

# TrachFlush

## **Operators Manual**

### **TrachFlush UK**

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## 1 Introduction

### 1.1 About this manual

This manual is written for clinical personnel using the TrachFlush device (TrachFlush); the consumables and accessories intended for use with TrachFlush.

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### 1.2 Units of measure

The document uses cmH<sub>2</sub>O representative of all pressure units. 1 cmH<sub>2</sub>O equals 0.981mbar, which equals 0.981 hPa.

### 1.3 General description and Intended Use

TrachFlush is an add-on to standard mechanical ventilation systems used in the Intensive Care Unit (ICU). TrachFlush has two functionalities:

**Cuff Controller:** TrachFlush continuously measures and automatically maintains the user set cuff pressure of an endotracheal tube (ETT) cuff or tracheostomy tube (TT) cuff during mechanical ventilation of adult patients.

**Flush Controller:** TrachFlush inflates and deflates the endotracheal tube (ETT) cuff or the tracheostomy (TT) cuff in alignment with the ventilator flow of pressure during mechanical ventilation of adults patients in the ICU when activated by the user.

TrachFlush is intended to be used in healthcare institutions and by trained healthcare professionals.

TrachFlush is NOT intended to be used on patients under the age of 18 years.

### 1.8 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.

### 1.9 General notes

#### WARNING

- MR UNSAFE. Keep away from magnetic resonance imaging (MRI) equipment. TrachFlush poses unacceptable risks to patient, medical staff, or another person within the MR environment.
- Modifications to the device are not permitted.
- To prevent increased emission, decreased immunity, or interrupted operation of the TrachFlush device or any accessories, use only accessories or cables that are expressly stated in this manual under Section 6.

#### CAUTION

















- Use only AW Technologies disposable tubing with filter, valve and lock. Use of any other tubing may result in malfunction of TrachFlush or the immediate loss of cuff pressure if disconnected on the ventilator end. Use of any other tubing without a filter may result in the device being contaminated.
- DO NOT kink the tubing.

#### NOTICE

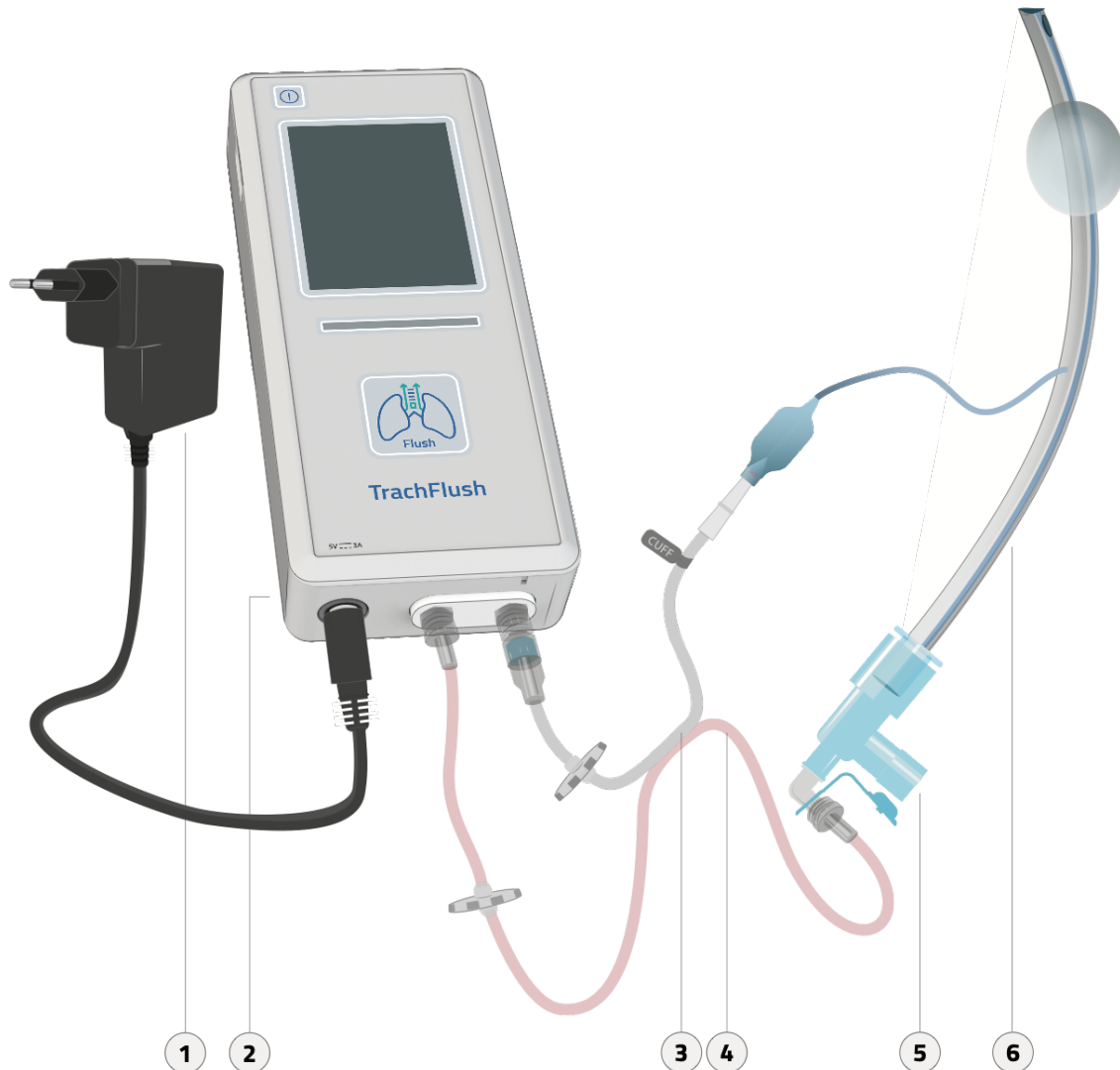
- The use of this equipment is restricted to one patient at a time who is intubated with an endotracheal tube (ETT) or tracheostomy tube (TT).
  - If there is visible damage to any part of the TrachFlush device, do not use the device. Technical service is required.
  - Familiarize yourself with these Instructions for Use or the Quick Guide before using the device on a patient.
- The device is not protected against the effects of defibrillator use.

## 1.10 Symbols and markings

**Table 1: Symbols and markings**

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 (product has 2xMOPP)
	Ingress Protection

## 2 TrachFlush Overview



### SYSTEM OVERVIEW

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

Figure 1: 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 TrachFlush Operations

### 3.1 Setting up TrachFlush for use

**CAUTION:**

Check if the ETT or TT cuff is made of Polyvinyl chloride (PVC) or Polyurethane (PU) as TrachFlush can ONLY be used with ETT cuff or TT cuff made of these materials.

Check if the ETT or TT is between 5.0mm and 10.0mm in Inner Diameter (ID) as TrachFlush only supports ETT and TT in these sizes.

**Device Connectivity:**

**Step 1:** Connect the Cuff Pressure Tube (transparent tube) connector to the cuff inlet socket of the TrachFlush device by twisting it on as shown in figure 2.

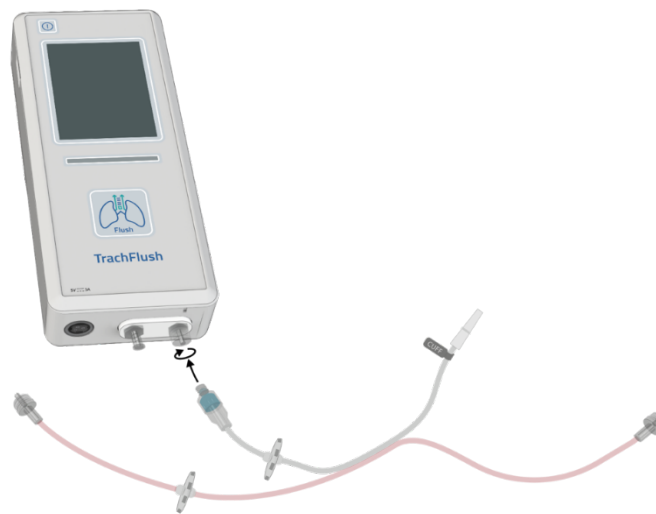


Figure 2: Device connectivity, connecting Cuff Pressure Tube

**Step 2:** Connect the Airway Tube (pink tube) connector to the airway inlet socket of the TrachFlush by twisting it on as shown on figure 3.

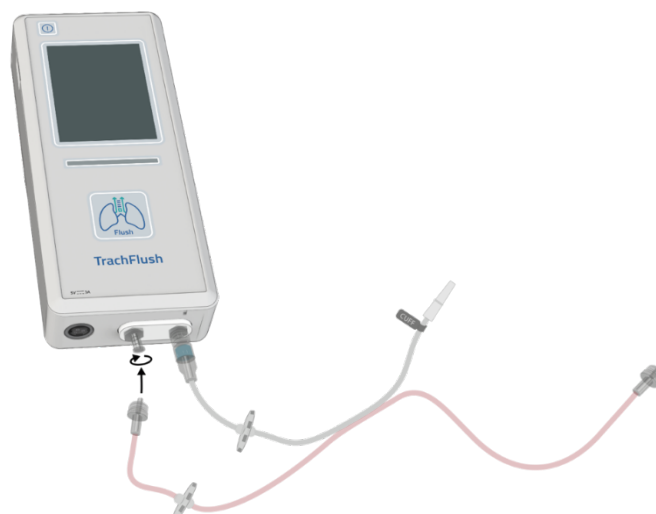


Figure 2: Device connectivity, connecting Airway Tube

### Airway and Cuff Connectivity:

**Step 1:** Connect the Airway Tube (pink tube) connector to the patients airway elbow or straight connector by twisting it on as shown on figure 4.

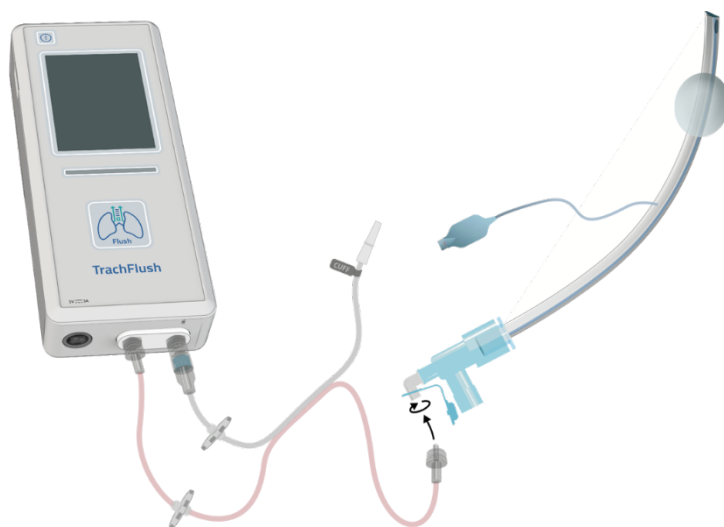


Figure 4: Patient connectivity, connecting Airway Tube

**NOTE:** If no elbow or straight connector is mounted on the patients airway system, then attach an elbow connector as shown on figure 5.

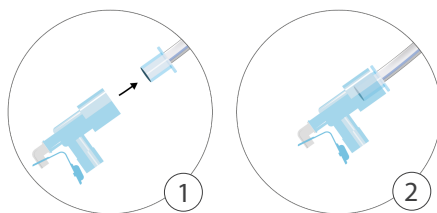


Figure 5: Patient connectivity, connecting Elbow Connector

**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 on figure 6.



Figure 6: Patient connectivity, connecting Cuff Pressure Tube



### 3.2 Turning ON TrachFlush

**Step 1:** Turn on the TrachFlush device by pressing and holding the On/Off button for 3 seconds as shown on figure 7 below.

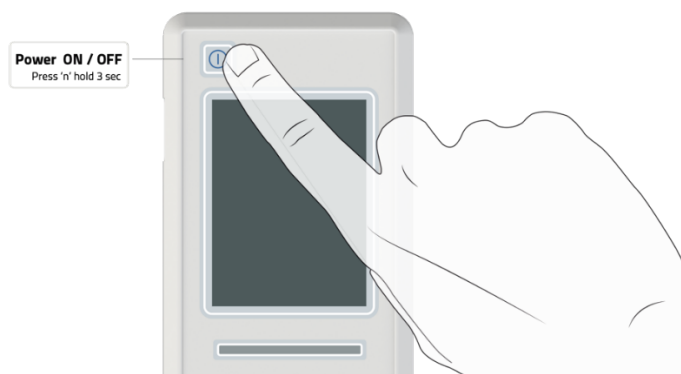


Figure 7: Turn on TrachFlush


**Step 2:** While turning on the signal  (Booting) will appear on the TrachFlush screen as shown on figure 8 below.



Figure 8: TrachFlush Booting

**Step 3:** Once turned on, the main screen will appear as shown on figure 9 and TrachFlush will automatically enable the Cuff Control functionality (see section 3.3 Setting Cuff Pressure).



Figure 9: TrachFlush Main Screen

**NOTICE:** On the mainscreen, the Actual Cuff Pressure measured () will be shown.

When powering up, the Set Cuff Pressure () will be the same as the measures Cuff Pressure.

### 3.3 Setting Cuff Pressure

When TrachFlush is turned on, the main screen will appear as shown on figure 10 and TrachFlush will automatically enable the Cuff Control functionality



Figure 10: TrachFlush Main Screen

**NOTICE:** TrachFlush Cuff Controller can regulate pressure between 5 and 50cmH2O.

In order to increase or decrease the set Cuff Pressure, follow the steps below:

#### Increase Cuff Pressure

**Step 1:** Increase the cuff pressure by pressing  (arrow up) as shown on figure 11 below.

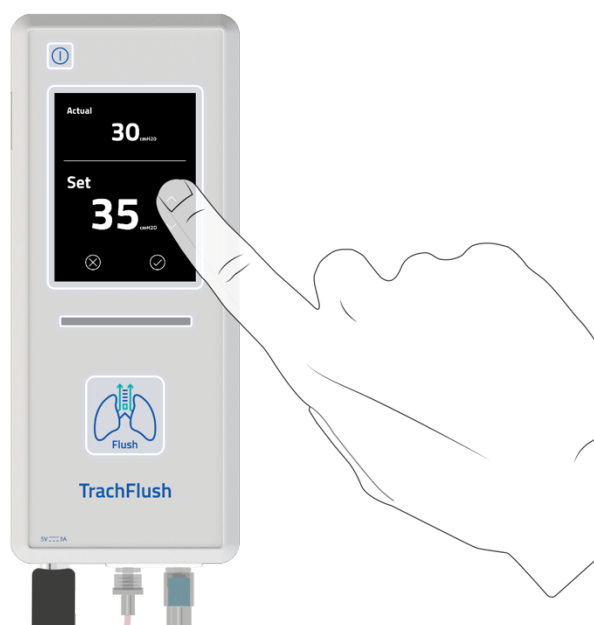



Figure 11: Increase cuff pressure

**Step 2:** To accept the new cuff pressure changes and apply a new pressure setting to the cuff, press  (accept) as shown on figure 12 below. The cuff will now be inflated until the Actual and Set cuff pressure is the same.

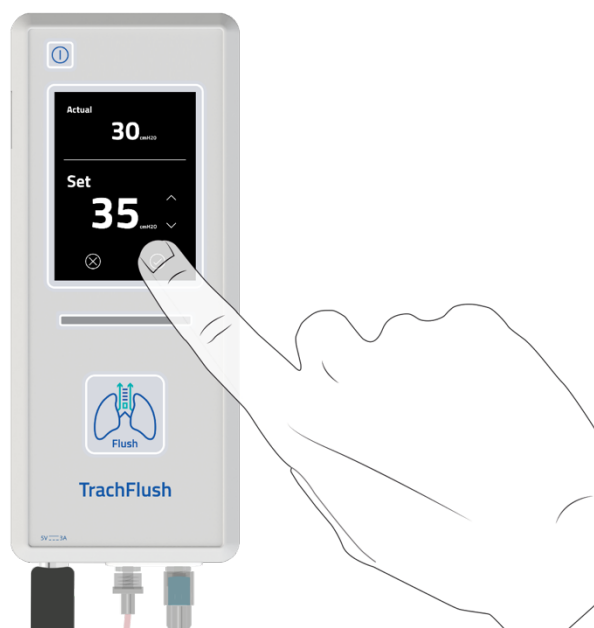


Figure 12: Accept increased cuff pressure

Following the cuff pressure changes, TrachFlush will automatically enable the Cuff Control functionality

To cancel the new changes, press  (cancel) as shown on figure 13 below.

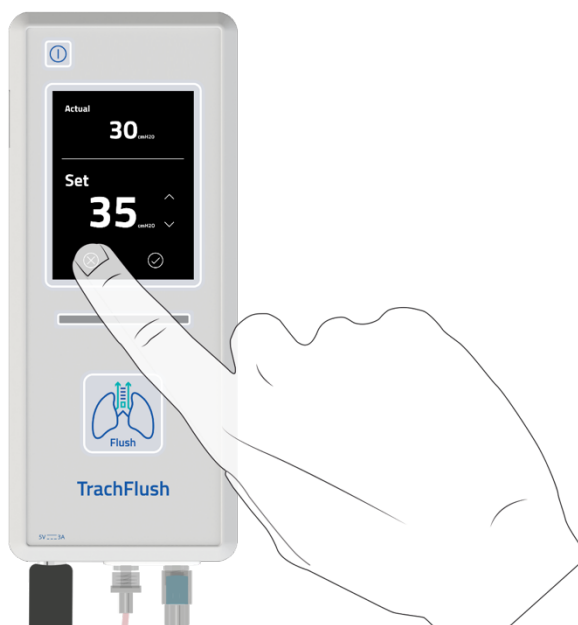



Figure 13: Cancel increased cuff pressure

## Decrease Cuff Pressure

**Step 1:** Decrease the cuff pressure by pressing  (arrow down) as shown on figure 14 below.

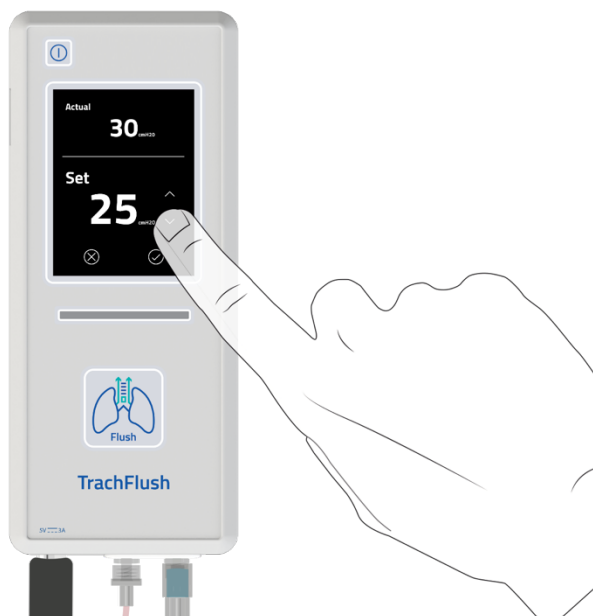



Figure 14: Decreasing cuff pressure

**Step 2:** To accept the new cuff pressure changes and apply a new pressure setting to the cuff, press  (accept) as shown on figure 15 below. The cuff will now be deflated until the Actual and Set cuff pressure is the same. .

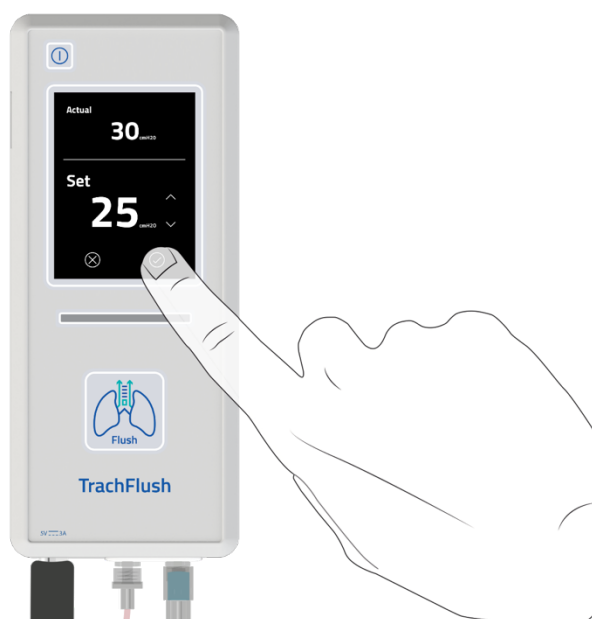


Figure15: Accept decreased cuff pressure

Following the cuff pressure changes, TrachFlush will automatically enable the Cuff Control functionality

To cancel the new changes, press  (cancel) as shown on figure 16 below.

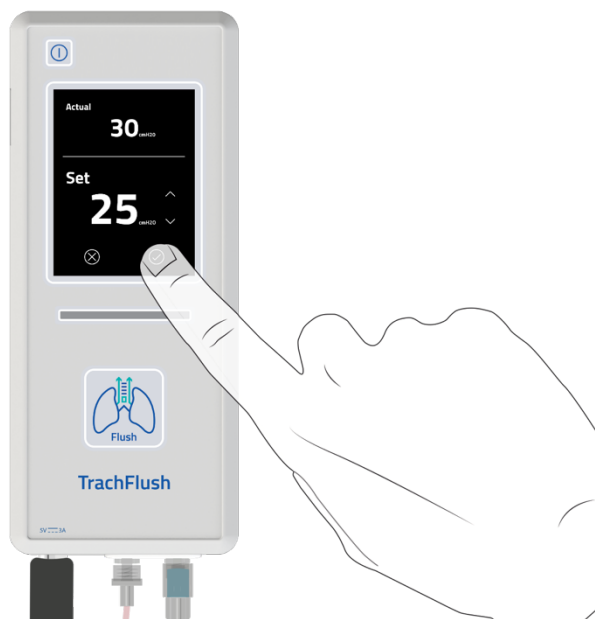


Figure 16: Cancel decreased cuff pressure

### 3.4 Flush Control

Please follow the following steps when you want to perform a Flush Control maneuver

**CAUTION:** Check if the mechanical ventilator is ventilating in either Pressure Control Ventilation (PCV) mode or Pressure Support Ventilation (PSV) mode as a Flush Control can only be performed in these two modes of ventilation

**CAUTION:** Check if ICU Ventilator settings are set at the following:

- P-insp is minimum 20cmH<sub>2</sub>O
- PEEP is minimum 5cmH<sub>2</sub>O
- Rf/RR is maximum 12b/min
- P-ramp is maximum 100ms

If the ICU ventilator setting is below these settings, adjust the ventilator settings to the above settings. Remember the current ventilator settings.

**CAUTION:** A Flush can only be performed with a cuff pressure of 15-35cmH<sub>2</sub>O .

**NOTICE:** TrachFlush will only perform the Flush Control if these ventilator settings are met.

**WARNING:** Only adjust the ICU Ventilator setting if it is clinically safe for the patient.

**Step 1:** Press and hold the Flush button for more than 3 seconds as shown on figure 17 below.

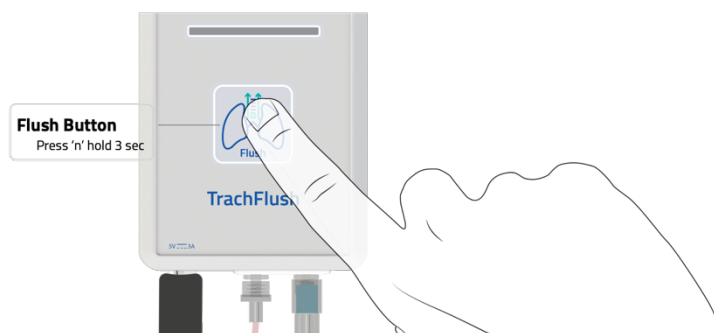


Figure 17: Performing a Flush


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 on figure 18.




Figure 18: Flush in Progress

**NOTICE:**

When flush is activated, then the TrachFlush device uses the two (2) first inspiratory cycles to check for correct ventilator settings as defined in section 3.4.

If the ventilator settings are correct, on the third inspiratory cycle the Flush will be performed.

If the ventilator settings are not correct, TrachFlush will not perform the Flush until corrected, and will revert to Cuff Controller mode.

Once the flush has completed, the signal  (Flush Complete) will appear on the screen as shown on figure 19

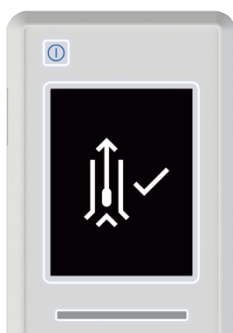


Figure 19: Flush Complete

Once complete, TrachFlush reverts to Cuff Controller mode, goes back to main screen and the LED-bar stops flashing cyan as shown in Figure 20.



Figure 20: Main screen

**Step 2:** Repeat step 1 three (3) times.

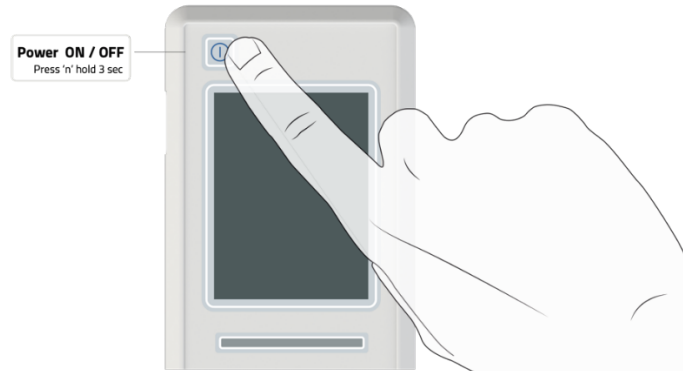
Following the flush, TrachFlush will automatically enable the Cuff Control functionality

**Step 3 (OPTIONAL):** Re-adjust the ventilator settings of pressure (P-insp), PEEP and T-insp back to original settings (see Section 3.4 above).



### 3.2 Turning OFF TrachFlush

**Step 1:** Turn off the TrachFlush device by pressing and holding the On/Off button for 3 seconds as shown on figure 20 below.



*Figure 21: Turn off TrachFlush*

**Step 2:** Disconnect

- the cuff pressure connector from the cuff
- the airway conector from the elbow or t-piece connector
- the cuff pressure and airway connector from the TrachFlush device

**Step 3:** Dispose the cuff pressure and airway tube as described in section 5.3

## 4 System alarms

When an alarm is generated, the device emits audible beeps and the alarm lamp lights yellow or red, depending on the alarm priority. The TrachFlush device has three alarm priorities: high, medium, and low. See Table 2 and 3 for details.





To silence an alarm











- Review the alarm, and if appropriate, press the Alarm silence button, which silences the alarm for 2 minutes.

**Table 2. 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 3
Medium-priority alarm	Yellow, flashing	A sequence of beeps, repeated periodically	Depends on the alarm; see Table 3
Low-priority alarm	Yellow, constant on	A sequence of beeps	Depends on the alarm; see Table 3
Technical alarm	Cyan, constant on	A sequence of beeps	Depends on the alarm; see Table 3
Information signal	Cyan, constant on	A sequence of beeps	Depends on the alarm; see Table 3

**Table 3. TrachFlush alarm names and symbols.**

Alarm name	Alarm type	Possible causes	Action required
Cuff Pressure Extremely High 	High-priority alarm	Cuff pressure is >70cmH2O	Lower cuff pressure
Cuff Pressure High 	Medium-priority alarm	Cuff pressure is >50cmH2O	Lower cuff pressure
Cuff Regulation Error 	Medium-priority alarm	<ul style="list-style-type: none"> <li>- Cuff loses pressure</li> <li>- Device error; cannot maintain cuff pressure</li> </ul>	<p>Check or change ETT/TT if needed</p> <p>Check Cuff Pressure and Airway tube</p> <p>Change Cuff Pressure and Airway tube if needed</p> <p>Disconnect device</p>
Cuff Pressure Low 	Medium-priority alarm	Cuff pressure is <5cmH2O	Increase cuff pressure

<b>Power Failure</b> 	Low-priority alarm	Power supply has been disconnected	Make sure the power supply is connected to the device and a power source
<b>Cuff Pressure Tube not Connected</b> 	Technical alarm	Cuff pressure tube not connected correctly	Check cuff pressure tube connection
<b>Airway Tube not Connected</b> 	Technical alarm	Airway tube not connected correctly	Check airway tube connection
<b>Incorrect Ventilator Settings</b> 	Technical alarm	Respiratory frequency is too high/low  I:E Ratio is too high/low  Airway pressure is too low	Manually lower/increase Rf on the ventilator  Manually lower/increase I:E Ratio on the ventilator  Manually increase Airway pressure on the ventilator
<b>User Shutdown Denied</b> 	Technical alarm	Flush or cuff adjustment in progress.	Wait 20 sec and try again.
<b>Flush Complete</b> 	Information signal	Flush completed	Reset ventilator settings if adjusted before performing a flush
<b>Flush in Progress</b> 	Information signal	Flush in progress	Wait until flush is complete.
<b>Booting</b> 	Information signal	Booting in progress	Wait until the device is fully booted.
<b>Processing</b> 	Information signal	Preparing for Flush Control	Wait until the device is ready before activating Flush Control.
<b>Service</b> 	Information signal	Service for the device is required	Disconnect the device and send to service.

## 5 Cleaning and maintenance

### 5.1 Cleaning the TrachFlush Mounting Bracket

Before cleaning or disinfecting the TrachFlush Mounting Bracket, turn off TrachFlush and unscrew the Mounting Bracket.

Clean the equipment with a soft cloth moistened in water or a mild soap solution. To disinfect the equipment, wipe with 70% isopropyl alcohol.

### 5.2 Cleaning the TrachFlush device

Always disconnect the device from electrical 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.

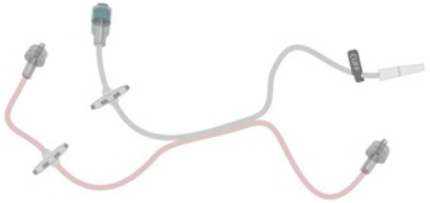


Clean the equipment with a soft cloth moistened in water or a mild soap solution. To disinfect the equipment, wipe with 70% isopropyl alcohol.

### 5.3 Disposal of the TrachFlush Cuff Pressure and Airway tube set

The TrachFlush Cuff Pressure and Airway Tube set

- Is intended for single patient use only and must not be used on multiple patients in order to avoid cross infections between patients.
- is a single use device, which shall not be cleaned, disinfected or re-processed in any way.
- should be disposed in accordance with local regulations for contaminated and biologically hazardous items.

## 6 Parts and accessories

Name	AW Technologies Part number
<p>Cuff Pressure and Airway Tube set</p> 	<p>TFSACO010001</p>
<p>TrachFlush Mounting bracket</p> 	<p>TFSAB010001</p>
<p>Power Supply incl. adaptors</p> 	<p>TFSAPSU010001</p>

## 7 Specifications

Physical characteristics	
Weight	500g (gram)
Dimensions	Length: 22cm Width: 8cm Height: 4,9cm
Technical performance data	
<b>Cuff Control:</b>	
Cuff pressure set range	5cmH <sub>2</sub> O to 50cmH <sub>2</sub> O
Resolution (setting/display)	±1cmH <sub>2</sub> O
Pressure accuracy	±1cmH <sub>2</sub> O
<b>Flush Control – ventilator settings:</b>	
P-insp	Minimum 20cmH <sub>2</sub> O
PEEP	Minimum 5cmH <sub>2</sub> O
Rf/RR	Maximum 12b/min
P-ramp	Maximum 100mSec
<b>Flush Control – ETT or TT cuff requirements:</b>	
Material	Either Polyvinyl chloride (PVC) or Polyurethane (PU)
Dimensions	From 5.0mm to 10.0mm Inner Diameter
Electrical specifications	
AC Power Input	100-240 VAC
DC Power input	5V DC 3A
Fuse	Fuse is integrated in the power supply (non-replaceable)
Alarm volume	dB(A) 45
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	>80dB(A)