	Customer information	NOA7035 Version: 1.0.0
	Processing/hygiene advices of NO-A / EZ-KINOX / CARDINO and connection accessories	Datum / Date: 03/20 Page 1

For current reasons, we would like to draw your attention to the hygiene measures for your gas therapy device and your connection accessories.

We ask you not only to observe the hygiene measures in your daily use but especially when you send products to us for service/maintenance:

- Please only send the products that are necessary for the scope of service/maintenance.
- Perform the preparation steps described below before packing.
- Please do not send disposable items.

Preparation of flow measuring / dosing modules (flow sensors)

The sterilization of the flow measuring / dosing modules described in instructions for use up to version 2.5.0 was rated as not necessary. The flow measuring / dosing modules are not in direct contact with the patient and are only flowed through with fresh gas. However, the flow measuring / dosing modules are in direct contact with the users / nursing staff during maintenance or installation. Cleaning and disinfection instructions are provided in the following.

Disposable items (e.g. adapters, water traps, dosing or measuring hoses) must be disposed of after use in accordance with local regulations. They must not be processed and reused.

Please note the following information in accordance with the requirements of EN ISO 17664.

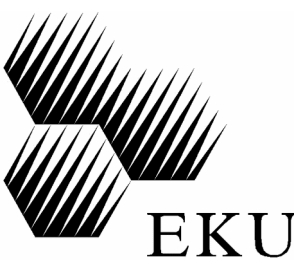
The instructions listed have been validated by us as suitable for the preparation of the medical device for reuse. It is the responsibility of the processor to ensure that the processing actually carried out with the equipment, materials and personnel used in the processing facility achieves the desired result. This requires verification and / or validation and routine monitoring of the process.

You will receive this information as a supplement to the instructions for use up to and including version 2.5.0. This information can also be found in the instructions for use from version 2.6.0.

Leiningen, 31.03.2020

Ort, Datum / Place, date

EKU Elektronik GmbH
Am Sportplatz
D-56291 Leiningen
+49 6746-80232-00
qm@eku-elektronik.de

	Customer information	NOA7035 Version: 1.0.0
	Processing/hygiene advices of NO-A / EZ-KINOX / CARDINO and connection accessories	Datum / Date: 03/20 Page 2

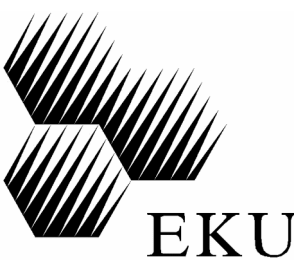
1. Processing NO-A

The following processing instructions are described in the following sections

- casing
- flow sensor (optional, connection accessories)


2. General information

Manufacturer: EKU Elektronik GmbH Processes: Manual cleaning and disinfection Symbol: not applicable Products: NO-therapy device	
WARNINGS	<p>After the end of the therapy, all parts that come into contact with the patient's air must be cleaned and disinfected.</p> <p>Detailed preparation steps are described below.</p> <p>Observe the manufacturer's instructions for the cleaning agents / disinfectants.</p> <p>The hospital's hygiene regulations must also be observed.</p> <p>Disposable items (e.g. adapters, water traps, dosing or measuring hoses) must be disposed of after use in accordance with local regulations. They must not be processed and reused.</p> <div style="border: 1px solid black; background-color: #f0f0f0; padding: 5px;"> <p>ATTENTION:</p> <p>In all steps of preparation (collection, pre-cleaning, intermediate storage and transport), the interests of occupational safety have to be kept, e.g. with suitable protective clothing, safety glasses and suitable gloves (TRBA 250).</p> </div> <p>Dispose corroded or damaged instruments.</p>
Restriction of reprocessing (all components)	<p>Mechanical reprocessing is excluded for all components. Failure to observe this can destroy other components during reprocessing.</p> <p>The preparation of the NO-therapy device has no influence on the service life.</p> <p>Regardless of the preparation cycles, the lifetime of the flow sensors is 2 years.</p>

	Customer information	NOA7035 Version: 1.0.0
	Processing/hygiene advices of NO-A / EZ-KINOX / CARDINO and connection accessories	Datum / Date: 03/20 Page 3

3. Casing

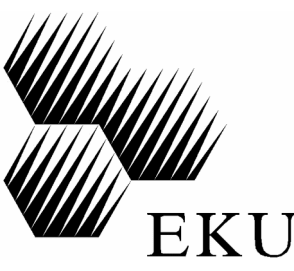
INSTRUCTIONS Casing	
Initial treatment on site	not applicable
Preparation for decontamination	not applicable
Cleaning: manual	The casing can be cleaned with a soft cloth and mild soapy water. It must be ensured that no liquid penetrates the device or connections.
Cleaning: machine	not applicable
Disinfection: manual	After cleaning, wipe the outer surfaces thoroughly with a suitable disinfectant cloth. Use suitable means according to the list of the Robert Koch Institute (RKI list).
Drying	Parts that have not yet dried completely after cleaning and disinfection must be dried again (e.g. with a lint-free cloth, do not use compressed air).
Maintenance, inspection and testing	You can find information on servicing and maintenance by a qualified specialist in the service instructions.
Sterilization	not applicable
Storage	Processed parts must be stored in a dust-free, dry and dark place.
Additional information	not applicable
Contact to manufacturer	EKU Elektronik GmbH Am Sportplatz 56291 Leiningen

	Customer information	NOA7035 Version: 1.0.0
	Processing/hygiene advices of NO-A / EZ-KINOX / CARDINO and connection accessories	Datum / Date: 03/20 Page 4

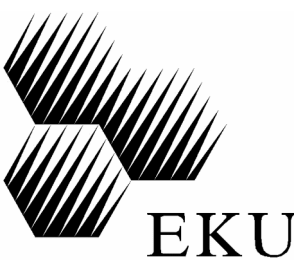
4. Flow sensors

4.1 Flow sensors with permanently installed cable

INSTRUCTIONS Flow sensors with permanently installed cable	
Initial treatment on site	The flow sensors must be cleaned or disinfected before the first use.
Preparation for decontamination	<p>The flow sensors have a measuring wire which can be damaged if the cleaning is not performed properly. Therefore, the following information should be strictly observed:</p> <div style="border: 1px solid black; background-color: #f0f0f0; padding: 5px;"> <p>ATTENTION: Never clean the sensor with compressed air or under running water. Never clean the sensor in the disinfection machine (machine preparation, RDG) or ultrasonic bath.</p> </div> <p>The instructions of the manufacturer of the cleaning agents and disinfectants used must be followed.</p> <p>From a technical point of view, cleaning / disinfection is only necessary if the sensor is contaminated.</p> <p>Such contamination is unlikely due to the recommended use in the inspiratory branch of the ventilator. Nevertheless, the hygiene regulations at the place of use must be observed.</p> <div style="border: 1px solid black; background-color: #f0f0f0; padding: 5px;"> <p>ATTENTION: Flow sensors with a permanently connected cable must not be sterilized or disinfected by rinsing. This will destroy the devices. Only wipe disinfection is permitted here.</p> </div>
Cleaning: manual	<p>First remove all coarse dirt on the sensor, for example with a soft, damp cloth. Mild soapy water can be used as a cleaner.</p> <div style="border: 1px solid black; background-color: #f0f0f0; padding: 5px;"> <p>ATTENTION: The cleanability has been validated for HAKA neutral soap (1%).</p> </div>
Cleaning: machine	not applicable
Disinfection: manual	<p>Only wipe disinfection possible.</p> <p>MinuteWipes (Alpro Medical) were used for the validation. First wipe the outer surface with a disinfectant cloth. Disinfect all surfaces thoroughly with another disinfectant cloth. Pay special attention to contact in the grooves of the instruments. Allow instruments to air dry after wiping.</p>


	Customer information	NOA7035 Version: 1.0.0
	Processing/hygiene advices of NO-A / EZ-KINOX / CARDINO and connection accessories	Datum / Date: 03/20 Page 5

Drying	Parts that have not yet dried completely after cleaning and disinfection must be dried again (e.g. with a lint-free cloth. Do not use compressed air).
Maintenance, inspection and testing	<p>You can find information on servicing and maintenance by a qualified specialist in the service instructions.</p> <p>After cleaning / disinfection, the sensor must be checked for cleanliness and damage.</p> <p>Finally, the function must be checked by connecting the sensor to the NO-A and performing a 0-point calibration (see instructions for use).</p>
Sterilization	not applicable
Storage	Processed parts must be stored in a dust-free, dry and dark place.
Additional information	not applicable
Contact to manufacturer	EKU Elektronik GmbH Am Sportplatz, 56291 Leiningen

	Customer information	NOA7035 Version: 1.0.0
	Processing/hygiene advices of NO-A / EZ-KINOX / CARDINO and connection accessories	Datum / Date: 03/20 Page 6

4.2 Flow sensors with separate cable

INSTRUCTIONS Flow sensors with separate cable	
Initial treatment on site	The flow sensors must be cleaned or disinfected before the first use.
Preparation for decontamination	<p>The flow sensors have a measuring wire which can be damaged if the cleaning is not performed properly. Therefore, the following information should be strictly observed:</p> <div style="border: 1px solid black; background-color: #e0e0e0; padding: 5px;"> <p>ATTENTION: Never clean the sensor with compressed air or under running water. Never clean the sensor in the disinfection machine (machine preparation, RDG) or ultrasonic bath.</p> </div> <p>The instructions of the manufacturer of the cleaning agents and disinfectants used must be followed.</p> <p>From a technical point of view, cleaning / disinfection is only necessary if the sensor is contaminated.</p> <p>Such contamination is unlikely due to the recommended use in the inspiratory branch of the ventilator. Nevertheless, the hygiene regulations at the place of use must be observed.</p>
Cleaning: manual	<p>The flow sensor (without cable) can be prepared in the immersion bath (e.g. instrument pan). To do this, gently move the flow sensor back and forth in the instrument pan using a soft cloth to clean the outer surface. Mild soapy water can be used as a cleaner.</p> <div style="border: 1px solid black; background-color: #e0e0e0; padding: 5px;"> <p>ATTENTION: The cleanability has been validated for HAKA neutral soap (1%).</p> </div>
Cleaning: machine	not applicable

	Customer information	NOA7035 Version: 1.0.0
	Processing/hygiene advices of NO-A / EZ-KINOX / CARDINO and connection accessories	Datum / Date: 03/20 Page 7

Disinfection: manual	<p>The flow sensor (without cable) can be prepared in the immersion bath (e.g. instrument pan).</p> <p>After cleaning, carry out disinfection in a disinfectant bath. For this, place the sensor in the instrument bath for the exposure time recommended by the disinfectant manufacturer so that no air bubbles remain in the instrument.</p> <p>Place the flow sensor in a disinfectant solution for the exposure time recommended by the manufacturer of the disinfectant e.g. ethanol or propanol (70%).</p> <p>Make sure that the solution flows through the sensor by gently moving the flow sensor back and forth in the immersion bath.</p> <p>The preparation validation was carried out with 70% ethanol with an exposure time of 10 minutes. When using other agents manufacturer's instructions for the disinfectant might require longer exposure times. Please follow the information provided by the disinfectant manufacturer regarding concentrations and exposure times.</p>
Drying	<p>Rinse the sensor carefully with distilled water and wipe the sensor dry with a lint-free cloth. If necessary wait until the sensor is completely dry, do not use compressed air to dry.</p>
Maintenance, inspection and testing	<p>You can find information on servicing and maintenance by a qualified specialist in the service instructions.</p> <p>After cleaning / disinfection, the sensor must be checked for cleanliness and damage.</p> <p>Finally, the function must be checked by connecting the sensor to the NO-A and performing a 0-point calibration (see instructions for use).</p>
Sterilization	<p>not applicable</p>
Storage	<p>Processed parts must be stored in a dust-free, dry and dark place.</p>
Additional information	<p>not applicable</p>
Contact to manufacturer	<p>EKU Elektronik GmbH Am Sportplatz, 56291 Leiningen</p>