PRODUCT DISRUPTION BRIEF

External defibrillators (reviewed May 29)

times are beginning to show improvement; work with your supplier representatives for alternative solutions.

Current conditions

In February 2023, Philips identified Regulatory Compliance issues with the Tempus Pro Monitor and has issued an urgent medical device correction. During Philips internal testing, regulatory compliance testing regarding fluid ingress and basic safety issues have been identified with the Tempus Pro Monitor, AC Mains Power Supply, and the Vehicle Adapter. Testing revealed the device does not meet the standards for fluid and particulate ingress. This may cause the possibility of the components overheating or unanticipated voltage emitted from the device's electrical components. There were no reports received by Philips of harm because of this issue in normal-use environments. The medical device correction affects all lot of Tempus Pro Monitor devices, part numbers 00-1004, 00-1004-R, 00-1007, 00-1007-R and 00-1026R. As there have been no indications of the issues resulting in degradation in product performance, Philips advise the Tempus Pro devices should remain in place.

Food and Drug Administration (FDA) changes to external defibrillators caused Philips to stop the sale of HeartStart XL. This along with raw material shortages has tightened the market, increasing demand with other suppliers who are experiencing longer lead times:

Stryker (CE7362) delays and lead times due to raw materials (copper) and chip shortages are improving, with lead times increasing from the standard four to eight weeks to the following:

- LIFEPAK 15, 32 to 33 weeks
- LUCAS, 14 to 18 weeks
- LIFEPAK CR2, 4 weeks
- Electrodes Adult, Standard Lead Times
- Electrodes QC, Standard Lead Times
- LIFEPAK 1000, 4 weeks
- HEARTSINE 300 Series, 10 weeks
- HEARTSINE 400 Series, 10 weeks
- Electrodes RTS, Standard Lead Times

Philips (CE7363) is waiting for FDA clearance for new technology and experiencing backlogs on the following products:

- All AEDs and AED Pads are shipping normally with one exception. The M5072A HeartStart OnSite Infant Child Pads will resume shipments in the May timeframe.
- All Monitor Defibs and pads are generally shipped with one exception. The Tempus Pro (EMS product) is on hold and expected to come off hold after FDA approval later in Q2 2024.
- All supplies and accessories are shipping normally.

Zoll R (CE7361) AED's lead times are 6-9 weeks. Crash cart R and X series defibrillators lead time are 4-6 weeks. Electrodes and Pads are 7 to 10 days.

Mitigation strategy

Philips and Zoll offer adapter options that can connect their pads to the LifePak 20e and 15 models related to electrodes and pads. Zoll-to-Physio Pad adapter part number is 2110. Smart Pads 3 part 989803149981 is the Philips adapter option.

Alternatives

All suppliers are experiencing longer lead times than usual but external defibrillators are still available from contracted suppliers Stryker, Philips and Zoll. If you decide to purchase from a non-contracted supplier, ensure the external defibrillator is FDA approved. US Med-Equip and Agiliti may have opportunities to rent. Please contact your local rep for further information regarding availability in your area.

Additional resources

Supply assurance webpage

Want to receive weekly Supply Assurance updates?
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Questions? Contact novaplus@vizientinc.com, pharmacyquestions@vizientinc.com, disasterresponse@vizientinc.com.

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