POLICY STATEMENT

Recommendations of the European Cardiac Arrhythmia Society Committee on Device Failures and Complications

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Introduction

Throughout the history of cardiac pacing, malfunctions of implanted devices and leads have presented clinical problems for the implanting physicians.

It is clear that any electronic apparatus may fail through a variety of possible unpredictable malfunctions. These occur despite best practice by the devices' manufacturers and the implanting physicians. The importance has recently been emphasized of the need for a system

(1) for follow-up of devices which is able to promptly identify actual or potential malfunctions;

(2) that informs the physicians and patients promptly and transparently in order to allow them to organize the most appropriate diagnostic or therapeutic strategy;

(3) that guarantees the best protection for the patients.

The year 2005 was a peculiar one with regard to failures of implanted pacemakers and defibrillators, with several manufacturers experiencing at least one device problem. These have attracted considerable attention from the lay public and have raised understandable concern for both physicians and patients. The European Cardiac Arrhythmia Society (ECAS) has responded to this by the creation of a special Committee for Device Failures and Complications, the aim of which is to generate a reasoned analysis of each individual failure and to give the community of implanting physicians recommendations on how to manage it.

All the data reported were submitted by the company that had manufactured each device with a problem. The advice of the ECAS Committee was, in the main, in agreement with the manufacturers' suggestions.

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The ECAS Committee appreciated the high level of cooperation received from the manufacturers with regard to either sharing information or aiding the physicians in providing prompt and appropriate actions for their patients.

This article must be interpreted solely as providing recommendations for the clinical management of the various reported device problems. They reflect the opinions of a small number of European cardiologists experienced in the field of cardiac pacing and electrophysiology. The recommendations are not obligatory on implanting physicians but are intended as a potential help in their daily practice.

The final decision will always remain with the patients and their doctors who will need to evaluate each case individually and make the most appropriate decision.

Section I: ICDs

Recommendation ECAS-DF-ICD-01-2006. DEVICE: Medtronic "Marquis" implantable defibrillators

Background

Medtronic has notified European pacemaker and ICD implanting centers that defibrillator models 7230, 7232, 7274, 7277, 7278, 7279, 7285, 7289 belonging to the Marquis family and supplied with batteries produced before December 2003 could be subject to a rapid discharge of the battery due to a short circuit in the battery.

The company has reported receiving 9 units exhibiting this abnormal behavior. So far 87,000 such devices have been implanted worldwide (18,000 in Europe) and clinical practice shows that the present risk of malfunctioning is 0.01%. The risk is expected to increase with time: a higher risk of malfunction is expected in the second half of the predicted battery life. Laboratory tests have forecast that the risk of malfunctioning ranges between 0.2% and 1.5% in the second half of the life of the battery. Devices belonging to the same series but with batteries produced after December 2003 do not exhibit this abnormal behavior. The American

Food and Drug Administration (FDA) has assessed this and classified the action to be taken as a Class II recall. Class II recalls indicate a situation in which the use of a device judged at risk may cause injuries which are temporary or reversible with appropriate medical treatment, or situations where the risk of seriously adverse events occurring is judged to be low. On February 23, 2005, the Heart Rhythm Society published recommendations regarding the management of devices at risk, emphasizing the importance of evaluating the risk of malfunction, and taking into account the risks associated with reoperation. This recommendation is applied to Class I recalls, which involve a reasonable probability of the device malfunction causing serious consequences for the patient's health, including death. In order to further limit the risk of failure to deliver therapy, Medtronic put forward the following four recommendations in an informative note:

1. Conduct quarterly (i.e., every 3 months) follow-up procedures.
2. Inform patients that should they experience warmth in the area surrounding the ICD they should seek follow-up care promptly.
3. Program Low Battery Voltage ERI Patient Alert™ to "On-High." This will result in an audible, alternating tone in the event that the battery depletes slowly over a number of days. However, data indicate that most short circuits will occur rapidly and will not be detected by this feature.
4. Also consider providing a handheld magnet to patients to check device status and program the Low Battery Voltage ERI Patient Alert™ to "On-High." Device operation may be monitored periodically (e.g., daily) by patients placing the magnet over the device for 1–2 seconds. If the device is functional, a steady tone will sound for approximately 20 seconds. If no tone is heard, follow-up care should be sought promptly.

ECAS Statement and Recommendations

Consistent with its principle of maintaining the highest standards of patient care, ECAS supports the recommendation that every device center must maintain an up-to-date record of all implanted devices including serial numbers and implant dates so that those at risk can be identified. This responsibility includes undertaking enhanced follow-up according to current recommendations and participating in the global surveillance of the performance of these devices by making returns to national and/or international audit bodies.

As a temporary measure before further information is released from the manufacturer, regarding the identification of new cases of device malfunction, it is thought advisable to follow the guidelines reported below for the management of patients.

Provide the patient with full information regarding the risk of early battery discharge, highlighting the fact that the risk is currently known to be very low. Each decision must be made on the basis of the unique features of each patient. However, ECAS suggest that:

(A) the device be replaced if at least one of the following conditions is met:
   1. The patient is pacemaker-dependent.
   2. The patient has undergone a secondary prevention implant for cardiac arrest or syncopal ventricular tachycardia (VT).
   3. The patient has received appropriate therapy for VT or Ventricular fibrillation (VF).

(B) the patient be reassured and subjected to regular checkups at intervals of not more than 3 months if
   1. the patient has a reliable spontaneous rhythm;
   2. implant was indicated for primary prevention;
   3. the patient has not required therapy for VT-VF.

(C) individualized assessment be conducted if
   1. sinus bradycardia and/or II or III degree AV block with a good escape rhythm (frequency over 40 beats/min) is present;
   2. implant was indicated for secondary prevention following nonsyncopal VT not requiring cardiopulmonary resuscitation or electrical cardioversion;
   3. the patient has received appropriate antitachycardia pacing (ATP) therapy, but no shocks (assessment must be made of the hemodynamic tolerance of the treated tachycardias)
   4. the battery has exceeded 50% of its expected life.

(D) the device be replaced in all patients who request it after being informed of the situation, if they consider the risk of therapy delivery failure to be unacceptable, making sure that they are aware of the risks associated with replacement of the device.

For those patients who accept regular follow-up, adopt the measures recommended above by the manufacturer:

1. Conduct quarterly (i.e., every 3 months) follow-up procedures.

2. Inform patients that they should experience warmth in the area surrounding the ICD to seek follow-up care promptly.

3. Program Low Battery Voltage ERI Patient Alert™ to "On-High." This will result in an audible, alternating tone in the limited circumstances where a battery depletes slowly over a number of days. Data indicate most short circuits will occur rapidly and will not be detected by this feature.

4. Also consider providing a handheld magnet to patients to check device status and program the Low Battery Voltage ERI Patient Alert™ to "On-High." Device operation may be monitored periodically (e.g., daily) by patients placing the magnet over the device for 1–2 seconds. If the device is functional, a steady tone will sound for approximately 20 seconds. If no tone is heard, follow-up care should be sought promptly.

The risk analysis should be explained to the patient including the risks associated with device replacement. We recommend that the patient be asked to sign a form indicating that he or she has been informed of the risks and that he or she understands and agrees with the choices made.

In case of device replacement, because of the possibility of surgical complications, it is recommended that the informed consent form contains

1. a statement indicating that the patient is aware that replacement will be performed solely as a precautionary measure and
2. a statement summarizing the risks and consequences of device failure and the risks of device replacement.

For example: "... in addition, I am aware of the fact that the replacement of the device is solely a precautionary measure, as a risk of early and sudden discharge of the battery has been identified in a series of implantable defibrillators of the same series as mine. The current risk, which has emerged from clinical practice, is of 0.01% and it is estimated to range between 0.2% and 1.5% in the second half of the functional life of the battery."

Recommendation ECAS-DF-ICD-02-2006. DEVICE: Guidant Cardioverter Defibrillators VENTAK PRIZM 2 DR Model 1861

Background

On May 23, 2005, a letter from Guidant was sent to physicians in which information about the performance of cardioverter defibrillators VENTAK PRIZM 2 DR was provided. This informed of a failure involving deterioration in a wire insulator within the lead connector block that, in conjunction with other factors, results in an electrical short circuit, resulting in the device's inability to deliver therapy. As of today, there have been 26 reports of this failure in about 37,000 devices worldwide, all manufactured prior to November 2002. This situation resulted in 25 replacements. In March 2005 a malfunctioning device was returned after a patient died. This device was found to have experienced failure in conjunction with the attempted delivery of at least one high-voltage therapy. In 2002, Guidant changed the manufacturing of the device on two different occasions (April and November) to reduce the risk of device failure. Guidant recommends that physicians continue normal monitoring for all patients with PRIZM 2 DR ICDs. Guidant does not recommend replacement of these devices prior to the appearance of normal elective replacement indicators (ERIs).

On June 17, 2005, Guidant notified the FDA and sent safety information regarding its cardioverter defibrillators VENTAK PRIZM 2 DR. The FDA has indicated that it will classify them as "recalls." Guidant indicated that this failure can occur in 26,000 devices built prior to the April 2002 change. No failure has been observed in the devices built after the April 2002 change. Approximately 17,000 devices built before April 2002 remain in service.

Currently there are 28 reports of this failure.

Following formal request for more information Guidant clarified that

1. in Italy 845 devices have been implanted and there has been no reported failure;
2. 28 failures have been reported in Germany, Australia, and the United States, and the relevant regulatory bodies were informed according to laws in those countries.
3. On May 24, 2005, Guidant notified physicians and implanting centers that the rate of occurrence of the failure is 0.1% per implant (0,002% per month).
4. Guidant recommends 3-month follow-up intervals for these devices.
5. Guidant does not recommend replacement of these devices prior to the appearance of normal ERIs.
6. Patients implanted with potentially affected PRIZM 2 DR ICDs should consult their follow-up clinic in the event that they receive a defibrillation shock, where their clinical situation will be analyzed.
7. If a patient or a physician decides to replace a device that was manufactured prior to November 13, 2002, that has not reached ERI yet, Guidant will provide a replacement device at no

cost under the PRIZM 2 DR Warranty Supplement Program.

Concerning the 28 identified device failures, Guidant provided an analytical report, with specific faults detected in each case. The faults included inability to recognize ventricular tachyarrhythmia, inability to deliver an effective shock, permanent loss of pacing therapy, device reset to fallback/safety mode, loss of telemetry/programming/interrogation, programmer display of a red warning screen on attempted device interrogation, and programmer display of yellow warning screen indicating out of range shocking impedance. These events, occurring in isolation or in combination, were observed between 11 and 45 months after implant.

ECAS Committee Statement and Recommendations

Consistent with its principle of maintaining the highest standards of patient care ECAS supports the recommendation that every device center must maintain an up-to-date record of all implanted devices including serial numbers and implant dates so that those at risk can be identified. This responsibility includes undertaking enhanced follow-up according to current recommendations and participating in the global surveillance of the performance of these devices by making returns to national and/or international audit bodies.

ECAS has taken note of information provided by Guidant and of the very low probability of device failure (0.1%). However, we cannot underestimate the concern this engenders for patients for whom these devices are implanted to prevent sudden death.

With regard to these events and while waiting for further information, particularly the identification of new cases or new types of failure, ECAS suggests that

(A) the device be replaced if one of the following conditions is met:

1. The patient underwent device implantation as secondary prevention following cardiac arrest or VT associated with hemodynamic collapse (syncope or near-syncope).
2. The patient has received appropriate therapy for VT or VF whether the device was implanted for secondary or primary prevention.
3. The patient is pacemaker-dependent.

The risk analysis should be explained to the patient including the risks associated with device replacement.

(B) an individual analysis be performed for patients with potentially affected devices and suggest follow-up at least every 3 months, or device replacement, when

1. the indication for device implantation was primary prevention but the patient has not required therapy for VT or VF
2. the indication for device implantation was secondary prevention for VT not associated with syncope, cardiopulmonary resuscitation or electrical cardioversion and with left ventricular ejection fraction (LVEF) $\geq$35%
3. the patient received appropriate ATP therapy and no shock therapy for hemodynamically well-tolerated VT and does not have a history of poorly tolerated VT or VF.
4. sinus bradycardia and/or 2nd–3rd degree heart block with satisfactory escape rhythm (heart rate over 40 beats/min).

When, in the judgment of the responsible physician it is felt that prophylactic replacement should be undertaken ECAS believes that the manufacturer must provide a replacement device at no charge and reimburse related medical expenses. The risk analysis should be explained to the patient including the risks associated with device replacement.

It should also be taken into consideration that in some instances the device may have been implanted for 3 years and therefore not far from the time for elective replacement.

We recommend that the patients be asked to sign a form indicating that they have been informed of the risks and that they understand and agree with the choices made.

In case of device replacement, because of the possibility of surgical complications, it is recommended that the informed consent form contains a statement indicating that the patient is aware that replacement will be performed solely as a precautionary measure and a statement summarizing the risks and consequences of device failure and the risks of device replacement.

Recommendation ECAS-ICD-03-2006. DEVICE: Guidant VENTAK PRIZM AVT, VITALITY AVT, RENEWAL 3 AVT, and RENEWAL 4 AVT

Background

On July 11, 2005, Guidant Corporation notified the FDA of safety information regarding its cardioverter defibrillators with atrial therapy: VENTAK PRIZM AVT, VITALITY AVT, and CONTAK RENEWAL AVT devices. These models are subject to a condition in which memory corruption may result in functional "latching," which limits available therapy. At that time,

two occurrences had been confirmed out of approximately 20,950 devices implanted worldwide. Guidant recommends a programming change that reduces the risk of this issue that can be implemented at the next scheduled follow-up visit. Guidant developed a noninvasive software solution for VITALITY AVT and all RENEWAL AVT devices. This solution should have been available in the fourth quarter of 2005, pending regulatory approval.

Guidant have further clarified that

1. latching of AVT devices will suspend detection and treatment of atrial and ventricular arrhythmias. Telemetry and programming are not available. Bradycardia pacing may continue, but will not be programmable and may not match programmed settings. In a latched state, battery usage may increase, but battery status indicators will not be available. In the extremely unlikely circumstance that latching occurs during delivery of ATP therapy, ATP therapy delivery could continue independent of patient need.
2. device replacement is required if latching occurs.

The recommendations suggested by the manufacturers are

- verify normal device function using routine clinical follow-up procedures
- program "Atrial Tachy Episode Data Storage" to 0%
- evaluate the risks and benefits of temporarily programming ATP therapy "OFF."

Current estimates of the rate of occurrence of this malfunction are 0.005%; if second and third recommendations are applied the risk reduces by 0.000066%.

Following implementation of the software solution, the estimated probability of latching is zero.

ECAS Committee Statement and Recommendations

Consistent with its principle of maintaining the highest standards of patient care ECAS supports the recommendation that every device center must maintain an up-to-date record of all implanted devices including serial numbers and implant dates so that those at risk can be identified. This responsibility includes undertaking enhanced follow-up according to current recommendations and participating in the global surveillance of the performance of these devices by making returns to national and/or international audit bodies.

The Society has considered the information provided by Guidant and notes the very low probability of life-threatening patient injury.

In regard of these events and waiting for further information, particularly about identification of possible new cases or new types of failure, ECAS considers that recommendations suggested by the manufacturer are adequate to assure patient safety.

Recommendation ECAS-ICD-04-2006. DEVICE: Guidant CONTAK RENEWAL Model H135 and CONTAK RENEWAL 2 Model H155

Background

On July 17, 2005, Guidant Corporation notified the FDA of safety information regarding the CONTAK RENEWAL (Model H135) and CONTAK RENEWAL 2 (Model H155) cardiac resynchronization therapy defibrillators (CRT-Ds), manufactured on or before August 26, 2004. The FDA has indicated that it will classify them as "recalls." Physicians were informed of this failure by letter from Guidant. The failure involves deterioration of the insulation surrounding a high-voltage wire within the lead connector block. In conjunction with other factors this can allow shorting of energy to the active titanium case during shock delivery, resulting in the inability of the device to deliver effective therapy.

Fifteen reports of this failure mode have been confirmed from approximately 16,000 devices implanted worldwide. This includes an event in which a device was returned after a patient death on May 30, 2005. This device is still being tested but it appears to have experienced this failure in conjunction with attempted delivery of at least one high-voltage therapy.

Approximately 11,900 devices built before August 26, 2004, remain in service.

Guidant has further clarified that

1. the current rate of occurrence is 0.094% per implant; theoretical estimates indicate that the rate of reported failures may increase between 0.20% and 0.59%.
2. Guidant recommends normal follow-up at 3-month intervals.
3. Guidant does not recommend replacement of these devices prior to the appearance of normal ERIs.
4. If a patient has recently received high-voltage therapy, Guidant recommends evaluating the condition of the device, and the patient's clinical situation, to determine whether the device should be electively replaced, in the event of which Guidant will provide a replacement device at no charge.

Documented failure includes one or more of the following:

1. Failure to recognize ventricular tachyarrhythmia,
2. Failure to deliver an effective shock,
3. Permanent loss of pacing therapy,
4. Device reversion to fallback/safety mode,
5. loss of telemetry/programming/interrogation,
6. programmer display of a red warning screen upon attempted device interrogation,
7. programmer display of yellow warning screen indicating out of range shocking impedance.

ECAS Committee Statement and Recommendations

Consistent with its principle of maintaining the highest standards of patient care ECAS supports the recommendation that every device center must maintain an up-to-date record of all implanted devices including serial numbers and implant dates so that those at risk can be identified. This responsibility includes undertaking enhanced follow-up according to current recommendations and participating in the global surveillance of the performance of these devices by making returns to national and/or international audit bodies.

The Society has taken note of the information provided by Guidant and of the low probability of failure risk (0.1%). However, it cannot be underestimated that such device failure can lead to a failure to deliver an effective shock, and the consequent failure to prevent sudden cardiac death. It is likely that this problem has already resulted in one patient's death. In other cases device malfunction resulted in the failure of pacing therapy.

ECAS suggests that in order to ensure the highest standard of patient care, the risk profile of each patient with a potentially affected device should be assessed individually and their device assessed in detail as recommended by Guidant.

With regard to these events and while waiting for further information, particularly the identification of new cases or new types of failure, ECAS suggests that

(A) the device be replaced if one of the following conditions is met:

1. The patient underwent device implantation as secondary prevention following cardiac arrest or VT associated with hemodynamic collapse (syncope or near-syncope).
2. The patient has required appropriate therapy for VT or VF whether the device was implanted for secondary or primary prevention.
3. The patient is pacemaker-dependent.

In case of prophylactic replacement in high-risk patients, ECAS believes that the manufacturer must provide a replacement device at no charge and reimburse related medical expenses. The risk analysis should be explained to the patient including the risks associated with device replacement.

(B) that an individual analysis of each patient with a potentially affected device be performed and suggest periodic follow-up every 3 months when:

1. Indication for implant was primary prevention and the patient has not required therapy for VT or VF
2. Secondary prevention implant but only for hemodynamically well-tolerated VT with LVEF $\geq$35% and without need for cardiac resynchronization or shock therapy.
3. The patient has received appropriate ATP therapy and no shock therapy for hemodynamically well-tolerated VT with LVEF $\geq$35% and does not have a history of poorly tolerated VT or VF.
4. Sinus bradycardia and/or 2nd–3rd degree heart block with satisfactory escape rhythm (heart rate over 40 beats/min).

Such individual risk assessment may indicate the need for elective device replacement in some patients. The risk analysis should be explained to the patient including the risks associated with device replacement. In case of prophylactic replacement in high-risk patients, ECAS believes that the manufacturer must provide a replacement device at no charge and reimburse related medical expenses.

We recommend that the patient be asked to sign a form indicating that he or she has been informed of the risks and that he or she understands and agrees with the choices made.

In case of device replacement, because of the possibility of surgical complications, it is recommended that the informed consent form contains a statement indicating that the patient is aware that replacement will be performed solely as a precautionary measure and a statement summarizing the risks and consequences of device failure and the risks of device replacement.

Recommendation ECAS-ICD-05-2006 DEVICE: Guidant Cardioverter Defibrillators CONTAK RENEWAL 3 E 4, CONTAK RENEWAL 3 e 4 AVT e RENEWAL RF

Background

On June 23, 2005, Guidant Corporation notified the FDA that a letter had been sent to physicians regarding safety of some devices: CONTAK RENEWAL 3 E 4, CONTAK RENEWAL 3 e 4 AVT e RENEWAL RF. The aim of the letter was to inform physicians and to limit possible adverse events. The FDA classified this enterprise as a "recall." The evaluation of the failure is in a very early phase, and the distribution and implant of these devices has been interrupted until the evaluation will be complete. Quality analysis identified a potential defect of a component that can limit the available therapies. Engineering analysis determined that a mode change with a magnet can be blocked in the close position. Four events in circa 46,000 implanted devices have been confirmed and a fifth event is under evaluation. In the documented events the patients and/or physicians were alerted by sounds from the devices signalling the block in close position of the mode change with a magnet. In these events the devices were replaced. No severe injury to patients has been reported.

If mode change with a magnet is blocked in the close position, the therapy of atrial and ventricular tachyarrhythmias is inhibited whereas antibradycardia pacing is conserved. In this condition the safety functions of the device will cause the production of acoustic sounds and the battery will discharge quickly. If the function "Magnet use available" is programmed "OFF" and the mode change with a magnet is blocked in the close position the device will continue to deliver the brady and tachy therapies as programmed; in this situation the available device lifetime will be significantly reduced and the time between ERI and EOL could be reduced.

The recommendations suggested by the manufacturers for the management of patient are the following:

- To program "Magnet Use Available" on "OFF." With this program:
- The magnet will not inhibit the therapy.
- The Triggered Monitor function of the patients is available.
- With the programmer it is possible to temporarily block the tachy therapy.
- To avoid the use of a magnet where possible.
- If an acoustic signal comes from the device the patients should contact the referral center for urgent device interrogation.

ECAS Committee Statement and Recommendations

Consistent with its principle of maintaining the highest standards of patient care ECAS supports the recommendation that every device center must maintain an up-to-date record of all implanted devices including serial numbers and implant dates so that those at risk can be identified. This responsibility includes undertaking enhanced follow-up according to current recommendations and participating in the global surveillance of the performance of these devices by making returns to national and/or international audit bodies.

The Society has considered the information provided by Guidant and notes the very low incidence of malfunction reported and the absence of life-threatening patient injury.

In regard of these events and waiting for further information, particularly about identification of possible new cases or new types of failure, ECAS considers that recommendations suggested by the manufacturer are adequate to assure patient safety.

Recommendation ECAS-ICD-06-2006. DEVICES: St. Jude Medical ICD models Epic DR/HF (V-233/V-337/V-338), Epic Plus DR/VR/HF (V-236/V-239/V196/V-239T/V-196T/V-350), Atlas DR (V-242), and Atlas Plus DR/VR/HF (V-243/V193/V-193C/V-340/V-341/V-343)

Background

On June 17, 2005, St. Jude Medical sent a letter to device implanting physicians regarding two anomalies that St. Jude Medical has uncovered during routine product monitoring.

The first anomaly can occur when one of the affected devices attempts to deliver multiple shocks in rapid succession. Due to a device software anomaly, it is possible that when the device's battery is nearing its ERI, a charging cycle may be skipped. If this were to occur, the first shock will always be delivered as programmed and, if needed, the next shock in the programmed sequence would be delivered after a delay of 2–4 seconds. A skipped charge would result in less than the full number of programmed shocks being available for delivery during that episode, but all delivered shocks would be at their programmed energy. This behavior was discovered as an incidental finding during analysis of one returned device that had delivered a large number of high-voltage shocks over a short-time period.

A second anomaly has been identified and is caused by electrical "noise" generated as a result of the charging of the device's high-voltage

capacitors. After a capacitor charge, if rate responsive pacing mode (e.g., DDDR, VVIR, etc.) is programmed "On," this "noise" may be interpreted by the device's accelerometer (activity sensor) as physical activity, causing a temporary increase in the pacing rate that may persist after charging is completed. The degree and duration of the rate increase will depend on a variety of factors, but the rate will never exceed the programmed maximum sensor rate (MSR), and the device will gradually return to the appropriate rate. This anomalous behavior, which has been observed during the performance of manual capacitor maintenance, has been traced back to a component supplied to St. Jude Medical by one vendor; therefore, only the subset of device models that were manufactured with the affected component (device serial numbers below 141000 for any model) will exhibit this behavior. The company is requesting that nonimplanted devices with these serial numbers be returned to St. Jude Medical.

These anomalies potentially affect approximately 9,600 ICDs distributed in Europe, the Middle East, and Africa. No clinical complication related to these anomalies has been identified so far.

St. Jude Medical has developed programmer software that will automatically detect the affected ICDs and download device software that will enable the "skipped charge" anomaly to be corrected. Once the upgrade is performed, the potential for a skipped charge will be eliminated. Additionally, if the rate responsive mode is programmed "On," devices with serial numbers below 141000 will have their rate response functions suspended for the time period during which the electrical noise could be present (i.e., while significant residual voltage remains on the high-voltage capacitors); appropriate nonrate responsive pacing at the programmed base rate will continue to be provided. The period during which rate response is suspended may last anywhere from a few minutes to approximately 90 minutes. If rate responsive pacing was ongoing prior to charging, the pacing rate will gradually decrease to the base pacing rate according to the normal rate response recovery algorithm and will remain there while rate responsive pacing is suspended. The rate response behavior for devices with serial number greater than 141000 will not be affected by the software download.

St. Jude Medical confirmed that its technical personnel will be installing new software, version 4.8.5, onto Model 3510 programmers. With this software in place the programmer will, upon interrogation, automatically determine whether the ICD requires one or both of the aforementioned software downloads and will prompt the user to continue with the upgrade.

Since a skipped charge is more likely to occur in devices that are closer to their ERI, St. Jude Medical recommends that if the next patient follow-up is not scheduled to occur within the next 6 months that the patient be seen within this time period. In addition, if devices are programmed to pacing settings that result in high current consumption, such as high output biventricular pacing, consideration should be given to scheduling the patient for a follow-up visit within 3 months.

ECAS Committee Statement and Recommendations

Consistent with its principle of maintaining the highest standards of patient care ECAS supports the recommendation that every device center must maintain an up-to-date record of all implanted devices including serial numbers and implant dates so that those at risk can be identified. This responsibility includes undertaking enhanced follow-up according to current recommendations and participating in the global surveillance of the performance of these devices by making returns to national and/or international audit bodies.

The Society takes note of the information provided by the manufacturing company and of the consequent lack of clinical complications related to these anomalies. In the light of the data provided, we consider that the software correction is sufficient to properly assure patients' safety. We recommend that physicians ensure that they identify patients in their care with affected devices, ensure that the new software is downloaded into all the relevant programmers as soon as possible, and that software upgrade of those devices is performed with minimal delay.

As with all these devices, ECAS recommends even greater clinical surveillance of these patients, paying particular attention to look for any complications that might result from these or other reported anomalies and to report to ECAS any comments that may be helpful for the optimum management of patients with these devices.

Recommendation ECAS-DF-ICD-07-2006. Recommendations for Management of Patients with the Following St. Jude Medical ICD Models "Photon DR V-230HV (a few Serial Numbers), Photon Micro VR/DR (V-194/V-232) and Atlas VR/DR (V-199/V-240)"

On October 6, 2005, St. Jude Medical Inc. sent a letter to cardiac pacing centers that indicated a possible functioning anomaly regarding a memory chip called static random access memory (SRAM) used in some ICD products within the Photon and Photon Micro device families and in certain Atlas devices.

Specifically it has been identified that this memory chip can rarely be affected by background levels of atmospheric ionizing cosmic radiation ("background cosmic radiation") causing an anomaly and triggering a high current drain. This condition has been replicated by St. Jude Medical in a nuclear laboratory and confirmed by the manufacturer of this component. The anomaly can trigger a temporary loss of pacing function and permanent loss of defibrillation support. There are no tests to predict if a particular device's memory chip component will exhibit this specific anomaly.

To date St. Jude Medical have reported 60 anomalies out of 36,000 devices implanted worldwide (1.67‰), with 53 of these being observed following device implantation and seven prior to device implantion. To date 26,000 devices are still in service; about 8,000 of these are in service in markets outside the United States. There has been no serious injury or death attributable to this anomaly. The nature of the anomaly is random and constant over time. The estimated incidence is 2.57% over the 5 year projected life of each device.

St. Jude points out that from 2002, a different design of a different vendor's SRAM memory chip component has been used in their devices. Laboratory testing and clinical experience indicate that this newer generation memory chip component does not share the same susceptibility to background cosmic radiation as the earlier generation.

Device Behavior in Case of Malfunction

In the event that a device chip is affected by background cosmic radiation, the high current drain condition will deplete the battery voltage rapidly. This can result in loss of output for a period up to approximately 48 hours. During this period, the patient would be without pacing or defibrillation therapy. After this initial period, the battery will reach a voltage level at which the device will enter its "Hardware Reset Mode." This safety mode is designed to preserve the device's ability to provide VVI pacing support. In this mode the device will operate in the VVI mode at 60 ppm, but will not be capable of providing tachycardia detection or therapy. This may only be notable by a warning message on the programmer screen upon device interrogation.

St. Jude Medical Recommendations

1. Performing routine device monitoring every 3 months
2. In determining whether additional patient management or follow-up may be needed, consider the low failure rate for the anomaly and the unique medical needs and situation of each individual patient, including whether the patient is pacemaker-dependent or at high risk for life-threatening arrhythmias.
3. If a device is found in "Hardware Reset Mode," a device replacement must be arranged as soon as possible
4. Suggest that the patient immediately informs the hospital in case of any change in symptoms

ECAS Committee Statement and Recommendations

Consistent with its principle of maintaining the highest standards of patient care ECAS supports the recommendation that every device center must maintain an up-to-date record of all implanted devices including serial numbers and implant dates so that those at risk can be identified. This responsibility includes undertaking enhanced follow-up according to current recommendations and participating in the global surveillance of the performance of these devices by making returns to national and/or international audit bodies.

That being stated and, while waiting for new information by the manufacturer in particular, regarding the identification of new malfunction cases, ECAS suggests the following guidelines for the management of these patients.

Every patient should be informed in detail of the problem and the risk of device malfunction but pointing out the low frequency of the known risk. ECAS suggests that

(A) the device be replaced if one of the following conditions is met:

1. The patient underwent device implantation as secondary prevention following cardiac arrest or VT associated with hemodynamic collapse (syncope or near-syncope).
2. The patient has required appropriate therapy for VT or VF.
3. The patient is pacemaker-dependent.

In case of prophylactic replacement in high-risk patients, ECAS believes that the manufacturer must provide a replacement device at no charge and reimburse related medical expenses. The risk analysis should be explained to the patient including the risks associated with device replacement.

(B) that an individual analysis of each patient with a potentially affected device be performed and suggest periodic follow-up every 3 months when:

1. The indication for implantation was primary prevention and the patient has not required therapy for VT or VF.

2. The indication for implantation was secondary prevention but only for hemodynamically well tolerated VT with LVEF ≥35% and without need for cardiac resynchronization or shock therapy.

3. The patient received appropriate ATP therapy and no shock therapy for hemodynamically well tolerated VT with LVEF ≥35% and does not have a history of poorly tolerated VT or VF.

4. Sinus bradycardia and/or 2nd–3rd degree heart block with satisfactory escape rhythm (heart rate over 40 beats/min).

Such individual risk assessment may indicate the need for elective device replacement in some patients. The risk analysis should be explained to the patient including the risks associated with device replacement. In case of prophylactic replacement in high-risk patients, ECAS believes that the manufacturer must provide a replacement device at no charge and reimburse related medical expenses.

We recommend that the patient be asked to sign a form indicating that he or she has been informed of the risks and that he or she understands and agrees with the choices made.

In case of device replacement, because of the possibility of surgical complications, it is recommended that the informed consent form contains a statement indicating that the patient is aware that replacement will be performed solely as a precautionary measure and a statement summarizing the risks and consequences of device failure and the risks of device replacement.

Recommendation ECAS-DF-ICD-08-2006. DEVICE: ELA Medical Cardioverter Defibrillators ALTO (DR 614, VR 615, MSP 617, DR 624, VR 625, MSP 627 Models)

Background

ELA Medical gave notification in 2004 that a limited number of cardioverter defibrillators ALTO (DR 614, VR 615, MSP 617, DR 624, VR 625, MSP 627 models) produced before April 17, 2003, could undergo a rapid discharge of the battery or a prolongation of defibrillation charge time caused by a metallic migration consequent upon a specific manufacturing process.

On July 25, 2005, ELA Medical sent a letter to implanting centers in order to supply the information and recommendations for the correct management of patients implanted with those devices. The communication reported that ongoing postmarketing surveillance demonstrated a significant reduction in incidence of this phenomenon after changes in the manufacturing process after April 2003, although the phenomenon was not completely eliminated.

A statistical analysis identified two more ICD groups presenting with a very low metallic migration incidence causing this fault.

Incidence

- In a first group of 430 devices produced between April and July 2003 the incidence of the problem is 2.6%.
- In a second group of 1,856 devices produced between August 2003 and August 2004 the incidence of the problem is 0.1%.

Corrective Management of the Phenomenon by Manufacturing Society

- In July 2003, ELA eliminated a phase of the manufacturing process, in which the circuits were exposed to high temperature in order to eliminate completely the delamination of a protective covering of high-voltage hybrid circuit and subsequently metallic migration in this circuit. So far, devices produced after July 2003 have not demonstrated the fault.
- Welding and covering processes of the low-voltage hybrid circuit have been modified after August 2004 with the aim of eliminating the residual probability of the fault. No evidence of the fault has been seen on devices produced after August 2004.

The Following Recommendations were made by ELA

- Patients implanted with the first group of devices should undergo a device follow-up visit every 3 months in accordance with the recommendations reported in the user manual. Depending on the circumstances, patients with frequent ventricular fibrillation episodes and pacemaker-dependent patients should be considered for prophylactic device replacement or a stricter follow-up.
- For patients implanted with the second group of devices, although the incidence of the fault is very low (2 of 1,856 devices), ELA will continue to monitor the occurrence of the fault and will furnish information about its incidence and any significant change in its occurrence. ELA recommend a follow-up visit every 3 months, in accordance with the recommendations reported in the user manual.

ECAS Committee Statement and Recommendations

Consistent with its principle of maintaining the highest standards of patient care ECAS supports the recommendation that every device center must maintain an up-to-date record of all implanted devices including serial numbers and implant dates so that those at risk can be identified. This responsibility includes undertaking enhanced follow-up according to current recommendations and participating in the global surveillance of the performance of these devices by making returns to national and/or international audit bodies.

The Society has considered the information and recommendations provided by ELA Medical. The reported incidence of device malfunction in the first group of devices (April to July 2003) of 2.6% is too high and it is not acceptable for high-risk patients.

In consideration of the absence of criteria for battery discharge prediction and in order to ensure the highest standard of patient care, ECAS suggests that

(A) the device replacement should be considered if at least one of the following conditions is met:

1. The patient underwent device implantation as secondary prevention following cardiac arrest or ventricular tachycardia associated with hemodynamic collapse (syncope or near-syncope).
2. The patient has required appropriate therapy for VT or VF.
3. The patient is pacemaker-dependent.

Such individual risk assessment may indicate the need for elective device replacement in some patients. The risk analysis should be explained to the patient including the risks associated with device replacement. In case of prophylactic replacement in high-risk patients, ECAS believes that the manufacturer must provide a replacement device at no charge and reimburse related medical expenses.

(B) That an individual analysis of each patient with a potentially affected device be performed and suggest periodic follow-up every 3 months when

1. the indication for implantation was primary prevention and the patient has not required therapy for VT or VF.
2. the indication for implantation was secondary prevention but only for hemodynamically well tolerated VT with LVEF $\geq$35% and without need for cardiac resynchronization or shock therapy.
3. the patient received appropriate ATP therapy and no shock therapy for hemodynamically well tolerated VT with LVEF $\geq$35% and does not have a history of poorly tolerated VT or VF.
4. sinus bradycardia and/or 2nd—3rd degree heart block with satisfactory escape rhythm (heart rate over 40 beats/min).

After an individual analysis of each patient, more conservative management could be appropriate for patients in the second group (August 2003 to August 2004) where the fault's incidence is 0.1% (2 malfunctions over 1,856 devices) observing a follow-up visit every three 3 months and considering a prophylactic device replacement for high-risk patients.

Every pacemaker and ICD center should ask ELA Medical for the complete list of implanted devices with serial number and implant data in order to facilitate the follow-up and to enable global surveillance on devices lost to follow-up.

Every center should report to ECAS new cases of malfunction in order to perform the best monitoring.

In case of prophylactic replacement in high-risk patients, ECAS believes that the manufacturer must provide a replacement device at no charge and reimburse related medical expenses.

Section II: Pacemakers (IPGs)

Recommendation ECAS-DF-IPG-01-2006. DEVICES: Guidant PULSAR MAX, PULSAR, DISCOVERY, MERIDIAN, PULSAR MAX II, DISCOVERY II, VIRTUS PLUS II, INTELIS II and CONTAK TR

Background

On July 18, 2005, Guidant sent a letter to physicians providing important medical device safety information regarding a subset of PULSAR MAX, PULSAR, DISCOVERY, MERIDIAN, PULSAR MAX II, DISCOVERY II, VIRTUS PLUS II, INTELIS II, and CONTAK TR pacemakers manufactured between November 25, 1997, and October 26, 2000.

The communication reports that a hermetic sealing component used in these devices may gradually degrade 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 behaviors:

1. Premature battery depletion resulting in loss of telemetry and/or loss of pacing output without warning.

2. Inappropriate accelerometer function (if programmed ON), resulting in:
3. Sustained pacing at the programmed maximum sensor rate (MSR).
4. Lack of appropriate accelerometer rate response during activity.
5. Appearance of a reset warning message upon interrogation.
6. Inappropriate early display of replacement indicators.

Guidant underline that up-to-date, failing devices can be identified during usual follow-up, and has not identified any test that will predict if a device will exhibit this failure mode in the future. Disabling accelerometer function will prevent inappropriate MSR pacing, but moisture penetration can still cause the other behaviors described above.

As of July 11, 2005, Guidant has identified 69 devices that may have exhibited this failure mode.

Of the 78,000 devices originally distributed, approximately 28,000 devices remain implanted worldwide; 18,000 of these devices remain in service in the United States with an average implant age of 69 months. No failure has been reported prior to 44 months of service, and the likelihood of occurrence increases with implant time.

Present estimates of the rate of failure in the remaining active implanted devices are 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.

In those cases observed to date there have been a variety of serious complications. In 20 patients loss of pacing output occurred, including 5 patients who experienced syncope and presyncope requiring hospitalization in the remainder. There have been two reports of sustained MSR pacing where heart failure may have developed as a consequence. In one report, a patient whose device exhibited sustained MSR pacing was admitted to the hospital and later expired.

The following recommendations were made by Guidant:

1. Consider replacing devices for pacemaker-dependent patients.
2. Advise patients to seek physician's attention if they notice a prolonged rapid heart rate, experience syncope or lightheadedness, or have symptoms of heart failure.
3. Select a suitable MSR setting, given the rare possibility that inappropriate sustained pacing at MSR can occur, or consider programming the accelerometer OFF
4. Consider increasing the frequency of programmed 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 follow-up:

1. Evaluate the patient's clinical condition.
2. Evaluate battery status indicator ("gas gauge") for signs of early or rapid depletion between sequential follow-up visits.
3. Evaluate the accelerometer rate response.
4. Look for inappropriate MSR pacing or pacing higher than the programmed lower rate limit while the patient is at rest.
5. Look for lack of rate response with activity.

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 ERI. This supplemental warranty program was available through December 31, 2005.

ECAS Committee Statement and Recommendations

Consistent with its principle of maintaining the highest standards of patient care ECAS supports the recommendation that every device center must maintain an up-to-date record of all implanted devices including serial numbers and implant dates so that those at risk can be identified. This responsibility includes undertaking enhanced follow-up according to current recommendations and participating in the global surveillance of the performance of these devices by making returns to national and/or international audit bodies.

ECAS suggests that in order to ensure the highest standard of patient care, the risk profile of each patient with a potentially affected device should be assessed individually and their device assessed in detail as recommended by Guidant.

The Society has reviewed the information provided by the company and takes note of the low reported risk of generator failure.

Recognizing that, because of underreporting, the risk rate may be greater than that currently noted, we encourage all colleagues to report to ECAS, the manufacturer, and relevant regulatory authorities any further cases that have been identified or become apparent.

Although the risk of generator failure is low, failure cannot be predicted and failure can result

in abrupt loss of pacing output. In our opinion, these elements should guide clinical decisions.

With regard to these events and while waiting for further information, particularly the identification of new cases or new types of failure, ECAS suggests that

(A) the pacemaker be replaced if at least one of the following conditions is met:

1. The patient is pacemaker-dependent.
2. The patients could suffer from symptomatic deterioration (such as syncope, presyncope, or heart failure) in the event of sudden loss of pacing. This category should include patients with atrial fibrillation and slow ventricular rate together with prolonged pauses, and those with sinus node dysfunction and prolonged pauses.

The risk analysis should be explained to the patient including the risks associate with device replacement. In case of entirely prophylactic replacement in high-risk patients, ECAS believes that the manufacturer must provide a replacement device at no charge and reimburse related medical expenses.

We recommend patients be asked to sign a form indicating that they have been informed of the risks and that they understand and agrees with the choices made.

In case of device replacement, because of the possibility of surgical complications, it is recommended that the informed consent form contains a statement indicating that the patient is aware that replacement will be performed solely as a precautionary measure and a statement summarizing the risks and consequences of device failure and the risks of device replacement.

(B) Individual evaluation be performed in:

1. Patients with symptomatic chronotropic incompetence, where deactivating rate-responsive function could induce worsening of their clinical condition.
2. Patients with sinus bradycardia and/or 2nd or 3rd degree AV block together with good escape rhythm (rate over 40 beats/min).
3. Patients with heart failure.

Such individual risk assessment may indicate the need for elective device replacement in some patients. The risk analysis should be explained to the patient including the risks associated with device replacement. In case of prophylactic replacement in high-risk patients, ECAS believes that the manufacturer must provide a replacement device at no charge and reimburse related medical expenses.

We recommend patients be asked to sign a form indicating that they have been informed of the risks and that they understand and agrees with the choices made.

In case of device replacement, because of the possibility of surgical complications, it is recommended that the informed consent form contains a statement indicating that the patient is aware that replacement will be performed solely as a precautionary measure and a statement summarizing the risks and consequences of device failure and the risks of device replacement.

(C) A 3 months follow-up routine be maintained in patients with:

1. Good spontaneous rhythm.
2. Normal chronotropic response.
3. Absence of heart failure.

As far as the rate-response function is concerned, we recommend that the default position should be for deactivation. In our opinion it can be maintained ON only in the absence of ischemia and/or heart failure and only if the maximum sensor pacing rate is programmed relatively low.

Recommendation ECAS-DF-IPG-02-2006. Suggestions for Managing Guidant Pacemakers INSIGNIA® and NEXUS® Patients

On September 22, 2005, Guidant sent a letter to doctors where important medical device safety information is provided regarding a subset of mentioned pacemakers manufactured by March 12, 2004 (Ref.).

The communication concern the following model number: 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, INSIGNA 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.

The communication reports that Guidant's Cardiac Rhythm Management Quality System has identified two separate failure modes, each occurring infrequently within the INSIGNIA and NEXUS families of implantable pacemakers. One

or more of the following device behaviors 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.

There has been no reported death resulting from these failure modes. Loss of pacing output associated with these failure modes has resulted in syncope as well as presyncope requiring hospitalization.

The communication points out that the United States FDA may classify this communication action as a recall (Ref).

First Failure Mode

As of September 6, 2005, 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 7 months. The likelihood of this failure mode decreases with implant time, and no failure has been reported beyond 22 months of service. Guidant has received three reports of syncope and six reports of bradycardia or heart block associated with this failure mode, which required emergency hospitalization. One device was determined to have failed briefly and resumed functioning with no detectable indication of this seen during routine follow-up. The 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 failure has 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% and 0.037% over the remaining device lifetime, thus anticipating approximately seven to fifteen additional failures.

Second Failure Mode

As of September 6, 2005, 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 preimplant testing. Guidant has received one 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.

Guidant 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, in agreement with the instructions contained in the device labeling. Guidant also recommends advising patients to seek for immediate clinical attention if they experience syncope or lightheadedness.

Guidant Recommendations Regarding Second Failure Mode

Guidant recommends verification of 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, in addition to the unique needs of individual patients, both the very low occurrence rate and that no failure has been observed after successful confirmation of pacing at implant in their clinical decisions regarding patient management.

ECAS Committee Statement and Recommendations

Consistent with its principle of maintaining the highest standards of patient care ECAS supports the recommendation that every device center must maintain an up-to-date record of all implanted devices including serial numbers and implant dates so that those at risk can be identified. This responsibility includes undertaking enhanced follow-up according to current recommendations and participating in the global surveillance of the performance of these devices by making returns to national and/or international audit bodies.

ECAS suggests that in order to ensure the highest standard of patient care, the risk profile of each patient with a potentially affected device should be assessed individually and their device assessed in detail as recommended by Guidant.

The Society has reviewed information provided by the company and understands the low reported risk of failures. Despite the low expected risk, and the declining trend of reported complications with a peak at 7 months after the implant, the most concerning aspects are the lack of ability to predict device failure and that failure can result in loss of pacing output. In our opinion, these elements should guide clinical decisions.

Recognizing that, because of underreporting, the risk rate may be greater than that currently noted, we encourage all colleagues to report to ECAS, the manufacturer, and relevant regulatory authorities any further cases that have been identified or become apparent.

Whilst awaiting any additional information from the manufacturers, specifically on additional failure reports, we suggest the following guidelines for managing these patients.

Consider pacemaker replacement if at least one of the following conditions applies:

1. The patient is pacemaker-dependent.
2. The patient could suffer deterioration of symptoms (such as syncope, presyncope, or heart failure) with sudden loss of pacing.

Otherwise arrange to follow the patients on a 3-month basis.

Hypothesizing that the risk rate may be greater than the numbers reported as of today, because of underreporting, all data concerning the failures found during this effort and the interventions made by each investigator to compensate for the failures should be reported to the Manufacturer and to ECAS. ECAS will create a general database for device failures which will be made available for online access in the ECAS website.

Recommendation ECAS-DF-IPG-03-2006. DEVICE: ELA Medical Symphony and Rhapsody Pacemakers

Background

On October 25, 2005, ELA Medical sent a letter to device implanting physicians containing important information about the performance of their devices. During routine product surveillance monitoring a situation of "no output" has been observed in a limited number of Symphony or Rhapsody pacemakers (models Symphony DR 2550, Rhapsody DR+ 2530, Rhapsody DR 2510, Rhapsody D 2410, Rhapsody SR 2210) produced before August 1, 2003.

The "no output" condition could be due to a metallic migration caused by a specific manufacturing process. No criteria for device failure prediction has been identified with usual surveillance techniques. No evidence of metallic migration has been identified in pacemakers produced after August 1, 2003.

Incidence

- In these pacemakers produced before August 1, 2003, the overall percentage (worldwide) of device failure has been reported to be 0.75%.
- In the pacemakers produced after August 1, 2003, there has been no report of device failure.

The following recommendations were made by ELA.

- The manufacturer suggests that pacemaker-dependent patients who have received a pacemaker manufactured before August 1, 2003, should be considered for a prophylactic replacement of the pacemaker.
- For those patients who have received a pacemaker manufactured after August 1, 2003, as no failures have been reported and considering that the risks of pacemaker replacement are greater than the mean percentage of all pacemakers failures (circa 0.15% per year) the manufacturer does not recommend the replacement of these devices.

ECAS Committee Statement and Recommendations

Consistent with its principle of maintaining the highest standards of patient care ECAS supports the recommendation that every device center must maintain an up-to-date record of all implanted devices including serial numbers and implant dates so that those at risk can be identified. This responsibility includes undertaking enhanced follow-up according to current recommendations and participating in the global surveillance of the performance of these devices by making returns to national and/or international audit bodies.

The Society has considered the information provided by ELA Medical and notes the very low incidence of malfunction reported and the absence of life-threatening patient injury.

Recognizing that, because of underreporting, the risk rate may be greater than that currently noted, we encourage all colleagues to report to ECAS, the manufacturer, and relevant regulatory authorities any further cases that have been identified or become apparent.

Even if the risk of "no output" is low, the absence of failure predicting criteria should be considered in determining our final clinical judgement.

With regard to these events and while waiting for further information, particularly the identification of new cases or new types of failure, ECAS suggests that

(A) to consider (only for those patients with pacemaker manufactured before August 1, 2003) pacemaker replacement if at least one of the following conditions is met:

1. The patient is pacemaker-dependent.
2. The patient could suffer from symptomatic deterioration (such as syncope, presyncope, or heart failure) in the event of sudden loss of pacing,

(B) Routine follow-up visits every 6 months in all the other patients.

In case of prophylactic replacement in high-risk patients, ECAS believes that the manufacturer must provide a replacement device at no charge and reimburse related medical expenses, as actual guarantee rules state.

Recommendation ECAS-DF-IPG-04-2006. DEVICE: Medtronic Sigma Pacemaker

Background

On December 5, 2005, Medtronic sent a letter to device implanting physicians containing important information about the performance of their devices. Specifically, the manufacturer furnished information regarding an anomalous behavior recorded during tests performed on devices returned for analysis.

The failure is related to a specific and limited number of pacemakers belonging to the Sigma model, that could present an anomalous behavior due to a disconnection of some electrical links at the level of the hybrid circuit.

Clinically, this anomalous behavior could present as the following: no rate response, rapid battery discharge, high impedance of the electrode catheters, complete or intermittent loss of telemetry, or loss of impulse delivery. No death or patient injury has been attributed to this fault.

At the level of the terminal blocks of the hybrid circuit the disconnection of some electrical links has been discovered. During October 2005, tests were completed that identified the cause of this anomaly as the use of a particular solvent to clean the hybrid circuits. This particular solvent, used in a subgroup of this pacemaker family, could reduce the capacity of the electrical connection.

Incidence

Worldwide circa 28,000 devices of this model have been implanted. Nineteen devices have been reported with this failure, an incidence of 0.068%. Only 5 out of 19 devices presented with the "no output" phenomenon. The time interval between implant and failure ranged between 17 and 38 months. Medtronic created some predictive models and the calculated incidence of this failure could reach 0.17–0.30% in the remaining lifetime of these pacemakers. No predictive test is available to identify the devices that will develop this failure.

The following recommendations were made by Medtronic:

- Because of the low probability of a life-threatening event in this patient population Medtronic does not recommend the replacement of these devices before the ERI battery level is reached.
- To continue the follow-up routine according to clinical practice, with visits at least every 6 months and to educate patients to seek medical aid if dizziness or syncope occur.
- To determine if device replacement is necessary by evaluating each individual case, and to inform the patient of the situation making sure that the patient is aware of the risks associated with replacement of the device.

In case of prophylactic replacement in high-risk patients, the manufacturer will provide a replacement device at no charge, as actual guarantee rules state.

ECAS Committee Statement and Recommendations

Consistent with its principle of maintaining the highest standards of patient care ECAS supports the recommendation that every device center must maintain an up-to-date record of all implanted devices including serial numbers and implant dates so that those at risk can be identified. This responsibility includes undertaking enhanced follow-up according to current recommendations and participating in the global surveillance of the performance of these devices by making returns to national and/or international audit bodies.

The Society has considered the information provided by Medtronic and notes the very low incidence of malfunction reported and the absence of life-threatening patient injury in the cases of device failure reported.

Recognizing that, because of underreporting, the risk rate may be greater than that currently noted, we encourage all colleagues to report to ECAS, the manufacturer, and relevant regulatory authorities any further cases that have been identified or become apparent.

Although the risk of failure is low and in only a minority of the cases did the anomaly present as a failure in impulse delivery, the inability to predict criteria failure should be considered in making the final clinical judgement.

In order to maintain the highest level of patient care, we recommend performing an individual evaluation of every single patient with risk assessment profile through a reevaluation of patients' files identifying the patients with the higher risk.

With regard to these events and while waiting for further information, particularly the identification of new cases or new types of failure, ECAS suggests that

(A) that pacemaker replacement be considered if at least one of the following conditions is met:

- The patient is pacemaker-dependent.
- The patient could suffer from symptomatic deterioration (such as syncope, presyncope or heart failure) in the event of sudden loss of pacing,

(B) Routine follow-up visits every 6 months in all the other patients.