IEC 80601-2-30

Edition 1.0 2013-07

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Medical electrical equipment –
Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

Appareils électromédicaux –
Partie 2-30: Exigences particulières pour la sécurité de base et les performances essentielles des sphygmomanomètres non invasifs automatiques

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Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

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FOREWORD

This amendment has been prepared by subcommittee 62D: Electromedical equipment of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62D/1072/FDIS	62D/1079/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 14 P-members out of 15 having cast a vote.

The committee has decided that the contents of this amendment and the base 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- withdrawn,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.

NOTE The attention of National Committees and Member Bodies is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO 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 be adopted for implementation nationally not earlier than 3 years from the date of publication

INTRODUCTION TO THE AMENDMENT

This amendment deals primarily with editorial corrections and clarifications, clarifies requirements for operation in the loss of SUPPLY MAINS and references new and updated collateral standards.

To meet needs for change which were identified by users of this particular standard, it was necessary to amend the standard before the previously approved maintenance cycle date.

201.1 Scope, object and related standards

Add at the end of footnote 1), "including Amendment 1:2012".

201.1.1 Scope

In the first paragraph, replace "intermittent" *with* "non-continuous".

201.2 Normative references

Replace the initial instruction concerning amendment of the reference to IEC 60601-1-2 by the same instruction in the plural form, as follows:

Amendment of the following references:

Add, after the existing reference to IEC 60601-1-2:2007, the following new references:

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

Add to the list of references under the existing instruction "Addition:" the following new references:

IEC 60601-1-11:2010, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices*

Replace the existing reference to ISO 81060-2 by the following:

ISO 81060-2:2013, *Non-invasive sphygmomanometers – Part 2: Clinical investigation of automated measurement type*

201.3 Terms and definitions

Replace the existing first paragraph with the following:

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+A1:2012, IEC 60601-1-2:2007, IEC 60601-1-8:2006+A1:2012, and IEC 60601-2-2:2009 apply, except as follows:

201.3.207
HOME HEALTHCARE ENVIRONMENT

Replace the existing definition with the following:

dwelling place in which a PATIENT lives or other places where PATIENTS are present, excluding professional healthcare facility environments where OPERATORS with medical training are continually available when PATIENTS are present

NOTE 1 Professional healthcare facilities include hospitals, physician offices, freestanding surgical centres, dental offices, freestanding birthing centres, limited care facilities, multiple treatment facilities and emergency medical services.

NOTE 2 For the purpose of this particular standard, nursing homes are considered the HOME HEALTHCARE ENVIRONMENT.

NOTE 3 Other places where PATIENTS are present include the outdoor environment and in vehicles.

EXAMPLES In a car, bus, train, boat or plane, in a wheelchair or walking outdoors.

[SOURCE: IEC 60601-1-11:2010, definition 3.2]

201.3.216
SELF-MEASUREMENT AUTOMATIC MODE

Replace the existing definition with the following:

mode of AUTOMATED SPHYGMOMANOMETER that is manually initiated and overseen by the OPERATOR and in which a limited number of repeated DETERMINATIONS are made over a limited period

201.3.217
SHORT-TERM AUTOMATIC MODE

Replace the existing definition with the following:

mode of AUTOMATED SPHYGMOMANOMETER that is manually initiated by the OPERATOR and in which rapid repetitive automatic DETERMINATIONS are made within a specified time period

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements

Replace, in the third row, the phrase "Limits of the change in the error" *with* "Reproducibility".

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

201.7.2.102 Automated sphygmomanometers for home healthcare environment

Replace the existing title and text of this subclause by the following:

201.7.2.102 AUTOMATED SPHYGMOMANOMETERS for the HOME HEALTHCARE ENVIRONMENT

Vacant.

201.7.9.2.13 Maintenance

Replace in the note, the reference "(see 201.12.1.107)" *with "*(see 201.12.1.106)"

201.8.5.5.101 * Patient connections of automated sphygmomanometer

Replace the existing title with the following:

201.8.5.5.101 * PATIENT CONNECTIONS of AUTOMATED SPHYGMOMANOMETERS

201.11.8.102 SUPPLY MAINS

Replace the existing second paragraph with the following:

When SUPPLY MAINS is restored, the AUTOMATED SPHYGMOMANOMETER:

a) shall continue in the same mode of operation with all OPERATOR settings unchanged, or

b) shall

- remain inoperative, and
- if provided with SHORT-TERM AUTOMATIC MODE or LONG-TERM AUTOMATIC MODE, be equipped with an ALARM SYSTEM that includes a TECHNICAL ALARM CONDITION that indicates the AUTOMATED SPHYGMOMANOMETER is inoperative.

Replace the final paragraph with the following:

Restore the SUPPLY MAINS and determine that the AUTOMATED SPHYGMOMANOMETER:

– *continues in the same mode of operation with all OPERATOR settings unchanged; or*

– *remains inoperative and, if equipped with SHORT-TERM AUTOMATIC MODE or LONG-TERM AUTOMATIC MODE, that a TECHNICAL ALARM CONDITION is generated.*

201.12.1.103 * NOMINAL BLOOD PRESSURE indication range

In the last sentence of the compliance check, replace "60 mmHg (8,0 kPa)" *with* "40 mmHg (5,3 kPa)"

201.12.1.105 * Maximum pressure in SINGLE FAULT CONDITION

Add at the beginning of the first paragraph, "In any automatic cycling mode of operation,".

201.12.1.107 Limits of the change in error of the blood pressure determination

Replace the title and entire existing text of the subclause with the following:

201.12.1.107 * Reproducibility of the BLOOD PRESSURE DETERMINATION

The laboratory reproducibility of the BLOOD PRESSURE DETERMINATION of the AUTOMATED SPHYGMOMANOMETER shall be less than or equal to 3,0 mmHg (0,4 kPa).

Compliance is checked with the following test:

Two samples of the AUTOMATED SPHYGMOMANOMETER of the same MODEL OR TYPE REFERENCE are needed to perform this test PROCEDURE.

NOTE At the beginning of this compliance test neither sample has been subjected to the mechanical stress tests of the general standard and the collateral standards. Step h) subjects AUTOMATED SPHYGMOMANOMETER A to the stress tests and the laboratory limits of the change in error of the BLOOD PRESSURE DETERMINATION are compared before and after these mechanical stresses.

a) Label one sample of the AUTOMATED SPHYGMOMANOMETER *as A and the other sample as B.*

b) *Prior to performing the other tests of this standard, adjust a PATIENT SIMULATOR to generate signals in such a way that the AUTOMATED SPHYGMOMANOMETER displays approximately a DIASTOLIC BLOOD PRESSURE value of 40 mmHg (5,3 kPa) and a SYSTOLIC BLOOD PRESSURE value of 70 mmHg (9,33 kPa) at a pulse rate of 140 beats/min in NEONATAL MODE and a DIASTOLIC BLOOD PRESSURE value of 80 mmHg (10,67 kPa) and a SYSTOLIC BLOOD PRESSURE value of 120 mmHg (16,0 kPa) at a pulse rate of 80 beats/min otherwise. Either sample of the AUTOMATED SPHYGMOMANOMETER may be used for this step.*

c) *Perform 20 consecutive DETERMINATIONS with AUTOMATED SPHYGMOMANOMETER B. Calculate the means and standard deviations for both the DIASTOLIC BLOOD PRESSURE and the SYSTOLIC BLOOD PRESSURE.*

d) *Record these results as the AUTOMATED SPHYGMOMANOMETER B starting values.*

e) *Verify that the standard deviation of the DIASTOLIC BLOOD PRESSURE and of the SYSTOLIC BLOOD PRESSURE are ≤ 2,0 mmHg (≤ 0,27 kPa) for the AUTOMATED SPHYGMOMANOMETER B starting values. If either one of these criterion is not met, the combination of the simulator and AUTOMATED SPHYGMOMANOMETER has insufficient stability to perform this test PROCEDURE.*

f) *Using the same PATIENT SIMULATOR and settings as in b), perform 20 consecutive DETERMINATIONS with AUTOMATED SPHYGMOMANOMETER A. Calculate the mean and standard deviation for both the DIASTOLIC BLOOD PRESSURE and the SYSTOLIC BLOOD PRESSURE.*

g) *Record these results as the AUTOMATED SPHYGMOMANOMETER A starting values.*

h) *Using AUTOMATED SPHYGMOMANOMETER A, perform at least the following tests, without the simulation of SINGLE FAULT CONDITIONS, of this particular standard: 201.11.6.5, 201.12.1.102, 201.15.3.5.101, and 201.15.3.5.102 as well as IEC 60601-1:2005, 15.3.2, 15.3.3 and 15.3.4.*

i) *Using the same PATIENT SIMULATOR and settings as in b), perform 20 DETERMINATIONS with AUTOMATED SPHYGMOMANOMETER A. Calculate the means of the DIASTOLIC BLOOD PRESSURE and the SYSTOLIC BLOOD PRESSURE.*

j) *Record these results as the AUTOMATED SPHYGMOMANOMETER A ending values.*

k) *Using the same PATIENT SIMULATOR and settings as in b), perform 20 DETERMINATIONS with AUTOMATED SPHYGMOMANOMETER B. Calculate the means of the DIASTOLIC BLOOD PRESSURE and the SYSTOLIC BLOOD PRESSURE.*

l) *Record these results as the AUTOMATED SPHYGMOMANOMETER B ending values.*

m) *For AUTOMATED SPHYGMOMANOMETER B ending values, verify that the standard deviation of the DIASTOLIC BLOOD PRESSURE and of the SYSTOLIC BLOOD PRESSURE are ≤ 2,0 mmHg (≤ 0,27 kPa). If either one of these criterion is not met, the combination of the simulator and AUTOMATED SPHYGMOMANOMETER has insufficient stability to perform this test PROCEDURE.*

n) *For AUTOMATED SPHYGMOMANOMETER B, verify that the absolute value of the difference between the mean starting values calculated in c) and ending values calculated in m) are ≤ 2,0 mmHg (≤ 0,27 kPa). If either one of these criterion is not met, the combination of the simulator and AUTOMATED SPHYGMOMANOMETER has insufficient stability to perform this test PROCEDURE.*

o) *For AUTOMATED SPHYGMOMANOMETER A, verify that the absolute value of the difference between the mean starting values calculated in f) and ending values calculated in i) are ≤ 5,0 mmHg (≤ 0,67 kPa).*

201.12.3 Alarm systems

201.12.3.101 Alarm systems

Replace the existing title with the following:

201.12.3.101 Additional ALARM SYSTEM requirements

201.15.3.5.101 Shock and vibration for other than transport

Replace the first dash of item a)1) with the following:

– *peak acceleration: 150 m/s^2 (15 g);*

201.104 Maximum inflating time

In the second paragraph add after "In SINGLE FAULT CONDITION" "in any automatic cycling mode of operation".

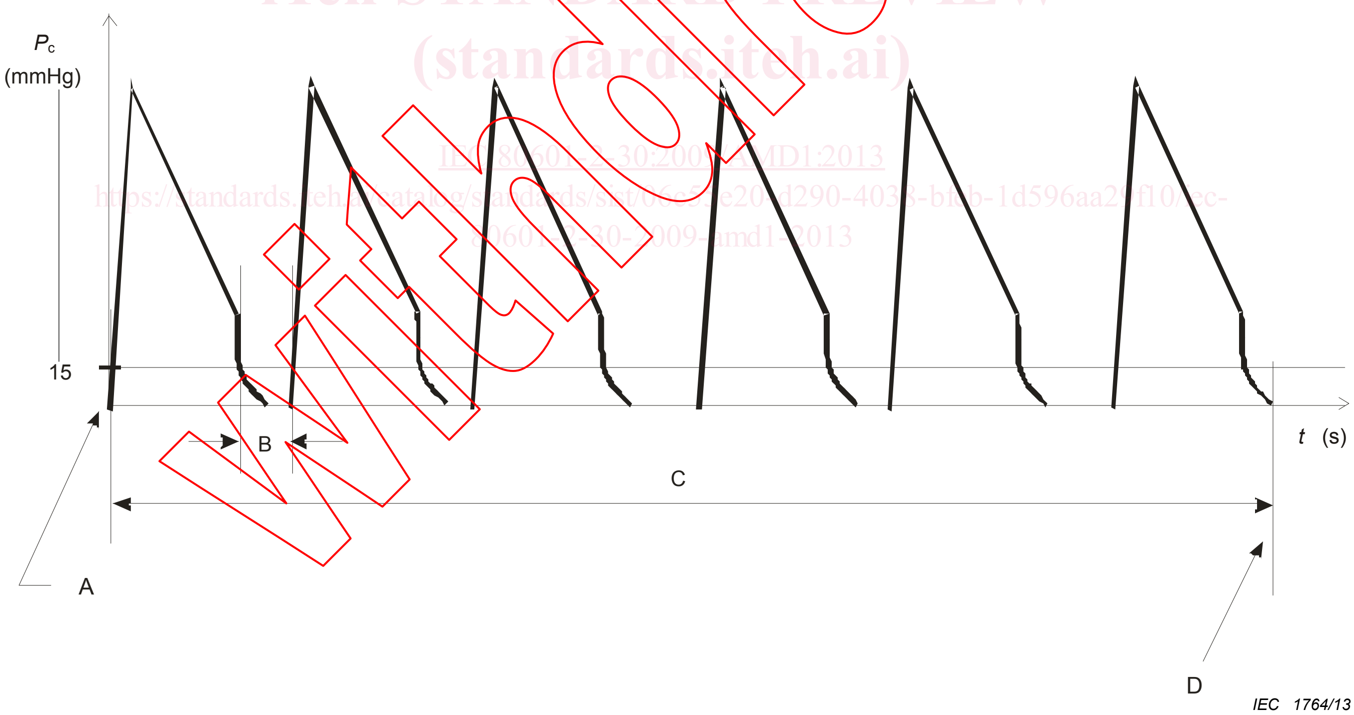
201.105.3 SELF-MEASUREMENT AUTOMATIC MODE

201.105.3.1 General

Add the following sentence in the first paragraph between the existing first and second sentences:

The maximum duration of SELF-MEASUREMENT AUTOMATIC MODE shall not exceed 30 min.

Replace existing Figure 201.107 with the following:



Key

A OPERATOR starts SELF-MEASUREMENT MODE

B Deflated time ≥ 5 s after each DETERMINATION

C SELF-MEASUREMENT MODE limited to 6 DETERMINATIONS

D SELF-MEASUREMENT MODE ends

CUFF pressure, P_c, as a function of time

Figure 201.107 – SELF-MEASUREMENT AUTOMATIC MODE CUFF pressure

201.105.3.2 NORMAL CONDITION

Replace the existing text of the second dash with the following:

– after each successful DETERMINATION, the CUFF pressure shall be released and shall remain below the pressure values in Table 201.102 for at least 5 s (see Figure 201.107).

201.105.3.3 * SINGLE FAULT CONDITION

Replace the existing dashed items with the following:

– if the duration of deflation below the pressure values in Table 201.102 is less than 5 s (see Figure 201.107), then a pressure relief PROTECTION DEVICE functioning independently of the NORMAL CONDITION PROTECTION DEVICE shall release the CUFF pressure to the values in Table 201.102;

– the pressure can be released from the CUFF by the OPERATOR; or

– the CUFF can be removed from the limb by the intended OPERATOR when the CUFF is inflated to 360 mmHg (48 kPa).

201.106 * Clinical accuracy

Replace the entire existing text of the clause with the following:

Except for the SHORT-TERM AUTOMATIC MODE, each clinical operating mode of an AUTOMATED SPHYGMOMANOMETER shall comply with ISO 81060-2:2013, which contains the requirements for clinical accuracy and the protocols for investigating the clinical accuracy.

The ACCOMPANYING DOCUMENT shall disclose that the SPHYGMOMANOMETER was clinically investigated according to the requirements of ISO 81060-2:2013.

NOTE Additional requirements for the ACCOMPANYING DOCUMENTS are found in ISO 81060-2.

Compliance is checked by application of the tests of ISO 81060-2:2013.

Add the following new clauses:

206 USABILITY

IEC 60601-1-6:2010+A1:2013 applies.

211 Requirements for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS used in the HOME HEALTHCARE ENVIRONMENT

IEC 60601-1-11:2010 applies, except as follows:

211.4.2.1 Environmental conditions of transport and storage between uses

*Add, in the first sentence after the phrase "*The instructions for use*" the words "*and the sales packaging".

211.4.2.2 Environmental operating conditions

*Add, in the first sentence after the phrase "*The instructions for use*" the words "*and the sales packaging*".*

211.7.4.5 Additional requirements for operating instructions

Add the following sentence to the existing text:

The instructions for use and the sales packaging shall indicate the RATED range of arm circumferences of the CUFF.

211.8.3.1 Ingress of water or particulate matter into ME EQUIPMENT

In the second sentence, replace "IP21" *with:* "IP20".

Annex C – Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

Table 201.C.101 – Marking on the outside of AUTOMATED SPHYGMOMANOMETERS or their parts

Delete the third, fourth and fifth rows referring to subclause 201.7.2.102.

Annex AA – Particular guidance and rationale

AA.2 Rationale for particular clauses and subclauses

Subclause 201.12.1.103 – NOMINAL BLOOD PRESSURE indication range

Replace in the second sentence, the phrase "clinically validated" *by* "clinically investigated".

Add, after the rationale for Subclause 201.12.1.106, the following new rationale:

Subclause 201.12.1.107 – Reproducibility of the BLOOD PRESSURE DETERMINATION

This requirement is designed to demonstrate that an AUTOMATED SPHYGMOMANOMETER continues to have acceptable reproducibility following the environmental stresses of this particular standard. During the development of this particular standard, concern was raised that the simulator used might not have sufficient reproducibility to successfully perform this test. This test PROCEDURE was developed to address this concern. The PROCEDURE allows one to determine that the combination of the AUTOMATED SPHYGMOMANOMETER and simulator works in a repeatable way, and that the simulator is generating the signals in a reproducible way, i.e. consistently for at least for the time required to perform the whole test sequence.

To accomplish these objectives, two samples of the AUTOMATED SPHYGMOMANOMETER are required. The first sample (A) is one that undergoes the TYPE TEST to the requirements of the subclause while the second sample (B) is used to demonstrate that the AUTOMATED SPHYGMOMANOMETER and simulator works in a repeatable way for the period required for completing the test sequence. Sample B is only used to demonstrate that the combination of AUTOMATED SPHYGMOMANOMETER and simulator works in a repeatable way and that the simulator is generating the signals in a reproducible way. As such its use is not necessary to perform the TYPE TESTS on sample A, but its use allows the tester to determine when the test set-up is inadequate.

Steps b) to e) are used to determine that the combination of the AUTOMATED SPHYGMOMANOMETER (sample B) and simulator works in a repeatable way. If either blood pressure standard deviation fails the acceptance criterion, the combination of the simulator and AUTOMATED SPHYGMOMANOMETER has insufficient reproducibility to perform this test PROCEDURE. Either the simulator needs adjustment or different simulator is required.