

## Subject: Field Safety Notice - Heating of nordicAudio Headsets

FSCA Identifier: CAPA-95

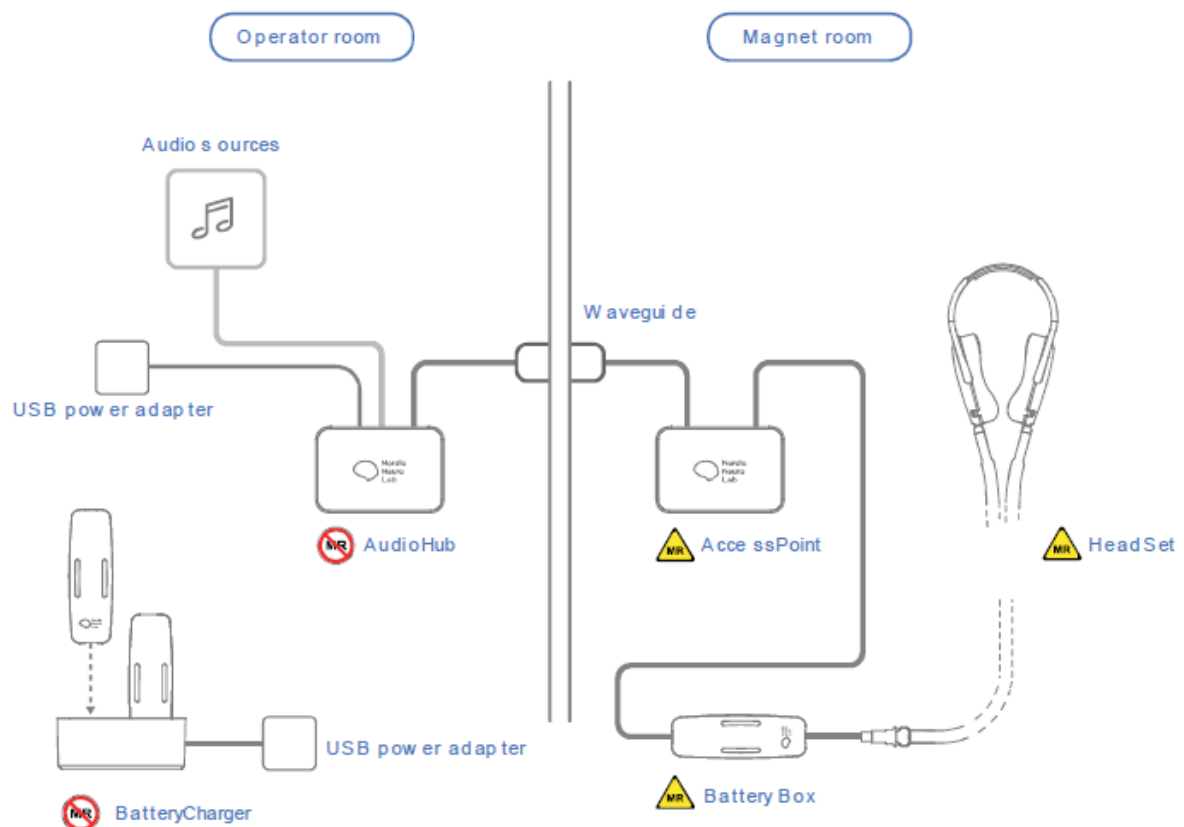
Type of action: Field Safety Corrective Action

Date: 2026-05-07

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, AccessPoint 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:**

It was reported during a patient scan, that the nordicAudio version 1.0.0 (nAu) had become uncomfortable as it became warm during the scan. Investigating the effected product showed clear indications that the heating has occurred due to overheating of the cable traps. The purpose of the cable traps is to reduce the antenna effect of the cable between the HeadSet and the BatteryBox. When the cable traps where degraded, the increased antenna effect led to overheating in the ear cups. Neither the patient nor the operator was injured.

The incident occurred on the 1.5T scanner during a spine examination.

### **Hazard giving rise to the FSCA**

Induced currents in conductive parts leading to heating of cable traps causing traps to lose function. This in turn can lead to increased antenna effect causing heating of the ear cups.

### **Probability of problems arising**

Heating of the ear cups have been observed in 1 of 28 distributed systems. The root cause of the heating has been eliminated in upgraded versions of the product.

### **Risk to patient/users**

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

### **Details of affected devices:**

nAu-HeadSet for 3.0T	nAu- HeadSet for 1.5T
1. 590004	25. 610000
2. 590005	26. 610002
3. 590006	27. 610003
4. 590007	28. 610004
5. 590008	
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24. 590027	

**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 and upgrade of your 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.

**Contact reference:**

Email: [productsolutions@nordicneurolab.com](mailto:productsolutions@nordicneurolab.com)

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

Best regards,  
Product Solutions Team  
NordicNeuroLab AS