



# **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







# **CUSTOMER REPLY FORM**

TO BE COMPLETED BY RECIPIENT

Customer Name: Facility Name:	
Facility Address:	
City, State Country	
Postal Code	
Please complete for red	ceived items
<ol> <li>We hereby declare that we a Denmark.</li> </ol>	are aware of the medical device recall by Natus Medical
2. Please mark as appropriate:	
□ We do not have any of the	•
□ we do have the affected p	roduct and will not use it until further notified.
List Serial Number(s) of affected de	vices:
Name of Person completing these	e actions (please print):
Signature:	Date:
Title:	Phone:
Return verification form via one o	of the following methods:
a. Email: (fill per territory)	







# **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 2ch, 230 VAC (50 Hz)
		Incl. Insert Earphone, TDH49 Earhone w cable,
		Bone Conduction Transducer (B71),
ICS CHARTR EP 200	8-04-12731	VEMP Monitor Kit and ASSR
		ICS Chartr EP 200 2ch, 230 VAC (50 Hz)
ICC CHAPTE ED 200	0.04.40700	Incl. Insert Earphone, TDH49 Earhone w cable,
ICS CHARTR EP 200	8-04-12730	Bone Conduction Transducer (B71) and ASSR ICS Chartr EP 200 2Ch, 230 VAC (50 Hz)
		Incl. Insert Earphone, Bone Conduction Transducer (B71)
ICS CHARTR EP 200	8-04-12729	and VEMP Monitor Kit
100 CHARTICE 200	0-04-12723	ICS Chartr EP 200 2Ch, 230 VAC (50 Hz)
		Incl. Insert Earphone, TDH49 Earhone w cable and
ICS CHARTR EP 200	8-04-12727	VEMP Monitor Kit
		ICS Chartr EP 200 2ch, 230 VAC (50 Hz)
		Incl. Insert Earphone, TDH49 Earhone w cable,
		Bone Conduction Transducer (B71), VEMP Monitor Kit,
ICS CHARTR EP 200	8-04-12725	P300 and ASSR
		ICS Chartr EP 200 2ch. 230 VAC (50 Hz)
ICS CHARTR EP 200	8-04-12723	Incl. Insert Earphone, TDH49 Earhone w cable
ICC CHAPTE ED 200	0.04.40704	ICS Chartr EP 200 2ch. 230 VAC (50 Hz)
ICS CHARTR EP 200	8-04-12721	Incl. Insert Earphone ICS Chartr EP 200 2ch. 230 VAC (50 Hz)
		Incl. Insert Earphone, TDH49 Earhone w cable,
ICS CHARTR EP 200	8-04-12720	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
	8-04-12702	
ICS CHARTR EP 200		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	00112102	ICS Chartr EP 200 Limited, 1 ch Insert, Bone, TDH49 & VEMP
LIMITED	8-04-12728	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	0.04.40705	100.01 / 50.001 / 1.4 / 1.4
LIMITED	8-04-12722	ICS Chartr EP 200 Limited, 1 ch, Insert
ICS CHARTR EP 200	0.04.40740	1072 Charte ED 200 Limited Chica
LIMITED	8-04-12712	1073 Chartr EP 200 Limited, China
ICS CHARTR EP 200 LIMITED	8-04-12704	1073 Chartr EP 200 Limited
LIIVII I ED	0-04-12/04	10/3 Charli Er 200 Lillilleu

