IEC 87: Ultrasonics – Overview update – July 2002

Roy C Preston
Secretary IEC TC 87: Ultrasonics

British Electrotechnical Committee, British Standards Institution, 389 Chiswick High Road, London W4 4AL
Address for correspondence:-
Centre for Mechanical and Acoustical Metrology, National Physical Laboratory, Teddington, Middlesex TW11 0LW

1. Introduction to IEC TC 87: Ultrasonics

Activity within the International Electrotechnical Commission (IEC) in the technical field of ultrasonics started in 1955 as Working Group 7 of TC 29. Sub-Committee 29D: Ultrasonics was formed following the 1966 Prague meeting of TC 29, and a decision to transform SC 29D into a full Technical Committee was taken at the 1985 Budapest meeting of SC29D. Since then, Technical Committee 87: Ultrasonics has been active in the development of international specification standards in the field of ultrasonics, with particular emphasis on medical applications. The defined terms of reference of TC 87 are set out in its Scope as follows:

> *To prepare standards related to the characteristics (including those of biological effects and of corresponding limits) and to the methods of measurement and specifications for fields, equipment and systems in the domain of ultrasonics.*
>
> *This scope includes the preparation, for use by product committees, of standards covering those aspects of ultrasound pertaining to human safety.*
>
> *Close liaison will be maintained with TC 62.*
>
> Group Safety Function was allocated to TC 87 in 1992:
>
> *Aspects of ultrasound pertaining to human safety*.

A consequence of these responsibilities for medical ultrasonic equipment is that TC 87 has responsibility for the safety of the ultrasonic field and the test methods for determining safety-related quantities. The standards produced by TC 87 would then be used by product committees such as TC 62: Electrical Equipment in Medical Practice, which has responsibility for equipment labelling related to the safety of the ultrasonic field and other non-ultrasound related aspects of safety. It is of concern for TC 87 that the safety classification work of TC 87 has not been able to progress to publication stage and has therefore not been incorporated in the TC 62 safety standard for diagnostic ultrasonic equipment.

2. Environment

Ultrasonic technology finds a wide range of medical and industrial applications. Medical use of ultrasonics includes diagnostic, monitoring, surgical and therapeutic applications and represents a major area of development and continuing evolution with market growths of between 10% and 30% depending on the technical area. Industrial use of ultrasound is mainly in the kilohertz frequency range and includes ultrasonic cleaning, welding and industrial processing. Trends in these areas are as follows:

- Medical ultrasonic equipment is an area of high expansion. Technology is continually changing and developing and this situation is likely to continue for the foreseeable future.

- Much slower changes are occurring in the well-established industrial applications of ultrasonics.

- There is no major field of ultrasonic technology which is decreasing in importance.

As a result of these trends, the majority of the current work of TC 87 is oriented to ultrasonic aspects of safety and performance of medical equipment and to safety of ultrasonic fields. This is reflected by the structure of its working groups (see Appendix A) and by the qualification of its active experts.

New developments in power transducer design for low ultrasonic frequency application in industry, more sophisticated arrays and signal processing techniques in the medical ultrasonic imaging applications, and 3-D techniques under development will shape demand for future standardising work in TC 87. New advances at the ultra high ultrasonic frequency range up to 75 MHz and above will establish requirements for new standards.

3. IEC TC 87 standards related to ultrasonic metrology

The main methods of measurement of ultrasonic fields in industry are based on the use of a hydrophone for measurement of acoustic pressure and a radiation force balance for the measurement of time-averaged total ultrasonic power emitted by a transducer. Specification standards have therefore been established or are under development covering the following three broad areas of calibration and measurement technology in the field of ultrasonics:

Specification of hydrophone performance and calibration methods;
Measurement of ultrasonic power;
Ultrasonic field measurement.

Traceable calibrations of hydrophones and radiation force balances are therefore needed world-wide in order to support IEC specification standards in these areas. The following sections summarise those standards which have been produced by TC 87 (see also Appendix B), or projects within TC 87's current Work Programme (see also Appendix C), which are related to these three areas.

3.1 Standards related to hydrophone performance and calibration methods

IEC 60565 (1977) *Calibration of hydrophones*.
Deals with the calibration of underwater acoustical hydrophones and specifies a number of different calibration methods including three-transducer reciprocity. This is now being revised as part of the Maintenance Cycle.

IEC 60565A (1980) *Calibration of hydrophones (First supplement)*.
Specifies methods of calibration at low frequency. In future, this standard is likely to be incorporated in the revised version of IEC 60565.

IEC 60866 (1987) *Characteristics and calibration of hydrophones for operation in the frequency range 0,5 MHz to 15 MHz.*
Provides detailed performance characteristics of hydrophones including requirements for Class A and B devices. Calibration methods are specified based on self-reciprocity.

IEC 61101 (1991) *The absolute calibration of hydrophones using the planar scanning technique in the frequency range 0,5 MHz to 15 MHz.*
Specifies the method of calibrating hydrophones based on the measurement of the total time-averaged output power of an ultrasonic transducer and spatially integrating the square of the hydrophone output voltage over the ultrasonic beam.

IEC 61102 (1991) *Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz*.
Specifies additional performance requirements for hydrophones and therefore establishes new calibration requirements.

IEC 62092 Ed.1 *Ultrasonics - Hydrophones - Characteristics and calibration in the frequency range from 15 MHz to 40 MHz.*
This standard specifies methods of calibrating hydrophones between 15 MHz and 40 MHz.

IEC PWI 87-16 *Ultrasonics - Hydrophones - Properties of hydrophones for medical ultrasonic fields from 50 kHz to 40 MHz*

IEC PWI 87-17 *Ultrasonics - Hydrophones - Calibration of hydrophones to be used in medical ultrasonic fields from 50 kHz to 40 MHz*

The above two proposed new standards will ultimately replace standards IEC 60866, 61101, 61102 and 62092.

3.2 Standard related to the measurement of ultrasonic power

IEC 61161 (1992) *Ultrasonic power measurement in liquids in the frequency range 0,5 MHz to 25 MHz*.
Specifies types of radiation force balances and performance aspects for measurement of ultrasonic power.

IEC 61161 Amendment 1 (1997) *Ultrasonic power measurement in liquids in the frequency range 0,5 MHz to 25 MHz.*
Assesses uncertainties associated with the measurement of ultrasonic power using radiation force balances.

3.3 Standards related to ultrasonic field measurement which require calibrated hydrophones or radiation force balances

IEC 61157 (1992) *Requirements for the declaration of the acoustic output of medical diagnostic equipment.*

Establishes a set of acoustic output parameters (mainly pressures, intensities and powers) for medical diagnostic ultrasonic equipment to be declared or made available by the manufacturer.

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

Specifies a wide range of acoustic output parameters and test methods for their determination.

IEC 61220 (1993) TR2 *Ultrasonics - Fields – Guidance for the measurement and characterization of ultrasonic fields generated by medical ultrasonic equipment using hydrophones in the frequency range 0,5 to 15 MHz.*

This gives guidance on measurements using hydrophones, dealing with spatial averaging and bandwidth limitation effects.

IEC 61266 (1994) *Ultrasonics - Hand-held probe Doppler foetal heartbeat detectors - Performance requirements and methods of measurement and reporting.*

Specifies test methods for the determination of sensitivity of foetal heart beat detectors and acoustic output information.

IEC 61689 (1996) *Ultrasonics - Physiotherapy systems - Performance requirements and methods of measurement in the frequency range 0,5 MHz to 5 MHz.*

Specifies test methods for determining the effective radiating area and other critical parameters for ultrasonic physiotherapy equipment.

Future IEC 61973 Ed.1 *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.*

Although this project is still on the TC 87 Work Programme, its future is in doubt as it conflicts with the publication of IEC 60601-2-37 dealing with the safety of diagnostic ultrasonic equipment, now approved and published by TC 62. The project aimed to specify methods of predicting thermal and mechanical exposure parameters based on acoustic measurements. The test methodology follows that of the USA AIUM/NEMA Output Display Standard. The future of this project will be determined at the Berlin meeting of TC 87 in August 2002.

IEC PWI 87-18 *Ultrasonics - Hydrophones - Measurement and characterisation of medical ultrasonic fields from 50 kHz to 40 MHz using hydrophones*

The above proposed new standard will ultimately replace standard IEC 61102 and the guidance document IEC 61220.

4. Conclusions

Standards developed by IEC TC 87 have already established extensive performance requirements for hydrophones and calibration requirements. Calibration methods have been specified and are being extended to cover wider frequency ranges, especially to frequencies above 15 MHz and to below 0,5 MHz. IEC 62092, dealing with hydrophone calibration in the frequency range up to 40 MHz has now

been published. Calibration of hydrophones for medical ultrasound is and will remain crucial to support the world-wide medical ultrasonics industry. Calibration of radiation force balances will also remain important especially to enable the prediction of temperature rise, a critical safety issue for medical ultrasound. There will be a need to develop improved calibration methods for hydrophones used at frequencies below 1 MHz in underwater acoustics, and the revision of IEC 60565 is now well underway.

In addition to the infrastructure of specification standards, there will be increasing emphasis, driven by regulations, quality systems and the move to open markets, for traceable calibrations of hydrophones and radiation force balances for medical ultrasound. Traceable calibrations of hydrophones used in underwater acoustics will also become increasingly important.

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Appendix A

IEC TC 87 Working Groups

WG3:	High power transducers
WG6:	Focussed transducers
WG7:	Ultrasonic surgical systems
WG8:	Ultrasonic field measurement
WG9:	Pulse-echo diagnostic equipment
WG10:	Ultrasonic diagnostic flow measurement systems
WG12:	Ultrasound exposure parameters
WG13:	Terminology
WG14:	Determination of ultrasound exposure parameters

Appendix B

IEC TC 87 publications

IEC 60500 (1974)	IEC standard hydrophone.
IEC 60565 (1977)	Calibration of hydrophones.
IEC 60565A (1980)	First supplement.
IEC 60782 (1984)	Measurements of ultrasonic magnetostrictive transducers.
IEC 60854 (1986)	Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment.
IEC 60866 (1987)	Characteristics and calibration of hydrophones for operation in the frequency range 0,5 MHz to 15 MHz.
IEC 60886 (1987)	Investigation on test procedures for ultrasonic cleaners.
IEC 61088 (1991)	Characteristics and measurements of ultrasonic piezo-ceramic transducers.
IEC 61101 (1991)	The absolute calibration of hydrophones using the planar scanning technique in the frequency range 0,5 MHz to 15 MHz.
IEC 61102 (1991)	Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz.
IEC 61102 (1993)	Amendment 1 (1993).
IEC 61157 (1992)	Requirements for the declaration of the acoustic output of medical diagnostic equipment.
IEC 61161 (1992)	Ultrasonic power measurement in liquids in the frequency range 0,5 MHz to 25 MHz.
IEC 61161 (1998)	Amendment No. 1
IEC 61205 (1993)	Ultrasonics - Dental descaler systems - Measurement and declaration of the output characteristics.
IEC 61206 TR2 (1993)	Ultrasonics - Continuous wave Doppler systems - Test procedures.
IEC 61220 TR2 (1993)	Ultrasonics - Fields – Guidance for the measurement and characterization of ultrasonic fields generated by medical ultrasonic equipment using hydrophones in the frequency range 0,5 to 15 MHz.
IEC 61266 (1994)	Ultrasonics - Hand-held probe Doppler foetal heartbeat detectors - Performance requirements and methods of measurement and reporting.
IEC 61390 TR2 (1996)	Ultrasonics - Real-time pulse-echo systems - Test procedures to determine performance specification.
IEC 61685 (2001)	Ultrasonics - Flow measurement systems - Flow test object
IEC 61689 (1996)	Ultrasonics - Physiotherapy systems - Performance requirements and methods of measurement in the frequency range 0,5 MHz to 5 MHz.
IEC 61828 (2001)	Ultrasonics - Focusing transducers - Measurement and characterisation of transmitting properties
IEC 61846 (1998)	Ultrasonics - Pressure pulse lithotripters - Characteristics of fields.
IEC 61847 (1998)	Ultrasonics - Surgical systems - Measurement and declaration of the output characteristics
IEC 61895 TR2 (2000)	Ultrasonics - Pulsed Doppler diagnostic systems - Test procedures to determine performance
IEC 62092 (2001)	Ultrasonics - Hydrophones - Characteristics and calibration in the frequency range from 15 MHz to 40 MHz

Appendix C

IEC TC 87 Work Programme

The items in the current work programme of TC 87 are given in the table below:

Title	Project No.	Stage*
Ultrasonics - Pulse-echo scanners - Techniques for calibrating special measurement systems and measurement of point spread function	Future IEC 61391-1 Ed.1	CD
Ultrasonics - Pulse-echo scanners - Measurement of system sensitivity, contrast resolution and dynamic range	Future IEC 61391-2 Ed.1	ST0
Ultrasonics - Field Safety - Part 1: Classification scheme for medical diagnostic fields	Future IEC 61681-1 Ed.1	?
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	Future IEC 61973 Ed.1	?
Ultrasonics - Resonant and non-resonant magnetostrictive transducers - Characterisation and measurement of performance (Revision of IEC 782)	Future IEC 61985 Ed.1	ST0
Ultrasonics - Field safety – Physical tissue models for application of medical ultrasound	PWI 87-1	ST0
Ultrasonics - Field characterization - Test object for determining temperature increase	Future IEC 62306 (formerly PWI 87-2)	ANW
Ultrasonics - Colour flow mapping systems - Test procedures to determine performance	PWI 87-3	ST0
Ultrasonics - Piezoceramic transducers – Measurement and declaration of characteristics	PWI 87-4	ST0

Title	Project No.	Stage
Ultrasonics - Cleaning systems - Operating parameters and acoustic field measurements	PWI 87-5	ST0
Ultrasonics - Fields - Requirements for standard methods to compute estimated temperature rise in selected applications of diagnostic ultrasonic fields	PWI 87-6	ST0
Ultrasonics - Nebuliser systems - Methods of measurement of performance	PWI 87-8	ST0
Ultrasonics - Physiotherapy systems - Performance requirements and methods of measurement - Thermal aspects	PWI 87-9	ST0
Chapter 802 in IEV - Definitions of terms in the field of ultrasonics	Future IEC 60050-802	ANW
Ultrasonics - Medical transducers - Characterisation and measurement of electrical, mechanical and acoustical properties	PWI 87-15	ST0
Ultrasonics – Colour flow mapping systems – CW and pulsed Doppler calibration	PWI 87-12	ST0
Ultrasonics – Fields – Exposure estimation in finite-amplitude ultrasonic beams	PWI 87-13	ST0
Ultrasonics High intensity focusing in tissue – Characterisation and measurement methods	PWI 87-14	ST0
Ultrasonics - Hydrophones - Properties of hydrophones for medical ultrasonic fields from 50 kHz to 40 MHz	PWI 87-16	ST0
Ultrasonics - Hydrophones - Calibration of hydrophones to be used in medical ultrasonic fields from 50 kHz to 40 MHz	PWI 87-17	ST0
Ultrasonics - Hydrophones - Measurement and characterisation of medicalultrasonic fields from 50 kHz to 40 MHz using hydrophones	PWI 87-18	ST0

* Abbreviations:

ADIS - Approved Draft International Standard
1CD - First Committee Draft for Comment
ANW - Approved New Work
NWIP - New Work Item
CDV - Committee Draft for Vote
ST0 - Stage Zero
TR2 - Technical Report Type 2