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.“

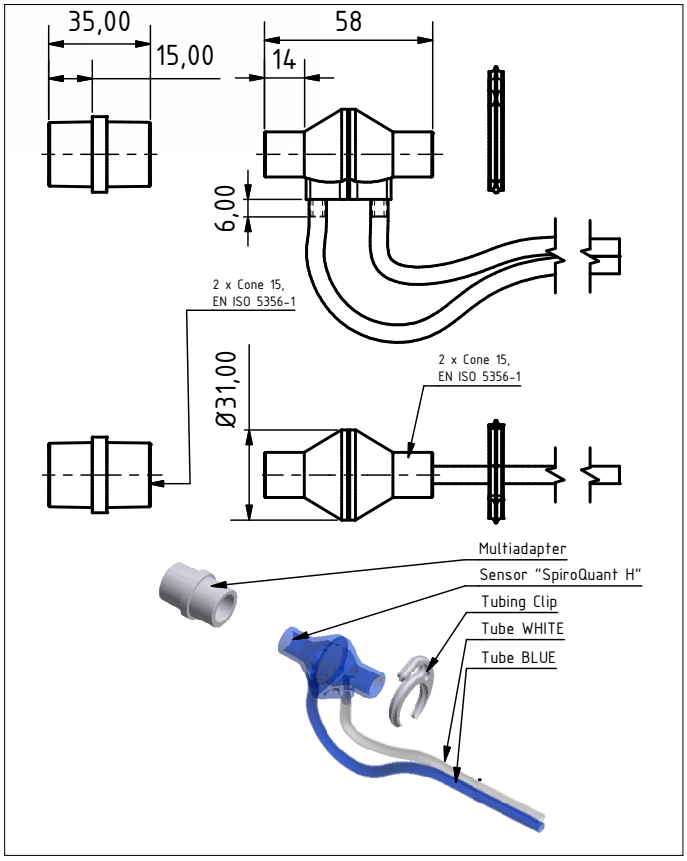
EnviteC has been developing and manufacturing highly specialized products for medical applications. EnviteC´s research and development activities are consistently aligned to customer and market needs – identification and optimization of sustainable product solutions are the main concerns of the company.

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

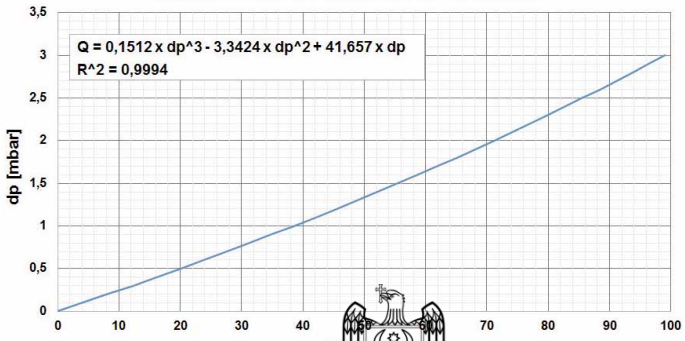
Experienced EnviteC engineers analyze customer requirements. This input is used for different standard and OEM applications, and ongoing support is provided right up to the final integration in the solution. EnviteC designs customized sensors characterized by a maximum possible degree of precision.

Mechanical drawing (All dimension in mm)



General tolerances ISO 2768-c

CHARACTERISTIC CURVE WITH EQUATION



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.

Digitally signed by Volcovschi Mihai
Date: 2022.09.05 12:45:55 EEST
Reason: MoldSign Signature
Location: Moldova

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: dI 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

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!
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EnviteC by Honeywell reserves the right to make changes in product specifications and adjust its production at any time and without notice.

ENVITEC
by Honeywell

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

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 021697 0017 Rev. 01

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 Equipment, 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 quality 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.: 713172795

Valid from: 2020-02-17
Valid until: 2024-05-26

Date, 2020-02-17

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

A4 / 07.17

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

C E R T I F I C A T E

No. QS6 021697 0022 Rev. 00

Certificate Holder: **EnviteC - Wismar GmbH**
Alter Holzhafen 18
23966 Wismar
GERMANY

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Sensors and Control Units for Monitoring of Vital Physiological Parameters, Sensors and Control Units for Monitoring of Respiratory Mechanics Parameters and Gas Exchange**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **33-094-3838**

Effective Date: **2021-03-10**

Expiry Date: **2022-01-28**

Date of Issue: 2021-03-18

(Tina Israel)
Manager, US Certification Body,
Medical and Health Services

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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

C E R T I F I C A T E

No. QS6 021697 0022 Rev. 00

Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Canada
- Medical Device Regulations – Part 1- SOR 98/282

Japan
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):
EnviteC - Wismar GmbH
Alter Holzhafen 18, 23966 Wismar, GERMANY

Facility Scopes:
Design and Development, Production and Distribution of Sensors and Control Units for Monitoring of Vital Physiological Parameters, Sensors and Control Units for Monitoring of Respiratory Mechanics Parameters and Gas Exchange
DUNS No: 33-094-3838

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