biovo technologies

EN

Cuff Pressure Regulator (Cuffix)

INSTRUCTIONS FOR USE

FR

Régulateur de pression de ballonnet (Cuffix)

MODE D'EMPLOI

DE

Cuffdruckregler (Cuffix), Ein-Patienten-Produkt

GEBRAUCHSANWEISUNG

IT

Cuffix - Regolatore di pressione della cuffia dei dispositivi di ventilazione - per pazienti

ISTRUZIONI PER L'USO

PT

Regulador de Manómetro Manual (Cuffix)

INSTRUÇÕES DE UTILIZAÇÃO

L0044 Rev.03

1.1. INDICATION FOR USE

The Cuffix is intended to measure and regulate, through passive control, the intracuff pressure of Endotracheal tubes, Tracheotomy tubes and Laryngeal Masks Airways (LMAs) (supraglottic airways). The device is intended for single patient use, under medical supervision in hospitals, pre-hospital (EMS), extended care facilities or outpatient clinics, where a patient may be intubated.

1.2. CAUTIONS

- Connect the Cuffix to the pilot balloon of airways with inflatable air-filled cuffs ONLY.
- Cuffix is specifically designed for use with air-cuffed artificial airways and is NOT to be used with uncuffed artificial airways, foam-filled-self-inflating cuffed, or artificial airway cuffs designed to be fluid filled.
- DO NOT attempt to sterilize or autoclave.
- Proper handling and storage of the Cuffix is mandatory.
- Do not use if the packaging has been compromised.
- Do not use the device if the expiration date is overdue.
- Do not use the Cuffix if any parts show signs of damage.
- The Cuffix is for a single patient only.
- Do not reuse, reprocess, or sterilize this medical device. Reuse, reprocessing, or sterilization may, compromise the structural integrity of the device, or lead to the device not performing as intended.

Note: the Cuffix shall be connected to a pre-inflated cuff only

1.3. WARNINGS

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- NOTE Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Cuffix, including cables specified by the manufacturer. Noncompliance may result in degradation of the performance of this equipment.

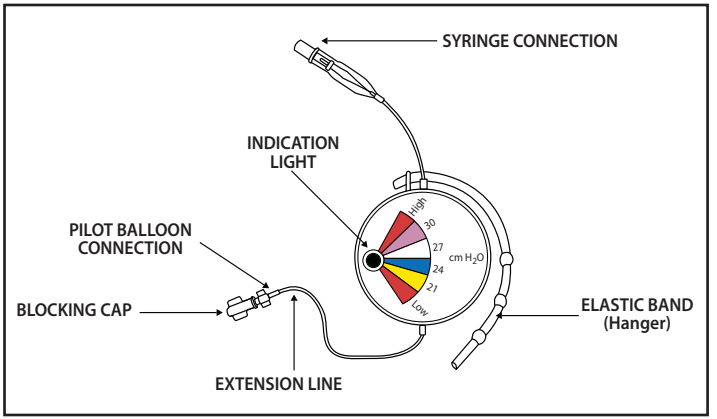
- NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- The Cuffix is designed to be used continuously for up to 10 days.
- The Cuffix is designed to work in a pressure range of 20-30cmH_2O.
- Federal law restricts this device to sale by or on the order of a physician.
- Disconnect the Cuffix prior to patient transport.

1.4. PACKAGING AND STERILIZATION

The Cuffix is supplied non-sterile and is intended for single patient use. All packaging should be inspected for damage and expiration prior to use. Do not use if the package is opened or damaged.

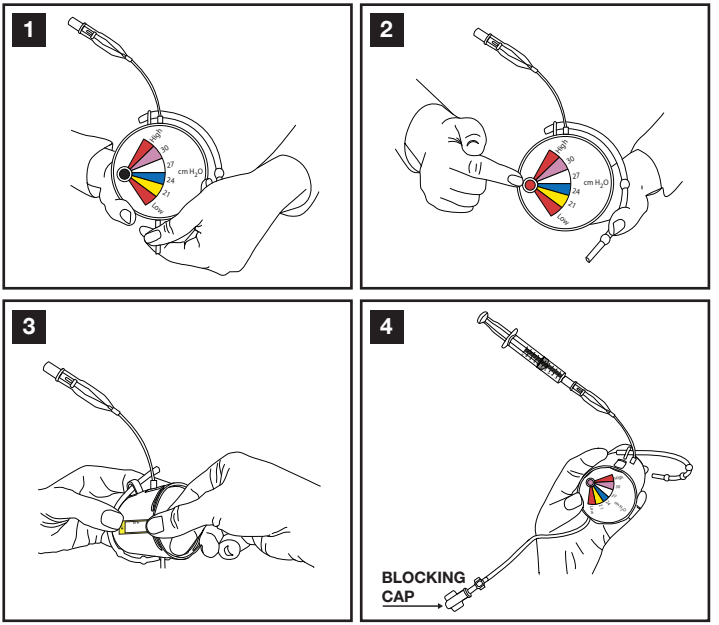
Storage: store at room temperature in a clean and dry environment.

2. DIRECTIONS FOR USE



1. CUFFIX SET-UP

1.1. Open the packaging and take out the Cuffix.
1.2. Turn on the Cuffix by pulling the strip [Figure 1].
1.3 Blinking red light will appear, indicating that the pressure is below 20cmH20 ("Low"). [Figure 2].
1.4. Attach a day sticker and write the intended replacement date, according to the 10 days lifetime of the device [Figure 3].
1.5. Verify that the Blocking Cap is attached to the edge of the extension line. Connect a syringe to the Syringe Connection port, insert 10cc of air and disconnect the syringe [Figure 4].



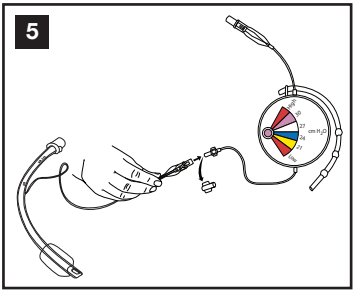
2. CUFFIX OPERATION

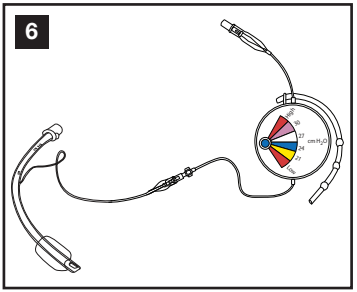
2.1. Remove the blocking cap from the edge of the extension line and immediately connect the Cuffix to the pilot balloon of ventilation with the Pilot Balloon Connector [Figure 5].

2.2. Wait for 30 seconds until pressure stabilizes. In case there is a need for pressure adjustment, connect a syringe to the Syringe Connection port and adjust until the light indicates the desired pressure. Disconnect the syringe.

2.3. From here on the Cuffix is continually regulating and monitoring the pressure of the cuff within the preferred range of 20-30cmH_2O and the pressure can be detected by the indication light at any time [Figure 6].

2.4. Hang/place the Cuffix in the desired location using the elastic band.





3. CONNECTION/DISCONNECTION

Note: Cuffix disconnection doesn't compromise the pressure in the cuff of ventilation tube.

3.1. In case re-connection of the Cuffix is required, connect the Cuffix to the pilot balloon of ventilation tube and adjust (using a syringe), until the desired pressure is indicated by the light.

4. CLEANING INSTRUCTIONS

Wipe the surface thoroughly with an alcohol-based disinfectant. While cleaning, prevent entry of any fluid into the luer connection. Do not submerge the Cuffix.

ATTENTION

- When the pressure is below 20cmH_2O the light will be blinking red.
- When the pressure is above 30cmH_2O the light will be constant red.
- Small deviations within the +/- 3cmH_2O is normal to the functionality of the device.
- Pressure adjustment can be done at any time by inflating or deflating via the Syringe Connection port.

CE

℞ Only
FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

NOT FOR GENERAL WASTE

SINGLE USE ONLY

DO NOT USE IF PACKAGE IS DAMAGED

ATTENTION READ INSTRUCTIONS

NON STERILE

STORE IN A DRY PLACE

MD

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Declaration – electromagnetic emissions		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group1 Class A	The Cuffix 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.
Harmonic emissions IEC 61000-3-2	N/A	The Cuffix is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Cuffix or shielding the location.
Voltage Fluctuations And Flicker IEC 61000-3-3:2013	N/A	

Declaration – electromagnetic immunity			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2, 4, 8, 15kV air	8 kV contact 2, 4, 8, 15kV 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	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/output) to earth	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°,	N/A	Mains power quality should be that of a typical commercial or
voltage variations on power supply input lines IEC 61000-4-11	225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle		hospital environment. If the user of the Cuffix requires continued operation during power mains interruptions, it is recommended that the Cuffix be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 (A/m)	30 (A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Declaration – electromagnetic immunity			
IMMUNITY test	**IEC 60601 TEST LEVEL**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	N/A	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the Cuffix, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3.5}{V_1}]\sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m	3V/m	$d = [\frac{12}{V_2}]\sqrt{P}$ $d = [\frac{12}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{23}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,
	3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz	3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz	
	10V/m from 80MHz to 2.7GHz	10V/m from	

		80MHz to 2.7GHz	should be less than the compliance level in each frequency range. D Interference may occur in the vicinity of equipment marked with the following symbol: 

Recommended separation distances between portable and mobile RF communications equipment and the Cuffix

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz outside ISM bands $d = [\frac{3.5}{V_1}]\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = [\frac{12}{V_2}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{12}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{23}{E_1}]\sqrt{P}$
0.01	0.12	0.2	0.4	1
0.1	0.37	0.64	1.3	2.6
1	1.17	2	4	8
10	3.7	6.4	13	26
100	11.7	20	40	80

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance level (V/m)
385	380 – 390	TETRA 400	Pulse modulation b) 18 Hz	1.8	0.3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0.2	0.3	9	9
810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0.3	28	28
1720 1845 1970	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0.3	28	28
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0.3	28	28
5240 5500 5785	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0.2	0.3	9	9

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the Cuffix may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.