

Subject: Field Safety Notice - Heating of nordicAudio Headsets

FSCA Identifier: CAPA-113

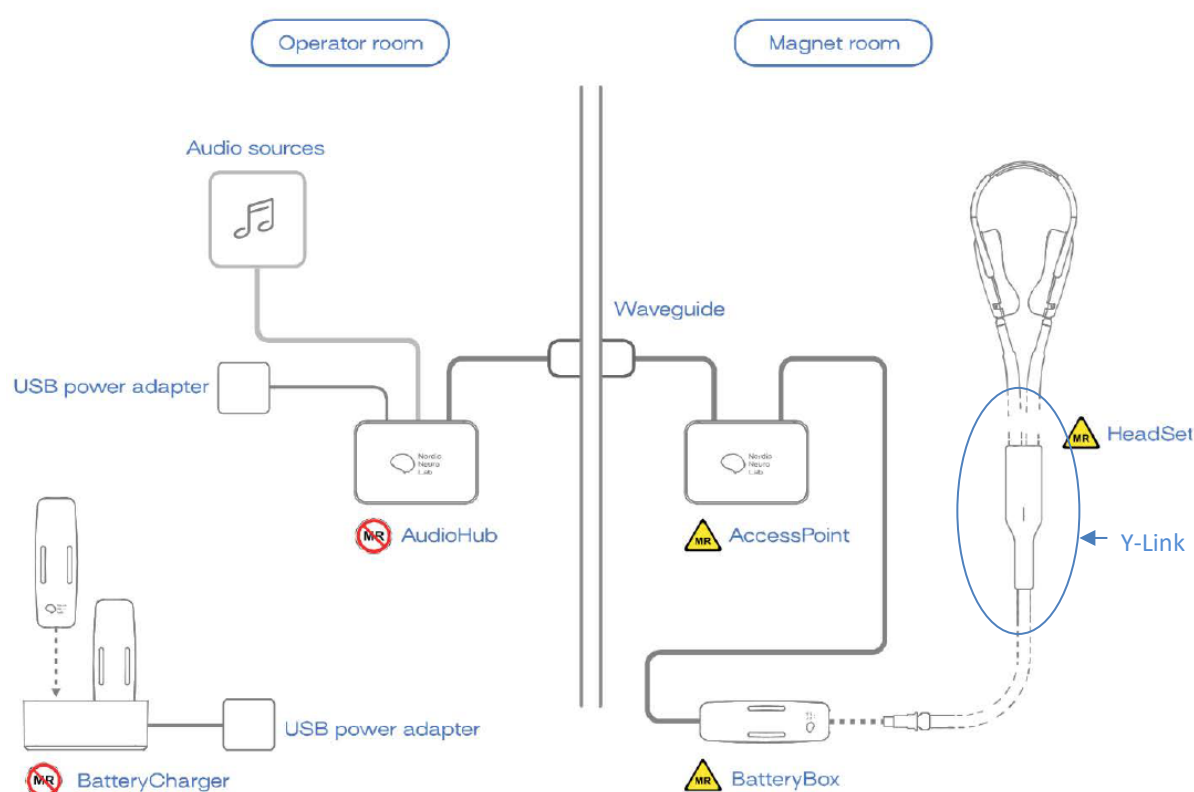
Type of action: Field Safety Corrective Action

Date: 2026-08-20

Attention: **All staff who may use or handle the following devices**

Information on affected device:

nordicAudio consisting of a MR compatible headphone with optical data transmission, Battery unit for powering the headphones, AudioHub for interfacing between commercial audio and optical transmission to headset.



Intended purpose:

The nordicAudio allows auditory signals from a source in the control room to enter the Magnet room and to be presented to the subject. The system consists of headphones connected through an access point. From this unit the system is connected to an audio hub unit in the control room, through a fiber cable. Standard audio sources can be connected to the audio hub and by this bring the audio to the subject.

Reason for FSCA

Description of the product problem:

Following the patient scan, it was reported that the Y-link, which houses the RF traps and is located on the cable between the HeadSet and the Battery Box of a nordicAudio HS (1.5T) version 1.0.2 (nAu), had overheated, resulting in deformation of the enclosure. Investigation of the affected product indicated that the RF traps within the Y-link were the likely source of heat. No injury to the patient or operator was reported.

The incident occurred on the 1.5T scanner during a series of spine examinations.

Hazard giving rise to the FSCA

Induced currents in conductive components, combined with elevated internal resistance within the cable traps, may result in cable traps heating above the accepted test threshold ($>43^{\circ}\text{C}$), thereby increasing the risk of patient burns.

Probability of problems arising

Medium/High probability –the problem will not occur in all MRI sequences but may occur during specific clinically relevant sequences.

Risk to patient/users

Excessive heating of the device can cause burns or discomfort to the patient.

Details of affected devices:

nAu- HeadSet for 1.5T	
1.	610000 (Demo- Internal)
2.	610002
3.	610003
4.	610004 (Demo- Internal)
5.	610006
6.	610007
7.	610008
8.	610009

Advice on action to be taken by users:

- *Immediately cease use of the product*
- *Extend the information to your accounts that may have this product in their possession*
- *Identify and quarantine any of the subject device in your facility*
- *Acknowledge receipt of this notice by completing and returning the attached form (Scanned or email confirmation is sufficient)*
- *NordicNeuroLab will contact you to coordinate the return of the affected HeadSet.*

Transmission of this FSN:

This notice must be forwarded to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

We sincerely apologize for any inconvenience this may have caused you and your patients.

User friendly, plug and play, MRI accessories



Contact reference:

Email: productsolutions@nordicneurolab.com

Phone Europe, Asia, ROW: +47 55 70 70 95 /option 3

Best regards,
Product Solutions Team
NordicNeuroLab AS