PRODUCT

Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this safety advisory is available at www.guidant.com.

INSIGNIA Entra
Models 0484/0485/0985/0986/1195/1198/1294/1295/1296

INSIGNIA Ultra
Models 1190/1290/1291

INSIGNIA Plus
Models 1194/1297/1298

INSIGNIA AVT
Models 0482/0882/0982/1192/1292

NEXUS Entra
Models 1325/1326/1395/1398/1425/1426/1466/1494/1495

NEXUS Ultra
Models 1390/1490/1491

NEXUS Plus
Models 1394/1467/1468

NEXUS AVT
Models 1328/1428/1432/1392/1492

Physician and patient letters, as well as Advisory Update(s), are available at www.guidant.com

ORIGINAL COMMUNICATION **22-Sep-05**

Voluntary Physician Advisory
FDA Classification: Class II

Two separate failure modes were identified that may result in intermittent or permanent loss of pacing output without warning, intermittent or permanent loss of telemetry, and/or reversion to VVI mode or appearance of a reset warning message upon interrogation. The root cause of the first failure mode is foreign material within a crystal timing component. As of September 22, 2005, the root cause of the second failure mode had not yet been determined and analysis was ongoing. As of the December 12, 2005 *Advisory Update*, root cause had been identified as a microscopic particle within the crystal timing component.

Reported Events

Failure Mode 1—As of September 6, 2005, thirty-six (36) malfunctions have been confirmed out of 49,500 devices distributed worldwide (0.073%). The majority of malfunctions occurred early in life, with a mean implant time of seven (7) months. This failure mode demonstrates a malfunction rate that decreases with implant time, and no malfunctions have been reported beyond twenty-two (22) months of service. There have been no reported patient deaths. The supplier of the crystal timing component used in this subset of devices has eliminated foreign material within the crystal chamber, and no malfunctions have been observed in any devices shipped after March 12, 2004.

Failure Mode 2—As of September 6, 2005, sixteen (16) malfunctions have been confirmed out of 341,000 devices distributed worldwide (0.0047%). All sixteen (16) devices exhibited a no-output condition at the implant procedure or during pre-implant testing. There have been no reported patient deaths.

Rate Projection

Failure Mode 1—As of the September 22, 2005 communication, Guidant's modeling, based on field experience and statistical analysis, predicted the malfunction 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 malfunctions.

CURRENT STATUS **07-Jul-06**

Failure Mode 1—Patient management recommendations from the September 22, 2005 physician communication remain unchanged and are provided below under CURRENT RECOMMENDATION.

Failure Mode 2—Patient management recommendations supersede those originally communicated on September 22, 2005 and are provided below under CURRENT RECOMMENDATION.

Reported Events (worldwide)

Failure Mode 1—One (1) additional malfunction has been confirmed since the original September 22, 2005 letter, as communicated in the December 12, 2005 Advisory Update. A total of thirty-seven (37) clinical malfunctions out of approximately 49,500 (0.075%) devices distributed has been confirmed by Guidant. There have been no reported patient deaths.

Failure Mode 2—Two (2) additional malfunctions have been confirmed since the original September 22, 2005 letter. Guidant has confirmed a total of seventeen (17) clinical malfunctions out of the subset of 257,000 (0.0066%) INSIGNIA and NEXUS devices manufactured and distributed with susceptible components. All malfunctions were identified before or during the implant procedure. There have been no reported patient deaths.

Rate Projection

Failure Mode 1—The predicted malfunction rate for the estimated worldwide active device population of 34,700 is projected to range between 0.017% and 0.037% over the remaining device lifetime, as reported in the original September 22, 2005 physician communication.

Failure Mode 2—There have been no reported malfunctions following successful confirmation of pacing at implant. Additionally, all INSIGNIA and NEXUS devices currently distributed by Guidant are not subject to this peri-implant malfunction mode.

CURRENT RECOMMENDATION **07-Jul-06**

- Normal follow-up for both Failure Mode 1 and Failure Mode 2 devices.
- Specific to Failure Mode 1, physicians should consider the projected low and declining malfunction 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 lightheadedness.

PRODUCT

Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this safety advisory is available at www.guidant.com.

PULSAR MAX
Models 1170/1171/1270

PULSAR
Models 0470/0870/0970/0972/1172/1272

DISCOVERY
Models 1174/1175/1273/1274/1275

MERIDIAN
Models 0476/0976/1176/1276

PULSAR MAX II
Models 1180/1181/1280

DISCOVERY II
Models 0481/0981/1184/1186/1187/1283/1284/1285/1286

CONTAK TR
Model 1241

VIRTUS PLUS II
Models 1380/1480

INTELIS II
Models 1483/1484/1485/1384/1385/1349/1499

Physician and patient letters are available at www.guidant.com

ORIGINAL COMMUNICATION **18-Jul-05 and 21-Jan-06**

Voluntary Physician Advisory (18-Jul-05)
FDA Classification: Class I

Voluntary Physician Advisory (21-Jan-06)
FDA Classification: Class I

A hermetic sealing component utilized in a subset of pacemakers may experience a gradual degradation, resulting in higher than normal moisture content within the pacemaker case late in the device's service life; this could lead to a variety of inappropriate clinical behaviors.

The original July 18, 2005 physician communication bounded the population to approximately 78,000 devices manufactured between November 25, 1997 and October 26, 2000; this number has been further refined to 77,500 devices manufactured between October 27, 1997 and October 26, 2000.

The original July 18, 2005 communication predicted the rate of malfunction in the remaining active implanted devices (estimated to be 28,000 worldwide) to be between 0.17% and 0.51% over the remaining device lifetime, based on field experience and statistical life-table analysis.

A Second Population of 54,000 devices was subsequently identified to be at risk of hermetic seal degradation (but at a much lower rate than the original population). This was communicated in the January 21, 2006 letter.

Original Population—Patient management recommendations from the July 18, 2005 physician letter remain unchanged and are provided below under CURRENT RECOMMENDATION; however, physicians should reassess patients in light of the increased projected rate of occurrence (detailed below).

Second Population—Physicians should consider the Original Population recommendations while taking into account the lower projected rate of occurrence.

Reported Events (worldwide)

Refined Original Population—A total of 145 devices that may have exhibited this malfunction mode has been identified; 130 such clinical malfunctions have been confirmed out of the 77,500 devices manufactured (0.17%).

Second Population—A total of five (5) devices that may have exhibited this malfunction mode has been identified; two (2) such malfunctions have been confirmed out of the 54,000 devices manufactured (0.004%).

Rate Projection

Refined Original Population—The predicted failure rate for the estimated worldwide active device population of 16,000 has increased from the July 18, 2005 estimate as communicated in the January 21, 2006 letter and is projected to range between 0.31% and 0.88% over the remaining device lifetime.

Second Population—For the remaining lifetime of the estimated worldwide 19,300 active devices, the projected rate of occurrence for reported events is estimated to be between 0.02% and 0.06%.

CURRENT STATUS **07-Jul-06**

Original Population—Patient management recommendations from the July 18, 2005 physician letter remain unchanged and are provided below under CURRENT RECOMMENDATION; however, physicians should reassess patients in light of the increased projected rate of occurrence (detailed below).

Second Population—Physicians should consider the Original Population recommendations while taking into account the lower projected rate of occurrence.

Reported Events (worldwide)

Refined Original Population—A total of 172 devices that may have exhibited this malfunction mode has been identified; 159 such clinical malfunctions have been confirmed out of the 77,500 devices manufactured (0.21%).

Second Population—A total of five (5) devices that may have exhibited this malfunction mode has been identified; three (3) such malfunctions have been confirmed out of the 54,000 devices manufactured (0.006%).

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PRODUCT

Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this safety advisory is available at www.guidant.com.

PULSAR MAX
Models 1170/1171/1270

PULSAR
Models 0470/0870/0970/0972/1172/1272

DISCOVERY
Models 1174/1175/1273/1274/1275

MERIDIAN
Models 0476/0976/1176/1276

PULSAR MAX II
Models 1180/1181/1280

DISCOVERY II
Models 0481/0981/1184/1186/1187/1283/1284/1285/1286

CONTAK TR
Model 1241

VIRTUS PLUS II
Models 1380/1480

INTELIS II
Models 1483/1484/1485/1384/1385/1349/1499

Physician and patient letters are available at www.guidant.com

CURRENT STATUS *continued*

Rate Projection

Refined Original Population—The predicted malfunction rate for the estimated worldwide active device population of 14,200 has increased from the July 18, 2005 estimate as communicated in the January 21, 2006 letter and is projected to range between 0.31% and 0.88% over the remaining device lifetime.

Second Population—For the remaining lifetime of the estimated worldwide 14,700 active devices, the projected rate of occurrence for reported events is estimated to be between 0.02% and 0.06%.

CURRENT RECOMMENDATION **07-Jul-06**

- Consider replacing devices for pacemaker-dependent patients.
- Advise patients to seek attention immediately if they notice a prolonged rapid heart rate, experience syncope or lightheadedness, or have new or increased symptoms of heart failure.
- Select a suitable MSR setting, given the rare possibility that inappropriate sustained pacing at MSR can occur.

OR

- Consider programming the accelerometer OFF to prevent inappropriate sustained pacing at MSR.
- Consider increasing the frequency of programmer follow-ups. This increases the likelihood of detecting a malfunction that has already occurred, but does not guarantee that the device will not exhibit this malfunction mode in the future. At each patient follow-up:
  - Evaluate for the clinical behaviors described in the July 18, 2005 letter.
  - Evaluate battery status indicator ("gas gauge") for signs of early or rapid depletion between sequential follow-up visits.
  - Evaluate the accelerometer rate response (for devices with this feature).

Accelerometer Status	Evaluation Criteria
ON	- Look for inappropriate MSR pacing or pacing higher than the programmed lower rate limit (LRL) while the patient is at rest. - Look for lack of rate response with activity (i.e., isometrics, short hall walk).
OFF	*Temporarily* program the accelerometer ON and evaluate as described above.

- Consider increasing the frequency of transtelephonic monitoring to detect inappropriate sustained MSR pacing and/or loss of pacing output.
- If any of these device behaviors are observed, contact your local Guidant representative or Guidant Technical Services for troubleshooting and recommendations.

PRODUCT

Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this safety advisory is available at www.guidant.com.

CONTAK RENEWAL 3
Models H170/H173/H175

CONTAK RENEWAL 3 HE
Models H177/H179

CONTAK RENEWAL 4
Models H190/H195

CONTAK RENEWAL 4 HE
Models H197/H199

CONTAK RENEWAL 3 AVT
Models M150/M155

CONTAK RENEWAL 3 AVT HE
Models M157/M159

CONTAK RENEWAL 4 AVT
Models M170/M175

CONTAK RENEWAL 4 AVT HE
Models M177/M179

RENEWAL RF
Models H230/H235

RENEWAL RF HE
Model H239

Physician and patient letters, as well as Advisory Update(s), are available at www.guidant.com

ORIGINAL COMMUNICATION **23-Jun-05**

Voluntary Physician Advisory
FDA Classification: Class II

Magnetic switch inside affected CRT-Ds may stick in the closed position, potentially inhibiting tachyarrhythmia therapy (with no impact on bradycardia pacing) and affecting battery longevity. A total of four (4) occurrences out of approximately 46,000 devices sold worldwide has been confirmed. A fifth occurrence is suspected but the device was not returned to Guidant for confirmation.

CURRENT STATUS **07-Jul-06**

Patient management recommendations from June 23, 2005 physician communication remain unchanged and are provided below under CURRENT RECOMMENDATION.

Reported Events (worldwide)

- Two (2) additional malfunctions have been identified since the original June 23, 2005 communication.
- A total of six (6) malfunctions out of approximately 46,000 devices sold has been confirmed, and an additional occurrence is suspected but the device was not returned to Guidant for confirmation, as reported in the June 23, 2005 communication.
- There have been no reported patient deaths.
- A programmer software application upgrade that a) tests the position of the magnetic switch at the beginning of each interrogation session and displays a yellow pop-up dialogue box if the software detects the switch in the closed position, and b) provides various programmer screen alerts has been developed and is available worldwide.

CURRENT RECOMMENDATION **07-Jul-06**

- Consider programming "Enable Magnet Use" to "OFF."
- Patients should contact their physicians or go to the hospital emergency room immediately if they hear tones from their device.

PRODUCT

A serialized search tool to determine if a specific device is affected by this safety advisory is available at www.guidant.com.

VENTAK PRIZM AVT
Model 1900

VITALITY AVT
Models A135/A155

CONTAK RENEWAL 3 AVT
Models M150/M155

CONTAK RENEWAL 3 AVT HE
Models M157/M159

CONTAK RENEWAL 4 AVT
Models M170/M175

CONTAK RENEWAL 4 AVT HE
Models M177/M179

Physician and patient letters are available at www.guidant.com

ORIGINAL COMMUNICATION **17-Jun-05 and 22-Jul-05**

Voluntary Physician Advisory (17-Jun-05)
FDA Classification: Class II

Voluntary Physician Advisory (22-Jul-05)
FDA Classification: Class I

Memory error leads to functional "latching" that limits available therapy in affected ICDs and CRT-Ds. Guidant issued recommendations in a June 17, 2005 advisory letter. Subsequent analysis determined that one of the recommendations set forth in that letter (programming Atrial Tachy Episode Data Storage to 0%) can increase the risk of a latching event. Accordingly, these original recommendations were revised in our July 22, 2005 advisory letter. These revised recommendations are provided here and supersede those originally communicated on June 17, 2005.

As of July 22, 2005, two latching events have been confirmed and a third event reported out of approximately 20,950 devices implanted to date.

CURRENT STATUS **07-Jul-06**

Patient management recommendations from July 22, 2005 physician communication remain unchanged and are provided below under CURRENT RECOMMENDATION.

Reported Events (worldwide)

There have been thirty-five (35) additional malfunctions since the July 22, 2005 communication. A total of thirty-eight (38) malfunctions has been confirmed out of approximately 22,600 devices implanted.
- Three (3) malfunctions (0.01%) are as described in the original June 17, 2005 physician letter
- Thirty-five (35) malfunctions (0.15%) are related to programming Atrial Tachy Episode Data Storage to 0% in a device that has previously stored atrial episode data.

No malfunctions have occurred with Atrial Tachy Episode Data Storage programmed to 20% (per current recommendation), and there have been no reported patient deaths.

A non-invasive software solution for the "latching" issue will be available (except for VENTAK PRIZM AVT) pending regulatory approvals.

CURRENT RECOMMENDATION **07-Jul-06**

The programming recommendations originally communicated to mitigate this latching issue were as follows:

- Schedule a patient follow-up visit:
  - As soon as possible for patients reprogrammed to 0% Atrial Tachy Episode Data Storage per the June 17, 2005 recommendation, or any patient with Atrial Tachy Episode Data Storage programmed to less than 20%.
  - Per normal scheduling if Atrial Tachy Episode Data Storage is at the nominal of 50% or is programmed to 20% or more.
- At this follow-up visit:
  - Verify normal device function using routine clinical follow-up procedures.
  - Program Atrial Tachy Episode Data Storage to 20%.
  - Review the rate of occurrence estimates in the physician communication dated July 22, 2005 to evaluate the additional risk reduction benefit of programming ATP therapy OFF.

Important note: Atrial Tachy Episode Data Storage should not be programmed to 0% if the device has previously stored atrial episode data.

Important note: For some patients for whom atrial episode data have not been previously stored, programming to 0% may afford additional risk reduction. Contact Technical Services for additional information before programming Atrial Episode Data Storage to 0%.

Please see the physician communication dated July 22, 2005 for additional information.

PRODUCT

Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this safety advisory is available at www.guidant.com.

CONTAK RENEWAL
Model H135

CONTAK RENEWAL 2
Model H155

Physician and patient letters, as well as Advisory Update(s), are available at www.guidant.com

ORIGINAL COMMUNICATION **17-Jun-05**

Voluntary Physician Advisory
FDA Classification: Class I

CRT-Ds manufactured on or before August 26, 2004 may experience deterioration in a wire insulator surrounding a wire within the lead connector block which, in conjunction with other factors, could cause a short circuit and loss of device function. In all cases, device replacement is required if this short circuit occurs.

Reported Events

Fifteen (15) reports confirmed from approximately 16,000 devices implanted worldwide, including one associated patient death.

Rate Projection

As of the June 17, 2005 communication, Guidant predicted that the reported rate of malfunctions may increase to between 0.20% and 0.59% over the device family lifetime, based on field experience and statistical life-table analysis.

CURRENT STATUS **07-Jul-06**

Patient management recommendations from the June 17, 2005 physician communication remain unchanged and are provided below under CURRENT RECOMMENDATION.

Reported Events (worldwide)

- A total of fifty-two (52) clinical malfunctions out of approximately 16,000 (0.33%) devices built on or before August 26, 2004 has been confirmed.
- A total of six (6) events has been reported as associated with patient death.

Rate Projection (worldwide)

Approximately 6,300 CONTAK RENEWAL and CONTAK RENEWAL 2 devices built on or before August 26, 2004 remain implanted worldwide. The expected malfunction rate remains unchanged since September 2005 and is projected to range between 0.72% and 1.83% over the remaining device lifetime.

Returned Product Testing (worldwide)

- 3,065 returned devices built on or before August 26, 2004 have been tested.
- Thirty-three (33) malfunctions (1.08%) were provoked.
- Returned products represent a small and non-random sample of the implanted population, and may not be representative of the remaining active device population.

CURRENT RECOMMENDATION **07-Jul-06**

- Physicians should reassess the balance of relative risks regarding device replacement as a result of the increased projected rate of occurrence as communicated in the September 12, 2005 *Advisory Update*.
- Patients should visit their follow-up clinic or doctor as soon as possible after receiving a shock.
- Patients should go to their follow-up clinic or hospital emergency room immediately after hearing beeping tones.
- If a patient has not recently received a high-voltage therapy, a commanded shock may be performed to confirm integrity of the high-voltage delivery circuit. While detailed statistical modeling and bench testing indicate that this cannot exclude the low likelihood of subsequent malfunction, a commanded shock may provide further confidence that high-voltage circuitry is working properly at the time of testing.
- During every patient visit, verify normal device function using routine clinical follow-up procedures.
- If a shock has been delivered since the last follow-up:
  - Examine the Last Delivered Shock Impedance stored in device memory (displayed on the Battery Status screen) for evidence of out-of-range values.
  - If a yellow warning screen is observed, refer to Guidant's February 14, 2005 *Product Update*.

PRODUCT

Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this safety advisory is available at www.guidant.com.

VENTAK PRIZM 2 DR
Model 1861

Physician and patient letters, as well as Advisory Update(s), are available at www.guidant.com

ORIGINAL COMMUNICATION **17-Jun-05**

Voluntary Physician Advisory
FDA Classification: Class I

ICDs manufactured on or before April 16, 2002 may experience deterioration in a wire insulator within the lead connector block which, in conjunction with other factors, could result in an electrical short circuit that can prevent the delivery of shock and pacing therapy.

Reported Events

Twenty-eight (28) reported malfunctions worldwide from approximately 26,000 devices built prior to the April 2002 manufacturing change, including one event in which a device was returned after a patient death. No such malfunctions have been observed in devices built after the April 2002 manufacturing change. Guidant recognizes that the actual number of clinical malfunctions may be greater than the number actually reported.

CURRENT STATUS **07-Jul-06**

Patient management recommendations from the June 17, 2005 physician communication remain unchanged and are provided below under CURRENT RECOMMENDATION.

Reported Events (worldwide)

- A total of thirty-three (33) clinical malfunctions out of approximately 27,000 (0.12%) devices built on or before April 16, 2002 has been confirmed, two (2) of which have been reported as associated with patient death.
- One (1) malfunction (0.009%), detected during device interrogation and resulting in no clinical injury, has been identified among the 11,000 devices manufactured after April 16, 2002 and before November 13, 2002 (non-advisory population).
- No malfunctions of this type have been reported to Guidant out of approximately 22,000 devices built after November 13, 2002 (non-advisory population).

Rate Projection (worldwide)

- Approximately 8,500 VENTAK PRIZM 2 DR devices built on or before April 16, 2002 remain implanted worldwide. The expected malfunction rate remains unchanged since September 2005 and is projected to range between 0.10% and 0.24% over the remaining device lifetime.
- Approximately 5,900 VENTAK PRIZM 2 DR devices manufactured after April 16, 2002 and before November 13, 2002 (non-advisory population) remain implanted worldwide; engineering analysis and accelerated life testing suggest that between two (2) and seven (7) additional malfunctions may occur before all remaining devices complete their service life (0.03% to 0.10%). Rate of occurrence predictions for this group are not statistically conclusive.

Returned Product Testing (worldwide)

- 4,682 returned devices built on or before April 16, 2002 have been tested; twenty-six (26) malfunctions (0.55%) were provoked.
- 791 returned devices manufactured after April 16, 2002 and before November 13, 2002 (non-advisory population) were tested; zero (0) malfunctions (0.0%) were provoked.
- Returned products represent a small and non-random sample of the implanted population, and may not be representative of the remaining active device population.

CURRENT RECOMMENDATION **07-Jul-06**

- Normal follow-up.

- Patients should consult with their follow-up clinic after receiving a shock.
- Guidant does not recommend device replacement prior to the appearance of normal elective replacement indicators.
- Guidant does not recommend routinely using a commanded shock to detect the shorting problem, since we have insufficient data to indicate that such testing will be worthwhile for VENTAK PRIZM 2 DR devices. If a patient has not recently received a high-voltage therapy, a commanded shock may be performed to confirm integrity of the high-voltage delivery circuit. While detailed statistical modeling and bench testing indicate that this cannot exclude the low likelihood of subsequent malfunction, a commanded shock may provide further confidence that high-voltage circuitry is working properly at the time of testing.

PRODUCT	ORIGINAL COMMUNICATION **23-Apr-01**
Identifiable by serial number. Not all serial numbers are affected. **VENTAK PRIZM VR** Model 1850 **VENTAK PRIZM DR** Model 1851 **VENTAK PRIZM VR HE** Models 1852/1857 **VENTAK PRIZM DR HE** Models 1853/1858	Voluntary Physician Advisory FDA Classification: Class II A subset of ICDs may switch to safety mode operation due to a rare interaction between the device and a specific memory component. Affected devices still provide full output shock delivery with ventricular detection rate of 165 bpm, 1.0-second initial duration, and VVI pacing at 60 bpm, 7.5 V. Affected devices emit beeping tones to alert the patient. Implanted devices confirmed to be in Safety Mode may effectively be returned to full function through the use of a non-invasive software diagnostic and restoration tool. CURRENT STATUS **07-Jul-06** Patient management recommendations from the April 23, 2001 physician communication remain unchanged and are provided below under CURRENT RECOMMENDATION. *Reported Events (worldwide)* A total of 411 devices that may have exhibited a change to the Safety Mode, out of an advisory population of approximately 14,300 units, has been reported to Guidant. - Most were successfully returned to full function through the use of the non-invasive software diagnostic and restoration tool. - Seventy (70) have been explanted and confirmed to have switched to safety mode operation while clinically implanted. Of these, fifty-two (52) occurred prior to availability of the software diagnostic and restoration tool. A total of six (6) occurrences of reversion to Safety Mode was reported in the last six months among the estimated 1,900 active devices; of these, three (3) were explanted and confirmed to have switched to safety mode operation while clinically implanted. There have been no reported patient deaths. Guidant recognizes that occurrences, particularly those that are successfully returned to full function via the software tool, may be underreported. CURRENT RECOMMENDATION **07-Jul-06** - Patients noting beeping tones should contact their physician, and the device should be interrogated. - Implanted devices confirmed to be in Safety Mode may effectively be returned to full function through the use of a non-invasive software diagnostic and restoration tool.

PRODUCT

Identifiable by serial number. Not all serial numbers are affected.

VENTAK MINI III
Models 1772/1782

VENTAK MINI III+
Models 1773/1783/1786

VENTAK MINI III+ HE
Models 1788/1789

ORIGINAL COMMUNICATION **01-Nov-99**

Voluntary Physician Advisory
FDA Classification: Class II

Subpectoral implantation of affected ICDs can exert unique forces on the pulse generator case that may cause a malfunction resulting in loss of telemetry and/or therapy delivery.

CURRENT STATUS **07-Jul-06**

Patient management recommendations from the November 1, 1999 physician communication remain unchanged and are below under CURRENT RECOMMENDATION.

Reported Events (worldwide)

A total of 169 MINI III devices from an advisory population of approximately 10,500 units has been confirmed to have exhibited this malfunction mode while clinically implanted. Of these, Guidant was able to confirm that 100 were implanted subpectorally. There have been no confirmed malfunctions in the last six months among the estimated 1,700 active advisory devices.

In addition, although not part of the November 1, 1999 communication, eight (8) out of approximately 9,700 MINI IV devices distributed with a similar design were confirmed to have experienced similar malfunctions. There have been no confirmed malfunctions in more than two years among the estimated 1,900 active MINI IV devices having a similar design.

In response to observed malfunctions among MINI III devices, and prior to any such observed malfunctions among MINI IV devices, Guidant modified the design of MINI IV devices to prevent susceptibility to this malfunction mode. All MINI IV devices manufactured since late October 1999 contain the design modification, and no malfunctions of this type have been identified among these devices.

There have been no reported patient deaths.

CURRENT RECOMMENDATION **07-Jul-06**

Quarterly monitoring or more frequently, depending upon individual patient circumstances.

PRODUCT	ORIGINAL COMMUNICATION **19-Jul-99**
Identifiable by serial number (serial numbers less than 230,000). Not all serial numbers are affected. **ENDOTAK DSP** Models 0095/0125	Voluntary Physician Advisory FDA Classification: Class II The integrity of affected defibrillation leads with "long" IS-1 terminal pins (serial numbers less than 230,000) can be compromised if the lead is bent sharply away from the terminal header block. Excessive bending of this lead could compromise lead insulation or conductor integrity and may occur when the system is placed in the implant pocket or if the pulse generator migrates from the implant site. A shorter version of the ENDOTAK DSP IS-1 terminal pin was implemented in 1997. This shorter version reduces the likelihood of damage caused by excessively sharp bends during implant and/or lead positioning. No confirmed malfunctions have been identified in leads with short terminal pins. In addition, Guidant device lead barrels have been lengthened to provide additional assurance that the terminal pin-conductor coil transition remains within the header.
	CURRENT STATUS **07-Jul-06**
	Patient management recommendations from the July 19, 1999 physician communication remain unchanged and are below under CURRENT RECOMMENDATION. These recommendations are also detailed in the April 2004 Guidant Product Publication entitled ENDOTAK DSP IS-1 "Long" Terminal Pin and ICD Replacement, located at www.guidant.com. *Reported Events (worldwide)* To date, a total of 598 "long" pin ENDOTAK DSP leads that may have exhibited this malfunction mode has been reported to Guidant from an advisory population of approximately 29,200 leads. - 222 leads have been removed and confirmed to have exhibited this malfunction mode while clinically implanted. - Four (4) occurrences were reported in the last six months among the estimated 10,800 active advisory devices; of these, one (1) was confirmed to have malfunctioned. - Two (2) Medical Device Reports (MDRs) have been filed for deaths associated with ENDOTAK DSP devices that exhibited malfunctions specific to this advisory. In addition, Guidant has confirmed ninety-five (95) similar clinical malfunctions out of approximately 320,000 leads of other models with long IS-1 terminal pins, including one MDR filed for death associated with this malfunction mode. Damage related to the use of "long" IS-1 pins is most common when implanted in pulse generators with "short" lead barrels, as is the case with ENDOTAK DSP leads. All IS-1 leads currently manufactured and distributed by Guidant have "short" terminal pins.
	CURRENT RECOMMENDATION **07-Jul-06**
	- Ensure that sensing is not affected when patient performs upper-arm movements. If warranted, inspect the lead-to-device connection on X-ray for sharp bends or device migration. - For ICD replacement procedures, visually check the implanted lead to verify insulation integrity at the terminal pin connection. Perform routine lead threshold and impedance measurements. If issues are identified, consider implanting a new ENDOTAK lead system and/or separate rate-sensing lead. Avoid stressing the lead at the lead-to-pulse generator connection when implanting a new system. A shorter version of the IS-1 terminal pin was implemented in 1997. This shorter version reduces the likelihood of damage caused by excessively sharp bends during implant and/or lead positioning.

PRODUCT

Identifiable by serial number. Not all serial numbers are affected.

PULSAR MAX
Models 1170/1171/1270

PULSAR
Models 0470/0870/0970/0972/1172/1272

DISCOVERY
Models 1174/1175/1273/1274/1275

MERIDIAN
Models 0476/0976/1176/1276

ORIGINAL COMMUNICATION **29-Mar-99**

Voluntary Physician Advisory
FDA Classification: Class II

A limited subset of pacemakers is susceptible to a short circuit between two integrated circuit chips, resulting in a high current drain. Clinical indicators include loss of pacing, premature replacement indicators, backup mode operation, and disruption of diagnostic measurements. An electrically insulative layer was added between the integrated circuits to prevent contact in similar devices manufactured outside this population.

CURRENT STATUS **07-Jul-06**

Patient management recommendations from the March 29, 1999 physician communication remain unchanged and are below under CURRENT RECOMMENDATION.

Reported Events (worldwide)

From an advisory population of approximately 9,100 devices, a total of 342 clinical malfunctions has been confirmed. One (1) malfunction has been confirmed in the last six months among the estimated 1,300 active advisory devices.

In addition, a total of 191 devices confirmed to have exhibited a similar malfunction mode has been identified among approximately 88,000 devices distributed outside the advisory population and manufactured prior to the addition of the electrically insulative layer. Of these 88,000 devices, an estimated 16,900 remain active, and none have been confirmed to exhibit this malfunction mode in the past six months. Additionally, no such malfunctions have been identified among devices manufactured with the insulative layer.

The malfunction rates for all devices manufactured prior to the insulative layer (advisory and non-advisory) have declined as devices age. Malfunctions among non-advisory devices have occurred at less than one-tenth the rate of advisory devices.

There have been no reported patient deaths.

CURRENT RECOMMENDATION **07-Jul-06**

Continue to monitor affected devices regularly. No additional follow-up is necessary.