

29th April 2015

<Contact Name>
<Hospital Department>
<Hospital Name>
<Address Line 1>
<Address Line 2>
<City>
<Post Code>

REFERENCE: FA2015-04

Important Information Enclosed

FIELD SAFETY NOTICE

St. Jude Medical: Eon™ Wall Charger Model 3701 and Eon™ Portable Charger Model 3711

Follow up on Field Safety Notice issued in July 2012

Potential For Excessive Warmth Or Heating At The Implant Site During Charging

Dear Valued Customer

Please find enclosed a Field Safety Notice, along with associated documents, which provides you with important information regarding the St. Jude Medical Eon™ Wall Charger Model 3701 and Eon™ Portable Charger Model 3711.

Only the external and portable Eon™ charging systems and their accessories are affected under this Field Safety Notice. Any implanted spinal cord stimulators are not affected by this Field Safety Notice. No other St. Jude Medical device models are affected.

Reason for Field Safety Notice:

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 Eon™ Rechargeable IPG family of Spinal Cord Stimulation (SCS) Systems. Some patients have reported experiencing an uncomfortable temperature increase at the IPG implant site during charging, with a small number of patients reporting burns at the implant site.

Please be aware that your Competent Authority is being notified of this
Field Safety Corrective Action.

Our records show that your facility has purchased or has product affected by this recall therefore, as part of this action, we require that you follow the instructions below and notify St Jude Medical, of your compliance with this Field Safety Corrective Action.

2...../



St Jude Medical U.K. Limited
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Banbury Road Stratford upon Avon
CV37 7GX
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Tel +44 (0)1789 207600 Opt 1 Customer
Services
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Emergency + 44 (0) 7808 910454

Required actions for you and your Healthcare Facility:

1. As per instruction included with this letter, please refrain from using or issuing the Eon™ Wall Charger System Model 3701, the Eon™ Portable Charger System Model 3711 and their accessories (Charger Antenna, AC Power Adapter and Power Cable) which you may have in stock (purchased or consigned items).
2. Do not use or further distribute any St Jude Medical, Eon™ Wall Charger System Model 3701, the Eon™ Portable Charger System Model 3711 and their accessories.
3. Check all inventory locations within your institution for St Jude Medical, Eon™ Wall Charger System Model 3701, the Eon™ Portable Charger System Model 3711 and their accessories. Please segregate, remove any identified product from your shelves and place them into quarantine.
4. Pass this Field Safety Notice to all those who need to be aware of it within your organization and to any organization where the potentially affected devices have been transferred.
5. If you have further distributed any of the Eon™ Wall Charger System Model 3701, the Eon™ Portable Charger System Model 3711 and their accessories please immediately contact that location, advise them of the recall and have them return the affected product to St Jude Medical, to the address listed on this letterhead.
6. If you have products to return please contact your local St Jude Medical Representative who will work with you, and your hospital administration to arrange collection and exchange of the affected devices at no cost.
7. Any external chargers that have already been issued to patients should be managed per the recommendations in the enclosed letter.

Please could I ask you to take note of the information contained within this Field Safety Notice 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 or assistance. Alternatively, you can contact our Customer Services Team on +44 (0)1789 207600, or Technical Support on +46 847 44147.

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

Yours sincerely,

Roland Back
Quality and Regulatory Manager
UK and Ireland

Karen Horner
NMD Divisional Manager
UK & Ireland

Follow up on Field Safety Notice issued in July 2012
Potential For Excessive Warmth Or Heating At The Implant Site During Charging
Eon™ Wall Charger Model 3701 and Eon™ Portable Charger Model 3711

April 29, 2015.

Dear **Customer**,

You are receiving this letter as a follow-up to the Important Medical Device Safety Information letter you received from St. Jude Medical in July 2012 regarding the potential for excessive warmth or heating at the implant site during charging for the Eon™ Implantable Pulse Generators.

In the July 2012 letter, St. Jude Medical informed you that we would be implementing design improvements to the charger to address the possibility of increased energy dissipation during charging. We would now like to inform you that a replacement charger, which is intended to address this concern, is now available.

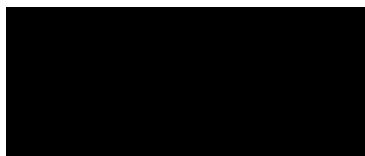
This letter is intended to:

- Briefly remind you of the issue and our commitment.
- Describe the corrective action(s).
- Provide patient management recommendations.

If you need any further information or support concerning this issue, please contact your local St. Jude Medical Representative at

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

Sincerely,



Jeff Fecho
Vice President, Global Quality

Follow up on Field Safety Notice issued on July 2012

Potential for warmth or heating at the IPG implant site during charging.

Affected products	Eon™ Wall Charger System model 3701 Eon™ Portable Charger System model 3711 Accessories (Charger Antenna, AC Power Adapter and Power Cable)
Problem description	Some patients have reported experiencing an uncomfortable temperature increase at the IPG implant site during charging, with a small number of patients reporting burns at the implant site.
Corrective action	<ul style="list-style-type: none"> • The Eon™ Wall Charger System Model 3701 and Eon™ Portable Charger System Model 3711 are discontinued and replaced by the Eon™ Charging System Model 3726. • Accessories of the Charger System 3701 and 3711 are not compatible with the new Charger System Model 3726. • All patient chargers will be replaced with the Charging System Model 3726
Depth of implant	Please note that recommended depth of implant of the Eon™ IPG remains unchanged at 2.5 cm.
Benefit of the new charger	The new Eon™ Charging System Model 3726 reduces the potential for uncomfortable temperature increases that may be felt near the spinal cord stimulator while recharging by automatically turning the energy it delivers on and off to reduce the rise in temperature of the spinal cord stimulator and of the charger wand during charging.
Hospital inventory to be placed in quarantine	<ul style="list-style-type: none"> • Please refrain from using the Wall Charger System 3701, the Portable Charger System Model 3711 and their accessories (Charger Antenna, AC Power Adapter and Power Cable). • The above devices shall be segregated and placed in quarantine. • Your St. Jude Medical representative will retrieve and replace all the above devices at no cost.
Patient's charger swap	<ul style="list-style-type: none"> • We recommend the prompt replacement of the charger for patients who report or have reported excessive heating during charging. • For other patients, replacement of the charger is suggested at the next follow up. • Upon replacement, proper charging function of the Charging System Model 3726 should be confirmed. • Until such time that your patients have had their chargers replaced, please inform patients using Eon™ Wall Charger Model 3701 and/or Eon™ Portable Charger Model 3711 to continue charging following the supplemental instructions provided in our July 2012 letter: <ul style="list-style-type: none"> • If the temperature at the implant site becomes uncomfortable during charging: <ul style="list-style-type: none"> ○ Stop charging until the discomfort subsides and then resume

	<p>charging;</p> <ul style="list-style-type: none"> ○ Reposition the charging antenna over the implant site; ○ Consider recharging more frequently for less time; ○ If the temperature continues to be uncomfortable, please contact your physician, SJM representative, or St. Jude Medical Technical Services. ● Avoid tightly inserting the charging wand between the body and a surface that may trap heat, such as a bed or chair. ● Use of topical anaesthetics, medicated balm, and/or pain relief patches on the implant site prior to or during charging is not recommended, as it may reduce the ability to perceive heat or warmth near or at the implant site. ● Do not charge the device while asleep. ● Do not consume alcohol immediately prior to or while charging.
Further information and support	<p>Your St. Jude Medical representative is at your disposal to support you with the implementation of this action.</p>