IRISH MEDICINES BOARD
SAFETY NOTICE

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HeartStart XL with M3516A batteries of lot number prefix 'LK'

IMB Safety Notice: SN2013(10)
Circulation Date: 2 September 2013

MANUFACTURER / SUPPLIER
Philips Healthcare

TARGET GROUPS
Paramedics
Emergency Medical Technicians
Ambulance Headquarters
Medical directors
Risk managers
Supplies managers
General practitioners
Private medical practitioners
Clinics
Hospitals
Nursing Homes

Please bring this safety notice to the attention of all who need to be aware of it.

ISSUE
Defibrillator battery life has been reduced from 1.5 years to 1 year.

BACKGROUND
Philips has reported a change in battery life for the HeartStart XL monitor / defibrillator. The battery life has been reduced from 1.5 years to 1 year and the capacity test interval is reduced from 6 months to 3 months. Changes apply to new batteries with lot number prefix 'LK'. HeartStart XL batteries with lot number prefixes 'P', 'R', and 'PCS' are not affected by this change. Philips is supplying an addendum with every new shipment of batteries, and updating the instructions for use and service manual accordingly. Problems can lead to the device not being ready for use when required.

The Irish Medicines Board (IMB) is issuing this Safety Notice to ensure all HeartStart XL users are aware of the issue.

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ACTION OR RECOMMENDATIONS

1. Ensure all relevant staff are aware of changes to battery life and capacity test frequency and follow up as appropriate.
2. Ensure that the addendum is attached to the instructions for use and service manual.

ENQUIRIES

Enquiries in relation to this action may be addressed to the Irish distributor:

Cardiac Services
128 Slaney Road
Glasnevin
Dublin 11

Telephone: +353-1-8307499
E-mail: recall@cardiac-services.com

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: vigilance@imb.ie
Website: www.imb.ie