Automated External Defibrillators (AEDs)

For Purchasers and Clinical Engineers
Letter on AEDs and Accessories (/media/131108/download)(PDF)

Automated external defibrillators (AEDs) are portable, life-saving devices designed to treat people experiencing sudden cardiac arrest, a medical condition in which the heart stops beating suddenly and unexpectedly.

The combination of CPR and early defibrillation is effective in saving lives when used in the first few minutes following collapse from sudden cardiac arrest.

On this page:

What Are AEDs?

AEDs are portable, life-saving devices designed to treat people experiencing sudden cardiac arrest, a medical condition in which the heart suddenly and unexpectedly stops beating. The AED system includes accessories, such as a battery and pad electrodes, that are necessary for the AED to detect and interpret an electrocardiogram and deliver an electrical shock. There are two main types of AEDs: public access and professional use.

- **Public access AEDs** can be found in airports, community centers, schools, government buildings, hospitals, and other public locations. They are intended to be used by laypeople who have received minimal training.
- **Professional use AEDs** are used by first responders, such as emergency medical technicians (EMTs) and paramedics, who receive additional AED training.

AEDs can be semi-automated or fully automated.

- **Semi-automated defibrillators** analyze the heart's rhythm, and if an abnormal heart rhythm is detected that requires a shock, then the device prompts the user to press a button to deliver a defibrillation shock.
- **Fully automated defibrillators** analyze the heart's rhythm and deliver a defibrillation shock if commanded by the device software without user intervention.

Check Your AED: Is it FDA Approved?

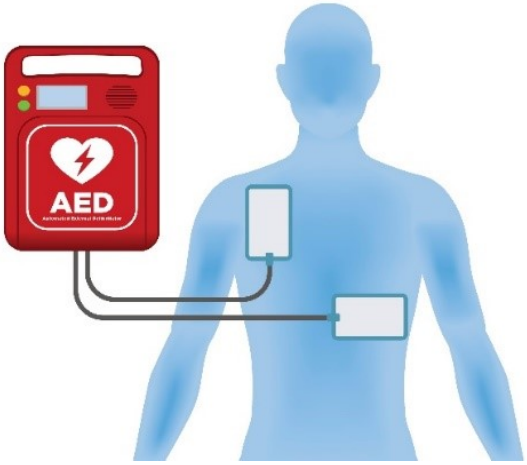
The FDA published a final order in February 2015 requiring premarket approval (PMA) applications for new and existing AEDs and necessary AED accessories. Manufacturers of all necessary AED accessories, such as batteries, pad electrodes, adapters and hardware keys for pediatric use, must file a premarket approval application (PMA) by February 3, 2020. If a PMA is not filed by February 3, 2020, the manufacturer must cease marketing their accessories by February 3, 2021.

There are now FDA-approved AEDs available, and we encourage you to ensure your AED is FDA-approved; if it is not, we encourage you to begin making plans to transition to an FDA-approved AED.

If you or your organization own(s) an AED system, the FDA recommends you:

- Check the table below to see if your AED is FDA-approved. Contact the manufacturer of your AED if you are not sure if your AED is FDA-approved.

- Contact the manufacturer of your AED if your AED is not FDA-approved and you have not received a letter about your AED.
- Be aware that if your AED is not FDA-approved, compatible necessary AED accessories may no longer be available to support your AED after February 3, 2021.



- Contact the manufacturer of your AED or AED accessories for information specific to your product.
- Given the importance of these devices in emergency situations, the FDA recommends you continue to keep your AED available for use until you receive an FDA- approved AED.
- Report problems with AEDs to the FDA by submitting a voluntary report online at MedWatch (https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program).

FDA-Approved AEDs

The table below lists all AEDs that have received premarket approval from the FDA. If your AED is listed below, no matter your purchase date, the AED is considered FDA-approved. The FDA will update this table when new AEDs are approved. For descriptions of these devices, their indications for use, and related information, follow the Premarket Database links.

> Important: If your AED is not listed in this table, please contact the manufacturer of your AED for more information about your device.

Manufacturer	Device Name	AED Type	Approval Date	Premarket Database
Cardiac Science Corporation	Powerheart G3 AED (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160033S001)	Public Access	12/07/2018	P160033 (https://www.accessdata.fda.gov/scripts/cdrh/cfid=P160033)
Cardiac Science Corporation	Powerheart G3 Plus AED (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160033S001)	Public Access	12/07/2018	P160033 (https://www.accessdata.fda.gov/scripts/cdrh/cfid=P160033)
Cardiac Science Corporation	Powerheart G5 AED (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160033S001)	Public Access	12/07/2018	P160033 (https://www.accessdata.fda.gov/scripts/cdrh/cfid=P160033)
Cardiac Science Corporation	Powerheart G3 PRO AED (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P160034)	Professional Use	12/06/2018	P160034 (https://www.accessdata.fda.gov/scripts/cdrh/cfid=P160034)
Defibtech, LLC	Lifeline/ReviveR DDU-100 (https://www.fda.gov/medical-devices/recently-approved-devices/lifelinereviver-ecg-and-ddu-automated-defibrillators-p160032)	Public Access	02/01/2018	P160032 (https://www.accessdata.fda.gov/scripts/cdrh/cfid=P160032)
Defibtech, LLC	Lifeline/ReviveR AUTO DDU-120 (https://www.fda.gov/medical-devices/recently-approved-devices/lifelinereviver-ecg-and-ddu-automated-defibrillators-p160032)	Public Access	02/01/2018	P160032 (https://www.accessdata.fda.gov/scripts/cdrh/cfid=P160032)
Defibtech, LLC	Lifeline/ReviveR VIEW DDU-2300 (https://www.fda.gov/medical-devices/recently-approved-devices/lifelinereviver-ecg-and-ddu-automated-defibrillators-p160032)	Public Access	02/01/2018	P160032 (https://www.accessdata.fda.gov/scripts/cdrh/cfid=P160032)
Defibtech, LLC	Lifeline/ReviveR VIEW AUTO DDU-2200 (https://www.fda.gov/medical-devices/recently-approved-devices/lifelinereviver-ecg-and-ddu-automated-defibrillators-p160032)	Public Access	02/01/2018	P160032 (https://www.accessdata.fda.gov/scripts/cdrh/cfid=P160032)
Defibtech,	Lifeline/ReviveR ECG DDU-2450 (https://www.fda.gov/medical-	Public	02/01/2018	P160032

LLC	devices/recently-approved-devices/lifelinereviver-ecg-and-ddu-automated-defibrillators-p160032)	Access		(https://www.accessdata.fda.gov/scripts/cdrh/cfid=P160032)
Defibtech, LLC	Lifeline/ReviveR ECG+ DDU-2475 (https://www.fda.gov/medical-devices/recently-approved-devices/lifelinereviver-ecg-and-ddu-automated-defibrillators-p160032)	Public Access	02/01/2018	P160032 (https://www.accessdata.fda.gov/scripts/cdrh/cfid=P160032)
HeartSine Technologies, LLC	SAM 350P (Samaritan Public Access Automated External Defibrillator) (https://www.fda.gov/medical-devices/recently-approved-devices/heartsine-samaritanr-sam-350p-sam-360p-and-sam-450p-pads-and-accessories-p160008)	Public Access	01/12/2017	P160008 (https://www.accessdata.fda.gov/scripts/cdrh/cfid=P160008)
HeartSine Technologies, LLC	SAM 360P (Samaritan Public Access Automated External Defibrillator) (https://www.fda.gov/medical-devices/recently-approved-devices/heartsine-samaritanr-sam-350p-sam-360p-and-sam-450p-pads-and-accessories-p160008)	Public Access	01/12/2017	P160008 (https://www.accessdata.fda.gov/scripts/cdrh/cfid=P160008)
HeartSine Technologies, LLC	SAM 450P (Samaritan Public Access Automated External Defibrillator) (https://www.fda.gov/medical-devices/recently-approved-devices/heartsine-samaritanr-sam-350p-sam-360p-and-sam-450p-pads-and-accessories-p160008)	Public Access	01/12/2017	P160008 (https://www.accessdata.fda.gov/scripts/cdrh/cfid=P160008)
Philips Medical Systems	HeartStart Home	Home Use	06/06/2019	P160029 (https://www.accessdata.fda.gov/scripts/cdrh/cfid=P160029)
Philips Medical Systems	HeartStart OnSite	Public Access	06/06/2019	P160029 (https://www.accessdata.fda.gov/scripts/cdrh/cfid=P160029)
Philips Medical Systems	HeartStart FR3	Public Access	*See note	*See note
Philips Medical Systems	HeartStart FRx	Public Access	*See note	*See note
Physio-Control, Inc.	LIFEPAK CR Plus Defibrillator (https://www.fda.gov/medical-devices/recently-approved-devices/lifepak-crr-plus-defibrillator-lifepak-expressr-defibrillator-and-charge-pakr-battery-charger)	Public Access	12/21/2017	P160012 (https://www.accessdata.fda.gov/scripts/cdrh/cfid=P160012)
Physio-Control, Inc.	LIFEPAK EXPRESS Defibrillator (https://www.fda.gov/medical-devices/recently-approved-devices/lifepak-crr-plus-defibrillator-lifepak-expressr-defibrillator-and-charge-pakr-battery-charger)	Public Access	12/21/2017	P160012 (https://www.accessdata.fda.gov/scripts/cdrh/cfid=P160012)
Physio-Control, Inc.	LIFEPAK CR2 Defibrillator (https://www.fda.gov/medical-devices/recently-approved-devices/lifepakr-cr2-defibrillator-p170018)	Public Access	12/21/2018	P170018 (https://www.accessdata.fda.gov/scripts/cdrh/cfid=P170018)
Physio-Control, Inc.	LIFEPAK 15 Monitor/Defibrillator (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160026S001)	Professional Use	07/02/2018	P160026 (https://www.accessdata.fda.gov/scripts/cdrh/cfid=P160026)
Physio-Control, Inc.	LIFEPAK 20E Defibrillator/ Monitor (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160026S006)	Professional Use	07/02/2018	P160026 (https://www.accessdata.fda.gov/scripts/cdrh/cfid=P160026)
Physio-Control, Inc.	LIFEPAK 1000 Defibrillator (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160026S006)	Professional Use	07/02/2018	P160026 (https://www.accessdata.fda.gov/scripts/cdrh/cfid=P160026)
ZOLL Medical Corporation	AED Plus and Fully Automatic AED Plus (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160015)	Public Access	05/26/2017	P160015 (https://www.accessdata.fda.gov/scripts/cdrh/cfid=P160015)
ZOLL Medical Corporation	X Series Defibrillator (https://www.fda.gov/medical-devices/recently-approved-devices/zollr-x-seriesr-r-seriesr-aed-pror-and-aed-3-blsr-professional-defibrillators-p160022)	Professional Use	12/27/2017	P160022 (https://www.accessdata.fda.gov/scripts/cdrh/cfid=P160022)
ZOLL Medical Corporation	R Series Defibrillator (https://www.fda.gov/medical-devices/recently-approved-devices/zollr-x-seriesr-r-seriesr-aed-pror-and-aed-3-blsr-professional-defibrillators-p160022)	Professional Use	12/27/2017	P160022 (https://www.accessdata.fda.gov/scripts/cdrh/cfid=P160022)
ZOLL Medical Corporation	AED Pro Defibrillator (https://www.fda.gov/medical-devices/recently-approved-devices/zollr-x-seriesr-r-seriesr-aed-pror-and-aed-3-blsr-professional-defibrillators-p160022)	Professional Use	12/27/2017	P160022 (https://www.accessdata.fda.gov/scripts/cdrh/cfid=P160022)
ZOLL Medical Corporation	AED 3 BLS Defibrillator (https://www.fda.gov/medical-devices/recently-approved-devices/zollr-x-seriesr-r-seriesr-aed-pror-and-aed-3-blsr-professional-defibrillators-p160022)	Professional Use	12/27/2017	P160022 (https://www.accessdata.fda.gov/scripts/cdrh/cfid=P160022)

*PMA is approvable subject to an FDA inspection that finds the manufacturing facilities, methods, and controls in compliance with the applicable requirements of the Quality System regulation (21

CFR Part 820)

Important Information for AED Manufacturers

To ensure the quality and reliability of AEDs the FDA now requires manufacturers to obtain premarket approval (https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma)for all AEDs.

Manufacturers of currently legally marketed necessary AED accessories, such as batteries, pad electrodes, adapters and hardware keys for pediatric use, must file a premarket approval application (PMA) by February 3, 2020.

FDA does not intend to enforce compliance with the February 3, 2020, deadline for necessary AED accessories for one year in order to allow health care facilities time to transition to FDA-approved AEDs. Therefore, if a PMA is not filed by February 3, 2020, the manufacturer must cease marketing their accessories by February 3, 2021. This marketing deadline includes necessary AED accessories that are labeled for AEDs that are not FDA-approved.

FDA expects that necessary AED accessories will be labeled for use with an FDA-approved AED device (on the list above). Manufacturers submitting a PMA for necessary AED accessories should be aware that they can continue to market those accessories while the PMA is pending until the FDA issues a decision (approval, not approvable, or denial decision). After a PMA decision is made, only FDA-approved accessories can continue to be marketed.

The FDA's premarket approval of new and existing AEDs is based on a determination that the application contains sufficient valid scientific evidence to reasonably assure the device is safe and effective for its intended use. This regulatory pathway requires manufacturers to receive FDA approval before initiating design, manufacturing, or labeling changes to the device, and imposes certain other annual reporting requirements.

Once the AEDs are on the market, the FDA proactively monitors the safety and reliability of AEDs by reviewing the AED manufacturers' manufacturing and design changes, performance reports, and medical device reports (MDRs). When a company initiates a correction or removal action, the FDA posts information about the action in the Medical Device Recall Database. For information on AED systems or necessary AED accessories that have been recalled, you can search the database using the device's product code. Once classified, the FDA monitors the recall to ensure that the recall strategy has been effective.

The FDA's Continued Efforts to Keep AEDs Reliable

The FDA recognizes the importance of AEDs as life-saving devices. Problems associated with many AEDs include design and manufacturing issues, such as inadequate control of components purchased from suppliers or inadequate validation of manufacturing processes. When this occurs, an AED device can malfunction and may contribute to patient harm or prevent the rescue of the patient.

Given this, the FDA has taken several actions to assure that current and future AED devices and accessories are safe and reliable. These actions include:

- **By February 3, 2021:** Manufacturers of necessary AED accessories (such as batteries, pad electrodes, adaptors and hardware keys for pediatric use) for AED systems that are not FDA-approved may market their AED accessories until February 3, 2021.
- **By February 3, 2020:** Manufacturers of necessary accessories (such as batteries, pad electrodes, adapters) for AED systems that are FDA-approved are required to file a premarket approval application.
- **April 2019:** The FDA sent letters to all AED manufacturers, who did not submit a premarket approval (PMA) application for their AEDs as required by the final order (https://www.federalregister.gov/documents/2015/02/03/2015-02049/effective-date-of-requirement-for-premarket-approval-for-automated-external-defibrillator-systems), reminding them they can no longer market their AED; the letters also informed the manufactures that necessary AED accessories may not be marketed after February 3, 2020, if a PMA is not filed. Manufacturers were asked to provide a plan for these AEDs and necessary AED accessories, including a timeline for servicing and phase-out activities, a plan for communicating with their customers, and an estimate of the volume of AEDs and accessories that remain in the field.

- **November 1, 2017:** The FDA and Philips Medical Systems LLC entered a consent decree (https://www.fda.gov/news-events/press-announcements/fda-reaches-agreement-automatic-external-defibrillator-manufacturer-over-quality-control-issues)of permanent injunction prohibiting Philips Medical Systems, Philips Healthcare, and those individually named from manufacturing, processing, packing, holding, or distributing AEDs from two facilities until they comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act).
- **February 2015:** The FDA published a final order (https://www.federalregister.gov/documents/2015/02/03/2015-02049/effective-date-of-requirement-for-premarket-approval-for-automated-external-defibrillator-systems)in February 2015 requiring premarket approval (PMA) applications for new and existing AEDs and necessary AED accessories.
- **December 2013:** The FDA issued a Safety Communication (http://wayback.archive-it.org/7993/20170722215732/https:/www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm376938.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) alerting all users of the Philips HeartStart FRx, HS1 Home and HS1 OnSite AEDs manufactured between 2005 and 2012 that these devices may fail to deliver a shock in the event of an emergency.
- **March 2013:** The FDA published a proposed order (https://www.regulations.gov/document?D=FDA-2013-N-0234-0001)to allow for notice and comment regarding the FDA's recommendation to require premarket approval (PMA) applications for AEDs and necessary AED accessories.
- **January 2011:** The FDA convened a public meeting (https://www.regulations.gov/document?D=FDA-2013-N-0234-0001)of the Circulatory System Device Panel of the Medical Devices Advisory Committee where the FDA presented its comprehensive assessment of AEDs. The panel of independent experts considered the FDA's assessment of AEDs and its recommendation that more stringent FDA oversight be applied to reduce future AED problems. The panel agreed with the FDA's recommendation to require PMA applications for AEDs.
- **November 2010:** The FDA released the External Defibrillator Improvement Initiative Paper (https://www.pharmamedtechbi.com/~/media/Images/Publications/Archive/The Gray Sheet/36/47/01101122002/112210_aed_paper.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) to foster the development of better-performing external defibrillators and to address the current industry practices for designing and manufacturing devices and identifying, reporting, and taking action to address device complaints they receive.