

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2005/90

Issued: 12 December 2005

For:

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



**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

	Section
<p><b>Medical Device/Equipment:</b> Guidant INSIGNIA and NEXUS implantable pacemakers.</p>	▶ ①
<p><b>Problem:</b> Device may exhibit:</p> <ul style="list-style-type: none"> <li>• intermittent or permanent loss of pacing output without warning</li> <li>• intermittent or permanent loss of telemetry</li> <li>• reversion to ventricular inhibited pacing (VVI), and/or a reset warning message upon interrogation.</li> </ul>	▶ ②
<p><b>Action by:</b> All cardiologists and cardiac physiologists who manage patients already implanted with or to be implanted with these devices.</p>	▶ ③
<p><b>Action:</b> See Action points on page 3.</p>	▶ ④
<p><b>Distributed by NIAIC to:</b> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p>	▶ ⑤
<p><b>Contacts</b> Details of manufacturer, National Pacing and ICD Database and, NIAIC contacts for technical aspects.</p>	▶ ⑥
<p><b>Feedback Requirements to NIAIC</b></p>	▶ ⑦

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

# 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

A list of UK serial numbers for devices distributed on or before 12 March 2004, affected by the first failure mode can be found in Appendix 1.

## 2. PROBLEM:

Guidant has informed MHRA that all INSIGNIA and NEXUS implantable pacemakers may be subject to either one of two separate failure modes, each having a different root cause.

Affected devices will exhibit one or more of the following:

- intermittent or permanent loss of pacing output without warning
- intermittent or permanent loss of telemetry
- reversion to ventricular inhibited pacing (VVI), and/or a reset warning message upon interrogation.

Although there have been no reports of death as a result of these failure modes, serious health complications may result from the abnormal device behaviours associated with these failure modes.

Details of the two failure modes are described below:

### First failure mode:

Guidant has identified the potential for loss of pacing output and/or telemetry in a subset of INSIGNIA and NEXUS devices distributed prior to 12 March 2004.

Guidant has confirmed that the root cause of this malfunction is the obstruction of a crystal timing component by loose material used in the component's manufacture. When this timing component is disrupted all device operations such as pacing, telemetry and magnet response may be prevented and the device can cease to function.

To date, all device malfunctions associated with this failure mode have occurred within the first 22 months of implantation. Guidant believes that the likelihood of this malfunction occurring decreases with implant time, with a mean time to failure of seven months.

Device failure is rare. As of November 2005, Guidant has received three reports of syncope and six reports of bradycardia requiring emergency hospitalisation. Engineering analysis by Guidant of an explanted device revealed that it had failed briefly but then resumed functioning with no detectable indication to the physician during routine follow-up.

Guidant has received 37 confirmed reports of device malfunction associated with this failure mode: 7 devices exhibited a no output condition during the implant procedure; 21 devices exhibited a no output condition post implant procedure and 9 devices reverted to VVI pacing at 65 bpm.

Out of 49,500 devices distributed prior to 12 March 2004, Guidant estimates that approximately 41,000 devices remain implanted, with approximately 2,200 implanted in the UK.

Guidant predicts that up to 14 additional devices may malfunction worldwide over the remaining lifetime of the implanted products. Guidant has ensured that corrective measures to address this issue have been implemented.

MHRA has received two UK reports of syncope associated with these devices. Guidant issued information related to this problem to UK clinicians on 29 September 2005 (see Appendix 2).

**Second failure mode:**

Guidant has identified that all INSIGNIA and NEXUS devices may exhibit a no output condition during verification testing prior to implant or during implantation. No malfunctions have been observed after successful verification of the device at implant.

As of November 2005, Guidant has received 17 confirmed reports of device malfunction at pre-implant testing or during implantation out of approximately 341,000 devices distributed worldwide. In one (non-UK) report a pacemaker dependent patient experienced syncope and was resuscitated following cardiac arrest. This was associated with loss of pacing output during an elective pacemaker replacement procedure.

There have been no reports of device malfunction at pre-implant testing or during implantation in the UK to date. The number of potentially affected devices in the UK is approximately 11,000.

Guidant has yet to determine a specific root cause for this failure mode and continues to investigate this failure. Guidant will issue further advice when more information is available.

Guidant also issued information related to this problem on 29 September 2005 (see Appendix 2).

MHRA and NIAIC will continue to monitor both these situations.

### 3. ACTION BY:

All cardiologists and cardiac physiologists who manage patients already implanted with or to be implanted with these devices.

### 4. ACTION:

#### First failure mode (see list of affected devices in Appendix 1):

- identify and review all patients implanted with affected pacemakers as soon as possible, **giving priority to those who are pacemaker dependent** or who have not been followed up within the last six months
- instruct patients to contact their follow-up centre immediately, or to go to a hospital Accident and Emergency department if they experience a slow heart rate, syncope/light headedness, or new or increased symptoms of heart failure
- during follow-up, verify device function using normal programmer follow-up procedures, checking for:
  - intermittent or permanent loss of telemetry/pacing output
  - reversion to ventricular inhibited pacing (VVI), and/or a reset warning message upon interrogation.
- consider elective device replacement if one or more of the above malfunctions is confirmed
- consider elective device replacement for pacemaker dependent patients
- schedule future pacemaker follow-ups at intervals of no longer than six months for early detection of device failure.

#### Second failure mode (all devices):

- verify device function when the device is still in its packaging prior to the implant procedure
- do not implant if device function verification confirms intermittent or permanent loss of telemetry/pacing output.

Report all instances of device failure to NIAIC and Guidant.

Report all explants to the National Pacing and ICD Database (see contacts).

### 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 and/or the National Pacing and ICD Database should be addressed to:

Ms Jayne Puckeridge	National Pacing and ICD database
Regulatory Affairs Manager	PO Box 9205
Guidant Limited	Bridge of Weir
Hampshire International Business Park	Strathclyde
Crockford Lane	PA11 3DZ
Chineham	
Basingstoke	
Hampshire, RG24 8WH	

Tel: 01256 374 010

Tel: 01505 612 829

Fax: 01256 374 014

Fax: 01505 612 829

E-mail: [jpuckeri@guidant.com](mailto:jpuckeri@guidant.com)

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

Enquires to NIAIC should quote reference number MDEA(NI)2005/90 and be addressed to:

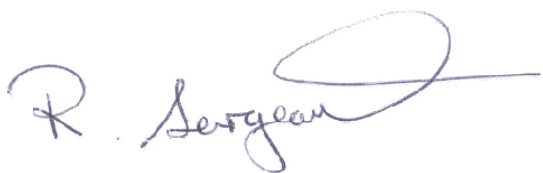
Northern Ireland Adverse Incident Centre (NIAIC)  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast BT16 1US

Tel: 028 9052 3868

Fax: 028 9052 3900

Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

## 7. FEEDBACK:



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](http://www.dhsspsni.gov.uk/niaic)

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

**APPENDIX 1 to MDEA(NI)2005/90**

List of UK serial numbers for Guidant INSIGNIA and NEXUS implantable pacemakers, distributed on or before 12 March 2004, affected by the first failure mode.

Model	Serial No	Model	Serial No	Model	Serial No	Model	Serial No	Model	Serial No	Model	Serial No
0484	100879	0484	101366	0484	101627	0982	100344	0986	100718	0986	100895
0484	100882	484	101377	484	101628	0982	100357	0986	100719	0986	100897
0484	100883	0484	101382	0484	101641	0985	100068	0986	100720	0986	100898
0484	100953	0484	101385	0484	101642	0985	100070	0986	100721	0986	100899
0484	100955	0484	101451	0484	101651	0985	100075	0986	100722	0986	100901
0484	100956	0484	101457	0484	101662	0985	100084	0986	100723	0986	100902
0484	100957	0484	101498	0484	101669	0986	100607	0986	100724	0986	100904
0484	100959	0484	101499	0484	101674	0986	100612	0986	100725	0986	100905
0484	100960	0484	101500	0484	101678	0986	100630	0986	100726	0986	100906
0484	100961	0484	101502	0484	101681	0986	100637	0986	100728	0986	100907
0484	100963	0484	101506	0484	101691	0986	100638	0986	100729	0986	100908
0484	101227	0484	101507	0484	101693	0986	100640	0986	100730	0986	100909
0484	101228	0484	101508	0484	101695	0986	100642	0986	100731	0986	100911
0484	101232	0484	101511	0484	101698	0986	100643	0986	100732	0986	100912
0484	101235	0484	101513	0484	101700	0986	100644	0986	100735	0986	100928
0484	101238	0484	101514	0484	101707	0986	100645	0986	100736	0986	100933
0484	101242	0484	101515	0484	101708	0986	100646	0986	100737	0986	100934
0484	101243	0484	101516	0484	101709	0986	100647	0986	100738	0986	100939
0484	101251	0484	101517	0484	101710	0986	100648	0986	100739	0986	100944
0484	101264	0484	101518	0484	101717	0986	100649	0986	100740	0986	100947
0484	101265	0484	101519	0484	101718	0986	100650	0986	100741	0986	100958
0484	101268	0484	101520	0484	101719	0986	100651	0986	100744	0986	100962
0484	101271	0484	101522	0484	101722	0986	100653	0986	100748	0986	100963
0484	101274	0484	101523	0484	101784	0986	100654	0986	100753	0986	100964
0484	101275	0484	101524	0484	101792	0986	100655	0986	100756	0986	100966
0484	101276	0484	101525	0484	101793	0986	100656	0986	100793	0986	100967
0484	101277	0484	101526	0484	101801	0986	100659	0986	100794	0986	100969
0484	101278	0484	101527	0484	101808	0986	100660	0986	100795	0986	100970
0484	101279	0484	101529	0484	101810	0986	100661	0986	100796	0986	100975
0484	101281	0484	101530	0484	101849	0986	100662	0986	100797	0986	100976
0484	101283	0484	101533	0484	101852	0986	100663	0986	100799	0986	100977
0484	101284	0484	101534	0484	101854	0986	100664	0986	100800	0986	100978
0484	101285	0484	101538	0484	101857	0986	100665	0986	100801	0986	100979
0484	101286	0484	101539	0484	101880	0986	100666	0986	100802	0986	100981
0484	101295	0484	101541	0484	101882	0986	100673	0986	100803	0986	101009
0484	101298	0484	101542	0484	101883	0986	100682	0986	100805	0986	101010
0484	101299	0484	101543	0484	101884	0986	100685	0986	100807	0986	101015
0484	101300	0484	101546	0484	101893	0986	100686	0986	100808	0986	101042
0484	101302	0484	101547	0484	101908	0986	100688	0986	100809	0986	101077
0484	101304	0484	101548	0484	101914	0986	100689	0986	100811	0986	101085
0484	101305	0484	101552	0484	101919	0986	100690	0986	100814	0986	101086
0484	101310	0484	101581	0484	101920	0986	100691	0986	100817	0986	101087
0484	101317	0484	101582	0484	101921	0986	100707	0986	100827	0986	101098
0484	101320	0484	101585	0484	102438	0986	100708	0986	100831	0986	101099
0484	101334	0484	101594	0484	115232	0986	100709	0986	100838	0986	101100
0484	101336	0484	101618	0484	115235	0986	100710	0986	100840	0986	101110
0484	101338	0484	101619	0484	115237	0986	100711	0986	100841	0986	101113
0484	101339	0484	101620	0485	100097	0986	100712	0986	100842	0986	101122
0484	101340	0484	101621	0485	100098	0986	100713	0986	100877	0986	101125
0484	101345	0484	101622	0485	100104	0986	100714	0986	100879	0986	101126
0484	101346	0484	101624	0982	100260	0986	100715	0986	100882	0986	101127
0484	101347	0484	101625	0982	100321	0986	100716	0986	100893	0986	101131
		0484	101626	0982	100343	0986	100717	0986	100894	0986	101132

**APPENDIX 1 to MDEA(NI)2005/90**

List of UK serial numbers for Guidant INSIGNIA and NEXUS implantable pacemakers, distributed on or before 12 March 2004, affected by the first failure mode.

Model	Serial No	Model	Serial No	Model	Serial No	Model	Serial No	Model	Serial No	Model	Serial No
0986	101134	0986	101818	0986	102110	0986	102327	0986	102476	0986	102580
0986	101135	0986	101821	0986	102112	0986	102328	0986	102482	0986	102596
0986	101192	0986	101822	0986	102113	0986	102329	0986	102483	0986	102597
0986	101478	0986	101827	0986	102114	0986	102330	0986	102496	0986	102598
0986	101597	0986	101831	0986	102118	0986	102331	0986	102504	0986	102599
0986	101675	0986	101832	0986	102120	0986	102333	0986	102506	0986	102604
0986	101697	0986	101834	0986	102121	0986	102335	0986	102507	0986	102605
0986	101724	0986	101835	0986	102131	0986	102336	0986	102508	0986	102608
0986	101725	0986	101836	0986	102136	0986	102337	0986	102512	0986	102609
0986	101727	0986	101839	0986	102138	0986	102343	0986	102513	0986	102610
0986	101730	0986	101841	0986	102139	0986	102344	0986	102514	0986	102612
0986	101731	0986	101842	0986	102141	0986	102348	0986	102515	0986	102613
0986	101732	0986	101843	0986	102144	0986	102349	0986	102518	0986	102614
0986	101733	0986	101847	0986	102145	0986	102350	0986	102519	0986	102615
0986	101735	0986	101848	0986	102149	0986	102351	0986	102520	0986	102616
0986	101736	0986	101849	0986	102151	0986	102352	0986	102521	0986	102618
0986	101737	0986	101850	0986	102156	0986	102353	0986	102522	0986	102619
0986	101739	0986	101851	0986	102157	0986	102354	0986	102523	0986	102620
0986	101740	0986	101853	0986	102158	0986	102355	0986	102524	0986	102621
0986	101742	0986	101869	0986	102159	0986	102356	0986	102528	0986	102622
0986	101743	0986	101874	0986	102163	0986	102357	0986	102529	0986	102623
0986	101744	0986	101896	0986	102170	0986	102362	0986	102530	0986	102624
0986	101746	0986	101897	0986	102172	0986	102364	0986	102536	0986	102631
0986	101747	0986	101898	0986	102177	0986	102365	0986	102537	0986	102640
0986	101748	0986	101900	0986	102178	0986	102366	0986	102538	0986	102641
0986	101750	0986	101901	0986	102183	0986	102367	0986	102539	0986	102659
0986	101751	0986	101903	0986	102191	0986	102368	0986	102542	0986	102677
0986	101753	0986	101904	0986	102192	0986	102369	0986	102548	0986	102681
0986	101754	0986	101905	0986	102196	0986	102379	0986	102549	0986	102682
0986	101755	0986	101910	0986	102199	0986	102380	0986	102551	0986	102683
0986	101756	0986	101911	0986	102200	0986	102381	0986	102552	0986	102685
0986	101757	0986	101913	0986	102204	0986	102383	0986	102554	0986	102686
0986	101758	0986	101915	0986	102208	0986	102386	0986	102557	0986	102687
0986	101759	0986	101932	0986	102209	0986	102388	0986	102559	0986	102690
0986	101760	0986	101935	0986	102213	0986	102389	0986	102560	0986	102697
0986	101761	0986	101936	0986	102216	0986	102391	0986	102561	0986	102699
0986	101768	0986	101937	0986	102218	0986	102392	0986	102562	0986	102700
0986	101769	0986	101938	0986	102220	0986	102395	0986	102563	0986	102702
0986	101770	0986	101939	0986	102225	0986	102398	0986	102564	0986	102704
0986	101771	0986	101941	0986	102226	0986	102399	0986	102565	0986	102711
0986	101777	0986	101943	0986	102231	0986	102403	0986	102566	0986	102712
0986	101779	0986	101948	0986	102235	0986	102406	0986	102567	0986	102733
0986	101794	0986	101951	0986	102237	0986	102407	0986	102568	0986	102734
0986	101804	0986	101952	0986	102238	0986	102408	0986	102569	0986	102735
0986	101805	0986	102018	0986	102242	0986	102409	0986	102570	0986	102736
0986	101807	0986	102041	0986	102250	0986	102410	0986	102571	0986	102737
0986	101809	0986	102043	0986	102251	0986	102412	0986	102572	0986	102738
0986	101810	0986	102057	0986	102253	0986	102414	0986	102573	0986	102768
0986	101811	0986	102092	0986	102259	0986	102416	0986	102574	0986	102769
0986	101814	0986	102094	0986	102261	0986	102419	0986	102576	0986	102770
0986	101815	0986	102096	0986	102264	0986	102420	0986	102577	0986	102771
0986	101816	0986	102097	0986	102301	0986	102431	0986	102578	0986	102772
0986	101817	0986	102108	0986	102314	0986	102463	0986	102579	0986	102773

**APPENDIX 1 to MDEA(NI)2005/90**

List of UK serial numbers for Guidant INSIGNIA and NEXUS implantable pacemakers, distributed on or before 12 March 2004, affected by the first failure mode.

Model	Serial No	Model	Serial No	Model	Serial No	Model	Serial No	Model	Serial No	Model	Serial No
0986	102774	1190	890439	1194	115730	1194	116996	1198	102560	1198	102750
0986	102775	1190	890480	1194	115731	1194	117011	1198	102561	1198	102751
0986	102776	1190	890489	1194	115733	1194	117117	1198	102562	1198	102757
0986	102780	1192	100110	1194	115734	1194	117336	1198	102587	1198	102758
0986	102781	1192	100266	1194	115735	1194	117347	1198	102602	1198	102759
0986	102782	1192	100280	1194	115738	1194	117373	1198	102636	1198	102762
0986	102783	1192	100326	1194	115739	1194	119321	1198	102651	1198	102764
0986	102784	1192	100406	1194	115741	1194	123324	1198	102660	1198	102766
0986	102785	1194	108883	1194	115742	1195	100795	1198	102663	1198	102767
0986	102786	1194	108886	1194	115743	1195	100949	1198	102667	1198	102768
0986	102787	1194	108970	1194	115744	1195	100965	1198	102669	1198	102769
0986	102789	1194	109037	1194	115745	1195	100967	1198	102672	1198	102771
0986	102791	1194	112622	1194	115746	1195	101084	1198	102673	1198	102778
0986	102792	1194	112634	1194	115747	1195	101126	1198	102674	1198	102947
0986	102793	1194	112776	1194	115749	1195	101151	1198	102677	1198	102972
0986	102794	1194	112791	1194	115751	1195	101166	1198	102678	1198	103024
0986	102796	1194	112795	1194	115753	1198	102500	1198	102680	1198	103028
0986	102797	1194	113198	1194	115754	1198	102502	1198	102683	1198	103049
0986	102798	1194	113199	1194	115755	1198	102503	1198	102684	1198	103051
0986	102799	1194	113202	1194	115757	1198	102506	1198	102685	1198	103053
0986	102837	1194	113207	1194	115822	1198	102507	1198	102686	1198	103080
0986	102838	1194	113934	1194	116222	1198	102509	1198	102687	1198	103083
0986	102839	1194	113956	1194	116225	1198	102514	1198	102689	1198	103085
0986	102842	1194	113978	1194	116227	1198	102515	1198	102691	1198	103087
0986	102843	1194	113980	1194	116230	1198	102517	1198	102692	1198	103092
0986	102844	1194	113982	1194	116233	1198	102522	1198	102693	1198	103100
0986	102846	1194	113991	1194	116240	1198	102523	1198	102694	1198	103150
0986	102847	1194	113994	1194	116287	1198	102524	1198	102695	1198	103187
0986	102848	1194	113999	1194	116307	1198	102527	1198	102696	1198	103189
0986	102851	1194	114002	1194	116318	1198	102529	1198	102698	1198	103213
0986	102852	1194	114117	1194	116319	1198	102532	1198	102699	1198	103247
0986	102854	1194	114137	1194	116420	1198	102533	1198	102700	1198	103273
0986	102856	1194	114146	1194	116602	1198	102535	1198	102701	1198	103274
0986	102859	1194	114186	1194	116603	1198	102537	1198	102702	1198	103283
0986	102931	1194	114188	1194	116607	1198	102538	1198	102703	1198	103310
0986	102948	1194	114206	1194	116618	1198	102539	1198	102704	1198	103355
0986	102974	1194	114244	1194	116621	1198	102541	1198	102705	1198	103372
0986	102978	1194	114255	1194	116622	1198	102543	1198	102706	1198	103378
0986	102979	1194	114416	1194	116623	1198	102544	1198	102707	1198	103384
0986	102980	1194	114472	1194	116741	1198	102545	1198	102711	1198	103503
0986	103115	1194	114473	1194	116742	1198	102546	1198	102712	1198	103577
0986	103116	1194	114503	1194	116745	1198	102547	1198	102713	1198	103585
0986	103117	1194	114504	1194	116804	1198	102548	1198	102718	1198	103588
0986	103131	1194	114516	1194	116947	1198	102549	1198	102727	1198	103601
0986	103142	1194	114708	1194	116948	1198	102550	1198	102729	1198	103613
0986	103288	1194	114772	1194	116953	1198	102551	1198	102730	1198	103618
0986	103289	1194	114783	1194	116955	1198	102552	1198	102732	1198	103647
1190	890292	1194	114789	1194	116967	1198	102553	1198	102733	1198	103664
1190	890320	1194	114813	1194	116969	1198	102554	1198	102736	1198	103673
1190	890362	1194	114828	1194	116970	1198	102555	1198	102737	1198	103676
1190	890363	1194	115727	1194	116971	1198	102556	1198	102742	1198	103711
1190	890373	1194	115728	1194	116973	1198	102557	1198	102746	1198	103717
1190	890378	1194	115729	1194	116974	1198	102559	1198	102748	1198	103719

**APPENDIX 1 to MDEA(NI)2005/90**

List of UK serial numbers for Guidant INSIGNIA and NEXUS implantable pacemakers, distributed on or before 12 March 2004, affected by the first failure mode.

Model	Serial No	Model	Serial No	Model	Serial No	Model	Serial No	Model	Serial No	Model	Serial No
1198	103720	1198	104311	1198	105371	1198	105899	1198	106159	1198	106680
1198	103809	1198	104313	1198	105372	1198	105900	1198	106160	1198	106681
1198	103810	1198	104315	1198	105374	1198	105925	1198	106161	1198	106684
1198	103828	1198	104316	1198	105376	1198	105926	1198	106162	1198	106686
1198	103829	1198	104332	1198	105460	1198	105931	1198	106164	1198	106687
1198	103833	1198	104334	1198	105532	1198	105932	1198	106167	1198	106690
1198	103834	1198	104335	1198	105539	1198	105938	1198	106169	1198	106692
1198	103848	1198	104338	1198	105551	1198	105940	1198	106170	1198	106693
1198	103849	1198	104348	1198	105554	1198	105942	1198	106171	1198	106694
1198	103855	1198	104349	1198	105555	1198	105944	1198	106172	1198	106719
1198	103858	1198	104351	1198	105557	1198	105945	1198	106174	1198	106720
1198	103860	1198	104404	1198	105560	1198	105949	1198	106177	1198	106721
1198	103882	1198	104405	1198	105561	1198	105952	1198	106183	1198	106722
1198	103888	1198	104441	1198	105565	1198	105953	1198	106185	1198	106739
1198	103890	1198	104444	1198	105567	1198	105954	1198	106186	1198	106740
1198	103892	1198	104445	1198	105833	1198	105955	1198	106229	1198	106741
1198	103896	1198	104460	1198	105835	1198	105956	1198	106231	1198	106742
1198	103905	1198	104461	1198	105836	1198	105957	1198	106242	1198	106743
1198	103906	1198	104462	1198	105837	1198	105958	1198	106296	1198	106744
1198	104100	1198	104467	1198	105838	1198	105959	1198	106369	1198	106755
1198	104106	1198	104471	1198	105839	1198	105961	1198	106373	1198	106756
1198	104127	1198	104514	1198	105840	1198	105962	1198	106374	1198	106757
1198	104134	1198	104597	1198	105841	1198	105964	1198	106375	1198	106758
1198	104137	1198	104633	1198	105842	1198	105965	1198	106378	1198	106759
1198	104138	1198	104653	1198	105844	1198	105968	1198	106379	1198	106760
1198	104140	1198	104683	1198	105845	1198	106013	1198	106382	1198	106761
1198	104141	1198	104715	1198	105846	1198	106014	1198	106386	1198	106763
1198	104143	1198	105133	1198	105847	1198	106015	1198	106387	1198	106764
1198	104146	1198	105135	1198	105848	1198	106016	1198	106490	1198	106765
1198	104154	1198	105137	1198	105850	1198	106017	1198	106536	1198	106766
1198	104155	1198	105147	1198	105851	1198	106019	1198	106538	1198	106775
1198	104159	1198	105155	1198	105853	1198	106020	1198	106544	1198	106776
1198	104161	1198	105157	1198	105855	1198	106021	1198	106582	1198	106777
1198	104165	1198	105195	1198	105856	1198	106023	1198	106584	1198	106778
1198	104173	1198	105203	1198	105857	1198	106024	1198	106585	1198	106779
1198	104178	1198	105206	1198	105873	1198	106027	1198	106588	1198	106780
1198	104181	1198	105208	1198	105874	1198	106065	1198	106589	1198	106781
1198	104189	1198	105217	1198	105877	1198	106071	1198	106595	1198	106782
1198	104262	1198	105223	1198	105878	1198	106075	1198	106596	1198	106783
1198	104264	1198	105226	1198	105880	1198	106076	1198	106598	1198	106784
1198	104269	1198	105232	1198	105881	1198	106077	1198	106601	1198	106785
1198	104275	1198	105233	1198	105882	1198	106078	1198	106602	1198	106786
1198	104289	1198	105238	1198	105884	1198	106083	1198	106603	1198	107532
1198	104292	1198	105293	1198	105885	1198	106089	1198	106606	1198	107534
1198	104293	1198	105298	1198	105886	1198	106090	1198	106608	1198	107559
1198	104295	1198	105331	1198	105887	1198	106091	1198	106611	1198	107561
1198	104300	1198	105343	1198	105888	1198	106092	1198	106612	1198	107562
1198	104301	1198	105344	1198	105890	1198	106150	1198	106613	1198	107568
1198	104302	1198	105347	1198	105891	1198	106151	1198	106648	1198	107569
1198	104303	1198	105351	1198	105892	1198	106153	1198	106673	1198	107570
1198	104304	1198	105356	1198	105893	1198	106154	1198	106675	1198	107967
1198	104307	1198	105366	1198	105896	1198	106157	1198	106678	1198	107968
1198	104310	1198	105370	1198	105897	1198	106158	1198	106679	1198	107969

**APPENDIX 1 to MDEA(NI)2005/90**

List of UK serial numbers for Guidant INSIGNIA and NEXUS implantable pacemakers, distributed on or before 12 March 2004, affected by the first failure mode.

Model	Serial No	Model	Serial No	Model	Serial No	Model	Serial No	Model	Serial No	Model	Serial No
1198	108058	1294	101681	1294	102903	1294	103806	1295	100761	1296	103598
1198	108059	1294	101683	1294	102906	1294	103807	1295	100762	1296	103605
1198	108066	1294	101684	1294	102907	1294	103809	1295	100763	1296	103606
1198	108072	1294	101723	1294	102908	1294	103838	1295	100764	1296	104315
1198	110191	1294	101740	1294	102980	1294	103840	1295	100765	1296	104542
1198	110214	1294	101867	1294	102984	1294	103841	1295	100766	1296	104565
1198	110241	1294	102021	1294	102989	1294	103842	1295	100777	1296	104572
1198	110243	1294	102029	1294	102991	1294	103843	1295	100974	1296	104584
1198	110251	1294	102030	1294	102996	1294	103846	1295	100993	1296	104635
1198	110252	1294	102033	1294	102997	1294	103881	1295	100994	1296	104694
1290	100708	1294	102034	1294	102998	1294	103882	1295	100996	1296	104705
1290	100737	1294	102062	1294	103003	1294	103883	1296	101519	1296	104706
1290	100739	1294	102084	1294	103017	1294	103885	1296	101824	1296	104707
1290	100740	1294	102088	1294	103021	1294	103886	1296	101829	1296	104716
1290	100742	1294	102096	1294	103032	1294	104043	1296	101830	1296	104723
1290	101682	1294	102100	1294	103596	1294	104046	1296	101831	1296	104725
1290	101687	1294	102148	1294	103599	1294	104047	1296	101833	1296	104726
1290	101708	1294	102201	1294	103618	1294	104048	1296	101834	1296	104727
1290	101740	1294	102202	1294	103621	1294	104049	1296	101835	1296	104778
1290	101859	1294	102219	1294	103631	1294	104051	1296	101836	1296	104779
1290	101880	1294	102223	1294	103636	1294	104052	1296	101837	1296	104780
1290	101881	1294	102227	1294	103637	1294	104054	1296	101847	1296	104781
1290	101916	1294	102307	1294	103638	1294	104055	1296	101862	1296	104783
1290	101953	1294	102321	1294	103719	1294	104078	1296	101863	1296	104788
1290	101956	1294	102629	1294	103720	1294	104081	1296	101873	1296	104790
1290	102004	1294	102683	1294	103724	1294	104083	1296	101879	1296	104791
1290	102106	1294	102689	1294	103725	1294	104085	1296	101882	1296	104792
1290	102107	1294	102691	1294	103727	1294	104086	1296	101883	1296	104806
1290	102119	1294	102698	1294	103728	1294	104151	1296	101884	1296	104972
1290	102120	1294	102749	1294	103740	1294	104152	1296	101886	1296	105084
1290	102128	1294	102761	1294	103741	1294	104153	1296	101888	1296	105087
1290	102159	1294	102773	1294	103745	1294	104154	1296	101895	1296	105095
1290	102172	1294	102778	1294	103762	1294	104156	1296	101932	1296	105096
1290	103742	1294	102783	1294	103763	1294	104628	1296	102095	1296	105097
1291	100426	1294	102785	1294	103764	1294	104665	1296	103180	1296	105098
1291	100440	1294	102810	1294	103766	1294	104714	1296	103245	1296	105099
1292	100117	1294	102817	1294	103767	1294	104719	1296	103250	1296	105100
1292	100118	1294	102823	1294	103768	1294	104720	1296	103251	1296	105101
1292	100122	1294	102834	1294	103769	1294	104722	1296	103262	1296	105102
1292	100125	1294	102839	1294	103770	1294	104724	1296	103263	1296	105103
1292	100131	1294	102840	1294	103771	1294	104725	1296	103277	1296	105104
1294	101351	1294	102842	1294	103772	1294	104726	1296	103288	1296	105105
1294	101353	1294	102843	1294	103773	1294	104727	1296	103291	1296	105106
1294	101354	1294	102851	1294	103775	1294	104729	1296	103292	1296	105123
1294	101364	1294	102854	1294	103776	1294	104730	1296	103293	1296	105124
1294	101385	1294	102856	1294	103777	1294	104732	1296	103302	1296	105125
1294	101559	1294	102858	1294	103791	1294	104733	1296	103308	1296	105139
1294	101620	1294	102861	1294	103792	1294	104736	1296	103335	1296	105142
1294	101635	1294	102863	1294	103793	1294	104737	1296	103341	1296	105266
1294	101668	1294	102876	1294	103796	1294	104777	1296	103349	1296	105267
1294	101670	1294	102881	1294	103800	1294	105359	1296	103350	1296	105268
1294	101678	1294	102897	1294	103802	1294	105671	1296	103592	1296	105273
1294	101680	1294	102902	1294	103803	1295	100758	1296	103597	1296	105274

## APPENDIX 1 to MDEA(NI)2005/90

List of UK serial numbers for Guidant INSIGNIA and NEXUS implantable pacemakers, distributed on or before 12 March 2004, affected by the first failure mode.

Model	Serial No	Model	Serial No	Model	Serial No	Model	Serial No	Model	Serial No	Model	Serial No
1296	105647	1297	282312	1297	286681	1297	288702	1298	130968	1298	131278
1296	105648	1297	282319	1297	286702	1297	288704	1298	130973	1298	131279
1296	105650	1297	282322	1297	286712	1297	288707	1298	130977	1298	131280
1296	105661	1297	282432	1297	286728	1297	288751	1298	130981	1298	131281
1296	105664	1297	282433	1297	286730	1297	288760	1298	130997	1298	131282
1296	105665	1297	282434	1297	286749	1297	288761	1298	131019	1298	131285
1296	105666	1297	282438	1297	286750	1297	288762	1298	131021	1298	131286
1296	105721	1297	282442	1297	286751	1297	288764	1298	131025	1298	131287
1296	105787	1297	282460	1297	286804	1297	288767	1298	131026	1298	131288
1296	105788	1297	282463	1297	286945	1297	288768	1298	131030	1298	131292
1296	105790	1297	282470	1297	286948	1297	288769	1298	131031	1298	131293
1296	105792	1297	282484	1297	286950	1297	288772	1298	131032	1298	131294
1296	105795	1297	282486	1297	286953	1297	288774	1298	131033	1298	131296
1296	105796	1297	282487	1297	286954	1297	288936	1298	131034	1298	131297
1296	105797	1297	282488	1297	286967	1297	288942	1298	131035	1298	131298
1296	105799	1297	282619	1297	286985	1297	288945	1298	131036	1298	131299
1296	105800	1297	282622	1297	286990	1297	288946	1298	131037	1298	131301
1296	105803	1297	282625	1297	287030	1297	288947	1298	131038	1298	131304
1296	105867	1297	282628	1297	287040	1297	288948	1298	131040	1298	131306
1296	105878	1297	282629	1297	287052	1297	289015	1298	131042	1298	131308
1296	105880	1297	282630	1297	287752	1297	289016	1298	131044	1298	131310
1296	105937	1297	282632	1297	287753	1297	289023	1298	131047	1298	131311
1296	105942	1297	282633	1297	287771	1297	289025	1298	131048	1298	131327
1296	105943	1297	282639	1297	287919	1297	289028	1298	131049	1298	131329
1296	105944	1297	282642	1297	287962	1297	289061	1298	131054	1298	132337
1296	105997	1297	282644	1297	287965	1297	289089	1298	131059	1298	132596
1296	105999	1297	282645	1297	287968	1297	289112	1298	131060	1298	132621
1296	106014	1297	282646	1297	287969	1297	289237	1298	131072	1298	132633
1296	106015	1297	282647	1297	288043	1297	289267	1298	131074	1298	132655
1296	106022	1297	282648	1297	288054	1297	289473	1298	131075	1298	132659
1296	106023	1297	282651	1297	288056	1297	289701	1298	131077	1298	132693
1296	106024	1297	282816	1297	288057	1297	289705	1298	131078	1298	132694
1296	106026	1297	282819	1297	288062	1297	289764	1298	131085	1298	133070
1296	106032	1297	282821	1297	288073	1297	289766	1298	131091	1298	133078
1296	106033	1297	282824	1297	288075	1297	289772	1298	131253	1298	133096
1296	106034	1297	282877	1297	288154	1297	289780	1298	131254	1298	135365
1296	106075	1297	283036	1297	288186	1297	289793	1298	131255	1298	135381
1296	106076	1297	283583	1297	288187	1297	289798	1298	131256	1298	135396
1296	106078	1297	283589	1297	288189	1297	289801	1298	131257	1298	135399
1296	106080	1297	283613	1297	288199	1297	289809	1298	131258	1298	135405
1296	106081	1297	285549	1297	288201	1297	289853	1298	131259	1298	135422
1296	106082	1297	285551	1297	288202	1298	129373	1298	131260	1298	136463
1296	106083	1297	285561	1297	288203	1298	129437	1298	131261	1298	142319
1296	106084	1297	285566	1297	288205	1298	129451	1298	131264	1298	142363
1296	106085	1297	285569	1297	288265	1298	129458	1298	131266	1298	142372
1296	106092	1297	285580	1297	288271	1298	129851	1298	131267	1298	142410
1296	106093	1297	285584	1297	288273	1298	130434	1298	131269	1298	142414
1296	106094	1297	285585	1297	288417	1298	130472	1298	131272	1298	142416
1296	106095	1297	285590	1297	288452	1298	130475	1298	131273	1298	142421
1297	282144	1297	285591	1297	288455	1298	130527	1298	131274	1298	142425
1297	282204	1297	286242	1297	288470	1298	130557	1298	131275	1298	142485
1297	282307	1297	286263	1297	288471	1298	130612	1298	131276	1298	142524
1297	282310	1297	286678	1297	288694	1298	130719	1298	131277	1298	142541

## APPENDIX 1 to MDEA(NI)2005/90

List of UK serial numbers for Guidant INSIGNIA and NEXUS implantable pacemakers, distributed on or before 12 March 2004, affected by the first failure mode.

Model	Serial No	Model	Serial No	Model	Serial No	Model	Serial No	Model	Serial No	Model	Serial No
1298	142949	1298	145495	1298	147978	1298	151473	1298	154316	1298	155183
1298	142991	1298	145496	1298	147984	1298	151474	1298	154317	1298	155185
1298	142996	1298	145497	1298	147989	1298	151488	1298	154466	1298	155187
1298	143013	1298	145522	1298	147991	1298	151489	1298	154476	1298	155189
1298	143017	1298	145523	1298	148005	1298	151510	1298	154482	1298	155190
1298	143032	1298	145551	1298	148014	1298	151517	1298	154488	1298	155595
1298	143034	1298	145552	1298	148034	1298	151533	1298	154491	1298	155605
1298	143337	1298	146971	1298	148084	1298	151546	1298	154502	1298	155612
1298	143846	1298	146972	1298	148470	1298	151550	1298	154625	1298	155616
1298	143850	1298	146981	1298	148476	1298	151766	1298	154632	1298	157743
1298	143853	1298	147268	1298	148486	1298	151995	1298	154642	1298	157749
1298	143855	1298	147269	1298	148487	1298	152001	1298	154650	1298	158122
1298	143896	1298	147280	1298	148497	1298	152002	1298	154653	1298	158123
1298	143897	1298	147282	1298	148501	1298	152003	1298	154661	1298	158126
1298	143899	1298	147293	1298	148537	1298	152004	1298	154662	1298	158129
1298	143904	1298	147361	1298	149059	1298	152010	1298	154732	1298	158131
1298	143905	1298	147382	1298	149072	1298	152027	1298	154737	1298	158132
1298	144122	1298	147400	1298	149080	1298	152036	1298	154831	1298	158135
1298	144428	1298	147404	1298	149082	1298	152069	1298	154843	1298	158136
1298	144431	1298	147439	1298	149086	1298	152077	1298	154867	1298	158139
1298	144480	1298	147456	1298	149124	1298	152089	1298	154954	1298	158140
1298	144483	1298	147466	1298	150399	1298	152090	1298	155035	1298	158141
1298	144489	1298	147470	1298	150635	1298	152091	1298	155036	1298	158148
1298	144509	1298	147471	1298	150725	1298	152249	1298	155037	1298	158583
1298	144524	1298	147490	1298	150745	1298	152263	1298	155038	1298	158590
1298	144525	1298	147559	1298	150746	1298	152271	1298	155045	1298	158591
1298	144640	1298	147601	1298	150747	1298	152367	1298	155046	1298	158630
1298	144778	1298	147636	1298	151206	1298	152530	1298	155048	1298	158632
1298	144820	1298	147702	1298	151243	1298	152556	1298	155052	1298	158644
1298	144823	1298	147710	1298	151267	1298	152567	1298	155054	1298	158841
1298	144854	1298	147731	1298	151268	1298	152707	1298	155055	1298	158888
1298	144859	1298	147754	1298	151277	1298	152715	1298	155056	1298	159039
1298	144866	1298	147763	1298	151283	1298	152888	1298	155057	1298	159043
1298	144867	1298	147800	1298	151294	1298	152889	1298	155058	1298	159051
1298	144876	1298	147802	1298	151299	1298	152895	1298	155059	1298	159055
1298	144877	1298	147806	1298	151301	1298	152899	1298	155060	1298	159059
1298	144898	1298	147810	1298	151415	1298	152911	1298	155066	1298	159060
1298	144900	1298	147814	1298	151417	1298	153313	1298	155067	1298	159071
1298	144901	1298	147815	1298	151424	1298	153315	1298	155071	1298	159073
1298	144910	1298	147818	1298	151426	1298	153330	1298	155072	1298	159076
1298	145139	1298	147819	1298	151427	1298	153331	1298	155074	1298	159077
1298	145146	1298	147831	1298	151434	1298	153831	1298	155155		
1298	145164	1298	147832	1298	151442	1298	153835	1298	155168		
1298	145167	1298	147835	1298	151449	1298	153857	1298	155171		
1298	145184	1298	147926	1298	151450	1298	153883	1298	155175		
1298	145254	1298	147936	1298	151456	1298	153885	1298	155176		
1298	145285	1298	147941	1298	151458	1298	154151	1298	155177		
1298	145288	1298	147943	1298	151461	1298	154188	1298	155178		
1298	145302	1298	147945	1298	151464	1298	154311	1298	155179		
1298	145315	1298	147951	1298	151466	1298	154312	1298	155180		
1298	145319	1298	147964	1298	151470	1298	154313	1298	155181		
1298	145486	1298	147970	1298	151471	1298	154315	1298	155182		

GUIDANT

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

29<sup>th</sup> September 2005

Dear Doctor

**Re: Guidant INSIGNIA<sup>®</sup> and NEXUS<sup>®</sup> implantable heart pacemakers (see table of models below)**

This letter is intended to inform you of important safety information regarding Guidant INSIGNIA and NEXUS\* implantable heart pacemakers. Our records indicate that you have a Guidant programmer and may have implanted or are monitoring patients implanted with these devices.

Guidant's Cardiac Rhythm Management Quality System has identified two separate failure modes, each occurring at a low rate, being monitored within the INSIGNIA and NEXUS families of implantable pacemakers. One or more of the following device behaviours may be 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

The clinical behaviour associated with these failure modes can result in serious health complications. There have been no reported deaths resulting from these failure modes. Loss of pacing output associated with these failure modes has resulted in syncope as well as presyncope requiring hospitalisation.

**First Failure Mode**

As of September 6, 2005, thirty-six (36) failures associated with a first failure mode have been confirmed out of 49,500 devices distributed worldwide (0.073%). Seven of these devices exhibited no output during the implant procedures. For devices successfully implanted, the majority of failures occurred early in life, with a mean implant time of seven (7) months. This failure mode demonstrates a failure rate that decreases with implant time, and no failures have been reported beyond twenty-two (22) months of service. Guidant has received three (3) reports of syncope and six (6) reports of bradycardia or heart block associated with this failure mode which required emergency hospitalisation. One device was determined to have failed briefly and resumed functioning with no indication to the physician detectable during routine follow-up.

Root cause has been identified as foreign material within a crystal timing component. The supplier of the crystal timing component used in this subset has eliminated foreign material within the crystal chamber, and no such failures have been observed in any devices shipped after March 12, 2004.

Guidant's modeling, based on field experience and statistical analysis, predicts the failure rate for the active device population of 41,000 to be between 0.017% to 0.037% over the remaining device lifetime, or approximately seven (7) to fifteen (15) additional failures.

**Recommendations regarding First Failure Mode:**

Physicians should consider the projected low and declining failure rate in addition to the unique needs of individual patients in their medical decisions regarding patient management. Guidant recommends normal monitoring, as per device labeling. As always, advise patients to seek attention immediately if they experience syncope or light-headedness.

**If our records indicate that affected devices have been distributed to your centre, a serial number list is attached to this letter.**

For information regarding devices distributed elsewhere, please use the device look up tool at

<http://www.guidant.com/webapp/emarketing/lookup.jsp>

**APPENDIX 2 TO MDEA(NI)2005/90**  
**UK Dear Doctor Letter 29 September 2005**

**Second Failure Mode**

As of September 6, 2005, sixteen (16) failures associated with a second failure mode have been confirmed out of 341,000 INSIGNIA and NEXUS devices distributed worldwide (0.0047%). For all sixteen devices, a no output condition was exhibited at the implant procedure or pre-implant testing. Guidant has received one (1) report of a pacemaker-dependent patient experiencing syncope and resuscitated cardiac arrest that occurred in association with loss of pacing output during an elective pulse generator replacement procedure. Root cause analysis is ongoing; a specific root cause for this observation has not yet been determined.

**Recommendations regarding Second Failure Mode:**

Guidant recommends verifying pacemaker operation in the packaging prior to the implant procedure. Devices exhibiting intermittent or permanent loss of output or telemetry should not be implanted.

Physicians should consider both the very low occurrence rate and that no failures have been observed after successful confirmation of pacing at implant, in addition to the unique needs of individual patients, in their medical decisions regarding patient management.

**Given the low rate of occurrence for this second failure mode, no serial number list is attached. Please contact your local Guidant Representative should you require additional information.**

**Devices Impacted**

The following model numbers are affected by this communication\*:

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

\*Not all models are available in all geographies.

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. Any updates that become available will be promptly communicated. As always, if you have any questions regarding this communication, please contact your local Guidant representative.

The MHRA has been informed of this action.

**Yours sincerely**



Paul McLean  
General Manager, UK