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Company Reg.: 2003/001618/07
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www.xavant.com

Urgent Field Safety Notice

PRODUCT AFFECTED	**STIMPOD NMS450 Nerve Stimulator**
MANUFACTURER	Xavant Technology (Pty) Ltd
PRODUCT CODE	XT-45011, XT-45011-NA, XT-45001 and XT-45001-NA
DATE OF NOTICE	20 MARCH 2014
TYPE OF ACTION	Device advisory
FSN REFERENCE:	**FSN450-14002**

Attention: Distributors, Product Specialists, Anesthesiologists, Ward Managers, Sisters

Details on affected devices:

STIMPOD NMS 450 Neuromuscular Stimulator manufactured by Xavant Technology. The unit is supplied in a black carry case with the Xavant Technology logo. It contains a unit, 3 cables and an instruction for use (IFU).
The product code is XT-45011, XT-45011-NA, XT-45001 and XT-45001-NA, indicated on the label affixed to the front left of the lid of the carry case.

Description of the problem:

It has come to the manufacturer's attention that in isolated incidences (less than 0.003%) while using the device in NMBA monitoring mode, electrodes used may deteriorate to a level where current densities may be large enough to cause superficial burns on the skin of the patient. It is imperative that users are properly trained to monitor the impedance of the electrode/ skin impedance through the actual current delivered function in NMBA mode with all Stimpod NMS450s.The occurrence of such phenomena is not a direct malfunction of the device but rather a lack of training on the impedance monitoring function of the Stimpod NMS450, leading to the continued use of deteriorated electrodes that cannot handle high current densities for extended periods of time.
All indications and research, as well as reports from the field indicate that the burn wound (if caused) will more than likely present as a first degree burn wound.

Advice on action to be taken by the user:

The following are some recommendations to avoid potential electrical burns

- Use Xavant NMBA Monitoring Electrodes (XT-45008)
- Alternatively use good quality paste-on electrodes
- Monitor the impedance of the electrode / skin junction during the procedure by comparing the current setting to the actual current delivered. The unit has a built in warning function where it will display a warning triangle if the variation between the set current and current delivered is more than 10%. If this occurs then the electrode must be changed.
- Avoid coiled wires against patients. These act as antennas and amplify currents.
- Have equipment regularly inspected by a biomedical engineer.
- Use only the minimal current needed for a specific procedure.
- ESU must always be properly grounded.
- Skin preparation should include gentle abrasion to reduce impedance to a minimum.
- If the procedure continues for longer than 2 hours, the electrodes should be changed for fresh, unused electrodes.
- Inspect the electrodes regularly for signs of deterioration (such as discoloration and cracking) and discontinue use if observed.

Transmission of this Field Safety Notice: (if appropriate)

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (If appropriate)

Please transfer this notice to other organisations on which this action has an impact. (If appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (if appropriate)

Contact reference person:

Name: Brian Rothman
Organisation: Xavant Technology
Address: Unit 201, The Tannery Industrial Park
309 Derdepoort Road
Silverton, Pretoria
South Africa
0184
Contact Number: +27 12 743 5959
Contact email: brian@xavant.com or support@xavant.com

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency

Brian Rothman
Quality Assurance and Regulatory Affairs Manager

25 MARCH 2014
Date:

FIELD SAFETY NOTICE – CUSTOMER REPLY FORM

Immediate action required – PLEASE complete form and return to Xavant Technology as soon as possible to the listed contact person.

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This receipt provides Xavant Technology (Pty) Ltd and subsequently the MHRA, with the means to monitor the progress of Field Safety Notices.

It is important that this acknowledgement form is returned for our records and to enable us to meet our obligations to notify the MHRA of non-responders

By signing this receipt of notice, it is acknowledged that the receiver has received, read, understood and carried out the respective actions as recommended in the FSN.

Acknowledgement of Receipt

Name:		**Date:**	
Signature		**Telephone:**	
Designation:		**Email:**	
Company:		**Address:**	