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1. Introduction

These instructions apply to the medical device – Cuff Pressure Regulator. Before use, read all the information in these instructions, on the packaging and on the device itself.

Intended use

Cuffix is designed to indicate and regulate the intracuff pressure of endotracheal tubes and tracheotomy tubes using passive control.

Intended user, working environment, service life

Cuffix is an electronic, non-sterile, single-use medical device intended for single patient use. The device is powered by an internal, non-replaceable battery.

After training, the device can be used by medical personnel (doctors, nurses, etc.) in hospitals, emergency medical services, extended care facilities, or clinics where patients can be intubated.

The use life of the device is 10 days from the time of activation. The expiration date of the device must be entered on the sticker with the symbol  supplied with the device when the device is first activated. After entering the date, the sticker should be affixed in a visible place on the outside of the device housing.



Warning: Do not use the product after the expiration date.



Once the use life has been exceeded, the product must be disposed of in accordance with the relevant regulations.

Indications/ Contraindications

- The device is intended for single patient use only.
- Cuffix may only be connected to a pre-inflated cuff.
- The device may only be connected to airway cuff pilot balloons that are filled with air.

Products compatible with Cuffix

Cuffix is specifically designed for use with artificial airways with an air cuff and must not be used with uncuffed artificial airways, self-inflating foam-filled cuffs, or artificial cuffs designed to be filled with fluid. The device is designed to be used with cuff inflation syringes.



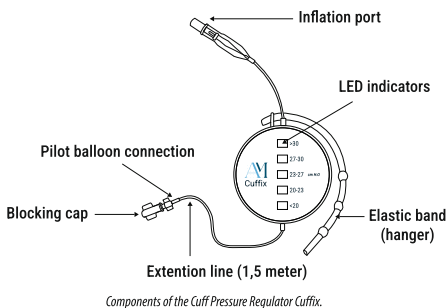
Warning: Avoid using this medical device near or on another device, as this may cause malfunction. If such use is necessary, observe this device and the other device to ensure that they are functioning properly.



Warning: Portable radio communication equipment (including peripheral devices such as antenna cables and external antennas) should not be used within 12 inches (30 cm) of any part of the Cuffix. Failure to comply with this recommendation may result in reduced performance of this device.

2. Components of the Cuffix product

The diagram below shows the components of the Cuffix cuff pressure regulator.



Components of the Cuff Pressure Regulator Cuffix.

3. Use of the Cuffix product

The following describes how to use cuff pressure regulator Cuffix. A cuff inflation syringe will be needed.

1. Take the device out of the box and check if there are no external signs of damage.



Warning: Do not use the product if any parts show signs of damage



Warning: During operation, protect the product from contact with liquids and prevent flooding.

2. Activate the Cuffix by pulling out the protective film [Figure 1].
3. A flashing red light will appear, indicating that the pressure is below 20 cm H₂O. [Figure 2].

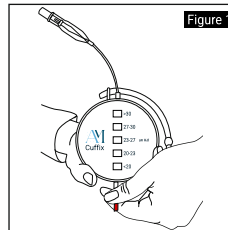


Figure 1

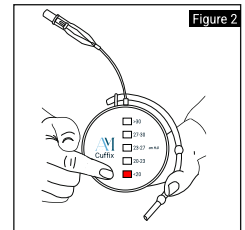


Figure 2

4. Connect a cuff inflation syringe and inject 10cm3 of air to the inflation port [Figure3]. Disconnect the syringe.



Warning: Applying pressure bigger than 60 cm H₂O to the device may damage it.

5. Wait 30 seconds for the pressure to stabilize. If the pressure needs to be adjusted, reconnect the syringe to the inflation port and adjust the pressure until the desired value is achieved. Then disconnect the syringe.



Warning: The device may only be connected to airway cuff pilot balloons that are filled with air.

6. Remove the blocking cap from the extension and immediately connect Cuffix to the endotracheal tube's pilot balloon using the pilot balloon connection [Figure 4].

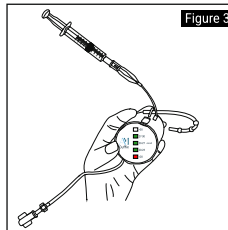


Figure 3

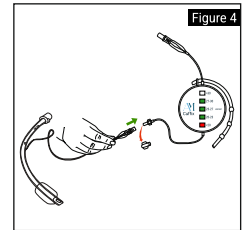


Figure 4

From this point on, Cuffix continuously indicates the cuff pressure range using the appropriate LED.

7. Take the sticker with the symbol  out of the box. Write the expiry date of the device in a permanent way on it (10 days from the date of activation of the product). Then apply the sticker in a clearly visible place on the outside of the product housing [Figure 5].

8. Fix the device with an elastic band (hanger) in place, so that the status of the device's indication LEDs can be observed without obstruction [Figure 6].

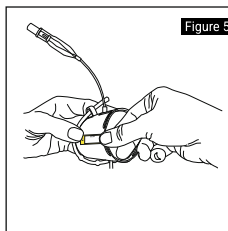


Figure 5

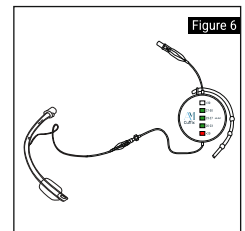


Figure 6

9. After use, dispose of the device in accordance with applicable regulations for waste electrical and electronic equipment.

Comments on the functioning of the product

- Disconnecting the Cuffix has no immediate effect on the endotracheal tube cuff pressure. If reconnection is necessary, connect the device to the endotracheal tube pilot balloon and then adjust pressure (using a syringe) until the required value is achieved.
- Cuffix is designed for a pressure range of 20 to 30 cm H₂O.
- The front of the device is equipped with LEDs that indicate the pressure ranges in the endotracheal tube cuff. The assignment of a specific LED color to a specific pressure range is shown below:

- Flashing red -cuff pressure is above 30cm H₂O
- Flashing green - cuff pressure is between 20 -30 H₂O
- Flashing red -cuff pressure is below 20 cm H₂O

	>30
	27-30
	23-27
	20-23
	<20

- Temporary deviations of +/- 3 cm H₂O are normal with regard to the functioning of the product.
- The pressure can be adjusted at any time by filling or deflating the air through the inflation port.

4. Safety warnings and cautions



Warning: Do not reuse, refurbish or sterilise this medical device. Reuse, fully refurbishing or sterilisation may compromise the structural integrity of the device or cause the device to not function as intended.



Warning: Do not use the product if any parts show signs of damage.



Warning: Do not use the product beyond its shelf life.



Warning: Do not use the device in a magnetic resonance imaging (MRI) environment as this may damage the device.



Warning: Do not modify the product in any way.

5. Symbols associated with the use of the product

Symbol	Description
	The symbol indicates information which has an impact on the safety of the user, the patient or third parties in relation to the device, and with which it is mandatory to be acquainted before using the device.
	The symbol indicates that the device is a medical device.
	The symbol indicates the compliance of the product with the requirements of Regulation 2017/745 EU (MDR) and other European Union regulations.
	The symbol refers to a medical device that should be protected from direct heat sources (e.g.: sunlight).
	The symbol indicates the need to protect the product from moisture.
	The symbol indicates the manufacturer of the medical device to which this Instruction applies.
	The symbol indicates the need to read the Instructions for Use.
	The symbol indicates the date of expiry until which the product can be safely used.
	The symbol indicates the serial number of the manufactured product. The first part of the serial number indicates the product number and the second part its production, for instance: SN: 00001-01012024 - product no. 00001 manufactured on 01.01.2024
	The symbol indicates the catalogue number of the medical device.
	The symbol indicates the UDI number of the medical device.
DC 3V 	The device is powered by an internal 3V DC battery.
IP20	The symbol indicates the degree of protection of the enclosure against harmful ingress of water or solid objects. Class IP20 means that the product is protected against the ingress of solid foreign objects with a diameter of 12.5 mm or more and is not waterproof.
	The symbol refers to a medical device that is intended for single use.
	The appliance must be disposed of in accordance with current legislation on waste electrical and electronic equipment.

6. Use, storage and transport

Keep the product at room temperature during use, transport and storage. Protect the product from moisture and direct heat (e.g. sunlight).

The conditions for use, transport, and storage of the product are presented below.
Use:
Temperature: from +15°C to +30°C
Humidity: from 30% RH to 75% RH (without condensation)

Storage and transport:
Temperature: from -20°C to +60°C
Humidity: from 10% RH to 95% RH (no condensation)

 Warning: After storing the product at temperatures below +10°C, allow the product to stabilize for at least 2 hours at temperatures between +15°C and +30°C before use.

7. Cleaning and disinfection

The device is not intended for routine cleaning or disinfection. However, if the device becomes contaminated, the outer casing of the device should be disinfected with agents intended for disinfecting the outer surfaces of medical devices.
In case of strong contamination of the device before disinfection, the device should be cleaned with a soft cloth moistened with a solution of water and mild detergent.

 Warning: When cleaning or disinfecting, prevent from getting into any fluids the tubing and inside the housing of the device. Do not immerse or spray the device with cleaning or disinfectant fluids.

 Warning: The product is not sterilisable.

8. Disposal

Disposal of the product and its packaging must be carried out in accordance with local regulations.

9. Contact with a healthcare professional

If you are not a medical professional and are in doubt about the performance of the device or do not know how to operate it, contact a healthcare professional familiar with the device or contact the manufacturer directly.

10. Manufacturer contact details

Manufacturer's contact details for technical support or to report unexpected actions or events related to the medical device:

Airway Medix S.A.
Street: Szara 10
00-420 Warsaw, Poland
e-mail: info@airway-medix.com
www.airway-medix.com

10. Reporting of serious product-related incidents

In the event of serious incidents involving the device, they should be reported immediately to the manufacturer and to the Office for Registration of Medicinal Products for Medical Devices and Biocidal Products.

www.urpl.gov.pl
www.airway-medix.com