St. Jude Medical UK Ltd
Capulet House
Stratford Business & Technology Park
Banbury Road
Stratford-upon-Avon, CV37 7GX
Tel: +44 (0)1789 207600 Switchboard
Fax: +44 (0)1789 207601
Emergency +44 (0)7808 910454

19 August 2014

Important Information Enclosed

FIELD SAFETY NOTICE

St. Jude Medical: Ellipse™ VR/DR
Model Numbers: CD1277, CD1377, CD2277, CD2377 (all -36, -36Q, -36C and -36QC suffixes)

Dear Valued Customer

Please find enclosed a Field Safety Notice, along with associated documents, regarding the St. Jude Medical Ellipse™ VR/DR, Model Numbers: CD1277, CD1377, CD2277, CD2377 (all -36, -36Q, -36C and -36QC suffixes).

As part of St. Jude Medical's focus on reliability and safety we continuously monitor the performance of our products. This letter is intended to provide you with important information regarding our Ellipse™ family of Implantable Cardioverter Defibrillators (ICDs). During capacitor maintenance or charging for high voltage therapy, a "Capacitor Charge Time Limit reached" message may occur due to an anomaly with the high voltage capacitor. This anomaly may result in delayed delivery of high voltage therapy or prevent delivery of part or all of a programmed high voltage therapy shock.

There have been no serious injuries or patient deaths reported to St. Jude Medical as a result of this anomaly. No other St. Jude Medical device models are affected.

Having received this letter, you or a member of your team will have received a call from a St Jude Medical representative.

As per instruction, please refrain from using any Ellipse devices which you may have in stock (purchased or consigned items).

Those devices will be retrieved and replaced by new Ellipse ICDs with redesigned high voltage capacitors, eliminating the source of capacitor damage at the front alignment hole.

Your St. Jude Medical representative will be working with you, and your hospital administration to retrieve and replace at no cost all of the potentially affected Ellipse ICDs that remain on your hospital shelves.

The MHRA have been notified of this issue.

Any models that have already been implanted should be managed per the recommendations on pages 3 & 4 in the enclosed letter.

Please could I ask you to take note of the information contained within and communicate it to any of your colleagues who you feel should be made aware.

Please do not hesitate to contact your local St. Jude Medical representative/agent should you require any further information. Alternatively, you can contact our Customer Services team on +44 (0) 1789 207600, and Technical Support on +46 84744147.

We understand the challenges that these communications present and thank you for your co-operation in this matter.

Yours sincerely

Sean Hogarth
Quality and Regulatory Manager, UK and Ireland

Mat Powell
CRM Divisional Manager, UK and Ireland

ST. JUDE MEDICAL

FIELD SAFETY NOTICE

Extended Charge Time on St. Jude Medical Ellipse™ VR/DR Implantable Cardioverter Defibrillators (ICDs)

Model Numbers: CD1277, CD1377, CD2277, CD2377 (all -36, -36Q, -36C and -36QC suffixes)

19 August, 2014

Dear Customer,

As part of St. Jude Medical's focus on reliability and safety we continuously monitor the performance of our products. This letter is intended to provide you with important information regarding our Ellipse™ family of Implantable Cardioverter Defibrillators (ICDs). During capacitor maintenance or charging for high voltage therapy, a "Capacitor Charge Time Limit reached" message may occur due to an anomaly with the high voltage capacitor. This anomaly may result in delayed delivery of high voltage therapy or prevent delivery of part or all of a programmed high voltage therapy shock. There have been no serious injuries or patient deaths reported to St. Jude Medical as a result of this anomaly. No other St. Jude Medical device models are affected.

This letter is aimed to provide you with information regarding this potential anomaly, its clinical implications and patient management recommendations.

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication. Please retain a copy with the equipment Instructions for Use.

The U.S. Food and Drug Administration (FDA) and Competent Authorities outside the U.S. have been notified of this issue.

If you need any further information or support concerning this issue, please contact your local St. Jude Medical Representative or Technical Support at +46 8 474 4147.

We apologize for any inconvenience this may cause and trust that this information adequately addresses any concerns you may have.

Yours Sincerely,

Mark Carlson, M.D.
Vice President, Global Clinical Affairs and Chief Medical Officer

Jeff Fecho
Vice President, Global Quality

Affected products	St. Jude Medical Ellipse™ VR/DR Implantable Cardioverter Defibrillators (ICDs)
Model Numbers	CD1277, CD1377, CD2277, CD2377 (all -36, -36Q, -36C and -36QC suffixes)
Serial Numbers	All serial numbers.
Anomaly identified	Extended charge time may present as a result of internal damage to the capacitors used in the high voltage charging circuitry of the subject devices. As designed, the device will deliver the available energy on the capacitors once the charge time limit of 32 seconds is reached, even if the energy is less than the programmed value. This anomaly may occur during capacitor maintenance or charging for high voltage therapy, and may result in delayed delivery of high voltage therapy and/or delivery of part of a programmed high voltage therapy shock.
Detection of the anomaly	If this condition occurs, it is detectable via a vibratory patient alert and, for patients enrolled and actively being followed, a Merlin.net notification. Additionally, upon device interrogation with the Merlin programmer, an alert message will indicate "Capacitor charge time limit reached" on a specific date. Approximately 97% of Ellipse extended charge time events reported to St. Jude Medical have been detected during capacitor maintenance with the remainder detected during defibrillation threshold (DFT) testing. There have been no reported cases of an Ellipse device failing to deliver high voltage therapy to a patient when needed. As designed, if this occurs during charging for high voltage therapy the device will deliver a shock with the available voltage.
Root cause	The capacitor geometry used in Ellipse ICDs is unique and therefore only Ellipse ICDs are impacted by this capacitor anomaly. Capacitors consist of individual layers of anodes (positive plates), cathodes (negative plates) and papers (insulation) which are stacked and aligned via a "front alignment hole." The completed stack is enclosed in a capacitor case which is then filled with electrolyte and sealed. Evidence of arcing has been observed between the anode and cathode at the front alignment hole in returned Ellipse devices that exhibited this anomaly. As a result of implementation of a standard manufacturing process operation, Ellipse ICDs with capacitors manufactured since August 2012 have demonstrated a lower likelihood of experiencing persistent damage

	to the capacitors after an initial extended charge time event compared to those manufactured prior to August 2012.
Clinical implications	1. During a device diagnosed tachyarrhythmia, the patient may receive full or partial high voltage therapy; however delivery of high voltage therapy delivery may take up to 32 seconds. 2. In the majority of cases where data were available to make an assessment, the capacitors did recover to perform normally during subsequent charges.
Risk assessment	There have been no serious injuries or patient deaths reported to St. Jude Medical as a result of this anomaly. As of July 31, 2014, there have been 179 extended charge time events associated with this anomaly reported on Ellipse devices, equivalent to an incidence rate of 0.42% (179 out of approximately 43,000 worldwide sales). There is a low probability of delayed therapy or insufficient therapy resulting from this anomaly. In accordance with our Health Hazard Evaluation process, the probability of serious injury due to delayed therapy is estimated to be 0.0032% (less than 1 in 31,000) and the probability of death due to insufficient therapy is estimated to be 0.00042% (less than 1 in 238,000).
Patient management recommendations	If your patient has received a vibratory notification and/or if a programmer or Merlin.net alert for an extended charge time has been observed: 1. Schedule your Ellipse ICD patient for an in-office follow-up evaluation as soon as possible. 2. Interrogate the Ellipse ICD and perform a manual capacitor maintenance charge. Note the charge time to full charge; it should be approximately 15 seconds or less. 3. Contact St. Jude Medical's Technical Support to review the results of the capacitor maintenance test and discuss if additional evaluation is required. 4. A device that has experienced repeated extended charge time out warnings should be considered for replacement. As the large majority of the extended charge time events have presented at the routine 6 month automatic capacitor maintenance interval, programming the interval to every 4 months at your patient's next scheduled follow up visit may provide an earlier indication of this potential anomaly. It should be noted that changing the device programming to a 4 month capacitor maintenance interval will reduce device longevity by approximately 9%.

	Device replacement is not recommended for an Ellipse device exhibiting normal charge times, and patients should continue to be followed at routine follow up intervals.[1] Where possible, St. Jude Medical recommends that patients with affected devices be enrolled in Merlin.net so that any extended charge time alert ("Capacitor Charge Time Limit reached" message) will be transmitted to Merlin.net for patients being actively monitored and can be viewed by your clinic staff. St. Jude Medical has reviewed these recommendations with its Medical Advisory Board (MAB) who support the above recommendations.
What do I do with Ellipse devices on my shelves?	Please refrain from using any Ellipse devices which may be on your shelves. Those devices will be retrieved and replaced by new Ellipse ICDs with the redesigned high voltage capacitor eliminating the source of capacitor damage at the front alignment hole. Your St. Jude Medical representative will work with you and your hospital administration to retrieve and replace at no cost all of the potentially affected Ellipse ICDs that remain on your hospital shelves Ellipse ICDs with serial numbers beginning with the number "1" and starting at 1132470, as well as Ellipse ICDs with serial numbers beginning with the number "7" and starting with 7126267, incorporate the new capacitors.
For further information	Please contact your St. Jude Medical representative or St. Jude Medical Technical Support: +46-8 4744147.

[1] HRS/EHRA Expert Consensus on Monitoring Cardiovascular Implantable Electronic Devices (CIED), April 2008.