# Medical Device Alert

Ref: MDA/2013/037 Issued: 03 June 2013 at 13:00

## Device

SERVO-i ventilator system battery modules.
Manufactured by Maquet.
Part number 6487180.
Product codes 1005-1243 (inclusive) and manufactured from 01/02/2010 to 25/10/2012.

## Problem

Risk of early or unexpected loss of ventilation due to certain battery modules having a shorter than specified run time.

## Action by

All those responsible for the use or maintenance of the SERVO-i ventilator system.

## Action

Be aware that Maquet has issued an updated Field Safety Notice dated 29 April 2013, which supersedes the Field Safety Notice dated 11 March 2013.

Follow the advice given in the updated Field Safety Notice – contact Maquet to arrange for appropriate replacement battery modules (free of charge) and ensure that these are installed immediately.

Users should re-familiarise themselves with the instructions for use and in particular:

- always respond to battery related warnings and alarms and be aware of the alarm sequence
- ensure a minimum of two battery modules are installed at all times
- ensure sufficient resuscitation equipment is available at all times
- only use the SERVO-i ventilator system for inter-hospital transport where the appropriate modification kit has been fitted.

## CAS deadlines

Action underway: 10 June 2013

Action complete: 17 June 2013

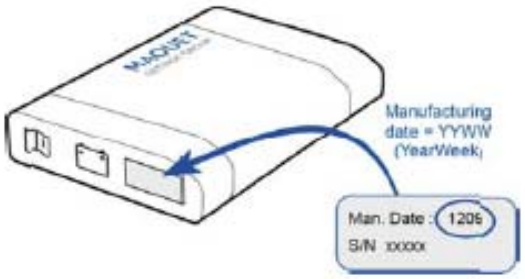
**Note: These deadlines are for battery modules to be identified and arrangements made for replacement.**

## Contact

**Manufacturer**
Colin Moralee
Maquet Ltd
Tel: 0191 519 6200
Fax: 0191 519 6201
Email: colin.moralee@maquet.com

## Device

Affected battery modules can be identified as follows:




## Problem

The MHRA is aware of an incident where a SERVO-i ventilator system used in conjunction with an affected battery module shut down unexpectedly.

In most cases the SERVO-i ventilator system will provide the user with a series of visual warnings and audible alarms before ventilation is lost. However, due to earlier than expected battery depletion, there is a possibility that ventilation may be lost without the normal sequence of alarms.

In the case of a sudden loss of ventilation due to premature battery depletion, the SERVO-i ventilator system will enter a state with valves open and an audible alarm will sound for a period of two minutes. Immediate intervention will be required to preserve adequate patient ventilation.

This situation will not arise when the SERVO-i ventilator system is being powered either from a mains outlet or by unaffected batteries.

## Action

Immediately identify affected battery modules and contact Maquet to receive one free battery module per SERVO-i ventilator system.

Additionally, all affected battery modules that have generated a ‘Replace battery’ alarm within 30 months of the date of manufacturer (see diagram above) will be replaced free of charge.

In the event of ‘Limited battery capacity’, ‘No battery capacity’, ‘Low battery voltage’ and ‘Replace battery’ alarms, immediately connect the SERVO-i ventilator system to a mains outlet.

## Distribution

This MDA has been sent to:

- Clinical commissioning groups (CCGs)
- Health and Safety Executive
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)

### Onward distribution

Please bring this notice to the attention of relevant employees in your establishment.
Below is a suggested list of recipients.

### Trusts

CAS and SABS (NI) 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
- Biomedical engineering staff
- EBME departments
- 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
- Medical physics departments
- Paediatric intensive care units
- Paramedics
- Patient transport managers
- Risk managers
- Special care baby units
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

### Independent distribution

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

This alert should be read by:

- Hospitals in the independent sector
- Independent treatment centres

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.

## Contacts

**Manufacturer**
Maquet Ltd
14-15 Burford Way
Boldon Business Park
Sunderland
Tyne & Wear
NE35 9PZ

Tel: 0191 519 6200 Fax: 0191 519 6201 Email: colin.moralee@maquet.com

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/037** or **2013/003/013/081/002**.

**Technical aspects**
Ian Sealey or Dr Louise Mulroy
Medicines & Healthcare Products Regulatory Agency
Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ

Tel: 020 3080 6691/7344 Fax: 020 8754 3965

Email: ian.sealey@mhra.gsi.gov.uk
louise.mulroy@mhra.gsi.gov.uk

**Clinical aspects**
Mark Grumbridge
Medicines & Healthcare Products Regulatory Agency
Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ
Tel: 020 3080 7128 Fax: 020 8754 3965
Email: mark.grumbridge@mhra.gsi.gov.uk

## How to report adverse incidents

Please report via our website http://www.mhra.gov.uk
Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

# Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group, Room 17, Annex 6, Castle Buildings, Stormont Estate, Dundonald BT4 3SQ

Tel: 02890 523 704 Fax: 02890 523 900 Email: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

## How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic
Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

# Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
Health Facilities Scotland, NHS National Services Scotland, Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB

Tel: 0131 275 7575 Fax: 0131 314 0722 Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

# Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team
Medical Directorate, Welsh Government, Cathays Park, Cardiff CF10 3NQ

Tel: 029 2082 3922 Email: Haz-Aic@wales.gsi.gov.uk