CONTRAfluran™-Anaesthetic Gas Filter with SENSOfluran™-Fill Level Control Unit

Instruction for Use
This instruction for use contains information about the CONTRAfluran™-System consisting of the CONTRAfluran™-Anaesthetic gas filter, the SENSOfluran™-Fill level control unit and the logistic.

Please read the instruction for use carefully before performing installation and operation of the CONTRAfluran™-System. The instruction for use is one of the product’s components and needs to be kept in direct proximity of the devices, so that it will be accessible for the operating personnel at any time.

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1. What is CONTRAfluran™ and what is SENSOfuran™?

CONTRAfluran™ is a world new innovation. It is a technology protected by international patents and other patent applications with which noxious anaesthetic gases are completely adsorbed out of the expiration air of a patient. The CONTRAfluran™-Anaesthetic gas filter is a special filter consisting of solid materials, distinguished by their rugged grain structure, extensive surface and high microporosity. This highly porous internal structure adsorbs efficiently and retains volatile anaesthetic gas components selectively from the exhaled gas as it passes through the filter. SENSOfuran™ is a mount that is integrated with a sensor to control the fill level of the filter. Thus, SENSOfuran™ gives signals for the punctual filter change.

2. Appropriate use

The CONTRAfluran™-Anaesthetic gas filter is intended to remove volatile anaesthetic gases in operation rooms, intensive care units, as well as mobile, and ambulatory treatment areas independent of the kind of the exhaust device used. The CONTRAfluran™-Anaesthetic gas filter is designed exclusively for these applications. The SENSOfuran™-Fill level control unit should only be used in combination with the CONTRAfluran™-Anaesthetic gas filter during sedation and operation of patients using volatile anaesthetics like Sevofluran, Isofluran or Desfluran. Every use of the CONTRAfluran™-Anaesthetic gas filter and the SENSOfuran™-Fill level control unit exceeding the specified purpose is prohibited! Moreover it must also be noted that the filter and the fill level control unit must only be used by trained skilled personnel.

Only strict compliance with the specifications included in this instruction for use can guarantee the safe and efficient use of the CONTRAfluran™-System. The ZeoSys GmbH or his authorized representatives will not accept any liability or damage, which is caused by incorrect or unreasonable use of the filter as well as its fill level control unit.

3. Safety instructions for the SENSOfuran™-Fill level control unit

The following safety instructions must always be considered during the operation as well as with all maintenance and repair work done at this device. Not considering these safety instructions can lead to the endangerment of the operating personnel and damage of the device!

- The device must not be opened and no modifications should be made to it. The exchange of components as well as other changes should only be done by qualified personnel.
- The device is to be operable in a temperature range of +5°C and +40°C.
- The device should only be connected to the provided plug-in power supply unit. It is designed for an operating voltage of 100..240 V AC/47..63 Hz.
- The device must not be operated in explosive or inflammable conditions without additional preventive measures!
- Damaged or defected devices are to be set out of operation immediately and be secured before unauthorized access.
- In order to avoid endangerments, no unauthorized changes in the device should be made. For repair work please send the device back to us.
4. Transportation, storage and operation of CONTRAfluran™-Filter and SENSOfluran™-Fill level control unit

This chapter describes the transportation, storage and operation of the CONTRAfluran™-Anaesthetic gas filter and the SENSOfluran™-Fill level control unit.

To make the performance of your filter effective and to help ensure your safety, be sure to follow all proper application procedures.

4.1. Transportation
During the transportation of the CONTRAfluran™-System, the following points should be considered:

- The dispatch carton should be transported with the label showing on the top.
- The carton should not be put on its top or on its side.
- Open the carton from the top.
- Keep the original carton for back transport.

4.2. Storage
If the filter and the fill level control unit are supposed to be stored while they are not being used, please consider the following facts:

- The dispatch carton should be stored with the label showing on the top.
- Do not store in the open air, but exclusively in suitable rooms which are dry and dust-free.
- We recommend a maximum relative humidity of 80%.
- Storage temperature should be –5°C to +40°C

4.3. Operation
Before using the filter, please ensure that all components needed for a proper use are available. These including:

- The CONTRAfluran™-Anaesthetic gas filter
- The SENSOfluran™-Fill level control unit
- Accessories: flexible hose ISO 22 and operationally adapters to use with different exhaust ports

For initial operation, please follow the procedures below:

A. Attach the CONTRAfluran™-Anaesthetic gas filter to the expired gas outlet valve of the respirator by means of a flexible hose. The following pictures show the steps, which are necessary to attach the filter to the expired gas outlet valve.

A1. Fasten the SENSOfluran™-Fill level control unit to the rail of the respirator/anaesthetic gas machine.

A2. Insert the filter into the mount of the SENSOfluran™-Fill level control unit.
A3. Remove the seal cap from the filter.

A4. Connect the flexible hose to the filter.

A5. Note down the applied anaesthetic gas on the top label of the filter.

B. Attach the power supply unit to the appropriate jack which is to be found on the bottom side of the fill level control unit and plug it into a power socket.

Green LED Flash: The filter is inserted correctly and the device is in a short warm-up phase. After approx. 2 min, the device switches into its measuring mode and the LED lights up permanently.

The differently colored LEDs (green, yellow, red) of the device indicate the quality of the filtered expired gas and thus the fill level of the filter.

- **LED:**
  - The filter cleans the expired gas and has still sufficient free capacity.

- **LED:**
  - The capacity of the filter diminishes. But the concentration of the anaesthetic gas in the filtered exhausted air lies within the MAK accepted values. A filter change is recommended when the second yellow LED lights up.

- **LED:**
  - The capacity of the filter is exhausted. The used filters must be replaced by a new.

- **Error message:**
  - All 4 LEDs light up at the same time: Either there is no filter assigned or the filter is not correctly inserted into the mount.

5. Application areas of the CONTRAfluran™-System

5.1. Application in operation areas with exhaust device
5.2. Application in intensive care units and ambulatory treatment areas

5.3. Application with the AnaConDa-System

6. What is to be considered during the application of the filter?

- Apply only one kind of anaesthetic gas per filter.
- Mark the respective applied anaesthetic gas on the corresponding label of the filter.
- Filter change must be done when the red LED lights up.
- Filter change is recommended when the second yellow LED lights up.
- The used filter should be clearly marked in order to avoid any repeated use.

7. Redemption and disposal of the CONTRA-fluran™-Anaesthetic gas filter

- Close the used filter with the seal cap.
- Put the used filter back into the original dispatch carton.
- Six used filters packed in each original dispatch carton should be returned (charge free) to the manufacturer or its legal distributor (Deposit returnable). The manufacturer takes over a professional disposal of the filter.
- For back transport use only the original dispatch cartons.

8. Maintenance and calibration interval of SENSOfluran™-Fill level control unit

Due to legal reason the device must be sent to ZeoSys GmbH in a period of 6 months for calibration. Please use the original carton for the dispatch. With payment, you will immediately get a new calibrated SENSOfluranTM -Fill level control unit as an exchange to avoid an interruption of the filter operation.

9. Disposal of the SENSOfluran™-Fill level control unit

For our environment’s sake and for the purpose of entire recycling of the used raw materials, we ask you to return the used and defected devices to the communal collection sites.
### Technical data

<table>
<thead>
<tr>
<th>CONTRAfluran™-Anaesthetic gas filter</th>
<th>Product-class according to MDD</th>
<th>Class 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>Operation: +5°C to +40°C</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Storage: –5°C to +40°C</td>
<td></td>
</tr>
<tr>
<td>Relative humidity</td>
<td>Operation: up to 80%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Storage: up to 80%</td>
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</tr>
<tr>
<td>Storage capacity</td>
<td>Approx. 400 g</td>
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<tr>
<td>Flow-Resistance</td>
<td>≤ 1,5 mmWS</td>
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</tr>
<tr>
<td>Height</td>
<td>19 cm</td>
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<tr>
<td>Diameter</td>
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</tr>
<tr>
<td>Weight</td>
<td>Approx. 1.000 g</td>
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</tr>
<tr>
<td>Volume</td>
<td>2 l</td>
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</table>

<table>
<thead>
<tr>
<th>SENSOfluran™-Fill level control unit</th>
<th>External material</th>
<th>Painted aluminum housing and V4A stainless steel (pins)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>+5°C to +40°C</td>
<td></td>
</tr>
<tr>
<td>Voltage</td>
<td>Power supply (Euro)</td>
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<tr>
<td></td>
<td>100..240 VAC/47..63 Hz</td>
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<tr>
<td></td>
<td>Output 7,5 VDC</td>
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<tr>
<td></td>
<td>Power input approx. 2 W</td>
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<tr>
<td>Weight</td>
<td>Approx. 950 g</td>
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### Product description

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<th>Art. no</th>
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<td>Zeo000066</td>
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<tr>
<td>Zeo000067</td>
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</tbody>
</table>
11. Customer service

In the case of a malfunction of any product, please contact our customer service.

You can reach our customer service as follows:

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