Medical Device Alert

Ref: MDA/2013/084 Issued: 19 December 2013 at 11:30

Device

Implantable pacemakers manufactured by Sorin.

REPLY – models D, DR, VDR, SR
ESPRIT – models D, DR, S, SR

Problem

Risk of loss of pacing due to overestimation of the time remaining to elective replacement indicator (ERI).

Action

- Review the last follow-up exam for all patients implanted with an affected pacemaker.
- Schedule three-month follow up:
  - > for those patients whose battery impedance displayed a value greater than or equal to 3.5kΩ. Priority should be given to pacemaker-dependent patients and those with high programmed settings
  - > if the last follow up was carried out without the use of a programmer and the magnet rate was less than 95 min^{-1}.

Once Sorin has upgraded your programmer software:

- obtain an accurate residual longevity reading by following up all patients within three months.
- continue with six-monthly follow-ups where pacemaker battery impedance becomes greater than or equal to 3.5kΩ.

Action by

All cardiologists and cardiac physiologists who manage patients implanted with pacemakers.

CAS deadlines

Action underway: 07 January 2014

Action complete: 21 January 2014

Note: These deadlines are for systems to be in place to take actions and not for the completion of patient follow-up.

Contact

Manufacturer
Elodie Vincent
Sorin Group
Tel: +33 1 46 01 36 65
Email: crm.complaints@sorin.com

Problem

Sorin has received eight reports where the residual longevity determined during follow-up was overestimated due to a software inaccuracy. This has arisen as a result of a difference between predicted and actual pacemaker battery depletion characteristics. All reports reached ERI within 4 to 5 years and involved pacemakers programmed with high pulse amplitude and width, combined with a high percentage of paced events.

Over 20,000 pacemakers affected by this issue have been distributed in the UK since 2007.

The manufacturer has determined that the majority of affected pacemakers should not reach ERI within eight years of implantation. However, it is important to note that this time may be significantly reduced for pacemakers with high programmed settings, for example in the case of pacing-dependent patients. It is also important to be aware that there are differences in nominal longevity between the pacemaker models (under Cenelec conditions of 70 min^{-1}, 2.5V, 0.5ms). Reply DR and Reply D models have an expected nominal longevity of less than eight years; being 7.1 and 7.4 years respectively, compared with Reply VDR and Reply SR at 9 years and 9.3 years respectively. Within the UK approximately 250 Reply DR and Reply D models were sold over 6 years ago. Early implants of these pacemaker models may be among the first to reach ERI, especially where they have a high percentage of pacing and/or high output settings.

The manufacturer will be issuing a new programmer software version to correct the quoted time to ERI and its presentation through the colour-coded gauge. All upgrades are expected to be completed in the UK within three months. However, the need for six-monthly follow-up when the battery impedance reaches 3.5kΩ will remain.

Sorin distributed a Field Safety Notice concerning this issue to affected customers on 20 November 2013.

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS trusts in England (chief executives)

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:

- Cardiac laboratory technicians
- Cardiac pacing technicians
- Cardiac physiologists
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Clinical governance leads
- Medical directors
- Nursing executive directors
- Risk managers

NHS England area teams

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

- General practitioners

Independent distribution

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

This alert should be read by:

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

Contacts

Manufacturer
Elodie Vincent
Sorin CRM
Parc d'affaires NOVEOS
4, Avenue Réaumur
92143 Clamart Cedex

Tel: +33 1 46 01 36 65

Email: crm.complaints@sorin.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/084** or **2013/011/021/291/004**

Technical aspects
Michelle Kelly or Simon Holmes or Hazel Randall
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7145 / 7240 / 7287
Fax: 020 8754 3965

Email: michelle.kelly@mhra.gsi.gov.uk
simon.holmes@mhra.gsi.gov.uk
hazel.randall@mhra.gsi.gov.uk

Clinical aspects
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7032 / 7248
Fax: 020 8754 3965

Email: kayleigh.purdon@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

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
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 5801

Email: Haz-Aic@wales.gsi.gov.uk