

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/24

Issued: 16 March 2007



HEALTH ESTATES

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For:

IMMEDIATE ACTION	
<b>ACTION</b>	✓
UPDATE	
INFORMATION	

	Section
<p><b>Medical Device/Equipment:</b>            Boston Scientific Ltd:            Vitality and Assure implantable cardioverter defibrillator (ICD) families and Contak Renewal cardiac resynchronisation therapy defibrillator (CRT-D) families (see Appendix 2 for full details of models affected)</p>	▶ ①
<p><b>Problem:</b></p> <ul style="list-style-type: none"> <li>Delay in delivery of therapy during device middle-of-life phase due to temporarily extended charge time limits.</li> <li>Transition to device end of life (EOL) without prior observation of elective replacement indication (ERI) even though battery capacity remains available.</li> </ul>	▶ ②
<p><b>Action by:</b>            All cardiologists, cardiothoracic surgeons and cardiac physiologists who implant any of these devices or manage patients implanted with them.</p>	▶ ③
<p><b>Action:</b>            Identify patients implanted with these devices, asses clinical risks associated with the above device problems, and follow the actions on page 2.</p>	▶ ④
<p><b>Distributed by NIAIC to:</b>            Chief Executive of each HSS Board            Chief Executive of each HSS Trust            Chief Executive of each Agency            NIAIC Liaison Officers</p>	▶ ⑤
<p><b>Contacts</b>            Details of manufacturer and NIAIC contacts for technical aspects.</p>	▶ ⑥
<p><b>Feedback Requirements to NIAIC</b>            None required.</p>	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

## 1. DEVICE/EQUIPMENT:

Boston Scientific Ltd:

Vitality and Assure implantable cardioverter defibrillator (ICD) families and Contak Renewal cardiac resynchronisation therapy defibrillator (CRT-D) families (see Appendix 2 for full details of models affected)

## 2. PROBLEM:

The MHRA has received 31 reports of early explants from four of the above device models (1870, 1871, 1872, A135) during the middle-of-life (MOL) phase. Replacement has been due to observation of premature elective replacement / end of life indicators (ERI/EOL), caused by long capacitor charge times. The MHRA has also become aware of confusion about ERI/EOL indicators throughout implant duration.

Incident reports have included devices displaying:

- extended charge times where no replacement / end of life indicators have been observed
- ERI where charge times have extended beyond 26 seconds giving rise to potentially inappropriate therapy delay for some patients
- EOL indicators with charge times in excess of 30 seconds without ERI being observed in the first instance.

Boston Scientific ICDs / CRTDs are designed to regularly monitor both battery voltage and capacitor charge time, and flag ERI when specified limits are exceeded. Charge time ERI is flagged whenever two charges (capacitor reform or therapeutic shock) occur within a 24hr period in which both exceed the specified limit.

Increase in charge time (due to a rise in battery impedance) is an expected behaviour of ICDs that have lithium-silver-vanadium-oxide batteries. However, early batteries used in some of the above models have a tendency to exhibit a more exaggerated increase in battery impedance during the MOL phase, due to a battery manufacturing anomaly.

Boston Scientific has confirmed that the above models have been programmed with temporarily extended ERI charge time limits during the MOL phase (compared to unaffected models). This is to prevent premature tripping of ERI due to the battery impedance characteristic.

In January 2007, Boston Scientific issued a product update about this issue via their website. The company issued a more detailed and informative product update about this problem in March 2007.

The MHRA is issuing this Medical Device Alert to ensure that all UK clinicians who implant these devices, or manage patients already implanted with these devices, are aware of Boston Scientific's communication and can therefore consider the clinical implications of long charge times that may be inappropriate for some patients.

## 3. ACTION BY:

Identify patients implanted with these devices, assess clinical risks associated with the above device problems, and follow the actions on page 2.

## 4. ACTION:

- Be aware of:
  - extended capacitor charge times during device MOL phase, as documented in the most recent Boston Scientific product update (see the MHRA's website for March 2007 issue)

- the higher prevalence of long charge times in earlier manufactured devices (see Appendix 2 below)
- the potential for earlier manufactured devices to pass from ERI to EOL in less than three months.
- At the next scheduled follow-up, review capacitor charge time history and evaluate the appropriateness of charge time according to patient condition and device dependency, giving priority to those who have not been followed up within the last three months (see Appendix 1 below).
- Consider the risks (infection etc) and benefits of elective device replacement where capacitor charge time is judged to be inappropriate for an individual patient.
- Consider scheduling future patient follow-ups at three monthly intervals – where the device is around MOL, to increase the likelihood of detecting longer charge times, early ERI and/or EOL as appropriate.
- Consider programming the ‘Beep When ERI is Reached’ feature to ‘ON’ (default) for all affected patients.
- Remind patients to contact their follow-up centre immediately if they hear beeping from their device and/or experience arrhythmias/resumption of symptoms that remain uncorrected by the device.
- Consult the Boston Scientific website for future related product updates.
- Report all instances of device failure to the MHRA and Boston Scientific.

***Report explants to the National Pacing and ICD Database (see contacts below).***

## **5. ONWARD DISTRIBUTION TO:**

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- A&E departments
- Cardiac physiologists
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Clinical directors of cardiology
- Clinical governance leads
- Coronary care units
- Directors of nursing
- Medical directors
- Risk managers

## **6. CONTACTS:**

Enquiries to the manufacturer and the National Pacing and ICD Database respectively should be addressed to:

Ms Jayne Puckeridge, Regulatory Affairs Manager  
 Boston Scientific Ltd  
 Hampshire International Business Park  
 Crockford Lane, Chineham  
 Basingstoke  
 Hampshire RG24 8WH

Tel: 01256 374 010  
 Fax: 01256 374 014

E-mail: [jpuckeri@guidant.com](mailto:jpuckeri@guidant.com)

National Pacing and ICD Database  
 PO Box 9205  
 Bridge of Weir  
 Strathclyde  
 PA11 3DZ

Tel: 01505 612 829  
 Fax: 01505 612 829

E-mail: [morag.cunningham@ic.nhs.uk](mailto:morag.cunningham@ic.nhs.uk)

Enquires to NIAIC should quote reference number MDEA(NI)2007/24 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast BT16 1US

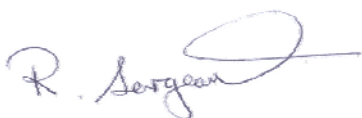
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

## 7. FEEDBACK:

None required.



Robert Sergeant  
NIAIC Operational Manager

### HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2006/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic)

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety*

## Appendix 1 to MDEA(NI)2007/24

Aspects of device behaviour to be considered during patient follow-up, when assessing the appropriateness of patient exposure to extended capacitor charge times:

- ERI capacitor charge times differ at beginning of device life and during/after MOL.
- Extended capacitor charge times can occur during MOL without programmer ERI indication.
- ERI will not 'flag' until two consecutive charge times in excess of the extended charge time limit occur within a 24 hour period (or when battery voltage falls to the battery ERI value).
- EOL will not 'flag' until a single charge time greater than 30 seconds occurs.
- Transition to EOL may in some instances appear rapid and may occur without display of programmer ERI indication.
- Device MOL occurs:
  - when battery voltage is between approximately 2.52V and 3.00V
  - typically between 24-38 months however, occurrence is dependent on device usage.
- Devices that trigger charge time-based ERI/EOL have several months (and in most cases more than one year) of remaining battery capacity. During this time ERI/EOL therapies are available (as per device manuals/labeling) as well as maximum energy shocks, bradycardia pacing and left ventricular pacing (according to device type).
- Extended ERI charge time design specifications and expected charge time performance are not documented in the current instructions for use.
- Where 'Beep When ERI is Reached' is programmed ON – 16 R-wave sync tones will be emitted from the device every 6 hours when ERI is reached. Other warning tones will require investigation of other related warning conditions.

Notes:

- (1) See also ACTION on page 2.
- (2) Refer to the MHRA's website (<http://www.mhra.gov.uk>) to access the Boston Scientific March 2007 product update.
- (3) Refer to the 'Product Updates' area of the Boston Scientific website (<http://www.guidant.com>) for future revised model listings and ERI extended charge time limits.

## Appendix 2 to MDEA(NI)2007/24

Affected models and projected rate of display of replacement indicators during the MOL phase

Note: Not all products listed have been distributed in the United Kingdom

Product family	Models	Projected Rates		
		Manufactured prior to July 2005	Manufactured between July 2005–July 2006	Manufactured after July 2006
VITALITY VR / DR VITALITY AVT <sup>®</sup> VITALITY DR+	1870 / 1871 A135 1872	8-10%	1%	< 1%
VITALITY AVT ASSURE <sup>™</sup> VITALITY DS DR / VR VITALITY 2 DR / VR	A155 B301 T125 / T135 T165 / T175	4-7%	1%	< 1%
VITALITY EL VITALITY 2 EL DR / VR VITALITY DR HE CONTAK RENEWAL <sup>®</sup> 3 & 4 CONTAK RENEWAL 3 & 4 RF CONTAK RENEWAL 3 & 4 AVT CONTAK RENEWAL 3 & 4 HE CONTAK RENEWAL 3 & 4 RF HE CONTAK RENEWAL 3 & 4 AVT HE	T127 T167 / T177 T180 H170 / H173 / H175 / H190 / H195 H210 / H215 / H230 / H235 M150 / M155 / M170 / M175 H177 / H179 / H197 / H199 H217 / H219 / H239 M157 / M159 / M177 / M179	1-2%	1%	< 1%

The projected rates above indicate Boston Scientific's estimate of the percentage of devices that are likely to be affected.

The percentages reflect battery design and manufacturing improvements implemented over time, intended to reduce variability in battery performance and reduce the likelihood of earlier than anticipated ERI/EOS.

Boston Scientific advises that ICDs currently being supplied will not exhibit the same mid-life ERI or EOL extended charge time behaviours.