

## Advisory Notification

**RE: Advisory Notice for the EMU40/EMU40EX Breakout Box**

Date: June 25, 2018

Dear Valued Customer,

**Attention: Please distribute this letter to all associated parties within the organization.**

You are receiving this advisory notification because our records indicate you have purchased the following EMU40/EMU40EX Breakout Boxes:

| Serial Number |
|---------------|
|               |
|               |

Natus has discovered in specific rare situations, due to degradation of an internal electronic component over time the EMU40/EMU40EX Breakout Box may fail. This rare case of component degradation occurs over time and occurs when the Breakout Box exceeds its expected lifespan (7 years).

While there have been no reports of patient harm this situation may cause blackening of EMU40/EMU40EX Breakout Box enclosure, smoke and burning smell but not in all cases. In cases where this does occur we advise that you to stop using the device immediately and contact Natus regarding your replacement options.

Additionally, we recommend that you no longer use the device in the Operating Room environment.

Please communicate this information to all applicable users. Once you have communicated to all applicable users, please complete the attached form and return it to the email or fax number below.

**Email:** [Emu40FCA@natus.com](mailto:Emu40FCA@natus.com)

**Fax:** 905-829-5304

This medical device advisory notification has been reported to the U.S. Food and Drug Administration and global regulatory agencies in accordance with applicable requirements.

Thank you for choosing Natus Neurology for your Neurology needs. We apologize for any inconvenience this may have caused.



Excel-Tech, Ltd (XLTEK) Division

Natus Medical Incorporated  
2568 Bristol Circle, Oakville, ON, L6H 5S1

**EMU40/EMU40EX Breakout Box Advisory  
Verification Form**

To Be Completed by Recipient

\_\_\_\_\_ Yes, I have communicated this information to all applicable users

\_\_\_\_\_ Device(s) is no longer in service, Serial No: \_\_\_\_\_

\_\_\_\_\_ Other, please explain: \_\_\_\_\_

\_\_\_\_\_

Name of person completing the Form (Please Print)

Name: \_\_\_\_\_

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

Company: \_\_\_\_\_

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

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

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

Signature of Person Completing this Form: \_\_\_\_\_

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

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

Email: [Emu40FCA@natus.com](mailto:Emu40FCA@natus.com)

Fax: 905-829-5304

Mail to: Technical Support (EMU40 FCA)

Excel-Tech, Ltd (XLTEK)

Natus Medical Incorporated

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