

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:** Does this product discontinuation include the LIFEPAK 20e?
- A:** No, the LIFEPAK 20e is PMA approved and is actively being sold and supported.
- 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:** Over the last year, the FDA has made several updates to their guidance.

April 2019

FDA communicated regarding the final order requiring premarket approval (PMA) applications for new and existing AEDs and necessary AED accessories.

July 2019

Stryker released a letter detailing the end of support for the LIFEPAK 500, LIFEPAK 20 and LIFEPAK 12, and sharing dates for the termination of service and availability to order accessories.

September 2019

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." **

October 2020

FDA updated the deadline for marketing AED accessories to no later than February 2, 2022 to allow customers additional time to transition due to the COVID-19 pandemic. Stryker had already taken steps to discontinue affected products and accessories. These plans will continue and include the following dates.

- Stryker honored existing service contracts for LIFEPAK 12 through **June 30, 2020**.
- LIFEPAK 20 batteries and service will be available as supplies last, but no later than **December 31, 2020**.
- Other accessories such as pad electrodes will continue to be available and will no longer be marketed after **February 3, 2022**.

Emergency Care

- Accessories that are part of some service plans, including LIFEPAK 500 and LIFEPAK 12 batteries, were discontinued as of **February 3, 2020**.

Stryker updated its customer letter to confirm previously communicated discontinuation dates. An update was also made to the www.strykeremergencycare.com website.

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.

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

Copyright © 2020 Stryker. GDR 3342605_C

Emergency Care

11811 Willows Road NE, Redmond, WA 98052 USA | P +1 425 867 4000 | Toll-free +1 800 442 1142 | stryker.com