AED product discontinuation FAQs

LIFEPAK® AEDs

For products marketed in the U.S.

Q: Which LIFEPAK devices were addressed in Stryker's product discontinuation notice?

A: LIFEPAK 12 monitor/defibrillator, LIFEPAK 20 defibrillator/monitor, and LIFEPAK 500 defibrillator.

Q: Why are service, accessories, and disposables being discontinued for these products?

A: Maintaining parts and service on aging products becomes increasingly complex and challenging. Production of these devices ceased multiple years ago and discontinuation notices have been sent for the last few years. In addition, the FDA has established a deadline where accessories specific to these devices will no longer be approved for sale in the US.

Q: What has the FDA implemented and how is Stryker responding?

A: In April 2019, the FDA communicated regarding the final order requiring premarket approval (PMA) applications for new and existing AEDs and necessary AED accessories:

> *"In 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, 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." **

In September 2019, the FDA updated the deadline for marketing AED accessories to no later than February 3, 2021 to allow customers adequate time to transition to PMA approved AEDs:

> *"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." **

In July 2019, Stryker released a letter detailing how we will continue to honor existing service contracts, as parts availability allows, until no later than **June 30, 2020**. Accessories that are part of some service plans, including LIFEPAK 500 and LIFEPAK 12 batteries, will no longer be available past **February 3, 2020**. LIFEPAK 20 devices which require battery replacement as part of its service will be available as supplies last, but no later than **December 31, 2020**.

Based on the additional time provided through FDA, other accessories such as electrodes will continue to be available until **February 3, 2021**.

Q: Who do I contact with any questions?

A: Please contact your local Stryker sales representative or authorized distributor to discuss trade-in and flexible financing options to support you during this transition. You may also contact Stryker Customer Service at (800) 442-1142, option 2.

*https://www.fda.gov/medical-devices/cardiovascular-devices/automated-external-defibrillators-aeds

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