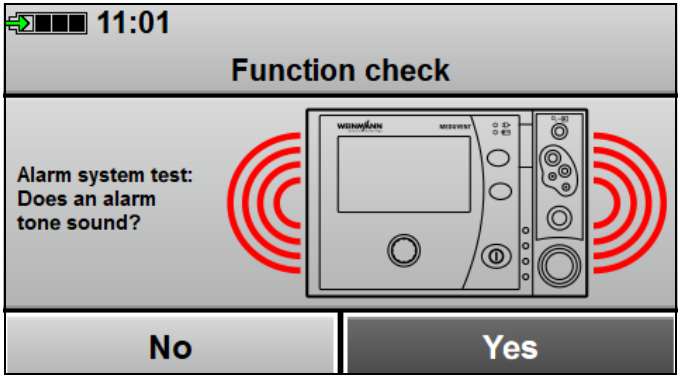
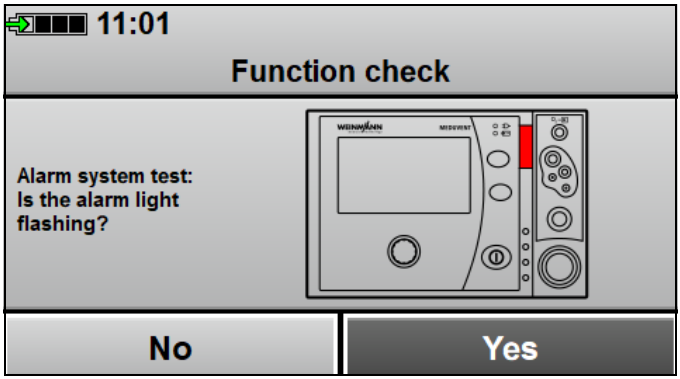
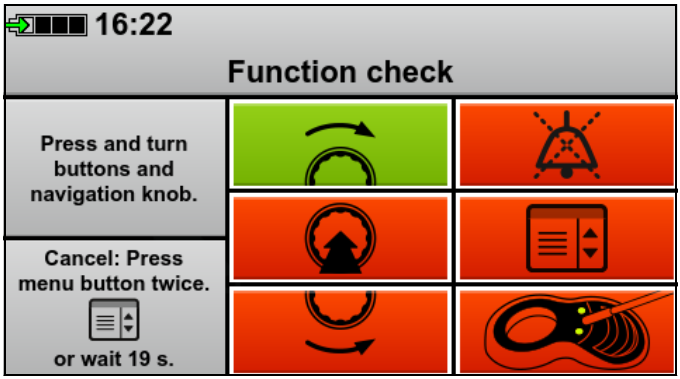


9. If an audio alarm is output: Select **Yes**.

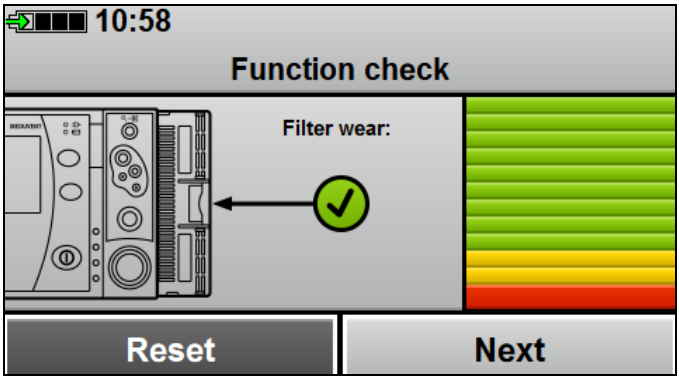


10. If the alarm light is red: Select **Yes**.



11. Press all the controls except the On/Off button one after another.

12. If the MEDUtrigger is not displayed in the function check: Activate MEDUtrigger in the operator menu and repeat the function check.

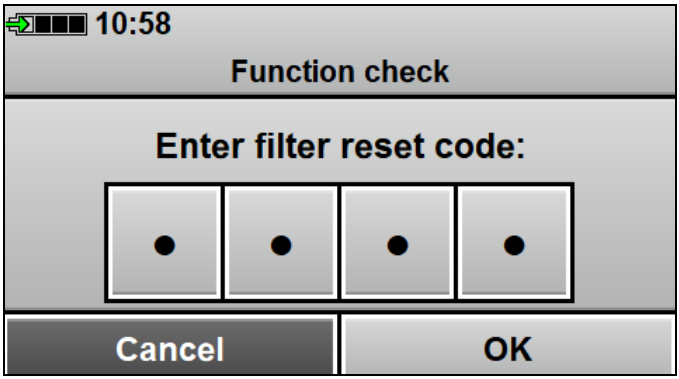


13. Proceed with the hygiene filter according to the following table:

Color	Action
Green	Continue to use hygiene filter.
Yellow	Keep hygiene filter at the ready **or** Order hygiene filter.
Red	Replace hygiene filter (see 11.3, p. 124).

14. If the hygiene filter has been replaced:

- Select **Reset**.



- Enter the filter reset code specified in the operator menu.

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On delivery, the filter reset code is 0000.

15. Select **Next**.
    The status report appears (example: Function check passed).

16. Proceed with the device in accordance with the following table:

Display	Meaning	Action
Device ready for use	Function check passed	Use device without restriction.
Device not ready for use	Function check failed **or** Function check canceled	Select **Details**. Check the parts listed in the display and replace them if necessary. Repeat the function check.
		If the function check is still not passed: Contact your authorized dealer or the manufacturer.
Device ready for use. The service symbol flashes in the start menu.	Guidance notes for the scheduled service	Contact your authorized dealer or the manufacturer.

For precise details on the individual tests in the function check, refer to the **fcheck** file (see "15.8.2 Recorded function checks (fcheck file)", page 153).

17. Select **Finish**.
18. Switch off the device.
19. Disconnect the test lung from the breathing circuit.

Result The function check is complete.

5.4 Checking the reusable breathing circuit

Requirement The patient valve of the reusable breathing circuit has been removed (see "8.3.1 Disassembling the reusable breathing circuit", page 87).

1. Check all parts of the patient valve for external damage.
2. If necessary: Replace damaged parts.
3. Check the PEEP control diaphragm and check valve diaphragm:
4. If the diaphragm is torn, corrugated, distorted or sticky: Replace the diaphragm.
5. Assemble the reusable breathing circuit (see "8.3.2 Assembling the reusable breathing circuit", page 90).
6. Check the system for leaks with a new function check.

Result The reusable breathing circuit has been checked.

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6 Operation

⚠ WARNING

Risk of fire resulting from simultaneous use of ventilator and defibrillator in oxygen-enriched environments!
If a ventilator and defibrillator are used simultaneously in oxygen-enriched atmospheres and in the presence of combustible materials (such as textiles), sparking associated with defibrillation might cause explosions and fires. This might expose the patient, user and persons in the vicinity to the risk of serious or life-threatening injury.
⇒ Use self-adhesive electrodes for defibrillation whenever possible.
⇒ Ensure that the oxygen/air mixture coming from the exhalation valve can flow away from the patient's torso.
⇒ Use the device only in ventilated rooms or environments.

⚠ WARNING

Inadequate patient monitoring due to concealed alarm transmitters!
A concealed alarm light, loudspeaker or display might prevent the user from noticing alarms and reacting to dangerous situations. This might expose the patient to the risk of serious or life-threatening injury.
⇒ Always keep the alarm transmitters (alarm light, loudspeaker and display) free.
⇒ Position the device's display facing upward (e.g. on a table) or forward (e.g. on a wall).

⚠ CAUTION

Increased breathing effort for the patient due to covered patient valve!
Covering the patient valve might impair its function and place the therapy at risk. This might injure the patient.
⇒ Do not cover/seal the expiration opening of the patient valve.

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6.1 Switching on the device

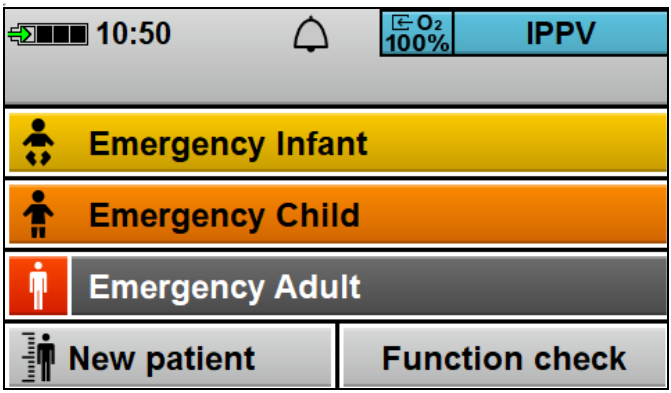
Requirement If present: The device is connected to the oxygen supply (see "4.4 Connecting the oxygen supply", page 40)

1. Briefly press the On/Off button ⏻.

   An automatic self-test starts, which comprises the following sequence:

   - Alarm light flashes twice and two short test tones are emitted in parallel
   - The start screen appears

   The self-test is successful when all of the steps have been completed.
   After the self-test, the device displays the start menu:



2. If one or more conditions are not met: Do not operate the device.

Result The device is switched on and on standby.

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6.2 Navigating in the device

Action	Result			
	In a menu	**Within a menu item**	**In the start menu**	**During ventilation**
 Turn navigation knob counter-clockwise	Navigate upward	Decrease value	Navigate upward	-
 Turn navigation knob clockwise	Navigate downward	Increase value	Navigate downward	-
 Press the navigation knob	Select the menu item	Confirm the set value	Select the menu item	Change marked ventilation parameter.
 Press the menu button	-	-	Activate the operator menu	Activate user menu to switch ventilation mode or patient group.
 Alarm mute button	-	-	-	Mutes an alarm for 120 seconds.

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6.3 Starting ventilation

⚠ WARNING

Hazardous therapy as a result of inadequate patient monitoring!

If the patient and the device are not observed and monitored during ventilation, delayed responses by medical personnel to alarms and faults might result in serious or life-threatening injury to the patient and incorrect therapy.

⇒ Continuously observe and monitor the patient and device during ventilation.

⚠ WARNING

Risk of injury resulting from incorrectly set limitation of maximum airway pressure!

An excessively high airway pressure might expose the patient to serious or life-threatening injury.

⇒ Always set the pressure limit pMax to suit the current patient and the current therapy.

⚠ WARNING

Hazardous therapy due to leaks during ventilation!

The measured MVi value indicates the volume the device is administering to the patient. In the event of leaks during ventilation, the measured MVi value will not match the tidal volume actually administered. If this is not observed, the patient might suffer serious or life-threatening injury.

⇒ Do not use the measured MVi value as an adequate means of assessing ventilation.

⇒ Use external monitoring (etCO_2 or expiratory volume measurement).

⚠ WARNING

Risk of contamination or infection resulting from failure to use hygiene filter!

If the device is used without a hygiene filter in a contaminated environment, it might draw in contaminated or infected ambient air. This might expose the patient and the user to the risk of serious or life-threatening injury.

⇒ Only operate the device with a hygiene filter.

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⚠ CAUTION

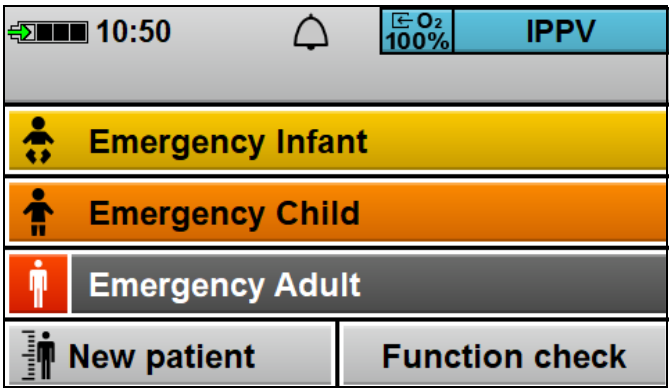
Hazardous therapy due to lack of monitoring of the oxygen concentration administered!
The device does not monitor inspiratory oxygen concentration in the same way as an RGM (respiratory gas monitor), and has no corresponding alarm. Dispensing respiratory gas with a differing oxygen concentration might place the therapy at risk. This might injure the patient.
⇒ Use a separate respiratory gas monitor to monitor the oxygen concentration administered to the patient.

6.3.1 Starting ventilation for a patient group

Requirement

- Function check has been carried out and passed (see "5 Function check", page 44).
- The device is switched on and, after the self-test, displays the start menu.

1. Connect the patient to the device by a ventilation mask or tracheal tube.



2. Set emergency mode:
   - **Emergency Infant**
   - **Emergency Child**
   - **Emergency Adult**

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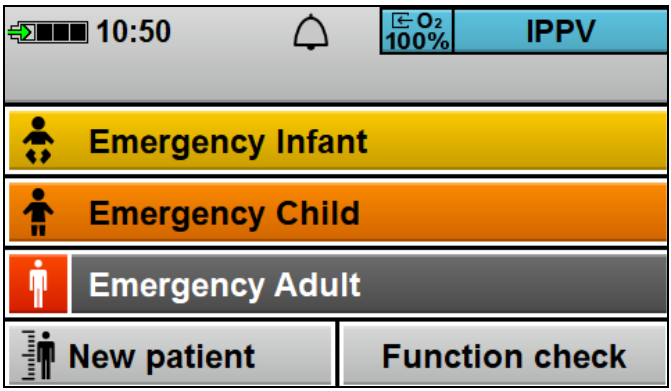
Depending on the preset in the operator menu, the device switches to a ventilation mode and immediately starts ventilation.

Result Ventilation for a specific patient group has been started.

6.3.2 Starting ventilation for a new patient

Requirement

- Function check has been carried out and passed (see "5 Function check", page 44).
- The device is switched on and, after the self-test, displays the start menu.



1. Select **New patient**.

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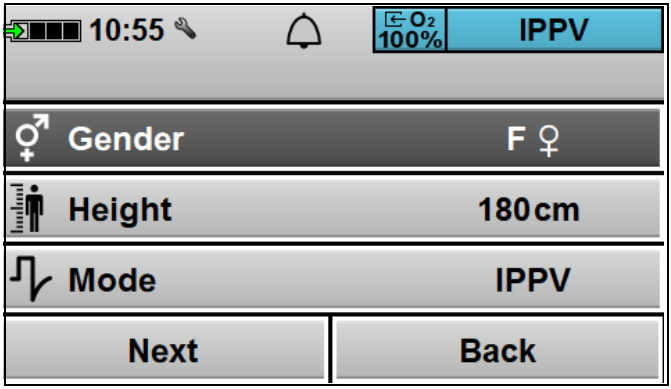
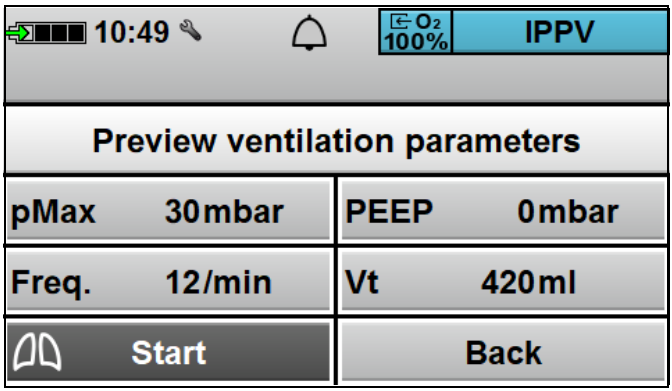


2. Select the following parameters:
   - **Gender**
   - **Height**
   - **Ventilation mode**



3. Select **Next**.
   The device shows a preview of the ventilation parameters calculated.
4. If necessary: Adjust ventilation parameters.
5. Connect the patient to the device by a ventilation mask or tracheal tube.
6. Select **Start**. The device starts ventilation.

Result Ventilation for a new patient has been started.

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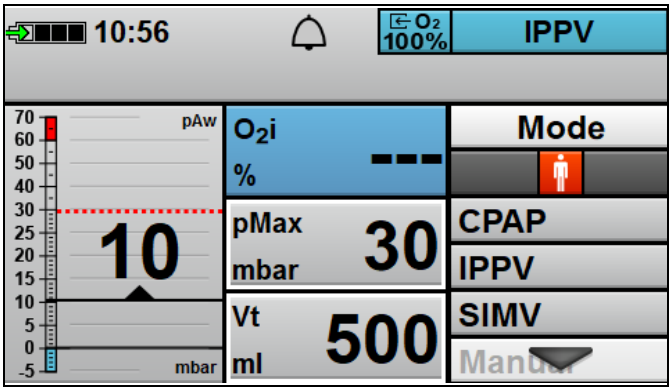
6.4 Switching ventilation mode

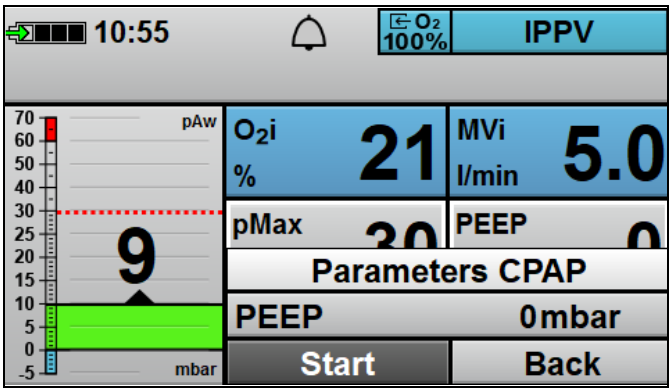
Requirement

- The device is switched on (see "6.1 Switching on the device", page 54).
- Ventilation has been started (see "6.3 Starting ventilation", page 56).

1. Briefly press the menu button .
   The user menu opens.



2. Select the desired ventilation mode.
   The parameters of the new ventilation mode are displayed.



3. If necessary: Change the ventilation mode parameters.

Result The ventilation mode has been switched.

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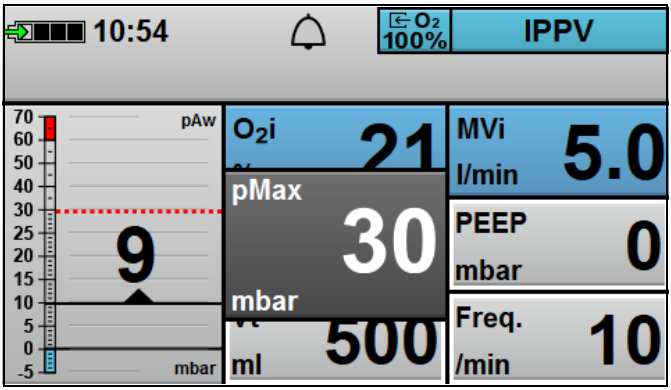
6.5 Changing ventilation parameters

Requirement

- The device is switched on (see "6.1 Switching on the device", page 54).
- Ventilation has been started (see "6.3 Starting ventilation", page 56).



1. Select the ventilation parameter you want to change using the navigation knob.
2. Change the ventilation parameter.
3. Confirm the value.
4. Repeat the steps for all the ventilation parameters you want to change.

Result Ventilation parameters have been changed.

The following parameters are mutually dependent:

- The minimum difference between pMax and PEEP is 5 mbar.
- Frequency /Vti: The product of freq. x Vti results in inspiratory minute volume MVi.
- The ventilation parameters "frequency" and "tidal volume" can only be set in meaningful combinations. Combinations resulting in a value below 1.5 l/min or above 20 l/min (BTPS) cannot be set.

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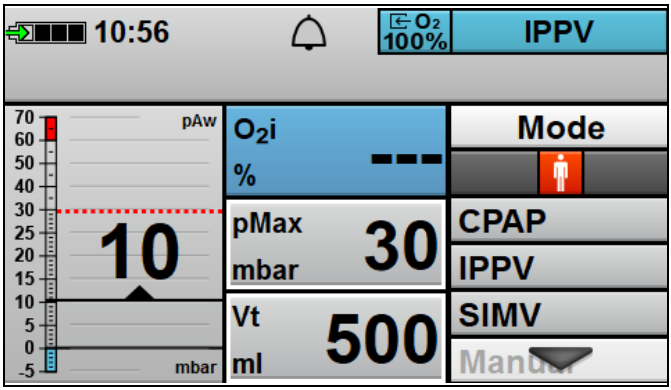
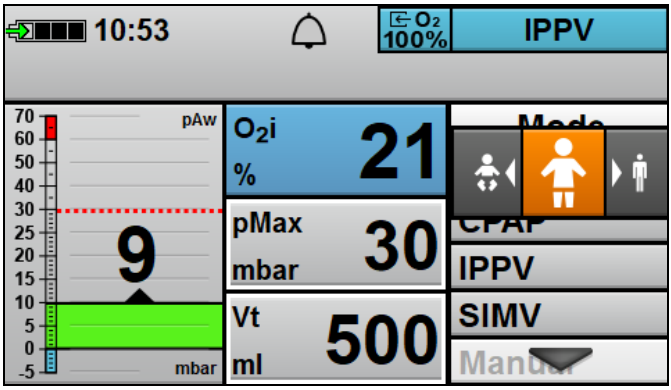
6.6 Switching patient group

Requirement

- The device is switched on (see "6.1 Switching on the device", page 54).
- Ventilation has been started (see "6.3 Starting ventilation", page 56).



1. Briefly press the menu button ⊟.
   The user menu opens.



2. Select and confirm another patient group.

Result The patient group has been switched.
The device switches to the pre-set ventilation mode for the selected patient group and starts ventilating.

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6.7 Introducing oxygen

⚠ CAUTION

Therapy disrupted by excessively high flow!
If the flow exceeds the maximum permissible value of 15 l/min, the pressure relief valve might unintentionally open during inspiration and place the therapy at risk. This might injure the patient.
⇒ Feed in oxygen only at a maximum flow of 15 l/min.

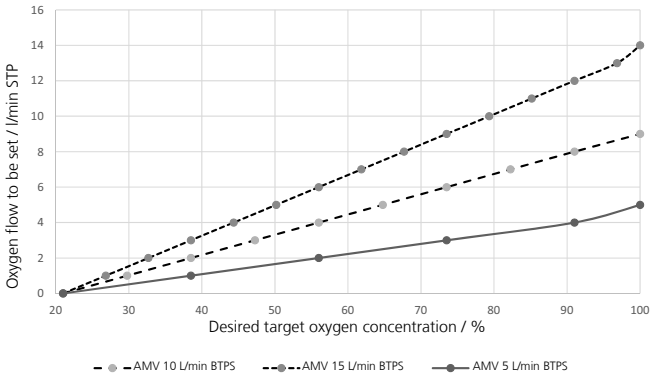
6.7.1 Setting the oxygen concentration

Requirement

- The oxygen supply is connected (see "4.4 Connecting the oxygen supply", page 40).
- The device is switched on (see "6.1 Switching on the device", page 54).
- Ventilation has been started (see "6.3 Starting ventilation", page 56).

1. Set the flow at the oxygen supply.
   The device indicates the measured oxygen concentration in the display.

If you want an oxygen concentration of 100 %, use the minute volume administered as a guide (MVi).



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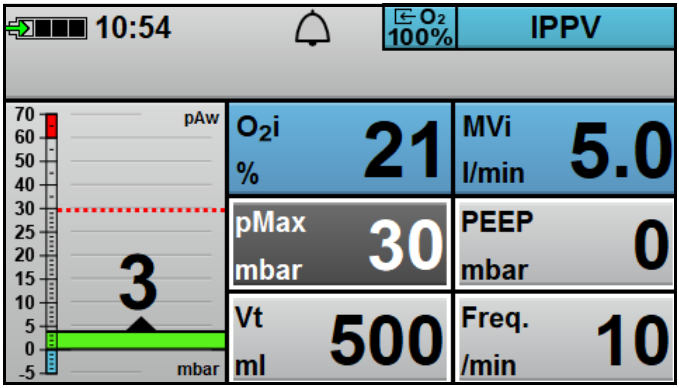
Example: If you are also feeding in oxygen at 5 l/min with a displayed MVi of 5 l/min, an oxygen concentration of 100 % will result.
If you want a lower concentration, set a lower flow on the oxygen supply until the device displays the desired oxygen concentration.



2. Read off the oxygen concentration from the display.
3. If necessary: Adjust the oxygen concentration.

Result The oxygen concentration has been set.

After starting up, the device calculates oxygen concentration for the first 30 seconds based on the ventilation parameters and flow set. After 30 seconds, the device displays the actual measured value.

6.7.2 Calculating operating time

1. Calculating the fill level of the oxygen cylinder (oxygen reserve):

Oxygen reserve = volume of oxygen cylinder x pressure in oxygen cylinder		
Example		
Volume of oxygen cylinder	10 l	2 l
Pressure in oxygen cylinder	200 bar	200 bar
Fill level of oxygen cylinder (oxygen reserve)	**2000 l**	**400 l**

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2. Calculate operating time in accordance with the table below:

Operating times of commercially-available oxygen cylinders		
$\text{Time (min)} = \frac{\text{Oxygen reserve (l)}}{\text{Flow}\left(\frac{\text{l}}{\text{min}}\right)}$		
Set FiO_2 (l/min)	**Operating time of oxygen cylinder (hh:mm)**	
	2 l volume	**10 l volume**
0.5	13:20	66:40
1	06:40	33:20
1.5	04:26	22:13
2	03:20	16:40
3	02:13	11:06
5	01:20	08:20
6	01:06	06:40
9	00:44	05:33
12	00:33	03:42
15	00:26	02:13

Result Operating time has been calculated.

6.8 Switching the device off

1. Press and hold the On/Off button ⏻ for at least 2 seconds.
2. Close the oxygen supply.

Result The device is completely switched off.

6.9 Disconnecting the oxygen supply

1. Close the oxygen cylinder valve.
2. Press and hold the On/Off button ⏻ for at least 2 seconds to switch the device off.
3. Disconnect the oxygen inlet tube from the device.
4. If necessary: Replace the empty oxygen cylinder.

Result The device has been disconnected from the oxygen supply.

6.10 After use

1. Disconnect the breathing circuit from the ventilation mask or tracheal tube.
2. Disconnect the breathing circuit from the device.
3. If necessary: Change the hygiene filter.
4. Hygienically reprocess the device and accessories (see "8 Hygienic reprocessing", page 83).
5. If necessary: Replace the ventilation mask or tracheal tube.
6. If necessary: Replace the disposable breathing circuit.
7. If necessary: Stow the accessories on the portable system.
8. If necessary: Place the device and accessories in storage (see "12 Storage", page 131).

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7 Operator menu

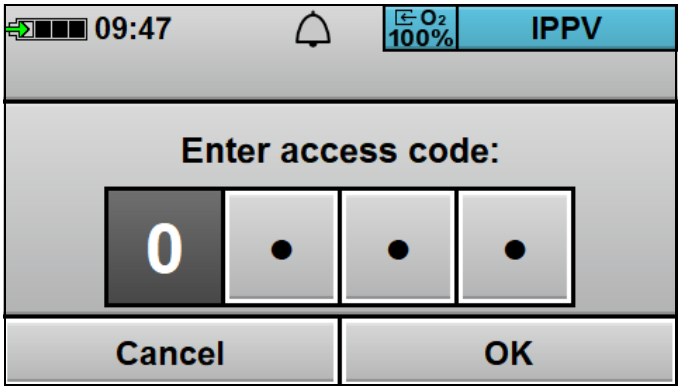
The operator menu contains the device presets which are permanently stored.

7.1 Activating the operator menu

Requirement

- The device is switched on (see "6.1 Switching on the device", page 54).
- The start screen is displayed.

1. Press and hold the menu button for 2 seconds.



2. Select access code with the navigation knob and confirm.

The operator menu is protected by an access code which on delivery is 0000. WEINMANN Emergency recommends changing this code as soon as the device is put into operation.

Result The operator menu has been activated and settings can be made.

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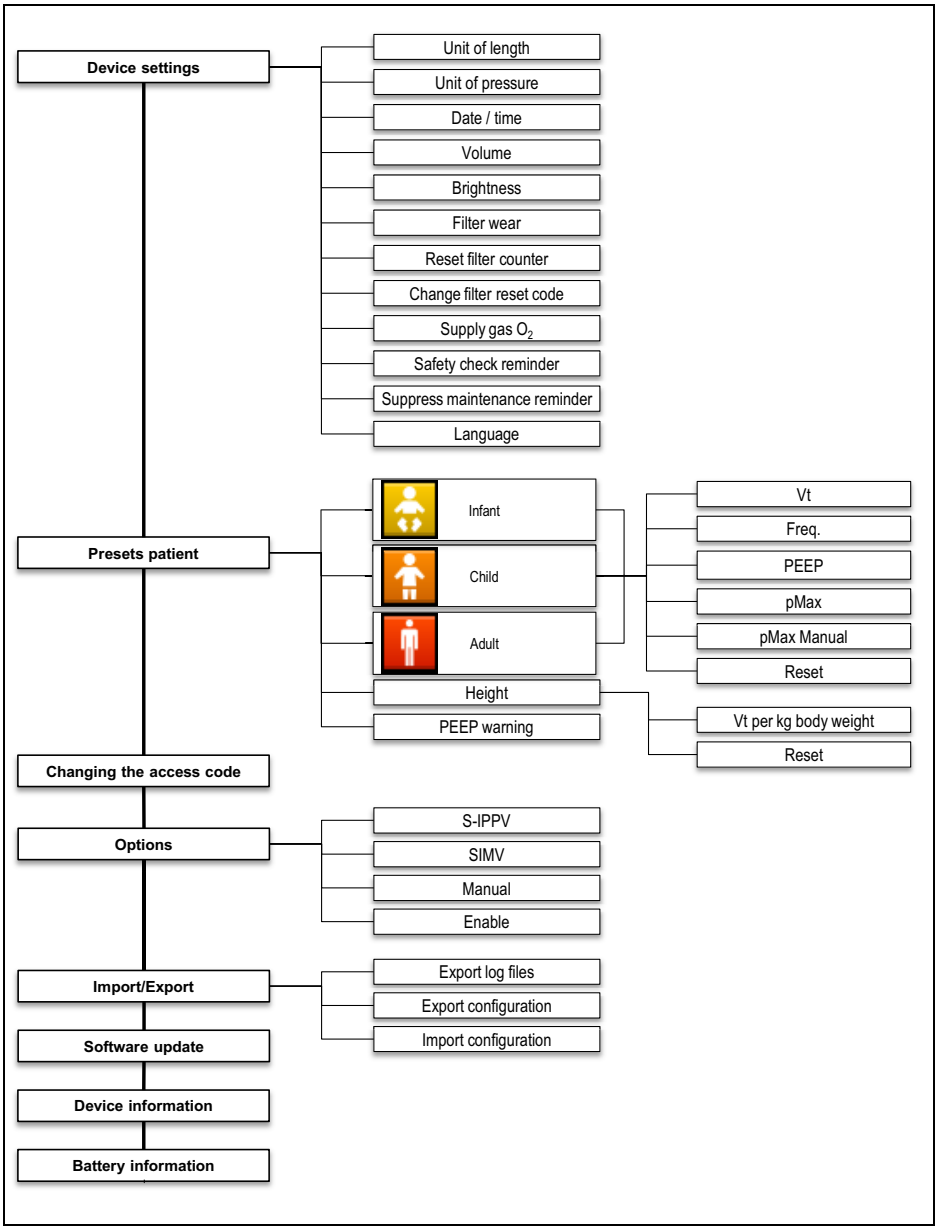
7.2 Menu structure



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7.3 Device settings

Parameter		Possible values	Description	Factory setting
Unit of length		cm inch	Here you can set the unit of length.	cm
Unit of pressure		mbar cmH_2O hPa	Here you can set the unit of pressure.	mbar
Date/time	Year	2017 to 2037	Here you can set the date and time.	-
	Month	1 to 12		
	Day	1 to 31		
	Hour	0 to 23		
	Minute	0 to 59		
Volume		100 % 50 %	Here you can set the volume of the alarm sounds.	100 %
Brightness		10 % to 100 %	Here you can set the brightness of the display.	100 %
Filter wear		Normal High Very high	Here you can select the pollution severity (e.g. by dust) for the hygiene filter.	Normal
Reset filter counter		✓	Here you can reset the filter counter.	-
Change filter reset code		Any	Here you can change the code required to reset the filter counter.	0000
Supply gas O_2		100 % 93 %	Here you can set the supply gas type.	100 %

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Parameter		Possible values	Description	Factory setting
Safety check reminder		✓	Here you can activate the safety check reminder.	Activated
Suppress maintenance reminder		Yes Cancel	The maintenance reminder can be suppressed once, for 180 days from the scheduled maintenance date. You cannot cancel this suppression.	-
Language		German (de DE) English (en US) Spanish (es ES) French (fr FR) Arabic (ar SA) Czech (cs CZ) Farsi (fa IR) Hebrew (he IL) Hindi (hi IN) Indonesian (id ID) Italian (it IT) Dutch (nl NL) Polish (pl PL) Brazilian Portuguese (pt BR) Portuguese (pt PT) Russian (ru RU) Swedish (sv SE) Thai (th TH) Chinese (zh CN)	Here you can set the language of the display texts.	-

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7.4 Patient presets

Parameter (IPPV mode)		Possible values	Description	Factory setting
Infant	Vt	50 ml – 2000 ml	Here you can preset the tidal volume.	60 ml
	Freq.	5/min – 40/min	Here you can preset the frequency.	30/min
	PEEP	0 mbar – 20 mbar	Here you can preset the positive end-expiratory pressure.	0 mbar
	pMax	10 mbar – 60 mbar	Here you can preset the maximum inspiratory pressure.	20 mbar
	pMax Manual	20 mbar – 60 mbar	Here you can preset the maximum inspiratory pressure in manual mode.	20 mbar
	Reset to factory settings	-	Here you can reset the settings for this patient group to their factory settings.	-
Child	Vt	50 ml – 2000 ml	Here you can preset the tidal volume.	200 ml
	Freq.	5/min – 40/min	Here you can preset the frequency.	20/min
	PEEP	0 mbar – 20 mbar	Here you can preset the positive end-expiratory pressure.	0 mbar
	pMax	10 mbar – 60 mbar	Here you can preset the maximum inspiratory pressure.	25 mbar
	pMax Manual	10 mbar – 60 mbar	Here you can preset the maximum inspiratory pressure in manual mode.	25 mbar
	Reset to factory settings	-	Here you can reset the settings for this patient group to their factory settings.	-
Adult	Vt	50 ml – 2000 ml	Here you can preset the tidal volume.	500 ml
	Freq.	5/min – 40/min	Here you can preset the frequency.	10/min
	PEEP	0 mbar – 20 mbar	Here you can preset the positive end-expiratory pressure.	0 mbar
	pMax	10 mbar – 60 mbar	Here you can preset the maximum inspiratory pressure.	30 mbar
	pMax Manual	20 mbar – 60 mbar	Here you can preset the maximum inspiratory pressure in manual mode.	30 mbar
	Reset to factory settings	-	Here you can reset the settings for this patient group to their factory settings.	-

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Parameter (IPPV mode)		Possible values	Description	Factory setting
Patient's height	Vt per kg body weight	4 ml/kg – 10 ml/kg	Here you can preset the tidal volume per kg body weight.	6 ml/kg
	Reset	-	Here you can reset the tidal volume per kg body weight to the factory setting.	
PEEP warning		1 mbar – 21 mbar	Here you can preset the PEEP at which the device generates a warning.	11 mbar

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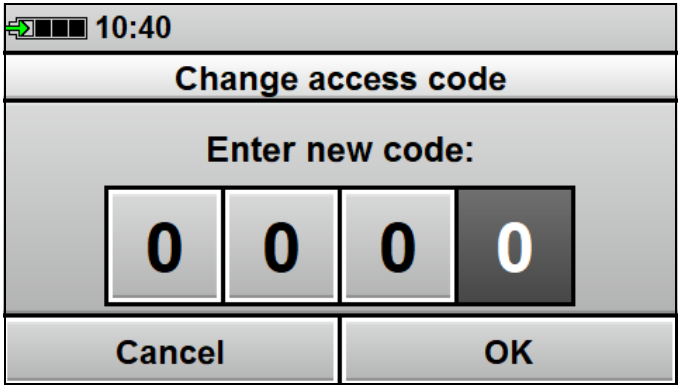
7.5 Changing the access code

Requirement The operator menu is activated (see "7.1 Activating the operator menu", page 67).

1. Select the **Change access code** menu item.



2. Select the new access code with the navigation knob and confirm with **OK**.

3. Click **OK** to confirm that you really want to change the access code.

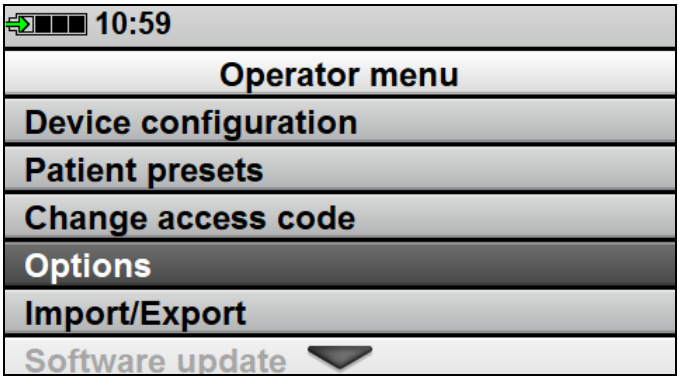
Result The access code for activating the operator menu has been changed.

7.6 Options

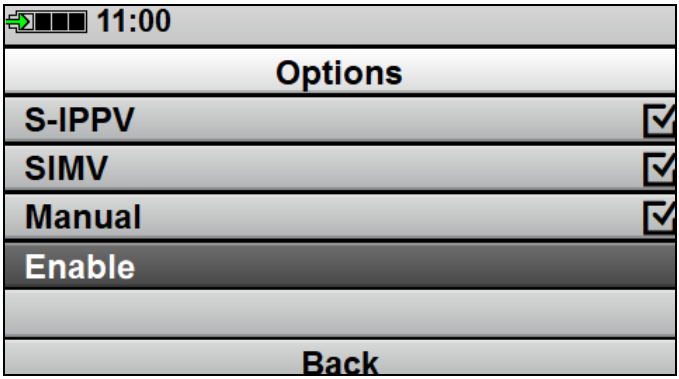
7.6.1 Enabling options

Requirement

- The operator menu is activated (see "7.1 Activating the operator menu", page 67).
- The latest software version has been installed on the device (see "7.8 Updating software", page 79).



1. Select the **Options** menu item.



2. Select the **Enable** menu item.

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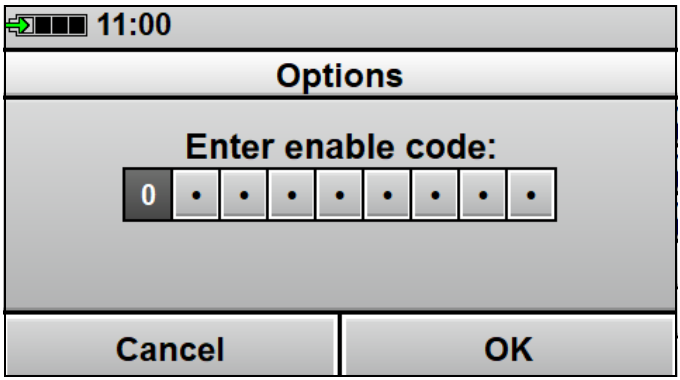

3. Enter the access code using the navigation knob.
4. Confirm the access code with **OK**.
   The display indicates the enabled option in the **Options** menu item of the operator menu.
5. Activate or deactivate an option using the navigation knob.
6. To exit the operator menu, select **Back**.

Result An option has been enabled for use and activated/deactivated.

7.6.2 Description of options

S-IPPV

See "9.4 S-IPPV", page 112.

SIMV

See "9.3 SIMV", page 111.

Manual

See "9.5 Manual", page 114.

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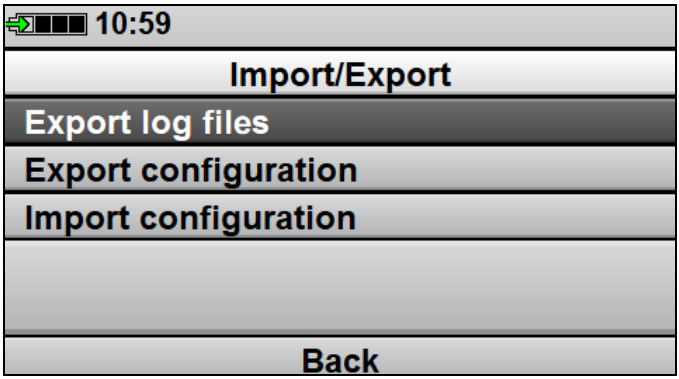
7.7 Importing/exporting data

Requirement

- There is an SD card in the device
  (see "7.7.1 Inserting an SD card", page 77).
- The operator menu is activated
  (see "7.1 Activating the operator menu", page 67).



1. Select the **Import/Export** menu item.
2. Use the navigation knob to select one of the following actions:
   - **Export log files**
     The device saves existing log files to the SD card.
   - **Export configuration**
     The device saves the current configuration to the SD card.
   - **Import configuration**
     The device imports a configuration from the SD card.

Result Data has been imported/exported. The device places a green check mark against the executed action ✓.

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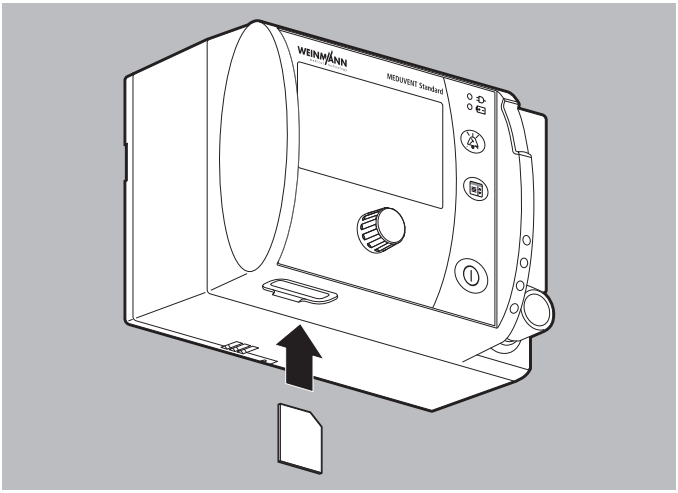
7.7.1 Inserting an SD card

1. Open the splash guard covering the SD card slot.



2. Push the SD card into the SD card slot until it clicks into place. When doing so: The beveled corner of the SD card must be at the front on the right during insertion.
3. Close the splash guard.

Result The SD card is inserted in the device and ready for use.

7.7.2 Removing the SD card

Requirement An SD card is in the SD card slot.

1. Open the splash guard covering the SD card slot.

NOTICE

Data loss or damage to property resulting from incorrect handling of the SD card during data export or software update

If you remove the SD card while exporting log files or updating the device software, data might be lost or the device might be damaged.

⇒ Only remove the SD card when no log files are being exported and the device software is not being updated.

2. Briefly press on the SD card.
   The SD card is ejected slightly.

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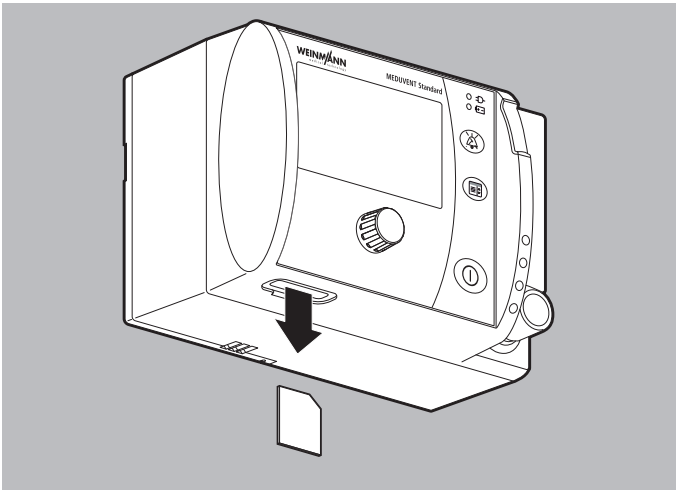

3. Remove SD card.

⚠ WARNING

Disrupted or failed therapy due to inadequate protection from dust and damp!
If the interfaces for the SD card or the breathing circuit are not protected when transporting the device in a dusty or damp environment, disruption or failure of therapy might occur as a result of device failure. This might expose the patient to the risk of serious or life-threatening injury and damage the device.
⇒ Close the SD card cover to assure IP protection.
⇒ Connect the breathing circuit or close the protective caps to assure IP protection.

4. Close the splash guard to protect the device from ingress of moisture.

Result The SD card is removed.

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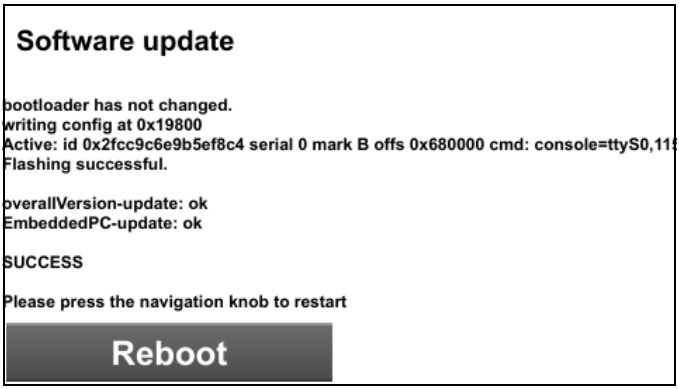
7.8 Updating software

7.8.1 Performing a software update

Requirement

- The device is connected to line power.
- The operator menu is activated (see "7.1 Activating the operator menu", page 67).

1. If necessary: Download software from the Login area of the WEINMANN Emergency website to the SD card.
2. If the software is available as a ZIP file: Unzip the software. The folder contains the software in a file named **WM35756-x.x.hex**.
3. Place the file in the SD card's root directory.
   When doing so: The software update file must not be in a sub-folder.
4. Insert SD card (see "7.7.1 Inserting an SD card", page 77).
5. Select the **Software update** menu item.



6. Select Software update.

NOTICE

Damage to property resulting from malfunctions during updating of the device software!
Moving the device and/or pressing buttons during the update might cancel the update and damage the device.
⇒ Do not turn the device off during the update.
⇒ Do not disconnect the device from line power during the update process.
⇒ Do not move the device during the update.
⇒ Do not press any buttons on the device during the update.
⇒ Do not remove the SD card during the update.

7. Select **OK** to perform the software update.
   The device updates the software. When the procedure is complete, **SUCCESS** appears on the display.
8. Press the navigation knob to restart the device.
   The device restarts and the start menu appears on the display.
9. Perform a function check (see "5 Function check", page 44).

Result The software has been updated.

After a software update has been performed, the file "update.txt" is saved to the SD card. The file contains information about the software update performed. This helps you in the context of quality management. You can open the file with a word processing program as well as print it out and sign it.

```
Softwareupdate durchgeführt / software update performed:
Datum / date: 2019-05-15 21:30:37
Seriennummer / serial number: 89
Updatedatei / update file: WM35756-X.XX.hex


Unterschrift / signature:
```

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7.9 Device information

Parameter		Description
Serial numbers	Device	Here you can find out the device serial number. This is located on the device information label.
	Mainboard	Here you can find out the mainboard serial number.
	Blower	Here you can find out the blower serial number.
Device ID	Device ID	Here you can find out the device ID. This is required to procure optional functions.
Counter	Days until next device check	Here you can find out the number of days remaining until the next device check is due.
	Days until next maintenance	Here you can find out the number of days remaining until the next maintenance is due.
	Last passed function check	Here you can find out the last time a function check was passed.
Version numbers	Software version	Here you can find out which software version is currently installed on the device.

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7.10 Battery information

Parameter		Description
Battery data	Serial number	Here you can find out the serial number of the rechargeable battery.
	Date of manufacture	Here you can find out the date of manufacture of the rechargeable battery.
	Temperature	Here you can find out the temperature of the rechargeable battery.
	Charging cycles	Here you can find out how many charging cycles the rechargeable battery has already completed.
	Battery capacity	Here you can find out the current rechargeable battery capacity.
	Remaining charge	Here you can find out the remaining charge of the rechargeable battery.
	Relative state of charge	Here you can find out the relative state of charge of the rechargeable battery in %.
	Battery voltage	Here you can find out the battery voltage measured by the rechargeable battery itself.
	Cell voltage 1	Here you can find out the voltage of the first internal rechargeable battery cell.
	Cell voltage 2	Here you can find out the voltage of the second internal rechargeable battery cell.
	Cell voltage 3	Here you can find out the voltage of the third internal rechargeable battery cell.
	Battery current	Here you can find out the current value for battery current.
	Max. error	Here you can find out the rechargeable battery's own estimate of the accuracy of the capacity calculation.
	Status word	Here different states of the rechargeable battery are displayed in encoded form.
Device data	Battery voltage	Here the rechargeable battery voltage measured by the device is displayed.
	Line voltage	Here the line voltage measured by the device is displayed.

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8 Hygienic reprocessing

The following sections set out the procedures necessary for hygienic reprocessing. The chapter is divided into the following sections:

- Device
- Accessories
- Breathing circuit

Read this chapter in full before starting hygienic reprocessing. If you have any questions regarding hygienic reprocessing, contact the manufacturer, WEINMANN Emergency, or a technician specifically authorized by the manufacturer.

⚠ WARNING

Disrupted and failed therapy due to incorrect use of disposables!
Reusing and reprocessing disposables might induce unpredictable reactions as a result of aging, embrittlement, wear, thermal loading and chemical action. This might place the functionality and safety of the device at risk, and cause the patient or user to suffer serious or life-threatening injury.
⇒ Do not reuse disposables.
⇒ Do not subject disposables to hygienic reprocessing.

⚠ WARNING

Infection of the user or of the next patient resulting from incorrect handling of a contaminated hygiene filter!
A contaminated hygiene filter might cause the patient or user to suffer serious or life-threatening injury.
⇒ Always wear suitable personal protective equipment when removing a contaminated hygiene filter.
⇒ Dispose of a contaminated hygiene filter when carrying out hygienic reprocessing and do not reuse it.

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⚠ WARNING

Disrupted or failed therapy due to unsuitable cleaning agents and disinfectants!

Using incorrect cleaning agents and disinfectants might cause the device to malfunction. This might expose the patient to the risk of serious or life-threatening injury.

⇒ Never clean the device and accessories with bleach, bleach solution, or compounds containing phenols.

⇒ Use only the cleaning agents and disinfectants recommended in these instructions for use (see "8.11 Cleaning and disinfection plan", page 105).

⚠ WARNING

Loss of mechanical or electrical safety resulting from reprocessing of the device and accessories with unsuitable cleaning agents and disinfectants!

Using incorrect cleaning and disinfectant products might cause damage to the surface of the device and/or accessories, as well as impairing electrical and insulating properties. This might expose the user and the patient to the risk of serious or life-threatening injury.

⇒ Carry out hygienic reprocessing in accordance with the cleaning and disinfection plan (see "8.11 Cleaning and disinfection plan", page 105).

⚠ WARNING

Disrupted or failed therapy due to liquid in the breathing circuit after hygienic reprocessing of the reusable measuring circuit!

Droplets inside the reusable measuring circuit might falsify the results delivered by it. This might expose the patient to the risk of serious or life-threatening injury.

⇒ After hygienic reprocessing of the reusable measuring circuit, allow all the tubes in the breathing circuit to dry thoroughly.

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⚠ CAUTION

Risk of infection resulting from defective hygienic reprocessing!

The use of devices and accessories which have not been subjected to hygienic reprocessing might lead to infections if they come into contact with the skin of the patient or user or the patient's airways. This might expose the patient and the user to the risk of serious or life-threatening injury.

⇒ Subject the device and accessories to hygienic reprocessing after every use.

⇒ Carry out hygienic reprocessing in accordance with the cleaning and disinfection plan (see "8.11 Cleaning and disinfection plan", page 105).

⇒ When reprocessing the device and accessories, use only the recommended cleaning agents and disinfectants.

⇒ Follow the instructions for use of the cleaning and disinfectant product being used.

⇒ Follow the instructions for use of the accessories.

⇒ Wear suitable personal protective equipment.

⇒ To reduce germ contamination, always disinfect the reusable measuring circuit by immersion (see "8.7 Disinfecting the reusable measuring circuit by immersion", page 100) or steam-sterilize it.

⚠ CAUTION

Risk of infection resulting from use of a contaminated device for subsequent ventilation procedures!

If the device is used in a contaminated environment, it might draw in contaminated ambient air. This might expose the patient to the risk of serious or life-threatening injury.

⇒ If you suspect that the interior of the device has been contaminated, take the device out of service and contact the manufacturer.

⚠ CAUTION

Risk of infection from contaminated disposables!

Reused disposables might cause infections if they come into contact with airways. This might expose the patient and the user to the risk of serious or life-threatening injury.

⇒ Do not reuse disposables.

⇒ Do not subject disposables to hygienic reprocessing.

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⚠ CAUTION

Risk of injury and damage to property from residues of disinfectants or cleaning agents in the device or the breathing circuit!

Residues of disinfectants or cleaning agents might get into the patient's lungs. This might cause the patient serious or life-threatening injury, as well as damaging the device.

⇒ After hygienic reprocessing, rinse all parts of the breathing circuit thoroughly with water and allow them to dry completely.

⇒ After hygienic reprocessing, check the device and the breathing circuit visually for residues of cleaning agents or disinfectants products, and remove any residues as necessary.

⇒ Perform a complete function check after every hygienic reprocessing procedure.

⇒ Do not immerse the device in liquids.

⇒ Always ensure the hygiene filter is inserted in the device when carrying out hygienic reprocessing.

⇒ Clean/disinfect the filter compartment only when replacing the filter.

⇒ When cleaning/disinfecting the filter compartment, only moisten it, do not wet it.

8.1 Intervals

Part	**Interval**		
	After every use	**At least 1x weekly**	**After infection transport or exceeding filter service life (at least every 6 months)**
All parts (except hygiene filter)	x	x	-
Hygiene filter	-	-	x

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8.2 Preparing for hygienic reprocessing

Requirement

- The device is switched off (see "6.8 Switching the device off", page 65).
- The device is disconnected from the patient.

1. Disconnect the device from the power supply.
2. Remove accessories from the device.
3. Disassemble the reusable breathing circuit into its constituent parts (see "8.3.1 Disassembling the reusable breathing circuit", page 87).
4. If necessary: Disassemble the accessories into their constituent parts.
5. Dispose of all disposables properly (see "13 Disposal", page 132).

Result All parts have been prepared for hygienic reprocessing.

8.3 Removing/installing the reusable breathing circuit

The illustrations in this section show all the possible components of the reusable breathing circuit. Depending on type, your reusable breathing circuit might not include some components.

8.3.1 Disassembling the reusable breathing circuit

Requirement

- The device is disconnected from the breathing circuit.
- The patient is disconnected from the breathing circuit.

1. Open the protective sleeve.
2. Open the hook and loop fasteners in the protective sleeve.
3. Detach the protective cap from the patient end of the reusable breathing circuit.

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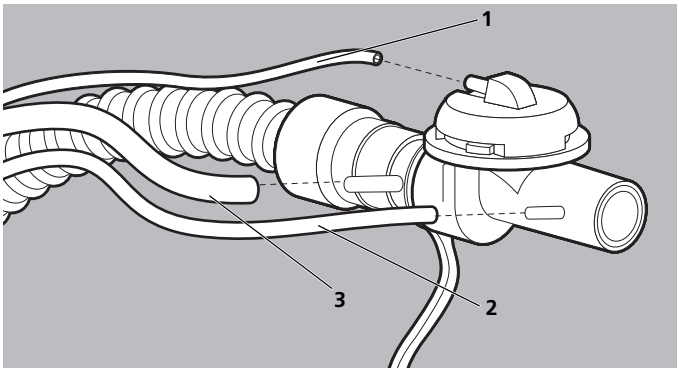
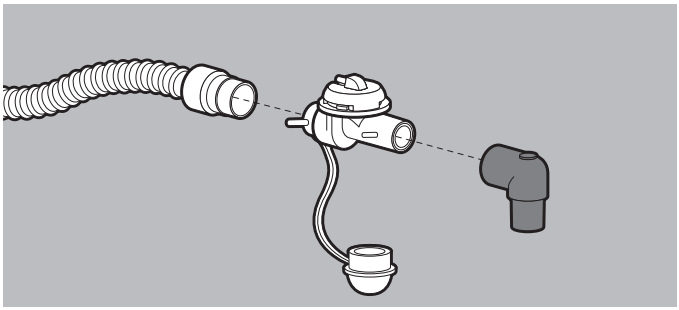
4. Disconnect the connecting cable of the MEDUtrigger from the patient end of the reusable breathing circuit.



5. Detach the following tubes from the patient valve:
   - PEEP control tube (**1**)
   - Pressure measuring tube (**2**)
   - Flexible oxygen tube (**3**)



6. Detach the elbow from the patient valve.
7. Disconnect the patient valve from the ventilation hose.

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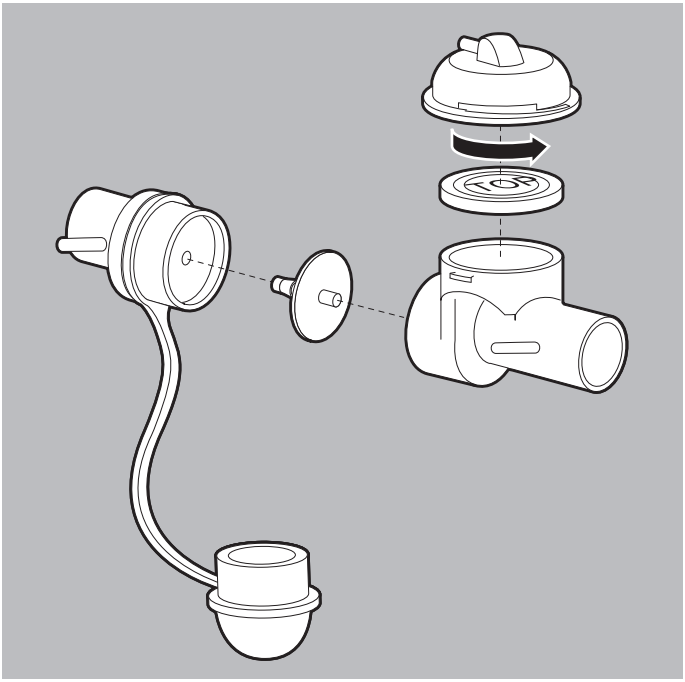
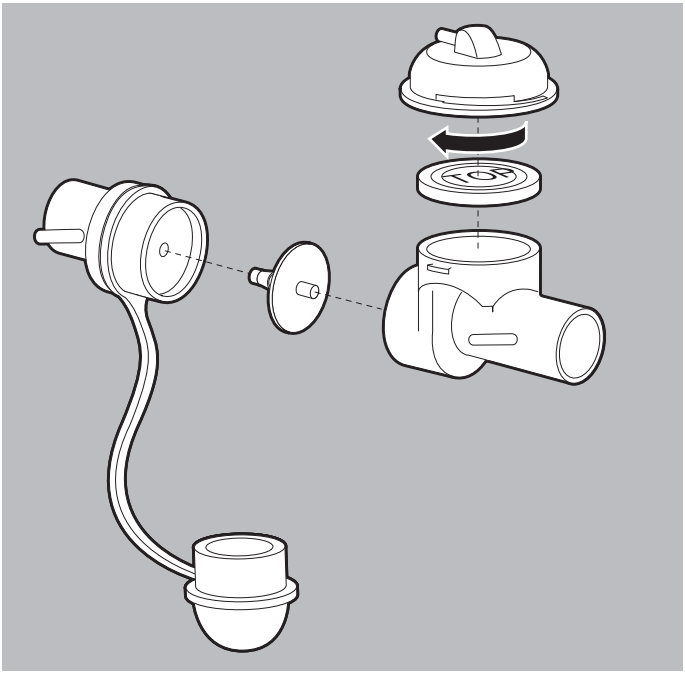


8. Remove the patient valve.
9. Detach the band of the protective cap from the check valve diaphragm holder.

Result The reusable breathing circuit has been disassembled.

8.3.2 Assembling the reusable breathing circuit

Requirement The reusable breathing circuit has been disassembled.



1. Attach the band of the protective cap to the check valve diaphragm holder.
2. Install the patient valve.
   When doing so:
   - The side of the PEEP control diaphragm marked "TOP" must be facing up toward the control cover.
   - The arrow on the control cover must be pointing toward the patient.

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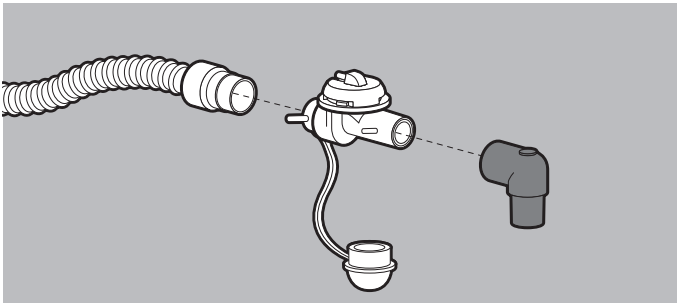
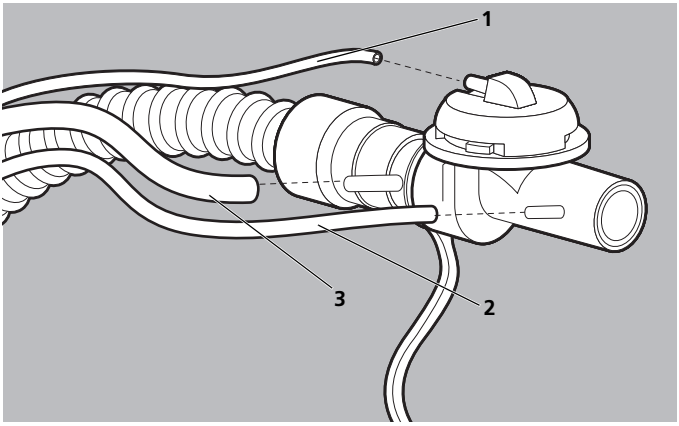


3. Connect the patient valve to the ventilation hose.
4. Connect the elbow to the patient valve.



5. Connect the following tubes to the patient valve:
   - PEEP control tube **1** (slimmest tube)
   - Pressure measuring tube **2** (medium tube)
   - Flexible oxygen tube **3** (thickest tube)

   When doing so: The tubes must be firmly attached to the patient valve.
6. Place all the tubes of the measuring circuit and the connecting cable of the MEDUtrigger in the protective sleeve.
7. Close off the patient end of the reusable breathing circuit with a protective cap.

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8. Close the hook and loop fasteners in the protective sleeve to secure all the tubes and the connecting cable of the MEDUtrigger.
9. Close the zip fastener of the protective sleeve.

Result The reusable breathing circuit has been assembled.

8.4 Cleaning parts manually

Permitted parts

Part	**Manual cleaning**
Device	Wipe down with neodisher® MediClean forte (Dr. Weigert). Dose: 10 ml/l, duration: treat all surfaces at least 2x until they are visibly clean
Filter compartment	
Hook and loop strap with clip	Wipe down with neodisher® MediClean forte (Dr. Weigert) **or** wash in a washing machine at up to 70 °C
12 V cable	Wipe down with neodisher® MediClean forte (Dr. Weigert). Dose: 10 ml/l, duration: treat all surfaces at least 2x until they are visibly clean
Charging adapter	
MEDUtrigger with connecting cable	
Reusable breathing circuit	
Ventilation hose	Immerse in neodisher® MediClean forte (Dr. Weigert) and clean Dose: 10 ml/l, duration: treat all surfaces at least 2x until they are visibly clean. Cleaning is only permissible in conjunction with disinfection by immersion or steam sterilization.
Patient valve	
Elbow	
Protective cap	
Reusable measuring circuit, comprising: • PEEP control tube • Pressure measuring tube • Flexible oxygen tube • Measuring circuit connector	

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Requirement

- The parts exhibit visible soiling.
- Hygienic reprocessing has been prepared (see "8.2 Preparing for hygienic reprocessing", page 87).

1. For parts approved for manual cleaning, refer to the cleaning and disinfection plan (see "8.11 Cleaning and disinfection plan", page 105).
2. For the cleaning products, dose and exposure time for the individual parts, refer to the cleaning and disinfection plan (see "8.11 Cleaning and disinfection plan", page 105).
3. Prepare the cleaning solution as specified by the cleaning product manufacturer.
4. To remove all visible soiling: Brush parts thoroughly inside and out using a commercially-available soft brush suitable for plastic and which has been moistened with the cleaning product.
   When doing so:
   - Keep uneven surfaces and grooves (e.g. top and bottom of the MEDUtrigger, knob, ventilation hose connection) moist throughout the time to take effect and brush off particularly thoroughly.
   - Brush hoses/tubes with a special lumen brush.

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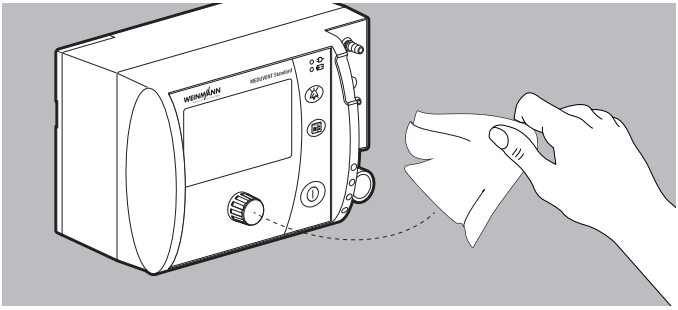

5. If the cleaning and disinfection plan stipulates that parts have to be wiped down: Wipe down parts using a clean, lint-free disposable cloth moistened with cleaning solution.
   When doing so:
   - Use a fresh wipe for every cleaning process.
   - Carefully wipe down all surfaces.
   - All surfaces must be wetted with cleaning solution.
   - The exposure time specified in the cleaning and disinfection plan must be observed.
   - Wipe over uneven surfaces and grooves, in particular, again.
6. If the cleaning and disinfection plan stipulates that parts have to be immersed: Immerse parts in the cleaning solution.
   When doing so:
   - Swirl parts around in the cleaning solution so as to wet all surfaces and any cavities completely.
   - Observe the exposure time specified in the cleaning and disinfection plan.
7. If visible soiling is still present: Repeat manual cleaning.
8. Thoroughly rinse parts immersed in the cleaning solution in water of potable quality.
9. Wipe down remaining parts with a damp cloth to remove residues of the cleaning product.
10. Wipe the MEDUtrigger dry with a dry cloth.

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11. Allow all parts to dry completely at room temperature.

Result Parts have been cleaned manually.

8.4.1 Cleaning the reusable measuring circuit manually

Requirement The reusable measuring circuit has been detached from the patient valve and the device.

1. For the cleaning products, dose and exposure time, refer to the cleaning and disinfection plan (see "8.11 Cleaning and disinfection plan", page 105).
2. Prepare the cleaning solution as specified by the cleaning product manufacturer.
3. Connect a sterile disposable syringe (20 ml) to a free end of the pressure measuring tube.
4. Draw the cleaning solution through the pressure measuring tube into the disposable syringe until both are completely full.
5. Detach the disposable syringe from the pressure measuring tube.
6. Immerse the reusable measuring circuit in cleaning solution. When doing so:
   - All surfaces and lumina must be wetted completely.
   - The exposure time specified in the cleaning and disinfection plan must be observed.
7. Rinse the outside of the reusable measuring circuit with water of potable quality.
8. Rinse the inside of the reusable measuring circuit at least 8 times with water of potable quality with the aid of the disposable syringe.
   When doing so: Flush only in one direction.
9. Allow the reusable measuring circuit to dry completely.
10. If necessary: Allow the ventilation hose to dry completely.

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11. Check the reusable measuring circuit for residues and residual soiling.
12. If visible soiling is still present: Repeat manual cleaning.

Result The reusable measuring circuit has been cleaned manually.

8.5 Disinfecting parts by wiping

Permitted parts

Part	Disinfection by wiping
Device	Wipe down with Incidin™ Oxywipe S (Ecolab)
Testing bag	
12 V cable	
Charging adapter	
Filter compartment	When replacing the filter: Wipe down with Incidin™ Oxywipe S (Ecolab)

Requirement The parts have been manually cleaned and are visibly clean (see "8.4 Cleaning parts manually", page 92).

1. For parts approved for disinfection by wiping, refer to the cleaning and disinfection plan (see "8.11 Cleaning and disinfection plan", page 105).
2. For the cleaning products, dose and exposure time for the individual parts, refer to the cleaning and disinfection plan (see "8.11 Cleaning and disinfection plan", page 105).
3. Prepare the solution for disinfection as specified by the disinfectant manufacturer.

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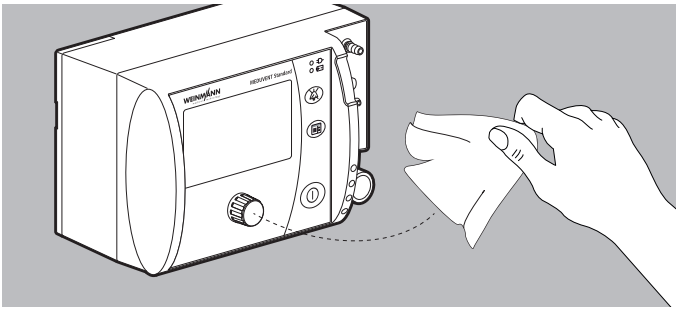
4. Disinfect parts by wiping with one of the products listed (see "8.11 Cleaning and disinfection plan", page 105). When doing so:



- Wet uneven surfaces and grooves (e.g. knob, ventilation hose connection) adequately with disinfectant.
- When replacing the filter: Disinfect the filter compartment by wiping.

5. Allow the parts to dry completely.
6. Check the parts for residues and residual soiling.
7. If visible soiling remains: Repeat disinfection by wiping.

Depending on the disinfectant, it might be necessary to wipe over with a neutralizing product afterward.

Result The parts have been disinfected by wiping.

8.6 Disinfecting parts by immersion

Permitted parts

Part	Disinfection by immersion
Reusable breathing circuit	
Ventilation hose	Immerse in gigasept® FF (new) (Schülke) Dose: 50 ml/l Exposure time: 15 min
Patient valve	
Elbow	
Protective cap	
Service label	
Protective sleeve	
Reusable measuring circuit, comprising: • PEEP control tube • Pressure measuring tube • Flexible oxygen tube • Measuring circuit connector	
Hook and loop strap with clip	

Requirement

The parts intended for disinfection by immersion have been cleaned manually (see "8.11 Cleaning and disinfection plan", page 105).

1. For parts approved for disinfection by immersion, refer to the cleaning and disinfection plan (see "8.11 Cleaning and disinfection plan", page 105).
2. For the disinfectants, dose and exposure time for the individual parts, refer to the cleaning and disinfection plan (see "8.11 Cleaning and disinfection plan", page 105).
3. Prepare the solution for disinfection by immersion as specified by the disinfectant manufacturer.
4. Immerse parts in the solution for disinfection by immersion. When doing so:
   - All cavities must be filled.
   - There must be no air bubbles.
   - All surfaces must be wetted.

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- Swirl parts around in the solution for disinfection by immersion so as to wet all surfaces and any cavities completely.
- Observe the exposure time specified in the cleaning and disinfection plan.

5. After the specified exposure time, rinse the parts in water of potable quality for 5 minutes to remove all disinfectant residues.
6. Allow the parts to dry completely.
7. Check the parts for residues and residual soiling.
8. In the case of visible soiling: Repeat cleaning and disinfection.

Result The parts have been disinfected by immersion.

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8.7 Disinfecting the reusable measuring circuit by immersion

The principle described applies to the following parts of the reusable measuring circuit:

- Pressure measuring tube
- PEEP control tube
- Flexible oxygen tube
- Measuring circuit connector

Requirement

- The reusable measuring circuit has been disconnected from the reusable breathing circuit (see "8.3.1 Disassembling the reusable breathing circuit", page 87).
- The reusable measuring circuit has been cleaned manually.

1. For the disinfectants, dose and exposure time for the individual parts, refer to the cleaning and disinfection plan (see "8.11 Cleaning and disinfection plan", page 105).
2. Prepare the solution for disinfection by immersion as specified by the disinfectant manufacturer.
3. Connect a sterile disposable syringe (20 ml) to a free end of a tube.

⚠ CAUTION

Risk of infection and contamination resulting from defective hygienic reprocessing of the measuring circuit!
Flushing the measuring circuit in alternate directions does not ensure absence of germs, and might injure the patient.
Flush measuring tubes only in one direction.

4. Draw the solution for disinfection by immersion through the tube into the disposable syringe until both are completely full.
5. Detach the disposable syringe from the tube.

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6. Immerse the tube in the solution for disinfection.
   When doing so:
   - All surfaces and lumina must be wetted completely.
   - Observe the exposure time specified in the cleaning and disinfection plan.
7. Once the exposure time has elapsed: Rinse the tube at least 8 times in water of potable quality using the syringe.
   When doing so: Flush only in one direction.
8. Following this principle and carry out the procedure for each tube.
9. Allow the tubes to dry completely.
10. If necessary: Dry the tubes with medical compressed air or medical oxygen.
11. Check the tubes for residues and residual soiling.
12. If visible soiling is present: Repeat disinfection by immersion.

Result The reusable measuring circuit has been disinfected by immersion.

8.8 Reprocessing parts mechanically

As an alternative to manual cleaning and disinfection, certain parts can also be cleaned and disinfected by mechanical means.

Permitted parts

Part	**Mechanical reprocessing**
Hook and loop strap with clip	Wash with Derval SOLO and Ottalin PERACET at up to 70 °C
Reusable breathing circuit	
Ventilation hose	Cleaning: neodisher® MediClean forte (Dr. Weigert): 0.5 %, 55 °C, 10 minutes Thermal disinfection: 90 °C, 5 min (corresponds to A0 value 3000)
Patient valve	
Elbow	
Protective cap	

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Part	Mechanical reprocessing
Protective sleeve	Wash at 60 °C in an industrial washing machine Cleaning product: Derval SOLO (RKI) (Kreussler) Dose: 2 ml/l and disinfectant: Ottalin PERACET (Kreussler) Dose: 2 ml/l Exposure time: 10 min, type AB
Reusable measuring circuit, comprising: • PEEP control tube • Pressure measuring tube • Flexible oxygen tube • Measuring circuit connector	Cleaning: neodisher® MediClean forte (Dr. Weigert): 0.5 %, 55 °C, 10 minutes Thermal disinfection: 90 °C, 5 min (corresponds to A0 value 3000)

Requirement The parts have been prepared for mechanical reprocessing (see "8.2 Preparing for hygienic reprocessing", page 87).

1. For parts approved for mechanical cleaning and disinfection, refer to the cleaning and disinfection plan (see "8.11 Cleaning and disinfection plan", page 105).
2. Place the parts in a washer-disinfector. When doing so:
   - The exposure time specified in the cleaning and disinfection plan must be observed.
   - Connect tubes to the washer-disinfector.
   - It must be possible for the flow to pass fully through all parts and lumina.
   - The water must be able to drain off.
3. Add cleaning product in accordance with the instructions for use for the washer-disinfector.

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4. If necessary: Add neutralizer in accordance with the instructions for use for the washer-disinfector.
5. Start the mechanical reprocessing program.
6. Allow parts to dry completely at room temperature.
7. Check the parts for residues and residual soiling.
8. If visible soiling remains: Repeat mechanical cleaning and disinfection.

Result The parts have been mechanically cleaned and disinfected.

8.8.1 Reprocessing protective sleeve mechanically

1. Open the protective sleeve completely.
2. Wash the protective sleeve at 60 °C in a washing machine, or by an approved industrial washing process, adding the cleaning product quoted in the cleaning and disinfection plan (see "8.11 Cleaning and disinfection plan", page 105). When doing so: The manufacturer's instructions must be followed.
3. Allow the protective sleeve to dry completely.

Result The protective sleeve is disinfected

8.9 Steam-sterilizing parts (optional)

If you intend to perform steam sterilization, do so in accordance with your in-house procedures.

Requirement
- The parts intended for steam sterilization are visibly clean.
- The parts intended for steam sterilization are disinfected.

1. For parts approved for steam sterilization, refer to the cleaning and disinfection plan (see "8.11 Cleaning and disinfection plan", page 105).

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2. Steam-sterilize parts using a device conforming to EN 285. When doing so:
   - Use a temperature of 134 °C and a dwell time of 5 minutes

   or

   - Use a temperature of 132 °C and a dwell time of 4 minutes
   - The instructions of the manufacturer of the steam sterilizer must be followed.

Result The parts have been steam-sterilized.

8.10 Preparing parts for reuse

Requirement The parts have been subjected to hygienic reprocessing according to the cleaning and disinfection plan.

1. Check all parts for damage resulting from use (e.g. tension cracks or cable breaks).
2. Replace damaged parts.
3. Assemble the reusable breathing circuit (see "8.3.2 Assembling the reusable breathing circuit", page 90).
4. Install the accessories.
5. Reconnect the power supply (see "4.2 Connecting a power supply", page 34).
6. Perform a function check (see "5 Function check", page 44).
7. Place parts in storage in accordance with the storage conditions (see "15 Technical data", page 138).

Result The parts are ready for use again.

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8.11 Cleaning and disinfection plan

Carry out hygienic reprocessing according to the following tables after **every** use:

8.11.1 Device and accessories

Part	Manual cleaning (only necessary in case of visible soiling)	Disinfection by wiping	Disinfection by immersion	Mechanical reprocessing	Sterilization
Device	Wipe down with neodisher® MediClean forte (Dr. Weigert). Dose: 10 ml/l, duration: treat all surfaces at least 2x until they are visibly clean	Wipe down with Incidin™ Oxywipe S (Ecolab)	Not permitted	Not permitted	Not permitted
12 V cable					
Charging adapter					
MEDUtrigger with connecting cable					
Filter compartment		When replacing the filter: Wipe down with Incidin™ Oxywipe S (Ecolab)			
Hook and loop strap with clip	Wipe down with neodisher® MediClean forte (Dr. Weigert)	Not permitted	Immerse in gigasept® FF (new) (Schülke) Dose: 50 ml/l Exposure time: 15 min	Wash with Derval SOLO and Ottalin PERACET at up to 70 °C	Not permitted

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Part	Manual cleaning (only necessary in case of visible soiling)	Disinfection by wiping	Disinfection by immersion	Mechanical reprocessing	Sterilization
Hygiene filter (after infection transport or exceeding filter service life (see 11.1, p. 122))	Disposable; do not reuse, dispose of properly (see 13, p. 132)				
Oxygen inlet tube					
Pressure reducer	Follow the manufacturer's instructions for use				
Portable system					
Ventilation mask					
Tracheal tube					
Breathing system filter					

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8.11.2 Breathing circuits

Part	Manual cleaning (only necessary in case of visible soiling)	Disinfection by wiping	Disinfection by immersion	Mechanical reprocessing	Sterilization
Reusable breathing circuit					
Ventilation hose Patient valve Elbow Protective cap Reusable measuring circuit	Immerse in neodisher® MediClean forte (Dr. Weigert) and clean. Dose: 10 ml/l, duration: treat all surfaces at least 2x until they are visibly clean	Not permitted	Immerse in gigasept® FF (new) (Schülke) Dose: 50 ml/l Exposure time: 15 min	Cleaning: neodisher® MediClean forte (Dr. Weigert): 0.5 %, 55 °C, 10 minutes Thermal disinfection: 90 °C, 5 min (corresponds to A0 value 3000)	Permitted as an option: Steam sterilization* **following prior disinfection:** 5 min at 134 °C or 4 min at 132 °C
Protective sleeve	Not permitted	Not permitted	Not permitted	Wash at 60 °C in an industrial washing machine Cleaning product: Derval SOLO (RKI) (Kreussler) Dose: 2 ml/l disinfectant: Ottalin PERACET (Kreussler) Dose: 2 ml/l Exposure time: 10 min, type AB	Not permitted

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Part	Manual cleaning (only necessary in case of visible soiling)	Disinfection by wiping	Disinfection by immersion	Mechanical reprocessing	Sterilization
Disposable breathing circuit					
Disposable breathing circuit	Disposable; do not reuse, dispose of properly (see 13, p. 132)				
Adapter for disposable breathing circuit	Wipe down with neodisher® MediClean forte (Dr. Weigert). Dose: 10 ml/l, duration: treat all surfaces at least 2x until they are visibly clean	Not permitted	Immerse in gigasept® FF (new) (Schülke) Dose: 50 ml/l Exposure time: 15 min	Cleaning: neodisher® MediClean forte (Dr. Weigert): 0.5 %, 55 °C, 10 minutes Thermal disinfection: 90 °C, 5 min (corresponds to A0 value 3000)	Permitted as an option: Steam sterilization* **following prior disinfection:** 5 min at 134 °C or 4 min at 132 °C

The applicable instructions are those in the instructions for use from the manufacturers of the individual components or parts. Follow these instructions for use.

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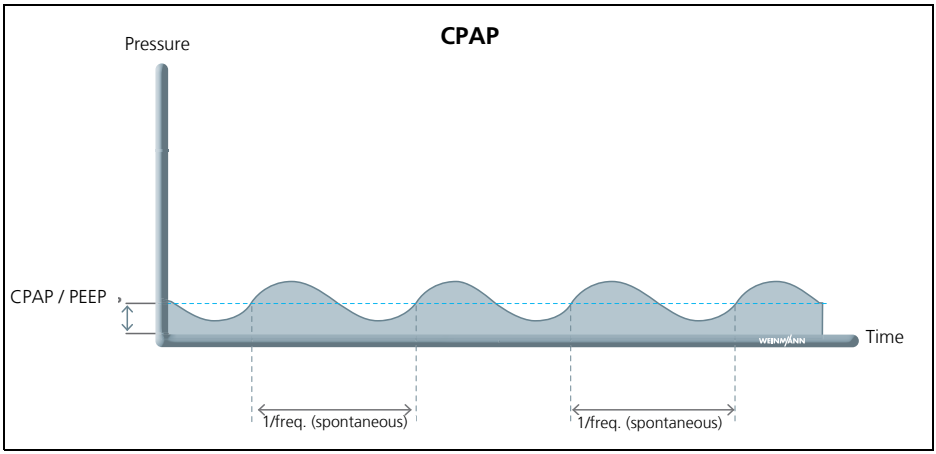
9 Description of the modes

9.1 CPAP

Description	
Abbreviation	CPAP
Long form	Continuous Positive Airway Pressure
Type	Pressure-controlled
Requirement	None
Ventilation parameters	
O_2i	MVi
pMax	PEEP



The CPAP / PEEP setting increases the lower pressure level during spontaneous breathing. This results in an increase in the functional residual capacity of spontaneously-breathing patients. The patient is able to breathe spontaneously without any restriction at the set pressure level. The CPAP mode is used exclusively on patients with adequate spontaneous breathing.

The pressure is generally set at the end of expiration (PEEP).

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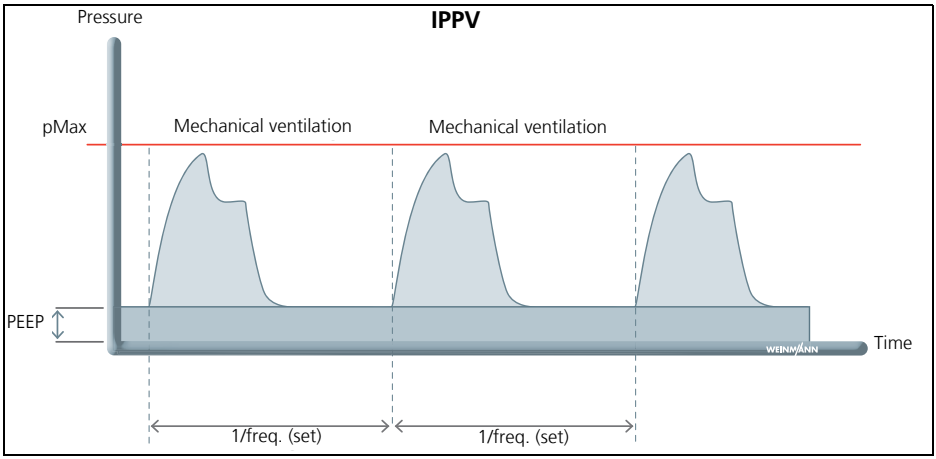
9.2 IPPV

Description	
Abbreviation	IPPV
Long form	Intermittent Positive Pressure Ventilation
Type	Volume-controlled
Requirement	None
Ventilation parameters	
pMax	PEEP
Vt	Freq.



IPPV mode is used for mandatory, volume-controlled ventilation at a fixed tidal volume. This mode is used on patients who have no spontaneous breathing. However, a spontaneously breathing patient can breathe deeply and freely during expiration. The set maximum pressure limit (pMax) ensures the safety of the patient.

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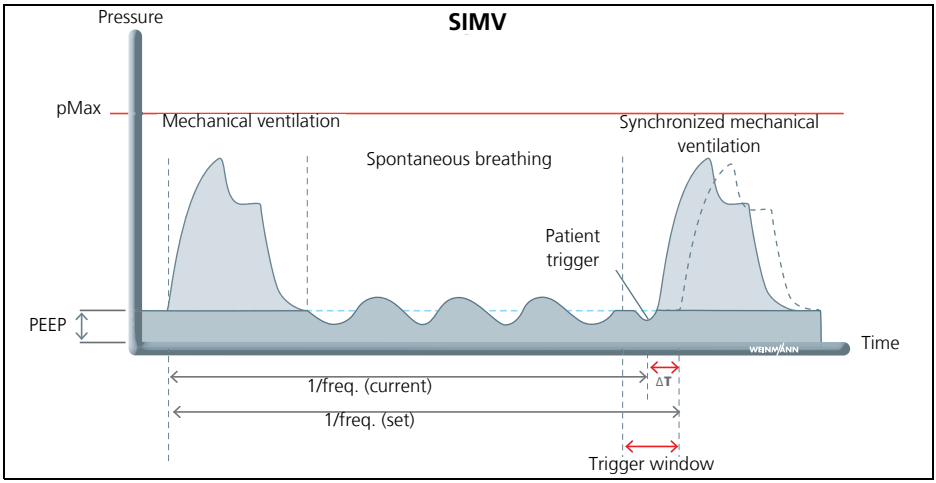
9.3 SIMV

Description	
Abbreviation	SIMV
Long form	Synchronized Intermittent Mandatory Ventilation
Type	Volume-controlled
Requirement	SIMV option has been activated
Ventilation parameters	
pMax	PEEP
Vt	Freq.



The SIMV mode is used for volume-controlled ventilation at a fixed mandatory minute volume. The patient can breathe spontaneously between the mandatory mechanical breaths and thereby increase the minute volume. During spontaneous breathing, the mandatory mechanical breath is synchronized with the patient's breathing. The mandatory minute volume and the mandatory respiratory rate remain unchanged. The set maximum pressure limit (pMax) ensures the safety of the patient.

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9.4 S-IPPV

⚠ WARNING

Risk of hyperventilation!
⇒ Monitor the patient continuously.
When using S-IPPV mode, the CO_2 concentration in the patient's blood might decrease and expose the patient to the risk of serious or life-threatening injury.

⚠ WARNING

Risk of air trapping!
⇒ Monitor airway pressure continuously.
When using S-IPPV mode, air might get trapped in the patient's lung and result in reduced gas exchange. This might expose the patient to the risk of serious or life-threatening injury.

⚠ WARNING

Risk of intrinsic PEEP!
⇒ Set the pressure limit correctly.
⇒ Monitor the patient continuously.
If the expiration phase is too short, pressure might rise slowly at the end of it. This might expose the patient to the risk of serious or life-threatening injury.

Description	
Abbreviation	S-IPPV
Long form	Synchronized Intermittent Positive Pressure Ventilation
Type	Volume-controlled
Requirement	S-IPPV option has been activated
Ventilation parameters	
pMax	PEEP
Vt	Freq.

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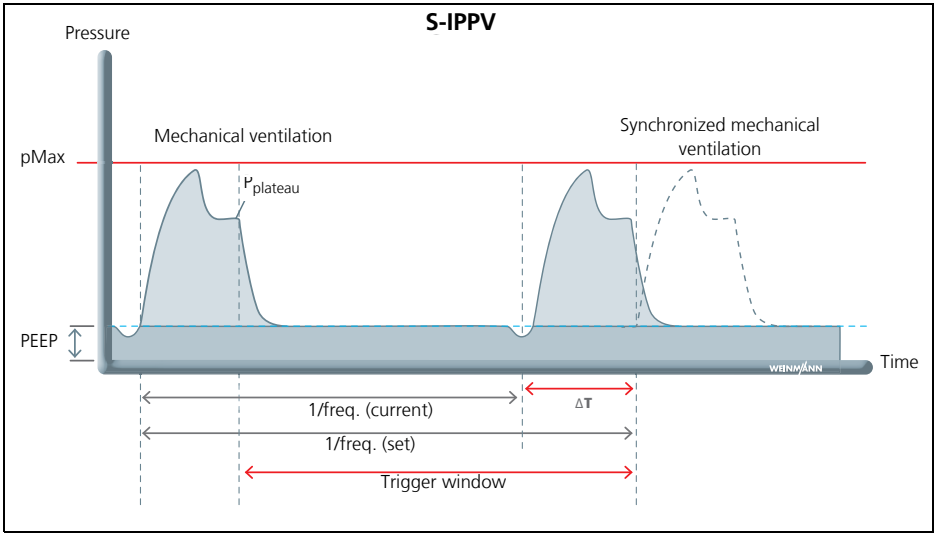

S-IPPV mode is used for volume-controlled ventilation at a variable mandatory minute volume. Throughout the entire expiratory phase, a trigger is active which enables the patient to trigger a new mechanical breath. This means the patient is able to increase his or her respiratory rate – and thus the minute volume – as needed. As a rule, this mode is used on patients who have inadequate spontaneous breathing.

Ventilation in S-IPPV mode is the same as ventilation in IPPV mode, except that synchronization with the patient's attempts to inhale is possible. Since the setting for respiratory rate is lower, the patient can trigger mandatory mechanical breaths spontaneously.
A trigger window extending throughout the expiratory time is available for this synchronization.

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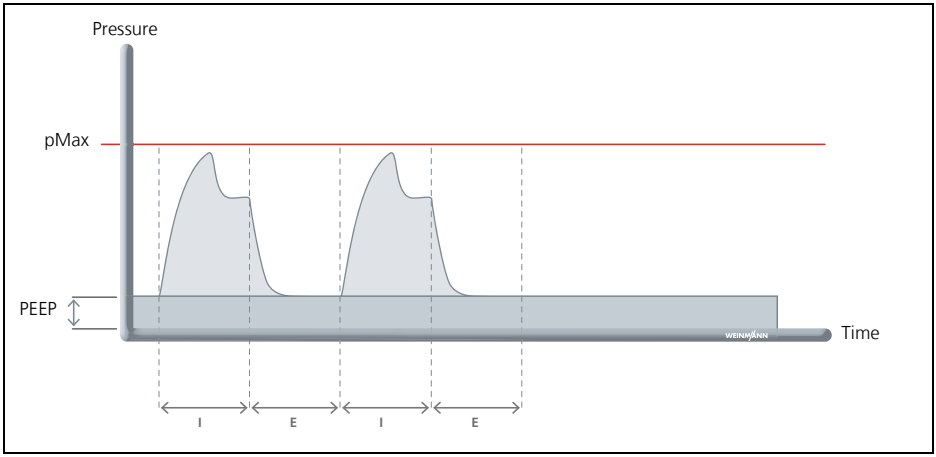
9.5 Manual

Description	
Abbreviation	Manual
Long form	Manual mode
Type	Volume-controlled
Requirement	MEDUtrigger is connected
Ventilation parameters	
Supply value for 100 % oxygen	
pMax	PEEP



Manual mode is used to support cardiopulmonary resuscitation (according to the resuscitation guidelines), rapid sequence induction (RSI) or manual ventilation in place of a bag valve mask. In the ventilation phase, apply the mechanical breaths at a defined volume and pressure limit (manually) using the trigger button of the MEDUtrigger. The I:E ratio is always 1:1 in this process. The set pressure limit (pMax) ensures the patient's safety. The basis for calculating the value of O_2 to be fed in is the algorithm 30:2.

For dispensing the maximum possible oxygen concentration in the inspiratory gas (O_2i) during resuscitation, a feed-in value is shown on the display. This value depends on tidal volume, and indicates how much oxygen is to be fed into the device.

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If Manual mode is used to administer a regular frequency, we recommend basing the oxygen concentration setting on the MVi displayed.

To attain the shortest hands-off time during resuscitation, keep the MEDUtrigger pressed down in the ventilation pause during CPR 30:2 until two inspiratory breaths have been administered. Press the trigger button again to trigger up to another two mechanical breaths.

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10 Alarms and faults

Alarms are shown in the alarm line of the display in the form of text. The text is displayed with a particular background color as a function of alarm priority:

Alarm color	Priority	Meaning
Red	High priority	High-priority alarms warn of imminent fatal or irreversible patient injuries or of device faults.
Yellow	Medium priority	Medium-priority alarms warn of immediate reversible patient injuries or of minor device faults.
Turquoise	Low priority	Low-priority alarms warn of delayed minor injuries or inconvenience to the patient or minor restrictions on the device.

If more than one alarm is active, the device handles this as follows:

- Several alarms of different priorities: The device displays the alarm with the highest priority. Alarms with a lower priority do not appear until the higher-priority alarm is no longer active.
- Multiple alarms of identical priorities: The device displays the alarms in rotation.
- Technical alarms predominate. They cannot be muted. Technical alarms are generated if no ventilation by the device is possible.

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10.1 Alarm messages

10.1.1 High-priority alarms (red)

Fault	Cause	Remedy
Airway pressure high ↑	Obstruction of the patient's airways	Clear the patient's airways.
	Tracheal tube incorrectly positioned	Position tracheal tube correctly.
	pMax set too low	Adjust pMax.
	Tubes kinked or trapped	Route tubes so that they are not kinked or trapped.
Airway pressure low ↓	Breathing circuit leaking	Replace the breathing circuit.
	Breathing circuit not correctly connected	Connect breathing circuit correctly.
	Tracheal tube incorrectly positioned	Position tracheal tube correctly.
	Tubes kinked or trapped	Route tubes so that they are not kinked or trapped.
	Ventilation settings incorrect	Adjust ventilation settings.
	Mask not sitting correctly or leaking	Ensure mask seals properly or replace it.
Apnea	Patient is not breathing spontaneously	Check the patient's condition. Select mandatory ventilation mode.
Check breathing circuit	Tubes incorrectly connected, kinked or defective	Check breathing circuit.
	Hygiene filter blocked	Check and replace hygiene filter.
Device temperature high ↑	Device temperature > 70 °C	Operate device within permitted temperature range (see "15 Technical data", page 138).
Device temperature low ↓	Device temperature < -20 °C	Operate device within permitted temperature range (see "15 Technical data", page 138).
MEDUtrigger disconnected	MEDUtrigger removed from device during manual ventilation	Reconnect MEDUtrigger to device.

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Patient disconnected	No patient connected	Connect patient to device.
	Mask not sitting correctly or leaking	Ensure mask seals properly or replace it.
PEEP high ↑	Obstruction of the patient's airways	Clear the patient's airways.
	Tracheal tube incorrectly positioned	Position tracheal tube correctly.
	Tubes kinked or trapped	Route tubes so that they are not kinked or trapped.
	Patient valve defective	Replace patient valve.
	Ventilation settings incorrect	Adjust ventilation settings.
Oxygen inlet flow high ↑	Flow setting higher than permitted	Reduce flow setting to a value below 15 l/min.
Rechargeable battery empty	Rechargeable battery charge status low	Connect device to line power and charge rechargeable battery. Keep alternative means of ventilation at the ready.
Vt low ↓ / Stenosis	Obstruction of the patient's airways	Clear the patient's airways.
	Tracheal tube incorrectly positioned	Position tracheal tube correctly.
	Tubes kinked or trapped	Route tubes so that they are not kinked or trapped.
	Patient valve defective	Replace patient valve.
	Hygiene filter blocked	Check and replace hygiene filter.

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10.1.2 Medium-priority alarms (yellow)

Fault	Cause	Remedy
Battery defective	Rechargeable battery defective	Run device on rechargeable battery without line power until it switches off. Fully recharge battery. If the device continues to display the alarm: Replace rechargeable battery.
	Rechargeable battery not inserted, or not inserted correctly	Insert rechargeable battery correctly.
Check battery	Wrong rechargeable battery inserted	Insert approved rechargeable battery.
Battery weak	Rechargeable battery charge status low	Connect device to line power and charge rechargeable battery.
Frequency high ↑	Patient's respiratory rate too high	Check the patient's condition. Check limit value settings for plausibility.
Oxygen inlet flow higher than necessary	Flow setting higher than necessary	Reduce flow setting in steps. Rule of thumb for 100 % oxygen: Flow = MV
Service required	Device defective	Have the device repaired.
Vt not achievable	Implausible ventilation parameters	Adjust ventilation parameters.
	pMax set too low	Modify setting for pMax.
Oxygen inlet leakage	Oxygen inlet is not sealed or no oxygen is being fed in.	Seal oxygen inlet with cap or feed in oxygen.

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10.1.3 Low-priority alarms (turquoise)

Fault	Cause	Remedy
Battery operation	Line power supply too weak or line power outage	The alarm appears: • When you take the portable system out of the wall mounting. • When you are running the device on the power supply unit and charger, and a line power outage occurs. In both cases the alarm goes out after 10 s.
Set date and time	Rechargeable battery replacement	Set date and time correctly.

10.2 Faults

If you are not able to clear faults at once with the aid of the table, you should contact the manufacturer, WEINMANN Emergency, or your authorized dealer to have the device repaired. To avoid serious damage, do not continue using the device.

Fault	Cause	Remedy
Alarm output too quiet	Sound volume set too low	In the operator menu, set sound volume to 100 %.
No audio alarm output	Loudspeaker or alarm light defective	Have the device repaired.
Alarm light not lit		
Display too dark	Brightness of display set too low	Increase brightness of display in operator menu.
Device cannot be switched on	Rechargeable battery not correctly inserted in device or empty	Check rechargeable battery.
	Rechargeable battery empty and device not connected to line power	Check power supply.
	Device defective	Have the device repaired.
Device cannot be switched off	Operating error	Press and hold On/Off button ⏻ for at least 2 seconds.
Software update not working	Update file or SD card defective	Perform software update with a different SD card. If the update still cannot be completed successfully, have the device repaired.

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Fault	Cause	Remedy
Rechargeable battery status indicator flickering between red and green	Rechargeable battery deeply discharged	Charge rechargeable battery in the device for 24 hours.
Option functionality not available	Option deactivated in operator menu	Activate option in operator menu.
	Option not enabled in operator menu	Enable option in operator menu using option code.
Power failure/device failure: • Black screen • The alarm light flashes • Audio alarm output	Rechargeable battery empty and device not connected to line power	Check power supply.
	Device defective	Switch the device off and have it repaired.
Device fault (yellow screen)	Temporary device malfunction	Switch device off and back on again. Perform a function check (see 5, p. 44). In the event of a device fault, the operator menu can be called up directly by pressing the menu button, allowing the log files to be exported in this way (see 7.7, p. 76).
		Press the menu button to call up the operator menu directly and export the log files (see 7.7, p. 76).
	Device defective	Switch the device off and have it repaired.

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11 Maintenance

⚠ WARNING

Disrupted or failed therapy due to inadequate or incorrect maintenance!
Incorrect maintenance might result in dangerous situations and failure or malfunctioning of the device. This might expose the patient and people in the vicinity to the risk of serious or life-threatening injury.
⇒ Ensure that maintenance, safety checks and servicing measures are carried out only by the manufacturer or by technicians specifically authorized by the manufacturer.
⇒ Observe the maintenance intervals also when placing the device into storage for a protracted period of time.
⇒ Observe the maintenance intervals as marked on the device.
⇒ Perform a complete function check prior to every use.

11.1 Intervals

⚠ WARNING

Disrupted or failed therapy due to lack of maintenance!
If maintenance intervals are not observed, malfunctions might occur. This might expose the patient to the risk of serious or life-threatening injury.
⇒ Observe the maintenance schedule according to the instructions for use and the displays on the device.
⇒ Also observe the maintenance schedule for devices and accessories in storage.

NOTICE

Reduction in rechargeable battery capacity due to aging!
The rechargeable battery is subject to a natural aging process, resulting in a decrease in capacity. This might result in premature failure of the power supply.
⇒ Note that the range of the rechargeable battery will gradually decrease due to aging.
⇒ Pay attention to the battery wear indicator in the function check.
⇒ If the rechargeable battery is worn out, replace it.

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Part concerned	Interval	Maintenance by
Device	Maintenance every 4 years	Manufacturer or a technician specifically authorized by the manufacturer
	Safety check every 2 years	
Rechargeable battery	Maintenance-free If the rechargeable battery is stored inside the device, charge every 6 months. If the rechargeable battery is stored outside the device, charge every 12 months. Replace rechargeable battery after 5 years.	Operator
Breathing circuit (reusable)	Maintenance every 2 years	User/operator (see "11.2 Maintaining the breathing circuit (reusable)", page 123)
Breathing circuit (disposable)	Maintenance-free	
Accessories	The accessories are subject to their own maintenance intervals. Please refer to the instructions for use supplied with the accessories.	User/operator
Hygiene filter	On request in the function check **or** At least every 6 months **or** After every infection transport of a ventilated patient	User/operator (see "11.3 Replacing the hygiene filter", page 124)

11.2 Maintaining the breathing circuit (reusable)

Requirement The reusable breathing circuit has been disassembled (see "8.3.1 Disassembling the reusable breathing circuit", page 87).

1. Check all parts of the reusable breathing circuit for external damage and to ensure that labeling is complete.
2. If necessary: Replace damaged or incorrectly labeled parts.
3. Replace PEEP control diaphragm and check valve diaphragm (maintenance set WM 15779).

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4. Assemble the reusable breathing circuit (see "8.3.2 Assembling the reusable breathing circuit", page 90).
5. Punch the scheduled time for the next maintenance into the service label (maintenance set WM 15779).
6. Attach the service label to the device end of the ventilation hose.
7. Perform a function check (see "5 Function check", page 44).

Result The reusable breathing circuit has been maintained and is ready for use.

11.3 Replacing the hygiene filter

⚠ WARNING

Risk of injury due to contaminated or damaged hygiene filter!
A hygiene filter which is damaged or has been contaminated by a prior infection transport might cause the patient and the user serious or life-threatening injury.
⇒ Check the hygiene filter and filter fleece for external signs of damage and do not use if damaged.
⇒ Replace damaged hygiene filter.
⇒ Replace hygiene filter after every infection transport.

⚠ WARNING

Infection of the user or of the next patient resulting from incorrect handling of a contaminated hygiene filter!
A contaminated hygiene filter might cause the patient or user to suffer serious or life-threatening injury.
⇒ Always wear suitable personal protective equipment when removing a contaminated hygiene filter.
⇒ Dispose of a contaminated hygiene filter when carrying out hygienic reprocessing and do not reuse it.

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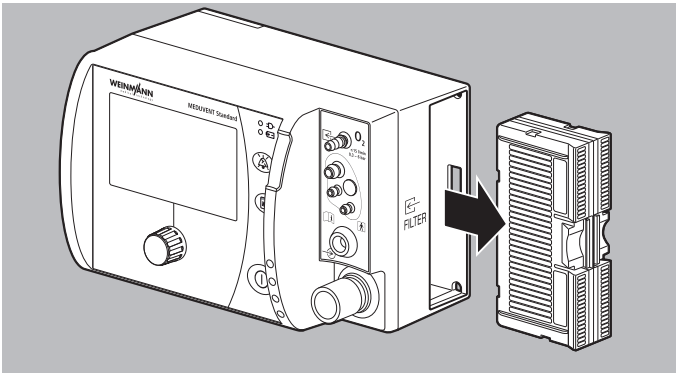
11.3.1 Removing the hygiene filter



1. Press together and hold the tabs of the locking mechanism.
2. Pull the hygiene filter out of the device's filter compartment.
3. Disinfect the filter compartment by wiping.

Result The hygiene filter has been removed.

11.3.2 Inserting the hygiene filter

⚠ WARNING

Risk of contamination or infection resulting from impaired filtration properties!
Soiling, foreign bodies or damage in the filter compartment or on the filter might mean that the filter element is not correctly seated. As a result, the system will not be leak-tight, and contamination or infection might occur which might cause the patient or user serious or life-threatening injury.
⇒ Check the filter compartment and filter for soiling, foreign bodies and damage.

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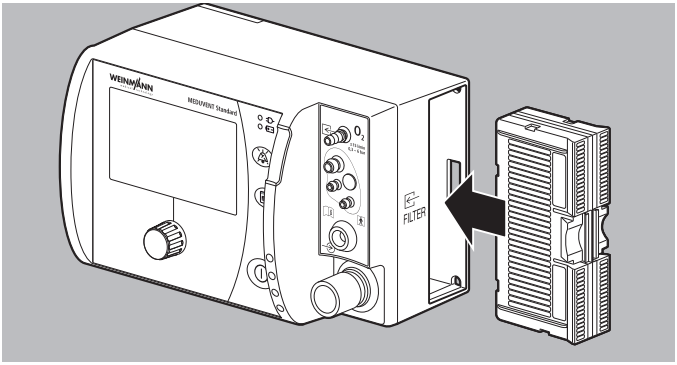

1. Push the hygiene filter into the filter compartment until the hygiene filter audibly engages and is flush with the device.
2. Perform a function check (see "5 Function check", page 44).

Result The hygiene filter has been inserted.

11.4 Replacing rechargeable battery

⚠ WARNING

Failure of therapy resulting from operation of device without rechargeable battery!
The device is not intended for operation without the rechargeable battery. A missing, discharged or defective rechargeable battery will prevent uninterrupted operation of the device in the event of failure of the external power supply. This might expose the patient to the risk of serious or life-threatening injury.
⇒ Always operate the device with the rechargeable battery charged.

You as the operator can replace the rechargeable battery yourself.

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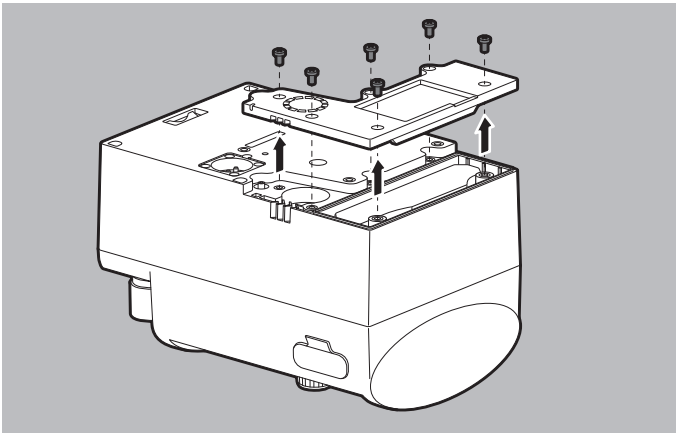
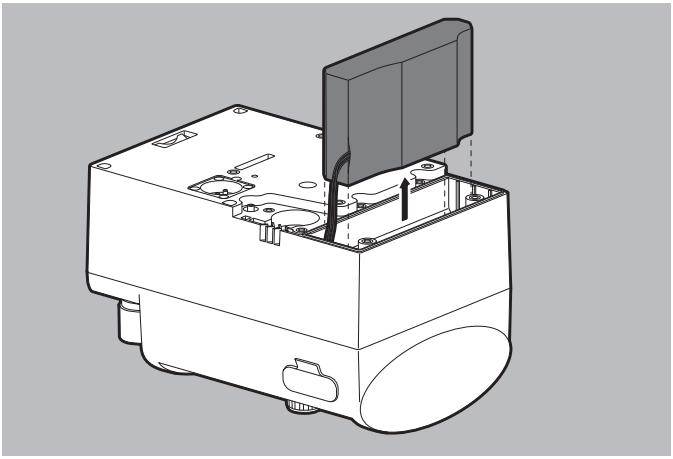
11.4.1 Removing the rechargeable battery

Requirement The device has been disconnected from the power supply.



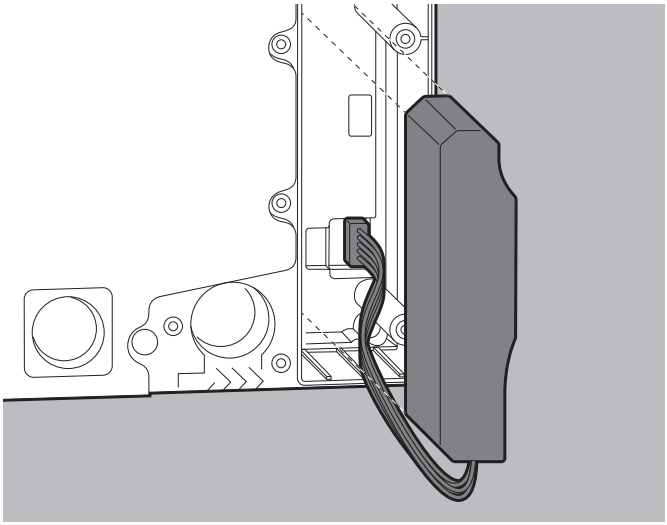
1. Loosen 6 screws from the rechargeable battery compartment cover on the back of the device.
2. Remove the 6 screws.
3. Remove the battery compartment cover.



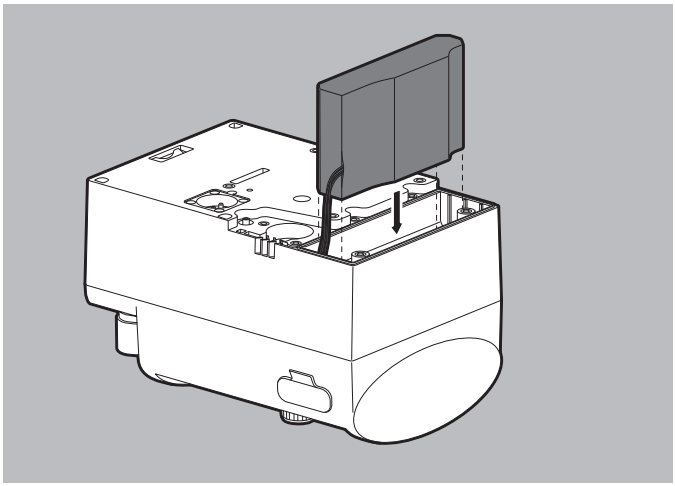
4. Remove the rechargeable battery from the device.
5. Unplug the battery's electrical connector.

Result The rechargeable battery has been removed.

11.4.2 Installing the rechargeable battery



1. Attach the battery's electrical connector. To do so, plug the battery connector into the socket.



2. Insert the rechargeable battery. Pay attention to the cable routing when doing this.

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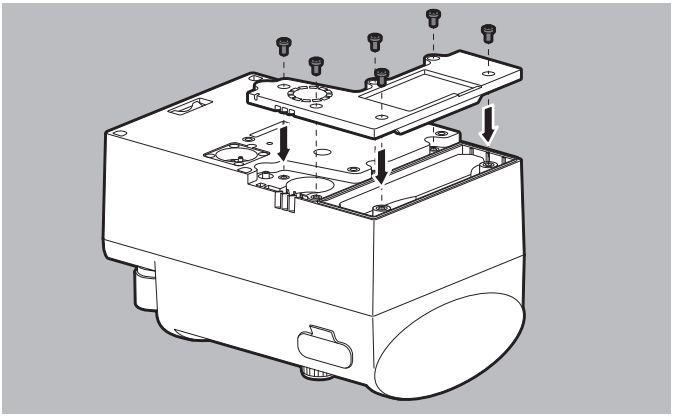

3. Fit the battery compartment cover.
4. Tighten the 6 screws on the battery compartment cover.
5. Reset the date and time in the operator menu
(see "7 Operator menu", page 67)

Result The rechargeable battery has been installed.

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11.5 Sending in the device

⚠ CAUTION

Risk of infection and contamination resulting from lack of hygienic safety in servicing measures!

The device and its accessories might be contaminated, causing technicians performing servicing measures or people in the vicinity to be infected with bacteria or viruses.

⇒ Subject the device and accessories to hygienic reprocessing prior to any maintenance procedure.

⇒ Never send potentially contaminated devices or accessories for servicing.

1. Remove the accessories.
2. Clean and disinfect the device and accessories (see "8 Hygienic reprocessing", page 83).
3. Send the device, and if necessary its accessories, to WEINMANN Emergency or to a technician specifically authorized by WEINMANN Emergency.

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If you send in parts that are obviously contaminated, they will be disposed of at your expense by WEINMANN Emergency or by a technician authorized by WEINMANN Emergency.

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12 Storage

⚠ WARNING

Disrupted or failed therapy due to defective or non-operational device following incorrect storage!
Incorrect storage might damage the device and accessories, and lead to disruption or failure of therapy. This might expose the patient to the risk of serious or life-threatening injury.
⇒ Observe storage conditions and storage times (see "15 Technical data", page 138).
⇒ Store the device and accessories in a dry location.
⇒ Following storage at extreme ambient conditions outside operational ambient conditions: Store the device and accessories at room temperature for at least 12 hours before reusing them.
⇒ Protect the device and accessories from UV light and direct sunlight.

NOTICE

Damage to the rechargeable battery due to incorrect storage!
Storing the rechargeable battery for a prolonged period of time without recharging might result in the rapid shutdown of, and irreparable damage to, the rechargeable battery.
⇒ Observe the storage conditions and the instructions regarding the rechargeable battery (see "15.2 Technical data, rechargeable battery", page 143).

1. Switch off the device (see "6.8 Switching the device off", page 65).
2. If necessary: Disconnect the device from line power.
3. Hygienically reprocess the device and accessories (see "8 Hygienic reprocessing", page 83).
4. Store the device and accessories in a dry location.

Result The device and accessories are stored in a dry location.

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13 Disposal

13.1 Electronic waste

NOTICE

Environmental hazard from electronic waste!
Electronic waste poses an environmental hazard, and must be subjected to proper disposal.
⇒ Do not dispose of electronic waste in household waste.

Do not dispose of the product in household waste. Consult an authorized, certified electronic waste dealer for proper disposal. You can find out their address from your environmental officer or from your local council. The device packaging (cardboard box and inserts) can be disposed of as waste paper.

The following products are categorized as electronic waste:

- Device
- Power supply unit and charger

13.2 Rechargeable battery

Do not dispose of used rechargeable batteries in household waste. Contact WEINMANN Emergency or a public waste disposal authority.

13.3 Breathing circuit/oxygen inlet tube

Dispose of the breathing circuit and the oxygen inlet tube in a proper manner applicable to plastics at the end of their useful lives.

13.4 Hygiene filter

Dispose of the hygiene filter in a proper manner.

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14 Scope of supply and accessories

14.1 Standard product

MEDUVENT Standard **WM 20010**

Part	Article number
MEDUVENT Standard, basic device with rechargeable battery	WM 35710
Reusable breathing circuit, 2 m	WM 35850
MEDUtrigger for 2 m breathing circuit for triggering mechanical breaths manually	WM 28992
Testing bag	WM 1454
Set of CPAP/NIV disposable masks with air cushion	WM 15807
Ventilation mask with self-inflating silicone cushion, for adults, size 5	WM 5074
Hygiene filter	WM 35730
Hook and loop strap with clip	WM 28964
Set of mounting elements for LIFE-BASE	WM 17806
Oxygen inlet tube	WM 35782
MEDUVENT Standard instructions for use	WM 67781

14.2 Accessories and other parts

Parts can be ordered separately, if required. A current list of parts can be obtained on the Internet at www.weinmann-emergency.com or through your specialist dealer.

Part	Article number
MEDUtrigger for 2 m breathing circuit for triggering mechanical breaths manually	WM 28992
Testing bag with trigger	WM 1454
Charging adapter for charging with the power supply unit and charger or 12 V adapter cable	WM 28979
Power supply unit and charger 100 W	WM 28937

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Part	Article number
Adapter cable for 12 V on-board power supply/ ODU connector	WM 28356
EasyLung test lung	WM 28625
Rechargeable battery for MEDUVENT Standard	WM 35775
SD card	WM 29791
Wall mounting for power supply unit and charger	WM 15846
Breathing system filter	WM 22162
Protective cap for 22 mm cone	WM 28942
Protective cap for oxygen inlet	WM 35732
Oxygen inlet tube	WM 35782
Adapter for reusable breathing circuit	WM 35867
Adapter for disposable breathing circuit	WM 35811
Hygiene filter for MEDUVENT Standard	WM 35730
Set of 5 hygiene filters	WM 17915
LIFE-BASE portable unit	Article number on request
CapnoDura Combi disposable CO_2 detector	WM 20760
Set of 10 CapnoDura Combi disposable CO_2 detectors	WM 20770

14.2.1 Breathing circuits

Reusable breathing circuit

Part	Article number
Reusable breathing circuit, 2 m	WM 35850
2 m reusable measuring circuit for breathing circuit	WM 35851
2 m reusable ventilation hose for reusable breathing circuits	WM 28421
2 m reusable protective sleeve for ventilation hose	WM 28585
Reusable patient valve, complete	WM 35865

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Disposable breathing circuit

Part	Article number
Disposable breathing circuit, 2 m	WM 35860
Set of 10 disposable breathing circuits, 2 m	WM 17910
Set of 25 disposable breathing circuits, 2 m	WM 17911
Set of 50 disposable breathing circuits, 2 m	WM 17912

14.2.2 Masks

Part	Article number
Premium disposable CPAP/NIV mask incl. headgear, size S (child)	WM 20717
Premium disposable CPAP/NIV mask incl. headgear, size M (adult)	WM 20718
Premium disposable CPAP/NIV mask incl. headgear, size L (large adult)	WM 20719
Set of 10 premium disposable CPAP/NIV masks incl. headgear, size S (child)	WM 17940
Set of 40 premium disposable CPAP/NIV masks incl. headgear, size S (child)	WM 17941
Set of 10 premium disposable CPAP/NIV masks incl. headgear, size M (adult)	WM 17942
Set of 40 premium disposable CPAP/NIV masks incl. headgear, size M (adult)	WM 17943
Set of 10 premium disposable CPAP/NIV masks incl. headgear, size L (large adult)	WM 17944
Set of 40 premium disposable CPAP/NIV masks incl. headgear, size L (large adult)	WM 17945
Disposable CPAP/NIV mask with air cushion, size S (child), with retaining ring for headgear	WM 20704
Disposable CPAP/NIV mask with air cushion, size L (large adult), with retaining ring for headgear	WM 20705
Set of disposable CPAP/NIV masks with air cushion	WM 15807
Set of 25 disposable CPAP/NIV masks with air cushion, size S (child), with retaining ring for headgear	WM 15831
Set of 25 disposable CPAP/NIV masks with air cushion, size M (adult), with retaining ring for headgear	WM 15832

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Part	Article number
Set of 25 disposable CPAP/NIV masks with air cushion, size L (large adult), with retaining ring for headgear	WM 15833
Set of 50 disposable CPAP/NIV masks with air cushion, size S (child), with retaining ring for headgear	WM 15834
Set of 50 disposable CPAP/NIV masks with air cushion, size M (adult), with retaining ring for headgear	WM 15835
Set of 50 disposable CPAP/NIV masks with air cushion, size L (large adult), with retaining ring for headgear	WM 15836
Reusable silicone CPAP/NIV mask, size S (child)	WM 20713
Reusable silicone CPAP/NIV mask, size M (adult)	WM 20714
Reusable silicone CPAP/NIV mask, size L (large adult)	WM 20715
Set of reusable silicone CPAP/NIV masks	WM 15808
Headgear for CPAP/NIV masks	WM 20702
Retaining ring for headgear, for reusable CPAP/NIV masks only	WM 20701
Ventilation mask with self-inflating silicone cushion, for adults, size 5	WM 5074
Ventilation mask with self-inflating silicone cushion, for children and adolescents, size 3	WM 5082
Ventilation mask with self-inflating silicone cushion, for infants, size 1	WM 5086
Silicone ventilation mask, size 3 (child)	WM 11113
Silicone ventilation mask, size 4 (adult)	WM 11114
Silicone ventilation mask, size 5 (adult)	WM 11115

14.2.3 Options

Part	Article number
S-IPPV mode option	WM 35815
SIMV mode option	WM 35816

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14.3 Spare parts

⚠ WARNING

Disrupted or failed therapy due to use of incorrect spare parts!
Using incorrect or defective spare parts might result in malfunctions or failure of the device. This might expose the patient to the risk of serious or life-threatening injury.
⇒ Use only original WEINMANN Emergency spare parts or spare parts approved by WEINMANN Emergency.

Spare parts can be ordered separately, if required.
A current list of spare parts can be obtained on the Internet from www.weinmann-emergency.com or through your specialist dealer.

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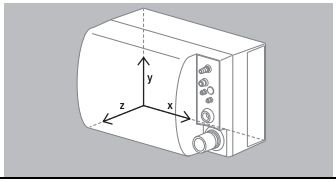
15 Technical data

15.1 Technical data, device

Specification	Device
Product class according to Directive 93/42/EEC	IIb
Dimensions (W x H x D)	206 mm x 137 mm x 130 mm
Weight: Without rechargeable battery With rechargeable battery	 1750 g 2100 g
Center of gravity	 X = 87 mm Y = 69 mm Z = 54 mm
Operation: Temperature range Temperature range for oxygen inlet tube Humidity Air pressure Height above sea level	 -20 °C to +50 °C -18 °C to +50 °C 5 % to 95 % rh, no condensation 540 hPa to 1100 hPa -500 m to 5000 m
Storage (device)/transport: Temperature range up to 48 h Temperature range longer than 48 h Temperature range for oxygen inlet tube Humidity Air pressure Height above sea level	 -40 °C to +70 °C -20 °C to +40 °C (recommendation: 0 °C to +25 °C) -18 °C to +50 °C 15 % rh to 95 % rh, no condensation 540 hPa to 1100 hPa -500 m to 5000 m
Heating-up time from minimum storage temperature to standby at 20 °C	8 hours
Cooling-down time from maximum storage temperature to standby at 20 °C	8 hours
Electrical connection (rated voltage)	12 V
Max. power consumption	60 W
Current consumption	0.15 A to 4 A

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Specification	Device
Operating hours with rechargeable battery without options	8 hours (under the following conditions: Mode: IPPV, f=12/min, Vt=600 mL, lung parameters of a healthy adult, PEEP=0 hPa, compliance=50 ml/hPa, resistance=5 hPa/l/s, display brightness=80 %, new fully-charged rechargeable battery, ambient temperature 23 °C ± 3 °C)
Operation with on-board power supply: Rated voltage Max. internal resistance of on-board power supply	 12 V 500 mΩ
Separator	Disconnection of the power supply (charging adapter or portable system) or unplugging of the line power connector.
Operating mode	Continuous duty
Classification acc. to EN 60601-1: • Type of protection against electric shock • Degree of protection against electric shock	 Protection class II Degree of protection BF
Degree of protection against: • Ingress of solid objects • Ingress of dust • Ingress of water with harmful effect	 IP54
Electromagnetic compatibility (EMC) in accordance with EN 60601-1-2 and ETSI EN 301489-: Radio interference suppression Radio interference immunity	Test parameters and limit values can be obtained from the manufacturer on request. EN 55011, EN 55025 EN 61000-4 (parts 2 to 6, 8, and 11) RTCA DO 160 G
Frequency range Signal strength	2.4 GHz to 2.4835 GHz Max. 12 dBm
Resistance to shock and vibration	• EN 1789 • EN 60601-1-12 (Categories: Secured in an emergency vehicle, secured in an airplane, secured in a helicopter, portable at the site of the emergency) • EUROCAE ED-14G / RTCA DO 160 G: Section 7 (Cat. A) and 8 (U/U2 + Cat. S)
Type of emergency vehicle	Secured in emergency vehicle, ship, airplane, and helicopter as well as portable at the site of the emergency
Display	4.3" TFT color display Resolution 480 pixels x 272 pixels

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Specification	Device
Alarm sound volume	100 %: > 60 dbA 50 %: > 55 dbA
Standards used	EN 60601-1 EN 60601-1-2 EN 60601-1-6 EN 60601-1-8 EN 60601-1-12 EN 62366-1 EN 1789 EN 13718-1 EN 794-3 ISO 10651-3 ISO 10993-1 RTCA DO-160 G MIL-STD 810 G
Applied parts acc. to EN 60601-1	• Ventilation mask • Tracheal tube
Essential performance	• Delivery of a ventilation volume or triggering of an alarm state • Limiting maximum ventilation pressure
Volume-controlled ventilation modes	IPPV, Manual, SIMV (optional), S-IPPV (optional)
Pressure-controlled ventilation modes	CPAP
Monitoring	Volume and pressure
Monitoring parameters	MVi, pAw
Operating gas	Medical oxygen (100 % oxygen) **or** concentrator oxygen (93 % ± 2 %)
Operating pressure range	0.3 bar to 6 bar at maximum 15 l/min STPD
Minimum operating pressure	3 hPa. Not adjustable.
Minimum limit pressure, vacuum, (Plim min)	10 hPa, the device generates no active vacuum
Maximum limit pressure (Plim max)	60 hPa
Means of limiting pressure	Pressure control
Means of safeguarding the minimum value	Pressure control
Maximum outlet flow	150 l/min (in BTPS)
Mechanical pressure relief/emergency air valve	Pressure limitation to < 100 hPa
I:E	1:2 (fixed), in Manual mode 1:1
Respiratory rate	5 min^{-1} to 40 min^{-1} ± 1 min^{-1}
Inspiratory time	0.5 s to 4 s

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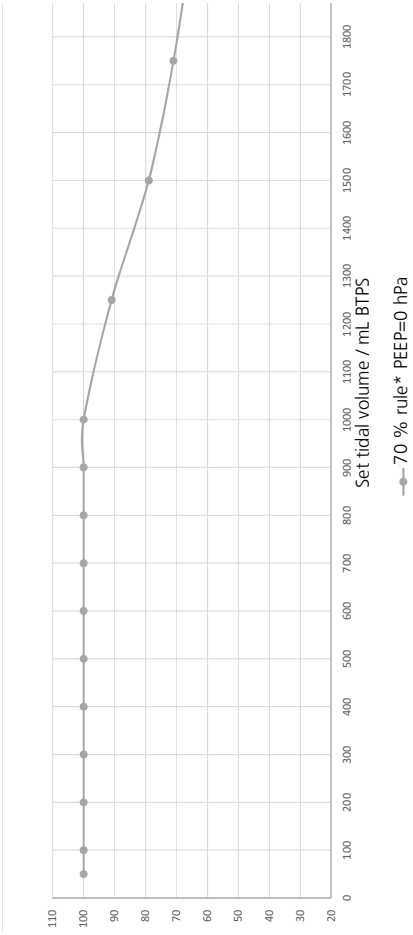
Specification	Device
Tidal volume	50 ml to 2000 ml (± 40 ml or ± 20 %) (BTPS)
Respiratory minute volume	1.5 l/min to 20 l/min (BTPS)
Maximum achievable O_2i at a flow of flow 15 l/min (ATPD)	 *70 % rule: From a physiological point of view, the alveolar area of a lung is crucial for gas exchange. Literature research shows that 60 % – 70 % of tidal volume reaches the alveolar area, with the remaining 40 % – 30 % remaining in the dead space volume of the lung.
Accuracy of the O_2i display	± 15 percent by volume (if the operating gas used matches the operating gas set in the operator menu)

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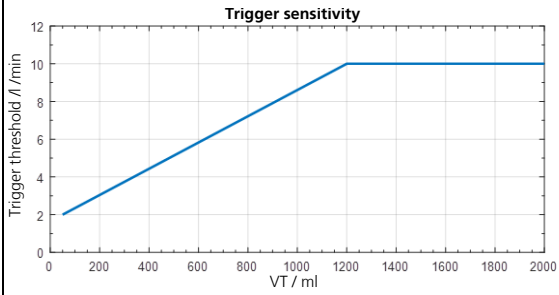
Specification	Device
Pressure limitation (pMax)	10 mbar to 60 mbar (± 3 mbar or ± 15 %)
PEEP	0 mbar to 20 mbar (± 3 mbar or ± 15 %)
Trigger (fixed)	
Airway pressure sensor	-5 hPa to 80 hPa, measurement location close to patient
Accuracy of airway pressure measurement	-5 hPa to 80 hPa (±5 % or ±1.5 hPa)
Volume sensor	-30 l/min to 150 l/min, measuring location ventilation hose connection (BTPS or APT, whichever value is lower)
Accuracy of measurement of tidal volume (Vti)	± 20 % or ± 40 ml (BTPS, whichever value is higher)
Gas composition	Mixture of air, oxygen, CO_2. Oxygen fraction 21 % to 100 %, CO_2 fraction 0 % to 10 %
Ventilation hose connection	22 mm outer cone
Patient valve connections	22 mm outer cone 15 mm inner cone
Hygiene filter service life	24 h in operation or 6 months service life
Hygiene filter separation rate	> 99 %

CE 0197 Subject to design modifications.

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15.2 Technical data, rechargeable battery

Specification	Rechargeable battery
Type	Li-ion
Dimensions (W x H x D)	66 mm x 120 mm x 28 mm
Weight	333 g ± 5 g
Rated capacity	4.5 Ah (46.8 Wh typical)
Rated voltage	10.8 V
Charging time (0 % to 95 %)	2.5 h
Charging temperature	0 °C to +45 °C
Temperature range for operation	-20 °C to +50 °C
Transport/storage: Temperature range Humidity	 -40 °C to +70 °C (at more than +60 °C maximum one week) 0 % rh to 95 % rh, no condensation
Service life	At least 300 charging cycles* or a maximum of 4 years and 7 months
Operating hours Without options	8 hours (under the following conditions: Mode: IPPV, f=12/min, Vt=600 mL, lung parameters of a healthy adult, PEEP=0 hPa, compliance=50 ml/hPa, resistance=5 hPa/l/s, display brightness=80 %, new fully-charged rechargeable battery, ambient temperature 23 °C ± 3 °C)
Charging intervals after 100 % charge	When stored in the device without power supply: Every 6 months When not stored in the device: Every 12 months

* A charging cycle corresponds to a 100 % rechargeable battery charge regardless of the current battery status. Example: If you charge the rechargeable battery twice from 50 % to 100 %, the device counts one charging cycle.

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15.3 Technical data, power supply unit and charger

Specification	Power supply unit and charger
Operation of power supply unit and charger 100 W (WM 28937): Temperature range Humidity Air pressure Height above sea level	 0 °C to +40 °C 5 % rh to 95 % rh, no condensation 700 hPa to 1100 hPa -500 m to 3000 m
Input voltage (external power supply unit and charger)	100 V-240 V~/50 Hz-60 Hz
Rated voltage output	15 V
Disconnection from line power	Taking out the line power connector disconnects the device from line power on all poles.
Type	PMP120F-13-K24

15.4 Technical data, breathing circuits

Specification	Breathing circuit
Operation: • Temperature range • Relative humidity	 -20 °C to +50 °C 15 % to 95 %, no condensation
Storage: • Temperature range • Relative humidity	 -30 °C to +70 °C Maximum 95 %
Patient valve: Patient connection mask/tracheal tube	15 mm inner cone 22 mm outer cone EN ISO 5356-1
Patient valve: Expiratory opening	Non-connectible expiratory opening
Compliance: • Reusable breathing circuit • Disposable breathing circuit	 0.79 ml/hPa (ml/cmH_2O) 0.90 ml/hPa (ml/cmH_2O)
Internal volume of complete breathing system: • Reusable breathing circuit • Disposable breathing circuit	 Approx. 573 ml Approx. 573 ml
Materials used	PC, silicone, TPE, PA, PP, TPR, PE, PU, polyisoprene

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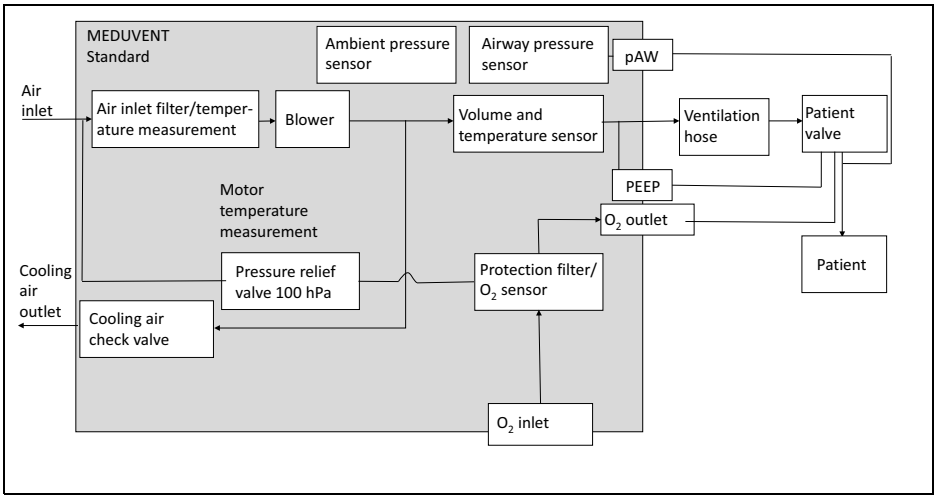
Dead space volumes		
	Without elbow	**With elbow**
Reusable patient valve	Approx. 16 ml	Approx. 28 ml
Disposable patient valve	Approx. 16 ml	Approx. 24 ml

15.5 Block diagram



15.6 Technical data on electromagnetic compatibility (EMC)

⚠ WARNING

Disrupted or failed therapy due to interaction between medical electrical devices!

Medical electrical devices which are operated directly next to or on top of each other can cause mutual interference to functionality. This might expose the patient to the risk of serious or life-threatening injury.

⇒ Do not stack the device with other medical electrical devices.

⇒ Do not operate the device in the direct vicinity of other medical electrical devices (exception: Other WEINMANN Emergency devices which have been tested to ensure that they can operate without problem alongside the device. A list of the other devices can be provided on request).

⇒ If stacking or operation in the immediate vicinity cannot be avoided: Closely monitor the functioning of all affected medical electrical devices and do not use if functions are disrupted.

⚠ WARNING

Disrupted or failed therapy due to portable high-frequency communication equipment in the immediate vicinity of the device!

Portable high-frequency communication equipment (e.g. mobile radios, antennas and antenna cables) in the immediate vicinity of the device can influence the functioning of the device. This might expose the patient to the risk of serious or life-threatening injury.

⇒ Keep portable high-frequency communication equipment a minimum distance of 30 cm away from the device and its accessories.

Medical electrical equipment is subject to special precautions in relation to electromagnetic compatibility (EMC). It must be installed and put into operation in accordance with the EMC information contained in the accompanying documentation.

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Guidelines and manufacturer declaration - emission of electromagnetic interference		
MEDUVENT Standard is designed for operation in an electromagnetic environment as described below. The customer or user of the MEDUVENT Standard device should ensure that it is operated in such an environment.		
Measurements of interference emission	**Compliance**	**Electromagnetic environment guidelines**
RF emissions acc. to CISPR 11	Group 1, Class B	The RF emission of MEDUVENT Standard is very low and it is unlikely to interfere with adjacent electronic devices.
Emission of oscillations to IEC 61000-3-2	Complies	MEDUVENT Standard is suitable for use in all facilities, including domestic environments and those which are connected directly to the public power supply which also supplies buildings used for residential purposes.
Emission of voltage fluctuations/flicker to IEC 61000-3-3	Complies	
RF emissions to RTCA DO-160 G	Section 21, Category M	MEDUVENT Standard is suitable for use in operating locations of Category M inside aircraft due to its low RF emission.
RF emissions acc. to UN/ECE Rule no. 10	Annex 6, Annex 7	MEDUVENT Standard is suitable for use in motor vehicles due to its low RF emission.
Emissions interfering with motor vehicle power supply lines acc. to ISO 7637-2	Complies	MEDUVENT Standard is suitable for connection to the on-board power supply due to its low RF emission.

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Guidelines and manufacturer declaration – electromagnetic immunity			
MEDUVENT Standard is designed for operation in the electromagnetic environment described below. The customer or user of the MEDUVENT Standard device should ensure that it is used in such an environment.			
Interference immunity tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidelines**
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be made of wood or concrete or have ceramic tiles laid on them. If the floor has a synthetic material laid on it, relative humidity must be at least 30 %.
Electrical fast transients/bursts acc. to IEC 61000-4-4	± 2 kV for line power cables ± 1 kV for input and output lines	± 2 kV for line power cables ± 1 kV for input and output lines	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Surges acc. to IEC 61000-4-5	± 1 kV Line-to-line ± 2 kV Line-to-ground	± 1 kV Line-to-line ± 2 kV Line-to-ground	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Voltage dips, short interruptions and voltage fluctuations in power supply voltage acc. to IEC 61000-4-11	0 % U_T; ½ cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees, 0 % U_T, 1 cycle and 70 % U_T, 25/30 cycles, single-phase: at 0 degrees, 0% U_T, 250/300 cycles	0 % U_T; ½ cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees, 0 % U_T, 1 cycle and 70 % U_T, 25/30 cycles, single-phase: at 0 degrees, 0% U_T, 250/300 cycles	The quality of the supply voltage should correspond to that of a typical business or hospital environment. If the user of MEDUVENT Standard device demands continued function even if interruptions to the power supply occur, we recommend supplying the MEDUVENT Standard using its fully-charged battery.
Note: U_T is the alternating line voltage prior to application of the test levels.			
Pulses interfering with motor vehicle power supply lines acc. to ISO 7637-2	Test pulses 1, 2a, 2b, 3a, 3b and 4	Test pulses 1, 2a, 2b, 3a, 3b and 4	The motor vehicle to which MEDUVENT Standard is fitted should be E1-certified.

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Guidelines and manufacturer declaration – electromagnetic immunity			
MEDUVENT Standard is designed for operation in the electromagnetic environment described below. The customer or user of the MEDUVENT Standard device should ensure that it is used in such an environment.			
Interference immunity tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidelines**
Conducted RF interference acc. to IEC 61000-4-6	3 $V_{effective\ value}$ 150 kHz to 80 MHz outside ISM bands[a]	3 V	Portable and mobile RF equipment should not be used any closer to the MEDUVENT Standard device including its cables than the recommended separation distance calculated in accordance with the formula applicable to the transmission frequency. **Recommended separation distance:** $d = 1,2\sqrt{P}$
	6 $V_{effective\ value}$ 150 kHz to 80 MHz within ISM bands[a]	6 V	$d = 1,2\sqrt{P}$
Radiated RF interference acc. to IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	30 V/m	$d = 0,4\sqrt{P}$ for 80 MHz to 800 MHz $d = 0,8\sqrt{P}$ for 800 MHz to 2.5 GHz where P is the maximum rated power of the transmitter in watts (W) according to the transmitter manufacturer's information and d is the recommended separation distance in meters (m)[b]. An on-site investigation should demonstrate that the field strength of stationary RF transmitters is below the compliance level at all frequencies[c],[d]. Interference is possible in the environment of devices which bear this symbol. 

Note 1: The higher frequency range applies at 80 MHz and 800 MHz.
Note 2: These guidelines may not be applicable in all cases. The propagation of electromagnetic fields is affected by absorption and reflection associated with buildings, objects and people.

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[a]The ISM frequency bands (for industrial, scientific and medical applications) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz.
The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

[b]The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range from 80 MHz to 2.7 GHz are intended to reduce the likelihood of mobile/portable communications equipment causing interference if it is unintentionally brought into the patient's vicinity. This is why the additional factor of 10/3 is applied when calculating the recommended separation distances in these frequency ranges.

[c]The field strength of stationary transmitters, such as the base stations for RF telephones and land-based mobile radio equipment, amateur radio stations, AM and FM radio and television transmitters, for example, cannot be precisely determined in advance in theory. A survey of the site should be considered in order to determine the electromagnetic environment with regard to stationary transmitters. If the field strength measured at the site where MEDUVENT Standard is used exceeds the above compliance levels, MEDUVENT Standard should be monitored to provide evidence of function in accordance with intended purpose. If unusual performance characteristics are observed, additional measures may be required – such as a different orientation or a different location for MEDUVENT Standard.

[d]Field strength should be below 3 V/m across the frequency range of 150 kHz to 80 MHz.

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Guidelines and manufacturer declaration – electromagnetic immunity

MEDUVENT Standard has been tested for immunity to the radio services listed below.
If the field strength measured at the site where MEDUVENT Standard is used exceeds the above compliance levels, MEDUVENT Standard should be monitored to provide evidence of function in accordance with intended purpose. If unusual performance characteristics are observed, additional measures may be required - such as a different orientation or a different location for MEDUVENT Standard.

Testing frequency MHz	**Frequency band** [a] MHz	**Radio service** [a]	**Modulation** [b]	**Max. output power** W	**Distance** m	**Immunity test level** V/m
385	380 to 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 to 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
810 870 930	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
1720 1845 1970	1700 to 1990	GSM 1800, CDMA 1900, GSM 1900 DECT, LTE Band 1, 3, 4, 25, UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
2450	2400 to 2570	Bluetooth, WLAN 802.11 b/g/n RFID 2450 LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240 5500 5785	5100 to 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9

[a] For many radio services, only the frequencies for radio connection of the mobile communications equipment to the base station ("uplink") were included in the table.
[b] The carrier must be modulated with a square wave with a 50 % duty cycle.
[c] As an alternative to frequency modulation (FM), pulse-width modulation with a scanning ratio of 50 % 18 Hz can be used, as this would represent the worst-case scenario even if it is not the actual modulation.

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15.7 Calculating tidal volume on the basis of height

In the start menu, you can set the patient's height under the **New patient** menu item.

This section explains how tidal volume is calculated from this.

Ideal body weight (IBW) is calculated from the height quoted (X) as shown below:

- Child[1] (height ≤ 154 cm):

$$\text{IBW (child)} = 2.05\ \text{kg} \bullet \exp\left(\frac{x}{50\ \text{cm}}\right)$$

- Adult[2] (height > 154 cm):

$$\text{IBW (female)} = 45\ \text{kg} + 2.3\ \text{kg}\left(\frac{x}{2.54\ \text{cm}} - 60\right)$$

$$\text{IBW (male)} = 50\ \text{kg} + 2.3\ \text{kg}\left(\frac{x}{2.54\ \text{cm}} - 60\right)$$

The tidal volume for the patient is calculated with the aid of ideal body weight and the setting **Vt per kg body weight** (Vt/kgBW) in the operator menu (see "7.4 Patient presets", page 71):

$$\text{Vt} = \text{IBW} \bullet \frac{\text{Vt}}{\text{kgBW}}$$

Example

- Patient, male, height 185 cm
- Setting for Vt/kg BW = 6 ml/kg

$$\text{IBW (male)} = 50\ \text{kg} + 2.3\ \text{kg} \bullet \left(\frac{185\ \text{cm}}{2.54\ \text{cm}} - 60\right) = 79.52\ \text{kg}$$

$$\text{Vt} = 79.52\ \text{kg} \bullet 6\ \frac{\text{ml}}{\text{kgBW}} = 477\ \text{ml} \approx 480\ \text{ml}$$

[1] Source: TRAUB, S.L.; JOHNSON, C.E.: Comparison of methods of estimating creatinine clearance in children. In: American journal of hospital pharmacy 37, 1980, No. 2, p. 195–201.
[2] Source: DEVINE, Ben J. Gentamicin therapy. The Annals of Pharmacotherapy, 1974, 8th year, No. 11, p. 650-655

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15.8 Exported log files

15.8.1 Setup and content of log files

When you have exported the log files to an SD card, there is a folder named **MEDUVENT Standard SNXXXX** on the SD card. The following files are located in this folder:

File name	Description
MVS_SNXXXX_debug.wm	Supports communication in the event of servicing. Only for internal use at WEINMANN Emergency.
MVS_SNXXXX_fcheck.txt	Recorded function checks (see "15.8.2 Recorded function checks (fcheck file)", page 153)
MVS_SNXXXX_status_A.txt	Supports troubleshooting and session reconstruction in the event of servicing.
MVS_SNXXXX_status_B.txt	
MVS_SNXXXX_status_C.txt	
update.txt	Contains information about software updates performed.

15.8.2 Recorded function checks (fcheck file)

The **fcheck** file stores the function checks which have been performed along with the date, time, and their results. This information helps you with documentation in the context of your quality management system. You can open the **fcheck** file using a spreadsheet program (e.g. Microsoft® Excel®).

The following tests are performed as part of the function check and listed in the **fcheck** file:

Columns	Description
#date	Date of the function check
time	Time of the function check
sequence	Consecutive session number
uid	Clear numerical description of log entry type
fcheck	Indicates that a log entry in the context of the function check is involved

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Columns	Description
result	Overall result of the function check: • **ok** = test passed • **failed** = test failed • **not tested** = test not performed A function check is considered failed if at least one test is failed.
alarmsystem	Check of visual and audio alarms including alarm for • airway pressure high ↑ • energy failure
buttontest	Check of buttons and navigation knob
filterwear	Test of hygiene filter
medutrigger	Check of MEDUtrigger
powerelectronics	Check of electronics
blower	Check of blower
flowout	Check of zero point of flowout differential pressure sensor
flowo2	Check of zero point of flowO_2 differential pressure sensor
presplausible	Check of the airway pressure sensor (pneumatic)
expvalvecontrol	Check of patient valve control
hosesystemtight	Check of breathing circuit for leaks
expvalvetight	Check of patient valve for leaks
volplausible	Check of volume administered
checkvalvetight	Check of check valve diaphragm in patient valve
flowoutplausible	Check flow measurement sensors (flowout and flowo2) against one another
pawaccurate	Check of the airway pressure sensor (pneumatic)

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15.9 Alarm delay times

Alarm	Delay time
Apnea	30 s
Vt not achievable • At 5/min • At 40/min	Triggers after 2 breaths Up to 24 s 3 s
Respiratory rate ↑ • At 5/min • At 40/min	Triggers after 2 breaths Up to 24 s 3 s
Vt ↓ • At 5/min • At 40/min	Triggers after 2 breaths Up to 24 s 3 s
PEEP high ↑ • At 5/min to 8/min • At 40/min	Triggers after 2 breaths 5 s 3 s

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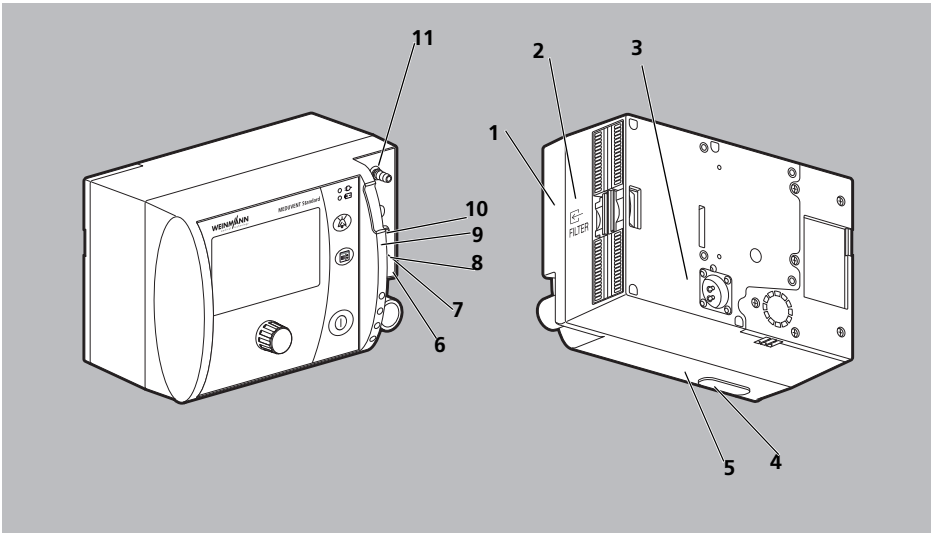
16 Symbols and labels

16.1 Labels on the device



16-1 Labels on the device

No.	Symbol	Description
1		Do not sit on device
		Do not climb on device
		Follow instructions for use.
		UL label with certification code (see "15.1 Technical data, device", page 138)
2		Inlet opening for ambient air
3		Input voltage (12 V – 15 V)

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No.	Symbol	Description
4		Follow instructions for use.
5		Date of manufacture
		Serial number
		Manufacturer
		Direct voltage
		Input voltage (12 V – 15 V)
	CE 0197	CE marking (confirms that the product complies with the applicable European directives)
		Do not dispose of device in domestic waste.
		Type of protection against electric shock: Protection class II device
	IP54	Degree of protection against: • Ingress of solid objects • Ingress of dust • Ingress of water with harmful effect
		Follow instructions for use.
		Type BF applied part
6		Connection for MEDUtrigger
7		Follow instructions for use.
8		Safety check label (STK, only applies to Germany): Indicates when the next safety check in accordance with §11 of the Medizinprodukte-Betreiberverordnung [German regulation concerning the operators of medical devices] is required.

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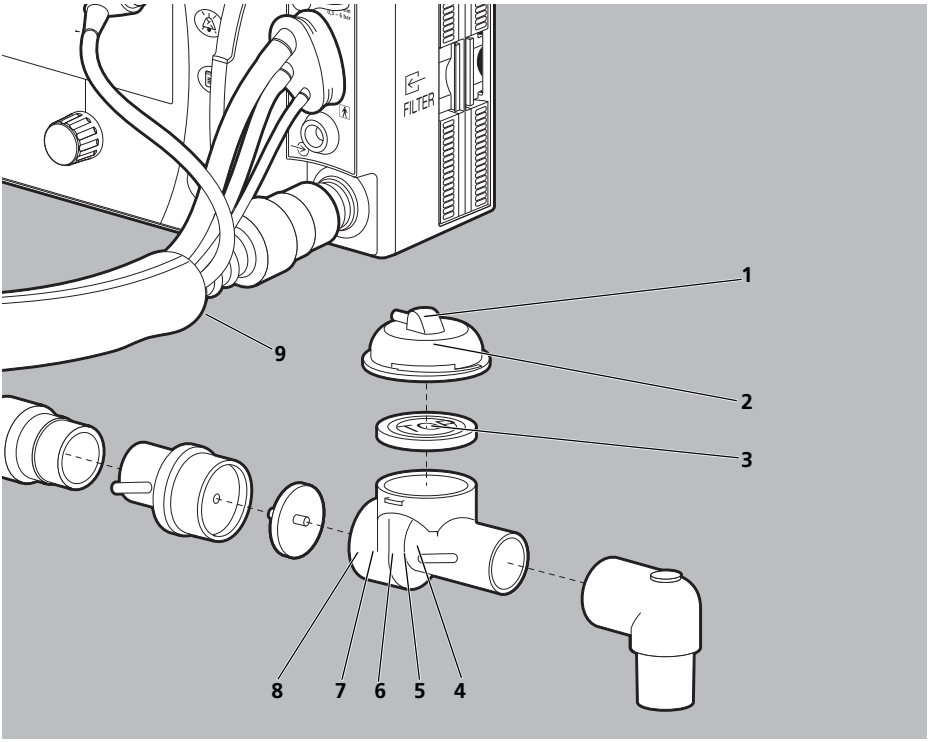
No.	Symbol	Description
9		Maintenance label: Indicates when the next maintenance is due.
10		Type BF applied part
11		Oxygen inlet 0.3 bar – 6 bar / 15 l/min O_2

16.2 Labels on the accessories

16.2.1 Labels on the breathing circuit



16-2 Labels on the breathing circuit

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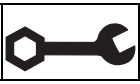
No.	Symbol	Description
Reusable breathing circuit and disposable breathing circuit		
1		Indicates the correct flow direction during inspiration.
3	TOP	Indicates the correct installation position of the PEEP control diaphragm.
4	CE 0197	CE marking (confirms that the product complies with the applicable European directives)
5		Date stamp for year and month
6		Follow instructions for use.
7	**>PC<**	Material designation: Polycarbonate
8	**134 °C**	Steam sterilization at 134 °C
Additionally for reusable breathing circuit only		
9		Indicates the date of the next maintenance (position: on service label).
Additionally for disposable breathing circuit only		
2		Disposable item, do not reuse

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16.2.2 Labeling on the device information label of the MEDUtrigger

Symbol	Description
Device information label	
	Degree of protection against electric shock: Device type BF
	Do not dispose of device in household waste
CE 0197	CE marking (confirms that the product complies with the applicable European directives)
IP54	Degree of protection against: • Ingress of solid objects • Ingress of dust • Ingress of water with harmful effect
	Type of protection against electric shock: Protection class II device
	Date of manufacture

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16.3 Labels on the packaging

16.3.1 Labels on the packaging of the breathing circuit (reusable)

Symbol	Description
	Article number
	Manufacturer with date of manufacture
	Limits of the storage temperature range
	Limits of the storage humidity range
	Follow instructions for use.
	Latex-free

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17 Warranty

Starting from the date of purchase, WEINMANN Emergency offers the customer a limited manufacturer's warranty on a new original WEINMANN Emergency product or replacement part installed by WEINMANN Emergency in accordance with applicable warranty terms and conditions for the particular product and the warranty periods listed below. The warranty terms and conditions are available on the Internet at www.weinmann-emergency.com. On request, we will also send you the warranty terms and conditions. If you wish to make a warranty claim, consult your authorized dealer.

Product	**Warranty periods**
WEINMANN Emergency devices including accessories (for exceptions see below) for oxygen medicine and emergency medicine	2 years
MEDUtrigger connection line	1 year
Masks, including accessories, rechargeable batteries, batteries (unless otherwise stated in the technical documentation), sensors, breathing circuits	6 months
Disposable products	None

18 EC Declaration of Conformity on Medical Devices

WEINMANN Emergency Medical Technology GmbH + Co. KG hereby declares that the product complies fully with the respective regulations of Medical Device Directive 93/42/EEC.
The unabridged text of the Declaration of Conformity can be found on our website at www.weinmann-emergency.com.

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Manufacturer
WEINMANN Emergency
Medical Technology GmbH + Co. KG
Frohbösestraße 12
22525 Hamburg
GERMANY
T: +49 40 88 18 96-120
E: customerservice@weinmann-emt.de

Center for Production, Logistics, Service
WEINMANN Emergency
Medical Technology GmbH + Co. KG
Siebenstücken 14
24558 Henstedt-Ulzburg
GERMANY

CE 0197

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