MoMe® ARC

Physician's Guide

#30815 rB

Copyright, Technical Support, Trademark, and Contact Information

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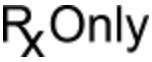

InfoBionic's MoMe® ARC System may be covered under one or more United States and International Patents. Please see the website: www.infobionic.com to satisfy the virtual patent marketing provisions including the America Invents Act and 35 U.S.C. § 287(a). Additional patents may be issued or pending in the US and elsewhere.

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Chapter 1. Welcome to MoMe® ARC

MoMe® ARC is a wireless, remote monitoring system intended to provide information that assists the physician, along with patient symptoms and other tests, in the diagnosis or monitoring of patients with cardiac arrhythmias.

MoMe® ARC includes the wearable MoMe® ARC Device that acquires and stores ECG data and transmits that data via cellular technology to the MoMe® Software Platform (K152491), a web-based remote server software with proprietary algorithms for analysis, using the MoMe® Device Communications Protocol. MoMe® Software Platform analyzes the data via the embedded algorithm and when indicated, data identified by the algorithm is flagged for physician review. MoMe® Arc requires no patient intervention to capture or analyze data, however, does provide a patient event trigger.

MoMe® ARC is intended to be used by licensed healthcare providers who are properly trained.

MoMe® ARC is suitable for the professional and home healthcare environments.

MoMe® ARC supports near real time collection and transmission of ECG data to the MoMe.Net Software Platform for monitoring of patient ECG.

The device is intended for use under prescription and has detailed reporting available for the following four cardiac monitoring tests:

1 Holter (24-48 Hrs.)
2 Event Monitoring
3 Mobile Cardiac Telemetry (MCT)
4 Extended Holter (3 – 14 days)

MoMe® Arc:

- Is non-invasive and poses no significant safety issues.
- Uses existing electrode and ECG technology.
- Is used in an adjunctive fashion, where physicians also use patient symptoms and other tests, in the diagnosis or monitoring of patients with cardiac arrhythmias.
- Is worn by the patient as they go about their normal day

  MoMe® Arc is not an emergency service. If the patient is experiencing symptoms that he/she is concerned about, the patient needs to seek immediate medical attention.

1.1 Features & Benefits

MoMe® Arc performs continuous ECG monitoring for arrhythmia detection. Benefits include:

- A universal device that replaces individual test monitors
- Provides context sensitive reporting of patient ECG and patient events when reported
- Stores and processes all data using a web-based application in the “cloud” for enhanced processing, storage, and display capabilities.

1.2 MoMe® Arc Components

The MoMe® Arc system has following main components:

1. **MoMe® ARC Device:**
    - A Gateway that continuously collects and stores ECG data from Bluetooth® connected sensors for up to 30 days at a time and sends the data via a built in Cellular module.
    - Wearable sensor with three color-coded lead wires, attached to off the shelf electrode gel pads, attached to the patient's torso.
    - Charging Cradle for daily charging of the Gateway
2. **Clinical review and reporting software:** MoMe® Arc is intended to be used with the InfoBionic MoMe® Software System (K152491).

1.3 Indications

MoMe® Arc is indicated for use on:

1 Patients who experience transient symptoms that may suggest cardiac arrhythmia.

2 Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation)

3 Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath)

4 Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring.

5 ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports.

1.4 Contraindications

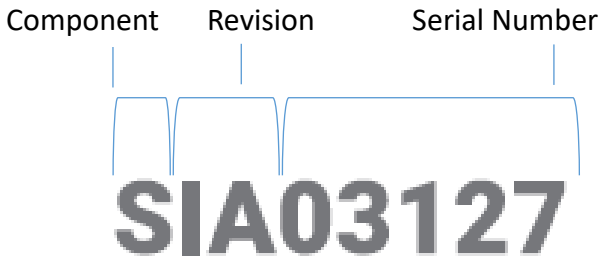
MoMe® Arc is contraindicated for those patients requiring attended, in-hospital monitoring for life threatening arrhythmias.

MoMe® Arc does not provide interpretive statements. Interpretation and diagnosis is the responsibility of a physician.

1.5 Symbols

These symbols are found on the MoMe® Arc labels, which are the back of the sensor, gateway and charging dock.

Table 1 Symbols

	Manufacturer Name and Address
	Type BF equipment
	FCC Symbol
	Wireless Transmission Symbol
	5 V, 2.5A, 12 W . Use only with supplied power adapter
	Refer to Manual/Instructions
	Component / Revision / Serial Number Component = C for charger, S for sensor , G for gateway Revision = 2-character revision identifier Serial number = 5 digit serial number
	Ingress Protection Rating 22
	UDI Symbol

1.6 Essential Performance

MoMe® ARC achieves its essential performance by acquiring and storing the ECG signal and subsequently transmitting those signals to the MoMe® Software Platform system for arrythmia analysis and physician review.

MoMe® ARC requires a Bluetooth® Low Energy connection between the wearable sensor and the gateway. The wearable device must be close enough to the gateway and free of significant obstruction to establish and maintain connection to transmit data to the gateway. When the sensor and the gateway are disconnected, the sensor continues to record data and store locally until the connection to the gateway can be established. The device will inform the user about loss of Bluetooth® connection between the sensor and gateway by vibrating the sensor and displaying an indication that the sensor and the gateway are not connected.

MoMe® ARC also requires a cellular network connection in order to transmit its data to the MSP for arrythmia analysis. When the device is out of cellular coverage, ECG data continues to be collected and stored. All stored data is transmitted to the MSP when cellular coverage is reacquired. The device initiates a connection to the MSP every 3 minutes.

1.7 Cellular Coverage Considerations

The device should not be used for monitoring applications where temporary or extended loss of cellular coverage poses an unacceptable risk to the patient. MoMe ARC is not an emergency response system and is not a replacement for attended, in-hospital telemetry monitoring. Patients should be instructed that if they experience symptoms of concern, they need to seek immediate medical attention.

Patients are monitored as they go about their normal daily routine. InfoBionic has no control over cellular network coverage and the patient could be out of cellular coverage for extended periods of time. Cellular coverage may be lost temporarily in basements, elevators, parking garages or while travelling through or staying in any other area where coverage is not available. Coverage may be absent in some or all areas of a patient's home, or at their place of work, and this could result in data transmission delays for extended periods of time.

1.7.1 Device Indicators

Low battery and leads off alerts will continue to operate in the absence of cellular network coverage, to ensure that data can still be collected for transmission when the cellular network is regained.

The gateway home page will display "Monitoring" if cellular coverage is available and the gateway can contact the MSP to transmit its data. If there is no cellular coverage available, the device will display "Recording" on the home page.

On initiation of service, verify that the device displays "Monitoring" in the patients home location. If the patient does not have coverage in their home location, clinical judgment should be used to determine whether the patient should continue to be monitored with MoMe ARC

1.7.2 MoMe® Software Platform Indicators

The current connection status of the device is always available on the MoMe Software Platform device status page. This page displays the last time the device connected and how many minutes of ECG data remain on the device waiting to be transmitted.

If the device status shows an unacceptable delay, contact the patient to determine the cause of the delay. Possible causes are:

1) Patient is non-compliant and is not wearing the device
2) Battery has depleted

3) Patient does not have coverage in their location
4) Cybersecurity event

. If a patient is unable to connect their device and a cybersecurity event is suspected contact InfoBionic.

Chapter 2. Safety

Before using the MoMe® Arc, carefully read this operator instructions manual. The MoMe® Arc must be used in accordance with the information provided in the accompanying documents. Failure to understand and follow all instructions, warnings or cautions may result in equipment damage, system malfunction, or user harm. All users, including patients and caregivers, must be trained in safe MoMe® Arc operation before use. Healthcare providers are responsible for training the patient on the proper use of the system.

2.1 Warnings

- **Warning:** MoMe Arc® is not intended for use on infants weighing less than 10kg (22lbs.). Clinical judgement is necessary to determine if the MoMe® ARC is appropriate for specific pediatric patients.
- **Warning:** Use only specified MoMe® Arc Sensors and accessories. Use of any other accessories may negatively affect EMC performance resulting in increased emissions and decreased immunity.
- **Warning:** To avoid possible strangulation, route Sensor wires away from the patient's throat.
- **Warning:** Use only specified MoMe® Arc accessories. Use of any other accessories may result in non-compliance and impact performance.
- **Warning:** MoMe® Arc 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® Arc Device is not defibrillation-proof. Remove the MoMe® Arc Sensor and disconnect patient leads before external defibrillation.
- **Warning:** Do not service or repair any components of the MoMe® Arc system. Removal or tampering of the lead wires or any other component may alter device performance and cause device malfunction or failure. Contact MoMe® Arc Technical Support at 1-844-401-9725 for product repair or replacement.
- **Warning:** The MoMe® Arc system may be affected by other electronic equipment even if that equipment is CISPR compliant.
- **Warning:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the MoMe® Arc Device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- **Warning:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

- **Warning:** The MoMe® Arc system should not be used in the presence of flammable anesthetics.
- **Warning:** The MoMe® Arc 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® Arc equipment. Repairs by untrained, unauthorized individuals may damage the equipment or cause system malfunction.
- **Warning:** The MoMe® Arc is not intended to be used in an Oxygen rich environment.
- **Warning:** The MoMe® Arc is not intended to be used near active HF surgical equipment.
- **Warning:** The MoMe® Arc is not intended to be used in magnetic resonance environments.
- **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.
- **Warning:** The MoMe® Arc employs multiple cybersecurity mechanisms to ensure secure storage and transmission of data to the MoMe® Software Platform. If a cybersecurity intrusion is suspected discontinue use of the device and contact InfoBionic for assistance
- **Warning:** Inspect the device for physical damage before each use**.** Do not use the MoMe Arc gateway if the touchscreen glass or device case is cracked or damaged.

2.2 Cautions

- MoMe® Arc 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® Arc will automatically store the data until cellular coverage or communication restored and then send the stored data.
- Use only MoMe® Arc parts and accessories with the MoMe® Arc system. Using non-MoMe® Arc equipment may result in system malfunction or failure.
- Use only with the supplied charging dock, and wall adapter.
- In order to disconnect the system from mains power, unplug the wall adapter from the power outlet
- Prior to setting up a new patient with MoMe® Arc, carefully inspect all system components for defects or damage. Check Sensor wires for cracks or fraying in the wiring, and cracks around the snap leads. Do not use the MoMe® Arc 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® Arc Technical Support at 1-844-401-9725 for a replacement, if needed.
- MoMe® Arc is not waterproof.
  - Protect all MoMe® Arc parts from water, liquids or moisture which will damage equipment and affect system operation;
  - Do not immerse any part of the MoMe® Arc system in water or fluids. Do not spray device with cleaners or other liquids;
  - Never bathe, shower, or swim while wearing the MoMe® Arc Device (while bathing or swimming, store MoMe® Arc equipment in a safe, dry location)
- Do not drop or subject MoMe® Arc parts to extreme physical shock.
- The MoMe® Arc system uses and generates radio frequency energy, so it may cause harmful interference to radio communication if not used according to instructions.
- The user should take precautions regarding electromagnetic compatibility, the MoMe® Arc system needs to be used according to the EMC information provided in this IFU.
- Do not use the MoMe® Arc 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.
- Do not store or transport MoMe® Arc in conditions that are:
  - Below -25°C or above 50°C;
  - Less than 15% or greater than 93% non-condensing atmospheric humidity.
- Keep the system out of reach of children and pets.
- Do not let the lead wire ends contact other conductive parts including earth.
- If the patient is unable to perform any of the operations related to daily use of the MoMe® Arc Device, please ensure a caregiver is available to assist the patient.

Chapter 3. Specifications and Components

3.1 Specifications

Table 2 Specifications

Specification	MoMe® Arc
Battery Life	Provides 24 hours of function before recharging
Operating Temperature	5°C to 40°C
Storage Temperature	-25°C to 50°C
Operating Humidity	15% to 93% non-condensing
Storage Humidity	15% to 93% non-condensing
Operating Pressure	700 hPa to 1060 hPa
ECG Sampling Rate Digital Resolution Input Dynamic Range Input Offset Dynamic Range	 200 Hz 5uV +/- 10 mV +/- 300 mV
Input Impedance Peak current injection RMS current injection	> 3 MOhm 24 nA (Lead off circuit) DC 29 microA
Data Storage Capacity	Minimum 30 days
Dimensions	108 mm x 67 mm x 17 mm max
Weight	80 +/- 5 g
Communication Means	WCDMA bands 2,4,5 LTE bands 2,4,5,12,13,14,66,71 BLE
Ingress Protection Rating (Gateway, Sensor, Charger Dock)	IP22
Display	Type: AMOLED, Size: 1.4" Diameter
Memory	Internal microSD card up to 32 GB, Not user accessible
Battery (Gateway)	Internal Li-Ion 1800mAh battery pack
Battery (Sensor)	Internal Li-Ion 240mAh battery pack
Charger Dock Power Supply	5V DC 2.4A, 12W

3.2 Components

Table 3 MoMe Arc Kit (30000) Components

Part #	Qty	Name	Description
30100	1	MoMe® Arc Gateway	Small lightweight battery-operated device that receives physiological data from the sensor, stores and transmits data to the remote server via built in cellular module. Charges the sensor
30400	1	MoMe® Arc Sensor	Small lightweight battery-operated device that incorporates a 3 wire color coded patient leadsets and collects, stores and transmits physiological data to the gateway.
30600	1	MoMe® Arc Charger Dock	Used to charge the MoMe® Arc Gateway
30702	1	Charger Dock power supply Model HDP12-MD05024U	Used to connect the charger dock to the wall outlet
30901	1	Gateway Cover	Protective cover for Gateway and connection to optional lanyard
30802	1	Belt Clip	Used to carry the MoMe® Arc on your belt or waistband during the day
30816	1	Patient Guide	Contains detailed instructions on using the MoMe® Arc device.
30800	1	Kit Carry Case	Carry Case for housing components for transport and shipping

3.3 Service Life

The MoMe® ARC has an expected service life of five (5) years after the manufacturing date. The device should not be used five years past this date of manufacture. InfoBionic will notify the device user when the device is approaching its end of service life.

Devices should only be used if fully functional and in working condition. InfoBionic provides a recycling platform through “Recycle Me” where devices can be returned to InfoBionic if they have reached their service life expiration or are no longer in working condition.

A visual inspection should be performed before use of the device. Please see 2.2 Cautions for further information regarding a visual inspection.

Chapter 4. Device Configuration, Patient Setup and Monitoring

The wearable MoMe® Arc Sensor continuously collects and stores ECG data through three color-coded electrode wires connected to the patient. The sensor transmits the collected data wirelessly using Bluetooth® to the MoMe® Arc Gateway, which then stores and transmits the data via cellular radio to the MoMe® Software Platform. The sensor relies on wireless communication to promptly transmit ECG data to the Gateway. If the patient goes out of range of the Gateway, the sensor will store all collected data and transmit it to the gateway when it comes back into range.

The Gateway relies on the cellular communication network to promptly transmit recorded data to the MoMe® Software Platform. If cellular communications are interrupted (i.e. patient goes out of range), the device will store all recorded data and transmit it to the MoMe® Software Platform when coverage is regained.

MoMe® Arc supports patient self-reporting of cardiac symptoms. Pressing the "Event Record" button on the MoMe® Arc Device. The patient will then choose from an available list of symptoms to indicate the experienced symptom at the time the button was pushed.

The MoMe® ARC system will continuously record ECG data when worn as directed.

4.1 Device Configuration

See the MoMe® Software Platform Instructions For Use for instructions on configuring the device for your patient.

4.2 Initial Patient Setup

Healthcare providers initially set the patient up with MoMe® Arc device and provide training and information about its use.

Subsequently, the patients are responsible for daily disconnecting and reconnecting of the MoMe® Arc Device (e.g. after bathing, showering, or as needed), charging the MoMe® Arc and changing the disposable gel pads as instructed by the physician

Step 1: Locate the kit components and ensure contents includes:

- 1 Carry Case
- 1 Wearable MoMe® Arc Sensor and Gateway
- 1 Charger dock for the MoMe® Arc Gateway
- 1 Charger dock power supply
- 1 MoMe Gateway Cover
- 1 Belt Clip

IMPORTANT: Fully charge the MoMe® Arc before patient setup.

Inspect all parts before use and make sure that nothing is damaged or missing.

Step 2: Prepare the Skin

- Trim as much hair as possible from the intended locations [for men] on the chest (Figure 1) (for example, using an electric razor or hair trimmer). Trim an area slightly larger than the gel pad.
- Clean and dry the area completely.

Step 3: Apply Gel Pads to Patient's Chest and Connect Electrode Wires

- Apply the three (3) gel pads to the patient's chest as indicated (Figure 1).

  IMPORTANT: Do not place the gel pads over broken or damaged skin.

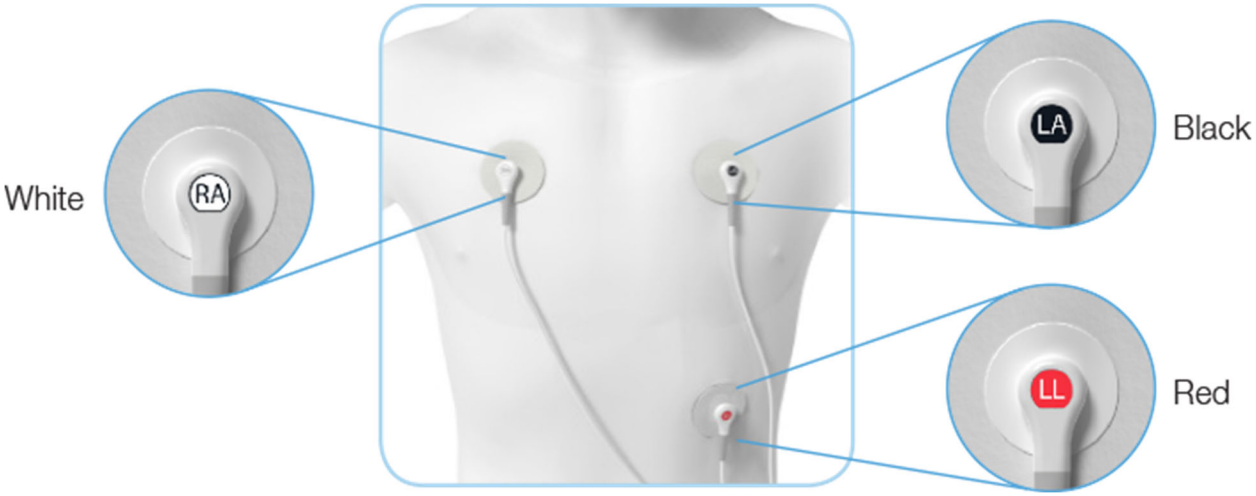


Figure 1 Electrode Placement Locations

- Snap MoMe® Arc color-coded electrode wires onto the appropriate gel pads.

Step 4: MoMe® Arc System Activation and Baseline Recording

1. Press the event button to light the display.
2. Verify that the patient's name displays on the device. The system is now activated for patient use.
3. Press the "Event Record" button. You may view the baseline recording generated by pressing the event record button to view the baseline recording.

4.3 Patient Monitoring

Once activated and operating normally the system requires no patient intervention to capture or analyze data, however, patients should be instructed to push the event record button to trigger an event if any symptoms occur during monitoring. Instruct the patients about their responsibilities:

- How to disconnect and reconnect MoMe® Arc Sensor when bathing
- Charging the MoMe® Arc Gateway and Sensor every day
- Keeping the MoMe® Arc Gateway near them at all times
- Initiating a Symptom capture and selecting from listed symptoms
- Changing the disposable gel pads
- Return the system to the practice at the end of monitoring

4.4 Patient Reminders

- Wear MoMe® Arc continuously until informed by the practice that the monitoring period has ended.

Chapter 5. Device Controls and User Interface

The MoMe® Arc has one button and a touchscreen display for controlling the device.

5.1 Event Record Button - Reporting Cardiac Symptoms

The MoMe® Arc system allows patients to report an event as follows:

1. On the MoMe® Arc Device: press the Event Record button – screen will display a prompt asking if the user would like to report symptoms
2. The MoMe® Software System will indicate that a patient symptomatic event has been generated.

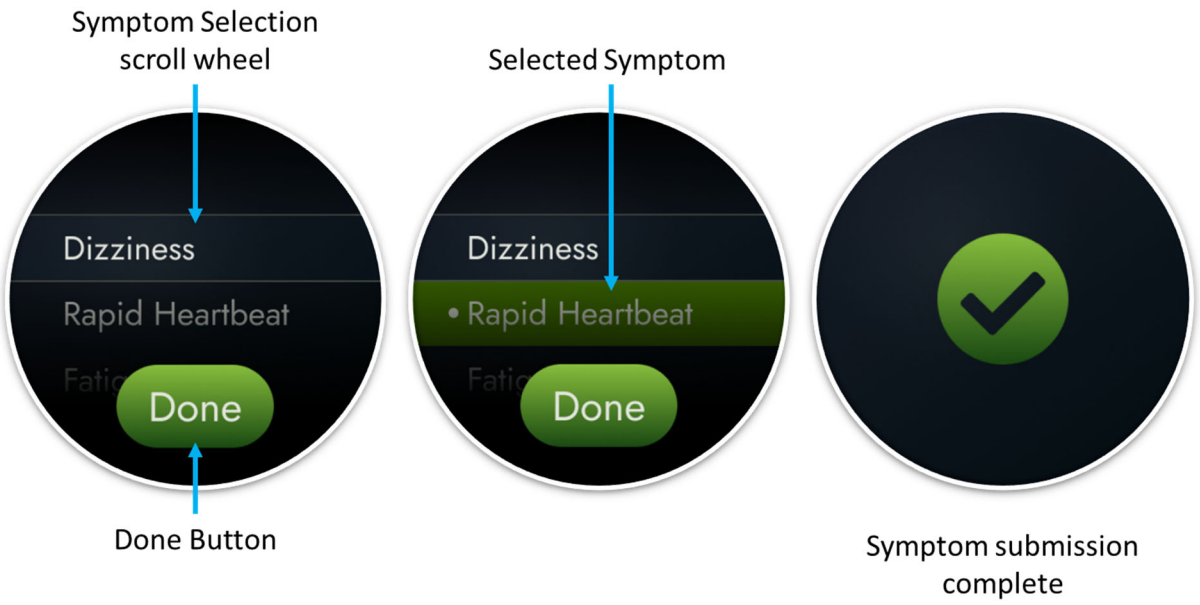
Figure 2 Event Button

Circular animation Lasting 3 seconds

Animation complete, "event" is recorded

More detailed symptom can be recorded via "YES" button and a generic "event" via "NO" button

As directed, the patient can select from available symptom descriptions. After selecting YES in the "Record Symptoms" screen shown . The symptoms reporting is done by highlighting (tapping via touchscreen) specific symptoms and when all desired symptoms are selected, pressing the "Done" button. The symptoms are customizable on per-patient basis.



5.2 Low Battery Alert

When the battery is low, the patient will be notified on the gateway with audio and visual indicators (per the current volume level).

Figure 3.2 Battery Low Indicator

			
0%-15%	15%-35%	35%-100%	Charging

Battery Percent (%) Charge and fill colors allow the patient to quickly identify the state of the battery charge for the Gateway and linked Sensor

5.3 Leads Off Alert

When it is detected that one or more leads have become detached from the body, the patient will be notified with audio and visual indicators (per the current volume level).

Figure 4.3 Leads Off Indicator

5.4 Sensor Disconnected Alert

If the sensor goes out of range of the gateway while in monitoring mode, the sensor disconnection alert is displayed on the gateway.

Figure 5.4 Sensor Disconnected

5.5 System Error

If the device detects a system error that prevents operation the following screen will be displayed. If this error is displayed, please call your provider for assistance.

Figure 6.5 System Error

5.6 Sensor Vibration

The sensor will vibrate periodically during any alert condition (low battery, leads off or sensor disconnection alert). The patient should go to the gateway to view the specific alert message.

5.7 LED Indicators

The Charger, gateway and sensor all have a single LED indicator. LED indicator meanings are listed below.

Charger:

- LED is yellow if the gateway is being charged or no gateway is present in charger, green if the charge is complete.
- LED is off if no device / load is present
- LED blinks red if there is a system error

Sensor:

- LED is off during normal use
- LED blinks yellow (continuous) during a warning (Leads off / batt low / etc)
- LED blinks red (continuous) in case of system error
- LED blinks blue (once) when a new Bluetooth® Low Energy connection is established
- LED blinks purple (continuous) when Sensor is being identified

Gateway

- LEDs off during normal use
- LEDs blink red (continuous) if there is a system error

5.8 Charging the MoMe® Arc Gateway and Sensor

Instruct the patient to charge the Gateway and Sensor each day. At night, detach the sensor from the gateway and place the gateway in the charging dock. In morning, place the sensor in the gateway and wear the mated gateway / sensor pair during the day. The charging dock should be set up in the room where the patient sleeps.

Figure 7 Charging Dock

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Chapter 6. Service, Cleaning, and Disposal

6.1 Service

There are no user serviceable parts in the MoMe® Arc Device. If you suspect that your device is not operating properly, please call Customer Care at 1-844-401-9725 for all questions regarding operation.

WARNING: For your safety, never attempt to repair or service any MoMe® Arc equipment. Repairs by untrained, unauthorized individuals may damage the equipment or cause system malfunction.

NOTE: The gateway and sensor batteries should be recharged at least once every three months. If the device has been unused for three (3) months, place the sensor in the gateway and the gateway on the charger dock until fully charged.

6.2 Cleaning

The following cleaning agents are recommended for decontamination of MoMe® Arc components between patients. Do not submerse any component in liquid when cleaning.

- Sodium hypochlorite (bleach) solution 10% in water
- Cavi Wipes

Visually inspect the device after cleaning to determine the adequacy of the cleaning. Repeat cleaning if necessary.

6.3 Disposal of Waste

Dispose used electrode gel pads consistent with local regulations for medical waste disposal. Dispose the MoMe® Arc device, accessories, and components according to local applicable regulations.

6.4 Software Updates

Software is updated automatically by InfoBionic and require no additional user actions.

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Chapter 7. Electromagnetic Emissions Compliance and Instructions

The MoMe® Arc device has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2014. 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.

MoMe® ARC is suitable for the professional and home healthcare environments.

MoMe® ARC achieves its essential performance under normal use only as part of a system which includes the MoMe® Software Platform. MoMe® ARC acquires the ECG signal presented at the lead wire electrodes and subsequently transmits those signals to the MoMe® Software Platform system for arrythmia analysis and physician review.

Should MoMe® ARC encounter electromagnetic interference that presents as artifact on the ECG at the MoMe® Software Platform, the artifact should be evaluated by a physician to determine if it will negatively impact patient diagnosis.

The MoMe ARC does not physically connect to any other equipment for its intended use.

The MoMe Arc will recover from transient phenomena within 1 minute.

The MoMe ARC was tested according to the recommendations of IEC TR 60601-4-2

7.1 Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The MoMe® Arc is intended for use in the electromagnetic environment specified below. The customer or the user of MoMe® Arc should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The MoMe® Arc 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® Arc 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.

Electromagnetic Immunity

Manufacturer's declaration – electromagnetic immunity			
The MoMe® Arc is intended for use in the electromagnetic environment specified below. The customer or the user of MoMe® Arc should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 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 IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency	
Surge IEC 61000-4-5	± 0,5 kV, ± 1 kV line(s) to line(s) ± 0,5 kV, ± 1 kV, ± 2 kV lines(s) to earth	± 0,5 kV, ± 1 kV line(s) to line(s) ± 0,5 kV, ± 1 kV, ± 2 kV lines(s) to earth	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° q) 0 % UT; 1 cycle and 70 % UT; 25/30 cycles h) Single phase: at 0°	0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° q) 0 % UT; 1 cycle and 70 % UT; 25/30 cycles h) Single phase: at 0	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m g) 50 Hz or 60 Hz	30 A/m g) 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

<table>
<tr><th colspan="4">Manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><th colspan="4">The MoMe® Arc is intended for use in the electromagnetic environment specified below. The customer or the user of MoMe® Arc should assure that it is used in such an environment.</th></tr>
<tr><th>Immunity Test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 V
0.15 MHz - 80 MHz

6V in ISM and amateur radio bands between 0.15 and 80 MHz</td><td>3 V

6 V/m</td><td>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</td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>10 V/m
80% AM @ 1 kHz
(Test at 120V, 60 Hz)</td><td>10 V/m</td><td>$d = 2.3\sqrt{P}$ 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:

  </td></tr>
<tr><td colspan="4">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.</td></tr>
<tr><td colspan="4">[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.</td></tr>
</table>

Recommended separation distances between portable and mobile RF communications equipment and MoMe® Arc System				
The MoMe® Arc is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the MoMe® Arc can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MoMe® Arc as recommended below, according to the maximum output power of the communications equipment				
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter (m)			
	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** $d = 2.3\sqrt{P}$	**Band specific interference Wi-Fi or LTE Co-channel, may perturb communications within**
0.01	0.12	0.12	0.23	0.76
0.1	0.38	0.38	0.73	2.42
1	1.2	1.2	2.3	7.65
10	3.8	3.8	7.3	NA
100	12	12	23	NA
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. Note1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note 2:These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.				

7.3 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.

7.4 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 MoMe® ARC Gateway must be used with the included Belt Clip when the sensor is in the gateway, or provide 13 mm separation distance between the Gateway (with sensor attached) and the users body to satisfy RF exposure requirements.

Ensure that the MoMe® ARC charging dock is installed and operated with a minimum distance of 20 cm from your body

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.

7.5 FCC Part 15 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.

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

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