INFOBIONIC

MoMe® Kardia System Patient Guide

Table of Contents

MoMe® Kardia System Components

MoMe® Kardia Kit Components		
No.	Component	Description
1	MoMe® Kardia Device	Small, lightweight battery operated device that collects, stores, and transmits physiological data to the remote server via built in cellular module
1	3 wire color coded lead set	Attaches to the MoMe® Kardia device and to each electrode
1	Belt Clip	Used to carry the MoMe® Kardia on your belt or waistband during the day
2	Rechargeable Battery Packs	Battery packs to power the MoMe® Kardia Device. A fully charged batttery will last for 24 hours and must be replaced with a charged battery each day to ensure uninterrupted monitoring
1	Charger Dock	Used to charge the MoMe® Kardia battery pack
1	Charger Dock Power Supply	Used to connect the charger dock to AC wall socket
1	Electrodes	The MoMe® Kardia leadset snaps to the electrodes. Electrodes will be provided by your physician

Inspect all parts before use to ensure nothing is damaged and/or missing

Unpacking the MoMe Kardia Device

1. Upack the MoMe® Kardia Kit and locate components listed in the Kit Components chart on the previous page.

2. Plug in the charger dock and place one of the two included battery packs in the charger.

3. Insert the second battery pack into the back of the MoMe® Kardia Device (for more detailed instructions, see diagram on page 10). The device should turn on.

4. Attach the color-coded leadset to the device.

5. Place electrodes as indicated on page 6. You are now monitoring

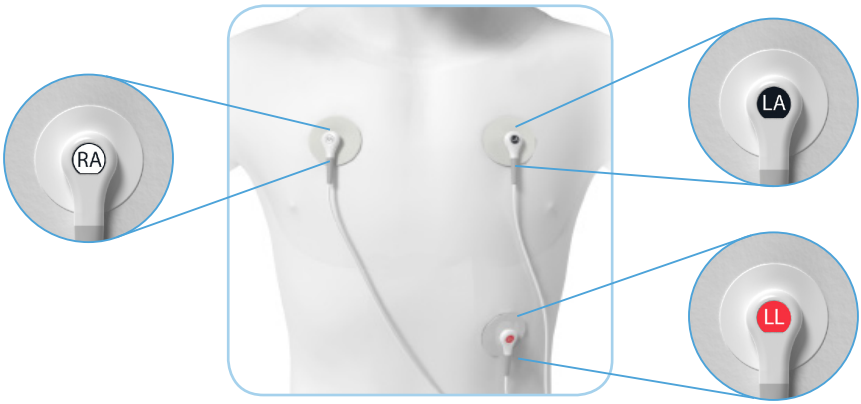


figure 2

Monitoring

Once the device is activated and operating normally, the system requires no intervention to capture or analyze data. However, your physician should instruct you about the following responsibilities:

- Charge the MoMe® Kardia Battery pack every day
- Report any symptomatic events by pressing the record button as instructed by your physician
- Return the system to the practice at the end of monitoring

Press and hold the Record Button for 3 seconds to record

Device Controls

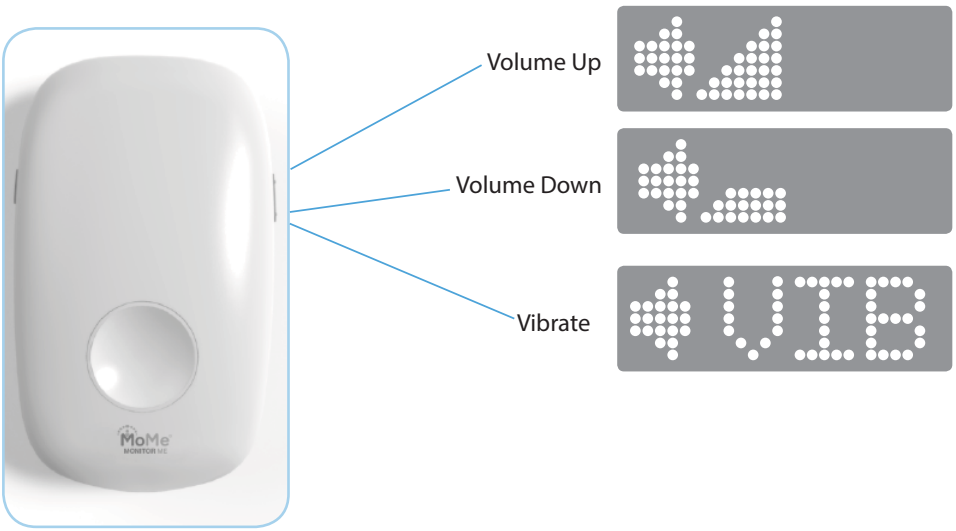
The MoMe® Kardia Device has three buttons: record, wake, and volume.

Record: Press the record button located on the face of the device to report a symptomatic event. The screen will display a solid heart (as seen in figure 4) when the event has been recorded.

Wake: Press the wake button at any time to display the current battery level and lead connection status.

figure 5

Volume: Press the volume button to adjust the volume or silence alerts on the device. To adjust the volume, press up or down on the volume button. The display will be updated with the current level and a tone will be played at the current volume for audible feedback of the volume level. The lowest volume setting mutes the speaker and can be used when the patients sleep should not be disturbed.



Notifications

Low Battery: When the battery level is low, the device will play an audio alert and will display the BATT LOW notification shown below.

figure 7

When the battery level is low the screen will display BATT LOW

Charging the MoMe® Kardia Battery Pack

To charge the MoMe® Kardia Battery Pack, follow these steps:

- First, remove the battery pack by sliding the lock and pulling the battery from the MoMe® Kardia Device
- Place battery pack in the charging dock. When the charge is complete, the indicator light will turn green.
- The battery must be replaced once daily. Promptly recharge the battery pack after replacing depleted battery.
- To replace battery, use the slide lock lever to release and insert the battery, as shown below in figure 8

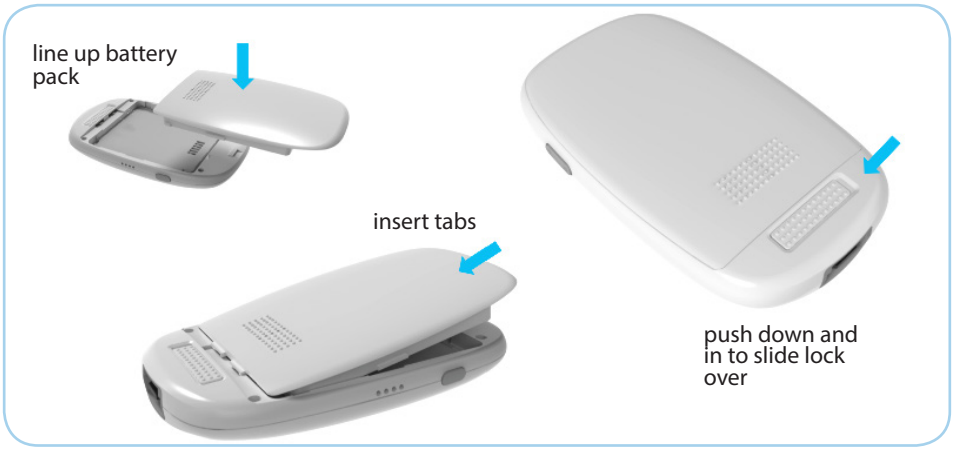


figure 8

Belt Clip

The MoMe® Kardia Device must be used with the included Belt Clip .Slide the device up and into the belt clip holster to secure the device in place then slide the clip over your belt or waistband with the leadset attachment facing upwards.

figure 9

Warnings

- Warning: MoMe® Kardia is not intended for use on infants weighing less than 10 kg (22 lb).
- Warning: Use only specified MoMe® Kardia cables and accessories. Use of any other cables and accessories may negatively affect EMC performance resulting in increased emissions and decreased immunity.
- Warning: Use only specified MoMe® Kardia accessories. Use of any other accessories may result in non-compliance.
- Warning: MoMe® Kardia is not intended for use as an emergency medical response system. Patients should be instructed that if they experience symptoms of concern they need to seek immediate medical attention.
- Warning: The MoMe® Kardia Device is not defibrillation-proof. Remove MoMe® Kardia Device and disconnect patient leads before external defibrillation.
- Warning: Do not service or repair any components of the MoMe® Kardia system. Removal or tampering of the lead wires or any other component may alter device performance and cause device malfunction or failure. Contact MoMe® Kardia Technical Support at 1.844.401.9725 for product repair or replacement.
- Warning: The MoMe® Kardia system may be affected by equipment even if the equipment is CISPR compliant.
- Warning: The MoMe® Kardia system should not be used in the presence of flammable anesthetics.
- Warning: The MoMe® Kardia contains a cellphone. If the patient has an implantable device, they should be instructed to follow their implantable device manufacturer's recommendations for use with a cellphone.
- Warning : Never attempt to repair or service any MoMe® Kardia equipment. Repairs by untrained, unauthorized individuals may damage the equipment or cause system malfunction.
- Warning : The MoMe® Kardia is not intended to be used in an Oxygen rich environment.
- Warning : Electrodes may cause skin irritation or breakdown. We recommend that standard FDA approved Ag/AgCL ambulatory monitoring electrode patches be used and that the patient be instructed on what to do if skin irritation occurs.ff

Cautions

1. MoMe® Kardia uses cellular phone technology, so the system operation and data transmission may be affected or interrupted by poor cellular

coverage or electromagnetic interference. If data transmission is interrupted, MoMe® Kardia will automatically cache the data until cellular coverage or communication between the two devices is restored and then send the stored data.

2. Use only MoMe® Kardia parts and accessories with the MoMe® Kardia system. Using non-MoMe® Kardia equipment may result in system malfunction or failure.
3. Use only with the supplied battery packs, charging dock, and wall adapter.
4. Prior to setting up a new patient with MoMe® Kardia, carefully inspect all system components for defects or damage. Check lead wires for cracks or fraying in the wiring, and cracks around the connector and snap leads. Do not use the MoMe® Kardia system if any component appears defective, damaged, or worn (e.g. cracks, dents, chips, cuts, kinks, or crushed or elongated sections), as this may result in system malfunction or failure. Contact MoMe® Kardia Technical Support at 1.844.401.9725 for a replacement, if needed.
5. MoMe® Kardia is not waterproof.:
    - Protect all MoMe® Kardia parts from water, liquids or moisture which will damage equipment and affect system operation;
    - Do not immerse any part of the MoMe® Kardia system in water or fluids. Do not spray device with cleaners or other liquids;
    - Never bathe, shower, or swim while wearing the MoMe® Kardia Device (while bathing or swimming, store MoMe® Kardia equipment in a safe, dry location)
6. Do not drop or subject MoMe® Kardia parts to extreme physical shock.
7. The MoMe® Kardia system uses and generates radio frequency energy, so it may cause harmful interference to radio communication if not used according to instructions.
8. The user should take precautions regarding electromagnetic compatibility, the MoMe® Kardia system needs to be used according to the EMC information provided in this IFU.
9. The MoMe® Kardia provided for use in the U.S. will not transmit recorded data if the patient travels outside of the U.S.
10. Do not use the MoMe® Kardia system in conditions that are:
    - Below 32°F (0°C) or above 104°F (40°C);
    - Less than 15% or greater than 93% non-condensing atmospheric humidity.
11. Do not store or transport MoMe® Kardia in conditions that are:
    - Below -25°C or above 70°C;
    - Less than 15% or greater than 93% non-condensing atmospheric humidity.
12. Keep the system out of reach of children and pets.

Battery Information

- Do not dismantle, open or shred secondary cells or batteries.
- Do not expose cells or batteries to heat or fire. Avoid storage in direct sunlight.
- Do not short-circuit a cell or a battery. Do not store cells or batteries haphazardly in a box or drawer where they may short-circuit each other or be short-circuited by other metal objects.
- Do not remove a cell or battery from its original packaging until required for use.
- Do not subject cells or batteries to mechanical shock.
- In the event of a cell leaking, do not allow the liquid to come in contact with the skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical advice.
- Do not use any charger other than that specifically provided for use with the equipment.
- Observe the plus (+) and minus (–) marks on the cell, battery and equipment and ensure correct use.
- Do not use any cell or battery which is not designed for use with the equipment.
- Battery usage by children should be supervised.
- Keep cells and batteries clean and dry.
- Wipe the cell or battery terminals with a clean dry cloth if they become dirty.
- Secondary cells and batteries need to be charged before use. Always use the correct charger and refer to the manufacturer's instructions or equipment manual for proper charging instructions.
- Do not leave a battery on prolonged charge when not in use.
- After extended periods of storage, it may be necessary to charge and discharge the cells or batteries several times to obtain maximum performance.
- Retain the original product literature for future reference.
- Use only the cell or battery in the application for which it was intended.
- Dispose of properly.

System Specifications

MoMe® Kardia Device Specification	
Specification	MoMe® Kardia Device
Battery Life	Provides 24 hours of function before recharging
Operating Temperature	5°C to 40°C
Storage Temperature (power off)	-25°C to 70°C
Operating Humidity	15% to 93% non-condensing
Storage Humidity	
Operating Pressure	
ECG	
Sampling Rate	200 Hz
Digital Resolution	5uV
Input Dynamic Range	+/- 10 mV
Input Offset Dynamic Range	+/- 300 mV
Input Impedence	> 3 MOhm
Peak Current Injection	24 nA (Lead off circuit) DC
RMS Current Injection	29 microA
Data Storage Capacity	Minimum 30 days
Dimensions	108 mm x 67 mm x 17 mm max
Weight	80 +/- 5 g
Communication Means	HSPA+, UMTS, GPRS, EDGE 800/850, AWS1700, 1900
Ingress Protection Rating	IPX0
Display	Type: LED Matrix, Size: 24 X 7
Memory	Internal microSD card up to 32 GB, Not user accessible
Battery	Li-Ion 1900mAh battery pack, Min 24 hour battery life

Electromagnetic Emissions Compliance

The MoMe® Kardia device has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2007. These limits are designed to provide reasonable protection against harmful interference in a typical installation.

1. This device radiates radio frequency energy in normal use and, if not installed and used in accordance with instructions in this manual, may cause harmful interferences to other devices in the vicinity. If this device does cause harmful interference to other devices, the user is encouraged to try to correct the interference by one or more of following measures:
   - Reorient or relocate the other device/s
   - Increase the separation distances between this device and other device/s
   - Consult the manufacturer/s of other device/s or call service for help
2. The device performance may be affected by heavy electrical equipment or other sources of electromagnetic interference.

Guidance and Manufacturer's Declaration - Electromagnetic emissions		
The MoMe® Kardia is intended for use in the electromagnetic environment specified below. The customer or the user of MoMe® Kardia should assure that it is used in such an environment		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The MoMe® Kardia uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	The MoMe® Kardia is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The MoMe® Kardia is intended for use in the electromagnetic environment specified below. The customer or the user of MoMe® Kardia should assure that it is used in such an environment

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Envioronment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst	+/- 2 kV for power supply lines +/- 1 kV for input/ output lines	Not applicable	
Surge IEC 61000-4-5	+/- 1 kV line(s) to line(s) +/- 2 kV lines(s) to earth	Not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5s	Not applicable	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The MoMe® Kardia is intended for use in the electromagnetic environment specified below. The customer or the user of MoMe® Kardia should assure that it is used in such an environment

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Not applicable Not applicable 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance: $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To 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 unit is used exceeds the applicable RF compliance level above, then the unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the unit.

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

Recommended seperation distances between portable and mobile RF communications equipment and MoMe® Kardia System

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

Rated maximum ouput power of transmitter W	Seperation distance according to frequency of transmit		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

SAR Exposure Information

This device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government.

The exposure standard employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit relevant for the application described in the manual is 1.6W/kg. Tests for SAR are conducted using standard operating positions accepted by the FCC with the device transmitting at its highest certified power level in all tested frequency bands.

Although the SAR is determined at the highest certified power level, the actual SAR level of the equipment while operating can be well below the maximum value. This is because the device is designed to operate at multiple power levels so as to use only the power required to reach the network. In general, the closer you are to a wireless base station antenna, the lower the power output.

Equipment Authorization has been granted to this device with the reported SAR level(s) evaluated as in compliance with the FCC RF exposure guidelines. SAR information on this equipment is on file with the FCC and can be found under the Display Grant section of www.fcc.gov/oet/ea/fccid after searching on the FCC ID as printed on the equipment.

This device has been tested to comply with FCC radiation exposure limits set forth for an uncontrolled environment when used for the documented intended purpose and when operated as shown in the user instructions provided with this product, i.e. when carried with the belt clip coming with the product as a bundled accessory.

The MoMe® Kardia Device must be used with the included Belt Clip to keep a safe minimum distance towards your body (6mm), ensuring compliance with regulatory limits regarding human exposure to radio frequency radiation.