

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

