Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2018/019 Issued: 11 June 2018 at 14:00 Valid until: June 2019

JM103 and JM105 Jaundice Meters – risk of misinterpretation of measurement in hyperbilirubinemia cases.

Summary

Draeger Medical Systems – misinterpretation of display may cause delay of treatment of neonatal jaundice

Action

- Identify any JM103 and JM105 devices in your organisation.
- Complete the “Confirmation of Receipt” form and the “Label Address Confirmation” form sent to you with the Safety Notice and return it to the manufacturer so that the warning stickers can be sent to you.
- Apply the warning stickers to the devices.
- Ensure there are systems in place so that users are trained to follow the Instructions for Use supplement (“Sample Usage Protocol Template”) in the Field Safety Notices for the JM103 and JM105.
- If you possess JM105 devices, the manufacturer will contact you to arrange a firmware upgrade, once available, to improve the out-of-range error message. It should be installed on all JM105 devices and will be free-of-charge. It is therefore essential that you provide the manufacturer with your contact details.

Action by
All healthcare professionals who are responsible for or who use these devices

Deadlines for actions
Actions underway: 25 June 2018
Actions complete: 06 August 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.

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

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Problem / background

In response to measuring values of bilirubin greater than 340 µmol/l or 20.0 mg/dl, the JM103 will display a flashing “- - -“error message whilst the JM105 will display a flashing “- 0 -“ error message. Misinterpretation of these messages has led to delay of treatment for jaundice in neonates. The manufacturer is supplying information labels to apply to these devices to clarify the meaning of these error messages.

The manufacturer will make a firmware upgrade available for JM105 devices that will allow the user to set the error message displayed in these circumstances to “>340 µmol/l” or “>20 mg/dl” or “- 0 -“. Organisations with JM105 devices will be contacted by the manufacturer via a Field Safety Notice to offer this upgrade which will be free of charge for all devices. The MHRA advises that this update is applied and option “- 0 -“ is not used.

Manufacturer contacts

Draeger Medical UK Ltd
Helen Glass
Tel: 01442 292870
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 nurses
- Biomedical engineering staff
- Community children’s nurses
- Community hospitals
- Community midwives
- Community nurses
- EBME departments
- Equipment stores
- Equipment libraries and stores
- Health visitors
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (paediatric)
- Intensive care units
- Maintenance staff
- Maternity units
- Midwifery departments
- Midwifery staff
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics and gynaecology directors

- Obstetrics departments
- Obstetrics nurses
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Risk managers
- Special care baby units
- Supplies managers

Independent distribution

- Clinics
- 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/2018/019** or **[2018/004/016/291/008]** for JM103 devices or [**2018/004/017/291/014]** for JM105 devices.

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).