DRAFT INTERNATIONAL STANDARD ISO/DIS 80369-2

ISO/TC **210** Secretariat: **ANSI**

Voting begins on **2015-07-30** Voting terminates on **2015-10-30**

Small bore connectors for liquids and gases in healthcare applications —

Part 2:
Connectors for breathing systems and driving gases applications

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé —

Partie 2: Raccords destinés à des systèmes respiratoires et applications au gaz propulseur

ICS 11.040.10; 11.040.20

This draft is submitted to a parallel enquiry in ISO and a CDV vote in the IEC.

ISO/CEN PARALLEL PROCESSING

This final draft has been developed within the European Committee for Standardization (CEN), and processed under the **CEN-lead** mode of collaboration as defined in the Vienna Agreement. The final draft was established on the basis of comments received during a parallel enquiry on the draft.

This final draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel two-month approval vote in ISO and two-month formal vote in CEN.

Positive votes shall not be accompanied by comments.

Negative votes shall be accompanied by the relevant technical reasons.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

38

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received. www.iso.org/patents

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

ISO 80369-2 was prepared by a Joint Working Group of Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, IEC/TC 62, *Electrical equipment*, Subcommittee SC 62D, *Electrical equipment in medical practice* and CEN/CENELEC TC3/WG 2, *Small-bore connectors.*

This is the first edition of ISO 80369-2.

ISO 80369 consists of the following parts, under the general title *Small-bore connectors for liquids and gases in healthcare applications*:

— *Part 1: General requirements*

— *Part 2: Connectors for breathing systems and driving gases applications* (this standard)

— *Part 3: Connectors for enteral applications*

— *Part 4: Connectors for urethral and urinary applications*[1]

— *Part 5: Connectors for limb cuff inflation applications*

[1] Planned but not yet begun as of the date of publication.

— *Part 6: Connectors for neuraxial applications*

— *Part 7: Connectors with 6% (Luer) taper for intravascular or hypodermic applications*

— *Part 20: Common test methods*

In this standard, the following print types are used:

— Requirements and definitions: roman type.

— Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

— TERMS DEFINED IN CLAUSE 3 OF THIS STANDARD OR AS NOTED: SMALL CAPITALS.

In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

— "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committees that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

European Foreword

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard “within the meaning of Annex ZA", the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When the ISO or IEC standard is referred to in the ISO text standard, this must be understood as a normative reference to the parallel EN standard or dated ISO standard, as outlined below, including the foreword and the Annexes ZZ.

NOTE The way in which these references documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table – Correlations between normative references and dated EN and ISO/IEC standards

Normative references as listed in Clause 2	Equivalent dated standard	
	EN	ISO/IEC
ISO 5356-1:2004	EN 5356-1:2004	ISO 5356-1:2004
ISO 5356-1:2015	EN 5356-1:— [2]	ISO 5356-1:2015
ISO 5356-2:2006	EN 5356-2:2007	ISO 5356-2:2006
ISO 5356-2:2012	EN 5356-2:2012	ISO 5356-2:2012
ISO 8185:2007	EN 8185:2009	ISO 8185:2007
EN 13544-2:2002	EN 13544-2:2002	—
EN 13544-2:2002+A1:2009	EN 13544-2:2002+A1:2009	—
ISO 80369-1:2010	EN 80369-1:2010	ISO 80369-1:2010
ISO 80369-3:2015 [2]	EN 80369-3:— [2]	ISO 80369-3:2015 [2]
ISO 80369-20:2015	EN 80369-20:— [2]	ISO 80369-20:2015
ASTM D638-10	—	—
ASTM D790-10	—	—

[2] To be published.

Introduction

This International Standard was developed because of several incidents, with catastrophic consequences, resultant from inappropriate medication, liquid nutritional formula or air being administered intravenously. Many incidents have been reported leading to international recognition of the importance of these issues, and a need has been identified to develop specific CONNECTORS for MEDICAL DEVICES and their ACCESSORIES used to deliver fluids in other APPLICATIONS.

The ISO 80369 series was developed to prevent misconnection between SMALL-BORE CONNECTORS used in different APPLICATIONS. Part 1 specifies the requirements necessary to verify the designs and dimensions of SMALL-BORE CONNECTORS to ensure that:

a) they do not misconnect with other SMALL-BORE CONNECTORS; and

b) they safely and securely connect with their mating half.

Part 20 contains the common TEST METHODS to support the performance requirements for SMALL-BORE CONNECTORS.

This part of ISO 80369 specifies the design, the dimensions and the drawings of SMALL-BORE CONNECTORS intended for use as an ancillary port CONNECTION in a BREATHING SYSTEM and respirable driving gases APPLICATIONS. The informative Annex D through Annex G describe the methods by which this design has been assessed. Other parts of ISO 80369 include requirements for SMALL-BORE CONNECTORS used in different APPLICATION categories.

CONNECTORS manufactured to the dimensions set out within this International Standard are dimensionally incompatible with any of the other CONNECTORS for APPLICATIONS identified in the ISO 80369 series of standards for SMALL-BORE CONNECTORS, except as indicated in Annex G. If fitted to the relevant MEDICAL DEVICES and ACCESSORIES, these CONNECTORS should reduce the RISK of air, non-vascular medication and liquid nutritional formula being delivered via an alternative route, such as intravenously or via an airway device.

Small-bore connectors for liquids and gases in healthcare applications — Part 2: Connectors for breathing systems and driving gases applications

1 * Scope

This part of ISO 80369 specifies dimensions and requirements for the design and functional performance of SMALL-BORE CONNECTORS intended to be used for CONNECTIONS either as an ancillary port CONNECTION in the BREATHING SYSTEM or in the respirable driving gas APPLICATIONS of MEDICAL DEVICES and ACCESSORIES.

This part of ISO 80369 does not specify requirements for the MEDICAL DEVICES or ACCESSORIES that use these CONNECTORS. Such requirements are given in particular International Standards for specific MEDICAL DEVICES or ACCESSORIES.

This part of ISO 80369 does not specify requirements for pressurizing and depressurizing the retention mechanism (e.g. balloon) used to hold invasive respiratory MEDICAL DEVICES in place.

NOTE 1 MANUFACTURERS are encouraged to incorporate the SMALL-BORE CONNECTORS specified in this part of ISO 80369 into MEDICAL DEVICES, medical systems or ACCESSORIES, even if currently not required by the relevant particular MEDICAL DEVICE standards. It is expected that when the relevant particular MEDICAL DEVICE standards are revised, requirements for SMALL-BORE CONNECTORS, as specified in this part of ISO 80369, will be included. Furthermore, it is recognised that standards need to be developed for many MEDICAL DEVICES used for the BREATHING SYSTEM and respirable driving gas APPLICATIONS.

NOTE 2 ISO 80369-1:2010, 5.8, specifies alternative methods of compliance with ISO 80369-1:2010, for SMALL-BORE CONNECTORS intended for use as an ancillary port CONNECTION in the BREATHING SYSTEM or in the respirable driving gas APPLICATIONS of MEDICAL DEVICES or ACCESSORIES, which do not comply with this part of ISO 80369.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 Informative references are listed in the bibliography on page 58.

ISO 5356-1:2004, *Anaesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and socket*

ISO 5356-1:2015[3], *Anaesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and socket*

ISO 5356-2:2006, *Anaesthetic and respiratory equipment -- Conical connectors -- Part 2: Screw-threaded weight-bearing connectors*

[3] Both the current and previous versions of this standard are normatively referenced.

ISO 5356-2:2012[4], *Anaesthetic and respiratory equipment -- Conical connectors -- Part 2: Screw-threaded weight-bearing connectors*

ISO 8185:2007, *Respiratory tract humidifiers for medical use -- Particular requirements for respiratory humidification systems*

EN 13544-2:2002, *Respiratory therapy equipment - Part 1: Nebulizing systems and their components*

EN 13544-2:2002, *Respiratory therapy equipment - Part 1: Nebulizing systems and their components* Amendment 1:2009[5]

ISO 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80369-3:2015 [6)], *Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications*

ISO 80369-6:2015 [7)], *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for neuraxial applications*

ISO 80369-20:2015, *Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*

ASTM D638-10, *Standard test methods for tensile properties of plastics*

ASTM D790-10, *Standard test methods for flexural properties of unreinforced and reinforced plastics and electrical insulating materials*

3 Terms and definitions

For the purposes of this document, the terms and definitions specified in ISO 80369-1:2010, ISO 80369-7:2015, ISO 80369-20:2015, ISO 14971:2007 and the following apply. For convenience, the sources of all defined terms used in this document are given in Annex I.

3.1

MEDICAL GAS PIPELINE SYSTEM

complete system which comprises a supply system, a monitoring and alarm system and a distribution system with terminal units at the points where medical gases or vacuum are required

[SOURCE: ISO 7396-1:2007, definition 3.29]

[4] Both the current and previous versions of this standard are normatively referenced.

[5] Both the current and previous versions of this standard are normatively referenced.

[6)] To be published.

[7)] To be published.

196 **3.2**
197 **NORMAL USE**
198 operation, including routine inspection and adjustments by any USER, and stand-by, according to the
199 instructions for use

200 NOTE 1 to entry: NORMAL USE should not be confused with INTENDED USE. While both include the concept of use as
201 intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only
202 the medical purpose, but maintenance, service, transport, etc. as well.

203 [SOURCE: IEC 60601-1:2005+A1:2012, definition 3.97, modified, replaced 'OPERATOR' with 'USER'.]

204 **3.3**
205 **RATED**
206 <value> term referring to a value assigned by the MANUFACTURER for a specified operating condition

207 [SOURCE: IEC 60601-1:2005, definition 3.97]

208 **3.4**
209 **USER**
210 person interacting with (i.e. operating or handling) the MEDICAL DEVICE

211 Note 1 to entry: There can be more than one USER of a MEDICAL DEVICE.

212 Note 2 to entry: Common USERS include clinicians, PATIENTS, cleaners, maintenance and service personnel.

213 [SOURCE: IEC 62366-1:2015, definition 3.24]

214 **3.5**

215 **USER PROFILE**
216 summary of the mental, physical and demographic traits of an intended USER group, as well as any special
217 characteristics, such as occupational skills, job requirements and working conditions, which can have a
218 bearing on design decisions

219 [SOURCE: IEC 62366-1:2015, definition 3.29]

220 # 4 General requirements

221 ## 4.1 General requirements for the respiratory APPLICATION

222 SMALL-BORE CONNECTORS made in compliance with this standard comply with the general requirements of
223 ISO 80369-1:2010 unless otherwise indicated in this standard.

224 Because the following CONNECTORS are inadequately specified, RESP-125 and RESP-6000 SMALL-BORE
225 CONNECTORS should not, but may connect with:

226 — the cones and sockets of ISO 5356-1:2004, ISO 5356-1:2015, ISO 5356-2:2006 and ISO 5356-2:2012;

227 — the temperature sensor CONNECTOR and mating ports made in compliance with Annex DD of
228 ISO 8185:2007; and

229 — the nipples of EN 13544-2:2002 and EN 13544-2:2002+A1:2009.

230 The reference CONNECTORS for evaluation of the NON-INTERCONNECTABLE characteristics are described in
231 Annex C.

Where the design of a CONNECTOR of this standard relies on dimensions or features of the MEDICAL DEVICE or ACCESSORY to ensure NON-INTERCONNECTABLE characteristics, the NON-INTERCONNECTABLE characteristics of the CONNECTOR shall be VERIFIED.

Check compliance by applying the tests of ISO 80369-1:2010, 5.1, and ISO 80369-1:2010, Annex B. Compliance also may be shown by applying a computer aided design (CAD) analysis of the dimensions of all of the ISO 80369 series SMALL BORE CONNECTORS and the SMALL BORE CONNECTOR under test, in conjunction with physical testing of the SMALL BORE CONNECTOR per Annex B where the CAD analysis does not demonstrate the NON-INTERCONNECTABLE characteristics. When necessary, the SMALL-BORE CONNECTOR may be installed on the MEDICAL DEVICE or ACCESSORY to demonstrate compliance with the NON-INTERCONNECTABLE characteristics test requirements of ISO 80369-1:2010, Annex B.

NOTE 1 MEDICAL DEVICES using the SMALL-BORE CONNECTORS of this standard that do not rely on the dimensions or features of the MEDICAL DEVICE or ACCESSORY to ensure NON-INTERCONNECTABLE characteristics are presumed to comply with the NON-INTERCONNECTABLE characteristics test requirements of this standard.

NOTE 2 The summary of MEDICAL DEVICES and their attributes with CONNECTIONS within this APPLICATION is provided in informative Annex D.

NOTE 3 The summary of the usability requirements for CONNECTORS for this APPLICATION is provided in informative Annex E.

NOTE 4 The summary of criteria and requirements for CONNECTORS for this APPLICATION is provided in informative Annex F.

NOTE 5 The summary of assessment of the design of CONNECTORS for this APPLICATION according to ISO 80369-1:2010, Clause 7, is contained in informative Annex G.

4.2 Material used for SMALL-BORE CONNECTORS

In addition to the requirements of ISO 80369-1:2010, Clause 4, RESP-125 and RESP-6000 SMALL-BORE CONNECTORS shall be made of materials with a nominal modulus of elasticity either in flexure or in tension greater than 700 MPa.

Check compliance by application of the tests of ASTM D638-10 or ASTM D790-10.

4.3 TYPE TESTS

Compliance with the requirements of this International Standard shall be determined by TYPE TESTS.

5 SMALL-BORE CONNECTORS for the respiratory APPLICATION

5.1 Dimensional requirements for RESP-125 SMALL-BORE CONNECTORS (R1)

SMALL-BORE CONNECTORS intended for use in this APPLICATION at pressures less than 150 hPa (15 kPa) above ambient shall comply with the relevant dimensions and tolerances as given in

— Figure B.1 and Table B.1 for the male RESP-125 CONNECTOR (R1).

— Figure B.2 and Table B.2 for the female -125 CONNECTOR (R1).

Check compliance by confirming the relevant dimensions and tolerances specified in Annex B.

5.2 Dimensional requirements for RESP-6000 SMALL-BORE CONNECTORS (R2)

SMALL-BORE CONNECTORS intended to be used to convey air or oxygen from one MEDICAL DEVICE or ACCESSORY to another in driving gas APPLICATIONS for respiratory use at pressures between 15 kPa and 600 kPa above ambient shall comply with the relevant dimensions and tolerances given in

— Figure B.3 and Table B.3 for a male RESP-6000 CONNECTOR (R2).

— Figure B.4 and Table B.4 for a female RESP-6000 CONNECTOR (R2).

Check compliance by confirming the relevant dimensions and tolerances specified in Annex B.

6 Performance requirements

6.1* Leakage by pressure decay

RESP-125 and RESP-6000 SMALL-BORE CONNECTORS shall be evaluated for fluid leakage using the leakage by pressure decay TEST METHOD. When tested over a hold period between 30 s and 35 s using air as the medium, the leakage flowrate of

— a RESP-125 (R1) SMALL-BORE CONNECTOR shall not exceed 0,005 Pa•m³/s while being subjected to an applied pressure of between 12.5 kPa and 15,0 kPa.

— a RESP-6000 (R2) SMALL-BORE CONNECTOR shall not exceed 0,005 Pa•m³/s while being subjected to an applied pressure of between 1 000 kPa and 1 050 kPa.

MANUFACTURERS may use a greater applied pressure or a longer hold period.

Check for compliance by applying the tests of ISO 80369-20:2015, Annex B, while using the leakage reference CONNECTOR specified in Annex C.

6.2 Subatmospheric pressure air leakage

RESP-125 and RESP-6000 SMALL-BORE CONNECTORS shall be evaluated for subatmospheric pressure air leakage. These SMALL-BORE CONNECTORS shall not leak by more than 0,005 Pa·m³/s while being subjected to an applied subatmospheric pressure of

— between 3,0 kPa and 5,0 kPa over a hold period of between 25 s and 35 s for a RESP-125 (R1) CONNECTOR.

— between 35,0 kPa and 45,0 kPa over a hold period of between 20 s and 30 s for a RESP-6000 (R2) CONNECTOR.

MANUFACTURERS may use a greater applied subatmospheric pressure.

Check compliance by applying the tests of ISO 80369-20:2015, Annex D, while using the stress cracking reference CONNECTOR specified in Annex C.

6.3 Stress cracking

RESP-125 and RESP-6000 SMALL-BORE CONNECTORS shall be evaluated for stress cracking. These SMALL-BORE CONNECTORS shall meet the requirements of 6.1 after being subjected to stresses of ISO 80369-20:2015, Annex E.

Check compliance by applying the tests of ISO 80369-20: 2015, Annex E, while using the stress cracking reference CONNECTOR specified in Annex C.

6.4 Resistance to separation from axial load

RESP-125 and RESP-6000 SMALL-BORE CONNECTORS shall be evaluated for separation from axial load. These SMALL-BORE CONNECTORS shall not separate from the reference CONNECTOR over a hold period between 10 s and 15 s while being subjected to a disconnection applied axial force between 32 N and 35 N.

MANUFACTURERS may use a greater disconnection applied axial force or a longer hold period.

Check compliance by applying the tests of ISO 80369-20:2015, Annex F, while using the separation from axial load reference CONNECTOR specified in Annex C.

6.5 Resistance to separation from unscrewing

RESP-125 and RESP-6000 SMALL-BORE CONNECTORS shall be evaluated for separation from unscrewing. These CONNECTORS shall not separate from the reference CONNECTOR for a hold period between 10 s and 15 s while being subjected to an unscrewing torque of between 0,0198 N·m to 0,02 N·m. MANUFACTURERS may use a greater applied unscrewing torque or a longer hold period.

Check compliance by applying the tests of ISO 80369-20:2015, Annex G, while using the separation from axial load reference CONNECTOR specified in Annex C.

6.6 Resistance to overriding

RESP-125 and RESP-6000 SMALL-BORE CONNECTORS shall be evaluated for resistance to overriding. These SMALL-BORE CONNECTORS shall not override the threads or lugs of the reference CONNECTOR while being subjected to an applied torque of

— between 0,15 N·m to 0,17 N·m over a hold period between 5 s and 10 s for a RESP-125 (R1) CONNECTOR.

— between 0,22 N·m to 0,25 N·m over a hold period between 5 s and 10 s for a RESP-6000 (R2) CONNECTOR.

MANUFACTURERS may use a greater applied torque or a longer hold period.

Check compliance by applying the tests of ISO 80369-20:2015, Annex H, while using the separation from axial load reference CONNECTOR specified in Annex C.

6.7 Disconnection by unscrewing

RESP-125 and RESP-6000 SMALL-BORE CONNECTORS shall be evaluated for disconnection by unscrewing. These SMALL-BORE CONNECTOR shall separate from the reference CONNECTOR with an applied unscrewing torque of no greater than 0,35 N·m.

Check compliance by applying the tests of ISO 80369-20:2015, Annex I, while using the disconnection by unscrewing reference CONNECTOR specified in Annex C.

Annex A
(informative)

Rationale and guidance

A.1 General guidance

This Annex provides a rationale for some requirements of ISO 80369-2, and is intended for those who are familiar with the subject of ISO 80369-2 but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate any revision of this document necessitated by those developments.

A.2 Rationale for particular clauses and subclauses

The clauses and subclauses in this Annex have been numbered to correspond to the numbering of the clauses and subclauses of this document to which they refer. The numbering is, therefore, not consecutive.

Clause 1 Scope

In 2000, a Task Group of the European standards organisation CEN proposed a strategy to reduce incidents of accidental misconnection of PATIENT therapy lines by the use of a series of NON-INTERCONNECTABLE CONNECTORS, differentiated by design, for use in different medical APPLICATIONS. The strategy reserves the use of LUER CONNECTORS solely for use in MEDICAL DEVICES used to access the vascular system or for hypodermic syringes so that they can achieve their intended function. [7] [8] The CONNECTORS of this standard are reserved for use as an ancillary port CONNECTION in the BREATHING SYSTEM or to be used for a respirable gas of MEDICAL DEVICES and ACCESSORIES intended for use with a PATIENT.

MANUFACTURERS and RESPONSIBLE ORGANIZATIONS are encouraged to report their experience with the SMALL-BORE CONNECTORS specified in this part of ISO 80369 to the Secretariat of ISO/TC 210, so that it can consider this feedback during the revision of the relevant part of this series of International Standards.

Subclause 6.1 Air leakage

The test pressures chosen are the worst-case pressures that could be generated under a SINGLE FAULT CONDITION for a BREATHING SYSTEM for the RESP-125 (R1) CONNECTOR and for a MEDICAL GAS PIPELINE SYSTEM for the RESP-6000 (R2) CONNECTOR.

[8] Figures in square brackets refer to the Bibliography.