Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/001 Issued: 17 January 2019 at 11:00 Valid until: January 2020

Datex-Ohmeda Aisys CS2 and Aisys anaesthesia devices with software version 11 and version 11 SP01 (Service Pack) – Risk of ventilation loss, inadequate anaesthesia and hypoxia or severe hypotension

Summary

Manufactured by GE Healthcare – Device may stop ventilation when in PSV Pro Mode and users may be unable to change gas and agent settings when using End-Tidal Control.

Action

- Be aware of and follow the instructions detailed in the manufacturer's FSN GEHC Ref# 34094 published 07 November 2018.
- Software version 11 SP01 (Service Pack) is not mentioned in this FSN but it is also affected.
- If devices are not using the listed software versions, no further action is required.
- Before using affected modes, clinicians should undertake an appropriate risk assessment and document their reasoning for continued use.
- If using the device in PSV Pro or End-Tidal Control modes conduct additional patient monitoring to ensure that patient safety is not compromised.
- Contact GE Healthcare at askuktechnicalsupport@ge.com or 01707 263570 to arrange the installation of the software update.

This MDA is to ensure that all relevant organisations are aware of these issues and take relevant actions.

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

Deadlines for actions
Actions underway: 31 January 2019
Actions complete: 14 March 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

Problem / background

There are two potential issues with Aisys anaesthesia devices.

1. When using End-Tidal Control mode (EtC mode) the user may not be able to adjust fresh gas and volatile agent concentrations. This could lead to a patient awareness event, or to the patient suffering hypoxia or severe hypotension.

2. When using PSVPro Spontaneous Breathing Modes, if the patient does not start or stops spontaneous breathing after the Cycling Procedure has completed, there will be no backup ventilation. This could result in patient apnoea with associated device alarms.

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
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Clinical governance leads
- Coronary care departments
- Coronary care nurses
- Day surgery units
- EBME departments
- General surgeons
- General surgery
- General surgical units, directors of
- Gynaecologists
- Gynaecology departments
- Health and safety managers
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Maternity units

- Maxillofacial departments
- Midwifery departments
- Midwifery staff
- Nursing executive directors
- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics and gynaecology directors
- Obstetrics departments
- Obstetrics nurses
- Operating department practitioners
- Ophthalmic nurses
- Ophthalmologists
- Ophthalmology departments
- Ophthalmology, directors of
- Oral surgeons
- Orthopaedic surgeons
- Paediatric intensive care units
- Paediatric surgeons
- Paediatric surgery, directors of
- Resuscitation officers and trainers
- Risk managers
- Theatre managers
- Theatre nurses
- Theatres
- Urological surgeons
- Urological surgery, directors of

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)
- 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/2019/001** or **2018/011/006/291/014**.

Technical aspects
Ben Satchell, and Enitan Taiwo, MHRA

Tel: 020 3080 6488 or 020 3080 7122

Email: Benjamin.Satchell@mhra.gov.uk or Enitan.Taiwo@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).