ECG Mini
User Guide

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1.800.517.6330
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LifeWatch

ECG Mini User Guide

This user guide includes information and instructions about the ECG Mini (Continuous ECG Monitor and Arrhythmia Detector) monitoring system. Please read it carefully before you begin testing.

If you have any questions regarding the ECG Mini please contact LifeWatch at 1-800-517-6330.

Federal Law (USA) restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

CAUTION:

This manual should always accompany the unit. All personnel utilizing the ECG Mini system must have read and be familiar with the contents of this manual.

First time use – You must call LifeWatch to receive instructions on how to proceed for the first time use.

The first time the ECG Mini is activated and is attached to you, it will display screens that are not seen in regular use. These screens are calibration procedures the ECG Mini needs to perform to adjust its operation for first time use.

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Illustrations included in this manual are general representations only and are not meant to comply with specific regulatory requirements.

ATTENTION: The ECG Mini is a near diagnostic tool only and is not part of an emergency service. Heart strips transmitted by the device are not viewed immediately by technicians. If when viewed, the technician sees an arrhythmia that is potentially harmful or life threatening, LifeWatch will attempt to facilitate care for the patient through either their doctor or an emergency medical service, although this care may be delayed.

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1 INTRODUCTION

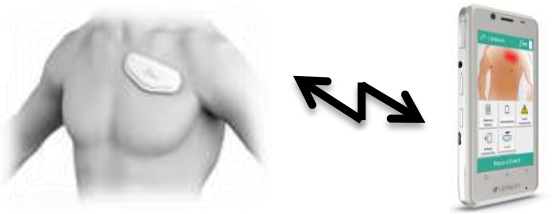
1.1 Intended Use

The ECG Mini System is intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia. The device continuously monitors patient ECG and transmits the recorded data wirelessly to a monitoring center. The monitoring center provides the ECG data to the medical practitioner for evaluation.
The device has not been tested for and it is not intended for pediatric use.

Contraindications for Use:

- The ECG Mini is not to be used in a magnetic resonance imaging (MRI) environment. The ECG Mini must be removed from the patient's skin before he/she undergoes MRI procedure
- The ECG Mini is not to be used with external defibrillator.
- The ECG Mini is not a "life-saving" or therapeutic device; the ECG Mini supplies vital signs data to a doctor or technician for the purpose of diagnosis by such (or other qualified) personnel
- The ECG Mini is not intended for use on patients with unhealed surgical incisions/dressings on the thoracic or abdominal regions
- The ECG Mini is not intended for use on patients with skin or soft tissue damage in the area where the Patch is placed (such as burns, irritation, infections, wounds, etc.).
- The ECG Mini is not intended for use in the diagnosis of myocardial infarction or for chest pain monitoring.

1.2 General Description



The ECG Mini system consists of 3 main components:

- Disposable 1-lead patch with ECG electrodes
- Reusable processing and transmitter device, also called “Brain”
- Gateway cellular device

The 1-lead ECG patch contains 3 electrodes which are used for 1-lead arrhythmia detection. The 1-lead patch ECG is attached to the upper chest of the body.

The 1-lead patch contains 3 ECG electrodes, a cradle for the Brain and one coin battery for powering the Brain.

The 1-lead patch is a disposable part which is mounted on the patient body throughout the service period. Special slot within the patch enables easy insertion of the brain to its cradle by the user. The brain receives its power from a 1.4V coin non-rechargeable battery integrated within the patch.

The brain transmits ECG raw data to the Gateway cellular device wirelessly using unique RF protocol. In addition, the Brain contains a 32MB Flash memory chip that can store 6 hours of data in case of communication failure with the Gateway cellular device.

The Gateway cellular device is located in the patient home and receives the ECG signs data from the Patch wirelessly over a unique RF protocol. The Gateway cellular device analyzes the ECG data and generates events which reflect 4 arrhythmias – Pause, AFIB, Tachycardia and Bradycardia. These events are transmitted to the monitoring center backend system of LifeWatch Services over

standard wide range cellular network. ECG events are displayed at the monitoring center (LifeWatch Services) by means of cardiac data software called “Paceart”.

The patient can manually trigger an event by clicking on an icon on the screen of the Gateway cellular device.

The following list represents patient populations for whom use of the ECG Mini is most appropriate. This list should be used in conjunction with Medicare and other payor medical necessity guidelines:

- Patients with dizziness or lightheadedness
- Patients with palpitations
- Patients with syncope of unknown etiology
- Patients who require monitoring for non-life-threatening arrhythmias, such as Atrial Fibrillation, Supra-ventricular Arrhythmias, evaluation of various Brady arrhythmias.
  This includes post-operative monitoring for these rhythms.
- Patients recovering from coronary artery bypass graft (CABG) surgery who require monitoring for arrhythmias
- Patients requiring monitoring for arrhythmias-including co-morbid conditions such as hyperthyroidism or chronic lung disease
- Patients with obstructive sleep apnea to evaluate possible nocturnal arrhythmias
- Patients requiring arrhythmia evaluation for etiology of stroke or transient cerebral ischemia, possibly secondary to Atrial Fibrillation

To use the ECG Mini, the user or primary care provider must be able to perform all of the following:

- Understand the principle of operation and system messages described in this manual
- Place the patch on the chest
- Operate a handheld device (Gateway)

The ECG Mini is safe for use by patients wearing an oxygen mask for breathing.

The function of the ECG Mini is dependent on cellular phone service and short range RF technology (Nordic). Limitations in data transmission may occur if there is limited cellular service in the area.

You may occasionally experience a delay in the ability to send recorded events due to unexpected cellular limitations. If this occurs, contact LifeWatch as soon as possible. Any technical difficulties should be reported as quickly as possible so as to resolve the issue with minimal service interruption.

As with all standard cell phones, charge the Gateway cellular device whenever possible, and at least every night. The performance of the Gateway cellular device, including data recording and transmission, may be adversely impacted if not adequately charged.

1.3 Symbols on Equipment and Labeling

The following section contains a complete description of all symbols that may be located on either the equipment or labeling of ECG Mini and accessories.

Label	Description
	Warning, consult accompanying text or documents
	Caution, consult accompanying text or documents
	Notes, indicates important general information for using the system successfully.
	Consult instructions for use

Label	Description
	Serial Number
	Date of Manufacture
	Type BF Applied Part
	Batch code
	Do not use if package is damaged
	Use by
	Keep dry
	Store at specified temperatures
	Electrical and Electronic Equipment
	The ECG Mini is MR unsafe

1.4 Warnings and Cautions

The following section contains a complete list of the major warnings and cautions relevant to the ECG Mini. These warnings and cautions are also repeated, as appropriate, in sections of this manual. Your prescribing physician is responsible for reading and understanding all warnings and cautions prior to prescribing the ECG Mini.

Warning 	• The ECG Mini is intended to be used in conjunction with a monitoring service that reviews the recorded transmissions and provides that information to the physician for his/her final diagnostic interpretation. • The ECG Mini is not intended for use as an emergency medical response system and should not be used by patients at risk for serious or life-threatening cardiac arrhythmias, such as ventricular tachycardia and ventricular fibrillation. Refer to the Physician Manual Specification for the types of arrhythmias detected by the ECG Mini. The ECG Mini is not intended for use in the diagnosis of myocardial infarction or for chest pain monitoring. • Due to the risk of ignition or fire, the ECG Mini is not intended for use in a hyperbaric chamber, within an oxygen tent or in the presence of flammable anesthetics / medical gases.

Warning 	• To prevent fire or shock hazard, do not expose the ECG Mini to moisture, liquids or condensation. • To prevent an allergic reaction, do not use the ECG Mini or accessories if you have a known allergy to nickel or other metals. • The ECG Mini is not defibrillation-proof. Exposure to defibrillation may damage the ECG Mini, or the ECG Mini may interfere with the operation of the defibrillator. The ECG Mini MUST be removed prior to defibrillation as it contains metals that could cause the defibrillator to arc. • Use of conductive, connected devices and patient lead wires/electrodes like the ECG Mini in MRI procedures may result in serious burns. • If you should come into possession of your ECG recording do not take any actions of a medical nature based on your understanding UNLESS you are a medical professional.

Warning 	**Use with Implanted Conventional Pacemakers and ICDs (ICD device max energy 30 Joules)** If you have an implanted pacemaker or ICD, the manufacturer may recommend certain precautions when using a cellular phone. Since the ECG Mini Gateway is also a cellular phone, you should take the same precautions when carrying and using the Gateway cellular device. In general, most manufacturers recommend the following: • Keep a distance of at least six inches (15 cm) between the Gateway cellular device and a pacemaker or ICD. • Carry the Gateway cellular device on the opposite side of the body from the pacemaker or ICD. • Don’t carry a cell phone in a breast pocket or on a belt if that would place the phone within six inches (15 cm) of the pacemaker or ICD. • Refer to the manufacturer's information for guidance regarding the pacemaker/ICD and interference issues.

Caution 	• The ECG Mini generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. • The ECG Mini employs Nordic and cellular technology. The location of the ECG Mini and the associated environment, including cellular phone coverage in the particular area, may cause transmission interruption or delay. • Do not open or attempt to repair the sensor. Only authorized service personnel may repair the system components. • To avoid damage to the system, the system and accessories should be kept away from extreme heat including placement of the ECG Mini on the dashboard of a car or near a heater. • The system should not be subjected to severe impact or bending force. Exposure to these types of stresses can damage the system components. • Charge the Gateway cellular device every night (irrespective of indicator status), making sure that it is within 10 feet (3 meter) of the sensor. In addition, charge the Gateway whenever possible during the day. • The energy consumption of the Gateway may be high during the first few days of monitoring (up to 72 hours). Keep the Gateway charged at all times.

Caution 	• Electrode disconnection might cause a faulty ECG analysis and/or false events due to noise created by the electrode disconnection. • Impedance test, which may be requested by the algorithm in rare cases, will override the ECG recording; this means that the ECG will lack ~1.5 seconds of recording in those cases. • Do not turn off the sound of the Gateway cellular device or reduce the volume so that it is inaudible. • Take the charged Gateway with you and wear the sensor at all times (except when bathing) during the monitoring period. • Keep the Gateway away from extreme heat. Do not leave it on the dashboard of a car or near a heater. Do not leave it in any place that is extremely damp or dusty. • Do not store the ECG Mini in a place where it will be continuously exposed to moisture or steam. Extended exposure to moisture may cause malfunction.

Caution 	• A disconnection between the Gateway cellular device and the sensor might occur due to electromagnetic interference. In this case the sensor will search for the Gateway cellular device every 3 minutes. • **First time use** – The patient must call LifeWatch to receive instructions on how to proceed for the first time use. The first time the ECG Mini is activated and is attached, certain screens are displayed that are not seen during normal operation. These screens are used for calibration. Please refer to “First Time Activation” section of the manual for more details.
Caution 	• Please refer to the user manual of the manufacturer of the Gateway cellular device for Health and Safety Information pertaining to the use and operation of the Gateway cellular device. • Do not use the Gateway cellular device for any reason outside of the designated monitoring function. • Keep kit contents away from children.

1.5 Glossary

ECG	Electrocardiogram; a representation of the heart's electrical activity recorded from electrodes on the body.
ECG Mini	Continuous ECG Monitor and Arrhythmia Detector (ECG sensor, Brain and Gateway)
Patch	ECG Mini device attached to patient.
Gateway	Hand held device/cellular phone using ECG Mini monitoring software.
Heart Rate	Number of heart beats per minute, measured as bpm (beats per minute).
Nordic RF	Wireless communication protocol.
Monitoring Center	Monitoring center responsible for reviewing clinical data transmissions, and providing them to the physician.
Charger	Power supply for recharging Gateway cellular device.
Arrhythmia	Irregular heartbeat.
Manual event	Event manually recorded (on Gateway) by a patient when he/she feels it is necessary.

2 GENERAL DESCRIPTION

The ECG Mini patch system comprises a disposable 1-lead ECG Patch with two active electrodes and additional one electrode as reference, a transmitter (Brain) and proprietary SW running on a standard cellular device (called the Gateway) with an Android based operating system. The SW installed in the Gateway is also called the Gateway application. The Gateway cellular device is equipped with short range 2.4 GHz ISM RF ("Nordic") communication capabilities.

The ECG Mini system consists of 3 main components:

- ECG Mini with ECG sensor
- Transmitter, also called "Brain"
- Gateway cellular device (with silicon cover)

The ECG Mini with its 3 ECG electrodes is a disposable part which is mounted on the patient body throughout the service period. The ECG Mini with ECG electrodes transmits the ECG signs via a reusable transmitter (Brain) to a Gateway cellular device.

The Brain plugs into a cradle, which is part of the 1-lead patch, and is connected to the cradle with a 7 pin connector. The brain receives the power from the patch from two 1.4V non rechargeable batteries.

The Brain transmits data to the Gateway cellular device using the RF component. In addition, the Brain contains a 32MB Flash memory chip that can store 6 hours of data in case of communication failure with the Gateway cellular device.

The Gateway cellular device located in the patient home receives the ECG signs data from the sensors patch over a unique RF protocol. The Gateway cellular device analyzes the ECG data and generates events which reflect 4 arrhythmias – Pause, AFIB, Tachycardia and Bradycardia. These events are transmitted to the monitoring center backend system of LifeWatch Services over standard wide range cellular network.

The patient can manually trigger an event by clicking on an icon on the screen of the Gateway cellular device.

	**Note** The Gateway automatically transmits the detected ECG events to the monitoring center and the user has the ability to send manually recorded events.

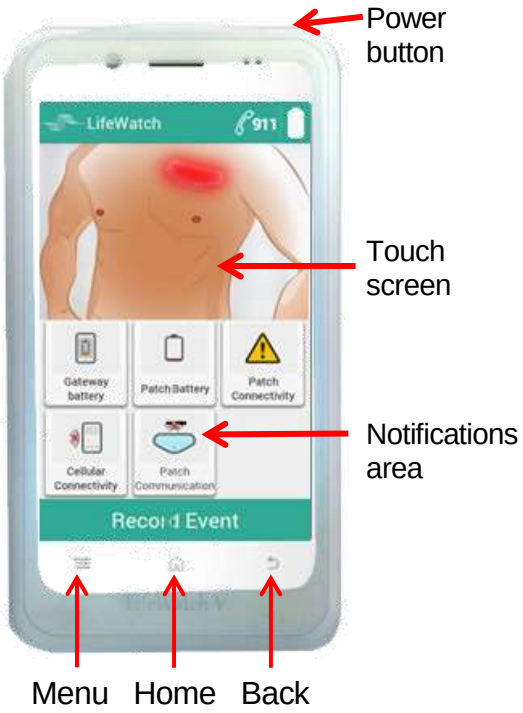
3 THE ECG MINI KIT

The ECG Mini Kit provides the ECG Mini (with Brain transmitter) and one Gateway (Gateway), including charger.

1-Lead ECG Configuration

3.1 Gateway Physical Description

Gateway keys and buttons



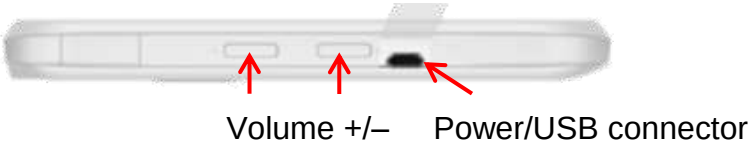


Figure 1 – Gateway Physical Description

Note: to access the USB connector the flap of the silicon cover must be lifted.

3.2 Charging the Gateway Battery

1. Connect the supplied USB plug to the USB/adapter jack. Ensure that you insert the plug with the correct orientation. Do not force the plug into the jack.

USB input is 5 VDC: maximum 5.25VDC to minimum 4.75VDC at 1A max.

2. Connect the USB cable's USB plug to the adapter.
3. Connect the adapter to a standard AC wall outlet.
4. Disconnect the adapter when the battery is fully charged.

NOTE: When you first receive your device verify the Gateway is fully charged.

Use only the supplied adaptor DSA-5PFK-05 FUS.
Input is 100 to 240 V, ~50 to 60 Hz, 0.3A;
Output is 5 V, 0.7A, 3.5 W maximum

How much charge is in the battery?

If the battery is low, a message appears. When charging, there will be an indication of the battery level.

3.2.1 Switching the Gateway On/Off

- Hold Power to switch on your device.

Top view

- To switch it off, hold Power to get the device options. Select Power off, and then tap OK.

Always place the adapter in easily accessible main plugs.
In case of electrical malfunction of the device during the connection to the adapter, remove the adapter from main plug immediately.

	**CAUTION** Please refer to Appendix A Gateway (Cellular Phone) Warnings for Health and Safety Information pertaining to the use and operation of the cellular phone. **CAUTION** • Do not change the settings of the Gateway cellular device. • Do not turn the Gateway sound off. • Do not mute the volume so that it is inaudible. • Do not use the Gateway for any reason outside of the designated monitoring function • The ECG Mini employs short range RF and cellular technology (Nordic). The location of the device and the associated environment, including cellular phone coverage in the particular area may cause transmission loss or delay.

4 IMPORTANT INFORMATION BEFORE USE

4.1 General

The recommended ambient temperature for use of the ECG Mini System sensor is between 50°F (10°C) and 113°F (45°C).

The Gateway cellular device is not to be exposed to direct water contact. The Gateway should not be in the bathroom while bathing or showering.

You must take the fully charged Gateway with you and wear the sensor at all times (except when showering or bathing).

	**Caution** Do not use the provided Gateway for any reason other than the designated monitoring function.

4.2 No Connection with Gateway cellular device

When the sensor disconnects from the Gateway the sensor will continue to record and store the ECG data (6 hours).

In case the disconnection period is longer than the maximum recording time, the sensor will store the LAST time period (6 hours) of the disconnection period.

5 USING THE ECG MINI

5.1 Before Starting

- Make sure you have all items needed to initiate the service:
  - ECG Mini patch (single use, disposable)
  - ECG Mini Brain (reusable)
  - ECG Mini Gateway cellular device with compatible application installed (reusable)

	**Note** Contact LifeWatch to receive instructions on using the system for the first time as shown in “First Time Activation”, section.

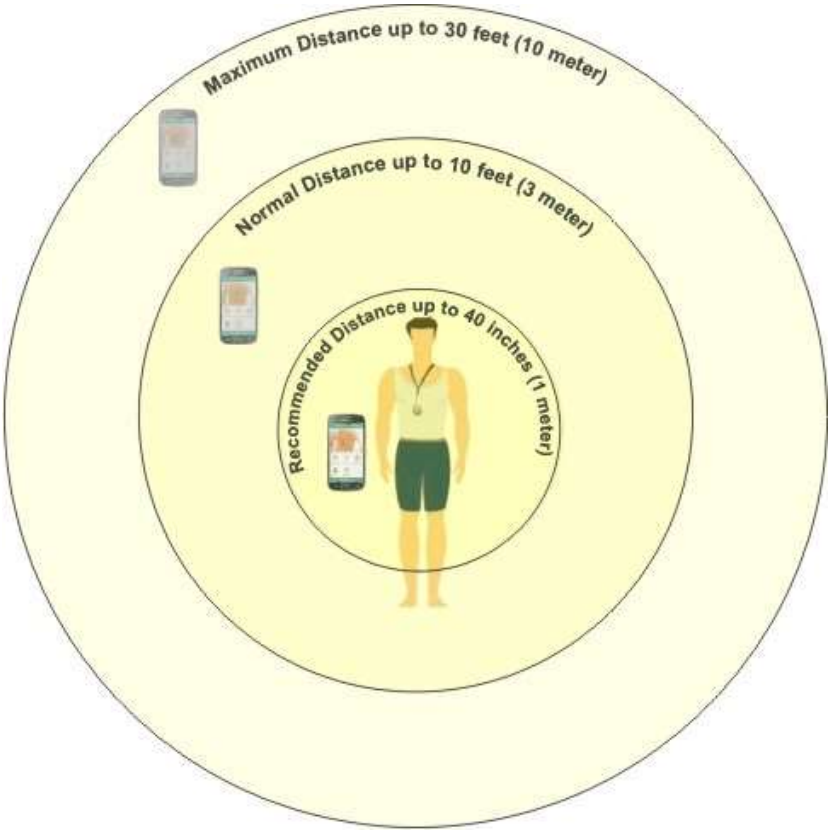
5.1.1 Placement of Gateway cellular device

For optimal system performance, the recommended distances between the Gateway and sensor should be as follows:

Within 40 inches (1 meter) for normal operation

Within 10 feet (3 meters) preferred distance

Within 30 feet (10 meters) maximum distance



5.2 Recharging the Gateway cellular device

Charge the Gateway whenever possible during the day. In addition, charge the monitor every night (regardless of battery indicator status).

1. Plug the Gateway charger power cord into the power socket on the Gateway.

Power/USB connector

2. Plug the supplied Gateway charger unit into a standard wall outlet. A red or yellow light (color depends on Gateway type) indicating charging is needed will appear on the Gateway when the charger is properly connected. When charging is complete, the light will turn green.
3. Disconnect the Gateway charger from the wall outlet and then from the Gateway.

	**Note** The Gateway battery energy consumption in the first few days (up to 72 hours) of monitoring may be high. Always have a charged Gateway and the charger with you during this time.

6 ATTACHING THE ECG MINI PATCH

6.1 General

A qualified physician or healthcare professional is responsible for guiding placement of the ECG Mini patch on the patient.

6.2 Initializing the ECG Mini kit

The Gateway application and Brain of the ECG Mini kit are pre-configured; the Gateway application will start running automatically after the Gateway cellular device is turned on.

6.3 Placing the Patch

Before attaching the Patch, prepare the chest skin as set out below.

6.3.1 Preparing the Skin

1. Remove excess hair from the areas by carefully clipping with scissors. Avoid shaving in order to minimize irritation.
2. Clean the skin on the upper part of the chest using a lint-free cloth lightly moistened with isopropyl alcohol (70%).

Figure 2 - Area to prepare for ECG Mini Patch

3. Make sure that the skin is clean and fully dry (wait 1 minute) before proceeding.
4. Do not apply the patch to skin that is broken or irritated.

	Note: There are conditions that may affect the Gateway from detecting the electrode connection for a certain period of time. Even though the sensors seem to be in good contact with the body, the alert message will continue to appear. Some examples that can cause delayed electrode recognition are very dry skin or contact immediately after attaching the electrodes. **Contact LifeWatch if you have any questions concerning the use of the device or if you experience any irritation problems.**

6.3.2 Placing the Patch

1. Remove the protective liner from the patch contact side.
2. Place the ECG Mini patch on the cleaned area of the chest as shown in the diagram below.

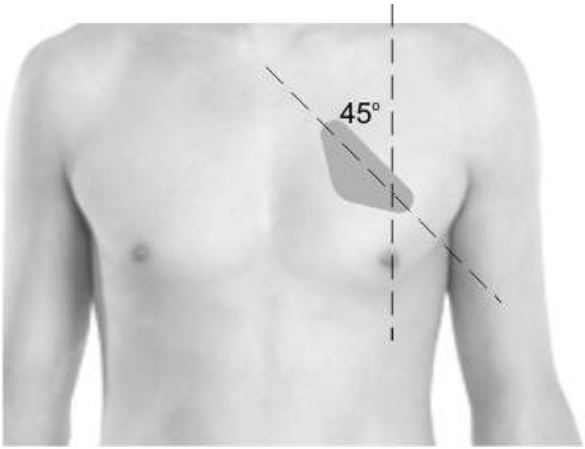


Figure 3 – ECG Mini Patch Placement

3. Patch should be pressed gently with the fingers around the patch edge for best adherence.

Figure 4 – ECG Mini Patch Properly Placed

6.4 Installing the ECG Mini Transmitter

To install the ECG Mini Transmitter

1. Position the ECG Mini Transmitter in the cradle with the inscription facing upwards.
2. Push gently on the ECG Mini Transmitter to ensure good contact with the contacts. If the ECG Mini Transmitter is correctly installed the GW will start to receive signals from the sensor (ECG Mini Transmitter in patch ON, removal of ECG Mini Transmitter OFF).

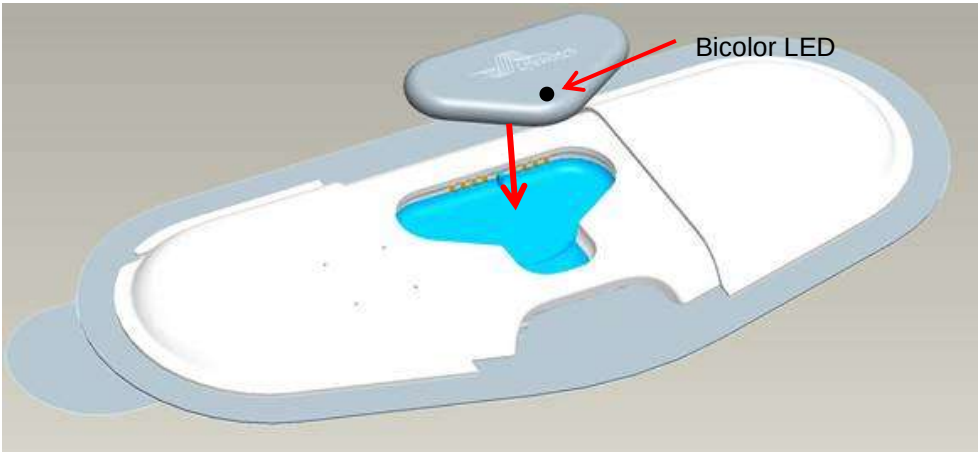


Figure 5 - Placing ECG Mini Transmitter into Cradle

Note: *Ensure that the ECG Mini Transmitter is positioned properly with the correct side up before pushing it into place. A Green LED will flicker when the ECG Mini Transmitter is placed properly.*

Precaution: Using excessive force when putting the ECG Mini Transmitter in the cradle can cause the pins to bend, preventing the ECG Mini Transmitter from being inserted or removed.

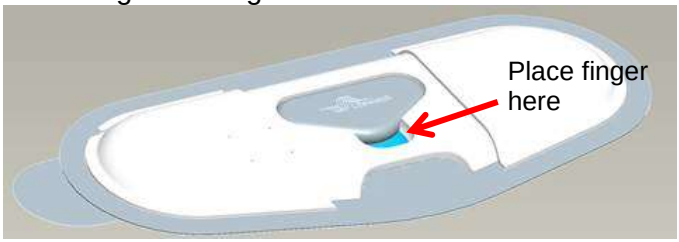
6.5 Removing the ECG Mini

- Peel the Patch contact pad from the skin.

Note: If it is difficult to remove the Patch, use warm water to weaken the adhesive.

To remove the ECG Mini Transmitter

1. Place finger in the groove in front of the ECG Mini Transmitter.



2. Gently pull-up the ECG Mini Transmitter to remove from the cradle.
3. Place the transmitter and patch in the envelope to return to LifeWatch.

If necessary to continue the monitoring, replace the patch and insert the Transmitter.

WARNING
The Patch is for single use only. Return it to LifeWatch Services for disposal.

WARNING

Dispose the battery in a disposal unit that meets WEEE requirements.

7 USING THE GATEWAY APPLICATION

7.1 Starting the Application

To start the Gateway application

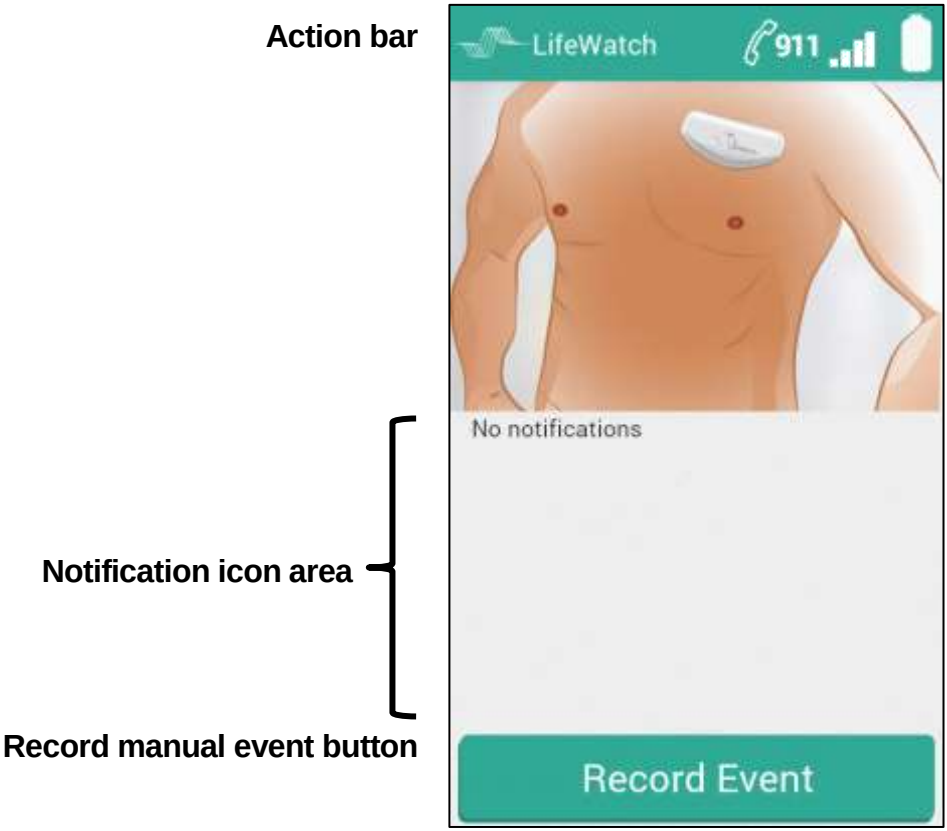
- Press the power ON button on the Gateway to start the application. The application is automatically launched and the will display the opening screen before the main application screen.

Press OK to proceed to the main screen.

Note: *The maximum unblocked distance between the ECG Mini Transmitter and the Gateway is 10 meters (30 ft.); walls and other obstructions will reduce this distance.*

7.2 ECG Mini Screen

The ECG Mini main screen comprises the following items:



7.2.1 Action Bar

1 - Logo Image

2 - Screen Title

3 - Active Alert — Notification, only shown if there is an active alert that doesn't appear on the main screen.

4 - 911 emergency call — Pressing will open a dialog box:

Press Yes to automatically dial 911.

5 - Signal strength — Indicates cellular communication status

6 - Battery status — Charge level of Gateway battery

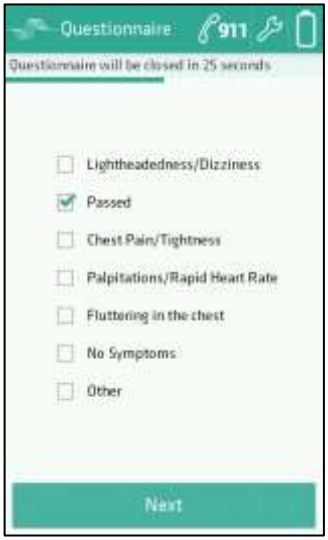
7.2.2 Manual Event Recording

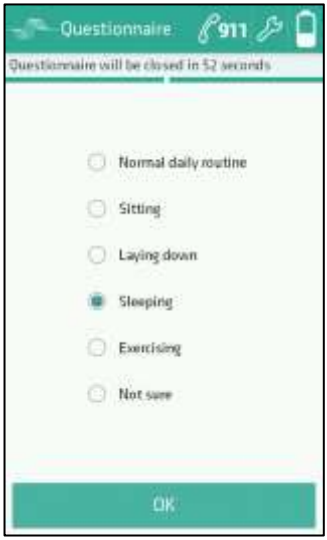
A manual event can be started by pressing the Record Event on the bottom of the touch screen.

When a manual event is initiated on the touch screen, then a confirmation screen will be displayed.

Confirm or cancel the event by pressing on the touch screen.

The questionnaire screens are for adding information on symptoms and activity.





Enter details, press on Next, enter details on second form and then press OK on touch screen to send the manual event.

7.3 Gateway Notifications

Outside of displaying the normal operation the application displays alerts with information concerning the type of alert.

7.3.1 ECG Mini Notification Screen

The ECG Mini main screen displays a notification and is indicated by either the patch turning red and/or the appropriate icon appearing.

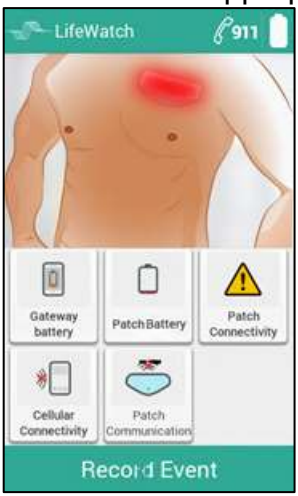


Figure 6 – ECG Mini notification screen with notifications

An error initiates one of two types of alerts – one for the ECG Mini Patch/Transmitter and one for the Gateway. Press the alert icon to open an information box describing what steps to take.
An alert will continue as long as the error exists.
Any errors occurring during an initial alert will be indicated as well.

Follow the accompanying message instructions.

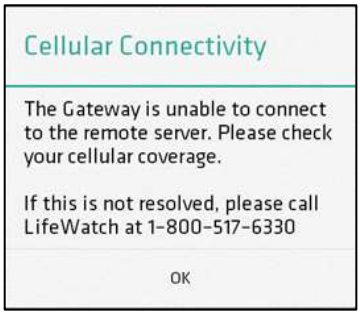
7.3.1.1 Patch Error Alerts

When the icon of a patch is red this indicates either:

Icon	Message
Brain Battery Depleted Press 	
Brain disconnected Press 	
Electrodes Disconnected Press 	

7.3.1.2 Gateway Error Alerts

A Gateway error triggers the following alerts:

Icon	Message
Charge Gateway Press 	
Cellular Connectivity Press 	

NOTE:
If the Gateway is not charged after the first message of low battery or the Gateway was not charged properly, reaching the depletion limit will end monitoring and require charging before continuing.

Once an error has been corrected, the alert stops and the main screen is displayed.

8 HEART RATE CALCULATION METHOD

8.1 Introduction

This section describes the Heart Rate (HR) calculation within the ECG Mini. HR is defined as the number of heart beats during a GIVEN TIME INTERVAL (usually one minute). It is reported by the algorithm each time a QRS complex is detected.

8.2 Method of Calculation

The momentary HR is the inverse of the time lasting between two consecutive heart beats. As the momentary HR fluctuates due to inaccuracies in detecting the exact R wave timing eight momentary HR values are averaged to generate the displayed HR. Therefore the reported HR is the mean of the last momentary HR values WHICH CORRESPOND TO THE DETECTED R COMPLEXES FOR THE LAST 8 SECONDS.

OCCASIONS IN WHICH THE HR IS NOT REPORTED: If during a specific QRS complex the signal is considered as too low to be considered accurate or is considered as noise, the displayed HR will be 0.

9 PAUSE CALCULATION

Pause is considered a lack of Ventricular activity for more than 3 seconds. In order to detect a pause one of two conditions needs to be detected:

1. Lack of QRS detection for more than 3 seconds
2. A flat signal (P complexes can occur) for slightly less than 3 seconds.

Once one of the above conditions is detected a pause event is called.

10 CARE

10.1 Conditions of Use

The ECG Mini conforms to international regulations insofar as it is used under normal conditions and in accordance with the instructions below.

10.2 Cleaning

	A trained and certified technician is responsible for maintaining and cleaning the reusable parts of the ECG Mini System.

If for any reason the ECG Mini gateway needs to be cleaned, clean parts by rubbing with a lint-free cloth.

10.3 Environmental Considerations

The battery and electronics of the ECG Mini are covered by the European Directive 2012/19/EC (WEEE) or by other local/national environmental regulations.

All electrical and electronic products will be disposed of separately from the municipal waste stream via designated collection facilities appointed by the government or the local authorities.

The ECG Mini is returned to LifeWatch as per their instructions. Correct disposal will help prevent potential negative consequences for the environment and human health.

11 TROUBLESHOOTING

Problem	Possible Cause(s)	Solution
ECG Mini gateway displays contact ECG sensor failure. 	Patch is loose or detached. Patch contact area not clean; skin is oily or with excessive hair.	1) Make sure Patch is correctly placed. 2) Restart Gateway.
Data not transmitted to the Gateway. 	Disconnected RF channel between ECG Mini Transmitter and Gateway.	1) Make sure the ECG Mini Transmitter closer to the Gateway (Gateway has a range of 10 meters). 3) Restart gateway. 4) Remove and replace Transmitter.
No display when Gateway is activated.	The battery is very low or depleted.	Connect the Gateway to charger to charge the battery. When charged press power ON/OFF.
Removing patch.	Need to release adhesive	Soak the area with warm water.
Gateway communication 	Error communicating with back-end	Check cellular coverage for your area. Check the cellular coverage icon for the cellular status.

If you are experiencing a critical error not included in this table, restart any running applications and then disconnect and reconnect the ECG Mini Transmitter. If the critical error is not resolved, contact LifeWatch Customer Service.

12 MAINTENANCE

12.1 Conditions of Use

Your ECG Mini system conforms to international standards as long as it is used under normal conditions and in accordance with the following instructions.

12.2 Caring for your ECG Mini

CAUTION

- Do not open or attempt to repair the patch or Gateway yourself. Only authorized service personnel may repair the product.
- Do not drop your patch or Gateway or subject them to severe impact.
- Do not use solvents to clean your ECG Mini sensor or Gateway.
- Do not spray perfume or other substances on the ECG Mini components.
- Do not bathe or swim with the ECG Mini components. Keep the Gateway out of the bathroom when showering or bathing.

12.3 Preventive Maintenance

The following simple preventive maintenance tasks should be performed monthly to ensure continued performance of the device at maximum capacity, and to reduce the possibility of a failure.

12.3.1 Mechanical Inspection

Check for splits, cracks or other related flaws in the ECG Mini components. If you have any questions or doubts, call LifeWatch.

12.3.2 Cleaning

To clean the outside of the Gateway cellular device use a lint-free cloth lightly.

Never use abrasives such as wire wool or metal polish.

13 TECHNICAL SPECIFICATIONS

Declaration of Conformity

Conformance to Standards – non-clinical testing demonstrated
conformance to voluntary Safety standard
IEC 60601-1: ed. 3.1
and to EMC standard IEC 60601-1-2:2014 Class B
LifeWatch Technologies's Quality System conforms to
ISO-9001:2008, ISO 13485:2003,
and complies with CE MDD requirements
Tested for compliance with FCC 47 CFR Part 15,
subpart B and subpart C

13.1 ECG Mini Technical Specifications

Transmitter Specifications

Parameter	Min	Max	Typical	Units
Input Operating DC voltage	0.9	1.5		V
Average Current consumption			4.5	mA
Peak Current Consumption			50	mA
Brain Dimensions				
Dimensions (max.)	N/A	N/A	38 x 20 x 4 (1.6 x 0.8 x 0.2)	mm (inch)
Net Weight			5 (0.17)	gr. (oz.)

ECG Mini Specifications

Parameter	Min	Max	Typical	Units
Dimensions (max.)				
1L Patch	N/A	N/A	167 x 69 x 5 (7.5 x 2.9 x 0.2)	mm (inches)
Net Weight			29 (1)	gr. (oz.)
Battery type			Zinc Air	
Battery voltage			1.4	V
Battery capacity			1400	mAh
Battery dimensions	N/A	N/A	20x4	mm
Battery life	6	7	Use dependent	Days (dependent upon mode)

Parameter	Min	Max	Typical	Units
ECG Input Impedance	10			MΩ
ECG Input dynamic range	N/A	+/- 5	N/A	mV
ECG ADC sample Rate	250	250	250	Hz
ECG DC offset correction	0	+/-300		mV
ECG HPF Cutoff Frequency	N/A	N/A	131	Hz
ECG System noise	0	30		µV
Operating temperature	10 (50)	45 (113)	N/A	°C (°F)
Environmental Operation humidity	10%	95%		
Environmental atmospheric pressure	70	106		kPA
Transport & storage temperature	10 (50)	32 (89.6)	N/A	°C (°F)
Transport & storage atmospheric pressure	50	106		kPA
Ingress Protection Rating	N/A	N/A	IP54	As per IEC 60529
Shelf life	6 months			

Transmission Specifications – RF Protocol

Parameter	Typical	Units
Operating Frequency	2.4GHz	GHz
Output power	0	dBm

Crystal frequency	16	MHz
Frequency deviation @ 250kbps	±160	kHz
Frequency deviation @ 1Mbps	±160	kHz
Frequency deviation @ 2Mbps	±320	kHz
Non-overlapping channel spacing @ 250kbps/1Mbps	1	MHz
Non-overlapping channel spacing @ 2Mbps	2	MHz

APPENDIX A MONITOR (CELLULAR PHONE) WARNINGS

Using Your Phone near Other Electronic Devices

Most modern electronic equipment is shielded from radio frequency (RF) signals.

However, certain electronic equipment may not be shielded against the RF signals from your wireless phone. Consult the manufacturer to discuss alternatives.

Implantable Medical Devices

A minimum separation of six (6) inches (15 cm) should be maintained between a handheld wireless phone and an implantable medical device, such as a pacemaker, to avoid potential interference with the device.

Persons who have such devices:

- Should ALWAYS keep the phone more than six (6) inches (15 cm) from their implantable medical device when the phone is turned ON;
- Should not carry the phone in a breast pocket;
- Should use the ear opposite the implantable medical device to minimize the potential for interference;
- Should turn the phone OFF immediately if there is any reason to suspect that interference is taking place.
- Should read and follow the directions from the manufacturer of your implantable medical device. If you have any questions about using your wireless phone with such a device, consult your health care provider.

Hearing Aid Compatibility with Mobile Phones

FCC Hearing-Aid Compatibility (HAC) Regulations for Wireless Devices

On July 10, 2003, the U.S. Federal Communications Commission (FCC) Report and Order in WT Docket 01-309 modified the exception of wireless phones under the Hearing Aid Compatibility ECG Mini of 1988 (HAC ECG Mini) to require digital wireless phones be compatible with hearing-aids. The intent of the HAC ECG Mini is to ensure reasonable access to telecommunications services for persons with hearing disabilities.

While some wireless phones are used near some hearing devices (hearing aids and cochlear implants), users may detect a buzzing, humming, or whining noise. Some hearing devices are more immune than others to this interference noise, and phones also vary in the amount of interference they generate.

The wireless telephone industry has developed a rating system for wireless phones, to assist hearing device users find phones that may be compatible with their hearing devices. Not all phones have been rated. Phones that are rated have the rating on their box or a label located on the box.

The ratings are not guarantees. Results will vary depending on the user's hearing device and hearing loss. If your hearing device happens to be vulnerable to interference, you may not be able to use a rated phone successfully. Trying out the phone with your hearing device is the best way to evaluate it for your personal needs.

M-Ratings: Phones rated M3 or M4 meet FCC requirements and are likely to generate less interference to hearing devices than phones that are not labeled. M4 is the better/higher of the two ratings.

T-Ratings: Phones rated T3 or T4 meet FCC requirements and are likely to be more usable with a hearing aid's telecoil than phones that are not rated. T4 is the better/higher of the two ratings.

Hearing devices may also be rated. Your hearing device manufacturer or hearing health professional may help you find this rating. Higher ratings mean that the hearing device is relatively immune to interference noise. The hearing aid and wireless phone

rating values are then added together. A sum of 5 is considered acceptable for normal use. A sum of 6 is considered for best use.

In the above example, if a hearing aid meets the M2 level rating and the wireless phone meets the M3 level rating, the sum of the two values equal M5. This should provide the hearing aid user with “normal usage” while using their hearing aid with the particular wireless phone. “Normal usage” in this context is defined as a signal quality that is acceptable for normal operation.

The M mark is intended to be synonymous with the U mark. The T mark is intended to be synonymous with the UT mark. The M and T marks are recommended by the Alliance for Telecommunications Industries Solutions (ATIS). The U and UT marks are referenced in Section 20.19 of the FCC Rules. The HAC rating and measurement procedure are described in the American National Standards Institute (ANSI) C63.19 standard.

Some digital wireless phones may interfere with some hearing aids. In the event of such interference, you may wish to consult your hearing aid manufacturer to discuss alternatives.

Other Medical Devices

If you use any other personal medical devices, consult the manufacturer of your device to determine if it is adequately shielded from external RF energy. Your physician may be able to assist you in obtaining this information. Switch your phone off in health care facilities when any regulations posted in these areas instruct you to do so. Hospitals or health care facilities may be using equipment that could be sensitive to external RF energy.

Children Using Wireless Phones

The scientific evidence does not show a danger to users of wireless phones, including children and teenagers. If you want to take steps to lower exposure to radio frequency energy (RF), the measures described above would apply to children and teenagers using wireless phones. Reducing the time of wireless phone use and increasing the distance between the user and the RF source will reduce RF exposure.

Some groups sponsored by other national governments have advised that children be discouraged from using wireless phones at all. For example, the government in the United Kingdom distributed leaflets containing such a recommendation in December 2000. They noted that no evidence exists that using a wireless phone causes brain tumors or other ill effects. Their recommendation to limit wireless phone use by children was strictly precautionary; it was not based on scientific evidence that any health hazard exists.

Body-worn Operation

To comply with RF exposure requirements, a minimum separation distance of 0.50 inch (1.5 cm) must be maintained between the user's body and the handset, including the antenna. Third-party belt-clips, holsters, and similar accessories used by this device should not contain any metallic components. Body-worn accessories that do not meet these requirements may not comply with RF exposure requirements and should be avoided.

Use only the supplied or an approved antenna. Unauthorized antennas, modifications, or attachments could impair call quality, damage the phone, or result in violation of regulations. Do not use the phone with a damaged antenna. If a damaged antenna comes into contact with the skin, a minor burn may result. Please contact your local dealer for replacement antenna.

FCC RADIO FREQUENCY INTERFERENCE STATEMENT

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

Consult the dealer or an experienced radio/TV technician for help.

LifeWatch Technologies Ltd. is not responsible for any radio or communication interference caused by using other than specified or recommended cables and battery or by unauthorized changes or modifications to this equipment. Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and

2. This device must accept any interference received, including interference that may cause undesired operation.

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PLEASE CALL

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FOR 24/7 CUSTOMER SUPPORT