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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- withdrawn,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

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[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.

The initial temperature of the surface of the test object at the object-transducer interface shall be the ambient temperature and the ambient temperature shall be 23 °C ± 3 °C. In the case where the ULTRASONIC TRANSDUCER is intended for external use, the surface temperature rise of the ULTRASONIC TRANSDUCER shall not exceed 10 °C during the test. In the case where the ULTRASONIC TRANSDUCER is not intended for external use, the surface temperature rise of the ULTRASONIC TRANSDUCER shall not exceed 6 °C during the test.

In the case of an ULTRASONIC TRANSDUCER which is intended for external use, the surface temperature under test conditions 42.3 a)1) is equal to the sum of 33 °C and the measured temperature rise. In the case of an ULTRASONIC TRANSDUCER which is not intended for external use, the surface temperature under test conditions 42.3 a)1) is equal to the sum of 37 °C and the measured temperature rise.

To meet the requirements of this standard, the surface temperature calculated in this way shall not exceed 43 °C during the test.

2) *Suspend the ULTRASONIC TRANSDUCER with a clean surface (no coupling gel applied) in still air or place it in a stationary position in an environmental chamber with minimal air flow to the surface of the ULTRASONIC TRANSDUCER.*

Test criteria are based upon temperature rise measurements.

The ambient temperature shall be 23 °C ± 3 °C and the initial temperature of the radiating surface of the TRANSDUCER ASSEMBLY shall be the ambient temperature. During the test the temperature rise of the radiating surface of the TRANSDUCER ASSEMBLY shall not exceed 27 °C.

To meet the requirements of not exceeding a surface temperature of 50 °C, the sum of the surface temperature rise obtained under these test conditions and 23 °C shall be regarded as the surface temperature under test conditions a)2).

b) *Operating settings*

Operate the ULTRASONIC DIAGNOSTIC EQUIPMENT at a setting which gives the highest surface temperature of the ULTRASONIC TRANSDUCER. The tests of a)1) and a)2) shall be performed under the same driving condition. The test driving condition shall be listed in the test report. The maximum temperature shall be disclosed in the instructions for use.

c) *Duty cycle*

The ULTRASONIC DIAGNOSTIC EQUIPMENT is continually operated for the duration of the test.

1) *The test according to 42.3 a)1) is conducted for 30 min.*

NOTE When the ULTRASONIC DIAGNOSTIC EQUIPMENT automatically freezes its output earlier than the time period given in c)1), the ULTRASONIC DIAGNOSTIC EQUIPMENT shall be switched on again immediately.

2) *The test according to 42.3 a)2) is conducted for the shorter of*

– *30 min or*

– *twice the time period limited by an automatic output freezing capability in case the OPERATOR is not able to switch off that capability.*

d) *Temperature measurement*

The temperature of the ULTRASONIC TRANSDUCER can be measured by any appropriate means, including radiometry and thermocouple methods.

When a thermocouple is used, the thermocouple junction and adjacent thermocouple lead wire are to be securely held in good thermal contact with the surface of the material whose temperature is being measured. Position and secure the thermocouple in such a way that it will have negligible effect on the temperature rise of the area being measured.

The temperature shall be measured on the surface of the ULTRASONIC TRANSDUCER in those areas that give the highest surface temperature.

The measurement uncertainty shall be declared.

NOTE 1 For the estimation of uncertainties, the ISO *Guide to the expression of uncertainty in measurement* should be used [18].

NOTE 2 Any means to measure the temperature should be a type that is not very sensitive to direct ultrasonic heating (for example, use a thin film or fine wire thermocouple). Also, the size of its sensitive area should be

such that any averaging effect will be minimised. The effects of conductive losses, ultrasonic heating and spatial averaging should be taken into account when accessing the measurement uncertainty.

e) Test criteria

The ULTRASONIC TRANSDUCER shall operate through the test at the duty cycle and for the duration specified in item c) above. During the test, the maximum temperature recorded or the maximum temperature rise recorded shall not have exceeded the limits specified.

Table 102 – Overview of the tests noted under 42.3

Transducer type ➔ / **Test to be applied ➓**		**External use**	**Non-external use**
a) 1) Simulated use test	**A) Temperature**	*Test object maintained at not less than 33 °C.* The temperature shall not exceed 43 °C.	*Test object maintained at not less than 37 °C.* The temperature shall not exceed 43 °C.
	B) Temperature rise	*Initially the temperature at the object-transducer interface shall be the ambient temperature.* *The ambient temperature shall be 23 °C ± 3 °C.* The temperature rise shall not exceed 10 °C.	*Initially the temperature at the object-transducer interface shall be the ambient temperature.* *The ambient temperature shall be 23 °C ± 3 °C.* The temperature rise shall not exceed 6 °C.
a) 2) Still air test (no gel)	**Temperature rise**	*The ambient temperature shall be 23 °C ± 3 °C.* *Initially the temperature at the surface of THE TRANSDUCER ASSEMBLY shall be the ambient temperature* The temperature rise shall not exceed 27 °C.	

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Annex BB – Guidance and rationale for particular subclauses

concerning 36 Electromagnetic compatibility

Replace, on page 31, the existing text (all three paragraphs) with the following:

Subclause 36.201.1

ULTRASONIC DIAGNOSTIC EQUIPMENT is categorized as class A (under IEC 60601-1-2) when the environment for the intended use as defined by the MANUFACTURER is in a hospital or a similar environment. For the extension of the intended use into a residential environment the ULTRASONIC DIAGNOSTIC EQUIPMENT is categorized as class B. For further details, see Annex CC.

Subclause 36.202.1 f)

ULTRASONIC DIAGNOSTIC EQUIPMENT that incorporates a variable gain shall be tested at the typical gain applied by the USER. This setting should be determined by using a tissue mimicking material or a flow phantom, appropriate for the application to adjust the gain and the other image enhancement adjustments to represent the typical settings applied by the USER. The phantom shall be removed prior to IMMUNITY testing in accordance with subclause 36.202 of IEC 60601-1-2.

If this requirement can be met with the normal software of the EQUIPMENT or SYSTEM, the test shall be performed using the normal software. If this requirement cannot be met using the normal software of the EQUIPMENT or SYSTEM, a method shall be provided to implement this operational mode. The use of special software may be required. If special software is used, it shall not inhibit changes in gain that may occur as a result of testing.

Subclause 36.202.1 j)

There is common agreement that it is not reasonable to require that nothing will happen when an electromagnetic disturbance is applied to an ULTRASOUND DIAGNOSTIC EQUIPMENT which is intended to acquire signals in the µV range by means of a transducer whose cable length is more than 2 m.

The sense of the requirement is that under the test conditions specified in 36.202, the ULTRASONIC DIAGNOSTIC EQUIPMENT shall be able to provide the ESSENTIAL PERFORMANCE and remain safe.

Examples of conformance to the compliance criteria include:

- ULTRASONIC DIAGNOSTIC EQUIPMENT displays an image that may have regular dots or dashes or lines produced by the disturbance, but in a way that is recognisable as other than physiologic and that would not affect diagnosis;
- ULTRASONIC DIAGNOSTIC EQUIPMENT displays an image that may have lines on a Doppler trace, but in a way that is recognisable as other than physiologic and that would not affect diagnosis;
- ULTRASONIC DIAGNOSTIC EQUIPMENT displays an image and Doppler traces which may be covered with noise signals, but in a way that is recognisable as other than physiologic and that would not affect diagnosis.

36.202.3 b)3) and 36.202.6 b)6)

Table 209 of IEC 60601-1-2 lists a 2 Hz modulation frequency when the intended use of the device is “control, monitor or measure a physiological parameter” and 1 kHz modulation frequency for “all other” intended use. Ultrasound diagnostic devices are intended to analyse both slow physiological parameters, like heart wall motion, and relatively fast phenomena, like blood velocity (detected as Doppler shift in the range of the kHz).

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concerning 42.3 Excessive temperatures

Replace the existing third paragraph by the following new paragraph:

This also counts for TRANSDUCER ASSEMBLIES intended for trans-oesophageal use. Although contact with the internal surface of the oesophagus is prolonged, the time in which the TRANSDUCER ASSEMBLY at its initial temperature is in contact with a single tissue site is relatively short. Furthermore, the transducer area which is heated is relatively small, providing little heat capacity, and the resulting heat is rapidly drawn away from the transducer as it passes through the mouth and into the oesophagus. As a result, no tissue encounters a temperature in excess of the steady-state temperature for clinical scanning for other than a brief moment. In the case of foetal endovaginal use, while exposure time plays an important role [17], because of intervening tissue and fluid structures and the same transient contact discussed for trans-oesophageal applications, the surface temperature of an endovaginal transducer does not translate directly to the temperature ultimately affecting the foetus.

Replace the existing fourth paragraph by the following new paragraph:

When carrying out a risk analysis for the ULTRASOUND DIAGNOSTIC EQUIPMENT the USER of this standard has to take into account that the temperature limit of 43°C in the current draft of the third edition of IEC 60601-1 is only applicable for long term (more than 10 min) contact with healthy skin of adults. Special consideration should be given for an application on children. The influence of drugs and the condition of the PATIENT are factors that should be also considered in the risk-benefit analysis. With respect to further not foreseeable developments the safety of a long-term use of transducers (more than 41°C) inside the body is currently not well investigated. The standard committee assume that the safe use of temperatures higher than 41 °C on children, inside the body and on PATIENTS with possible risky conditions should also be a subject of the clinical evaluation.

Add, after the first paragraph on page 32, the following new paragraph:

As ultrasound diagnostic devices generally are used in temperature controlled locations the ambient temperature of 23 °C ± 3 °C has been chosen for the environment during the measurement of transducer surface temperature.

Replace, in the second paragraph on page 32, the sentence:

"…, such that the ambient temperature is that of the patient's internal body temperature."

by:

"…, such that the ambient temperature is the PATIENT's internal body temperature."

Replace, in the third paragraph on page 32, the sentence:

"...; the body of the probe assembly is in contact with ambient air temperature, …."

by:

"...; the body of the probe assembly is in contact with ambient air,..."

Add, in the fourth paragraph on page 32, the following new dashed item

– *alternative materials may be used where the results can be shown to be comparable; most significantly, however, the material used shall exhibit an ultrasonic absorption coefficient and thermal properties appropriate to the intended model.*

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Annex CC – Guidance in classification according to CISPR 11

Replace the first paragraph of this annex and the information about subclause 4.1 of CISPR 11, by the following new paragraph:

Rules for classification and separation into groups of equipment are contained in CISPR 11. EQUIPMENT that is the subject of this Particular Standard is classified in Group 1 (under IEC 60601-1-2), since the device must intentionally generate radiofrequency energy and transmit it through a shielded external cable (up to 2 m or longer in length) to a TRANSDUCER ASSEMBLY at the end of the cable. The purpose of this annex is to provide summarized information for the assignment of the ULTRASONIC DIAGNOSTIC EQUIPMENT to the appropriate CISPR 11 class.

Delete the final existing paragraph.

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Add the following new Annex:

Annex II
(informative)

Example set-up to measure surface temperature for externally applied transducers

II.1 General

The test object set-up described below is based on measurements presented in the report [31]. For at least 10 different transducers, the surface temperature of the transducers as measured when radiating into human under-arms was compared with the set-up described.

Basically the set-up consists of a piece of soft tissue mimicking material (TMM) covered by a slab of silicone rubber on which a (thin film) thermocouple is placed (see Figure II.1). The TMM is placed on a piece of material that absorbs all acoustic energy.

The properties of the materials used will be those of silicone and TMM as listed in Table II.1.

Table II.1 – Acoustic and thermal properties of tissues and materials

Tissue/ Material	Velocity c (m s^{-1})	Density ρ (kg m^{-3})	Attenuation -coefficient α (dB cm^{-1} MHz^{-1})	Acoustic impedance Z (10^6 kg m^{-2} s^{-1})	Spec. heat capacity C (J kg^{-1} K^{-1})	Thermal conductivity κ (W m^{-1} K^{-1})	Thermal diffusivity D (10^{-6} m^2 s^{-1})	Source
Skin	1 615	1 090	2,3 – 4,7 3,5	1,76	3430	0,335	0,09	ICRU rep.61 1998 [28] Chivers 1978 [34]
Soft tissue	1 575	1 055	0,6 – 2,24 [a]	1,66	3550	0,525	0,150	ICRU rep.61 1998 [28]
Soft tissue fatty	1 465	985	0,4	1,44	3000	0,350	0,135	ICRU rep.61 1998 [28]
Cortical bone [b]	3 635	1 920	14 – 22	6,98	1300	0,3 – 0,79	0,32	ICRU rep.61 1998 [28]
Silicone	1 021	1 243	1,8 [c]	1,3		0,25		TNO / Dow Corning
TMM	1 540	1 050	0,5 [c]	1,6	3800	0,58	0,15	TNO (Soft Tissue Model)

[a] Frequency dependence: $f^{1.2}$

[b] Wide uncertainty has been reported in bone properties - Duck, 1990 [35]

[c] Determined at 3 MHz.

II.2 Preparation of the soft tissue mimicking material (TMM)

A mixture is made from the materials listed in Table II.2

Table II.2 – Weight % pure components

Component	Share, weight in %
Glycerol	11,21
Water	82,95
Benzalkoniumchloride	0,47
Silicone Carbide (SiC (–400 mesh))	0,53
Aluminium Oxide (Al_2O_3 (0,3 μm))	0,88
Aluminium Oxide (Al_2O_3 (3 μm))	0,94
Agar	3,02
Sum	**100,00**

The recipe for preparation of the soft tissue mimicking material (TMM) and the set-up is as follows.

(1) Mix all components listed in the table and degas at laboratory temperature.

(2) Heat, while stirring, until 90 °C. To avoid evaporation and hence a change in components ratio, the substance should be covered during this process.

(3) Cool the substance, while stirring as long as the viscosity allows, until about 47 °C. To avoid evaporation and hence a change in the components ratio, the substance should be covered during this process.

(4) Pour the substance quickly in a mould and let it cool down further while the mould is covered.

(5) The TMM is now ready for use. To prepare the total measurements set-up, the TMM should be covered with a slab of silicone rubber with a thickness of 1,5 mm. Take care that there is no air between the TMM and the silicone rubber. (This will result in about equal measurement results as when using human under-arms). Although Figure II.1 shows a set-up for a flat transducer surface, a curved surface is easily obtained by cutting the curvature in the TMM.

(6) A (thin film) thermocouple is to be placed on top of the silicone rubber layer.

(7) Finally the transducer under test has to be placed, coupled with acoustic coupling gel.