Cardiac Design Labs

# MIRCaM beatWISE User Manual

Revision No 5.0

Document no: CDL-MCF-S2-UM-5.0

www.cardiacdesignlabs.com

# Revision History

| VERSION | DESCRIPTION OF CHANGE | AUTHOR | DATE |
|---|---|---|---|
| 1.0 | Initial Version | Evangeline Smita | O8/02/2019 |
| 2.0 | Regulatory requirements are addressed in this version | Evangeline Smita | 10/04/2019 |
| 3.0 | Additional regulatory requirements are addressed in this version | Evangeline Smita | 24/05/2019 |
| 3.1 | Result of using any other parts or accessories other than what is supplied with MIRCaM beatWISE system is added in this version | Evangeline Smita | 29/05/2019 |
| 3.2 | Operating Humidity, Labelling information for Humidity limitation, Expected Service life of MIRCaM beat WISE and Notes in Section 3.1.2 and 5.1 are added in this version | Evangeline Smita | 06/06/2019 |
| 3.3 | Addressed additional requirements from the regulatory body | Ankitha Reddy | 05/08/2019 |
| 4.0 | Recording time of the device is changed to 14 days<br>Patient Leakage Current is added in this version<br>Name of the Section 3.3 is changed to “Audible Indications to the User”<br>Steps to calibrate the screen is added in this version<br>Essential Performance of the device is added in this version | Shreya Patted | 17/10/2019 |
| 5.0 | An additional explanation is added in this version | Shreya Patted | 27/05/2020 |

# Review & Approvals

| NAME | DESIGNATION/TITLE | SIGNATURE | DATE |
|---|---|---|---|
| Praveen L Murthy | VP-Production and Engineering | | 27/05/2020 |
| Ajax Thomas | Management Representative | | 27/05/2020 |

# Table of Contents

# 1. User safety Information

MIRCaM beatWISE is a battery operated, wearable device that is designed to continuously record and store ambulatory ECG for up to 14 days, in either 12 or reduced lead configuration.
The device as such does not perform any analysis on the recorded ECG, but the data can be analysed and reported by a trained technician or licensed healthcare practitioner manually using the software application provided with the device.

## 1.1. Indications for Use

MIRCaM beatWISE is indicated for use by qualified medical professionals only, for continuous recording of ECG data of patients in a home and/or clinical environment. It is intended for patients who may benefit from a long-term continuous electrocardiographic (ECG) recording. This is most frequently used for the purpose of prospective and retrospective cardiac data and arrhythmia analysis. Holter analysis is appropriate for the indications below:

- Evaluation of symptoms suggesting arrhythmia or myocardial ischemia
- Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients.
- Evaluation of patients for ST segment changes
- Evaluation of a patient's response after resuming occupational or recreational activities (example, after myocardial infarction or cardiac surgery)
- Clinical and epidemiological research studies
- Reporting of QT interval

## 1.2. Warnings and Cautions


Warning: Describes conditions or actions that can result in personal injury or loss of life.


Caution: Describes conditions or actions that can result in damage to the equipment or loss of data.

***Note***: Provides information to further assist in the use of the device.

### 1.2.1 Warnings:


This manual gives important information about the use and safety of this device. Deviating from operating procedures, misuse or misapplication of the device, or ignoring specifications and recommendations could result in increased risk of harm to users, patients and bystanders, or damage to the device.


Cables present a possible strangulation hazard. To avoid the possibility of a strangulation, ensure the lead wires are positioned properly and routed away from the patient's neck. When not in use, patient cables should be stored after forming them into a loose loop


The device stores data that reflects a patient's physiological condition. This can be reviewed by a trained physician or ECG technician using MIRCaM ECG Viewer - the full disclosure software provided by Cardiac Design Labs (CDL). Although this aids a trained physician or clinician in determining a diagnosis, this data should not be used as a sole means for determining a patient's diagnosis.


Users are expected to be qualified clinical professionals knowledgeable about medical procedures and patient care, and adequately trained in the use of this device. Before attempting to use this device for clinical applications, the operator must read and understand the contents of the user manual and other accompanying documents. Inadequate knowledge or training could result in increased risk of harm to users, patients and bystanders, or damage to the device.


MIRCaM beatWISE system has been tested and found to be compliant with IEC 60601-1, IEC 60601-1-2 and IEC 60601-1-11. It is recommended to use the parts and accessories that are supplied with MIRCaM beatWISE system only. Use of any other parts or accessories may cause increased electromagnetic emissions or decreased electromagnetic immunity and could result in improper operation of the system.


Conductive parts of the patient cable, electrodes, and associated connections of applied parts should not come in contact with any other conductive parts including earth ground.


It is recommended that a certified electrode patch be used to avoid episodes of skin irritation. Proper clinical procedure must be employed to prep the electrode sites and to monitor the patient for excessive skin irritation, inflammation, or other adverse reactions.


ECG electrodes should be changed routinely for recordings extending beyond 24-hour duration, depending on quality and type of electrodes used.


To avoid potential for spread of disease or infection, single-use consumables (e.g., electrodes) must not be reused. To maintain safety and effectiveness, electrodes must not be used beyond their expiration date.


This device is not recommended for use in the presence of imaging equipment such as Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) devices, etc.


The device is restricted to be used on one patient at a time.

 Use of unspecified cleaning/disinfecting agents, failure to follow recommended procedures, or contact with unspecified materials could result in increased risk of harm to users, patients and bystanders, or damage to the device. For general cleaning, refer 5.1 section “Cleaning”.

 Unauthorized modification of the device could result in increased risk of harm to users, patients and bystanders, or damage to the device.

### 1.2.2 Cautions:

 To prevent possible damage to the device, do not use sharp or hard objects to depress buttons. Operate the device using fingertips only.

 The device and patient cable should be cleaned after each use. Do not attempt to clean the device or patient cables by submerging into any liquid, autoclaving, or steam cleaning as this may damage equipment or reduce its usable life.

 Do not sterilize the device or patient cables with Ethylene Oxide (EtO) gas. For general cleaning, refer section 5.1 “Cleaning”

 Do not pull or stretch patient cables as this could result in mechanical and/or electrical failures.

 Do not bathe, swim or shower while wearing the device.

 There is no known safety hazard if pacemakers or other stimulators are used simultaneously with the device. However, disturbance to the signal may occur.

 The quality of the signal produced by the device may be adversely affected by the use of other medical equipment, including but not limited to defibrillators and ultrasound machines.

 The device may be permanently damaged if used along with or in the vicinity of defibrillators

 Operations may be affected in the presence of strong electromagnetic sources such as electrosurgery equipment.


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 [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.


The performance of the device may be affected when patients are in contact with/ or in the vicinity of electromagnetic home appliances like microwave, refrigerators, television, etc.


Patient cables, device clip-locks, device battery doors and the device body should be checked for cracks or breakage prior to use. The LEDs present on the device should also be checked prior to usage. In-case any damage to the mentioned components is noticed, contact CDL Support mentioned under section 5.3 “Helpline and Contact”


The device does not contain any user-serviceable parts. Damaged or suspected inoperative equipment must be immediately removed from use and must be checked/repaired by qualified service personnel prior to continued use.


Use a fresh battery of recommended brand for every new test. Re-use or usage of batteries with lower power capacity can result in premature interruption of an on-going test.


Remove battery when device is not being used for an extended period of time to avoid leakage


The performance of the device may be compromised by excessive movement of the patient.


Acquire the recorded patient data before starting a new test.


At the end of life -dispose the device, its components and accessories and/or packing materials in accordance with local regulations. In situations where it may require a replacement, contact CDL Support under section 5.3 “Helpline and Contact”


To prevent possible damage to the device, the following environmental conditions must be adhered to:

Operating Temperature: **+5 to + 40˚C**

Operating Humidity: **15 to 90% RH**

Storage and Transportation Temperature: -**25 to + 70˚C**

Storage and Transportation Humidity**: 10 to 95% RH**

Ambient Air Pressure: **700 to 1060 hPa**

**If the device is exposed to environment conditions beyond the above mentioned threshold, the device may fail to operate and function as explained under section 2.**

### 1.2.3 Notes:

- Proper patient preparation is important for proper application of ECG electrodes and recording by the device.
- It is the responsibility of the medical facility to provide the patient with instructions during use. Please refer to the section 4.5 in this user manual.
- If the electrode is not properly connected to the patient, or one or more of the patient cable lead wires are disconnected, device will visibly and/or audibly indicate an error in recording status.
- The patient cable life expectancy is six months with continuous use with proper care.
- The device will automatically turn off, if the batteries have been severely discharged.

**No preliminary or ongoing scheduled periodic calibration by the user or CDL personnel is required. The device is designed to contain no elements requiring calibration.**

## 1.3. Device Labelling Information

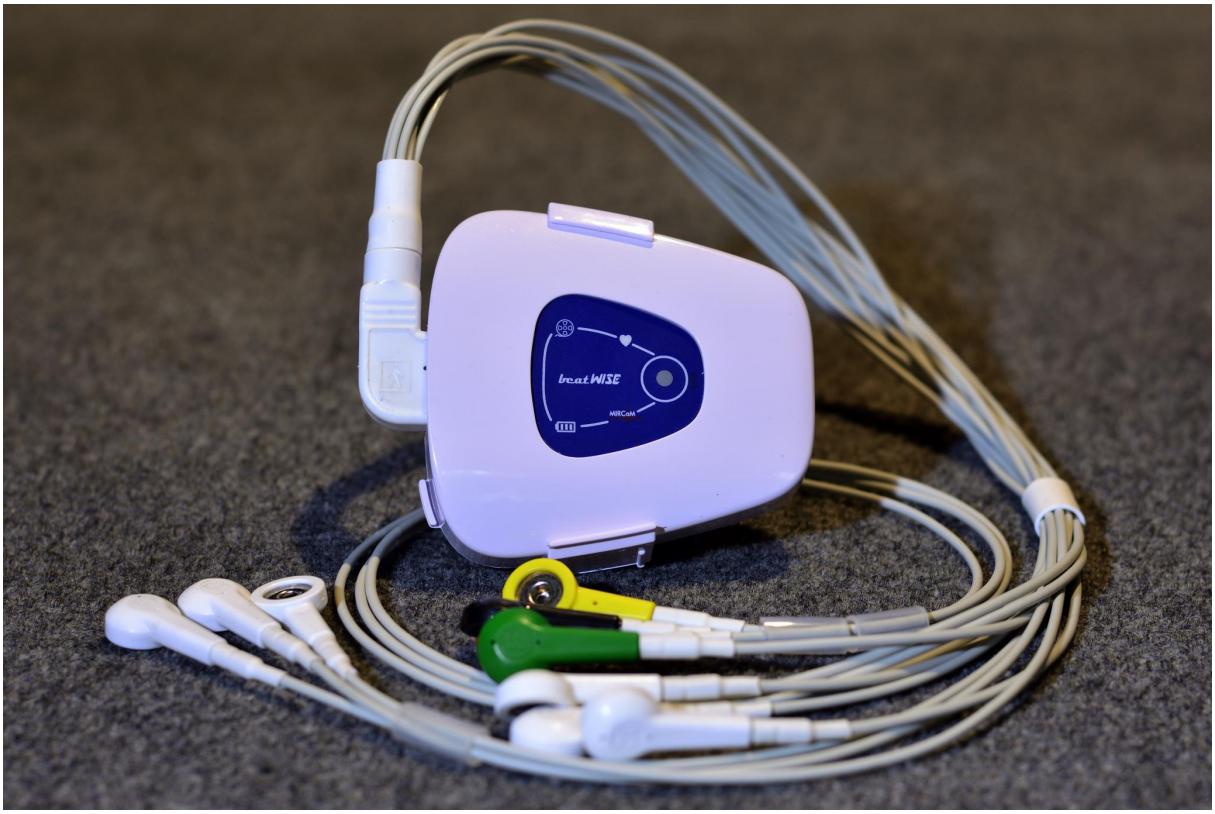

| | |
|---|---|
|  | Warnings.<br>Please refer to section 1.2.1 of this manual for Warnings |
|  | Indicates the serial number of device |

| | |
|---|---|
|  | Indicates the details of the manufacturer and the year of manufacturing |
|  | Indicates that this device is Type BF applied part |
|   | Indicates that this device operates on a single AAA battery, 1.5V DC |
| 17.5 mA/230 mA | 17.5 mA @ 1.5V is the normal operating power consumption<br><br>230 mA @ 1.5V is the Momentary power consumption |
|  | Indicates that this device emits non-ionizing radiation |
|  | Indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment |
| IP22 | Indicates that this device is protected against solid foreign objects of 12.5mm (0.5 in) diameter and greater; And is also protected against vertically falling water drops when enclosure titled up to 15 degree |
|  | Please refer to instruction manual/booklet |

# 2. About MIRCaM beatWISE

## 2.1. Intended Use

MIRCaM beatWISE is intended to be used for continuous ECG recording in either 12 lead or reduced lead configurations. The recorded ECG can be analyzed and reported with separate software applications by a trained technician or licensed healthcare practitioner.




MIRCaM beatWISE

## 2.2. Indications for Use

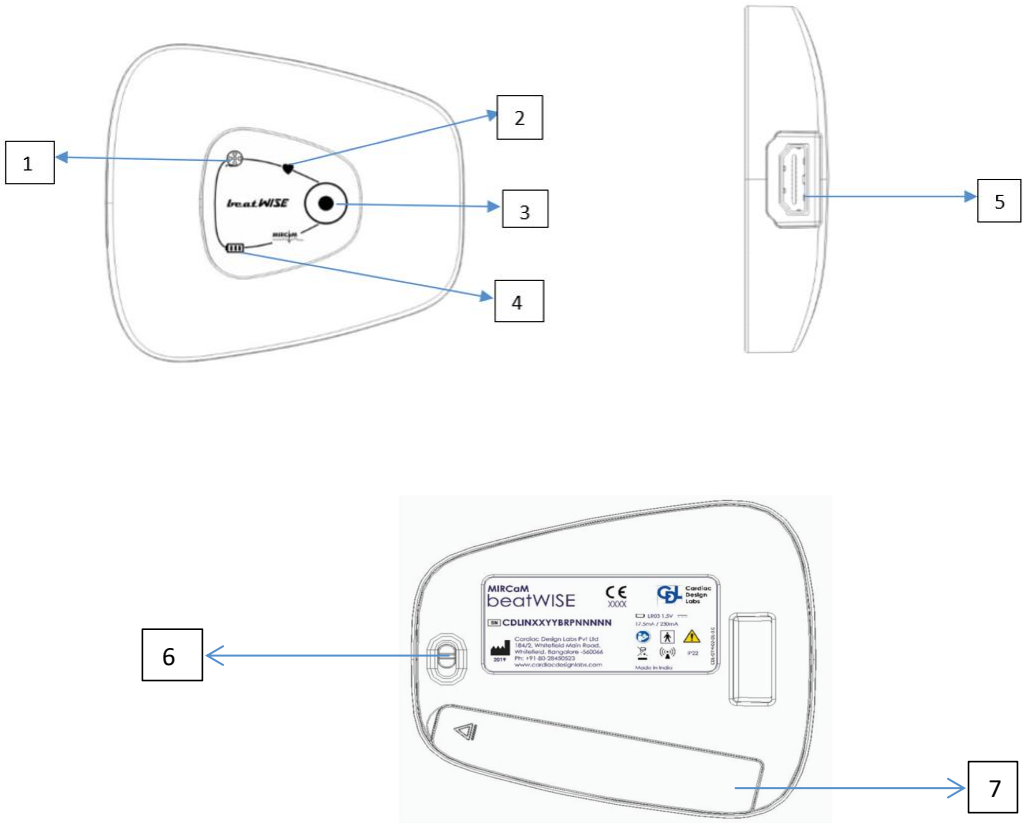
MIRCaM beatWISE is indicated for use by qualified medical professionals only, for continuous recording of ECG data of patients in a home and/or clinical environment. It is intended for patients who may benefit from a long-term continuous electrocardiographic (ECG) recording. Such monitoring is most frequently used for the purpose of prospective and retrospective cardiac data and arrhythmia analysis. Holter analysis is appropriate for the indications below:

- Evaluation of symptoms suggesting arrhythmia or myocardial ischemia
- Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients.
- Evaluation of patients for ST segment changes
- Evaluation of a patient's response after resuming occupational or recreational activities (example, after myocardial infarction or cardiac surgery)
- Clinical and epidemiological research studies
- Reporting of QT interval

## 2.3. Contraindications for use

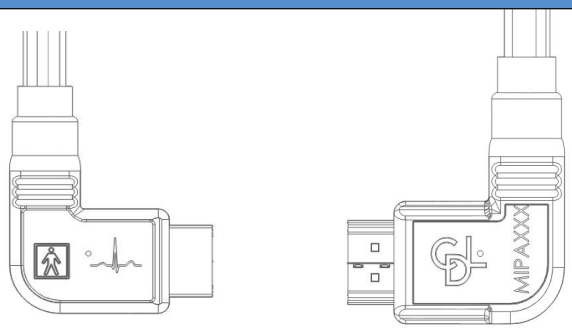
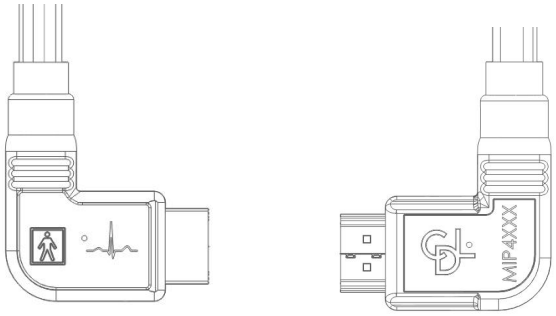
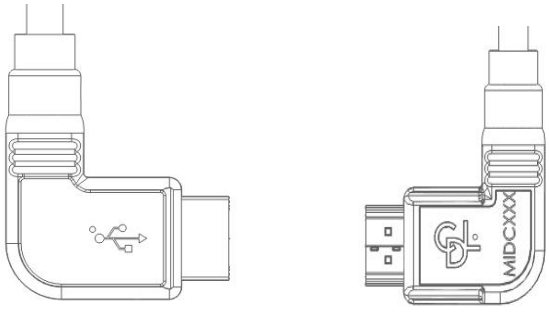
- Liquids must not be allowed to enter the device
- Don't bathe, shower or swim while wearing the device.
- Do not have any X-Ray, MRI or CAT scan tests done while wearing the Holter device
- When wearing the device at night, do not use an electric blanket.
- Do not bring the device near metal detectors.
- Do not tamper with the recorder, electrodes, batteries, or wires.

## 2.4. Part Summary Description




| | Name | Function |
|---|---|---|
| 1 | Recording Status LED | Indicates whether the device is recording or not. |
| 2 | Patient Trigger Indicator LED | Indicates that the patient triggered event has been captured. |
| 3 | Device status button | -When clicked once displays the device status.<br>-When double clicked, registers ECG recording at the instant, as Patient Alert. This is advised to be used when the patient feels any kind of discomfort |
| 4 | Battery status LED | Indicates the status of battery in the device |
| 5 | Cable slot | The patient cable or the data transfer cable should be inserted here. |
| 6 | Power ON/OFF switch | Allows powering on/off the device |

| | | |
|---|---|---|
| 7 | Battery Door | Encloses the battery slot, in which a single LR03/ AAA battery (1.5V) should be inserted |

| Cable description | | Part Number Description |
|---|---|---|
| **12 lead Patient cable** |   | **MIPAxxx** |
| **Reduced Lead Patient Cable** |   | **MIP4xxx** |
| **Data Transfer Cable** |   | **MIDCxxx** |

***NOTE: xxx – Indicates the Batch Code***

# 3. Using the MIRCaM beatWISE

## 3.1. Equipment Overview

### 3.1.1. MIRCaM beatWISE

MIRCaM beatWISE is a battery operated, wearable device that is designed to continuously record and store ambulatory ECG for up to 14 days, in either 12 or reduced lead configuration. The device can be directly connected to a PC hosting MIRCaM ECG Viewer, using the data transfer cable provided by CDL. Using this software, it is possible to start and stop test, and also acquire and view patient data.

The device can run for up to 48 hours on a single AAA alkaline battery and stores recorded ECG data in its on-board memory. It has LED indicators to show device status. There is also a provision for capturing patient triggered events which can be used by patients to register the time period during which the symptomatic events were experienced.

The recording will continue and automatically end when the test duration is completed, after which you can acquire patient data to the PC and view it.

The recorded data will remain in memory even when the battery is removed. The memory is erased/re-written each time a new patient test is started.

### 3.1.2. MIRCaM ECG Viewer

MIRCaM ECG Viewer is the full disclosure software which provides a platform for the entry of patient demographic information, allows for the starting and stopping of a test, as well as acquiring and viewing of patient data.

***NOTE: It is recommended that MIRCaM ECG Viewer be installed only on a Windows 7/10 PC or Desktop as it compatible with only these configurations.***

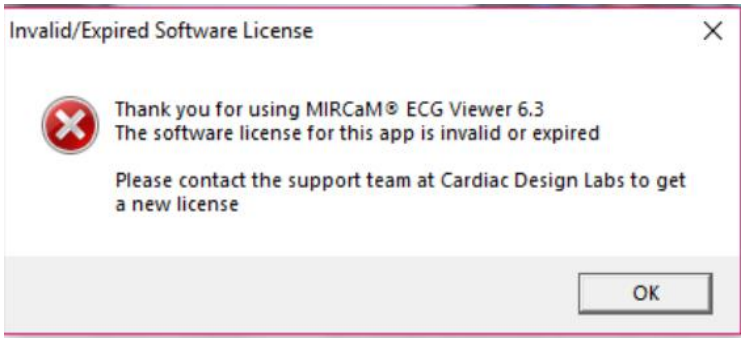
#### 3.1.2.1. SETTING UP MIRCAM ECG VIEWER:

***NOTE: The PC should be connected to the Internet until the entire Set-up of ECG Viewer is complete.***

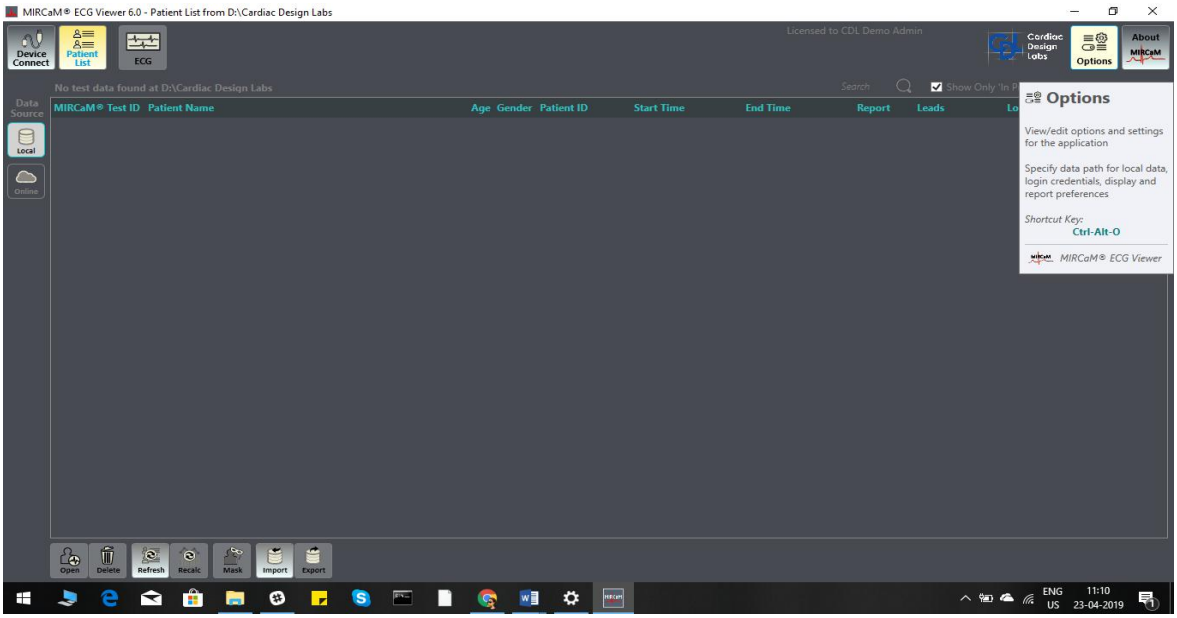
Step 1: Use the set-up file given by CDL only, to install MIRCaM ECG Viewer.
Step 2: Follow the on-screen instructions to complete the installation.
Step 3: Open MIRCaM ECG Viewer by double clicking on the application. By default, the application is saved on the Desktop

Enter the 20-character license key provided by CDL, to validate the software. Click on "Validate License"


When invalid license key is entered, "Invalid/Expired Software License" error message pops up.

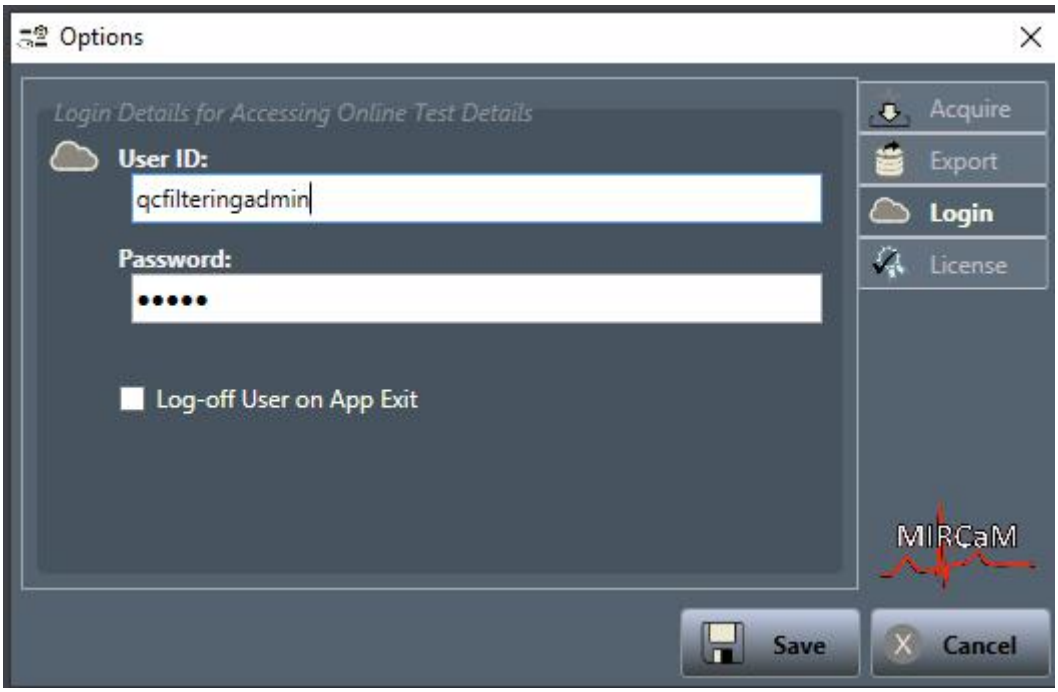


Step 4: Click on “Options” at the top right corner of the MIRCaM ECG Viewer Screen




Clicking on the Options, a dialog box will appear to facilitate entering the log in credentials.

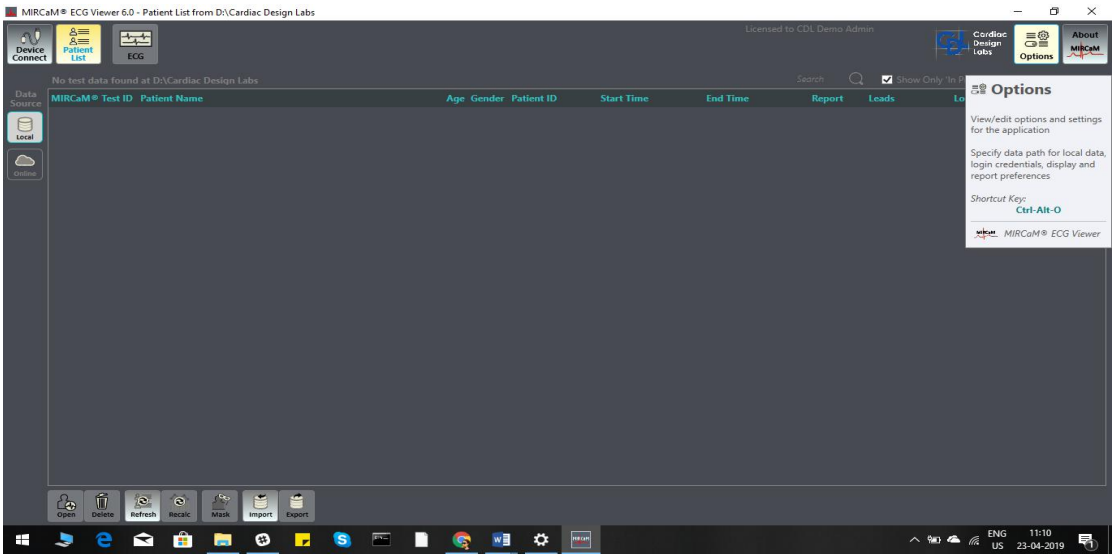
Step 5: Select “Log-In” option. Enter the login credentials provided by CDL and click “Save”.




When wrong login credentials are entered, the above error message pops up on the screen

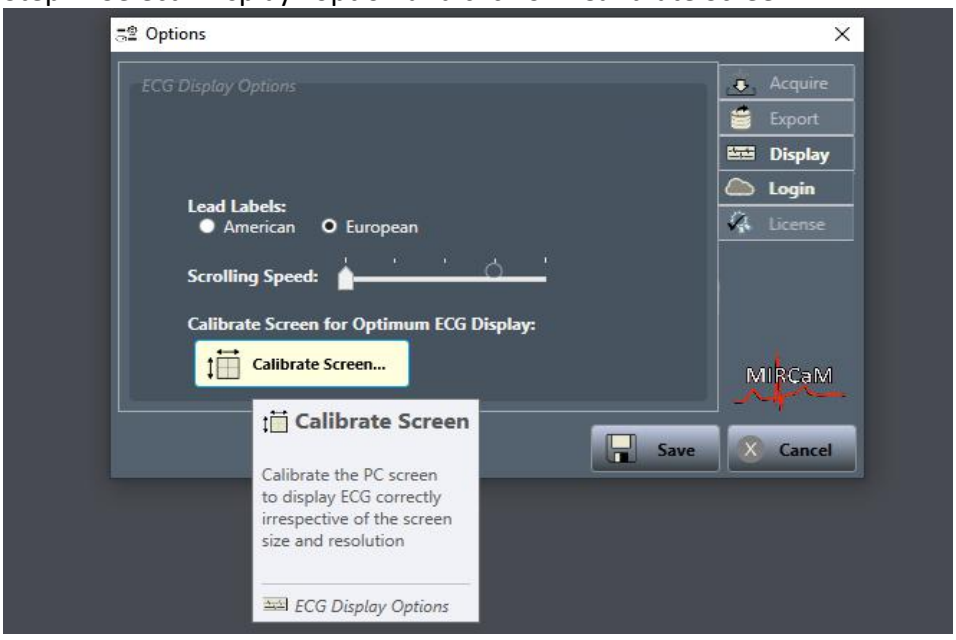
### 3.1.2.2. CALIBRATING THE SCREEN

Step 1: Click on “Options” at the top right corner of the MIRCaM ECG Viewer Screen

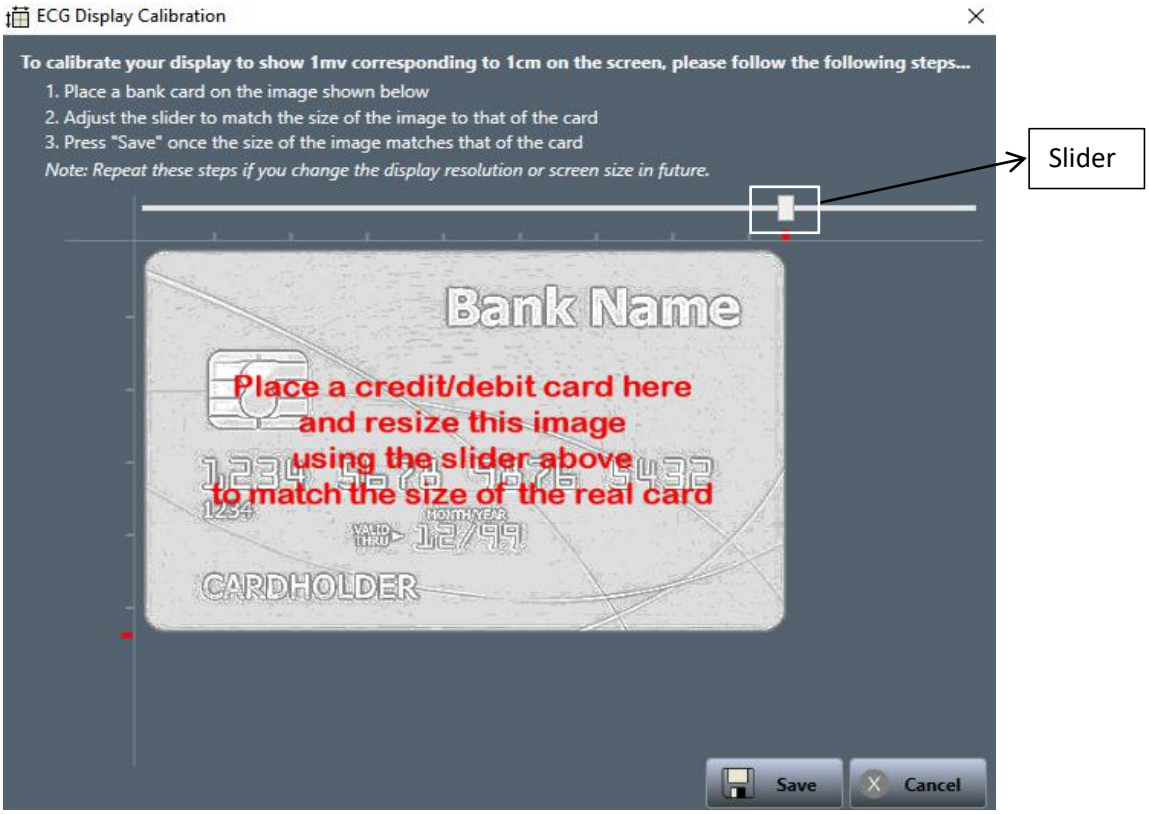



Clicking on the Options, a dialog box will appear to facilitate the calibration of the screen

Step 2: Select “Display” option and click on “Calibrate Screen”



Step 3: Follow the instructions displayed on the screen and click “Save”
Note: Place a credit/debit card on the image shown and adjust the slider to match the size of the image to that of the card and click “Save” once the size of the image matches that of the card.




MIRCaM ECG Viewer has been set-up and is ready for use.

### 3.1.3. Storage Capacity

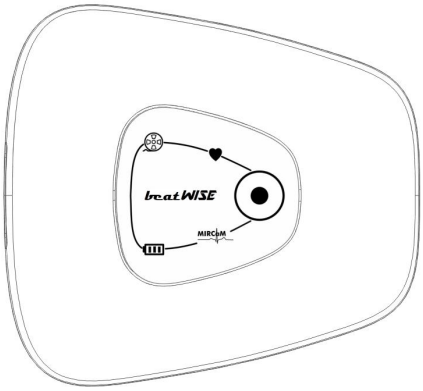
MIRCaM beatWISE has a capacity to store up to 14 days of patient test data. This data is automatically erased/re-written on the start of every new test. It is therefore important to acquire the patient data to the PC after the completion of each test and before starting a new one.

### 3.1.4. Battery

MIRCaM beatWISE operates for up to 48 hours on a single AAA alkaline battery. Always remove the battery when storing the device.

## 3.2. Device Icons and Indications

| | Icons Descriptions | Indications | Significance |
|---|---|---|---|

<table>
<tr>
<td rowspan="5"> 
</td>
<td rowspan="2">1.Recording status LED<br>  </td>
<td>  </td>
<td>Indicates that the device is recording, and all the leads have been affixed properly.</td>
</tr>
<tr>
<td>  </td>
<td>Indicates that one or more of the leads have come off or not affixed properly.<br><br>Action: Affix the leads properly</td>
</tr>
<tr>
<td rowspan="2">2.Battery Status LED<br>  </td>
<td>  </td>
<td>Indicates that the battery charge is sufficient</td>
</tr>
<tr>
<td>  </td>
<td>Indicates that the battery charge is low and the device may turn off soon<br><br>Action: Replace with fresh AAA battery in order to avoid the device from turning off.</td>
</tr>
<tr>
<td>3. Device status button<br>  <br><br>4.Patient Trigger LED<br>  </td>
<td>  </td>
<td>When this button is pressed once, the recording status LED and battery status LED should light up to show the current status of recording and battery.<br><br>Pressing the device status button twice, lights up the patient trigger LED to confirm the recording of the patient trigger.</td>
</tr>
</table>

### 3.3. Audible Indications to the User

| Audible Indications | Description |
|---|---|
| Two beeps | Indicates that the device has detected a lead-off condition<br>**Action**: Affix leads properly |
| A single, short beep | Indicates that the leads are affixed properly after a lead-off is detected |
| Three beeps | Indicates that the test duration has been completed |

# 4. Procedure to Run a Complete Test

## 4.1. Positioning of Electrodes

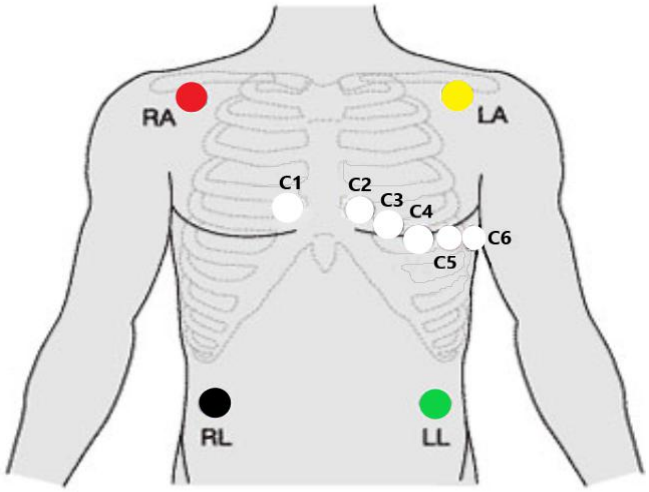



Fig.2 For a 12 lead

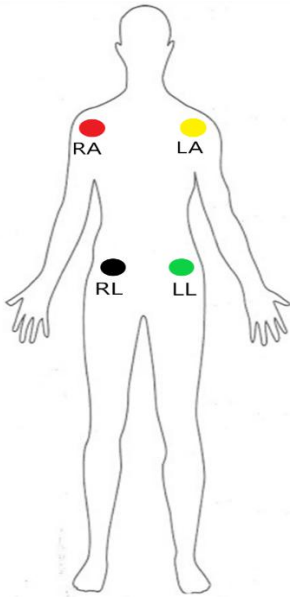



Fig.3 For a reduced lead

***NOTE: Before starting the test procedure, ensure that the lead cables of the required configuration(12/reduced) is snapped onto the electrode patch and kept ready.***

## 4.2. Preparing the Patient

Determine electrode placement according to one of the configurations shown in section 4.1. Use this procedure to ensure good quality ECG data.

***CAUTION:***

***ELECTRODES: Make sure that the electrodes conducting elements do not make contact with each other or other metal parts.***

***Make sure that the device is not subject to disturbances from the electric mains***

- To minimize electrode related problems, be sure to use the proper type of electrode. Check the expiration date on any pre-gelled electrode before using it. Also check for dry gel pads on any pre-gelled electrodes that have been left out of their foil package.
- Shave hair from each electrode site. This improves conductivity, helps hold the electrode to the skin, and makes the removal of the electrode easier and less painful.
- Rub each electrode site thoroughly with alcohol or sandpaper. This removes oil from the skin.
  Place an electrode on each prepared site

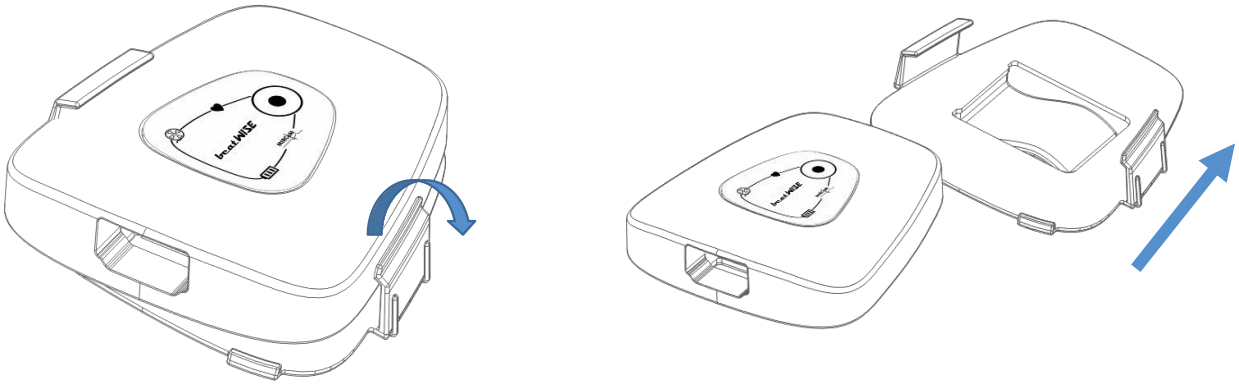
***WARNING:***

***ELECTRODE CONDUCTIVITY: Keep the conductive parts of the lead electrodes and associated parts away from other conductive parts, including earth.***

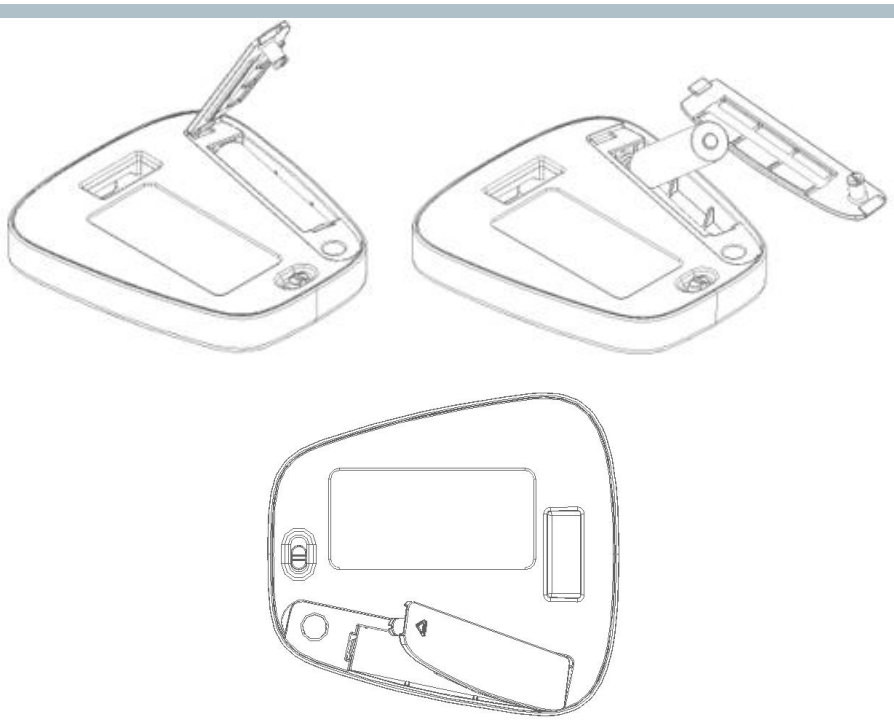
### 4.3. Steps to initiate a test using MIRCaM beatWISE

***NOTE: Before starting the test procedure, ensure that the lead cables of the required configuration (12/reduced) is snapped onto the electrode patch and kept ready.***
***Refer Section 4.1 "Positioning of Electrodes"***

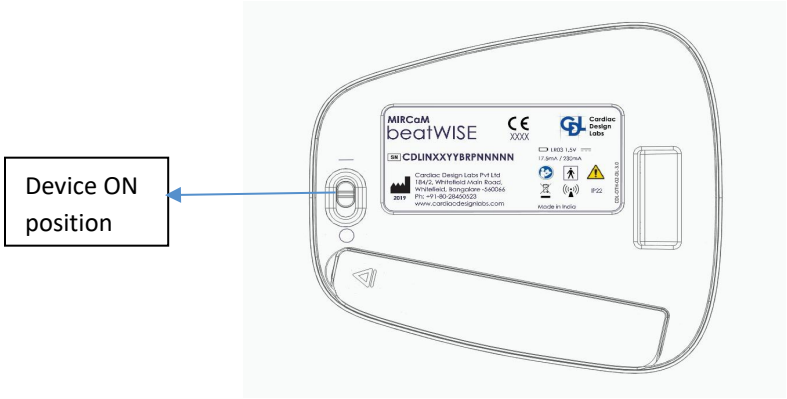
Step 1: Remove the device clip-lock from behind the device



Step 2: Open the battery door, insert a fresh, single AAA battery according to the polarity. Close the battery door once inserted.



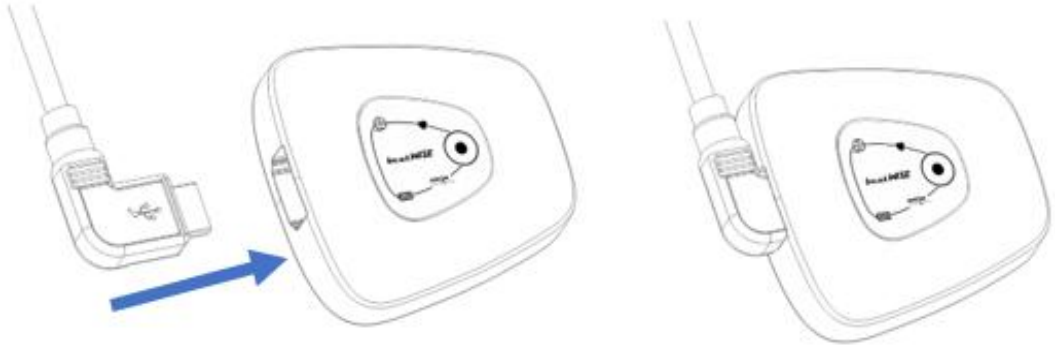
Step 3: Ensure the device is turned ON before connecting it to the PC



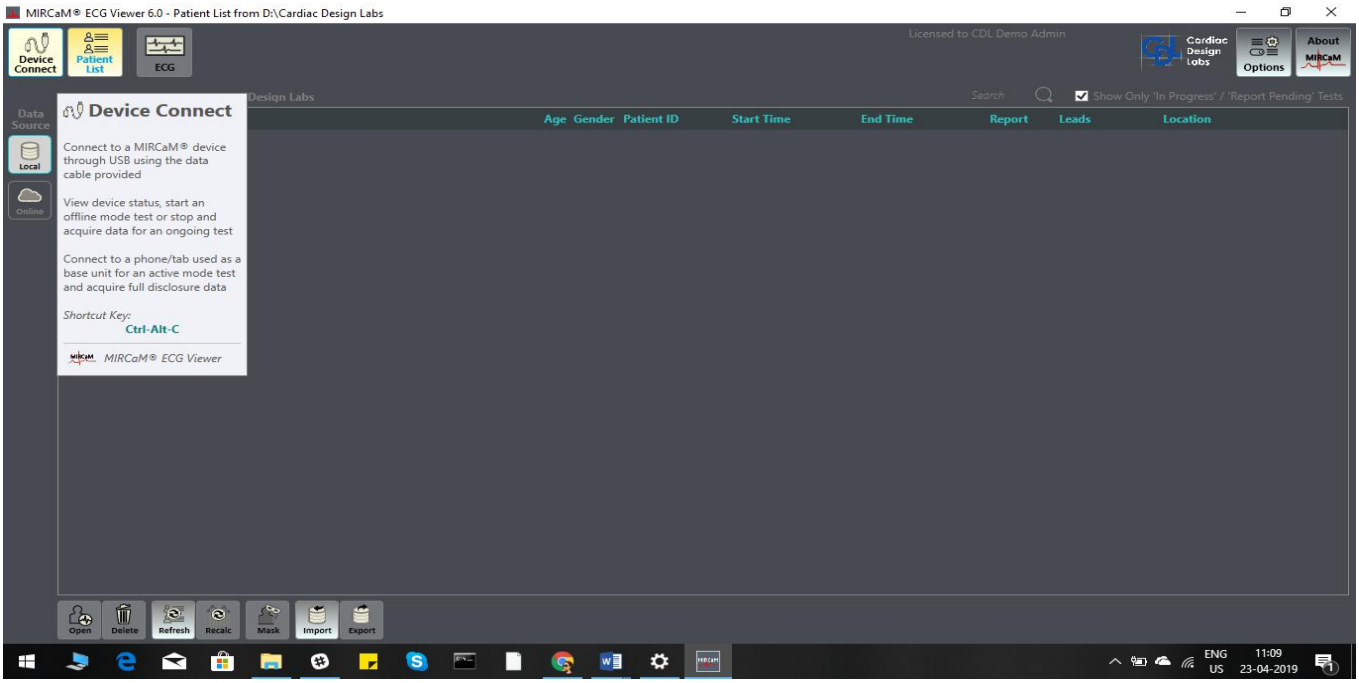

Step 4: Open the MIRCaM ECG Viewer software on the PC.

***NOTE: Make sure it is Licensed to your particular location***

Step 5: Connect the device to PC with the data transfer cable provided with the device, by CDL.



Step 6: Click on “Device Connect” option on MIRCaM ECG Viewer.




***Note: Ensure that that your Location Name and Department is reflecting on MIRCaM ECG Viewer before you begin a test.***

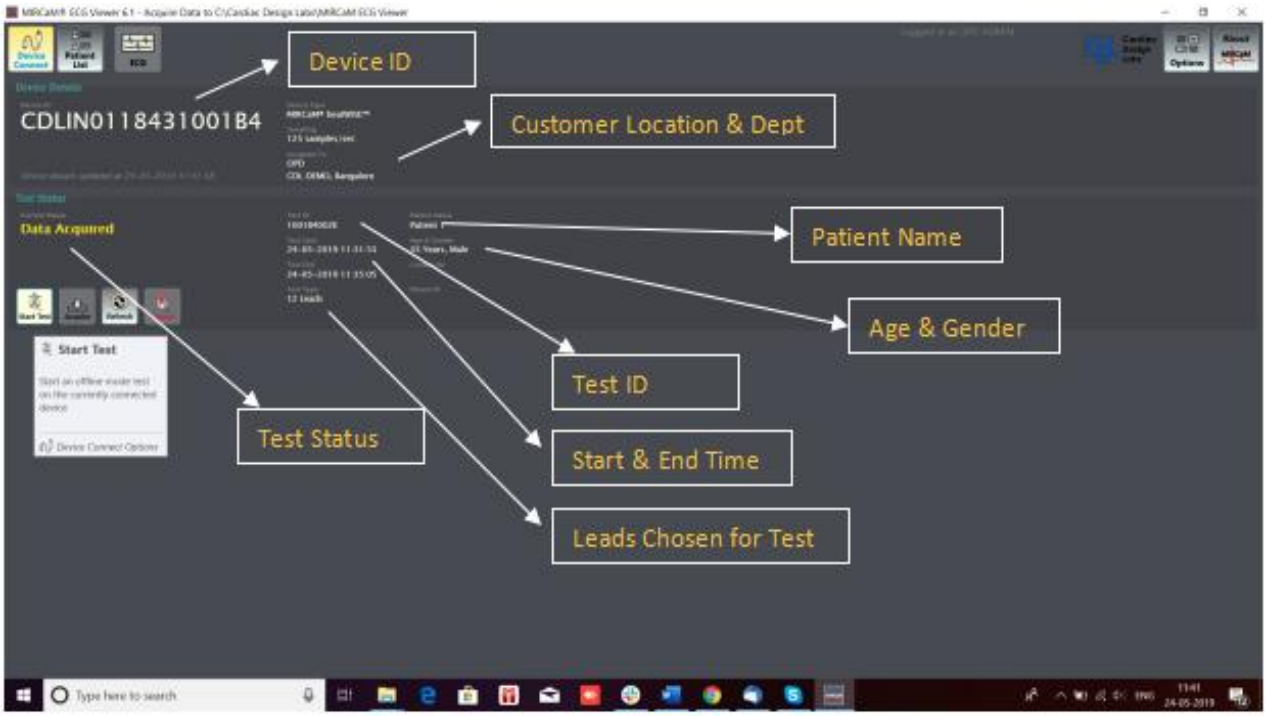
If the device is not connected properly or not switched on, Device connection error appears on the screen upon clicking the Device Connect option on MIRCaM ECG Viewer.


If the device is connected, clicking the “Device Connect” takes the user to the following page where device details and status are shown. The details shown on this page are as follows:

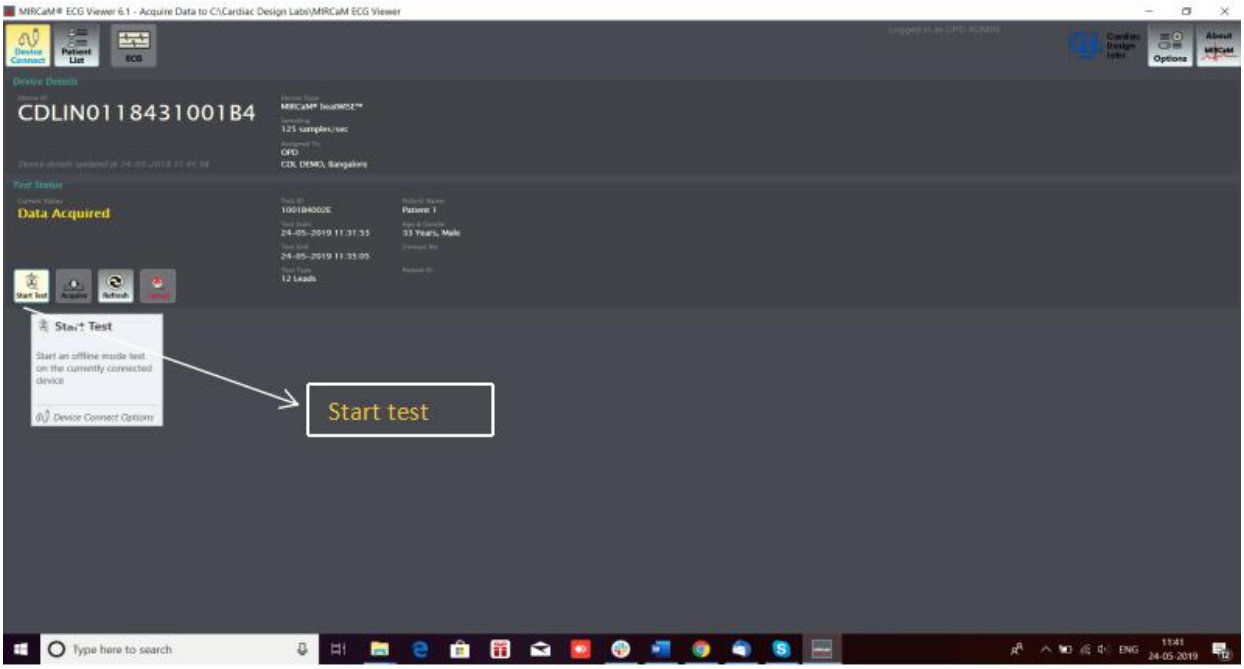
1. Unique Device ID
2. The customer location and department to which the device is assigned
3. Status of any ongoing tests
4. Test ID of the last test or the currently ongoing test
5. Test Start Time
6. Test End Time
7. No of Leads used in the test
8. Patient Name, Age and Gender
9. Hospital ID of the patient (if specified)

In addition to displaying the above information, the “Device Connect” page also provides the following options to the user by means of clickable buttons on the screen:

1. Start/Stop Test: Allows the user to start or stop the test when the device is connected.
2. Acquire Data: Allows the user to acquire the test once done.
3. Cancel Test: Allows the user to cancel the test.
4. Refresh Screen:Allows the user to refresh the screen.

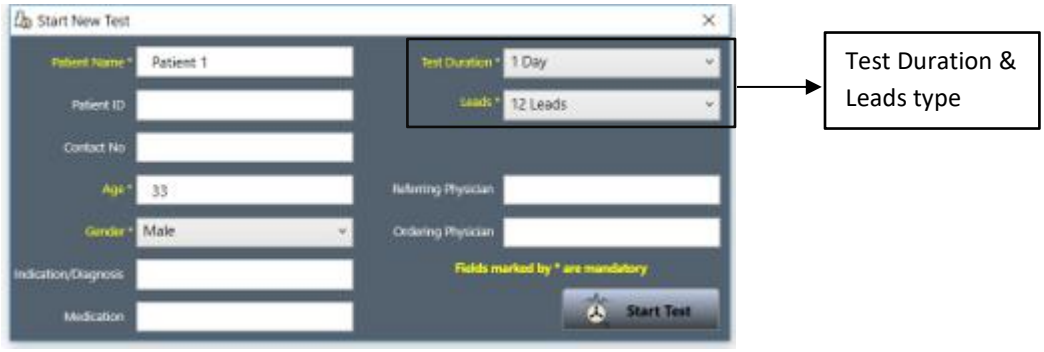


Step 7: On the Device Connect Page, Click on the option “Start Test”.




Clicking on the Start Test button will pop up the following dialog to facilitate entering the test details to the system as mentioned in the next step.

Step 8: Enter the patient details on the dialog box that pops up
***NOTE: All the fields highlighted in Yellow and marked by an * are mandatory.***
***NOTE: Ensure that “Test Duration” and “Leads Type” are selected correctly.***
***NOTE: Ensure PC is connected to the Internet while starting a test.***
Then click on “Start Test”

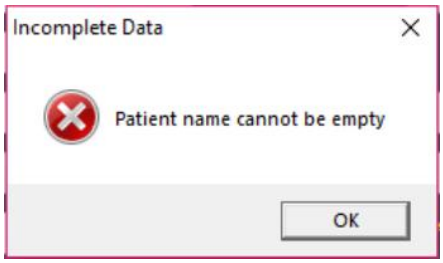



The user can specify the patient name, age, gender, any past medication history etc. in addition to specifying the test duration and the number of leads to be used for the test. The user can either specify 12 leads (where test using the 10 lead wire cable is to be conducted) or Limb Leads Only (where test using a 4 lead wire cable is to be conducted).

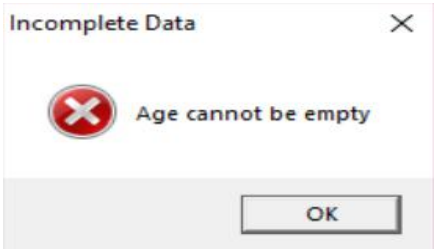
Once the patient and test details are entered, click on the “Start Test” button to initiate the test. A new unique test ID is assigned to the test based on the device ID. The test ID, start and end time of test are stored in the device. All other details specified including patient details are stored within the PC where the application runs.

When the Patient name/Age/Gender is not mentioned, the following error messages pop up.

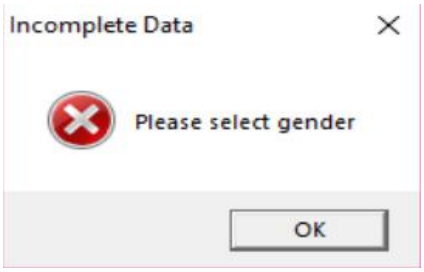
- Patient Name not populated



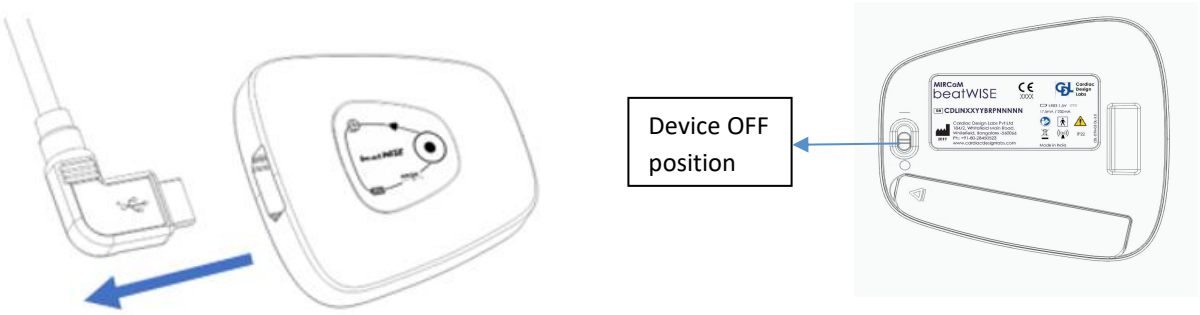

- Age not populated



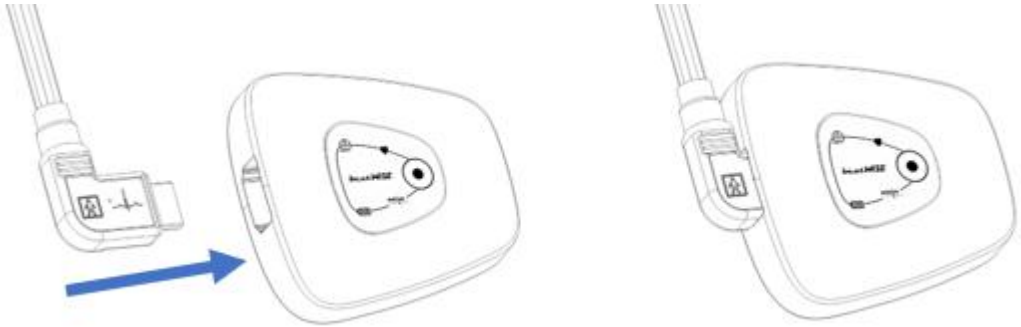

- Gender not selected



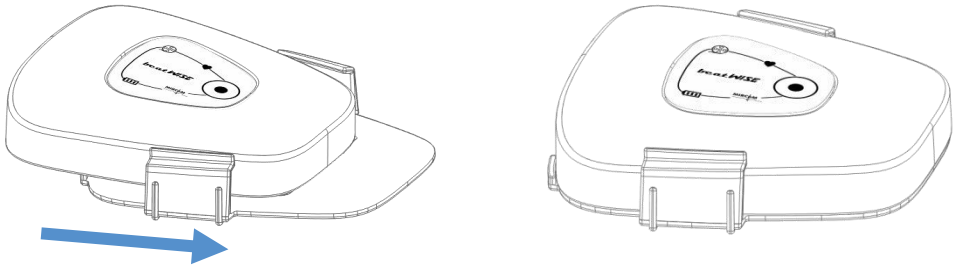
Step 9: Disconnect the data transfer cable from the device and turn OFF the device using the slide switch




Step 10: Connect the respective patient cable (12Lead or reduced lead) in the cable slot of the device



Step 11: Just before the device is hooked onto the patient, ensure the device is turned “ON”.
Step 12: Slide the device clip-lock back on.

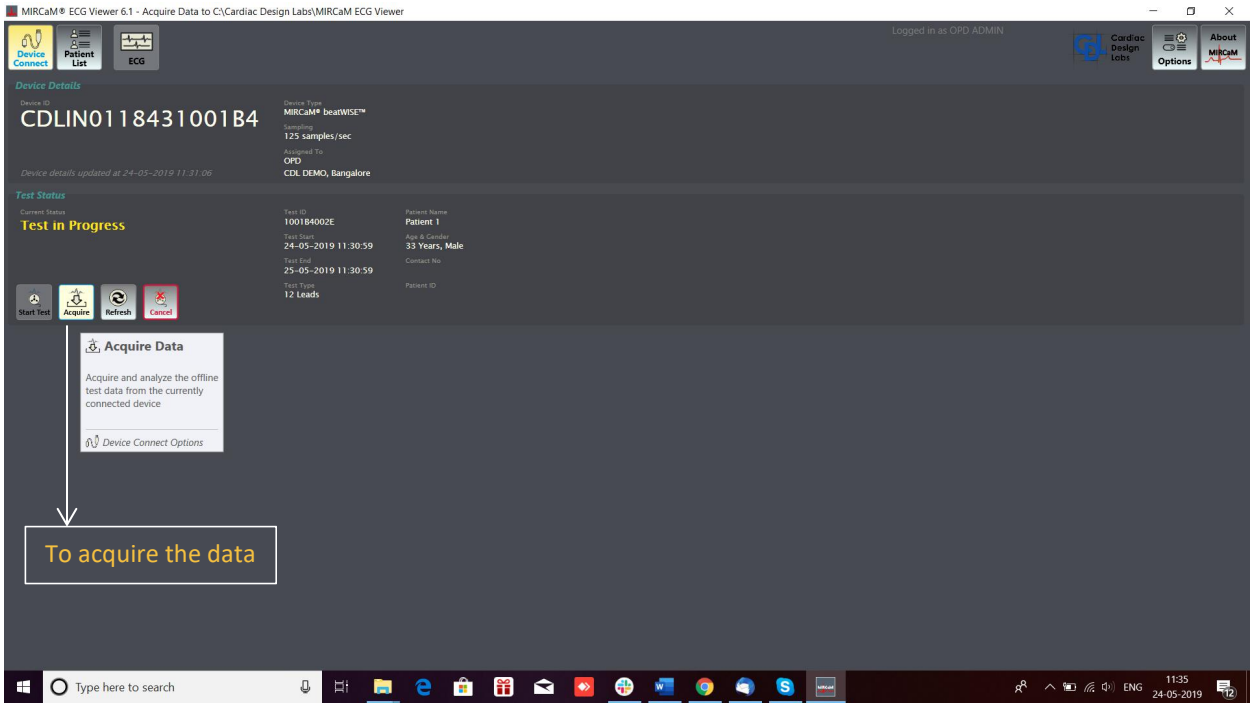


Step 13: Clip the device onto the waist belt.
Step 14: Press the device status button once, to verify if the battery and recording status LEDs light up green.

### 4.4. Steps to acquire recorded data from MIRCaM beatWISE

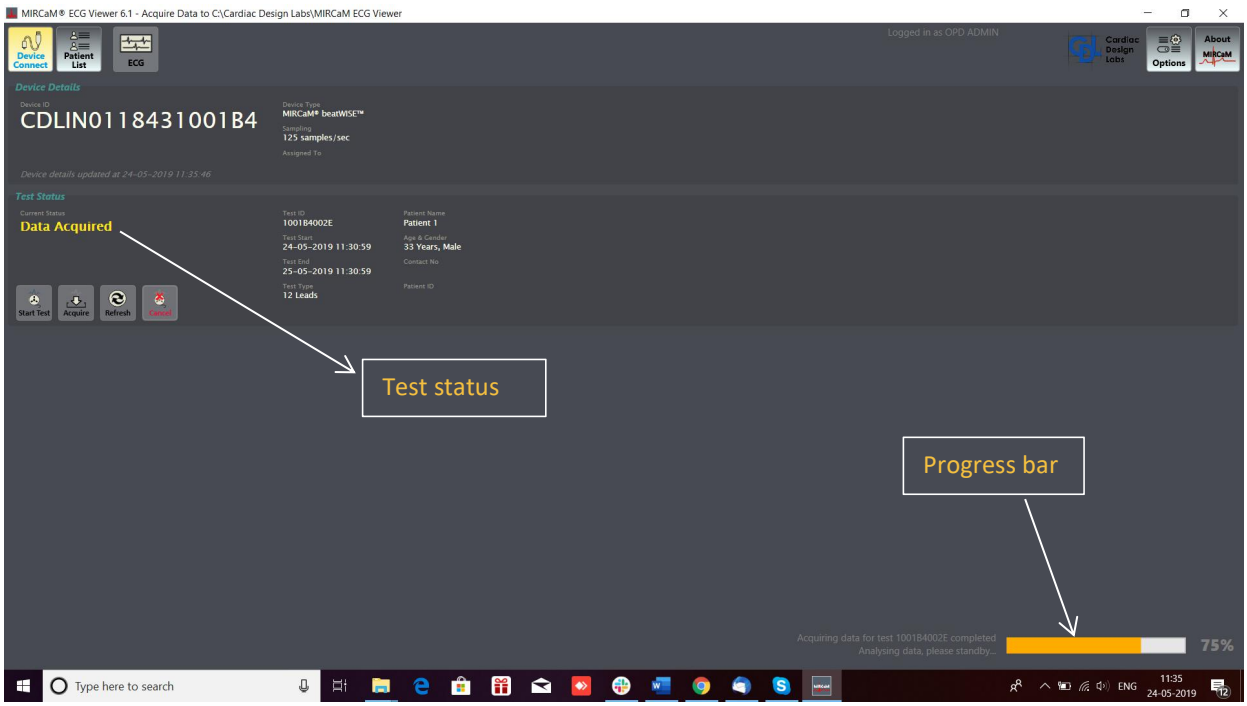
Step 1: Collect the device from the patient, once the test is completed.
Step 2: Disconnect the patient cable from the device
***NOTE: Ensure that the device is turned “ON” before connecting it to the PC***
Step 3: Connect the device to the PC hosting the MIRCaM ECG Viewer software using the data transfer cable provided by CDL

Step 4: Open the MIRCaM ECG Viewer software and click on “Device Connect”. On this page, Click on the option “Acquire”




Clicking on the “Acquire”, the acquiring process of the recorded data will start.

Step 5: The acquiring process is indicated by a progress bar at the bottom-right of the screen.

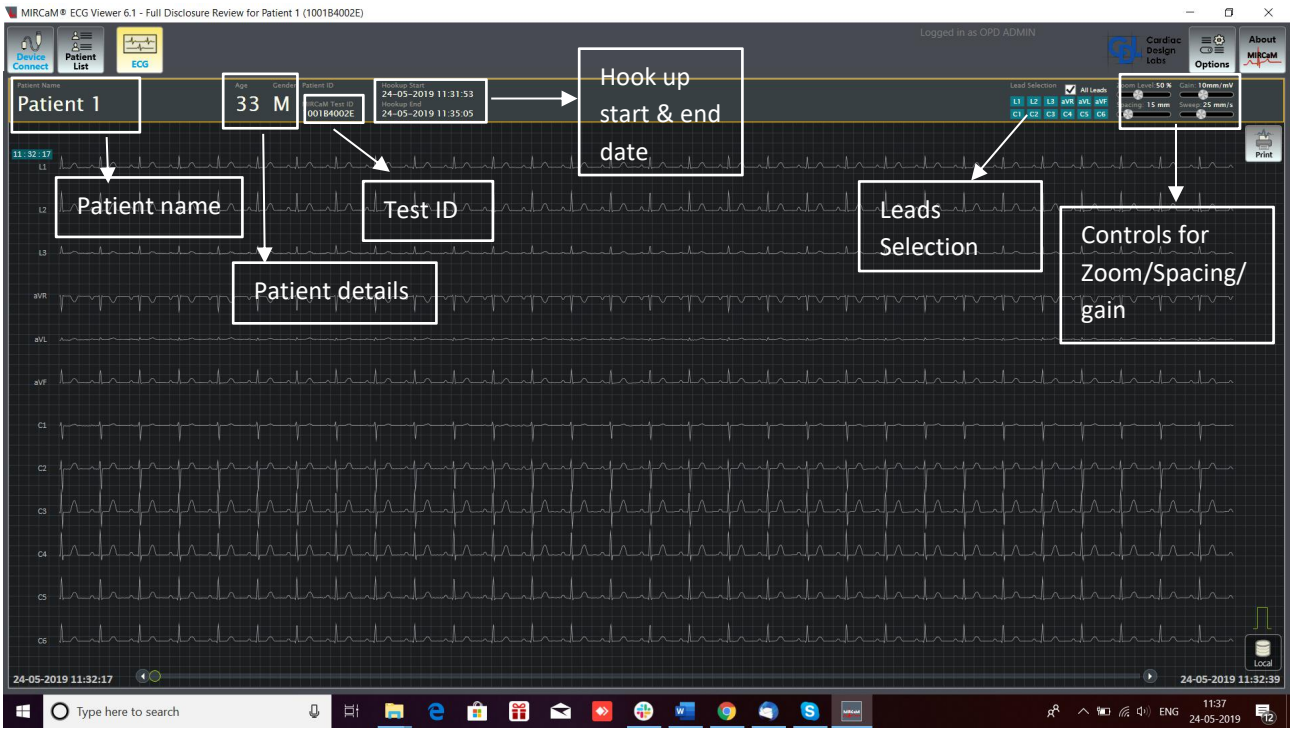


Wait for the progress bar to reach 100% for the recorded data to acquire.
Once the progress bar reaches 100% check for the test status to display “Data Acquired”

Step 6: Recorded ECG now displays on the software by which the certified professional can view and analyse to form a diagnosis

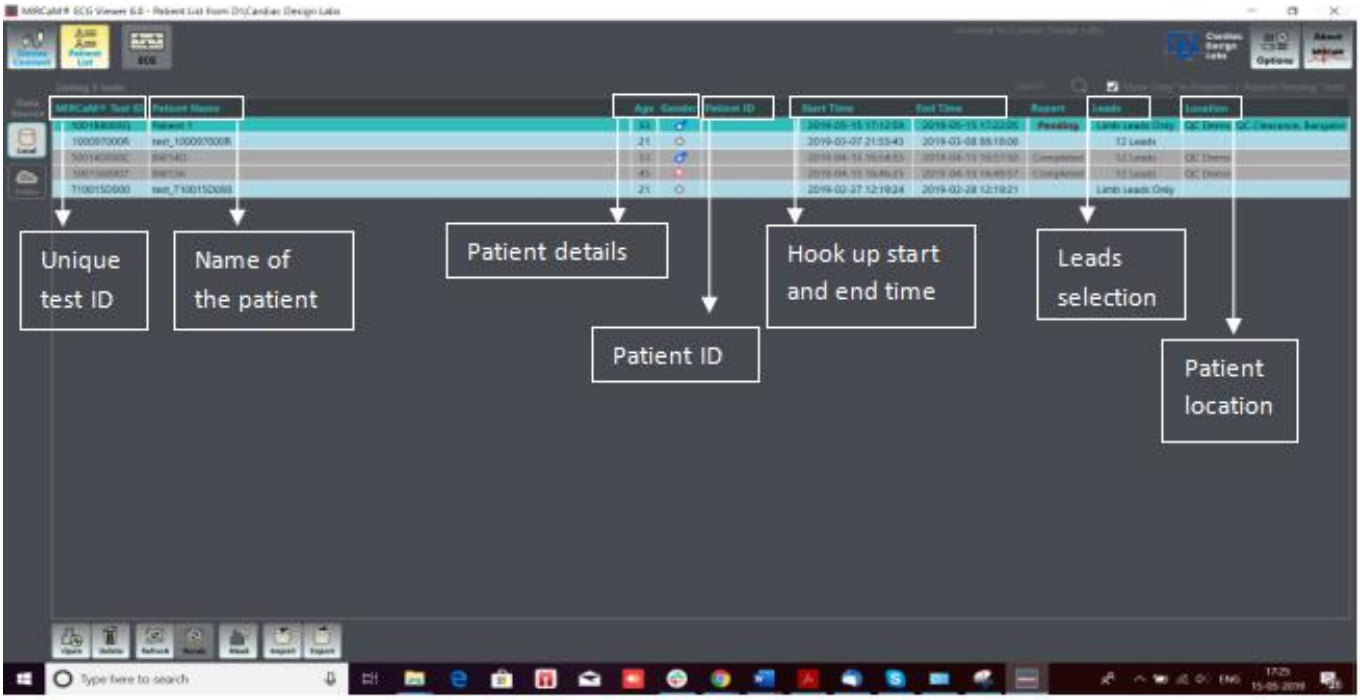
In addition to displaying the recorded ECG, the page also provides the following details to the user:

1. Patient details such as name, age, gender, test ID
2. The controls for Zoom and Spacing to view the data accordingly using the options Zoom level (Min: 20%, Max: 1x), Gain (Min: 2.5mm/mv, Max: 20mm/mv), Spacing (Min: 5mm, Max: 75mm), Sweep (Min: 10mm/s, Max: 50mm/s)
3. To view any particular lead or all leads using Lead Selection option
4. To view the start and end time of the test



Step 7: You can view all the tests that have been conducted and acquired to the PC, under “Patient List” ---> “Local Data”

All the test details such as Test ID, Patient name, age, gender, patient ID(if required), start time and end time of the test, type of leads used(12 lead/limb lead), patient location are displayed.




In addition to displaying the patient list, the page also provides the following options to the user by means of clickable buttons on the screen at the bottom left corner:

1. Open: Open/view test data for the selected patient
2. Delete: Delete test data for the selected patient
3. Refresh: Refresh the list of patient/test data
4. Mask: Mask the patient details
5. Import: Import test data available in MDEX format into the local database
6. Export: Export test data into local folder

## 4.5. Patient Instructions

When hooking up the device onto the respective patient, following instructions must be given to the patient and/or caretaker to ensure an uninterrupted/complete recording and to avoid any damage to the device.

As mentioned in section 3.2 “Device Icons and Indications” – The patient alert button is to be double-clicked by the patient at the onset of any symptom he/she experiences, which is captured by the device as patient alerts.

The MIRCaM beatWISE recorder is not waterproof. Hence it should not be submerged in water under any circumstances.

Ensure that the electrodes (sticky patches) are adhering well to your skin. At times, you may need to remove and replace the electrodes with fresh ones, should they dry out or you wish to bathe. To do this, use the following steps while ECG Recording will continue during this process:

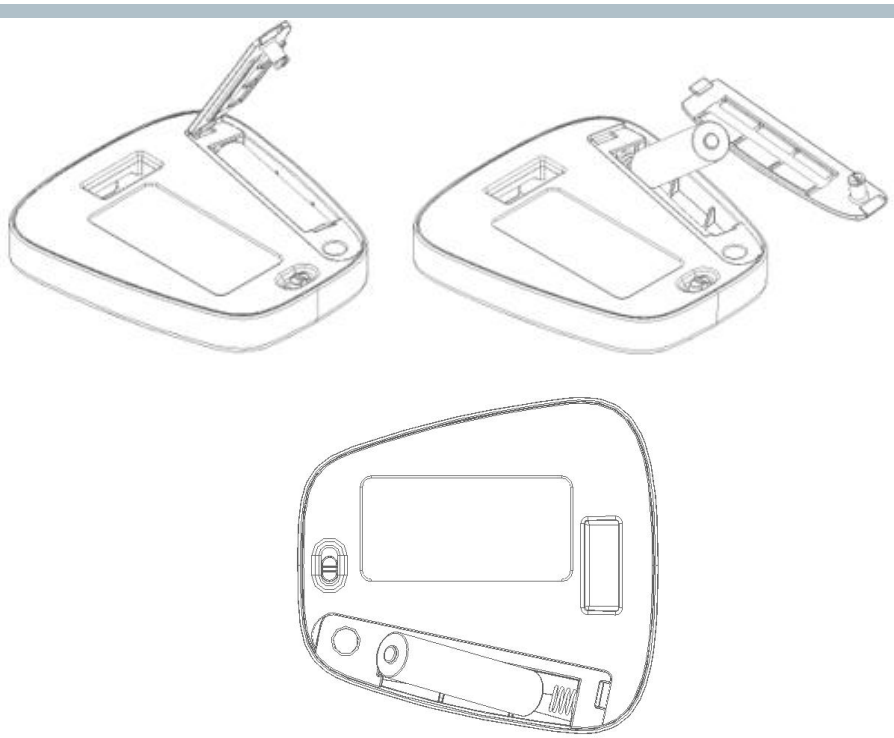
Step 1: Remove the recorder from the waist belt and un-snap the lead wires from the electrode patches placed on your skin.
Step 2: Carefully peel the electrodes from your skin and then discard the used electrodes.
***NOTE: Please remove the device while you go in for a shower.***
Step 3: Snap the lead wires onto fresh electrodes.
Step 4: Apply the electrodes to your clean and dry skin (no lotions, oils, or powder) in the lead locations shown under the section 4.1 “Positioning the electrodes”
Step 5: Hook the recorder onto the waist belt.

### 4.5.1. For Battery Change:

For tests that require the heart rhythms to be recorded for over 48+ hours, there is a necessity for the battery to be replaced as well.

To do this, follow the steps below:

ECG recording will be interrupted during a brief interval of time where the battery is being replaced.
Step 1: Remove the recorder from the waist belt
Step 2: Remove the device clip-lock which is placed at the back of the device.
Step 3: Open the battery door, remove the used battery and replace it with a fresh single AAA battery.
***NOTE: Ensure to insert the battery according to the polarity.***



Step 4: Close the battery door.
***NOTE: Ensure that device is ON. For this, check the slide switch***

Step 5: Slide the device clip-lock back on.
The device is powered and running
Refer to section 3.2 “Device icons and Indications” for battery status.

***CAUTION: For longer duration tests, ensure that the battery is replaced every once in 48 hours to avoid the device turning off.***

# 5. Maintenance and Specifications

## 5.1. Cleaning

***NOTE: Cleaning should be done after every use***

- To clean the recorder, remove the battery from the recorder.
- Use a clean, lint-free cloth, and dampen it with IPA.
- Clean the recorder, lead wires, and belt clip.
- Remove any adhesives from the patient lead wires with an adhesive tape remover solution or swab with mild detergent.

Do not use solvents.

Do not use abrasive cleaners or materials.

## 5.2. Device Specifications

| General Specifications | |
|---|---|
| ECG channels | 2 and 8 Channel(6 lead/12 lead) |
| Lead wire cable options | 4 Lead & 10 Lead wire cables |
| Recording time options | Up to 14 days |
| Pacemaker detection | No |
| LEDs | Recording status, Battery Status, Patient Alert |
| Demographic data entry and hook-up preview | PC Application via data transfer cable |
| Download and data transfer | MIRCaM beatWISE data cable via data transfer cable |
| Memory | Stores upto 14 days |
| Mode of operation | Continuous |
| Internally powered ME Equipment | |
| **Technical Specifications** | |
| Power requirements | 1 LR03/AAA alkaline battery<br>1.5V DC power |
| Battery Life | 48 hours |
| Weight | 60 grams |
| Dimensions | 83*76*17.5 mm |
| Frequency response | 0.05- 58 Hz |
| Sampling rate | 250 sps |
| Resolution | 16 bits |
| Gain Accuracy | ±1% |
| Patient Leakage Current | Less than 2 µA |
| Input dynamic range | ± 400 mV |
| Input dynamic range ECG | ±10mV |
| Power consumption | 17.5 mA @ 1.5V is the normal operating power consumption<br>230 mA @ 1.5V is the Momentary power consumption |
| Common mode rejection | 100 dB |
| Input impedance | 500 MΩ |
| Ingress protection rating | IP22 |
| Expected Service Life of MIRCaM beatWISE | 5 Years |
| MIRCaM beatWISE does not contain any electromagnetic sensitive component | |
| MIRCaM beatWISE can be used in conjunction with oxygen rich environment as the source of ignition does not exist in normal and single fault condition. The temperature of the material does not raise to its ignition temperature or 300 deg C. | |
| **Compatibility** | |
| PC Application | Windows 7 or 10 |

## 5.3. Essential performance

### 5.3.1. Normal condition

- Record, acquire and display correct ECG output with 4 lead and 10 lead wire cable
- Data storage upto 14 days
- Battery life during the intended use-48 hours
- MIRCaM beatWISE is expected to run as per the expected service life(5 years)

### 5.3.2. Single fault condition

The device will fail to operate in single fault condition and the device will be called back to CDL.

## 5.4. Helpline and Contact

**For Product Information:**
Email: info@cardiacdesignlabs.com
Phone: +91 8028450523

**For User Assistance:**
Email: support@cardiacdesignlabs.com
Helpline Number: +91 8049202370 (Monday to Friday 9 AM to 7PM - IST)

For more details, please visit us at www.cardiacdesignlabs.com

**Manufacturer Details**
Cardiac Design Labs Pvt Ltd
#184/2, Whitefield Main Road, Bangalore 560066


**EU REP Details**
Medical Device Safety Service GmbH
Schiffgraben 41, 30175 Hannover, Germany
Email: info@mdss.com
Phone: +49 511 62 62 86 30

# APPENDIX

## 6. Electromagnetic Compatibility

Electromagnetic compatibility with surrounding devices should be assessed when using the device. An electronic device can either generate or receive electromagnetic interference. Testing for electromagnetic compatibility (EMC) has been performed on the device according to the international standard for EMC for medical devices (IEC 60601-1-2). This IEC standard has been adopted in Europe as the European Norm (EN 60601-1-2). The device should not be used adjacent to or stacked on top of other equipment. If the device must be used adjacent to or stacked on top of other equipment, verify that the device operates in an acceptable manner in the configuration in which it will be used. Fixed, portable, and mobile radio frequency communications equipment can affect the performance of medical equipment. See the appropriate EMC table for recommended separation distances between the radio equipment and the device. The use of accessories, transducers, and cables other than those specified by CDL Instrument may result in increased emissions or decreased immunity of the equipment.

| Emissions Test | Compliance | Electromagnetic Environment: Guidance |
|---|---|---|
| RF Emissions CISPR 11 | Group 1 | The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment. |
| RF Emissions CISPR 11 | Class B | The equipment 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. |
| Harmonic Emissions IEC 61000-3-2 | Not Applicable Reason: Device is battery operated and it is not connected to electrical mains | |
| Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3 | Not Applicable Reason: Device is battery operated and it is not connected to electrical mains | |

### 6.1. Guidance and Manufacturer's Declaration:

Electromagnetic Immunity - The equipment is intended for use in the electromagnetic environment specified in the table below. The customer or the user of the equipment should ensure that it is used in such an environment.

| Table 4 – Enclosure Port | | |
|---|---|---|
| **Emissions Test** | **Compliance** | **Remarks** |
| Electrostatic discharge (ESD) IEC 61000-4-2 | +/- 8 kV contact | Not applicable;<br>Reason: No metal parts exposed |
| | +/- 2 kV, +/- 4 kV, +/- 8kV<br>+/- 15kV air | |
| Radiated RF<br>IEC 61000-4-3 | 10Vrms<br>80 MHz to 2.7 GHz | Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance of 30 cm.<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |
| Power frequency magnetic field<br>IEC 61000-4-8 | 30 A/m<br>50/60 Hz | Not Applicable;<br>Reason: The device does not contain electromagnetic sensitive components or circuitry |

| Table 6- Input D.C Power Port | | |
|---|---|---|
| **Emissions Test** | **Compliance** | **Remarks** |
| Electrical fast transient/burst IEC 61000-4-4 | +/- 2kV for power supply lines<br><br>+/-1kV for input/output lines | Not Applicable;<br>Reason: Device is battery operated and it is not connected to electrical mains |
| Surge IEC 61000-4-5 | +/- 1kV differential mode<br>+/- 2kV common mode | Not Applicable;<br>Reason: Device is battery operated and it is not connected to electrical mains |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5% UT (>95% dip in UT) for 0.5 cycle<br>40% UT (60% dip in UT) for 5 cycles | Not Applicable;<br>Reason: Device is battery operated and it is not connected to electrical mains |
| ***NOTE: UT is the AC Mains voltage prior to application of the test level*** | | |
| Conducted disturbances induced by RF fields.<br>IEC 61000-4-6 | 3Vrms<br>150kHz to 80Mhz | Portable and mobile RF communications equipment should be used no closer to any part of the |

| | | |
|---|---|---|
| | | equipment, including cables, than the recommended separation distance of 30 cm.<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |

**Table 7- Patient Coupling Port**

| Emissions Test | Compliance | Remarks |
|---|---|---|
| Electrostatic discharge (ESD) IEC 61000-4-2 | +/- 8kV contact<br><br>+/- 2 kV, +/- 4 kV, +/- 8kV<br>+/- 15kV air | |
| Conducted disturbances induced by RF fields.<br>IEC 61000-4-6 | 3Vrms<br>150kHz to 80Mhz | Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance of 30 cm.<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |

**Table 9 – Test Specifications for Enclosure Port Immunity to RF wireless communications equipment**

| Test Frequency (MHz) | Band [a)] | Service [a)] | Modulation [b)] | Maximum Power (W) | Distance (m) | Immunity Test Level (V/m) |
|---|---|---|---|---|---|---|
| 385 | 380 - 390 | TETRA 400 | Pulse modulation [b)]<br>18Hz | 1.8 | 0.3 | 27 |
| 450 | 430 - 470 | GMRS 460, FRS 460 | FM [c)]<br>+/- 5kHz deviation | 2 | 0.3 | 28 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | 1kHz sine | | | |
| 710<br>745<br>780 | 704 - 787 | LTE band 13, 17 | Pulse modulation [b] 217 Hz | 0.2 | 0.3 | 9 |
| 810<br>870<br>930 | 800 - 960 | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 | Pulse modulation [b] 18 Hz | 2 | 0.3 | 28 |
| 1720<br>1845<br>1970 | 1700 - 1990 | GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25; UMTS | Pulse modulation [b] 217 Hz | 2 | 0.3 | 28 |
| 2450 | 2400 - 2570 | Bluetooth WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulation [b] 217 Hz | 2 | 0.3 | 28 |
| 5240<br>5500<br>5785 | 5100 - 5800 | WLAN 802.11 a/n | Pulse modulation [b] 217 Hz | 0.2 | 0.3 | 9 |

## 6.2. Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Equipment

The equipment is intended for use in electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the equipment can help to prevent electromagnetic interference by maintaining a minimum distance of 30cm (12 inches) between portable and mobile RF communications equipment(transmitters) and the equipment.