Urgent safety information

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

(in combination with ventilators Servo-n and Servo-u)

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

When operating the NO therapy device NO-A (manufacturer: EKU Elektronik GmbH) together with the Servo-n resp. Servo-u ventilators in neonatal mode (manufacturer: Getinge), it can happen in certain cases that too little nitric oxide (NO) is delivered by the device and therefore the NO concentration produced is significantly lower than specified by the user.

This behaviour is observed when the devices are coupled via the RS232 interface if there is a high leakage in the respiratory system and the ventilator actively compensates for this leakage. In this case, the values received by the NO therapy device NO-A from the ventilator via the RS232 interface deviate from the real ones to such an extent that an undersupply of NO occurs.

When operating with an external flow sensor, the above problem does not occur.

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 a RS232 coupling in combination with a Servo-n resp. a Servo-u in neonatal mode.

However, coupling via an external flow sensor is still possible with both devices.

Action Being Taken by the Manufacturer

The manufacturer will revise and distribute the ventilator compatibility information.

Furthermore, a software update will be made available in Q2/2023 which will not allow RS232 coupling with the Servo-n resp. Servo-u in neonate mode.

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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