

Instructions for Use

Before You Begin

LifeLens Wireless ECG Monitor:

LifeLens Wireless ECG Monitor is an ultra-miniature, wireless, health monitor. It records your ECG, or heart rhythm, throughout the day without interfering with your regular activities. When prescribed or used under the care of a healthcare professional, it can be used to help diagnose and manage cardiac conditions.

Intended Use:

LifeLens Wireless ECG Monitor is intended to obtain an ECG from patients in a non-emergency or home setting. LifeLens Wireless ECG Monitor does not provide interpretative statements. Only a U.S. board-certified cardiologist can provide a medical interpretation of your data.

Intended Users:

Patients requiring an ECG, nurses, cardiologists and physicians.

Indications for Use:

LifeLens Wireless ECG Monitor is indicated for use with patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety. The LifeLens Wireless ECG Monitor is intended for use by adults and all pediatric subgroups.



LifeLens Wireless ECG Monitor is not an emergency response service and may not diagnose your condition in real-time. Contact your doctor immediately if your symptoms worsen.

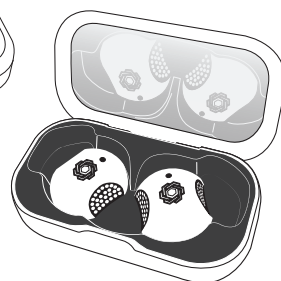
If You are Experiencing a Medical Emergency, Dial 911

LifeLens Wireless ECG Monitor Kit Components

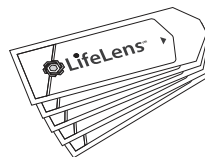
Gateway-Recharger
Carrying case and recharging dock



2 HUBs
Reusable sensor hardware units; used one at a time



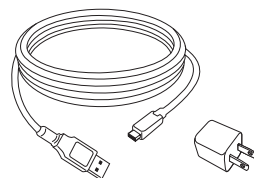
5 Patches
Single-use only, disposable patches



For technical specifications and more information, please visit <https://lifelenstech.com/specifications>

LifeLens Accessory Pack

USB Cable and Power Adapter



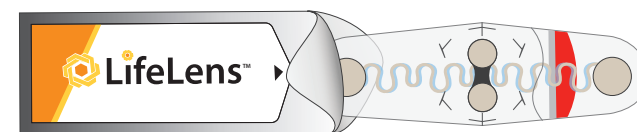
5 Alcohol Pads



Storage Instructions

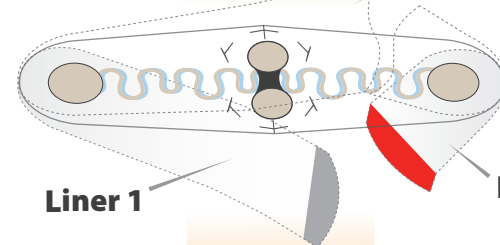
Your Gateway-Recharger is the perfect place for storing your HUBs. Keep your LifeLens Wireless ECG Monitor Kit and its components at room temperature and in a dry area.

The LifeLens PATCH



Top side of PATCH sticks to the HUB

Liner 3

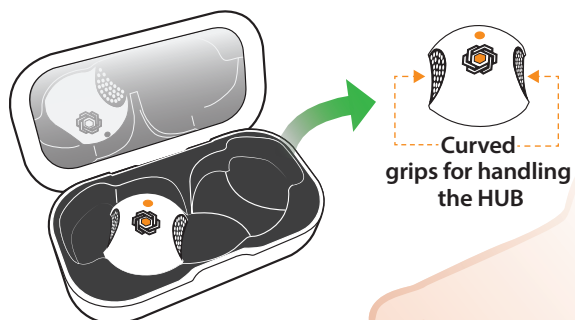


Liner 1

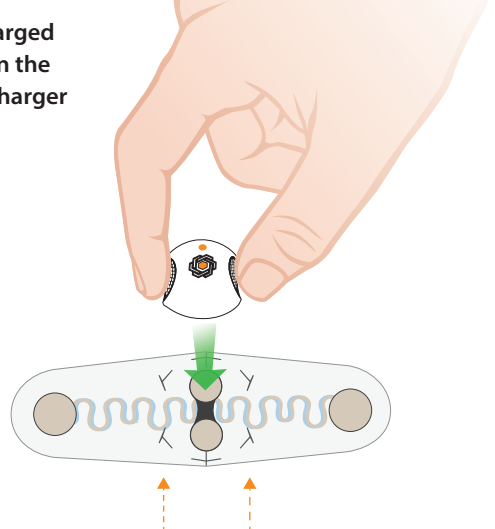
Liner 2

Bottom side of PATCH sticks to the chest surface

The LifeLens Gateway-Recharger & HUBs



HUBs are charged and stored in the Gateway-Recharger



HUB aligns with markings on PATCH

Step 1 | Power up the Gateway-Recharger & HUBs

- 1 Make sure the 2 HUBs are sitting in their charging dock in the Gateway-Recharger.
- 2 Connect the provided USB cable into the Gateway-Recharger and plug the adapter to a power supply. The light on the Gateway-Recharger will glow **BLUE**.
- 3 The Gateway-Recharger will automatically power up and charge the HUBs stored inside. Once the HUBs are fully charged, the light on the Gateway-Recharger will turn **GREEN**.

The HUBs are now ready for use.

LED Light Indications

Gateway-Recharger Light Indications

GREEN | Case is fully charged and ready for use*
YELLOW | Case needs to be recharged
BLUE | Case is being recharged

HUB Light Indications

GREEN | HUBs are fully charged and ready for use
YELLOW | HUBs need to be recharged
BLUE | HUB is being recharged

* LED indications will only be present when Gateway-Recharger is open.
If no LED indicators are visible on HUB(s) and/or Gateway-Recharger when recharging, please discontinue use and contact prescribing health care provider.

To recharge your Gateway-Recharger & HUBs repeat Step 1: 1 through 3

Step 2 | Prepare Your Skin

- 1 Identify the area of your chest to prepare for PATCH placement
- 2 Remove/Shave any hair where you will place the PATCH.
- 3 Wipe the desired area with an alcohol pad.
- 4 Dry the area completely.
- 5 DO NOT Apply lotions, oils, or perfumes.

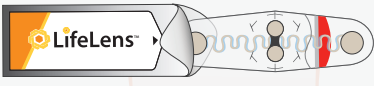
Clavicle (collarbone)
Sternum
Xiphoid process

Area for PATCH placement

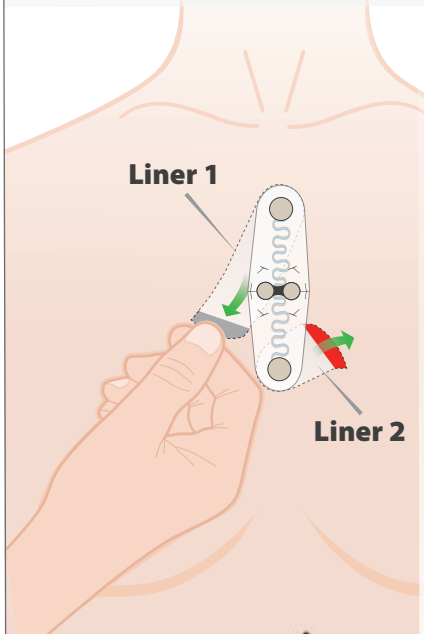
Alcohol Pad

The PATCH should be positioned vertically, in the central part of the chest, along the sternum between the clavicle and the xiphoid process

Step 3 | Applying the LifeLens PATCH



- 1 **Take the PATCH out of its packaging.**
 - 2 **Remove liner 1 from the bottom side of the PATCH**
Apply the sticky side of the PATCH onto your prepared skin.
Gently press the PATCH to your skin for 3 seconds.
 - 3 **Remove liner 2 from the bottom side of the PATCH**
Gently press the sticky side to your skin for 3 seconds.
- The Gateway-Recharger has a mirror you can use to help you apply the PATCH and HUB.

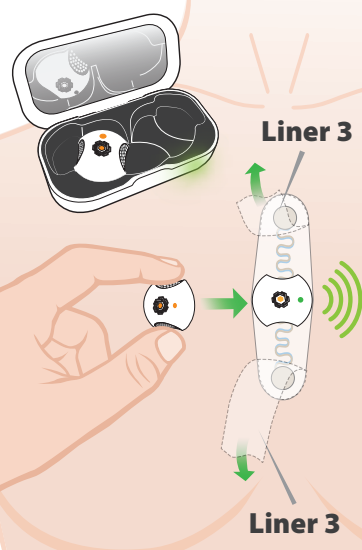


CAUTION

If the PATCH becomes ripped, twisted, crumpled, wrinkled, folded, bent, contaminated, loses adhesion or otherwise damaged, you will need to replace it with a new PATCH.
Repeat Step 3: 1 through 3 to apply a new PATCH.

Step 4 | Applying & using the LifeLens HUB

Keep the Gateway-Recharger within 3 feet of the HUB whenever possible to ensure accurate data transmission.



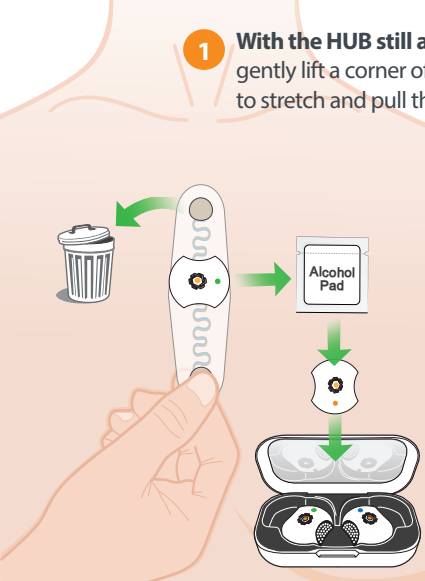
- 1 **Remove liner 3 from the topside of PATCH.** This exposes the HUB connection point.
- 2 **Open the Gateway-Recharger and take out ONE charged HUB. (Light is GREEN)**
- 3 **Align the HUB with the markings on the PATCH.** The curved grips of the HUB should be at 90 degrees to the length of the PATCH.
- 4 **Gently press the HUB onto the PATCH.** The HUB will stick to the PATCH.
- 5 **The HUB will blink GREEN for 30 seconds to indicate that the recording is started.**
The HUB is now recording.

CAUTION If you are replacing a HUB you have already used

If you are replacing a HUB you have already used, follow **Step 6: Removing the LifeLens PATCH and HUB**, before applying a new PATCH and HUB.

Step 5 | Removing the LifeLens PATCH & HUB

DO NOT pull the HUB to remove the LifeLens PATCH



- 1 **With the HUB still attached to the PATCH,** gently lift a corner of the PATCH, and proceed to stretch and pull the PATCH and HUB off your skin.
- 2 **Once you have removed the PATCH from your chest,** gently pull the HUB off of the PATCH.
- 3 **Throw the PATCH in the garbage.**
- 4 **Wipe the HUB with an alcohol pad.**
- 5 **Once the HUB is dry,** place it in its dock in the Gateway-Recharger.

Your LifeLens device continuously records your heart's activity

You may continue the recording by changing the PATCH and the HUB for a new PATCH and HUB. Or you may discontinue the recording by removing the PATCH and the HUB.
Your physician will advise you on how long you should use LifeLens Wireless ECG Monitor.

Step 6 | Daily Life

LifeLens Wireless ECG Monitor has is designed to not interfere with your daily activities. You may exercise and shower the way you normally would. Keep the Gateway-Recharger within 3 feet of the HUB whenever possible to ensure accurate data transmission.

Continuing Your Heart Recording

- 1 Remove your PATCH and HUB. Follow Step 5 for instructions on how to remove the PATCH and HUB.
- 2 Your HUB should be replaced whenever it flashes **YELLOW**, or when the battery's charge runs out. Immediately replace your HUB by following Step 4.
- 3 Your PATCH should be replaced every time you replace your HUB. Immediately replace your PATCH by following Step 2 and Step 3.

Discontinuing Your Heart Recording

- 1 Remove your PATCH and HUB by following the Step 5 instructions.
- 2 Return LifeLens Wireless ECG Monitor Kit to your prescribing physician.

Cleaning Instructions

- 1 To clean the HUBs and Gateway-Recharger, use **ONLY** alcohol pads/wipes.
- 2 Allow HUBs to fully dry before returning HUBs to the Gateway-Recharger.

Recording an Annotation

- 1 To record audio annotations or patient events, **TAP TWICE** on the HUB before speaking and describing the event.
- 2 The LED will flash **GREEN** rapidly for 10 seconds indicating that recording is in progress. The HUB records audio for 10 seconds. The audio recording will then be saved.

Keep the HUB clean and free of fluid.
Only use audio recording when in a low noise environment.

Warnings & Precautions

When using LifeLens Wireless ECG Monitor, always follow these basic safety precautions to ensure that the system functions correctly. Failure to follow these precautions could result in skin irritation and inaccurate data collection.

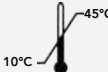
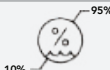
- **DO NOT** use the LifeLens Wireless ECG Monitor for any other purpose besides those outlined in this User Manual.
- **DO NOT** place the PATCH over dry skin, wounds, sores, or abrasions.
- **DO NOT** excessively bend or twist the PATCH prior to application.
- **DO NOT** use the PATCH if it appears damaged.
- **DO NOT** put any part of the HUB or PATCH in your mouth
- **DO NOT** attempt to take the HUB, Gateway-Recharger, or the PATCH apart; there are no user serviceable parts.
- **DO NOT** attempt to pull the HUB off your skin.
- **DO NOT** wear the LifeLens Wireless ECG Monitor during air travel.
- **DO NOT** use any parts that appear damaged or contaminated.
- **DO NOT** immerse in water. Prolonged exposure to standing water may damage the device.
- **DO** consult your doctor if you have skin irritation or inflammation around the PATCH.
- **KEEP OUT OF REACH of children.** The HUB is a potential choking hazard.
- **May interfere with defibrillation therapy.** Remove Hub and Patch prior to defibrillation therapy.
- **May interfere with MRI scanning.** Remove Hub and Patch prior to MRI scanning.
- **Battery/Electronic waste may present environmental hazard.** Do not dispose of device with household waste.
- **Battery Warning.** These device(s) use rechargeable lithium-ion batteries, and with any battery, a risk of overheating can occur. If any device feels warm to the touch, discontinue use and return to prescribing healthcare provider.
- **Electrical shock warning.** Do not allow conductive parts on this device to come in contact with other conductive parts.
- **Electromagnetic field warning.** Exposure to electromagnetic fields greater than 3v/m could interfere with data collection.
- **Some barriers (such as wet clothing)** may prevent HUB and Gateway-Recharger communication.

FCC Warning

Statement 15.19(a)(3): 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.

FCC Part 15.21: THE GRANTEE IS NOT RESPONSIBLE FOR ANY CHANGES OR MODIFICATIONS NOT EXPRESSLY APPROVED BY THE PARTY RESPONSIBLE FOR COMPLIANCE. SUCH MODIFICATIONS COULD VOID THE USER'S AUTHORITY TO OPERATE THE EQUIPMENT.

Symbol Glossary

	Temperature must be within these limits		
	Atmospheric pressure must be within these limits		
	Humidity must be within these limits		
	Date of manufacture		Manufacturer
	Contains electronic equipment. Dispose of properly in accordance with local regulations.		
Rx ONLY	Prescription device. Sold to or on the order of a medical professional only.		
	Warning and caution symbol		
	Expiration date		
	Instructions for use		
	Type BF applied part		
	FCC compliant		
	Single-use only		
REF	Orderable part number	LOT	Batch number



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