

NIHON KOHDEN EUROPE GmbH, Raiffeisenstraße 10, 61191 Rosbach v.d.H.

To all users of NIHON KOHDEN EMG/EP Measuring System
series *Neuropack S3* MEB-9600

Rosbach v.d.H., December 2020

Subject: Important FIELD SAFETY NOTICE (FSN)
FSCA Ref. „FSCA-9161“

Information about a Field Safety Corrective Action for NIHON KOHDEN EMG/EP Measuring Systems series *Neuropack S3* MEB-9600 with software version below 04-02

Dear Valued Customer,

With this Field Safety Notice (FSN) we want to inform you about a Field Safety Corrective Action (FSCA) for NIHON KOHDEN EMG/EP Measuring Systems series *Neuropack S3* MEB-9600 with software versions below 04-02.

Based on our product tracking we found that we have delivered at least one unit of EMG/EP Measuring System series *Neuropack S3* MEB-9600 to you. You will find a detailed list of affected products attached to this Field Safety Notice. The affected EMG/EP Measuring Systems can be identified by the model name and the software version.



Please make sure that all potential users in your facility are informed about this Field Safety Notice!

Please confirm by returning attached receipt of this Field Safety Notice!

Affected Products:

All NIHON KOHDEN EMG/EP Measuring Systems series *Neuropack S3* MEB-9600 with software version below 04-02

Checking the model number:

Information on the nameplate on the left side of the main unit

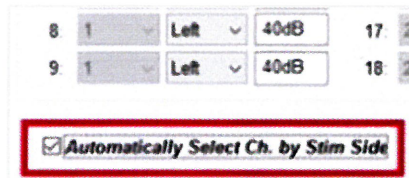
Checking the software version:

To display the software version, click on „Help“ in the menu bar of the examination program and select the „About...“ submenu. The installed software version is specified in the first line in the format „Vxx-xx“.

../2

Description of the malfunction:

In the standard ABR examination program, the ABR waveform is shown reduced in the amplitude if the parameter „Automatically Select Ch. by Stim Side“ is activated in the measurement setting window for the ABR examination program.



This parameter setting activates the measurement channel on the electrode junction box that is assigned to the current stimulation side automatically. In connection with the use of a short-cut lead for the common use of the reference electrode (e.g. "Cz") for both measurement channels, a software error results in a significant asymmetry of the input impedances between the two inputs of the differential amplifier of the active measurement channel. This leads to a reduction of the signal amplitude of the ABR waveform to approx. 1/10 of the normal expected value.

There are no reports of damage to patients, users or third parties that are directly or indirectly related to this malfunction.

Corrective action:

The improved software version 04-02 eliminates the malfunction.

Procedure of the Field Safety Corrective Action (FSCA):

Your NIHON KOHDEN representative will contact you automatically to arrange an appointment for installing the software upgrade to version 04-02 or higher. The affected EMG/EP measuring systems can continue be used if the precautionary measures are met.

Precautionary measures for users:

Until the software update is installed, please switch off the automatic assignment of the measurement channels in the measurement settings window of the ABR examination program (ABR measurement setting window → ABR → „Automatically Select Ch. by Stim Side“) temporary. Your NIHON KOHDEN representative or the technical service of the NIHON KOHDEN European headquarters (please refer to the contact details listed below) will provide you with assistance if required.

Required actions of the user:

- Please check the model number and software version whether your EMG/EP measuring system is affected by this Field Safety Corrective Action!
- Please inform all potential users of the EMG/EP measuring system in your facility about this Field Safety Notice!
- Please follow the precautionary measures for recording ABR waveforms until the software upgrade is installed by your NIHON KOHDEN representative!
- Please return the completed „① Receipt of the Field Safety Notice (FSN)“ to your NIHON KOHDEN representative!

The European Competent Authorities are informed about this Field Safety Corrective Action and are monitoring progress and finalization.

If you have any question to this Field Safety Notice or to the software upgrade, please do not hesitate to contact either your local NIHON KOHDEN Representative or the Technical Department of the European NIHON KOHDEN Headquarter in Germany:

NIHON KOHDEN EUROPE GmbH
Technical Department
Raiffeisenstrasse 10
61191 Rosbach
Germany

Phone: +49 6003 827160
Fax: +49 6003-827596
E-mail: NKE-SERVICE2@nke.de

We apologize for the inconvenience this Field Safety Corrective Action may cause and thank you for your understanding and co-operation.

Best regards
NIHON KOHDEN EUROPE GmbH
Quality Assurance Department

Attachments: List of affected products
 ① Receipt of the Field Safety Notice (FSN)