NIHON KOHDEN

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

To all users of NIHON KOHDEN Multiple Patient Receivers series ORG-9200K and ORG-9700K

Rosbach v.d.H., February 2021

Subject: **Important FIELD SAFETY NOTICE (FSN)**
FSCA Ref. „FSCA-9164B“

Information about a Field Safety Corrective Action for NIHON KOHDEN Multiple Patient Receivers series ORG-9200K and ORG-9700K with software version below 05-01

Dear Valued Customer,

With this Field Safety Notice (FSN) we want to inform you about a Field Safety Corrective Action (FSCA) for NIHON KOHDEN Multiple Patient Receivers series ORG-9200K and ORG-9700K with software versions below 05-01.

Multiple Patient Receivers are a technical component of the UHF Telemetry Antenna System. This component receives the signals from individual Patient Transmitters via antenna system and transfers the data into the Patient Monitoring Network (LAN IT network) for display on Central Monitors.

The distribution of these multiple patient receivers ORG-9200K was discontinued in 2004 already, for the successor series ORG-9700K in 2009. For both models, service and support was ended in 2014 and 2017, respectively. However, we know that multiple patient receivers of both series are still in use and therefore we offer the implementation of a corrective measure for these devices.

Based on our product tracking we found that we have delivered at least one unit of an affected Multiple Patient Receiver ORG-9200K and/or ORG-9700K to you. You will find a detailed list of affected products attached to this Field Safety Notice. The affected Multiple Patient Receivers can be identified by the model name and serial number on the nameplate of the device and a software version label beside of the nameplate.

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 Multiple Patient Receivers series ORG-9200K and ORG-9700K with software version below 05-01.
Checking the model number:	Information “MODEL” on the nameplate.
Checking the serial number:	Information “SN” on the nameplate.
Checking the software version:	Information “VER” on the version label.

../2

[redacted]

Description of the malfunction:

Depending on the setting of the time zone on the Central Monitors the symptoms described below occur on that Central Monitors around January 1st, 2021 at 0:00 a.m. ± 12 hours:

1. *Arrhythmia Recall* data after 0:00 a.m. on 01.01.2021 (based on GMT±0) is not displayed, or the data is stored at the time after 0:00 a.m. on 01.02.1970.

2. *ST Recall* data after 0:00 a.m. on 01.01.2021 (based on GMT±0) is not displayed, or the data is stored at the time after 0:00 a.m. on 01.02.1970.

3. On *Graphical Trend* and *Tabular Trend* screens, NIBP measurement data after 0:00 a.m. on 01.01.2021 (based on GMT±0) is not displayed.

4. On *All Patient* and *Individual Patient* screens, display of NIBP measurement data after 0:00 a.m. on 01.01.2021 based on GMT±0 is dimmed like below:

5. There might be an impact to Gateway Servers and HL7 connections (e.g., for communication with Hospital Information Systems) because of missing data or incorrect time stamp of data. The related symptoms depend on the individual configuration of the communication interfaces.

Which and how the symptoms occur depends on the model and software version of the Central Monitor.

All other monitoring functions like display of real-time waveform and numerical data and alarming work correctly, except above-described symptoms 1 to 5!

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 05-01 or higher eliminates the malfunction.

Precautionary measures for users:

The affected Multiple Patient Receivers ORG-9200K and ORG-9700K can continue be used. Please consider the temporary limitations described above for your clinical workflow!
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.

../3

Required actions of the user:

- Please check the model number, serial number and software version whether Multiple Patient Receivers series ORG-9200K and/or ORG-9700K are still in use in your medical facility!
- If so, please inform all potential users of the Multiple Patient Receivers ORG-9200K and ORG-9700K in your facility about this Field Safety Notice!
- Please follow the precautionary measures 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! With this you might request the software update to be carried out.

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
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61191 Rosbach
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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)