MEDUMAT Easy^{CPR}

Ventilator

Instructions for Use for devices from Serial Number 25000 or software version 29

Read the instructions for use before using the product. Failure to observe the instructions for use can result in serious injuries or death.

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1 Information on these instructions for use

These instructions for use are meant to enable the safe and efficient handling of the emergency and transport ventilator MEDUMAT Easy^{CPR} (referred to below as the "device"). These instructions for use form part of the device and must be kept in the vicinity thereof and be accessible at all times.

Read these instructions for use carefully before any use, care or maintenance of the device. To ensure the safe use of the device, compliance with all the safety information, warning notices and operating procedures stated in these instructions must be ensured.

In addition, the local accident prevention regulations and general safety provisions for use of the device apply.

Report all serious incidents arising in connection with the device to the manufacturer and the responsible body in your Member State.

Diagrams in these instructions for use serve to improve basic understanding and may differ from the actual design. No claims can be derived from any deviations.

1.1 Copyright protection

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1.2 Customer Service

Should you have any questions, the WEINMANN Emergency Customer Service will be delighted to be of assistance:

Address	WEINMANN Emergency GmbH + Co. KG Frohbösestraße 12 22525 Hamburg Germany
E-mail	kundenservice@weinmann-emt.de
Internet	www.weinmann-emergency.com
Telephone	+49 (0)4088 1896-120

1.3 Warning notices in these instructions for use

⚠ DANGER

Danger!
DANGER indicates a hazardous situation that, if not avoided, will result in death or serious injury.

⚠ WARNING

Warning!
WARNING indicates a hazardous situation that, if not avoided, could result in death or serious injury.

⚠ CAUTION

Caution!
CAUTION indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.

NOTICE

Notice!
NOTICE indicates information considered important, but not hazard-related (e.g., messages related to damage to property or the environment).

i Designates useful tips relating to a particular action.

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Warning notices in actions

Safety information can relate to individual actions. To avoid interrupting the reading flow, this safety information is embedded in the action. The symbols and signal words described above are used.

Example of embedded safety information:

1. Undo screw.
2. ⚠ **CAUTION!**
   Risk of pinching on lid!
   Carefully close the lid.
3. Tighten the screw.

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2 Safety

The instructions for use are part of the device. If the instructions for use and the following safety information are not fully complied with, the treatment may fail or be compromised. This could cause severe or life-threatening injuries to the patient and user.

⇒ Fully comply with the instructions for use.

⇒ Keep the instructions for use with the device so that they can be accessed at any time.

⇒ Only use the device as defined by the intended use (see "2.1 Intended use", page 8).

⇒ Do **not** use the device in the event of contraindications.

2.1 Intended use

MEDUMAT Easy^{CPR} is an electrical, pneumatically operated emergency and transport ventilator used for ventilation and oxygen inhalation with either a mask or tube.

Patient groups

Adults and children with a body weight of over 10 kg (22 lbs) where spontaneous respiration has failed or is inadequate.

User

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

Intended application areas

- Mobile use for emergency medicine and primary care during emergency deployments
- During transport between hospital rooms and departments
- During transport between the hospital and other sites in an ambulance, airplane, helicopter, or ship

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Contraindications

None currently known.

Possible side effects and complications

- Undesirable effects on the cardiovascular system (e.g., reduction of cardiac output, reduction of venous return flow)
- Drying out of the airways
- Overinflation of the lung tissue (lung rupture)
- Overinflation of the stomach during mask ventilation (e.g., aspiration of stomach contents)

2.1.1 Exclusions and restrictions of intended use

The device is **not** approved for the following applications:

- Operation for long-term ventilation in excess of 24 hours
- Operation in hyperbaric chambers
- Operation in combination with magnetic resonance scanners (MRT, NMR, NMI)

2.2 Personnel requirements

Personnel must meet the following requirements:

- Personnel must have a medical qualification and the necessary specialist knowledge and experience in the ventilation of patients.
- As a result of this specialist knowledge and experience, the personnel must be able to safely perform the tasks they have been assigned, and must be able to independently recognize, evaluate and prevent any possible risks for themselves or the patient.
- The personnel must have been trained and instructed in the operation of the device.

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2.3 Preventing a device failure

2.3.1 Pay attention to the correct ambient conditions

If the device or accessories are operated in a non-specified environment, the treatment may be compromised as a result of malfunctions.

⇒ Do **not** operate the device and accessories outside of the specified ambient conditions.(see "13.1 Device", page 134)

2.3.2 Only operate the device and accessories in perfect condition

If the device is not in perfect condition, this can lead to malfunctions and a loss of pneumatic and electrical energy, and can compromise the treatment.

⇒ Perform a full function check before every use (see "5 Function check", page 51).

⇒ Only use devices and accessories that have successfully passed the function check.

2.3.3 Ensuring correct maintenance

Inadequate or incorrect maintenance will impair the functioning of the device and can compromise the treatment.

⇒ Do **not** open the device.

⇒ Follow the maintenance intervals as stated on the device labeling.

⇒ Make sure that the maintenance work is performed. This work must only be carried out by the manufacturer or by specialist personnel who have been explicitly authorized by the manufacturer.

⇒ Also observe and comply with the maintenance intervals for devices in storage (see "10.1 Intervals", page 125).

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2.3.4 Do not perform any modifications to the construction of the device or accessories

If modifications are performed to the construction of the device or accessories, the treatment may be compromised as a result of malfunctions.

⇒ Do **not** perform any modifications to the construction of the device or accessories.

2.3.5 Provide alternative respiration units

⇒ If the device fails or the oxygen supply is interrupted: Provide alternative respiration units.

2.3.6 Keep spare battery available

The battery may die during longer uses and result in failure of the device during the treatment.

⇒ Always keep a spare battery available.

2.3.7 Note shorter battery life at temperatures below 0°C!

Failure to note that the battery life can be significantly shortened at temperatures below 0°C can result in failure of the device during the treatment.

⇒ Note shorter battery life as of temperatures below 0°C!

2.4 Ensuring good hygiene practices

2.4.1 Device and accessories

Inadequate hygiene causes the following risks:

- Inadequately cleaned and disinfected devices or accessories can infect the user or patient via the skin or airways.
- Unsuitable cleaning products or disinfectants can damage the device and lead to malfunctions.

⇒ Carry out cleaning and disinfection of the device and accessories after every use in accordance with the cleaning and

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disinfection plan (see "8.2 Cleaning and disinfection plan", page 100).

⇒ Wear suitable protective equipment (e.g., gloves) during cleaning and disinfection.

⇒ Only use the specified products for cleaning and disinfection.

2.4.2 Disposable items

Re-using disposable items causes the following risks:

- Infection if items come into contact with airways
- Malfunctions when using the device
- Unforeseeable reactions as a result of aging, embrittlement, wear, thermal load and the effects of chemical processes

⇒ **Never** perform cleaning and disinfection of disposable items.

⇒ **Never** use disposable items more than once.

2.5 Safe use of the device and accessories

2.5.1 Preventing interference between the devices

Electrical devices which are operated directly next to or on top of each other can cause mutual interference to functionality. Portable high-frequency communication devices in the direct vicinity of the device can also influence the functioning of the device.

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

⇒ Do **not** operate the device directly next to other electrical devices. Exception: Other WEINMANN Emergency devices which have been tested and shown to guarantee interference-free operation with the adjacent device. A list of other devices is available 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.

⇒ With portable RF communication devices, maintain a minimum distance of 30 cm (approx 12 inches) to the device and accessories. Examples: Wireless device, mobile telephone.

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2.5.2 Do not use the device in magnetic resonance scanners

Use of the device in magnetic resonance scanners can cause the device to malfunction and compromise the treatment.

⇒ Never operate the device in combination with magnetic resonance scanners (MRT, NMR, NMI).

2.5.3 Use of approved accessories and approved spare parts

Non-approved accessories or non-approved spare parts can lead to device malfunctions or interfere with other devices. For example, the connection of non-approved accessories can result in increased electromagnetic interference or reduced electromagnetic immunity.

⇒ Only use approved accessories.

⇒ Only use spare parts from WEINMANN Emergency or spare parts that have been approved by WEINMANN Emergency.

2.5.4 Monitoring the patient and the device

If alarm lights and loudspeakers are covered up, the personnel will not be able to see or hear the alarms and will therefore not be able to respond to dangerous situations.

⇒ Always keep alarm lights and loudspeakers clear and uncovered.

⇒ The patient and device must be continually monitored during ventilation.

⇒ Use additional external monitoring during ventilation (e.g., SpO_2 or $etCO_2$).

2.5.5 Avoid oxygen poisoning as a result of prolonged ventilation

Prolonged use of the device with a high oxygen concentration can result in oxygen poisoning of the patient.

⇒ Do not use the device for long-term ventilation (in excess of 24 hours).

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2.5.6 Preventing the risk of fire and explosion during defibrillation

Simultaneous use of the ventilator and the defibrillator can cause explosion and fire in oxygen-enriched atmospheres.

⇒ Wherever possible, use adhesive electrodes for defibrillation.

⇒ Ensure that the oxygen-air mixture coming from the patient valve flows **away** from the patient's torso.

⇒ Ensure adequate ventilation.

2.5.7 Preventing the risk of fire and explosion as a result of oxygen

Compressed oxygen can quickly enrich the atmosphere with oxygen and lead to fire or explosion of combustible substances.

⇒ Ensure adequate ventilation.

⇒ **Never** smoke in the vicinity of fittings carrying oxygen.

⇒ Keep the oxygen supply away from naked flames or other ignition sources.

⇒ Keep the device and screwed unions free from oil and grease.

⇒ Wash your hands before working on the oxygen supply to remove any oil or grease.

⇒ Secure the oxygen cylinder so that it cannot fall over.

⇒ Tighten or loosen all screwed unions on the oxygen cylinder and on the pressure reducer by hand only. If necessary, use a wrench suitable for pin index oxygen cylinders.

2.5.8 Preventing the risk of fire and explosion due to flammable anesthetic gases or gases

Flammable gases and anesthetic gases may cause explosions.

⇒ Do **not** use the device in combination with flammable gases or flammable anesthetic gases.

2.5.9 Risk of explosion if the device is used in hyperbaric chambers

The device may produce explosions if used in hyperbaric chambers.

⇒ **Never** use the device in hyperbaric chambers.

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2.5.10 Risk of poisoning if the device is used in a toxic environment

Use of the device in a toxic environment can allow toxic gases to enter the patient's lungs.

⇒ Do **not** operate the device in a toxic environment.

2.5.11 Keeping the device labeling legible

Unsuitable wipe disinfectants could remove the device's labeling and markings and cause material damage meaning that the user may not be able to use the device and accessories correctly in an emergency.

⇒ Only use the recommended wipe disinfectants.

⇒ Replace illegible labels.

2.5.12 Batteries

Handling batteries incorrectly can lead to injuries.

⇒ Do **not** throw the battery into the fire.

⇒ **Never** expose the battery to high temperatures.

⇒ Note shorter battery life as of temperatures below 0°C!

⇒ Do **not** open the battery and do **not** disassemble the battery.

⇒ Do **not** recharge the battery.

⇒ Do **not** short circuit the battery.

⇒ Protect the battery from moisture.

⇒ Do **not** expose the battery to high pressures.

⇒ Prevent escaping battery fluid from coming into contact with skin or eyes. If battery fluid comes into contact with skin or eyes, immediately rinse the skin or eye thoroughly with plenty of water and consult a doctor.

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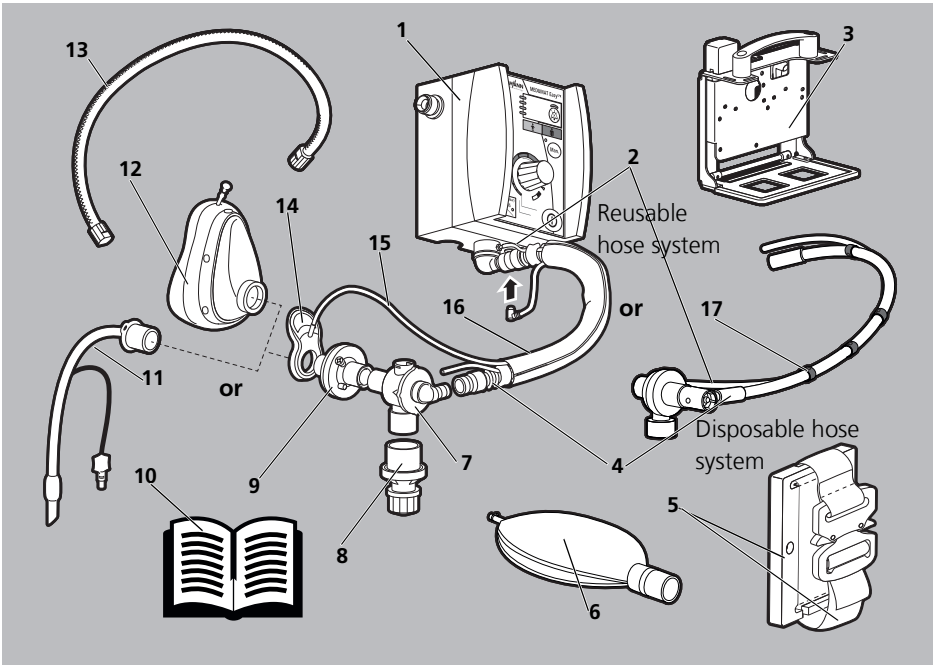
3 Description

3.1 Overview of device and accessories



3-1 Device and accessories

No.	Designation	Description
1	MEDUMAT Easy^{CPR}	The device ventilates the patient.
2	Pressure measuring tube	Measures the ventilation pressure.
3	Carrying system LIFE-BASE	Used to hold and transport the device and other therapy devices as well as the requisite components.
4	Ventilation hose	Conducts oxygen from the device to the patient.
5	Mounting plate and the fastening strap	Used to secure the device.
6	Testing bag	Used to check the functioning of the device.
7	Patient valve	Switches between inspiration and expiration.
8	PEEP valve*	Prevents a pressure drop during expiration.

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No.	Designation	Description
9	Breathing system filter*	Cleans and air-conditions the respiratory air.
10	Instructions for Use	Serve to ensure safe use of the device.
11	Tube*	Connects the patient to be ventilated with the patient hose system.
12	Ventilation mask	Connects the patient to be ventilated with the patient hose system.
13	Compressed gas tube	Conducts oxygen from the compressed gas supply to the device.
14	MEDUtrigger	Manually triggers mechanical breaths.
15	MEDUtrigger cable	Connects the MEDUtrigger to the device.
16	Hose protection sleeve	Keeps the ventilation hose, pressure measuring tube, and MEDUtrigger cable together and protects the patient hose system from soiling.
17	Clips	Keep the ventilation hose and pressure measuring tube together and secure the MEDUtrigger cable to the patient hose system.

* Third-party accessories, not included in the purchase of the device.

3.2 Function

MEDUMAT Easy^{CPR} is an automatic emergency and transport ventilator. Highly compressed medical oxygen is used as the ventilation gas; this is reduced to the necessary operating pressure via an external pressure reducer. The oxygen is supplied at the compressed gas connection.

The ventilation parameters – frequency and tidal volume – are linked together and can be set using the adjusting knob on the device.

The ventilation gas is transported to the patient through the ventilation hose via the patient valve and ventilation mask or via the tube. The lip membrane in the patient valve guarantees that the expiration gas can be exhaled via the expiration side. In order to monitor the patient, the device features continuous measurement of the airway pressure as well as a visual and audible alarm system.

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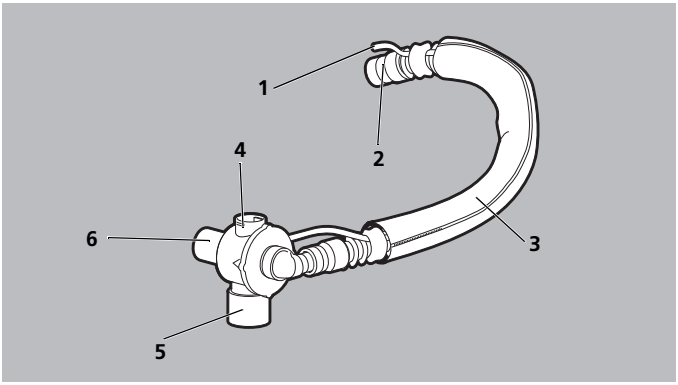
The device also features a voice prompt and a metronome, intended as an aid to users with little experience with the device in particular. If the voice prompt is not required, it can be switched off with a key combination (see "6.7 Activating/deactivating the voice prompt", page 85). The same applies for the metronome (see "6.8 Activating/deactivating the metronome", page 87).

3.3 Accessories

3.3.1 Patient hose system with patient valve

The patient hose system with patient valve is available as a reusable hose system with reusable patient valve or a disposable hose system with disposable patient valve.



3-2 Reusable hose system with reusable patient valve

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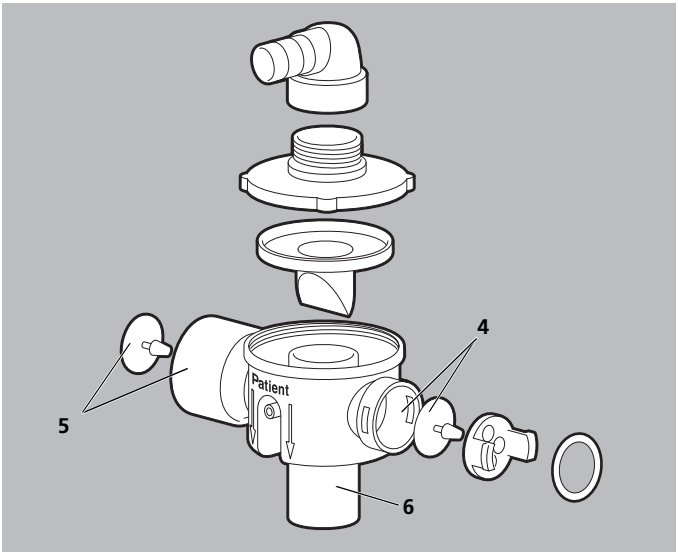
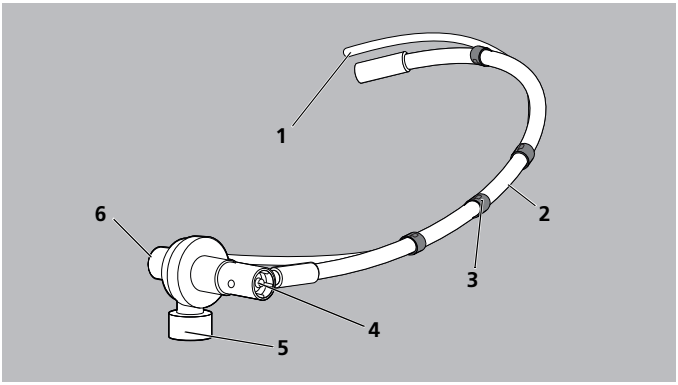


3-3 Reusable patient valve



3-4 Disposable hose system with disposable patient valve

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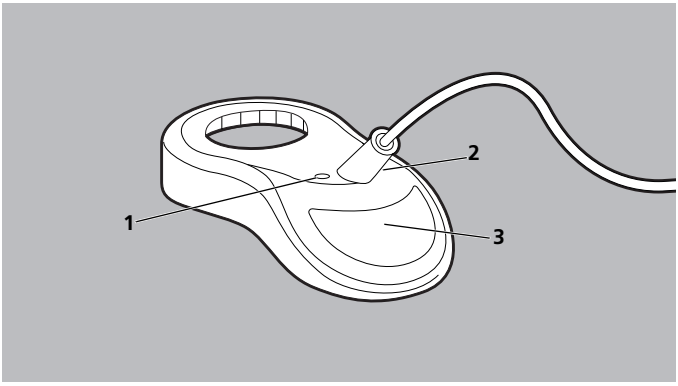
The ventilation gas is delivered to the patient via the patient hose system with patient valve. The patient hose system comprises a pressure measuring tube (**1**) and a ventilation hose (**2**). Both hoses are connected to the patient valve and the device. The pressure measuring tube conducts the pressure on the inspiration side to the device. The pressure measuring tube, ventilation hose, and the MEDUtrigger cable are connected together with clips (**3**) in the disposable hose system. In the reusable hose system, the hose protection sleeve (**3**) keeps the pressure measuring tube, the ventilation hose, and the MEDUtrigger cable together.

The patient valve is designed so that if the device fails, spontaneous respiration is possible regardless of the ventilation mode set. If necessary, fresh air can be inhaled via the spontaneous respiration side with emergency air membrane (**4**).

The inspiration side (**6**) serves to enable a breathing system filter, a ventilation mask or a tube to be attached to the patient valve or to connect a testing bag to perform a function check. The expiration side with disk diaphragm (**5**) serves to discharge the respiratory air to the environment during expiration and, if necessary, to connect a PEEP valve to the patient valve.

3.3.2 MEDUtrigger



3-5 MEDUtrigger

The MEDUtrigger serves to trigger individual mechanical breaths with the set tidal volume. In this way, you determine the respiratory rate administered yourself. The mechanical breaths are triggered by actuating the button (**3**) on the MEDUtrigger.

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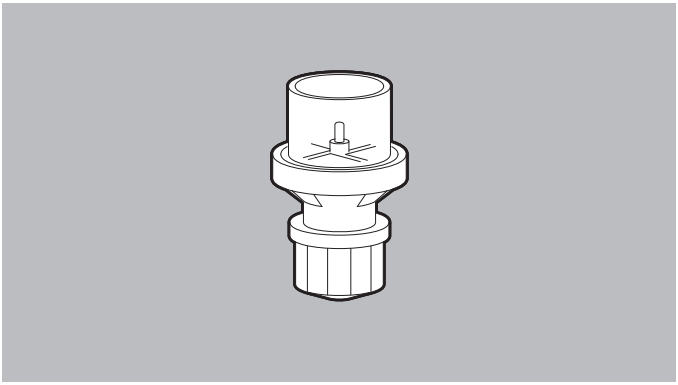
The two LEDs (**1** and **2**) on the MEDUtrigger show the current operating status.

3.3.3 PEEP valve

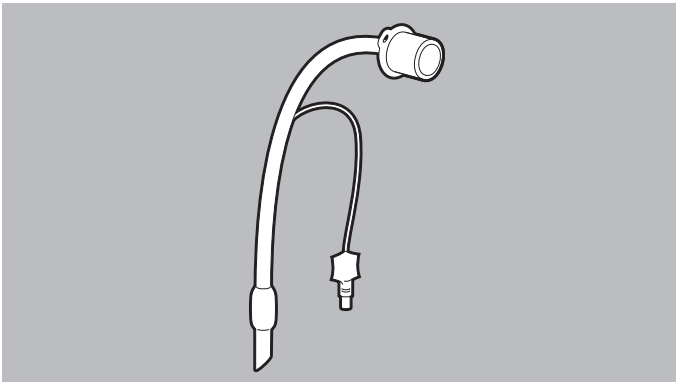


3-6 PEEP valve

The PEEP valve enables ventilation with a positive end-expiratory pressure (PEEP). The PEEP valve prevents the pressure dropping to the ambient air pressure during expiration.

Attach the PEEP valve to the expiration side of the patient valve. A PEEP valve is not included in the purchase of the device.

3.3.4 Tube



3-7 Tube

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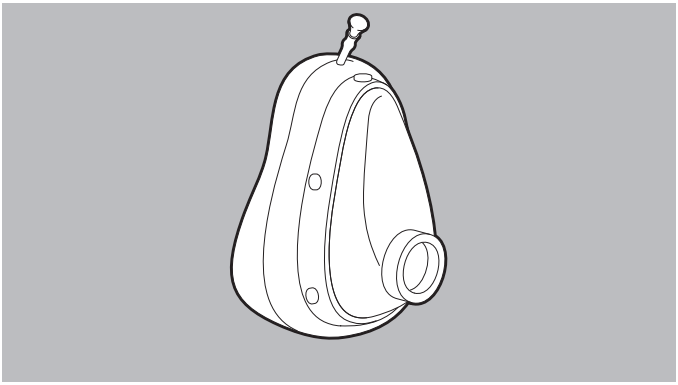
The tube can be used in addition to the ventilation mask for patient ventilation. For this, the tube must firstly be inserted into the patient's trachea by a medical specialist (intubation). The tube is not included in the purchase of the device.

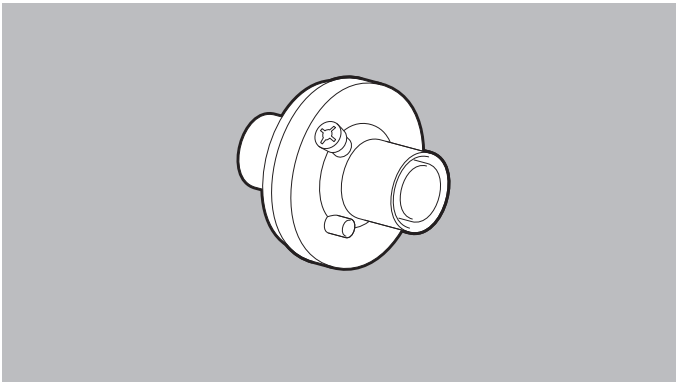
3.3.5 Ventilation mask



3-8 Ventilation mask

The ventilation mask is used for non-invasive ventilation.

3.3.6 Breathing system filter



3-9 Breathing system filter

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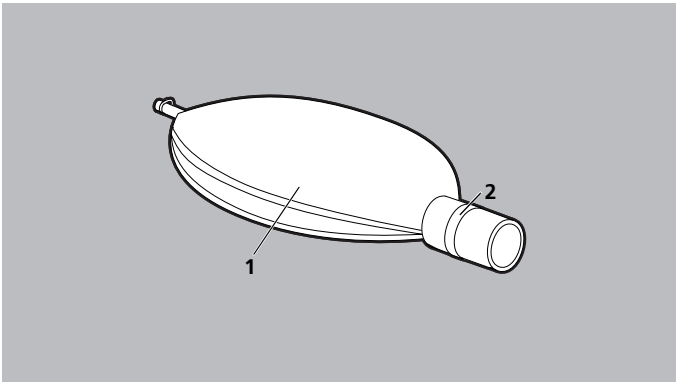
Commercially available HME breathing system filters (HME = Heat Moisture Exchange) with standard connections (15/22 mm) can be attached to the inspiration side of the patient valve to filter and air-condition the respiratory air. The breathing system filter is not included in the purchase of the device.

3.3.7 Testing bag



3-10 Testing bag

The testing bag (**1**) serves to check the functionality of the device prior to use. During testing, the testing bag simulates the human lung.

The connector (**2**) is connected to the patient valve for the function check.

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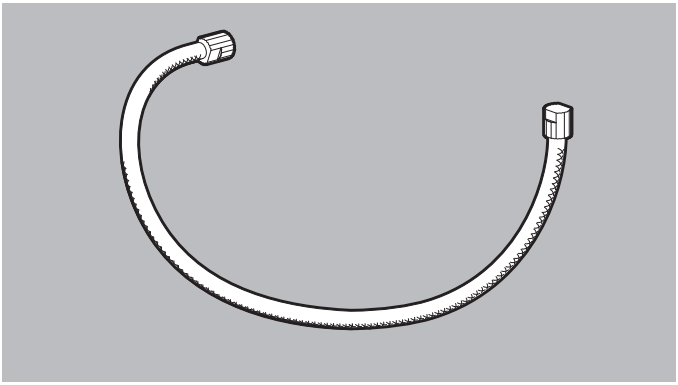
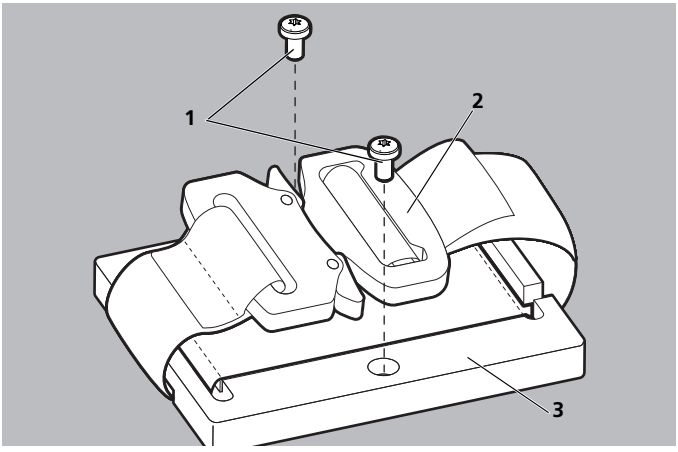
3.3.8 Compressed gas tube



3-11 Compressed gas tube

The compressed gas tube connects the device to the oxygen supply.

3.3.9 Mounting set with mounting plate and fastening strap



3-12 Mounting set with mounting plate and fastening strap

The mounting set serves to temporarily secure the device to the site of use. It comprises a mounting plate (**3**), screws (**1**), and a fastening strap with a safety lock (**2**).

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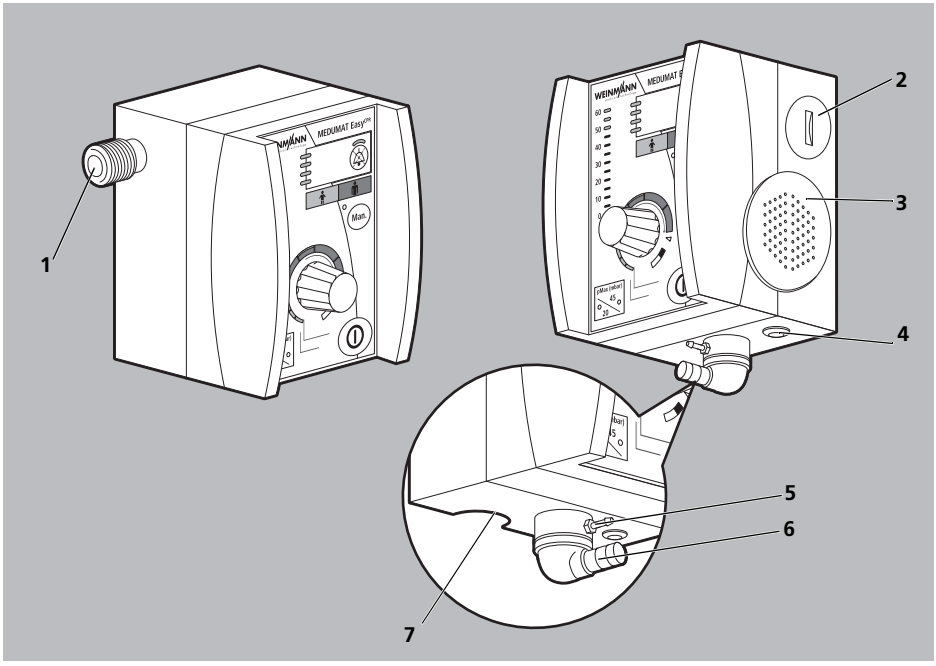
3.4 Connections and interfaces



3-13 Connections and interfaces

No.	Designation	Description
1	Compressed gas connection	Connects the oxygen supply to the device.
2	Battery compartment	Houses the battery.
3	Loudspeaker	Emits audible alarms.
4	Connection for MEDUtrigger	Connects the MEDUtrigger to the device.
5	Connection for pressure measuring tube	Connects the pressure measuring tube to the device. Conducts the airway pressure at the patient valve to the pressure sensor inside the device.
6	Connection for ventilation hose	Connects the ventilation hose to the device.
7	Pressure relief valve	Serves to limit the ventilation pressure.

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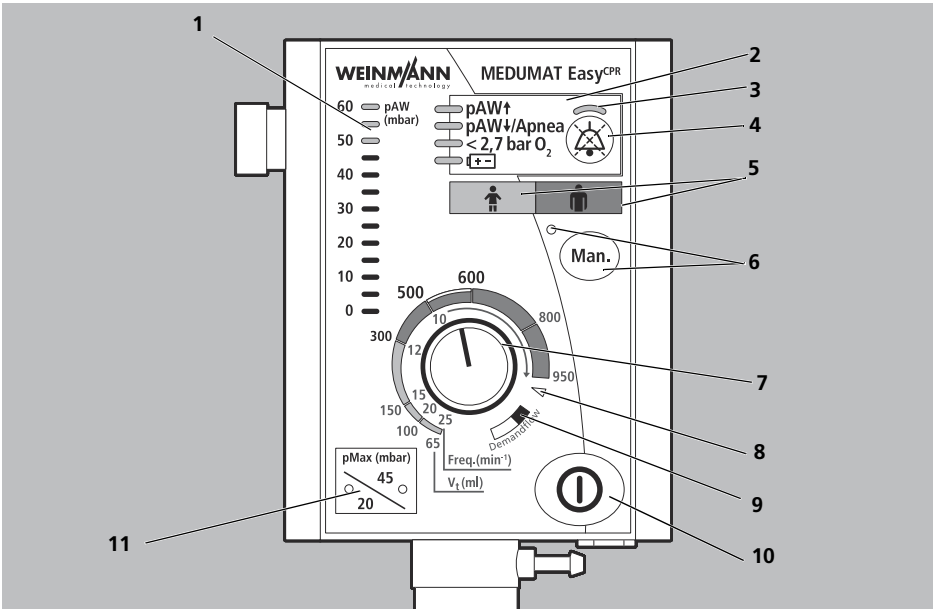
3.5 Control panel



3-14 Control panel

No.	Designation	Description
1	Ventilation pressure display	Displays the ventilation pressure in mbar.
2	Alarm field	Indicates alarm states visually. • LED is lit: Alarm is active. • LED is not lit: Alarm is not active.
3	LED for alarm muting	Indicates the status of alarm muting. • LED is lit: The alarm is muted for 120 seconds. • LED is not lit: The alarm is switched on.
4	Alarm mute button	Serves to mute the alarm and switch the audible alarm back on.
5	Color legend	Displays assignment of the ventilation parameters: • Orange: Child • Red: Adult
6	Man. button with control LED	Activates and deactivates the manual mode (CPR mode). Shows readiness for operation.
7	Adjusting knob for the ventilation parameters	Serves to set the ventilation rate freq (breaths per minute) and tidal volume Vt (ml).

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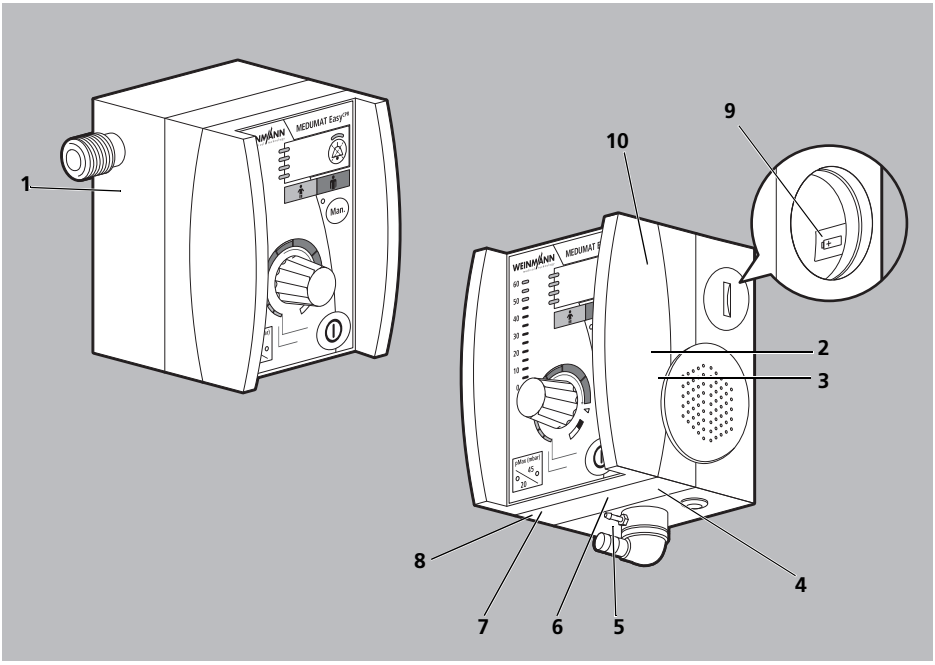
No.	Designation	Description
8	Snap-in position	Switches between continuous mode and the demand flow mode.
9	LED demand flow	Visually displays the status of the demand flow mode. • Illuminated: The demand flow mode is switched on. • Not illuminated: The demand flow mode is switched off.
10	On/Off button	Switches the device on or off.
11	pMax button with control LEDs	Switches between the ventilation pressure limit for mask ventilation (20 mbar) and tube ventilation (45 mbar).

3.6 Labels and symbols

3.6.1 Labels on the device



3-15 Labels on the device

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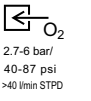
No.	Symbol	Description
1		Input 2.7-6 bar (40-87 psi) O_2 STPD – Standard Temperature and Pressure, dry
2		Article number
		Serial number
2	**IP54**	Protection against the ingress of dust and splash water from all sides
		Type BF applied part
		Do not dispose of device in household waste
	CE 0197	CE mark (confirms that the product complies with the applicable European directives)
	Rx only	Device only available with prescription as per US legislation [Code of Federal Regulations (CFR) Title 21]
		Manufacturer with date of manufacture (YYYY-MM-DD)
		UDI marking - possible application identifiers: (01): Global Trade Item Number (GTIN) – globally unique Identification Number (10): Batch/Lot number (11): Date of manufacture in format YYMMDD (17): Expiration date in format YYMMDD (21): Serial number

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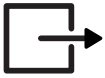
No.	Symbol	Description
3		Follow the instructions for use
		Do not sit on the device
		Do not climb on the device
		UL marking with certification label (see "13.1 Device", page 134)
4		Indicates the MEDUtrigger connection
		Type BF applied part
5	pMax ≤100 mbar/ ≤ 1.45 psi	Opening pressure of release valve ≤ 100 mbar (1.45 psi)
6		Hose system connection (ventilation hose and pressure measuring tube)
		Type BF applied part
7		Service label: Indicates when the next maintenance is required
8		STK sticker (only in the Federal Republic of Germany): Indicates when the next safety check in accordance with §11 of the MPBetreibV (German regulations governing owners/operators of medical devices) is required.

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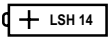
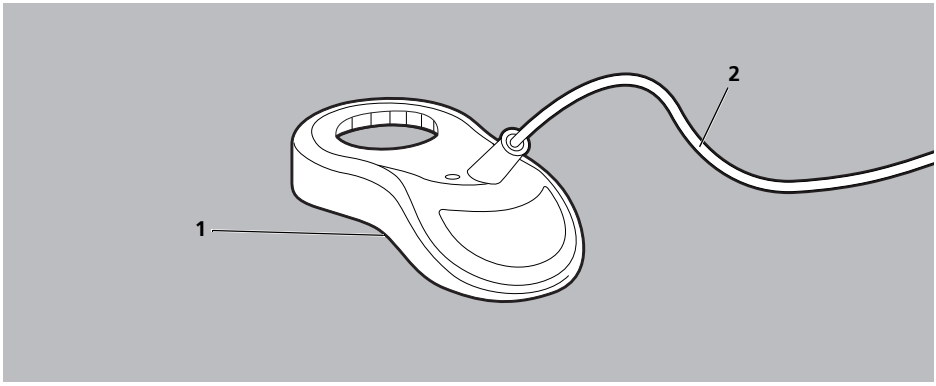
No.	Symbol	Description
9		Indicates the battery position
10		Optional: Integrated software version

3.6.2 Labels on the MEDUtrigger



3-16 Labels on the MEDUtrigger

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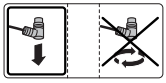
No.	Symbol	Description
1		Protection class II, protective insulation
	IP54	Protection against the ingress of dust and splash water from all sides
		Do not dispose of device in household waste
		Type BF applied part
		Observe the instructions for use
	CE 0197	CE mark (confirms that the product complies with the applicable European directives)
		Manufacturer
2		Pull out the plug vertically and do not turn
		UDI marking - possible application identifiers: (01): Global Trade Item Number (GTIN) – globally unique Identification Number (10): Batch/Lot number (11): Date of manufacture in format YYMMDD (17): Expiration date in format YYMMDD (21): Serial number

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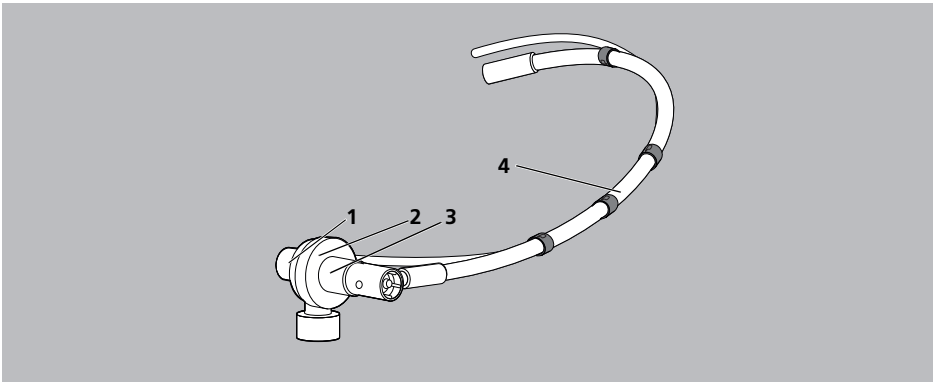
3.6.3 Labels on the disposable hose system with disposable patient valve



3-17 Labels on the disposable hose system with patient valve

No.	Symbol	Description
1	REF WM 28110 ↓ Patient ↓	Adhesive label with article number and flow direction arrows
2	EXHALE	Direction of flow during expiration
3	SINGLE PATIENT USE	Disposable item, do not reuse.
4	REF	Article number
		Disposable item, do not reuse.
		Manufacturer
	LOT	Batch code

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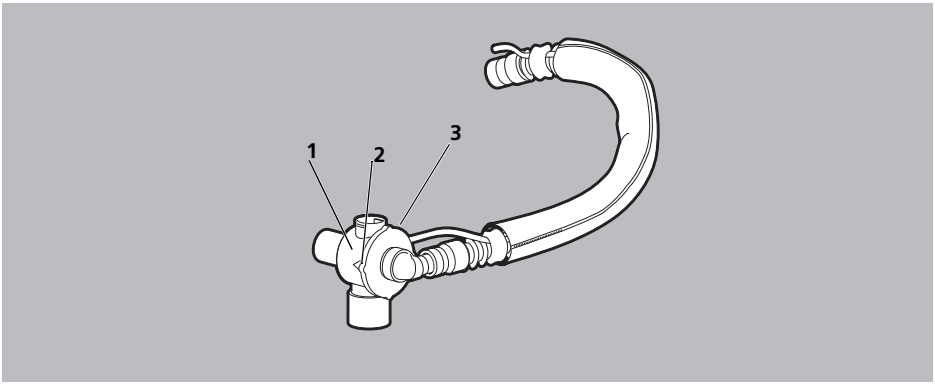
3.6.4 Labels on the reusable hose system with reusable patient valve



3-18 Labels on the reusable hose system with patient valve

No.	Symbol	Description
1		Observe instructions for use and correct assembly.
2		Installation direction of lip membrane
3		Shows inspiration direction.

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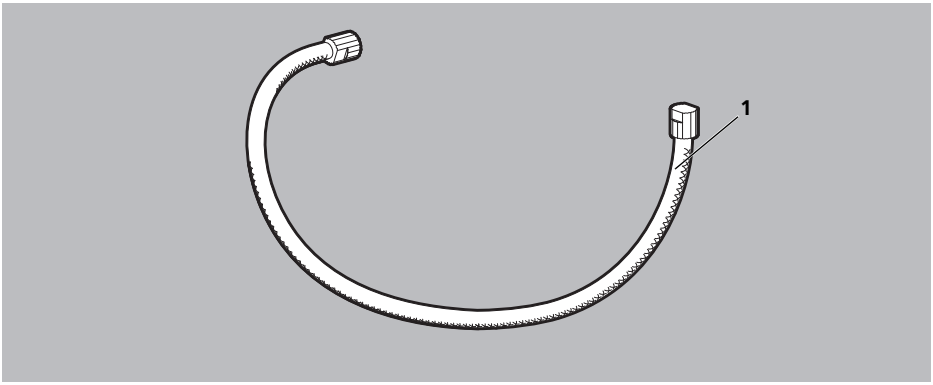
3.6.5 Labels on the compressed gas tube



3-19 Labels on the compressed gas tube

No.	Symbol	Description
1	REF	Article number
	(01)04054685075750 (10)20190306	UDI marking - possible application identifiers: (01): Global Trade Item Number (GTIN) – globally unique Identification Number (10): Batch/Lot number (11): Date of manufacture in format YYMMDD (17): Expiration date in format YYMMDD (21): Serial number
		Manufacturer
	CE 0197	CE mark (confirms that the product complies with the applicable European directives)
	Rx only	Device only available with prescription as per US legislation [Code of Federal Regulations (CFR) Title 21]
	LOT	Batch code

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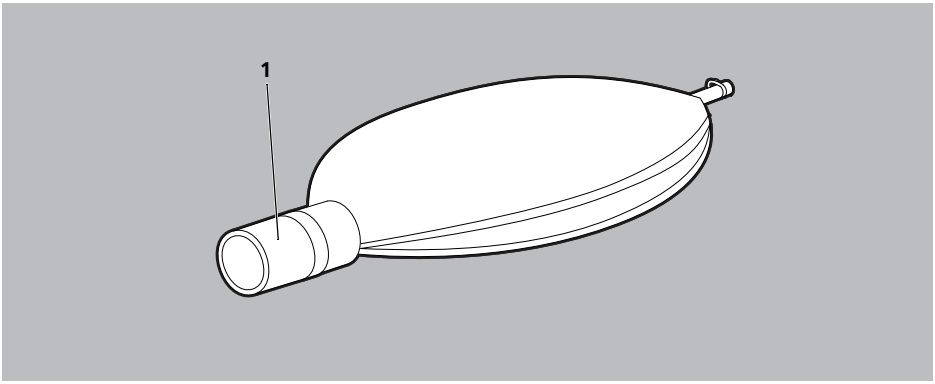
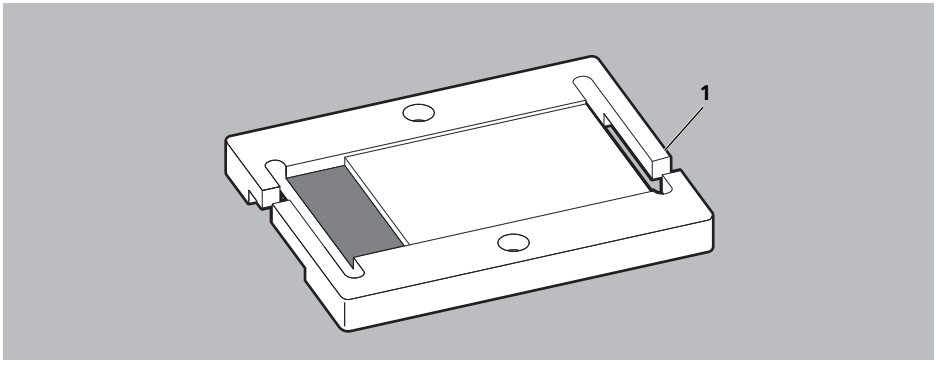
3.6.6 Labels on the testing bag



3-20 Labels on the testing bag

No.	Symbol	Description
1		Manufacturer with date of manufacture (YYYY-MM-DD)
		Article number

3.6.7 Labels on the mounting plate



3-21 Labels on the mounting plate

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No.	Symbol	Description
1	REF	Article number
	CE	CE mark (confirms that the product complies with the applicable European directives)
		Observe the instructions for use
	Rx only	Device only available with prescription as per US legislation [Code of Federal Regulations (CFR) Title 21]
		Manufacturer with date of manufacture (YYYY-MM-DD)
	LOT	Batch code
		UDI marking - possible application identifiers: (01): Global Trade Item Number (GTIN) – globally unique Identification Number (10): Batch/Lot number (11): Date of manufacture in format YYMMDD (17): Expiration date in format YYMMDD (21): Serial number

3.6.8 Labels on the packaging

Symbol	Description
REF	Article number
	Observe the instructions for use
SN	Serial number

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Symbol	Description
LOT	Batch code
CE 0197	CE mark (confirms that the product complies with the applicable European directives)
	Manufacturer, possibly with date of manufacture (YYYY-MM-DD)
	Observe the instructions for use
Rx only	Device only available with prescription as per US legislation [Code of Federal Regulations (CFR) Title 21]
	UL marking with certification label (see "13.1 Device", page 134)
	UDI marking - possible application identifiers: (01): Global Trade Item Number (GTIN) – globally unique Identification Number (10): Batch/Lot number (11): Date of manufacture in format YYMMDD (17): Expiration date in format YYMMDD (21): Serial number
	Fragile
	Important! Important safety-related information such as warnings and precautions are included in the instructions for use. These are not stated on the label or the device itself.
	Storage temperature range limits
	Storage humidity range limits

Symbol	Description
	Disposable item, do not reuse
	Store in a dry place
	Can be used up to YYYY-MM-DD

3.7 Ventilation modes

3.7.1 Demand flow mode

In demand flow mode, the device switches to respiration-controlled oxygen inhalation. As a result, the patient's breathing is supported. In demand flow mode, ventilation is performed exclusively with the ventilation mask. Due to slight negative pressure on the patient valve (inspiration trigger), oxygen flows until slight excess pressure interrupts the flow and expiration is via the patient valve.

In demand flow mode, the ventilation pressure limit is automatically set to 20 mbar (20 cmH_2) and cannot be changed. As such, the device emits an information tone if the pMax button with control LEDs is pressed in demand flow mode.

Further information on the demand flow mode can be found in the section "Operation" (see "6.4.1 Ventilating the patient in demand flow mode", page 73).

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3.7.2 Manual mode (CPR mode)

It is possible to specify the respiratory rate oneself in manual mode. It can only be activated when MEDUtrigger is connected. MEDUtrigger can be used to vent manual breaths to the patient with the adjusted tidal volume.
For example, manual mode is used to check the tube after intubation or for cardiopulmonary resuscitation.

If the voice prompt and/or metronome function is switched on, the device guides you through the cardiopulmonary resuscitation. Manual mode is called CPR mode when the voice prompt is activated.

The length of the expiration phase corresponds to the length of inspiration phase in manual mode (CPR mode). The respiratory time ratio is 1:1.

Further information on the manual mode (CPR mode) can be found in the section "Operation" (see "6.4.2 Ventilating the patient in manual mode (CPR mode)", page 75).

3.7.3 Continuous mode (IPPV)

The continuous mode (IPPV mode) is used for mandatory volume-controlled ventilation with a fixed minute volume. The minute volume is set via a combined setting of the tidal volume and frequency. This mode is used on patients who have no spontaneous respiration. The set ventilation pressure limitation (pMax) ensures the safety of the patient.

Further information on the continuous mode can be found in the section "Operation" (see "6.4.3 Ventilating the patient in continuous mode", page 81).

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4 Preparation

4.1 Unpacking the delivery and visual inspection

1. Remove the packaging material.
2. Recycle the packaging material and dispose of properly.
3. Check the delivery to ensure nothing is missing (see "12.1 Standard scope of supply", page 132).
4. Check the device and accessories for external damage.
5. Do not operate the device in the event of damage or if accessories are missing. Contact the Customer Service (see "1.2 Customer Service", page 6).

Result The delivery has been unpacked and visually checked.

4.2 Install the device on a carrying system or carrying structures

If the device is installed on a carrying system, you will require the fastening elements set WM 15007 (see "12.1 Standard scope of supply", page 132).
Use screws for installation on carrying structures (M4). Pay attention to the requisite insertion depth when selecting the screws. The screws must insert between 6 and 7 mm into the sockets on the rear in the installed state.

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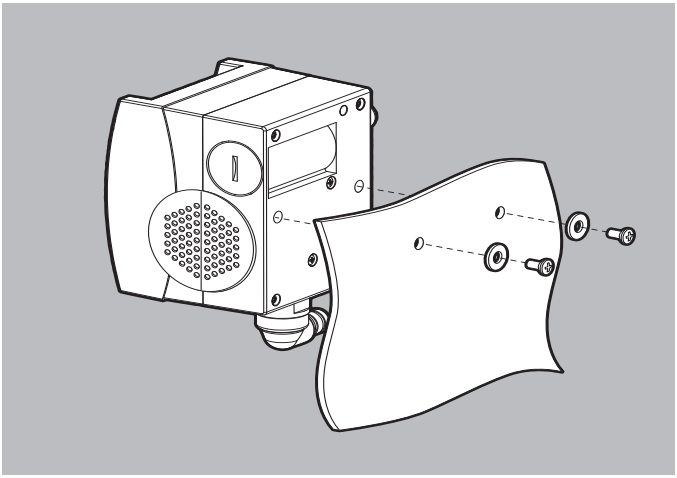

1. Install the device on the carrying system or carrying structures using screws and protective disks.
2. Tighten screws.

Result The device is installed on a carrying system or carrying structures.

4.3 Securing the mounting plate with fastening strap to the device

⚠ WARNING

Malfunction or failure of treatment as a result of insufficiently secured devices!
If the device is not sufficiently secured, its uncontrolled movement can lead to functional failure. This can result in serious or life-threatening injury to the patient.
⇒ Always pull the fastening strap tight.

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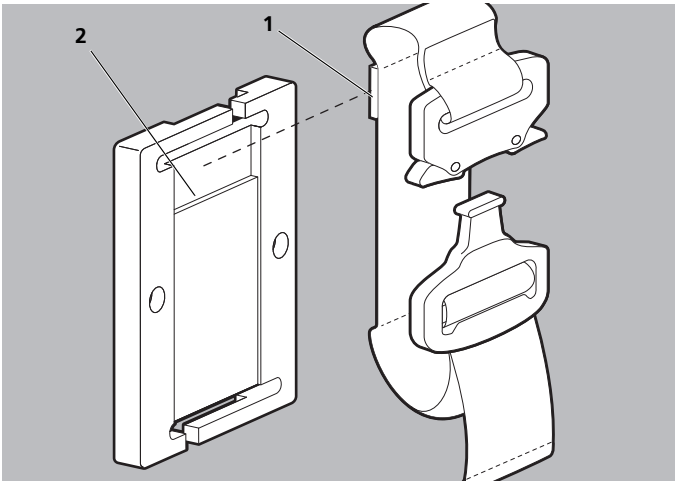
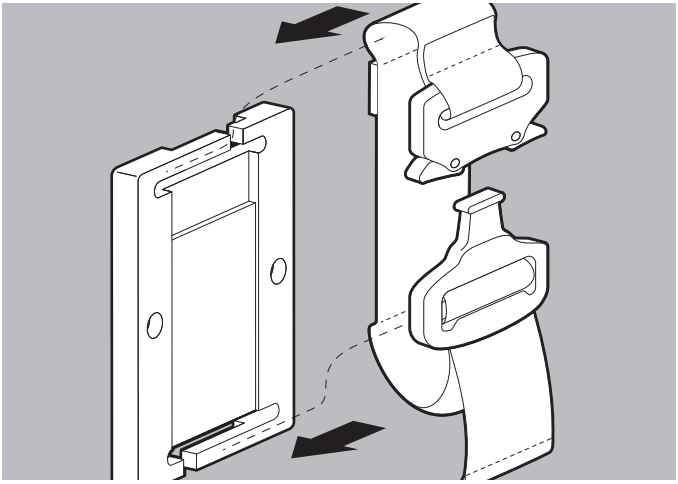


1. Position the red marking of the fastening strap (**1**) on the red recess on the mounting plate (**2**).



2. Insert the ends of the fastening strap into the depressions on the mounting plate.

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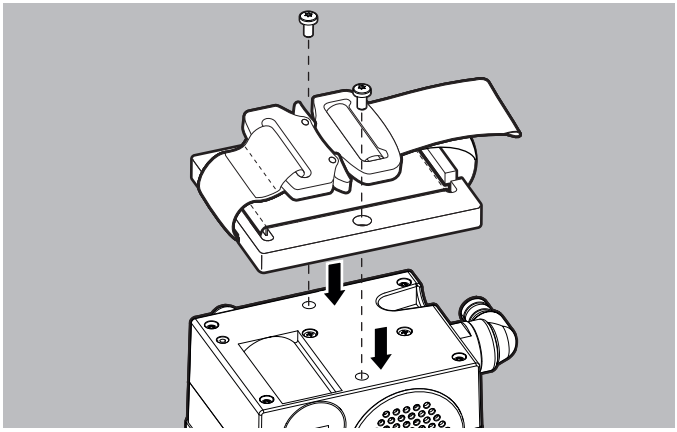
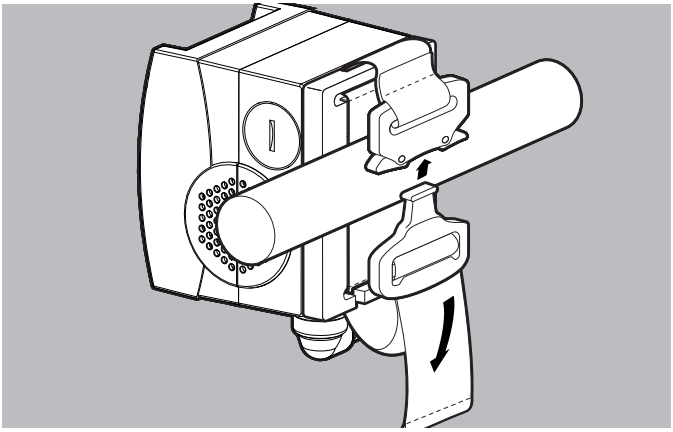


3. Screw the mounting plate onto the device by turning the supplied screws clockwise.



4. Place the fastening strap around the desired piece of equipment.
5. Close the safety lock on the fastening strap. To do so, connect the two buckles until they securely lock into place.
6. ⚠ **Warning! Risk of injury due to uncontrolled movements!**
   Pull the fastening strap tight.

Result The device is assembled on the equipment with the mounting plate and fastening strap.

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4.4 Connecting an oxygen supply

⚠ WARNING

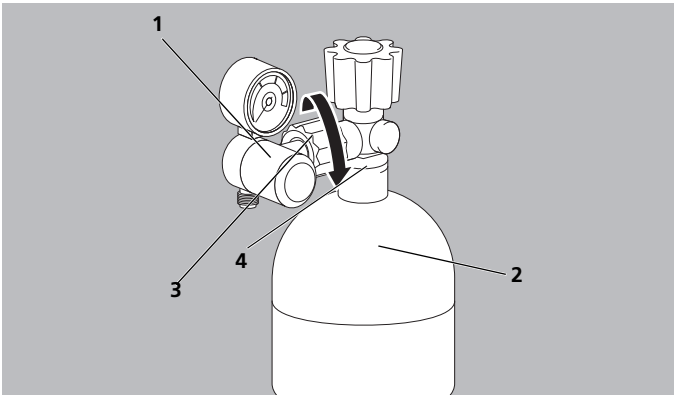
Risk of fire and explosion due to highly compressed oxygen combined with hydrocarbon compounds!
Hydrocarbon compounds (e.g., oil, grease, cleaning alcohol, hand cream or adhesive plasters) can cause explosive reactions if they come into contact with highly compressed oxygen. This can result in severe or life-threatening injury to the patient, user or bystanders.
⇒ Always wash hands thoroughly and remove adhesive plasters before working with the oxygen supply.

⚠ WARNING

Compromised oxygen therapy as a result of unsuitable oxygen!
Unsuitable oxygen can compromise the treatment. This can result in serious or life-threatening injury to the patient.
⇒ Do **not** operate the device with compressed gas or non-medical oxygen

NOTICE

Material damage due to use of a tool!
All the screwed unions have been designed such that they can be released by hand. The use of a wrench or other tool could damage the device or accessories.
⇒ Do not use wrenches or other tools to tighten or release union nuts.



1. Connect the pressure reducer (**1**) to the oxygen cylinder (**2**). To do so, screw on the pressure reducer (**1**) onto the cylinder valve (**4**) with the knurled union nut (**3**) and tighten by hand.

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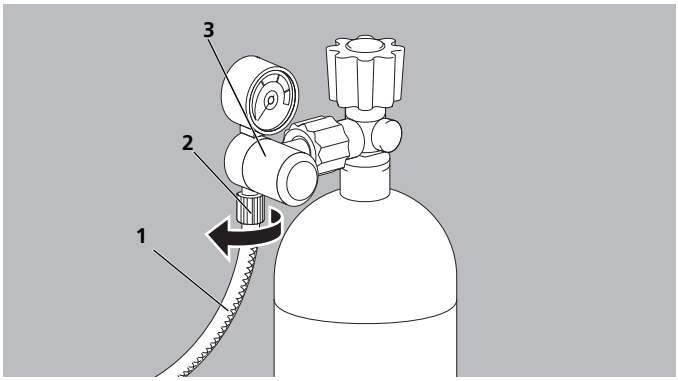
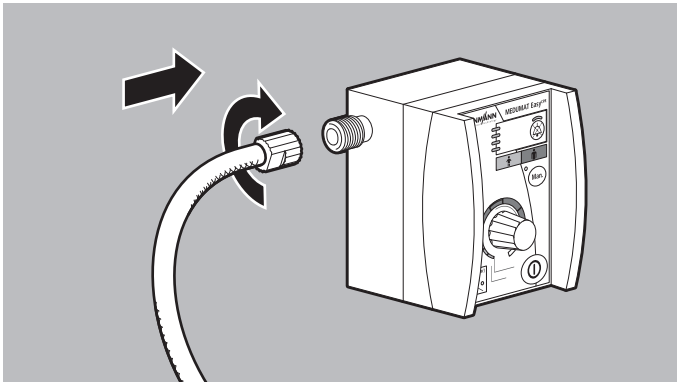


2. Using the union nut (**2**) or quick-release coupling, connect the compressed gas hose (**1**) to the pressure reducer (**3**) or central gas supply by hand. To this end, screw the union nut (**2**) clockwise.



3. Connect the other end of the compressed gas tube to the device using the union nut. To do this, screw the union nut onto the device's compressed gas connection in a clockwise direction.

Result The oxygen supply is connected.

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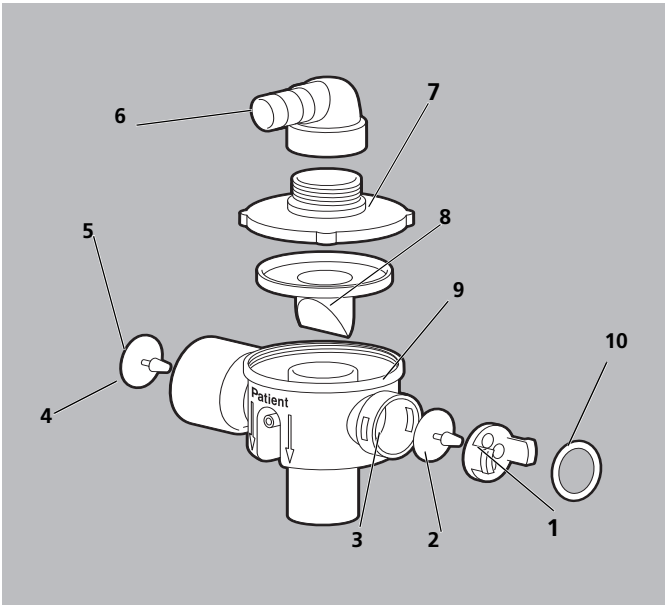
4.5 Assemble reusable hose system

Requirement The reusable hose system is disassembled.



1. If necessary: Install the reusable patient valve:
   - Insert the O-ring (**10**) into the groove on the spontaneous respiration insert (**1**) of the reusable patient valve.
   - Insert disk diaphragm/emergency air membrane (**2**) in spontaneous respiration side (**3**) of the reusable patient valve.
   - Insert spontaneous respiration insert (**1**) in spontaneous respiration side (**3**) of the reusable patient valve.
   - Insert disk diaphragm (**4**) in expiration side (**5**) of the reusable patient valve.
   - Insert flawless lip membrane (**8**).
     When doing so, pay attention to the insertion direction symbol on the patient valve ▽ (**9**).

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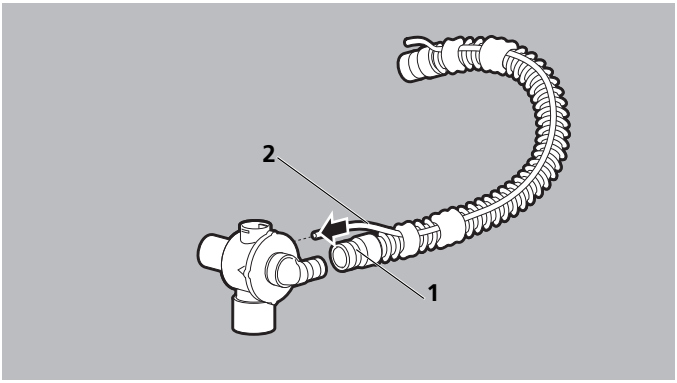
- **⚠ Warning! Treatment fault due to patient valve lip membrane installation errors!**
  Check the correct positioning of the lip membrane in accordance with the installation direction symbol on the patient valve ▽ (**9**).
- Screw the connection for ventilation hose (**6**) onto the reusable patient valve lid (**7**) in a clockwise direction.
- Install the reusable patient valve lid (**7**) in a clockwise direction.



2. Connect the reusable ventilation hose (**1**) and pressure measuring tube (**2**) to the reusable patient valve.
   When doing so, note: The hoses must be firmly attached to the patient valve.

Result The reusable hose system is assembled.

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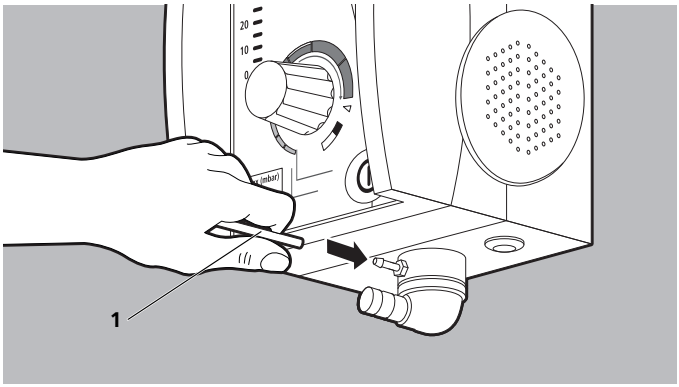
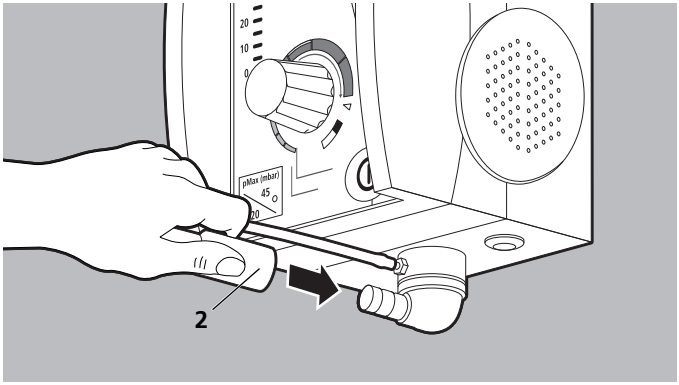
4.6 Connecting the patient hose system and MEDUtrigger to the device

Requirement The patient hose system has been assembled (see "4.5 Assemble reusable hose system", page 46).



1. Grasp the end of the pressure measuring tube (**1**) and push onto the connection.



2. Grasp the end of the ventilation hose (**2**) and push onto the connection. If necessary: Turn the ventilation hose (**2**) slightly to avoid bending the pressure measuring tube (**1**).

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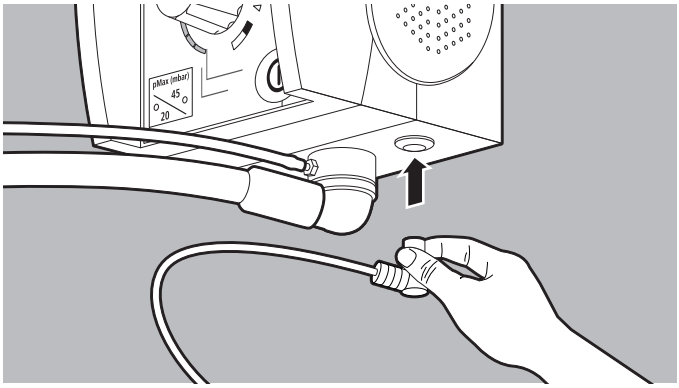
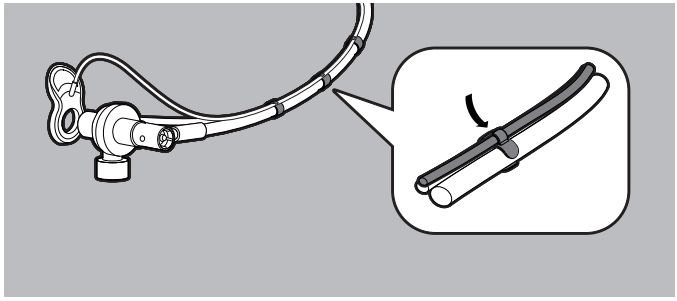


3. Connect the MEDUtrigger connector to the MEDUtrigger connection. To do this, insert the connector, without turning, straight into the socket.
   The MEDUtrigger cable points towards the front of the device.



4. Connect the MEDUtrigger cable to the patient hose system:

   - With the disposable hose system: Connect the MEDUtrigger cable to the patient hose system using the clips.

   or

   - With the reusable hose system: Pull the hose protection sleeve over the ventilation hose, pressure measuring tube, and MEDUtrigger cable.

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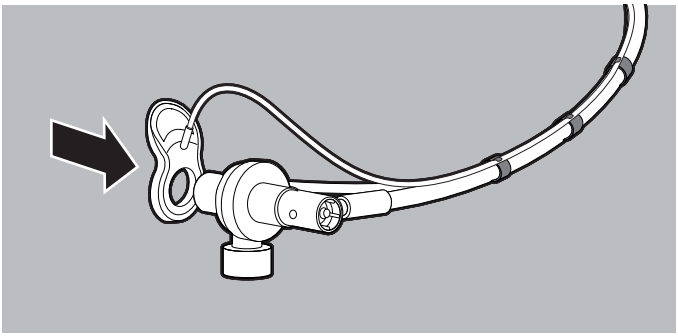

5. ⚠ **CAUTION! Delayed treatment due to incorrect position of MEDUtrigger on the patient valve!**
   Push MEDUtrigger fully onto the inspiration side of the patient valve.

Result The patient hose system and MEDUtrigger are connected.

The device is now ready for the function check (see "5 Function check", page 51).

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5 Function check

If this function check reveals any faults or deviations from the specified values, you must not use the MEDUMAT Easy^{CPR}.

You should first try to rectify the fault with the aid of the information provided in the section "Error messages" (see "9.2 Faults", page 123). If you are unable to rectify the faults using the table, please contact WEINMANN Emergency or a technician who has been expressly authorized by WEINMANN Emergency promptly.

⚠ WARNING

Devices and accessories which are defective or not ready for use can disrupt the therapy or cause it to fail completely!
The use of defective devices or accessories can cause the device to malfunction. This can result in severe or life-threatening injury to the patient and user.
⇒ Perform a full function check before every use.
⇒ Only use devices and accessories which have successfully passed the function check.

5.1 Intervals for function check

Perform the function check at the following intervals:

Part concerned	Interval
Device and accessories	• Before each use • After each cleaning and disinfection • After each disassembly • At least every 6 months (if not used)

5.2 Visually checking the device and accessories

Requirement The device is switched off (see "6.6 Switching the device off", page 84).

1. Check the device and accessories for external damage.
2. Carefully bend the MEDUtrigger cable and check for:

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- Damage
- Wear
- Exposed wires
- Bent connection lines

3. Check that all the connectors and connections engage properly.
4. Check the testing bag for damage. Check the balloon and the integrity of the connector.
   - Check that the testing bag's balloon is firmly attached to the connector.
5. Check the patient valve, connectors, and membranes for external damage, cracks, distortions, and soiling.
6. If necessary: Replace any damaged accessories.
7. If necessary: Dispose of any damaged accessories (see "11.3 Disposal", page 131).
8. ⚠ **WARNING! Device failure due to dead batteries!** Check whether a spare battery is available.

Result The device and accessories have been checked visually.

5.3 Preparing for the function check

Required material Oxygen supply

Requirement The device and accessories have been checked visually and are in perfect condition (see "5.2 Visually checking the device and accessories", page 51).

1. Connect the device to the oxygen supply (see "4.4 Connecting an oxygen supply", page 44).
2. Connect the patient hose system and MEDUtrigger up to the device (see "4.6 Connecting the patient hose system and MEDUtrigger to the device", page 48).
3. Keep a testing bag available for subsequent steps.

Result The device is ready for the function check.

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5.4 Checking the system for leaks

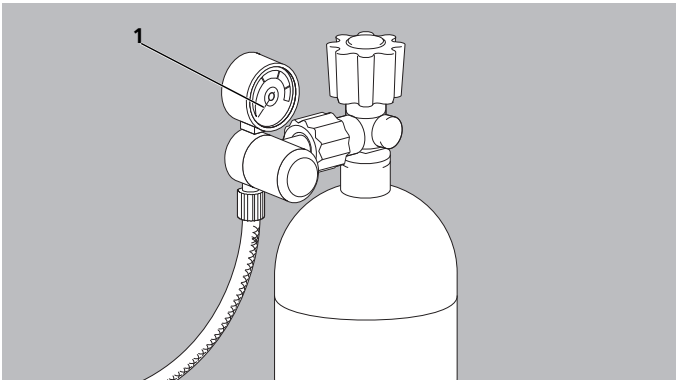
NOTICE

Damage to the device due to pressure blows on fittings!
Opening the oxygen cylinder valve too quickly can lead to strong pressure surges and damage the oxygen cylinder or the fitting.
⇒ Always open the oxygen cylinder valve slowly.

Requirement

- The device is connected to the oxygen supply (see "4.4 Connecting an oxygen supply", page 44).
- The device is switched off (see "6.6 Switching the device off", page 84).

1. Open the oxygen cylinder slowly.
   To do this, turn the handwheel counterclockwise slowly.



2. Read off the oxygen cylinder pressure on the contents gauge (**1**) of the pressure reducer.
3. Close the oxygen cylinder.
4. Monitor the needle on the contents gauge (**1**) on the pressure reducer for 1 minute.
   - If the position of the needle remains constant: The system is free from leaks.
   - If the needle falls continuously: The system is *not* leakproof.

Result

The system has been checked for leaks.

If the system is leaking, remedy the system leak as described below.

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Rectifying leaks in the system

Requirement The system is *not* leakproof.

1. Check that the tubes are connected correctly (see "5.2 Visually checking the device and accessories", page 51).
2. Check that the screw connections are tightened correctly (see "5.2 Visually checking the device and accessories", page 51).
3. Check the system for leaks once more (see "5.4 Checking the system for leaks", page 53).
4. If a leak in the system cannot be remedied, have the device repaired (see "1.2 Customer Service", page 6).

Result The leak in the system has been rectified.

5.5 Checking device functions

In order to perform the function check comprehensively and rapidly, check all functions in succession in the order below.

⚠ CAUTION

Risk of injury from improperly removed testing bag!
If the testing bag is removed improperly, the connector of the testing bag may remain on the patient hose system. The resulting increase in inspiratory airway resistance can injure the patient.
⇒ When disassembling always pull the testing bag off at the connector.

NOTICE

Damage to the device due to pressure blows on fittings!
Opening the oxygen cylinder valve too quickly can lead to strong pressure surges and damage the oxygen cylinder or the fitting.
⇒ Always open the oxygen cylinder valve slowly.

The **pAW** ↑ alarm can be ignored when performing the following testing steps unless testing the alarm itself is specifically required.

5.5.1 Checking visual and audio alarm output

Requirement

- The device and accessories have been checked visually (see "5.2 Visually checking the device and accessories", page 51).
- The function check is ready (see "5.3 Preparing for the function check", page 52).

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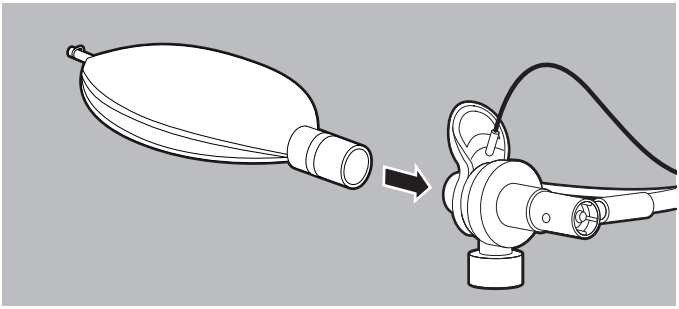
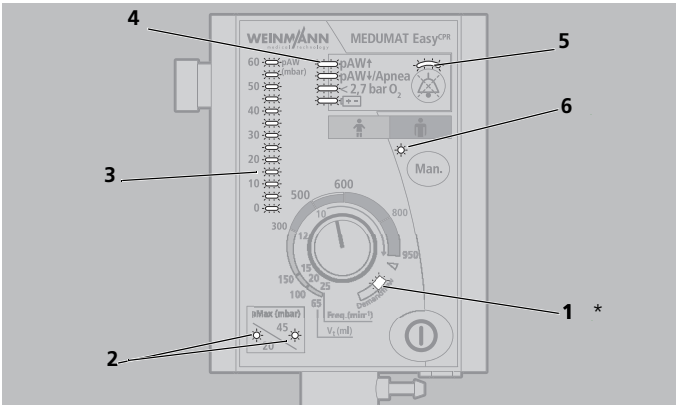
- The device is switched off.

1. Open the oxygen cylinder slowly.



2. Connect the testing bag to the inspiration side of the patient valve.
3. Switch on the device using the On/Off button.
   Upon being switched on, the device performs an automatic self-test which takes approx. 2 seconds.
4. Monitor the self-test and also check the following signals:
   - Check whether the device emits an audio signal when being switched on.



   - Check that all the LEDs in the control panel light up at least once when being switched on: Demand flow (**1**), pMax (**2**), ventilation pressure display (**3**), alarm (**4**), alarm mute (**5**), Man.(**6**).

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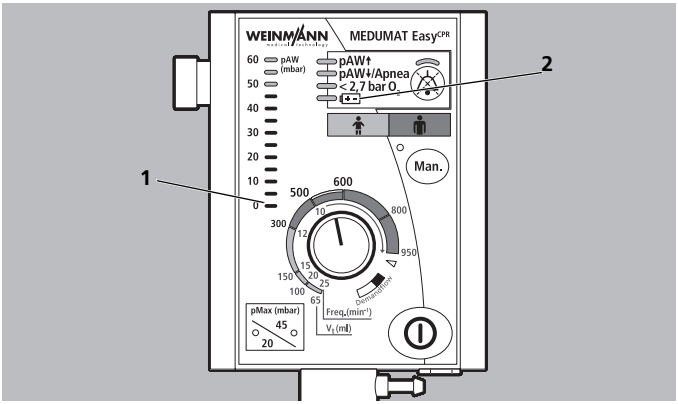
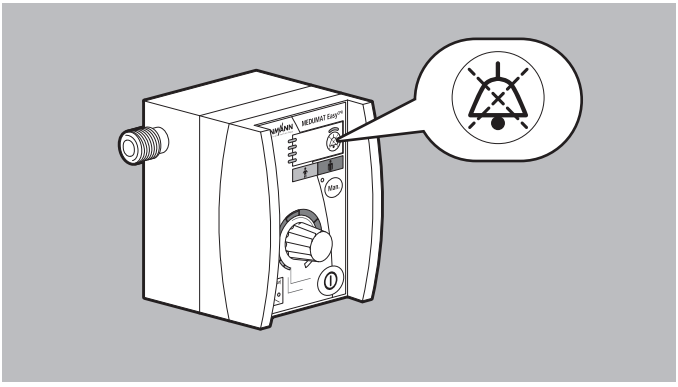


- Check whether the bottom most LED on the ventilation pressure display (**1**) lights up green.
- Check that the LED [+ −] (**2**) for the alarm goes out and that the device commences ventilation in the correct manner.



5. Press the alarm mute button.
   - Check that the alarm mute LED lights up.

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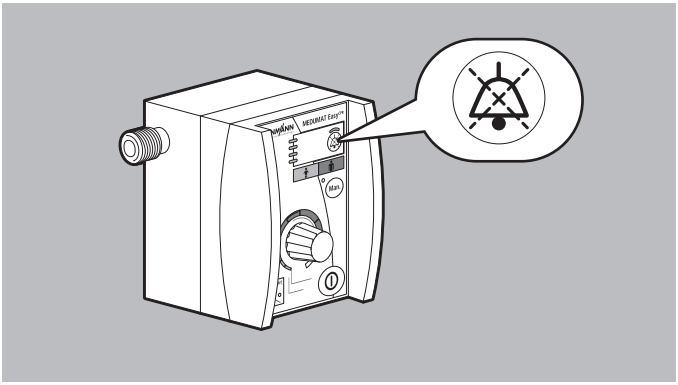

6. Press the alarm mute button again.
   - Check that the alarm mute LED goes out.

Result The visual and audio alarm output has been checked.

5.5.2 Checking the supply pressure alarm

1. Close the oxygen cylinder.
   - Check whether the **< 2.7 bar O_2** alarm is triggered once the device supply pressure falls below 2.7 bar O_2.
2. Open the oxygen cylinder slowly.
   - Check whether the **< 2.7 bar O_2** alarm is switched off once there is sufficient supply pressure.

Result The supply pressure alarm has been checked.

5.5.3 Checking the ventilation rate

1. Select the following settings:

   Via the adjusting knob: Vt = 65 ml at rate = 25 breaths per minute

   Via the pMax button with control LEDs: 45 mbar

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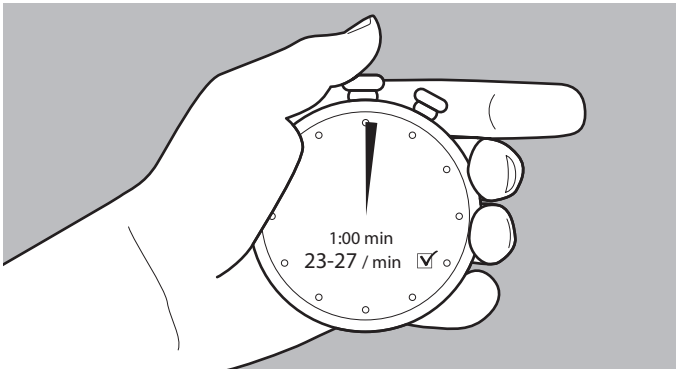

2. Count the number of inspiration phases for exactly 1 minute.
   - Check whether the ventilation rate is between 23 and 27 breaths per minute.

In combination with the testing bag, these settings can cause the **pAW ↓ /Apnea** alarm to be triggered. The alarm can be ignored during this test step.

Result The ventilation rate has been checked.

5.5.4 Checking the tidal volume and aware pressure measurement

1. Select the following settings:

   Via the adjusting knob: Vt = 950 ml at rate = 10 breaths per minute

   Via the pMax button with control LEDs: 45 mbar

In combination with the testing bag, these settings can cause the **pAW ↑** alarm to be triggered. The alarm can be ignored during this test step.

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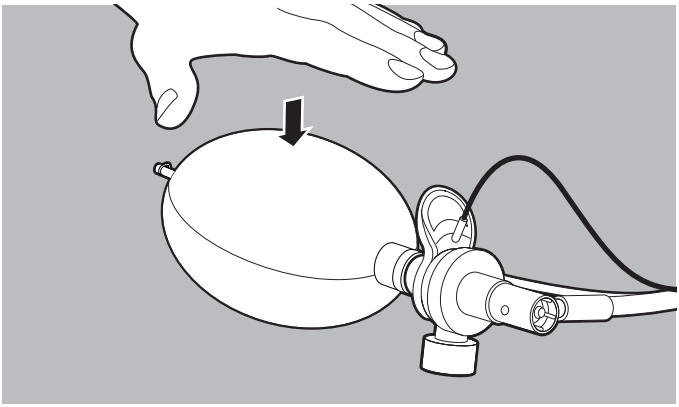

2. Simulate the expiration phase by hand with the testing bag. To this end, place the testing bag on a firm surface and, during the expiration phase, press on the testing bag with your hand flat until the volume has been completely discharged via the patient valve.
   - Check whether the testing bag fills completely during inspiration.
   - Check whether the LEDs in the ventilation pressure display light up to the 40-45 mbar range during inspiration.

The testing bag is not sufficiently filled if the **pAW ↓ /Apnea** alarm is triggered.

3. Allow the device to ventilate without simulating the expiration phase.
   - Check whether the device triggers the **pAW ↑** alarm after the third inspiration breath at 40-50 mbar.

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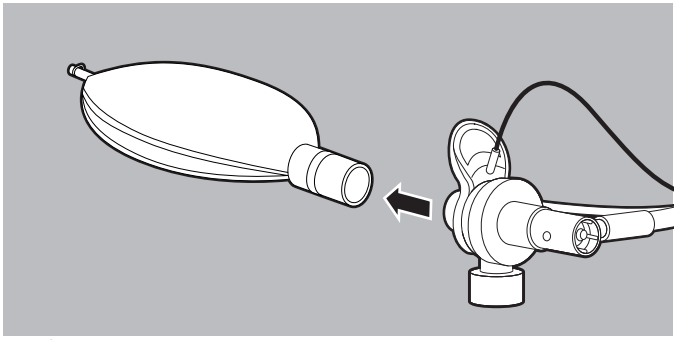
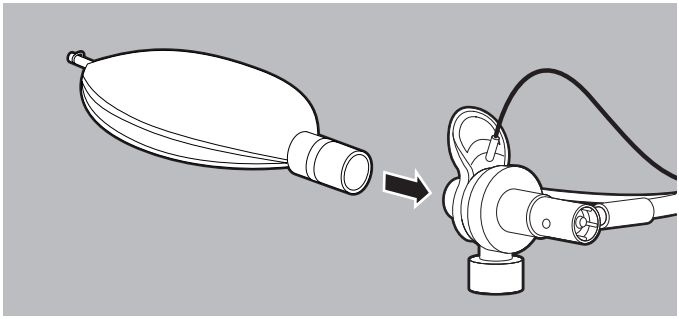


4. ⚠**CAUTION! Risk of injury from improperly removed testing bag!**
   Grasp the testing bag by the connector and pull the bag and connector off the patient valve.

   - Check whether the device triggers the **pAW ↓ /Apnea** alarm after the second inspiration breath.



5. Connect the testing bag to the inspiration side of the patient valve again.

Result The tidal volume and airway pressure measurement have been checked.

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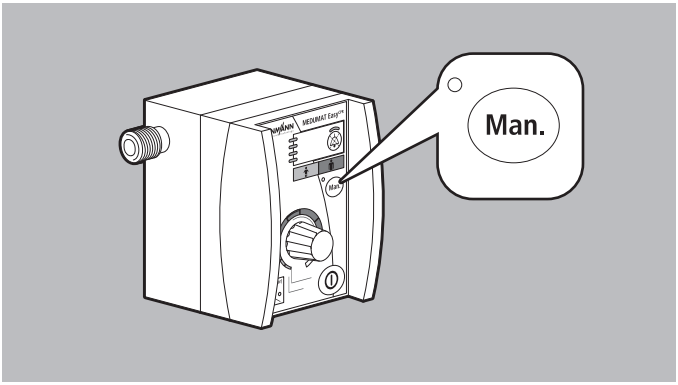
5.5.5 Checking the MEDUtrigger

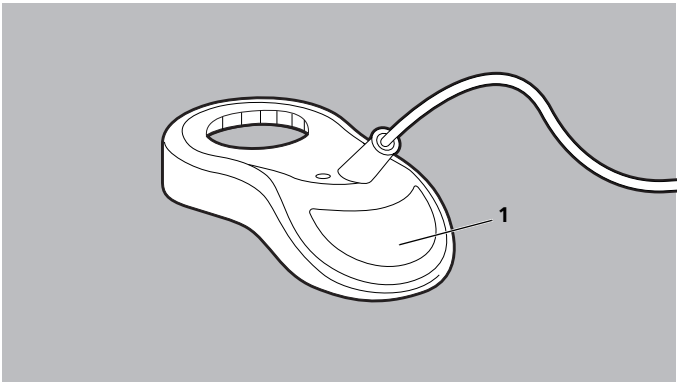
1. Select the following setting:

   Via the adjusting knob: Vt = 950 ml at rate = 10 breaths per minute

   Via the pMax button with control LEDs: 45 mbar



2. Press the Man. button.
   - Check whether the control LED on the Man. button lights up.
   - Check whether both LEDs on the MEDUtrigger light up.



3. Press the button on the MEDUtrigger (**1**).
   - Check whether a mechanical breath is triggered.

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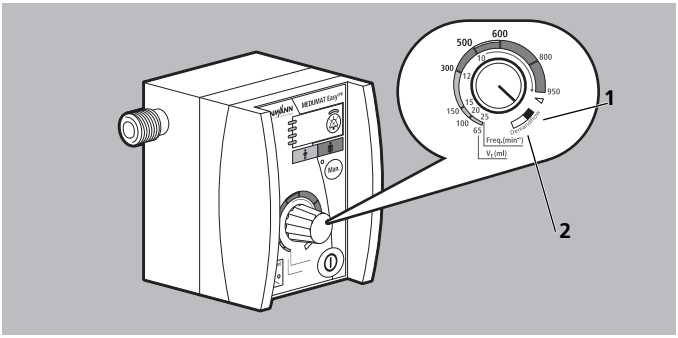
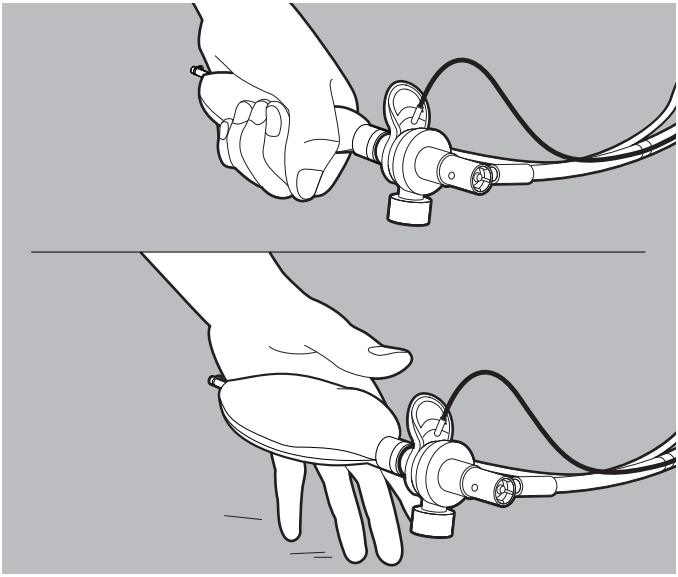
4. Exit manual mode (CPR mode). To do this, press the Man. button again.

Result The MEDUtrigger has been checked.

5.5.6 Checking the demand flow mode



1. Select the "demand flow" setting. To do this, turn the adjusting knob for ventilation parameters clockwise past the snap-in position (**1**).
   - Check whether the green demand flow LED (**2**) lights up.



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2. Simulate the inspiration trigger with one hand. To do this, press the testing bag firmly together in your hand and then release with a jerk.
   - Check whether the device switches the flow on and immediately off again. You can hear a slight click.
3. Switch off the device using the On/Off button. To do this, keep the On/Off button depressed until all 4 alarm LEDs light up. Then release the On/Off button.
4. **⚠CAUTION! Risk of injury from improperly removed testing bag!**
   Grasp the testing bag by the connector and pull the bag and connector off the patient valve.
5. Close the oxygen cylinder.

Result The demand flow mode has been checked.
The function check is complete.

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6 Operation

6.1 Preparing for ventilation

Requirement

- The device and accessories have been cleaned and disinfected (see "8 Cleaning and disinfection", page 100).
- The device is ready for use (see "4 Preparation", page 40).
- The function check is complete (see "5 Function check", page 51).

⚠ WARNING

Failure of treatment due to insufficient oxygen capacity and/or battery capacity!
Insufficient oxygen capacity and/or battery capacity prevents patient ventilation. This can result in serious or life-threatening injury to the patient.
⇒ Perform a full function check before every use.
⇒ Only start ventilation if, during the function check, the alarm indicating insufficient battery capacity is not emitted.
⇒ Check the oxygen cylinder pressure prior to ventilation.
⇒ Do not start ventilation if there is insufficient oxygen cylinder pressure.
⇒ Keep an alternative ventilation unit at the ready.

NOTICE

Damage to the oxygen cylinder due to corrosion!
Moist ambient air may enter oxygen cylinders which have been completely emptied and cause corrosion.
⇒ Do not empty oxygen cylinders completely.

NOTICE

Damage to the device due to pressure blows on fittings!
Opening the oxygen cylinder valve too quickly can lead to strong pressure surges and damage the oxygen cylinder or the fitting.
⇒ Always open the oxygen cylinder valve slowly.

1. If necessary: Connect the compressed gas tube to the oxygen cylinder or the central gas supply.

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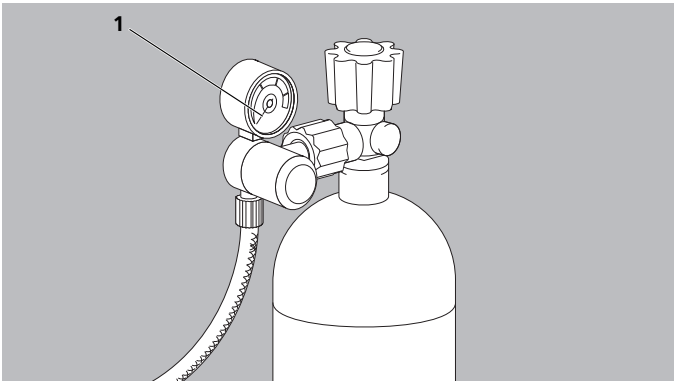

2. Open the oxygen cylinder slowly.
   The contents gauge (**1**) displays the oxygen cylinder pressure.
3. Calculate the remaining operating time to ensure that the device does not stop unexpectedly (see "14 Appendix", page 141).
4. Connect accessories.
   - Connect ventilation mask or tube (see "6.1.1 Connecting the ventilation mask or tube", page 65)
   - Connect breathing system filter (see "6.1.2 Connecting the breathing system filter", page 67)
   - Connect PEEP valve (see "6.1.3 Connecting the PEEP valve", page 69)

Result The device is ready for use.

6.1.1 Connecting the ventilation mask or tube

⚠ CAUTION

Delayed treatment due to incorrect position of MEDUtrigger on the patient valve!
If MEDUtrigger is incorrectly connected to the patient valve, it will not be possible to properly attach the ventilation mask, which can lead to incorrect or delayed treatment. This can injure the patient.
⇒ Push MEDUtrigger fully onto the inspiration side of the patient valve.

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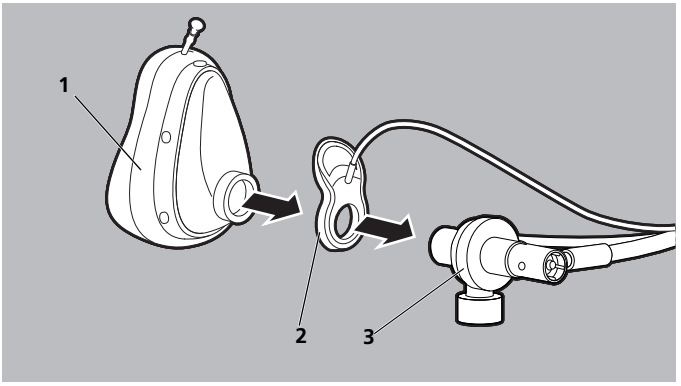
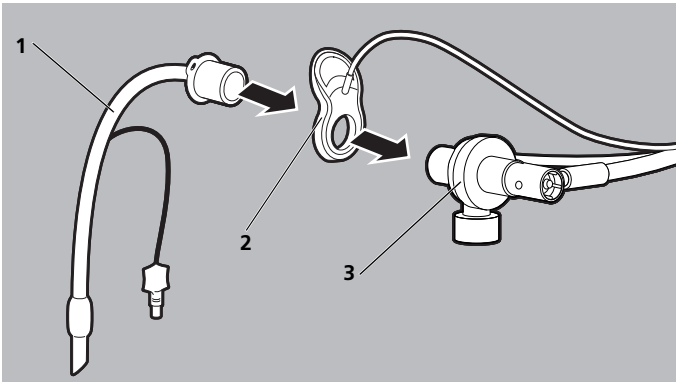


1. Connect the ventilation mask (**1**) together with MEDUtrigger (**2**) on the patient valve (**3**).

   or



   Connect the tube (**1**) together with the MEDUtrigger (**2**) on the patient valve (**3**).

2. Check whether the MEDUtrigger has been pushed down fully on the patient valve.

Result The ventilation mask or tube is connected.

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6.1.2 Connecting the breathing system filter

⚠ WARNING

Fault or treatment failure due to incompatibility of the device with consumables, accessories or other medical devices!
Defective and unauthorized accessories can result in malfunctions, increased electromagnetic interference emissions and reduced electromagnetic immunity of the device, incorrect output values and reduced ventilation performance. This can result in serious or life-threatening injury to the patient.
⇒ Only connect approved accessories.

⚠ WARNING

Hypoventilation due to the use of additional breathing system filters!
The dead space of the overall system increases due to the use of additional breathing system filters (breathing system filter, bacteria filter or combined breathing system bacteria filter). Increased dead space can result in hypoventilation. This can result in serious or life-threatening injury to the patient.
⇒ Only use approved accessories.
⇒ Increase in the dead space with ventilation with small tidal volumes.

⚠ CAUTION

Increased breathing effort due to the use of additional accessories!
The spontaneous respiration resistance of the overall system increases due to the use of additional accessories such as a filter (breathing system filter, bacteria filter or combined breathing system bacteria filter). This can injure the patient.
⇒ Only use approved accessories.
⇒ Monitor increase in spontaneous respiratory resistance for the patient.

Connecting the breathing system filter for mask ventilation

1. Observe the instructions for use from the breathing system filter manufacturer.

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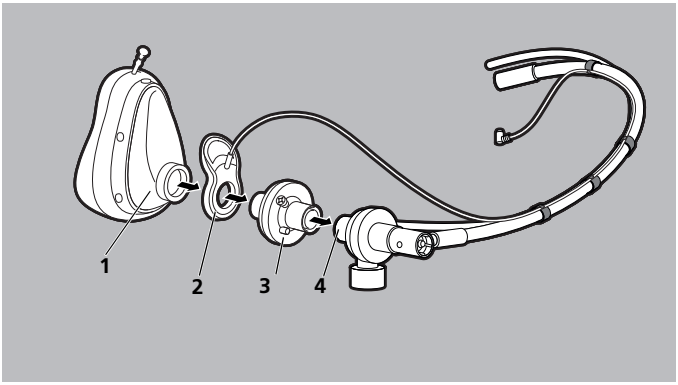
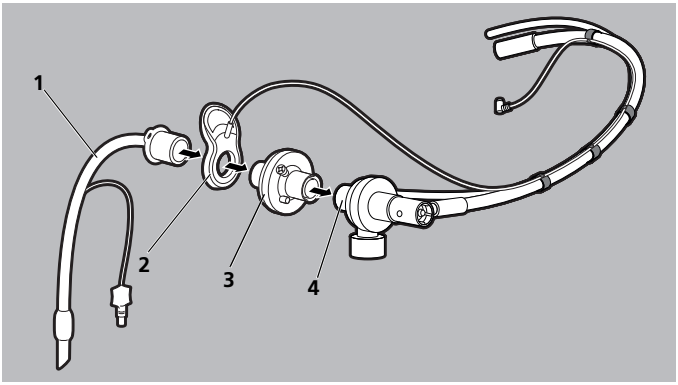


2. Connect the breathing system filter (**3**) to the patient connection of the patient valve (**4**).
3. Connect MEDUtrigger (**2**) to the breathing system filter (**3**).
4. Connect the ventilation mask (**1**) to MEDUtrigger (**2**).

Result The breathing system filter is ready for mask ventilation.

Connecting the breathing system filter for tube ventilation

1. Observe the instructions for use from the breathing system filter manufacturer.



2. Connect the breathing system filter (**3**) to the patient connection of the patient valve (**4**).

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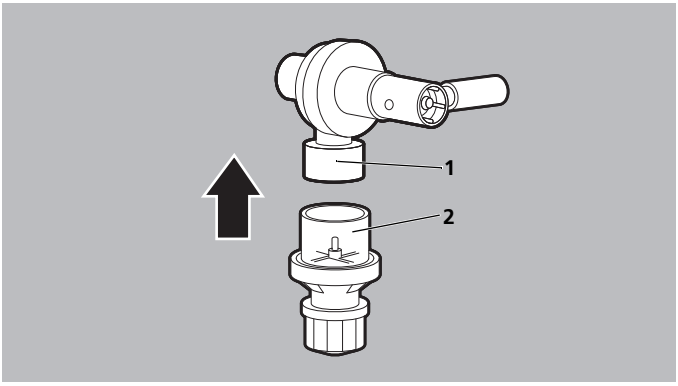
3. Connect MEDUtrigger (**2**) to the breathing system filter (**3**).
4. Following intubation, connect the tube (**1**) to the MEDUtrigger (**2**).

Result The breathing system filter is ready for tube ventilation.

6.1.3 Connecting the PEEP valve

1. Observe the instructions for use from the PEEP valve manufacturer.



2. Attach the PEEP valve (**2**) to the expiration side (**1**) of the patient valve.

Result The PEEP valve is attached.

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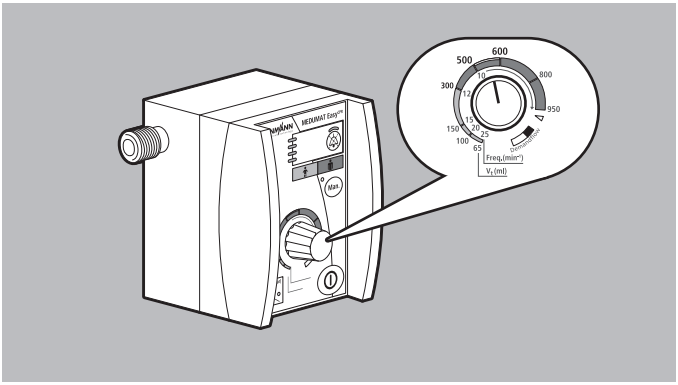
6.2 Setting the ventilation parameters

6.2.1 Setting the respiratory rate and tidal volume



1. Set the tidal volume V_t and associated respiratory rate. To do this, turn the adjusting knob for ventilation parameters.

Result The respiratory rate and tidal volume are set.

Assignment of the ventilation parameters

	Orange			Red				
Age (in years)	approx. 1-12			from approx. 13				
Body weight in kg (lbs)	10 (22)	15 (33)	20 (44)	45 (100)	75 (165)	90 (198)	120 (265)	140 (308)
Respiratory rate (breaths per minute)	25	20	15	12	10	10	10	10
Tidal volume (ml)	65	100	150	300	500	600	800	950

The values given in the table are recommendations. Please note that the values may deviate with pulmonary diseases or special indications.

The correlation between the ventilation parameters can be found in the section "Technical data" (see "13.5 Correlation between ventilation parameters", page 140).

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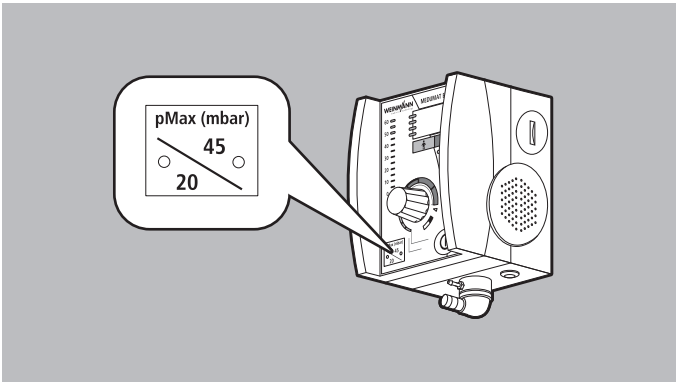
6.2.2 Setting the maximum ventilation pressure

Requirement The device is switched on (see "6.3 Switching the device on", page 72).



1. Set the ventilation pressure. To do this, press the pMax button with control LEDs.
   The associated LED displays the set maximum ventilation pressure.

Result The maximum ventilation pressure is set.

Recommendation for maximum ventilation pressure

Mask ventilation	Tube ventilation
20 mbar (20 cmH_2O)	45 mbar (45 cmH_2O)

If, for example, with reduced lung compliance the set maximum ventilation pressure is reached, the device emits the **pAW** ↑ alarm.

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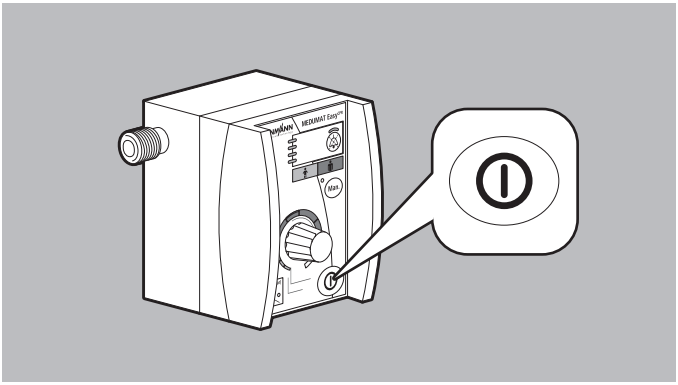
6.3 Switching the device on



1. Switch on the device using the On/Off button.
   Upon being switched on, the device performs an automatic self-test which takes approx. 2 seconds. During the self-test, all the LEDs in the alarm field flash and a brief audible alarm sounds.
2. ⚠ **WARNING! Risk of injury from using a defective device!**
   Do not operate the device in the following cases:
   - 4 alarm LEDs in the alarm field do not flash.
   - LEDs in the alarm field flash uninterruptedly and an alarm sounds.
   - Alarm **< 2.7 bar O_2** is active despite the oxygen cylinder being open.
   - Alarm [+ −] is active.

Result The device is switched on.

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6.4 Ventilating the patient

⚠ CAUTION

Impaired treatment due to increased breathing effort!
If the expiration side and/or the spontaneous respiration side is covered, the breathing effort required of the patient increases and impairs treatment. This can injure the patient.
⇒ Never cover the expiration side and spontaneous respiration side of the patient valve.

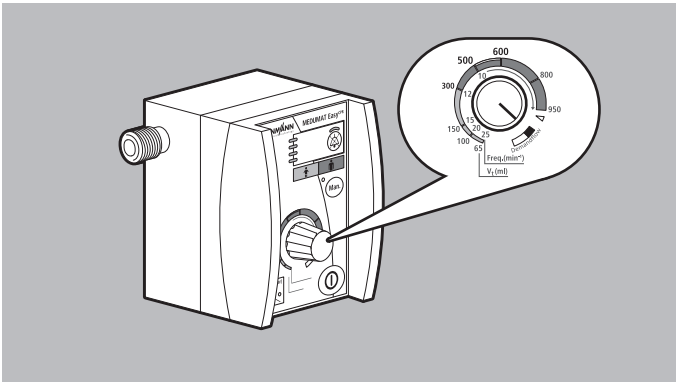
6.4.1 Ventilating the patient in demand flow mode

Switching on demand flow mode

Requirement The device is ready for use (see "6.1 Preparing for ventilation", page 64).

⚠ CAUTION

Impaired treatment due to reduced trigger performance in demand flow mode!
In demand flow mode, a PEEP valve can lead to reduced trigger performance and can impair treatment. This can injure the patient.
⇒ Do not use a PEEP valve in demand flow mode.



1. Switch on demand flow mode. To do this, turn the adjusting knob for ventilation parameters clockwise past the snap-in position.
   The green LED displays the operational status.
2. Switch on the device (see "6.3 Switching the device on", page 72).

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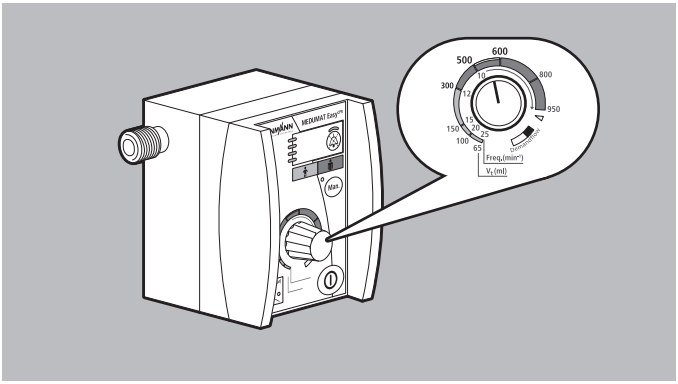
3. Place the ventilation mask on the mouth and nose. Hold the ventilation mask firmly in place.
   - With inspiration (triggering): Flow is switched on.
   - At the start of expiration: Flow stops and the expiration air is discharged via the patient valve.
4. Make sure that the patient breathes calmly and evenly.

If the device does not detect breathing within 20 seconds, the **pAW ↓ /Apnea** alarm is triggered.

Result The device is operated in demand flow mode.

Switching off demand flow mode

1. Switch off the device (see "6.6 Switching the device off", page 84).



2. Turn the adjusting knob for ventilation parameters past the snap-in position in a counterclockwise direction.

Result The demand flow mode is switched off.

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6.4.2 Ventilating the patient in manual mode (CPR mode)

⚠ CAUTION

Lack of treatment due to the attempt to trigger manual breaths in demand mode and continuous mode!
If the device is not in manual mode (CPR mode) and the MEDUtrigger is not connected, the device/user cannot manually trigger mechanical breaths. This can injure the patient.
⇒ For manual mechanical breaths, connect MEDUtrigger and switch to manual mode (CPR mode).

Switching on manual mode

Requirement

- The device is ready for use (see "6.1 Preparing for ventilation", page 64).
- MEDUtrigger is connected (see "4.6 Connecting the patient hose system and MEDUtrigger to the device", page 48).
- A tidal volume is set with the adjusting knob for the ventilation parameters (see "6.2.1 Setting the respiratory rate and tidal volume", page 70).
- The device is switched on (see "6.3 Switching the device on", page 72).
- Voice prompt is deactivated (see "6.7 Activating/deactivating the voice prompt", page 85).
- The metronome is deactivated (see "6.8 Activating/deactivating the metronome", page 87).

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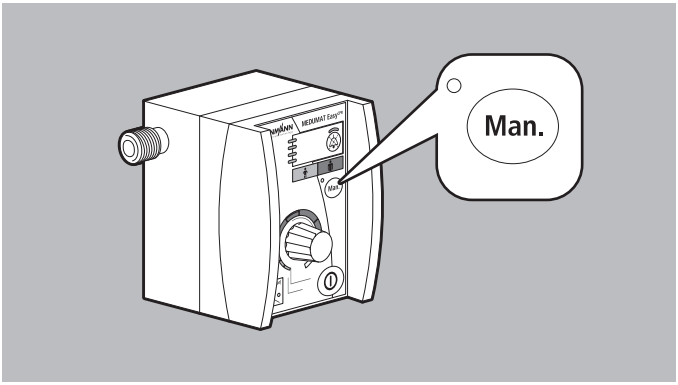

1. Press the Man. button.
   The LEDs on the Man. button and on the MEDUtrigger display the operational status.

   Upon activation of the manual mode, continuous ventilation with the set frequency stops.

If the button on the MEDUtrigger is pressed and the manual mode is not activated, an information tone sounds. This occurs, for example, if the Man. button or the button on the MEDUtrigger is pressed in demand flow mode.

2. If necessary: Place the ventilation mask on the mouth and nose. Hold the ventilation mask firmly in place.
3. Press the button on MEDUtrigger to ventilate the patient:
   - To trigger a single mechanical breath, press the button on the MEDUtrigger once.

   or

   - To trigger two mechanical breaths one after the other, press and hold the button on MEDUtrigger.

A new mechanical breath can only be triggered if the inspiration and expiration phase of the previous mechanical breath has already ended.
An information tone sounds if the inspiration and expiration phase has not yet ended.

Result The device is operated in manual mode.

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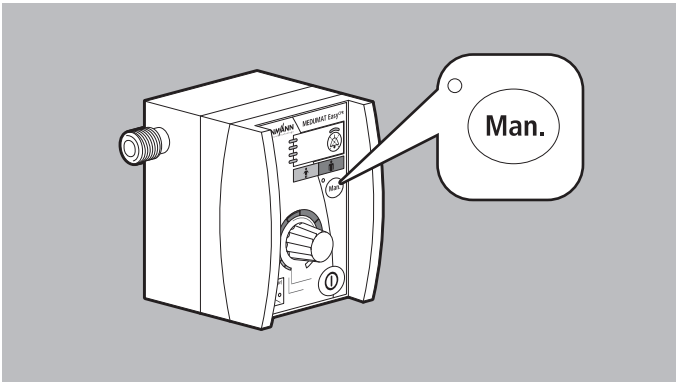
Switching off manual mode



1. Press the Man. button.
   The device continues to ventilate in continuous mode.

   or

2. Activate the demand flow mode (see "6.4.1 Ventilating the patient in demand flow mode", page 73)

   or

3. Switch off the device (see "6.6 Switching the device off", page 84).

Result The manual mode is switched off.

Switching on CPR mode

Requirement

- The device is ready for use (see "6.1 Preparing for ventilation", page 64).
- MEDUtrigger is connected (see "4.6 Connecting the patient hose system and MEDUtrigger to the device", page 48).
- A tidal volume is set with the adjusting knob for the ventilation parameters (see "6.2.1 Setting the respiratory rate and tidal volume", page 70).
- The device is switched on (see "6.3 Switching the device on", page 72).
- Voice prompt and/or the metronome is switched on (see "6.7 Activating/deactivating the voice prompt", page 85) and (see "6.8 Activating/deactivating the metronome", page 87).

⚠ CAUTION

Risk of limited treatment due to insufficient patient monitoring!
If the metronome is switched on, the audible alarms in CPR mode pause during the chest compression and voice prompt phases. In case of limited patient monitoring, this may compromise the treatment. This can injure the patient.
⇒ Monitor patients in CPR mode continuously.

⚠ CAUTION

Limited patient monitoring via deactivated voice prompt for the pAW ↑ and pAW ↓ /Apnea alarms in CPR mode!
Voice prompt is deactivated for the **pAW ↑** and **pAW ↓ /Apnea** alarms in CPR mode.
In case of limited patient monitoring, this may result in injuries to the patient.
⇒ Monitor patients in CPR mode continuously.

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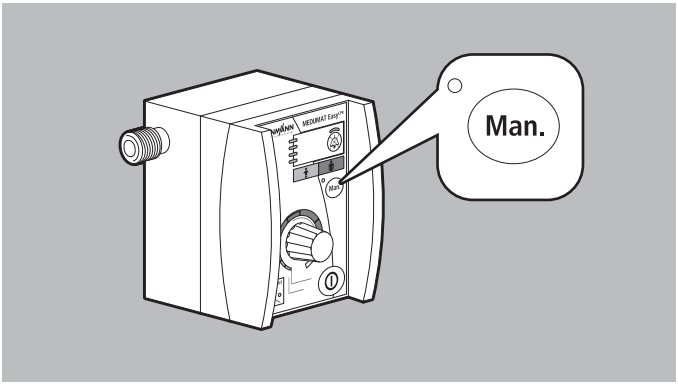

1. Press the Man. button.
   - The LEDs on the Man. button and on the MEDUtrigger display the operational status.
   - The continuous ventilation with the set rate stops.
   - The device outputs the message: *CPR mode switched on, manual triggering of ventilation*.

If the metronome is switched on, the device outputs the message:

Perform chest compressions now!

2. Perform 30 chest compressions.
   When doing so, note: The metronome sets the ideal frequency. The tone pitch increases with the metronome's last three strikes.

The device outputs the message:

Provide 2 ventilations now!

3. Trigger two mechanical breaths:

   Press and hold the button on the MEDUtrigger until two mechanical breaths have been triggered.

   or

   Press the button on the MEDUtrigger twice in a row.

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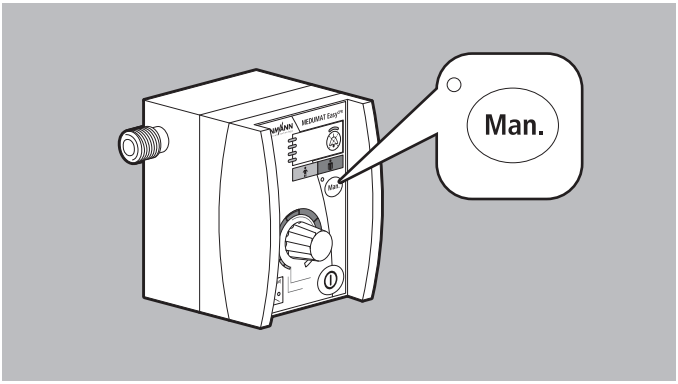
A new mechanical breath can only be triggered if the inspiration and expiration phase of the previous mechanical breath has already ended.
An information tone sounds if the inspiration and expiration phase has not yet ended.
If the button on the MEDUtrigger is pressed continuously, the device triggers an unlimited number of subsequent mechanical breaths.

4. Perform 30 chest compressions and two mechanical breaths in alternation.

The voice prompts and metronome are static. We recommend adjusting to the metronome and voice prompts.

Result The device is operated in CPR mode.

Switching off CPR mode



1. Press the Man. button.
   The device continues to ventilate in continuous mode.

   or

2. Activate the demand flow mode (see "6.4.1 Ventilating the patient in demand flow mode", page 73).

   or

3. Switch off the device (see "6.6 Switching the device off", page 84).

Result The CPR mode is switched off.

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6.4.3 Ventilating the patient in continuous mode

Switching on continuous mode

Requirement

- The device is ready for use (see "6.1 Preparing for ventilation", page 64).
- The device is switched off (see "6.6 Switching the device off", page 84).
- A tidal volume and frequency are set on the adjusting knob for ventilation parameters (see "6.2.1 Setting the respiratory rate and tidal volume", page 70).
- The patient is intubated.

1. Switch on the device using the On/Off button.

Result The device is operated in continuous mode.

Switching off continuous mode

1. Switch off the device (see "6.6 Switching the device off", page 84)

   or

2. Change to manual mode (see "6.4.2 Ventilating the patient in manual mode (CPR mode)", page 75)

   or

3. Change to demand flow mode (see "6.4.1 Ventilating the patient in demand flow mode", page 73).

Result The continuous mode is switched off.

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6.4.4 Monitoring the patient

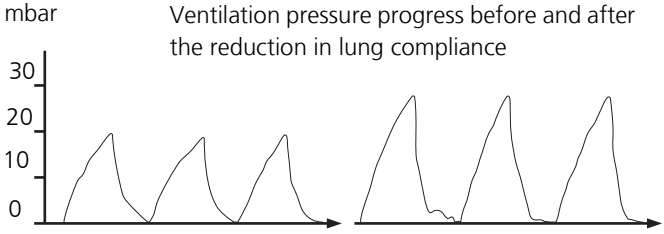
⚠ WARNING

Risk of incorrect treatment due to insufficient patient monitoring!
If the patient and device are not supervised and monitored during ventilation, delayed responses of medical personnel to alarms and error messages may result in serious or life-threatening injuries to the patient and to incorrect treatment.
⇒ The patient and device must be kept under continuous observation and monitoring during ventilation.
⇒ Use additional external monitoring during ventilation (e.g., SpO_2 or $etCO_2$).

1. Check the ventilation pressure. To do this, read off the ventilation pressure on the ventilation pressure display.
2. Check the ventilation parameters.
3. Check the cause of the emitted alarms (see "9 Alarms and error messages", page 118).

i High air resistances, e.g., due to obstructions of the airways or during external chest compression, change the set tidal volume.

With reduced lung compliance, the device reacts as per the diagram shown below by way of example, with an increase in the ventilation pressure whilst the ventilation volume remains constant.



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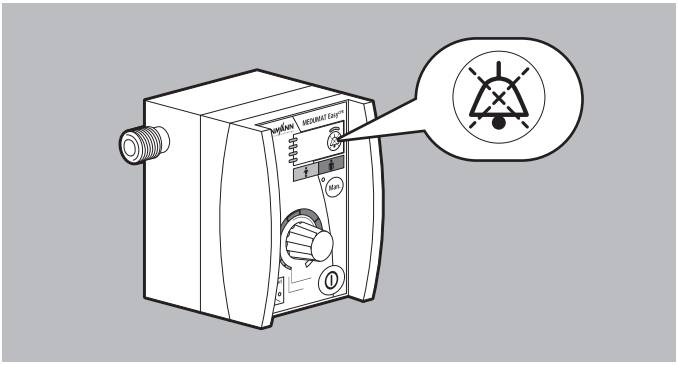
6.5 Muting alarms

6.5.1 Activating alarm mute function

When an alarm is emitted, you can suppress the alarm tone for a maximum of 120 seconds. The exception to this is the supply pressure alarm **< 2.7 bar O_2**. The supply pressure alarm can *not* be muted.
If the cause of the alarm continues to exist after 120 seconds, a new alarm is emitted.
If the error is remedied, the visual and audible alarms are automatically reset.
Alarm muting also applies to new alarms which are emitted within these 120 seconds. The visual alarm is always active when in muted state.

Requirement

- The device is switched on.
- An alarm is triggered.



1. Press the alarm mute button.

Result

- The audible alarm is deactivated for 120 seconds.
- The orange LED above the alarm mute button lights up.

6.5.2 Deactivating alarm mute function

Requirement

- The audible alarm is activated (see "6.5.1 Activating alarm mute function", page 83).
- The orange LED above the alarm mute button lights up.

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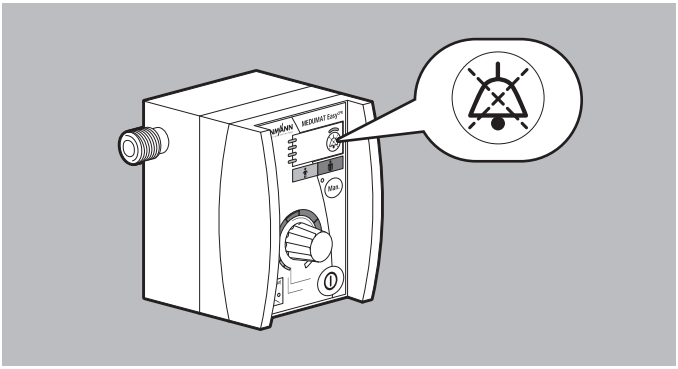
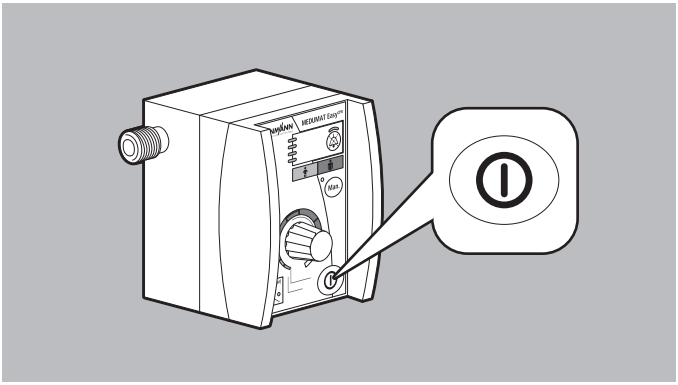


1. Press the alarm mute button.

Result
- The alarm mute function is deactivated.
- The orange LED goes out.

6.6 Switching the device off

Requirement The device is switched on.



1. Press and hold the On/Off button for approx. 3 seconds until all 4 alarm LEDs light up.
2. Release the On/Off button.
3. Close the oxygen cylinder.

Result The device is switched off.

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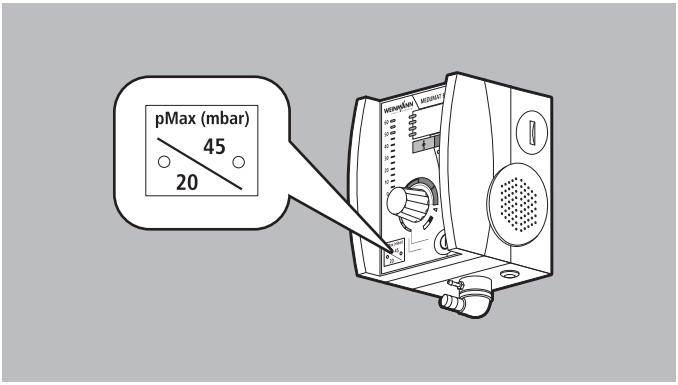
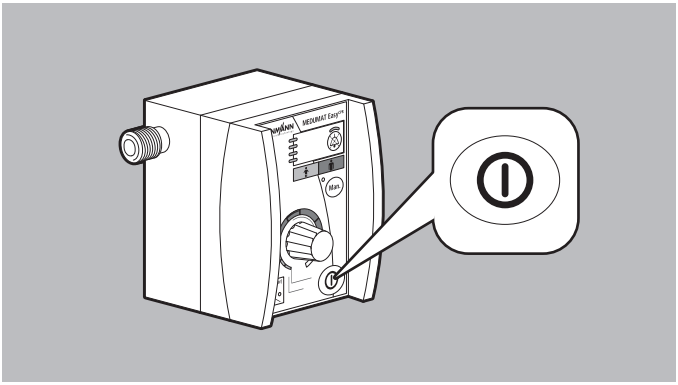
6.7 Activating/deactivating the voice prompt

Requirement The device is switched off.



1. Press and hold the pMax button with control LEDs continuously.



2. Press the On/Off button until the following LEDs light up: Alarm mute, Man., Demand flow.
3. Release the pMax button with control LEDs.
   The device is now in the language selection menu. The ventilation pressure display shows the last selected language setting.

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4. To change the language setting: press the pMax button with control LEDs repeatedly until the LED for the required language lights up. A corresponding voice prompt in the selected language is output.

   The languages are assigned to the individual LEDs as per the following table.

Device no.	**mbar**	**Language level 1**	**Language level 2 (Alarm LEDs pAW ↑ and pAW ↓ / Apnea light up)**
WM 20300	60	Farsi	Not assigned
	55	Thai	
	50	Indonesian	
	45	Turkish	
	40	Arabic	Hebrew
	35	Japanese	Brazilian Portuguese
	30	Chinese	Spanish
	25	Czech	Dutch
	20	Russian	Italian
	15	Polish	French
	10	English	Hindi
	5	German	Korean
	0	Voice prompt switched off	Voice prompt switched off

Depending on the firmware version, additional languages may be available.

If the 60 mbar LED on the ventilation pressure display is reached, a new cycle begins in level 2. This is indicated by the **pAW ↑** and **pAW ↓ /Apnea** alarm LEDs. Once the last language in level 2 is reached, a new cycle begins at 0 mbar in level 1 and the **pAW ↑** and **pAW ↓ /Apnea** alarm LEDs go out.

5. To save the language setting:

   Wait 5 seconds.

   or

   Press the On/Off button briefly.

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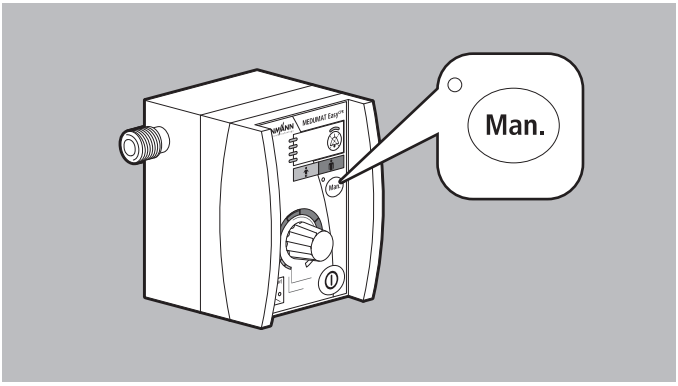
6. To switch off the voice prompt: Select the 0 mbar LED.
   The device outputs the message *Audio response is off!* in the last language selected.

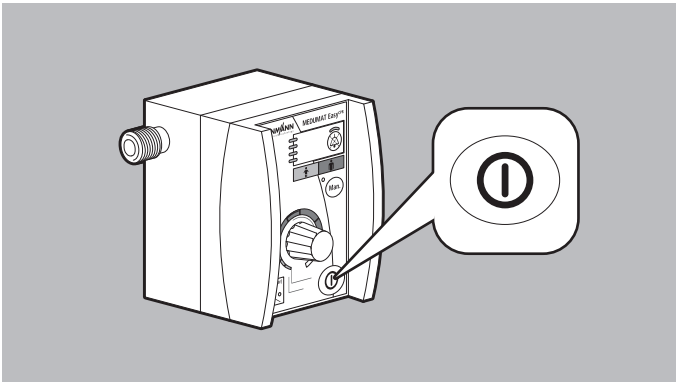
Result Voice prompt is activated or deactivated.

6.8 Activating/deactivating the metronome

Requirement The device is switched off.



1. Hold and press the Man. button continuously.



2. Press the On/Off button briefly.

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3. If the 45 mbar or 50 mbar LED lights up on the ventilation pressure display: Release the Man. button.
   The device displays the metronome's operating status.
   - 50 mbar LED lights up red: Metronome is deactivated.
   - 45 mbar LED lights up green: Metronome is activated.
4. To change the metronome's operating status: Press the Man. button.
5. To confirm the metronome's operating status: Press the On/Off button.
   A confirmation sounds:
   - If the confirmation sounds once: Deactivated metronome is confirmed.
   - If the confirmation sounds twice: Activated metronome is confirmed.

Result The metronome is activated or deactivated.

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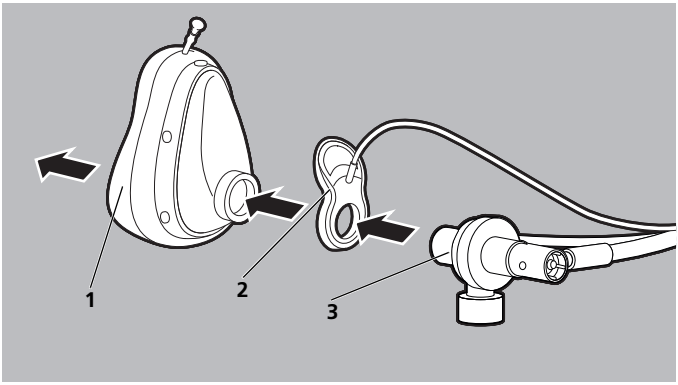
7 Disassembly

7.1 Disassembling the ventilation mask and tube

NOTICE

Damage to the hose system or MEDUtrigger as a result of incorrect handling!
Carelessly grasping and pulling off the patient hose system at the wrong point can result in damage to the system.
⇒ Always grasp hose systems at the end and pull off in a straight line.
⇒ Pull off MEDUtrigger in a straight line without twisting.

Disassembling the ventilation mask and MEDUtrigger



1. Pull the ventilation mask (**1**) and MEDUtrigger (**2**) off the patient valve (**3**).

   or

   Pull the ventilation mask (**1**) and MEDUtrigger (**2**) off the breathing system filter (not shown in image).

Result The ventilation mask and the MEDUtrigger are disassembled.

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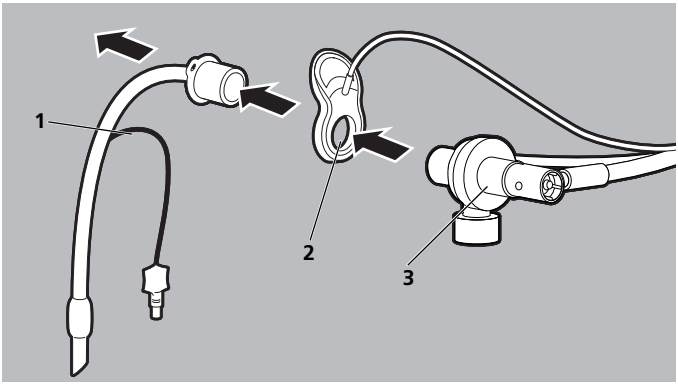
Disassembling the tube and MEDUtrigger



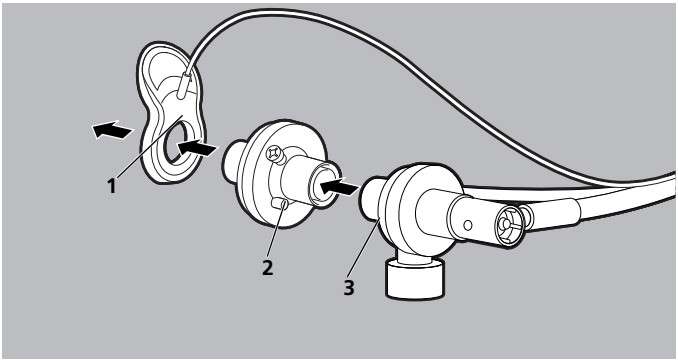
1. Pull the tube (**1**) and MEDUtrigger (**2**) off the patient valve (**3**).

Result The tube and the MEDUtrigger are disassembled.

7.2 Disassembling the breathing system filter

Requirement The ventilation mask or tube is disassembled (see "7.1 Disassembling the ventilation mask and tube", page 89).

1. Observe the instructions for use from the breathing system filter manufacturer.



2. Pull the MEDUtrigger (**1**) and breathing system filter (**2**) off the patient valve (**3**).

Result The breathing system filter is disassembled.

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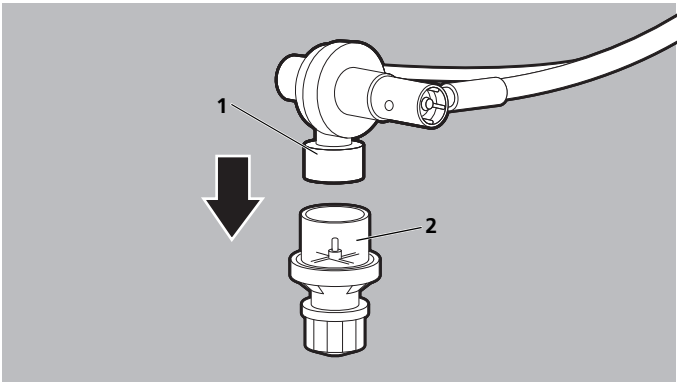
7.3 Disassembling the PEEP valve



1. Pull off the PEEP valve (**2**) from the expiration side (**1**) of the patient valve.

Result The PEEP valve is disassembled.

7.4 Disconnecting the patient hose system and MEDUtrigger from the device

Requirement

- The ventilation mask or tube and MEDUtrigger are disassembled (see "7.1 Disassembling the ventilation mask and tube", page 89).
- The breathing system filter is disassembled (see "7.2 Disassembling the breathing system filter", page 90).
- The PEEP valve is disassembled (see "7.3 Disassembling the PEEP valve", page 91).

NOTICE

Damage to the hose system or MEDUtrigger as a result of incorrect handling!

Carelessly grasping and pulling off the patient hose system at the wrong point can result in damage to the system.

⇒ Always grasp hose systems at the end and pull off in a straight line.

⇒ Pull off MEDUtrigger in a straight line without twisting.

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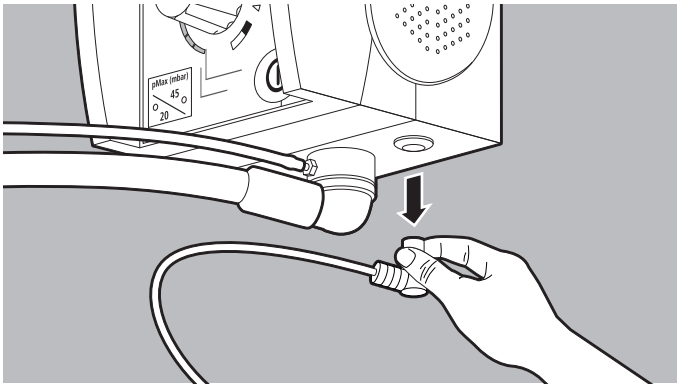
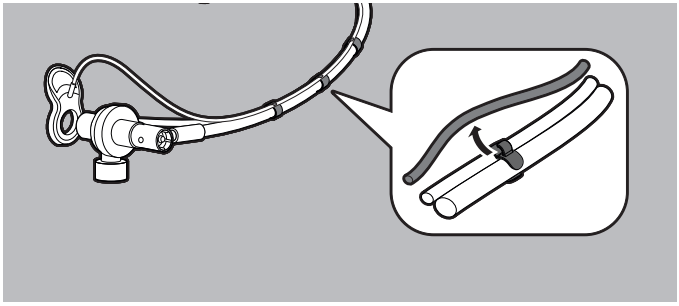


1. **NOTICE! Material damage caused by twisting the MEDUtrigger connector back and forth!**
   Pull the MEDUtrigger connector out of the MEDUtrigger connection. To do this, grasp the grooved part of the connector and pull it straight out of the socket without turning.



2. With the disposable hose system: Disconnect the MEDUtrigger cable from the patient hose system. To do this, release the MEDUtrigger cable from the clips.

   or

   With the reusable hose system: Remove the MEDUtrigger cable from the hose protection sleeve.

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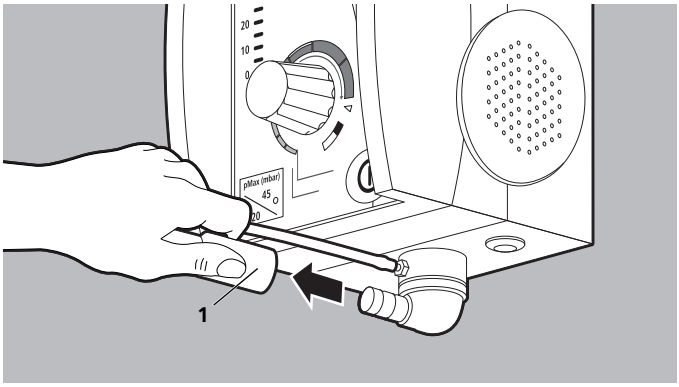
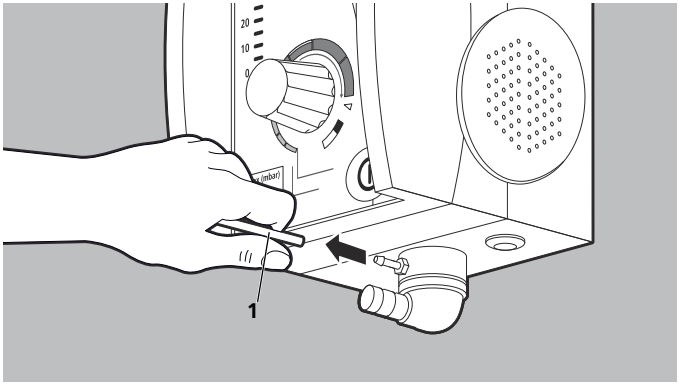


3. **NOTICE! Material damage from pulling out the tubes incorrectly!**
   Grasp the end of the ventilation hose (**1**) and pull out of the ventilation hose connection on the device.



4. **NOTICE! Material damage from pulling out the tubes incorrectly!**
   Grasp the end of the pressure measuring tube (**1**) and pull out of the pressure measuring tube connection on the device.

Result The patient hose system and MEDUtrigger are disconnected.

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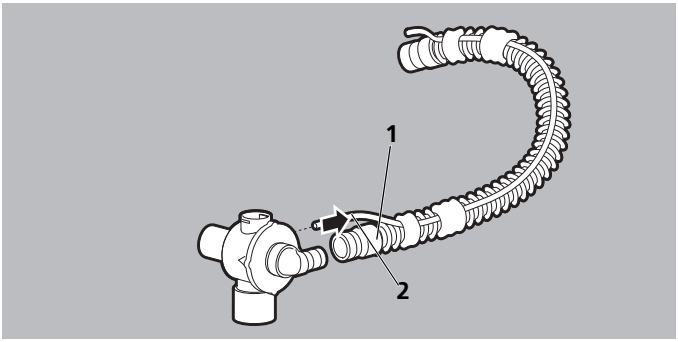
7.5 Disassembly of the reusable hose system

Requirement The patient hose system and MEDUtrigger are disconnected from the device (see "7.4 Disconnecting the patient hose system and MEDUtrigger from the device", page 91).

1. If necessary: Remove the hose protection sleeve from the reusable hose system.



2. **NOTICE! Material damage from pulling out the tubes incorrectly!**
   Remove the reusable ventilation hose (**1**) and pressure measuring tube (**2**) from the reusable patient valve. Grasp the hoses by their ends when pulling off.

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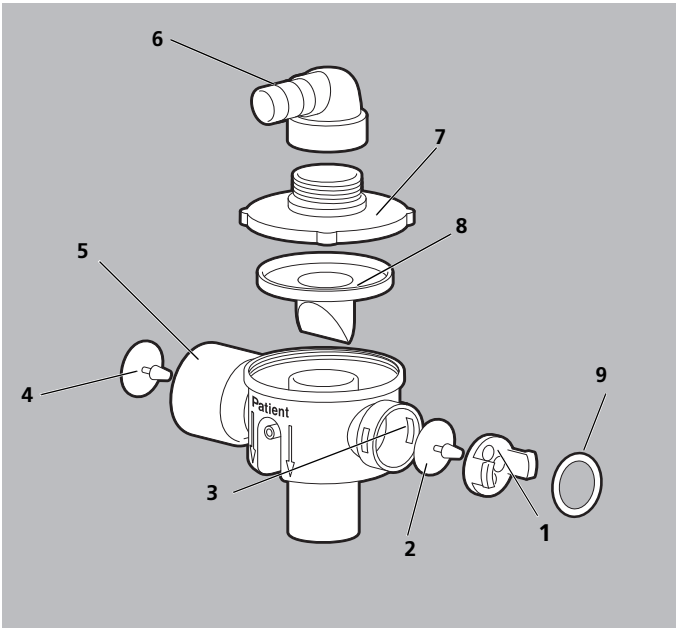

3. Disassembling the reusable patient valve:

   - Remove the spontaneous respiration insert (**1**) from the spontaneous respiration side (**3**) of the reusable patient valve.
     To do so, push both locking tabs out of the mount using a small slot-head screwdriver.
   - Remove the O-ring (**9**) from the spontaneous respiration insert (**1**).
   - Remove the disk diaphragm/emergency air membrane (**2**) from the spontaneous respiration side (**3**) of the reusable patient valve with pointed pliers.
   - Remove the disk diaphragm (**4**) from the expiration side (**5**) of the reusable patient valve with pointed pliers.
   - Unscrew the connection for ventilation hose (**6**) from the reusable patient valve lid (**7**) in a counterclockwise direction.
   - Unscrew the reusable patient valve lid (**7**) in a counterclockwise direction.

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- Remove the lip membrane (**8**).

Result The reusable hose system is disassembled.

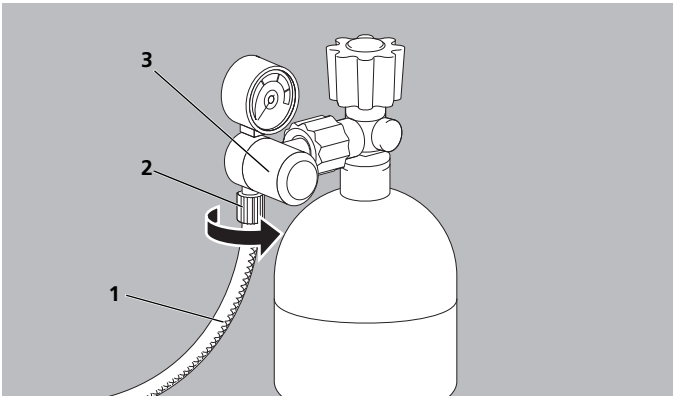
7.6 Removing the oxygen supply

Requirement

- The device is switched off (see "6.6 Switching the device off", page 84).
- The oxygen supply is closed.

1. **NOTICE! Material damage due to the disconnection of a non-ventilated system!**
   Switch on the device using the On/Off button.

   The remaining oxygen can escape and the device is depressurized. The compressed gas hose can only be disconnected without tools if the contents gauge indicates **0 bar (0 psi)** on the pressure reducer.
2. Switch off the device using the On/Off button. To do this, keep the On/Off button depressed until all 4 alarm LEDs light up. Then release the On/Off button.



3. **NOTICE! Material damage due to the use of a tool!**
   Disconnect the compressed gas tube (**1**) from the pressure reducer (**3**) or the central gas supply by hand using the union nut (**2**) or the quick-release coupling. To do this, turn the knurled union nut (**2**) counterclockwise.

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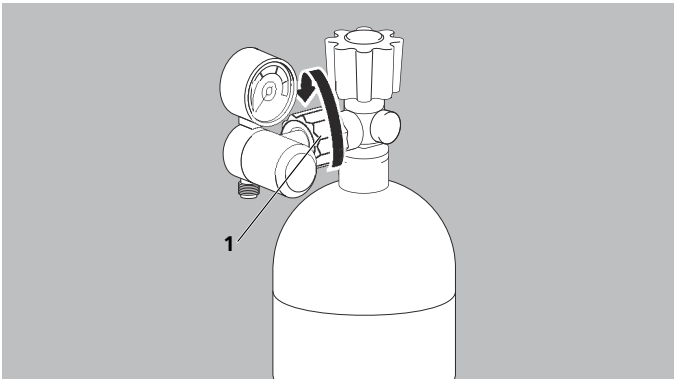

4. Remove the pressure reducer from the cylinder valve on the oxygen cylinder using the knurled union nut (**1**). To do so, turn the union nut counterclockwise.

Result The oxygen supply is removed.

7.7 Disconnecting the mounting plate and fastening strap from the device

Requirement

- The mounting plate and fastening strap are secured to the device(see "4.3 Securing the mounting plate with fastening strap to the device", page 41).
- The device is switched off (see "6.6 Switching the device off", page 84).

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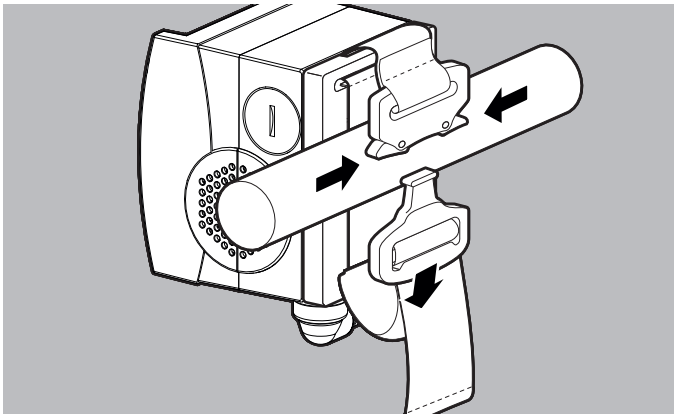
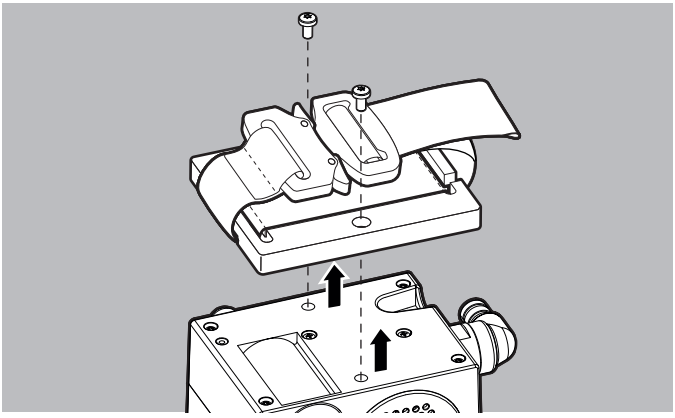


1. Hold the device securely and open the safety lock on the fastening strap. To do so, actuate both side levers at the same time and disconnect the buckles.



2. Remove the mounting plate. To do this, turn the screws counterclockwise out of the device.

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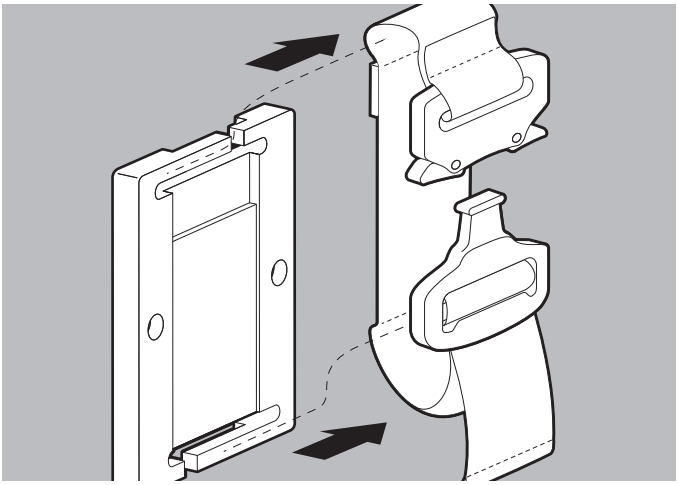

3. Remove the ends of the fastening strap from the depressions on the mounting plate.

Result The mounting plate and fastening strap are removed.

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8 Cleaning and disinfection

The following sections describe the activities required for cleaning and disinfection.

If you have any queries on cleaning and disinfection, please contact our Customer Service (see "1.2 Customer Service", page 6).

8.1 Intervals

Perform cleaning and disinfection at the following intervals.

Part	Interval	
	After each use	**At least 1x weekly**
Basic device including all accessories	x	x

8.2 Cleaning and disinfection plan

Perform cleaning and disinfection after **every** use as per the table below. When doing so, please observe the **following** section. It describes the requisite steps for the reprocessing in detail.

For reliable reprocessing, perform the cleaning, disinfection, and (optional) sterilization steps one after another.

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Part	Manual cleaning	Wipe disinfection	Immersion disinfection	Machine cleaning and disinfection	Steam sterilization
Device Mounting plate Compressed gas tube	Wipe-down cleaning with neodisher® MediClean forte (Dr. Weigert) Dosage: 10 ml/l, Duration: treat all surfaces at least twice until visibly clean	Wipe down with Incidin™ OxyWipes S (Ecolab) Exposure time: 5 min.	Not permitted	Not permitted	Not permitted
MEDUtrigger	or CIDEZYME® Enzymatic Detergent Solution (Johnson& Johnson) Dosage: 16 ml/l Duration: for at least 3 min. until all surfaces are visibly clean	or Super Sani-Cloth® Disposable Wipes (PDI Healthcare) Exposure time: 2 min.			

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Part	Manual cleaning	Wipe disinfection	Immersion disinfection	Machine cleaning and disinfection	Steam sterilization
Fastening strap with buckle	Immerse in neodisher® MediClean forte (Dr. Weigert) Dosage: 10 ml/l, Duration: for at least 10 min. until all surfaces are visibly clean or CIDEZYME® Enzymatic Detergent Solution (Johnson& Johnson) Dosage: 16 ml/l Duration: for at least 3 min. until all surfaces are visibly clean	Not permitted	Immerse in gigasept® FF neu (Schülke) Dosage: 5 ml/l Exposure time: 15 min. or cidex® OPA (Johnson& Johnson) Dosage: undiluted Exposure time: 5 min.	Not permitted	Not permitted

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Part	Manual cleaning	Wipe disinfection	Immersion disinfection	Machine cleaning and disinfection	Steam sterilization
Reusable ventilation hose with patient valve and reusable pressure hose	Immerse in neodisher® MediClean forte (Dr. Weigert) Dosage: 10 ml/l Duration: for at least 10 min. until all surfaces are visibly clean	Not permitted	Immerse in gigasept® FF neu (Schülke) Dosage: 5 ml/l Exposure time: 15 min.	Cleaning: neodisher® MediClean forte (Dr. Weigert): 0.5%, 55°C, 10 min. thermal disinfection: 90°C, 5 min. (corresponding to A0 value 3000)	Optionally permissible: steam sterilization* **following disinfection:** 5 min. at 134°C or 4 min. at 132°C
Hose protection sleeve	Not permitted	Not permitted	Not permitted	Washing at 60°C in industrial washing machine with cleaning agent: Derval SOLO (RKI) (Kreussler) Dosage: 2 ml/l and Disinfectant: Ottalin PERACET (Kreussler) Dosage: 2 ml/l Exposure time: 10 min., type AB	Not permitted
Single-patient hose with single-patient valve and single-patient pressure tube	Disposable item, do not reuse. Dispose of correctly (see 11.3, p. 131).				

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Part	Manual cleaning	Wipe disinfection	Immersion disinfection	Machine cleaning and disinfection	Steam sterilization
Accessories manufactured by third parties (PEEP valve, breathing system filter, hose)	Note the manufacturer's instructions on cleaning and disinfection.				

* It is not possible to guarantee the sterility of the internal lumen of the pressure measuring tube due to the design of the product.

8.3 Performing cleaning and disinfection

⚠ WARNING

Risk of explosion due to ingress of liquids in combination with oxygen!

The ingress of liquids can result in explosion and cause serious or life-threatening injuries to the patient, user or bystanders.

⇒ Never immerse fittings, e.g., pressure reducers, valves and compressed gas tubes in disinfectant or other liquids.

⇒ Do not remove the compressed gas tube from the compressed gas connection to ensure that **no** liquids enter the device.

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⚠ CAUTION

Risk of injury and material damage due to disinfectant or cleaning agent residues in the device or hose system!

Disinfectant or cleaning agent residues can get into the patient's lung. This can injure the patient and cause material damage to the device.

⇒ Never immerse the device in disinfectant or other liquids.
⇒ Only use accessories approved for immersion disinfection.
⇒ Turn the connection for the ventilation hose downwards during cleaning and disinfection so that no liquids can get into the device.
⇒ Keep the battery compartment closed during cleaning so that no liquids can get into the device.
⇒ Do not remove the compressed gas tube from the compressed gas connection so that no liquids can get into the device.
⇒ All parts of the hose system must be rinsed thoroughly with water and allowed to dry completely following the cleaning and disinfection.
⇒ Following cleaning and disinfection, visually inspect the device and hose system for any cleaning agent residue and remove any residue if necessary.
⇒ Perform a full function check after every cleaning and disinfection.

NOTICE

Material damage due to the ingress of liquids!

The device is protected against the ingress of water. This only applies when the battery compartment is closed. The ingress of liquids may cause damage to the device and accessories.

⇒ Do not immerse the device in liquids.
⇒ Only use accessories approved for immersion disinfection.
⇒ Only clean the battery compartment with a dry cloth to avoid liquids entering the device.

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8.3.1 Preparing cleaning and disinfection

⚠ CAUTION

Risk of infection due to inadequate hygienic safety!
Adequate cleaning and disinfection is not guaranteed if the mounting plate with fastening strap is not removed and the belt around the buckle is not slackened prior to the cleaning and disinfection. If contaminated surfaces come into contact with the skin of the patient or user, this can lead to infections. This can result in injury to the patient or user.
⇒ Remove the mounting plate and fastening strap from the device before cleaning and disinfection.
⇒ Slacken the buckle on the fastening strap.

Requirement

- The device is switched off (see "6.6 Switching the device off", page 84).
- The accessories are removed (see "7 Disassembly", page 89).
- The compressed gas tube is assembled on the device.

1. **⚠ Warning! Risk of injury and damage to the device caused by ingress of liquids!**
   Do **not** remove the compressed gas hose from the compressed gas connection.
2. **⚠ CAUTION! Risk of injury and damage to the device caused by ingress of liquids!**
   Turn the connection for ventilation hose downward.

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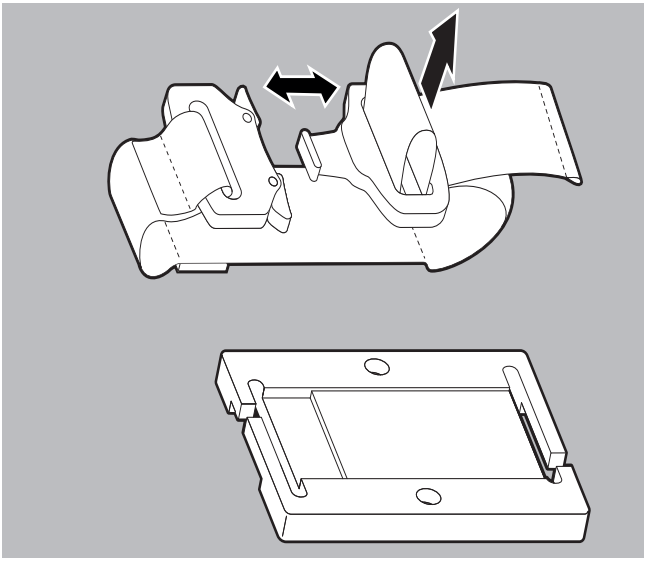

3. ⚠ **CAUTION! Risk of injury and damage to the device as a result of unsatisfactory hygienic reliability!**
   Detach the fastening strap from the mounting plate (see "7.7 Disconnecting the mounting plate and fastening strap from the device", page 97).
4. Open the buckle on the fastening strap.
5. Slacken the buckle on the fastening strap.
6. Dispose of all disposable articles correctly (see "11.3 Disposal", page 131).

Result All parts are prepared for cleaning.

8.3.2 Cleaning parts manually

Requirement

- The parts intended for manual cleaning are visibly contaminated.
- The cleaning and disinfection is prepared (see "8.3.1 Preparing cleaning and disinfection", page 106).

1. The parts approved for manual cleaning can be found in the cleaning and disinfection plan (see "8.2 Cleaning and disinfection plan", page 100).

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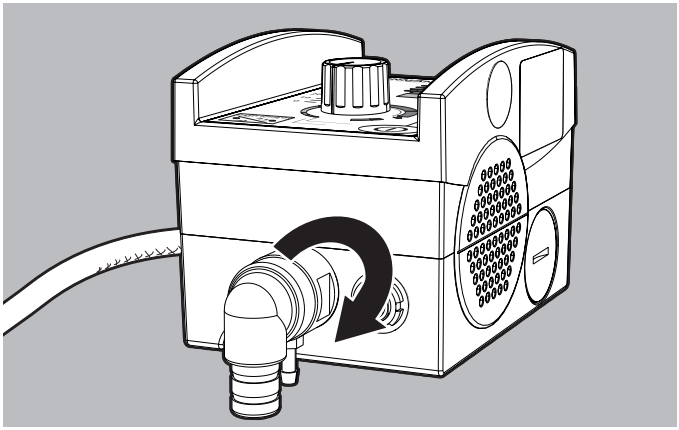
2. The cleaning agents, doses, and exposure time for the individual parts can be found in the cleaning and disinfection plan (see "8.2 Cleaning and disinfection plan", page 100).
3. Prepare the cleaning solution in accordance with the specifications of the cleaning agent manufacturer.
4. ⚠ **Warning! Risk of injury and damage to the device caused by ingress of liquids!**
   Do **not** remove the compressed gas hose from the compressed gas connection.



5. ⚠ **CAUTION! Risk of injury and damage to the device caused by ingress of liquids!**
   Turn the connection for ventilation hose downward.
6. To remove all visible soiling: Thoroughly brush down parts on the inside and outside using a standard soft lumen brush or other brush that is suitable for use on plastics and that has been wetted with the cleaning agent.
   When doing so, note: Keep uneven surfaces and grooves (e.g., belt buckle and complete belt surfaces, top and bottom of MEDUtrigger, adjusting knob, connection for ventilation hose) moist for the duration of the posure time and brush them off particularly thoroughly.
7. If the parts need to be wiped down acc. to the cleaning and disinfection plan: Wipe parts down with a clean, lint-free cloth that has been moistened with cleaning solution.
   When doing so, note:

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- Use a new cloth for each cleaning procedure.
- All surfaces must be wiped down carefully.
- All surfaces must be wetted with cleaning solution.
- Ensure compliance with the exposure time specified in the cleaning and disinfection plan.
- Rewipe uneven surfaces and grooves in particular (e.g., top and bottom of MEDUtrigger, adjusting knob, connection for ventilation hose).

8. If the parts need to be immersed acc. to the cleaning and disinfection plan: Immerse parts in the cleaning solution. When doing so, note:
   - ⚠ **CAUTION! Risk of injury and damage to the device as a result of unsatisfactory hygienic reliability!** The fastening strap must be detached from the mounting plate (see "7.7 Disconnecting the mounting plate and fastening strap from the device", page 97).
   - Open and close the fastening strap buckle repeatedly in the immersion disinfection solution.
   - The fastening strap buckle must be opened.
   - The fastening strap around the buckle must be slackened.
   - Swirl the parts in the cleaning solution to coat all surfaces and any cavities completely.
   - Ensure compliance with the exposure time specified in the cleaning and disinfection plan.
9. If visible soiling remains: Repeat the manual cleaning.
10. ⚠ **CAUTION! Risk of injury due to disinfectant or cleaning agent residues in the device or hose system!** Rinse parts that have been immersed in the cleaning solution thoroughly with water of drinking-water quality.
11. Wipe down the remaining parts with a damp cloth in order to remove cleaning agent residue.
12. Wipe MEDUtrigger with a dry cloth.

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13. ⚠ **CAUTION! Risk of injury due to disinfectant or cleaning agent residues in the device or hose system!** Allow all parts to dry fully at room temperature.

Result The parts are manually cleaned.

Cleaning the pressure measuring tube manually

Requirement The pressure measuring tube is disconnected from the patient valve and device (see "7.4 Disconnecting the patient hose system and MEDUtrigger from the device", page 91) and (see "7.5 Disassembly of the reusable hose system", page 94).

1. The cleaning agents, doses, and exposure time can be found in the cleaning and disinfection plan (see "8.2 Cleaning and disinfection plan", page 100).
2. Prepare the cleaning solution in accordance with the specifications of the cleaning agent manufacturer.
3. Connect a sterile disposable syringe (20 ml) to a free end of the pressure measuring tube.
4. Draw the cleaning solution up through the pressure measuring tube into the disposable syringe by means of suction until both are completely full.
5. Disconnect the disposable syringe from the pressure measuring tube.
6. Immerse the pressure measuring tube in cleaning solution. When doing so, note:
   - All surfaces and lumens must be completely wetted.
   - Ensure compliance with the exposure time specified in the cleaning and disinfection plan.
7. Rinse the pressure measuring tube with drinking-water quality from outside.
8. ⚠ **CAUTION! Risk of injury due to disinfectant or cleaning agent residues in the device or hose system!** Rinse the pressure measuring tube with drinking-water quality from inside at least eight times with a disposable syringe. When doing so, note: Only rinse in one direction.

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9. ⚠ **CAUTION! Risk of injury due to disinfectant or cleaning agent residues in the device or hose system!**
   Allow the pressure measuring tube to dry fully.
10. If necessary: Allow the ventilation hose to dry fully.
11. Check the pressure measuring tube for residue and any remaining soiling.
12. If visible soiling remains: Repeat the manual cleaning.

Result The pressure measuring tube is cleaned manually.

8.3.3 Wipe disinfecting parts

Requirement

- The parts intended for wipe disinfection have been manually cleaned (see "8.3.2 Cleaning parts manually", page 107).

1. The parts approved for wipe disinfection can be found in the cleaning and disinfection plan (see "8.2 Cleaning and disinfection plan", page 100).
2. The disinfectants, doses, and exposure time for the individual parts can be found in the cleaning and disinfection plan (see "8.2 Cleaning and disinfection plan", page 100).
3. ⚠ **Warning! Risk of injury and damage to the device caused by ingress of liquids!**
   Do **not** remove the compressed gas hose from the compressed gas connection.
4. ⚠ **CAUTION! Risk of injury and damage to the device caused by ingress of liquids!**
   Turn the connection for the ventilation hose downward.
5. Wipe-disinfect the parts with one of the agents listed (see "8.2 Cleaning and disinfection plan", page 100).
   When doing so, note:

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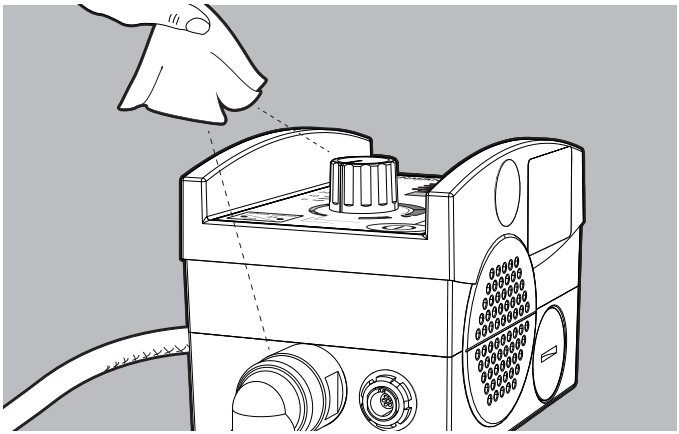

- Wet any uneven surfaces and grooves (e.g., adjusting knob, connection for ventilation hose) sufficiently with the disinfectant.
- Ensure compliance with the exposure time specified in the cleaning and disinfection plan.

6. ⚠ **CAUTION! Risk of injury due to disinfectant or cleaning agent residues in the device or hose system!** Allow the parts to dry fully.
7. Check the parts for residue and any remaining soiling.
8. If visible soiling remains: Repeat the cleaning and wipe disinfection procedure.

Depending on the disinfectant, rewiping with a neutralizing agent may be necessary.

Result The parts are wipe disinfected.

8.3.4 Immersion disinfecting parts

Requirement

- The parts intended for immersion disinfection have been manually cleaned (see "8.3.2 Cleaning parts manually", page 107).

1. The parts approved for immersion disinfection can be found in the cleaning and disinfection plan (see "8.2 Cleaning and disinfection plan", page 100).

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2. The disinfectants, doses, and exposure time for the individual parts can be found in the cleaning and disinfection plan (see "8.2 Cleaning and disinfection plan", page 100).
3. Prepare the immersion disinfection solution in accordance with the specifications of the disinfectant agent manufacturer.
4. Immerse the parts in the immersion disinfection solution. When doing so, note:
   - ⚠ **CAUTION! Risk of injury and damage to the device as a result of unsatisfactory hygienic reliability!** The fastening strap must be detached from the mounting plate (see "7.7 Disconnecting the mounting plate and fastening strap from the device", page 97).
   - Open and close the fastening strap buckle repeatedly in the immersion disinfection solution.
   - The fastening strap buckle must be opened.
   - The fastening strap around the buckle must be slackened.
   - All cavities must be filled.
   - There must not be any air bubbles.
   - All surfaces must be wetted.
   - Swirl the parts in the immersion disinfection solution to coat all surfaces and any cavities completely.
   - Ensure compliance with the exposure time specified in the cleaning and disinfection plan.
5. ⚠ **CAUTION! Risk of injury due to disinfectant or cleaning agent residues in the device or hose system!** After the specified exposure time, rinse the parts in water of drinking-water quality for 5 minutes in order to remove all of the disinfectant residue.
6. ⚠ **CAUTION! Risk of injury due to disinfectant or cleaning agent residues in the device or hose system!** Allow the parts to dry fully.
7. Check the parts for residue and any remaining soiling.
8. If soiling is visible: Repeat the cleaning and disinfection.

Result The parts are immersion disinfected.

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Immersion disinfecting the pressure measuring tube

Requirement The pressure measuring tube is cleaned manually.

1. The disinfectants, doses, and exposure time can be found in the cleaning and disinfection plan (see "8.2 Cleaning and disinfection plan", page 100).
2. Prepare the immersion disinfection solution in accordance with the specifications of the disinfectant agent manufacturer.
3. Connect a sterile disposable syringe (20 ml) to a free end of the pressure measuring tube.
4. Draw the disinfectant solution up through the pressure measuring tube into the disposable syringe by means of suction until both are completely full.
5. Disconnect the disposable syringe from the pressure measuring tube.
6. Immerse the pressure measuring tube in the immersion disinfection solution.
   When doing so, note:
   - All surfaces and lumens must be completely wetted.
   - Ensure compliance with the exposure time specified in the cleaning and disinfection plan.
7. Rinse the pressure measuring tube with drinking-water quality from outside.
8. ⚠ **CAUTION! Risk of injury due to disinfectant or cleaning agent residues in the device or hose system!**
   Rinse the pressure measuring tube with drinking-water quality from inside at least eight times with a disposable syringe.
   When doing so, note: Only rinse in one direction.
9. ⚠ **CAUTION! Risk of injury due to disinfectant or cleaning agent residues in the device or hose system!**
   Allow the pressure measuring tube to dry fully.
10. If necessary: Allow the ventilation hose to dry fully.
11. If necessary: Dry hoses with sterile compressed air or medical oxygen.

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12. Check the pressure measuring tube for residue and any remaining soiling.
13. If visible soiling remains: Repeat the manual cleaning and immersion disinfection.

Result The pressure measuring tube has been immersion disinfected.

8.3.5 Machine cleaning and disinfecting parts

Alternatively to manual cleaning and disinfection, certain parts can also be machine cleaned and disinfected.

Requirement The cleaning and disinfection is prepared (see "8.3.1 Preparing cleaning and disinfection", page 106).

1. The parts approved for machine cleaning and disinfection can be found in the cleaning and disinfection plan (see "8.2 Cleaning and disinfection plan", page 100).
2. Place the parts in a washer and disinfector. When doing so, note:
   - Ensure compliance with the exposure time specified in the cleaning and disinfection plan.
   - Connect the hoses to the washer and disinfector using the corresponding hose connector.
   - All parts and cavities must be completely flushed.
   - The water must be able to run away.
3. Add cleaning agent and, if necessary, neutralizing agent in accordance with the washer and disinfector's instructions for use.
4. Start machine reprocessing cycle acc. to cleaning and disinfection plan.
5. ⚠ **CAUTION! Risk of injury due to disinfectant or cleaning agent residues in the device or hose system!** Allow parts to dry fully at room temperature.
6. Check the parts for residue and any remaining soiling.
7. If visible soiling remains: Repeat the machine cleaning and disinfection.

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Result The parts are machine cleaned and disinfected.

Clean and disinfect the hose protection sleeve.

1. Open the hose protection sleeve completely.
2. Wash the hose protection sleeve in the domestic or industrial washing machine at 60°C adding the cleaning agent and disinfectant specified in the cleaning and disinfection plan (see "8.2 Cleaning and disinfection plan", page 100).
   When doing so, note: Compliance with the manufacturer's specifications must be assured.
3. Allow the hose protection sleeve to dry completely.

8.3.6 Steam sterilizing parts (optional)

If steam sterilization is to be performed, do so in accordance with the internal processes in place at your facility.

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

1. The parts approved for steam sterilization can be found in the cleaning and disinfection plan (see "8.2 Cleaning and disinfection plan", page 100).
2. Steam sterilize parts with a device corresponding to EN 285.
   When doing so, note:
   - At 134°C with a hold time of 5 minutes.

   or

   - At 132°C with a hold time of 4 minutes.
   - The sterilizer manufacturer's instructions must be observed and followed.

Result The parts are steam sterilized.

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8.3.7 Preparing for re-use

Requirement The parts have been cleaned and disinfected (see "8.3 Performing cleaning and disinfection", page 104).

1. Check parts visually (see "5.2 Visually checking the device and accessories", page 51).
2. If necessary: Replace damaged parts.
3. Prepare the device (see "4 Preparation", page 40).
4. Perform a function check (see "5 Function check", page 51).
5. Store the device and accessories in accordance with the storage conditions (see "11.2 Storing the device", page 130).

Result The parts are ready for use again.

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9 Alarms and error messages

The device's alarm system is based on the concept of self-preserving alarms. The device emits an alarm for as long as the cause continues to exist. Once the cause of the alarm no longer exists, the device no longer emits the alarm.

The device emits physiological and technical alarms. These alarms are high-priority alarms.

High-priority alarms warn of imminent fatal or irreversible patient injuries or of device faults.

Technical alarms dominate and cannot be muted. Technical alarms occur if ventilation is not possible with the device (e.g., in the event of a device fault, a supply pressure < 2.7 bar).

The device displays alarms as follows:

- Acoustically as an audible alarm (via the loudspeaker on the device)
- Visually as a red LED with the associated alarm in the alarm field (see "9.1 Alarms", page 94)

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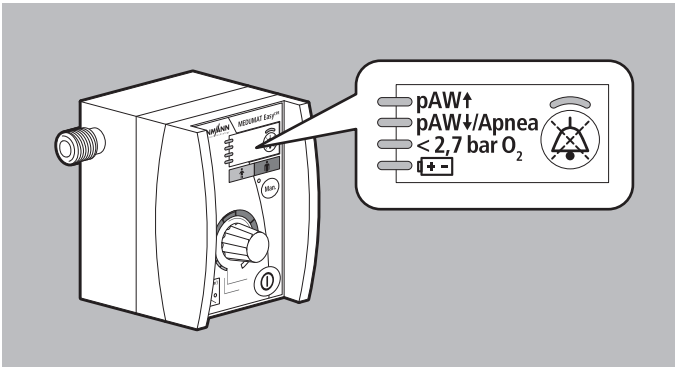
9.1 Alarms



9-1 Alarm field with alarms

Alarm	Possible cause	Remedy	To be remedied by
Alarm **pAW** ↑ (excessively high airway resistance)	Airway obstruction	Remove obstruction.	User
	Reduced lung compliance	Reduce tidal volume.	User
	Tidal volume set too high	Reduce tidal volume.	User
	Ventilation mask/tube kinked or blocked	Remove kink or blockage; if necessary, replace the accessory.	User
	Device defective	Have the device repaired (see 1.2, p. 6).	Manufacturer or authorized technician
	Selected pMax (after intubation) too low	Set pMax to 45 mbar.	User
	The testing bag is connected to the expiration side of the patient valve during ventilation	Remove the testing bag.	User

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Alarm	Possible cause	Remedy	To be remedied by
Alarm **pAW ↓ / Apnea** (respiratory system interrupted)	Patient hose leaking/ slipped off/kinked	Check connections and the patient hose system and remedy any leaks.	User
	Ventilation mask/tube not seated correctly/ kinked		
	Pressure measuring tube leaking/slipped off/kinked		
	The ventilation mask is connected to the expiration side of the patient valve	Attach the ventilation mask to the inspiration side (see 5.5, p. 54).	User
	The patient has no/ insufficient spontaneous respiration in demand flow mode	Switch to manual mode (CPR mode) or continuous mode (see 6.4, p. 73).	User
	Defective MEDUtrigger / MEDUtrigger button continually pressed in manual mode	• Release the MEDUtrigger button • Check MEDUtrigger • If possible, switch to continuous mode (see 6.4.3, p. 72) • Replace the device	User
	MEDUtrigger is not actuated in manual mode	• Perform ventilation • If necessary: Switch to continuous mode	User
	Device defective	Have the device repaired (see 1.2, p. 6).	Manufacturer or authorized technician

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Alarm	Possible cause	Remedy	To be remedied by
Alarm **< 2.7 bar O_2** (supply pressure is too low)	Oxygen cylinder almost empty	Change the oxygen cylinder (see 4.4, p. 44).	User
	Oxygen cylinder valve closed	Open oxygen cylinder valve.	User
	Pressure reducer defective	Replace pressure reducer.	User
	Compressed gas tube kinked or pinched	Remove kink or blockage; if necessary, replace the compressed gas tube.	User
	Compressed gas tube not connected/not connected correctly	Connect the compressed gas tube correctly and check the connection.	User
	Device defective	Have the device repaired (see 1.2, p. 6).	Manufacturer or authorized technician
Alarm  (first appearance)	Battery almost empty (remaining time of at least 20 minutes after this alarm appears for the first time)	Keep an alternative ventilation unit at the ready. Replace the battery at the next opportunity (see 10.3, p. 126).	User/manufacturer or authorized technician
Device malfunction/ device failure alarm (all alarm LEDs flash and successive acoustic signals sound)	Device malfunction or device defective	• Remove the battery from the battery compartment and re-insert (see 10.3, p. 126). Before re-inserting the battery, it must be ensured that the acoustic and visual alarms are no longer active. If necessary: Repeat the procedure with a new battery. If the device does not work after changing the battery, have the device repaired (see 1.2, p. 6). • Perform a function check. • Switch to an alternative ventilation unit.	User/manufacturer or authorized technician

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Alarm	Possible cause	Remedy	To be remedied by
Power failure alarm (all alarm LEDs flash and two audible signals sound in succession. Alarm  occurred previously)	Battery empty or fuse defective	• Change the battery in the battery compartment (see 10.3, p. 126). • If the device does not work after changing the battery, have the device repaired (see 1.2, p. 6). • Switch to an alternative ventilation unit.	User/manufacturer or authorized technician

If you have any queries on alarms, please contact our Customer Service (see "1.2 Customer Service", page 6).

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9.2 Faults

If you have any queries on faults or the table of faults, please contact our Customer Service (see "1.2 Customer Service", page 6). If you cannot remedy a fault using the table, have the device or accessories repaired by the manufacturer. Do not continue operating the device in such cases.

Fault	Possible cause	Remedy	To be remedied by
Device cannot be switched on	Battery empty	• Change the battery in the battery compartment (see 10.3, p. 126). • If the device does not work after changing the battery, have the device repaired.	User/manufacturer or authorized technician
	Incompatible battery inserted		
	Device defective	Have the device repaired (see 1.2, p. 6).	Manufacturer or authorized technician
Device in operation but no ventilation pressure is displayed	Pressure measuring tube on the device or on the patient valve has slipped	Check the pressure measuring tube.	User
	Pressure measuring tube is kinked		
Tidal volume Vt too low	Ventilation parameters incorrectly selected	Check the ventilation parameters.	User
	Device defective	Have the device repaired (see 1.2, p. 6).	Manufacturer or authorized technician
	Leak in the system	Check the compressed gas supply, patient hose system and ventilation mask/tube (see 5.2, p. 51).	User
Unusually high oxygen consumption	Leak in oxygen feed line	Check the system for leaks and rectify as necessary (see 5.4, p. 53).	User
Device cannot be switched off	Operating error	Press and hold the On/Off button for at least 3 seconds.	User
The ventilation pressure display does not show "0" when depressurized	Device defective	Have the device repaired (see 1.2, p. 6).	Manufacturer or authorized technician

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Fault	Possible cause	Remedy	To be remedied by
MEDUtrigger does not trigger a breath	Mechanical breath was triggered during the expiration phase	Wait to trigger the breath until the expiration phase is over. The length of the expiration phase corresponds to the length of the inspiration phase.	User
	MEDUtrigger not properly connected	Check and correct the position of the MEDUtrigger connector.	User
	Manual mode (CPR mode) not activated	Activate manual mode (CPR mode) (see 6.4.2, p. 75).	User
	MEDUtrigger defective	Replace MEDUtrigger.	User
The testing bag does not fill as expected with oxygen	The testing bag is connected to the expiration side of the patient valve	Attach the testing bag to the inspiration side (see 5.5, p. 54).	User
Alarms flash, but no alarm sounds	Temporary electronic error or electronics defective	Switch device off and back on again. If the error occurs again, have the device repaired (see 1.2, p. 6).	User/manufacturer or authorized technician
Alarm sounds, but no alarm flashes			
Alarm sounds and all alarms flash			

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10 Maintenance

⚠ WARNING

Fault or treatment failure due to insufficient or incorrect maintenance!

Incorrect maintenance can lead to dangerous situations and failure or malfunctioning of the device. This can result in severe or life-threatening injury to the patient and bystanders.

⇒ Make sure that maintenance, safety checks and maintenance measures are only performed by the manufacturer or technicians who have been expressly authorized by the manufacturer.

⇒ Also observe and comply with the maintenance intervals for devices in storage.

⇒ Follow the maintenance intervals as stated on the device labeling.

⇒ Perform a full function check before every use.

10.1 Intervals

Part concerned	Interval	Maintenance by
Device	Every 2 years	Manufacturer or a technician specifically authorized by the manufacturer (see "1.2 Customer Service", page 6)
Reusable accessories		
Testing bag		
Fittings carrying oxygen		
Mounting plate and the fastening strap		
Disposable hose system with disposable patient valve	Maintenance-free	

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10.2 Sending the device in for maintenance

⚠ CAUTION

Risk of infection and contamination due to inadequate hygienic safety during maintenance measures!
The device and accessories may be contaminated, and infect the technicians or bystanders with bacteria or viruses.
⇒ Carry out cleaning and disinfection of the device and accessories prior to all maintenance.
⇒ Never send in potentially contaminated devices or accessories for maintenance work.

1. Remove the accessories (see "7 Disassembly", page 89).
2. Clean and disinfect the device and accessories (see "8 Cleaning and disinfection", page 100).
3. Send the device and accessories to the manufacturer or technicians who have been expressly authorized by the manufacturer (see "1.2 Customer Service", page 6).

Result The device has been sent in for maintenance.

If you send in devices or accessories which are visibly contaminated, they will be disposed of by the manufacturer or a technician specifically authorized by manufacturer at your expense.

10.3 Changing the battery

The device comes with a special 3.6 V battery.

As a rule, the battery is changed regularly within the scope of 2-yearly maintenance and, as such, if the device is used normally, the operator does not have to change the battery.

Nevertheless, it is recommended always to keep a spare battery (WM 28045 LSH 14) with the device (see "12.3 Replacement parts", page 133) and (see "5 Function check", page 51).

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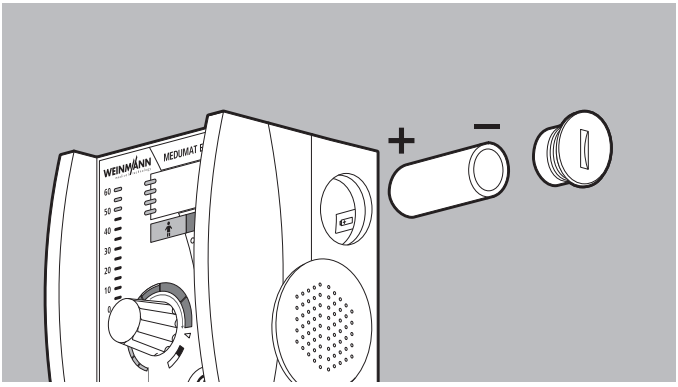
⚠ WARNING

Premature failure of treatment due to the use of non-approved batteries!
The 3.6 V battery is a special battery. Only use WEINMANN Emergency batteries as there is otherwise a risk of premature functional failure due to the reduced battery life of third-party batteries. This can result in serious or life-threatening injury to the patient.
⇒ Only use OEM batteries.

Requirement The device is switched off (see "6.6 Switching the device off", page 84).



1. Open the battery compartment on the side of the device. To do this, use a coin, for example, and turn counterclockwise to open the cover.
2. Remove the old battery.
3. **⚠ CAUTION! Material damage from incorrectly inserted battery!**
   Ensure correct polarity when inserting the new battery!
4. Close the battery compartment again.
5. Perform a function check (see "5 Function check", page 51).

Result The battery has been changed.

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10.4 Changing the membranes and O-ring in the reusable patient valve

⚠ WARNING

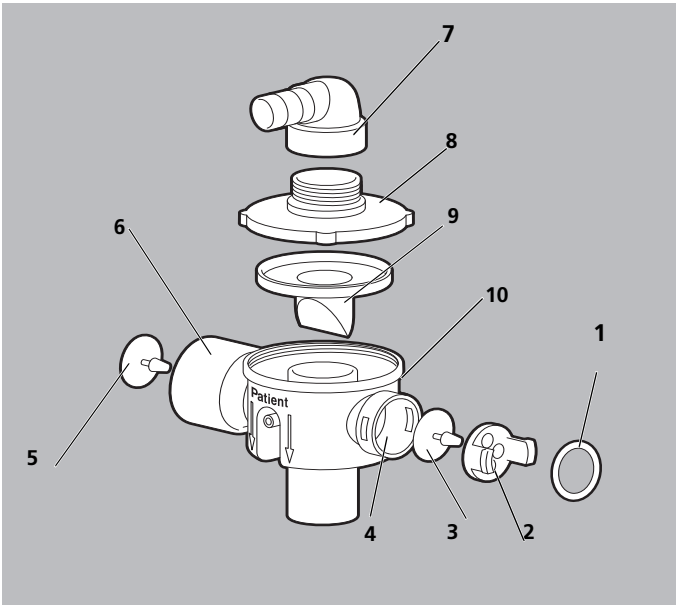
Treatment fault due to installation errors or damaged patient valve lip membrane!

Damaged or incorrectly inserted membranes can cause the device to malfunction. This can result in serious or life-threatening injury to the patient.

⇒ Do not use any wavy, sticky, or distorted membranes.

⇒ Following a change or visual inspection of the lip membrane, pay attention to the correct positioning of the lip membrane when assembling the patient valve.

Requirement The reusable hose system has been disassembled (see "7.5 Disassembly of the reusable hose system", page 94).



1. Insert the new O-ring (**1**) in the groove in the spontaneous respiration insert.
2. Insert new disk diaphragm/emergency air membrane (**3**) in spontaneous respiration side (**4**) of the reusable patient valve.

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3. Insert spontaneous respiration insert (**2**) in spontaneous respiration side (**4**) of the reusable patient valve.
4. Insert new disk diaphragm (**5**) in expiration side (**6**) of the reusable patient valve.
5. Insert a new lip membrane (**9**).
   When doing so, pay attention to the insertion direction symbol on the reusable patient valve ▽ (**10**) (see "3.6.4 Labels on the reusable hose system with reusable patient valve", page 33).
6. ⚠ **Warning! Treatment fault due to patient valve lip membrane installation errors!**
   Check the correct positioning of the lip membrane in accordance with the installation direction symbol on the reusable patient valve ▽ (**10**) .
7. Screw the connection for the ventilation hose (**7**) onto the reusable patient valve lid (**8**) in a clockwise direction.
8. Install the reusable patient valve lid (**8**) in a clockwise direction.
9. Assemble the reusable hose system (see "4.5 Assemble reusable hose system", page 46).
10. Perform a function check (see "5 Function check", page 51).

Result The membranes in the reusable patient valve have been changed.

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11 Transport, storage and disposal

11.1 Transporting the device

You can transport the device in the following ways:

- In the protective transport bag from WEINMANN Emergency
- On the LIFE-BASE light carrying system
- On the LIFE-BASE mini II carrying system
- On the LIFE-BASE 1 NG XS carrying system
- On the LIFE-BASE 1 NG XL carrying system
- On the LIFE-BASE 3 NG carrying system

11.2 Storing the device

NOTICE

Material damage due to incorrectly stored patient hose system (disposable)!
Material changes can result from incorrect storage of the patient hose system.
⇒ Observe the storage conditions Device (see "13.1 Device", page 134).
⇒ Observe the maximum storage duration of 2 years.

NOTICE

Material damage due to incorrect storage!
Silicone and rubber parts can become brittle and fragile due to incorrect storage, thus resulting in material damage.
⇒ Protect silicone and rubber parts from UV light and direct sunlight.
⇒ Store the device and accessories in a dry place.

1. If the device is not used for an extended period:
   Clean and disinfect the device (see "8 Cleaning and disinfection", page 100).
2. Store the device in a dry place and, if available, in the protective transport bag.

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The battery can remain in the device whilst in storage.

3. Also observe maintenance intervals for the device in storage. The device can otherwise not be used after it is removed from storage.

Result The device is stored.

11.3 Disposal

11.3.1 Electronic waste

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

The following products are categorized as electronic waste:

- Device
- MEDUtrigger

11.3.2 Battery

After use, dispose of the battery properly as per the regional legislation and the local provisions.

Do not dispose of the battery as household waste.

11.3.3 Patient hose system and additional accessories

Dispose of the patient hose system and additional accessories properly in accordance with the regional legislation and the local provisions.
Do not dispose of the patient hose system as household waste.

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12 Scope of supply, replacement parts and accessories

12.1 Standard scope of supply

MEDUMAT Easy^{CPR} **WM 20300**

Part	Article number
MEDUMAT Easy^{CPR}, basic device (incl. battery LSH 14)	WM 20305 (WM 28045)
Reusable patient hose system with patient valve	WM 22520
Hose protection sleeve	WM 8297
Ventilation mask with self-inflating cushion	WM 5074
MEDUtrigger	WM 20900
Testing bag for function check	WM 1454
Set, mounting elements	WM 15007
Instructions for Use	WM 68270
Function check supplementary sheet	WM 68310
Medical device logbook	WM 16430
Delivery record	WM 16318

12.2 Accessories

Part	Article number
Reusable patient hose system with patient valve, 1.55 m	WM 22520
Disposable patient hose system with patient valve, 1.70 m	WM 28110
Set of 10 disposable patient hose systems with patient valve	WM 15454
Set of 25 disposable patient hose systems with patient valve	WM 15455
Set of 50 disposable patient hose systems with patient valve	WM 15456
Rendell-Baker ventilation mask, silicone, for toddlers aged 1 to 3, size 2	WM 5062

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Part	Article number
Rendell-Baker ventilation mask, silicone, for children aged 3 to 12, size 3	WM 5063
Silicone ventilation mask, size 2, toddler	WM 11112
Silicone ventilation mask, size 3, child	WM 11113
Silicone ventilation mask, size 4, adult	WM 11114
Silicone ventilation mask, size 5, adult	WM 11115
Ventilation mask with self-inflating silicone cushion, size 3, children and young adults	WM 5082
Reusable PEEP valve	WM 3215
Breathing system filter for MEDUMAT ventilators	WM 22162
CapnoDura Combi CO_2 detector, disposable	WM 20760
Set of 10 CapnoDura CO_2 detectors, disposable	WM 20770
Testing bag with triggering	WM 1454
EasyLung test lung	WM 28625
Mounting set with mounting plate and fastening strap	WM 17870
Set for permanently installing a module or MEDUMAT Easy^{CPR}	WM 15197
Protective transport bag MEDUMAT Easy^{CPR}	WM 20320

12.3 Replacement parts

If necessary, you can order replacement parts separately via either the manufacturer or your dealer.

If you have any queries on replacement parts, please contact our Customer Service (see "1.2 Customer Service", page 6).

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13 Technical data

13.1 Device

Specification	Device
Dimensions W x H x D incl. connections	100 x 145 x 90 mm (3.9 x 5.7 x 3.5 inch)
Weight of entire system WM 20300	1.25 kg (2.8 lbs)
Weight of device WM 20315 (without accessories)	700 g (1.5 lbs) The position of the basic device's center of gravity (in reference to the central point between the threaded sleeves, view towards control panel, right-hand Cartesian coordinate system) x direction: + 2 mm y direction: - 35 mm z direction - 5 mm
Device class according to 93/42/EEC	II b
Operation • Temperature range • Temperature range for continuous operation • Humidity • Air pressure	 • -20°C to +50°C (-4°F to +122°F) • -18°C to +50°C (0°F to +122°F) • Max. 95% RH without condensation • 62 kPa to 110 kPa (62 kPa corresponds to approx. 3800 meters)
Storage • Temperature range • Humidity	 • -40°C to +70°C (-40°F to +158°F) • Max. 95% RH without condensation Reaching the operational ready state following storage outside of the ambient conditions for continuous operation: • Necessary warm-up time for the device from minimum storage temperature to operational ready state at ambient operating temperature of 20°C (68°F): 0.75 h • Necessary cool-down time for the device from minimum storage temperature to operational ready state at ambient operating temperature of 20°C (68°F): 0.75 h
Control	Time-controlled, volume-controlled
Supply gas	Medical oxygen
Own oxygen consumption for device operation	0 l/min

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Specification	Device
Permitted operating pressure for oxygen source	2.7 bar to 6 bar (40 psi to 87 psi)
Minimum necessary flow of oxygen source	40 l/min O_2 STPD(1)
Respiratory time ratio (I:E)	1:2 (Vt ≤ 150 ml)*, 1:3 (Vt > 150 ml)* * Tolerance ± 10%
Respiratory time ratio (I:E) in manual mode (CPR mode)	1:1* * Tolerance ± 10%
Ventilation rate (freq.)	10 to 25 breaths per minute
Tolerance for ventilation rate	± 2 breaths per minute
Tidal volume (Vt)	65 to 950 ml (± 40 ml or ± 20%) The larger tolerance applies. No negative pressures are applied for the ventilation.
Max. ventilation pressure	20 or 45 mbar
O_2 concentration	100% O_2
Compressed gas connection	External thread G3/8
Power supply	Maintenance-free lithium battery 3.6 V; 5.2 Ah
Max. storage duration of lithium battery	4 years following delivery
Battery life	Approx. 100 hours* *At room temperature and Vt 500 ml. (Temperatures below 0°C (32°F) and activated voice prompt reduce battery life).
Degree of protection against dust and water	IP54 - protection against the ingress of dust and splash water from all sides
Sound pressure alarm	≥ 60 dB (A)
Reading accuracy of ventilation pressure display	± 2.5 mbar
Accuracy of measured ventilation pressure	± (1.2 mbar + 5% of measured value)
Components dependent on the direction of flow	Patient valve
Parts containing latex	None
Demand flow mode: • Trigger • Peak flow • Switch-off pressure	 • 0.8 mbar ± 0.3 mbar • ≥ 40 l/min O_2 STPD*(2) • 3 mbar ± 0.3 mbar * The value depends on the performance capacity of the oxygen source.

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Specification	Device
Application parts	• Ventilation mask • Ventilation tube
Essential characteristics	• Delivery of ventilation volume or triggering of alarm status • Limitation of maximum ventilation pressure
Electromagnetic compatibility (EMC) as per EN 60601-1-2:	Test parameters and limit values are available on request from the manufacturer (WEINMANN Emergency Medical Technology GmbH + Co. KG, Frohbösestraße 12, 22525 Hamburg, GERMANY).
• Radio interference suppression	EN 55011, Group 1, Class B UN/ECE R 10, Annexes 6 and 7 RTCA DO 160 G, Section 21, Category M
• Radio interference immunity	EN 61000-4-2, contact ± 8kV, air ± 15 kV EN 61000-4-3, 30 V/m to 2.7 GHz (ISM bands up to approx. 6 GHz) EN 61000-4-6, 3 Vrms (ISM bands with 6 Vrms) EN 61000-4-8, 30 A/m
Resistance to shock and vibration	• EN 1789 • EN 60601 60601-1-12 (Categories: Secured in a rescue vehicle, secured in an aeroplane, secured in a helicopter, portable at the site of the emergency) • EUROCAE ED-14G (RTCA DO 160 G) (Section 8 - Vibration Aeroplanes Cat. S and Helicopter Cat. U2)
Type of rescue vehicle	Secured in rescue vehicle, aeroplane and helicopter as well as portable at the site of the emergency
The device satisfies all the relevant parts of the following standards	DIN EN 794-3 ISO 10651-3 EN 1789 EN 60601-1 EN 60601-1-2 EN 60601-1-12 RTCA DO-160 G
UL certification	Regarding protection against electric shock, fire prevention, and protection from mechanical hazards ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012) CAN/CSA-C22.2 No, 60601-1 (2014) IEC 60601-1-6:2010, AMD1:2013 IEC 60601-1-8:2006, AMD1:2012 IEC 60601-1-12:2014

(1) STPD = Standard Temperature and Pressure, dry (21°C, 1.013 mbar)

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Subject to alterations in design.

13.2 Patient hose system

	Patient hose system (reusable), 2 m WM 22520	**Patient hose system (disposable), 2 m WM 28110**
Operation: Temperature range: Relative humidity:	-20°C to +50°C (-4°F to +122°F) Max. 95%	
Storage	-40°C to +70°C (-40°F to +158°F)	
Patient valve: Patient connection	Standard connection as per ISO 5356-1 15 mm internal taper 22 mm external taper	
Patient valve: Expiration opening	Standard connection as per ISO 5356-1 30 mm external taper	
The patient hose system satisfies all the relevant parts of the following standards	ISO 10651-3; EN 794-3	
Patient valve resistance (acc. to 794-3 / ISO 10651-3): Inspiration Expiration Spontaneous respiration	< 6 mbar(1) at 30 l/min to 60 l/min < 6 mbar(1) at 30 l/min to 60 l/min 1.5 mbar(1) at 30 l/min	< 6 mbar(1) at 30 l/min to 60 l/min < 6 mbar(1) at 30 l/min to 60 l/min 1.36 mbar(1) at 30 l/min
Dead space Patient valve	12.8 ml	8 ml
Materials used	PSU, silicone	EVA, K-Resin®, PS, PVC (DEHP free), silicone

(1) 1 mbar corresponds to 1 hPa

13.3 Protective transport bag

Dimensions WxHxD	13.78 x 10.24 x 6.89 inch (35 x 26 x 17 cm)
Weight	Approx. 1.6 kg (3.53 lbs)

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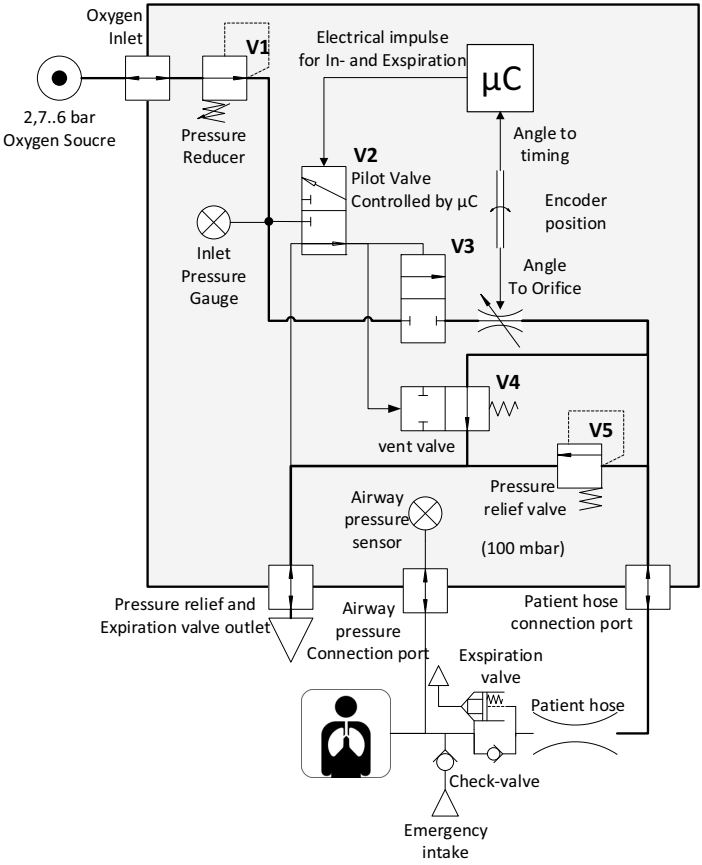
13.4 Pneumatic system diagram



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The pneumatic unit comprises the following components:

- Compressed gas connection with filter sieve
- Input pressure regulator
- 3/2-way valve
- Booster valve with metering device
- Vent valve
- Pressure relief valve
- Connection for ventilation hose

There is a pressure of max. 87 psi (6 bar) at the compressed gas connection, which is reduced dynamically by the input pressure regulator (V1) to approx. 36 psi (2.5 bar). This pressure is found at the 3/2-way valve (V2), the booster valve (V3) with metering device and the vent valve (V4).

For inspiration, an electrical impulse opens the 3/2-way valve (V2). The booster valve (V3) with metering device opens and the vent valve closes (V4). Oxygen flows via the ventilation hose to the patient valve. The quantity of oxygen depends on the encoder position and the opening within the metering device. If the ventilation pressure in the patient valve increases to > 100 cmH_2O (> 100 mbar), the pressure relief valve (V5) is triggered.

For expiration, an electrical impulse closes the 3/2-way valve (V2). The booster valve (V3) with metering device closes and the vent valve opens (V4). The ventilation hose is vented. The patient exhales via the patient valve.

The demand flow is triggered by an inhalation trigger. At the same time, the 3/2-way valve (V2) is switched. The booster valve (V3) with metering device opens and the vent valve closes (V4).

The microprocessor-controlled electronics set the ventilation parameters and monitor ventilation as well as the oxygen and power supply. A visual and audible alarm may occur.

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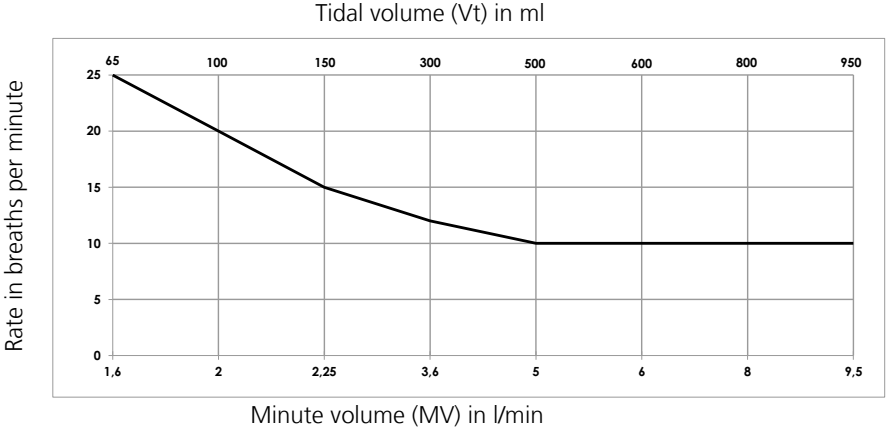
13.5 Correlation between ventilation parameters

The following diagram shows the correlation between ventilation parameters tidal volume and respiratory rate and the resulting minute volume.



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14 Appendix

14.1 Calculating the operating times

General calculations	Parameter	Example 1 (2 L oxygen cylinder)	Example 2* (Size M-15 (D) oxygen cylinder)
Oxygen capacity			
Oxygen capacity = Cylinder volume x oxygen cylinder pressure (bar)	Cylinder volume	2 liters	~ 2.8 liters*
	Cylinder pressure	200 bar/2900 psi	152 bar/2200 psi
	Oxygen capacity	400 liters	425 liters*
Ventilation operating time			
Ventilation operating time = Oxygen capacity/(respiratory rate x tidal volume)	Respiratory rate	10 min^{-1}	
	Tidal volume	600 ml	
	Operating time	67 min	71 min
Demand flow operating time			
	Demand mode inhalation flow	45 l/min	
	Inspiration / Expiration (I:E)	1:2	
	Respiratory rate	10	
	Inhalation time	2 sec./0.033 min	
Inhalation volume = Inhalation flow x inhalation time (min)	Inhalation volume	1.5 liters	
Demand flow operating time = Oxygen capacity/(respiratory rate x inhalation volume)		27 min	28 min

* Can deviate. Depends on the oxygen cylinder manufacturer.

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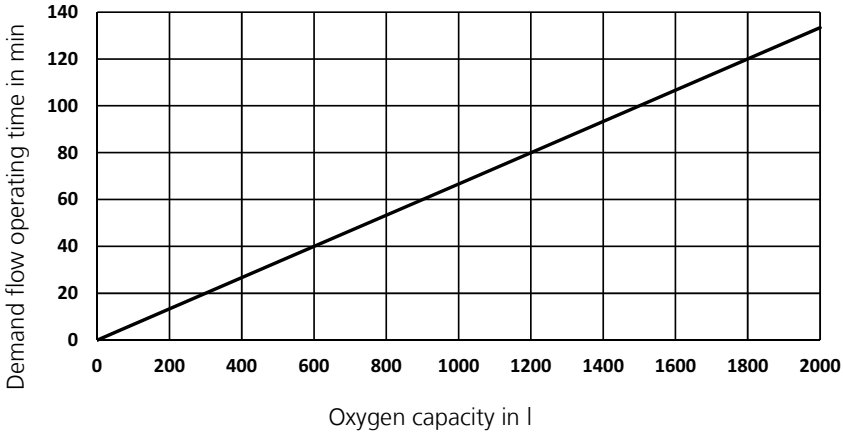
14.2 Demand flow operating time



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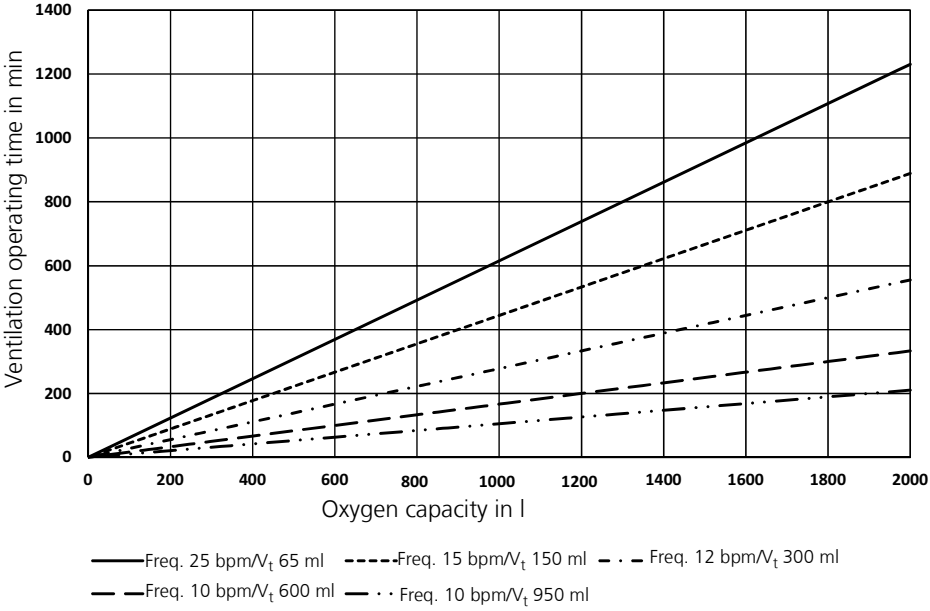
14.3 Ventilation operating time (min)



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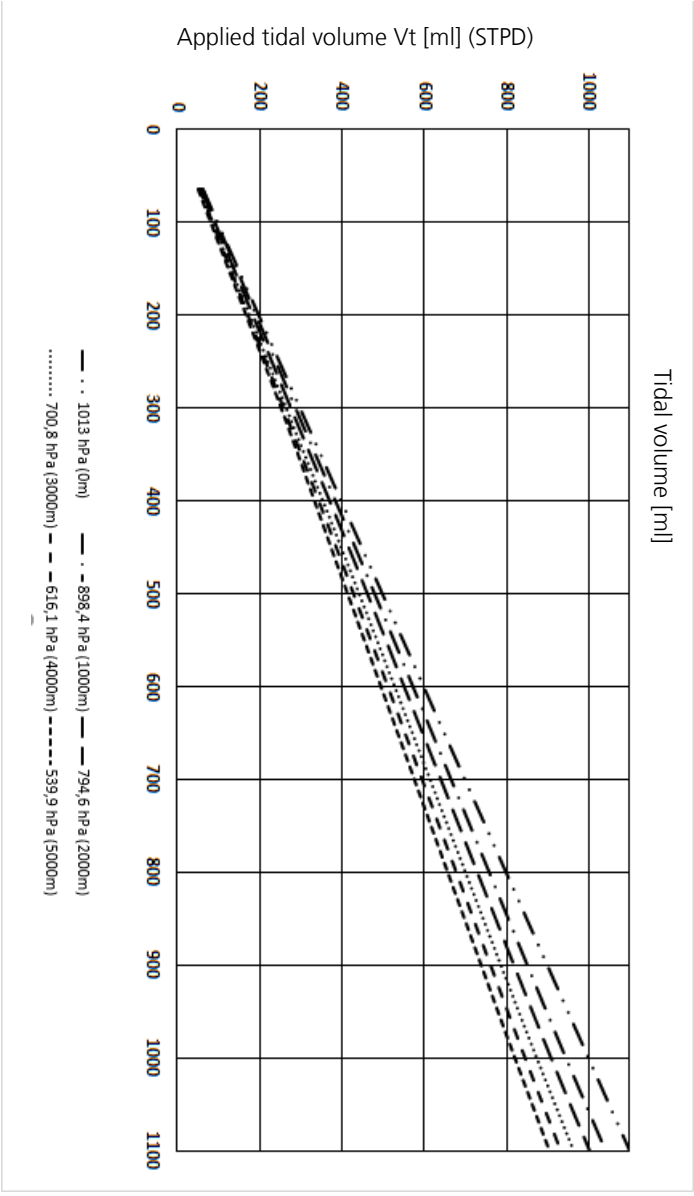
14.4 Height compensation



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Applied tidal volume subjected to ambient pressure/operation height [ml] (STP)						
Tidal volume [ml] (set on the device)	**Air pressure (Height above sea level)**					
	1013 hPa 0 m	**898 hPa 1,000 m**	**795 hPa 2,000 m**	**701 hPa 3,000 m**	**616 hPa 4,000 m**	**540 hPa 5,000 m**
65	65	64	62	60	57	57
100	100	97	94	90	87	86
150	150	145	139	134	129	127
300	300	286	275	265	256	249
500	500	475	457	440	426	413
600	600	570	548	528	510	495
800	800	759	729	703	680	659
950	950	901	865	834	807	782

14.5 Voice prompts

Voice prompt	Meaning
Open oxygen cylinder	Open the valve on the oxygen cylinder **slowly**.
Adjust settings and connect patient	Set the respiratory rate and tidal volume according to the patient weight. Connect the device with the patient mask or the endotracheal tube connector using the ventilation hose and patient valve.
Demand flow mode	Demand flow mode is set.
Ventilation pressure limit 45 mbar	Tube ventilation mode is set. Maximum ventilation pressure for tube ventilation.
Ventilation pressure limit 20 mbar	Mask ventilation mode is set. Maximum ventilation pressure for mask ventilation.
Check airways and settings	The inspiratory airway resistance measured by MEDUMAT Easy^{CPR} is too high. Check the airways or adapt the respiratory rate and tidal volume settings to the patient.
Check pressure hose system and gas supply	The pressure on the inlet side measured by MEDUMAT Easy^{CPR} is too low. Check whether the oxygen cylinder is sufficiently filled and whether the oxygen hose is leaking, kinked or pinched.

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Voice prompt	Meaning
Rule out respiratory arrest and check mask fit	When in demand flow mode: MEDUMAT Easy^{CPR} does not measure a respiratory drive (trigger). Check the breathing and switch to another ventilation mode, if necessary. Check the connections and mask seat. When in CPR mode without metronome: There was no mechanical breath triggered for 45 s. Trigger at least one mechanical breath by pressing the key on MEDUtrigger.
Close oxygen cylinder	After switching the device off, close the oxygen cylinder or the external oxygen supply.
Check ventilation system and settings	Disconnection: During the inspirations phase in a controlled ventilation, a pressure increase of 8 mbar is not achieved. This is normally due to an interruption of the ventilation system or too low a setting of the tidal volume. Check the connections or adapt the tidal volume setting to the patient.
Selected language: English (Deutsch, Français, ...)	When selecting the language for the voice prompts, press the key for mask/tube ventilation repeatedly until the required language is announced.
Audio response is off	Confirmation of deactivation of voice prompts.
CPR mode activated Ventilation triggered manually	Automatic ventilation is stopped. Trigger the breaths with MEDUtrigger at the appropriate moment.
CPR mode deactivated	MEDUMAT Easy^{CPR} ventilates the patient with the set frequency.
Provide 2 ventilations now	Trigger two breaths with MEDUtrigger.
Perform chest compressions now	Perform 30 chest compressions in time with the metronome.

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15 Warranty terms and conditions

15.1 Warranty

Starting from the date of purchase, WEINMANN Emergency offers the customer a limited manufacturer's warranty on a new original WEINMANN Emergency product or replacement parts 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 send you the warranty terms and conditions by mail.

If you wish to make a warranty claim, consult your authorized dealer.

Product	**Warranty periods**
WEINMANN Emergency devices, incl. accessories (excluding: masks) for oxygen therapy and emergency medicine	2 years
Masks, incl. accessories, batteries (unless otherwise stated in the technical documentation), sensors, hose systems	6 months
Disposable products	None

15.2 Declaration of Conformity

WEINMANN Emergency Medical Technology GmbH + Co. KG declares herewith that the product complies fully with the respective regulations of the Medical Device Directive 93/42/EEC.

The unabridged text of the Declaration of Conformity can be found on our website at www.weinmann-emergency.com.

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