

Flow Sensor SpiroQuant H

Use the advantages:

- Proven passive flow diffential pressure converter
- Measuring of breathing gas flow in adult applications
- High product quality
- RoHS conform
- Biocompatible components
- Short delivery times
- Technical support
- Made in Germany
- Certified quality management system according EN ISO 13485

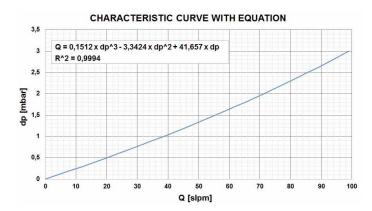
"We keep your devices operating at their best."

EnviteC has been developing and manufacturing highly specialized products for medical applications. EnviteC's research and development activities are consistently aligned to customer and market needs – identification and optimization of sustainable product solutions are the main concerns of the company.

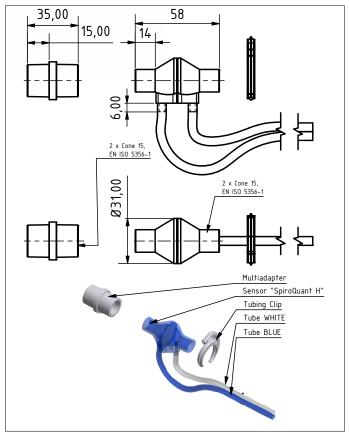
The company trusts in the quality of advanced production methods and processes. The result are flow measurement solutions for medical applications, which share the same extraordinary quality, excellent signal stability and reliable response for accurate readings. The Flow sensor SpiroQuant H is a passive flow differential pressure converter for measuring of breathing gas flow in connection with the appropiate measuring unit (differential pressure gauge). The sensor is designed as disposable sensor for single patient use in adult applications. A re-use or cleaning is not allowed.

From standard sensors to customized sensors

Experienced EnviteC engineers analyze customer requirements. This input is used for different standard and OEM applications, and ongoing support is provided right up to the final integration in the solution. EnviteC designs customized sensors characterized by a maximum possible degree of precision.



Mechanical drawing (All dimension in mm)



General tolerances ISO 2768-c

Additional information

If the sensor is intended to replace the original flow-sensing component in anesthesia machines or ventilators, consult the EnviteC XRL Cross Reference List under www. EnviteC.com for selecting the appropriate sensor.

For more information please contact us!

We look forward to assisting you either on the phone or in a personal talk.



Technical Specifications SpiroQuant H

| Measuring principle | Differential pressure principle |
|--------------------------|--|
| Cross reference | Compatible to Hamilton flow sensor PN 279331 |
| Sensor type | Disposable sensor for single patient use |
| Application | Adult applications |
| Flow range | 0 100 slpm (standard liters per minute) |
| Accuracy | ± 15 % over measuring range |
| Flow resistance | Approx. 1.0 mbar equals 60 slpm |
| Operating temperature | 0 °C +50 °C |
| Operating humidity | 5 95 % RH non-condensing |
| Operating conditions | 570 1200 hPa only with external pressure compensation |
| Operating time | Single patient use, applicable as long as a sensor calibration is successful |
| Storage temperature | -20 °C +70 °C |
| Storage ambient pressure | 570 1200 hPa |
| Storage humidity | 5 % 95 % RH non-condensing |
| Storage time | Max. 5 years |
| Dead space | 11 cm ³ (without cone adaption) |
| Cleaning / disinfection | No re-use, cleaning or disfection not allowed |
| Weight | Sensor without tubes: approx. 11 g; |
| | Sensor incl. tubes: approx. 51 g |
| Material | Housing parts: MABS; |
| | Inner part: PET; |
| | Tube: PVC - medical grade; |
| | Tube length: 1.8 m; |
| | Tube diameters: dl 0 3.0 mm -0.1 +0.05; dA = 4.6 mm |
| Part number | 07-00-0001: SpiroQuant H (Pack with 6 pieces incl. clip and adapter); |
| | 07-000027: Tubing clip; |
| | 07-000025: Multi adapter |

Q TUV SUD EN ISO 13485 All specifications are applicable at standard conditions: 1013 hPa, 25 °C dry ambient air

Certified Quality Management

EnviteC is maintaining a quality management system, which meets the requirements of EN ISO 13485 for medical devices.

EnviteC-Wismar GmbH a Honeywell Company

Alter Holzhafen 18, 23966 Wismar, Germany Phone: +49 (0)3841-360-1 Phone: +49 (0)3841-360-200 Fax: +49 (0)3841-360-222 Internet: www.envitec.com Email: info@envitec.com Doc. No. 007-05-SpiroQuant_H_Spec-0 December 2017 Technical information is subject to change without notice! © 2017 Honeywell International Inc.

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Flow Sensor SpiroQuant A+

Use the advantages:

- Proven constant temperature hot-wire anemometry
- Fast response time
- High product quality
- RoHS conform
- Biocompatible components
- Short delivery times
- Technical support
- Made in Germany
- Certified quality management system according EN ISO 13485

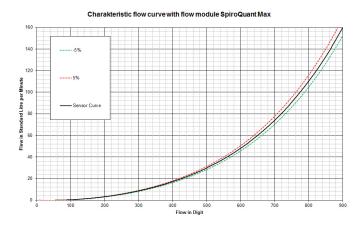
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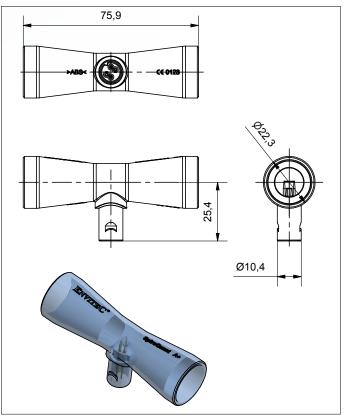
The company trusts in the quality of advanced production methods and processes. The result are flow measurement solutions for medical applications, which share the same extraordinary quality, excellent signal stability and reliable response for accurate readings. The flow sensor SpiroQuant A+ is a hot-wire sensor for measuring volume gas flow in anesthesia machines and ventilators. The flow sensor is not suitable for sterilization. For operation please refer to the instructions for use of the basic device to which this sensor is connected.

From standard sensors to customized sensors

Experienced EnviteC engineers analyze customer requirements. This input is used for different standard and OEM applications, and ongoing support is provided right up to the final integration in the solution. EnviteC designs customized sensors characterized by a maximum possible degree of precision.



Mechanical drawing (All dimension in mm)



General tolerances ISO 2768-c

Additional information

If the sensor is intended to replace the original flow-sensing component in anesthesia machines or ventilators, consult the EnviteC XRL Cross Reference List under www. EnviteC.com for selecting the appropriate sensor.

For more information please contact us!

We look forward to assisting you either on the phone or in a personal talk.

Technical Specifications SpiroQuant A+

| Measuring principle | Constant temperature hot-wire anemometry |
|--------------------------|---|
| Cross reference | Designed for EnviteC SpiroQuant MAX module; compatible with Dräger Spirolog [®] flow |
| | sensor |
| Sensor type | Disposable sensor for single patient use |
| Flow range | 0 160 slpm (standard liters per minute) |
| Accuracy | ± 7% from measured value between 0 10 l/min with flow module SpiroQuant MAX; |
| | \pm 5% from measured value between 10 160 l/min with flow module SpiroQuant MAX; |
| | (± 8 % reading used in Dräger ventilators) |
| Flow resistance | < 2.5 mbar (added resistance) |
| Operating temperature | +15 °C +40 °C |
| Operating time | Single patient use, applicable as long as a sensor calibration is successful |
| Storage temperature | -20 °C +70 °C |
| Storage ambient pressure | 570 1200 hPa |
| Storage humidity | 5 % 95 % RH in orginal packaging |
| Storage time | Max. 5 years in original packaging |
| Cleaning / disinfection | Single patient use |
| Weight | Approx. 10 g |
| Electrical connection | Gold plated 4 pin (compatible with Dräger Spirolog [®] sensor) |
| Material | Housing parts: MABS; |
| | Contact pins: gold-plated; |
| | Hot-wires: platin |
| Part number | 1000470: Flow sensor SpiroQuant A+ (Box with 5 pieces); |
| | 1001487: Flow module SpiroQuant MAX |

All specifications are applicable at standard conditions: 1013 hPa, 25 °C dry ambient air



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EC Certificate

Full Quality Assurance System Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III)

No. G1 15 06 21697 017

| Manufacturer: | EnviteC - Wismar GmbH Alter Holzhafen 18 23966 Wismar GERMANY |
|---------------------------|--|
| Facility(ies): | EnviteC - Wismar GmbH Alter Holzhafen 18, 23966 Wismar, GERMANY |
| Product Category(ies): | Oxygen Saturation Sensors and Monitors, Sensors and Control Units for Monitoring of Respiratory Parameters and Gas Exchange, Non-invasive Blood Pressure Euipment, Temperature Sensors |

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This guality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

713063594

Valid from: Valid until: 2015-09-02 2020-09-01

Date, 2015-08-28

Hans-Heiner Junker



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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ZERTIFIKAT

Nr. Q5 17 12 21697 018

Zertifikatsinhaber:

EnviteC - Wismar GmbH

Alter Holzhafen 18 23966 Wismar DEUTSCHLAND

Betriebsstätte(n):

EnviteC - Wismar GmbH Alter Holzhafen 18, 23966 Wismar, DEUTSCHLAND

Zertifizierungszeichen:



Geltungsbereich:

Design und Entwicklung, Produktion und Vertrieb von Sensoren und Überwachungseinheiten für vitale physiologische Parameter, Sensoren und Überwachungseinheiten für Beatmungsparameter und Gasaustauschmonitoring, Messgeräte und Sensoren zur Messung der Blutalkoholkonzentration

Angewandte Norm(en):

EN ISO 13485:2016 Medizinprodukte - Qualitätsmanagementsysteme -Anforderungen für regulatorische Zwecke (ISO 13485:2016) DIN EN ISO 13485:2016

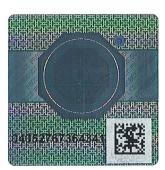
Die Zertifizierstelle von TÜV SÜD Product Service GmbH bescheinigt, dass das oben genannte Unternehmen ein Qualitätsmanagementsystem eingeführt hat und anwendet, das den Anforderungen der genannten Norm(en) entspricht. Umseitige Hinweise sind zu beachten.

Bericht Nr.:

713119332

Gültig ab: Gültig bis: 2018-02-06 2021-01-30

1. Pumil



Datum, 2018-02-06

Seite 1 von 1

Stefan Preiß



