

Safety of Diagnostic Ultrasound: Relevance of TI, MI, Safety Class, ETI or RTI, EAS or RAS

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Introduction

The first observations of biological effects of ultrasound date back to LANGEVIN and his co-workers TOURNIER and HOLWECK [1]. Since more than 60 years of ultrasound in medicine, its safety is a field of fierce controversies.

In the last 20 years, ultrasound has become the most widely used diagnostic commodity in industrialised countries. As the medical operators of ultrasonic diagnostic equipment in the USA came mainly from a radiological background, ultrasound exposure was understood to present a general risk to the patient, which could be managed by minimising – similar to x-rays – the ultrasonic energy dose, while limiting the time-average acoustical intensity to $100 \text{ mW} / \text{cm}^2$ was considered to be prudent.

In 1984, this view of ultrasonic safety was challenged by the safety philosophy embedded in the Scope for a newly established Technical Committee 'Ultrasonics', TC 87 of the IEC. This Scope authorised TC 87 to develop International Standards on human safety, including biological effects and corresponding limits, with respect to ultrasound.

Up to now, the safety related standards developed by the experts of IEC TC 87 are irreconcilable with competing industrial and international standards, which reflect a radiological approach to ultrasound. Irrespective of the historical background, the real cause for this persistent conflict is not of scientific, but of commercial nature.

While manufacturers always must pay lip service to the safety of the patient, short-time profit is the first priority and safety only a marginal consideration in the global market, if safety regulations do not impose safety as the first priority. One response of global commercial cartels under the pressure of globalisation, to dictate unilaterally the content of International Safety Standards for diagnostic ultrasound in the IEC and by implication in Europe, has become effective since 5 years.

The conflict between the ultrasound field safety classification standard [2], [3], resulting from work of IEC TC 87 and the standard for the safety of ultrasonic diagnostic and monitoring equipment [4], resulting from IEC SC 62B is not yet resolved in Europe. The responsible European committee CENELEC has asked IEC to revise its standard as pre-condition for a listing as harmonised European Standard.

This publication is meant to clarify the philosophies behind the conflicting safety standards and to explain the confusing acronyms in the title, in order to give decision-makers in Europe information on their scientific relevance.

The radiological approach

Acronyms related to the radiological approach:

TI THERMAL INDEX

in a specific tissue model, ratio of attenuated power in a specified point to the attenuated power required to raise the temperature in that point by 1°C

MI MECHANICAL INDEX

attenuated peak-rarefaction pressure in MPa divided by the square root of the acoustic working frequency in MHz

ALARA-PRINCIPLE

dose-related prudent use statement, that in the diagnostic process risk exposure must be kept As Low As Reasonably Achievable

ODS OUTPUT DISPLAY STANDARD

standard of an electrotechnical manufacturers association in the USA, requiring display of MI- or TI-values to the operator as basis for application of the ALARA-principle

The philosophy behind this approach:

For medical users not knowing that ultrasound is no radiation, acoustical intensity seems to be equivalent to x-ray radiation intensity and exposure to any diagnostic ultrasound dose seems to constitute a risk exposure. This seems to justify the application of the ALARA-principle on the basis guiding indexes, useful for the indication of greater or lesser risk, dependent on the setting of the diagnostic device by the operator.

On this intensity-based presumption, use of MI and TI has been advised by manufacturers for the prediction of probable temperature rise and for the indication of cavitation hazard.

As safety limits, below of which hazard might be absent, are not consistent with the underlying radiological philosophy, MI and TI have not been designed to serve as relevant bio-physical safety parameters, which take into account reasonable worst case conditions. MI and TI were not meant to be used for the delineation of conditions in the ultrasonic field free of thermal and cavitation hazard.

Unfortunately, as the frequency dependency of MI is different from experimental experience and research results, and as the TI is linked to an unsuitable acoustic attenuation coefficient, limits for TI and MI would be unsuitable as safety related limits pertaining to bio-effects.

This less than scientific radiological approach does not allow for the definition and characterisation of a condition of minimal safety concern by relevant limits.

Therefore it can only disadvantage patients by avoidable exposure to risk or by unnecessary degradation of diagnostic quality due to ALARA.

The bio-physical approach

Acronyms related to the bio-physical approach:

SAFETY-CLASS

display of the safety condition of an diagnostic ultrasonic field by a single letter: A in case of minimal safety concern and B in the other case

ETI EXCESS TEMPERATURE INCREASE

digital display of the difference between the probable maximum temperature increase and the threshold temperature increase for the onset of thermal hazard in living human tissue

EAS EXCESS ACOUSTICAL STRESS INCREASE

digital display of the difference between the probable maximum acoustical stress and the threshold acoustical stress for the onset of cavitation hazard in living human tissue

RTI RELATIVE TEMPERATURE INCREASE

digital display of the ratio of the probable maximum temperature increase to the threshold temperature increase for the onset of thermal hazard in living human tissue

RAS RELATIVE ACOUSTICAL STRESS INCREASE

Digital display of the ratio of the probable maximum acoustical stress to the threshold acoustical stress for the onset of cavitation hazard in living human tissue

The philosophy behind this approach:

The safety philosophy embedded in the Scope of IEC TC 87 is based on physical wisdom that sound is a physical energy and no radiation. As life has evolved in the presence of significant physical energies, such physical energies can not cause bio-effects of more than minimal concern, if the relevant parameters for biological endpoints do not exceed certain threshold values. For medical diagnostic ultrasonic fields, the experts in IEC TC 87 have considered the characteristics of two biological endpoints, the possibility of thermal effects causing biological hazards and the possibility of cavitation effects causing biological hazards.

For thermal effects, it has been found that a biological hazard of more than minimal concern does not exist, if a certain thermal exposure limit is not exceeded. For a specified set of exposure conditions, which apply for most ultrasonic diagnostic exams, probable maximum temperature rise has been identified as the safety relevant parameter, and by consensus of the experts, its limit has been set to **4 Kelvin**.

For cavitation effects, it has been found that a probability of occurrence of more than minimal concern does not exist, if a certain acoustical exposure limit is not exceeded. For a specified set of exposure conditions, which apply for most ultrasonic diagnostic exams in the absence of contrast agents, probable maximum acoustical stress has been identified as the safety relevant parameter, and by consensus of the experts, its limit has been set to **4 Megapascal**.

Essential part of this approach is the observation that no other biological hazard of more than minimal concern exists as long as both the thermal limit and the cavitation limit for the truly safety relevant parameters are not exceeded. For diagnostic ultrasound, this logical consequence has been fundamental for the concept of Safety Class A with minimal safety concern and for Safety Class B with more than minimal safety concern. For Safety Class B result additional requirements for the indication of the extent to which safety limits are exceeded.

Safety of the European patient

The European legislator with insight into the philosophies behind the conflicting safety standards has presently, as long as IEC and CENELEC have not yet been able to complete their designs, the opportunity of establishing the safety classification as harmonised European standard.

As IEC and by association CENELEC do no longer deserve public trust in safety standards, which are dictated by the unilateral interests of those for whom compliance with the safety interest of the patient should be made mandatory. Under the pressure from the global market, more trustworthy, mechanisms for the development of European safety standards need to be introduced.

A first step for improving the situation, which has already become lethal in the case of nursing beds, would be to make the CEN/CENELEC mandates by the European Commission contingent on proof of consensus: that no significant non-commercial party maintains serious objections in a mandatory public European enquiry procedure, before the Commission accepts a European Safety Standard as Harmonised Document. CENELEC has disregarded such complaints with respect to EN 60601-2-37.

References

- [1] R. Pohlman: Die Ultraschalltherapie, Huber Bern, 1951
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- [3] Measurement Good Practice Guide No. 50: Recommended ultrasound field safety classification for medical diagnostic devices, National Physical Laboratory, Teddington, ISSN 1368-6550, Crown Copyright 2001
- [4] IEC 60601-2-37 Medical electrical equipment – Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment, IEC Geneva, 2001(E)