Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2020/022 Issued: 23 July 2020 at 13:00

Philips sterilizable defibrillator internal paddles (specific models) – may fail to deliver therapy if pre-use checks are not followed

Summary

Manufactured by Philips – defibrillator internal paddles may wear over time and might fail to deliver therapy, so it is important to do routine operational checks between each usage.

Action

Note: This is a targeted MDA, sent via the Central Alerting System (CAS), to organisations in England supplied with these devices.

Different distribution arrangements may apply in the Devolved Administrations.

- Identify devices affected by the manufacturer's Field Safety Notice.
- Check all paddles between each usage, in accordance with the instructions for use, to confirm they are safe and ready for use. The checks include mechanical check, visual inspection, functional check and continuity check.
- If the device fails one or more of these checks, remove it from service and replace the paddles.
- Report suspected or actual adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales. You should also report directly to manufacturers if your local or national systems do not.

Action by
All medical, nursing and technical staff involved in the use and maintenance of these devices.

Deadlines for actions
Actions underway: 06 August 2020
Actions complete: 20 August 2020

Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

Remember: if your organisation receives an FSN from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Device details

Models numbers of affected devices:
M1741A, M1742A, M1743A, M1744A, M4741A, M4742A, M4743A, M4744A.

Manufacturer contacts

Philips Customer Care Service Centre
Tel: 0870 532 9741
Email: safetynoticeuki@philips.com
Quote FSN number: FSN86100197A

Distribution

Note: This is a targeted MDA, sent via the Central Alerting System (CAS), to organisations in England supplied with these devices.

Different distribution arrangements may apply in the Devolved Administrations.

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

CAS and NICAS liaison officers for onward distribution to all relevant staff including:

- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Operating department practitioners
- Sterile services departments
- Theatre managers
- Theatre nurses
- Theatres

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number MDA/2020/022 or 2020/004/023/291/002.

Technical aspects

Paul Sandhu, MHRA
Tel: 020 3080 6000
Email: DSS-TM@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA
Tel: 020 3080 7274
Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the Yellow Card reporting page

Northern Ireland

Northern Ireland Adverse Incident Centre (NIAIC), CMO Group, Department of Health (Northern Ireland)
Tel: 028 9052 3868
Email: niaic@health-ni.gov.uk

To report an adverse incident involving a medical device in Northern Ireland use the forms on the website.

Alerts in Northern Ireland are distributed via the NICAS system.

Scotland

Incident Reporting and Investigation Centre (IRIC), Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.iric@nhs.net

To report an adverse incident involving a medical device in Scotland, email IRIC to request a webform account.

For more information, or if you can't access the webform, visit the website: how to report an adverse incident

Wales

Population Healthcare Division, Welsh Government
Tel: 03000 255278 or 03000 255510
Email: Haz-Aic@gov.wales

To report an adverse incident involving a medical device in Wales, use the Yellow Card reporting page and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).