Drägerwerk AG & Co. KGaA, 23542 Lübeck

To the users of Dräger ventilation systems in the US

April 24, 2020

Reprocessing information for the US: Neonatal Flow Sensors

Dear Ladies and Gentlemen,

We have recently updated the validation report with cleaning agents and disinfectants available in the US (proof of effectiveness). Attached you will find the approved reprocessing section of the IFU for the neonatal flow sensors Y-piece (Ref.: 8410185) and ISO 15 (Ref.: 8411130). Since the IFU for the flow sensor itself is still in the final implementation process, final changes e.g. on wording/ layout are still possible.

Please strictly follow the instructions for use of the Dräger main device to which this medical device is connected.

Please follow the national infection prevention policies and reprocessing regulations and the infection prevention policies and reprocessing regulations of the healthcare facility (e.g., concerning the reprocessing cycles).

Should you have any further questions on this topic, please contact your local representative.

Yours faithfully,

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Attachment

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Attachment:

Reprocessing information for the US for neonatal flow sensor Y-piece (Ref.: 8410185) and ISO 15 (Ref.: 8411130)

Safety-related information

Safety instructions

Reusable products
Reusable products must be reprocessed, otherwise there is an increased risk of infection.
► Follow the infection prevention policies and reprocessing regulations of the healthcare facility.
► Follow the national infection prevention policies and reprocessing regulations.
► Use validated procedures for reprocessing.
► Follow the manufacturer's instructions for cleaning agents, disinfectants, and reprocessing devices.

Signs of wear, e.g., cracks, deformation, discoloration, or peeling, may occur with reprocessed products.
► Check products for signs of wear and replace them if necessary.

Flow sensors
Flammable substances
The flow sensor may ignite medications or other substances based on easily flammable substances.
The patient may be put at risk.
► Do not nebulize medications or other substances that are easily flammable or spray them into the device.
► Do not use substances containing alcohol.
► Do not allow combustible or explosive substances to enter the breathing system or the breathing circuit.

Residual vapors of highly flammable disinfectants
Residual vapors of highly flammable disinfectants (e.g., alcohols) and deposits that were not removed during reprocessing may ignite when the flow sensor is in use.
The patient may be put at risk.
► Ensure particle-free cleaning and disinfection.
► After disinfection, allow the flow sensor to air-dry for at least 30 minutes.
► Before inserting, check the flow sensor for visible damage and soiling, such as residual mucus, medication aerosols, and particles.
► Replace flow sensors when damaged, soiled, or not particle-free.

Neonatal flow sensor
Improper reprocessing and soiling, such as deposits or particles, may damage the flow sensor. The flow measurement may fail. As a result, the patient may be put at risk.
► No machine cleaning or disinfection of the sensor insert
► No plasma sterilization or radiation sterilization
► No water jets, compressed air, brushes or the like when cleaning the sensor insert
► No ultrasonic bath

► Clean and disinfect the flow sensor in accordance with the reprocessing instructions.
► For disinfecting the flow sensor use only clean disinfectant solutions.

Reprocessing

Information on reprocessing

Follow the national infection prevention policies and reprocessing regulations.

Follow the infection prevention policies and reprocessing regulations of the healthcare facility (e.g., concerning the reprocessing cycles).

Reusable components through which contaminated breathing gas passes during normal operation and in the event of a fault must be reprocessed. In normal operation, contaminated breathing gas passes through the expiratory valve and other accessories in the expiratory path. In the event of a fault, the inspiratory valve and other accessories in the inspiratory path may become contaminated

Classifications for reprocessing

Classification of medical devices

The classification depends on the intended use of the medical device. The risk of infection transmission through the application of the product to the patient without proper reprocessing is the basis of the Spaulding classification.

Classification	**Explanation**
Non-critical	Components that come into contact only with skin that is intact
Semi-critical	Components that carry breathing gas or come into contact with mucous membranes or pathologically altered skin
Critical	Components that penetrate skin or mucous membranes or come into contact with blood

Categorization

Category	**Classification**	**Part number**
Neonatal flow sensor	Semi-critical	8410185 (Y-piece); 8411130 (ISO 15)

Validated reprocessing of the neonatal flow sensor

Preparation
Remove the sensor insert from the sensor housing before cleaning and disinfection.

Note the following when reprocessing the sensor insert:
– Do not use any brushes.
– Do not spray the sensor insert.
– Do not clean the sensor insert by machine, and do not disinfect it thermally.

Manual cleaning followed by disinfection by immersion

Components:
– Sensor housing of the ISO 15 flow sensor
– Sensor housing of the flow sensor Y-piece
– Sensor insert

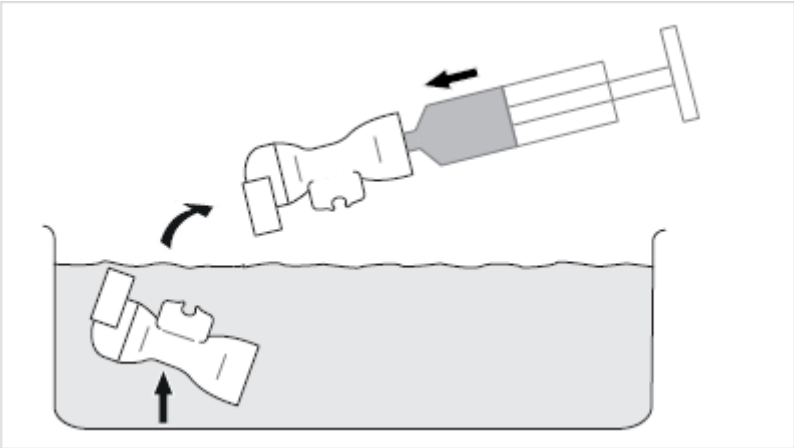
Manufacturer	Concentration	Contact time
Cleaning agent: neodisher mediclean forte / Dr. Weigert	0.5%	10 min
Disinfectant: CIDEX OPA / ASP	100 %	5 min

Prerequisites:
– The cleaning agent and the disinfectant have been prepared in accordance with the manufacturer's instructions.

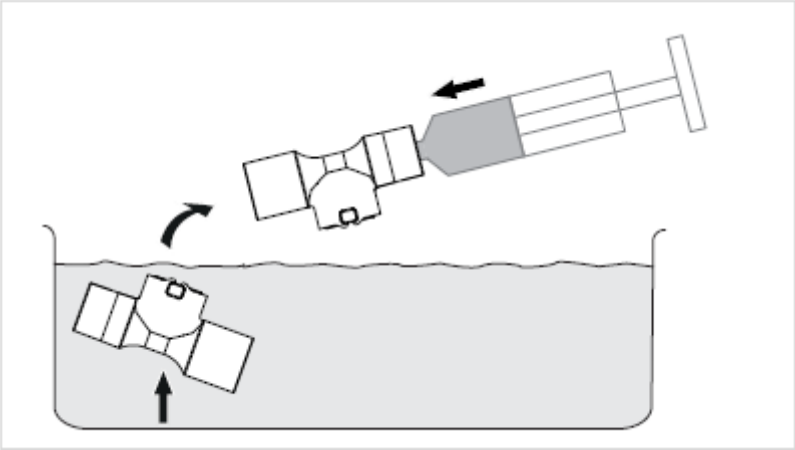
Manual cleaning

1. Place the components in the cleaning agent.
2. Swirl the components back and forth at least 3 times. Make sure the cleaning agent reaches all surfaces and interior spaces.
3. Fill a syringe that can hold at least 50 mL with the cleaning agent. Remove the flow sensor housing from the cleaning agent and spray at least 50 mL through each opening. Put the flow sensor housing back into the cleaning agent.

Sensor housing of the flow sensor Y-piece:



Sensor housing of the ISO 15 flow sensor:



4. At the end of the specified contact time, swirl the components back and forth again at least 3 times.
5. Fill a syringe that can hold at least 50 mL with the cleaning agent again. Remove the flow sensor housing from the cleaning agent again and spray 50 mL through each opening.
6. After the contact time, rinse the components in the water bath (at least drinking water quality) until no cleaning agent residue is visible.
7. Shake out residual water carefully. Allow the components to dry completely.
8. Check the components for visible soiling and repeat steps 1 through 7, if necessary.
9. Check the components for visible damage, paying particular attention to the measuring wires and their pins, and replace if necessary.

Disinfection by immersion

10. Place the components in the disinfectant. Observe the specified contact time.
11. At the beginning of the contact time, swirl the components back and forth at least 3 times. Make sure the disinfectant reaches all surfaces and interiors.
12. At the end of the contact time, swirl the components back and forth again at least 3 times.
13. After the contact time, rinse the components in the water bath (at least drinking water quality) until no disinfectant residue is visible.
14. Shake out residual water carefully. Allow the components to dry completely.
15. Check the components for visible damage, paying particular attention to the measuring wires and their pins, and replace if necessary.

Machine cleaning with thermal disinfection

Use a legally marketed washer-disinfector. Dräger recommends the use of a load carrier for anesthesia accessories and ventilation accessories. Follow the manufacturer's instructions for the washer-disinfector.

Components:

NOTICE

► Do not clean the flow sensor insert by machine, and do not disinfect it thermally.

– Flow sensor housing (without flow sensor insert)

Step	Agent	Manufacturer	Concentration	Temperature	Contact time
Preliminary cleaning	Tap water	–	–	Tap water temperature	Min. 2 min
Cleaning	neodisher mediclean forte	Dr. Weigert	Min. 0.2 %	Min. 55 °C (131 °F)	Min. 5 min
Neutralizing	neodisher Z	Dr. Weigert	Min. 0.1 %	Tap water temperature	Min. 1 min
Flushing	Demineralized water	–	–	Tap water temperature	Min. 1 min
Disinfecting	–	–	–	Min. 90 °C (194 °F)	Min. 5 min
Drying	–	–	–	–	Drying time depends on the load

Prerequisites:

– Before machine cleaning with thermal disinfection, manual cleaning "Manual cleaning followed by disinfection by immersion", must be performed.

– The washer-disinfector has been prepared in accordance with the manufacturer's instructions.

Positioning the components in the load carrier

Procedure:
1. Position the components to be stable.
2. Ensure the following:
– All surfaces and interior spaces can be completely rinsed.
– The water can drain off freely.

Performing reprocessing
1. Select a cycle.
2. When the cycle has ended, check the components for visible soiling and repeat the cycle if necessary.
3. Check the components for visible damage and replace if necessary.