

Measurement Good Practice Guide

Recommended ultrasound field safety classification for medical diagnostic devices

Roy C Preston and Adam Shaw



Measurement Good Practice Guide No. 50

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Abstract:

Ultrasound has been used intensively in our hospitals for over twenty years and it continues to command an ever increasing share of the diagnostic imaging market with tens of millions of ultrasound examinations being undertaken in the EC each year. Acoustic output levels of diagnostic ultrasonic systems have increased over the years and it has always been recognised that there is potential for adverse biological effects during clinical examination. The aim of this Guide is to provide some basic principles for assessing the safety of medical diagnostic ultrasonic fields, a topic of great importance to the patient, clinical user and manufacturer. The principles laid down are based on the quantitative assessment of two important biophysical end-points, temperature rise and the likelihood of cavitation taking place. A safety classification scheme is defined that establishes two simple classes of ultrasonic field safety. Class A is the highest safety class representing ultrasonic fields that can be used with minimal concern for patient safety. Class B relates to ultrasonic fields which require indication of additional information concerning thermal and cavitation hazard. Threshold levels of 4 kelvin for temperature rise and 4 megapascals for acoustic stress (peak rarefactional acoustic pressure) define the safety classes, and test methods needed to determine these biophysical quantities are specified. Various options are provided for the declaration of the safety class for either ultrasonic fields, modes of operation, probes or consoles. Finally, guidance on the use of the safety classes is given for patients and clinical operators.

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PREFACE TO THE GUIDE

The safety of medical diagnostic ultrasound used in our hospitals is of great importance to all concerned and especially to the patient. Diagnostic ultrasound has an excellent safety record over a period of intensive clinical use for more than twenty years, and it is important to ensure that safe clinical practices are continued. Vigilance must be maintained under circumstances where diagnostic equipment is continually developing and becoming more complex, and patient exposure levels are increasing. As virtually all the ultrasonic energy entering a patient is absorbed, it is essential that the potential adverse consequences of this absorption process are recognised and taken into account when assessing the safety of the patient in clinical practice. The primary purpose of this Guide is to set down the basic principles of a simple scheme for assessing the safety of ultrasonic fields in a manner that is useful for the patient and clinical operator, and is based on simple well-founded concepts.

This Guide presents a safety classification scheme that establishes two simple classes of ultrasonic field safety, one being the highest safety class representing ultrasonic fields that can be used with minimal concern for patient safety. The second class relates to ultrasonic fields where the hazard cannot be considered minimal. For this lower safety class, the provision of additional information concerning thermal and cavitation hazard allows the user to assess the significance of the hazard in relation to the benefit expected from the examination. A major benefit of the safety classification scheme is that it is based on absolute biophysical quantities, such as temperature rise, which do not depend on the methods used to estimate them. Therefore, this approach can be applied to all types of diagnostic ultrasonic fields, irrespective of whether the fields are generated by single element transducers, arrays, three-dimensional scanning systems or any future transducer technology. Furthermore, the underlying principles of the classification scheme do not have to change as better and more accurate methods of determining the biophysical quantities are developed in the future.

The National Physical Laboratory (NPL) is the UK's national measurement standards laboratory and has been involved for many years in the development of measurement standards for medical diagnostic ultrasonic equipment and the drafting of related specification standards through the International Electrotechnical Commission (IEC). The establishment of an IEC safety classification scheme for medical diagnostic ultrasonic fields has been one of the major goals of the medical ultrasonics work at NPL, both in terms of developing the technical requirements for the safety classification scheme and in terms of developing objective test methodologies. Considerable effort has therefore been devoted to the development and validation of methods of determining temperature rise using thermal test objects and to accurate measurement of acoustic pressure distributions. Absolute levels of temperature rise and acoustic stress (peak rarefactional acoustic pressure) are the key biophysical end-points that are believed to be directly related to any possible adverse biological effects. They are therefore the key parameters that need to be monitored once levels exceed the safety threshold. Furthermore, research and development work undertaken by NPL on behalf of the UK Department of Health has enabled the validation of methods of determining temperature rise to be undertaken for pulsed Doppler systems, and more recently the investigation of temperature rises in vivo. These studies confirm the importance of determining temperature rise when assessing the interaction of ultrasound with tissue. Hence, adopting the proposed principles embodied in the safety classification scheme provides a basis for controlling the risk to the patient, and indeed reducing the risk compared with alternative schemes that do not utilise absolute biophysical quantities.

The development of an IEC safety classification scheme has been undertaken through international committee work involving many technical experts. Much technical progress has been made but the final progression of the work to the publication stage as an international standard has not been achieved because the methodology differs from that developed in the USA and utilised for compliance with US regulations.

Nevertheless, there are valuable scientific and technical principles that have been embodied in the work. It is our view that during the next ten years these principles, such as the use of absolute biophysical quantities and the assessment of safety boundaries, will gain favour in the wide international community. It is for this reason that it is considered appropriate to present these principles in this Guide.

This Guide will:

- allow the principles of safety classification to gain wider understanding and acceptance by interested groups;
- provide a basis for further development of the safety classification concept;
- contribute to ensuring the continued safe use of diagnostic ultrasound;
- provide a published document to which reference can be made.

In presenting this guide, the contributions of all the technical experts involved with IEC Technical Committee 87 'Ultrasonics' over the years are gratefully acknowledged.

NPL has collaborated with Gesellschaft für angewandte Ultraschallforschung e.V. (GEFAU) in the preparation of this safety classification scheme which is based on the first Committee Draft for Vote, IEC document 87/149/CDV 'Classification scheme for medical diagnostic ultrasonic fields'. The majority of the technical content of this Guide is identical to the published standard GEFAU N 01* entitled 'Ultrasound Field Safety Classification for Medical Diagnostic Devices'. The permission given by Professor Dr. Joachim Herbertz, Managing Director GEFAU, to reproduce much of the text of GEFAU N 01 is gratefully acknowledged; the preface to GEFAU N 01 is reproduced in this Guide. The one major change from the text of GEFAU N 01 is that the requirements for declaration of safety class by manufacturers are now included as recommendations. Other minor changes have been introduced which suit the Guide better to the UK user, however these do not affect the safety classification assessment for ultrasonic fields.



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* GEFAU N 01: 'Ultrasound Field Safety Classification for Medical Diagnostic Devices', ISBN 3-9805013-1-0, GEFAU Gesellschaft für angewandte Ultraschallforschung e.V., Duisburg, Germany, 15 May 2001.

PREFACE TO GEFAU N 01

GEFAU, a non-governmental organisation for applied research in ultrasonics, has been registered in Germany since 1968 as a technical scientific society of public benefit. GEFAU promotes national and international standardisation in the field of ultrasonics as a consequence of its charter. With respect to the International Electrotechnical Commission IEC, GEFAU is supporting the Scope and the IEC Group Safety Function of Technical Committee 'Ultrasonics', which include ultrasonic biological effects and corresponding limits, pertaining to human safety.

From 1963 on, IEC has been publishing standards for medical ultrasonic devices. Experts of many countries have developed these ultrasonics standards, initially in Technical Committee IEC TC 29 'Electroacoustics', Working Group 7, later in Sub-Committee IEC SC 29D and since 1984 in the successor Technical Committee IEC TC 87 'Ultrasonics'.

IEC TC 87 has submitted in 1998 the Committee Draft for Vote IEC 87/149/CDV 'Classification scheme for medical diagnostic ultrasonic fields'. This CDV has been approved in April 1999 by more than a required 67% majority of those countries, who with their experts had participated in its preparation. Four of the participating countries have voted against: Austria, Denmark, Japan and USA. On the other hand, nine of the participating countries have voted in favour: Australia, China, Czech Republic, Germany, Korea (Rep. of), Netherlands, Romania, Russian Federation and United Kingdom.

Irrespective of the acceptance by the participating countries, there exists an additional requirement for publishing a standard in IEC: those countries, who are not participating in developing a standard, are entitled to vote as well, and no more than 25% of the total votes cast must be against. Lobbying of commercial interest groups, backed by a most powerful country, took place against any publication of the safety classification for medical diagnostic ultrasonic fields, resulting in blocking minorities, which have become effective in IEC voting procedures since 1999.

GEFAU takes the position that public trust and acceptance of ultrasound in medicine is at risk, while safety of the patient is inadequately guaranteed. As it is imperative to protect the patient against potential hazards of ultrasound, which are of more than minimal concern in diagnostic screening, publication of the safety classification standard must not be held at the mercy of interest groups. GEFAU is therefore establishing the ultrasound safety classification standard by this publication, so that it can be made available world-wide through booksellers.

In spite of all editorial and linguistic differences between this standard GEFAU N 01 and document IEC 87/149/CDV, the resulting normative provisions of both documents are identical. This standard will be reviewed in three year intervals, in the light of progress of work in IEC TC 87. It will be retracted when an equivalent IEC safety standard for the ultrasonic field will have become effective for medical diagnostic devices.



Managing Director GEFAU

INTRODUCTION

The use of ultrasonic fields in the human body for diagnostic purposes is one of the important areas of medicine.

As ultrasound deposits physical energy in human tissue, it is essential to assess in every case of application, whether the effects of this deposition of energy can be considered as of minimal concern, or whether as a matter of precaution the effects must be considered as potential risk.

For this purpose, this Guide specifies which conditions must be fulfilled in the ultrasonic field if, from the biological viewpoint, no significant hazard is expected from either heating effects or the arising of cavitation. These conditions are based on thresholds for two relevant biophysical quantities, temperature rise and acoustical stress, as follows:

Temperature rise less than 4 kelvin
Acoustical stress less than 4 megapascal

An ultrasonic field, diagnostic mode or device which has been verified to comply to these conditions is in class A. No additional information with respect to the safety of the ultrasonic field is required in safety class A.

All ultrasonic fields, diagnostic modes and devices not shown to be in class A must be considered to be in safety class B. In class B additional information should be given on the extent to which relevant limits of safety class A are exceeded.

This Guide does not specify how the assessment of medical diagnostic advantage for the patient compared to the magnitude of the risk, which is dependent on the safety class, must be carried out. But the safety classes A and B make it possible to decide on a medical or ethical basis, whether it is allowed to expose the patient in ultrasonic diagnosis to more than a minimal risk.

Impact of this Guide:

Ultrasound can be used in safety class A with minimal concern in such cases in which it is not allowed for medical or ethical reasons to expose the patient to more than a minimal potential risk.

Ultrasound can be used in safety class B in such cases in which it is allowed for medical or ethical reasons to expose the patient to more than a minimal potential risk.

The publication of this Guide is addressed to patients and equipment operators. It offers an internationally accessible basis for protection of the patient from more than minimal potential risk, where this is acceptable for medical or ethical reasons.

The publication of this Guide is also addressed to manufacturers of medical diagnostic equipment and test houses. It offers an internationally accessible basis for compliance to recommendations of this Guide for the safety classification of these products.

1 SCOPE

This Guide applies to all types of medical diagnostic ultrasonic imaging and monitoring equipment.

This Guide:

- provides a method of safety classification for medical diagnostic **ultrasonic fields** in the frequency range 1 MHz to 15 MHz.
- provides safety classification on the basis of the relevant biophysical parameters in the **ultrasonic field**, specifically **temperature increase** and **acoustical stress**.
- specifies criteria for assigning a safety class to **ultrasonic fields** of medical diagnostic ultrasonic equipment.
- provides two safety classes of **ultrasonic fields** for allocation of safety class for medical diagnostic **modes, probes** and **consoles**.
- provides for normal patients, and for exposure periods of less than 15 minutes, a safety class A of **ultrasonic fields** which can be used with minimal concern for patient safety with respect to thermal and cavitation hazard.
- provides a safety class B of **ultrasonic fields** of medical diagnostic equipment in which the thermal or cavitation hazard is of more than minimal concern; in this safety class, additional information related to patient safety is recommended for a proper risk assessment.

NOTE 1

The safety class defined in this Guide is attributed to the **ultrasonic field** for the purpose of assessing the hazard potential of normal diagnostic exposure to that field. Minimum concern for safety is limited to **ultrasonic fields** with the attributed class A. The safety class is determined by applying the methods of this Guide on the basis of an **appropriate worst-case model** and measurement procedures implying a normal patient. Prior to clinical use, the operator would need to take into account whether the physiological state of the individual patient (e.g. the presence of contrast agent, the presence of fever) may increase thermal and cavitation hazard in **ultrasonic fields** of medical diagnostic equipment.

NOTE 2

The safety classification of the **ultrasonic field** of medical diagnostic operational **modes, consoles** and **probes**, and the indication of additional information related to patient safety with respect to thermal and cavitation hazard in class B is intended to support the operator in assessing the risk for the individual patient.

NOTE 3

For screening of normal patients, medical diagnostic operational **modes, consoles** and **probes** in safety class A can be used with minimal concern for patient safety with respect to thermal and cavitation hazard, if the operator limits exposure time to the **ultrasonic field** to less than 15 minutes.

2 LIST OF SYMBOLS

p	=	acoustical stress
p_{th}	=	threshold acoustical stress
ΔT	=	temperature increase
ΔT_{th}	=	threshold temperature increase

3 REFERENCE TO PUBLISHED STANDARDS

The following publication contains normative content which by reference in this Guide complements this Guide.

IEC 61157

Critères pour la déclaration des émissions acoustiques des appareils de diagnostic médical à ultrasons
Requirements for the declaration of the acoustic output of medical ultrasonic equipment

First Edition 1992-07, Reference number CEI/IEC 1157:1992

Bureau Central de la Commission Electrotechnique Internationale
3, rue de Varembe
Genève, Suisse

4 DEFINITIONS

- 4.1 probe**
component of medical diagnostic device which contains one or more ultrasonic transducer elements together with passive components contributing to characteristics of the **ultrasonic field**, normally detachable from the **console**
- 4.2 console**
component of medical diagnostic device providing an interface to the operator, which is connected to the **probe**
- 4.3 mode**
operational configuration of medical diagnostic device during which the **probe** generates ultrasonic energy

NOTE

Examples of **modes** include A-mode, B-mode, C-mode, pulsed Doppler, real-time flow mapping, colour Doppler, B-mode combined with pulsed Doppler etc.

4.4 ultrasonic field

region of a medium containing ultrasonic energy, which has been generated for medical purposes

4.5 cavity

volume enclosed by elastic medium, filled with gas, or gas and plasma

4.6 ultrasonic cavitation

arising of **cavities**, their oscillation and collapse in an **ultrasonic field**

4.7 temperature increase

temperature rise in the medium, relevant to the potential arising of risk of thermal harm or damage in an **ultrasonic field**, to be determined using a specified classification measurement procedure at a specified point of interest in an **ultrasonic field**

Unit: kelvin (K)

Symbol: ΔT

4.8 acoustical stress

acoustical tension in the medium, relevant to the potential risk of **ultrasonic cavitation**, to be determined using a specified classification measurement procedure at a point of interest in an **ultrasonic field** as peak rarefactional acoustical pressure

Unit: megapascal (MPa)

Symbol: p

4.9 appropriate worst-case model

model (physical or theoretical) yielding values for **temperature increase** and **acoustical stress** in the **ultrasonic field** of an intended medical diagnostic application, such that these will not be exceeded by actual values in these examinations in more than 10% of exposures

4.10 probable maximum

characteristic of the value of a quantity, where this value is the sum of the measured maximum value of the quantity in an **ultrasonic field** and the combined standard uncertainty of the measurement procedure for this quantity at the 67% confidence level

4.11 threshold temperature increase

value of **temperature increase** specified in this standard, which mandates allocation of safety class B to a particular **ultrasonic field**, if the value of **probable maximum temperature increase** for that **ultrasonic field** is not lower

Unit: kelvin (K)

Symbol: ΔT_{th}

4.12 threshold acoustical stress

value of **acoustical stress** specified in this standard, which mandates allocation of safety class B to a particular **ultrasonic field**, if the value of **probable maximum acoustical stress** for that **ultrasonic field** is not lower

Unit: megapascal (MPa)

Symbol: p_{th}

5 SAFETY CLASSES OF ULTRASONIC FIELDS

5.1 Classification process

Safety classification applies to all **ultrasonic fields** generated by all types of medical diagnostic ultrasonic imaging and monitoring equipment.

If an **ultrasonic field** meets the exemption requirements specified in Clause 6 of **IEC 61157**, it is presumed to be in class A. It is allocated class A(exempt), which may be abbreviated class A(E) or class A_E.

NOTE

For assessment of safety for exposure periods of more than 15 minutes by the operator, it may be appropriate to provide this additional information by declaring the exempt **ultrasonic field** class A(E) instead of class A or B, see A.3.2.

If an **ultrasonic field** does not meet the exemption requirements specified in Clause 6 of **IEC 61157**, the following classification process is used for establishing the allocation of safety class:

- A measurement procedure and an **appropriate worst-case model**, which simulates relevant conditions in the patient, are selected for **temperature increase**;

Using this measurement procedure, the **probable maximum temperature increase** is determined for the **ultrasonic field**;

- A measurement procedure and an **appropriate worst-case model**, which simulates relevant conditions in the patient, are selected for **acoustical stress**;

Using this measurement procedure, the **probable maximum acoustical stress** is determined for the **ultrasonic field**.

For establishing the allocation of safety class, see 5.3, the values of **probable maximum temperature increase** and **probable maximum acoustical stress** are compared with the respective thresholds.

5.2 Thresholds

For establishing the allocation of safety class of **ultrasonic fields**, **threshold temperature increase** shall be 4 kelvin ($\Delta T_{th} = 4 \text{ K}$).

NOTE 1

While temperature is understood to be the immediately relevant parameter for the potential arising of thermal risk within a given exposure period, the parameter **temperature increase for the normothermic patient** has been chosen for the purpose of this Guide. This equally relevant parameter has the practical advantage, that it can be determined using a specified classification measurement procedure at a temperature different from normal physiological temperature.

NOTE 2

It is known [1] that the value of **temperature increase** for minimal concern to a normothermic patient can be 4 K for up to 15 minutes. Exposure period is considered to begin with the first exposure to the **ultrasonic field** and to finish with the end of the last such exposure in the context of an examination.

For establishing the allocation of safety class of **ultrasonic fields**, **threshold acoustical stress** shall be 4 megapascal ($p_{th} = 4 \text{ MPa}$).

NOTE 3

While peak tension is understood to be the immediately relevant parameter for the potential arising of cavitation, the parameter **acoustical stress** has been chosen for the purpose of this Guide. This equally relevant parameter has the practical advantage, that it can be determined using a specified classification measurement procedure independently of atmospheric pressure. The threshold value of 4 MPa has been chosen as one half the theoretical value [2].

NOTE 4

Future classification standards for safety of **ultrasonic fields** in the presence of contrast agents or cavitation nuclei may specify other relevant parameters.

5.3 Allocation of safety class

An **ultrasonic field** in which the **probable maximum temperature increase** is less than the **threshold temperature increase**, and the **probable maximum acoustical stress** is less than the **threshold acoustical stress**, is allocated class A.

An **ultrasonic field** in which the **probable maximum temperature increase** is not less than the **threshold temperature increase**, and/or the **probable maximum acoustical stress** is not less than the **threshold acoustical stress**, is allocated class B.

NOTE

If a class A **ultrasonic field** is used for exposure periods of more than 15 minutes, or if the patient is above normothermal, or in the presence of contrast agents or cavitation nuclei, the operator may simply assess the risk in the same way that is used in risk assessment for class B exposures.

5.4 Classification measurement procedures

Classification measurement procedures are to be specified.

Classification measurement procedures and models for **temperature increase**, ΔT , are to comply with those International Standards that specify measurement procedures for **temperature increase**, or are to be based on other published methods, which have been shown to yield equivalent or superior results.

Classification measurement procedures and models for **acoustical stress**, p , are to comply with those International Standards that specify measurement procedures for **acoustical stress**, or are to be based on other published methods, which have been shown to yield equivalent or superior results.

Classification measurement procedures should be carried out in stable exposure conditions, if possible keeping the **probe** stationary.

NOTE 1

Some **probes** may not operate unless being moved.

An **appropriate worst-case model** for **temperature increase** to be used by a classification measurement procedure is one which yields in every kind of medical diagnostic application, for which

the model is intended, values of **probable maximum temperature increase** in the whole **ultrasonic field** which will not be exceeded by actual values in more than 10% of exposures.

An **appropriate worst-case model** for **acoustical stress** to be used by a classification measurement procedure is one which yields in every kind of medical diagnostic application, for which the model is intended, values of **probable maximum acoustical stress** in the whole **ultrasonic field** which will not be exceeded by actual values in more than 10% of exposures.

NOTE 2

In this case, the use of the 10% level instead of a 2.5% level is appropriate, as it only serves to derive **probable maximum** values from selected measurement procedures.

Classification measurement procedures shall use **appropriate worst-case models**, or use other models and apply specified safety factors to values obtained, in order to make realistic estimates of **appropriate worst-case model** values of **probable maximum temperature increase** and **probable maximum acoustical stress** respectively. If other than specified safety factors are applied, explicit justification is to be provided.

For the allocation of a safety class in accordance with 5.3, **probable maximum temperature increase** is the sum of the measured maximum value of **temperature increase** in the **ultrasonic field** and the combined standard uncertainty of the selected measurement procedure for **temperature increase** at the 67% confidence level.

For the allocation of a safety class in accordance with 5.3, **probable maximum acoustical stress** is the sum of the measured maximum value of **acoustical stress** in the **ultrasonic field** and the combined standard uncertainty of the selected measurement procedure for **acoustical stress** at the 67% confidence level.

NOTE 3

The combined standard uncertainty of the selected measurement procedures does not include such factors as different medical applications or differences between individual patients. Such variations are taken into account by the **appropriate worst-case model**.

ANNEX A - GUIDANCE FOR IMPLEMENTING CLASSIFICATION

A.1 Options for implementation

This Guide may be used voluntarily by manufacturers, test houses, hospitals or other relevant groups. Anyone choosing to comply with this Guide, can take advantage of the possibility to indicate devices with **ultrasonic fields**, diagnostic **modes** and **probes** declared to be in the safety classes A(exempt) or A. Minimal concern for patient safety with respect to thermal and cavitation hazard in these classes may be one of the preconditions for ultrasonic diagnostic screening, where no justification exists for exposing the patients to the potential risk present in safety class B.

While this Guide does not restrict the possibility that the safety class changes for example from A to B during diagnostic examination of a patient, or that the exposure period time in safety class A exceeds 15 minutes, the manufacturer may choose to limit some **ultrasonic fields**, diagnostic **modes** and **probes** of the device in a way preventing automatically a change from class A to class B. For instance, a **console** with one or more **probes** may offer to the operator a choice of *unlimited* or *limited to class A* or *limited to class A(exempt)* operation for its **ultrasonic fields**, diagnostic **modes** and **probes**.

A.2 Guidance on determining safety class

A.2.1 Classification measurement procedures and appropriate worst-case models

In addition to the IEC classification project¹, which is the basis of this Guide, a standard for test methods² for determination of exposure parameters and **appropriate worst-case models** for the safety classification has been under development in the IEC.

As a measurement procedure for classification in compliance with this Guide needs not to be based on a specified standard, any measurement procedure specified by the manufacturer or test house is suitable, providing that it:

- yields **probable maximum** values in compliance with this Guide and
- is specified together with an **appropriate worst-case model** in compliance with this Guide.

A.2.2 Measurement procedures for temperature increase

The gold standard of measuring in-vivo **temperature increase** in the **ultrasonic field** at the biophysical site of interest may not be practical.

¹ Circulated to national committees by the International Electrotechnical Commission, project IEC 61681, document reference 87/149/CDV: "Ultrasonics – Field safety – Part 1: Classification scheme for medical diagnostic fields", 1999.

² Circulated to national committees by the International Electrotechnical Commission, project IEC 61973, document reference 87/150/CDV: "Ultrasonics – Field characterisation – Test methods for the determination of thermal and mechanical exposure parameters for the purposes of defining the safety classification of medical diagnostic ultrasonic fields", 1999.

A standard for determining **temperature increase** using a test object and a standard for methods of calculating **temperature increase** in selected diagnostic applications of **ultrasonic fields** are under development in the IEC.

Physical measurements may be carried out using measurement techniques similar to those described in the AIUM/NEMA Output Display Standard ODS [3]. While this industrial standard of the USA has been developed in only one country, and is not based on consensus of the majority of countries participating with their experts in the ‘Ultrasonics’ committee TC 87 of the IEC, some contents of the ODS may be useful for the purpose of safety classification. The ODS makes use of a theoretical acoustical attenuation factor of $0,3 \text{ dB cm}^{-1} \text{ MHz}^{-1}$, which yields a Thermal Index *TI* for typical conditions in a specified application. From experimental investigations [4], it has been concluded in draft IEC 61681 (see footnote 1 in A.2.1), that for the conversion of a *TI* into **probable maximum temperature increase**, the dimensionless *TI* should be multiplied by a factor of 3 kelvin.

A.2.3 Measurement procedures for acoustical stress

The gold standard of measuring in-vivo **acoustical stress** in the **ultrasonic field** at the biophysical point of interest may not be practical.

A standard for determining maximum **acoustical stress** using water as a test object exists. It is the normative complement to this Guide, **IEC 61157**. As no acoustical attenuation factor is used, *peak negative (rarefactional) acoustical pressure* measured in accordance with clause 4.2.1 b) of that standard can be considered to be equal to the maximum **acoustical stress** in any diagnostic situation, where no reflecting boundary is nearby. If the worst-case model contains a reflecting tissue/gas boundary, for instance in the neighbourhood of the lung, superposition of the ongoing *peak rarefactional acoustical pressure* and the reflected inverted peak positive acoustical pressure should be considered. A plane-wave reflection model would yield maximum **acoustical stress** to be the sum of peak positive acoustical pressure and *peak rarefactional acoustical pressure*.

Measurement similar to **IEC 61157**, using no acoustical attenuation factor, may be essential if the **appropriate worst-case model** includes the possibility of a significant external and/or internal acoustical path through a liquid with low attenuation, for example water. This may be the case for instance in ophthalmological or obstetric use of diagnostic ultrasound.

If the specified worst-case model does take attenuation into account, physical measurements may be carried out using measurement techniques similar to those described in the AIUM/NEMA Output Display Standard ODS [3]. According to models described in draft IEC 61973 (see footnote 2 in A.2.1), which differs from the derating based on the square root of frequency used in the ODS [3], the measured **acoustical stress** must not be de-rated by the square root of frequency for the purpose of safety classification.

When the peak rarefactional acoustic pressure is not known, then the **acoustical stress** may be calculated from the mechanical index, *MI*, as follows:

$$\text{acoustical stress (MPa)} = MI \sqrt{f_{\text{awf}}} 10^{(a f_{\text{awf}} z / 20)} \times (1 \text{ MPa MHz}^{-1/2})$$

where:

a is the derating factor (normally $0,3 \text{ dB cm}^{-1} \text{ MHz}^{-1}$);

f_{awf} is the acoustic working frequency in MHz;

z is the distance in cm from the **probe** to the location of the maximum attenuated pulse-pressure-squared integral.

A.3 Declaration of safety class for medical diagnostic ultrasonic equipment

A.3.1 Methods of declaration

The safety class for medical diagnostic ultrasonic equipment should be declared using one of the following three methods:

- Declaration of safety class for **ultrasonic fields** in accordance with A.3.2;
- Declaration of safety class for diagnostic **modes** in accordance with A.3.3;
- Declaration of safety class for **probes** and **consoles** in accordance with A.3.4.

NOTE 1

These three options provide flexibility to the manufacturer in using the safety class allocated to the **ultrasonic field** for the declaration of safety class for medical diagnostic ultrasonic equipment.

The safety class may be declared for a specified application, for instance:
'Class B in ophthalmological use'.

The declared safety class should be indicated to the operator.

When safety class A is indicated to the operator, a clear additional indication should be given to the operator when the exposure period reaches 15 minutes.

Safety class A(exempt) is considered to be a higher level of safety than safety class A, and safety class A is considered to be a higher level of safety than safety class B.

When safety class B is declared, additional information should be made available to the operator. This information should indicate the extent that **probable maximum temperature increase** exceeds **threshold temperature increase**, and/or **probable maximum acoustical stress** exceeds **threshold acoustical stress**.

NOTE 2

This Guide does not specify the methods for informing the operator on the 'extent' of an excess. This provides additional flexibility to the manufacturer, to comply in the market with rules of regulatory authorities.

NOTE 3

Keeping in mind that the risk associated with exposure excesses would be expected to increase rapidly once the thresholds are exceeded, the indicated value should be not lower than the actual value, and the indicated value should not exceed the actual value significantly. In order not to exceed the actual value significantly, the accuracy of the indicated value should be better than the sum of 25% of the threshold value and the combined standard uncertainty of the measurement procedure at the 67% confidence level.

NOTE 4

The excess may be indicated by a digital display of the difference between the **probable maximum temperature increase** and the **threshold temperature increase**, (*Excess Temperature Increase* or ETI), if this difference is positive, and/or the difference between the **probable maximum acoustical stress** and the **threshold acoustical stress**, (*Excess Acoustical Stress* or EAS), if this difference is positive. It may be appropriate to display these quantities with a resolution of 0,5 K and/or 0,5 MPa, respectively. In order to ensure readability, the display should be updated at intervals of 1 s, when the next value to be indicated is not higher. If this method is used for informing the operator on the extent of an excess, the on screen display may read for example: 'ETI = 3,0 K' or 'EAS = 1,5 MPa'.

NOTE 5

The excess may be indicated by a digital display of the ratio of the **probable maximum temperature increase** and the **threshold temperature increase**, (*Relative Temperature Increase* or RTI), and/or the ratio of the **probable maximum acoustical stress** and the **threshold acoustical stress**, (*Relative Acoustical Stress* or RAS). It may be appropriate to display these values with a resolution of 0,1 or 0,2, respectively. In order to ensure readability, the display should be updated at intervals of 1 s, when the next value to be indicated is not higher. If this method is used for informing the operator on the extent of an excess, the on screen display may read for example: 'RTI = 1,8' or 'RAS = 1,4'.

NOTE 6

For peace of mind of the operator, additional information on the absence of any excess should be made available, if no threshold is exceeded while class B is declared. An on screen display may read in this case: 'no ETI, no EAS' or 'RTI < 1,0, RAS < 1,0'.

NOTE 7

The option of activating on screen display of RTI and RAS values in cases of abnormal conditions of the patient, for instance fever or presence of contrast agents in the body, may be provided to the operator, making available additional information, when the **ultrasonic field** is in class A.

A.3.2 Declaration of safety class for ultrasonic fields

The declared safety class of an **ultrasonic field** should not be higher than the class allocated to this **ultrasonic field** in accordance with clause 5.

A change of declared safety class should be indicated whenever the **ultrasonic field**, for which the safety class is declared, is changed.

A clear and unambiguous alert should be given to the operator whenever the safety class of the **ultrasonic field** changes to class B.

If the safety class of the **ultrasonic field** changes to a class lower than that declared (e.g. from class A to class B), the indication of declared class should immediately change.

If the safety class of the **ultrasonic field** changes to a class higher than that declared (e.g. from class B to class A), the indication of declared class should change, if appropriate.

Consequently, the safety class of the **ultrasonic field** should be declared in conformity with the following set of rules:

- If the allocated safety class of an **ultrasonic field** is A(exempt) in accordance with 5.1, the declared safety class of this **ultrasonic field** should be either A(exempt), A or B;
- If the allocated safety class of an **ultrasonic field** is A in accordance with 5.3, the declared safety class of this **ultrasonic field** should be either A or B;

- If the allocated safety class of an **ultrasonic field** is B in accordance with 5.3, the declared safety class of this **ultrasonic field** should be B.

NOTE

The possibility of declaring a lower safety class than that allocated to the **ultrasonic field** provides additional flexibility to the manufacturer, which may be useful in cases of uncertainty in the allocation of the class. Such uncertainty may exist, if **probable maximum temperature increase** is close to the **threshold temperature increase** or if the **probable maximum acoustical stress** is close to the **threshold acoustical stress**. In other cases, a manufacturer may wish to declare the same safety class for all **ultrasonic fields**.

A.3.3 Declaration of safety class for diagnostic modes

The declared safety class of a diagnostic **mode** should not be higher than the lowest class allocated to any of the **ultrasonic fields** of that diagnostic **mode** in accordance with clause 5.

A change of declared safety class should be indicated whenever the diagnostic **mode**, for which the safety class is declared, is changed.

A clear and unambiguous alert should be given to the operator whenever the safety class of the diagnostic **mode** changes to class B.

If the safety class of the diagnostic **mode** changes to a class lower than that declared, the indication of declared class should immediately change.

If the safety class of the diagnostic **mode** changes to a class higher than that declared, the indication of declared class should change, if appropriate.

Consequently, the safety class of diagnostic **mode** should be declared in conformity with the following set of rules:

- If the allocated safety class of all **ultrasonic fields** of a diagnostic **mode** is A(exempt) in accordance with 5.1, the declared safety class of this diagnostic **mode** should be either A(exempt), A or B;
- If the lowest safety class allocated to any of the **ultrasonic fields** of a diagnostic **mode** is A in accordance with 5.3, the declared safety class of this diagnostic **mode** should be either A or B;
- If the allocated safety class of any of the **ultrasonic fields** of a diagnostic **mode** is B in accordance with 5.3, the declared safety class of this diagnostic **mode** should be B.

NOTE

The possibility of declaring a lower safety class than the lowest class allocated to any of the **ultrasonic fields** of the diagnostic mode provides additional flexibility to the manufacturer, which may be useful in cases of uncertainty in the allocation of the class. Such uncertainty may exist, if **probable maximum temperature increase** is close to the **threshold temperature increase** or if the **probable maximum acoustical stress** is close to the **threshold acoustical stress**. In other cases a manufacturer may wish to declare the same safety class for all diagnostic **modes**.

A.3.4 Declaration of safety class for probes and consoles

A safety class should be declared for a **probe** only if that **probe** is combined with a specified **console**.

A clear and unambiguous warning should be given to the operator when the safety class of the **probe** and **console** is class B.

NOTE 1

If the declaration of safety class is intended for the combination any **probe** of a particular type with any **console** of a particular type, then the additional uncertainty resulting from combining samples of nominally identical systems should be taken into account. This Guide does not deal with this additional uncertainty.

The declared safety class of a **probe** should not be higher than the lowest class allocated to any of the **ultrasonic fields** for that **probe** in accordance with clause 5. It may be indicated on the **probe** itself.

Consequently, the safety class of a **probe** should be declared in conformity with the following set of rules:

- If the allocated safety class of all **ultrasonic fields** for a **probe** is A(exempt) in accordance with 5.1, the declared safety class of this **probe** should be either A(exempt), A or B;
- If the lowest safety class allocated to any of the **ultrasonic fields** for a **probe** is A in accordance with 5.3, the declared safety class of this **probe** should be either A or B;
- If the allocated safety class of any of the **ultrasonic fields** for a **probe** is B in accordance with 5.3, the declared safety class of this **probe** should be B.

NOTE 2

The possibility of declaring a lower safety class than the lowest class allocated to any of the **ultrasonic fields** for the **probe** provides additional flexibility to the manufacturer, which may be useful in cases of uncertainty in the allocation of the class. Such uncertainty may exist, if **probable maximum temperature increase** is close to the **threshold temperature increase** or if the **probable maximum acoustical stress** is close to the **threshold acoustical stress**. In other cases, a manufacturer may wish to declare the same safety class for all **probes**.

ANNEX B - GUIDANCE FOR PATIENTS AND EQUIPMENT OPERATORS

B.1 Is safety of the patient in the ultrasonic field of minimal concern or not?

For more than 60 years, the safety of the patient in the ultrasonic field has been subject of scientific research and controversies.

Without any doubt, some ultrasonic fields constitute a potential undesirable risk to the patient. Such fields may be used for example in surgery and therapy. Such fields may also be generated by some diagnostic ultrasound equipment [5].

If exposure to a diagnostic ultrasonic field would carry a potential risk of more than minimal concern, it would be appropriate that patients and equipment operators should be informed before accepting that potential risk for good medical reasons.

As the AIUM/NEMA Output Display Standard ODS [3] requires manufacturers of diagnostic ultrasound equipment to caution operators against a potential risk, when a patient is exposed to any ultrasonic field, the ODS is equivalent to committing diagnostic ultrasound equipment to safety class B. Consequently, the ODS keeps patients and equipment operators in the dark when exposed only to an ultrasonic field in safety class A, where the risks of known ultrasound bio-effects are of minimal concern.

The ODS does not answer the question most important to the patient: is ultrasound safety of minimal concern or not?

B.2 Answer given by the classification of safety of the ultrasonic field

Up to now, patients and equipment operators in many countries have trusted the safety of ultrasonic diagnostic examinations based on the absence of published cases of damage. Now the safety classification provides to patients and equipment operators the most important information on whether safety of an ultrasonic diagnostic examination is a matter of concern.

The answer is that ultrasound field safety is only of minimal concern in 'normal' cases, when the medical diagnostic device is operated in class A.

More than minimal concern is warranted when the medical diagnostic device is operated in class B or in abnormal conditions of the patient, for instance fever or presence of contrast agents in the body.

The main advantages of this classification Guide are:

- Traditional trust of the patient in the safety of ultrasonic diagnostic examinations can be carried forward into examinations using safety class A;
- Equipment operators are alerted if during examinations the safety class actually changes to B;
- In safety class B, additional data on the relevant exposure parameters are provided to the operator, thereby supporting qualified equipment operators in minimising potential risk to the patient.

B.3 Guidance for operators on scientific background and the ALARA principle

This safety classification is based on scientific knowledge that

- intensity is not the single relevant safety parameter in the ultrasonic field [6];
- thresholds exist for the onset of relevant thermal [1] and cavitation [2] bioeffects;
- the radiological dose concept of the ALARA principle does not apply to ultrasound [7].

The first step in establishing safety of diagnostic ultrasound on this scientific basis has been the standard **IEC 61157**, which in paragraph 4.2.1 requires manufacturers to provide technical data sheets to prospective purchasers of equipment. These data sheets must declare the maximum values for a set of five acoustic output parameters relevant to thermal and cavitation risk assessment.

The second step in establishing safety of diagnostic ultrasound on the same scientific basis has been the development of the safety classification scheme, as given in this Guide.

As this Guide does not specify a principle for ultrasound equivalent to the ALARA principle for radiation, only the following guidance can be offered:

- Begin and try to stay in safety class A, if that would be sufficient for the purpose of the diagnostic examination;
- Once in safety class B, keep the maximal exposure excesses to thermal and cavitation risk as low as reasonably achievable.

ANNEX C - REFERENCES

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