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AMENDMENT 1
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Amendment 1

Medical electrical equipment –

Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment

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FOREWORD

This amendment has been prepared by subcommittee 62B: Diagnostic imaging 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
62B/524/FDIS	62B/542/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.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the maintenance result 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- withdrawn,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.

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INTRODUCTION

Replace the last three paragraphs and the note of the existing text by the following new paragraphs:

It should be noted that although UD-3 Rev.1, 1998[1] was developed as a national standard, it has since been referenced by numerous countries worldwide and by all internationally operating manufacturers and test houses; regulatory authorities also follow the standard, as it has become a *de facto* international standard. The material taken from UD-3 Rev.1, 1998 forms only a part of this Particular Standard.

This standard contains normative measurement methodologies. These clauses may be replaced in a future revision by reference to an appropriate future measurement standard.

This standard does not cover ultrasonic therapeutic equipment. Equipment used for the imaging and diagnosis of body structures by ultrasound in conjunction with other medical procedure is covered.

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1 Scope and object

1.3 Particular Standards

[1] See reference [19] in the Bibliography.

Replace the existing reference to IEC 60601-1-2:1993 with the following revised reference:

IEC 60601-1-2:2001, *Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests*

Page 8

2 Terminology and definitions

2.1.124
MECHANICAL INDEX

Replace, on page 14, the existing definition of this term with the following:

the displayed parameter representing potential cavitation bio-effects

NOTE See DD.2.2 for methods of determining the MECHANICAL INDEX.

Add, on page 17, the following new definition:

2.1.147
ESSENTIAL PERFORMANCE
performance characteristics necessary to maintain the RESIDUAL RISK within acceptable limits

[IEC 60601-1-2, definition 2.210]

NOTE See also 3.201.2 of IEC 60601-1-2.

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Add the following clause:

3 General requirements

This clause of the General Standard applies except as follows:

***3.101 ESSENTIAL PERFORMANCE**

NOTE See 2.1.145 for intended use definition of ULTRASONIC DIAGNOSTIC EQUIPMENT.

The following are the potential sources of harm identified as characterizing the ESSENTIAL PERFORMANCE of ULTRASONIC DIAGNOSTIC EQUIPMENT:

– noise on a waveform, artefacts, distortion in an image or error of a displayed numerical value which cannot be attributed to a physiological effect and which may alter the diagnosis;
– the display of inaccurate numerical values associated with the diagnosis to be performed;
– the display of inaccurate safety-related indications;
– the production of unintended or excessive ultrasound output;
– the production of unintended or excessive TRANSDUCER ASSEMBLY surface temperature;
– the production of unintended or uncontrolled motion of TRANSDUCER ASSEMBLIES intended for intra-corporeal use.

In some circumstances the need for the repetition of an ultrasound examination should be evaluated as a potential hazard, for example, intra-corporeal investigation and stress testing for cardiopathic PATIENTS.

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*36 Electromagnetic compatibility

Replace the existing text of this clause completely with the following:

Addition:

ULTRASONIC DIAGNOSTIC EQUIPMENT shall comply with the requirements of IEC 60601-1-2 with the following modifications.

36.201.1 Protection of radio services

Replacement:

ULTRASONIC DIAGNOSTIC EQUIPMENT shall be classified as Group 1 and class A or class B, in accordance with CISPR 11, as per their intended use, specified by the MANUFACTURER in the INSTRUCTIONS FOR USE. Guidance for classification according to CISPR 11 is reported in Annex CC of this standard.

36.202 IMMUNITY

*36.202.1 f) Variable gain

Addition:

NOTE See Annex BB of this standard for gain adjustment technique.

*36.202.1 j) Compliance criteria

Replace the eighth to eleventh dashed items with the following:

– noise on a waveform or artefacts or distortion in an image or error of a displayed numerical value which cannot be attributed to a physiological effect and which may alter the diagnosis;
– an error in a displayed safety related indication;
– unintended or excessive ultrasound output;
– unintended or excessive TRANSDUCER ASSEMBLY surface temperature;
– unintended or uncontrolled motion of TRANSDUCER ASSEMBLIES intended for intra-corporeal use;

* 36.202.3 Radiated RF electromagnetic fields

b) Tests

Replacement:

3) According to the intended use, the ULTRASONIC DIAGNOSTIC EQUIPMENT shall be tested using a 2 Hz or 1 kHz modulation frequency (physiological simulation frequency), whichever represents the worst case condition. The modulation frequency adopted shall be disclosed in the test report.

*36.202.6 Conducted disturbances, induced by RF fields

b) Tests

Replacement:

3) PATIENT-coupled cables including the ULTRASOUND TRANSDUCER cable shall be tested using a current clamp. All PATIENT-coupled cables including the ULTRASOUND TRANSDUCER cable may be tested simultaneously using a single current clamp.

The ULTRASOUND TRANSDUCER of the ULTRASONIC DIAGNOSTIC EQUIPMENT and SYSTEM shall be terminated during the test as specified below. In all cases, no intentional decoupling device shall be used between the injection point and the PATIENT coupling point.

- *For PATIENT coupling points that have conductive contact to the PATIENT, terminal M of the RC element (see CISPR 16-1-2) shall be connected directly to the conductive PATIENT connection, and the other terminal of the RC element shall be connected to the ground reference plane. If normal operation of the ULTRASONIC DIAGNOSTIC EQUIPMENT cannot be verified with terminal M of the artificial hand connected to the coupling point, a PATIENT simulator may be used between terminal M of the artificial hand and the PATIENT coupling point or points.*
- *ULTRASOUND TRANSDUCERS shall be terminated with the artificial hand and RC element specified in CISPR 16-1-2. The metal foil of the artificial hand shall be sized and placed to simulate the approximate area of PATIENT and OPERATOR coupling in NORMAL USE.*
- *For ULTRASONIC DIAGNOSTIC EQUIPMENT that have multiple PATIENT coupling points intended to be connected to a single PATIENT, each artificial hand shall be tied to a single common connection and this common connection shall be connected to terminal M of the RC element, as specified in CISPR 16-1-2.*

Replacement:

6) According to the intended use, the ULTRASONIC DIAGNOSTIC EQUIPMENT shall be tested using a 2 Hz or 1 kHz modulation frequency, whichever represents the worst-case condition. The modulation frequency adopted shall be disclosed in the test report.

36.202.7 Voltage dips, short interruptions and voltage variations on power supply input lines

*a) Requirements

Replacement:

1) ULTRASONIC DIAGNOSTIC EQUIPMENT shall comply with the requirements of 36.202.1 j) at the IMMUNITY TEST LEVELS specified in Table 210. Deviation from the requirements of 36.202.1 j) is allowed at the IMMUNITY TEST LEVELS specified in Table 210, provided the ULTRASONIC DIAGNOSTIC EQUIPMENT remains safe, experiences no component failures and is restorable to the pre-test state with OPERATOR intervention. Determination of compliance is based upon performance of the ULTRASONIC DIAGNOSTIC EQUIPMENT during and after application of the test sequence. ULTRASONIC DIAGNOSTIC EQUIPMENT for which the RATED input current exceeds 16 A per phase are exempt from the testing specified in Table 210.

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42 Excessive temperatures

Replace the existing text of this clause with the following:

This clause of the General Standard applies except as follows:

42.3 *Replacement:*

***42.3** ULTRASONIC TRANSDUCERS applied to the PATIENT shall have a PATIENT contact surface temperature not exceeding 43 °C when measured under test conditions a)1) below.

In addition, ULTRASONIC TRANSDUCERS applied to the PATIENT shall have a PATIENT contact surface temperature not exceeding 50 °C when measured under test conditions a)2) below.

Compliance is checked by operation of the ULTRASONIC DIAGNOSTIC EQUIPMENT and temperature tests as follows.

a) Test conditions

1) The ULTRASONIC TRANSDUCER shall be tested under simulated use conditions.

Test conditions for simulated use include:

- *the ULTRASONIC TRANSDUCER shall be coupled acoustically to and be initially in thermal equilibrium with a test object such that the ultrasound emitted from the active surface of the ULTRASONIC TRANSDUCER enters the test object;*
- *the position and heating and/or cooling of the ULTRASONIC TRANSDUCER shall resemble those corresponding to the intended application of that ULTRASONIC TRANSDUCER;*
- *the position at which the temperature is measured shall be at the active surface of the ULTRASONIC TRANSDUCER;*
- *the test object shall have thermal and acoustical properties mimicking those of an appropriate tissue. In the case where the ULTRASONIC TRANSDUCER is intended for external use this test object shall account for a skin layer. The test object shall have values for the specific heat capacity, thermal conductivity and attenuation coefficient as specified in Note 1.*

NOTE 1 A general guidance for the acoustic properties of appropriate tissue is given in ICRU report 61 of the International Commission of Radiation Units and Measurements [28]. For test objects mimicking soft tissue, the material of the test object shall have the following properties:

- specific heat capacity: (3 500 ± 500) J kg^{-1} K^{-1};
- thermal conductivity: (0,5 ± 0,1) W m^{-1} K^{-1};
- attenuation at 5 MHz: (2,5 ± 1,0) dB cm^{-1}.

NOTE 2 As temperature changes occur at different rates in tissue surfaces containing skin, bone or soft tissue, careful consideration should be given to the choice of the model in relation to the intended use of the ULTRASONIC TRANSDUCER. Additional guidance can be found in Annex BB and in the TNO report PG/TG/2001.246 [30].

- *the test object shall be designed (for example, using acoustic absorbers) to minimize ultrasound reflections that could result in heating the surface of the ULTRASONIC TRANSDUCER;*
- *the minimum size of the test object should be such that increasing the size will have a negligible effect on the surface temperature of the TRANSDUCER ASSEMBLY;*

Test methods: either test method A) or B) specified below shall be selected.

NOTE 3 Because test method B) could yield inappropriate results where the ULTRASOUND DIAGNOSTIC EQUIPMENT uses a closed loop temperature monitoring system, test method A) shall be used for these cases.

Test method A): *Test criteria based upon temperature measurements*

In the case where the ULTRASONIC TRANSDUCER is intended for external use, the initial temperature of the surface of the test object at the object-transducer interface shall be not less than 33 °C and the ambient temperature shall be 23 °C ± 3 °C.

In the case where the ULTRASONIC TRANSDUCER is intended for internal/invasive use, the initial temperature of the surface of the test object material at the object-transducer interface shall be not less than 37 °C and the ambient temperature shall be 23 °C ± 3 °C.

To meet the requirements, the temperature of the radiating surface of the TRANSDUCER ASSEMBLY shall not exceed 43 °C during the test.

Test method B): *Test criteria based upon temperature rise measurements.*

NOTE 4 When following test method B), the temperature rise is defined as the difference between the surface temperature of the ultrasonic transducer just before the test and the maximum surface temperature of the ultrasonic transducer during the test.