CONTRAfluran™ Zeo000100

SENSOfluran CONNECT System

Instructions for Use

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Instruction for Use

These Instructions For Use contain information about the CONTRAfluran Zeo000100 / SENSOfluran CONNECT System, consisting of the CONTRAfluran Zeo000100 Anaesthetic gas canister, the SENSOfluran CONNECT Fill level control unit and associated components.

Please read the Instructions For Use carefully before performing installation and operation of the CONTRAfluran / SENSOfluran CONNECT Anaesthetic Gas Capture System. These instructions for use must be kept in a convenient location providing direct and ready access for the Operating Room and biomedical technical personnel at any time.

WARNING: CONTRAfluran / SENSOfluran CONNECT are not designed to adsorb, capture or detect nitrous oxide. Since CONTRAfluran / SENSOfluran CONNECT CANNOT adsorb nitrous oxide, the system must be connected correctly to the Waste Anaesthesia Gas Disposal (WAGD) System to ensure safe and complete removal of nitrous oxide anesthetic gas.

WARNING! Follow strictly these Instructions For Use

Table of Contents

1. What is CONTRAfluran Anaesthetic gas canister and what is the SENSOfluran CONNECT Fill level control unit?

CONTRAfluran / SENSOfluran CONNECT System is a new, innovative technology protected by international patents and patent applications with which fluorinated halocarbon inhaled anaesthetic gases such as sevoflurane, desflurane and isoflurane administered during surgery are completely adsorbed and removed from the exhaust of the anaesthetic machine.
The CONTRAfluran Anaesthetic gas filter canister contains a unique adsorber material characterized by its highly specific and controlled physical and chemical properties such as grain structure, porosity and surface area.
The adsorber is highly selective and efficient in retaining volatile fluorinated halocarbon anaesthetic gases which enter the canister. The SENSOfluran CONNECT Fill level control unit functions as a canister holder and is equipped with a sensor to monitor the fill level (adsorbed gas capacity) of the CONTRAfluran Anaesthetic gas canister.
SENSOfluran CONNECT indicates when the CONTRAfluran Anesthetic gas canister is filled and must be changed.

SENSOfluran CONNECT is designed to actively scavenge waste anaesthesia gases exiting the Anaesthetic Gas Scavenging (AGS) outlet on the anaesthesia machine in Hospital environments equipped with the Waste Anaesthetic Gas Disposal (WAGD) system where Anaesthetic procedures are routinely performed. Ensure that the WAGD is functioning with a flow rate of between 25 and 80 LPM.

WARNING! CONTRAfluran / SENSOfluran CONNECT System CANNOT adsorb, capture or detect nitrous oxide. Since CONTRAfluran CANNOT adsorb nitrous oxide, the system must be connected correctly to the WAGD gas removal system to ensure safe removal of non-adsorbed gases. CONTRAfluran and SENSOfluran CONNECT are only indicated for with the adsorption of halogenated anaesthetic gases (sevoflurane, desflurane and isoflurane).

WARNING! Ensure that SENSOfluran CONNECT is installed on anaesthesia machines that have been appropriately converted from ACTIVE to PASSIVE* mode or that have already been purchased in PASSIVE mode.

2. Appropriate use

The CONTRAfluran Anaesthetic gas canister is intended to adsorb and remove halogenated anaesthesia gases (such as sevoflurane, desflurane and isoflurane). The CONTRAfluran/SENSOfluran CONNECT Anaesthetic Gas Capture System is designed exclusively for use in Hospital environments equipped with the Waste Anaesthesia Gas Disposal (WAGD) system where Anaesthetic procedures are routinely performed.
The SENSOfluran CONNECT Fill level control unit must only be used in combination with the CONTRAfluran Anaesthetic gas canister during anaesthesia.
CONTRAfluran and SENSOfluran CONNECT may safely be used in situations where N2O (nitrous oxide) sedation is being administered however, they are not intended to detect or capture nitrous oxide or other non-halogenated anaesthetic gases!
Please note that the CONTRAfluran Anaesthetic gas canister and the SENSOfluran CONNECT Fill level control unit must only be installed and used as instructed by qualified personnel.
Strict compliance with the instructions included in these Instructions for Use will ensure the safe and efficient use of the CONTRAfluran /SENSOfluran CONNECT System. Only the ZeoSys Medical supplied hose-connector and hose-watertrap systems (section 9 products) shall be used, forming a tight seal to the 30mm inlet port of the CONTRAfluran, Zeo000100 Anaesthetic gas canister on the one end and to the AGS outlet port on the other end. So the connectors are securely fixed to the hose by clamps on both ends of the hose. The tight seal shall be installed and securely fixed by suitable tools. ZeoSys GmbH or its authorized representatives will not accept any liability or damage, which is caused by incorrect or unreasonable use of the CONTRAfluran Anaesthetic gas canister or the SENSOfluran CONNECT Fill level control unit.

***Definition passive mode: The expiratory air is conducted in a closed system from the exhaust AGS outlet port of the anaesthesia machine into the anaesthetic gas canister.**

Please follow the ZeoSys provided general or device-specific Installation Instructions of the CONTRAfluran/SENSOflurane CONNECT system.
In addition, follow the Instructions for Use provided by the manufacturer of your anaesthesia machine.

WARNING! It is mandatory that the connectors to which the 22 mm flexible ZeoSys hose has been attached to be connected to the AGS outlet port at one end and to the inlet port of the CONTRAfluran canister at the other end are each secured with a clamp. The clamps are used to ensure that the connectors always remain connected to the 22 mm hose when changing the hose. Upon installation of this clamp, the provided warning label/information label must be affixed and clearly visible on the anaesthesia machine.

3. Safety instructions for the CONTRAfluran / SENSOfluran CONNECT System

The following safety instructions must always be followed during the operation, maintenance and repair work performed on this device.

Failure to comply with these safety instructions can lead to danger for the operating personnel, and damage to the device!

- The SENSOfluran CONNECT Fill level control unit must never be opened and no modifications shall be made to it. The exchange of components and repairs must be done by trained personnel only.
- The CONTRAfluran / SENSOfluran CONNECT System is to be operated within its specified temperature range from +5°C to +35°C.
- SENSOfluran CONNECT has to be operated with WAGD flow rates of not less than 25 LPM up to 80 LPM.
- Verify that the WAGD flow rate, as measured at the entrance to the Visual Flow Indicator, is **NOT LESS THAN** 25 LPM (per ISO 80601-2-13)
- The SENSOfluran CONNECT Fill level control unit must be connected to and powered using only the provided plug-in power supply unit. It is designed for an operating voltage of 100V -240V AC / 47 -63 Hz.
- Caution should be exercised when installing and operating the CONTRAfluran / SENSOfluran CONNECT System in an area where there is significant exposure to explosive and/or combustible materials.
- Ensure that the area under the CONTRAfluran /SENSOfluran CONNECT system is free of flammable materials and liquids
- The CONTRAfluran/SENSOfluran system must be positioned in such a way that no gas sensor of the anaesthesia machine can be affected
- The ZeoSys provided general or device-specific Installation Instructions of the CONTRAfluran /SENSOfluran CONNECT as well as the Instruction for Use provided by the anaesthesia machine manufacturer system shall be strictly followed.
- The SENSOfluran Fill level control unit shall not be used in an MRI environment.
- Damaged or inoperable or defective part of the CONTRAfluran / SENSOfluran CONNECT System must be removed from operation and secured from unauthorized use. Return all such systems to ZeoSys Medical immediately for replacement.
- SENSOfluran CONNECT Fill level control unit and CONTRAfluran Anaesthetic gas canister contain no user device serviceable parts or components and shall be returned immediately to ZeoSys Medical for repair and/ or replacement.
- CONTRAfluran/SENSOfluran CONNECT must be removed from the anaesthesia machine before in-hospital or out-of-hospital transport.
- If the anaesthesia machine is a ceiling mounted version, care must be taken when adjusting the height to ensure that the CONTRAfluran /SENSOfluran CONNECT components do not touch the floor or other obstacles.
- It must be ensured that the medical inlet and outlet hose connections of the CONTRAfluran / SENSOfluranCONNECT System provide a tight seal, and that the anaesthesia workstation/ machine is configured to operate in **passive scavenging mode**.

• SENSOfluran CONNECT can only be used on anaesthesia machines that can be configured for passive scavenging mode. Confirmation that the individual anaesthesia machine is configurable for operation in passive mode must be obtained by the user by the anaesthesia machine manufacturer.

• The examples of the anaesthesia machines listed below do not currently allow this passive mode, or allow it only through device intervention, and are therefore **NOT** suitable for the intended use of the CONTRAfluran Anaesthetic gas canister with the SENSOfluran CONNECT Fill level control unit.
- Getinge anaesthesia machines (but planned 01/2024)
- Dameca Philips anaesthesia machines

• For the following anaesthesia machines, a conversion into passive mode is only possible with the installation of additional parts by arrangement with the anaesthesia machine manufacturer.
- Dräger Perseus
- Dräger Atlan
- GE (Avance, Aisys, Aestiva, Aespire, Carestation 600/650/750)
- Mindray A8/A9

In this case the representative of the respective anaesthesia machine company must be consulted for installation of the additional part needed for converting the specific anaesthesia machine model into passive mode.

• Upon connection of CONTRAfluran / SENSOfluran CONNECT System, the anaesthesia workstation shall be put through the manufacturers recommended start-up /operational testing (e.g. "self-test").
Any test errors shall be corrected and evaluated to confirm that they do not result from the installation of CONTRAfluran /SENSOfluran CONNECT System, prior to proceeding with the use of the workstation.

3.1. Attaching the ZeoSys Medical provided Checklist label on your anaesthesia machine for daily checks of the CONTRAfluran/SENSOfluran CONNECT system is recommended

For daily check make sure:

-The SENSOfluran CONNECT device is connected to the mains power supply (LED lights up)
-The connector between the transparent hose and the AGS is secured with a clamp and is firmly attached to the AGS outlet port
-The ZeoSys hose-connector system or hose-watertrap system between the AGS outlet port and the CONTRAfluran canister is undamaged and the hose not kinked
-The ZeoSys Medical transparent hose-connector or transparent hose-watertrap system, which is located between the anaesthesia machine and the CONTRAfluran canister is checked for condensed water that may have formed. Possible condensed water must be (drained).
(A Zeosys Medical watertrap system is highly recommended for users practising minimal flow anaesthesia. Please ask customer service for further information.)
-The visible Flow indicator is working-the flap of the flow indicator shall not be vertical

4. Transportation, storage and operation of CONTRAfluran Anaesthetic gas canister and SENSOfluran CONNECT Fill level control unit

This section describes the transportation, storage, and operation of the CONTRAfluran Anaesthetic gas canister and the SENSOfluran CONNECT Fill level control unit.

To ensure the performance of your CONTRAfluran Anaesthetic gas canister and SENSOfluran CONNECT Fill level control unit and in order to help ensure your safety, be sure to follow all recommended application procedures.

4.1. Transportation

During the transportation of the CONTRAfluran / SENSOfluran CONNECT System, the following points should be considered:

- The shipping carton should be transported upright with the label showing right-side up.
- The shipping carton should not be inverted or stored on its side.
- Carefully open the carton from the top avoiding damage to the contents.
- Retain the original CONTRAfluran shipping carton, red caps and zipper bags for sealing and return transportation of filled canisters.

4.2 Storage of new (unused) CONTRAfluran Anaesthetic gas canisters

For storage of new CONTRAfluran Anaesthetic gas canisters and / or SENSOfluran CONNECT Fill level control units which are not currently in use, please consider the following:

- The shipping carton should be stored with the label showing right-side up.
- Packaging materials including shipping carton, cardboard inlays, cardboard inlays, zipper bags and red caps should be retained for the return of canisters.
- Store in a dry, clean location at room temperature.

4.3 Operation

Before using the CONTRAfluran / SENSOfluran CONNECT System, please ensure that all components needed for proper installation and use are available.

This includes:

- CONTRAfluran, Zeo000100, Anaesthetic gas canister
- The SENSOfluran CONNECT Fill level control unit
- ZeoSys Medical supplied hose-connector system or hose-watertrap system (section 9 products) which is fitting to the specific aneasthesia machine.
- The ZeoSys general and device specific Installation Instructions describe the connector dimensions to be used to connect the CONTRAfluran / SENSOfluran CONNECT system to the AGS port of the most common anaesthesia machines. ZeoSys Medical offers pre-assembled hose-connector or hose-watertrap systems for the most common anaesthesia machines. These are suitable for the initial installation of the CONTRAFluran / SENSOfluran CONNECT system and available as consumables for the periodic replacement of the hose-connector system or the hose- watertrap system (see section 9 products)
- Mounting rail splint at the anaesthesia machine for attaching the CONTRAfluran / SENSOfluran CONNECT System
- An accessible power socket so that the SENSOfluran CONNECT Fill level control can easily be pluged in

Prior to use, confirm that the anaesthesia machine has been converted to **passive scavenging mode**.

A.(A1-A10) Operation of the CONTRAfluran /SENSOfluran CONNECT system in several steps

A1. Securely fasten the SENSOfluran CONNECT Fill level control unit to the mounting rail of the anaesthesia workstation / machine.

A2. Connect the mains adapter into a suitable power outlet.

***Note**: Be sure that the mains adapter is connected to an easily accessible power outlet. Unplug the mains adapter from the power outlet in case of emergency.*

The SENSOfluran CONNECT Fill level control unit enters a self-diagnostic mode and performs a self-test:
Do not place the canister into the SENSOfluran CONNECT Fill level control unit before this self-test is complete.
Self-test steps:

- 1 second visual and acoustic test
  the green and yellow LEDs will illuminate
  and an acoustic signal sounds
- 10 second test of the canister detection sensor
- 5 minutes warm-up period
  -the green LED flashes

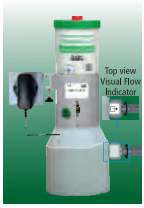
At the end of this self-test, 3 LEDs light up one after the other and an acoustic signal sounds.
(This means that no CONTRAfluran Anaesthetic gas canister has been placed into the SENSOfluran CONNECT Fill level control unit)
Follow the next steps to continue and complete the connection of the CONTRAfluran / SENSOfluran CONNECT System to the anaesthesia machine as shown schematically on the following pictures:

A3. Place a new CONTRAfluran Anaesthetic gas canister with a red sealed screw cap into the SENSOfluran CONNECT Fill level control unit. Open the red security seal by unscrewing the red screw cap. Retain the red screw cap from the CONTRAfluran Anaesthetic gas canister.
The green (bottom) LED flashes, indicating that the sensor is in warm-up period of 15 minutes. The warm-up time of the SENSOfluran CONNECT has no influence on the functioning of the new CONTRAfluran canister. When the warm-up period is complete, the bottom LED will return to a steady green light.

A4. Connect the CONTRAfluran Anaesthetic gas canister to the AGS outlet (exhaust AGS outlet) of the anaesthesia machine using the Zeosys Medical pre-assembled hose-connector or hose-watertrap system. Choose the suitable pre-assembled Zeosys Medical hose-connector or hose-watertrap system according to Installation Instructions for your specific anaesthesia machine.
The safety clamps on both sides of the Zeosys Medical hose-connector or hose-watertrap systems ensure that the connection between the hose and the connectors is firmly secured such that, in the event of a hose disconnection the 2 connectors remain connected/fixed on the hose and/or watertrap.

A5. Stick the information label (see left) to indicate that the anaesthesia machine is converted to passive mode clearly visible next to the AGS outlet port on your anaesthesia machine.

WARNING! Do not connect the AGS outlet port or the connector to the AGS outlet port directly to the Waste Anaesthetic Gas Disposal (WAGD) System.



A6. Connect the Visual flow indicator outlet port of the SENSOfluran CONNECT Fill level control unit to The WAGD wall or ceiling connection as shown in section 5. Make sure the connection is tight and secure and the clamp is installed. Check the operational readiness of the Waste Anaesthetic Gas Disposal (WAGD) connection with the help of the Visual flow indicator.
The black flap of the Visual flow indicator shall not be vertical.

A7. Make sure that the hose between the AGS port and the CONTRAfluran canister does not have a U loop and that any excess water is removed regularly. Additionally there is a flexible hose-watertrap sytem available. Please contact Customer Service for further information.

A8. Fix Checklist label for daily routine

A9. Record the anaesthetic gas(es) being collected by checking the appropriate box on the top of the canister.

A10. Ensure that the LED signals of the SENSOfluran CONNECT Fill level control unit are clearly visible from the anaesthesia workstation

B. Possible LED Display Signals of SENSOfluran CONNECT Fill level control unit. Make sure that the LEDs of the SENSOfluran CONNECT are visible from the workstation.

B1. Fill level indication

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

NOTE: The top-most LED of 4 LEDs (red) does not illuminate under any conditions of normal use.

GREEN LED (steady ON, bottom)
Indicates that the CONTRAfluran Anaesthetic gas canister is adsorbing halogenated anaesthesia gases exhausted from anaesthesia workstation (other gases pass through and are removed by the WAGD).

GREEN/YELLOW LED (bottom)
The filter is still functioning and filtering out anaesthetic gas however the CONTRAfluran Anaesthetic gas canister is nearing its capacity.

YELLOW LED (bottom)
The capacity of the filter is almost full but still has some remaining capacity.
Have a new canister available for change when indicated to do so.

YELLOW flashing LED + audible interval signal (top)
The capacity of the filter is full.
The CONTRAfluran Anaesthetic gas canister must immediately be replaced with a new one.

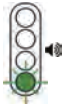
B2. Message during Warm-up period:

FLASHING GREEN
After a canister change, the green (bottom) LED flashes, indicating that the sensor is in the warm-up period. When the warm-up period of 15 minutes is complete, the bottom LED will return to a steady green light.

NOTE: The CONTRAfluran Anaesthetic gas canister remains operational during the warm-up period.

B3. Error messages:

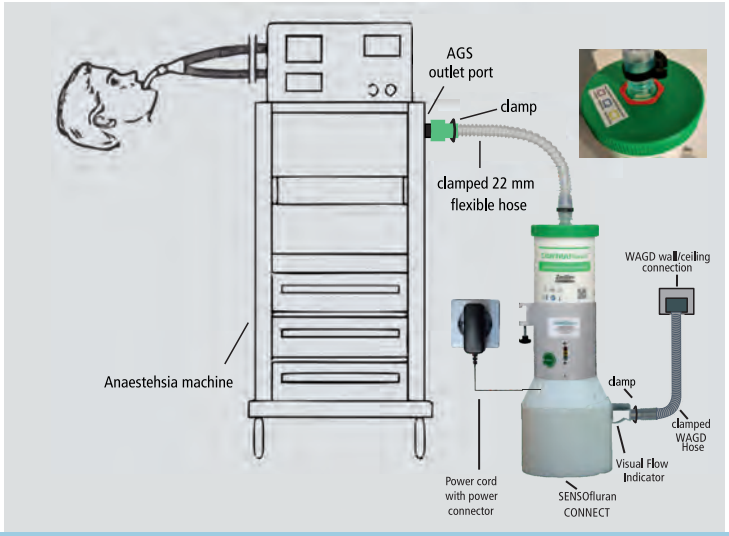
GREEN / YELLOW / YELLOW
3 LEDs light up one after the other and an acoustic signal sounds.
This means that no canister has been placed in the SENSOfluran CONNECT Fill level control unit. Place the CONTRAfluran Anaesthetic gas canister in the SENSOfluran CONNECT Fill level control unit and wait for the green continuous light.



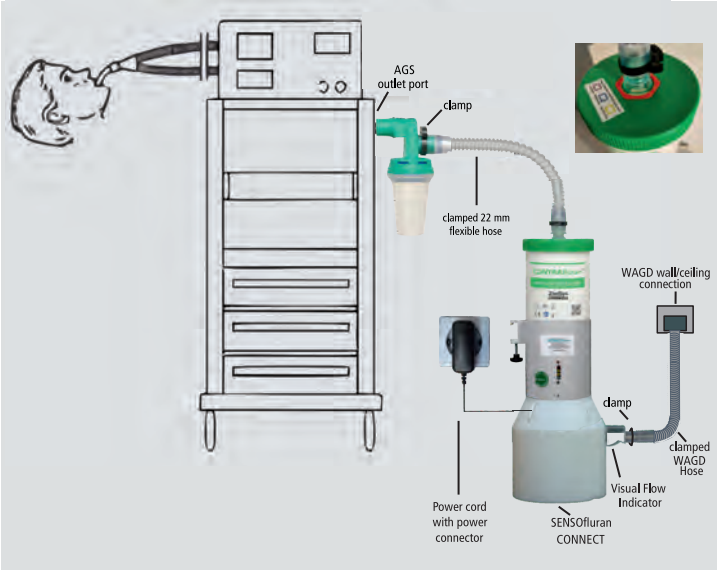
GREEN FLASHING WITH ACOUSTIC SIGNAL
If the green LED flashes and an acoustic signal sounds at the same time, the gas sensor is defective. Please remove from service and arrange replacement with the customer service.

5. Application area of CONTRAfluran/SENSOfluran CONNECT Anaesthetic gas capture system in units with Waste Anaesthetic Gas Disposal System (WAGD)

5.1 Connection between AGS outlet port and CONTRAfluran canister with ZeoSys Medical hose-connector system.



5.2 Connection between AGS outlet port and CONTRAfluran canister with ZeoSys Medical hose-watertrap system.



6. When and how to replace the used CONTRAfluran Anaesthetic gas canister

YELLOW LED (bottom)
The capacity of the filter is almost full but still has some remaining capacity. Have a new canister available for change when indicated to do so.

YELLOW flashing LED + audible interval signal (top)
The capacity of the filter has been reached.
The CONTRAfluran Anaesthetic gas canister must immediately be replaced with a new one.

Place a CONTRAfluran Anaesthetic gas canister with an intact red safety seal into the SENSOfluran CONNECT Fill level control unit. Break the safety seal by removing (and retaining) the red seal cap from the CONTRAfluran Anaesthetic gas canister.
The green (bottom) LED flashes, indicating that the sensor is in a warm-up period of 15 minutes.
After completion of this warm-up period the bottom LED will return to steady green light.

7. Return and handling of the used (filled) CONTRAfluran Anaesthetic gas canister

Where possible, replace the red cap onto the used CONTRAfluran Anaesthetic gas canister.
Prior to storage and return, please ensure that the exterior surface of the CONTRAfluran Anaesthetic gas canister is wiped with a cloth dampened with an aqueous-based cleaning solution (ZeoSys Medical recommends the use of hydrogen peroxide wipes, concentration 1% -1.5%).

WARNING! DO NOT USE alcohol or aldehyde-based cleaning agents as they will damage the SENSOfluran CONNECT sensor.

- The canister must then be placed into the protective zipper bag and **securely sealed**.

- Six used canisters, **securely sealed in their zipper bags** , should be packed into the **original shipping carton** and stored in a cool, dry, well-ventilated place.

- Before returning the used (filled) canisters to ZeoSys Medical for the recovery of the volatile anaesthetics please label the **shipping carton** with the name and address of your hospital.

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

Follow hospital-established protocol for cleaning the anaesthesia workstation to determine cleaning frequency for SENSOfluran CONNECT Fill level control unit.

To clean the surface of the SENSOfluran CONNECT Fill level control unit, wipe down with a cloth dampened with hydrogen peroxide (1%-1.5%) or other aqueous biocidal detergent. **DO NOT USE** alcohol or aldehyde-based cleaners, as they will damage the sensor and negatively impact the performance of the SENSOfluran CONNECT Fill level control unit.

CAUTION: Avoid excessive „wetting" near the electrical components or the sensor during cleaning period or sanitization activities! Use non-alcohol-based wipes only!

Allow at least 10 minutes for exposure and drying time before placing the SENSOfluran CONNECT Fill level control unit back into operation.

Ensure that the Zeosys Medical transparent flexible hose-connector system and hose-watertrap Systems are replaced regularly according to your hospital's protocol, but a change at least every 3 months is recommended.

.The gas sensor unit within the SENSOfluran CONNECT Fill level control unit must be re-calibrated every **12 months**. Calibration can only be conducted by ZeoSys Medical GmbH. Please refer to the **calibration sticker** showing the re-calibration date applied to the side of SENSOfluran CONNECT Fill level control unit. For a newly-calibrated unit, please contact Customer Service at least 1 month prior to expiration date.

9. Technical data

CONTRAfluran Anesthetic gas canister	Product-class according to EU MDR	Class 1
	Temperature	Operation: +5°C to +35°C Storage: -5°C to +35°C
	Relative humidity	Operation: to 70% Storage: to 70%
	Storage capacity	Approx. 400g
	Flow-Resistance (at 60 l LPM flow-rate air)	2,3 [hPa]
	Height	21 cm
	Diameter	12 cm
	Weight	Approx. 1000 g
	Volume	2 liters
SENSOfluran CONNECT Fill level control unit	External material	Powder-coated aluminum
	Temperature	+5°C to +35°C
	Voltage	Power supply 100V-240V AC / 47-63Hz Output 6,0V DC Power consumption approx: 6W
	Weight	Approx. 1400g
	Gas sensor circuit board	(50x55x20) mm
	Circuit board coating	Bectron MR 3404
	External wall mains power adapter	GSM06E06-P1J; GEM06I6-P1J

Products	Art.-Nr.
StarterKit CONNECT EU	Zeo000173
SENSOfluran CONNECT EU	Zeo000073
StarterKit CONNECT US	Zeo000175
SENSOfluran CONNECT US	Zeo000075
CONTRAfluran™ Anaesthetic gas canister	Zeo000100
Power supply unit	Zeo000053
Flexible Hose 0.3m with Watertrap (30M-30M)	Zeo000181
Flexible Hose 0.4m with Watertrap (30M-30M)	Zeo000182
Flexible Hose 0.5m with Watertrap (30M-30M)	Zeo000183
Flexible Hose 0.6m with Watertrap (30M-30M)	Zeo000184
Flexible Hose 0.8m with Watertrap (30M-30M)	Zeo000185
Flexible Hose 1m with Watertrap (30M-30M)	Zeo000186
Flexible Hose 1.2m with Watertrap (30M-30M)	Zeo000187
Flexible Hose 1.5m with Watertrap (30M-30M)	Zeo000188
Flexible Hose 1.8m with Watertrap (30M-30M)	Zeo000189
Flexible Hose 2m with Watertrap (30M-30M)	Zeo000190
Flexible Hose 0.3m with Watertrap (30F-30M)	Zeo000191
Flexible Hose 0.4m with Watertrap (30F-30M)	Zeo000192
Flexible Hose 0.5m with Watertrap (30F-30M)	Zeo000193
Flexible Hose 0.6m with Watertrap (30F-30M)	Zeo000194

Products	Art.-Nr.
Flexible Hose 0.8m with Watertrap (30F-30M)	Zeo000195
Flexible Hose 1m with Watertrap (30F-30M)	Zeo000196
Flexible Hose 1.2m with Watertrap (30F-30M)	Zeo000197
Flexible Hose 1.5m with Watertrap (30F-30M)	Zeo000198
Flexible Hose 1.8m with Watertrap (30F-30M)	Zeo000199
Flexible Hose 2m with Watertrap (30F-30M)	Zeo000200
Flexible Hose 0.3m with Watertrap (22F-30M)	Zeo000201
Flexible Hose 0.4m with Watertrap (22F-30M)	Zeo000202
Flexible Hose 0.5m with Watertrap (22F-30M)	Zeo000203
Flexible Hose 0.6m with Watertrap (22F-30M)	Zeo000204
Flexible Hose 0.8m with Watertrap (22F-30M)	Zeo000205
Flexible Hose 1m with Watertrap (22F-30M)	Zeo000206
Flexible Hose 1.2m with Watertrap (22F-30M)	Zeo000207
Flexible Hose 1.5m with Watertrap (22F-30M)	Zeo000208
Flexible Hose 1.8m with Watertrap (22F-30M)	Zeo000209
Flexible Hose 2m with Watertrap (22F-30M)	Zeo000210
Flexible Hose 0.3m (30M-30M)	Zeo000211
Flexible Hose 0.4m (30M-30M)	Zeo000212
Flexible Hose 0.5m (30M-30M)	Zeo000213
Flexible Hose 0.6m (30M-30M)	Zeo000214
Flexible Hose 0.8m (30M-30M)	Zeo000215
Flexible Hose 1m (30M-30M)	Zeo000216
Flexible Hose 1.2m (30M-30M)	Zeo000217
Flexible Hose 1.5m (30M-30M)	Zeo000218
Flexible Hose 1.8m (30M-30M)	Zeo000219
Flexible Hose 2m (30M-30M)	Zeo000220
Flexible Hose 0.3m (30F-30M)	Zeo000221
Flexible Hose 0.4m (30F-30M)	Zeo000222
Flexible Hose 0.5m (30F-30M)	Zeo000223
Flexible Hose 0.6m (30F-30M)	Zeo000224
Flexible Hose 0.8m (30F-30M)	Zeo000225
Flexible Hose 1m (30F-30M)	Zeo000226
Flexible Hose 1.2m (30F-30M)	Zeo000227
Flexible Hose 1.5m (30F-30M)	Zeo000228

Products	Art.-Nr.
Flexible Hose 1.8m (30F-30M)	Zeo000229
Flexible Hose 2m (30F-30M)	Zeo000230
Flexible Hose 0.3m (22F-30M)	Zeo000231
Flexible Hose 0.4m (22F-30M)	Zeo000232
Flexible Hose 0.5m (22F-30M)	Zeo000233
Flexible Hose 0.6m (22F-30M)	Zeo000234
Flexible Hose 0.8m (22F-30M)	Zeo000235
Flexible Hose 1m (22F-30M)	Zeo000236
Flexible Hose 1.2m (22F-30M)	Zeo000237
Flexible Hose 1.5m (22F-30M)	Zeo000238
Flexible Hose 1.8m (22F-30M)	Zeo000239
Flexible Hose 2m (22F-30M)	Zeo000240

Manufacturer's declaration

Applicable Classifications per IEC 60601-1, Clause 6:

Classification	
Protection against electric shock	Class II
Suitability for an oxygen rich environment (greater than 25 % for ambient pressures up to 110 kPa)	Suitable
Mode of operation	Continuous

EMC Compliance

The **SENSOfluran CONNECT Fill level control unit** complies with IEC 60601-1-2:2014+AMD1:2020. However, special precautions concerning EMC must be taken for all medical electrical equipment.

WARNING: Use of the **SENSOfluran CONNECT Fill level control unit** adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the **SENSOfluran CONNECT Fill level control unit** and the other equipment should be observed to verify that they are operating normally.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the **SENSOfluran CONNECT Fill level control unit**, including cables specified by Baxter or ZeoSys. Otherwise, degradation of the performance of this equipment could result.

NOTE: The **SENSOfluran CONNECT Fill level control unit** may display inconsistent indications of the filter fill level in the presence of EM disturbances (e.g. high-frequency surgical equipment). Once these EM disturbances stop the **SENSOfluran CONNECT Fill level control unit** will perform as intended.

Emissions and Immunity

Table 1 - Emission limits and compliance

Phenomenon	Emission Limits	Compliance
Conducted and radiated RF EMISSIONS	CISPR 11	Group 1, Class B

Table 2 - Immunity test levels (Enclosure Port)

Phenomenon	Basic EMC standard or test method	Immunity Test Levels
Electrostatic Discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 60 Hz
Proximity magnetic fields	IEC 61000-4-39	See table 4

Table 3 - Test levels -proximity fields from RF wireless communication equipment

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Level (V/m)
385	380–390	TETRA 400	Pulse 18 Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	Frequency ±5 kHz 1 kHz Sine	2	0.3	28
710 745 780	704-787	LTE Band 13,17	Pulse 217 Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse 18 Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1,3, 4, 25 UMTS	Pulse 217 Hz	2	0.3	28
2450	2400-2570	Bluetooth WLAN 802.11 (b/g/n) RFID 2450 LTE Band 7	Pulse 217 Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 (a/n)	Pulse 217 Hz	0.2	0.3	9

Table 4 – Text levels - Proximity magnetic fields

Test Frequency	Modulation	Immunity Level (A/m)
30 kHz	CW	8
134.2 kHz	Pulse 2.1 kHz	65
13.56 MHz	Pulse 50 kHz	7.5

Table 5 - Immunity test levels (a.c. port)

Phenomenon	Basic EMC standard or test method	ImmunityTest Levels
Electrical fast transients / bursts	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	± 0.5 kV, ± 1 kV
Surges Line-to-ground	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz
Voltage dips	IEC 61000-4-11	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0 % U_T; 250/300 cycle
Note: UT is the a.c. mains voltage prior to application of the test level.		

10. Customer service

In the case of a malfunction of any product, please contact our customer service.
You can reach our customer service as follows:

Region	Customer Service ZeoSys Medical	Customer Service Baxter
Germany, Austria & Switzerland	**ZeoSys Medical GmbH** Im Biotechnologiepark 9 14943 Luckenwalde Telephone: +49 -3371-4039-914/-915 Fax: +49-3371-4059444 E-Mail: info@zeosys.de ZeoSys Medical GmbH	**AU Kundenservice:** E-Mail: kunden_austria@baxter.com Telefon: 0043 -1-71120-0 FAX: 0043-1-71120-2452420 **DE Kundenservice:** E-Mail: kundenservice_hospital_de@baxter.com Telefon: 0800 -7235636 Fax: 0800 -1010619 **CH Kundenservice:** E-Mail: Service@baxter.com Telefon: +41 800 820 860 Baxter

Region	Customer Service Baxter	
UK & Ireland	**UK Customer Services:** Email: services@baxter.com Telephone: 0800 0289 881	**IE Customer Services:** Email: shs_customer_services_Dublin@baxter.com Telephone: +353 1206 5500
France & BeLUX	**FR Service Clients:** Telephone : 01.34.61.51.25 Fax : 01.34.61.53.95 E-Mail : serviceclientele_france@baxter.com	**BE Klantenservice:** E-Mail : Customerservice_bedux@baxter.com T +32 (0)2 3868870
Italy	**Customer Service Hospital:** E-Mail: cs_italyosp@baxter.com Telefono: 800 77 22 33 Fax: 800 55 33 66	
Spain	**ES SERVICIO CLIENTE:** E-Mail: atencion_clientes@baxter.com Telefono: 902 20 04 40 Fax: 902 20 04 41	
Portugal	**PT Atendimento ao Cliente:** E Mail: apoioaocliente@baxter.com Telefone: 219 252 559 Fax: 219 252 579	
BeLux & Netherlands	**BE Klantenservice:** E-Mail: Customerservice.belux@baxter.com Telefoon: +32 (0)2 3868870	**NL Klantenservice:** E-Mail: Utrecht_customerservice@baxter.com Telefoon: +31 (0) 302488800
Denmark	**BE Kundeservice:** E-Mail: Kundeservice.denmark@baxter.com Telefon: 80 30 01 41	
Finland	**FN Asiakaspalvelu:** Email: asiakaspalvelu@baxter.com Puhelin: 0800 144 233	
Norway	**NO Kundeservice:** E-Mail: Kundeservice_NO@baxter.com Telefonen: 800 33 313	
Sweden	**SK Kundservice** E-mail: Kundservice_sverige@baxter.com Telefon: 020 788 115	
Greece	**GR Εξυπηρέτηση πελατών** Email: philippos_michailidis@baxter.com Τηλέφωνο: +30 (690) 8394979	