Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2020/001 Issued: 15 January 2020 at 12:00 Valid until January 2021

NIPPY ventilator range (all models) – update to instructions for use

Summary

Manufactured by Breas Medical Limited – maintenance schedule now includes changing the internal memory/alarm battery every 3 years.

Action

- Check all stock for affected devices listed in the manufacturer's Field Safety Notice (FSN).
- Replace internal memory/alarm battery if it has not been replaced in the past 3 years.
- Ensure that all ventilators are serviced by a trained engineer on a 12-month schedule.
- Ensure that all staff are trained to use the device according to the latest version of the instructions for use. This can be found on the Breas Medical website.
- Complete and return the response form attached to the FSN.
- 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

- Clinical engineering/EBME department
- All clinical users

Deadlines for actions

Actions underway: 22 January 2020
Actions complete: 26 February 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

Background

The manufacturer has updated the instructions for use for this device. The update requires the internal memory/alarm battery to be replaced every 3 years. If this battery is depleted the device will alarm to inform the user of the need to change the battery.

The MHRA decided to issue this alert due to the low response rate from users to the manufacturer's Field Safety Notice (FSN).

Manufacturer contacts

Name of manufacturer: Breas Medical Limited
Email: Jeremy.day@breas.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
- Ambulance services directors
- Ambulance staff
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Community hospitals
- Community nurses
- EBME departments
- Equipment stores
- Equipment libraries and stores
- Hospital at home units
- In-house maintenance staff
- Medical physics departments
- Palliative care teams
- Paramedics
- Patient transport managers
- Risk managers

Social services

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Community care staff
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- Equipment stores
- In-house domiciliary care providers (personal care services in the home)
- In-house residential care homes

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)
- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Domiciliary care providers
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector

Establishments registered with OFSTED
- Educational establishments with beds for children
- Residential special schools

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/2020/001** or **2019/010/018/291/001**

Technical aspects

Ben Satchell, 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).