DOC-038815/01

natus

otometrics
a division of natus

URGENT
FIELD SAFETY NOTICE (FSN)
MEDICAL DEVICE RECALL
ICS CHARTR EP200

Date: 24 September 2019

(Customer
Address
City, State Zip
Country)

cc: Chairman Medical Board and relevant Head of Departments

Re: Field Safety Corrective Action (FSCA) for ICS CHARTR EP 200: Follow-up
(Ref: HSA 600:41/01-104/19/01_68)

Dear Valued Customer,

Follow Up: Action Required
Information on Affected Device

Device Description & Intended use
The ICS Chartr EP200 records auditory and vestibular evoked potentials. It is used to make inferences about hearing levels, assess the integrity of the hearing nerve, assess central auditory processing and also assess some structures related to balance. Evoked potentials are recorded, displayed and measured on the ICS Chartr EP200. 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
ICS Chartr EP200
See Affected Part numbers attached

Reason for Field Safety Corrective Action

Description of issue

You recently received a Field Safety Notice to communicate an issue with the ICS Chartr EP200 device. As previously communicated Natus Medical Denmark, going on the market under the GN Otometrics A/S brand name, is conducting a voluntary field corrective action for the ICS Chartr EP200 device. Our records show that you received at least one of the ICS Chartr EP200 device at your location.

We realize the severity of this action and understand the challenges it presents for you as a valued Natus customer. 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 the inconvenience caused through this process, and appreciate your patience as we worked towards the solution.

Hazard giving rise to the FSCA
It has been determined that the device does not fully meet 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.

Type of Action Required

We are pleased to share that we have determined a solution for repair that will address the safety issues described above. The repair solution will be available starting September 30, 2019.

In order to enable this repair, you will be required to ship the device to Natus. To facilitate this process, we will be sending you a postage-paid box for shipping with detailed return instructions included.

- **If you have already returned the customer reply form** (attached), please contact your Authorized Natus Distributor to arrange return of the device.
- **If you have not returned the customer reply form** (attached), please review and complete the attached customer reply form to confirm that you have received this letter. Please contact your Authorized Natus Distributor to arrange return of the device.

Once the repair has been completed, the device will be shipped back to you or your Authorized Natus Distributor.

In addition to the repair, please note that we are adding the following warnings to the instructions for use:

Warning: Do not touch the output DC plug of the power supply, or any Chartr EP 200 device connectors AND the patient at the same time.

Warning: The DC power supply ring terminal wire (Green/Yellow) must always be securely attached to the DC Power Functional Earth Connection on the Chartr EP 200 Back Panel when operating the device.

General Information

FSN Type: Update

Natus requests that you return the ICS Chartr EP200 system. Natus continues to request that you do not use the system in the interim.

Further information or advice
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 potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organizations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback

The Competent Authority of your country has been informed about this communication to customers.

Attached
Customer Reply Form
List of affected part numbers

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CUSTOMER REPLY FORM

TO BE COMPLETED BY RECIPIENT

Customer Name: _____
Facility Name: _____
Facility Address: _____
City, State Country _____
Postal Code _____
Email address: _____
Contact Name: _____
Phone Number: _____
SR number: _____

Please complete/correct any details above if inaccurate.

Please complete for received items

1. We hereby declare that we are aware of the medical device recall by Natus Medical Denmark.
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.

List Serial Number(s) of affected devices:

_____

_____

Name of Person completing these actions (please print):

Signature: _____ Date: _____

Title: _____ Phone: _____

Return verification form via one of the following methods:

a. **Email:** ra@surgipro.com.sg
b. **Fax:** 6894 6036

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AFFECTED PART NUMBERS

Product name	Part number	Component Description
ICS CHARTR EP 200	8-04-12733	ICS Chartr EP 200 2Ch, TDH49 , 115/60
ICS CHARTR EP 200	8-04-12734	ICS Chartr EP 200 2Ch,Insert&Bone
ICS CHARTR EP 200	8-04-12731	ICS Chartr EP 200 2ch, 230 VAC (50 Hz) Incl. Insert Earphone, TDH49 Earhone w cable, Bone Conduction Transducer (B71), VEMP Monitor Kit and ASSR
ICS CHARTR EP 200	8-04-12730	ICS Chartr EP 200 2ch, 230 VAC (50 Hz) Incl. Insert Earphone, TDH49 Earhone w cable, Bone Conduction Transducer (B71) and ASSR
ICS CHARTR EP 200	8-04-12729	ICS Chartr EP 200 2Ch, 230 VAC (50 Hz) Incl. Insert Earphone, Bone Conduction Transducer (B71) and VEMP Monitor Kit
ICS CHARTR EP 200	8-04-12727	ICS Chartr EP 200 2Ch, 230 VAC (50 Hz) Incl. Insert Earphone, TDH49 Earhone w cable and VEMP Monitor Kit
ICS CHARTR EP 200	8-04-12725	ICS Chartr EP 200 2ch, 230 VAC (50 Hz) Incl. Insert Earphone, TDH49 Earhone w cable, Bone Conduction Transducer (B71), VEMP Monitor Kit, P300 and ASSR
ICS CHARTR EP 200	8-04-12723	ICS Chartr EP 200 2ch. 230 VAC (50 Hz) Incl. Insert Earphone, TDH49 Earhone w cable
ICS CHARTR EP 200	8-04-12721	ICS Chartr EP 200 2ch. 230 VAC (50 Hz) Incl. Insert Earphone
ICS CHARTR EP 200	8-04-12720	ICS Chartr EP 200 2ch. 230 VAC (50 Hz) Incl. Insert Earphone, TDH49 Earhone w cable, Bone Conduction Transducer (B71) and EU power cord.
ICS CHARTR EP 200	8-04-12711	1073 ICS Chartr EP 200 w/o Vemp, CN only
ICS CHARTR EP 200	8-04-12710	1073 ICS Chartr EP 200, CN only
ICS CHARTR EP 200	8-04-12703	1073 ICS Chartr EP 200 Insert, Bone & TDH49 2Ch, US only
ICS CHARTR EP 200	8-04-12702	1073 ICS Chartr EP 200 Insert, Bone 2 Ch, US only
ICS CHARTR EP 200	8-04-12701	1073 ICS Chartr EP 200 ROW 2 Ch.
ICS CHARTR EP 200	8-04-12700	1073 ICS Chartr EP 200 Insert 2 Ch, US Only
ICS CHARTR EP 200 LIMITED	8-04-12732	ICS Chartr EP 200 Limited, 1 ch, TDH49, 115/60
ICS CHARTR EP 200 LIMITED	8-04-12728	ICS Chartr EP 200 Limited, 1 ch Insert, Bone, TDH49 & VEMP Monitor Kit
ICS CHARTR EP 200 LIMITED	8-04-12726	ICS Chartr EP 200 Limited, 1 ch, TDH49
ICS CHARTR EP 200 LIMITED	8-04-12724	ICS Chartr EP 200 Limited, 1 ch Insert & TDH49
ICS CHARTR EP 200 LIMITED	8-04-12722	ICS Chartr EP 200 Limited, 1 ch, Insert
ICS CHARTR EP 200 LIMITED	8-04-12712	1073 Chartr EP 200 Limited, China
ICS CHARTR EP 200 LIMITED	8-04-12704	1073 Chartr EP 200 Limited