



Unit 102
The Tannery Industrial Park
309 Derdepoort Road
Silverton, 0184
Pretoria, South Africa
Tel: +27 12-743 59 59

Company Reg.: 2003/001618/07
E-mail: sales@xavant.com
www.xavant.com

Urgent Field Safety Notice

| | |
|-------------------------|--|
| PRODUCT AFFECTED | STIMPOD NMS410 / NMS450 Nerve Stimulator |
| MANUFACTURER | Xavant Technology (Pty) Ltd |
| PRODUCT CODE | XT-41000, XT-41000-NA, XT-41001, XT-41001-NA XT-45011, XT-45011-NA, XT-45001, XT-45001-NA |
| DATE OF NOTICE | 31 JANUARY 2014 |
| TYPE OF ACTION | Device advisory |
| FSN REFERENCE: | FSN450-14001 |

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

Details on affected devices:

STIMPOD NMS410 / NMS450 Neuromuscular Stimulator manufactured by Xavant Technology. The unit is supplied in a black carry case with the Xavant Technology logo. It contains a unit, relevant cables and an instruction for use (IFU). The product code is XT-41000, XT-41000-NA, XT-41001, XT-41001-NA, XT-45011, XT-45011-NA, XT-45001, 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 the user continues to use the device if the keypad has been broken or is damaged. The damage to the keypad could possibly be caused by wear and tear, the ingress of aggressive cleaning solutions or by abuse such as pressing the buttons with sharp objects like a pen, tweezers or long finger nails. This could cause the internal circuitry of the keypad to become exposed, which could potentially lead to an electric shock if the keypad and the electrodes are handled simultaneously. The occurrence of such phenomena is not a direct malfunction of the device but rather due to negligence.

Advice on action to be taken by the user:

If a user detects that there is damage to the keypad, a RMA form (Return Merchandise Authorisation) must be submitted to Xavant technology for approval to have the unit serviced. Xavant will instruct where to send the unit for servicing. The unit should not be used if the keypad is damaged or broken.

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 102, 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: | |