



Medicines and Healthcare products  
Regulatory Agency

# Medical Device ALERT

Ref. MDA/2005/045

Issued: 25 July 2005

For:

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

	Further Information						
<p><b>DEVICE:</b>  <b>St Jude Medical implantable cardioverter defibrillators (ICDs):</b>  <b>Atlas DR</b> model: V-242  <b>Atlas Plus DR/VR/HF</b> models: V-243, V-193, V-193C, V-340, V-341, V-343  <b>Epic DR/HF</b> models: V-233, V-337, V-338  <b>Epic Plus DR/VR/HF</b> models: V-236, V-239, V-196, V-239T, V-196T, V-350</p>							
<p><b>PROBLEM:</b></p> <ul style="list-style-type: none"> <li>• Potential for reduction in number of shocks (skipped charge) delivered per therapy episode (serial numbers below 225000).</li> <li>• Potential for inappropriate rate responsive pacing for up to 90 minutes during automatic and clinician initiated capacitor reformation (serial numbers below 141000 only).</li> </ul>	▶						
<p><b>ACTION BY:</b>  All cardiologists and cardiac technicians who manage patients implanted with the above ICD models.</p>							
<p><b>ACTION:</b>  See actions on page 3.</p>	▶						
<p><b>DISTRIBUTED to:</b></p> <table> <tr> <td>NHS Trusts (England)</td> <td>– Chief Executives*</td> </tr> <tr> <td>Healthcare Commission (CHAI)</td> <td>– Headquarters</td> </tr> <tr> <td>Primary Care Trusts (England)</td> <td>– Chief Executives*</td> </tr> </table> <p style="text-align: right;">* via CE Bulletin</p>	NHS Trusts (England)	– Chief Executives*	Healthcare Commission (CHAI)	– Headquarters	Primary Care Trusts (England)	– Chief Executives*	▶
NHS Trusts (England)	– Chief Executives*						
Healthcare Commission (CHAI)	– Headquarters						
Primary Care Trusts (England)	– Chief Executives*						
<p><b>CONTACTS:</b>  Details of manufacturer contacts, National Pacing and ICD Database and MHRA contacts for technical and clinical aspects. Change of address or removal from address list for the Healthcare Commission.</p>	▶						

▶ Further information supplied in the following pages.

The full text of this notice is on our website: <http://www.mhra.gov.uk>

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## **PROBLEM:**

St Jude Medical has informed the MHRA and all customers (Dear Doctor Letter dated 14 June 2005) that the above Atlas and Epic ICD models have the potential to experience either or both of the following problems:

- **'Skipped charge'**

This problem is due to a software anomaly, which may occur as the battery approaches elective replacement indication (ERI). A prematurely terminated capacitor charging cycle ('skipped charge') can result in a reduction in the number of shocks delivered per therapy episode; in a worst case scenario three shocks may be delivered instead of six. The problem may occur on alternate capacitor charge cycles, but the first shock will always be delivered. The programmed energy per shock is not affected by this problem.

The anomaly affects all Atlas and Epic ICD models listed above having a serial number below 225000. There are 844 affected devices in the UK, all of which were distributed since January 2004. The anomaly can be corrected by a software upgrade (see below). Therefore St Jude Medical has not recalled unimplanted ICDs affected by this anomaly as they will be automatically updated during programmer use at implantation.

No risk to patients implanted with affected devices is expected providing the downloading of the software upgrade to these devices is arranged well before their battery reaches ERI.

- **Inappropriate rate responsive pacing**

Inappropriate higher rate pacing may be initiated without being indicated by physiological need, when rate responsive pacing is programmed 'on' during automatic and clinician initiated capacitor reformation. The problem does not occur during capacitor charging prior to therapy delivery since automatic rate response function is suspended during arrhythmia detection.

This anomaly is due to an out of specification component (hybrid circuit) and it is caused by electrical 'noise' being misinterpreted as a physiologically derived signal, during capacitor reformation. This misinterpretation can cause the pacing rate to increase up to the maximum programmed sensor rate for up to 90 minutes.

The anomaly can occur in all Atlas and Epic ICD models listed above with serial numbers below 141000. This affects 609 implanted devices in the UK; St Jude Medical has informed the MHRA that they have recalled and retrieved all UK unimplanted ICDs affected by this anomaly.

For implanted devices, a software upgrade (see below) will manage this anomaly in patients by suspending rate responsive pacing during capacitor charging and for up to 90 minutes afterwards. If rate responsive pacing is already in progress when capacitor charging takes place, the rate response function will be suspended and the pacing rate will gradually reduce to the programmed base rate for a period of up to 90 minutes.

### **Software upgrade**

St Jude Medical has released software version 4.8.5 for its 3510 and 3510+ programmers to manage both anomalies and plans to upgrade all programmers in the UK by 27 July 2005. When performing ICD interrogation for the first time with an upgraded programmer, automatic downloading of the software upgrade from the programmer to the ICD will take approximately 45 seconds.

No adverse events regarding these anomalies have been reported to St Jude Medical or the MHRA.

## **ACTION:**

- Verify that all St Jude Medical Model 3510 and 3510+ ICD programmers have been upgraded by St Jude Medical with software version 4.8.5 (or higher) by 27 July 2005.
- Identify all patients implanted with the affected Epic or Atlas ICDs (serial number below 225000).
- Ensure that identified patients are followed up (including interrogation of ICDs using a St Jude Medical upgraded programmer Model 3510 or 3510+):
  - by the end of September 2005, where the affected implanted devices are programmed at higher electrical current settings
  - by the end of December 2005, for all other affected implanted devices.
- Report any instances of device failure to MHRA and St Jude Medical.
- Report any explants to the National Pacing and ICD database.

### **ACTION DEADLINES FOR THE SAFETY ALERT BROADCAST SYSTEM (SABS)**

**Trust managers should ensure that measures to implement the 'Actions' specified above are planned and completed in line with the following SABS deadlines.**

**Deadline (Action underway): 19 August 2005**  
Action plan to be agreed and actions started.

**Deadline (Action complete): 13 January 2006**  
All actions to be completed.

Further information about SABS can be found at [www.info.doh.gov.uk/sar/cmopatie.nsf](http://www.info.doh.gov.uk/sar/cmopatie.nsf)

## **DISTRIBUTION:**

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

### **TRUSTS to:**

- Liaison officers (for onward distribution)
- Accident & emergency departments
- Cardiac pacemaker/ICD technicians
- Cardiologists
- Clinical governance leads
- Medical directors
- Nursing executive directors
- Risk managers

### **HEALTHCARE COMMISSION (CHAI) to:**

- Headquarters (for onward distribution)
- Hospitals in the independent sector

### **PRIMARY CARE TRUSTS to:**

- Liaison officers (for onward distribution)
- Clinical governance leads
- Directors of public health

## **CONTACTS:**

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

Dr Jennifer Cooke  
Regulatory/Quality Manager  
St Jude Medical UK Ltd  
Capulet House  
Stratford Business & Technology Park  
Banbury Road  
Stratford-upon-Avon  
CV37 7GX

Tel: 01789 207 600

Fax: 01789 207 601

E-mail: [jcooke@sjm.com](mailto:jcooke@sjm.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: [mwc@btconnect.com](mailto:mwc@btconnect.com)

## **CONTACTS (continued):**

Enquiries to the MHRA should quote reference number **2005/006/020/291/010** and be addressed to:

### **Technical aspects:**

Dr Crina Cacou or Mr Peter M Solesbury  
Medicines & Healthcare products Regulatory Agency  
Market Towers  
1 Nine Elms Lane  
Vauxhall  
London SW8 5NQ

Tel: 020 7084 3338 / 3215

Fax: 020 7084 3106

E-mail: [crina.cacou@mhra.gsi.gov.uk](mailto:crina.cacou@mhra.gsi.gov.uk)  
[peter.solesbury@mhra.gsi.gov.uk](mailto:peter.solesbury@mhra.gsi.gov.uk)

### **Clinical aspects:**

Dr Jon Hopper  
Medicines & Healthcare products Regulatory Agency  
Market Towers  
1 Nine Elms Lane  
Vauxhall  
London SW8 5NQ

Tel: 020 7084 3126

Fax: 020 7084 3111

E-mail: [jon.hopper@mhra.gsi.gov.uk](mailto:jon.hopper@mhra.gsi.gov.uk)

### **Change of address or removal from address list for the Healthcare Commission:**

Healthcare Commission  
Finsbury Tower  
103-105 Bunhill Row  
London EC1Y 8TG

Tel: 020 7448 0842

E-mail: [contacts@healthcarecommission.org.uk](mailto:contacts@healthcarecommission.org.uk)

### **HOW TO REPORT ADVERSE INCIDENTS**

Incidents relating to medical devices must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) as soon as possible.

Further information about reporting incidents; on-line incident reporting facilities; and downloadable report forms are available from MHRA's website (<http://www.mhra.gov.uk>).

Alternatively, further information and printed incident report forms are available from:

MHRA Adverse Incident Centre

Medicines and Healthcare products Regulatory Agency

Market Towers, 1 Nine Elms Lane, London SW8 5NQ

Telephone 020 7084 3080 or Fax 020 7084 3109

or e-mail: [aic@mhra.gsi.gov.uk](mailto:aic@mhra.gsi.gov.uk)

(An answerphone service operates outside normal office hours)

**Medical Device Alerts are available in full text on the MHRA website:** <http://www.mhra.gov.uk>

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