



Llywodraeth Cymru
Welsh Government

Medical Device Alert

3rd May 2018

Parc Cathays
Caerdydd CF10 3NQ

Cathays Park
Cardiff CF10 3NQ

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

- 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.

Sent to:

NHS Wales Shared Services Partnership
Directors of Public Health,
Chief Executives, NHS Trusts
Chief Executives, LHBs
Medical Directors, NHS Trusts
Nurse Directors, LHBs
Executive Nurses, NHS Trusts
NHS Direct
CSSIW
Social Services
HIW

A list of people who need to have early sight of this information is given in the Notice.
This Notice has been endorsed by the Welsh Government as being relevant to NHS Wales.

Points of particular importance in Wales:

**Healthcare Quality Division
Welsh Government
Cathays Park
Cardiff CF10 3NQ**



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.

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.irc@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
© Crown Copyright 2018

Addressees may take copies for distribution within their own organisations