NIHON KOHDEN

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

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

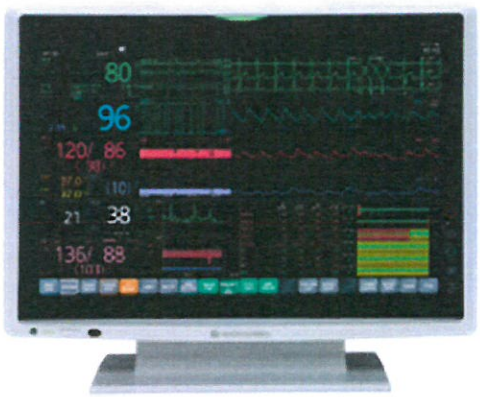
Rosbach v.d.H., March 2019

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, CU-192RK) Software version 01-29 FSCA Ref. "FSCA-9150"

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 the main units CU-191RK and CU-192RK and the **software version 01-29**. Other software versions are NOT affected by this potential malfunction!
You get this FSN because you received at least one potential affected unit. Please consider that delivered non-affected units might have received a software upgrade later on and became affected after the software upgrade. 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* as well as the software version indicated in the software version window of the device.



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:
There is a risk for an unexpected reboot of the Bedside Monitors series *Life Scope G9* using the software version 01-29 which was released in November 2018 in rare cases. The malfunction is limited to this software version only – other software versions are not affected! During the reboot the monitoring of the patient is not available and therefore there might be a delay in detecting abnormal patient conditions.

Corrective Action:
An improved software version 01-30 eliminates the potential malfunction.

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

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(I) Procedure for checking if the Bedside Monitor *Life Scope G9* uses the software version 01-29:

Method A:
(In normal operation mode)
- Click the "Menu Home" button, then click "Setup".
- Enter the Administrator password and click "Ent".
- Click the button "Maintenance".
- The actual installed software version is displayed in the software version window ("Version CU-19xR Op.No.01K 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 Administrator password and click "Ent".
- The actual installed software version is displayed in the software version window ("Version CU-19xR Op.No.01K Ver **XX-XX**").

(IIa) When the software version 01-29 is installed on the Bedside Monitor *Life Scope G9*:

Please contact your NIHON KOHDEN Representative for the software upgrade to the software version 01-30 by completing the section a) of 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.

(IIb) When the software version 01-29 is NOT installed on the Bedside Monitor *Life Scope G9* or you do not want to participate at the Field Safety Corrective Action:

Please confirm that the Bedside Monitor(s) Life Scope G9 are not affected by the Field Safety Corrective Action by marking the section b) or c) of the attached ① *Receipt of the Field Safety Notice*. Please return the ① *Receipt of the Field Safety Notice* to your NIHON KOHDEN Representative or to the Technical Department of the European NIHON KOHDEN Headquarter in Germany.

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:

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

①

To: ______________________________
(your NIHON KOHDEN Representative)

Receipt of the Field Safety Notice (FSN)

- End-users -

Bedside Monitor *Life Scope G9* CSM-1901
[FSCA-9150: "Software version 01-29"]

We,

Customer: ______________________________

confirm receiving the Field Safety Notice FSCA-9150 related to the Bedside Monitors series *Life Scope G9* CSM-1901. We informed all potential users in our facility.

(Please mark the related check box!)

☐ a) We detected Bedside Monitors with the potential affected software version 01-29!

S/N: ______________________________ *(Please add the related S/N!)*

Please contact the person mentioned below for arranging the required software update:

Name: ______________________________

e-mail: ____________________ phone: ____________________

or

☐ b) We do <u>not</u> have Bedside Monitors with the potential affected software version 01-29 in operation!

or

☐ c) We do not have any of the potential affected Bedside Monitors in operation anymore!
(Please check this check box only if the Bedside Monitor is irrevocably out of service with absolutely no intention of putting it into operation again or if the Bedside Monitor was disposed already.)

- -

Name: ______________________________

Date: ____________________ Signature: ____________________

Please return the completed and signed receipt to us by fax or by e-mail!

Thank you for your co-operation!