

HeartHero™
Elliot® AED Technical Manual

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HeartHero™
3200 Cherry Creek S Drive
Suite 470
Denver CO, 80209, USA

CE
1282

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Note: Be sure to read the Warnings and Cautions in section 1.10 before putting the device into service.

1. Elliot® AED Overview

1.1 Product Description

Welcome to the Elliot® Automated External Defibrillator (AED) from HeartHero™. Elliot® combines a compact, rugged, battery-operated unit with reliable, easy-to-use operation. This small, yet powerful AED features a user-friendly interface with both physical and graphical controls, as well as audio prompts.

Elliot features Bluetooth Low Energy (BLE) connectivity to assist with the management of the device.

1.2 Product Diagram

The following diagram shows the features found on the Elliot AED. See the table and diagram below for an explanation of each feature.



High-Quality Speakers

Loud, clear voice prompts and alerts designed to be easily heard in noisy environments, ensuring effective communication during emergencies.

Visual Prompt Panel / Display

Easy-to-follow lights and icons that guide users through every step of the rescue process, complementing voice instructions for maximum clarity.

Battery Compartment

The compartment features a flush flap with a secure turning knob that unlocks the battery door for easy replacement.

Red Pull Tab

Designed for intuitive one-step pull to power on the device and simultaneously deploy the pre-connected pad cartridge. Automatically starts clear voice and visual prompts to guide rescuers through every step.

Figure 1 Product Image

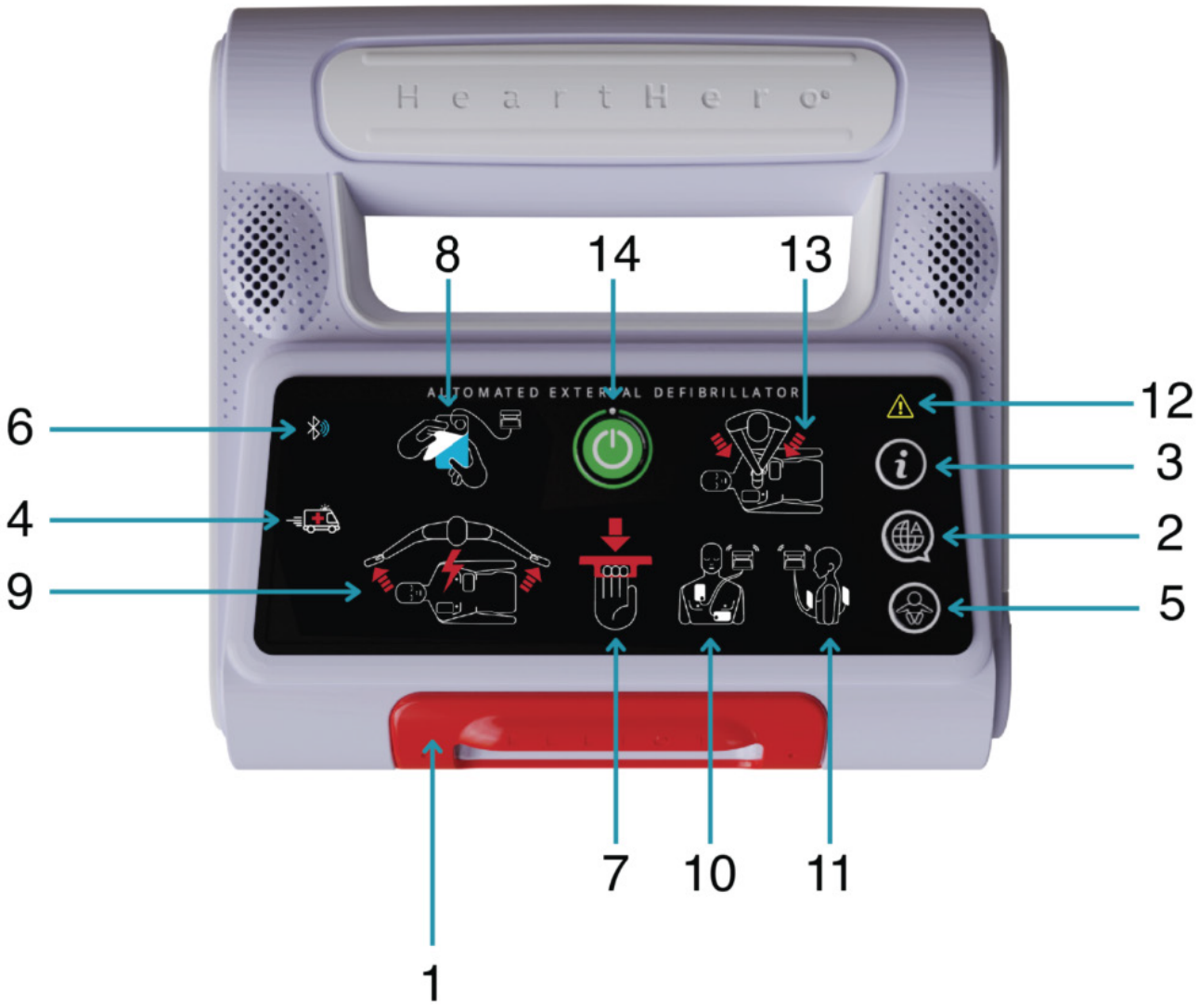


Figure 2 User Interface Features

Feature	Description
1. Red Pull Tab	Use the red pull tab, located on the front of the unit, to turn on the device and access the pads package. Pulling the pads will enter treatment mode.
2. Language Button	Press the **Language** button to toggle the language between the primary and secondary languages.

Feature	Description
3. Information Button	The **Information** button provides information on the status and use of the device and illuminates in Yellow when there is a non-critical fault report. See section 1.3, "User Interface Layout/Controls" for an explanation of each indicator.
4. Contacting EMS / EMS Contacted Indicator	The Contacting EMS indicator visually informs the user that EMS is being contacted by blinking white. Once EMS has been contacted the EMS indicator illuminates solidly. If the EMS contact failed the indicator blinks rapidly. **Warning**: The device will not automatically alert Emergency Medical Services (EMS). You must call EMS immediately to obtain emergency medical assistance.
5. Child / Adult Button	The **Child / Adult** button should be pressed to treat a child (under 55 lbs./25kg.). The circle around the button will illuminate to indicate the device is in Child mode. Press the button to toggle between child and adult, depending on the patient to be treated. The button is not active once the pads are on the patient.
6. Bluetooth connectivity	Standby mode (press the info button for more than 3 seconds) will allow the AED to pair and connect to a mobile device. This icon illuminates solid when the Bluetooth link is connected.
7. Pull Red Handle	Pull Red Handle Icon illuminated when entering Treatment mode. Audio prompt assist (see below)
8. Separate Pads	An icon indicates to pull pads out of the pouch and separate from the blue liner. Audio prompt assist (see below)
9. Shocking, stay clear	An icon indicating shock detection, shock charge, and shock delivery is in progress. **Stay clear of the patient.** Audio prompt assist (see below)
10. Place Adult Pads	An icon indicating the location of placement for Adult mode. Audio prompt assist (see below)
11. Place Child Pads	An icon indicating the location of placement for Child mode. Audio prompt assist (see below)
12. System fault	The System Fault icon is illuminated when a critical system fault has occurred.
13. CPR	An icon indicating CPR mode. Audible instructions are provided to assist with performing CPR (see below)
14. On Button	Press the **On (Power) Button** after unpacking Elliot to awaken Elliot and perform system self-check. The **System OK** light blinks green when the system is ready to use. The On Button may be pressed to initiate Treatment mode.

1.3 User Interface Layout/Controls

The following sections define each of the elements comprising Elliot's user interface, indicators, and associated controls.
The following figure shows Elliot's user interface when the system is off. No lights illuminate when the system is off.

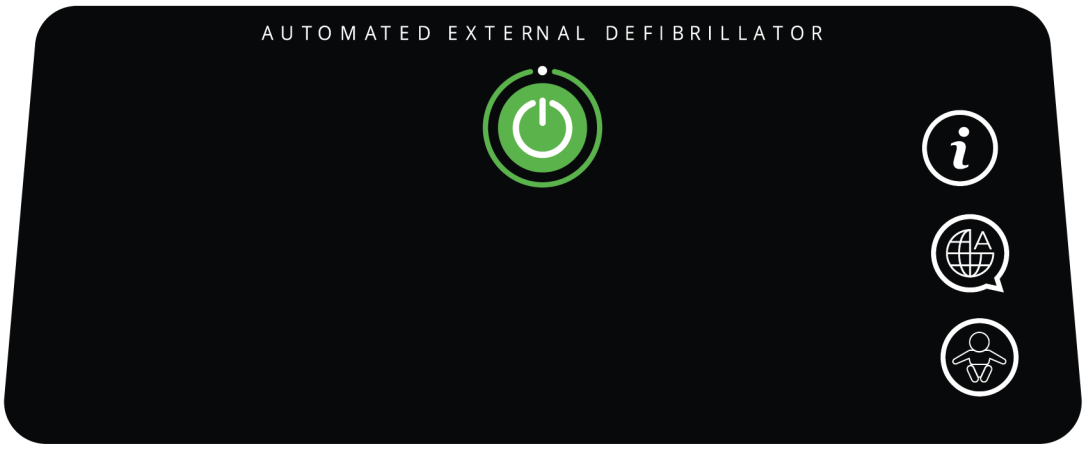


Figure 3 User Interface Display when the system is OFF

The following figure displays the Elliot user interface with all possible elements illuminated. These elements are explained in the table following the figure below.

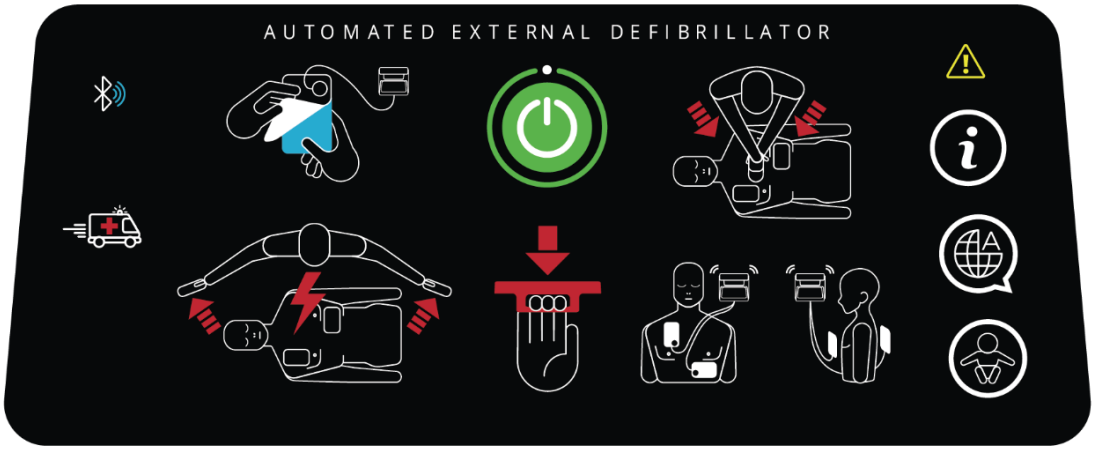
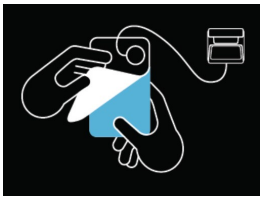


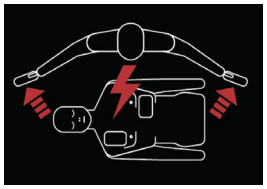
Figure 4 User Interface Displaying with All Elements Illuminated

User Interface Displaying with All Elements Illuminated

The following table outlines the elements found on the Elliot user interface.

UI Element	Description
	**On Button** Press the ON Button to turn Elliot on to awaken Elliot for initial power on or to begin treatment. The System OK indicator light above the ON Button illuminates Green when active (self-tests passed, battery OK). When the system is off and in an OK state, this indicator will blink. When active and the system is on, this indicator will be continuously illuminated.
	**System Fault** The System Fault indicator illuminates Yellow when active (critical Self-Test fails, low battery, the pads have been used on a patient, or the electrode pad cartridge is uninstalled or expired). When active and the system is off, this indicator will blink. The indicator light also draws attention to the **Information** button when it can provide additional information; when there is a system fault or non-critical fault.
	**Information Button** When a Non-Critical Fault is active (a non-critical Self-Test has failed, such as pads have expired, the device is outside the operating temperature range, the battery needs to be replaced soon, or there is no cellular connection) and the system is off, this indicator will blink yellow. Press the Information Button to learn about the last fault.
	**Language Button** Press the **Language** button to toggle between a primary and secondary language. After the user presses this button, Elliot provides an audio notification to inform the user in which mode the system is currently operating. However, if the **Language** button is pressed during a critical voice prompt, the current voice prompt will complete before the audio announces the name of the language to which it is switching. If the button is pressed during a non-critical voice prompt, the current voice prompt will be interrupted and then will be repeated in the new language.
	**Adult / Child Button** When the system is on and Child mode is active, this indicator will be lit in white. The user presses the mode button to transition from Child to Adult mode. Additionally, after the user presses this button, Elliot provides an audible notification to inform the user in which mode the system is currently operating. The system is in Adult mode by default.

UI Element	Description
	**Bluetooth Icon** Bluetooth can be enabled by pressing the **Information** button for more than 3 seconds when the device is in Standby Mode. The icon blinks when pairing and illuminates solid when connected. The pairing window is active for 20 seconds after entering INFO mode.
	**EMS contact initiated** During treatment mode, this icon flashes slowly while EMS is being contacted and illuminates solid when EMS contact is complete. If contact to EMS fails, this icon flashes rapidly. **Warning**: The device will not automatically alert Emergency Medical Services (EMS). You must call EMS immediately to obtain emergency medical assistance.
	**Pull Red Handle icon** When entering Treatment mode using the **System OK** button (see above), the indicator blinks indicating that the pads need to be pulled out from the car-tridge and pouch. Pulling the red handle directly will also start treatment mode but will bypass this icon indication.
	**Separate Pads icon** After pads have been pulled from the pouch, they need to be separated, and the blue liner needs to be removed completely. **Pads Off** The system issues audio and visual prompts when it detects that the pads are off the patient. If the pads were placed improperly while in Treatment mode, the system gives the user an audio alert that there is a bad connection. If previously applied pads are removed while in Treatment mode, an audio alert sounds, indicating that the pads are off. If the pads are off for two minutes, the system verbally alerts the user that the pads are off and that the system is shutting off. The Pad Placement indicator illuminates for the duration of the voice prompt.

UI Element	Description
	**Shocking icon** This icon blinks when shock detection, charge, and delivery are in progress. **Do Not Touch Patient** It is very important to stand clear while shock is delivered. **Shock** To differentiate charging vs. ready to shock, the indicator blinks while charging (after shockable rhythm first detected) and during the count-down prompt. If the defibrillator capacitor is charged, the indicator will illuminate in a steady-state for the last 1 second of the count-down prompt. If a decision to shock is made by the algorithm, the unit will count down "Shocking in 3…2…1…" followed by "Shock delivered." After which CPR will be prompted for the 2-minute cycle preceding the next analysis period. During the "Shocking in 3…2…1…" countdown, the unit will perform a final 4-second ECG analysis to confirm a shock is necessary. If this final 4-second analysis is deemed a non-shockable rhythm, the unit will report "Shock aborted" and CPR will be prompted for the 2-minute cycle preceding the next analysis period. If a no-shock decision is made by the algorithm, the unit will prompt CPR for the 2-minute cycle preceding the next analysis period.
	**Adult pad placement** Please follow the instructions per this icon for proper placement of the pads.
	**Child pad placement** For Child mode, please follow instructions on the Elliot AED user interface. One pad is placed on the chest while the other is placed on the back.
	**Perform CPR** The Perform CPR indicator illuminates when the user is being instructed to perform CPR on the patient. After Elliot analyzes the patient's heart rhythm and delivers a shock, if necessary, the user will be instructed to perform CPR. Audio prompts tell the user to start CPR, followed by CPR metronome to guide the user in chest compression rate. For an adult patient, only compressions are performed. For a child patient, compressions and rescue breaths are performed.

1.4 Modes

Elliot comes equipped with several different functional modes. Elliot issues specific voice and visual prompts based on the mode. The following table describes these modes:

Mode	Description
Adult Mode	Performs system functions associated with an adult patient. For example, the system administers a different shock intensity level. Press the **Adult/Child** button to toggle between Adult and Child modes.
Child/Pediatric Mode	Performs system functions associated with a child (under 55 lbs./25 kg.) patient. For example, the system administers a different shock intensity level. Press the **Adult/Child** button to toggle between Adult and Child modes.
Info Mode	Reports device status and advertises Bluetooth Low-Energy (BLE). Enter Info Mode by pressing the **Information** button. To enter Info Mode and enable BLE press the Information Button for longer than 3 seconds when the device is in Standby Mode.
Stand-by Mode	When Elliot is powered on (batteries are installed), but the red handle/pull tab has not been pulled and the ON Button has not been pressed to initiate Treatment mode. The System Fault indicator will flash periodically to indicate device status during Stand-by Mode.
Treatment Mode	When a user pulls the red handle or presses the ON (Power) Button, the system initiates Treatment mode and the subsequently associated audio and visual prompts. See section 1.5, "Voice Prompts" for an alphabetical listing of all voice prompts the system issues.

1.5 Voice Prompts

The following table outlines all voice prompts used by Elliot. The table alphabetically lists the event and the associated verbal prompt.

Event	Audio Prompt
15 Seconds Until Next	"15 seconds until next rhythm check. Continue CPR"
30 Seconds Until Next	"30 seconds until next rhythm check. Continue CPR"
Adult Mode	"Adult mode."
Analyzing	"Do not touch the patient. Analyzing heart rhythm."
Artifact	
Bad Connection	"Poor pad contact. Ensure blue liner has been removed. Skin is clean and dry. Press down firmly on pads."
Batteries Waning	"Batteries waning. Can only provide a limited number of shocks. Changing batteries is recommended."
Battery Low	"Batteries are low. Replace batteries now."
Breath	<breath sound>
Call EMS	"Ensure emergency services has been called."
Cannot Connect To EMS	"Device not able to connect. Call emergency services now."
Charging	"Charging."
Child Mode	"Child mode. For adult, press button again."
Confirm EMS	"Emergency Services have been contacted. Press the Info Button to confirm help is needed." **Warning**: The device will not automatically alert Emergency Medical Services (EMS). You must call EMS immediately to obtain emergency medical assistance.
Confirming Rhythm	"Confirming rhythm."
Connected Patient	"I will not turn off when connected to a patient. If your emergency has ended, remove the pad cartridge and hold the info button for three seconds to turn off."
Dark Mode Off	"Dark mode off"
Dark Mode On	"Dark mode on"

Event	Audio Prompt
Do Not Touch	"Do not touch the patient"
EMS Contacted	"Emergency services have been initiated. Call to confirm location." Note: contacting EMS is not enabled in the current version **Warning**: The device will not automatically alert Emergency Medical Services (EMS). You must call EMS immediately to obtain emergency medical assistance.
Ensure 911	"Ensure emergency services have been called, and start CPR."
Finish Self-Check	"Please wait while I finish my self-check."
Give Rescue Breaths 1	"Give one rescue breath"
Give Rescue Breaths 2	"Give two rescue breaths"
Hello	"Hello, I am Elliot, your personal adult and child life-saving device. I am to be used if someone is unconscious and not breathing normally."
Here To Help	"I am here to help."
If Child	"If patient is less than fifty-five pounds (or twenty-five kilograms), press child button."
Invalid Cartridge	"The Pad cartridge is not a valid cartridge. Install a HeartHero Pad cartridge."
Language	"English"
More Info	"If more information is needed, please visit HeartHero.com"
No Cellular Connection	"You're out of range of cellular connection, but I am still ready to help."
No Cellular Contract	"Cellular contract is not active, but I am still ready to help. Visit HeartHero.com for more information."
No Shockable Rhythm	"No shockable rhythm detected."
One Minute Until Next	"One minute until next rhythm check. Continue CPR"
Open Pads	"Open and remove pads from the pouch."
Open Airway 1	"Ensure open airway – give one rescue breath"
Open Airway 2	"Ensure open airway – give two rescue breaths"
Pad Cartridge Not Installed	"The Pad cartridge is not installed. Install the Pad cartridge."
Pad Connector	"Pads connector not fully seated. Press down on the connector to ensure its inserted completely."
Pads Expired	"Hmm. Pads expired. Please replace the Pads cartridge"

Event	Audio Prompt
Pads Off	“Pads Off. Check Pads.”
Pads Off Turn Off	"Pads off. Check pads. If system is no longer needed, press and hold power button to turn off."
Pads Off Used	"Pads Off. Check Pads. If device was used, bring to the hospital with the patient."
Pads On	"Pads On"
Pads Used	“The pads have been used. Replace the Pads cartridge.”
Pairing	"Pairing."
Place Pads	"Apply pads on bare chest as shown on pads"
Place Pads and Check	“Ensure pads have firm contact with skin.”
Place Pads Child	“Apply one pad on bare chest and one pad on center of bare back as shown on device.”
Please Contact	"Please review the user manual or contact customer support.”
Please Download	"Please download the HeartHero app and follow the on-screen instructions to register and configure your device."
Press The Green Power Button	"Press the green power button"
Pull Red Handle	"Pull red handle and slide the pads out."
Pull The Red Tab	"Or pull the red tab to activate"
Push Hard	“Push down hard on every beat.”
Ready To Help	“I am ready to help. If needed for an emergency, pull the red tab to activate. Or press the green power button”
Ready When You Need Me	"I will be ready when you need me."
Reset Clock	"Please connect me to the mobile app to reset the clock."
Self-Check	"Self-check"
Self-Check Fail	"Self-check completed. Problem found."
Self-Check Pass	“I have just completed a self-check. I am ready to help. In the event of an emergency,”

Event	Audio Prompt
Separate Pads	"Open pad pouch, and separate from blue liner."
Shock Aborted	“Shock aborted. Patient's condition has changed. No shock delivered.”
Shock Delivered	“Shock delivered”
Shocking	“Do not touch the patient. Shocking in three, two, one.”
Shocking Sweep	"Do not touch the patient. Shocking in three, two, one."
Stand Clear	"Stand clear."
Start CPR	"Start CPR now. Push down hard and fast on center of chest between nipples."
Step By Step Instructions	"When activated, I will give you step-by-step instructions."
Stop CPR	“Stop CPR now."
System Off	“System turning off.”
System Off 10s	"System will turn off in ten seconds. Press power button to cancel. If device was used, please bring to the hospital with the patient."
System Off_5s	“System will turn off in five seconds. Press power button to cancel.”
System Unable	"Not able to deliver a shock."
There Is a Problem	"There is a problem with the device system."

1.6 Electrode Pad Cartridge

Elliot is to be used with a single-use HeartHero Electrode Pad Cartridge that houses a package containing the pads, or electrodes, used to deliver energy to a patient. The Electrode Package is accessed by pulling the red handle. The package is connected to the red handle.

The following figure below displays the information label on the electrode package. The expiration, or use by, date and additional informative symbols are included in this label. Refer to Section 6.4 for symbol definitions.

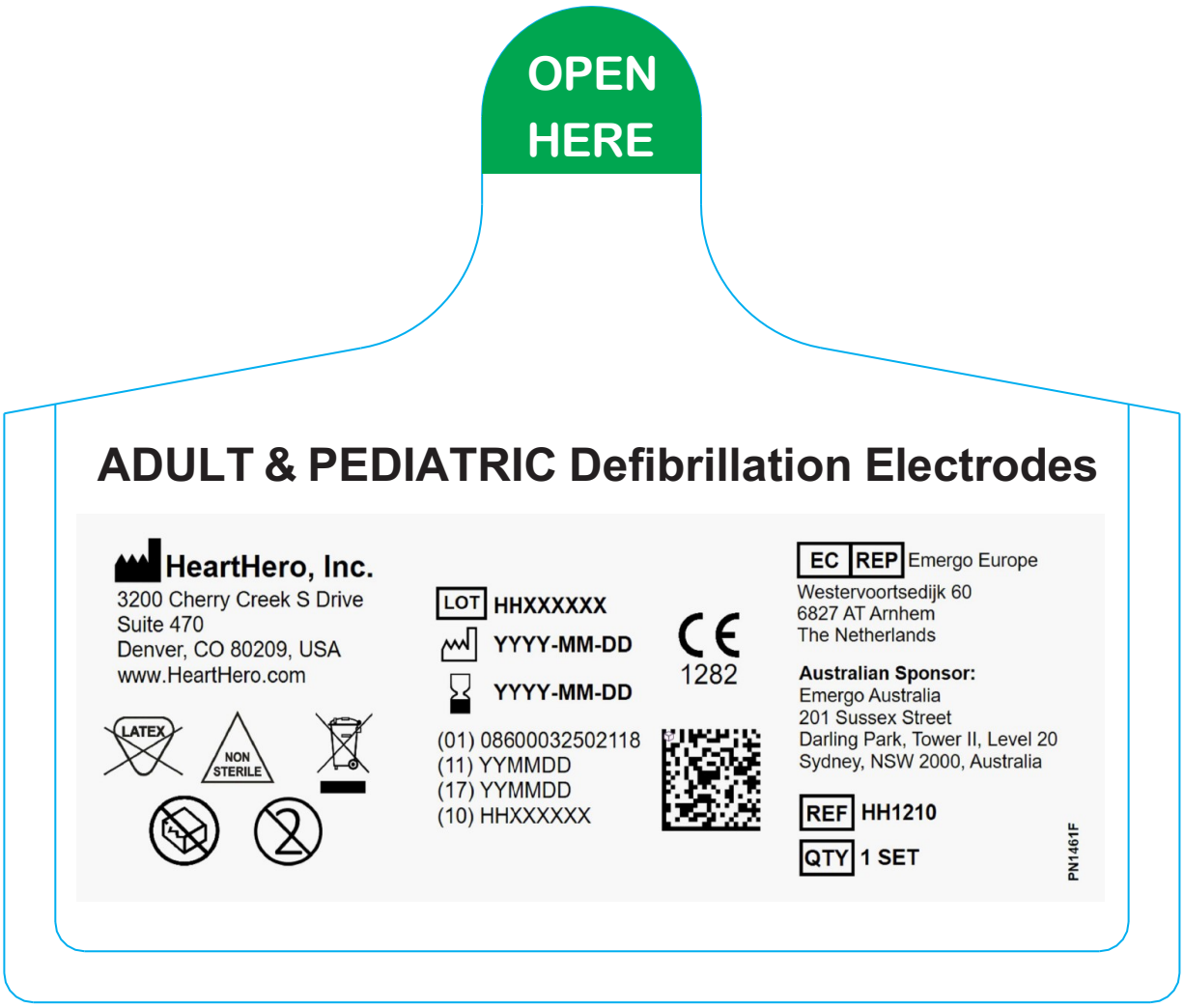


Figure 5 Electrode Package Information Label

The other side of the Electrode Package, shown below, depicts instructions for how to access the electrodes. Once the white package is peeled apart from the tab near the wires, the electrodes need to be peeled completely off the blueliner before being placed on the patient.

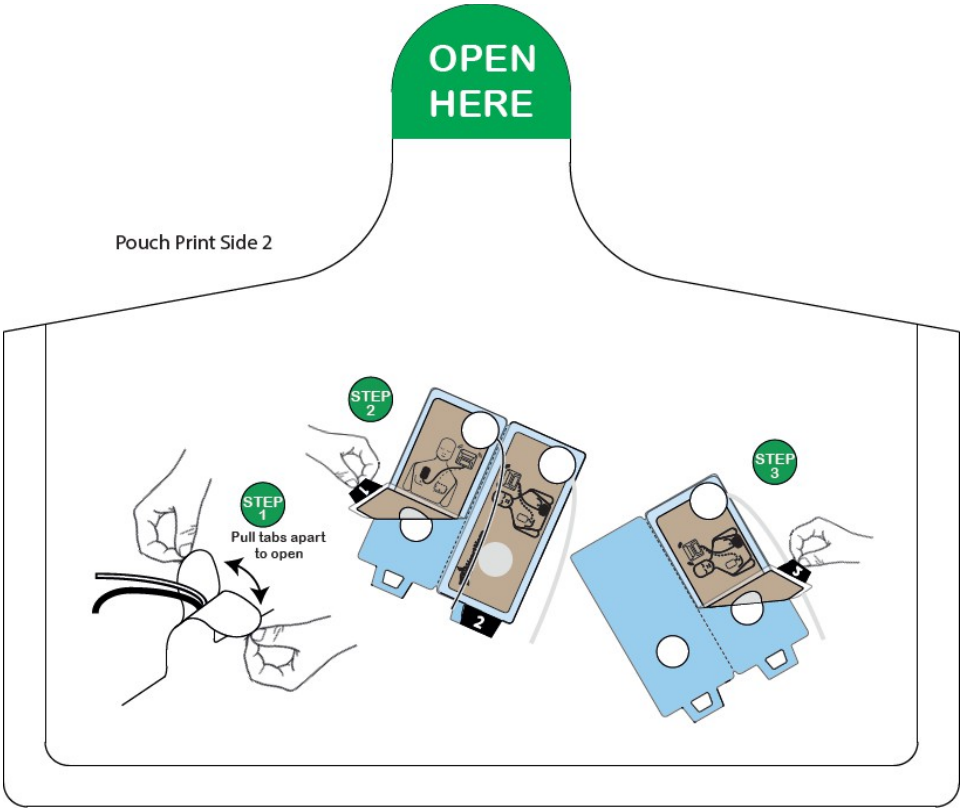


Figure 6 Electrode Package Instructions

The electrodes have images shown below to show proper placement on an adult patient.

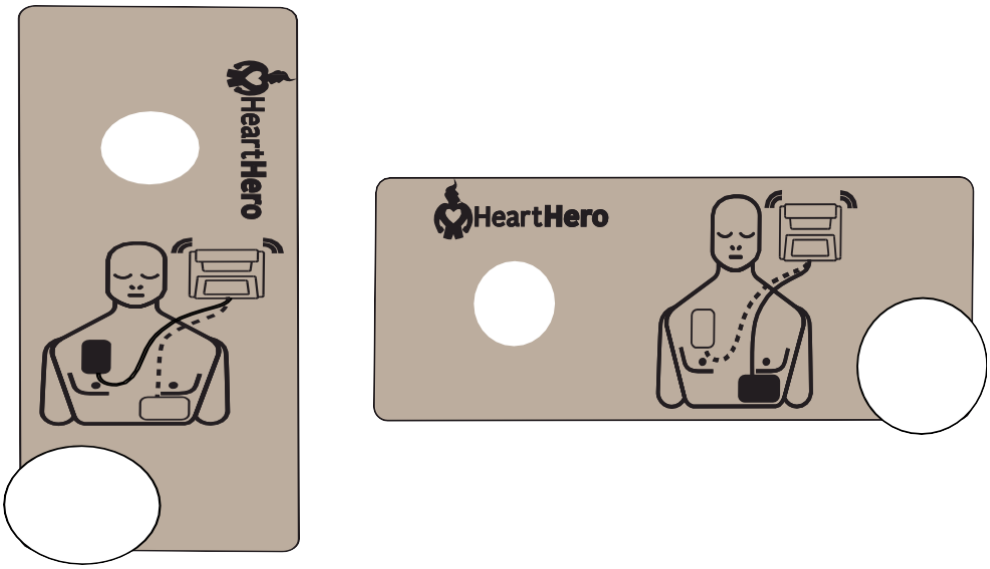


Figure 7 Electrode Placement Instructional Image

1.7 Sudden Cardiac Arrest

Elliot is used to treat ventricular fibrillation (VF), the most common cause of sudden cardiac arrest (SCA).

Defibrillation does not ensure survival, regardless of how soon treatment is administered. Cardiac arrest causes are occasionally not survivable despite all available care.

1.8 Indications for Use

The HeartHero AED is indicated for use on suspected adult or pediatric victims of sudden cardiac arrest. Patients in sudden cardiac arrest are unresponsive and not breathing or not breathing normally. The device is intended to terminate ventricular fibrillation and pulseless ventricular tachycardia.



CAUTION: Federal law restricts this device to sale by or on the order of a qualified healthcare professional.

1.9 Contraindications



CAUTION: Do not use near an MRI.

1.10 Safety Warnings and Cautions

It is important to understand how to use Elliot safely. Please read these warnings and cautions carefully.



WARNING: A warning describes something that could cause serious personal injury or death to the user or others.



CAUTION: A caution describes something that could cause minor personal injury, damage to Elliot, loss of data stored in Elliot, or less chance of successful defibrillation.

Note: Only HeartHero may service this equipment. Refer all servicing to HeartHero support.

	**WARNING:**	If Elliot is used to give a shock in the presence of flammable gases such as in an oxygen tent, there is a risk of explosion. Move supplemental oxygen and oxygen delivery devices away from the defibrillation pads. (However, it is safe to use Elliot on someone wearing an oxygen mask.)
	**WARNING:**	Shock Hazard: Do not touch the patient unless instructed to place or check the electrode pads or perform CPR with the device.
	**WARNING:**	Keep Elliot and batteries out of the reach of pets and small children.
	**WARNING:**	Elliot batteries are not rechargeable. Do not try to recharge, open, crush, or burn the battery, or it may explode or catch fire.
	**WARNING:**	Using damaged or expired equipment or accessories may cause Elliot to perform improperly, and/or injure the victim or user.
	**WARNING:**	Do not let the pads touch each other or other electrodes, lead wires, dressings, medicine patches, etc. while placing them on the patient. Such contact can cause electrical arcing and skin burns during a shock and may also divert the electrical current away from the patient's heart. During a shock, air pockets between the skin and pads can cause skin burns. To help prevent air pockets, make sure pads stick well to the skin. Do not reuse pads or use driedout pads because they will not provide good contact with the skin.
	**WARNING:**	Before delivering a shock, it is important to disconnect the patient from other medical electrical equipment, such as blood-flow meters, that may not incorporate defibrillation protection. In addition, make sure the pads are not in contact with metal objects such as a bed frame or stretcher.
	**WARNING:**	Performing CPR or otherwise handling or moving the patient while Elliot is analyzing heart rhythm can cause an incorrect or delayed analysis. If Elliot tells you to keep the patient still while you are handling or moving the patient, stop the vehicle or CPR and keep the patient as still as possible for at least 15 seconds. This will give Elliot time to reconfirm the analysis before proceeding with defibrillation if necessary.
	**WARNING:**	Do not use the AED in locations where large electromagnetic or RF fields are expected to occur. Keep equipment like emergency two-way radios and cell phones only as close as necessary to the patient and Elliot during use. Refer to Electromagnetic Compatibility declarations below for additional information
	**WARNING:**	Do not allow the pads to contact other electrodes or metal parts that are in contact with the patient.
	**WARNING:**	Do not place Elliot on patient. Only the pads should contact the patient during use.

	**WARNING:**	Electrical shock hazard. Do NOT open Elliot, remove its covers, or attempt a repair. There are no user-serviceable components in Elliot. If repair is required, return Elliot to an authorized service center.
	**WARNING:**	Hazardous Material Disposal Device batteries are not user-serviceable or rechargeable. For replacement and disposal instructions, contact HeartHero support.
	**WARNING:**	Hazardous Material Disposal Device batteries are not user-serviceable or rechargeable. For replacement and disposal instructions, contact HeartHero support.
	**WARNING:**	The use of accessories other than those sold by HeartHero may result in increased emissions or decreased immunity of Elliot.
	**CAUTION:**	Elliot was designed to be sturdy and reliable for many different use conditions. However, handling Elliot too roughly can damage it or its accessories and will invalidate the warranty. Check Elliot and accessories regularly for damage, according to directions. Improper maintenance may damage Elliot or cause it to function improperly. Maintain Elliot according to directions. Do not open or attempt to open Elliot's sealed enclosure.
	**CAUTION:**	Comply with local regulations when recycling or disposing of Elliot components, consumables, and accessories.
	**CAUTION:**	When moving Elliot from temperature extremes outside of the operating limits to an area within the operating limits, allow at least 10 minutes to ensure that Elliot has adjusted to the operating temperature.

1.11 Who Should Use Elliot

The Elliot AED is intended to be used by personnel who are familiar with the operation of the device and the warnings and precautions in this manual.

1.12 Training

Users should have a thorough understanding of the procedures, warnings, and precautions in this Manual.

1.13 Local Requirements

Check with your state health department to see if any local or state requirements exist regarding defibrillator use, training, and ownership.

1.14 For More Information

Contact your local HeartHero distributor for additional information about Elliot.

Your distributor can answer any questions you may have.

A copy of this document is also available online at www.hearthero.com.

FUNCTIONS

2. Setting Up Elliot

Do not operate Elliot **until you fully understand** all warnings, cautions, and conditions for use. If you have any questions, contact HeartHero support.

2.1 Package Contents

Check the contents of the Elliot box to be sure it contains the following items.

Part	Qty	MFR	Part Number
Elliot AED	1	HeartHero	HH0527
Batteries (pre-installed)	4	Duracell	CR123A
Electrode Pads Cartridge (pre-installed)	1	HeartHero	HH1210
Elliot box printed with Quick Start Instructions	1	HeartHero	MSC-1690

2.2 Getting Started

NOTE: Always store Elliot with a set of pads connected and batteries installed, so it will be ready to use.

Setting up Elliot is quick and easy.

Unpack the device and accessories carefully and visually inspect for damage. If any physical damage is found, DO NOT USE THE DEVICE. Contact HeartHero for a replacement.

After checking the Elliot box contents to make sure it is complete, perform the following steps to get Elliot up and running.

Elliot ships ready to use, but in sleep mode. It will remain in a sleep state until the user presses the green ON Button.

1. Wake up the device by pressing the green ON Button. Elliot will introduce itself and perform a power on self-test. After all testing is complete and passed successfully the unit will respond with the Ready to Help audio prompt.

2.3 Elliot Configuration

NOTE: When Elliot is configured with certain settings, the battery life will be shorter. This includes the Discoverable setting.

2.4 Recommended Accessories

NOTE: It is a recommended practice to keep a spare set of pads and a spare set of batteries.

CAUTION: Elliot is only designed to be used with HeartHero specified accessories. Attempting to use other accessories may cause Elliot to function improperly.

The following table lists other useful accessories to carry.

Accessory	Description
Disposable Gloves	To protect the user.
Disposable Mask	
Scissors	For cutting the victim's clothes, if necessary.
Disposable Wipes/Cloths	To wipe and dry the victim's skin for good pad contact, if necessary.
Disposable Razor	To shave the victim's chest for good pad contact, if necessary.

3. Using Elliot

There are two basic steps to using the defibrillator to treat someone who may be in sudden cardiac arrest:

1. Press the ON Button or Pull the red handle to remove the pads from the device.
2. Follow Elliot's voice prompts. See section 1.5, "Voice Prompts" for a full list of all voice prompts.

See section 3.2, "Procedure for Use" for detailed procedures.

If the victim is an infant or child, see section 3.1, "Treating Infants and Children".

The pads' placement is very important. The pad placement indicators (see Figure 4) on the Elliot user interface initially illuminate to help guide you. Place the pads on the patient's bare skin exactly as shown on the pad placement indicators and press the adhesive portion of the pad down firmly.

As soon as Elliot detects that the pads are attached to the patient, the lights on the pad placement indicator turn to green if properly attached; to yellow if the pads have been improperly placed. As soon as the pads have been properly attached to the patient, Elliot begins analyzing the patient's heart rhythm. At this point, Elliot tells you that no one should be touching the patient.

If Elliot determines that a shock is needed:

- The Shock light illuminates in yellow, and Elliot issues an audio warning to not touch the patient and a countdown to when the shock will be delivered. A visual warning also appears to warn you not to touch the patient.
- Immediately following the shock, Elliot announces that the shock has been delivered, and to start CPR, and to push hard and fast in the center of the chest. A metronome now plays a beat to time the frequency of the CPR chest compressions.
- Continue to follow the audio prompts until EMS help arrives.

If Elliot determines that a shock is not advised:

- Audio and visual prompts indicate that a shock is not advised
- Begin CPR if prompted by pushing hard and fast in the center of the chest. A metronome will play a beat to time the frequency of the CPR chest compressions.
- Continue to follow the audio prompts until EMS help arrives.

3.1 Treating Infants and Children

Press the **Child Mode** button if the patient is under 55 lbs./25 kg. The button displays the child highlighted in white, as shown in the following figure when Elliot is in Child mode.



Figure 8 Child/Adult Mode Button in Child Mode

It is important to be sure that Elliot is in Child mode when treating a pediatric or infant patient, as Elliot will give different prompts appropriate for treating a child, as well as administer a lowered shock energy level, if applicable.

NOTE: The Child mode selection should be made after entering Treatment Mode and before placing the pads on the patient.

3.2 Procedure for Use

Use the following steps to deploy and use the Elliot AED. It is recommended to first familiarize yourself with section 1.3, "User Interface Layout/Controls", and section 1.5, "Voice Prompts" before performing these steps.

The icons on Elliot's user interface will illuminate, and if appropriate, blink to help guide you. The pad placement indicators (see section 1.3) on the Elliot user interface initially illuminate to help guide you. Place the pads on the patient's bare skin exactly as shown on the pad placement indicators and press the adhesive portion of the pad down firmly.

NOTE: Press the Language button to toggle between a primary and secondary language.

To use Elliot:

1. **Press the ON (Power) green button or Pull the red handle/pull tab to turn Elliot on and to deploy the pads.** This action initiates what is referred to as "Treatment mode", and the system will begin associated audio and visual prompts. The System OK indicator light blinks green to let you know the system is on.

2. **Follow the voice prompts.** You will be directed to do the following:

NOTE: Expose the victim's chest. Cut or rip the clothing from the victim's chest in order to place the pads. You must place the pads directly on bare skin.

   a. **Open the white pouch, separate both pads from the blue liner, and place on bare chest.** On Elliot's user interface, the Pad Placement indicator lights illuminate to call out where you need to place the pads. The white pouch must be peeled open using the tab near where the wires exit the pouch. Then both pads must be peeled completely from the blue liner and the blue liner set to the side. The pads are to be placed according to the images on the pads or Elliot user interface.

   b. **If the victim is an infant or child (under 55 lbs./25 kg.)**, press the Child button. An audio prompt alerts you that you are in Child mode. For an adult patient, press the button again. Elliot issues an audio verification that you are in Adult mode. See Figure 2 for **Adult/Child** button information.

   c. You are again reminded to separate pads from the blue liner and place them on bare chest until Elliot detects this has been performed.

   d. An audio alert informs you that Elliot is now analyzing the patient's heart rhythm. Visual and audio cues tell you to **stay clear of the patient while Elliot performs the analysis.**

e. If the system determines a shock must be delivered to the patient, the system then delivers a shock with an audio warning of "shocking in 3, 2, 1," and the Shock indicator illuminates.

f. The system issues an audio prompt that the shock has been delivered, and to **start CPR now**. Audio and visual prompts guide you on how and where to perform chest compressions, and a CPR rate rhythmic sequence of beats guides you on the frequency that chest compressions should be conducted.

g. An audio prompt tells you to **continue performing CPR to the beat of the clicks**, that it is 30 seconds until the next heart rhythm check, and to **push hard and fast in the center of the chest.**

h. Elliot informs you that it is now 15 seconds until the next heart rythm check.

i. Continue to follow voice prompts until EMS arrives.

3.3 Reminders

The following helpful reminders aid in maximizing Elliot's effectiveness.

- Remove any existing patches from the patient's chest that may interfere with direct pad placement with skin, and clean residual adhesive before applying pads.
- Dry the patient's chest if possible to improve pad adhesion and prevent possible burns to the patient's skin.
- Place pads exactly as directed by the Pads Placement indicators, and do not place the pads directly over an implanted pacemaker or defibrillator.
- Do not allow the pads to come into contact with metal (such as necklaces) on the patient.
- Keep the patient still during heart rhythm analysis.
- Stay clear of the patient or the pads while the Shock indicator is illuminated.
- Simply remove the pads from the patient to disengage the defibrillator during use to return the device to standby mode.
- Ensure that expired pads are replaced when indicated to prevent problems with the pads adhering to the patient's chest.
- Replace batteries when indicated or after each use.

4. After Using Elliot

4.1 After Each Use

After each use, be sure to replace used pads with a new Electrode Pad Cartridge. Also replace the batteries. See sections Replacing Batteries and Replacing Pads for directions on how to replace these items.

Be sure to perform the following simple maintenance steps to ensure that Elliot is ready for the next use.

1. Perform an external inspection of Elliot. Perform a visual inspection for dirt, contamination, or damage. If contaminated, clean per Section 5.6. Ensure the device is dry and free of visible soil before storage.. If damage is detected, contact HeartHero™ for technical support advice. If you find the unit to be dirty or contaminated in any way, clean it as directed. See the "Cleaning" section for details.

2. Pads must be replaced after each use. See section Replacing Pads for the procedure to replace the pads.

3. Batteries must be replaced after each use. See section Replacing Batteries for the procedure to replace the batteries. Upon installation, the power on self-test executes to ensure Elliot is functioning properly. Following test completion, check that the System OK indicator light is blinking green.

4. Keep Elliot in its storage location so it will be ready to use when needed.

See section Maintaining Elliot for information about Elliot maintenance.

5. Maintaining Elliot

5.1 Routine Maintenance

Elliot is intended for infrequent use. See section 4.1, "After Each Use" for information on what should be checked on Elliot each time the unit is used.

Elliot is simple to maintain as the defibrillator performs daily, weekly, and monthly self-tests which eliminate the need for any manual calibration.



WARNING: Electrical shock hazard. Do **NOT** open Elliot, remove its covers, or attempt a repair. There are no user-serviceable components in Elliot. If repair is required, return Elliot to an authorized service center.

5.2 Replacing Batteries

Elliot ships with batteries pre-installed. When batteries are re-installed, the system boots and performs a power on self-test after the battery door is rotated clockwise to the closed position. The system then issues a single beep audio prompt, followed by the Hello audio prompt. The activity indicator briefly illuminates, and all LEDs briefly illuminate during the power on self-test.

After running and passing the power on self-test, the system issues an audio notification letting you know the self-test passed successfully. The activity indicator also displays a system OK (green light) notification during the voice prompt and then blinks after the voice prompt completes.

If the battery installation self-test fails, the system issues an audio prompt that the self-check failed, and provides information on corrective actions or prompts to contact HeartHero™ customer support. Additional failure-specific voice prompts will be spoken if the Information button is pressed. If the self-test fails and the device is not ready to use, the activity indicator displays a system fault (yellow) upon completion of the voice prompt.

NOTE: The battery door must be FULLY TURNED to the locking position to ensure proper contact and IP rating protection.

NOTE: The battery door must be inspected to ensure the o-ring seal is properly seated on the door to prevent damage to the o-ring when closing the battery door.

To replace batteries:

CAUTION: Batteries must be installed in a dry environment.

1. Lift the battery door tab on the battery door located on Elliot's right side and rotate the door counterclockwise until the battery door is removed. (Figure 9)
2. Remove batteries. You may need to gently tap the unit to slide out all **FOUR** batteries
3. Install new batteries, loading the negative (flat) end first. (Figure 11)



Figure 9 Lifting Battery Door Handle



Figure 10 Removing Battery Door

NOTE: Elliot requires four (4) CR123A Duracell non-rechargeable batteries.



Figure 11 Replacing Batteries

4. Replace the battery cover. Rotate the battery door clockwise until snug and Elliot powers back on. Make sure the battery door tab lines up like Figure 9.

5. Elliot will complete its self-test to ensure the batteries are properly installed and the system is functioning properly.

6. Elliot issues audio and visual prompts in response to battery installation events.

When batteries are installed, the system reboots and performs a battery install self-test following battery installation. The system then issues a single beep audio prompt, followed by "Hello, I am Elliot, your personal, adult, and child life-saving device. I am to be used if someone is unconscious and not breathing normally. I am here to help." The activity indicator briefly illuminates white, and all LEDs briefly illuminate during the battery install self-test.

After running and passing the battery install self-test, the system issues an audio notification letting you know the self-check passed successfully. The activity indicator also displays a system OK (green light) notification during the voice prompt and then blinks after the voice prompt completes.

If the self-test fails, the system issues an audio prompt that the self-check failed and instructs the user to contact HeartHero support. Additional failure-specific voice prompts follow. During the duration of the voice prompt, the activity indicator displays a system fault (yellow) and then blinks upon completion of the voice prompt.

5.3 Replacing Pads

Contact HeartHero™ to order replacement pads. It is advised that you always keep an extra set on hand.

Pads are housed in the Electrode Pad Cartridge, which is shown in the following images. Replace the Electrode Pad Cartridge if:

- Pads have been used
- Electrode Pad Cartridge is damaged
- Pads are beyond their expiration date
- Pad Quality self-test fails (Elliot will prompt to replace pads)

To replace the Electrode Pad Cartridge:



CAUTION: The Electrode Pad Cartridge must be replaced in a dry environment. Remove any moisture from the cartridge and AED contacts before installing the cartridge.

1. **ONLY** HeartHero pads can be used with Elliot. No other brand pads will work with Elliot.
2. To prevent Elliot going into Treatment Mode and unnecessary audio prompts, remove the battery door as shown in the picture below. (Figure 12)



Figure 12: Removing Battery Door

3. Turn Elliot over and pull out the red handle/pull tab all the way as shown in Figure 13.



Figure 13: Pull red handle and slide cartridge



Figure 14: Remove Connector

4. Remove pad connector by pinching inward the release lever at the toe of the connector (opposite end of the wires).



Figure 15: Clicking in new Pad Cartridge

5. Lift up the toe end of the connector by the release lever. Rotate the connector upward until the rubber gasket clears the recessed area and the heel end tab of the connector (nearest the wires) is able to be removed from the connector heel catch.

6. Inspect the new cartridge connector and ensure that it is dry and clean.

7. Install the new Electrode Pad Cartridge by reversing the removal steps above.

8. Align the new cartridge to the rails in the back of Elliot and slide partially into place. Make sure the connector is clear and not underneath the pad cartridge.

9. Attach the pad connector by holding the connector at a 45° to 60° angle with the toe end of the connector pointed up.

10. Insert the heel end tab into the heel catch on Elliot and gently rotate the connector down into the connector tub on the back of Elliot. Be careful to make sure the rubber gasket slips fully into the tub and does not roll out of the tub.

11. Fully seat the connector by latching the toe release lever until it locks in the catch at the toe end of the connector.

12. Making sure no wires are pinched, fully slide the pad cartridge in until it locks in place and all seams are aligned.

13. Turn Elliot onto its back and close the red handle making sure the red handle aligns flush with the front housing.

14. Reinstall the battery door and turn it clockwise until snug (Note: make sure the battery door tab lines up as shown in **figure 9**) and Elliot powers back on. Elliot will complete its self-test to ensure the pads were properly installed.



Figure 16: New Pad Cartridge Installed

5.4 Self-Tests

A self-test occurs daily, weekly, and monthly, when a device is powered on. When the device is powered on, there is an audio beep, and all device LEDs illuminate briefly.

When all self-tests have passed, the System OK indicator light (button) blinks green to indicate the system is OK.

If there is a failure during a critical self-test, there will be an audio chirp every 30 seconds, and the System Fault indicator will blink yellow. If this occurs, press the Information button for additional information about the failure.

In the event there is a non-critical failure during a self-test, the Non-Critical Fault indicator (Information button) blinks yellow. If this occurs, press the Information button for additional information about the failure.

5.5 Periodic Checks

Beyond the checks recommended after each use of Elliot (see section 4.1, "After Each Use"), maintenance consists of periodically checking the following:

1. Check that the green System OK light is blinking. If the light is not blinking, replace the batteries (see section Replacing Batteries)

2. Replace any used, damaged, or expired supplies and accessories.

3. Inspect the outside of the unit for cracks or other signs of damage.

5.6 Cleaning



CAUTION: Do NOT sterilize Elliot or any of its accessories.



WARNING: Avoid applying excess liquid to the device, as it may seep into unsealed seams or crevices and damage internal components. Do not immerse the device in any cleaning liquid.

It is important to keep the Elliot AED clean to ensure proper performance. Ensure that the battery door is closed. Cleaning should only occur while the battery door is in place. Clean Elliot's outside with a soft damp cloth with soapy water, hydrogen peroxide solution (mixed to the proportion of two tablespoons per quart or liter of water), ammonia-based cleaners, or 70% Isopropyl Alcohol (rubbing alcohol). After cleaning, visually inspect the device for any remaining soil or residue. The endpoint is no visible contamination. If visible soil remains, repeat the cleaning process. Allow the device to air dry completely at room temperature before use or storage to prevent moisture-related damage.

NOTE: Do not use strong solvents like acetone-based cleaners, anything abrasive, or enzymatic cleaners on Elliot or its accessories.

5.7 Storage After Cleaning

Store the device in a clean, dry environment away from extreme temperatures or humidity to maintain readiness.

5.8 Recycling



WARNING: Hazardous Material Disposal
Device batteries are not rechargeable. Properly dispose of batteries according to local regulations.



CAUTION: Comply with local regulations when recycling or disposing of Elliot components, consumables, and accessories.

Remove batteries before disposal. You may return components to HeartHero™ for recycling or disposal if desired. Contact HeartHero support to arrange for this service.

5.9 Troubleshooting

Press the Information button to hear Elliot's status.

Observation	Voice Prompt (when info button is pressed)	Action
No System OK light	N/A	1. Check that the battery door is in place and the arrows line up. 2. Replace the batteries. 3. If there is no response, contact HeartHero™ customer support.
During Use, Apply Pads Icon Lights Up	"Pads Off. Check Pads" OR "Pads Off. Check Pads. If system is no longer needed, press and hold Info Button to turn off" OR "Pads Off. Check Pads. If I was just used, please bring me to the hospital with the patient."	1. Elliot no longer detects that the patient is connected. Check the pads to make sure a cable has not broken or come loose. 2. If unable to resolve the issue, continue CPR.
During Treatment after analyzing patient's heart rhythm, prompted that Elliot cannot analyze	"Cannot analyze the patient heart rhythm. Too much movement."	1. Movement of the patient or pressing on the pads can prevent analysis. Ensure the patient is as still as possible, then stop touching the patient. 2. If unable to resolve the issue, continue CPR.
During battery install, yellow blinking System Fault indicator	"Self-check completed. Problem found. Please review the user manual or contact customer support."	1. Contact HeartHero™ customer support.
	"Self-check completed. Problem found. The battery is low. Replace the batteries now."	1. Replace the batteries. NOTE: The AED will still attempt to perform its functions and should be used if needed, but batteries must be replaced as soon as possible to ensure that it will function if needed.
	"Self-check completed. Problem found. The Pad cartridge is not installed. Install the Pad cartridge."	1. Ensure the Electrode Pad Cartridge is installed properly. 2. If not responding, remove the Electrode Pad Cartridge and make sure that there is nothing obstructing the connector from making contact.

Observation	Voice Prompt (when info button is pressed)	Action
Yellow Blinking Information Button	“The battery is low. Replace the batteries now.”	1. Replace the batteries. NOTE: The AED is still able to be used if needed, but new batteries should be obtained.
	"You are out of range of cellular connection. I can still be used, but I cannot notify emergency services if the device is used." **Warning**: The device will not automatically alert Emergency Medical Services (EMS). You must call EMS immediately to obtain emergency medical assistance.	1. No action required. The device cannot connect to a cellular network. It may still be used, but emergency services must be contacted separately.
	“Hmm. Pads expired. Please replace the pads cartridge”	1. Replace the Electrode Pad Cartridge via the instructions above. 2. NOTE: The AED will still attempt to perform its functions and should be used if needed, but pads must be replaced as soon as possible to ensure that it will function if needed.
	“There is a problem with the device system. Please review the user manual or contact customer support.”	Contact HeartHero™ customer support.
System Fault blinking and Chirping sound	“The Pad cartridge is not installed. Install the Pad cartridge.”	1. Ensure the Electrode Pad Cartridge is installed and snapped into place. If not responding, remove the cartridge and make sure that there is nothing obstructing the connector from making contact.
	“There is a problem with the device system. Please review the user manual or contact customer support.”	1. Contact HeartHero™ customer support.
Pulled red tab and AED did not turn on or has System Fault indicator illuminated	"Not able to deliver a shock. Ensure emergency services have been called and start CPR."	1. Perform CPR. The AED will continue CPR coaching, but will not deliver a defibrillation shock.

5.10 Support, Repairs, and Documentation

If you have a question, please:

- For urgent issues, contact HeartHero immediately.
- For non-urgent issues, do the following before contacting HeartHero:
    - **Isolate the problem.** Try to repeat and define the problem.
    - **Document the problem.** Carefully record the symptoms of the problem.
    - Report the problem. Contact HeartHero.

Technical Support web page	www.hearthero.com
Email Technical Support	support@hearthero.com
Address	 HeartHero, Inc. **3200 Cherry Creek S Drive Suite 470 Denver CO, 80209, USA**

6. Technical Information

6.1 Transport and Storage Conditions

Environmental conditions for the transport and storage of Elliot:

Condition	Storage/Transport
Shipping/Storage temperature	-40˚ to 70˚C (-40˚ to 158˚F)
Shipping/Storage humidity	10% to 95% non-condensing
Shipping/Storage altitude/atmospheric pressure	5,000 m (16,400 ft) maximum / 405 mmHg
Ambulance Use	Fixed wing and rotary aircraft and ground vehicles

6.2 Use Conditions

Environmental conditions for the use of Elliot:

Condition	Environment
Operating temperature	-20˚ to 50˚C (-4˚ to 122˚F)
Relative operating humidity	15% to 90% non-condensing
Operating altitude/atmospheric pressure	5,000 m (16,400 ft) maximum / 405 mmHg

6.3 Technical Characteristics

Technical conditions for the use of Elliot:

Characteristic	Description
General	
Operation	Fully automatic AED (pull pads to turn on and begin analysis)
Device Self-checks	Power On, Daily, Weekly, Monthly, and Pre-Treatment self-test
Characteristic	**Description**
Independent Adult & Pediatric Energy Protocols	Adult: 150J Pediatric: 50J
CPR Support	Prompts and rate metronome
AED dimensions	6.10” x 6.24” x 1.80” (15.50 cm x 15.85 cm x 4.58 cm)
Weight w/Battery and Pads	1.5 lbs. (0.68kg)
Weight	1.1 lbs. (0.5kg)
Ingress Protection (IP) Rating (Dust/Moisture)	IP66
Expected Service Life	6 years with periodic battery and electrode replacement
Controls and Indicators	
CPR Time – Countdown Timer during which CPR is to be Performed	120 seconds (default)
Voice Prompts	Yes
Visual Prompts	LED icons
Rescue Battery Indicator	Yes
Low Battery Indicator	Yes
Battery capacity Gauge	No
Defibrillation Waveform	
Waveform Type	Biphasic Truncated Exponential (BTE) with duration compensation for patient impedance
Minimum Patient Impedance Range	25 ohms
Maximum Compensated Patient Impedance Range	200 ohms

Energy Output	Adult: 150J (+/-15% into 50Ω load) Pediatric: 50J (+/-15% into 50Ω load)
Synchronous Energy Delivery	Yes, Synchronized energy delivery for Ventricular Tachycardia with-in 60ms of the peak of the R-wave.
Analysis Algorithm	
Arrythmia Detection	Shockable rhythms:
Characteristic	**Description**
	VF (P-P amplitude of > 160 uV) Fast VT (HR > 160 bpm adult); (HR > 200 bpm pediatric)
Analysis during CPR	No
Power and Communications	
Battery Type	Four Duracell 3V CR123A lithium primary batteries.
Battery Capacity	20 shocks and 40 minutes run time at 20°C after 3 years of stand-by.
Battery Service Life	3 years
Charge Time from Pads on Patient	25s with new batteries
Charge Time from “Stand Clear” Warning	5s with new batteries
Charge Time from Power On	35s with batteries depleted by 6 charges
Electrodes	
Electrode Pads	Self-adhesive; single-use
Pre-Connected Electrodes	Yes
Electrode Shelf Life	5.5 years (1 year storage life prior to deployment + 4.5 year life installed in device)
Data Storage and Transmission	
Fixed Internal Memory	Yes
Internal Data Storage Capacity	1Gb internal Flash memory
Removable Memory	No
Ability to Store Multiple Events	Yes, up to 8 separate treatment summaries

6.4 Essential Performance

The essential performance of the HeartHero Elliot AED is defined per IEC 60601-2-4 as follows:

- Deliver Defibrillation Therapy
- Accurately Differentiate between Shockable and Non-Shockable Rhythms

6.5 Symbols

Symbols used on Elliot, its accessories, packaging and in this manual:

Symbol	Description	Symbol	Description
	Imminent hazard		European conformity
	Caution		EU authorized representative
	Manufacturer		Refer to instruction manual/ booklet
	Manufacture Date		Fragile, Handle with Care
	Keep dry		Type BF Applied Part
	High Voltage		Waste Electrical and Electronic Equipment (WEEE)
	Temperature Limits		Prescription Only
	Humidity Limits		Pressure limits
	Recyclable		Lot Number
	Federal Communications Commission		Do not use if package is damaged
	Non-Sterile		Not made with Latex
	Single Use		Expiration Date
	Serial Number		Model Number

6.6 Analysis Algorithm

The waveform detection algorithm has the following sensitivities and specificities.

Pediatric Waveform Detection Performance

Rhythms	Required Performance	Measured Performance
Shockable		
Rhythms	**Required Performance**	**Measured Performance**
Coarse VF	>90% sensitivity	96% sensitivity
Rapid VT	>75% sensitivity	100% sensitivity
Nonshockable		
NSR	>99% specificity	100% specificity
AF, SB, SVT, heart block, idioventricular, PVCs	>95% specificity	97% specificity
Asystole	>95% specificity	100% specificity

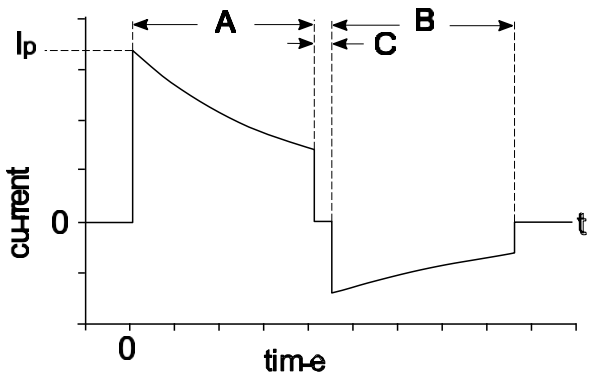
Adult Waveform Detection Performance

Rhythms	Required Performance	Measured Performance
Shockable		
Rhythms	**Required Performance**	**Measured Performance**
Coarse VF	>90% sensitivity	100% sensitivity
Rapid VT	>75% sensitivity	96% sensitivity
Nonshockable		
NSR	>99% specificity	100% specificity
AF, SB, SVT, heart block, idioventricular, PVCs	>95% specificity	98% specificity
Asystole	>95% specificity	98% specificity

6.7 Defibrillation Specifications

6.7.1 Waveform

The Elliot defibrillation waveform is a biphasic truncated exponential. The waveform phase duration automatically adjusts as a function of patient transthoracic impedance. In the diagram, A and B are the durations of phase 1 and phase 2, respectively. C is the interphase delay (500 µs). Ip is the peak current.



Elliot delivers defibrillation therapy to patient load impedances within the range of 25 to 200 ohms.

ADULT Waveform Characteristics (150J +/- 15%)

Impedance (Ω)	Phase 1 Pulse Duration (msec)	Phase 2 Pulse Duration (msec)	Peak Current (A)	Delivered Energy (J)
25	2.8	2.8	58.9	133
50	4.5	4.5	32.7	149
75	6.3	5	22.6	151
100	8	5.3	17.3	151
125	9.7	6.4	14	151
150	11.5	7.7	11.8	152
175	12	8	10.2	148

Pediatric Waveform Characteristics (150J +/- 15%)

Impedance (Ω)	Phase 1 Pulse Duration (msec)	Phase 2 Pulse Duration (msec)	Peak Current (A)	Delivered Energy (J)
25	2.8	2.8	34.4	46.4
50	4.5	4.5	19.3	51.1
75	6.3	5	13.5	52
100	8	5.3	10.3	51.8
125	9	6	8.4	51.2
150	9	6	7.1	49
175	9	6	6.2	46.7

7. Cybersecurity Information for users

This section provides cybersecurity information to help users and responsible organizations deploy and operate the Elliot AED securely and to understand their responsibilities in maintaining the device's security. It complements clinical and safety instructions and is informed by the FDA's cybersecurity guidance for premarket submissions and postmarket management.

7.1 At a high level, users are required to:

- Maintain physical control of the Elliot AED and accessories
    - Inspect it for tampering before use.
- Only use supported iOS devices and recommended networking hardware.
    - Minimum iOS versions are specified by the app
- Maintain HeartHero iOS app and Elliot AED firmware
    - Update software and firmware when updates are made available
- Report suspected cybersecurity issues to HeartHero
    - Contact information provided below

7.2 Connectivity and Interfaces

- Wireless interfaces include:
    - Bluetooth Low Energy (BLE) to the HeartHero iOS Mobile App
    - Elliot AED LTE cellular connection to HeartHero Cloud services
    - iOS Mobile App Wi-Fi or cellular connection to HeartHero Cloud services
        - HeartHero recommends connecting to known access points via WPA3
- Elliot AED local interface includes physical controls, audio, and visual indicators
- No network services are exposed for clinical use
    - Pairing and management of the Elliot AED occurs via the HeartHero Mobile App via BLE, which requires physical access to AED
    - Elliot AED connectivity to HeartHero Cloud services is via outbound RESTful API over HTTPS
- External data paths include:
    - Elliot AED ↔ HeartHero Mobile App (BLE)
    - Elliot AED ↔ HeartHero Cloud Service (LTE)
    - HeartHero Mobile App ↔ HeartHero Cloud Service (Wi-Fi or cellular on the mobile device)
- Operate the AED in environments where wireless communication such as LTE, BLE, and Wi-Fi are permitted and managed per your organization's policies.

7.3 User Managed Devices

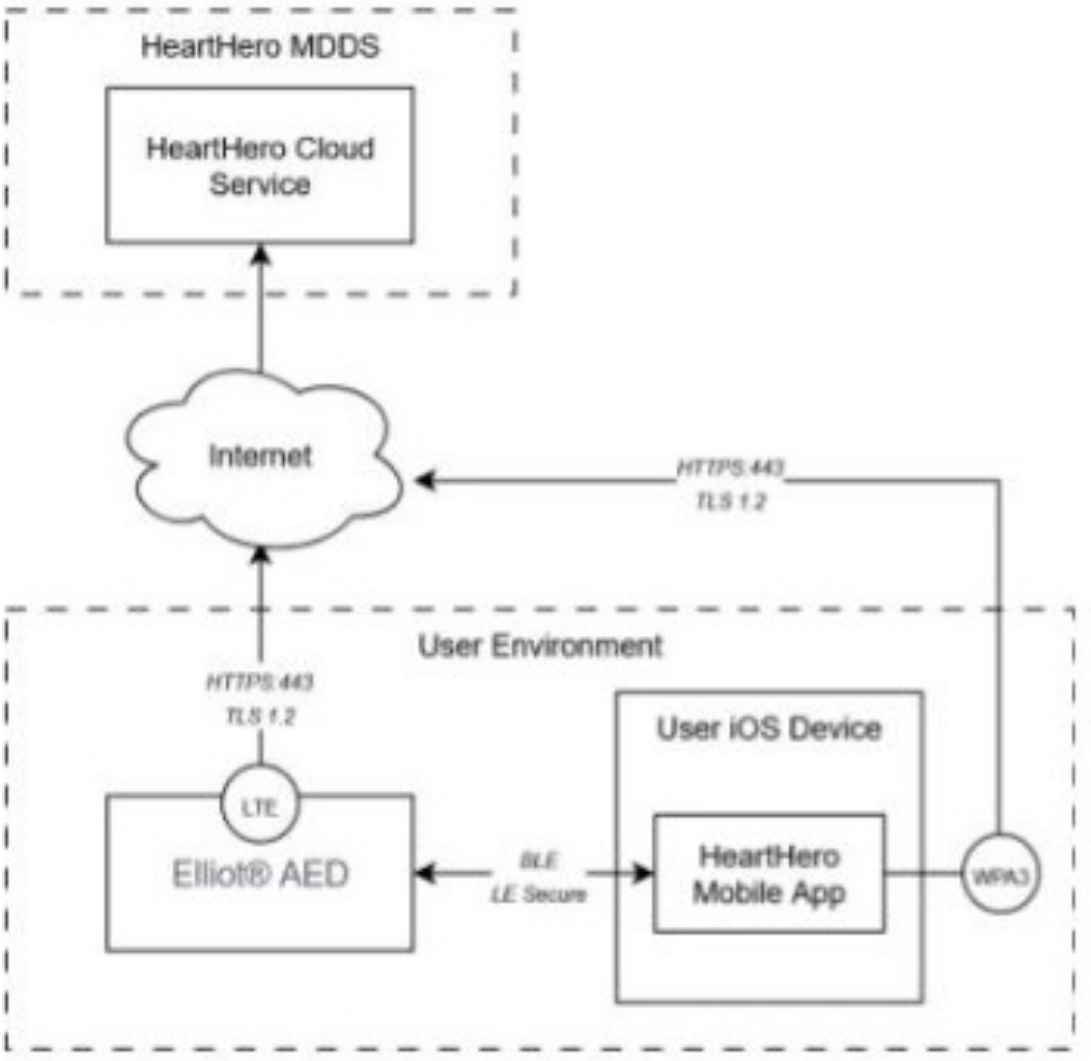
- External iOS device version and web browser support:
    - iOS app: HeartHero AED on iOS 15 or later
    - Web browsers for cloud portal (if used by operators): Latest versions of Chrome, Edge and Safari
- HeartHero tests and supports the versions listed above; use outside these parameters may reduce security or functionality.

7.4 Data Handling and Privacy

- The following data is processed by the Elliot AED system:
    - Device event data and logs
        - Timestamps, status codes, self-test results, and movement events
    - Physiological data
        - ECG waveform segments acquired during use
    - Identifiers/metadata
        - Elliot AED ID, app user account identifiers
    - User, organization, account, and configuration data
- Backup are stored in the cloud at a daily basis

7.5 Data Transmission and Storage Security

- Data in transit is secured dependent upon communicating devices:
    - TLS 1.2 is enforced between the HeartHero Mobile App and the Cloud
        - HTTPS over port 443
    - TLS 1.2 is enforced between the Elliot AED and the Cloud
        - HTTPS over port 443
- Data at rest is secured dependent upon the device:
    - Elliot AED stored data is not electronic PHI and is not encrypted
    - HeartHero Mobile App data is sandboxed by iOS
        - HeartHero strongly recommends that users enable iOS data protection by setting a passcode which subsequently enables encryption at rest
- The figure below illustrates the Elliot AED product and supporting systems, their connectivity and data flow, and the ports and services that enable communication between them.



7.6 Access Control and Authentication

- App sign-in and cloud access require authenticated user accounts
    - Do not share user credentials
    - Follow NIST 800-63B when choosing a pin/password
- BLE pairing requires physical access to the Elliot AED to enable the paring process
    - Do not share user credentials
    - Follow NIST 800-63B when choosing a pin/password
- The user is responsible for enforcing physical access control, tamper validation, and other controls such as locking their iOS device to minimize spoofing, tampering, and denial of service threats.

7.7 Software Maintenance, Updates, and Upgrades

- Elliot AED firmware is updated via an over-the-air (OTA) mechanism triggered by the iOS app or LTE connection when HeartHero makes updates available
- iOS App is maintained by the user via the Apple App Store
- Cloud service is maintained by HeartHero.
- HeartHero strongly recommends that users apply firmware and software updates as soon as they're available to patch defects, mitigate vulnerabilities, improve performance, etc.
    - HeartHero publishes security advisories and release notes for security-relevant changes
    - HeartHero intends to provide security patches until End of Support (EOS) on 12/17/2025
        - After EOS, connected features and security updates may no longer be provided; plan for device replacement or offline operation per organizational policy.

7.8 Logging and Audit

- Elliot AED and supporting systems log the following data:
    - The AED device logs operational events, alerts, and (when applicable) ECG event markers.
    - The App logs pairing, configuration, update attempts, and synchronization status.
    - The Cloud logs device management actions, user account operations, API access.
- Data is sent to the HeartHero Cloud service and managed access for HeartHero employees and auditors is enabled through the service.

7.9 Physical Security

- HeartHero strongly recommends users to control physical access to the Elliot AED and its peripherals, including the electrode pads and battery.
- Do not use the device if physical tampering is suspected (e.g., enclosure damage, missing seals, unexpected adhesives, or altered labels).
- Follow your facility's incident procedure and notify HeartHero.

7.10 Security Best Practices

- Use the app and cloud only on supported OS/browser versions and fully updated devices
- Avoid pairing in untrusted environments.
- Confirm you are connecting to the correct Elliot AED.
- Do not connect the AED to any accessory, cable, or software not supplied or authorized by HeartHero.
- Avoid using public or unknown Wi-Fi access points or follow your organization's prescribed mobile security controls and best practices.

7.11 Decommissioning

- For the mobile application:

    1. Log in to the user's app.
    2. Navigate to the Profile section.
    3. Select Delete Account.
    4. When prompted, confirm the deletion to complete the decommissioning process.
    5. Delete application.

- For the Elliot AED device:
    - Elliot devices do not store any patient or owner-identifying information. No owner names, phone numbers, or other personal identifiers are retained on the device. As a result, decommissioning a unit does not require any data-wiping procedures related to personal information.

7.12 Coordinated Vulnerability Disclosure

HeartHero monitors, identifies, and addresses postmarket cybersecurity vulnerabilities and provides reasonable assurance of continued device security. Users and researchers can report suspected vulnerabilities via the Product Security page and security contacts below. HeartHero follows a Coordinated Vulnerability Disclosure (CVD) process and publishes advisories, mitigations, and patch guidance.

https://www.hearthero.com/product-security

8. Regulatory Information

8.1 Regulatory Compliance

8.1.1 European Union (EU) Authorized Representative

Contact
Emergo Europe

EC REP

Mailing Address
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

8.1.2 United Kingdom Responsible Person (UKRP)

Contact

Emergo Consulting (UK) Limited

Mailing Address
Compass House, Vision Park Histon c/o Cr360 – UL International
Cambridge
CB24 9BZ
England, United Kingdom

8.1.3 Australian Sponsor

Contact

Emergo Australia

Mailing Address
Level 20 Tower II
Darling Park
201 Sussex Street
Sydney, NSW 2000
Australia

8.1.4 Notified Body

Contact

Ente Certificazione Macchine

CE 1282

Mailing Address

Via Cà Bella, 243
40053 Valsamoggia

Location Castello di Serravalle (Bo) Italy

8.2 Certifications and Classifications

For current HeartHero regulatory certifications, including CE declarations, go to www.HeartHero.com or contact HeartHero support (see section 5.10, “Support, Repairs, and Documentation”).

This medical equipment is certified to the following:

- IEC 60601-1 2005 + AMD1:2012 + AMD2:2020 (Edition 3.2)
- IEC 60601-2-4:2010 +A1:2018
- IEC 60601-1-11:2015 /A1:2020
- IEC 60601-1-2 2014 + A1:2020 (Edition 4.1)
- FCC Part 15.109 (Group1, Class B)

This medical equipment is classified as follows:

- Applied part: Type BF (defibrillator pads)
- Elliot: <MDD CLASS IIb>

8.3 EMC Interference

Elliot has been tested and found to comply with the electromagnetic compliance limits for the Medical Device Directive 93/42/EEC (EN 60601-1-2:2014 and FCC Part 15.109 (Group1, Class B)).

BLE and Cellular modules comply with FCC, ICES, and EN emissions standards.

Cellular Module: FCC ID: XMR201910BG95M3 IC: 10224A-2019BG95M3

BLE Module: FCC ID: 2AA9B04 IC: 12208A-04

These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates radio-frequency energy and, if not installed and used in accordance with the instructions, may cause interference to other devices in the vicinity. If this equipment does interfere with other devices, which can be determined by turning the equipment off and on, try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment to an outlet on a different circuit than the one used by the other devic
- Contact HeartHero™ support (see section 5.9, “Support, Repairs, and Documentation”).

Elliot must be installed and put into service according to the electromagnetic compliance (EMC) guidelines and declarations provided here.

- Electromagnetic emissions (see Table A-1) on page 49.
- Electromagnetic immunity (see Table A-2) on page 50.
- Electromagnetic immunity for non-life-supporting equipment (see Table A-3) on page 51.
- Recommended separation distances between radio-frequency (RF) communications equipment and Elliot (see Table A-4) on page 52.

NOTE: Portable and mobile RF communications equipment can affect Elliot.



WARNING: Do not use the AED in locations where large electromagnetic or RF fields are expected to occur. Refer to Electromagnetic Compatibility declarations below for additional information



WARNING: The use of accessories other than those sold by HeartHero™ may result in increased emissions or decreased immunity of Elliot.



WARNING: HeartHero equipment should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, HeartHero™ equipment should be observed to verify normal operation in the configuration in which it will be used.

Electromagnetic Emissions

Table A-1. Electromagnetic compatibility (EMC) emissions guidelines and declarations for

Elliot is intended for use in the electromagnetic environment specified below. Elliot customers or users should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment—Guidance**
RF emissions CISPR 11	Group 1	Elliot 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	Elliot is suitable for use in all establishments other than domestic 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	

Electromagnetic Immunity

Table A-2. Electromagnetic compatibility (EMC) immunity guidelines and declarations for

Elliot is intended for use in the electromagnetic environment specified below. The customer or user of Elliot should ensure 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	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
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 input lines IEC 61000-4-11	< 5% UT (> 95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) for 5 sec.	Not Applicable	Not Applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the AC mains voltage before application of the test level.			

Electromagnetic Immunity for Life-supporting Equipment

Table A-3. Electromagnetic compatibility (EMC) immunity guidelines and declarations for life-supporting equipment (such as Elliot)

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
Conducted RF IEC 61000-4-6	10 Vrms 80 MHz to 6.0 GHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of Elliot, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation:** d = 1.2√P 80MHz to 800 MHz d = 2.3√P 80MHz to 800 MHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by the electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10V/m	10V/m 80MHz to 2.5GHz 20V/m (no inadvertent energy delivery)	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

A. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which Elliot is used exceeds the applicable RF compliance level above, Elliot should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocation of Elliot.

B. Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3

Recommended Separation Distances Between Radio-frequency (RF) Communications Equipment

Table A-4. Recommended separation distances between RF communications equipment (portable and mobile) and Elliot

Elliot is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of Elliot can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Elliot as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (in watts)	**Separation Distance According to Frequency of Transmitter** (in meters)		
	150 kHz to 80 MHz d = 1.2 ÖP	**80 MHz to 800 MHz d = 1.2 ÖP**	**800 MHz to 2.5 GHz d = 2.3 ÖP**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.