



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 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 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.:

713063594

Valid from:

2015-09-02

Valid until:

2020-09-01



Date, 2015-08-28

Hans-Heiner Junker

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

Page 1 of 1

Oxygen Sensor OOM201

Use the advantages:

- Compliant with European MDD (CE certification)
- Meets ISO 80601-2-55
- Designed and manufactured according to EN ISO 13485
- Accurate and reliable fast response
- Resistant to N_2O
- Excellent signal stability
- High product quality
- Short delivery times
- Technical support
- Made in Germany
- FDA cleared



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 integrator in the solution. EnviteC designs customized sensors characterized by a maximum possible degree of precision, for example with different signal levels or temperature compensation elements.

Intendend use

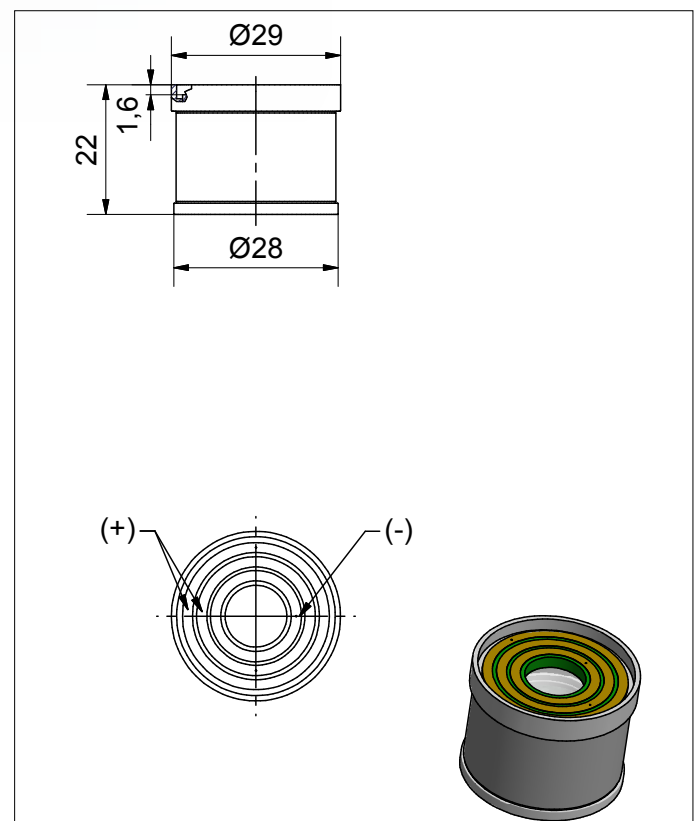
The EnviteC Medical Oxygen Sensors are intended as oxygen-sensing component of an oxygen analyzer that measures oxygen concentration in breathing gas mixtures in the following applications:

Sensing device for oxygen in

- control device of oxygen concentrators
- medical ventilators
- anaesthesia equipment
- incubators.

The use is limited to system monitoring. The sensors are not suited for breath by breath analysis of breath gases. Please refer to the Instructions for Use! If the sensor is intended to replace the original oxygen-sensing component of an oxygen analyzer, consult the EnviteC XRL Cross Reference List for selecting the appropriate sensor.

Mechanical drawing (All dimension in mm)



General tolerances ISO 2768-c

Additional information

The Instructions for Use as well as the EnviteC XRL Cross Reference List are available under www.EnviteC.com and in the Apple App Store under EnviteC XRL as free download.

For more information please contact us!

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



Technical Specifications OOM201

| | |
|-------------------------------|---|
| Measurement range | 0 % ... 100 % oxygen (at atmospheric pressure) |
| Nominal sensor lifetime | ≥ 500 000 % volume oxygen hours |
| Output in ambient air | 14 mV ... 20.7 mV (Dual Cathode), load 600 Ohms |
| Electrical interface | Gold plated slip rings |
| Accuracy | meets ISO 80601-2-55 requirements |
| Repeatability | < 1 % volume O ₂ at constant temperature and pressure |
| Linearity error | < 3 % relative |
| Response time | < 12 s to 90 % of final value |
| Zero offset voltage | < 200 µV in 100 % nitrogen, applied for 5 min |
| Cross interference | meets ISO 80601-2-55 requirements |
| Influence of humidity | -0.03 % rel. per % RH at 25 °C |
| Pressure range | 0.6 bar ... 2 bar (ppO ₂ 0 ... 1250 mbar O ₂) |
| Influence of pressure | proportional to change in oxygen partial pressure |
| Influence of mechanical shock | < 1 % relative after a fall from 1 m |
| Operating temperature | 0 °C ... +50 °C |
| Temperature compensation | no temperature compensation |
| Operating humidity | 0 % ... 99 % RH non-condensing |
| Long term output drift | < 1 % volume oxygen per month typically < -15 % relative over lifetime |
| Storage temperature | -20 °C ... +50 °C |
| Recommended storage | +5 °C ... +15 °C |
| Recommended load | ≥ 10 kOhms |
| Warm-up time | < 30 minutes, after replacement of sensor |
| Weight | approximately 28 grams |
| Part number | 01-00-0014 |

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



For suitable accessories and sensors please refer to the EnviteC Cross Reference List under www.EnviteC.com and in the Apple App Store under EnviteC XRL as free download.

EnviteC-Wismar GmbH a Honeywell Company

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Doc. No. 001-33-Datasheet_OOM201-0

March 2016

Technical information is subject
to change without notice!

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right to make changes in product
specifications and adjust its production
at any time and without notice.

ENVITEC
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Oxygen Sensor OOM202

Use the advantages:

- Compliant with European MDD (CE certification)
- Meets ISO 80601-2-55
- Designed and manufactured according to EN ISO 13485
- Accurate and reliable fast response
- Resistant to N_2O
- Excellent signal stability
- High product quality
- Short delivery times
- Technical support
- Made in Germany
- FDA cleared



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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 integrator in the solution. EnviteC designs customized sensors characterized by a maximum possible degree of precision, for example with different signal levels or temperature compensation elements.

Intendend use

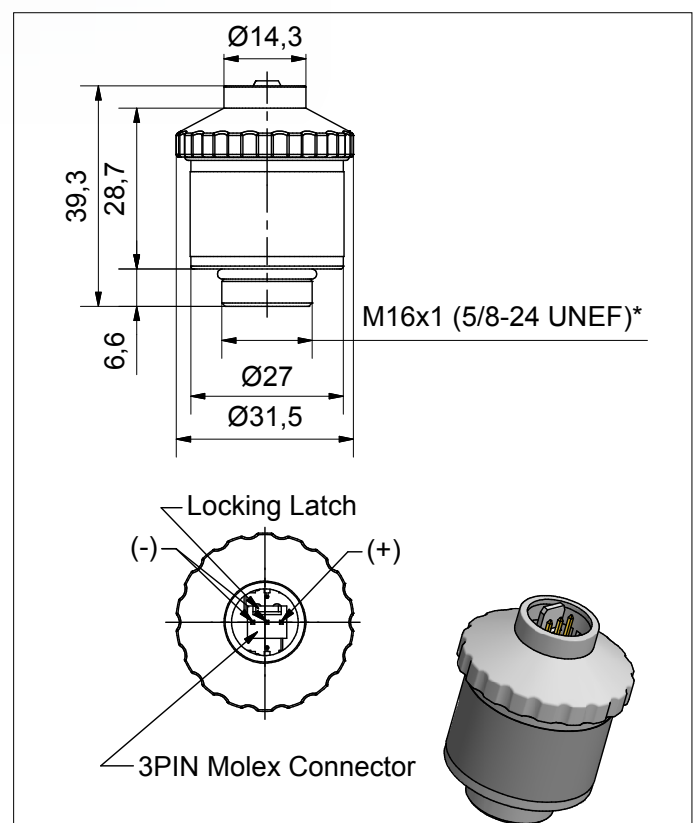
The EnviteC Medical Oxygen Sensors are intended as oxygen-sensing component of an oxygen analyzer that measures oxygen concentration in breathing gas mixtures in the following applications:

Sensing device for oxygen in

- control device of oxygen concentrators
- medical ventilators
- anaesthesia equipment
- incubators.

The use is limited to system monitoring. The sensors are not suited for breath by breath analysis of breath gases. Please refer to the Instructions for Use! If the sensor is intended to replace the original oxygen-sensing component of an oxygen analyzer, consult the EnviteC XRL Cross Reference List for selecting the appropriate sensor.

Mechanical drawing (All dimension in mm)



General tolerances ISO 2768-c

*Intermediate thread: Metric / Unified Extra Fine

Additional information

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Technical Specifications OOM202

| | |
|---|--|
| Measurement range | 0 % ... 100 % oxygen (at atmospheric pressure) |
| Nominal sensor lifetime | ≥ 1 000 000 % volume oxygen hours |
| Output in ambient air | 13 mV ... 16 mV |
| Electrical interface | 3 pin (Molex® 22-11-1031) |
| Accuracy | meets ISO 80601-2-55 requirements |
| Repeatability | < 1 % volume O ₂ at constant temperature and pressure |
| Linearity error | < 3 % relative |
| Response time | < 12 s to 90 % of final value |
| Zero offset voltage | < 200 µV in 100 % nitrogen, applied for 5 min |
| Cross interference | meets ISO 80601-2-55 requirements |
| Influence of humidity | -0.03 % rel. per % RH at 25 °C |
| Pressure range | 0.6 bar ... 2 bar (ppO ₂ 0 ... 1250 mbar O ₂) |
| Influence of pressure | proportional to change in oxygen partial pressure |
| Influence of mechanical shock | < 1 % relative after a fall from 1 m |
| Operating temperature | 0 °C ... +50 °C |
| Temperature compensation | built-in NTC compensation |
| Effect of temperature compensation (steady state) | between +25 °C and +40 °C: 3 % relative error between 0 °C and +50 °C: 8 % relative error |
| Operating humidity | 0 % ... 99 % RH non-condensing |
| Long term output drift | < 1 % volume oxygen per month typically < -15 % relative over lifetime |
| Storage temperature | -20 °C ... +50 °C |
| Recommended storage | +5 °C ... +15 °C |
| Recommended load | ≥ 10 kOhms |
| Warm-up time | < 30 minutes, after replacement of sensor |
| Weight | approximately 28 grams |
| Part number | 01-00-0047 |

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



For suitable accessories and sensors please refer to the EnviteC Cross Reference List under www.EnviteC.com and in the Apple App Store under EnviteC XRL as free download.

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Doc. No. 001-33-Datasheet_OOM202-0

March 2016

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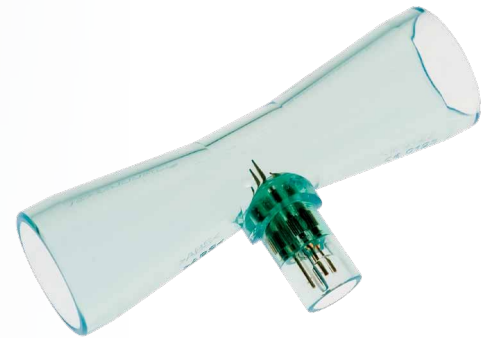
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Flow Sensor SpiroQuant A+

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



„We keep your devices operating at their best.“

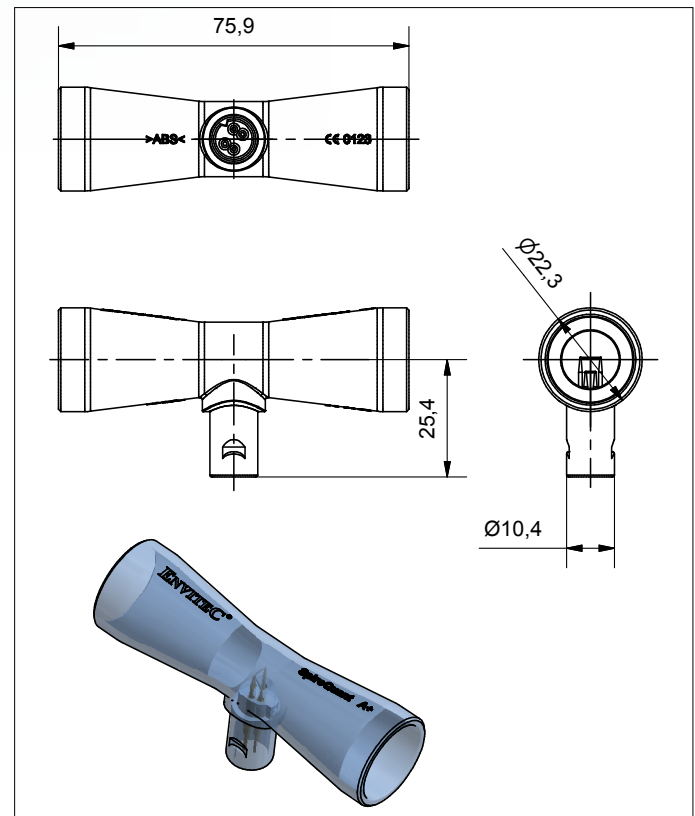
EnviteC has been developing and manufacturing highly specialized products for medical applications. EnviteC's research and development activities are consistently aligned to customer and market needs – identification and optimization of sustainable product solutions are the main concerns of the company.

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 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

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Mechanical drawing (All dimension in mm)



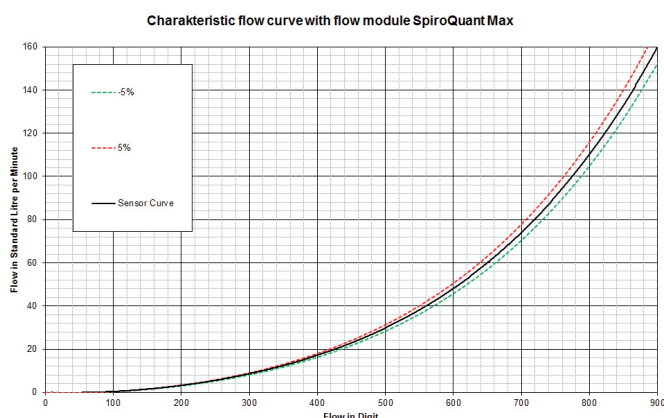
General tolerances ISO 2768-c

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](http://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; ± 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 original 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



Certified Quality Management

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

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Doc. No. 007-05-SpiroQuant_A+_Spec-0
December 2017

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Product Service

CERTIFICATE

No. Q5 17 12 21697 018

Holder of Certificate: EnviteC - Wismar GmbH

 Alter Holzhafen 18
 23966 Wismar
 GERMANY

Facility(ies):

 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, measurement devices and sensors
 for alcohol blood concentration

**Applied
Standard(s):**

 EN ISO 13485:2016
 Medical devices - Quality management systems -
 Requirements for regulatory purposes
 (ISO 13485:2016)
 DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.:

713119332

Valid from:

2018-02-06

Valid until:

2021-01-30

Date, 2018-02-06

Stefan Preiß



Page 1 of 1