Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2020/017 Issued: 29 June 2020 at 10:00 Valid until July 2021

Philips Respironics V60 ventilator – potential unexpected shutdown leading to complete loss of ventilation

Summary

Manufactured by Philips Respironics – sudden loss of power due to component failure, which may not always be accompanied by an alarm or visual warning.

Action

- Identify all affected devices using the instructions in the manufacturer's field safety notice (FSN).
- Complete the response form in the FSN and return to safetynoticeuki@philips.com
- Arrange for Philips to replace the affected part in your ventilator(s).
- Carry out a thorough risk assessment, considering alternative devices, and the availability of back-up ventilation sources.
- If you need to keep using an affected ventilator carry out a through risk assessment, based on a clinical risk-benefit analysis, before using it and take the following precautions:
    - use an external O_2 monitor with all alarm thresholds set appropriately
    - ensure that all alarms are addressed in good time
    - always ensure that an alternative means of ventilation is available
- If the V60 unexpectedly shuts down, immediately switch to an alternative source of ventilation, remove the affected V60 from service and contact your local Philips customer service centre.
- 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 relevant staff who receive this notification.

Deadlines for actions
Actions underway: 20 July 2020
Actions complete: 10 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

Problem / background

This issue is caused by a problem with a solder connection on the first-generation power management printed circuit board assembly (P/N 1055906). The FSN has detailed instructions on how to identify this component and what actions to take.

Manufacturer contacts

Philips Respironics
Tel: 0870 532 9741
Email: Safetynoticeuki@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:

- Adult intensive care units
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Biomedical engineering staff
- Clinical governance leads
- EBME departments
- Equipment stores
- Equipment libraries and stores
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Medical directors
- Paediatric intensive care units
- Purchasing managers
- Risk managers
- Special care baby units
- Supplies managers

Independent distribution

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

- Hospices
- Hospitals in the independent sector

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/2020/017 or 2020/003/016/487/007.

Technical aspects

Ben Satchell or Emma Rooke 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).