AG Cuffill Intended Use and Intended User

1

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.

2

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

3

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

4

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

5

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).

  When using any of the wipes above, always follow manufacturer’s recommendations and instructions.

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

6

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:
Under **P**ressure, Vacuum.

Display reads OP:
Over **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)

7

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 CISPR 11	Group 1	AG Cuffill belongs to this group of equipment where RF energy is used only for internal function.
RF emissions 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) 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 %.
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 atypical location in a typical commercial or hospital environment.
Radiated RF IEC 61000-4-3	10V/m 3V from 0.15 to 80MHz; 6V from 0.15 to80MHz and 80% AMat 1kHz 10V/m from 80MHzto 2.7GHz	10V/m 3V from 0.15 to80MHz; 6V from 0.15 to80MHz and 80% AMat 1kHz 20V/m from 80MHzto 2.5GHz 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. $d=[\frac{3.5}{V_1}]\sqrt{P}$ $d=[\frac{12}{V_2}]\sqrt{P}$ $d=[\frac{12}{E_1}]\sqrt{P}$ 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:
Mil-STD-461E Radiated immunity	20V/m 100kHz – 150KHz 20V/m 13.5MHz – 13.6MHz	20V/m 100kHz – 150KHz 20V/m 13.5MHz – 13.6MHz	

Symbol Description

30°C / 10°C Temperature limits for storage

Consult operating instructions

MR MRI not suitable

MD Medical device

Not for general waste

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

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
710 745 780	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	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 5500 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; 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.

EN

HOSPITECH RESPIRATION

AG Cuffill®

User Manual

Hospitech Respiration Proprietary Information

EC REP

MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster Germany

CE 0483

Hospitech Respiration
15 Atir Yeda,Kfar Saba
4464312, ISRAEL
Email: info@hospitech.co.il

Patent: www.cuffill.com/patents