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Medical electrical equipment —

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

Appareils électromédicaux —

Partie 2-13: Exigences particulières de sécurité de base et de performance essentielle pour les systèmes d'anesthésie

Reference number
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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.

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

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>
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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