BSI Standards Publication

Medical electrical equipment

Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation

bsi.

Documents
Document Sharing Hub

Full document details: BS EN ISO 80601-2-13:2012+A2:2019

National foreword

This British Standard is the UK implementation of EN ISO 80601-2-13:2012+A2:2019. It is identical to ISO 80601-2-13:2011, incorporating amendments 1:2015 and 2:2019. It supersedes BS EN ISO 80601-2-13:2012, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by 〚A1〉 〈A1〛.

The UK participation in its preparation was entrusted to Technical Committee CH/121, Anaesthetic and respiratory equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2020
Published by BSI Standards Limited 2020

ISBN 978 0 580 95410 8

ICS 11.040.10

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 28 February 2013.

Amendments/corrigenda issued since publication

Date	Text affected
31 January 2020	Implementation of ISO amendment 1:2015 with CEN endorsement A1:2019
31 January 2020	Implementation of ISO amendment 2:2019 with CEN endorsement A2:2019

Documents
Document Sharing Hub

Full document details: BS EN ISO 80601-2-13:2012+A2:2019

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80601-2-13:2012 +A2

November 2019

ICS 11.040.10

English Version

Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation (ISO 80601-2- 13:2011)

Appareils électromédicaux - Partie 2-13: Exigences particulières de sécurité de base et de performances essentielles pour les postes de travail d'anesthésie (ISO 80601-2-13:2011)

Medizinische elektrische Geräte - Teil 2-13: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale für Anästhesie-Arbeitsplätzen (ISO 80601-2-13:2011)

This European Standard was approved by CEN on 18 November 2012.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

© 2019 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.

Ref. No. EN ISO 80601-2-13:2012/A2:2019 E

Documents
Document Sharing Hub

Full document details: BS EN ISO 80601-2-13:2012+A2:2019

European foreword

The text of ISO 80601-2-13:2011 has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 80601-2-13:2012 by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2013, and conflicting national standards shall be withdrawn at the latest by December 2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 8835-2:2009, EN ISO 8835-3:2009, EN ISO 8835-4:2009, EN ISO 8835-5:2009, EN 60601-2-13:2006.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-13:2011 has been approved by CEN as a EN ISO 80601-2-13:2012 without any modification.

Foreword to amendment A1

The text of ISO 80601-2-13:2011/Amd 1:2015 has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 80601-2-13:2012/A1:2019 by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This Amendment to the European Standard EN ISO 80601-2-13:2012 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2020, and conflicting national standards shall be withdrawn at the latest by May 2020.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-13:2011/Amd 1:2015 has been approved by CEN as EN ISO 80601-2-13:2012/A1:2019 without any modification.

AVA Documents Document Sharing Hub

Foreword to amendment A2

This document (EN ISO 80601-2-13:2012/A2:2019) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This Amendment to the European Standard EN ISO 80601-2-13:2012 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2020, and conflicting national standards shall be withdrawn at the latest by May 2020.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-13:2011/Amd 2:2018 has been approved by CEN as EN ISO 80601-2-13:2012/A2:2019 without any modification.

Documents
Document Sharing Hub

Full document details: BS EN ISO 80601-2-13:2012+A2:2019

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means to conforming to Essential Requirements of the New Approach Directive 93/42/EEC, Council Directive of 14 June 1993 on the approximation of the laws of the Member States concerning medical devices" (Medical Device Directive).

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/subclause(s) of this EN	Corresponding essential requirements of Directive 93/42/EEC	Qualifying remarks/ynotes
201.11.6.8; 201.102.3; 201.104.7	7.2	only the risks to patients during NORMAL USE are addressed
201.11.6.3; 201.11.6.8	7.3	
201.7.2.105, 201.7.9.2.14	7.5, 2nd and 3rd paragraph	
201.101.4.1.2; 201.11.6.3	7.6	IP classification according IEC 60529 is governed by EN 60601-1:2006
201.11.101; 201.104.7	8.1	Easy handling and contamination by the patients are not addressed.
201.11.101	8.6	
201.16.9.2.1; 201.16.101; 201.101.3; 201.101.4.1 201.101.4.2; 201.101.9; 201.102.5; 201.102.9; 201.103.4 to 201.103.7; 201.104.4; 201.104.5, 201.104.6; 201.105.4; 201.105.6	9.1	
201.9.4; 201.9.4.2.4.3; 201.105.7, 202; 209	9.2 (First and second indents)	Clause 202 refers to EN 60601-1-2:2007, Clause 209 refers to EN 60601-1-9:2008
201.11; 201.102.4	9.3	
201.12.4.104.1; 201.101.6.1; 201.104.2.2	10.1	

AVA Documents
Document Sharing Hub

Full document details: BS EN ISO 80601-2-13:2012+A2:2019

Clause(s)/subclause(s) of this EN	Corresponding essential requirements of Directive 93/42/EEC	Qualifying remarks/ynotes
201.7.4.2;	10.2	
201.7.4.3	10.3	
201.14	12.1	EN 62304:2006, 1.4
201.14, 201.14.101	12.1 a)	EN 62304:2006, 1.4
201.11.8.102; 201.11.8.103	12.2	
201.11.8.102	12.3	
201.12.4.104.2; 201.12.4.105; 201.12.4.106; 208	12.4	Clause 208 refers to EN 60601-1-8:2006
202	12.5	Clause 202 refers to EN 60601-1-2:2007
201.9	12.7.1	
201.9, 201.9.2.103	12.7.2	
201.9, 201.11.8.102	12.7.3	
201.15, 201.16, 201.101.4.2.1	12.7.4	Covered by compliance with EN 60601-1:2006, 15.4.1 and 16.9
201.11	12.7.5	EN 60601-1:2006, Clause 11
201.101.4.1.3; 201.101.6.2; 201.101.6.3; 201.102.2.1; 201.102.2.2; 201.102.10.4; 201.104.2.1; 201.104.5; 201.105.2.1; 201.105.2.2;	12.8.1	
201.12.4.104.2; 201.12.4.106; 201.12.4.107.1; 201.12.4.107.2; 201.12.4.107.3; 201.12.4.109; 201.101.2; 201.101.4.3; 201.102.10: 201.102.10.4; 201.104.5; 201.105.5; 201.105.8; 208	12.8.2	
201.101.6.1; 201.104.2.1;	12.9	
201.7, 201.7.2.104; 201.7.9.1; 201.102.1.1.1	13.1	
201.7, 201.7.2.3; 201.7.2.101; 201.7.2.103; 201.7.2.107; 201.7.4.2	13.2	
201.7.9.1	13.3 a)	
201.7.2.101	13.3 e)	

AVA Documents
Document Sharing Hub

Full document details: BS EN ISO 80601-2-13:2012+A2:2019

Clause(s)/subclause(s) of this EN	Corresponding essential requirements of Directive 93/42/EEC	Qualifying remarks/ynotes
201.7, 201.7.2.101	13.3 f)	The indication that the device is for single use must be consistent across the Community is not addressed in a requirement.
201.7, 201.7.9.3.102	13.3 i)	
201.7, 201.7.2 201.7.2.102, 201.7.2.103, 201.7.2.104 201.7.2.107 201.7.4.2 201.101.6.1 201.102.1.1.2 201.102.1.1.3 201.102.1.1.4 201.102.5.2 201.102.5.3 201.102.5.4 201.102.5.7 201.103.1.1 201.104.1.1 201.104.2.1 201.104.6 201.105.6	13.3 j)	
201.7, 201.7.2.3 201.104.1.1	13.3 k)	
201.7.2.101	13.3.l)	
201.7.2.102; 201.102.5.2; 201.102.5.4; 201.102.5.5; 201.102.5.6; 201.103.5; 201.103.6; 201.104.4	13.5	
201.7	13.6 a)	Covered by compliance with EN 60601-1:2006, 7.9.2
201.7	13.6 b)	Covered by compliance with EN 60601-1:2006, 7.9.2
201.7.9.2.1 201.7.9.2.14 201.11.8 201.11.8.101 201.11.8.103 201.12.4.102 201.12.4.103.3 201.12.4.106 201.12.4.107.2 201.12.4.108 201.101.1.1 201.101.1.2 201.102.1.2	13.6 c)	

AVA Documents
Document Sharing Hub

Full document details: BS EN ISO 80601-2-13:2012+A2:2019

Clause(s)/subclause(s) of this EN	Corresponding essential requirements of Directive 93/42/EEC	Qualifying remarks/ynotes
201.102.7 201.102.8.2 201.102.9.2 201.102.9.3 201.102.10.3 201.103.1.2 201.104.1.2 201.104.2.1 201.104.6 201.105.1 201.105.2.2 201.105.5		
201.7, 201.102.10.1 201.103.3.1.5 208.5.2.2	13.6 d)	maintenance and frequency covered by compliance with EN 60601-1:2006, 7.9.2.13
201.7.9.2.14	13.6 f)	
201.7 201.7.9.2.14	13.6 h), first paragraph only	Covered by compliance with EN 60601-1:2006, 7.9.2
201.7 201.7.9.2.1 201.7.9.2.8	13.6 i)	Covered by compliance with EN 60601-1:2006, 7.9
201.7.9.2.2 201.7.9.2.14	13.6 k)	
201.12.4.103 ; 201.12.4.104.1, 201.12.4.109; 201.101.6.1; 201.104.2.2;	13.6 p)	
201.7.9.2.1	13.6 q)	

AVA Documents
Document Sharing Hub

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following table ZA.102 details the relevant essential health and safety requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than essential requirements of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.102, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.102 — Relevant Essential Requirements from Directive 2006/42/EC on machinery that are addressed by this European Standard
(according to article 3 of amended Directive 93/42/EEC)

Clause(s)/subclause(s) of this EN	EHSR of Directive 2006/42/EC	Qualifying remarks/notes
201.9.2.102	1.1.4	
201.9.2.103	1.1.8	
201.7.4.2 201.9.2 201.9.2.104 201.101.6.1 201.102.1.1.2 201.102.1.1.3 201.102.9.2 201.104.1.1 201.104.2.1 206 208	1.2.2	
201.101.3 201.101.4.1.1 201.101.4.1.2 201.101.9 201.102.5 201.102.8.1 201.102.9.1 201.103.4, 201.103.5; 201.103.6 201.103.7 201.104.4 201.105.4 201.105.6	1.5.4	
201.9.2.101	1.6.2	
201.8	1.6.3	
201.7 201.7.2.106	3.6.2	Covered by compliance with EN 60601-1:2006, 7.2

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this European Standard.

AVA Documents
Document Sharing Hub

Full document details: BS EN ISO 80601-2-13:2012+A2:2019

Contents

Page

Foreword v
Introduction vi
201.1 Scope, object and related standards 1
201.2 Normative references 3
201.3 Terms and definitions 5
201.4 General requirements 9
201.5 General requirements for testing ME EQUIPMENT 11
201.6 Classification of ME EQUIPMENT and ME SYSTEMS 11
201.7 ME EQUIPMENT identification, marking and documents 11
201.8 Protection against electrical HAZARDS from ME EQUIPMENT 15
201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS 16
201.10 Protection against unwanted and excessive radiation HAZARDS 17
201.11 Protection against excessive temperatures and other HAZARDS 17
201.12 Accuracy of controls and instruments and protection against hazardous outputs 19
201.13 HAZARDOUS SITUATIONS and fault conditions 24
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 24
201.15 Construction of ME EQUIPMENT 25
201.16 ME SYSTEMS 25
201.17 Electromagnetic compatibility of ME EQUIPMENT AND ME SYSTEMS 26
201.101 Additional requirements for ANAESTHETIC GAS DELIVERY SYSTEMS 26
201.102 Additional requirements for an ANAESTHETIC BREATHING SYSTEM 32
201.103 Additional requirements for an ANAESTHETIC GAS SCAVENGING SYSTEM 39
201.104 Additional requirements for an ANAESTHETIC VAPOUR DELIVERY SYSTEM 43
201.105 Additional requirements for an ANAESTHETIC VENTILATOR 47
201.105.7 * Timed ventilatory pause 50
201.105.7.1 Expiratory pause 50
201.105.7.2 Inspiratory pause 50
201.106 Display loops 53
201.107 Clinical evaluation 53
202 Electromagnetic compatibility — Requirements and tests 54
203 General requirements for radiation protection in diagnostic X-ray equipment 54
206 Usability 54
208 General requirements, tests and guidance for ALARM SYSTEMS in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS 55
209 Requirements for environmentally conscious design 55

Documents
Document Sharing Hub

© ISO 2011 – All rights reserved

Full document details: BS EN ISO 80601-2-13:2012+A2:2019

210 PROCESS requirements for the development of physiologic closed-loop controllers 56

211 Requirements for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS used in the home healthcare 56

Annex C (informative) **Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS or their parts 57**

Annex D (informative) **Symbols on marking 67**

Annex AA (informative) **Particular guidance and rationale 69**

Annex BB (normative) **Test for flammability of anaesthetic agent 84**

Annex CC (informative) **Environmental aspects 85**

Annex DD (informative) **Reference to the essential principles 87**

Bibliography 94

Alphabetized index of defined terms used in this particular standard 96

© ISO 2011 – All rights reserved

Documents
Document Sharing Hub

Full document details: BS EN ISO 80601-2-13:2012+A2:2019

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 80601-2-13 was prepared by a joint working group of Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice,* Subcommittee SC D, *Electromedical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This first edition of ISO 80601-2-13 cancels and replaces the following:

— ISO 8835-2:2007, *Inhalational anaesthesia systems — Part 2: Anaesthetic breathing systems*

— ISO 8835-3:2007, *Inhalational anaesthesia systems — Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems*

— ISO 8835-4:2004, *Inhalational anaesthesia systems — Part 4: Anaesthetic vapour delivery devices*

— ISO 8835-5:2004, *Inhalational anaesthesia systems — Part 5: Anaesthetic ventilators*

— IEC 60601-2-13:2003, *Medical electrical equipment — Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems*

This edition constitutes a major technical revision of the material that was contained in the previous standards by consolidating it into a single document, removing duplications and inconsistencies as well as harmonization with the third edition of IEC 60601-1.

© ISO 2011 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS EN ISO 80601-2-13:2012+A2:2019

Introduction

In this International Standard, the following print types are used:

— Requirements and definitions: roman type.

— Test specifications: italic 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 the general standard, in this particular standard or as noted: small capitals.

In referring to the structure of this standard, the term

— "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

— "subclause" means a numbered subdivision of a clause (e.g. 201.7.1, 201.7.2 and 201.7.2.1 are all subclauses of Clause 201.7).

References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this International 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 International 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 AA.

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 committee that the content of this publication not be adopted for mandatory implementation nationally 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.

This International Standard considers both an ANAESTHETIC WORKSTATION supplied complete and its individual components. It has been structured to allow RESPONSIBLE ORGANIZATIONS to configure an ANAESTHETIC WORKSTATION from individual components in conformance with professional guidelines and to meet the needs of their clinical practice. In order to achieve this aim, this International Standard identifies particular

Documents
Document Sharing Hub

© ISO 2011 – All rights reserved

Full document details: BS EN ISO 80601-2-13:2012+A2:2019

requirements pertinent to specific ANAESTHETIC WORKSTATION components, and to their associated MONITORING EQUIPMENT, ALARM SYSTEM(S) and PROTECTION DEVICE(S), and defines the interfaces.

Figure 201.101 is a graphical representation of the structure of this International Standard and is provided for informational purposes only.

<table>
<tr><td colspan="3">ANAESTHETIC WORKSTATION</td></tr>
<tr><td>General requirements
Clauses 201.1 – 201.17, 201.106, 201.107, 202-211</td><td rowspan="3">MONITORING EQUIPMENT, ALARM SYSTEMS and PROTECTION DEVICES</td><td rowspan="3">Mandatory elements;
see also Table AA.1</td></tr>
<tr><td>ANAESTHETIC GAS DELIVERY SYSTEM
Clause 201.101</td></tr>
<tr><td>ANAESTHETIC BREATHING SYSTEM
Clause 201.102</td></tr>
<tr><td>ANAESTHETIC GAS SCAVENGING SYSTEM
Clause 201.103</td><td rowspan="3">MONITORING EQUIPMENT, ALARM SYSTEMS and PROTECTION DEVICES</td><td rowspan="3">Optionally present;
see also Table AA.1</td></tr>
<tr><td>ANAESTHETIC VAPOUR DELIVERY SYSTEM
Clause 201.104</td></tr>
<tr><td>ANAESTHETIC VENTILATOR
Clause 201.105</td></tr>
</table>

Figure 201.101 — Configuration of an ANAESTHETIC WORKSTATION and corresponding organization of this International Standard

© ISO 2011 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS EN ISO 80601-2-13:2012+A2:2019

Documents
Document Sharing Hub

Full document details: BS EN ISO 80601-2-13:2012+A2:2019

Medical electrical equipment —

Part 2-13:
Particular requirements for basic safety and essential performance of an anaesthetic workstation

201.1 Scope, object and related standards

〈A1〉 IEC 60601-1:2005+A1:2012 〈A1〉, Clause 1 applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard is applicable to the BASIC SAFETY and ESSENTIAL PERFORMANCE of an ANAESTHETIC WORKSTATION for administering inhalational anaesthesia whilst continuously attended by a professional OPERATOR.

This International Standard specifies particular requirements for a complete ANAESTHETIC WORKSTATION and the following ANAESTHETIC WORKSTATION components which, although considered as individual devices in their own right, may be utilized, in conjunction with other relevant ANAESTHETIC WORKSTATION components, to form an ANAESTHETIC WORKSTATION to a given specification:

— ANAESTHETIC GAS DELIVERY SYSTEM;

— ANAESTHETIC BREATHING SYSTEM;

— ANAESTHETIC GAS SCAVENGING SYSTEM;

— ANAESTHETIC VAPOUR DELIVERY SYSTEM;

— ANAESTHETIC VENTILATOR;

— MONITORING EQUIPMENT;

— ALARM SYSTEM;

— PROTECTION DEVICE.

NOTE 1 MONITORING EQUIPMENT, ALARM SYSTEMS and PROTECTION DEVICES are summarized in Table AA.1.

An ANAESTHETIC WORKSTATION supplied complete and its individual components are considered as ME EQUIPMENT or ME SYSTEMS with regard to the general standard.

NOTE 2 The applicability of this International Standard is indicated in Table AA.2.

This International Standard is also applicable to those ACCESSORIES intended by their MANUFACTURER to be connected to an ANAESTHETIC WORKSTATION where the characteristics of those ACCESSORIES can affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the ANAESTHETIC WORKSTATION.

© ISO 2011 – All rights reserved

AVA Documents Document Sharing Hub
Full document details: BS EN ISO 80601-2-13:2012+A2:2019

If a clause or subclause is specifically intended to be applicable to ANAESTHETIC WORKSTATION components only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to an ANAESTHETIC WORKSTATION and its individual components, as relevant.

HAZARDS inherent in the intended physiological function of an ANAESTHETIC WORKSTATION and its individual components within the scope of this International Standard are not covered by specific requirements in this International Standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE 3 See also 4.2 of the general standard.

This International Standard is not applicable to any ANAESTHETIC WORKSTATION intended for use with flammable anaesthetic agents, as determined by Annex BB.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for an ANAESTHETIC WORKSTATION and its individual components designed for use in the ANAESTHETIC WORKSTATION (as defined in 201.3.211) and its ACCESSORIES.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

〈A2〉 IEC 60601-1-3:2008, IEC 60601-1-9:2007+AMD1: 2013 and IEC 60601-1-11:2010 do not apply. 〈A2〉

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards, as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, 〈A1〉 IEC 60601-1:2005+A1:2012 〈A1〉 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 206.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-6 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

“Addition” means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

“Amendment” means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

© ISO 2011 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS EN ISO 80601-2-13:2012+A2:2019

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 to 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 206 for IEC 60601-1-6, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

〉A1〈 If an ANAESTHETIC WORKSTATION is supplied with physiological monitoring, having more than one APPLIED PART on the PATIENT, then IEC 60601-2-49 applies. Measured parameters related to the inherent function of an ANAESTHETIC WORKSTATION (i.e. airway pressure, ventilation volume, oxygen concentration, volatile anaesthetic agent concentration, CO_2/N_2O), including derived and related parameters such as spontaneous ventilation volume or CO_2 production, are not considered to be a PHYSIOLOGICAL MONITORING UNIT as per IEC 60601-2-49. 〉A1〈

201.2 Normative references

〉A1〈 The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 〉A1〈 For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-1:2005, Clause 2 applies, except as follows:

Replacement:

Replace references to ISO 2878, ISO 15223, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8 by the following:

ISO 2878:2005, *Rubber — Antistatic and conductive products — Determination of electrical resistance*

ISO 15223-1:—[1)], *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

IEC 60601-1-2:2007, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-1-6:2010, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*

〉A1〈 +Amendment 1:2013 〉A1〈

IEC 60601-1-8:2006, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

〉A1〈 +Amendment 1:2012 〉A1〈

Addition:

ISO 407:2004, *Small medical gas cylinders — Pin-index yoke-type valve connections* [alternative normative reference to ISO 5145]

ISO 594-2:1998[2)] , *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

1) To be published.

2) To be revised by ISO 80369-7, *Small bore connectors for liquids and gases in healthcare applications — Part 7: Connectors with 6% (Luer) taper for intravascular or hypodermic applications*, which is under preparation.

© ISO 2011 – All rights reserved

AVA Documents Document Sharing Hub
Full document details: BS EN ISO 80601-2-13:2012+A2:2019

ISO 5145:2004, *Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning* [alternative normative reference to ISO 407]

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

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

ISO 5359:2008, *Low-pressure hose assemblies for use with medical gases*

ISO 5360:2006, *Anaesthetic vaporizers — Agent-specific filling systems*

ISO 5362:2006, *Anaesthetic reservoir bags*

ISO 5367:2000, *Breathing tubes intended for use with anaesthetic apparatus and ventilators*

ISO 7396-1:2007, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 7396-2:2007, *Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems*

ISO 8836, *Suction catheters for use in the respiratory tract*

ISO 9170-1:2008, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

ISO 9170-2, *Terminal units for medical gas pipeline systems — Part 2: Terminal units for anaesthetic gas scavenging systems*

ISO 10079-1, *Medical suction equipment — Part 1: Electrically powered suction equipment — Safety requirements* [alternative normative reference to ISO 10079-3]

ISO 10079-3, *Medical suction equipment — Part 3: Suction equipment powered from a vacuum or pressure source* [alternative normative reference to ISO 10079-1]

ISO 10524-1:2006, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

ISO 80601-2-55:—[3)], *Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*

IEC 60079-11, *Explosive atmospheres — Part 11: Equipment protection by intrinsic safety "i"*

IEC 60079-20-1, *Explosive atmospheres — Part 20-1: Material characteristics for gas and vapour classification — Test methods and data*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

〚A1〛 +Amendment 1:2012 〚A1〛

IEC 60601-1-2:2007, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-1-6:2010, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*

〚A1〛 +Amendment 1:2013 〚A1〛

3) To be published.

© ISO 2011 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS EN ISO 80601-2-13:2012+A2:2019

IEC 60601-1-8:2006, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

〚A1〛 +Amendment 1:2012 〚A1〛

〚A2〛 *Text deleted* 〚A2〛

IEC 60601-1-10:2007, *Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance — Collateral standard: Requirements for the development of physiologic closed-loop controllers*

〚A1〛 +Amendment 1:2012 〚A1〛

〚A1〛 IEC 60601-2-49:2011, *Medical electrical equipment — Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment* 〚A1〛

IEC 62304:2006, *Medical device software — Software life cycle processes*

201.3 Terms and definitions

〚A1〛 For the purposes of this document, the terms and definitions given in ISO 4135:2001, IEC 60601- 1:2005+A1:2012, IEC 60601-1-2:2007, IEC 60601-1-6:2010+A1:2013, IEC 60601-1-8:2006+A1:2012 and the following apply. 〚A1〛

NOTE An index of defined terms is found at the end of this document.

Addition:

201.3.201
ACTIVE ANAESTHETIC GAS SCAVENGING SYSTEM
ANAESTHETIC GAS SCAVENGING SYSTEM in which gas flow in the DISPOSAL SYSTEM results from a POWER DEVICE

NOTE Adapted from ISO 4135:2001, definition 7.1.2.

201.3.202
AIRWAY PRESSURE
pressure at the PATIENT CONNECTION PORT

201.3.203
ANAESTHETIC BREATHING SYSTEM
inspiratory and expiratory pathways through which ANAESTHETIC GAS flows at respiratory pressure between the FRESH-GAS INLET, the PATIENT CONNECTION PORT and an EXHAUST VALVE or EXHAUST PORT

NOTE Adapted from ISO 4135:2001, definitions 3.1.6 and 4.1.1.

201.3.204
ANAESTHETIC GAS
gases and, if present, vapour of a volatile anaesthetic agent, used in anaesthesia

NOTE In parts of an ANAESTHETIC BREATHING SYSTEM, ANAESTHETIC GAS includes gases exhaled by the PATIENT.

201.3.205
ANAESTHETIC GAS DELIVERY SYSTEM
ANAESTHETIC WORKSTATION component that receives separate supplies of MEDICAL GAS(ES) and delivers mixed gases in concentrations or individual flow rates adjustable by the OPERATOR

NOTE An ANAESTHETIC GAS DELIVERY SYSTEM can include a means of flow rate adjustment control, FLOWMETERS or a gas mixer and ANAESTHETIC GAS DELIVERY SYSTEM PIPING but does not include vaporizers.

201.3.206
ANAESTHETIC GAS DELIVERY SYSTEM PIPING
all piping, including unions, from the UNIDIRECTIONAL VALVES in the pipeline inlets and from the outlets of the PRESSURE REGULATOR(S) to the means of flow rate adjustment control, as well as the piping connecting the

Documents
Document Sharing Hub

© ISO 2011 – All rights reserved

Full document details: BS EN ISO 80601-2-13:2012+A2:2019

means of flow rate adjustment control and the piping connecting the ANAESTHETIC VAPOUR DELIVERY SYSTEM to the FRESH-GAS OUTLET

NOTE ANAESTHETIC GAS DELIVERY SYSTEM PIPING includes piping leading to and from pneumatic loss of pressure ALARM SIGNAL generators, pressure indicators, the oxygen flush and gas power outlets.

201.3.207
ANAESTHETIC GAS SCAVENGING SYSTEM
PROTECTION DEVICE that is connected to an ANAESTHETIC BREATHING SYSTEM or to associated equipment for the purpose of conveying excess ANAESTHETIC GAS to an appropriate place of discharge

NOTE 1 Adapted from ISO 4135:2001, definition 7.1.1.

NOTE 2 Functionally, an ANAESTHETIC GAS SCAVENGING SYSTEM comprises three different parts: a TRANSFER SYSTEM, a RECEIVING SYSTEM and a DISPOSAL SYSTEM. These three functionally discrete parts can be either separate or sequentially combined in part or in total. In addition, one or more parts of an ANAESTHETIC GAS SCAVENGING SYSTEM can be sequentially combined with an ANAESTHETIC BREATHING SYSTEM or an ANAESTHETIC VENTILATOR, to include the TRANSFER SYSTEM or the TRANSFER and RECEIVING SYSTEM.

201.3.208
ANAESTHETIC PATIENT VALVE
valve at the PATIENT end of an ANAESTHETIC BREATHING SYSTEM that has three operating functions:

— as a UNIDIRECTIONAL VALVE to prevent flow towards the vaporizer during exhalation,

— as an inflating valve to permit intermittent positive-pressure ventilation, and

— as a unidirectional EXHAUST VALVE to prevent inhalation of air through the EXHAUST PORT during spontaneous ventilation

201.3.209
ANAESTHETIC VAPOUR DELIVERY SYSTEM
ANAESTHETIC WORKSTATION component that provides the vapour of a volatile anaesthetic agent in a calibrated concentration

NOTE Adapted from ISO 4135:2001, definition 2.2.2.

201.3.210
ANAESTHETIC VENTILATOR
ANAESTHETIC WORKSTATION component that is connected via the ANAESTHETIC BREATHING SYSTEM to the PATIENT'S airway and automatically augments or provides ventilation during anaesthesia

201.3.211
ANAESTHETIC WORKSTATION
system for administering inhalational anaesthesia that contains an ANAESTHETIC GAS DELIVERY SYSTEM, an ANAESTHETIC BREATHING SYSTEM and any required MONITORING EQUIPMENT, ALARM SYSTEMS, and PROTECTION DEVICES

NOTE The ANAESTHETIC WORKSTATION can also include, but is not limited to, one or more of the following: ANAESTHETIC VAPOUR DELIVERY SYSTEM, ANAESTHETIC VENTILATOR, ANAESTHETIC GAS SCAVENGING SYSTEM, and any associated MONITORING EQUIPMENT, ALARM SYSTEMS and PROTECTION DEVICES.

201.3.212
BREATHING TUBE
non-rigid tube used to convey ANAESTHETIC GAS between components of an ANAESTHETIC BREATHING SYSTEM

NOTE Adapted from ISO 4135:2001, definition 4.1.2.

© ISO 2011 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS EN ISO 80601-2-13:2012+A2:2019

201.3.213
CIRCLE ABSORBER ASSEMBLY
part of a CIRCLE BREATHING SYSTEM that comprises one or more carbon-dioxide-absorbent containers, INSPIRATORY and EXPIRATORY VALVES or other means of ensuring unidirectional gas flow, two ports for connection to BREATHING TUBES, a FRESH-GAS INLET, and a reservoir bag port or an ANAESTHETIC VENTILATOR port or both

201.3.214
CIRCLE BREATHING SYSTEM
ANAESTHETIC BREATHING SYSTEM in which the direction of gas flow through inspiratory and expiratory pathways is unidirectional and in which the two pathways form a circle

201.3.215
DANGER ZONE
any zone within and/or around an ANAESTHETIC WORKSTATION in which a person is subject to a RISK to their health or safety from the powered movement of the ANAESTHETIC WORKSTATION or its components

201.3.216
DELIVERED VOLUME
V_{DEL}
volume of gas delivered through a PATIENT CONNECTION PORT during a breath

NOTE 1 Adapted from ISO 4135:2001, definition 3.4.2.

NOTE 2 DELIVERED VOLUME is also referred to as tidal volume when all of the DELIVERED VOLUME enters the PATIENT'S respiratory tract. This is frequently not the case when there is significant TRACHEAL TUBE cuff leakage (as in neonates) or in non-invasive ventilation.

201.3.217
DISPOSAL HOSE
part of an ANAESTHETIC GAS SCAVENGING SYSTEM that conveys excess ANAESTHETIC GAS from the RECEIVING SYSTEM to the DISPOSAL SYSTEM

201.3.218
DISPOSAL SYSTEM
part of an ANAESTHETIC GAS SCAVENGING SYSTEM by means of which the excess ANAESTHETIC GAS is conveyed to the point of discharge

NOTE The point of discharge can be, for example, the exterior of a building or a non-recirculating extract ventilation system.

201.3.219
EXHAUST PORT
port through which waste or excess ANAESTHETIC GAS is discharged to the atmosphere or to an ANAESTHETIC GAS SCAVENGING SYSTEM

NOTE Adapted from ISO 4135:2001, definition 4.2.1.6.

201.3.220
EXHAUST VALVE
valve connected to an EXHAUST PORT

NOTE An ADJUSTABLE PRESSURE-LIMITING (APL) VALVE can be an EXHAUST VALVE.

201.3.221
EXHAUST FLOW RATE
flow rate of gas from the RECEIVING SYSTEM at the entry to the DISPOSAL SYSTEM

Documents
Document Sharing Hub

© ISO 2011 – All rights reserved

Full document details: BS EN ISO 80601-2-13:2012+A2:2019

201.3.222
FRESH GAS
respirable gas delivered to an ANAESTHETIC BREATHING SYSTEM

NOTE Adapted from ISO 4135:2001, definition 3.1.8.

201.3.223
FRESH-GAS INLET
port through which FRESH GAS enters the ANAESTHETIC BREATHING SYSTEM

NOTE Adapted from ISO 4135:2001, definition 4.2.1.5.

201.3.224
FRESH-GAS OUTLET
port through which FRESH GAS is delivered from the ANAESTHETIC GAS DELIVERY SYSTEM

NOTE Adapted from ISO 4135:2001, definition 4.2.1.1.

201.3.225
HIGH-FLOW TRANSFER AND RECEIVING SYSTEM
TRANSFER and RECEIVING SYSTEM that connects to a high-flow-rate DISPOSAL SYSTEM

201.3.226
INDUCED FLOW RATE
flow rate at the inlet of the TRANSFER SYSTEM, that is generated by the DISPOSAL SYSTEM

201.3.227
LOW-FLOW TRANSFER AND RECEIVING SYSTEM
TRANSFER and RECEIVING SYSTEM that connects to a low-flow-rate DISPOSAL SYSTEM

201.3.228
MAXIMUM EXHAUST FLOW RATE
largest EXHAUST FLOW RATE that can be accommodated without exceeding the specified limitations for INDUCED FLOW RATE

201.3.229
MAXIMUM LIMITED PRESSURE
highest pressure at the PATIENT CONNECTION PORT during NORMAL USE and under a SINGLE FAULT CONDITION

NOTE Adapted from ISO 4135:2001, definitions 3.3.3 and 3.3.4.

201.3.230
MINIMUM EXHAUST FLOW RATE
smallest EXHAUST FLOW RATE that ensures that the specified limit of SPILLAGE to atmosphere is not exceeded

201.3.231
MONITORING EQUIPMENT
ANAESTHETIC WORKSTATION component that continuously or continually measures and displays the value of a variable to the OPERATOR

201.3.232
PATIENT CONNECTION PORT
port of an ANAESTHETIC BREATHING SYSTEM, intended for connection to the connector of an airway device

NOTE Adapted from ISO 4135:2001, definition 4.2.1.2.

EXAMPLE PATIENT CONNECTION PORT can connect to a TRACHEAL TUBE, TRACHEOSTOMY TUBE, face mask or supraglottic device.

© ISO 2011 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS EN ISO 80601-2-13:2012+A2:2019

201.3.233
POWER DEVICE
component of the DISPOSAL SYSTEM of an ACTIVE ANAESTHETIC GAS SCAVENGING SYSTEM that generates the EXHAUST FLOW RATE

201.3.234
POWER SUPPLY
source of energy other than that generated directly by the human body or by gravity that makes the device function

EXAMPLE SUPPLY MAINS, INTERNAL ELECTRICAL POWER SOURCE, compressed gas from a MEDICAL GAS PIPELINE SYSTEM or cylinder.

201.3.235
PROTECTION DEVICE
device that without intervention by the OPERATOR, protects the PATIENT, OPERATOR or others from hazardous output due to incorrect delivery or removal of energy or substances

201.3.236
RECEIVING SYSTEM
part of an ANAESTHETIC GAS SCAVENGING SYSTEM that provides an interface between the TRANSFER SYSTEM and the DISPOSAL SYSTEM

201.3.237
SPILLAGE
volume of ANAESTHETIC GAS that cannot be accommodated by the ANAESTHETIC GAS SCAVENGING SYSTEM over a specified period

201.3.238
TRANSFER SYSTEM
component of an ANAESTHETIC GAS SCAVENGING SYSTEM, which can incorporate a transfer tube, that transfers ANAESTHETIC GAS from the EXHAUST PORT of an ANAESTHETIC BREATHING SYSTEM, or associated equipment to the RECEIVING SYSTEM

201.3.239
Y-PIECE
3-way connector with a PATIENT CONNECTION PORT and two ports for connection to BREATHING TUBES

〚A1〛 **201.3.240**

*** INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY SYSTEM**

ANAESTHETIC VAPOUR DELIVERY SYSTEM that

— by design is intended to be used with different ANAESTHETIC WORKSTATIONS, and
— can be exchanged by the clinical user without the use of tools and without the need for specific tests 〚A1〛

201.4 General requirements

〚A1〛 IEC 60601-1:2005+A1:2012 〚A1〛, Clause 4 applies, except as follows:

201.4.3 * ESSENTIAL PERFORMANCE

Addition:

Additional ESSENTIAL PERFORMANCE requirements are identified in the subclauses listed in Table 201.101.

© ISO 2011 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS EN ISO 80601-2-13:2012+A2:2019

Table 201.101 — Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Oxygen flow under all conditions except the failure of the oxygen supply (pipeline or cylinder) to the ANAESTHETIC WORKSTATION or the generation of a TECHNICAL ALARM CONDITION	201.12.4.107.2 (oxygen supply failure PROTECTION DEVICE) 201.101.2 (interruption of the electrical POWER SUPPLY) 201.101.8 (oxygen flush)
Delivery of a non-hypoxic gas mixture to the PATIENT or generation of a TECHNICAL ALARM CONDITION	201.11.8.102 (ALARM CONDITION for POWER SUPPLY failure) 201.11.8.103 (INTERNAL ELECTRICAL POWER SOURCE) 201.12.4 (protection against hazardous output) 201.101.4.2.3 (〈A1〉 reverse flow 〈A1〉 and cross flow PROTECTION DEVICE) 201.101.7 (gas mixers) 201.101.8 (oxygen flush)
Non-delivery of excessive concentrations of a volatile anaesthetic agent or generation of a TECHNICAL ALARM CONDITION	201.104.2 (delivered vapour concentration) 201.12.4.103.3 (anaesthetic agent MONITORING EQUIPMENT)
AIRWAY PRESSURE monitoring and associated alarm	201.12.4.109 (AIRWAY PRESSURE MONITORING EQUIPMENT)

201.4.10 POWER SUPPLY

Addition:

201.4.10.101 * Requirements for pneumatic power input

The ANAESTHETIC WORKSTATION or its individual components shall operate and meet the requirements of this International Standard throughout the RATED range of inlet pressures and shall not cause an unacceptable RISK under the SINGLE FAULT CONDITION to a maximum pressure of 1 000kPa (10 bar).

If the ANAESTHETIC WORKSTATION or individual ANAESTHETIC WORKSTATION component is intended to be connected to either

— a MEDICAL GAS PIPELINE SYSTEM complying with ISO 7396-1 via TERMINAL UNITS complying with ISO 9170-1 and flexible hose connections complying with ISO 5359, or

— a PRESSURE REGULATOR complying with ISO 10524-1,

then

— the RATED range of inlet pressures shall cover the range specified in those standards,

— the time-weighted average input flow (over 10 s) required by the ANAESTHETIC WORKSTATION or all individual ANAESTHETIC WORKSTATION components for each gas shall not exceed 60 l/min at a pressure of 280 kPa measured at the gas inlet port, with the oxygen flush not activated,

— the transient input flow shall not exceed the equivalent of 200 l/min for 3 s.

NOTE 1 Internal PRESSURE REGULATORS can be required to accommodate the RATED range of inlet pressure and the SINGLE FAULT CONDITION of maximum inlet pressure.

NOTE 2 Under the SINGLE FAULT CONDITION of overpressure of twice the maximum RATED inlet pressure, it is desirable for gas to continue to flow to the ANAESTHETIC BREATHING SYSTEM. Under this condition, the flow rate from the ANAESTHETIC WORKSTATION is likely to be outside its specification.

© ISO 2011 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS EN ISO 80601-2-13:2012+A2:2019

NOTE 3 Flow values are expressed under STPD conditions (Standard Temperature and Pressure Dry); see 201.7.4.3.

Check compliance by functional testing in NORMAL USE and under NORMAL CONDITION with the most adverse operating settings (e.g. highest driving gas consumption, highest FRESH GAS delivery and highest RATED gas consumption at any gas POWER SUPPLY output, if provided, but without activating the oxygen flush).

201.5 General requirements for testing ME EQUIPMENT

〖A1〗 IEC 60601-1:2005+A1:2012 〈A1〉, Clause 5 applies, except as follows:

Addition:

201.5.101 Additional general requirements for testing of ANAESTHETIC WORKSTATIONS and ANAESTHETIC WORKSTATION components

201.5.101.1 Test conditions

The ambient temperature for the duration of each test should be between 20 °C and 25 °C, except where otherwise stated.

The accuracy of the test equipment used to carry out gas measurements shall be ±5 % of the variable to be measured, except where otherwise stated. Dry air should be used as the test gas, except where otherwise stated.

201.5.101.2 * Gas flow rate and leakage specifications

Gas flow rate, volume and leakage specifications in this International Standard are expressed at STPD (Standard Temperature and Pressure Dry) except for those associated with the ANAESTHETIC BREATHING SYSTEM, which are expressed at BTPS (Body Temperature and Pressure Saturated).

NOTE 1 For the purposes of this International Standard, STPD is 101,3 kPa at an operating temperature of 20 °C.

NOTE 2 For the purposes of this International Standard, BTPS is local atmospheric pressure and a relative humidity of 100 % at an operating temperature of 37 °C.

Correct all test measurements to STPD or BTPS, as appropriate.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, Clause 6 applies.

201.7 ME EQUIPMENT identification, marking and documents

〖A1〗 IEC 60601-1:2005+A1:2012 〈A1〉, Clause 7 applies, except as follows:

201.7.2.3 * Consult ACCOMPANYING DOCUMENTS

Replacement:

The ANAESTHETIC WORKSTATION and its individual components shall be marked with the safety sign for the mandatory action: “follow instructions for use”, ISO 7010-M002 (see IEC 60601-1:2005+TC1, Table D.2, number 10).

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

Addition:

〖A1〗 201.7.2.21 * Mass of MOBILE EQUIPMENT

Replacement:

The ANAESTHETIC WORKSTATION shall be legibly marked with its maximum mass in kilograms [see also 201.101.1.1 k)]. 〈A1〉

© ISO 2011 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS EN ISO 80601-2-13:2012+A2:2019

201.7.2.101 Marking with year of manufacture or use-by date

The ANAESTHETIC WORKSTATION and its OPERATOR-detachable components or their packaging shall be marked with the year of manufacture except for single use devices and those covered by a use-by date (see symbol 5.1.4 of ISO 15223-1:—).

NOTE The MANUFACTURER'S attention is drawn to the importance of consistent use of indication for single-use devices.

If applicable, the ANAESTHETIC WORKSTATION and its OPERATOR-detachable components or their packaging shall be marked with a use-by date (see symbol 5.1.4 of ISO 15223-1:—).

Check compliance by inspection.

201.7.2.102 OPERATOR-detachable, flow-direction-sensitive components

Any OPERATOR-detachable components of the ANAESTHETIC WORKSTATION that are flow-direction-sensitive, unless designed in such a way that prevents incorrect assembly, shall be marked with an arrow showing the direction of flow.

Check compliance by inspection.

201.7.2.103 OPERATOR-accessible GAS-SPECIFIC inlet and outlet

Each OPERATOR-accessible GAS-SPECIFIC inlet and outlet shall be marked with the gas name or chemical symbol in accordance with Table 6 of ISO 5359:2008. If colour coding is used it shall be in accordance with Table 6 of ISO 5359:2008.

Check compliance by inspection.

201.7.2.104 * OPERATOR-accessible gas POWER SUPPLY outlet

Each OPERATOR-accessible gas POWER SUPPLY outlet shall be marked with the RATED output pressure and RATED flow rate.

EXAMPLE 1 280 kPa - 600 kPa, 20 l/min.

EXAMPLE 2 280 kPa - 600 kPa, 20 l/min - 40 l/min.

Check compliance by inspection.

201.7.2.105 Devices containing phthalates

If parts of the ANAESTHETIC WORKSTATION or its individual components in contact with gas to be inhaled by the PATIENT contain phthalates, which are known to be carcinogenic, mutagenic or toxic to reproduction, the ANAESTHETIC WORKSTATION and its individual components shall be marked accordingly.

NOTE The symbol given in Reference [18] can be used.

Check compliance by inspection.

〖A1〗 *Text deleted* 〖A1〗

Documents
Document Sharing Hub
© ISO 2011 – All rights reserved
Full document details: BS EN ISO 80601-2-13:2012+A2:2019

201.7.2.107 Cylinder and pipeline pressure indicators

All cylinder and pipeline pressure indicators shall be identified with the gas name or the chemical symbol in accordance with Table 6 of ISO 5359:2008. If colour coding is used it shall be in accordance with Table 6 of ISO 5359:2008.

Check compliance by inspection.

201.7.4.2 * Control devices

Addition:

Each GAS-SPECIFIC flow rate adjustment control of an ANAESTHETIC GAS DELIVERY SYSTEM shall be identified with the gas that it controls by the gas name or the chemical symbol in accordance with Table 6 of ISO 5359:2008. If colour coding is used it shall be in accordance with Table 6 of ISO 5359:2008. Each flow rate adjustment control of an ANAESTHETIC GAS DELIVERY SYSTEM shall be marked with an indication of how to increase and decrease the gas flow rate. If applicable, the point of reference for reading the flow rate indication shall be identified.

NOTE A multifunctional control that can be used to control multiple items is not considered a GAS-SPECIFIC control.

The oxygen flush control shall be marked with one of the following:

— "Oxygen Flush", or

— "O_2 Flush", or

— "O_2 +".

201.7.4.3 * Unit of measure

Addition:

All gas volume, flow and leakage specifications shall be expressed as STPD, except those associated with the ANAESTHETIC BREATHING SYSTEM, which shall be expressed as BTPS.

NOTE 1 For the purposes of this International Standard, STPD is 101,3 kPa at an operating temperature of 20 °C.

NOTE 2 For the purposes of this International Standard, BTPS is local atmospheric pressure and a relative humidity of 100 % at an operating temperature of 37 °C.

201.7.9.1 General

Replacement:

Replace the first dash with:

— name or trade name and address of

  — the MANUFACTURER, and

  — where the MANUFACTURER does not have an address within the locale, an authorized representative within the locale,

to which the RESPONSIBLE ORGANIZATION can refer.

© ISO 2011 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS EN ISO 80601-2-13:2012+A2:2019

201.7.9.2.1 General

Addition:

The instructions for use shall contain the date of issue or the latest revision.

For ANAESTHETIC WORKSTATIONS not supplied complete, the instructions for use shall contain, as far as applicable, information about the MONITORING EQUIPMENT, ALARM SYSTEMS and PROTECTION DEVICES required by this International Standard and how to connect them.

201.7.9.2.2 * Warnings and safety notices

Addition:

The instructions for use shall contain a statement to the effect that, in case of ANAESTHETIC WORKSTATION failure, the lack of immediate access to appropriate alternative means of ventilation can result in PATIENT injury.

EXAMPLE An alternative means of ventilation would be a self-inflating, manually-powered RESUSCITATOR (see ISO 10651-4) with mask.

201.7.9.2.8 * Start-up PROCEDURE

Amendment:

Delete the given EXAMPLE and add the following text at the end of the subclause:

The instructions for use shall contain at least one OPERATOR pre-use checklist.

EXAMPLE 1 Beginning of day or shift pre-use checklist.

EXAMPLE 2 Between PATIENTS pre-use checklist.

NOTE Attention is drawn to additional pre-use checklists required by regional or national medical associations or authorities with jurisdiction.

Electronic displays integral to, or provided with, the ANAESTHETIC WORKSTATION or its individual components may be used to provide such a pre-use checklist.

201.7.9.2.14 ACCESSORIES, supplementary equipment, used material

Addition:

The instructions for use of the ANAESTHETIC WORKSTATION and its individual components shall include the following:

aa) information on the method of enabling the ANAESTHETIC WORKSTATION or its individual components, including the MONITORING EQUIPMENT, ALARM SYSTEMS and PROTECTION DEVICES, required by this International Standard; this information may form part of the pre-use checklist (see 201.7.9.2.8);

bb) the conditions under which the measured values are displayed, e.g. BTPS, STPD;

cc) where an ANAESTHETIC WORKSTATION is not supplied complete, a statement to the effect that whoever assembles the ANAESTHETIC WORKSTATION from individual components shall provide the pre-use checklist for the ANAESTHETIC WORKSTATION (see 201.7.9.2.8);

dd) where applicable, a statement to the effect that a malfunction of the MEDICAL GAS PIPELINE SYSTEM can cause one or more ANAESTHETIC WORKSTATIONS and other ANAESTHETIC WORKSTATION components connected to the MEDICAL GAS PIPELINE SYSTEM to stop their operation simultaneously; this is not applicable to ANAESTHETIC WORKSTATIONS that only use cylinders for gas supply;

© ISO 2011 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS EN ISO 80601-2-13:2012+A2:2019

ee) where applicable, disclosure of the presence of all natural rubber latex-based components and their location (see also Symbol 5.4.5 in ISO 15223-1:—;

ff) where applicable, whether the ANAESTHETIC WORKSTATION or its individual components is/are suitable for use in a magnetic resonance imaging (MRI) environment and any related restrictions;

gg) if an ANAESTHETIC WORKSTATION or its individual components is/are used for the treatment of children or treatment of pregnant or nursing women, the RESIDUAL RISK from phthalates that are carcinogenic, mutagenic or toxic to reproduction;

hh) for single-use ACCESSORIES to the ANAESTHETIC WORKSTATION or its individual components, disclosure of the RISKS associated with reusing; this information may be given upon request.

201.7.9.3 Technical description

Addition:

201.7.9.3.101 Components

The technical description shall describe the maximum weight of components, as well as the height of and length of arms on which these components may be mounted on the ANAESTHETIC WORKSTATION or its individual components so as not to compromise the stability requirements tested in 〚A1〛 IEC 60601-1:2005+A1:2012 〚A1〛, Clause 9.

Check compliance by inspection of the technical description.

201.7.9.3.102 ANAESTHETIC WORKSTATIONS intended to be mounted to a wall or ceiling pendant

For ANAESTHETIC WORKSTATIONS intended to be mounted to a wall or a ceiling pendant and that are not considered mobile equipment and consequently need not comply with the requirement on moving over a threshold in 201.9.4.2.4.3, the technical description shall contain a warning to the effect of: “Warning: This device, when removed from its wall or ceiling mount, does not meet the stability requirements of IEC 80601-2-13 and IEC 60601-1 respectively. Special caution has to be taken.” The technical description shall contain any additional handling instructions necessary to allow transport with an acceptable RISK according to the RISK MANAGEMENT FILE.

Check compliance by inspection of the technical description.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

〚A1〛 IEC 60601-1:2005+A1:2012 〚A1〛, Clause 8 applies, except as follows:

201.8.11.3 POWER SUPPLY CORDS

Addition:

201.8.11.3.101 * Additional requirements for POWER SUPPLY CORDS

Unless the ANAESTHETIC WORKSTATION or its individual components automatically switch over to an INTERNAL ELECTRICAL POWER SOURCE (see 201.11.8.102) or the functionality of the complete ANAESTHETIC WORKSTATION can be restored in less than 30 s following the restoration of power, the POWER SUPPLY CORD of the ANAESTHETIC WORKSTATION or its individual components shall be a non-detachable cord or shall be protected against accidental disconnection.

Check compliance by inspection. For an ANAESTHETIC WORKSTATION and its individual components provided with an APPLIANCE COUPLER, subject the DETACHABLE POWER SUPPLY CORD to an axial pull of force for 1 min as shown in Table 201.102. During the test, the MAINS CONNECTOR shall not become disconnected from the APPLIANCE INLET, and the ME EQUIPMENT shall continue to function normally.

© ISO 2011 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS EN ISO 80601-2-13:2012+A2:2019

Table 201.102 — Force of axial pull

Mass (m) of ME EQUIPMENT kg	Pull force N
m ≤ 1	30
1 < m ≤ 4	60
m > 4	100

201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS

〈A1〉 IEC 60601-1:2005+A1:2012 〈A1〉, Clause 9 applies, except as follows:

201.9.2.1 General

Addition:

Where the direction of movement of a moving part needs to be known in order to avoid a HAZARDOUS SITUATION, the direction of movement shall be marked on the moving part or its housing.

Check compliance by inspection.

201.9.2 HAZARDS associated with moving parts

Addition:

201.9.2.101 Maintenance points

Any maintenance points shall be located outside DANGER ZONES and adjustment, maintenance, repair, cleaning and servicing operations shall be possible when the ANAESTHETIC WORKSTATION is not being operated.

Where this is not achievable, alternative means of RISK mitigation, e.g. alarming and information of safety and training, are permitted to reduce the RISK to acceptable levels.

Check compliance by inspection of the RISK MANAGEMENT FILE and USABILITY ENGINEERING FILE.

201.9.2.102 * Lighting

ANAESTHETIC WORKSTATIONS shall be supplied with lighting where the absence thereof causes an unacceptable RISK.

NOTE Attention is drawn to areas of shadows likely to cause nuisance, irritating dazzles, dangerous stroboscopic effects on moving parts, to internal parts requiring frequent inspection and adjustment, and to maintenance areas.

Check compliance by inspection of the RISK MANAGEMENT FILE and USABILITY ENGINEERING FILE.

201.9.2.103 * Integrated seating

Where a seat for the OPERATOR is an integral part of the ANAESTHETIC WORKSTATION, the seat shall

— enable the OPERATOR to maintain a stable position,

— be adaptable for the OPERATOR's distance from the control device,

— be adaptable for the OPERATOR, e.g. arm length, height, etc.,

— be designed to minimize transmission of vibrations to the OPERATOR,

© ISO 2011 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS EN ISO 80601-2-13:2012+A2:2019

— withstand maximum operational stresses, and

— be provided with slip-resistant footrests where no floor is underneath the OPERATOR.

Check compliance by functional testing.

201.9.2.104 * Arrangement of control positions

For ANAESTHETIC WORKSTATIONS which contain one or more DANGER ZONES

— the OPERATOR shall be able to ensure, from each control position, that no one is in the DANGER ZONE(S), or

— the control system shall be designed in such a way that starting is prevented while someone is in the DANGER ZONE, or

— an audible or visual ALARM SIGNAL shall be given long enough before the ANAESTHETIC WORKSTATION is started to allow anyone wholly or partially in a DANGER ZONE to leave the area.

Where there is more than one control position for an ANAESTHETIC WORKSTATION, the control systems shall be designed in such a way that the use of one of them precludes the use of the others, except for stop controls and emergency stops.

When an ANAESTHETIC WORKSTATION has two or more operating positions, each position shall be provided with all the required control devices without the OPERATORS hindering or putting each other into a HAZARDOUS SITUATION.

Check compliance by visual inspection and functional testing.

201.9.4 Instability HAZARDS

〖A1〗 IEC 60601-1:2005+A1:2012 〖A1〗, 9.4 applies, except as follows:

201.9.4.2.4.3 Movement over a threshold

Amendment:

〖A1〗 ANAESTHETIC WORKSTATIONS that are intended only to be used when mounted to a wall or pendant, but may need to be removed from the wall or pendant for service or at initial installation, are not considered MOBILE EQUIPMENT and the threshold test specified in IEC 60601-1:2005+A1:2012, 9.4.2.4.3 does not apply. Such non-MOBILE machines can use small casters to aid service and installation of the device. See also 201.7.9.3.102. 〖A1〗

201.10 Protection against unwanted and excessive radiation HAZARDS

〖A1〗 IEC 60601-1:2005+A1:2012 〖A1〗, Clause 10 applies.

201.11 Protection against excessive temperatures and other HAZARDS

〖A1〗 IEC 60601-1:2005+A1:2012 〖A1〗, Clause 11 applies, except as follows:

201.11.6.3 SPILLAGE on ME EQUIPMENT and ME SYSTEMS

Replacement:

The ANAESTHETIC WORKSTATION and its individual components shall be so constructed that SPILLAGE does not wet parts which, when wetted, pose an unacceptable RISK.

© ISO 2011 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS EN ISO 80601-2-13:2012+A2:2019

Check compliance by the following test:

Test the ANAESTHETIC WORKSTATION and its individual components under the least favourable specified working conditions, but in accordance with the instructions for use. Pour a quantity of 200 ml of normal tap water steadily on an arbitrary point on the top surface of the ANAESTHETIC WORKSTATION and its individual components, for approximately 15 s, from a height not exceeding 5 cm. After the test, the ANAESTHETIC WORKSTATION and its individual components shall comply with all the requirements of this International Standard for NORMAL CONDITION.

201.11.6.8 Compatibility with substances used with the ME EQUIPMENT

Addition:

The ANAESTHETIC WORKSTATION and its individual components shall be designed and manufactured to minimize health RISKS due to substances leached or leaking from the ANAESTHETIC WORKSTATION or its individual components during NORMAL USE. Particular attention shall be paid to the toxicity of materials and their compatibility with substances and gases with which they come into contact during NORMAL USE.

NOTE Attention is drawn to substances which are carcinogenic, mutagenic or toxic to reproduction.

201.11.8 Interruption of the POWER SUPPLY/SUPPLY MAINS to ME EQUIPMENT

Addition:

201.11.8.101 * General requirements

The instructions for use shall describe the functioning of the ANAESTHETIC WORKSTATION or its individual components after interruption of the POWER SUPPLY, and where applicable following a switchover to an INTERNAL ELECTRICAL POWER SOURCE. Particular emphasis shall be placed on the flow rate and composition of the FRESH GAS and the behaviour of any OPERATOR-accessible gas POWER SUPPLY outlet under these circumstances.

Check compliance by inspection of the instructions for use.

201.11.8.102 * ALARM CONDITION for POWER SUPPLY failure

The ANAESTHETIC WORKSTATION shall be equipped with an ALARM SYSTEM that includes a POWER SUPPLY failure ALARM SIGNAL that indicates when the POWER SUPPLY is outside the range specified by the MANUFACTURER. The ALARM SIGNALS for the POWER SUPPLY failure ALARM CONDITION shall be

— generated for at least 7 s if pneumatically generated, or

— at least 5 bursts and a HIGH PRIORITY alarm that complies with IEC 60601-1-8, if electronically generated.

EXAMPLE The Ritchie Whistle is a pneumatic alarm sound generator.

NOTE 1 The POWER SUPPLY failure TECHNICAL ALARM CONDITION applies to the supply mains, an internal electrical power source or pneumatic (driving) power supply.

NOTE 2 The 7 s duration of the ALARM SIGNALS for the POWER SUPPLY failure ALARM CONDITION is measured exclusive of any INTERBURST INTERVAL.

The A-weighted sound pressure level shall be at least 2 dB above a white background sound level of 55 dB when tested as described in ISO 3746.

If the normal operation of the ANAESTHETIC WORKSTATION or its individual components is maintained by the automatic switchover to an INTERNAL ELECTRICAL POWER SOURCE or alternate pneumatic POWER SUPPLY, the POWER SUPPLY failure HIGH PRIORITY TECHNICAL ALARM CONDITION shall not occur. Any such switchover to an INTERNAL ELECTRICAL POWER SOURCE or alternate pneumatic POWER SUPPLY shall be indicated by an INFORMATION SIGNAL or a LOW PRIORITY TECHNICAL ALARM CONDITION.

© ISO 2011 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS EN ISO 80601-2-13:2012+A2:2019

Check compliance by functional testing.

201.11.8.103 * INTERNAL ELECTRICAL POWER SOURCE

If the ANAESTHETIC WORKSTATION or its individual components has/have an INTERNAL ELECTRICAL POWER SOURCE,

a) it/they shall be equipped with:

1) a means of determining the state of the INTERNAL ELECTRICAL POWER SOURCE; this means may be qualitative;

EXAMPLE 1 An indication of the remaining time provided by the INTERNAL ELECTRICAL POWER SOURCE.

EXAMPLE 2 An indication of the percentage of the remaining capacity provided by the INTERNAL ELECTRICAL POWER SOURCE.

EXAMPLE 3 A fuel gauge of the remaining capacity provided by the INTERNAL ELECTRICAL POWER SOURCE.

NOTE An uncalibrated fuel gauge that only indicates the state of the power source could be qualitative.

2) an ALARM SYSTEM that is equipped with a TECHNICAL ALARM CONDITION of at least MEDIUM PRIORITY that indicates when the INTERNAL ELECTRICAL POWER SOURCE nears depletion; this ALARM CONDITION shall occur prior to the loss of function;

EXAMPLE 4 A MEDIUM PRIORITY TECHNICAL ALARM CONDITION 5 min prior to the loss of all function.

b) the instructions for use shall include the following:

1) the operational time of the INTERNAL ELECTRICAL POWER SOURCE when fully charged;

2) the behaviour after a switchover to the INTERNAL ELECTRICAL POWER SOURCE;

3) the behaviour while the INTERNAL ELECTRICAL POWER SOURCE is recharging.

Check compliance by functional testing and inspection of the instructions for use.

201.11.101 Packaging systems for components intended to be sterilized

Packaging systems shall be designed to maintain components at their intended level of cleanliness and to reduce the RISK of microbial contamination.

Check compliance by inspection.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

〈A1〉 IEC 60601-1:2005+A1:2012 〈A1〉, Clause 12 applies, except as follows:

201.12.4 Protection against hazardous output

Addition:

201.12.4.101 * Accidental adjustment of operating controls

A means of protection against accidental adjustment of operating controls that can create a HAZARDOUS SITUATION shall be provided. This includes the accidental turning off of the ANAESTHETIC WORKSTATION or its individual components.

© ISO 2011 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS EN ISO 80601-2-13:2012+A2:2019