



Medicines and Healthcare products  
Regulatory Agency

# Medical Device ALERT

Ref. MDA/2005/047

Issued: 09 August 2005

For:

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

	Further Information						
<p><b>DEVICE:</b> Guidant implantable pacemaker models: PULSAR<sup>®</sup>, PULSAR MAX, PULSAR MAX II, DISCOVERY<sup>®</sup>, DISCOVERY II, MERIDIAN<sup>®</sup>, CONTAK<sup>®</sup> TR, Manufactured between 25 November 1997 and 26 October 2000.</p>	▶						
<p><b>PROBLEM:</b> Failure of a hermetic seal, potentially leading to one or more of the following problems:</p> <ul style="list-style-type: none"> <li>• loss of pacing output without warning</li> <li>• inappropriate rate response function</li> <li>• loss of telemetry</li> <li>• premature battery depletion</li> <li>• earlier than expected display of replacement indicators</li> <li>• device reset to manufacturer's default settings.</li> </ul>	▶						
<p><b>ACTION BY:</b> All cardiologists and cardiac technicians who manage patients with any of these devices.</p>							
<p><b>ACTION:</b> See detailed actions for patient management on page 3 – these include:</p> <ul style="list-style-type: none"> <li>• Review all patients as soon as possible</li> <li>• Consider device replacement if pacemaker dependent.</li> </ul>	▶						
<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*	▶
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>

**DEVICE:**

Device Family	Pacemaker Model Numbers
PULSAR MAX	1170, 1171, 1270
PULSAR	0470, 0870, 0970, 0972, 1172, 1272
DISCOVERY	1174, 1175, 1273, 1274, 1275
MERIDIAN	0476, 0976, 1176, 1276
PULSAR MAX II	1180, 1181, 1280
DISCOVERY II	0481, 0981, 1184, 1186, 1187, 1283, 1284, 1285, 1286
CONTAK TR	1241
*VIRTUS PLUS II	1380, 1480
*INTELIS II	1483, 1484, 1485, 1384, 1385, 1349, 1499

Devices manufactured between 25 November 1997 and 26 October 2000

\*Not distributed within the UK – contact Guidant for affected serial numbers for these models if required.

Specific devices may also be verified using Guidant's device look up tool at:  
<http://www.guidant.com/webapp/emarketing/lookup.jsp>

A full list of UK affected serial numbers is available on the MHRA website.

**PROBLEM:**

Guidant has advised the MHRA that the above pacemakers have the potential to malfunction due to failure of a hermetic sealing component within the casing, adjacent to the lead connector header. Hermeticity failure may lead to ingress of body fluids, which may adversely affect the operation of electronic circuits and device performance. Guidant has not identified a mean time-to-failure but notes that the likelihood of hermeticity failure appears to increase with implant time. To date, all reports of hermeticity failure have occurred after the first 44 months of implant life. Guidant issued written advice to UK clinicians about this problem on 21 July 2005.

**Guidant has advised that some abnormal device behaviours resulting from this failure mode can present a serious health risk to patients**, such as loss of pacing output, or inappropriate rate response function – e.g. sustained pacing at the programmed maximum sensor rate (MSR) or lack of appropriate rate response during patient exercise. Loss of telemetry, device reset, premature battery depletion and early display of replacement indicators have also been observed. Guidant has not identified a test to predict this failure mode.

As of 11 July 2005, Guidant had received 69 worldwide reports of affected pacemakers exhibiting one or more of the above device behaviours. Fifty-two (52) of these have been confirmed as hermeticity failures and four are undergoing analysis. A further 13 devices may have suffered hermeticity failure but were not returned to Guidant for analysis. Guidant has received 20 reports of loss of pacing output, which include five reports of syncope. Loss of output has also been associated with reports of presyncope requiring patient hospitalisation. Guidant is aware of two reports of sustained MSR pacing in which heart failure may have developed in association with sustained high rate pacing. In one report, a patient whose device exhibited sustained MSR pacing was hospitalised with multiple health issues and later died. It is unknown if this device experienced hermeticity failure as the pacemaker was not returned to Guidant and the failure mode could not be confirmed.

Of the 78,000 pacemakers distributed worldwide, Guidant estimate that approximately 28,000 devices remain implanted, with approximately 1,400 in the UK. Affected models are those manufactured between 25 November 1997 and 26 October 2000.

Guidant predict that up to 143 devices may fail worldwide over the remaining lifetime of the implanted product.

The MHRA has received one UK report of sustained pacing at MSR without sequelae.

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## **ACTION:**

- Identify all patients having the above affected pacemakers and review them as soon as possible, giving priority to those who are pacing dependent or who have not been followed up within the last three months.
- Instruct patients to go to a hospital Accident and Emergency department or to contact their pacing clinic immediately, if they experience prolonged rapid heart rate, syncope / light-headedness, or have new or increased symptoms of heart failure.
- Verify device function using normal programmer follow-up procedures checking for:
  - loss of telemetry or pacing output
  - appearance of a reset warning message upon interrogation
  - earlier than expected display of replacement indicators and/or signs of premature/rapid battery depletion (e.g. compared with previous follow-up data - by observing battery status indicators and 'gas gauge')
  - inappropriate rate response function (if featured and programmed ON) e.g.:
    - pacing at the programmed MSR, or pacing higher than the programmed rate when the patient is at rest
    - lack of appropriate accelerometer rate response during patient activity.

Note: where rate response is programmed OFF, **temporarily** programme ON to evaluate.
- Where one or more of the above device behaviours is confirmed, consider elective replacement.
- Consider either programming rate response function OFF, or selecting a reduced MSR according to patient needs.
- Consider elective device replacement for pacing dependent patients.
- Consider scheduling future pacemaker follow-ups at three-monthly intervals to increase the likelihood of detecting device failure.
- Report all instances of device failure to the MHRA and Guidant.
- Report explants to the National Pacing and ICD Database (see contacts).

### **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): 09 September 2005**

**Deadline (Action complete): 09 December 2005**

Action plan to be agreed and actions started.

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 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

**Ref. MDA/2005/047**  
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## **CONTACTS:**

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

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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)

Enquiries to the MHRA should quote reference number **2005/007/018/291/025** and be addressed to:

### **Technical aspects:**

Miss Andleeb Arshad or Mr Peter M Solesbury  
Medicines & Healthcare products Regulatory Agency  
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London SW8 5NQ

Tel: 020 7084 3145 / 3215  
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[peter.solesbury@mhra.gsi.gov.uk](mailto:peter.solesbury@mhra.gsi.gov.uk)

### **Clinical aspects:**

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

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Tel: 020 7448 0842

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

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