Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2018/013 Issued: 01 May 2018 at 15:00 Valid until: May 2019

cobas b 221 instruments with AutoQC module – software limitation affecting automatic QC measurements

Summary

Manufactured by Roche Diagnostics GmbH – Under specific circumstances scheduled automatic QC measurements may no longer be performed and erroneous patient results may remain undetected.

Action

- Identify affected devices, which are listed in the manufacturers Field Safety Notice (FSN)
- Ensure that all relevant members of staff receive the manufacturers FSN and that they understand the problem and actions to be taken.
- Follow the manufacturers workaround until the planned software patch is available and has been installed.
- If any adverse event occurs relating to this issue please report this to MHRA via Yellow Card or the relevant devolved administrations (Scotland, Wales and Northern Ireland).

Action by
Point of Care testing Co-ordinators
Laboratory Managers
Biomedical scientists
Critical Care medical and nursing staff
Paediatric medical and nursing staff
A&E medical and nursing staff
Theatre medical and nursing staff
Special care baby unit medical and nursing staff
Paediatric medical and nursing staff

Deadlines for actions
Actions underway: 16/05/2018
Actions complete: 01/06/2018

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

The cobas b 221 instruments are point of care systems used for the determination of multiple blood gas and metabolic parameters, as well as electrolytes. Automated QC measurements may be used to ensure system validity. The reported software limitation issue affecting automatic QC measurements does not directly impact patient results. However, the absence of quality control results may lead to erroneous patient results caused by an unrelated system issue to remain undetected. Erroneous patient results (high, normal, or low) may lead to wrong or delayed diagnosis and/or treatment.

Manufacturer contacts

Roche Diagnostics Ltd
Charles Avenue
Burgess Hill
West Sussex RH15 9RY
Registration number: 571546

Technical Support Hotline UK: 08081001920
Email: burgesshill.technicalenquiry@roche.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 consultants
- A&E departments
- A&E nurses
- Adult intensive care units
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Biochemists
- Biomedical science departments
- Cardiac laboratory technicians
- Cardiac pacing technicians
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiothoracic departments
- Cardiothoracic surgeons
- Clinical pathologists
- Clinical perfusionists
- Community hospitals
- Coronary care departments
- Coronary care nurses
- Day surgery units

- Diabetes nurse specialists
- Endocrinology units
- ENT departments
- ENT medical staff
- Gastroenterology departments
- Gastro-intestinal surgeons
- General surgeons
- General surgery
- Gynaecologists
- Haematologists
- Haemodialysis nurses
- Haemodialysis units
- Hospital at home units
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- IV nurse specialists
- Minor injury units
- Maternity units
- Maxillofacial departments
- Medical oncologists
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- Nursing executive directors
- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics departments
- Obstetrics nurses
- Oncology nurse specialists
- Operating department practitioners
- Orthopaedic surgeons
- Outpatient theatre nurses
- Paediatric intensive care units
- Paediatric nurse specialists
- Paediatric oncologists
- Paediatric surgeons
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Peritoneal dialysis units
- Point of care testing co-ordinators
- Purchasing managers
- Renal medicine departments
- Risk managers
- Special care baby units
- Theatre managers
- Theatre nurses
- Theatres
- Urological surgeons
- Urology departments

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

- 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/2018/013** or 2018/002/014/478/011

Technical aspects
Daryl Colombage, MHRA

Tel: 020 3080 6740

Email: daryl.colombage@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).