HD Steth™ User manual

Thank you 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.

Contraindications: None Known

Caution: Federal law restricts this device to sale to or on the order of a clinician.

Precautions:

When using the device standard procedures for proper auscultation and optimal patient positioning should be followed

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.

General Cautionary Notice

Failure to follow the directions given in this manual could result in damage to the device and/or possible injury to the user/patient.

Failure to follow operating and maintenance instructions, listed in the manual could result in malfunction of the device.

The device is not recommended for use in the presence of equipment producing strong electromagnetic radiation/MRI and stacked device environment as it may affect the device functionality.

Do not place the device on wet surfaces. Allowing the chest piece diaphragm to come into contact with liquids will affect the device functionality.

Do not use the device on open wounds or on chest during surgeries.

Do not use any sharp pointed tool to reset the device.

Do not expose the battery to a flame or excessive heat, immerse in or expose to water, short the terminals or disassemble the battery as doing so could damage the battery cause fire, injury or environmental contamination.

Liquid leaking from the battery can cause skin burns or damage the device.
If the battery leaks inside the instrument, return the Device to the nearest service centre.

Remove the battery during shipment or if the device is going to be stored or unused for an extended period of time

Do not use on patients with cardiac pacemakers or other electronic implanted devices.
Do not use as sole basis for medication or treatment decisions.

Essential Performance:

Heart rate display on the device. BLE pairing of device and smart device. The Heart sounds and ECG signal are transferred in real time via BLE to the smart device. Visual representation of ECG and heart sounds are displayed on the smart device screen are stored on the smart Device. If any pairing issue occurs between device and smart device, automatically the issue will get resolved and get paired. No information is stored on the device. The Heart sounds and ECG signal are communicated in real time via BLE to the smart device, displayed on the smart device screen and are stored on the smart 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 if 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.
	The Product is ROHS Compliant.
	MR unsafe
	The Product Degree of protection - IPX1

EMC Compliance

FCC Intentional Radiator Certification

Contains

FCC ID: SQGBT900

IC: 3147A-BT900

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.

CAUTION

TO REDUCE THE RISK OF DEVICE INTERFERENCE, KEEP THE HD Steth AT LEAST .3 METERS AWAY FROM ALL Proximal 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.

To reduce the risks associated with very strong electromagnetic fields avoid using the device 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, transducers, and cables not supplied by HD Medical Inc., may result in increased RF emissions or decreased immunity of HD Steth.

MR-unsafe! Do not expose the device to a magnetic resonance (MR) environment. The device may present a risk of projectile injury due to the presence of ferromagnetic

materials that can be attracted by the MR magnet core. Thermal injury and burns may occur due to the metal components of the device that can heat during MR scanning. The device may generate artifacts in the MR image. The device may not function properly due to the strong magnetic and radio frequency fields generated by the MR scanner

Conductive parts of electrodes and associated connectors for Type BF Applied Parts, including the neutral electrode, should not contact other conductive parts including earth.

Device Keypad and Description of Controls

1. Record Button
2. Home Button
3. Left/Down Button
4. Power ON/OFF Button
5. Mode Selection Button
6. Right/Up Button

Symbols	Functions
	Power Button to Turn device ON/OFF
REC	REC Button to record 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 Button to go to Home Screen

Applied part

Device Image - HD Steth™

Battery insertion procedure

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

Close the battery compartment lid.

Warning: ***Care to be taken while inserting the battery. Battery is to be inserted with correct polarity.*** **Ensure positive symbol on the battery and the positive symbol in the battery compartment matches at the time of battery insertion**

CAUTION
The device is powered with a rechargeable Li-Ion battery. To ensure user safety, functionality of the device is completely disabled while charging.

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
vi. HD Speaker

Operating Warnings

Failure to follow care and maintenance recommendations could result in damage to the internal components of the HD Steth.

Internal damage to the product could cause malfunction of the product, possibly leading to complete loss of function. If problems are encountered with the HD Steth, do not attempt to repair it. Please notify our support team for assistance.

1.1 Device Power

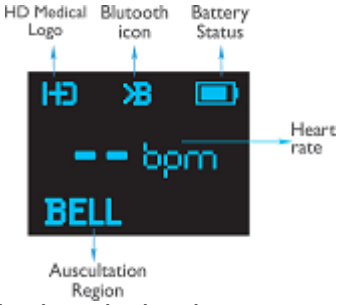
Momentarily press the Power button to switch the device ON.

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. Then a screen with Default mode BELL will be displayed.

1.2 Default display

The following functional screen will be displayed after device initialization.

It shows the following icons:



Once this initialization screen is displayed, the device is ready for use.

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 battery.

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

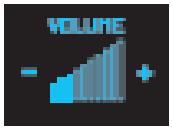
If the Battery icon starts blinking, the device needs to be charged.

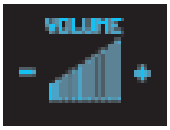
1.4 Default settings of the device

- Audio Mode: Set to BELL
- Bluetooth: Set to ON
- Volume: Set to Level 3

1.5 Volume Settings

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





Whenever used on fat subjects the user may be required to increase volume level to hear the heart sounds or the user will need to use more force when placing the chest piece of the stethoscope onto a fat subject.

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 Gently 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:

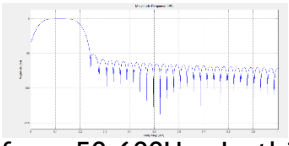
2.3.1 Appropriate mode can be selected using Mode Selection button. It is a toggle button and set to BELL by default

2.3.2 When pressed once it will go to DIA mode and again pressed it will go to LUNG mode

BEL → DIA → LUNG → BELL as shown in the below images

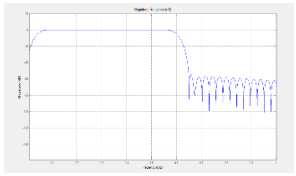
The BELL mode frequencies are from 50-200Hz. In this mode the user can hear low frequency sounds.

Frequency response of BELL mode



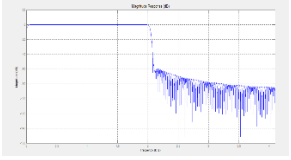
The DIA mode frequencies are from 50-600Hz. In this mode the user can hear low, mid and high frequency sounds.

Frequency response of DIA mode



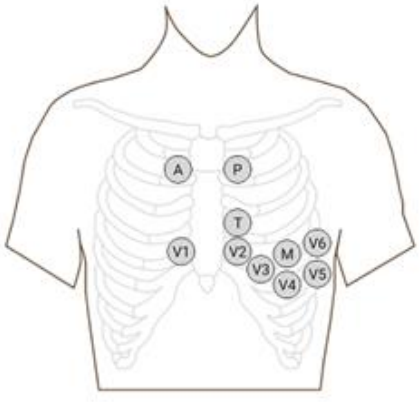
The LUNG mode frequencies are within 20-2000Hz. This mode user to hear wide range of frequencies.

Frequency response of LUNG mode



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 Auscultation positions representation: The below picture describes the location where the device can be placed for auscultation.



2.6 The heart sounds will be heard through the earpiece while auscultating.

2.7 Safe contact duration of applied part is 1 to 10 minutes.

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. The displayed heart rate values shall be within the specified range of ±5% or ±3 BPM.

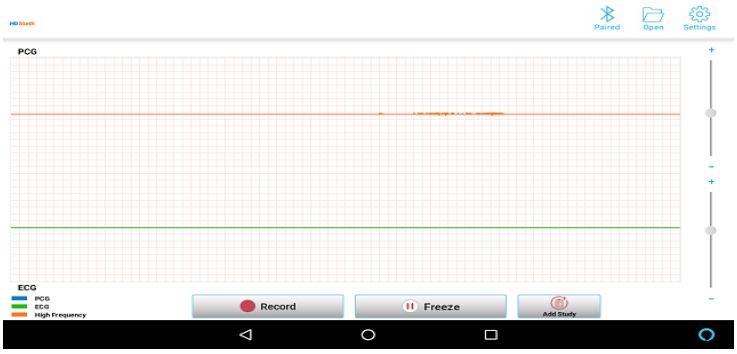
4. Recording the waveforms

Transferring the waveforms to Smart phone/tablet:

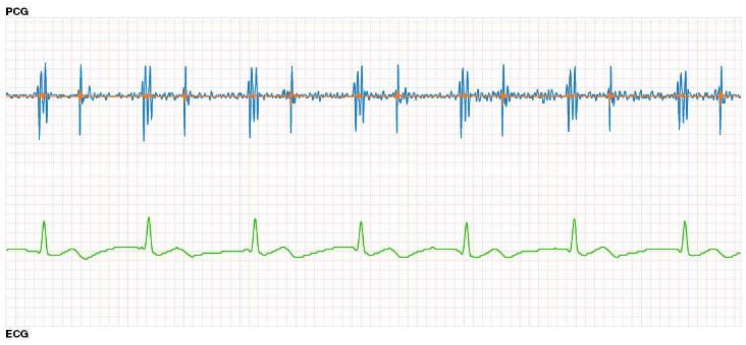
4.1 Open the HD Steth™ mobile app on mobile device and connect the HD Steth™ device.
4.2 The heart sounds and EKG waveforms will be displayed in the connected smart phone/tablet.
4.3 The waveforms are displayed corresponding to the auscultation mode for PCG and EKG.
4.4 Place the device chest piece directly on one auscultation point for more than 10 secs and live heart rate displayed on the device screen.
4.5 Ensure the EKG, PCG and colour highlighted frequency murmur content of PCG signal in sync are displayed on the Smartphone screen.

4.6 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.

4.7 When the device is connected to a smart phone/TAB, there will be a similar visual display on the smart phone/TAB, as shown below before starting auscultation.



4.8 Once the device is placed in correct position and stabilized, there will be a similar visual display on the smart phone/TAB, as shown below



4.9 The display on the Smart phone/TAB (duration usually 30 minutes) will be seen as per the back-light settings on the respective device. Once the back-light option is evoked it will be seen next 30 minutes or so.

5. Replaying Recorded Audio using HD Speaker

5.1 Connect the HD Speaker using the 3.5mm jack to the Audio port on the Smart phone/TAB
5.2 Place the HD Steth Chest piece over the HD Speaker to hear the audio

5.3 Make sure the HD Steth ECG Electrodes align with the three holes on the HD speaker for precise fit.
5.4 Select “Open” Menu from the Main screen of the APP. Select the Patient file to be replayed and Press “Replay”

6. Turning the device off

Momentary press the Power button to switch OFF the device.

Auto OFF: The device will automatically be switched OFF, if no key is pressed for 15 minutes. To Switch ON the device the power button is to be pressed.

7. Recharging battery

7.1 You may operate the device uninterrupted as long as the battery icon shows at least one bar on it. Once one bar shows, charge the device.

7.2 Insert the charger cable into USB slot in the device and plug in the charger to the AC wall point.

7.3 When the Charger USB cable is connected, there will be a momentary display as "CHARGING". During charging, all functions are disabled. This device is battery operated and cannot be used while charging.

7.4 100% charging completed can be checked when you switch on the device and see the battery icon is fully lighted.

7.5 Li-ion battery can self-discharge and its voltage will continuously decrease over time when in storage. It is advised to remove the battery and store the device safely. Mount the battery again for charging to reuse the device. The battery should be periodically recharged (every 3 or 4 months) during time of storage. This will enhance endurance of the battery to retain its charge.

CAUTION 
The device is powered with a rechargeable Li-Ion battery. To ensure user safety, functionality of the device is completely disabled while charging. **USE ONLY HDI SUPPLIED BATTERY & BATTERY CHARGER.**

8. Accessories

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

8.1 Diaphragm (HDS060-001)

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 (HDS060-002)

Micro USB Type-B Male connector to USB 4-Pin Type-A Male connector can be used to connect the device to the charger. Length is 1 metre.

8.3 Earplugs (HDS060-003)

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 (HDS060-004)

Rechargeable Li-Ion 18650 (Size) 3400mAh 3.7 V– 1 No.

8.5 Battery Charger (HDS060-005)

Input: 100-240V AC, 50/60 Hz,
Output: 5.0V DC, 2000 mA

8.6 HD Speaker (HDS060-006)

HD Speaker is used to replaying recorded audio.

CAUTION 
Use of accessories and cables other than those provided by HD Medical Inc of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation

9. 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 though it may not be readily visible	Contact HD Representative
4	Unexpected device behaviour	Failure of the Processor	Contact HD Representative

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. All cleaning instructions pertaining to stethoscopes and ECG units in general apply.
2. The chest piece diaphragm should be cleaned after each use with an alcohol wipe followed by a soft clean cloth.
3. Do not immerse in water or any other form of liquid sterilization for cleaning.
4. To clean the device, use only a lint soft clean dry cloth.

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. Shelf-Life:

Since HD Steth does not contain any component that degrade by itself over a period of usage, specific shelf-life is not applicable. However, the company will render product support for HD Steth for a period of seven years from the date of purchase by the user

13. Warranty

13.1 HD Medical Inc (HDI) warrants to the Purchaser that the device is free from all defects in material and workmanship. HDI provides 24 months warranty for the device from date of purchase.

13.2 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.

13.3 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.

13.4 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.

13.5 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.

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

13.7 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.

14. 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 Li-Ion 18650 (Size) 3400mAh 3.7V – 1 No.

Back up of 8 hours of continuous operation

Charger : 100-240V AC, 50/60 Hz, Output: 5.0 V DC, 2000 mA.

Environmental

Operating temperatures	: 5˚C to 47˚C
Storage Temperature	: -10˚C to +60˚C
Humidity	: 20% to 80%
Atmospheric Pressure (kPa)	: 101.3 kPa to 79.4 kPa
Physical Weight	: 230 grams (approx. - including battery)
Emission compliance	: EN55011, CISPR 11, Group 1 Class A
Type of protection	: Internally powered
Degree of Protection	: Type BF
Enclosure Degree of protection	: IPX1
Biocompatibility	: Device is biocompatible as per ANSI/AAMI/ISO 10993

International Regulatory Standards

ANSI / AAMI / IEC 60601-1-2:2014 / EN 60601-1-2:2015

Test	Test Procedure	EN Standard	Regulatory Acceptable Limits / Specification	HD Steth Capability
Conducted Emission	CISPR 11:2015+A2:2019	EN 55011:2016+A1:2017	Group 1, Class A, 0.15 to 30 MHz	PASS
Radiated Emission	CISPR 11:2015+A2:2019	EN 55011:2016+A1:2017	Group 1, Class A, 30MHz – 1GHz	PASS
Harmonics on AC Mains	IEC 61000-3-2-2018	EN 61000-3-2:2014	Class A	PASS
Flicker	IEC 61000-3-3-2013+A1:2017	EN 61000-3-3:2013	0 - 2KHz	PASS
Electrostatic Discharge	IEC 61000-4-2:2008	EN 61000-4-2:2009	Contact: level 4 (± 8KV) Air: level 4 (± 15KV)	PASS
Radiated Susceptibility	IEC 61000-4-3:2010	EN 61000-4-3:2006+A2:2010	80MHz – 2700MHz: 3V/m, 1 KHz, AM 80%; (level 2)	PASS
Electrical Fast Transients and Bursts	IEC 61000-4-4:2012	EN61000-4-4:2012	±2KV (100 KHz, 60s) for AC Power Ports; (level 3)	PASS
High Energy Surge	IEC 61000-4-5:2014+A1:2017	EN 61000-4-5:2014	Differential mode: ±0.5kV, ±1kV (90°, 180°, 270°) for AC Power Ports (level 2)	PASS
Conducted RF	IEC 61000-4-6:2013	EN 61000-4-6:2014	150KHz – 80MHz: 3Vrms, (1KHz, AM 80%), for AC Power Ports (level 2)	PASS
Power Frequency Magnetic Field	IEC 61000-4-8:2009	EN 61000-4-8:2010	30A/m, (50Hz), continuous field (Level 4)	PASS
Voltage dips & interruptions	IEC 61000-4-11:2004+A1:2017	EN 61000-4-11:2004	Dips: 0% UT, 0.5 cycle, 10ms @50Hz (0°, 45°, 90°,135°, 180°,235°,270°& 315°) 0% UT, 1 cycle, 20ms @ 50Hz (0°) 70% UT, 25 cycles, 500ms @50Hz (0°) Interruptions: 0% UT for 250 cycles, 5s @ 50Hz	PASS

Guidance and Manufacturer's Declaration—Electromagnetic Emissions

Tablet 1-1

Guidance and Manufacturer's Declaration—Electromagnetic Emissions		
The product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment- Guidance**
RF emissions CISPR 11	Group 1	The product 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 A	The product is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Tablet 1-2

Electromagnetic Immunity for Equipment and Systems Fully Compliant with EN 60601-1-2:2015			
The productis intended for use in the electromagnetic environment specified below.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment-Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2:2008	± 8kV Contact ± 15kV Air	± 8kV Contact ± 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 61000-4-4:2012	± 2kV (100 kHz, 60s) for AC Power Ports: (level 3)	± 2kV (100 kHz, 60s) for AC Power Ports: (level 3)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5:2014+A1:2017	Differential mode: ± 0.5kV, ± 1kV for AC Power Ports: level 2	Differential mode: ± 0.5kV, ± 1kV for AC Power Ports: level 2	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11:2004+A1:2017	Dips: (0% dip in U_T) for 0.5 cycle, 10ms @50Hz (0°, 45°, 90°, 135°, 180°, 235°, 270° & 315°) (0% dip in U_T) for 1 cycle, 20ms @50Hz (0°) (70% dip in U_T) for 25 cycles, 500ms @50Hz (0°) Interruptions: (0% in U_T) for 250 cycles, 5s @50Hz	Dips: (0% dip in U_T) for 0.5 cycle, 10ms @50Hz (0°, 45°, 90°, 135°, 180°, 235°, 270° & 315°) (0% dip in U_T) for 1 cycle, 20ms @50Hz (0°) (70% dip in U_T) for 25 cycles, 500ms @50Hz (0°) Interruptions: (0% in U_T) for 250 cycles, 5s @50Hz	Mains power quality should be that of a typical commercial or hospital environment. Mains power is used only for charging. The device cannot be used during mains Charging. It is a battery-operated device.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8:2009	30 A/m, (50Hz), Continuous field (Level 4)	30 A/m, (50Hz), Continuous field (Level 4)	Power frequency magnetic fields should be at levels characteristic of a typical location , in a typical commercial or hospital environment.

Tablet 1-3

Guidance and manufacturer's declaration – electromagnetic immunity			
The product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment-Guidance**
Radiated RF IEC 61000-4-3:2010	80MHz to 2.7GHz: 3V/m, 1 KHz, AM 80%; (level 2)	3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d = [3.5/3V/m]√P 80MHz to 800MHz d = [7/3V/m]√P 800MHz to 2.7GHz 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, [a] should be less than the compliance level in each frequency range. 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 reflection from structures, objects and people.

[a] Field strength 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 product is used exceeds the applicable RF compliance level above, the product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the product.

NOTE 3 Any lost or degraded essential performance of the device due to EM disturbances, performance of the device can be recovered by Switching OFF the Device and switching ON.

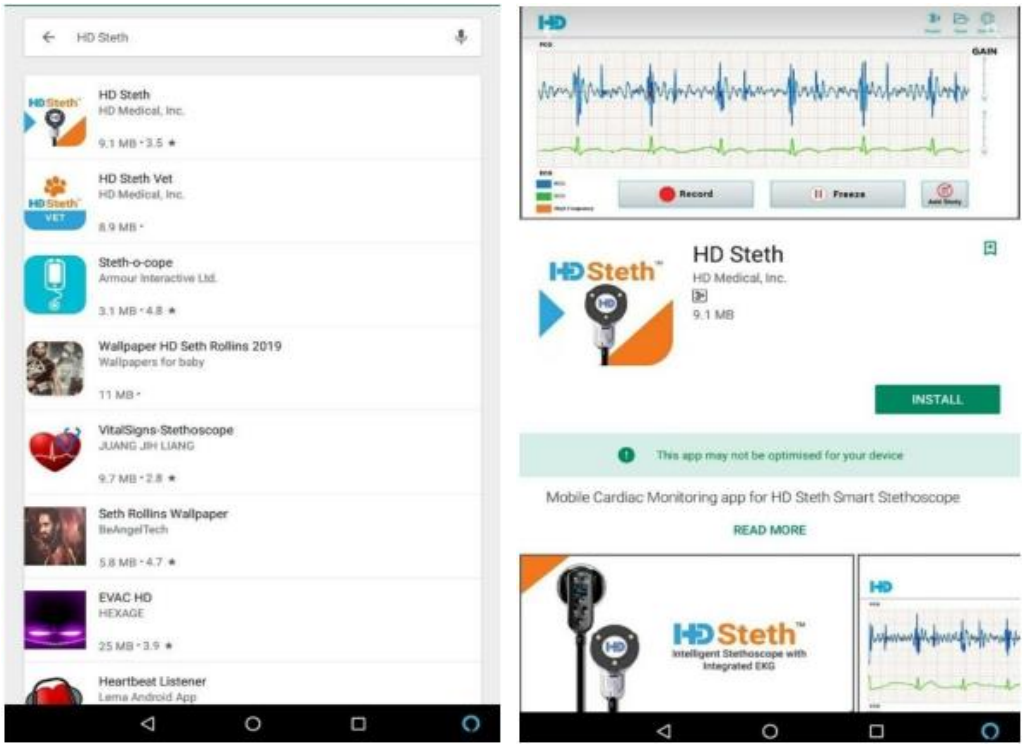
Tablet 1-4

Recommended separation distances between **portable and mobile RF communications equipment and product**		
The product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the product 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	
	80 MHz to 800 MHz d = [3.5/3V/m]√P	800 MHz to 2.7 GHz d = [3.5/3V/m]√P
0.01	0.117	0.233
0.1	0.37	0.737
1	1.17	2.33
10	3.7	7.36
100	11.7	23.3
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined 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. NOTE 1 At 80 MHz and 900 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. NOTE 3 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 HD Steth, including cables specified by HD Medical Inc. Otherwise, degradation of the performance of this equipment could result.”		

15. Installation for Android

The HD Steth pairs with an android application available for download on the Google Play Store. Detailed HD Steth App User guide is available for download at the following https://hdmedicalgroup.com/wp-content/uploads/2020/06/HD-Steth-App-User-Manual.pdf

As shown in below screen, search for the ‘HD Steth’ App and initiate the download.



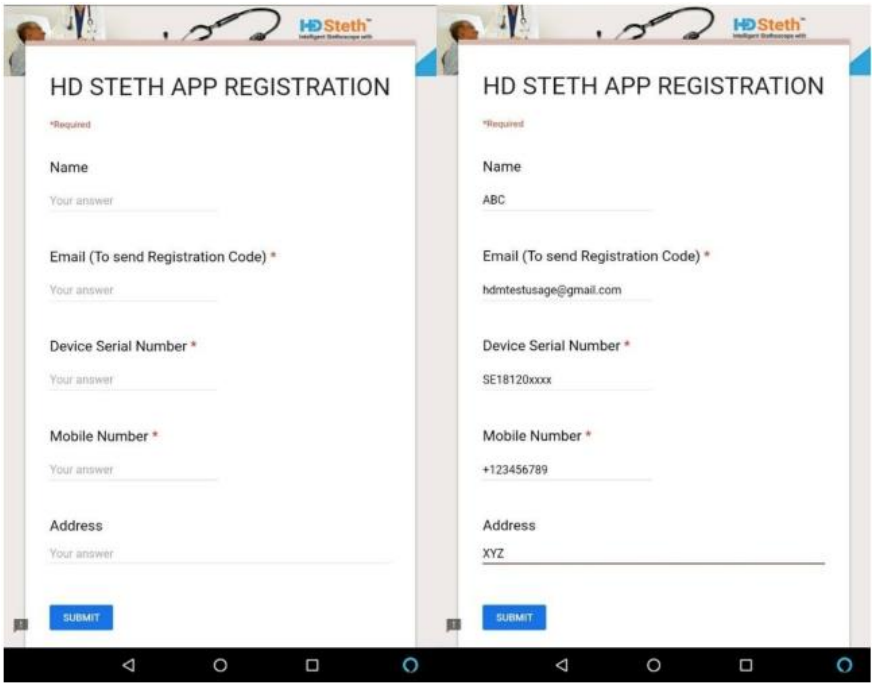
16. App Minimum Requirements

Please find below the minimum specifications for the HD Steth app to run on Android OS:

- **Snapdragon 425 processor**
- **2 GB RAM**
- **8 GB Storage**
- **Screen size - 8”**
- **Screen Resolution - 1280X800 - 190dpi**
- **Android 5.0(Lollipop) or above**
- **Bluetooth 4.0**
- **BLE (Bluetooth Low Energy)**
- **GPS**
- **Wi-Fi (For installing from Play Store)**
- **3.5mm jack (to listen to heartbeat from external audio)**

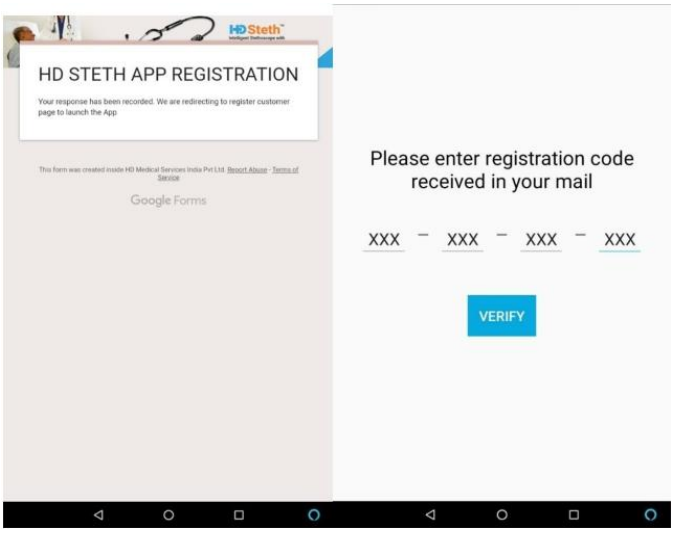
17. App User Registration (New Customers Only)

If you are a new HD Steth customer, you have to register customer details for first time to launch the App. In the registration screen, enter customer Name, Email, Device Serial Number, Mobile Number and Address.



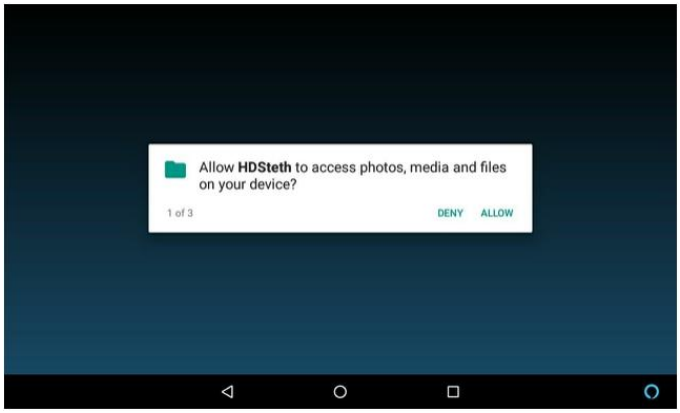
While submitting the user registration form ensure internet connection is active. If internet connection is not enabled then App will not be allowed for user registration.

On successful submission of user registration 12 digit auto registration code is sent to subscribed email from support@hdmedicalgroup.com. If the registration code is valid then App will be launched.

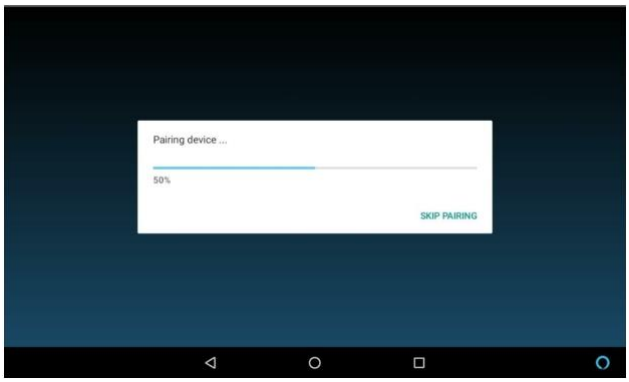


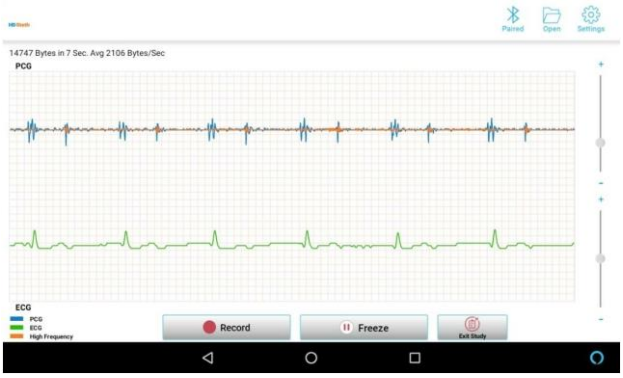
18. App Launch and Bluetooth Pairing

4.1 By clicking the HD Steth icon for first time the App request to access photos, media, files, device location, pictures and record video of the device. If the user allows these settings then App could resume further. These permissions are to access device file system and Bluetooth. If Bluetooth is OFF in tablet then App will request to turn Bluetooth ON to communicate with HD Steth device.



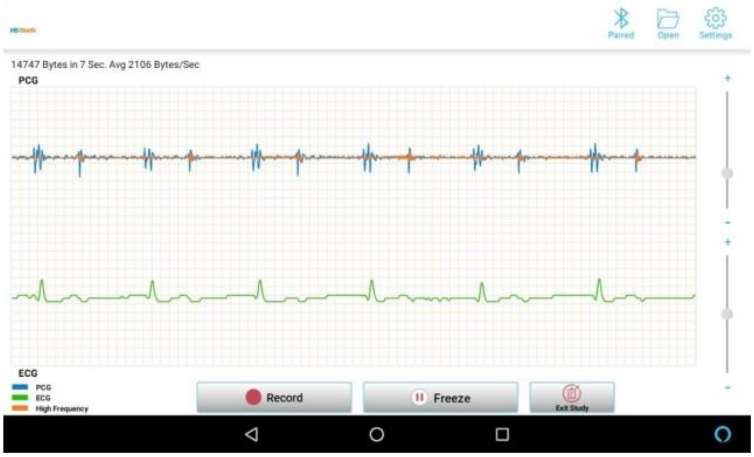
As soon as the App is launched it proceeds to scan for HD Steth devices in the vicinity. By selecting specific device from the list then it proceeds to pair with that device. On successful pairing the App routes to auscultation graph.





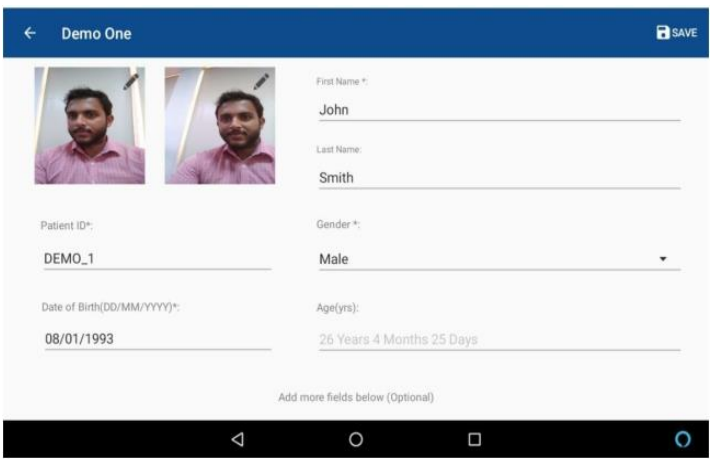
19. Capture & Save Recordings using the App

On successful connection with the device the main screen appears depicting the live auscultation waveforms received from the device.



On tapping anywhere on the Record button, recording starts and the progress is indicated.

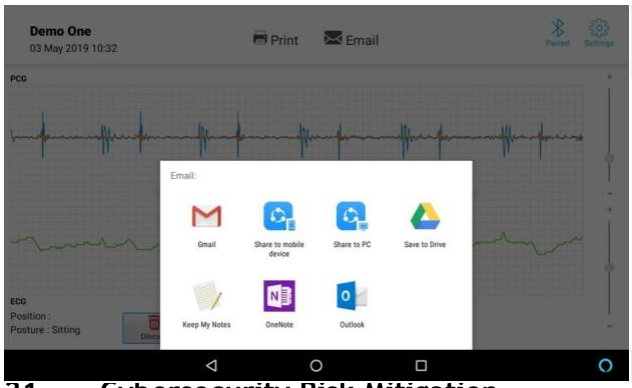
After 10 secs of recording, select position and posture screen appears to choose appropriate position and posture done during recording. Followed by position and posture screen, a preview screen appears where the user can decide whether to save or discard that recording.

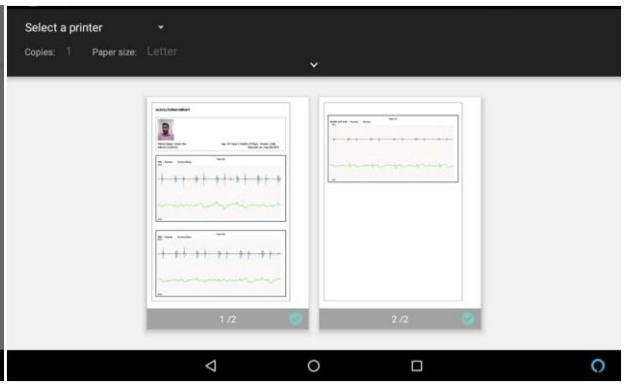


By pressing the save button the patient record along with additional clinical notes will be stored in the database for archival. These patient records will be played back to hear heart sound on the HD Steth device by connecting HD speaker to the tablet.

20. E-mail or Print Patient Records from App

The user has option to email current patient study to multiple recipients also has option to print the patient study by connecting with external printer





21. Cybersecurity Risk Mitigation

HD Steth Mobile app is designed to connect directly with HD Steth devices via Bluetooth without need of any network for transfer of data. Neither the HD Steth nor the app connect to the internet or intranet. So direct Cybersecurity challenges will not be applicable to HD Steth Mobile app. HD Steth Mobile app is hosted on Mobile devices (smart phones/tablets) which can be connected to other networks hence there is a probability of indirect Cybersecurity challenges. All users should ensure the confidentiality, integrity, and availability of all e-PHI (electronic protected health information) they create, receive, maintain or transmit. The cybersecurity controls that were established for the device include

21.1 Cybersecurity controls established for device and App

21.1.1 Direct connection between HD Steth and Mobile App without need of any network.

21.1.2 Clinical data from device is packed (propriety format) in transit to the App.

21.1.3 Smart device controls user access to the App.

21.1.4 Bluetooth protocol employed (SPP - Serial Port Protocol) allows only 1-to-1 connection. Data tapping is not possible.

21.1.5 App monitors for Bluetooth connection, and alerts user upon sudden event of disconnection.

21.1.6 Medical Practitioners are advised not to connect the mobile device which have Steth App to unknown / public networks

EMC related labelling as per IEC 60601-1-2

Clause	Requirement	IFU page
5.2.1.1 a)	a statement of the environments for which the ME EQUIPMENT or ME SYSTEM is suitable.	1. Indications for use "The device must be used in a clinical setting by trained and qualified personnel only"
5.2.1.1 b)	the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE	Page 2 "**Essential Performance**: Heart rate display on the device. BLE pairing of device and smart device. The Heart sounds and ECG signal are transferred in real time via BLE to the smart device. Visual representation of ECG and heart sounds are displayed on the smart device screen are stored on the smart Device. If any pairing issue occurs between device and smart device, automatically the issue will get resolved and get paired. No information is stored on the device. The Heart sounds and ECG signal are communicated in real time via BLE to the smart device, displayed on the smart device screen and are stored on the smart Device.
5.2.1.1 c)	a warning statement to the effect that "WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation	Page 1 "The device is not recommended for use in the presence of equipment producing Strong electromagnetic radiation/MRI and stacked device environment as it may affect the device functionality."
5.2.1.1 d)	a list of all cables and maximum lengths of cables	Page 13 section 8.2
5.2.1.1 e)	a warning statement to the effect that "WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."	Page 13 Caution "Use of accessories and cables other than those provided by HD Medical Inc of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation"
5.2.1.1 f)	a warning statement to the effect that: "WARNING: Portable RF	Page 4 Caution "To reduce the risk of device

	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 [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer.	interference, keep HD Steth at least 0.3 meters away from all Proximal RF emitters including Wi-fi routers and radios when operating or charging.”
5.2.1.2	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.	Page 18
5.2.2.4	shall include each frequency or frequency band of transmission, the type and frequency characteristics of the modulation and the EFFECTIVE RADIATED POWER.	Page 17

Table-9 as per IEC 60601-1-2

Proximity Fields from RF Wireless Communications Equipment						
Test Frequency (MHz)	**Band (MHz)**	**Modulation**	**Maximum Power (W)**	**Distance (M)**	**Immunity Level (V/m)**	**Verdict**
385	380-390	Pulse Modulation 18 Hz	1.8	0.3	27	PASS
450	430-470	FM ±5 kHz deviation, 1 kHz sine	2	0.3	28	PASS
710	704-787	Pulse Modulation 217 Hz	0.2	0.3	9	PASS
745						
780						
810	800-960	Pulse Modulation 18 Hz	2	0.3	28	PASS
870						
930						
1 720	1 700- 1 990	Pulse Modulation 217 Hz	2	0.3	28	PASS
1 845						
1 970						
2 450	2 400- 2 570	Pulse Modulation 217 Hz	2	0.3	28	PASS
5 240	5 100 -5 800	Pulse Modulation 217 Hz	0.2	0.3	9	PASS
5 500						
5 785						

For assistance and help contact

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Manufacturing Information

Manufactured by:

HD Medical Inc.
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Santa Clara, CA, USA 95054

Revision History

Date of release	Revision	Change Description
16-Apr-18	0	Initial release
05-Apr-20	1	1. Revision History added
		2. As per 21 CFR 801.109 Caution is updated
		3. Indications for use is updated
		4. Contraindications Updated
		5. Battery Charger Part number updated
18-Jun-20	2	1. Enclosure Degree of protection: IPX1
		1. Instruction to use on fat subject is included
		2. How to select modes is included
		3. Cleaning & disinfecting instructions are updated
		4. Details on storing device when not used for 1 week or more instruction is included
		5. App. Installation on Android smart device is included
		6. EMC related labelling as per IEC 60601-1-2 included
26-Jun-20	3	1. IPX1 - Symbol added in the safety related symbols & labels
		2. The numerical value of E1 in tablet 1-3 is added as 3 in page 20
		3. Table-9 as per IEC 60601-1-2 is added on page 29
02-Mar-21	4	1. All screen shots updated
		2. Switch ON Screen details updated