Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/017 Issued: 20 March 2019 at 11:00

Pagewriter Cardiographs (TC20/30/50/70) manufactured before 20 November 2018 and Efficia Monitors (CM10/12/100/120/150) manufactured before 25 October 2018 – risk of batteries overheating or igniting

Summary

Manufactured by Philips – this problem affects lithium ion batteries that have exceeded their specified replacement interval or number of charging cycles.

Action

Identify all affected devices using the manufacturer's Field Safety Notices (FSNs) for the TC Cardiograph and the Efficia monitor.

Contact Philips to confirm receipt of each FSN using their response form.

- For TC Cardiographs:
  - Check if the battery has exceeded 300 charge-discharge cycles or if the battery state of health is less than 80%. If necessary, replace the battery in accordance with the instructions in the FSN. Contact Philips to order replacement batteries.
  - Ensure that systems are in place to routinely assess battery condition. Philips are developing a software update that will assist in battery management and will contact you once this is available.

- For Efficia Monitors:
  - Install the software update (version A.01.11) described in the FSN
  - Once installed, the device will indicate via an error message if battery replacement is necessary. Contact Philips to order replacement batteries.

- Report 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: 10 April 2019
Actions complete: 01 May 2019

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

Images of TC Cardiographs

Images of Efficia Monitors

Problem / background

Philips have received reports of lithium ion batteries overheating and igniting when they exceed 300 charge/discharge cycles or when battery capacity fell below 80% that of a new battery. The device can display actual information on the battery state of health and charge-discharge cycles. However, the existing labelling does not include full instructions on how to use this information to determine when to replace the battery.

A previous medical device alert MDA/2018/0031 was published for the same issue in Philips Suresigns VS and VM patient monitors and viewing stations manufactured before the 03 May 2018. If you have these devices, please ensure that the actions described in that MDA have been completed.

Manufacturer contacts

Philips Customer Care Service Centre
Tel: 0870 532 9741
Email: DeviceVigilanceUKI@Philips.com

Distribution

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:

- A&E consultants
- A&E departments
- A&E directors

- A&E nurses
- Adult intensive care units
- Ambulance services directors
- Ambulance staff
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Biomedical engineering staff
- Biomedical science departments
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic surgery directors
- Community children’s nurses
- Community hospitals
- Coronary care departments
- Coronary care nurses
- Day surgery units
- EBME departments
- Endocrinology units
- Endocrinology, directors of
- ENT departments
- ENT medical staff
- ENT services, directors of
- Equipment stores
- Equipment libraries and stores
- Fire Safety Advisors
- Gastroenterology departments
- Gastroenterology, directors of
- Gastro-intestinal surgeons
- General surgeons
- General surgery
- General surgical units, directors of
- Gynaecologists
- Gynaecology departments
- Gynaecology nurses
- Haematologists
- Haemodialysis nurses
- Haemodialysis units
- Health and safety managers
- Hospital at home units
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Maintenance staff
- Maternity units
- Medical directors
- Midwifery departments
- Midwifery staff
- Neonatal nurse specialists

- Neonatology departments
- Neonatology directors
- NHS walk-in centres
- Nursing executive directors
- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics and gynaecology directors
- Obstetrics departments
- Obstetrics nurses
- Operating department practitioners
- Oral surgeons
- Outpatient clinics
- Outpatient theatre managers
- Outpatient theatre nurses
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric surgeons
- Paediatric surgery, directors of
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Paramedics
- Resuscitation officers and trainers
- Risk managers
- Theatre managers
- Theatre nurses
- Theatres

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

- Care homes providing nursing care (adults)
- Clinics
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2019/017** or 2019/001/015/487/001 for TC Cardiographs, 2019/001/021/487/001 for Efficia Monitors.

Technical aspects

Phillip Davenport, 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, Social Services and Public Safety

Tel: 0208 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 250986 / 03000 255510

Email: haz-aic@wales.gov

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).