

Drägerwerk AG & Co. KGaA, 23542 Lübeck

To the users of Dräger ventilation and anesthesia systems in the US

April 24, 2020

Reprocessing information for the US: Expiratory flow sensors Spirolog and Infinity ID

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 expiratory flow sensors Spirolog (Ref.: 8403735) and Infinity ID (Ref.: 6871980). Since the IFU for the flow sensor itself is still in the 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:

Reprocessing information for the US for the expiratory flow sensor Spirolog (Ref.: 8403735) and Infinity ID (Ref.:6871980)

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 health-care 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.

Expiratory 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
- ▶ No plasma sterilization or radiation sterilization
- ▶ No water jets, compressed air, brushes or the like
- ▶ No ultrasonic bath

- ▶ No hot steam sterilization of the flow sensor
- ▶ 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
Expiratory flow sensor	Semi-critical	8403735 (Spirolog); 6871980 (Infinity ID)

Validated reprocessing of the expiratory flow sensor

Manual cleaning followed by disinfection by immersion

Components:

– Expiratory flow sensor

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

Note the following when reprocessing the flow sensor:

– Do not shake the flow sensor forcefully. Carefully shake out the remaining water.

Prerequisites:

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

Manual cleaning

1. Place the flow sensor in the cleaning agent.
2. Swirl the flow sensor back and forth at least 3 times. Make sure the cleaning agent reaches all surfaces and interior spaces.
3. At the end of the specified contact time, swirl the flow sensor back and forth again at least 3 times.
4. After the contact time, rinse the flow sensor in the water bath (at least drinking water quality) until no more cleaning agent residue is visible.
5. Shake out residual water carefully. Allow the flow sensor to dry completely.
6. Check the flow sensor for visible soiling and repeat steps 1 through 5, if necessary.
7. Check the flow sensor for visible damage, paying particular attention to its measuring wires and their pins, and replace if necessary.

Disinfection by immersion

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