|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Supplementary Table 1. Recall reasons analysis of cardiac implants** | | | | | | | | |
| categorizes | sub-categorizes | Recall reason in details | ICD | CRT | Pacemaker | Stent | Leads | Implantable artificial organ |
| Battery | Capacitor | Some of the devices with suspect capacitors have had unexpected charge circuit time-outs or charge circuit inactive conditions as the battery voltage nears the level for Elective Replacement of the devices.[[1](#_ENREF_1)] | 10 |  |  |  |  |  |
| A rare condition in which an internal protective fuse can be unintentionally activated while the device is charging its capacitors for shock delivery or induction. Should this occur, defibrillator would not be able to deliver therapy. [[2](#_ENREF_2)] |  |  |  |  |  |
| A rare condition in which an internal protective fuse can be unintentionally activated while the device is charging its capacitors for shock delivery or induction. The defibrillator may not be able to deliver therapy or communicate with the programmer, and may be unable to emit tones or otherwise respond to magnet application. [[3](#_ENREF_3)] |  |  |  |  |  |
| Specific low-voltage capacitors from a former supplier may be subject to degradation, which may cause accelerated battery depletion and may reduce the time between elective replacement indicator (ERI) and battery end of life (EOL) to less than three months. [[4](#_ENREF_4)] |  |  |  |  |  |
| Potential for reduced ERI to EOL time due to low-voltage capacitor degradation in a subset of ICDs and CRT-Ds.[[5](#_ENREF_5)] |  |  |  |  |  |
| Risk of loss of CRT/ICD therapy due to rapid battery depletion as a result of capacitor degradation occurring in a subset of devices. [[6](#_ENREF_6)] | 6 |  |  |  |  |
| Five reports regarding capacitors have had temporary or permanent degradation, premature battery depletion occur.[[7](#_ENREF_7)] |  |  |  |  |
| Premature battery depletion may occur because of capacitor damage in a series CRT-Ds and ICDs. [[8](#_ENREF_8)] |  |  |  |  |
| The devices may not meet expected device longevity due to gradually increasing current drain caused by low voltage capacitor degradation. This issue may present in the affected devices as reaching the Recommended Replacement Time (RRT) earlier than projected. [[9](#_ENREF_9)] |  |  |  |  |
| Boston Scientific has determined that the performance of a low voltage capacitor in this subset of devices may be compromised over time, causing increased current drain that can lead to premature battery depletion. [[10](#_ENREF_10)] |  |  |  |  |
| Some capacitors from specific lots may perform in a manner that leads to device malfunction, including intermittent or permanent loss of therapy or premature battery depletion. [[11](#_ENREF_11)] |  |  |  |  |  |
| Voltage | Technical investigations confirmed that the observed drop in the battery voltage is available with an unexpected, persistent minimal current flow in context, which can only occur in transport mode, in which the aggregates are up to the time of implantation.[[12](#_ENREF_12)] | 2 |  |  |  |  |  |
| Premature battery depletion and/or prolonged charge time may occur in a limited number of alto implantable cardioverter defibrillator.[[13](#_ENREF_13)] |  |  |  |  |  |
| Connection | Deterioration in a wire insulator could cause a short circuit, resulting in the devices' inability to deliver an electrical shock during episodes of arrhythmia. [[14](#_ENREF_14)] | 2 | 1 |  |  |  |  |
| The ICDs cannot deliver shock for therapy properly because the circuit board connection temporary or permanent unstable. [[15](#_ENREF_15)] |  |  |  |  |  |
| We have noticed that may arise in the course of use by an initial damage to the cable sheath during implantation cause damage to the cable. [[16](#_ENREF_16)] |  |  |  |  |  | 1 |
| Battery defect | Potential battery defect; possible rapid depletion, prevalence unknown. [[17](#_ENREF_17)] | 3 |  |  |  |  |  |
| The affected batteries may have a shorted battery cell, which would lead to a reduction of the total capacity of the battery. [[18](#_ENREF_18)] |  |  |  |  |  |
| These defibrillators include a particular electrical component may fail. Such a failure could cause a short circuit through which would prematurely discharge the battery in the defibrillator. A defibrillator is no longer functional when the battery is fully discharged. [[19](#_ENREF_19)] |  |  |  |  |  |
| Reporting | This report indicated that the battery of the device was still in the "Begin Of Life (BOL) function start" condition and an adequate residual-operating system runtime (e.g. several years) was shown. In case this inconsistency resulted in unnecessary explanation of the device. [[20](#_ENREF_20)] |  |  | 2 |  |  |  |
| As is the possibility of a faulty display and alarm reporting a low electrode impedance value. [[21](#_ENREF_21)] |  |  |  |  |  |
| Premature battery depletion | They may not operate for as long as expected; They may not operate for the full timeframe of at least three months between the alert for it to be replaced [the Elective Replacement Indicator (ERI)] and the End of Life (EOL) alert.[[22](#_ENREF_22)] | 4 |  |  |  |  |  |
| Risk of S-ICD being unable to deliver shock for therapy after elective replacement indicator (ERI) audible warning. The ERI may occur earlier than expected and the end of life (EOL) indicator may occur before the nominal 3 months.[[23](#_ENREF_23)] |  |  |  |  |  |
| Patients with relevant pacemakers or CRT-Ps may experience a temporary or permanent loss of therapy, telemetry, or premature battery depletion. Patients with ICDs in question can learn an incorrect detection or premature battery depletion. [[24](#_ENREF_24)] | 2 |  |  |  |  |
| Delay in delivery of therapy during device middle-of-life phase due to temporarily extended charge time limits; Transition to device end of life (EOL) without prior observation of elective replacement indication (ERI) even though battery capacity remains available. [[25](#_ENREF_25)] |  |  |  |  |
| Risk of loss of pacing due to overestimation of the time remaining to elective replacement indicator (ERI). [[26](#_ENREF_26)] |  |  | 1 |  |  |  |
| Software | Performance inconsistency | The manufacturer is informing you of an issue related to installation or removal of the Lead Integrity Alert (LIA) software in En Trust defibrillators. In those devices only, installation or removal of LIA will inadvertently turn off two audible patient alerts described below. This does not affect LIA or other device functionality. [[27](#_ENREF_27)] | 5 |  |  |  |  |  |
| The manufacturer has detected a risk of high voltage (HV) therapy not being available after anti-tachycardia pacing (ATP) in the ventricular tachycardia (VT) zone, as a result of a programmer software error that can lead to an unanticipated parameter change. High Voltage Therapy remains available in the VF detection zone. [[28](#_ENREF_28)] |  |  |  |  |  |
| Careful examination showed that this software can only occur anomaly at a rarely occurring sequence of events: The criterion for charging the capacitors shock (ventricular arrhythmias) and the criterion for the mode switch (atrial arrhythmia) are satisfied at exactly the same time. The unit is (because of sustained ventricular arrhythmia) delivers a shock. [[29](#_ENREF_29)] |  |  |  |  |  |
| The manufacturer is informing you of a rare device software issue in the ICD and CRT-D device models listed above. A software update will be available to correct this issue. The root cause to be a rare and specific sequence of events that must occur within a few milliseconds of each other: High voltage capacitors reach programmed energy (charge end); Battery voltage measurement in-process at charge end VT/VF rhythm self terminates and therapy is aborted.[[30](#_ENREF_30)] |  |  |  |  |  |
| The manufacturer has found that under certain conditions the biphasic with the above software versions can only give 100 joules to a patient with defibrillation, which is lower than the minimum recommended factory default setting of 200 J. [[31](#_ENREF_31)] |  |  |  |  |  |
| This letter is to inform you about a software anomaly in Vitatron dual-chamber pacemakers, the C-and T-series. If these devices are programmed for certain parameters, the software anomaly may manifest clinically in a reset of the pacemaker or in the absence of stimulation, ie when the underlying rhythm of the patient falls below the programmed lower rate. [[32](#_ENREF_32)] |  |  | 1 |  |  |  |
| A rare indicator of the software has been shown while the dual-chamber cardiac pacing at the same time. [[33](#_ENREF_33)] |  | 1 |  |  |  |  |
| Inappropriately set | When using the Merlin Programmer with software version17.2.2 as part of a single VF detection zone configuration for ICD/CRT-D devices, the sinus redetection value will be inappropriately set to zero milliseconds. As a result, any intrinsic activity following the first shock will be considered a “sinus rate” and the device will diagnose “return to sinus”. [[34](#_ENREF_34)] | 2 | 1 |  |  |  |  |
| Measurement error will lead to set “zero” for the battery voltage, and achieve Elective Replacement Indicator. [[35](#_ENREF_35)] |  |  |  |  |  |
| The manufacturer has identified that a subset of Accent SR single chamber model PM1110 and Accent DR dual chamber model PM2112 pacemakers will not provide a change in sensor driven (rate responsive) pacing rates in response to patient physical activity due to an incorrect software setting. [[36](#_ENREF_36)] |  |  | 1 |  |  |  |
| Lead to battery defect | The manufacturer sets all customers of the fact that the software version 2.002 and earlier versions of AEDs, the DDU-series, under certain circumstances, the warning "Low Battery" and "Replace Battery" does not indicate the previously determined by an automatic self-test. In this case, the user may not be aware of the almost dead battery and the device is not able to release a shock. [[37](#_ENREF_37)] | 2 |  |  |  |  |  |
| The wrong indicators of voltage and Elective Replacement Indicator have been reported because of the software issues. [[38](#_ENREF_38)] |  |  |  |  |  |
| Following a software update the new battery impedance elective replacement indicator (ERI) threshold may trigger an unexpected ERI in some EnRhythm® and EnRhythm MRI™ devices. [[39](#_ENREF_39)] |  |  | 2 |  |  |  |
| A programmer software anomaly can lead to incorrect reporting of battery voltage, expected battery longevity and Elective Replacement Indicator (ERI) status in certain St. Jude Medical pacemakers. The anomaly does not affect the device’s actual battery voltage, longevity or functionality, but could result in inaccurate reporting of the status of these measured data parameters. [[40](#_ENREF_40)] |  |  |  |  |  |
| Influence by environment | The manufacturer has identified that a small subset of 2090 Programmers have an incorrect software configuration for the country in which that are physically located. When a programmer is manufactured, it is configured for the region in which it will be located. [[41](#_ENREF_41)] |  |  | 1 |  |  |  |
| Output data | Incorrect express | Device delivers the proper charge, but prints the wrong number on the programmer. [[42](#_ENREF_42)] | 1 |  |  |  |  |  |
| The device may display an “electrical neutral line” which could be misinterpreted as an asystoly of the patient. Reboot of the Monitoring Unit if the view number 4 is selected and the realtime printout is being started. [[43](#_ENREF_43)] |  |  | 1 |  |  |  |
| No output | The manufacturer observed that a no output condition could occur in a limited number of Symphony or Rhapsody pacemakers. The no-output condition could occur due to metal migration caused by a specific manufacturing process.[[44](#_ENREF_44)] |  |  | 1 |  |  |  |
| No or incorrect alarm | An investigation of a single customer report has confirmed that it is possible in a specific circumstance for medium priority (Low Flow, High Power, and Suction) alarm limits to be exceeded without an audible notification or a visible alarm message being displayed. [[45](#_ENREF_45)] |  |  |  |  |  | 3 |
| A recent incident involving a patient death thirty-four months post. Log file analysis confirmed that the pump had stopped. Functional testing of the returned controller showed that the device (including motor control circuits) performed all functions as intended within specification and with no fault alarms or errors. The exact cause of the event cannot be conclusively determined. [[46](#_ENREF_46)] |  |  |  |  |  |
| It is possible in a specific circumstance for medium priority alarm limits to be exceeded without an audible notification or a visible alarm message being displayed. [[47](#_ENREF_47)] |  |  |  |  |  |
| Therapy delivery | Background influence | A particular vendor-supplied memory chip can be affected at a low frequency rate by background levels of atmospheric ionizing cosmic radiation ("background cosmic radiation"). The anomaly can trigger a temporary loss of pacing function and permanent loss of defibrillation support. [[48](#_ENREF_48)] | 1 |  |  |  |  |  |
| Pacing inhibition | Potential for reduction in number of shocks (skipped charge) delivered per therapy episode. Potential for inappropriate rate responsive pacing for up to 90 minutes during automatic and clinician initiated capacitor reformation. [[49](#_ENREF_49)] | 4 |  |  |  |  |  |
| Risk of inappropriate shocking, pacing inhibition or shocking inhibition due to internal insulation abrasion. [[50](#_ENREF_50)] |  |  |  |  |  |
| The above-referenced CRT-Ds are programmed to LV-only pacing, it is possible for the patient’s intrinsic signals to cause the RV refractory period to be prematurely terminated. The premature termination of the RV refractory period can result in inappropriate sensing of intrinsic RV activity that would normally fall into refractory. [[51](#_ENREF_51)] | 1 |  |  |  |  |
| Risk of bradycardia / syncope due to pacing inhibition. Potential for pacing inhibition associated with ventricular oversensing if the follow-up monitoring feature, PhD, is programmed ON and the device is connected to high polarization defibrillation leads. [[52](#_ENREF_52)] |  |  |  |  |  |
| Inappropriate therapy | A printed circuit board assembly (PCBA) may cause an intermittent short. If this occurs, it may result in no therapy delivery or delivery of an incorrect defibrillation waveform. [[53](#_ENREF_53)] |  |  | 2 |  |  |  |
| There is a possibility that these make the decision to deliver a shock or no shock faulty if the semi-automated external defibrillator is set to auto analysis. [[54](#_ENREF_54)] |  |  |  |  |  |
| The manufacturer has recently determined that if the Respiratory Sensor is programmed On, such RV lead complications may cause additional oversensing, thereby increasing the probability of inappropriate therapy. Five to eight successive inappropriate shocks could leave the device unable to treat an actual arrhythmia until the current episode ends. [[55](#_ENREF_55)] | 2 |  |  |  |  |  |
| The manufacturer recently received four reports from Germany concerning the OPTIMIZER III IPG. One of the device components, the reed switch, became stuck during IPG recharge. When it became stuck the devices went into "magnet mode" which is a setting which automatically turns off Cardiac Contractility Modulation therapy. This state can typically be changed to reinitiate therapy by reprogramming the OPTIMIZER® III device with the OMNI Programmer. However, a stuck reed switch affects the telemetry reception by the IPG, preventing reprogramming until the reed switch is released. [[56](#_ENREF_56)] |  |  |  |  |  |
| Equipment malfunction | With this letter is to provide you with important safety information about a particular, but rarely applied implantation technique. Guidant reported two cases of equipment malfunction in connection with a rarely applied subpectoral implantation technique. The vast majority of these aggregates was implanted subcutaneously at the estimates and is therefore not affected by this disorder. [[57](#_ENREF_57)] | 3 |  |  |  |  |  |
| A recurrent mechanical stress on the titanium case lead to damage to components and thus to an equipment malfunction. [[58](#_ENREF_58)] | 1 |  |  |  |  |
| Recall due to component failure resulting in potential loss of cardioversion, defibrillation, and reduced device longevity. [[59](#_ENREF_59)] |  |  |  |  |  |
| To date, the manufacturer has received complaints regarding the inability to flush the device when purging the instrument. [[60](#_ENREF_60)] |  |  |  | 1 |  |  |
| Fractured | These leads are being recalled because a small number of fractures have been detected. When the lead breaks (fractures), it may cause inappropriate shocks or result in a loss of therapy, such as pacing or shocking. [[61](#_ENREF_61)] |  |  |  |  | 1 |  |
| A consistent increase in the internal scrap rate (failure mode: broken stent struts) of nitinol stents was observed. [[62](#_ENREF_62)] |  |  |  | 6 |  |  |
| One case is a partially deployed stent fractured upon attempting to retrieve the device from the patient, and a small surgical cut down procedure was performed to retrieve the fractured stent segment. [[63](#_ENREF_63)] |  |  |  |  |  |
| In the course of internal controls we found out that during the sterilization, a damage of the distal spring of the mounted implant might be happen. This damage could lead to a fracture and a reduced radial force in the distal spring of the stent graft. In this case the integrity of the stent graft would no longer be guaranteed. [[64](#_ENREF_64)] |  |  |  |  |  |
| A detachment of the tip from the stent delivery system has been reported, potential health hazard events resulting from this type of failure include increased procedure time, vessel wall injury, stoke and/or emergency surgery to remove the detached tip. [[65](#_ENREF_65)] |  |  |  |  |  |
| A potential issue with a specific subset where deployment complication may occur. This type of issue could potentially lead to a sub-optimal deployment resulting in serious deterioration to a patient’s health. [[66](#_ENREF_66)] |  |  |  |  |  |
| Two complaints have been reported in Europe for a detachment of the tip from the stent delivery system. Potential health hazard events resulting from this type of failure include increased procedure time, vessel wall injury and/or stent displacement during attempts to retrieve the tip. There is also a risk that the patient may require emergency surgery to remove the tip. [[67](#_ENREF_67)] |  |  |  |  |  |
| Failed or partially to deploy | During routine final product lot release testing, a NexStent Carotid Stent device failed to deploy when the outer catheter (proximal outer and distal sheath) did not pull back and expose the self-expanding stent. [[68](#_ENREF_68)] |  |  |  | 6 |  |  |
| Characteristics in the design of these two lots resulted in failure of the balloon to deflate and impeded removal of the balloon after stent placement. [[69](#_ENREF_69), [70](#_ENREF_70)] |  |  |  |  |  |
| The deployment mechanism for the affected LifeStent Solo Vascular Stents may not perform properly when used. Deployment issues range from failure to deploy, partial deployment, and difficult deployment. [[71](#_ENREF_71)] |  |  |  |  |  |
| The Innova™ Self-Expanding Stent System is indicated for the treatment of peripheral vascular lesions. The manufacturer has received 6 complaints involving no deployment or partial deployment of the Innova Stents. Potential health hazard events resulting from this type of failure include increased procedure time, vessel wall injury, and emergency surgery to remove the partially deployed stent. [[72](#_ENREF_72)] |  |  |  |  |  |
| It seems that a possible defect in the deployment of the balloon has led to some incident reporting for the above-mentioned codes. [[73](#_ENREF_73)] |  |  |  |  |  |
| Leak | A seal within the devices can leak, allowing moisture to affect the electronic circuits. [[74](#_ENREF_74)] |  |  | 1 |  |  |  |
| Inadequate size | The IntraStent is a peripheral / biliary stent. The manufacturer initiated the recall of certain lots of this product following the discovery that two symbols (the symbol for length and the symbol for diameter) on the side and end-flaps of IntraStent boxes in the affected lots are reversed. The length and diameter symbols on the top of the box and on the device pouch are correct. [[75](#_ENREF_75)] |  |  |  | 2 |  |  |
| Stent Expansion Uniformity refers to the percentage difference between the largest and smallest outer diameter measurement on a single stent deployed in an unconstrained manner to its rated burst pressure in engineering laboratory testing. [[76](#_ENREF_76)] |  |  |  |  |  |
| The Manufacturer has issued a hazard alert for its Mosaic Porcine Aortic Bioprosthesis Model 305 due to the potential for implanting oversized valves. [[77](#_ENREF_77)] |  |  |  |  |  | 1 |
| Connection | Weakened bond | The manufacturer has determined that the bond between the header and case could be weakened by significant forces associated with a subpectoral implant procedure or when a device in a subpectoral position is pushed against a rib during contraction of the pectoralis muscle. A weakened header bond may alter lead impedance and introduce noise that may inhibit pacing therapy or initiate inappropriate tachy therapy. Additional mechanical stress applied to a weakened bond may eventually cause header connection wires to fracture, resulting in loss of therapy. [[78](#_ENREF_78)] | 1 |  |  |  |  |  |
| The root cause of these events has been attributed to a weakened bond between the capsule containing the valve and the delivery shaft. There is no potential for a component to separate from the device (the valve capsule remains connected to the DCS inner lumen). However, the weakened bond could result in the inability to unsheathe and deploy the valve from the capsule. [[79](#_ENREF_79)] |  |  |  |  |  | 1 |
| Partially or fully separated | The HVAD Pump’s driveline connector housing became partially or fully separated from the front portion of the driveline connector. In the unlikely event of a separation, we advised that a repair is necessary. If left unattended, electrical connection to the controller could be affected and a VAD stop alarm could result. [[80](#_ENREF_80)] |  |  |  |  |  | 1 |
| Separation of wires | The Kappa and Sigma pacemakers in these identified series may fail due to a separation of wires that connect the electronic circuit to other pacemaker components, such as the battery. [[81](#_ENREF_81)] |  |  | 2 |  |  |  |
| May fail due to separation of interconnect wires from the hybrid circuit. This failure mechanism may present clinically as loss of rate response, premature battery depletion, intermittent or total loss of telemetry, or no output.[[82](#_ENREF_82)] |  |  |  |  |  |
| The manufacturer has identified that the device will lose function due to the separation of wire. When that happens, it may cause loss of therapy delivery, premature battery depletion, and temporary or permanent loss of signal. [[83](#_ENREF_83)] |  |  |  |  | 2 |  |
| The manufacturer has identified that the device will lose function due to the separation of wire. When that happens, it may cause loss of therapy delivery, premature battery depletion, and temporary or permanent loss of signal. [[84](#_ENREF_84)] |  |  |  |  |  |
| Bend relief | The manufacturer is aware of a recent trend in reports of disconnection of the bend relief from the sealed outflow graft, a component of the HeartMate II LVAS. The bend relief is a tube of ePTFE surrounding the outflow graft proximal to the pump that is designed to prevent kinking of the outflow graft. Disconnection of bend relief from the sealed outflow graft may potentially lead to outflow graft kinking and/or graft abrasion. Symptoms of outflow graft kinking included low pump flow, hemolysis, bleeding, and fluctuations in pump flow, speed and/or power, or worsening symptoms of heart failure. Graft abrasion may lead to serious bleeding. [[85](#_ENREF_85)] |  |  |  |  |  | 1 |
| Lead insulation abrasion | Failures associated with lead insulation abrasion on the St. Jude Medical Riata and Riata ST Silicone Endocardial Defibrillation Leads may cause the conductors to become externalized. [[86](#_ENREF_86)] |  |  |  |  | 5 |  |
| The manufacturer has confirmed that the analysis of the returned leads identified internal insulation breach under the right ventricular (RV) and Superior Vena Cava (SVC) defibrillation coil electrode, resulting in low pacing impedance, and/or ventricular oversensing and/or inappropriate therapies. [[87](#_ENREF_87)] |  |  |  |  |  |
| Risk of inappropriate shock or therapy failure due to wearing of lead insulation after implantation. [[88](#_ENREF_88)] |  |  |  |  |  |
| Risk of worsening heart failure symptoms due to wear and/or abrasion of lead insulation after implantation. [[89](#_ENREF_89)] |  |  |  |  |  |
| Lead abrasion failures identified in the Riata silicone insulated defibrillation leads as compared to our newer lead models utilizing the Optim® insulation material (Riata ST Optim and Durata® family of defibrillation leads). [[90](#_ENREF_90)] |  |  |  |  |  |
| Materials detached from guide wires | There is a potential for PTFE (polytetrafluroethylene) coating to delaminate and detach from guide wire. Medtronic steerable guide wires are used to aid in the placement of ventricular leads in the coronary vasculature. [[91](#_ENREF_91)] |  |  |  |  | 2 |  |
| We identified that the PTFE coating on the gold plated distal coil of the Back-up Meier Steerable Guidewires of the identified lots/batches have the potential for PTFE delamination. [[92](#_ENREF_92)] |  |  |  |  |  |

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