GUIDANT

19 July 2005

URGENT HAZARD ALERT

Re: PULSAR® MAX, PULSAR, DISCOVERY®, MERIDIAN®, PULSAR MAX II, DISCOVERY II, and CONTAK® TR devices

Following consultation with the Therapeutic Goods Administration (TGA) Guidant is providing important safety information regarding a *subset* of PULSAR MAX, PULSAR, DISCOVERY, MERIDIAN, PULSAR MAX II, DISCOVERY II, and CONTAK TR pacemakers manufactured between November 25, 1997 and October 26, 2000. Our records indicate that you have implanted or are monitoring patients with these devices. This letter advises physicians about the potential unanticipated device behaviours and is intended to limit adverse events. **You are requested to contact all patients you have implanted or are monitoring as soon as possible and preferably with in the next forty eight (48) hours.**

Issue Description and Clinical Implications
Guidant's Cardiac Rhythm Management Quality System has recently determined that a hermetic sealing component utilized in these devices may experience a gradual degradation, resulting in a higher than normal moisture content within the pacemaker case late in the device's service life. This may lead to one or more of the following behaviours:

- Premature battery depletion resulting in loss of telemetry and/or loss of pacing output without warning
- Inappropriate accelerometer function (if programmed ON), resulting in
  - Sustained pacing at the programmed maximum sensor rate (MSR)
  - Lack of appropriate accelerometer rate response during activity
- Appearance of a reset warning message upon interrogation
- Inappropriate early display of replacement indicators

***Important Notes**:*

1. *While interrogation of the device may identify devices that have already experienced this failure mode, Guidant has not identified any test that will predict if a device will exhibit this failure mode in the future.*
2. *While inappropriate accelerometer function has been observed in 60% of the failures reported to date, it cannot be relied upon as an early indicator of this failure mode.*

While disabling accelerometer function will mitigate inappropriate MSR pacing, moisture penetration can still cause the other behaviours described above, including loss of output.

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Engineering analysis has determined that these clinical behaviours may be exhibited individually or in combination. As of July 11, 2005, Guidant has identified sixty-nine (69) devices that may have exhibited this failure mode. Fifty-two (52) such failures have been confirmed worldwide; four (4) devices are currently undergoing analysis, and thirteen (13) devices may have experienced this failure mode but were not returned to Guidant for confirmation.

Of the 78,000 devices originally distributed, approximately 28,000 devices remain implanted worldwide; approximately 1000 of these devices remain in service in Australia. No failures have been reported prior to forty-four (44) months of service, and the likelihood of occurrence increases with implant time. Guidant's modelling based on field experience and statistical life-table analysis predicts the rate of failure in the remaining active implanted devices to be between 0.17% and 0.51% over the remaining device lifetime. The actual occurrence rate and predicted rate may be greater than the stated numbers, because of underreporting and the limitations of projections.

The clinical behaviours associated with this failure mode can result in serious health complications. The majority of events to date have been associated with the accelerometer and MSR pacing. Guidant has confirmed twenty (20) reports of loss of pacing output associated with this failure mode, including five (5) patients experiencing syncope. Loss of pacing output has also been associated with reports of presyncope requiring hospitalisation. Additionally, Guidant has received two reports of sustained MSR pacing in which heart failure may have developed in association with sustained high rate pacing. In one report, a patient whose device exhibited sustained MSR pacing was admitted to the hospital with multiple health issues and later expired. It is unknown if this device experienced the failure described above as the device was not returned and this failure mode could not be confirmed.

Recommendations

Please contact your patients **as soon as possible and preferably with in the next forty-eight (48) hours** to determine the most appropriate patient management option. Physicians should consider the unique needs of each individual patient, including pacemaker dependency, as well as the age and remaining service life of the pacemaker.

Guidant recommends the following:

- Consider replacing devices for pacemaker-dependent patients.
- Advise patients to seek attention immediately if they notice a prolonged rapid heart rate, experience syncope or light-headedness, 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 failure that has already occurred, but does not guarantee that the device will not exhibit this failure mode in the future. At each patient follow-up:
  - Evaluate for the clinical behaviours described above.
  - 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 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.

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≠ Consider increasing the frequency of transtelephonic monitoring to detect inappropriate sustained MSR pacing and/or loss of pacing output.

If any of these device behaviours are observed, contact your local Guidant representative or Guidant Australia for troubleshooting and recommendations.

Devices Impacted
A subset of the following model numbers are affected by this communication:

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

* Models sold in Australia

A list of affected devices specific to your clinic accompanies this communication. **Please indicate on this list when you have contacted each patient and return it to Guidant on fax (02) 9421 2805.**

Warranty
Many of these devices are nearing or have exceeded their estimated longevity and have thus outlived their warranty. Even if a device is no longer covered by warranty, Guidant will provide a replacement device at no charge for pacemaker-dependent patients and other patients deemed by their physicians to be best served by replacement, provided the replacement occurs prior to the normal appearance of elective replacement indicators. This supplemental warranty program is available through 31st December, 2005.

Further Information
We recognize the impact of this communication on both you and your patients, and want 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 or Guidant Australia on 1-800-245-559.

Please confirm receipt of this communication by signing the attached acknowledgement form and forwarding it to Guidant Australia on fax (02) 9421-2805.

Yours faithfully

M. Wallwork

Mark Wallwork
Managing Director