

For:

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

<p><b>This alert supersedes MDA/2005/039. It is important that the guidance issued on 27 June 2005 is NOT followed.</b></p>		Further Information										
<p><b>DEVICE:</b> Guidant implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) – Specific AVT models:</p> <table border="1"> <thead> <tr> <th>Device Family</th> <th>Model Numbers</th> </tr> </thead> <tbody> <tr> <td>VENTAK PRIZM AVT<sup>®</sup></td> <td>1900</td> </tr> <tr> <td>VITALITY<sup>®</sup> AVT</td> <td>A135, A155</td> </tr> <tr> <td>CONTAK RENEWAL<sup>®</sup> 4 AVT</td> <td>M170, M175</td> </tr> <tr> <td>CONTAK RENEWAL<sup>®</sup> 4 AVT HE</td> <td>M177, M179</td> </tr> </tbody> </table> <p>See Appendix for list of serial numbers.</p>		Device Family	Model Numbers	VENTAK PRIZM AVT <sup>®</sup>	1900	VITALITY <sup>®</sup> AVT	A135, A155	CONTAK RENEWAL <sup>®</sup> 4 AVT	M170, M175	CONTAK RENEWAL <sup>®</sup> 4 AVT HE	M177, M179	
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CONTAK RENEWAL <sup>®</sup> 4 AVT HE	M177, M179											
<p><b>PROBLEM:</b> Guidant has revised programming recommendations (previously issued and described in MDA/2005/039) – to reduce risk of a software error that can potentially cause loss of cardioversion, defibrillation, telemetry and programmability.</p>		▶										
<p><b>ACTION BY:</b> All cardiologists and cardiac technicians who implant and manage patients with any of these devices.</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>* via CE Bulletin</p>		NHS Trusts (England)	– Chief Executives*	Healthcare Commission (CHAI)	– Headquarters	Primary Care Trusts (England)	– Chief Executives*	▶				
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<p><b>CONTACTS:</b> Details of manufacturer, National Pacing and ICD Database, and MHRA contacts for technical and clinical aspects. Change of address or removal from address list for 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>

## **PROBLEM:**

**The information provided in this alert supersedes the information provided in MDA/2005/039 issued on 27 June 2005.**

In June 2005, Guidant informed MHRA and UK clinicians that certain atrial therapy (AVT) subgroups of the Guidant ICD and CRT-D models, (see 'Device'), are subject to a random memory error, that could result in limited available therapy, inappropriate therapy and reduced device longevity.

Guidant has since informed MHRA that the original recommendations issued by Guidant to UK clinicians on 23 June 2005, may, under certain conditions, increase the risk of the software error occurring. Guidant has now revised these original recommendations (see 'Action' on page 3 for revised programming recommendations).

In their 23 June 2005 communication to clinicians, Guidant advised that a software error may occur when atrial tachycardia detection/therapy information is being stored to a defective area of memory. The memory error causes a continuous software loop that effectively 'freezes' the device into the mode operating at the time of occurrence. In this mode, the additional processor activity will increase battery consumption.

In this 'frozen' state:

- Detection and treatment of atrial and ventricular arrhythmias is suspended.
- Telemetry and programming is disabled.
- Bradycardia pacing will continue, but bradycardia will not be reprogrammable and may not match programmed settings.
- Battery usage will increase, but battery status indicators will not be available.
- Atrial and ventricular anti-tachycardia pacing (ATP) therapy will not stop following the treatment of an arrhythmia; if a memory error occurs during atrial and/or ventricular ATP therapy.

As of 23 June 2005, approximately 21,000 potentially affected devices have been distributed worldwide, with 248 devices distributed in the UK. Guidant confirmed that there had been two reports (non-UK), of memory error.

To reduce the likelihood of this memory error and freezing occurring, Guidant originally recommended programming the device's 'Atrial Tachy Episode Data Storage' to 0%. However, on 11 July 2005, Guidant received a third report (non-UK), of memory error and freezing occurring after reprogramming the device's 'Atrial Tachy Episode Data Storage' to 0%.

Guidant has now identified that devices with previously stored atrial tachy data may additionally experience a software logic error and freezing when 'Atrial Tachy Episode Data Storage' is programmed to 0%.

Based on these new observations, Guidant has established that the software logic error and freezing can occur in all devices where there is at least one atrial episode recorded in the device memory. Guidant estimates that the probability of memory error and freezing occurring is now 1 in 1,160 per month, for devices with previously stored data, where 'Atrial Tachy Episode Data Storage' has been reprogrammed to 0%.

Guidant has now determined that reprogramming 'Atrial Tachy Episode Data Storage' to 20% will reduce the risk of this software logic error and freezing occurring within this subset of AVT devices. Guidant has also established that programming 'Atrial Tachy Episode Data Storage' to 0%, for devices that have no previously stored atrial episodes, may also offer additional risk reduction.

In addition, Guidant has determined that programming all atrial and ventricular ATP therapies to 'OFF', will further reduce the likelihood of this software logic error occurring and causing continuous ATP therapy. However, disabling atrial and/or ventricular ATP therapy may have serious implications for some patients.

## **PROBLEM continued:**

Guidant is developing modifications to the software to enable full restoration of device function via the programmer. This will be available by the end of 2005 subject to regulatory approval (excluding Ventak Prizm AVT®).

Guidant will not modify software for the Ventak Prizm AVT®, since most implanted devices will have reached end of life before this software modification will be available. Clinicians should consider prophylactic explantation if the proposed programming options do not meet patient requirements.

Due to the low incidence level and reduced risk following programming recommendations, Guidant does not plan to recall unused hospital stock. The AVT product range will therefore remain available on the market. Before implanting a new device from this range, clinicians should be aware of these issues and should assess whether the potential benefits of the device outweigh the risks.

Guidant issued revised advice to UK clinicians on 28 July 2005.

## **ACTION:**

**Recommendations in this alert supersede the recommendations given in MDA/2005/039 issued on 27 June 2005, which has been withdrawn.**

- Identify all patients with affected devices where 'Atrial Episode Data Storage' was reprogrammed to 0%, or is less than 20%, and schedule a follow-up visit immediately.
- Identify and schedule a follow-up visit as soon as possible (and within three months of the last follow-up), for all patients where 'Atrial Episode Data Storage' is set at the default setting of 50%, or programmed to 20% or more.
- Verify device function using normal follow-up procedures.
- Verify number of 'Total Atrial Episodes' in the 'Quick Notes' report using the following steps:
  - 1) print a 'Quick Notes' report
  - 2) go to the 'Episode Counters' section
  - 3) review the 'Device Totals' section for 'Total Atrial Episodes'  
(DO NOT USE THE 'SINCE LAST RESET' SECTION).
- If stored 'Total Atrial Episodes' is not '0', consider programming 'Atrial Data Episode Storage' to 20%.
- If stored 'Total Atrial Episodes' is '0', consider programming 'Atrial Data Episode Storage' to 0%.
- If unable to confirm, consider programming 'Atrial Data Episode Storage' to 20%.
- Consider programming all atrial and/or ventricular ATP therapies to 'OFF'.
- Print 'Quick Notes' to verify and record changes.
- Instruct patients to contact their follow-up centre immediately if they experience shock therapy and/or arrhythmias/resumption of symptoms, which remain uncorrected by the device.
- For Ventak Prizm AVT® devices, consider prophylactic explantation if proposed programming recommendations do not meet patients' requirements.
- Ensure that follow-up intervals are no greater than three months (as per instructions for use).
- Report all instances of device failure to MHRA and Guidant.
- Report explants to the National Pacing and ICD Database (see contacts).

**Ref. MDA/2005/048**  
**Issued: 11 August 2005**

## **ACTION continued:**

### **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): 12 September 2005**

Action plan to be agreed and actions started.

**Ignore previous deadline given in MDA/2005/039**

**Deadline (Action complete): 12 December 2005**

All actions to be completed.

**Ignore previous deadline given in MDA/2005/039**

#### **Note to SABS Liaison Officers:**

In order to close electronic response form for MDA/2005/039, select "No action is required", indicating "Alert superseded by MDA/2005/048" in the action text box.

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 with pacemaker/ICD responsibilities
- 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:

Ms Jayne Puckeridge  
Regulatory Affairs Manager  
Guidant Limited  
Hampshire International Business Park  
Crockford Lane  
Chineham  
Basingstoke 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: [mwc@btconnect.com](mailto:mwc@btconnect.com)

**Ref. MDA/2005/048**  
**Issued: 11 August 2005**

## **CONTACTS continued:**

Enquiries to the MHRA should quote reference number **2005/006/020/291/015** and be addressed to:

### **Technical aspects:**

Miss Andleeb Arshad or Mr Peter Solesbury  
Medicines & Healthcare products Regulatory Agency  
Market Towers  
1 Nine Elms Lane  
Vauxhall  
London SW8 5NQ

Tel: 020 7084 3145 / 3215

Fax: 020 7084 3106

E-mail: andleeb.arshad@mhra.gsi.gov.uk  
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

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

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

Tel: 020 7448 0842

E-mail: 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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**APPENDIX TO MDA/2005/048**  
**List of affected UK serial numbers.**

MODEL	SERIAL	MODEL	SERIAL	MODEL	SERIAL
1900	100008	A135	108350	A135	768234
1900	100023	A135	108355	A135	768238
1900	100043	A135	108358	A135	768241
1900	100156	A135	108361	A135	768244
1900	100400	A135	108366	A135	768245
1900	100411	A135	108367	A135	768257
1900	100437	A135	108369	A135	768297
1900	100438	A135	108370	A135	768411
1900	100440	A135	108379	A135	768419
1900	100444	A135	108381	A135	925103
1900	100465	A135	108400	A135	926201
1900	100476	A135	108403	A135	926202
1900	100526	A135	108406	A155	112859
1900	100631	A135	108410	A155	113124
1900	100673	A135	108411	A155	113381
1900	100692	A135	108416	A155	113385
1900	100706	A135	108421	A155	113397
1900	100759	A135	108423	A155	113399
1900	100877	A135	108426	A155	977901
1900	100891	A135	108433	A155	977902
1900	100976	A135	108436	A155	977903
1900	100980	A135	108440	M170	100055
1900	101077	A135	108449	M170	100057
A135	107608	A135	108450	M170	100110
A135	107646	A135	108452	M170	100113
A135	107870	A135	108453	M175	100029
A135	107874	A135	108455	M175	100050
A135	107875	A135	108463	M175	100094
A135	107876	A135	108465	M175	100096
A135	108018	A135	108466	M175	100115
A135	108114	A135	108467	M175	100173
A135	108124	A135	108469	M177	100043
A135	108137	A135	108470	M177	100113
A135	108139	A135	108476	M177	100116
A135	108157	A135	108479	M177	100119
A135	108165	A135	108483	M177	100120
A135	108179	A135	108485	M177	100125
A135	108193	A135	108489	M177	100163
A135	108227	A135	108492	M177	100168
A135	108228	A135	108502	M177	100169
A135	108229	A135	108542	M177	100172
A135	108231	A135	108556	M177	100173
A135	108236	A135	108585	M177	100174
A135	108237	A135	108592	M177	100177
A135	108243	A135	108606	M177	100182
A135	108247	A135	108615	M177	100190
A135	108259	A135	768211	M177	100192
A135	108267	A135	768221	M177	100196
A135	108341	A135	768222	M177	100199

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**APPENDIX TO MDA/2005/048**  
**List of affected UK serial numbers.**

MODEL	SERIAL	MODEL	SERIAL
M177	100202	M179	100258
M177	100207	M179	100260
M179	100008	M179	100264
M179	100025	M179	100269
M179	100026	M179	100270
M179	100027	M179	100276
M179	100028	M179	100279
M179	100029	M179	100284
M179	100031	M179	100286
M179	100033	M179	100292
M179	100037	M179	100301
M179	100039	M179	100306
M179	100042	M179	100310
M179	100050	M179	100448
M179	100051	M179	100450
M179	100055	M179	100451
M179	100056	M179	100455
M179	100065	M179	100456
M179	100068	M179	100457
M179	100083	M179	100459
M179	100084	M179	100460
M179	100085	M179	100467
M179	100089	M179	100469
M179	100091	M179	100475
M179	100095	M179	100493
M179	100096	M179	100495
M179	100097	M179	100505
M179	100100	M179	100507
M179	100102	M179	100509
M179	100107	M179	100510
M179	100111	M179	100514
M179	100116	M179	100518
M179	100119	M179	100523
M179	100120	M179	100527
M179	100121	M179	100532
M179	100130	M179	100533
M179	100132	M179	100534
M179	100138	M179	100535
M179	100141	M179	100538
M179	100163	M179	100540
M179	100170	M179	100541
M179	100178	M179	100542
M179	100179	M179	100546
M179	100211	M179	100548
M179	100218	M179	100551
M179	100221	M179	100553
M179	100236	M179	100554
M179	100245	M179	100560
M179	100246	M179	100562
M179	100248		
M179	100252		
M179	100255		

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