

Ultrasonics — Field characterisation — Test objects for determining temperature elevation in diagnostic ultrasound fields

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National foreword

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Comments arising from the use of this Draft for Development are requested so that UK experience can be reported to the international organization responsible for its conversion to an international standard. A review of this publication will be initiated not later than three years after its publication by the international organization so that a decision can be taken on its status. Notification of the start of the review period will be made in an announcement in the appropriate issue of *Update Standards*.

According to the replies received by the end of the review period, the responsible BSI Committee will decide whether to support the conversion into an international Standard, to extend the life of the Technical Specification or to withdraw it. Comments should be sent to the Secretary of the responsible BSI Technical Committee at British Standards House, 389 Chiswick High Road, London W4 4AL.

The UK participation in its preparation was entrusted to Technical Committee EPL/87, Ultrasonics.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Test objects for determining temperature
elevation in diagnostic ultrasound fields**



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INTRODUCTION

This Technical Specification specifies the design and performance characteristics of test objects for determining temperature rise in medical diagnostic ultrasound fields. It also describes how such test objects can be used to determine ultrasonically-induced temperature rises from diagnostic equipment. This standard specifically relates to test objects which contain an embedded thermal sensor (such as a thermocouple or thermistor) although some parts may also be relevant to alternative method of temperature determination.

The test objects are for the measurement of temperature rise and not for the determination of thermal index which is, by definition, an algebraic combination of acoustical field quantities and is therefore not a physically measurable quantity.

ULTRASONICS – FIELD CHARACTERISATION – TEST OBJECTS FOR DETERMINING TEMPERATURE ELEVATION IN DIAGNOSTIC ULTRASOUND FIELDS

1 Scope

This Technical Specification is applicable to medical diagnostic ultrasonic fields.

This Technical Specification establishes:

- the important characteristics and terminology for test objects containing an embedded thermal sensor to determine ultrasonic heating;
- requirements for defining particular types of test object for specific applications;
- examples of design features which will ensure that the performance specifications are achieved;
- validation procedures;
- general test methods for using test objects to determine standardised temperature rises.

NOTE 1 This Technical Specification specifically relates to test objects which contain an embedded thermal sensor (such as a thermocouple or thermistor). Although it may be possible to use non-embedded methods of temperature determination to achieve the same ends, these are outside of the scope of this Technical Specification.

NOTE 2 The test objects specified in this Technical Specification are for the measurement of temperature rise and not for the determination of Thermal Index which is, by definition, an algebraic combination of acoustical field quantities and is therefore not a physically measurable quantity.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 61102:1991, *Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range of 0,5 MHz to 15 MHz*

IEC 61157:1992, *Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment*

IEC 61161, *Ultrasonic power measurement in liquids in the frequency range 0,5 MHz to 25 MHz*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

acoustic coupling medium

material placed between different parts of a **thermal test assembly** in order to maintain acoustic transmission

3.2

acoustic working frequency

arithmetic mean of the frequencies f_1 and f_2 at which the amplitude of the spectrum of the acoustic signal, i.e. the output of a hydrophone placed in an acoustic field at a specified position, first becomes 3 dB lower than the peak amplitude

Conforms to definition 3.4.2 of IEC 61102.

Symbol: f_{awf}

Unit: megahertz, MHz.

3.3

backing region

region of a thermal sensor test object between the **target region** and the back surface of the **thermal sensor test object enclosure**

3.4

calibration factor

ratio of the temperature rise, measured for a particular **thermal sensor test object**, to the **reference temperature rise** for that type of **thermal sensor test object**

Symbol: F_c

Units: dimensionless

3.5

clinical model

a term used to specify a clinical application of diagnostic ultrasound which is represented by a **physical tissue model**

3.6

entrance window

outer surface region of the **thermal sensor test object** that interfaces with the **simulated tissue path**

3.7

incremental transmission loss coefficient

for a specified **physical tissue model**, the increase in transmission loss of the tissue-simulating material between the face of the **probe** and the **point of interest** per unit increase in the distance between the **probe** face and the **point of interest**, divided by the **acoustic working frequency** at which the transmission loss is determined

Symbol: L'_{inc}

Unit: decibel per centimetre per megahertz, dB cm⁻¹ MHz⁻¹

3.8

measured temperature rise

temperature increase measured in a **thermal sensor test object** after the **standard insonation time**

3.9**minimum distance**

for a specific **physical tissue model**, the minimum allowed value of the separation between the **probe** face and the **point of interest**. This value depends on the clinical application

Symbol: d_0

Unit: metre, m.

3.10**minimum transmission loss**

for a specific **physical tissue model**, the transmission loss at the **minimum distance** of the tissue-simulating material between the **probe** face and the **point of interest**

Symbol: L_0

Unit: decibel per megahertz, dB MHz⁻¹.

3.11**physical tissue model**

a layered model representation of the physical characteristics, such as the transmission loss and the thermal conductivity, of a particular **clinical model** of ultrasound under **reasonable worst-case conditions**

3.12**point of interest**

the particular point in a **physical tissue model** at which the **temperature rise** is to be determined

3.13**primary junction**

that part of a thermocouple-based **thermal sensor** that converts the local temperature increase to an electrical potential. It should normally be placed at the **point of interest**

3.14**probe**

those parts of medical ultrasound diagnostic equipment comprising the ultrasonic transducer and/or ultrasonic transducer element group together with any integral components, such as an acoustic lens or integral stand-off. The **probe** is usually separable from the ultrasonic instrument console

[IEC 61157, definition 3.22, modified]

3.15**reference temperature rise**

a temperature increase specified for a particular type of **thermal sensor test object**, used in calibrating a practical implementation of the **thermal sensor test object** under specified insonation conditions

Symbol: T_{ref}

Units: degree Celsius, C.

3.16**reference transducer**

transducer with specified properties and output characteristics that is used for validating the conformance of a **thermal sensor test object** with its specification

3.17

residual transmission loss

for a specified **physical tissue model**, the transmission loss at the **minimum distance** of the tissue-simulating material between the **probe** face and the surface of a **thermal sensor test object**]

Symbol: L_r

Unit: decibel per megahertz, dB MHz⁻¹.

3.18

secondary junctions

any part (except for the **primary junction**) of a thermocouple-based **thermal sensor** that converts the local temperature increase to an electrical potential. For certain thermocouple configurations, including thin-film thermocouples, the **secondary junctions** are the connections between the thermocouple and the main leads that conduct the signal away from the thermocouple assembly

3.19

simulated target tissue

any tissue-simulating material in the **target region** of a **physical tissue model**

3.20

simulated tissue path

path of variable depth between the face of a **probe** and the surface of the **target region** which has a transmission loss determined from the **residual transmission loss** and the **incremental transmission loss coefficient** of a particular **physical tissue model**

3.21

standard insonation time

the period over which the **reference temperature rise** is to be measured, defined here as 3 min (180 s)

3.22

target plane

plane within the **target region**, normally perpendicular to the direction of propagation of the ultrasound beam, in which the **point of interest** lies

3.23

target region

region that surrounds the **point of interest** (normally within ±5 mm to ±10 mm of the **point of interest**). The **target region** may contain one or more **simulated target**

3.24

thermal sensor

device that measures a temperature increase, usually by converting it to an electrical signal

NOTE An effective **thermal sensor** in diagnostic ultrasound fields needs to introduce minimal interaction with the ultrasound beam and have a suitably small spatial and thermal resolution.

3.25

thermal sensor test object

test object containing the **target region** and a **thermal sensor**

NOTE The **thermal sensor test object** may also contain other components, for example, the backing region.

3.26**thermal sensor test object enclosure**

outer enclosure of the **thermal sensor test object**, which includes the **entrance window**

3.27**thermal test assembly**

apparatus incorporating a thermal sensor test object and a simulated tissue path and configured to a specified physical tissue model or worst-case model

4 List of symbols

d	distance between the face of a probe and the point of interest .
d_0	minimum distance between the face of a probe and the point of interest .
f_{awf}	acoustic working frequency .
F_c	calibration factor .
h	thickness of material used to provide the attenuation for a simulated tissue path .
k_0	thermal conductivity of medium in target region .
k_1, k_2	thermal conductivities of thermocouple leads.
κ	thermal diffusivity of the target region .
l_p	distance between the face of a probe and the point of maximum pulse pressure squared integral.
L	transmission loss of material used for a simulated tissue path .
L'_c	transmission loss coefficient for material used for a simulated tissue path .
L'_{inc}	incremental transmission loss coefficient of a specified physical tissue model
L_0	minimum transmission loss of a specified physical tissue model .
L_r	residual transmission loss .
L_w	transmission loss of an acoustic window as part of a thermal sensor test object .
s	thermal spatial resolution .
T	temperature rise.
T_{ref}	reference temperature rise

5 Thermal test assembly

The general configuration for the **thermal test assembly** is shown in Figure 1. Acoustic coupling between the face of the **probe**, the **simulated tissue path** and the **thermal sensor test object** shall be achieved using water or any other **acoustic coupling medium** with a characteristic acoustic impedance close to that of water. Different combinations of a **thermal sensor test object** and a **simulated tissue path** shall be assembled in order to simulate an appropriate **physical tissue model**: recommendations are given in Annex B.

NOTE 1 If the **simulated tissue path** is fluid or semi-fluid, there may be no need for separate layers of **acoustic coupling medium**.

NOTE 2 Although this Technical Specification considers the simulated tissue path and the thermal sensor test object as being separate, there may be some situations where both parts are permanently joined.

The general configuration for the **thermal sensor test object** is shown in Figure 2.

NOTE 3 Depending on the materials used in the **thermal sensor test object**, parts such as the entrance window may not be required.

The **probe** should normally be mounted on a coordinate positioning system to provide lateral adjustment of its position and to allow the separation between the face of the **probe** and the **thermal sensor test object** to be varied.

All estimates of temperature rise used for standardisation purposes should be undertaken using a **thermal test assembly** and using the **standard insonation time**.

The **thermal test assembly** shall meet the requirements of 5.1; a **thermal test assembly** of the type described in Clause C.1 is considered to meet these requirements .

5.1 Specification of a thermal test assembly

The properties recommended for the **simulated tissue path** and the **target region** of a particular **reference thermal test object** are given in Annex B. When it is not possible to match the recommendations exactly, the errors introduced by the lack of ideal materials shall be assessed and should be corrected for by calculation, if possible.

5.1.1 Accuracy and stability

In addition to meeting the detailed requirements specified in the rest of subclause 5.1, the overall stability of a reference thermal test object shall be tested by monitoring the **measured temperature rise** produced by insonation with a **reference transducer** under prescribed conditions. Agreement shall be within ± 15 % of the **reference temperature rise**.

5.1.2 Simulated tissue path

For each **physical tissue model**, the acoustical path between the **probe** face and the **thermal sensor test object** shall be simulated by introducing attenuating material with a transmission loss equal to the **residual transmission loss**. In addition, there is a need to introduce additional attenuating material in order to account for the **incremental transmission loss coefficient**.

The simulation of the tissue path may be achieved by introducing tissue-simulating material of the appropriate transmission loss to fill the whole path between the face of the **probe** and the surface of the **thermal sensor test object**. Alternatively, an equivalent transmission loss may be achieved by introducing thin acoustical attenuators in the ultrasound beam.

In addition, the variation of acoustic velocity with temperature shall be less than $0,5 \text{ \% } ^\circ\text{C}^{-1}$ to minimise thermal self-focussing of the ultrasound beam.

5.1.3 Coupling media

The coupling media (if present) shall introduce additional acoustic losses of less than 0,3 dB over the entire frequency range of interest. This requirement for low loss applies to the materials used in making contact with the transducer as well as in coupling to the **thermal sensor test object**. Alternatively, it may be possible to immerse the surfaces of the **probe face** and **thermal sensor test object** in the material used for the **simulated tissue path**, thus eliminating the need for coupling media.

NOTE This can normally be achieved using a layer of oil or water, less than 0,01 mm thick.

5.1.4 Entrance window

The **entrance window** (if present) shall be sufficient to prevent significant degradation with time in the properties of the thermal sensor test object (see 5.1.1). The transmission loss of the **entrance window** shall be less than 1 dB at the **acoustic working frequency** and shall be included in any calculations of the transmission loss.

5.1.5 Target region

The properties of the **target region** shall be as specified in the appropriate **physical tissue model**.

5.1.6 Backing region

Reflection from any part of the **backing region** shall be less than –20 dB when measured at the thermal sensor.

NOTE A backing region may not be required if the attenuation between the **primary junction** and the rear of the **target region** is sufficiently high (>10 dB)

5.1.7 Thermal test object enclosure

The purpose of this enclosure is to protect the contents from degradation with time and to reduce environmental effects during the measurement. If the test object is to be used in an electrically noisy environment, it should be designed so as to provide good electromagnetic shielding. The material used for the enclosure walls shall be such as to prevent degradation of the contents. Changes in properties with time may occur by the transfer of material through the enclosure walls, or by the action of radiation (particularly ultra-violet radiation) entering the test object. In addition, the material may degrade spontaneously with time or as a result of exposure to high ultrasonic amplitudes during its use.

NOTE If parts of the test object are not liable to degradation, the thermal test object enclosure may not be required, or may enclose only part of the thermal test object.

5.1.8 Design of thermal-sensor test object

The design shall be such as to allow the lateral diameter of the **target region** to be at least 40 mm. If this region is less than 40 mm across, then the remaining space shall be made up using material of similar or lower thermal diffusivity than the target material. There shall be at least 20 mm of material between the **target plane** and the lower surface of the enclosure. The region beyond the **target region** shall have a thermal diffusivity of $2 \times 10^{-7} \text{ m}^2\text{s}^{-1}$ or less.

NOTE Optimum thermal stability is achieved by the **thermal sensor test object** having a large thermal mass.