

HiCardi series

Operator's Manual

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Part Code: PU241002-XA

FCC Compliance Statement

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.

FCC Interference Statement

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 correct the interference by one 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 which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

FCC Caution

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

FCC ID : 2BN73-MEZ-H1

Directive

- Copyright law allows no part of this instruction manual to be reproduced without permission.
- The contents of this manual are subject to change without notice.
- The contents of this manual should be correct. If, for some reason, there are any questionable points, please do not hesitate to contact our technical support.
- The manual will be replaced if any pages are missing or collation is incorrect.

Warranty

- Please contact your local distributor about the warranty period.
- Device failure or damage related to the following situations during the guarantee period is not covered by this warranty:
 - Installation, transfer installation, maintenance and repairs by any person other than an authorized MEZOO employee or technician specified by MEZOO.
 - Damage sustained to the MEZOO product(s) caused by product(s) from another company excluding products delivered by MEZOO.
 - Damage – caused by mishandling and/or misuse – is the responsibility of the user.
 - Maintenance and repairs utilizing maintenance components that are not specified by MEZOO.
 - Device modifications or use of accessories not recommended by MEZOO.
 - Damage caused by accidents or natural disasters (earthquakes, flooding, etc.).
 - Damage resulting from usage where caution statements and operating instructions shown in this manual have not been followed.
 - Damage due to neglect of specified maintenance checks.
- This warranty only covers the hardware of the HiCardi. The warranty does not cover the following selections:
 - Whatever damage or loss results from the attachment of accessories or their operation.
 - In the event of a defect in the product.
- contact our sales outlet or EU representative as noted on the back cover.
- The HiCardi series conforms to the EMC standard IEC60601-1-2.

Note: Any device not complying to the EMC standard IEC60601-1-2 that is used with the HiCardi series renders the HiCardi as non-compliant to the EMC standard IEC60601-1-2.

Trademark

Product brand names shown in this manual are likely to be the trademark or registered trademark of the company concerned.

FCC Operation Guide

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.

Note : This equipment has been tested and found to comply with the limits for CLASS B digital device, pursuant to Part 15 FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. 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 correct the interference by one or more of the following measures;

- 1.1. Reorient or relocate the receiving antenna.
- 1.2. Increase the separation between the equipment and receiver.
- 1.3. Connect the equipment into an outlet on a circuit different from that to which receiver is connected.
- 1.4. Consult the dealer or experienced radio/TV technician for help.

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SAFETY INFORMATION

General Safety Information

This section contains important safety information related to general use of HiCardi series wearable patch device in the HiCardi series Holter. Other important safety information appears throughout the manual.

- The HiCardi series Holter will be referred to as the HiCardi series throughout this manual.
- The HiCardi series wearable patch device will be referred to as the HiCardi series.
- The HiCardi series mobile application will be referred to as the HiCardi Series mobile application or mobile application throughout this manual.

Important! Before use, carefully read this manual, accessory directions for use, all precautionary information and specifications.

Warning

Warnings alert you to potential serious outcomes (death, injury, or adverse events) to the patient or user.

WARNING

Do not open cover or disassemble the HiCardi series. Doing so could cause electric shock or fire. When the device is repaired or changed without the manufacturer's approval, it is not covered by the warranty. It is prohibited by law to modify the device without authorization.

The HiCardi series should be disassembled and repaired only by MEZOO technical support. There are no internal user-serviceable parts.

In order to prevent damage to the HiCardi series, do not use the HiCardi series with electrosurgical equipment.

The HiCardi series conforms to the requirements of the EMC standard (IEC60601-1-2), and may therefore be used simultaneously with pacemakers and other electrical simulators. It should, however, be noted that the HiCardi series may be affected by electrical scalpels and microwave therapeutic apparatus. Please check operation of the HiCardi series during and after use of such equipment.

The following cautions apply when connecting the HiCardi series with other equipment.

1. **Ensure that the connected equipment is in accordance with the IEC60601-1 or IEC safety standards, so that the system complies with IEC60601-1.**
2. **Employ additional protective measures (e.g., additional protective earthing) as necessary.**

Any connections between the HiCardi series and other devices must comply with applicable medical systems safety standards such as IEC 60601-1. Failure to do so could result in unsafe leakage current and grounding conditions.

Do not connect devices that do not meet medical safety standards (such as commercial PCs), as they may cause electric shock. The HiCardi series meets the restricted level of leakage current required for medical devices. Therefore, the HiCardi series cannot be connected to a device that would give a combined total of leakage current beyond the restricted level.

Do not cover the charging cradle that is on charging the HiCardi series with anything else to avoid generating heat.

When the HiCardi series is not used or on charging or in storage, keep it out of reach of babies and children to avoid any accidents.

To ensure accurate performance and prevent device failure, do not expose the HiCardi series to extreme moisture, including direct exposure to rain. Such exposure may cause inaccurate performance or device failure. Refer to *Specification* section.

WARNING

Check the electrode quality before attaching it to the HiCardi series. Do not use electrode when it is defective or wet, apply new electrode. Do not immerse electrode in water or cleaning solutions.

Never use electrodes that are past the expiration date. The expiration date of unopened packages is labeled outside the package.

Once a package of electrodes has been opened, try to use the immediately. It is often a good practice to mark on the outside of the package the date the package was opened.

Tissue damage can be caused by incorrect application or use of an electrode and leaving an electrode on too long (e.g. over 25 hours) in one place. Inspect the electrode site periodically to ensure skin integrity, correct positioning and adhesion of the electrode.

Before placing the HiCardi series on the skin, check the condition of the skin. If the skin is relatively sensitive or damaged, do not place the HiCardi series on that area to prevent skin damage.

ECG electrode application period shall be carefully determined considering skin sensitivity of the person. HiCardi series can operate for about 25 hours under internal battery.

Used electrode should be disposed at designated collection site. Do not reuse the electrode to prevent the risk of infection. Also, reusing may cause performance degradation or malfunction.

When the electrode is attached to the skin, apply the HiCardi series firmly with strong pressure to make sure that there is no gap between the skin and the electrode. Improper attachment of electrode may cause performance degradation.

For best product performance and measurement accuracy, use only accessories supplied or recommended by MEZOO. Use accessories according to the manufacturer's directions for use and your facility's standards. Use only accessories that have passed the recommended biocompatibility testing in compliance with ISO10993-1.

For best product performance and measurement accuracy, use only accessories supplied or recommended by MEZOO. Use accessories according to the manufacturer's directions for use and your facility's standards. The use of accessories, transducers, and cables other than those specified may result in increased emission and/or decreased immunity of the HiCardi series.

Before using the HiCardi series, confirm that the HiCardi series is working properly and is safe to use.

The HiCardi series cannot be used when MRI(Magnetic Resonance Imaging) is in progress. If MRI is in use, keep patient attachments away from patients to prevent accidents.



The HiCardi series direct threat to users, patients or equipment within a magnetic resonance environment. Do not use the HiCardi series in a magnetic resonance environment.

Do not take into or use the HiCardi series in locations where highly combustible anesthetics or flammable gases are used or in high-pressure oxygen rooms or inside oxygen tents, as this may cause a flammable explosion.

Any HiCardi series reading can be affected by the physiologic condition, the excessive movement and shivering, electromyography or other therapy.

Keep people under close surveillance when monitoring. It is possible, although unlikely, that radiated electromagnetic signals from sources external to the patient and the HiCardi series can cause inaccurate measurement readings. Do not rely entirely on the HiCardi series readings.

The HiCardi series is designed for use in environments in which the signal can be obscured by electromagnetic interference. During such interference, measurements may seem inappropriate or the HiCardi series may not seem to operate correctly.

Portable and mobile RF communications equipment (including peripheral units as antenna cables or external antennas) should be used at distance of 30cm from any part of the HiCardi series including cables. Otherwise, the performance of HiCardi series may be deteriorated.

If you are uncertain about the accuracy of any measurement, check the vital signs by alternate means; then make sure the HiCardi series is functioning correctly.

It is possible that any radio frequency transmitting equipment and other nearby sources of electrical noise may result in distortion of signal or disruption in the HiCardi series operation.

WARNING

It is possible, although unlikely, that large equipment using a switching relay for its power on/off may affect HiCardi series operation. Do not operate the HiCardi series in such environments.

Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

Do not attach the HiCardi series to the body while in the shower.

Do not touch signal input, signal output or other connectors, and the people simultaneously.

To ensure the safety, the conductive parts of the electrodes (including associated connectors) and other applied parts should not contact other conductive parts, including earth ground, at any time.

Look for display motion before accepting any displayed data as a current measurement.

Do not share sensitive information to prevent security threats, such as:

1. The device information of the HiCardi series (e.g., HiCardi series's ID and MAC address)

If the device information of the HiCardi series is leaked, the connection between the HiCardi series and mobile application may be breached by unauthorized person. Check the connection between the HiCardi series and mobile application periodically. If you suspect a security threat, stop using the HiCardi and contact your local distributor or MEZOO technical support immediately.

Do not share your smartphone with others. Doing so may cause leakage of sensitive information related to security.

If the HiCardi series or the smartphone with mobile application installed are lost or stolen, stop using the HiCardi series and contact your local distributor or MEZOO technical support immediately.

Do not leave the Mobile application unattended. When you stop using them or leave for a while, lock the smartphone or logout of user account.

Do not turn off the HiCardi series or the smartphone while the firmware update is in progress. Doing so may cause firmware corruption and the HiCardi series may not operate properly.

Even if a firmware update is failed or canceled in the middle of the update procedure, the HiCardi series is designed to operate normally with the previous firmware. But if you suspect firmware corruption or the HiCardi series does not operate properly, please contact your local distributor or MEZOO technical support.

Do not place anything on top of the HiCardi series or the charging cradle. If something is spilled over or get into them, such spillage may cause fire or electric shock. If fluid spills on the HiCardi series or the charging cradle accidentally, disconnect power cord, wipe dry immediately, and contact MEZOO technical support for safe use.

During cleaning the HiCardi series, do not spray, pour, or spill any liquid or cleaning solutions on its accessories, connectors, switches or the chassis.

Do not spray, pour, or spill any liquid on its accessories, connectors, switches or the chassis.

Turn off the HiCardi series before cleaning.

When a commercial electric power source is using to charge the HiCardi series, use an electric power wall socket with a grounding wire for medical use. Not doing so could cause electric shock.

Do not use power source other than the specified voltage (100-240Vac, 50/60Hz, 93-120VA), as this may cause fire or electric shock.

Thoroughly read the instruction manuals supplied with accessories and options to ensure correct use. This manual does not carry the caution selections for such equipment.

Do not place heavy objects on the charging cable, as doing so may cause fire or electric shock.

When the following occur, turn the power OFF immediately and unplug the DC power supply from the wall socket. Continued use in such situations may cause fire or electric shock.

1. There is smoke or a strange odor leaking out of the HiCardi series or charging cradle.
2. The HiCardi series or charging cradle has been dropped or impacted by an object.
3. Liquid or foreign matter gets inside the HiCardi series or charging cradle.
4. Device failure has occurred.

Also, when any of the above occurs, promptly do the following:

1. Check to see that the DC power supply has been unplugged from the wall socket.
2. Place an "Out of Order" sign on the HiCardi series or charging cradle and do not use it.

WARNING

Use a charging cable that is certified for electrical safety in your country. Not doing so could cause fire or electric shock.

Do not connect more than one HiCardi series to one patient.

Never lift the HiCardi series and the charging cradle by the charging cable.

Do not put the HiCardi series in the mouth or swallow it. It may be harmful or cause choking hazard.

Attention should be paid to children and pets in particular.

Note: The HiCardi series conforms to the EMC standard IEC60601-1-2.

Caution

Caution statements identify conditions or practices that could result in damage to the equipment or other property.

CAUTION

Do not use a damaged device, contact your local distributor or MEZOO technical support.

If the case appears damaged, do not use the HiCardi series and contact your local distributor or MEZOO technical support.

Recharging the HiCardi series is strongly recommended when receives the device for the initial installation or when the battery has not been recharged for 2 or more months.

Partial charge of the HiCardi series results in a shortened service life.

When the battery's voltage of the HiCardi series is very low, it is a possibility of not operating.

Do not use any chargers not specified by MEZOO.

If there are any problems with the battery, immediately put the HiCardi series in a safe place and contact MEZOO technical support.

Do not disassemble the HiCardi series arbitrarily to remove or replace the battery.

Risk of explosion if battery is replaced by an incorrect type.

Follow local government ordinances and recycling instructions regarding disposal or recycling of the HiCardi series device components, including battery.

When the electrode is attached to the HiCardi series, align the electrode with the snaps and press it until you hear a click sound. After that, verify if the electrode is connected to the HiCardi series firmly.

When the protective film on the electrode is removed, be careful to minimize the effects of lint, dust, etc.

When power is turned on, the HiCardi series automatically starts the Power-On Self-Test (POST), which tests the HiCardi series circuitry and functions. Confirm that the status indicator (green LED) on the front of the HiCardi series turns on during POST. If the status indicator does not function, do not use the HiCardi series. Instead, contact your local distributor or MEZOO technical support.

The HiCardi series checks the battery condition just before the Power-On Self-Test (POST). If in the low battery and critically low battery condition, notification sound (error tone) is generated and the HiCardi series can automatically shut down. Put the HiCardi series in the charging cradle to fully charge it before use.

The HiCardi series does not have a function to disable sound. If the POST passing tone is not heard when using the HiCardi series, do not use the HiCardi series and contact your local distributor or MEZOO technical support.

Check the display periodically to see if all symbols and information can be legible on the screen.

If you find any sign of unintentional equipment (or software) changes or attacks from outside, do not use the HiCardi series, contact your local distributor or MEZOO technical support.

To prevent leakage of personal information, delete all patient data before recycling or disposing of the HiCardi series. In particular, delete the mobile application from the smartphone.

CAUTION

To ensure patient safety, carefully read this manual before use. The HiCardi series may not operate properly if it is operated or stored at conditions outside the ranges stated in this manual, or subjected to excessive shock or dropping.

When connecting the HiCardi series to any instrument, verify proper operation before clinical use. Both the HiCardi series and the instrument connected to it must be connected to a grounded outlet.

Accessory equipment connected to data interface of the HiCardi series must be certified according to IEC60950 for data-processing equipment or IEC60601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC60601-1 system requirements. Anyone who connects additional equipment to the signal input or signal output port configures a medical system and is therefore responsible that the system complies with the requirements of IEC 60601-1 and the electromagnetic compatibility system standard IEC60601-1-2. If in doubt, consult MEZOO technical support.

Security

Cybersecurity threats result mainly from network connectivity and may impact safe and secure operation of user's network or any devices attached to this network.

As part of security concept, users are responsible for establishing controls to protect network and any networked devices, including the mobile application against such cybersecurity threats.

Only connect the HiCardi series to networks that are explicitly intended for that purpose. The HiCardi series is intended to be used for collecting physiological data from a patient. If user connects the HiCardi series to a network, it is therefore highly recommended that user implements measures for protecting the network against cybersecurity threats. This includes the deployment of firewalls to limit remote access and antivirus protection of standard computer systems.

User shall carefully read this manual and follow the instructions of communication related for the safe and secure operation of HiCardi series within hospital network.

To prevent malware from affecting network performance or device operation, always ensure that all networked devices with standard operating systems have virus protection installed and kept up to date.

Despite all this effort, connection of the HiCardi series to a network that includes other device or changing of configuration or items of a network could result in previously unidentified risks to patients or users. So, while using the HiCardi series, users shall keep paying attention to identify, analyze, evaluate and control these new risks.

For managing risks in clinical network implementation, MEZOO recommends that you apply a formal process such as the IEC 80001 series of standards to address safety, effectiveness, and data and system security.

INTRODUCTION

⚠ CAUTION

To ensure patient safety, carefully read this manual before use. The HiCardi series may not operate properly if it is operated or stored at conditions outside the ranges stated in this manual, or subjected to excessive shock or dropping.

HiCardi series

HiCardi series is a system that consists of mobile application and server. HiCardi series is a wearable patch device to provide health information (ECG, Respiration and temperature measurement)

This HiCardi series should be used with and connected to mobile application via Bluetooth Low Energy. The user can monitor the data transferred from HiCardi series in real time.

About This Manual

This manual explains how to set up and use the HiCardi series and the Mobile application. And warnings and cautions are indicated for important matters that should be considered when using the HiCardi series in general.

Read the entire manual including the *Safety Information* section, before you operate the HiCardi series.

Revision History

| Revision | Revised on | Revision Summary |
|----------|------------|------------------|
| 0 | 2025-03 | Initial draft |

Identifying the HiCardi series Components

Before using the HiCardi series, check that all components are included. If the HiCardi series is damaged or the component is missing, contact your local distributor or MEZOO technical support. You can also purchase additional electrodes from your local distributor. Performance is not guaranteed when other than the specified electrodes are used.

Features for the HiCardi series

ECG Measurement

The process of depolarization and repolarization of the myocardium generates electric potentials that are sensed by ECG electrodes on the skin surface. The HiCardi series processes and amplifies these signals and presents the ECG waveform on the screen of Mobile application. Also, the monitor computes the minute heart rate by averaging of 12 QRS beats in normal condition. In addition to the acquisition of the QRS complex, the circuitry performs a number of other functions.

Respiration Measurement

The respiration is detected by detecting change of thoracic impedance using the ECG electrodes. Real-time respiratory information is presented as a waveform and numeric data.

Temperature Measurement

Measurement of the temperature is accomplished by processing the signal from a probe containing a resistance element whose impedance is temperature dependent. This probe is connected to the ECG electrode. These devices are called thermistors. The measuring time required to obtain accurate readings is about 20 minutes after applying the HiCardi series.

Physical/Mechanical

The HiCardi series is an ultra-lightweight and ultra-compact physiological measurement device. Dimensions are 42 x 30 x 7 (mm) (WxHxD) and weight is 8g.

Electrical

The HiCardi series is powered by an internal battery pack that typically provides 25 hours of monitoring from fully charged battery. The internal battery of the series is continuously recharged when it is in the Charging cradle. Refer to the ***Battery Operation*** section for details.

Display

The HiCardi series Mobile application is used as external display for the series. You can check operation of the series by checking the waveform, vital signs value and status displays on the Mobile application.

Auxiliary Input/Output(s)

The HiCardi series and Mobile application provide Bluetooth Low Energy(BLE) communication.

DESCRIPTION OF THE HiCardi series

HiCardi series – Front Components



HiCardi



HiCardi-P1



HiCardi-G1



HiCardi-N1



HiCardi-B1

Note: HiCardi series models differ only in color and share the same product specifications



1 Power On/Off switch 2 Status indicator

Figure 1. HiCardi series – Front Components

Table 1. HiCardi series Controls and Indicators

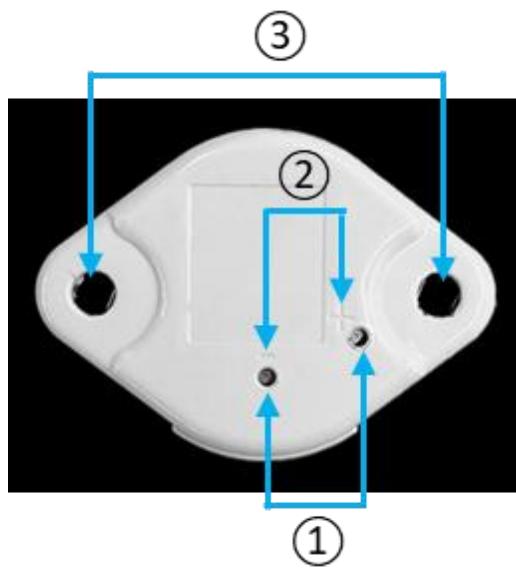
| Symbol/ Indication | Description |
|-----------------------|---|
| | Power On/Off switch Turns on the HiCardi series by pressing the Power On/Off switch for approximately 3 seconds. Turns off the HiCardi series by pressing the Power On/Off switch for approximately 3 seconds. |

Table 2. HiCardi series Controls and Indicators

| Symbol/Indication | Description |
|---|--|
| Power on and POST | On |
| Waiting BLE connection | Flashing (Dimming) |
| Normal operation | Off |
| BLE connection is lost | Flashing (Dimming) |
| Lead off condition | Flashing (0.5 Hz) |
| POST/Device error condition | Flashing (0.5 Hz) |
| Finding device | On (during about 2 seconds) |
| Checking operation (while the HiCardi series is turned on) | On (during Power On/Off switch is pressed) |

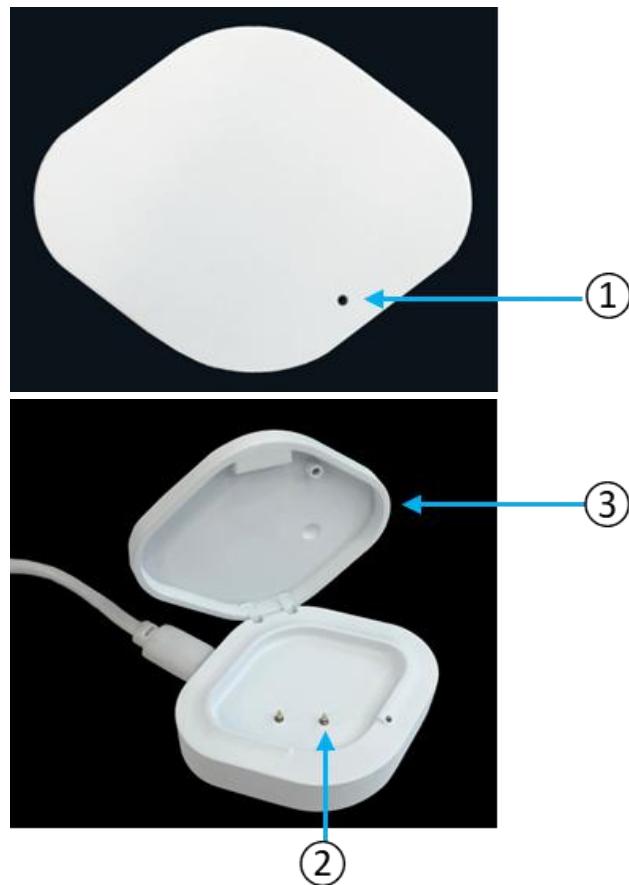
Note: HiCardi series models differ only in color and share the same product specifications.

HiCardi series – Rear Components



| | | | |
|---|--|---|---------------------|
| 1 | Charging connector | 3 | Electrode connector |
| 2 | Polarity symbols for charging connector | | |

Figure 2. HiCardi series – Rear Components

Charging Cradle – Front Components

1 Charging connector
3 Cover

2 Charging status indicator

Figure 3. Charging Cradle – Front Components

Table 2. Charging Cradle – Controls and Indicators

| Symbol/Indication | Description |
|------------------------------|-------------|
| Device is on charging | Blue On |
| Charging device is completed | Blue Off |

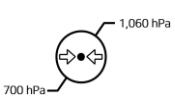
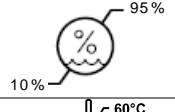
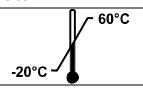
Charging Cradle – Side Components



1 Charging cable connector

Figure 4. Charging Cradle – Side Components

Table 3. Panel and Label Symbols

| Symbol | Description | Symbol | Description |
|---|--|---|---|
| - + | Polarity of charging connector | IPX2 | Water resistance |
|  | USB C type connector |  | Caution |
|  | Warning |  | Follow instructions for use |
|  | Prohibition of use in magnetic resonance environment | Rx ONLY | CAUTION: Federal law restricts this device to sale by or on the order of a physician. |
|  | Disposal instructions |  | Environmental shipping/storage Atmospheric pressure limitations |
|  | Manufacturer |  | Environmental shipping/storage humidity limitations |
|  | Date of manufacture |  | Environmental shipping/storage temperature limitations |
|  | Fragile – handle with care | REF | Reference number |
|  | This way up | SN | Serial number |
|  | Keep dry |  | Wireless communication device |
|  | Do not reuse |  | Bluetooth® communication device |
| FCC | FCC Mark |  | Japan MIC Mark |

SETTING UP THE HiCardi series

⚠ WARNING

To ensure accurate performance and prevent device failure, do not expose the HiCardi to extreme moisture, including direct exposure to rain. Such exposure may cause inaccurate performance or device failure. Refer to *Specification* section.

To ensure the safety, the conductive parts of the electrodes (including associated connectors) and other applied parts should not contact other conductive parts, including earth ground, at any time.

The following cautions apply when connecting the HiCardi with other equipment.

1. Ensure that the connected equipment is in accordance with the IEC60601-1 or IEC safety standards, so that the system complies with IEC60601-1.
2. Employ additional protective measures (e.g. additional protective earthing) as necessary.

Any connections between the HiCardi and other devices must comply with applicable medical systems safety standards such as IEC 60601-1. Failure to do so could result in unsafe leakage current and grounding conditions.

Do not connect devices that do not meet medical safety standards (such as commercial PCs), as they may cause electric shock. The HiCardi meets the restricted level of leakage current required for medical devices. Therefore, the HiCardi cannot be connected to a device that would give a combined total of leakage current beyond the restricted level.

Do not share sensitive information to prevent security threats, such as:

1. The device information of the HiCardi series (e.g. HiCardi series's ID and MAC address)

If the device information of the HiCardi series is leaked, the connection between the HiCardi series and mobile application may be breached by unauthorized person. Check the connection between the HiCardi series and mobile application periodically. If you suspect a security threat, stop using the HiCardi and contact your local distributor or MEZOO technical support immediately.

Do not share your smartphone with others. Doing so may cause leakage of sensitive information related to security.

If the HiCardi series, the smartphone with mobile application installed are lost or stolen, stop using the HiCardi series and contact your local distributor or MEZOO technical support immediately.

Do not leave the mobile application unattended. When you stop using them or leave for a while, lock the smartphone or logout of user account.

Do not use a damaged device, contact your local distributor or MEZOO technical support.

If the case appears damaged, do not use the HiCardi series and contact your local distributor or MEZOO technical support.

If you find any sign of unintentional equipment (or software) changes or attacks from outside, do not use the HiCardi, contact your local distributor or MEZOO technical support.

⚠ CAUTION

Recharging the HiCardi series is strongly recommended when receives the device for the initial installation or when the battery has not been recharged for 2 or more months.

Follow local government ordinances and recycling instructions regarding disposal or recycling of the HiCardi series device components, including battery.

To ensure patient safety, carefully read this manual before use. The HiCardi series may not operate properly if it is operated or stored at conditions

outside the ranges stated in this manual, or subjected to excessive shock or dropping.

When connecting the HiCardi series to any instrument, verify proper operation before clinical use. Both the monitor and the instrument connected to it must be connected to a grounded outlet.

Accessory equipment connected to data interface of the HiCardi series must be certified according to IEC60950 for data-processing equipment or IEC60601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC60601-1 system requirements. Anyone who connects additional equipment to the signal input or signal output port configures a medical system and is therefore responsible that the system complies with the requirements of IEC 60601-1 and the electromagnetic compatibility system standard IEC60601-1-2. If in doubt, consult MEZOO technical support.

Unpacking and Inspection

The HiCardi series is shipped in one carton. Examine the carton carefully for evidence of damage. Contact your local distributor or MEZOO technical support immediately if any damage is discovered. Refer to the **Maintenance** section for instructions on returning damaged items.

Contact your local distributor or MEZOO technical support if any switch of the HiCardi series is not operative.

List of Components

Before using the HiCardi series, check that all components are included. If the HiCardi series is damaged or the component is missing, contact your local distributor or MEZOO technical support. You can also purchase additional electrodes from your local distributor. Performance is not guaranteed when other than the specified electrodes are used.

Table 4. List of Components

| Item | Quantity |
|----------------------|----------|
| HiCardi series | 1 |
| Charging Cradle | 1 |
| Quick Guidance | 1 |
| USB-C charging cable | 1 |

Data measured by the HiCardi series can be checked in the mobile application on the smartphone.

Preparing HiCardi series (Wearable Patch Device)

Charging HiCardi series

1. Connect the charging cable to charging cradle and connect the charging cable to DC power supply.
2. Put the HiCardi series in the charging cradle.
3. When charging is started, charging status indicator of the charging cradle will be lit with blue.
4. When charging is completed, charging status indicator of the charging cradle will be off.

Table 5. Charging Cradle – Controls and Indicators

| Symbol/Indication | Description |
|--------------------------------------|-------------|
| HiCardi series is on charging | Blue On |
| Charging HiCardi series is completed | Blue Off |

Note: Even if the HiCardi series is powered off, the charging status indicator of charging cradle will continue to show the charging status while the HiCardi series is charging.

Note: The HiCardi series cannot be used when it's on charging.

Note: A full charge of a depleted HiCardi series's battery takes over 1 hour.

Note: As the HiCardi series is used and recharged over a period of time, the amount of time between the onset of the low battery condition and the HiCardi series shut-off may become shorter. It is recommended for service personnel to check periodically, and contact your local distributor or MEZOO technical support if it necessary to replace the HiCardi series's battery.

Note: If the charging status indicator is not lit, check:

- ▶ The charging connector
- ▶ DC inlet connector of the charging cradle
- ▶ DC power supply
- ▶ The power/main outlet

Note: Use a DC power supply that is in accordance with the IEC60601-1 or IEC safety standards, so that the system complies with IEC60601-1. (Recommended output of DC power supply: 5Vdc, 500mA or more)

If the charging status indicator still is not lit although no problem is found, contact your local distributor or MEZOO technical support for assistance.

Electrode Connection

| | |
|------------------|---|
| ⚠ WARNING | <p>Check the electrode quality before attaching it to the HiCardi series. Do not use electrode when it is defective or wet, apply new electrode. Do not immerse electrode in water or cleaning solutions.</p> <p>Never use electrodes that are past the expiration date. The expiration date of unopened packages is labeled outside the package.</p> <p>Once a package of electrodes has been opened, try to use the immediately. It is often a good practice to mark on the outside of the package the date the package was opened.</p> <p>Tissue damage can be caused by incorrect application or use of an electrode and leaving an electrode on too long (e.g. over 25 hours) in one place. Inspect the electrode site periodically to ensure skin integrity, correct positioning and adhesion of the electrode.</p> |
| | |
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|--|--|
| | <p>Before placing the HiCardi series on the skin, check the condition of the skin. If the skin is relatively sensitive or damaged, do not place the HiCardi series on that area to prevent skin damage.</p> <p>ECG electrode application period shall be carefully determined considering skin sensitivity of the person. HiCardi series can operate for about 25 hours under internal battery.</p> <p>For best product performance and measurement accuracy, use only accessories supplied or recommended by MEZOO. Use accessories according to the manufacturer's directions for use and your facility's standards. Use only accessories that have passed the recommended biocompatibility testing in compliance with ISO10993-1.</p> <p>For best product performance and measurement accuracy, use only accessories supplied or recommended by MEZOO. Use accessories according to the manufacturer's directions for use and your facility's standards. The use of accessories, transducers, and cables other than those specified may result in increased emission and/or decreased immunity of the HiCardi series.</p> |
|--|--|

⚠ CAUTION

When the electrode is attached to the HiCardi series, align the electrode with the snaps and press it until you hear a click sound. After that, verify if the electrode is connected to the HiCardi series firmly.

1. Attach the electrode to the snaps on the rear of the HiCardi series and then press the HiCardi series until you hear a click sound.
2. Do not remove the protective film on the electrode until the electrode is placed on the patient's chest.

Note: According to ISO10993 biocompatibility, ECG electrode has been verified to be used for permanent period of time. The biocompatibility tests required for skin application of surface device are cytotoxicity, sensitization, and irritation or intracutaneous reactivity.

However, ECG electrode application period shall be carefully determined considering skin sensitivity of the people. HiCardi series can operate for about 25 hours under internal battery.

Preparation for Patient's Skin

Before placing the HiCardi series on the patient, prepare the patient's skin. Refer to **Preparation of Patient's Skin** section for details.

Care and Storage of Electrodes

Proper care and handling of electrodes are extremely important. Using unsuitable, old, or dried-out electrodes can lead to unexpected results or error messages with the device.

To Maximize the Life of Electrodes

To maximize the life and care of your electrodes, we recommend the following:

1. Open only a single package of electrodes at a time
2. Once a package has been opened, try to use the electrodes immediately. It is often a good practice to mark on the outside of the package the date the package was opened.
3. The Electrodes should be stored in a cool dry place to avoid excessive heat or cold, which might cause dryness or melting.
4. The expiration date of unopened packages is labeled outside the package. Never use electrodes that are past the expiration date.

Note: Unopened packages of electrodes have a shelf life depending upon the storage condition.

Other Key Points of Care

Electrodes are designed to be disposable items and not reused. Reusing electrodes can cause unexpected results. In addition, for clean and hygienic practices, electrodes should only be used once.

We do not recommend cutting electrodes in half, as this will result in inconsistent results. Instead, use the whole electrode to ensure proper adhesion and pad placement on the skin.

External Interface

The HiCardi series provide Bluetooth (BLE) function to support external communication with the Mobile application of the smartphone. The HiCardi series exchanges patient's data through the application, the data measured by the HiCardi series can be checked with the Mobile application on the smartphone.

⚠️WARNING

Any connections between the HiCardi series and other devices must comply with applicable medical systems safety standards such as IEC 60601-1. Failure to do so could result in unsafe leakage current and grounding conditions.

Preparing HiCardi series Mobile Application

Installing HiCardi series mobile application

The user can download and install the Mobile application at the App store or Play store of the smartphone.

Note: Some models of the smartphone may not support the Mobile application. If there is a problem using the Mobile application on your smartphone, contact your local distributor or MEZOO technical support.

Enabling Bluetooth and Wi-Fi

Note: Some models of the smartphone may not enable the Bluetooth setting when the GPS setting is disabled. If the GPS setting is disabled in your smartphone, change it to enable.

Note: Check the Airplane Mode setting in your smartphone. If the Airplane Mode is enabled, change it to disable.

For iPhone User

Open the Settings app or Control Center from the top screen, check the Bluetooth setting. If the Bluetooth setting is off, change it to on.

Open the Settings app or Control Center from the top screen, check the Wi-Fi setting. If the Wi-Fi setting is off, change it to on. If necessary, join your Wi-Fi network.

For Android User

Open the Settings app or Quick Settings from the top screen, check the Bluetooth setting. If the Bluetooth setting is off, change it to on.

Open the Settings app or Quick Settings from the top screen, check the Wi-Fi setting. If the Wi-Fi setting is off, change it to on. If necessary, join your Wi-Fi network.

Note: When the user joins the Wi-Fi network, the password would be necessary.

Running the HiCardi series mobile Application

Run the Mobile application on your smartphone.

Login/Sign up

1. Select your preferred social login method.
2. Choose the email account to use.
3. Agree to provide personal information.

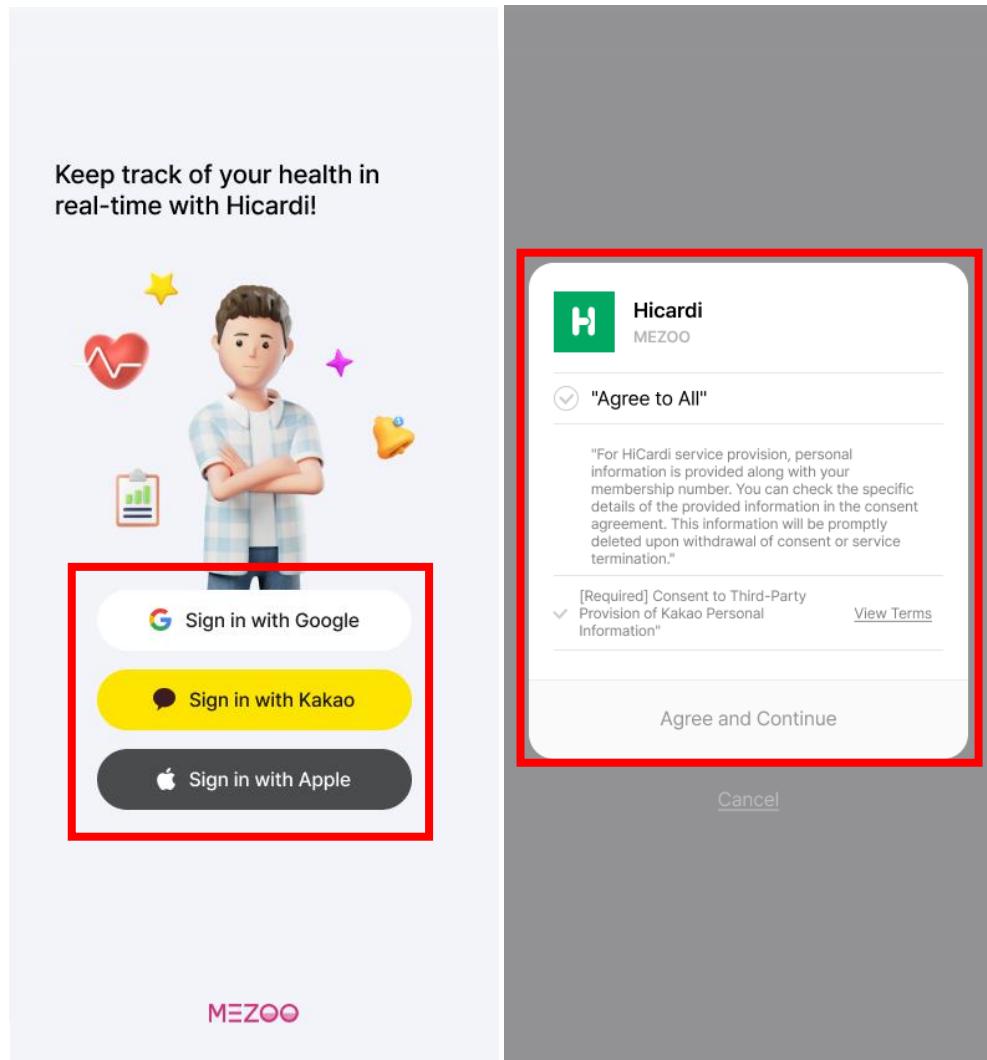
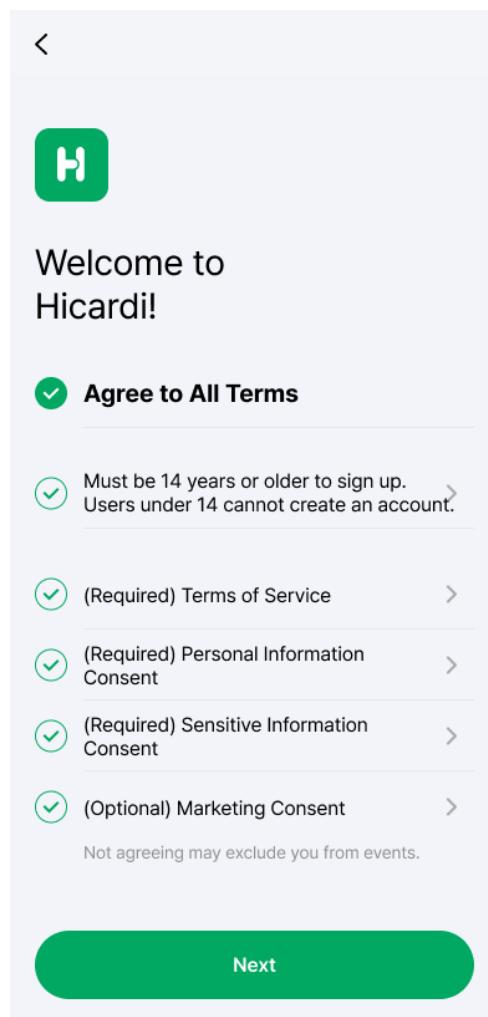


Figure 5. Login/sign up Screen

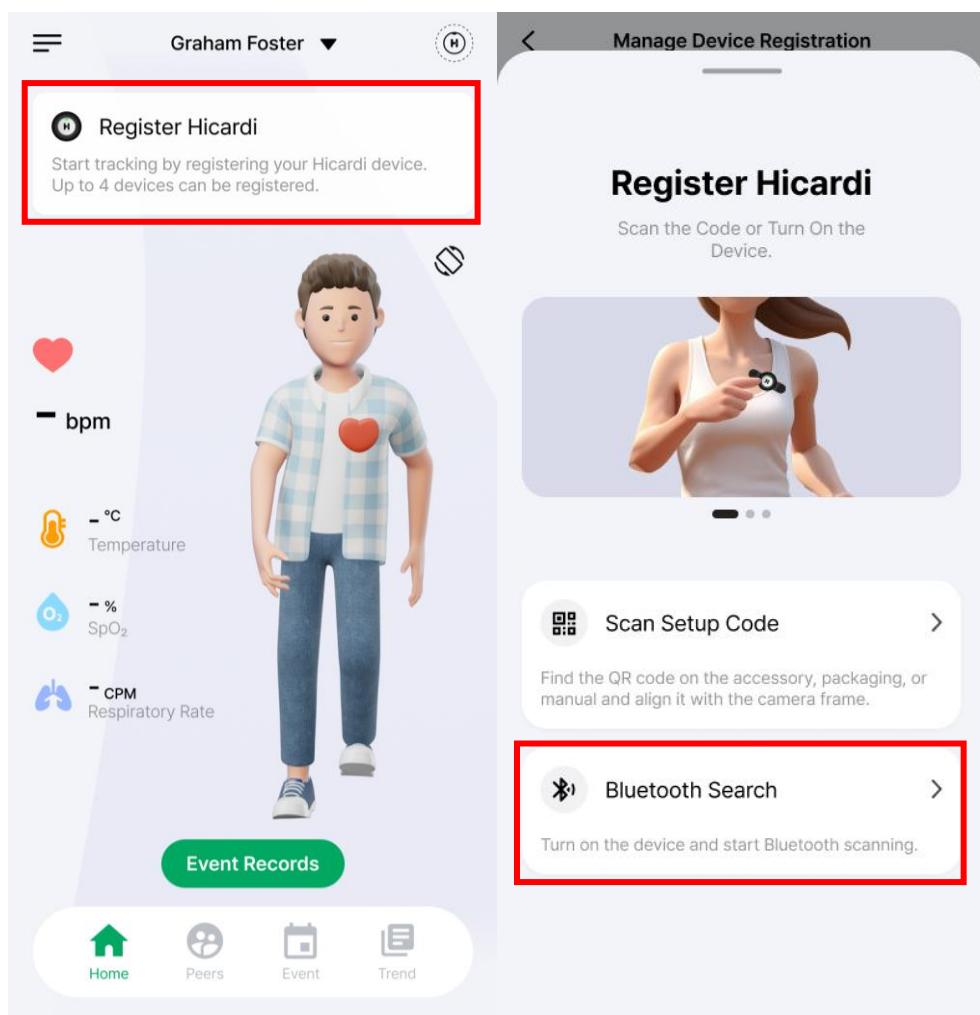
4. Agree to the terms of service.
5. Start creating your profile.



6. Enter the profile information.(Name, Gender, Date of Birth, Height, Weight)

Device Registration

1. Click the "Register HiCardi Core" banner on the main screen.
2. Tap the "Search Bluetooth" button to start searching for devices.
3. Select the HiCardi number to register from the list of devices discovered.



X

Scanning for Bluetooth...

Please turn on the device.
Looking for HiCardi.



X

Device Search Results

Select a device from the list to use.

- HiCardi-A01234 
- HiCardi-A01234 
- HiCardi-A01234 

START MEASURING

Do not open cover or disassemble the HiCardi series. Doing so could cause electric shock or fire. When the device is repaired or changed without the manufacturer's approval, it is not covered by the warranty. It is prohibited by law to modify the device without authorization.

In order to prevent damage to the HiCardi series, do not use the HiCardi series with electrosurgical equipment.

The HiCardi series cannot be used when MRI(Magnetic Resonance Imaging) is in progress. If MRI is in use, keep patient attachments away from patients to prevent accidents.



The HiCardi series direct threat to users, patients or equipment within a magnetic resonance environment. Do not use the HiCardi series in a magnetic resonance environment.

Do not take into or use the HiCardi series in locations where highly combustible anesthetics or flammable gases are used or in high-pressure oxygen rooms or inside oxygen tents, as this may cause a flammable explosion.

Any HiCardi series reading can be affected by the physiologic condition, the excessive movement and shivering, electromyography or other therapy.

Keep people under close surveillance when monitoring. It is possible, although unlikely, that radiated electromagnetic signals from sources external to the patient and the HiCardi series can cause inaccurate measurement readings. Do not rely entirely on the HiCardi series readings.

WARNING

If you are uncertain about the accuracy of any measurement, check the vital signs by alternate means; then make sure the HiCardi series is functioning correctly.

Do not rely entirely on the HiCardi readings for the clinical judgment to determine the arrhythmia except for the asystole.

Look for display motion before accepting any displayed data as a current measurement.

Before using the HiCardi series, confirm that the HiCardi series is working properly and is safe to use.

Do not attach the HiCardi series to the body while in the shower.

Do not share sensitive information to prevent security threats, such as:

- 1. The device information of the HiCardi series (e.g. HiCardi series's ID and MAC address)**

If the device information of the HiCardi series is leaked, the connection between the HiCardi series and mobile application may be breached by unauthorized person. Check the connection between the HiCardi series and mobile application periodically. If you suspect a security threat, stop using the HiCardi series and contact your local distributor or MEZOO technical support immediately.

If the HiCardi series, the smartphone with mobile application installed are lost or stolen, stop using the HiCardi series and contact your local distributor or MEZOO technical support immediately.

Do not put the HiCardi series in the mouth or swallow it. It may be harmful or cause choking hazard. Attention should be paid to children and pets in particular.

CAUTION

When power is turned on, the HiCardi series automatically starts the Power-On Self-Test (POST), which tests the HiCardi series circuitry and functions. Confirm that the status indicator (green LED) on the front of the HiCardi series turns on during POST. If the status indicator does not function, do not use the HiCardi series. Instead, contact your local distributor or MEZOO technical support.

The HiCardi series checks the battery condition just before the Power-On Self-Test (POST). If in the low battery and critically low battery condition, notification sound (error tone) is generated and the HiCardi series can automatically shut down. Put the HiCardi series in the charging cradle to fully charge it before use.

The HiCardi series does not have a function to disable sound. If the POST passing tone is not heard when using the HiCardi series, do not use the HiCardi series and contact your local distributor or MEZOO technical support.

The HiCardi series is a wearable patch device to provide ECG, Respiration and temperature measurement.

Power On/Off

Before using the HiCardi series, confirm that the HiCardi series is working properly and is safe to use as described. This description allows users to operate **Power On/Off switch**.

Power On

When **Power On/Off switch** is pressed while the HiCardi series is turned off:

1. Press the **Power On/Off switch** for more than 3 seconds to turn on the HiCardi series.
2. The HiCardi series automatically starts the Power-On-Self-Test (POST), and the status indicator(LED) of the HiCardi series's front is lit with green.

Note: When HiCardi is powered on, it starts measuring and Bluetooth (BLE) is activated to enter connection standby status automatically.

Power Off

When **Power On/Off switch** is pressed while the HiCardi series is turned on:

1. Press the **Power On/Off switch** for more than 3 seconds to turn off the HiCardi series.
2. The HiCardi series is turned off.
3. When the HiCardi series is turned off, the status indicator(LED) on the top right side of the HiCardi series's front is off.

Placement of HiCardi series

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|---|---|
|  | <p>Check the electrode quality before attaching it to the HiCardi series. Do not use electrode when it is defective or wet, apply new electrode. Do not immerse electrode in water or cleaning solutions.</p> |
| | <p>Never use electrodes that are past the expiration date. The expiration date of unopened packages is labeled outside the package.</p> |
| | <p>Once a package of electrodes has been opened, try to use the immediately. It is often a good practice to mark on the outside of the package the date the package was opened.</p> |
| | <p>Do not attach the HiCardi series to the body while in the shower.</p> |
| | <p>Used electrode should be disposed at designated collection site. Do not reuse the electrode to prevent the risk of infection. Also, reusing may cause performance degradation or malfunction.</p> |
| | <p>When the electrode is attached to the skin, apply the HiCardi series firmly with strong pressure to make sure that there is no gap between the skin and the electrode. Improper attachment of electrode may cause performance degradation.</p> |

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| | <p>Tissue damage can be caused by incorrect application or use of an electrode and leaving an electrode on too long (e.g. over 25 hours) in one place. Inspect the electrode site periodically to ensure skin integrity, correct positioning and adhesion of the electrode.</p> <p>Before placing the HiCardi series on the skin, check the condition of the skin. If the skin is relatively sensitive or damaged, do not place the HiCardi series on that area to prevent skin damage.</p> <p>ECG electrode application period shall be carefully determined considering skin sensitivity of the person. HiCardi series can operate for about 25 hours under internal battery.</p> <p>Do not touch signal input, signal output or other connectors, and the people simultaneously.</p> <p>When the following occur, turn the power OFF immediately and unplug the DC power supply from the wall socket. Continued use in such situations may cause fire or electric shock.</p> <ol style="list-style-type: none">1. There is smoke or a strange odor leaking out of the HiCardi series or charging cradle.2. The HiCardi series or charging cradle has been dropped or impacted by an object.3. Liquid or foreign matter gets inside the HiCardi series or charging cradle.4. Device failure has occurred. <p>Also, when any of the above occurs, promptly do the following:</p> <ol style="list-style-type: none">1. Check to see that the DC power supply has been unplugged from the wall socket. Place an "Out of Order" sign on the HiCardi series or charging cradle and do not use it. <p>Do not connect more than one HiCardi series to one patient.</p> |
| ⚠ CAUTION | <p>When the electrode is attached to the HiCardi series, align the electrode with the snaps and press it until you hear a click sound. After that, verify if the electrode is connected to the HiCardi series firmly.</p> <p>When the protective film on the electrode is removed, be careful to minimize the effects of lint, dust, etc.</p> |

Choosing HiCardi series's Position

Two positions for the HiCardi series placement are recommended, the primary and secondary positions. When the user chooses a position, the user must consider a quality of ECG signal, interference by patient's movement and conditions of uses. And also choose a flat, non-muscular site where the signal will not be interfered with by either movement or bones. Correct placement is very important for accurate measurement.

When the HiCardi series placed on the position where the user chose, if a size of ECG signal is too small or baseline is unstable, use a different position.

The primary position is stronger against interference by patient's movement than the secondary position, but in the case of a patient with a lot of sweat or muscle, the adhesion of the electrode may be poor. The secondary position can obtain an ECG signal closer to the standard ECG than the primary position.

Primary Position

The primary position is located on the sternum (centerline) at two-thirds from the start of the sternum. The Power On/Off switch of the HiCardi series is located toward the right.

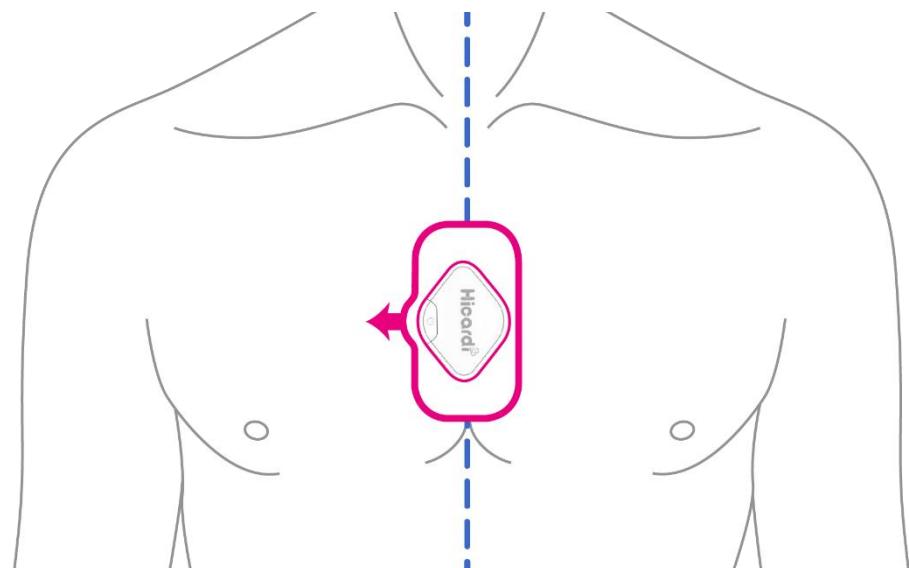


Figure 6. Primary Position for HiCardi series

If the HiCardi series cannot be placed on the primary position, place it on the secondary position.

Secondary Position

The secondary position is located on the left chest at an angle of 30~45 degrees from the centerline. The Power On/Off switch of the HiCardi series is located toward the bottom right diagonally.

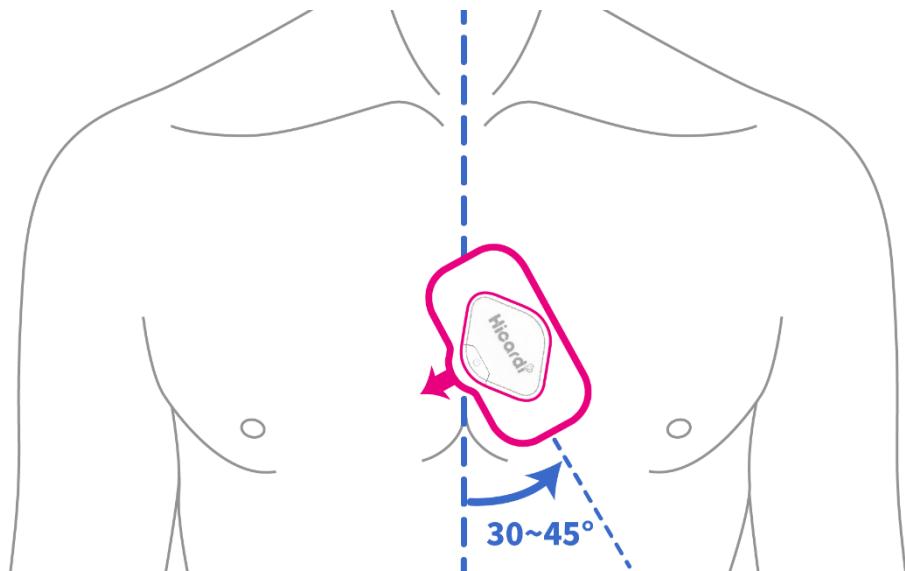


Figure 7. Secondary Position for HiCardi series

Note: If the Power On/Off switch of the HiCardi series is located toward the opposite direction, the ECG signal will be measured in reverse(upside down).

Note: Introduction of HiCardi series's position is also displayed when the Mobile application starts.

Preparation of Patient's Skin

Note: Do not place the HiCardi series on body hair, bones close to skin and layers of fat and major muscles.

For a good connection and quality of measurement signal, do the following procedure if it necessary:

- Remove body hair on the area of the HiCardi series placement.
- Clean the patient's skin using alcohol wipe and let it dry.

Placement of the HiCardi series

1. Remove the protective film on the electrode that is attached to the HiCardi series.
2. Place the electrode side on the primary or secondary position, apply the HiCardi series firmly with strong pressure.

Note: If the electrode loses its adhesion and the HiCardi series comes off the patient, replace the electrode with a new one. Clean the patient's skin using alcohol wipe and let it dry before the HiCardi series is applied again.

Note: If the HiCardi series is applied in different position, this may result in poor ECG signal measurement.

Note: For best product performance and measurement accuracy, allow the patient to remain in stable condition for about 10 seconds after the HiCardi series is applied.

Note: According to ISO10993 biocompatibility, ECG electrode has been verified to be used for permanent period of time. The biocompatibility tests required for skin application of surface device are cytotoxicity, sensitization, and irritation or intracutaneous reactivity.

However, ECG electrode application period shall be carefully determined considering skin sensitivity of the people. HiCardi series can operate for about 25 hours under internal battery.

After Using HiCardi series

1. Turn off the HiCardi series and remove it from the patient.
2. End measurement on the Mobile application and close the app on the smartphone.
3. Remove the electrode from the patient.
4. To avoid malfunction, clean the HiCardi series.
5. The used electrode should be disposed of separately from the municipal waste stream via designated collection facilities appointed by the government or the local authorities.

Battery Operation

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|------------------|---|
| ⚠ WARNING | <p>Do not cover the charging cradle that is on charging the HiCardi series with anything else to avoid generating heat.</p> <p>Do not place anything on top of the HiCardi series or the charging cradle. If something is spilled over or get into them, such spillage may cause fire or electric shock. If fluid spills on the HiCardi series or the charging cradle accidentally, disconnect power cord, wipe dry immediately, and contact MEZOO technical support for safe use.</p> <p>When the HiCardi series is not used or on charging or in storage, keep it out of reach of babies and children to avoid any accidents.</p> <p>When a commercial electric power source is using to charge the HiCardi series, use an electric power wall socket with a grounding wire for medical use. Not doing so could cause electric shock.</p> <p>Do not use power source other than the specified voltage (100-240Vac, 50/60Hz, 93-120VA), as this may cause fire or electric shock.</p> <p>Do not place heavy objects on the charging cable, as doing so may cause fire or electric shock.</p> <p>Use a charging cable that is certified for electrical safety in your country. Not doing so could cause fire or electric shock.</p> <p>Never lift the HiCardi series and the charging cradle by the charging cable.</p> |
| | <p>Recharging the HiCardi series is strongly recommended when receives the device for the initial installation or when the battery has not been recharged for 2 or more months.</p> |
| | <p>Partial charge of the HiCardi series results in a shortened service life.</p> |
| | <p>When the battery's voltage of the HiCardi series is very low, it is a possibility of not operating.</p> |
| | <p>Do not disassemble the HiCardi series arbitrarily to remove or replace the battery.</p> |
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The new, fully charged HiCardi series will provide over 25 hours of monitoring in a typical indoor environment under the following conditions:

- Real-Time measurement (ECG, Respiration and Temperature)
- Activity and posture measurement
- BLE communication

- Ambient temperature at 25°C

Note: It is recommended that the HiCardi series remain in the charging cradle when not in use. This will ensure the fully charged HiCardi series whenever it is needed.

Note: If in the low battery and critically low battery condition, the notification sound (error tone) is generated, and the status indicator is flashing and the HiCardi series can automatically shut down.

Charging HiCardi series

1. Open cover of the charging cradle.
2. Put the HiCardi series in the charging cradle, and charging starts automatically. (If necessary, connect the charging cable to charging cradle and connect the charging cable to DC power supply.)

Note: Use a DC power supply that is in accordance with the IEC60601-1 or IEC safety standards, so that the system complies with IEC60601-1. (Recommended output of DC power supply: 5Vdc, 500mA or more)

3. When charging is started, charging status indicator of the charging cradle will be lit with blue.
4. When charging is completed, charging status indicator of the charging cradle will be off.

Table 6. charging cradle – Charging status Indicator

| Charging status | Indication |
|-----------------|------------|
| On charging | Blue |
| Full charged | Off |

Note: The HiCardi series cannot be used when it's on charging.

Note: A full charge of a depleted HiCardi series's battery takes over 1 hour.

Note: As the HiCardi series is used and recharged over a period of time, the amount of time between the onset of the low battery condition and the HiCardi series shut-off may become shorter. It is recommended for service personnel to check periodically, and contact your local distributor or MEZOO technical support if it necessary to replace the HiCardi series's battery.

Note: Partial charge of the HiCardi series results in a shortened service life and a shortened time until low battery condition. It is recommended for service personnel to check periodically, and contact your local distributor or MEZOO technical support if it necessary to replace the HiCardi series's battery.

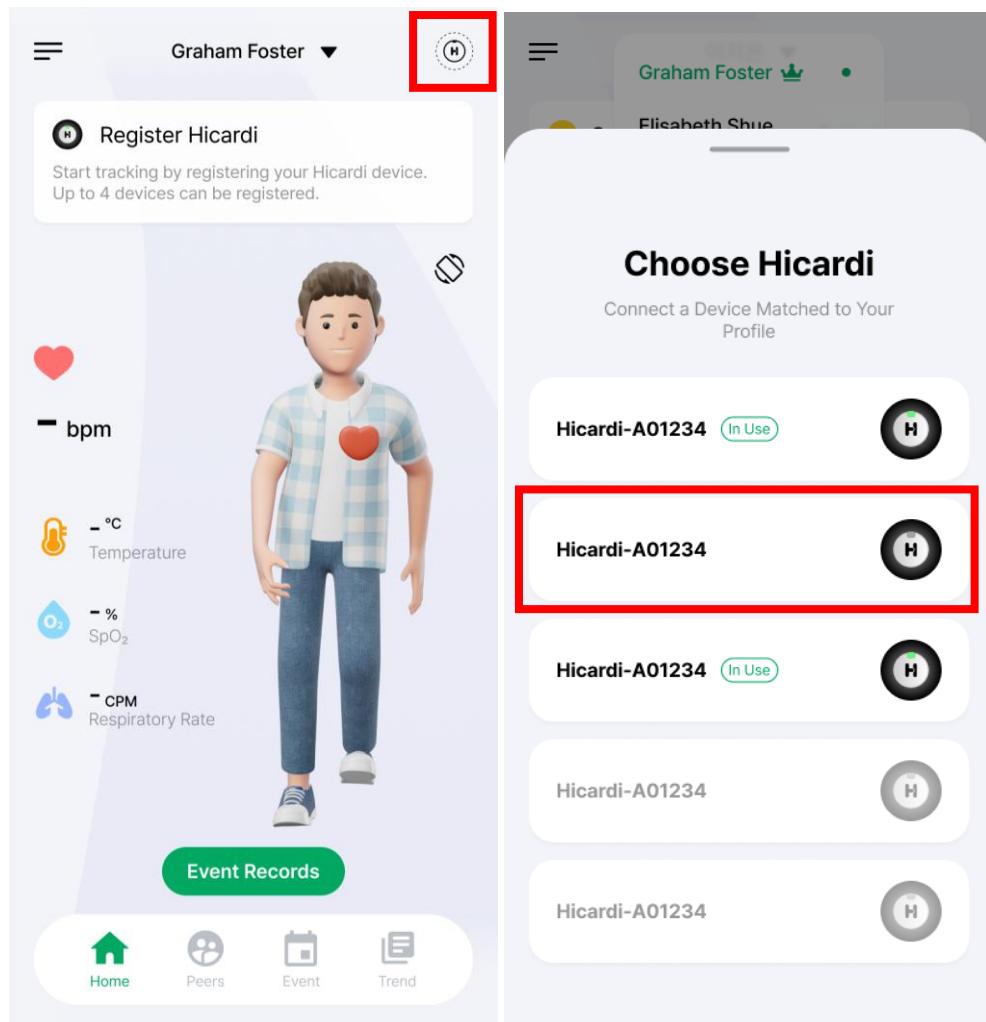
Note: If the charging status indicator is not lit, check:

- The charging cable
- DC inlet connector of the charging cradle
- DC power supply
- The power/main outlet

If the charging status indicator still is not lit although no problem is found, contact your local distributor or MEZOO technical support for assistance.

| | |
|------------------|--|
| ⚠ WARNING | <p>Any HiCardi reading can be affected by the patient's physiologic condition, the excessive patient's movement and shivering, electromyography or other therapy.</p> <p>Keep people under close surveillance when monitoring. It is possible, although unlikely, that radiated electromagnetic signals from sources external to the patient and the HiCardi series can cause inaccurate measurement readings. Do not rely entirely on the HiCardi series readings.</p> <p>If you are uncertain about the accuracy of any measurement, check the vital signs by alternate means; then make sure the HiCardi series is functioning correctly.</p> <p>Do not rely entirely on the HiCardi readings for the clinical judgment to determine the arrhythmia except for the asystole.</p> <p>Look for display motion before accepting any displayed data as a current measurement.</p> <p>Do not share sensitive information to prevent security threats, such as:</p> <ol style="list-style-type: none"> 1. The device information of the HiCardi series (e.g. HiCardi series's ID and MAC address) <p>If the device information of the HiCardi series is leaked, the connection between the HiCardi series and mobile application may be breached by unauthorized person. Check the connection between the HiCardi series and mobile application periodically. If you suspect a security threat, stop using the HiCardi and contact your local distributor or MEZOO technical support immediately.</p> <p>If the HiCardi series, the smartphone with mobile application installed are lost or stolen, stop using the HiCardi series and contact your local distributor or MEZOO technical support immediately.</p> <p>Do not share your smartphone with others. Doing so may cause leakage of sensitive information related to security.</p> <p>Do not leave the mobile application unattended. When you stop using them or leave for a while, lock the smartphone or logout of user account.</p> |
| | ⚠ CAUTION |
| | <p>Check the display periodically to see if all symbols and information can be legible on the screen.</p> |
| | <p>The mobile application is provide displaying physiological data of the patient for checking status of measurement and communication of system.</p> |
| | <p><i>Note: When the connection is lost between the HiCardi series and Mobile application, turn off and on the HiCardi series or exit and re-run the Mobile application to establish connection again.</i></p> |
| | <p><i>Note: When the Mobile application notify the security threats or the communication delay, stop using the HiCardi series. In the Mobile application, logout of user account and stop using the Mobile application. Contact your local distributor or MEZOO technical support for assistance.</i></p> |
| | <p>Device Connection</p> |
| | <p><i>Note: Enable the Bluetooth function on the smartphone before you proceed the following instructions.</i></p> |
| | <p><i>Note: Some models of the smartphone may not enable the Bluetooth setting when the GPS setting is disabled. If the GPS setting is disabled in your smartphone, change it to enable.</i></p> |
| | <p><i>Note: Check the Airplane Mode setting in your smartphone. If the Airplane Mode is enabled, change it to disable.</i></p> |

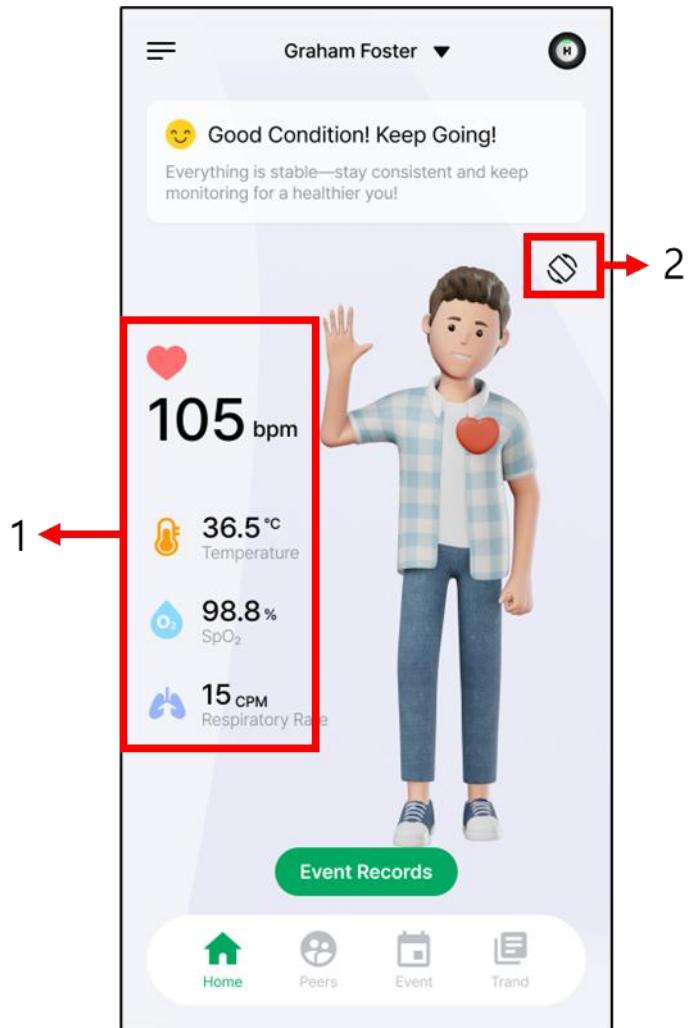
1. Clicking the button at the top right will display the list of devices registered to the account.
2. Select the device you want to use from the list.



Main Screen

Checking the Vital sign

The **Main screen** displays the vital signs and waveform



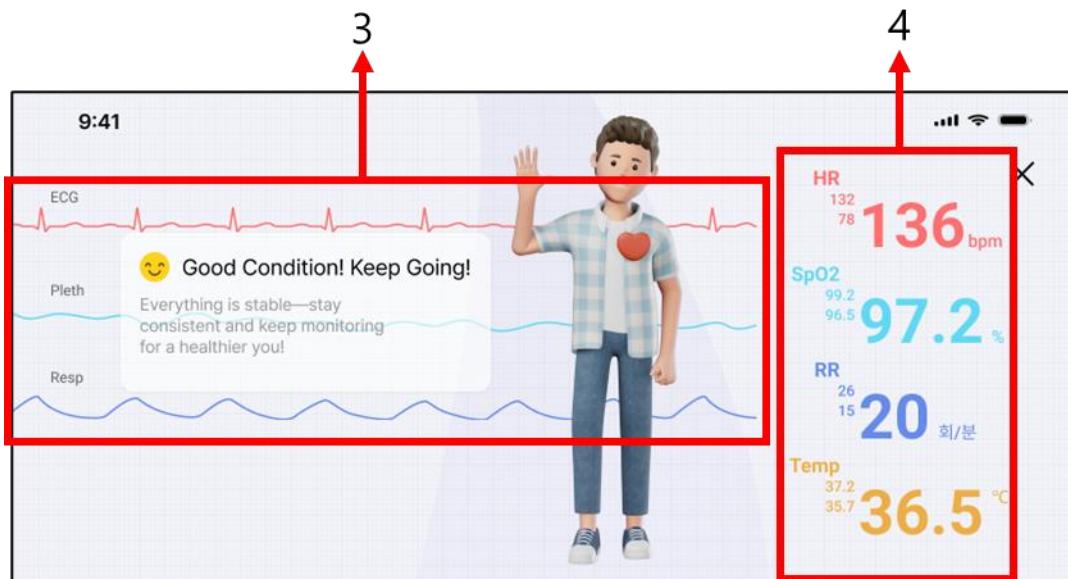


Figure 8. Main screen (Portrait Mode/Landscape Mode)

| | |
|---|---|
| 1 | Display real-time heart rate, skin temperature, SpO ₂ , and respiration rate. |
| 2 | Press the button to switch to landscape mode. |
| 3 | Display real-time ECG waveform, photoplethysmogram (PPG) waveform, and respiration waveform. |
| 4 | Show real-time values and the maximum and minimum values for heart rate, SpO ₂ , respiration rate, and skin temperature. |

Heart Rate

The patient's heart rate is displayed in beats per minute(bpm). Maximum and minimum heart rate of measurement duration are also displayed.

Respiration Rate

The patient's respiration rate is displayed in breaths per minute(Bpm).

Temperature

The patient's temperature is displayed in Celsius(°C).

Note: For correct temperature readings, wait about 20 minutes after applying the HiCardi series to make sure that the temperature sensor is in a stable condition.

ECG/Respiration Waveform

The user can check the respiration waveform by swipe left action across the waveform area.

Checking the Device and Measurement Information

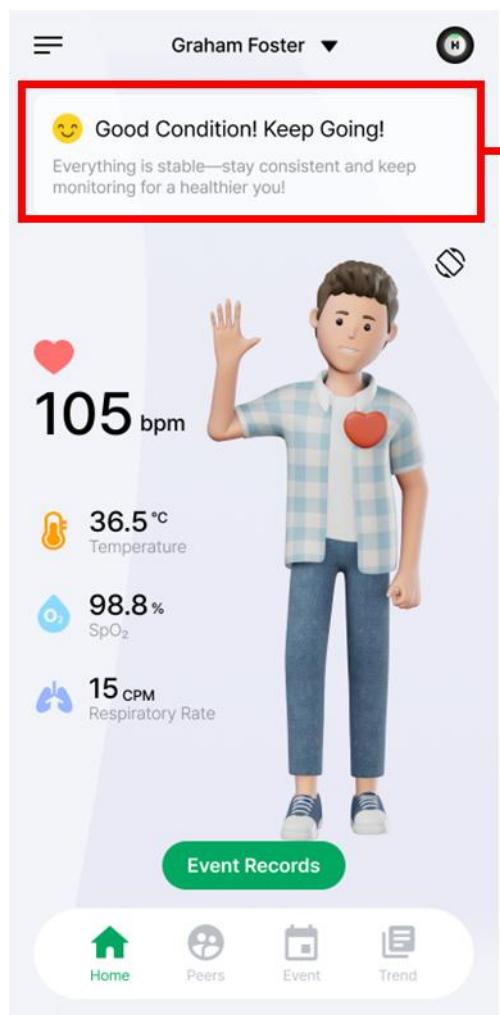
An alert message will be shown when heart rate, SpO₂, respiration rate, or skin temperature exceeds the normal range.

An alert message will be shown when the sleep mode starts/ends.

A low battery alert message will be shown when the HiCardi series battery reaches 20% or less,

and again at 5% or less.

An alert message will be shown when there are new announcements, app updates, or other updates.



The screenshot shows the HiCardi app's main interface. At the top, it says "Graham Foster". Below that is a 3D character of a young man in a plaid shirt and jeans. To the left of the character are the following vital signs: Heart Rate (105 bpm), Temperature (36.5 °C), SpO₂ (98.8%), and Respiratory Rate (15 cpm). At the bottom are navigation icons for Home, Peers, Event, and Trend. A red box highlights a message in a box: "Good Condition! Keep Going! Everything is stable—stay consistent and keep monitoring for a healthier you!" An arrow points from this message to the "Heart Rate Spiked Above 150bpm" alert. The app also displays "Sleep Tracking in Progress...", "Sleep Tracking Complete.", "Battery at 20%", and a "New Announcement!" message.

Good Condition! Keep Going!
Everything is stable—stay consistent and keep monitoring for a healthier you!

105 bpm

36.5 °C
Temperature

98.8%
SpO₂

15 cpm
Respiratory Rate

Event Records

Home Peers Event Trend

⚠️ Heart Rate Spiked Above 150bpm
Heart Rate Spiked Above 150 BPM. Please check if everything is okay with your health.

😴 Sleep Tracking in Progress...
HiCardi is working properly and recording sleep data steadily.

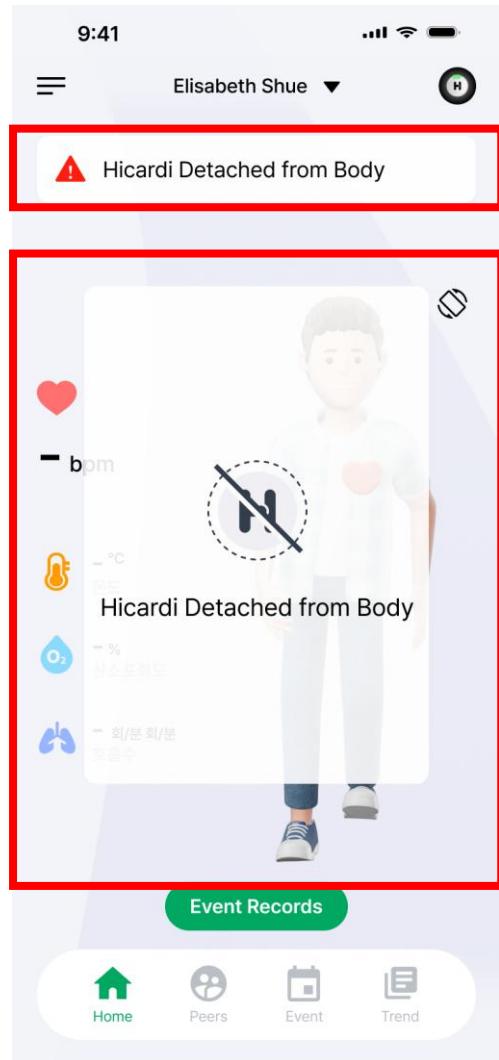
✓ Sleep Tracking Complete.
Your sleep tracking is complete, and the data has been successfully saved.

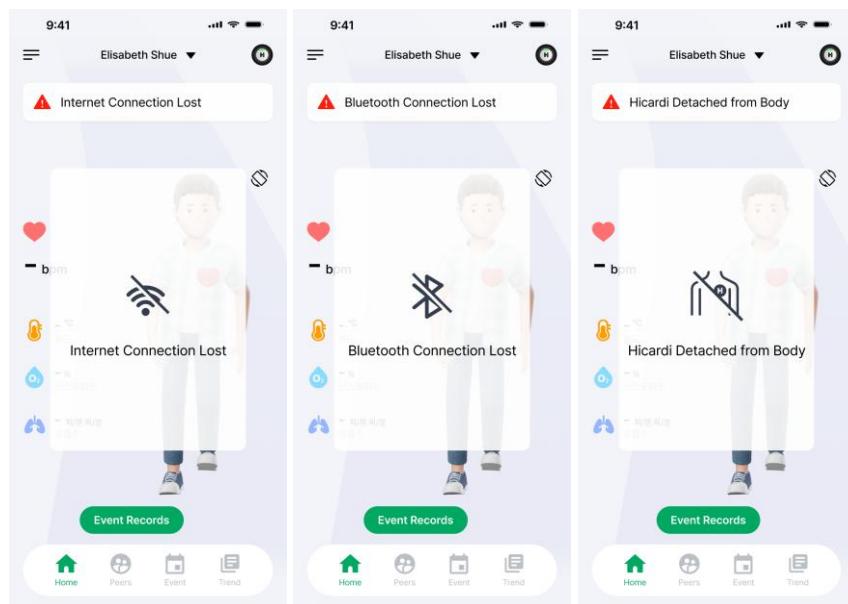
⚠️ Battery at 20%
HiCardi's battery is at 20%. Please prepare to charge for uninterrupted use.

❗ New Announcement!
Check the latest updates and important news in the app settings.

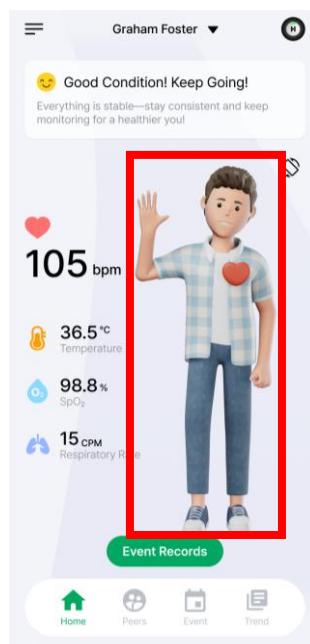
An alert message and pop-up will be displayed when the connection is lost.

The types of alerts include device connection, internet, Bluetooth, and device disconnection (Lead Off).

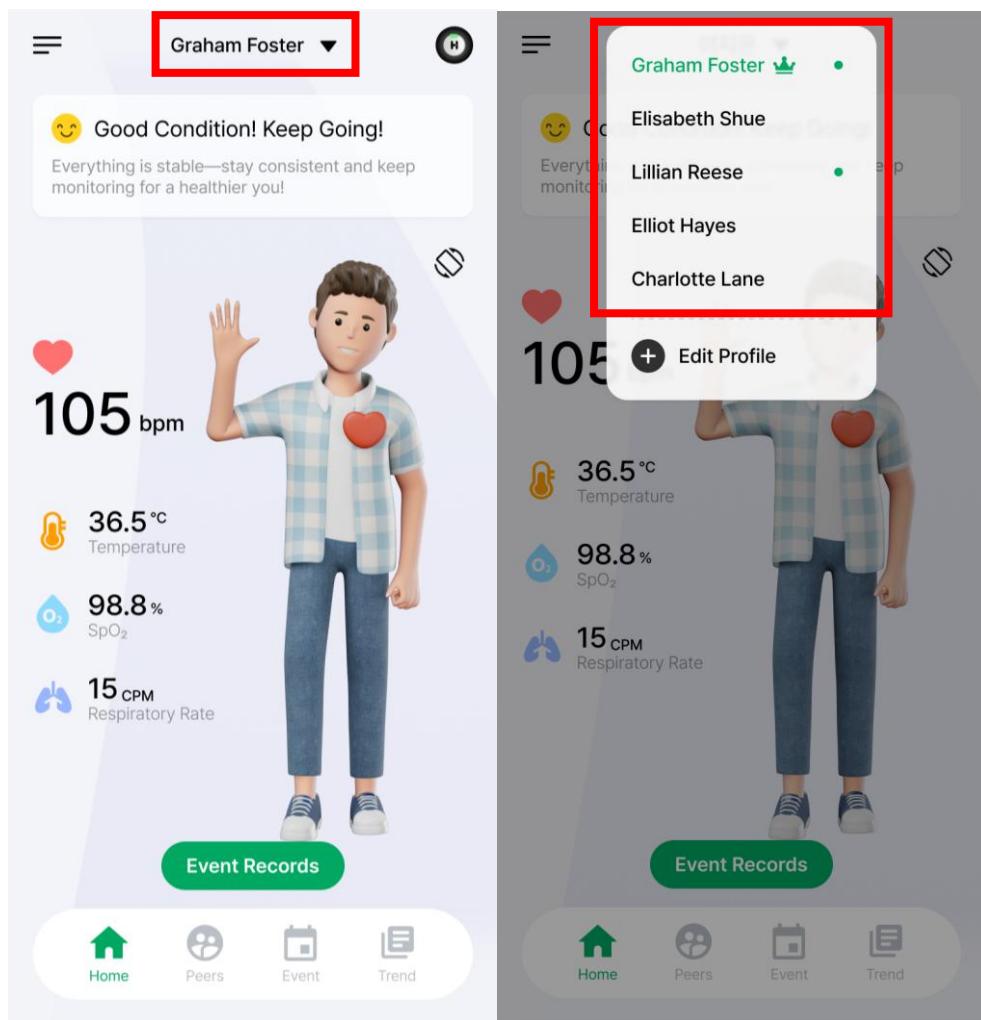




The avatar is automatically selected based on the gender and age entered during profile registration.

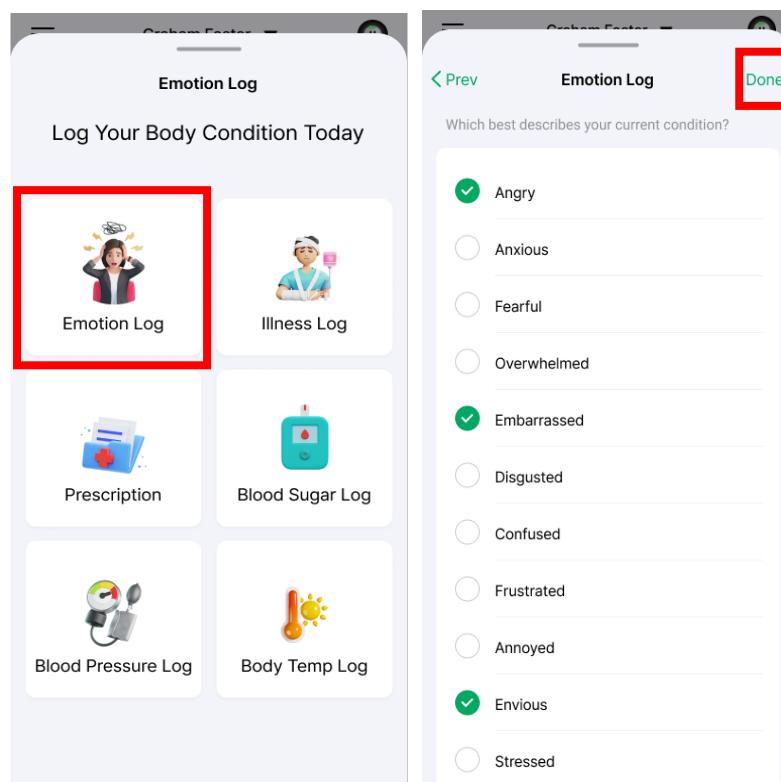
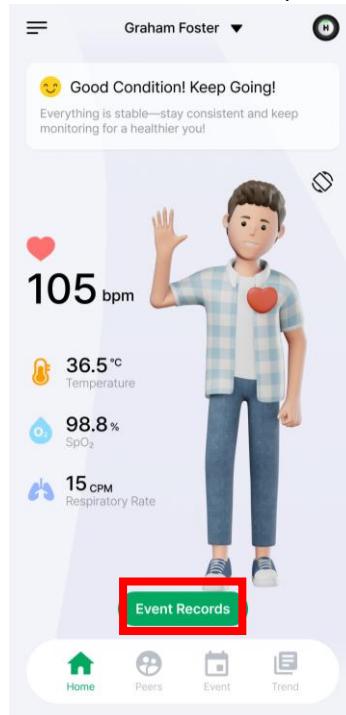


1. Clicking the profile name at the top will display the profile list.
2. The main profile will show a crown icon.
3. The profile currently being measured will show a circle icon.



Event Record

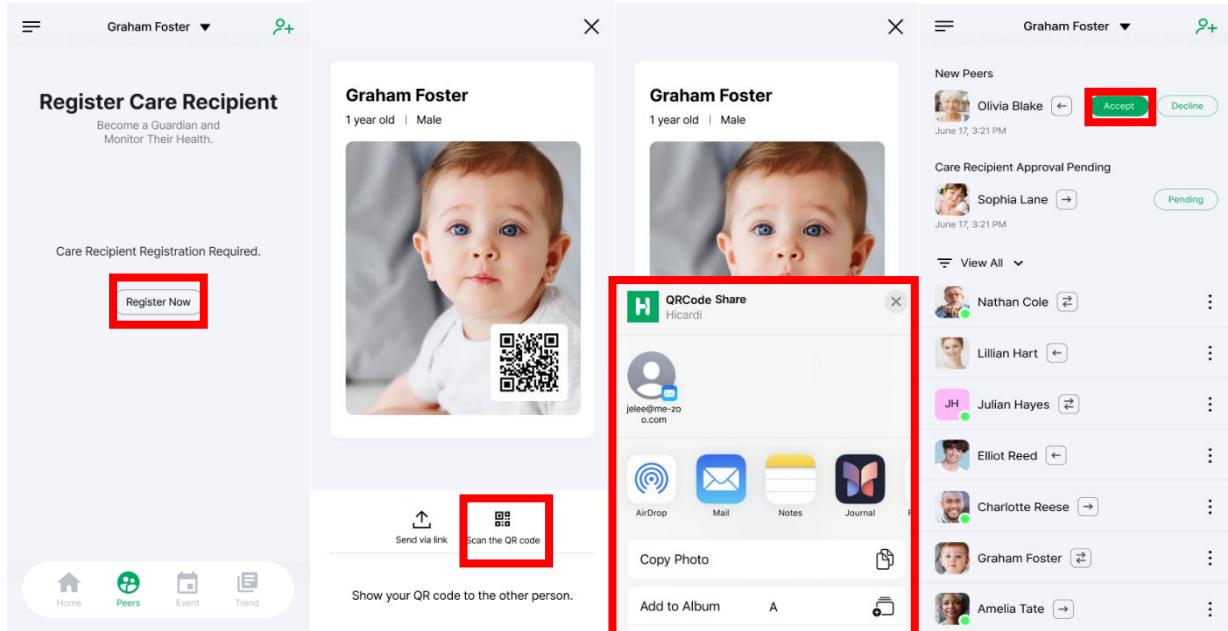
1. Click the "Event Record" button.
2. Select the type of event you want to record.
3. Choose the content from the list or enter it manually, then press the "Done" button.



Peers Screen

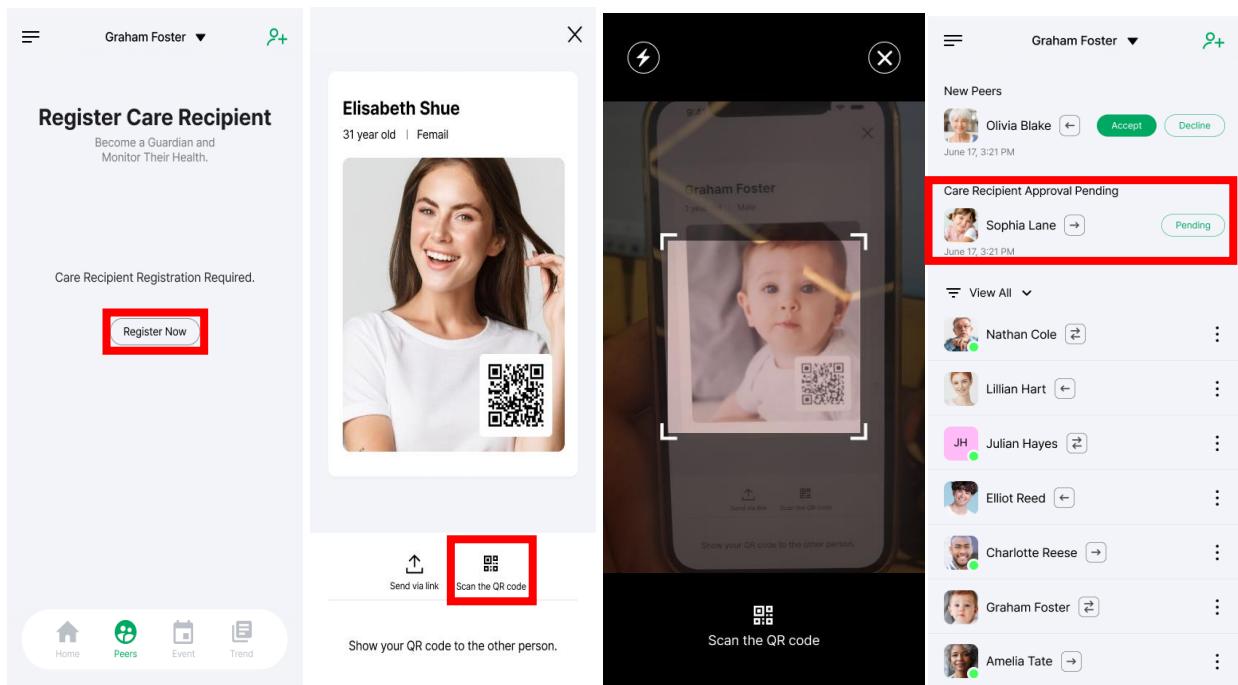
Register Care Recipient

1. Click the "Register" button.
2. Show the QR code to the peers or press the "Send via Link" button to share the QR code image.
3. A new peers will appear in the peers list and press the "Accept" button to register the guardian.



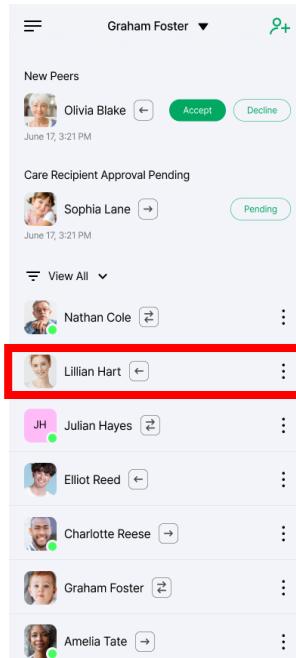
Register Care Recipient

1. Click the "Register" button.
2. Click the "Scan QR Code" button.
3. Scan the care recipient's QR code.
4. It will be displayed as "Pending" until the care recipient accepts the peers registration.



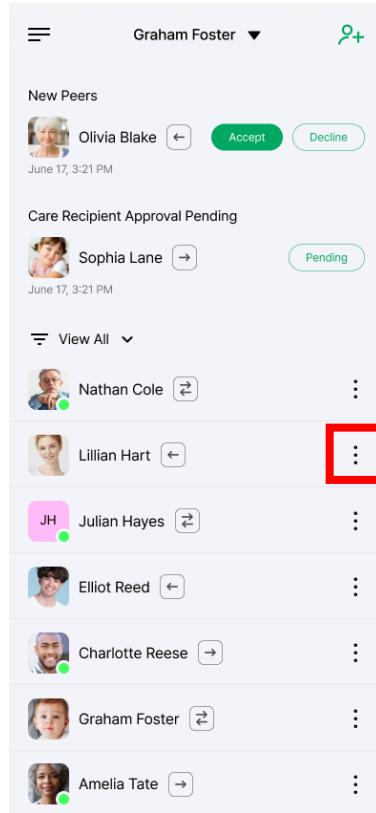
Monitoring

Select the care recipient to monitor from the list. You can observe the care recipient's real-time data.



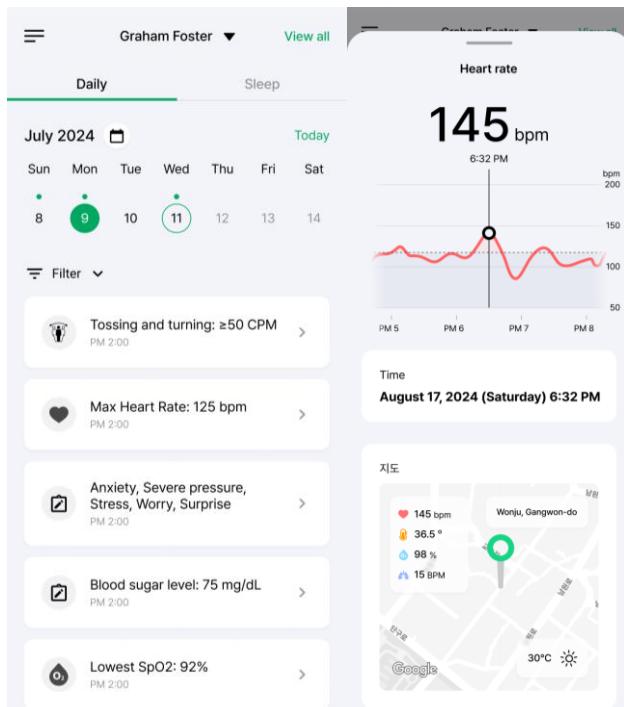
Disconnect Peers

You can stop real-time monitoring by clicking the three-dot icon to the right of the name of the person you want to disconnect.



Event Screen

- Events generated through HiCardi measurements and manually entered events in the event record are displayed.
- You can check the list of events by date and view the detailed information for each event.
- Records for 2 hours before and after the event, along with the event's location, heart rate, and other vital information, are shown.



Trend Screen

Daily/Sleep Tab

The **Daily** tab displays trend charts for heart rate, body temperature, respiration rate, and SpO2. The **Sleep** tab shows the trend chart along with the sleep score and sleep duration.

Sleep score

The sleep score is calculated based on events that occurred during sleep.

Sleep time

Sleep duration shows events that occurred during sleep, including sleep stages, apnea, irregular heartbeat, and tossing.

The period can be selected as 1 day, 1 week, 1 month, 6 months, or 1 year.

Download the Report

- Click the "Report" button at the top right.
- Click the "Download Report" button to download the report in PDF format.

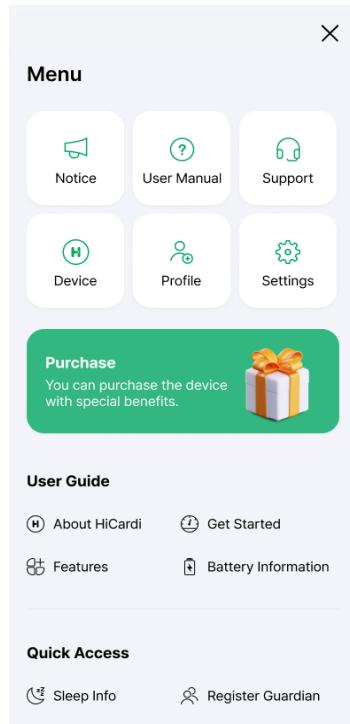
Main Screen

Device management

1. Selecting the "Device Management" menu will display the list of devices registered to the account.
2. Selecting a device from the list will show the detailed information for that device.
3. Press the "Remove Device" button to delete the selected device.

Profile Management

1. Selecting the "Profile Management" menu will display the list of profiles registered to the account.
2. Selecting a profile from the list will take you to the "Edit Profile" page.
3. The main profile cannot be deleted, and up to 4 sub-profiles can be created.



MAINTENANCE

Care and Storage of Electrodes

WARNING

Never use electrodes that are past the expiration date. The expiration date of unopened packages is labeled outside the package.

Once a package of electrodes has been opened, try to use the immediately. It is often a good practice to mark on the outside of the package the date the package was opened.

Proper care and handling of electrodes are extremely important. Using unsuitable, old, or dried-out electrodes can lead to unexpected results or error messages with the device.

To Maximize the Life of Electrodes

To maximize the life and care of your electrodes, we recommend the following:

1. Open only a single package of electrodes at a time
2. Once a package has been opened, try to use the electrodes immediately. It is often a good practice to mark on the outside of the package the date the package was opened.
3. The Electrodes should be stored in a cool dry place to avoid excessive heat or cold, which might cause dryness or melting.
4. The expiration date of unopened packages is labeled outside the package. Never use electrodes that are past the expiration date.

Note: Unopened packages of electrodes have a shelf life depending upon the storage condition.

Other Key Points of Care

Electrodes are designed to be disposable items and not reused. Reusing electrodes can cause unexpected results. In addition, for clean and hygienic practices, electrodes should only be used once.

We do not recommend cutting electrodes in half, as this will result in inconsistent results. Instead, use the whole electrode to ensure proper adhesion and pad placement on the skin.

Recycling and Disposal

WARNING

Used electrode should be disposed at designated collection site. Do not reuse the electrode to prevent the risk of infection. Also, reusing may cause performance degradation or malfunction.

When the HiCardi series, the charging cradle or accessories reach the end of useful life, recycle or dispose of the equipment according to appropriate local and regional regulations.

Note: The HiCardi series and the charging cradle should be disposed of separately from the municipal waste stream via designated collection facilities appointed by the government or the local authorities.

Note: The correct disposal of your old appliance will help prevent potential negative consequences for the environment and human health.

Note: For more detailed information about disposal of your old appliance, please contact your city office, waste disposal service or the shop where you purchased the HiCardi series.

Returning the Product and System Components

When the product is received, if any damage is discovered in the product or accessories, immediately stop unpacking and contact your local distributor or MEZOO technical support.

Pack the product with electrodes or other accessory items in its original shipping carton. If the original carton is not available, use a suitable carton with appropriate packing material to protect the product during shipping.

Ship the product according to the instruction provided by MEZOO.

Service

The HiCardi series requires no routine service other than cleaning and battery maintenance which is mandated by the user's institution. The user should perform periodic inspections of the HiCardi series. If service is necessary, contact your local distributor or MEZOO technical support.

Periodic Safety Check

It is recommended that the following checks be performed every year.

- Inspect whether the HiCardi series has a systemic or functional problem.
- Inspect whether the speaker of the HiCardi series is performing properly.
- Inspect whether the status indicator of the HiCardi series, charging status indicator and internal battery status indicator of the charging cradle is displayed and identified properly.
- Inspect whether external labels are identified without a damage.

Cleaning

The HiCardi series may be surface-cleaned by using a soft cloth dampened with either a commercial, nonabrasive cleaner or one of the solutions listed below. Lightly wipe the front, rear and side surfaces of the HiCardi series.

- 70% Isopropyl alcohol
- 10% Chlorine bleach solution

Avoid spilling liquid on the HiCardi series, especially in connector areas. If liquid is accidentally spilled on the HiCardi series, clean and dry thoroughly before reuse. If in doubt about the HiCardi series's safety, refer the device to MEZOO technical support for checking.

After Using HiCardi series

1. Turn off the HiCardi series and remove it from the patient.
2. Remove the electrode from the patient.
3. To avoid malfunction, clean the HiCardi series.
4. The used electrode should be disposed of separately from the municipal waste stream via designated collection facilities appointed by the government or the local authorities.

Battery Maintenance

⚠ CAUTION

Recharging the HiCardi series is strongly recommended when receives the device for the initial installation or when the battery has not been recharged for 2 or more months.

Partial charge of the HiCardi series results in a shortened service life.

Follow local government ordinances and recycling instructions regarding disposal or recycling of the HiCardi series device components, including battery.

Do not use any chargers not specified by MEZOO.

If there are any problems with the battery, immediately put the HiCardi series in a safe place and contact MEZOO technical support.

Do not disassemble the HiCardi series arbitrarily to remove or replace the battery.

Risk of explosion if battery is replaced by an incorrect type.

If the HiCardi series has not been used for 2 or more months, it will need charging. To charge the HiCardi series, put the HiCardi series in the charging cradle as described in the **Battery Operation** section.

Note: Storing the HiCardi series for a long period without charging may degrade the battery capacity. A full charge of a depleted HiCardi series's battery takes over 1 hour.

S

It is recommended that the HiCardi series's battery be replaced every 6 months. Contact your local distributor or MEZOO technical support if it necessary to replace the battery.

TROUBLESHOOTING

If you are uncertain about the accuracy of any measurement, check the vital signs by alternate means; then make sure the HiCardi series is functioning correctly.

Do not open cover or disassemble the HiCardi series. Doing so could cause electric shock or fire. When the device is repaired or changed without the manufacturer's approval, it is not covered by the warranty. It is prohibited by law to modify the device without authorization.

The HiCardi series should be disassembled and repaired only by MEZOO technical support. There are no internal user-serviceable parts.

Do not use a damaged device, contact your local distributor or MEZOO technical support.

If the case appears damaged, do not use the HiCardi series and contact your local distributor or MEZOO technical support.

When power is turned on, the HiCardi series automatically starts the Power-On Self-Test (POST), which tests the HiCardi series circuitry and functions. Confirm that the status indicator (green LED) on the front of the HiCardi series turns on during POST. If the status indicator does not function, do not use the HiCardi series. Instead, contact your local distributor or MEZOO technical support.

If you find any sign of unintentional equipment (or software) changes or attacks from outside, do not use the HiCardi, contact your local distributor or MEZOO technical support.

CAUTION

Note: If you are an outpatient prescribed by the healthcare professionals and need help with maintenance and troubleshooting of the HiCardi, please contact your healthcare professionals.

General

Before contacting your local distributor or MEZOO technical support, make sure that the HiCardi series is charged and that power connection for the charging cradle is in place.

Corrective Action

If you experience a problem while using the HiCardi and are unable to correct it, contact your local distributor or MEZOO technical support.

Following is a list of possible errors and suggestions for corrective action.

Table 7. Error Conditions and Corrective Action

| Error | Corrective Action |
|--|---|
| No response to Power switch press | For the HiCardi series <ul style="list-style-type: none"> Press the Power On/Off switch. For charging the HiCardi series, put the HiCardi series in the charging cradle. Check the charging status indicator of the charging cradle is lit. For fully charged HiCardi series, use it after about 1 hour. If error continues, contact MEZOO technical support. |
| Low battery / Critically low battery condition | For the HiCardi series <ul style="list-style-type: none"> For charging the HiCardi series, put the HiCardi series in the charging cradle. Check the charging status indicator of the charging cradle is lit. If error continues, contact MEZOO technical support. |
| Indicator (LED)s are not lit. | For the HiCardi series <ul style="list-style-type: none"> Contact MEZOO technical support. |
| No sound generation | For the HiCardi series <ul style="list-style-type: none"> Contact MEZOO technical support. |
| | For the HiCardi Mobile application <ul style="list-style-type: none"> Verify the volume setting of the smartphone is loud enough to hear. Verify the smartphone is not on mute. Verify the sound is not off. If error continues, contact MEZOO technical support. |
| Abnormally shut down | For the HiCardi series <ul style="list-style-type: none"> Turn on the HiCardi series, verify the operation is normal. If error continues, contact MEZOO technical support. |
| Unintended shut down or freeze | For the HiCardi series <ul style="list-style-type: none"> Turn off and on the HiCardi series, verify the operation is normal. If error continues, contact MEZOO technical support. |
| | For the HiCardi Mobile application <ul style="list-style-type: none"> Exit and re-run the Mobile application, verify the operation is normal. If error continues, contact MEZOO technical support. |
| Technical system error (ex: No POST passing tone) | For the HiCardi series <ul style="list-style-type: none"> Do not use the HiCardi series. Contact MEZOO technical support. |
| Sound like buzzer is heard and the HiCardi series cannot be turned off. | For the HiCardi series <ul style="list-style-type: none"> Press the Power On/Off switch for more than 15 seconds. Contact MEZOO technical support. |
| Poor ECG signal quality (noisy trace, wandering baseline, etc.) or no QRS is detected. | For the HiCardi series <ul style="list-style-type: none"> Check that the patient is not shivering. Check the electrode quality and positioning Change the electrode. Prepare the patient's skin and apply new electrode, if necessary <ul style="list-style-type: none"> <i>Pre-gelled electrodes are recommended. Do not place them on body hair, bones close to skin, and layers of fat and major muscles.</i> Check the connection between the HiCardi series and electrode. Relocate or turn off equipment that may be causing RFI. If error continues, contact MEZOO technical support. |

| Error | Corrective Action |
|--|--|
| Lead off | For the HiCardi series <ul style="list-style-type: none"> Check the electrode quality and positioning Check the connection between the HiCardi series and electrode. If error continues, contact MEZOO technical support. |
| Respiration measurement does not work and measurement values are in doubt. | For the HiCardi series <ul style="list-style-type: none"> Select appropriate gain from the setting menu. Check the electrode quality and positioning. Change the electrode. Remove other electrical devices from the vicinity of the respiration measurement as they may cause interference. If error continues, contact MEZOO technical support. |
| Temperature measurement does not work and measurement values are in doubt. | For the HiCardi series <ul style="list-style-type: none"> Check the electrode quality and positioning. Change the electrode. If error continues, contact MEZOO technical support. |
| Notification of the security threats | For the HiCardi <ul style="list-style-type: none"> Do not use the HiCardi. Log out of the Mobile application. Contact a MEZOO technical support. |
| Notification of the communication delay | For the HiCardi <ul style="list-style-type: none"> Do not use the HiCardi. Log out of the Mobile application. Contact MEZOO technical support. |

Note: If the Main MCU or oscillator is defected, the product might be not turned on or not operated properly. Contact your local distributor or MEZOO technical support.

Note: The ProSim 8 patient simulator (specified by MEZOO) could be used to verify the measurement performance and whether operation is normal. Contact your local distributor or MEZOO technical support to purchase or rent a tester.

EMI (Electromagnetic Interference)

Note: This section describes EMI-related information for the entire HiCardi series

| | |
|--|--|
|  WARNING | <p>The HiCardi conforms to the requirements of the EMC standard (IEC60601-1-2), and may therefore be used simultaneously with pacemakers and other electrical simulators. It should, however, be noted that the HiCardi may be affected by electrical scalpels and microwave therapeutic apparatus. Please check operation of the HiCardi during and after use of such equipment.</p> <p>In order to prevent damage to the HiCardi series, do not use the HiCardi series with electrosurgical equipment.</p> |
| | <p> The HiCardi series direct threat to users, patients or equipment within a magnetic resonance environment. Do not use the HiCardi series in a magnetic resonance environment.</p> |
| | <p>Keep people under close surveillance when monitoring. It is possible, although unlikely, that radiated electromagnetic signals from sources external to the patient and the HiCardi series can cause inaccurate measurement readings. Do not rely entirely on the HiCardi series readings.</p> |
| | <p>It is possible that any radio frequency transmitting equipment and other nearby sources of electrical noise may result in distortion of signal or disruption in the HiCardi series operation.</p> |
| | <p>It is possible, although unlikely, that large equipment using a switching relay for its power on/off may affect HiCardi series operation. Do not operate the HiCardi series in such environments.</p> |

This device has been tested and found to comply with the limits for medical devices to the IEC60601-1-2, and the Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in health care environments (such as cellular phones, radio transmitter, motors, telephones, lamps, electrosurgical units, defibrillators and other medical devices, etc), it is possible that high levels of such interference due to close proximity or strength of a source may affect device operation.

| | |
|--|---|
|  WARNING | <p>The HiCardi is designed for use in environments in which the signal can be obscured by electromagnetic interference. During such interference, measurements may seem inappropriate or the HiCardi may not seem to operate correctly.</p> |
|--|---|

Device disruption may be indicated by erratic readings, cessation of operation, or other incorrect functioning. If this occurs, survey the site to determine the source of this disruption. Try the following actions to see if they eliminate the disruption:

- Turn device in the vicinity off and on to isolate the offending equipment.
- Reorient or relocate the interfering equipment.
- Increase the separation between the interfering equipment and this device.

The device generates, uses, and can radiate radio frequency energy. If the device is not installed and used in accordance with these instructions, the device may cause harmful interference with other devices in the vicinity.

If assistance is required, contact your local distributor or MEZOO technical support.

Obtaining Technical Assistance

For technical information and assistance, contact your local distributor or MEZOO technical support.

When contacting your local distributor or MEZOO technical support, you may be asked to provide the firmware version number of your device.

SPECIFICATION

Physical Characteristics

| HiCardi series | |
|---|---|
| Dimensions | 42 x 30 x 7 (mm) (WxHxD) Excluding accessories |
| Weight | Approx. 8g Excluding accessories |
| Degree of Protection against Electric Shock | Type CF |
| Parts which contact the human body | ECG electrode |
| Mode of operation | Continuous |
| Ingress protection | IPX2: Protected from vertically falling water drops when enclosure is tilted < 15°. |

| Charging Cradle | |
|-----------------|--|
| Dimensions | 57.3 x 45.9 x 17.4 (mm) (WxHxD) Excluding accessories |
| Weight | Approx. 20 g Excluding accessories |

Controls

| Controls for HiCardi series | |
|-----------------------------|--------------------------|
| Standard | 1 Button Power On/Off |

Measurement Parameters

ECG

| Heart Rate | |
|--------------------------------|--------------------------------------|
| Measurement range | 0, 15 to 300 bpm |
| Accuracy | ±2% or ±2 bpm (whichever is greater) |
| ECG (Electrocardiograph) | |
| CMRR | 75dB or more |
| Input impedance | 100 MΩ |
| Frequency response (Bandwidth) | Monitoring 0.5 to 40 Hz |

Respiration

| Respiration | |
|-------------------|--------------------|
| Method | Thoracic impedance |
| Carrier frequency | 32 kHz |

Temperature

| Skin and Calibrated Body Temperature | |
|---|--|
| Method | Thermistor |
| Measurement range (Rated output range) | 15.0 to 45.0 °C (59.0 to 113.0 °F) (for skin temperature) |
| Resolution | 0.1 °C |
| Accuracy (Laboratory accuracy) | ±0.3 °C |
| Measuring site | Chest skin |

Electrical

| Internal Battery of HiCardi series | |
|------------------------------------|--|
| Type | Li-ion Polymer battery |
| Operating time | 25 hours |
| Voltage/Capacity | 3.7 Vdc / 75 mAh |
| Recharge | 1 hour for full recharge with device turned off. |

Communication

| HiCardi series | |
|-------------------|--------------------------|
| Bluetooth | Bluetooth Low Energy 4.2 |
| Antenna supported | |

Environmental Conditions

| Operation | |
|---|--|
| Temperature | 10 to 45°C (50 to 113°F) |
| Humidity | 10 to 95% RH, non-condensing |
| Atmospheric pressure (Altitude) | 700 to 1,060hPa (-382 to 3,010m (-1,253 to 9,878ft) at 15°C and 1,013.25hPa at sea level) |
| Transport and Storage (in shipping container) | |
| Temperature | -20 to 60°C (-4 to 140°F) |
| Humidity | 10 to 95% RH, non-condensing |
| Atmospheric pressure (Altitude) | 700 to 1,060hPa (-382 to 3,010m (-1,253 to 9,878ft) at 15°C and 1,013.25hPa at sea level) |

Note: The system may not meet its performance specifications if stored or used outside the specified temperature and humidity range.

Service Life

| HiCardi series | |
|---|---|
| Expected service life | 5 years (Excluding internal batteries) |
| <i>Note: Warranty may be different upon sales of country.</i> | |

Sound Definitions

Notification Sound for HiCardi series

| Power On Tone (POST Passing Tone) | |
|-----------------------------------|------------|
| Pitch ($\pm 5\%$) | 100 Hz |
| Pulse width ($\pm 5\%$) | 100 ms |
| Number of pulses | 1 pulse |
| Repetitions | No repeat |
| Power Off Tone | |
| Pitch ($\pm 5\%$) | 100 Hz |
| Pulse width ($\pm 5\%$) | 100 ms |
| Number of pulses | 3 pulses |
| Repetitions | No repeat |
| BLE Connection Tone | |
| Pitch ($\pm 5\%$) | 100 Hz |
| Pulse width ($\pm 5\%$) | 100 ms |
| Number of pulses | 2 pulses |
| Repetitions | No repeat |
| Finding HiCardi series Tone | |
| Pitch ($\pm 5\%$) | 100 Hz |
| Pulse width ($\pm 5\%$) | 100 ms |
| Number of pulses | 2 pulses |
| Repetitions | No repeat |
| Error Tone | |
| Pitch ($\pm 5\%$) | 100 Hz |
| Pulse width ($\pm 5\%$) | 100 ms |
| Number of pulses | 5 pulses |
| Repetitions | 30 seconds |

MANUFACTURER's EMC DECLARATION

| | |
|-------------------|---|
| ⚠️ WARNING | <p>The HiCardi conforms to the requirements of the EMC standard (IEC60601-1-2), and may therefore be used simultaneously with pacemakers and other electrical simulators. It should, however, be noted that the HiCardi may be affected by electrical scalpels and microwave therapeutic apparatus. Please check operation of the HiCardi during and after use of such equipment.</p> <p>For best product performance and measurement accuracy, use only accessories supplied or recommended by MEZOO. Use accessories according to the manufacturer's directions for use and your facility's standards. The use of accessories, transducers, and cables other than those specified may result in increased emission and/or decreased immunity of the HiCardi series.</p> <p>Portable and mobile RF communications equipment (including peripheral units as antenna cables or external antennas) should be used at distance of 30cm from any part of the HiCardi series including cables. Otherwise, the performance of HiCardi series may be deteriorated.</p> |
|-------------------|---|

The HiCardi series is suitable for use in the specified electromagnetic environment. The customer and/or user of the HiCardi series should assure that it is used in an electromagnetic environment as described below.

Table 8. Electromagnetic Emissions (IEC60601-1-2)

| Emission Test | Compliance | Electromagnetic Environment |
|--|------------|---|
| RF emission CISPR 11 | Group 1 | The HiCardi series must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. |
| RF emissions CISPR 11 | Class B | The HiCardi series is suitable for use in all establishments. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/flicker emission IEC 61000-3-3 | Complies | |

Table 9. Electromagnetic Immunity (IEC60601-1-2)

| Immunity Test | IEC 60601-1-2 Test Level | Compliance Level | Electromagnetic Environment Guidance |
|--|--|--|--|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 8 kV contact $\pm 2, 4, 8, 15$ kV air | ± 8 kV contact $\pm 2, 4, 8, 15$ kV air ± 8 kV Horizontal coupling plane ± 8 kV Vertical coupling plane | Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electric fast transient/burst IEC 61000-4-4 | ± 2 kV for power supply lines ± 1 kV for input/output lines | ± 2 kV for power supply lines no signal lines | Mains power quality for charging battery should be that of a typical commercial and/or hospital environment |
| Surge IEC 61000-4-5 | $\pm 0.5, 1$ kV differential mode for power supply lines $\pm 0.5, 1, 2$ kV common mode for power supply lines ± 2 kV common mode for input/output lines | $\pm 0.5, 1$ kV differential mode for power supply lines No ground for power supply lines no signal lines | Mains power quality for charging battery should be that of a typical commercial and/or hospital environment |

| Immunity Test | IEC 60601-1-2 Test Level | Compliance Level | Electromagnetic Environment Guidance |
|--|---|---|---|
| Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4-11 | 0 % U_T for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° | 0 % U_T for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° | Mains power quality for charging battery should be that of a typical commercial and/or hospital environment |
| | 0 % U_T for 1 cycle At 0° | 0 % U_T for 1 cycle At 0° | |
| | 70 % U_T for 25/30 cycles At 0° | 70 % U_T for 25/30 cycle At 0° | |
| | 0 % U_T for 250/300 cycle At 0° | 0 % U_T for 250/300 cycle At 0° | |
| Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8 | 30 A/m | 30 A/m | It may be necessary to position the HiCardi series further from the sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low. |
| <i>Note: UT is the AC mains voltage prior to application of the test level.</i> | | | |

Table 10. Electromagnetic Immunity (IEC60601-1-2)

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment Guidance |
|---|---|---|--|
| The HiCardi series is intended for use in the electromagnetic environment specified below. The customer or the user of the HiCardi series should assure that it is used in such an environment. | | | |
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the HiCardi series including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. |
| | | | Minimum separation distance |
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 3 Vrms | $d = 2.0 \sqrt{P}$ |
| | 6 Vrms ISM bands and amateur radio bands 150 kHz to 80 MHz | 6 Vrms ISM bands and amateur radio bands | $d = 1.0 \sqrt{P}$ ISM bands: 6.765 MHz to 6.795 MHz, 13.553 MHz to 13.567 MHz, 26.957 MHz to 27.283 MHz, 40.66 MHz to 40.70 MHz amateur radio bands: 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.5 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz, 50.0 MHz to 54.0 MHz |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.7 GHz (80 % AM at 1 kHz) According to IEC 60601-1-2:2014 | | $d = 2.0 \sqrt{P}$ 80 MHz to 2.7 GHz |
| | 10 V/m 80 MHz to 2.7 GHz (80 % AM at 1 kHz) According to IEC 60601-1- | 10 V/m 80 MHz to 2.7 GHz (80 % AM at 1 kHz) | $d = 0.6 \sqrt{P}$ 80 MHz to 2.7 GHz |

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment Guidance |
|---------------|----------------------|------------------|---|
| | 2:2014 | | <p>where P is the maximum power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |

Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile 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 HiCardi series is used exceeds the applicable RF compliance level above, the HiCardi series should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HiCardi series.

b Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m

Table 11. Recommended Separation Distances

| Recommended separation distance between portable and mobile RF communications equipment and the HiCardi series | | | | |
|--|--|---|--|---|
| Rated Maximum Output Power of Transmitter in watt | Separation distance according to frequency of transmitter in meter | | | |
| | 150 kHz to 80MHz $d = 2.0 \sqrt{P}$ | 150 kHz to 80MHz (ISM and amateur radio bands) $d = 1.0 \sqrt{P}$ | 80 MHz to 2.7GHz (Test level 3 V/m) $d = 2.0 \sqrt{P}$ | 80 MHz to 2.7GHz (Test level 10 V/m) $d = 0.6 \sqrt{P}$ |
| 0.01 | 0.2 | 0.1 | 0.2 | 0.06 |
| 0.1 | 0.63 | 0.32 | 0.63 | 0.19 |
| 1 | 2 | 1 | 2 | 0.6 |
| 10 | 6.32 | 3.16 | 6.32 | 1.9 |
| 100 | 20 | 10 | 20 | 6 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated 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: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 12. Immunity to Proximity Fields from RF Wireless Communications Equipment (IEC 60601-1-2)

| Test Frequency (MHz) | Band ^a (MHz) | Service ^a | Modulation ^b | Maximum Power (W) | Distance (m) | Immunity Test Level (V/m) |
|---|-------------------------|--|--|-------------------|--------------|---------------------------|
| 385 | 360 – 390 | TETRA 400 | Pulse modulation ^b 18 Hz | 1.8 | 0.3 | 27 |
| 450 | 430 – 470 | GMRS 460, FRS 460 | FM ^c ± 5 kHz deviation 1 kHz sine | 2 | 0.3 | 28 |
| 710 745 780 | 704 – 787 | LTE Band 13, 17 | Pulse modulation ^b 217 Hz | 0.2 | 0.3 | 9 |
| 810 870 930 | 800 – 960 | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 | Pulse modulation ^b 18 Hz | 2 | 0.3 | 28 |
| 1720 1845 1970 | 1700 – 1990 | GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS | Pulse modulation ^b 217 Hz | 2 | 0.3 | 28 |
| 2450 | 2400 – 2570 | Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulation ^b 217 Hz | 2 | 0.3 | 28 |
| 5240 5500 5785 | 5100 – 5800 | WLAN 802.11 a/n | Pulse modulation ^b 217 Hz | 0.2 | 0.3 | 9 |
| <i>NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.</i> | | | | | | |
| a For some services, only the uplink frequencies are included. b The carrier shall be modulated using a 50 % duty cycle square wave signal. c As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. | | | | | | |

Table 13. Cables (IEC 60601-1-2)

| Cable and Sensors | Maximum Length | Complies with |
|-------------------|----------------|--|
| No Cable | - | - RF emissions, CISPR 11, Class B/ Group 1 - Harmonic emissions, IEC 61000-3-2 - Voltage fluctuations/flicker emission, IEC 61000-3-3 - Electrostatic discharge (ESD), IEC 61000-4-2 - Electric fast transient/burst, IEC 61000-4-4 - Surge, IEC 61000-4-5 - Conducted RF, IEC 61000-4-6 - Radiated RF, IEC 61000-4-3 |