Manufactured by ZeoSys Medical GmbH

Distributed by Baxter

CONTRAfluran™ Anaesthetic Gas Capture System: User Guide

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What is the CONTRAfluran™ Anaesthetic Gas Capture System?

The **CONTRAfluran™** Anaesthetic Gas Capture System helps to reduce hospitals carbon footprint by collecting exhaled desflurane and sevoflurane in the surgical suite.

What is included in the starter kit?

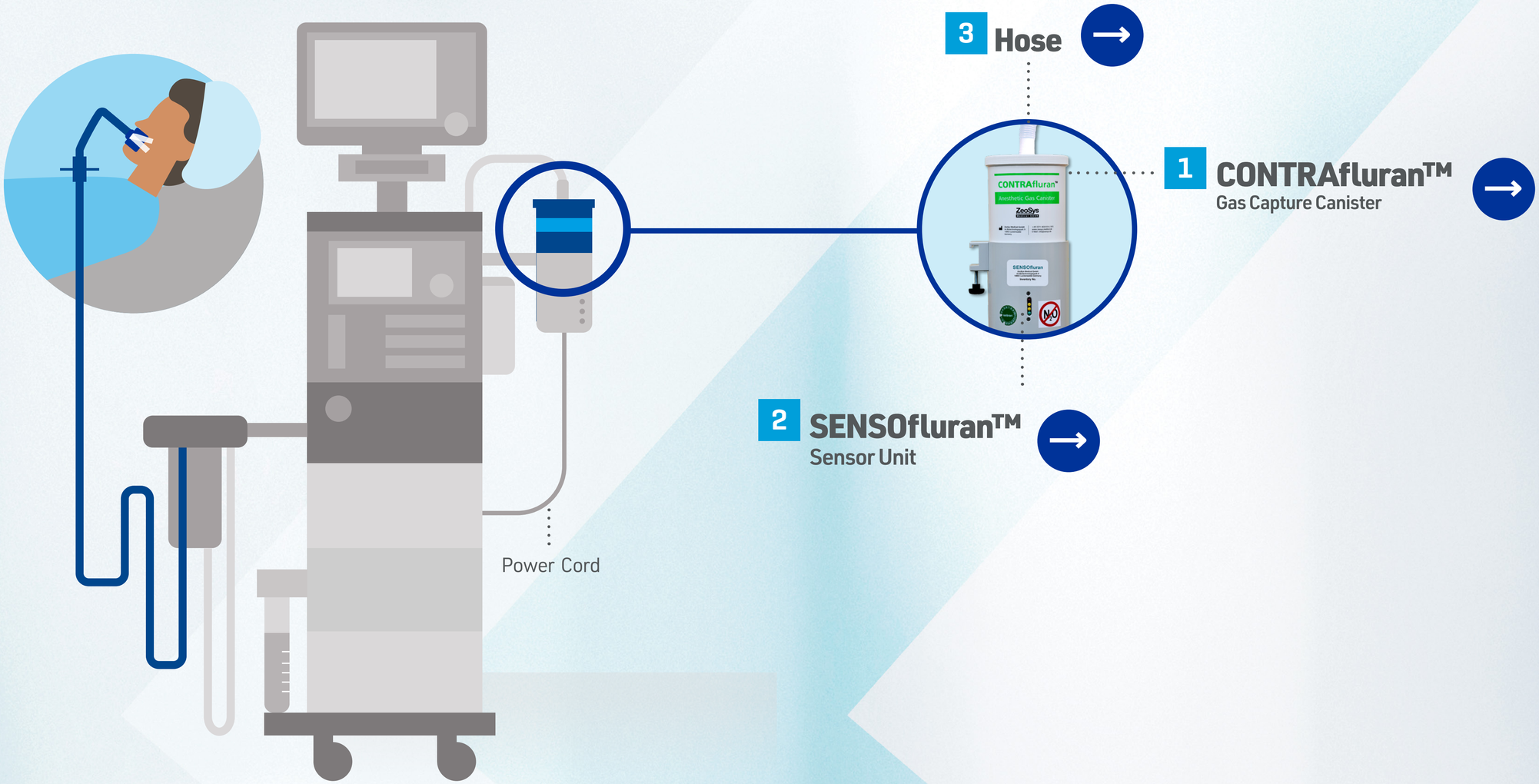
The starter kit and the **CONTRAfluran™** Gas Capture Canister pack provide everything needed to install the system.[1]

Item	Part number
Starter kit includes: 1 x **SENSOfluran™** Sensor Unit 5 x medical adapters 1 x hose 1 x power supply 2 x power adapters (UK & EU)	ZEO000040
Gas Capture Canister (pack/6)	ZEO000050

The CONTRAfluran™ canister captures all modern fluorinated gases.[1] However, from a manufacturing/reprocessing perspective, it is recommended that the CONTRAfluran™ canister is used only to capture desflurane and/or sevoflurane. Should the CONTRAfluran™ canister be used to capture isoflurane, it is recommended that is is captured in a dedicated canister which is separate from that used to capture desflurane and/or sevoflurane. For complete installation support, please contact your Baxter sales representative.

WARNING: When **CONTRAfluran™** is used without an Anaesthetic Gas Scavenging System (AGSS), nitrous oxide cannot be used as this cannot be adsorbed.[1] Nitrous oxide should also not be used when the anaesthetic ventilator is in passive mode.

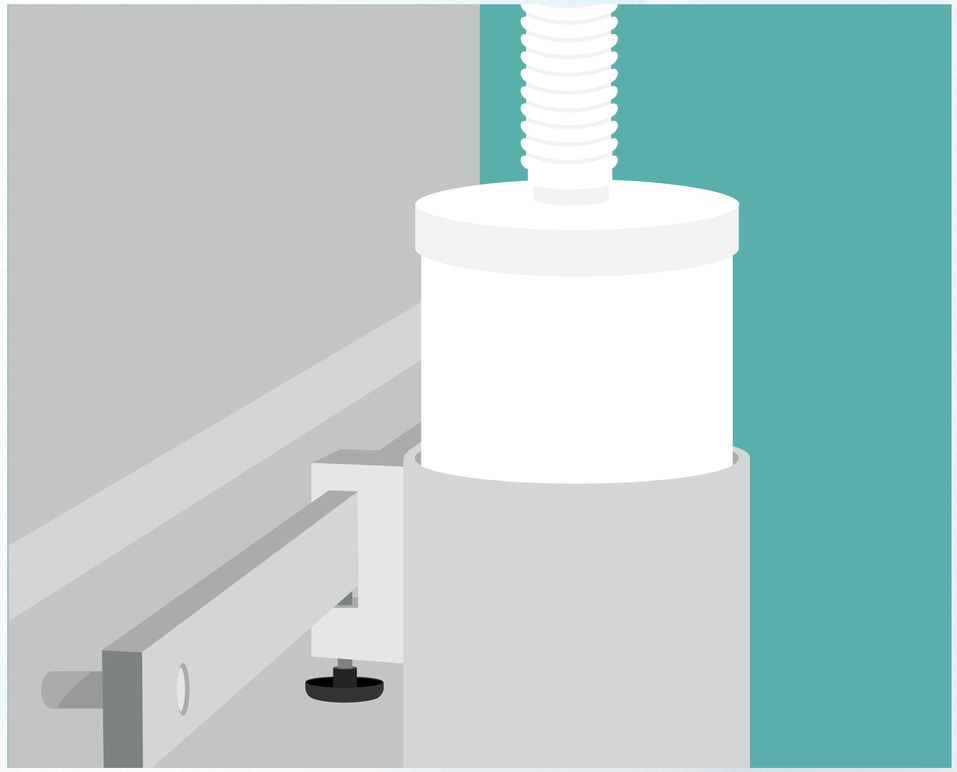
The components of the CONTRAfluran™ Anaesthetic Gas Capture System



CONTRAfluran™

1 CONTRAfluran™ Gas Capture Canister

The **CONTRAfluran™** canister contains a highly porous material that adsorbs and retains volatile anaesthetics.[1] One canister holds approximately 240 mL (one bottle) of **Suprane** (desflurane, USP) and/or **sevoflurane**.



SENSOfluran™

2 SENSOfluran™ Sensor Unit

The **CONTRAfluran™** canister is placed into the **SENSOfluran™** Sensor Unit.[1] The sensor unit is attached to the mounting rail on the anesthesia machine. The anaesthetic gas scavenging (AGS) waste gas outlet from the anesthesia machine is hose-connected to the inlet of the **CONTRAfluran™** canister. The **SENSOfluran™** Sensor Unit signals when the filter canister is full with both a visual and audible signal.[1]

The coloured LEDs of the device (green, yellow and red) indicate the quality of the remaining adsorption capacity of the CONTRAfluran™ filter.[1]

Green LED

The filter captures the expired gas and still has sufficient free capacity.[1]

1 yellow LED and 1 green LED

The capacity of the canister is diminishing, but the concentration of the anaesthetic gas in the filtered exhausted air lies within the minimum alveolar concentration (MAC) accepted values.[1]

2 yellow LEDs

The filter is approaching maximum capacity.[1] The canister should be replaced as soon as possible.[1]

Red LED

The maximum capacity of the filter has been reached.[1] The red LED light and audible alarm signify that the canister needs replacing immediately.[1]

If the red and green LEDs light up simultaneously and a warning signal sounds, this indicates the gas sensor is defective.[1] After ensuring that a spare **SENSOfluran™** Sensor Unit is not available, please contact customer service for a replacement. If all 4 LEDs light up one after the other, this indicates that a canister has not been placed into the **SENSOfluran™** unit.[1] Place a canister into the **SENSOfluran™** unit and wait for a permanent green light.[1]

Hose and other components

3 Hose

The flexible hose connects the **CONTRAfluran™** anaesthetic gas canister to the expiration gas outlet of the respirator (AGS outlet).[1] The anaesthesia machine should be in passive operating mode before connecting the **CONTRAfluran™** canister to the outlet valve.

Other components:

Adapters

The operational adapters are for use with different exhaust ports.[1]

Power cord and power supply

The device must be connected to the provided plug-in power supply unit.[1]

How to install the CONTRAfluran™ Anaesthetic Gas Capture System

Before using the **CONTRAfluran™** Anaesthetic Gas Capture System, please ensure that the following components are available:

CONTRAfluran™ Anaesthetic Gas Capture Canister
SENSOfluran™ Sensor Unit
Accessories: flexible hose, operational adapters for use with different exhaust ports, power supply and power cord

Step 1:

Ensure the anaesthesia machine has been converted to passive gas scavenging mode/configuration.

- Please consult your anaesthesia machine User Manual or contact your anaesthesia machine company for support to convert below model(s) of anaesthesia machines (or if your machine is not listed) to passive scavenging mode:

Anaesthesia machine company	Passive mode conversion possible (✓)	Passive mode conversion possible with additional part*	Passive mode conversion not possible (X)
Dräger	Primus, Fabius, Zeus, Apollo	Perseus	Atlan
GE	-	Avance, Aisys, Aestiva, Aespire, Carestation 600/650	-
Löwenstein	Leon/Leon Plus	-	-
Mindray	All models	-	-
Getinge	-	-	Flow-i
Dameca Philips	-	-	All models

*Please consult representative of anaesthesia machine company for installation of the additional part needed for converting the specific anaesthesia machine model into passive mode

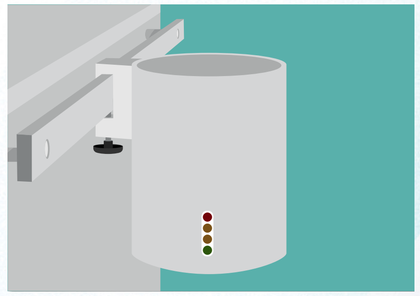
WARNING: when **CONTRAfluran™** is used without an Anaesthetic Gas Scavenging System (AGSS), nitrous oxide cannot be used as this cannot be adsorbed.[1] For more information on **CONTRAfluran™** and **SENSOfluran™**, including the anaesthetic gases these can be used with, please see the **CONTRAfluran™** and **SENSOfluran™** Instructions For Use.[1]

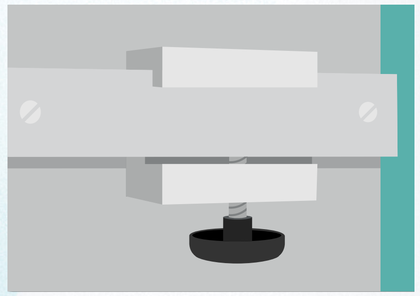
How to install the CONTRAfluran™ Anaesthetic Gas Capture System (continued)

Step 2:

Securely fasten the **SENSOfluran™** Sensor Unit to the rail of the respirator or anaesthesia machine.[1]

- The bracket can rotate 90 degrees to accommodate either a vertical or horizontal bar. This allows the **SENSOfluran™** unit to be operated either with a view to the front or to the back of the anaesthesia machine
- Place the **SENSOfluran™** unit on the bar or rail at the point furthest away from the anaesthesia machine. Ensure the area beneath is clear of any obstruction, such as electrical equipment or a drawer
- The bar or rail should be 27x30 mm in height and 6x10 mm in width. This ensures that the clamp does not slip off the rail as soon as it is loosened and that the star screw can always fix the rail firmly in place



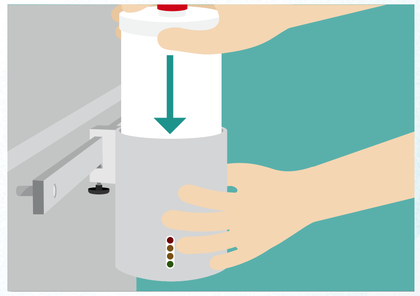


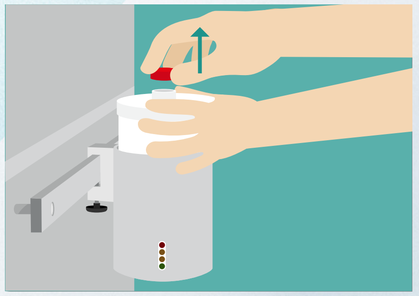
How to install the CONTRAfluran™ Anaesthetic Gas Capture System (continued)

Step 3:

Place the **CONTRAfluran™** canister into the **SENSOfluran™** unit and remove the seal cap from the canister.[1]

- Hold the white lid down with one hand when removing the seal cap
- Retain the red cap for sealing the used canisters into zipper bags later on





Step 4:

Attach the hose between the AGS outlet and **CONTRAfluran™** in a straight configuration (keep this as short as possible with no U-loop).

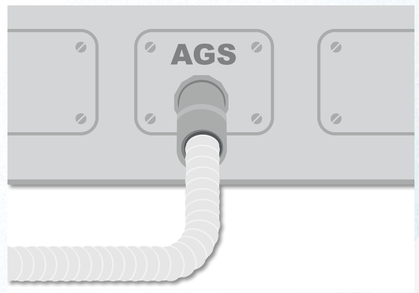
- If required, reduce the length of hose by cutting it to approximately 80 cm to make it as straight as possible with no U-loop going from the anaesthesia machine to the **CONTRAfluran™** inlet

How to install the CONTRAfluran™ Anaesthetic Gas Capture System (continued)

Step 5:

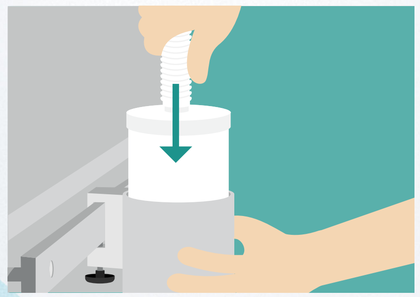
Attach one end of the flexible hose to the AGS outlet on the anaesthesia machine using one of the adapters provided in the starter kit.

- Please note that the location and appearance of the AGS outlet will vary from one anaesthesia machine to another
- The colour of the hose provided in the starter kit may vary
- Usually, a 30 mm (F; female) and 22 mm (M; male) hose adaptor/connector (Intersurgical Scavenging Connector No. 197100) can fit with most Dräger and Löwenstein anaesthesia machines. Other adapters can also work with an AnaConDa connection



Step 6:

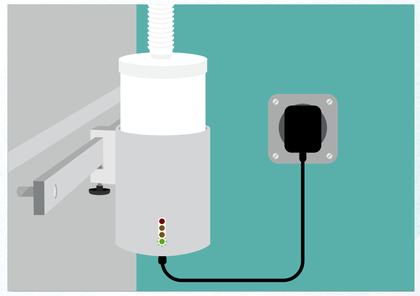
Attach the inlet of the **CONTRAfluran™** canister to the expiration gas outlet valve (AGS outlet) of the anaesthesia machine by means of a flexible hose.[1]



How to install the CONTRAfluran™ Anaesthetic Gas Capture System (continued)

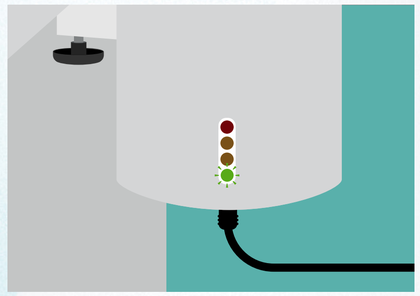
Step 7:

Connect the mains adapter to the plug socket located on the bottom of the **SENSOfluran™** unit and plug it into a wall outlet.[1]



The **SENSOfluran™** unit will enter a self-diagnostic mode consisting of:[1]

- **An LED and acoustic test:**
  - All 4 LEDs will light up and an acoustic signal will sound for 1 second
- **CONTRAfluran™ filter placement test:**
  - The red LED will light up for 10 seconds. If there is a canister detected, the green LED will illuminate
  - Following this, the green light will blink steadily and repetitively for about 5 minutes until the sensor is ready for use
  - After approximately 5 minutes, the green LED should be in a steady state of illumination
  - The system will now be ready for use



WARNING: When **CONTRAfluran™** is used without an Anaesthetic Gas Scavenging System (AGSS), nitrous oxide cannot be used as this cannot be adsorbed.[1] Nitrous oxide should also not be used when the anaesthetic ventilator is in passive mode.

Maintenance and calibration interval of SENSOfluran™

To determine how often the **SENSOfluran™** unit needs to be wiped down, please follow the hospital-established protocol for wiping down the anaesthesia cart.[1]

To clean the surface of the **SENSOfluran™** unit, wipe down with a cloth that is dampened with hydrogen peroxide (1%–1.5%) or aqueous detergents.[1] **DO NOT USE alcohol or aldehyde-based cleaners**, as these will impact the performance of the **SENSOfluran™** unit.[1] Please check daily for condensation in the hose.

CAUTION: Avoid wetting the electrical unit or the sensor during cleaning or sanitisation activities.[1]
Allow 10 minutes for exposure and drying time before placing the **SENSOfluran™** Sensor Unit back into operation.[1]

The electrical unit within the **SENSOfluran™** must be replaced every 12 months.[1] Please refer to the sticker on the **SENSOfluran™** unit that shows the replacement date.[1] For a newly-calibrated unit, please contact Baxter customer service before the date of expiration.[1]

Please keep spare **SENSOfluran™** units in case of any malfunction.

Returning the CONTRAfluran™ gas canisters

Once a **CONTRAfluran™** gas canister is full, the red seal cap needs to be closed.[1] The canister then needs to be marked as used and securely sealed in a protective zipper bag.[1] Six used filters (each in zipper bags) should be packed into the original shipping carton and stored in a cool, dry, well-ventilated place.[1]

Baxter collects full canisters from the hospital and holds them in environmentally safe conditions. To arrange a canister collection, please contact Baxter customer service.

To help optimise the gas recycling process, the correct box(es) should be ticked on the sticker on top of each canister, indicating which gas (or gases) are contained within.[1]

SENSOfluran™ Sensor Unit: Dos and Don'ts

Dos

- ✓ Run a self-testing sequence in a separate area
- ✓ Check if passive mode is available and configured on the anaesthesia machine being used
- ✓ Connect the **SENSOfluran™** unit on a medical-rail system (or similar system)[1]
- ✓ Change the anaesthesia machine to passive mode
- ✓ Use a connector to attach the transparent hose to the AGS outlet
- ✓ Insert a canister and connect the hose to the port of the canister[1]
- ✓ Run the system until the red light shows.[1] Remove the used canister and replace with a new, unused canister[1]
- ✓ Note that the canister may be changed at any time
- ✓ Disconnect the power plug and reconnect it again if the alarm and red light are inadvertently triggered
- ✓ Use the original cardboard box (inserted into zipper bags) to send back used canisters[1]
- ✓ Clean the exterior of **SENSOfluran™** unit with a hydrogen peroxide swab[1]

Don'ts

- ✗ Do not use any disinfectant near the base of the **SENSOfluran™** unit as the sensor is highly sensitive (it may even be triggered by small amounts on your hands), but not very selective, so this could pick up vapours from alcohols and halogenated gases[1]
- ✗ Do not make any modifications to the anaesthesia machine without first consulting and gaining approval from the manufacturer
- ✗ Do not disconnect the hose without connecting a new canister
- ✗ Do not use this gas capture system if nitrous oxide is going to be used.[1] This relates to cases when **CONTRAfluran™** is used without an AGSS. The activated carbon filter will not adsorb nitrous oxide, and **SENSOfluran™** does NOT detect nitrous oxide[1]

FAQs about CONTRAfluran™ and SENSOfluran™

Section 1) Installation

1. Which gases does the CONTRAfluran™ canister capture?

The **CONTRAfluran™** canister captures all fluorinated gases.[1] However, for practical purposes, it is recommended that this is used with desflurane and sevoflurane, since the capturing of isoflurane will delay the desorption process of desflurane and sevoflurane from the canister.

2. What are the components of starter kit?

The starter kit includes the following components:

Item	Part number
Starter kit includes: 1 x **SENSOfluran™** Sensor Unit 5 x medical adapters 1 x hose 1 x power supply 2 x power adapters (UK & EU)	ZEO000040
Gas Capture Canister (pack/6)	ZEO000050

3. Who is responsible for the system installation and return of used canisters?

The Baxter sales team will support customers with installing the **CONTRAfluran™** Gas Capture System. For returning used canisters, the hospital will need to inform/call Baxter customer service to discuss their return request.

4. What voltage does the unit/power cord use?

It is designed for an operating voltage of 100V–240 V AC/47–63 Hz.[1]

5. If CONTRAfluran™ is not classified as a medical device, what is it categorised as?

The **CONTRAfluran™** Gas Capture System falls under Class 1 of medical devices.[1] The devices in this category are mostly exempt from registration in the EU due to low-to-moderate patient impact.

FAQs about CONTRAfluran™ and SENSOfluran™

Section 1) Installation

6. What will make the alarm on the SENSOfluran™ unit go off inadvertently?

Do not use volatile alcohol-based disinfectant near the base of the **SENSOfluran™** unit as the sensor is highly sensitive and this will trigger the alarm (even small amounts of disinfectant on your hands may trigger the alarm). The sensor is not very selective and could pick up vapours from alcohol and halogenated gases.

If the alarm and red light are inadvertently triggered, disconnect the power plug and reconnect it again.

Please consider writing the date of installation on a new canister to help evaluate whether this needs to be changed in the event of false alarms.

7. Have the canisters been validated to be placed on anaesthesia machines by the manufacturers? Will it affect the machines warranty OEMs?

Baxter has informed Dräger/GE/Maquet of this product. To make any mechanical changes in order to use **CONTRAfluran™** with a Dräger/GE/Maquet anaesthesia machine, the hospital should contact their local anaesthesia machine sales representative.

8. What are the dimensions of the Sensor Unit and the canister?

Technical data[1]

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. 400 g
	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 aluminium
	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. 700 g
	Measurements of the circuit board	(50x55x20) mm
	Grout circuit board	Bectron MR 3404
	External wall wart	ATM006T-W060E; GSM06E06-P1J; GEM06106-P1J

FAQs about CONTRAfluran™ and SENSOfluran™

Section 1) Installation

9. Is the device MRI compatible?

The **SENSOfluran™** Sensor Unit should not be used in the vicinity of an MRI scanner. The strong, static magnetic field of the MRI scanner may cause unwanted movement, including dangerous projectile motion of the device. The radiofrequency energy and magnetic fields that change with time may also cause heating of the metallic housing, which could lead to burns.

However, the **CONTRAfluran™** canister is non-metallic and could be used alone in the vicinity of an MRI scanner if connected to a hose that does not contain any metallic components (e.g. reinforcing ribs).

To ensure the safe use of **CONTRAfluran™** inside an MRI room, hospital staff should conduct a thorough check of the hose and other accessories connected to the **CONTRAfluran™** canister to confirm that there are no metallic materials inside the safety zone defined by the MRI scanner manufacturer.

10. Is it device latex free?

Yes, the **SENSOfluran™** unit is latex free.

11. Can we purchase circuit boards separately?

Yes, there is a separate part number for ordering circuit boards.[1] This is: ZEO000042.[1]

12. I believe the AGSS needs to be turned off when using CONTRAfluran™ with an anaesthesia machine. Do we have detailed instructions on how this is done? Or preferably, will the hospital or manufacturer representatives do this?

Anaesthesia machines need to be configured for PASSIVE gas scavenging. The Hospital Biomedical engineers/qualified technicians will be able to make changes to the anaesthesia machine AGSS. To make the mechanical changes required to use the **CONTRAfluran™** unit with a Dräger/GE/Maquet anaesthesia machine, the hospital should contact their local anaesthesia machine sales representative.

For hospitals that do not want to switch off their AGSS, we have developed **SENSOfluran™ PLUS**. This can be connected to the AGSS, but the anaesthesia machine still needs to be changed to passive mode. **SENSOFluran™ PLUS** also provides a solution for hospitals using nitrous oxide.
Please note, nitrous oxide must ONLY be used when the hospital's AGSS is connected to **SENSOFluran™ PLUS**.

FAQs about CONTRAfluran™ and SENSOfluran™

Section 1) Installation

13. How do we know that we can switch off the AGSS and it will still be safe for staff?

The **CONTRAfluran™** unit captures 99% of a patient's exhaled anaesthetic gas in the operating theatre.[2] ZeoSys conducted testing that showed how gas escape was minimal. Hospitals should exercise caution when setting up their inhaled anaesthetic circuits to ensure that there are no leaks elsewhere in the system.

Only gas that passes through the **CONTRAfluran™** filter will be adsorbed. There is a test protocol available for hospitals to test this themselves if they choose to. In the event that hospital personnel smell any anesthetic gas when using the **CONTRAfluran™** system, please check all connections to determine the source.

14. What are the mounting options available?

The bracket on the **SENSOfluran™** unit seems to work for all anaesthesia machines seen to date. It can rotate 90 degrees to accommodate either a vertical or horizontal bracket on the back of all anaesthesia machines. This allows **SENSOfluran™** to be operated either with a view to the front or to the back of the anaesthesia machine.

The images below demonstrate how the **SENSOfluran™** unit can be installed on different anaesthesia machines

15. When we try to pull off the red cap, the lid also comes off quite easily. How do we stop this?

Hold the white lid down with one hand while removing the red cap. Ensure the lid is firmly attached after removing the red cap and hose connection.

FAQs about CONTRAfluran™ and SENSOfluran™

Section 1) Installation

16. Will there be any risks (such as activated carbon spilling on the floor or captured gas leakage) if the container falls on the floor and lid comes off?

No, there is no risk. In the event of a spillage, collect and place the contents in a Ziploc® bag and place it in the normal waste receptacle.

17. Does this system fit all anaesthesia machines?

Currently the Zeosys gas capturing technology can function with any anaesthesia machine that can be configured for **passive** scavenging mode. Dräger, GE and machines from other manufacturers are designed to provide this scavenging configuration. There are a few machines, such as Dräger Atlan and Getinge Flow, that do not have the ability to be configured to **passive** mode. In case of doubt, please consult the manufacturer of the anaesthesia machine.

FAQs about CONTRAfluran™ and SENSOfluran™

Section 2) During surgery

1. Can one canister capture a combination of sevoflurane and desflurane?

Yes, one canister can capture a mixture of the two gases.

2. Do the inhalational anesthetic gases need to be manufactured by Baxter, or can the canisters capture gases regardless of the manufacturer?

The canisters are designed to capture sevoflurane or desflurane[1] regardless of the manufacturer.

3. How long does it take to fill one canister?

The time taken to fill one canister will vary depending on the FGF (fresh gas flow) rate and concentration (similar to how the length of time a container of sevoflurane or desflurane lasts seems to vary). However, on average, the canister lasts ~3 days, but this will vary significantly depending on the circumstances. Regardless, a **CONTRAfluran™** filter is likely to accommodate a full canister of inhalational anaesthetic gas.

4. Can the canister be changed mid-surgery?

Yes, the amount of gas released from the hose while changing the canister is not significant. The new canister should be readily accessible so that the anaesthesia gas hose can be disconnected quickly from the used canister and attached to the new one.

5. Does the SENSOfluran™ Sensor Unit work by weighing the canister or does it physically analyse the gas flow?

The sensor unit does not work by weighing the canister. Instead, there is a gas sensor built into the bottom of the sensor unit. The gas detector analyses the air that flows out of the canister through a small hole in the bottom of the canister. The gas sensor can detect different types of anaesthetic gases.

- Please note, **SENSOfluran™** does not detect nitrous oxide and **CONTRAfluran™** does not capture nitrous oxide[1]

6. Will the CONTRAfluran™ canister capture all gases (including nitrous oxide and isoflurane) or just sevoflurane and desflurane?

The technology is currently designed to capture only fluorinated halocarbon inhaled anaesthetic gases (more specifically, sevoflurane and desflurane) from the expired air of a patient.[1] The system can capture isoflurane, but Baxter will not collect the canisters filled with isoflurane. It does not capture nitrous oxide.

FAQs about CONTRAfluran™ and SENSOfluran™

Section 2) During surgery

7. Will the exhaled gas be recycled and be delivered back to the patient during surgery?

No, the exhausted anaesthesia gas will be fully adsorbed as this binds to the filter in the canister.

8. Does the canister capture oxygen, nitrous oxide, sevoflurane and desflurane in one canister? As the canister is small, how is it able to do this?

Currently, this system is designed to capture only sevoflurane and desflurane.[1] The **CONTRAfluran™** canister cannot capture nitrous oxide.[1]
The size of the canister is 240 mL and one canister holds approximately one bottle of either desflurane or sevoflurane.

9. What mechanism does the filter use to capture the inhaled anesthetic gas?

The anaesthetic gas capture canister contains a unique adsorber material[1] (sustainably sourced activated charcoal). This is characterised by highly specialised and well-controlled physical and chemical properties, such as grain structure, porosity and surface area.[1] The adsorber is highly selective and efficient in retaining volatile fluorinated halocarbon anesthetic gases which pass through the canister.[1]

10. What happens when the device has a RED indicator, but the user has not switched the device to a new one?

The gas will start to break-through the fully adsorbed filter material and enter the operating room environment, so it's important to change the canister immediately when the visual signal and audible alarm signal are shown on the **SENSOfluran™** device. The changing of the canister and other technical processes will be a part of the customer training plan once the device is launched in each country. We recommend having an empty canister near the anesthesia machine to facilitate full canister replacement during surgery.

11. Can this system be used with less than 1L/min fresh gas flow?

Yes, it can be used in 'high flow' and 'low flow' anaesthesia cases that use fluorinated halocarbon inhaled anaesthetic gases.

12. Can I proceed with the oxygen flush while the surgery is taking place and the canister is attached?

Yes, the oxygen flush does not disrupt the loading of the canister. Please ensure that there is no electrical equipment installed directly below the **SENSOfluran™** unit. This is because prolonged oxygen flush could lead to a locally, temporarily oxygen enriched environment within ~15 cm (~5.9 inch) below the **SENSOfluran™** unit. The oxygen flush should be limited in frequency and the duration should be no more than a few seconds to prevent the local, transient build-up of oxygen.

FAQs about CONTRAfluran™ and SENSOfluran™

Section 2) During surgery

13. Can we use the canisters without the sensor?

We recommend using the canisters only if these are attached to the sensor unit and not without it. While **CONTRAfluran™** will continue to adsorb anaesthetic gases, the **SENSOfluran™** unit provides operating room staff with information regarding capacity and operation of the **CONTRAfluran™** filter.

14. Does SENSOfluran™ need to be switched off when the anaesthesia machine is turned off or between surgeries?

No, the sensor unit does not need to be switched off during these times.

15. Does the CONTRAfluran™ Anaesthesia Gas Capture system generate any system back pressure to the anaesthesia machine or patient?

No, the **CONTRAfluran™** Anaesthesia Gas Capture system has been tested and confirmed to cause no additional back pressure in compatible anaesthesia machines.

16. Is it possible to use another gas capture canister with the SENSOfluran™ Sensor Unit?

No, the **SENSOfluran™** Sensor Unit is only compatible with the Zeosys **CONTRAfluran™** canister.[1]

17. Will the CONTRAfluran™ canister capture all gases (including nitrous oxide and isoflurane) or just sevoflurane and desflurane?

The technology is currently designed to capture only fluorinated halocarbon inhaled anaesthetic gases (more specifically, sevoflurane and desflurane) from the expired air of a patient. The system will capture isoflurane, however it is recommended that this be captured in a separate **CONTRAfluran™** canister than that used for desflurane and/or sevoflurane to assist in downstream canister processing. **CONTRAfluran™** does not capture nitrous oxide.[1] If nitrous oxide must be used for anaesthesia, please contact your Baxter sales representative for guidance on the proper installation of **CONTRAfluran™** with an active anaesthetic gas scavenging system (AGSS). The **CONTRAfluran™** Anaesthesia Gas Capture system can be configured to allow the use of nitrous oxide along with an AGSS system to vent the nitrous oxide gas.

FAQs about CONTRAfluran™ and SENSOfluran™

Section 2) During surgery

18. What is the amount of PPM per LED light in the SENSOfluran™ Sensor Unit?

The red LED is triggered by 2000 ppm at the sensor location. This is in the last 2 minutes of loading as the loading curve for the canister is very sharp. The space in the sensor unit which triggers the red light is a few cubic centimetres, which is extremely small compared with the air volume of a typical operating room. The concentration of anaesthetic gas outside of the **SENSOfluran™** unit has never been found to exceed 2 ppm during the course of operation.

19. Every time the power is cut off from the SENSOfluran™ it starts to light or warm up again. Why does this occur?

The sensor needs to attain a certain temperature before working properly;[1] this period is the warm-up phase for the unit.[1] The green blinking after change of canister is different – it allows the residual anaesthetic gas in the **SENSOfluran™** to clear before resuming monitoring as not to generate alarms after the change.[1]

FAQs about CONTRAfluran™ and SENSOfluran™

Section 3) After the canister is filled

1. Who is responsible for the pick-up of the canisters?

Baxter will support our customers in the collection of canisters. Please contact Baxter customer service for canister collection.

2. Where should I store the full, used canisters whilst awaiting collection?

Place the used canisters in the protective zipper bags and ensure these are sealed tightly.[1] These then need to be stored in a well-ventilated space at room temperature.[1]

3. What happens to the canister and charcoal after processing?

The canister is recycled. The charcoal will be sterilised and then recycled.

4. If the canister can capture both gases, why do the gases need to be labelled? More importantly, how does this need to be done if both gases are captured in one canister?

On top of the canister, there is a sticker with gas options. The healthcare professionals need to tick the box that corresponds with gas (or gases) contained within each canister.[1] Desflurane and sevoflurane can be collected in one canister. Labelling the canisters with the gas (or gases) contained within each one helps optimise the gas recycling process.

5. Why does the sensor unit need to be replaced every 12 months?

This is to ensure that the electric board inside the sensor unit does not have much wear and tear and is in keeping with calibration standards in the medical device industry. In some cases, the electric board may need to be replaced and Baxter will provide the necessary instruction videos to help hospital Biomeds with this process.

FAQs about CONTRAfluran™ and SENSOfluran™

Section 3) After the canister is filled

6. Does the sensor unit come with a replacement warranty in case it fails during the first 12 months of use?

Yes, it does come with a replacement warranty.

7. Does the entire grey sensor unit need to be replaced or just the electrical board?

Only the electrical board inside the sensor unit needs to be replaced.

8. How often do the hoses need to be changed?

There is no fixed period for changing the hose, as it depends mostly on how often the system is used. However, it is recommended that the hose is changed every 4 weeks to ensure the smooth running of the system.

9. Who is the first point of contact should the system fail or if a device needs to be exchanged?

Customers should contact the local Baxter salesperson or customer service for any complaints or questions.[1] The customer service contact details for your specific country are available at the end of this User Guide or in the Instructions For Use document.[1]

10. Is an environmental monitoring device needed when using this system?

This is not required if the correct process for replacing the canister is followed by customer.

FAQs about CONTRAfluran™ and SENSOfluran™

Section 3) After the canister is filled

11. Where can I find the canister expiry date?

The shelf life of a canister is 2 years. The expiry date will be indicated on stickers found on top of the canister box, as well as on the side of the canister.
Please find below a sample sticker and a photo of a sticker on a canister:

SUPRANE (desflurane)

Abbreviated Summary of Product Characteristics (SPC)

This prescribing information is based on the Irish summary of product characteristics (SPC) and is intended for international use only. Please always consult your full country-specific SPC as licenses and licensing conditions may vary from country to country.

Name and composition: Desflurane 100% v/v Inhalation vapour, solution

Indications: Desflurane is indicated as an inhalation agent for induction and maintenance of anaesthesia in adults, and for maintenance of anaesthesia in intubated infants and children under 12 years. Desflurane is not indicated for induction of anaesthesia in paediatric patients. Use of desflurane in dental anaesthesia should be restricted to hospitals and day care units only.

Posology and Method of Administration: See SPC for full details. Desflurane is administered by inhalation. The concentration of desflurane should be delivered from a vaporizer specifically designed and designated for use with desflurane. The administration of general anaesthesia must be individualized based on the patient's response. The minimum alveolar concentration (MAC) of desflurane decreases with increasing patient age. The dose of desflurane should be adjusted accordingly. Induction: Inspired concentrations of 4-11% usually produces surgical anaesthesia in 2-4 minutes. Not for induction in paediatrics. Maintenance: 2-6% with concomitant nitrous oxide or 2.5-8.5% in oxygen or enriched air. 5.2-10% with or without nitrous oxide in paediatrics. Not for use in non-intubated children under 6 years old. Due to limited data available, desflurane is not approved for maintenance of anaesthesia in children 12-18 years of age. Blood pressure and heart rate should be monitored carefully during maintenance as part of the evaluation of depth of anaesthesia. Concentrations of 1-4% desflurane in nitrous oxide/ oxygen have been used in patients with chronic renal or hepatic impairment and during renal transplantation surgery.

Contraindications: Desflurane should not be used for patients in whom general anaesthesia is contraindicated. Desflurane is also contraindicated: in patients with known sensitivity to halogenated agents; in patients with known or genetic susceptibility to malignant hyperthermia; in all patients (adults and children) undergoing dental procedures outside a hospital or day care unit. Desflurane should not be used in patients in whom liver dysfunction, jaundice, unexplained fever, leucocytosis or eosinophilia has occurred after a previous halogenated anaesthetic administration. Myocardial ischaemia has occurred during induction with desflurane in a significant proportion of patients undergoing CABG. The product is not suitable for such use. Desflurane is contraindicated for use as an inhalation induction agent in paediatric patients because of the frequent occurrence of cough, breath holding, apnea, laryngospasm and increased secretions.

Undesirable Effects: May cause dose dependant cardio-respiratory depression. Nausea and vomiting has been reported postoperatively – may be due to a range of factors and common following surgery under general anaesthesia. Common (≥1/100 - <1/10) Pharyngitis, breath holding, headache, conjunctivitis, nodal arrhythmia, bradycardia, tachycardia, hypertension, apnea, cough, laryngospasm, salivary hypersecretion, increased creatinine phosphokinase, ECG abnormal.

Precautions: Only to be administered by people trained in administration of general anaesthesia using a vaporizer specifically designed and designated for use with desflurane. Use in a setting with appropriate emergency equipment and trained staff in emergency techniques are available. Monitor blood pressure and heart rate as part of evaluation of the depth of anaesthesia. Caution in use with LMA or face mask in children under 6 years. May trigger malignant hyperthermia. Inhaled anaesthetics have been associated with increases in serum potassium. Prompt and vigorous treatment for hyperkalaemia and arrhythmias recommended. Disruption of hepatic function, icterus and fatal liver necrosis have been reported with halogenated anaesthetics. May increase CSF pressure but attention to maintain CPP. Rapid increase in end-tidal concentration may increase heart rate and blood pressure. Hypotension and respiratory depression increases as anaesthesia deepens. Use in hypovolaemia, hypotension and debilitated patients has not been investigated, a lower concentration is recommended. Carbon dioxide absorbers should not dry out. Appropriate analgesia should be administered at the end of surgery or early in PACU. Caution with repeated anaesthesia in a short period of time. Desflurane has been associated with some blood sugar elevation intra-operatively. Safety of desflurane has not been established in obstetric procedures.

Interactions: MAC reduced by concomitant N_2O administration. Concomitant administration of opioids or benzodiazepines show a marked reduction in MAC. Neuromuscular blocks are potentiated by desflurane.

Overdose: Discontinue desflurane, establish clear airway and initiate assisted/controlled ventilation with pure oxygen. Support and maintain adequate haemodynamics.

Legal category: POM

Date of Preparation: October 2019. For complete posology, Warnings and precautions for use, incompatibilities and interactions, please refer to the full SPC.

SEVOFLURANE

Abbreviated Summary of Product Characteristics (SPC)

This prescribing information is based on the UK summary of product characteristics (SPC) and is intended for international use only. Please always consult your full country-specific SPC as licenses and licensing conditions may vary from country to country.

Name and composition: Sevoflurane – 100% - clear, colourless liquid for vapour inhalation.

Indications: Induction and maintenance of general anaesthesia in adults and children.

Posology and method of administration: See SPC for full details. Premedication should be selected according to the need of the individual patient, and at the discretion of the anaesthesiologist. Anaesthesia induction: Dosage should be individualised and titrated to the desired effect according to the patient's age and clinical status.A short acting barbiturate or other intravenous induction agent may be administered followed by inhalation of sevoflurane. Induction with sevoflurane may be achieved by inhalation of 0.5-1.0% sevoflurane in oxygen (O_2) with or without nitrous oxide (N_2O), increasing by increments of 0.5-1.0% sevoflurane, to a maximum of 8% in adults and children until the required depth of anaesthesia is achieved. In adults inspired concentrations of up to 5% sevoflurane usually produce surgical anaesthesia in less than two minutes. In children, inspired concentrations of up to 7% sevoflurane usually produce surgical anaesthesia in less than two minutes. Maintenance of anaesthesia: Surgical levels of anaesthesia may be maintained by inhalation of 0.5-3% sevoflurane in O_2 with or without concomitant use of N_2O.

Undesirable Effects: As with all potent inhalational anaesthetics, sevoflurane can produce dose-dependent cardiac respiratory depression. Most of the adverse reactions are mild to moderate in severity and transient in duration. Nausea and vomiting have been reported in the post-operative period – common symptoms following surgery and general anaesthesia – which may be due to the inhalational anaesthetic, other agents administered intra-operatively or post-operatively, or the patient's reaction to the surgical procedure. The most commonly reported adverse reactions were as follows: In adult patients: hypotension, nausea and vomiting; In elderly patients: bradycardia, hypotension and nausea; and In paediatric patients: agitation, cough, vomiting and nausea.

Precautions: Sevoflurane should be administered only by persons trained in the administration of general anaesthesia. Facilities for maintenance of a patent airway, artificial ventilation, oxygen enrichment and circulatory resuscitation must be immediately available. All patients anaesthetised with sevoflurane should be constantly monitored, including electrocardiogram (ECG), blood pressure (BP), oxygen saturation and end tidal carbon dioxide (CO_2.) The concentration of sevoflurane being delivered from a vaporizer must be known exactly. As volatile anaesthetics differ in their physical properties, only vaporizers specifically calibrated for sevoflurane must be used. The administration of general anaesthesia must be individualized based on the patient's response. Hypotension and respiratory depression increase as anaesthesia is deepened.

Contraindications: Sevoflurane should not be used in patients with known or suspected hypersensitivity to sevoflurane or to other halogenated anaesthetics (e. g. history of liver function disorder, fever or leucocytosis of unknown cause after anesthesia with one of these agents). Sevoflurane should not be used in patients with a history of confirmed hepatitis due to a halogenated inhalational anesthetic or a history of unexplained moderate to severe hepatic dysfunction with jaundice, fever and eosinophilia after anaesthesia with sevoflurane. Sevoflurane should not be used in patients with known or suspected genetic susceptibility to malignant hyperthermia. Sevoflurane is contraindicated in patients in whom general anesthesia is contraindicated.

Interactions: See SPC for full details. Sevoflurane has been shown to be safe and effective when administered concurrently with a wide variety of agents commonly encountered in surgical situations such as central nervous system agents, autonomic drugs, skeletal muscle relaxants, anti-infective agents including aminoglycosides, hormones and synthetic substitutes, blood derivatives and cardiovascular drugs, including epinephrine. Nitrous oxide, Benzodiazepines and opioids are expected to decrease the MAC of sevoflurane. Opioids such as fentanyl, alfentanil and sufentail, when combined with sevoflurane, may lead to a synergistic fall in heart rate, blood pressure and respiratory rate.

Overdose: Symptoms of overdose include respiratory depression and circulatory insufficiency. In the event of apparent overdosage the following action should be taken: Sevoflurane administration should be discontinued and supportive measures provided.

Legal Category: POM

Date of Preparation: February 2018. For complete posology, Warnings and precautions for use, incompatibilities and interactions, please refer to the full SPC.

AERRANE (isoflurane)

Abbreviated Summary of Product Characteristics (SPC)

Name and composition: AErrane 100% (isoflurane) liquid for inhalation vapour

Indications: Volatile halogenated anaesthetic for general anaesthesia.

Dosage and Route: Inhalation via a specific vaporiser calibrated for isoflurane. *Induction*. Initially 0.5% is recommended. 1.3-3.0% usually produces surgical anaesthesia in 7-10 minutes. Recommend hypnotic dose of a short acting barbiturate or another product (eg propofol, etomidate, midazolam) to avoid coughing or laryngospasm. *Maintenance*. 1.0-2.5% with the simultaneous administration of N_2O and O_2. Higher concentration of 1.5-3.5% if administered with pure oxygen. *Recovery*. Reduce to 0.5% at the end of the operation, or to 0% during closure of the wound. Once anaesthetic stopped, ventilate several times with 100% oxygen until complete awakening. Not recommended for use as an inhalation induction agent in infants and children.

Side effects: Potential serious undesirable effects include malignant hyperthermia, anaphylactic reactions and liver adverse reactions Frequency not know: Carboxyhaemoglobinaemia, Anaphylactic reaction, Hypersensitivity, Hyperkalaemia, Blood glucose increased, Agitation, Delirium, Mood altered, Convulsion, Mental impairment, Arrhythmia, Bradycardia, Cardiac arrest, Electrocardiogram QT prolonged, Tachycardia, Torsade de pointes, Hypotension, Haemorrhage, Bronchospasm, Dyspnoea, Wheezing, Respiratory depression, Laryngospasm, Ileus, Vomiting, Nausea, Hepatic necrosis, Hepatocellular injury, Blood bilirubin increased, Swelling face, Dermatitis contact, Rash, Blood creatinine increased, Blood urea decreased, Hyperthermia malignant, Chest discomfort, Chills, White blood cell count increased, Hepatic enzyme increased, Fluoride increased, Electroencephalogram abnormal, Blood cholesterol decreased, Blood alkaline phosphatase decreased, Blood creatine phosphokinase increased, Myoglobinuria, Rhabdomyolysis.

Precautions: Avoid use during pregnancy. Only to be administered by an anaesthetist using a specially calibrated vaporiser. Hypotension and respiratory depression increase as anesthesia depended. Caution when administering isoflurane to patients at risk for QT prolongation. Can produce hepatic injury. Pre-existing liver disease can be a reason to select a non-halogenated anaesthetic. Respiratory depressant effect accentuated by narcotics or other respiratory depressants. Respiration supervision. Relatively little is metabolised. Caution in repeated anaesthesia within a short period of time. Caution in patients with myasthenia gravis. Control ventilation in neurosurgery patients, cerebral blood flow tends to rise in deeper anaesthesia. Increases in intracranial, cerebrospinal fluid pressure can be prevented by hyperventilation. Not for administration to patients who can develop bronchoconstriction. Lower the dose in hypovolaemic, hypotensive and debilitated patients.Maintenance of normal hemodynamics is important. In children saliva flow and tracheobronchial secretions can cause laryngospasms. In abortus provocatus procedures, increased blood loss has been observed. Can cause malignant hyperthermia. Can react with carbon dioxide absorbers to form carbon monoxide. In rare cases has been associated with increase in serum potassium levels. Increase in potassium levels has resulted in arrhythmias and death in children with neuromuscular disease, associated with the use of suxamethonium in most cases.

Contraindications: known sensitivity to isoflurane or halogenated anaesthetics. Known or suspected genetic susceptibility to malignant hyperthermia.

Interactions: Stop nonselective MAOI 15 days prior to surgery. Risk of serious ventricular arrhythmia with alpha and/or beta-sympathomimetics. Caution with beta-blockers, isoniazid (stop therapy 1 week before operating and not resume for 15 days after), adrenaline, indirect sympathomimetics, potentiation of muscle relaxants. Potentiation of depressive action of morphine. Marked hypotension with calcium antagonists, opioids, benzodiazepines, sedative agents, calcium antagonists. MAC is reduced by concomitant N_2O administration.

Overdose: Discontinue anaesthetic, check whether air passages are open, and depending on the circumstances, continue with assisted or controlled respiration using pure oxygen.

Legal category: POM

Basic NHS price: FDG9623 250ml bottle £27.00

Marketing Authorisation Number and Holder: PL00116/0326 Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk IP24 3SE

Date of Preparation: March 2019.

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	**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

	Customer Service Fa. Baxter	
UK & Ireland	**UK Customer Services:** E-Mail: 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
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 Téléfono: 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

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

Customer Service Fa. Baxter	
Denmark	**DK Kundeservice:** E-Mail: Kundeservice_denmark@baxter.com Telefon: 80 30 01 41
Finland	**FN Asiakaspalvelu:** E-Mail: 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: Kundeservice_sverige@baxter.com Telefon: 020 788 115
Greece	**GR Εξυπηρέτηση πελατών:** E-Mail: philippos_michailidis@baxter.com Τηλέφωνο: +30 (690) 8394979
Canada	**Canadian Service Clients:** Telephone: 1-888-719-9955

Manufactured by

ZeoSys Medical GmbH

Distributed by

Baxter

References: 1. ZeoSys Medical GmbH CONTRAfluran™ and SENSOfluran™ Instructions For Use. **2.** Data on file. Efficiency Test Canister. Berlin: ZeoSys Medical; 2020.

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