MEDUVENT Standard

CBRN option

Instructions for use

⚠ Read these instructions for use and the instructions for use for MEDUVENT Standard from software version 3.1 before using the product.
Ignoring the instructions for use may lead to serious injury or death.

Table of contents

1 Introduction

1.1 About this document

These instructions for use are a supplement to the instructions for use for MEDUVENT Standard from software version 3.1.

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

1.2 Explanation of warnings

⚠ DANGER

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

⚠ WARNING

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

⚠ CAUTION

Caution!
CAUTION indicates a dangerous situation which may result in minor injury if not prevented.

NOTICE

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

Warnings in action steps

Warnings can refer to individual action steps. In order not to interrupt the flow of reading, these warnings are embedded in the action. The symbols and signal words described above are used.

Example of an embedded warning:

1. **WARNING! Risk of injury from contaminated respiratory gas!** Check all connections are secure.

2 Safety

Observe the instructions and safety information both in these instructions for use and in the instructions for use for MEDUVENT Standard from software version 3.1.

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

⇒ Follow instructions for use in their entirety.
⇒ Keep the instructions for use accessible and near the device at all times.
⇒ Use the device only for the intended purpose (see "2.1 Intended purpose", page 5).
⇒ Do not use the device if it is contra-indicated.
⇒ Follow the instructions for use of accessories and other parts.

2.1 Intended purpose

2.1.1 Indications and medical purpose

CAD-MVS adapter for CBRN filter

CAD-MVS in conjunction with a connected CBRN filter protects the respiratory gas against foreign particles and has a medical purpose only in combination with MEDUVENT Standard.

2.1.2 Patient target group(s)

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

The patient target group of the accessory corresponds to the permissible patient target group of the combined emergency and transport ventilator.

2.1.3 Intended users

Qualified healthcare professionals

2.1.4 Contra-indications

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

2.1.5 Intended environments of use

- Mobile use in emergency medicine or primary care at the site of the emergency

- In rooms and departments of healthcare facilities and during transport between such rooms and departments

- During transport between the hospital and other premises by ambulance, aircraft, helicopter or ship

2.1.6 Undesirable side effects and complications

There are no known side effects or complications related to the use of the accessory. When used in combination with MEDUVENT Standard, undesirable side effects and complications may occur.

2.1.7 Clinical benefit of the product

The accessories have no clinical benefit of their own but support the clinical benefit of MEDUVENT Standard.

2.1.8 Exclusions and limitations of the intended purpose

The accessories are subject to the same exclusions and limitations of the intended purpose as MEDUVENT Standard.

2.2 Requirements on the user

The user must meet the following requirements:

- The user is medically trained and has the necessary technical knowledge and experience in the emergency medical treatment of patients.

- On the basis of this technical knowledge and experience, the user is in a position to perform the tasks assigned to him or her safely, and to independently recognize, assess and avoid potential risks to him or herself, to the patient or to bystanders.

- The user has been trained and has received instruction in the use of the device.

- The user has been trained to apply the necessary hygiene procedures.

- The user has been trained in dealing with CBRN hazards.

2.3 Requirements on the operator

The operator must ensure that accessories and other parts connected to MEDUVENT Standard are compatible with the device. The compatibility of the accessories is indicated by the ☑ symbol and the name of the device.

2.4 Safety information

For a session in CBRN-contaminated environments, the device is operated with a breathing circuit with a CBRN patient valve and a separately available CBRN filter, which is connected to the device using the CAD-MVS adapter for CBRN filter. Please also observe the safety information in the instructions for use for the CBRN filter.

2.4.1 Handling CBRN accessories

⚠ DANGER

Danger from contaminated respiratory gas due to incorrect installation!
If the CAD-MVS adapter for CBRN filter and the CBRN filter are not connected correctly, the device will draw in contaminated ambient air. Ventilation with contaminated ambient air is life threatening or fatal for the patient.
⇒ Before the session, check that the CAD-MVS adapter for CBRN filter is correctly positioned in the device and correctly locked by turning the lock 90°.
⇒ Before the session, check the screw connection of the CBRN filter and retighten if necessary.

⚠ DANGER

Danger from contaminated ambient air if the filter is changed during the session!
Contaminated ambient air can be drawn in when the CBRN filter is changed. Any CBRN contamination of the respiratory gas is life threatening or fatal for the patient.
⇒ If possible, change the CBRN filter in a non-contaminated environment.
If the CBRN filter needs to be changed during a session in a contaminated environment:
⇒ Ensure that a spontaneously breathing patient does not inhale any contaminated ambient air during the filter change.
⇒ Switch off the device before changing the filter and leave it switched off during the change so that no contaminated ambient air is drawn in.
⇒ Prevent contamination of the open connection for CBRN filter on the CAD-MVS adapter for CBRN filter during the filter change.

⚠ WARNING

Reduced ventilation performance or failed therapy due to blocked intake opening!
If the CBRN filter's intake opening is blocked or covered, ventilation will be disrupted or may fail. This may injure the patient.
⇒ Remove the protective cap from the CBRN filter before starting ventilation.
⇒ Position the device so that the intake opening of the CBRN filter is not blocked or covered.

⚠ WARNING

Disrupted or failed therapy due to incompatible accessories!
The use of non-approved accessories can impair the function of the device and injure the patient.
⇒ Only connect CBRN filters recommended by WEINMANN Emergency to the CAD-MVS adapter for CBRN filter.
⇒ Only use the device with the recommended CBRN breathing circuit with CBRN patient valve.

⚠ WARNING

Danger from contaminated ambient air during non-invasive mask ventilation!
During ventilation with a ventilation mask, the patient can generate negative pressure due to spontaneous breathing and thereby draw in and inhale contaminated ambient air. This may injure the patient.
⇒ If non-invasive ventilation masks are used, ensure that the mask fits tightly.

2.4.2 Protection from hazardous substances during the session

⚠ DANGER

Danger from contamination of the device's breathing system!
Any CBRN contamination of the respiratory gas is life threatening or fatal for the patient. Hazardous substances can damage the device and accessories.
⇒ During therapy in a CBRN environment, only use oxygen sources that are protected against contamination.
⇒ Only operate the device with a recommended CBRN filter.

⚠ WARNING

Risk of injury from contaminated respiratory gas!
If the device's breathing system is not adequately protected against hazardous substances or if the patient generates negative pressure due to spontaneous breathing, ventilation with contaminated respiratory gas may occur.
⇒ Take suitable measures to protect the device and accessories from CBRN substances in the environment.
⇒ Perform ventilation with a PEEP of ≥ 5 mbar.
⇒ Change the CBRN filter in good time before wear, if possible in a non-contaminated environment.
⇒ Only use the device with the recommended CBRN breathing circuit with CBRN patient valve.
⇒ Check all connections for correct assembly and tight fit.

2.4.3 Protection from hazardous substances after the session

⚠ WARNING

Risk of injury and infection from contaminated device and accessories!
The reprocessing and reuse of CBRN-contaminated parts can injure users or subsequent patients.
⇒ Wherever possible, decontaminate contaminated parts before disposal, otherwise dispose of them as hazardous waste in accordance with the applicable regulations.
⇒ Do not reprocess or reuse the breathing circuit with CBRN patient valve, CAD-MVS adapter for CBRN filter and CBRN filter.
⇒ Do not reuse MEDUVENT Standard if the inside of the device is suspected of being contaminated. Decommission the device.

3 Description

## 3.1 CAD-MVS adapter for CBRN filter

The CAD-MVS adapter for the CBRN filter replaces the
HF-MVS hygiene filter. CBRN filters with Rd40 threads can be
connected to the CAD-MVS adapter.
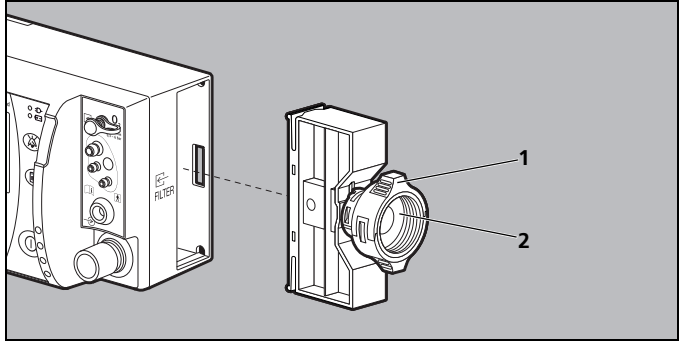
3-1   CAD-MVS adapter for CBRN filter

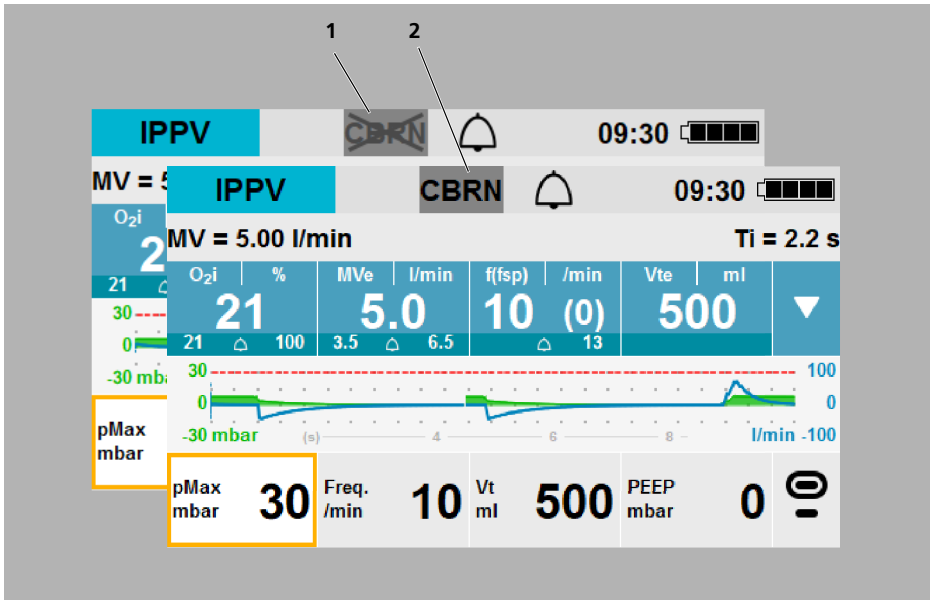| No.	Designation	Description
1	Lock	The lock must be turned 90° clockwise so that the adapter is correctly positioned in the device.
2	Connection for CBRN filter	CBRN filters with Rd40 threads can be connected.

3.2 Disposable breathing circuit VENTcirc-MVS for CBRN
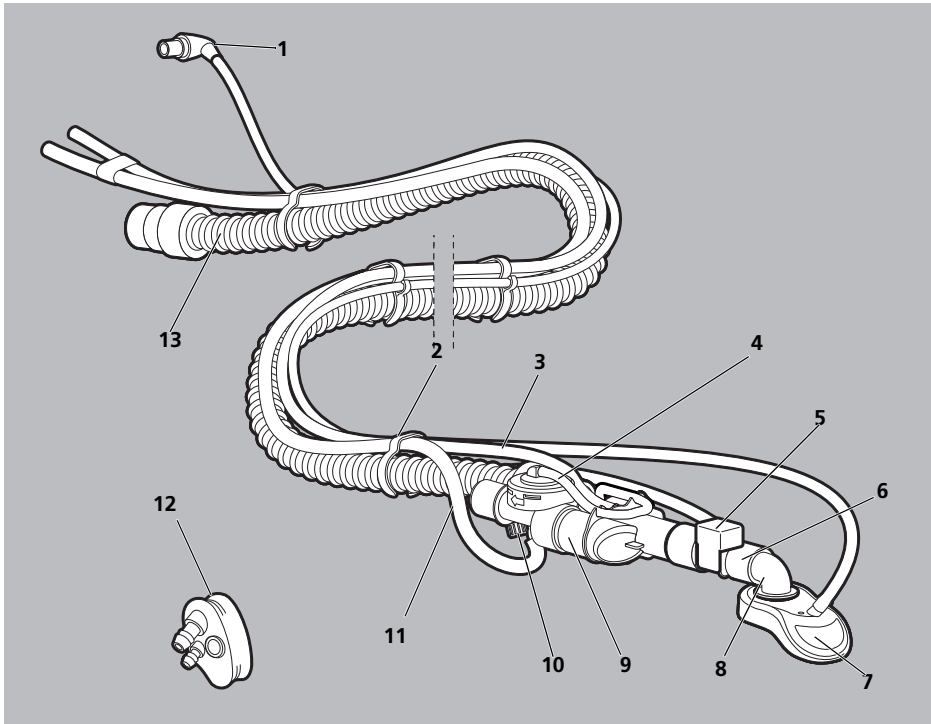
3-2   CBRN breathing circuit with FlowCheck sensor

No.	Designation	Description
1	MEDUtrigger with FlowLine-FlowCheck connection line (only with FlowCurve Pro option)	Connects the MEDUtrigger and the FlowCheck sensor to the device. Alternatively, you can use the MEDUtrigger connection line.
2	Tube clip	Holds the tubes and the MEDUtrigger connection line together.
3	Pressure measuring tube	Passes ventilation pressure on to the device.
4	PEEP control tube	The device controls the patient valve and PEEP by way of the PEEP control tube.
5	FlowCheck sensor connector (only with FlowCurve Pro option)	Part of the FlowLine-FlowCheck connection line with MEDUtrigger. Connects the FlowCheck sensor to the device.

No.	Designation	Description
6	FlowCheck sensor (only with FlowCurve Pro option)	Measures the flow toward the patient and toward the device.
7	MEDUtrigger	Triggers manual mechanical breaths.
8	Elbow	Connects the breathing circuit to the mask or tracheal tube.
9	CBRN patient valve	Implements device commands relating to inspiration and expiration.
10	Luer-Lock connector	Not used in combination with MEDUVENT Standard.
11	Flexible oxygen tube	Routes oxygen into the breathing circuit.
12	Adapter for disposable breathing circuit	Connects the device to the measuring circuit of the disposable breathing circuit. The adapter for disposable breathing circuit remains permanently connected to the device.
13	Ventilation hose	The respiratory gas flows through the ventilation hose from the device to the patient valve.

3.3 Display

3-3 CBRN mode symbol in the display

No.	Designation	Description
1	"CBRN mode not active" symbol.	The CBRN option is enabled, but CBRN mode is not activated.
2	"CBRN mode active" symbol.	CBRN mode is active.

CBRN mode is activated by default during the initial function check (see "5 Function check", page 25). CBRN mode can also be activated subsequently in the quick settings or during ventilation (see "6.1 Activating CBRN mode subsequently", page 27).

4 Preparation

To operate the device in CBRN-contaminated environments, the following parts and settings are required:

• The CBRN option is enabled.

• The CBRN filter adapter and a separately available CBRN filter are fitted.

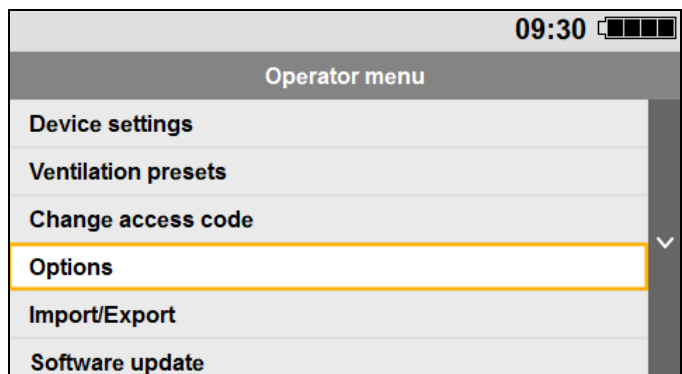• The VENTcirc-MVS disposable breathing circuit for CBRN is assembled.

or

With an existing disposable breathing circuit: The disposable patient valve has been replaced with a CBRN patient valve.
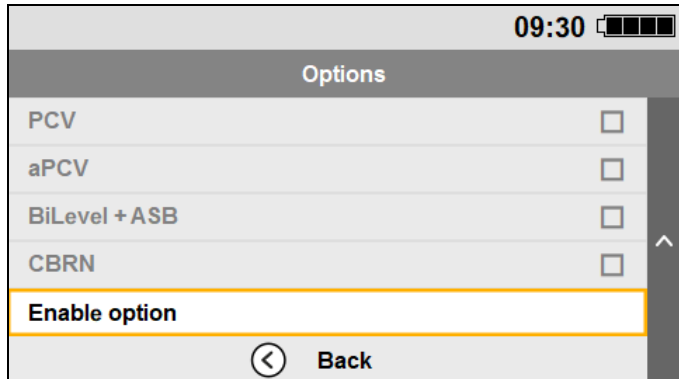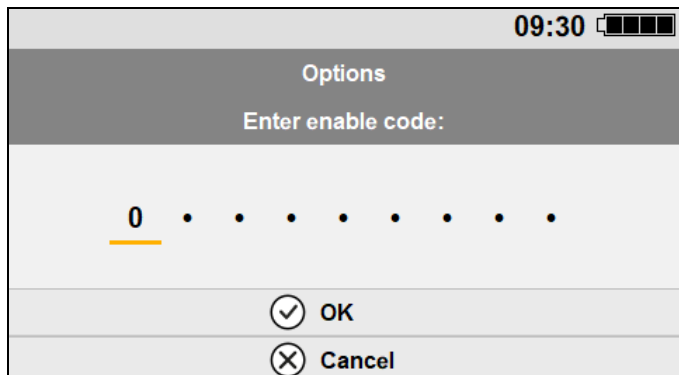
• CBRN mode is activated.

4.1 Enabling the CBRN option

Prerequisite The operator menu is activated (see chapter "9.1 Activating operator menu" in the instructions for use for MEDUVENT Standard from software version 3.1).


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

	09:30 ▮▮▮▮
Options	
PCV	☐
aPCV	☐
BiLevel + ASB	☐
CBRN	☐
Enable option	
ⓒ **Back**	

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

	09:30 ▮▮▮▮
Options	
Enter enable code:	
0 • • • • • • • •	
⊘ **OK**	
⊗ **Cancel**	

3. Enter the enable code using the navigation knob.

4. Confirm the enable code with **OK**.
   The display shows the enabled option in the **Options** menu item of the operator menu.

CBRN	09:30 ▮▮▮▮
Options	
PCV	☐
aPCV	☐
BiLevel + ASB	☐
CBRN	☑
Enable option	
‹ **Back**	
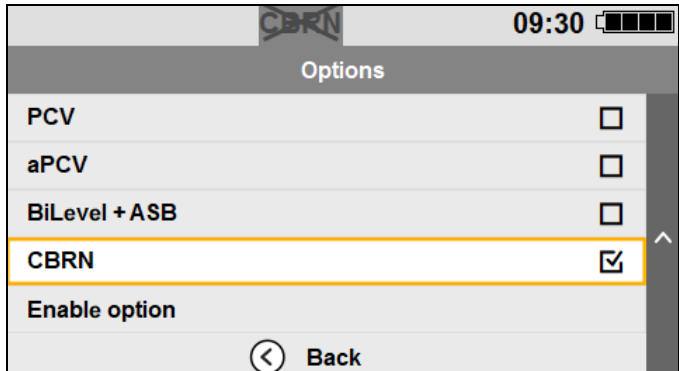
5. Activate option with navigation knob.

6. To exit the operator menu, select **Back**.

4.2 Fitting the CBRN adapter and the CBRN filter

⚠ DANGER

Danger from contaminated ambient air due to incorrect installation!
If the CAD-MVS adapter for CBRN filter and the CBRN filter are not connected correctly, the device will draw in contaminated ambient air. Ventilation with contaminated ambient air is life threatening or fatal for the patient.
⇒ Before the session, check that the CAD-MVS adapter for CBRN filter is correctly positioned in the device and correctly locked by turning the lock 90°.
⇒ Before the session, check the screw connection of the CBRN filter and retighten if necessary.

⚠ DANGER	**Danger from contaminated ambient air if the filter is changed during the session!**

Contaminated ambient air can be drawn in when the CBRN filter is changed. Any CBRN contamination of the respiratory gas is life threatening or fatal for the patient.

⇒ If possible, change the CBRN filter in a non-contaminated environment.

If the CBRN filter needs to be changed during a session in a contaminated environment:

⇒ Ensure that a spontaneously breathing patient does not inhale any contaminated ambient air during the filter change.

⇒ Switch off the device before changing the filter and leave it switched off during the change so that no contaminated ambient air is drawn in.

⇒ Prevent contamination of the open connection for CBRN filter on the CAD-MVS adapter for CBRN filter during the filter change.

⚠ WARNING	**Reduced ventilation performance or failed therapy due to blocked intake opening!**

If the CBRN filter's intake opening is blocked or covered, ventilation will be disrupted or may fail. This may injure the patient.

⇒ Remove the protective cap from the CBRN filter before starting ventilation.

⇒ Position the device so that the intake opening of the CBRN filter is not blocked or covered.

| **⚠ WARNING**	**Disrupted or failed therapy due to incompatible accessories!**

The use of non-approved accessories can impair the function of the device and injure the patient.

⇒ Only connect CBRN filters recommended by WEINMANN Emergency to the CAD-MVS adapter for CBRN filter.
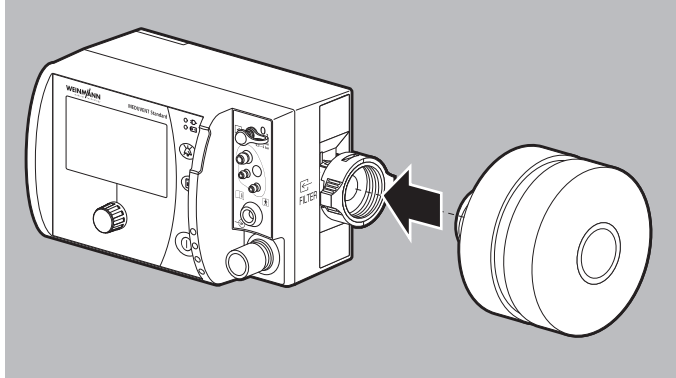
1. To remove the hygiene filter from the device, press the wings of the lock together and keep them pressed.
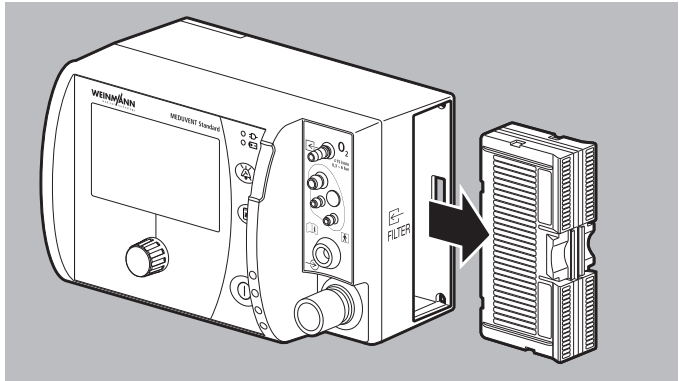
2. Pull the hygiene filter out of the device's filter compartment.
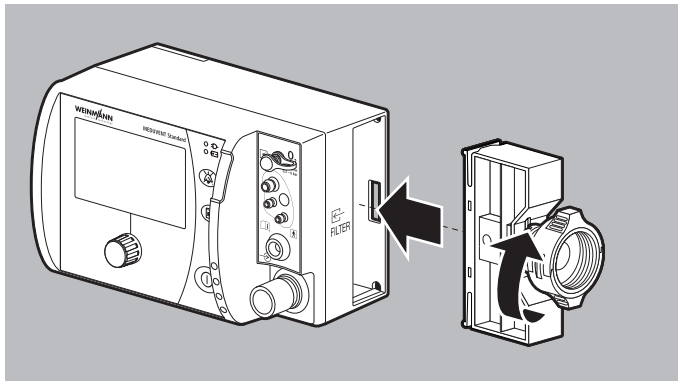
3. Insert the CBRN filter adapter into the filter shaft.

   Please note: The lock must be in a vertical position.

4. Turn the lock clockwise by 90°.

5. Connect the CBRN filter with Rd40 threads to the CBRN filter adapter.

4.3 Assembling the VENTcirc-MVS disposable breathing circuit for CBRN

To operate the device with a disposable breathing circuit, the adapter for disposable breathing circuit must be firmly assembled to the device. The flexible oxygen tube and pressure measuring tube of the disposable breathing circuit are connected to the adapter for disposable breathing circuit.

4.3.1 Converting the device to a disposable breathing circuit

Required tools   Phillips screwdriver, size PH1

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

WM 67921 2024-03
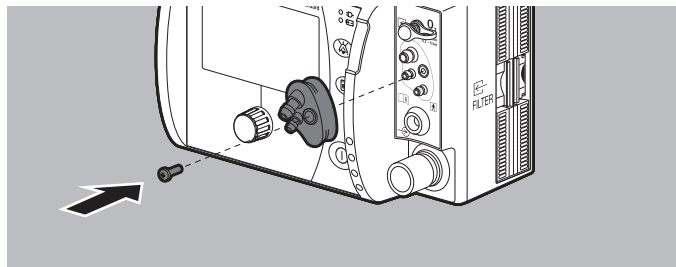
2. Fit the adapter for disposable breathing circuit on the measuring circuit connector.

3. Secure the adapter for disposable breathing circuit using the screw supplied.

4. Fit the protective cap for the connection terminal in the adapter for disposable breathing circuit to cover the screw.

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

## 4.3.2 Connecting the VENTcirc-MVS disposable breathing circuit for CBRN

⚠ WARNING

**Danger from contaminated ambient air during non-invasive mask ventilation!**
During ventilation with a ventilation mask, the patient can generate negative pressure due to spontaneous breathing and draw in contaminated ambient air.
⇒ If non-invasive ventilation masks are used, ensure that the mask fits tightly.

Prerequisite   The adapter for disposable breathing circuit is fitted to the device (see "4.3.1 Converting the device to a disposable breathing circuit", page 20).
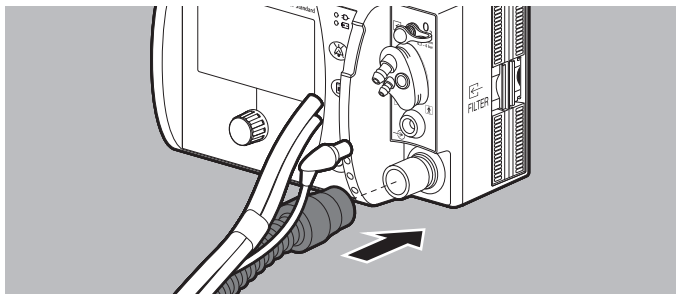
1. Connect the ventilation hose to the ventilation hose connection.
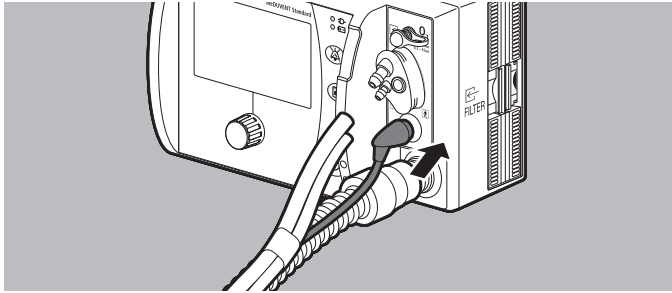
2. Connect MEDUtrigger (optional) or MEDUtrigger with FlowLine-FlowCheck connection line (optional).
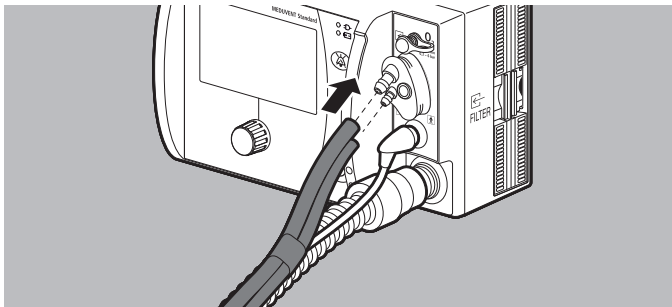

3. Connect the flexible oxygen tube and pressure measuring tube.

4.4 Replacing the disposable patient valve with a CBRN patient valve

An existing disposable breathing circuit can be used in a CBRN session if a CBRN patient valve is connected instead of the disposable patient valve.
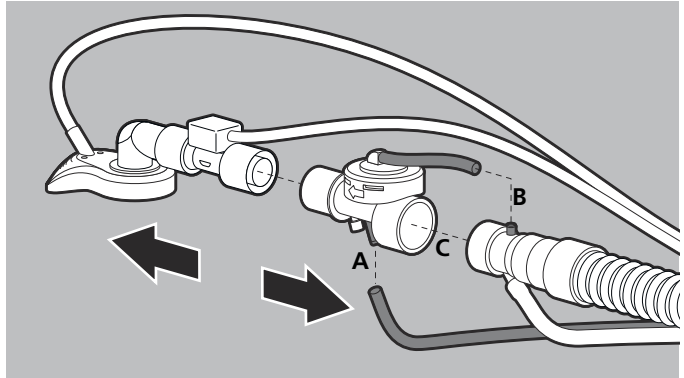
1. Remove the elbow with MEDUtrigger or (if present) FlowCheck sensor from the disposable patient valve.

2. Remove the pressure measuring tube from the main body of the patient valve (**A**).

3. Remove the PEEP control tube from the holder for check valve diaphragm (**B**).
   The flexible oxygen tube remains connected to the holder for check valve diaphragm.

4. Remove the main body of the disposable patient valve from the holder for check valve diaphragm (**C**).
   The holder for check valve diaphragm (red) remains on the ventilation hose.
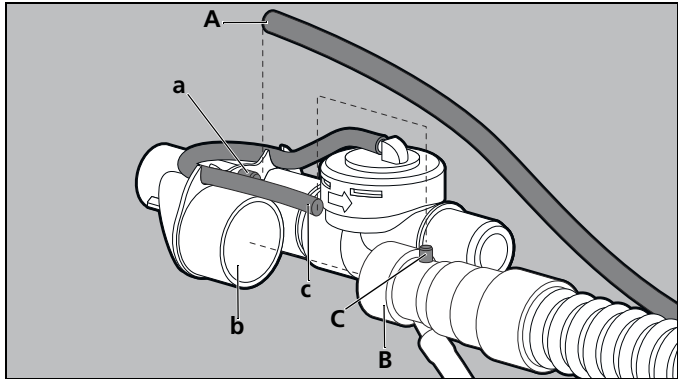
5. Connect the pressure measuring tube (**A**) to the CBRN patient valve (**a**).
   Please note: Push the pressure measuring tube up to the stop.

6. Push the holder for check valve diaphragm (**B**) firmly into the CBRN patient valve (**b**).

7. Connect the PEEP control tube of the CBRN patient valve (**c**) to the holder for check valve diaphragm (**C**).
   Please note: Push the PEEP control tube up to the stop.

8. Connect the elbow with MEDUtrigger or (if present) the FlowCheck sensor to the patient's end of the CBRN patient valve.

9. **WARNING! Risk of injury from contaminated respiratory gas!** Check all connections are secure.
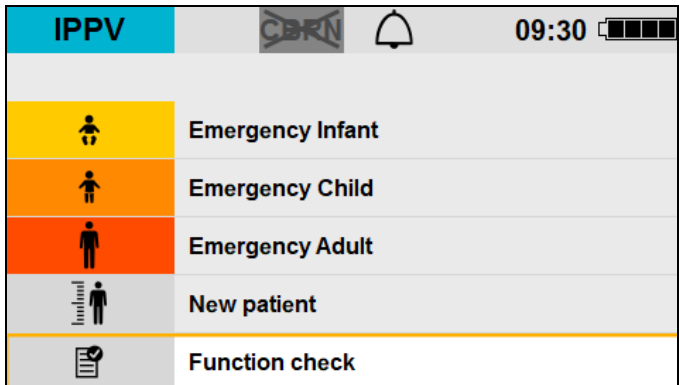
5 Function check

Observe the function check instructions in the instructions for use for MEDUVENT Standard from software version 3.1. At the start of the function check, you must confirm that the CBRN filter is connected.

Prerequisite The CBRN option is enabled and activated (see "4.1 Enabling the CBRN option", page 15).
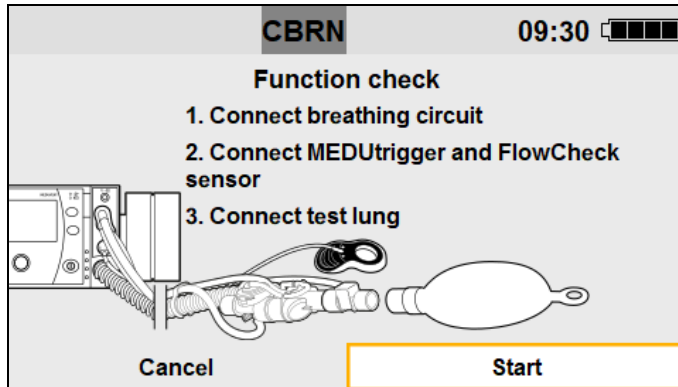
1. Switch on the device.

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

3. Check the connection of the adapter for CBRN filter and the CBRN filter connection.
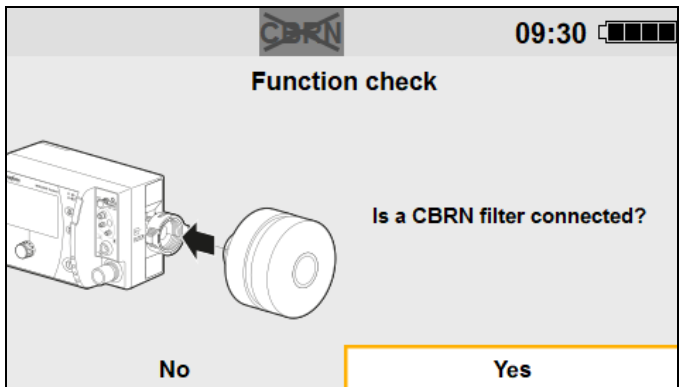
4. Confirm correct connection of the CBRN filter with **Yes** to activate **CBRN** mode.

5. Prepare the device:

   • Connect the breathing circuit to the device.

   • Connect MEDUtrigger or FlowLine-FlowCheck connection line with MEDUtrigger and FlowCheck sensor.

   • Connect the test lung to the breathing circuit.

6. Select **Start**.

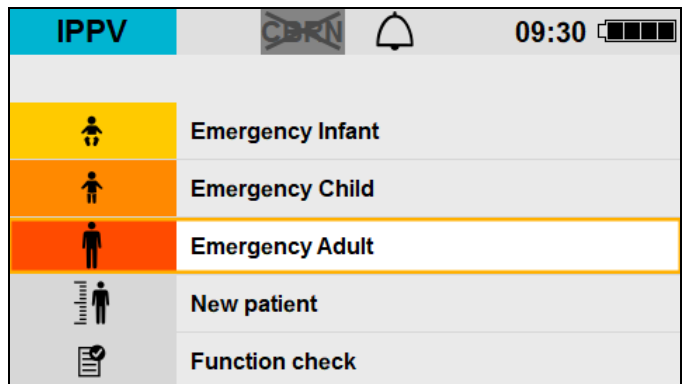7. Follow the further steps of the function check.

6 Operation

6.1 Activating CBRN mode subsequently

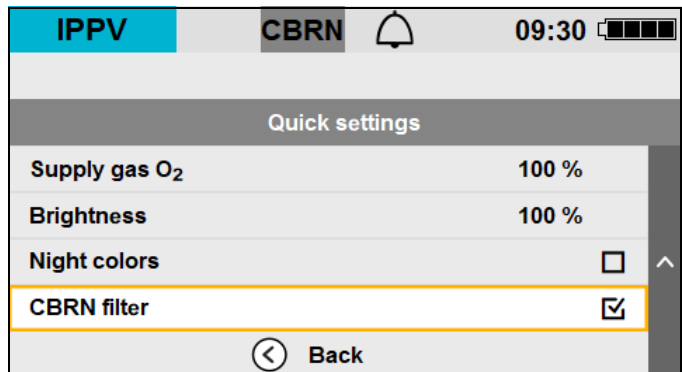If CBRN mode was not activated during the function check, there are 2 ways to activate CBRN mode subsequently:

- In the start menu: **Quick settings**
- During ventilation: **Device settings** in the user menu

6.1.1 Activating CBRN mode in the start menu

1. Briefly press the menu button (▤).
   The **Quick settings** context menu opens.

2. Navigate to menu item **CBRN filter** and activate it with the navigation knob.

3. To exit the menu: Select **Back** or press the menu button (⊞).
   The menu closes automatically after 5 seconds with no input.

6.1.2 Activating CBRN mode during ventilation

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

2. Select **Device settings** menu item using the navigation knob.
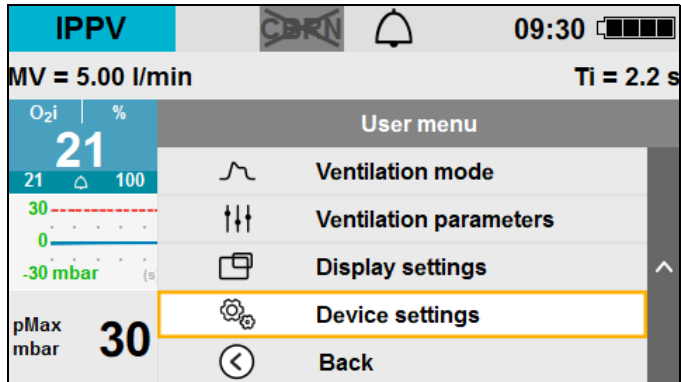

3. Navigate to menu item **CBRN filter** and activate it with the
   navigation knob.

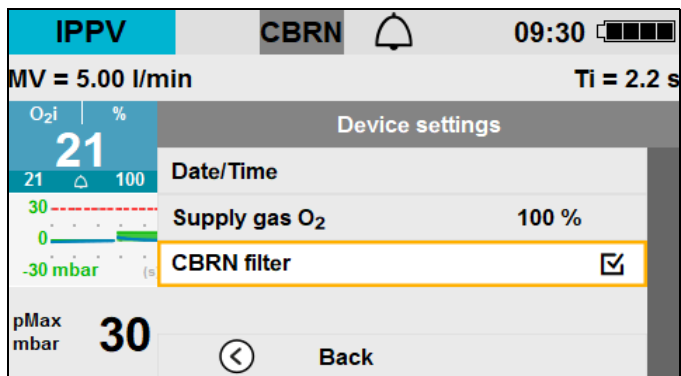4. To exit the menu: Select **Back** or press the menu button (⊞).
   The menu closes automatically after 5 seconds with no input.

7 Alarm messages

In addition to the alarm messages described in the instructions for use for MEDUVENT Standard from software version 3.1, the following alarm message is possible when the device is operated in CBRN mode.

7.1 High-priority alarms (red)

Alarm	Cause	Remedy
Oxygen inlet leakage	Oxygen inlet is not sealed and no oxygen is being supplied.	Seal oxygen inlet with protective cap for oxygen inlet or supply oxygen.

8 Hygienic reprocessing

⚠ WARNING

Risk of injury and infection from contaminated device and accessories!

The reprocessing and reuse of CBRN-contaminated parts can injure users or subsequent patients.

⇒ Wherever possible, decontaminate contaminated parts before disposal, otherwise dispose of them as hazardous waste in accordance with the applicable regulations.

⇒ Do not reprocess or reuse the breathing circuit with CBRN patient valve, CAD-MVS adapter for CBRN filter and CBRN filter.

⇒ Do not reuse MEDUVENT Standard if the inside of the device is suspected of being contaminated. Decommission the device.

After a session in a CBRN environment, all parts of the ventilation system are potentially contaminated and may not be reprocessed.

9 Storage

Observe the storage conditions and storage period for the device and accessories stipulated in the instructions for use for MEDUVENT Standard from software version 3.1.

10 Disposal

Follow the applicable regulations for the proper disposal of contaminated parts.

11 Scope of supply

11.1 Accessories and other parts

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

Designation	Supplementary information	UDI-DI	Article no.
Kit, connection for CBRN filter	For single use	–	WM 17750
Comprising:			
CAD-MVS adapter for CBRN filter	For single use	04054685300319	
CBRN patient valve	For single use	–	
Assembly instructions connection kit for CBRN filter	–	–	
Kit, connection for CBRN filter, with VENTcirc-MVS disposable breathing circuit, 2 m	For single use	–	WM 18090
Comprising:			
VENTcirc-MVS breathing circuit, 2 m, with CBRN patient valve	For single use	04054685270834	
Adapter for disposable breathing circuit	For CBRN application: for single use	–	
CAD-MVS adapter for CBRN filter	For single use		
Assembly instructions connection kit for CBRN filter	–	–	

Designation	Supplementary information	UDI-DI	Article no.
Kit, connection for CBRN filter, with VENTcirc-MVS disposable breathing circuit with FlowCheck, 2 m	For single use	–	WM 18096
Comprising:			
VENTcirc-MVS breathing circuit, 2 m, with CBRN patient valve	For single use	04054685270834	
FlowCheck sensor	For single use	04054685276539	
Adapter for disposable breathing circuit	For CBRN application: for single use	–	
CAD-MVS adapter for CBRN filter	For single use	04054685300319	
Assembly instructions connection kit for CBRN filter	–	–	
CBRN option	–	–	WM 35888
Instructions for use CBRN option for MEDUVENT Standard	–	–	WM 67921

12 Technical data

12.1 Device and accessories

Specification	Device and accessories
Classification according to maximum inward leakage and maximum particle filter permeability	EN 12942 TM 3 in combination with Dräger combination filter A2B2E2K2 P3 R D/NBC

12.2 CAD-MVS adapter for CBRN filter

Specification	CAD-MVS adapter for CBRN filter
Operation: Temperature range Relative humidity Air pressure	-20 °C to +50 °C 15 % to 95 %, no condensation 540 hPa to 1100 hPa
Storage/transport: Temperature range up to 48 h longer than 48 h Relative humidity Air pressure	-40 °C to +70 °C -20 °C to +40 °C 15 % to 95 %, no condensation 540 hPa to 1100 hPa

12.3 Breathing circuit

Specification	VENTcirc-MVS disposable breathing circuit with CBRN patient valve
Operation: Temperature range Relative humidity Air pressure	-20 °C to +50 °C 15 % to 95 %, no condensation 540 hPa to 1100 hPa
Storage/transport: Temperature range up to 48 h longer than 48 h Relative humidity Air pressure	-40 °C to +70 °C -20 °C to +40 °C 15 % to 95 %, no condensation 540 hPa to 1100 hPa
Compliance	0.90 ml/hPa (ml/cmH$_2$O)
Internal volume of entire breathing system • without FlowCheck sensor • with FlowCheck sensor	Approx. 616 ml Approx. 668 ml

Dead space volumes	Without elbow	With elbow
CBRN patient valve (disposable)	Approx. 10 ml	Approx. 18 ml

Pressure drop [hPa] over the section of inspiratory and expiratory flow at different flows [l/min] as per EN 794-3		
	Flow [l/min]	VENTcirc-MVS disposable breathing circuit WM 35935, for CBRN filter connection kit, 2 m, additionally with disposable FlowCheck sensor and elbow
Spontaneous breathing in the event of energy failure, inspiratory (STP)	2.5 l/min	< 1.25 hPa
	15 l/min	< 2.95 hPa
	30 l/min	< 5.75 hPa
Spontaneous breathing in the event of energy failure, expiratory (BTPS)	2.5 l/min	< 1.15 hPa
	15 l/min	< 2.1 hPa
	30 l/min	< 3.55 hPa
Normal operation, inspiratory (STP)	5 l/min	< 0.2 hPa
	30 l/min	< 0.9 hPa
	60 l/min	< 3.1 hPa
Normal operation, expiratory (BTPS)	5 l/min	< 3.0 hPa
	30 l/min	< 3.45 hPa
	60 l/min	< 6.6 hPa

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

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

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