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Development of transfer standard devices for ensuring the accurate calibration of ultrasonic therapy machines in clinical use

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Contents

1 GENERAL

Ultrasound therapy as a clinical treatment is extremely common in the Western World. Internationally, regulation to ensure safe application of ultrasound therapy by regular calibration of the therapy machine ranges from nil to mandatory. Unfortunately, even where it is mandatory to test, there is no effective scheme for ensuring that those who routinely test therapy machines are proficient in doing so. It is concluded that the western world countries all have very similar protocols for clinical use of ultrasound therapy and similar technical performance standards for the ultrasound therapy machines. The conclusions drawn below are then applicable to the EU as well as the rest of the western world.

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

Extreme cases have often been reported where machines in use are delivering effectively no ultrasound or up to many factors greater than the amount indicated. This creates patient injury problems as well as mistreatment. To address this problem the project aimed to:

- Develop an ultrasound Portable Power Standard (PPS) into a robust form, for use at physiotherapy levels. The power standard would consist of a Driver, a set of clinically representative Transducers and a Cavitation Detector (CD). The power standard would be suitable for conducting in-the-field proficiency testing of small companies, hospitals and manufacturers undertaking routine ultrasound therapy machine testing. Four systems will be produced, presently exclusively for European national standards laboratories, so that at the end of the project each partner has a unit.
- Produce a number of advisory publications and international standards for physiotherapists and those testing ultrasound therapy machines. They will advise in a transparent and accessible manner, the mechanism for obtaining traceability and the key documentation to seek.

The work has been carried out in six Work-packages which are described in Section 2.

This report describes the development process and the results of the project. As the ultrasonic output from the Driver and some specifications of the Cavitation Detector should stay unknown to the general public this report does not present any result that could identify the performance of the devices. This information is however known to the project partners.

NOTE: It was unavoidable in the report to use both the . (point) and the , (comma) as decimal separator sign, as contributions from various countries have been included and various software producing graphs and preformatted tables has been used.

1.1 Partners in the project

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2 Work in the project

The ultrasound Portable Power Standard (PPS) acts as a transfer standard and includes a Cavitation Detector (CD). Four PPS's have been produced so that each partner at the end of the project has a unit on which to base regulatory work in their respective country. The work has been carried out in the following Work-packages.

1. The selection, modification and testing of ultrasound treatment heads to be used as ultrasonic transducers for the PPS. Five heads will comprise a set for each PPS so that the range of treatment heads seen in clinical use is bracketed.
2. The design and production of the Driver of the ultrasound transducer (treatment head). An assessment will be done as to whether it is efficient to modify a commercial ultrasound machine or whether the Driver should be assembled from a number of off-the-shelf components.
3. The transducers selected will have their ultrasonic power measured.
4. Under certain conditions, the ultrasonic field can liberate bubbles within the test medium (usually water), a process known as cavitation. As this may not be immediately apparent to the operator, cavitation can lead to under-estimates in the measured of power of up to 30 % and may indeed be responsible for some of the differences reported in literature. In order to assess a commercial tester's technique the use of a CD would be of immense valuable diagnostic help. The design specification for a CD generated during the EC project SMT4-CT96-2139, will be refined to produce a prototype hand-held detector.
5. It is necessary to bring all the elements of the previous Work-packages together in order to realise the complete PPS, with Driver, Transducers and CD testing units and subject all four sets to a round of travel journeys with tests by potential users.
6. The motivation for commercial testers to be certified and for clinical users to request a traceable calibration will be different for each country. Common is the requirement for guidelines in the use of the PPS by the commercial testers and what clinical users should demand of their commercial testers. A draft standard through consensus with all the stakeholders in ultrasound therapy use will be produced to be submitted to IEC TC87, upon which a number of the partners participate. In addition a joint publication between the partners will be produced to disseminate the results of the work to the parties in the field.

During the project, meetings were organised in Braunschweig, DE (PTB), Sydney, AUS (CSIRO), Teddington, UK (NPL) and Leiden, NL (TNO). The overall co-ordination of the project is the responsibility of TNO. For each of these Work-packages the "General results" and "Conclusions" will be presented.

2.1 WP 1: Selection and testing of sources

The selection, modification and testing of ultrasound treatment heads to be used as the ultrasonic transducers for the Driver of the PPS. Five transducers would comprise a set for each Driver such that the range of treatment heads seen in clinical use is bracketed. This will include one transducer exhibiting an unusual output as a negative control. The partner responsible for the execution of this task is TNO (NL).

2.1.1 General results

The brand and type of transducers used in a previous EC project, SMT4-CT96-2139, were found to be appropriate for use in this project too.

Characterisation of transducers
The basic beam characteristics of the transducers used in the project were measured following the IEC 61689 standard. The results, including graphical representations of the beam behaviour of each transducer, are presented in TNO-report PG/TG/2002.077r. This report has been distributed among the partners and is a part of the specifications of each partners Portable Power Standard. Typical characteristics of one set of these transducers is given in Annex A.
The following ultrasonic beam parameters were taken into account:

- the effective radiating area,
- the beam non-uniformity ratio,
- cylindrical asymmetry,
- the distance where the maximum pressure in the beam occurs,
- frequency for maximum radiation conductance,
- radiation conductance.

Apart from the above list the temperature dependencies of the radiation conductance G and the ultrasonic power P were determined for 4 transducers. It is to be expected that these transducers are typical for the whole set of these types of transducers. See Annex A.

5 of each type of transducer have been selected, four for use in a PPS and one as a spare.
Criteria for this selection were relatively small variations of the most important parameters showed. The selected transducers have been subject to stability measurements. See Figure 1 for a typical finalised set of transducers. Figure 2 shows the mounting arrangement.

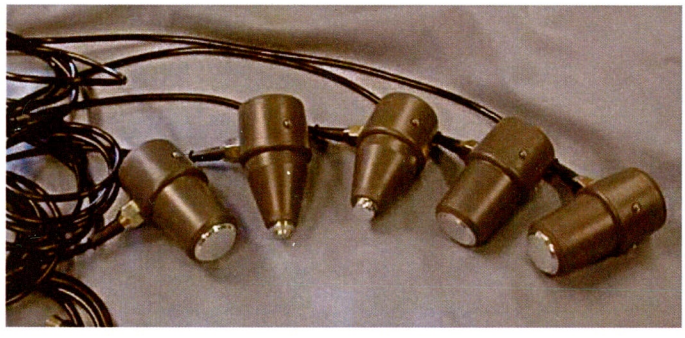


Figure 1. A finalised set of transducers to be used with the Driver of the PPS

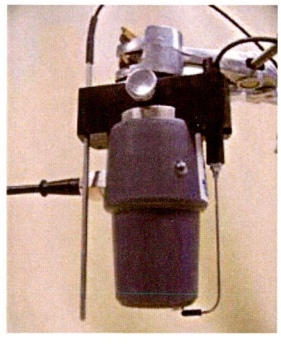


Figure 2. Mounting of transducer, temperature probe and CD sensor

Stability measurements by TNO
Stability measurements have been carried out by TNO starting in April 2002 and continuing for the eight successive months. After a long period in which the PTB also performed the final calibration of the PPS's a final stability measurement has been carried out by TNO in February 2004. The variation in the results of all stability measurements was about 2 %, see Figure 3. The project group agreed that these results give confidence. See also Section 2.5.3.

Negative control transducers

For one type of transducer the element size, position, driving frequency and shielding were modified. Due to this modification the ultrasonic beam became very asymmetric. NPL has measured the effect of RF emission on their ordinary commercial balance. The results are presented in Annex E. Although the effect of the RF emission was negligible, the effect due to beam asymmetry was clearly notified. As the power measured differed about 10 % from the power measured with their reference balance the transducer was considered to be suitable as negative control. TNO has determined the working frequency, *G*max and beam characteristics for the 3 MHz situation.

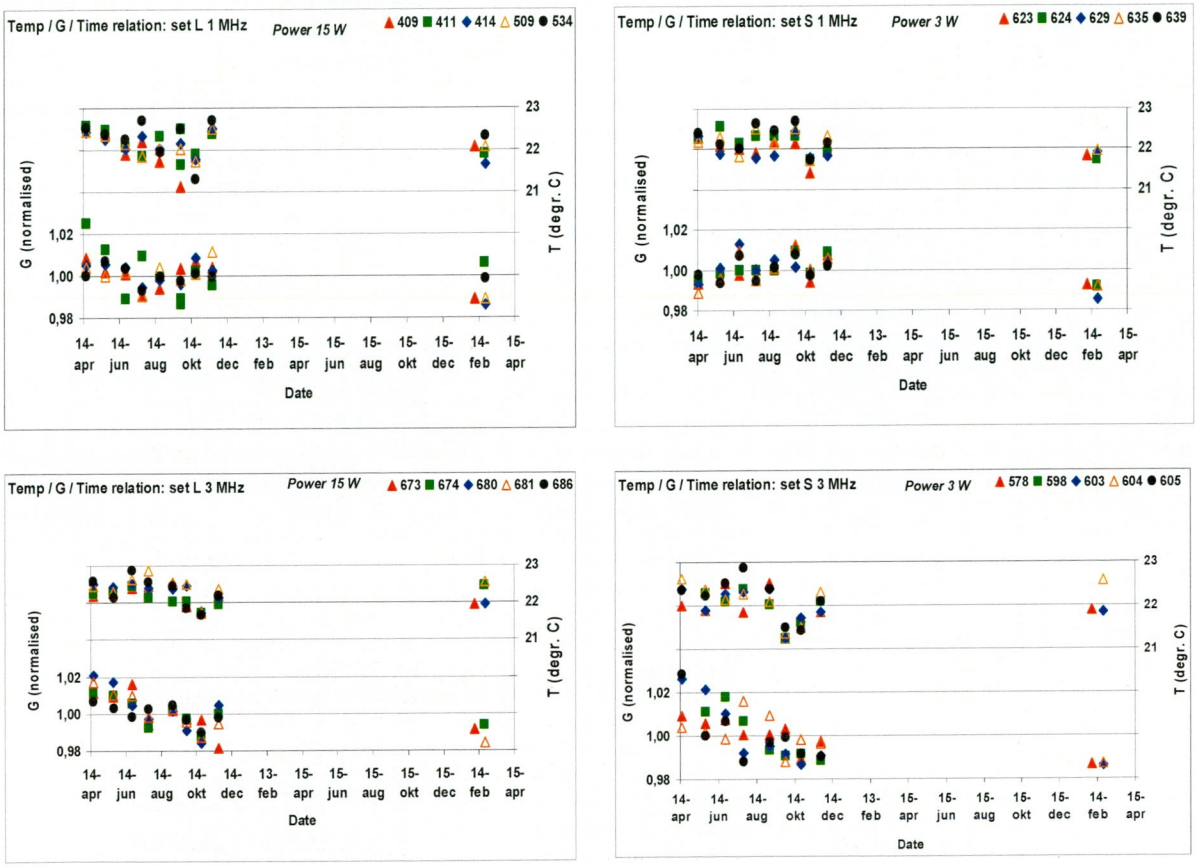


Figure 3.Final stability measurement results. Each of the graphs present the relation between time and the radiation conductance (G). Also the temperature of the water during the measurement is given.

2.1.2 *Conclusions for Work-package 1*

The conclusions from the work carried out are the following:

- The variation (2·standard deviations) of the radiation conductance of each of the selected transducers over time is not more than 3% (for 1 MHz transducers: 2 %).
- In general, the radiation conductance of the 1 MHz transducers changes by less than 0,2% per month. The decrease for the 3 MHz transducers is up to 0,6 % per month (average 0,2 % to 0,35 %).
- The type of negative control transducer that has been constructed is driven best at a 3 MHz nominal frequency. Although it shows only errors in some power measurements of about 10 % it was agreed to evaluate the usage of this transducer.

2.2 WP 2: Design or modification of a driver

The design and production of the Driver of the ultrasound transducer *(treatment head)*. Partner responsible for the execution of this task is CSIRO (AUS).

2.2.1 General results

CSIRO has manufactured six drivers. Four of them were calibrated by PTB in Work-package 3 with the appropriate transducers delivered by Work-package 1. The drivers were also subjected to a number of travel trials (see Section. 2.5)

A complete description of the hardware, including functioning, mechanical description, electrical diagrams, block diagrams, part lists, has been delivered on a CD-Rom disk. See Annex B for an introduction and a summary of the work.

Driver performance

The Driver unit, see Figure 4, contains an electrical signal generator and programmable power amplifier to drive the ultrasound transducers. The one unit can drive the full set of transducers described in par. 2.1. The ultrasonic output can range 0,1-15 W.
The Driver analogue output to the transducers is stable with time, the expected environmental conditions and robust for travel through the usual commercial courier routes of air, rail and road. The stability of the output is better than ±3 % with a transferable accuracy to the tester of approximately ± 1 % well within the ± 20 % required in IEC standard 61689. Of particular concern is that the frequency stability is sufficient to ensure that measurements made upon the transducers in TNO and PTB will relate closely to the Driver in the industrial and the clinical environment. The frequency resolution is 100 Hz and accuracy is to 50 Hz.

Figure 4. The Driver of the Portable Power Standard (PPS)

The Driver also contains a programmable interface. This is to allow:

- Encryption of the front panel control and display settings used by the tester in their measurements. This will enable blind testing, "Proficiency Testing".
- Remedial tutorials should the candidate fail the proficiency test and in addition it allows the PPS to act as a transfer standard.

- Automated calibration.
- Background data logging to monitor the responses of the tester (length of time and date on which transducers used). Shock and temperature sensors are also installed.

The driver software has been written in C, whereas the communication interface has been written in Labview.

The cavitation detector (CD) as described in Section 2.4 can be connected to the Driver so that cavitation events in the water can be logged automatically.

An external temperature probe to measure the temperature of the water bath is delivered with the Driver. When connected the driver automatically logs its measurement. The accuracy and resolution of the external temperature probe is ± 0,2 °C.

2.2.2 Conclusions for Work-package 2

The main conclusions from the work carried out are the following:

- Four final sets of Drivers plus Transducers) have been produced, and calibrated by PTB under Work-package 3. The results of the calibration were within the limits defined earlier in the project.
- The PPS's were also tested by each individual laboratory and it was found that after improvement of the software the sensing system for detecting changes in the transducer impedance (and acoustic load) does function reliably.
- A User manual and a full report with the technical and manufacturing description have been delivered.
- The user manual has been modified to include also safety aspects, packing and the use of the Cavitation Detector. See Annex F.

2.3 WP 3: Fundamental power measurement of transducers

PTB was responsible for the fundamental ultrasonic power measurement under Workpackage 3. This involved 4 Drivers of the PPS's with 4 transducers each, and each transducer at 4 power values. These measurements were carried out from 20 August 2003 to 6 February 2004.

2.3.1 General results

The ultrasonic power measurements (in water) were carried out using the primary PTB radiation force balance with absorbing target in accordance with IEC 61161, see Figure 5. The measurements were performed under computer control. The drivers had been provided with appropriate software so that they were able to communicate with the computer under Basic. This means that the internal driver parameters, namely frequency and "level", were set by the computer. "Level" is the internal driver parameter that determines the amplitude of the output voltage and thus the ultrasonic power.

The nominal ultrasonic power values were 0,1 W, 0,3 W, 1 W and 3 W for the "small" transducers and 0,1 W, 0,5 W, 3 W and 15 W for the "large" transducers. Three independent measurements were carried out in each case (for the exception see below). "Independent" means on different days, and it was ideally intended to cover a large time interval in order to check the temporal stability. This, however, was not always possible, for the following reasons: (1) Two of the drivers had to be technically modified during the campaign and this changed the output. (2) The Australian PPS had

to be returned to CSIRO already after the second measurement round. (3) Three of the transducers were found to be unstable during the measurements and were replaced. The unstable transducers were sent to TNO for repair. This was possible with two of them, and these were then re-measured by PTB, but only once.

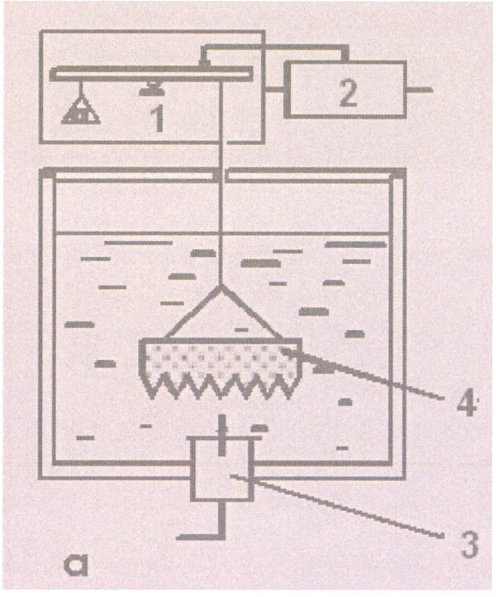


Figure 5. Principle set-up for the fundamental power measurements. The set-up complies to Arrangement A in the IEC 61161 standard, where:
1 balance,
2 balance control,
3 transducer,
4 absorbing target

After the fundamental power measurements all devices were sent to the partners.
The report on the measurements is given in Annex C. For reason of confidentiality the actual figures provided to the project partners are not included here in the Final project report.

2.3.2 Conclusions for Work-package 3

The main conclusions from the work carried out are the following:

- The software to calibrate the PPS's works well.
- Apart from driver modification and unstable transducers, all Driver/Transducer combinations were found to be stable within less than ± 1 %, but this was only over a limited time interval of up to 9 weeks in each case (for the reasons mentioned above).
- Fundamental power measurements over the full range of frequencies and power values have been carried out for the sets of Driver/Transducer combinations. It can be stated that the Driver's and the transducers behave well and according to the specifications laid down for this project.

2.4 WP 4: Cavitation detectors

The formation of bubbles within the test medium (usually water), some of which may not be readily apparent to the operator, can be expected to lead to under-estimation in the measurement of power of up to 30 % and may indeed be responsible for some of the differences reported in literature. The design specification for a cavitation detector (CD) generated during the EC project SMT4-CT96-2139 has been refined to produce the hand-held detectors. Partner responsible for the execution of this task is NPL (UK).

2.4.1 *General results*

Four cavitation detectors following specifications that have been discussed in the project group have been manufactured, see Figure 6. A threshold criterion to detect cavitation has been established by NPL and tested by the other partners. A separate report containing the functioning, the design and manufacture report and includes a user manual is delivered. The user manual has been included in Annex F. The technical manual is included in this Final report as Annex D.

Confirmation of detection principle

The experimental work investigated the acoustic emissions generated by cavitation from a typical physiotherapy source, using different propagation media, and measuring over a range of distances of the cavitation detector, a needle hydrophone, from the cavitating region. Large (25 mm diameter) 1 MHz and 3 MHz Enraf therapy transducers of the type to be used with the Driver of the Portable Power Standard (PPS) were used.

Acoustic emissions from cavitation were detected by a Dapco 0,6 mm diameter right-angled hydrophone, connected to a spectrum analyser, see the schematic set-up in Figure 7. Acoustic spectra were acquired as a function of transducer drive level, using drive voltages corresponding to power levels of nominally 1, 3, 5, 10 and 15 W, and at different measurement planes from the transducer.

Correlation studies, examining acoustic emissions from cavitation whilst measuring acoustic power simultaneously, were carried out in a range of water samples, over a range of frequencies. From the previous EC project SMT4-CT96-2139, for power levels approaching 20 W, reductions in measured power reasonably attributable to cavitation exceeded 15 %. The experiments completed were not able to reproduce to the same extent the findings of the previous project. It is clear from the correlation measurements carried out on two separate sets of transducers that it can be difficult to generate significant cavitation activity at 1 MHz, and that at 3 MHz, even power levels of 15 W are insufficient to produce cavitation of any real degree. Even in cases where cavitation is generated, the effects on measured power are small: at worst, a reduction of 6 % for a 0,75 MHz transducer when measured in tap water, in comparison to the 'reference' degassed water case. The transducers employed for this project are likely to have more evenly-distributed beams than in the previous project.

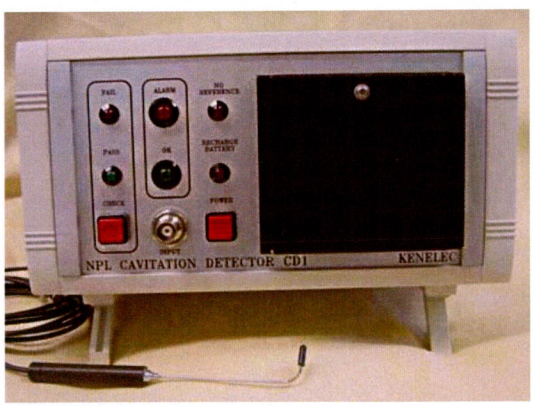


Fig. 6. The Cavitation Detector

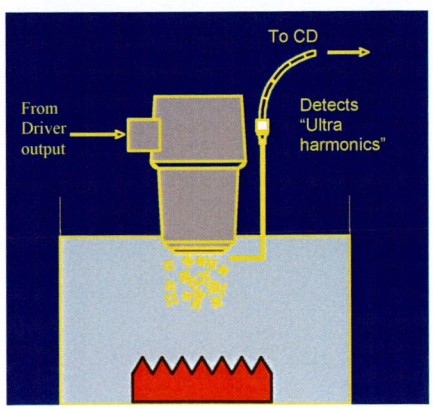


Fig. 7. Measurement set-up to sense the onset of cavitation

The higher standard deviations seen when analysing repeat measurements if tap water is used as the propagation medium are accompanied by a detectable increase in the level of the ultra-harmonic component in the cavitation spectrum, and so there exists an important role for the cavitation detector, to indicate deteriorations in water quality. The cavitation detector concept provides an instant indicator that the medium is rich in dissolved gas and cavitation nuclei, and so highlights the increased risk of measurement uncertainty.

The measurements have shown that when cavitation does occur, it can be readily detected by means of the ultra-harmonic component from the 1 MHz Enraf transducer, and (if required), the sub-harmonic component from the 3 MHz Enraf transducer. This means that the detection electronics required can be simplified, such that detection is carried out in a single narrow frequency band, rather than a separate setting for each transducer frequency. The CD was hence designed to listen for cavitation around a frequency of 1,5 MHz.

To test the units under conditions representative of those likely to be encountered in 'real world' environments, as well as 'reference' conditions, three different media were used in the experimental vessel: degassed deionised water, deionised water, and tap water. The transducer drive voltage was measured, and nominal ultrasonic power values in the range 0,5 W – 15 W were generated in each case. The output from the CD hydrophone as a function of transducer drive voltage was examined using both a spectrum analyser (looking at the magnitude of the 1,5 MHz component: 1,5x the fundamental frequency) and the CD being tested. For all CD's, each medium type was tested four times to generate some statistical data, with repeats being done on different days. An example data set is shown in Figure 8, and shows averaged results over 2 runs (spectrum analyser, SA) and 4 runs (CD) for each medium type. The SA results are plotted on the left-hand Y-axis, and the CD results on the right-hand Y-axis.

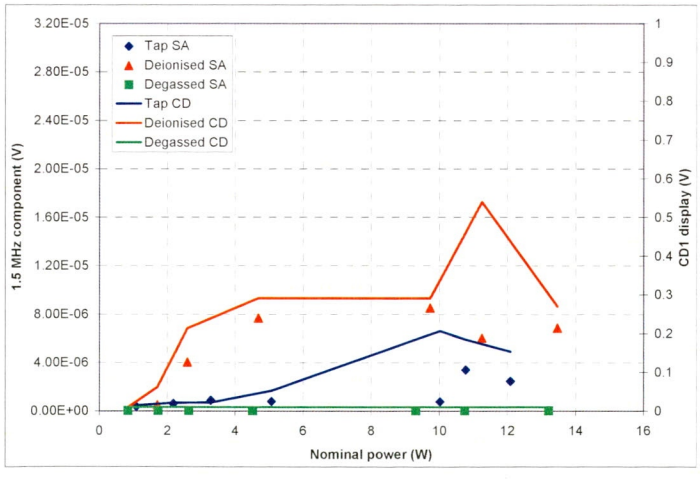


Fig. 8. Example of results obtained from testing of CD units – three different media cases

Generally, the trends seen in the CD and SA data for a given medium (as listed in the graph legend) are similar, and show that the CD unit is responding to cavitation activity (characterised by displayed level of the filtered 1,5 MHz signal) in the same way as the spectrum analyser (characterised by the appearance of the 1,5 MHz ultra-harmonic component). The data suggests that cavitation occurs in the nuclei-rich media beyond

about 3-4 W, and at a displayed CD level of around 100-200 mV. From this, it was decided to set the alarm threshold of the cavitation detector at 150 mV, and then amend this if required following testing experience of the project partners and testers.

2.4.2 *Conclusions for Work-package 4*

The main conclusions from the work carried out are the following:

- In general the partners are happy with the functioning of the CD. Its usefulness will be proven in future practical use.

2.5 WP 5: Realisation of PPS

All the elements of the previous Work-packages were brought together in order to realise the complete PPS, containing a Driver a number of Transducers and a CD testing units, and subject all four sets to a round of travel journeys with tests by potential users like commercial testers and SME's. The Euro-partners contacted prospective SME's interested in using the PPS as an 'in-house' quality tool. Partner responsible for the execution of this task is TNO (NL).

2.5.1 *Revised content of Work-package 5*

Early in the project the partners agreed to change the division of work in the work-package. The next table summarises the individual steps and the progress made.

Work-package 5 (revised): Realization of Portable Powers Standard and Cavitation Detector	
Step	**Activity**
1	Assembling & Testing transducers, Drivers and CDs by all partners:
2	Scan ultrasound beams for uniformity by TNO:
3	Total ultrasound power measurement by PTB and after that by all partners:
4	Cavitation Detector measurements by all partners:
5	Travel durability tests by CSIRO:
6	Transfer of Driver + Transducers + CD to EU-partners, they qualify the performance:
7	Performance qualification of Driver + Transducers + CD using third parties by European partners:
8	Report of the PPS realization: • The report will refer to the Work-packages 1-4. • Describe the measurement results of calibrations executed in Australia and Europe by SME's and hospitals.
Deliverables:	**D7** Four sets of the PPS **D8** Final report on the PPS.
Milestones:	**M6** Four sets of PPS ready for proficiency testing of commercial testers of ultrasound therapy machines.
Interrelation	**The previous W.P.'s has to be completed satisfactory. Milestone decision M5 has to be positive prior to the start of W.P.6**
1) Delivery date as planned in the mid-term progress report dated 24-11-03 in month from the start of the project.	

2.5.2 *Report on travel loops*

The usefulness of the PPS can be judged from the comments given by the third parties in their travel loops. Each partner has contributed to the report on travel loops, see Annex E.

Remarks on the measurement results

The participants' results for the small 1 MHz transducer (diverging) and for the negative control transducer were significantly low, with the exception of the CSIRO data, see below. Obviously the problem of the influence of a diverging field structure on power results, particularly with convex-conical reflector, is not sufficiently known (or compensated for) in practice.

In general the reproducibility of measurement of the testers was very good. Some of them had significant systematic errors in the calibration of their power meter. If these offsets were taken into account by the tester via the Calibration/Tutorial mode then a successful, accurate calibration could be done.

It is interesting to observe that the deviations in the measurement results in the European travel loops are smaller than those in Australia. A graphical presentation of the results is given in Figure 9.

In Australia the Negative Control transducer produced problems for four of the six testers. The power meters used may hence be unsuitable for testing the dual frequency applicator heads of the newer ultrasound therapy machines, which are able to produce stray RF radiation. In Europe a similar trend was not observed. The reason may be that the Negative Control transducer used in Australia showed a larger RF radiation, see Figure 10.

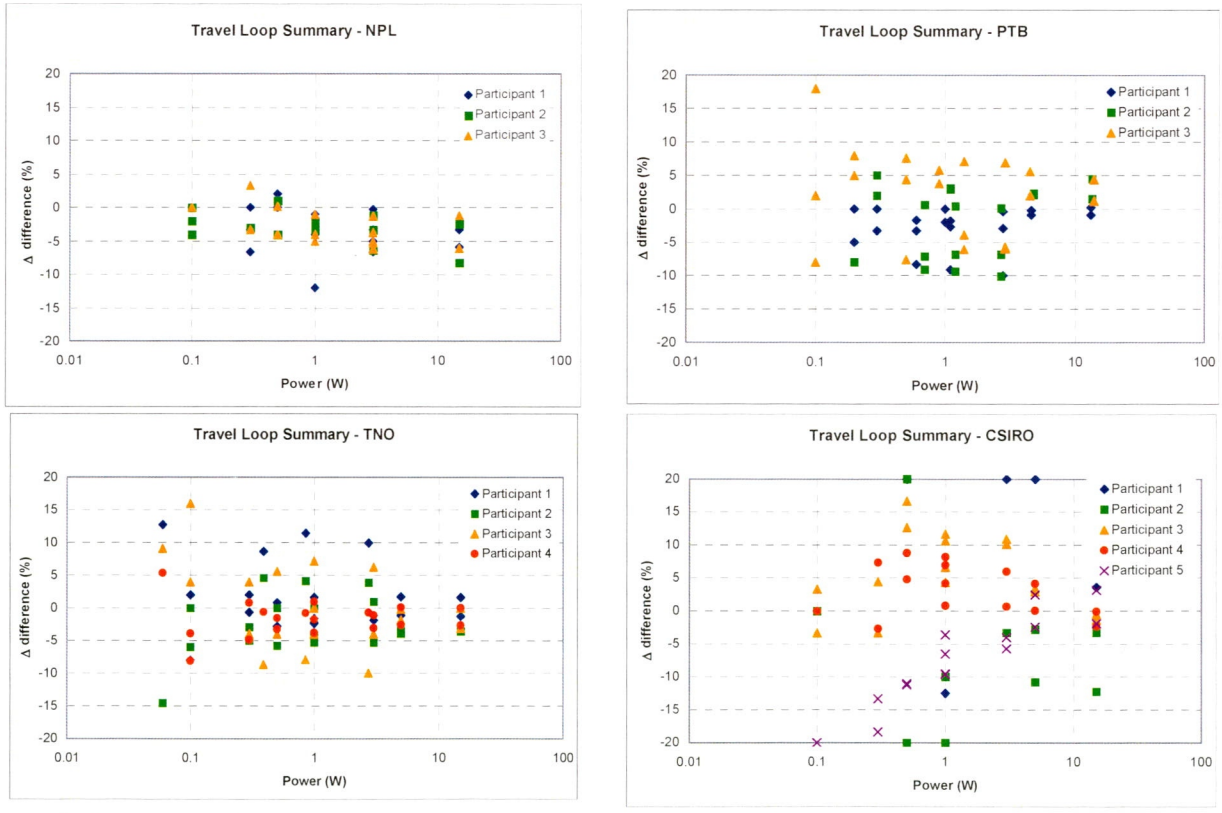


Figure 9. Graphical presentation of the calibration results of the preliminary testers in Europe and Australia using the proficiency test mode.

The cavitation alarms found show that refreshing the degassed water once a week is not sufficient, but obviously it is a widely-established practice. On the other hand, the ultrasonic power results obviously are not influenced that much.

Variation in the power results could be caused by vibrations or incomplete fixation of the transducer and its cable. Fixation of the transducer + cable to the table is necessary in TNO's experience. This need should be made clear to the tester.

One manufacturer uses calibrated correction factors to calibrate their own transducers. In using the PPS, this was not possible, which basically introduces an additional error.

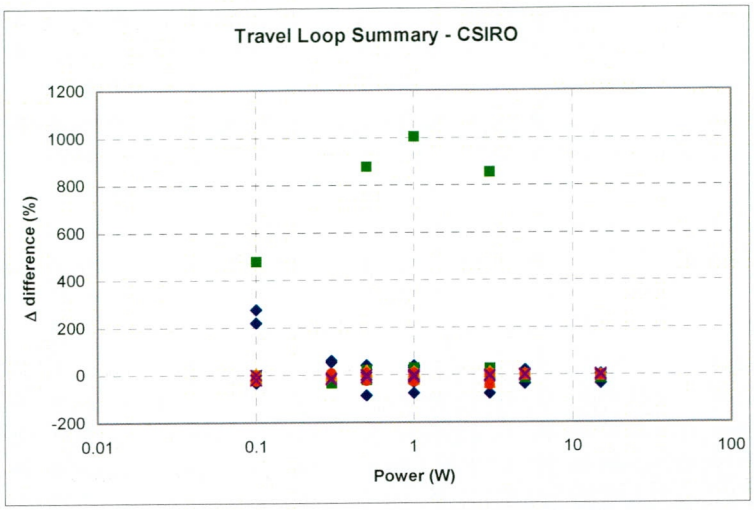


Figure 10. Graphical presentation of the calibration results of the preliminary testers in Australia having problems with the RF stray field.

Comments of the preliminary testers on the use
Most testers found the Portable Power Standard easy to use, especially after one or two tutorial sessions.
The use of the Cavitation Detector was educational. There was much complaint on the mounting of the detector hydrophone from the German and Netherlands testers.

General remarks
The PPS survived the travel, despite the shock/impact sensors on the transit cases being triggered a number of times. This also occurred once when a Driver was sent to PTB, Germany.
Special attention has to be given to avoid water ingress in the transducers, as this caused significant errors during candidate tests in Germany and the UK.

2.5.3 *Long-term stability as inferred from PTB measurements*

A large number of ultrasonic output power measurements were carried out by PTB over the time, particularly with PTB's own PPS. These measurements include the fundamental power measurements (2.3), the measurements before and after the travel loops (2.5.2) and a final measurement round in April/May 2005 near the end of the project, and they cover a time interval of up to 19 months. The following stability conclusions can be drawn for the combination Driver + transducer.

For each transducer, the output power results were analysed for two nominal power values, namely for 0,3 W and 3 W (small transducers and negative control transducer) and for 0,5 W and 15 W (large transducers). Following the history of each transducer, the DAC level values (excitation amplitude of the Driver) were not constant in all cases but were slightly changed from time to time. Therefore in order to be comparable, the output power values had to be corrected as a function of the DAC level used and applying a curve-fitting algorithm to the relation between DAC level and power.

The final stability result is as follows. Apart from two transducers that suffered from water ingress at one participant, the worst case was transducer SN 23 (negative control) at 3 W, the results of which can be characterized by a relative experimental standard deviation of σ = 1,6 % and a percentage difference between the highest and the lowest value of *diff* = 5,3 % (i.e., ± 2,65 %). The negative control transducer obviously is sensitive to changes with time and to environmental conditions as it is driven in the third harmonic. Apart from the negative control transducer, the worst case was transducer SN 26 (3 MHz large) at 0,5 W with σ = 1,4 % and *diff* = 3,3 % (i.e., ± 1,65 %). The stability of the other transducers was better than expressed by these values.

2.6 WP 6: Publication for clinical users & commercial testers

This work package basically concerns about the information provided to the potential users about the value of the PPS. It also concerns about a strategy how to use the PPS in the traceability process of power calibration of physiotherapy devices. The partner responsible for the execution of this task is TNO (NL)

2.6.1 Work undertaken

- CSIRO has made a guideline document that includes a description of the logistics of using the PPS and has examples of report sheets. The document also gives advice on periodic checks for physiotherapists.
- A draft advisory standard has been discussed in IEC TC87, WG8. Based on the previous listed CSIRO guidelines there is an Australian "Good Practice Guide", which is now a "Standards Australia" document. To be suitable as an IEC document the Australian guide is heavily rewritten. The draft guide has also been discussed with members of the project advisory group. Participants from industry found the maintenance too restrictive. Participants from hospitals wanted the guide to be more precise. The project team believes that by adding an acceptance test and relaxing the other tests we meet the wishes of both parties best. The project team agreed to work towards a "European Commission Report" which would have an ISBN number, also because it is and be then widely and freely available. This Guide is now called: "Guide for the maintenance of ultrasound physiotherapy systems". It is also included as Annex H. In this form it can then be referenced in IEC documents.
- The project has been presented at several national and international conferences:

  The project has been introduced at the EC conference "Towards an integrated infrastructure for measurements", 18-19 June 2002, Warsaw, Poland:
  - *R.T. Hekkenberg, Primary ultrasonic power measurements promotes treatment quality in physiotherapy, European Research Area, Book of abstracts and posters, June, 2002, Warsaw, Poland.*

  The project has been presented for an audience of physiotherapists during the 14th World Physical Therapy Conference in Barcelona, June 2003:
  - *R.T. Hekkenberg, K. Beissner, B. Zeqiri, A. Richards, Ultrasound Therapy: Is your machine giving the indicated amount?, WCPT, SI-PL-0725 , Barcelona, June 2003.*

  The project has been presented for an audience of medical physicists the World Congress on Medical Physics and Biomedical Engineering in Sydney. August 2003:
  - *A. Richards, Ch. Cantrall, G. Prout, R.T. Hekkenberg, K. Beissner, B. Zeqiri, R.A. Bezemer, Ch. Koch, M Hodnett, V. Wilkens, Ultrasound Therapy: Are your machines giving the right amount?", MPBE WC2003, Sydney, August 2003,*

  At the conference of Advanced Metrology in Ultrasound in Medicine 2004 (London, UK) the intermediate results of the overall project were presented. A

second presentation on the CD was given. They are were subsequently also published in the Journal of Physics Conference Series:
- *R.T. Hekkenberg, A. Richards, K. Beissner, B. Zeqiri, G. Prout, Ch. Cantrall, R.A. Bezemer, Ch. Koch, M Hodnett, Development of transfer standard devices for ensuring the accurate calibration of ultrasonic physical therapy machines in clinical use. Journal of Physics Conference Series 1 (2004) 99-104, (Institute of Physics Publishing), 2004.*
- *M. Hodnett, B. Zeqiri, A detector for monitoring the onset of cavitation during therapy-level measurements of ultrasonic power, Journal of Physics Conference Series 1 (2004) 112-117, (Institute of Physics Publishing), 2004.*

At the 5th International Conference on Advances in Metrology, 23-25 February 2005 in New Delhi/India the project was discussed as a part of the presentation:
- *K. Beissner, Advances in ultrasonic power measurement, Conference abstracts, ICAM, February, 2005.*

During the meeting Physics and Technology of Medical Ultrasound Biennial Meeting, 3 March 2005 (York, UK):
- *M. Hodnett, R.T. Hekkenberg, A. Richards, K. Beissner, B. Zeqiri, G. Prout, Ch. Cantrall, R.A. Bezemer, Ch. Koch, A Portable Power Standard for improving the quality of ultrasound physiotherapy treatments, PTMUB, York, UK, March 2005.*

- At several occasions the project progress has been presented and discussed at the meetings of the Ultrasound Sub-committee of Euromet. Within Euromet the project has been identified with project number: 671. This committee has expressed their expectation that the PPS form a link in the chain of traceability.
- During the project, 3 Newsletters describing the progress in the project were distributed among interested parties. These parties in Europe were manufacturers, test-houses and Notified bodies. A final newsletter has been distributed advertising the availability of the Portable Power Standard.

2.6.2 Work to be done

- To prepare a publication to be published in a journal important for the interested field and appropriate for interested parties (manufacturers, test-houses, hospitals and clinicians)
- To inform the standards organisation Euromet about the final results of the project.
- To propose a New Work Item Proposal to the IEC TC87 for preparing a Guide on the Maintenance of Physiotherapy Systems. The document will be discussed during the IEC TC87 Working Group 8 meeting in Madrid in week 26, 2005.
- To organise the logistics to put the PPS into practical use.

3 Organisational aspects

3.1 Time schedule

Eight project meetings have been arranged. The minutes of these meetings have been distributed to the partners and to the Commission.

In the first period of the project the progress looked very promising and was carried out according to the original time schedule. Following the date of the contract the project started at 1 December 2001. As no practical work could be carried out before 1 January 2002 the project immediately encountered a month of delay at the start. The project group expected that this delay could be made up during the project. Later on however the project encountered a considerable delay.
The reasons for this delay were as follows:

- The weather conditions in Australia in the latter part of 2002 and the early part of 2003 have been adverse. In late 2002 there were extensive bushfires which required some of the CSIRO staff to stay home to defend against the fires. In early 2003 heavy rainfall led to the manufacturing factory of the special Driver enclosures being flooded for 1 week. This delayed the receiving of the special enclosures by many weeks. There was also a flood in the laboratory housing the environment chamber at CSIRO, so that no work could be done for two weeks. A total delay of 9 months to finish Work-package 2 has been incurred by CSIRO due to the above.
- Due to delayed delivery of the hydrophones to be used in the CD, including their encapsulation through a protective polyurethane rubber shield, a manufacturing problem associated with the printed circuit boards used in the unit and extended testing of the CD, a delay of 8 months to the original plan for delivery of the CD's has occurred.

These delays affected the time schedule for the whole project. It was agreed with the Commission to extend the project with 6 month. From then on the project stayed on the time schedule and finished on 31 May 2005.

3.2 The effect that CSIRO has ended all their ultrasound activities

As reported in the Mid-term report CSIRO had ended all their activities in the field of ultrasound. The scientific officer, Dr Adrian Richards, has departed from CSIRO. Mr Glen Prout of CSIRO became the contact person instead
The effects of this move were discussed with all project partners.

The conclusions were:

- In order for CSIRO to comply with its critical, contracted contributions to the project the following has been done:
  - i Delivering all the Drivers, hardware and software,
  - ii The negative control transducers have been modified and interfaced to the Driver, then delivered to TNO
  - iii The work concerning travel loops in Australia and New Zealand has been moved forward to the latter part of 2003, prior to the departure of Dr Richards. Results are reported.

iv The following documents have been completed: Driver user manual, technical and manufacture report for the Driver, draft advisory publications for the physiotherapists, equipment testers and manufacturers.
v Some remedial programming work on the driver has already been completed in response to problems found by the European partners. There remained 2 Items that were important to be solved.

- It can be concluded that especially Glen Prout and Adrian Richards at CSIRO have taken good care about the proper ending of their part of the project. Some of the remedial work on the software of the PPS was for the European partners essential. This work has been properly completed.

- As CSIRO has changed their organisation there may rise a problem in future in case there is a need to duplicate the Driver of the Portable Power Standard. The documentation delivered by CSIRO is appropriate for duplication, but if another organisation carries out the manufacture, this will take much more time. A negotiation is going on to arrange that one of the spare PPS units of CSIRO will be stored in Europe.

3.3 Finances

Due to the project delay of 6 months there was a shift of costs from the third year of the project to the fourth year. All partners did spend more man-hours in the project than originally planned.
The original planned funding for PTB is not totally used by PTB and the European project partners agree to reallocate the funding between the partners. A table presenting the revised cost estimates per reporting period of 12 months has been attached to the minutes of the last project meeting (dated: 26-27 May 2005).

4 Final project assessment

4.1 Technical and scientific progress

During the project meeting, dated 26-27 May 2005, at TNO, Leiden (NL) the final technical and scientific progress has been discussed. The results of the discussion are summarized below.

4.1.1 Table of Milestones

Milestone	Objective	Decision criteria for assessment	Conclusion from the project team
M1	Transducers are characterized.	The ultrasonic beam behaviour of the transducers meet the agreed specifications	**The milestone is reached.**
M2	Completion of four sets of drivers for the ultrasound transducers	Drivers to ultrasound transducers are manufactured, delivered and meet the agreed specifications.	**The milestone is reached.**
M3	Transducers are calibrated in connection to their specific Driver	The calibration results meet the agreed specifications	**The milestone is reached.**
M4	Cavitation Detectors are produced	Four sets of CD's are manufactured and delivered, each capable of detecting the onset of cavitation under standard conditions.	**The milestone is reached.**
M6	Four sets of PPS ready for proficiency testing of commercial testers of ultrasound therapy machines.	Four sets of PPS are ready for use by the different type of testers of ultrasound therapy machines, e.g. biomedical engineer, medical physicist, medical device service agent, commercial tester, test house, National Measurement Institute or manufacturer.	**The milestone is reached.**
M7	Draft advisory standards are at hand to enable the proficiency testing of commercial testers and to enable the efficient calibration of clinical ultrasound therapy equipment	A draft maintenance guidance has been introduced to the IEC as a Technical Specification document. A similar document has been attached to the final report, and is also intended to be published separately by the EC. It is anticipated that the work has to continue after the project has ended.	**The milestone is reached as far as was possible within the project.**

4.1.2 Table of Deliverables

Deliverable	Title	Date 1)	Comments	Conclusion from the project team
D1	Four sets of characterized transducers	28	The transducers are delivered, and they are calibrated with each specific PPS	**The product is delivered.**
D2	Selection and testing of transducers report	28	The transducers are delivered and a report concerning their characteristics has been prepared. Calibration results are delivered to each participant.	**The product is delivered.**
D3	Four drivers for the ultrasound transducers	25	Four drivers are delivered.	**The product is delivered.**
D4	Driver design and manufacture report.	26	The design and manufacture report, including the user manual is delivered.	**The product is delivered.**
D5	Four sets of Cavitation Detectors	24	The cavitation detectors have been delivered and functions generally well.	**The product is delivered.**
D6	Production of Cavitation Detectors report	25	The design and manufacture report, including the user manual are delivered.	**The product is delivered.**
D7	Four sets of the PPS ready for use	34	All remedial work has been carried out on the Driver and CD. Travel trial have been carried out successfully. The PPS including the CD is ready for use.	**The product is delivered.**
D8	Final report on the PPS	34	The final report on the Driver of the PPS has been delivered. The final report on the CD has been delivered. The user manual in both reports are combined into one user manual for the PPS. A complete final report (the present report) on the work in the project has been written.	**The product is delivered.**
D9	A draft advisory standard for clinical users	42	A draft maintenance guidance has been introduced to the IEC as a Technical Specification document. A similar document has been attached to the final report, and is also intended to be published separately by the EC. It is anticipated that the work has to continue after the project has ended	**The product is delivered.**
D10	A draft advisory standard for commercial testers	42	It has been agreed during the project to produce only one advisory standard, to be used by all parties involved.	**The product is delivered.**

4.2 Project Technological Implementation Plan (TIP)

A Technological Implementation Plan has been prepared. The content has been agreed on by the European partners in the project meeting of 26-27 May, 2005.

5 Conclusions

From the positive response of the proficiency testers we expect that the Portable Power Standard will fulfil a useful completion of the traceability of the measurement results in ultrasonic power measurements of physiotherapy devices.

The Portable Power Standard, which is made up by Transducers, the Driver, the software, and the Cavitation Detector fulfils the requirements stated at the start of the project.

Deliverable 9 and 10 (draft advisory standards) were combined to produce one maintenance guidance. This guide has been offered to the IEC TC87 (Ultrasonics). Whether or not this will become an IEC Document is outside the reach of the present project.
As all other deliverables are delivered the project has ended successfully.

Annex A
TNO Report for Workpackage 1, Selection and testing transducers

Contents

1 Introduction

This report presents the work carried out by TNO Prevention and Health in Workpackage 1 of EC project GRD1-CT-2001-00600. It concerns the testing, selection and rigorous characterisation of 4 types of ultrasound physiotherapy transducers to be used in connection with the Driver of the Portable Power Standard later in the project. A total of 41 transducers has been tested, based on which 20 transducers have been selected, 5 of each type. This selection was based on the requirement that the most important parameters show a relatively small variation. Parameters taken into account were:

- effective radiating area, beam non-uniformity ratio,
- cylindrical asymmetry,
- the distance where the maximum pressure in the beam occurs,
- frequency for maximum radiation conductance
- radiation conductance.

The selected transducers have been subjected to stability measurements. These basically comprise measurement of the radiation conductance each month over a period of 8 months. Stability of the radiation conductance over time has been investigated. Also possible temperature dependence has been monitored to be able to apply corrections to the radiation conductance for temperature variations. Stability measurements have been finished.

An existing transducer has gone through several modifications to obtain a negative control transducer. The beam of this transducer has been characterised and power measurements have been carried out to determine whether it can be considered as a negative control.

2 Working frequency and electrical impedance

The working frequency for each transducer was defined as the frequency at which the radiation conductance G shows a maximum. Measurement of G is carried out by sweeping the drive frequency to the transducer while measuring the ultrasonic power and drive voltage. The voltage has been measured by a rms voltmeter. The power has been measured using the set-up with the water tank including the absorbing target directly placed on the balance. As only relative values were of importance the results of power, voltage and radiation conductance are indicative and not meant to be highly accurate. Although the drive frequency is known within 50 Hz the final estimate of the working frequency at maximum radiation conductance also depend on variations in the voltage and power measurements. For the 1 MHz transducers the working frequency should be accurate within 500 Hz. This corresponds to a variation of 0,5 % in the radiation conductance. For the 3 MHz transducers the working frequency should be accurate within 500 Hz. This corresponds to a variation of 0,05 % in the radiation conductance.

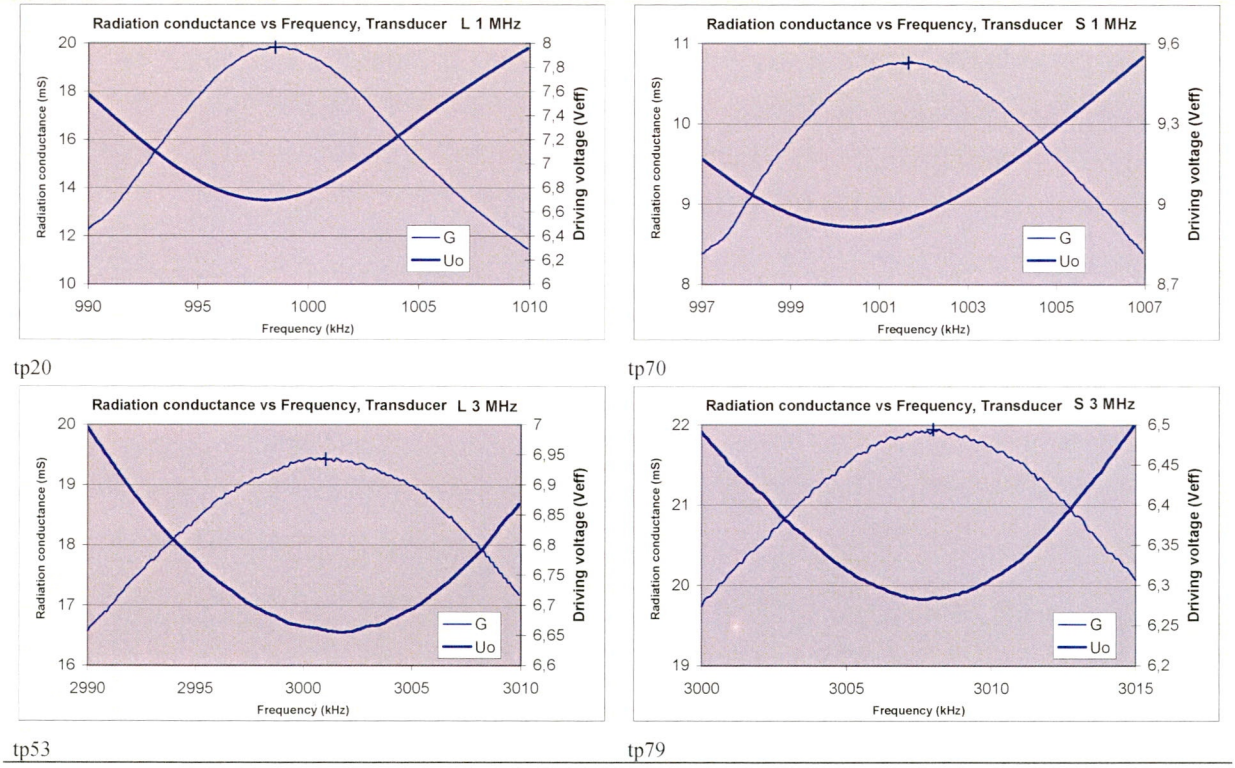


Figure A.1.1 *Typical variation of the radiation conductance (G) and drive voltage with frequency (f). The transducers presented in these plots have the greatest variation of G with f around maximum G .*

The frequency at which the maximum of the radiation conductance G occurs is found to be slightly temperature dependent. All subsequent measurements (mainly long-term stability measurements) have been carried out at the defined working frequencies.

The impedance measurements are carried out using a vector-impedance meter, see Figure A.1.1. The uncertainty in the measurement will be ± 0,7 Ohm for the impedance and 3 degrees for the phase. Some measurements are carried out with an air bubble on the surface of the transducer. From these measurement the sensitivity for this kind of mis-behaviour can be estimated.

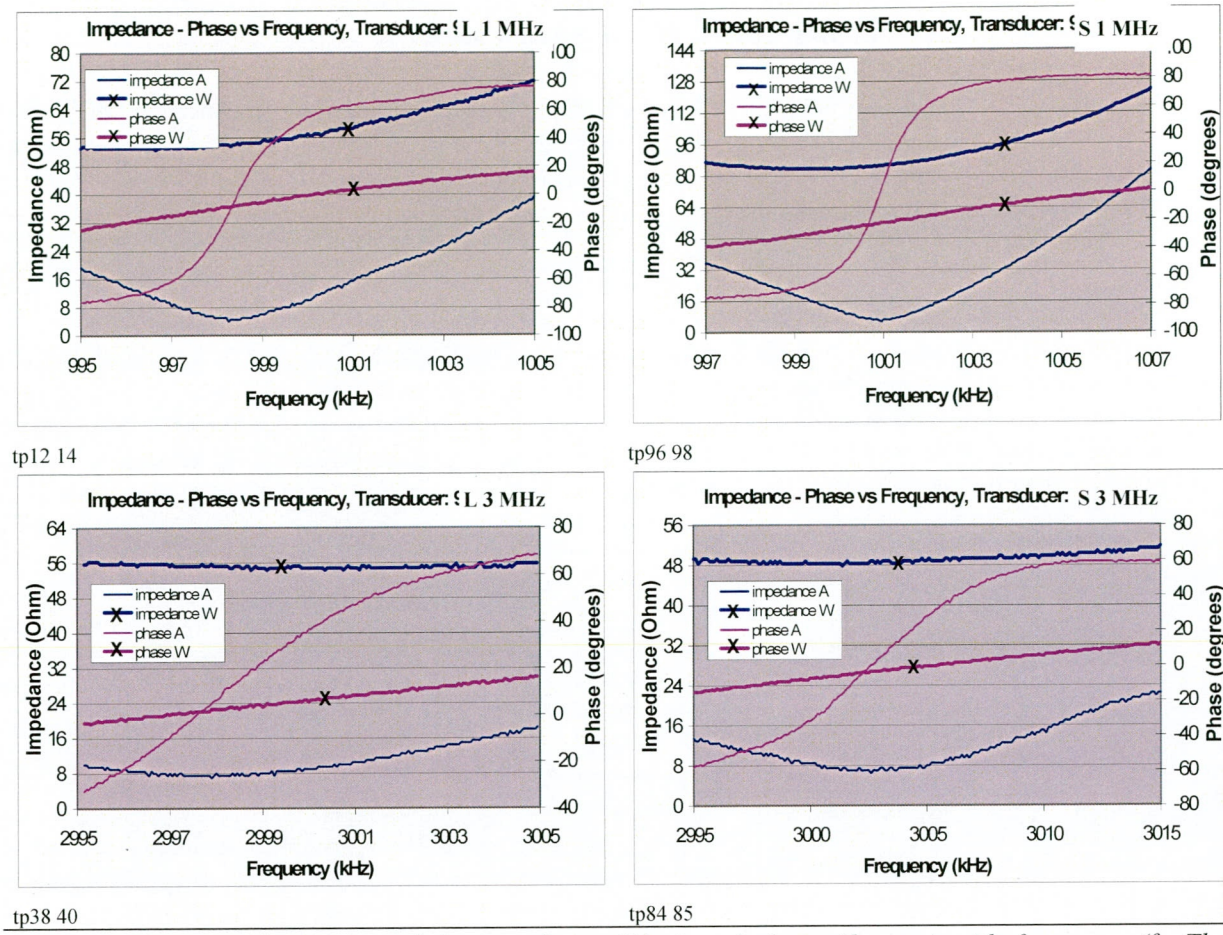


Figure A.1.2 *Typical variation of the impedance (Ohm) and phase (degrees) with frequency (f). The transducers presented in these plots are the same as presented in figure 3.1*

Based on the results of the frequency and impedance measurements and on the beam characterisation a selection has been made of 20 transducers (4 types, 5 of each type) potentially suitable to be used in the PPS. Tables 1 to 4 give the relevant information about the selected transducers of each type.

3 Temperature dependence

For one transducer of each type the temperature dependence of the radiation conductance G and the ultrasonic power P are determined by varying temperature in the water bath. It was expected that each transducer is typical for the whole set of that type. Figure 1 shows the results of these measurements

During the stability measurements, the temperature has been monitored. Afterwards, G has been related to the temperature at which the stability measurements were carried out. Figure A.1.3 graphically presents the temperature dependence of all 20 transducers (5 of each type).

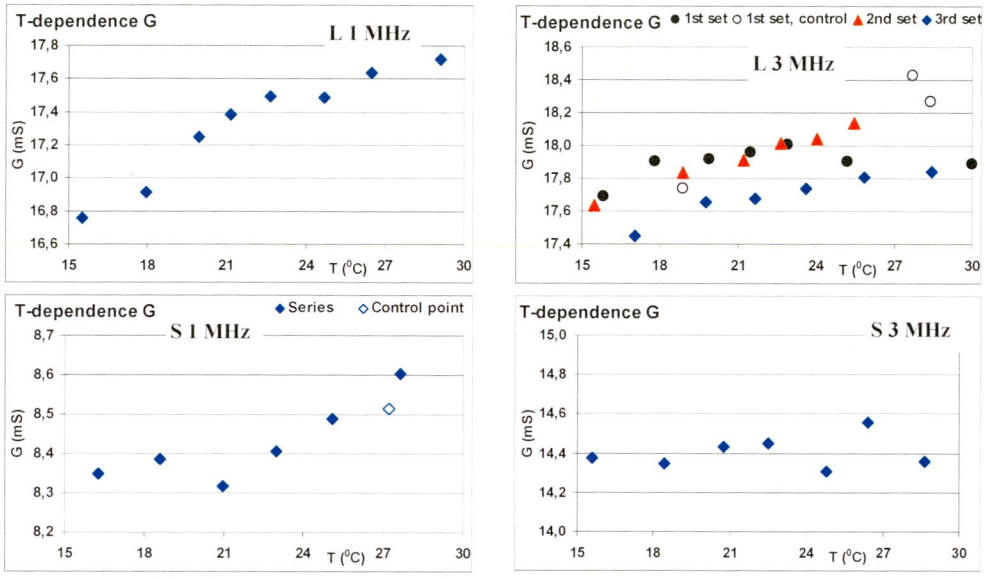
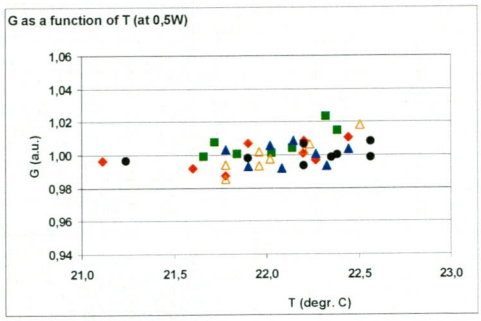
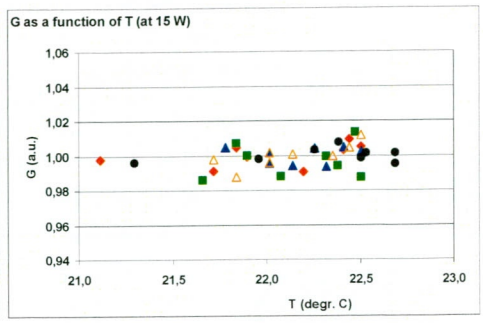


***Figure A.1.3**. Temperature dependence of G, determined by direct variation of temperature*

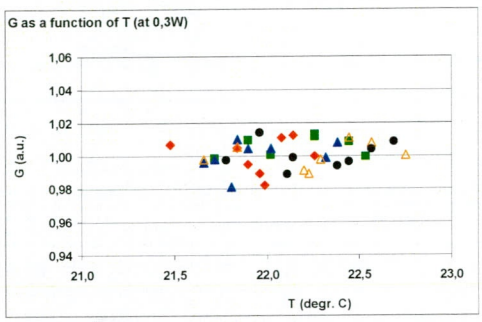
***Table A.1.1**. Temperature dependence of G, found by varying temperature in the water bath from 19 to 25 °C. The result is given as (Max. value – Min. value)/2 and as change per degree Celsius in the range 21 to 23 °C (the range in which stability measurements have been carried out, see there).*		
Transducer	**Variation in G (19-25°C)**	**T-dependence at 21-23°C**
Large 1 MHz	± 1,2 %	0,51 %/°C
Small 1 MHz	± 1,0 %	0,49 %/°C
Large 3 MHz	± 0,4 %	0,17 %/°C
Small 3 MHz	± 0,5 %	0,07 %/°C

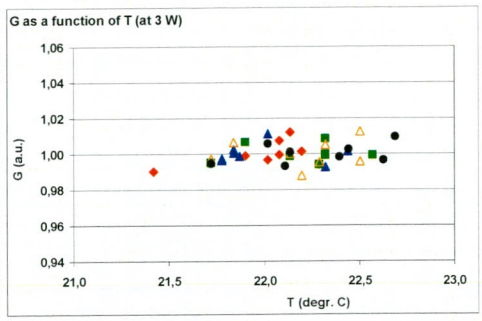
1 MHz, big



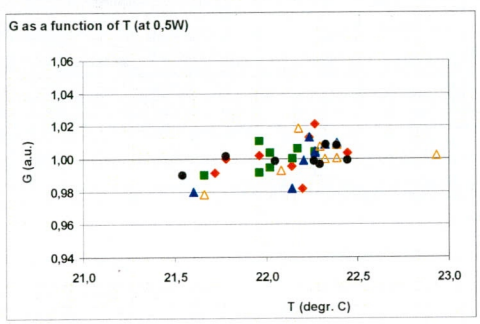


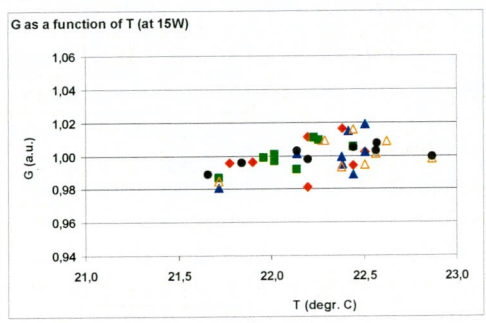
1 MHz, small



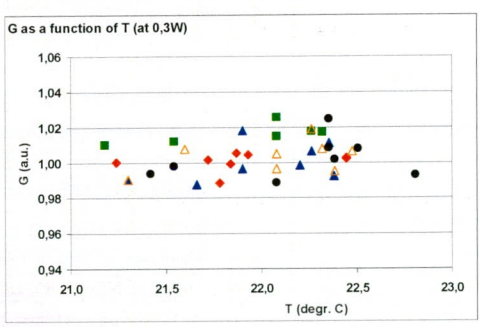


3 MHz, big





3 MHz, small



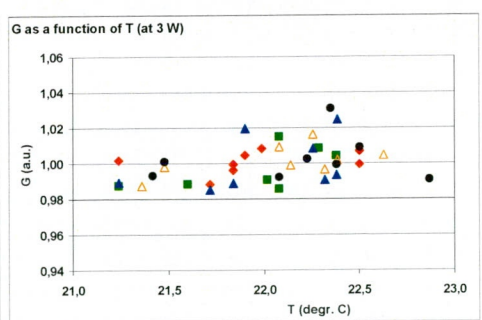


***Figure A.1.4**. Temperature dependence of* G, *found from stability measurements over 7 months.*

The 4 rows of figures represent 4 types of transducers. The left figure gives the temperature dependence at low power (0,5 or 0,3 W) and the right figure at high power (3 or 15 W). Each figure contains the information of the 5 transducers of that type. G *is normalised to the average value of these 5 transducers at this power.*

Figure A.1.4 shows the variation of G with temperature, but also contains the variability of G over time. Therefore these plots are not suitable to determine temperature dependence of the transducers; this has been done based on the data in Figure A.1.3. Since for some transducers the plots in Figure A.1.4 show only a small influence of temperature, it is concluded that variability of G over time is more important than temperature dependence of G.

4 Beam characterisation

The basic beam characteristics of the transducers used in the project were measured following the IEC 61689 standard. As explained earlier measurement results are confidential, they are known by the project partners. In this section some typical and average figures and graphical presentations of beam behaviour will be given.

Table A.1.2. Transducer: 1 MHz large, Drive: 15,0 V_{pp} [1)]

Transducer serialno	Frequency (MHz)	P (scans) (W)	A_{ER} (mm^2)	R_{BN}	z_{max} (mm)	Max. Cyl. Asymm. (%)	Divergence factor (cm^{-1})	Beam Type
Average	**0,9992**	**0,457**	**342**	**3,7**		**15,8**	**-0,020**	Coll.
SD	**0,0003**	**0,031**	**4**	**0,37**		**2,1**	**0,003**	

1) measurements conform IEC 61689, Power (P) is obtained from the hydrophone measurements

Table A.1.3. Transducer: 1 MHz small, Drive: 6,0 V_{pp} [1)]

Transducer serialno	Frequency (MHz)	P (scans) (W)	A_{ER} (mm^2)	R_{BN}	z_{max} (mm)	Max. Cyl. Asymm. (%)	Divergence factor (cm^{-1})	Beam Type
Average	**1,0021**	**0,034**	**84,8**	**5,8**	**5,7**	**26**	**0,203**	Div.
SD	**0,0014**	**0,002**	**3,5**	**0,6**	**0,3**	**6,1**	**0,030**	

1) measurements conform IEC 61689, Power (P) is obtained from the hydrophone measurements

Table A.1.4. Transducer: 3 MHz large, Drive: 15,0 V_{pp} [1)]

Transducer serialno	Frequency (MHz)	P (scans) (W)	A_{ER} (mm^2)	R_{BN}	z_{max} (mm)	Max. Cyl. Asymm. (%)	Divergence factor (cm^{-1})	Beam Type
Average	**3,0000**	**0,374**	**360**	**2,3**		**12,9**	**-0,008**	Coll
SD	**0,0007**	**0,023**	**10**	**0,34**		**3,1**	**0,003**	

1) measurements conform IEC 61689, Power (P) is obtained from the hydrophone measurements

Table A.1.5. Transducer: 3 MHz small, Drive: 6,0 V_{pp} [1)]

Transducer serialno	Frequency (MHz)	P (scans) (W)	A_{ER} (mm^2)	R_{BN}	z_{max} (mm)	Max. Cyl. Asymm. (%)	Divergence factor (cm^{-1})	Beam Type
Average	**3,0039**	**0,0565**	**37,8**	**2,9**		**19,2**	**-0,013**	Coll.
SD	**0,0032**	**0,0059**	**1,2**	**0,16**		**1,8**	**0,010**	

1) measurements conform IEC 61689, Power (P) is obtained from the hydrophone measurements

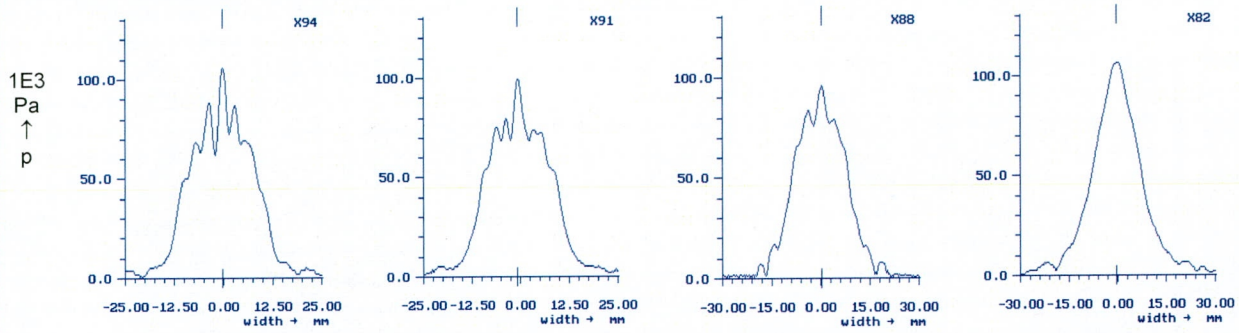
BEAM CHARACTERISATION

Transducer-model : Large 1 MHz, -serialno.: typical

STANDARDS USED: IEC 61689

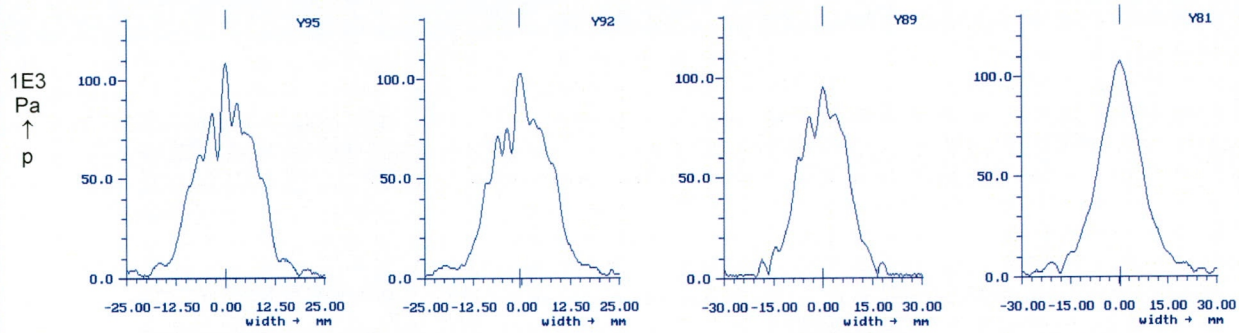
Figure A.1.5. Ultrasonic Beam Characteristics, Large, 1 MHz

Measured parameters	Measured values	Measurement settings
Ultrasonic frequency	0,9992 ± 0,0001 MHz	Drive Voltage: 15,0 V_{pp}
Effective Radiating Area (A_{ER})	3,43 ± 0,27 cm^2	Setting R&S: -15,3 dB
Beam Nonuniformity Ratio (R_{BN})	3,2 ± 0,29	Avg power: 0,492 W
p_{max} occurs at distance z_p from front	96 mm	p_{max}: 117 kPa
Beam type	collimating (fact: -0,022 cm^{-1})	
Max. cylindrical asymmetry parameter	18%	



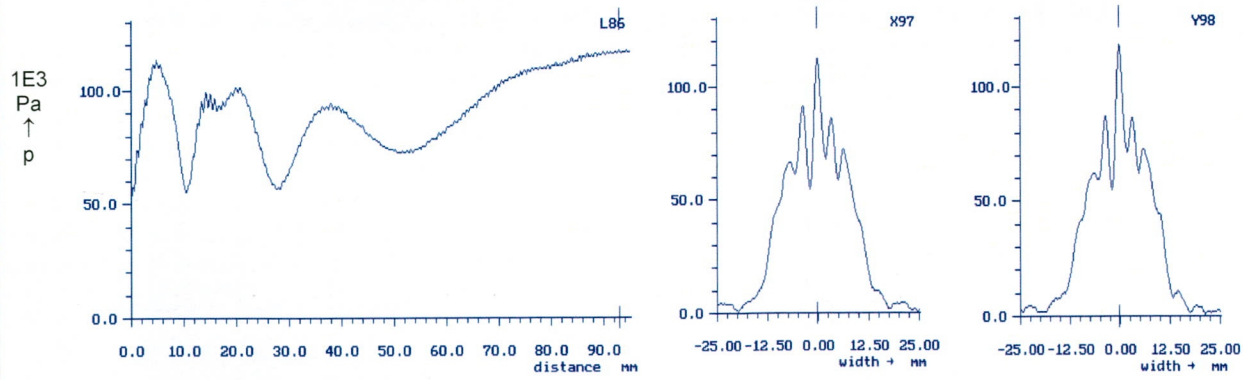
z = 10,0 mm z = 20,0 mm z = 40,0 mm z = 80,0 mm

A. Transversal beamprofiles at distances z from the transducer face.



z = 10,0 mm z = 20,0 mm z = 40,0 mm z = 80,0 mm

B. Lateral beamprofiles at distances z from the transducer face.



C. Pressure distribution on the acoustic axis (at 0.0 the real z = 3,0 mm)

D. Transversal and lateral beamprofile at 8.0 mm (max. p) from the transducer face.

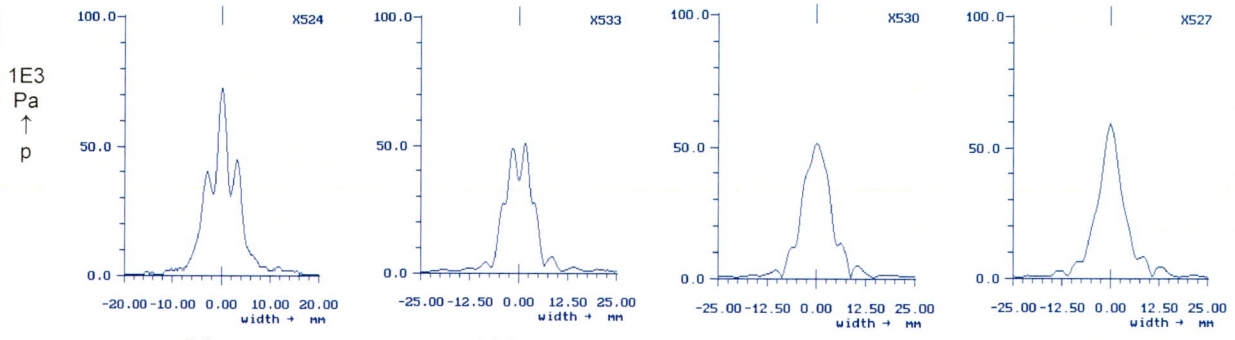
BEAM CHARACTERISATION

Transducer-model : Small 1 MHz, -serialno.: typical

STANDARDS USED: IEC 61689

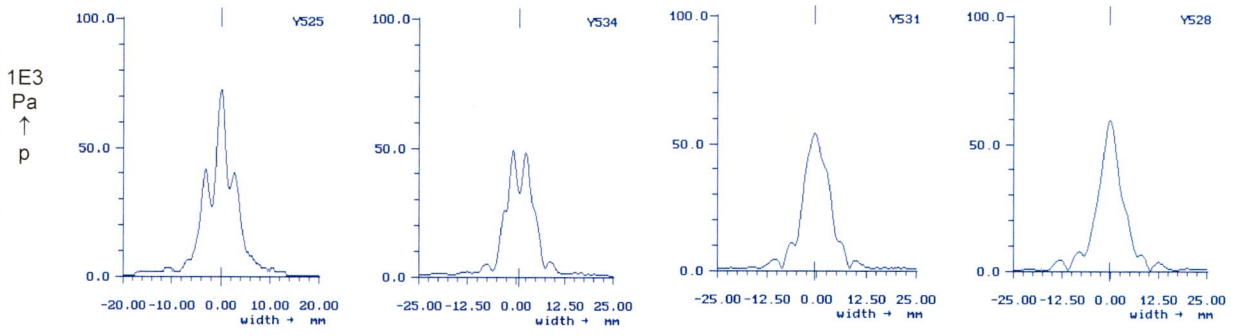
Figure A.1.6. Ultrasonic Beam Characteristics, Small, 1 MHz

Measured parameters	Measured values	Measurement settings	
Ultrasonic frequency	1,00215 ± 0,0001 MHz	Drive Voltage:	6,0 V_{pp}
Effective Radiating Area (A_{ER})	0,825 ± 0,74 cm^2	Setting R&S:	- 28,1 dB
Beam Nonuniformity Ratio (R_{BN})	5,5 ± 0,66	Avg power:	0,032 W
p_{max} occurs at distance z_p from front	5,9 mm	p_{max}:	80 kPa
Beam type	diverging (fact: 0,197 cm^{-1})		
Max. cylindrical asymmetry parameter	42%		



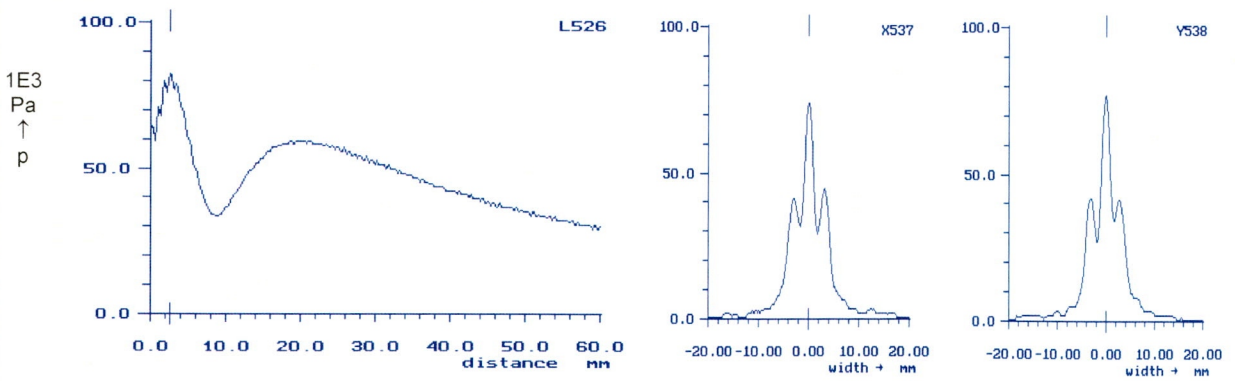
z = 5,0 mm z = 11,0 mm z = 17,0 mm z = 23,0 mm

A. Transversal beamprofiles at distances z from the transducer face.



z = 5,0 mm z = 11,0 mm z = 17,0 mm z = 23,0 mm

B. Lateral beamprofiles at distances z from the transducer face.



C. Pressure distribution on the acoustic axis (at 0.0 the real z = 3,0 mm)

D. Transversal and lateral beamprofiles at 5,9 mm (max. p) from the transducer face.

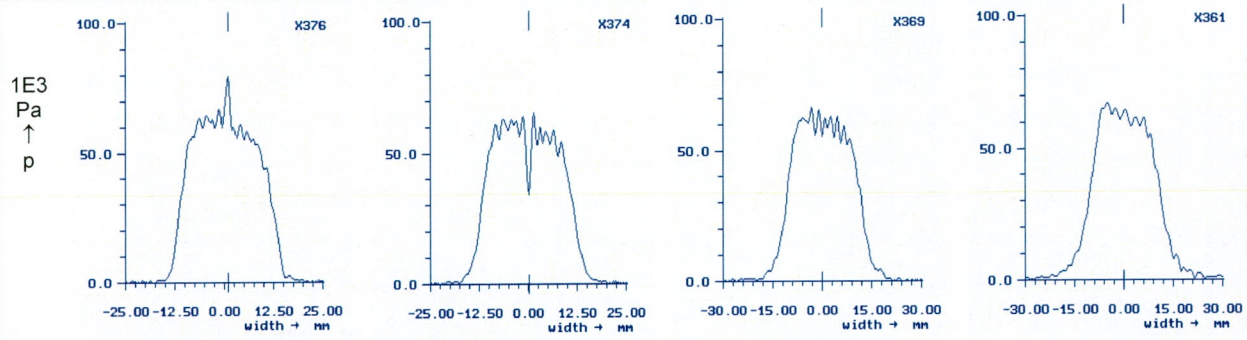
BEAM CHARACTERISATION

Transducer-model : Large 3 MHz, -serialno.: typical

STANDARDS USED: IEC 61689

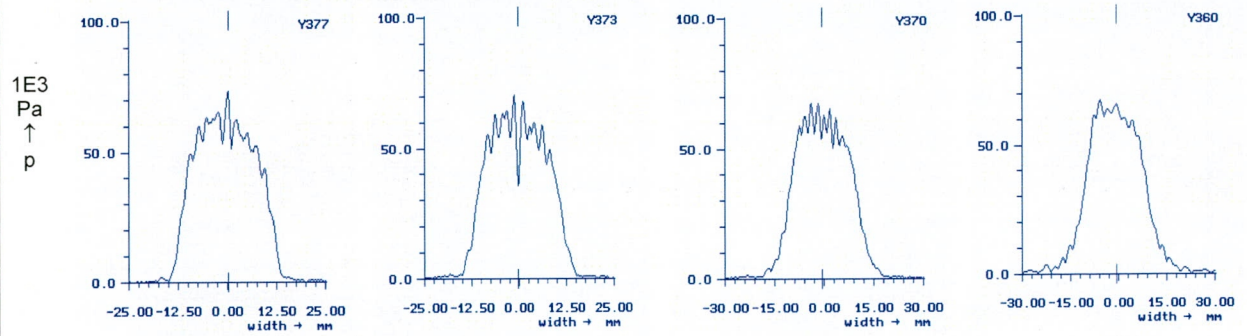
Figure A.1.7. Ultrasonic Beam Characteristics, Large, 3 MHz

Measured parameters	Measured values	Measurement settings
Ultrasonic frequency	2,9997 ± 0,0001 MHz	Drive Voltage: 15,0 V_{pp}
Effective Radiating Area (A_{ER})	3,66 ± 0,29 cm^2	Setting R&S: - 9,8 dB
Beam Nonuniformity Ratio (R_{BN})	2,2 ± 0,22	Avg power: 0,385 W
p_{max} occurs at distance z_p from front	53 mm	p_{max}: 83 kPa
Beam type	collimating (fact: -0,01 cm^{-1})	
Max. cylindrical asymmetry parameter	13%	



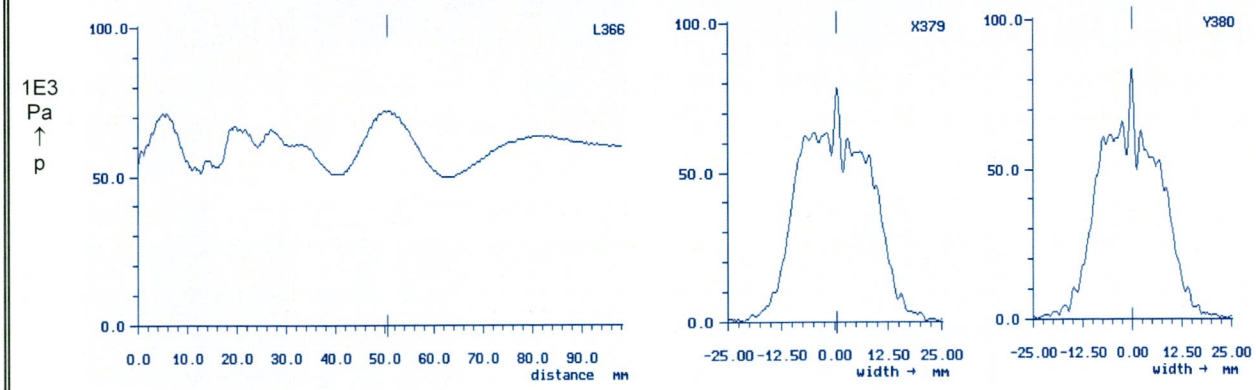
z = 10,0 mm z = 20,0 mm z = 40,0 mm z = 80,0 mm

A. Transversal beamprofiles at distances z from the transducer face.



z = 10,0 mm z = 20,0 mm z = 40,0 mm z = 80,0 mm

B. Lateral beamprofiles at distances z from the transducer face.



C. Pressure distribution on the acoustic axis (at 0.0 the real z = 3,0 mm)

D. Transversal and lateral beamprofile at 52,8 mm (max. p) from the transducer face.

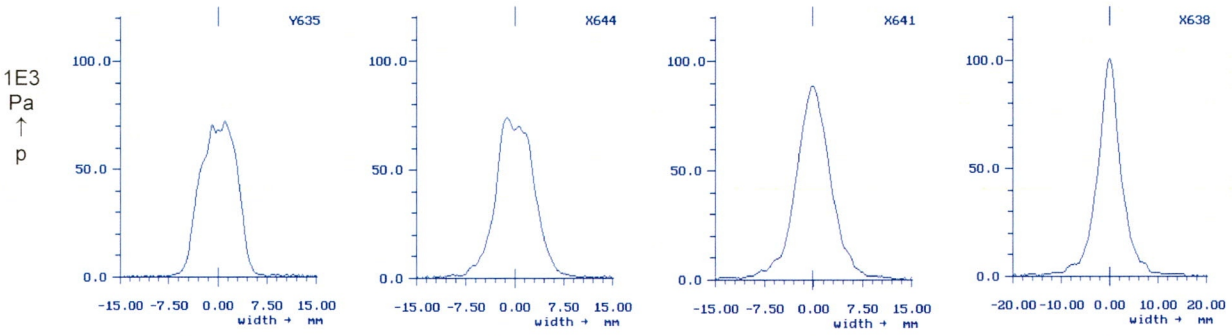
BEAM CHARACTERISATION

Transducer-model : Small 3 MHz, -serialno.: typical

STANDARDS USED: IEC 61689

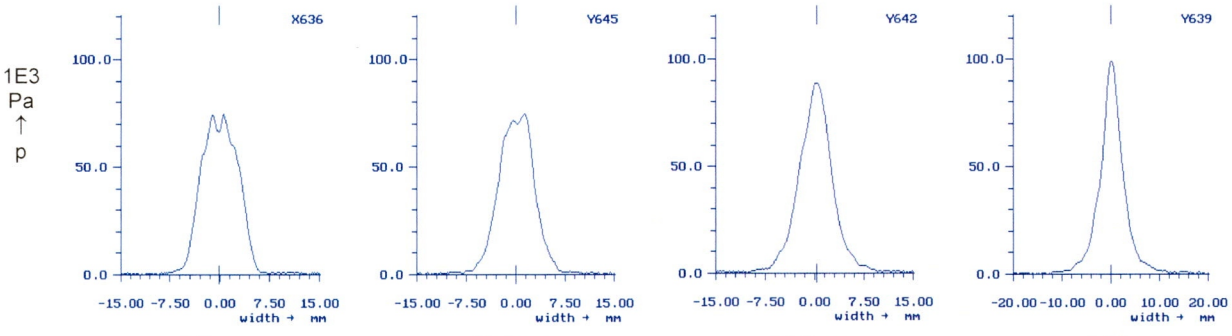
Figure A.1.8. Ultrasonic Beam Characteristics, Small, 3 MHz

Measured parameters	Measured values	Measurement settings	
Ultrasonic frequency	3,0068 ± 0,0001 MHz	Drive Voltage:	6,0 V_{pp}
Effective Radiating Area (A_{ER})	0,38 ± 0,030 cm^2	Setting R&S:	- 20,2 dB
Beam Nonuniformity Ratio (R_{BN})	3,0 ± 0,27	Avg power:	0,045 W
p_{max} occurs at distance z_p from front	34 mm	p_{max}:	102 kPa
Beam type	collimating (fact: -0,007 cm^{-1})		
Max. cylindrical asymmetry parameter	18 %		



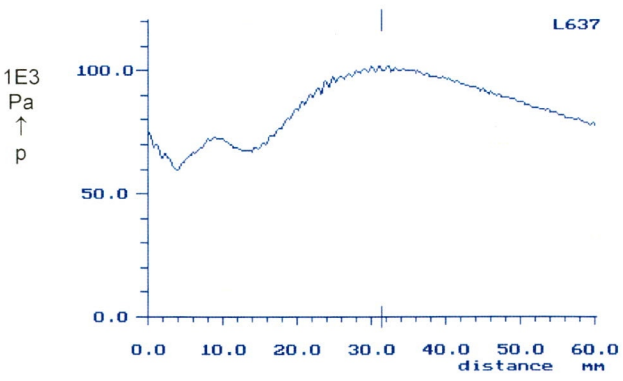
z = 5,0 mm z = 14,9 mm z = 24,7 mm z = 34,6 mm

A. Transversal beamprofiles at distances z from the transducer face.



z = 5,0 mm z = 14,9 mm z = 24,7 mm z = 34,6 mm

B. Lateral beamprofiles at distances z from the transducer face.



C. Pressure distribution on the acoustic axis
(at 0.0 the real z = 3,0 mm)

5 Long term stability

Relatively long term stability has been assessed by determining the radiation conductance G over a period of 8 months (April 2002 to November 2002. A final measurement series of the stability measurements has been carried out after the fundamental power calibration at PTB in work-package 3. The measurement system used was identical to that used earlier in the project. The measurements were performed at a low (0,3-0,5 W) and at a high (3-15 W) power level. The water temperature variation over the measurement sessions has been kept relatively low: all measurements were done between 21°C and 23°C; the temperature range for each transducer type was less than 1,5°C. Each transducer was left in the water for at least 10 minutes to make sure that the front was more or less in thermal equilibrium with the surrounding water. The results are graphically shown in Figure A.1.9 and A.1.10.

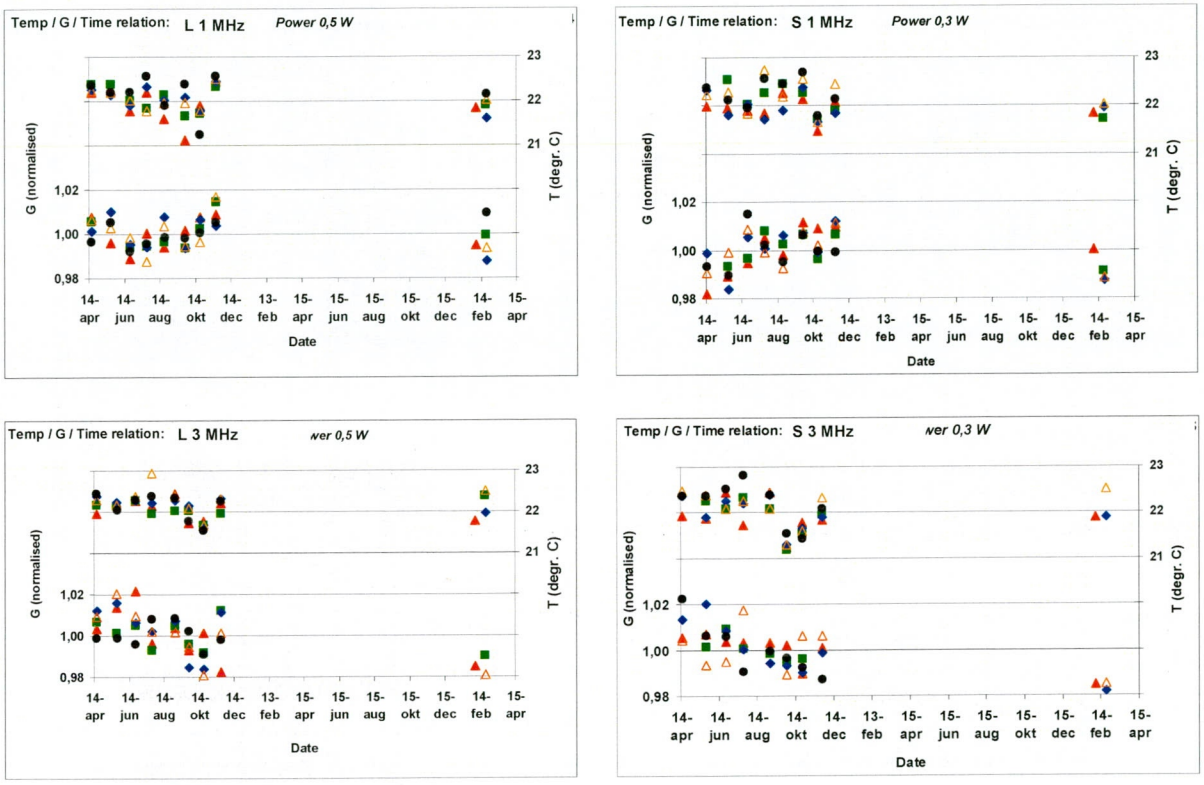


Figure A.1.9 *Final stability measurement results at a low power level. Each of the graphs presents the relation between time and the radiation conductance (G). Also the temperature of the water during the measurement is given.*

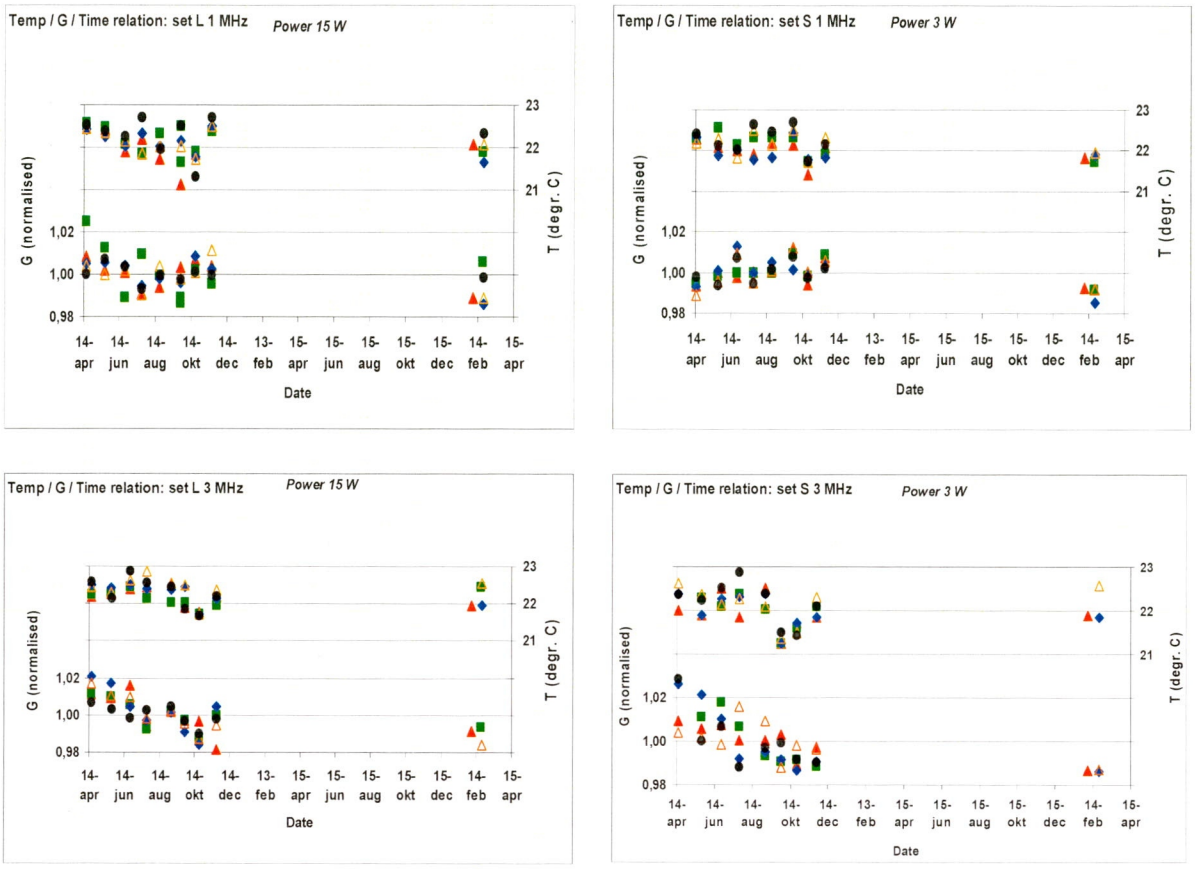


Figure A.1. 10. *Final stability measurement results at a high power level. Each of the graphs presents the relation between time and the radiation conductance (G). Also the temperature of the water during the measurement is given.*

The following observations are made:

- The 1 MHz transducers are more like each other than the 3 MHz transducers.
- The big transducers are more like each other than the small transducers.
- The variation (2·s) of each 1 MHz transducer is not more than 2 %.
- The variation (2·s) of each 3 MHz transducer is not more than 2,5 % for the big transducers and 3 % for the small transducers.
- Due to aging the radiation conductance of the 1 MHz transducers changes by less than 0,2 % per month.
- The decrease for the 3 MHz transducers is up to 0,6 % per month (average 0,2 % to 0,35 %).One small 3 MHz transducer has a much lower G than the other four; this is the only 3 MHz transducer with a G-value that is not significantly time dependent.

6 Negative Control Transducer

A negative control transducer is required to see whether testers are able to note from the measurements the difference with a normal transducer. Each set should have one negative control, so consist of five transducers: the 4 types plus a negative control. It has been decided that the negative control is made from the big 1 MHz transducer. The element is partly removed and the transducer is driven at about 1 and 3 MHz (both at resonance).

To construct a negative control transducer, one normal functioning transducer ($A_{ER(nom)}$: 5 cm^2, f_{nom}: 1 MHz) is modified. The ultrasonic power of the modified transducer is measured with two a radiation force balances, one based on an absorbing target and one based on a reflecting target. From the powers, radiation conductances G are calculated. Since a radiation force balance with a reflector is supposed to be more sensitive to beam asymmetry (which is deliberately produced) than one with an absorber, the difference between the results from the two balance set-ups is a measure for beam asymmetry: the difference between the two set-ups should be clearly larger for the negative control transducer than for a normal transducer.

As this transducer will be used as a negative control this Final report, which is a public report will not detail the modifications and specifications of this transducer.

7 Conclusions

The main conclusions from the work carried out in Workpackage 1, are the following:

- Temperature dependence of the radiation conductance of the transducers should be taken into account in converting input voltage into ultrasonic power, especially for the 1 MHz transducers. This aspect has been taken care of by defining an allowed temperature range of use.
- The variation (2·s) of the radiation conductance of each of the selected transducers over time is not more than 3 % (for 1 MHz transducers: 2 %).
- In general, the radiation conductance of the 1 MHz transducers changes less than 0,2 % per month. The decrease for the 3 MHz transducers is up to 0,6 % per month (average 0,2 % to 0,35 %).

Negative control transducers have been constructed. Their ultrasonic performance has been tested. It has been agreed that the effectiveness of using such a negative control transducers has to be proven in practice

Annex B
CSIRO Report for Workpackage 2, Design or modification of a Driver, An introduction

Report on the CSIRO work during the project
(1 December 2001 to 20 July 2004)
Adrian Richards

20 July 2004

This project was proudly supported by the
International Science Linkages program established under the
Australian Government's innovation statement Backing Australia's Ability.

Contents

INTRODUCTION

This document provides a summary of the CSIRO report on the work for:

European Commission 5th Framework Project:
Ultrasound Therapy Calibration (U/S Ther. Calibration) Proposal No.GRD1-2000-40005
Contract No. G6RD-CT-2001-0600.
Technology/Research Sector: Competitive and Sustainable Growth
www.ecdel.org.au/scienceandtech/FP5/US_Therapy_Calibratio.htm

Grant from the Innovation Access Program: "Ultrasound Therapy Calibration"
International S&T Policy and Programs
International Relations and Collaboration Branch
Science Group
Location Code 743
Dept of Education, Science and Training (**DEST**), Australia.

The details of the work are referred to in sub-reports that are located on a compact disc, dated: 20-07-2004. The sub-reports are in two formats, Microsoft's "Word" (*.doc) and rich text format (*RTF.rtf).

The present contact persons at CSIRO are:

Mr Glen Prout
Email: glen.prout@csiro.au
Tel: (02) 9413 7614

Mr Trevor Bell
Email: Trevor.bell@measurement.gov.au
Tel: (02) 8467 3545

The original contact person and Australian partner can be contacted at:
Dr Adrian Richards
14A Rickard Rd, Berowra 2081 NSW
Tel: (02) 9456 6519
Email: Adrian.Richards@physics.org

DEST REPORT

A separate document "Dest-Rpt.doc" in "/Disk-1/Report-Docs/" details the work done for the specific items in the Deed of Grant.

FINANCIAL REPORTS

The audited financial reports for the EC and DEST are located in the directory "/Disk-1/Report-Docs/financial-rpts/". Warren Bax, the financial controller of the CSIRO Division of Industrial Physics, has audited the original records.

DEST REPORT
This is located in the subdirectory "/Dest/" as an Excel spreadsheet file "FS80A-Trans Rpt.xls". The "FS80A" denotes the CSIRO cost code used to record all direct activity associated with the DEST grant. There are three worksheets in the file:

Complete Transaction Report: gives all the financial transactions in detail.

Life Summary: shows a summary of the above worksheet.

DEST Report: for the above worksheet, the items appropriate to grant expenditure are summarized under the terms used in the Schedule 3, Item 2 of the Deed of Grant.

Please Note:

- To this date CSIRO has only received $30000 from DEST, the balance of $9900 is due on the production of the final report by CSIRO and DEST's satisfaction that the terms of the Deed of Grant have been met. All the objectives of the Deed of Grant have not been met.

- There was more expenditure under consumables due to the additional international freight. These were additional return trips of the portable power standard to Europe during the evaluation and calibration process.

- The bench fees was under spent due to one New Zealand ($500) and one Australian ($1000) candidate tester being slow to claim them.

EC REPORT
This is located in the subdirectory "/Ec/" as an Excel spreadsheet file "Final-3yr-rpt-EC-budget". The Year 3 entries (Partner 2 CSIRO) have been updated to the close of the CSIRO project 13 July 2004. The spreadsheet is the EC formal reporting spreadsheet.

GUIDANCE STANDARD

This is an advisory document for the clinical users of ultrasound therapy machines, testers of such machines and manufacturers. It gives advice on:

- Why an ultrasound therapy machine should be checked.

- How to have the machine checked.

- Who is accredited to do the check.

- How a service organization or manufacturer can become accredited.

The document has been reviewed by the Medical Ultrasound Committee of Standards Australia and all the Candidate Testers who participated in the trial of the PPS.

It is expected that the document will be published by Standards Australia. The European partners will be proposing the document as a new work item for the IEC.

The report on this document is "Guidance-Rpt.doc" and it is located in "/Disk-1/Report-Docs/guide-std/".

TRAVEL TRIAL

It was necessary to evaluate the usefulness of the PPS (Driver plus transducers and the Cavitation Detector (CD)) as a method for remotely disseminating ultrasound therapy power standards to the testing community. In Australia and New Zealand there was a pool of interested testing organizations willing to trial the PPS. Six of the most enthusiastic were selected, however thirteen more could have participated in the trial if time had permitted.

Through these "Travel Trials" to various testing organizations it was hoped to be able to evaluate the reliability, ease of use and usefulness to the candidate testers of the PPS. Also some feedback would be obtained on the calibration state and expertise of those providing a testing service.

Critical Conclusions

- Enthusiasm amongst the six Australian and New Zealand Candidate Testers was high. Thirteen more testing organizations would have liked to participate in the trials, but time did not permit this.

- The PPS survived the travel, despite the shock/impact sensors on the transit cases being triggered a number of times. This also occurred once when a Driver was sent to PTB, Germany.

- Reproducibility of measurement of all the Candidate Testers was very good. Some of them had significant systematic errors in the calibration of their power meter. If these offsets were taken into account by the tester via the Calibration/Tutorial mode then a successful, accurate calibration could be done. Power meters which could be calibrated with masses by the user had comparatively very little accuracy offsets

- The Negative Control transducer failed four of the six Candidate Testers. Their power meters were unsuitable for testing the new dual frequency applicator heads of the newer ultrasound therapy machines. For more detail about the Negative Control see its report.

- The feedback about the Cavitation Detector was limited, this was due to:

(a) Only two Candidate Testers had access to it, due to the limited time available.

(b) The Candidate Testers were highly focused on the making the power measurements and so tended to focus on the PPS and their power meter. Also their water preparation technique followed the suggestions in the guide manual supplied to them. Two instances of cavitation were reported though.

The conditions under which the cavitation was observed should be followed up. It may be that simply allowing distilled water to stand open at room temperature for 24 hours may be marginal.

It was felt that the Cavitation Detector was fairly easy to use and would be of diagnostic benefit, especially for those reporting results with poor reproducibility at higher powers.

- Each of the Candidate Testers indicated a willingness to use the PPS Calibration and Proficiency Test program for calibration of the power meter and accreditation of their service. However a number of prerequisites a needed:

    1. The PPS needs to administered by an organization. At present CSIRO and the new National Measurement Institute do not have the resources to do this.

    2. There needs to be an awareness amongst the Physiotherapists and other clinical users of ultrasound therapy machines that an accreditation service exists for testing service providers.

    3. The Physiotherapists and other clinical users need to request the accreditation and calibration status of their testing service provider.

- Two of the Candidate Testers in Australia are located in large hospitals and have extensive experience in providing testing services. Accordingly the two Australian PPSs, including the CD, have gone to them on an extended loan. PPS-1 and the CD is in Western Australia and PPS-5 is in South Australia

The full report "Test-Travel.doc" is located in "/Disk-1/Report-Docs/"

NEGATIVE CONTROL TRANSDUCER

Purpose

The function of the negative control transducer is to test the ability of those testing ultrasound therapy machines to detect misbehaving applicator heads (transducers). There are two types of misbehaving applicator heads; besides poor calibration!

(a) The ultrasound beam is not circularly symmetric and not in the geometric center of the faceplate.

(b) The applicator head emits an excessive amount of electromagnetic radiation. Three cases (Australia and New Zealand) have been reported to CSIRO where this causes ultrasound power meters either to read very low or negative or ten times too high!! The problem seems to be isolated to some types of dual frequency applicator head (1 & 3 MHz).

A negative control transducer was designed to test for (a) and (b).

Summary

The Negative Control transducer was a very useful device to identify electromagnetic radiation susceptible power meters. The success rate in identification was excellent. The Negative Control transducer failed four of the six Candidate Testers. Their power meters were unsuitable for testing the new dual frequency applicator heads of the newer ultrasound therapy machines.

It was heartening to see that we can detect troublesome power meters before dual frequency transducers are widespread in Australia and New Zealand.

For the full details of the Negative Control transducer, see the report "Negative-Ctrl-Rpt.doc" located in directory "/Disk-1/Report-Docs/".

MANUALS

The operating manuals for the Ultrasound Portable Power Standard (PPS) and the Cavitation Detector (CD) are located in "/Disk-1/Report-Docs/manuals/". They consist of:

"user-Super.doc": The Super User manual for the PPS.

"user-Tut-Prof.doc": The manual for those undertaking the Calibration/Tutorial and Proficiency Test the PPS.

"CD-UserMan-CSIRO": The manual for the CD. It was adapted from the NPL, UK manuals which are located in "/Disk-1/Testing/Travel-Trial/general/Cd/".

DESIGN & ASSEMBLY OF THE DRIVER OF THE PPS

Requirements

Workpackage 2 of "Annex I: Description of Work" of the EC contract had the following requirements for the four PPS driver electronics that was to be designed and constructed by CSIRO.

- The driver unit was to be self-contained, the electrical signal generator and the amplifier with the ultrasound power transducers will be in the one package. The one unit can drive the full set of transducers. The transducers are Enraf (the Netherlands) physiotherapy heads operating at frequencies 1 and 3 MHz with ultrasonic output of 0,1-15 W. A set of four Enraf transducers will be supplied by TNO for each driver and a fifth transducer, as a negative control will be produced by CSIRO and TNO. The four transducers will bracket what is seen in clinical use in terms of frequency, total power, intensity and radiating area.

- Programmable interface to the Driver. This is to allow:
  1. Encryption of the front panel control and display settings used by the commercial tester in their measurements. This would enable blind testing, "Proficiency Testing".
  2. Remedial tutorials should the candidate fail the proficiency test. In addition the PPS to act as a transfer standard.
  3. Automated calibration.
  4. Background data logging.

- The Driver analogue output to the transducers is stable with time, the expected environmental conditions and robust for travel through the usual commercial courier routes of air, rail and road. The stability of the output will be better than ±3 % with a transferable accuracy to the commercial tester of approximately ±10 % well within the ±20 % required in IEC standard 61689 Of particular concern is that the frequency stability is sufficient to ensure that measurements made upon the transducers in TNO and PTB will relate closely to the PPS in the industrial and the clinical environment.

- The components are readily available from reputable manufacturers with minimal modifications, conservative specifications and at reasonable cost. The possibility of modifying a commercial therapy machine will be investigated as well a custom design based on off-the-shelf components.

- The presence of some background data logging to monitor the responses of the commercial tester (length of time and date on which transducers used). Shock and temperature sensors will also be installed to give an indication of any rough treatment.

Additional Features

After the commencement of the contracted work it was agreed between the partners that there were a number of extra, desirable performance specifications necessary for the PPS.

1. The Driver is capable of driving ultrasound transducers in the band 0,8 to 3,5 MHz. It can drive transducers other than the Enraf ones nominated for this project.

2. The frequency resolution is 100 Hz and accuracy is to 50 Hz. An improvement of ×10.

3. A high spectral purity (or harmonic content) for the signal driving the transducers. This was so that transducer characterization measurements using high quality signal generators and power amplifiers could be related to the performance of the transducers when driven by the PPS Driver.

4. The cavitation detector (CD) can be connected to the Driver so that cavitation events in the water can be logged automatically.

5. An external temperature probe to measure the temperature of the water bath and log it automatically. The accuracy and resolution of the external temperature probe was to be ± 0,2 °C.

6. A special, steel enclosure for the Driver electronics. This gives electromagnetic screening and enabled the driver to resemble a physiotherapy ultrasound unit.

7. The electrical mains supply can be from 110 – 250 VAC. This would enable a PPS to be evaluated in North America if there is interest from their regulatory agencies.

8. Environmental Chamber testing of all the Drivers.
    a. Electrical performance in its operational range of 19-25 °C to be characterized. In addition
    b. A 48 hour "burn-in / life test" over a wide range of temperatures (10-45 °C) and humidity's (20-90 %RH) so that any unreliable components are identified.

The full report "Assembly-Rpt.doc" is located in the directory "/Disk-1/Report-Docs/". It gives all the design and production details for the Driver of the PPS so that a complete reproduction may be made.

SOFTWARE

The report "Software-Rpt.doc" located in "/Disk-1/Report-Docs/" only describes the technical aspects of the software developed. It is information for those wishing to undertake maintenance or changes. A description of how to use the software is in the Super User manual, "user-Super.doc" in the directory "/Disk-1/Report-Docs/manuals/"
The software programs are located in "/Disk-1/Software-Progs/pps/".

Summary Statistics

- Number of lines of C code Firmware for the PPS: 10000 lines. 230kB
- LabVIEW programs for running the PPS: 1,8 MB.
- LabVIEW programs for testing the PPS: 8 MB

ACCEPTANCE TESTING

This was the testing done at CSIRO before the PPS was sent to PTB, Germany for ultrasound power calibration and evaluation. All the PPSs used in the travel trial went through these tests before the trials.

Some of the more important test results are given here. For a full description of the acceptance testing refer to document "Test-inHouse.doc" located in directory "/Disk-1/Report-Docs/".

Temperature Step Test

(a) The temperature dependence of the power output is often very low except for 10 and 15 W at 3,3 MHz and some 1 W values were measurement resolution is an issue. The worst was approximately 0,7 % or 0,1 %/°C.

(b) The current sensed dependence at 3,3MHz was mostly 2 to 7 % and in one case 15 %. However this quantity is only used for coarse sensing to determine whether the transducer is immersed during operation. The temperature coefficient was low enough for this function in the expected operating environment.

(c) The frequency temperature coefficient is excellent, 3 Hz/°C.

Short Term Stability

The most sensitive measurements of ultrasound power stability were made by PTB, Germany since they had the resolution for this. However those results include the short-term stability of the ultrasound transducer. At CSIRO the ability of the Driver to deliver constant power was measured by monitoring power into an electrical load of 50 Ohm.

(a) Short-term stability deteriorates with higher powers and frequencies.

(b) The worst at 1 MHz is 0,3 %.

(c) The worst at 3.3 MHz is 0,6 %.

PUBLICATIONS & PRESENTATIONS

Boldface authors are Australian.

"Why Bother Calibrating Your Ultrasound Therapy Machine?"
A. Richards, R. Cupit, R. Ferdinands, M. Gledhill, **E. Henley, R. Hopkins, R. Price, V. Robertson, R. Thompson & D. Young.**
VIIth International Physiotherapy Congress, 25-28 May 2002, Darling Harbour, Sydney.

"Primary Ultrasonic Power Measurement Promotes Treatment Quality in Physiotherapy"
R. Hekkenberg, R. Bezemer, B. Zeqiri, M. Hodnett, K. Beissner, V. Wilkens, **A. Richards, C. Cantrall & G. Prout.**
European Commission Conference: "Towards an Integrated Infrastructure for Measurements", 18-19 June 2002, Warsaw Poland.

"Ultrasound Therapy: Is Your Machine Giving The Indicated Amount?"
R. Hekkenberg, K. Beissner, B. Zeqiri & **A. Richards**
World Physical Therapy 2003, 7-12 June 2003, Barcelona Spain.

"Ultrasound Therapy: Are Your Machines Giving The Right Amount?"
A.J. Richards, C.J. Cantrall, G.C. Prout, R. Hekkenberg, R. Bezemer, K. Beissner, V. Wilkens, B. Zeqiri & M. Hodnett. WC2003, "World Congress on Medical Physics and Biomedical Engineering" 24-29 August 2003, Sydney, Australia.

"Development of transfer standard devices for ensuring the accurate calibration of ultrasonic physical therapy machines in clinical use."
R T Hekkenberg, **A Richards**, K Beissner, B Zeqiri, **G Prout**, **C Cantrall**, R A Bezemer, Ch Koch and M Hodnett. International Conference on Advanced Metrology for Ultrasound in Medicine, 27-28 April 2004, NPL, Teddington, UK.

&
Published by the Institute of Physics (IOP) UK, in-press (expected September 2004).

These presentations and publications can be found in the directory "/Disk-1/Report-Docs/presentations/".

PHOTOGRAPHS

Photographs of the PPS Driver and CD can be found in the following directories and some of the documents within them:
"/Disk-1/Assembly/Enclosure/Photos/"
"/Disk-1/Travel-Trial/General/"
"/Disk-1/Travel-Trial/General/Cd/"
"/Disk-1/Report-Docs/presentations/"

FUTURE DEVELOPMENT

Contacts

Some suggested individuals and organizations that could be contacted regarding the development and future use of the PPS in Australia and New Zealand:

ACOPRA
Australian Council of Physiotherapy Regulatory Authorities
www.acopra.com.au
Email: acopra@uq.net.au

ACHS
Australian Council on Healthcare Standard.
Tel: (02) 9251 7400 Fax: (02) 9251 7477
www.achs.org.au
Email: achs@achs.org.au

TGA
Therapeutic Goods Authority
www.tga.gov.au

APA
Australian Physiotherapy Association.
Level 3, 201 Fitzroy St., St Kilda 3182 Vic
PO Box 6465, St Kilda Road Central 8008 Vic
Tel: (03) 9534 9400 Fax: (03) 9534 9199
Email: national.office@physiotherapy.asn.au
www.physiotherapy.asn.au

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Candidate Testers
All those who participated in the trials of the PPS.

Mark II Version of the DRIVER of the PPS

If the production of more PPSs is considered then refer to the document "Mark-II-PPS.doc" located in "/Disk-1/Report-Docs/".

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Annex C
PTB Report for Workpackage 3, Fundamental power measurements

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February 2004

Contents

Because the relation between ultrasonic output power and the device setting should stay unknown to the user the following Annexes are considered confidential and therefore not presented:

Annex A. Compilation of measurement results
Annex B. Final results and fitted values
Annex C. Final results and fitted values for two replaced transducers

1. Introduction

The present project aims at developing an ultrasound power standard for use at therapy levels. The main parts of the device are: an electronic driver, a set of ultrasonic transducers and a cavitation detector. One transducer set includes four "normal" transducers which are intended to cover the types widely used in clinical practice, and a special negative control transducer. The "normal" transducer types are: 1 MHz large, 1 MHz small, 3 MHz large, 3 MHz small. Four nominally identical power standards with associated transducers and cavitation detectors are to be produced, one for each partner.

Partner 1 (TNO) was responsible for the selection and testing of the transducers. Partner 2 (CSIRO) was responsible for the design and production of the drivers (note that in this report the term PPS, for "Portable Power Standard", often has been used instead of "driver"). Partner 3 (PTB) was responsible for the fundamental power measurement of the transducers, each in connection with the appropriate PPS. These measurements and their results will be reported here. Partner 4 (NPL) was responsible for the design and production of the cavitation detectors. This report will not deal with the negative control transducers and the cavitation detectors.

The task in Work-package 3 was to drive each transducer by the respective PPS Driver and to measure the transducer's ultrasonic output power emitted into an anechoic water volume at room temperature, and all this near four specified, nominal power values each. The nominal power values are 100 mW, 500 mW, 3 W and 15 W for the "large" transducers, and 100 mW, 300 mW, 1 W and 3 W for the "small" transducers. Each transducer is excited by the PPS Driver in continuous-wave mode and using a particular frequency as specified by TNO. The excitation amplitude is to be given to the PPS-Driver in the form of a dimensionless number which in some documents is called the DAC level but will be referred to here simply as the "level" throughout. The aim is to finally derive a quantitative formula representing the empirical relation between input level and output power, so that any desired ultrasonic power can be produced by entering the appropriate level value.

The ultrasonic power was measured using a radiation force balance in accordance with IEC 61161.

2. Overview

Ultrasonic power measurements are performed at PTB with an electronic balance under computer control, i.e. via an RS 232 interface and using the language Basic. It was, therefore, agreed to

also supply the PPS's with RS 232 interfaces and to provide for Basic communication.

A "transducer set" is understood in the following to include 4 "normal" transducers and to exclude the negative control transducer. In June 2002 PTB got a preliminary set of transducers from TNO. In March 2003 PTB got the full package of 4 transducer sets for the fundamental power measurements from TNO, together with a list of the transducer frequencies and identifiers. The transducers were numbered from sn01 to sn17 (excluding 13) and these numbers were given in the list together with the manufacturer's original transducer designation numbers. The specified frequencies were given up to 4 decimal places behind the (MHz) comma and were understood to be the frequencies of maximum radiation conductance.

At the meeting in Braunschweig in July 2002, the CSIRO colleagues brought a rough prototype of the PPS Driver. A few sample programs were written and simple balance measurements were carried out. The proper functioning of the device could in principle be demonstrated.

An "interim" PPS Driver was available to PTB in January 2003. It was operated under manual control. Using the preliminary transducer set, power measurements were performed over the full range of frequencies and power values. An "interim II" PPS Driver was available to PTB in February/March 2003. Again using the preliminary transducer set, power measurements over the full frequency and power range were now performed under computer control. Measurement details and results were reported at the meeting in Teddington.

The final PPS01 was received in July 2003. The full computer programs for ultrasonic power measurements with target distance variation and with voltage measurement were developed. In addition, programs for frequency sweep experiments with the PPS were developed. Test measurements were carried out and were successful. The first day of fundamental power measurement was 20 August 2003. The other drivers, PPS02 to 04, arrived at certain intervals and the full number of fundamental measurements were carried out. The last day of fundamental power measurement was 6 February 2004. Finally the PPS Drivers were sent to the respective partners and the transducers to TNO.

It was intended to measure each PPS Driver/transducer twice and then to add a third measurement round after a certain time interval in order to check the long-term stability, if possible, but this was not possible in all cases. 1) PPS01 was measured twice and then technically modified during the meeting in Braunschweig, 15 to 17 October 2003. Later it had to be returned to CSIRO for the field tests,

and it remained there. So there are only two early sets of results for PPS01 and they probably do not represent the current state of the device, due to the technical changes. 2) PPS02 was measured before the October meeting, then technically modified and again measured. Then it had to be returned to CSIRO (November/December 2003) for another technical change. Finally it was re-measured in January/February 2004. The results reflect the influence of the technical changes. The tables in annex A include at least 3 results for PPS02 in each case, but only the results from January/February 2004 will be considered "valid" results for the subsequent evaluation. 3) PPS03 and 04 were measured three times without any technical change in-between, and all their results will be considered "valid", and aver-aged. But the time interval covered by these measurements is not as big as it would have been with PPS01 or 02.

With three of the transducers, temporal instabilities were seen in the balance readout and these transducers were returned to TNO and replaced as follows. Transducer sn05 was replaced with sn20, sn08 was replaced with sn18, and sn09 with sn19. All results are included in the tables in annex A, so the tables deal with a total of 19 transducers. The unstable transducers were checked by TNO, with the following results: Transducer sn08 suffered from a damage during the checks, so this transducer should no longer be used and the reasons for the instabilities remain unclear. The results for this transducer are only of "historical" interest. In transducer sn05, an insulation layer (residue of soldering) was found at a place where it could lead to a bad earth contact. This was repaired and all contacts were cleaned, and the transducer was re-measured at PTB on 6 February 2004. In transducer sn09, indications of an ingress of water could be seen. The transducer was cleaned and repaired, and then re-measured at PTB on 2 February 2004. Only these re-measurement results should be considered to be "valid" results for the two transducers.

3. Measurements and results

The measurements were carried out in the same way, and using the same devices, as in the CIPM key comparison, namely in arrangement A with the Mettler AT250 balance and alternatively using one of two absorbing targets (A1 being 50 mm and A2 being 110 mm in diameter, respectively). In all cases a number (typically: 12) of single measurements at increasing target distances were carried out. The ultrasonic power was extrapolated back to zero distance and all other quantities (e.g., U, V_{on}, I_{on}) were averaged. The out-put voltage was measured with a Racal Dana rf voltmeter (via a high-impedance probe) which was calibrated against Ballantine thermal converters. The probe was directly connected to the PPS voltage output, and no

other probes or electronic devices were connected to this output (with the exception of special checks as, for example, checks of the frequency value and of the harmonic content).

In most cases after the (typically: 12) single measurements, the target distance was again reduced to the first value and a "repeat" single measurement carried out. Its result was not included in the extrapolation but served to assess the power stability.

The measurements were performed in deionised, degassed water. The oxygen content was below 3 mg/l. The water temperature was between 20,4 and 22,5 °C. The power-on time was 24 s in all cases; the power-off time went from 27 s at low powers to 120 s at 15 W. Generally, off-to-on and on-to-off results were used and averaged but at the highest power for each transducer, only off-to-on results were used.

The ultrasonic power values were derived from the measured radiation force values by multiplication with the temperature-dependent speed of sound in water (plane-wave assumption).

The PPS Driver was always operated under computer control (RS 232, Basic), not manually. The following commands were used: set frequency, set level, switch the power on, switch the power off, read the sensed voltage value, read the sensed current value. The frequency of the PPS Driver output signal was checked from time to time with a frequency counter; it proved to be correct as to within the resolution of 0,0001 MHz. The harmonic content of the PPS Driver output signal under load was checked with a spectrum analyzer, the values are given in the tables. It can be seen that the values are highest with the "1 MHz large" transducers. The difference between off-to-on and on-to-off power values was generally insignificant, with one exception: With the respective "3 MHz large" transducer at 15 W, the ultrasonic power decreased over the 24 s by about 1,0 % with PPS01 and by about 0,8 % with the other PPS Drivers. This was accompanied by a corresponding voltage decrease, i.e., it is an effect of the PPS Driver output voltage, not a transducer drift.

In order to check the frequencies of maximum radiation conductance, frequency sweep experiments were carried out with all transducers driven by the respective PPS Driver under computer control (using the "set frequency" command). The frequency values found showed slight deviations from the frequencies stated by TNO, deviations of up to 0,0008 MHz for the 1 MHz transducers and of up to 0,0024 MHz for the 3 MHz transducers. These frequency differences were considered insignificant inasmuch as the associated radiation conductance values differed by less than 0,6 %. But there was one exception: With transducer sn08 the frequency difference was about

0,008 MHz which means a radiation conductance difference of about 5 %. This transducer, however, later was replaced. The fundamental power measurements were carried out throughout at the frequency values specified by TNO, irrespective of the results of the PTB frequency sweep experiments.

It was found that the electric load, particularly the capacitive load, at the parallel voltage output of the PPS Driver has an influence on the measurement results. In the intended practical use, this output connector will be empty and covered by a panel but in the fundamental power measurements, the voltage was to be measured. In order to keep the load as low as possible, only the high-impedance probe of the voltmeter was connected here (no tee-connectors, no cables). All the results given in tables 1 to 19 in annex A have been obtained under this load condition.

The electroacoustic radiation conductance *G* usually is understood as a characteristic transducer property if the voltage is measured at the transducer input which is not the case here. Instead, the voltage is measured at the parallel output of the PPS Driver. The *G* values thus obtained are given in the tables but their special meaning should always be kept in mind.

Tables 1 to 19 in annex A give the results of the fundamental power measurements. The quantities and symbols are explained there. Stability is expressed by various quantities, especially by *diff* which is the percentage difference between the highest and the lowest of the values considered. Of particular interest are the stability of the PPS Driver output voltage *U*, of the ultrasonic power P_m ("m" stands for "measured", to be distinguished from "corrected" in the next section) and of the radiation conductance *G*. The obtained *diff* values will be discussed from PPS to PPS as follows.

PPS01 has only been measured twice, and within about a month. The maximum *diff* values are 0,28 % for the voltage, 1,09 % for the ultrasonic power and 0,62 % for the radiation conductance. The *diff* values for PPS02 are generally much higher, but this is mainly due to the technical changes and to the instability of some of the transducers. Only the replacement transducer sn20 should be considered here. It has been measured three times within two weeks, and the maximum *diff* values are 0,50 % for the volt-age, 0,48 % for the ultrasonic power and 0,83 % for the radiation conductance. PPS03 has been measured three times within slightly more than two months and if transducer sn09 is neglected, the maximum *diff* values are 0,81 % for the voltage, 1,82 % for the ultrasonic power and 1,57 % for the radiation conductance. PPS04 has been measured three times within about seven weeks and the maximum *diff* values are 0,54 % for the voltage, 1,44 % for the ultrasonic power and 1,78 % for the

radiation conductance. It should be noted that the general repeatability of independent ultrasonic power results at PTB is about 0,5 % (to be understood as twice the standard deviation).

The sensed *V* and *I* values are also given in the tables in annex A. They have been found to be different from PPS to PPS.

4. Final results and interpolation

4.1. Correction

The corrected ultrasonic power P_c is obtained from the measured ultrasonic power P_m applying two correction factors according to

$$P_c = corr_1 \cdot corr_2 \cdot P_m \quad (1)$$

Values for $corr_1$, the correction factor for beam divergence, are given in annex A. This correction affects particularly the 1 MHz small transducers.

The factor $corr_2$ corrects for the influence of the electric load of the high-impedance probe at the voltage output. P_c is understood to be the ultrasonic power with the voltage output being empty. In almost all measurements, one single measurement was repeated with the high-impedance probe removed, and so values for $corr_2$ could be derived. They are as follows:

	1 MHz large	1 MHz small	3 MHz large	3 MHz small
$corr_2$	1,0013	1,0010	0,9978	0,9968

Note – The radiation conductance *G* also would have to be corrected, at least with $corr_1$, but *G* is no longer dealt with in section 4.

4.2. Power measurement uncertainty

The following are the relative standard uncertainty contributions for P_m:

- Uncertainty of the speed of sound due to temperature uncertainty: 0,12 %
- Uncertainty of the acceleration of free fall: neglected
- Uncertainty of the balance calibration: 0,4 %
- Uncertainty of the extrapolation to zero distance: for the divergent 1 MHz small transducer 0,3 %, for all other transducer types 0,1 %
- Target imperfections: 1,1 %
- Random influences that cannot clearly be attributed to particular effects: 0,25 %

The following are the relative standard uncertainty contributions of the correction factors:
– Uncertainty of $corr_1$ is $(1-1/corr_1)/\sqrt{3}$
– Uncertainty of $corr_2$: 0,05 %

When these uncertainty contributions are added in quadrature and multiplied with the coverage factor 2, the final, expanded relative uncertainties of the measurement of P_c are:

	1 MHz large	1 MHz small	3 MHz large	3 MHz small
$ku(P_c)$ / %	2,6	3,2	2,5	2,6

4.3. Final P_c results

The final, measured power results P_m and corrected power results P_c are given for the four transducer sets in annex B and for two of the replaced transducers in annex C. The values are averaged from N results in each case. Generally, N is the number of measurements, but with the exceptions already mentioned in section 2 above: With PPS02, only the results obtained after its return from CSIRO have been used here, and with the replaced transducers in annex C, only the results obtained after the return from TNO have been used. Again, the values for PPS01 probably do not fully reflect the present state.

4.4. Interpolation

An approximation formula for P_c as a function of the *level* is desired. After several trial solutions the following mathematical approach will be used here, where P is the approximation of P_c:

$$P = P_{ref} \cdot ((level - alo) / 1000)^{\gamma} . \qquad (2)$$

This formula contains three free parameters, namely the characteristic power value P_{ref}, the apparent level offset *alo* and the exponent γ. The search for the best fit of P with P_c leads to quantitative values for these three parameters which are given in annex B and C. Incidentally, P_{ref} is the power $P(level=1000+alo)$.

Once the three values have been obtained, the power P can be calculated for any level. This can, of course, also be done for the levels used in the measurements and these P results are also given in the tables in annex B and C. Finally, the relative difference between the experimental values P_c and the fitted values P is given in

the tables. This is a measure of the quality of the fit. The differences shown are much better than ± 1 % in all cases.

Considering the parameter values obtained, the following should be mentioned. With PPS01, the *alo* values are close to zero so that a reasonable fit would be possible with *alo* = 0, but the γ values are clearly greater than 2. With the other PPS's, the γ values are close to 2 so that a reasonable fit would be possible with γ = 2 in most of these cases, but the *alo* values are clearly nonzero. The different behaviour is obviously due to the technical PPS change by CSIRO.

Of special interest is the inverse function of Eq. (2) giving the level needed to produce any desired power value *P*. The inverse function is as follows

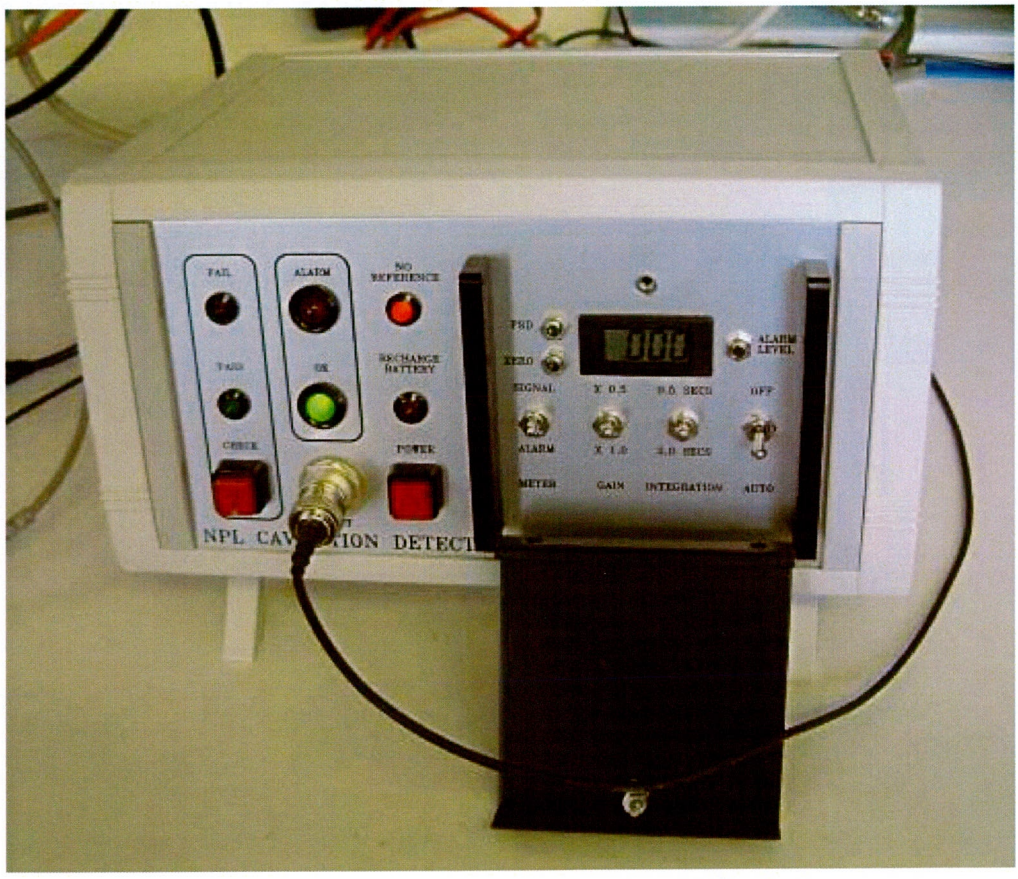
$$level = alo + 1000 \cdot (P / P_{ref})^{1/\gamma} . \qquad (3)$$

Two final remarks seem to be advised. 1. What has been done here is not an interpolation in the strict sense, for which a formula with four free parameters would be needed. Instead, having fewer parameters leads to a certain smoothing of the experimental values. 2. There is no theory behind formulas (2) and (3). They simply are empirical approaches in order to represent the experimental results.

Annex D
NPL Report for Workpackage 4, Cavitation Detectors, Technical Manual

NPL CAVITATION DETECTOR – CD1

TECHNICAL MANUAL v1.0



CONTENTS

1 SYSTEM CALIBRATION

1.1 HYDROPHONE

The hydrophone used in conjunction with the Cavitation Detector (CD) is a Dapco needle hydrophone that has been specially encapsulated with a polyurethane rubber. This has been done to protect the hydrophone active element (a nominal 1 mm diameter disc of PZT) from damage caused by collapsing cavitation bubbles. The recipe of the polyurethane material has been chosen such that the acoustic impedance over the frequency range of interest is very close to that water, so that effect of the protective layer on the sensitivity of the hydrophone is small.

The hydrophone has been calibrated at NPL as part of the CD testing process, and the set up of the CD and hydrophone in combination has been optimised. To ensure the continued performance of system, it is recommended that the hydrophone sensitivity be checked at yearly intervals. This may be done through a full hydrophone calibration procedure, or alternatively using a source transducer of known output.

The calibration data for the hydrophone when it was supplied was provided to each partner organisation: this data is unique to each system, and is not intended for public release, so is not shown here.

When checked again the values provided, the sensitivity of the hydrophone should be within ±15 % of the calibration value when supplied. If the sensitivity is outside of this range, consideration should be given to adjusting the detection threshold of the CD electronics accordingly, so that cavitation detection capability is maintained.

1.2 ELECTRONICS

The CD electronics can be tested using the 'Test' button on the front panel. If a gain of x1 is selected and the Check Button depressed, a reading should be displayed of 1,000 ± 0,050 V. If a gain of x0,5 is selected, the value should be 0,500 ± 0,025 V. if the displayed reading is outside of these bounds, then it is recommended that the CD unit be subjected to the set-up procedure described in Section 4.

2 CIRCUIT OVERVIEW

Refer to accompanying PDF document "CD Circuit Diagrams".

The system comprises four main modules or circuit boards:

Module/PCB

1 Input Buffer and Pre-amplifier
2 Amplifier/Oscillator
3 Mean Level Converter
4 Power Supply

In addition to the above, a panel mounted digital voltmeter is used to display the Mean Level output. The complete unit is powered by ±5 V, derived from a 12 V Lead-Acid battery charged using a 230 VAC mains plug-in charger.

2.1 INPUT BUFFER AND PRE-AMPLIFIER (MODULE 1)

A hydrophone is connected to the Input Buffer which offers a high input impedance for the hydrophone, equivalent to a parallel combination of 2 MΩ resistance and 20 pF capacitance. The unit produces two outputs, one x4 signal output and a second x10 output used to control the Local Oscillator. A simple protection circuit is included to protect the sensitive input to the buffer if the input exceeds approximately 1 V pk-pk.

2.2 AMPLIFIER/OSCILLATOR (MODULE 2)

2.2.1 Amplifier

The x4 output from the Input Buffer is fed to a mixer and narrow bandwidth amplifier whose gain can be set from the front panel to 1,0 or 0,5, because the input buffer gain is 4, the gain of this amplifier is 250 or 125 to produce an overall gain of 1000 or 500. The output is fed to the Mean Level Converter and to a Signal Output socket mounted on the rear panel of the unit. If loaded with 50 Ω, the gain at this socket is 500 for a gain setting of 1,0, or 250 for a gain setting of 0,5.

2.2.2 Oscillator

The Local Oscillator determines the way the Monitor functions. However, its main purpose is to produce a stable signal for the Mixer that forms part of the IF Amplifier. It also produces a reference signal of 1,5 MHz, which is switched to the Input Buffer for checking purposes.

2.3 MEAN LEVEL CONVERTER (MODULE 3)

The converter has five main parts:

- A rectifier circuit, to produce a voltage proportional to the signal amplitude.

- An Integrator, which produces the mean of the output from the rectifier.
- An Integrator Control, allowing integration times of 0,5 or 2,0 seconds.
- An Alarm circuit which sets the alarm level and illuminates the appropriate panel LED's
- An Alarm circuit which measures the output when the Check Button is pressed. A red Fail LED illuminates on the panel if this level falls outside a preset limit. Otherwise a green LED illuminates.

2.4 POWER SUPPLY (MODULE 4)

The Monitor runs from a single 12 V 2 AH Lead Acid battery. A 230 VAC charger is provided which plugs into the Monitor. A dc-dc converter is used to produce ±5 V. An indicator is incorporated which flashes when the battery requires charging.

3 BRIEF CIRCUIT DESCRIPTIONS

3.1 INPUT BUFFER/PRE-AMPLIFIER

A "source follower" configuration is used where the two parts of a dual N channel FET are connected in parallel to increase the value of *gm*. The "real" part of the input impedance of the two FET's is extremely high, and so the impedance at the input socket is determined mainly by the 2,2 MΩ input resistor. Similarly, the input capacitance is very low, < 30 pF determined primarily by the gate-drain capacitance, connectors and wiring etc.

An input "clamp" circuit is added comprising D2 and D3 to protect the buffer. In normal operation when the input amplitude is < 1 V pk-pk, the voltage across D2 and D3 will be zero (because the input and output are more or less the same) and will not therefore significantly affect the input impedance. However, when the input amplitude increases, the diodes start to conduct and excess current is conducted to 0 V via R4.

An amplifier with a gain of approximately 4 follows which feeds the signal input to the mixer in the Amplifier. A further amplifier stage of gain approximately 10, but clamped at about ± 0,6 V, feeds the automatic frequency reference circuits. A relay is used at the input of the buffer so that a 1,5 MHz signal can be fed into its input in Check Mode. The amplitude of this signal is set to an appropriate level so that the display reads 1,000 when the gain is set to X1,0 and 0,500 when the gain is set to X0,5. The test signal is generated by the Oscillator.

3.2 AMPLIFIER/OSCILLATOR

3.2.1 Amplifier

The output from the Input Buffer is fed to the Amplifier part of this PCB. The first stage (IC1) forms a "1 MHz Stop Filter". This is used to remove much of the 1 MHz content of the signal which would otherwise overload the amplifier. This circuit is particularly prone to noise pick-up and so is located separately, away from other influential parts of the monitor electronics (behind the front panel). The output from this is fed to an analogue multiplier, IC2, which acts as a mixer. The signal it is mixed with is an internally generated one which has a frequency 500 kHz higher than the signal frequency. This is generated by the Oscillator. A "low pass" filter follows, to remove unwanted frequencies above the selected intermediate frequency of 500 kHz (see Section XX). Two tuned amplifier stages follow, each tuned to 500 kHz. The bandwidth of each of the amplifiers is chosen so that the two together have an overall bandwidth of 40 kHz. The second amplifier has two inputs (X 1,0 and X0,5): the output from the first is fed to the appropriate of these using the front panel Gain switch.

3.2.2 Oscillator

The purpose of the Oscillator is to produce a "reference" signal for the mixer so that, taken together with the input signal, an IF frequency of 500 kHz is produced. For this to happen, the Oscillator produces a signal whose

frequency is 500 kHz higher than the input signal frequency. The input source for the Oscillator determines the unit's mode of operation.

The oscillator circuit produces the reference signal when driven by one of two possible inputs switched by RLY1, depending on the mode selected. Referring to the circuit diagram, the signal used to drive the Oscillator is fed into the first stage IC4a. This stage produces a square wave if an input signal of 1 MHz is applied. The next stage selects the third harmonic (3 MHz) and the following stage is used to produce a suitable signal to drive the 42 circuit of IC5. The fundamental frequency of the digital output produced by IC5 (1,5 MHz) is selected by L13 etc. and fed to a multiplier, IC6. This signal is mixed with one whose frequency is 500 kHz (almost exactly, by dividing the output of the 1 MHz crystal oscillator IC8 by two). The upper sideband, nominally of 2,0 MHz is selected by the filter comprising IC7. The output from this is further filtered by L17 etc., and then fed to the stage formed by IC9. This produces a square waveform for the output stage TR1. It is very important that the output waveform from TR1 has a constant amplitude and since it is a square waveform, the mark-space ratio should be constant and preferably 1:1 (see Section XX). The stage IC9 and the output stage TR1 satisfy this requirement.

A ±2,5 V reference voltage is also generated using parts of IC9 used for the output stage TR1.
It is very important that the frequency of the Oscillator is stable bearing in mind the narrow bandwidth requirement of the unit.

3.2.2.1 Auto Off Mode
In this mode, the input to the Oscillator is fed from the crystal oscillator IC8. This produces a square waveform of 1 MHz. The 3 MHz component is selected by IC4 and divided by two to produce a signal of 1,5 MHz as described above. The 500 kHz signal is also derived from the crystal oscillator and so a signal of 2,0 MHz appears at the output via TR1. It can be appreciated that in this mode, the frequency stability of the reference signal is determined solely by the crystal oscillator.

3.2.2.2 Auto On Mode
We have assumed that the incoming signal to the unit will not only consist of the signal of interest, nominally 1,5 MHz, but will also have a larger "operating" signal of at least 10 mV pk-pk whose frequency will be nominally 1 MHz. It has also been assumed that the frequency of interest is always exactly 1.5 x the "operating" frequency.

The X10 output of the Input Buffer is fed to the Local Oscillator input IC4 and as explained above, the output produced by TR1 will be 2,0 MHz. However, we have assumed that different systems being tested will operate at slightly different frequencies. We have assumed that this frequency will fall within the range of 0,93 MHz to 1,07 MHz. The signal of interest will be directly related to this, i.e. 1,4 MHz to 1,6 MHz. The Oscillator, however, will always produce a reference signal whose frequency is 500 kHz higher

than the frequency of the signal of interest which is nominally 1,5 MHz, (1,4 MHz to 1,6 MHz).

3.3 MEAN LEVEL CONVERTER

3.3.1 Input Rectifier

The rectifier circuit comprises the two parts of IC7. Its function is to produce a voltage level representing the amplitude of the signal from the Amplifier.

3.3.2 Integrator

This circuit is basically in two parts: the integrator itself with its sample and hold circuit IC6, and an integrator control circuit comprised of IC1, 2, 3 & 4 etc.

3.3.2.1 Integrator

This is a simple integrator circuit using a low bias current op-amp, IC6. The input signal from the rectifier is constantly applied to it. At the start of an integration period, the integrator is re-set to zero momentarily by the control circuit using the switch IC5a across its capacitor, after which integration is allowed to start. At the end of the integration period, the output is sampled and held by momentarily closing the switch IC5b. (Integration actually continues, but is ignored, until a new integration period is started.)

The integrator is actually a "mean value generator" and performs the function:

$$V_o = \frac{1}{T}\int_0^T V_{in}\, dt$$

The limit of integration, T, is simply the integration time set by one part of the panel switch. The other part of this switch produces the 1/T term by introducing appropriate series resistors VR3 & 4 etc to alter the "gain" of the integrator (i.e. as the integration time T is increased, the integration time constant is also increased in proportion).

3.3.2.2 Integrator Control

The integration period is controlled by the monostable comprising IC1a. The timing period is selected by switching in the appropriate resistor (comprising a fixed and variable resistor VR1 and 2) which charges the timing capacitor C2.

When a period is completed, the falling edge of the timing monostable (or timer) triggers the monostable IC1b which has a fixed period of about 0,5 seconds. The output of this re-triggers the timer and continuous operation is obtained. Monostable IC4a produces an integrator reset pulse at the start or rising edge of the timer. The integrator then starts to integrate the signal present at its input. When the timing period is complete, a sample pulse

generated by IC4b (from the falling edge of the timer) enables the sample and hold circuit (IC5b and IC6b) to read the output of the integrator. The output is fed to the Display and Alarm circuits.

3.3.3 Signal Level Alarm Circuit

The function of this alarm circuit is to indicate if the mean signal level has exceeded a pre-set value at any time during the integration cycles: if it has, the red Alarm LED illuminates. If there is not an alarm condition, the green OK LED illuminates. The circuit also provides a TTL level output to the rear panel when an alarm condition is reached.

IC8d forms a simple voltage comparator. The threshold (alarm) level is set by the front panel Alarm Level potentiometer. If the mean level exceeds the threshold, the output of IC8d switches on TR7 via IC10. This illuminates the Alarm LED, otherwise the green OK LED will illuminate. Both LED's are turned off by the action of the Check Button via IC10. (This is done to avoid confusion during the check process).

3.3.4 Check Level Alarm Circuit

The mean level signal is also applied to this alarm circuit, which compares it to a pre-set value set by VR6 (and the +ve reference voltage). The comparator circuit comprising IC8a and IC8b produces a uni-polar voltage proportional to the difference of the mean level signal and the pre-set level. This is applied to a comparator IC8c whose reference is set by VR7. This voltage represents the range within which the mean level should fall when Check Mode is selected. The output of IC8c is used to illuminate the pass or fail LED's in the same way as the circuit above. In order for the pass/fail criteria to apply for both gain settings, the mean level signal is switched (by part of the Gain Switch) to PL6/4 for gain X1.0 or PL6/5 for gain x 0.5.

When the Check button is pressed, the voltage on pin 7, IC8b should be less than 300 mV, which means that the difference between the level produced by the check signal and the reference is small enough to produce a pass. The limits of the Check mode can be adjusted by VR7 on the board, as follows: the voltage on pin 9, IC8c should be about 300 mV. To widen the limits, this voltage could be set to 600mV to double it to ± 0,04 in gain setting x 1, and ± 0,02 in gain setting x 0,5.

3.4 POWER SUPPLY

The unit is powered by an internal rechargeable 12 V lead-acid battery. A dc-dc converter is used to produce ±5 V. A comparator circuit is used, which indicates to the user that the battery voltage is low (currently set to approx. 10 V). A charger can be connected to the battery via a connector on the rear panel.

4 SET-UP PROCEDURE

The following procedure should be used if the calibration needs to be checked. It is not intended as a fault finding procedure (although faults may be identified during the process!). It is assumed that the unit is basically functioning correctly for this procedure. Although there is no danger of electric shock, care should be taken not to short the battery. During this procedure, certain connections are removed and made. When this is done, switch the unit off! When complete, switch on again.

Before starting the process:

- Ensure the unit is isolated from power and switched off.
- Remove the unit from its enclosure.
- Switch on the unit.

4.1 MEAN LEVEL CONVERTER SET-UP

1. Using an oscilloscope, monitor the output (pin 5) of IC1a on the Mean Level Converter Board.
2. Set the integration time to 2,0 seconds (on the front panel).
3. Adjust VR1 until the pulse width observed is 2,0 ± 0,05 seconds.
4. Set the integration time to 0,5 seconds
5. Adjust VR2 until the pulse width observed is 5,0 ± 0,1 seconds
6. Remove PL3.
7. Apply +1 V dc to pin 2 of skt3 on the PCB (the chassis is 0 V).
8. Set the Integration time to 2.0 seconds.
9. Monitor the sample and hold circuit at pin6 of IC6b.
10. Adjust VR3 until the output voltage is approximately the same as the input voltage (+1 V DC). Bear in mind that the output voltage will be updated once every 2 seconds and so the effect of adjusting VR3 is not immediate.
11. Repeat for an integration time of 0,5 seconds, adjusting VR4 instead of VR3.
12. Replace PL3.

4.2 METER FULL SCALE ADJUSTMENT

1. Set the Meter Panel Switch to Alarm Level.
2. Turn the Alarm Level control fully clockwise.
3. Adjust the FSD adjustment on the front panel so that the display reads 1.999.

4.3 Amplifier Set-up

1. Set the Gain to x1.0
2. Set to Auto Off
3. Press the Check Button and monitor the signal present at the Signal Output socket at the rear panel.
4. Adjust L9 (and VC5 if necessary) for maximum amplitude
5. Adjust L10 (and VC6 if necessary) for maximum amplitude
6. Connect a sine wave oscillator set to 1,5 MHz with an amplitude of 2 mV pk-pk to the unit's Input socket.
7. Adjust VR1 on the Amplifier board until the output amplitude at the rear socket is 2,00V ± 0,02V pk-pk when unloaded.
8. Set the Gain control to x0.5 and adjust VR2 until the amplitude at the rear socket is 1,00V ± 0,05V pk-pk when unloaded.

4.4 Overall Gain Set-Up

1. Set the Gain to x1.0
2. Set to Auto Off
3. Connect a sine wave oscillator set to 1,5 MHz with an amplitude of 2 mV pk-pk to the unit's Input socket.
4. Adjust VR5 on the Mean Level Board until the display reads 1.999 ± 0.05.

4.5 Calibration Signal Set-up

1. Set the Gain to x1,0
2. Push the Check Button and adjust VR4 on the Oscillator board so that the display reads 1.000.
3. Set the Gain to x0.5 and check the display reads 0.500 ± 0.005.

5 OPERATING PRINCIPLE

The operation of CDI is based on the Super- Heterodyne principle. This involves the production of a lower frequency signal by "mixing" the incoming signal with a locally generated one of slightly higher frequency. This effect has also been used to generate the reference signal produced by the Amplifier/Oscillator.

If the incoming signal is represented by:

$$S_S = A_S Sin\omega_S t$$

and the local oscillator signal is represented by:

$$S_L = A_L Sin\omega_L t$$

Then the resultant signal given when the two are mixed, or in the case of this unit, multiplied together, is:

$$S_O = A_S A_L Sin\omega_S t.Sin\omega_L t$$

or

$$S_O = \frac{A_S A_L}{2}[Cos(\omega_S + \omega_L)t + Cos(\omega_S - \omega_L)t]$$

This signal is fed to an amplifier tuned to $(\omega_S - \omega_L)$ and so the higher frequency component is ignored. In fact if the Local Oscillator produced a square wave-form instead of a sinusoidal one (which in the case of this unit, it does), all the additional higher components will also be ignored.

In this case, the amplifier is tuned to 500 kHz, so as long as $2\pi.(\omega_S - \omega_L)$ is equal to 500 kHz, a signal will be detected, i.e. the Local Oscillator simply has to have its frequency adjusted to be 500 kHz above the input frequency.

It can be seen that the amplitude of the resultant signal, S_0 is dependent on the amplitude of the Local Oscillator, so this must be made constant. It can also be appreciated that if a square wave-form is used, then the mark-space ratio must also be constant (so that the amplitude of the fundamental component is constant).

6 TESTING OF CAVITATION DETECTOR AND HYDROPHONE

The CD1 and hydrophone were set up according to the User's Manual v1.0. To generate cavitation, NPL's reference 1 MHz large Enraf transducer s/n 16.312 was driven by a Hewlett Packard HP3336c synthesiser at a frequency of 1.002 MHz, operating through an Amplifier Research model 150A100B RF power amplifier. The rms drive voltage applied to the transducer was determined using a Hewlett Packard 3403c voltmeter.

The transducer was set up to radiate into a 1 l container lined with Wallgone acoustic absorber. Using prior knowledge of the radiation conductance of the transducer, drive voltages were applied in order to generate acoustic powers in the approximate range from 1-15 W. During measurements, the hydrophone output BNC was switched between an Agilent 4395A Spectrum Analyser and the CD1 to confirm the occurrence of the first ultraharmonic component.

The testing was carried out in three different media types, four times each:

1. Filtered, deionised, degassed water;
2. Filtered deionised water;
3. Tap water.

The data was gathered with the CD1 in its default settings, as listed in the User's Manual v1.0. The results obtained are shown in Figures 1, 2 and 3, for the three media cases as listed above respectively. In each medium case, the first two runs were completed using both the CD1 and the Spectrum Analyser, and the latter two runs were carried out using the CD1 unit only. In all cases, the value from either the Spectrum Analyser, or from the CD1 display was read after an insonation period of 5 seconds.

The results show that when cavitation occurs, as manifested by the appearance of the first ultraharmonic, the CD1 and the Spectrum Analyser both detect it. Cavitation can be seen to occur readily in the non-degassed water samples, but not in the degassed water case.

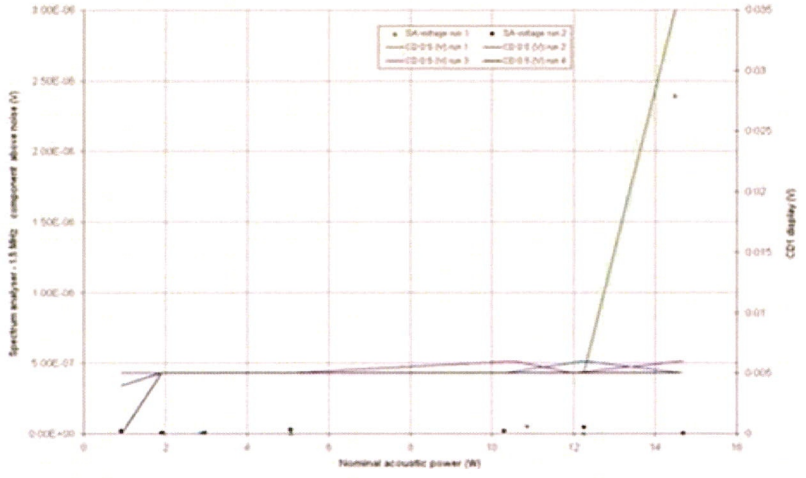


Figure 1: Results obtained in filtered, deionised, degassed water. The average temperature over the four runs was 21,7 ± 0,5 °C.

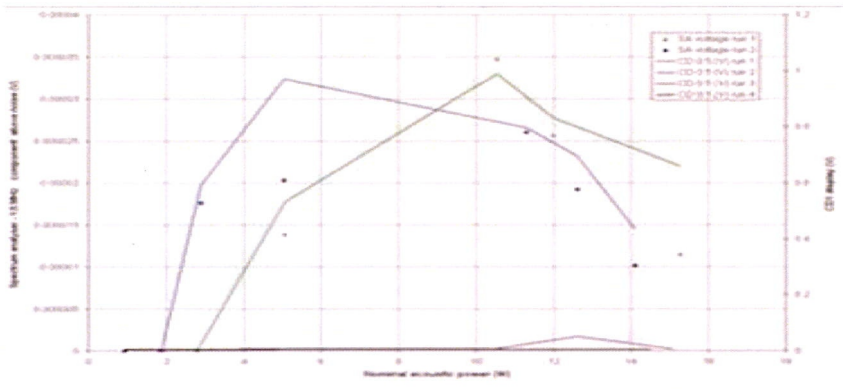


Figure 2: Results obtained in filtered, deionised water. The average temperature over the four runs was 22,2 ± 0,5 °C.

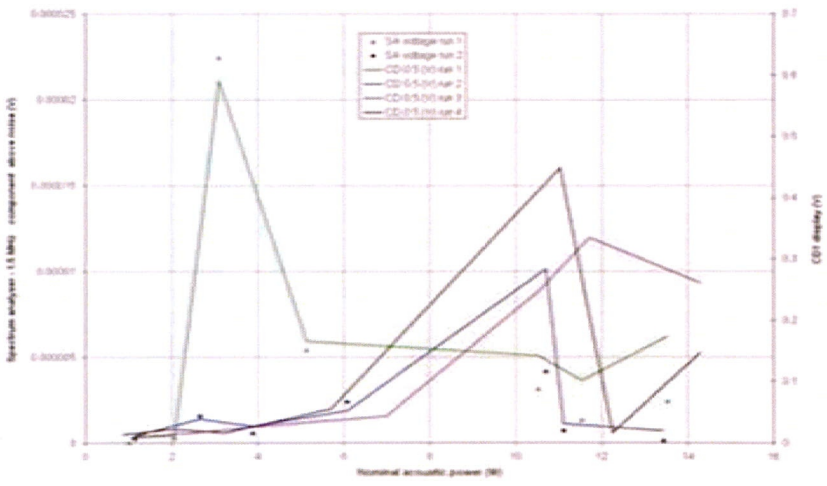


Figure 3: Results obtained in tap water. The average temperature over the four runs was 22,4 ± 0,8 °C

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Annex E
Travel Loops in Europe and Australia

1 Report on travel loops organised by TNO

Table E.1.1 and Figure E.1.1 shows the differences between the ultrasonic powers reported by the 4 preliminary testers contracted and the powers as calibrated by TNO.
The four testers had deviations ≤8 % of the average, except for the negative control and the lowest power of the 1 MHz small transducer (probably resolution problem). The power of this transducer was generally underestimated, which is ascribed to divergence. Testers 1 and 2 clearly overestimate the powers of the negative control transducer, and tester 3 underestimated them. For the other transducers, no tester stands out for his under- or overestimations. No deviations over 20 % were observed. Results of tester 1 were very good (<3 % deviation except for the negative control and the very low 0,1 W in 3 MHz small). In Table E.1.2 the comments of the preliminary testers are summarised. In Table E.1.3 the balance set-up used by the preliminary testers is given.

Table E.1.1 Summarising measurement results of travel loops

		Participant 1	Participant 2	Participant 3	Participant 4
Transducer	P_{nom} / W	Δ / %	Δ / %	Δ / %	Δ / %
3 MHz small 1	0,1	-8,0	-6,0	4,0	-3,9
	0,5	0,8	0,0	5,6	-1,5
	1,0	-2,4	0,0	7,2	-1,8
	3,0	-1,1	1,0	6,3	-1,1
3 MHz large 2	0,3	-0,7	-5,0	4,0	-4,9
	1,0	-1,6	-4,1	0,0	-3,8
	5,0	-1,2	-3,6	-1,8	-2,6
	15	-1,3	-3,6	-3,1	-2,6
1 MHz small 3	0,1	2,0	0,0	**16,0**	-8,1
	0,5	-2,8	-5,8	-4,0	-3,2
	1,0	-2,2	-5,3	-4,0	-3,7
	3,0	-1,9	-5,3	-4,0	-3,1
1 MHz large 4	0,3	2,0	-3,0	-4,0	0,8
	1,0	1,6	-4,4	0,0	1,0
	5,0	1,7	-3,9	-0,2	0,1
	15	1,6	-3,6	-	0,0
Negative Control 5	0,06	**12,7**	**-14,5**	9,1	5,4
	0,39	8,6	4,6	-8,6	-0,6
	0,85	**11,5**	4,1	-7,9	-0,7
	2,7	9,9	3,8	-9,9	-0,7

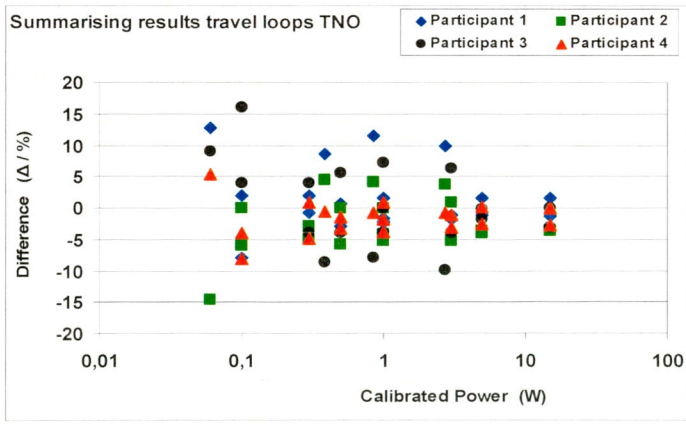

Figure E.1.1 Results of 4 participating testers in the TNO travel loops.

Table E.1.2, Summarising comments of the preliminary testers

	Participant 1	Participant 2	Participant 3	Participant 4
Freight and Packing:				
• Well packed?	Yes	Yes	Yes	Yes
• Courier service ok?	Yes	Yes	Yes	Yes
• Any shock or temperature sensors activated?	No	No	No	No
Tips for Measurement:				
• Useful?	Result is beam dependent, So?	Yes	Yes	Yes
• Lacking clarity on?	Beam dependency	No	No	No
• More information required on?		No	No	No
Calibration / Tutorial Mode:				
• Useful for checking the calibration of your power meter?	Less, due to transducer type	Yes		Yes
• Gives a good familiarisation with the use of the PPS?		-		Yes
• Did you have trouble staying in the desired temperature range?	No, Are using forced cooling	-		Needed to cool the water
• Was an individual session time (180 min) enough?	No, forced to finish in one run	Yes, but I switched of in 2 min.		Yes
• How many times (passwords) do you think you need access the Calibration / Tutorial Mode?	At least 2, need to allow a break	Could not access a 2nd time, so need min 2 passwords		2 or 3
Transducer 5:				
• Did this give you any problems?	No	No	No	No
• What sort of problem?	-	-	-	-
Temperature Probe:				
• Was this easy to use?	Yes	Yes	Yes	Yes
Cavitation Detector:				
• Was this a useful device?	We think so	Yes Boiled water + $NaSiO_4$	The light was green, but with Tx4 it turned red at L4, Using distilled, at least 1 day old water.	Yes
• Easy to setup and use?	Unsure about proper working Sensor mount difficult	Yes	Yes Sensor mount difficult	Unsure about proper working Sensor mount difficult
• The instructions are sufficient?	Yes	Yes	Yes	Yes
• Did you try a range of water types? For example tap water fresh from the tap?	No	No	No	Yes, found cavitation On
• Did you try it with a transducer from a physiotherapy machine?	No	No	No	No
• Would you like access to the digital signal readout on the front panel? It is presently secured behind a black panel	Yes, would be instructive	Yes, would be instructive	No	Yes, would be instructive
Proficiency Test:				
• Instructions clear?	Yes	Yes	Yes [But failed to finish correct]	Yes
• Did you have trouble staying in the desired temperature range?	No	No, 2 times alarm: too hot	25°	No
• Sufficient session time (180min) to complete?	No, forced to finish in one run	Yes	Yes	Yes
• Would you like a number of staff members to be tested? How many?	No	Possibly in future	No	No
• Is it an effective and convenient test and calibration method?	Less, due to transducer type	Yes	Yes	Yes
Report Form:				
• Is this clear?	Yes, Prefer an Excel format	Yes	Yes	Yes, Prefer an Excel format
• Would an example form, filled out help?	Not needed	No	No [But failed to finish correct]	Not needed
General:				
• Did Error messages come up when everything was ok? Which ones and when?	No, -	No, -	No, CD → Red	No, -
• Is the language, syntax and commands with the PPS fairly easy to follow?	Easy enough	Clear	Yes	Easy enough
• Suggested improvements?	-	-	-	-
• The transducers are easy to handle and mount in your power meter ok?	Was difficult to fit	Yes	Heavy for our mount	Yes

Table E.1.3 Types of power meter used by the preliminary testers

Participant 1	Participant 2	Participant 3	Participant 4
Balance: Ohmic, UPM-DT10 Resolution: 10 mW Target: 45° convex conical reflector Tank: circular ~2 l water	Balance:Mettler PG 403-S Electronic analytical Resolution: 15 mW Target: Thin flat metal plate under angle of 45° Tank: large, ~3 l water	Balance: Ohmic, UPM-DT10 Resolution: 10 mW Target: 45° convex conical reflector Tank: circular ~2 l water	Balance: Mettler PR2004 Electronic analytical Resolution: 1,5 mW Target: flat large absorbing target Tank: rectangular ~1 l water

2 Report on travel loops organised by PTB

The following table presents the ultrasonic power results reported by the participants in Germany. The meaning of the symbols: P_{ref} is the respective power value (unknown to the participant) selected by PTB and entered into the PPS using the passwords sheet. The values are based on the PTB measurements and the obtained relation between excitation level and power. Δ is the percentage deviation of the participant's reported power result from P_{ref}.

Table E.2.1. Results of proficiency tests

	Participant A		Participant B		Participant C	
Transducer	P_{ref} / W	Δ / %	P_{ref} / W	Δ / %	P_{ref} / W	Δ / %
3 MHz small	0,2	-5,0	0,2	-8,0	0,1	+18
	0,6	-3,3	0,7	+0,6	0,5	+7,6
	1,1	-2,7	1,2	+0,4	1,4	+7,1
	2,8	-0,4	2,7	+0,1	2,9	+6,9
3 MHz large	0,3	0	0,3	+2,0	0,2	+5,0
	1,0	0	1,1	+3,1	0,9	+3,8
	4,6	-0,2	4,8	+2,3	4,5	+2,0
	13,2	-0,9	13,5	+1,5	14,0	+1,2
1 MHz small	0,2	0	0,2	-8,0	0,1	+2,0
	0,6	-1,7	0,7	-9,1	0,5	+4,4
	1,1	-1,8	1,2	-9,4	1,4	-3,9
	2,8	-2,9	2,7	-10,1	2,9	-5,7
1 MHz large	0,3	-3,3	0,3	+5,0	0,2	+8,0
	1,0	-2,0	1,1	+2,9	0,9	+5,8
	4,6	-0,9	4,8	+2,1	4,5	+5,6
	13,2	+0,2	13,5	+4,5	14,0	+4,4
Negative control	0,2	-5,0	0,2	-8,0	0,1	-8,0
	0,6	-8,3	0,7	-7,1	0,5	-7,6
	1,1	-9,1	1,2	-6,8	1,4	-6,1
	2,8	-10,0	2,7	-6,8	2,9	-6,0

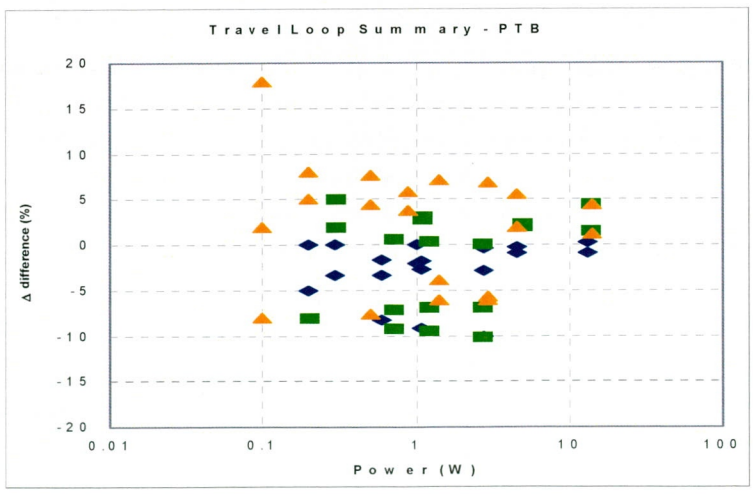

Figure E.2.1 Results of 3 participating testers in the PTB travel loops.

Remarks on the results of participant A

Participant A used a non-commercial device with an absorbing target. He submerged the transducers. He carried out 2 proficiency tests with an interval of several days (the above results are from the first one). Obviously transducer problems due to water

ingress occurred and influenced his second results and the PTB re-measurements. Maybe the transducer lids (those with O-rings and without holes, not the usual ones) had not been fastened tightly enough by PTB.

The above results of participant A are generally good. (Increased percentage differences at low levels are obviously due to the influence of resolution. For example, 0,19 W instead of 0,2 W means a difference of -5 %.) There are two exceptions: (a) The 1 MHz small transducer has a diverging field, and the participant obviously has not applied the field correction which would lead to an increase of 1,7 %. (b) His results for the negative control transducer are low by 5 to 10 %.

Findings from the logged PPS data: The participant needed much time for his measurements, obviously due to submerging and to the adjustment procedures for his non-commercial device. The bath temperatures were rather high, it was in the summer. One cavitation alarm was reported; strange effect: with the small 1 MHz transducer at the lowest power level.

Comments of participant A

The participant was happy with the PPS and its use. He only criticized the mounting procedure of the hydrophone ("schwergaengig" ≈ difficult).

Remarks on the results of participant B

Participant B used a commercial device with a convex-conical reflector. His results are generally acceptable (possible resolution problems at small powers have already been mentioned). Again there are two exceptions: (a) His results for the small 1 MHz transducer with its diverging field are low by roughly 9 %. This is clearly due to the convex-conical reflector. (b) His results for the negative control transducer are low by roughly 7 %.

Findings from the logged PPS data: The participant obviously did not need much more than one hour for all his work. There were 6 cavitation alarms for the large 1 MHz transducer, one at level 3 and five at level 4 (highest). The participant said that they refresh their degassed water at certain intervals and this water obviously was relatively "old".

Comments of participant B

The participant generally was content with the PPS and its use. He said that the time required for applying the PPS is comparable with the time required for a calibration by other means. But, according to him, the use of the PPS requires some familiarization and could be more intuitive, and mounting the transducer and the hydrophone is somehow uncomfortable and time-consuming (small screws; tools needed). He then complained that the alignment of the transducer by eye in relation to his conical target was unsatisfactory and that they will have to construct a special transducer mount if the PPS is formally established in the future.

Remarks on the results of participant C

Participant C also used a commercial device with a convex-conical reflector, but of a different make and type as compared with participant B. His results are generally not so good, namely too high. Again there are two exceptions: (a) His results for the small 1 MHz transducer with its diverging field are lower than his other results. This is again obviously due to the convex-conical reflector. (b) His results for the negative control transducer are low by roughly 7 %.

Findings from the logged PPS data: This participant also obviously did not need much more than one hour for all his work. There were 3 cavitation alarms for the small 1

MHz transducer at level 4 (highest). There were 6 cavitation alarms for the large 1 MHz transducer at level 4 (highest). The participant said that they refresh their degassed water every week and this water obviously was relatively "old".

Comments of participant C

The measurements and using the PPS are OK if one strictly keeps to the manual. Changing the transducer is a little difficult ("aufwaendig" ≈ laborious, complicated). This participant also is not happy with the way of clamping the transducer. The measurement results have been found to be fluctuating. Maybe this has to do with the cavitation alarms.

General remarks

The participants' results for the small 1 MHz transducer (diverging) and for the negative control transducer were significantly low. Obviously the problem of the influence of a diverging field structure on power results, particularly with convex-conical reflector, is not sufficiently known in practice.

The cavitation alarms show that refreshing the degassed water once a week is not sufficient, but obviously it is a widely-established practice. On the other hand, the ultrasonic power results obviously are not influenced that much.

Manufacturers obviously have special transducer mounts for their own transducers and these cannot generally be used for other transducers (such as those of the project). It is not possible to solve this problem as shape and size of transducers are not standardized and we cannot provide mounts for all potential users and their ultrasonic wattmeters.

3 Report on travel loops organised by NPL

The identified candidate testers before the start of the process were 2 UK hospitals (Medical Physics departments) and a UK manufacturer, and the travel loops were carried out over the period July to October 2004. During this period, only the 2 UK hospitals were able to complete the tests, due to the problems found with Transducer 4 (see above). It is hoped that the third participant will be able to test the PPS in the early part of 2005. To provide a third data set, a member of NPL staff who had not previously been involved with testing and using the PPS carried out a proficiency test.

Table E.3.1: Results of proficiency tests.
'Nominal' and 'Actual' columns refer to the set and measured power values in watts, and the 'Diff.' column is the percentage difference between the two. Participant 3 is data measured at NPL by a different operator to the remainder of the project work

	1			2			*3*		
	Nominal	Actual	Diff. (%)	Nominal	Actual	Diff. (%)	*Nominal*	*Actual*	*Diff. (%)*
Transducer 1	0,10	0,10	0,0	0,50	0,49	-2,0	*0,10*	*0,10*	*0,0*
3 MHz small	0,30	0,30	0,0	1,00	0,97	-3,0	*0,30*	*0,29*	*-3,3*
	1,00	0,99	-1,0	1,50	1,47	-2,0	*1,00*	*0,98*	*-2,0*
	3,00	2,99	-0,3	3,00	2,96	-1,3	*3,00*	*2,93*	*-2,3*
Transducer 2	0,10	0,10	0,0	0,50	0,50	0,0	*0,10*	*0,10*	*0,0*
3 MHz large	0,50	0,51	2,0	1,00	1,01	1,0	*0,50*	*0,49*	*0,2*
	3,00	2,90	-3,3	5,00	4,94	-1,2	*3,00*	*2,96*	*-1,3*
	15,00	14,50	-3,3	15,00	14,63	-2,5	*15,00*	*14,65*	*-2,3*
Transducer 3	0,10	0,10	0,0	0,50	0,49	-2,0	*0,10*	*0,10*	*0,0*
1 MHz small	0,30	0,29	-3,3	1,00	0,97	-3,0	*0,30*	*0,29*	*-3,3*
	1,00	0,96	-4,0	1,50	1,45	-3,3	*1,00*	*0,97*	*-3,0*
	3,00	2,80	-6,7	3,00	2,90	-3,3	*3,00*	*2,87*	*-4,3*
Transducer 4	0,10	0,10	0,0	0,50	0,48	-4,0	*0,10*	*0,10*	*0,0*
1 MHz large	0,50	0,50	0,0	1,00	0,96	-4,0	*0,50*	*0,49*	*-2,0*
	3,00	2,85	-5,0	5,00	4,68	-6,4	*3,00*	*2,76*	*-8,0*
	15,00	14,10	-6,0	15,00	13,77	-8,2	*15,00*	*14,22*	*-5,2*
Transducer 5	0,10	0,10	0,0				*0,10*	*0,10*	*0,0*
Negative control	0,30	0,28	-6,7				*0,30*	*0,31*	*3,3*
	1,00	0,88	-12,0				*1,00*	*0,98*	*-2,0*
	3,00	2,37	-21,0				*3,00*	*2,77*	*-7,7*

The travel loops were generally successful, with the PPS found to be straightforward and intuitive to use, and with the exception of Transducer 4, reliable and stable. No problems arose as a result of the devices being transported, although the PPS packing case showed that it had received an impact during transit from the second tester to NPL: the PPS itself was apparently unaffected. The results obtained by the testers on the conventional transducers were all within 8 % of the NPL values. This is within the requirements of the standards for accuracy of power measurements, and so it can be stated that the testers are producing data of good quality.

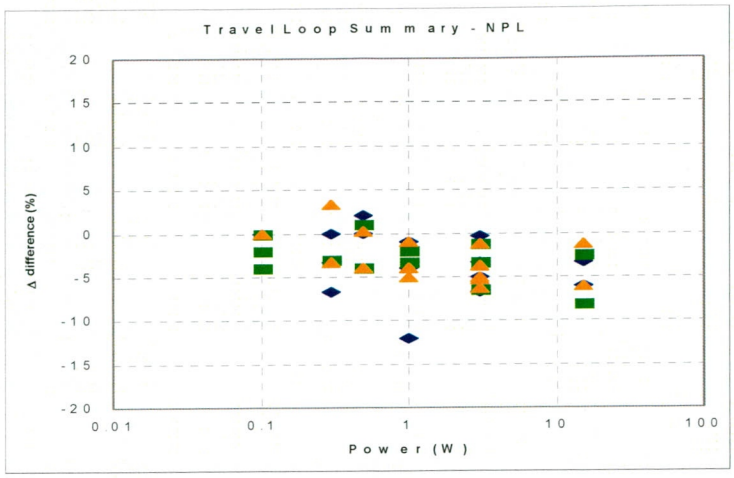

Figure E.3.1 Results of 3 participating testers in the NPL travel loops

Tester 1 used a horizontal balance configuration for their tests, such that the transducers were submerged. The transducers themselves are compliant with IEC 601-2-5, and so are required to be able to work underwater. There was a problem with water ingression for transducer 5 (negative control), however, and even with trying a series of different O-ring seals it was not possible to prevent water leaking into the transducer at a slow rate. Results for transducer 5 for Tester 1 should therefore be analysed with caution. The difference of –21 % seen at 3 W for the negative control when compared to the NPL data may therefore be unreliable, as water ingression was noticed immediately after this measurement was made. On return to NPL, transducer 5 was dismantled and dried out, and in subsequent testing appears to have recovered to its previous output levels.

Tester 2 encountered problems with transducers 1 and 3. When these were connected (as prompted by the PPS) in proficiency test mode, the PPS displayed "Transducer 6". Following communication with CSIRO, it was discovered that such a display refers to the transducer being unrecognisable (the identification of transducer type is made via detecting the value of the resistor that is connected inside each transducer. The problem is likely to be limited to NPL's PPS only, as the current sensing circuitry in NPL's PPS is significantly lower than in the remaining units, due to different component values. It is potentially solvable by broadening the acceptance window of the resistance value look-up table, but more testing over a broad range of temperatures is required to determine the most appropriate window. This work is ongoing, and the solution will be implemented through a change in the PPS code (carried out by CSIRO).

Following discussion, it was discovered that the recognition problem did not occur in tutorial mode, and so tester 2 was still able to carry out some useful measurements. In doing this, transducer 4 illustrated some instability, which have also been observed at NPL – an example of this is shown in Figure E. 3.2.

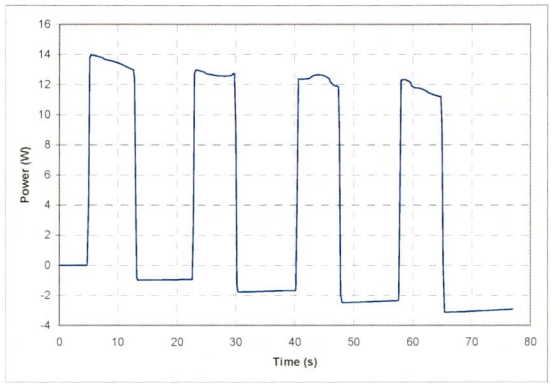

Figure E.3.2: Power-time trace (4 power cycles) for transducer 4

This shows that during the on-period, the power produced is unstable, particularly for the later power-cycles. Similar traces were not seen at lower operating levels, and so it is believed that the problem is related to thermal effects, with the transducer output becoming unstable as the crystal heats up. The extent of the problem can be reduced by limiting the on-time to 5 s, by increasing the off-time, and by reducing the number of transitions in a given measurement run. Considered alongside the longer-term stability issues seen with transducer 4 (see above), this suggests that the transducer is unreliable, and a replacement should be procured.
Table E.3.1 shows the ultrasonic power results reported by the 2 candidate testers in the UK.

Tester 1
Tester 1 used a non-commercial counterbalance device with a 60 mm conical reflecting target, deployed in a horizontal configuration, and so the transducers needed to be submerged for measurement. Power values were read from a needle display. A single proficiency test was carried out: transducer 5 exhibited problems due to water ingress, which influences the results for this transducer only. One cavitation alarm was obtained (distilled and filtered gassy water was used as the propagation medium), for transducer 4 at nominally 15 W. This is likely to be a reason for the slight underestimate seen at this power level. Additionally, no corrections were applied for transducer *ka*, which means that the results for transducers 3 and 4 may be underestimates at all power levels. The bath temperature rose as high as 26 °C during the measurements (summer day).

Tester 1 comments
- PPS found to be easy and intuitive to use after a couple of tutorial sessions (two individuals used it, although only one carried out the proficiency test);
- Cavitation detector hydrophone set-up initially difficult, but easier with practice;
- Some investigations in tutorial mode of repeated exposures to 15 W at 1 MHz showed medium has cavitation history: it became easier to cause a cavitation alarm to occur at 5 W after a series of 10 second exposures at 10 W;
- Number of passwords considered too limited for this 'trialling' phase of project;
- Transducer 5 would not seal sufficiently well for full testing;
- Proficiency test took just over 1 hour to complete.

Tester 2
Tester 2 used a custom-designed top-loading Sartorius balance (Arrangement C approach) with (70 mm by 50 mm) rectangular target made from NPL Absorber. The water tank contained 500 ml of deionised, degassed water (obtained by distilling, boiling and cooling), and a LabView PC programme was used to record mass change values from the balance, which were then converted to powers. Time history was hence obtained (see above).

The problems found with transducer recognition documented above allowed only the tutorial mode to be used: however, two separate measurement runs were completed (around 1 hour each), the second of which was more complete, and is shown in table B.1. The results are generally very good – no cavitation alarms were seen. The low value measured for transducer 4 at the 15 W setting, are thought to be due to the fluctuations reported previously.

Tester 2 comments

- Tester 2 was impressed with the appearance and features of the PPS, despite the problems faced;
- The power balance used was only just big enough for the transducer and hydrophone (in the mount) to fit inside the water tank;
- The number of passwords available (tutorial mode) was again considered too limited for this 'trialling' phase of the project.

Tester 3

Tester 3 measured the PPS and transducers with the NPL Reference Therapy Level Balance, as developed under the project SMT4-CT96-2139, with degassed, deionised water and an 80 mm diameter absorbing target. The results produced are consistent with the long-term trends presented in table A.1.

The tester found the system easy to use once the Tutorial Mode had been run through, but found the hydrophone holder a little time-consuming to use. The test was completed in 80 minutes, with no cavitation alarms seen, and a bath temperature in the range 21-22,5 °C

4 Report on travel loops organised by CSIRO

It was necessary to evaluate the usefulness of the PPS (Driver, Transducers and the Cavitation Detector (CD)) as a method for remotely disseminating ultrasound therapy power standards to the testing community. In Australia and New Zealand there was a pool of interested testing organizations willing to trial the PPS. Six of the most enthusiastic were selected, however thirteen more could have participated in the trial if time had permitted.

Through these "Travel Trials" to various testing organizations it was hoped to be able to evaluate the reliability, ease of use and usefulness to the candidate testers of the PPS. Also some feedback would be obtained on the calibration state and expertise of those providing a testing service.

Critical Conclusions

- Enthusiasm amongst the six Australian and New Zealand Candidate Testers was high. Thirteen more testing organizations would have liked to participate in the trials, but time did not permit this.

- The PPS survived the travel, despite the shock/impact sensors on the transit cases being triggered a number of times. This also occurred once when a Driver was sent to PTB, Germany.

- Reproducibility of measurement of all the Candidate Testers was very good. Some of them had significant systematic errors in the calibration of their power meter. If these offsets were taken into account by the tester via the Calibration/Tutorial mode then a successful, accurate calibration could be done. See Figure E.4.1. Power meters which could be calibrated with masses by the user had comparatively very little accuracy offsets

- The Negative Control transducer failed four of the six Candidate Testers. Their power meters were unsuitable for testing the new dual frequency applicator heads of the newer ultrasound therapy machines. See Figure E.4.2.

- The feedback about the Cavitation Detector was limited, this was due to:

  (a) Only two Candidate Testers had access to it, due to the limited time available.

  (b) The Candidate Testers were highly focused on the making the power measurements and so tended to focus on the PPS and their power meter. Also their water preparation technique followed the suggestions in the guide manual supplied to them. Two instances of cavitation were reported though.

The conditions under which the cavitation was observed should be followed up. It may be that simply allowing distilled water to stand open at room temperature for 24 hours may be marginal.

It was felt that the Cavitation Detector was fairly easy to use and would be of diagnostic benefit, especially for those reporting results with poor reproducibility at higher powers.

- Each of the Candidate Testers indicated a willingness to use the PPS Calibration and Proficiency Test program for calibration of the power meter and accreditation of their service. However a number of prerequisites a needed:

  1. The PPS needs to administered by an organization. At present CSIRO and the new National Measurement Institute do not have the resources to do this.

2. There needs to be an awareness amongst the Physiotherapists and other clinical users of ultrasound therapy machines that an accreditation service exists for testing service providers.

3. The Physiotherapists and other clinical users need to request the accreditation and calibration status of their testing service provider.

Two of the Candidate Testers in Australia are located in large hospitals and have extensive experience in providing testing services. Accordingly the two Australian PPSs ,including the CD, have gone to them on an extended loan. PPS-1 and the CD is in Western Australia and PPS-5 is in South Australia

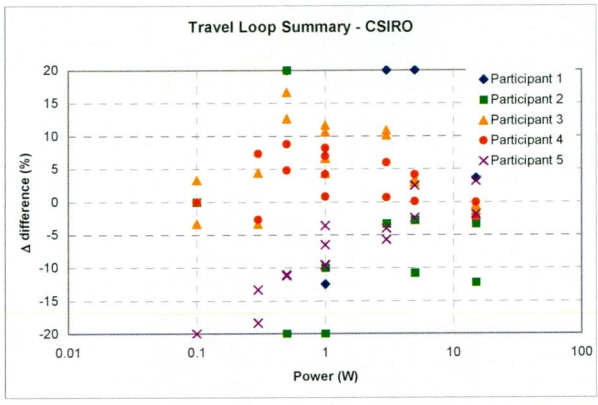

Figure E.4.1 Results of 5 participating testers in the CSIRO travel loops

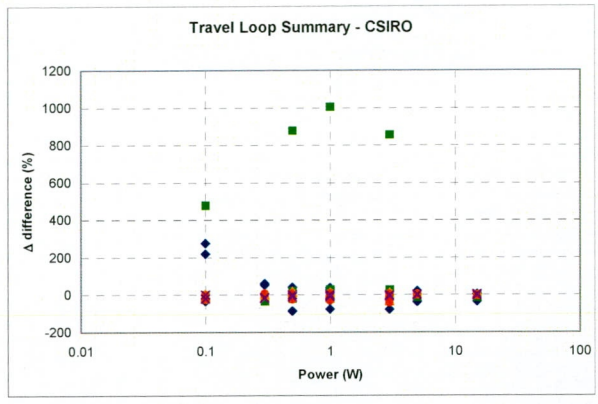

Figure E.4.2 Results of power measurements with a power measurement set-up that seems sensitive for RF stray fields.

Annex F

User Manual Portable Power Standard Calibration - Tutorial Mode and Proficiency test

Date: 22 October 2007
Version number: V01

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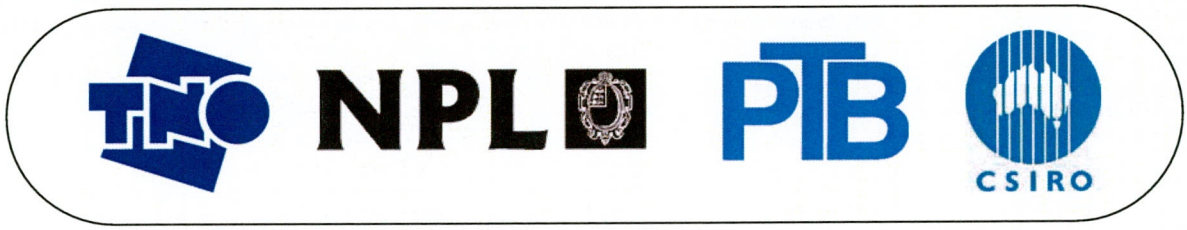
Number of appendices: 5



PREFACE

The Portable Power Standard (PPS) consists of a Driver, five transducers (treatment heads) and a Cavitation Detector (CD). The Portable Power Standard (PPS) would be suitable for conducting in-the-field proficiency testing of small companies, hospitals and manufacturers undertaking routine ultrasound therapy machine testing.
It can also be used for tutorial and calibration purposes.

The Driver unit contains an electrical signal generator and programmable power amplifier to drive the ultrasound transducers. The unit can drive the full set of transducers described. The ultrasonic output can range 0.1-15 W. The internal programmer stores signals from the Cavitation Detector (CD) and the temperature probe to measure the water bath temperature.

Five transducers comprise a set for Portable Power Standard (PPS) such that the range of treatment heads seen in clinical use is bracketed. This includes one transducer exhibiting an unusual output as a negative control.

The purpose of the Cavitation Detector (CD) is to alert the user to the presence of cavitation activity occurring, which may then affect the accuracy of power measurements. Cavitation bubbles produced and excited at 1 MHz will radiate a broad spectrum of acoustic radiation into the water. This is measured by the sensor that transfers the ultrasonic signal into a RF voltage. So, the Cavitation Detector (CD) is essentially an RF Voltmeter with a very narrow bandwidth tuned to a nominal centre frequency of 1.5 MHz.

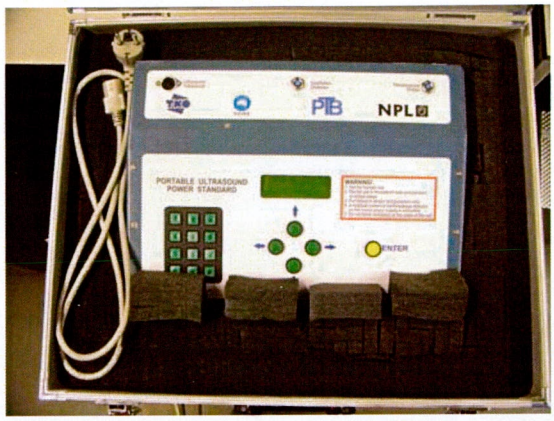
NOTE: Cavitation has not been observed for high quality physiotherapy applicator heads of 3 MHz.

Contents

1 Receipt of the equipment

1.1 Packing

The equipment has been shipped in two foam filled aluminium transit cases. After use, to avoid damage, re-pack the content the way it is shown in the photographs.



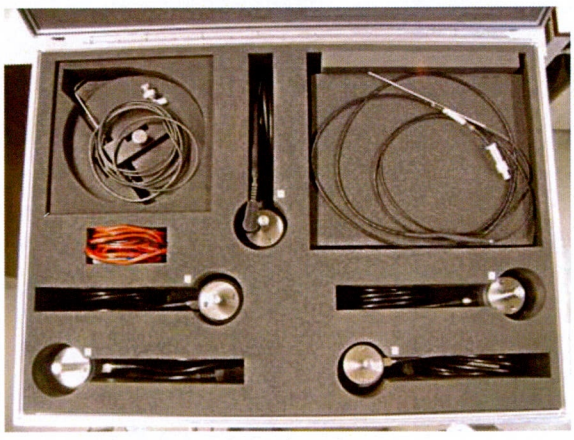
The transit case for the Driver of the Portable Power Standard.

The case shown above contains:

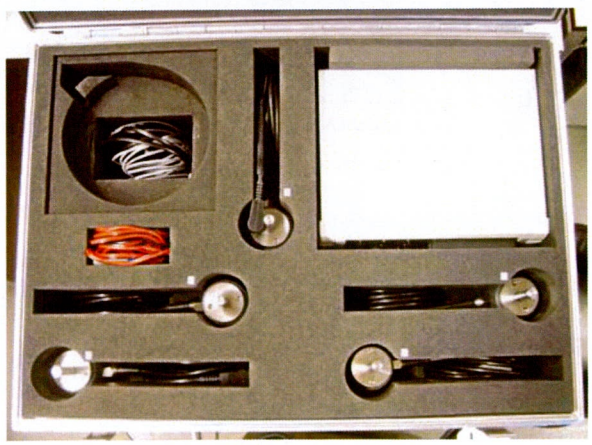
- the Driver of the Portable Power Standard (PPS),
- a mains power cable

The case shown below contains:

- the five ultrasound transducers (applicator heads),
- the Cavitation Detector (CD),
- a connection cable to connect the Cavitation Detector to the Driver
- the Cavitation Detector sensor,
- a temperature probe,
- a transducer and probes mounting block,
- a battery charger for the Cavitation Detector
- a mains power cable for the charger



A



B

The transit case for the transducers and Cavitation Detector. After un-packing the top layer (see A) the separation sheets should be taken away to un-pack the other equipment (see B)

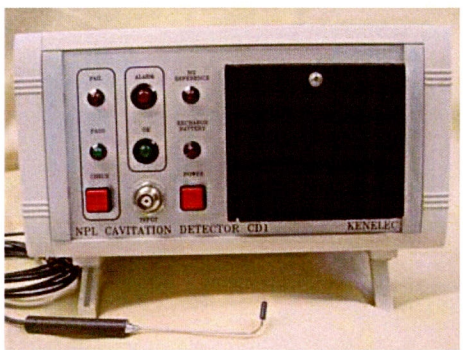
1.2 Inspection

Check whether there are indications of damage during the transport, e.g. an activated shock sensor on the back of the PPS Driver.

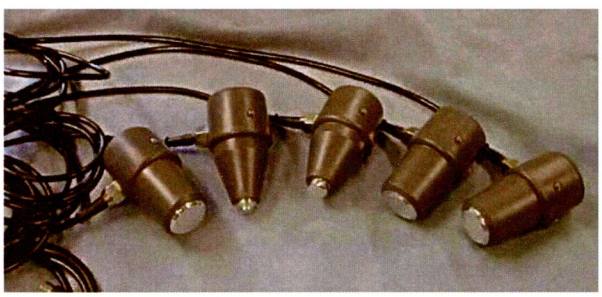
1.3 The equipment

The photographs below show the equipment that together forms the set-up to perform the calibration and proficiency tests.

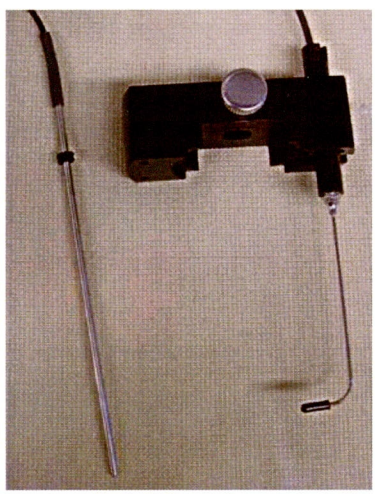
The driver of the Portable Power Standard



The Cavitation Detector



Ultrasound transducers to be used for calibration



Mounting of transducer, temperature probe and CD sensor

2 Precautions

2.1 Ventilation – Fan Forced

It is important that at least 100 mm clearance is given to the fans located on the left and right hand side panels of the PPS.

2.2 Temperature Limits During Use

Do not leave the PPS or the transducers sitting in the sun or exposed to frost and snow.

The Driver, the ultrasound transducers and the CD should only be used in the room temperature range 19 °C – 25 °C.

The PPS logs its internal temperature regularly.

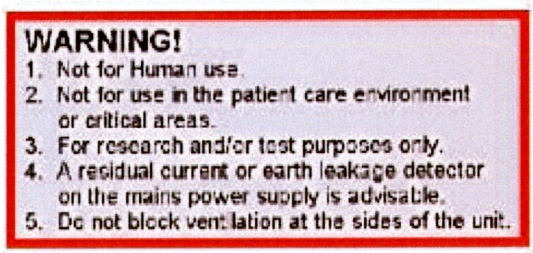
The external temperature probe is used to monitor the temperature of the water bath in the ultrasound power meter.

2.3 Connection to 110-250 V AC mains supply

The devices are intended for connection to a 110-240 V AC mains supply. It is highly advisable to use a residual current or an earth leakage detector with the Driver, in accordance with good laboratory and industrial practice for work with water.

2.4 Warnings

Please note the warnings on the top panel of the PPS.



2.5 Safety aspects

This device shall not be used in Medical locations and associated area defined as such in the IEC 60364-7-710 (2000) standard.

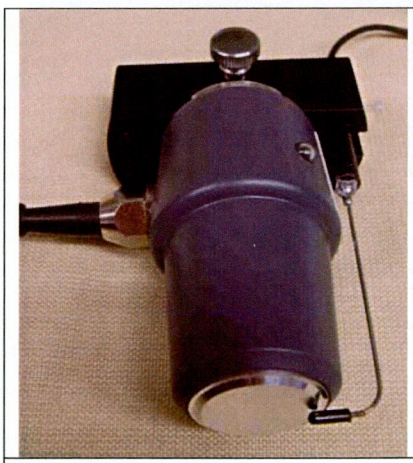
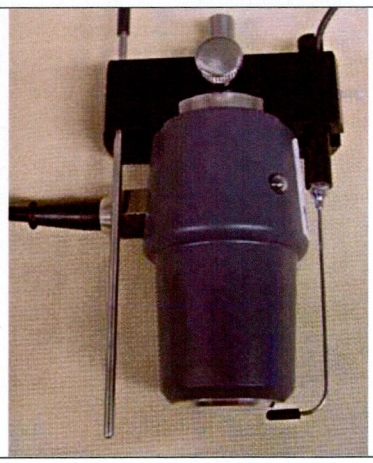
Due to the nature of the device it may emit electro magnetic fields. The user should be aware that this may affect other devices in the area.

The device has openings in its cover, e.g. position of the fan, where water can easily enter the device. One should be careful not to spill water.

The device is able to produce a high level of ultrasonic energy. If transferred into human tissue this energy is harmful. In addition, if the transducer is switched on in air the emitting surface may become hot. Consequently never touch the front of the transducer when the "power on" signalling lights on the transducer housing are on.

3 SETTING UP

3.1 Mounting the Hydrophone and temperature probe

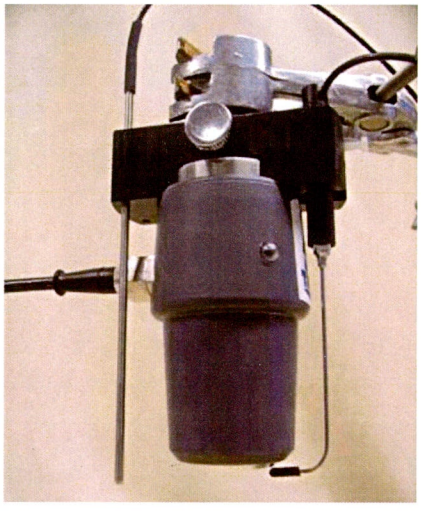
		
1. As found in the transport case, the hydrophone and the mounting plate are already mounted.	2. The hydrophone should be turned 90°, by unscrewing the nylon retention screw by hand, rotating the hydrophone, and then re-tightening the screw.	3. Mount the transducer into the block, pushing the rod and disc assembly firmly into the recess and tighten the metal screw.
		
4. Next the hydrophone should be turned back 90° by reversing Step 2. **Important: see NOTE 1 below**	5. Now the temperature probe can be mounted. Use one of the 4 holes in the mounting plate.	6. The little ring on the temperature probe can be used to adjust the depth of the probe. **Important: see NOTE 2 below**

NOTE 1: Move the hydrophone sleeve through the block until the tip of the hydrophone is 1 - 2 mm below the radiating faceplate, and angled towards the geometric centre of it.
For the transducers with the smaller face, the hydrophone tip will be in the same vertical position.
Do not bend the hydrophone closer to the transducer face.

NOTE 2: The procedure above has to be repeated for all 5 transducers. Do not forget to rotate the hydrophone through 90° before the transducer is dismounted in each case

FINALLY: The overall assembly can be supported for use with the power meter using a laboratory clamp and stand, gripping onto the transducer rod. However this may be unwieldy. In that case use the power meter clamp to grip the upper part of the ultrasound transducer gently. Be careful to not distort the hydrophone or the transducer case.

NOTE 3: Movement of the assembly will affect the power measurement.



NOTE 4: If the geometry of the power meter does not allow for the hydrophone holder to be used, it is recommended that the hydrophone be positioned using a separate mounting arrangement. Pass the angled end of the hydrophone through the top hole in the block and *gently* pull through. The black sleeve on the end of the hydrophone can stay attached to the hydrophone. When mounted independently from the transducer, the hydrophone tip must be 1 - 2 mm below the output face of the transducer and coincident with the edge of the faceplate. The tip shaft must be orientated towards the geometric centre of the faceplate.
When the block is not used the temperature probe should be mounted in the power meter bath by other means.

3.2 Panel Connections

- Ensure that the Driver and CD are both turned OFF.
- Connect the three-way plug to the socket marked "ALARM OUT" on the CD. The other end of the cable must be inserted in the top panel socket on the PPS, marked "Cavitation Detector".
- Once the hydrophone has been mounted in position, connect the hydrophone BNC to the socket marked "INPUT" on the front panel of the CD.

- Plug in the temperature probe into the PPS before turning it on.
- Connect the battery charger of the CD to its socket marked "CHARGER" – this plug has a locking clip at the top. Connect the battery charger to the mains supply.
- Connect the PPS to the mains supply.

3.3 Operation

Switch the CD on - the "NO REFERENCE" and "OK" LED's should illuminate. The CD should be left for 30 minutes so that the internal electronics may equilibrate.

Switch the Driver on.

When the transducer/hydrophone combination is located in the power meter, start the PPS procedures. See Section 4.3 and 4.4.

NOTE: When a 1MHz transducer is turned on, the "NO REFERENCE" LED on the CD should immediately extinguish.

When measurements are complete, switch off the CD and Driver and disconnect everything. To replace the component parts into the transit case, reverse the initial set-up procedure.

4 OPERATION

4.1 Introduction

Access to the PPS is controlled by the use of single use passwords and maximum session times for each password. Passwords enabling access to the different operating modes will be provided by the Reference Laboratory.

NOTE: There is an Error and Glossary of Terms lists in Section 5 and 6.

The performance ranges of the transducers supplied by the Reference Laboratory are:

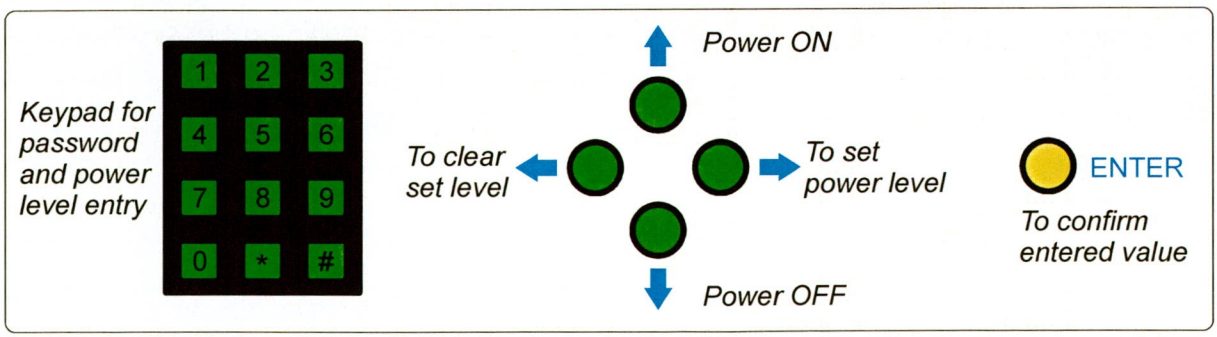
Transducer	Frequency	Effective radiating area	Beamtype	*ka*	Power range
	Nom (MHz)	A_{er} (cm^2)			(W)
1	3.0	0.4	collimating	43	0.1 – 3.0
2	3.0	3.4	collimating	72	0.1 – 15.0
3	1.0	0.9	diverging	22	0.1 – 3.0
4	1.0	3.4	collimating	43	0.1 – 15.0
5	3.1	0.8	collimating	57	0.1 – 3.0
NOTE: The values in the table can be used for correcting measurement results.					

All transducers are continuous wave; there are no duty cycle or pulse regime options.

The power output displayed for all transducers has been calibrated against, and is traceable to, National Standards.

4.2 Keyboard Entry & Syntax

Text which is displayed on the upper panel of the PPS is shown below. This will also be used for the commands given by the keyboard.



Upper panel of the PPS Driver.

- Keyboard Entry: this is done using the numerical keypad. For the entry of numerical values (e.g. the transducer power) the value should be entered followed by the ENTER button. The * key on the keypad is the decimal point.
- ← button enables wrongly entered numbers to be erased. This includes the passwords to assess the PPS.

- The button enables a new power level or a new transducer.
- The (on) (off) button toggle the power on and off.
- Lights on the transducer are set to turn on whenever the ultrasound is on.
- To reversly back up a menu, simply press the ENTER button.
- Exit from a Calibration / Tutorial mode or Proficiency Test session by pressing the # key on the keypad at the topmost menu.
- Error List: this is located at the end of this document.
- Glossary of Terms: this is located at the end of this document

4.3 Calibration / Tutorial mode

The tutorial mode enables familiarisation with the PPS, and power meter calibration.

NOTE: please read the General information in Section 2 carefully.

1. Turn on the PPS. At the prompt enter the 8 digit Calibration / Tutorial mode password provided by the Reference Laboratory and press ENTER.

2. The PPS will display:

   OUTPUT LEVEL = OFF

   CAV = Y IT = 27.5 °C
   BT=+22.2 °C TL=180min

   The numbers shown above are arbitrary examples.

   The Cavitation detector state is indicated by CAV = Y (yes) or N (no cavitation present).

   The internal temperature of the PPS is shown at IT =. The acceptable range is 22 °C – 35 °C. The internal temperature has a resolution of 0.5 °C only.

   The temperature of the probe which is placed in the ultrasound power meter's water bath is indicated at BT=. The acceptable temperature range is 19 °C – 25 °C.

   The time left in the Calibration / Tutorial mode session is indicated at TL=.

3. Plug in the appropriate transducer and ensure that the transducer face is fully immersed in the power meter water bath. Check for the items given in the Tips for Good Measurements section.

4. Press the button. The PPS will display:

   0/P Level (W)= 0.0 *This identifies the present output level*
   New Output (W)=
   Tx *X* *X stands for the transducer number connected*

ENTER to return

5. The transducer number should correspond to the device connected.

6. Input the desired power level by using the keypad and then press ENTER. The full number with the digit after the decimal point is needed eg 7.0, 12.3 or 0.6. If the wrong number is pressed, use the ← button to clear the number.
   Note that:
   - The power resolution is 0.1 W.
   - The transducers 1, 3 and 5 have a maximum power output of 3.0 W. Transducers 2 and 4 have a maximum power output of 15.0 W.
   - The maximum on period is 24 seconds. If this time is exceeded, the PPS will automatically switch the transducer off, and allow a 120 seconds cooling time before measurements can be resumed.
   - The transducer face **MUST BE** fully immersed in water; otherwise the PPS will switch the transducer off in the manner described above.

7. The display similar to step 4 will then be seen, but with the entered power level shown. The power can be turned on by pressing the ↑ button and then off by pressing the ↓ button. The power level selected will be displayed and the lights on the transducer will illuminate. The power can be turned on and off as many times as desired.

8. To input a new power level, go to step 6.

9. To use another transducer, go to step 3.

10. To exit the tutorial session press the # key on the keypad and then the ENTER key.

4.4 Proficiency test

The Proficiency Test is the proposed way to test organisations who provide calibration/testing services for ultrasound therapy machines. It is a "blind" test of the proficiency of a user to calibrate/test ultrasound therapy machines.

The five transducers must be connected to the PPS in the numbered sequence.

For each transducer there are four power levels, denoted by **L1, L2, L3** and **L4** on the PPS display.

The PPS monitors several aspects during the test:
- the immersion of the transducers
- whether the on time was exceeded
- the presence of cavitation
- the internal and external temperatures.

NOTE: please read the General information in Section 2 carefully.

1. Turn on the PPS. At the prompt enter the 8 digit Proviciency mode password provided by the Reference Laboratory and press ENTER.

2. The PPS will display: **Connect Transducer 1**

3. Plug in the appropriate transducer and ensure that the transducer face is fully immersed in the power meter water bath. Check for the items given in the Tips for Good Measurements section.

4. The PPS will display:

   Tx=1 Lvl=? Pwr= OFF
   Enter Power Level
   L1=5 L2=5 L3=5 L4=5
   BT=+21.1 °C TL=180min

   The above display is indicating that transducer 1 is connected (**Tx=1**).
   No power level has been selected (**Lvl=?**).
   The ultrasound power is off (**Pwr= OFF**).
   Five attempts are available for each of the four power levels (**L1=5 L2=5 L3=5 L4=5**).

   NOTE: An attempt ends by pushing the ENTER button.

   For **BT** and **TL** see the glossary or the Calibration / Tutorial mode section.

5. To select a power level press on the keypad number 1 or 2 or 3 or 4, corresponding to power levels **L1, L2, L3, L4.** The choice will show in **Lvl=?**.

6. Turn on the power using the button. To turn off use the button. The power may be turned on/off as many times as desired. Record the power meter result on the Report Sheet given at the end of this document.

   NOTE: Each power level should be measured at least twice and average value calculated.

7. To proceed to the next power level press ENTER so that the PPS can record some of its parameters. To make measurements of the next power level go to step 5. Repeat this if desired, up to a maximum of 5 times for each power level.

8. To proceed to the next transducer press the button, then press ENTER and go to step 3.
   OR in case to stop the test, go to step 10.

9. Repeat step 3 - 8 until all five transducers have been used. In case a transducer is not used repeat step 8.

10. At the end of the test press the # key and ENTER to exit and to display the report code. Write down the report code on the report sheet!

    NOTE: The information from the report code provides the Reference Laboratory with specific information to troubleshoot any problems that may have occurred so that they can be rectified.

11. Fax or email the signed and dated report sheet to the supplier of the PPS. Post the original report sheet.

12. Retain the PPS until instructed to return it.

5 ERROR LIST & TROUBLE SHOOTING

BT=0000
The external temperature probe was not plugged in when the PPS was turned on. Turn off the PPS, plug in the temperature probe and then turn on the PPS.

Erratic Response from the PPS
The PPS was acting normally but then becomes erratic or doesn't respond at all. Turn off the PPS and restart it. Use another password.

ERROR 1 Tx match!!:
The transducer is not fully immersed or a large bubble is present. The PPS cannot be used for 2 minutes whilst the transducer cools down. Immerse the transducer face FULLY and check for bubbles. If the problem persists use another power level and notify the supplier of the PPS of the conditions when the problem occurred.

ERROR 2 Tx Cooldown:
The power on time for the transducer has been exceeded (>24 s). The PPS cannot be used for 2 minutes whilst the transducer cools down.

ERROR 3 Wrong Tx!!:
There is a problem with the transducer:
There is no transducer plugged in.
OR
The wrong numbered transducer is plugged in.
OR
The transducer is plugged in the wrong way. The cable should pass over the REAR of the PPS, not over the front panel.
OR
The transducer is faulty, please proceed to another transducer and notify the supplier of the PPS of the problem.

No Response from PPS
The PPS does not respond to anything. Turn off the PPS and restart it. Use another password.

Unexpected results from transducer 5
Transducer 5 is a special design that operates at 3.1 MHz. If unexpected results are obtained, e.g. negative or very high readings, it is likely that the power meter being used has very poor EMI screening. This will require attention to screening or limits to be placed on what ultrasound transducers the power meter may calibrate.

Transducer recognition
In case the screen shows a Tx6 then the transducer connected has been improperly recognised. Switch off the driver and contact the Reference Laboratory.

6 GLOSSARY

Applicator Head: in this document the ultrasound transducer is sometimes referred to as an *applicator head*, which is the normal term used in the physiotherapy and manufacturing community.

BT= the temperature of the probe which is placed in r ultrasound power meter's water bath. The acceptable temperature range is 19 °C – 25 °C.

CAV = The presence or absence of cavitation in the water by CAV = Y (yes) or N (no cavitation present).

CD: Cavitation Detector.

ENTER: the yellow button which is pressed to enter a number or to reverse r way back up a menu

IT = the internal temperature of the PPS. The acceptable range is 22 °C – 35 °C. The internal temperature has a resolution of 0.5 °C only.

Lvl= indicating the power level which has been selected during the proficiency test. The choices are 1, 2, 3 or 4 corresponding to the power levels **L1, L2, L3 and L4**.

L1=5 L2=4 L3=2 L4=0 the number of remaining attempts in each of the 4 power levels (L1, L2, L3 & L4) of the proficiency test. In this example 5 more attempts remain for L1, 4 attempts left for L2, only 2 attempts left for L3 and L4 is finished.

New Output (W)= the new power level which is being entered via the keypad in the Calibration / Tutorial mode.

0/P Level (W)= the power output level presently active in the Calibration / Tutorial mode.

OUTPUT LEVEL= the ultrasound power level from the transducer in the Calibration / Tutorial mode. OFF is shown when no power is being outputted.

PPS: the ultrasound Portable Power Standard.

Pwr= indicating whether the ultrasound power is ON or OFF during the Proficiency Test.

TL= the time left in the Calibration / Tutorial mode or the Proficiency Test.

Tx= the transducer number being used in the Proficiency Test.

Transducer: commonly called an applicator head in the physiotherapy and manufacturer community. It is used to apply the ultrasound to the power meter or patient.

Annex F - A Cavitation detector

F – A.1 Cavitation Detector (CD)

F – A.1.1 Why Monitor Cavitation?

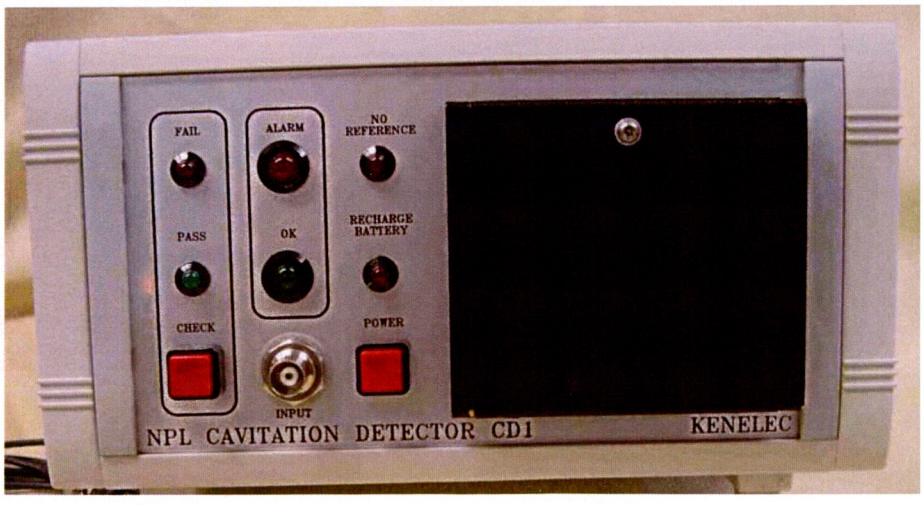
For applications of therapy ultrasound, cavitation is the formation and collapse of fine (<0.5 mm) bubbles in water by ultrasound. These fine bubbles can grow to >1 mm and lead to errors of up to 50 % in the ultrasound power measurement. Cavitation presents itself most commonly when there is a high dissolved gas content in the water and/or fine particles are present: such as with cold tap water.

The Cavitation Detector (CD) is used with the Portable Power Standard (PPS) to alert the user to the presence of cavitation occurring in the water bath during power measurements.

F – A.1.2 Principle of Operation

Cavitation bubbles produced and excited at 1 MHz will radiate a broad spectrum of acoustic radiation into the water. Cavitation has not been observed for high quality physiotherapy applicator heads of 3 MHz. The CD's purpose is to alert the user to the presence of cavitation activity occurring, which may then affect the accuracy of power measurements. It does this by measuring the cavitation induced by acoustic radiation in the water at 1.5× the fundamental frequency of the physiotherapy transducer. At a narrow bandwidth about this frequency (1.5 MHz) the detection of cavitation was found to be the most reliable. So the CD is effectively an RF Voltmeter with a very narrow bandwidth tuned to a nominal centre frequency of 1.5 MHz, but with frequency tracking circuitry onboard to ensure that any cavitation activity occurring is detected.

F – A.2 Front panel controls and indicators



F – A.2.1 power button

This switches the CD on and off. When the device is first turned on the "OK" and the "NO REFERENCE" lights should both illuminate.

F – A.2.2 input bnc connector

The supplied hydrophone is connected to the CD via the INPUT BNC.

F – A.2.3 check button

Allow the CD to warm up for 30 minutes and then press the CHECK button. The green PASS light should illuminate to show that the CD internal tests have all passed. If the FAIL light shows then contact the Reference Laboratory.

F – A.2.4 alarm light

It will illuminate if cavitation is detected by the hydrophone above a pre-set threshold.

F – A.2.5 no reference light

If this illuminates then it means that the CD hydrophone cannot detect the 1 MHz signal through the water from the ultrasound transducer.

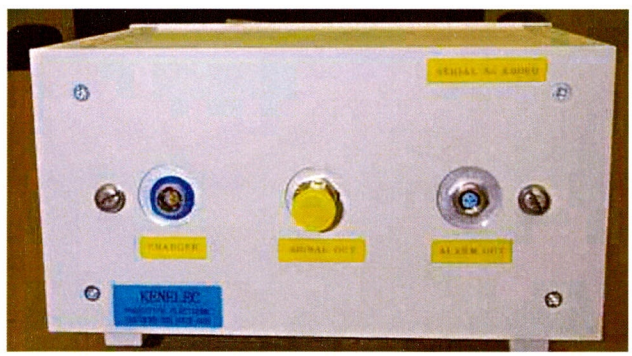
F – A.2.6 recharge battery light

When this illuminates, the battery needs to be charged. See the rear panel description for where to connect the battery charger. The CD can be used whilst the battery is recharging.

F – A.2.7black panel

This part of the front panel is housed behind a secured panel. It should not be opened and is secured with a calibration sticker. Behind the panel are adjustment controls.

F – A.2 Rear panel



F – A.3.1 charger

The CD can be run on its internal batteries until the front panel "RECHARGE BATTERY" light illuminates. The mains supply charger should then be used to recharge the CD until the light turns off. The CD can be used whilst the battery is recharging.

F – A.3.2 signal out

This BNC connector can be used to monitor the level of cavitation, and is intended for expert users only. Contact the Reference Laboratory for further information.

F – A.3.3 alarm out

This is the connection to the Portable Power Standard (PPS). It indicates to the PPS when cavitation is detected. The PPS will record every cavitation event. If the CD and PPS are not connected, then the PPS records continuous cavitation which is not a desirable indicator for a good Proficiency Test.

The cable with the 3-pin plugs at either end is used to connect the CD with the PPS. ***Both the CD and the PPS must be turned OFF when the cable is connected.*** The socket for connection on the PPS is located on the top panel and marked "Cavitation Detector".

Annex F - B Tips for Good Measurements

F – B.1 Room and Water Temperature

19 °C – 25 °C.

F – B.2 Water

It is advisable to use distilled or deionised water that has been degassed. Tap water is NOT advisable since it will have a high dissolved gas content from being cold and under pressure in the water supply. High dissolved gas content will cause problems due to the formation of bubbles when ultrasound at higher powers is applied to it.

NOTE: For appropriate degassed water the level of dissolved oxygen should be < 4 mg/l. Depending on the dimensions of the water bath an oxygen level of 3 mg/l rises, in normal water, in 1.5 hours to 4 mg/l. In case sodium sulphate is used to bind the oxygen the level stays low for a much longer period. See the literature references in Annex F-E.

F – B.3 Draft Exclusion

Drafts of air can affect the output of some ultrasound power meters. Common sources of drafts are overhead fans or the close proximity of an air-conditioning outlet. A large cardboard box over the power meter and transducer will eliminate the effect of drafts. A plastic window in the cardboard box is needed so that the display of the power meter can be read.

F – B.4 Power Meter Checks

1. Read the manufacturer's instructions.
2. Check that have followed the manufacturer's guidelines for calibration or be prepared to use the PPS' Calibration / Tutorial mode to calibrate r power meter. Does the calibration depend on the frequency, the divergency factor or radiating area of the transducer?
3. Check water level reservoirs and top up if necessary.
4. Those power meters with membranes in front of the target should be checked to ensure that the membrane is flat, to within a couple of mm, and in good condition.
5. The power meter is levelled, if required by the manufacturer
6. Mount on an independent solid bench to reduce the effect of vibration from equipment with fans etc. Also fix the transducer cables to avoid such influence through the transducer.

F – B.5 Power Meter Technique

1. Obtain a small paint brush and bend the end to a right angle. The brush can be used to brush the face of the immersed transducer. A small inspection mirror (like a dental mirror or mechanic's inspection mirror) is useful for checking for bubbles on the face of the transducer.
2. If the power meter's target is open to access, it should also be brushed down lightly with the brush once it has been immersed. Brush the upper and lower surfaces to ensure all bubbles are removed.

3. If the power meter is a sealed system with a membrane in front of the target, ensure that the membrane is lightly brushed down after immersing in water.
4. It is desirable to have the transducer face as close as possible to the power meter target, 5-10 mm. This may not be possible for power meters that supply positioning rings for the transducer or have a membrane in front of the target. If this is the case then endeavour to have a reproducible distance, within a couple of mm
5. Tape or clamp the cable of the transducer down to the bench.
6. In the case of a convex conical target the transducer faceplate should be centralised over the target apex to within +/- 2 mm. This can be performed with the naked eye, and is adequate for transducers complying to the IEC 61689 standard. When using an absorbing target balance, it is good measurement practice to similarly align the central axis of the transducer faceplate with the centre of the balance target.
7. A power meter equipped with a reflecting target always needs lateral absorbers, see IEC 61161.
8. To lessen the effects of thermal drifts on measurement accuracy, measurements from both OFF to ON and ON to OFF should be made, and an average value calculated.

F – B.6 Power meter styles that can often give irregular performance are:

1. The target has a rounded tip at the apex of the cone. The tip of the cone should be sharp so that the target geometry is constant over the full extent of the ultrasound beam.
2. Conical reflecting targets or targets that consist of a 45 ^{o} plate/s may have difficulty dealing with less than ideal beam cylindrical symmetry due to the radiation force measurement mechanism.
3. Concave geometry target: these targets can reflect ultrasound energy back into the transducer. Most modern ultrasound physiotherapy machines will shut down if the transducer is subjected to high levels of reflected ultrasound. A bad acoustic load will also give the same response; such has removing the transducer from water or the patient.
4. Absorbing targets that do not comply to the requirements given in the IEC 61161 standard. Absorbers are theoretically very attractive but can be highly variable in performance. Their evaluation and construction is a complex and time consuming task.
5. The use of membranes in front of the target. Membranes often have frequency variable transmission properties in the range of interest. Their properties also tend to vary with time.
6. Poor electromagnetic screening within the power meter.

F – B.7 Positioning of the transducer to the target

The reproducibility of a measurement and the accuracy of the final (averaged) result is most affected by the positioning of the transducer to the target in the power meter. Probably the most time efficient technique is to:

a) Set up a transducer in the power meter.
b) Run through all the desired power levels once,
c) Remove the transducer from the power meter and place it back again, readjusting the transducer clamping mechanism to the power meter.

d) Repeat two to five times, steps (a) to (c) for an applicator head.

It is not unusual to see the range of results from transducer repositioning being in the order of 10 % to 20 %. The most accurate result is then obtained from the average of a number of measurements, say 3 to 5.

The technique of raising the transducer out of the water whilst it is running in order to "clear the head" for an adverse reading, should be avoided. Such a practice can reduce the lifetime and change the calibration of the transducer. Modern Physiotherapy units (and this one) have automatic cut offs when the applicator head has insufficient contact with the patient or is not immersed.

Annex F - C Addresses Reference Laboratories

Institute for Applied Scientific Research (TNO)
TNO Quality of Life
Attn. R.T. Hekkenberg
Zernikedreef 9, 2333 CK, Leiden, The Netherlands

Tel: +31 (71) 518 1242
Fax: +31 (71) 518 1902
Email: RT.Hekkenberg@pg.tno.nl

Physikalisch-Technische Bundesanstalt (PTB)
Department 1.6: Sound
Attn. K. Beissner
Bundesallee 100
D-38116 Braunschweig, Germany

Tel: +49 531 592 1431
Fax: +49 531 592 9292
E-Mail: Klaus.Beissner@ptb.de

National Physical Laboratory (NPL)
Quality of Life Division
Attn. M. Hodnett
Hampton Rd, Teddington, Middlesex, TW11 0LW
United Kingdom
Tel: +44 (0)208 943 6365
Fax: +44 (0)208 943 6161
Email: Mark.Hodnett@npl.co.uk

Annex F - D Proficiency Test Report Sheet

F – D.1 Introduction

Following this page is the Report Form. Please feel free to photocopy it.

The table is used to record the individual results obtain during the Proficiency Test. The average column is used to calculate the average of the results for a particular power level of a transducer.

In case problems are encountered or there is any question then contact:

Person: .....
Reference Laboratory: .....
Address: .....

Tel: +.....
Fax: +.....
Email: .....

FAX TO: + ……..
Attention of:…….., Reference Laboratory: …….. EMAIL TO:

PROFICIENCY TEST REPORT SHEET

Name of Tester:

Organisation / Company:

Ultrasound Power Meter

Model:

Manufacturer:

Serial Number:

Password Number:

PROFICIENCY TEST RESULTS (Measured Power)

TRANSDUCER 1						Average
L1						
L2						
L3						
L4						

TRANSDUCER 2						Average
L1						
L2						
L3						
L4						

TRANSDUCER 3						Average
L1						
L2						
L3						
L4						

TRANSDUCER 4						Average
L1						
L2						
L3						
L4						
TRANSDUCER 5						Average
L1						
L2						
L3						
L4						

Report Code: **← do not forget to complete !!!!!!**

Signature:

Time and Date:

Annex F - E Useful Literature

"Ultrasonic Power Measurement in Liquids in the Frequency Range 0.5 MHz to 25 MHz." IEC 61161:1992/Amd.1:1998.

"Ultrasonics – Physiotherapy Systems – Performance Requirements and Methods of Measurements in the Frequency Range 0.5 MHz to 5 MHz.", IEC 61689:1996.

"Medical Electrical Equipment – Part 2.5: Particular Requirements for Safety – Ultrasonic Physiotherapy Equipment.", IEC 60601-2-5:2000.

R.T.Hekkenberg, K.Beissner, B.Zeqiri, Therapy-level ultrasonic power measurement, Final Technical Report, EC project SMT4-CT96-2139, European Commission report EUR 19510, ISBN 92-828-9027-9, 2000.

R.T.Hekkenberg, K.Beissner, B.Zeqiri, Guidance on propagation medium and degassing for ultrasonic power measurements in the range of physiotherapy-level ultrasonic power, EC project SMT4-CT96-2139, European Commission report EUR 19511, ISBN 92-828-9838-5, 2000.

R.T.Hekkenberg, K.Beissner, B.Zeqiri, R.A. Bezemer, M. Hodnett. Validated ultrasonic power measurements up to 20 W, Ultrasound in Med. & Biol. Vol. 27, No.3, pp.427-438, 2001

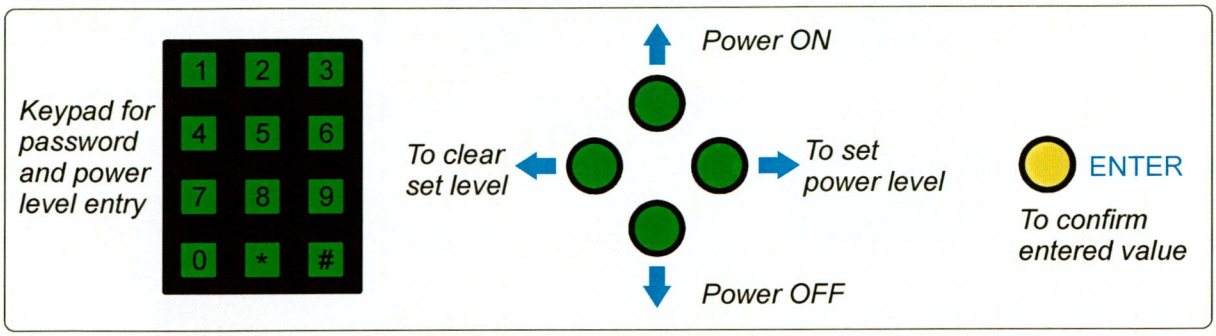
S. Pye & B. Zeqiri, "Guidelines for the Testing and Calibration of Physiotherapy Ultrasound Machines", The Institute of Physics and Engineering in Medicine 2001, Report 84, PO Box 303, York YO31 2WR, United Kingdom. www.ipem.org.uk

Annex G QUICK REFERENCE: CALIBRATION/TUTORIAL

This guide requires that the user follows the procedures and requirements of Sections 1-3 in the PPS User Manual, and that the power meter being used is set up and working.

MODE

DRIVER CONTROLS – CALIBRATION/TUTORIAL MODE:



11. Turn on the driver, enter the Calibration/Tutorial mode 8 digit password using the keypad, and press ENTER. If the wrong number is pressed, use the ← key to clear the password and re-enter.

12. The driver display will show the following (the numbers are arbitrary examples):

OUTPUT LEVEL = OFF
CAV = NIT = 27.5°C *This shows No Cavitation, and an internal driver temperature of 27.5 ℃*
BT=+22.2°C TL=180min *This shows a bath temperature of 22.2 ℃ and 180 min left in the session*

13. Plug in one of the transducers supplied and ensure that the transducer face is fully immersed. Check for the items given in the Tips for Good Measurements section.

14. Press the → key. The driver will display:

0/P Level (W)= 0.0 *This identifies the present output level*
New Output (W)=
Tx *X* *The transducer number(X) should correspond to the device connected.*
ENTER to return

Enter the desired power level by using the keypad: the * is the decimal point, and then press ENTER. The driver requires the digit after the decimal point to be included, e.g. 7.0, 12.3 or 0.6. If the wrong number is pressed, use the ← key to clear the number and re-enter. The display as shown in step 4 will then be seen again, but now with the entered power level shown. NOTE: For transducers 1, 3, 5, the maximum power level is 3.0 W. For transducers 2, 4: the maximum power level is 15.0 W.

15. The transducer can then be powered by pressing the ↑ key, and then off by pressing the ↓ key. When energised, the lights on the transducer will illuminate. The power can be turned on and off as many times as desired. NOTE: The maximum 'on' period is 24 seconds, after which the driver automatically switches the transducer off for 120 s. The transducer face MUST BE fully immersed in water.

16. To input a new power level, repeat step 5.

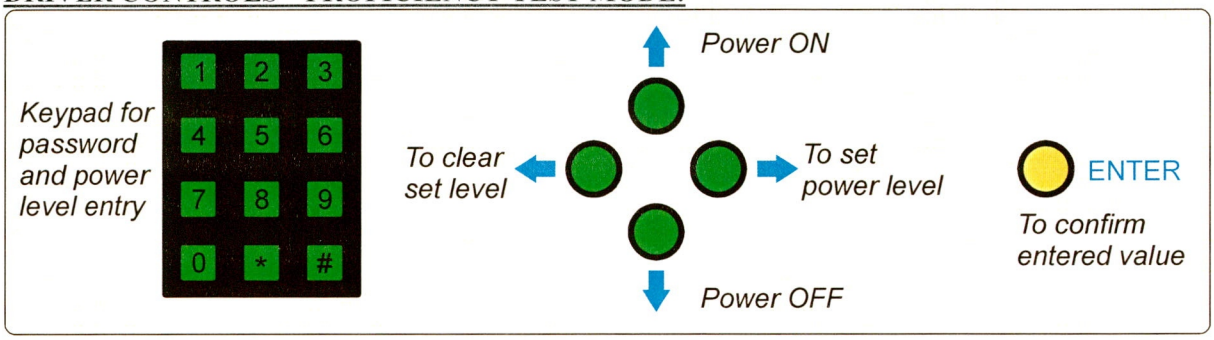
17. To use another transducer, go to step 3.

18. To exit the tutorial session press the # key on the keypad and then press ENTER.

QUICK REFERENCE: PROFICIENCY TEST MODE

This guide requires that the user follows the procedures and requirements of Sections 1-3 in the PPS User Manual, and that the power meter being used is set up and working.

DRIVER CONTROLS – PROFICIENCY TEST MODE:



1. Turn on the driver, enter the 8 digit Proficiency Test password using the keypad and press ENTER. If the wrong number is pressed, use the ← key to clear the password and re-enter.

2. The driver will display: **Connect Transducer 1**. Plug in transducer 1 and fully immerse the transducer face in the water.

3. The driver will then display:

Tx=1 Lvl=? Pwr= OFF	*Transducer 1 is connected; no power level has been set*
Enter Power Level	
L1=5 L2=5 L3=5 L4=5	*Five attempts remain for each of the four power levels*
BT=+21.1°C TL=180min	*This shows a bath temperature of 22.2 °C and 180 min left in the session*

4. To select a power level, press number 1 or 2 or 3 or 4 on the keypad, to select power level **L1, L2, L3,** or **L4** respectively**.** The selection will then be shown on the screen, as **Lvl=1**, for example.

5. The transducer can then be powered by pressing the ↑ key, and then off by pressing the ↓ key. When energised, the lights on the transducer will illuminate. The power can be turned on and off as many times as desired. NOTE: The maximum 'on' period is 24 seconds, after which the driver automatically switches the transducer off for 120 s. The transducer face MUST BE fully immersed in water. Record your power meter's result on the Report Sheet provided.

6. To proceed to the next power level, press ENTER so the driver can record some of its parameters. The next power level can then be selected as described in step 4. Each power level can be selected up to a maximum of 5 times.

7. To proceed to the next transducer press the → key, then press ENTER and go to step 3. If desired, the test may be stopped by proceeding to step 9.

8. Repeat step 7 until all five transducers have been used. If a particular transducer is not required to be used, press ENTER to skip to the next transducer.

9. At the end of the test press the # key and then press ENTER to exit and to display the report code.

10. Write down the report code on the report sheet, sign and date it, and fax or email the report sheet to the supplier of the PPS.

Guide for the maintenance of ultrasound physiotherapy systems

R.T. Hekkenberg([1]), K.Beissner([2]), B. Zeqiri([3]), A.Richards([4]), R.A.Bezemer([1]) and M. Hodnett([3])

([1]) Netherlands Organisation for Applied Scientific Research (TNO), NL

([2]) Physikalisch-Technische Bundesanstalt (PTB), DE

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([4]) Commonwealth Scientific and Industrial Research Organisation (CSIRO), AU

Annex H

Final Technical Report
Contract No: G6RD-CT-2001-00600

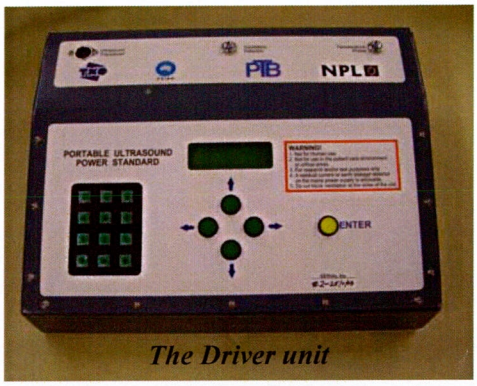
This guide is published as a separate document.

Annex I

Final Newsletter on EC project
Transfer standard device for ensuring the accurate calibration of ultrasonic therapy machines in clinical use.

⇨ *PORTABLE POWER STANDARD NOW AVAILABLE* ⇦

INTRODUCTION. The Portable Power Standard that has been developed in a European collaborative project is now ready for use. It consists of a Driver, five transducers (treatment heads) and a Cavitation Detector. The Portable Power Standard would be suitable for conducting in-the-field proficiency testing of small companies, hospitals and manufacturers undertaking routine ultrasound physio-therapy machine testing. It can also be used for tutorial and calibration purposes. Those active in this field are encouraged to use the tool to provide for a traceable calibration of their equipment.



The Driver unit

The Driver unit contains an electrical signal generator and programmable power amplifier to drive the ultrasound transducers. The unit can drive the full set of transducers described. The internal programmer stores signals from the Cavitation Detector and the temperature probe to measure the water bath temperature.

The Cavitation Detector's purpose is to alert the user to the presence of cavitation activity occurring, which may then affect the accuracy of power measurements. Cavitation bubbles produced and excited at 1 MHz will radiate a broad spectrum of acoustic radiation into the water. This is measured by the sensor that transfers the ultrasonic signal into an RF voltage. So, the Cavitation Detector is essentially an RF Voltmeter with a very narrow bandwidth tuned to a nominal centre frequency of 1,5 MHz.

The Cavitation Detector

Five transducers comprise the set used with the Portable Power Standard, and these are representative of treatment heads used in clinical practice. The set includes one transducer exhibiting an unusual output as a negative control.

Nominal specifications of transducers used in the Portable Power Standard					
Transducer	Frequency (nom)	Effective radiating area	Beamtype	*ka*	Power range
	(MHz)	A_{er} (cm^2)			(W)
1	3,0	0,4	collimating	43	0,1 – 3,0
2	3,0	3,4	collimating	72	0,1 – 15,0
3	1,0	0,9	diverging	22	0,1 – 3,0
4	1,0	3,4	collimating	43	0,1 – 15,0
5	3,1	0,8	collimating	57	0,1 – 3,0


Ultrasound transducers to be used

Contact details of institutes that offer the Portable Power Standard on a short term rental basis are:

In the Netherlands: TNO Quality of Life, Zernikedreef 9, 2333 CK, Leiden, The Netherlands,
☎ +31 (71) 518 1242, Email: RT.Hekkenberg@pg.tno.nl

In Germany: Physikalisch-Technische Bundesanstalt, PTB, Bundesallee 100, D-38116, Braunschweig, Germany
☎ +49 (531) 592 1431, Email: Klaus.Beissner@ptb.de

In the United Kingdom: National Physical Laboratory, NPL, Hampton Rd, Teddington, TW11 0LW, United Kingdom
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European Commission

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