

10.6 Monitoring

The LifePath-C system does not require any constant supervision or intervention by the physician/nurse or patient when monitoring. It is intended to unobtrusively collect data while the patient carries on with their daily activities, except those which are contraindicated by use of the LifePath-C system, such as showering or other water related activities.

It is important, that while the LifePath-C system is in a monitoring state, the patient follows instructions and heeds all warnings and cautions found on the **Patient Instruction Card**. As well, they should be instructed to contact the healthcare facility if any discomfort or other problems arise while being monitored.

10.7 Monitoring Campaign Procedure

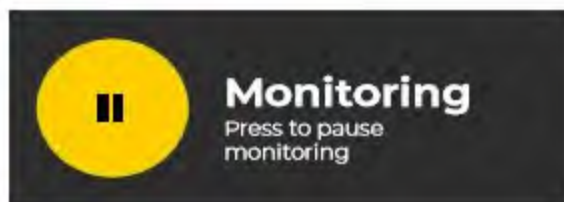
The following outlines the general procedures during a monitoring campaign:

1. Nurse at healthcare facility sets up monitoring campaign and attaches LifePath-C to the patient.
2. Monitoring starts. Patient Information Card, warnings, and instructions reviewed with Patient.
3. Patient is discharged from healthcare facility with LifePath-C and Smartphone and returns to their daily activities, following instructions for safe use.
4. Maintenance reminder given approximately 24 hours after monitoring starts. Patient contacts healthcare facility for scheduled maintenance.
5. Monitoring paused. Maintenance procedure performed by nurse.
6. Monitoring resumed. Patient is discharged and returns home.
7. Patient returns for all scheduled maintenance during campaign.
8. Monitoring campaign ends. LifePath-C system removed from patient.

* Refer to sections titled '**Maintenance**' and '**Pausing Monitoring**' for more information on these topics.

10.8 Pausing Monitoring

You can pause monitoring by tapping the **Pause Monitoring** button. The Monitoring State will revert to '**Not Monitoring**' and the Wearable Medical Monitor will halt signal collection, as well as data transmission to the Smartphone.



The LifePath-C system **will remain in the 'Not Monitoring' state until the Start Monitoring button is tapped again and monitoring resumes.**

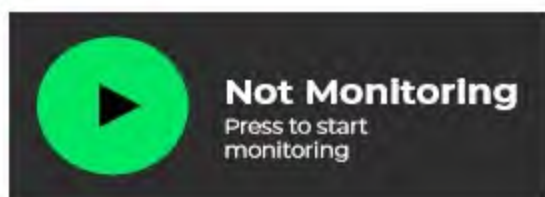
Important! The Campaign timer will continue to elapse while the monitoring has been paused.

When to Pause Monitoring

Monitoring should always be paused prior to any battery swaps, removal of the Wearable Medical Monitor from the patient, maintenance, cleaning, or disconnection of the cable harness or ECG leads. Failure to pause monitoring may result in loss of data or compromised signal quality.

10.9 Resuming Monitoring

Monitoring can be resumed by tapping the **Start Monitoring** button. When tapped, the Smartphone will reconnect to the Wearable Medical Monitor, run through the Pre-Launch Check, and upon successful completion, resume monitoring.



Tapping the **Start Monitoring** button will resume monitoring.

10.10 Monitoring Errors

Errors or problems encountered while monitoring will be identified and displayed as popups on the Dashboard.

The popups will;

1. Instruct the patient to contact their healthcare provider (for Cable Harness disconnected, ECG Lead disconnected, and low battery warning popups).
2. Provide an image and description of the error.
3. Provide instructions to correct the error.

It is important that the patient does not attempt to perform the corrective actions themselves in cases where they are instructed to contact their healthcare provider. The nurse/healthcare provider must perform these tasks.

Popups will persist until the error has been corrected. If a popup is dismissed and the error remains un-corrected, it will re-appear in a few minutes.

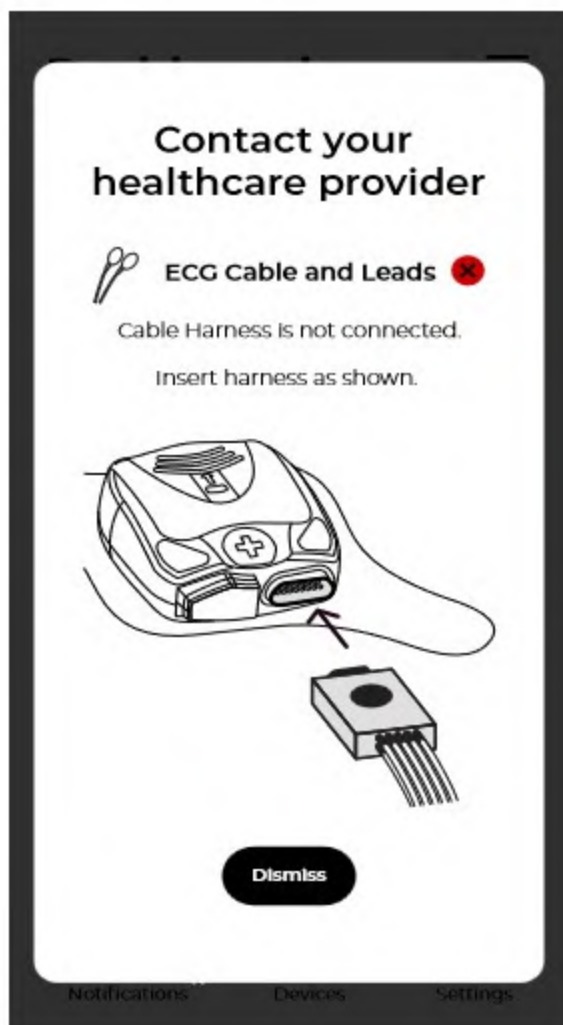


Vibration and LED Alerts

LifePath-C also provides tactile and visual feedback to the patient when errors are encountered. The Wearable Medical Monitor will vibrate and the Info/Status Indicator LED will blink.

See the section titled '**Wearable Medical Monitor Alerts**' for more information.

10.10 Monitoring Errors

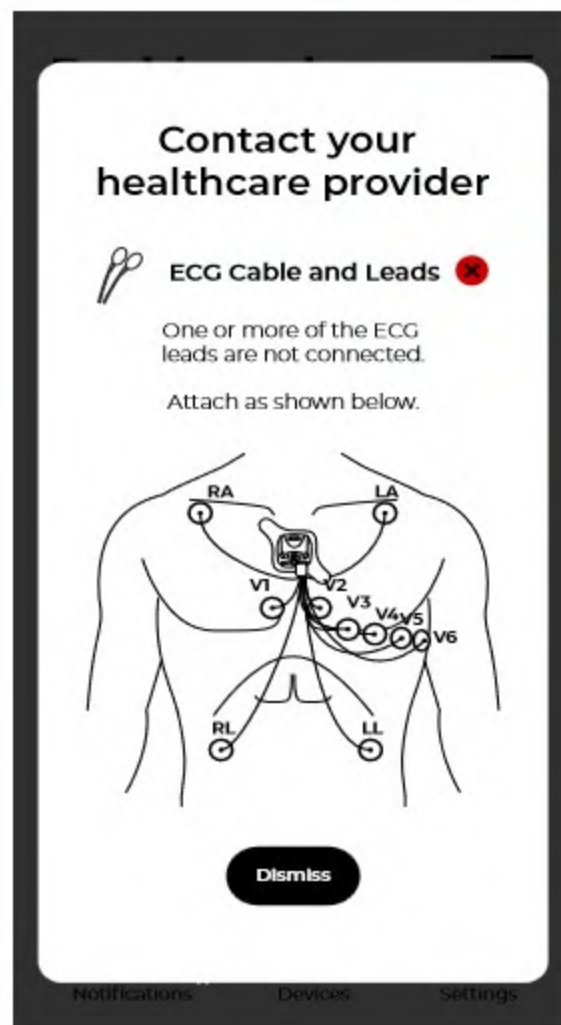


ECG Cable Harness Disconnected

The ECG Cable harness is not connected to the Wearable Medical Monitor.

Solution:

Insert the Cable Harness connector into the port as shown.



ECG Leads Disconnected

One or more of the ECG leads are disconnected or improperly attached.

Solution:

Ensure all leads are attached as described in the diagram above. Ensure each electrode is in contact with the patient's skin.

10.10 Monitoring Errors

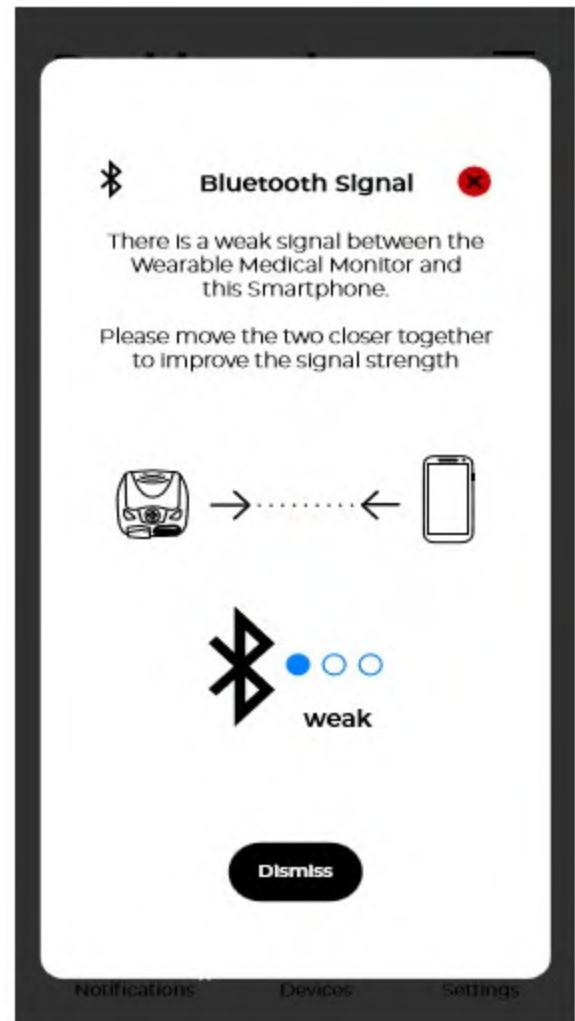


Wearable Medical Monitor Battery Low

The Wearable Medical Monitor Battery is low.

Solution:

Press the pause monitoring button and insert a fully charged Wearable Medical Monitor battery. Once replaced, resume monitoring. See the section titled '**Swapping Batteries**' for more information.



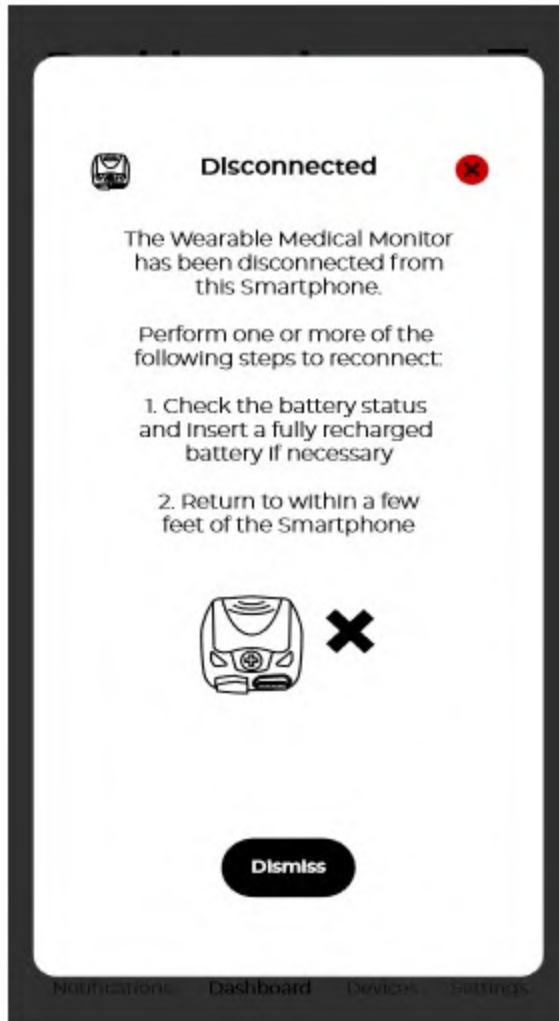
Weak Bluetooth Signal

Weak Bluetooth signal between the Wearable Medical Monitor and Smartphone.

Solution:

Move the two devices closer together until the signal strength improves.

10.10 Monitoring Errors



Wearable Medical Monitor Disconnected

The Wearable Medical Monitor has been disconnected from the Smartphone

Solution:

Check the battery status of the Wearable Medical Monitor and replace with a fully charged battery if necessary. Or, return to within a few feet of the Smartphone.



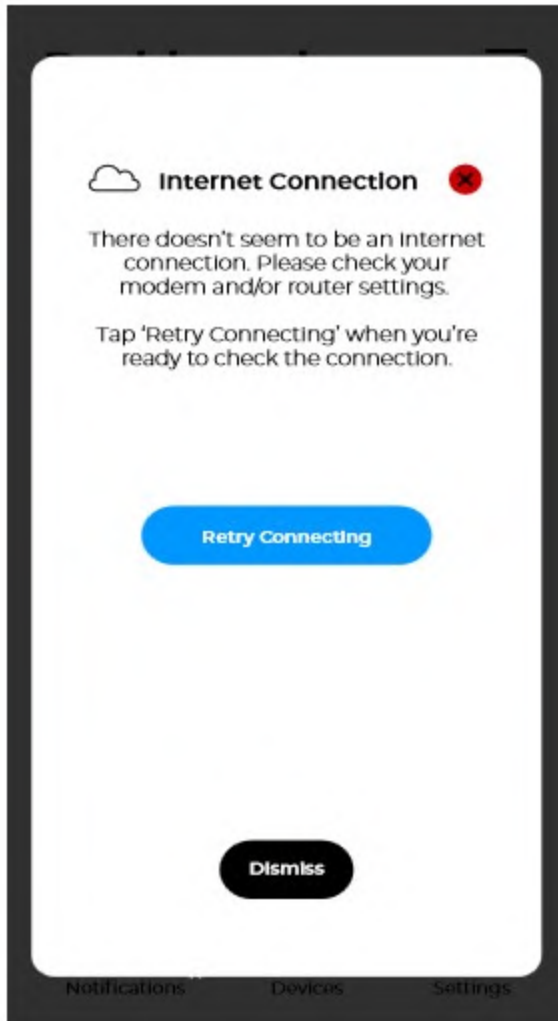
No Wi-Fi Connection

The Smartphone is not connected to a Wi-Fi network.

Solution:

Tap 'Proceed' to access the Smartphone's Wi-Fi settings and connect to an available wireless network.

10.10 Monitoring Errors

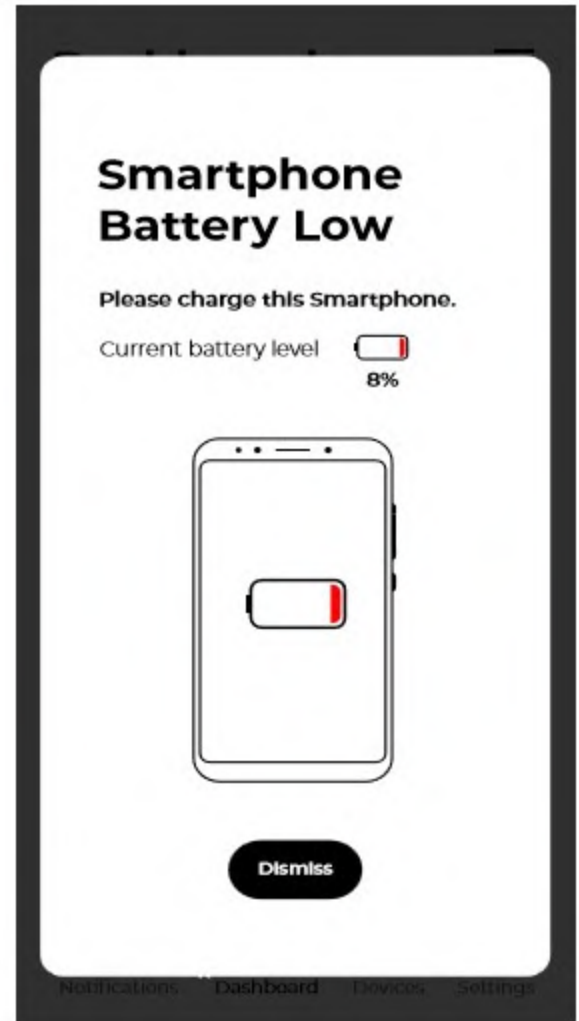


No Internet Connection

There is no internet connection.

Solution:

Check your modem and/or router settings and retry connecting.



Smartphone Battery Low

The Smartphone battery is low

Solution:

Plug the Smartphone into a power outlet using the included Smartphone charger to charge.

11 Connectivity

11.1 Bluetooth Connection

During monitoring, the Wearable Medical Monitor collects biometric data and transmits it over **Bluetooth**, in real time, to the Smartphone with which it is paired.

When the **Start Monitoring** button is tapped, the Bluetooth connection between the Wearable Medical Monitor and Smartphone is established.

Once connected, the Smartphone will be able to:

1. Control the monitoring state (Start/Pause monitoring)
2. Receive biometric data collected by the Wearable Medical Monitor
3. Receive the hardware status of the Wearable Medical Monitor, Wearable Medical Monitor Battery, Cable Harness and ECG leads
4. Receive alerts, alarms, and error messages from the Wearable Medical Monitor, such as those for disconnected ECG leads and low battery

It is important to maintain the Bluetooth connection between the Wearable Medical Monitor and Smartphone for this data transmission to occur. This is accomplished by ensuring that the patient and Smartphone are at a maximum distance of 1.5 m of each other.

When monitoring is paused and the monitoring state reverts to 'Not Monitoring' the Bluetooth connection is **suspended**.

Not Monitoring

No Bluetooth Connection between Wearable Medical Monitor and Smartphone.

No Data being transmitted from Wearable Medical Monitor to Smartphone.

LED light on Wearable Medical Monitor NOT blinking BLUE.

Monitoring

Smartphone and Wearable Medical Monitor connected via Bluetooth

Smartphone can control Wearable Medical Monitor and monitoring state

Data being transmitted from Wearable Medical Monitor to Smartphone

LED light on Wearable Medical Monitor will blink BLUE.

11.2 Bluetooth Signal Strength

If the Bluetooth signal between the Wearable Medical Monitor and the Smartphone weakens while monitoring (either due to the maximum allowable distance between the two being exceeded, or electromagnetic interference), a popup will be displayed on the Dashboard, alerting the user to the weakened Bluetooth signal strength and instructions to move closer.



Weak Bluetooth Signal popup displayed on top of Dashboard. The popup will dismiss automatically when signal strength improves.



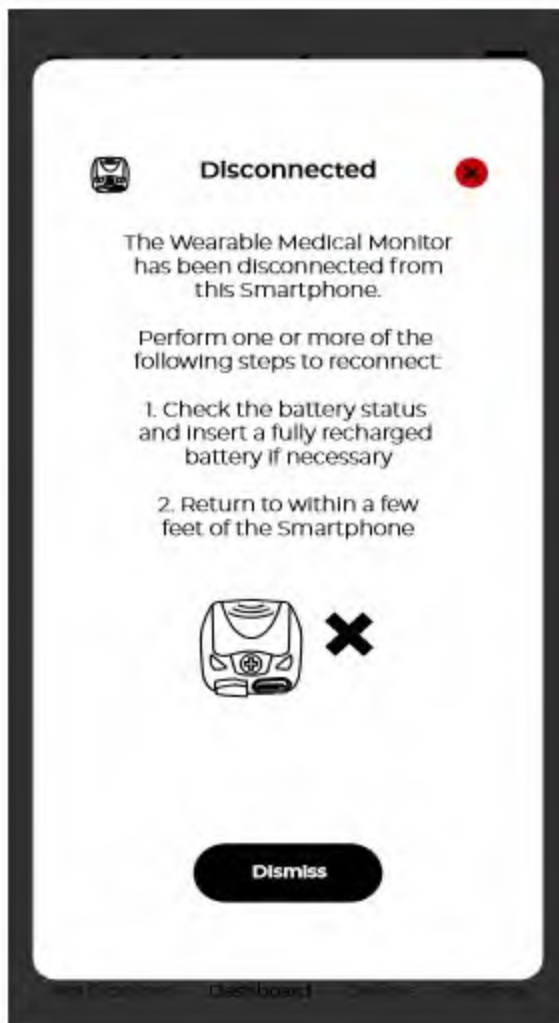
Bluetooth signal strength is indicated by 3 blue dots. It is always displayed on the Device Control Card on the Dashboard. It is also displayed on the Weak Bluetooth Signal popup seen here.

Hollow dots (outlines) indicate a weakened signal. Two out of three dots that are hollow indicate a very weak. Three solid dots indicate a strong signal.

11.3 Bluetooth Disconnection

The Bluetooth connection can be involuntarily terminated while monitoring in several ways:

1. Excessive distance between the Wearable Medical Monitor and Smartphone.
2. Wearable Medical Monitor battery completely depleted (0%)
3. Smartphone battery completely depleted (0%)



Disconnection popup displayed on Dashboard. The popup will dismiss automatically when connection has been re-established.

In cases **1** and **2**, a popup indicating that the Wearable Medical Monitor has been disconnected will be displayed on the Dashboard. Instructions to come back within Bluetooth range and/or insert a fully charged battery into the Wearable Medical Monitor are given.

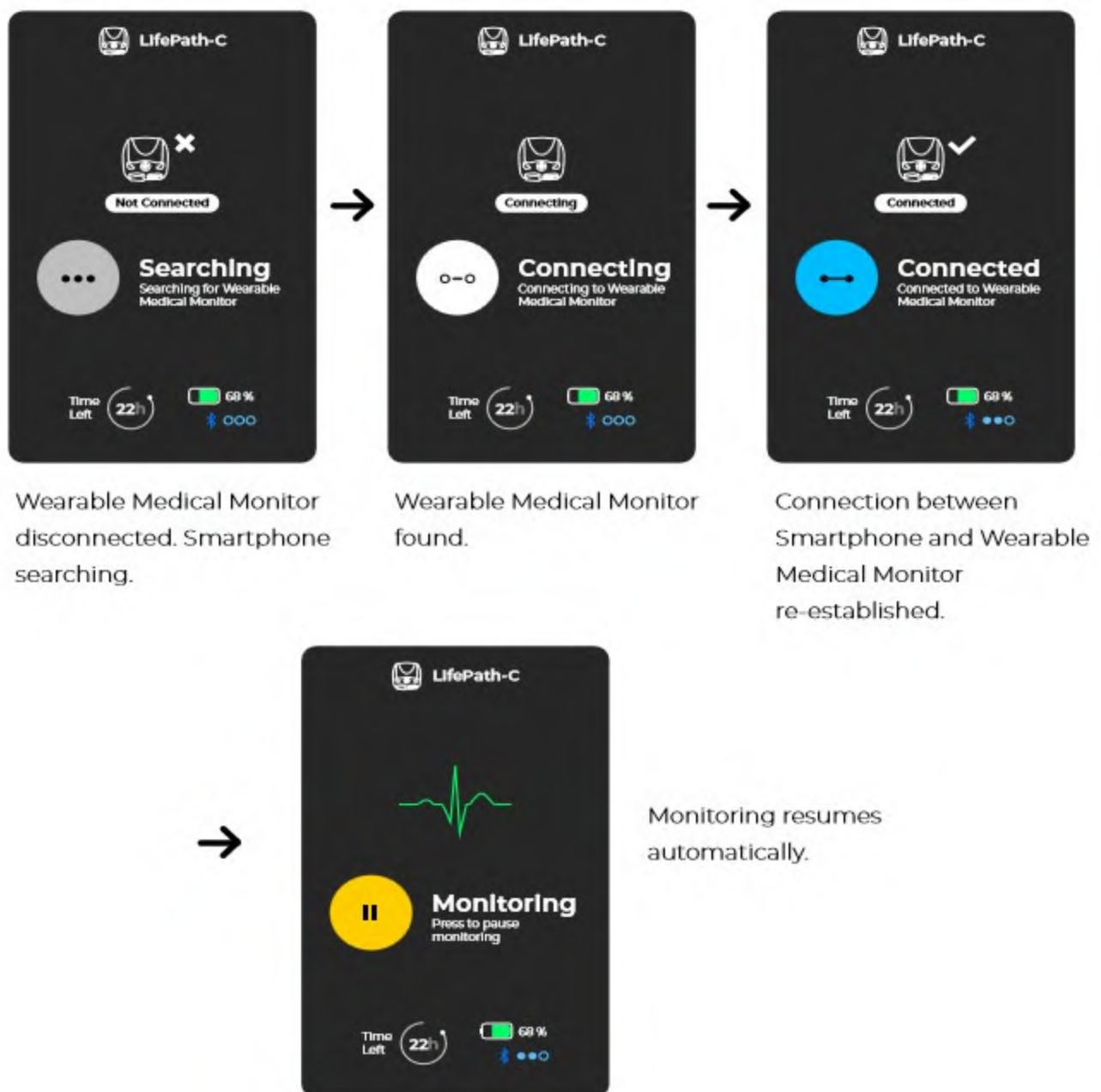
While disconnected, the Smartphone will continue to search for the paired Wearable Medical Monitor. If found (by returning within range, or if a charged battery is inserted into the Wearable Medical Monitor), the connection will be **automatically re-established**.

In the case that the Wearable Medical Monitor is out of range, **but still has battery power**, it will **continue to collect data**. This data will be transmitted to the Smartphone once the connection is re-established.

* If the Wearable Medical Monitor has battery power, but is out of range, the LED will stop blinking BLUE.

11.3 Bluetooth Disconnection

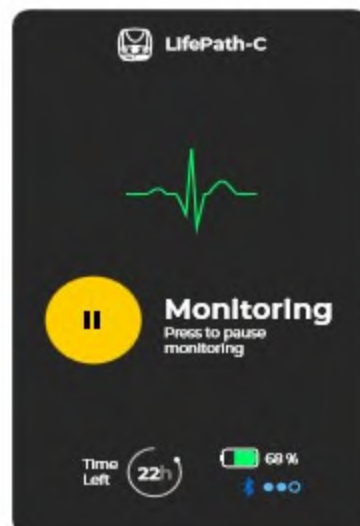
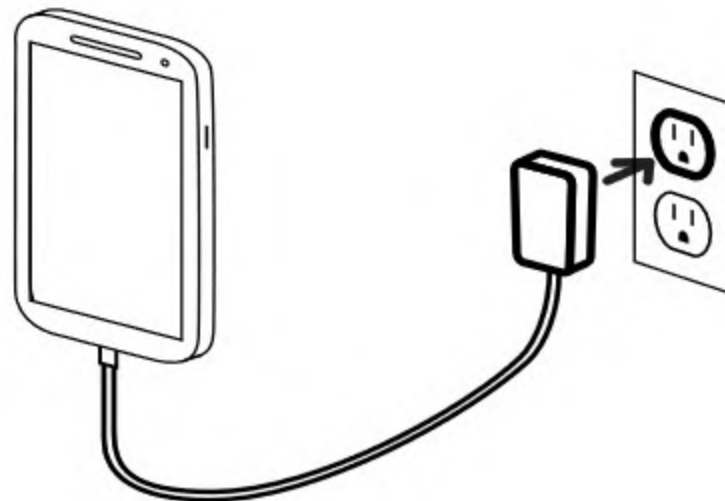
If the Disconnection popup is dismissed, the Dashboard will reflect the current **'Searching'** monitoring state. The Smartphone will search indefinitely until the Wearable Medical Monitor is found, or a scheduled maintenance is started. When the Wearable Medical Monitor comes back into range and/or a charged battery is inserted into it, the Bluetooth connection will automatically be restored and monitoring will resume.



11.3 Bluetooth Disconnection

In the case **3**, wherein the Smartphone battery is completely depleted and the device powers OFF while in a monitoring state, the Wearable Medical Monitor will continue to collect data (provided it has battery power).

Plug the Smartphone into the Smartphone Charger. Then plug the Smartphone Charger into a wall power outlet to begin recharging. Once powered ON, the Smartphone will boot automatically into the Elastic Care Mobile Application Dashboard and monitoring will automatically resume.



Smartphone boots into Elastic Care Mobile Application once sufficiently charged.

Monitoring automatically resumed.

11.4 Wi-Fi Disconnection

If the Smartphone gets disconnected from the current Wi-Fi network, a popup will be displayed on the Dashboard indicating the loss of connectivity. Tap the **'Proceed'** button to be taken to the Smartphone's Wi-Fi settings and connect to a network. Note: an internet connection is required for the operation of the LifePath-C system.



It is important to connect to a network as soon as possible after loss of connectivity.

The popup shown here will be displayed every few minutes until the Smartphone is connected to a Wi-Fi network with internet access.

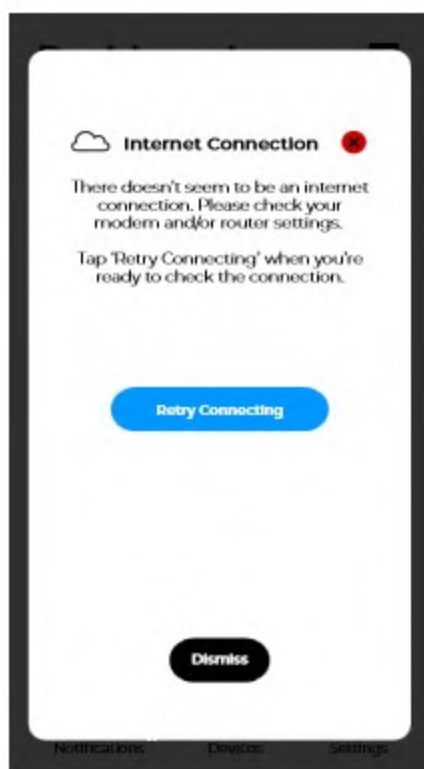
If there is no Wi-Fi access, and LifePath-C has been set up with an LTE connection, the Smartphone will switch to mobile data (LTE). Carrier charges may apply.

If no internet connection is available, the Smartphone will store up to **7 days of data** received from the Wearable Medical Monitor. As long as a Bluetooth connection between the two devices exists, which facilitates transfer of collected data from the Wearable Medical Monitor to the Smartphone, monitoring can continue. However, this may require the stored data backlog to be transferred to Elastic Care's servers at the end of the monitoring campaign in order to generate a complete report.

See the section titled **'Campaign End - Stored Data Transfer'** for more information.

11.5 No Internet Connectivity

If the Smartphone is connected to a Wi-Fi network, but there is no internet access, a popup will be displayed on the Dashboard. Check the modem and/or router settings to troubleshoot. The popup will dismiss automatically when internet connectivity is restored.



Tap the **'Retry Connecting'** button to be taken to the Smartphone's Wi-Fi settings to attempt to connect to another Wi-Fi network.

Check the modem and/or router settings in order to restore internet connectivity. As mentioned in the previous sub-section, without an active internet connection, the Smartphone will **store up to 7 days of collected data** received from the Wearable Medical Monitor.

See the section titled **'Campaign End - Stored Data Transfer'** for more information.

12 Wearable Medical Monitor Alerts

12.1 Vibration Alerts

The Wearable Medical Monitor will vibrate in the following scenarios: **When a vibration is felt, check the Elastic Care Mobile Application** on the Smartphone to view any accompanying notifications. These notifications will contain additional information and, when applicable, instructions to troubleshoot any issues.

Wearable Medical Monitor has been disconnected from the Smartphone

- 1 The Wearable Medical Monitor has moved out of range of the Smartphone.
The Wearable Medical Monitor will vibrate ONCE.
- 2 Monitoring has been paused.
The Wearable Medical Monitor will vibrate ONCE.

Cable Harness unplugged from Wearable Medical Monitor

The Cable Harness has been disconnected from the Wearable Medical Monitor's Cable Harness Port.

The Wearable Medical Monitor will vibrate ONCE every minute.

One or more ECG Leads off

One or more ECG leads have come off contact with the patient's torso.

The Wearable Medical Monitor will vibrate ONCE every minute.

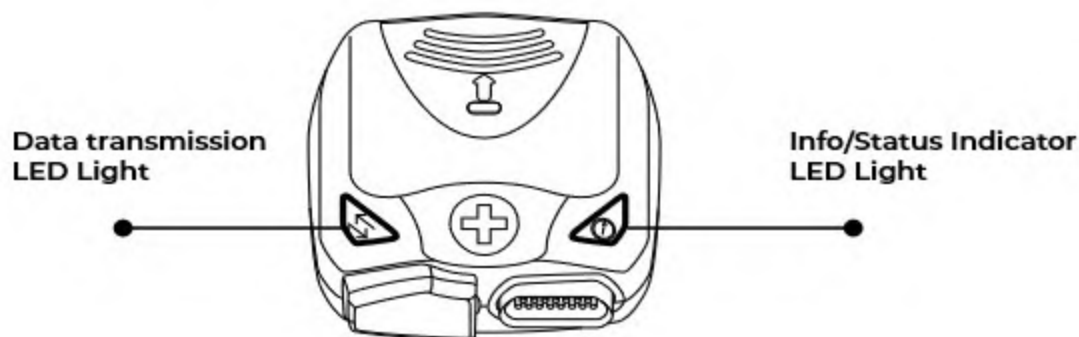
Wearable Medical Monitor Battery Low

The Wearable Medical Monitor battery is low in power (5% and lower)

The Wearable Medical Monitor will vibrate ONCE every minute.

12.2 LED Alerts

The Wearable Medical Monitor has two LED's which will indicate hardware and connection statuses.



Wearable Medical Monitor has been disconnected from the Smartphone

Data transmission LED: Blue LED stops blinking

Info/Status Indicator LED: Green LED blinks every second

Cable Harness unplugged from Wearable Medical Monitor

Data transmission LED: Blue LED continues blinking every second

Info/Status Indicator LED: Amber LED blinks every second

One or more ECG Leads off

Data transmission LED: Blue LED continues blinking every second

Info/Status Indicator LED: Amber LED blinks every second

Wearable Medical Monitor Battery Low

Data transmission LED: Blue LED continues blinking every second

Info/Status Indicator LED: Amber LED blinks every second

13 Battery and Power

13.1 Wearable Medical Monitor Battery Power

The Wearable Medical Monitor is powered by its rechargeable, removable lithium ion battery and can operate continuously for up to 24 hours, at which point, the battery must be replaced with one that is fully charged in order to continue operation. Failure to replace a depleted battery with one that is fully charged can result in data loss.

13.2 Spare Wearable Medical Monitor Battery

In order to facilitate uninterrupted, continuous monitoring without the need to wait for a battery to recharge, **two** (2) Wearable Medical Monitor Batteries are included in each LifePath-C package. Ensure one battery is always charging in the Battery Dock charger while the other is inserted in the Wearable Medical Monitor to allow for the fast swapping of a depleted battery with one that is fully charged when required. Swapping of batteries should be done during scheduled Maintenance.

13.3 Battery Safety

Keep Wearable Medical Monitor Batteries away from fire, excessive heat, and ignition sources.



Do not get the Wearable Medical Monitor Battery wet.

Do not attempt to puncture, or tamper with the Wearable Medical Monitor Battery.

Do not use a Wearable Medical Monitor Battery that is damaged.

Do not insert a Wearable Medical Monitor Battery into a damaged Wearable Medical Monitor.

Do not dispose of Wearable Medical Monitor Batteries in the trash.

13.4 Low Battery Warning

When the Wearable Medical Monitor Battery is low (approximately 5% or less), a popup will be displayed on the Dashboard indicating the low battery status. The patient will be instructed to return to the healthcare facility in order to have the battery changed with one that is fully charged.

In addition, the Wearable Medical Monitor will vibrate once per minute while the battery is under 5% and the LED Indicator Light will blink AMBER.



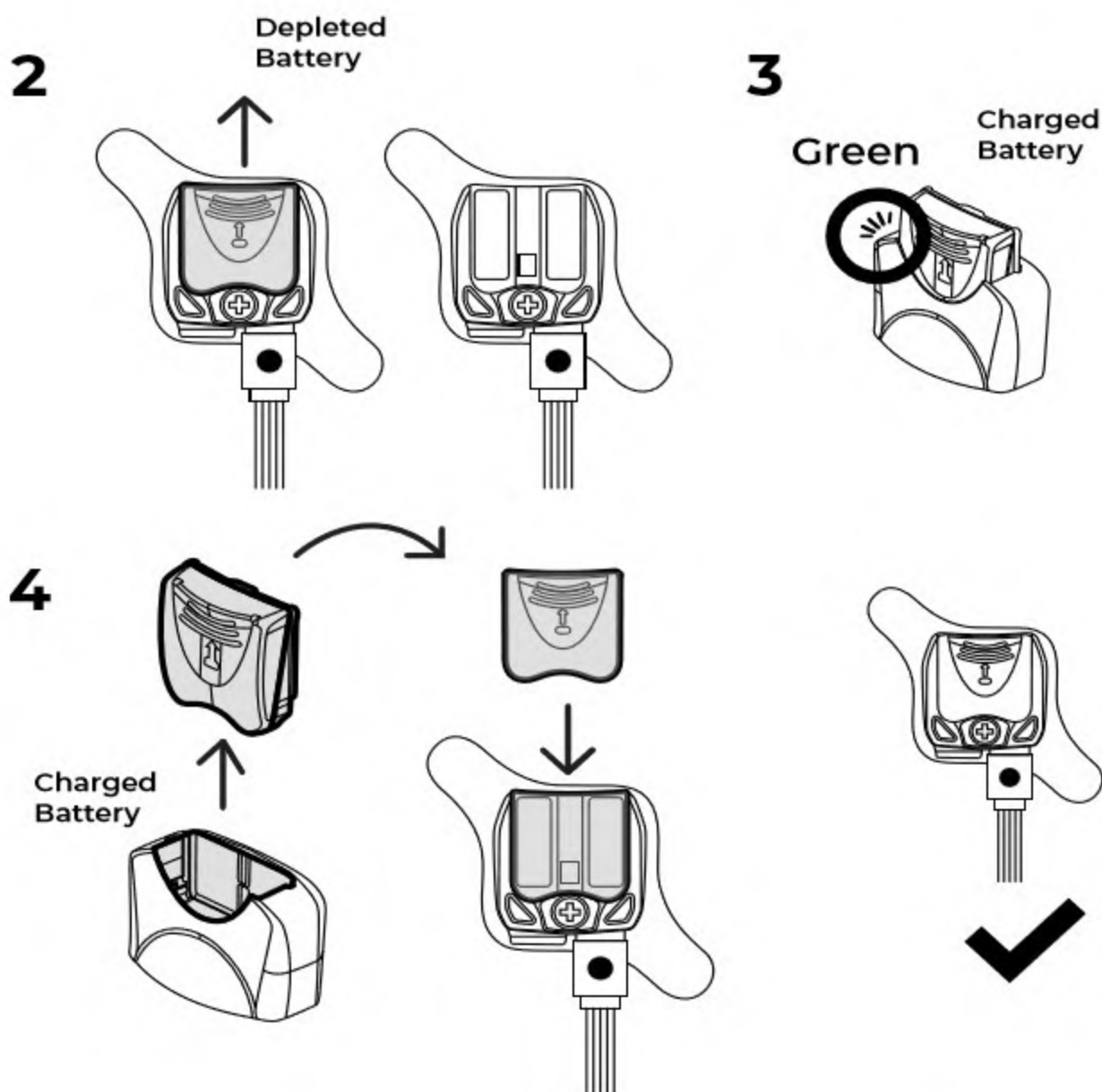
The healthcare facility should ensure that one of the two Wearable Medical Monitor batteries included in the LifePath-C package is always fully charged. This reduces the risk of lost data due to The Wearable Medical Monitor having no battery power for an extended period of time.

Ensure that a depleted battery is always placed immediately into the Battery Dock Charger and is charging.

13.5 Swapping Batteries

- 1 Prior to swapping batteries, tap the **Pause Monitoring** button on the Dashboard to pause the monitoring.

While attached to the patient, remove current Wearable Medical Monitor battery and slide in a fully charged battery. Press the **Start Monitoring** button to resume monitoring. Insert depleted battery into the Battery Dock charger to charge.



14 Data Storage

14.1 Wearable Medical Monitor Data Storage

In the event that the Wearable Medical Monitor is disconnected from the Smartphone while monitoring, it will store the **most recent 24 hours of data collected** to its onboard storage. Upon re-connecting with the Smartphone, the stored data is sent before resuming real-time data transfer.

Depending on the amount of stored data, this may create a 'buffer' or backlog of data, which will need to be flushed to the Smartphone at the end of the monitoring campaign. See the section titled '**Campaign End - Stored Data Transfer**'

14.2 Smartphone Data Storage

In the event that the Smartphone is disconnected from the internet during the monitoring campaign, it will store the **most recent 7 days of data** to its onboard storage. Upon re-connecting to the internet, the stored data is sent to Elastic Care's servers before resuming real-time data transfer.

Depending on the amount of stored data, this may create a 'buffer' or backlog of data, which will need to be flushed from the Smartphone to Elastic Care's Servers at the end of the monitoring campaign. See the section titled '**Campaign End - Stored Data Transfer**'

15 Cleaning the LifePath-C System

15.1 Warnings and Cautions for Cleaning the LifePath-C System

The following warnings apply to the cleaning of the LifePath-C system hardware. Where applicable, refer to relevant steps during the Maintenance Procedure for more information.

-  Use only materials supplied and recommended for cleaning the LifePath-C system hardware.
-  Do not pour water on any LifePath-C hardware.
-  Do not submerge LifePath-C hardware in a bleach solution.
-  To avoid cross contamination, properly clean all reusable components of the LifePath-C system and use disinfecting wipes on all hardware surfaces.
-  Do not pour any liquid on the Wearable Medical Monitor, Wearable Medical Monitor Battery, Battery Dock Charger, or Charging Adapter.
-  Do not clean Wearable Medical Monitor Battery or Battery Dock Charger while battery is charging.
-  Do not use abrasive cleaning agents.
-  Do not autoclave LifePath-C hardware.
-  Ensure the ECG cable is dry before connecting it to the Wearable Medical Monitor.

15.2 Cleaning Procedure

1. Use one of the provided Adhesive Remover Wipes to remove any remaining adhesive from the back surface of the Wearable Medical Monitor.
2. With the provided 70% Isopropyl Alcohol Swabs, wipe away any dirt, oil, or debris from all surfaces of LifePath-C hardware; Wearable Medical Monitor, Wearable Medical Monitor Battery, Harness, ECG Snaps, and Wearable Medical Monitor Battery Dock Charger.
2. Use multiple swabs if necessary. Do not use any other cleaning materials or chemicals.

15.3 Additional Cleaning Measures

1. Use a **disinfecting wipe** to wipe down all LifePath-C hardware surfaces.
2. Use a clean, dry soft cloth or paper towel to thoroughly dry LifePath-C hardware surfaces.

15.4 Disposing of Used Consumables



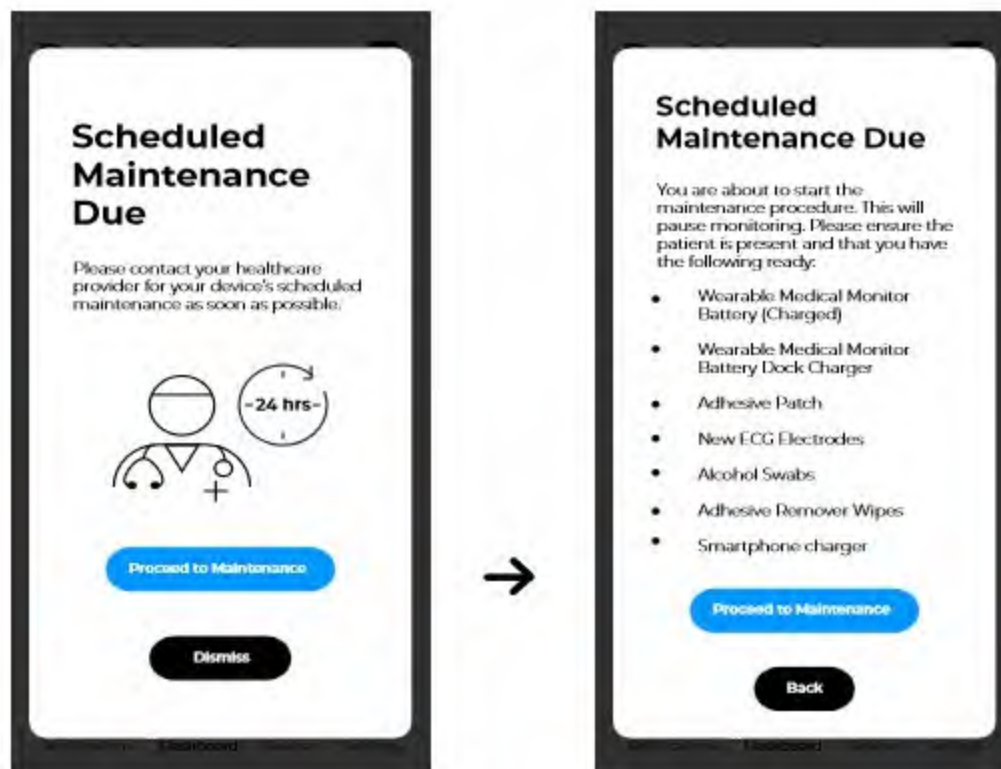
Do not re-use single use disposable components such as Adhesive Patches, ECG Electrodes, Alcohol Swabs, or Adhesive Remover Wipes. These components may contain bio-hazard materials. Handle and dispose of these materials according to your facility's policies.

16 Maintenance

During the monitoring campaign, scheduled maintenance of the LifePath-C system will need to be performed by the nurse or nurse equivalent approximately every 24 hours.

A reminder message popup will be displayed on the mobile application Dashboard, instructing the patient to contact the healthcare facility for the scheduled maintenance as soon as possible.

*Ensure the patient is present, along with the listed items, **prior** to tapping the 'Proceed to Maintenance' button. **When the maintenance procedure begins, monitoring will be paused automatically.**



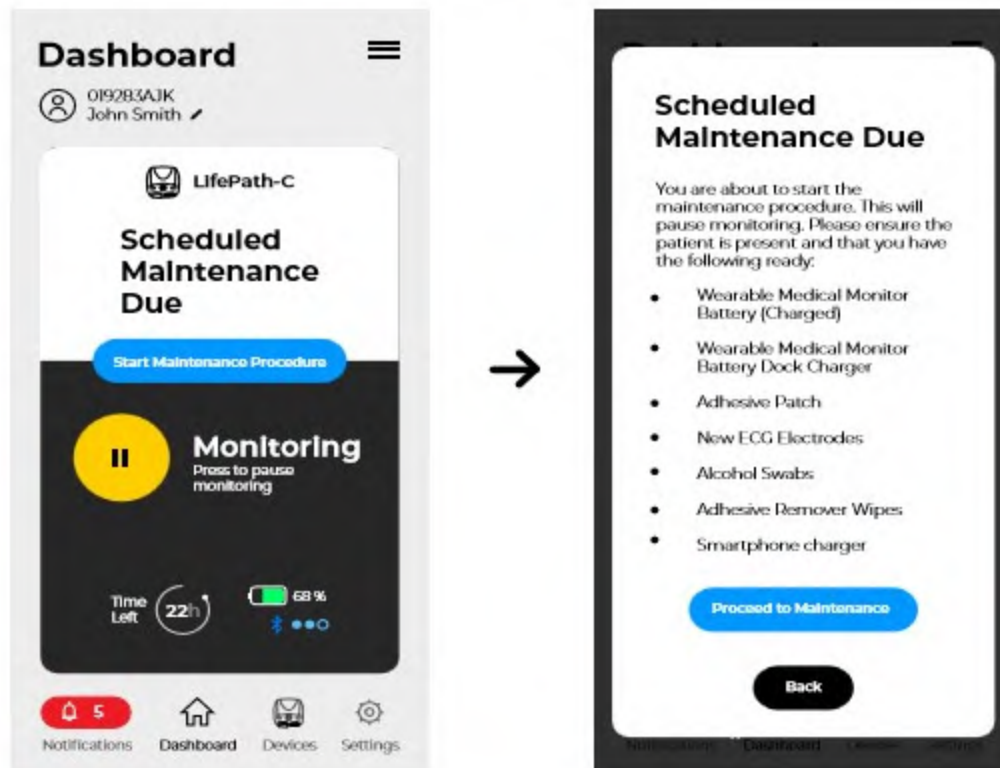
Maintenance Due reminder popup. Tapping 'Start Maintenance Procedure' button will bring up list of required persons and items for scheduled maintenance.

List of required persons and items for scheduled maintenance.

Tapping 'Proceed to Maintenance' button will start Maintenance Procedure.

16 Maintenance

If the Maintenance Due reminder popup is dismissed, the Dashboard will appear as it does below until the Scheduled Maintenance is performed. In order to start the maintenance procedure, tap the 'Start Maintenance Procedure' button on the Dashboard.



Maintenance Due reminder on Dashboard. Tapping 'Start Maintenance Procedure' button will bring up list of required persons and items for scheduled maintenance.

List of required persons and items for scheduled maintenance.

Maintenance screens will be displayed on the Elastic Care Mobile Application. Tap the 'Next' button after each step is completed to advance to the next step.

16 Maintenance

List of required items for Scheduled Maintenance:

- Wearable Medical Monitor Battery (Charged)
- Wearable Medical Monitor Battery Dock Charger
- Adhesive Patch
- New ECG Electrodes
- Alcohol Swabs
- Adhesive Remover Wipes
- Smartphone charger

Tap the 'Proceed to Maintenance' button. Read and acknowledge all warnings and cautions. Tap the 'I Acknowledge' button to begin when prompted.

Warning

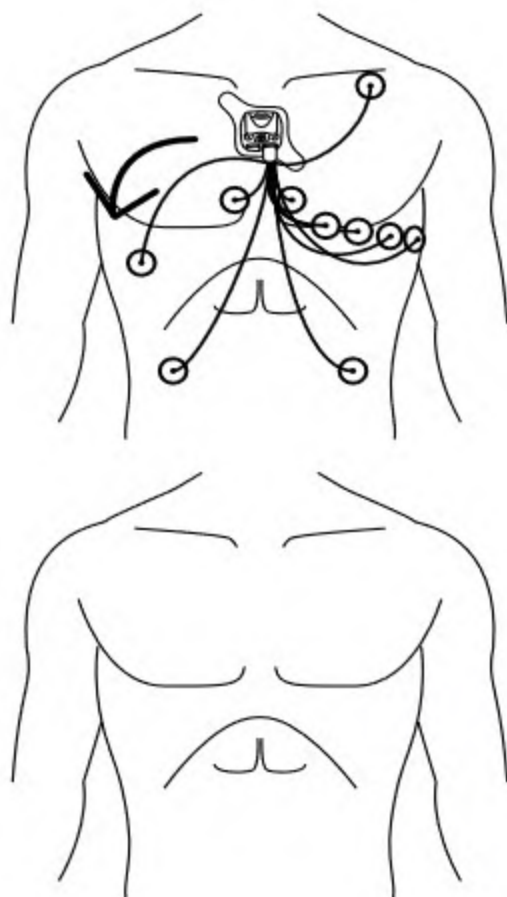
The following warnings apply to the cleaning the LifePath-C system hardware. Refer to the relevant steps during this maintenance procedure for more information.

- Use only materials supplied and recommended for cleaning LifePath-C hardware.
- Do not pour water on any LifePath-C hardware.
- Do not submerge the LifePath-C system in bleach solutions
- To avoid cross contamination, properly clean all reusable components of the LifePath-C system.
- Do not pour any liquid on the Wearable Medical Monitor, Wearable Medical Monitor Battery, Battery Dock Charger, or Charging Adapter.
- Do not clean Wearable Medical Monitor Battery or Battery Dock Charger while battery is charging.
- Do not use abrasive cleaning agents.
- Clean all LifePath-C hardware after every use.
- Do not autoclave LifePath-C hardware.
- Ensure the ECG cable is dry before connecting it to the Wearable Medical Monitor.
- Disposable components such as ECG electrodes, alcohol swabs, and adhesive remover wipes may contain bio-hazard materials. Handle and dispose of these materials according to your facility's policies.
- Do not re-use disposable components.

Step 1

Remove from Patient

Carefully remove the Wearable Medical Monitor with the attached harness + Adhesive Patch, and all electrodes from the patient's torso.

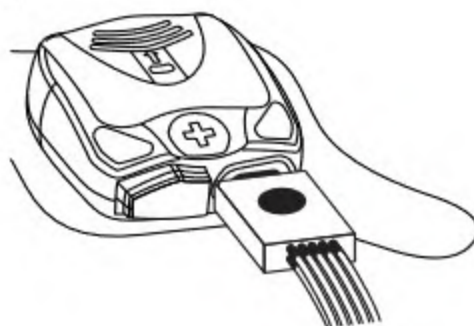


Step 2

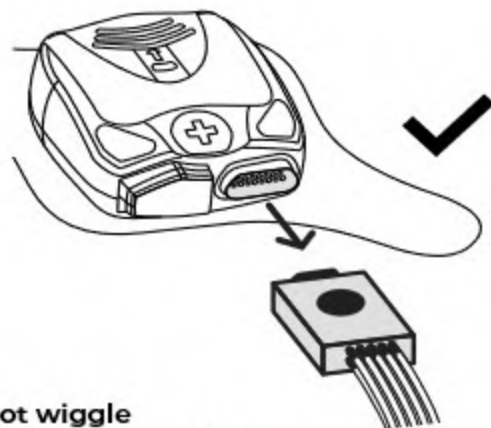
Detaching

Detach the Cable Harness from the Wearable Medical Monitor.

1



2



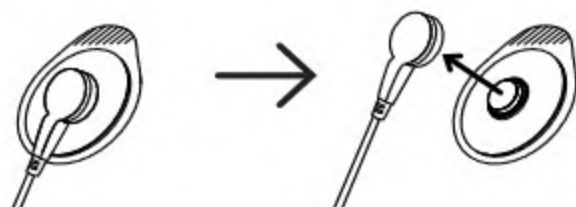
Do not wiggle the harness connector as it may damage the Wearable Medical Monitor and/or Cable Harness.

Step 3

Detaching

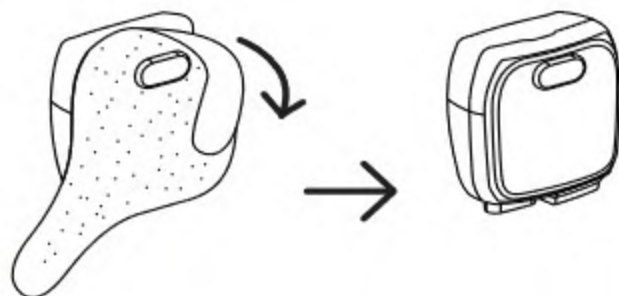
Detach all ECG electrodes and discard. Peel off Adhesive patch from Wearable Medical Monitor and discard.

1



x 10 (or x 4)

2

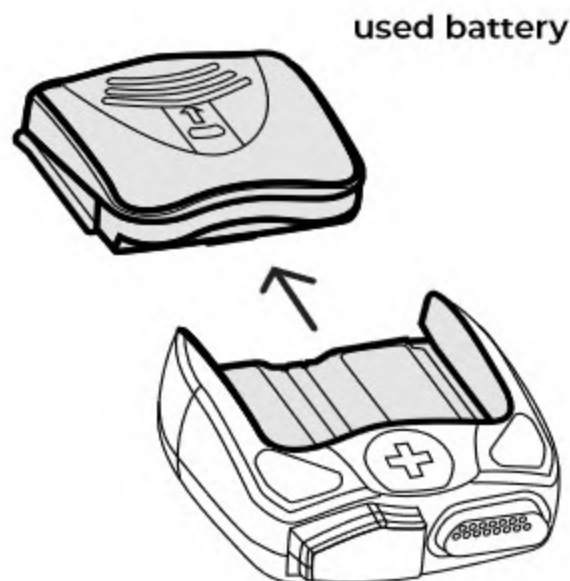


Do not re-use single use products.

Step 4

Remove used battery

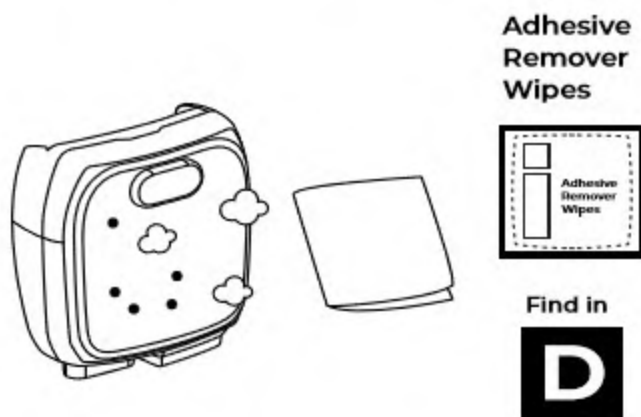
Slide out the used battery from the Wearable Medical Monitor.



Step 5

Clean Device

Use one of the included Adhesive Remover Wipes to remove any remaining adhesive from the back surface of the Wearable Medical Monitor.



***Note-** do not re-use Adhesive Remover Wipes. Discard after each use.



Do not re-use single use products.

Step 6

Clean Device

Use a disinfecting wipe (not included) to thoroughly wipe down the LifePath-C system hardware.



Do not use excessive amounts of liquid when cleaning LifePath-C hardware.

Step 7

Dry Surfaces

Use a clean dry cloth to remove excess alcohol or liquid from all surfaces. Ensure the device is completely dry.



Do not re-use single use products.

Step 8

Clean Patient

Use an alcohol swab (included) and clean patient's torso.

Alcohol
swab



Find in



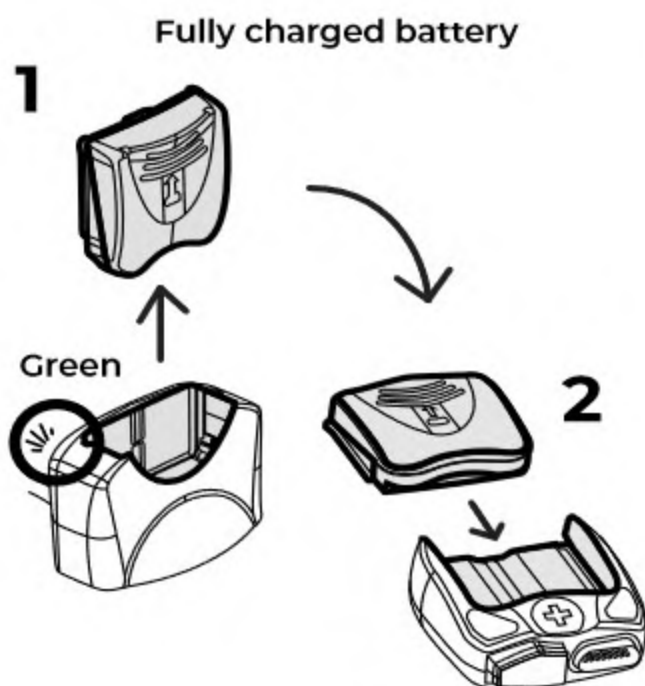
***Note-** do not re-use alcohol swabs. Discard after each use



Do not re-use single use products.

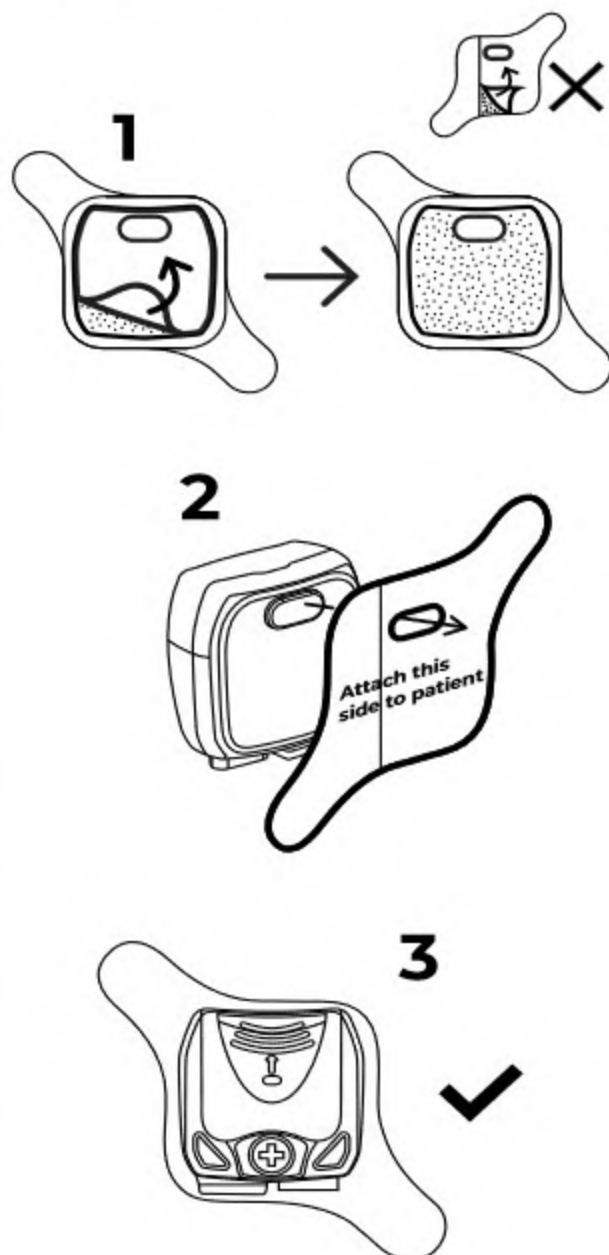
Step 9

Insert a fully charged battery



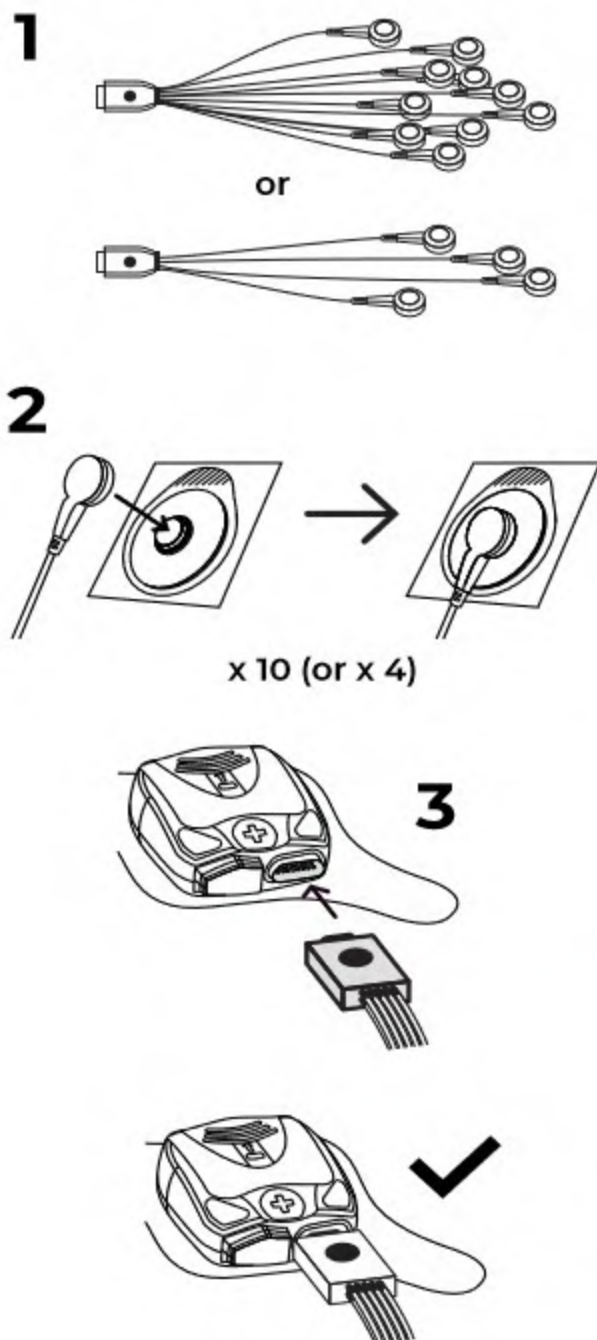
Step 10

Peel, align, and attach a new adhesive patch.



Step 11

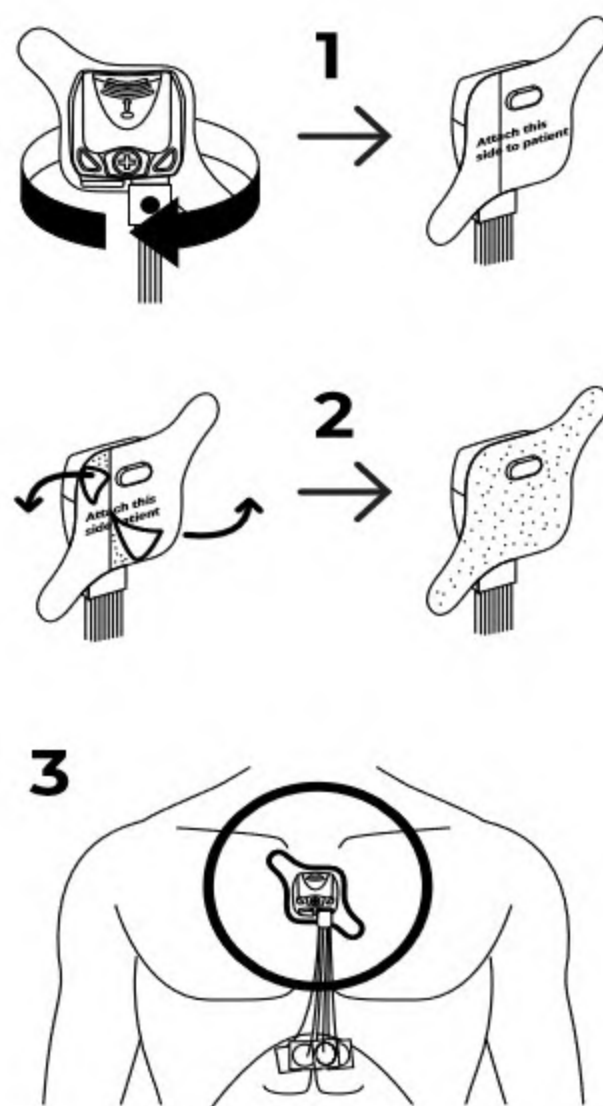
Select harness, snap electrodes, and insert harness.



Step 12

Attaching

Flip, peel backing, and attach to patient's sternum,

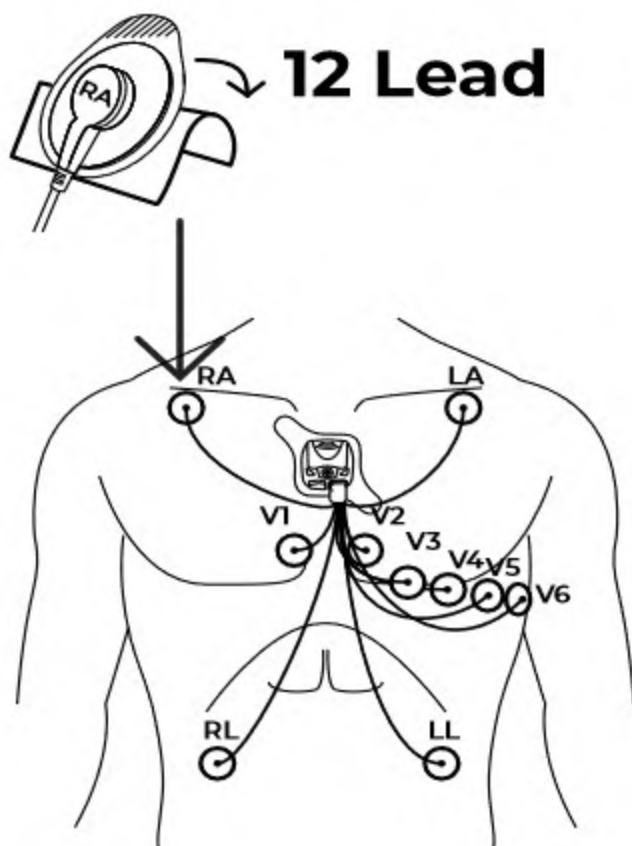


***Note- do not re-use adhesive patch. Discard after each use**

Step 13 (12-Lead)

Attaching

One at a time, peel electrodes and attach to the patient's torso as shown.

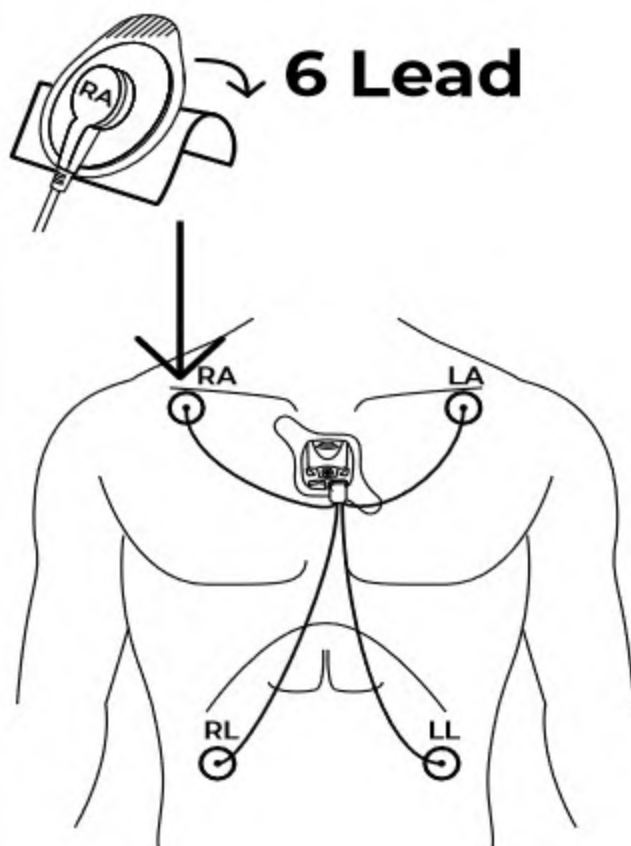


*Note- do not re-use electrodes.
Discard after each use.

Step 13 (6-Lead)

Attaching

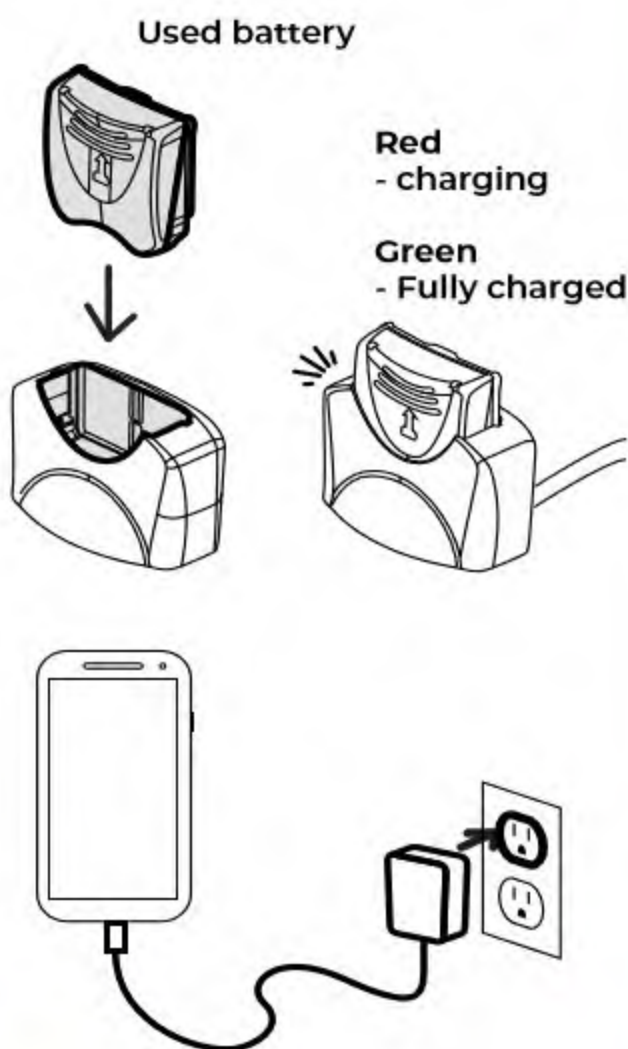
One at a time, peel electrodes and attach to the patient's torso as shown.



Step 14

Recharge

Charge the discharged Wearable Medical Monitor Battery as well as the Smartphone.



 Use only provided Smartphone charger. Use of other cables and/or adapters can cause damage to the Smartphone.

Maintenance Complete



*This step must be performed during the Maintenance Procedure in the Elastic Care App.

Tapping the 'Finish' button on the final maintenance screen will bring you back to the Dashboard.

Finish

Tap the 'Start Monitoring' button on the Dashboard to resume monitoring. After doing so, you can discharge the patient.



Not Monitoring

Press to start monitoring

17 Campaign End

When the selected length of time for the monitoring campaign has elapsed, the campaign will end **automatically**. Monitoring will stop and the Wearable Medical Monitor will halt data collection. The monitoring state will revert to 'Not Monitoring'.



Monitoring will automatically stop when the campaign duration has elapsed.

Note: it is NOT possible to re-initiate monitoring after a campaign has ended. If you would like to continue monitoring, you will be required to set up a new monitoring campaign.

Ending a Monitoring Campaign Early

If required, you can end a monitoring campaign early by tapping the **Logout** button inside the Settings menu. **Note:** this should be carried out by **authorized personnel only** (physician, nurse, or healthcare provider responsible for the patient). Ending a campaign early cannot be undone.

Remove LifePath-C System

Once the campaign has ended, you may remove the LifePath-C system from the patient. For more information, see the section titled '**Removing and Returning**'.

Important Steps After End of Monitoring

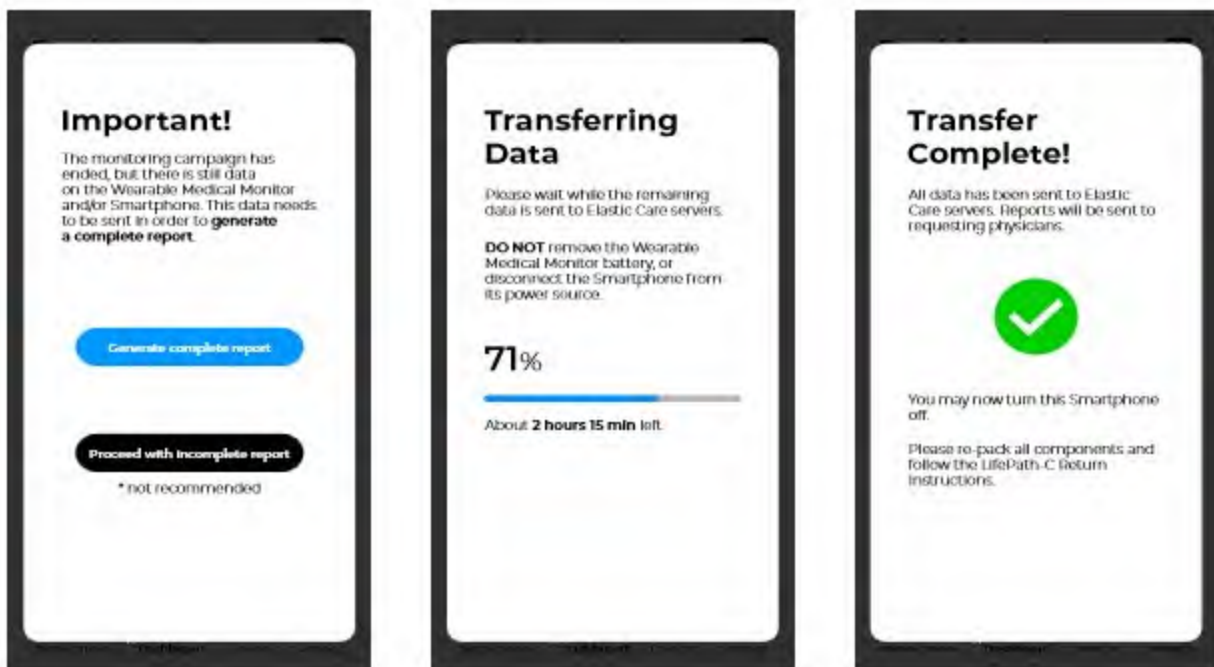
While the monitoring campaign has ended, there may still be data on board the Wearable Medical Monitor and/or Smartphone. This data needs to be sent to Elastic Care's servers in order to generate a complete report. At the end of the monitoring campaign, you will be given the option to transfer this data. See the section titled '**Campaign End - Stored Data Transfer**' for more information.

17.1 Campaign End - Stored Data Transfer

If there is data stored either on the Wearable Medical Monitor or the Smartphone at the end of a monitoring campaign, you will be notified and a given the option to transfer the stored data to Elastic Care's servers. It is **highly recommended** that this be done in order to generate a complete report.

Follow the prompts given on the screen to transfer the stored data. Ensure that the Wearable Medical Monitor has a full battery, and the Smartphone is connected to a power source, as well as a Wi-Fi network, prior to beginning the data transfer.

***Do NOT remove the Wearable Medical Monitor battery or turn the Smartphone OFF during data transfer. If the Wearable Medical Monitor's battery runs low during the transfer, you'll be prompted to charge it. Follow instructions for charging, insert a fully charged battery into the Wearable Medical Monitor, and resume the data transfer.**



Once the transfer has been completed, you can turn the Smartphone OFF, remove the LifePath-C system from the patient and follow the cleaning procedure as outlined in this user manual.

If the Wearable Medical Monitor Battery becomes low, the transfer will automatically pause, and you will be instructed to insert a fully charged battery before continuing the transfer.

18 Removing and Returning

18.1 Removing LifePath-C

After the monitoring campaign has ended, you may detach LifePath-C from the patient. Follow **Steps 1 through 8 of Maintenance Procedure** in order to :

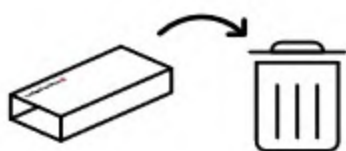
1. Remove the Wearable Medical Monitor from the patient
2. Unplug the Cable Harness from the Wearable Medical Monitor
3. Peel off the Adhesive Patch from the Wearable Medical Monitor and discard the used Adhesive Patch.
4. Unsnap the ECG Leads from the ECG Electrodes and discard the used ECG Electrodes.
5. Use one of the included Adhesive Remover Wipes to remove any residual adhesive on the back surface of the Wearable Medical Monitor.

Once completed, follow the following steps (Also outlined in the Return Instructions Card) to return the LifePath-C to Elastic Care.

18.2 Returning LifePath-C

Ensure that the Wearable Medical Monitor, batteries, and all other components are accounted for prior to returning. **Do not mix components from different LifePath-C packages.**

1 Discard the sleeve



2 Collect all components and complete checklist as you carefully repack them into their slots in the LifePath-C box.

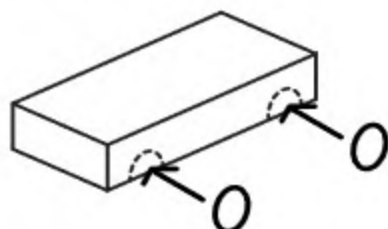


Component checklist

- ☐ Smartphone
- ☐ Wearable Medical Monitor
- ☐ Wearable Medical Monitor Battery x2
- ☐ Wearable Medical Monitor Battery Dock
- ☐ Battery Dock Charging Adapter
- ☐ Smartphone Charger
- ☐ ECG Harness (12 Lead & 6 Lead)
- ☐ Wearable Medical Monitor Adhesive Patches
- ☐ Alcohol Swabs
- ☐ Adhesive Remover Wipes
- ☐ ECG Electrodes

18.2 Returning LifePath-C

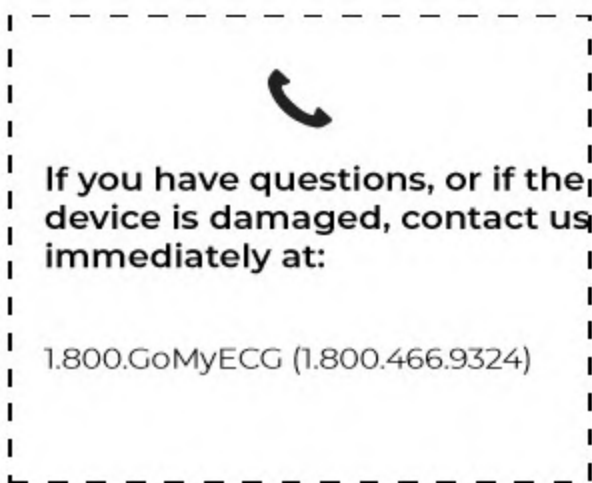
- 3** Attach included seals on the spaces indicated on the box



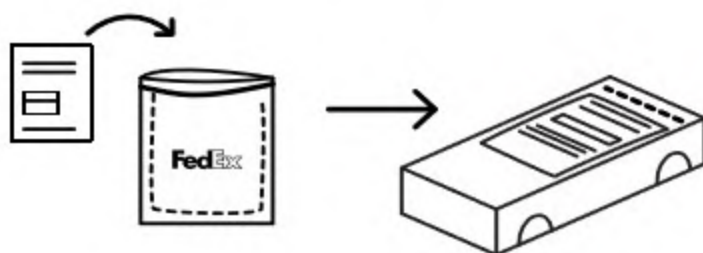
- 6** Call FedEx at 1.800.463.3339 (1.800.GoFedEx) to arrange for a pickup.



- 4** Fill the Shipping Air Waybill provided



- 5** Place waybill into shipping pouch and attach pouch where indicated on the box



19 Third Party Devices

LifePath-C can be used with Elastic Care-approved, Bluetooth enabled third-party devices in order to collect additional signals/data during the monitoring campaign. Blood pressure monitors, pulse oximeters, and glucometers can be added to the LifePath-C monitoring campaign by tapping the 'Devices' tab, then the **+Add Devices** button.

With a device added, you can control it, as well as see the readings it has obtained within the Dashboard for the selected device. Data obtained from third party devices are sent to Elastic Care's servers, and are added to the campaign reports.

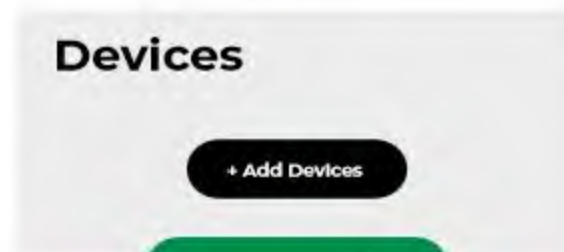
Note: All readings displayed on the LifePath-C Dashboard for the device are as they appear on the device, with no processing, analysis, or approximation.

19.1 Adding A Third-Party Device



During a monitoring campaign. Tap the 'Devices' tab in the bottom navigation menu. You will see a **Device Card** for the current device, LifePath-C, along with information pertaining to the connection and monitoring status of the Wearable Medical Monitor.

Tap the **+Add Devices** button at the top of the screen to begin the Add Devices procedure.



19.1 Adding A Third-Party Device

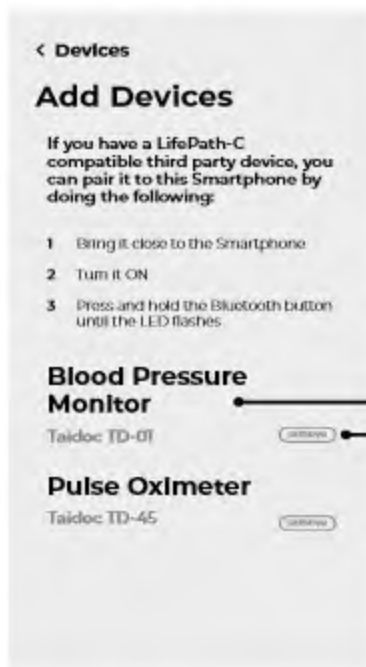


The 'Add Devices' procedure consists of the following three steps.

1. Bring the third-party device close to the Smartphone
2. Turn the device ON
3. Press and hold the Bluetooth button on the device until the device's Bluetooth LED begins to flash. This will enter it into Bluetooth pairing mode.

With the device in Bluetooth pairing mode, the Smartphone will automatically detect its presence and add it to LifePath-C campaign.

Note: Devices must be added one a time.



Successfully added devices will be listed, along with the type of device (Ex: Blood Pressure Monitor), and model number.

You can remove an added device by tapping the **remove** button

Note: If the device does not have a Bluetooth pairing button, consult the manufacturer's instructions regarding entering the device into Bluetooth pairing mode.

With the devices added, you can tap the back < button at the top of the screen to return to the 'Devices' screen.

< **Devices**

Successfully added devices will automatically be shown.

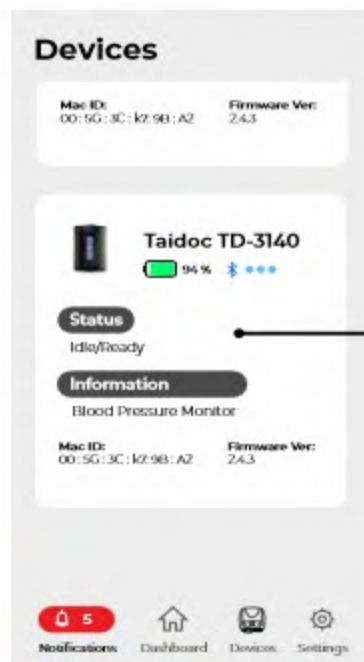
19.1 Adding A Third-Party Device



When a third-party device has been successfully added to the LifePath-C campaign, it will appear in the list of devices in the 'Devices' section of the

Scroll down to view its **Device Card**, which will contain information about the device.

19.2 Switching To A Third-Party Device



Tap the device's **Device Card** to switch to the selected device.

A popup prompting you to confirm switching to the third party device will be displayed.



Read the manufacturer's instructions for use, and ensure to heed all warnings and cautions prior to tapping the Proceed button



19.2 Switching To A Third-Party Device



Upon confirming the switch to a third-party device, it will be labeled as the 'Current Device'.

To switch back to LifePath-C, tap its device card. The Dashboard will revert back to displaying its Device Control Card.

Note: If the last known state of the Wearable Medical Monitor was 'Monitoring' and the Wearable Medical Monitor has battery power, it will continue to collect data while third-party devices are in use.

19.3 Using A Third-Party Device



When switched over to a third-party device, the Dashboard will display its **Device Control Card**, as it is the **current device**.

The Dashboard will display all readings obtained with the device.

Readings are not modified, adjusted, processed, or altered in any way.

Tapping the **Start button** will instruct the device to begin taking a measurement. Results are displayed in real time.

Note: Prior to tapping start, ensure the device is powered ON and near the Smartphone.

19.3 Using A Third-Party Device



Example: A blood pressure measurement being taken with a paired blood pressure cuff. Time of most recent reading will be displayed under each measurement.

Multiple Measurements

There is no limit to the number of measurements you can take with third-party devices.

Tapping the **Start button** after a measurement has completed will take a new one. Only results of the *most recent measurement* will be displayed.

All measurements obtained by third-party devices will be added, along with their time stamps, to LifePath-C campaign report.

Switching Back to LifePath-C

Tapping the LifePath-C **Device Card** from the Devices screen will make the Wearable Medical Monitor the current device once again. The monitoring state will revert to last known state prior to switching to a third-party device.

20 Thresholds For Vitals

During the setup process, you will be prompted to enter **upper and lower thresholds** for various biometric parameters collected during the monitoring campaign. **Reports** will show when these have been breached. It is important to check with the assigning physician for these values prior to setting up a monitoring campaign.


Heart Rate
 tap to change

44 bpm

115 bpm

lower threshold

upper threshold

• • •

Heart Rate

Resp. Rate

Skin Temp.


Respiration Rate
 tap to change

10 brpm

33 brpm

lower threshold

upper threshold

• • •

Heart Rate

Resp. Rate

Skin Temp.


Skin Temperature
 tap to change

35 °C

39.5 °C

lower threshold

upper threshold

• • •

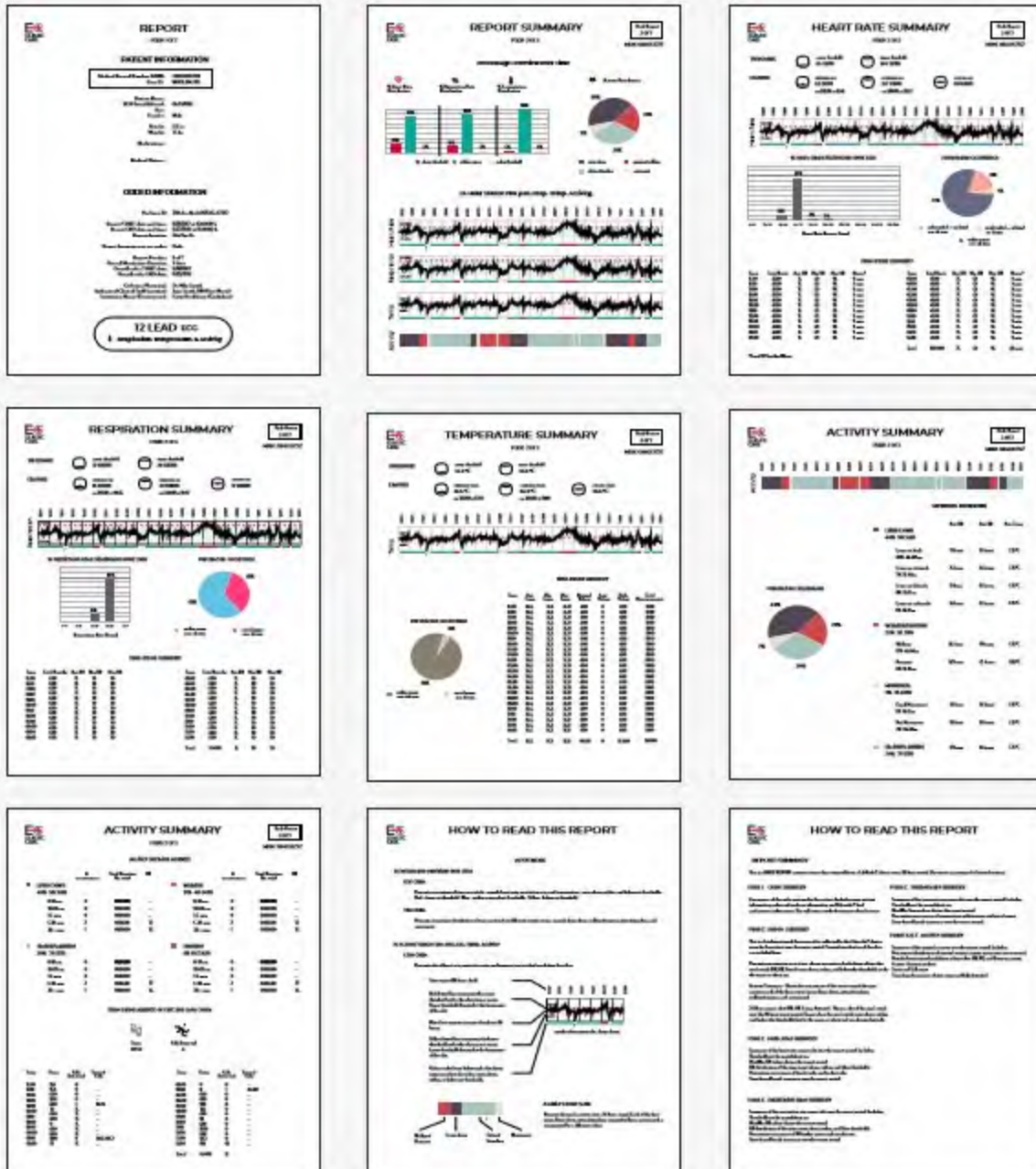
Heart Rate

Resp. Rate

Skin Temp.

21 Reports

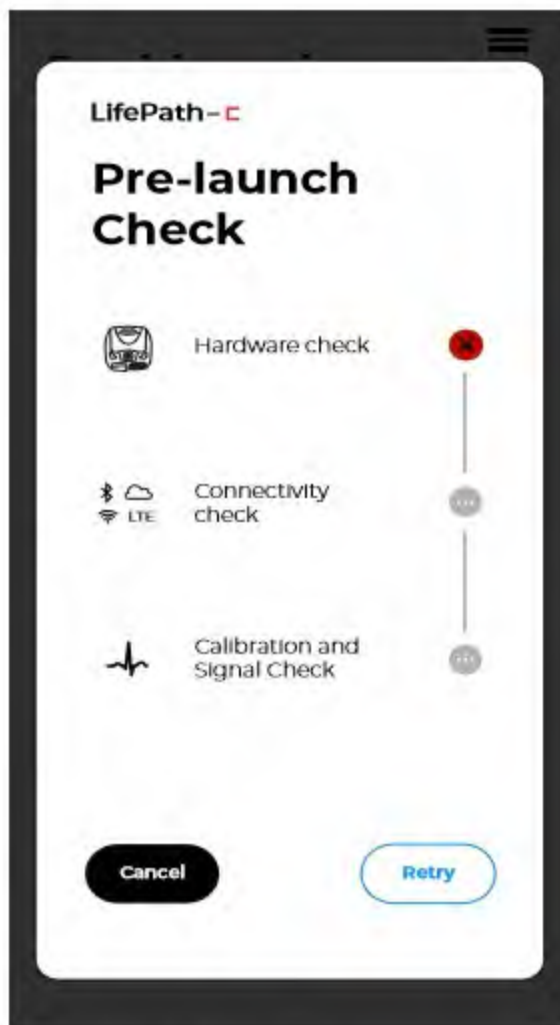
Clinical reports as shown below will be sent in a periodic manner based on the delivery frequency selected during the campaign configuration. The report period starts when the patient monitoring has commenced.



22 Pre-Launch Check Errors

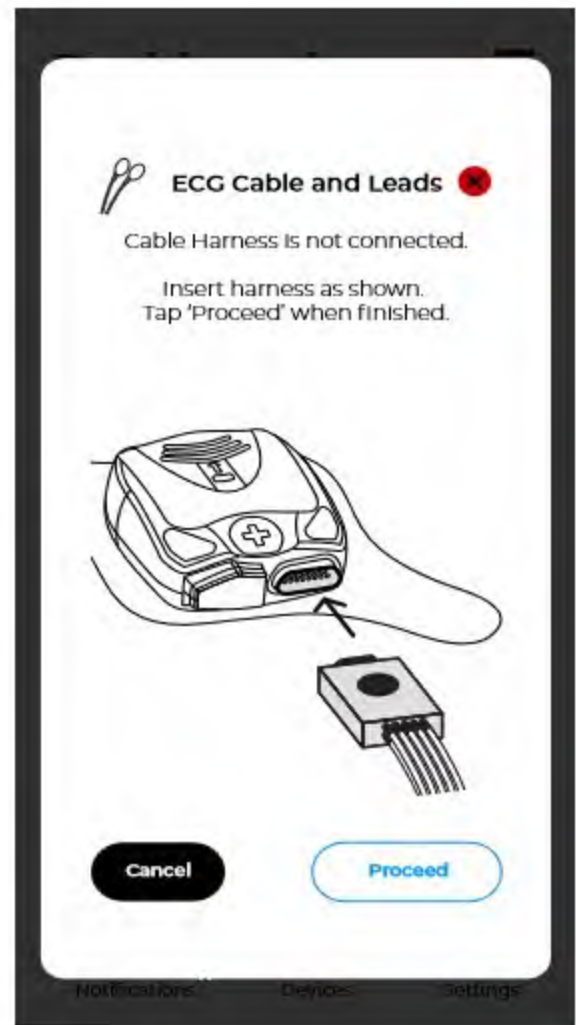
The following will detail the error cases you may encounter during the Pre-Launch Check. If an error is found during one of the stages, it will be indicated with a red 'x'  symbol and you will be **required** to correct the error before advancing to the next stage of the Pre-Launch Check.

In each error case, you will be provided with a description of the error, as well as steps to troubleshoot it. Once corrected, a large green checkmark symbol will be displayed, and the 'Proceed' button will become active. Tapping this button will re-initiate the Pre-Launch check.



Pre-Launch Error Example

A red 'x' indicating an error relating to Hardware.



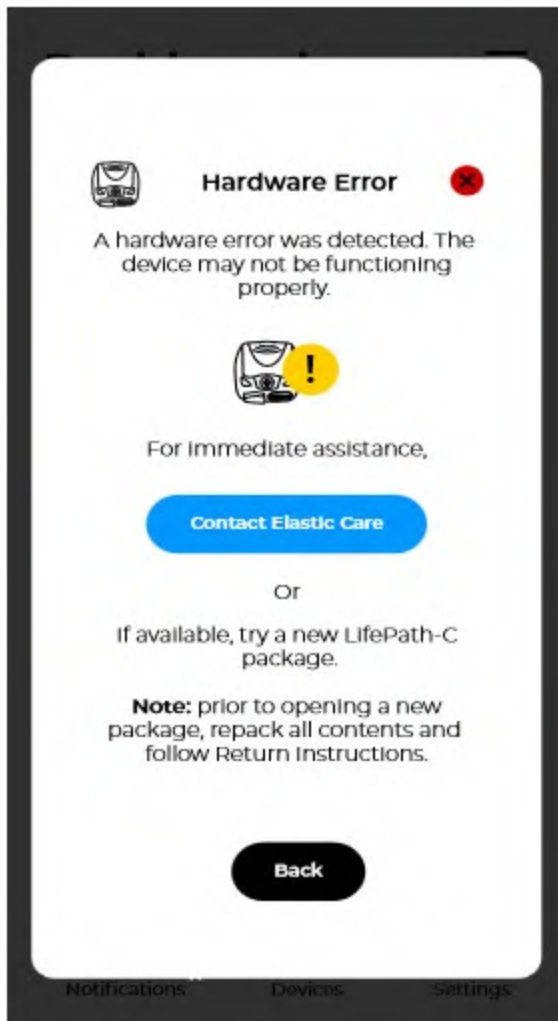
Description of Error Example

Description of error given with troubleshooting steps. 'Proceed' button will activate once corrected.

22 Pre-Launch Check Errors



Hardware Errors

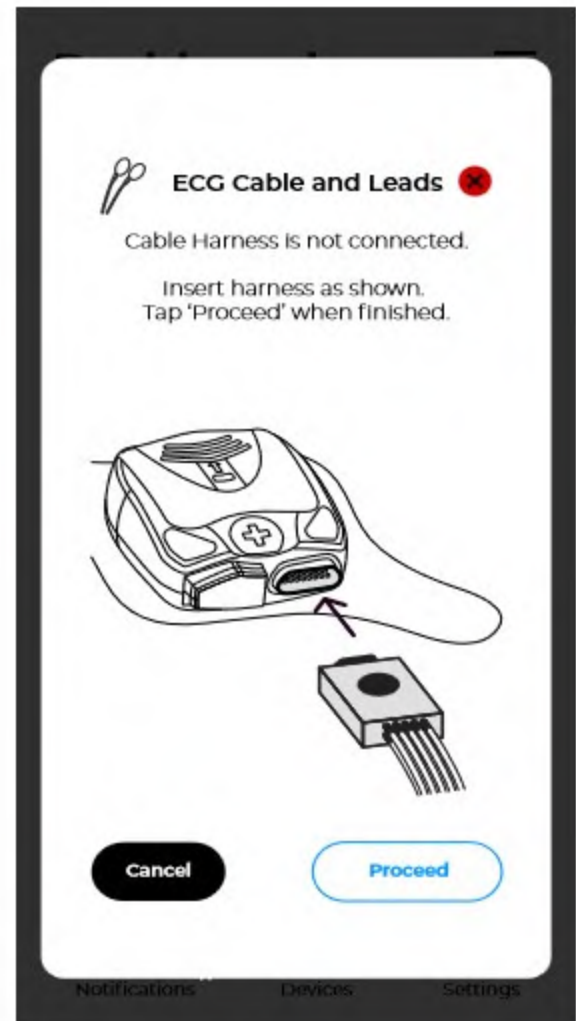


Hardware Error

A hardware error was detected. The device may be malfunctioning.

Solution:

Call Elastic Care for immediate assistance, or try a new LifePath-C package if available.



ECG Cable Harness Disconnected

The ECG Cable harness is not connected to the Wearable Medical Monitor.

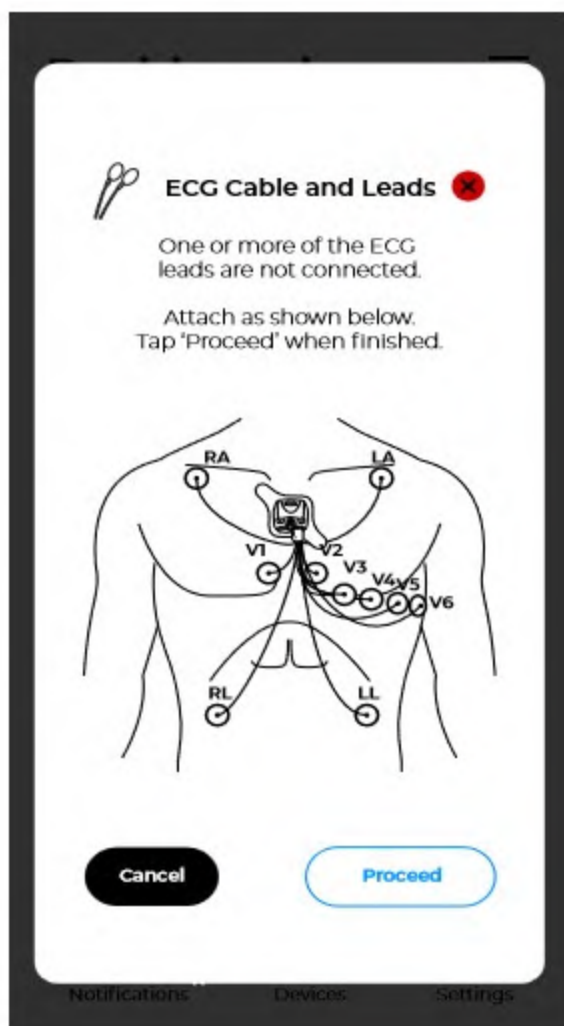
Solution:

Insert the Cable Harness connector into the port as shown.

22 Pre-Launch Check Errors



Hardware Errors



ECG Leads Disconnected

One or more of the ECG leads are disconnected or improperly attached.

Solution:

Ensure all leads are attached as described in the diagram above. Ensure each electrode is in contact with the patient's skin.



Connectivity Errors



No Wi-Fi Connection

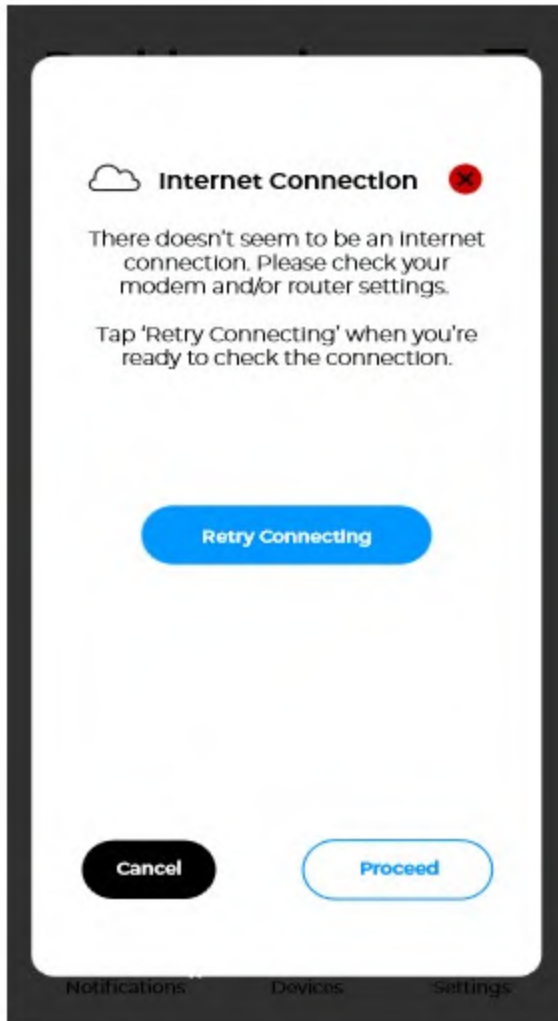
The Smartphone is not connected to a Wi-Fi network.

Solution:

Tap 'Proceed' to access the Smartphone's Wi-Fi settings and connect to an available wireless network.

22 Pre-Launch Check Errors

Connectivity Errors

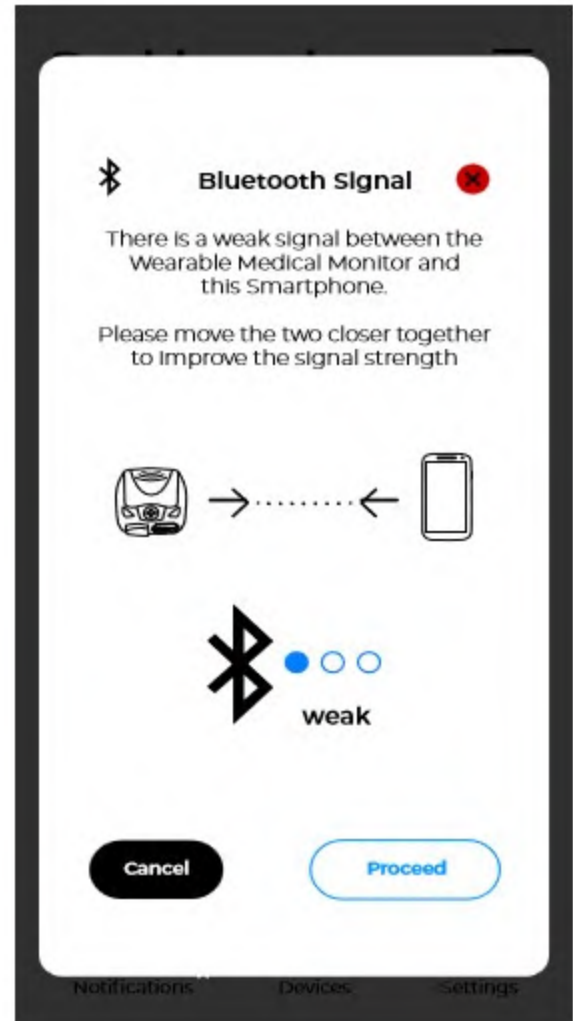


No Internet Connection

There is no internet connection.

Solution:

Check your modem and/or router settings and retry connecting. Or, try connecting to another Wi-Fi network.



Weak Bluetooth Signal

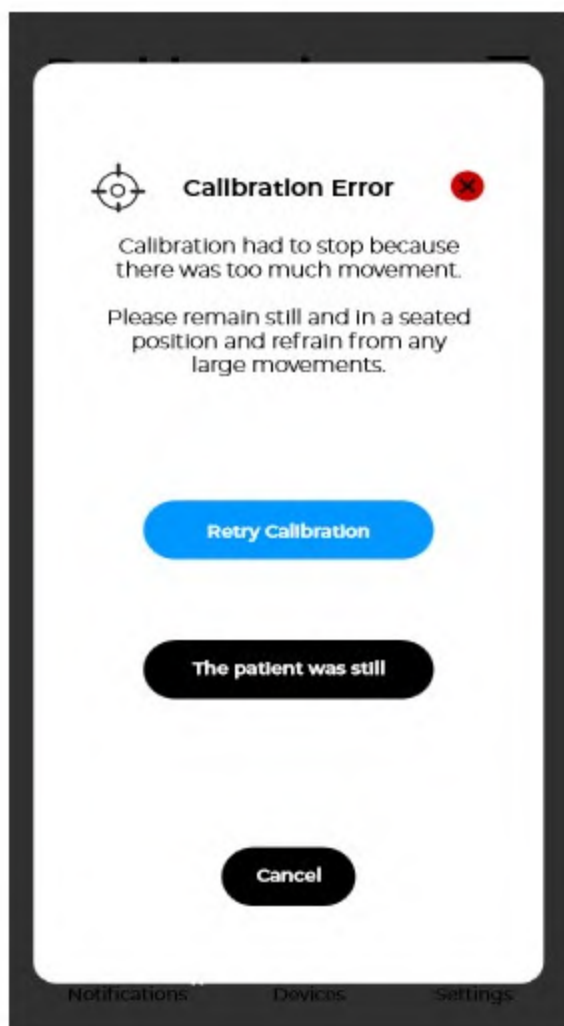
Weak Bluetooth signal between the Wearable Medical Monitor and Smartphone.

Solution:

Move the two devices closer together until the signal strength improves.

22 Pre-Launch Check Errors

Calibration & Signal Errors

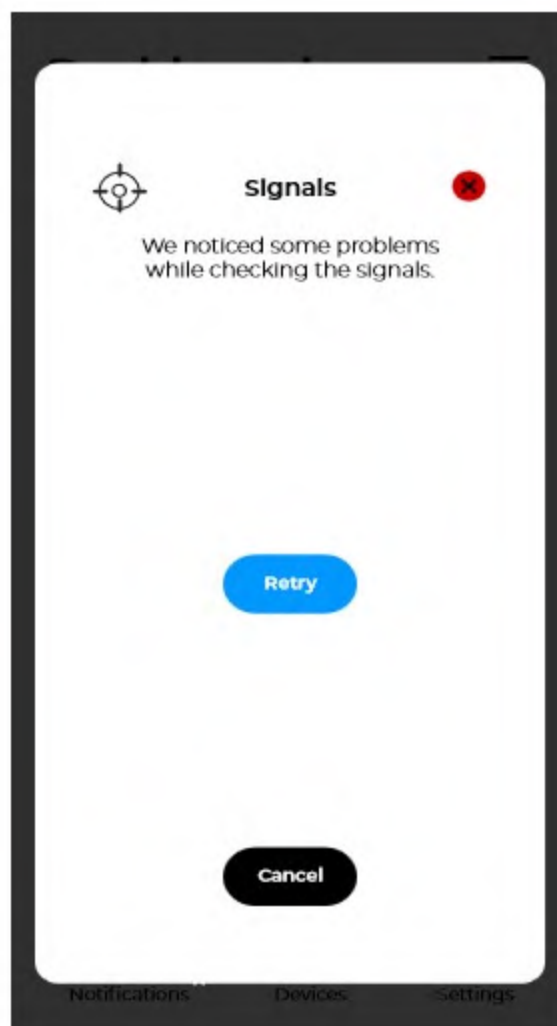


Calibration Error

There was too much movement detected during calibration which caused it to stop.

Solution:

Ensure the patient is still, and in a seated position. Refrain from any large movements until calibration has completed.



Signals Error

There were problems with the signals collected during the calibration.

Solution:

Retry calibration. Ensure the contact areas of electrodes and skin are clean. Or, contact Elastic Care for assistance.

23 FAQ's

Q Where do I find the login information for the Elastic Care Mobile Application?

A The physician and/or nurse email addresses your facility provided on the Elastic Care Client Sign Up Form will receive a welcome email with login details to be used on the Elastic Care Mobile Application.

Q How do I know that the Wearable Medical Monitor is functioning normally?

A The LED on the Wearable Medical Monitor will blink a green light every second.

Q How long can the Wearable Medical Monitor be continuously worn at one time?

A The Wearable Medical Monitor can be worn no longer than 24 hours. A scheduled maintenance must be performed every 24 hours.

Q How can I access the patient's physiological data?

A Patient reports will be sent to the Physician's email in a PDF format at a frequency of their choosing (hourly, daily, weekly). This frequency is selected during the Campaign Configuration performed on the Smartphone when setting up a new monitoring campaign. You can also set additional recipients of these reports during this time (limited to physicians and nurses in the healthcare facility).

Q Can the Wearable Medical Monitor be used without the included Smartphone?

A No. The Wearable Medical Monitor only works in conjunction with the Smartphone provided in the LifePath-C package. It cannot function as a standalone device.

23 FAQ's

Q Is there an emergency button on the device that the patient can use to alert someone?

A No. There is no emergency button on the Wearable Medical Monitor.

Q Can the patient wear the Wearable Medical Monitor while taking a shower or doing other water-based activities?

A No. The Wearable Medical Monitor and other components are not intended for use while showering or other water-based activities.

Q Will an alert be sent if the patient's vitals are above or below set thresholds?

A No alerts will be sent if thresholds are breached. However, the physician will be informed of any out of bound parameters in the Patient Report sent to them.

Q What should I do if the Werable Medical Monitor or Smartphone are broken?

A If the Wearable Medical Monitor or Smartphone are physically damaged or broken, contact Elastic Care immediately.

Q Where can I see notifications for the Wearable Medical Monitor?

A In the Elastic Care Mobile Application, the Notifications button in the Navigation Menu will contain a red badge, along with the number of pending notifications. Tapping this will take you to the 'Notifications' section, where you will be able to view all logs and alarms.

23 FAQ's

Q There is a Device Reset and Recovered Notification. What does this mean?

A The Wearable Medical Monitor was reset and recovered to a normal, working condition.

Q Why is the Wearable Medical Monitor vibrating?

A The Wearable Medical Monitor vibrates if any of the ECG leads are off, the ECG Cable Harness is disconnected from the Wearable Medical Monitor, the Wearable Medical Monitor Battery is low, or if the Bluetooth connection between the Smartphon and Wearable Medical Monitor has been lost.

24 Troubleshooting

The Wearable Medical Monitor is not turning ON

- | | |
|-----------------|---|
| Cause | <ul style="list-style-type: none">• Wearable Medical Monitor Battery is not inserted properly.• Wearable Medical Monitor Battery might be completely depleted. |
| Solution | <ul style="list-style-type: none">• Insert a spare, fully charged battery into the Wearable Medical Monitor. |

The Smartphone is not turning ON

- | | |
|-----------------|---|
| Cause | <ul style="list-style-type: none">• Smartphone battery might be completely depleted. |
| Solution | <ul style="list-style-type: none">• Charge the Smartphone by plugging it into a wall power outlet using the provided cable and power adapter. |

The Wearable Medical Monitor is vibrating, the LED is blinking an amber light and there is an ECG Lead Disconnected notification.

- | | |
|-----------------|--|
| Cause | <ul style="list-style-type: none">• One or more of the ECG leads are disconnected. |
| Solution | <ul style="list-style-type: none">• Connect the snaps to the respective electrodes and ensure all ECG electrodes are firmly attached to the patient's torso. |

24 Troubleshooting

The Wearable Medical Monitor is vibrating, the LED is blinking an amber light and there is an ECG Cable Disconnected notification.

- | | |
|-----------------|---|
| Cause | <ul style="list-style-type: none"> The Cable Harness is disconnected from the Wearable Medical Monitor. |
| Solution | <ul style="list-style-type: none"> Insert the Cable Harness connector into the Wearable Medical Monitor port marked in blue. |

The LED on the Wearable Medical Monitor is *not* blinking a blue light and there is a Disconnected notification.

- | | |
|-----------------|--|
| Cause | <ul style="list-style-type: none"> There is no Bluetooth connectivity between the Wearable Medical Monitor and the Smartphone. |
| Solution | <ul style="list-style-type: none"> Bring the Smartphone closer to the Wearable Medical Monitor in order to improve Bluetooth signal strength. |

The Wearable Medical Monitor is vibrating, the LED is blinking an amber light, and there is a Low Battery 10% notification.

- | | |
|-----------------|--|
| Cause | <ul style="list-style-type: none"> Wearable Medical Monitor Battery is low. |
| Solution | <ul style="list-style-type: none"> Tap the 'Pause Monitoring' button on the Dashboard. Insert a fully charged spare battery into the Wearable Medical Monitor. Place the discharged battery into the charging dock to charge. Tap the 'Start Monitoring' button on the Dashboard to resume monitoring. |

24 Troubleshooting

There is a Device Error Detected notification

- | | |
|-----------------|--|
| Cause | <ul style="list-style-type: none">• There is a problem with the Wearable Medical Monitor. |
| Solution | <ul style="list-style-type: none">• Tap the 'Pause Monitoring' button on the Dashboard.• Remove and re-insert the battery into the Wearable Medical Monitor.• Wait for the device to start.• If the notification persists, contact Elastic Care . |

There is a notification log in the Elastic Care Mobile Application indicating lost Wi-Fi or Data connection

- | | |
|-----------------|--|
| Cause | <ul style="list-style-type: none">• Your patient may have walked way from the Wi-Fi zone/network you are connected to.• There is no internet connectivity on your Wi-Fi or Data network. |
| Solution | <ul style="list-style-type: none">• Instruct the patient to walk back to the area or zone with Wi-Fi or data connectivity or connect to a new Wi-Fi network.• Troubleshoot your router and/or modem to re-establish internet and Wi-Fi/Data connectivity. |

Still having trouble?

If a problem you're encountering is not mentioned above, or the provided solutions are not resolving the issue, please contact Elastic Care for support.

25 Technical Specifications

25.1 Wearable Medical Monitor

Environmental conditions for use	
Temperature	Operation: 5°C to 45°C Charging: 5°C to 40°C
Relative humidity	Operation: 10% to 95% without condensation Charging: 10% to 90% without condensation
Atmospheric pressure	70 kPa to 106 kPa
Environmental conditions for storage (Maximum 6 months)	
Temperature	15°C - 25°C
Relative humidity	40% to 60%
Atmospheric pressure	70 kPa to 106 kPa
External dimensions and weight	
Length	42.7mm
Width	41.3mm
Height	19.8mm
Weight	35g (excluding cable harness)
Case material	Polycarbonate and Thermoplastic Polyurethane
Battery Specification	
Capacity	350mAh (Nominal) 335mAh (Minimum)
Battery type	Lithium Ion
Battery voltage	3.7V (Nominal)
Full charge operating time	24 hours
ECG	
Sampling rate	250Hz
Digital resolution	20bits
Heart Rate (Range)	30 bpm to 240 bpm for normal sinus
Heart Rate Accuracy	amplitudes of 0.05mV to 5.00mV 96%
Respiration	
Modulation Excitation Signal	29uA @32KHz (typical)
Sampling	125 Hz
Respiration Range	15 brpm to 40 brpm
Respiration Accuracy	99%
Accelerometer	
Activity Sampling	83.33 Hz
Accelerometer	3-axis, 12 bit, ±4g
Activity/Posture Ranges	No activity – Running/ Sitting up – Lying down

25.1 Wearable Medical Monitor

Skin Temperature	
Sampling Rate	1 Hz
Resolution	0.1 °C
Skin Temperature Sense Range	28°C to 45°C
Accuracy of Reported Skin Temperature	+/- 0.2 °C
Setting Time	10 minutes

25.2 AC/DC Medical Power Supply

Manufacturer	Phihong
Model	PSAC05R-050L6M
Input	100-240VAC at 50-60Hz (worldwide support)
Output	5VDC at 1A maximum
Safety Standards	cUL/ UL TUV NOM CE CB FCC Class B EN55022 Class B AS/ NZS 3546 EN50082-1 EN 61000-4-2, Level 4 EN 61000-4-5 Level
Electrical protection level	Double Insulated Primary to Secondary Hipot Result: 3KV AC 10mA, 60 seconds
Case	72mm x 45mm x 30mm

25.3 Wearable Medical Monitor Battery Charger

Input	5VDC at 200mA maximum
Output	Constant Current / Constant Voltage as required by the WMM Lithium Ion battery pack: 175mA/ 4.2V
Case Material	Polycarbonate
External Dimensions	
Length	36mm
Width	45.5mm
Height	30mm

25.4 Vital Sign Measurement

ECG Sensing

The ECG system measures the electrical activity of the heart. The fidelity of the ECG waveforms and heart rate metric are influenced by ambulation, patient chest preparation (good contact with electrodes) and environmental EMI.

Respiration Sensing

Respiration rate is determined through the variation in the patient's thoracic cavity impedance. Thoracic cavity impedance changes through expansion and contraction of the chest during respiration. Patient breathing depth, ambulation and breathing style affect the respiration sensing system.

Skin Temperature Sensing

Measures local skin temperature taken through skin contact on the thoracic region. Does not reflect patient core temperature or imply the temperature of a traditional human body reference site.

Activity and Posture Sensing

A 3-axis accelerometer is used to collect a patient's activity and posture. Activity and posture measurements obtained from this device should not be used for clinical diagnosis. This data should be used for reference only. Fall indications are not provided in real-time and should be used for reference only.