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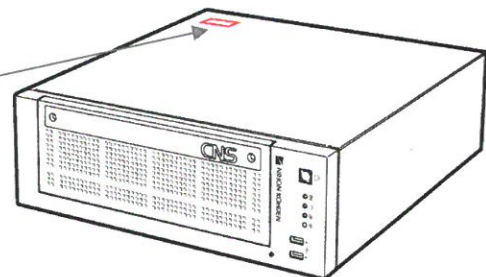
To all end-users of
NIHON KOHDEN Central Monitors CNS-6201 series

Rosbach v.d.H., June 2015

Subject: IMPORTANT FIELD SAFETY NOTICE (FSN)**Information about a Field Safety Corrective Action (FSCA) for NIHON KOHDEN
Central Monitors model CNS-6201,
Graphic board VBIOS settings
[Referenznummer: CNS-6201/2015/1]**

Dear Valued Customer,

With this Field Safety Notice we want to inform you about a potential malfunction of NIHON KOHDEN Central Monitors model CNS-6201 with serial numbers between 00461 and 00519.

Note: You can find the model name and serial number of the Central Monitor CNS-6201 on the name plate of the device on top of the housing.

Central Monitor CNS-6201

Please make sure that all potential users in your medical facility are informed about this Field Safety Notice! Please confirm by returning attached confirmation of receipt of the Field Safety Notice!Description of the potential malfunction:

The manufacturer of the used graphic board has informed us that they detected a delay of the screen drawing processing up to a few seconds during an internal validation of a temperature loading test. The delay was related to the display of the vital data (numerical values and waveforms) as well as for the visual alarming on screen.

The potential malfunction is limited to a small LOT of graphic boards and could not be duplicated under routine operation conditions yet. However, with reference to the present results of the detailed investigation a potential malfunction could not be ruled out completely. Therefore we decided to initiate a corrective action to all potentially affected Central Monitors CNS-6201.

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