

Guidance and manufacturer's declaration electromagnetic Immunity

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The EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the EQUIPMENT should assure that it is used in such an environment

Immunity Test	IEC 60601 Test Level	Compliance Level	Electro-magnetic Guidance Level
IEC 61000-4-3 Radiated Immunity	20V/m 80-2500MHz	20V/m 80-2500MHz	Portable and mobile RF communications equipment should be used no closer to any part of the AG Cuffill, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a) and 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.
MIL-STD-461E Radiated Immunity	20V/m 100kHz-150kHz 20V/m 13.5MH-13.6MHz	20V/m 100kHz-150kHz 20V/m 13.5MH-13.6MHz	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation 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 and TV 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 the AG Cuffill is used exceeds the applicable RF compliance level above, the [ME EQUIPMENT or ME SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the V-touch. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.			
IEC 61000-4-8 Magnetic Immunity	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
IEC 61000-4-2 Electronic Discharge	15 kVAir 9kV Contact	15 kVAir 9kV Contact	Increasing relative humidity will reduce the potential for ESD related difficulties.



Guidance and Manufacturer's Declaration – Electromagnetic emission.

Emission Test	IEC 60601 Test Level	15 kVAir 9kV Contact	Electro magnetic Guidance Level
CISPR11	CLASS B	Complies	The AG Cuffill 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.

AG Cuffill information regarding Electro-Magnetic Compatibility (EMC)

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As an electrical device, the AG Cuffill has been tested for electromagnetic emissions and is susceptible to electromagnetic interferences within the required criteria of the IEC 60601-1-2 standard.

Warning:

The following warnings and informative tables are provided:
The AG Cuffill has been tested and found to comply with the limits for the medical devices to the IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical residential installation. This device generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity.

Recommended separation distance between portable and mobile RF communications equipment and the AG Cuffill

The AG Cuffill is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AG Cuffill can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AG Cuffill as recommended below, according to the maximum output power of the communications equipment.

Separation distance according to frequency of transmitter in meter

Output power of Transmitter in Watts	150 kHz to 80 MHz d=1.2√P	80MHz to 800 MHz d=1.2√P	800MHz to 2.5GHz d=2.3√P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies. Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people



ONLY

Caution: Federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner (Rx ONLY)

Not made with natural rubber latex.



EC	REP
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HOSPITECH
RESPIRATION

AG Cuffill

User Manual

Hospitech Respiration
Proprietary Information



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AG Cuffill ① Description & Identification for Use

The Hospitech AG Cuffill measures and regulates the cuff pressure of Endotracheal tubes, Tracheostomy tubes and Laryngeal Masks Airways (supraglottic airways).

The Hospitech AG Cuffill should be used only 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 Cuffill should not be used for continuous monitoring. It should be disconnected each time, after use.

Handling Instructions:

The AG Cuffill is intended for air-filled cuffs and should not be used with liquids. The AG Cuffill should be kept in a dry environment during transport and storage.

Cleaning Instructions:

Wipe the surface thoroughly with an alcohol-based disinfectant or 1.4% hydrogen peroxide. While cleaning, prevent entry of any fluid into the AG Cuffill luer (inflation line).

Before Use:

Make sure that the luer is clear of any obstruction and is open to ambient pressure.

Specifications:

Size: Length: 13 cm; Diameter: (ID) 15 mm Weight: 18 gr	Range of measured cuff pressure: Model HSCUFF0031: 0-99 mmHg Model HSCUFF0041: 0-99 cmH2O	Recommended temperature operating range: 10°C - 30°C (50°F - 85°F)	Number of operations: 100
Power: CR1632 3VDC / 130mAh battery	Accuracy of cuff pressure measurement: Model HSCUFF0031: ±2 mmHg Model HSCUFF0041: ±2 cmH2O	Volume delivered: 0-10 cc in 0.5 cc graduations	EMC Compliance: IEC 60601-1-2 ; RF emissions CISPR 11 Class B IEC 61000-4-3 , IEC 61000-4-8 ; IEC 61000-4-2 Safety Compliance: IEC 60601-1-1 3rd Edition

Instructions for Use ② 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 4 - Display)
2. Push the plunger to the distal end of the syringe (all the way in).
3. Connect the AG Cuffill to the 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.

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

ATTENTION: When disconnecting, the Cuff pressure may be reduced by 1-2 mmHg/cmH2O.

Instructions for Use (cont.) ③ 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 4 - Display)
2. Position the plunger about half way out.
3. Connect the AG Cuffill to the 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 cuff inflation line.

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

ATTENTION: When disconnecting, the Cuff pressure may be reduced by 1-2 mmHg/cmH2O.

Display ④

Immediately after pressing the power button, the display will blink twice, indicating the number of operations left on the device and then will read 00 to indicate the device is ready for use.

Display blinks 1H:

Number of operations left is above 1 Hundred.
NOTE: on a new device, 1H may appear a few times until counter goes below one hundred.

Display blinks 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:

Under Pressure, Vacuum.

Display reads OP:

Over Pressure, above 99 mmHg / cmH2O.

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.

Calibration:

Calibration can only be carried out when the Cuffill is disconnected from the airway.

- 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.