



Metran Co., Ltd.

2-12-18 Kawaguchi, Kawaguchi-shi, Saitama

332-0015 Japan

TEL: +81 48 242 0333 FAX: +81 48 242 0550



Urgent FIELD SAFETY NOTICE

Commercial name of the affected product: R100 Patient Set (REF 10020405002, LOT A-20180731)

FSCA-identifier: R100PS-010119

Type of action: Replacement of wrong component in the tubes set of the R100 Patient Set used with R100/Vision Alpha ventilator

Date: January 31, 2019

Attention: R100 Patient Set users

Details on affected devices:

R100 patient set is composed by all the components (tubes, connectors, filters, humidification chamber and oscillation diaphragm chamber) needed to act as the interface between the patient and the ventilator R100/Vision Alpha manufactured by Metran.

The tubes, filter, and humidification chamber are pre-configured and supplied as a set by the manufacturer Intersurgical (<https://uk.intersurgical.com>) packed in a closed plastic bag with REF 5026002. Intersurgical components along with other parts from three different manufacturers are packed together under Metran's MDD certification and identified as PN 10020405002 in the package's label.

Description of the problem:

We recognized that the 15mm Smoothbore limb 22F cuffs, 0.4m tube included in the Intersurgical set (REF 5026002) was supplied with wrong cuffs instead of 22F cuffs, hence it cannot be connected to the inspiration port of the ventilator. Leaving the ventilator without interface to the patient. (See attached pictures)

The incorrect configuration was not detected at Metran during the check and packing procedures of the components in the R100 Patient Set.

According to traceability records, only one affected LOT of R100 Patient Set shipped to EU had been identified: LOT A-20180731 with a total of 35 patient sets.

Corrective Action:

Metran will exchange the incorrect Intersurgical sets (REF 5026002) for free as soon as possible. You will receive the exchange products automatically as soon as possible.

Action to be taken:

- Please inform all related persons in your organization about this Field Safety Notice!
- Please identify the related end-users and the actual location of the affected METRAN R100 Patient Sets (REF 10020405002, LOT A-20180731)!
- Please confirm receiving this Field Safety Notice by the return of the attached Receiving Confirmation!
- Please exchange the affected Intersurgical sets (REF 5026002 LOT 31856744) by the new replacement sets!
- Please dispose the exchanged Intersurgical sets according the local waste disposal regulations to avoid their further unintended use!
- Please confirm the exchange and disposal by the return of the attached Response Sheet!



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The Related European Competent Authorities are informed about this Field Safety Corrective Action.

If you have any question to this Field Safety Notice or to the exchange of the affected Intersurgical sets please do not hesitate to contact our European Authorized Representative directly:

NIHON KOHDEN EUROPE GmbH
QA/RA Department
Raiffeisenstrasse 10
61191 Rosbach
Germany

phone: +49 6003-827-160
fax: +49 6003 827596
e-mail: info@nke.de

Our European Authorized Representative NIHON KOHDEN EUROPE GmbH will take care for this Field Safety Corrective Action in Europe. You also will receive the exchange products from them.

Metran apologize for this inconvenience caused to R100 Patient Set users and thank you for your understanding and cooperation!

Best regards
METRAN Co., Ltd.

- Attachments: List of affected products
 ① Receipt of the Field Safety Notice!
 ② Response Sheet

Pictures of the affected Intersurgical set (REF 5026002):





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Labelling of the R100 Patient Set:

Product Name		R100 Patient Set	 0120
REF	<input checked="" type="checkbox"/> 10020405002 (22mm) <input type="checkbox"/> 10020405003 (15mm)		
	Lot number A-20180731		 2023-05
	2018-07		 Single use
	Name	Metran Co., Ltd	
	Address	2-12-18 Kawaguchi, Kawaguchi-shi, Saitama, Japan	
	Name	NIHON KOHDEN EUROPE GmbH	
	Address	Raiffeisenstrasse 10 D-61191 Rosbach, Germany	
	 See Instructions for Use	 LATEX Latex	
Classification according to Directive 93/42/EEC	Class IIa		
Temperature limit	 -20°C to 60°C		