NIHON KOHDEN

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

To all users of NIHON KOHDEN Bedside Monitors
series *Life Scope G5* (CSM-1501/1502) and *Life Scope G7* (CSM-1701/1702)

Rosbach v.d.H., August 2019

Subject: **Important FIELD SAFETY NOTICE**

Information about a Field Safety Corrective Action for NIHON KOHDEN Bedside Monitors series *Life Scope G5* (CSM-1501/1502) and *Life Scope G7* (CSM-1701/1702) with software versions below 02-15
FSCA Ref. "FSCA-9153"

Dear Valued Customer,

With this Field Safety Notice (FSN) we want to inform you about a Field Safety Corrective Action (FSCA) for NIHON KOHDEN Bedside Monitors series *Life Scope G5* (CSM-1501/1502) with the main units CU-151RK and CU-152RK and *Life Scope G7* (CSM-1701/1702) with the main units CU-171RK and CU-172RK using software versions below 02-15.

You get this FSN because you received at least one potential affected Bedside Monitor *Life Scope G5* or *Life Scope G7*. The potential affected Bedside Monitors 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 as well as the software version indicated in the software version window of the device.

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 malfunctions:
(I) There is a risk for an unexpected shut-down of the Bedside Monitors. This potential malfunction occurs very rarely (<0,000004%) and is alarmed on the Bedside Monitor both acoustically (beep") and visually (power lamp blinks orange/green). A message is displayed on a connected Central Monitor to alert the interrupt of the network connection to the patient monitor.
While the Bedside Monitors *Life Scope G5* reboot automatically, the Bedside Monitors *Life Scope G7* requires action by the operator to remove the power cord or the battery (only in battery operation mode). Until the Bedside Monitor is rebooted, no numerical and waveform data are displayed, no alarm occurs and no data is transmitted to the central monitor.

(II) There is a risk for false displayed message "Connect Input Unit" or "Input Unit Disconnect" while the Input Units is connected to the Bedside Monitor *Life Scope G7*. This false recognition status is resolved in a short time and the connection is correctly recognized. When this event occurs while the transport function is enabled, the patient information dialog is displayed to request to confirm. Until patient information is confirmed, monitoring does not start, numerical and waveform data are not displayed, no alarm occurs and data is not transferred to the central monitor. This potential malfunction occurs very rarely (0,000002%).

Corrective Action:
An improved software version 02-15 eliminates the potential malfunctions on both Bedside Monitors.

Based on our product tracking we found that we have delivered at least one Bedside Monitor *Life Scope G5* or *Life Scope G7* to you. You will find a detailed list of affected products attached to this Field Safety Notice.

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Procedure for checking the software version of the Bedside Monitor:

Method A:
(In normal operation mode)
- Click the "Menu Home" button, then click "Setup".
- Enter the password and click "Ent".
- Click the button "Maintenance".
- The actual installed software version is displayed in the software version window ("Version CU-1xxR Op.No.0xK Ver **XX-XX**").

Method B:
(When the Bedside Monitor is switched off actually)
- Push the "CHECK" key on the front side of the main unit and keep it pressed until the "Bong" sound appears when switching-on the Bedside Monitor.
- Enter the password and click "Ent".
- The actual installed software version is displayed in the software version window ("Version CU-1xxR Op.No.0xK Ver **XX-XX**").

When a software version below 02-15 is installed on the Bedside Monitor:

Please contact your NIHON KOHDEN Representative for the software upgrade to the software version 02-15 or higher by completing the attached ① *Receipt of the Field Safety Notice* and return it to your NIHON KOHDEN Representative or to the Technical Department of the European NIHON KOHDEN Headquarter in Germany. Your NIHON KOHDEN Representative will contact you after receiving your request immediately.

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 upgrades please do not hesitate to contact either your local NIHON KOHDEN Representative or the Technical Department of the European NIHON KOHDEN Headquarter in Germany:

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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