ULTRASOUND CALIBRATION AT THE NATIONAL MEASUREMENT LABORATORY.

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ABSTRACT The National Measurement Laboratory (NML) has had interactions in ultrasound ranging from the medical (therapy and diagnostic), non-destructive testing/evaluation (NDT/E) to high power cleaning and sonic processing. A present emphasis is in therapy ultrasound. In this area there is a problem with poorly calibrated ultrasound therapy machines either delivering a dangerous amount of ultrasound or so little that it is of no clinical benefit. A traceability chain is required from the clinical user of the ultrasound therapy machine to national standards. A portable power standard (PPS) is presently being designed to enable the traceability to occur. Just as importantly the associated advisory publications are being formulated to enable its deployment in the traceability chain. The next major effort in ultrasound standards is expected to be NDT/E for Australian and New Zealand industry. A review of what is required for standards support in the NDT/E community is to be undertaken.

1. INTRODUCTION

Ultrasound is sound at a frequency greater than the audible (>20kHz), with the upper limit presently being constrained by technology to approximately 100 MHz. Power levels can be substantial, to some kW, with some hundreds of MPa of pressure. These large ranges in frequency and power indicate that there is a very broad range of applications for ultrasound.

In the Australian medical community, ultrasound has a strong presence:

- 14,000 registered physiotherapists use therapeutic ultrasound.
- 10% of the Australian population in one year have a diagnostic imaging ultrasound examination and virtually all unborn children are examined with ultrasound.
- Approximately 7,000 people per year in Australia are treated with lithotripsy for kidney stones, gall stones and the like.
- Countless surgical ultrasound units and dental descalers are in use.

For non-destructive testing/evaluation (NDT/E) of large and small mechanical plant, building and road structures, and aerospace components, the use of ultrasound is commonplace.

In the military, submarine warfare is heavily dependent on sonar technology. The same technology is also seeing applications in marine biology research.

Finally there are an increasing number of industrial processes being developed that make use of "high power" ultrasound to impart physical and chemical changes.

Metrology wise though, ultrasound is a comparatively new area. Many of the measurement techniques and standards are still in a high rate of evolution. The effort at the National Measurement Laboratory (NML-CSIRO) is even more recent.

The efforts of the ultrasound standards group at NML in recent years has focussed on:

- commissioning equipment and techniques to a level where useful standards measurements can be made,
- reviewing what is required for standards support in the ultrasound communities of Australia and New Zealand,
- commencing efforts to support the users of therapy ultrasound.

This paper will review the present state and future plans for ultrasound standards at NML and for the ultrasound community. The NML facilities will first be briefly described, followed by a more detailed description of the present efforts being directed towards therapeutic ultrasound and then the other areas of present and future interest. The therapy ultrasound effort has also been quite instructive in how to approach an area requiring measurement traceability as well as a more accurate and precise application of its particular technique or technology.

2. NML FACILITIES

Absolute Fundamental Standard

There are three fundamental quantities of interest for a propagating ultrasonic wave. These are the displacement and the frequency of the wave and the spatial distribution of the wavefront. The displacement and frequency can be measured absolutely using a path length stabilised He-Ne Michelson interferometer. The absolute displacement measurement is derived from the 632.8 nm wavelength of the laser, whilst the absolute frequency is obtained by comparison with the NML in-house atomic clocks. The fundamental standard Michelson interferometer is presently capable of a bandwidth of 0.1 to 50 MHz and a displacement resolution of 0.05 nm. There are only a handful of such absolute ultrasound standards operating in the world, all of which are resident in national standards laboratories.

In practice, the interferometer is commonly used to calibrate a secondary standard membrane hydrophone which is immersed in water and subjected to a well-characterised ultrasound field. The secondary standard is then used to calibrate client hydrophones for ultrasonic pressure sensitivity with respect to frequency. Occasionally, the interferometer is used to measure the ultrasonic displacement directly on a transmitting transducer in air or water and on solids which have an ultrasonic field excited within them.

Scan System

The other property of fundamental interest is the spatial distribution of the ultrasound field. This is often required when determining the ultrasound beam profile of transmitting transducers or the angular directivity of hydrophones (receivers). A sophisticated positioning system, more commonly termed a scan system, is used to accurately move the transducer about the ultrasound field. The scan system has the following features:

- Six degrees of freedom with a single manipulator.
- XYZ motion of 1000(400(400 mm with 1 μm resolution,
- Three angular motions of ±165°, ±100° and ±10° with respective resolutions of 0.001°, 0.01° and 0.05°.

NDT/E scans using pulse-echo transducers can be done on test pieces that are commonly used in testing work.

The scan system at NML will be calibrated using optical interferometry so that its spatial measurements are traceable to national length and angle standards. It will be the highest specification scan system for any ultrasound standards laboratory in the world. However, large defence and civilian NDT/E testing laboratories often have scan systems with specifications that are tighter by a factor of two.

Total Power Standard

Ultrasound transmitting transducers operating at higher powers will produce an ultrasonic field that exhibits a strong radiation force. This radiation force can be measured by directing it against a 45°, air-backed cone connected to a sensitive mass balance. The total ultrasonic power in the transducer's beam can then be calculated from the radiation force. The mass standards used to calibrate the mass balance are traceable to NML in-house standards. This power measurement device is typically termed a radiation force balance. The one used at NML has a bandwidth of 0.1-10 MHz and a power range of 0.1 to 30 W.

Miscellaneous

A range of standard, medical, NDT/E and industrial transducers are kept in order to produce a range of ultrasound fields and to undertake informal comparisons with other national standards laboratories. NML will participate in two formal international CIPM comparisons of ultrasound standards in the next 1-2 years. One will involve the measurement of hydrophone sensitivity and the other the measurement of ultrasound power at therapy levels. The latter comparison is particularly timely given the current effort in therapy ultrasound at NML.

3. THERAPY ULTRASOUND

The Problem

An ultrasound therapy machine typically consists of a high frequency generator driving a piezoelectric disc encapsulated in a metal housing which is then applied to the skin of the patient through a coupling gel or water bath. Clinical therapy ultrasound machines operate in the frequency range 1-3 MHz with a power range of 0-15 W or an intensity of 0-3 Wcm^{-2}.

The clinical users are commonly trained and registered physiotherapists. Ultrasound is one of the most common electro-physical therapy modalities used by physiotherapists. Some examples of medical conditions it is used to treat are sporting and repetitive strain injuries, rheumatiod arthritis, nerve pain, circulatory disorders, and deep scar tissue.

It has been estimated [1] that there are approximately 7,000 registered clinical users of therapy ultrasound machines per 10 million population in the western world. The widespread use of ultrasound is reflected in the extensive literature, eg [2-6]. Although ultrasound therapy is widely used, it is difficult to obtain a written clinical protocol [7, 8]. In a common teaching text [8] and a general literature review [9], the authors admit that there is a lack of controlled clinical trials to ascertain optimum treatment parameters.

It could be the lack of calibrated machines in clinical use that is contributing to the vagaries in clinical application of this therapy. Twelve surveys of the calibration of therapy machines have been conducted between 1973-95 in Australia, Canada, the Netherlands, New Zealand, United Kingdom, and the USA [10-21]. From these surveys, several features were clear:

- On average 70% (range 50-80%) of machines failed the standard applicable in that country. The allowed power inaccuracy is ±30% (sometimes ±20%).
- Regular calibration checking of ultrasound therapy machines was required.

It has only been in New Zealand (NZ) that a comprehensive follow-up survey has been done after corrective action. The 1985 NZ survey of 230 machines found that 65% had a maximum output that differed by more than (30% from that indicated [15]. Following this poor result, the NZ Society of Physiotherapists Private Practitioners' Association instituted a voluntary accreditation scheme for hospitals and private practices. The follow-up survey 10 years later [21] was encouraging in that only 18% of the machines failed (c.f. 65%). However, this is for a measurement that is made at full power as is commonly stipulated in IEC standards [22]. Disturbingly, it was found that 50% did not give the correct value over their full output range. Furthermore there was no correlation between calibration accuracy and period of use (hours of service) or the calendar period since the last calibration check. In NZ, routine testers are under no requirement to have their proficiency in testing examined; common practice in the western world. The NZ study suggests [23] that some machines cannot be calibrated properly, and/or may be incorrectly calibrated at manufacture. Furthermore, subsequent calibrations performed during its clinical life may be in error.

Anecdotal tales of patient discomfort or injury due to ultrasound therapy exist, but are seldom made widely known for reasons involving malpractice and liability. It was documented at an Edinburgh, UK, hospital recently that two patients did receive injuries due to treatment from a faulty and un-calibrated machine [20-22, 24, 25]. The alternate situation is no effective treatment. The NZ surveys [15, 21] showed that 4-7% of machines were either delivering no ultrasound or less than 10% of what was indicated (clinically ineffective). It is clear that in this situation the patients are paying for treatment and receiving none.

Conclusions

The western world countries covered by this short analysis all have very similar protocols for clinical use of ultrasound therapy and technical performance standards for the ultrasound therapy machines. The findings in each country can be amalgamated to make a number of conclusions:

- Therapy ultrasound is widely used but poorly applied clinically.
- International surveys have shown that there is an enormous calibration fail rate.
- Calibrations performed by routine testers who have not been proficiency tested are often unsatisfactory and of little value.
- Significant injurious and ineffective treatment occurs due to poorly calibrated ultrasound therapy machines.

Virtually all the western world countries hold satisfactory national physical standards for ultrasound therapy. There is also an abundance of equipment on the market to test ultrasound therapy machines. Regulation to ensure safe application of therapy ultrasound by regular calibration of the therapy machine ranges from nil to mandatory. Unfortunately, even where it is mandatory to test (USA), there is no effective scheme for ensuring that those who routinely test therapy machines are proficient in doing so.

What is missing is a cost effective traceability link from the clinical users through the routine testers to the national standards.

Corrective Action

It is clear that corrective action is overdue. The logistics of reaching each party involved in the use and testing of ultrasound therapy machines are forbidding. There are at least 14,000 therapy machines across Australia and about 100 individuals doing some routine testing. A routine tester may test anything from 10 machines/year (medium sized hospital) to 1,000 machines/year when servicing a large number of private practices and hospitals over a portion of a city. This type of test work is very seldom the sole source of income for a routine tester, neither is it particularly profitable. It is therefore unrealistic to expect a routine tester to report with his measuring equipment to a laboratory in order to assess his/her measuring proficiency and the calibration of his/her equipment.

One scheme to test the proficiency of the routine tester would be to dispatch to him/her a portable power standard (PPS). The PPS would resemble a commercial, clinical therapy machine but differ in several key aspects:

- It will be robust for travel through the usual commercial courier routes of air, rail and road.
- It will have a range of ultrasound transducers that bracket what is seen in clinical use. A negative control transducer would also be present.
- The output power will not be indicated on the front panel, rather a corresponding alphanumeric code. The code is to be quoted with the ultrasound power measured by the routine tester.
- The quality of the ultrasound will be more stable and of higher specification (eg beam uniformity, power) than what is available from commercial machines.

The proficiency assessment of the routine tester would occur by simply receiving the PPS, measuring its ultrasonic output as they would for a clinical machine (as a function of the front display codes), and then reporting their results with the display codes to the administering laboratory of the PPS. The administering laboratory would then assess whether the routine tester was performing an accurate measurement or if corrective tuition and/or equipment calibration were required.

The production of the PPS requires extensive experience in ultrasound measurement and the production of ultrasound fields. An European Union 5th Framework proposal is presently being put forward by NML and the national standards laboratories of the UK, the Netherlands and Germany. It is expected that NML will have a prototype PPS for trial use late in the year 2000.

The present IEC standards for therapy ultrasound machines [22, 26] are more suited for type, pattern and manufacturing QA testing. They are too unwieldy for clinical users and routine testers who require short, prescriptive documents for their particular situations. It is envisaged that the nature of these documents would be:

- Information articles in the professional journals and trade publications for clinical users and routine testers of medical equipment.
- Two standards in medical ultrasound:
  1. The clinical users' standard would prescribe simple daily checks for gross operational faults and how to obtain an annual calibration by a legally traceable routine tester.
  2. A standard giving detailed instructions to the routine tester on the minimum requirements for testing and reporting of the annual calibration of ultrasound therapy machines.

The work on the advisory standards has already begun in the Standards Australia technical committee HE/3/3 Medical Ultrasound.

The availability of a PPS together with the advisory publications and standards will provide a mechanism to enable the corrective action to be taken. The motivation for clinical users and routine testers to use the mechanism will be provided by ISO9000 quality assurance, medical insurance and voluntary accreditation through professional associations.

Spin-Offs

The effort in improving patient treatment with ultrasound therapy does have some useful spin-offs. The PPS as an exceptionally well defined source would enable considerably better dose estimation when conducting clinical research trials.

Australian manufacturers of ultrasound therapy machines will be able to draw on the expertise gained by NML staff. Some possible outcomes might include:

- an international review of what contributes to making an internationally competitive machine.
- advice on how quality control can be done most cost-effectively.
- the provision of compliance testing to Australian and overseas standards.

Lessons Learnt

In formulating and beginning this effort in therapy ultrasound, a number of lessons for a body like NML have been learnt:

Consultation: Extensive consultation is required with all levels of use of the technology, from the patients to regulators in other countries. This information gathering can be done effectively through the use of both formal and informal advisory groups. A good mechanism for the formal group is a Standards Australia technical committee. The informal group arises from identification of key players and stakeholders.

Effective Compliance: The correct questions need to be asked. Will the management scheme, advisory publications, standards and technical devices employed actually give a high degree of effective compliance at the end use of the technology? Does all the effort really make a difference to society and patient well-being?

A Driver: The gulf between NML and the patient is a wide one. The person required to bridge that gulf and ensure that useful work flows across it requires familiarity with all the levels of the problem.

4. OTHER AREAS

The breadth of ultrasound use can be seen in the range of Standards Australia committees that NML has interacted with:

- HE/3/3 Medical Ultrasonics.
- HE/3/-/5 Lithotripters.
- ME3 Sterilising Equipment
- MT7/3 NDT Acoustical Methods.
- TE6 Printed Circuit Boards.

Interestingly, interactions with such technical committees and introduction to other ultrasound technology areas often arises from users and manufacturers requesting NML assistance, sometimes anonymously. These anonymous alerts or "tip-offs" are, in the experience of overseas colleagues, often extremely valuable sources of information. A brief review of NML's interaction with the other uses of ultrasound of present interest will be given here.

Medical Ultrasonics

The use of ultrasound in medicine is very widespread. Millions of Australians every year will have some exposure to it.

Lithotripters generate ultrasonic shockwaves of more than 100 MPa with a duration greater than 100 ns. These multiple shockwaves are used to fragment hard deposits such as kidney and gall stones in humans. NML's interaction to the present has been restricted to the Standards Australia committee (HE/3/-/5) and maintaining an international watching brief on the standards of use of lithotripsy.

Diagnostic imaging ultrasound is extremely widely used (see the Introduction). It has been the area of highest growth in diagnostic imaging services funded by Medicare. NML interaction in this area has been restricted to providing information regarding the safety of diagnostic ultrasound to the Australian Health Technology Advisory Committee's (AHTAC) review of this technology. The peak power outputs of diagnostic imaging machines are often comparable to therapy ultrasound, but the duty cycles are extremely low, usually (2%. The dose and probability of adverse effects are accordingly extremely low. There has been some discussion in the Standards Australian committee (HE/3/3) regarding the introduction of some random compliance testing of diagnostic machines in Australia. The compliance test would be to FDA USA standards for these devices.

The use of ultrasound surgical units and dental descalers is very widespread. There have been comparatively few adverse problems with the clinical use of these devices. Accordingly, international standards activity in this area is low.

Power Ultrasonics

This area covers industrial applications where the total power is from 1 W to many kW. The most common application is the use of ultrasonic cleaning baths. These baths may be used in such diverse situations as cleaning surgical implements of human material (ME3 Sterilising Equipment), removal of solder flux from printed circuit boards (TE6 Printed Circuit Boards) and cleaning vegetables.

NML's involvement has been to resolve conflicts between stakeholders during the production of standards and to provide design and measurement advice for ultrasonic baths. However, due to the large power densities involved, conventional in-situ measurement methods are often of limited value and difficult to interpret. The number of queries in this application area is expected to rise slowly as industry explores the use of high power ultrasonics in the sonic processing of materials.

Underwater Acoustics

The term underwater acoustics is often used to describe waterborne military acoustics from the audible range to 500 kHz. The military use is usually confined to ranging, imaging and passive detection of other watercraft. Dr Suszanne Thwaites of NML is presently conducting a review of Australian military and civilian uses of underwater acoustics. This is in preparation for a forthcoming international comparison in underwater acoustics.

Non Destructive Testing/Evaluation (NDT/E)

This is probably the area where NML can make the most impact. However, to date, the medical area has consumed most of the NML effort. NML has provided informal advice and Quality Assurance testing of NDT/E transducers for a major Australian manufacturer of aerospace components for international clients. In addition NML is a member of the relevant Standards Australia committee (MT7/3) and interacts with the Australian Institute of Non-Destructive Testing (AINDT). A review of ultrasound NDT/E users in Australia and New Zealand by NML will shortly begin. The review will

identify what is required in the way of measurement standards support and what measurement research assistance is desirable. In the long term it is expected that NDT/E will absorb most of NML's effort in ultrasound.

5. SUMMARY

Only a brief description of the effort in ultrasound by NML has been given. The present effort is directed towards therapy ultrasound but in the longer term NDT/E is expected to absorb most of the NML effort. Your comments would be most appreciated. [Adrian.Richards@tip.csiro.au]

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