Physikalisch-Technische Bundesanstalt
Braunschweig und Berlin
Nationales Metrologieinstitut

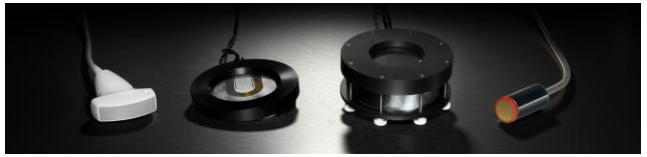
Ultrasound Standardisation

within the International Electrotechnical Commission – IEC

Volker Wilkens

Chair IEC TC 87
Convenor IEC TC 87 WG 8
Obmann DKE GUK 821.3 Medizinische Ultraschallgeräte

Ultrasonics Working Group 1.62
Physikalisch-Technische Bundesanstalt, PTB
Braunschweig, Germany
volker.wilkens@ptb.de



International Photoacoustic Standardisation Consortium
1st Annual Meeting, 2019-11-04
NPL, Teddington, UK

IEC in Figures 2019

World's leading provider of International Standards and Conformity Assessment Systems in Electrotechnology

86 Members

87 Affiliates

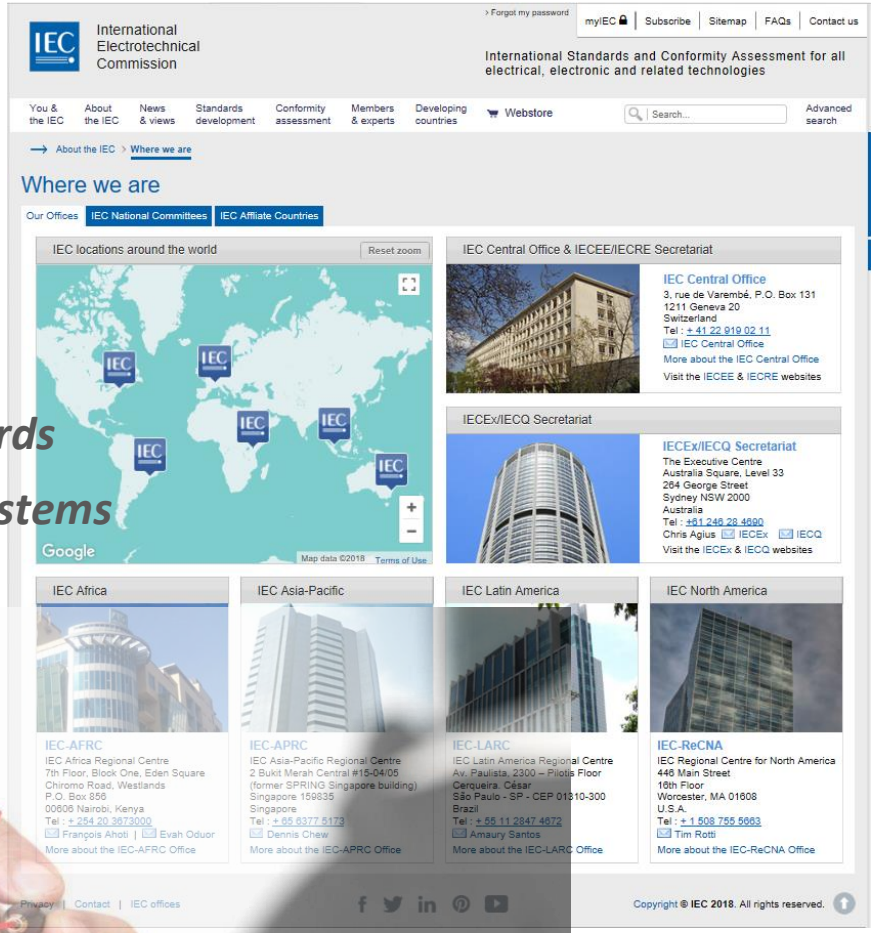
206 Committees

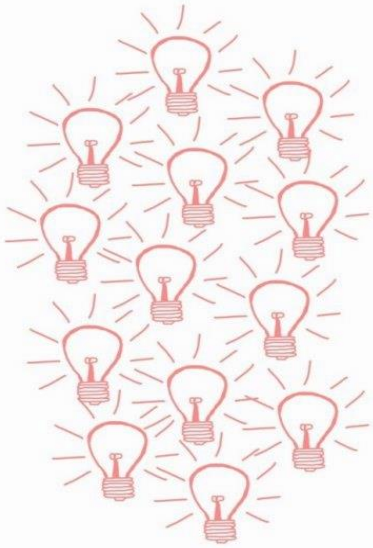
20 000 Experts

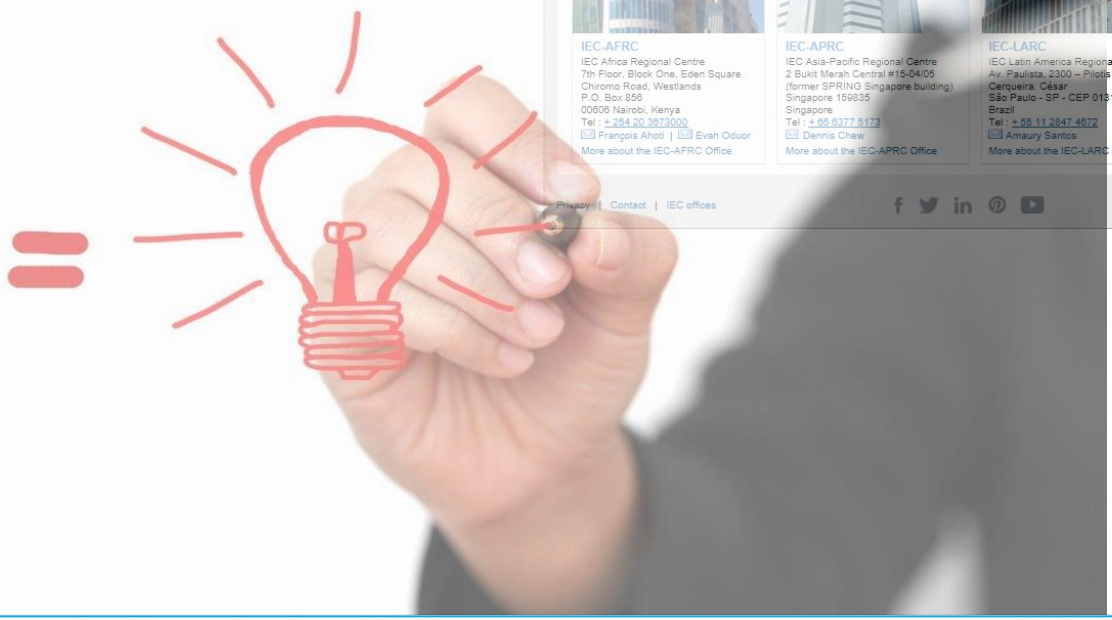
10 000 International Standards

4 Conformity Assessment Systems

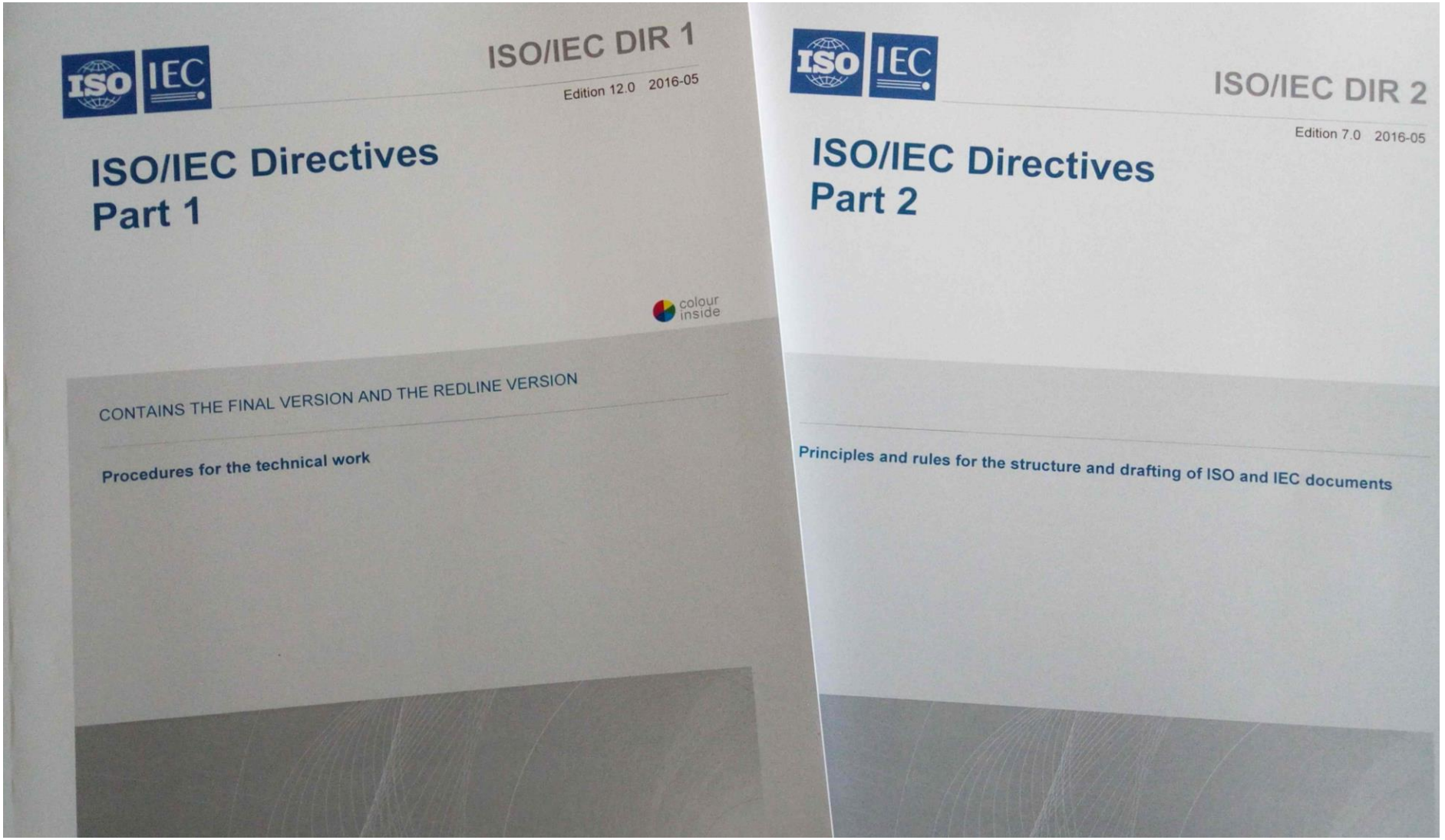
1 million Certificates issued







IEC Rules and Directives



IEC Rules and Directives

IEC Technical work is based on

Consensus*

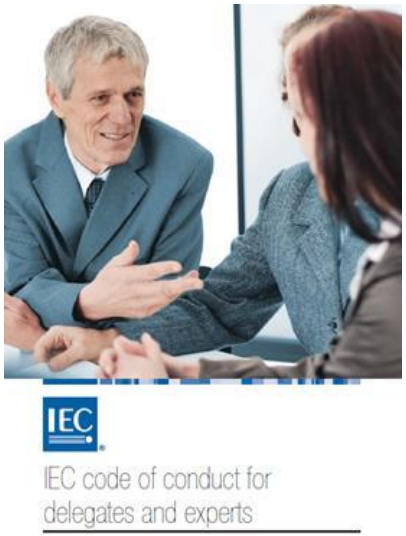
and

Transparency

* “General agreement, characterized by the **absence of sustained opposition** to substantial issues by any important part of concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments.“

IEC Messages on Ethics and Respect

- Escalate & resolve disputes
  - Identify & escalate disputes in a timely manner for rapid resolution
  - Uphold the agreed dispute resolution processes
- Behave ethically
  - Act in good faith & with due care & diligence
  - Avoid collusive or anticompetitive behaviour
  - Promote a culture of fair & ethical behaviour
- Respect others in meetings
  - Be professional
  - Respect others & their opinions
  - Accept group decision
  - Ensure that all views are heard & understood
  - Be tolerant of different cultural practices
  - Avoid metaphors, irony & be aware that jokes and humour may not translate
- Respect others on social media
  - Be respectful & not abusive
  - Don't say anything that you might regret or don't want your friends, family or colleagues to see
- Complete ISO and IEC documents can be found as follows:
  - https://www.iso.org/publication/PUB100397.html
  - https://basecamp.iec.ch/download/iec-code-of-conduct-for-delegates-and-experts/



IEC Technical Committee 87: Ultrasonics – Scope

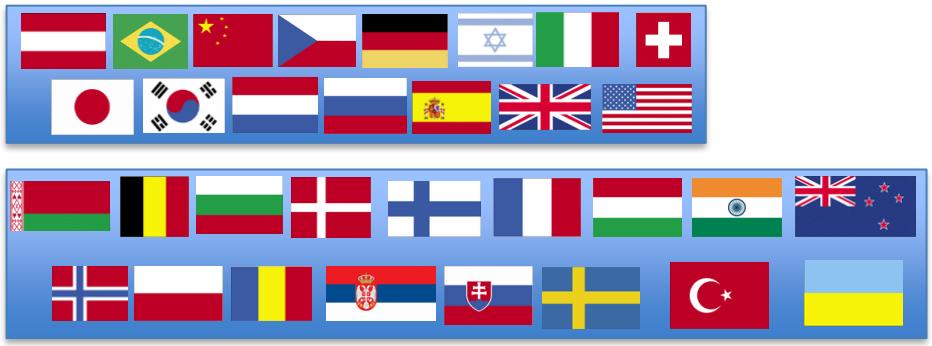
- To prepare standards related to the characteristics, methods of measurement, safety, and specifications of fields, equipment and systems in the domain of ultrasonics.
- Close liaison will be maintained with TC 62 (Electrical Equipment in Medical Practice) and TC 29 (Electroacoustics) in fields of common interest.
- The safety standards
  - 60601-2-37 (diagnostic ultrasound systems)
  - 60601-2-5 (ultrasound physiotherapy equipment)
  - 60601-2-62 (high intensity therapeutic ultrasound (HITU) equipment)

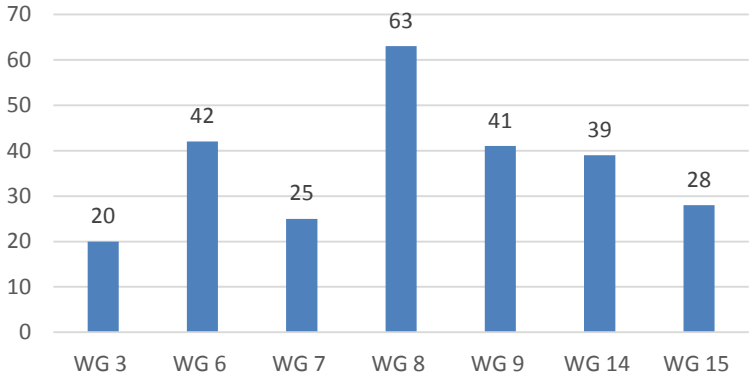
  are maintained by TC 62 teams, one being a joint working group with TC 87: JWG 38, the other SC 62B MT 34

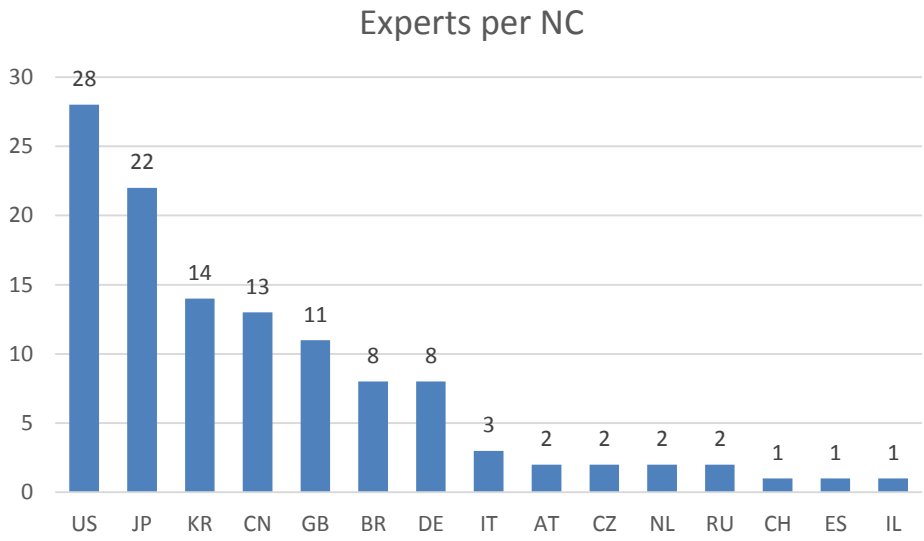
  These documents point at TC 87 documents regarding measurement procedures.

IEC TC 87 Ultrasonics – Facts and Figures

- P-member countries (participating) 15
- O-member counties (observing) 17
- Number of WG/PT/MT/JWGs 8
- Number of experts 118
- Number of published standards 47
- Number of ongoing projects 9
- Number of documents in 2019 28
- Number of NPs in 2019 0
- Number of publications in 2019 4







Types 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

Types of IEC Documents

- TR – Technical Report
  - contains collected data of a kind different from that normally published as an International Standard, for example data obtained from a survey carried out among national committees, data of work in other international organizations or 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
- NWP – 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 14 Determination of ultrasound exposure parameters
- WG 15 Underwater Acoustics
- JWG 38 Ultrasound Therapeutic Equipment – managed by SC 62D

WG 3 – High Power Transducers

SCOPE

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

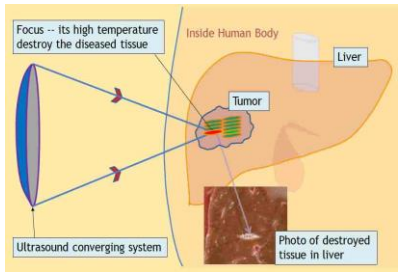
DOCUMENTS

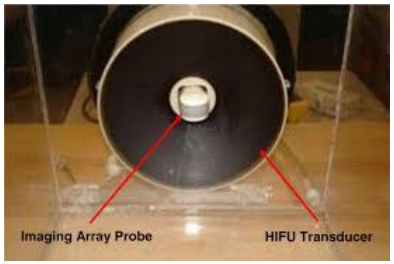
- **IEC/TR 60782**: 1984 Ed.1: Measurement of ultrasonic magnetostrictive transducers.
- **IEC/TR 60886**: 1987 Ed.1: Investigations on test procedures for ultrasonic cleaners.
- **IEC/TR 61088**: 1991 Ed.1: Characteristics and measurements of ultrasonic piezoceramic transducers
- **IEC/TS 63001**: 2019 Ed.1: Measurement of cavitation noise in ultrasonic baths and cleaning reactors

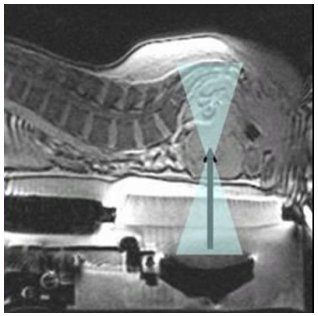
WG 6 – High Intensity Therapeutic Ultrasound (HITU) and Focusing Transducers

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
- **NP IEC 62937**: Ultrasonics - Measurement of ultrasound field parameters at high pressure therapeutic levels in water
- **NP IEC 62900**: Ultrasonics - Field Characterisation - measurement-based simulation in water and other media

WG 7 – Surgical and Therapeutic Devices

SCOPE

- To prepare documents for ultrasonic surgical equipment.

DOCUMENTS

- ~~**IEC 61205**: 1993: Ultrasonics - Dental descaler systems - Measurement and declaration of the output characteristics~~
- **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 CDV**: Ultrasonics – Non-focusing and weakly focusing pressure pulse sources – Characteristics of fields

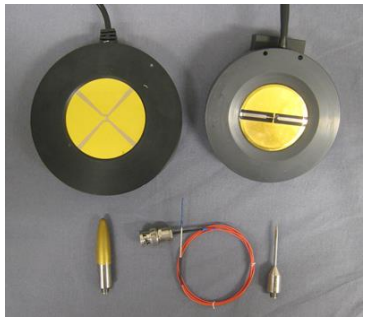
WG 8 – Ultrasonic Field measurement

SCOPE

- 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 (2013) Ed. 1.1: Ultrasonics - Hydrophones - Part 1: Measurement and characterisation of medical ultrasonic fields up to 40 MHz
- **IEC 62127-2**: 2007 (2017) Ed. 1.2: Ultrasonics - Hydrophones - Part 2: Calibration for ultrasonic fields up to 40 MHz
- **IEC 62127-3**: 2007 (2013) Ed. 1.1: Ultrasonics - Hydrophones - Part 3: Properties of hydrophones for ultrasonic fields up to 40 MHz



WG 8 – Ultrasonic Field measurement

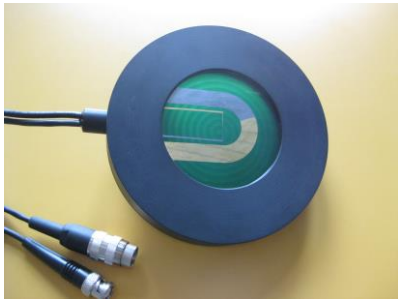
DOCUMENTS, cont.

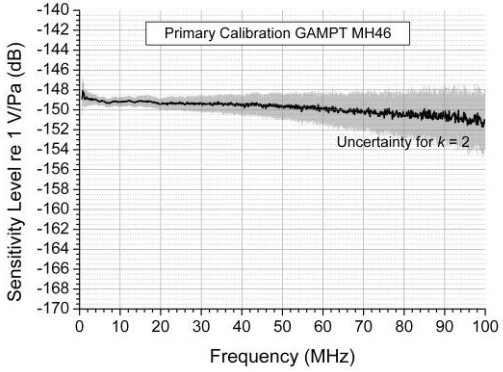
- **IEC 61161**: 2013 Ed. 3 - Ultrasonics - Power measurement - Radiation force balances and performance requirements
- **IEC/TR 62781**: 2012 Ed. 1 - Ultrasonics - Conditioning of water for ultrasonic measurements
- **IEC 62359**: 2010 (2017) Ed. 2.1: Ultrasonics - Field Characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields
- **IEC 61157**:2007 (2013) 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 TS 62903**: 2018 Ed. 1: Measurement of electroacoustic parameters and acoustic output power of transducers using self-reciprocity method
- **IEC 62462**: 2017 Ed. 2: Ultrasonics - Output test - Guide for the maintenance of ultrasound physiotherapy systems
- **IEC 61689**: 2013 Ed. 3: Ultrasonics - Physiotherapy output measurement
- **IEC 63009**: 2019 Ed. 1: Ultrasonics – Physiotherapy systems – Field specifications and methods of measurement in the frequency range of 20 kHz to 500 kHz
- **IEC TS 63081**: 2019 Ed. 1: – Methods for the characterization of the ultrasonic properties of materials





WG 9 – Pulse-echo Diagnostic Equipment

SCOPE

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

DOCUMENTS

- **IEC/TR 60854**: 1986 Ed.1: Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment
- **IEC/TS 62736**: 2016 Ed.1: 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**: 2015 Ed.1: 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/TS 61390**: 1996 Ed.1, IEC/TR 61390: 2019 Ed.1: Ultrasonics - Real-time pulse-echo systems - Test procedures to determine performance specifications

WG 9 – Pulse-echo Diagnostic Equipment

DOCUMENTS, cont.

- **IEC 61391-1**: 2006 (2017) Ed.1.1: Ultrasonics – Pulse-echo scanners - Part 1: Techniques for calibrating spatial measurement systems and measurement of point-spread function response
- **IEC 61391-2**: 2010 Ed.1: Ultrasonics - Pulse-echo scanners - Part 2: Measurement of maximum depth of penetration and local dynamic range
- **IEC/TS 62558**: 2011 Ed.1: 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 Ed.1: Ultrasonics - Continuous-wave Doppler systems - Test procedures
- **IEC 61266**: 1994 Ed.1: Ultrasonics - Hand-held probe Doppler foetal heartbeat detectors - Performance requirements and methods of measurement and reporting
- **IEC 61685**: 2001 Ed.1: Ultrasonics - Flow measurement systems - Flow test object
- NP on monitor harmonization
- NPs on shear wave elastography
- NP on compression elastography

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

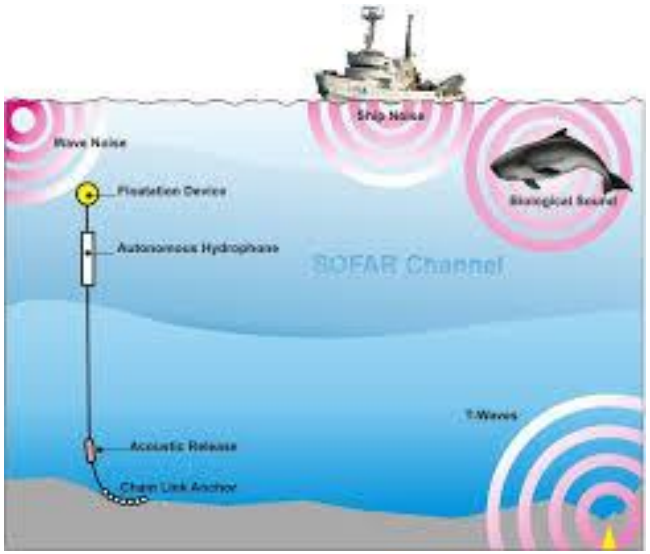
DOCUMENTS

- **IEC/TR 62799**: 2013 Ed.1: Models for evaluation of thermal hazard in medical diagnostic ultrasound fields
- **IEC/TS 62306**: 2006 Ed.1: Test Objects for determining temperature elevation in diagnostic ultrasound fields
- **IEC/TS 61949**: 2007 Ed.1: Ultrasonics - Fields – In–situ exposure estimation in finite-amplitude ultrasonic beams
- **IEC/TS 63070**: 2019 Ed.1: 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

WG 15 – Underwater Acoustics

SCOPE

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



DOCUMENTS

- **IEC 60500**: 2017 Ed.2: Underwater acoustics - Hydrophones - Properties of hydrophones in the frequency range 1 Hz to 500 kHz
- **IEC 60565-1** CDV: Ed.1: Underwater acoustics - Hydrophones - Calibration of hydrophones, Part 1: Procedures for free field calibration
- **IEC 60565-2**: 2019 Ed.1: Underwater acoustics - Hydrophones - Calibration of hydrophones, Part 2: Procedures for low frequency pressure calibration
- NP on “Calibration of acoustic wave vector receivers in the frequency range of 5 Hz to 10 kHz”
- NP on “Calibration of digital hydrophones and autonomous recorders”

Discussion and exchange at nice meetings and locations…