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Session 5pBAa, Standardization of Ultrasound Medical Devices

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OVERVIEW OF INTERNATIONAL ELECTROTECHNICAL COMMISSION (IEC) TECHNICAL COMMITTEE (TC) 87 ULTRASOUND ORGANIZATION AND STANDARDS

Scope of TC 87

- To prepare standards related to the characteristics, methods of measurement, safety, and specifications of fields, equipment and systems in the domain of ultrasonics.
- Excluded from this scope are:
 - Safety standards for medical electrical equipment and systems.
- NOTE - Close liaison will be maintained with TC 62 (Electrical Equipment in Medical Practice) and TC 29 (Electroacoustics) in fields of common interest.

Scope of TC 87, cont.

- The safety standards are maintained by TC 62 teams, one being a joint working group with TC 87
 - 60601-2-37 Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
 - 60601-2-5 'Medical electrical equipment - Particular requirements for the basic safety and essential performance of ultrasound physiotherapy equipment'
 - 60601-2-62 'Medical electrical equipment - Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment'
 - these documents point at TC 87 documents regarding measurement procedures
 - JWG (Joint Working Group) 38 - Ultrasound Therapeutic Equipment Managed by SC 62D - to maintain IEC 60601-2-5 and IEC 60601-2-62.

Structure of TC 87

- Chair: Volker Wilkens
- Secretary: Bernd Borchert
- 14 Participating Countries



- 18 Observing Countries



Structure of IEC Documents

- IS – International Standard
 - standard adopted by an international standards organization, **publicly available**
 - Definition: "A normative document, developed according to consensus procedures, which has been approved by the IEC National Committee members of the responsible committee in accordance with Part 1 of the ISO/IEC Directives."
- TS – Technical Specification
 - published when subject under question is still under development or when insufficient consensus for approval of an International Standard is available
 - approaches International Standard in terms of detail and completeness, but has not yet passed through all approval stages either because consensus has not been reached or because standardization is seen to be premature

Structure of IEC Documents, cont.

- TR – Technical Report
 - contains collected data of a kind different from that normally published as an International Standard
 - data obtained from a survey carried out among national committees
 - data of work in other international organizations
 - data on "the state of the art" in relation to standards of national committees on a particular subject
 - entirely **informative** in nature and **shall** not contain matter implying that they are normative
- NWIP – New Work Item Proposal
 - Initiation of a **new** IEC document



TC 87 Working Groups

- WG 3 High power transducers
- WG 6 High Intensity Therapeutic Ultrasound (HITU) and Focusing transducers
- WG 7 Surgical and therapeutic devices
- WG 8 Ultrasonic field measurement
- WG 9 Pulse-echo diagnostic equipment
- WG 13 Terminology
- WG 14 Determination of ultrasound exposure parameters
- WG 15 Underwater Acoustics

WG 3 – High Power Transducers

Convener: Sam Howard

SCOPE

- To prepare standards measuring procedures for ultrasonic high power transducers.

DOCUMENTS

- IEC/TR 60886: 1987: Investigations on test procedures for ultrasonic cleaners.



Fig. 1 - Illustration of an imploding cavity in a liquid irradiated with ultrasound

WG 6 -High Intensity Therapeutic Ultrasound (HITU) and Focusing transducers



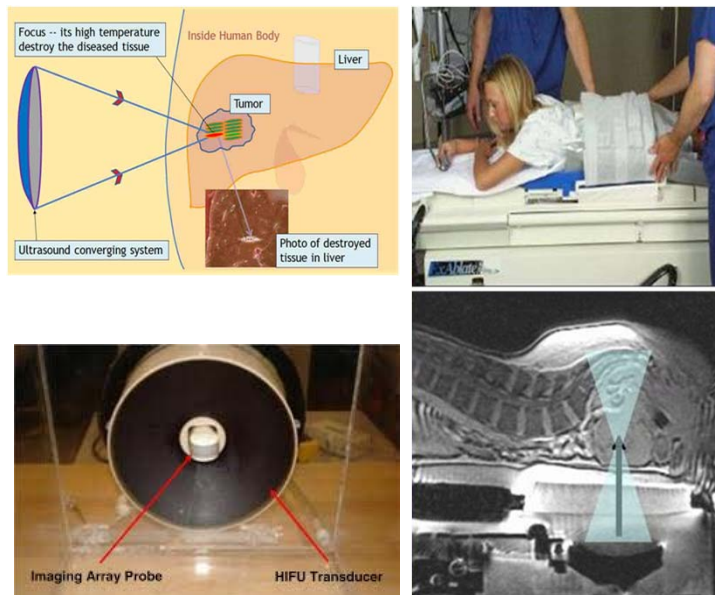
Convener: Tom Szabo

SCOPE

- To develop standards for the characterization of High Intensity Therapeutic Ultrasound (HITU) systems and (focusing) transducers

DOCUMENTS

- IEC 62555:2013: Ultrasonics - Power measurement - Output power measurement for High Intensity Therapeutic Ultrasound (HITU) transducers and systems
- IEC 62556:2014: Surgical Systems - Specification and measurement of field parameters for High Intensity Therapeutic Ultrasound (HITU) transducers and systems
- IEC 61828: 2001:Ultrasonics: Focusing transducers, Definitions and measurement methods for the transmitted fields
- IEC 62937: Ultrasonics - Measurement of ultrasound field parameters at high pressure therapeutic levels in water
- IEC 62900: Ultrasonics - Field Characterisation - measurement-based simulation in water and other media



WG 7 - Surgical and Therapeutic Devices



Convener: Friedrich Ueberle

SCOPE

- To prepare documents for ultrasonic surgical equipment.



DOCUMENTS

- IEC 61846:1998: Ultrasonics – Pressure pulse lithotripters – Characteristics of fields
- IEC 61847:1998: Ultrasonics – Surgical systems – Measurement and declaration of the basic output characteristics
 - ultrasonic surgical systems operating in the frequency range 20 kHz to 60 kHz;
- IEC 63045: "Ultrasonics – Non-focusing and weakly focusing pressure pulse sources – Characteristics of fields"

WG 8 - Ultrasonic Field Measurement



SCOPE

Convener: Volker Wilkens

- The preparation of documents concerning standard measurement procedures for the characterization of ultrasonic fields generated by ultrasonic equipment, and the preparation of documents concerning standard procedures for the calibration of measurement tools and instruments used for the characterization of ultrasonic fields generated by ultrasonic equipment.

DOCUMENTS

- IEC 62127-1:2007 Ed. 1.1: Ultrasonics - Hydrophones - Part 1: Measurement and characterisation of medical ultrasonic fields up to 40 MHz
- IEC 62127-2:2007 Ed. 1.2: Ultrasonics - Hydrophones - Part 2: Calibration for ultrasonic fields up to 40 MHz
- IEC 62127-3:2007 Ed. 1.1: Ultrasonics - Hydrophones - Part 3: Properties of hydrophones for ultrasonic fields up to 40 MHz



WG 8 - Ultrasonic Field Measurement

DOCUMENTS, cont.

- IEC 61161:2013 Ed. 3 - Ultrasonics - Power measurement - Radiation force balances and performance requirements
- IEC TS 62903 Ed. 1: Measurement of electroacoustic parameters and acoustic output power of transducers using self-reciprocity method
- IEC TR 62781: 2012 Ed. 1 - Ultrasonics - Conditioning of water for ultrasonic measurements
- IEC 62359:2010 Ed. 2: Ultrasonics - Field Characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields
- IEC 61157:2007 Ed. 2.1 - Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment



WG 8 - Ultrasonic Field Measurement



DOCUMENTS, cont.

- IEC 62462:2007 Ed. 2: Ultrasonics - Output test - Guide for the maintenance of ultrasound physiotherapy systems
- IEC 61689:2007 Ed. 3: Ultrasonics - Physiotherapy output measurement
- IEC 63009 ed. 1: Ultrasonics – Physiotherapy systems – Field specifications and methods of measurement in the frequency range of 20 kHz to 500 kHz
- IEC TS 63081 Ed. 1: – Methods for the characterization of the ultrasonic properties of materials



WG 9 - Pulse-echo Diagnostic Equipment



Convener: Peter Edmonds

SCOPE

- To prepare documents relating to test procedures for measurement of pulse-echo real time scanners.



DOCUMENTS

- IEC 62736: Pulse-Echo Scanners – Quality Control of Diagnostic Medical Ultrasound Systems - Simple Methods for Periodic Testing to Verify Stability of an Imaging System’s Elementary Performance
- IEC/TS 62791: Pulse-echo scanners - Low-echo sphere phantoms for performance testing of gray-scale medical ultrasound scanners applicable to a broad range of transducer types
- IEC 61391 -1/AMD1 ED1: Amendment 1-Ultrasonics – Pulse - echo scanners - Part 1: Techniques for calibrating spatial measurement systems and measurement of point - spread function response

WG 9 - Pulse-echo Diagnostic Equipment



DOCUMENTS, cont.

- IEC TS 61390:1996 Ultrasonics - Real-time pulse-echo systems - Test procedures to determine performance specifications
- IEC 61391-2:2010 Ultrasonics - Pulse-echo scanners - Part 2: Measurement of maximum depth of penetration and local dynamic range
- IEC TS 62558:2011 Ultrasonics - Real-time pulse-echo scanners - Phantom with cylindrical, artificial cysts in tissue-mimicking material and method for evaluation and periodic testing of 3D-distributions of void-detectability ratio (VDR)
- IEC TS 61206:1993 Ultrasonics - Continuous-wave Doppler systems - Test procedures
- IEC 61266:1994 Ultrasonics - Hand-held probe Doppler foetal heartbeat detectors - Performance requirements and methods of measurement and reporting
- IEC 61685:2001 Ultrasonics - Flow measurement systems - Flow test object

WG 14 - Determination of Ultrasound Exposure Parameters



SCOPE

- To prepare documents related to exposure, dose and safety for ultrasound fields. Excluded from this task are safety standards for medical electrical equipment and systems

Convener: Subha Maruvada

DOCUMENTS

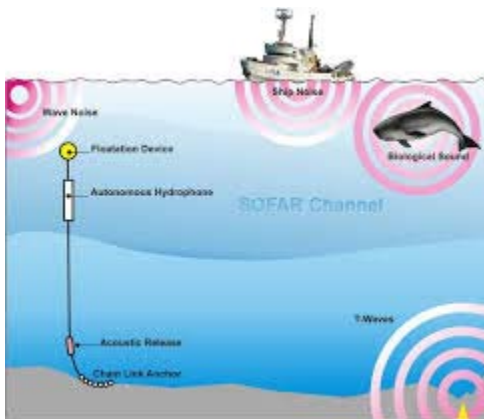
- IEC 62799: Models for evaluation of thermal hazard in medical diagnostic ultrasound fields
- IEC 62306: Test Objects for determining temperature elevation in diagnostic ultrasound fields
- IEC 61949: Ed.1: Ultrasonics - Fields – In-situ exposure estimation in finite-amplitude ultrasonic beams
- IEC 63070: Ultrasonics - Field characterisation - Infra -red imaging techniques for determining temperature elevation in tissue -mimicking material and at the radiation surface of a transducer in still air
- NWP – “Measurement Of Biologically-relevant Temperature Rise Produced By Medical Ultrasonic Equipment”

WG 15 Underwater Acoustics

Convener: Stephen Robinson

SCOPE

- To provide standards for underwater acoustics hydrophone calibration and measurement.



DOCUMENTS

- IEC 60500: Underwater acoustics - Hydrophones - Properties of hydrophones in the frequency range 1 Hz to 500 kHz
- IEC 60565-2 ED1: Underwater acoustics - Hydrophones - Calibration of hydrophones, Part 2: Procedures for low frequency pressure calibration



Summary

- 8 WGs cover all areas of measurement consideration for ultrasound medical devices
- Attendance and participation is voluntary – contact your National Chair (IEC website) if you are interested in getting involved
- **Now for the really interesting talks...**