

## **MEDUVENT Standard**

Ventilator

Instructions for Use for Devices from Software Version 2.1





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

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### Introduction

#### About this document 11

This document describes all possible versions of the device.

The functions, accessories and other parts described in this document or shown in illustrations depend on the version procured, and are not available in all cases.

If functions of the device can only be enabled by purchasing a specific option, this document makes this clear by appending "(optional)" and "(only with option XXXX)" to the text.

Illustrations in these instructions for use are for general understanding, and may differ from the actual version. No claims can be brought on the basis of any deviations.

Texts shown in the device display appear in this document in bold. Example: Select Start.

## **Explanation of warnings**



#### Danger!

DANGER indicates a dangerous situation which will result in death or serious injury if not prevented.



#### Warning!

WARNING indicates a dangerous situation which might result in death or serious injury if not prevented.



#### Caution!

CAUTION indicates a dangerous situation which might result in minor injury if not prevented.

#### NOTICE

#### Notice!

NOTICE indicates risks which might possibly cause material or environmental damage.



Designates useful tips relating to a particular sequence of actions.

The instructions for use are part of the device. If the instructions for use and the following safety instructions are not followed in their entirety, therapy might fail or be put at risk. This could cause the patient, the user and bystanders serious or life-threatening injury.

- ⇒ Follow instructions for use in their entirety.
- ⇒ Keep the instructions for use accessible and near the device at all times.
- ⇒ Use the device only for the intended purpose (see "2.1 Intended purpose", page 7).
- $\Rightarrow$  Do not use the device if it is contra-indicated.
- ⇒ Follow the instructions for use of accessories and other parts.

Report any serious incidents involving the device to the manufacturer and to the responsible authority.

## 2.1 Intended purpose

#### **Indications**

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 target group(s)

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.

#### Intended users

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

#### Contra-indications

There are no known contra-indications for the use of this product.

#### **Intended areas of application** 2.1.1

- 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

#### Possible side effects and complications 2.1.2

- Undesired effect on 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)

#### 2.1.3 Exclusions and limitations of the intended use

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

## 2.2 Clinical benefit of the product

The medical benefit of ventilation therapy is the sustained oxygenation and ventilation (CO<sub>2</sub> evacuation) of the lungs in the event that spontaneous breathing fails. A mechanical ventilator also offers the following benefits relative to a bag-valve mask:

More constant tidal volume and lower peak pressures

- Less risk of hyperventilation
- Less risk of undesired hypoventilation
- Less risk of gastric insufflation

### 2.3 Requirements on the user

The user must meet the following requirements:

- The user is medically trained and has the necessary technical knowledge and experience in the emergency medical treatment of patients.
- On the basis of this technical knowledge and experience, the
  user is in a position to perform the tasks assigned to him or her
  safely, and to independently recognize, assess and avoid
  potential risks to him or herself, to the patient or to bystanders.
- The user has been trained and has received instruction in the use of the device.
- The user has been trained to apply the necessary hygiene procedures.

## 2.4 Using the device safely



## 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 can cause serious or life-threatening injury to the patient.

 $\Rightarrow$  Do not use the device for sustained ventilation (longer than 24 hours).

## **A** WARNING

## Hazardous therapy as a result of inadequate patient monitoring!

If the patient and the device are not observed and monitored during ventilation, delayed response 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.
- $\Rightarrow$  Additionally use external monitoring (e.g. SpO<sub>2</sub> and/or etCO<sub>2</sub>).

## **A** 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 can cause serious or life-threatening injury to the patient.

 $\Rightarrow$  Have an alternative means of ventilation at the ready.

## **A** WARNING

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

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

⇒ Always set the pressure limit pMax to match 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 becomes disconnected during patient transport, the patient might be extubated, resulting in laryngospasm. This can cause serious or life-threatening injury to the patient.

- ⇒ Secure the device against falling while transporting the patient on a stretcher.
- ⇒ Always fix the breathing circuit in place while transporting the patient.

## **A** WARNING

#### Risk of asphyxia as a result of aspiration!

Mask ventilation at excessive ventilation pressures can lead to gastric insufflation and aspiration of stomach contents. This can cause serious or life-threatening injury to the patient.

 $\Rightarrow$  Avoid high pressures during mask ventilation.

#### 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.

- ⇒ Check that the mask or tracheal tube is correctly positioned.
- $\Rightarrow$  Do not use the measured MVi value as an adequate means of assessing ventilation.
- ⇒ Use external monitoring (etCO<sub>2</sub>, SpO<sub>2</sub> or expiratory volume measurement).



#### 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 cause the patient and the user serious or life-threatening injury.

⇒ Always use a hygiene filter when operating the device in a contaminated environment.



# 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 can cause serious or lifethreatening injury to the patient, and damage the device.

- $\Rightarrow$  Only operate the device with a hygiene filter.
- ⇒ Replace the hygiene filter after operating the device in a very dusty atmosphere.

## **▲** WARNING

#### Disrupted or failed therapy due to defective or nonoperational device or accessories!

Using defective devices or defective accessories may result in device malfunctions. This might cause the patient and the user 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.
- ⇒ Follow the instructions for use of the accessories.
- ⇒ Observe maintenance intervals.



#### 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 can cause serious or life-threatening injury to the patient, 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.



#### 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 can cause serious or life-threatening injury to the patient.

- ⇒ 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 unit for example).

## Risk of injury and treatment delay due to imperceptible alarm signals!

Alarm signals below 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 ambient noise level.

**A** 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 can cause serious or life-threatening injuries to the user.

 $\Rightarrow$  Use only approved accessories.

**A** WARNING

## Disrupted or failed therapy due to operation of the device and accessories outside the specified ambient conditions!

Using the device and accessories outside the specified ambient conditions might result in tolerances being exceeded, and in device failure. This can cause serious or life-threatening injury to the patient.

- ⇒ Only operate the device and accessories within the specified ambient conditions (see "16 Technical data", page 157).
- $\Rightarrow$  Never use the device and accessories in hyperbaric chambers.

**A** 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.

 $\Rightarrow$  Never use the device in hyperbaric chambers.

**A** 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 can cause serious or life-threatening injury to the patient.

 $\Rightarrow$  Do not use bubble humidifiers.

**A** 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, causing him or her serious or lifethreatening injury.

⇒ Do not use the 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 can cause serious or life-threatening injury to the patient.

- ⇒ Observe the maintenance schedule according to the instructions for use and the displays on the device.
- ⇒ Observe the maintenance schedule even 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 can cause serious or life-threatening injury to the patient.

⇒ 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 can cause serious or life-threatening injury to the patient, user and bystanders.

- ⇒ 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.



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

Flammable gases and anesthetics can cause spontaneous explosions. This might cause the patient, user and bystanders serious or life-threatening injury, as well as damage the device.

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



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

Incorrect handling of the rechargeable battery might cause the patient, user and bystanders serious or life-threatening injury.

- ⇒ Do not throw the rechargeable battery into a fire, and never expose it to high temperatures.
- $\Rightarrow$  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.
- $\Rightarrow$  Do not subject the rechargeable battery to high pressure.
- ⇒ Have the rechargeable battery replaced only by trained personnel.



# 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 can cause serious or life-threatening injury to the patient.

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



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

Medical electrical devices which are operated directly next to or on top of one another can cause mutual interference to functionality. This can cause serious or life-threatening injury to the patient.

- $\Rightarrow$  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: WEINMANN Emergency devices which have been tested to ensure that they can be operated alongside the device without problems. A list of the tested 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 might lead to therapy being interrupted, and cause the patient serious or life-threatening injury.

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

## **▲** WARNING

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

Portable high-frequency communication equipment (e.g. 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 radio-frequency communication equipment a minimum distance of 30 cm away from the device and its accessories

### **WARNING**

#### Faults 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 can cause serious or life-threatening injury to the patient.

⇒ Do not use the device and its accessories in the vicinity of highfrequency 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 can cause serious or life-threatening injury to the patient.

- ⇒ Use only approved accessories.
- ⇒ Follow the instructions for use of the accessories.



## 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 serious or life-threatening injury.

- $\Rightarrow$  Do not reuse disposables.
- ⇒ Do not subject disposables to hygienic reprocessing.

## **A** 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 cause the patient and the user serious or life-threatening injury.

- $\Rightarrow$  Do not reuse disposables.
- ⇒ Do not subject disposables to hygienic reprocessing.



## 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 can cause serious or life-threatening injury to the patient.

- $\Rightarrow$  Quickly move the patient to a warmer location.
- ⇒ At temperatures below 5 °C, use a breathing system filter to extend application time.



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

Unsuitable cleaning agents and disinfectants may remove 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 can cause serious or lifethreatening injury to the patient.

- ⇒ Only use the recommended cleaning agents and disinfectants.
- ⇒ Replace illegible labels.



## 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.



# Increased spontaneous breathing resistance and reduced ventilation performance resulting from blocked intake opening/blocked 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.

### **A** 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.



## Inadequate oxygen concentration due to leaks during ventilation!

Leaks during ventilation may lead to the concentration of oxygen administered in the respiratory gas being reduced. This might injure the patient.

- ⇒ Check that the mask or tracheal tube is correctly positioned.
- ⇒ Note measured value O₂i for assessing ventilation. Also correct oxygen supply if necessary.
- $\Rightarrow$  Use suitable external patient monitoring methods.



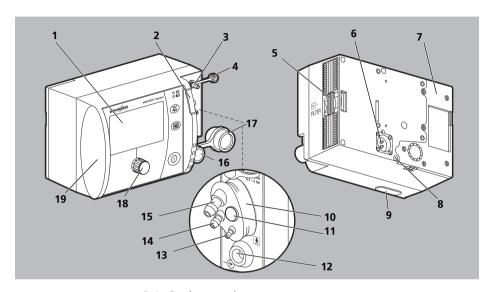
## Risk of injury as a result of using the device at high ambient temperatures!

Using the device at high ambient temperatures might result in the temperatures of the respiratory gas and of applied parts rising. Temperatures > 41 °C might injure the patient if applied for a prolonged period.

- ⇒ Note that all applied parts can warm up to ambient temperature.
- $\Rightarrow$  Note that the applied respiratory gas can reach a temperature > 41 °C.
- $\Rightarrow$  Shorten the application time at ambient temperatures > 41 °C.

## 3 Description

## 3.1 Overview



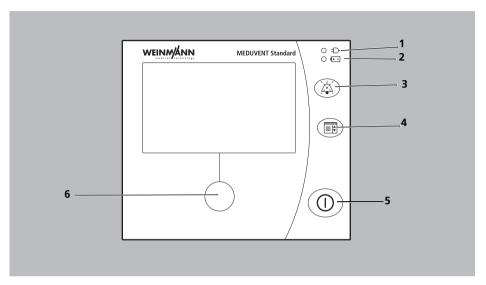
3-1 Device overview

No.	Designation	Description
1	Display	Displays settings and current values (see "3.3 Symbols in the display", page 25).
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	Protective cap for connection terminal	Covers the bore in the measuring circuit connection.

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

## 3.2 Control panel and display

### 3.2.1 Control panel



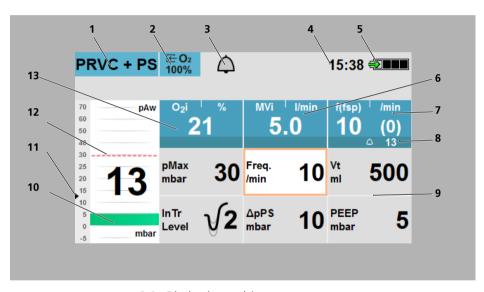
3-2 Control panel

No.	Designation	Description
1	Line power indicator	<ul> <li>LED showing green: Indicates that the device is connected to line power.</li> <li>LED not on: The device is being operated by the rechargeable battery and not by line power.</li> </ul>
2	Battery status indicator	<ul> <li>LED showing green: The rechargeable battery is fully charged.</li> <li>LED flashing green: The rechargeable battery is being charged.</li> <li>LED showing red: The rechargeable battery is defective or not in the device.</li> <li>LED not on: The device is being operated by the rechargeable battery and not by line power.</li> <li>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.</li> </ul>

ΕN

No.	Designation	Description
3	Alarm mute button	<ul> <li>Mutes an alarm for 120 s.</li> <li>During ventilation: Press and hold to open alarm limit settings.</li> </ul>
4	Menu button	<ul><li>In the start menu: Opens the operator menu.</li><li>During ventilation: Opens the user menu.</li></ul>
5	On/Off button	Switches the device on or off.
6	Navigation knob	Permits values for ventilation parameters to be selected and confirmed.

### 3.2.2 Display



3-3 Display (example)

No.	Designation	Description
1	Ventilation mode	Indicates the ventilation mode set.
		Indicates the oxygen content being supplied (see "3.3 Symbols in the display", page 25).
3	Alarm	Indicates whether the audio alarm output is active or muted (see "3.3 Symbols in the display", page 25).
4	4 Time Displays current time.	
5	Battery status	Indicates the charge level of the battery (see "3.5 Rechargeable battery and battery status indicator", page 32).

### 3 Description

No.	Designation	Description
6	MVi	Indicates the minute volume delivered by the device.
7	Respiratory rate (f(fsp))	<ul> <li>f indicates the total respiratory rate per minute.</li> <li>(fsp) indicates the number of spontaneous breaths per minute.</li> </ul>
8	Alarm limit	Displays the set alarm limit.
	Ventilation parameters	Ventilation parameters which can be set to control ventilation:
	Vt	Tidal volume
9	Freq.	Ventilation rate
9	PEEP	Positive end-expiratory pressure
	pMax	Maximum ventilation pressure
	ΔpPS	Pressure support
	InTr	Inspiratory trigger (3-level)
10	Bar graph	Indicates the level of ventilation pressure being administered.
11	Maximum value indicator	Indicates the ventilation pressure achieved at the end of inspiration.
12	Pressure limit	Indicates the value set for pressure limit pMax.
13	O <sub>2</sub> i	Displays the oxygen concentration delivered.

## 3.3 Symbols in the display

Symbol	Designation	Description
$\triangle$	Alarm symbol	Audio alarm output active
	7 IIIIII Symbol	Audio alarm output muted for 120 seconds
	Battery status symbol	Indicates current battery status (see "3.5 Rechargeable battery and battery status indicator", page 32).
<u>^</u>		Fault determined during function check
(II)	Function check symbols	Follow instructions for use
4		Servicing measure required
*	Service reminder symbol	Flashing on the start screen:  Maintenance interval has expired  Interval for device Technical Safety Check ("Sicherheitstechnische Kontrolle" in accordance with § 11 of the German regulation MPBetreibV) has expired  Battery life has expired
*		Emergency mode Infant (up to about 1 year old)
<b>†</b>	Emergency mode symbol	Emergency mode Child (between about 1 and 12 years old)
Ť		Emergency mode Adult (from about 13 years old)
- Instruction of the second	New patient symbol	Set ventilation mode and parameters for a new patient individually
<b>S</b>	Function check symbol	Start function check

Symbol	Designation	Description
√1		Inspiratory trigger Level 1: high sensitivity
√2	Trigger level symbol	Inspiratory trigger Level 2: medium sensitivity
√3		Inspiratory trigger Level 3: low sensitivity
<b>⊆ O</b> ₂ 93%	Supply gas symbol	Operation with concentrator oxygen
<b>€</b> O₂ 100%		Operation with 100 % oxygen

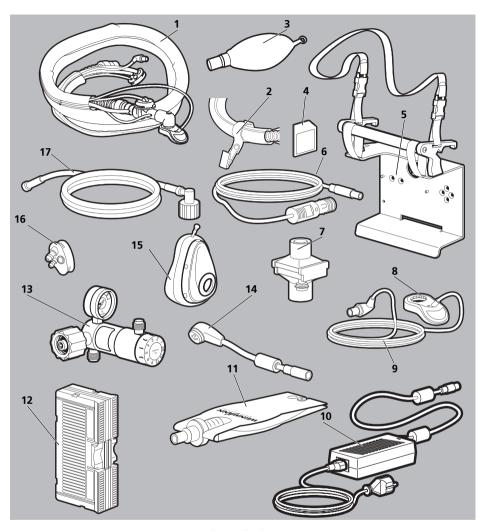
There is an overview of the symbols and labels on the device and its packaging in the Symbols and labels section (see "17 Symbols and labels", page 177).

## 3.4 Accessories and other parts

The following presents an overview of accessories and other parts of the device. For a complete list, including the relevant article numbers, refer to the "Scope of supply" section (see "15 Scope of supply", page 151). Please follow the instructions for use for accessories and other parts.

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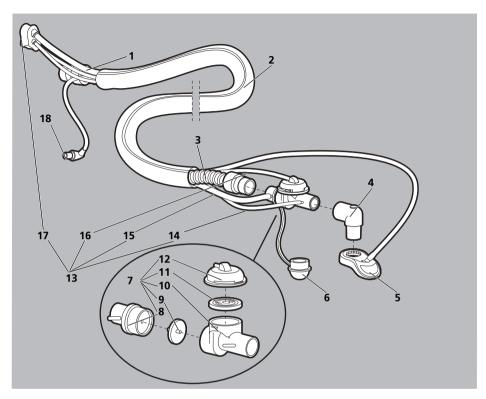
### 3.4.1 Overview



3-4 Accessories and other parts

No.	Designation	Description
1	Breathing circuit	Administers the inspiratory gas to the patient via a mask or tracheal tube. There are 2 types of breathing circuit:  Reusable breathing circuit (see 3.4.2, p.29)  Disposable breathing circuit (see 3.4.3, p.31)
2	Hook and loop strap with clip	Attaches the breathing circuit to the patient's clothing.
3	Testing bag	Simulates a ventilated patient in the function check.
4	SD card	For reading out session data and service data, and for performing software updates.
5	Portable unit (example)	Used to transport the device (see "3.6 Transport options", page 33).
6	12 V cable	Supplies the device with power from the vehicle's onboard power supply.
7	Breathing system filter	For filtering and humidifying respiratory air.
8	MEDUtrigger	Used to trigger mechanical breaths manually.
9	MEDUtrigger connecting cable	Connects the MEDUtrigger to the device.
10	Power supply unit and charger	Supplies power to the device.
11	EasyLung for WEINMANN Emergency	Simulates a ventilated patient for presentation purposes and in the function check.
12	Hygiene filter	Protects the device from viral and bacterial contamination.
13	Pressure reducer	Reduces the pressure of the oxygen from the oxygen cylinder to the operating pressure for the device.
14	Charging adapter	Connects the power supply unit and charger or the adapter cable for 12 V on-board power to the device.
15	Ventilation mask	Connects the breathing circuit to the patient.
16	Adapter for disposable breathing circuit	Allows the device to be operated with a disposable breathing circuit.
17	Oxygen inlet tube	Routes the oxygen from the oxygen supply to the device.

### 3.4.2 Reusable breathing circuit



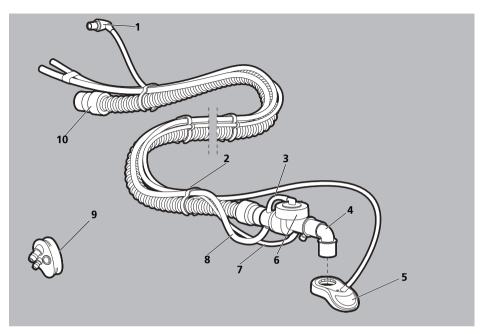
3-5 Reusable breathing circuit

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	Used to trigger mechanical breaths manually.
6	Protective cap	Protects the patient end of the breathing circuit from damage and dirt.

### 3 Description

No.	Designation	Description	
7	Patient valve	Switches between inspiration and expiration.	
Compris	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)		
Compris	ing:		
14	Pressure measuring tube	Measures ventilation pressure at the patient.	
15	Flexible oxygen tube	Supplies oxygen to the patient.	
16	PEEP control tube	The device controls the patient valve and PEEP by way of the PEEP control tube.	
17	Adapter for reusable breathing circuit	Connects the measuring circuit to the device.	
18	MEDUtrigger connecting cable	Connects the MEDUtrigger to the device.	

### 3.4.3 Disposable breathing circuit



3-6 Disposable breathing circuit

No.	Designation	Description
1	MEDUtrigger connecting cable	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 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 ventilation pressure at the patient.
8	Flexible oxygen tube	Supplies oxygen to the patient.
9	Adapter for disposable breathing circuit	Connects the device to the measuring circuit of the disposable breathing circuit. The adapter for the disposable breathing circuit remains permanently attached to the device.
10	Ventilation hose	The respiratory gas flows through the ventilation hose from the device to the patient valve.

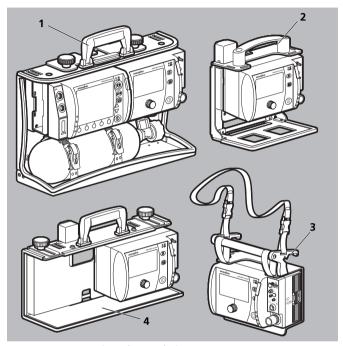
# 3.5 Rechargeable battery and battery status indicator

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
<b>(</b>	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 indicator is red.  Battery weak appears in the display.
(0000	Battery almost empty  Battery empty appears in the display.  The device can be used for at least another 5 min.
	<ul> <li>Battery is defective.</li> <li>or</li> <li>No battery.</li> <li>or</li> <li>Battery not at suitable temperature.</li> </ul>
€200■	Green arrow: Battery is charging.

## 3.6 Transport options

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



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

#### 4 **Preparation**

### **▲** WARNING

#### Electric shock on contact with 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 can cause serious or life-threatening injury to the patient. ⇒ Use only patient valves approved by WEINMANN Emergency.

#### 4.1 Mounting the device

The device is mounted on a portable unit and is ready for use as standard. Follow the instructions for use of the portable unit for mounting the device on the portable unit, and mounting the portable unit in emergency vehicles.

## 4.2 Connecting a power supply



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

If you are using a portable unit with the MEDUVENT Standard and MEDUCORE Standard or MEDUCORE Standard<sup>2</sup> device combination, the devices might lose power when using the 50 W power supply unit and charger, and 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<sup>2</sup> device combination.

## Failure of therapy as a result of defective power supply unit and charger!

A power supply unit and charger which is defective due to shock, vibration or wet can no longer charge the battery, and so might lead to therapy failing.

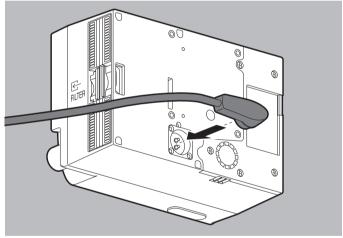
- ⇒ Do not use the power supply unit and charger outdoors.
- ⇒ Protect the power supply unit and charger from wet.
- ⇒ Do not use the power supply unit and charger in an emergency vehicle.



## Risk of infection from contaminated power supply unit and charger!

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

 $\Rightarrow$  Protect the power supply unit and charger from contamination.



1. Connect the device to line power by its charging adapter (WM 28979) and power supply unit and charger.

#### or

When operating on a portable unit: Attach the portable unit 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 battery.

### 4.3 Connecting the breathing circuit

The disposable breathing circuit and the reusable breathing circuit are connected to the device differently:

- Reusable breathing circuit: The measuring circuit connector is connected directly to the device.
- Disposable breathing circuit: The adapter for the disposable breathing circuit is permanently connected to the device.
   The flexible oxygen tube and pressure measuring tube are connected to the adapter for the disposable breathing circuit.

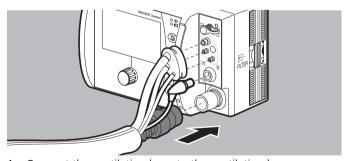
### **A** WARNING

## 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 volume of the overall system. Increased dead space volume may lead to hypoventilation. This can cause serious or life-threatening injury to the patient.

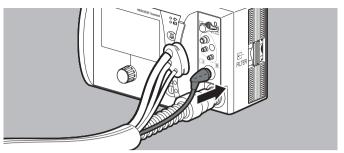
- ⇒ Use only approved accessories.
- ⇒ Pay attention to increased dead space volume when ventilating at low tidal volumes.

### 4.3.1 Connecting the reusable breathing circuit

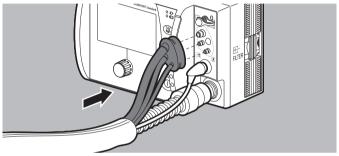


1. Connect the ventilation hose to the ventilation hose connection.

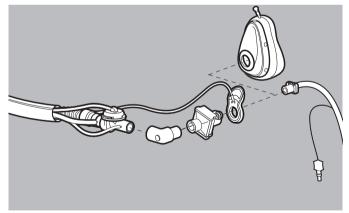
36



2. If present: Connect the MEDUtrigger.



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

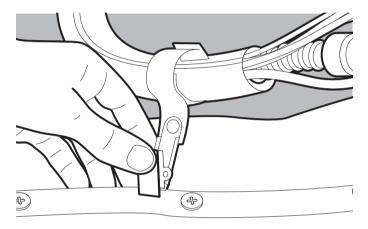


- 4. In the case of invasive ventilation: Connect the patient valve of the breathing circuit to the tracheal tube following intubation:
  - With/without elbow
  - With breathing system filter

#### or

For mask ventilation: Connect the ventilation mask to the patient valve of the breathing circuit:

- With/without elbow
- With breathing system filter
- 5. With disposable CPAP/NIV masks: Check mask is positioned correctly. The mask must be positioned firmly on the patient valve or the breathing system filter.



6. If necessary: Fix the breathing circuit to the patient's clothing using the hook and loop strap with clip.

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

### 4.3.2 Connecting the disposable breathing circuit

Requirements

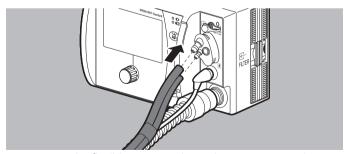
The adapter for the disposable breathing circuit is fitted to the device (see "4.5.1 Converting the device to a disposable breathing circuit", page 43).



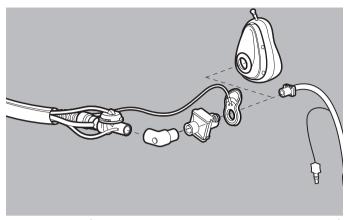
1. Connect the ventilation hose to the ventilation hose connection.



2. If present: Connect the MEDUtrigger.



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



- 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
- 5. With disposable CPAP/NIV masks: Check mask is positioned correctly. The mask must be positioned firmly on the patient valve or the 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

# **A** 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 "16 Technical data", page 157).
- ⇒ Use only oxygen sources which are free of particles, clean and dry.



# Corrupted oxygen therapy resulting from use of unsuitable oxygen!

Unsuitable oxygen might corrupt the therapy. This can cause serious or life-threatening injury to the patient.

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



# 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.

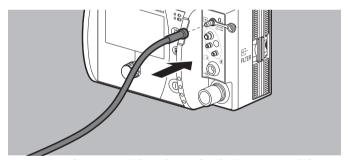
#### Requirements

- The oxygen cylinder has been filled.
- The outlet flow of the inhalation source for the oxygen supply is < 15 l/min.</li>

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



- 2. Connect the pressure reducer to the oxygen cylinder valve using a fluted union nut, and tighten it by hand.
- 3. Connect the oxygen inlet tube to the inhalation outlet of the pressure reducer.



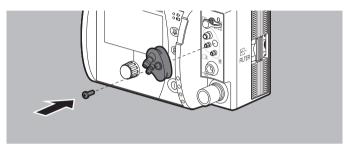
- 4. Connect the oxygen inlet tube to the device's oxygen inlet.
- 5. Set the type of supply gas  $(O_2 100 \% \text{ or } O_2 93 \%)$  in the operator menu (see "9.3 Device settings", page 107).

Result The device has been connected to the oxygen supply.

### 4.5 Converting the device

#### 4.5.1 Converting the device to a disposable breathing circuit

1. Remove the protective cap for the connection terminal from the bore on the measuring circuit connector.

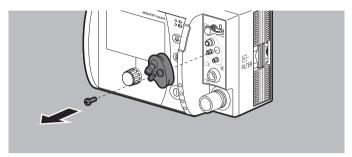


- 2. Fit the disposable breathing circuit adapter on the measuring circuit connector.
- 3. Secure the disposable breathing circuit adapter using the screw supplied.
- 4. Fit the protective cap for the connection terminal in the disposable breathing circuit adapter to cover the screw.

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

device.

# 4.5.2 Converting the device to a reusable breathing circuit



- 1. Release the protective cap for the connection terminal from the disposable breathing circuit adapter.
- 2. Loosen the screw on the disposable breathing circuit adapter.
- 3. Remove the disposable breathing circuit adapter from the device.
- 4. Fit the protective cap for the connection terminal on the open bore on the measuring circuit connection.

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

### 5 Function check

### **A** WARNING

### Disrupted or failed therapy due to defective or nonoperational device or accessories!

Using defective devices or defective accessories may result in device malfunctions. This might cause the patient and the user 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.
- $\Rightarrow$  Keep alternative means of ventilation at the ready.

### 5.1 Intervals

Perform a function check at the following intervals:

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

# 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 that the hygiene filter is positioned correctly.
- 5. Check the patient valve of the reusable breathing circuit (see "5.4 Checking reusable breathing circuit", page 53).
- 6. If necessary: Replace breathing circuit.
- 7. Check the fill level of the oxygen cylinder.
- 8. 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



# Hazardous therapy if device connected to patient during function check!

If the device is connected to the patient during the function check, this might lead to therapy posing a risk as a result of excessively high pressures or unsuitable ventilation volumes. This can cause serious or life-threatening injury to the patient.

⇒ Always disconnect the device from the patient during the function check.

### Requirements

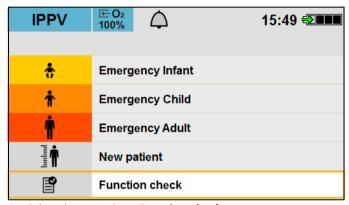
- The device is disconnected from the patient.
- The rechargeable battery is fully charged.
- The SD card is in the SD card slot.
- The hygiene filter is inserted in the filter compartment.

If the oxygen supply is to be tested: The oxygen inlet tube is connected to the oxygen inlet of the device and to the oxygen supply. The oxygen supply is shut off.

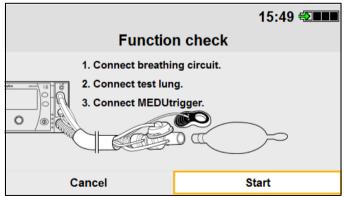
#### or

If the oxygen supply is not to be tested: The oxygen inlet is sealed off by the protective cap for oxygen inlet.

- 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 55).

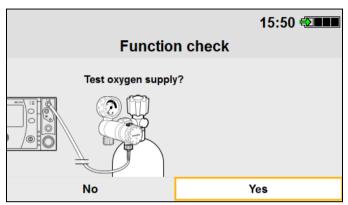


1. Select the menu item Function check.



- 2. Prepare the device:
  - Connect the breathing circuit to the device.

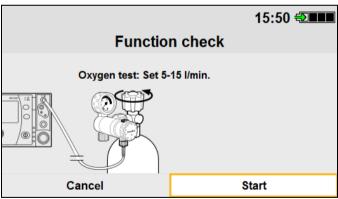
- Connect the test lung to the breathing circuit.
- Connect the MEDUtrigger.
- 3. Select Start.



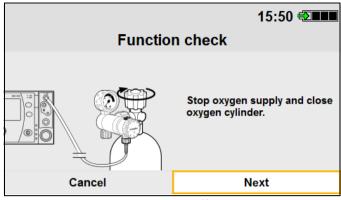
4. If you want to test the oxygen supply: Select **Yes**.

or

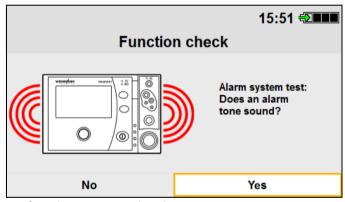
If you do not want to test the oxygen supply: Select **No**. The device skips the oxygen test.



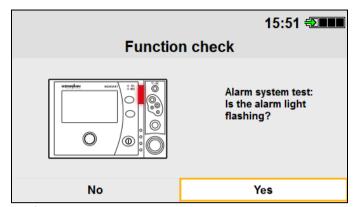
- 5. Set oxygen supply (5 l/min 15 l/min) (see "6.7 Supplying oxygen", page 66).
- 6. Select **Start**.



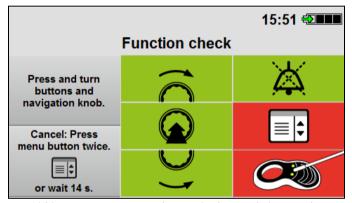
- 7. Stop the oxygen supply and shut off the oxygen cylinder (see "6.7 Supplying oxygen", page 66).
- 8. Select **Next**.



9. If an alarm tone sounds: select **Yes**.



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



- 11. Within 20 s, press or turn the required controls (except the On/ Off button ①) one after the other until all the fields go green.
- 12. If the MEDUtrigger is connected but is not displayed in the function check: Activate the Manual option in the operator menu (see "9.6.1 Enabling options", page 112). Repeat the function check.

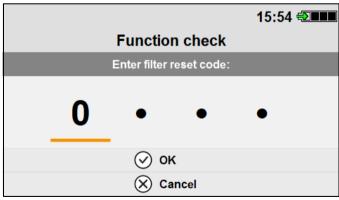
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13. Proceed with the hygiene filter in accordance with the following table:

Color	Action
Green	Continue to use hygiene filter.
	Keep hygiene filter at the ready
Yellow	or
	Order hygiene filter.
Red	Replace hygiene filter (see 12.4, p.140).
Gray	Indicates the filter life used.

14. If the hygiene filter has been replaced:

Select Reset.

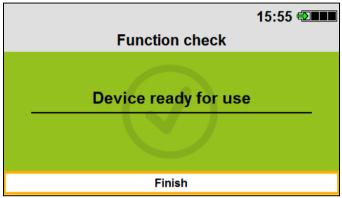


• Enter the filter reset code specified in the operator menu.

On delivery, the filter reset code is 0000. WEINMANN Emergency recommends changing this code as soon as the device is put into operation.

#### 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 <b>Details</b> . Check the parts listed in the display and replace them if necessary. Repeat the function check. If the function check is
	runction theck canceled	still not passed: Contact your authorized dealer or the manufacturer.
Device ready for use. After the function check, the service symbol in the start screen flashes.	Function check passed, but service required. Information about 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 on the SD card (see "16.8.2 Recorded function checks (fcheck file)", page 174).

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 reusable breathing circuit

#### Requirements

The patient valve of the reusable breathing circuit has been disassembled (see "7.3.1 Disassembling the reusable breathing circuit", page 74).

- 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. If a diaphragm is torn, corrugated, distorted or sticky: Replace the diaphragm.
- Assemble the reusable breathing circuit (see "7.3.2 Assembling the reusable breathing circuit", page 77).
- 5. Check the system for leaks with a new function check.

Result The reusable breathing circuit has been tested.

#### 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 oxygenenriched atmospheres and in the presence of combustible materials (e.g. textiles), sparking associated with defibrillation might cause explosions and fires. This can cause serious or lifethreatening injury to the patient, user and bystanders.

- ⇒ 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.

# **A** 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 can cause serious or life-threatening injury to the patient.

- ⇒ Always keep the alarm transmitters (alarm light, loudspeaker and display) clear.
- ⇒ Position the device display facing upward (e.g. on a table) or forward (e.g. on a wall).



### Increased breathing effort for the patient due to covered patient valve!

Covering the patient valve might impair its function and put therapy at risk. This might injure the patient.

⇒ Do not cover/seal the expiration opening of the patient valve.

# 6.1 Switching on the device

#### Requirements

If present: The device has been connected to the oxygen supply (see "4.4 Connecting the oxygen supply", page 41).

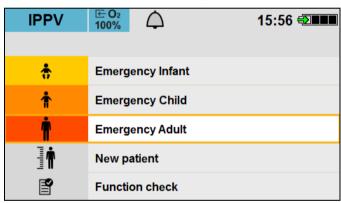
1. Briefly press the On/Off button (1).

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

- Alarm light flashes twice and 2 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:



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

Result The device is switched on and on standby.

# 6.2 Navigating in the device

	Result				
Action	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 menu item	Confirm the set value	Select menu item	Change marked ventilation parameter.	
Press the menu button	-	-	Activate the operator menu: Press and hold menu button for 2 s	Activate the user menu: Briefly press the menu button	
Alarm mute button	-	-	-	<ul> <li>Mutes an alarm for 120 seconds.</li> <li>Press and hold to open alarm limit settings.</li> </ul>	

### 6.3 Starting ventilation

# **M** 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.
- $\Rightarrow$  Additionally use external monitoring (e.g. SpO<sub>2</sub> and/or etCO<sub>2</sub>).

# **A** WARNING

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

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

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



### 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.

- $\Rightarrow$  Check that the mask or tracheal tube is correctly positioned.
- ⇒ Do not use the measured MVi value as an adequate means of assessing ventilation.
- ⇒ Use external monitoring (etCO<sub>2</sub>, SpO<sub>2</sub> or expiratory volume measurement).



# 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 cause the patient and the user serious or life-threatening injury.

⇒ Only operate the device with a hygiene filter.



# 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.



# Inadequate oxygen concentration due to leaks during ventilation!

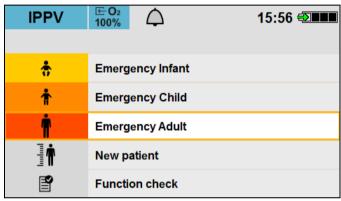
Leaks during ventilation may lead to the concentration of oxygen administered in the respiratory gas being reduced. This might injure the patient.

- ⇒ Check that the mask or tracheal tube is correctly positioned.
- $\Rightarrow$  Note measured value  $O_2$ i for assessing ventilation. Also correct oxygen supply if necessary.
- ⇒ Use suitable external patient monitoring methods.

### 6.3.1 Starting ventilation for a patient group

### Requirements

- Function check has been carried out and passed (see "5 Function check", page 45).
- The device is switched on and, after the self-test, displays the start menu.
- Connect the patient to the device via a ventilation mask or tracheal tube.



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

The device starts ventilation in IPPV ventilation mode.

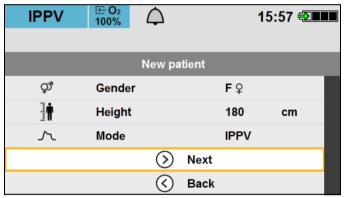
Result Ventilation for a specific patient group has been started.

### 6.3.2 Starting ventilation for a new patient

#### Requirements

- Function check has been carried out and passed (see "5 Function check", page 45).
- The device is switched on and, after the self-test, displays the start menu.

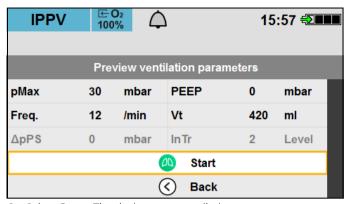
1. Select **New patient**.



- 2. Select the following parameters:
  - Gender
  - Height
  - Mode
- Select Next.

The device shows a preview of the ventilation parameters calculated. The parameters which are not active in ventilation mode are grayed out and cannot be set.

- 4. If necessary: Adjust ventilation parameters.
- 5. Connect the patient to the device via a ventilation mask or tracheal tube.



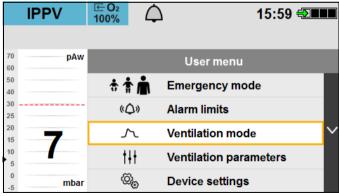
6. Select **Start**. The device starts ventilation.

Result Ventilation for a new patient has been started.

# 6.4 Changing ventilation mode

Requirements

- The device is switched on (see "6.1 Switching on the device", page 55).
- Ventilation has been started (see "6.3 Starting ventilation", page 57).
- 1. Briefly press the menu button .
  The user menu opens.

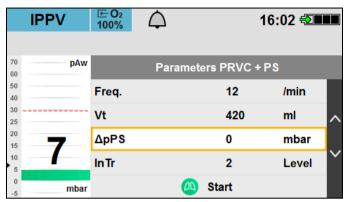


2. Select the menu item **Ventilation mode**.

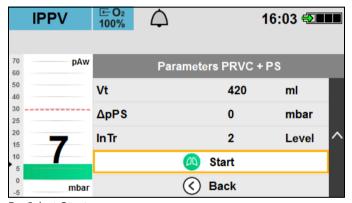
EN

3. Select the desired ventilation mode.

The parameters of the new ventilation mode are displayed.



4. If necessary: Change the ventilation mode parameters.



Select **Start**.
 The change of ventilation mode is displayed briefly.

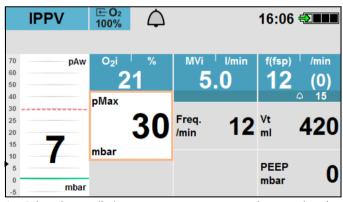
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Result The ventilation mode has been changed.

## 6.5 Changing ventilation parameters

Requirements

- The device is switched on (see "6.1 Switching on the device", page 55).
- Ventilation has been started (see "6.3 Starting ventilation", page 57).



- 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.

i

The following parameters are mutually dependent:

pMax/PEEP:

The minimum difference between pMax and PEEP is 5 mbar.  $pMax \ge PEEP + 5$  mbar

pMax/ΔpPS:

The minimum difference between PEEP +  $\Delta$ pPS and pMax is 1 mbar if  $\Delta$ pPS  $\geq$  5 mbar.

 $\Delta pPS < 5 \text{ mbar: } pMax \ge PEEP + 5 \text{ mbar}$ 

 $\Delta pPS \ge 5 \text{ mbar: } pMax \ge PEEP + \Delta pPS + 1 \text{ mbar}$ 

Frequency/Vti:

The product of Freq. x Vti results in inspiratory minute volume MVi.

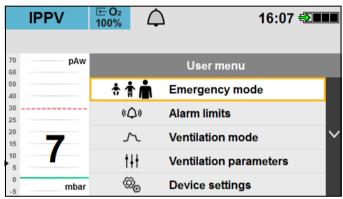
 $MVi = Freq. \times Vti$ 

 The frequency and tidal volume ventilation parameters 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.

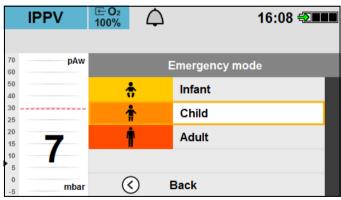
## 6.6 Changing patient group

#### Requirements

- The device is switched on (see "6.1 Switching on the device", page 55).
- Ventilation has been started (see "6.3 Starting ventilation", page 57).
- 1. Briefly press the menu button .
  The user menu opens.



2. Select Emergency mode.



3. Select and confirm a different patient group.

#### Result

t The patient group has been changed.

The device switches to the preset ventilation mode for the selected patient group and starts ventilation.

### 6.7 Supplying oxygen

### **A** CAUTION

### Therapy disrupted by supply of excessively high flow!

If the flow exceeds the maximum permitted 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.

⇒ Supply oxygen only at a maximum flow of 15 l/min.

### 6.7.1 Setting oxygen concentration

### **A** CAUTION

# Inadequate oxygen concentration due to leaks during ventilation!

Leaks during ventilation may lead to the concentration of oxygen administered in the respiratory gas being reduced. This might injure the patient.

- ⇒ Check that the mask or tracheal tube is correctly positioned.
- $\Rightarrow$  Note measured value  $O_2$ i for assessing ventilation. Also correct oxygen supply if necessary.
- ⇒ Use suitable external patient monitoring methods.

### Requirements

- The oxygen supply is connected (see "4.4 Connecting the oxygen supply", page 41).
- The type of supply gas (O<sub>2</sub> 100 % or O<sub>2</sub> 93 %) is set in the operator menu (see "9.3 Device settings", page 107).
- The device is switched on (see "6.1 Switching on the device", page 55).
- Ventilation has been started (see "6.3 Starting ventilation", page 57).



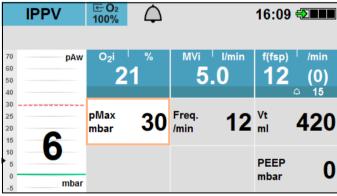
If you want an oxygen concentration of 100 %, use the administered minute volume (MVi) as a guide.

#### Example:

If you are also supplying oxygen at 5 l/min at a displayed MVi of 5 l/min, this will result in an inspiratory oxygen concentration of 100 %.

If you want a lower concentration, set a lower flow on the oxygen supply until the device displays the desired oxygen concentration.

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



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

Result The oxygen concentration has been set.

ΕN



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. Calculate 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	
Pressure in oxygen cylinder	200 bar	200 bar	
Fill level of oxygen cylinder (oxygen reserve)	2000 I	400 I	

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

Operating times of commercially-available oxygen cylinders				
Time (min) = $\frac{\text{Oxygen reserve (I)}}{\text{Flow } \left(\frac{\text{I}}{\text{min}}\right)}$				
Set FiO <sub>2</sub>	-	Operating time of oxygen cylinder (hh:mm)		
(1/11111)	2 l vo	lume	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 off the device

- 1. Press and hold the On/Off button (1) for at least 2 seconds.
- 2. Shut off 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 **(1)** 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

- 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 (see "12.4 Replacing the hygiene filter", page 140).
- 4. Hygienically reprocess the device and accessories (see "7 Hygienic reprocessing", page 70).
- 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 unit.
- 8. If necessary: Place the device and accessories in storage (see "13 Storage", page 148).

# **Hygienic reprocessing**

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

- Device
- Accessories and other parts
- 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 WEINMANN Emergency.

### **A** 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 serious or life-threatening injury.

- $\Rightarrow$  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 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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# **A** 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 can cause serious or life-threatening injury to the patient.

- ⇒ 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 "7.11 Cleaning and disinfection plan", page 92).



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

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

⇒ Use only the cleaning agents and disinfectants recommended in these instructions for use (see "7.11 Cleaning and disinfection plan", page 92).



# 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 it delivers. This can cause serious or life-threatening injury to the patient.

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



# 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 cause the patient and the user serious or lifethreatening 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 "7.11 Cleaning and disinfection plan", page 92).
- ⇒ Device and accessories are not supplied in a sterile condition. Only reuse the device and accessories if they have been subjected to hygienic reprocessing in accordance with the cleaning and disinfection plan.
- ⇒ When reprocessing the device and accessories, use only the recommended cleaning agents and disinfectants.
- ⇒ Follow the instructions for use of the cleaning agent and disinfectant 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 "7.7 Disinfecting the reusable measuring circuit by immersion", page 86) or steamsterilize it.



# 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 can cause serious or lifethreatening injury to the patient.

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



### Risk of infection from contaminated disposables!

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

- $\Rightarrow$  Do not reuse disposables.
- $\Rightarrow$  Do not subject disposables to hygienic reprocessing.



# Risk of injury and material damage 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 can cause serious or life-threatening injury to the patient, and damage 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, and remove any residues as necessary.
- ⇒ Perform a complete function check after every hygienic reprocessing procedure.
- $\Rightarrow$  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.

# 7.1 Hygienic reprocessing 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)	х	х	-			
Hygiene filter	-	-	Х			

# Preparing for hygienic reprocessing

#### Requirements

- The device is switched off (see "6.8 Switching off the device", page 69).
- 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 "7.3.1 Disassembling the reusable breathing circuit", page 74).
- 4. If necessary: Disassemble the accessories into their constituent parts.
- 5. Dispose of all disposables properly (see "14 Disposal", page 149).

All parts have been prepared for hygienic reprocessing. Result

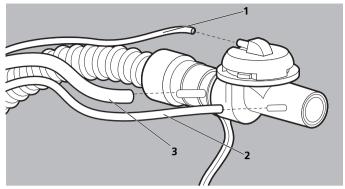
#### 7.3 Disassembling/assembling the reusable breathing circuit

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

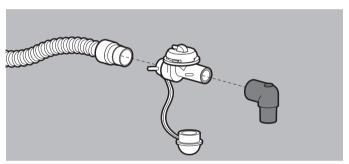
#### 7.3.1 Disassembling the reusable breathing circuit

#### Requirements

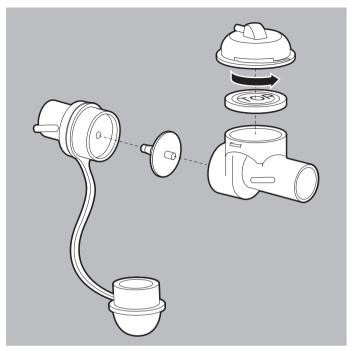
- The device is disconnected from the breathing circuit.
- The patient is disconnected from the breathing circuit.
- 1. Open the protective sleeve.
- 2. Open the hook and loop fasteners in the protective sleeve.
- 3. Detach the protective cap from the patient end of the reusable breathing circuit.
- 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. Disconnect the elbow from the patient valve.
- 7. Disconnect the patient valve from the ventilation hose.



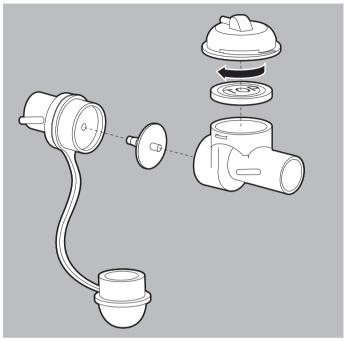
- 8. Remove the patient valve.
- 9. Detach the band of the protective cap from the check valve diaphragm holder.

Result The reusable breathing circuit has been disassembled.

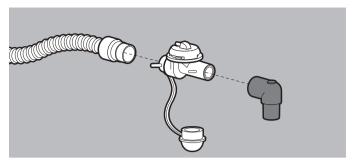
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### 7.3.2 Assembling the reusable breathing circuit

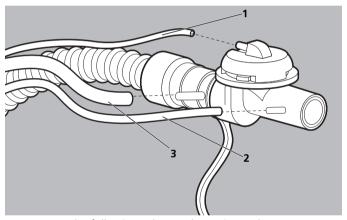
Requirements The reusable breathing circuit has been disassembled.



- 1. Attach the band of the protective cap to the check valve diaphragm holder.
- 2. Fit the patient valve. Please note:
  - 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.



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



- 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)

Please note: 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 the 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.

# 7.4 Cleaning parts manually

#### Permitted parts

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

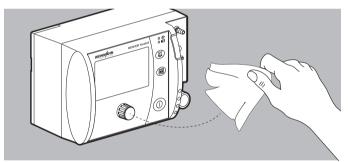
Requirements

 Hygienic reprocessing has been prepared (see "7.2 Preparing for hygienic reprocessing", page 74).

- 1. For parts approved for manual cleaning, refer to the cleaning and disinfection plan (see "7.11 Cleaning and disinfection plan", page 92).
- 2. For the cleaning agents, dose and exposure time for the individual parts, refer to the cleaning and disinfection plan (see "7.11 Cleaning and disinfection plan", page 92).
- 3. Prepare the cleaning solution as specified by the cleaning agent manufacturer
- 4. To remove all visible soiling: Brush parts thoroughly inside and out using a commercially available soft brush suitable for plastic moistened with the cleaning agent.

Please note:

- Keep uneven surfaces and grooves (e.g. top and bottom of the MEDUtrigger, navigation knob, ventilation hose connection) moist throughout exposure time, and brush off particularly thoroughly.
- Brush hoses/tubes with a special lumen brush.



- 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. Please note:
  - Use a fresh wipe for every cleaning process.
  - Carefully wipe down all surfaces.
  - All surfaces must be wetted with cleaning solution.
  - Observe the exposure time specified in the cleaning and disinfection plan.

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- 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. Please note:
  - 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 agent.
- 10. Wipe the MEDUtrigger dry with a dry cloth.
- 11. Allow all parts to dry completely at room temperature.

Result Parts have been cleaned manually.

# 7.4.1 Cleaning the reusable measuring circuit manually

Requirements

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

- For the cleaning agents, dose and exposure time, refer to the cleaning and disinfection plan (see "7.11 Cleaning and disinfection plan", page 92).
- Prepare the cleaning solution as specified by the cleaning agent manufacturer.
- Connect a sterile disposable syringe (20 ml) to a free end of the PEEP control tube.
- 4. Draw the cleaning solution through the PEEP control tube into the disposable syringe until both are completely full.
- 5. Disconnect the disposable syringe from the PEEP control tube.

- 6. Use the disposable syringe to fill the pressure measuring tube and the flexible oxygen tube with cleaning solution in the same way.
- 7. Immerse the reusable measuring circuit in cleaning solution. Please note:
  - All surfaces and lumina must be wetted completely.
  - Observe the exposure time specified in the cleaning and disinfection plan.
- 8. Rinse the outside of the reusable measuring circuit with water of potable quality.
- 9. Using the disposable syringe, rinse the inside of the reusable measuring circuit at least 8 times with water of potable quality. Please note: Flush only in one direction.
- 10. Allow the reusable measuring circuit to dry completely.
- 11. If necessary: Allow the ventilation hose to dry completely.
- 12. Check the reusable measuring circuit for residues and residual soiling.
- 13. If visible soiling is still present: Repeat manual cleaning.

Result The reusable measuring circuit has been cleaned manually.

# 7.5 Disinfecting parts by wiping

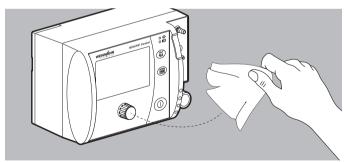
#### Permitted parts

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

#### Requirements

The parts have been cleaned manually and are visibly clean (see "7.4 Cleaning parts manually", page 79).

- For parts approved for disinfection by wiping, refer to the cleaning and disinfection plan (see "7.11 Cleaning and disinfection plan", page 92).
- For the cleaning agents, dose and exposure time for the individual parts, refer to the cleaning and disinfection plan (see "7.11 Cleaning and disinfection plan", page 92).
- 3. Prepare the solution for disinfection as specified by the disinfectant manufacturer.
- 4. Disinfect parts by wiping with one of the products listed (see "7.11 Cleaning and disinfection plan", page 92). Please note:



- Wet uneven surfaces and grooves (e.g. navigation 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.

# 7.6 Disinfecting parts by immersion

#### Permitted parts

Part	Disinfection by immersion
Reusable breathing circuit	
Ventilation hose	
Patient valve	
Elbow	
Protective cap	
Service label	
Protective sleeve	Immerse in gigasept <sup>®</sup> FF new
Reusable measuring circuit, comprising:  PEEP control tube  Pressure measuring tube  Flexible oxygen tube  Measuring circuit connector (see "7.7 Disinfecting the reusable measuring circuit by immersion", page 86)	(Schülke) Dose: 50 ml/l Exposure time: 15 min.
Hook and loop strap with clip	

#### Requirements

The parts intended for disinfection by immersion have been cleaned manually (see "7.11 Cleaning and disinfection plan", page 92). Disinfection of the reusable measuring circuit by means of immersion is described separately (see "7.7 Disinfecting the reusable measuring circuit by immersion", page 86).

 For parts approved for disinfection by immersion, refer to the cleaning and disinfection plan (see "7.11 Cleaning and disinfection plan", page 92).

- 2. For the disinfectants, dose and exposure time for the individual parts, refer to the cleaning and disinfection plan (see "7.11 Cleaning and disinfection plan", page 92).
- 3. Prepare the solution for disinfection by immersion as specified by the disinfectant manufacturer.
- 4. Immerse parts in the solution for disinfection by immersion.

  Please note:
  - All cavities must be filled
  - There must be no air bubbles.
  - All surfaces must be wetted.
  - 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.
- 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 case of visible soiling: Repeat cleaning and disinfection.

Result The parts have been disinfected by immersion.

# 7.7 Disinfecting the reusable measuring circuit by immersion

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

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

#### Requirements

- The reusable measuring circuit has been disconnected from the reusable breathing circuit (see "7.3.1 Disassembling the reusable breathing circuit", page 74).
- 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 "7.11 Cleaning and disinfection plan", page 92).
- 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.

### **A** 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. Disconnect the disposable syringe from the tube.

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- 6. Immerse the tube in the solution for disinfection. Please note:
  - 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: Use the syringe to rinse the tube at least 8 times in water of potable quality. Please note: Flush only in one direction.
- 8. Follow this principle and repeat the procedure for each tube.
- 9. Allow the tubes to dry completely.
- 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.

#### Reprocessing parts mechanically 7.8

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	Wash with Derval SOLO and Ottalin PERACET at
clip	up to 70 °C
Reusable breathing circu	iit
Ventilation hose	Cleaning:
Patient valve	neodisher <sup>®</sup> MediClean forte (Dr. Weigert):
Elbow	0.5 %, 55 °C, 10 minutes
Protective cap	Thermal disinfection: 90 °C, 5 min (corresponds to A0 value 3000)
Protective sleeve	Wash at 60 °C in an industrial washing machine Cleaning agent: 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 agent: neodisher <sup>®</sup> MediClean forte (Dr. Weigert): 0.5 %, 55 °C, 10 minutes  Thermal disinfection: 90 °C, 5 min (corresponds to A0 value 3000)

#### Requirements

The parts have been prepared for mechanical reprocessing (see "7.2 Preparing for hygienic reprocessing", page 74).

1. For parts approved for mechanical cleaning and disinfection, refer to the cleaning and disinfection plan (see "7.11 Cleaning and disinfection plan", page 92).

- 2. Place the parts in a washer-disinfector. Please note:
  - Observe the exposure time specified in the cleaning and disinfection plan.
  - 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.
- Add cleaning agent in accordance with the instructions for use of the washer-disinfector.
- 4. If necessary: Add neutralizer in accordance with the instructions for use of 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.
- If visible soiling remains: Repeat mechanical cleaning and disinfection.

Result The parts have been mechanically cleaned and disinfected.

### 7.8.1 Reprocessing protective sleeve mechanically

- 1. Open the protective sleeve completely.
- Wash the protective sleeve at 60 °C in a washing machine, or by an approved industrial washing process, adding the cleaning agent specified in the cleaning and disinfection plan (see "7.11 Cleaning and disinfection plan", page 92).
   Please note: The manufacturer's instructions must be followed.
- 3. Allow the protective sleeve to dry completely.

Result The protective sleeve is disinfected.

### 7.9 Steam-sterilizing parts (optional)

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

#### Requirements

- 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 "7.11 Cleaning and disinfection plan", page 92).
- Steam-sterilize parts using a device conforming to EN 285. Please note:
  - 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 steam sterilizer manufacturer must be followed.

Result The parts have been steam-sterilized.

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# 7.10 Preparing parts for reuse

#### Requirements

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

- 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 "7.3.2 Assembling the reusable breathing circuit", page 77).
- 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 45).
- Place parts in storage in accordance with the storage conditions (see "16 Technical data", page 157).

Result The parts are ready for use again.

# 7.11 Cleaning and disinfection plan

### 7.11.1 Levels of disinfection

Level of disinfection	Description
High-level disinfection	A germicidal process with a sterilizing agent under non-sterile conditions. The process kills all forms of microbial life apart from a large number of bacterial spores.
Intermediate-level disinfection	A germicidal process using a disinfectant which destroys viruses, mycobacteria, molds and vegetative bacteria, but not bacterial spores.
Low-level disinfection	A germicidal process using a disinfectant which destroys some molds, vegetative forms of bacteria and lipid viruses.

ΕN

### 7.11.2 Device and accessories

Carry out hygienic reprocessing according to the table below after **every** use:

Part	Level of disinfec- tion	Manual cleaning (only nec- essary in case of visible soiling)	Disinfec- tion by wiping	Disinfec- tion by immersion	Mechani- cal repro- cessing	Steriliza- tion
Device		Wipe down				
12 V cable Charging adapter		with neodisher® MediClean forte (Dr. Weigert). Dose: 10 ml/l Duration: Treat all surfaces at least twice until they are visibly clean	Wipe down with Incidin™			
MEDUtrigger with connect- ing cable			Oxywipe S (Ecolab)	Not permitted	Not permitted	Not permitted
Filter compartment	Intermediate- level disinfection		When replacing the filter: Wipe down with Incidin <sup>TM</sup> Oxywipe S (Ecolab)	'	'	
Hook and loop strap with clip		Wipe down with neodisher <sup>®</sup> MediClean forte (Dr. Weigert)	Not permitted	Immerse in gigasept <sup>®</sup> 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

### 7 Hygienic reprocessing

Part	Level of disinfec- tion	Manual cleaning (only nec- essary in case of visible soiling)	Disinfec- tion by wiping	Disinfec- tion by immersion	Mechani- cal repro- cessing	Steriliza- tion
Hygiene filter (following in- fection trans- port or expiry of filter service life (see 12.1, p.137)) Oxygen inlet tube	Disposable; do not reuse, dispose of properly (see 14, p.149)					
Pressure reducer						
Portable unit Ventilation mask	Follow the manufacturer's instructions for use					
Tracheal tube						
Breathing system filter						

ΕN

# 7.11.3 Breathing circuits

Part Reusable bre	Level of disinfec- tion	Manual cleaning (only nec- essary in case of visible soiling)	Disinfec- tion by wiping	Disinfec- tion by immersion	Mechani- cal repro- cessing	Steriliza- tion
Ventilation		Immerse in			Cleaning:	
hose		neodisher <sup>®</sup>			neodisher <sup>®</sup>	Permitted as
Patient valve		MediClean			MediClean	an option:
Elbow		forte (Dr.		Immerse in	forte (Dr.	Steam
Protective cap		Weigert) and wash.		gigasept® FF	Weigert): 0.5 %,55 °C,	sterilization* following
Reusable mea- suring circuit	Intermediate- level disinfection	Dose: 10 ml/l Duration: Treat all surfaces at least twice until they are visibly clean	Not permitted	Dose: 50 ml/l Exposure time: 15 min.	Thermal disinfection: 90 °C, 5 min (corresponds to A0 value 3000)	prior disin- fection: 5 min at 134 °C

Part	Level of disinfec- tion	Manual cleaning (only nec- essary in case of visible soiling)	Disinfec- tion by wiping	Disinfection by immersion	Mechani- cal repro- cessing	Steriliza- tion
Protective sleeve	Intermediate- level disinfection	Not permitted	Not permitted	Not permitted	Wash at 60 °C in an industrial washing machine Cleaning agent: Derval SOLO (RKI) (Kreussler) Dose: 2 ml/l Disinfectant: Ottalin PERACET (Kreussler) Dose: 2 ml/l Exposure time: 10 min, Type AB	Not permitted

Part	Level of disinfec- tion	Manual cleaning (only nec- essary in case of visible soiling)	Disinfec- tion by wiping	Disinfec- tion by immersion	Mechani- cal repro- cessing	Steriliza- tion
Disposable b	reathing circ	cuit				
Disposable breathing cir- cuit	Disposable; do	o not reuse, dis	pose of properly	y (see 14, p.14!		
Adapter for disposable breathing cir- cuit	Intermediate- level disinfection	Wipe down with neodisher <sup>®</sup> MediClean forte (Dr. Weigert). Dose: 10 ml/l Duration: Treat all surfaces at least twice until they are visibly clean	Not permitted	Dose:	Cleaning: neodisher® MediClean forte (Dr. Weigert): 0.5 %,55 °C, 10 min Thermal dis- infection: 90 °C, 5 min (corresponds to A0 value 3000)	prior disin- fection: 5 min at 134 °C or

Reusable parts are designed for 50 reprocessing cycles. The applicable instructions are those in the instructions for use enclosed by the manufacturers of the individual parts. Follow these instructions for use.

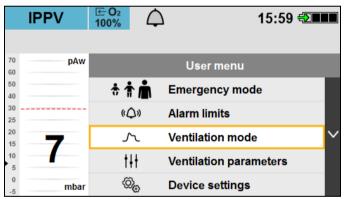
### 8 User menu

The user menu contains functions and settings which affect the current session, and which are not saved permanently as device presets (except date and time settings).

# 8.1 Navigating the user menu

Requirements

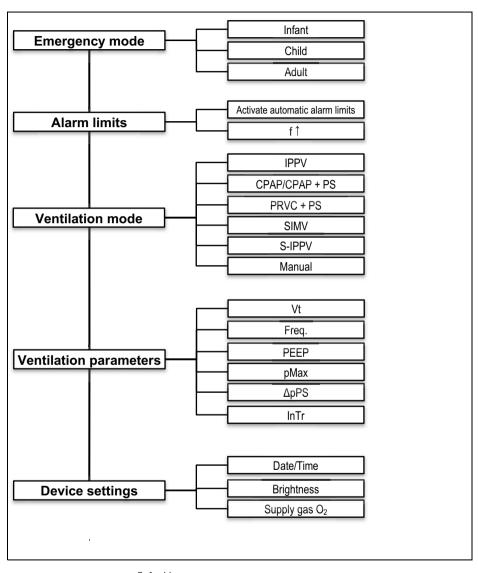
- The device is switched on (see "6.1 Switching on the device", page 55).
- Ventilation has been started (see "6.3 Starting ventilation", page 57).
- 1. Briefly press the menu button .
  The user menu opens.



- 2. Select the setting with the navigation knob and confirm.
- 3. Change the setting with the navigation knob and confirm.
- 4. To exit the menu: Select **Back** or press the menu button EB. The user menu closes automatically after 5 seconds with no input.

Result Settings are made and apply to the current session.

### 8.2 User menu structure



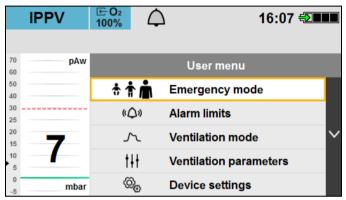
8-1 User menu

# 8.3 Settings in the user menu

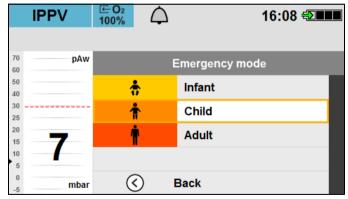
### 8.3.1 Emergency mode

In the **Emergency mode** submenu, you can change patient group during ventilation.

1. Briefly press the menu button (E). The user menu opens.



Select Emergency mode with the navigation knob and confirm.



- 3. Select patient group:
  - Infant
  - Child
  - Adult

to match the patient group selected.

Result

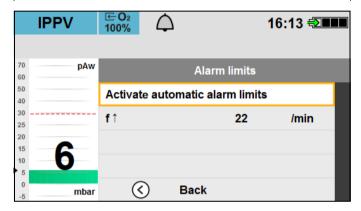
#### 8.3.2 Alarm limits



# Risk of injury due to alarm limits which are too high or too low!

The ventilation parameters of the set ventilation mode are adapted

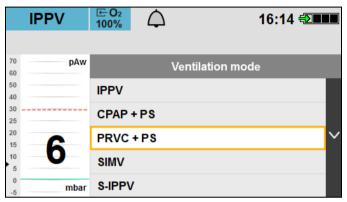
Alarm limits which are either too high or too low can prevent the device from emitting an alarm, thereby putting the patient at risk. ⇒ Always set alarm limits which have been adapted to the patient.



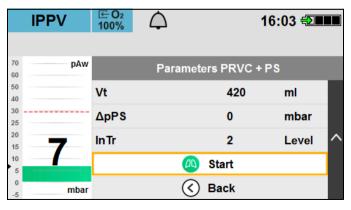
Alarm limits submenu				
Alarm	Setting range			
Activate automatic alarm limits	The device automatically sets the respiratory physiology alarm limits. The automatic limit value is 130 % of the measured value at the point of activation. At the start of ventilation, the deviation is 130 % of the value set for the ventilation parameter.			
f <b>†</b>	1/min to 140/min			

#### **Ventilation mode** 8.3.3

In the **Ventilation mode** submenu, you can change ventilation mode during ventilation (see "10 Description of the modes", page 121). You can adjust the ventilation parameters before you start the new ventilation mode.



- Select ventilation mode:
  - **IPPV**
  - **CPAP** or **CPAP** + **PS** (optional)
  - PRVC + PS (optional)
  - **SIMV** (optional)
  - **S-IPPV** (optional)
  - Manual



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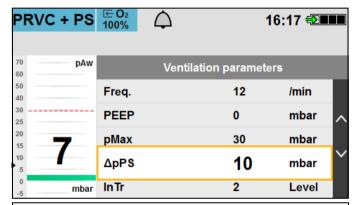
or

set ventilation parameters and select **Start**.

Result The ventilation mode has been changed.

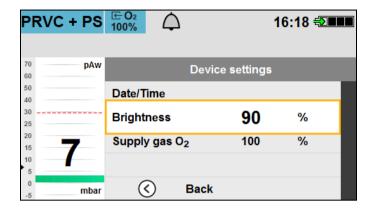
### 8.3.4 Ventilation parameters

In the **Ventilation parameters** submenu, you can change the ventilation parameters of the selected ventilation mode.



Ventilation parameters submenu					
Parameter	Parameter Unit Description				
Vt	ml	Tidal volume			
Freq.	1/min	Ventilation rate			
PEEP	mbar	Positive end-expiratory pressure			
pMax	mbar	Maximum ventilation pressure			
ΔpPS	mbar	Pressure support			
InTr		Inspiratory trigger (3-level)			

### 8.3.5 Device settings



Device settings submenu					
Setting		Setting range			
	Year	2017 to 2037			
	Month	1 to 12			
Date/Time	Day	1 to 31			
	Hour	0 to 23			
	Minute	0 to 59			
Brightness		10 % to 100 %			
Supply gas O <sub>2</sub>		100 % 93 %			

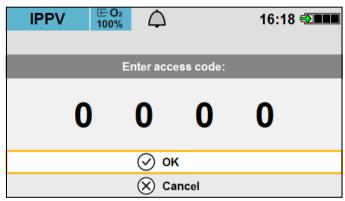
# 9 Operator menu

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

# 9.1 Activating the operator menu

Requirements

- The device is switched on (see "6.1 Switching on the device", page 55).
- The start screen is displayed.
- 1. Press and hold the menu button (ii) for 2 seconds.



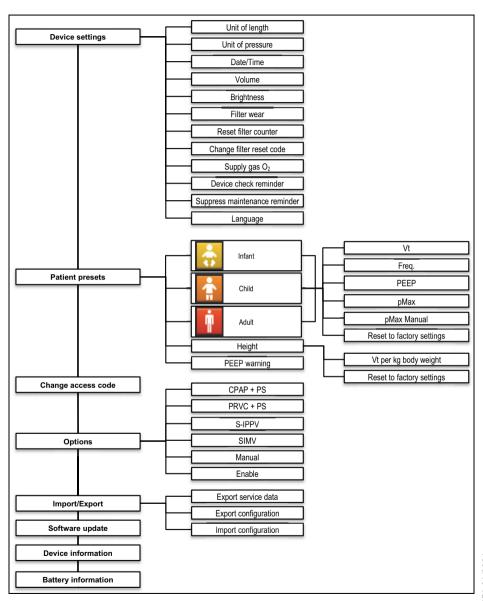
2. Enter the access code with the navigation knob and confirm.



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

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

## 9.2 Operator menu structure



9-1 Operator menu

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# 9.3 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 <sub>2</sub> O 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 tones.	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		<b>/</b>	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 <sub>2</sub>		100 % 93 %	Here you can set the supply gas type.	100 %

Parameter	Possible values	Description	Factory setting
Device check reminder	<b>&gt;</b>	Here you can activate the device check reminder (in Germany: Technical Safety Check ("Sicherheitstechnische Kontrolle" in accordance with § 11 of the German regulation MPBetreibV).	Activated
Suppress mainte- nance reminder	Yes Cancel	The maintenance reminder can be suppressed once, for 180 days from the scheduled maintenance date. You cannot cancel this suppression. If the maintenance reminder is suppressed, the device behaves as if it were not due for maintenance.  Even if the reminder is suppressed, maintenance is required (see "12.1 Intervals", page 137).	-
Language	The languages available in the device are displayed here.	Here you can set the language of the display texts.	-

# 9.4 Patient presets

Paramet	er (IPPV mode)	Possible values	Description	Factory setting
	Vt	50 ml - 2000 ml	Here you can preset the tidal volume.	60 ml
	Freq.	5 /min - 40 /min	Here you can preset the ventilation frequency.	30 /min
	PEEP	0 mbar - 20 mbar	Here you can preset the positive end- expiratory pressure.	0 mbar
Infant	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 facto- ry 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 ventilation 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 facto- ry settings	-	Here you can reset the settings for this patient group to their factory settings.	ı
	Vt	50 ml - 2000 ml	Here you can preset the tidal volume.	500 ml
Adult	Freq.	5 /min - 40 /min	Here you can preset the ventilation 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 facto- ry settings	-	Here you can reset the settings for this patient group to their factory settings.	-

#### 9 Operator menu

Parameter (IPPV mode)		Possible values	Description	Factory setting
	Vt per kg body weight	4 ml/kg - 10 ml/kg	Here you can preset the tidal volume per kilogram body weight.	6 ml/kg
Height	Reset	-	Here you can reset the tidal volume per kilogram 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

### 9.5 Changing the access code

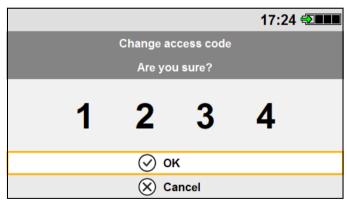
Requirements

The operator menu is activated (see "9.1 Activating the operator menu", page 105).

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



2. Enter 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.

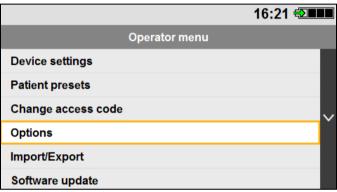
Result The access code for activating the operator menu has been changed.

### 9.6 Options

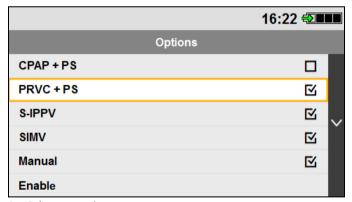
#### **Enabling options** 9.6.1

Requirements

- The operator menu is activated (see "9.1 Activating the operator menu", page 105).
- The latest software version has been installed on the device. (see "9.8 Software update", page 117).

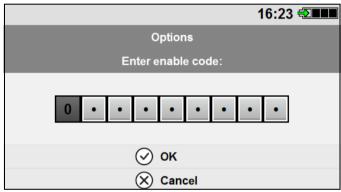


1. Select the menu item **Options**.



2. Select an option.

The checkbox is activated.



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

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

### 9.6.2 Description of options

CPAP + PS

See "10.3 CPAP + PS (optional)", page123.

#### PRVC + PS

See "10.4 PRVC + PS (optional)", page125.

#### S-IPPV

See "10.6 S-IPPV (optional)", page127.

#### SIMV

See "10.5 SIMV (optional)", page126.

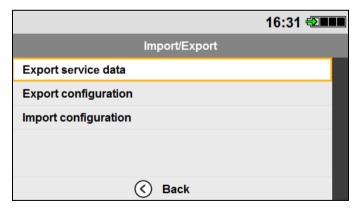
#### Manual

See "10.7 Manual", page129.

#### Importing/exporting data 9.7

Requirements

- There is an SD card in the device (see "9.7.1 Inserting an SD card", page 115).
- The operator menu is activated (see "9.1 Activating the operator menu", page 105).
- 1. Select the menu item **Import/Export**.



- 2. Use the navigation knob to select one of the following actions:
  - **Export service data**

The device saves existing service data and function check results to the SD card.

The device saves the current configuration to the SD card.

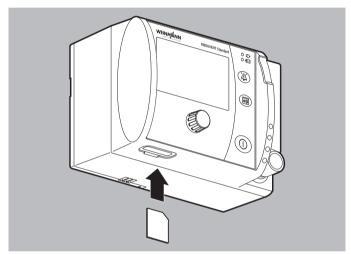
• Import configuration

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 . . . .

### 9.7.1 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. Please note: The beveled corner of the SD card must be at the front right during insertion.
- 3. Close the splash guard.

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

### 9.7.2 Removing the SD card

Requirements Ar

An SD card is in the SD card slot.

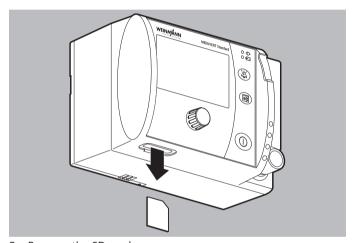
1. Open the splash guard covering the SD card slot.

#### **NOTICE**

# Data loss or material damage resulting from incorrect handling of the SD card during data export or software update!

If you remove the SD card while exporting service data or performing a software update, data might be lost or the device damaged.

- ⇒ Only remove the SD card when no service data are being exported and the device software is not being updated.
- Briefly press on the SD card. The SD card is ejected slightly.



3. Remove the SD card.

### **A** 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 can cause serious or life-threatening injury to the patient, and damage the device.

- $\Rightarrow$  Close the SD card cover to assure IP protection.
- ⇒ Connect the breathing circuit or close the protective caps to assure IP protection.
- Close the splash guard to protect the device from ingress of moisture.

Result The SD card has been removed.

### 9.8 Software update

### 9.8.1 Performing a software update

#### Requirements

- The device is connected to line power.
- The operator menu is activated (see "9.1 Activating the operator menu", page 105).

#### **NOTICE**

# Material damage resulting from malfunctions during updating of the device software!

Moving the device and/or pressing buttons during the update process may cancel the update and damage the device.

- $\Rightarrow$  Do not turn the device off during the update.
- ⇒ Do not disconnect the device from line power during the update.
- $\Rightarrow$  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.
- 1. If necessary: Download software from the Login area of the WEINMANN Emergency website to the SD card.
- If the software is available as a ZIP file: Unzip the software. The
  software is in the unzipped folder in the form of a file called
  WM####-x.x.hex. The file name of the hex file corresponds
  to the article number of the software and the software version.
- Place the file in the SD card's root directory.Please note: The software update file must not be in a subfolder.
- 4. Insert the SD card (see "9.7.1 Inserting an SD card", page 115).
- 5. Select the menu item **Software update** in the operator menu. The files on the SD card are displayed.

- 6. Select the latest software version **WM####-x.x.hex** using the navigation knob.
- 7. Press the navigation knob to start the software update. The device updates the software in several steps. When the procedure is complete, the message **SUCCESS** appears on the display.

# Software update Step 1: Updating M4 100% Step 2: Verifying M4 100% Step 3: Updating Filesystem 100% SUCCESS Please press the navigation knob to restart Reboot

- 8. Press the navigation knob to restart the device. The device restarts. The start menu appears on the display.
- 9. Perform a function check (see "5 Function check", page 45).

Result The software update has been carried out.

> After the software update, information on it is saved in the update.txt file on the SD card. You can use a word processing program to open the file as well as to 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:

### 9.9 Device information

Parameter		Description
Control mounts and	Device	Here you can find out the device serial number. This is located on the device information label.
Serial numbers	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.
	Days until next device check	Here you can find out the number of days remaining until the next device check is due.
Counter	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.

# 9.10 Battery information

Parameter		Description
	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.
	Full charge capacity	Here you can find out the capacity of the rechargeable battery when fully charged.
	Remaining charge	Here you can find out the remaining charge of the rechargeable battery.
Battery data	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 battery cell.
	Cell voltage 2	Here you can find out the voltage of the second internal battery cell.
	Cell voltage 3	Here you can find out the voltage of the third internal 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 capacity calculation.
	Status word	Here different states of the rechargeable battery are displayed in encoded form.
Device data	Battery voltage	Here the battery voltage measured by the device is displayed.
Device data	Line voltage	Here the line voltage measured by the device is displayed.

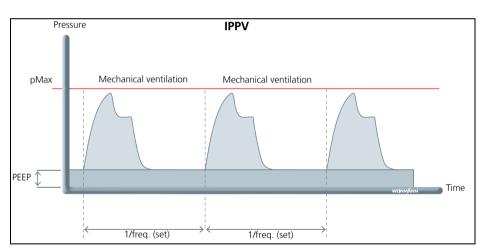
# 10 Description of the modes

#### 10.1 IPPV

Description		
Abbreviation	IPPV	
Long form	Intermittent Positive Pressure Ventilation	
Type Volume-controlled		
Requirements	None	

#### **Ventilation parameters**

- pMax
- Freq.
- Vt
- PEEP



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.

#### 10.2 CPAP

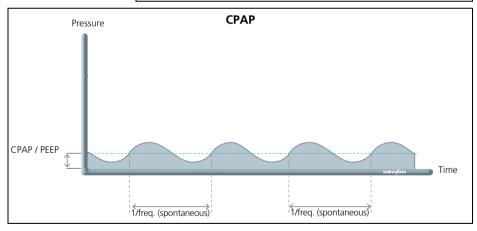


# Hazardous therapy as a result of an unsuitable ventilation mode!

In ventilation modes CPAP and CPAP + PS, patients do not receive any mandatory mechanical breaths. In patients with inadequate spontaneous breathing or respiratory arrest, use of these modes might lead to hypoventilation, and cause the patient serious or life-threatening injury.

- ⇒ Use CPAP or CPAP + PS modes only on patients with adequate spontaneous breathing.
- ⇒ Continuously monitor the patient and device during ventilation.

Description		
Abbreviation	СРАР	
Long form	Continuous Positive Airway Pressure	
Туре	Pressure-controlled	
Requirements	None	
Ventilation parameters		
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. Pressure is generally set at the end of expiration (PEEP).

### 10.3 CPAP + PS (optional)

### **A** WARNING

# Hazardous therapy as a result of an unsuitable ventilation mode!

In ventilation modes CPAP and CPAP + PS, patients do not receive any mandatory mechanical breaths. In patients with inadequate spontaneous breathing or respiratory arrest, use of these modes might lead to hypoventilation, and cause the patient serious or life-threatening injury.

- ⇒ Use CPAP or CPAP + PS modes only on patients with adequate spontaneous breathing.
- ⇒ Continuously monitor the patient and device during ventilation.



#### Risk of asphyxia as a result of aspiration!

Mask ventilation at excessive ventilation pressures can lead to gastric insufflation and aspiration of stomach contents. This can cause serious or life-threatening injury to the patient.

⇒ Avoid high pressures during mask ventilation.



#### Risk of injury from autotriggering!

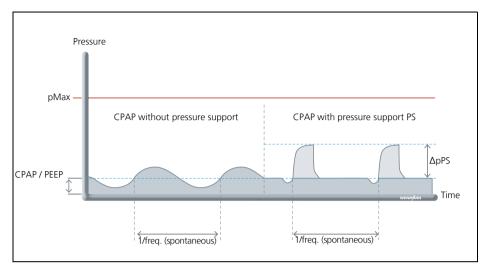
Automatic triggering of the inspiratory trigger by artifacts (autotriggers) can lead to the patient hyperventilating.

⇒ Reduce the sensitivity of the inspiratory trigger in the event of autotriggers.

Description		
Abbreviation	CPAP + PS	
Long form	Continuous Positive Airway Pressure + Pressure Support	
Type Pressure-controlled		
Requirements	CPAP + PS option has been activated.	

#### Ventilation parameters

- pMax
- InTr
- ΔpPS
- PEEP



CPAP + PS mode can be separated into its individual elements:

- The CPAP/PEEP set value is used to increase the pressure level of breathing in order to raise the functional residual capacity (FRC) of spontaneously breathing patients.
- The PS function is used for pressure support of insufficient or exhausted spontaneous breathing. The patient is able to breathe spontaneously without any restriction, but is supported in his or her breathing effort by the device.
- | i |

On switching to CPAP + PS mode, pMax is automatically reduced to 20 mbar. A value < 20 mbar is retained.

Pressure is generally set at the end of expiration (PEEP). If necessary, pressure support ( $\Delta$ pPS) can also be switched on. Ventilation can be individually adapted to the patient with the aid of the inspiratory trigger. The inspiratory trigger indicates the sensitivity for triggering of pressure support. The expiratory trigger\* determines when the device cancels pressure support. This allows the administered volume and inspiration time to be set indirectly. The set maximum pressure limit (pMax) ensures the safety of the patient.

\*Corresponds to a permanently set value of 35 % of maximum inspiratory flow.

### 10.4 PRVC + PS (optional)

### **A** CAUTION

#### Risk of injury from autotriggering!

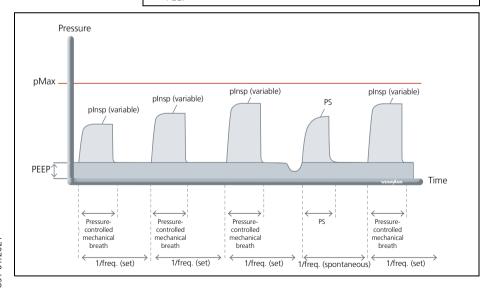
Automatic triggering of the inspiratory trigger by artifacts (autotriggers) can lead to the patient hyperventilating.

⇒ Reduce the sensitivity of the inspiratory trigger in the event of autotriggers.

Description		
Abbreviation	PRVC + PS	
Long form	Pressure-Regulated Volume-Controlled Ventilation + Pressure Support	
Туре	Pressure-controlled	
Requirements	PRVC + PS option has been activated	

#### Ventilation parameters

- pMax
- Freq.
- Vt
- InTr
- ΔpPS
- PEEP



PRVC + PS mode combines the benefits of pressure-controlled and volume-controlled ventilation. The set tidal volume is administered with the minimum ventilation pressure possible. Ventilation starts at low ventilation pressures P<sub>insp</sub> and reaches target volume after a few breaths. In the phase between mandatory mechanical breaths, the patient can breathe spontaneously at CPAP level or trigger pressure support (PS). If triggers are triggered within the trigger window (20 % before the mandatory breath), the mandatory breath is synchronized.

The volumes administered are measured and ventilation pressure adapted according to the situation. If lung parameters change during ventilation, the device alters inspiratory pressure P<sub>insp</sub> in order to achieve the set tidal volume again and thereby automatically compensate for changes in the patient. Measuring the volume administered is improved by compensating hose compliance. This enables precise control of the required tidal volume, in particular at low tidal volumes under high airway pressures. The set maximum pressure limit (pMax) ensures the safety of the patient. For safety reasons, the maximum inspiratory pressure (P<sub>insp</sub>) is at the level of the pressure limit (pMax).

If the volume achieved deviates from the set tidal volume, the device triggers the medium-priority alarm **Vt not achievable**.

### 10.5 SIMV (optional)

Description		
Abbreviation	SIMV	
Long form	Synchronized Intermittent Mandatory Ventilation	
Type Volume-controlled		
Requirements	SIMV option has been activated	
Ventilation navameters		

#### Ventilation parameters

- pMax
- Freq.
- Vt
- InTr
- PEEP

SIMV mode is used for volume-controlled ventilation at a fixed mandatory minute volume. The patient can breathe spontaneously between mandatory mechanical breaths, thereby increasing minute volume. Ventilation can be individually adapted to the patient with the aid of the inspiratory trigger. During spontaneous breathing, the mandatory mechanical breath is synchronized with the patient's breathing. The mandatory minute volume and mandatory respiratory rate remain unchanged in this instance. The set maximum pressure limit (pMax) ensures the safety of the patient.

### 10.6 S-IPPV (optional)



#### **Risk of hyperventilation!**

When using S-IPPV mode, the  ${\rm CO_2}$  concentration in the patient's blood might decrease and cause the patient serious or life-threatening injury.

 $\Rightarrow$  Monitor the patient continuously.



#### Risk of air trapping!

When using S-IPPV mode, air might get trapped in the patient's lung and result in reduced gas exchange. This can cause serious or life-threatening injury to the patient.

⇒ Monitor airway pressure continuously.



#### **Risk of intrinsic PEEP!**

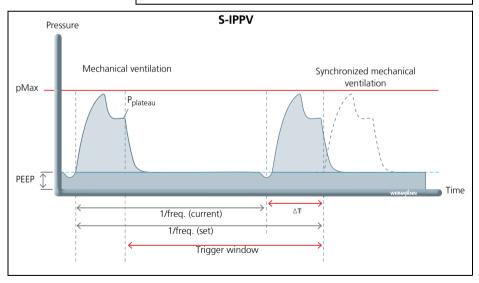
If the expiration phase is too short, pressure might rise slowly at the end of it. This can cause serious or life-threatening injury to the patient.

- $\Rightarrow$  Set the pressure limit correctly.
- $\Rightarrow$  Monitor the patient continuously.

Description		
Abbreviation S-IPPV		
Long form	Synchronized Intermittent Positive Pressure Ventilation	
Type Volume-controlled		
Requirements S-IPPV option has been activated		

#### **Ventilation parameters**

- pMax
- Freq.
- Vt
- InTr
- PEEP



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 minute volume – as needed. As a rule, this mode is used on patients who have inadequate spontaneous breathing. Ventilation can be individually adjusted to match the patient with the aid of the inspiratory triggers.

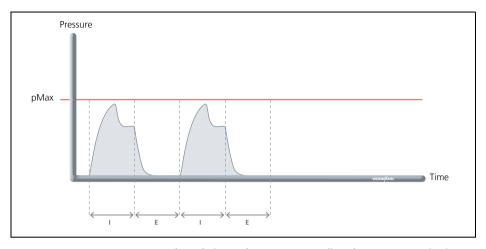
Ventilation in S-IPPV mode corresponds to ventilation in IPPV mode, with the difference that it is possible to synchronize with the patient's own efforts to inhale. Since the setting for respiratory rate is lower, the patient can trigger mandatory mechanical breaths spontaneously. A trigger window extending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

### 10.7 Manual

Description		
Abbreviation	Manual	
Long form	Manual mode	
Туре	Volume-controlled	
Requirements MEDUtrigger is connected		
Ventilation parameters		
Supply value for 100 % oxygen		
• pMax		
- \/+		

\/1

The setting loaded when you change to Manual mode is specified in the presets for the patient group in the operator menu.



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, mechanical breaths are administered at a defined volume and pressure limit (manually) using the trigger button of the MEDUtrigger. In this process, the I:E ratio is always 1: 1. PEEP is 0 mbar and cannot be adjusted. The set pressure limit (pMax) ensures the safety of the patient. The basis for calculating the value of O<sub>2</sub> to be supplied is the algorithm 30: 2. (In this case, 2 mechanical breaths are administered in quick succession with a subsequent pause in ventilation).

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

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



In order to achieve the shortest-possible hands-off time during resuscitation, during CPR 30: 2, keep the MEDUtrigger depressed during the ventilation pause until two inspirations have been delivered.

Press the trigger button again to trigger up to another 2 mechanical breaths

### 11 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 responds as follows:

- Multiple 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 priority: 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.

## 11.1 Alarm messages

### 11.1.1 High-priority alarms (red)

Alarm	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.
	Breathing circuit leaking	Replace breathing circuit.
	Breathing circuit not correctly connected	Connect breathing circuit correctly.
	Tracheal tube incorrectly positioned	Position tracheal tube correctly.
Airway pressure low ↓	Tubes kinked or trapped	Route tubes so that they are not kinked or trapped.
	Ventilation settings incorrect	Adapt the ventilation settings to the patient.
	Mask not positioned 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.
Battery empty	Rechargeable battery state of charge low	Connect device to line power and charge rechargeable battery. Keep alternative means of ventilation at the ready.
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 "16 Technical data", page 157).
Device temperature low ↓	Device temperature < -20 °C	Operate device within permitted temperature range (see "16 Technical data", page 157).

Alarm	Cause	Remedy
MEDUtrigger disconnected	MEDUtrigger removed from device during manual ventilation	Reconnect MEDUtrigger to device.
Oxygen inlet flow high †	Flow setting higher than permitted	Reduce flow setting to a value below 15 l/min.
	No patient connected	Connect patient to device.
Patient disconnected	Mask not positioned 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.
Vt low \footnote{\psi}/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.

### 11.1.2 Medium-priority alarms (yellow)

Alarm	Cause	Remedy
Battery defective	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.
Battery weak	Rechargeable battery state of charge low	Connect device to line power and charge rechargeable battery.
Check battery	Wrong rechargeable battery inserted	Insert approved rechargeable battery.
Frequency high †	Patient's respiratory rate too high	Check the patient's condition. Check limit value settings for plausibility.
	Inspiratory trigger triggered by artifacts (autotriggers)	Check mask for leaks. Reduce the sensitivity of the inspiratory trigger.
Oxygen inlet flow higher than necessary	Flow setting higher than necessary	Reduce flow setting in steps. Rule of thumb for 100 % oxygen: Flow = MVi.
Oxygen inlet leakage	Oxygen inlet is not sealed and no oxygen is being supplied.	Seal oxygen inlet with protective cap for oxygen inlet or supply oxygen.
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.

### 11.1.3 Low-priority alarms (turquoise)

Alarm	Cause	Remedy
Battery operation	Line power supply too weak or line power outage	The alarm appears:  When you take the portable unit 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.

### 11.2 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 more 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 the volume to 100 %.
No audio alarm output	Loudspeaker or alarm light	Have the device repaired.
Alarm light not lit	defective	
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 battery.
	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 of for at least 2 s.
Software update not working	Update file or SD card defective	Perform the software update with a different SD card. If the update still cannot be completed successfully, have the device repaired.

### 11 Alarms and faults

Fault	Cause	Remedy
Battery status indicator flickering between red and green	Battery deeply discharged	Charge 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.
Energy failure/device failure: Black screen	Battery empty and device not connected to line power	Check power supply.
<ul><li>Alarm light flashing</li><li>Audio alarm output</li></ul>	Device defective	Switch the device off and have it repaired.
Device malfunction (yellow screen)	Temporary device malfunction	Switch device off and back on again. Perform a function check (see 5, p.45).
		Press the menu button to call up the operator menu directly and export the service data (see 9.7, p.114).
	Device defective	Switch the device off and have it repaired.

### 12 Maintenance

### **A** 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 cause the patient and bystanders 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 even when the device is in storage for a prolonged period.
- ⇒ Observe the maintenance intervals as marked on the device.
- ⇒ Perform a complete function check prior to every use.

### 12.1 Intervals



#### Disrupted or failed therapy due to lack of maintenance!

If maintenance intervals are not observed, malfunctions might occur. This can cause serious or life-threatening injury to the patient.

- ⇒ Observe the maintenance schedule according to the instructions for use and the displays on the device.
- ⇒ Observe the maintenance schedule even 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 battery life has expired, replace the rechargeable battery.

#### 12 Maintenance

Item	Interval	Maintenance by
Device	Maintenance every 4 years	Manufacturer, or technician
	Safety check every 2 years	specifically authorized by the manufacturer
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 approx. 5 years. The device indicates the necessary battery replacement.	Operator
Reusable breathing circuit	Maintenance every 2 years Replace after 50 reprocessing cycles.	User/operator (see "12.3 Maintaining the reusable breathing circuit", page 140)
Reusable breathing circuit	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	When prompted in the function check or At least every 6 months or After every infection transport of a ventilated patient	User/operator (see "12.4 Replacing the hygiene filter", page 140)

### 12.2 Maintenance reminder

### **A** WARNING

#### Disrupted or failed therapy due to lack of maintenance!

The maintenance reminder can be suppressed by the operator once for 180 days. No maintenance notices will be displayed during this period. If maintenance intervals are not observed, malfunctions might occur. This can cause serious or lifethreatening injury to the patient.

⇒ Observe the maintenance intervals in accordance with the instructions for use.

The service symbol flashes in the start screen to indicate one of the following conditions:

- Maintenance interval has expired
- Interval for device Technical Safety Check
   ("Sicherheitstechnische Kontrolle" in accordance with § 11 of
   the German regulation MPBetreibV) has expired
- Battery life has expired

If maintenance or a Technical Safety Check ("Sicherheitstechnische Kontrolle" in accordance with § 11 of the German regulation MPBetreibV) is due, you can suppress the maintenance reminder once within a maintenance cycle for a maximum of 180 days from the due date. The device then behaves as if it were not due for maintenance.

Suppression of the maintenance reminder cannot be canceled within the maintenance cycle. Once the 180 days have elapsed, the maintenance reminder is active until the next service, and cannot be deactivated again.

Maintenance intervals must be observed even if the maintenance reminder has been suppressed.

### 12.3 Maintaining the reusable breathing circuit

#### Requirements

The reusable breathing circuit has been disassembled (see "7.3.1 Disassembling the reusable breathing circuit", page 74).

- 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 kit WM 17937).
- 4. Assemble the reusable breathing circuit (see "7.3.2 Assembling the reusable breathing circuit", page 77).
- 5. Punch the scheduled time for the next maintenance into the service label (maintenance kit WM 17937).
- 6. Attach the service label to the device end of the ventilation hose.
- 7. Perform a function check (see "5 Function check", page 45).

Result

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

### 12.4 Replacing the hygiene filter



#### 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.

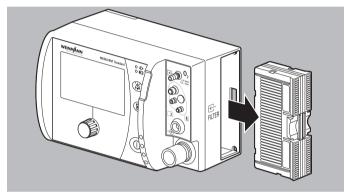
- ⇒ Check the hygiene filter and filter fleece for external signs of damage and do not use if damaged.
- ⇒ Replace damaged hygiene filter.
- ⇒ Replace hygiene filter after every infection transport.

# 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 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.

### 12.4.1 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.

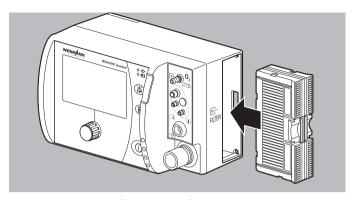
### 12.4.2 Inserting the hygiene filter



# Risk of contamination or infection resulting from impaired filter properties!

Soiling, foreign bodies or damage in the filter compartment or on the hygiene filter might mean that the filter element is not correctly positioned. 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 the hygiene filter for soiling, foreign bodies and damage.



- Push the hygiene filter into the filter compartment until the hygiene filter audibly clicks into place and is flush with the device.
- 2. Perform a function check (see "5 Function check", page 45).
- 3. Reset the filter counter during the function check.

*Result* The hygiene filter has been inserted.

### 12.5 Replacing the rechargeable battery



# 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 can cause serious or life-threatening injury to the patient.

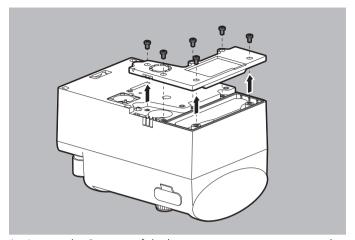
⇒ Always operate the device with the battery charged.

You as the operator can replace the rechargeable battery yourself.

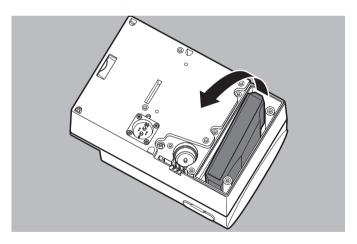
### 12.5.1 Removing the rechargeable battery

Requirements

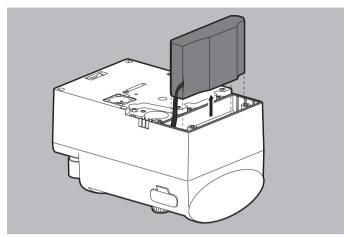
- The device has been disconnected from the power supply.
- The device has been removed from the portable unit.



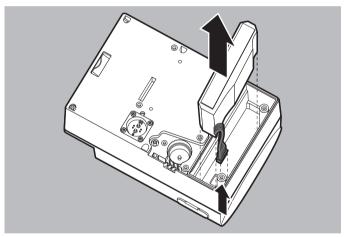
- 1. Loosen the 6 screws of the battery compartment cover on the back of the device.
- 2. Remove the 6 screws.
- 3. Remove the battery compartment cover.



4. Tilt the battery at one end and carefully pull it up and out of the housing.



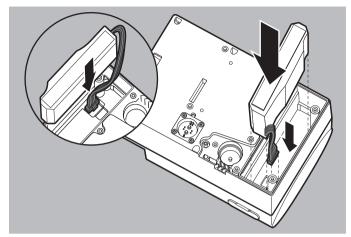
5. Remove the battery from the device.



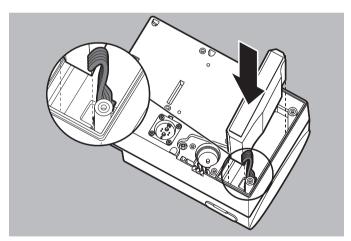
6. Unplug the battery's electrical connector.

Result The rechargeable battery has been removed.

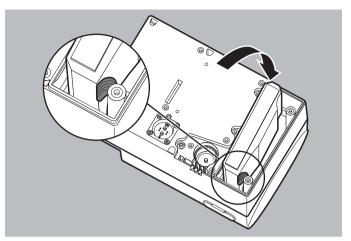
### 12.5.2 Installing the rechargeable battery



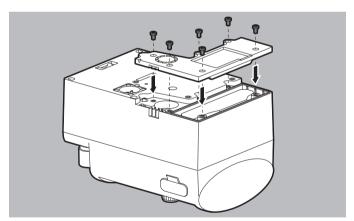
1. Attach the battery's electrical connector. To do so, plug the battery connector into the socket. The connector engages.



- 2. Position the battery so that the cable is facing the socket.
- 3. Make the battery cable into a loop.



- 4. Insert the battery. To do this, guide the battery cable along between the housing and the battery.
- 5. Push the battery down in the battery compartment until the battery is flush with the housing.



- 6. Fit the battery compartment cover.
- 7. Tighten the 6 screws on the battery compartment cover.
- 8. Reset the date and time in the operator menu (see "9 Operator menu", page 105).

Result The rechargeable battery has been installed.

### 12.6 Sending in parts



# Risk of infection due to contaminated parts during maintenance work!

The device, accessories and other parts may be contaminated and infect the technicians with bacteria and viruses. Parts sent in which are clearly contaminated will be disposed of at the cost of the sender by WEINMANN Emergency or by technicians authorized by WEINMANN Emergency.

- ⇒ Clean and disinfect parts required for maintenance measures.
- ⇒ Do not send in parts which are potentially contaminated.
- 1. Dismantle parts.
- Clean and disinfect parts (see "7 Hygienic reprocessing", page 70).
- 3. Send parts to WEINMANN Emergency, or to a technician specifically authorized by WEINMANN Emergency.

### 13 Storage

### **▲** WARNING

#### Disrupted or failed therapy due to defective or nonoperational device following incorrect storage!

Incorrect storage might damage the device and accessories, and lead to disruption or failure of therapy. This can cause serious or life-threatening injury to the patient.

- ⇒ Observe storage conditions and storage times (see "16 Technical data", page 157).
- ⇒ Store the device and accessories in a dry location.
- ⇒ Following storage at extreme ambient conditions outside ambient operating conditions: Store the device and accessories at room temperature for at least 12 hours before starting to use 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 rapid shutdown of, and irreparable damage to, the rechargeable battery.

- ⇒ Observe the storage conditions and the instructions regarding the rechargeable battery (see "16.2 Rechargeable battery", page 163).
- 1. Switch off the device (see "6.8 Switching off the device", page 69).
- 2. If necessary: Disconnect the device from line power.
- 3. Hygienically reprocess the device and accessories (see "7 Hygienic reprocessing", page 70).
- 4. Store the device and accessories in a dry location.

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

### 14 Disposal

### 14.1 Electronic waste

#### NOTICE

#### Environmental hazard from electronic waste!

Electronic waste poses an environmental hazard, and must be subjected to proper disposal.

 $\Rightarrow$  Do not dispose of electronic waste in domestic waste.



Do not dispose of the product in domestic waste. Use a licensed, certified electronic waste management contractor for proper disposal. You can find out the 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

### 14.2 Rechargeable battery



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

### 14.3 Plastics

Dispose of plastics in a proper manner applicable to plastics at the end of their useful lives.

### 14.4 Hygiene filter

Dispose of the hygiene filter in a proper manner.

## 14.5 Contaminated parts

Do not dispose of contaminated parts in domestic waste. Use a licensed, certified specialist waste management contractor to dispose of contaminated parts properly.

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# 15 Scope of supply

### 15.1 Standard scope of supply

This section describes the basis for all configurations which can be put together for an individual customer.

Designation	Supplementary information	UDI-DI	Article number
MEDUVENT Standard Emergency and transport ventilator	with integrated turnine drive	e and MEDUtrigger	WM 20010
Comprising:	with integrated tarbine and	e and MEDOLINGSCI	
MEDUVENT Standard, basic device	With rechargeable battery	04054685276515	WM 35710
Breathing circuit VENTcirc-MVS, 2 m	Reusable	04054685270827	WM 35850
MEDUtrigger, 2 m	_	04054685137236	WM 28992
Testing bag for function check	-	_	WM 1454
Set of disposable CPAP/NIV masks with air cushion	-	_	WM 15807
Ventilation mask with self-inflating silicone cushion, for adults, size 5	-	_	WM 5074
Hygiene filter HF-MVS	-	04054685275464	WM 35730
Hook and loop strap with clip for ventilators	-	-	WM 28964
Fastening element set	For LIFE-BASE	_	WM 17806
Oxygen inlet tube	Third-party product	_	WM 35782
MEDUVENT Standard instructions for use	_	_	WM 67851

### 15.2 Accessories and other parts

This section describes accessories and other parts in accordance with the Medical Device Regulation (MDR). Accessories are marked with a UDI-DI. Other parts do not have a UDI-DI. For parts made by other manufacturers you can request the UDI-DI from the manufacturer.

Designation	Supplementary information	UDI-DI	Article number
Breathing circuits			
Breathing circuit VENTcirc-MVS, 2 m	Reusable	04054685270827	WM 35850
Breathing circuit VENTcirc-MVS, 2 m	Disposable	04054685270834	WM 35860
Set of 10, VENTcirc-MVS breathing circuit, 2 m	Disposable	04054685277284	WM 17910
Set of 25, VENTcirc-MVS breathing circuit, 2 m	Disposable	04054685277291	WM 17911
Set of 50, VENTcirc-MVS breathing circuit, 2 m	Disposable	04054685277307	WM 17912
MEDUtrigger, 2 m	_	04054685137236	WM 28992
Adapter for disposable breathing circuit	_	04054685277314	WM 17916
Other parts of the breathing of 2 m reusable measuring circuit for	<b>circuit</b> Reusable		WM 35851
breathing circuit  2 m reusable ventilation hose for reusable breathing circuits	Reusable	_	WM 28421
2 m reusable protective sleeve for ventilation hose	Reusable	-	WM 28585
Reusable patient valve, complete	Reusable	-	WM 35865
Adapter for reusable breathing circuit	Reusable	_	WM 35867
Breathing system filter	Third-party product		WM 22162
Portable units			
LIFE-BASE portable unit	_	UDI-DI on request	Article number on request

Designation	Supplementary information	UDI-DI	Article number
Options			
S-IPPV mode option	For MEDUVENT Standard	_	WM 35815
SIMV mode option	For MEDUVENT Standard	_	WM 35816
CPAP+PS mode option	For MEDUVENT Standard	-	WM 35871
PRVC+PS mode option	For MEDUVENT Standard	_	WM 35872
Power supply			
Accu-Pack rechargeable battery	For MEDUVENT Standard	04054685277321	WM 35775
Power supply unit and charger 100 W	Third-party product		WM 28937
Charging adapter for charging with power supply unit and charger or 12 V adapter cable	_	_	WM 28979
Adapter cable for 12 V on-board power supply/round plug connector	_	_	WM 28356
Wall mounting for power supply unit and charger	For WM 28937	_	WM 15846
Testing bags/test lungs			
Testing bag for function check	-	_	WM 1454
EasyLung test lung for function check	Third-party product	_	WM 28625
Protective caps			
Protective cap for 22 mm cone	_	_	WM 28942
Protective cap for oxygen inlet	_	_	WM 35732
Protective cap for connection terminal	_	_	WM 35857
Hygiene filter			
Hygiene filter HF-MVS	For MEDUVENT Standard	04054685275464	WM 35730
Set of 5 HF-MVS hygiene filters	For MEDUVENT Standard	04054685279387	WM 17915
Miscellaneous			
Oxygen inlet tube	Third-party product		WM 35782
CapnoDura Combi disposable CO <sub>2</sub> detector	Third-party product		WM 20760

Designation	Supplementary information	UDI-DI	Article number
Set of 10 CapnoDura Combi disposable CO <sub>2</sub> detectors	Third-party product		WM 20770
SD card, 2 GB	_	_	WM 29791
Cap for navigation knob	_	_	WM 35803
Battery compartment cover	_	_	WM 17907
Battery compartment cover seal	_	_	WM 35739
Masks from WEINMANN Emer	gency		
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
Masks from other manufactur	rers		
Premium disposable CPAP/NIV mask incl. headgear, size S (child)	Disposable		WM 20717
Premium disposable CPAP/NIV mask incl. headgear, size M (adult)	Disposable		WM 20718
Premium disposable CPAP/NIV mask incl. headgear, size L (large adult)	Disposable		WM 20719
Set of 10 premium disposable CPAP/ NIV masks incl. headgear, size S (child)	Disposable		WM 17940
Set of 40 premium disposable CPAP/ NIV masks incl. headgear, size S (child)	Disposable		WM 17941
Set of 10 premium disposable CPAP/ NIV masks incl. headgear, size M (adult)	Disposable		WM 17942
Set of 40 premium disposable CPAP/ NIV masks incl. headgear, size M (adult)	Disposable		WM 17943
Set of 10 premium disposable CPAP/ NIV masks incl. headgear, size L (large adult)	Disposable		WM 17944

Designation	Supplementary information	UDI-DI	Article number
Set of 40 premium disposable CPAP/ NIV masks incl. headgear, size L (large adult)	Disposable		WM 17945
Disposable CPAP/NIV mask with air cushion, size S (child), with retaining ring for headgear	Disposable		WM 20703
Disposable CPAP/NIV mask with air cushion, size M (adult), with retaining ring for headgear	Disposable		WM 20704
Disposable CPAP/NIV mask with air cushion, size L (large adult), with retaining ring for headgear	Disposable		WM 20705
Set of disposable CPAP/NIV masks with air cushion	Disposable		WM 15807
Set of 25 disposable CPAP/NIV masks with air cushion, size S (child), with retaining ring for headgear	Disposable		WM 15831
Set of 25 disposable CPAP/NIV masks with air cushion, size M (adult), with retaining ring for headgear	Disposable		WM 15832
Set of 25 disposable CPAP/NIV masks with air cushion, size L (large adult), with retaining ring for headgear	Disposable		WM 15833
Set of 50 disposable CPAP/NIV masks with air cushion, size S (child), with retaining ring for headgear	Disposable		WM 15834
Set of 50 disposable CPAP/NIV masks with air cushion, size M (adult), with retaining ring for headgear	Disposable		WM 15835
Set of 50 disposable CPAP/NIV masks with air cushion, size L (large adult), with retaining ring for headgear	Disposable		WM 15836
Reusable silicone CPAP/NIV mask, size S (child)	Reusable		WM 20713

### 15 Scope of supply

Designation	Supplementary information	UDI-DI	Article number
Reusable silicone CPAP/NIV mask, size M (adult)	Reusable		WM 20714
Reusable silicone CPAP/NIV mask, size L (large adult)	Reusable		WM 20715
Set of reusable silicone CPAP/NIV masks	Reusable		WM 15808
Headgear for CPAP/NIV masks	_		WM 20702
Retaining ring for headgear, for reusable CPAP/NIV masks only	_		WM 20701

## 16 Technical data

### 16.1 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	-20 °C to +50 °C
Temperature range for oxygen inlet tube Humidity Air pressure Altitude above mean sea level	-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	-40 °C to +70 °C -20 °C to +40 °C (recommended: 0 °C to +25 °C)
tube Humidity Air pressure Altitude above mean sea level	-18 °C to +50 °C 15 % rh to 95 % rh, no condensation 540 hPa to 1100 hPa -500 m to 5000 m
Warm-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 rating	<ul><li>Rated voltage: 12 V</li><li>Permitted input voltage range: 10 V to 16 V</li></ul>
Max. power consumption	60 W
Current consumption	0.15 A to 4 A

Specification	Device
Operating hours on 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 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
Disconnector	Disconnection of the power supply (charging adapter or portable unit) or unplugging of the line power connector.
Disconnection from line power	Taking out the line power connector disconnects the device from line power on all poles.
Operating mode	Continuous operation
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:	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 if required. 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	<ul> <li>EN 1789</li> <li>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)</li> <li>EUROCAE ED-14G/RTCA DO 160 G: Section 7 (Cat. A) and 8 (U/U2 + Cat. S)</li> </ul>
Type of emergency vehicle	Secured in emergency vehicle, ship, airplane, and helicopter, as well as portable at the site of the emergency

#### 16 Technical data

Specification	Device
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
Ventilation rate	5 min <sup>-1</sup> to 40 min <sup>-1</sup> ±1 min <sup>-1</sup>
Respiratory rate measurement	Measuring range: 3 min <sup>-1</sup> to 140 min <sup>-1</sup> Tolerance:  • fsp: ±1 min <sup>-1</sup> • ftotal: ±1 min <sup>-1</sup>
Inspiratory time	0.5 s to 4 s
Tidal volume	50 ml to 2000 ml (±40 ml or ±20 %) (BTPS)
Respiratory minute volume	1.5 l/min to 20 l/min (BTPS)

EN

Specification	Device	
PEEP	0 mbar to 20 mbar (±3 mbar or ±15 %)	
Trigger Can be set to Levels 1 to 3 (not in IPPV, CPAP and Manual modes)	Trigger sensitivity  Trigger sensitivity  Trigger sensitivity  16 14 12 10 10 10 10 10 10 10 10 10 10 10 10 10	
Airway pressure sensor	-5 hPa to 80 hPa, measurement position close to patient	
Accuracy of airway pressure measurement	-5 hPa to 80 hPa (±5 % or ±1.5 hPa)	
Pressure support ΔpPS (only with CPAP + PS and PRVC + PS options)	0 hPa to 30 hPa (±3 hPa or ±15 %) above PEEP	
Volume sensor	-30 l/min to 150 l/min, measuring position ventilation hose connection (BTPS oder ATP, whichever value is lower)	
Accuracy of measurement of respiratory minute volume (MVi)	$\pm 20$ % or $\pm 1.2$ ml/min (BTPS, whichever value is higher)	
Accuracy of measurement of tidal volume (Vti)	±20 % or ±40 ml (BTPS, whichever value is higher)	
Gas composition	Mixture of air, oxygen, CO <sub>2</sub> . Oxygen fraction 21 % to 100 %, CO <sub>2</sub> 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	Service life: 6 months Operating time as a function of filter wear:  Filter wear normal, 100 %: 24 h operation Filter wear high, 150 %: 16 h operation Filter wear very high, 200 %: 12 h operation	
Hygiene filter separation rate	> 99 %	

**CE 0197** Subject to design modifications.

## 16.2 Rechargeable battery

Specification	Rechargeable battery
Туре	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
Storage/transport: Temperature range up to 48 h Temperature range longer than 48 h Humidity Service life	-40 °C to +70 °C -20 °C to +40 °C (recommended: 0 °C to +25 °C) 0 % to 95 % rh, no condensation At least 300 charging cycles* or a maximum of 5 years
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 battery, ambient temperature 23 °C ±3 °C
Charging intervals after 100 % charge	When stored in the device without power supply: every 6 months When stored outside the device: every 12 months

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

# **16.3 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 Altitude above mean sea level	0 °C to +40 °C 5 % 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 output voltage	15 V
Disconnection from line power	Taking out the line power connector disconnects the device from line power on all poles.
Туре	PMP120F-13-K24

# **16.4 Breathing circuits**

Specification	Breathing circuit	
Operation:		
Temperature range	-20 °C to +50 °C	
Relative humidity	15 % to 95 %, no condensation	
Storage:		
Temperature range	-30 °C to +70 °C	
Relative humidity	Maximum 95 %	
Patient valve:	15 mm inner cone	
Patient valve.  Patient connection mask/tracheal tube	22 mm outer cone	
ratient connection mask/trachear tube	EN ISO 5356-1	
Patient valve:	Non-connectible expiratory opening	
Expiratory opening		
Compliance:		
Reusable breathing circuit	0.79 ml/hPa (ml/cmH <sub>2</sub> O)	
Disposable breathing circuit	0.90 ml/hPa (ml/cmH <sub>2</sub> O)	
Internal volume of entire breathing system:		
Reusable breathing circuit	Approx. 573 ml	
Disposable breathing circuit	Approx. 573 ml	
Materials used	PC, silicone, TPE, PA, PP, TPR, PE, PU, polyisoprene	
Reusable breathing circuit service life	50 reprocessing cycles	

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	

#### Pressure drop [hPa] over the section of inspiratory and expiratory flow at different flows [l/min] as per EN 794-3

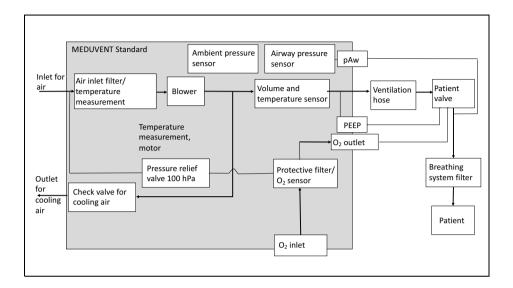
Breathing circuits (2 m), additionally with FlowCheck sensor and elbow

	Flow [l/min]	Breathing circuit (reusable), 2 m WM 35850	Breathing circuit (disposable), 2 m WM 35860
Chantanagus breathing in the quant	2.5	< 2.4	< 1.8
Spontaneous breathing in the event of energy failure, inspiratory (STP)	15	< 2.4	< 1.8
of energy failure, inspiratory (511)	30	< 4.1	< 3.4
Constanceus breathing in the event	2.5	< 1.7	< 1.8
Spontaneous breathing in the event of energy failure, expiratory (BTPS)	15	< 1.7	< 1.8
or energy failure, expiratory (BTF3)	30	< 2.5	< 2.6
	5	< 0.7	< 0.5
Normal operation, inspiratory (STP)	30	< 1.3	< 1.3
	60	< 2.9	< 2.8
Normal operation, expiratory (BTPS)	5	< 0.9	< 0.9
	30	< 2.8	< 2.4
	60	< 4.8	< 4.6

STP (Standard Temperature and Pressure): Volume/flow at 21 °C and 1013 hPa

BTPS (Body Temperature and Pressure, saturated): Volume/flow at current ambient pressure and 37 °C at 100 % saturated moist gas

### 16.5 Block diagram



### 16.6 Electromagnetic compatibility (EMC)



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

Medical electrical devices which are operated directly next to or on top of one another can cause mutual interference to functionality. This can cause serious or life-threatening injury to the patient.

- $\Rightarrow$  Do not stack the device with other medical electrical devices.
- ⇒ Do not operate the device in the immediate vicinity of other medical electrical devices (exception: other WEINMANN Emergency devices which have been tested to ensure that they can be operated alongside the device without problems. 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.



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

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

⇒ Keep portable radio-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 documents.

#### Guidelines and manufacturer's declaration - emission of electromagnetic interference

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 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 acc. to IEC 61000-3-2	Compliant	MEDUVENT Standard is suitable for use in all facilities, including domestic environments, and
Emission of voltage fluctuations/flicker acc. to IEC 61000-3-3	Compliant	those which are connected directly to the public power grid which also supplies buildings used for residential purposes.
RF emissions acc. 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	Compliant	MEDUVENT Standard is suitable for connection to the on-board power supply due to its low RF emission.

#### Guidelines and manufacturer's 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.

customer of user of the MEDOVERT 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 cables	±2 kV for line power cables  ±1 kV for input and output cables	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 <sub>T</sub> ; ½ cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees, 0 % U <sub>T</sub> , 1 cycle and 70 % U <sub>T</sub> , 25/30 cycles, single-phase: at 0 degrees, 0 % U <sub>T</sub> , 250/300 cycles	0 % U <sub>T</sub> ; ½ cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees, 0 % U <sub>T</sub> , 1 cycle and 70 % U <sub>T</sub> , 25/30 cycles, single-phase: at 0 degrees, 0 % U <sub>T</sub> , 250/300 cycles	fully charged battery.	
Note: U <sub>T</sub> 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.	

#### Guidelines and manufacturer's 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	IEC 60601 test	Compliance	Electromagnetic environment -
immunity tests	level	level	guidelines
			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:
Conducted RF interference acc. to	3 V <sub>effective value</sub> 150 kHz to 80 MHz outside ISM bands <sup>a</sup>	3 V	$d = 1, 2\sqrt{P}$
IEC 61000-4-6	6 V <sub>effective value</sub> 150 kHz to 80 MHz within ISM bands <sup>a</sup>	6 V	$d = 1, 2\sqrt{P}$
			$d = 0, 4\sqrt{P}$
Radiated RF interference acc. to	10 V/m 80 MHz to 2.7 GHz	30 V/m	for 80 MHz to 800 MHz
IEC 61000-4-3			$d = 0, 8\sqrt{P}$
			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). <sup>b</sup> An on-site investigation <sup>c</sup> should demonstrate that the field strength of stationary RF transmitters is below the compliance level at all frequencies. <sup>d</sup> 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.

<sup>a</sup>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.

<sup>b</sup>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 communication 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.

The field strength of stationary transmitters, such as the base stations for radio-frequency telephones and land-based mobile radio equipment, amateur radio stations, AM and FM radio and television transmitters, for example, cannot be precisely determined theoretically in advance. 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 its intended purpose. If unusual performance characteristics are observed, additional measures may be required, such as a different orientation or location for MEDUVENT Standard.

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

#### Guidelines and manufacturer's 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 its intended purpose. If unusual performance characteristics are observed, additional measures may be required, such as a different orientation or location for MEDUVENT Standard.

Testing fre- quency	Frequency band <sup>a</sup>	Radio service <sup>a</sup>	Modulation <sup>b</sup>	Max. output power	Dis- tance	Immunity test level
MHz	MHz			W	m	V/m
385	380 to 390	TETRA 400	Pulse modulation <sup>b</sup> 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM <sup>c</sup> ±5 kHz deviation 1 kHz sine	2	0.3	28

#### Guidelines and manufacturer's 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 its intended purpose. If unusual performance characteristics are observed, additional measures may be required, such as a different orientation or location for MEDUVENT Standard.

Testing fre-	Frequency band <sup>a</sup>	Radio service <sup>a</sup>	Modulation <sup>b</sup>	Max. output	Dis- tance	Immunity test level
quency	B411-			power		Wire
MHz	MHz			W	m	V/m
710		LTE Band 13,	Pulse modulation b			
745	704 to 787	17	217 Hz	0.2	0.3	9
780						
810		GSM 800/900,				
870	1	TETRA 800,	Pulse modulation b			
930	800 to 960	iDEN 820, CDMA 850, LTE Band 5	18 Hz	2	0.3	28
1720		GSM 1800,				
1845	1	CDMA 1900,				
1970	1700 to 1990	GSM 1900 DECT, LTE Band 1, 3, 4, 25, UMTS	Pulse modulation <sup>b</sup> 217 Hz	2	0.3	28
2450	2400 to 2570	Bluetooth, WLAN 802.11 b/g/n RFID 2450 LTE Band 7	Pulse modulation <sup>b</sup> 217 Hz	2	0.3	28
5240		M/I AN 002 44	Dulas masalulasticii h			
5500	5100 to 5800	WLAN 802.11 a/n	Pulse modulation <sup>b</sup> 217 Hz	0.2	0.3	9
5785	1	a/II	Δ   /   Π			
	1					

<sup>&</sup>lt;sup>a</sup> For some radio services, only the frequencies for uplinking the mobile communication equipment to the base station were included in the table.

<sup>&</sup>lt;sup>b</sup> The carrier must be modulated with a square wave with a 50 % signal ratio.

<sup>&</sup>lt;sup>c</sup> As an alternative to frequency modulation (FM), pulse-width modulation with a 50 % 18 Hz signal ratio can be used, as this would represent the worst-case scenario even if it is not the actual modulation.

# 16.7 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 stated height (X) as shown below:

Child<sup>(1)</sup> (height  $\leq$  154 cm):

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

• Adult<sup>(2)</sup> (height > 154 cm):

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

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

The tidal volume for the patient is calculated in the operator menu with the aid of ideal body weight and the setting **Vt per kg body weight** (Vt/kgBW) (see "9.4 Patient presets", page 109):

$$Vt = IBW \cdot \frac{Vt}{kgBW}$$

Example

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

IBW (male) = 50 kg + 2.3 kg 
$$\cdot \left(\frac{185 \text{ cm}}{2.54 \text{ cm}} - 60\right)$$
 = 79.52 kg  
Vt = 79.52 kg  $\cdot$  6  $\frac{\text{ml}}{\text{kgBW}}$  = 477 ml  $\approx$  480 ml

- <sup>(1)</sup> 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, B. J. Gentamicin therapy. The Annals of Pharmacotherapy, 1974, 8th year, No. 11, p. 650-655

### 16.8 Exported service data

#### 16.8.1 Structure and content of service data

When you have exported the service data 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 "16.8.2 Recorded function checks (fcheck file)", page 174)	
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	Teconstruction in the event of servicing.	
update.txt	Contains information about software updates performed.	

### 16.8.2 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 with a spreadsheet program (e.g. Microsoft<sup>®</sup> Excel<sup>®</sup>).

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	Sequential session number
uid	Unique numerical description of the log entry type
fcheck	Indicates that this is a log entry in the context of the function check

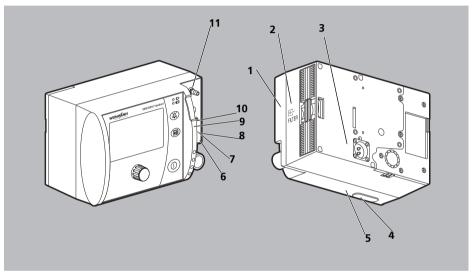
# 16.9 Alarm delay times

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

# 17 Symbols and labels

A summary of the symbols in the display can be found in the section entitled Symbols in the display (see "3.3 Symbols in the display", page 25).

### 17.1 Labels on the device



17-1 Labels on the device

No.	Symbol	Description
		Do not sit on device
1		Do not climb on device
		Follow instructions for use.
	CETTHED SATTREES E12345	UL label with certification code
2		Inlet opening for ambient air
3	12-15V=	Input voltage (12 V-15 V)
4	(II)	Follow instructions for use.

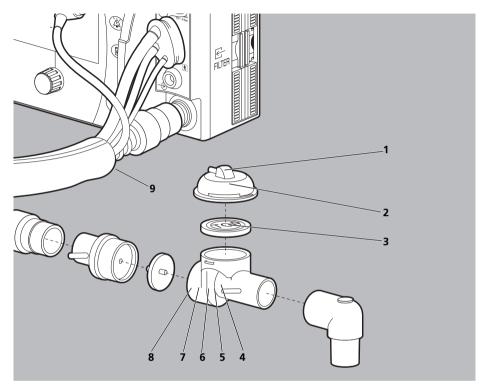
No.	Symbol	Description		
	M	Date of manufacture		
	SN	Serial number		
	•••	Manufacturer		
		Direct voltage		
	$\rightarrow$	Input voltage (12 V-15 V)		
	C€ 0197	CE mark (confirms that the product complies with the applicable European directives)		
5		Do not dispose of device in domestic waste.		
		Type of protection against electric shock: Protection class II device		
	IP54	<ul> <li>Complete protection against solid objects</li> <li>Protected from ingress of dust</li> <li>Protected from splashes from any angle</li> </ul>		
	(II)	Follow instructions for use.		
	<b>†</b>	Type BF applied part		
	UDI (xx)xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	Unique Device Identifier (UDI): Allows individual products to be uniquely identified in the market		
6	<b>→</b>	Connection for MEDUtrigger		
7	(ii	Follow instructions for use.		

### 17 Symbols and labels

No.	Symbol	Description
8	(FSTK)	Safety check label (STK, only applies to Germany): Indicates when the next Technical Safety Check ("Sicherheitstechnische Kontrolle" in accordance with § 11 of the German regulation MPBetreibV) is required.
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 <sub>2</sub>

### 17.2 Labels on the accessories

### 17.2.1 Labels on the breathing circuit



17-2 Labels on the breathing circuit

No.	Symbol	Description	
Reusable breathing circuit and disposable breathing circuit			
1	INSP	Indicates the correct flow direction during inspiration.	
3	TOP	Indicates the correct installation position of the PEEP control diaphragm.	
4	C€ 0197	CE mark (confirms that the product complies with the applicable European directives)	

#### 17 Symbols and labels

No.	Symbol	Description			
5		Date stamp for year and month			
6	ŢŢ	Follow instructions for use.			
7	>PC<	Material designation: Polycarbonate			
8	134 °C	Steam sterilization at 134 °C			
Extra, f	Extra, for reusable breathing circuit only				
9	<b>~</b>	Indicates the date of the next maintenance (position: on service label).			
Extra, f	Extra, for disposable breathing circuit only				
2	2	Disposable item, do not reuse			

# 17.2.2 Labeling on the device information label of the MEDUtrigger

Symbol	Description		
Device inform	Device information label		
<b>†</b>	Degree of protection against electric shock: Device type BF		
X	Do not dispose of device in domestic waste		
C€ 0197	CE mark (confirms that the product complies with the applicable European directives)		
IP54	<ul> <li>Complete protection against solid objects</li> <li>Protected from ingress of dust</li> <li>Protected from splashes from any angle</li> </ul>		
	Type of protection against electric shock: Protection class II device		
(li	Follow instructions for use.		
سا	Date of manufacture		

## 17.3 Labels on the packaging

# 17.3.1 Labels on the packaging of the breathing circuit (reusable)

Symbol	Description
REF	Article number
***	Manufacturer with date of manufacture
	Limits of the storage temperature range
<b>%</b>	Limits of the storage humidity range
(li	Follow instructions for use.
Latex	Latex-free

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### 18 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 spare 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 connecting cable	1 year
Masks, including accessories, rechargeable and non-rechargeable batteries (unless otherwise stated in the technical documentation), sensors, breathing circuits	6 months
Disposable products	None

# 19 EC Declaration of Conformity on Medical Devices

WEINMANN Emergency Medical Technology GmbH + Co. KG hereby declares that the product complies 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.



#### 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





