URGENT: MEDICAL DEVICE CORRECTION AND REMOVAL NOTIFICATION

February XX, 2013

Customer Name
Facility Name
Facility Address
City, State/Country, Postal Code

RE: Urgent Field Correction and Removal Notice for the Nicolet™ EEG Wireless Amplifier

Dear Valued Customer:

You are receiving this urgent Field Correction and Removal notice because you have purchased a Nicolet™ EEG Wireless Amplifier. Action is required by you to ensure the appropriate continued use of these products.

The Nicolet™ EEG Wireless Amplifier may overheat and become uncomfortable to touch around the area of the on/off button. The overheating may result in discomfort ranging from too hot up to the potential for a burn.

Our records indicate that you have purchased the following items from Natus Neurology Incorporated:

PO#	Part Number	Description	Quantity	Shipment Date	Order #

{Customer Specific information entry}

Your Nicolet Wireless Amplifier(s) will be replaced at no cost to you. A Field Service Technician will contact you to set up a time to install the replacement amplifier(s). Once the replacement unit is installed, the defective unit will be returned to Natus Neurology Incorporated.

This urgent correction and removal has been reported to the U.S. Food and Drug Administration and global regulatory agencies in accordance with applicable requirements.

If you have transferred any of these products to another location, please forward a copy of this urgent correction and removal notification to that location and notify Natus, Attention: Sue Niesen, at (800) 356-0007 ext. 5129, or via email at susan.niesen@natus.com of this transfer.

Thank you in advance for your support and timely cooperation in this matter.

Sincerely,

Robert J. Burdge

Director, Quality and Regulatory Affairs
Natus Neurology Incorporated
1850 Deming Way
Middleton, WI USA 53562
(608) 829-8655
robert.burdge@natus.com

Enclosures (as applicable)
Attachment A - Verification Form (Enclosed in letter)

URGENT MEDICAL DEVICE CORRECTION and REMOVAL NOTIFICATION

Attachment A: HARDWARE REPLACEMENT VERIFICATION

TO BE COMPLETED BY NATUS FIELD SERVICE TECHNICIAN

Customer Name
Facility Name
Facility Address
City, State Country Postal Code

Certification that these corrective actions have been completed

{Duplication of TABLE from letter – remove once populated}

EEG WIRELESS AMPLIFIERS replaced:

I have replaced (number) ___ EEG Wireless Amplifier(s) as follows:

	Serial number removed from service	Serial number placed into service
1.		
2.		
3.		
4.		
5.		
6.		

Name of Person completing these actions (please print):

Signature: _____ Date: _____

Title: _____ Telephone number: _____

Email: _____

Complete the fields below if changed from the information above:

Facility Name _____

Facility Address: _____

City, State, Zip _____

Return verification form via one of the following methods:

a. FAX to the ATTENTION of:

Natus Neurology Incorporated
Regulatory Affairs Department
Fax #: 608-829-8517

Or

b. MAIL to the ATTENTION of:

Ms. Sue Niesen
Regulatory Affairs
Natus Neurology Incorporated
1850 Deming Way
Middleton, WI USA 53562

Or

c. EMAIL (PDF) to the ATTENTION of: Susan.Niesen@natus.com

If you have any questions on this matter please contact Ms. Sue Niesen at 800-356-0007 X 5129