TrachFlush

Instructions for Use

REF TFSAIN

Software version 4.1.x.x

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TrachFlush

Rx ONLY TrachFlush is for prescription use only

AW Technologies

TrachFlush

Instructions for Use

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AWT-1450

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Table of Contents

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Document conventions

WARNING

A WARNING alerts the user to the possibility of a serious adverse reactions associated with the use or misuse of the device.

CAUTION

A CAUTION alerts the user to the possibility of a problem with the device associated with its use or misuse, such as device malfunction, device failure, damage to the device, or damage to other property.

NOTICE

A NOTICE emphasizes information of particular importance.

Units of measure

The document uses cmH_2O representative for all pressure units. 1 cmH_2O equals 0.981mbar, which equals 0.981 hPa. The TrachFlush device is available upon order in cmH_2O and hPa versions.

General notes

WARNING

- MR UNSAFE. Keep away from magnetic resonance imaging (MRI) equipment. TrachFlush is not designed for the MR environment.
- Modifications to the device are not permitted.
- To prevent increased emissions, decreased immunity, or interrupted operation of the TrachFlush device or any accessories, use only accessories or cables that are expressly stated in this manual.

CAUTION

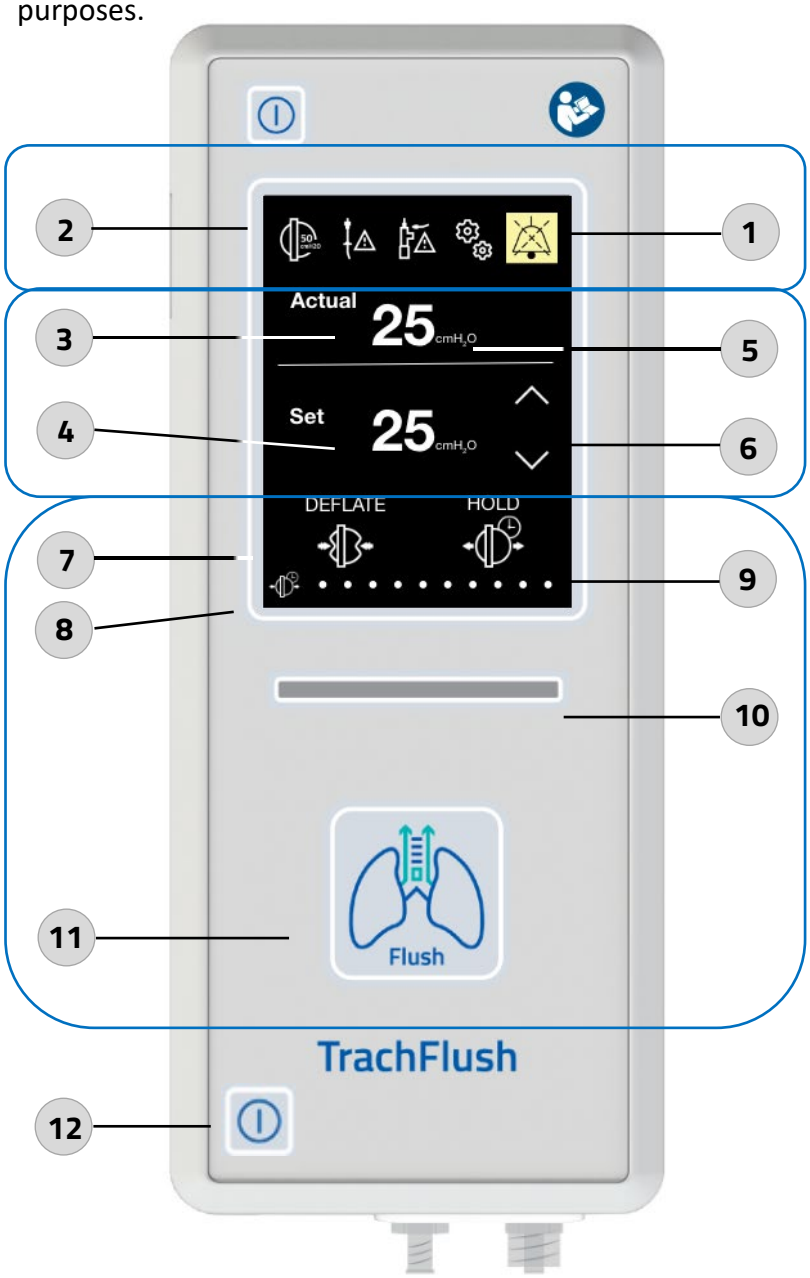
- Use only the AW Technologies disposable Cuff Pressure and Airway Tube Set and safety valve. Use of any other tubing will result in the immediate loss of cuff pressure if disconnected on the ventilator end. Use of any other tubing may result in the device being contaminated.
- Do NOT kink the tubing.

NOTICE

- The use of this equipment is restricted to one patient at a time who is intubated with an endotracheal tube or tracheal cannula (both are referred to as ET tube or ETT in this document).
- If there is visible damage to any part of the TrachFlush device, do not use the device. Technical service is required.
- Familiarize yourself with these Instructions for Use before using this device on a patient.
- To electrically isolate the TrachFlush device from all poles of the primary power supply simultaneously, disconnect the power plug.
- The device is not protected against the effects of defibrillator use.
- The manufacturer can only be responsible for the safety, reliability, and performance of the TrachFlush device if all the following requirements are met:
    - Appropriately trained personnel carry out assembly operations, extensions, readjustments, modifications, maintenance, or repairs.
    - The electrical installation of the relevant room complies with the appropriate requirements.
    - The TrachFlush device is used in accordance with the Instructions for Use.
- The TrachFlush device requires special precautions regarding EMC and must be installed and put into service according to the EMC information provided in the EMC declarations in section 12

1. Device overview

Not all elements are displayed at the same time and are only shown here for information purposes.



Alarms

1. Alarm silence button
2. Alarm bar

Pressure display

3. Actual cuff pressure
4. Set cuff pressure (target)
5. Unit of measure
6. Adjustment buttons

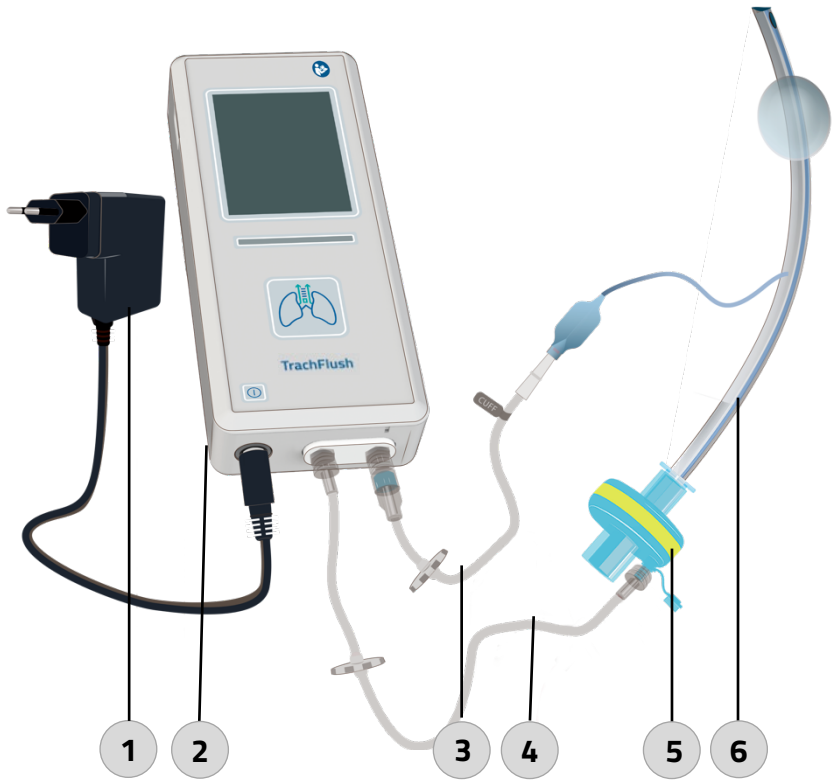
Control panel

7. Deflate cuff
8. Cuff-Hold information bar
9. Perform Cuff Hold
10. Alarm bar (LED)
11. Quick Deflate/Inflate cuff

Power

12. Power ON / OFF button

Figure 1: TrachFlush overview



TrachFlush connections

1. Power supply
2. TrachFlush
3. Cuff Tube
4. Airway Tube
5. HME filter
6. Endotracheal tube

Figure 2: TrachFlush connections

NOTICE

Only #1, #2, #3, and #4 above is a part of the TrachFlush device. The HME filter (#5) and the endotracheal tube (#6) is not a part of the TrachFlush device but is shown here for connectivity overview.

2. Getting started

2.1. Connect the device to primary power

WARNING

Only use the supplied PSU with the device, use of unauthorized PSU may damage the device. If the PSU is damaged a new PSU should be ordered from AW Technologies. (PSU part nr. AWT-1129)

Device contains no battery and must not be used during transport.

NOTICE

If power is lost, the device will alarm for 30 seconds while performing a safe shut down which prevents the cuff from deflating.

Connect the power cable as follows:

1. Connect the USA plug adaptor to the power adapter
2. Plug the adapter into a mains AC power source
3. Connect the power plug end of the power cable to the power port on the TrachFlush device. The power plug is locked to the device when inserted. (3) (To disconnect the power plug, pull on the housing of the power cable to disconnect)

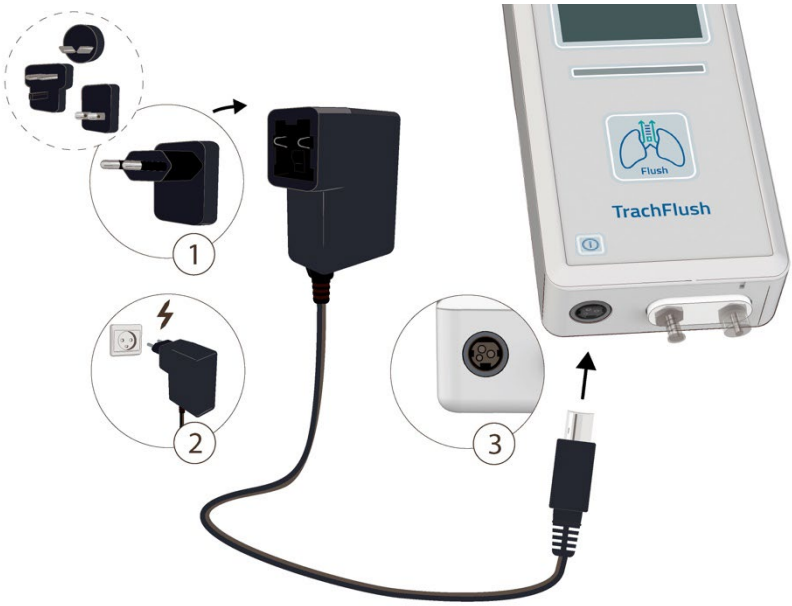


Figure 3: Connect power

2.2. Turn on or off the device

Long-Press the Power ON / OFF button (Long-press is more than three (3) seconds).

When turning on, the device performs a self-test, during which the display turns on, alarm bar lights up and the alarm sounds. If this does not occur, see Section 6.

Figure 4: Turn on / off the device

2.3. Calibration after turn on of device

Once the device is turned on, calibration is required. Remove tubes before calibration. To perform calibration, press  (accept) and await calibration. Once calibration is completed, connect tubes, see section 2.4.

Figure 5: Calibration process

NOTICE

If TrachFlush detects that the tubes are not removed prior to calibration, the arrows will be highlighted in red as shown in Figure 6.

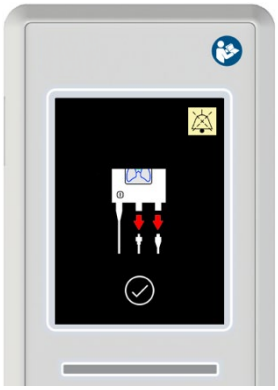


Figure 6: TrachFlush detects that tubes are not disconnected

2.4. Connect the Tubing Set to the device and patient

Following calibration, connect the Tubing Set as shown in Figure 7. Once connected, the device starts applying the set target pressure.

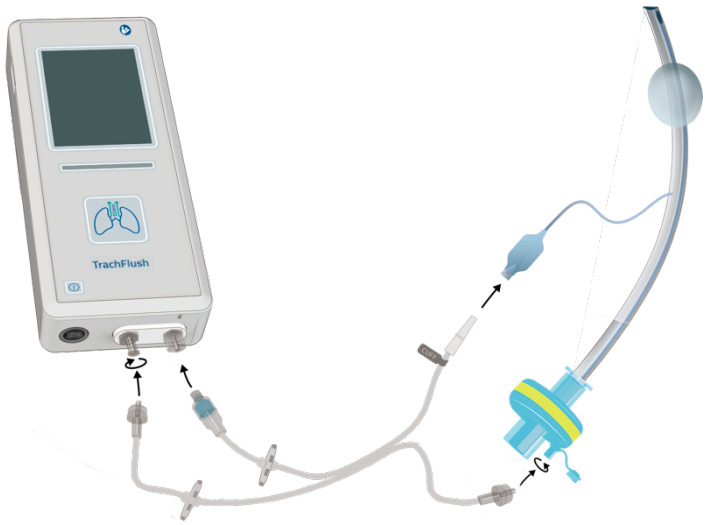


Figure 7: Connect Tubing Set

NOTICE

- *Only use an AW Technologies Cuff Pressure and Airway Tube Set (PN: TF-CO-IN)*
- *ET tube with high-volume cuffs may take longer to inflate*
- *The AW Technologies Cuff Pressure and Airway Tube Set (PN: TF-CO-IN) is intended for single patient use only and must be replaced if visible liquid accumulations occur in or around the filter(s) or in the tube(s).*

2.5. Check for airway and cuff leaks

Leaks in the airway. TrachFlush may help to reduce airway leakage around the cuff. You may increase the cuff pressure based on leakages detected by the ventilator. For pressure settings above 30 cmH_2O, consider using a larger tube. Also check the patient's throat for bubbling or gurgling sounds.

Leaks in the cuff. When present, the Cuff Tube not Connected alarm is generated on the TrachFlush device. See section 6 for further instructions on required action.

3. Review and adjust cuff pressure setting

For an overview of the pressure display, see Section 1.

The device shows both the Set and Actual Cuff Pressure of 25 cmH_2O.

NOTICE

It is recommend that you keep cuff pressure (default 25 cmH_2O) below 30 cmH_2O for adult ETTs/TTs.

To adjust the set (target) pressure:

1. Press the Increase ( ) or Decrease ( ) button to enable adjustment of the pressure.

   The set (target) pressure adjusts the Accept ( ) and Decline ( ) button appears.

2. Press the Accept ( ) button to apply the new setting, or press the Decline ( ) button to cancel the adjustment and return to previous setting.

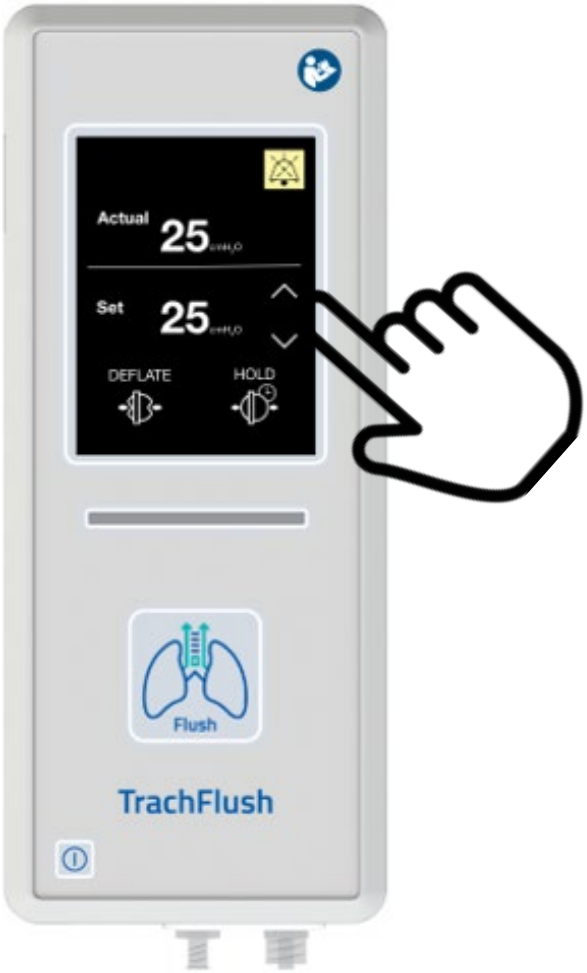


Figure 5: Adjust cuff pressure

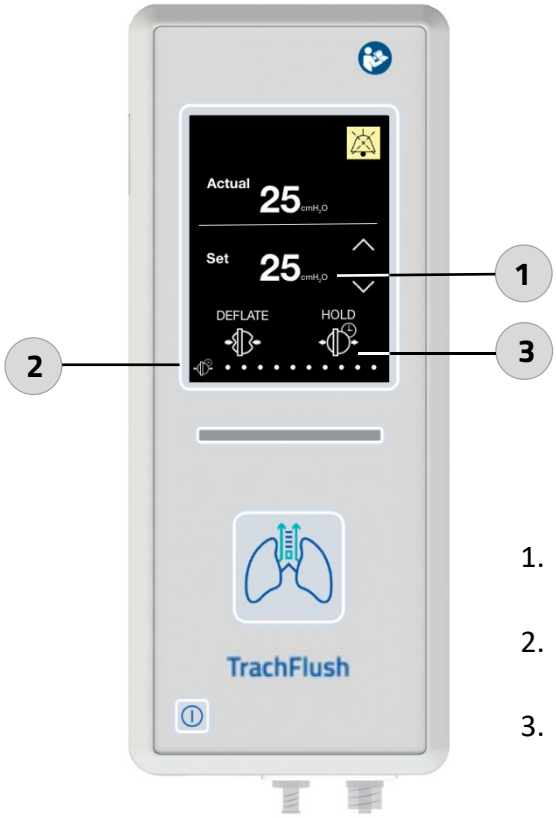
4. Cuff-Hold

The Cuff-Hold function can be activated by pressing the Hold button.

NOTICE

Any changes made to the hold pressure or time are reset to the factory defaults once the device is turned off.

The maximum pressure allowed under any circumstances is limited to a total of 55 cmH_2O.



1. The set target pressure plus the hold pressure
2. Time-limited hold timer (1 dot = 1 minute left)
3. Cuff-Hold button

Figure 6: Time-limited hold

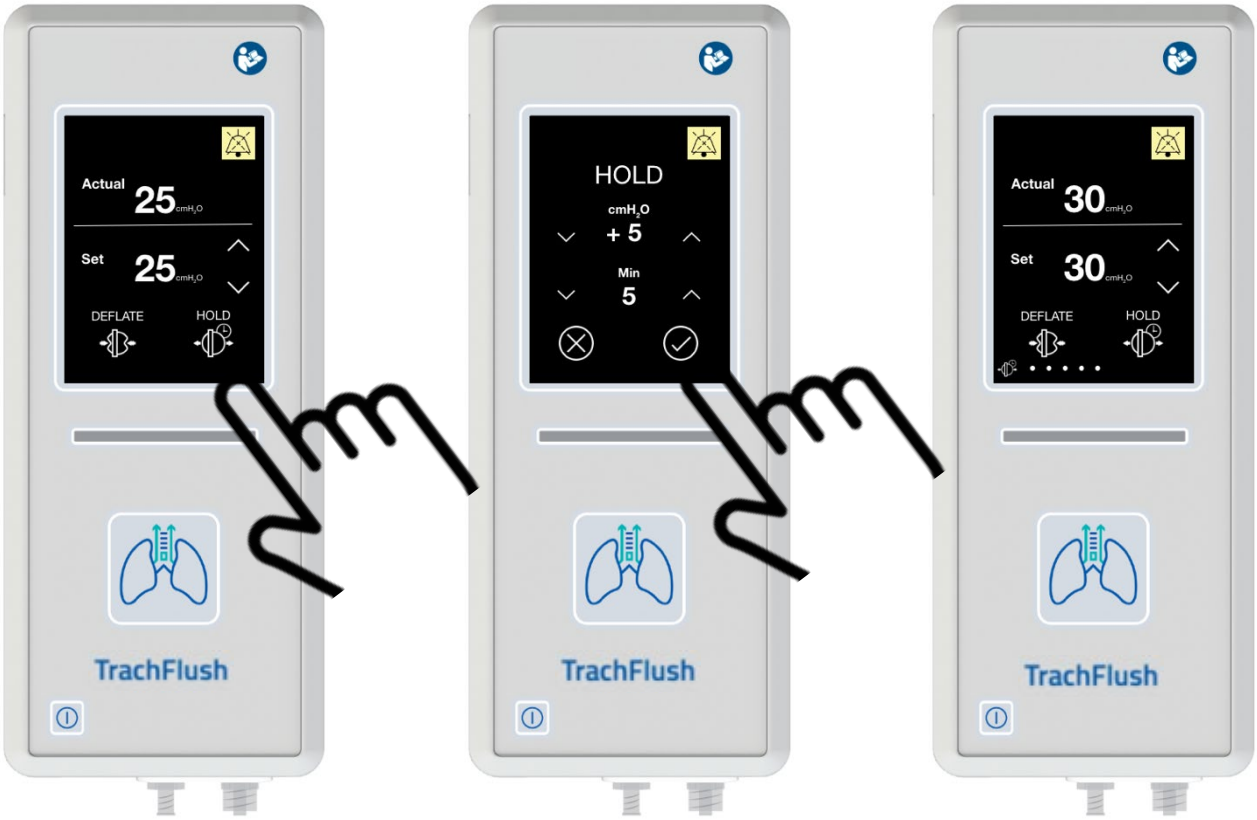
The Cuff-Hold function temporarily increases the cuff pressure by a specified amount for a set period of time to more completely seal the airway and prevent aspiration.

By default, hold is activated for 5 minutes and applies 5 cmH_2O above the currently set pressure.

You can change the increased pressure setting in 5 cmH_2O increments from a minimum of 5 cmH_2O to a maximum of 25 cmH_2O and set the hold duration to either 5 or 10 minutes.

For details on changing the duration of the hold, see Section 7.

4.1. To perform a Cuff-Hold



Press Hold button
Press the **(Hold)** button to activate Cuff-Hold

Press Accept button
Press the **(Accept)** button to activate time-limited hold

Hold in progress
Cuff-Hold information bar will display the remain time

During the Hold maneuver
The pressure increases to the set amount. The Cuff-Hold information bar on the display shows and displays the remaining time. Each of the dots indicates one minute left of the Hold maneuver. When set to five (5) minutes, five (5) dots are shown. When set to ten (10) minutes, ten (10) dots are shown.
As the Cuff-Hold information bar counts down, the dots disappear one by one from right to left until the Hold maneuver is complete. One dot disappears each minute.

At the end of the Hold maneuver

1. The device beeps to indicate the Hold maneuver is complete
2. The pressure returns to the previous target pressure.
3. The Cuff-Hold information bar disappears (no dots are shown).

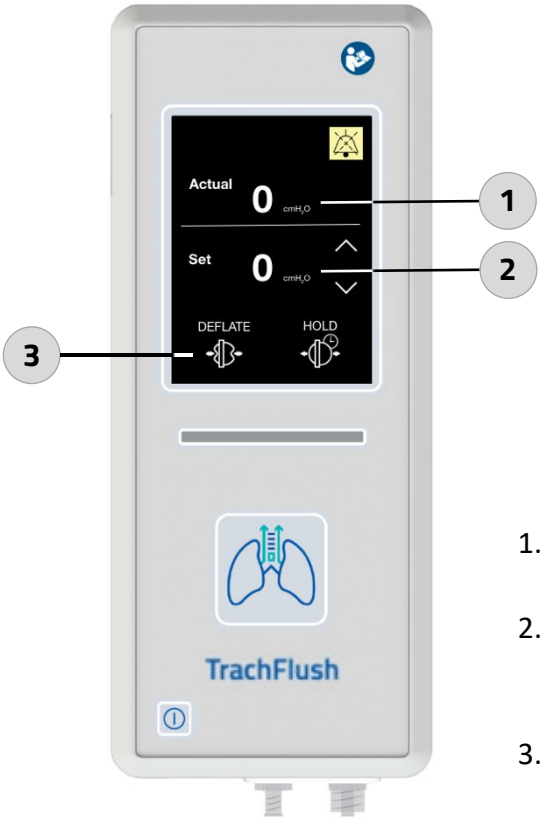
Stop the Hold at any time
Press the Hold button on the display to cancel the Hold maneuver and return the previous target pressure.

5. Deflate cuff

WARNING

Do not rely on the TrachFlush device to fully deflate the cuff, as some cuff's have an internal volume of air at zero pressure. Always manually deflate the cuff before adjustment or extubation.

The deflation function can be activated by pressing the Deflate button.



1. The actual cuff pressure when deflated
2. Target pressure sets to 0 when Deflate function is activated
3. Deflate button

Figure 7: Deflation

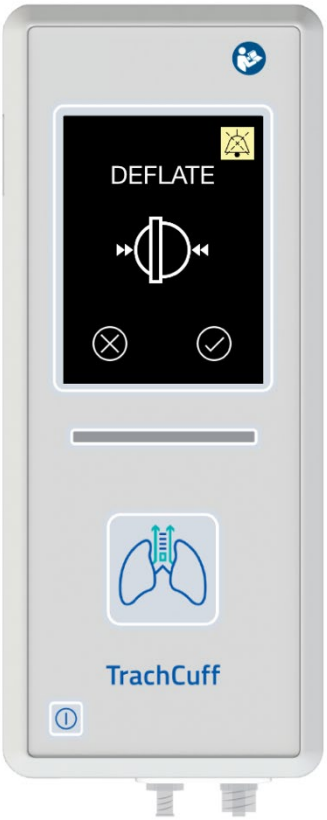
The Deflate function deflates the cuff to 0cmH2O upon activation by the user to allow for decuffing of the patient and extubation.

By default, the cuff is kept deflated for an unlimited period of time. However, if the cuff is deflated for > 60 seconds without being either reinflated or the device being turned off, you are reminded through an alarm that you deflated the cuff and that the cuff is still in the deflated state.

5.1. To deflate the cuff

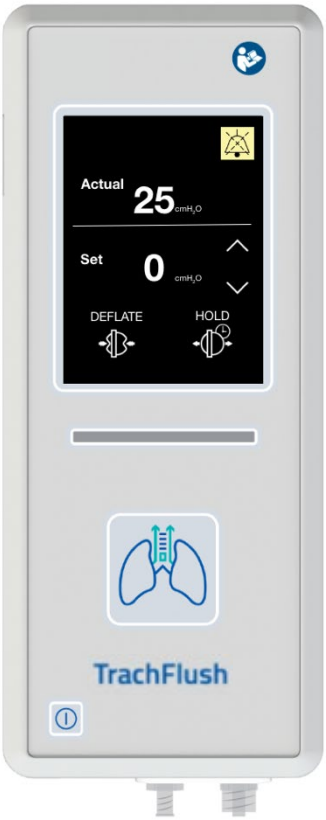
Press Deflate button

Press the **(Deflate)** button to activate deflation



Press Accept button

Press the **(Accept)** button to activate deflation



In progress

Set is 0 cmH_2O and actual pressure starts decreasing to 0 cmH_2O

To Deflate the cuff

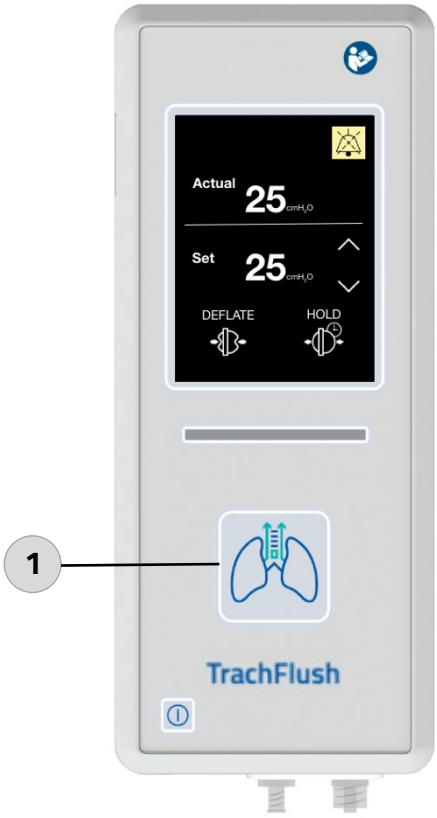
1. The device beeps to indicate that the deflation is in progress. The target pressure displays 0 and the device applies negative pressure until the actual pressure is 0 cmH_2O.
   When the pressure reaches 0 cmH_2O, the actual and set pressure both display 0. The device beeps again to indicate that the cuff is deflated.

2. After deflating the cuff, you can extubate the patient, disconnect the TrachFlush device from the ETT/TT tube.

3. Turn of the device within 1 minute of deflating the cuff.
   If the cuff is deflated for > 60 seconds without being either reinflated or the device being turned off, you are reminded that you deflated the cuff and that the cuff is still in the deflated state.

6. Quick Deflate and Inflate cuff

The Quick Deflate/Inflate function can be activated by pressing the Deflate/Inflate button.



1. Quick Deflate/Inflate button

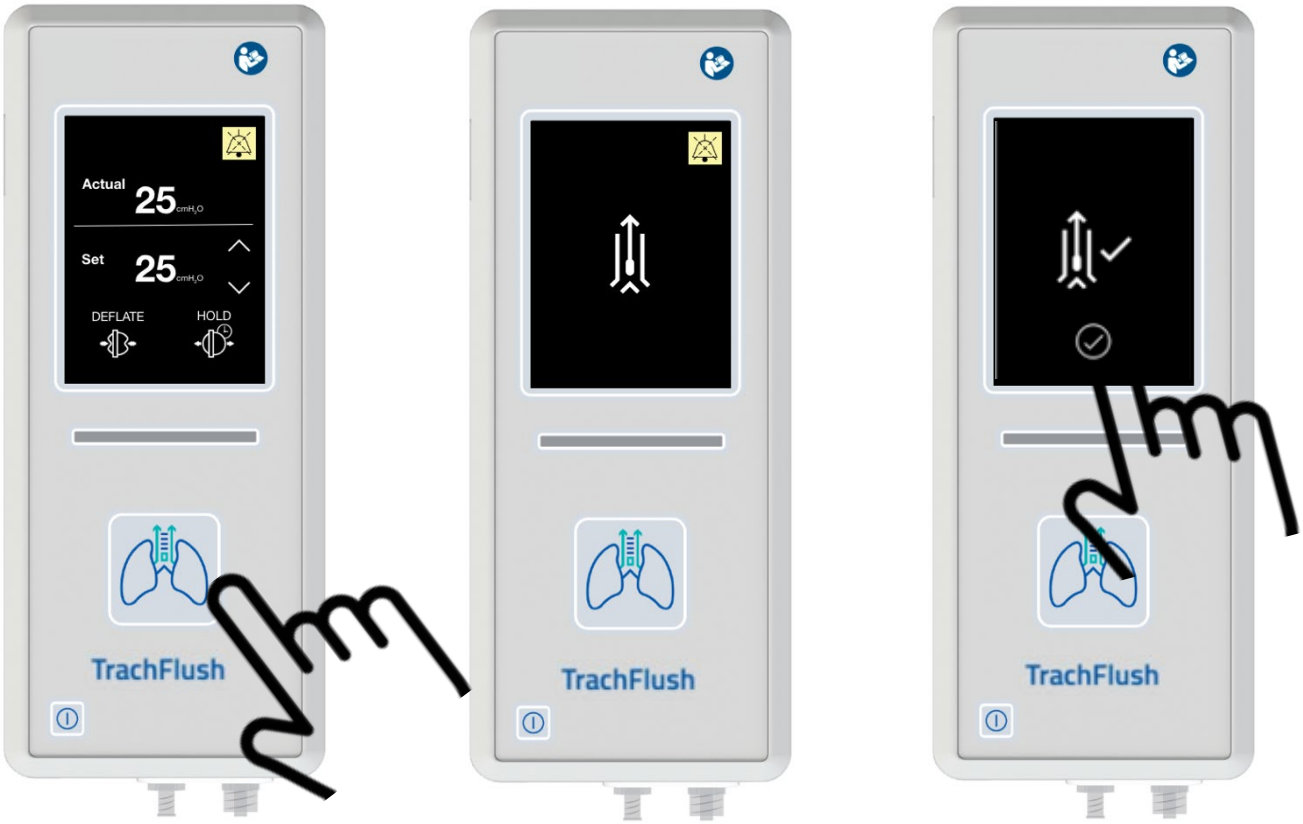
Figure 8: Deflation/inflation

The Quick Deflate/Inflate function deflates the cuff to 0cmH_2O and inflates the cuff to set target pressure during an inspiratory cycle upon activation to allow for temporary decuffing of the patient.

The device applies negative pressure until the actual pressure is 0 cmH_2O. Once reached, the device applies positive pressure to re-inflate the cuff to the set target pressure. When the function has started (deflation is started), the maneuver cannot be exited. If the power source is lost, TrachFlush will have sufficient backup power to complete the function before shutting down safely.

The complete time of the Quick Deflate/Inflate function is equal to the time of one inspiratory cycle.

6.1. To Quickly Deflate/Inflate the cuff



Press button

Press the (**deflation/ inflation)** button to activate the

In progress

TrachFlush displays the deflate and inflate symbol

Complete

Deflate and inflate complete, press the **(Accept)** button

To Quickly Deflate / Inflate the cuff

1. Long-press the Deflate/Inflate button for > 3 seconds.

   The device displays the Deflate/Inflate icon to indicate that the Deflate/Inflate is in progress.

   When the pressure reaches 0 cmH_2O, the device re-inflates the pressure to the set target.

2. Press the (Accept) button

7. Alarms and troubleshooting

When an alarm is generated, the device emits audible beeps and the alarm bar lights white, yellow or red, depending on the alarm priority. The TrachFlush device has four alarm types: high-priority, medium-priority, low-priority, and technical. See Table 1and Table 2 for details.

Information signals triggers a sequency of audible beeps and the alarm bar lights cyan. See Table 1 and Table 3 for details.

To silence an alarm or information signal

- Review the alarm or information signal and, if appropriate, press the Alarm silence button. The Alarm is silenced for 2 minutes.

Table 1: TrachFlush alarm types and information signals

Type	Lamp	Audio response	Action required
High-priority alarm	Color: Red Flashing: 2,5Hz Duty cycle: 50% on	A sequence of beeps, repeated until the alarm is reset. Nodes: C5 A5 F5 – A5 F5 Sound level: 50dB ± 6	Depends on the alarm; see Table 2
Medium-priority alarm	Color: Yellow Flashing: 0,8Hz Duty cycle: 60% on	A sequence of beeps, repeated periodically. Nodes: C5 C4 C5 Sound level: 50dB ± 6	Depends on the alarm; see Table 2
Low-priority alarm	Color: Yellow Flashing: No, steady light	A sequence of beeps. Nodes: E5 C5 Sound level: 50dB ± 6	Depends on the alarm; see Table 2
Technical alarm	Color: White Flashing: 1Hz Duty cycle: 50% on	A sequence of beeps, repeated until the device is turned off. The alarm cannot be silenced. Nodes: E5 C5 Sound level: 50dB ± 6	Depends on the alarm; see Table 2
Information signal	Color: Cyan Flashing: No	A sequence of beeps. Nodes: E5 C5 Sound level: 50dB ± 6	Depends on the signal; see Table 3

7.1. Alarms

Table 2: TrachFlush alarm names and symbols

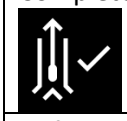
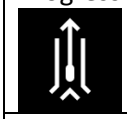
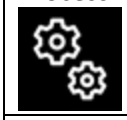
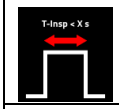
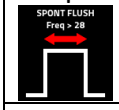
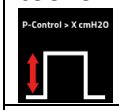
Alarm name	Alarm type	Possible causes	Action required
Cuff system leakage 	High-priority alarm Color: Red, flashing	Cuff loses pressure The cuff tube is not correctly connected	Check and change ETT/TT if needed Check and change the Cuff Pressure and Airway Tube Set and safety valve if needed If not solved, disconnect device from patient and proceed with appropriate alternative treatment.
Pressure above set limit 	Medium-priority alarm Color: Yellow, flashing	The device is unable to meet the specified pressure setting	Check cuff tube, ETT/TT, all connections Replace the tube
Cuff Pressure >50cmH2O 	Medium-priority alarm Color: Yellow, flashing	Cuff pressure is above 50cmH2O.	Lower the cuff pressure
Cuff Pressure <5cmH2O 	Medium-priority alarm Color: Yellow, flashing	Cuff pressure is lower than 5cmH2O	Increase cuff pressure
Cuff Deflated 	Medium-priority alarm Color: Yellow, flashing	Cuff has been deflated over 1 minute	Increase cuff pressure
User Shutdown Denied 	Medium-priority alarm Color: Yellow, flashing	Cuff pressure is above 5 cmH_2O when trying to turn off the device.	Wait 20 sec and try again.
Power Failure 	Low-priority alarm Color: Yellow, constant light	Power supply has been disconnected	Make sure the power supply is connected to the device and a power source

Alarm name	Alarm type	Possible causes	Action required
Service 	Technical alarm Color: White, flashing	Various	Disconnect the device and send to service.

Should multiple alarms occur at the same time, the alarm with the highest priority will be shown on top.

7.2. Information signals

Table 3: Information signals

Alarm name	Alarm type	Possible causes	Action required
Cuff Tube not Connected 	Information signal	Cuff tube not connected correctly	Check cuff tube connection
Airway Tube not Connected 	Information signal	Airway tube not connected correctly	Check airway tube connection
Deflation / inflation Complete 	Information signal	Deflation and inflation function completed	Reset ventilator settings if adjusted before performing a deflation and inflation
Deflation / inflation in Progress 	Information signal	Deflation and inflation function in progress	Wait until Deflation and inflation function is complete.
Starting up 	Information signal	Start up in progress	Wait until the start up screen disappears.
Processing 	Information signal	Preparing for Deflation and inflation function	Wait until the device is ready before activating Deflation and inflation function.
Inspiratory time too short 	Information signal	Inspiratory time too short for Deflation and Inflation function	Increase inspiratory time
Respiratory frequencey too high 	Information signal	Respiratory frequency too high for Deflation and Inflation function	Reduce respiratory frequency
Ventilator pressure too low 	Information signal	Ventilator pressure too low for Deflation and Inflation function	Increase ventilator pressure
Return ventilator settings 	Information signal	Return to the settings prior to activating Deflation and Inflation function	Return ventilator settings

Unstable ventilator signal 	Information signal	Unstable ventilator signal for Deflation and Inflation function	Stable ventilator signal
Ventilator settings OK 	Information signal	Ventilator settings OK for Deflation and Inflation function	Deflation and Inflation function can be activated

8. Configuring time-limited hold settings

Any changes/configurations you make to the TrachFlush device's default settings will only apply until the device is turned off. When it is turned on again, the device resets to the factory default settings.

You can configure the amount of pressure the Hold function will add to the target pressure during a Hold maneuver (Hold pressure) and the time of the Hold maneuver (Hold time).

1. The Hold pressure can be set in increments of 5 cmH_2O, from a minimum of 5 cmH_2O to a maximum of 25 cmH_2O.
2. The Hold time can be set to 5 minutes or 10 minutes

The device must be turned on when you start configuration. Make sure the device is running

Press Hold button
Press the **(Hold)** button to open the configuration menu

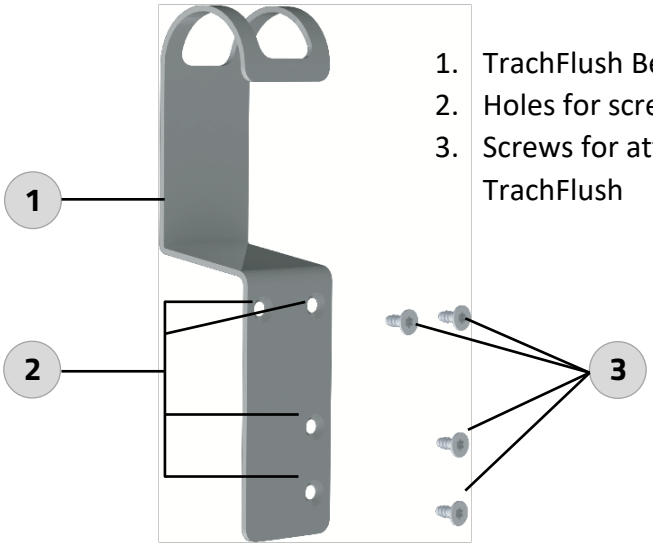
Adjust Hold pressure
Use the buttons to adjust the Hold pressure

Adjust Hold time
Use the buttons to adjust the Hold time

9. Mounting the TrachFlush device

The TrachFlush has a bed-side bracket mounting option available.

The back of the TrachFlush device is designed for the bed-side bracket to be attached directly using the included screws and hexagon key.



1. TrachFlush Bed-side bracket
2. Holes for screws
3. Screws for attachment to TrachFlush

Figure 9: Bed-side bracket overview

Attach or detach the bed-side bracket to the TrachFlush device

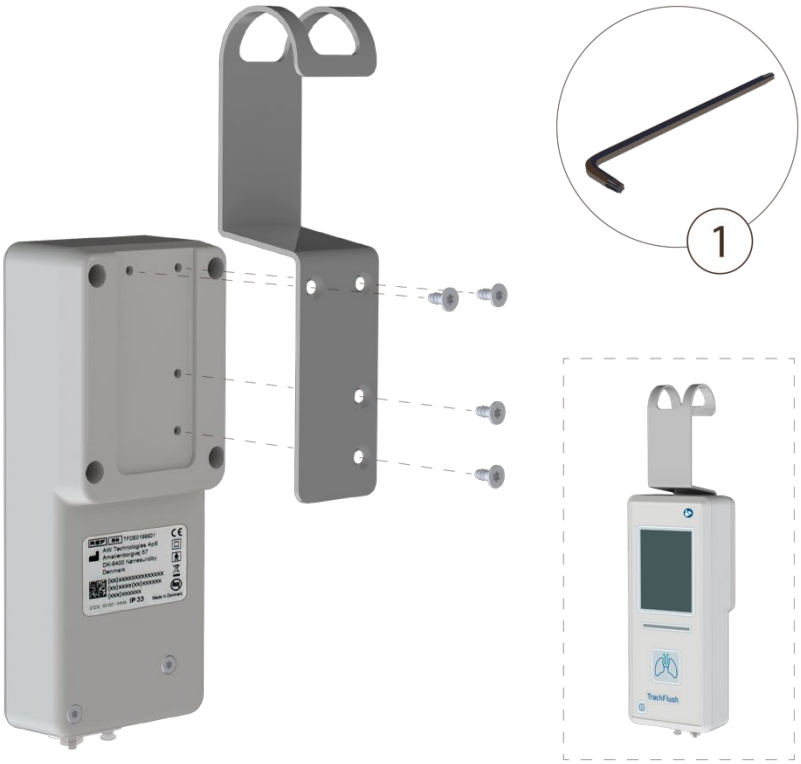


Figure 10: Mounting bed-side bracket

10. Cleaning, reprocessing, and maintenance

10.1. Cleaning and reprocessing of TrachFlush device and equipment

WARNING

Always disconnect the device from mains power before cleaning.

CAUTION

Use of cleaning and disinfection agents other than recommended may cause damage to or deterioration of the device materials and device failure may result.

The use of abrasive cleaning tools or brushes, or applying excessive mechanical force to the device surfaces during cleaning and may damage the device's materials and device failure may result.

Avoid excessive pulling on the power supply cable during cleaning and disinfection or damage to or deterioration of the cable may result.

NOTICE

Strong solvents, such as acetone or trichlorethylene, may damage the surface

Be sure to only clean around the connection ports, not inside them

Be particularly careful with infectious patients and follow your hospital infection protocol procedures.

Recommended Cleaning and Disinfection Agents

The following agents are recommended for use with the TrachFlush device, mounting bracket, and mains power supply.

Refer also to the Instructions for Use for the listed agent manufacturers for information on application, contact time, and disposal.

Table 4: List of recommended agents for cleaning and disinfection.

Agent Name / Mfgr.	Application	Composition – Active Ingredients
WEBCOL® Alcohol Prep Pads (Kendall) or equivalent	Cleaning and low-level disinfection	70% Isopropyl Alcohol
Super Sani-Cloth® (PDI, Inc.)	Cleaning and intermediate-level disinfection (quaternary ammonium/alcohol blend)	0.25% n-Alkyl (68% C_{12}, 32% C_{14}) dimethyl ethylbenzyl ammonium chlorides 0.25% n-Alkyl (60% C_{14}, 30% C_{16}, 5% C_{12}, 5% C_{18}) dimethyl benzyl ammonium chlorides 55% Isopropyl Alcohol
Sani-Cloth® Bleach (PDI, Inc.)	Intermediate-level disinfection (including pathogens *C. difficile*, Norovirus as supported by agent claims)	0.63% Sodium Hypochlorite

Webcol® is a registered trademark of Kendall Company, under ownership of Medtronic Inc.
Sani-Cloth® is a registered trademark of Professional Disposables International, Inc.

Reprocessing Instructions

Table 5: Instructions for cleaning, disinfection, and reprocessing of the equipment.

Initial treatment:	Power down TrachFlush and disconnect power supply from AC mains power
Preparation before cleaning:	Visually inspect TrachFlush and accessories for damage before cleaning. If damage is found, take the device out of operation.
Manual Cleaning and Low-level Disinfection:	Gently wipe TrachFlush and accessory surfaces with the 70% isopropyl alcohol wipe to remove any visible soil. Use additional wipes as needed to remove any visible soil.
Manual Cleaning and Intermediate-level Disinfection:	Manual Cleaning: Gently wipe TrachFlush and accessory surfaces with the quaternary ammonium/ alcohol wipe. Use additional wipes as needed to remove all visible soil prior to disinfection.
	Disinfection: Allow treated surfaces to remain visibly wet for the full manufacturer's specified wet contact time – use additional wipes as needed to achieve the wet contact time. Refer to the agent manufacturer's instructions for use.
Intermediate-level Disinfection:	Visually inspect for contaminants and soil on surfaces and remove prior to disinfection. Gently wipe the surfaces of TrachFlush and accessory surfaces with the bleach wipe. Allow treated surfaces to remain visibly wet for the full manufacturer's specified wet contact time – use additional wipes as needed to achieve the wet contact time. Refer to the agent manufacturer's instructions for use.
Drying:	Allow surfaces to dry fully before placing reprocessed items back into service.
Inspection and Maintenance:	Visually inspect the TrachFlush and accessory surfaces after reprocessing: If visual evidence of soil is found, repeat reprocessing until a visually clean condition has been reached. If damage is found, take the device out of operation.
Reuse Life:	TrachFlush and accessories have been validated for the stated reprocessing cycles: Manual cleaning, low-level and intermediate-level disinfection: up to 600 cycles Intermediate level disinfection (bleach wipes): up to 150 cycles

The Cuff Pressure and Airway Tube Set (P/N TF-CO-IN) is intended for single patient use only and should be disposed in accordance with local regulations for contaminated and biologically hazardous items.

10.2. Maintenance of TrachFlush device

The TrachFlush device does not contain any replaceable parts. Preventive maintenance or service is not mandatory, except for cleaning. However, if preventive maintenance is required by hospital protocol, AW Technologies recommends to perform the tests once per year as described in section 16, Service.

10.3. Disposal of TrachFlush device

Dispose of all parts removed from the TrachFlush device according to your institution's protocol. Follow all local, state, and federal regulations with respect to environmental protection, especially when disposing of the electronic device or parts of it.

11. Intended use and operators

11.1. Intended use and Indications for Use

The TrachFlush device is intended to continuously measure and automatically maintain the user-set cuff pressure of an endotracheal tube (ETT) or tracheostomy tube (TT) during mechanical ventilation.

TrachFlush can be used with any mechanical ventilator.

The TrachFlush is to be used during ventilation of adults at least 18 years who are intubated with ETT or TT, in the following areas:

- In the intensive care ward by Respiratory Therapists

Prescription use only

11.2. Intended operators

The TrachFlush device is a medical device intended for use by qualified, trained personnel under the direction of a licensed physician and within the limits of its stated technical specifications.

CAUTION

(USA only): Federal law restricts this device to sale by or on the order of a physician.

11.3. Contraindications

There are no contraindications for the TrachFlush itself.

11.4. Limitations for use

The TrachFlush Cuff Controller is limited to be used only with cleared endotracheal tubes and/or tracheostomy tubes with the following characteristics:

- Air-inflatable cuff
- Luer port connection with valve
- Cuff pressure operating range 5-50cmH_2O

11.5. Essential Performance

The applied cuff pressure must be maintained and monitored. If it is higher or lower than the set limits, this must be detected and the operator must be informed through an alarm.

12. Standards and approvals

TrachFlush was developed in accordance with pertinent international standards and FDA guidelines.

The device is manufactured under a quality management system compliant with

- ISO 13485:2016/AC:2018 Medical devices - Quality management systems - Requirements for regulatory purposes and;
- FDA 21 CFR Part 820 Quality System Regulation (QSR)

The device meets the essential requirements of Council Directive 93/42/EEC as amended in 2007/47/EC. It is a class I device.

The device meets relevant parts of, among others, the following standards:

- ISO 14971:2019 Medical devices – Application of risk management to medical devices.
- IEC 60601-1:2006+A1:2013+A12:2014 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014 Medical electrical equipment - Electromagnetic compatibility
- IEC 62304:2006 +A1:2015 Medical device software – Software life-cycle processes
- IEC 62366-1:2015 Medical devices – Usability
- IEC 60601-1-8:2007/A1:2013 Medical electrical equipment – Alarm systems

13. EMC Declarations IEC 60601-1-2:2014

Medical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document.

The TrachFlush device complies with IEC 60601-1-2:2014, providing reasonable protection against electromagnetic interference in a typical medical installation. The equipment generates, uses and can radiate electromagnetic interference (EMI), and if not installed and used in accordance with the instructions, may cause interference with other devices in the vicinity.

The Essential Performance of the TrachFlush device is: The applied cuff pressure must be maintained and monitored. If it is higher or lower than the set limits, this must be detected, and the operator informed through an alarm.

Interference caused by electromagnetic interference may cause temporary interruptions, which may trigger an alarm, where recovery from the disruption within 30 seconds without operator intervention is allowed. The TrachFlush device is designed to handle such interruptions and will return to normal operation, when the electromagnetic interference is removed. This ensures that the subsequent calculation of ventilator setting advices are kept intact.

If interference does occur, correct it using on or more if the following measures:

- Move the receiving device or increase separation between the equipment.
- Consult your dealer of the TrachFlush device or members of the hospital's engineering department for more information.

The TrachFlush device complies with the requirements of AIM Standard 7351731 regarding EMC test for RFID immunity using the test procedure AIM RFID. Interference caused by RFID readers may cause temporary interruptions, which may trigger an alarm. The TrachFlush device is designed to handle such interruptions and will return to normal operation, when the RFID reader is moved to a safe distance from the TrachFlush device.

WARNING

Portable RF equipment and communications devices (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the TrachFlush device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The use of accessories and cables other than those specified for the TrachFlush device may increase emissions or decrease immunity of the equipment.

The TrachFlush device is not to be used in or brought into an environment where MRI, diathermy and electrocautery is used.

NOTICE

Observe precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and find other equipment.

Sudden erratic changes in equipment performance that do not correlate to the physiological condition of the patient may be signs that the device is subject to electromagnetic interference.

Guidance and manufacturer's declaration – electromagnetic emissions		
TrachFlush is intended for use in the electromagnetic environment specified below. The customer or the user of the TrachFlush device should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	TrachFlush uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class A	TrachFlush is suitable for use in its use environment
Harmonic emissions IEC 60000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
TrachFlush is intended for use in the electromagnetic environment specified below. The customer or the user of the TrachFlush device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	⍰8 kV contact ⍰15 kV air	⍰8 kV contact ⍰15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment

	±2 kV common mode	±2 kV common mode	
Voltage dips, short interruptions and voltage variations on power supply input lines (50/60Hz) IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle) 40% U_T (60% dip in U_T) for 5 cycles) 70% U_T (30% dip in U_T) for 25 cycles) <5% U_T (>95% dip in U_T) for 5 s)	<5% U_T (>95% dip in U_T) for 0.5 cycle) 40% U_T (60% dip in U_T) for 5 cycles) 70% U_T (30% dip in U_T) for 25 cycles) <5% U_T (>95% dip in U_T) for 5 s)	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruption, it is recommended that TrachFlush be powered from an uninterruptible power supply.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristics of a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level			

Guidance and manufacturer's declaration – electromagnetic immunity

TrachFlush is intended for use in the electromagnetic environment specified below. The customer or the user of the TrachFlush device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM band	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM band	Field strengths from fixed RF transmitters as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz Up to 28 V/m for RF wireless communication equipment	3 V/m 80 MHz to 2.5 GHz Up to 28 V/m for RF wireless communication equipment	

NOTE 1 - At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 - These guidelines may not apply in all situations. Electromagnetic propagations is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which TrachFlush is used exceeds the applicable RF compliance level, TrachFlush should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating TrachFlush.

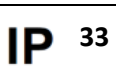
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

14. Specifications

14.1. Physical, performance, and environmental data

Physical characteristics	
Weight (without Bed-side bracket)	500g (grams)
Dimensions (without Bed-side bracket)	Length: 22cm Width: 8cm Height: 4,9cm
Technical performance data	
Cuff pressure set range	5 cmH_2O to 50 cmH_2O
Default target pressure	25 cmH_2O
Resolution (setting/display)	± 1 cmH_2O
Pressure accuracy	± 1 cmH_2O
Cuff-Hold	
Above pressure target	5 cmH_2O to 25 cmH_2O (increments of 5)
Hold duration time	5 minutes or 10 minutes
Electrical specifications	
AC Power Input	100-240 VAC, 50/60 Hz 24VA
DC Power Input	5V DC 24VA
Fuses	Fuses are integrated in the power supply unit (non-replaceable)
Alarm volume	50 dB(A) ± 6 dB(A)
Environmental conditions	
Relative humidity	Operating: 30% to 75%, noncondensing Storage/transport: 5% to 95%, noncondensing
Temperature	Operating: 5°C to 35°C Storage/transport: -15°C to 70°C
Operating atmospheric pressure range	70,0 kPa to 106,0 kPa
Operational noise level	< 40 dB(A)

14.2. Symbols on labels

Symbol	Description
	Manufacturer information
	MR Unsafe
	ATTENTION: Follow Operator's Manual
	CE Marking of Conformity
	Medical prescription
	Type BF Applied Part (IEC 60601-1) (protection against electrical shock)
	Class II Equipment
	The equipment should not be disposed of in the normal waste stream
	Serial number
	AW Technologies Reference or Part Number
	Temperature limits
	Ingress Protection. Protected from water spray less than 60 degrees from vertical and protected from particles larger than 2.5 mm
	DC Current/Voltage
	Batch code
	Do not reuse
	Do not use if packaging is damaged
	Not made with natural rubber latex
	ON / OFF button (for powering on and powering off the device)

15. Parts and accessories

Name	AW Technologies Part number
TrachFlush Instructions for Use *(this document)* 	AWT-1450
Cuff Pressure and Airway Tube Set Package Sheet 	AWT-1451
Cuff Pressure and Airway Tube Set 	TF-CO-IN
TrachFlush Bed-side bracket 	AWT-1117
Power Supply incl. adaptors 	AWT-1130

16. Warranty

LIMITED WARRANTY

THE WARRANTY DESCRIBED IN THIS AGREEMENT IS IN LIEU OF ANY AND ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. HOWEVER, IMPLIED WARRANTIES ARE NOT DISCLAIMED DURING THE PERIOD OF THIS LIMITED WARRANTY.

AW Technologies guarantees its products to be shipped free from defect in material and workmanship. The warranty does not include disposable items. Disposable items and consumable products are considered to be of single use or of limited use only and must be replaced regularly as required for proper operation of the product following the operator's manual.

AW Technologies as the manufacturer shall have no obligations nor liabilities in connection with the product other than what is specified herein, including without limitation, obligations and/or liabilities for alleged negligence, or for strict liability. In no event shall the company be liable for incidental or consequential damages, either direct or contingent.

This Limited Warranty shall be void and not apply:

1. If the product has not been installed and connected by an authorized local representative of AW Technologies in accordance with the instructions furnished by AW Technologies and by an AW Technologies representative.
2. If no evidence is present that the occurrence of damage/repair happened within the certified warranty period.
3. If the serial number has been altered effaced or removed and there is no bill of sale or evidence to verify the product's purchase date.
4. If the defects arise from misuse, negligence, or accidents or from repair, adjustment, modification, or replacement made outside AW Technologies' factories or other than an authorized service center or authorized service representative.
5. If the product has been modified, or in any nature altered without prior written authorization from AW Technologies
6. If the product is or has been used in any way that is not specified under "Intended Use".
7. If the product has been used by anyone but properly trained personnel under the supervision of a physician.

Replacement and/or repairs furnished under this Limited Warranty do not carry a new warranty but carry only the unexpired portion of the original Limited Warranty. The warranty of repaired and/or replaced components does not exceed the Limited Warranty of the device.

To obtain service under this Limited Warranty, claimant must promptly notify the country's sales partner of AW Technologies regarding the nature of the problem, serial number, and the date of purchase of the product.

Except as stated above, AW Technologies shall not be liable for any damages, claims or liabilities including, but not limited to, personal bodily injury, or incidental, consequential, or special damages. Nor will AW Technologies be liable for any damages, claims or liabilities including, but not limited to, personal bodily injury, incidental, consequential, or special damages resulting from misuse of the device or failure to comply with any of the provision made in this manual.

16.1. Miscellaneous

The general terms and conditions of AW Technologies shall be applicable. This agreement shall be governed by and construed in according with the laws of Denmark and may be enforced by either party under the jurisdiction of the court of Copenhagen, Denmark.

17. Service

17.1. Introduction

This section describes what steps should be done in case a preventive maintenance is required.

- The TrachFlush device does not contain any replaceable parts. Preventive maintenance or service is not mandatory, except for cleaning. However, if preventive maintenance is required by hospital protocol, AW Technologies recommends to perform the tests once per year as described in this section.
- Only hospital technicians are allowed to perform the tests.
- If any test will not pass, do not use the device, and call your local distributor

17.2. Requirements

Before you begin, ensure you have

- A functional TrachFlush
- A functional Cuff Pressure and Airway Tube Set (PN: TF-CO-IN).
- An endotracheal tube
- An external pressure gauge

17.3. Primary Function Tests

The primary function tests comprise three separate tests:

- Pressure test
- Leakage alarm test
- Deflation test

17.4. Test protocol

TrachFlush serial number:_____

Pressure Test	Performed	
	Yes	No
Connect TrachFlush to the Cuff Pressure and Airway Tube Set (PN: TF-CO-IN).		
Connect the external pressure gauge to the Cuff Pressure and Airway Tube Set – Cuff Tube.		
Set the cuff pressure to 5 cmH2O.	Performed	
	Yes	No

Verify that the externally measured cuff pressure is 5 cmH2O ± 1 cmH2O.	Passed	
	Yes	No
Set the cuff pressure to 20 cmH2O.	Performed	
	Yes	No
Verify that the externally measured cuff pressure is 20 cmH2O ± 1 cmH2O.	Passed	
	Yes	No
Set the cuff pressure to 30 cmH2O.	Performed	
	Yes	No
Verify that the externally measured cuff pressure is 30 cmH2O ± 1 cmH2O.	Passed	
	Yes	No
Set the cuff pressure to 50 cmH2O.	Performed	
	Yes	No
Verify that the externally measured cuff pressure is 50 cmH2O ± 1 cmH2O.	Passed	
	Yes	No

Leakage Test	Performed	
	Yes	No
Connect TrachFlush to the pilot balloon of the endotracheal tube		
Set the cuff pressure to 30 cmH2O.		
Remove the Cuff Pressure and Airway Tube Set (PN: TF-CO-IN) – Cuff Tube, from TrachFlush		
Check that the Cuff system leakage alarm symbol appears and the device activates the red flashing light and alarm sound	Passed	
	Yes	No
Connect the Cuff Pressure and Airway Tube Set (PN: TF-CO-IN) – Cuff Tube, to TrachFlush	Performed	
	Yes	No
	Passed	

Check that the applied pressure of 30 cmH2O is generated and the alarm stops.	Yes	No

Deflation Test	Performed	
	Yes	No
Connect TrachFlush to the pilot balloon of the endotracheal tube		
Set the cuff pressure to 30 cmH2O.		
Press the Deflation button to start deflation of the endotracheal tube cuff		
Check that TrachFlush deflates the cuff	Passed	
	Yes	No
Switch off TrachFlush	Performed	
	Yes	No