

Medical Device/Equipment ALERT

Ref. MDEA(NI)2005/93

Issued: 20 December 2005

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	✓
INFORMATION	



NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE

This alert is an update to MDEA(NI)2005/90 issued on 12 December 2005.	Further Information
Medical Device/Equipment: Guidant INSIGNIA and NEXUS implantable pacemakers - see list of affected serial numbers distributed in the UK on our website at http:// www.dhsspsni.gov.uk/niaic/mdea.asp	▶ ①
Problem: Recall due to component failure.	▶ ②
Action by: All cardiologists and cardiac physiologists who implant these devices.	▶ ③
Action: <ul style="list-style-type: none"> ▪ Do not implant affected INSIGNIA or NEXUS implantable pacemakers. ▪ Review stocks of INSIGNIA and NEXUS implantable pacemakers and identify those included in the recall. ▪ Immediately quarantine affected devices and return them to Guidant in accordance with their instructions. ▪ Report all instances of device failure to MHRA and Guidant. 	▶ 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 and NIAIC contacts for technical aspects.	▶ ⑥
Feedback Requirements to NIAIC None Required	▶ ⑦

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

1. DEVICE/EQUIPMENT:

Guidant Pacemakers		Guidant Intermedics Pacemakers	
Device family	Model numbers	Device family	Model numbers
INSIGNIA Entra SSI	0484, 0485	NEXUS Entra SSI	1325, 1326
INSIGNIA Entra DDD	0985, 0986	NEXUS Entra DDD	1425, 1426
INSIGNIA Entra SR	1195, 1198	NEXUS Entra SR	1395, 1398
INSIGNIA Entra DR	1294, 1295, 1296	NEXUS Entra DR	1466, 1494, 1495
INSIGNIA Ultra SR	1190	NEXUS Ultra SR	1390
INSIGNIA Ultra DR	1290, 1291	NEXUS Ultra DR	1490, 1491
INSIGNIA Plus SR	1194	NEXUS Plus SR	1394
INSIGNIA Plus DR	1297, 1298	NEXUS Plus DR	1467, 1468
INSIGNIA AVT SSI	482	NEXUS AVT SSI	1328
INSIGNIA AVT VDD	882	NEXUS AVT VDD	1428
INSIGNIA AVT DDD	982	NEXUS AVT DDD	1432
INSIGNIA AVT SR	1192	NEXUS AVT SR	1392
INSIGNIA AVT DR	1292	NEXUS AVT DR	1492

* NB Not all models are available in the UK

Due to the number of products involved it is not possible to include the list of serial numbers in this alert. A comprehensive list of serial numbers of affected devices distributed in the UK can be found on our website at www.dhsspsni.gov.uk/niaic/mdea.asp

2. PROBLEM:

The information provided in this alert is an update to the information provided in MDEA(NI)2005/90 issued on 12 December 2005 which advised of two failure modes, which were described as: 'First failure mode' and 'Second failure mode'.

This Alert provides updated information concerning the second failure mode. There is no change to previous information provided about the first failure mode.

Guidant has initiated a world-wide recall of certain INSIGNIA and NEXUS implantable pacemakers and has now identified why a subset of these devices exhibits no output conditions during verification testing prior to implant or during the implantation procedure (the second failure mode).

Guidant has identified that these devices can malfunction if they incorporate a defective crystal timing component manufactured by one of two suppliers.

Guidant has determined that a problem with the manufacturing process of this component can, in rare instances, result in a microscopic particle of quartz crystal entering the internal cavity of the crystal timing component. This particle can electrostatically attach to the inner surface of the crystal casing and subsequently detach through normal handling or during transit. The loose particle can then adhere to the crystal tuning mechanism causing crystal malfunction, and consequential malfunction of the master oscillator circuit that controls all pacemaker timing functions. Malfunction of the master oscillator will result in intermittent/permanent loss of pacing or telemetry.

Although all models of INSIGNIA and NEXUS implantable pacemakers are affected, this recall is restricted to those devices that have been assembled using defective crystal timing components (see list of affected serial numbers distributed in the UK on our website at [http:// www.dhsspsni.gov.uk/niaic/mdea.asp](http://www.dhsspsni.gov.uk/niaic/mdea.asp)).

To date, Guidant has received 17 confirmed reports of device malfunction out of 257,000 devices distributed worldwide. These all occurred at pre-implant testing or during the implantation procedure.

There have been no reports of device malfunction in the UK at pre-implant testing or during the implantation procedure. The number of potentially affected devices in the UK is approximately 8,000.

Since all failures have occurred before or during the implantation procedure neither Guidant nor MHRA advise additional follow-up for successfully implanted devices at this time.

Guidant also issued updated information related to this problem to UK clinicians on 16 December 2005 (see Appendix 1).

MHRA and NIAIC will continue to monitor the situation and will consider issuing further advice.

3. ACTION BY:

All cardiologists and cardiac physiologists who implant these devices.

4. ACTION:

- Do not implant affected INSIGNIA or NEXUS implantable pacemakers.
- Review stocks of INSIGNIA and NEXUS implantable pacemakers and identify those included in the recall.
- Immediately quarantine affected devices and return them to Guidant in accordance with their instructions.
- Report all instances of device failure to MHRA and Guidant.

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:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Medical Directors
- Clinical Directors
- Nurse Directors
- Independent Health and Social Care Providers – Private Clinics through HSSRIA
- Accident & Emergency Departments
- Cardiac Pacemaker/ICD Physiologists
- Cardiologists with Pacemaker/ICD Responsibilities

6. CONTACTS:

Enquiries to the manufacturer 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

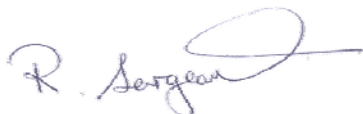
Enquires to NIAIC should quote reference number MDEA(NI)2005/93 and be addressed to:

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



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)2005/01. 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

**IMPORTANT MEDICAL DEVICE SAFETY INFORMATION
& CORRECTIVE ACTION**

December 16, 2005

Dear Doctor

Re: Guidant INSIGNIA® and NEXUS® implantable heart pacemakers Advisory - UPDATE

On September 29, 2005 Guidant issued a product advisory regarding important safety information relating to Guidant INSIGNIA® and NEXUS® implantable heart pacemakers. Two separate failure modes, each occurring at a low rate, had been identified within the INSIGNIA® and NEXUS® families of implantable pacemakers where one or more of the following device behaviours had been observed:

- Intermittent or permanent loss of pacing output without warning
- Intermittent or permanent loss of telemetry
- Reversion to VVI mode or appearance of a reset warning message upon interrogation

Attached to this letter is an update to our communication of 29, September 2005. The following information summarizes the update.

Summary and Rate of Occurrence for “Failure Mode 1”

As of November 30, 2005 Guidant has confirmed one (1) additional “Mode 1” failure for a total of thirty seven (37) failures out of a subset of 49,500 INSIGNIA® and NEXUS® devices distributed worldwide.

Guidant continues to predict the incidence rate for the active device population of approximately 40,000 to be between 0.017% and 0.037% over the remaining device lifetime (no change since the September 29, 2005 physician letter).

Guidant recommends normal monitoring for patients implanted with these devices.

Summary and Rate of Occurrence for “Failure Mode 2”

Root cause for “Failure Mode 2” has now been identified as a microscopic particle within the crystal timing component used in a subset of 257,000 INSIGNIA® and NEXUS® devices. This problem is entirely different to that identified in the investigation of “Failure Mode 1. This recent identification of root cause now allows Guidant to clarify that only a subset of devices are susceptible to “Failure Mode 2.”

As of November 30, 2005, Guidant has confirmed one (1) additional “Mode 2” failure for a total of seventeen (17) failures out of the subset of 257,000 (0.0066%) INSIGNIA® and NEXUS® distributed worldwide. All seventeen failures were identified before or during the implant procedure.

There have been no reports of a “Mode 2” failure in over 3.8 million months of service life accumulated by this subset after successful implantation.

Guidant recommends normal monitoring for patients implanted with these devices.

Guidant representatives will retrieve and replace all remaining hospital inventory with a product free from susceptibility to “Mode 2” peri-implant failure.

Guidant recognizes the impact of any product performance communication on both you and your patients, and wants to reassure you that patient safety remains Guidant’s primary concern. As always, if you have any questions regarding this communication, please contact your local Guidant representative.



Yours sincerely
Jayne Puckeridge
Regulatory Affairs Manager, UK, Ireland and Nordic.

GUIDANT

Advisory Update

INSIGNIA[®] and NEXUS[®]

This is an update to Guidant's September 29, 2005 letter to physicians regarding failures within the INSIGNIA and NEXUS family of pacemakers. This update provides the following information:

- Summary and Rate of Occurrence Update for "Failure Mode 1"
- Summary and Rate of Occurrence Update for "Failure Mode 2"
- United States Food and Drug Administration (FDA) Recall Classifications
- Product Distribution
- Update of Recommended Actions

Summary and Rate of Occurrence Update for "Failure Mode 1"

As of September 6, 2005, thirty-six (36) failures had been reported to Guidant out of a subset of 49,500 INSIGNIA and NEXUS devices distributed worldwide (0.073%). The majority of these devices exhibited a 'no output' condition during the implant procedure or shortly after implant. Root cause was identified as foreign material within a crystal timing component.

As of November 30, 2005, Guidant has confirmed one (1) additional "Mode 1" failure for a total of thirty-seven (37) failures out of the subset of 49,500 INSIGNIA and NEXUS devices distributed worldwide (0.075%). Most of these failures have occurred at implant or early in life, and demonstrate a failure rate that rapidly decreases with time following implant. Guidant continues to predict the incidence rate for the active device population of approximately 40,000 to be between 0.017% and 0.037% over the remaining device lifetime (no change since the September 29, 2005 physician letter). In our September 29, 2005 physician letter, Guidant stated that this failure mode was associated with three reports of syncope and six reports of bradycardia or heart block; no additional clinical consequences have been reported as of November 30, 2005.

Summary and Rate of Occurrence Update for "Failure Mode 2"

As of September 6, 2005, sixteen (16) failures had been reported to Guidant out of 341,000 INSIGNIA and NEXUS devices distributed worldwide (0.0047%). For all sixteen devices, a 'no output' condition was discovered peri-implant (i.e., at the implant procedure or during pre-implant testing). While a specific root cause had not been determined at that time, no failures had been observed after successful confirmation of pacing at implant.

Root cause for INSIGNIA and NEXUS "Failure Mode 2" has now been identified as a microscopic particle within the crystal timing component used in a subset of 257,000 INSIGNIA and NEXUS devices. Although devices manufactured with this crystal timing component passed all manufacturing tests prior to distribution, in rare instances, mechanical shock conditions such as those experienced during shipping have caused the particle to relocate to a point where it interferes with the crystal and therefore pacemaker operation prior to implant. No "Mode 2" failures have been reported following confirmation of successful implantation.

Guidant has utilized two suppliers for the crystal timing component used in the INSIGNIA and NEXUS pacemaker families. Although the September 29, 2005 letter stated that *all* INSIGNIA and NEXUS pacemakers were potentially susceptible to "Failure Mode 2," the recent identification of root cause now allows Guidant to clarify that only a subset of devices that incorporate a crystal timing component from one of the two suppliers are susceptible to "Failure Mode 2." No other INSIGNIA or NEXUS devices are susceptible to "Failure Mode 2." Devices incorporating a crystal timing component from the other supplier are no longer included in this advisory action.

As of November 30, 2005, Guidant has confirmed one (1) additional "Mode 2" failure for a total of seventeen (17) failures out of the subset of 257,000 (0.0066%) INSIGNIA and NEXUS devices manufactured and distributed worldwide that utilize a crystal timing component susceptible to "Failure Mode 2." All seventeen failures were identified before or during the implant procedure. There have been no reports of a "Mode 2" failure in over 3.8 million months of service life accumulated by this subset after successful implantation.

FDA Recall Classification

On November 23, 2005, the FDA classified both "Failure Mode 1" and "Failure Mode 2" issues as described in Guidant's September 29, 2005 letter to physicians as Class II recalls. A Class II recall is defined by the FDA as a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

Product Distribution

In March of 2004, Guidant discontinued shipping from manufacturing facilities INSIGNIA and NEXUS devices susceptible to "Failure Mode 1."

Guidant has recently discontinued shipping from manufacturing facilities INSIGNIA and NEXUS devices susceptible to "Failure Mode 2." While Guidant recommends normal monitoring for patients implanted with these devices, Guidant representatives will retrieve and replace remaining hospital inventory with product free from susceptibility to "Mode 2" peri-implant failure.

INSIGNIA and NEXUS devices currently being distributed by Guidant are not subject to either failure mode and therefore are not included in either recall.

Your local sales representative can provide a list of *all* INSIGNIA devices specific to your clinic. A device model/serial number look-up/search tool is also available at guidant.com in the Product Safety Information section.

Update of Recommended Actions

- Guidant recommends normal monitoring, as per device labelling, for *all* implanted INSIGNIA and NEXUS pacemakers.
- Physicians should consider the projected low and declining INSIGNIA and NEXUS "Mode 1" failure rate in addition to the unique needs of individual patients in their medical decisions regarding patient management. As always, advise patients to seek attention immediately if they experience syncope or light-headedness.

Updates regarding these devices will be provided in Guidant CRM Product Performance Reports. If you have any questions, please contact your local Guidant sales representative or Guidant Technical Services.

Guidant Corporation
Cardiac Rhythm Management (CRM)
U.S. Technical Services
Tel: 651.582.4000; Toll Free: 1.800.CARDIAC (227.3422)
European Technical Services
Tel: +32 2 416 93 57

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