NIHON KOHDEN

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NIHON KOHDEN EUROPE GmbH, Raiffeisenstrasse 10, 61191 Rosbach v.d.H.

To all users of NIHON KOHDEN Ventilators series NKV-550

Rosbach v.d.H., August 2021

Subject: **Important FIELD SAFETY NOTICE (FSN)**
FSCA Ref. „FSCA2021-001“

Information about a Field Safety Corrective Action for NIHON KOHDEN Ventilators NKV-550-U

Dear Valued Customer,

With this Field Safety Notice (FSN) we want to inform you about a voluntary Field Safety Corrective Action (FSCA) for NIHON KOHDEN ventilators series NKV-550-U.

This FSN is intended:

- to explain how to check whether your specific unit is affected by this FSCA,
- to describe the potential failure and symptoms,
- to describe the correction plan by the manufacturer,
- to define actions required by the customer/user to prevent risks to patients.

Based on our product tracking we found that we have delivered at least one unit of an affected ventilator NKV-550-U to you. You will find a detailed list of affected products attached to this Field Safety Notice.
The affected ventilator NKV-550-U can be identified by the model’s name and serial number on the nameplate on the rear panel of the NKV-550-U ventilator.

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!

Localisation of the name plate at the rear panel:

Checking the model number: REF NKV-550-U on the nameplate

Checking the serial number: SN NKV550YYWWssss on the nameplate
(YY = manufacturing year, WW = manufacturing week, ssss = number)

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Description of the malfunction:	The manufacturer Nihon Kohden OrangeMed (NKOM) has observed a trend in the gas pressure regulator failure through its post market surveillance. This pressure regulator is used to reduce the pressure of the supply gas (air or oxygen) from hospitals to a predetermined pressure level, before the ventilator control system uses the gas for patients. NKOM has identified that the pressure regulator may fail prematurely because the component from the supplier may be defective. When this failure occurs, users may hear a gas releasing noise from the bottom of the ventilator, see a High Air/O2 Inlet Pressure alarm or a High/Low O2 alarm, or could not pass Device Check prior to use. During these failures, ventilation always continued. Users may also see a false positive Circuit Obstruction alarm, and in one case of Circuit Obstruction alarm the ventilator opened the safety valve for four minutes during which the ventilator did not deliver mandatory breaths and the patient would only be able to breathe through the open safety valve. There has been no severe patient injury or death reported as the result of this premature failure.
Potential Risk:	When High/Low O2 alarm is initiated, the actual O2 concentration to the patient deviates by ≥7% from the set O2 concentration. If this alarm is not handled, the patient may receive more or less O2 concentration than the set value, potentially resulting in hyperoxemia or hypoxemia. When false positive Circuit Obstruction alarm is initiated, the ventilator releases the pressure to ambient and then reinitiates a breath, and repeats the sequence of releasing the pressure and reinitiating breath, until the false positive Circuit Obstruction alarm is no longer active. In one case of Circuit Obstruction alarm, the ventilator opened the safety valve for four minutes during which the ventilator did not deliver mandatory breaths and the patient would only be able to breathe through the open safety valve. Although there was no patient injury or death, if it occurs again, it may result in patient injury due to hypoventilation. When a gas releasing noise is heard, High Air/O2 Inlet Pressure alarm is initiated, or a false positive High Baseline Pressure alarm is initiated, the ventilation continues as the user set. The hazard to the patient is the intervention to the care due to the switch of the ventilator to an alternate ventilator.
Corrective action:	Replacement of the internal pressure regulators by an improved version.
Procedure of the Field Safety Corrective Action (FSCA):	Step 1: From September 2021 you will receive sets of external pressure regulators to be attached between the wall socket of the central gas supply or gas cylinder and the gas input terminal of the ventilator as temporary solution until the final solution in step 2 can be implemented in your hospital. Please follow the instructions provided together with the external pressure regulators for their installation! Your NIHON KOHDEN representative will provide you with assistance if required. Step 2: Your NIHON KOHDEN representative will contact you automatically to arrange an appointment for replacing the internal pressure regulators.

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Precautionary measures for users:	Perform Device Check and Circuit Check as instructed in the NKV-550 ventilator Operator's Manual. A defective regulator can be identified during the Device Check and Circuit Check. If the gas outlet from the hospital wall has an individually adjustable pressure regulator, adjust the outlet pressure to 16 psi/110kPa for the air and O2 gases to the NKV-550 ventilator. This will allow the ventilator not to depend on its internal regulators to regulate the gas pressure. If the ventilator has a failed internal regulator, remove the ventilator from service and contact your local NIHON KOHDEN representative or the technical service of the NIHON KOHDEN European headquarters (please refer to the contact details listed below).
Required actions of the user:	Please check the model number and serial number whether your NIHON KOHDEN ventilator NKV-550-U affected by this Field Safety Corrective Action! Please inform all potential users of the NIHON KOHDEN ventilator NKV-550-U in your facility about this Field Safety Notice! Please follow the precautionary measures until the internal regulators are replaced by your local NIHON KOHDEN representative! Please return the completed „① Receipt of the Field Safety Notice (FSN)“ to your NIHON KOHDEN representative!

The European Competent Authorities are informed about this Field Safety Corrective Action and are monitoring progress and finalization.

If you have any question to this Field Safety Notice or to the Field Safety Corrective Action, please do not hesitate to contact either your local NIHON KOHDEN Representative or the Technical Department of the European NIHON KOHDEN Headquarter in Germany:

NIHON KOHDEN EUROPE GmbH
Technical Department
Raiffeisenstrasse 10
61191 Rosbach
Germany

Phone: +49 6003 827150
Fax: +49 6003-827596
E-mail: NKE-SERVICE2@nke.de

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 EUROPE GmbH
Quality Assurance Department

Attachments: List of affected products
① Receipt of the Field Safety Notice (FSN)

To: ____________________ **Fax no.:** ____________________ - or -

e-mail: ____________________

Receipt of the Field Safety Notice (FSN)

Ventilator NKV-550-U
[FSCA2021-001: “potential malfunction of internal pressure regulator”]

End-users

We,

Medical facility: ____________________

confirm receiving the Field Safety Notice FSCA2021-001 related to the ventilator model NKV-550-U.
I have read and understand the contents of this Field Safety Notice and informed all related users inside our organization.

Please contact the person mentioned below for arranging the corrective action in our facility:

Name: ____________________

e-mail: ____________________ phone: ____________________

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Name: ____________________

Date: ____________________ Signature: ____________________

Please return the completed and signed receipt to us by fax or by e-mail!

Thank you for your co-operation!