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

December 18, 2019

Dear Valued Philips HeartStart MRx Customer,

We appreciate your loyalty as a customer of our Philips HeartStart MRx to help you care for your patients.

The United States Food and Drug Administration (FDA) imposed new requirements in February 2015 on manufacturers of AEDs and devices with an integrated AED mode. Under these new requirements, manufacturers must comply with the premarket approval (PMA) process instead of the previous 510(k) clearance process for these devices and their accessories, e.g., electrode pads and batteries. In September this year, the FDA clarified its position and informed all manufacturers that currently marketed AED accessories for which no PMA is filed by February 3, 2020 cannot be sold or delivered after February 3, 2021. The MRx devices in the United States that were legally sold under a 510(k) clearance can continue to be used by their owners.

This letter is to update you that the new end-of-life date for supplying HeartStart MRx pads, batteries and accessories for the MRx in the United States will be **February 3, 2021**. After this date, Philips will no longer be able to ship MRx pads, batteries and accessories in the USA. The last day to place orders for MRx pads, batteries and accessories will be **December 31, 2020**. Philips intends to honor orders, as inventory allows, until February 2, 2021.

Philips does not have a PMA-approved Advanced Life Support (ALS) monitor/defibrillator to replace the MRx available in the USA at this time. Philips intends to release the Philips RDT Tempus ALS solution[1], a unique pre-hospital modular monitor-defibrillator with manual mode only that also facilitates an easy capture and sharing of data, following submission and clearance of 510(k) for the solution. We also recently launched a next-generation Advanced Life Support HeartStart Intrepid monitor/defibrillator for the hospital and pre-hospital markets. It is now available in a number of countries, and Philips is beginning the regulatory work to bring the HeartStart Intrepid to the USA market.

We will update you when new Philips solutions become available in the USA. In addition, there are PMA-approved monitor/defibrillators available from other vendors. In the meantime, please contact your Philips representative to discuss in greater detail your best options for managing your current MRx devices during this transition period.

We appreciate your loyalty as a Philips HeartStart customer. Please contact your Philips representative if you have questions, need assistance in planning for this upcoming transition, or would like additional information about PMA-approved devices.

1 – With respect to other RDT products, Tempus Pro Monitor and Philips IntelliSpace Corsium are 510(k) cleared and available in the USA, and Tempus LS and Tempus LS-Manual are not available for commercial distribution in the US.