Avive Connect 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® Connect. This information is subject to change. Please contact Avive or visit www.avive.life/AviveConnect if you have any questions.

Revision: C
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Manufacturer Info

Avive Solutions, Inc.
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(800)-489-4428

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

Table of Contents

1. Warnings & Precautions

The following section describes how to use your Avive® Connect 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 Connect or Avive AED®.

Warnings

Battery Fluids – The Avive Connect battery is rechargeable via the USB Charging Port on the Avive AED. 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 Connect. While the fully assembled Avive Connect AED has an IP rating of 54, exposure to fluids can still damage the device. Avoid spilling any fluids on the Avive Connect. Exposing the Avive Connect to excess water and particle ingress, or spilling fluids into the Avive Connect may damage it or cause a fire or shock hazard. Do not use the Avive Connect in puddles of water.

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

Precautions

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

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

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

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

Operating in a Hot Environment – If the Avive Connect 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 Connect may emit electromagnetic or radio frequency interference. If use of equipment in close proximity is necessary, observe the Avive Connect to verify normal operation. Avoid operating the Avive Connect near diathermy equipment, cauterizers, security systems, or RFID sources.

RF Devices – Keep cell phones and other radio-frequency (RF) devices at least 1ft (31 cm) from the Avive Connect.

2. Initial Device Setup

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

Step 2: Press the Power Button on the Avive AED. After the Avive AED has completed its initialization, the Avive Connect will provide prompts for Wi-Fi Setup. Setup your Avive Connect to be on your local Wi-Fi network by selecting the Wi-Fi network name and entering the Wi-Fi password.

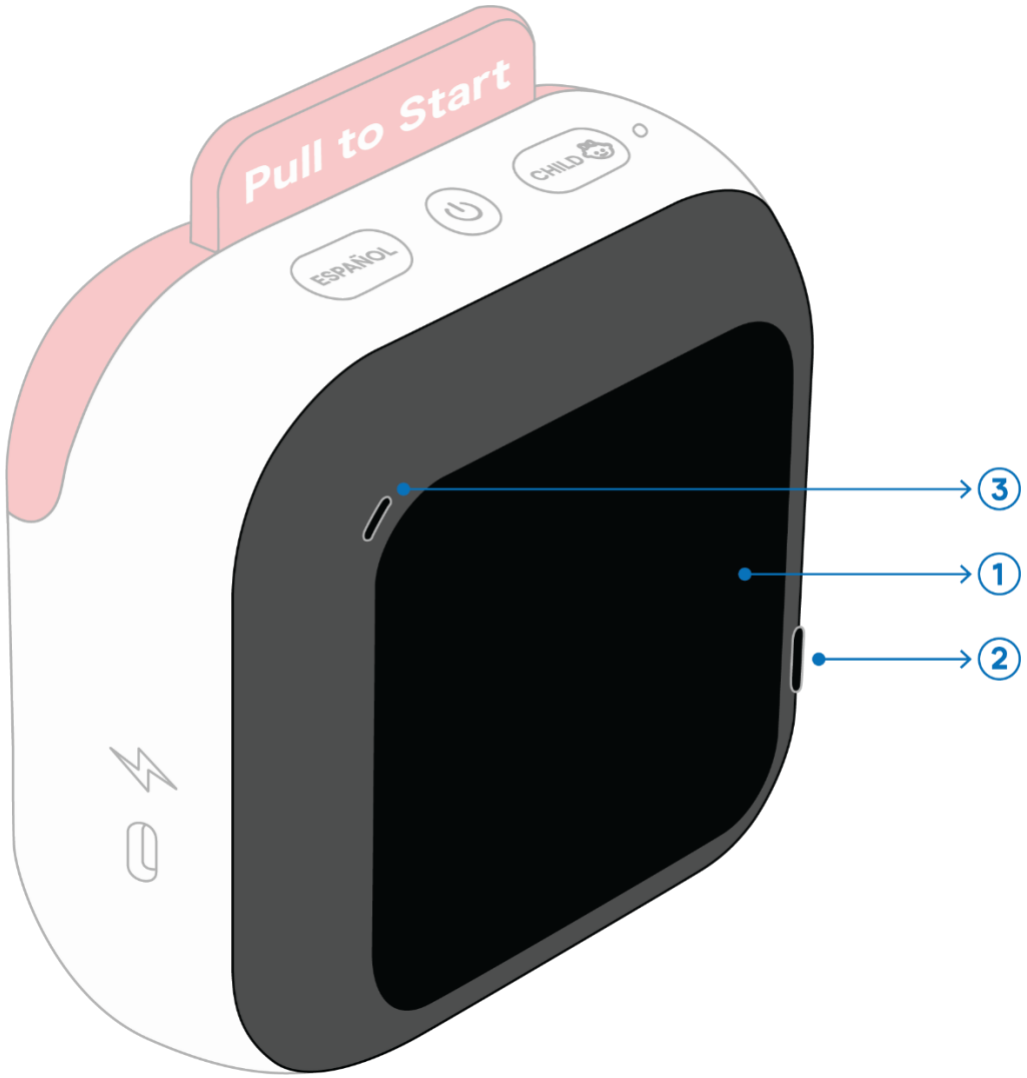
Step 3: Connect the device to the Avive® USB Power Adapter with the Avive® USB Charging Cable to charge the battery.

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.

3. Getting to Know the Avive Connect



① **Touchscreen Display**
Displays graphics that correspond to the audio instructions provided by the Avive AED during an emergency. Outside of emergency use, the touchscreen is used to view device information, configure setting, or view informational material.

② **Display Button**
Toggles the display on and off.

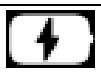
③ **Speaker**
Audio from the Avive Connect is provided only outside of emergency use.

4. Using the Avive Connect

The Avive Connect AED® product configuration provides the Avive Connect module in addition to the full functionality of the Avive AED described in the Avive AED Owner's Manual. The Avive Connect has Wi-Fi, Cellular, and GNSS (location) wireless connectivity built in. It is factory installed onto the Avive AED and there is no user installation required.

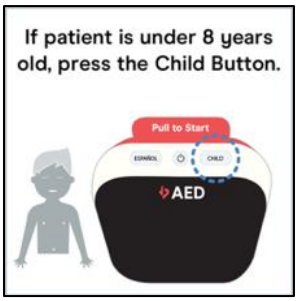
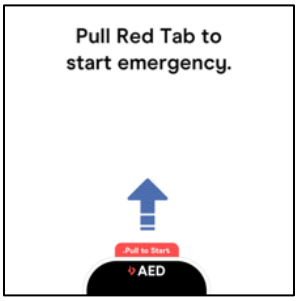
A. Connect Menu Bar Icons

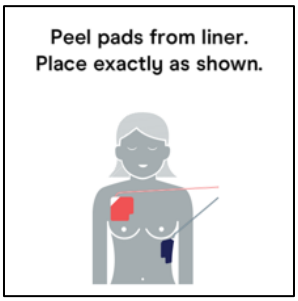
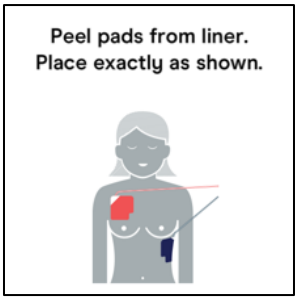
The following icons will be found on the top menu bar of the Avive Connect.

	Wi-Fi Connectivity; number of bars indicates signal strength
	No Wi-Fi Connectivity
	Cellular Connectivity; number of bars indicates signal strength
	No Cellular Connectivity
	Satellite GNSS – location based on multiple satellite constellations
	Geolocation – location is based on available Wi-Fi and Cellular networks
	No location information
	Batteries are good
	Connect Battery is Low
	AED Battery is Low
	Charger is plugged in, and batteries are charging
	High Priority Notification
	Medium Priority Notification
	Low Priority Notification

B. Graphics During Emergency Use

During emergency use, the Connect displays graphics that correspond to the audio instructions provided by the Avive AED. Some graphics are animated during use.

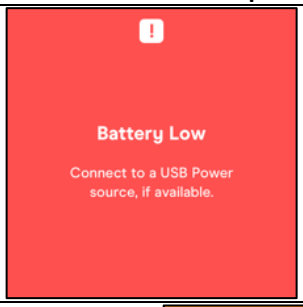
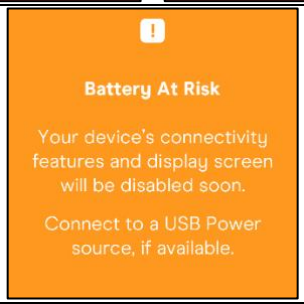
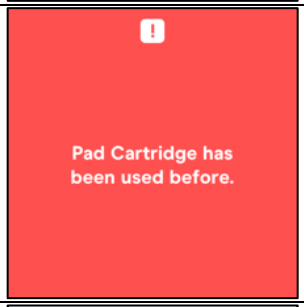
	Audio Instruction	Graphic Displayed
Powered On	"Powered On. Make sure 911 has been contacted."	
Configure for Child Use	"If the patient is under 8 years old, you must press the child button on the top of the device."	
Apply Pads	*If Red Tab has not been pulled:* "Pull the red tab to start emergency."	
	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."	

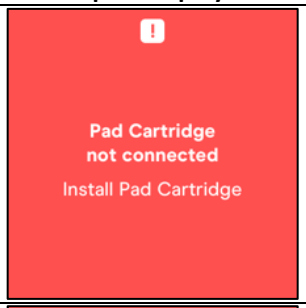
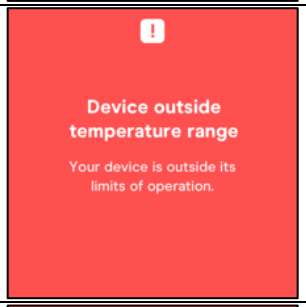
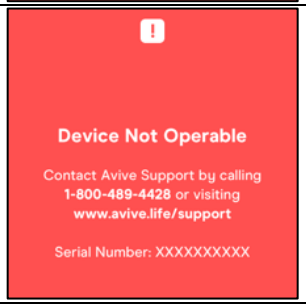
	Audio Instruction	Graphic Displayed
	"Look at the picture on the red pad. Peel off the red pad from the white liner, and firmly stick on the patient's bare skin, exactly as shown." "Peel off the blue pad from the white liner, and firmly stick on the patient's bare skin, exactly as shown." "Make sure 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."	

	Audio Instruction	Graphic Displayed
	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."	

C. Displayed Notifications

Outside of emergency use the following notifications may also be displayed to convey information related to the continued maintenance of the device.

Graphic Displayed	Cause and Solution
 	The AED battery is low. The Connect AED requires charging. Refer to the Maintenance section on how to charge your device.
	The Connect battery is low. The Connect AED requires charging. Refer to the Maintenance section on how to charge your device.
	The Pad Cartridge is expired and needs to be replaced. Contact Avive for a replacement Pad Cartridge.
	The Pad Cartridge has been used before and needs to be replaced. Contact Avive for a replacement Pad Cartridge.
	A 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.

	Graphic Displayed	Cause and Solution
		No cartridge is installed. Install a Pad Cartridge.
		The AED is outside the 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.
		The AED has been damaged and is inoperable. Contact Avive to resolve the issue.

D. Device Self-Tests

The Avive Connect performs daily internal self-tests to check device readiness. The Avive Connect indicates device readiness via symbols and notifications on the display.

E. Training

In addition to emergency use, the Connect provides graphics when the Avive AED is in Training Mode. The Connect allows the user to setup training scenarios and simulate pad placement when the AED is used in its training mode.

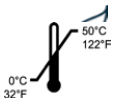
For more information, visit www.avive.life/AviveAED/Training

F. Accessing & Sharing Event Data

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

5. Troubleshooting

Battery Low – The Avive Connect 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 Connect 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.



Extreme Temperatures – If the Avive Connect is too hot or too cold it cannot operate. Only store and operate your device in the recommended environmental conditions.

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

A. Troubleshooting Guide

Issue	Possible Causes	Solutions
No Location	Satellite GNSS is out of range	Move your device near a window or with visibility of the sky for Satellite GNSS reception. Typically, GNSS requires line of sight to the sky with minimal cloud cover.
	Wi-Fi and/or Cellular networks are out of range	Move your device to an area with known cellular and/or Wi-Fi coverage for geolocation.
	Wi-Fi is connected to a network with an IT administrator that has created locally managed MAC addresses	The device should be connected to a known Wi-Fi network with no MAC address management to maximize the chances of attaining geolocation.
	Connect requires a reset	Reset the Connect by going to the settings menu and selecting "Reboot System." You will see the screen display a message that it is rebooting. This is the recommended method for resetting the Connect. If "Reboot System" does not resolve the issue, a hard reset can be performed by holding the display button for several seconds until you see the screen go dark. Release the button, and the Avive logo will appear on the screen as the device reboots.
No Cellular	Cellular networks are out of range	Move your device to an area with known cellular coverage.
	Connect requires a reset	Reset the Connect by going to the settings menu and selecting "Reboot System." You will see the screen display a message that it is rebooting. This is the recommended method for resetting the Connect. If "Reboot System" does not resolve the issue, a hard reset can be performed by holding the display button for several seconds until you see the screen go dark. Release the button, and the Avive logo will appear on the screen as the device reboots.
No Wi-Fi	Known Wi-Fi networks are out of range or not operational	Move your device to an area with known and functional Wi-Fi coverage.

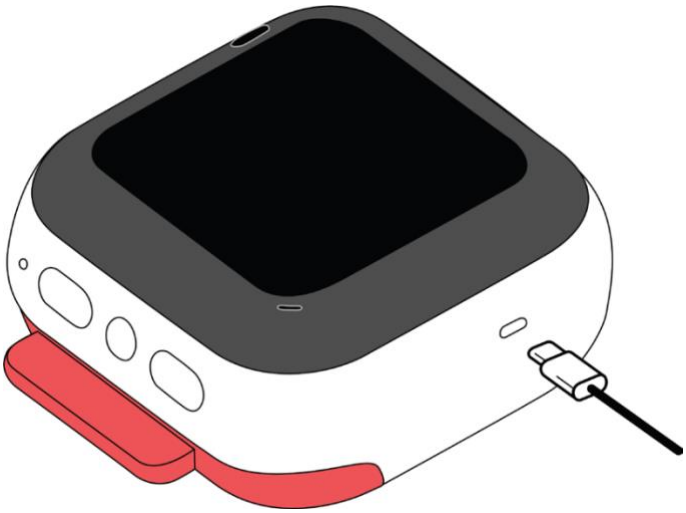
	The Wi-Fi network name and/or password have been entered incorrectly	Go to the settings screen and ensure the device is connected to the correct Wi-Fi network. If not, choose the desired network and enter the correct password.
	Only 5GHz Wi-Fi networks are available	The device must be connected to a 2.4GHz Wi-Fi network.
	Wi-Fi network has no security or security that is not supported.	Networks with no security will not appear. The device must be connected to a Wi-Fi network that has WPA or WPA2 security.
	Connect requires a reset	Reset the Connect by going to the settings menu and selecting "Reboot System." You will see the screen display a message that it is rebooting. This is the recommended method for resetting the Connect. If "Reboot System" does not resolve the issue, a hard reset can be performed by holding the display button for several seconds until you see the screen go dark. Release the button, and the Avive logo will appear on the screen as the device reboots.
Connect is not Charging	Connect 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 of the Avive AED.
	Power Adapter or Charging Cable damaged.	Do NOT use Power Adapters or Charging cables with visible damage. Contact Avive for replacement components.
Touchscreen is not responsive	Liquids are on the screen	Wipe the display with a clean, dry cloth.
	Fingers may be wet or covered	Ensure you are touching the display with a bare finger that is clean and dry.
	Connect requires a hard reset	Reset the Connect by holding the display button for several seconds until you see the screen go dark. Release the button, and the Avive logo will appear on the screen as the device reboots.
Connect is unresponsive: Display does not turn on when the display button is pressed or when the AED is powered on, or touchscreen is not responsive.	Battery has been discharged	The Connect may require charging. Refer to the Maintenance section on how to charge your Connect.
	The Connect has been stored in an extremely cold or hot environment.	As a safety measure, the Connect 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.
	Connect requires a hard reset	Reset the Connect by holding the display button for several seconds. Release the button, and the Avive logo should appear on the screen as the device reboots.
	The Avive Connect has been damaged and is inoperable.	Contact Avive to resolve the issue.

6. Maintenance

A. Charging the Avive Connect

Attach the Avive USB Power Adapter to the Avive AED with the Avive USB Charging Cable to recharge the device.

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 Connect AED.*



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

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

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

B. Cleaning

Clean the Avive Connect by gently wiping down the exterior with a clean damp cloth.

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

C. 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.

7. Operating & Storage Conditions

Operating Conditions

The Avive Connect 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 Connect is rated to IP54 when installed onto an Avive AED® with an Avive® Pad Cartridge - dust protected, splash and spray proof.

Storage Conditions

It is important that the Avive Connect 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

8. Technical Data

Physical Specifications of Avive Connect with Avive AED and Avive Pad Cartridge Installed
Size: 143mm x 160mm x 66mm (5.63in x 6.30in x 2.60in)
Weight: 0.95 kg (2.1 lbs.)

Connect Battery
Battery Type: 3.7V, 4600mAH, Lithium Ion, Rechargeable, not user replaceable
Battery Standby Time: Up to 5 months

Wireless Connectivity
The Avive Connect has hardware that can communicate with compatible products that support Wi-Fi 802.11 b/g/n and/or cellular LTE-CATM to allow for remote monitoring of the Avive AED.
FCC ID: N7NHL78
FCC ID: 2ADHKATWILC1000

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

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

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

Test	Compliance Level	Guidance
RF Emissions CISPR 11	Group 1	The Avive Connect AED 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 Avive Connect AED 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 Avive Connect AED is intended for use in the electromagnetic environment specified below. The customer or the user of the Avive Connect AED 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 Avive Connect AED requires continued operation during power mains interruptions, it is recommended that the Avive Connect AED 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 Avive Connect AED, 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 Avive Connect AED is used exceeds the applicable RF compliance level above, the Avive Connect AED should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Avive Connect AED.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Avive Connect AED

The Avive Connect AED is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Avive Connect AED can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Avive Connect AED 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;	Pulse modulation [b] 217 Hz	2	0.3	28
1845						

1970		DECT; LTE Band 1, 3, 4, 25; UMTS				
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.

IMMUNITY to proximity magnetic fields		
Test Frequency Hz	**Modulation**	**Level (A/m)**
30 kHz [a]	CW	8
134.2 kHz	Pulse modulation [b] 2.1kHz	65 [c]
13.56 MHz	Pulse modulation [b] 50kHz	7.5 [c]

a) This test is applicable only to Avive Connect AED intended for use in the HOME HEALTHCARE ENVIRONMENT.
b) Carrier modulated using a 50% duty cycle square wave.
c) r.m.s., before modulation is applied.

Battery Safety UN38.3, IEC 62133, UL2054

Ingress Protection IEC60529, IP54 when installed with Avive AED and Avive Pad Cartridge

Shipping and Transportation ASTMD4169-16 Assurance Level I

Expected Service Life 7 years