

MESSTECHNIK FÜR NEUROLOGIE, KARDIOLOGIE, LABORDIAGNOSTIK UND INTENSIVÜBERWACHUNG

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

To all end-users of NIHON KOHDEN Bedside Monitors series *Life Scope G9* (CSM-1901)

Rosbach v.d.H., April 2017

Subject: Important FIELD SAFETY NOTICE

Information about a Field Safety Corrective Action for NIHON KOHDEN Bedside Monitors series *Life Scope G9* (CSM-1901, CU-191RK and CU-192RK) FSCA Ref. "CSM-1901/2017/1"

Dear Valued Customer,

With this Field Safety Notice (FSN) we want to inform you about a potential malfunction of NIHON KOHDEN Bedside Monitors series *Life Scope G9* (CSM-1901) with main units CU-191RK and CU-192RK and software versions 01-16 to 01-22.

You get this FSN because you received at least one potential affected unit from your NIHON KOHDEN Representative or your installed units received a software update to one of the affected software versions.

The potential affected units can be identified by the model name and serial number which both are located on the product identification label at the backside of the Bedside Monitor *Life Scope G9*.



Life Scope G9 (CSM-1901)

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!

Description of the potential malfunction:

The Bedside Monitors series *Life Scope G9* and the Central Monitor connected to the Bedside Monitor have an auto resume function. When a patient is temporarily away from the bed for examination or others reasons, monitoring can be paused to pause vital signs monitoring and alarm function. When monitoring at the Bedside Monitor is resumed after pause while auto resume function is set to ON, monitoring at Central Monitor also resumes automatically.

In software versions of the Bedside Monitors *Life Scope G9* from 01-19 to 01-22 it happens that the Central Monitor does not resume monitoring automatically even when the Bedside Monitor resumes monitoring correctly and the Central Monitor receives vital signs data from the Bedside Monitor. This leads to the situation that alarms are shown at the Bedside Monitor but are disabled at the Central Monitor until the pause mode is deactivated at the Central Monitor manually.

Advise to users:

Please deactivate the pause mode at the Central Monitor manually until your Bedside Monitor Life Scope G9 received a software update. Please contact your NIHON KOHDEN Representative in case you have any question for deactivating the pause mode at the Central Monitor manually!

../2

Corrective Action:

An improved software version 01-24 eliminates the potential malfunction.

Based on our product tracking we found that we have delivered at least one affected Bedside Monitor Life Scope G9 to you. You will find a detailed list of affected products attached to this Field Safety Notice.

Procedure for receiving the software update to the new software version 01-24:

- 1. Please inform all potential users in your facility about this Field Safety Notice!
- 2. Please check about the actual location of the potential affected Bedside Monitors Life Scope G9 in your medical facility!
- 3. Please complete attached receipt "@ Receipt of the Field Safety Notice (FSN)" and return it by fax or e-mail! Please do not forget to add the contacts of your local contact person!
- 4. After receiving your receipt your responsible NIHON KOHDEN Representative will contact your specified local contact person for arranging the software update. You will receive the software update free of charge.

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

If you have any question please do not hesitate to contact your known local NIHON KOHDEN Representative or the European NIHON KOHDEN Headquarter in Germany:

NIHON KOHDEN EUROPE GmbH Technical Department Raiffeisenstrasse 10 61191 Rosbach Germany

Phone: +49 6003 827-160

Fax:

+49 6003-827-596

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

2 Receipt of the Field Safety Notice