AfibAlert®
Instruction Manual

Please read this entire booklet before using the AfibAlert®.
It contains important information on its use.

CAUTION! ⚠️

Note: 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 AAMI EC-38 applicable specifications regarding electromagnetic compatibility.

The AfibAlert® 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.

If you are experiencing any symptoms (see page 13), please consult with your physician, or if you feel you are in immediate danger, call 911 or other emergency personnel immediately.

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 GREEN LIGHT ILLUMINATES. AGAIN, ITS ONLY PURPOSE IS TO DETECT THE PRESENCE OF ATRIAL FIBRILLATION.

Although the AfibAlert® is highly accurate in the detection of Atrial Fibrillation, certain cardiac rhythms and electrode contact failure can reduce the accuracy. If you feel you are in Atrial Fibrillation or are unsure of your symptom, please consult with your physician. It is always best to take a reading and transmit the data if you are symptomatic. If properly transmitted, your data will be available if your physician would like to review it at a later date.

The AfibAlert® only monitors for Atrial Fibrillation during the 45-second testing period. It does not continuously monitor your heart and therefore cannot alert you if Atrial Fibrillation happens at any other time.

IF YOU FEEL YOU ARE IN IMMEDIATE DANGER, CALL 911 OR OTHER EMERGENCY PERSONNEL IMMEDIATELY!

Save all packaging materials in the event you must return the AfibAlert® for software updates and/or exchanges.

IMPORTANT: Stored test data must be sent to your physician for interpretation. This can be done by either:

a) uploading the data through your computer to an Internet web site (see page 30)
b) transmitting the data over the telephone.

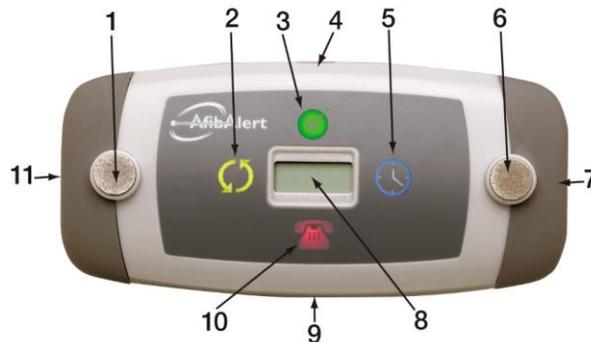**CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED HEALTHCARE PROFESSIONAL.**

TABLE OF CONTENTS

1. INTRODUCTION

AfibAlert® Physical Features

1. Left Thumb Electrode – Used for acquiring ECG data from thumbs.

2. YELLOW Light (Circular Arrow Icon) – Lights when the test needs to be repeated due to a poor connection between your thumb(s) and an electrode(s) or you removed your thumbs before the test was complete.

3. GREEN Light (Circle with Checkmark Icon) – When lit at end of test, it means that data has been successfully stored for later transmission. If you are experiencing symptoms (see page 7), you should transmit your data (see page 13). If there is any question about the seriousness of the symptoms, call 911. Also lights at end of successful data transmission or web upload.

4. Side Mounted Blue Light – Lights while test is in progress or while transmission of data is in progress. This is the same as #5.

5. BLUE Light (Clock Icon) – Lights while test is in progress or while transmission of data is in progress.

6. Right Thumb Electrode – Used for acquiring ECG data from thumbs.

7. Power Button – Activates either data acquisition, data transmission, or to upload data to web site.

8. Heart Rate LCD – Displays your average heart rate in beats per minute (BPM) while your ECG is being recorded.

9. Patient Cable Connector Port – Electrode cable is plugged into this connector for use with wrist band electrodes or sticky leads.

10. RED Light (Telephone Icon) – When lit at end of test, call your receiving service and transmit your data immediately, or upload the data to the web site and contact your physician (see page 13). If appropriate, the nurse or technologist will contact your physician. Your physician may contact you and provide further instructions.

11. USB Port – Small end of USB cable is plugged into this connector to connect the AfibAlert® to a Windows computer.

12. Battery Door – Slides off for inserting or replacing batteries.

13. Speaker – When transmitting data over a phone, place the mouthpiece of the phone over this speaker.

14. Flash Erase Button – Used for deleting all stored ECG data from device memory.

AfibAlert® Description and Purpose

The AfibAlert® is a cardiac event recorder capable of storing 34, 45-second events, in solid state non-volatile memory. The AfibAlert® allows patients who have been diagnosed with, or are susceptible to developing Atrial Fibrillation to take periodic readings with a computerized heart rhythm monitor. The system was developed for the patient who has been previously diagnosed with Atrial Fibrillation, has a history of heart bypass, ablation or other cardiac abnormalities, or is taking heart (antiarrhythmic) medications.

The AfibAlert® can record a single channel of ECG data in two ways: (1) via the two raised thumb electrodes, or (2) by utilizing the patient cable with wristband or sticky electrodes. In each case, the patient initiates the recording and the test takes approximately 45 seconds. Immediately following data acquisition, an internal computer algorithm is used to analyze the patient's rhythm and the appropriate LED (light emitting diode) lights signaling what action is needed (see page 9 for description of lights).

If the RED Light illuminates, or concerning symptoms are present, the patient should immediately make a telephone call to a service provider as specified by their physician and transmit or upload the ECG data to the receiving personnel or the website. If uploading data to the web site, upload the data and immediately notify your physician new data has been uploaded.

Indications for Use

The 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 rhythm on an intermittent basis.

⚠️

Contra-Indications for Use

This device is contra-indicated (not recommended) for use in combination with pacemakers.
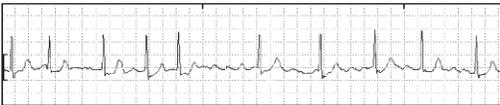
What is Atrial Fibrillation?

We've all heard or felt our heart beat, often when lying with our head on a pillow. Most often it is a steady rhythm, but sometimes there is a noticeable change which may be caused either by a simple ectopic beat (sometimes called a skipped beat), by Atrial Fibrillation, or a number of other cardiac arrhythmias.

The heart is a four-chambered mechanical pump that keeps blood circulating throughout the body. Normally, it beats regularly at 60 to 80 times per minute but does increase with exercise, excitement, or in response to outside factors.

1.3 A normal heart rhythm

1.4 A heart rhythm experiencing Atrial Fibrillation

A normal heart beat starts as a tiny impulse that originates in the sino-atrial node (S - A node) and as this pulse spreads throughout the heart, it causes first the upper chambers (atria) to contract and then the lower (ventricles), forcing blood to flow to the lungs and throughout the body.

This process becomes unreliable when Atrial Fibrillation causes the atria to beat erratically (fibrillate). If the blood does not flow effectively, it can stagnate and cause clots in the atria. When this occurs, the patient is at risk of having either a heart attack or stroke. A stroke occurs when one of the formed clots breaks loose from the atria, lodges in an artery and blocks the blood flow to the brain.

Atrial Fibrillation is a chaotic and rapid beating of the atria (upper chambers of the heart). But no matter how rapid the atria contract, the lower chambers (the ventricles) tend to respond at will, although just as chaotically. It is this erratic heart beat that is detected by the computer algorithm located in the AfibAlert®. If the resulting heart rate exceeds 120 BPM for long periods of time, damage to the heart muscles can occur.

Atrial Fibrillation Symptoms

While some patients with Atrial Fibrillation are asymptomatic (do not feel symptoms), others can experience symptoms such as:

- palpitations (heart thumping or skipping)
- shortness of breath
- dizziness, wooziness
- syncope (fainting)
- angina (chest pain)
- fatigue
- cough
- anxiety (severe apprehension or sweating)
- hypotension (low blood pressure)
- pulmonary edema
- congestive heart failure

These are a just a few of the many possible symptoms and is not intended to be a complete list. These symptoms can also be associated with arrhythmias other than Atrial Fibrillation.

Note: when using the AfibAlert®, 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 or not the Red Light illuminates, if you are symptomatic, it is best to transmit or upload your ECG data for professional review!**

How the AfibAlert® Works

The AfibAlert® allows daily or even hourly checks of your heart rhythm. Your physician needs to be contacted when the Red Light illuminates and/or when you are experiencing concerning symptoms (see page 7).

- The AfibAlert® has 17 memory sectors capable of storing 2 recordings in each sector for a maximum total of 34 recordings/events. A failed recording (i.e, yellow light) will be stored just like a successfully completed recording (green or red light). The AfibAlert® memory functions in a cascading fashion that cycles saved tests through its memory system. When it gets to the maximum number of events stored before you upload, it will overwrite the first memory slot removing your first two recordings (i.e. the oldest two recordings on the device).
- As each new test is performed, the internal computer algorithm analyzes and stores the data in one of the memory sectors. As subsequent tests are performed, the oldest data is discarded and the most recent recordings are saved in memory.
- The AfibAlert® can connect with your computer through the USB port to upload the data to a web site your physician can access (see page 13).

- When used with a cardiology monitoring service, the 5 most recent recordings can be transmitted to a receiving center for analysis by trained technologists or cardiac nurses. (To view important information about data interpretation see page 8).

Operation Summary

The AfibAlert® records 45 seconds of your heart rhythm and a computer algorithm analyzes the data. You have the option of uploading it to the AfibAlert® web site (www.AfibAlert.com) or transmitting the saved ECG data to a qualified receiving center for your physician's review (see page 13).

Additional System Features

Patient Cable and Wrist Electrodes are for patients who prefer, have physical limitations, or are unable to obtain a reading using the thumb electrodes. A patient cable allows the use of wrist electrodes. The wrist electrodes eliminate the need to press and hold your thumbs to the recorder. (Please see page 11)

Universal Serial Bus (USB) Cable Connection allows the AfibAlert® to be connected to a Windows PC to upload recordings to the secure AfibAlert® website and download software updates to the device. If your physician or receiving service would like to use the Internet to review your ECG strips, you can use the USB cable to connect your device and upload your data to the AfibAlert® web site (www.AfibAlert.com). Once uploaded, your physician or designated service will be able to (or your own) review them. For either a physician or receiving center to have direct data access, you must authorize them to view your uploaded ECG data. To request a physician or receiving center be provided access to your account, submit a support request with their information from the AfibAlert application under the Support tab. The AfibAlert® will have periodic software updates to maximize its effectiveness. This is done by connecting a USB cable (included with purchase) between the AfibAlert® and your computer. Lohman Technologies will contact you when updates are available. (Please see page 38 for details.)

The AfibAlert® is capable of storing up to 34 recordings. However, due to analog phone line limitations, only 5 tests can be sent trans-telephonically. Only the most recent tests (not previously uploaded) will be sent with each transmission whether you use the USB or trans-telephonic upload method. It is not recommended to use a cell or smartphone in conjunction with the trans-telephonic upload option.

2. DATA INTERPRETATION

IMPORTANT: Stored test data can be sent to your physician for interpretation. This can be done by either a) uploading the data through your computer to an Internet web site or b) transmitting the data over the telephone.

Unlimited uploading of recordings to the AfibAlert® website is included with your purchase for either 1 or 3 years and can be renewed as needed while you are using the device. Additional fees for physician interpretation may apply. Please consult with your physician regarding interpretation fees. It is the

patient's responsibility to verify insurance coverage. Service provider and physician interpretation fees may not be reimbursable.

Transmitting the data over the phone: Verify with your physician to whom your data should be transmitted. If your physician's office is unable to receive your data, you must contract directly with an independent service provider. Your physician may provide you with the name and phone number of a service provider. The service provider may charge a fee for this service. Costs may vary among services. It is the patient's responsibility to contract directly with the service. A physician interpretation fee may also apply. It is the patient's responsibility to verify insurance coverage. Service provider and physician interpretation fees may not be reimbursable.

ALERT: The AfibAlert® web site is NOT a monitored web site. You must contact your physician immediately after uploading data to inform them that data has been uploaded for their review.

3. INSTRUCTIONS FOR USE

What the Lights Mean

It is recommended that the AfibAlert® be used indoors. The display may not be visible outdoors or under bright light conditions. The light and recorder will automatically shut off after 30 seconds.

 A RED Light means that Atrial Fibrillation might be present in that particular recording. You should transmit your data immediately (See page 13). Your physician may contact you and provide further instructions.

 A GREEN Light will illuminate at the end of a test. It means that data has been successfully stored for later transmission and the algorithm did not detect the likelihood of Atrial Fibrillation being present. However, if you are experiencing symptoms (see page 7), contact your physician or receiving service and upload or transmit your data. If there is any question about the seriousness of the symptoms, call 911. The GREEN Light will also illuminate at the end of a successful data transmission or data upload to the AfibAlert® web site. (See page 13).

Special note: If the GREEN Light comes on but symptoms are or were present, it is recommended that you transmit your data for review.

 A YELLOW Light means that poor electrode contact was present and the test should be repeated. Be certain that you are holding the electrodes firmly (though not too firm that it causes tremor) Consistently poor contact may require a more diligent preparation such as moistening your thumbs or cleaning your skin with an ECG prep pad or alcohol before application. If you cannot get accurate readings with the thumb, you may need to use the wrist electrodes. (See page 11).

 A BLUE Light will appear while taking the reading. This icon indicates the recorder is acquiring and analyzing your data. Remember to stay as relaxed as possible during this process. Your heart rate will appear in the display during the analysis process. Continue with the test until a RED, GREEN or YELLOW indicator light appears. The BLUE Light will also appear while data is being transmitted (see page 13).

Taking a Reading

Insert new batteries as described on page 18, if you have not already done so.

There are two methods of taking a reading.

1. Placing your thumbs on the thumb pad electrodes
2. Using the electrode cable and wristband electrodes

The BLUE Light will appear on the front and the top side while taking a reading. This indicates the recorder is acquiring and analyzing your data. Remember to stay as relaxed and still as possible during this process.

Note: Three dashes will appear in the LCD display until your heart rate is calculated and displayed. It takes typically 10 to 15 seconds to before your heart rate will display. Continue to hold your thumbs on the electrodes. Your heart rate will appear in the display during the analysis process and may fluctuate during the test. Continue keeping your thumbs on the thumb pad electrodes or the wristbands on until a RED, GREEN, or YELLOW indicator light appears.

IT IS BEST TO TAKE THE READING IN THE EARLY MORNING, JUST AFTER RISING FROM BED. You must be at rest while taking the test. Do not take the test during or immediately following exercise. If subsequent readings are taken during the day, it is best to relax for 5-10 minutes before taking the test. Watch TV, read a book or just sit and relax. This provides the best opportunity for a high quality reading.

Using the Thumb Pad Electrodes

Relax for 10 minutes before taking the reading. Sit down or get in a comfortable position so you can remain motionless while the test is taking place.

1. Turn On the recorder. Press the Black Power button on the right side of the recorder for one second. The recorder will emit a high-low beep and all five lights will flash once. (If "Lo Bat" appears on display, or it does not turn on, please replace the batteries as described on page 18.)

3.1 Press the Black Start button to turn on the recorder.

2. Immediately place your thumbs firmly on the electrodes (raised metal tabs). The BLUE Light will illuminate while the recorder is taking the reading. Three (3) dashes will flash on the LCD display until your heart rate reading is calculated and displayed. Continue to hold your thumbs on the electrodes. Your heart rate will appear in the display during the analysis process. **KEEP YOUR THUMBS ON THE ELECTRODES** until a RED, GREEN, or YELLOW indicator light appears. This will take approximately 45 seconds.

3.2 Press thumbs firmly on the electrodes. The Blue light will illuminate during the test.

Note: Take caution not to grasp the recorder too firmly. You will not damage the recorder but holding it with all your strength can cause muscle interference. This may distort the ECG signal and induce artifacts into the tracing producing erroneous results.

3. Once the reading is completed, the recorder will beep and a RED, GREEN or YELLOW indicator light will illuminate. (Please see page 9 for a description of each light.) The recorder will shut off automatically after 30 seconds.

Installing the Electrode Cable

The electrode cable is needed to use the wristband electrodes. Insert the black connector at the end of the cable into the socket on the bottom of the AfibAlert®. The connector can only be inserted one direction. Push the connector straight into the socket.

To remove the cable, squeeze the connector and pull straight out.

Note: The cable can remain connected to the recorder if the wrist electrodes will always be used. Do not twist the cable connector when installing or removing.

3.3 The cable can only be inserted in one direction.

Wristband Electrodes

Relax for 10 minutes before taking a reading. Sit down or get in a comfortable position so you can remain motionless while the recording is taking place.

1. Attach the patient cable to recorder (see Installing Electrode Cable on previous page).

2. Slide a wristband electrode onto each wrist, with the snaps placed on the underside of the wrist (palm side). For some patients, it may help to slightly wet the underside of your wrist with water. If you do moisten your wrist, position the snap over the moistened skin and connect the snaps from the patient cable to each wristband electrode.

3.4 The snaps should be on the underside of the wrist. Snap onto wristband electrode.

3. Connect the White Snap to the right wristband electrode and the Red Snap to the left wristband electrode. (Just remember "White on Right")

⚠️ Never place the device on any conductive surface when wristband electrodes are installed.

3.5 Red snap to the left wrist. White snap to the right wrist.

4. Turn ON the recorder by pressing the Black Power button on the right side of the recorder. The recorder will emit a high low beep and all five lights will flash once. The BLUE Light will illuminate while the recorder is taking the reading. Three (3) dashes will flash on the LCD display until your heart rate reading is calculated and displayed. Your heart rate will continue to appear in the display during the analysis process. Continue with the test until a RED, GREEN, or YELLOW indicator light appears. This will take approximately 45 seconds.

3.6 Press the BLACK button to turn on the recorder.

5. Once the reading is complete, the recorder will beep and a RED, GREEN, or YELLOW indicator light will illuminate. (Please see page 9 for a description of each light.) The recorder will shut off automatically after 30 seconds.

6. Remove the wristband electrodes upon completion of the test.

4. DATA TRANSMISSION

After taking a reading (see page 10), the AfibAlert® allows you to transmit the data by two methods.

1. USB connection: By connecting the recorder through a computer, you can upload the data to the AfibAlert™ web site.

2. Standard telephone: By pressing the Black button on the end of the recorder and holding the recorder's speaker next to the mouthpiece of a standard telephone, the receiving center can hear and interpret the transmitted data (see image 4.4 on page 15).

You are not restricted as to how the ECG data is transmitted. You may use one method exclusively or alternate between the two or use both in selected circumstances.

Uploading to the AfibAlert® Web Site Using a USB Connection

To use the USB method of uploading your ECG data, you must install the AfibAlert® application on a Windows Computer. Installation instructions can be found in a separate document called "AfibAlert® Software Installation Guide." This document will be provided to users in either a hard copy or an electronic form at time of purchase or can be downloaded as needed from the AfibAlert® website. It is recommended that you check to confirm you have the most recent version of the Installation Guidelines prior to installing or reinstalling the software. The current version will always be available online.

Computer Minimum Requirements:

> Windows 98SE, Me, 2000, XP, Vista, Windows 7, Windows 8 or Windows 10
> Available USB Port (1.1 or greater)
> Minimum of a Pentium Processor
> 10 MB free HD space
> Microsoft Internet Explorer 6.0, 7.0, 8.0, 9.0, 10.0 or 11.0

Connect the USB cable provided to your computer and to your AfibAlert® monitor according to the diagram below. Connect the end with the large connector to the USB port on the computer and plug the end with the smaller connector into the AfibAlert® (most computers have at least 2 USB ports. It does not matter which one you use).

4.1 Connect USB cable to the AfibAlert®

After connecting the USB cable to the recorder, your computer will prompt you with a "New Hardware Found" alert. Follow the directions for installing the new hardware. This is your computer linking with the AfibAlert® recorder. This typically will only happen the first time you connect the AfibAlert® recorder to your computer.

After the new hardware has been installed, you can open up the AfibAlert® application that you installed on your Windows computer and enter your login name and password. On the top part of the application, the Device Connection Status field will display "Disconnected" as shown in the figure below.
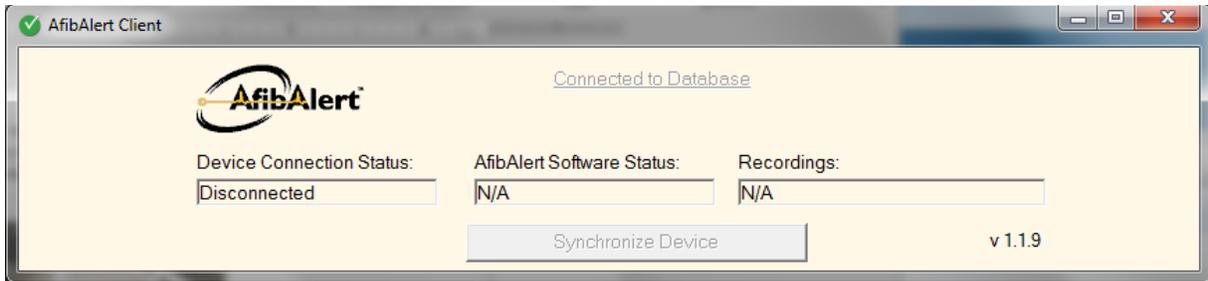
4.2 Screen shot of when your AfibAlert® recorder is plugged into your PC but not powered on.

With the USB cable still connected between the computer and the AfibAlert®, turn the recorder on. When properly connected "u56" (stands for USB) will appear on the AfibAlert® LCD display and the Device Connection Status field will display "Connected" as shown in the figure below.
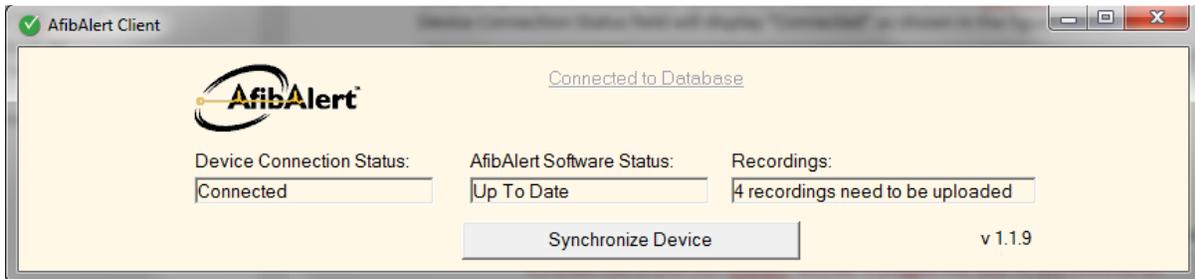
4.3 Screen shot of when your AfibAlert® recorder is plugged into your PC and powered on.

In addition to the Device Connection Status, the status of your Software ("Up To Date" or "Update Required"), and Recordings (number of recordings that need to be uploaded) are also displayed.

Click on the "Synchronize Device" button if a software update is indicated or if you want to upload your Recordings. This will upload your Recordings to the Internet for your physician to review. A progress bar will appear while this process takes place. After the Recordings have been uploaded, the progress bar will close. When the word "Disconnected" appears next to the Device Status, you may disconnect the USB cable from the recorder. The recorder is now ready for use. The Recordings can now be viewed by you or your physician by clicking on the "Recordings" tab.

To view your Recordings, click on the Recordings tab. A list of all uploaded Recordings will appear. To view a specific Recording, click on the date and time of the Recording you wish to view. To return to the list of tests, click on "Return to Recording List" on the bottom of the rhythm strip.

IMPORTANT: A physician must review the test to ensure a proper diagnosis. You must contact your physician or contracted receiving service to let them know that new data is available for review. To insure security, uploaded recordings are stored on www.AfibAlert.com, not on your personal computer.

Once you are completed with uploading and viewing your recordings, you can close the application by clicking on the "X" in the upper right hand corner of the screen.

Transmitting Using a Standard (Analog) Telephone

Your physician may provide you with instructions to transmit your data to what is called a receiving center. This may be the physician's office or it may be a 3rd party receiving service. You must contract with the receiving service prior to transmitting your ECG data. There may be an additional charge for the transmission of your data. In some cases, it may be reimbursable by your insurance company.

Call the receiving center. Answer all questions asked by the technician. The receiving center will inform you whether they want to receive only the latest test data or if they want to receive all of the stored data.

4.4 When directed, press the Black Start button. Hold the recorder's speaker to the phone mouthpiece.

Note: Use a hard-wired phone whenever possible. Cell phones and cordless phones, due to their varying signal quality, may provide poor quality transmissions.

If transmitting only the most recent recording:

1. When directed, hold the recorder's speaker (see image 4.1) next to the mouthpiece of the telephone. Press and hold the Black Power button for three (3) seconds or until a single beep is heard. Release the button. After releasing the button, you will hear a long tone and the BLUE icon will light.

2. Be certain you are holding the recorder's speaker to the mouthpiece of the phone so the receiving center can hear and interpret the transmitted data.

When the tone stops, the transmission is complete, and the GREEN Light will illuminate. Take the recorder away from the phone and speak to the receiving center for further instructions. The AfibAlert® will shut off automatically after 30 seconds.

If transmitting all stored recordings (up to a maximum of 5 recordings):

1. When directed, hold the recorder's speaker next to the mouthpiece of the telephone as shown above. Press and hold the Black Start button for six (6) seconds or until the second beep is heard. Release the button. After releasing the button, you will hear a long tone and the BLUE icon will light. You will hear a 45 second tone followed by a brief pause for each test that is transmitted (up to five tests).

2. Be certain you are holding the recorder's speaker to the mouthpiece of the phone so the receiving center can hear and interpret the transmitted data.

When the tone stops, the transmission is complete, and the GREEN Light will illuminate. Take the recorder away from the phone and speak to the receiving center for further instructions. The AfibAlert® will shut off automatically after 30 seconds.

5. SOFTWARE UPDATES

Device Software Updates

Software updates for your device require a USB port on your computer and the USB cable provided with your AfibAlert®. Connect your AfibAlert® to your computer as described under the section titled "Uploading to the AfibAlert® Web Site Using a USB Connection."

The AfibAlert® Software Status will inform you if an update is available for your AfibAlert® device by displaying either "Up To Date" or "Update Required" messages. Click on the "Synchronize Device" button, if a software update is required.
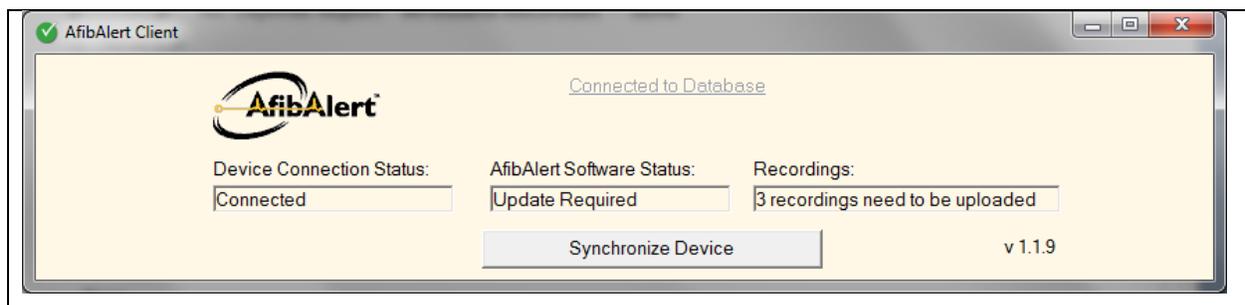
5.1 Screen shot of when your AfibAlert® recorder indicates a software update is available for the device.

Note: If the USB cable is unplugged or loss of power occurs while doing a software update your device will not function until you reconnect your AfibAlert® and reopened your application. You can follow the same process as above to complete the installation process.

Mail-In Software Updates

If you are unable to upgrade the software on your AfibAlert® through the AfibAlert® application, you may send it in to have your device updated. You may send an email to info@lohmantech.com or call 1-866-321-AFIB (2342) to request this service and receive a Return Merchandise Authorization (RMA) number. You must get an RMA number from our customer service department before sending your device to us. There is a nominal charge for shipping, handling, and upgrading the device, thus a credit card will be required.

Once you have your RMA number, mail your AfibAlert® to the address below and we will return it reprogrammed with the latest software version. (To ensure against damage, please use the original packaging materials.)

Shipping Instructions:

- Use original packaging materials if possible
- Insure the package for the cost of a replacement AfibAlert®
- Make sure to have the RMA Number visible on the outside packaging
- Include your name and address on outside of package

Mailing address:

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

Resetting the ECG Data

On the back side of the AfibAlert® is a small hole providing access to the reset button. This symbol and arrow on the back label point to that access hole that allows the ECG data to be erased from device memory. This will erase all saved ECG data stored in the memory. It is not necessary to reset the device after each test. New tests automatically replace the oldest data.

1. Press and release the Black Power button. The AfibAlert® will emit a high-low beep.

2. As shown in the picture below, immediately insert a paper clip, ball point pen, or similar item into the recessed area. The recorder will beep once.

5.1 Insert paper clip into hole to erase all data.

3. All four icons will illuminate up for 10 seconds, after which only the GREEN icon will remain lit for another 30 seconds.

4. After 30 seconds, the recorder will beep and the GREEN icon will turn off. The AfibAlert® automatically shuts off and all recordings have been deleted from memory.

6. MAINTENANCE AND SERVICE

The AfibAlert® recorder 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 on page 24.

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

Handling Precautions

Damage to the AfibAlert® can result in inaccurate readings or a defective device and may void the warranty.

Always treat the AfibAlert® with care

⚠️ Never immerse or place the AfibAlert® in any pool of liquid. Moisture can damage the internal circuitry.

⚠️ Never pour any liquid on the AfibAlert® or allow liquid to enter through the openings.

⚠️ Never use abrasive materials or chemicals to clean the AfibAlert®.

⚠️ Avoid dropping the AfibAlert®.

⚠️ Never expose the AfibAlert® to dirt, dust or extreme conditions.

- Store the AfibAlert® in its protective case whenever it is not being used. Never leave the wrist straps, or any other metal object, in contact with the Thumb Electrodes for long periods of time. Contact between Thumb electrodes and other metallic objects should be minimized to prevent corrosion.

- There are no exposed shock hazards on the device.

Batteries

Battery Type – Use two (2) high quality 'AAA' Alkaline batteries.

Inserting the batteries – Remove the battery cover by placing slight pressure on the ridged arrow, and then slide the cover in the direction of the arrow. Remove the old batteries if necessary. Insert the new batteries and replace the cover. It will snap into place.

6.1 The battery cover slides off by applying a slight pressure on the arrow.

6.2 Insert 2 'AAA' Alkaline batteries in either direction.

Note: It does not matter what direction the batteries are facing, as the electronic circuitry allows them to work regardless of which direction they face.

Removal of the batteries will not erase previously stored data.

Defective Batteries – If the LED's do not illuminate when pressing the Power button, "Lo Bat" is displayed on the LCD screen, or if recorder shuts down prematurely, the batteries may be depleted. Insert two (2) new 'AAA' high quality Alkaline batteries. Used batteries must be disposed of properly.

Care and Handling of Your Batteries

⚠️ Read the instructions on your device before installing batteries.

⚠️ Insert or replace batteries on a non-conductive surface.

⚠️ Keep battery contact surfaces clean by gently rubbing with a clean pencil eraser or cloth.

⚠️ Remove batteries from devices that will be stored for extended periods.

- Replace batteries with the size and type specified. Remove all used batteries from the device at the same time, and then replace them with new batteries of the same size and type.
- Store batteries in a cool, dry place at normal room temperature.
- Never dispose of 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 recharge a battery unless it is specifically marked "rechargeable." Attempting to recharge a normal battery could result in rupture or leakage. Don't use rechargeable alkaline batteries in nickel metal hydride battery chargers.
- 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 mix different types or makes of batteries. This can cause rupture or leakage, resulting in personal injury or property damage. Never give batteries to young children.

Cleaning the AfibAlert®

The AfibAlert® and all accessories can be cleaned with a soft cloth dampened with antibacterial soap and water. You may also use a solution of Isopropyl Alcohol. Do not use any corrosive or abrasive materials. Do not submerse in water.

Troubleshooting

Poor Electrode Contact – If the YELLOW Light LED illuminates at the end of a test, it is an indication that poor electrode contact was present and the test will have to be repeated. Make sure the electrodes are in firm contact with the thumbs, but not so strongly that the recorder picks up muscle tremor. Dry or calloused skin degrades the signal. It is normal for different skin types to have an effect on signal quality. Generally, the wristband electrodes provide the best connection. If using the wristband electrodes, be sure to moisten your wrists with water for best results and leave your arms in a relaxed position. Experimentation may be required to find a suitable and reliable combination.

AfibAlert® does not function properly – If the device does not power on or function properly, replace the batteries as described above. If the problem continues, contact Lohman Technologies for support.

Limited Written Warranty

This EXCLUSIVE LIMITED WRITTEN WARRANTY shall be in effect for ONE YEAR from the date of purchase unless you have purchased a THREE YEAR option or extended your originally warranty. This limited written warranty is provided in place of any other warranty, express or implied. TO THE MAXIMUM EXTENT PERMITTED BY   APPLICABLE LAW, LOHMAN TECHNOLOGIES, LLC DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. This LIMITED WRITTEN WARRANTY is your EXCLUSIVE REMEDY for product defects and excludes product failure due to or arising from product abuse or misuse, user modification or attachments to the product. If you experience a product failure within the warranty period and the failure is covered by the terms and limitations of this limited written warranty, the product will be repaired or replaced at the sole discretion of LOHMAN TECHNOLOGIES, LLC. THIS EXCLUSIVE REMEDY IS PROVIDED IN PLACE OF ANY OTHER REMEDIES; LOHMAN TECHNOLOGIES, LLC SHALL NOT BE LIABLE TO BUYER, OR TO ANYONE CLAIMING UNDER BUYER,

FOR ANY OTHER OBLIGATIONS OR LIABILITIES, INCLUDING, BUT NOT LIMITED TO, OBLIGATIONS OR LIABILITIES ARISING OUT OF BREACH OF CONTRACT OR WARRANTY, NEGLIGENCE OR OTHER TORT OR ANY THEORY OF STRICT LIABILITY, WITH RESPECT TO THE PRODUCT. IN NO EVENT SHALL LOHMAN TECHNOLOGIES, LLC BE LIABLE FOR INCIDENTAL, COMPENSATORY, PUNITIVE, CONSEQUENTIAL, INDIRECT, SPECIAL OR OTHER DAMAGES.

LOHMAN TECHNOLOGIES, LLC'S AGGREGATE LIABILITY WITH RESPECT TO BREACH OF THIS EXPRESS LIMITED WRITTEN WARRANTY SHALL BE LIMITED TO THE REPAIR OR REPLACEMENT REMEDY PROVIDED ABOVE.

Please provide proof of purchase with your warranty inquiry. Warranty claims may be submitted to Lohman Technologies, LLC, N27 W23953 Paul Rd, Ste 204, Pewaukee, WI 53072.

Supplies

The following supplies may be ordered directly from Lohman Technologies, LLC and can be found in our online catalog

Item	Part Number
Patient Cable	30043
Plastic Carrying Case	30047
Wrist Electrodes (1 Pair)	30048
USB Cable	30049
1.5V AAA Battery (1 Pair)	30050

7. SYMBOLS

On/Off Switch – Powers device on or off (Not Mains Connected)

Attention: consult accompanying documents

IPX 1   Drip-proof equipment provided with sufficient protection to prevent fluid ingress

Reset Button – Arrow points to access hole

Speaker

TUV certification mark

Date of manufacture

B-type (body-protected symbol) - This means that the applied part(s) so marked are suitable for connection to humans and animals (provided there is no direct electrical connection to the heart) and gives a basic level of protection against electric shock. This applied part is not electrically isolated from mains earth.

BF-type (body-protected floating symbol) - This means that the applied part(s) so marked are suitable for connection to humans and animals provided there is no direct electrical connection to the heart and gives greater protection from electric shock than B-type applied parts. This applied part is electrically isolated from mains earth.

8. SPECIFICATIONS

Device Classification
Type 3 per ANSI/AAMI EC38:1998

Physical & Environmental	
Size	5.88" X 2.75" X 1.11"
Weight (without batteries)	5 ounces
Weight (with batteries)	6.5 ounces
Cable connector	4-position, in-line safety
Operational temperature	0ºCt o+ 45ºC(+32ºFt o+ 113ºF)
Storage and transport	-120ºC to +60ºC (-4ºF to +140ºF)

General Electrical	
Battery type	Two AAA 1.5V Eveready® X-92, Titanium Alkaline or equivalent
Battery life (used once daily)	27 days nominal

Memory Specifications	
Maximum number of stored events	34
Maximum number of stored events available for phone transmissions	5
Event length	45 seconds

Transmission System	
Transmission media	Voice grade telephone line
Coupling	Acoustic
Modulation type	FM
Center Frequency	1900 Hz – 100 Hz/mV sensitivity
Transmission speeds	1x (Times real Time)

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)

Guidance and manufacturers declaration – electromagnetic emissions

The AfibAlert® is intended for use in the electromagnetic environment specified below. The customer or the user of the AfibAlert® should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The AfibAlert® uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The AfibAlert® is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and manufacturers declaration – electromagnetic immunity

The AfibAlert® is intended for use in the electromagnetic environment specified below. The customer or the user of the AfibAlert® should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air (full compliance)	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. If the display or unit does become locked, the unit should be re-started and a repeat test should be done.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not Applicable	Not Applicable
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not Applicable	Not Applicable
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5% U_t (>95% dip in U_t) for 0,5 cycle 40% U_t (60% dip in U_t) for 5 cycles 70% U_t (30% dip in U_t) for 25 cycles <5% U_t (>95% dip in U_t) for 5 sec	Not Applicable	Not Applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m (full compliance)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_t is the a.c. mains voltage prior to application of the test level

9. CONTACT INFORMATION

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Pewaukee, WI 53072

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