iHealth®
Portable ECG monitor (ECG3)
OWNER'S MANUAL

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INTRODUCTION

Thank you for selecting the ECG3. The ECG3 is an automatic single - lead dynamic electrocardiogram (ECG) recorder, which can record and store 72 hour ECG data at most. ECG3 can transmit current ECG data to an iOS device with Bluetooth on which user can watch the current ECG waveform and heart rate. The ECG data stored in ECG3 can be uploaded on an iOS device with a data cable, which will be automatically analyzed and displayed. The heart rate is calculated by counting the heart beats in each 30s and the maximum and minimum heart rate is calculated in every hour.

PACKAGE CONTENTS
- · 1 ECG Recorder
- · 1 Owner's Manual
- · 3 Electrodes
- · 1 Data cable
- · 1 Charging cable

Cable	Max. cable length, Shielded/unshielded		Number	Cable classification
DC Power Line (USB Cable)	0.26m	Unshielded	1Set	DC Power
Signal Line (USB Cable)	0.26m	Unshielded	1Set	Data transition

INTENDED USE

The ECG3 is intended for use in a community hospital or at home and it is a dynamic electrocardiogram measurement system. It is designed to measure and record ECG data of an adult individual in the long term by using a technique in which an electrode was pasted on the chest.

CONTRAINDICATION

⚠ People wearing a cardiac pacemaker should not use this product.

⚠ People with sensitive skin or skin allergies are not suggested to use this product.

PARTS AND DISPLAY INDICATORS
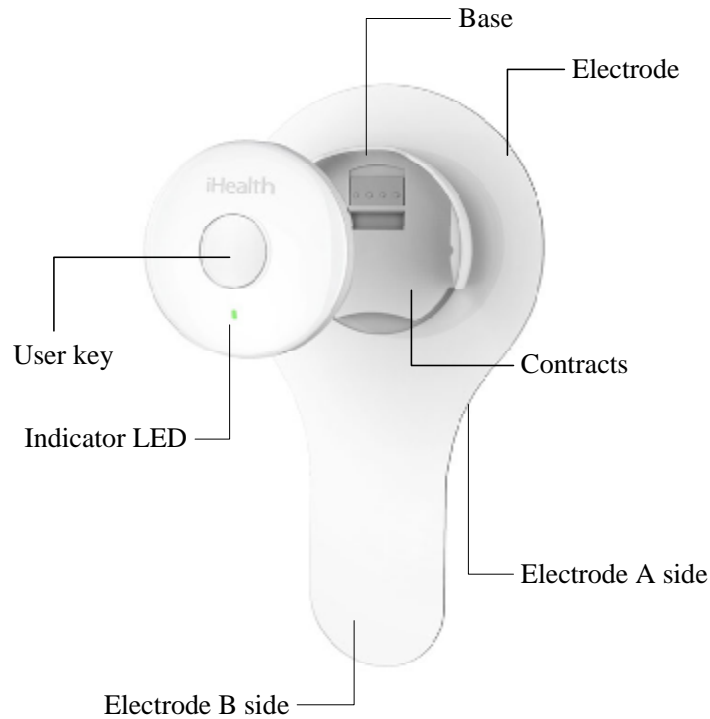
SETUP AND OPERATING PROCEDURES

Download The Free iHealth ECG3 App

Prior to first use, download and install the iHealth ECG3 App from the App Store (iOS device). Use keyword search terms "iHealth" or "ECG3".

Note: The iHealth ECG3 App is only supported in iPad mini 4, iPad Air 2, iPad mini 3, iPad Air, iPad mini 2, iPad mini and iPad(4th generation) .The system version should be above 10.0.0.

Add new user item in **iHealth ECG3 App**

User need to add a new user item in iHealth ECG3 App to store the measuring history. Do the following steps to create a new user item:

a. Press the Select patient button to get into the user list.

b. Click the "Add" button at the bottom of this page to enter the "Add User" page. Input the information of the patient according to the prompt.

c. Click the "Save" button to save the new user item.

Activate the ECG3

ECG3 should be activated on first use, or you will not be able to use this unit. Connecting ECG3 to an AC adapter or a USB port on PC using the charging cable, the green indicator LED on the ECG3 begins to blink. Disconnecting ECG3 with charging cable, the green indicator LED blinks 4 times indicating that the device has been activated.

Update the firmware of **ECG3**

If a new version of the ECG3's firmware is released, the iHealth ECG3 App will inform user to update when the ECG3 is connected to the iOS device with the data cable. User can choose whether to update this version of the ECG3's firmware, but it is strongly recommended to do this updating to get a better experience. Do the following steps to update the firmware of ECG3:

a. Connect ECG3 to the iOS device with the data cable and launch the iHealth ECG3 App. If there is

ECG Device firmware update
New iHealth Lite firmware version
(x.x.x) avaliable for use.

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a new version of firmware, the App will prompt user as is shown in the figure at right side.

b. Click the "Install" button to do the updating, keep the connection between ECG3 and iOS device and wait until the firmware download finish, then disconnect ECG3 with the iOS device.

c. ECG3 will update automatically and the green LED will blinks during updating. The green LED will lighten When updating finish.

d. Press the button to reset ECG3, the green LED will blink 4 times, which indicates updating success.

Note: The clock in ECG3 will reset after each updating finish, so please calibrate the clock in the ECG3 by watching the current ECG waveform introduced in the following introductions after each updating.

OPERATION INSTRUCTIONS

a. Remove the release paper at A side of the electrode, and paste the electrode at the position of chest shown in the figure on the right side (Note: Clean skin before pasting the electrode if possible, which is conducive to the accuracy of measurement). Then remove the release paper at B side of the electrode. The electrode is disposable and do not try to use it again.
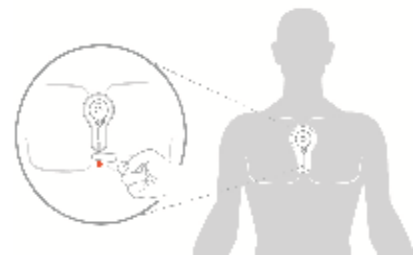
b. Fasten ECG3 with the base on the electrode and ensure that the ECG3 has a good contact with the electrode. Press the User key on ECG3 for about 2s, the ECG3 will vibrate once, which indicate the measurement beginning. And the green indicator LED on ECG3 will blink once in 3s.The blinking will last until measurement stopped.

c. User can watch the current ECG waveform during measurement processing. Please do the following steps to watch current ECG waveform:
1) Open Bluetooth of the iOS device.

2) Launch the iHealth ECG3 App, wait until the icon turns blue. Press this icon, the iHealth ECG3 App will show a new page. The current ECG waveform, heart rate and battery volume are shown in this page.
3) When several ECG3 are working at the same time, the iHealth ECG3 App will show a device list. User needs to choose a device in the list according to the MAC printed at the bottom of the ECG3.
4) If the ECG3 does not contact well with the electrode, the iHealth ECG3 App will prompt a lead off message shown in the figure at the right side and the ECG3 will vibrate continuously (4 times vibration in each 5s). Please check the contact between skin and the electrode and the contact between the ECG3 and the electrode.

d. If user feels uncomfortable in heart during measurement processing, please press the user key to mark this time point, which is conducive to the diagnosis of the heart abnormality.
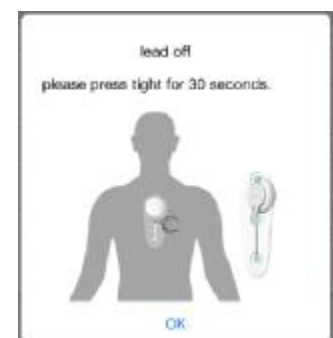
e. If user wants to finish the measurement, take down the ECG3 from the electrode, the ECG3 will begin to vibrate and will stop working 30s later. User can also stop the ECG3 working by charging it.

f. If user needs to watch the ECG data stored in the ECG3, please connect the ECG3 to an iOS device with the data cable. Launch the iHealth ECG3 App and the App will show the page indicating that the ECG3 begins to upload the ECG data to the iOS device. Waiting until the ECG data uploading finish, user can watch the recorded ECG waveform and the time points added by user or analyzed automatically by the iHealth ECG3 App indicating the heart abnormality.

Note: The iHealth ECG3 App will calibrate the clock in ECG3 which is used to record the start time, stop time and time points that user marks while the ECG3 is transmitting the current ECG data. So it is strongly suggested to watch the current ECG waveform in each measurement.

SPECIFICATIONS

1. Product name: Portable ECG monitor
2. Model: ECG3
3. Classification: Internally powered, Type BF applied part, IP22, Continuous operation
4. Machine size: approx. 45mm × 45mm × 14mm
5. Weight: approx. 17g
6. Memory volume: more than 72 hour ECG data
7. Power:
   DC: 5V ⎓ 500mA
   Battery: 1*3.7V ⎓ Li-ion 165mAh
8. Measurement range:
   Heart rate: 30 - 280BPM
9. Heart rate Accuracy: $\pm$2BPM or $\pm$5%(which is larger)
10. Wireless communication:
    Bluetooth low energy
11. Storage Condition (recorder): -20℃ ～ 65℃ (-4℉ ～ 149℉)+0 ～ 95%RH without condensation
12. Operation condition: 10℃～40℃(50℉～104℉) + 10～95%RH without condensation
13. Environmental pressure: 700hPa-1060hPa
14. Battery life: 300 charge/ discharge cycles, 72 hour continuous measurement on a full charge

Note: These specifications are subject to change without notice.

GENERAL SAFETY AND PRECAUTIONS

1. Read all of the information in the Owner's Manual and other provided instructions before operating the unit.
2. Please contact the manufacturer to get information in maintaining and using ECG3 or to report unexpected operation or events.
3. ⚠ This ECG Recorder is designed for adults and should never be used on infants weighing less than 10kg.
4. ⚠ Do not diagnose by yourself according to the measurement results, please always consult your doctor. Self-diagnosis may lead to deterioration in your condition.
5. ⚠ Keep the ECG3 and other accessories out of reach of young children and pets to prevent the unit being swallowed or causing contact injuries.

6. ⚠ Use of ECG3 adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, ECG3 and the other equipment should be observed to verify that they are operating normally.

7. ⚠ 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 ECG3, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

8. The use of accessories, transmitters and cables other than those specified by Andon Health, with the exception of accessories and cables sold by Andon Health of PORTABLE ECG MONITOR as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the PORTABLE ECG MONITOR.

9. Following ESSENTIAL PERFORMANCE is intended used in Homecare environment. ESSENTIAL PERFORMANCE: Heart rate Accuracy: ±2BPM or ±5%(which is larger)

10. The ECG3 can be used at home and in a community hospital. If use ECG3 in a hospital, keep the unit away from active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high. If use ECG3 at home, keep the unit away from devices emitting strong electromagnetic radio such as mobile phone and microwave.

11. Uploading and watching the ECG data recorded in the ECG3 in an iOS device is the only operation that user can do in an ambient condition with high intensity of EM DISTURBANCES.

12. ⚠ Do not use this product with a defibrillator, which will be dangerous. Remove the ECG3 before using a defibrillator.

13. The skin which the electrodes are contacted or pasted should be clean, because excessive body hair will influence the ECG measurement.

14. ⚠ If a skin allergy or other unfitted symptoms happened during measurement, stop measuring immediately.

15. ⚠ Please do not share the unit with any infectious person to avoid cross-infection.

16. Sweat and steam have no harmful effect on ECG3, but you should keep this unit dry as possible. Avoid activities in wet environment such as taking a shower.

17. The ECG3 will not send warning message to user when a heart abnormality occurs during taking measurement.

18. ⚠ Wrong operation and inappropriate position of electrode will lead to an unreliable measuring result. Please read the Owner's Manual carefully and operate the ECG3 cautiously while taking measurement.

19. Avoid strenuous exercise while taking measurement, which may cause a wrong measuring result.

20. The device would not apply to the patients who use an artificial heart and lung (there will be no ECG waveform).

21. The patient can be an intended operator. All functions of the unit can be used safely by patient. Charging is the only maintenance can be operated by patient.

22. Please don't use accessories (e.g. electrode, data cable, etc.) that are not described in the instructions. Do the opposite will possibly damage this unit and cause dangers.

23. This product should not be used as a USB device.

24. ⚠ This product might not meet its performance specifications if stored or used outside the specified temperature and humidity ranges.

25. ⚠ No maintenance can be carried on when the ECG3 is working on a patient.

26. ⚠️ Do not be nervous or anxious when taking measurement, an unreliable will occur otherwise.
27. Electrode of ECG3 should not contact other conductive parts including earth.
28. This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment.
29. This device complies with part 15 of the FCC rules. Operation is subject to the 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.
30. The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate the equipment.
31. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.   This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.   However, there is no guarantee that interference will not occur in a particular installation.   If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

    - Reorient or relocate the receiving antenna.

    - Increase the separation between the equipment and receiver.

    -Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

    -Consult the dealer or an experienced radio/TV technician for help.

    -This device and its antenna(s) must not be co-located or operating in conjunction with any other antenna or transmitter.

BATTERY HANDLING AND USAGE

⚠️ Do not change the battery. If the battery can no longer be charged, please contact Customer Service.

- Please ensure the ECG3 has at least 40% power before a 24 hour measurement. If an ECG3 does not have enough power to start a measurement, it will stop recording ECG data and will prompt user. Please charge this unit for at least 1 hour.
- When charging is needed, please connect ECG3 to an AC adapter or a USB port on PC with the charging cable. The ECG3 will not work while charging, please wait until charging is complete.
- A medical AC adapter with an output of DC 5.0V, above 500mA and complies with IEC 60601-1/UL 60601-1 and IEC 60601-1-2/EN 60601-1-2 is suitable for this unit. Please note that the jack size is USB micro-B.
- When charging the ECG3, the ECG3 will show with different indicator indicating the power status. See the table below for details.
- It is suggested that you charge the battery when the battery is less than 20%. Overcharging the battery may reduce its lifetime.

    ⚠️ Lithium battery replacement by inadequately trained personnel could result in a hazard such as a fire or explosion.

⚠ Do not plug or unplug the AC adapter into the electrical outlet with wet hands.

⚠ If the AC adapter is abnormal, please change the adapter.

⚠ When battery charging, the AC input voltage is interrupted, ECG3 will stop battery charging, and if the power supply restored, battery charging recovered automatically, this degradation could be accepted because it will not lead to unacceptable risks and it will not result in the loss of basic safety or essential performance

⚠ The ECG3, data cable, charging cable, *battery* and electrodes must be disposed of according to local regulations at the end of their usage.

Note: The battery has limited charge cycles and may eventually need to be replaced by an iHealth service provider. Battery life and charge cycles vary by use and settings.

ECG3 Status	Status Indicator
Charging	The green indicator LED breathes(The process that LED turns dim to brilliant gradually and then do the opposite) continuously
Fully charged	The green indicator LED lights up constantly
Low battery	ECG3 vibrates 2 times and the red indicator LED breathes for 10 times

TROUBLE SHOOTING

PROBLEM	POSSIBLE CAUSE	SOLUTION
Low Battery	Battery is too low	Charge the battery
ECG3 vibrates continuously during measurement	ECG3 and electrode do not contact well	Check and ensure that the ECG3 and the electrode, the electrode and skin have a good contact
ECG3 cannot connect to iOS device through Bluetooth	The iHealth ECG3 App occurs an error or the Bluetooth of the iOS device is not open	Check and ensure the Bluetooth of the iOS device is open and launch the App again
The iHealth ECG3 App shows wrong waveform when watching the current ECG waveform or the uploaded ECG waveform	ECG3 and electrode do not contact well	Check and ensure that the ECG3 and the electrode, the electrode and skin have a good contact
	ECG3 is expose in strong electromagnetic field	Keep the ECG3 away from units emitting strong electromagnetic radio during measurement

	ECG3 has a hardware problem	Contact customer service
The time and date recorded in ECG3 is not accurate	The clock in ECG3 needs to be calibrated or the ECG3 was restarted before	Start a measurement and watch the current ECG waveform, which will calibrate the clock in ECG3
ECG3 cannot upload ECG data through the data cable	The data cable is damaged	Contact customer service to get another data cable
Red indicator LED lights up for 10s when a measurement starts	Firmware error	Start a measurement again
The green indicator LED blinks continuously after updating the firmware	Updating is failed and the previous firmware has been damaged	Contact customer service
Red indicator LED lights up constantly	Firmware fault or hardware damage	Push the user key for about 8s to reset the device or contact customer service
No response	Firmware fault or hardware damage	Push the user key for about 8s to reset the device or contact customer service

CARE AND MAINTENANCE

1. ⚠ Do not attempt to disassemble, repair or modify this unit. To do otherwise will possibly damage this unit or cause dangers.
2. ⚠ Avoid strong shocks or vibrations, or drop or step on the ECG3.
3. ⚠ Do not expose the unit to static electricity. Always disperse any static electricity from your body before using this unit.
4. ⚠ Avoid high temperature and direct sunlight. Do not immerse the unit into water or any other liquid as this will result in damage to ECG3.
5. ⚠ Do not keep this unit in the following ambient conditions:
   - Exposed to direct sunlight.
   - Subject to high temperatures or high humidity.
   - Wet or damp locations where water may get on the unit.
   - Dusty locations.
   - Near fires or open flames.
   - Locations exposed to strong vibration.
   - Locations exposed to strong electromagnetic fields.
   Keep this unit in above ambient conditions may cause damage to this unit.
6. Wipe the ECG3 with a moistened and well wrung soft cloth using warm water to clean the unit. Then air dry the unit.

7. ⚠ Do not sterilize this unit in an autoclave or gas sterilizers, which will do damage to the unit.
8. The ECG3 can maintain the safety and performance characteristics for a minimum of three years of usage.
9. ⚠ The electrode is single use only. Please use the electrode in the validity period on the packing of the electrode.
10. The ECG3 will not measure the ECG data and will prompt user when the electrode is loosened. Using a degraded electrode will lead to an unreliable measuring result.
11. Do not use immediately if the unit is stored at temperature below 0℃ or above 45℃. Leave this unit at room temperature for at least one hour.
12. The battery can maintain the performance characteristics for a minimum of 300 charge cycles. Battery replacement should only be performed by a qualified iHealth technician. To do otherwise will void your warranty and possibly damage your unit.
13. If ECG3 is not used for a long time, please sure to fully charge it every 2 months.
14. ⚠ No component can be maintained by user in the unit. The circuit diagrams, component part lists, descriptions, or other information which will assist the appropriately qualified technical personnel to repair those parts of the unit designated reparably can be supplied by the manufacturer.
15. It is recommended that product performance be checked every 2 years or after each repair. Please contact the service center.
16. The ECG3 can only connect to an iOS device with the data cable or connect to a USB port on PC or an AC adaptor with the charging cable. It will be unsafe to connect this unit to other equipment not described in the instructions, please don't do this.
17. The electrode and other conductive parts on ECG3 should not contact other conductive parts. Do otherwise may cause damage to the ECG3.
18. ⚠ Do not touch the electrodes on the backside of the unit. To do otherwise may cause damage to this unit.

WARRANTY INFORMATION
The Portable ECG monitor is warranted to be free from defects in materials and workmanship within one year from the date of purchase when used in accordance with the provided instructions. The warranty extends only to the end user. We will, at our option, repair or replace without charge the Portable ECG monitor covered by the warranty. Repair or replacement is our only responsibility and your only remedy under the warranty.

EXPLANATION OF SYMBOLS

Symbol for "THE OPERATION GUIDE MUST BE READ"
            The sign background color: blue.
            The sign graphical symbol: white.

Symbol for "WARNING"

Symbol for "TYPE BF APPLIED PARTS"

IP22   Symbol for "INGRESS PROTECTION" -"IP22" indicates that the level of ingress of solid foreign objects is 2 and the level of ingress of water is 2.

⚕ Symbol for "ENVIRONMENT PROTECTION" – Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice.

🏭 Symbol for "MANUFACTURER"
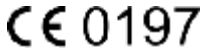
CE 0197 Symbol for "COMPILES WITH MDD93/42/EEC REQUIREMENTS"

🏭 Symbol for "DATE OF MANUFACTURE"

SN Symbol for "SERIAL NUMBER"

EC REP Symbol for "EUROPEAN REPRESENTATIVE"

⊗ Symbol for "DO NOT CONTAIN AND NO PRESENCE OF NATURAL RUBBER LATEX"

☂ Symbol for "KEEP DRY"

☀ Symbol for "KEEP AWAY FROM SUNLIGHT"

Ag/AgCl Symbol for "MATERAL OF ELECTRODE"

⧗ Symbol for "USE-BY DATE"

LOT Symbol for "BATCH CODE"

REF Symbol for "CATALOGUE NUMBER"

⊘ Symbol for "DO NOT RE-USE"

🌡 Symbol for "TEMPERATURE LIMIT"

Symbol for "STORED HERMETICALLY"

Rx Only Symbol for "PRESCRIPTION"

🚫MR Symbol for "MAGNETIC RESONANCE(MR) UNSAFE"

"Made for iPad," mean that an electronic accessory has been designed to connect specifically to iPad, respectively, and has been certified by the developer to meet Apple performance standards. Apple is not responsible for the operation of this device or its

compliance with safety and regulatory standards. Please note that the use of this accessory with iPad may affect wireless performance.
iHealth is a trademark of iHealth Labs Inc.

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OTHER STANDARDS AND COMPLIANCES

The Portable ECG monitor corresponds to the following standards: IEC 60601-1:2005 +A1:2012(E)/EN 60601-1:2006/A1: 2013 (Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance), IEC 60601-1-2:2014(Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and Tests), ISO60601-2-47:2001 (Medical Electrical Equipment -- Part 2-47: Particular Requirements For The Basic Safety And Essential Performance Of Ambulatory Electrocardiographic).

ELECTROMAGNETIC COMPATIBILITY INFORMATION

This product is applicable to the equipment and system requirements for the purpose of receiving radio frequency energy for the purpose of the work, Bluetooth low energy receive bandwidth 2M. This product can also be used to include RF transmitter equipment and system requirements and emission frequency of 2.4GHz ISM band, BLE modulation types: GFSK, effective radiated power: < 0dBm

Table 1 - Emission

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class B	Home healthcare environment
Harmonic distortion	IEC 61000-3-2 Class A	Home healthcare environment
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	Home healthcare environment

Table 2 - Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels
		Home Healthcare Environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	10V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

Table 3 – Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, $\pm$5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

Table 4 –Input a.c. power PORT

Phenomenon	Basic EMC standard	Immunity test levels
		Homecare environment
Electrical fast transients/burst	IEC 61000-4-4	±2 kV 100kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	±0.5 kV, ±1 kV
Conducted disturbances induced by RF	IEC 61000-4-6	3V, 0.15MHz-80MHz 6V in ISM bands and and amateur radio bands between 0.15MHz and 80MHz

fields		80%AM at 1kHz
Voltage dips	IEC 61000-4-11	0% UT; 0.5 cycle At 0º, 45º, 90º, 135º, 180º, 225º, 270º and 315º
		0% UT; 1 cycle and 70% UT; 20/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0% UT; 250/300 cycles

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