

Medical Device Alert

Ref: MDA/2011/067 Issued: 14 June 2011 at 12:00

Device

Subcutaneous implantable cardioverter defibrillator (S-ICD): SQ-RX[®] pulse generator, model 1010.

Manufactured by Cameron Health.

Problem	Action
<p>Risk of S-ICD being unable to deliver shock for therapy after elective replacement indicator (ERI) audible warning.</p> <p>The ERI may occur earlier than expected and the end of life (EOL) indicator may occur before the nominal 3 months.</p> <p>The manufacturer has identified 2 populations of devices in the UK that are at higher risk of premature battery depletion.</p> <p>Population 1: 33% risk of premature battery failure over 5 years – 3 devices in the UK.</p> <p>Population 2: 3.3% risk of premature battery failure over 5 years – 81 devices in the UK.</p>	<ul style="list-style-type: none"> Identify all patients with affected S-ICD (see appendix) and schedule immediate follow-up to: <ul style="list-style-type: none"> > familiarise patients with audible alert on the S-ICD (using magnet); > remind patients of the importance of contacting their follow-up clinic as soon as possible in the event of symptoms or the onset of any audible patient alarm. For patients identified in population 1, consider an immediate box change only for high risk patients, such that they are likely to require multiple shocks within the space of a few days. For all patients in population 2, arrange follow-up at 3-month intervals, to review if the battery voltage is dropping at a faster rate than predicted.
Action by	
<p>All cardiologists and cardiac physiologists who manage patients implanted with S-ICD.</p>	
CAS deadlines	Contact
<p>Action underway: 17 June 2011</p> <p>Action complete: 21 June 2011</p>	<p>Manufacturer Stephen O'Connor Cameron Health Tel: 07984 590 639 Fax: 01223 280 382 Email: soconnor@cameronhealth.com</p>

Problem

The MHRA has received one confirmed report of premature battery failure associated with this issue, occurring after 9 months.

Bench tests performed by the manufacturer showed that the affected devices may deplete over a period of between 1 month and 2 years.

Cameron Health issued a [Field Safety Notice on 1 June 2011](#) to highlight this risk to physicians.

Please note that the FSN contains worldwide number of affected devices.

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- Local authorities 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
- Arrhythmia nurses
- Cardiac laboratory technicians
- Cardiac pacing technicians
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Clinical governance managers
- Coronary care departments
- Coronary care nurses
- Medical directors
- Risk managers

Independent distribution

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

This alert should be read by:

- Hospitals in the independent sector

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

Stephen O'Connor
Cameron Health
4 The Green
Bromham
Bedfordshire MK43 8JR

Tel: 07984 590 639

Fax: 01223 280 382

Email: soconnor@cameronhealth.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/067** or **2011/004/011/081/017**

Technical aspects

Ms Nicola Harris or Ms Sam Baxter
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 6243 or 7242

Fax: 020 8754 3965

Email: nicola.harris@mhra.gsi.gov.uk
sam.baxter@mhra.gsi.gov.uk

Clinical aspects

Dr Nicola Lennard
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

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.irc@nhs.net

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

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

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Addressees may take copies for distribution within their own organisations

Appendix

FIELD SAFETY CORRECTIVE ACTION – REPORT ATTACHMENT

Medical Device Information for United Kingdom



Serial Number	Population	Manufacturing Date	Expiration Date
1010-A001327	Population I	23-Apr-2009	23-Feb-2010
1010-A001332	Population I	6-May-2009	6-Mar-2010
1010-A001630	Population I	22-Jul-2009	22-May-2010
1010-A001005	Population II	2-Oct-2008	2-Aug-2009
1010-A001040	Population II	2-Oct-2008	2-Aug-2009
1010-A001053	Population II	28-Oct-2008	28-Aug-2009
1010-A001124	Population II	6-Nov-2008	29-Aug-2009
1010-A001146	Population II	10-Nov-2008	21-Aug-2009
1010-A001152	Population II	22-May-2009	22-Mar-2010
1010-A001174	Population II	12-Nov-2008	29-Aug-2009
1010-A001180	Population II	26-Nov-2008	26-Sep-2009
1010-A001188	Population II	4-Dec-2008	4-Oct-2009
1010-A001194	Population II	4-Dec-2008	4-Oct-2009
1010-A001195	Population II	4-Dec-2008	4-Oct-2009
1010-A001197	Population II	24-Mar-2009	11-Jan-2010
1010-A001211	Population II	7-Dec-2009	7-Oct-2010
1010-A001233	Population II	9-Mar-2009	9-Jan-2010
1010-A001235	Population II	26-May-2009	22-Mar-2010
1010-A001270	Population II	11-Mar-2009	11-Jan-2010
1010-A001271	Population II	16-Dec-2009	16-Oct-2010
1010-A001273	Population II	10-Mar-2009	10-Jan-2010
1010-A001278	Population II	12-Mar-2009	12-Jan-2010
1010-A001294	Population II	23-Mar-2009	15-Jan-2010
1010-A001317	Population II	22-May-2009	22-Mar-2010
1010-A001334	Population II	12-Jun-2009	12-Apr-2010
1010-A001338	Population II	23-Apr-2009	2-Feb-2010
1010-A001344	Population II	22-Apr-2009	22-Feb-2010
1010-A001368	Population II	22-Apr-2009	22-Feb-2010
1010-A001392	Population II	26-May-2009	26-Mar-2010
1010-A001403	Population II	22-May-2009	22-Mar-2010
1010-A001419	Population II	12-Jun-2009	12-Apr-2010
1010-A001437	Population II	11-Mar-2010	4-Jan-2011
1010-A001480	Population II	15-Jun-2009	15-Apr-2010
1010-A001489	Population II	15-Jun-2009	15-Apr-2010
1010-A001500	Population II	15-Jun-2009	15-Apr-2010
1010-A001506	Population II	12-Jun-2009	12-Apr-2010
1010-A001509	Population II	15-Jun-2009	12-Apr-2010
1010-A001512	Population II	12-Jun-2009	12-Apr-2010
1010-A001538	Population II	15-Jun-2009	12-Apr-2010
1010-A001573	Population II	21-Jul-2009	14-Aug-2010
1010-A001605	Population II	18-Mar-2010	3-Jan-2011
1010-A001636	Population II	14-Jul-2009	14-Aug-2010
1010-A001647	Population II	23-Jul-2009	23-May-2010

Cameron Health, Inc.

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FIELD SAFETY CORRECTIVE ACTION – REPORT ATTACHMENT

Medical Device Information for United Kingdom



Serial Number	Population	Manufacturing Date	Expiration Date
1010-A001652	Population II	23-Jul-2009	23-May-2010
1010-A001674	Population II	27-Jul-2009	27-Aug-2010
1010-A001680	Population II	13-Jul-2009	13-May-2010
1010-A001684	Population II	28-Jul-2009	28-May-2010
1010-A001696	Population II	10-Aug-2009	27-May-2010
1010-A001711	Population II	30-Jan-2010	15-Nov-2010
1010-A001740	Population II	11-Aug-2009	11-Jun-2010
1010-A001750	Population II	11-Aug-2009	11-Sep-2010
1010-A001768	Population II	8-Jun-2010	8-Jul-2011
1010-A001781	Population II	17-Dec-2009	14-Oct-2010
1010-A001789	Population II	3-Aug-2009	27-May-2010
1010-A001820	Population II	4-Aug-2009	4-Jun-2010
1010-A001826	Population II	2-Feb-2010	15-Nov-2010
1010-A001828	Population II	4-Aug-2009	3-Sep-2010
1010-A001860	Population II	26-Mar-2010	20-Apr-2011
1010-A001882	Population II	19-Mar-2010	13-Jan-2011
1010-A001888	Population II	2-Mar-2010	2-Jan-2011
1010-A001900	Population II	11-Feb-2010	2-Dec-2010
1010-A001910	Population II	8-Feb-2010	25-Nov-2010
1010-A001934	Population II	19-Mar-2010	19-Apr-2011
1010-A001977	Population II	2-Jun-2010	2-Jul-2011
1010-A002004*	Population II	21-Mar-2010	21-Apr-2011
1010-A002014	Population II	30-Mar-2010	30-Apr-2011
1010-A002015	Population II	19-Mar-2010	19-Apr-2011
1010-A002045	Population II	25-Mar-2010	25-Apr-2011
1010-A002050	Population II	25-Mar-2010	1-Jan-2011
1010-A002087	Population II	3-Jun-2010	3-Jul-2011
1010-A002144	Population II	8-May-2010	8-Jun-2011
1010-A002158	Population II	6-May-2010	6-Jun-2011
1010-A002187	Population II	2-Jun-2010	2-Jul-2011
1010-A002194	Population II	7-Jun-2010	7-Jul-2011
1010-A002228	Population II	16-Jun-2010	16-Jul-2011
1010-A002234	Population II	21-May-2010	21-Jun-2011
1010-A002261	Population II	4-Jun-2010	25-Jun-2011
1010-A002263	Population II	1-Jun-2010	1-Jul-2011
1010-A002268	Population II	3-Jun-2010	3-Jul-2011
1010-A002276	Population II	7-Jul-2010	7-Aug-2011
1010-A002286	Population II	14-Jun-2010	13-Jul-2011
1010-A002292	Population II	14-Jun-2010	14-Jul-2011
1010-A002295	Population II	3-Jun-2010	3-Jul-2011
1010-A002459	Population II	1-Jul-2010	1-Aug-2011
1010-A002485	Population II	6-Jul-2010	6-Aug-2011

* This device has been explanted.

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