

To all users of NIHON KOHDEN Recording Paper  
Models NKUK-A054 and NKUK-MLSC-125

Guildford, 21/11/24

**Subject: Important FIELD SAFETY NOTICE (FSN)**  
**FSCA Ref. „FSCA2024-001“**

**Information about a Field Safety Corrective Action for NIHON KOHDEN recording paper models NKUK-A054 and NKUK-MLSC-125 for electrocardiographs due to incorrect labelling**

Dear Customer,

In this Field Safety Notice (FSN) we'd like to inform you about a voluntary Field Safety Corrective Action (FSCA) related to NIHON KOHDEN recording paper models *NKUK-A054* and *NKUK-MLSC-125* for Electrocardiographs.



NKUK-A054



NKUK-MLSC-125

This FSN shall:

- describe the identified non-conformity in the labelling,
- inform about potential risks associated with the use of these non-compliant products, and
- describe the corrective action plan.

Based on our product tracking we found that we have delivered at least one set of the non-conforming recording paper to you.

The non-conforming recording paper can be identified by the labelling on the packaging easily.

**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!**

<u>Affected products:</u>	Recording paper, models: NKUK-A054 (210mm, grid, Z-fold) NKUK-MLSC-125 (110mm, grid, Z-fold)												
<u>Description of the non-conformity:</u>	<p>It was determined that the recording papers do not meet the regulatory requirements for the labelling of medical devices. However, there is no restriction in the intended use, technical specification, manufacture, function, performance or safety of the recording papers. The non-conformity relates exclusively to the labelling.</p> <p>NIHON KOHDEN UK Ltd. falsely marketed the recording paper under its own name, although NIHON KOHDEN UK Ltd. is not the actual manufacturer of the recording paper. This has created the impression that NIHON KOHDEN UK Ltd. is the manufacturer of the related recording paper.</p> <p>The company Nissha Medical Technologies Ltd. is the actual manufacturer of the recording paper and has offered and provided us with customised branding for these recording papers.</p> <p>Due to an internal misunderstanding regarding the associated responsibilities, we started marketing these incorrectly labelled papers in April 2020.</p>												
<u>Potential risk:</u>	There is no risk to patients or operators or for documenting/archiving purposes if the incorrectly labelled recording paper is used.												
<u>Corrective action:</u>	<p>NIHON KOHDEN UK Ltd. has stopped the delivery of the incorrectly labelled recording papers.</p> <p>From now on, NIHON KOHDEN UK Ltd. will deliver the recording papers with the correct labelling of the actual manufacturer.</p> <p>The item numbers of the recording papers therefore change as follows:</p> <table><thead><tr><th>Model number Nihon Kohden</th><th>Model number Manufacturer</th><th>Order number Old (incorrect)</th><th>Order number New (correct)</th></tr></thead><tbody><tr><td>NKUK-A054</td><td><b>NMT-000248</b></td><td>NKUK-A054</td><td>→ <b>E/NKUK-A054-1</b></td></tr><tr><td>NKUK-MLSC-125</td><td><b>4009690C</b></td><td>NKUK-MLSC-125</td><td>→ <b>E/NKUK-MLSC-125-1</b></td></tr></tbody></table>	Model number Nihon Kohden	Model number Manufacturer	Order number Old (incorrect)	Order number New (correct)	NKUK-A054	<b>NMT-000248</b>	NKUK-A054	→ <b>E/NKUK-A054-1</b>	NKUK-MLSC-125	<b>4009690C</b>	NKUK-MLSC-125	→ <b>E/NKUK-MLSC-125-1</b>
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<u>Required actions of the user:</u>	<ul style="list-style-type: none"><li>• Existing stocks of incorrectly labelled recording paper can continue to be used. There is no risk for patients and operators or for documentation/archiving purpose.</li><li>• Please continue to send queries or information about incidents with the incorrectly labelled recording papers to us.</li><li>• Please inform all potential users of the affected NIHON KOHDEN Electro-cardiographs in your facility about this Field Safety Notice!</li><li>• Please return the completed „① Receipt of the Field Safety Notice (FSN)“ to us as proof for the receipt of this Field Safety Notice!</li></ul>												

The Competent Authorities MHRA in the UK have been informed about this Field Safety Corrective Action and is monitoring progress and finalization.

- 3 -

If you have any question regarding this Field Safety Notice or the Field Safety Corrective Action, please do not hesitate to contact us:

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UK

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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 UK Ltd.

Attachments:      ① Receipt of the Field Safety Notice (FSN)  
UK Declaration of Conformity for the conform recording paper