ENVITEC
by Honeywell

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

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 integraton 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

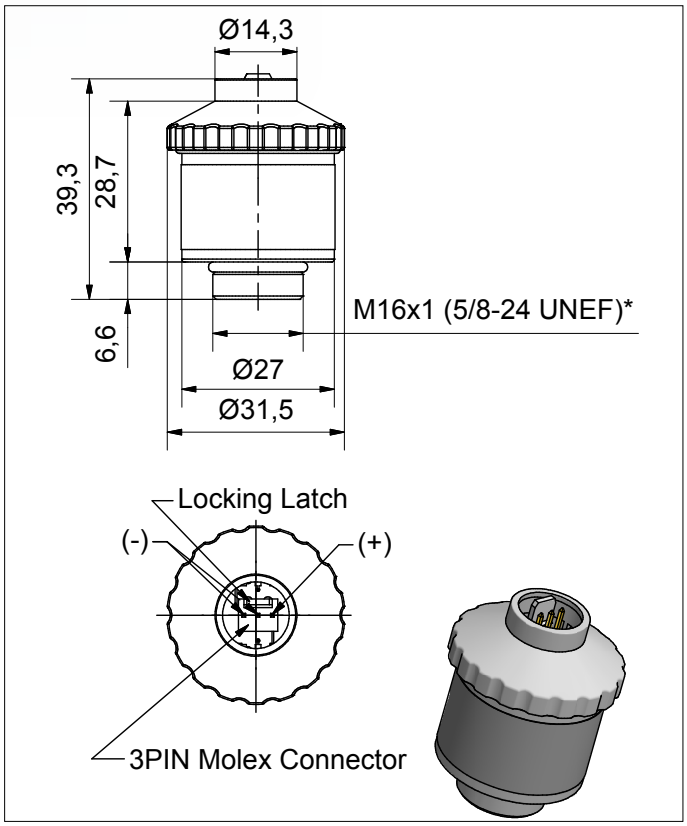
The EnviteC Medical Oxygen Sensors are intended as oxygen-sensing component of an oxygen analyzer that measures oxygen concentration in breathing gas mixtures in the following applications:

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

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 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 unter EnviteC XRL as free download.

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

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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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

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