

NNL EarPlug

User Manual

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1. Introduction

NordicNeuroLab's EarPlug is an alternative device to the NNL Headphones to deliver audio stimuli within the MR environment. Its main objective is to deal with the restricted space requirement in new type of head coils. It is based on electrostatic technology, as this proved to be superior in sound quality compared to pneumatic systems.

The EarPlug is an add-on to the NNL Audio System. It uses the same amplifier and signal transmission as the NNL Audio System. The EarPlug can be used instead of the Headphones, as they share the same connector and signal type.

This manual is a supplement to the NNL fMRI Hardware System User Manual and covers all important information about the NNL EarPlug.

This manual is divided into two main sections, an Installation Guide to illustrate the set-up of the system, and a "How to use...." section, providing a detailed description of how to operate the components.

We strongly suggest that you carefully read this manual to ensure safe operation of the EarPlug and to be able to take maximum advantage of the features offered by the EarPlug.



2. Safety

2.1. General information




This equipment must only be operated by personnel properly trained in identifying artifacts, streaks and distortions in image data

- Make sure that all personnel handling the equipment are familiar with the safety instructions given in this manual and other documentation provided by NordicNeuroLab to ensure safe operation of the equipment.

2.2. General safety information

	<p>Caution</p> <p>Artifacts in the MR image (caused by the EarPlug)</p> <p>Incorrect interpretation of image/data</p> <ul style="list-style-type: none">– check the MR image for bright spots, streaks and lines– test equipment regularly to identify any artifacts– if artifacts are observed, make sure that the supervising physician is properly trained to identify these artifacts
	<p>Warning</p> <p>Self-heating of cables due to improper cable routing!</p> <p>Injury to subject and operating personnel</p> <ul style="list-style-type: none">– avoid looping of cables– make sure that all cables are in straight lines before starting an examination

2.3. Explanation of product marking and labeling

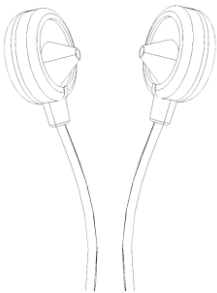





	<p>Consult accompanying documentation</p> <p>This is a general symbol used to encourage users to get familiar with the accompanying documentation and safety precautions before taking the system into use.</p>
	<p>Type BF applied part</p> <p>Indicates that all parts attached to the subject are insulated from the electronics inside to limit the magnitude of current running through the subject in the event of an unintended voltage originating from an external source connected to the subject.</p>
	<p>Attention</p> <p>Consult the manual for more information.</p>

**MR Conditional**

An item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use.

3. System Overview Installation Guide

3.1. What's included ...

	<p>EarPlug</p> <p>An electrostatic in-the-ear speaker system. A small unite to be used in tight coils. An add-on system for the NNL Audio System. Right side EarPlug is labeled with a RED marking</p> <div><p>The cable attached to the EarPlug must be kept in straight lines to avoid self-heating.</p></div>
	<p>Ear tips</p> <p>Disposable MR compatible ear tips with good sound attenuation. Ear tips come in two different sizes</p>
	<p>Ear Ring</p> <p>MR compatible Ear Ring to easen the positioning of the EarPlug and to reduce tension on the cable.</p>
	<p>Headphones extension cable</p> <p>additional extension cables to increase cable length of the EarPlug</p> <div><p>One of the extension cables contains a ferrite bead and must be kept at a safe distance from the MR scanner (outside the 20 mT line).</p></div>

3.2. EarPlug installation instructions

Please refer to the NNL fMRI Hardware System User Manual for information on installation of the complete NNL fMRI Hardware System. This document describes the EarPlug only.

The EarPlug consists of three components:

- EarPlug: an MR-compatible ear plug that is connected to the NNL Audio System. A device that offers flexible solutions for auditory stimulus presentation and operator-subject communication.
- Ear tips: a hearing protecting unit, that's allows the presented sound reach the pasient ear channel, but protect the subject from environment noise.
- Ear ring: a unit that supports the EarPlug and keeps the EarPlug on place.

The installation is identical to the installation of the NNL Audio System as described in the User Manual of NNL fMRI Hardware Solution.

Simply just remove the Headphones and connect the EarPlug to the same connector as the Headphones were connected to. This operation should be done with the power turned off on the SIU.

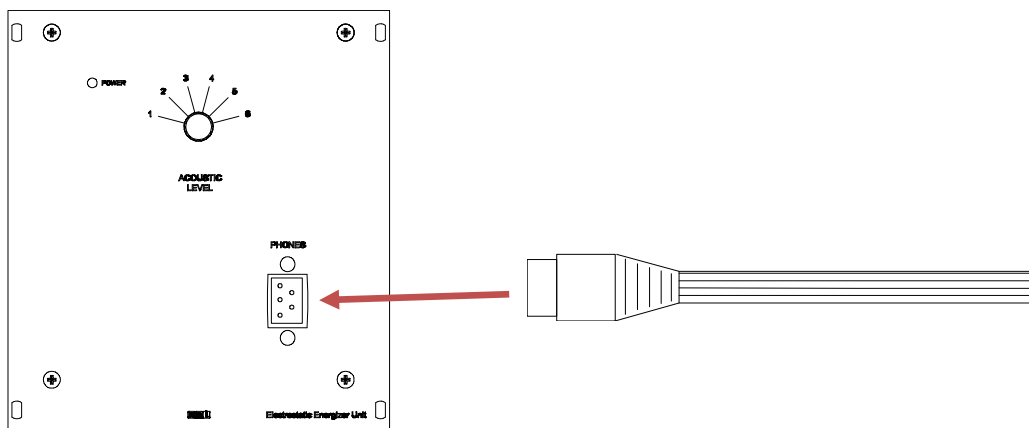


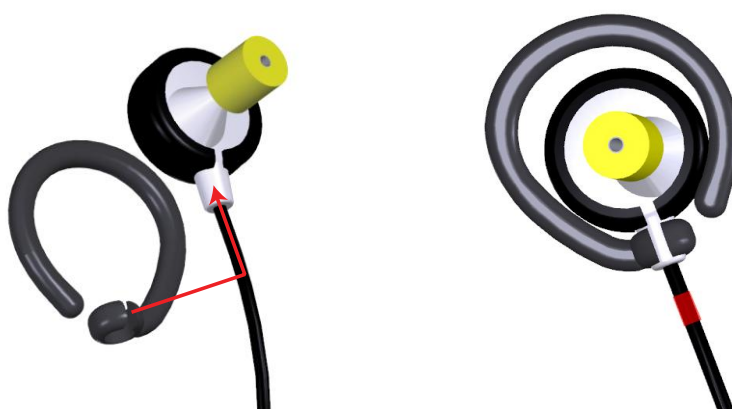
Figure 1: Simply just remove the headphones and connect the EarPlug

4. How to use the Earplug

1. Choose the correct size of foam inserts for your patient's ear canal.
2. Push/screw the black tube of the foam inserts into the EarPlug. The black plastic has to touch the base of the EarPlug. If it's difficult to insert the black tube, you could cut the tube as showed in the picture below (right side).



3. Add the Ear ring to the EarPlug (optional) as shown in the picture below



4. Between your fingers, roll the foam insert to compress to the smallest diameter possible.
5. Insert the rolled-up/compressed foam insert well into the ear canal. The right side EarPlug is labeled with a **red** marking.
6. Hold the EarPlug in place until the foam insert has fully expanded.
7. Make sure the foam inserts provide good sound attenuation.
8. Make sure the EarPlug cable runs in a straight line to the amplifier.

Tips:

- In order to improve sound quality, shorten the black tube of the foam inserts down to half their length.
- If the patient has a very short ear canal, slightly shorten the foam of the foam inserts.

WARNING:

- Make sure that the EarPlug is fitted correctly into the ear channel and that it cannot fall out.
- Use additional foam pads to secure the EarPlug once the subject is placed comfortably in the head coil.

5. Cleaning & Equipment Disposal

5.1. Cleaning of Equipment

Make sure that the EarPlug is disconnected from the SIU. Gently clean the surface of EarPlug and Ear ring with a slightly damp, soft cloth. Allow any moisture to completely evaporate before re-connecting and operating the system. Avoid moisture to get inside the tube hole of the Earplug.

All parts in contact with subjects should be cleaned daily, and between every examination when deemed necessary. All other parts should be cleaned weekly or more frequently if needed.

5.2. Correct Disposal of this Product (Waste Electrical & Electronic Equipment)

To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this product from other types of waste and recycle it responsibly at the end of its working life.

Users should contact their local government office for details of where and how they can take this product for environmentally safe recycling.

Alternatively, the product can be returned to NordicNeuroLab for appropriate disposal.

NordicNeuroLab AS
Møllendalsveien 65 C
5009 Bergen, Norway

6. Troubleshooting & Support



General note

When reconnecting cables and checking power supplies, make sure all units are turned OFF and mains supply connections are disconnected.

6.1. Problems

Problem: There is no sound in the EarPlug

Possible cause(s):

1. The EarPlug is not properly connected to the Shielded Interface Unit.
2. The SIU is not turned on.
3. The Volume on the SIU is not turned up

Solution(s):

1. Check the connections along the EarPlug cable and its extensions.
2. Check that the SIU is turned on and the lights are on.
3. Check that the volume knob is set to an appropriate level.

6.2. Unsolved problems?

If you are still experiencing problems, abnormal operation or system failure, or if the EarPlug is not performing up to your expectations, please report this to NNL at support@nordicneurolab.com or contact your local distributor.

7. Technical Specifications

General Specifications		
Dimensions		
Weight and Size	12g without Cord, 29mm Diameter	
Speakers		
Type	Electrostatic Canal Type, In-The-Earspeakers/ Pushpull Driving	
Bias Voltage	580V/DC	

8. Declaration of Conformity

The EarPlug is an add-on to the NNL AudioSystem. The attachment is a research tool only. It is not approved by FDA or CE labeled like the standard NNL fMRI Hardware System.

9. Limited Warranty

NordicNeuroLab AS warrants to the original consumer or other end user that the EarPlug is free of defects in materials and workmanship for a period of two years from the date of purchase. During the limited warranty period this product will be repaired or replaced at our option, without charge.

This warranty shall be voided if the product is modified, tampered with, misused, or subjected to abnormal working conditions. This warranty does not cover physical damage to the surface of this product. This warranty does not apply when the malfunction results from the use of this product in conjunction with accessories, other products, or peripheral equipment.

Repair or replacement as provided under this warranty is the exclusive remedy of the purchaser. This warranty is in lieu of all other warranties, express or implied, including any implied warranty of fitness or suitability for a particular use or purpose, and NordicNeuroLab AS shall in no event be liable to the purchaser for indirect or consequential damages of any kind or character.

10. Contact

If you have any questions or problems, please contact us through any of the following routes. If you purchased your system through one of our international distributors, please contact the distributor first, especially if your system is under warranty.

In all other cases, please contact info@nordicneurolab.com if you have any questions or support@nordicneurolab.com to get assistance with technical problems.

Alternatively, you can call us on +47 5570 7095 during office hours.

For Sales related questions, please contact your local distributor, or contact us at sales@nordicneurolab.com.

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