

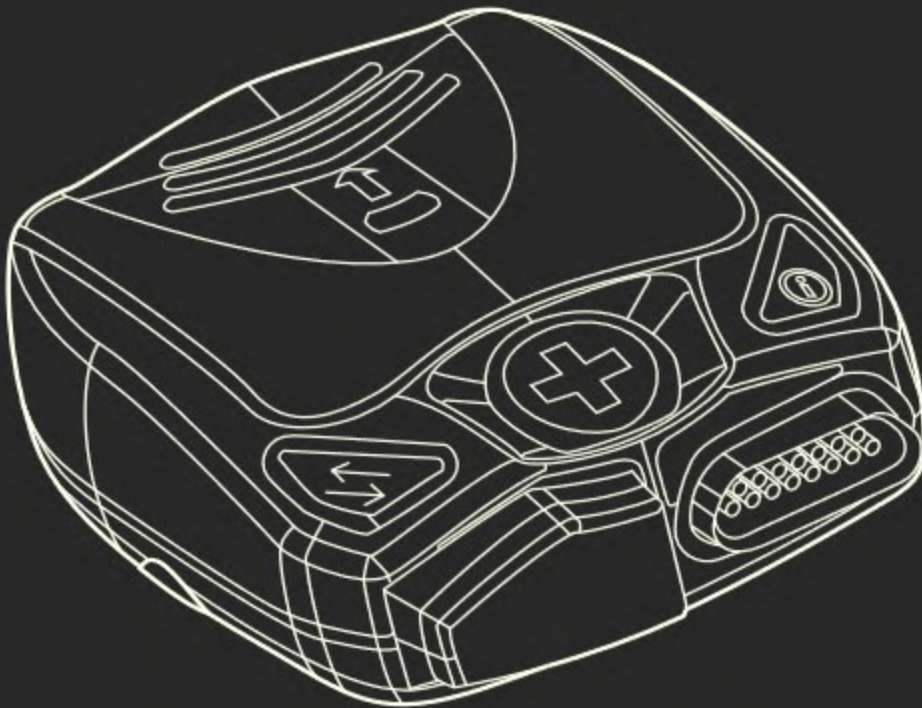


LifePath –

Mobile ECG and multi-sensor
medical monitor

Clinical Instructions for Use

Version 01





ELASTIC
CARE

LifePath –

Mobile ECG and multi-sensor
medical monitor

Clinical Instructions for Use

Version 01

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Preface

Thank you for purchasing Lifepath-C. Carefully read this user manual for correct use of the unit.

Keep this manual handy after reading. It will continue to be of your service in finding specific information about this instrument.

This manual is also available online at:
www.elasticcare.com/support

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Contacts

For support, or further information on this product, please contact:

Address

Elastic Care Inc.
95 Apple Creek Blvd
Markham, Ontario, CA
L3R 1C7

Contact

Web www.elasticcare.com
Email info@elasticcare.com
Phone +1 833 GOMYECC (+1 833 466 9324)

Version History

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|---------|-----------------|--------------|
| 01 | Initial release | 2023/01/17 |

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1 Warnings, Cautions & Notes

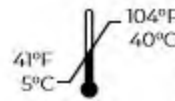
1.1 Operating Conditions



Temperature Limit

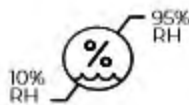
Operation of device

From 5°C to 45°C (41°F to 113°F)



Charging of battery

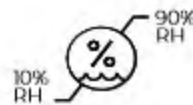
From 5°C to 40°C (41°F to 104 °F)



Relative Humidity Limit

Operation of device

10% to 95% without condensation



Charging of battery

10% to 90% without condensation



Atmospheric Pressure Limit

Maintain atmospheric pressure from 70 kPa to 106 kPa

1.2 Warnings and Cautions



The symbol shown to the left indicates a warning. Failure to heed the text accompanying the symbol exposes the patient or operator to risk of serious injury, compromises safe operation of the device, or may result in adverse events associated with the operation of the LifePath-C system.



The symbol shown to the left indicates a caution statement. Failure to heed the text accompanying the symbol may result in injury to the patient or operator, compromise the safe operation of the LifePath-C system, or may result in irreparable damage to the LifePath-C hardware.

1.2 Warnings and Cautions

Safety Warnings

Not for use on patients/individuals less than 22 years of age.

Not for use on patients requiring attended, in-hospital monitoring for life-threatening arrhythmias.

Not for use on patients/individuals with any active implantable devices such as pacemakers.

Not for use on patients during pregnancy.

Not for use on patients/individuals with broken or fragile skin on the torso.

Not for use on patients/individuals who are allergic to acrylic, hydro gel, or silicone adhesives.

Do not use LifePath-C in an MRI suite or hyperbaric chamber.

Remove LifePath-C system from patient prior to defibrillation.

Do not tamper with, open up, or attempt to modify the Wearable Medical Monitor, Smartphone, Wearable Medical Monitor batteries, Cable Harness, Battery Dock Charger, or any adapters. Failure to comply can cause serious risk of injury, and irreparable damage to the components.

Do not interact with the Wearable Medical Monitor or Smartphone while driving.

Do not expose Wearable Medical Monitor, Wearable Medical Monitor Batteries, or Smartphone to fire or excessive heat.

Do not expose the Wearable Medical Monitor, Wearable Medical Monitor Batteries, or any of its accessories and components to magnetic fields, electrostatic discharge and thermal ignition sources.

Do not attempt to connect any patient worn component to an electrical outlet of any kind.

Do not use the Wearable Medical Monitor, or any other components in the LifePath-C system, if it is damaged, as it may affect its functional use, intended use, and/or the safety of the wearer.

1.2 Warnings and Cautions

Cautions

Do not shower with the LifePath-C system.

Do not get the Wearable Medical Monitor, batteries, cable harness, or other components wet.

Do not attempt to plug in or use any third party cable harnesses with the Wearable Medical Monitor.

Do not remove the Wearable Medical Monitor diagnostic port cover.

Do not unplug the Cable Harness from the Wearable Medical Monitor while in a monitoring state.

Do not detach or remove the Wearable Medical Monitor from the patient while in a monitoring state.

Do not discard of Wearable Medical Monitor batteries in the garbage.

Thoroughly examine skin on patient's torso for lesions, cuts, tears, abrasions or other damage or irritation prior to attaching the LifePath-C system.

Do not use any third party power supplies or charging adapters to charge the Wearable Medical Monitor, Battery Dock Charging Adapter, or Smartphone.

Do not twist or tangle the Cable Harness cables, Battery Dock Charging Adapter cable, or Smartphone Charger cable.

Do not re-use exhaustable components such as Adhesive Patches, Alcohol Swabs, Adhesive Remover Wipes, or ECG Electrodes. Discard them after use.






Only use provided accessories and exhaustible components with the LifePath-C system. If your facility requires additional consumables or replacement parts, contact Elastic Care as soon as possible.

Do not engage in any water-based activities while attached to the LifePath-C system.







Do not connect or use a Wearable Medical Monitor and Cable Harness on more than one patient at a time.

Do not connect or use more than one Wearable Medical Monitor and Cable Harness to a patient.







2 Symbols

| Symbol | Title and Description | Standard Title & Reference |
|---|---|--|
|  | <p>Caution</p> <p>Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.</p> | <p>ISO 15223-1-2016/ Medical Devices - Symbols to be used with medical device labels, labelling, and information to be supplied.</p> <p>Standard Reference: 5.4.4</p> |
|  | <p>Consult Instructions for Use</p> <p>Indicates the need for the user to consult the instructions for use.</p> | <p>ISO 15223-1-2016 / Medical Devices - Symbols to be used with medical device labels, labelling, and information to be supplied.</p> <p>Standard Reference: 5.4.3</p> |
|  | <p>Manufacturer</p> <p>Indicates the medical device manufacturer.</p> | <p>ISO 15223-1-2016 / Medical Devices - Symbols to be used with medical device labels, labelling, and information to be supplied.</p> <p>Standard Reference: 5.1.1</p> |
|  | <p>FCC Marking</p> <p>FCC marking indicates the electronic device, which sold in the United States, is certified and the electromagnetic interference from the device is under the limits that are approved by Federal Communications Commission</p> | <p>Federal Communications Commission</p> |
|  | <p>Prescription Device</p> <p>Federal law restricts the device to sale by or on the order of a licensed practitioner or therapist.</p> | <p>Prescription Devices</p> <p>Standard Reference: 21 CFR 801.109</p> |

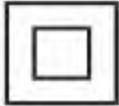



2 Symbols

| Symbol | Title and Description | Standard Title & Reference |
|---|--|--|
|  | <p>Serial Number</p> <p>Indicates the manufacturer's serial number so that a specific medical device can be identified.</p> | <p>ISO 15223-1-2016 / Medical Devices - Symbols to be used with medical device labels, labelling, and information to be supplied.</p> <p>Standard Reference: 5.1.7</p> |
|  | <p>Batch Code</p> <p>Indicates the manufacturer's batch code so that the batch or lot can be identified.</p> | <p>ISO 15223-1-2016 / Medical Devices - Symbols to be used with medical device labels, labelling, and information to be supplied.</p> <p>Standard Reference: 5.1.5</p> |
|  | <p>Catalogue Number</p> <p>Indicates the manufacturer's catalogue number so that the medical device can be identified.</p> | <p>ISO 15223-1-2016 / Medical Devices - Symbols to be used with medical device labels, labelling, and information to be supplied.</p> <p>Standard Reference: 5.1.6</p> |
|  | <p>Patient Number</p> <p>Indicates a unique number associated with an individual patient.</p> | <p>ISO 15223-1-2016 / Medical Devices - Symbols to be used with medical device labels, labelling, and information to be supplied.</p> <p>Standard Reference: 5.7.1</p> |
|  | <p>Non-Sterile</p> <p>Indicates a medical device that has not been subjected to a sterilization process.</p> | <p>ISO 15223-1-2016 / Medical Devices - Symbols to be used with medical device labels, labelling, and information to be supplied.</p> <p>Standard Reference: 5.2.7</p> |
|  | <p>Recycle: Electronic Equipment</p> <p>Do not throw in trash.</p> | <p>BS EN 50419 Marking of Electrical and Electronic Equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE).</p> |

2 Symbols

| Symbol | Title and Description | Standard Title & Reference |
|---|---|--|
|  | <p>Temperature Limit</p> <p>Indicates the temperature limits to which the medical device can be safely exposed</p> | <p>ISO 15223-1-2016 / Medical Devices - Symbols to be used with medical device labels, labelling, and information to be supplied.</p> <p>Standard Reference: 5.3.7</p> |
|  | <p>Humidity Limit</p> <p>Indicates the range of humidity to which the medical device can be safely exposed.</p> | <p>ISO 15223-1-2016 / Medical Devices - Symbols to be used with medical device labels, labelling, and information to be supplied.</p> <p>Standard Reference: 5.3.8</p> |
|  | <p>Atmospheric Pressure Limit</p> <p>Indicates the range of atmospheric pressure to which the medical device can be safely exposed.</p> | <p>ISO 15223-1-2016 / Medical Devices - Symbols to be used with medical device labels, labelling, and information to be supplied.</p> <p>Standard Reference: 5.3.9</p> |
|  | <p>Fragile, handle with care</p> <p>Indicates a medical device that can be broken or damaged if not handled carefully.</p> | <p>ISO 15223-1-2016 / Medical Devices - Symbols to be used with medical device labels, labelling, and information to be supplied.</p> <p>Standard Reference: 5.3.1</p> |
|  | <p>Do not use if package is damaged</p> <p>Indicates a medical device that should not be used if the package has been damaged or opened.</p> | <p>ISO 15223-1-2016 / Medical Devices - Symbols to be used with medical device labels, labelling, and information to be supplied.</p> <p>Standard Reference: 5.2.8</p> |
|  | <p>This way up</p> <p>To indicate correct upright position of the transport package</p> | <p>ISO 7000: 2019 / Graphical symbols for use</p> <p>Standard Reference: No. 0623</p> |

2 Symbols

| Symbol | Title and Description | Standard Title & Reference |
|---|--|--|
|  | <p>Class II Equipment</p> <p>Identifies equipment meeting the safety requirements specified for Class II equipment according to IEC 61140.</p> | <p>IEC 60417: 2002 DB / Graphical symbols for use on equipment.</p> <p>Standard Reference: 5172</p> |
|  | <p>Keep Dry</p> <p>Indicates a medical device that needs to be protected from moisture.</p> | <p>ISO 15223-1-2016 / Medical Devices - Symbols to be used with medical device labels, labelling, and information to be supplied.</p> <p>Standard Reference: 5.3.4</p> |
|  | <p>Do Not Re-use</p> <p>Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.</p> | <p>ISO 15223-1-2016 / Medical Devices - Symbols to be used with medical device labels, labelling, and information to be supplied.</p> <p>Standard Reference: 5.4.2</p> |
| IP22 | <p>IP Classification</p> <p>Wearable Medical Monitor with battery pack and cable harness installed are protected from ingress of finger sized objects and from dripping water ingress at an angle of 15 degrees from normal device orientation.</p> | <p>IP Classification Standard</p> |
|  | <p>Keep Away from Sunlight</p> <p>Indicates a medical device that needs protection from light sources.</p> | <p>ISO 15223-1-2012 / Medical Devices - Symbols to be used with medical device labels, labelling, and information to be supplied.</p> <p>Standard Reference: 5.3.2</p> |

3 LifePath-C Symbols

Symbol Title and Description



Wearable Medical Monitor

Wearable Medical Monitor symbol.



Battery Status

Wearable Medical Monitor battery status symbol.



Smartphone

Symbol for included Smartphone.



Elastic Care Mobile App

Elastic Care Mobile Application symbol.



Wi-Fi

Wireless Network symbol.



Cloud/Server

Cloud/Internet or Data server/center symbol symbol.



LTE

LTE (Long-Term Evolution) broadband symbol.



LifePath-C ECG Cable/Leads

LifePath-C ECG Cable and/or leads symbol.



Calibration

Calibration symbol.



Monitoring Symbol

Symbol to indicate current state is Monitoring. Wearable Medical Monitor is collecting data and transmitting it to the Smartphone. **Note:** this is NOT an ECG waveform.

3 LifePath-C Symbols

Symbol Title and Description



Bluetooth Symbol

Symbol to indicate Bluetooth connection



Start Monitoring Button

Starts monitoring when tapped. Also takes a measurement if the current device is a third-party device.



Searching for Wearable Medical Monitor Symbol

Indicates Smartphone is searching for the Wearable Medical Monitor with which it is paired.



Connecting to Wearable Medical Monitor Symbol

Indicates Smartphone is connecting to paired Wearable Medical Monitor.



Connected to Wearable Medical Monitor Symbol

Indicates Smartphone has successfully connected to paired Wearable Medical Monitor.



Pause Monitoring Button

Pauses monitoring when tapped. Data collection by Wearable Medical Monitor and transmission to Smartphone will stop.



Stop Measurement

Halts the measurement being taken by a third-party device.



Not Monitoring / Not Collecting Data Symbol

Symbol to indicate that the current state is Not Monitoring. Wearable Medical Monitor or current third-party device is not collecting data.



Not Connected to Wearable Medical Monitor

Indicates that Smartphone is not connected to the Wearable Medical Monitor. Appears when initiating a connection or if the Bluetooth connection has been severed while monitoring.

3 LifePath-C Symbols

Symbol Title and Description



Bluetooth Signal Strength

Indicates strength of Bluetooth connection between Smartphone and Wearable Medical Monitor. More solid dots indicates stronger connection.



Time Remaining Countdown

Counts down the time remaining in the LifePath-C monitoring campaign. D- Days. H- hours. M- Minutes. S- Seconds.



Hardware Error

Indicates a hardware error with the LifePath-C system. Contact Elastic Care for immediate assistance.



Error Detected

Appears alongside descriptions of errors detected during the LifePath-C monitoring campaign.



Error Corrected OR Pre-Launch Check Stage Successful

Appears when a Pre-Launch Check stage has been successfully completed. Also appears when errors during the monitoring campaign are corrected.

4 Standards

ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)

ANSI/AAMI/IEC 60601-1-2:2014

Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests

ANSI AAMI HA60601-1-11:2015

Medical Electrical Equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2015 MOD)

ANSI AAMI IEC 62366-1:2015

Medical devices - Part 1: Application of usability engineering to medical devices

ANSI AAMI IEC 62304:2006/A1:2016

Medical device software - Software life cycle processes [Including Amendment 1 (2016)]

ANSI AAMI IEC 60601-2-47:2012(R)2016

Medical electrical equipment -- Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems

ANSI AAMI ISO 10993-1:2009/(R)2013

Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]

ANSI AAMI ISO 10993-5:2009/(R)2014

Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

4 Standards

ANSI AAMI ISO 10993-10:2010/(R)2014

Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

ANSI/AAMI/ISO 14971:2007/(R)2010 (Corrected 4 October 2007)

Medical devices - Applications of risk management to medical devices

ISO 80601-2-56:2017(E)

Medical electrical equipment —Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

ISO 80601-2-56:2017/Amd.1:2018(E)

Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.[Including: Amendment 1 (2018)]

ASTM D4169-16

Standard Practice for Performance Testing of Shipping Containers and Systems

ANSI AAMI ISO 15223-1:2016

Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied—Part 1: General requirements

ANSI AAMI ISO 14155:2011

Clinical investigation of medical devices for human subjects - Good clinical practice [Including: Technical Corrigendum 1 (2011)]

ANSI AAMI ISO 17664:2017

Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices

UN38.3

Transport of Dangerous Goods, Manual of Test and Criteria outlines, Fifth edition with Amendment 1 and Amendment 2

4 Standards

IEC 62133-2 Edition 1.0 2017-02

Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

Radio testing as per FCC 15.247 / RSS 24 using ANSI C63.10:2013

American National Standard of Procedures for Compliance Testing of Unlicensed Wireless Devices

ANSI AAMI EC12:2000/(R)2015

Disposable ECG electrodes

IEC/TR 80001-2-8:2016

Application of risk management for IT-networks incorporating medical devices — Part 2-8: Application guidance — Guidance on standards for establishing the security capabilities identified in IEC 80001-2-2

IEC/TR 80001-2-2:2012

Application of risk management for IT-networks incorporating medical devices — Part 2-2: Guidance for the communication of medical device security needs, risks and controls

ISO 7000 Sixth edition 2019-07

Graphical symbols for use on equipment - Registered symbols

IEC 60417:2002 DB

Graphical symbols for use on equipment

WEEE Directive 2002/96/EC

5 Introduction

5.1 Intended Use

The LifePath-C (LPC) Monitoring System consists of the LifePath-C wearable device and a mobile application that are intended for prescription use by healthcare professionals in order to collect quantitative biometric data from the thoracic region of adult patients. LPC captures ECG (6/12 Lead), Heart Rate, Skin Temperature, Respiration Rate and Activity data for ambulatory and non-ambulatory patients as an adjunct to other methods to assess and record biometric data. The device is intended to be used in professional healthcare and home environments.

The LPC mobile application can be used as a platform for the collection and reporting of biometric data from low risk bluetooth-enabled class I and class II blood pressure meters, glucometers and pulse oximeter medical devices that are cleared for sale in USA by the FDA. These devices are to be used only as intended by the respective manufacturers; the labelling, functionalities and instructions are to be followed as stated by the respective device manufacturers. Furthermore, these devices are to be used as indicated by a qualified medical practitioner, as applicable. Finally, the collected data is not altered or interpreted in any fashion, and is presented on an as-is basis. The LPC mobile application displays the relevant notices and disclaimers.

5.2 Intended user knowledge base

LifePath-C (LPC) is to be prescribed by a Physician and attached / administered by a Physician or equivalent or certified Nurse or equivalent in a health-care setup.

5.3 Contraindication

The use of LifePath-C is contraindicated for the following;

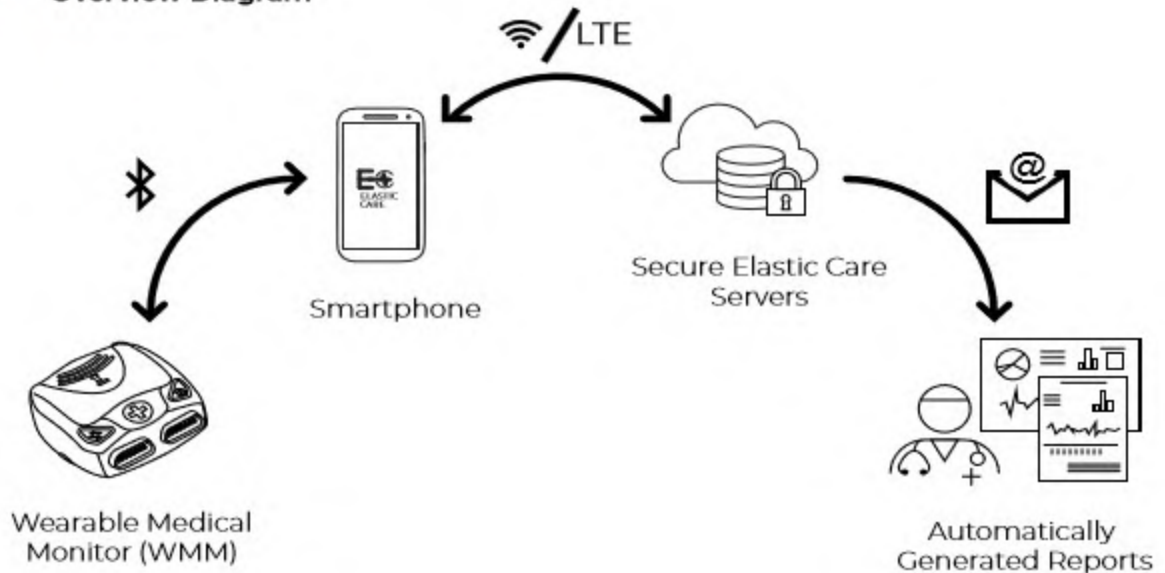


- Patients/individuals less than 22 years of age.
- Patients requiring attended, in-hospital monitoring for life-threatening arrhythmias.
- Patients/individuals with any active implantable devices.
- Patients during pregnancy.
- Patients/individuals with broken or fragile skin on the torso.
- Patients/individuals who are allergic to acrylic, hydro gel, or silicone adhesives

5.4 Overview

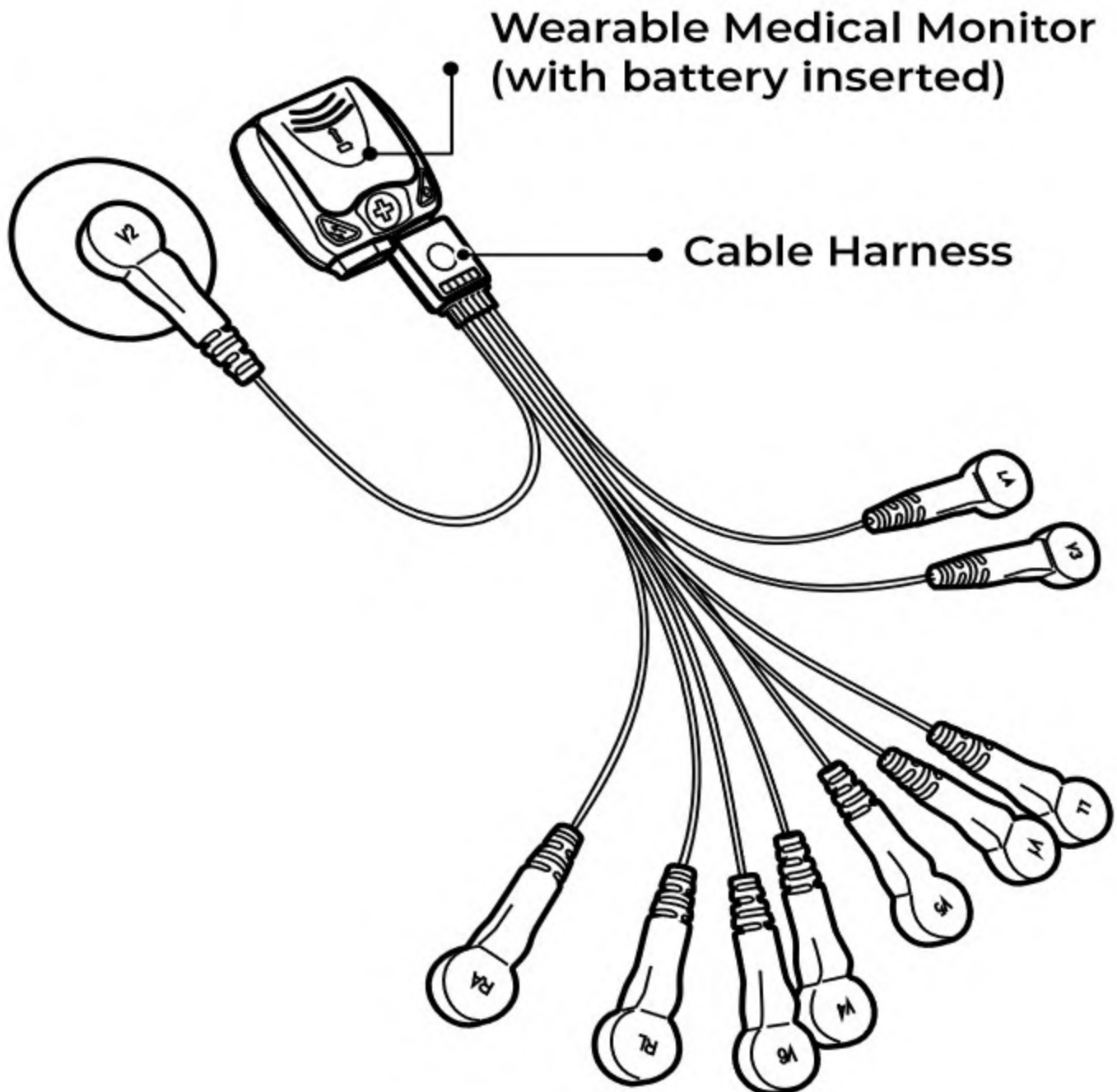


LifePath-C Platform Overview Diagram



6 Hardware Overview

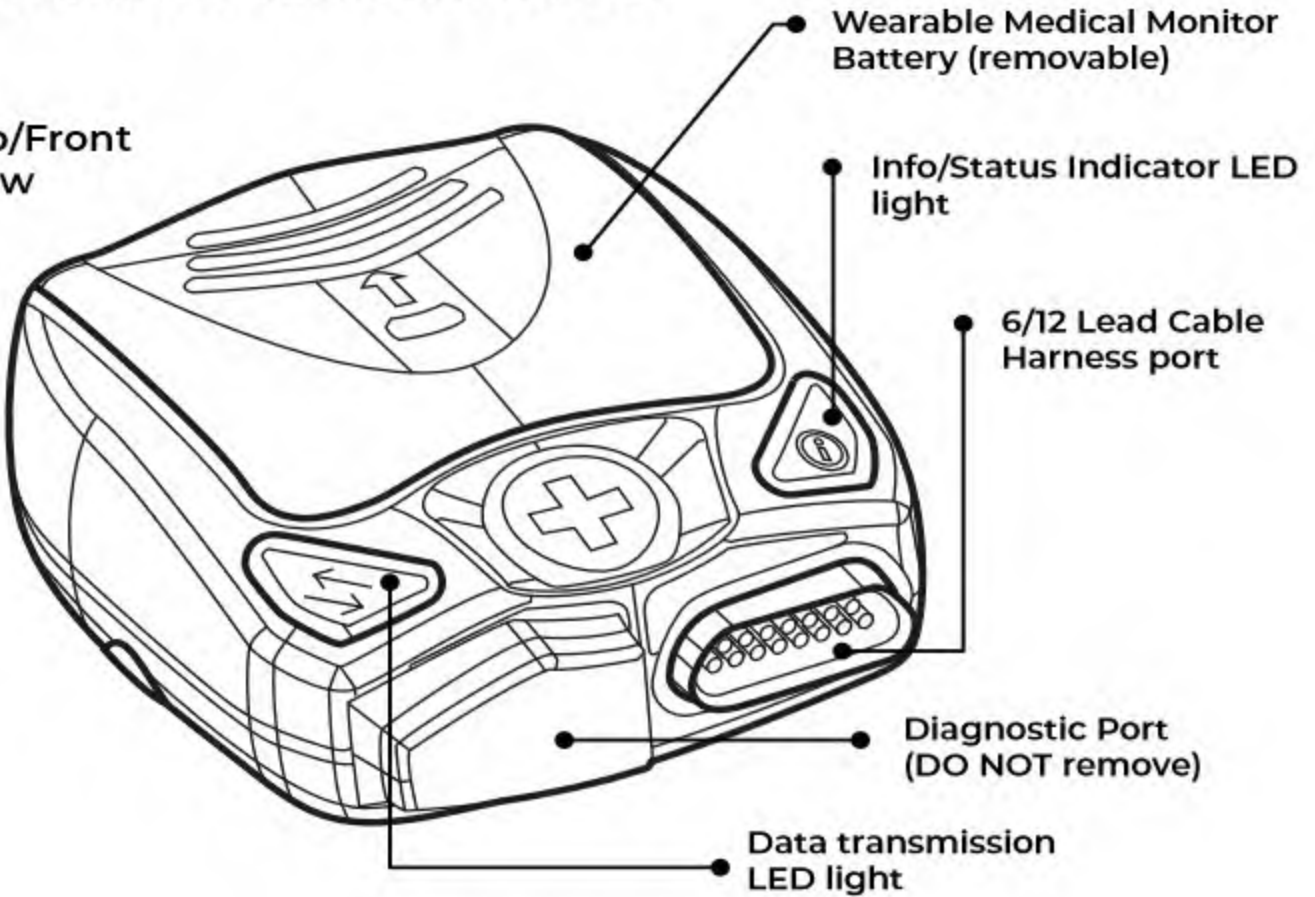
Wearable Medical Monitor & Cable Harness (attached)



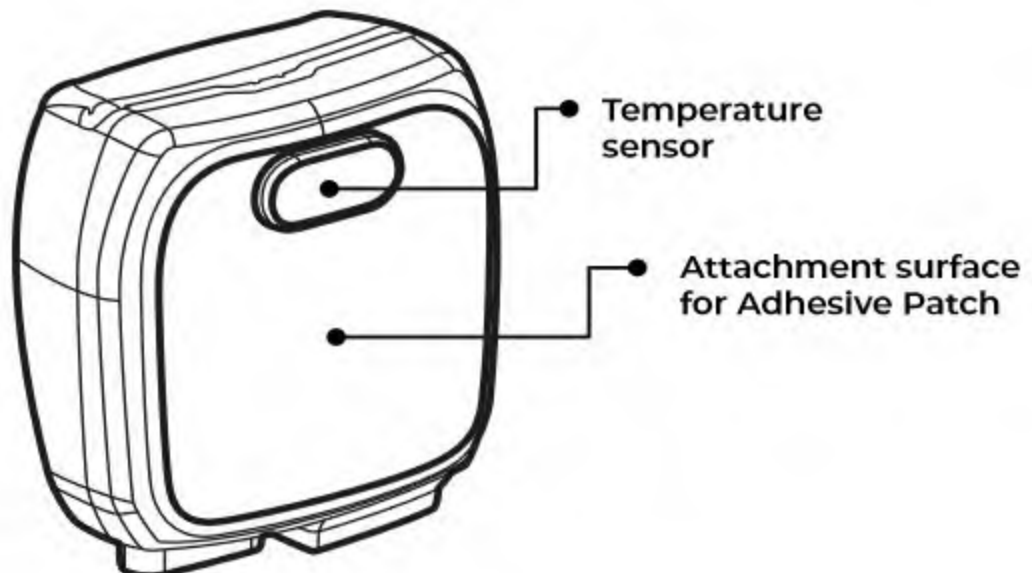
6 Hardware Overview

Wearable Medical Monitor

Top/Front
View

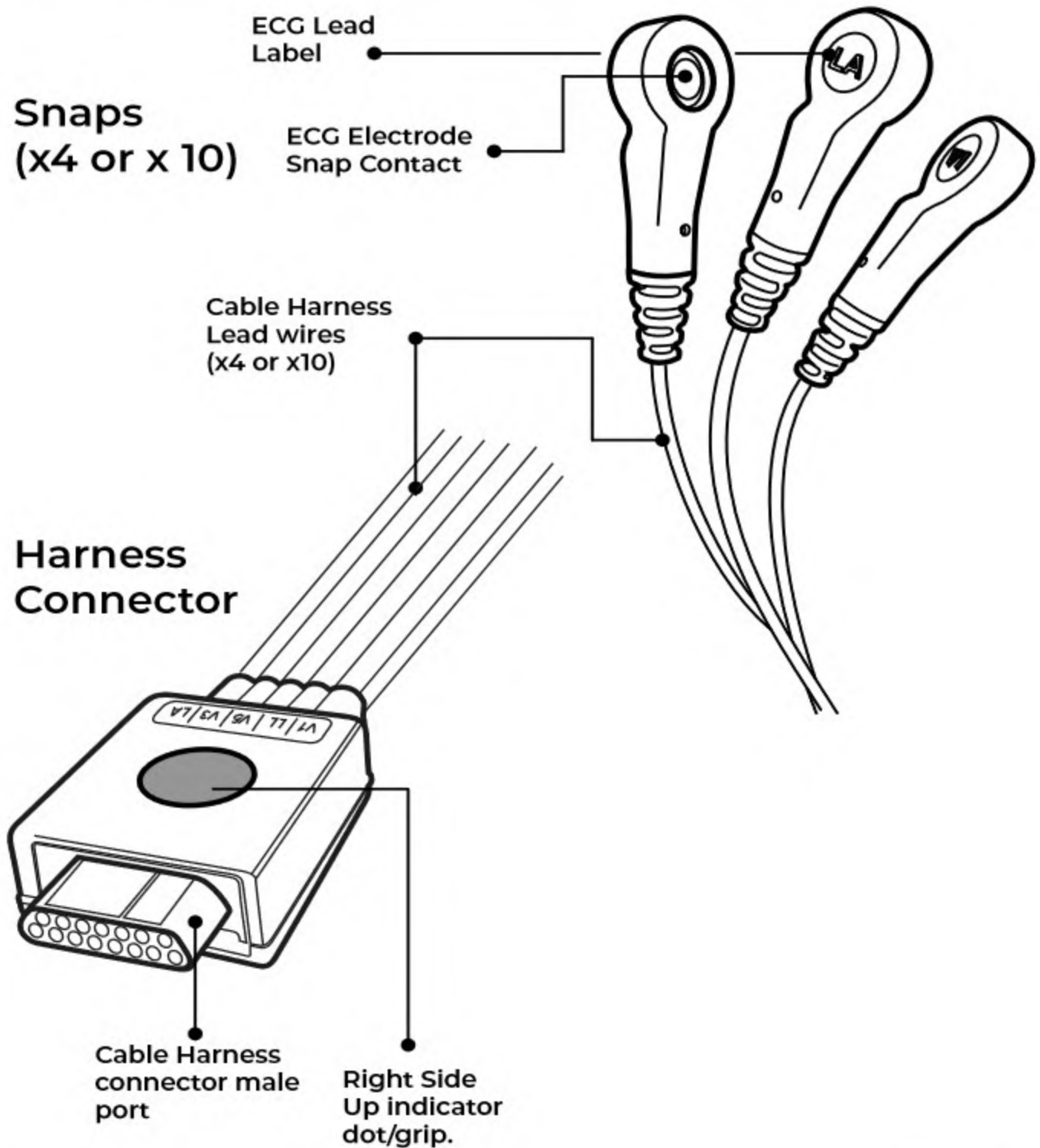


Bottom
View



6 Hardware Overview

Cable Harness



7 Package Contents



Wearable Medical Monitor (WMM)

This unit is attached to the patient's chest using the Adhesive Patch.

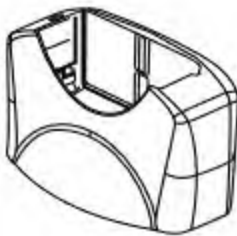
x 1 find in **C**



Wearable Medical Monitor Battery

Battery to be inserted into the Wearable Medical Monitor. Batteries are charged using the Wearable Medical Monitor Battery Dock.

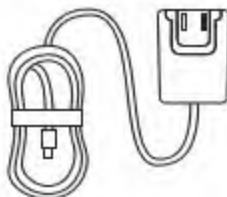
x 2 find in **B**



Wearable Medical Monitor Battery Dock

Charges the Wearable Medical Monitor's battery when the battery is inserted.

x 1 find in **B**



Battery Dock Charging Adapter

Connects the Wearable Medical Monitor Battery Dock to a wall power outlet.

x 1 find in **B**

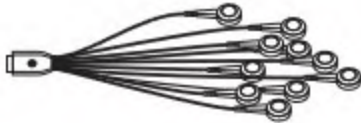


Adhesive Patches

A double sided adhesive patch to affix the Wearable Medical Monitor to the patient's chest.
1 patch/day + 3 extra

x 10 find in **C**

7 Package Contents



Wearable Medical Monitor Harness (12-Lead)

10-wire ECG cable harness.

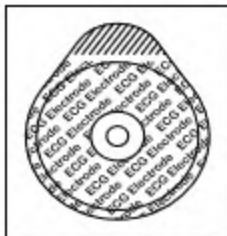
X 1 find in **D**



Wearable Medical Monitor Harness (6-Lead)

4-wire ECG cable harness.

X 1 find in **D**



ECG Electrodes

12-lead configuration - 10 electrodes/day + extra
6-Lead configuration - 4 electrodes/day + extra

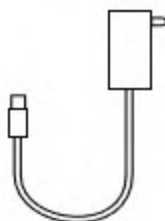
X 80 find in **D**



Smartphone

A pre-configured smartphone, pre-loaded with the Elastic Care application used to interface with LifePath-C.

X 1 find in **A**



Smartphone Charger

Charges the Smartphone when connected to a wall power outlet.

X 1 find in **A**

7 Package Contents



Alcohol Swabs

To prepare the patient's skin prior to attaching LifePath-C.

x 10 find in **D**



Adhesive Remover Wipes

To remove adhesive residue from the Wearable Medical Monitor and ECG lead cables.

x 10 find in **D**

Documents

Quick Start One Pager

Instruction Document Folder

Clinical Instructions for Use

This document. LifePath-C Clinical Instructions For Use.

Patient Instructions

To be handed to and explained to the patient after LifePath-C has been attached and monitoring has begun. Contains a list of precautions, warnings and instructions for use.

Return Instruction Folder

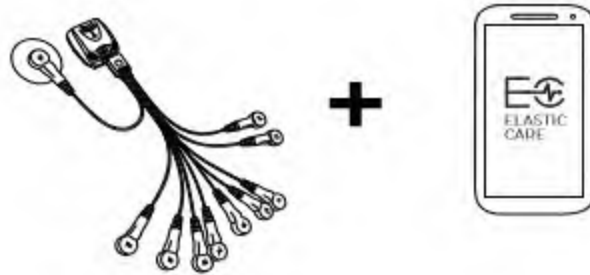
Return Instructions

Shipping Air Waybill

Shipping Pouch

8 Getting Started With LifePath-C

The LifePath-C Monitoring System consists of the **LifePath-C Hardware** and **Elastic Care Mobile Application**, which has been pre-loaded onto the included Smartphone.



The Elastic Care Mobile Application is **required** to setup, configure, and operate the LifePath-C Monitoring System. It requires personnel to log in using their **Elastic Care Login Credentials** for that facility.

8.1 Receiving Elastic Care Login Credentials

During the sign up process for LifePath-C, your healthcare administrator (or personnel responsible for ordering LifePath-C packages) will be asked for the names and email addresses of the physicians and nurses within the health-care facility who will be prescribing LifePath-C to patients. Unique login credentials (usernames and passwords) for the Elastic Care Mobile Application are sent to these personnel via the email addresses provided. If your facility does not receive login credentials after signing up, contact Elastic Care support as soon as possible.



8.2 Preparation

Prior to setting up a LifePath-C monitoring campaign, ensure that you have the following:

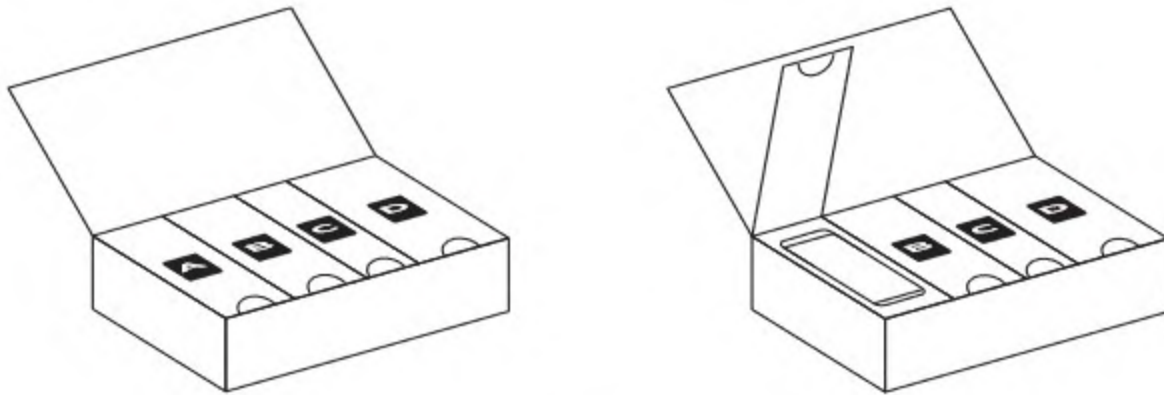
1. The physician's/nurse's email addresses provided by your healthcare facility when signing up for LifePath-C. This will contain their login credentials for the Elastic Care Mobile Application.
2. Access to a LifePath-C package.
3. The patient, for whom LifePath-C is being prescribed, is present.
4. Access to a wireless network and an internet connection.
5. The prescribing physician's requirements for monitoring (number of leads, monitoring duration, report delivery frequency)

9 Setup

The following section outlines the setup, configuration, assembly, and attachment of the LifePath-C Monitoring System to a patient. Please carefully read all contraindications before affixing LifePath-C to a patient.

The unboxing process is integrated into the setup and assembly of the LifePath-C system. Please carefully read each step and ensure it has been performed correctly before advancing further. The various components of the LifePath-C system are separated into sections, each covered with a flap (4 flaps, marked **A**, **B**, **C**, and **D**). Do **not** open a flap and/or attempt to assemble the components until being instructed to in the LifePath-C setup instructions.

Unboxing



Only open Flaps when instructed on the Elastic Care Mobile Application

9.1 Turning ON Included Smartphone

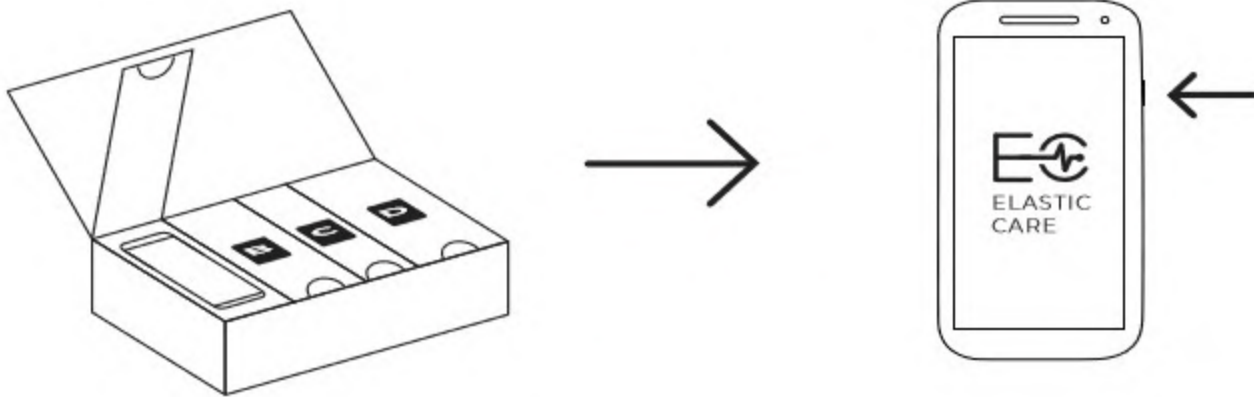
LifePath - C Setup Instructions

Step 1

Open **A**

**Remove
Smartphone
and turn it ON**

Press and hold the side button on the phone until the screen turns on.




*** You will be required to use the Elastic Care mobile app to complete this setup.**

9.2 Logging into the Elastic Care Mobile Application

After turning the Smartphone ON, you will be guided through the setup of the LifePath-C system. Follow the on screen instructions. Setup and operation of the Lifepath-C system requires a wireless internet connection. Please ensure you have access to a reliable wireless network before proceeding.

1: Read and acknowledge warnings and cautions

“Warning: to be used by licensed healthcare providers only”. This screen will show a list of warnings, cautions, and contraindications for use of the LifePath-C monitoring system. Tap the **[I Acknowledge]** button **only if** you are a licensed healthcare provider and have read these warnings.

 *Next Screen: Connect to a Wi-Fi network*

2: Connect to a Wi-Fi network:

If the **Smartphone** is not connected to a Wi-Fi network, you will be prompted to connect to one. Tap the **[Proceed]** button on the popup to be taken to the smartphone’s Wi-Fi settings. Select a network from the list of available networks and enter its password to connect. Once successful, you will be taken back to the Elastic Care Mobile Application.

Next Screen: End User License Agreement (EULA)

3: Read and accept End User License Agreement

Read the Elastic Care End User License Agreement. Scroll down to the bottom of the screen and tap the **[I Accept]** button if you agree to the terms.

Next Section: Patient Setup

4: Log in to the Elastic Care Mobile Application

If you are a physician or nurse, use the login credentials for the Elastic Care Mobile Application sent to you by Elastic Care. Enter your username and password and tap **[Login]** to login.

Next Section: Patient Setup

9.3 Patient Onboarding

After logging in, you may begin setup of a patient’s monitoring campaign. However, patients must be registered with LifePath-C in order to assign monitoring campaigns to them. The following outlines this procedure:

9.3 Patient Onboarding (Cont'd.)

1: Select an Institute

You will now be presented with a greeting (Ex: 'Welcome, Dr. Stephanie Smith'), and a list of healthcare institutes you're associated to will appear underneath. Tap the name of the institute under which you will be starting a monitoring campaign.

Next Screen: Enter Patient ID

*** If your healthcare facility has previously registered this patient with LifePath-C, proceed to 2B after selecting an institute***

2A: Enter Patient ID - Create a New Patient

1: If the patient has not been registered under your healthcare facility as a LifePath-C patient, enter a Patient ID (the ID *your* institution uses to track a patient) and associated Alias in the indicated fields, then tap the **[+ Add a New Patient]** button to create a Patient ID.

2: A popup window will appear titled 'Confirm Patient ID' with the Patient ID you've entered displayed below it. If this is correct, tap the **[Next]** button.

If it is not correct, or you need to change it, tap the **[Cancel]** button to go back and re-enter the information.

3: A popup confirming that the Patient ID was successfully created will be displayed. Tap the **[Proceed to Configuration]** button to begin configuring the monitoring campaign.

Next Section: Configuration

2B: Enter Patient ID - Existing LifePath-C Patients of your healthcare facility:

1: If your healthcare facility *has previously registered* the current patient with LifePath-C, enter the Patient ID used in your healthcare facility to identify them in the text entry field and tap the **[Submit]** button.

2: A popup window will appear titled 'Confirm Patient ID' with the Patient ID you've entered displayed below it. If this is correct, tap the **[Next]** button.

If it is not correct, or you need to change it, tap the **[Cancel]** button to go back and re-enter the information.

3. If the Patient ID was successfully found, a popup titled 'Success! Patient Found' with the Patient ID shown below, will be displayed. Tap the **[Proceed to Configuration]** button to begin configuring the monitoring campaign.

Note: If the Patient ID you've entered was not found, a popup will be displayed with option to re-enter the details.

Next Section: Configuration

9.4 Campaign Configuration

After a new LifePath-C patient has been created or an existing LifePath-C patient has been entered, the screens which follow will take you through the configuration of the LifePath-C monitoring campaign. Confirm the prescribing physician's requirements for the campaign *before* proceeding, as it cannot be modified after it has been configured.

The first configuration screen will require you to select the vitals to be monitored and monitoring campaign duration:

Step 1: Select vitals to be monitored

Select between a **6-Lead** or **12-Lead** ECG configuration. A 6-Lead configuration consist of LA, RA, LL, RL + Respiration Rate, Skin Temperature, and Activity/Posture. 12-Lead configurations consist of LA, RA, LL, RL, and V1-V6 + Respiration Rate, Skin Temperature, and Activity/Posture. Tap the button with desired option. It will turn pink to indicate that it has been selected.

Step 2: Select Monitoring Duration

Monitoring campaigns can last from **1 to 7 days**. Drag the slider on the screen to select the desired length of time. Tap the **[Next]** button to proceed to the next step

Next Screen: Report Delivery Frequency

Step 3: Select Report Delivery Frequency

PDF reports can be sent on an **hourly, daily, or weekly** basis to physicians and nurses via e-mail. Choose one of the three options. Report periods start when monitoring has been started. Tap the **[Next]** button to proceed to the next step

Next Screen: Enter Physician Details


Step 4: Enter Physician Details

Enter the names and email addresses of the physician(s) who will receive reports for this monitoring campaign. You can add additional physicians or nurses who are also registered to Elastic Care under the same facility. Tap the **[Next]** button to proceed to the next step

Next Screen: Scan Wearable Medical Monitor

9.4 Campaign Configuration (Cont'd)

Step 5: Scan Wearable Medical Monitor

Open Flap  and remove the Wearable Medical Monitor from its slot. Tap the **[Scan Code]** button displayed on Smartphone.

Next Screen: Camera Viewfinder

Step 6: Place QR Code Inside Box

The Smartphone camera viewfinder will be displayed. Place the QR code (Quick Response Code) sticker attached to the Wearable Medical Monitor inside the camera viewfinder box. When **the camera successfully scans the QR Code, you will be automatically taken to the next screen.**



The QR code sticker will be located as shown.

You may need to adjust your distance so that the camera can focus. If you are having difficulty, tap the **[Enter Serial Number]** button to manually enter the Wearable Medical Monitor serial number.

Next Screen: Scan Successful

Step 6: Scan Successful Confirmation

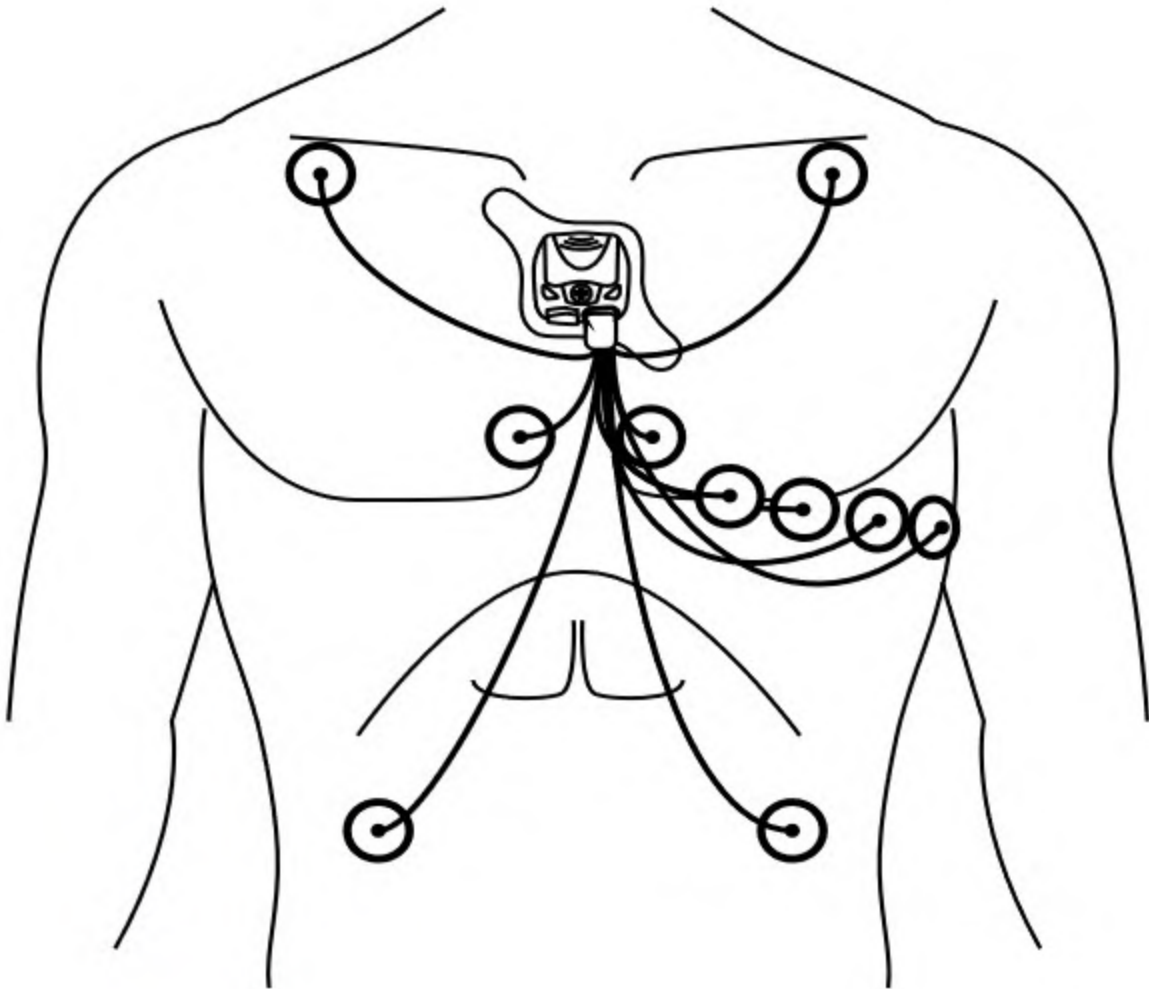
The next screen will confirm the successful scan of the Wearable Medical Monitor and display its serial number.

Next Screen: Review Summary

Step 7: Review Summary

Review the configuration you've selected on this Summary screen. If modifications need to be made, tap the **[Back]** button to go back to the desired step and make the changes. If you are satisfied with the configuration, tap the **[Proceed to Setup]** button to complete the order configuration and begin the LifePath-C Setup.

9.5 Device and Patient Setup



Follow steps 2 through 13 to ensure proper setup and attachment of the LifePath-C system to your patient.



Do not attempt to skip steps or perform any tasks without first carefully reviewing the provided instructions.

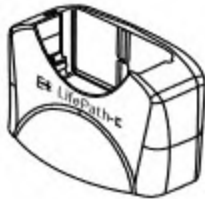
Failure to do so may result in incorrect attachment and/or compromised signal quality.

Step 2

Let's get started.

Open **B**

Parts:



Battery
Dock

x 1



Wearable Medical
Monitor Battery

x 2



Battery Dock
Charging Adapter

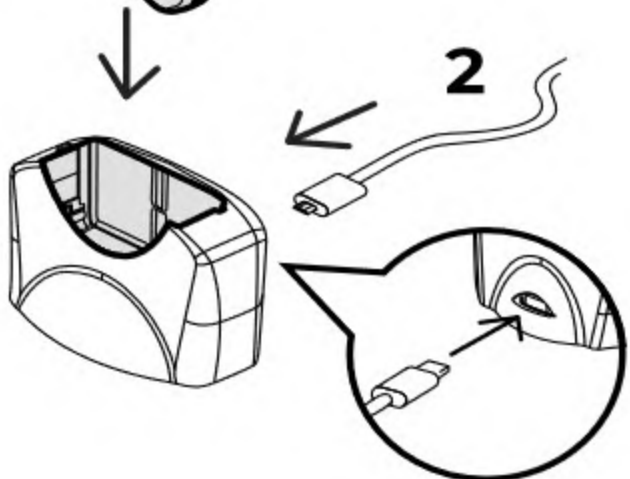
x 1

Step 3

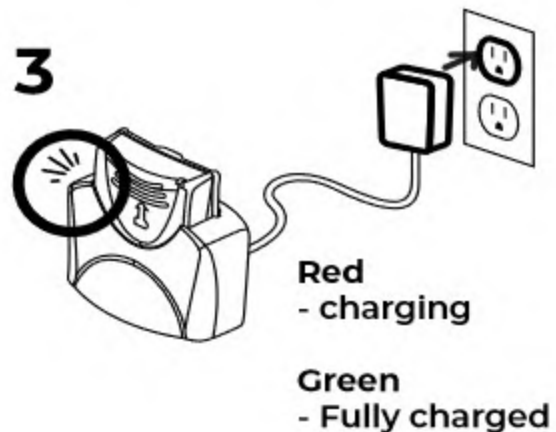
Charging

Charge Wearable Medical
Monitor Battery.

1



3



Step 4

Green

if



Open



Parts:



Wearable
Medical
Monitor

x 1

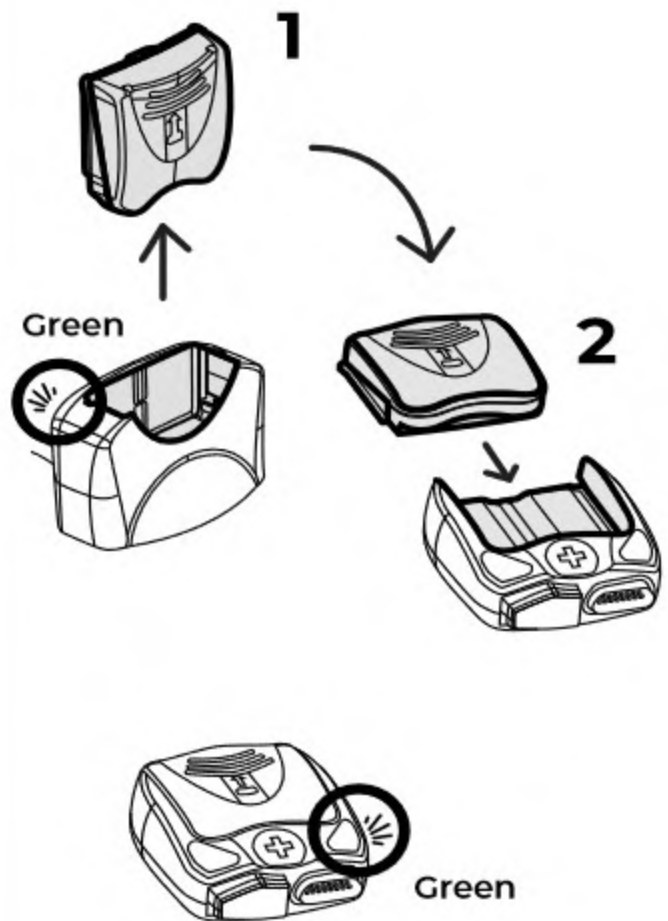


Adhesive
Patch

x 10

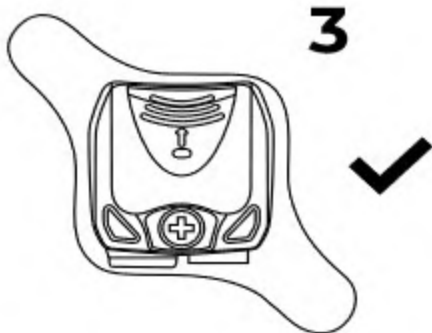
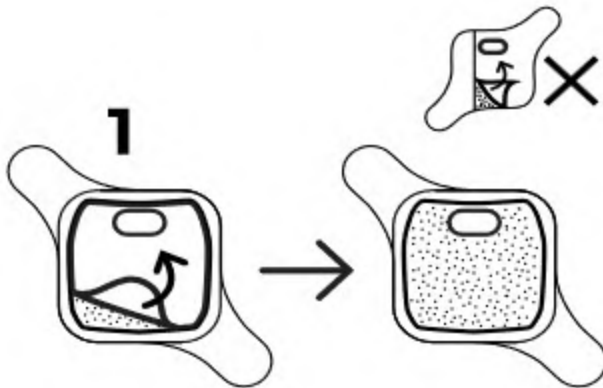
Step 5

Remove fully charged battery and slide into Wearable Medical Monitor.



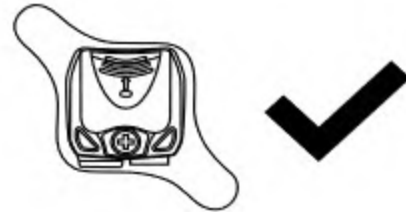
Step 6

Peel, align, and attach.



Step 7

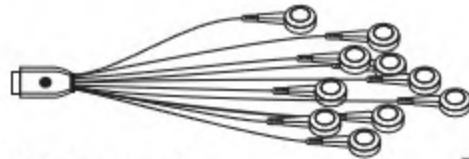
if



Open



Parts:



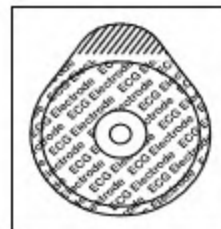
12 Lead

x 1



6 Lead

x 1

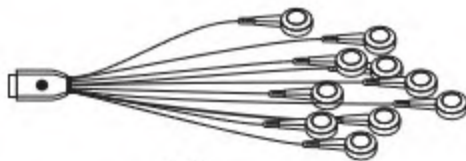


ECG
Electrodes
x 80

Step 8

Select harness, snap electrodes, and insert harness.

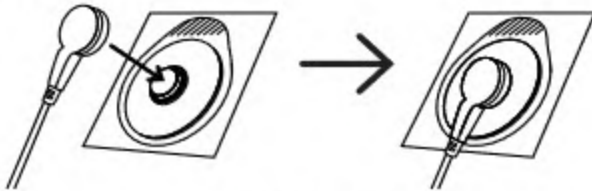
1



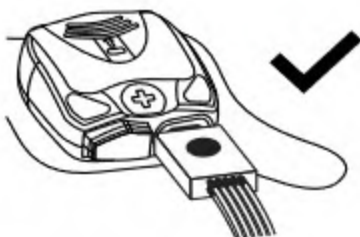
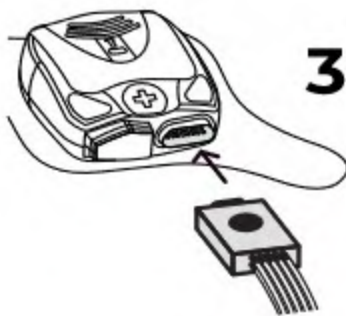
or



2



x 10 (or x 4)

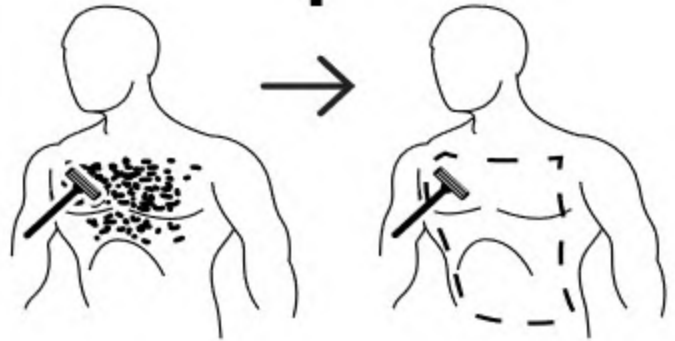


Step 9

Patient Preparation

Shave and clean patient's torso

1



2

Alcohol swab



Find in

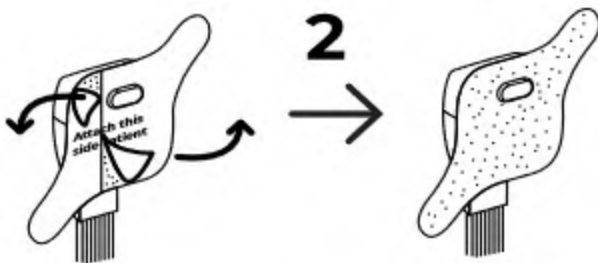
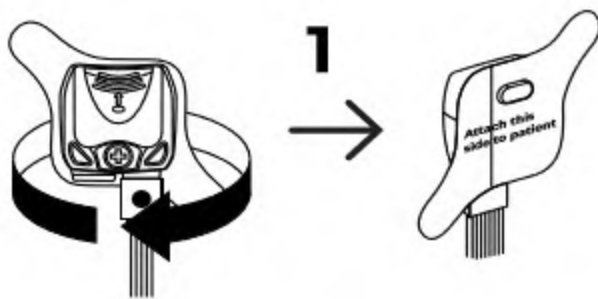


*Note- do not re-use alcohol swabs. Discard after each use

Step 10

Attaching

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

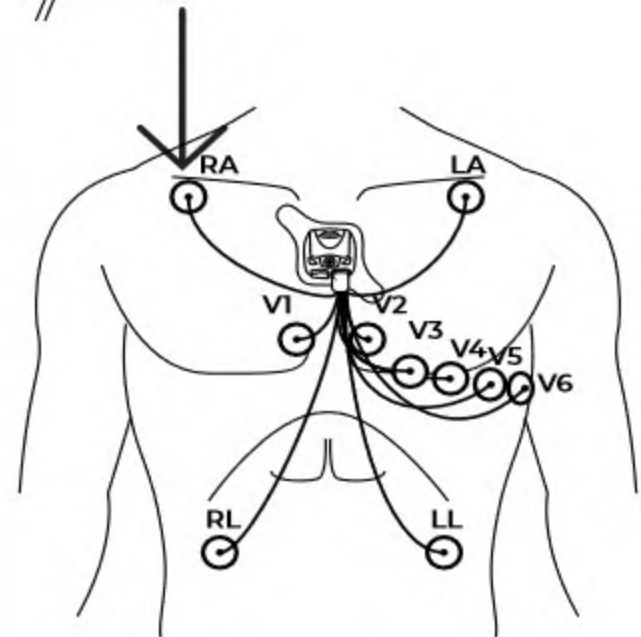


***Note-** do not re-use adhesive patch. Discard after each use

Step 11 (12-Lead)

Attaching

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

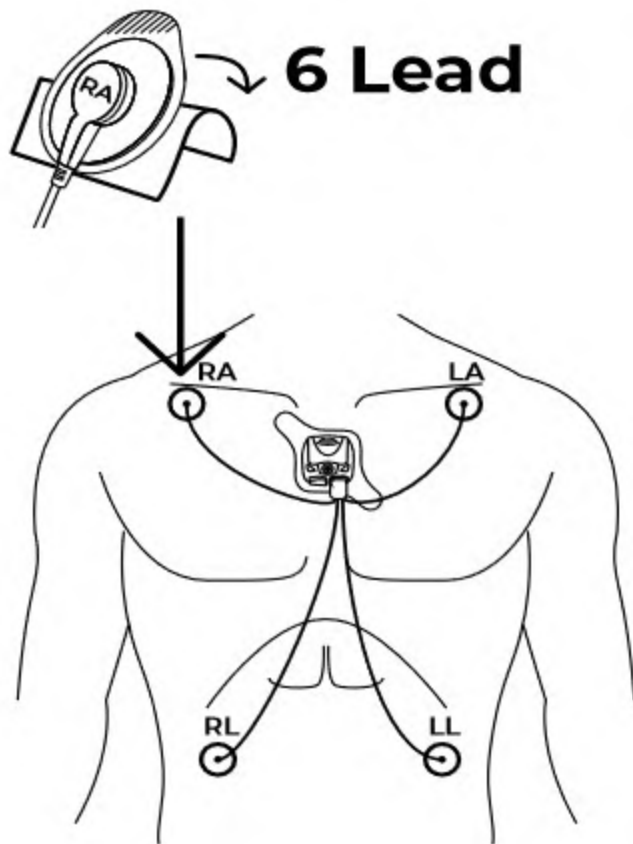


***Note-** do not re-use electrodes. Discard after each use.

Step 11 (6-Lead)

Attaching

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




Step 12

Define Thresholds

Define upper and lower thresholds for Heart Rate, Respiration Rate, and Skin Temperature. Reports will show when these have been breached.



*This step must be performed during the setup process in the Elastic Care App.



Heart Rate

tap to change

44 bpm

lower threshold

115 bpm

upper threshold



Heart Rate

Resp. Rate

Skin Temp.

swipe to advance

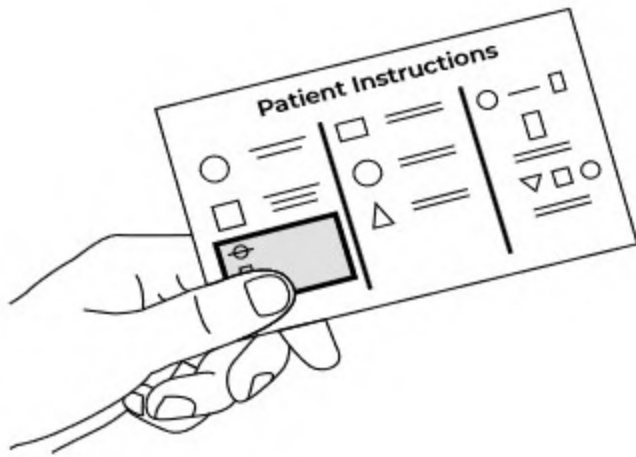
* You must input values for all three parameters before proceeding.

Step 13

Handover

Fill your contact information on the Patient Instruction Card (in white folder). Review it with the patient.

Hand over Patient Instruction Card to the patient.




**Setup
Complete.**



* In order to proceed to the LifePath-C Dashboard, you must tap the 'Next' button.

Next

10 Operation

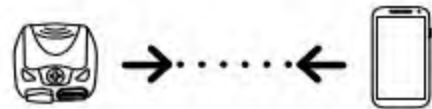
This section will detail the operation of LifePath-C with the Elastic Care mobile application. Please ensure the following;

1. Setup has been successfully completed and LifePath-C has been affixed to the patient.
2. Thresholds have been set for the various biometric parameters collected during the monitoring campaign (Ex: Heart Rate, Respiration Rate, Skin Temperature)
3. You have reviewed the Patient Instruction Card with the patient and handed it over to them along with the included Smartphone.

10.1 Operating Requirements



Smartphone is connected to a Wi-Fi network with an Internet connection or have an LTE/cellular data connection.



A MAX distance of 1.5m is maintained between the Wearable Medical Monitor and the Smartphone.



Bluetooth on the Smartphone is turned ON.



The Smartphone is LOCKED when not in use.



Wearable Medical Monitor Battery fully charged prior to start of monitoring.



Smartphone battery charged and/or plugged into a power source during monitoring.

After completing the LifePath-C Setup Procedure, you will be taken to the LifePath-C **Dashboard**. This screen will facilitate operation of LifePath-C.

10.2 Elastic Care Mobile Application Overview

This sub-section will outline the operation and use of the Elastic Care Mobile Application, which is pre-installed on the included Smartphone.

The Smartphone and Elastic Care Mobile Application perform several primary functions:

1. Receive all biometric data from a paired Wearable Medical Monitor and third-party devices, and transmit them, in real-time, to Elastic Care's secure servers via Wi-Fi or an LTE connection.



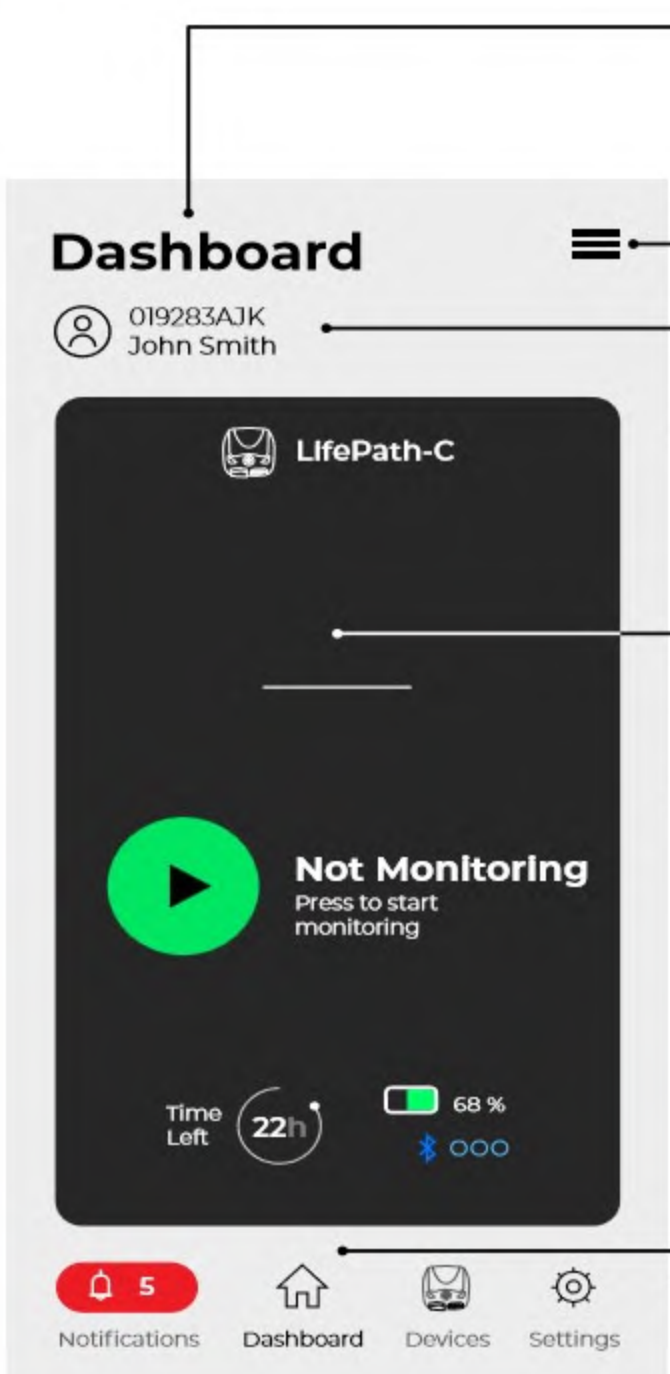
2. Provide an interface for creating, configuring, and controlling a LifePath-C monitoring campaign.

Below are the additional functions of the mobile application:

- Starting/stopping LifePath-C monitoring
- Pairing a Wearable Medical Monitor to the Smartphone
- Pairing and controlling approved third party devices and where applicable, displaying collected biometric data
- Patient ID creation (see section 'Getting Started with LifePath-C')
- The viewing and management of notifications and alerts
- Viewing setup and onboarding instructions of LifePath-C and third-party devices
- Displaying the time remaining of monitoring campaign
- Displaying the hardware status, battery status and bluetooth signal strength of a paired Wearable Medical Monitor, and other connected third-party devices.

10.2 Elastic Care Mobile Application Overview

LifePath-C Interface Overview



Section
Indicates which section you are currently viewing.

Menu
access to Help, Troubleshooting, FAQ's, Version number, etc.

Patient Information
Patient ID and patient alias.

Device Control Card
Interface for controlling LifePath-C and other paired third-party devices.

The Dashboard will display the Device Control Card for the **Current Device**

Navigation Menu
Tap to go to **Notifications**, **Dashboard**, **Devices**, and **Settings**

*Dashboard section shown

10.2 Elastic Care Mobile Application Overview

Dashboard Overview

After creating, configuring and setting up a LifePath-C monitoring campaign, you will be taken to the **Dashboard**. Here, you will be able to start and pause monitoring, and control paired third-party devices. The screen below shows the **Device Control Card** for the LifePath-C Wearable Medical Monitor.



Dashboard

019283AJK
John Smith

LifePath-C

Not Monitoring
Press to start monitoring

Time Left 22h

68 %

Notifications 5 Dashboard Devices Settings

Device Type
Displays the current device in use.

Monitoring Controls
Starts and pauses LifePath-C monitoring.

- When pressed, will **start** Monitoring.
- When pressed, will **pause** Monitoring.

Monitoring State
Displays the current state of monitoring

Time Remaining
Displays how much time is remaining in the monitoring campaign.

Battery
Wearable Medical Monitor battery percentage.

Bluetooth Strength
Bluetooth signal strength.

- strong
- good
- low/weak
- not connected

10.2 Elastic Care Mobile Application Overview

Notifications Overview

The Notifications page will display alerts pertaining to the LifePath-C device in use, and monitoring campaign. Notifications are split into two sub-categories; **Logs** and **Alarms**.

Logs

List of events for informative purposes only.

Alarms

Events which require action by the patient or healthcare provider. The red bubble in the navigation bar indicates the number of alarms that are pending.

The **most recent alarm will also be displayed on the Dashboard as a popup** with corrective actions to be performed. Once completed, the alarm popup will be automatically dismissed.

The red bubble indicator will revert back to clear when the Notifications button has been tapped and notifications have been viewed.



Notifications

Logs **Alarms**

Today

| | |
|---------------------|---------|
| Lead-off detected | 7:15 am |
| Bluetooth connected | 6:48am |
| Monitoring started | 2:29 am |
| Low battery | 2:07am |

Yesterday

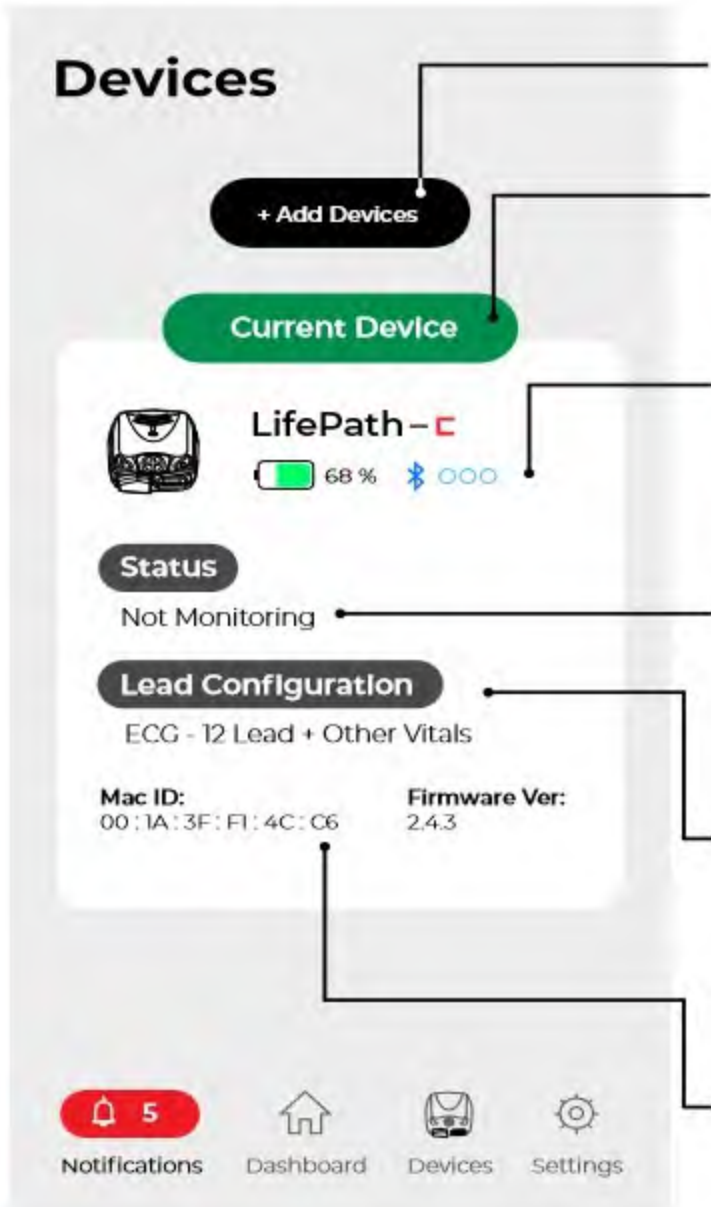
| | |
|------------------------|----------|
| Monitoring paused | 10:02 pm |
| Bluetooth disconnected | 9:18 pm |
| Lead-off detected | 6:42 pm |
| Monitoring started | 10:43 am |

Notifications Dashboard Devices Settings

10.2 Elastic Care Mobile Application Overview

Devices Overview

The Devices section provides an overview of the connected devices. Every paired device will be represented by its own **Device Card**



Devices

- + Add Devices**: Tap to add approved third-party devices to the monitoring campaign.
- Current Device**: Tap device card to make it the current device.
- System Indicators**: Device (Wearable Medical Monitor or third-party device) battery and Bluetooth status.
- Monitoring State**: Displays the connected LifePath-C's monitoring state.
- Lead Configuration**: Lead Configuration for the connected Wearable Medical Monitor. Can be either 12-Lead or 6-Lead.
- Device Information**: Device MAC ID and Firmware version.

Status: Not Monitoring

Lead Configuration: ECG - 12 Lead + Other Vitals

Mac ID: 00:1A:3F:F1:4C:C6 **Firmware Ver:** 2.4.3

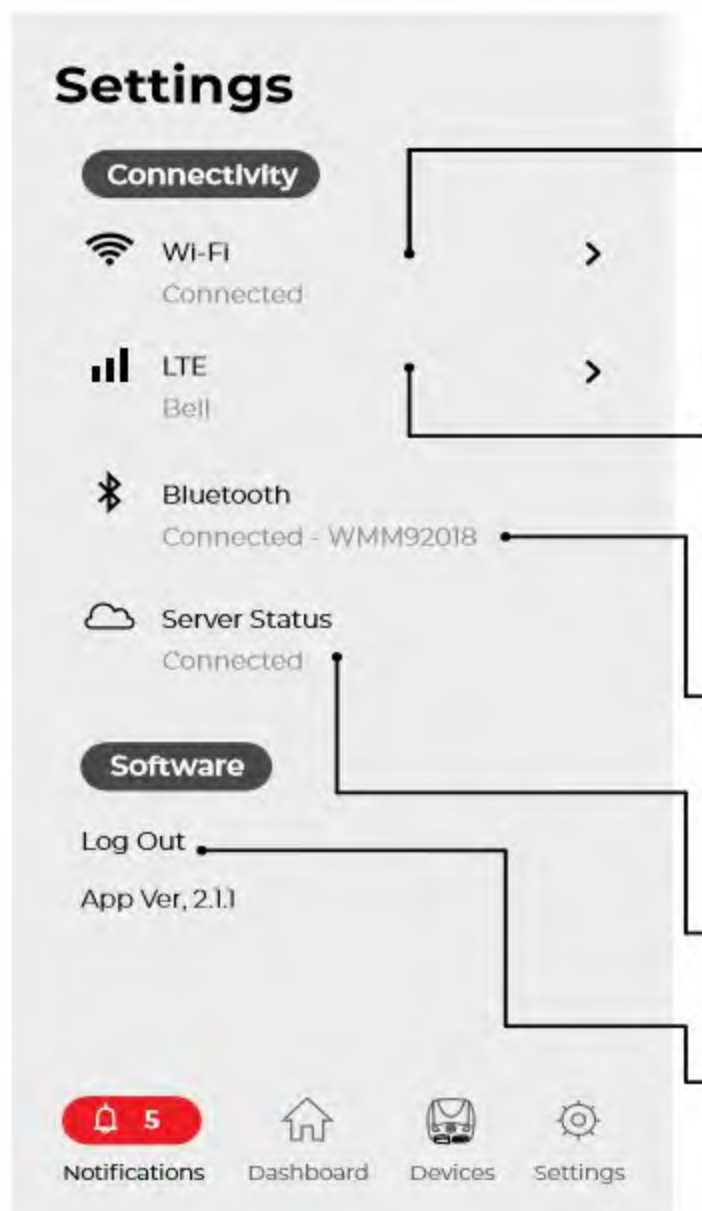
Notifications 5 **Dashboard** **Devices** **Settings**

10.2 Elastic Care Mobile Application Overview

Settings Overview

Within the Settings section, Wi-Fi and LTE networks can be set up, connected to, and configured. Bluetooth and Server status can be viewed,

Note Always be connected to either a Wi-Fi or LTE network to ensure data collected is transmitted to Elastic Care servers for processing.



Wi-Fi Settings

Tap here to go into Wi-Fi settings in order to connect to, view, and configure available Wi-Fi networks.

LTE Settings

Tap here to go into LTE data settings in order to setup an LTE data connection. Carrier charges may apply.

Bluetooth Status

Bluetooth Status and connected device ID. Tap to access Bluetooth settings.

Server Status


Displays Elastic Care server status.

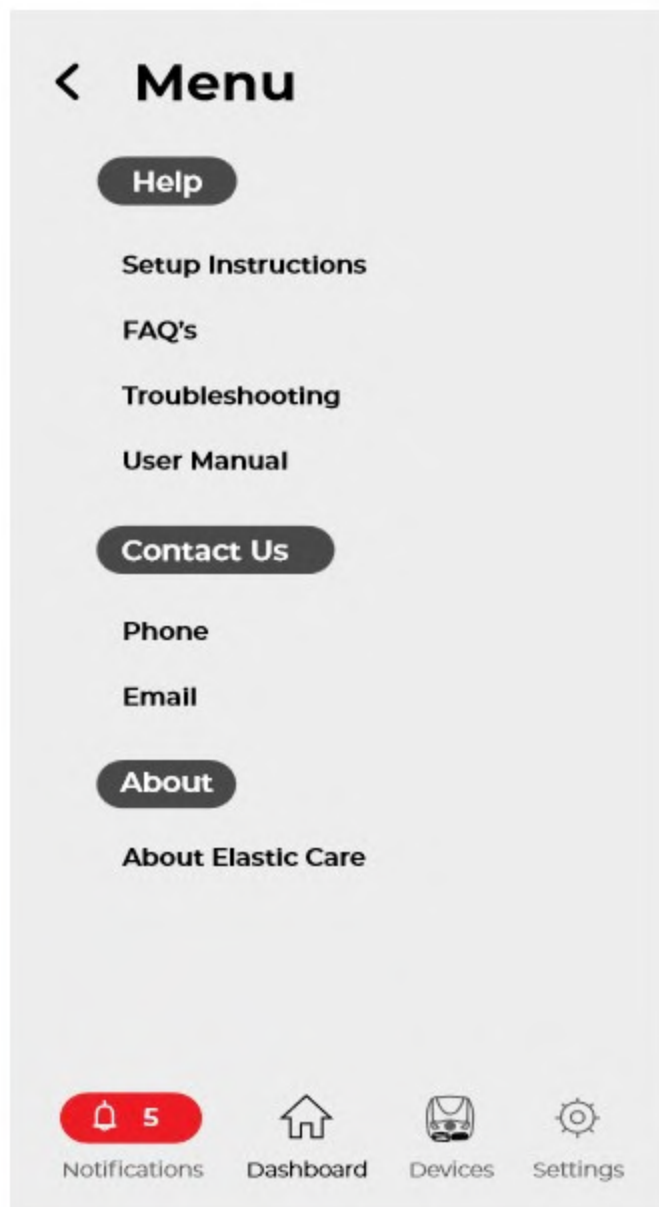
Log Out

Logs user out of the Elastic Care Mobile Application. You will need to re-enter credentials in order to log back in.

10.2 Elastic Care Mobile Application Overview

Menu

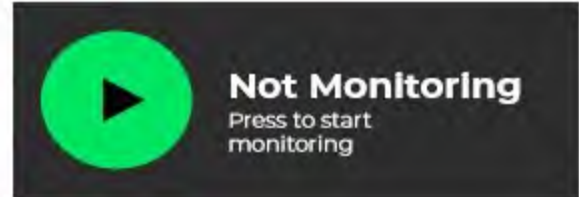
Access to various resources, such as Setup Instructions, FAQ's, Troubleshooting, and a digital version of these Clinical Instructions For Use can be accessed by tapping the Menu icon  from within the Dashboard.



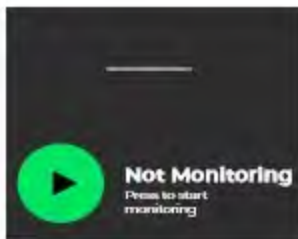
10.3 Starting Monitoring

Starting Monitoring

With a monitoring campaign configured and the Wearable Medical Monitor attached to the patient, tap the **Start Monitoring** button as shown in order to begin monitoring.



The Elastic Care Mobile Application will connect and pair with Wearable Medical Monitor. The monitoring controls will quickly display the connection progress.



Not Monitoring →

Not connected to Wearable Medical Monitor. Smartphone not receiving data from Wearable Medical Monitor.



Searching →

Smartphone looking for paired Wearable Medical Monitor.



Connecting →

Wearable Medical Monitor found. Connection being established.

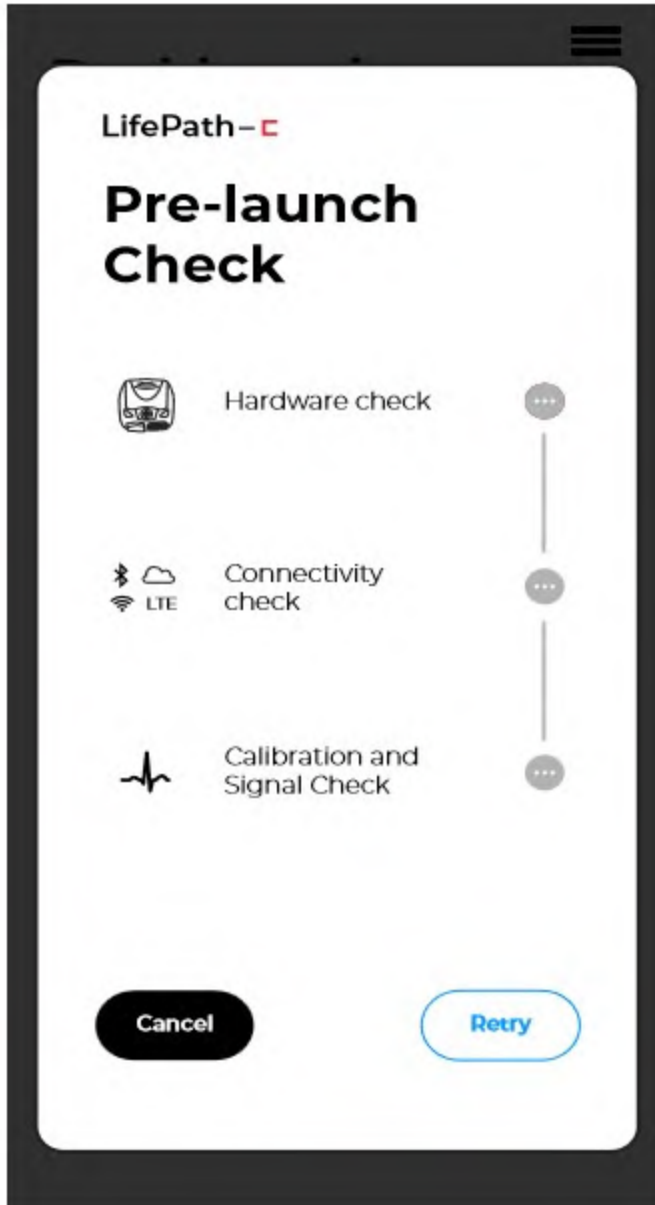


Connected

Connection established. Data now being transmitted from Wearable Medical Monitor to Smartphone.

Once connected, a **Pre-Launch Check** will begin to ensure all parts of the LifePath-C system are functioning correctly prior to the start of monitoring.

10.4 Pre-Launch Check



The **Pre-Launch Check** will be performed to ensure the correct attachment and functioning of the Wearable Medical Monitor, test wireless connections, check signal fidelity, and perform a calibration(*) prior to the monitoring beginning.

This check is done sequentially in stages. In order for the Pre-Launch Check to be successful and monitoring to begin, **all three stages must be free of errors.**

Once successful, monitoring will commence, and you will be returned to the Dashboard.

The Pre-Launch check will occur every time monitoring starts or re-starts.

* *Calibration* refers to the LifePath-C system taking a collection of initial measurements to produce a patient's baseline vitals.

10.4 Pre-Launch Check

The Pre-Launch Check is split into three stages.



Hardware check

Checks all hardware functionalities required for normal operations:

Internal hardware, electrode connections, and cable harness.





Connectivity check

Checks for a valid Wi-Fi or LTE connection, internet connection, Bluetooth connection and strength, and verifies status of Elastic Care servers.



Calibration and Signal Check

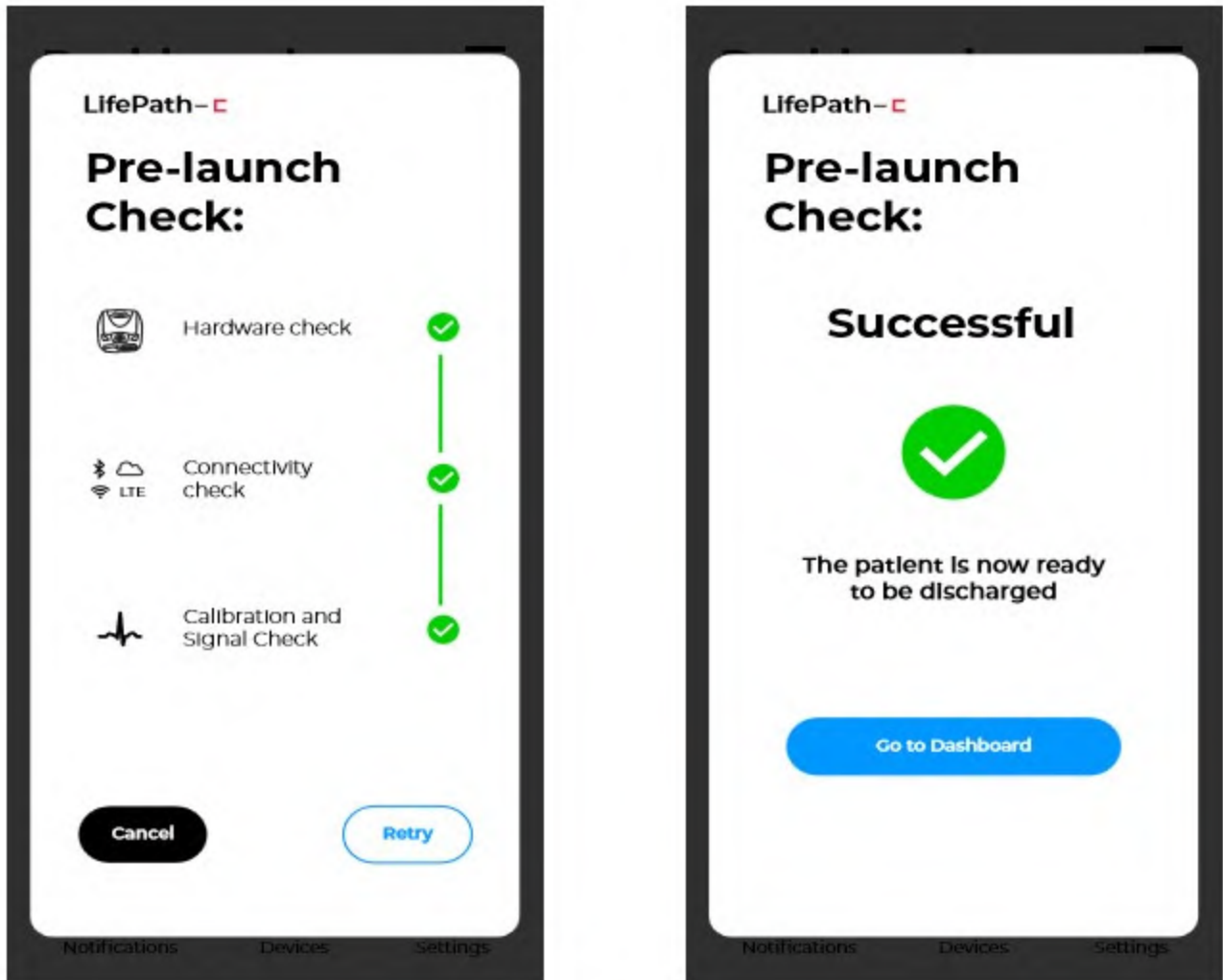
Calibrates the Wearable Medical Monitor and checks signal fidelity. During this stage, the patient will be instructed to remain still in a seated position for **approximately 2 minutes**.

Successful stages of the Pre-Launch Check will be indicated by a green check mark symbol  and will **automatically** advance to the next stage. Stages during which errors are encountered will be indicated by a red 'x'  symbol and will require correction/troubleshooting before proceeding.

Refer to the section of this manual titled '**Pre-Launch Check Errors**' for more information.

If a stage is free of errors, you will not be required to take any action.

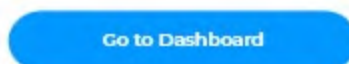
10.5 Successful Pre-Launch Check



Once all three stages of the Pre-Launch check have been successfully completed, the LifePath-C system will be in a **Monitoring** state.

Hand the Smartphone over to the patient and instruct them to keep it on, charged, and nearby during the monitoring campaign.

Tap the `Go to Dashboard` button shown to proceed to the Dashboard screen.



10.6 Monitoring

While monitoring, the Monitoring State will be **'Monitoring'** and the monitoring control will be a **Pause Monitoring** button. At this time, the Wearable Medical Monitor is continuously collecting biometric data with its various sensors (ECG, Respiration Rate, Skin Temperature, and Activity /Posture) and transmitting it, in real-time, to the Smartphone via Bluetooth. This data is then transmitted, also in real-time, to Elastic Care's servers by the Smartphone via a Wi-Fi or an LTE connection.



Dashboard screen while in a monitoring state. Smartphone is receiving signals from Wearable Medical Monitor.

The monitoring campaign will begin the *first time* monitoring starts. It will run for the duration of time selected during the Campaign Configuration stage.

The Wearable Medical Monitor will remain in a monitoring state unless

- The Wearable Medical Monitor battery is completely drained.
- or** The **Pause Monitoring** button is tapped
- or** The Scheduled Maintenance procedure is started.

The time remaining is displayed beside the **'Time Left'** label on the Device Control Card.

Recommendation: Stay on the Dashboard screen

It is recommended that the mobile application be kept on the Dashboard screen during the campaign, as notifications for problems encountered during the campaign, reminders to charge the Wearable Medical Monitor battery and scheduled maintenance, will be easily seen.