Test Report issued under the responsibility of: CEcert

TEST REPORT
ISO 80601-2-55
Medical electrical equipment
Part 2: Particular requirements for the basic safety and essential performance of respiratory gas monitors

Report Number. .....:	**413.097.1A**
Date of issue.....:	**2015-10-23**
Total number of pages	**71**
Applicant's name.....:	**EnviteC-Wismar GmbH**
Address .....:	**Alter Holzhafen 18** **D-23966 Wismar (Germany)**
Test specification:	
Standard.....:	ISO 80601-2-55:2011 (First Edition) for use with IEC 60601-1: 2005 (Third Edition) + CORR.1 (2005) + CORR. 2 (2007)
Exceptions .....:	see 'Summary of testing'
Test procedure .....:	ISO/IEC 17025
Non-standard test method……..:	N/A
Test Report Form No.....:	ISO80601_2_55A (V403SEB80601-2-55A)
Test Report Form(s) Originator.....:	CSA International
Master TRF.....:	2012-12

Test item description .....:	oxygen sensor
Trade Mark .....:	ENVITEC
Manufacturer.....:	EnviteC-Wismar GmbH, Alter Holzhafen 18, D-23966 Wismar
Model/Type reference .....:	**OOMXXX-X** (where X is to be replaced by numbers and characters, see page 2)
Ratings .....:	Measurement range: 0 – 100 %V/VO_2

This certification includes the following oxygen sensors:

OOM101;

OOM102, OOM102-1; OOM102-1-HEYM; OOM102-G; OOM102-HS, OOM102-S

OOM103; OOM103-1; OOM103-C; OOM103-CC; OOM103-1M

OOM104;

OOM105;

OOM106;

OOM107; OOM107-2; OOM107-3;

OOM108;

OOM110;

OOM111; OOM111-H

OOM112;

OOM113;

OOM201;

OOM202; OOM202-1; OOM202-2; OOM202-E; OOM202-2R; OOM202-2S;

OOM204

For detailed model description, see ‘General product information’.

Testing procedure and testing location:			
☒	**Testing Laboratory:**	**CEcert GmbH**	
Testing location/ address .....:		**Alter Holzhafen 19a** **D-23966 Wismar (Germany)**	
☐	**Associated Laboratory:**		
Testing location/ address .....:			
	Tested by (name + signature).....:	**Sebastian Lupp**	S. Lupp
	Approved by (name + signature)...:	**Bernd Schmidt**	
☐	**Testing procedure: TMP**		
Testing location/ address .....:			
	Tested by (name + signature).....:		
	Approved by (name + signature)...:		
☐	**Testing procedure: WMT**		
Testing location/ address .....:			
	Tested by (name + signature).....:		
	Witnessed by (name + signature) .:		
	Approved by (name + signature)...:		
☐	**Testing procedure: SMT**		
Testing location/ address .....:			
	Tested by (name + signature).....:		
	Approved by (name + signature)...:		
	Supervised by (name + signature) :		

Table 1. **List of Attachments (including a total number of pages in each attachment):**		
Item	Description	Page
Appendix 1	Photos	61 - 62
Appendix 2	Test Equipment Log Sheet	63 - 63
Appendix 3	Instructions for use	64 - 66
Appendix 4	General Specifications – Medical Oxygen Sensors (Doc. No.: 001-33-00000011 / 07/2006)	67 - 70
Appendix 5	Evaluation of Essential Performance	71 - 71
Attachment 1	Test report 413.097.2 regarding mechanical strength according ISO 80601-2-55:2011 for 'Oxygen Sensors' of EnviteC-Wismar GmbH by CEcert GmbH (dated 2015-07-01)	32 pages
Attachment 2	Manufacturers verification report: 'Test Report for Oxygen Sensor – Family Type: OOM 101' dated 2008-07-18, revised 2014	21 pages
Attachment 3	Manufacturers verification report: 'Test Report for Oxygen Sensor – Family Type: OOM 102, OOM102-1, OOM106, OOM111, OOM202, OOM202-1, OOM202-2, OOM202-2S' dated 2008-07-14, revised 2014	23 pages
Attachment 4	Manufacturers verification report: 'Test Report for Oxygen Sensor – Family Type: OOM 103' dated 2008-07-15, revised 2014	20 pages
Attachment 5	Manufacturers verification report: 'Test Report for Oxygen Sensor – Family Type: OOM 107' dated 2008-07-01, revised 2014	21 pages
Attachment 6	Manufacturers verification report: 'Test Report for Oxygen Sensor – Family Type: OOM 110' dated 2008-06-24, revised 2014	21 pages
Attachment 7	Manufacturers verification report: 'Test Report for Oxygen Sensor – Family Type: OOM 204' dated 2008-07-04, revised 2014	23 pages
kept in file	'Risk Management Master File – Medical Oxygen Sensors' Model: OOMXXX-X, version D, date 2015-06-04	--
kept in file	'Risikoanalyse TOP DOWN (Anlage 1)' Template 2014-06-27	--
kept in file	'Usability Engineering File (Table)' Medical Oxygen Sensors, dated 2015-06-02	--
Due to big files and bulk of paperwork, the documents listed as Appendix # are included in this document only. Documents listed as Attachment # are kept separately. The documents assessed and listed as 'kept in file' can be supplied upon request. The manufacturer is responsible for this information to be provided.		

Summary of testing:

Brief description:

This test report is related to the particular requirements for basic safety and essential performance of respiratory gas monitors. The general tests and evaluations according IEC 60601-1 are not part of applicants order.

The oxygen probes are intended for generic gas monitor use. The interface specification pertaining gas readings is used for conformity assessment.

Application of requirements and tests:

The following requirements and tests are not applied and have to be performed in intended final application:

201.11.6.5 Ingress of water or particulate matter

201.102 Gas leakage

EMC testing is considered not applicable (related to intended monitor type).

The sensor accuracy and interference claims are verified in this test report but associated alarm system performance pertains to the intended monitor type.

Conditions of acceptability:

The sensors are intended for use in supply gas monitoring only.

The sensors do not provide any protection against ingress of liquids. Related performance is to be provided by intended installation.

Equipment is tested as intended to be used during patient transport outside healthcare facilities.

Restrictions/Consideration for the installation in a end product:

The equipment under test is intended for use only with other certified equipment or devices where the suitability of the combination is in accordance with the manufacturer's authorization and the national law.

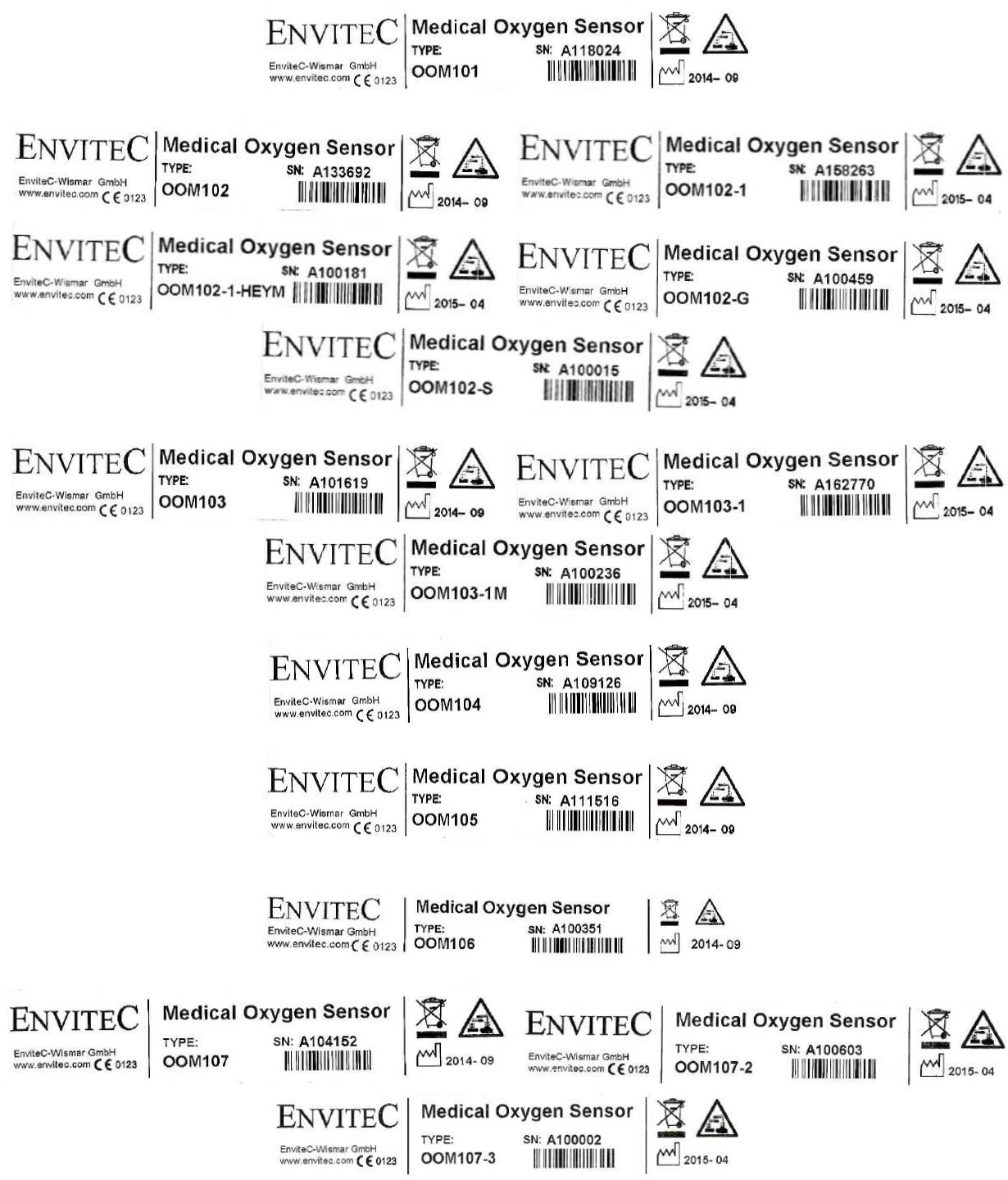
This test report is restricted to the combination with the applied parts and accessories listed under 'Product configuration tested'.

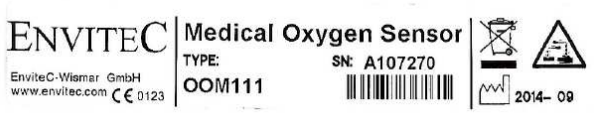
Tests performed (name of test and test clause):		**Testing location:**
The following tests have been performed by:		CEcert GmbH Alter Holzhafen 19a, D-23966 Wismar
201.4.3.101-102	Evaluation of essential performance and acceptance criteria	
201.11.6.6	Cleaning and disinfection	
201.15.3.5.101	Mechanical shock, vibration and free fall test for respiratory gas monitors or its parts	
The following tests have been performed by the manufacturer:		EnviteC-Wismar GmbH Alter Holzhafen 18, D-23966 Wismar
201.12.1.101.1	Measurement accuracy	
201.12.1.101.2	Drift of measurement accuracy	
201.12.1.101.3	Measurement accuracy of gas reading for gas mixtures	
201.12.1.102	Total system response time and rise time	

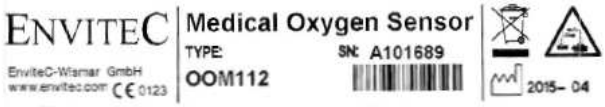
Summary of compliance with National Differences
List of countries addressed: none
Overall-compliance with the applied standard: **The Equipment under Test complies with the applied requirements of the standard(s).**

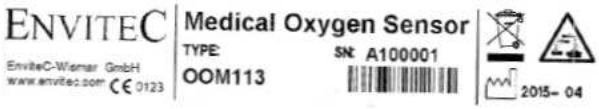
Copy of marking plate

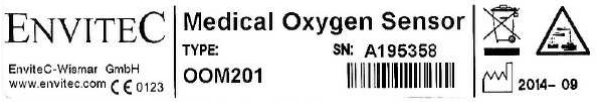
The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

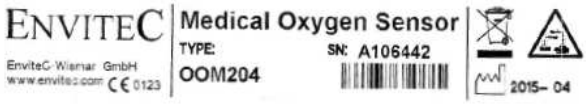












(labels listed above are representative for all family members certified)

Test item particulars:	
Classification of installation and use ..... :	**N/A (applicable to intended monitor type)**
Device type (component/sub-assembly/ equipment/ system ..... :	**component (oxygen sensor)**
Intended use (Including type of patient, application location)..... :	**measuring oxygen concentration in medical applications**
Mode of operation..... :	**continuous**
Supply Connection ..... :	**permanently installed**
Accessories and detachable parts included ..... :	**adapter for medical gas supply system insertion, see 'Product configuration tested'**
Other options included ..... :	**none**

Possible test case verdicts:	
- test case does not apply to the test object..... :	**N/A (Not Applicable)**
- test object does meet the requirement ..... :	**P (Pass)**
- test object does not meet the requirement ..... :	**F (Fail)**

Testing.....:	
Date of receipt of test item ..... :	**2014-11-18**
Date (s) of performance of tests ..... :	**2014-11-18 - 2015-03-19**

General remarks:
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the issuing testing laboratory.
"(see Appendix #)" refers to additional information appended to the report. "(see Attachment #)" refers to additional information appended separately. "(see appended table)" refers to a table appended to the report.
List of test equipment must be kept on file and available for review.
Throughout this report a ☐ comma / ☒ point is used as the decimal separator.
All measurement values given in this report are checked against the requirements considering an overall measurement uncertainty equivalent to the values stated in CTL decision No. 251B for the measurement equipment itself. If not otherwise stated in this report, only in cases where the measurement value including the measurement uncertainty exceeds/undergo the required values, a calculation of the measurement uncertainty is performed and included in Attachments to show, that the measured value is still ok.
This Test Report Form is intended for the investigation of the basic safety and essential performance of respiratory gas monitors medical devices in accordance with ISO 80601-2-55. It can only be used together with the IEC 60601-1 (3rd edition) Test Report Form (TRF).

Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:	
The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided..... :	☐ **Yes** ☒ **Not applicable**
When differences exist; they shall be identified in the General product information section.	
Name and address of factory (ies).....:	**EnviteC Wismar GmbH; Alter Holzhafen 18; D-23966 Wismar**

General product information:

Intended use:
The EnviteC Medical Oxygen electro-galvanic sensors are the oxygen-sensing component of an oxygen analyzer that measures oxygen concentration in inspiratory breathing gas mixtures. The sensors are intended for generic monitor allocation according to manufacturer's compatibility declaration 'Cross Reference List' disclosed for each sensor type.

Model Differences:

The sensors covered in this report differ in cathode dimension, membrane thickness, integrated load resistor, temperature compensation means, electrical connection and housing shape:

Table 2: Model differences

Sensor	Cathode dimension	Membrane thickness	Load resistor	Temperature compen-sation	Housing	Electrical interface	Group
OOM101	medium	thick	no	no	HA	gold plated slip rings	A
OOM112	medium	thick	yes	yes	HA	gold plated slip rings	A
OOM102	small	thick	yes	yes	HB	3pin molex	B
OOM102-1	small	thick	yes	yes	HB	3,5 mm Mono Jack	B
OOM102-G	small	thick	yes	yes	HB	Molex plug 4P4C	B
OOM102-1-HEYM	small	thick	yes	yes	HB	3,5 mm Mono Jack	B
OOM102-HS	small	thick	yes	yes	HB	3pin molex	B
OOM102-S	small	thick	yes	yes	HB	Modular Jack	B
OOM106	small	thick	yes	yes	HB	3pin molex	B
OOM108	small	thick	yes	yes	HB	6pin molex	B
OOM111	small	thick	yes	yes	HB	3,5mm Stereo Jack	B
OOM111-H	small	thick	yes	yes	HB	3,5mm Stereo Jack	B
OOM113	small	thick	yes	yes	HB	3pin molex	B
OOM202	small	thick	yes	yes	HB	3pin molex	B
OOM202-1	small	thick	yes	yes	HB	3,5 mm Mono Jack	B
OOM202-E	small	thick	yes	yes	HB	contact pads	B
OOM202-2	small	thick	yes	yes	HB	flying leads with 3 pin female molex connector	B
OOM202-2R	small	thick	yes	yes	HB	Flying leads with HARWIN connector (M80-8980205)	B
OOM202-2S	small	thick	yes	yes	HB	AMP MATE-N-LOK	B
OOM103	small	thin	yes	yes	HB	3pin molex	C

Sensor	Cathode dimension	Membrane thickness	Load resistor	Temperature compen-sation	Housing	Electrical interface	Group
OOM103-1	small	thin	yes	yes	HB	3,5 mm Mono Jack	C
OOM103-C	small	thin	yes	yes	HB	3pin molex	C
OOM103-CC	small	thin	yes	yes	HB	3pin molex	C
OOM103-1M	small	thin	yes	yes	HB	Swithchcraft Mini Power Jack	C
OOM105	small	thin	yes	yes	HB	Molex Plug 4P4C	C
OOM107	big	thick	no	no	HC	gold plated slip rings	D
OOM107-2	big	thick	no	no	HC	gold plated slip rings with flying leads	D
OOM107-3	big	thick	yes	yes	HC	gold plated slip rings with flying leads	D
OOM110	medium	thick	yes	yes	HD	Modular Jack 6P4C	E
OOM104	double cathode	thick	no	no	HA	gold plated slip rings	F
OOM201	double cathode	thick	no	no	HA	gold plated slip rings	F
OOM204	double cathode	thick	yes	yes	HA	3pin molex	F

The column 'Class' assigns the sensor class/category due to the design properties listed. Table 3 lists the associated selection of sensors to certify the family covered.

Table 3: **Product configuration tested**

Item	Model	P/N, S/N	Manufacturer	Comment
oxygen sensor	OOM101	01-00-0013, A118605	EnviteC-Wismar GmbH	group A
oxygen sensor	OOM102	01-00-0019, A134174	EnviteC-Wismar GmbH	group B
oxygen sensor	OOM103	01-00-0015, A101620	EnviteC-Wismar GmbH	group C
oxygen sensor	OOM107	01-00-0058, A104191	EnviteC-Wismar GmbH	group D
oxygen sensor	OOM110	01-00-0098, A109046	EnviteC-Wismar GmbH	group E
oxygen sensor	OOM201	01-00-0014, A197104	EnviteC-Wismar GmbH	group F

Comment:

group allocation as listed in Table 2

Rationale for selection of samples:

The electrical interface has no effect to the sensor performance and properties. Performance is affected by the cathode dimension and membrane thickness. The load resistor provides signal alignment for the intended monitor only and does not affect the sensor performance. The temperature compensation is to be provided in combination with the intended monitor and in some cases already installed on sensor. Due to particular dimension housing type 'HD' is tested separately.

With the above listed rationale the following sensors can be treated representative for the product group listed:
OOM101 is representative for all sensors with medium cathode and thick membrane identified group 'A'.
OOM102 is representative for all sensors with small cathode and thick membrane identified group 'B'.
OOM103 is representative for all sensors with small cathode and thin membrane identified group 'C'.
OOM107 is representative for all sensors with big cathode and thick membrane identified group 'D'.
OOM110 is representative for all sensors with medium cathode and thick membrane and housing type HD identified as group 'E'.
OOM201 is representative for all sensors with double cathode and thick membrane identified group 'F'.

Technical Considerations:

max. ambient temperature (operation)....	0 to 50 °C
max. ambient temperature (storage)	-20 to +50 °C
operating humidity.....	0 – 99 %rh
ambient pressure range	600 – 2000 hPa

Test Report History:

This report may consist of more than one report and is valid only with additional or previous issued reports:

Ref.	Date of issue	Comment	Approved by
413.097.1	2015-07-01	first certification	B. Schmidt
413.097.1A	2015-10-23	new release with the following changes: - manufacturer has changed the technical specification (accuracy, repeatability) - new models included (equivalent to tested representatives) - instructions for use updated (Appendix 3) - General Specifications updated (Appendix 4) (due to changes no new tests needed)	B. Schmidt

Comment:

This test report contains the latest results obtained including the results of the previous tests performed as long as these results are still valid. (Superseded results are deleted)

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

201.4	**General requirements**		**P**
201.4.3	**ESSENTIAL PERFORMANCE**		**P**
201.4.3.101	**Additional ESSENTIAL PERFORMANCE requirements**		**---**
	Applicable ESSENTIAL PERFORMANCE requirements as found in the subclauses listed in Table 201.101 of this standard	**See Appended Table 201.4.3.101**	**P**
201.4.3.102	**Additional requirements for acceptance criteria**		**P**
	When the MANUFACTURER specifies in the ACCOMPANYING DOCUMENT performance levels better than those specified within this International Standard, these MANUFACTURER-specified levels become the acceptance levels……..…:	**the following accuracy content is identified by the manufacturer (see Appendix 4):** **repeatability: < 1 % vol. O_2 (when calibrated at 100 % O_2)** **zero offset: < 0.5 % vol. O2 in 100 % N2** **linearity error: < 3 % relative**	**P**
201.4.6	**ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT**		**P**
	Parts and ACCESSORIES of an RGM intended to be connected with the breathing system shall be subject to the requirements for APPLIED PARTS.		**P**
201.4.10.2.101	**Additional requirements for SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS**		**N/A**
	For an RGM intended for use during professional transport of a PATIENT outside a healthcare facility, the characteristics of the SUPPLY MAINS specified in ISO 80601-2-55 clause 201.4.10.2.101 apply	**related to intended monitor type only**	**N/A**

201.7	**ME EQUIPMENT identification, marking and documents**		**P**
201.7.2.3	**Consult ACCOMPANYING DOCUMENTS**		**P**
	The RGM shall be marked with the safety sign for the mandatory action: “Follow instructions for use”, ISO 7010-M002 (see IEC 60601-1:2005, Table D.2, Number 10).	 **marked on secondary packaging, accepted for sensors and intended application**	**P**

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict
201.7.2.101	**Additional requirements for marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts**		**P**
	ME EQUIPMENT, parts or ACCESSORIES shall be CLEARLY LEGIBLY marked as follows:		---
	a) with any particular storage and/or handling instructions ……..:	**refer to box label in Appendix 1**	**P**
	b) with a serial number (or Symbol 5.16 from ISO 15223-1) or lot identifying number or batch identifying number (or Symbol 5.14 from ISO 15223-1)…….....:	SN **see copy of marking plate**	**P**
	c) for the RGM, its parts and ACCESSORIES, with information for proper disposal, as appropriate……..:	**marking according WEEE**	**P**
	d) for an OPERATOR-interchangeable component of an RGM that is flow-direction sensitive, with an arrow showing the direction of gas flow..……..…...:	**no such flow-direction sensitive parts**	**N/A**
	e) for an RGM sampling gas inlet, either with the text “Gas sample” or the Symbol ISO 7000-0794……..:	**no such parts**	**N/A**
	f) for an RGM sampling gas outlet, either with the text “Gas exhaust” or the Symbol ISO 7000-0795……...:	**no such parts**	**N/A**
	g) for a SAMPLING TUBE, either with the text “Gas sample” or the Symbol ISO 7000-0794…:	**no such parts**	**N/A**
	h) for an exhaust tube for a DIVERTING RGM, either with the text “Gas exhaust” or the Symbol ISO 7000-0795……..:	**no such parts**	**N/A**
	i) for a TRANSPORTABLE RGM, the mass of the most usual configuration of the ME EQUIPMENT (Kg)……..:	**related to intended monitor**	**N/A**
	ME EQUIPMENT, parts or ACCESSORIES with a use-by date shall be CLEARLY LEGIBLY marked with an indication of the date after which it should not be used, expressed as the year and month. Symbol 5.12 of ISO 15223-1 may be used……..…..:	**no such use-by date**	**N/A**
201.7.2.4.101	**Additional requirements for ACCESSORIES**		**N/A**
	For an ACCESSORY intended for single PATIENT use, the package or the ACCESSORY itself shall be marked with an indication that the ACCESSORY is for single PATIENT use.	**no such restrictions**	**N/A**

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict
201.7.2.13.101	**Additional requirements for physiological effects (safety signs and warning statements)**		**N/A**
	ME EQUIPMENT, parts or ACCESSORIES containing natural rubber latex shall be CLEARLY LEGIBLY marked as containing natural rubber latex. Symbol ISO 7000-2725 may be used. All components containing natural rubber latex shall be disclosed as such in the instructions for use.	**no such material**	**N/A**
201.7.2.17.101	**Additional requirements for protective packaging**		**P**
	Packages of ME EQUIPMENT, parts or ACCESSORIES shall be CLEARLY LEGIBLY marked: a) with the following		**---**
	- a description of the contents……:	**see Appendix 1**	**P**
	- an identification reference to the batch, type or serial number or Symbols 5.14, 5.15, 5.16 from ISO 15223-1……..:	**SN serial no. and addition bar graph**	**P**
	- for packages containing natural rubber latex, the word “LATEX”, or symbol ISO 7000-2725;	**no such material**	**N/A**
	- if applicable, the word “STERILE” or one of the Symbols 5.20 to 5.24 from ISO 15223-1; packaging of sterile ME EQUIPMENT, parts or ACCESSORIES shall ensure sterile conditions until opened or damaged or until its expiration date is reached;	**no such sterile parts**	**N/A**
	b) for those parts intended for single use, with the words “SINGLE USE”, “DO NOT REUSE”, “NOT FOR REUSE”, Symbol ISO 7000-1051 or Symbol 5.25 from ISO 15223-1; for a specific MODEL or TYPE REFERENCE, the indication of single use shall be consistent.	**no such restrictions**	**N/A**
201.7.4.3	**Unit of measure**		**N/A**
	Table 1 units outside the SI units systems that may be used on ME EQUIPMENT……..:	**requirements applicable to intended monitor only**	**N/A**
	TABLE 1 Unit / Base quantity / Name / Symbol GAS READING[b] / % (VOLUME FRACTION) / - GAS READING[b] / millimetres of mercury / mmHg GAS READING of anaesthetic agents / % (VOLUME FRACTION) / - GAS READING of anaesthetic agents / MINIMUM ALVEOLAR CONCENTRATION[c] / MAC [b] The GAS READING of respiratory gases may be expressed as a PARTIAL PRESSURE. [c] MINIMUM ALVEOLAR CONCENTRATION may be utilized as an additional unit.		**--**
201.7.9.1	**General requirements**		**P**
	- name or trade name and address of:	**see Appendix 3**	**P**
	- the MANUFACTURER……..……:	**section ‘Manufacturer’**	**P**

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict
	- where the MANUFACTURER does not have an address within the locale, an authorized representative within the locale to which the RESPONSIBLE ORGANIZATION can refer….:	**manufacturer within the locale**	**N/A**
201.7.9.2.1.101	**Additional general requirements**		**P**
	The instructions for use shall include the following information.		**---**
	a) For each RGM and ACCESSORY, the specified use of the RGM and ACCESSORY regarding	**see Appendix 3**	**P**
	- PATIENT population……..…….:	**no such restrictions**	**N/A**
	- part of the body or type of tissue to which it is applied ……..…….:	**no such restrictions**	**N/A**
	- application……..…….:	**section 'Instructions'**	**P**
	b) a statement indicating whether or not the RGM is equipped with automatic barometric pressure compensation……..…….:	**no such means, requirements are related to intended monitor type**	**N/A**
	c) if automatic compensation is not provided, the quantitative effect of barometric pressure on the GAS READING……..…….:	**see Appendix 4 'General Specifications' section 'Influence of Pressure'**	**P**
201.7.9.2.2.101	**Additional requirements for warnings and safety notices**		**N/A**
	The instructions for use of a DIVERTING RGM that is equipped with a gas exhaust connection shall include a warning regarding the RISK of PATIENT cross-infection if the sampled gas is returned to the breathing system. Additional requirements are found in 201.105.2.	**related to intended monitor type only**	**N/A**
201.7.9.2.5.101	**Additional requirements for ME EQUIPMENT description**		**N/A**
	The instructions for use shall include:		**---**
	a) a diagram illustrating the features of the RGM, indicating the function and location of all operating controls, adjustments, and system components necessary for correct operation…:	**related to intended monitor only**	**N/A**
	b) a description of the correct installation of the RGM and a description of sampling arrangements and any connecting tubing…….:	**reference to intended monitor**	**N/A**
	c) the location of all natural-rubber-latex-based components……..……..…….:	**no such parts**	**N/A**
201.7.9.2.8.101	**Additional requirements for start-up procedure**		**P**
	The instructions for use shall include:		**---**
	a) a method of verifying all OPERATOR-adjustable ALARM SYSTEM functions……..:	**reference to intended monitor**	**N/A**

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict
	b) the time duration from start-up to providing ESSENTIAL PERFORMANCE……..……:	**see Appendix 3 section 'Environmental specification'**	**P**
201.7.9.2.9.101	**Additional requirements for operating instructions**		**P**
	The instructions for use shall include the following:		**---**
	a) the range of adjustment of the ALARM LIMITS……..:	**related to intended monitor only**	**N/A**
	b) the maximum specified interval between any necessary OPERATOR interventions to the water-handling system, based on a sample gas temperature of 37 °C, a room temperature of 23 °C and sample relative humidity of 100 %	**no such water-handling system**	**N/A**
	Maximum Specified Interval (Hours) at specified minimum sample flow rate……..:		**---**
	Maximum Specified Interval (Hours) at specified maximum sample flow rate……..:		**---**
	c) the detection threshold for a single halogenated anaesthetic gas in a gas mixture, and the detection threshold(s) for multiple halogenated anaesthetic gases in a gas mixture……..:	**no such halogenated anaesthetic gas detection means**	**N/A**
	d) if MAC GAS READINGS are provided, the MAC values or algorithms used to determine the MAC values displayed by the RGM;	**no such MAC gas readings**	**N/A**
	e) method for connecting the exhaust port of a DIVERTING RGM to an ANAESTHETIC GAS SCAVENGING SYSTEM;	**related to intended monitor only**	**N/A**
	f) for a DIVERTING RGM, the sampled gas flow rates and their tolerances……..:	**related to intended monitor only**	**N/A**
	g) if applicable, a statement that the RGM is suitable for use in a magnetic resonance imaging (MRI) environment, including the maximum magnetic field (gauss) line in which the RGM will function normally……..:	**no such claim** **(according instructions for use)**	**N/A**
	h) for a DIVERTING RGM intended to permit the return of the sampled gas to the breathing system in which the GAS LEVEL has changed from that at the SAMPLING SITE, an indication that the returned GAS LEVEL has changed;	**related to intended monitor only**	**N/A**
	i) the RATED respiration rate……..:	**related to intended monitor only** **(the sensor specification identifies the response time for the use in intended monitor)**	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	j) any degradation in MEASUREMENT ACCURACY of the end-tidal GAS READING as a function of respiratory rate and I/E ratio (inspiratory/expiratory time ratio) over their RATED ranges……..…..:	**related to intended monitor only**	**N/A**
	k) known adverse effects on stated performance due to the following:		**---**
	- quantitative effects of gas sample humidity or condensate……..:	**refer to specification (Appendix 4) section 'Influence of Humidity'**	**P**
	- leaks or internal venting of sampled gas…….:	**related to intended monitor only**	**N/A**
	- cyclical pressure of up to 10 kPa (100 cmH2O)……...:	**related to intended monitor only**	**N/A**
	- other sources of interference……..:	**refer to specification (Appendix 4) section 'Influence of Mechanical Shock', 'Effect of Temperature'**	**P**
	l) if the RGM, its parts or ACCESSORIES are intended for single use, information on characteristics and technical factors known to the MANUFACTURER that could pose a RISK if the RGM, its parts or ACCESSORIES were re-used……...:	**no such single use parts**	**N/A**
	m) date of issue or revision of the instructions for use……..:	**05.03.15**	**P**
	n) highest GAS LEVEL for a single halogenated anaesthetic gas in a gas mixture that is concealed when the anaesthetic concentration falls……..:	**no such halogenated anaesthetic gas measurement**	**N/A**
201.7.9.2.13.101	**Additional requirements for maintenance**		**N/A**
	The instructions for use shall include the following:		**---**
	a) PROCEDURES for calibration before or during use	**related to intended monitor only**	**N/A**
	b) methods and frequency of routine inspection and testing.	**related to intended monitor, if applicable**	**N/A**
201.7.9.2.14.101	**Additional requirements for ACCESSORIES, supplementary equipment, used material**		**P**
	The instructions for use shall include the following:		**---**
	a) all known information regarding toxicity and/or the effect on tissues of any materials that can come into contact with the PATIENT or any other person	**see Appendix 3 section 'Warnings and Precautions'**	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	b) if an ACCESSORY delivered in sterile packaging is permitted to be re-sterilized, the necessary information regarding how to re-sterilize in the event of damage to the sterile packaging	**no such sterile parts**	**N/A**
	c) advice on the proper disposal of accumulated fluids.	**no such accumulated fluids**	**N/A**
201.7.9.2.15.101	**Additional requirements for environmental protection**		**N/A**
	The instructions for use shall include:		**---**
	a) advice on the proper disposal of calibration gases	**related to intended monitor, if applicable**	**N/A**
	b) advice on the proper disposal of sampled gases.	**related to intended monitor, if applicable**	**N/A**
201.7.9.3.101	**Additional requirements for technical description**		**N/A**
	The technical description shall include:		**---**
	a) a summary of the test method used to determine the RATED respiration rate range and the corresponding effects of end-tidal GAS READING accuracy as a function of respiratory rate as required in 201.7.9.2.9 i) and j)……..:	**sensors are intended for use in supply gas monitoring** **(according instructions for use)**	**N/A**
	b) the data sample rate……..:	**related to intended monitor, if applicable**	**N/A**
	c) a description of the method used to calculate end-tidal GAS READINGS……..:	**related to intended monitor, if applicable**	**N/A**

201.11	**Protection against excessive temperatures and other HAZARDS**		**P**
201.11.6.4	**Leakage**		**P**
	The MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with the leaching or leaking of substances into the gas pathway from		**P**
	aa) the SAMPLING SITE……..:	**See Appended RM Table 201.11.6.4 aa)**	**P**
	bb) for a DIVERTING RGM which permits the return of the sampled gas to the breathing system, the gas pathways through the RGM and ACCESSORIES……..:	**related to intended monitor only**	**N/A**
	Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction.		**---**

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Clause	Requirement + Test	Result - Remark	Verdict
	If these parts or ACCESSORIES contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, it shall be marked on the device itself or on the packaging that it contains phthalates. If, in addition, the INTENDED USE of the RGM and these parts or ACCESSORIES includes treatment of children or treatment of pregnant or nursing women, a specific justification for the use of these items shall be included in the RISK MANAGEMENT FILE. The instructions for use shall contain information on RESIDUAL RISKS for these PATIENT groups and, if applicable, on appropriate precautionary measures……..:	**no such materials in direct or indirect patient contact** **(refer to 'Risk Management Master File – Medical Oxygen Sensors' section 2.1 item E.5.6.g)**	**N/A**
201.11.6.5	**Ingress of water or particulate matter into ME EQUIPMENT or ME SYSTEMS**		**N/A**
	The ENCLOSURE of an RGM shall provide a degree of protection from the harmful ingress of water of		**---**
	- at least IPX1, and	**to be provided by intended installation**	**N/A**
	- for an RGM or its parts intended for use during professional transport of a PATIENT outside a healthcare facility, at least IPX2.		**N/A**
201.11.6.6	**Cleaning and disinfection of ME EQUIPMENT or ME SYSTEMS**		**P**
	Gas pathways through the RGM and its ACCESSORIES not specified as for single PATIENT use, which can become contaminated with body fluids or expired gases during NORMAL CONDITION or SINGLE FAULT CONDITION and in which gases can be re-breathed, shall be designed to allow for cleaning and disinfection or cleaning and sterilization……..:	**sensors intended for implementation into medical gas supply mains, contamination with body fluids or expired gases is considered negligible; sensor – gas interface decontamination not applicable**	**N/A**
	RGM ENCLOSURES shall be designed to allow for surface cleaning or cleaning and disinfection to reduce the RISK of cross-infection to acceptable levels.	**See Appended RM Table 201.11.6.6** **(due to application of sensors enclosure cleaning and disinfection only)**	**P**
	Processing and/or reprocessing PROCESS instructions for the RGM and its ACCESSORIES shall comply with ISO 17664 and ISO 14937 and shall be disclosed in the instructions for use……..:	**refer to Appendix 3 section 'Cleaning/ Disinfection'**	**P**
	Clean and disinfect 30 times in accordance with the methods indicated in the instructions for use……..:	**See Appended Table 201.11.6.6**	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
201.11.6.8	**Compatibility with substances used with ME EQUIPMENT**		**P**
	Particular attention should be paid to the toxicity of materials and their compatibility with substances and gases with which they enter into contact during NORMAL USE.	**refer to 'Risk Management Master File – Medical Oxygen Sensors' section 2.1 item E.5.6**	**P**
201.11.8.101.1	**Supply failure TECHNICAL ALARM CONDITION**		**N/A**
	When the power supply falls outside the values for normal operation, an RGM shall:		**---**
	a) generate a MEDIUM PRIORITY TECHNICAL ALARM CONDITION;	**applicable to intended monitor type, if applicable**	**N/A**
	b) stop displaying the respiratory GAS READING.		**N/A**
	If the function of the RGM is maintained by the switchover to an INTERNAL ELECTRICAL POWER SOURCE**,** the supply failure MEDIUM PRIORITY TECHNICAL ALARM CONDITION shall not be generated. Any such switchover to an INTERNAL ELECTRICAL POWER SOURCE shall be indicated by an INFORMATION SIGNAL or a LOW PRIORITY TECHNICAL ALARM CONDITION.		**N/A**
201.11.8.101.2	**Settings and data storage following short interruptions or automatic switchover**		**N/A**
	When the SUPPLY MAINS to the RGM is interrupted for less than 30 s or automatic switchover to an INTERNAL ELECTRICAL POWER SOURCE occurs, all settings and all stored PATIENT data shall be maintained…….:	**applicable to intended monitor type, if applicable**	**N/A**
201.11.8.101.3	**Operation following long interruptions**		**N/A**
	The ACCOMPANYING DOCUMENT shall disclose the operation of the RGM after the SUPPLY MAINS has been interrupted when the "on-off" switch remains in the "on" position and is restored after a period of time that is 30 s or longer (sec)……:	**applicable to intended monitor type, if applicable**	**N/A**
201.11.8.101.4	**RESERVE ELECTRICAL POWER SOURCE**		**N/A**
	There shall be a continual visual indication when the RGM is operating from the RESERVE ELECTRICAL POWER SOURCE.	**applicable to intended monitor type, if applicable**	**N/A**
	When the RGM is equipped with a RESERVE ELECTRICAL POWER SOURCE it shall provide at least 30 min normal operation under the conditions specified in the instructions for use……:		**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
201.11.8.101.5	**RESERVE ELECTRICAL POWER SOURCE for transport outside a healthcare facility**		**N/A**
	An RGM intended for use during professional transport of a PATIENT outside a healthcare facility shall be provided with either an INTERNAL ELECTRICAL POWER SOURCE or a RESERVE ELECTRICAL POWER SOURCE capable of supporting at least 1 h of normal operation……:	**applicable to intended monitor type, if applicable**	**N/A**
201.12	**Accuracy of controls and instruments and protection against hazardous outputs**		**P**
201.12.1	The controls of an RGM shall be CLEARLY LEGIBLE under the conditions of IEC 60601-1:2005, clause 7.1.2.	**applicable to intended monitor type, if applicable**	**N/A**
201.12.1.101	**Measurement accuracy**		**P**
201.12.1.101.1	**General**		**P**
	For each respiratory gas that an RGM is intended to monitor, the MEASUREMENT ACCURACY levels given in Table 201.102 shall be achieved. The GAS READING range, the MEASUREMENT ACCURACY and, for a DIVERTING RGM, the minimum sample flow rate at which the RGM meets its MEASUREMENT ACCURACY specifications shall be disclosed in the instructions for use….:	**See Appended Table 201.12.1.101.1** **disclosed in Technical specification, see Appendix 4**	**P**
201.12.1.101.2	**DRIFT of MEASUREMENT ACCURACY**		**P**
	For each respiratory gas that an RGM is intended to monitor, the DRIFT of MEASUREMENT ACCURACY shall meet the accuracy requirements specified in Table 201.102 for not less than 6 h when used in accordance with the instructions for use with mixtures of gases as indicated in Table 201.103. The DRIFT of MEASUREMENT ACCURACY shall be disclosed in the instructions for use……:	**See Appended Table 201.12.1.101.2**	**P**
201.12.1.101.3	**MEASUREMENT ACCURACY of GAS READINGS for gas mixtures**		**P**
	For each respiratory gas that an RGM is intended to monitor, the MEASUREMENT ACCURACY of GAS READINGS in gas mixtures as specified in Table 201.102 shall be achieved with the gas mixtures of Table 201.104.	**See Appended Table 201.12.1.101.3**	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
201.12.1.102	**TOTAL SYSTEM RESPONSE TIME and rise time**		**P**
	The TOTAL SYSTEM RESPONSE TIME shall be disclosed in the instructions for use. For a DIVERTING RGM, the TOTAL SYSTEM RESPONSE TIME and the 10 % to 90 % rise time, both over the RATED gas diversion flowrate, shall be disclosed in the instructions for use. The TOTAL SYSTEM RESPONSE TIME and rise time may be reported separately, as appropriate, by breathing system configuration……:	**See Appended Table 201.12.1.102**	**P**
201.12.1.103	**Indication of units of measure for GAS READINGS**		**N/A**
	Units of measure of GAS READINGS shall be indicated either continuously or on demand from the OPERATOR. If the OPERATOR changes the units of measure from the default units of measure selected by the MANUFACTURER or RESPONSIBLE ORGANIZATION, the units of measure shall be displayed continuously.	**applicable to intended monitor type, if applicable**	**N/A**
201.12.1.104	**Indication of operating mode**		**N/A**
	Modes, other than normal operating modes (e.g. demonstration, self-test, set-up, standby, etc.), shall be indicated continuously. After 1 min without OPERATOR interaction, other modes except standby should return automatically to normal operating mode……..:	**applicable to intended monitor type, if applicable**	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
201.15	**Construction of ME EQUIPMENT**		**P**
201.15.3.5.101.1	**Shock and vibration**		**N/A**
	An RGM or its parts not intended for use during professional transportation of a PATIENT outside a healthcare facility shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, pushing, impact, dropping and rough handling. STATIONARY ME EQUIPMENT is exempt from the requirements of this subclause……:	**sensors tested to be used during professional transportation of a patient outside a healthcare facility**	**N/A**
201.15.3.5.101.2	**Shock and vibration for professional transportation**		**P**
	An RGM or its parts intended for use during professional transportation of a PATIENT outside a healthcare facility shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, pushing, impact, dropping and rough handling.	**See Appended Tables 201.15.3.5.102 a) and b)**	**P**
201.15.101	**Mode of operation**		**P**
	An RGM shall be suitable for CONTINUOUS OPERATION……..……:	**continuous**	**P**
201.101	**Interfering gas and vapour effects**		**P**
	The quantitative effects (if any) on GAS READINGS caused by the interfering gases given by the GAS LEVELS listed in Table 201.105 shall be disclosed in the instructions for use……..:	**see Appendix 4 section 'Cross Interference'** **interfering gas effects are tested by the manufacturer, refer to Attachment 2 – Attachment 7**	**P**
201.102	**Gas leakage**		**N/A**
	The rate of leakage from the SENSOR of a NON-DIVERTING RGM shall not be greater than 10 ml/min at a pressure of 60 hPa (60 cmH2O)	**intended attachment jigs are not part of testing; test is to be performed in final application**	**N/A**
	Measured rate of leakage (ml/min)……..:		**---**
201.103	**Port connector for DIVERTING RGM**		**N/A**
	The port connectors of a DIVERTING RGM and its ACCESSORIES shall comply with ISO 80369-1:2010……..:	**related to intended monitor, if applicable**	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
201.104	**Minimum sampling flow rate**		**N/A**
	A DIVERTING RGM shall indicate when it is not able to maintain the NORMAL USE flow rate……..:	**related to intended monitor, if applicable**	**N/A**
201.105	**Contamination of breathing systems**		**N/A**
201.105.1	**Sampling tube**		**N/A**
	Reversal of the direction of flow through the SAMPLING TUBE in a DIVERTING RGM shall not be possible……..:	**related to intended monitor, if applicable**	**N/A**
201.105.2	**Exhaust tube**		**N/A**
	If there is an unacceptable RISK of cross-infection under NORMAL CONDITIONS and SINGLE FAULT CONDITIONS, the RGM shall be designed so that the sample gas is not returned to the breathing system.	**related to intended monitor**	**N/A**
202	**Electromagnetic compatibility — Requirements and tests**		**N/A**
202.6.2.1.7	**PATIENT simulation**		**N/A**
	To verify the IMMUNITY of the RGM with each SENSOR indicated in the instructions for use, the RGM shall be tested with the gas mixture which generates the signal-to-noise ratio simulating a worst-case PATIENT physiological signal. If the RGM does not display instantaneous GAS READINGS in normal operating mode, the test may be conducted in a special mode or with special software where instantaneous values are displayed.	**related to intended monitor type**	**N/A**
202.6.2.1.10	**Compliance criteria**		**N/A**
	Under the IMMUNITY TEST LEVELS specified in IEC 60601-1-2:2007, 6.2, the RGM shall continue to provide BASIC SAFETY and ESSENTIAL PERFORMANCE.		**N/A**
	The following conditions associated with BASIC SAFETY and ESSENTIAL PERFORMANCE shall apply:		**---**
	aa) no permanent degradation or unrecoverable loss of function, due to damage of ME EQUIPMENT (components) or software, or loss of data shall be observed at any IMMUNITY TEST LEVEL specified in IEC 60601-1-2:2007, 6.2 and in 202.6.2.3.1 a)		**N/A**
	bb) no change of operating mode		**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	cc) operation within the specified MEASUREMENT ACCURACY limits or generation of a TECHNICAL ALARM CONDITION		**N/A**
	dd) in the event of disruption during IMMUNITY tests of IEC 60601-1-2:2007, 6.2.2, 6.2.4, 6.2.5 and 6.2.7, the RGM shall recover from any disruption within 30 s without OPERATOR intervention.		**N/A**
202.6.2.3.1	**Requirements**		**N/A**
	In addition to these requirements, an RGM intended for use during professional transportation of a PATIENT outside the healthcare facility shall comply with IEC 60601-1-2:2007, 6.2.1.10 at the IMMUNITY TEST LEVEL of 20 V/m (80 % amplitude-modulated at 1 000 Hz) over the range of 80 MHz to 2,5 GHz (see IEC 60601-1-2:2007, Table 9)…….:		**N/A**

206	**Usability**		**P**
206.6.2.2.2	**Primary operating functions**		**P**
	For an RGM, the following shall be considered PRIMARY OPERATING FUNCTIONS:		**---**
	aa) observing the GAS READING;	**related to intended monitor**	**N/A**
	bb) setting ALARM LIMITS;	**related to intended monitor**	**N/A**
	cc) deactivating ALARM SIGNALS;	**related to intended monitor**	**N/A**
	dd) for a DIVERTING RGM, adjusting the sampled gas flowrates, if so equipped;	**related to intended monitor**	**N/A**
	ee) connecting the SENSOR or SAMPLING SITE to or into the breathing system;	**refer to 'Usability Engineering File (Table)'**	**P**
	ff) starting the RGM from power-off;	**related to intended monitor**	**N/A**
	gg) starting the RGM from standby mode	**related to intended monitor**	**N/A**

208	**General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems**		**N/A**
208.6.1.2	**ALARM CONDITION priority -** IEC 60601-1-8:2006 applies except as follows:		**N/A**
	For each respiratory gas that an RGM is designed to monitor, the ALARM SYSTEM shall generate each GAS READING ALARM CONDITION, with its minimum priority, as given in Table 201.106……..:	**related to intended monitor type, requirements are not applicable**	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	If the RGM is capable of detecting the presence of more than one halogenated anaesthetic agent within a gas mixture, but not of quantifying GAS LEVELS and displaying the GAS READINGS of that mixture, it shall be capable of generating a MEDIUM PRIORITY ALARM CONDITION in the presence of such a mixture (see Table 201.106)……..:		**N/A**
	If the RGM is capable of detecting, quantifying and displaying a mixture of halogenated agents, the RGM shall:		**---**
	- generate a LOW PRIORITY ALARM CONDITION whenever the RGM detects a mixture of halogenated agents of less than 3 MAC (see Table 201.107), and		**N/A**
	- generate a MEDIUM PRIORITY ALARM CONDITION whenever the RGM detects a mixture of halogenated agents equal to or greater than 3 MAC.		**N/A**
	An ALARM SYSTEM that automatically changes ALARM CONDITION priority without OPERATOR intervention shall not change to a priority lower than that specified in this International Standard.		**N/A**
208.6.5.1	**General requirements**		**N/A**
	It shall not be possible to set the ALARM LIMIT for the low inspired oxygen GAS READING below 18 % in an ALARM PRESET.	**related to intended monitor type, requirements are not applicable**	**N/A**
208.6.6.2.101	**Additional requirements for adjustable ALARM LIMIT**		**N/A**
	The ALARM LIMIT(S) for every provided GAS READING ALARM CONDITION, except for the high GAS LEVEL for inspired nitrous oxide, shall be OPERATOR adjustable. The OPERATOR shall be required to take deliberate action to adjust ALARM LIMITS. An additional deliberate action shall be required to set the low ALARM LIMIT for the inspired oxygen GAS READING below 18 %……..:	**related to intended monitor type, requirements are not applicable**	**N/A**
208.6.8.5.101	**Additional requirements for ALARM SIGNAL deactivation states, indication and access**		**N/A**
	The MANUFACTURER-configured default AUDIO PAUSED or ALARM PAUSED interval of the RGM shall not exceed 2 min……..:	**related to intended monitor type, requirements are not applicable**	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict

201.4.3.101	ESSENTIAL PERFORMANCE		P
Distributed Essential Performance requirements			
Requirements	**Document Ref (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
MEASUREMENT ACCURACY* and GAS READING ALARM CONDITION (Sub clause- 201.12.1.101 and 208.6.1.2) or	**'Risk Management Master File – Medical Oxygen Sensors' section 1.3.1**	**output voltage/current proportional to partial pressure of oxygen, accuracy in compliance with ISO80601-2-55, 1)** **(accuracy content identified:** **repeatability: < 1 % vol. O_2 (when calibrated at 100 % O_2) +** **zero offset: < 0.5 % vol. O2 in 100 % N2 +** **linearity error: < 3 % relative)**	**P**
Generation of a TECHNICAL ALARM CONDITION (Sub clause – 201.11.8.101)	**--**	**1)**	**N/A**
*** Note:** Methods of evaluating MEASUREMENT ACCURACY as acceptance criteria following specific tests required by this International Standard are found in 202.6.2.1.7. **1) alarm system requirements are applicable to the intended monitor type only** **For detailed document identification, see Table 1.**			

201.11.6.4 – aa)	RM RESULTS TABLE: Leakage - aa) the SAMPLING SITE		P
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
4.2	**'Risk Management Master File – Medical Oxygen Sensors' section 1.3.5**	**no direct patient contact; indirect patient contact via sampling line and sensor membrane**	**P**
4.3	**'Risk Management Master File – Medical Oxygen Sensors' section 2**	**refer to item E.5 (biological, chemical hazards)**	**P**

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Clause	Requirement + Test	Result - Remark	Verdict

201.11.6.4 – aa)	**RM RESULTS TABLE: Leakage - aa) the SAMPLING SITE**		**P**
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
4.4	**'Risikoanalyse TOP DOWN (Anlage 1) - Medical Oxygen Sensors' column 'Risk evaluation'**	**E.5.2 (biological hazard) severity has been estimated (4) very low, occurrence has been estimated (3) low, detectability has been estimated (8) difficult** **E.5.6 (chemical hazards) severity has been estimated up to (6) moderate, occurrence has been estimated up to (2) few, detectability has been estimated up to (10) not detectable**	**P**
5	**'Risikoanalyse TOP DOWN (Anlage 1) - Medical Oxygen Sensors' column 'Risk evaluation'**	**associated risks have been evaluated not acceptable**	**P**
6.2	**'Risikoanalyse TOP DOWN (Anlage 1) - Medical Oxygen Sensors' column 'Risk Management Method'**	**E.5.2 restriction of intended user profile to professionals via instructions for use** **E.5.6 limitation of amount of chemicals, production process and test to prevent chemical hazards**	**P**
6.3	**'Risikoanalyse TOP DOWN (Anlage 1) - Medical Oxygen Sensors' column 'Identification in user manual (IFU)'**	**refer to Appendix 3 section 'Warnings and Precautions'**	**P**
6.4	**'Risikoanalyse TOP DOWN (Anlage 1) - Medical Oxygen Sensors' column 'Residual risk'**	**E.5.2 residual risk has been evaluated ALARP (as low as reasonable possible)** **E.5.6 residual risk has been evaluated acceptable**	**P**
6.5	**'Risk Management Master File – Medical Oxygen Sensors' section 5**	**no such unacceptable residual risk**	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict

201.11.6.4 –bb)	RM RESULTS TABLE: Leakage - bb) for a DIVERTING RGM		N/A
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
4.2			N/A
4.3			N/A
4.4			N/A
5			N/A
6.2			N/A
6.3			N/A
6.4			N/A
6.5			N/A
Supplementary information: related to intended monitor only			

201.11.6.4	RM RESULTS TABLE: Leakage – parts or accessories contain phthalates		N/A
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
4.2			N/A
4.3			N/A
4.4			N/A
5			N/A
6.2			N/A
6.3			N/A
6.4			N/A
6.5			N/A
Supplementary information: no such materials in direct or indirect patient contact			

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Clause	Requirement + Test	Result - Remark	Verdict

201.11.6.5		TABLE: Ingress of water	N/A
☐	IPX1	Enclosure of an RGM	
☐	IPX2	RGM or its parts intended for use during professional transport of a PATIENT outside a professional healthcare facility	

Test Condition/Method	Part under test	Remarks
--		

Supplementary information:

to be provided in final installation

201.11.6.6	TABLE: Cleaning and disinfection			P
Part under test	**Method indicated in IFU (30 x)**	**Basic Safety Verification**	**Essential Performance Verification**	**Remarks**
OOM110	**wipe disinfection of outer enclosure (no sampling interface, not signal interface)**	**P**	**P**	**1)**
OOM101	**wipe disinfection of outer enclosure (no sampling interface, not signal interface)**	**P**	**P**	**1)**

Supplementary information:

The test was carried out according to IEC 60601-1:2012; section 7.1.3.

2 types of labels are used for the oxygen sensors (due to enclosure design OOM110 is different). One sample of each type is conditioned 30 times as follows: Markings were rubbed by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with pure ethanol and then for 15 s with a cloth rag soaked with isopropyl alcohol. The labels were checked visually after that treatment.

Environmental conditions: 23 ± 2 °C, 45 ± 10 %rH

1) Marking does not work loose and did not curl at the edges. The markings were clearly readable

Test was performed before general accuracy determination in clause 12.

Tested by: **Sebastian Lupp** Date: **2014-11-18** Test equipment list item: **052/06**

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

201.11.6.6	**RM RESULTS TABLE: Cleaning and disinfection of ME EQUIPMENT or ME SYSTEMS**		**P**
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
4.2	**'Risk Management Master File – Medical Oxygen Sensors' section 1.1**	**refer to item 9** **(…The sensor membrane and the printed circuit board must not come in contact with disinfectant. The other parts of the sensor can be disinfected by disinfectant wipes or with a surface disinfection agent.)**	**P**
4.3	**'Risk Management Master File – Medical Oxygen Sensors' section 2**	**refer to E.5.6.d**	**P**
4.4	**'Risikoanalyse TOP DOWN (Anlage 1)' column 'Risk evaluation'**	**E.5.6d: severity has been estimated (2) extremely low, occurrence has been estimated (1) unlikely, detectability has been estimated (10) not detactable**	**P**
5	**'Risikoanalyse TOP DOWN (Anlage 1)' column 'Risk evaluation'**	**associated risk has been estimated acceptable**	**P**
6.2			**N/A**
6.3			**N/A**
6.4			**N/A**
6.5			**N/A**

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

201.12.1.101.1	TABLE: Measurement accuracy		P
Gas	**Measurement accuracy requirement**	**Measured Accuracy**	**Verdict**
OOM101			
O_2	Specification by the manufacturer: **accuracy: ISO 80601-2-55** **repeatability: < 1 % vol. O_2 (when calibrated at 100 % O_2)** **zero offset: < 0.5 % vol. O2 in 100 % N2, applied 5 min** **linearity error: < 3 % relative**	Gas level (%O2) / Deviation from target value (%O2): 15 / 0.4 21 / (calibration point) 40 / 1.4 60 / 2.1 100 / 3.5 **Ambient conditions during test: 22.7 °C, 998 mbar**	P
OOM102			
O_2	Specification by the manufacturer: **accuracy: ISO 80601-2-55** **repeatability: < 1 % vol. O_2 (when calibrated at 100 % O_2)** **zero offset: < 0.5 % vol. O2 in 100 % N2, applied 5 min** **linearity error: < 3 % relative**	Gas level (%O2) / Deviation from target value (%O2): 15 / 0.6 21 / (calibration point) 40 / 1.3 60 / 2.0 100 / 2.6 **Ambient conditions during test: 24.0 °C, 1026 mbar**	P
OOM103			
O_2	Specification by the manufacturer: **accuracy: ISO 80601-2-55** **repeatability: < 1 % vol. O_2 (when calibrated at 100 % O_2)** **zero offset: < 0.5 % vol. O2 in 100 % N2, applied 5 min** **linearity error: < 3 % relative**	Gas level (%O2) / Deviation from target value (%O2): 15 / 0.3 21 / (calibration point) 40 / 1.2 60 / 1.7 100 / 2.9 **Ambient conditions during test: 22.0 °C, 1012 mbar**	P

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

201.12.1.101.1	TABLE: Measurement accuracy		P
Gas	**Measurement accuracy requirement**	**Measured Accuracy**	**Verdict**
OOM107			
O_2	Specification by the manufacturer: **accuracy: ISO 80601-2-55** **repeatability: < 1 % vol. O_2 (when calibrated at 100 % O_2)** **zero offset: < 0.5 % vol. O2 in 100 % N2, applied 5 min** **linearity error: < 3 % relative**	Gas level (%O2) / Deviation from target value (%O2) 15 / 0.3 21 / (calibration point) 40 / 1.0 60 / 2.2 100 / 3.1 **Ambient conditions during test: 22.0 °C, 991 mbar**	**P**
OOM110			
O_2	Specification by the manufacturer: **accuracy: ISO 80601-2-55** **repeatability: < 1 % vol. O_2 (when calibrated at 100 % O_2)** **zero offset: < 0.5 % vol. O2 in 100 % N2, applied 5 min** **linearity error: < 3 % relative**	Gas level (%O2) / Deviation from target value (%O2) 15 / 0.4 21 / (calibration point) 40 / 1.1 60 / 1.8 100 / 3.8 **Ambient conditions during test: 22.0 °C, 1012 mbar**	**P**
OOM201			
O_2	Specification by the manufacturer: **accuracy: ISO 80601-2-55** **repeatability: < 1 % vol. O_2 (when calibrated at 100 % O_2)** **zero offset: < 0.5 % vol. O2 in 100 % N2, applied 5 min** **linearity error: < 3 % relative**	Gas level (%O2) / Deviation from target value (%O2) 15 / 0.4 21 / (calibration point) 40 / 1.2 60 / 2.2 100 / 3.9 **Ambient conditions during test: 22.5 °C, 1003 mbar**	**P**

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

201.12.1.101.1	TABLE: Measurement accuracy		P
Gas	**Measurement accuracy requirement**	**Measured Accuracy**	**Verdict**

Note:

a) Set up and calibrate the RGM in accordance with the instructions for use.

b) Use the appropriate test gas mixture specified in Table 201.103 with a tolerance of less than 0,2 times the error tolerance given in Table 201.102.

c) Take GAS READINGS at the specified GAS LEVELS for each gas that the RGM is intended to measure.

d) Verify that the MEASUREMENT ACCURACY for each gas that the RGM is intended to measure is within the limits of Table 201.102.

Tests performed by the manufacturer.

Gas supply flow rate: 2 L/min at bore size 3.65 mm (same flowrate/mm2 as for a flow of 60L/min at a bore size of 20 mm);

Stabilization time at least 30 min in air, calibration in air, contact with test gas 5 min. 6 sensors were investigated from each type, The highest deviation is given.

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

201.12.1.101.2	TABLE: Drift of Measurement Accuracy					P
Gas		Measurement accuracy requirement	Drift Measurement			Verdict
			Initial	3 h	6 h	
OOM101						
O_2	60,0 C	Specification by the manufacturer: accuracy: ISO 80601-2-55 repeatability: < 1 % vol. O2 (when calibrated at 100 % O2) zero offset: < 0.5 % vol. O2 in 100 % N2, applied 5 min linearity error: < 3 % relative	2.1	2.1	2.1	**P**
OOM102						
O_2	60,0 C	Specification by the manufacturer: accuracy: ISO 80601-2-55 repeatability: < 1 % vol. O2 (when calibrated at 100 % O2) zero offset: < 0.5 % vol. O2 in 100 % N2, applied 5 min linearity error: < 3 % relative	1.4	1.4	2.0	**P**
OOM103						
O_2	60,0 C	Specification by the manufacturer: accuracy: ISO 80601-2-55 repeatability: < 1 % vol. O2 (when calibrated at 100 % O2) zero offset: < 0.5 % vol. O2 in 100 % N2, applied 5 min linearity error: < 3 % relative	1.7	1.7	1.6	**P**

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

201.12.1.101.2	TABLE: Drift of Measurement Accuracy					P
Gas		Measurement accuracy requirement	Drift Measurement			Verdict
			Initial	3 h	6 h	
OOM107						
O_2	60,0 C	Specification by the manufacturer: accuracy: ISO 80601-2-55 repeatability: < 1 % vol. O2 (when calibrated at 100 % O2) zero offset: < 0.5 % vol. O2 in 100 % N2, applied 5 min linearity error: < 3 % relative	1.9	1.6	2.1	**P**
OOM110						
O_2	60,0 C	Specification by the manufacturer: accuracy: ISO 80601-2-55 repeatability: < 1 % vol. O2 (when calibrated at 100 % O2) zero offset: < 0.5 % vol. O2 in 100 % N2, applied 5 min linearity error: < 3 % relative	1.8	0.9	0.9	**P**
OOM201						
O_2	60,0 C	Specification by the manufacturer: accuracy: ISO 80601-2-55 repeatability: < 1 % vol. O2 (when calibrated at 100 % O2) zero offset: < 0.5 % vol. O2 in 100 % N2, applied 5 min linearity error: < 3 % relative	2.2	1.6	2.3	**P**

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

201.12.1.101.2	TABLE: Drift of Measurement Accuracy				P
Gas	Measurement accuracy requirement	Drift Measurement			Verdict
		Initial	3 h	6 h	

Note:

Test for not less than 6 h when used in accordance with the instructions for use with mixtures of gases as indicated in Table 201.103.

Sample all of the identified test gas mixtures every 3 h at least 3 times (total of 6 h). Between the sampling points, allow the RGM to sample ambient air. The proper disposal of test gas mixtures should be considered.

Verify that the MEASUREMENT ACCURACY requirements of Table 201.102 are met at each sample point for each test GAS LEVEL.

[C] This mixture is to be used for TOTAL SYSTEM RESPONSE TIME testing (if applicable).

Test performed by the manufacturer:

Ambient conditions during test: 23 ± 2 °C, 1013 ± 30 mbar

Every 3 hours the sensor signals are logged. Before the measurement cycle begins the sensors are calibrated with air (21% O2). 6 sensors were investigated from each type. The results from the sensor with the highest deviation are given.

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

201.12.1.101.3	TABLE: Measurement accuracy of Gas Reading for gas mixtures							P
Measurement accuracy requirement	**Monitored Gas**	**Test Gas Mixture**					**Measured Accuracy of Gas Readings**	**Verdict**
		Carbon Dioxide	**Nitrous Oxide[b]**	**Oxygen**	**Nitrogen**	**Halogenated Agent[a]**		
OOM101								
O_2	O_2	5	30	40	Balance	Halothane	**1.2 %**	**P**
						2,0		
Specification by the manufacturer:		5	30	40	Balance	Enflurane	**0.9 %**	**P**
						2,0		
accuracy: ISO 80601-2-55		5	30	40	Balance	Isoflurane	**0.6 %**	**P**
						2,0		
repeatability:		5	30	40	Balance	Sevoflurane	**0.9 %**	**P**
						2,0		
< 1 % vol. O2 (when calibrated at 100 % O2)		5	30	40	Balance	Desflurane	**0.9 %**	**P**
						8,0		
zero offset: < 0.5 % vol. O2 in 100 % N2, applied 5 min		5	Balance[c]	30	-	-	**0.8 %**	**P**
linearity error: < 3 % relative		5	Balance[c]	60	-	-	**2.4 %**	**P**
OOM102								
O_2	O_2	5	30	40	Balance	Halothane	**1.1 %**	**P**
						2,0		
Specification by the manufacturer:		5	30	40	Balance	Enflurane	**1.1 %**	**P**
						2,0		
accuracy: ISO 80601-2-55		5	30	40	Balance	Isoflurane	**1.2 %**	**P**
						2,0		
repeatability:		5	30	40	Balance	Sevoflurane	**1.2 %**	**P**
						2,0		
< 1 % vol. O2 (when calibrated at 100 % O2)		5	30	40	Balance	Desflurane	**1.2 %**	**P**
						8,0		
zero offset: < 0.5 % vol. O2 in 100 % N2, applied 5 min		5	Balance[c]	30	-	-	**0.5 %**	**P**
linearity error: < 3 % relative		5	Balance[c]	60	-	-	**1.8 %**	**P**
OOM103								
O_2	O_2	5	30	40	Balance	Halothane	**1.4 %**	**P**
						2,0		
Specification by the manufacturer:		5	30	40	Balance	Enflurane	**1.2 %**	**P**
						2,0		

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

201.12.1.101.3	TABLE: Measurement accuracy of Gas Reading for gas mixtures							P
Measurement accuracy requirement	**Monitored Gas**	**Test Gas Mixture**					**Measured Accuracy of Gas Readings**	**Verdict**
		Carbon Dioxide	**Nitrous Oxide[b]**	**Oxygen**	**Nitrogen**	**Halogenated Agent[a]**		
accuracy: ISO 80601-2-55 repeatability: < 1 % vol. O2 (when calibrated at 100 % O2) zero offset: < 0.5 % vol. O2 in 100 % N2, applied 5 min linearity error: < 3 % relative		5	30	40	Balance	Isoflurane 2,0	**1.3 %**	**P**
		5	30	40	Balance	Sevoflurane 2,0	**1.1 %**	**P**
		5	30	40	Balance	Desflurane 8,0	**1.1 %**	**P**
		5	Balance[c]	30	-	-	**0.5 %**	**P**
		5	Balance[c]	60	-	-	**1.5 %**	**P**
OOM107								
O_2	O_2	5	30	40	Balance	Halothane 2,0	**1.5 %**	**P**
Specification by the manufacturer: accuracy: ISO 80601-2-55 repeatability: < 1 % vol. O2 (when calibrated at 100 % O2) zero offset: < 0.5 % vol. O2 in 100 % N2, applied 5 min linearity error: < 3 % relative		5	30	40	Balance	Enflurane 2,0	**1.5 %**	**P**
		5	30	40	Balance	Isoflurane 2,0	**1.5 %**	**P**
		5	30	40	Balance	Sevoflurane 2,0	**1.5 %**	**P**
		5	30	40	Balance	Desflurane 8,0	**1.1 %**	**P**
		5	Balance[c]	30	-	-	**1.2 %**	**P**
		5	Balance[c]	60	-	-	**2.2 %**	**P**
OOM110								
O_2	O_2	5	30	40	Balance	Halothane 2,0	**1.3 %**	**P**
Specification by the manufacturer: accuracy: ISO 80601-2-55 repeatability: < 1 % vol. O2 (when calibrated at 100 % O2) zero offset: < 0.5		5	30	40	Balance	Enflurane 2,0	**0.8 %**	**P**
		5	30	40	Balance	Isoflurane 2,0	**0.8 %**	**P**
		5	30	40	Balance	Sevoflurane 2,0	**1.0 %**	**P**
		5	30	40	Balance	Desflurane 8,0	**1.0 %**	**P**

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

201.12.1.101.3	TABLE: Measurement accuracy of Gas Reading for gas mixtures							P
Measurement accuracy requirement	**Monitored Gas**	**Test Gas Mixture**					**Measured Accuracy of Gas Readings**	**Verdict**
		Carbon Dioxide	**Nitrous Oxide[b]**	**Oxygen**	**Nitrogen**	**Halogenated Agent[a]**		
% vol. O2 in 100 % N2, applied 5 min linearity error: < 3 % relative		5	Balance[c]	30	-	-	**0.5 %**	**P**
		5	Balance[c]	60	-	-	**0.9 %**	**P**
OOM201								
O_2	O_2	5	30	40	Balance	Halothane 2,0	**1.0 %**	**P**
Specification by the manufacturer: accuracy: ISO 80601-2-55 repeatability: < 1 % vol. O2 (when calibrated at 100 % O2) zero offset: < 0.5 % vol. O2 in 100 % N2, applied 5 min linearity error: < 3 % relative		5	30	40	Balance	Enflurane 2,0	**1.1 %**	**P**
		5	30	40	Balance	Isoflurane 2,0	**1.3 %**	**P**
		5	30	40	Balance	Sevoflurane 2,0	**1.0 %**	**P**
		5	30	40	Balance	Desflurane 8,0	**1.4 %**	**P**
		5	Balance[c]	30	-	-	**0.8 %**	**P**
		5	Balance[c]	60	-	-	**2.2 %**	**P**

Note:

For each respiratory gas that an RGM is intended to monitor, the MEASUREMENT ACCURACY of GAS READINGS in gas mixtures as specified in Table 201.102 shall be achieved with the gas mixtures of Table 201.104.

Set up and calibrate the RGM in accordance with the instructions for use, and test it using the test gases given in Table 201.104, at an ambient temperature of (23 ± 2) °C. For each numerically displayed respiratory GAS LEVEL, verify that the MEASUREMENT ACCURACY requirements of Table 201.102 are met. The proper disposal of test gas mixtures should be considered.

Use test gas mixtures with GAS LEVELS as indicated in Table 201.104 and a tolerance of less than 0,2 times the error tolerance given in Table 201.102.

[a] Included if the RGM is intended for use with these gas mixtures.

[b] For test gases prepared in-house, nitrous oxide can be increased to “balance” and nitrogen eliminated.

[c] If not for use with nitrous oxide, use nitrogen.

Supplementary information:

Test performed by the manufacturer.

Ambient conditions during test: 23 ± 2 °C, 1013 ± 30 hPa

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

201.12.1.102	TABLE: TOTAL SYSTEM RESPONSE TIME and rise time	P
Setup	Connect the RGM to a suitable recording device. With the relevant gas mixture from Table 201.103 (additional information is found in footnote d of Table 201.103) at a flow rate of 60 l/min for a bore size of 20 mm (or the equivalent average linear gas velocity for other bore sizes), where bore size is measured at the SAMPLING SITE, cycle the valve(s) and record the TOTAL SYSTEM RESPONSE TIME and, for a DIVERTING RGM, the 10 % to 90 % rise time. Repeat the PROCEDURE for this single gas mixture 20 times, and determine the average TOTAL SYSTEM RESPONSE TIME. For a DIVERTING RGM, repeat at every specified gas diversion flow rate. Repeat for each breathing system configuration indicated in the instructions for use.	

Instructions for use (IFU) specified total system response time (for diverting GRM over the rated gas diversion flow rate), (may be reported by breathing system configuration):	identified for each sensor in the associated technical specification: OOM101: < 12 sec. OOM102: < 12 sec. OOM103: < 5 sec. OOM107: < 12 sec. OOM110: < 12 sec. OOM201: < 12 sec.
Instructions for use (IFU) specified 10 % to 90 % rise time for diverting RGM (over the rated gas diversion flow rate), (may be reported by breathing system configuration):	N/A
Bore Size (at the sampling site):	3,65 mm
Flow rate……:	2 L/min (same flowrate/mm^2 as for a flow of 60L/min at a bore size of 20 mm)
Breathing System Configuration……..:	N/A (probe attached to testing equipment directly)

Gas mixture used:

Used	Monitored Gas	Gas Mixture[d]	
		Monitored Gas	Nitrogen
☐	CO_2	5,0	Balance
☒	O_2	60,0	Balance
☐	Nitrous Oxide	65,0	Balance
☐	Halothane	4,0	Balance
☐	Enflurane	5,0	Balance
☐	Isoflurane	5,0	Balance
☐	Sevoflurane	5,0	Balance
☐	Desflurane	15,0	Balance

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

Test	Total System Response Time [s]	10 % to 90 % Rise Time for a Diverting RGM	Result - Remarks	Verdict
OOM101				
1	9.88	N/A		P
2	9.77	N/A		P
3	9.69	N/A		P
4	9.67	N/A		P
5	9.56	N/A		P
6	9.63	N/A		P
7	9.61	N/A		P
8	9.51	N/A		P
9	9.58	N/A		P
10	9.5	N/A		P
11	9.46	N/A		P
12	9.47	N/A		P
13	9.45	N/A		P
14	9.48	N/A		P
15	9.45	N/A		P
16	9.97	N/A		P
17	9.45	N/A		P
18	9.4	N/A		P
19	9.31	N/A		P
20	9.47	N/A		P
Average of Total System Response Time.....:			**9.57 sec**	P
OOM102				
1	10.47	N/A		P
2	10.54	N/A		P
3	10.57	N/A		P
4	10.45	N/A		P
5	10.48	N/A		P
6	10.44	N/A		P
7	10.55	N/A		P
8	10.63	N/A		P
9	10.42	N/A		P

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

Test	Total System Response Time [s]	10 % to 90 % Rise Time for a Diverting RGM	Result - Remarks	Verdict
10	10.36	N/A		P
11	10.38	N/A		P
12	10.34	N/A		P
13	10.33	N/A		P
14	10.34	N/A		P
15	10.35	N/A		P
16	10.32	N/A		P
17	10.3	N/A		P
18	10.32	N/A		P
19	10.29	N/A		P
20	10.27	N/A		P
Average of Total System Response Time.....:			10.41 sec.	P
OOM103				
1	3.45	N/A		P
2	3.46	N/A		P
3	3.46	N/A		P
4	3.44	N/A		P
5	3.45	N/A		P
6	3.72	N/A		P
7	3.46	N/A		P
8	3.62	N/A		P
9	3.45	N/A		P
10	3.44	N/A		P
11	3.45	N/A		P
12	3.46	N/A		P
13	3.46	N/A		P
14	3.59	N/A		P
15	3.45	N/A		P
16	3.44	N/A		P
17	3.44	N/A		P
18	3.48	N/A		P
19	3.42	N/A		P

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

Test	Total System Response Time [s]	10 % to 90 % Rise Time for a Diverting RGM	Result - Remarks	Verdict
20	3.43	N/A		P
Average of Total System Response Time.....:			3.48 sec	P
OOM107				
1	8.95	N/A		P
2	8.91	N/A		P
3	8.89	N/A		P
4	9.34	N/A		P
5	8.81	N/A		P
6	8.93	N/A		P
7	8.88	N/A		P
8	8.84	N/A		P
9	8.78	N/A		P
10	8.8	N/A		P
11	8.83	N/A		P
12	9.3	N/A		P
13	8.84	N/A		P
14	8.83	N/A		P
15	8.99	N/A		P
16	9.17	N/A		P
17	8.8	N/A		P
18	8.79	N/A		P
19	8.78	N/A		P
20	9.8	N/A		P
Average of Total System Response Time.....:			8.96 sec.	P
OOM110				
1	8.69	N/A		P
2	9.54	N/A		P
3	9.51	N/A		P
4	9.74	N/A		P
5	9.75	N/A		P
6	9.74	N/A		P
7	9.75	N/A		P

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

Test	Total System Response Time [s]	10 % to 90 % Rise Time for a Diverting RGM	Result - Remarks	Verdict
8	9.69	N/A		P
9	9.69	N/A		P
10	9.7	N/A		P
11	9.7	N/A		P
12	9.7	N/A		P
13	9.7	N/A		P
14	9.65	N/A		P
15	9.7	N/A		P
16	9.67	N/A		P
17	9.65	N/A		P
18	9.65	N/A		P
19	9.77	N/A		P
20	9.68	N/A		P
Average of Total System Response Time.....:			9.63 sec	P
OOM201				
1	5.54	N/A		P
2	5.13	N/A		P
3	5.26	N/A		P
4	5.27	N/A		P
5	5.30	N/A		P
6	5.29	N/A		P
7	5.28	N/A		P
8	5.28	N/A		P
9	5.27	N/A		P
10	5.27	N/A		P
11	5.26	N/A		P
12	5.26	N/A		P
13	5.27	N/A		P
14	5.26	N/A		P
15	5.27	N/A		P
16	5.26	N/A		P
17	5.26	N/A		P

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

Test	Total System Response Time [s]	10 % to 90 % Rise Time for a Diverting RGM	Result - Remarks	Verdict
18	**5.21**	**N/A**		**P**
19	**5.22**	**N/A**		**P**
20	**5.22**	**N/A**		**P**
Average of Total System Response Time.....:			**5.27**	**P**

Note:

For DIVERTING RGM, repeat this table for each specified gas diversion flow rate.

Repeat this table for each breathing system configuration indicated in the instructions for use.

Repeat this table for each gas mixture, where applicable.

[d] This mixture is to be used for TOTAL SYSTEM RESPONSE TIME testing (if applicable). For TOTAL SYSTEM RESPONSE TIME testing, a lower accuracy of the test gas mixture is acceptable.

Supplementary information:

Test performed by the manufacturer.

Stabilization at ambient each gas level (ambient air, test gas): 3 min.

Ambient conditions during test: 23 ± 2 °C, 1013 ± 30 hPa

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

201.15.3.5. 101.1 a) **(Type 1)**	**TABLE: Shock test (IEC 60068-2-27:2008) for an RGM or its parts <u>not intended</u> for use during professional transport of a patient outside a professional health care facility under the following conditions (Test Type 1):**		**N/A**
	Peak acceleration……..……..:	150 m/s^2 (15 g)	
	Duration .....:	11 ms	
	Pulse shape .....:	half-sine	
	Number of shocks .....:	3 shocks per direction per axis (18 total)	

Applied Shock Direction	Applied Shock Axis	Method	Remarks
--			
BASIC SAFETY Verification			
ESSENTIAL PERFORMANCE Verification			
Supplementary information: **sensors tested to be used during professional transport of a patient outside a professional health care facility**			

201.15.3.5.101. 1 a) **(Type 2)**	**TABLE: Shock test (IEC 60068-2-27:2008) for an RGM or its parts <u>not intended</u> for use during professional transport of a patient outside a professional health care facility under the following conditions (Test Type 2):**		**N/A**
	Peak acceleration	300 m/s^2 (30 g)	
	Duration.....	6 ms	
	Pulse shape	half-sine	
	Number of shocks.....	3 shocks per direction per axis (18 total)	

Applied Shock Direction	Applied Shock Axis	Method	Remarks
--			
BASIC SAFETY Verification			
ESSENTIAL PERFORMANCE Verification			
Supplementary information: **sensors tested to be used during professional transport of a patient outside a professional health care facility**			

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

201.15.3.5.101.1 b) **(Broad-band random)**	**TABLE: Broad-band random Vibration (IEC 60068-2-64:2008) for an RGM or its parts <u>not intended</u> for use during professional transport of a patient outside a professional health care facility under the following conditions (Broad-band random vibration test):**		**N/A**
1	Acceleration amplitude.....	10 Hz to 100 Hz: 1,0 $(m/s^2)^2$/Hz	
2	Acceleration amplitude.....	100 Hz to 200 Hz: - 3 db per octave	
3	Acceleration amplitude.....	200 Hz to 2 000 Hz: 0,5 $(m/s^2)^2$/Hz	
	Duration.....	10 min* per perpendicular axis (3 total) or 30 min per perpendicular axis (3 total) is recommended	

Perpendicular axis subjected to broad-band random vibration test	Acceleration amplitude	Method	Remarks
--	--		
	--		
	--		
BASIC SAFETY Verification:			
ESSENTIAL PERFORMANCE Verification:			

Supplementary information:

sensors tested to be used during professional transport of a patient outside a professional health care facility

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

201.15.3.5.101.2 a) **(Type 1)**	**TABLE: Shock test for professional transportation (IEC 60068-2-27:2008) for an RGM or its parts intended for use during professional transportation of a PATIENT outside a healthcare facility under the following conditions (Test Type 1):**		**P**
	Peak acceleration	300 m/s^2 (30 g)	
	Duration	11 ms	
	Pulse shape	half-sine	
	Number of shocks	3 shocks per direction per axis (18 total)	

Applied Shock Direction	Applied Shock Axis	Method	Remarks
+	rotation axis	half-sine shock Ea	OOM101
-	rotation axis	half-sine shock Ea	OOM101
+	transverse 0°	half-sine shock Ea	OOM101
-	transverse 0°	half-sine shock Ea	OOM101
+	transverse 90°	half-sine shock Ea	OOM101
-	transverse 90°	half-sine shock Ea	OOM101
+	rotation axis	half-sine shock Ea	OOM102
-	rotation axis	half-sine shock Ea	OOM102
+	transverse 0°	half-sine shock Ea	OOM102
-	transverse 0°	half-sine shock Ea	OOM102
+	transverse 90°	half-sine shock Ea	OOM102
-	transverse 90°	half-sine shock Ea	OOM102
+	rotation axis	half-sine shock Ea	OOM103
-	rotation axis	half-sine shock Ea	OOM103
+	transverse 0°	half-sine shock Ea	OOM103
-	transverse 0°	half-sine shock Ea	OOM103
+	transverse 90°	half-sine shock Ea	OOM103
-	transverse 90°	half-sine shock Ea	OOM103
+	rotation axis	half-sine shock Ea	OOM107
-	rotation axis	half-sine shock Ea	OOM107
+	transverse 0°	half-sine shock Ea	OOM107
-	transverse 0°	half-sine shock Ea	OOM107
+	transverse 90°	half-sine shock Ea	OOM107
-	transverse 90°	half-sine shock Ea	OOM107
+	rotation axis	half-sine shock Ea	OOM110

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

Applied Shock Direction	Applied Shock Axis	Method	Remarks
-	rotation axis	half-sine shock Ea	OOM110
+	transverse 0°	half-sine shock Ea	OOM110
-	transverse 0°	half-sine shock Ea	OOM110
+	transverse 90°	half-sine shock Ea	OOM110
-	transverse 90°	half-sine shock Ea	OOM110
+	rotation axis	half-sine shock Ea	OOM201
-	rotation axis	half-sine shock Ea	OOM201
+	transverse 0°	half-sine shock Ea	OOM201
-	transverse 0°	half-sine shock Ea	OOM201
+	transverse 90°	half-sine shock Ea	OOM201
-	transverse 90°	half-sine shock Ea	OOM201
BASIC SAFETY Verification:		leakage of liquids OOM101	no
		leakage of liquids OOM102	no
		leakage of liquids OOM103	no
		leakage of liquids OOM107	no
		leakage of liquids OOM110	no
		leakage of liquids OOM201	no
ESSENTIAL PERFORMANCE Verification:		accuracy of output voltage OOM101	pass, 1)
		accuracy of output voltage OOM102	pass, 1)
		accuracy of output voltage OOM103	pass, 1)
		accuracy of output voltage OOM107	pass, 1)
		accuracy of output voltage OOM110	pass, 1)
		accuracy of output voltage OOM201	pass, 1)

Supplementary information:

NOTE This represents Class 7M3 as described in IEC/TR 60721-4-7:2001

To investigate the sensor in 3 perpendicular directions, the sensors are conditioned in longitudinal (rotation axis) and in two perpendicular transverse directions (0° and 90 °).

1) detailed results of accuracy tests see Appendix 5

2) For test set-up and process of mechanical strength tests performed refer to attached mechanical strength test report (see Attachment 1).

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

201.15.3.5.101 .2 a) **(Type 2)**	**TABLE: Shock test for professional transportation (IEC 60068-2-27:2008) for an RGM or its parts intended for use during professional transport of a patient outside a professional health care facility under the following conditions (Test Type 2):**		**P**
	Peak acceleration	1000 m/s^2 (100 g)	
	Duration.....	6 ms	
	Pulse shape	half-sine	
	Number of shocks.....	3 shocks per direction per axis (18 total)	

Applied Shock Direction	Applied Shock Axis	Method	Remarks
+	rotation axis	half-sine shock Ea	OOM101
-	rotation axis	half-sine shock Ea	OOM101
+	transverse 0°	half-sine shock Ea	OOM101
-	transverse 0°	half-sine shock Ea	OOM101
+	transverse 90°	half-sine shock Ea	OOM101
-	transverse 90°	half-sine shock Ea	OOM101
+	rotation axis	half-sine shock Ea	OOM102
-	rotation axis	half-sine shock Ea	OOM102
+	transverse 0°	half-sine shock Ea	OOM102
-	transverse 0°	half-sine shock Ea	OOM102
+	transverse 90°	half-sine shock Ea	OOM102
-	transverse 90°	half-sine shock Ea	OOM102
+	rotation axis	half-sine shock Ea	OOM103
-	rotation axis	half-sine shock Ea	OOM103
+	transverse 0°	half-sine shock Ea	OOM103
-	transverse 0°	half-sine shock Ea	OOM103
+	transverse 90°	half-sine shock Ea	OOM103
-	transverse 90°	half-sine shock Ea	OOM103
+	rotation axis	half-sine shock Ea	OOM107
-	rotation axis	half-sine shock Ea	OOM107
+	transverse 0°	half-sine shock Ea	OOM107
-	transverse 0°	half-sine shock Ea	OOM107
+	transverse 90°	half-sine shock Ea	OOM107
-	transverse 90°	half-sine shock Ea	OOM107
+	rotation axis	half-sine shock Ea	OOM110

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

Applied Shock Direction	Applied Shock Axis	Method	Remarks
-	rotation axis	half-sine shock Ea	OOM110
+	transverse 0°	half-sine shock Ea	OOM110
-	transverse 0°	half-sine shock Ea	OOM110
+	transverse 90°	half-sine shock Ea	OOM110
-	transverse 90°	half-sine shock Ea	OOM110
+	rotation axis	half-sine shock Ea	OOM201
-	rotation axis	half-sine shock Ea	OOM201
+	transverse 0°	half-sine shock Ea	OOM201
-	transverse 0°	half-sine shock Ea	OOM201
+	transverse 90°	half-sine shock Ea	OOM201
-	transverse 90°	half-sine shock Ea	OOM201

BASIC SAFETY Verification:	leakage of liquids OOM101	no
	leakage of liquids OOM102	no
	leakage of liquids OOM103	no
	leakage of liquids OOM107	no
	leakage of liquids OOM110	no
	leakage of liquids OOM201	no
ESSENTIAL PERFORMANCE Verification:	accuracy of output voltage OOM101	pass, 1)
	accuracy of output voltage OOM102	pass, 1)
	accuracy of output voltage OOM103	pass, 1)
	accuracy of output voltage OOM107	pass, 1)
	accuracy of output voltage OOM110	pass, 1)
	accuracy of output voltage OOM201	pass, 1)

Supplementary information:

NOTE: This represents Class 7M3 as described in IEC/TR 60721-4-7:2001

To investigate the sensor in 3 perpendicular directions, the sensors are conditioned in longitudinal (rotation axis) and in two perpendicular transverse directions (0° and 90 °).

1) detailed results of accuracy tests see Appendix 5

2) For test set-up and process of mechanical strength tests performed refer to attached mechanical strength test report (see Attachment 1).

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

201.15.3.5.101.2 b) **(Broad-band random)**	**TABLE: Broad-band random Vibration test (IEC 60068-2-64:2008) for an RGM or its parts intended for use during professional transport of a patient outside a professional health care facility under the following conditions (Broad-band random vibration test):**		**P**
1	Acceleration amplitude.....	10 Hz to 100 Hz: 5,0 $(m/s^2)^2$/Hz	
2	Acceleration amplitude.....	100 Hz to 200 Hz: - 7 db per octave	
3	Acceleration amplitude.....	200 Hz to 2 000 Hz: 1,0 $(m/s^2)^2$/Hz	
	Duration.....	30 min per perpendicular axis (3 total)	

Perpendicular axis subjected to broad-band random vibration test	Acceleration amplitude	Method	Remarks
rotation axis	1, 2, 3	random vibration broadband Fh	OOM101
transverse 0°	1, 2, 3	random vibration broadband Fh	OOM101
transverse 90°	1, 2, 3	random vibration broadband Fh	OOM101
rotation axis	1, 2, 3	random vibration broadband Fh	OOM102
transverse 0°	1, 2, 3	random vibration broadband Fh	OOM102
transverse 90°	1, 2, 3	random vibration broadband Fh	OOM102
rotation axis	1, 2, 3	random vibration broadband Fh	OOM103
transverse 0°	1, 2, 3	random vibration broadband Fh	OOM103
transverse 90°	1, 2, 3	random vibration broadband Fh	OOM103
rotation axis	1, 2, 3	random vibration broadband Fh	OOM107
transverse 0°	1, 2, 3	random vibration broadband Fh	OOM107
transverse 90°	1, 2, 3	random vibration broadband Fh	OOM107
rotation axis	1, 2, 3	random vibration broadband Fh	OOM110
transverse 0°	1, 2, 3	random vibration broadband Fh	OOM110
transverse 90°	1, 2, 3	random vibration broadband Fh	OOM110
rotation axis	1, 2, 3	random vibration broadband Fh	OOM201
transverse 0°	1, 2, 3	random vibration broadband Fh	OOM201
transverse 90°	1, 2, 3	random vibration broadband Fh	OOM201
BASIC SAFETY Verification:		leakage of liquids OOM101	no
		leakage of liquids OOM102	no
		leakage of liquids OOM103	no
		leakage of liquids OOM107	no
		leakage of liquids OOM110	no
		leakage of liquids OOM201	no

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

ESSENTIAL PERFORMANCE Verification:	accuracy of output voltage OOM101	pass, 1)
	accuracy of output voltage OOM102	pass, 1)
	accuracy of output voltage OOM103	pass, 1)
	accuracy of output voltage OOM107	pass, 1)
	accuracy of output voltage OOM110	pass, 1)
	accuracy of output voltage OOM201	pass, 1)

Supplementary information:

NOTE : This represents Class 7M1 and 7M2 as described in IEC/TR 60721-4-7:2001

To investigate the sensor in 3 perpendicular directions, the sensors are conditioned in longitudinal (rotation axis) and in two perpendicular transverse directions (0° and 90 °).

1) detailed results of accuracy tests see Appendix 5

2) For test set-up and process of mechanical strength tests performed refer to attached mechanical strength test report (see Attachment 1).

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

201.15.3.5.101 .2 c) **(Free - Fall)**	**TABLE: Free fall test (IEC 60068-2-31:2008), using PROCEDURE 1, for an RGM or its parts intended for use during professional transport of a patient outside a professional health care facility under the following conditions (Free-Fall):**	**P**

1	Fall height for mass ≤ 1 kg	0,25 m
2	Fall height for mass > 1 kg and ≤ 10 Kg	0,1 m
3	Fall height for mass > 10 kg and ≤ 50 Kg	0,05 m
4	Fall height for mass > 50 kg	0,01 m

Specified Attitude (Orientation)	Mass (Kg)	Fall No.	Remarks
rotation axis terminal part	< 1 kg	1	OOM101
rotation axis terminal part	< 1 kg	2*	OOM101
rotation axis gas input part	< 1 kg	1	OOM101
rotation axis gas input part	< 1 kg	2*	OOM101
transverse 0°	< 1 kg	1	OOM101
transverse 0°	< 1 kg	2*	OOM101
transverse 90°	< 1 kg	1	OOM101
transverse 90°	< 1 kg	2*	OOM101
transverse 180°	< 1 kg	1	OOM101
transverse 180°	< 1 kg	2*	OOM101
transverse 180°	< 1 kg	1	OOM101
transverse 180°	< 1 kg	2*	OOM101
rotation axis terminal part	< 1 kg	1	OOM102
rotation axis terminal part	< 1 kg	2*	OOM102
rotation axis gas input part	< 1 kg	1	OOM102
rotation axis gas input part	< 1 kg	2*	OOM102
transverse 0°	< 1 kg	1	OOM102
transverse 0°	< 1 kg	2*	OOM102
transverse 90°	< 1 kg	1	OOM102
transverse 90°	< 1 kg	2*	OOM102
transverse 180°	< 1 kg	1	OOM102
transverse 180°	< 1 kg	2*	OOM102
transverse 180°	< 1 kg	1	OOM102
transverse 180°	< 1 kg	2*	OOM102
rotation axis terminal part	< 1 kg	1	OOM103

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

Specified Attitude (Orientation)	Mass (Kg)	Fall No.	Remarks
rotation axis terminal part	< 1 kg	2*	OOM103
rotation axis gas input part	< 1 kg	1	OOM103
rotation axis gas input part	< 1 kg	2*	OOM103
transverse 0°	< 1 kg	1	OOM107
transverse 0°	< 1 kg	2*	OOM107
transverse 90°	< 1 kg	1	OOM107
transverse 90°	< 1 kg	2*	OOM107
transverse 180°	< 1 kg	1	OOM107
transverse 180°	< 1 kg	2*	OOM107
transverse 180°	< 1 kg	1	OOM107
transverse 180°	< 1 kg	2*	OOM107
rotation axis terminal part	< 1 kg	1	OOM110
rotation axis terminal part	< 1 kg	2*	OOM110
rotation axis gas input part	< 1 kg	1	OOM110
rotation axis gas input part	< 1 kg	2*	OOM110
transverse 0°	< 1 kg	1	OOM110
transverse 0°	< 1 kg	2*	OOM110
transverse 90°	< 1 kg	1	OOM110
transverse 90°	< 1 kg	2*	OOM110
transverse 180°	< 1 kg	1	OOM110
transverse 180°	< 1 kg	2*	OOM110
transverse 180°	< 1 kg	1	OOM110
transverse 180°	< 1 kg	2*	OOM110
rotation axis terminal part	< 1 kg	1	OOM201
rotation axis terminal part	< 1 kg	2*	OOM201
rotation axis gas input part	< 1 kg	1	OOM201
rotation axis gas input part	< 1 kg	2*	OOM201
transverse 0°	< 1 kg	1	OOM201
transverse 0°	< 1 kg	2*	OOM201
transverse 90°	< 1 kg	1	OOM201
transverse 90°	< 1 kg	2*	OOM201
transverse 180°	< 1 kg	1	OOM201
transverse 180°	< 1 kg	2*	OOM201

ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

Specified Attitude (Orientation)	Mass (Kg)	Fall No.	Remarks
transverse 180°	< 1 kg	1	OOM201
transverse 180°	< 1 kg	2*	OOM201

Verification Type	Verification Method	Remarks
BASIC SAFETY	leakage of liquids OOM101	no
	leakage of liquids OOM102	no
	leakage of liquids OOM103	no
	leakage of liquids OOM107	no
	leakage of liquids OOM110	no
	leakage of liquids OOM201	no
ESSENTIAL PERFORMANCE	accuracy of output voltage OOM101	pass, 1)
	accuracy of output voltage OOM102	pass, 1)
	accuracy of output voltage OOM103	pass, 1)
	accuracy of output voltage OOM107	pass, 1)
	accuracy of output voltage OOM110	pass, 1)
	accuracy of output voltage OOM201	pass, 1)

Supplementary information:

2*: Number of falls: 1 in each specified attitude. Two falls in each specified attitude is recommended.

NOTE This represents Class 7M2 as described in IEC/TR 60721-4-7:2001

To investigate the sensor in 3 perpendicular directions, the sensors are conditioned in longitudinal (rotation axis) and in two perpendicular transverse directions (0° and 90 °).

1) detailed results of accuracy tests see Appendix 5

2) For test set-up and process of mechanical strength tests performed refer to attached mechanical strength test report (see Attachment 1).

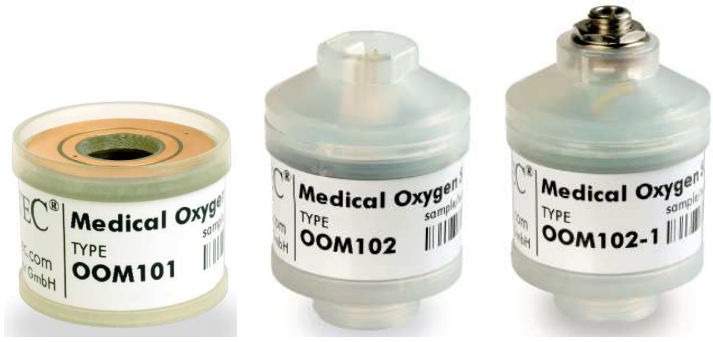
ISO 80601-2-55			
Clause	Requirement + Test	Result - Remark	Verdict

201.105.2	RM TABLE: Exhaust tube		N/A
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
4.2			N/A
4.3			N/A
4.4			N/A
5			N/A
6.2			N/A
6.3			N/A
6.4			N/A
6.5			N/A
Supplementary information: requirements related to intended monitor type, if applicable			

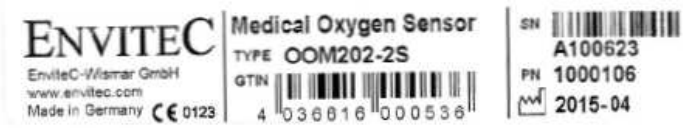
208.6.1.2	Table: Alarm Condition Priority		N/A
Condition	**Minimum alarm condition priority**	**Alarm condition priority**	**Remarks**
--			
essential performance of the sensors is restricted to accuracy of gas readings, requirements applicable to intended monitor type			

Appendix No. 1
Photos

Sensors tested



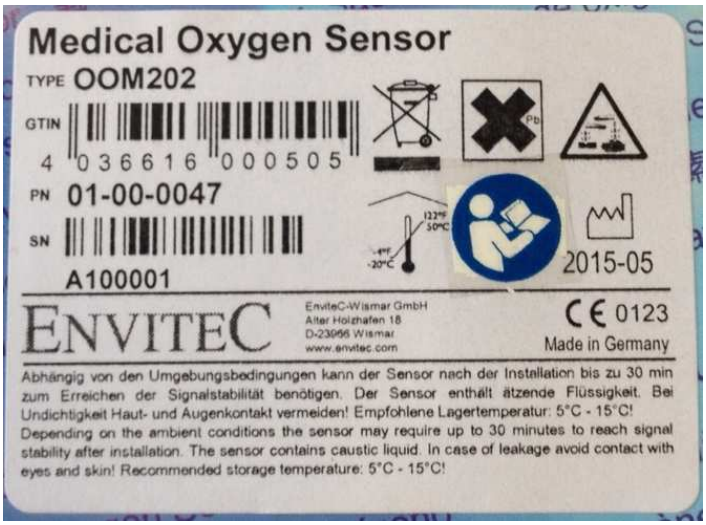
Electrical sensor terminals (gold plated slip ring, 3 pin molex, 3.5 mm jack)



Secondary packaging label (example for the product family certified)

PLEASE NOTE	WARNING
Depend on storage time, the sensor may require up 30 minutes to reach signal stability. Recommended storage temperature: 5°C - 15°C	This sensor contains caustic liquid. Should leakage occur, avoid contact with eyes or skin. If liquid does contact eyes or skin, wash copious amount of clean water.

Additional Box label marking



Box label (example for the product family certified)

Appendix No. 2
Test Equipment Log Sheet

Item	Equipment	Model	Manufacturer	Range used	Last Cal.	Next Cal.
052/06	Triple Timer	KW9161	eurochron	sec - minutes - hours (Autorange)	2014,08	2015,09
053/00	True RMS multi meter	189	FLUKE	mVac/dc - 1000V (Auto Range); mA - 10 Aac/dc (Auto Range); Ω - 500MΩ (Auto Range)	2014,03	2015,03
062/06	U-tube manometer	1000 mmH2O	Gebr. Neubert	1000 mmH_2O (1ml = 45mmH2O/ 4,413hPa)	2012,12	ICO 2015,09
062/22	Digital pressure gauge	Digima UNI 3	Special Instruments	0 - 200mbar	2013,12	2015,03
065/07	Data logger temp./humid./pressure *	SP-2000-35R-123 + PTB110	Veriteq	-35°C-85°C / 0-100%r.F. / 800-1100hPa	2014,04	2015,03
065/08	Data logger temp./humid. *	SP-2000-20R-117	Veriteq	-35°C-85°C / 0-100%r.F.	2014,10	2015,09
ICO	Initial calibration only (next verification stated)					
*	used for laboratory ambient monitoring					

Appendix No. 3
Instructions for use

ENVITEC
by Honeywell

Instructions for Use: OOM Series Medical Oxygen Sensor (except OOM109-X)

Warnings and Precautions:

It is the responsibility of the user to determine the suitability for use of the sensor.
Follow the instructions for use of the oxygen analyzer and for replacement of oxygen sensor.
To avoid cross infection please follow strictly the instructions of the oxygen analyzer manufacturer.
Refer to the oxygen analyzer operation manual to determine any needed preoperative checks.
Sensor contains encapsulated by a housing, lead (Pb), lead oxide (PbO) and concentrated potassium hydroxide solution (between 2 and 5 mol / L). Lead and lead oxide are toxic and dangerous for the environment. Concentrated potassium hydroxide is corrosive (see safety data sheet). Do not open the housing or penetrate the permeable membrane. Do not touch a damaged sensor without protective gloves. In the case of leakage avoid contact with eyes.
The sensor is not suited for use in a magnetic resonance imaging (MRI) environment.

Indications for 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
- Sensing device for oxygen in medical ventilators
- Sensing device for oxygen in anesthesia equipment
- Sensing device for oxygen in incubators

The use is limited to system monitoring. The sensors are not suited for breath by breath analysis of breath gases.

If the sensor is intended to replace the original oxygen-sensing component of an oxygen analyzer, consult the cross reference list under http://www.envitec.com for choosing the appropriate sensor. Do not use sensor/device combinations that are not specified in the cross reference list nor in the operating manual of the device. The use of the sensor is restricted to professional users.
Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Instructions:

The sensor should be replaced only by a professional user. Before insertion into the device check the sensor for mechanical damages and for humidity or crystallization of salts on the housing. Do not use a damaged sensor or a sensor with crystallization of salts outside. Follow the instructions for use of the oxygen analyzer for replacement of the sensor. Verify that the sensor can be properly attached to the mechanical and electrical connections of the oxygen analyzer. Calibrate the analyzer according to the instructions in the analyzer's operation manual and verify proper gas readings. Oxygen analyzer readings in room air will typically be between 19% and 23% when calibrated in 100% oxygen or another calibration gas level required in accordance with the analyzer's instructions. The sensor should be calibrated in regular intervals (see instructions for use of the analyzer). If calibration problems or instable signals occur the sensor must be replaced.

Technical Sensor Specifications:

The sensor meets the requirements of ISO 80601-2-55. For detailed technical specifications, please refer to the sensor's technical specification sheets (http://www.envitec.com).

Enviromental specification:

	Created – Erstellt:	Date:	Page – Seite:
Z:\ARBEIT\aktuelle Projekte\2013\13097 EnviteC-Wismar GmbH -by Honeywell Sauerstoffsensoren\Doku\Instruction_for_use _Entwurf_30sep15.docx	CD3	**05.03.15**	**1 / 3**

Vorlage: Memo.dot

Operating Temperature:	0 to 50°C (no fast temperature changes, 30 minutes equilibrium time after fast temperature change)
Operating Humidity:	0-99 % RH non-condensing
Storage Temperature:	-20 to +50 °C
Recommended Storage:	+5 to +15 °C
Pressure Range:	600hPa – 2000hPa
Warm-Up Time:	< 30 minutes, after replacement of sensor
Influence from Anesthetic agents	Meets ISO 80601-2-55 requirements

Principles of Operation:

EnviteC Medical Oxygen Sensors are based on the principle of electro-galvanic sensors. They are constructed in a plastic housing containing two electrodes - a precious metal cathode and a lead anode immersed in a liquid electrolyte medium. Electrically the device resembles a very low voltage battery cell. A gas permeable diffusion membrane provides the interface to the gas sample. The oxygen gas is reduced on the sensing electrode (Cathode) and lead is oxidized on the second electrode (Anode). The resulting current produces on the load resistor an external electrical voltage signal that is proportional to the conversion of the oxygen. The sensor signal is temperature dependent and typically compensated with an internal temperature-compensating resistor network.

Cleaning/ Disinfection:

The sensor membrane and the printed circuit board should not come in contact with disinfectant or cleaning agent. The other parts of the sensor can be disinfected by disinfectant wipes or with a surface disinfection agent. Follow the instructions of the producer of the disinfection material.

Disposal:

Medical Oxygen Sensors contain Lead (Pb) and should be disposed of in accordance with local regulations.

Manufacturer:

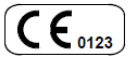
EnviteC-Wismar GmbH, a Honeywell Company

Alter Holzhafen 18

23966 Wismar, Germany

Symbols on Label:

Symbol	Description
TYPE	Sensor Type
SN	Serial number
	Observe instructions for use (Monitor operator's manual)
	Risk: Lead inside

	Date of manufacture
	CE-Symbol with EnviteC Body Number
	In accordance with Directive 2002/96/EC (WEEE), the manufacturer will accept the return of the electrical and electronic device for proper disposal. Please note: Medical Oxygen Sensors contain Lead (Pb) and should be disposed of in accordance with local regulations.
	Corrosive
	Storage Conditions

Appendix No. 4

Medical Sensors

ENVITEC
by Honeywell

High Quality O_2 Gas Sensors for Multiple Applications

Use the benefits:

Quality
- Low cross interferences from common components of breathing gases
- Industry-leading life time
- Highest manufacturing standards

Flexibility
- Customized sensor design
- Simple analysis of sensor signal
- Flexible response times

Accuracy
- Linearity of sensor signal between 0 to 100% oxygen better than 3% relative
- Low signal drift (<1% volume O_2/month)
- Built-in NTC compensation

Ongoing Research
- Lead-free technology
- Clinical studies
- Multiple inventions
- Long-term tests

	Oxygen sensor part number	Output signal in air	Response time T 90 %	Nominal sensor lifetime	Electrical interface
	OOM101	46 µA–63 µA no temperature compensation	< 12 seconds	≥ 500 000 % volume oxygen hours	gold plated slip rings
	OOM102	9 mV–14 mV temperature compensated	< 12 seconds	≥ 1 000 000 % volume oxygen hours	3 pin Molex® connector
	OOM102-1	9 mV–14 mV temperature compensated	< 12 seconds	≥ 1 000 000 % volume oxygen hours	3.5 mm mono Jack
	OOM103	9 mV–13 mV temperature compensated	< 5 seconds	≥ 500 000 % volume oxygen hours	3 pin Molex® connector
	OOM103-1	9 mV–13 mV temperature compensated	< 5 seconds	≥ 500 000 % volume oxygen hours	3.5 mm mono Jack
	OOM103-1M	9 mV–13 mV temperature compensated	< 5 seconds	≥ 500 000 % volume oxygen hours	Switchcraft® mini power Jack
	OOM104	24 µA–32 µA no temperature compensation	< 12 seconds	≥ 750 000 % volume oxygen hours	gold plated slip rings
	OOM105	Teledyne® TED range	< 5 seconds	≥ 500 000 % volume oxygen hours	Molex® plug 4P4C
	1001825 with OOM111	11 mV–13 mV	< 12 seconds	≥ 1 000 000 % volume oxygen hours	Stereo phone Jack (3.5 mm)

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	Oxygen sensor part number	Output signal in air	Response time T 90 %	Nominal sensor lifetime	Electrical interface
	OOM106	9 mV – 13 mV temperature compensated	< 12 seconds	≥ 1 000 000 % volume oxygen hours	3 pin Molex® connector
	OOM107	170 µA – 230 µA no temperature compensation	< 12 seconds	≥ 250 000 % volume oxygen hours	gold plated slip rings
	OOM107-2	170 µA – 230 µA no temperature compensation	< 12 seconds	≥ 250 000 % volume oxygen hours	flying leads with pin-connectors
	OOM109	9 mV – 13 mV temperature compensation	< 300 msec.	≥ 200 000 % volume oxygen hours	3 pin molex®
	OOM109-LF2	9 mV to 13 mV temperature compensation	< 300 msec.	≥ 200 000 % volume oxygen hours	3 pin molex®
	OOM111	11 mV – 13 mV temperature compensated	< 12 seconds	≥ 1 000 000 % volume oxygen hours	3 mm stereo Jack
	OOM112	25 mV – 38 mV temperature compensated	< 12 seconds	≥ 500 000 % volume oxygen hours	gold plated slip rings
	OOM201	24 µA – 35 µA (Dual Cathode) no temperature compensation	< 12 seconds	≥ 500 000 % volume oxygen hours	gold plated slip rings
	OOM202	13 mV – 16 mV temperature compensated	< 12 seconds	≥ 1 000 000 % volume oxygen hours	3 pin molex®
	OOM202-1	13 mV – 16 mV temperature compensated	< 12 seconds	≥ 1 000 000 % volume oxygen hours	3.5 mm mono Jack
	OOM202-2	9 mV – 13 mV temperature compensated	< 12 seconds	≥ 1 000 000 % volume oxygen hours	flying leads with 3 pin female molex® connector
	OOM202-2S	9 mV – 11.5 mV temperature compensated	< 12 seconds	≥ 1 000 000 % volume oxygen hours	AMP MATE-N-LOK/ 2 circuit
	OOM204	9 mV – 13.5 mV (dual cathode) temperature compensated	< 12 seconds	≥ 500 000 % volume oxygen hours	3 pin molex®
	OOM110	10 mV – 12 mV temperature compensated	< 12 seconds	≥ 1 000 000 % volume oxygen hours	modular Jack 6P4C

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Oxygen Sensors General Specifications

Measurement range	0–100% oxygen (at atmospheric pressure)
Accuracy	meets ISO 80601-2-55 requirements
Repeatability	< 1 % vol. O2 @ constant temp. and pressure
Zero offset	<0.5% vol. O_2 in 100% N_2, applied 5 minutes
Linearity error	<3% relative
Cross interference	meets ISO 80601-2-55 requirements
Influence of humidity	– 0.03% rel. per % RH at 25°C
Pressure range	0.6 to 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 1m
Operating temperature	0°C to 50°C
Temperature compensation (steady state)	built-in NTC compensation (depends on type) Effect of temperature compensation 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 typically < – 15% relative over lifetime	< 1% vol oxygen per month
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
Weight	approximately 28 grams approximately 43 grams OOM107 series

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

meet EN ISO 21647 / ISO 80601-2-55
Designed and manufactured according to
EN ISO 9001 and EN ISO 13485

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 MySign® O: High-performance handheld monitor from a new family of devices for clinical, emergency and home ventilation applications.

CE-compliant / FDA-cleared

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Technical information is subject to change without notice!

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

Appendix No. 5
Evaluation of Essential Performance

Before conditioning:

Sensor investigated	Performance characteristics investigated:					Comment
	Output signal in air			Linearity		
	limits specified	load resistor [Ohm]	readings	limits specified [%]	readings [%]	
OOM101	46 – 63 µA	250	52.6 µA	< 3 %	-0.77	
OOM102	9 – 14 mV	--	12.90 mV	< 3 %	-1.26	
OOM103	9 – 13 mV	--	11.22 mV	< 3 %	-1.26	
OOM107	170 – 230 µA	50	193.8 µA	< 3 %	-1.31	
OOM110	9 – 13 mV	--	10.91 mV	< 3 %	-0.99	
OOM201	24 - 32 µA	500	31.6 µA	< 3 %	-1.34	
OOM201	24 – 32 µA	500	31.3 µA	< 3 %	-1.32	
Supplementary information: Test performed by the manufacturer. Test equipment used: SMPIII_0210. Ambient conditions during tests: 1014 hPa						

After mechanical strength test according ISO 80601-2-55 sub-clause 201.15.3.5.101:

Sensor investigated	Performance characteristics investigated:					Comment
	Output signal in air			Linearity		
	limits specified	load resistor [Ohm]	readings	limits specified [%]	readings [%]	
OOM101	46 – 63 µA	250	52.9 µA	< 3 %	-0.64	
OOM102	9 – 14 mV	--	12.91 mV	< 3 %	-1.37	
OOM103	9 – 13 mV	--	10.35 mV	< 3 %	-1.27	
OOM107	170 – 230 µA	50	192.8 µA	< 3 %	-1.05	
OOM110	9 – 13 mV	--	10.71 mV	< 3 %	-0.90	
OOM201	24 - 32 µA	500	31.1 µA	< 3 %	-0.73	
OOM201	24 – 32 µA	500	31.4 µA	< 3 %	-0.75	
Supplementary information: Test performed by the manufacturer. Test equipment used: SMPIII_0210. Ambient conditions during tests: 1029 hPa						