



September 26, 2019

Dear AED Owner, Healthcare Value Analysis Professional, Clinical Engineer, Physician Prescriber, or Physician Supervisor:

To help ensure the quality and reliability of automated external defibrillator (AED) systems, the FDA has established more stringent regulatory requirements for AEDs and their accessories by requiring these devices to be FDA-approved. If your AED is not FDA-approved, the accessories necessary for your AED may no longer be supported by the manufacturer, and thus no longer available after **February 3, 2021**.

To ensure the availability of life-saving treatment with the AEDs in your facilities, we encourage you to ensure that your AED is FDA-approved and if it is not, begin making plans to transition to an FDA-approved AED. To assist you, these are the steps the FDA recommends that you take.

- 1. Check the [list of FDA-approved AEDs](#) on the Automated External Defibrillators (AEDs) webpage on FDA.gov to see if your AED is FDA-approved.**
- 2. If your AED is not listed, you should plan to transition to an FDA-approved AED system. Contact the manufacturer of your current AED to discuss your transition plans.**
- 3. Ensure that you have compatible AED accessories to meet your needs until you transition to an FDA-approved AED. This is particularly important because AED accessories may require frequent replacement.**

AEDs can be highly effective in saving the lives of people suffering cardiac arrest when used in the first few minutes following collapse from cardiac arrest. **Given the importance of these devices in emergency situations, the FDA recommends you continue to keep your AED available for use until you obtain an FDA-approved AED.**

For a medical device to be FDA-approved, the manufacturer must obtain premarket approval. Approval is based on a determination that there is sufficient valid scientific evidence to demonstrate a reasonable assurance of safety and effectiveness. In 2015, the FDA published a [final order](#) describing concerns about adverse event reports and product recalls for AED systems, and concluded that AED systems and necessary AED accessories require more FDA oversight. The final order established the requirement for premarket approval for all AEDs and necessary accessories.

<https://www.federalregister.gov/documents/2015/02/03/2015-02049/effective-date-of-requirement-for-premarket-approval-for-automated-external-defibrillator-systems>).

The FDA will continue to update the list of FDA-approved AEDs on the [Automated External Defibrillators \(AEDs\) page](#) on FDA.gov.



If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV 800-638-2041 or 301-796-7100.

Sincerely,

/s/

William Maisel, MD, MPH

Director

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

U.S. Food and Drug Administration