

Medical Device/Equipment ALERT

Ref.

MDEA(NI)2006/38

Issued: 17 July 2006



HEALTH ESTATES

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For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION	✓

	Section
Medical Device/Equipment: Guidant implantable pacemaker and implantable defibrillator families: INSIGNIA, NEXUS, CONTAK RENEWAL TR, CONTAK RENEWAL TR 2, VENTAK PRIZM 2 VITALITY, VITALITY 2 – See list of affected serial numbers distributed in the UK and the Republic of Ireland on our website at http://www.dhsspsni.gov.uk/niaic	▶ ①
Problem: Recall due to component failure.	▶ ②
Action by: All cardiologists, cardiothoracic surgeons and cardiac physiologists who manage patients implanted with any of these devices.	▶ ③
Action: See actions on Page 3.	▶ ④
Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers For onward distribution see Section 5	▶ ⑤
Contacts Details of manufacturer, National Pacing and ICD Database and NIAIC contacts for technical aspects.	▶ ⑥
Feedback Requirements to NIAIC	▶ ⑦

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

1. DEVICE/EQUIPMENT:

Device Family	Model Numbers
INSIGNIA	482, 484, 485, 882, 982, 985, 986, 1190, 1192, 1194, 1195, 1198, 1290, 1291, 1292, 1294, 1295, 1296, 1297, 1298
NEXUS*	1325, 1326, 1328, 1390, 1392, 1394, 1395, 1398, 1426, 1428, 1432, 1466, 1467, 1468, 1490, 1491, 1492, 1494, 1495
CONTAK RENEWAL TR*	H120, H125
CONTAK RENEWAL TR 2	H140, H145
VENTAK PRIZM 2	1860, 1861
VITALITY	1870, 1871, *T125, *T127, *T135
VITALITY 2	T165, T167, T175, T177

*Not distributed within Europe

A comprehensive list of serial numbers of affected devices distributed in the UK and the Republic of Ireland is available on our website at <http://www.dhsspsni.gov.uk/niaic>

2. PROBLEM:

Guidant has informed MHRA that a sub-set of the implantable pacemakers/defibrillators listed above may suffer degradation of a high-stability low-voltage capacitor leading to device malfunction or premature battery depletion. Prevalence of device malfunction in the future and the mean time to failure have not yet been established.

Contaminated material used in the manufacturing process of a low-voltage capacitor for these devices can cause a leakage of current resulting in inappropriate device behaviour or premature battery depletion. One or two of these capacitors are used in each device depending on device design.

Guidant has identified the actual failure mechanism and corrective action has now been implemented. Based on experience of reported incidents, capacitor failure is likely to occur in the early part of the device's life period; however it is not possible to estimate when capacitor failure will occur. Analysis is ongoing to improve understanding of the prevalence and the time to failure of these devices.

To date Guidant has confirmed 5 reports of device malfunction associated with this issue out of approximately 27,200 implanted devices worldwide. One device malfunction was discovered at the time of implant; in the other four reports the devices required replacement.

To date, approximately 1,500 potentially affected devices have been distributed in the UK and the Republic of Ireland. Guidant believe that the majority of these have already been implanted. Approximately 49,800 affected devices have been distributed worldwide.

Guidant issued a letter with patient management recommendations to clinicians in the UK on 28/06/06 (see attached).

3. ACTION BY:

All cardiologists, cardiothoracic surgeons and cardiac physiologists who manage patients implanted with any of these devices.

4. ACTION:

- Do not implant affected devices. (See list of affected serial numbers distributed in the UK and the Republic of Ireland on our website at <http://www.dhsspsni.gov.uk/niaic>)
- Immediately quarantine all affected devices and return them to Guidant in accordance with their instructions.
- Identify patients implanted with affected devices and review them as soon as possible, giving priority to those who are device dependent or who have not been followed up within the last three months.
- During follow-up, verify device function using normal programmer follow-up procedures, checking for:
 - no telemetry/pacing output
 - ERI or EOL indications
 - suspected premature battery depletion
- For specific model families, possible device malfunction behaviours may include (but are not limited to):

	Device Family	Device Behaviour
	INSIGNIA, NEXUS*	<ul style="list-style-type: none"> • Incomplete or missing PRM daily measurements • Gas gauge not indicating BOL when checked at six month follow-up where the device is not programmed to high output settings
	CONTAK RENEWAL TR 2 CONTAK RENEWAL TR*	<ul style="list-style-type: none"> • Fault code 11 upon interrogation • Gas gauge not indicating BOL when checked at six month follow-up where the device is not programmed to high output settings
	PRIZM 2, VITALITY, VITALITY 2	<ul style="list-style-type: none"> • Battery voltage less than 3.10 V within six months of implant • Abnormal P&R wave measurements • Abnormal signals and markers on real-time or stored electrogram, which may result in inappropriate sensing and therapy

**Not distributed within Europe*

- Consult Guidant if you identify any of the above.
- Consider the risks and benefits of elective device replacement in device dependant patients if any of the above is confirmed.
- Schedule future patient follow-ups at intervals of no longer than three months for early detection of device failure.
- Instruct patients to contact their follow-up centre immediately or go to a hospital Accident and Emergency department if they experience a slow heart rate, syncope/light-headedness, inappropriate therapy or new or increased symptoms of heart failure.
- Report all instances of device failure to MHRA via NIAIC and Guidant.
- Report explants to the National Pacing and ICD Database (see Contacts on page 4).

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:

- | | |
|---|--|
| <ul style="list-style-type: none"> • Liaison Officers • Risk Managers • Health & Safety Officers/Advisors • Clinical Governance Leads • Device Managers • Medical Directors | <ul style="list-style-type: none"> • Clinical Directors • Nurse Directors • Coronary Care Departments • Cardiac pacemaker/ ICD technicians • Cardiologists with pacemaker/ ICD responsibilities |
|---|--|

6. CONTACTS:

Enquires to NIAIC should quote reference number MDEA(NI)2006/38 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

Reports to National Pacing and ICD Database should be addressed to:

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

Tel: 01505 612 829
Fax: 01505 612 829

Enquiries to the manufacturer should be addressed to:

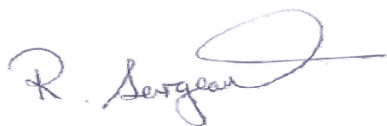
Ms Jayne Puckeridge, Regulatory Affairs Manager
Guidant Limited
Hampshire International Business Park
Crockford Lane, Chineham
Basingstoke, Hampshire, RG24 8WH

Tel: 01256 374 010
Fax: 01256 374 014

E-mail: jpuckeri@guidant.com

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

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

URGENT MEDICAL DEVICE SAFETY INFORMATION & CORRECTIVE ACTION

June 28, 2006

Dear Doctor,

Subject: Potential for malfunction (and device field withdrawal) in a subset of implantable pacemakers, cardiac resynchronization therapy pacemakers (CRT-Ps), and cardioverter defibrillators (ICDs) manufactured by Guidant Cardiac Rhythm Management (CRM), a Boston Scientific Company

We have an important safety information regarding the potential for malfunction in a subset of INSIGNIA[®] and NEXUS[®] pacemakers, CONTAK RENEWAL[®] TR/TR 2 CRT-Ps, and VENTAK PRIZM[®] 2, VITALITY[®] and VITALITY 2 ICDs.

As a precautionary measure, Guidant has initiated action to retrieve from hospital and sales force inventory all non-implanted devices within this well-defined subset. Consistent with Heart Rhythm Society and Independent Panel (Robert J. Myerburg, MD, chair) recommendations for timely, transparent and responsible actions, Guidant is taking this product retrieval action before our investigation is complete and prior to finalising patient care recommendations.

Description of Issue

Guidant has recently confirmed five (5) reports of device malfunction associated with the failure of a low-voltage capacitor from a single component supplier. Some capacitors from specific lots may perform in a manner that leads to device malfunction, including intermittent or permanent loss of therapy or premature battery depletion. One device malfunction was discovered at the time of implant, while four devices were implanted and subsequently required replacement. To date, approximately 49,800 devices have been distributed and approximately 27,200 devices have been implanted worldwide.

Clinical Implications

Patients with affected pacemakers or CRT-Ps may experience intermittent or permanent loss of output or telemetry, or premature battery depletion. Patients with affected ICDs may experience inappropriate sensing or premature battery depletion. There have been no reported patient deaths associated with this issue. There have been two reports of pacemaker patients experiencing syncope associated with loss of pacing output.

Projected Rate of Occurrence

We are very early in our investigation and do not have sufficient information to provide a projected rate of occurrence. We are continuing to diligently gather and analyse data to provide physicians with additional information regarding projected rate of occurrence for implanted devices. This information will be provided in a subsequent communication as soon as it is available.

Recommendations

- Physicians are asked to perform an in-clinic follow-up visit as soon as possible for all patients with implanted devices from this subset. At this follow-up visit, please look for the following device behaviour, which may be indicative of capacitor malfunction: premature battery depletion, intermittent or permanent loss of therapy or telemetry, fault codes, pacing or sensing abnormalities, or loss of daily measurements. Your local representative can provide additional technical guidance to assist in the evaluation of devices in this subset. Please document and report any observations of abnormal behaviour through your local representative or Guidant Technical Services.
- Guidant requests that all non-implanted inventory in this subset be returned to Guidant.

Devices Affected

The following models are affected by this communication:

Device Family	Model Numbers
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VITALITY	1870, 1871, *T125, *T127, *T135
VITALITY 2	T165, T167, T175, T177

**Not distributed in Europe*

Further Information

The Heart Rhythm Society's recommended "Advisory Notice" for this communication is attached.

Guidant recognises the impact of this communication on you and your patients and wants to reassure you that patient safety remains our primary concern. If you have any questions regarding this communication, please contact your local Guidant representative.

Yours sincerely



Gary Slack
UK Country Manager CRM