Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2018/014 Issued: 02 May 2018 at 15:00 Valid until: May/2019

Infinity Acute Care System and M540 Patient Monitors software versions VG2.2-VG6.0 – risk that alarms are not activated

Summary

Manufactured by Draeger – a software issue may prevent the activation of audible and visual invasive blood pressure measurement alarms, risking a delay to treatment

Action

- Identify any affected devices in your organisation.
- Follow the instructions in the Field Safety Notice issued by Draeger to avoid blood pressure alarms being inadvertently deactivated.
- If you possess affected devices, return the response form included on the FSN to Draeger.

Action by
All healthcare professionals involved in the set-up and use of these devices

Deadlines for actions
Actions underway: 18 May 2018
Actions complete: 05 June 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.

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

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Background

Under certain circumstances the device can be accurately displaying invasive blood pressure measurements on the patient monitor and central display but have no active audible or visual alarms to alert users when these measurements are abnormal because of a software problem.

Manufacturer contacts

Draeger Medical UK Ltd
Tel: 01442 213542
Helen Glass
Email: helen.glass@draeger.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 departments
- A&E directors
- Adult intensive care units
- Anaesthesia, directors of
- Biomedical engineering staff
- Coronary care departments
- Day surgery units
- EBME departments
- Equipment stores
- Equipment libraries and stores
- General surgical units, directors of
- Intensive care units
- Intensive care, directors of
- Minor injury units
- Maternity units
- Medical directors
- Obstetrics and gynaecology departments
- Obstetrics departments
- Operating department practitioners
- Outpatient theatre managers
- Paediatric intensive care units
- Paediatrics departments
- Renal medicine departments
- Renal medicine, directors of
- Resuscitation officers and trainers
- Supplies managers
- Theatre managers
- Theatres

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only) 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 Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Enquiries

England
Send enquiries about this notice to MHRA, quoting reference number **MDA/2018/014** or [**2018/002/026/291/006**].

Technical aspects
Phillip Davenport or Andy Marsden, MHRA

Tel: 020 3080 6461 or 7205

Email: phillip.davenport@mhra.gov.uk or Andrew.marsden@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).