

**URGENT: MEDICAL DEVICE CORRECTION NOTIFICATION**

September 08, 2015

**RE: Urgent Medical Device Correction Notification for the NicoletOne Software v5.94**

Dear Valued Customer:

You are receiving this urgent Field Correction notice because you have purchased NicoletOne v5.94 software between the dates of May 20, 2015 and June 24, 2015.

Natus has discovered that when using the NicoletOne v5.94 software, after exiting the impedance check function and returning to the EEG screen, the impedance check signal remains active in waveform, obscuring the EEG signals. This could result in the inability to record or assess real-time EEG data leading to missed or delayed diagnosis or clinical intervention.

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

<u>PO#</u>	<u>Part Number</u>	<u>Description</u>	<u>Quantity</u>	<u>Shipment Date</u>	<u>Order #</u>
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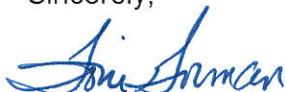
A Field Service Technician (FST) will contact you to set up a time to install the new NicoletOne v5.94.1 software, which has corrected this issue.

Once this software has been installed, we ask that the Recipient or Field Service Technician complete and return Attachment A: Verification Form enclosed in this letter.

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

Thank you, in advance, for your support and timely cooperation.

Sincerely,



Toni Gorman  
Quality Assurance Manager  
Natus Neurology Incorporated  
3150 Pleasant View Road  
Middleton, WI USA 53562



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Enclosures (as applicable)

Attachment A - Verification Form (Enclosed in letter)

Attachment A:

**VERIFICATION FORM**

*TO BE COMPLETED BY RECIPIENT or FIELD SERVICE TECHNICIAN*

**Certification that this corrective action has been completed**

*I have updated the NicoletOne system software to version 5.49.1 on the following Nicolet system(s). List Serial Number(s) of NicoletOne systems corrected: \_\_\_\_\_*

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**Name of Person completing these actions (please print):**

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Title: \_\_\_\_\_ Phone: \_\_\_\_\_

Facility Name \_\_\_\_\_

Address: \_\_\_\_\_

City, State Zip \_\_\_\_\_

Telephone number: \_\_\_\_\_

Email: \_\_\_\_\_

Please return this verification form by any of the following methods:

Email PDF to: [Susan.Niesen@natus.com](mailto:Susan.Niesen@natus.com)

Fax to: Regulatory Affairs, Attn: Susan Niesen at: 608-829-8771

Mail to:

Susan Niesen  
Regulatory Affairs Specialist  
Natus Neurology Incorporated  
3150 Pleasant View Road  
Middleton, WI 53562