# MoMe ARC® Modular System
# Physician's Guide


#10852 rA

# Copyright, Technical Support, Trademark, and Contact Information

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# 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 Platform® (K152491), a web-based remote server software with proprietary algorithms for analysis, using the MoMe® Device Communications Protocol. MoMe 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 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 for the monitoring of patients with suspected arrhythmias and when connected to the MoMe Platform® has detailed reporting available for the following four cardiac monitoring tests:

- Holter (24-48 Hrs.)
- Event Monitoring
- Mobile Cardiac Telemetry (MCT)
- 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 they are 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 versatile device that can perform Holter, Extended Holter, Event, and MCT in a single monitor, eliminating the need for individual test monitors.
- 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:

- 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.
  - A wearable sensor that can be used in the following configurations:
    - 2 color-coded lead wires, sensor cradle and off-the-shelf electrode gel pads, attached to the patient's torso.
    - A wearable adhesive patch cradle that the sensor connects to for single lead ECG data collection.
  - A charging Cradle for charging of the sensor.
  - A charging cable and adapter for the Gateway.
- Clinical review and reporting software: MoMe ARC® is intended to be used with the InfoBionic MoMe Platform® (K152491).

## 1.3. Indications

MoMe ARC® is indicated for use on:

- Patients who experience transient symptoms that may suggest cardiac arrhythmia.
- Patients who require monitoring of the effects of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation).
- 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).
- Patients recovering from cardiac surgery or interventional procedures that are indicated for outpatient arrhythmia monitoring.
- 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:

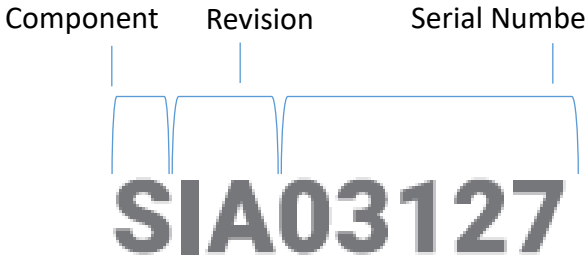
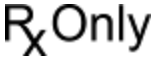
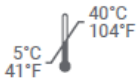
- Detection or notification of hemodynamically unstable or life-threatening arrhythmias or cardiac events requiring urgent medical response.
- Patients at elevated risk of serious cardiovascular events that would require prompt intervention.
- Monitoring patients during cardiac rehabilitation outside of healthcare facilities.

Note: MoMe ARC® does not provide interpretive statements. Interpretation and diagnosis are the responsibility of a physician.

## 1.5. Symbols

These symbols are found on the MoMe ARC® labels, which are the back of the sensorand charging dock.

Table 1 Symbols

| | |
|---|---|
|  | Manufacturer Name and Address |
|  | Sensor is 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<br><br>Component = C for charger, S for sensor, G for Gateway<br><br>Revision = 2-character revision identifier<br><br>Serial number = 5-digit serial number |
|  | Ingress Protection Rating 22 |
|  | UDI Symbol |
|  | Prescription use only |
|  | Magnetic Resonance (MR) Unsafe |
|  | Storage Temperature limits |
|  | Lot Number |

| | |
|---|---|
|  | Single Use Only |
|  2025-01-17 | Expiration Date |
|  | Keep Packaging dry |

## 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 it 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 displaying an indication on the Gateway screen that the sensor and the Gateway are not connected.

MoMe ARC® also requires a cellular network or Wi-Fi connection to transmit its data to the Managed Service Provider (MSP) for arrythmia analysis. When the device is out of cellular coverage, and if not connected to Wi-Fi, ECG data continues to be collected and stored. All stored data is transmitted to the MSP when cellular coverage or Wi-Fi 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.

The device is designed to continuously seek cellular coverage as its primary mode of connectivity. Wi-Fi is available as a secondary option, and its ability to be enabled can be discussed with patient provider at time of hook-up, particularly when a patient is at home and experiencing poor cellular coverage. However, Wi-Fi connections may also encounter transmission delays. Like cellular connections, InfoBionic has no control over the connectivity to a Wi-Fi network. Transmission delays may occur due to slow Wi-Fi connections or loss of Wi-Fi connectivity, especially in the presence of

poor or lost cellular coverage. This setting must be enabled by a Practice Administrator and communication with a Patient must occur for Wi-Fi to be enabled as a secondary option.

## 1.8. 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 screen 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 continue to display "Monitoring" on the home screen. If the technician or patient suspects no or poor cell coverage they can utilize the "Sync to MoMe" feature to confirm Connection or Connection Failed.

On initiation of service, verify that the device displays "Monitoring" in the patient's 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®.

## 1.9. MoMe® Software Platform Indicators

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

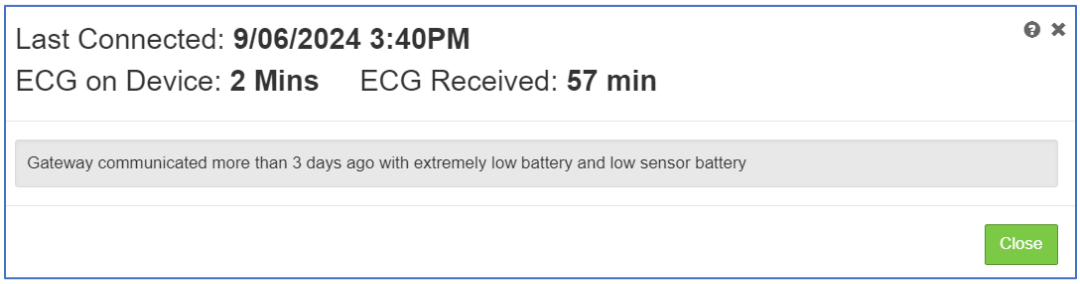



**Figure 1 Device Status**

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

Possible causes are:

- Patient is non-compliant and is not wearing the device.
- Battery has depleted.
- Patient does not have coverage in their location.
- Cybersecurity event.

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

## 1.10. Cybersecurity

The MoMe ARC® employs multiple cybersecurity mechanisms to ensure secure storage and transmission of data to the MoMe® Software Platform.

MoMe ARC® requires no user action to enable or maintain the cybersecurity protections. These protections include, but are not limited to, industry standard encryption, secure pairing of devices to each other and the patient, and continuous threat detection and monitoring at the MoMe Software platform.

InfoBionic regularly reviews emerging cybersecurity risks and provides software updates if warranted.

# 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:** 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 used in the WLS configuration 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:** MoMe ARC® Patch may cause skin irritation or breakdown. Please inform a staff member if you have any known skin sensitivities to adhesives and/or experience any adverse reactions while wearing the MoMe ARC® Patch.
- **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 is restored and then send the stored data.
- MoMe ARC Gateway device is not a cellphone and cannot make outgoing or emergency calls.
- 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.
- 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 the device with cleaners or other liquids.
  - Never bathe, shower, or swim while wearing the MoMe® ARC Device in the WLS configuration (while bathing or swimming, store MoMe ARC® WLS equipment in a safe, dry location).
  - For the MoMe ARC® Patch patient should remove the Sensor prior to showering, or shower with their back to the spray to not get the patch and Sensor wet.
- 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 41°F (5°C) or above 113°F (45°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.

# 3. Specifications and Components

## 3.1. Sensor Specifications

Table 2 Sensor Specifications

| Specification | MoMe® ARC |
|---|---|
| Battery Life | ≥ 3 days before needing to be charged |
| Operating Temperature | 5°C to 45°C |
| Storage Temperature | -25°C to 50°C |
| Operating Humidity | 15% to 93% non-condensing |
| Storage Humidity | 15% to 93% non-condensing |
| Patch Packaging Storage Temperature | 5°C to 40°C |
| Operating Pressure | 700 hPa to 1060 hPa |
| ECG<br>Sampling Rate<br>Digital Resolution<br>Input Dynamic Range<br>Input Offset Dynamic Range<br>Bandwidth | <br>200 Hz<br>3.06 uV<br>+/- 6.27 mV<br>+/- 300 mV<br>0.5 Hz to 40 Hz |
| Input Impedance<br>Peak current injection<br>RMS current injection | > 3 MOhm<br>24 nA (Lead off circuit) DC<br>29 microA |
| Data Storage Capacity (Sensor) | 14 days |
| Dimensions | 59 mm x 39 mm x 11 mm |
| Weight | 22 g |
| Ingress Protection Rating | IP22 |
| Battery | Internal Li-Ion 240mAh battery pack |
| Charger Dock Power Supply | 5V DC 2.4A, 12W |

## 3.2. Gateway Hardware Requirements

| Specification | MoMe® Arc |
|---|---|
| Operating System | Android Enterprise |
| Communication Means | Cellular: 4G LTE<br>Wi-Fi 802.11 a/b/g/n/ac, 2.4GHz, 5GHz<br>Bluetooth 5.1 |
| Battery Life | ≥ 24 hours under nominal operating conditions using the MoMe Mobile App |
| Charging | USB Type C Charging |
| Minimum Processor Speed | 1.4 GHz |
| Memory | Minimum RAM: 3GB, Minimum Storage 32GB |
| Display | Touchscreen display |
| Data Storage Capacity | Minimum 30 days |
| Display | Type: AMOLED, Size: 1.4" Diameter |
| Certifications | FCC, CE, UKCA, PTCRB<br>Google Play Protect Certified |

| Specification | MoMe® Arc |
|---|---|
| Android EMM features | Zero-Touch Enrollment<br>OEMConfig |

The only OTS device currently approved by InfoBionic is the Social Mobile Rhino C6D.

## 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.

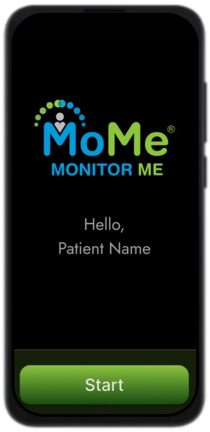
Devices should only be used if fully functional and in working condition. InfoBionic provides a recycling platform through "Recycle Me" where devices can be returned to InfoBionic if they have reached their service life expiration or are no longer in working condition.

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

## 3.4. MoMe ARC® Kit Components

Table 3 MoMe ARC® Kit (Model Number 32000) Components

| Part # | Qty | Name | Description |
|---|---|---|---|
| 32100 | 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. |
| 30750 | 1 | MoMe ARC® Sensor | Small lightweight battery-operated device that can be integrated into a cradle designed to securely hold the sensor and collect, store and transmit physiological data to the Gateway. Can be used in either single lead or WLS configuration. |
| 30570 | 1 | MoMe ARC® WLS Lead Set | If prescribed in this configuration, a two-wire, color-coded patient lead set, with one wire integrated into a cradle designed to securely hold the sensor. This lead set is designed to connect to standard, off-the-shelf electrodes for application to the patient's body, facilitating accurate physiological data collection. |
| 30560 | X | MoMe ARC® Patch Cradles | Provided by Physician if prescribed in this configuration. The Sensor connects to the patch cradle, facilitating single lead ECG collection. Patch Cradles are single use only. Do not reuse. Ensure proper attachment and secure Sensor connection for accurate readings. Quantity provided will be determined by your Physician. |
| 32600 | 1 | MoMe Sensor Charger Cradle | Used to charge the MoMe ARC® Sensor |
| 3060B | 1 | Cradle and charger power adapter. Model HDP12-MD05024U | Used to connect the charger cradle to the wall outlet and to charge the Gateway. |
| 30702 | 1 | Charging Power Cord | USB-C for connecting power adapter to Charger cradle and Gateway |
| 32901 | 1 | Gateway Cover | Protective cover for Gateway |
| 32816 | 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 |

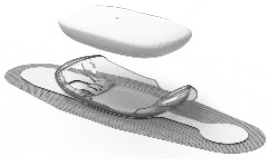



Gateway

Sensor + WLS Lead set

Sensor Charger Cradle

Charging Block



Sensor + Patch

**Figure 2 MoMe ARC® Kit All Possible Configurations**

**IMPORTANT: Only one type of lead set configuration is worn by a patient at a given time.**

# Device Configuration, Patient Setup and Monitoring

For the WLS configuration, the wearable MoMe ARC® Sensor continuously collects and stores ECG data through three color-electrode connections, color coded and labeled RA, LA and LL. For the patch configuration the MoMe ARC® Sensor collects and stores single-lead ECG data through the adhesive patch cradle worn by 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. As a secondary mode of connectivity, the device can connect to a secure Wi-Fi network at the Patient's residence or Medical Facility. If Wi-Fi communication is interrupted (i.e. patient goes out of range or the network goes down), the device will still always seek cellular communication, but if cellular communication is also poor or absent the device will continue to store until connection is regained.

MoMe ARC® supports patient self-reporting of cardiac symptoms by sliding the "Record Event" button on the MoMe ARC® Gateway. The patient will then choose from an available list of symptoms to indicate the experienced symptom at the time the button was pushed. If no symptom is selected, but the "Record Event" button is activated, a generic "Symptom" will be sent to the MSP.

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

## 3.5. Initial Patient Setup for WLS Configuration

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 electrode pads as instructed by the physician.

### Step 1: MoMe Device Assignment

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

### Step 2: Locate the kit components and ensure contents includes:

- 1 Carry Case
- 1 Wearable MoMe ARC® Sensor and Gateway
- 1 Charger Cradle for the MoMe ARC® Sensor
- 1 MoMe Gateway Cover
- 1 USB-C charging cable and adapter for Gateway and charging cradle
- 1 MoMe ARC® WLS Lead Set

**IMPORTANT:** Fully charge the MoMe ARC® before patient setup.
Inspect all parts before use and make sure that nothing is damaged or missing.

### Step 3: Prepare the Skin

Follow the electrode manufacturer instructions for skin preparation OR use the following procedure:

a) Application sites must be clean, dry, and free of any body lotions. Electrode sites should be cleaned with soap and water. Cleaning with isopropyl alcohol should be avoided or limited to situations in which electrode adhesion is an issue (excessively oily or lotion covered skin). If alcohol is used, allow it to dry prior to skin abrasion.

b) Remove excessive hair.

c) Abrading the skin with an ECG abrading prep pad may increase signal quality and reduce artifact in some patients. If you wish the patient to abrade skin when replacing electrodes, please provide ECG abrading prep pads and instruct the patient on how to follow the manufacturers recommended abrading procedure.

## Step 4: Apply Gel Electrodes to Patient's Chest and Connect Electrode Wires

a) Locate the orientation labels on the sensor and insert the sensor into the RA cradle as shown below.

b) Snap the gel electrode into the RA cradle and apply it to the patient's chest as indicated (Figure 1).

c) Apply the remaining two (2) gel electrode to the patient's chest as indicated (Figure 2).

d) Snap MoMe ARC® color-coded electrode snaps onto the appropriate gel electrode.

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

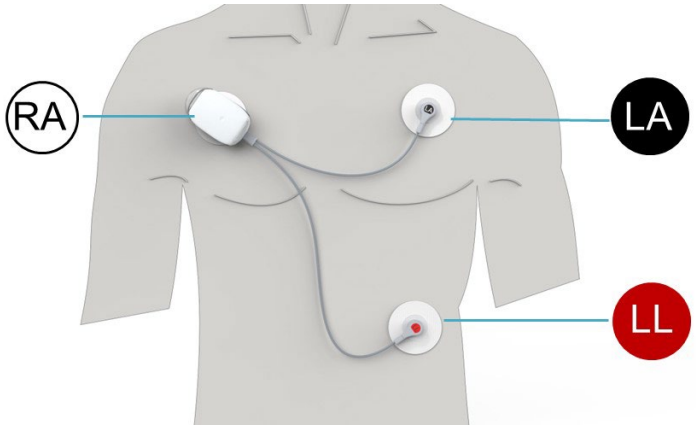



**Figure 3 Electrode Placement Locations**

## 3.6. Patient Monitoring and Responsibilities

Once activated and operating normally, the system requires no patient intervention to capture or analyze data; however, patients should be instructed to slide the "Record Event" on the home screen to trigger an event if any symptoms occur during monitoring.

Instruct the patient about their responsibilities including:

- How to disconnect and reconnect MoMe ARC® Sensor when bathing.
- Charging the MoMe ARC® Gateway and Sensor.
- Always Keeping the MoMe ARC® Gateway near them.
- Initiating a symptom capture and selecting from listed symptoms.
- Changing the disposable gel electrodes.
- Return the system to the practice at the end of monitoring.

## 3.7. Initial Patient Setup for Patch Configuration

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 or as needed), charging the MoMe ARC® and changing the single-use patch as instructed by the physician.

### Step 1: MoMe Device Assignment

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

### Step 2: Locate the kit components and ensure contents includes:

- 1 Carry Case
- 1 MoMe ARC® Sensor
- 1 Gateway
- 1 Charger cradle for the MoMe ARC® Sensor
- 1 MoMe Gateway Cover
- MoMe ARC® Single Lead patches
- 1 USB-C charging cable and adaptor for Gateway and charging cradle

**IMPORTANT:** Fully charge the MoMe ARC® Sensor before patient setup.
Inspect all parts before use and make sure that nothing is damaged or missing.

### Step 3: Prepare the Skin

a) Prepare the skin:
   - Identify placement of electrodes as shown in the image below, or as directed by your provider.
   - If hair is present, remove the hair at the electrode positions.
   - Skin should be cleaned with soap and water. Ensure the skin is clean and free of any lotions. Allow skin to dry before placing electrodes.
   - Follow any other skin preparation instructions recommended by your provider.

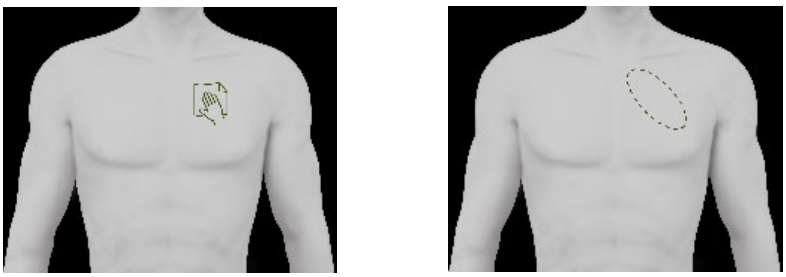


**Figure 4 Skin Preparation**

## Step 4: Apply the Patch and Sensor to the Patient's Chest

Proper placement of the MoMe ARC® 1-Lead Patch is critical to ensuring the cleanest signal transmission possible. The patch should be placed on the left side of the patient's torso with the section of the patch placed directly below to the subclavicular notch. The guideline printed on the round section should be completely vertical with the Sensor cradle pointing down and to the patient's left side.

a) Remove the backing of the patch being careful not to allow the patch to stick to itself, or anything else in the vicinity of the patient.

b) The patch should be placed on the left side of the torso with the **Round** electrode of the patch placed directly below the sub clavicular notch. The **Guide Line** printed on the round section should be completely vertical. The patch cradle should be pointing down and to the left side.

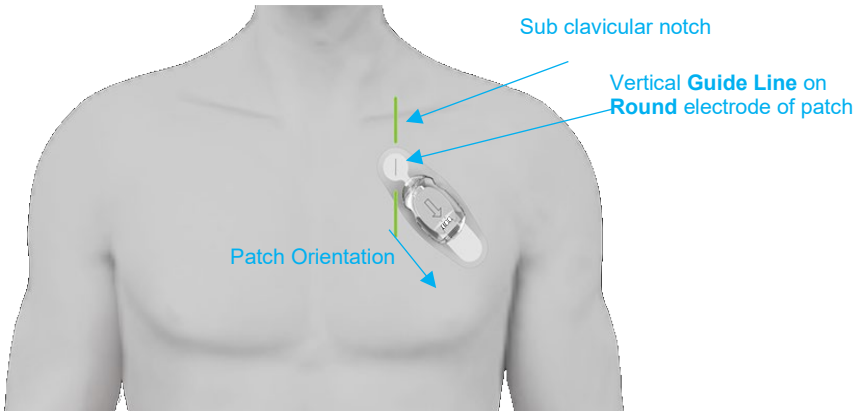



**Figure 5 Patch Placement**

c) Firmly press on the patch to smooth out the adhesive to the skin to remove any air bubbles under the patch and to allow the adhesive to completely adhere to the skin.

d) Once the patch is on, place the Sensor into the cradle. Align the arrow in the Sensor cradle with the arrow on the Sensor and slide the bottom portion of the Sensor into place. There will be a "click" as the Sensor seats into the cradle.


**Figure 6 Sensor Arrow Alignment for Placement into Cradle**

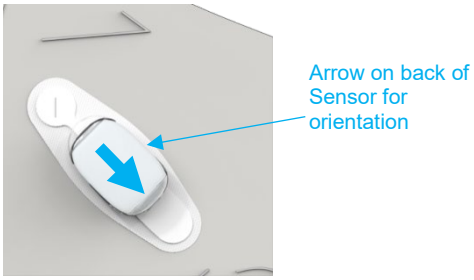



**Figure 7 Sensor Placement into Patch from View of Facing the Patient**

## 3.8. Patient Monitoring and Responsibilities

Once activated and operating normally the system requires no patient intervention to capture or analyze data, however, patients should be instructed to slide the "Record Event" on the home screen to trigger an event if any symptoms occur during monitoring.

Instruct the patient about their responsibilities including:

- Patient should remove sensor prior to showering, or shower with their back to the spray to not get the patch and sensor wet. Charging the MoMe ARC® Gateway and Sensor.
- Keeping the MoMe ARC® Gateway near them at all times.
- Initiating symptom capture and selecting from listed symptoms.
- Removal of the patch.
- Return the system to the practice at the end of monitoring.

# 4. Patch Removal

Once the monitoring study has concluded, the sensor and patch can be removed with the following instructions.

a) Remove the sensor from the cradle by holding the sides of the sensor and pulling back on the top tab of the cradle. The sensor should pop out.
b) The patch can be removed by gently pulling it off the patient's skin. If the adhesive is strongly attached or there is difficulty removing the patch contact your provider.
c) Return the sensor and remainder of the MoMe ARC® kit to the practice staff for data retrieval.
d) The patch should then be discarded.

# 5. Device Controls and User Interface

The MoMe ARC® Gateway has a touchscreen display for controlling the device and three side buttons, 2 to control volume, and 1 to wake the screen, or power on the device.

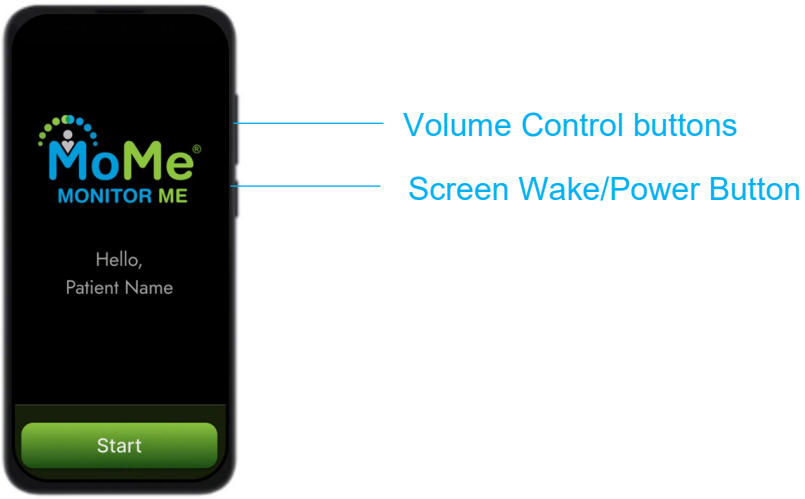



**Figure 8 Gateway Device**

After the device has been assigned to a patient the **Start** button will appear with the patient's name within 10 minutes. Verify that the patient's name appears correct. The device is now ready to ship or be hooked up to a patient.

- If shipping directly to a patient **do not press Start**.
- If hooking up directly to a patient **press Start**. After instructional screens appear the device will display the **Monitoring** screen. If the patient's name is not displayed, please refer to the **MoMe® Software Platform Instructions For Use** for instructions.

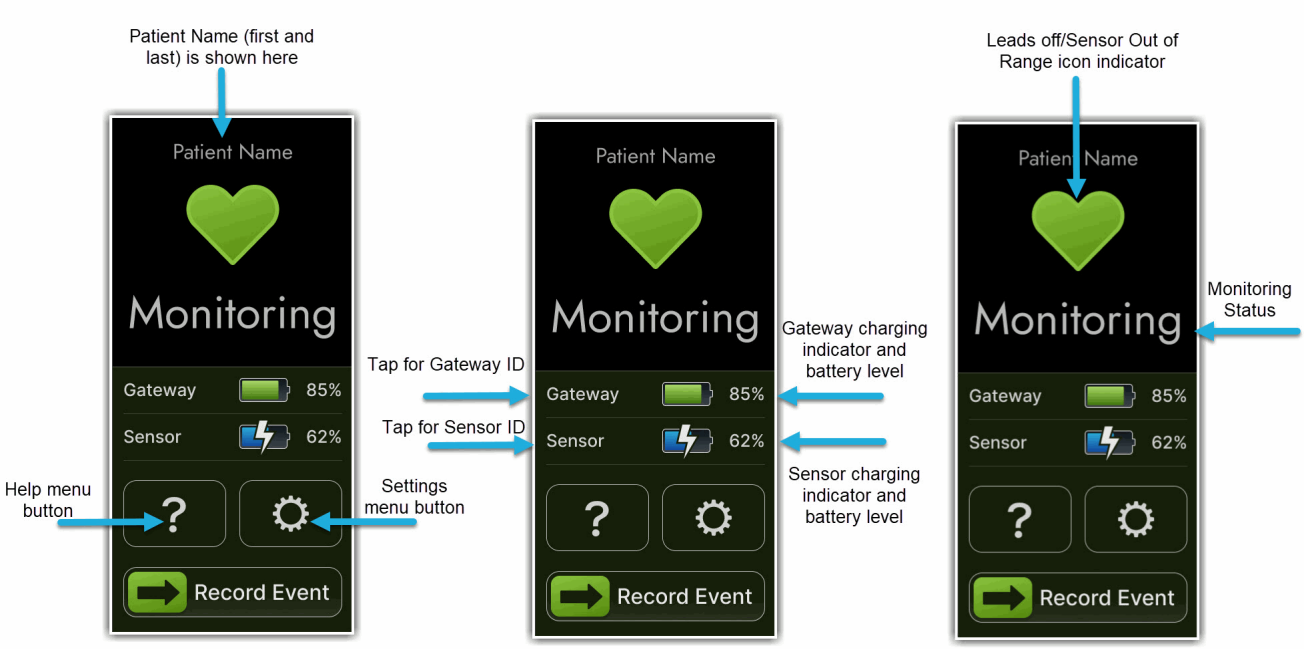



**Figure 9 Device Screens**

## 5.1. Event Record Button - Reporting Cardiac Symptoms

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

a) Patients should be instructed to **slide** the **Record Event** button.

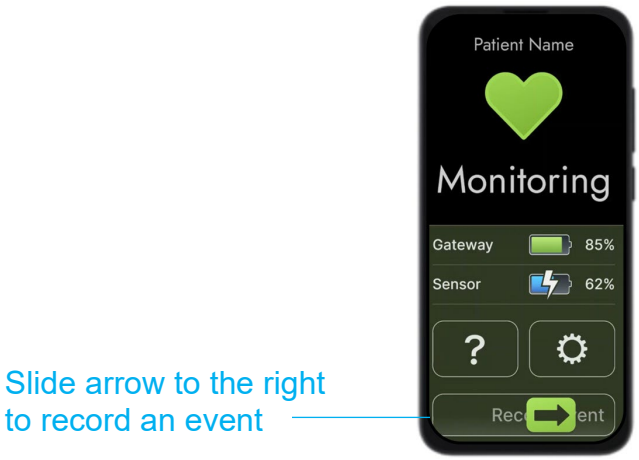



**Figure 10 Record Event**

b) The **My Symptoms** screen is displayed.

- Selecting **symptoms** with the checkboxes will submit symptom(s) with the event. Multiple symptoms can be selected to send with the event.
- Selecting **no symptoms and Submit** will send no symptoms with the event.

- Once all symptoms are checked select **Submit**.
- The MoMe® Software System will indicate that a patient symptomatic event has been generated.

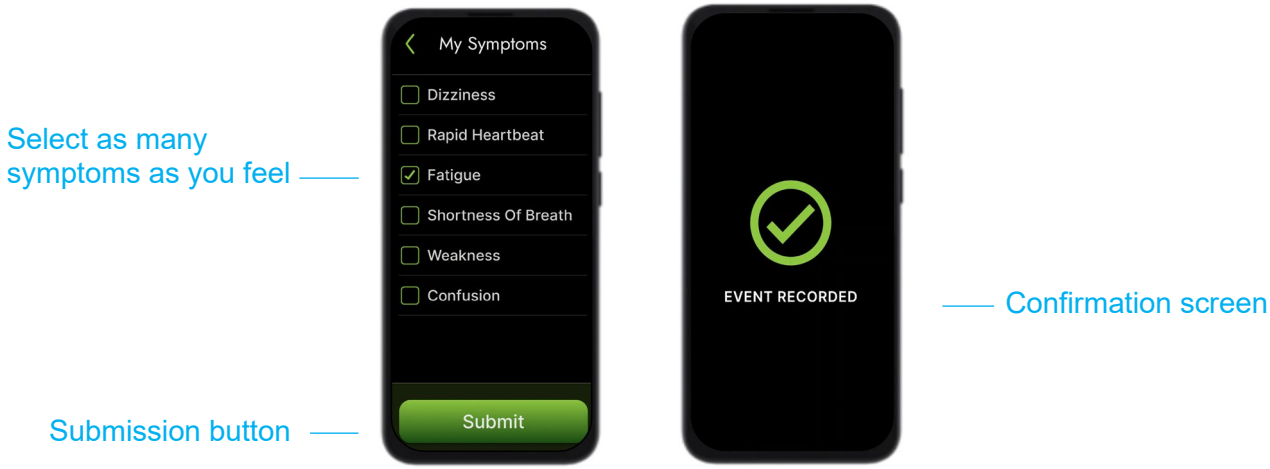



**Figure 11 Monitoring Screen**

## 5.2. Monitoring / Recording

When the Sensor is within range of the Gateway the main screen will display **Monitoring** indicating data is being transmitted to your provider.

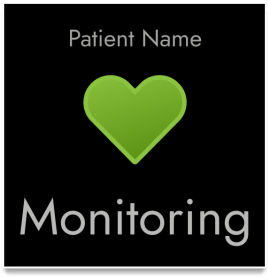



**Figure 12 Monitoring Screen**

When the Sensor is out of range of the Gateway the main screen will display **Recording** indicating data is being saved on the Sensor and will transmit to the MoMe® system once the Sensor is back in range of the Gateway. If out of range greater than 10 minutes the heart will show gray in color and the Sensor battery status will change to "Out of Range" indicating it hasn't had recent communication with the Gateway.

**Note: If the sensor is out of range for an extended period bring them back in range of each other and monitor screen to turn back to "Monitoring."**

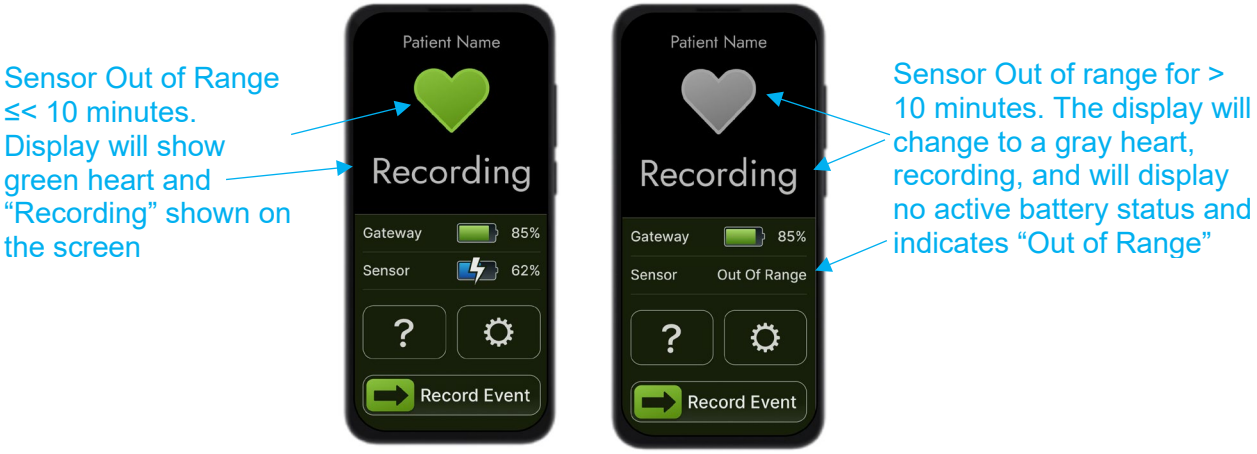



**Figure 13 Recording Screens**

## 5.3. Adjust Volume

a) To adjust the volume, use the buttons on the right of the device. A volume indicator menu will appear showing what level it is at.

Available settings are:

- Silent
- Vibration Only
- Volume on levels 1-5


**Figure 14 Adjust Volume**

b) To adjust the press the up and down buttons on the right side of the device. Available settings are: Silent, Vibration Only, or Volume on levels 1-5.

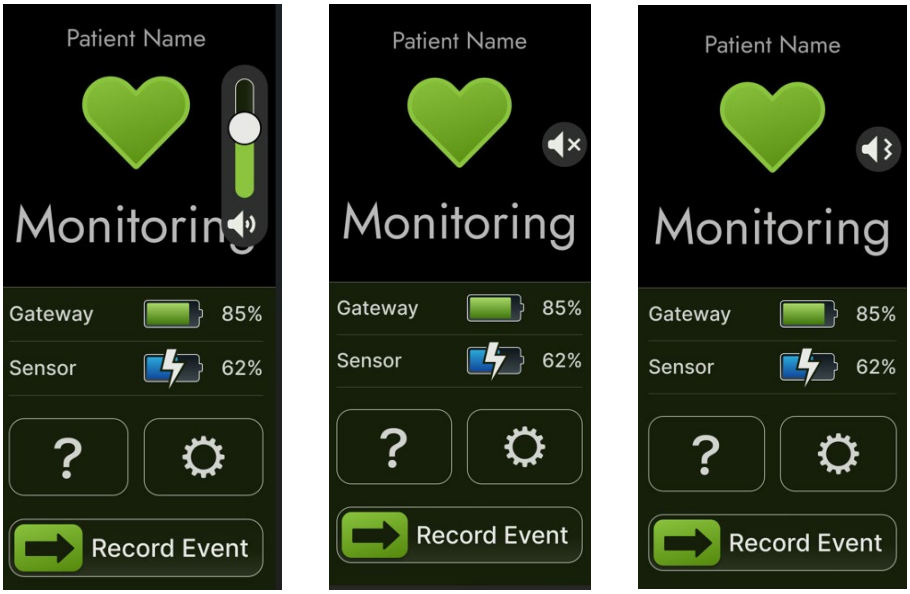



**Figure 15 Volume Settings**

## 5.4. Battery Status

The main screen always displays the battery status of both the Gateway and the Sensor. Selecting each one will display the battery status as well as device ID.

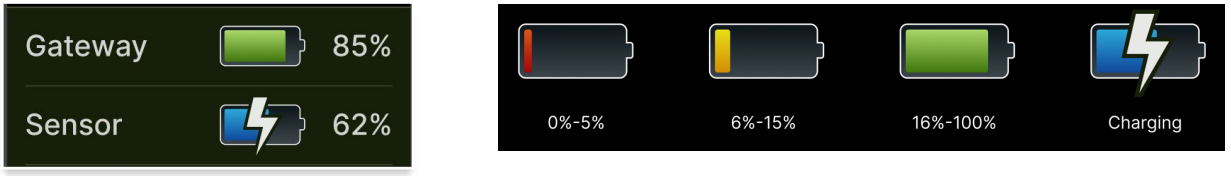



**Figure 16 Battery Status**

## 5.5. Airplane Mode

This device does not have Airplane Mode. Please turn off the device when traveling or whenever Airplane Mode is required.

Ensure the Sensor is within in range. To turn off the device select the **Settings** menu and select **Power Off**. The Sensor will continue to collect data.

To power **ON** device when Airplane Mode is no longer required, hold down the wake button on the side of the phone until phone turns on.

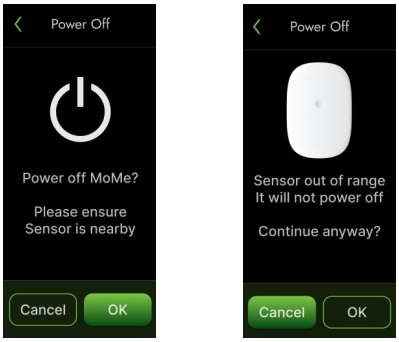



**Figure 17 Power Off**

## 5.6. Wi-Fi Configuration

Wi-Fi configuration may be used in the case of no cellular connection. If this secondary form of communication is desired, contact and instruct the patient with the below instructions on how to configure a Wi-Fi connection. The cellular connection will still be used when the patient is out of Wi-Fi range.

To connect to Wi-Fi:

a) Navigate to the **Settings** Screen and select **WiFi**.

b) Select the private network you wish to connect to. The list is sorted by signal strength, so it is likely the top one is the place of residence WiFi network.

c) Enter in the private network password and select **Connect**.


**Figure 18 Wi-Fi Screens**

d) The device will then try to connect to the network and sync to the MoMe portal. If connection is a success the user will see a green checkmark and "Connected."

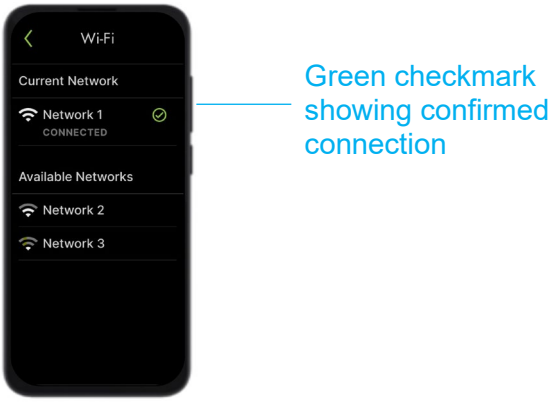



**Figure 19 Wi-Fi Connected**

If connection fails, a **Connection Failed** message will appear. Please try connection again if this occurs by selecting **Refresh**. This can be for several reasons: incorrect password, poor connection, no internet, but due to security reasons the only message that will display is connection failed. If issues persist, please contact InfoBionic Representative for more information.

**Note:** Wi-Fi connection is dependent on being in range and connected to a secure network and the signal strength of the network. There could be times there is a delay in signal transmissions if cellular coverage is poor so Wi-Fi is being used as the connection mode in these cases there can also be a delay in transmissions if Wi-Fi becomes disconnected and/or is a poor connection. The sensor will continue to collect and store data and send it to the Gateway and the Gateway will send stored data when either cellular coverage or Wi-Fi connection is reconnected. InfoBionic and MoMe does not store and cannot view users Wi-Fi connection or passwords.

# 6. Device Alerts

## 6.1. Low Battery Alert

When the battery is low for either Sensor or Gateway, the patient will be notified on the Gateway with audio and visual indicators (per the current volume level). Alert will repeat approximately every 3 minutes until resolved (up to 5 alerts).


**Figure 20 Battery Low Indicator**

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

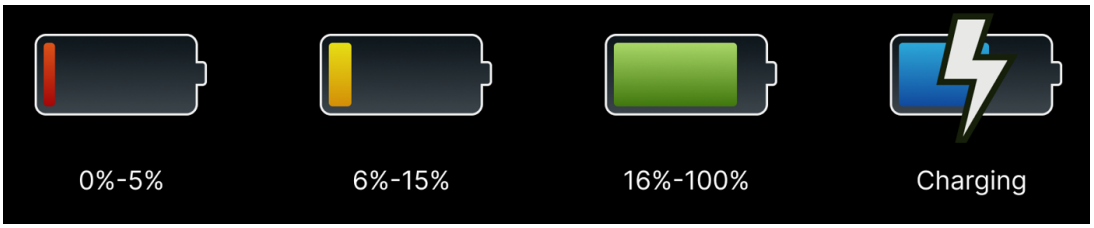



**Figure 21 Battery Percentages**

## 6.2. Leads Off Alert

When it is detected that one or more leads for the WLS configuration have become detached from the body, the patient will be notified with audio and visual indicators (per the current volume level). Alert will repeat approximately every 3 minutes until resolved (up to 5 alerts). The same notification for the patch will occur if the patch detects poor contact with the skin or the sensor is removed from the patch cradle.

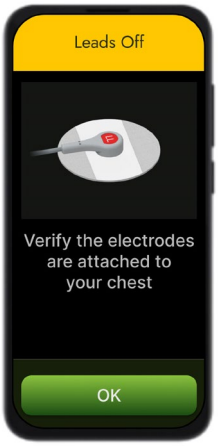



**Figure 22 Leads Off Alert**

## 6.3. Sensor Disconnected Alert

If the Sensor disconnects from the Gateway (goes out of range) this screen will be displayed on the Gateway. The Sensor should be brought back to the Gateway to reconnect. Alert will repeat approximately every 3 minutes until resolved (up to 5 alerts).

**Note:** The Sensor will continue to store all data while disconnected and will transmit it to the MoMe system when it reconnects. If this error persists when the Sensor is paired with the Gateway, please call your provider for assistance.


**Figure 23 Sensor Disconnected**

## 6.4. LED Indicators

The sensor has a single LED indicator.

- LED is off during normal use.
- LED blinks green (one series) when Bluetooth® connection is established.
- LED blinks red (continuous) in case of system error.
- LED blinks blue (one series) when a new Bluetooth® Low Energy connection is established.
- LED blinks purple (continuous) when Sensor is being identified by the Gateway this occurs in the "Find my Sensor" use case.

# 7. Charging the MoMe ARC® Gateway and Sensor

Instruct the patient to charge Gateway and sensor periodically or when a low battery alert occurs. To charge the sensor, detach the WLS lead set and sensor from the body. While holding the base of the sensor where the wires extend, apply light pressure to the thumb tab on the cradle until the sensor releases. Instruct the patient to refer to the Patient Guide and demonstrate for them at time of service. Place the sensor in the charging cradle and charge until LED indicator and Gateway screen shows sufficient charge. When complete, reapply using the patient visual guide.

## 7.1. Charging the Gateway

Use the provided power adapter and USB cable to charge the Gateway.


**Figure 24 Gateway Charging**

## 7.2. Charging the Sensor

If a low battery alert for the sensor occurs, place the Sensor in the provided charging cradle and plug charging cradle into wall outlet using provided adaptor and USB cable.

**Figure 25 Sensor Charging**

The Sensor takes approximately 1.5 hours to fully charge from full depletion. The Gateway will indicate the Sensor is charging when viewing the battery status. See Battery Status on Page 28.

Once charged, the Sensor can be placed back into the lead set cradle and worn.

## 8. Help Menu

The **Help** menu displays information screens about the MoMe ARC® System. To access the help screens, select the question mark option on the main Monitoring screen.

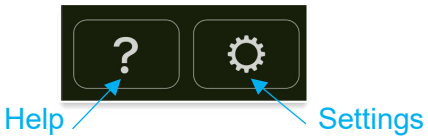



**Figure 26 Help Settings Menu**

## 9. Power On and Off

The device can be powered off for inactive service periods.

To power off the device select the **Settings** menu option and select **Power Off** then select **OK** to power off the device. The Gateway will check to make sure sensor is in range to power off the sensor first then the device. Note: If the sensor is out of range, it will not power off the sensor.

To power **ON** the device, hold down the bottom right wake button until the device powers up.

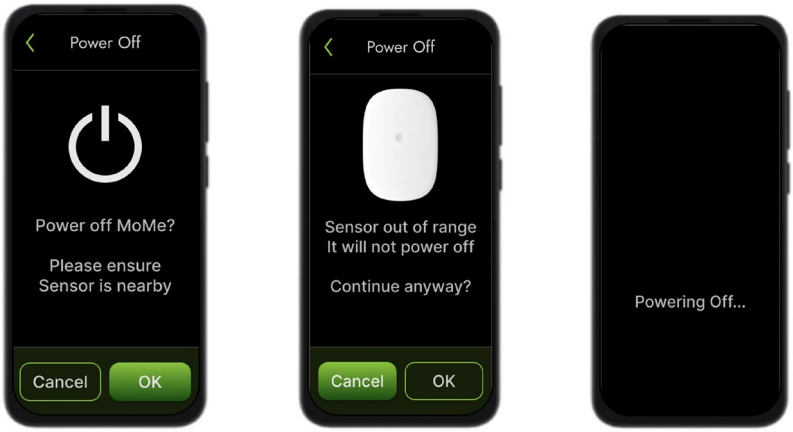



**Figure 27 Settings Power Off**

# 10. Find My Sensor

In the event the sensor cannot be located the Gateway can communicate to the sensor and cause it to vibrate and buzz. To access **Find My Sensor** select the **Settings** menu and select **Find My Sensor**. The sensor will begin to vibrate and buzz and LED will blink purple (if in range).

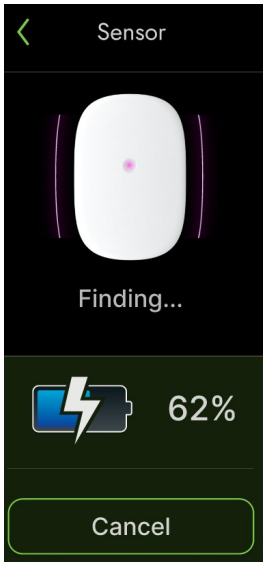



**Figure 28 Find My Sensor**

# 11. Additional Settings

Additional information about the device is located by selecting **Settings** and scrolling to **About**. Selecting **Patient info** or **MoMe Info** will display version and serial numbers.

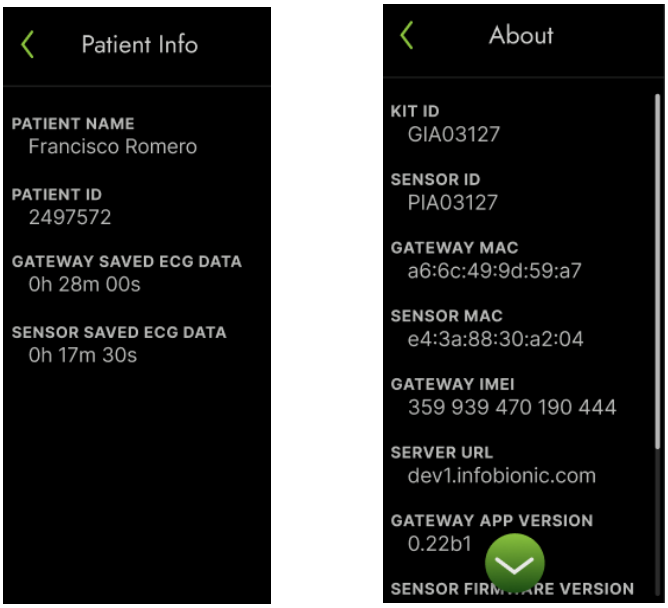



**Figure 29 About and Patient Info**

# 12. Service, Cleaning and Disposal

## 12.1. 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 sensor batteries should be recharged at least once every three months. If the device has been unused for three (3) months, place the sensor on the charger dock until fully charged.

## 12.2. 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.

## 12.3. 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. Dispose used patches consistent with local regulations for medical waste dispose.

## 12.4. Software Updates

Software for the Sensor will periodically update and will display a prompt when available. Device must be in storage mode for software update to occur. When displayed follow prompts to confirm software update.

# 13. 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.

a) 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

b) 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.

## 13.1. 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 internal function. Therefore, the 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. |

## 13.2. 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<br>± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air | ± 8 kV contact<br>± 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<br>100 kHz repetition frequency | ± 2 kV<br>100 kHz repetition frequency | |
| Surge IEC 61000-4-5 | ± 0,5 kV, ± 1 kV line(s) to line(s)<br>± 0,5 kV, ± 1 kV, ± 2 kV lines(s) to earth | ± 0,5 kV, ± 1 kV line(s) to line(s)<br>± 0,5 kV, ± 1 kV, ± 2 kV lines(s) to earth | |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30 A/m g)<br>50 Hz or 60 Hz | 30 A/m g)<br>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. |

| **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** |
| Conducted RF<br>IEC 61000-4-6 | 3 V<br>0.15 MHz - 80 MHz<br><br>6V in ISM and amateur radio bands between 0.15 and 80 MHz | 3 V<br><br>6 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.<br>Recommended Separation Distance:<br><br>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz |
| Radiated RF<br>IEC 61000-4-3 | 10 V/m<br>80% AM @ 1 kHz<br>(Test at 120V, 60 Hz) | 10 V/m | $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz<br><br>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).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br><br>  |
| Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.<br>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.<br><br>[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. | | | |

| **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**<br>W | Separation distance according to frequency of transmitter (m) | | | |
| | **150 kHz to 80 MHz**<br>$d = 1.2\sqrt{P}$ | **80 MHz to 800 MHz**<br>$d = 1.2\sqrt{P}$ | **800 MHz to 2,5 GHz**<br>$d = 2.3\sqrt{P}$ | **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.<br>Note1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.<br>Note 2:These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | | |

## 13.3. 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.

## 13.4. 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.