Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/005 Issued: 30 January 2019 at 15:30 Valid until: January 2020

Recall of certain batches of Eurotrol haemoglobin controls due to microbial contamination

Summary

Manufactured by Eurotrol B.V – may give readings below the values assigned to the product, leading to incorrect measurement results.

Action

- Identify affected lots, which are listed in the manufacturer's Field Safety Notice (FSN)
- Ensure all relevant members of staff receive the manufacturer's FSN and that they understand the problem and actions to be taken.
- Complete and return the acknowledgement form in the FSN.
- Follow the manufacturer's actions listed in the FSN until advised otherwise by the manufacturer.
- Report 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
Directors of pathology
Laboratory managers
Lead biomedical scientists (haematologists)
Purchasing managers

Deadlines for actions
Actions underway: 13 February 2019
Actions complete: 27 February 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

The manufacturer has informed the MHRA that due to microbial contamination of quality controls, users may get readings below the values assigned to the product.

There is a risk of 2 possible situations occurring:

- a functional haemoglobin analyser wrongly failing its quality control (QC) test, resulting in a delay in results as the analyser cannot be used on patient samples

- a faulty haemoglobin analyser is wrongfully passed during its quality control (QC) test, possibly leading to an incorrect treatment.

The Eurotrol haemoglobin controls are intended for professional use in the verification of the precision and accuracy of haemoglobin analysers. The purpose of these quality controls is to check calibration and other performance related characteristics.

The manufacturer has taken the action to remove the products from the market and provide alternative batches to prevent interrupted use of the products.

Manufacturer contacts

Manufacturer

Eurotrol, Netherlands
Daniel Philippens
Tel: +31 318695777
Email: recall@eurotrol.com

UK distributors

Radiometer Ltd
Sarah Oliver
Tel: 01293 517599
Email: sarah.oliver@radiometer.co.uk

Prospect Ltd
Sarah McCahill
Tel: 01246 296 401
Email: sarah.mccahill@prospectdiagnostics.co.uk

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 directors

- A&E nurses
- Adult intensive care units
- All departments
- All staff
- All wards
- Ambulance services directors
- Ambulance staff
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Anti-coagulation clinics
- Biochemists
- Biomedical engineering staff
- Biomedical science departments
- Cardiac laboratory technicians
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Chief pharmacists
- Clinical governance leads
- Clinical pathologists
- Clinical pathology directors
- Clinical perfusionists
- Colposcopy departments
- Community children’s nurses
- Community defibrillation officers
- Community dental practices
- Community diabetes specialist nurses
- Community hospitals
- Community midwives
- Community nurses
- Coronary care departments
- Coronary care nurses
- Day surgery units
- Dental departments
- Dental nurses
- Dentists
- Dermatologists
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- Dietetics departments
- District nurses
- EBME departments
- Endocrinology units
- Endocrinology, directors of
- ENT departments
- ENT medical staff

- Equipment stores
- Equipment libraries and stores
- Gastroenterology departments
- Gastroenterology, directors of
- Gastro-intestinal surgeons
- General surgeons
- General surgery
- General surgical units, directors of
- Gynaecologists
- Gynaecology departments
- Gynaecology nurses
- Haematologists
- Haemodialysis nurses
- Haemodialysis units
- Health and safety managers
- Health visitors
- Hospital at home units
- Hospital pharmacies
- Hospital pharmacists
- Infection control departments
- Infection control nurses
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- IV nurse specialists
- Minor injury units
- Maternity units
- Maxillofacial departments
- Medical directors
- Medical libraries
- Medical oncologists
- Medical oncology, directors of
- Medical physics departments
- Microbiologists
- Midwifery departments
- Midwifery staff
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- NHS walk-in centres
- Nursing executive directors
- Nutrition nurses
- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics and gynaecology directors
- Obstetrics departments
- Obstetrics nurses
- Occupational health departments
- Occupational therapists
- Oncology nurse specialists
- Operating department practitioners

- Ophthalmic nurses
- Ophthalmologists
- Ophthalmology departments
- Ophthalmology, directors of
- Oral surgeons
- Orthopaedic surgeons
- Outpatient clinics
- Outpatient theatre managers
- Outpatient theatre nurses
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric oncologists
- Paediatric surgeons
- Paediatric surgery, directors of
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Palliative care teams
- Paramedics
- Patient transport managers
- Peritoneal dialysis units
- Radiation & medical oncology departments
- Radiation oncologists
- Radiation oncology, directors of
- Radiographer superintendents
- Radiologists
- Radiology departments
- Radiology directors
- Renal medicine departments
- Renal medicine, directors of
- School nurses
- Special care baby units
- Staff supporting patients receiving haemodialysis at home
- Theatre managers
- Theatre nurses
- Theatres
- Urological surgeons
- Urological surgery, directors of
- Urology departments
- Virologists
- Walk-in centres

Public Health England

Directors for onward distribution to:

- PHE laboratories
- Laboratory managers
- Safety officers

NHS England area teams

CAS liaison officers for onward distribution to all relevant staff including:

- General dental practitioners
- General practitioners
- General practice managers
- General practice nurses

Social services

Liaison officers for onward distribution to all relevant staff including:

- Children's disability services
- Community care staff
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- In-house domiciliary care providers (personal care services in the home)

Independent distribution

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

- Care homes providing nursing care (adults)
- 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/2019/005** or **2018/010/030/701/009**.

Technical aspects

Jazmin McCalla-Bedward, 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).