

Medical Device Alert

Ref: MDA/2011/073 Issued: 29 June 2011 at 14:00

Device

Implantable cardioverter defibrillator (ICD).

Paradym, model numbers: VR 8250, DR 8550, CRT-D 8750 and 8770, VR 9250, DR 9550, CRT-D 9750 and 9770.

Manufactured by Sorin CRM.

Problem	Action
<p>Risk of bradycardia / syncope due to pacing inhibition.</p> <p>Potential for pacing inhibition associated with ventricular oversensing if the follow-up monitoring feature, PhD, is programmed ON and the device is connected to high polarisation defibrillation leads.</p> <p>The manufacturer issued a Field Safety Notice (FSN) on 27 April 2011.</p>	<ul style="list-style-type: none"> • Identify patients implanted with a Paradym ICD and <ul style="list-style-type: none"> ○ for those patients known to be pacemaker dependent arrange follow-up within 1 month, in order to turn OFF the PhD feature. ○ for all other affected patients, arrange for follow-up within 3 months in order to turn OFF the PhD feature. • Put systems in place to ensure that the PhD feature is switched off at the end of every programming session until the programmer software upgrade has been implemented Note: The PhD feature is automatically activated when the shock therapy is switched on. • Put systems in place to ensure that the PhD feature is switched OFF in newly implanted Paradym ICDs.
Action by	
<p>All cardiologists and cardiac physiologists who manage patients implanted with ICDs.</p>	
CAS deadlines	Contact
<p>Action underway: 06 July 2011</p> <p>Action complete: 27 July 2011</p>	<p>Manufacturer Sorin CRM Ms Carmel Breen Email: carmel.breen@sorin.com</p>

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)
- NHS boards and trusts in Wales (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 physiologists
- Cardiologists
- Medical directors

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 (regulatory issues)

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Sorin Group

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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/073** or **2011/005/003/291/018**

Technical aspects

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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

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