PHILIPS

Emergency Care & Resuscitation
22100 Bothell Everett Highway
Bothell, WA 98021

December 16, 2019

Dear Philips HeartStart Customers,

On December 31, 2012, Philips announced its intention to discontinue the HeartStart FR2/FR2+. Six years later, on December 31, 2018, Philips announced end of life support for HeartStart FR2/FR2+ AEDs and most FR2/FR2+ accessories.

This letter is to inform you that Philips will not ship any of the products listed below to USA locations after February 2, 2021. In order to accommodate this stoppage of shipments, the last day to place orders for the HeartStart FR2/FR2+ AED accessories listed below will be December 31, 2020. Orders for these part numbers that cannot be shipped by February 2, 2021 will be cancelled.

Part Number	Description	USA Customers: Last day to place orders
M3863A	Battery Pack. Disposable lithium battery.	December 31, 2020
M3848A	Lithium ION Rechargeable battery	December 31, 2020
989803136291	Battery, Aviation, LiMnO2, FR2 series	December 31, 2020
M3870A	FR2 Pediatric Defibrillator Pads	December 31, 2020
07-10900	Defibrillator Training Pads: 1 Set	December 31, 2020
07-11000	Defibrillator Trainer Carry Case	December 31, 2020
M3871A	FR2 Series Infant/Child Training Pads	December 31, 2020
989803158211	Defibrillation Pads: 1-pack (for use with FR2)	December 31, 2020
989803158221	Defibrillation Pads: 5-pack (for use with FR2)	December 31, 2020

The United States Food and Drug Administration (FDA) published a final order in February 2015 requiring premarket approval (PMA) applications for new and existing AEDs and necessary AED accessories. There are now FDA-approved AEDs available, and we encourage you to begin making plans to transition to an FDA-approved AED.

Philips currently offers the following PMA approved AEDs:

> **HeartStart OnSite** (Model M5066A) and **HeartStart Home** (Model M5068A) - The HeartStart OnSite and Home Defibrillators are light-weight, easy-to-use Automated External Defibrillators (AED), indicated to treat potential victims of cardiac arrest. The HeartStart OnSite and HeartStart Home defibrillator are designed for use by a lay-person and are intended for public access defibrillation (HeartStart OnSite) and home use (HeartStart Home). Both devices are designated for over-the-counter sale; the infant/child SMART pads cartridge (M5072A) is prescription-use only.
>
> Both the HeartStart OnSite and HeartStart Home prompt users to take specific actions if a potentially shockable rhythm is detected. HeartStart OnSite and HeartStart Home are able to provide verbal instructions to the user, detect where the user is in the event response, and provide general CPR guidance.

This communication is intended for Philips HeartStart customers in the United States and United States territories.

PHILIPS

Emergency Care & Resuscitation
22100 Bothell Everett Highway
Bothell, WA 98021

In addition, the following existing Philips AEDs currently have PMA applications which FDA has determined are approvable, subject to a successful FDA final inspection of the manufacturing facility. These devices are available for order and Philips will issue a subsequent communication at the time these devices become available for shipment.

- **HeartStart FRx** (Model 861304) - The HeartStart FRx AED is a small, lightweight, portable, rugged, battery powered automated external defibrillator (AED) indicated to treat potential victims of sudden cardiac arrest (SCA). This device is designated prescription-use only. The FRx is a public access AED. Users should have received training in basic life support/AED, or a physician-authorized emergency medical response training program. The FRx is highly configurable for local protocol considerations. The HeartStart FRx (Model 861304) is indicated for adults over 55 pounds (25kg). The Model 861304 is also indicated for infants and children under 55 pounds (25 kg) or 8 years old when used with the optional Infant/Child Key. The Infant/Child key is designated prescription-use only

- **HeartStart FR3** (Models 861388 and 861389) - The HeartStart FR3 AED is a compact, light-weight, battery-powered, automated external defibrillator (AED) indicated to treat potential victims of sudden cardiac arrest. This device is designated prescription-use only. The use environment of this AED is in pre-hospital emergency response settings. The intended user is trained in Basic Life Support (BLS), Advanced Life Support (ALS), or another physician-authorized training program. The device has an easy to use interface for the responder to activate the device, apply the pads, and deliver a shock. The models 861388 and 861389 are indicated for adults over 55 pounds (25 kg). The models 861388 and 861389 are also indicated for infants and children under 55 pounds (25 kg) or 8 years old when used with the optional Infant/Child Key.

Please contact your Philips representative or Philips authorized distributor if you have questions, need assistance in planning for this upcoming end of support, or would like additional information about PMA approved or PMA approvable AED devices.

Yours Sincerely,

Arman Voskerchyan
Business Leader
Therapeutic Care
Philips