

URGENT
FIELD SAFETY NOTICE (FSN)
MEDICAL DEVICE RECALL
MULTIPLE GOLD CUP ELECTRODES and SNAP ELECTRODE LEADS

Date: XXX 2019

(Customer
Address
City, State Zip
Country)

Re: SR - _____

Natus reference: CAPA004513

Dear Valued Customer,

Information on Affected Device

Device Description & Intended use

The snap electrode leads are used in conjunction with disposable electrodes and the Gold Cup electrodes are reusable electrodes and leads. Both types of electrodes and leads are used for evoked potential testing for audiological, neurological and/or vestibular testing. The electrode leads are connected to the main device by the electrode lead connector and the electrode is attached to the patient contact end of electrode lead. The device is to be used only by qualified medical personnel with prior knowledge of the medical and scientific facts underlying the procedure.

Commercial name and part numbers affected

Multiple electrode leads

See Affected Part numbers attached

Reason for Field Safety Corrective Action

Description of issue

You are receiving this notification because Natus Medical Denmark, going on the market under the GN Otometrics A/S brand name, is conducting a voluntary recall for the gold cup electrodes and electrode leads. Our records show that you received at least one of the gold cup electrodes and snap electrode lead at your location. The electrode lead connector has a protruding conductor beyond insulation of approximately 0.1 mm.



Image 1: Electrode lead connector to main device.



Snap Electrode Lead Identification

Snap, cable, and connector are all the same color: red, blue, green, brown, orange, white, black, or yellow. The connector has an angled taper as shown in the image below. No text or actual printed/molded identifiers are located on the leads.



Image 2: Snap Electrode lead

Cup Electrode Lead Identification

Connector and cable have the same color; there is a white transition between the cup and cable. The connector has an angled taper as shown in the image below. No text or actual printed/molded identifiers are located on the leads.



Image 3: Cup Electrode lead

Hazard giving rise to the FSCA

It has been determined that the device does not fully meet the current regulatory standard for basic electrical safety and essential performance. There is a potential risk to the healthcare professional or patient of exposure to electrical shock from the electrode connector.

There have been zero reported injury related events to date. Natus requests that you do not use the gold cup electrodes and snap electrode leads.

Type of Action Required

Please review and complete the accompanying instructions to help you return your gold cup electrodes or snap electrode leads or contact Natus or your Authorized Natus Distribution Partner for assistance in returning your gold cup electrodes or snap electrode leads. Once the gold cup electrode or snap electrode leads are received back, you will receive an alternative replacement product or refund depending on the age of the device and your region.



General Information

FSN Type: Recall

Natus requests that you do not use the electrode leads and return them.

Further information or advice

While there have not been any reported safety incidences, our commitment to providing only the highest quality products and information to our customers and distribution partners is our top priority. We sincerely apologize for any inconvenience this may cause. If there are any questions about this notice, please contact Natus or your authorized Natus distributor.

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the affected gold cup electrodes and electrode leads have been transferred.

Please implement the requested action and maintain this notice in your files for reference of the corrective action,

Please report all gold cup electrodes and electrode leads related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

EU customers only: The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

Attached

Instructions for device return
Customer Reply Form
List of affected part numbers

INSTRUCTIONS FOR DEVICE RETURN

We kindly ask that you initiate the following activities immediately:

1. Identify and quarantine the affected electrode leads. Cease use of all affected electrode leads immediately.
2. Review this communication in its entirety and ensure that all users of the listed products in your organization are informed of this notification.
3. Distribute this notification to all associated parties within your organization.
4. Complete and return the Verification Form enclosed in this letter via e-mail, fax or postal mail.
5. Contact Natus or your Authorized Natus Distribution Partner for assistance in returning your gold cup electrodes or snap electrode leads.
6. Return the electrode leads to the below address with a copy of the completed customer reply form:

US Customers

Natus Medical
50 Commerce Dr., Suite 180
Schaumburg, IL 60173
USA

Rest of World

Natus Medical Denmark
Hoerskaetten 9
Taastrup
Denmark, 2630



CUSTOMER REPLY FORM

TO BE COMPLETED BY RECIPIENT

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

Please complete for received items

1. We hereby declare that we are aware of the gold cup electrodes and snap electrode leads recall by Natus Medical Denmark effective **XXX** 2019.
2. Please mark as appropriate:
 - We do not have any of the affected products/The affected device was disposed of
 - We do have the affected product(s) and will return it/them.

Return this form via fax or email and MAIL any affected products, --the gold cup electrodes and/or snap electrode leads to the appropriate address below.

Please include the quantity of items to be returned on the Affected Part Numbers page below.

Return addresses

US Customers

Natus Medical
 50 Commerce Dr., Suite 180
 Schaumburg, IL 60173
 USA

Rest of World

Natus Medical Denmark
 Hoerskaetten 9
 Taastrup
 Denmark, 2630

Name of Person completing these actions (please print):

Signature: _____ Date: _____

Print name: _____ Email: _____

Title: _____ Phone: _____

Return verification form via one of the following methods:

- a. Email: OtoChartrLeads@natus.com
- b. FAX: +4577311553



AFFECTED PART NUMBERS

Part Number	Component Description	Quantity of affected part number being returned
7590310-24	24" Snap Leadwire, Blue	
7590310-40	40" Snap Leadwire, Blue	
7590311-24	24" Snap Leadwire, Red	
7590311-40	40" Snap Leadwire, Red	
7590312-24	24" Snap Leadwire, Green	
7590312-40	40" Snap Leadwire, Green	
7590313-24	24" Snap Leadwire, Brown	
7590313-40	40" Snap Leadwire, Brown	
7590314-24	24" Snap Leadwire, Orange	
7590314-40	40" Snap Leadwire, Orange	
7590315-24	24" Snap Leadwire, White	
7590315-40	40" Snap Leadwire, White	
7590316-24	24" Snap Leadwire, Black	
7590316-40	40" Snap Leadwire, Black	
7590317-24	24" Snap Leadwire, Yellow	
7590317-40	40" Snap Leadwire, Yellow	
7590318-24-5	24" Snap Leadwire, Set of 5	
7590318-24-7	24" Snap Leadwire, Set of 7	
7590318-40-5	40" Snap Leadwire, Set of 5	
7590318-40-7	40" Snap Leadwire, Set of 7	
7590319-24-5	24" Snap Leadwire, Set of 5	
7590319-40-5	40" Snap Leadwire, Set of 5	



7590440	48" Gold Cup Leadwires, Blue	
7590441	48" Gold Cup Leadwires, Red	
7590442	48" Gold Cup Leadwires, Green	
7590443	48" Gold Cup Leadwires, Brown	
7590444	48" Gold Cup Leadwires, Orange	
7590445	48" Gold Cup Leadwires, White	
7590446	48" Gold Cup Leadwires, Black	
7590447	48" Gold Cup Leadwires, Yellow	
7590450-5	48" Gold Cup Leadwires, Set of 5	
7590450-8	48" Gold Cup Leadwires, Set of 8	