CONTRAfluran[™]

SENSOfluran PLUS - Fill Level Control Unit

SUPPLEMENTARY INSTRUCTIONS FOR USE



These operating instructions contain information about the SENSOfluran PLUS Fill Level Control Unit.



Please read these Instructions for Use carefully before installing and commissioning the SENSOfluran PLUS Fill Level Control Unit. The Instructions for Use are an integral part of the product and must be kept in the immediate vicinity of the equipment, readily accessible to the operating personnel at all times.

Table of Contents

- 1. What is SENSOfluran PLUS?
- 2. Intended Use
- 3. Installation Instructions for the SENSOfluran PLUS Fill Level Control Unit
- 4. Transport and Storage
- 5. Cleaning and Maintenance of the SENSOfluran PLUS Fill Level Control Unit

1. What isSENSOfluran PLUS?

The SENSOfluran PLUS Fill Level Control Unit is a canister holder with an integrated sensory level control that indicates when the canister is full and needs to be replaced. The SENSOfluran PLUS can be connected, via the appropriate hose, to the anesthetic gas scavenging system (AGSS). If the SENSOfluran PLUS connection is installed correctly and as intended, the warning regarding nitrous oxide (N₂O) in regards to the SENSOfluran PLUS Fill Level Control Unit does not apply, and nitrou s oxide can be used.

2. Intended Use

The safe and effective use of the CONTRAfluran[™] anestheticgas canister in combination with the SENSOfluran PLUS Fill Level Control Unit is only guaranteed if the information in these Instructions for Use is strictly followed. Only authorized recommended hoses or other connectors that form a tight seal with the CONTRAfluran[™] canister inlet may be used. Claims of any kind against ZeoSys Medical GmbH or its a uthorized representatives in regards to damage resulting from improper use of the canister and the fill level control unit shall be excluded.

All applicable aspects such as Safety instructions and Commissioning for the SENSOfluran PLUS Fill Level Control Unit are found in the CONTRAfluran[™] Anesthetic Gas Canister and SENSOfluran PLUS Fill Level Control Unit Instructions for Use.

3. SENSOfluran PLUS Fill Level Control Unit Installation Instructions

Before commissioning the SENSOfluran PLUS Fill Level Control Unit, please ensure that all necessary components required for proper operation are available.

These are :

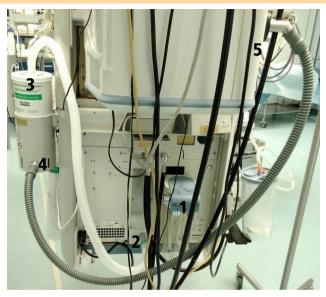
The CONTRAfluran[™] Anesthetic Gas Canister The SENSOfluran PLUS Fill Level Control Unit Accessories: 22 mm corrugated hose and associated adapters for use with different connectors as applicable for each anesthesia machine

Installation of the SENSOfluran PLUS Fill Level Control Unit must be performed by trained personnel. It must be ensured that the medical inlet and outlet hose connections of the CONTRAfluran^{III} / SENSOfluran PLUS system provide a tight seal, and functionality is only guaranteed when the anesthesia machine is operated in **passive mode** The examples of anesthesia machines liste d below do not allow this **passive mode**, or allow it only through device intervention, and are therefore **NOT** suitable for the intended use ofthe CONTRAfluran^{IIII} Anesthetic Gas Canisters with the SENSOfluran PLUS Fill level Control Unit per the Instructions for Use:

- Dräger Atlan
- Getinge Flow I

In case of questions, please contact the anesthesia machine manufacturer.

3.1 SENSOfluran PLUS Installation Example



Initially, the **reservoir (1)**, which is interposedbetween your anesthesia machine and the AGSS (in or on the machine), must be disconnected from the System. The outlet connector of the anesthesia machine (2) should then be directly connected to the CONTRAFluranTM Anesthetic Gas canister inlet (3). Place the CONTRAFluran canister into the SENSOFluran PLUS unit ($3 \rightarrow 4$). The SENSOFluran PLUS Fill Level Control Unit connector is connected to the AGSS (one example of such a connection is shown in figure ($4 \rightarrow 5$).



With certain anesthesia machine settings, such as a prolonged oxygen flush, oxygenmay briefly be released into the environment in the area of the CONTRAfluran/SENSOfluran PLUS filter system. Therefore, the attachment to the anesthesia machine or in its vicinity must be performed in such a way that the

functionality of the anesthesia machine, such as self-tests/calibrations or electrical components for example, is not impacted at any time. Should the anesthesia machine, in combination with the CONTRAfluran/SENSOfluran PLUS filter system, exhibit behavior that deviates from its normal operation, such as error messages during the self-test or impaired ventilation, which do not occur during operation without this filter system, then this combination may not be operated as configured, and the cause of such behavior must first be determined.

4. Transport and Storage

The following items must be observed when transporting the SENSOfluran PLUS Fill Level Control Unit:

- · The shipping container must always remain upright, during the entire transport process.
- Do not tilt or turn over the shipping container.
- · Open the container carefully from the top to avoid damaging the contents.

For storage instructions of the SENSOfluran PLUS Fill Level Control Unit, please refer to the CONTRAfluran[™] Anesthetic Gas Canister with SENSOfluran PLUS Fill Level Control Unit Instructions for Use.

5. Cleaning and Maintenance of the SENSOfluran PLUS Fill Level Control Unit

The SENSOfluran PLUS Fill Level Control Unit surfaces can be wiped down with cleaning agents containing hydrogen peroxide or detergents. **DO NOT use any alcohol -based cleaners**, as these will impair the sensor performance of the SENSOfluran Fill Level Control Unit. How often the SENSOfluran PLUS Fill Level Control Unit is wiped down depends on the existing hospital protocol for wiping down the anesthesia cart. Maintenance intervals are specified in the CONTRAFiuran[™] Anesthetic Gas Canister with SENSOfluran PLUS Fill Level Control Unit Instructions for Use.

CAUTION: During cleaning or disinfection, be careful not to wet the sensor and electronic unit inside the SENSOfluran PLUS Fill Level Control Unit with liquid!

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