

Rosbach v.d.H., xx.xx.2008

**Subject: safety information
patient monitors of the series Life Scope P BSM-4100K and Life Scope A
BSM-5100K**

Dear ,

with this safety information we want to inform you about a potential malfunction by using the FREE LEAD function („Ca“ / „Cb“) in 6 lead ECG mode for thorax ECG monitoring.

Please make sure that all potential users in your medical facility are informed about this safety information!

affected patient monitors:

- Life Scope P, series BSM-4101K, BSM-4103K, BSM-411K and BSM-4113K with software version from 03-10 to 04-10
- Life Scope A, series BSM-5105K and BSM-5135K: all software versions

You can find out the software version of your patient monitor by switching on your equipment while pressing the “SILENCE ALARMS” key (keep the SILENCE ALARM key pressed until the software version screen appears). The software version is indicated in the section “CPU (Program)”.

description of the potential malfunction:

Beside the common standard 6 lead ECG mode support the patient monitors some FREE LEAD mode for an individual selection of the acquired waveforms for thorax ECG monitoring with the electrode labels “Ca” and “Cb”.

When selecting the waveform „V4“ out of the range from „V1“ to „V6“ for the electrode label „Cb“ AND is the selected waveform for electrode label „Ca“ IDENTICAL to the selected waveform for the display of the ECG trace on screen, than does the actual displayed waveform data not correspond to the displayed waveform label! In only this special condition correspond the actual displayed waveform data always to lead “V4”. Furthermore, the waveform data of the lead “V4” is used for the print-out [BSM-41xxK series], for the network output [BSM-41xxK series], for the analogue output [BSM-41xxK series and BSM-51xxK series], for the transmitter output [BSM-41xxK series and BSM-51xxK series] and for the ST alarming [BSM-41xxK series].

All other leads (“V1”, “V2”, “V3”, “V5” or “V6”) for the electrode label “Cb” and all other ECG modes are NOT affected by this potential malfunction!

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Please make sure, that in the 6 lead ECG modus by using the function „FREE LEAD“

either for the electrode label „Cb“ the lead „V4“ is not used,

or by using the lead „V4“ for the electrode label „Cb“ the selection for the lead for the display is different from the lead for the electrode label „Ca“!

Based on our product tracking we found, that we have delivered potential affected patient monitors to you . You will find a detailed list of your affected products attached to this safety information. Furthermore you receive with this safety information a modified operator's manual which include some notes about this potential malfunction.

When the corrected software version is released we will install the software upgrade to your affected patient monitors step by step during regularly service and maintenance (repair, safety check, calibration, etc.).

We apologize for the inconvenience this corrective action may cause and thank you for your support and co-operation.

If you have any question please do not hesitate to contact us.

Best regards

NIHON KOHDEN EUROPE GmbH
Quality Assurance Division

Attachments: list of affected patient monitors