Medical Device Alert

Ref: MDA/2011/056 Issued: 25 May 2011 at 15:30

Device

Pacemaker.
Reply and Esprit models that have been interrogated with programmer containing software version 2.24.
Manufactured by Sorin CRM.

Problem

The manufacturer has issued a Field Safety Notice (see appendix) following a programmer software anomaly that could lead to:

1) cardiac instability during surgery when a magnet is applied; or
2) unnecessary explant due to inconsistent battery information.

This software anomaly sets the magnet rate at 30 beats per minute following interrogation by a programmer with the 2.24 software version.

Action by

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

Anaesthetists who manage affected patients during the peri-operative period.

Action

- Do not use a programmer with 2.24 software version.
- Ensure that the manufacturer has provided you with an alternative software version, 2.26 or higher (or 2.22 if necessary).
- Identify all patients implanted with Reply or Esprit pacemakers that have previously been interrogated with the 2.24 programmer software version:
    - arrange for follow-up of affected patients in order to interrogate with the alternative software version to correct the magnet rate within 3 months
    - consider the need to review end-of-life explant decisions made following interrogation with 2.24 version.

For patients undergoing surgery:

- Identify affected patients preoperatively
    - interrogate with the alternative software
    - alternatively do not use a magnet in affected patients.
- If a magnet is used and the heart rate drops to 30 beats per minute, remove the magnet.

CAS deadlines

Action underway: 03 June 2011

Action complete: 24 June 2011

Contact

Manufacturer
Ms Chantal Cadiou
Sorin CRM, France
Tel: +33 146013687
Fax: +33 149655451
Email: Chantal.cadiou@sorin.com

Device

Model	Serial number configuration (where x is any alphanumeric character)		
Reply DR	8xxZKxxx	9xxZKxxx	0xxZKxxx
Reply D	8xxZLxxx	9xxZLxxx	0xxZLxxx
Reply VDR	8xxZMxxx	9xxZMxxx	0xxZMxxx
Reply SR	8xxZNxxx	9xxZNxxx	0xxZNxxx
Esprit DR	8xxZPxxx	9xxZPxxx	0xxZPxxx
Esprit D	8xxZRxxx	9xxZRxxx	0xxZRxxx
Esprit SR	8xxZSxxx	9xxZSxxx	0xxZSxxx
Esprit S	8xxZTxxx	9xxZTxxx	0xxZTxxx

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care 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:

- A&E departments
- Anaesthetists
- Arrhythmia nurses
- Cardiac laboratory technicians
- Cardiac pacing technicians
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Clinical governance leads
- Coronary care departments
- Coronary care nurses
- Directors of nursing
- Medical directors
- Operating department practitioners
- Preoperative assessment units
- Risk managers
- Theatre managers

Independent distribution

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

This alert should be read by:

- 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
Ms Chantal Cadiou
Sorin Group
France

Tel: +33 146013687
Fax: +33 149655451

Email: Chantal.cadiou@sorin.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/056** or **2011/005/003/291/005**

Technical aspects
Michelle Kelly or Simon Holmes
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Floor 4
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Tel: 020 3080 7145 / 7240
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Clinical aspects
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Tel: 020 3080 7126
Fax: 020 8754 3965

Email: nicola.lennard@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:

Dr Sara Hayes
Senior Medical Officer
Medical Device Alerts
Welsh Assembly Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

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

Appendix

[Physician / medical center contact information to be inserted]

April 27, 2011

Urgent Medical Device Field Safety Notice

2.24 programmer software version and Reply / Esprit pacemakers

Dear Doctor,

This letter is written to provide you with important information regarding a programmer software anomaly in the European 2.24 programmer software version when interrogating Reply and Esprit pacemakers: this anomaly results in an incorrect magnet rate (30 min^{-1}). This will be addressed by a Sorin software update available mid-2011. The anomaly only affects the pacing rate when a magnet is applied (30 min^{-1}) but does not affect other functions of the device. Once the magnet is removed, the device reverts to programmed settings.

Description of the software anomaly

As of April 8, 2011, Sorin has received five (5) reports out of approximately 60000 units:

- In each of these 5 reports, a magnet rate of 30 min^{-1} was displayed upon device interrogation;
- In one of these 5 reports, an "End Of Life" message was also displayed.

These observations were inconsistent with the other battery information in these 5 devices: the battery impedance indicated that the devices were still at Beginning Of Life (BOL) and their residual longevity were adequate (i.e. several years). In one case, the inconsistency resulted in unnecessary device explant.

Sorin's investigation has shown that this inconsistency resulted from a programmer software anomaly **when using the latest European programmer software version (2.24)** with Reply or Esprit pacemakers:

- Only devices manufactured between November 2008 and mid-October 2010 are affected by the issue if they are interrogated with 2.24 version (refer to the note at the end of the document about potentially affected devices).
- 24 hours after a first interrogation with 2.24 version, a magnet rate of 30 min^{-1} is displayed upon new device interrogation on the programmer screen; if a magnet is applied, the pacemaker reverts to magnet mode (asynchronous mode) with a magnet rate of 30 min^{-1}. The battery depletion curve is also incorrect. **The battery impedance and the residual longevity are not affected by the software anomaly.**
- In addition, if the initial interrogation is performed prior to implant, then an "End Of Life" warning is also displayed upon device interrogation;

The anomaly only relates to the pacing rate (30 min^{-1}) during magnet test and does not affect other functions of the device; once the magnet is removed, the device reverts to programmed settings.

This programmer software anomaly does not affect any other Sorin implantable devices.

Immediate action

Sorin CRM has stopped installation of 2.24 software version. In case this version has already been installed on your Sorin programmer, your Sorin representative will promptly install a software version that will prevent new devices from being affected upon interrogation.

Recommendations

After consultation with Sorin CRM's independent Product Performance Monitoring Board, Sorin recommends that physicians continue to use the battery impedance and residual longevity to determine time for device replacement.

Sorin will release by mid-2011 a software update (2.28 or higher revision) that will address this anomaly and that will automatically correct the erroneous magnet rate upon interrogation with this new programmer software. Your Sorin representative will inform you when the software update is available, after regulatory approval.

Before this software update is available, devices that have already been interrogated with 2.24 can be reset to normal operation with the current programmer software; the attached Technical Note describes the steps to follow.

Depending on the circumstances (e.g. for pacemaker-dependent patients undergoing surgery during which the magnet could be applied to avoid pacing inhibition), you may consider scheduling a follow up for devices that have already been interrogated with 2.24 to correct the magnet rate (with the procedure described in the Technical Note or with the 2.28 or higher revision).

Sorin is communicating this information to the MHRA.

Please make sure that all personnel involved in the management of patients implanted with Reply or Esprit pacemakers in your organisation are aware of the information described in this letter.

We regret the inconvenience this could cause you and your patients. If you have any questions, please contact your local Sorin representative or contact Sorin Group at 01452 638500

Sincerely,

Carmel Breen

Sorin UK Vigilance Representative

Note:
The potentially affected devices have the following eight-character serial number configuration:

Models	**Serial number configuration** (where x is any alphanumeric character)		
Reply DR	**8**xx**ZK**xxx	**9**xx**ZK**xxx	**0**xx**ZK**xxx
Reply D	**8**xx**ZL**xxx	**9**xx**ZL**xxx	**0**xx**ZL**xxx
Reply VDR	**8**xx**ZM**xxx	**9**xx**ZM**xxx	**0**xx**ZM**xxx

Reply SR	**8**xx**ZN**xxx	**9**xx**ZN**xxx	**0**xx**ZN**xxx
Esprit DR	**8**xx**ZP**xxx	**9**xx**ZP**xxx	**0**xx**ZP**xxx
Esprit D	**8**xx**ZR**xxx	**9**xx**ZR**xxx	**0**xx**ZR**xxx
Esprit SR	**8**xx**ZS**xxx	**9**xx**ZS**xxx	**0**xx**ZS**xxx
Esprit S	**8**xx**ZT**xxx	**9**xx**ZT**xxx	**0**xx**ZT**xxx