

Urgent Field Safety Notice: Recall

Commercial name of affected product: Surface Temperature Probe, part 268-411800
FSCA – identifier: V40894
Type of action: Recall

Date:

Customer
Address
City, State Zip
Country

Dear Valued Customer,

You are receiving this Field Safety Notification because our records indicate you have purchased Surface Temperature Probe, 268-411800 from Natus Neurology Incorporated. All lots are affected for this recall.

Details on affected devices:

Device: Surface Temperature Probe
See attached consignee list.

GMDN Code: 154
Intended Use: Measures body temperature

Manufacturer Name: Measurement Specialties (TE)
Contact: Lisa Parkos
Email: lisa.parkos@te.com

Description of the problem:

This medical device does not contain a CE mark, yet it was distributed in Europe, which is not compliant with the Medical Device Directive. Natus became aware of this issue when we conducted a review of our product labeling.

Corrective Action:

Destroy all Surface Temperature Probes, part 268-411800.

For product that has not been consumed, take a picture of the product, complete the attached certificate of destruction form and return the form and pictures to the contact person listed below. Upon receipt of the certificate of destruction, a credit for the cost of the product will be issued.

Transmission of this Field Safety Notice

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



Return forms and pictures to Janessa Boone by email or fax by October 30, 2019.

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

This medical device recall notification has been reported to the applicable regulatory agencies in accordance with regulatory requirements.

There have been zero reported injuries related to use of this product.

Our records indicate you have received the following device(s):

Part No.	Description	Ship Date	Lot#

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

Respectfully,

Toni Gorman
Quality Assurance Manager
Natus Neurology Incorporated/Nicolet® Brand Products
3150 Pleasant View Road
Middleton, WI 53562
608-829-8600

Enclosure:
Surface Temperature Probe Verification Form
Certificate of Destruction



**Field Safety Notice
Surface Temperature Probe
Verification Form**

To Be Completed by Recipient

_____ Certification of Destruction with pictures are attached

_____ Device(s) have been consumed

Number of Devices Consumed: _____

_____ Other, please explain: _____

Part No.	Description	Ship Date	Lot No.

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 PDF to: Janessa.boone@natus.com

Fax to: Attn: Janessa Boone at: 608-829-8771

Mail to:

Janessa Boone, Complaint Specialist

Natus Neurology Incorporated

3150 Pleasant View Road

Middleton, WI 53562

natus [®]	DOCUMENT NUMBER FRM 0236 / DCO#33702 / DOC-037394	Page 1 of 1
	TITLE Certification of Destruction	REV 01

CERTIFICATE OF DESTRUCTION

It is hereby certified that the product(s) listed below have been completely destroyed and rendered unusable.

Part Number(s): _____

Method of Destruction:

Quantity Destroyed: _____

Full Signatures Required:

Destroyed By: _____

Title: _____

Date: _____

Witness: _____

Title: _____

Date: _____

Attach picture that includes number of device to be destroyed