

URGENT RECALL NOTIFICATION / FIELD NOTICE

Date

Distributor

Address

Address

City State Zip

Country

Dear Valued Distributor,

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

You are receiving this Urgent Recall Notification/Field Recall notice because you have ordered an Elite 2 or 3 MHz Obstetric probe or a 5 MHz Vascular probe, either with an Elite Doppler system or an Elite probe individually.

Natus has discovered that when using the Elite 2 and 3 Obstetric probes and 5 MHz Vascular probes may exhibit excessive background noise that may mask the user's ability to clearly hear heart rate and/or blood flow.

For your convenience, we have attached a photo to help identify the probe and serial number. We ask that you forward the attached customer letter, verification form and photo to customers impacted by this field action. **Translate the letters as applicable.**

This Field Action is being reported to the U.S. Food and Drug Administration. **If required by local country regulations, please report this field action without delay to your competent authority or regulatory agency.** Please let Natus Neurology know when you report, or contact Natus Neurology for assistance in reporting if needed.

There are two options available to you for providing this important information to your customer.

You have two options available to you:

Option 1 – As a distributor, you are authorized to complete the Verification Form on behalf of your customer and return it to Janessa Boone, Complaint Specialist at the e-mail listed below.

Option 2 – If your customer decides to return their functioning probe (serial # indicated below) for replacement, please have them contact you directly. Natus will replace functioning probes free of charge that are returned following the process described below. We ask you, as our distributor, to please contact Janessa Boone to get a return authorization number and instructions on returning the probe(s). We would also ask that you make an effort to consolidate shipments when returning multiple probes. Natus will be responsible for freight, taxes and duty charges for both directions. Only probes that are returned in functioning order will be replaced.

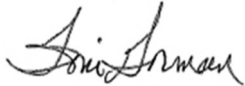
In either case, we ask that the completed verification form be forward to the contact below:

Email: Janessa.boone@natus.com
Fax: 608-829-8771

Probe Ordered in Catalog Number	Probe Part Number	Probe Description	P.O. Number	Date of Shipment	Serial Number

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

Sincerely,



Toni Gorman
Quality Assurance Manager
Natus Neurology Incorporated
Nicolet® Brand Products
3150 Pleasant View Road
Middleton, WI 53562
(800)356-0007

Enclosure: Photo, Customer Letter and Verification Form

Letter on Distributor letterhead

URGENT RECALL NOTIFICATION / FIELD NOTICE

Date:

Customer
Address
Address
City State Zip
Country

Dear Valued Customer,

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

You are receiving this Urgent Recall Notification/Field Recall notice because you have ordered an Elite 2 or 3 MHz Obstetric probe or a 5 MHz Vascular probe, either with an Elite Doppler system or an Elite probe individually from;
Insert Distributor Name here.

Natus has discovered that when using the Elite 2 and 3 Obstetric probes and 5 MHz Vascular probes may exhibit excessive background noise that may mask the user's ability to clearly hear heart rate and/or blood flow. For your convenience, we have attached a photo to help identify the probe name and serial number.

This Field Action is being reported to the U.S. Food and Drug Administration. **If required by local country regulations, please report this field action without delay to your competent authority or regulatory agency.** Please let Natus Neurology know when you report, or contact Natus Neurology for assistance in reporting if needed.

Please complete the attached verification form. Natus will replace functioning probes free of charge that are returned following the process described below.

Once you have completed the verification form, please return it to **Insert Distributor Name Here** by one of the means described below. To return the probe, we ask that you contact the individual below to make arrangements for returning your probe for replacement. **Note, only probes that are returned in functioning order will be replaced.**

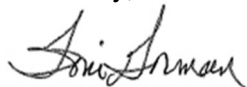
Please contact:

Distributor Contact Name
Distributor Contact E-mail
Distributor Contact Phone #
Distributor Contact Fax #

Probe Ordered in Catalog Number	Probe Part Number	Probe Description	P.O. Number	Date of Shipment	Serial Number

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

Sincerely,



Toni Gorman
Quality Assurance Manager
Natus Neurology Incorporated
Nicolet® Brand Products
3150 Pleasant View Road
Middleton, WI 53562
(800)356-0007

Enclosures: Verification Form and Photo

Verification Form

To Be Completed by Recipient

Customer
Department
Address
City, State Zip
Country

_____ Yes, I am returning this device, Serial No: _____

_____ Probe does not exhibit excessive static

_____ Device is no longer in service, Serial No: _____

_____ I acknowledge this notification and choose not to return the probe,

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:

Distributor Contact Name
Distributor Contact E-mail
Distributor Contact Phone #
Distributor Contact Fax #