Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2018/031 Issued: 19 September 2018 at 14:00 Valid until: September 2019

SureSigns VS & VM patient monitors and Viewing stations manufactured before 3 May 2018- risk of batteries overheating or igniting

Summary

Manufactured by Philips – Lithium ion batteries which have exceeded their specified replacement interval or number of charging cycles are at risk of overheating or igniting

Action

List action(s) here. Make sure they make sense with the deadlines below.

- Identify all affected devices (see manufacturers' Field Safety Notice (FSN))
- Check whether the battery has exceeded its' three-year replacement interval or has reached 300 charge-discharge cycles in line with the FSN.
- Refer to the Philips SureSigns VS & VM monitors and View station Service Guide for details on how to replace the battery if required. Contact Philips to order replacement batteries.
- Ensure that there are systems in place to routinely check battery life until the software update is made available (November 2018) and installed.
- Contact Philips to confirm receipt of their FSN using their response form.
- 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: 17 October 2018
Actions complete: 14 November 2018

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.

Device details

Images of SureSigns VS & VM patient monitors and Viewing stations.

Problem / background

Philips have received reports of their SureSigns monitors with lithium ion batteries overheating or igniting when exceeding their three-year service interval or reaching 300 charge-discharge cycles. The current labelling and instructions for use (IFU) do not provide full instructions on when to replace the batteries. As a result, Philips are issuing an updated IFU and software upgrade to provide system warnings in aid of managing the battery replacement cycle.

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

- 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
- 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
- Medical libraries
- 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
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- 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/2018/031** or **2018/007/019/291/016**.

Technical aspects
Jillan Hussein, MHRA

Tel: 020 3080 7148

Email: jillan.hussein@mhra.gov.uk

Paul Sandhu, MHRA

Tel: 020 3080 7266

Email: paul.sandhu@mhra.gov.uk

Clinical aspects
Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

Reporting adverse incidents in England
Through Yellow Card https://yellowcard.mhra.gov.uk/

Northern Ireland
Alerts in Northern Ireland are distributed via the NICAS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre, CMO Group,
Department of Health, Social Services and Public Safety

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk
https://www.health-ni.gov.uk/niaic

Reporting adverse incidents in Northern Ireland
Please report directly to NIAIC using the forms on our website.

Scotland
Enquiries and adverse incident reports in Scotland should be addressed to:

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

Tel: 0131 275 7575

Email: nss.iric@nhs.net

Reporting adverse incidents in Scotland

NHS Boards and Local Authorities in Scotland – report to Health Facilities Scotland.

Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to Health Facilities Scotland.

Private facilities providing care to private clients report to the Care Inspectorate and MHRA.

Wales
Enquiries in Wales should be addressed to:
Healthcare Quality Division, Welsh Government

Tel: 02920 823 624 / 02920 825 510

Email: Haz-Aic@wales.gsi.gov.uk

Reporting adverse incidents in Wales
Report to MHRA through Yellow Card https://yellowcard.mhra.gov.uk/ and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).

MHRA is a centre of the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health and Social Care.
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