WiPatch

Version No. 1.4

Instruction for Use (IFU)

HM/WP/DT/001/IFU

HMicro Inc.

39355 California Street
Suite 303
Fremont, CA 94538.

List of Reference Documents	Version
HMicro_ ECP_ MRD	V2.0
HMicro_ Device Requirements Specification	V2.0

TABLE OF CONTENTS

TABLE OF FIGURES

1. INTRODUCTION AND FEATURES

1.1. About the Company

HMicro is the wireless solutions company with domain knowledge essential to understand business needs and technical requirements in healthcare and other existing markets. We develop innovative products engineered to address the unique requirements of wireless peripherals, focused on the most demanding applications in the broad Internet of Things.

Our REACH™ Wireless Technology provides wired-class reliability, on-the-network native IP operation and exceptional energy efficiency—a truly unique combination that enables our customers to develop distinctive and disruptive products.

HMicro's system-on-a-chip (SoC) solutions address today's requirements and tomorrow's challenges.

HMicro delivers a true platform with flexibility and programmability for a wide variety of applications, enabling our customers to add differentiated value through our:

1. Triple-Mode Hybrid Radio supporting multiple modes
2. Sensor Subsystem providing many analog and digital interfaces
3. Application Processor dedicated for OEM implementation of signal processing algorithms, sensor management and host interface

We are co-developing clinical-grade wireless physiological monitoring solutions that replace today's wired systems in facility, remote and home applications. Such wireless solutions must be safe, cost-effective, compact and comfortable and perform clinical monitoring effectiveness equivalent to conventional wired systems. These technical requirements can only be met by REACH™ Wireless Technology.

HMicro's first reference design is a cost-effective, single-patient wireless ECG solution.

Electrocardiograph (ECG) monitoring in the acute healthcare setting is critical. Today's ECG wiring harness consists of electrodes attached to the skin, leads that connect the electrodes to the patient cable, which in turn attaches to a patient monitor.

Our customers can start with the wireless ECG patch reference design and customize it thanks to the flexibility and programmability outlined above. HMicro uses the reference design to replace the wiring harness with a fully integrated wireless device much smaller than 10 cm in diameter. This end-to-end

solution also includes an adaptor that plugs into legacy patient monitoring equipment, delivering data in the same manner as a conventional wiring harness.

This application is comprehensive confirmation of REACH Wireless Technology:

1. Reliability must be wired-class in acute healthcare facilities that present a noisy RF environment with tens of devices operating in close proximity
2. The continuous streaming data rate is well over 100 Kbps
3. A lightweight coin cell must power the device for at least one week of constant operation

COMPANY CONTACT INFORMATION

Manufacturer Address:

HMicro INC

39355 California Street
Suite 303
Fremont, CA 94538.

Manufactured at:

DreamTech

3F, Uniquest Bldg., 271-2,
Seohyeon-Dong, Bundang-GU,
Seongnam-SI, Gyeonggi- DO, Korea
463-824.

Email Address: info@hmicro.com

Customer Helpline: 510.790.3303

Fax: 650.887.3393

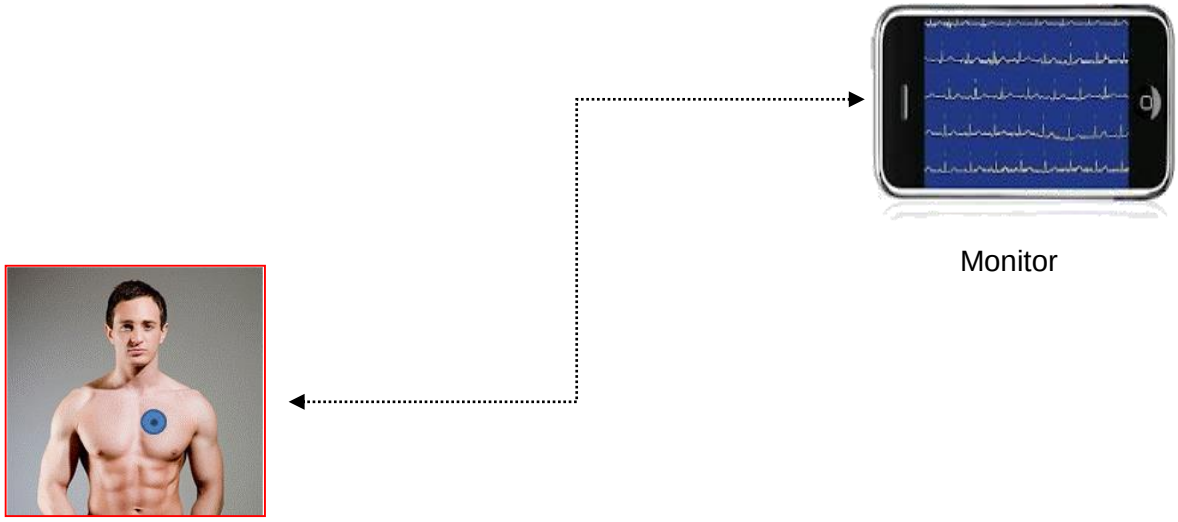
2. INTRODUCING WiPatch

2.1. ABOUT WiPatch

WiPatch is a lightweight disposable wireless ECG monitor and it provides systems and methods for monitoring a user.

The applications of the Medical Device are as follows:

1. This compact integrated wireless patch may be used to collect physiological data.
2. The WiPatch may be utilized in everyday life as well as in clinical environments. Data acquired by the WiPatch and/or external devices may be interpreted and/or be utilized by healthcare professionals and/or computer algorithms (e.g., third party applications).
3. Data acquired by the patch may be interpreted and be presented for viewing to healthcare professionals and/or ordinary users.



Monitor

WiPatch on patient

There are many wireless ECG monitoring patches for both wellness and health sector. WiPatch is a lightweight disposable ECG and respiration monitoring product. Most of them uses low bit rate Bluetooth connectivity whereas WiPatch uses WiFi with higher data rates. This also makes the device application scalable with more number of simultaneous users in one given place.

2.2. INTENDED USE

The intended use of the WiPatch electrodes when used with an iPad tablet installed with an iOS APP is to monitor up to 6 lead ECG output and the respiration rate of adults at rest for rhythm monitoring applications by health care professionals. Use can be in acute care facilities.

2.3. CONTRAINDICATION

1. WiPatch does not detect or diagnose medical conditions
2. It is not intended for use, while doing CT or MRI scans or X-ray exposure.
3. The reading displayed by the device should not be used for Specific Clinical Investigation.
4. This device does not replace a doctor, hence should not be used for self-medication.
5. Hospital or hospital like facilities or home environment should be relatively free from radio frequency interference.
6. WiPatch is not waterproof

3. UNPACKING THE DEVICE

3.1. PACKAGE CONTENTS

The package contains the WiPatch (1 number) along with Instructions for Use.

3.2. UNPACKING THE DEVICE

1. Open the carton box.
2. Check for any visible damage to package or pouch or patch, check for any leakage or discolouration of electrodes.
3. Open the pouch.
4. Remove the bottom liner gently by pulling the tab as shown in the Figure 1.

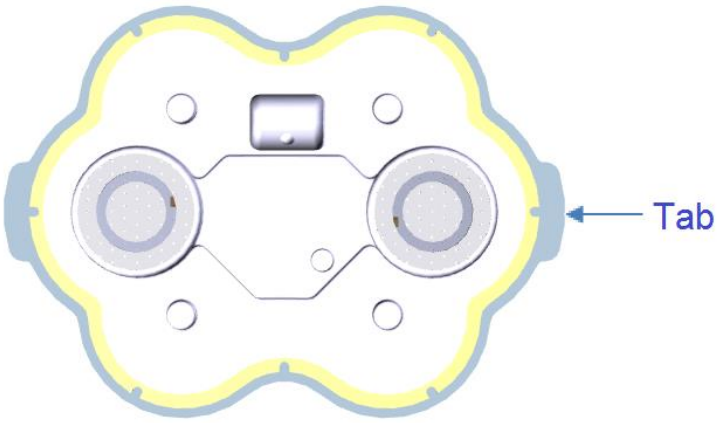


Figure 1: Patch Tab

3.3. GENERAL GUIDE

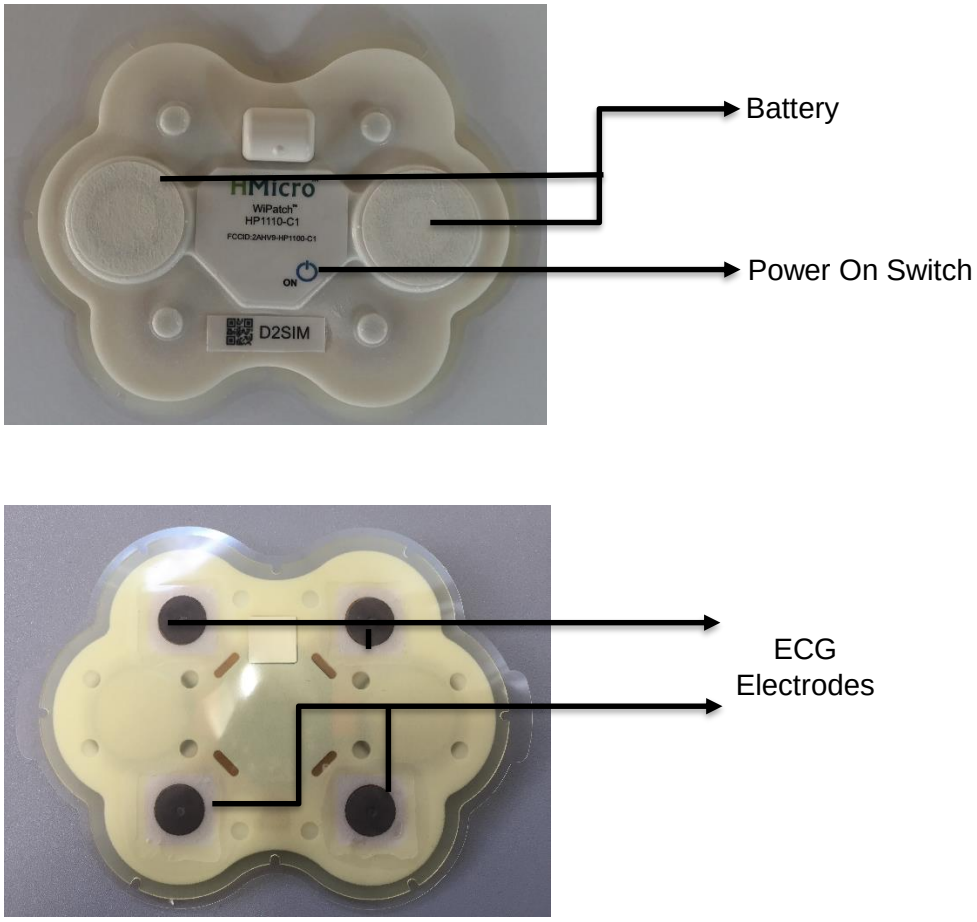


Figure 2: WiPatch Front and Rear View

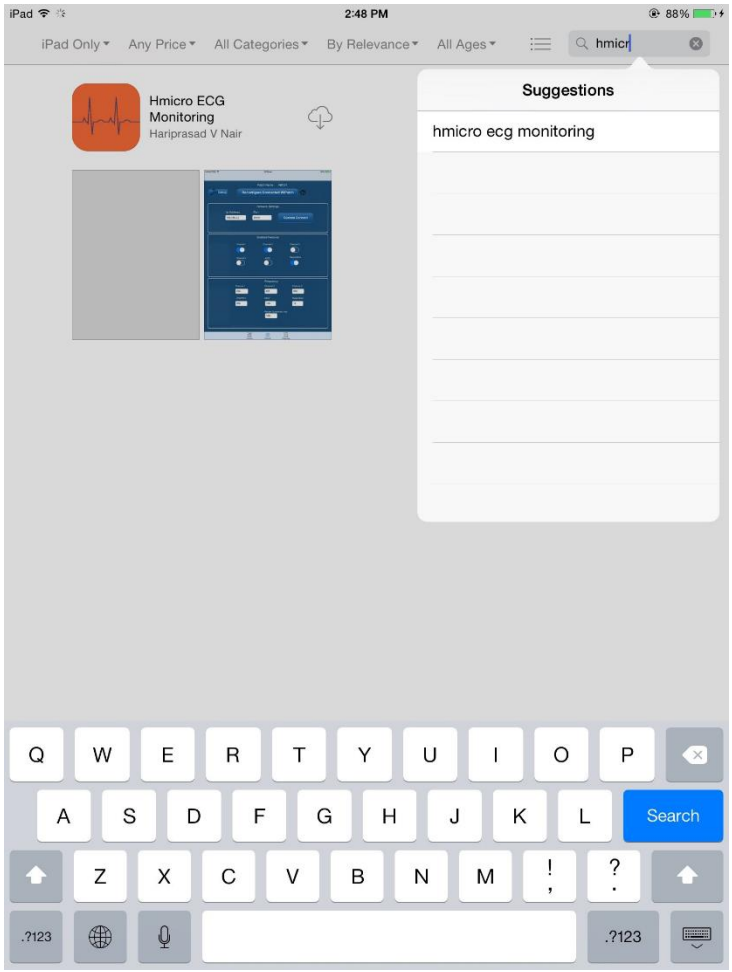
3.4. SYSTEM REQUIREMENTS FOR APP INSTALLATION

WiPatch application's system prerequisites are:

1. iOS 9.0 or higher
2. Additionally, device should have internet connectivity.

3.5. APP INSTALLATION

The application – "HMicro ECG Monitoring" can be downloaded from the Apple iStore.



3.6. BASIC OPERATIONS AND SETUP

The WiPatch should be attached to the body as described and illustrated below:

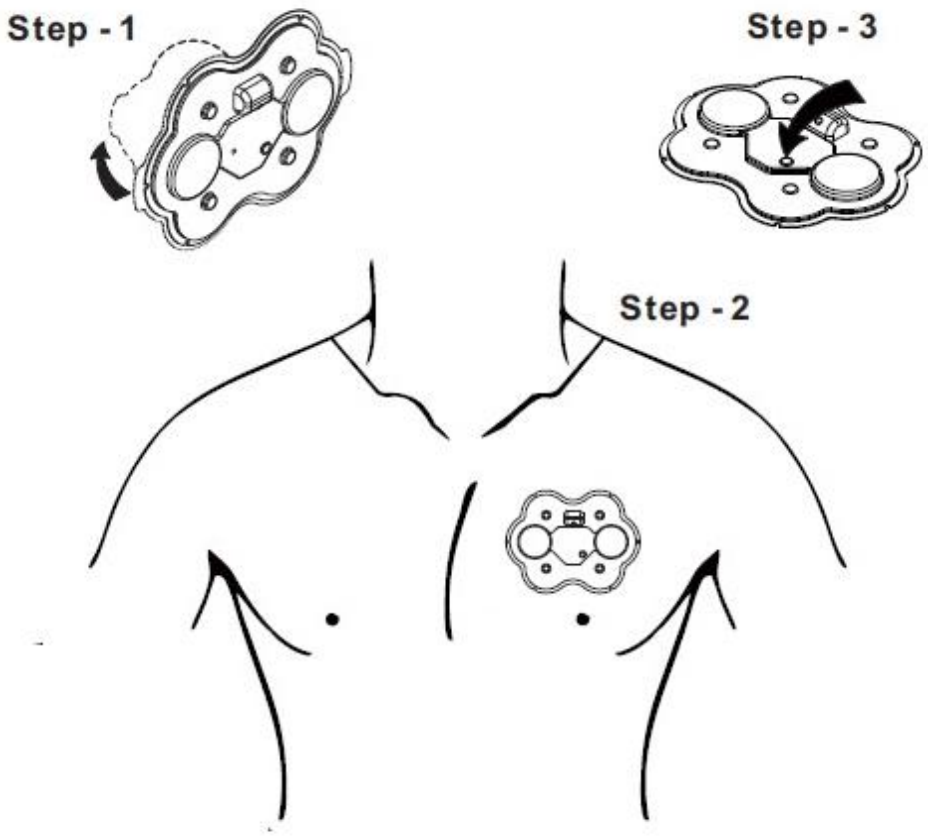


Figure 3: WiPatch Setup

1. Remove the bottom liner by pulling the tab as shown in Step 1.
2. Place the place on the left top of your chest, with the right position and orientation, as illustrated in Step 2.
3. Ensure that the Access point is turned on and its SSID Name and Password are set as required.
4. Turn the Patch on as illustrated with Step 3 by pressing the “Power on Switch” Shown in Figure2.
5. The Patch will now start blinking green.
6. Open the Application and Start the device pairing process described in further sections.

3.7. INDICATIONS

Device Indication	Description
Slowly Blinking Green Light	Device is connected to an Access Point
Rapidly Blinking Green Light	Device is attempting to connect to an Access Point
Continuous Red Light	Device is out of battery
Blinking Red and green light in sequence	User has pressed “Identify WiPatch” icon on the APP
Blinking Red light followed by LED off	User has pressed the “Turn Off WiPatch” icon on the APP

APP Indication	Description
Find Nearby WiPatches	Initiate the search process to find wi-patches associated with the same network
Patch Not Found	APP could not find any patch in the connected network
Searching for patches connected to “SSID_R1D”	Indicates that a search for patches connected to Access Point with example network ID “SSID_R1D”
Searching for patches	Indicates that the APP is in hotspot mode and is searching for patches.
Choose a patch – Green	Patch is not connected to any other APP and is available for connection.
Choose a patch – Red	Patch is already connected to another APP and is not available for connection, but is in the same network.
Lead OFF (Red)	Indicates poor contact of corresponding Lead/Electrode.
Identify Patch	Indicates the patch that is currently connected to the APP, user can identify by observing a blinking sequence of red and green light on the connected patch.
Turn Off WiPatch	Turns off the patch that was connected to the APP.
Connection Lost – Red Blinking	Connection to patch is lost.
HR Too High	Heart Rate is too high
Heart Rate	Indicates heart rate of the patient
Respiration Rate	Indicates respiration rate
Settings	Enters setting menu

Figure 4: Wi APP Start screen

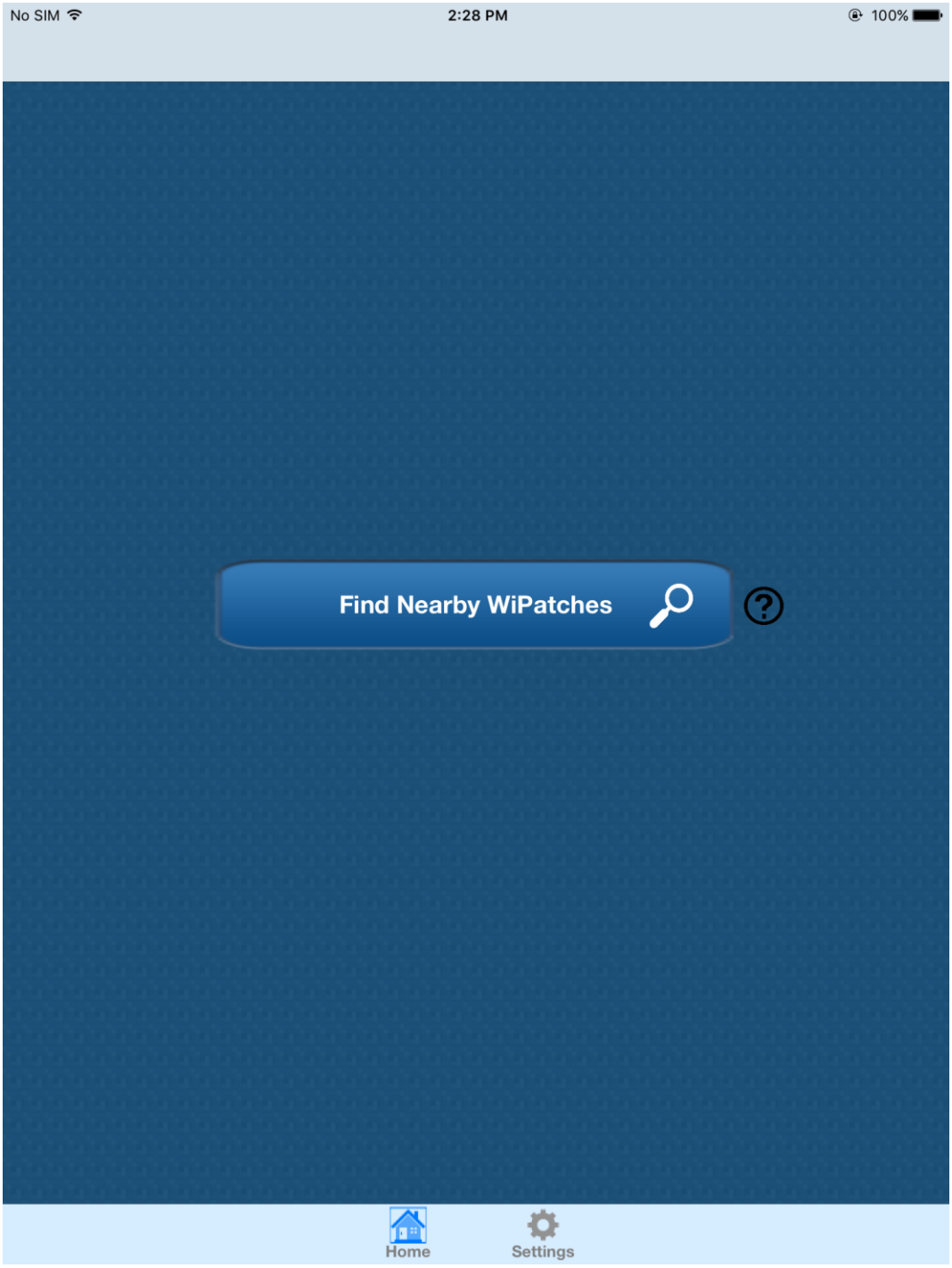


Figure 5: Wi APP Screen - Patches

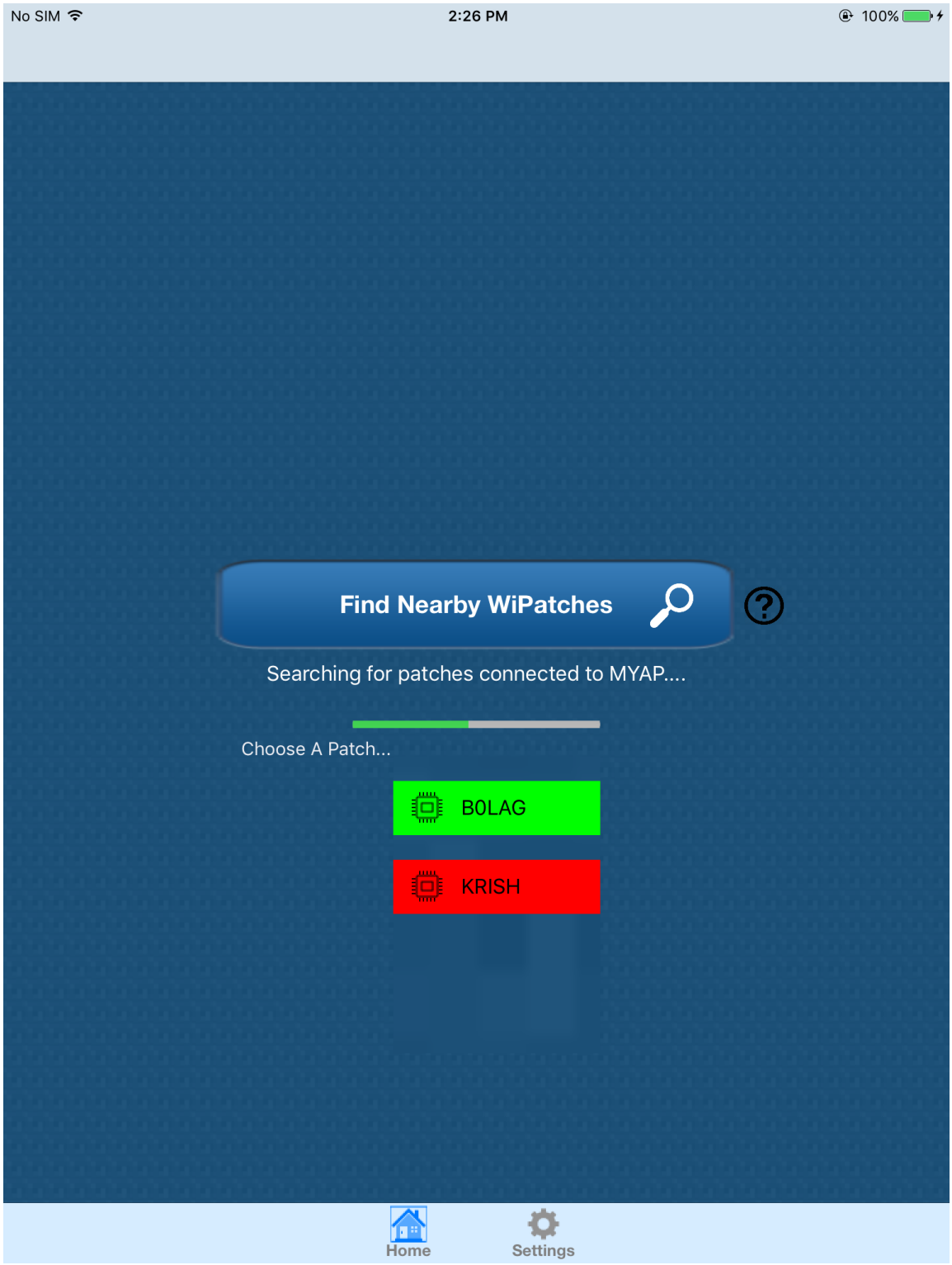
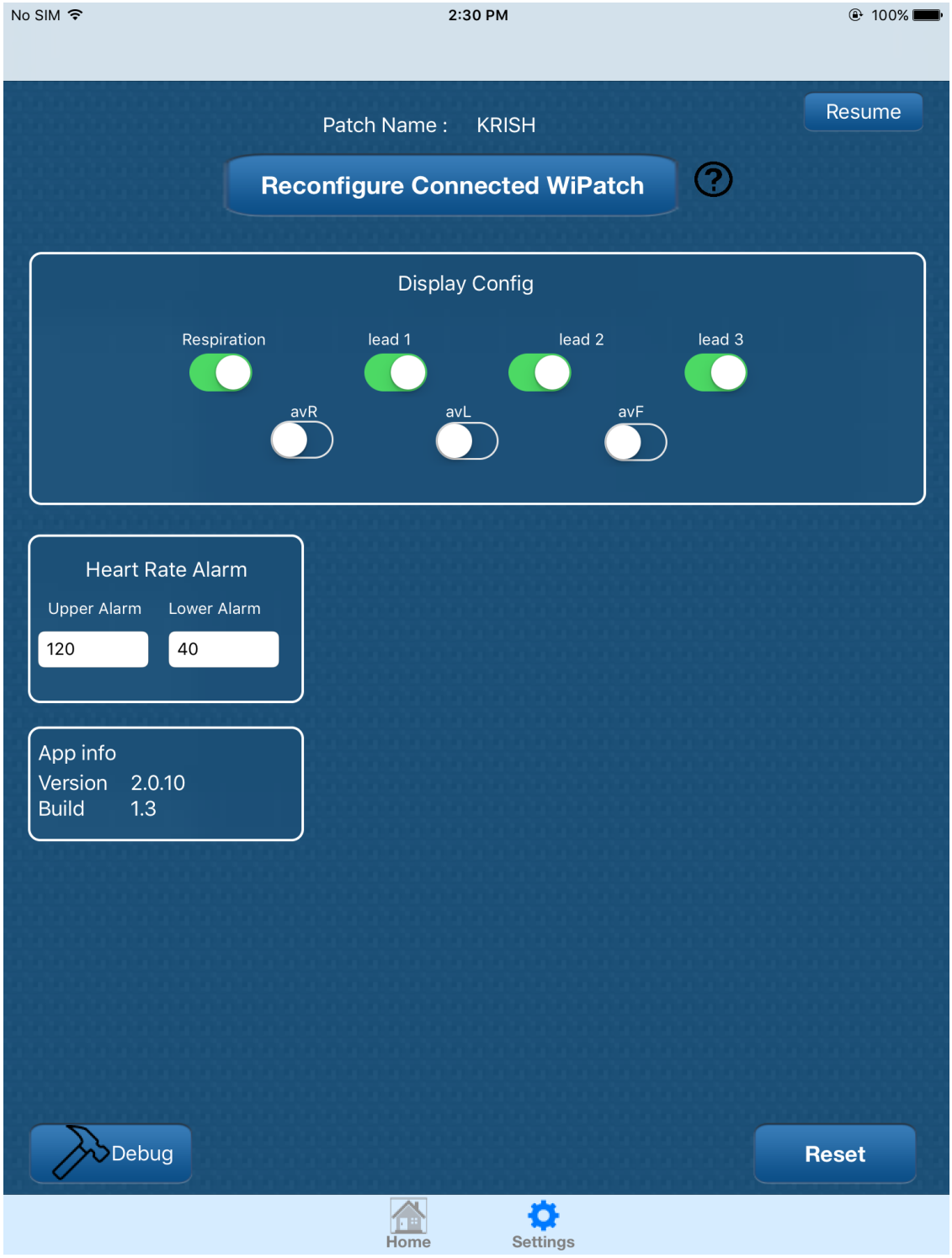


Figure 6: Wi APP Waveform screen

Figure 7: Wi APP Setting Screen



3.8. PAIR YOUR DEVICE

In order to pair the device with Monitor(APP), both WiPatch and Monitor(APP) need to be in the same network.

Each device has a 5-digits alphanumeric unique id as shown in Figure 8 (Placed in form of Serial Number on the device).

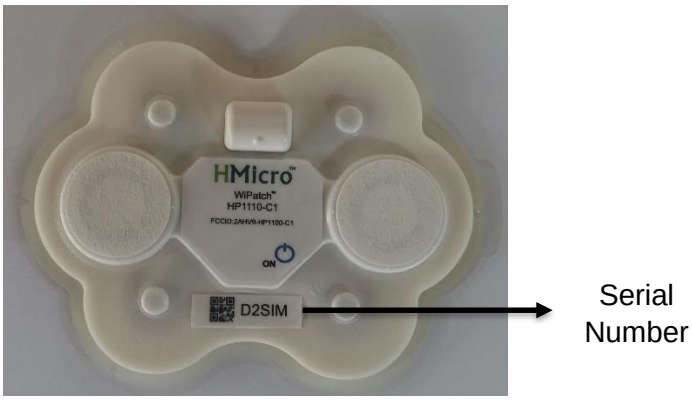


Figure 8: WiPatch Front View

The WiPatch is first removed from the packaging and turned off as specified in the basic operations section.

The WiPatch first associates with the Access Point and the LED on the WiPatch guides the user, as detailed in the earlier section.

The WiPatch's PATCH ID broadcast can then be seen by the Ipad

On invoking the APP, the IPAD displays a screen as shown in Figure 4.

On pressing the "Find Nearby WiPatches" icon, the APP will search and display all WiPatches connected to the same network.

The Unique IDs of WiPatches that are available for connection in the same network are displayed in Green, while the ones that are already connected to another Ipad in the same network are displayed in Red, as shown in Figure 5.

On selecting the appropriate Patch, identified by its ID and Green display, connection is established and the user can start viewing the ECG Waveform as shown in Figure 6.

4. GETTING STARTED

4.1. KNOW YOUR VITALS

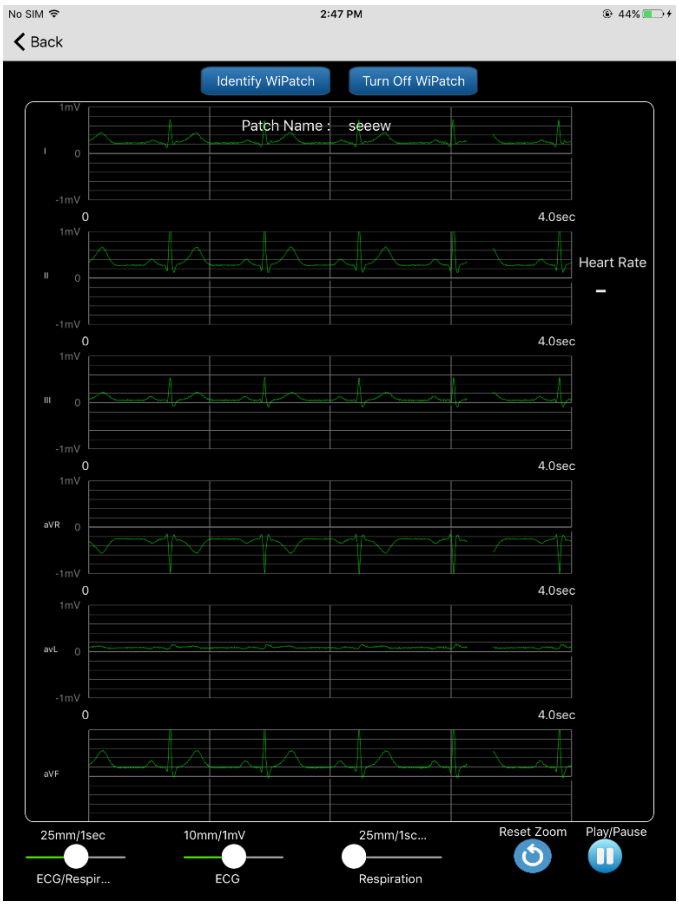
Electrocardiogram (ECG): ECG, alternatively know as EKG, is a test that records the heart's electrical activity. In simple terms, the heart's activity is captured a plotted on a waveform graph.

Heart Rate (HR): Heart Rate is the number of times your heart beats in a minute and is an important indicator of cardiovascular fitness. The Heart Rate of a Healthy adult in a relaxed state, lies in the range of 60 to 100 beats per minute.

Respiration: The Respiration Rate is the number of breaths taken per minute. Normal Respiration Rate for an Adult in a relaxed state, ranges from 12 to 18 breaths per minutes.

4.2. ECG ON WiPatch

The Wi APP displays 3 Limb Lead and 3 Augmented lead views corresponding to the three electrodes RA, LA and LL as shown in the Figure 9.

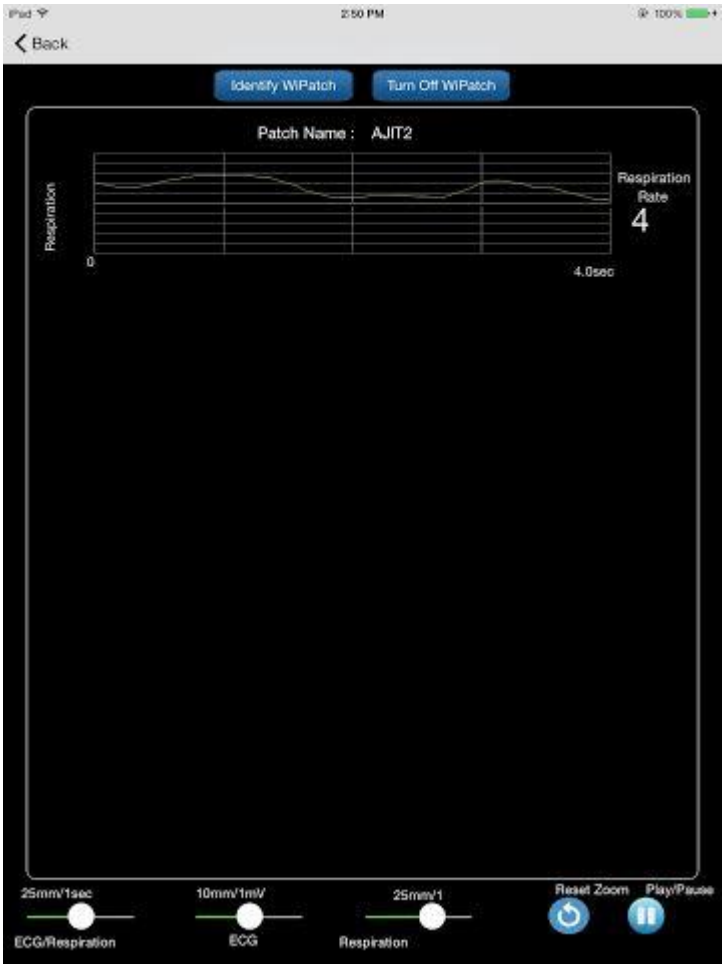


Each view waveform can be independently turned on or off using the "Display Config" section in "Settings" Page of the APP as shown in Figure 7.

The user can also specify the Heart Rate Alarm Threshold by changing the “Upper Alarm” and “Lower Alarm” in the “Heart Rate Alarm” section in “Settings Page of the APP, shown in Figure 7.

4.3. RESPIRATION ON WiPatch

The Respiration is measure Rate is displayed as shown in figure.



5. CAUTIONS OR WARNINGS

CAUTIONS OR WARNING	DESCRIPTIONS
Placing the device on user	Do not use if the package or the device is damaged, leaking or is tampered with.
Placing the device on user	Remove hair on the patient body (point of contact) and always ensure that user skin is clean and dry.
Placing the device on user	IF PATIENT COMPLIANTS OF SKIN IRRITATION OR ITCHING OR DISCONFORT, REMOVE THE PATCH IMMEDIATELY AND CONSULT THE DOCTOR
Placing the device on user	Do not drop the device on hard surfaces, against the sharp edges and corner. Do not apply weight or pressure or excessive stress on the device.
Placing the device on user	Strictly follow the placement guidelines and orientation provided.
Cleaning	Do not wash or immerse the device in water or fluids or any other chemicals.
Operating Conditions	Do not expose the device to extreme moisture
Operating Conditions	Do not use the device in EMI-EMC interference
Operating Conditions	Patient has to be in 5-meter distance from the IPad and Network
Operating Conditions	Do not use the device in MRI/CT environment
Operating Conditions	Do Not use the device in OT environment
Operating Conditions	Consult doctor when device used along with PACEMAKER
Operating Conditions	DEVICE CAN ONLY RUN WITH AN APPLICATION WHICH HAS iOS 9 or GREATER
Operating Conditions	Do not expose the device to strong shocks and vibrations
Operating Conditions	Place the device minimum 5 cm from the pacemaker
Operating Conditions	Do not open the device till patient is ready to use
Operating Conditions	Do not use the device with Lotion and cream on skin
Operating Conditions	Do not use the device under direct sunlight
Operating Conditions	Do not use the device on or with injured skin
Usage Conditions	Do not use the device beyond or after its specified life time (i.e. 4days)
Maintenance Condition	Do not try to open or repair the device
Storage Conditions	Do not store the device under Direct Sunlight

Storage Conditions	Do not store the device under High Temperature
Storage Conditions	Do not store the device under High humidity
Storage Conditions	Do not store the device under Wet or damp locations where water or other liquids may get on the unit
Storage Conditions	Do not store the device under Dusty Locations
Storage Conditions	Do not store the device near heat sources or hot objects or fires or open flames
Storage Conditions	Do not store the device near locations with Strong vibrations
Storage Conditions	Do not store the device near strong electromagnetic fields

6. ERROR MESSAGES

Error Message APP	Countermeasure	Cause
Connection Lost	Bring the device back in to the network.	Device strays Out of network coverage area
Lead OFF	Ensure that all electrodes are connected to the body.	Poor Electrode contact
Patch Not Found	Ensure that the Patch and APP are connected to the same network	Patch or APP is not connected to the same/expected network
Error Condition – Device		
Device turns off	Replace the device	Battery is completely drained

7. GENERAL HAZARDS

Potential HAZARD	Potential HARM	Control
No LED indication on WiPatch after turning ON the Switch	Unable to connect the device to Monitor/APP	WiPatch Battery is completely drained. Replace the device
Unable to pair the WiPatch with the Monitor	Network Issue	Restart the Monitor and re-establish the network.

Patch is exposed to water or any fluid or chemical or extreme temperature	Damage to Patch	Remove the patch immediately from body
Discoloration of patch/ Battery leakage	Damage to Patch	Remove the patch immediately from body and gently wash the skin.

8. SPECIFICATIONS

ECG Specifications	
ECG channels	6 Lead
Classification of Applied parts	Defib proof type CF
FDA Classification	Class- 2, Patient Monitoring
Frequency Response	0.67 Hz to 40 Hz
CMRR	> 90Db
Input impedance	> 2.5 M ohms at 10Hz
Differential range	+/- 310mV
ADC sampling rate	250 SPS
ADC resolution	16 bits
Respiration Specifications	
Injected Current	< 10uA
Injected Frequency	10 KHz
Resolution	< 1 ohm

Accuracy	
Heart Rate	+/- 5 BPM
Respiration	+/- 3 BrPM

Measuring Range	
Heart Rate	30 BPM to 200 BPM

Respiration	5 BrPM to 24 BrPM

Power Requirements	
Battery Type	Zinc-Air
Battery Life	4 days
Battery Capacity	900 mAh
Output Voltage	2.4 V
Charging Mode	Not Rechargeable
Compatibility	iOS 9 or higher
Wireless Communication	Wi-Fi (802.11b)

Environmental Specifications	
Operational temperature	$+10^0$C to $+40^0$C (50^0F to 104^0F)
Operational relative humidity	45% to 70% (non-condensing)
Storage temperature	$+10^0$C to $+30^0$C (50^0F to 86^0F)
Storage relative humidity	45% to 70% (non-condensing)

Physical Characteristics	
Dimensions	10cm x 8cm
Weight	30gms
Colours	White
Ingress Protection	IP22

9. INFORAMTION OF LABEL USED

LABEL	NAME	DESCRIPTION
	Caution or Warning	This symbol instructs the user to consult the instructions for warnings and safety precautions that could not be presented on the device.
	Latex Free	Latex Free
	Non Sterile	Non-Sterile
	Manufacturer	Legal manufacturer. (HMicro INC)
	Recycle	Disposal of the medical device to be controlled according to local regulations
	Reference Number	Device Reference Number – HP1110
	Serial number	Serial number of the device
	Quantity	Number of devices in Pouch/Carton Box
	Consult instructions for use	Refer to Instruction manual/booklet.
	Storage Temperature	Store packaged device within the specified temperature range

	Expiry Date (YYYY-MM)	Use Device in packaged condition before expiry date.
	Manufacturing Date	Device Manufacturing/Packaging Date
	Applied Part	DEFIBRILLATION-PROOF TYPE CF APPLIED PART
	Do not Reuse	Do not Reuse
IP22	Ingress Protection	Ingress Protection
	Do not Wet	Keep away from liquids or water or chemicals
	Caution, Consult accompanying document.	This symbol instructs the user to consult the instructions for warnings and safety precautions that could not be presented on the device.
FCC ID	Federal Communications Commission	Federal Communications Commission ID

10. DEACTIVE

10.1. UNPAIR

To Unpair the device from the patch, click on the “Turn Off WiPatch” icon on the APP screen as shown in Figure 6. The patch shall flash Red and turn off.

10.2. UNINSTALL

To uninstall the APP, follow the standard application uninstallation procedure described by iOS.

10.3. DISPOSAL

The device should not be discarded with household waste.

To prevent possible harm to human health and environment, dispose it off as a recyclable waste to promote sustainable reuse of material resources.

Please carry out disposal for battery in accordance with national and other local regulations.

11. INTERNATIONAL STANDARDS AND COMPLIANCES

Standards	Revision	Description
IEC 60601-1 ed3.1	2012	Medical electrical equipment - Part 1: General requirements for basic safety & essential performance
IEC 60601-2-27 ed3.0	2011	Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
IEC 60601-1-2	2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances -Requirements and tests
IEC 61000-4-2	2008	Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
IEC 61000-4-3	2010	Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
IEC 61000-4-6	2013	Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields
IEC 61000-4-8	2009	Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test
RE (CISPR11)	2010	Electromagnetic Radiation Disturbance (Radiated Emissions) CISPR 11 (Class A/B, Group 1/2)
FCC		Part 15
ISO 10993-1	2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 14971	2012	Medical devices - Application of risk management to medical devices [Authority: The European Union Per Directive 90/385/EEC]

IEC 62304	2006	Medical device software -- Software life cycle processes [MDD (93/42/EEC), AIMD (90/385/EEC), IVD (98/79/EC)]
IEC 62366	2007	Medical devices -- Application of usability engineering to medical Devices
ASTM D4169		Standard Practice for Performance Testing of Shipping Containers and Systems

12. GUIDANCE AND MANUFACTURE'S DECLARATION- ELECTOMAGNETIC EMISSIONS

Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR11	Group 1	The device 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 CISPR11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly to the public low-voltage power supply network that supplies building used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

13. GUIDANCE AND MANUFACTURE'S DECLARATION- ELECTOMAGNETIC IMMUNITY

Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be of wood, concrete or ceramic tiles. If the floor is tiled with synthetic material the relative air humidity must have 30 % at least.
Electrical fast transient /bursts IEC 61000-4-4	2 kV for power supply lines ± 1 kV for input/output lines	Not Applicable	
Surge IEC 61000-4-5	±1 kV 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 61000-4-11	< 5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60% dip in UT) for 5 cycle s 70 % UT (30% dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 s	Not Applicable	
Power frequency magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power Frequency magnetic fields should be at levels characteristic of typical location in a typical commercial or hospital environment
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	Not Applicable	Portable and mobile RF communications

Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=1,2√P d =1,2√P 80MHz to 800 MHz d =2,3√P 800 MHz to 2,5 GHz where ***P*** is the maximum output power rating of the transmitter in watt (W) according to the transmitter manufacturer and ***d*** is the recommended separation distance in meters(m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency rangeb . Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 Hz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorptions and reflections from structures, objects and people.

1. Field strength from transmitters such as base stations for radio (cellular/cordes) telephones and mobile radio, amateur radio, AM and FM radio 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 device is used exceeds the applicable RF compliance above, the 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 device.
2. Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

14. FCC Statement

This device complies with Part 15 of the FCC rules.
Operation is subject to following Two conditions:
1. This device may not cause harmful interference and
2. This device must accept any interference received including interference that may cause undesired Operation of this device.
The changes or modifications not expressly approved by the party responsible for Compliance could void the user's authority to operate the equipment.