PHILIPS

12 July 2021

Dear valued Philips customer,

We are currently facing several supply challenges in our Emergency Care business. First, our HeartStart HS1 and FRx Automated External Defibrillator (AED) devices, as well as select accessories, are experiencing shipping delays due to component supply availability at our vendors, largely related to the global semiconductor component shortage. Next, we are making changes to comply with the European Union Medical Device Directive (EU MDR). Finally, our ALS HeartStart Intrepid monitor/defibrillator, which runs on AC power, is currently on ship hold. We take these issues seriously. This letter gives you an overview of each challenge and the steps we are taking to resolve the challenges.

First, we are concerned about the global shortage of semiconductor components currently affecting the technology industry and the impact this shortage has on our commitment to deliver AEDs to our customers. This shortage is particularly acute because the medical technology industry is under pressure to produce the lifesaving products and solutions needed to combat COVID-19 and restore elective care. Frans van Houten, Philips' CEO, has called on the semiconductor industry to prioritize supply to the healthcare sector. Philips has strong cross-functional teams that collaborate with our suppliers to manage its supply chain as the semiconductor and commodity supply landscape changes almost daily. Despite the dynamic and unreliable supply of components, we remain committed to delivering as many AEDs as possible.

Second, to continue to sell AEDs in the European Union (EU), AEDs and accessories will need to comply with the European Union Medical Device Regulation (EU MDR). In connection with this requirement, please be aware of the following:

- AEDs Monitor/Defibrillators are Class IIb devices under the Medical Device Directive (MDD). These devices may continue to be placed on the EU market under the MDD until 26 May 2024 and made available on the market until 26 May 2025. Any AEDs manufactured and available after 26 May 2024 must be EU MDR compliant. This requirement also applies to AED accessories that are class II or class III under the MDD.
- Accessories that are class I under the MDD and have been placed on the market prior to 26 May 2021 can continue to be made available on the market until 26 May 2025. Any class I accessory manufactured and placed on the market after 26 May 2021 must be EU MDR compliant.

To optimally support customers and distributors, we intend to ready all products and accessories to comply with the new EU MDR regulatory requirements in a timely manner and with no shipping disruption. We achieved this goal for over 95% of products and accessories and expect the balance of products and accessories to achieve full compliance during the next six to eight weeks.

As a third and separate issue, Philips released a Field Safety Notice (FSN) on the HeartStart Intrepid Monitor/Defibrillator device. This FSN is to inform customers that in certain circumstances, when the device is connected to an AC power source, it may cause interference on other monitoring devices if both devices are connected to a patient at the same time. While the Intrepid device meets the applicable standards for electromagnetic compatibility (EMC), Philips has alerted current customers to the potential risk. Please refer to the FSN for more information about actions to be taken by customer and distributors.

We will resolve these challenges and get back to the business we care about the most – providing our customers with the lifesaving medical devices so very much needed.

Sincerely,

Maegan Wilkinson

General Manager, Emergency Care & Resuscitation Business Category

Date: 12 July 2021