Avive AED Owner’s Manual

About this Owner's Manual
This owner's manual provides information on the setup, use, maintenance, and technical specifications of the Avive AED®. This information is subject to change. Please contact Avive or visit www.avive.life/AviveAED if you have any questions.

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Copyright Statement

Patents: www.avive.life/patents

Manufacturer Info
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Caution
U.S. Federal Law restricts this device to sale by or on the order of a physician.

Avive AED Emergency Quick Reference

Avive AED Emergency Steps

Follow these steps in a cardiac arrest emergency.

1 Pull the Red Tab

2 Apply Pads

Place pads as shown.

Adult Pad Placement

Child Pad Placement

3 Stand Back

Do not touch the patient. Device will perform Automated Analysis & Treatment, if necessary.

Avive

www.avive.life

Table of Contents

1. When to Use the Avive AED®

A. Indications for Use

The Avive Automated External Defibrillator (AED) is intended for emergency treatment of individuals who are exhibiting symptoms of cardiac arrest. A person in cardiac arrest:
• Is unresponsive; and
• Is not breathing normally

The Avive AED analyzes the patient's electrocardiogram, interprets the cardiac rhythm, and automatically delivers an electrical shock to treat ventricular fibrillation or pulseless ventricular tachycardia.

The Avive AED is indicated for adult and pediatric patients over 1 years of age. When a patient is less than 8 years old, or weighs less than 55 lbs., the Avive AED should be used in Child Mode. Otherwise, the Avive AED should be used in Adult Mode. Therapy should not be delayed in order to determine exact age and/or weight.

B. Contraindications for Use

Avive® defibrillators should not be used if the patient is responsive or conscious.

C. What is Cardiac Arrest?

Cardiac arrest is when the heart unexpectedly and suddenly stops pumping blood to the body, caused by an irregular heartbeat (arrhythmia). Cardiac arrest can happen to anyone – male, female, child, or adult – and often happens suddenly, without warning signs. If left untreated, cardiac arrest will lead to death within minutes.

A defibrillation shock provides the only effective treatment for cardiac arrest. Every minute that someone in cardiac arrest does not receive a defibrillation shock reduces their survival chances, even if effective defibrillation is eventually delivered.

CPR should be performed as soon as possible on a patient in cardiac arrest, to maintain blood flow and oxygen to the brain. However, it is critical to note that CPR alone cannot return a heartbeat to a normal rhythm. The survival chances of someone in cardiac arrest is largely dependent on how soon they receive treatment from a defibrillator

Important: It is important to note that a cardiac arrest victim's chance at survival is largely dependent on how soon they receive treatment. Every minute the victim does not receive treatment, their survival chances decrease by 7-10%. Therefore, treatment from an AED cannot guarantee survival. In addition, in some cases, the root cause of the victim experiencing cardiac arrest makes it highly unlikely that person will survive, even if treatment is available.

2. Warnings & Precautions

The following section describes how to use your Avive AED® safely. Please read these warnings and precautions carefully.

Warnings describe something that can cause serious personal injury or death.
Precautions describe something that can cause minor personal injury, or damage to the Avive AED.

Warnings

Flammable Agents – If the Avive AED is used to give a shock in the presence of flammable agents, there is a risk of explosion. Move flammable agents such as supplemental oxygen, oxygen delivery devices, gasoline, and pressurized cannisters away from the Avive AED and defibrillation pads.

Environment – Do not operate the Avive AED outside of the specified operating conditions. Do not store the Avive AED outside of the specified storage conditions.

Dry Chest – Dry off the patient's chest if wet before applying electrode pads.

Battery Fluids – The Avive AED battery is rechargeable via the USB Charging Port on the product. Do not try to open the unit to access the battery. Do not attempt to replace the battery. Do not open, crush, or burn the unit, or it may explode or catch fire.

Fluids – Do not let fluids get into the Avive AED. While the fully assembled Avive AED has an IP rating of 54, exposure to fluids can still damage the device. When an Avive® Pad Cartridge is not installed, the device is susceptible to water damage. Do not use the Avive Power Adapter when it is wet. Avoid spilling any fluids on the Avive AED or its accessories. Exposing the Avive AED to excess water and particle ingress or spilling fluids into the Avive AED may damage it or cause a fire or shock hazard. Do not use the Avive AED in puddles of water.

Accessories – Using damaged or expired equipment or accessories may cause the Avive AED to perform improperly, and/or injure the patient or the user. Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment.

Avive Accessories Only – Only use accessories approved by Avive for use with the Avive AED. Using unauthorized accessories may cause the Avive AED to perform improperly, and/or injure the patient or the user, and their use may void Avive's warranty.

Patient Handling – Do not touch the patient while the Avive AED is analyzing the patient's heart rhythm or during defibrillation. Touching the patient during heart rhythm analysis can lead to an incorrect or delayed analysis. Touching the patient during defibrillation can cause electric shock to the user, and potentially reduce the efficacy of defibrillation.

RF Devices – Keep cell phones and other radiofrequency (RF) devices at least 1ft (31 cm) from the Avive AED.

Pads – Do not allow the pads to contact other electrodes or metal parts that are in contact with the patient.

Implanted Pacemakers – Do not apply pads directly over an implanted pacemaker in the patient.

Choking & Asphyxiation – Keep the Avive AED® and its accessories out of reach of children to avoid the potential risk of inhalation, swallowing of small parts or strangulation by cables.

Do Not Modify – Do not modify or attempt to disassemble the Avive AED.

Stacked Equipment – Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally

Precautions

Device Handling – Do not intentionally drop, throw, mishandle, or apply excessive force to the Avive AED. Rough handling can damage the device and its accessories and may invalidate the warranty.

Multiple Defibrillators - Do not apply a second defibrillator to the patient before removing the Avive AED.

Maintenance – Improper maintenance may damage the Avive AED or cause it to function improperly. Maintain the Avive AED according to directions.

Skin Burns – Do not let the pads touch each other or other electrodes, lead wires, dressings, medicine patches, etc. Such contact can cause skin burning and potentially reduce the efficacy of defibrillation.

Pad Adhesion - Do not use expired, previously used, or previously opened electrode pads because they may not provide good contact with the skin, which may impact performance.

Patient Handling – Disconnect the patient from all non-defibrillator proof electrical medical equipment before defibrillation. In addition, make sure the pads and patient are not in contact with electrically conductive surfaces such as a metal bed frame or stretcher, and do not touch metal objects in contact with the patient.

Skin Irritation – Do not leave the electrode pads on a patient for more than 24 hours.

Cleaning - Do not sterilize the Avive AED or its accessories. Do not use harsh chemicals, flammable agents, or solvents to clean the device. Clean the device according to directions.

Exposed Contacts – Do not touch exposed electrical contacts on the Avive AED, when no Avive® Pad Cartridge is installed. Do not touch exposed electrical contacts on the Avive Pad Cartridge during installation.

Pad Packaging – The Avive Pad Cartridge must be replaced after the sealed pad packaging has been opened.

Operating in a Hot Environment – If the Avive AED has been stored and being used in a hot environment the product and its components may be hot to the touch, and cause discomfort.

Radio Frequency Interference: Equipment operating in close proximity to the Avive AED may emit electromagnetic or radiofrequency interference. If use of equipment in close proximity is necessary, observe the Avive AED to verify normal operation. Avoid operating the Avive AED near diathermy equipment, cauterizers, security systems, or RFID sources.

Aircraft: Do not operate the Avive AED in an aircraft environment.

3. Initial Device Setup

Step 1: Remove the Avive AED® from the packaging.

Step 2: Press the Power Button. The Avive AED will run some initialization self-checks to make sure it is ready to go. You will be prompted to press the Child Button and Español Button to ensure they are functioning properly.

Once initialization is complete, the Avive AED will prompt you to press the Power Button to power off the AED.

Step 3: Connect the device to the Avive® USB Power Adapter with the Avive USB Charging Cable to charge the battery. [See Section 8A]

After you've followed the steps above, your device should be ready to help save a life!

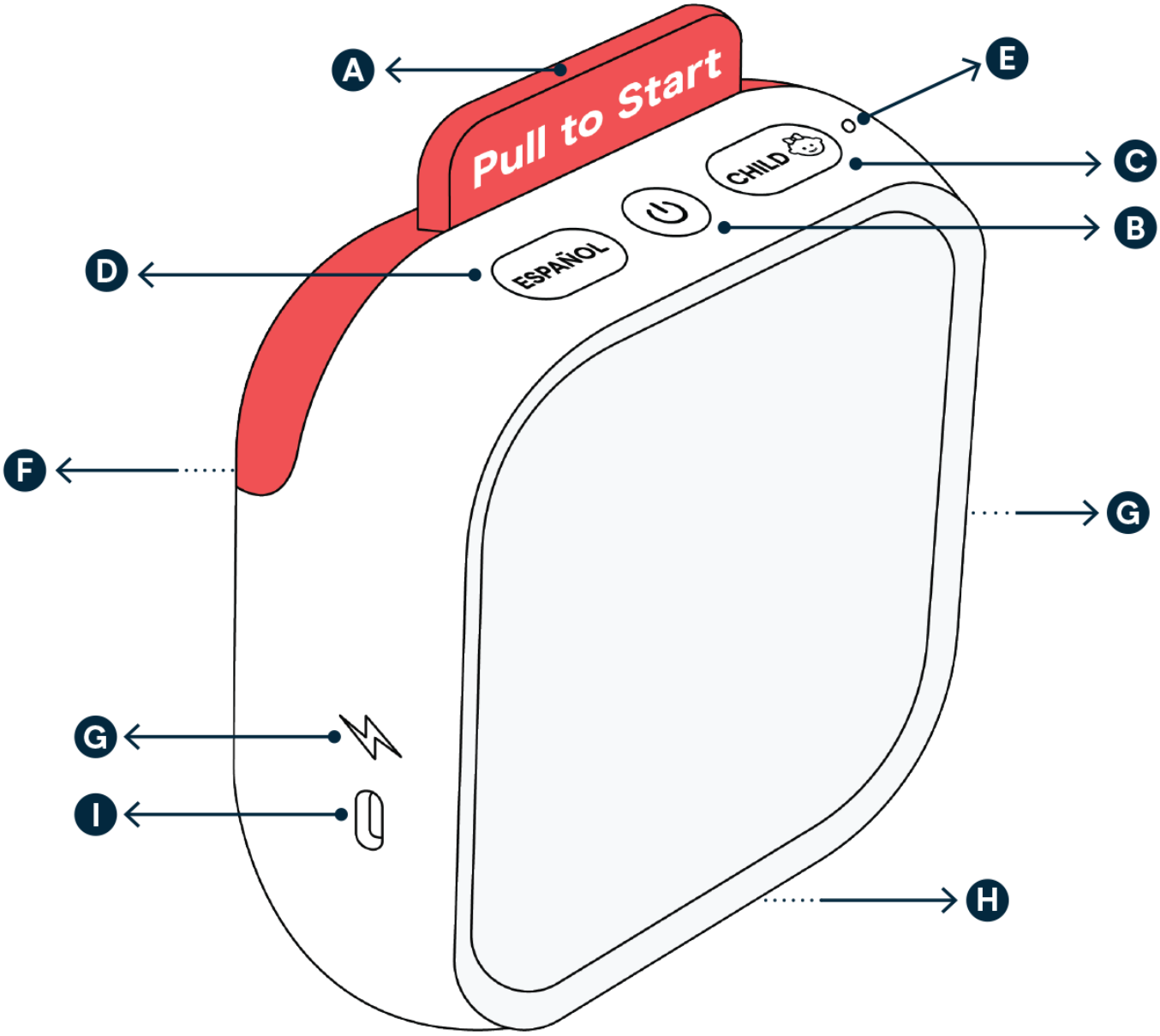
Account Setup

Be sure to set up an account and register your device for device tracking, product warranty, and the full benefits of the Avive platform. Visit www.avive.life/register to get started.

Tracking Requirements

Avive Solutions, Inc. is required to track each Avive AED per U.S. medical device regulations.

4. Getting to Know the Avive AED®



See next page for descriptions of each identified feature.

A. Red Tab
Pull the Red Tab to access the packaged pads in the Pad Cartridge and activate the Avive AED® for use. [See Section 5A]

***IMPORTANT**: Only pull the Red Tab in an emergency. If the packaged pads have been opened the Pad Cartridge will need to be replaced.*

B. Power Button
Press the Power Button to turn on or turn off the Avive AED.

C. Child Button
Upon power on, the Avive AED defaults to Adult Mode. When treating children under 8 years old or under 55 lbs, it is important to press the Child Button to switch the device into Child Mode. Press the Child Button again to switch the device back to Adult Mode. [See Section 5B]

D. Español Button
Upon power on, the Avive AED defaults to providing audio instructions in English. Press the Español Button to switch the device to Spanish Mode, which will provide audio instructions in Spanish. Press the Español Button again to switch back to English Mode. [See Section 5C]

E. Status Light
If this light is blinking green, your device is ready to use! If it's blinking red, then the Avive AED needs attention. [See Section 6B]

F. Pad Cartridge
Self-adhesive pads used for treatment are stored in a sealed package within the Pad Cartridge. The pads are accessed by pulling the Red Tab out from the Pad Cartridge and peeling open the package. [See Section 8B]

***IMPORTANT**: The Pad Cartridge is single-use, disposable and must be replaced after the expiration date is reached or the Pad Cartridge has been used.*

G. Stand Back Lights
When these lights are flashing – stand back, and do not touch the patient. The Stand Back Lights flash when the device is analyzing the patient's heart rhythm or delivering therapy. It is important that no one touches the patient during this time.

H. Speaker
The Avive AED provides audio instructions and notifications during use through this speaker.

I. USB Charging Port
The Avive AED has a rechargeable battery. Use the USB Charging Port to connect the device to a charger in order to charge the AED. [See Section 8A]

***IMPORTANT**: Use the Avive® USB Power Adapter and Avive USB Charging Cable for optimal charging performance.*

5. Using the Avive AED®

A. Using the Avive AED in an Emergency

Step 1: Pull the Red Tab

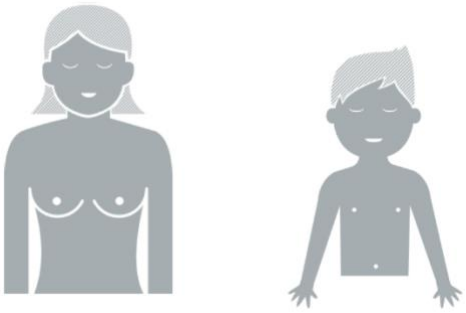
First, activate the Avive AED by pulling the Red Tab. The unit can also be activated by pressing the Power Button.

Once powered on, the Avive AED will begin providing audio instructions. Stay calm and follow all audio instructions.

Continue to next page for the next step.

Step 2: Apply Pads to Patient

Apply the pads to the patient's bare skin. Placing the pads correctly on the patient's bare skin is crucial for the Avive AED® to correctly analyze and treat the patient.

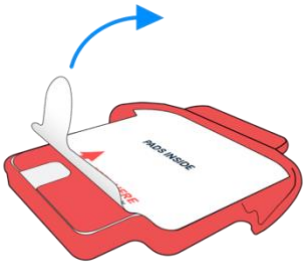


a) Remove Clothing & Expose Patient's Chest

Before placing the pads, the Avive AED will direct you to expose the patient's bare chest and remove the patient's bra if necessary.

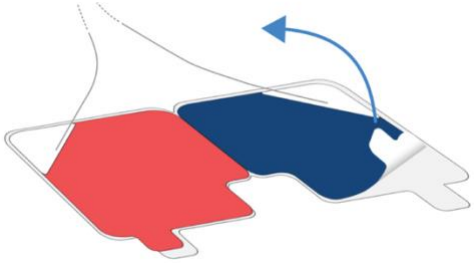
NOTE: Dry off the patient's chest if it is wet or sweaty. A wet chest can reduce the success of treatment.

NOTE: Remove hair where the pads will be placed, if necessary.



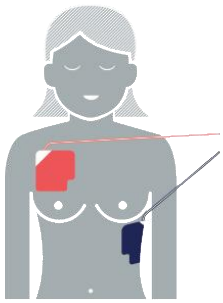
b) Peel Open Package & Remove Pads

Once the patient's chest is exposed, peel open the package you pulled from the device, and take out the pads inside.

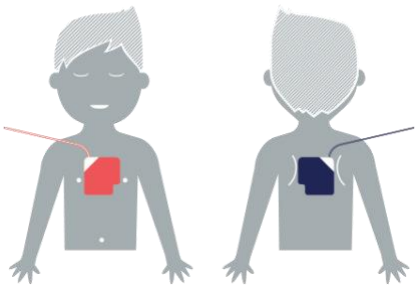


c) Peel and Place each Pad

Peel each pad from the white liner and firmly stick on the patient's bare skin exactly as shown in the picture on each pad.



Adult Pad Placement



Child Pad Placement

Continue to next page for the next step.

Step 3: Stand Back - Automated Analysis & Treatment

a) Heart Analysis

Once the pads are placed on the patient's bare skin, **stand back and do not touch the patient**. The Avive AED® will automatically analyze the patient's heart rhythm to diagnose whether or not a defibrillation shock is needed.

⚠ DO NOT TOUCH PATIENT

b) Automated Treatment

If the Avive AED determines that a shock is required, the AED will automatically deliver a defibrillation shock to the patient. **Stand back and do not touch the patient.**

⚠ DO NOT TOUCH PATIENT

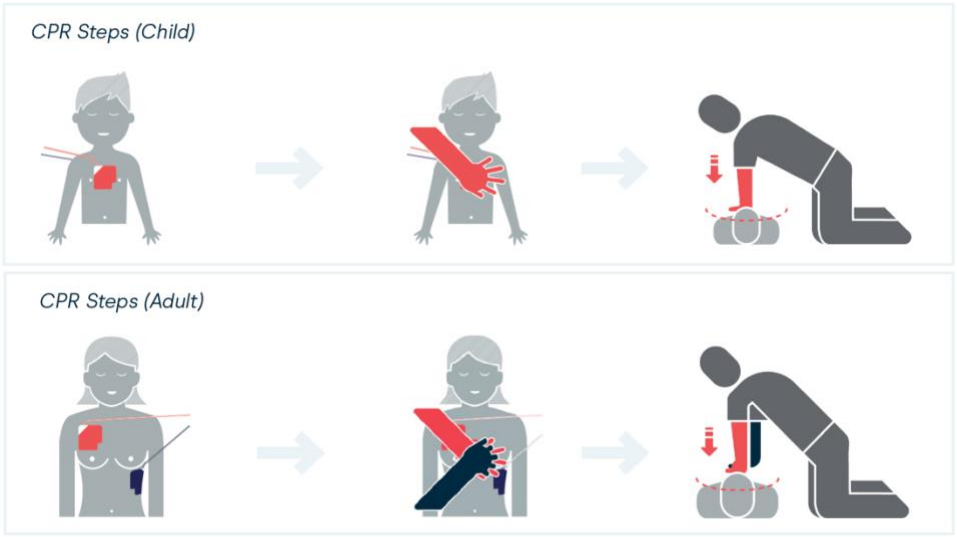
IMPORTANT: *The Avive AED will provide you audible instructions and stop flashing the Stand Back Lights when it is safe to touch the patient.*

c) Perform CPR

After automated analysis and treatment (if needed), the Avive AED will audibly instruct you that it is safe to touch the patient and to perform CPR. The device will provide hands-only CPR instructions. The Avive AED will instruct you when to stop CPR so that it can re-analyze the patient's heart rhythm and deliver treatment (if needed).

NOTE: Continue following instructions from the Avive AED until the patient regains consciousness or Emergency Medical Services arrive and take over care of the patient.

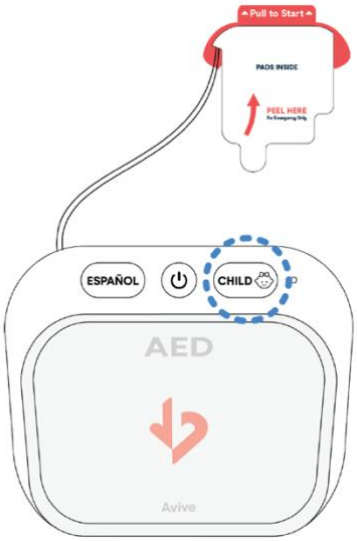
After the emergency situation has been resolved, make sure to maintain the Avive AED and accessories [See Section 8A].



B. Child Mode - For Children Press the Child Button.

The Avive AED® will power on in Adult Mode. If the patient is a child under 8 years old or under 55 lbs., make sure to switch the Avive AED to Child Mode by pressing the Child Button.

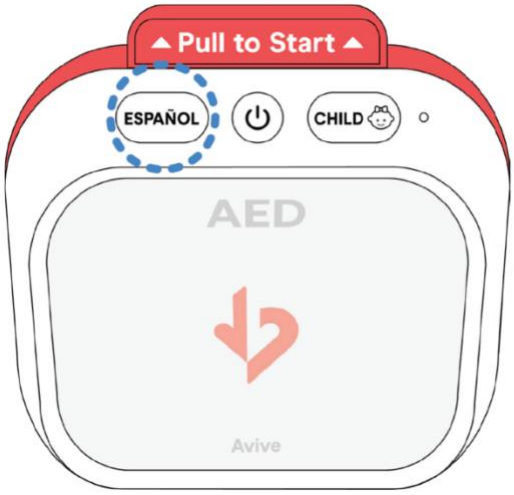
When switched to Child Mode, the device will verbally indicate “Now in Child Mode,” and the Child Button will light up. To switch back to Adult Mode, press the Child Button again.



C. Spanish Mode

The Avive AED will provide audio instructions in English Language by default. If Spanish language is preferred, switch the Avive AED to Spanish Language by pressing the Español Button.

When switched to Spanish Language, the device will verbally indicate in Spanish that it is in Spanish mode, and the Español button will light up. To switch back to English language, press the Español Button again.



D. Accessing & Sharing Event Data

The Avive AED® stores data gathered during emergency use of the product and automatically transfers the data to Avive Solutions, Inc. once it establishes a network connection.

Event data can be accessed after emergency use of the Avive AED by visiting www.avive.life/Event-Data

E. Training Mode

Install an Avive® Training Cartridge to switch the Avive AED to Training Mode. Training Mode allows a user to practice using the Avive AED in a training environment.

When a Training Cartridge is installed, there is no electrical connection between the training pads and the Avive AED. In Training Mode, the Avive AED provides audio instructions as if it were being used in an emergency, however, the device will not actually analyze a heart rhythm or deliver defibrillation therapy. Audio instructions are for user training only.

For more information, visit www.avive.life/AviveAED/Training

CAUTION – The Training Cartridge is for training only and cannot deliver therapy. It is recommended that the Avive AED is stored with an Avive Pad Cartridge installed.

6. Device Readiness

A. Device Self-Tests

The Avive AED® performs daily, weekly, and monthly internal self-tests to check device readiness. The Avive AED indicates device readiness via the Status Light [See Section 6B] and Speaker [See Section 6D].

B. Status Light

The color of the Status Light indicates the functionality status as illustrated below. The flashing behavior indicates the battery charging state.

The status of the Avive AED should be checked periodically to ensure it is ready for emergency use. In addition to checking the Status Light on the Avive AED, the device status may also be checked through a variety of compatible Avive® products. For the full list of supported compatible products, visit www.avive.life/products.

Ready to Use
If the Status Light is blinking green, your device is ready to use in an emergency.

Device Needs Attention!
If the Status Light is blinking red, or the device is beeping, then your device needs attention! Press and hold the Power Button for 5 seconds and the Avive AED will tell you what is wrong.

		Ready to Use	Needs Attention
Battery Charging	Status Light blinks once every second	1s	1s
Battery Fully Charged	Status Light quickly blinks twice every 10 seconds	10s	10s
Battery Not Charging	Status Light blinks once every 10 second	10s	10s

C. Checking Status

To check the status of your Avive AED®, press and hold the Power Button on the device for 5 seconds. The device will verbally tell you its status.

D. Speaker

The Avive AED will periodically produce audible beeps when the device determines that it needs attention.

When cartridges are installed or removed from the Avive AED, it will provide an audible announcement.

7. Troubleshooting

If your device's Status Light is blinking red and/or beeping, press and hold the Power Button on the device for 5 seconds. The device will verbally tell you what is wrong.

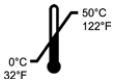
Battery Low – The Avive AED has a rechargeable battery, and over time the device's battery will drain if it is not connected to a charger. As soon as the Avive AED indicates that it has a low battery, the device should be connected to the Avive® USB Power Adapter with the Avive USB Charging Cable to recharge.

***Important**: The Avive AED is still safe to use with a Low Battery. A charged AED should be used if available.*

Pad Cartridge is:

- **Expired** – If the Pad Cartridge is expired it will need to be replaced. The expiration date can be found on the back of the Pad Cartridge.
- **Previously Used** – Once the packaged pads have been opened the Pad Cartridge will need to be replaced.
- **Not Installed** – A Pad Cartridge must be installed to operate the Avive AED. If there is a Training Cartridge, no cartridge, or an invalid cartridge installed, the device will not be ready for use.

[See Section 8B to learn how to replace the Pad Cartridge]



Extreme Temperatures – If the AED is too hot or too cold it cannot operate. Only store and operate your device in the recommended environmental conditions. [See Section 9]

Device Not Operable – In the unlikely case that the Avive AED self-diagnoses a device malfunction you should contact Avive Customer Support immediately to resolve the issue.

A. Troubleshooting Guide

Issue	Possible Causes	Solutions
Status Light or periodic beeping indicates that the AED Needs Attention	Battery is Low	The AED requires charging. Refer to the Maintenance section [Section 8A] on how to charge your AED.
	Pad Cartridge is expired	The Pad Cartridge needs to be replaced. Contact Avive for a replacement Pad Cartridge
	Pad Cartridge has been used	The Pad Cartridge needs to be replaced. Contact Avive for a replacement Pad Cartridge.
	Training Cartridge is installed	The Training Cartridge is for training only and cannot deliver therapy. When training is complete, install a new or unused Pad Cartridge.
	No cartridge is installed	Install a Pad Cartridge.
	Invalid Cartridge is installed	Install a valid Pad Cartridge. Only use Avive® Pad Cartridges.
	Failed Self-Test	Refer to the Checking Status section [Section 6C] to help determine which tests failed.
	AED outside operating temperature limits	Move your device to the allowable operating range of 0°C – 50°C for at least 24 hours to ensure proper operation.
AED is not Charging [See Section 6B for battery charging states]	AED outside battery charging temperature limits	Move your device to the allowable battery charging temperature range of 0°C – 45°C for at least 1 hour.
	Power Adapter or Charging Cable disconnected.	Check to make sure the Charging Cable is firmly plugged into the Power Adapter, that the Power Adapter is completely plugged into an outlet, and that the Charging Cable is fully inserted into the Charging Port.
	Power Adapter or Charging Cable damaged.	Do NOT use Power Adapters or Charging cables with visible damage. Contact Avive for replacement components.
Device is unresponsive: No Status Light blinking No audio when the Power Button is pressed or when Red Tab is pulled Power Button is not backlit when pressed	Battery has been discharged	The AED may require charging. Refer to the Maintenance section [Section 8A] on how to charge your AED.
	The AED has been stored in an extremely cold or hot environment.	As a safety measure, the AED shuts down when stored outside of the allowable Storage Conditions. Move your device to the allowable operating range of 0°C – 50°C for at least 24 hours.
	The AED has been damaged and is inoperable.	Contact Avive to resolve the issue.

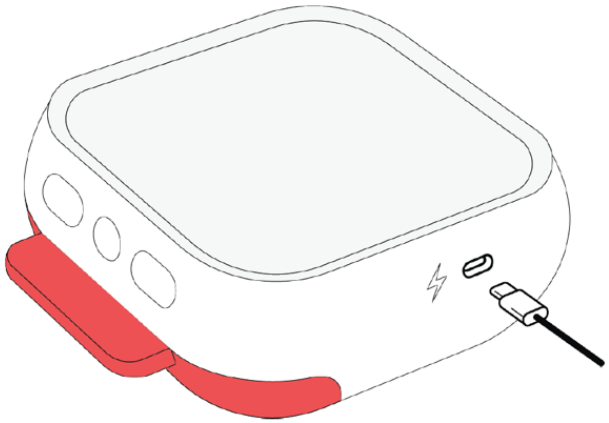
8. Maintenance

A. Charging the Avive AED®

Connect the Avive® USB Power Adapter to the Avive AED with the Avive USB Charging Cable to recharge the device. See Section 6B on the Status Light to check that your device is charging.

1) *Connect the Avive USB Power Adapter to the Avive USB Charging Cable.*
2) *Plug the Avive USB Power Adapter into an outlet.*
3) *Plug the USB Charging Cable into the Avive AED.*

***IMPORTANT**: The Status Light may blink green or red when the device is in any of its charging states to indicate its functionality status. To determine which charging state the device is in, pay attention to the frequency that the Status Light blinks [See Section 6B].*



CHARGING TIPS:
• The best way to prevent a low battery is to store the Avive AED in room temperature conditions, connected to the Avive USB Power Adapter with the Avive USB Charging Cable.
• After you've connected the Avive AED to the charger, make sure the device is charging or fully charged.

Caution – Only use Avive approved charging accessories to charge the Avive AED.

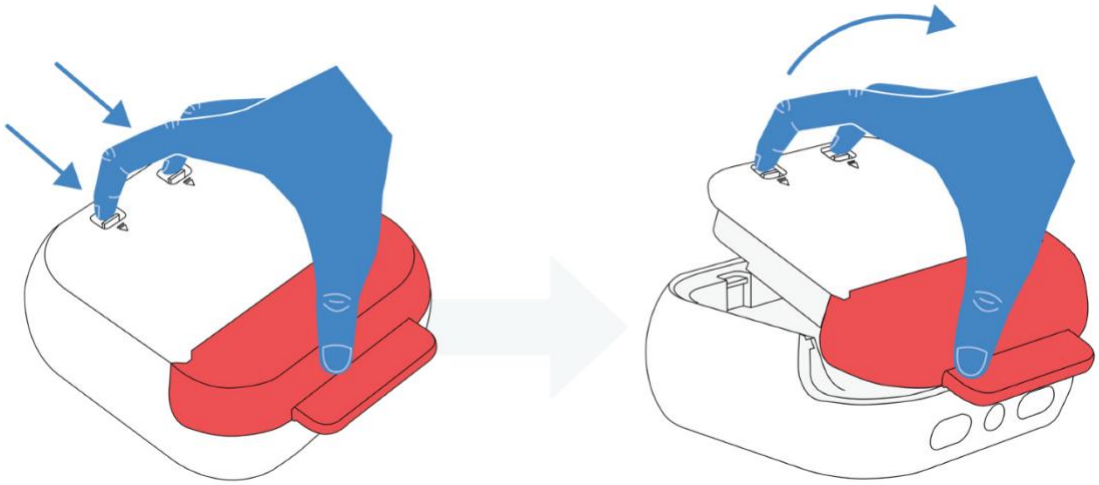
For more information on available charging accessories approved for use in charging the Avive AED visit www.avive.life/AviveAED/accessories

B. Replacing the Avive® Pad Cartridge

Removing a Pad Cartridge

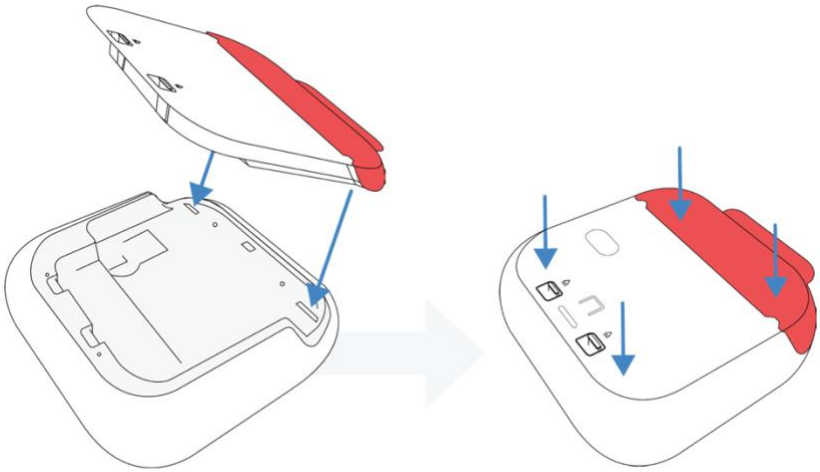
IMPORTANT: Replace the Pad Cartridge if it's expired, previously used, or the sealed pad package has been opened. (See Section 7).

When replacing cartridges make sure the device is powered off and no charging cable is connected.



1. Firmly pull back and lift up on both snaps on the back of the device to release the cartridge.

Installing a New Pad Cartridge



1. Install a new Pad Cartridge by first aligning the cartridge with the back of the AED. Push the cartridge firmly into the recess on the back of the AED.
2. **IMPORTANT:** Press down firmly on the corners of the cartridge. Make sure the cartridge is fully inserted around all sides of the AED.

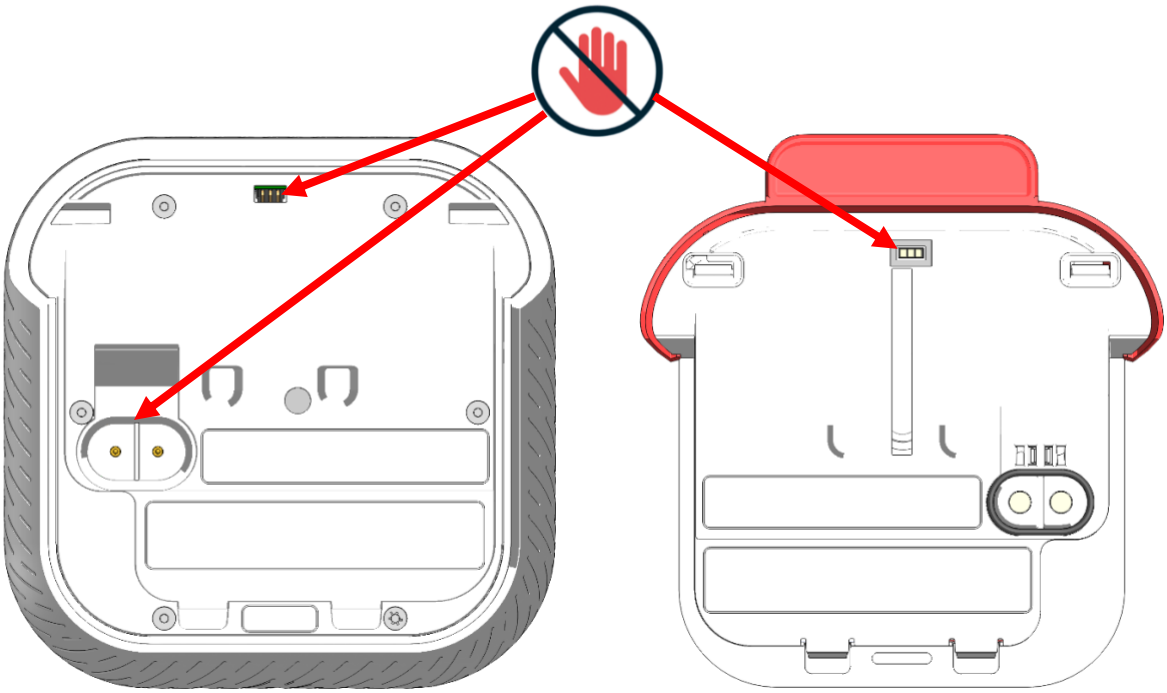
TIP: The Avive AED® will say "Pad Cartridge Connected" once it senses that a new Pad Cartridge is correctly installed.

C. Cleaning

Clean the Avive AED® only when assembled with an Avive® Pad Cartridge. Gently wipe down the exterior with a clean damp cloth.

Caution - Do not use any harsh chemicals or solvents to clean the Avive AED.

Caution - Do not clean the Avive AED if a cartridge is not installed. Do not touch or clean the electrical contacts on the back of the Avive AED, or on the Avive Pad Cartridge.



D. Disposal

Dispose of the Avive AED and its accessories in accordance with local regulations.

E. Software Updates

From time to time, software updates may be made available from Avive Solutions, Inc. Be sure to set up an account and register your device at www.avive.life/register to receive notification of available updates and instructions for installation. For information on available updates, visit www.avive.life/updates.

9. Operating & Storage Conditions

Operating Conditions

The Avive AED® is intended for use in professional or home healthcare environments, including public and private locations. It should only be used in the following environmental conditions:

Temperature: 32˚F – 122˚F (0˚C – 50˚C)
Battery Charging: 32˚F – 113˚F (0˚C – 45˚C)
Humidity: 5 – 95% non-condensing
Altitude: -280 ft. to 15,000 ft. (-85 m to 4572 m)
Water & Ingress: The Avive AED is rated to IP54 (with Avive® Pad Cartridge installed) - dust protected, splash and spray proof.

IMPORTANT*: Do not expose the Avive AED to any liquids or dust when a Pad Cartridge is not installed.*

Storage Conditions

It is important that the Avive AED be stored within the following environmental ranges. If the device is stored outside of these ranges, then the device may be damaged and no longer functional for emergency use.

Long-term Storage Temperature: 41˚F to 104˚F (5˚C to 40˚C)
Short-term Storage Temperature (Up to 14 Days): -4˚F to 140˚F (-20˚C to 60˚C)
Humidity: 5 – 95% non-condensing
Altitude: -280 ft. to 15,000 ft. (-85 m to 4572 m)

IMPORTANT*: If the device has been stored outside of 0˚C-50˚C, then it should be returned to ambient temperature for at least 24 hours.*

STORAGE TIP:
To keep your device healthy, looking good, and maximize lifetime, store it:
- In a clean and dry place
- At room temperature
- Out of direct sunlight

10. Meaning of Symbols & Device Markings

The following symbols may be found on the defibrillator, its accessories, or packaging. Product labeling can be viewed on the back of the Avive AED® after removing the Pad Cartridge. See Section 8.B for instructions on removing the Pad Cartridge.

	On / Off Power Button
	Español Button – pressing this button toggles the audio instructions between English and Spanish language
	Child Button – pressing this button toggles defibrillation therapy between Adult and Child modes.
	Refer to operating instructions.
	Federal law (USA) restricts this device to sale by or on the order of a physician
	Pad Cartridge Use By date: YYYY-MM-DD
	Device contains a rechargeable battery with Li-Ion chemistry
	Wastes must be discarded in an environmentally sound manner in compliance with local regulations.
	Type BF applied part
	Warning, high voltage
IP54	Protected against dust and water spray
	Manufacturer information
	Date of manufacture: YYYY-MM-DD
	This product is not sterile.
	This product is not made with natural rubber latex.
	Electrode pads are disposable and for single patient use only.
	Temperature limits
LOT	Lot number
SN	Serial number
SN:	Serial number
REF	Reference order number
$5V_{DC}$ ⎓ 2A	AED Input power specifications: can accept 5 Volt DC power source, up to 2 Amps current.

11. Technical Data

Physical Specifications (with Avive® Pad Cartridge Installed)
Size: 143mm x 160mm x 52mm (5.63in x 6.30in x 2.05in)
Weight: 0.73 kg (1.6 lbs.)

Battery
Battery Type: 3.635V, 3500mAH, Lithium Ion, Rechargeable, not user replaceable
Time to Full Battery Charge: <5 hours
Capacity [Battery Fully Charged]: ≥75 shocks at 150J or 2.5 hours of continuous operation
Low Battery Indicator: < 10 150J Shocks, < 20 minutes continuous operation.
Battery Standby Time until Low Battery: Up to 8.5 Months

Pad Cartridge Specifications

Electrode Type:	Single-use combined ECG / defibrillation multifunction electrode. Type BF Applied Part
Electrode Placement:	Adult: Anterior-Lateral Pediatric: Anterior-posterior
Electrode Active Area:	>75 cm^2
Electrode Cable Length:	53 in (1.3 m) each
Shelf-Life:	See use-by date on the Pad Cartridge [Section 7]

Accessories

Avive USB Power Adapter	
Input Voltage	100-240 VAC 50-60 Hz
Output Voltage	5V DC 2A
Avive USB Charging Cable	
Cable Length	3.3 ft (1 m)
Connectors	USB Type A to USB Type C

Defibrillator Performance

Time to Shock Delivery following Patient Detection:	150J in less than 20 seconds
Patient Impedance Range:	25 Ohms to 200 Ohms

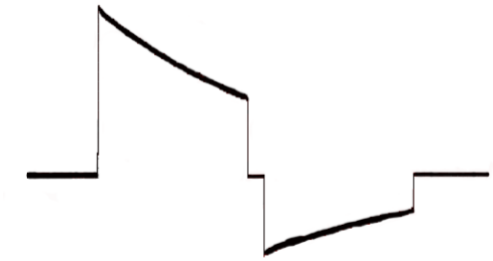
If the detected impedance is outside of this range, the user is prompted to check pad placement. The Avive AED will not deliver a shock outside of this range.

Patient Analysis
The Avive AED® measures the patient's electrocardiogram (ECG) and uses a machine learning algorithm [Rhythm Recognition Detector] to determine if defibrillation is appropriate. The Rhythm Recognition Detector has been trained using numerous databases of adult and pediatric ECGs recorded from real patients. ECGs are classified according to strict agreement criteria by independent cardiologists, and are divided into distinct sets of data used for development and testing of the algorithm. A publication entitled "*Convolution Neural Network Algorithm for Shockable Arrhythmia Classification Within a Digitally Connected Automated External Defibrillator"* was published in the Journal of the American Heart Association (JAHA).

The performance of the Rhythm Recognition Detector exceeds sensitivity and specificity recommendations of the American Heart Association, and the requirements set forth by IEC 60601-2-4. Performance results for the algorithm are summarized below.

Rhythm	Test Sample Size	Observed Performance	Performance Goal	90% One-Sided Lower Confidence Limit
Shockable				
Coarse V-Fib	274	98.9% sensitivity	>90% sensitivity	97.9%
Rapid V-Tach	101	99.0% sensitivity	>75% sensitivity	97.4%
Non-Shockable				
NSR	137	100% specificity	>99% specificity	100%
AF, SB, SVT, Blockage, Idioventricular, PVC's	288	99.3% specificity	>95% specificity	98.5%
Asystole	105	100% specificity	>95% specificity	100%
Intermediate				
Fine VF	80	92.5% Shock	Report Only	-
Other VT	66	86.4% Shock	Report Only	-

Defibrillation Waveform



The Avive AED® delivers an impedance-compensating, biphasic truncated exponential (BTE) waveform configurable for both adult and pediatric therapy. The waveform dynamically adjusts to optimize energy delivery to a wide range of patient impedances. Both the adult and pediatric waveforms use a non-escalating energy delivery protocol of 150 Joules and 50 Joules respectively.

	Nominal Adult Values			Nominal Pediatric Values		
Impedance (Ω)	Delivered Energy (J)	Phase 1 Duration (ms)	Phase 2 Duration (ms)	Delivered Energy (J)	Phase 1 Duration (ms)	Phase 2 Duration (ms)
25	139.8	2.6	2.4	48.3	2.2	2.0
50	146.9	4.4	3.7	50.1	3.7	2.9
75	148.6	6.5	4.4	49.9	4.8	3.6
100	149.8	8.5	5.5	49.2	5.8	4.1
125	150.6	10.6	6.8	48.4	6.6	4.6
150	148.6	11.4	6.8	47.4	7.4	5.0
175	145.0	11.4	6.8	46.0	7.7	5.3
200	140.8	11.4	6.8	43.9	7.7	5.3

The Avive defibrillation waveform safety and effectiveness is supported through published clinical data for defibrillation, including studies by Schneider et al., Poole et al., and White et al.

Schneider et al.

Schneider T, et al. Multicenter, Randomized, Controlled Trial of 150-J Biphasic Shocks Compared with 200-J to 360-J Monophasic shocks in the Resuscitation of Out-of-Hospital Cardiac Arrest Victims. Circulation. 2000;102:1780-1787.

A prospective, multicenter, out-of-hospital clinical trial was conducted to support adult defibrillation by comparing AEDs that delivered 150 J biphasic shocks with AEDs that delivered high-energy 200 - 360 J monophasic shocks. The Schneider et al. study delivered a sequence of up to three defibrillation shocks for the biphasic devices (150 J – 150 J – 150 J). Monophasic units delivered 200 J – 200 J – 360 J shocks. In the Schneider study, a greater percentage of patients achieved return of spontaneous circulation (ROSC) after biphasic shock (76% vs. 54%). There was no statistical difference between the two waveforms for rates of survival to hospital admission and discharge.

Poole et al.

Poole J, et al. Low-Energy Impedance-Compensating Biphasic Waveforms Terminate Ventricular Fibrillation at High Rates in Victims of Out-of-Hospital Cardiac Arrest. Journal of Cardiovascular Electrophysiology. 1997;8:1373-1385.

The performance of the 150 J impedance-compensating biphasic waveform was observed in the out-of-hospital setting on 100 consecutive victims of sudden cardiac arrest across 12 EMS systems. A total of 202 VF episodes were handled in the 44 patients presenting with VF. A single 150 J biphasic shock defibrillated the initial VF episode in 39 of 44 (89%) patients. 95% terminated VF after two shocks, and 99% terminated with 3 shocks or fewer. At patient transfer to ALS or ED care, an organized rhythm was present in 34 of 44 (77%) of patients presenting with VF. Asystole was present in 7 (16%) and VF in 3 (7%). The average number of shocks delivered per initial VF episode was 1.2 ± 0.5. A very wide range of patient resistances (36 Ω to 171 Ω) was exhibited, confirming that automated impedance compensation maintains high efficacy without the need to either step-up energy levels or use high-energy shocks. The 150 J impedance-compensating biphasic waveform terminates long-duration VF at high rates in out-of-hospital cardiac arrest.

White et al.

White R, et al. Transthoracic impedance does not affect defibrillation, resuscitation or survival in patients with out-of-hospital cardiac arrest treated with a non-escalating biphasic waveform defibrillator. Resuscitation. 2005;64(1):63–69.

Cardiac arrest data from two EMS systems were analyzed retrospectively, totaling 102 out-of-hospital-cardiac-arrest patients treated by fixed, 150 J, biphasic AEDs. Initial shocks defibrillated 90% of patients. Cumulative success with two shocks was 98% and with three shocks was 99%. Patient impedance ranged from 27 Ω to 152 Ω. First-shock success, cumulative success through two shocks, and cumulative success through the first-shock series were unrelated to transthoracic impedance, as were BLS ROSC, pre-hospital ROSC, hospital admission, and discharge. Consistent with previous findings, call-to-shock time was highly predictive of survival. High impedance patients were defibrillated by the biphasic waveform used in this study at high rates with a fixed energy of 150 J and without energy escalation. Rapid defibrillation rather than differences in patient impedance accounts for resuscitation success.

Pediatric Animal Study

A pediatric porcine animal study provides evidence to support the reasonable assurance of safety and effectiveness of the Avive® pediatric defibrillation waveform in the pediatric sub-population of children 1 to 8 years old. The Avive pediatric defibrillation waveform successfully defibrillated all animals in the pediatric animal model, with no clinically significant abnormal clinical pathology, daily observations, macroscopic, or microscopic findings.

Audio Instructions

The Avive AED® provides the following audio instructions during normal emergency operation.

	Audio Instruction
Powered On	"Powered On. Make sure 911 has been contacted."
Configure for Child Use	"If the patient is under 8 years old, you must press the child button on the top of the device."
Apply Pads	*If Red Tab has not been pulled:* "Pull the red tab to start emergency." *If Red Tab has been pulled:* "Expose the patient's bare chest, including bra." "Once the patient's chest is exposed, peel open the package you pulled from the device, and take out the pads inside." "Look at the picture on the red pad. Peel off the red pad from the white liner, and firmly stick on the patient's bare skin, exactly as shown." "Peel off the blue pad from the white liner, and firmly stick on the patient's bare skin, exactly as shown." "Make sure the pads are placed on the patient's bare skin, exactly as shown in the pictures." "Make sure the patient's chest is clean and dry." "There are two pads that need to be placed." "Look at the picture on the red pad and blue pad. Peel off the blue pad from the white liner, and firmly stick on the patient's bare skin, exactly as shown. Peel off the red pad from the white liner, and firmly stick on the patient's bare skin, exactly as shown."
Heart Analysis	*If patient is detected:* "Patient detected. Do not touch the patient or pads, analyzing heart rhythm." *If patient becomes not detected:* "Patient not detected. Make sure pads are placed directly on the patient's bare skin."
Automated Treatment	*If a shock is not advised:* "Shock is not advised." *If a shock is advised:* "Shock is advised. Move away from the patient now." "Charging; do not touch the patient or pads." "Stand back, delivering shock in three, two, one." "Shock delivered." *If device needs to re-analyze the heart rhythm:* "Re-analysis required."
CPR Instruction	"It is now safe to touch the patient. Let's begin CPR. Stack both of your hands on the center of the patient's chest. If the patient is under 8 years old, use one hand for compressions. Start compressing hard and fast on each beat. Push, push, push." "Keep your arms straight." "1 Minute remaining. Push, push, push." "Make sure your hands are stacked, if the patient is an adult." "30 seconds remaining." "Keep up the pace." "Stop Compressions."

Wireless Connectivity
The Avive AED® can connect with compatible products that support Bluetooth 5.0.
FCC ID: SQGBL654

Event Recording
Type: Internal Memory
Memory: At least one hour of ECG and event / incident recording
Review: Event data can be accessed via www.avive.life/EventData [See Section 5E]

Device Readiness Tests
The Avive AED performs multiple self-tests on a daily basis to evaluate health, functionality, and readiness. If any self-tests fail, the functionality status of the AED is updated to indicate that the device needs attention.

Self-Tests	Daily	Weekly	Monthly
Battery Level	✓	✓	✓
Circuit Functionality	✓	✓	✓
Pad Readiness	✓	✓	✓
Partial Defibrillation		✓	
Full Defibrillation			✓

Basic Safety and Essential Performance
IEC 60601-1
IEC 60601-2-4
IEC 60601-1-11
IEC 60601-1-2

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

Test	Compliance Level	Guidance
RF Emissions CISPR 11	Group 1	The EQUIPMENT 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 EQUIPMENT 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	Class A	
Voltage Fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

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

Test	Test Level	Compliance Level	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	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical residential environment.
Surge IEC 61000-4-5*	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical residential environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage Dips 30% reduction, 25/30 periods At 0°	Voltage Dips 30% reduction, 25/30 periods At 0°	Mains power quality should be that of a typical residential environment. If the user of the EQUIPMENT requires continued operation during power mains interruptions, it is recommended that the EQUIPMENT be powered from an uninterruptible power supply or a battery.
	Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	
	Voltage Dips > 95% reduction, 1 period At 0°	Voltage Dips > 95% reduction, 1 period At 0°	
	Voltage Interruptions > 95% reduction, 250/300 periods	Voltage Interruptions > 95% reduction, 250/300 periods	
Power frequency magnetic field (50/60 Hz)* 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.
Conducted RF IEC 61000-4-6*	3 Vrms 150 kHz to 80 MHz (6 Vrms in ISM and amateur radio Bands within 150kHz – 80MHz)	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3*	10 V/m 80 MHz to 2.7 GHz	10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz 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 an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b]

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, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EQUIPMENT is used exceeds the applicable RF compliance level above, the EQUIPMENT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the EQUIPMENT.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

* Exceptions from Standard IEC 60601-2-4 Section 202 were applied.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT

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

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
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.

Immunity to RF Wireless Communications Equipment						
Test Frequency (MHz)	**Band [a] (MHz)**	**Service [a]**	**Modulation [b]**	**Maximum Power (W)**	**Distance (m)**	**IMMUNITY TEST LEVEL (V/m)**
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Battery Safety UN38.3, IEC 62133, UL2054

Ingress Protection IEC60529, IP54

Shipping and Transportation ASTMD4169-16 Assurance Level I

Expected Service Life 7 years