Verity Medical Ltd.
Unit 7, Upper Slackstead Farm, Farley Lane, Braishfield
Romsey, Hampshire SO51 0QL, United Kingdom
Tel: 01794 367 110, Fax: 01794 367 890,
email: sales@veritymedical.co.uk

Urgent Field Safety Notice (FSN)

Commercial name of the affected product: ***Neurotrac™ MyoPlus2***
FSCA-identifier: ***QF18b – 01/11 dated 24.05.2011***
Type of action: ***Recall***
Date: ***26.05.2011***
Attention: ***To Whom It May Concern***

Details on affected devices:

Model name and number: MyoPlus2 , model number: MYO220
Batch number: Batch number: 2011 MYO220 001
Serial numbers range of affected devices: 00001 ~ 00055

Description of the problem:

Dear Customer:

This is to let you know that we have found an anomaly in the software in a limited number of MyoPlus 2 devices. The serial numbers of the devices concerned range from 00001 to 00055 inclusive.
In certain circumstances (both stimulation Channels turned up, the difference in intensity level between the channels is more than 5 mA), this anomaly can cause the muscle stimulation output of channel 1 to stop increasing when the display on the LCD passes 45 mA. Even though continued pressing of the Channel 1 "mA+" control button increases the reading on the LCD display up to the maximum of 90mA the actual output stays at 45mA.
However, if and when intensity of Channel 2 is increased, as when you pass 47mA, Channel 1 immediately corrects itself so that the output mA is the same as the LCD display for Channel 1.
The same problem exists in Channel 2 if channel 2 is the first to be turned up past 45 mA and then Channel 1 is increase above 47mA.
Potential hazardous situation associated with use of the device is a sudden surge of stimulation on one of the output channels which could be experience by users as unpleasant shock sensation.

Advice on action to be taken by the user/distributor:
There have been no complaints or adverse events reported to us due to this problem and we do not believe that this problem could result in a serious injury however If you have any of the devices within the serial ranges identified above please:

- *Immediately identify and quarantine the devices*
- *Confirm receipt of Field Safety Notice by signing Confirmation of Receipt and sending it back to us.*
- *Return the devices to us for software upgrade.*

Transmission of this Field Safety Notice: (if appropriate)
This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (If appropriate)
Please transfer this notice to other organizations 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:

If you should have any questions regarding this information, please contact Verity Medical at sales@veritymedical.co.uk or by telephone : 01794 367 110

We regret this inconvenience, but we believe this action is necessary to mitigate any potential risk that may be associated with the use of these devices.

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

Sincerely,

[redacted]

[redacted]
Managing Director of Verity Medical Ltd.