HD STETH™ Quick Start User Guide

Thank you and for choosing the futuristic HD Steth™ manufactured by HD Medical Inc. USA

Indications for Use (IFU)

HD Steth is an electronic stethoscope meant to assist a qualified clinician to capture, record and replay heart sounds and electrocardiogram (ECG or EKG) rhythm. It is intended to be used on one patient at a time. Heart sounds (PCG) and 1-lead EKG rhythm are acquired and displayed simultaneously on an accompanying mobile application on a hand-held smart device like a phone or tablet. The waveforms can be recorded and saved on the smart device on which the app is running.

The device has 3 auscultation modes – Bell, Diaphragm and Lung (Wide). These modes and volume levels can be changed by the press of a button. The EKG rhythm recording assists in getting an indicative Heart Rate (HR) that gets displayed on a display panel on the device.

The device must be used in a clinical setting by trained and qualified personnel only. HD Steth is not intended to be used as a diagnostic device. It does not supersede the judgement of a qualified clinician. The device is intended to aid the physician in the evaluation of PCG and EKG rhythm. The clinicians are completely responsible for reviewing and interpreting the results, along with all other relevant information, when making a referral decision.

Caution: The sale of this device is restricted to licensed clinicians or entities referred to by a licensed clinician. It is intended for use by a licensed clinician only.

Precautions:

It is to be used in accordance with Standard procedures for auscultation should be followed including background noise reduction and optimal patient positioning.

This manual provides instructions for the use of HD Steth™ and mobile applications. It is assumed that the user is familiar with basic mobile application.

To transmit sounds to the HD Steth™, the stethoscope and device must be connected via Bluetooth, and in order to fully use certain functions, the mobile device must be connected to the smart display unit / mobile.

HD Steth™ uses a Bluetooth Class 2 wireless data link. The Bluetooth range will be reduced when objects (walls, furniture, people, etc.) are between the Device and a paired mobile device. To improve Bluetooth connection, reduce the distance and ensure a line of sight between HD Steth™ and mobile device.

Safety related symbols & Labels

	**Refer IFU - Indications for Use**
	**Power Class II Internally powered (Battery Operated)**
	**Type BF Applied Part**
	**Caution: Refer accompanying Document for indicated hazardous situation, which is not avoided, could result in injury and or damage to property or the device.**
	**Manufacturer details symbol**
	**Serial Number**
	**This product is built in International FCC certified RF radiator**
	**This device contains electronic, electrical and rechargeable batteries and must be disposed as per standard procedure. Please refer local directives for disposal of the parts.**
	**This product is non- sterile. Do not attempt to sterilize the device**
	**This product uses wireless Bluetooth Communication.**

EMC Compliance

FCC Intentional Radiator Certification

Contains FCC ID: SQGBT900

Contains IC: 3147A-BT900

Equipment Class:Part 15 Spread Spectrum Transmitter

This equipment uses an intentional radiator approved by the FCC under the FCC ID number shown above. This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions:

(1) This device may not be causing harmful interference, and

(2) this device must accept any interference received, including interference that may cause undesirable operation.

NO MODIFICATION: Modifications to this device shall not be made without the written consent of HD Medical Inc. Unauthorized modifications may void the authority granted under Federal Communications Commission rules permitting the operation of this device.

EMC Compliance Europe

This equipment complies with the EMC requirements of the IEC 60601-1-2.

CAUTION 

TO REDUCE THE RISK OF DEVICE INTERFERENCE, KEEP THE HD STETH AT LEAST 1 METER AWAY FROM ALL RF EMITTERS INCLUDING WIFI-ROUTERS AND RADIOS

TO REDUCE THE RISKS ASSOCIATED WITH VERY STRONG ELECTROMAGNETIC FIELDS AVOID USING HD STETH NEAR STRONG RADIO FREQUENCY (RF) SIGNALS OR PORTABLE AND/OR MOBILE RF DEVICES.

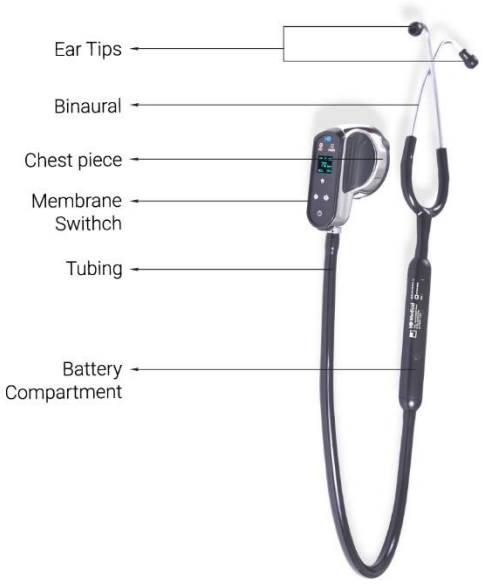
IF SUDDEN OR UNEXPECTED SOUNDS ARE HEARD, MOVE AWAY FROM ANY RADIO TRANSMITTING ANTENNAS.

USING ACCESSORIES AND CABLES NOT PRODUCED BY HD MEDICAL, INC MAY RESULT IN INCREASED RF EMISSIONS OR DECREASED IMMUNITY OF THE HD STETH SYSTEM.

Membrane Keypad and Description of Controls

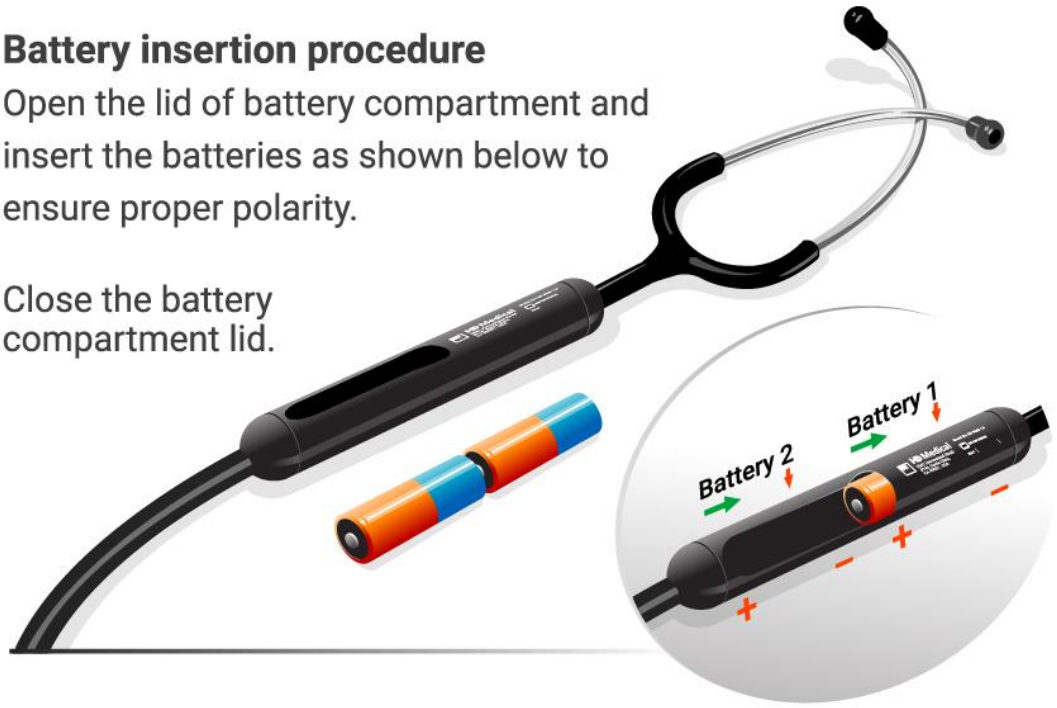
Symbols	Functions
	Power Button to Turn the device ON/OFF
REC	REC Button to record the heart sounds
Ω MODE	Mode Selection Button - To change between Bell, Diaphragm & Lung modes
	Right/UP Button to increase volume level.
	Left/Down Button to decrease volume.
	Home/Select Button - Used to turn Bluetooth ON/OFF and to go to Home Screen

Device Image - HD Steth™



Battery insertion procedure

Open the lid of battery compartment and insert the batteries as shown below to ensure proper polarity.



Close the battery compartment lid.

1. **Operations:**

Contents: The package includes

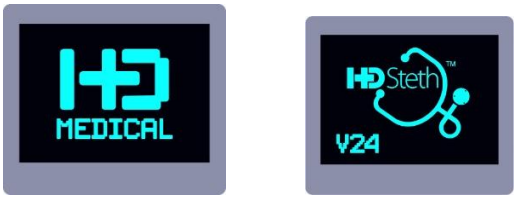
i. HD Steth device
ii. Micro USB cable
iii. USB charger
iv. Quick Start guide
v. Spare ear plugs 1 set

Operating Warnings
Failure to follow care and maintenance recommendations could result in damage to the internal components of the Core.
Internal damage to the product could cause malfunction of the product, possibly leading to complete loss of function. If problems are encountered with the Core, do not attempt to repair it. Please notify our support team for assistance.

1.1 Device Power

Momentarily press the Power button to switch the device ON.

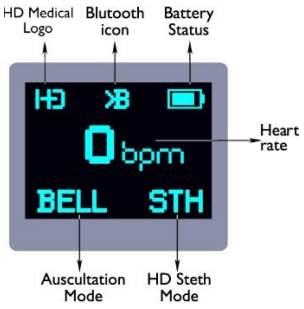
Once the device is switched ON, the display will show the HD Medical logo followed by the HD Steth™ logo screens. The bottom left corner shows the version of the firmware loaded in the device.



1.2 Default display

The following functional screen will be displayed after device initialization.

It shows the following icons:



1.3 Battery Indication

The battery icon on the right top corner of the screen indicates battery charge level in the device.

The battery indication shows the level of charge present in the inserted batteries.

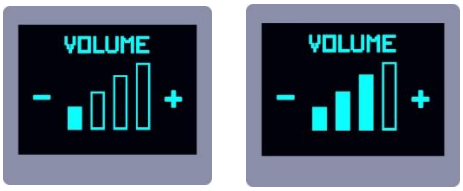
Ensure the battery charger displays at least one bar so that the device can be operated.

1.4 Default settings of the device

- Audio Mode: Set to BELL
- Bluetooth: Set to ON
- Volume: Set to Level 2

1.5 Volume Settings

The volume can be decreased by pressing the Left/Down or can be increased by pressing the Right/Up button



1.6 Bluetooth settings

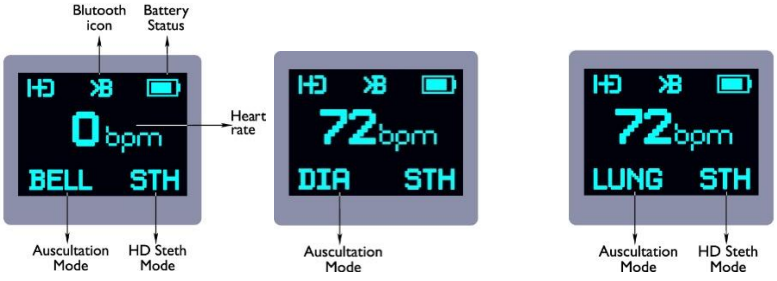
Bluetooth is enabled by default. To switch Bluetooth OFF, press Home/select button and the screen will display as shown below.

Pressing the Home/Select button again will be switch ON Bluetooth functionality.

The Bluetooth symbol is located between the HD logo and the battery icon on the display panel. Absence of the symbol indicates Bluetooth is OFF and presence of the symbol indicates Bluetooth is ON.

2. **Auscultating with the Device**

2.1 Insert the earpiece in your ears & instruct the patient to assume the necessary posture for auscultating – sitting/supine/side-supine.
2.2 Place the device on the patient's chest at the required auscultation location to hear the heart sound. Ensure that the chest piece is in contact with patient's chest.
2.3 Select the appropriate auscultation mode: Bell, Diaphragm or Lung by pressing the "Mode selection" button.
2.4 Place the device on the patient such that the chest piece is in contact with patient's chest at one of the four auscultation positions.
2.5 The heart sounds will be heard through the earpiece while auscultating.



3. **Heart Rate Display:**

The Heart rate will be displayed once the EKG electrodes make perfect contact with the muscle and the heart sounds are stable.

4. **Recording the waveforms**

Ensure the HD Steth™ device displays Bluetooth ON (to transfer the recorded waveforms to the smart phone/tablet).

Once the waveforms displayed on the App have stabilized, press the REC button. The display will change and show 'RECORDING IN PROGRESS PLEASE WAIT' while recording is in progress.

5. Transferring the recorded waveforms to Smart phone/tablet:

5.1 Open the HD Steth™ mobile app on mobile device and connect the HD Steth™ device.

5.2 The heart sounds and EKG waveforms will be displayed in the connected smart phone/tablet.

5.3 The waveforms are displayed corresponding to the auscultation mode for PCG and corresponding to the HD Steth™ mode for EKG.

5.4 Place the device chest piece directly on one auscultation point for more than 10 secs and live heart rate should be displayed on the OLED screen.

5.5 Ensure the EKG, PCG and colour highlighted frequency murmur content of PCG signal in sync are displayed on the Smartphone screen.

6. Turning the device off

Momentary press the Power button to switch OFF the device.

Note: If no button is operated for 7 minutes, the device will be automatically switched OFF.

7. Recharging battery

7.1 You may operate the device uninterrupted as long as the battery icon shows at least one bar. Once the icon has no bar and starts blinking, charge the device (Use Ni-MH Battery only).

7.2 Prior to charging, switch OFF the device. Insert the charger unit into USB slot in the device and plug in the charger to the AC wall point (Use Ni-MH battery only).

CAUTION ⚠
IT IS RECOMMENDED NOT TO USE THE DEVICE FOR AUSCULTATION, WHEN THE BATTERY IS BEING CHARGED THROUGH CHARGER. ATTEMPTING TO USE THE DEVICE AT THIS TIME MAY NOT BE SAFE. **USE ONLY HDI SUPPLIED / AUTHORIZED BATTERY CHARGERS**

8. Accessories

USE OF ACCESSORIES NOT AUTHORIZED BY HD MEDICAL (HDI) MAY DAMAGE THE UNIT

8.1 Diaphragm

Use only HD diaphragm with the device. Use of non-HD diaphragms can result in faulty audio and display and possible analysis irregularities in any future detection/screening algorithms.

8.2 USB Cable

Micro USB Type-B Male connector to USB 4-Pin Type-A Male connector can be used to connect the device to the PC/Laptop.

8.3 Earplugs

Use only HD earplugs.
Use of non-HD earplugs can result in pain in ears due to material hardness and may degrade audio.

8.4 Battery

Rechargeable AA Ni MH 2600mAh 1.2V rechargeable battery – 2 Nos.

8.5 Battery Charger

Input: 100-240V AC, 50/60 Hz,
Output: 5V DC, 2000 mA

Note: Use of Accessories not authorized by HD Medical Inc (HDI) may damage the unit and may result in wrong diagnosis.

Troubleshooting

Sl. No	Problem	Possible Reason	Solution
1	Device does not turn ON when Power button is pressed	Battery could be completely drained	Charge the Battery
2	If the device battery does not get charge	Battery could be faulty	Replace with new/functional batteries
3	Unable to see anything on the OLED display	In case the device is subjected to large mechanical shock, it is possible that the OLED may be damaged internally through it may not be readily visible	Contact HD Representative
4	Unexpected device behaviour	Failure of the Processor	Contact HD Representative
5	The battery compartment locks 	In the event of an accidental fall, the battery compartment lock may come out as shown in the figure	This can be fixed manually by pressing

10. Cleaning and Disinfecting Procedure

The device may be used on several patients each day. Cleaning the chest piece and the body of the device is imperative since failure to do so may cause infections or allergies to be transferred to susceptible patients

1. Ideally the chest piece diaphragm should be cleaned after each use while the body of the should be cleaned at the end of each day.
2. Use a soft clean cloth or alcohol wipe to clean
3. Do not immerse in water or any other form of liquid sterilization for cleaning.

CAUTION 
THE DEVICE SHOULD NOT BE USED ON OPEN WOUNDS **THE DEVICE SHOULD BE USED WITH PERSONAL PROTECTIVE EQUIPMENT SUCH AS GLOVES**

11. STORAGE:

1. Always store the device in a cool, dry place.

2. It is advisable to place the device on a soft surface to avoid damage to the device in general and to the chest piece – diaphragm side.

CAUTION 
DO NOT STORE THE DEVICE IN DAMP/HOT PLACES. THIS CAN SPOIL THE DEVICE AND AFFECT THE FUNCTIONALITY. **THE DEVICE IS NOT FLUID INGRESS PROTECTED.** **DO NOT STORE THE DEVICE IN PLACES PRONE TO SPRAYING OF LIQUIDS. INGRESS OF LIQUID CAN RESULT IN REDUCED DEVICE RESPONSE AND IN ACUTE CASES CAUSE DEVICE FAILURE AND EVEN SHOCK TO THE USER.**

12. Warranty

12.1 HD Medical Inc (HDI) warrants to the Purchaser that the device is free from all defects in material and workmanship. HDI provides 12 months warranty for the device from date of purchase.

12.2 This warranty excludes any defect or injury caused by or resulting from misuse, abuse, neglect, accidental damage, improper voltage, vermin infestation or any alteration which affects the reliability or performance of the unit, not attributable to faulty manufacture, parts and labor.

12.3 This warranty does not cover the following items.

a) Ear Plugs and Diaphragm.
b) If the device has been modified or altered by anyway whatsoever.

12.4. If warranty service is required:

a) Contact HDI at the below mentioned address.
b) Enclose a copy of your purchase receipt as proof and date of purchase.
c) Send or bring the product to HDI.

12.5 The warranty hereby conferred do not extend to any costs associated with the delivery, handling, freighting or transportation of the device or any part thereof or replacement of and do not extend to any damage or loss occurring during, or associated with, transit.

12.6 The warranty will be void if the device has been modified or altered by anyone other than HDI/HDI authorized personnel.

12.7 The HDI warranty card enclosed must be filled in all respects by the dealer/customer at the time of delivery/ purchase of the device and to be sent to HDI within 10 days from the date of purchase.

Technical Specifications:

Display: Graphic OLED, 64 x 48, Blue on Black, 2.8V, I2C, Parallel, SPI, 18.5mm x 18.1mm, -40 ˚C

Electrical

Battery: Rechargeable AA Ni MH 2600mAh 1.2V rechargeable battery – 2 Nos.

Back up of 4 hours of continuous operation

Charger: 100-240V AC, 50/60 Hz, Output: 5V DC, 2000 mA.

Environmental

Operating temperatures	: 5˚C to 40˚C
Operating/Storage Temperature	: -10˚C to +60˚C
Humidity	: 20% to 80%
Physical Weight	: grams (approx. - including battery)
Emission compliance	: EN55011, CISPR 11, Group 1 Class B
Type of protection	: Internally powered
Degree of Protection	: Type BF
Enclosure Degree of protection	: IPX0
Biocompatibility	: Device is biocompatible as per ANSI/AAMI/ISO 10993

Electrical Safety

Guidance and Manufacturer's Declaration - Electromagnetic Emission		
The HD Steth™ Smart Electronic Stethoscope integrated ECG Leads is intended for use in the electromagnetic environment specified below. The user of the should assure that it is used in such an environment.		
Applicable Emissions Test	**Compliance**	**Electromagnetic Environment-Guidance**
RF emissions CISPR 11	Group 1	The 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.
RF emissions CISPR 11	Class B	The HD Steth™ device is suitable for use in all establishments, including domestic establishments.
Harmonic Emissions IEC 6100-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The HD Steth™ Device is intended for use in the electromagnetic environment specified below. The user of the HD Steth™ Device should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment- Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV	+/- 6 kV contact +/- 8 kV 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 supply lines +/- 1 kV for input/ output lines	Not Applicable	
Surge IEC 61000-4-5	+/- 1kV line(s) to line(s) +/- 2 kV line(s) to earth	Not Applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 610004-11	< 5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycle 70% UT (30% dip in UT) for 25 cycle < 5% UT (>95% dip in UT) for 5 secs	Not Applicable	
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment-Guidance**
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial magnetic field or hospital environment.
NOTE UT is the A.C mains voltage prior to application of the test level			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The HD Steth™ Device is intended for use in the electromagnetic environment specified below. The user of the HD Steth™ Device should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment-Guidance**
Conducted RF IEC 61000-4-6	3 V rms 150 kHz to 80 MHz	Not Applicable	
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 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, as determined by an electromagnetic site survey, a 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: 

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 is affected by absorption and reflection from structures, objects and people.

- 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 address 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 HD Steth™ device is used exceeds the applicable RF compliance level above, the HD Steth™ device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HD Steth™ device.
- Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the HD Steth™

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

Rated Maximum Output Power of Transmitter (W)	**Separation Distance According to Frequency of Transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	*0.12*	*0.12*	*0.23*
0.1	*0.37*	*0.37*	*0.74*
1	*1.2*	*1.2*	*2.3*
10	*3.7*	*3.7*	*7.4*
100	*12*	*12*	*23*

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* is meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.

For assistance and help contact

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E-mail: service@hdmedicalgroup.com

Website: www.hdmedicalgroup.com

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Manufacturing Information

Manufactured by:

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