Product Specification

Oxygen Sensor OOM202

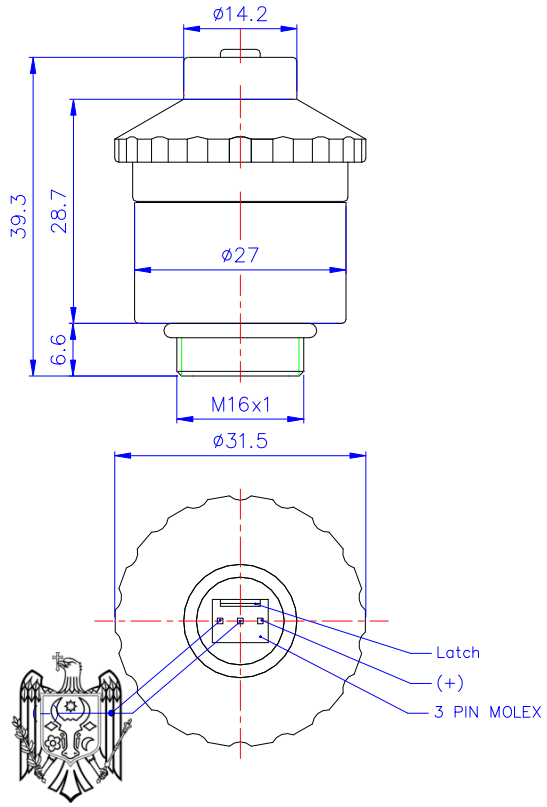
ENVITEC

Measurement Range:	0-100 % oxygen
Output in ambient air:	13 to 16mV
Electrical Interface:	3pin (Molex 22-11-1031)
Accuracy and Repeatability:	< 1 % vol. O2 when calibrated at 100 % Oxygen
Linearity error:	< 3 % relative
Response time:	< 12 sec. to 90 % of final value
Zero Offset Voltage:	< 200 µV in 100 % nitrogen applied for 5 min
Cross Interference:	< 0.5 % vol. O_2 response to: 10 % CO_2 balance N_2 80% N_2O balance N_2 7.5% Halothane balance N_2 7.5 % Isoflurane balance N_2 7.5 % Enflurane balance N_2 9% Sevoflurane balance N_2 20% Desflurane balance N_2
Influence of Humidity:	- 0.03 % rel. per % RH at 25°C
Influence of Pressure:	proportional to change in oxygen partial pressure
Influence of Mechanical Shock:	< 1% relative after a fall from 1m
Operating Temperature:	0 to 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 % vol oxygen per month typically < - 15 % relative over lifetime
Storage Temperature:	-20 to +50 °C
Recommended Storage:	+5 to +15 °C
Recommended Load:	≥ 10 kOhms
Warm-Up Time:	< 30 minutes, after replacement of sensor
Nominal Sensor Lifetime:	≥ 1.000 000 % vol oxygen hours
Weight:	approximately 28 grams
Part No.:	01-00-0047

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

Use the advantages:

- Meet DIN EN 21647
- Designed and manufactured according to EN ISO 9001 : 2000 and EN ISO 13485 : 2003
- Accurate and reliable response
- Resistant to N_2O
- Excellent signal stability
- High product quality
- Short lead times
- Technical support



Dimension in mm

ENVITEC- WISMAR GMBH

Alter Holzhafen 18
D-23966 Wismar

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http://www.envitec.com

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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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

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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(Tina Israel)
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TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

ENVITEC
by Honeywell

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 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

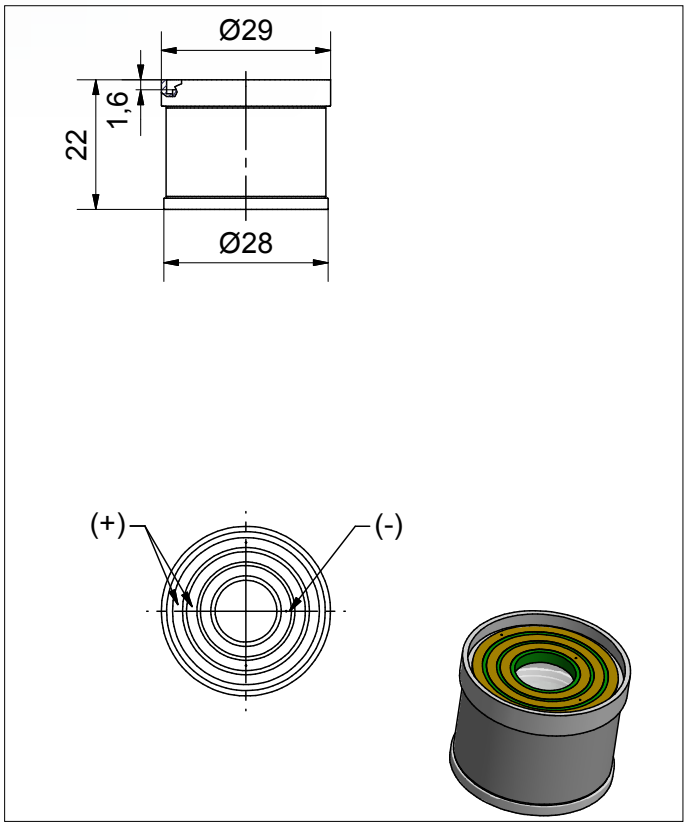
The EnviteC Medical Oxygen Sensors are intended as oxygen-sensing component of an oxygen analyzer that measures oxygen concentration in breathing gas mixtures in the following applications:

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

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 unter EnviteC XRL as free download.

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Doc. No. 001-33-Datasheet_OOM201-0
March 2016

ENVITEC
by Honeywell