## AG Cuffill Intended Use and Intended User

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### Intended Use: (Indications for Use):

The Hospitech AG Cuffill is intended to measure and regulate the intra-cuff pressure of Endotracheal tubes, Tracheotomy tubes and Laryngeal Masks Airways (LMAs) (supraglottic airways).

**Intended User:** The Hospitech AG Cuffill is used under medical supervision in hospitals, pre-hospital (EMS), extended care facilities and outpatient clinics, where a patient may be intubated.

⚠ The AG Cuffill is intended for an air-filled cuff and should not be used with liquids, which will cause damage.

⚠ The AG Cuffll should not be used for continuous monitoring. It should be disconnected each time, after use.

⚠ The AG Cuffill should be kept in a dry environment during transport and storage.

⚠ Make sure that the luer (connector) at the tip of the cuffill is clear of any obstruction and is open to ambient pressure.

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## Specifications:

**Range of measured cuff pressure:**
Model HSCUFF0031: 0-99 mmHg
Model HSCUFF0041: 0-99 $cmH_20$

**Accuracy of cuff pressure measurement:**
Model HSCUFF0031: ±2 mmHg
Model HSCUFF0041: ±2 $cmH_20$

**Size:** Length: 13 cm; Diameter: (ID) 15 mm
**Weight:** 18 gr.

**Power:** CR1632 3VDC battery

**Volume delivered:** 0-10 cc

**Number of operations:** 100

**Environmental conditions:**

**Storage/Operation:**
Temperature: +10… +30ºC (50…85ºF)
Relative air humidity without condensation: 5…95%
Atmospheric Pressure: 700hPa-1060hPa

**Transport:**
Temperature: -30…+60 ºC (-22…140ºF)
Relative air humidity without condensation: 30…95%
Atmospheric Pressure:700hPa-1060hPa

**Not made with natural rubber latex.**

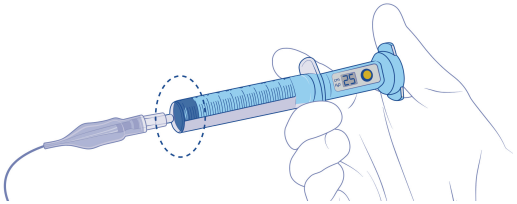
**Disposal:**

After the final use, discard the AG Cuffill according to hospital policy for hazardous waste.

## Instructions for Use

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**Measuring Cuff Pressure:**(See the following figure.)

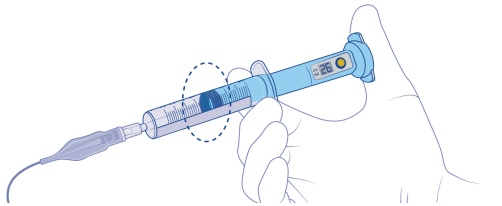


1. Turn ON the AG Cuffill by pressing the power button on the right side of the display. The display will blink twice showing the number of readings left and then will display “00”. (see section 6 - Display)
2. Push the syringe plunger in until it stops.
3. Connect the AG Cuffill to the Airway cuff inflation line and read the pressure value.
4. If required, cuff pressure may be reduced by pulling back the plunger until required pressure is achieved.
5. Disconnect the AG Cuffill from the cuff inflation line.

## Instructions for Use

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**Adjusting Cuff Pressure:**(See the following figure.)



1. Turn the AG Cuffill ON by pressing the power button on the right side of the display. The display will blink twice showing the number of readings left and then will display “00”. (see section 6 - Display)
2. Position the plunger about half way out.
3. Connect the AG Cuffill to the Airway cuff inflation line.
4. Adjust the plunger until the required pressure is achieved.

   If the required pressure is not achieved, disconnect the AG Cuffill, pull the plunger 1-2 cc backward and repeat this step.
5. Disconnect the AG Cuffill from the Airway cuff inflation line.

**ATTENTION: When disconnecting, the Cuff pressure may be may drop by 1-2 $cmH_2O$/mmHg.**

## Cleaning, Disinfection and Storage Instructions

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### General instructions for cleaning and disinfection

One of the cleaning and disinfection options described below are to be applied after each patient. The Cuffill is limited to 100 uses on the same or different patients.

- ✓ Pull out the plunger from the syringe barrel.
- ✓ While cleaning or disinfection, prevent entry of any fluid into the AG Cuffill sensor at the tip of the black gasket.

**Option A:**

**Cleaning and disinfection with germicidal/ disinfectant wipes**

- ✓ Use either one of the following Alcohol based wipes: Super Sani Cloth™ or Maxiwipe™ (55% Alcohol and 0.5% Quat); Sani Cloth Prime™ (56% Alcohol and 0.6% Quat); Medline Micro-Kill One™ or Peak™ or Wedge™ (each with 72.5 % Alcohol and 0.33% Quat).

  Clean by wiping. Remain wet for 2 (two) minutes. Disinfect by wiping with a new wipe and let air dry.

**Option B:**

**Cleaning and disinfection with solutions and pads**

- ✓ Use soft, clean, new pads, taking care not to saturate the pads.

**Cleaning:**

- Soak a clean pad with Alconox 1% (diluted with distilled water) or Septal Scrub 4% Chlorhexidine solution.
- Wipe the device surfaces (barrel and plunger) and clean thoroughly until product is clean from contamination. Repeat at least 4 times.
- Soak a clean pad with distilled water. Wipe and clean the device surfaces.
- Wipe the device surfaces with a dry pad and make sure to leave to dry for one hour on a clean surface in the room.

**Disinfection:**

- Soak a clean pad with either: Alcohol IPA 70% or a Hydrogen Peroxide 1.4 %.
- Wipe the device surfaces (barrel and plunger) and clean thoroughly until product is clean from contamination. Repeat at least 4 times.
- Wipe the device surfaces with a dry pad and make sure to leave to dry for 2 minutes on a clean surface in the room.
- After completing the cleaning process and the disinfection process, insert the plunger back to the syringe barrel. The Cuffill is now ready to be used on a new patient.

### Storage Between Same or New Patients:

- While being used in an ICU for same patient: the device should be kept at the patient bedside trolley/bench.
- While stored between patients: As other medical devices, it should be kept in a closed cabinet in the unit storage room. It is recommended to store in a disposable plastic bag.

## Display




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**When first pressing the button:**
Immediately after pressing the power button, the display blinks twice, indicating the number of operations left and then will display 00 indicating the device is ready for use.

**Display blinks 1H:**
Counter –over 1 Hundred operations left.
**NOTE:** a new device may show 1H a few times.
**Display blinking values 99 to 01:**
Counter - number of operations left.
**Display reads 00 after blinking**:
Normal. Ready for Use.

### During measurement:

**Display reads 00 to 99:**
Value of pressure measured.
**Display reads UP:**
**U**nder **P**ressure, Vacuum.
**Display reads OP**:
**O**ver **P**ressure, above 99 $cmH_2O$ /mmHg.

### Diagnostics:

**Display reads E1 and shuts down:**
End of allowed user operations.
**Display reads E2, E3, or E4 and shuts down:**
System error. Device unusable.
**Display reads any value other than '00' after blinking:**
Calibration required. Perform calibration. (See below)
**Display Flickers:**
EMC interference: Do not use. (See more in chapter 7)

### Calibration:

**Calibration can only be carried out when the Cuffill is disconnected from the cuff inflation line.**

- Make sure that the AG Cuffill connector (Luer) is clear of any obstructions.
- Press and hold the Power Button for more than 5 seconds.
- ' - - ' followed by '00' should be displayed. If a value other than '00' appears, the device is not usable.

**NOTE: The device automatically turns OFF 60 seconds after activation.**

## Information on Electro Magnetic Compatibility (EMC) &EMC Declarations (IEC 60606-1-2)

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**WARNING:** "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."

**WARNING:** "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 AG Cuffill including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."

**WARNING:** "Avoid using equipment in case the display flickers with no ability to read the value during the disturbance".

| **Manufacturer Declaration- electromagnetic emissions** | | |
|---|---|---|
| **Classification of Equipment (CISPR11/EN 55011)** | | |
| **Compliance Test** | **Compliance** | **Electromagnetic environment -guidance** |
| RF emissions<br>CISPR 11 | Group 1 | AG Cuffill belongs to this group of equipment where RF energy is used only for internal function. |
| RF emissions<br>CISPR 11 | Class B | AG Cuffill belongs to this group which offers suitable protection in both domestic (residential) environment and in hospitals, and any other facilities were ventilated patients are taken care of (e.g. outpatient clinics). |

| **Manufacturer declaration – electromagnetic immunity** | | | |
|---|---|---|---|
| IMMUNITY test | IEC 60601-1-2 TESTLEVEL | Compliance level | Electromagnetic environment –guidance |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | 8 kV contact<br>2, 4, 8, 15kV air | 8 kV contact<br>2, 4, 8, 15kV air | Floors should be wood, concrete or ceramic tile.<br>If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Power frequency(50/60 Hz) magnetic field<br>IEC 61000-4-8 | 30 (A/m) | 30 (A/m) | Power frequency magnetic fields should be at levels characteristic of atypical location in a typical commercial or hospital environment. |
| Radiated RF<br>IEC 61000-4-3 | 10V/m<br>3V from 0.15 to 80MHz;<br>6V from 0.15 to 80MHz and 80% AM at 1kHz<br>10V/m from 80 MHzto 2.7GHz | 10V/m<br>3V from 0.15 to 80MHz;<br>6V from 0.15 to 80MHz and 80% AM at 1kHz<br>20V/m from 80MHz to 2.5GHz<br>10V/m from2.5GHz to 2.7GHz | Portable and mobile RF communications equipment should be used no closer to any part of the AGCuffillincluding cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance. |
| Mil-STD-461E<br>Radiated immunity | 20V/m 100kHz – 150KHz<br>20V/m 13.5MHz –13.6MHz | 20V/m 100kHz –150kHz<br>20V/m 13.5MHz –13.6MHz | |

$d = [\frac{3.5}{V_1}]\sqrt{P}$

$d = [\frac{12}{V_2}]\sqrt{P}$

$d = [\frac{12}{E_1}]\sqrt{P}$ 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 meters (m).Field strengths from fixed RF transmitters, asdetermined by an electromagnetic site survey, should be less than the compliance level in eachfrequency range.
Interference may occur in the vicinity of equipment marked with the following symbol:

### Symbol Description

Rx only — Caution: Federal law restricts this device to sale by or on the order of a physician. For USA only.

LATEX — Not made with natural rubber latex

Manufacturer

Expiry date

Consult operating instructions

Date of manufacture

REF — Catalogue number

LOT — Batch code

-30°C / 60°C — Temperature limits of safe exposure

30 / 95 — Humidity limits of safe exposure

MR — MRI not suitable

MD — Medical device

Not for general waste

10 — Number of devices in package

| **Recommended separation distances between portable and mobile RF communications equipment and theAGCuffill** | | | | |
|---|---|---|---|---|
| **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<br>745<br>780 | 704 – 787 | LTE Band 13, 17 | Pulse modulation[b)] 217 Hz | 0.2 | 0.3 | 9 | 9 |
| 810<br>870<br>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<br>1845<br>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 | 2400 –2570 | Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulation[b)] 217 Hz | 2 | 0.3 | 28 | 28 |
| 5240<br>5500<br>5785 | 5100 –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 ME EQUIPMENT or ME SYSTEM 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.

| | |
|---|---|
| **Safety Compliance:** | Safety Compliance: IEC 60601-1edition 3.1 |
| **EMC Compliance:** | IEC 60601-1-2 2014: RF emissions CISPR 11 Group 1 Class B;<br>IEC 61000-4-3; IEC 61000-4-8; IEC 61000-4-2; |

Notice to user and patient: Any serious incident that has occurred in relation to the AG Cuffill should be reported to the Hospitech Respiration Ltd and the competent authority of the Member State in which the user and/or patient is established.

Additional copies of these instructions are available on the product website www.cuffill.com and permission is granted under Hospitech's copyrights to make additional copies of these instructions for use by purchasers of this product from Hospitech Respiration Ltd, or its authorized distributors.



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HOSPITECH RESPIRATION

# AG Cuffill®

measuring and regulating cuff pressure

## User Manual

## Hospitech Respiration Proprietary Information

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