IEC 60601-2-23

Edition 3.0 2011-02

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment

Appareils électromédicaux –
Partie 2-23: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de surveillance de la pression partielle transcutanée

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International standard IEC 60601-2-23 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 1999 and constitutes a technical revision. This edition of IEC 60601-2-23 was revised to align structurally with the 2005 edition of IEC 60601-1.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/885/FDIS	62D/907/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this 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. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 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 standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

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

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

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

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

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

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of TRANSCUTANEOUS PARTIAL PRESSURE MONITORING EQUIPMENT. It amends and supplements IEC 60601-1 (third edition, 2005): *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard.

The aim of this third edition is to bring this particular standard up to date with reference to the third edition of the general standard through reformatting and technical changes.

The requirements of this particular standard take priority over those of the general standard.

A “General guidance and rationale” for the more important requirements of this particular standard is included in Annex AA. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, Annex AA does not form part of the requirements of this Standard.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of TRANSCUTANEOUS PARTIAL PRESSURE MONITORING EQUIPMENT as defined in 201.3.63 and hereinafter referred to as ME EQUIPMENT, whether this ME EQUIPMENT is stand alone or part of a system.

This standard applies to transcutaneous monitors used with adults, children and neonates, and it includes the use of these devices in foetal monitoring during birth.

This standard does not apply to haemoglobin saturation oximeters or to devices applied to surfaces of the body other than the skin (for example conjunctiva, mucosa).

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS 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 ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the General Standard.

201.1.2 Object

Replacement:

The object of this particular standard is to establish BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for TRANSCUTANEOUS PARTIAL PRESSURE MONITORING EQUIPMENT as defined in 201.3.63.

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.

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[1] The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2:2007 and IEC 60601-1-8:2006 apply as modified in Clauses 202 and 208 respectively. IEC 60601-1-3 and IEC 60601-1-10 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published

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, IEC 60601-1 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 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 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.

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 through 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, figures or tables 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, 203 for IEC 60601-1-3, 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.

201.2 Normative references

Clause 2 of the general standard applies, *except as follows:*

Replacement:

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 60601-1-8:2006, *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*

Addition:

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*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 apply, except as follows:

201.3.8
APPLIED PART

Addition:

TRANSDUCER and its connecting lead

Replacement:

201.3.63
TRANSCUTANEOUS PARTIAL PRESSURE MONITORING EQUIPMENT
ME EQUIPMENT
device and associated TRANSDUCERS for the monitoring of partial pressures of oxygen and/or carbon dioxide at the skin surface

Additional definitions:

201.3.201
APPLIED PART INTERFACE
that portion of the APPLIED PART intended to come into contact with the PATIENT'S skin

201.3.202
PATIENT CABLE
insulated wire(s) between the TRANSDUCER and the ME EQUIPMENT

201.3.203
SET TEMPERATURE
desired APPLIED PART INTERFACE temperature

201.3.204
TEMPERATURE LIMITER
means of limiting the temperature of the APPLIED PART INTERFACE

201.3.205
TRANSDUCER
device for converting the partial pressure of a gas into a signal for monitoring or recording

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.7 SINGLE FAULT CONDITION for ME EQUIPMENT

Addition:

SINGLE FAULT CONDITION includes any single failure in the ME EQUIPMENT resulting in a transfer of energy to the APPLIED PART which is greater than that necessary to maintain the SET TEMPERATURE value.

Additional subclause:

201.4.101 Additional ESSENTIAL PERFORMANCE requirements

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

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Non-linearity and hysteresis	201.12.1.101.1
Time to alarm for pO_2 and pCO_2 ALARM CONDITIONS	208.6.6.1.103

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.4 Other conditions

Addition:

Unless otherwise stated, tests shall be carried out with the ACCESSORIES and the recording materials specified by the MANUFACTURER.

For ME EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE, if the test result is affected by the INTERNAL ELECTRICAL POWER SOURCE voltage, then the test shall be performed using the least favourable INTERNAL ELECTRICAL POWER SOURCE voltage specified by the MANUFACTURER. If necessary for the purpose of conducting the test, an external battery or d.c. power supply may be used to provide the necessary test voltage.

The values used in test circuits, unless otherwise specified, shall have at least an accuracy as given below:

– resistors: ± 1 %;
– capacitors: ± 10 %;
– inductors: ± 10 %;
– test voltages: ± 1 %

201.5.8 * Sequence of tests

Amendment:

If applicable, the tests specified in 8.5.5 of the general standard shall be carried out prior to the LEAKAGE CURRENT and dielectric strength tests described in subclauses 8.7 and 8.8 of the general standard.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.2 * Protection against electric shock

Replacement of the last paragraph:

APPLIED PARTS shall be classified as TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS (see 7.2.10 and 8.3 b) of the general standard).

201.6.6 Mode of operation

Replacement:

ME EQUIPMENT shall be classified for CONTINUOUS OPERATION (see 7.2.11).

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.9.2 Instructions for use

Additional subclause:

201.7.9.2.101 Additional instructions for use

The operating instructions shall include the following:

a) the INTENDED USE including the environment of use;

b) procedures affecting the safety of operation, in particular the temperature selection and duration of monitoring time, on that particular site at that temperature, based upon clinical evaluation of the PATIENT, for example age, weight and physiological condition;

c) instructions for connecting a POTENTIAL EQUALIZATION CONDUCTOR, if applicable;

d) the choice and application of the specified TRANSDUCERS and ACCESSORIES;

e) * use of the ME EQUIPMENT with high frequency surgical ME EQUIPMENT, to avoid burns to the PATIENT and damage to the TRANSDUCER; a statement, if applicable, that the TRANSDUCER is to be removed from the PATIENT during the high frequency surgical procedures;

f) precautions to take when using a defibrillator on a PATIENT; a description how the discharge of a defibrillator affects the ME EQUIPMENT and the TRANSDUCER; a warning that defibrillator protection requires use of MANUFACTURER specified ACCESSORIES including TRANSDUCERS and PATIENT CABLES, if applicable. The specification (or type-number) of such ACCESSORIES is to be disclosed;

g) a statement to the effect: "This equipment is not a blood gas device";

h) * for TRANSDUCERS and cables, particularly disposable TRANSDUCERS, its MANUFACTURER shall state the recommended usable safe life;

i) * proper handling of TRANSDUCERS and their ACCESSORIES to avoid damage to these delicate components, thereby extending their useful life. In addition, these instructions shall refer, in particular, to the TRANSDUCER to cable connection and provide information on the measures that the clinical OPERATOR should adopt to prevent damage to this connection;

j) information on the warm-up time for the TRANSDUCER and ME EQUIPMENT;

k) the drift per hour for O_2 and CO_2 and recommendations for recalibration;

l) any interfering gases or vapours that are known to cause deviation outside the range specified;

m) the maximum time required for the ME EQUIPMENT to display a 10 % to 90 % response to a step change between test gases 1 and 2 in either direction;

n) advice regarding testing of the ME EQUIPMENT and ACCESSORIES on a daily basis (by the clinical OPERATOR) and on a scheduled basis (as a service activity). Emphasis should be placed on how the clinician may test visual and auditory ALARM SIGNALS;

o) simple fault finding methods for troubleshooting problems by which the clinical OPERATOR can locate problems if the ME EQUIPMENT appears to be functioning incorrectly;

NOTE This relates to simple operator difficulties, not to technical malfunctions;

p) the subsequent operation of the ME EQUIPMENT after interruption of SUPPLY MAINS exceeding 30 s (see 201.11.8);

q) * description of how to disable ALARM SIGNALS for TECHNICAL ALARM CONDITIONS if the TRANSDUCER or module is intentionally disconnected by the clinical OPERATOR;

r) the configuration procedure that allows the ALARM SIGNAL inactivation states (ALARM PAUSED, AUDIO PAUSED, ALARM OFF or AUDIO OFF) or the function ALARM RESET to be controlled remotely (see 208.6.11.101), if provided;

s) advice on the preferred ALARM SETTINGS and configurations of the ALARM SYSTEM when its INTENDED USE includes the monitoring of PATIENTS that are not continuously attended by a clinical OPERATOR;

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

Additional subclause:

201.8.101 * TRANSDUCERS and cables

Re-usable TRANSDUCERS and cables shall be provided with strain relief at the cable/TRANSDUCER junction capable of withstanding the tensile forces occurring during NORMAL USE.

After the test, neither the insulation of the cable nor the strain relief shall show any DEGRADATION and the TRANSDUCER shall function normally.

Compliance is checked by the following test:

Suddenly apply a load of 5 N to the cable in any direction within the conic sectional space having an apex angle of 90°, with said apex coinciding with the point of exit of the cable from the TRANSDUCER, and limited by a flat plane coinciding with the intended plane of application of the TRANSDUCER to the PATIENT.

Repeat this test five times at different angles of the cable from the TRANSDUCER; choose these angles being at random within the conic section (see Figure 201.101).