



Llywodraeth Cymru
Welsh Government

Medical Device Alert

27th February 2018

Parc Cathays
Caerdydd CF10 3NQ

Cathays Park
Cardiff CF10 3NQ

MDA/2018/008: Aquilon series of nebulisers – CE mark withdrawn and supply ceased

- Identify affected devices from the list below.
- Identify patients and relevant healthcare professionals and advise them to:
 - > stop using and dispose of the nebulisers
 - > use an alternative nebuliser where available
- Patients who have any concerns should contact their GP or other healthcare professional.

Sent to:

NHS Wales Shared Services Partnership
Directors of Public Health,
Chief Executives, NHS Trusts
Chief Executives, LHBs
Medical Directors, NHS Trusts
Nurse Directors, LHBs
Executive Nurses, NHS Trusts
NHS Direct
CSSIW
Social Services
HIW

A list of people who need to have early sight of this information is given in the Notice.
This Notice has been endorsed by the Welsh Government as being relevant to NHS Wales.

Points of particular importance in Wales:

Healthcare Quality Division
Welsh Government
Cathays Park
Cardiff CF10 3NQ



Medical Device Alert

MDA/2018/008

Issued: 22 February 2018 at 14:00

Aquilon series of nebulisers – CE mark withdrawn and supply ceased

Summary

Manufactured by AFP Medical – do not use affected nebulisers as they have been manufactured to unknown standards and their safety cannot be verified.

Action

- Identify affected devices from the list below.
- Identify patients and relevant healthcare professionals and advise them to:
 - > stop using and dispose of the nebulisers
 - > use an alternative nebuliser where available
- Patients who have any concerns should contact their GP or other healthcare professional.

Action by

All medical, nursing and technical staff involved in the use and maintenance of these devices.

Deadlines for actions

Actions underway: 15 March 2018

Actions complete: 05 April 2018

Device details

Aquilon2, Aquilon, Aquilon+ and Aquilon Pro series manufactured since 01 April 2015 are affected.

Detailed list of models and manufacturing dates of these devices:

Model	Start	End
AL1	2015-4152	2015-4782
	2016-5000	2016-5921
	2017-6000	2017-6999
AL7	2015-5478	2015-6999
	2015-4659	2015-4689
	2016-7000	2016-9887
	2017-5000	2017-5995
H02	2017-2000	2017-3968
	2015-2056	2015-2522
	2016-3000	2016-3724
H51	2017-4000	2017-4698
	2015-9795	2015-9868
	2016-9875	2016-9965
	2017-1000	2017-1150

Problem

Following withdrawal of the CE mark for the Aquilon series of nebulisers, the manufacturer (AFP Medical) has continued to place the nebulisers on the market.

The nebuliser and packaging have a CE mark but this has not been obtained through appropriate regulatory oversight.

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
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Biomedical engineering staff
- Biomedical science departments

- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Clinical governance leads
- Community children's nurses
- Community defibrillation officers
- Community hospitals
- Community nurses
- Coronary care departments
- Coronary care nurses
- Day surgery units
- District nurses
- EBME departments
- Endocrinology
- ENT departments
- ENT medical staff
- Equipment stores
- Equipment libraries and stores
- Fracture clinics
- Gastroenterology departments
- General surgeons
- General surgery
- General surgical units, directors of
- Gynaecology departments
- Haematologists
- Haemodialysis nurses
- Haemodialysis units
- Health and safety managers
- Health visitors
- Hospital at home units
- Hospital pharmacies
- In-house maintenance staff
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Maintenance staff
- Minor injury units
- Maternity units
- Maxillofacial departments
- Medical directors
- Medical libraries
- Medical oncologists
- Medical oncology, directors of
- Medical physics departments
- Midwifery staff
- NHS walk-in centres
- Nursing executive directors

- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics departments
- Obstetrics nurses
- Occupational health departments
- Occupational therapists
- Oncology nurse specialists
- Operating department practitioners
- 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
- Pharmacists
- Physiotherapists
- Purchasing managers
- Resuscitation officers and trainers
- Risk managers
- School nurses
- Staff supporting patients receiving haemodialysis at home
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Urology departments
- Virologists
- Walk-in centres

Social services

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Care management team managers
- In-house domiciliary care providers (personal care services in the home)
- In-house residential care homes
- Loan store managers
- Loaned equipment store managers

Independent distribution

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

- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Establishments registered with OFSTED

- Children's services
- Educational establishments with beds for children
- Residential special schools

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 Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2018/008** or **2018/001/016/291/008**.

Technical aspects

Enitan Taiwo or Emma Rooke, MHRA

Tel: 020 3080 7122 / 6609

Email: enitan.taiwo@mhra.gov.uk or emma.rooke@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.irc@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 \(Wales\)](#).

MHRA is a centre of the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health
© Crown Copyright 2018

Addressees may take copies for distribution within their own organisations