Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2020/012 Issued: 08 April 2020 at 4:00

Anaesthetic machines: off-label use during the COVID-19 pandemic

Summary

All anaesthesia machines with ventilators - using the anaesthesia device in treatment of critical illness, outside its intended use is considered off-label use but may be essential due to ventilator availability.

Action

- Carry out an appropriate risk assessment and document the reason for off-label use.
- Healthcare professionals using these machines off-label must be trained and familiar with the unique performance characteristics of the device, including the device interface and alarm systems.
- Follow the instructions for use (IFU), and the additional off-label use information from the manufacturer. This may include more regular maintenance, testing or calibration.
- Monitor carbon dioxide levels in the breathing system. If levels are rising, replace the soda lime according to the manufacturer's instructions. This is because most anaesthesia machines have a carbon dioxide absorber which needs to be regularly replaced or replenished whereas ICU ventilators do not.
- Regularly check for condensate build-up, which may affect functionality. This is because most ICU ventilators include advanced condensate management, anaesthesia machines do not.
- When suctioning, monitor for drops in pressure, which can exacerbate atelectasis. This is because ICU ventilators have autocompensation when inline suction is used, anaesthesia machines do not.
- Ensure appropriate infection control is undertaken using local and national guidelines.
- 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: As soon as possible.
Actions complete: As soon as possible.

Note: We won't be collecting responses.

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

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

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.

Problem / background

The use of an anaesthesia machine as a (long-term) ventilator in a health care setting when it has only received regulatory clearance as an anaesthetic machine is considered as off-label use.

It is the responsibility of the clinicians/end user to make the decision to use a device off label, but the MHRA recognises it is essential in these times.

Some manufacturers have now issued statements on this issue:
Maquet Getinge
Mindray
Penlon

Check relevant manufacturers' websites for their statements.

This alert is intended to remain in effect only for the duration of the COVID-19 pandemic.

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
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Clinical governance leads
- Day surgery units
- EBME departments
- Equipment stores
- Equipment libraries and stores
- Infection control departments
- Infection control nurses
- Infection prevention and control directors
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Medical directors
- Nursing executive directors
- Operating department practitioners

- Outpatient theatre managers
- Outpatient theatre nurses
- Pharmacists
- Risk managers
- Theatre managers
- Theatre nurses
- Theatres

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)
- Hospitals in the independent sector
- Independent treatment centres
- 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/2020/012** or **2020/004/002/223/001**.

Technical aspects

Enitan Taiwo and Becky Owen, 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 (Northern Ireland)
Tel: 028 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 255278 or 03000 255510

Email: Haz-Aic@gov.wales

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).