Instruction for Use

These instructions for use contain information about the CONTRAfluran™- System, consisting of the CONTRAfluran™-Anaesthetic gas canister, the SENSOfluran™-Fill level control unit and associated components.

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.

WARNING: NOT FOR USE with nitrous oxide. CONTRAfluran™ CANNOT adsorb nitrous oxide.

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

CONTRAfluran™ is a new, innovative technology protected by international patents and other patent applications with which fluorinated halocarbon inhaled anaesthetic gases such as sevoflurane, desflurane and isoflurane are completely adsorbed out of the expiration air of a patient.
The CONTRAfluran™ anaesthetic gas canister contains a unique adsorber material characterized by its highly specialized 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 pass through the canister.
SENSOfluran™ is a canister holder equipped with a sensor to monitor the fill level of the canister. SENSOfluran™ indicates when the canister is filled and must be changed.
WARNING! This system is NOT for use with nitrous oxide and cannot adsorb nitrous oxide. CONTRAfluran™ and SENSOfluran™ are only indicated for use with sevoflurane, desflurane and isoflurane.

2. Appropriate use

The CONTRAfluran™-Anaesthetic gas canister is intended to remove fluorinated halocarbons (such as sevoflurane, desflurane and isoflurane) in operation rooms, intensive care units, and mobile or ambulatory treatment areas, regardless of the type of exhaust device used. The CONTRAfluran™-Anaesthetic gas canister is designed exclusively for these applications.
The SENSOfluran™-Fill level control unit must only be used in combination with the CONTRAfluran™-Anaesthetic gas canister during sedation and operation of patients using volatile anaesthetics. CONTRAfluran™ and SENSOfluran™ are not intended for use with nitrous oxide or other anaesthetic gases!
Please note that the canister and the fill level control unit must only be used by qualified personnel.

Strict compliance with the specifications included in these Instruction for Use can ensure the safe and efficient use of the CONTRAfluran™-System. Only the ZeoSys supplied hose, or other connectors forming a tight seal to the 22 mm ID inlet port should be used. ZeoSys GmbH or its authorized representatives will not accept any liability or damage, which is caused by incorrect or unreasonable use of the canister as well as the fill level control unit.

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

The following safety instructions must always be followed during the operation as well as with all maintenance and repair work done on this device.

Not following these safety instructions can lead to danger for the operating personnel, and damage to 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 must be done by qualified personnel.
- The device is to be operated in a temperature range of +5°C and +35°C.
- The device must be connected to 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 device in an area where there is significant exposure to explosive and / or combustible materials.
- Damaged or inoperable or defective devices must be removed from operation and secured from unauthorized use. Return all such devices to Zeosys immediately for replacement.
- SENSOfluran™ and CONTRAfluran™ contain no user serviceable parts of components and should be returned immediately to Zeosys for repair and / or replacement.

4. Transportation, storage and operation of CONTRAfluran™-Filter and SENSOfluran™-Fill level control unit

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

To ensure the performance of your canister and to help ensure your safety, be sure to follow all recommended 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 right-side up.
- The carton should not be put placed on its top or on its side.
- Carefully open the carton from the top avoiding damage to the contents.
- Retain the original carton and zipper bags for return transport.

4.2 Storage of new canisters

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

- The dispatch carton should be stored with the label showing right-side up.
- Packaging material including shipping carton, zipper bags and red caps should be retained for the return of canisters.
- Store in a dry, dust-free room.

4.3 Operation

Before using the canister, please ensure that all components needed for proper use are available. This includes:

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

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

A2. Connect the mains adapter to the plug socket located on the bottom of the fill level control unit and plug it into a wall outlet.

The SENSOfluran™-fill level control unit will enter a self-diagnostic mode consisting of:

- a short visual and acoustic test:
  - -all 4 LEDs light up and an acoustic signal will sound for 1 second
- a test of the infrared light barrier:
  - -the red LED will light up for 10 seconds. If there is an object detected, the green LED is also illuminated.
  - -afterwards a steady and repetitive blinking of the green light will occur for about 5 minutes until the sensor is ready for use.

Remove and retain the red cap:
The retained cap is required again to cap the used CONTRAfluran™ Anaesthetic gas canister. Attach the CONTRAfluran™ Anaesthetic gas canister to the expiration gas outlet valve of the respirator by means of a flexible hose. The following pictures show the required steps to attach the filter to the expired gas outlet valve.

A3. Remove and Retain the seal cap from the canister.

A4. Connect the flexible hose to the canister.

A5. Record the anaesthetic gas to be used on the top label of the canister.

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 canister is inserted correctly and the device is in a short warm-up phase. After approx. 5 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 outlet gas and thus the fill level of the canister.

- GREEN LED (bottom):
  The filter captures the expired gas and has sufficient free capacity.

- YELLOW LED (second from bottom):
  The capacity of the canister diminishes. But the concentration of the anaesthetic gas in the filtered exhausted air lies within the MAK accepted values. A canister change is recommended when the second yellow LED lights up.

- TWO YELLOW LEDs (middle two):
  The maximum capacity of the filter is approaching. The canister should be replaced as soon as possible.

- RED LED (top):
  The maximum capacity of the filter is reached. The canister must be replaced.

Error message:

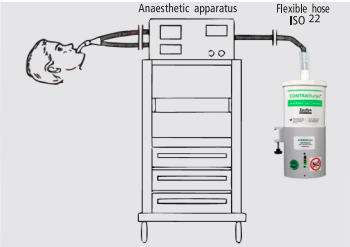
- If all 4 LEDs light up one after the other, this indicates that a canister has not been placed into the SENSOfluranTM unit. Place a canister into the SENSOfluranTM unit and wait for a permanent green light.

- After a Canister change, the green (bottom) LED will flash, indicating that the sensor is in start-up phase. After the start-up time has elapsed, the light will return to steady green. NOTE: The system remains acceptable for use during the new Canister start-up phase.

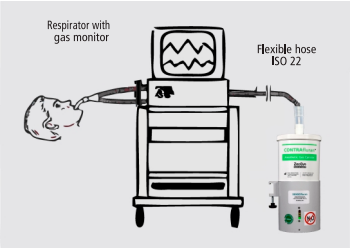
- If the RED (top) and green (bottom) LEDs light up simultaneously and a warning signal sounds, this indicates the gas sensor is defective. Please contact Customer Service for a replacement.

5. Application areas of the CONTRAfluran™-System

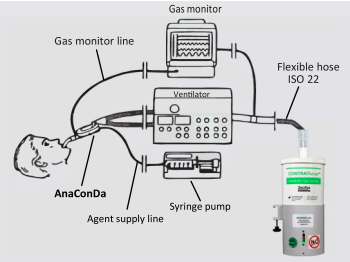
5.1. Application in operation areas with exhaust device



5.2. Application in intensive care units and ambulatory treatment areas



5.3. Application with the AnaConDa-System



6. When should the canister be replaced?

- Filter change is recommended when the second yellow LED lights up.
- The used canister should be clearly marked in order to avoid any repeated use.

7. Return of the CONTRAfluran™-Filled Anaesthetic gas canister

- Close the used canister with the red seal cap. Mark canister as used.
- To reduce microbial or viral transmission prior to storage and return, the exterior surface of the CONTRAfluran™ canister should be wiped with a cloth dampened with an aqueous-based cleaning agent (recommended hydrogen peroxide wipes, concentration 1% - 1.5%).

  DO NOT USE alcohol or aldehyde-based cleaning agents as they will impact the performance of the SENSOfluran™ unit.
- The canister must be placed into the protective zipper bag and securely sealed.
- Six used filters in their zipper bags should be packed into the original shipping carton and stored in a cool, dry, well- ventilated place.

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

Follow hospital-established protocol for wiping down the anaesthesia cart to determine frequency of SENSOfluran™ wipe-down.

To clean the surface of the SensoFluran™ unit, wipe down with a cloth dampened with hydrogen peroxide (1% - 1.5%) or aqueous detergents. DO NOT USE alcohol or aldehyde-based cleaners, as they will impact the performance of the SensoFluran™ unit.

CAUTION: Avoid wetting the electrical unit or the sensor during cleaning or sanitization activities!

Allow 10 minutes for exposure and drying time before placing the SENSOfluran™ Fill Level Control Unit back into operation.

The electrical unit within the SENSOfluran™ must be re-calibrated every 12 months. Refer to the sticker showing the re-calibration date, applied to the SensoFluran™ unit. For a newly-calibrated unit, contact Customer Service before the date of expiration.

9. Technical data

CONTRAfluran™ Anaesthetic gas canister	Product-class according to MPG	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	≤ 0,15 mbar
	Height	19 cm
	Diameter	12 cm
	Weight	Approx. 1.000 g
	Volume	2 l
SENSOfluran™ - Fill level control unit	External material	powder-coated aluminum
	Temperature	+5°C to +35°C
	Voltage	Power supply (Euro) 100V-240V AC / 47-63 Hz Output 6,0V DC Power consumption approx: 6W
	Weight	Approx. 700g
	measurements of the circuit board	(50x55x20)mm
	grout circuit board	Bectron MR 3404
	external wall wart	ATM006T-W060E; GSM06E06-P1J; GEM06106-P1J

Products	Art.-Nr.
Starter Kit	Zeo000040
Electronic board	Zeo000042
CONTRAfluran™ - Anaesthetic gas canister	Zeo000050
Standard mount (without fill level control unit)	Zeo000051
Mount with SENSOfluran™ -Fill level control unit	Zeo000052
Power supply unit	Zeo000053
Flexible hose 22 mm (interface 17 cm)	Zeo000060
Flexible hose 22 mm (interface 40 cm)	1574000
Flexible hose 6 mm (Length 180 cm)	Zeo000062
Connector 22 mm (a/i), with 6 mm port	Zeo000066
Connector 22M–30F	1971000
Connector 22M–30M	1970000
Connector 22M–22F	1961000
Y-joint: 22mm a/15mm i/22mm a, 22mm a	Zeo000069

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:

	Customer Service ZeoSys Medical	Customer Service Fa. Baxter
Germany, Austria & Switzerland	**ZeoSys Medical GmbH** 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

	Customer Service Fa. Baxter	
UK & Ireland	**UK Customer Services:** Email: services@baxter.com Telephone: 0800 0289 881	**IE Customer Service:** E-Mail: shs_customer_services_Dublin@baxter.com Telephone: +353 1206 5500
France & BeLUX	**FR Service Clients:** Téléphone : 01.34.61.51.25 Fax : 01.34.61.53.95 E-Mail : servicedientele_france@baxter.com	**BE Klantenservice:** E-Mail: Customerservice.belux@baxter.com T +32 (0)2 386 88 70
Italy	**Customer Service Hospital**: E-Mail: cs_italyosp@baxter.com Telefono: 800 77 22 33 Fax: 800 55 33 66	
Spain	**ES SERVICIO AL CLIENTE:** E-Mail: atencion_clientes@baxter.com Teléfono: 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)2 386 88 70	**NL Klantenservice**: E-Mail: Utrecht.customerservice@baxter.com Telefoon: +31 (0) 30 2488800
Denmark	**DK 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	**SE Kundservice** E-Mail: Kundservice_sverige@baxter.com Telefon: 020 788 115	
Greece	**GR Εξυπηρέτηση πελατών:** Email: philippos_michailidis@baxter.com Τηλέφωνο: +30 (690) 8394979	
Canada	**Canadian Service Clients:** Telephone: 1-888-719-9955.	Baxter

	Customer Service ZeoSys Medical	Customer Service Fa. 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

	Customer Service Fa. Baxter	
UK & Ireland	**UK Customer Services:** Email: services@baxter.com Telephone: 0800 0289 881	**IE Customer Service:** E-Mail: shs_customer_services_Dublin@baxter.com Telephone: +353 1206 5500
France & BeLUX	**FR Service Clients:** Téléphone : 01.34.61.51.25 Fax : 01.34.61.53.95 E-Mail : serviceclientele_france@baxter.com	**BE Klantenservice:** E-Mail: Customerservice.belux@baxter.com T +32 (0)2 386 88 70
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Spain	**ES SERVICIO AL CLIENTE:** E-Mail: atencion_clientes@baxter.com Teléfono: 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)2 386 88 70	**NL Klantenservice**: E-Mail: Utrecht.customerservice@baxter.com Telefoon: +31 (0) 30 2488800
Denmark	**DK 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	**SE Kundservice** E-Mail: Kundservice_sverige@baxter.com Telefon: 020 788 115	
Greece	**GR Εξυπηρέτηση πελατών:** Email: philippos_michailidis@baxter.com Τηλέφωνο: +30 (690) 8394979	
Canada	**Canadian Service Clients:** Telephone: 1-888-719-9955.	Baxter