



**Instructions for Use (IFU)
for
eWave™**

LBL 0001.F

WearLinq, Inc.
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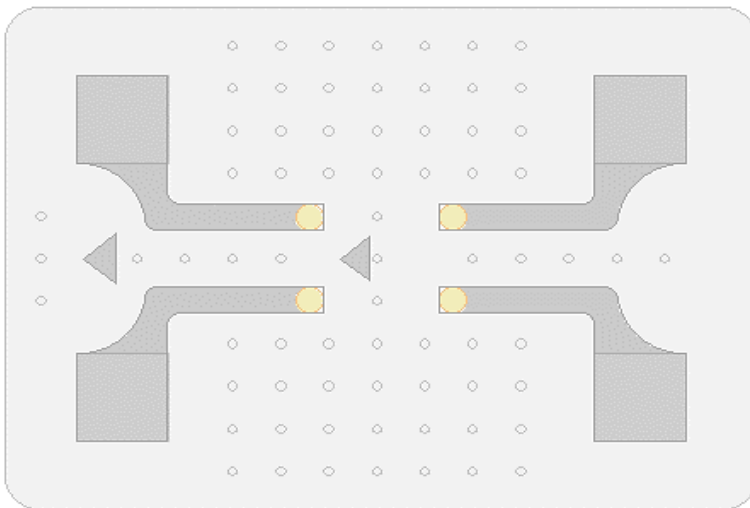
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About the eWave

The eWave is a continuous wearable electrocardiogram (ECG) monitor that collects and transfers your ECG data to WearLinq's databases through your smartphone when paired with the WearLinq app. An ECG signal shows your heart's activity and enables trained health care providers to diagnose abnormal heart rhythms, which is why you were prescribed one.

Guide to Parts

Adhesive Patches



The package includes enough adhesive to get you through your prescribed monitoring period. One of the sides is covered with a protective liner, this side is going to stick to your chest, and the other side has 4 exposed magnets used to attach the eWave transmitter. You'll also find an indicator arrow that should point up when placed on the body. One adhesive patch is intended to last 3 days on average and can be disposed of in regular trash after the wear time. It has been designed with the latest electronics technology to maximize your comfort.

Transmitter



The transmitter sits inside the charging case when you first open the package. It attaches with magnets to the adhesive patch. It has on average 5 days of battery life on one charge and on-device storage for over 24 hours of data for when you're out of range. Otherwise it transmits data to your cell phone throughout the day when the WearLinq app is opened or in the background.



NOTE: The eWave transmitter/app does not summon physicians or emergency assistance. Call 911 if you're experiencing concerning symptoms (for example chest pain).

Charging Case/System



The Charging Case accessory is used to store and recharge the eWave transmitter. It holds on average 7 weeks of charge for the transmitter and can be recharged with the included USB-C cable and wall adapter. The LED indicators are described in the Daily Usage section.



NOTE: Please only use the included power cords to recharge the charging case and only recharge the transmitter with the charging case.

All eWave components and accessories comply with the appropriate IEC and ISO safety standards.

Skin Preparation Kit



The skin preparation kit consists of a regular razor and alcohol pad. It's important to shave and clean the skin where the patch will adhere to ensure good signal quality and wear duration. A guide is available in the Getting Started section.

Getting Started

Charge the Transmitter

1. If this is your first charge, plug the charging case into an outlet with the attached cable since it might not be fully charged.
2. Place the transmitter in the charging case, the magnets will guide you to ensure the correct orientation.
3. Wait for 2 hours to ensure the transmitter is fully charged. Whenever charging is complete the LED on the case will blink green for 3 minutes and shut down afterwards. More details on the LED are included in the Daily Usage / Recharging Section of this document.
4. If you need to also charge the charging case, that can take up to 2:45 to be fully charged. Whenever charging is complete the LED on the case will blink green for 3 minutes and shut down afterwards. More details on the LED are included in the Daily Usage / Recharging Section of this document.

Downloading the app & setting up your account

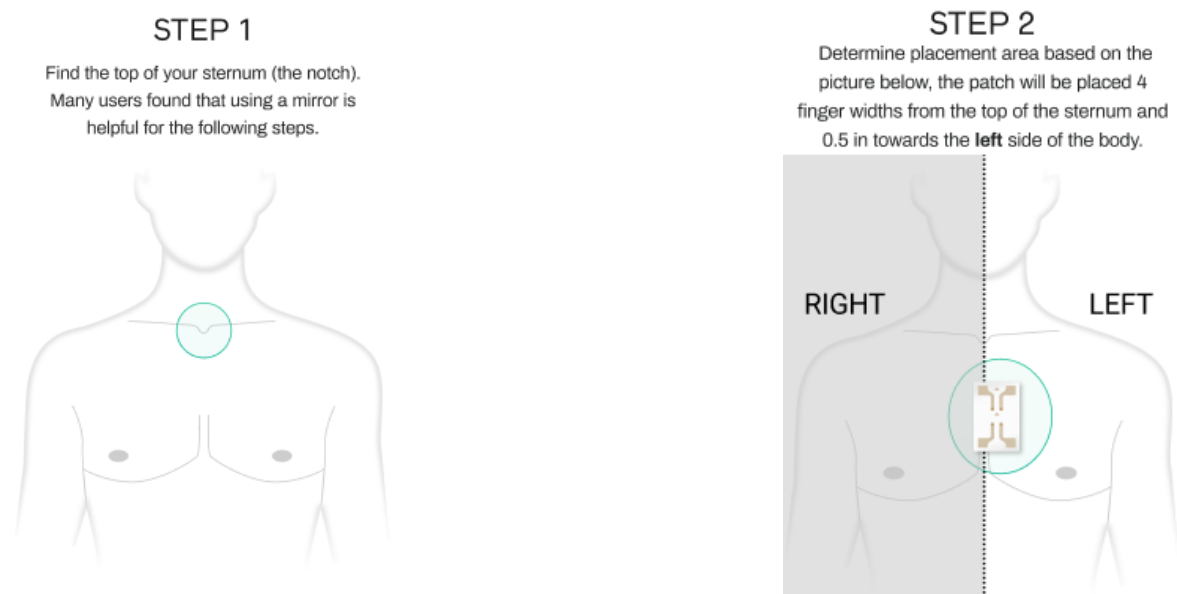


1. Download the WearLinq app from the App Store or Play Store.
2. Ensure that Bluetooth is on in your smartphone settings.
3. Follow the on-screen instructions to create an account.
4. Remove the transmitter from the charging case. Whenever the transmitter is outside of the case it's turned on.
5. The Home Page will have a green button saying "CONNECT MY DEVICE". Click on that and follow the on-screen instruction.
6. The Home Page is where your daily reminders and to-dos will show up. It will also help to guide you through the steps below with more interactive tutorials with pictures.

Skin Preparation, Patch Placement & Transmitter Attachment

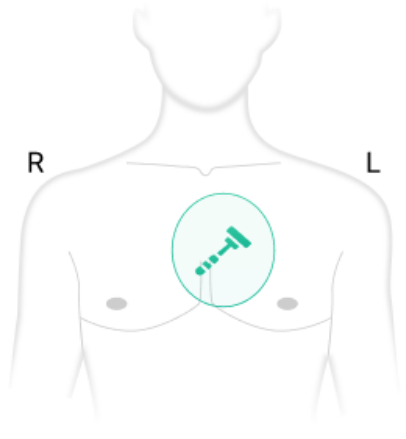
For a better experience, follow the interactive tutorials in the app or watch the video. They're available in Settings -> Help Center and will also show up on your Home screen during the first use. Below are screenshots of those instructions:

Skin Preparation



STEP 3

Please clean & shave this area on your chest, a razor is included. Make sure it's at least slightly larger than the patch. You may use shaving cream if necessary.



STEP 4

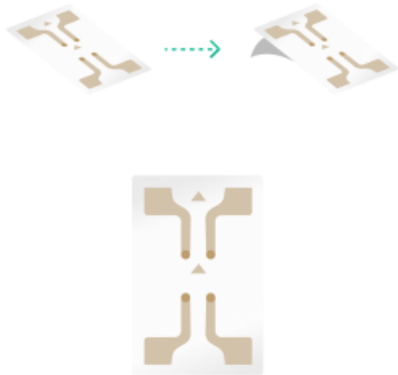
Use the alcohol wipe provided to clean your skin, then dry. Your skin must be completely clean and dry. Do not apply lotions or oils.



Patch Placement

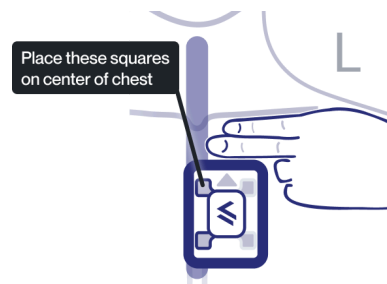
STEP 1

Remove protective paper and make sure the arrows are pointing up as shown.



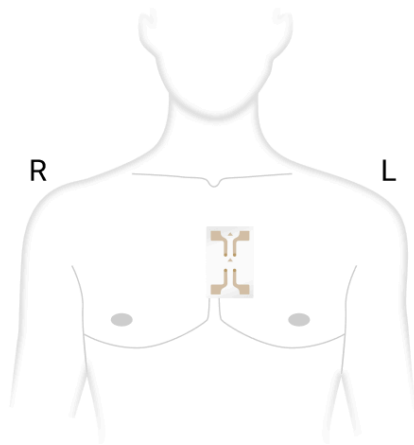
STEP 2

Align the top side of the patch 4 fingerwidths below the top of your sternum and center the right side electrodes on the sternum so the patch is to the **left** of your body (closer your heart).



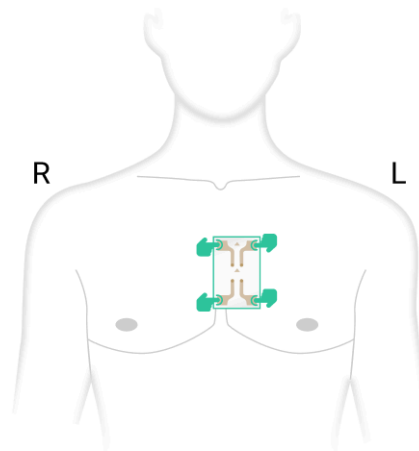
STEP 3

Gently place patch on your chest and make sure it is in the correct position.



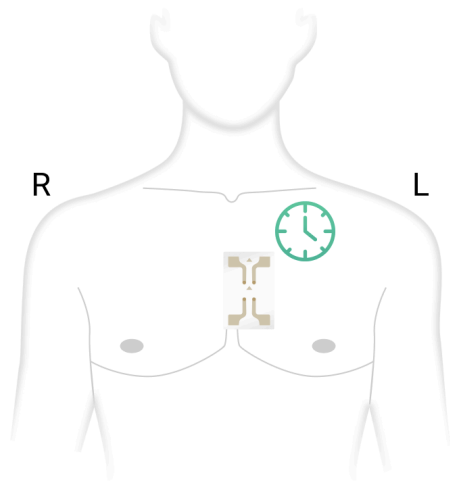
STEP 4

Press down on all 4 sides of the patch so it adheres to your skin.



STEP 5

Avoid exercise or any activities that can cause sweating during the first hour after placing the adhesive patch.

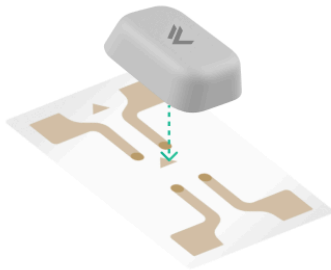


NOTE: The adhesive patch can be at a maximum 0.5in vertical offset from the placement described above for the eWave to maintain effectiveness.

Transmitter Attachment (note: Wipe the patch magnets and the back of the transmitter with an alcohol pad prior to attaching the transmitter.)

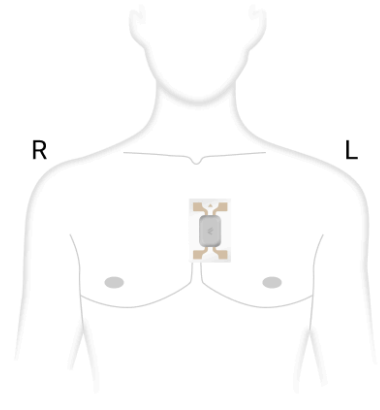
STEP 1

Place the transmitter on the patch. The magnets will only snap on if the transmitter is properly oriented, ensure that all 4 magnets on the patch are covered by the transmitter.



STEP 2

Congratulations, eWave is recording your ECG! The next few tutorials will walk you through daily use of the eWave device and link you to the full instruction manual.



Daily Usage

Uploading Data

The app is automatically downloading and transmitting your data as you go about your day. If data is not getting through, you will get notified by the app. There are only three things you need to keep in mind to ensure all your data gets properly saved and is ready for interpretation:

1. Keep a Wi-Fi connection available on your cellphone as often as possible. The amount of time you can go without a network connection depends on the storage available on your cell phone.
2. DO NOT close the WearLinq app. It's fine if it's running in the background but DO NOT swipe it away from recent apps. DO NOT remove the WearLinq app from your smartphone during your prescribed recording period.
3. Keep your cell phone in the same room as your device for at least 8 hours per day. If your prescription type is MCT please keep your cell phone in the same room as your device at all times for your data to be transmitted to the cloud and monitored. The eWave transmitter has local storage for over 24 hours so you can always catch up on past data if you're out of range.

Recharging / LED Indicators

Approximately every 5 days you'll get a notification to recharge the transmitter. It takes 2:45 for it to fully recharge. The LED indicators on the charging case accessory if **the transmitter is inside the charging case (charging case can be plugged in or not)** mean the following:

- Transmitter fully charged = 3 Minutes of blinking green and then no light
- Transmitter charging = Solid yellow
- Charging case low battery warning = Blinking orange when transmitter is placed inside

And the LED indicators on the charging case accessory if the charging case is plugged in without the transmitter inside mean the following:

- Solid green: Charging case fully charged
- Solid yellow: Charging case is charging
- Charging case low battery warning = Blinking orange when USB cable is connected

Removing the Patch

Prior to removing a patch, please make sure you can do so safely. If you believe the adhesive is too strong in the middle but the edges have fallen off, please use the supplied alcohol pad (or other alcohol-based wipes) to wipe around the edges of the patch as it's being peeled back to continuously dissolve the adhesive.

After removal, cleanse skin with mild soap and water to remove any remaining adhesive. Petroleum jelly or baby oil works as well.

It is normal to have slight redness and odor on your skin after removal. It should disappear after a few days. If redness with itching continues or gets worse, or if you have any concerns about your skin's appearance or condition, contact your Healthcare Provider.



WARNING: If continuous reapplications are causing excessive skin irritation or tenderness, please stop using the eWave device and contact customer service.

Replacing the Patch

The patch will last for 3 days on average after placement. Replace your patch as soon as it starts falling off (any of the corners starts folding) until you've completed your prescribed monitoring period. You'll get notifications from the

WearLinq app to do so. Please refer to the instructions in the app or in the Getting Started section of this document for a placement guide and remember to wipe your skin with an alcohol pad before placing the patch on again. Also, wipe the patch magnets and the back of the transmitter with an alcohol pad before attaching the transmitter to the new patch.

Reporting Symptoms

It's important to keep logging your symptoms for the physician to be able to provide you with the right diagnosis. You can log your symptoms as you experience them or retroactively in the app in the home screen. The app will also remind you to log any symptoms at the end of each day in the home screen. These segments of your data will be marked - there will be extra emphasis on these in the final review by the cardiologist and will help them with symptom/rhythm correlation.



TIP: You can double-tap on the transmitter to mark a time for later review. When you open the app the next time, you will be reminded to input the symptoms you felt at that time.

Exercising, Sweat & Signal Disturbance

Please avoid exercise or any activities that can cause sweating during the first day after placing the adhesive patch. This ensures it will last as long as possible. Otherwise you're free to exercise as recommended by your prescribing physician. Heavy exercise can lead to the adhesive patch falling off early due to sweat. In that case, just follow the replacement steps above.

During movements with quick acceleration, flexing of the chest muscles, or pressure applied to the transmitter that may happen during exercise, the eWave may record a temporary disturbance in the ECG signal. These disturbances caused by exercise are short lived.

Showering, Bathing & Swimming

Remove the transmitter from the adhesive patch when you shower, bathe, or swim. The transmitter is not waterproof, but the adhesive patch is. Wearing the adhesive patch during bathing or swimming may reduce the wear time. In that case, follow the replacement instructions.

1. Remove the transmitter from the adhesive patch and place the transmitter into the charging case.

2. When you are ready to put the transmitter back on, dry off your skin and the electrode patch completely, including the magnetic connector on the adhesive patch.
3. Snap the transmitter to the adhesive patch via the magnetic connector.

Traveling on Aircraft

eWave is safe to wear while traveling on aircraft, but its performance has not been verified in aircraft environments. WearLinq therefore recommends temporarily removing the eWave transmitter and storing it in the charging case while in aircraft environments.

Undergoing an MRI

Warning: MR-unsafe! Do not expose the device to a magnetic resonance (MR) environment since it contains magnetic and metal pieces. Please temporarily detach the adhesive patch and transmitter.



The device may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core.

Thermal injury and burns may occur due to the metal components of the device that can heat during MR scanning.

The device may generate artifacts in the MR image.

The device may not function properly due to the strong magnetic and radiofrequency fields generated by the MR scanner.

Indications for Use

The eWave monitor is an ambulatory ECG monitor intended to provide continuous extended duration cardiac monitoring. It is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, lightheadedness, pre-syncope, syncope, fatigue, or anxiety.

Contraindications

The eWave device has not been tested for and is not intended for pediatric use (younger than 18 years old).

Warnings

Patients with potentially life-threatening arrhythmias who require inpatient Monitoring.

Portable and mobile wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, computers with wireless internet, and Bluetooth connected devices can affect the eWave and should be kept at least a distance of 30 centimeters (12 inches) away from the equipment. Position the eWave away from other electrical or electronic equipment, if possible. The presence of strong EMI fields, or electronic, surgical, or diathermy instruments in close proximity to the ECG device may cause trace noise or input overload conditions. The ECG device is compliant with IEC 60601-1-2 EMC immunity requirements

Do not use the eWave patch on patients with known allergic reaction to adhesives or hydrogels or with family history of adhesive skin allergies. Patients may experience skin irritation.

Do not reuse the eWave on multiple patients during a single prescription period. Reuse will cause incorrect patient data and patients may experience cross contamination.

DO NOT use the eWave to self-diagnose heart related conditions. Consult with your physician before making any medical decision, including altering your use of any drug or treatment.

Keep the device away from young children. Contents may be harmful if swallowed. The transmitter contains batteries that are not accessible during normal use but, if exposed, are known choking hazards and may cause severe tissue injury if ingested.

DO temporarily remove the device while exposed to a magnetic resonance (MR) environment.

DO NOT use the device with a cardiac pacemaker, ICDs, or other implanted electronic devices.

DO NOT use the device adjacent to or stacked with other equipment because it could result in improper operation.

DO NOT use portable RF communications equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 inches) to any part of the eWave. Otherwise, degradation of the performance of the eWave could result.

Temporarily take off and store the eWave transmitter in the charging case while in aircraft environments.

May interfere with defibrillation therapy. To avoid ineffective defibrillation therapy, remove the eWave and patch before applying any external cardiac defibrillators.

This device is solely intended for manual interpretation of the recorded ECG.

Precautions

Do not keep the eWave transmitter or your cell phone within 10 cm of a Wi-Fi router.

Apply the adhesive patches only to intact, clean skin. Do not apply over open wounds, lesions, infected or inflamed areas.

Do not use lotions, oils or sprays on the skin location where you will apply the adhesive patch.

Do not use the eWave if the casing is broken or damaged.

Do not disassemble the eWave.

United States federal law restricts the device to sale by or on the order of a licensed practitioner or therapist.

Safety and effectiveness of the eWave on patients receiving any form of pacing therapy has not been established. Paced cardiac rhythms may not be accurately detected and may be incorrectly classified.

Safety and effectiveness of the eWave on pediatric patients (younger than 18 years old) has not been established.

The eWave system includes temperature and humidity limitations when stored/transported. If exposed during storage/transport, patients may experience degradation of adhesive performance causing the patch to slip or fall off during the patient wear duration. In that case, just apply a new patch.

The adhesive patches and transmitter have a shelf-life date. Use of expired devices may cause a degradation of ECG signal quality and/or low battery condition. The lot number and expiry date for the patches can be found on the pouch they arrive in.

Specifications

Device Type	
Type of ECG Monitor	Single User, continuous recording multi-channel ECG Monitor, with replaceable disposable non-sterile patch electrodes
RX/ OTC	RX. Use by prescription only
Recording Standard Type	2 channel ambulatory monitor
Number of Electrodes	4 electrodes
Wear Time	Prescribed for 7 days at the discretion of the physician
Performance Characteristics	
ECG recorded channels	2 physical ECG channels, 4 calculated channels spanning the same plane as the recorded channels.
Recording capacity	Up to 24 hours without app connection, practically infinite with app and internet connection to cloud storage.
Recording format	Continuous
Service Life	2 years for device; minimum of 2 days per replaceable electrode patch
Shelf Life	2 years for device; 1 year for sensor electrode patch
Electrical Input Characteristics	
ECG Bandwidth	0.1 Hz to 54 Hz
Differential range	+/- 400mV
A/D sampling frequency & Rate	260.4 Hz 3.84 ms
Input Impedance	500 Mohms
Resolution	24-bit
Power Requirements	
Battery type	Lithium Polymer battery with a capacity of 110mAh in the transmitter and 800 mAh in the charging case
Charging time	2:45 – Charging Case 2 hours - Transmitter
Physical Characteristics	
Dimensions	36 mm x 27 mm x 8 mm
Weight	8g
Enclosure material	ABS
Flammability rating	HB-UL94
Classification	
Type of protection	Internal power
Degree of protection	Type BF applied part
Protection against objects and water ingress	IP65 water resistance
Electrode Characteristics	
number of electrodes	1 multi electrode patch (4 hydrogel/Ag/AgCl electrodes)
Type	Patch Electrode incorporates electrodes, hydrogel, and internal lead wire
Supplied as	Disposable, non-sterile single use
Lead wire	Electrodes are embedded in the patch. No patient electrical contact with lead wires from electrode to device ECG inputs.
Materials	Biocompatible hydrocolloid adhesive and adhesive hydrogel
Anatomical site	Sternum
Environmental Specifications	
Operating temperature	50°F to 113°F (10°C to 45°C)
Operating Pressure	700 to 1060 hPa
Operating humidity	10% to 95% (non-condensing)
Transport temperature	32°F to 104°F 0°C to 40°C)
Storage temperature	32°F to 104°F (0°C to 40°C)

Transport/Storage humidity	10% to 95% (non-condensing)
Transport/ Storage altitude	500 to 1060 hPa
Safety Standards Compliance	
Electrical Safety	IEC 60601-1 Basic Electrical Safety
	Applicable sections of IEC 60601-1, 60601-1-2, 60601-1-11, Safety & Essential Performance IEC 60601-2-47
Biological Safety	ISO 10933-5, 10993-10.
ECG Data Transfer method	
ECG Data Transfer method	Wireless transfers: BLE used from eWave to App, then automatic to qualified cloud storage. One device works with one account. Real-time display of ECG trace only available in the WearLinq app.

Mobile App Compatibility

The WearLinq app is compatible with iPhones running iOS 15 or higher and the specific Android phones and OS versions listed below:

- Samsung A10E running Android OS 11 or higher
- Rhino C6 Enterprise Android Phone running Android OS 11 or higher

Maintenance

No service or repair should be performed on the eWave transmitter or charging case. The adhesive patches are disposable.

Software Updates

Occasionally, we'll be releasing updates to the app. It's important that you update the app to ensure the security of your data. Updates will be pushed through the App Store or Play Store.

Updates for your eWave transmitter will automatically be performed through the WearLinq app – there's no action needed by you but you'll be notified when an update is being installed on the transmitter.

Cybersecurity Events

If there are any cybersecurity events (such as suspicious activity on your account), WearLinq will reach out to you over email with details. There is no interaction required from you unless prompted by WearLinq.

Electromagnetic & Other Interferences

eWave has been tested and deemed in conformance with the relevant requirements in IEC 60601-1 -2 for Electromagnetic Compatibility (EMC).

FCC Compliance

FCC ID: 2AA9B05

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.

CAUTION: Changes or modifications not expressly approved by WearLinq could void your authority to use this equipment.

Ingress Protection Marking

The eWave transmitter is IP65 rated. The eWave transmitter is fully protected against dust ingress and is protected against low pressure water jets from any direction. The eWave transmitter has been tested with relevant requirement standard IEC 60601-1-11:2015. The charging case is not rated and should not be in contact with water.

Troubleshooting

If you're experiencing any technical issues or need help with setup you can reach us by phone at +1 (800) 785 4354 or by email at support@wearlinq.com

Electrical Safety and Electromagnetic Compatibility





Guidance and manufacturer's declaration - electromagnetic emissions		
eWave is intended for use in the electromagnetic environment specified below. The customer or the user of eWave should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	eWave L is intended for use in domestic surroundings.
Harmonic emissions IEC 61000-3-2	N/A	eWave is powered from a lithium ion battery and does not require AC mains power.
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

Immunity test	Compliance	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	IEC 60601-1-2 Test level	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated EM field immunity and Proximity fields from RF wireless communications EQUIPMENT IEC 61000-4-3	IEC 60601-1-2 Test level	Portable and mobile RF communications equipment is recommended to be used no closer to any part of the eWave transmitter than 1m
Proximity magnetic fields Immunity IEC 61000-4-39	IEC 60601-1-2 Test level	Portable and mobile RF communications equipment is recommended to be used no closer to any part of the eWave transmitter than 1m

The Essential Performance for the eWave is:

- The eWave shall maintain integrity of the recorded, stored, and transferred ECG data across all trust boundaries [if affected by EM disturbances the user/operator can expect a delay of use of the device]
- The electrode spacing of the eWave shall be sufficient to produce ECG data equivalent to Holter ECG data for rhythm assessment [not affected by EM disturbances]

Equipment Symbols

	<p>Type BF applied part; denotes device is not in direct contact with cardiac muscle.</p>
	<p>The electromagnetic radiation from the device is below the limits specified by the Federal Communications Commission and the manufacturer has followed the requirements of the Supplier's Declaration of Conformity authorization procedures</p>
	<p>Refer to instruction manual.</p>
	<p>Do not dispose of in trash</p>
<p>IP22</p>	<p>Protected against insertion of fingers and is not affected by vertically dripping water.</p>
<p>SN</p>	<p>Series number</p>
<p>PN</p>	<p>Product number</p>

Contains FCC ID: 2AA9B05