

hōm^{ecg+}
Version 2.0
User Manual

August 2022

TABLE OF CONTENTS

1. PRODUCT DESCRIPTION	3
1.1 Data Storage/Transmission.....	3
1.2 Indications for Use.....	3
1.3 Contraindications for Use.....	3
1.4 Warnings and Precautions.....	4
1.5 Disclaimers.....	4
2. INSTRUCTIONS FOR USE	4
2.1 Getting to Know Your Device.....	5
2.2 Taking a Reading-Using Thumb Sensors.....	6
2.2.1 Troubleshooting	6
2.3 Taking a Reading-Using Wristbands.....	7
2.3.1 Troubleshooting	7
3. MAINTENANCE AND SERVICE	8
3.1 Proper Handling	8
3.2 Resetting the hōm ^{ecg+}	8
3.3 Batteries.....	8
3.4 Cleaning and Disinfecting the hōm ^{ecg+}	9
3.5 Troubleshooting.....	9
4. REISSUING A DEVICE	10
5. SPECIFICATIONS	10
6. SYMBOLS	11
7. CONTACTING SUPPORT	11

1. PRODUCT DESCRIPTION

The hōm^{ecg+} / AfibAlert[®] is a cardiac event recorder capable of recording and storing approximately one-hundred twenty-eight 45-second events in solid-state non-volatile memory. The hōm^{ecg+} / AfibAlert[®] allows patients who have been diagnosed with, or are susceptible to developing, atrial fibrillation (AF) to take periodic readings with a computerized rhythm monitor. The system was developed for the patient that is at risk or has been previously diagnosed with AF, has a history of heart bypass, ablation, or other cardiac abnormality, or is on heart (anti-arrhythmic) medication. In these cases, detecting and determining AF early can potentially reduce the risk of heart attack and stroke.

The device can record a single channel of ECG data in two ways: (1) via the two thumb sensors, and (2) by applying (optional) wristband. In each case, the patient initiates the recording. An individual recording will take ~45 seconds. Immediately following data acquisition, an internal AF algorithm is used to analyze the patient's rhythm.

The built-in graphical LCD display indicates the presence or absence of AF. If ECG data is present (whether or not AF is indicated) the device uses an internal cellular modem to transfer the ECG data to the cloud to be viewed and/or shared with their physician or health care practitioner using either company developed or third party developed internet based software program(s).

1.1 Data Storage/Transmission

- Auxiliary 8MB small-sectored serial flash memory is available for off-line storage of ECG readings when a cellular network signal (LTE service) is not available.
- Up to 128 readings can be stored.
- The cellular modem will automatically transfer the raw ECG data to the Cloud (to be viewed by a healthcare professional).
- The ECG reading is also sent directly to the provider if a remote patient monitoring (RPM) platform is being utilized by the patient's provider.
- If a cellular connection is not immediately available, the reading will be stored for transfer later.



1.2 Indications for Use

The hōm^{ecg+} / AfibAlert[®] is indicated for self-testing by patients who have been diagnosed with, or are susceptible to developing, atrial fibrillation and who would like to monitor and record their heart rhythms on an intermittent basis.

1.3 Contraindications for Use

- Do not use the hōm^{ecg+} if you have a pacemaker. It will not harm you or the pacemaker, but the pacemaker pulses will negate the accuracy of the internal hōm^{ecg+} algorithm.
- No other contraindications known.

1.4 Warnings and Precautions

-  Do not use the hōm^{ecg+} if you have a pacemaker. It will not harm you or the pacemaker, but the pacemaker pulses will negate the accuracy of the internal hōm^{ecg+} algorithm.
-  Operation of this device near sources of electromagnetic interference (such as radio transmitters) may adversely affect the quality of the ECG signal. This device complies with the applicable specifications of IEC 60601-1-2 Ed 4.1 and AIM Standard 7351731 regarding electromagnetic compatibility.

1.5 Disclaimers

- The hōm^{ecg+} is designed to help you and your physician manage your Atrial Fibrillation. It is not a substitute for medical care. Only your physician can make a conclusive diagnosis of Atrial Fibrillation.
- This device monitors for atrial fibrillation only. It will not detect other potentially life-threatening arrhythmias, and it is possible that other cardiac arrhythmias may be present even if the **AFIB NOT DETECTED** screen is displayed.
- When using the hōm^{ecg+} do not rely solely on the computer algorithm. While computer algorithms can be 90%–95% accurate, there is no guarantee that it will detect all episodes, especially when poor electrode contact causes artifact and algorithm confusion. Therefore, regardless of whether the **POSSIBLE AFIB DETECTED** screen is displayed, if you are symptomatic, seek medical attention.
- Federal law restricts this device to sale by or on the order of a licensed healthcare professional.

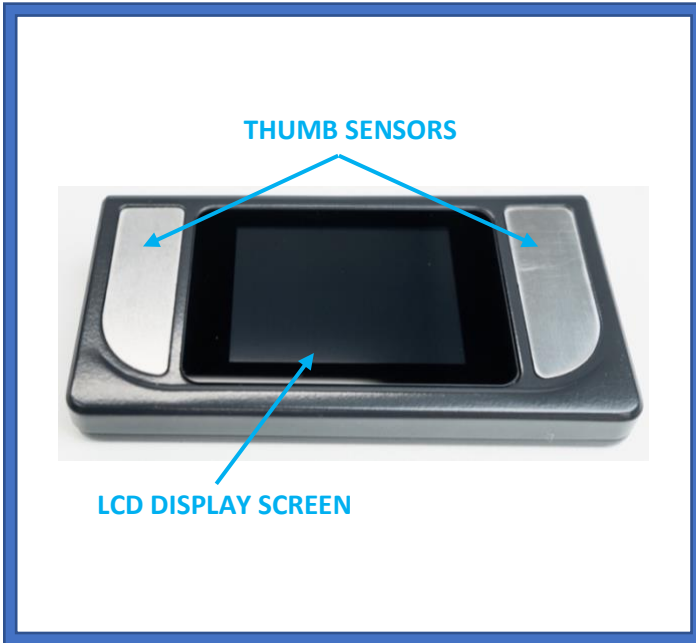
2. INSTRUCTIONS FOR USE

The hōm^{ecg+} records 45 seconds of your heart rhythm and a computer algorithm analyzes the data. It is designed to detect the presence or absence of Atrial Fibrillation (AF) in each reading and displays results in the LCD display of the device.

- Your healthcare provider will instruct you how often to use your device and what action to take when receiving the displayed messages.
- Do not use your device during exercise.
- For the most accurate result, it is best to rest for at least 5 minutes prior to taking a reading.
- Be sure that you are seated, legs uncrossed, and still during the reading.
- The LCD display will illuminate a white screen reading hōm^{ecg+} when the unit is turned on.
- If Afib is not detected the hōm^{ecg+} LCD screen will illuminate a green display with the message **“AFIB NOT DETECTED.”**
- If Afib is detected the hōm^{ecg+} will emit 3 beeps and the LCD screen will illuminate a red display with the message **“POSSIBLE AFIB DETECTED.”**

2.1 Getting to Know Your Device

FRONT



BACK



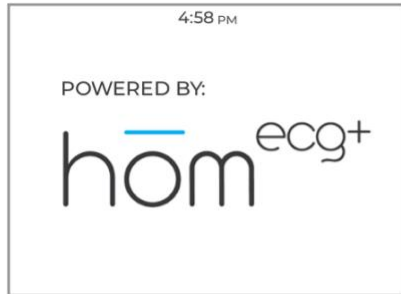
LEFT SIDE



RIGHT SIDE



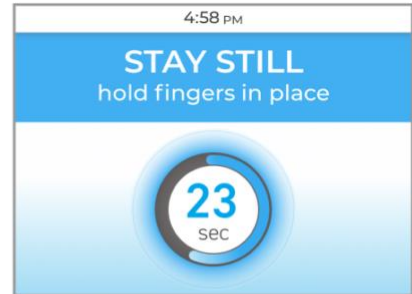
2.2 Taking a Reading - Using Thumb Sensors



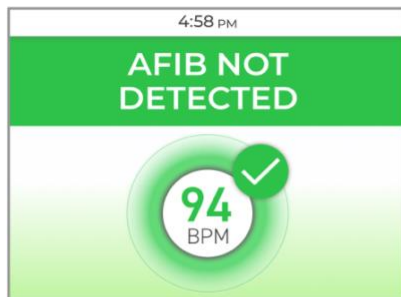
Step 1. Press the blue power button on the right side of the device to power on.



Step 2. Gently rest your thumbs on the sensor pads as shown above.



Step 3. Hold your fingers in place while the device takes a reading. The timer will count down the time remaining.

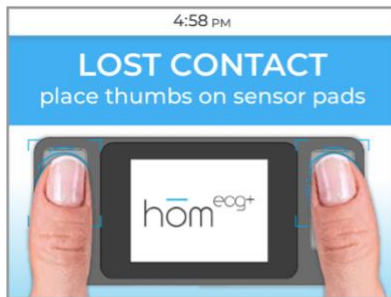


Step 4a. If AFIB is not detected, you will be shown the above screen with your BPM reading. The device will shut down automatically after 10 seconds.



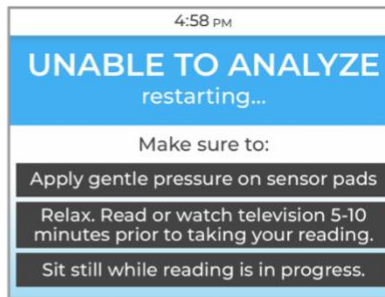
Step 4b. You will be alerted if Afib is detected with 3 beeps and a message to contact your healthcare provider. The device will shut down automatically after 30 seconds.

2.2.1 Troubleshooting



Issue: The hōm^{ecg+} device has lost contact with one of your fingers.

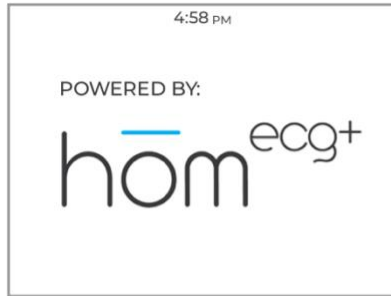
Solution: Ensure both of your fingers are placed correctly to continue the reading.



Issue: The hōm^{ecg+} device is unable to analyze your ECG.

Solution: Follow the on screen tips to ensure a successful reading.

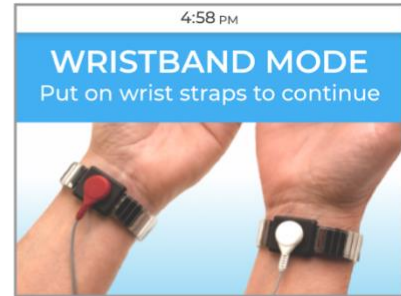
2.3 Taking a Reading - Using (Optional) Wristbands



Step 1. Press the blue power button on the right side of the device to power on.



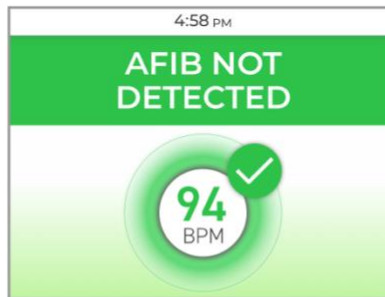
Step 2. Plug the wristband cable into the left side of the hōm^{ecg+} device.



Step 3. Attach the wrist straps to each wrist as shown above.



Step 4. Keep your arms relaxed while the device takes a reading. The timer will count down the time remaining.



Step 5a. If AFIB is not detected, you will be shown the above screen with your BPM reading. The device will shut down automatically after 10 seconds.



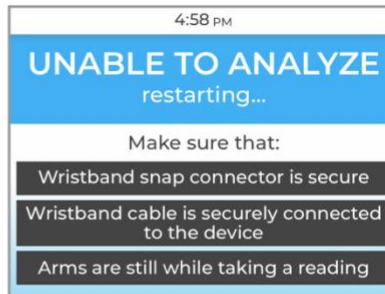
Step 5b. You will be alerted if Afib is detected with 3 beeps and a message to contact your healthcare provider. The device will shut down automatically after 30 seconds.

2.3.1 Troubleshooting



Issue: The hōm^{ecg+} device has lost contact with one of your wrist bands.

Solution: Ensure each of the wrist band connections are secure to continue the reading.



Issue: The hōm^{ecg+} device is unable to analyze your ECG.

Solution: Follow the on screen tips to ensure a successful reading.

3. MAINTENANCE AND SERVICE

The hōm^{ecg+} requires no regular maintenance, except battery replacement, and has no user serviceable parts. Do not remove the cover or attempt to service any internal components. Contact Lohman Technologies for service using the contact information provided at the end of this document.

Note: Service documentation will be provided upon request to authorized repair facilities.

3.1 Proper Handling of the hōm^{ecg+}

Damage to the hōm^{ecg+} can result in inaccurate readings or a defective device and may void the warranty.

Always treat the hōm^{ecg+} with care

- Never use abrasive materials or chemicals to clean the hōm^{ecg+}
- Never pour any liquid on the hōm^{ecg+} or allow liquid to enter through the openings.
- Never immerse or place the hōm^{ecg+} in any pool of liquid. Moisture can damage the internal circuitry.
- Never expose the hōm^{ecg+} to dirt, dust, or extreme conditions.
- Avoid dropping the hōm^{ecg+}
- Never leave the wristbands, or any other metal object, in contact with the Thumb Sensors for long periods of time. Contact between Thumb Sensors and other metallic objects should be minimized to prevent corrosion.
- The radiated output power of this device meets the limits of FCC/IC radio frequency exposure limits. This device should be operated with a minimum separation distance of 20 cm (8 inches) between the equipment and a person's body.
- There are no exposed shock hazards on the device.

3.2 Resetting the hōm^{ecg+}

If your device becomes inoperable and troubleshooting tips were not effective you may attempt to reset your device. On the back side of the hōm^{ecg+} is a small hole providing access to the reset button. **Insert paper clip into hole to reset the device.**

3.3 Batteries

- The hōm^{ecg+} is powered by two 1.5V (series) "AA" Alkaline cells.
- The useful battery life is targeted at approximately 6 months before replacement.
- The battery life is based on a typical user taking 1-2 reading per day.
- Units notifies of low battery status via LCD indication.
- The battery level indicator appears when power from the alkaline battery drops to 2.4V. (approximately 10%) to inform the use that the battery level is low.
- Read the instructions on your hōm^{ecg+} before installing batteries.
- Insert or replace batteries on a non-conductive surface.
- If necessary, clean the battery contact surfaces by gently rubbing with a clean pencil eraser or cloth.

- Replace the batteries with the size and type specified. Remove all used batteries from the hōm^{ecg+} at the same time, and then replace them with new batteries of the same size and type.
- Store the batteries in a cool, dry place at normal room temperature.
- Never dispose of the batteries in a fire; they may rupture or leak.
- Never carry loose batteries in a pocket or purse with metal objects like coins, paper clips, etc. This will short-circuit the battery, generating high heat.
- Never put batteries or battery-powered devices in hot places; elevated temperatures increase the self-discharge of batteries.
- Never mix old and new batteries, or different types of batteries. This can cause rupture or leakage, resulting in personal injury or property damage.

3.4 Cleaning and Disinfecting the hōm^{ecg+}

- Do not let fluid "pool" around connection ports. If this should happen, blot dry with a soft, lint-free cloth.
- NEVER immerse device in any liquid or pour liquid onto device.
- NEVER use conductive solutions, solutions that contain chlorides, wax, or wax compounds to clean device.
- Use one of the following cleaning agents to clean the device in combination with a damp, soft, lint-free cloth.
 - hydrogen peroxide*
 - 3% bleach solution*
- NEVER use the following solutions:
 - Abrasive cleaners or solvents of any kind
 - Acetone, Ketone, Betadine
 - Alcohol-based cleaning agents
 - Quaternary ammonia solution

3.5 Troubleshooting

PROBLEM	SOLUTION
Lost Contact message using thumb sensors	<ul style="list-style-type: none"> • Repeat the test. • Make sure the sensors are in firm contact with the thumbs, but not so strongly that the recorder picks up muscle tremor. • Consider cleaning your skin with an ECG prep pad or alcohol before application • Dry or calloused skin degrades the signal. • Consider using wristbands.
Lost Contact message using wristbands	<ul style="list-style-type: none"> • Repeat the test • Try to moisten your wrists with water. • Leave your arms in a relaxed position.
Low Battery indicator	<ul style="list-style-type: none"> • Change batteries according to directions on page 9.

PROBLEM	SOLUTION
Device will not turn on	<ul style="list-style-type: none"> ● Change batteries according to directions on page 9 ● Contact your provider or support on page 13.

4. REISSUING A DEVICE (by designated staff only):

Follow these steps to ensure device is functional to reissue to new patient:

- 1) Remove back cover (battery door) and **discard batteries**.
- 2) **Inspect inside of battery door** for signs of corrosion.
 - a. If corrosion present, email Lohman support with serial number of unit and description of issue and return device to address below.
- 3) **Clean** exterior of the device with a soft, damp, lint-free cloth, according to your infection control policy using *hydrogen peroxide or bleach-based solutions (Do not exceed 3% hydrogen peroxide or 3% bleach).

*No statement regarding the efficacy of these chemicals against any bacteria or virus is implied.
- 4) **Allow device to dry according to the cleaning product manufacturer’s timeline recommendation**, then **insert new batteries** (only standard alkaline AA batteries).
- 5) Turn the device on and follow appropriate steps to **take an ECG reading**.
 - a. If device not working, email Lohman support with serial number of unit and description of issue
- 6) **Press and hold the power button and while holding the power button, press the RESET** button via the hole on the back of the device with a paper clip or similar object. This will clear any previous readings from the memory of the device.
 - a. If the device does not display the factory reset screen email Lohman support with serial number of unit and description of issue.

5. SPECIFICATIONS

Device Classification	
Type 3 per ANSI/AAMI EC38:1998	
Physical & Environmental	
Size	5.5in X 3in X 1.12in
Weight (without batteries)	0.35 lbs
Weight (with batteries)	0.4 lbs
Cable connector	4-position, in-line safety

Operational temperature	0°C to+ 45°C (+32°F to +113°F)
Storage and transport	-120°C to +60°C (-4°F to +140°F)
General Electrical	
Battery type	Two AA 1.5V EverReady® Titanium Alkaline or equivalent
Battery life (used once daily)	6 months
Memory Specifications	
Maximum number of stored events	128
Event length	45 seconds
Transmission System	
Transmission media	Cellular Radio
Functional Features	
User programmable	No
Low battery detection	Yes
Baseline Centering	Yes – automatic
Heart rate accuracy	±1 BPM - (Average for data collected, updated every three seconds)

6. SYMBOLS

Symbol	Meaning
	CAUTION: Consult Instructions for Use
	Manufacturer
	Reference (Catalog) Number
	Prescription only device.
	Serial Number
	Type BF Medical Equipment

7. CONTACTING SUPPORT

Lohman Technologies, LLC
N27 W23953 Paul Rd, Ste 204
Pewaukee, WI 53072

Phone: (262)672-6232
Toll Free: (866)321-AFIB (2342)
Fax: (888)494-8950

Email: websupport@lohmantech.com