Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/022 Issued: 30 May 2019 at 14:00

Aisys and Aisys CS2 anaesthesia devices with Et Control option and software versions 11, 11SP01 and 11SP02 – risk of patient awareness due to inadequate anaesthesia

Summary

Manufactured by GE Healthcare – device may fail to deliver the set agent concentration in End Tidal Control mode.

Action

- Follow the instructions to upgrade software on devices listed in the manufacturer's FSN GEHC Ref# 34098.
- Devices with software upgraded as part of MDA/2019/001 are affected and will need the latest software upgrade.
- If devices are not using the listed software versions, no further action is required.
- Before using End Tidal Control (Et Control) mode, clinicians should undertake an appropriate risk assessment.
- If using the device in End Tidal Control mode, additional patient monitoring is recommended.
- Contact GE Healthcare at askuktechnicalsupport@ge.com or 01707 263570 to arrange the installation of the software update.
- 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
All healthcare professionals who are responsible for or who use these devices.

Deadlines for actions
Actions underway: 13 June 2019
Actions complete: 30 July 2019

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

Device details

In addition to the Field Safety Notice, which details affected products, please refer to the spreadsheet which accompanies this MDA for additional unique device identification information.

Manufacturer contacts

GE Healthcare
Tel: 01707 263570
Email: askuktechnicalsupport@ge.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
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Clinical governance leads
- EBME departments
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Operating department practitioners
- Paediatric intensive care units

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 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/2019/022** or 2019/004/002/291/004.

Technical aspects

Emma Rooke and Ben Satchell, 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, Social Services and Public Safety

Tel: 0208 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 250986 / 03000 255510

Email: haz-aic@wales.gov

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).