Urgent safety information

NO-Therapy device NO-A (CARDINO, EZ-KINOX)

(in combination with ventilator Leoni Plus)

3. March 2023

Recipients

Customers and users of the NO therapy device NO-A, medical device safety officer, medical technology management, management and medical staff of intensive care units.

Affected devices

NO-Therapy device NO-A (EKU Elektronik GmbH)

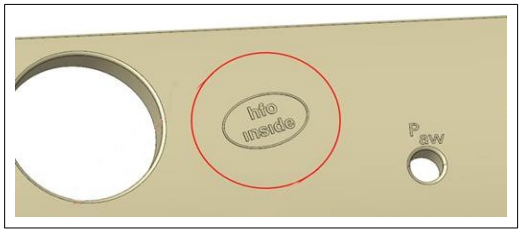
Trade name *CARDINO* (distributed by Linde Gas Therapeutics GmbH)

Trade name *EZ-KINOX* (distributed by Air Liquide Santé Services)

Reason for Field Safety Corrective Action

The NO therapy device NO-A from EKU Elektronik GmbH is not compatible with the HFO ventilation mode of the updated version of the ventilator Leoni Plus from the manufacturer Löwenstein Medical when operated with an external flow sensor.

The updated version of the Leoni Plus can be identified by the label “hfo inside”:



The new hardware of the updated Leoni Plus leads to the fact that in HFO ventilation mode, when using an external flow sensor to control the NO dosage of the NO-A (as described in chapter 4.6 of the instructions for use), too much nitric oxide (NO) may be delivered by the unit and therefore the generated NO concentration may be significantly higher than specified by the user.

This problem does not occur when operating with an RS232 coupling to the Leoni Plus (see chapter 7 of the NO-A operating instructions).

Action To Be Taken by the User

Users of the NO therapy device NO-A are hereby instructed not to use the NO-A in conjunction with an external flow sensor with an updated version of the Leoni Plus ventilator in HFO ventilation mode.

However, coupling via the RS232 interface with the Leoni Plus is still possible.

Action Being Taken by the Manufacturer

The manufacturer will revise and distribute the ventilator compatibility information.

Transmission of this Field Safety Notice

This safety information must be provided to all appropriate hospital staff, including nurses and physicians who use the NO-A as a treatment method.

Please acknowledge receipt of this Safety Notice by completing and returning the enclosed confirmation form.

We hereby confirm that this safety information has been communicated to the relevant competent authorities. BfArM is the lead competent authority for this field safety corrective action (FSCA).

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