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

July 31st, 2020

Dear Valued Philips HeartStart MRx Customer,

I deeply appreciate your loyalty as a Philips customer. Philips remains fully committed to helping you provide the best possible care for your patients. This letter is to inform you on an additional year extension on the availability of non-PMA accessories and an update to the support date for the MRx in the USA, based on recent communications we have received from the U.S. Food and Drug Administration (FDA).

Philips previously communicated that the FDA imposed new requirements in February 2015 on manufacturers of automated external defibrillators (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., pad electrodes and batteries. Previously in September of 2019, the FDA clarified its position and informed all manufacturers that currently marketed accessories for use on AEDs and devices containing an AED mode, for which no PMA is filed ("Legacy AED Accessories"), could not be sold or delivered after February 3, 2021. This restriction on the sale and delivery of accessories does not prevent owners of MRx's and other defibrillators that were legally sold under a 510(k) clearance from continuing to use their devices.

In June 2020, FDA informed Philips that due to the COVID-19 pandemic, it will permit the distribution of Legacy AED Accessories for an additional year, i.e., until February 3, 2022. Therefore, the new end-of-life date for supplying HeartStart MRx pad electrodes, batteries and accessories in the United States has been extended to **February 3, 2022**. After this date, Philips will no longer be able to ship HeartStart MRx pad electrodes and batteries in the USA. The last day to place orders for MRx pad electrodes, batteries and accessories will be January 2, 2022. Philips intends to honor orders, as inventory allows, until February 2, 2022.

The FDA has also clarified to Philips that it expects the cessation of supply of accessories to coincide with cessation of service. This means that the new USA-only, effective end-of-life date for MRx is February 3, 2022, earlier than the originally announced MRx end-of-life date of December 31, 2022.

We understand this may affect your asset management planning and to assist, Philips is accelerating steps to be able to offer commercial solutions to replace your MRx devices. Specifically, we have just received 510(k) clearance to market a new Advanced Life Support (ALS) monitor/defibrillator solution, Tempus LS-Manual, to replace the MRx in pre-hospital markets. Tempus LS-Manual is a unique modular monitor/defibrillator with robust data capture capabilities and a manual defibrillation mode only. Philips 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 we have begun the regulatory preparation to bring the HeartStart Intrepid to the United States.

Again, I sincerely appreciate your loyalty as a Philips HeartStart customer and want to ensure you understand the facts and your options associated with these new dates. As such, Philips will update you immediately when new Philips solutions continue to become available in the USA. In the meantime, please know that we are committed to your ongoing support as we transition to powerful, next-generation solutions for emergency care. Your local Philips representative stands ready to help if you have questions about PMA-approved devices or need assistance in planning during this transition period.

Yours Sincerely,

Arman Voskerchyan
Business Leader
Philips, Therapeutic Care