Moving Rehabilitation Forward™

CHATTANOOGA GROUP

January 8, 2008

Urgent Field Safety Notice

Dear User:

Chattanooga Group is immediately initiating a field correction for the following electrotherapy devices due to a malfunction and potential for electrical shock and burn:

Unit Name	Model Number	Serial Number Range
INTELECT XT	MODEL No. 2760	SERIAL Nos. 1000-5886
INTELECT LEGEND XT	MODEL No. 2763	SERIAL Nos. 1000-1683
VECTRA GENISYS	MODEL No. 2761	SERIAL Nos. 1000-5047
VECTRA GENISYS	MODEL No. 2764	SERIAL Nos. 1000-1713
VECTRA TRANSPORTABLE	MODEL No. 2783	SERIAL Nos. 1000-1615
INTELECT VET	MODEL No. 2756	SERIAL Nos. 1000-1140
INTELECT VET	MODEL No. 2843	SERIAL Nos. 1000-1015
INTELECT ADVANCED COMBO	MODEL No. 2752CC	SERIAL Nos. 1000-1079
INTELECT ADVANCED STIM	MODEL No. 2755CS	SERIAL Nos. 1000-1017
INTELECT ADVANCED COMBO	MODEL No. 2762CC	SERIAL Nos. 1000-3993
INTELECT ADVANCED STIM	MODEL No. 2765CS	SERIAL Nos. 1000-1452
INTELECT ADVANCED COMBO	MODEL No. 2772MC	SERIAL Nos. 1000-3002
INTELECT ADVANCED STIM	MODEL No. 2773MS	SERIAL Nos. 1000-2018
INTELECT MOBILE COMBO	MODEL No. 2778	SERIAL Nos. 1000-3541
INTELECT MOBILE STIM	MODEL No. 2777	SERIAL Nos. 1000-2799

Chattanooga Group has received 60 complaints of these devices malfunctioning. This malfunction causes the printed circuit board to change the stimulatory patient output from the intended output to an unintended higher voltage output. When such a malfunction occurs, it results in a shock sensation and possible burn to the area beneath the electrode pads where the malfunction occurred.

If you have any of the devices within the serial ranges identified above, immediately discontinue the use of the device and follow the instructions for downloading the ***PCB 2.3 Revision Stimulator Software Upgrade***. This software upgrade is designed to repair the malfunction in the device. The process should take less than 30 minutes and only requires insertion of a software card or attachment of a USB device containing the software upgrade. If you need to upgrade multiple devices the software card or USB device enclosed can be reused to upgrade as many devices as necessary.

You will receive a free extended one-year warranty for your electrotherapy product once the upgrade confirmation is received by Chattanooga Group.

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In accordance with U.S. Food and Drug Administration (FDA) guidance and applicable international directives and guidance, please register the device(s) upgrade as directed by one of the following:

1. go online to www.chattgroup.com/productupdate
2. fax the enclosed Product Upgrade Fax Sheet to +1-423-870-7491
3. mail the Product Upgrade Fax sheet to Chattanooga Group, P.O. Box 489, Hixson, TN USA 37343

It is imperative that all upgrades are tracked by one of the above mentioned methods. This field correction will be audited by the FDA and other governmental authorities.

If you need assistance, cannot perform the software upgrade, or if you have any related questions or concerns, please do not hesitate to contact us at our corporate office in the US at +1-423-870-7267 or by email at Product_UpdateInternational@chattgroup.com.

We regret this inconvenience, but we believe this action is necessary to mitigate any risk that may be associated with the use of these devices. The first priority at Chattanooga Group is to create safe, effective and innovative product that provide real-world solutions for clinicians and their patients. Our goal is not only to make great products, but also to make a positive impact on the lives of people who use them.

Sincerely,

Michael Treas,
Manager of Regulatory Affairs, Chattanooga Group