# Spirolog Flow Sensor

| | | |
|---|---|---|
| de | Flowsensor | Gebrauchsanweisung |
| en/enUS | Flow Sensor | Instructions for Use |
| fr | Capteur de débit | Notice d'utilisation |
| es | Sensor de flujo | Instrucciones de uso |
| it | Sensore di flusso | Istruzioni per l'uso |
| ptBR | Sensor de fluxo | Instruções de Uso |
| nl | Flowsensor | Gebruiksanwijzing |
| da | Flowsensor | Brugervejledning |
| no | Flowsensor | Bruksanvisning |
| sv | Flödessensor | Bruksanvisning |
| fi | Virtausanturi | Käyttöohjeet |
| lt | Srauto matuoklis | Naudojimo instrukcija |

WARNING

To properly use this medical device, read and comply with these Instructions for Use.



CE 0123

Directive 93/42/EEC
concerning Medical Device


Manufactured by:

**Dräger Medical GmbH**

Moislinger Allee 53 - 55
D-23542 Lübeck
Germany
+49 451 8 82-0
FAX +49 451 8 82-20 80
http://www.draeger.com

Distributed in the USA by:

**Draeger Medical, Inc.**

3135 Quarry Road
Telford, PA 18969-1042
U.S.A.
(215) 721-5400
(800) 4DRAGER
(800 437-2437)
FAX (215) 723-5935
http://www.draeger.com

Distributed in Japan by: 製造販売業者

ドレーゲル・メディカル ジャパン株式会社

東京都江東区富岡 2-4-10
03-5245-2301
FAX 03-5245-2320
http://www.draeger.com

Distributed in China by: 经销商

德尔格医疗设备（上海）有限公司

上海市浦东新区上海国际医学园区琥珀路 229 号
邮政编码：201 321
800-820-3400
+86 21 3811 6000
传真 +86 21 3811 6011
http://www.draeger.com

Представитель в Рф

**ООО Дрегер Медицинская Техника**

1-й Щемиловский пер., д 15
127473, Москва
Россия
+ 7 (495) 775 15 20
ФАКС + 7 (495) 775 15 21

Сервисная служба

**ООО Дрегер Медицинская Техника**

+ 7 (495) 775 15 20



**9037745** – me



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**en/enUS Instructions for Use**
**Spirolog**
**Flow Sensor**

## Trademarks

- Spirolog® is a trademark of Dräger
- Sekusept® is a trademark of Ecolab Deutschland GmbH
- Korsolex® is a trademark of Bode Chemie
- Gigasept® is a trademark of Schülke & Mayr
- Cidex® is a trademark of Johnson & Johnson Medical GmbH

## Definitions

**WARNING**
**A WARNING statement provides important information about a potentially hazardous situation which, if not avoided, could result in death or serious injury.**

**CAUTION**
A CAUTION statement provides important information about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or in damage to the medical device or other property.

**NOTE**
A NOTE provides additional information intended to avoid inconvenience during operation.

## For Your Safety and that of Your Patients

**WARNING**
**For a full understanding of the performance characteristics of this medical device, the user should carefully read these Instructions for Use befor use of the medical device. The medical device is only to be used for the purpose specified. Strictly follow the Instructions for Use of the Dräger basic device that can be used in combination with this accessory.**

In these Instructions for Use, the Spirolog Flow Sensor is also referred to as flow sensor.

## Intended Use

The flow sensor is a hot-wire sensor for measuring volumetric gas flow (flow) delivered by Dräger anesthesia machines and ventilators. The flow sensor is not suitable for sterilization.

## Operation

**WARNING**
**Patient hazard due to ignition in the flow sensor.**

**The flow sensor can ignite medications or other substances based on highly flammable substances.**

**Do not use highly flammable substances in conjunction with the flow sensor.**

Check flow sensor for visible damage on a regular basis.

Strictly follow the Instructions for Use of the Dräger basic device to which this medical device is connected.

## Reprocessing

**WARNING**
**Patient hazard due to failure of flow measurement.**

**Deposits, which have not been removed during reprocessing, can damage the measuring wires in the flow sensor.**

**Carry out a regular visual inspection for dried residues of mucus, medication aerosols, and lint.**
**Replace flow sensor when it is damaged or when the reprocessing did not remove all deposits.**

**CAUTION**
Risk of damage to the flow sensor.
Improper reprocessing can damage the flow sensor.
Do not clean the flow sensor in an ultrasonic bath, a washer-disinfector, with compressed air, water jets, brushes or the like.

**WARNING**
**Patient hazard due to ignition in the flow sensor.**

**During sensor calibration remaining vapors of highly flammable substances (e. g., alcohols) can ignite. This can destroy the flow sensor and harm the patient or the user.**

**After reprocessing, allow the flow sensor to air for at least 30 minutes.**

Complete reprocessing comprises cleaning and disinfection of the flow sensor.

The material compatibility of Dräger accessories to be reprocessed has been tested with various cleaning agents and disinfectants. The following cleaning agents and disinfectants showed good material compatibility at the time of the test:

**Cleaning**

| Cleaning agent | Manufacturer |
|---|---|
| Sekusept Powder Classic | Ecolab Deutschland GmbH, Düsseldorf, Germany |

1 Prepare a 4 % Sekusept Powder Classic solution in a container with cover.
2 Immerse flow sensor bubble-free for 15 minutes. Swirl vigorously at least 3 times during the contact time.
3 Repeat application.

**Disinfecting**

| Disinfectants | Manufacturer |
|---|---|
| Korsolex Basic, Korsolex Extra | Bode Chemie, Hamburg, Germany |
| Gigasept FF | Schülke & Mayr, Norderstedt, Germany |
| Cidex OPA | Johnson & Johnson Medical GmbH, Norderstedt, Germany |

The composition of the disinfectant is the responsibility of the manufacturer and can change over time.

Strictly follow the manufacturer's instructions on the disinfectant.

1 Disinfect the flow sensor by immersion.
2 Sufficiently rinse the flow sensor under water (preferably drinking-water quality) until no disinfectant residues can be recognized.
3 Inspect flow sensor for visible soiling and damage (measuring wires and corresponding pins). Repeat manual disinfection if necessary.
4 Remove remaining water and allow the flow sensor to air for at least 30 minutes.

**Sterilizing**

**CAUTION**
Patient hazard due to failure of flow measurement.
Sterilization can damage the flow sensor.
The flow sensor must not be sterilized.

## Disposal

- The flow sensor must be disposed of as infectious waste.

Low-emission combustion is possible at over 800 °C (1472 °F).

## Technical Data

| | |
|---|---|
| **Material** | Acrylonitrile-butadiene-styrene (ABS) with 13 µm platinum wire |
| **Ambient conditions** | |
| **Operation** | Strictly follow the Instructions for Use of the Dräger device that can be used in combination with this medical device. |
| **Storage** | |
| Temperature | –40 to 75 °C (–40 to 167 °F) |
| Atmospheric pressure | 115 to 1100 hPa (1.67 to 15.96 psi) |
| Relative humidity | 5 to 95 % (no condensation) |
| **Measuring principle** | Hot wire anemometry |
| **Service life** | The flow sensor is subject to wear and can be used as long as successful calibration is possible. |
| **Classification** | Class IIa |
| In accordance with Directive 93/42/EEC Annex IX | |
| **UMDNS code** | 14-117 |
| Universal Medical Device Nomenclature System – Nomenclature for medical devices | |

For USA: Rx only

Caution: Federal law restricts this device to sale by or on the order of a physician

## Order List

| Designation | Order number |
|---|---|
| Spirolog Flow Sensor (5 pcs.) | 8403735 |