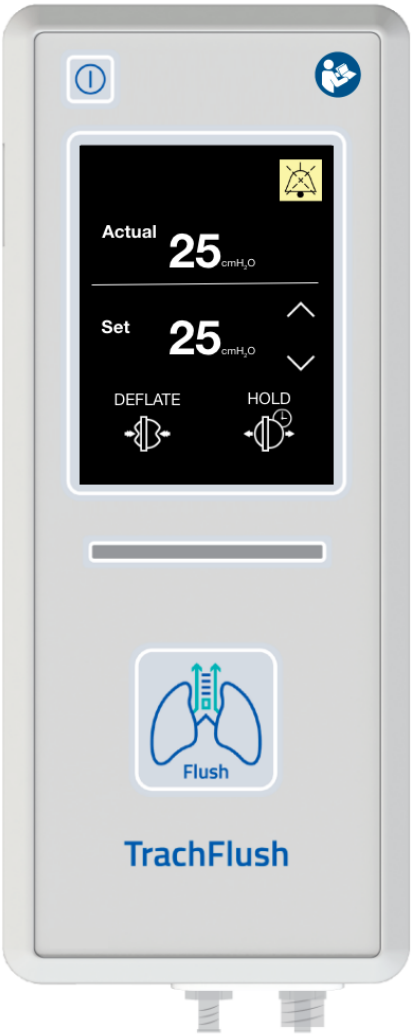
TrachFlush



Instructions for Use

REF TF-SA-XX

Software version 4.0.x.x

AWT-1030 | 2022-10-12

TrachFlush

CE

AW Technologies

TrachFlush

Instructions for Use

October 2022
AWT-1030

Table of Contents

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Document conventions

WARNING

A WARNING alerts the user to the possibility of injury, death, or other 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 of all pressure units. 1 cmH_2O equals 0.981mbar, which equals 0.981 hPa.

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.
- Only for use on adults (+18 years of age).

CAUTION

- Use only the AW Technologies disposable Cuff Pressure and Airway Tube with filter, safety valve, and lock. Use of any other tubing will damage the device and result in loss of cuff pressure. Use of any other tubing without a filter may result in the device being contaminated.
- Do NOT kink the tubing.

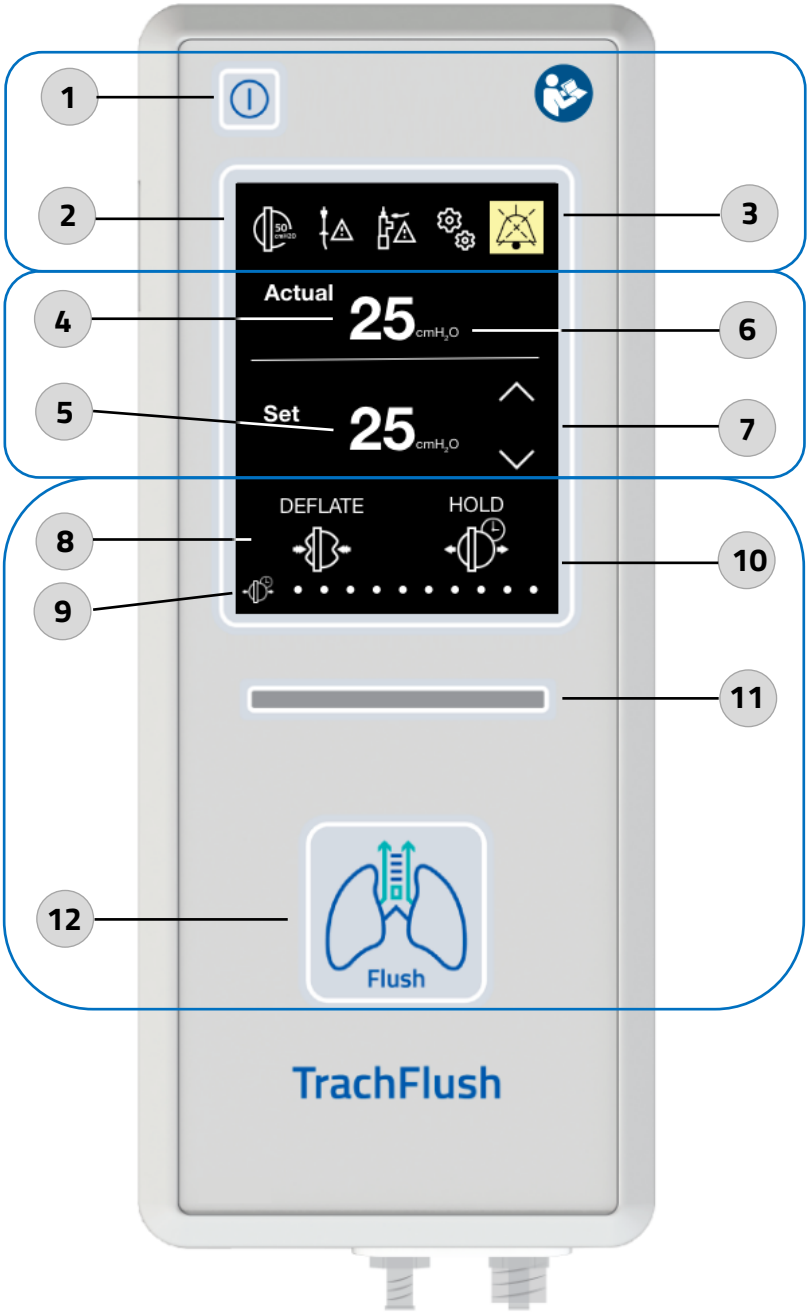
NOTICE

- The use of this equipment is restricted to one patient at a time who is intubated with an endotracheal tube (ETT) or tracheostomy tube (TT).
- 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.

- Install the TrachFlush device in a position where the primary power supply can easily be disconnected.
- 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 13.

1. Device overview

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



Alarms and power

1. Power ON / OFF button
2. Alarm bar
3. Alarm silence button

Pressure display

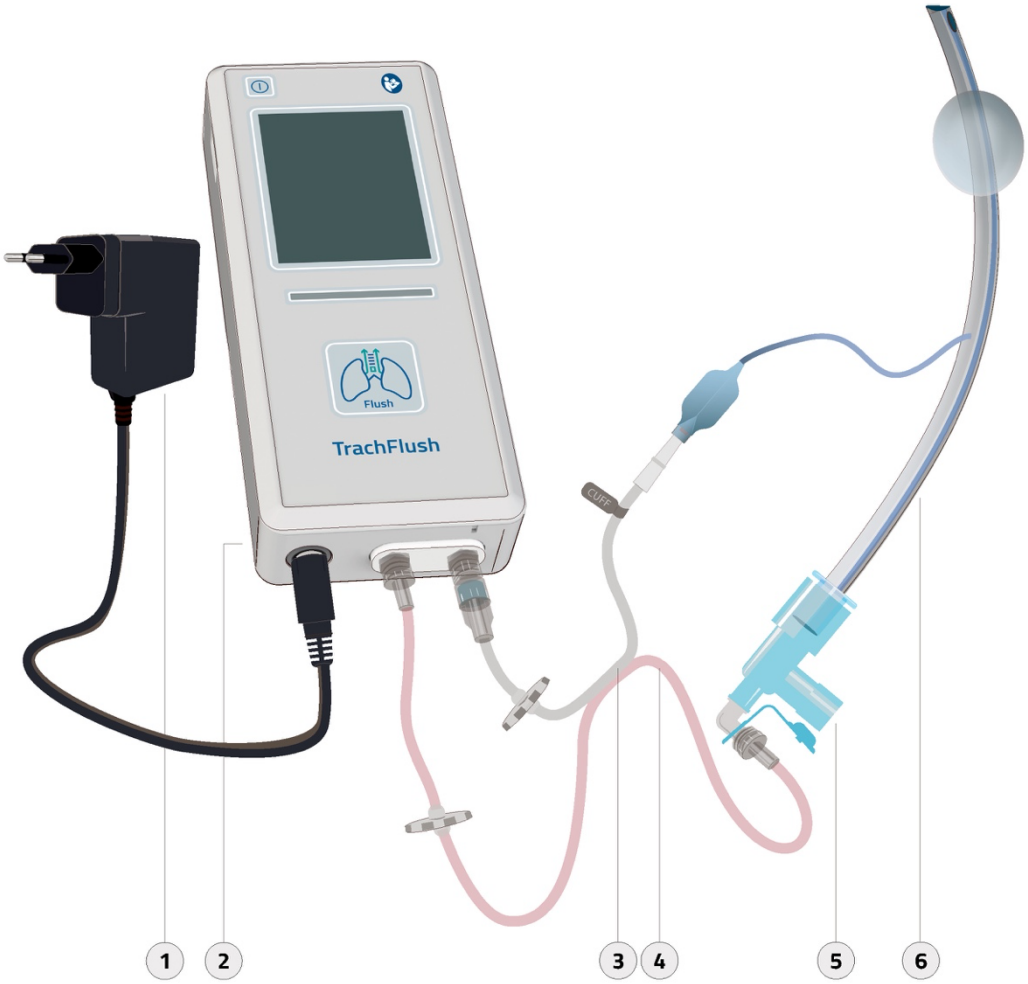
4. Actual cuff pressure
5. Set cuff pressure (target)
6. Unit of measure
7. Adjustment buttons

Control panel

8. Deflate button
9. Cuff hold information bar
10. Cuff hold button
11. Alarm bar (LED)
12. Flush Button

Figure 1: Device overview

2. TrachFlush Connections



SYSTEM OVERVIEW

1. Power Supply
2. Trachflush
3. Cuff Pressure Tube
4. Airway Tube
5. Elbow Connector
6. Endotracheal tube

Figure 2: TrachFlush Setup Overview

NOTICE

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

3. Getting started

CAUTION

Prior to use, confirm that the ETT or TT cuff is made of Polyvinyl chloride (PVC) or Polyurethane (PU). TrachFlush can ONLY be used with ETT cuffs or TT cuffs made of these materials.

Prior to use, confirm that the ETT or TT is between 5.0mm and 10.0mm in Inner Diameter (ID) as TrachFlush only supports ETTs and TTs in these sizes.

3.1. 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.

NOTICE

Keep the power supply always connected to stable power. If disconnected from power or power is lost, the TrachFlush device will alarm and shut down within 30 seconds.

The TrachFlush device is powered by a power supply unit (PSU) connected to AC power.

Connect the power cable as follows:

1. Connect the appropriate plug adaptor.
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.

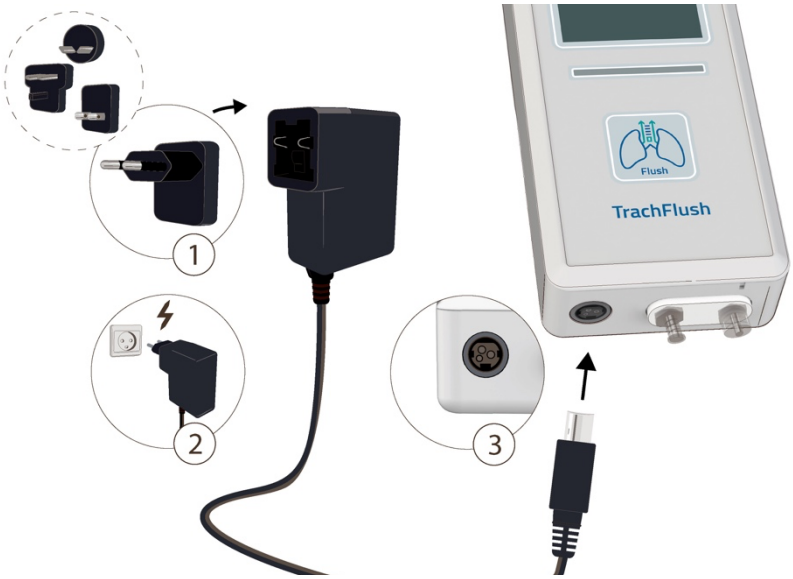


Figure 3: Connecting the device to primary power

3.2. Turning ON the device

Press and hold the Power ON / OFF button for three (3) seconds.

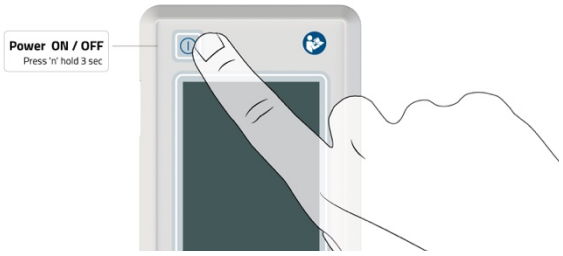


Figure 4: Turning on TrachFlush

When turning on, the device performs a self-test, during which the display turns on, LED-bar lights up and the alarm sounds, and the signal  (booting) will appear on the screen. If this does not occur, see Section 8.

Figure 5: TrachFlush Booting

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 3.3 and 3.4.

Figure 6: Calibration process

If TrachFlush detects that the tubes are not removed prior to calibration, the text will be highlighted in red as shown in Figure 7.

Figure 7: TrachFlush detects tubes are not disconnected

Once the device is calibrated, the main screen will appear (as shown in Figure 8) and Cuff Control functionality will be OFF until pressure is set, see section 3.5.

Figure 8: TrachFlush main screen

NOTICE

On the main screen, the Actual Cuff Pressure measured (Actual 25 cmH_2O) will be shown, in this case 25 cmH_2O. When powering up, the Set Cuff Pressure (Set OFF) will be off until set by the operator.

3.3. Connect the Cuff Pressure Tube and Airway Tube to the device

Step 1: Connect the Cuff Pressure Tube (transparent tube) connector to the cuff inlet socket of the TrachFlush by twisting it on as shown in Figure 9.

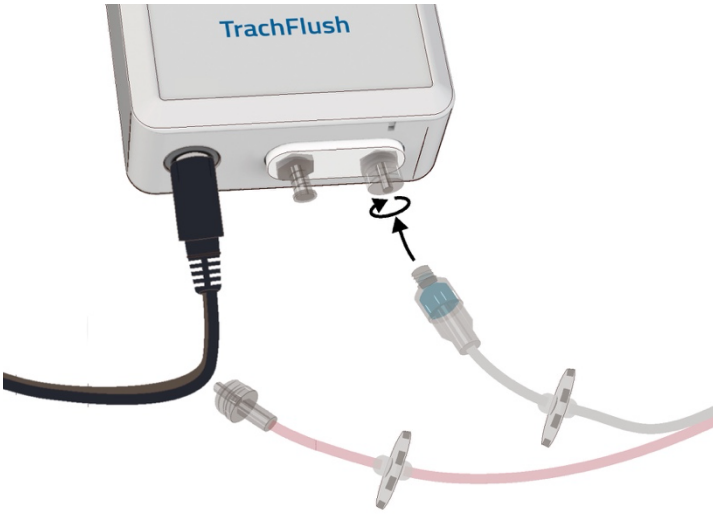


Figure 9: Device connectivity, connecting Cuff Pressure Tube

Step 2: Connect the Airway Tube (pink tube) connector to the airway inlet socket of the TrachFlush device by twisting it on as shown in Figure 10.

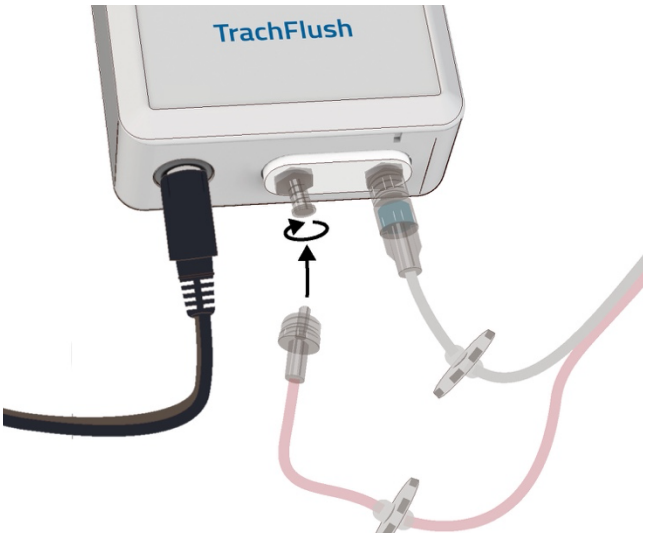


Figure 10: Device connectivity, connecting Airway Tube

3.4. Connect the Cuff Pressure Tube and Airway Tube to the patient

Step 1: Connect the Airway Tube (pink tube) connector to the standard luer lock gas outlet on the patient's connector or HME filter by twisting it on as shown in Figure 11.

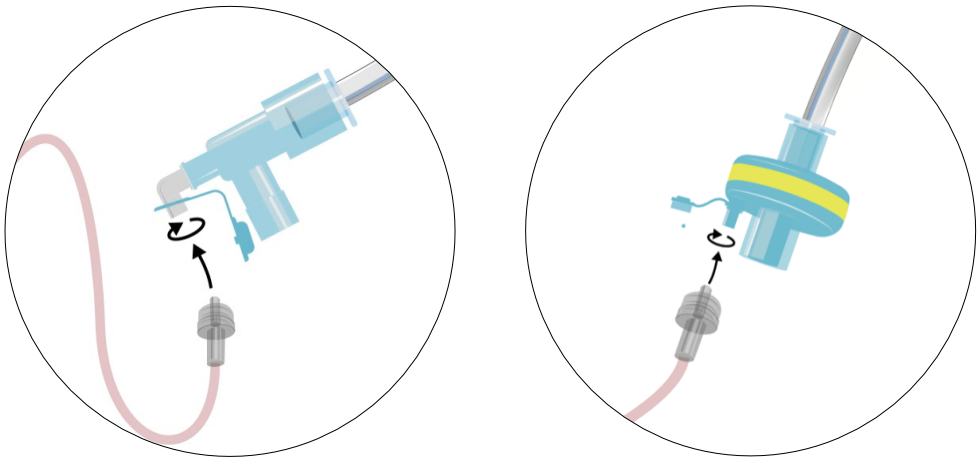


Figure 11: Patient connectivity, connecting Airway Tube

NOTICE

If no standard luer lock gas outlet is available, attach a connector or an HME filter with luer gas outlet. to the patients breathing system.

Step 2: Connect the Cuff Pressure Tube (transparent tube) connector (labelled "Cuff") to the ETT or TT cuff connector by pushing it in as shown in Figure 12

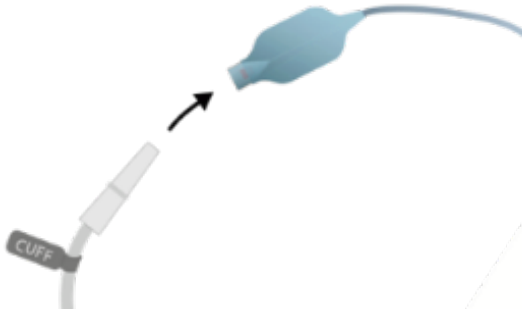


Figure 12: Patient connectivity, connecting Cuff Pressure Tube

3.5. Adjust cuff pressure

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

NOTICE

It is recommended to keep the cuff pressure between 25cmH_2O and 30cmH_2O for adult ETTs/TTs.

TrachFlush Cuff Controller can regulate cuff pressures between 5 and 50cmH_2O.

To adjust the set (target) pressure:

Step 1: Press the (increase) or (decrease) button to increase or decrease the cuff pressure.

Step 2: Press the (accept) button to apply the new cuff pressure or press the (decline) button to cancel the cuff pressure adjustment and return to previous settings.

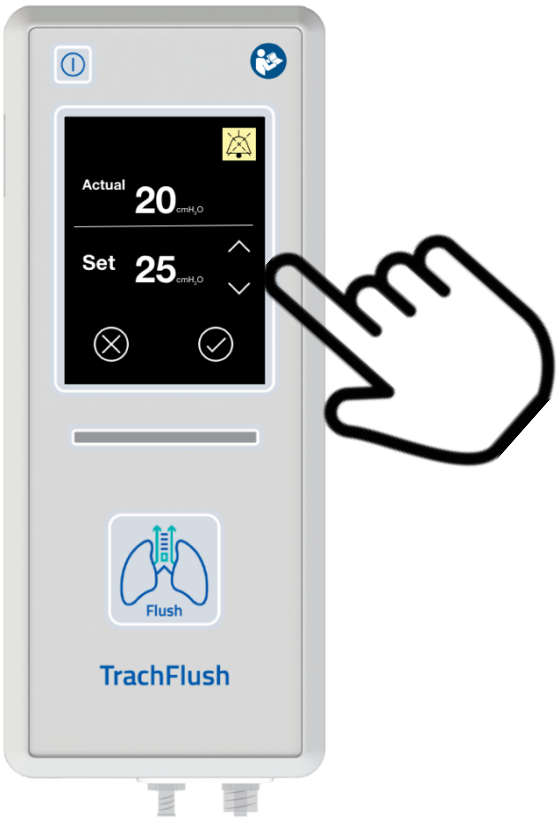
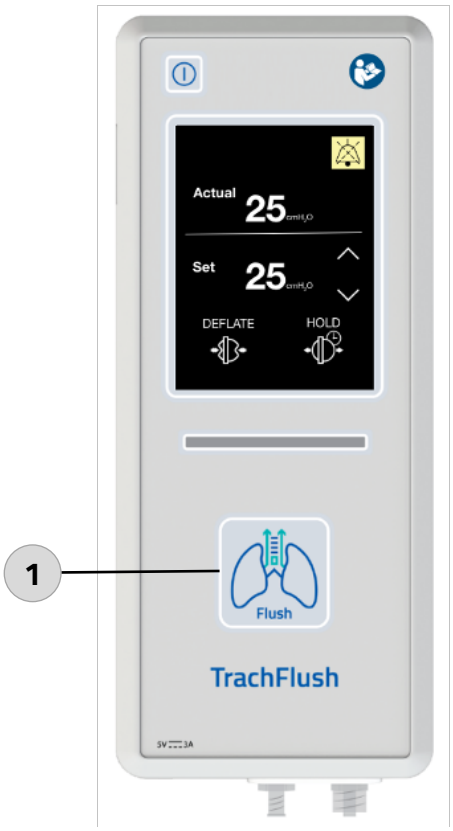


Figure 13: Adjust cuff pressure

As shown in Figure 13 above, the device will increase the pressure, currently at 20 cmH_2O, to the target of 25 cmH_2O once the new set pressure is accepted by the operator.

4. Flush Control

The Flush Control for pressure control ventilation (PCV) can be activated by pressing the Flush button, see section 4.1. The Spont Flush Control for pressure support ventilation (PSV) can be activated by pressing and holding the Flush button for three (3) seconds, see section 4.2



1. Flush button

Figure 14: Flush Control

The Flush Control and Spont Flush Control maneuver rapidly deflates and inflates the cuff during the inspiratory phase upon activation.

Upon activation, the device checks the ventilator settings to ensure the function activates under proper conditions, see section 14.1 for information on appropriate ventilator settings.

By default, the cuff will after the deflation automatically return to the set target pressure.

4.1. Perform Flush Control on Pressure Control Ventilation (PCV)

Please follow these steps to perform a Flush Control maneuver.

WARNING

Only adjust the ventilator settings if it is clinically safe for the patient and adjustments should only be temporarily when performing the Flush Control maneuver(s). Remember to return settings if adjusted.

Do not disconnect the tubes during Flush Control.

CAUTION

Check if ventilator settings are set as follows:

1. *Mode*
    a. *Pressure Control Ventilation (PCV)*
2. *Settings*
    a. *Pressure above PEEP is minimum 10 cmH_2O*
    b. *PEEP is minimum 5 cmH_2O*
    c. *Inspiratory time is minimum 1.33 seconds*
    d. *P-ramp is maximum 100 mSec*
    e. *Cuff pressure is between 15 cmH_2O and 35 cmH_2O*

NOTICE

TrachFlush will only perform the Flush Control maneuver if these ventilator and cuff pressure settings are met.

Step 1: Press the Flush button to activate the Flush Control as shown in Figure 15 below

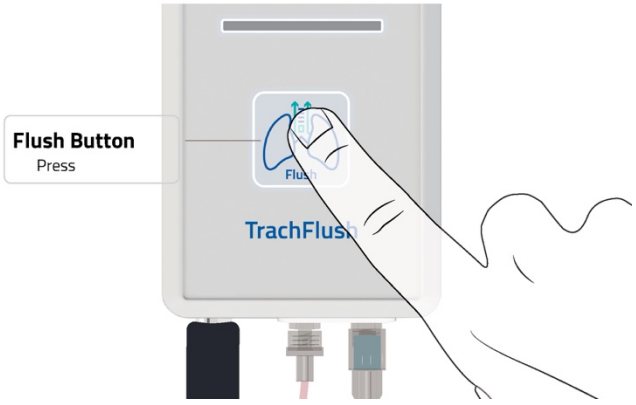


Figure 15: Performing a Flush

When Flush is activated, then on the TrachFlush screen, the signal  (Flush in Progress) will be shown and the LED-bar will flash cyan until Flush has completed, as shown in Figure 16.

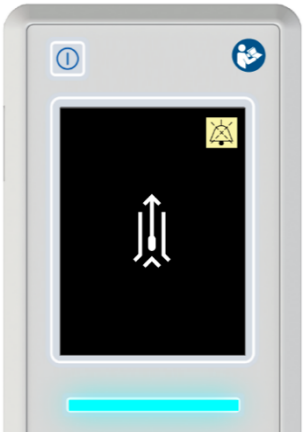


Figure 16: Flush in Progress

NOTICE

When Flush is activated, the TrachFlush device uses at least one (1) inspiratory cycle to check for correct ventilator settings as defined in Section 14.1.

If the ventilator settings are found correct, on the next inspiratory cycle the Flush Control maneuver is performed.

If the ventilator settings are not found correct, TrachFlush will not perform the Flush Control until corrected. On the screen, information signals will inform what settings are not found correct, see Section 8.1 for description of information signals. Until the settings are found correct, the device provides options for “Initiate Spont Flush” (see section 4.2) or “Cancel” the Flush Control maneuver. If cancelled, TrachFlush will return to Cuff Controller mode.
Once settings are found correct, the Flush Control maneuver will automatically start.

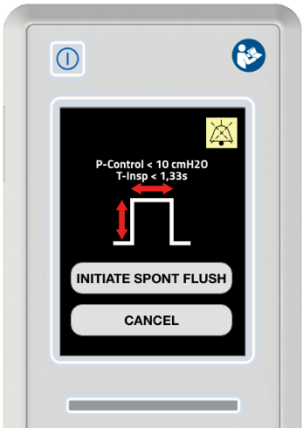


Figure 17: Ventilator settings incorrect

When the Flush Control maneuver is completed, the signal  (Flush Complete) and “OK” button will appear on the screen as shown on Figure 18.

Figure 18: Flush Complete

After the “OK” button has been pressed to acknowledge the Flush is completed, TrachFlush returns to main screen as shown in Figure 19.

Figure 19: Main screen

Step 2(OPTIONAL): Evaluate the effect of the Flush Control maneuver and, if considered necessary, repeat Step 1.

Step 3: Return to Pre-Flush Control ventilator settings after Flush Control maneuver(s) (only if the ventilator settings were adjusted before performing a Flush Control maneuver)

TrachFlush will display the  (Return to Pre-Flush Ventilator Settings) symbol 15 seconds after the last Flush Control maneuver, if TrachFlush has detected changes to ventilator settings, as shown in Figure 20.

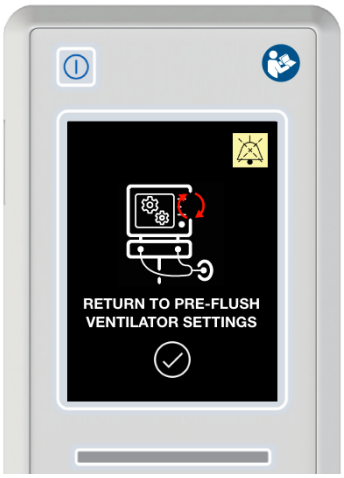


Figure 20: Return to Pre-Flush Ventilator Settings

4.2. Perform Spont Flush Control on Pressure Support Ventilation (PSV)

Please follow these steps to perform a Spont Flush Control maneuver.

WARNING

Only adjust the ventilator settings if it is clinically safe for the patient and adjustments should only be temporarily when performing the Spont Flush Control maneuver. Remember to return settings.

When a Spont Flush Control is activated, TrachFlush will perform the Flush during the next inspiratory cycle.

Use ONLY on Pressure Support Ventilation (PSV).

Do not disconnect the tubes during Spont Flush Control.

CAUTION

Check if ventilator settings are set as follows:

1. *Mode*
    a. *Pressure Support Ventilation (PSV)*
2. *Settings*
    a. *Pressure above PEEP is minimum 10 cmH_2O*
    b. *PEEP is minimum 5 cmH_2O*
    c. *Frequency is less than 28 b/min*

NOTICE

TrachFlush will only perform the Spont Flush Control maneuver if the frequency is less than 28 b/min.

Step 1: Press and hold the Flush button for 3 seconds to enter the Spont Flush Control menu as shown in Figure 21 below

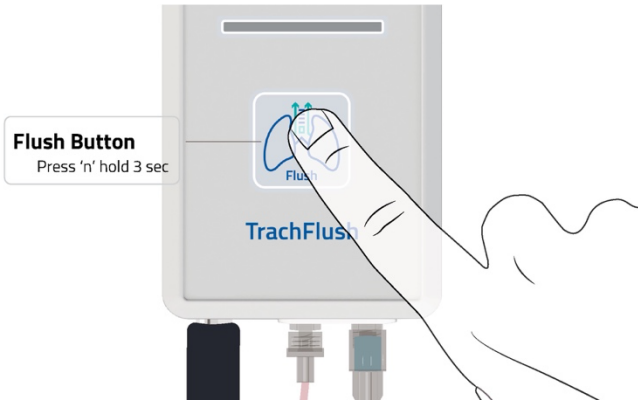


Figure 21: Activate a Spont Flush Control maneuver

When the Flush button is pressed and held for 3 seconds, the Spont Flush menu is displayed, as shown on Figure 22.

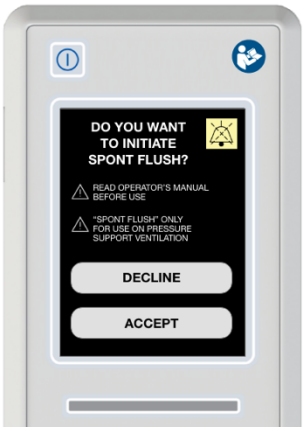


Figure 22: Spont Flush menu

Step 2: Activate the Spont Flush Control maneuver by pressing the “ACCEPT” button to confirm activation.

When the Spont Flush is activated, the signal  (Flush In Progress) and text “SPONT FLUSHING” will be shown, and the LED-bar will light cyan until the Spont Flush is completed, as shown in Figure 23.

Figure 23: Spont Flushing

Once the Spont Flush is completed, the signal  (Flush Complete) and “OK” button will appear on the screen as shown in Figure 24.

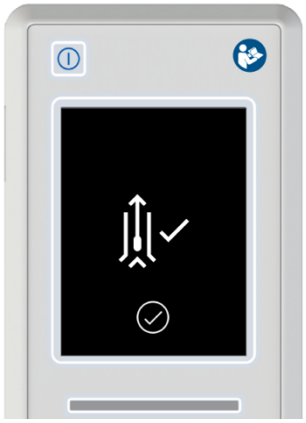


Figure 24: Spont Flush Complete

After the “OK” button has been pressed to acknowledge the Spont Flush is completed, TrachFlush returns to main screen as shown in Figure 25.

Figure 25: Main screen

Step 3: Repeat Step 1+2 (OPTIONAL): Evaluate the effect of the Spont Flush Control maneuver and, if considered necessary, repeat Step 1 and 2.

Step 4: Return to Pre-Spont Flush Control ventilator settings after the Spont Flush Control maneuver(s) (only if the ventilator settings were adjusted before performing a Spont Flush Control maneuver)

TrachFlush will display the  (Return to Pre-Flush Ventilator Settings) symbol 15 seconds after the last Spont Flush maneuver, if TrachFlush has detected changes to ventilator settings, as shown in Figure 26.

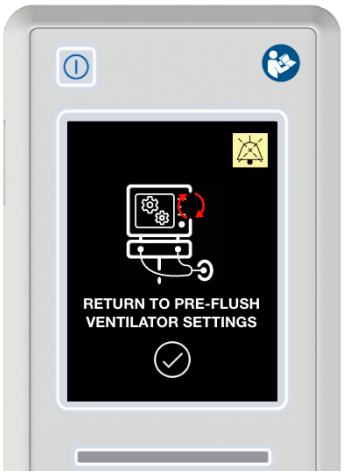
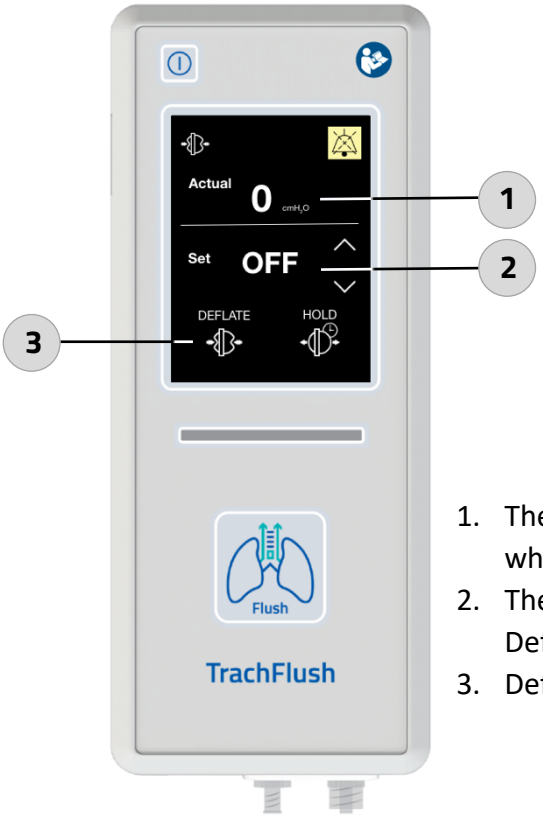


Figure 26: Return to Pre-Spont Flush Ventilator Settings

5. Deflate

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



1. The actual cuff pressure when deflated
2. The target pressure when Deflate function is activated
3. Deflate button

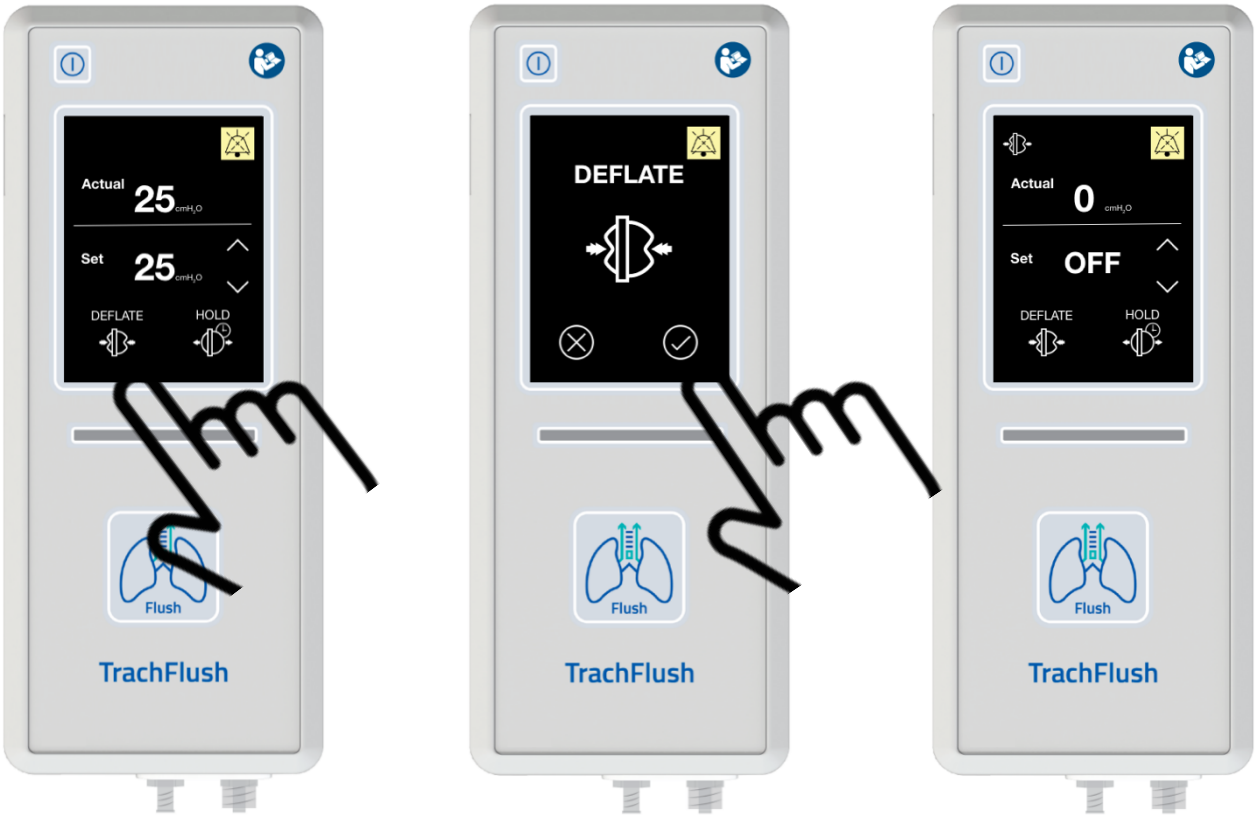
Figure 27: Deflate

The deflate function completely empties the cuff upon activation by the user to allow for permanent decuffing of the patient and extubation.

Upon activation, the device applies negative pressure to the cuff until the cuff pressure is reduced to at least 0 cmH_2O.

By default, the cuff is kept deflated for un unlimited period. However, if the cuff is deflated for more than 60 seconds without being TrachFlush being turned off or the cuff reinflated, you are reminded that you deflated the cuff and that the cuff is still in the deflated state.

5.1. Perform deflate



Press Deflate button

Press the (deflate) button to activate deflation

Press Accept button

Press the (accept) button to activate deflation

In progress

Set is OFF and actual pressure starts decreasing to 0 cmH_2O

The device displays the (deflate) symbol in the alarm bar to indicate that the deflate is in progress. The target pressure displays “OFF”, and the device applies negative pressure until the actual pressure is at least 0 cmH_2O.

After deflating the cuff, you can extubate the patient, disconnect the TrachFlush, and turn off the device.

If the cuff is deflated for > 60 seconds without being 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.

Stop the deflate

To stop the deflate, click on the (deflate) button or the (increase/decrease) buttons to set the target pressure, see section 3.5. When clicking the deflate button, the device will by default suggest the previous target pressure.

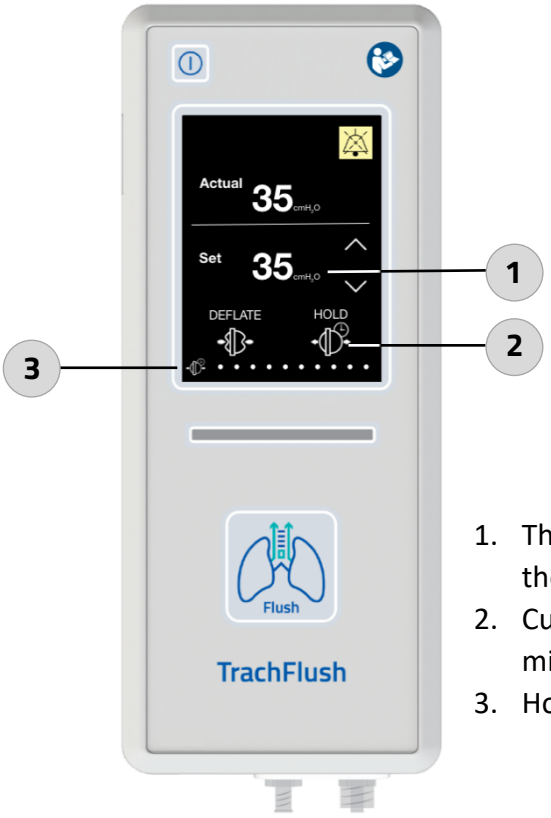
6. Cuff hold

The cuff hold function can be activated by pressing the Hold button

NOTICE

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

The maximum cuff pressure allowed under any circumstances is limited to a total of 55 cmH2O



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

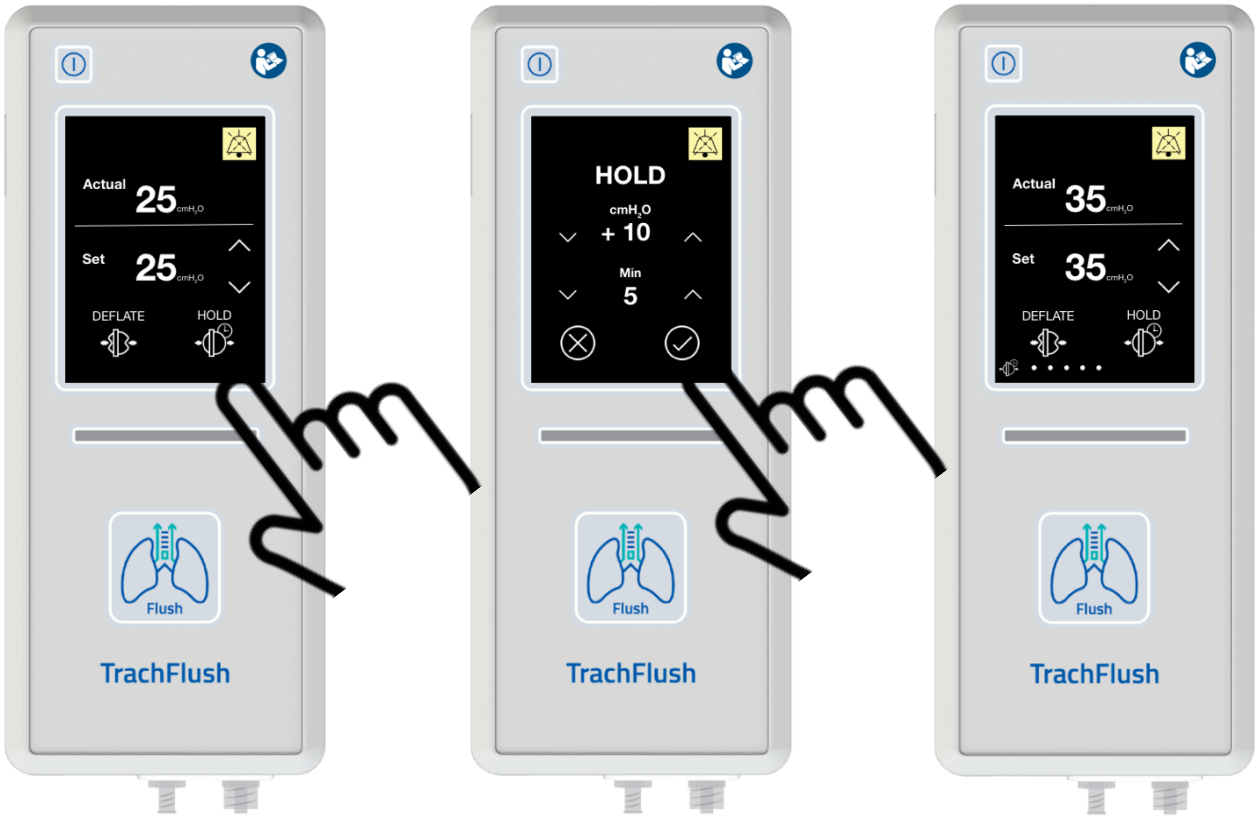
Figure 28: Cuff hold

The cuff hold function increases the cuff pressure temporarily by an operator specified amount for a set period of time. It can be used in situations requiring better seal of 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.

6.1. Perform cuff hold



1) Press Hold button
Press the (hold) button to activate cuff hold

2) Press Accept button
Press the (accept) button to activate cuff hold

3) Hold in progress
Cuff hold information bar will display the remain time

The cuff pressure increases to the operator adjusted pressure. The cuff hold information bar on the display shows and displays the remaining time. Each of the dots indicates one minute left of the cuff hold maneuver.
As the cuff hold information bar counts down, the dots disappear one by one from right to left until the cuff hold maneuver is complete. One dot disappears each minute.

At the end of the cuff hold maneuver, the pressure returns to the previous target pressure and the cuff hold information bar disappears.

Stop the cuff hold
To stop the cuff hold, readjust the cuff pressure to the desired cuff pressure and accept, see section 3.5 on how to adjust pressure. The cuff hold will then turn off.

7. Turning OFF the device

Step 1: Disconnect the Airway Tube (pink tube) from the connector and the Cuff Pressure Tube (transparent tube) from the cuff pilot balloon.

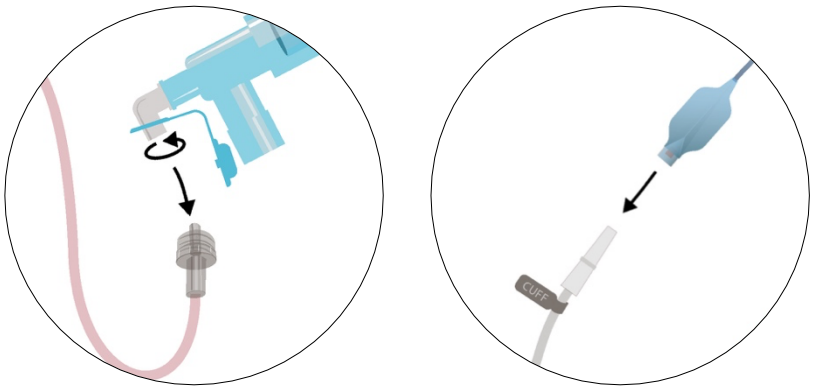


Figure 29: Disconnect tubes from patient

Step 2: Disconnect the Airway Tube (pink tube) from the TrachFlush device and the Cuff Pressure Tube (transparent tube).

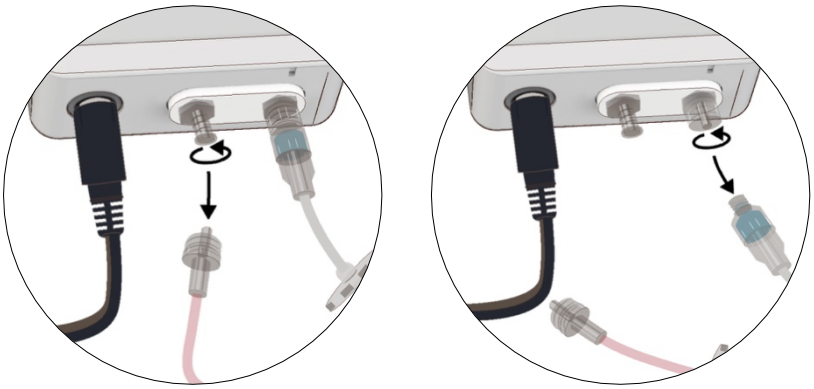


Figure 30: Disconnect tubes from device

Step 3: Turn off the TrachFlush device by pressing and holding the Power ON/OFF button for 3 seconds as shown in Figure 31 below.

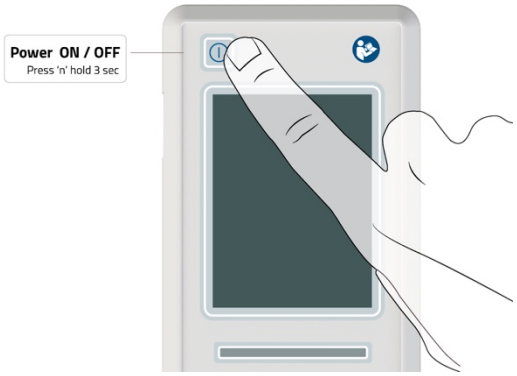


Figure 31: Turn off TrachFlush

Step 4: Dispose the Cuff Pressure and Airway Tube as described in section 10.2.

8. Alarms and troubleshooting

When an alarm is generated, the device emits audible beeps and the alarm lamp lights cyan, yellow or red, depending on the alarm priority. The TrachFlush device has three alarm priorities: high, medium, and low. See Table 1 and Table 2 for details.

To silence an alarm

- Review the alarm, and if appropriate, press the Alarm silence button.
- The Alarm is silenced for 2 minutes.
- Take action to mitigate alarm as in Table 2 Action required column

Table 1: TrachFlush alarm types

Alarm type	Alarm lamp	Audio response	Action required
High-priority alarm	Red, flashing	A sequence of beeps, repeated until the alarm is reset	Depends on the alarm; see Table 2
Medium-priority alarm	Yellow, flashing	A sequency of beeps, repeated periodically	Depends on the alarm; see Table 2
Low-priority alarm	Yellow, constant on	A sequency of beeps	Depends on the alarm; see Table 2
Technical alarm	White, constant on	A sequency of beeps	Depends on the alarm; see Table 2

Table 2: TrachFlush alarm names and symbols

Alarm name	Alarm type	Possible causes	Action required
Cuff Pressure ≥ 70 cmH_2O 	High-priority alarm	Cuff pressure is ≥ 70 cmH_2O.	Decrease cuff pressure.
Cuff Pressure > 50 cmH_2O 	Medium-priority alarm	Cuff pressure is > 50 cmH_2O.	Decrease cuff pressure.
Cuff Pressure < 5 cmH_2O 	Medium-priority alarm	Cuff pressure is < 5 cmH_2O.	Increase cuff pressure
Cuff Regulation Error 	Medium-priority alarm	Pressure cannot be maintained in cuff. Device error; cannot maintain cuff pressure.	Check and change ETT/TT if needed. Check and change Cuff Pressure and Airway tube if needed. Or disconnect device.

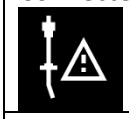
Flush or Cuff adjustment in progress 	Medium-priority alarm	Tubes not removed from device. Flush Control in progress.	Wait 20 sec and try again.
Cuff deflated > 60 seconds 	Medium-priority alarm	The cuff has been deflated for more than 60 seconds.	Reinflate the cuff. Or disconnect and turn of TrachFlush.
Power is Disconnected 	Low-priority alarm	Power supply has been disconnected.	Make sure the power supply is connected to the device and a power source.
Service of the device is required 	Technical alarm	Service of the device is required.	Disconnect the device and send to service.

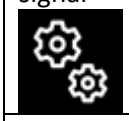
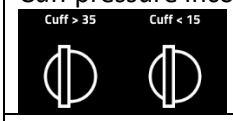
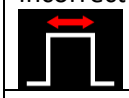
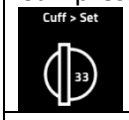
Should multiple alarms occur at the same time, the alarm with the highest priority will be shown on top.

8.1. Information Signals

Information signals are displayed to provide useful information to the operator of TrachFlush. In Table 3 you will find detailed information on possible causes and what to do for each information signal.

Table 3: Information signals

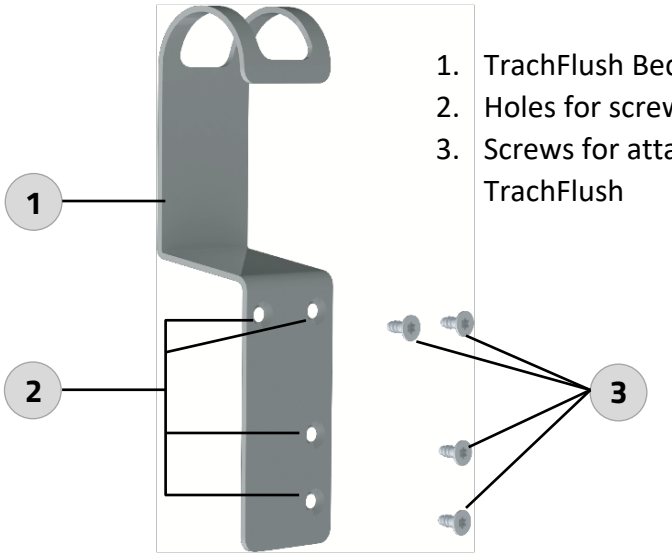
Signal name	Light / Audio	Possible causes	Action required
Cuff Pressure Tube not Connected 	Light: *Cyan, constant on.* Audio: *Sequence of beeps.*	Cuff pressure tube not connected correctly	Check cuff pressure tube connection.
Airway Tube not Connected 	Light: *Cyan, constant on.* Audio: *Sequence of beeps.*	Airway tube not connected correctly	Check airway tube connection.
Flush Control Complete 	Light: *No light.* Audio: *No audio.*	Flush Control completed	Press  to acknowledge the Flush Control is completed

Flush Control in Progress 	Light: *Cyan, constant on.* Audio: *No audio.*	Deflation and inflation function in progress	Wait until Flush Control is complete.
Booting 	Light: *White, constant on.* Audio: *Long beep.*	Booting in progress	Wait until the device is fully booted.
Reading ventilator signal 	Light: *No light.* Audio: *No audio.*	Changes in ventilator settings	Wait until the device is ready before activating Flush Control.
Cuff pressure incorrect 	Light: *No light.* Audio: *No audio*	Cuff pressure is out of the acceptable range for Flush Control	Adjust the cuff pressure and try again.
Pressure above PEEP incorrect 	Light: *No light.* Audio: *No audio.*	The pressure above PEEP is found incorrect for Flush Control.	Inspect ventilator settings. If clinically safe, adjust ventilator settings.
Inspiratory time incorrect 	Light: *No light.* Audio: *No audio.*	The inspiratory time is found incorrect for Flush Control.	Inspect ventilator settings. If clinically safe, adjust ventilator settings.
Cuff pressure above set 	Light: *No light.* Audio: *No audio.*	The cuff pressure is above the set following a Flush Control	Please wait until TrachFlush has reduced the cuff pressure.
Ventilator settings OK 	Light: *No light.* Audio: *No audio.*	The ventilator settings are correct.	Please wait, a Flush Control will be initiated.
Unstable ventilator signal 	Light: *No light.* Audio: *No audio.*	The Flush Control could not be performed as the signal from the ventilator is found unstable.	Inspect ventilator/patient. If clinically safe, stabilize the ventilator/patient. Press Flush button again to initiate Flush Control
Return to pre-flush ventilator settings 	Light: *Cyan, constant on.* Audio: *Sequence of beeps.*	Ventilator settings where found adjusted prior to Flush Control.	Return to pre-flush control ventilator settings. Press ✓ on the screen to confirm settings are returned.

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 32: Bedside bracket

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

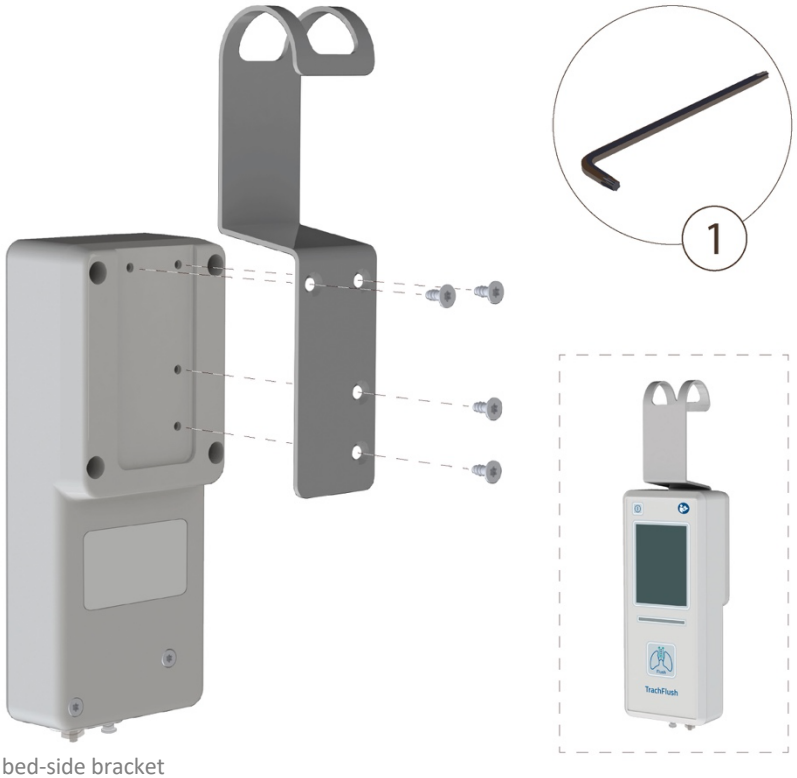


Figure 33: Mounting bed-side bracket

10. Cleaning and maintenance

10.1. Cleaning of TrachFlush device and equipment

WARNING

Always disconnect the device from main power before cleaning.

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.

Clean the TrachFlush device and bed-side bracket with a soft cloth moistened in water or a mild soap solution. To disinfect the equipment, wipe with 70% isopropyl alcohol.

The device shall be cleaned after each patient.

10.2. Disposal of Cuff Pressure and Airway Tube set

The TrachFlush Cuff Pressure and Airway Tube set is intended for single patient use only and should be disposed in accordance with local regulations for contaminated and biologically hazardous items.

10.3. Maintenance of TrachFlush device

Preventive maintenance is not required, except for cleaning.

Service of TrachFlush device is required after 5 years from date of manufacturing.

10.4. 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

Intended use

The TrachFlush device is intended to:

- Continuously measure and automatically maintain the user set cuff pressure of an ETT cuff or TT cuff during mechanical ventilation of adult patients, and
- Inflate and deflate the ETT cuff or TT cuff in alignment with the ventilator flow of pressure during mechanical ventilation of adult patients in the Intensive Care Unit (ICU) when activated by the user.

TrachFlush is to be used during mechanical ventilation in the ICU of adults who are intubated with ETT or TT

TrachFlush is intended to be used in healthcare institution ICUs

TrachFlush can be used with any mechanical ventilator.

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.

12. Standards and approvals

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

The device is manufactured within the requirements specified by ISO 13485:2016/AC:2018 Medical devices - Quality management systems - Requirements for regulatory purposes, and Council Directive 93/42/EEC as amended in 2007/47/EC, Annex II, Article 1 quality management system.

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:

- EN 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 60601-1-2:2015 Medical electrical equipment - Electromagnetic compatibility
- IEC 62304:2006 +A1:2015 Medical device software – Software life-cycle processes
- IEC 62366-1:2015 Medical devices – Usability
- EN 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 to maintain normal mode operation during electromagnetic inference, i.e., the applied cuff pressure must be maintained and monitored.

Interreference 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.

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. Interreference 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

The use of accessories, sensors, 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 B	TrachFlush is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
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]
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	

	Up to 28 V/m for RF wireless communication equipment	Up to 28 V/m for RF wireless communication equipment	Interference may occur in the vicinity of equipment marked with the following symbol: 
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 Control mode	
Cuff pressure set range	5 cmH_2O to 50 cmH_2O
Resolution (setting/display)	± 1 cmH_2O
Pressure accuracy	± 1 cmH_2O
Flush Control mode – ventilator settings	
Ventilation mode supported	Pressure Controlled Ventilation (PVC)
Pressure above PEEP	Minimum 10 cmH_2O
PEEP	Minimum 5 cmH_2O
Inspiratory time (T-Insp)	Minimum 1.33 seconds
P-Ramp	Maximum 100mSec
Cuff pressure range	15 cmH_2O to 35 cmH_2O
Spont Flush mode – ventilator settings	
Ventilation mode supported	Pressure Support Ventilation (PSV)
Pressure above PEEP	Minimum 10cmH_2O
PEEP	Minimum 5 cmH_2O
Frequency	Maximum 28 b/min
Flush Control and Force Flush – ETT and TT Cuff requirements	
Cuff material	Polyvinyl chloride (PVC) Polyurethane (PU)
ETT or TT dimensions	5.0mm to 10.0mm (Inner Diameter)
Electrical specifications	
AC Power Input	100-240 VAC, 50/60 Hz
DC Power Input	5V DC 3A
Fuse	Fuse is integrated in the power supply unit (non-replaceable)
Alarm volume	55 dB(A) ± 6 dB(A)
Environmental conditions	
Relative humidity	30% to 75%
Operating temperature	5°C to 40°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
	ATTENTION: Follow Operator's Manual
	The equipment should not be disposed of in the normal waste stream
	MR Unsafe
	Type BF Applied Part (IEC 60601-1) (protection against electrical shock)
	DC Current/Voltage
	Manufacturer information
	Serial number
	Batch code
	AW Technologies Reference or Part Number
	Date of manufacture
	Do not reuse
	Do not use if packaging is damaged
	Use-by-date
	Not made with natural rubber latex
	Temperature limits
	Class II Equipment
IP33	Ingress Protection. Protected from water spray less than 60 degrees from vertical and protected from particles larger than 2.5 mm
	ON /OFF button (for powering on and powering off the device)

15. Parts and accessories

Name	AW Technologies Part number
Cuff Pressure and Airway Tube set 	TF-SA-XX
Bed-side bracket 	TF-SA-B
Power Supply 2 meters incl. adaptors 	TF-SA-PSU

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 and 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.