

---

---

**Medical electrical equipment —**  
**Part 2-13:**  
**Particular requirements for basic**  
**safety and essential performance of an**  
**anaesthetic workstation**

**AMENDMENT 1**

iTeh STANDARD PREVIEW  
(standards.iteh.ai)

*Appareils électromédicaux —*

*Partie 2-13: Exigences particulières de sécurité de base et de*  
*performances essentielles pour les postes de travail d'anesthésie*

<https://standards.iteh.ai/catalog/standards/sist/4486778-cl04-44a1-8d22-7bf01e90a400/iso-80601-2-13-2011-amd-1-2015>

**AMENDEMENT 1**

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

ISO 80601-2-13:2011/Amd.1:2015  
<https://standards.iteh.ai/catalog/standards/sist/f4f86778-cf04-44a1-8d22-7bf01e908818/iso-80601-2-13-2011-amd-1-2015>



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2015

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Published in Switzerland

## Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work. In the field of information technology, ISO and IEC have established a joint technical committee, ISO/IEC JTC 1.

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 document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://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 and IEC 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 (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.

The committee responsible for this document is 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*.

## Introduction

The first edition of IEC 80601-2-13 was published in 2011. This amendment is intended to update the references to IEC 60601-1:2005 to include Amendment 1:2012, to update the references to IEC 60601-1-6:2010 to include Amendment 1:2013, to update the references to IEC 60601-1-8:2006 to include Amendment 1:2012 and to update the references to IEC 60601-1-10 to include Amendment 1:2012. This amendment also introduces technical modifications to clarify the relationship between this standard and IEC 60601-2-49 and to further specify ACCESSORIES. It amends requirements on the following aspects, in part due to the publication of the before-mentioned amendments:

- addition of a definition on INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY SYSTEM;
- marking the mass of MOBILE ME EQUIPMENT;
- movement over a threshold;
- rough handling test;
- MULTIPLE SOCKET-OUTLETS;
- specific requirements on ANAESTHETIC GAS DELIVERY SYSTEMS and ANAESTHETIC BREATHING SYSTEMS including instructions for use;
- vapour concentration during and after oxygen flush;
- inspiratory pause.

Where appropriate, this amendment also includes modifications of specific informative annexes related to the amended requirements as listed above. Finally, minor editorial updates were made.

[ISO 80601-2-13:2011/Amd 1:2015  
https://standards.iteh.ai/catalog/standards/sist/f4f86778-cf04-44a1-8d22-7bf01e908818/iso-80601-2-13-2011-amd-1-2015](https://standards.iteh.ai/catalog/standards/sist/f4f86778-cf04-44a1-8d22-7bf01e908818/iso-80601-2-13-2011-amd-1-2015)

# Medical electrical equipment —

## Part 2-13:

## Particular requirements for basic safety and essential performance of an anaesthetic workstation

### AMENDMENT 1

#### 201.1 Scope, object and related standards

Replace IEC 60601-1:2005 by IEC 60601-1:2005+A1:2012.

#### 201.1.4 \* Particular standards

Replace IEC 60601-1:2005 by IEC 60601-1:2005+A1:2012.

Add the following paragraph at the end of this subclause:

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<sub>2</sub>/N<sub>2</sub>O), including derived and related parameters such as spontaneous ventilation volume or CO<sub>2</sub> production, are not considered to be a PHYSIOLOGICAL MONITORING UNIT as per IEC 60601-2-49.

#### 201.2 Normative references

In the existing introductory paragraph, replace the first sentence with:

*The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application.*

Add the following reference:

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*

Amend the following existing references:

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

+Amendment 1:2012

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

+Amendment 1:2013

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*

+Amendment 1:2012

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*

+Amendment 1:2012

### 201.3 Terms and definitions

*Replace the introductory sentence by the following sentence:*

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.

*Add the following new term and definition:*

#### 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

### 201.4 General requirements

*Replace IEC 60601-1:2005 by IEC 60601-1:2005+A1:2012.*

#### Table 201.101 — Distributed **ESSENTIAL PERFORMANCE requirements**

*In the second column, fourth line, replace “reserve flow” by “reverse flow”.*

### 201.5 General requirements for testing ME EQUIPMENT

*Replace IEC 60601-1:2005 by IEC 60601-1:2005+A1:2012.*

### 201.7 ME EQUIPMENT identification, marking and documents

*Replace IEC 60601-1:2005 by IEC 60601-1:2005+A1:2012.*

*Add the following subclause:*

#### 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)].

#### 201.7.2.106 \* Marking with mass

*Delete this subclause completely.*

#### 201.7.9.3.101 Components

*Replace IEC 60601-1:2005 by IEC 60601-1:2005+A1:2012.*

### 201.8 Protection against electrical HAZARDS from ME EQUIPMENT

*Replace IEC 60601-1:2005 by IEC 60601-1:2005+A1:2012.*

## 201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS

Replace IEC 60601-1:2005 by IEC 60601-1:2005+A1:2012.

### 201.9.4 Instability HAZARDS

Replace IEC 60601-1:2005 by IEC 60601-1:2005+A1:2012.

#### 201.9.4.2.4.3 Movement over a threshold

Replace the text by the following text:

*Amendment:*

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.

*The first paragraph*

*("In the requirement replace the height of the threshold by 10 mm (instead of 20 mm) and in the test method replace the height of the solid vertical plane obstruction by 10 mm (instead of 20 mm.")*

*is deleted.*

### 201.10 Protection against unwanted and excessive radiation HAZARDS

Replace IEC 60601-1:2005 by IEC 60601-1:2005+A1:2012.

### 201.11 Protection against excessive temperatures and other HAZARDS

Replace IEC 60601-1:2005 by IEC 60601-1:2005+A1:2012.

### 201.12 Accuracy of controls and instruments and protection against hazardous outputs

Replace IEC 60601-1:2005 by IEC 60601-1:2005+A1:2012.

#### 201.12.4.102 \* Additional requirements for ANAESTHETIC WORKSTATIONS

Correct the reference in the 9<sup>th</sup> list item and correct the corresponding text in Table 201.C.103 (ACCOMPANYING DOCUMENTS, general) to read:

- ANAESTHETIC BREATHING SYSTEM continuing-positive-pressure ALARM CONDITION complying with 201.12.4.106;

### 201.13 HAZARDOUS SITUATIONS and fault conditions

Replace IEC 60601-1:2005 by IEC 60601-1:2005+A1:2012.

### 201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Replace IEC 60601-1:2005 by IEC 60601-1:2005+A1:2012.

### 201.15 Construction of ME EQUIPMENT

Replace IEC 60601-1:2005 by IEC 60601-1:2005+A1:2012.

*Add the following subclause:*

### **201.15.3.5 Rough handling test**

*Amend as follows:*

For an ANAESTHETIC WORKSTATION with a weight exceeding 125 kg in its NOMINAL configuration and only movable manually, the speed in a) ascending step shock and b) descending step shock shall be reduced from 0,8 m/s to 0,4 m/s.

### **201.16 ME SYSTEMS**

*Replace IEC 60601-1:2005 by IEC 60601-1:2005+A1:2012.*

#### **201.16.9.2.1 MULTIPLE SOCKET-OUTLET**

*Replace the existing text by the following:*

*Delete the second dash of 16.9.2.1 a) and add the following text under the last list item in 16.9.2.1 a):*

An ANAESTHETIC WORKSTATION may provide MULTIPLE SOCKET-OUTLETS that can accept standard MAINS PLUGS of the kind specified in IEC/TR 60083.

*Addition:*

*Add the following list item:*

ee) The ANAESTHETIC WORKSTATION and each MULTIPLE SOCKET-OUTLET which can accept a standard MAINS PLUG shall be provided with separate fuses or over-current releases as required for a single piece of ME EQUIPMENT in IEC 60601-1:2005+A1:2012, 8.11.5.

These fuses or over-current releases shall be designed such that the ANAESTHETIC WORKSTATION including the MULTIPLE SOCKET-OUTLET maintain normal function with each MULTIPLE SOCKET-OUTLET loaded to the maximum rating.

If any MULTIPLE SOCKET-OUTLET is overloaded by a factor of  $7,5 \pm 2,5$ , all remaining MULTIPLE SOCKET-OUTLETS and the ANAESTHETIC WORKSTATION shall maintain normal function.

*Check compliance by visual inspection and functional testing.*

*Replace the 3<sup>rd</sup> dash of 16.9.2.1 c) by:*

- PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS shall comply with 8.6, except that the total impedance of the protective earth path for an ANAESTHETIC WORKSTATION may be up to 400 mΩ, or higher if the conditions of 8.6.4 b) are satisfied.

### **201.101 Additional requirements for ANAESTHETIC GAS DELIVERY SYSTEMS**

#### **201.101.1.1 Instructions for use**

*Amend this subclause and the corresponding text in Table 201 C.103 (ACCOMPANYING DOCUMENTS, general) as follows:*

*Amend item g) as follows:*

- g) if the ANAESTHETIC GAS DELIVERY SYSTEM is designed to be equipped with an INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY SYSTEM, a statement to the effect that the INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY SYSTEM used with the ANAESTHETIC GAS DELIVERY SYSTEM shall comply with this International Standard;



Add a new list item k):

- k) the mass in kilograms (kg) in the NOMINAL configuration and a definition of the NOMINAL configuration. The mass in kilograms (kg) shall be disclosed for each ACCESSORY with a mass exceeding 1,5 kg.

#### **201.101.4.1.4 \* Reserve oxygen supply**

Amend this subclause as follows:

In addition to a connection for the main oxygen supply, the ANAESTHETIC GAS DELIVERY SYSTEM shall be equipped with means of connection to a reserve (back-up) oxygen supply.

Add a new Subclause 201.101.10:

#### **201.101.10 Interface to INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY SYSTEMS**

For ANAESTHETIC GAS DELIVERY SYSTEMS intended to be used with INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY SYSTEMS the flow of gas from the oxygen flush shall be delivered to the FRESH-GAS OUTLET without passing through an anaesthetic vapour delivery module.

When the FRESH-GAS OUTLET is open to atmosphere, the pressure at the outlet from the ANAESTHETIC VAPOUR DELIVERY SYSTEM shall not increase by more than 10 kPa above its normal working pressure and not decrease by more than 10 kPa below its normal working pressure when the oxygen flush is operated throughout the RATED range of inlet pressure.

Compliance is checked by functional testing. For test procedures see 201.104.2.2.

#### **201.102.1.2 Instructions for use** (standards.iteh.ai)

Amend this subclause and the corresponding text in Table 201.C.103 (ACCOMPANYING DOCUMENTS, general) as follows:

[ISO 80601-2-13:2011/Amd 1:2015](https://standards.iteh.ai/catalog/standards/sist/f4f86778-cf04-44a1-8d22-7bf01e908818/iso-80601-2-13-2011-amd-1-2015)

[https://standards.iteh.ai/catalog/standards/sist/f4f86778-cf04-44a1-8d22-](https://standards.iteh.ai/catalog/standards/sist/f4f86778-cf04-44a1-8d22-7bf01e908818/iso-80601-2-13-2011-amd-1-2015)

Amend item l) as follows: [7bf01e908818/iso-80601-2-13-2011-amd-1-2015](https://standards.iteh.ai/catalog/standards/sist/f4f86778-cf04-44a1-8d22-7bf01e908818/iso-80601-2-13-2011-amd-1-2015)

- l) for breathing ACCESSORIES intended to be assembled by the OPERATOR, the resistance at 2,5 l/min, 15 l/min and 30 l/min and the compliance of those ACCESSORIES;

add a new item n) as follows:

- n) The instructions for use shall disclose the inspiratory and expiratory pressure/flow rate characteristics of the ANAESTHETIC BREATHING SYSTEM, including the pressure at

- 30 l/min if the ANAESTHETIC BREATHING SYSTEM is intended for adult PATIENTS;
- 15 l/min if the ANAESTHETIC BREATHING SYSTEM is intended for paediatric PATIENTS;
- 2,5 l/min if the ANAESTHETIC BREATHING SYSTEM is intended for neonatal PATIENTS;

at a FRESH GAS flow rate of 10 l/min  $\pm$  1 l/min or the maximum FRESH-GAS INLET flow rate specified in the instructions for use, whichever is greater.

#### **201.102.5.3 \* Reservoir bag connection port**

Amend this subclause as follows:

The reservoir bag connection port, if provided, shall be

- compatible with a reservoir bag complying with ISO 5362 and a BREATHING TUBE complying with ISO 5367, or
- a 22 mm socket complying with ISO 5356-1.