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To all users of affected products

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

Subject: IMPORTANT SAFETY INFORMATION
patient monitors of the series Life Scope J BSM-9101K

With this safety information we want to inform you about a potential malfunction by using patient monitors series Life Scope J BSM-9101K.

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

affected patient monitors:

- Life Scope J, series BSM-9101K with software version 04-74

You can find out the software version of your patient monitor as follows:

1. Switch on the patient monitor!
2. After booting push „MENU / HOME“ button on junction box!
3. Push softkey „Other“ → „ADMINISTRATOR“!
4. After entering the password push softkey „MAINTENANCE“ → „VERSION“!
5. The actual software version is indicated in the block labelled „MU-910R Group Ver.“!

description of the potential malfunction:

The phenomenon appears after setting three conditions:

1. Screen setting: „FIX MODE“.
- AND
2. IBP measurement by using the cursor in Wedge pressure window
- AND
3. After condition 1 and 2 when shut down the patient monitor and restart.

The patient monitor shows an error message during booting and the booting is stopped. The monitoring function is not available!

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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.

When the corrected software version is released we will install the software upgrade to your affected patient monitors.

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 equipments