International Standards: IEC TC87 Working Group 7, Ultrasonic Surgical Equipment

Mark E. Schafer, Ph.D. FAIUM FASA
Sonic Tech, Inc.
Convenor, WG7

42nd Annual Symposium of the Ultrasonic Industry Association

Outline

- IEC Standardization
- Medical Equipment Safety Hierarchy
- Scope of TC87, Working Group 7
- Current Standards
- Proposed New Work Item Proposals (NWIP)
- Getting Involved, Staying Informed

The IEC and you!

- The International Electrotechnical Commission is one of the most recognized standards setting organizations in the world, and covers electrotechnology, and especially for medical devices
- Along with the International Organization for Standardization (ISO) and the International Telecommunication Union (ITU), standards cover nearly all technical fields, a number of service sectors, management systems and conformity assessment.
- Many regulatory bodies, such as the FDA and the EU/CE, harmonize to IEC/ISO standards
- Divided into Technical Committees (95), and Subcommittees (77)
- These are further divided into Working Groups (WGs)
- and Maintenance Teams (MTs)

Standards Process

- Very specific process for the development of new standards:
  - Preliminary (PWI)
  - Proposal (NP)
  - Preparatory (WD – working draft)
  - Committee (CD – committee draft)
  - Enquiry (CDV – Committee Draft for vote)
  - Approval (FDIS – Final Draft International Standard)
  - Publication (Standard released and sold)

Types of Standards

- **General Safety Standard** (Parent), i.e. 60601-1-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
  - Applied broadly across a range of equipment
  - Establishes uniform overall safety requirements
- **Particular Standard**, e.g. 60601-2-36: Medical electrical equipment - Particular requirements for the basic safety and essential performance of extracorporeally induced lithotripsy
  - Includes additional safety information applicable to a specific type of equipment
  - Developed/Managed by subcommittees of SC62 – Medical Safety
- **Technical Standard,** e.g. 61846 Ultrasonics – Pressure pulse lithotripters – Characteristics of fields
  - Provides detail on tests and measurement techniques which support the Particular Standard
  - Developed/Managed by Technical Committees such as TC87 - Ultrasonics

Scope of TC 87 and WG7

- Technical Committee 87 is dedicated to Ultrasonics, especially medical, including diagnostic, therapeutic (HIFU/HITU), surgical, and lithotripsy
- It is not responsible for Safety or Performance ("Part 2") standards
- Working Group 7 specializes in "Ultrasonic Surgical Equipment", which includes ultrasonic surgery and lithotripsy
- HIFU/HITU has been assigned to WG6, "Focused Transducers"

Safety Standards based on TC87 standards

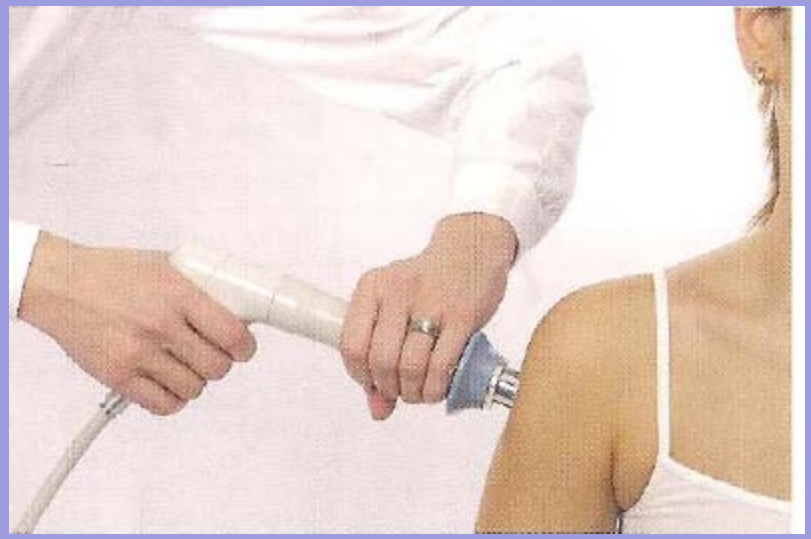
- 60601-2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment
- 60601-2-36: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy
- 60601-2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
- Eye surgery standard about to be published

Current Standards under WG 7

- IEC 61846, “Ultrasonics – Pressure pulse lithotripters – Characteristics of fields.”
  - Deals with lithotripsy field measurements, and it is proposed that it be updated to include new measurement definitions and new hydrophones
- IEC 61847, “Ultrasonics – Surgical systems – Measurement and declaration of the basic output characteristics.”
  - Deals with invasive or minimally invasive probes, but in longitudinal mode only, and it is proposed that it be extended to include torsional and other modes

Other proposed efforts

New effort on “Ballistic Shock Wave” devices used for pain management; although they produce “pressure pulses”, the 61847 standard is not appropriate



61847 Ultrasonics – Surgical systems

- Written primarily for CUSA and basic phacoemulsification devices
- Assumed linear motion of tip as primary action
- Defined measurements and declarations based on tip excursion
- Newer devices now specifically operate in “non-linear”, i.e. torsional and ellipsoidal modes
- Plan is to start a revision process to bring the standard up to date

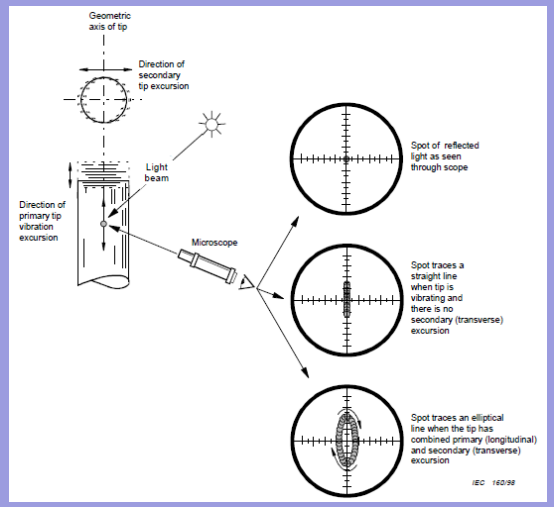
Excerpts from the standard

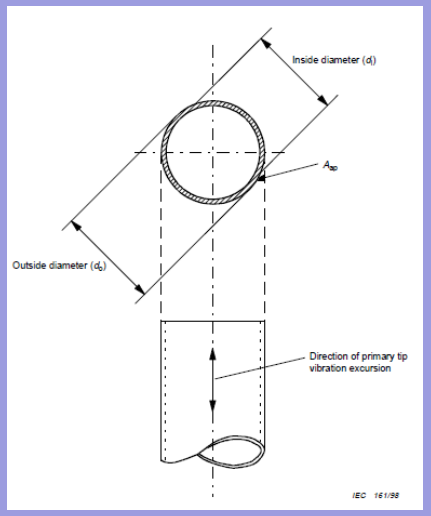
7 Declaration of output characteristics

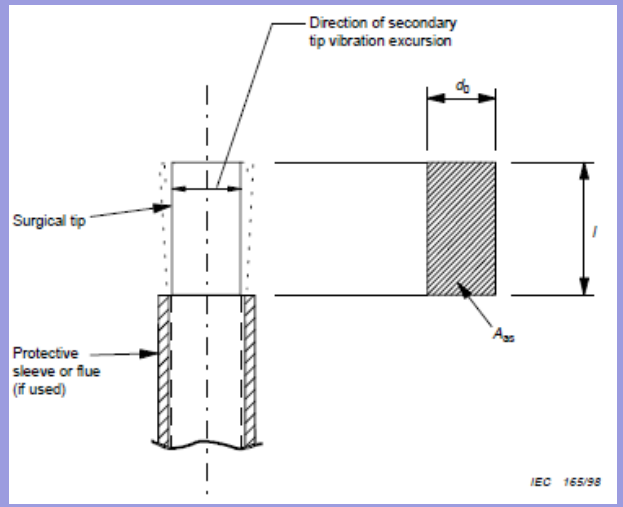
The following characteristics shall be declared in the accompanying documents of an ultrasonic surgical system:

NOTE 1 – For the rationale on the use and specification of these parameters, see clause B.4.

- **reference primary tip vibration excursion** for each type of **applicator tip** (i.e. the maximum **primary tip vibration excursion**);
- **primary acoustic output area** for each type of **applicator tip**;
- **drive frequency** for each ultrasonic handpiece;
- **derived output acoustic power or output acoustic power** for each type of **applicator tip** operating at the **reference primary tip vibration excursion**;







How to be involved?

- Propose or sponsor an expert
  - Submit proper credentials to ANSI to become a expert and part of the US Technical Advisory Group (TAG)
  - Will put you (or your employee) on the email list for all documents relative to your specific Working Group
  - Can be a “corresponding” member, who does not necessarily travel to all meetings
- Also consider contributions from your overseas colleagues
- We intend to provide informal information sessions through UIA

Summary

- These standards directly affect you and your company
  - Product Requirements and Design
  - Product Testing and Measurement
- Note that the FDA has a goal to recognize these standards rather than internal guidelines where possible
- Efforts made to direct or at least anticipate the process will reap benefits
- You are invited to participate in any way that makes sense for your company