TrachFlush

Instructions for Use

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TrachFlush

CE

AW Technologies

TrachFlush

Instructions for Use

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AWT-1030

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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.

CAUTION

- Use only the AW Technologies disposable Cuff Pressure and Airway Tube with filter, safety valve, and lock. 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 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 12

1. Device overview

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

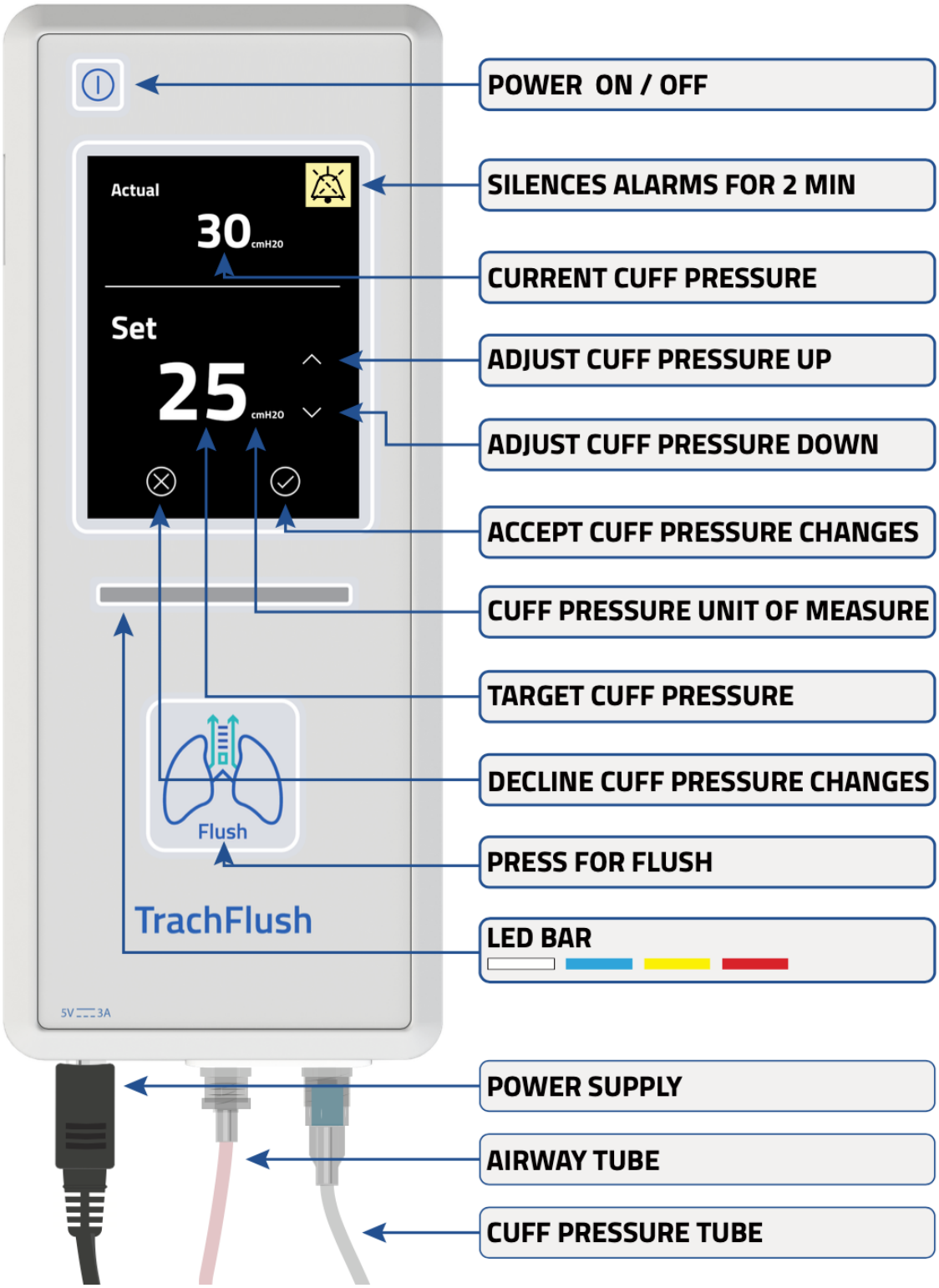
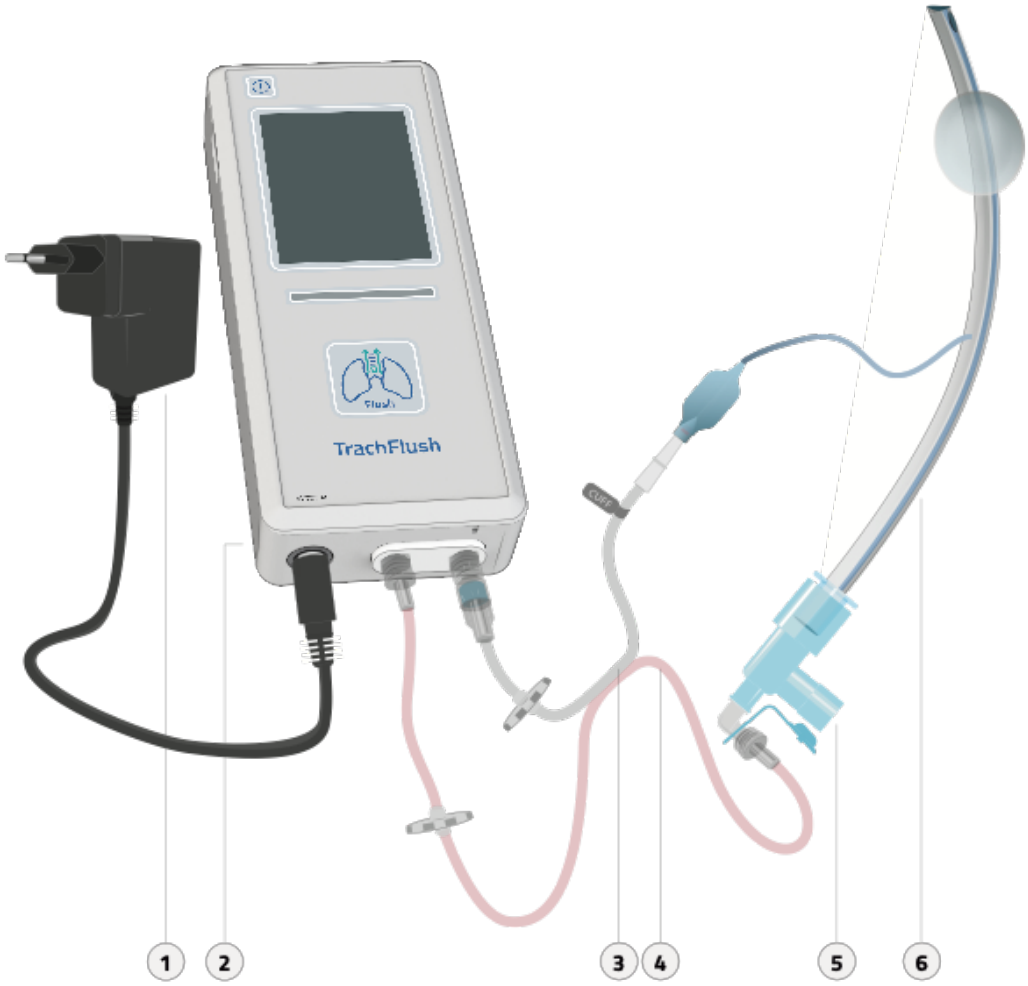


Figure 1: Device overview

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 Cuff Pressure Tube and Airway Tube to the device

Step 1: Connect the Cuff Pressure Tube (transparent tube) connector to the cuff inlect socket of the TrachFlush by twisting it on as shown in figure 3.

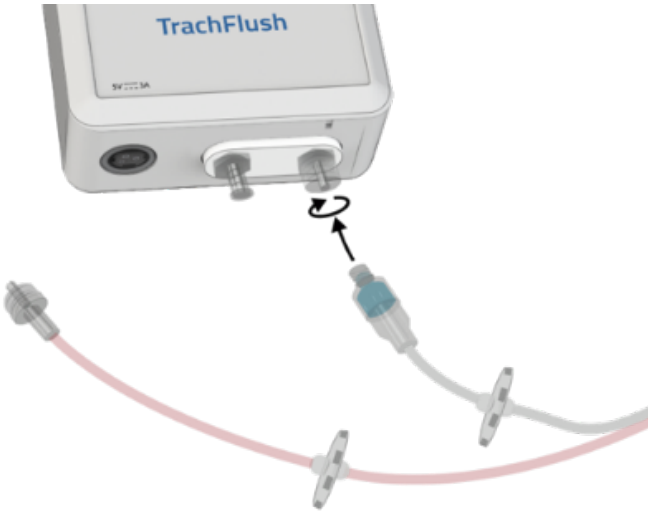


Figure 3: Device connectivity, connecting Cuff Pressure Tube

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 4.

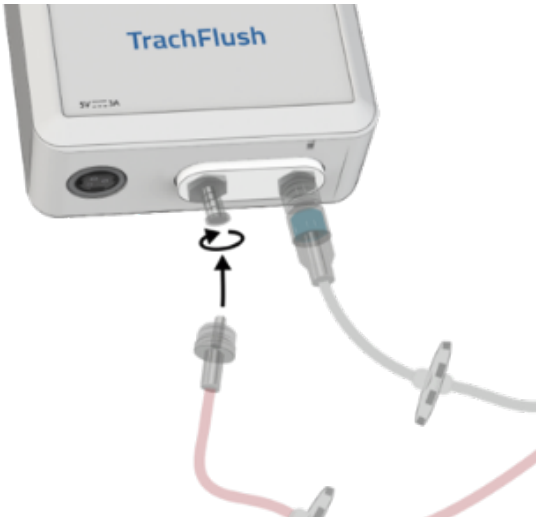


Figure 4: Device connectivity, connecting Airway Tube

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

Step 1: Connect the Airway Tube (pink tube) connector to the patient's airway elbow or straight connector by twisting it on as shown in figure 5.

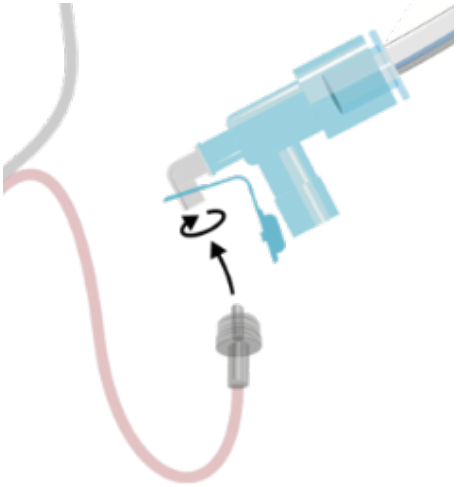


Figure 5: Patient connectivity, connecting Airway Tube

NOTICE

If no standard luer lock gas outlet is available, attach a connector to the patients breathing system.

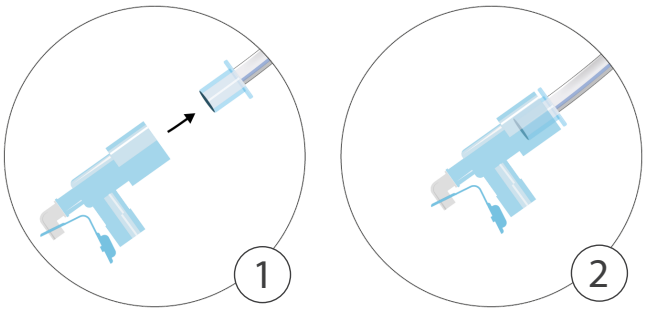


Figure 6: Patient connectivity, connecting elbow connector

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 in figure 7.

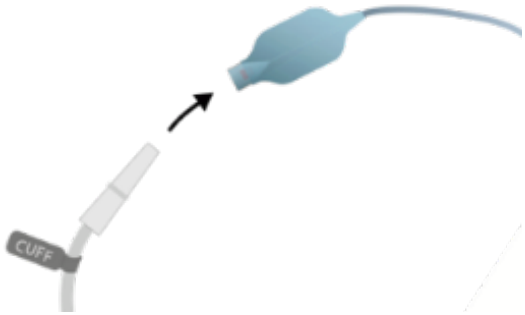


Figure 7: Patient connectivity, connecting Cuff Pressure Tube

3.3. 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 / AWT-1130)

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 marked 5V ⎓ 3A

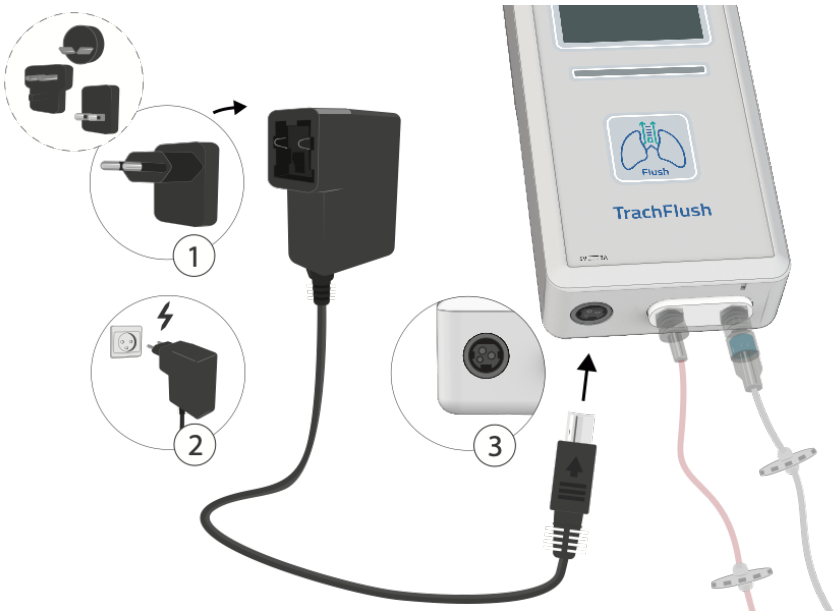


Figure 8: Connecting the device to primary power

3.4. Turning ON the device

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

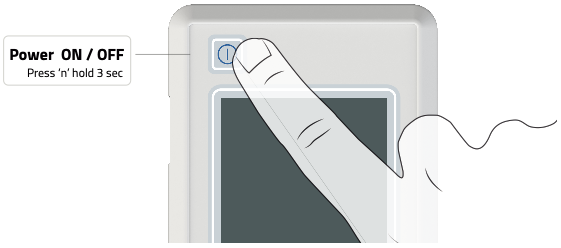


Figure 9: Turning on TrachFlush

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 5.

Figure 10: TrachFlush Booting

Once the device has turned on, the main screen will appear (as shown in figure 11) and TrachFlush will automatically enable the Cuff Control functionality (see section 3.6)

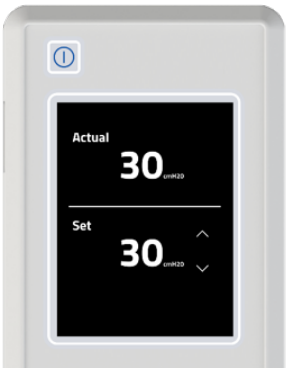
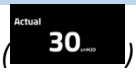


Figure 11: TrachFlush mainscreen

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 Actual Cuff Pressure measured.*

3.5. 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 30cmH_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 Leakage alarm appears on the TrachFlush device display. See section 5 for further instructions on required action.

3.6. Adjsut cuff pressure

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

NOTICE

It is recommend that you keep cuff pressure between 25cmH_2O and 30cmH_2O for adult ETTs/TTs.

TrachFlush Cuff Controller can regulatre pressure between 5 and 50cmH2O.

3.6.1. Increase cuff pressure

Step 1: Increase the cuff pressure by pressing (arrow up) as shown in figure 12 below.

Figure 12: 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 in figure 13 below. The cuff will now be inflated until the Actual and Se cuff pressure is the same.

Figure 13: Accept increased cuff pressure

To cancel the new changes, press (cancel) as shown in figure 14 below.

Figure 14: Cancel increased cuff pressure

3.6.2. Decrase cuff pressure

Step 1: Decrease the cuff pressure by pressing (arrow down) as shown in figure 15 below.

Figure 15: 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 in figure 16 below. The cuff will now be inflated until the Actual and Se cuff pressure is the same.

Figure 16: Accept decreased cuff pressure

To cancel the new changes, press (cancel) as shown in figure 17 below.

Figure 17: Cancel decreased cuff pressure

4. Flush Control

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

CAUTION

Check if ICU Ventilator settings are set at the following

1. *Mode*
    a. *Pressure Control Ventilation (PCV)*
2. *Settings*
    a. *Pressure above PEEP is minimum 10cmH2O*
    b. *PEEP is minimum 5cmH2O*
    c. *Inspiratory time is minimum 1.4 seconds*
    d. *P-ramp is maximum 100mSec*
    e. *Cuff pressure is between 15 cmH_2O and 35 cmH_2O*

NOTICE

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

WARNING

Only adjust the ICU Ventilator settings if it is clinically safe for the patient.

Step 1: Press the Flush button as shown in figure 18 below.

Figure 18: 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 19.

Figure 19: 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 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, but will give you the option of performing a Force Flush (see section 5). If Force Flush is “Canceled”, TrachFlush will revert to Cuff Controller mode.

Figure 20: Ventilator settings incorrect

Once the flush has completed, the signal  (Flush Complete) and “OK” button will appear on the screen as shown on figure 21.

Figure 21: Flush Complete

After the Flush has been complete, TrachFlush reverts to Cuff Controller mode, and once “OK” button has been pressed to register Flush is complete, TrachFlush goes back to main screen and the LED-bar stops flashing cyan as shown in Figure 22.

Figure 22: Main screen

Step 2 (OPTIONAL): Repeat Step 1 three (3) times for best result.

Step 3 (OPTIONAL): If ventilator settings were adjusted before performing a Flush, re-adjust the ventilator settings of pressure (Pressure above PEEP), PEEP and inspiratory time back to original settings.

5. Force Flush

Please follow the following step when you want to perform a Force Flush maneuver.

CAUTION

Check if ICU Ventilator settings are set at the following

1. *Mode*
    a. *Pressure Support Ventilation (PCV)*
2. *Settings*
    a. *Pressure above PEEP is minimum 10cmH2O*
    b. *PEEP is minimum 5cmH2O*
    c. *Inspiratory time is minimum 1.4 seconds*
    d. *P-ramp is maximum 100mSec*
    e. *Cuff pressure is between 15 cmH_2O and 35 cmH_2O*

NOTICE

TrachFlush will only perform the Force Flush is these ventilator settings are met.

WARNING

Only adjust the ICU Ventilator settings if it is clinically safe for the patient.

When Force Flush is activated, then the TrachFlush device will perform the Force Flush during the next inspiratory cycle no matter the ventilator settings.

Step 1: Press the Flush button as shown in figure 23 below.

Figure 23: Performing a Force Flush

When the Flush button is presse, the signal  (Flush Not Possible), the buttons “INITIATE FORCE FLUSH” and “CANCEL” will be shown, and the LED-bar will light cyan, as shown on figure 24.

Figure 24: Initiaite Force Flush

Step 2: Press the “INITIATE FORCE FLUSH” button to activate Force Flush.

Once “INITIATE FORCE FLUSH” has been pressed, the text “DO YOU WANT TO INITIATE FORCE FLUSH”, the buttons “ACCEPT” and “DECLINE” will be shown, and the LED-bar will light cyan, as shown on figure 25.

Figure 25: Do you want to initiate Force Flush?

Step 3: Press the “ACCEPT” button to confirm activation of the Force Flush.

When the Force Flush is activated, then on the TrachFlush screen, the signal  (Flush In Progress), and text “FORCE FLUSHING” will be shown, and the LED-bar will light cyan until the Force Flush has completed, as shown on figure 26.

Figure 26: Force Flushing

Once the Force Flush has completed, the signal  (Flush Complete) and “OK” button will appear on the screen as shown in figure 27.

Figure 27: Force Flush Complete

After the Force Flush has been complete, TrachFlush reverts to Cuff Controller mode, and once “OK” button has been pressed to register Force Flush is complete, TrachFlush goes back to main screen and the LED-bar stops flashing cyan as shown in Figure 28.

Figure 28: Main screen

Step 4 (OPTIONAL): Repeat step 1 three (3) times for best result.

Step 5 (OPTIONAL): If ventilator settings were adjusted before performing a Flush, re-adjust the ventilator settings of pressure (Pressure above PEEP), PEEP and inspiratory time back to original settings.

6. Turning OFF the device

Step 1: Turn off the TrachFlush device by pressing and holding the On/Off button for 3 seconds as shown in figure 29 below.

Figure 29: Turn off TrachFlush

Step 2: Disconnect:

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

Step 3: Dispose the cuff pressure and airway tube as described in section 9.3.

7. 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

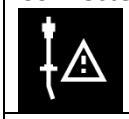
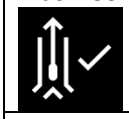
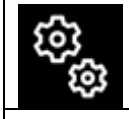
- Review the alarm, and if appropriate, press the Alarm silence button.
- The Alarm is silenced for 2 minutes.
- Take action to mitigate alarm as in Table 2 Action required collun

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	Cyan, constant on	A sequency of beeps	Depends on the alarm; see Table 2
Information signal	Cyan, 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 >=70cmH2 	High-priority alarm	Cuff pressure is >=70cmH2O	Lower cuff pressure
Cuff Pressure >50cmH2O 	Medium-priority alarm	Cuff pressure is >50cmH2O	Lower cuff pressure
Cuff Leakage 	Medium-priority alarm	Cuff loses pressure Device error; cannot maintain cuff pressure	Check and change ETT/TT if needed Check and change Cuff Pressure and Airway tube if needed Disconnect device
Cuff Pressure <5cmH2O	Medium-priority alarm	Cuff pressure is <5cmH2O	Increase cuff pressure

			
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
Cuff Pressure Tube not Connected 	Technical alarm	Cuff pressure tube not connected correctly	Check cuff pressure tube connection
Airway Tube not Connected 	Technical alarm	Airway tube not connected correctly	Check airway tube connection
Flush not Possible 	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
Flush or Cuff adjustment in progress 	Technical alarm	Flush or Cuff adjustment in progress.	Wait 20 sec and try again.
Flush Complete 	Information signal	Deflation and inflation mode completed	Reset ventilator settings if adjusted before perfoming a deflation and inflation
Flush in Progress 	Information signal	Deflation and inflation mode in progress	Wait until Deflation and inflation mode is complete.
Booting 	Information signal	Booting in progress	Wait until the device is fully booted.
Checking ventilator and cuff settings 	Information signal	Preparing for Deflation and inflation mode	Wait until the device is ready before activating Deflation and inflation mode.
Service of the device is required	Information signal	Service of the device is required	Disconnect the device and send to service.

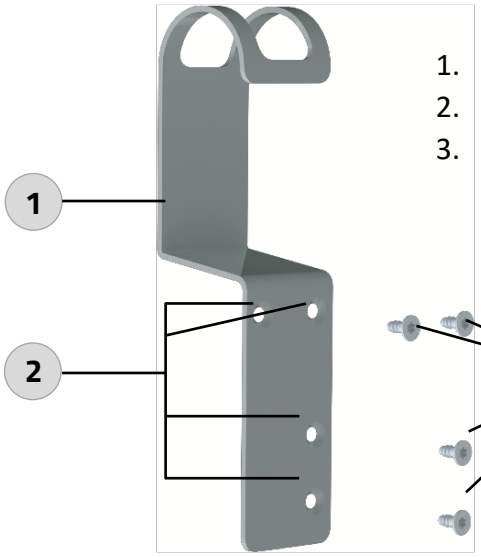
				

Should multiple alarms occur at the same time, the alarm with the highest priority will be shown on top.

8. Mounting the TrachFlush device

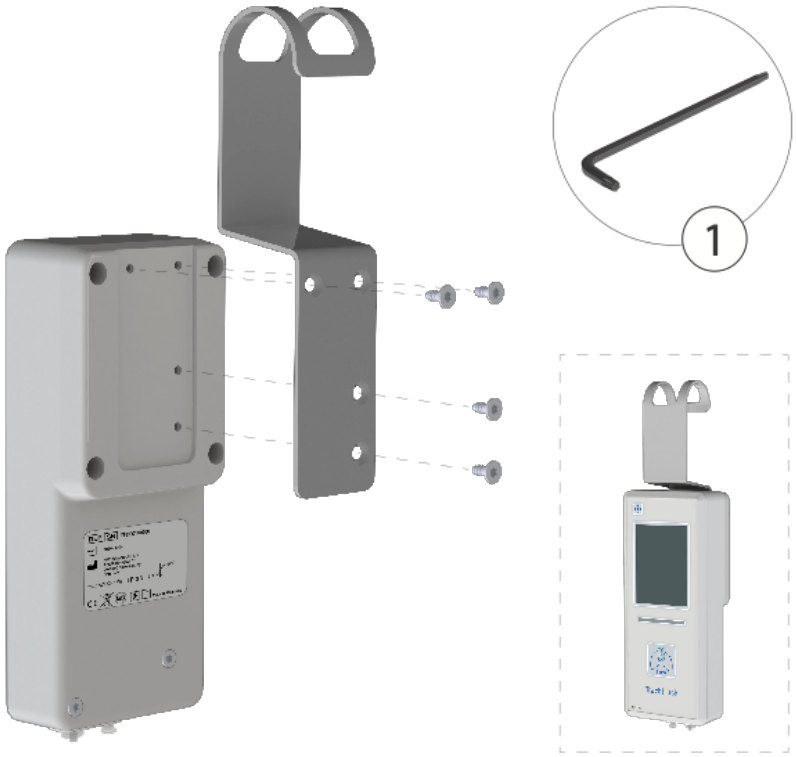
The TrachFlush has a bed-side bracket mounting option available.

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

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



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9. Cleaning and maintenance

9.1. 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 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.

9.2. Maintenance of TrachFlush device

Preventive maintenance is not required, except for cleaning.

9.3. 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.

10. Intended use and operators

Intended use

The TrachFlush device is intended to:

- Continiously 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.

11. 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

12. 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 elextromagnetic 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.

Intereference 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. Intereference 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 perpherals 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 ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment
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

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	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: 
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.			

13. Specifications

13.1. 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 10cmH2O
PEEP	Minimum 5cmH2O
Inspiratory time (T-Insp)	Minimum 1.4 seconds
P-Ramp	Maximum 100mSec
Cuff pressure range	15cmH2O to 35cmH2O
Force Flush mode – ventilator settings	
Ventilation mode supported	Pressure Support Ventilation (PSV)
Pressure above PEEP	Minimum 10cmH2O
PEEP	Minimum 5cmH2O
Cuff pressure range	15cmH2O to 35cmH2O
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)

13.2. 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)

14. Parts and accessories

Name	AW Technologies Part number
Cuff Pressure and Airway Tube set 	TFSACO01
Bed-side bracket 	AWT-1117
Power Supply 1 meter incl. adaptors 	AWT-1129
Power Supply 2 meters incl. adaptors	AWT-1130

	

15. 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.

15.1. 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.