Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2017/032 Issued: 03 October 2017 at 11:00

Intra-aortic balloon pump (IABP): Maquet/Datascope CS100, CS100i and CS300 – potential for interruption or delay to therapy of critically ill patients

Summary

Manufactured by Maquet/Gettinge – a false blood detection alarm and/or fluid ingress could result in the failure of therapy to patients

Action

Note: *this MDA is for a different issue to the one described in MDA/2017/027 issued 24 August 2017.*

- Identify all affected devices – see the manufacturer's Field Safety Notice (FSN) dated 17 July 2017. Products distributed from 24 March 2003 to 16 June 2017 inclusive are affected.
- Use an alternative IABP or an alternative therapy for treatment if available.
- If no alternative is available, undertake a risk assessment based on a clinical risk-benefit analysis. Affected devices which remain in use should be used in accordance with the manufacturer's FSN.
- Contact Maquet to confirm receipt of the FSN and to schedule both the software and hardware updates to prevent false alarms and installation of gaskets to prevent fluid ingress.

Action by
All healthcare professionals involved with the use of these devices.

Deadlines for actions
Actions underway: 17 October 2017
Actions complete: 14 November 2017

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

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Manufacturer contacts

Maquet/Getinge
Hari Rajendran
Post Market Surveillance Manager
SSU North Europe QRC/ EMEA

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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
- Adult intensive care units
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Cardiac laboratory technicians
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Coronary care departments
- Coronary care nurses
- General surgical units, directors of
- Health and safety managers
- In-house maintenance staff
- Intensive care units
- Intensive care, directors of
- Maintenance staff
- Operating department practitioners
- Paediatric intensive care units
- Paediatric surgeons
- Paediatric surgery, directors of
- Risk managers
- Theatre managers
- Theatre nurses
- 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/2017/032** or 2017/007/018/291/020.

Technical aspects
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Clinical aspects

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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 Fax: 0131 314 0722

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).