DOC-037554/01

natus

otometrics
a division of natus

URGENT
FIELD SAFETY NOTICE (FSN)
MEDICAL DEVICE RECALL
ICS CHARTR EP 200

Date: July 2019

(Customer
Address
City, State Zip
Country)

Re: SR -_____

Dear Valued Customer,

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 Urgent Field Safety Notice to communicate an issue with the ICS Chartr EP200 device. We realize the severity of this action and understand the challenges it presents for you as a valued Natus customer.

As previously communicated by 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 EP 200 device. Our records show that you received at least one of the ICS CHARTR EP 200 device at your location.

We have been working to determine a resolution and have identified a repair solution which will allow you to use the ICS Chartr EP200 device again. Natus continues to request that you do not use the system in the interim.
At this point we estimate that the solution will be available between September 2019 and March 2020 depending on the age of device that is in your possession.

We will continue to communicate after we work through the details of the solution, and will send a follow-up letter including specifics on repair solution and next steps.

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.
Natus requests that you do not use the system further.

Type of Action Required

Please review and complete the attached customer reply form to confirm that you have received this letter. Natus continues to request that you do not use the system in the interim.

General Information

FSN Type: Follow up

Natus requests that you do not use the Chartr EP 200 system.

Further information or advice
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 will cause. If there are any questions about this notice, please contact 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

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 _____

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 product in stock
   □ We do have the affected product and will not use it until further notified.

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: (fill per territory)
b. FAX: (fill per territory)

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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