

Supply Alert update July 1th, 2021

To AED360 partners,

Update on the Philips problems with MDR certification. The consumables of the Philips AED's are affected by this and therefore also the AED's themselves. In concrete terms, Philips cannot deliver its products.

Obviously, Philips is working hard to ensure that the issues are resolved as soon as possible.

Updates

HS1/FRx M5070A batteries

MDR registration will be completed this week. Stock arrival is estimated by the end of July/early August

FRx 861304 Devices

Estimate production of FRx MDR devices is mid-July. Shipments will resume soon after, but remain subject to battery and PCBA board availability.

HS1 M5071A Adult Pads & HS1 M5072A Infant Pads

Release is based on the completion of the verification, validation and the regulatory timeline. European countries estimated release is mid/end August.

HS1 M5066A Devices

Resuming shipments in Europe is dependent on MDR battery and pads releases. Shipments will resume soon after, but remain subject to PCBA board availability

Please find below all updated details

Supply Alert	
Affected countries	All European countries
Product(s) affected	FRx AED (861304) HS1 AED (M5066A) HS1/ FRx Battery (M5070A) HS1 Adult Pads (M5071A) HS1 Infant/ Child Pads (M5072A)
Situation	Shipment hold
Reason	Consumables of the AED's are not yet compliant with the MDR regulation, which means that the AED's themselves cannot comply either.
Alternative	No alternative available
Estimated restart of shipment	Not yet known
Impact (general)	High: no shipment from Philips effective immediately