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# 15TH EUROPEAN CONGRESS OF Ultrasound First Joint Scandinavian Meeting 27-30 April 2003 - Copenhagen





### **EFSUMB** EUROPEAN FEDERATION OF SOCIETIES FOR ULTRASOUND IN MEDICINE AND BIOLOGY

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# **EFSUMB NEWSLETTER EDITORIAL**

This is the first edition of the Newsletter under new editorship. My predecessor Hylton Meire had undertaken this task with considerable enthusiasm for a number of years previously and leaves the Newsletter in a sound position although as you will notice from the lack of advertising, the previous sponsors have unfortunately after supporting the Newsletter so well for a



period of time felt the need to move on. New funding initiatives are being sought out and a number of other options for production of the Newsletter are being considered over the next few months.

It is also a sad time for the Federation to have to announce that December 2002 saw the last edition of the European Journal of Ultrasound in its current format. Again a number of other options are being considered for the future so that hopefully the title can continue but in a different way in the future.

On a brighter note you will have noticed the new type face used and the change in layout of the Newsletter. As well as the usual popular items including news from the various Officers of the Federation, I hope to include new features in the future and would be very happy to receive suggestions from the membership as to what they would like to see in the Newsletter in the future.

The next Newsletter will follow Euroson in Copenhagen which looks to be a very stimulating meeting and with planning for next year's meeting in Zagreb also going very well the Federation goes from strength to strength.

#### David W Pilling Editor EFSUMB Newsletter

### **REPORT FROM THE PRESIDENT**



After 100 days in office, a political government is subjected to evaluation: one adds, subtracts, makes a balance, judges and weighs the achievements made to date. It is most fortunate that the Managing Board of Directors of a medical society does not have to undergo the same process, even after almost six months into its term. For it seems that we still have not identified the "rogue nations" in our society, and we still have not yet declared war on anyone, nor has anyone threatened us with war. Perhaps we are too unimportant politically - or perhaps our society's almost-empty treasury is just not attractive enough. Maybe we should change our society's orientation and, for example, only use a lipophilic, oily ultrasound gel instead of one that is hydro-

philic. Our spectrum of thoughts might possibly function differently and be even more spectacular. Naturally, the Executive Bureau has established its strategy, not as military as it possibly could have been, but rather in the shape of a business plan for the current term of office. The Executive Bureau met at a conference that helped us sort out the impending problems of the Federation, to accordingly weigh our priorities, and to plan solutions to solve these problems.

The direction and orientation of the EUROSON Congresses remains of central importance to us. We thus extend to all of you the most cordial of invitation to attend the 15th European Congress of Ultrasound and the 1st Joint Scandinavian meeting that will be held on April 27–30, 2003 in Copenhagen. The scientific program is almost finalised and it promises to be most interesting. In addition to the open scientific contributions, more than 75 invited speakers will lecture on all current topics in diagnostic ultrasound. Safety aspects as well as the new information technology (IT) are of special interest for EFSUMB. In addition, numerous refresher courses will be offered. Standing side-by-side with the scientific program is the social program where friendships are made and rekindled. I would like to take this opportunity to recognize the local organizers and express our thanks to Michael N. Bachmann and the rest of the crew.

Preparations are already running at full speed for the next EUROSON Congress 2004 to be held June 6–9, 2004 in Zagreb. And still to come in February, the EUROSON Committee will meet with Ivan Drinkovic and his colleagues in Zagreb. Perhaps you would likewise be interested in knowing that the Organization Committee of the EUROSON Congress 2005 (September 23–29, 2005) is already up and running in Geneva. The EUROSON Congress is indispensable EFSUMB and should increasingly be, for all our members, the main event of the year.

I am pleased to report that the various Committees of the EFSUMB are quite active. With impressive regularity, the Safety Committee (ECMUS) organizes independent sessions at the Euroson Congresses. Here in this newsletter as well you will find objective opinions, and I would heartily recommend their reading.

EFSUMB Officers and Committees	2
EFSUMB newsletter Editorial	
Report from the President	3
Report from the Honorary Secretary	4
Report from the Publication Committee	4
Report from the Honorary Treasurer	4
Report from the Swedish Society of Medical Ultrasound	5
Education and Professional Standards Committee	6-7
Minimum Training Requirements for the Practice of	
Medical Ultrasound in Europe	
Euroson Lecture by Dr Francis Duck	8–11
"Working Towards the Boundaries of Safety"	

David Pilling has admirably taken over the chairmanship of the Publication Committee. This is certainly not a simple task – on the one hand, because his predecessor, Hylton Meire, set high expectations, and on the other hand, due to the growing importance of communication among the EFSUMB members. After prolonged agony, the European Journal of Ultrasound, the official journal of EFSUMB, discontinued its production at the end of 2002. The Publication Committee will have to come to terms with this problem and will certainly submit new suggestions. In the meantime, our Newsletter becomes even more important. I am sure that David Pilling, together with the Publication Committee, will present us with a new and polished design.

Under the chairmanship of Lil Valentin, the Education and Publication Committee has evaluated the status of education and training in ultrasound throughout Europe. The results of this evaluation show that the first order of business is to define "Minimum training requirements for the practice of medical ultrasound in Europe." These are likewise listed in this newsletter, and all members are cordially invited to read them, to participate in the noteworthy discussion and to help shape the future.

Some might find it strange to categorize training into three different levels. Diagnostic Ultrasound is practiced on different levels and it would thus seem appropriate to assign the education, the training as well as the accreditation to a ranked plan. EFSUMB is not alone in this 3-level split. In some of our societies, this 3level ranking is already being successfully practiced. Furthermore, the World Federation (WFUMB) and the WHO are also in favour and actively pursue the same categorization. In a certain sense, this also parallels the division of medical treatment into primary, secondary and tertiary care.

The use of ultrasound techniques is rapidly expanding and is now the most extensively used diagnostic imaging process. Thanks to technical progress, the methods have become simpler and easier to use. Portable instruments facilitate and additionally broaden its use. The statement that says the ultrasound probe is the equivalent of the stethoscope to the modern doctor increasingly applies. Users must have achieved at least a basic level of expertise. However, with the technical development, the specialization of the examiner and the demands placed on him are likewise growing. As an example, one could simply mention the key-word harmonic imaging. Not all users can satisfy the highest requirements, and therefore, the highly-specialized users should enjoy a higher level of distinction and recognition. If we have acknowledged the existence of various training levels - and there don't have to be three levels for everything or for all specialties – then the real work has just begun. The chart must be filled in with the corresponding contents for education, training and likewise accreditation and guidelines must be defined for quality control. This work cannot be undertaken solely by the Education and Professional Standards Committee, but rather, requires the active collaboration and cooperation of all members and particularly the national societies. I am looking forward to the EUROSON 2003 in Copenhagen and to meeting as many of you as possible there.

Kurt Jäger President EFSUMB

5	2	15th Euroson Congress 2003, Copenhagen, Denmark	12–13	
	2	EFSUMB Safety Tutorial	14–17	
	3	ECMUS Literature Reviews	18–19	
ary	4	Report from 14th EUROSON'2002 in Warsaw EJU	20	
mittee	4	Imperial College Course MSc	20	
rer	5	16th Euroson Congress 2004, Zagreb, Croatia	21	
of Medical Ultrasound	5	EUROSON SCHOOL London, UK, 22 – 4 April 2003	22	
dards Committee	6–7	Constanta, Romania, 17–18 May 2003	22	
for the Practice of		Sigmaringen, Germany, 3–5 July 2003	22	
		Vascular Medicine 2003, 8–10 October 2003,		
ick	8–11	Toulouse, France	23	
s of Safety"		Contents of EJU	23	

### **REPORT FROM THE HONORARY SECRETARY**



How do I begin the first report as the new Honorary Secretary of our federation? Well – firstly, many thanks to David Evans for having fulfilled the tasks of the Honorary Secretary so brilliantly for the last three years and thanks to the members of the Board of Directors of EFSUMB and to Gianna Stanford as Secretary for their friendly and patient way of welcoming their new member, to the Executive Bureau strategy meeting in Locarno/ Switzerland from 1st – 2nd of Nov in 2002.

The really important work and role of all the national societies included (26 altogether with about 15000 members to date) and the EFSUMB as an umbrella need not to be underlined. It is important to remember the importance of our watchdog group on ultrasound safety, and the important role of our committee on education and professional standards. Please take special note of the committee's paper on minimum requirements for the practice of medical ultrasound in Europe.

Since the last issue of The Newsletter, the following EFSUMB activities and events deserve special mention.

The Warsaw EUROSON conference from 4th–6th of July, 2002, was a great success with respect to all the scientific and teaching aspects. We gratefully mention the successful efforts of the members of the Polish national society responsible for this and give a special thanks for their warm hospitality.

As scheduled, a new Board of Directors was elected at the general assembly at Warsaw with Prof Kurt Jaeger from Switzerland as our new President, Prof Michel Claudon from France as our Past President (thank you for the last three years work), Prof. David Evans from the UK as our new President Elect, Niels Juul from Denmark as Honorary Treasurer, and Lucas Greiner from Germany as new Honorary Secretary.

The Locarno meeting of the Executive Bureau has already been mentioned. Without going into too much a detail, some topics covered included:

- the President's and the other Executive Bureau members reports.
- the Young Investigator's award invitational letter since sent to all societies for the forthcoming EUROSON meeting in Copenhagen, Denmark from 26th–30th of April 2003.

- The invitation to the winner of the Dreiländertreffen lecture in Basel, Switzerland to come to Copenhagen.
- The organization of the EUROSON meeting in Zagreb 2004 and in Geneva in 2005 (in conjunction with the national society's and the Dreiländertreffen meeting, respectively).
- The Congress of Vascular Medicine in Toulouse, France from 8th–10th of October in 2003.
- The EUROSON school meetings in London, United Kingdom on 3D Ultrasound Imaging, from 2 to 4 April in 2003, in Constanza, Romania on interventional ultrasound from 17th to 18th of May in 2003 and in Sigmaringen/Germany from 3rd to 5th July 2003. (http://www.sonoweb.de for further details).

Other topics were our links to WFUMB and to other organisations and societies including the EFSUMB role within the political EU framework, and questions concerning The Newsletter and the European Journal of Ultrasound.

Continuity of communication between EFSUMB and all the national societies and their members is a really important issue for all of us. And this must always be a two way system – to give ultrasonography the role it needs and deserves in any field of application and in any area of scientific interest. I would like to ask for extensive communication from all our readers to challenge the EFSUMB organisation in general and especially "the new one" – the new Honorary Secretary. No e-mail or any other form of communication will be unanswered in due time.

Medical ultrasonography is an exciting diagnostic and interventional tool for the patients and for those using it. It exceeds in many aspects by far the capabilities of other imaging modalities.

Medical ultrasonography, however, needs in order to reach its goal and fulfil its purposes, the structures of communication, research, dissemination, teaching, and general promotion granted by our national and international organisations. Please participate actively.

We are pleased to include the "Echoes" the new format newsletter of the World Federation for Ultrasound in Medicine and Biology which I am sure will be welcomed by all members of EFSUMB.

Yours sincerely,

Lucas Greiner Honorary Secretary EFSUMB

# **REPORT FROM THE PUBLICATIONS COMMITTEE**

The committee has not met since the last edition of the Newsletter and will be meeting during the Euroson Congress in Copenhagen in April. We will be welcoming a number of new members as Hylton Meire noted in the last report and hope by the time the Committee meets we will have more news about a way of re-launching the EJU. These discussions are already well advanced and are looking more hopeful than expected at the last meeting. The Committee will obviously be considering other forms of publication that the Federation may wish to consider and any suggestions would be welcomed.

D W Pilling Chairman Publication Committee

# **REPORT FROM THE HONORARY TREASURER**



It was a great honor for me to be re-elected as Honorary Treasurer at the General Assembly in Warsaw in July last year. I shall do my best to the benefit of EFSUMB in the coming years, and I look forward to a continuing fruitful co-operation with the Executive Bureau, the Board of Directors and the General Secretary.

As I have stated previously the EFSUMB economy is now stable and solid. In 2000 we had a surplus of £ 12'000 and in 2001 a surplus of £ 11'000. The final result of 2002 is at this moment not available, but

I am convinced, we will also have a surplus that year. The budget for 2003 is in balance and thus previous deficits have been partly regained.

As Treasurer I am very grateful for the contributions from the Euroson Schools held in Germany, Romania and UK. Futhermore a considerable surplus has arisen from the Euroson Congress held in Edinburgh. Details will appear in my next report.

I would like to thank Bracco for generous sponsorship of the newsletter over the years and COCIR for sponsorship of sessions at our latest congresses.

Finally I would thank all member societies for paying the annual fee promptly.

Niels Juul Honorary Treasurer EFSUMB

Country	number of members in database
AUSTRIA	813
BELGIUM	211
BULGARIA	75
CROATIA	67
CZECH REP	45
DENMARK	332
FINLAND	270
FRANCE	361
GERMANY	5502
GREECE	100
HUNGARY	49
ISRAEL	101
ITALY	1850
NETHERLANDS	49
NORWAY	194
POLAND	800
PORTUGAL	63
ROMANIA	247
RUSSIA	68
Slovak Rep	40
SLOVENIA	108
SPAIN	168
SWEDEN	96
SWITZERLAND	2321
UK	2248
TOTAL	16178

# SHORT REPORT FROM THE SWEDISH SOCIETY OF MEDICAL ULTRASOUND (SFMU) REGARDING "MINIMUM TRAINING REQUIREMENTS FOR THE PRACTICE OF MEDICAL ULTRASOUND IN EUROPE"



The 2002 annual meeting of the Swedish Society of Medical Ultrasound was held in Gothenburg on the 29th of November. The meeting included a scientific session, where education in medical ultrasound was discussed. As president of the Swedish Medical Ultrasound Society, I presented the document "Minimum training requirements for the practice of medical ultrasound in Europe", where after representatives of different medical specialties practising diagnostic ultrasound gave their views on this document.

In addition Professor Sturla Eik-Nes (President of EFSUMB 1993–1996) gave an excellent lecture on education and training in obstetric ultrasound.

The European document was very well received by all specialties represented at the meeting (obstetrics and gynaecology, radiology, cardiology, gastroenterology). It was quite clear, that every specialty represented wanted to adopt the guidelines. In fact, the obstetricians and the cardiologists had already started to design education and training programmes at three levels. The cardiologists were contemplating certification. The obstetricians will start examination and certification as early as in the spring of 2003.

Lil Valentin President of the Swedish Society of Medical Ultrasound

# EDUCATION AND PROFESSIONAL STANDARDS COMMITTEE INTRODUCTION BY LIL VALENTIN AND KURT JAGER

#### Dear members of EFSUMB

EFSUMB's Education and Professional Standards Committee has worked for years establishing recommendations for "Minimum Training Requirements For The Practice Of Medical Ultrasound In Europe". A preliminary document was published in the EFSUMB Newsletter, Volume 15, Issue 1, July 2001. Thereafter, the document was discussed at a Euroson workshop at the Euroson Congress in Edinburgh in 2001. Distinguished invited representatives of different specialties practising diagnostic ultrasound in Europe gave their views on the preliminary document at this workshop. The Education and Professional Standards Committee are grateful for their input, and for the comments given by the audience. We considered the points of view given and revised the preliminary document. The speakers invited to the workshop in Edinburgh have reviewed the revised document, but some of them feel that they need more time to contemplate the contents. Nonetheless, EFSUMB Executive Bureau has accepted the document, and the final document "Minimum Training Requirements For The Practice Of Medical Diagnostic Ultrasound In Europe" is given below. We would very much appreciate input from EFSUMB members on this document.

Send any comments to EFSUMB's General Secretary, Mrs Gianna Stanford, Carpenters Court, 4a Lewes Road, Bromley, Kent BR1 2RN, UK, Tel: +44 (0)20 8402 8973, Fax: +44 (0)20 8402 9344, Email: efsumb@compuserve.com

#### Lil Valentin

Chairperson of EFSUMB Education & Professional Standards Committee President of EFSUMB

Kurt Jäger

# MINIMUM TRAINING REQUIREMENTS FOR THE PRACTICE OF MEDICAL ULTRA-SOUND IN EUROPE

#### **1. INTRODUCTION**

- 1.1 The increasing applications of ultrasound imaging throughout medical practice, together with the increasing availability of cheaper and smaller ultrasound scanners, mean that more medical personnel are using ultrasound equipment to perform and interpret ultrasound scans.
- 1.2 Ultrasound has an enviable safety record to date. Various bodies, including scientific societies and manufacturers associations have made recommendations concerning the safe and prudent operation of ultrasound equipment, but, unlike imaging equipment which makes use of ionising radiation<sup>1, 2</sup>. there is virtually no national or international regulation of ultrasound usage.
- 1.3 More than with any other imaging modality, the medical use of ultrasound is highly operator dependent and is fraught with scope for diagnostic error, the potential for which is magnified by the on-going development of more sophisticated equipment with extended applications.
- 1.4 In order to gain maximum clinical benefit, as well as to achieve optimal use of resources, there is a need for operators of ultrasound equipment to have the appropriate skills for the performance and interpretation of ultrasound examinations.
- 1.5 EFSUMB, (which is a federation of national ultrasound societies in Europe), has established that, in Europe, there is no standardisation of training requirements for ultrasound practitioners, either between different countries or between different medical disciplines<sup>3</sup>.

This document is an attempt to stimulate national and pan-European speciality groups to consider training in ultrasound and to work towards the setting of minimum Europe-wide standards for such training.

#### **2. LEVELS OF PRACTICE**

- 2.1 Most national associations and speciality groups will recognise that ultrasound can be practised at different levels.
- 2.2 However, because of variations in medical systems between countries and variations in the organisation of the different specialities in those countries, it is difficult to strictly define

the different levels of practice, and hence the training requirements for each level.

- 2.3 In the document 'Training in Diagnostic Ultrasound: Essentials, Principles and Standards'<sup>4</sup> a WHO Study Group have indicated that ultrasound training needs may be defined according to equipment availability, and suggest three levels of training requirement.
- 2.4 In Europe, certain countries have pursued the multi-level concept of ultrasound practice, based on clinical experience, ultrasound experience, practical competencies, research record and ability to teach, and are introducing regulated training requirements for each level.
- 2.5 Whilst it would be unrealistic to expect every speciality group in every European country to agree upon the precise definitions of the levels of practice, it is hoped that certain general principles concerning the requisite abilities for each level may be accepted. Recommendations for the minimum training requirements for each level of practice can then be based on these principles

#### 2.6 LEVEL 1:

Practice at this level would usually require the following abilities:

- a. to perform common examinations safely and accurately
- b. to recognise and differentiate normal anatomy and pathology
- c. to diagnose common abnormalities within certain organ systems

d. to recognise when referral for a second opinion is indicated Within most medical specialities, the training requisite to this level of practice would be gained during conventional postgraduate specialist training programmes.

#### 2.7 LEVEL 2:

Practice at this level would usually require the following abilities:

- a. to accept and manage referrals from Level 1 practitionersb. to recognise and correctly diagnose almost all pathology
- within the relevant organ system
- c. to perform basic, non-complex ultrasound-guided invasive procedures
- d. to teach ultrasound to trainees and to Level 1 practitioners
- e. to conduct some research in ultrasound

The training requisite to this level of practice would be gained during a period of sub-speciality training, which may either be within or after the completion of a specialist training programme.

#### 2.8 LEVEL 3:

This is an advanced level of practice which involves the following abilities:

- a. to accept tertiary referrals from Level 1 and 2 practitioners
- b. to perform specialised ultrasound examinations
- c. to perform advanced ultrasound-guided invasive procedures
- d. to conduct substantial research in ultrasound
- e to teach ultrasound at all levels
- f. to be aware of and to pursue developments in ultrasound

#### **3. MINIMUM TRAINING REQUIREMENTS**

- 3.1 For each level of ultrasound practice, national and/or European speciality groups should formulate a detailed syllabus with comprehensive recommendations for necessary amounts of practical experience (target numbers).
- 3.2 Syllabuses should include, at the appropriate level, theoretical knowledge of:
  - Ultrasound physics
  - · Safety of ultrasound and contrast agents
  - Ultrasound instrumentation
  - Scanning techniques
  - Ultrasound artefacts
  - Anatomy (of the relevant body systems)
  - Pathology (of the relevant body systems)
  - Ultrasound findings in the normal condition
  - Ultrasound findings in pathological conditions
  - Scan interpretation
  - Indications for ultrasound and inter-relationship with other imaging modalities
  - Ultrasound-guided procedures
- 3.3 Recommendations should include an indication of the minimum numbers of scans which should be performed (at the appropriate level) as
  - Supervised scanning
- Independent scanning, with review by a designated trainer 3.4 Training programmes should include recommendations and/or
- regulations for evaluation of both theoretical knowledge and practical scanning and interpretive skills. In each country and/or speciality there should be a recognised competent authority with responsibility for the evaluation of training, using whatever methods are felt to be appropriate in that country and/or speciality. Similarly, methods for, and the implications of, accreditation of individuals who have completed training programmes will vary, and it is essential that there should be recognition of the necessity for limiting the use of ultrasound to suitably trained individuals.
- 3.5 Continuing professional education and development is essential for any individual practising ultrasound. Training recommendations and/or regulations should include consideration of minimum scanning practice in order to maintain skills and minimum levels of educational activities in order for individuals to remain up-to-date in the rapidly developing field of medical ultrasound.

#### 4. SONOGRAPHERS

- 4.1 Sonographers are healthcare professionals without a medical degree who use ultrasound for medical purposes in some specialities in some European countries.
- 4.2 In virtually all countries and medical specialities in Europe where sonographers currently practice, there are comprehensive training programmes for sonographers which require high standards of knowledge and practical scanning skills, and they are strictly regulated with well developed schemes for the evaluation and accreditation of the trainees.

4.3 It is possible that the practice of ultrasound by sonographers will increase and will be introduced into more countries over the next few years. It is therefore important that consideration be given to the setting up of suitable training programmes in order to ensure that the sonographers are properly trained for their job.

#### **CONCLUSIONS**

- 5.1 The medical use of ultrasound can be practised at different levels
- 5.2 Those physicians and sonographers practising ultrasound should be properly trained for the appropriate level of practice.
- 5.3 There should be mechanisms in place to evaluate the theoretical knowledge and practical skills of ultrasound trainees.
- 5.4 National and European speciality associations are urged to subscribe to these concepts, and to recommend and supervise the theoretical and practical training that is requisite for the various levels of ultrasound practice.

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- Department of Health (2000) Ionising Radiation (Medical Exposure) Regulations IS 1999/3232. Norwich: Stationary Office
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- Training in Diagnostic Ultrasound: Essentials, Principles and Standards: Report of WHO Study Group 1998. WHO technical report series: 875

#### FOOTNOTE

This document has been prepared by the EFSUMB Education and Professional Standards Committee, and has been approved by the EFSUMB Executive Bureau. As part of the consultation process, this committee organised a Workshop at the Euroson Congress which was held in Edinburgh, Scotland on Thursday 13th December 2001, to which representatives of different medical specialties in Europe were invited to contribute.

# **MEMBERS OF EFSUMB EDUCATION AND PROFESSIONAL STANDARDS COMMITTEE:**

Dr Lil Valentin (Sweden) – Chairman, Dr Henry Irving (UK) – Secretary, Prof David H Evans – (UK), Prof Jochen Hackeloer – (Germany), Prof Kurt Jäger – (Switzerland), Dr Pentii Lohela – (Finland), Dr Ioan Sporea – (Romania).

#### **CONTRIBUTORS TO EDINBURGH WORKSHOP:**

- Prof Dr. med.Uli Hoffmann, Representative of the International Union of Angiology
- Dr George R Sutherland, Chairman of the Echocardiography working group 7 of the European Society of Cardiology
- Prof Juriy Wladimiroff, Education committee member of the International Society of Ultrasound in Obstetrics and Gynaecology
- Prof Rolf W. Günther, President of the European Association of Radiology
- Prof Carlo Trombetta, President of the Italian Society of Urological Imaging and the coordinator of the European Society of Urological Imaging
- Dr Ioan Sporea, replaced Prof. Rapaccini as representative of European Gastroenterologists
- Prof Michel Claudon, President of EFSUMB

Final version of this document prepared following meeting of EFSUMB Education and Professional Standards Committee in Warsaw, Poland, on Saturday 6th July 2002.

### "WORKING TOWARDS THE BOUNDARIES OF SAFETY"

THE FOLLOWING ARTICLE IS BASED ON THE EUROSON LECTURE 2002, GIVEN AT EUROSON 2002, WARSAW, 6 JULY 2002 BY Francis A Duck PhD DSc, Medical Physics Department, Royal United Hospital, Bath BA1 3NG UK



Ultrasound is the safest of the main medical imaging modalities. The use of X-rays in radiology and gamma radiation in nuclear medicine is associated with known somatic and genetic effects associated with ionisation. The risks of cancer induction, or of causing developmental malformations, are known and weighed against the diagnostic value of the procedure. Magnetic resonance imaging is also hazardous. Metallic objects can be accelerated by the magnetic field to become potentially lethal projectiles.

Pacemakers may be induced to malfunction, metal implants can be displaced, and induced currents can cause skin burns. Knowledge of these hazards has not prevented a number of cases of trauma and even death to patients associated with MR investigations. Known hazards of ultrasound are minor by comparison. Ultrasound may cause some warming of the tissue, and could cause bruising in particular conditions. These effects are very small when compared to those that are accepted in the use of X-rays and MRI. Nevertheless, as the potential uses of diagnostic ultrasound continue to be explored, it will become necessary to develop a very clear understanding of the boundaries beyond which safety can no longer be assumed.

#### Three stages in safety development *Childhood*

The question of safety has always been part of the responsible exploitation of ultrasound in clinical practice. Taking a broad historical view, ideas and perceptions of ultrasound safety have passed through three stages, which may be called "childhood", "adolescence" and "maturity". Lasting until about the late 1970s, the childhood stage was characterised by active exploration of the important biophysical processes on which safety judgements could be made. The proceedings of a 1971 workshop (Ried and Sikov, 1972) give a good overview of the detailed discussions which were being carried out, informed by scientists from laboratories throughout the world. We are honoured that two contributors to that workshop, Professor Marvin Ziskin and Professor Lesek Filipczynski, are also speaking in the Safety Session at Euroson 2002. The main hazards from ultrasound were thought to be heating and cavitation, but it was agreed that other mechanical effects exist which may need to be considered. The importance of accurate measurement of acoustic field quantities was also noted: and the complexity of biological responses and range of possible biological endpoints was reviewed.

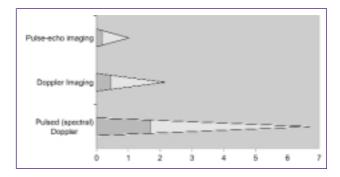
#### **Adolescence**

The second, "adolescent", stage of ultrasound safety may be characterised by the introduction and application of rules, regulations and standards for safety. Since the late 1980s

the International Electrotechnical Commission (IEC) has prepared a number of relevant international standards. The first standards specified how manufacturers should declare acoustic output, whilst more recently the calculation and display of safety indexes have been specified. Other aspects of performance including that of Doppler systems, and allowed transducer temperature have also been subject to IEC specification. These standards have usually been adopted by individual countries and applied as guides to best practice throughout the world. Independently of the IEC, early in the 1980s, the Food and Drug Administration (FDA) in the USA applied upper limits to the allowed output from diagnostic equipment. The details of these limits have altered a little since, but the fact remains that the FDA controls remain the only boundary placed on manufacturers to keep output below defined limits. At present, for most equipment, the estimated in-situ intensity (time averaged) must not exceed 720 mW cm-2, and the mechanical index (MI) must not exceed 1.9. In addition, manufacturers must justify a thermal index (TI) greater than 6.0. In order to operate at the highest exposures, they are obliged to display values of the safety indices, MI and TI, on the screen. Relaxation of the regulatory limits during the early 1990s had two main practical effects. First, Doppler techniques became widely available for obstetric use, both spectral Doppler and Doppler imaging. And secondly the output from each subsequent generation of scanners showed a general trend upwards toward the overall limits on output. Pulse-echo imaging modes still, broadly, use the lowest intensities, and pulsed Doppler the highest, but in some circumstances the imaging modes operate at intensities which clearly overlap with those used in spectral Doppler (see figure 1).

#### Maturity

Clinical users were aware that manufacturers must conform to safety regulations and standards when designing and manufacturing scanners. In parallel with the regulation of ma-



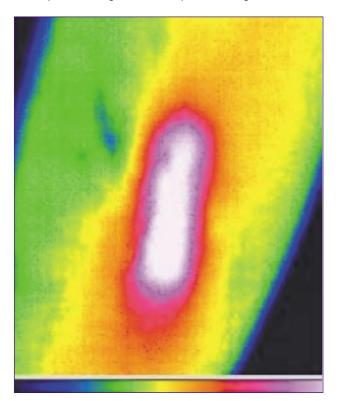
**Figure 1:** Diagram showing the approximate range and median values of greatest time-averaged intensity in water from surveys of output of a wide range of scanners and transducers. I(spta) for pulse-echo imaging, Doppler imaging and spectral pulsed Doppler are compared. The line in each distribution indicates, approximately, the median value in each survey (from Whittingham, 2000)

nufacturers, however, there has been a maturing awareness of the responsibility of the professional user for the safe operation of scanners. Users became expected to assess the risk of the study and set this against the resulting diagnostic benefit. Safety indices, MI and TI, were seen as the means by which users may assess risk. The move towards users carrying a greater responsibility has been given significant impetus by recent discussions on possible relaxation or removal of upper limits on output (O'Brien et al, 2002). It has been suggested that the elimination of the upper-limit regulatory approach would "make available research opportunities to develop advanced procedures" and "provide diagnostic capability if higher levels are required" (O'Brien and Miller, 2001). It is the new context of greater user responsibility for risk/benefit assessment, with relaxed limits on output, which focuses attention firmly and urgently on the boundaries of safety in the title of this article.

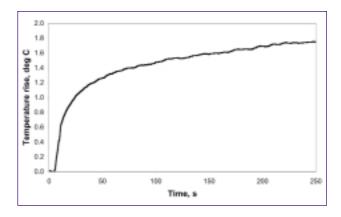
The changes in safety management take on a particular urgency for European clinical users of ultrasound. The use of higher levels of output is strictly limited only in the USA, and such restrictions do not exist in Europe. In principle, European workers are free to develop uses of ultrasound exploiting higher levels of output, without being limited by a Governmental body. Such freedoms come at a price however. Any clinician who wishes to exploit these possibilities needs to gain the highest knowledge of their safety implications in order to demonstrate clinical responsibility for protection of the patient and to avoid bringing diagnostic ultrasound into disrepute.

#### **The Boundaries of Safety** *Boundaries for thermal safety*

The framework of knowledge to assess thermal safety is well developed, although still incomplete. During examinations



*Figure 2:* Thermal image showing the pattern of skin temperature rise immediately after removal of a transducer.

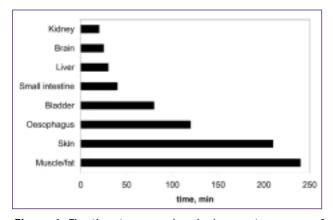


*Figure 3:* Temperature rise measured at the surface of a human 39-week fetal vertebra in vitro at the focus of a 3.5 MHz transducer during pulsed exposure at 50 mW (redrawn from Doody et al, 1999).

using ultrasound the highest temperatures are generated at the surface, and this is primarily because the transducer itself acts as a source of heat (Figure 2). The contact temperature should not exceed 43°C according to present IEC standards (IEC, 2001), although many systems in use can still operate at temperatures in excess of this temperature. Within the body the greatest temperatures are caused by bone absorption, resulting in local temperature "hot spots" with increased temperatures in the region around the surface of the bone. Increases in temperature of bone invivo of 2-3°C are well within the capability of many modern scanners, especially when operating in Doppler modes. Figure 3, from Doody et al 2000, shows the temperature rise measured in human fetal vertebrae, in vitro, exposed to only 50 mW acoustic power under standard pulsed Doppler conditions. This result shows bone from a 39 week gestation fetus heated by 1°C within about 20 seconds.

The temperature approached 2°C after longer exposure. The use of higher acoustic powers would increase these temperatures, with an approximately linear dependence of temperature increase on power.

Cells are damaged by excessive increases in temperature, but they are also able to protect themselves from small thermal variations. A complex matrix of gene responses occur as the temperature increases. Heat-shock, or chaperone, proteins are created which warn and partially protect the cell. There is a temporary slowing of the cell cycle, and a development of thermo-tolerence. These responses are not immediate, however, and may take some time to develop fully. Following these protective measures, the cell may behave in one of two ways. Either it resumes normal function and behaviour, or it dies through apoptosis. Provided that apoptosis is restricted to only a part of the tissue cell population, the outcome should be normally functioning tissue. Some tissues also partially protect themselves from an increase in temperature by increasing blood perfusion in order to extract excess heat. This mechanism is well studied for skin, which is well supplied with thermal sensors. It is less clear whether internal organs respond to modest temperature changes by altering perfusion. Furthermore, perfusion is of limited importance in controlling temperature when the heat is localised to a narrow focal zone. For these reasons, changes in perfusion may be considered to be of secondary importance as protective measures.



**Figure 4:** The time to cause chronic damage to a range of tissues following a temperature rise of 43°C. (from Dewey, 1994)

Once tissue temperature exceeds about 43°C, natural protective measures become increasingly less effective. Uncontrolled cell death starts to occur due to protein denaturation. For temperatures above 43°C, the time to cause a thermal effect reduces by a factor of 2 for each 1 degree increase in temperature. This rule appears to be broadly true for very many cells and tissues. The time to cause tissue death varies between tissues, however. Figure 4 summarises the times sufficient to cause chronic damage at 43°C for a range of tissues (from Dewey, 1994). Damage occurs most rapidly in brain and viscera, whereas damage to skin and muscle takes much longer to occur. At 43°C, the times are measured in tens of minutes for all tissues. Times rapidly decrease as the temperature increases. The time, t, at any higher temperature, T, is easily calculated from the time at 43°C,  $t_{43}$ , using the expression  $t = t_{43} 2^{(T-43)}$ .

This background allows a clearer view to be taken of actual boundaries to safe use which would be reached were higher intensities and powers to be used. Current clinical scanners can, under some conditions, operate with a displayed Thermal Index of 6.0 or more, which predicts a worst-case temperature rise of 6°C, or 43°C in vivo. Temperature increases similar to this have been demonstrated in vitro with commercial systems (Shaw et al, 1998). In Table 1, the facts are assembled to indicate the practical limitations to increases in power. The first row associates a power,  $W_{43}$ , with conditions causing a temperature rise in tissue of 43°C, equivalent to TI of 6.0. Figure 4 shows that, for tissues with the greatest thermal sensitivity, about 30 minutes exposure at this temperature causes chronic damage, and this time is entered in the last column. The second and third rows give temperature rise, TI and time to damage at powers twice

Power	Temp °C	"TI <i>"</i>	Time to damage
W <sub>43</sub>	43	6	30 min
2W <sub>43</sub>	49	12	28 s
3W <sub>43</sub>	55	18	0.44 s

**Table 1:** A comparison of the thermal consequences of using 3 levels of acoustic power,  $W_{43}$ ,  $2W_{43}$  and  $3W_{43}$ .  $W_{43}$  is the power capable of increasing tissue temperature by 6°C. It is assumed that the sensitivity of the exposed tissue to thermal damage is high.

and three times  $W_{_{43}}$ . To a good first approximation, the temperature increase is linearly dependent on acoustic power. Doubling acoustic power (and temperature rise) reduces the time for damage to only about 30 s: increasing power by a factor of three reduces the time before damage to be so short as to make these conditions, in practice, unusable. Whilst the details in this very simplified analysis may be debated, it serves to emphasise that there is very little scope to increase acoustic power before absolute boundaries to safe use are reached.

Obstetric scanning introduces different and more limiting boundaries to safety. The evidence from thermal teratology suggests that a sustained temperature rise in the embryo of about 1.5–2°C can result in developmental defects. Higher temperatures sustained over shorter times result in the development of similar defects. The evidence is largely derived from experimental studies of heating at the time of neural tube closure, and the fetus presents subsequently with very unusual cephalic defects. For this reason they are easy to distinguish, and so thermal thresholds can be established with some confidence. Other possible developmental outcomes from embryological heating may exist, but little or no evidence is available on which to base firm judgements. Based, therefore, on the known evidence, the World Federation for Ultrasound in Medicine and Biology has issued the following recommendations (WFUMB, 1998).

- A diagnostic exposure that produces a maximum temperature rise of no more than 1.5°C above normal physiological levels (37°C) may be used clinically without reservation on thermal grounds.
- A diagnostic exposure that elevates embryonic and fetal in situ temperature above 41°C (4°C above normal temperature) for 5 minutes or more should be considered potentially hazardous.

#### Boundaries for mechanical safety

Having dealt with the safe boundaries for thermal hazard, we now turn to consideration of mechanical hazards. Acoustic cavitation is commonly viewed as the main mechanical hazard. In the absence of pre-existing gas bodies in-vivo, however, there is neither experimental nor theoretical evidence that cavitation occurs in-vivo with present diagnostic scanners.

There is a threshold of acoustic pressure (that is, pulse amplitude) below which bruising does not occur, and this appears to be at the upper limit of exposures used in current practice. Bruising caused by ultrasound exposure has also been observed at bone interfaces in the rat fetus, although the exposures used lay outside current diagnostic range (Dalecki et al 1997). This suggests that any high gradient in radiation pressure may stress tissues beyond their breaking strain. Although bruising is a probable outcome of exposure to pulses of very high amplitude under some circumstances, such damage would normally be expected to resolve itself completely through natural tissue repair. In reviewing the safe boundaries, therefore, it may be satisfactory to accept some local bruising if there is a clear diagnostic justification to use very high amplitude pulses. Particular patients would be especially at risk, such as those with

clotting disorders, and additional care would have to taken to ensure their care would not be compromised.

Discussions of the biological effects of inertial cavitation also recognise its potential to generate free radicals. In order to interact with cell development, free-radicals must exist inside the cell membrane, and the likelihood of this occurring would seem to be vanishingly small. Extra-cellular free radicals would need to enter it within their lifetime and, were any intertial cavitation to be activated within the cell, this would inevitably cause lysis and cell death. Present understanding leads to the conclusion of a very low likelihood of free radical generation, and essentially no possibility of any effect on cell development.

Capillary damage has also been observed during the use of gas contrast agents. To quote Miller (2000) "Injection of gas-body-based contrast agents into the circulation introduces an entirely novel risk factor for diagnostic ultrasound". Whilst safety concerns are central to the increasing use of contrast agents, there is not enough space to cover this new aspect of safety in this brief review.

#### Summary

The management of safety for diagnostic ultrasound is maturing. Regulatory limits may be relaxed or removed, encouraging users to exploit more fully the diagnostic potential available from this safest of imaging modalities. Ultimate boundaries exist, however, beyond which the risk of damage to the patient clearly outweighs any potential diagnostic benefit. There is little scope to extend safely the upper limits presently applied on acoustic power, because the induced temperatures would result in cell destruction within very brief periods. Higher pulse amplitudes might be used, but only if minor bruising was tolerated as a potential sideeffect. There is now a mature understanding of the key safety issues for diagnostic ultrasound, and EFSUMB and ECMUS give strong guidance on safe practice in Europe. EFSUMB tutorials on safety are available at www.efsumb.org/ ecmus.htm. European clinical researchers have the freedom to exploit higher exposures, if they need to use them for new ultrasound diagnostic techniques, but must be very aware of the bio-effects associated with their use. As responsible safety management matures, it is essential to invest in further basic research to gain the necessary detailed knowledge on which safe practice must be based.

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# 15<sup>TH</sup> EUROPEAN CONG FIRST JOINT SCANI Hosted by EFSUMB and the Sca

## INVITED GUEST LECTURES

#### GENERAL ULTRASOUND

D Amy (France) "Breast US" (Title to be confirmed)

R de Bruyn (UK) "The normal and abnormal female pelvis in childhood and adolescence" "US of the head and neck in children"

M Claudon (France) "US in medical renal disease"

FC Hamdy (UK) "3-D US of prostatic cancer. Current status"

OH Gilja (Norway) "3-D of the upper GI-tract"

N Gritzmann (Austria) "US of the salivary glands" "The painful right lower quadrant"

G Harmat (Hungary) "Use and benefit of early age US in examining the urinary tract"

T Hausken (Norway) "3-D US of the liver"

L Hegedüs (Denmark) "US of the solitary thyroid nodule. From an endocrinologist's point of view"

WR Lees (UK) "US of liver and pancreas"

H Madjar (Germany) "Breast US" (Title to be confirmed)

A Nilsson (Sweden) "US contrast agents in abdominal trauma"

H Strasser (Austria) "3-D US in female incontinence"

C Weismann (Austria) "Breast US" (Title to be confirmed) R Wilson (UK) "Breast US" (Title to be confirmed)

#### VASCULAR ULTRASOUND

D Evans (UK) "Doppler detection of cerebral flow

K Jäger (Switzerland) "Duplexsonography of the mesenteric circulation"

J Radermacher (Germany) "Renal artery stenosis: role of Doppler US before and after treatment"

K Vogt (Denmark) "Implementation of intravascular US in vascular surgery"

HP Weskott (Germany) "Turnour angiogenesis - contribution of different US techniques in turnour vessel imaging"

#### MUSCULOSKELETAL ULTRASOUND

Bianchi (Switzerland) "US of the elbow and wrist"

M Court-Payen (Denmark) "US of the knee" "US of soft tissue turnours"

P Farin (Finland) "Painful shoulder: The significance of shoulder sonography"

P Peetrons (Belgium) "US of the ankle"

J Uzon (Spain) \*Musculoskeletal US in arthritis\*

#### SURGICAL & INTERVENTIONAL ULTRASOUND

B Djavan (Austria) "Transrectal US following radical prostatectomy and radiation therapy" J Djurup (Denmark) "Laparoscopic US in staging of upper Gl cancer"

A Heilo (Norway) "Complications to interventional US"

F John (UK) "Surgical US. Current status"

S Karstrup (Denmark) "Interventional US"

T Livraghi (Italy) "Multimodality treatment of hepatoma with percutaneous techniques"

MB Nielsen (Denmark) "New trends in ano-rectal endosonography"

B Skjoldbye (Denmark) "Intraoperative US in liver and pancreatic disease"

L Solbiati (Italy) "RF tissue ablation of liver metastases"

M Starck (Sweden) "Ano-rectal US in neoplastic disease"

I Sudol-Szopinska (Poland) "Anal US in benign diseases"

P Vilmann (Denmark) "Endoluminal US of the upper GI-tract"

#### TECHNOLOGY AND PHYSICS

T Albrecht (Germany) "Contrast agent kinetics in liver perfusion"

P Burns (Canada) "US contrast. Current status"

D Cosgrove (UK) "Time-intensity curves in tumour vascularity. Current status"



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# RESS OF ULTRASOUND DINAVIAN MEETING andinavian Ultrasound Societies

OH Gilja (Norway) "Strain-rate imaging - a tissue Doppler method for the study of gastric motility"

JA Jensen (Denmark) "Vector velocity"

MH Pedersen (Denmark) "Coded ultrasound"

OT von Ramm (USA) "3-D and 4-D ultrasound"

HP Weskott (Germany) "B-flow - a non Doppler technique for imaging blood flow"

#### GYNAECOLOGY AND OBSTETRICS

HG Blaas (Norway) "Holoprosencephaly"

B Cacciatore (Finland) "The fallopian tube" "Conservative treatment of tubal pregnancies"

R Chaoui (Germany) "Fetal echocardiography: More than for the exclusion of fetal heart defects"

J Deprest (Belgium) "Sono-endoscopic procedures in fetal therapy"

S Eik-Nes (Norway) Title to be confirmed

E Epstein (Sweden) "The role of Doppler US in the diagnosis of endometrial cancer"

D Jurkovic (UK) "Diagnosis and management of ovarian cysts in pregnancy" "Diagnosis and treatment of rare types of ectopic pregnancies"

T Kiserud (Norway) "Function of the fetal foramen ovale" T Larsen (Denmark) "Intrauterine growth"

K Marsal (Sweden) "Computer analysis of Doppler examinations in obstetrics"

A Testa (Italy) "The vascular 3D analysis of cervical carcinoma"

D Timmermann (Belgium) "Uterine vascular malformations"

L Valentin (Sweden) "Adnexal cysts in postmenopausal women"

#### SONOGRAPHERS

E Crang-Svalenius (Sweden) "Information about routine ultrasound - who's needs are we fulfilling?"

M Ekelin (Sweden) "Not without my ultrasoundparents" experiences of routine examinations during pregnancy"

N Jones (UK) "Post-graduate programme from St Martin's College, Lancaster UK"

G Jensen (Denmark) "Experience with distance learning"

L Nordvig (Denmark) "Psychological aspects, women's views, attitudes and expectations regarding ultrasound during pregnancy"

N Uldbjerg (Denmark) "Telemedicine and education in ultrasound"

#### SAFETY

K Marsal (Sweden) "Safety aspects from the clinical per spective" R Laurini (Portugal) "Cell biology and safety aspects"

T Whittingham (UK) "Safety consequences of modern developments"

KÅ Salvesen (Norway) "Update on epidemiology"

#### EUROSON LECTURE

BJ Hackelöer (Germany) "Intrauterine therapy - standard and future"

#### THÉRÈSE PLANIOL LECTURE

R Bessis (France) Title to be confirmed

#### WFUMB LECTURE

M Ziskin (USA) "State of the art: US safety"

#### DREILÄNDERTREFFEN LECTURE

J Hänsler (Germany) Title to be confirmed

#### Awards

"Young Investigator's Award" Award (€ 1000) according to EFSUMB bylaws. EFSUMB calls for suggestions from the national ultrasound societies.

"Ultrasound Contrast Poster Award" Award (€ 2000) for the best poster with a main topic on US contrast agents. Sponsored by Bracco.



## ECMUS SAFETY COMMITTEE TUTORIAL "DIAGNOSTIC ULTRASOUND EXPOSURE"

#### 1. Introduction

A knowledge of the acoustic output levels produced by commercial equipment is fundamental to the question of the safety of diagnostic ultrasound. This tutorial discusses basic acoustic output terminology including worst case values, as well as control settings that lead to high outputs. Results of recent and previous output surveys are summarised, along with a discussion of the differences between in-water, in-situ and derated quantities. Finally, the role of the on-screen indices, TI and MI, is discussed.

#### 2. Basic terminology

The "pressure" of an ultrasound pulse at any moment means the excess pressure due to the sound wave. It can be positive (compressing the medium) or negative (stretching the medium). The unit of pressure is the pascal (Pa). Note that atmospheric pressure is close to 0.1 MPa (= $10^5$  Pa).

"Acoustic power" is the rate at which energy is passed along the beam. "Acoustic output power" is the rate at which energy leaves the transducer. In the absence of attenuation (e.g. in water) the acoustic power at any distance from the transducer will equal the acoustic output power. The unit of power is the watt (W), equal to 1 joule (J) of energy per second.

"Intensity" is the power per unit area, through a surface at right angles to the wave direction. The unit of intensity is the  $W/m^2$  (sometimes written  $W m^2$ ) or whatever derivative is more convenient, such as  $mW/cm^2$ .

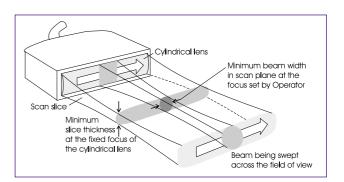
All three of the above quantities vary from moment to moment through a cycle of a wave, whilst pressure and intensity are also likely to vary from point to point. Consequently it is necessary to specify whether instantaneous values are meant, or some spatial or temporal average is intended.

# 3. The three principal acoustic output quantities: p-, I<sub>SPTA</sub> and acoustic power.

Each of these quantities is measured for a specified combination of machine, probe and operating mode. The term "stationary beam mode" refers to A-mode, M-mode or Spectral Doppler, while "scanning mode" refers to B-mode or colour Doppler imaging (CFM). Note that measurements of these quantities are made in water. Spatial-peak temporal-peak negative pressure (p-) is the largest negative pressure excursion to be found anywhere in the ultrasound field, at any time in the scan sequence. It is related to the likelihood of cavitation. In water, the greatest value is found where the cross-sectional area of an individual beam is least (*Fig 1*), irrespective of whether a stationary or a scanned beam mode is selected. In an attenuating medium such as tissue it will be found nearer the probe.

Spatial-peak temporal-average intensity ( $I_{SPTA}$ ) is the largest value of time-averaged intensity ( $I_{TA}$ ) to be found anywhere in the ultrasound field. In stationary beam modes the position of the greatest  $I_{TA}$  is the same as that of p-. In scanning modes the power is distributed fairly uniformly across the width of the field of view, so  $I_{TA}$  is fairly constant across this width, but varies with depth. For a linear array probe, the greatest value ( $I_{SPTA}$ ) in water is generally close to the depth where the fixed cylindrical lens is focused (*Fig 1*), more or less irrespective of the depth to which the operator's focus control is set. However, for a curvilinear or sector probe, or in an attenuating medium such as tissue, the  $I_{SPTA}$  will be located nearer the probe.

Temporal-average acoustic output power (W) is the average rate over time at which acoustic wave energy leaves the probe.



**Figure 1:** In scanned modes, time averaged intensity is distributed fairly evenly across the field of view. In water, the greatest value is found where the beam width perpendicular to the scan plane (slice thickness) is least, i.e. at the fixed focus of the cylindrical lens. The position of greatest *p*- is the same as for an individual beam and hence subject to the setting of the focus control.

Both  $I_{SPTA}$  and temporal average acoustic output power are important parameters in determining the rise in tissue temperature produced by the probe. For a given setting of the machine's output controls (e.g. number and depth of foci, zoom, frequency etc.) they are proportional to each other, and to the temperature rise.

#### 4. How output quantities are measured.

Acoustic pressure is normally measured with a hydrophone based on a film of the piezo-electric polymer polyvinylidene difluoride (PVDF) stretched across a ring frame (ECMUS Safety Tutorial No. 5, 1994). Typical measurement accuracy is about  $\pm 12\%$ . If a plane wave is assumed, as is customary, the instantaneous intensity is equal to the square of the instantaneous acoustic pressure divided by the characteristic acoustic impedance of the medium (water). Hence, in order to monitor and measure temporal-average intensity, the time average of the square of the signal from the hydrophone is measured. By moving the hydrophone around in front of the transducer under test, the position giving the largest value of temporal average intensity anywhere in the field may be found. The temporal average intensity value at this position is the I<sub>SPTA</sub> value of the field. The accuracy of an I<sub>SPTA</sub> measurement is typically around  $\pm 30\%$ .

The acoustic power from diagnostic equipment is most conveniently measured by a portable radiation force balance. With care, an accuracy of about  $\pm 15\%$  is achievable.

#### 5. Worst-case values.

When there is interest in the hazard potential of an ultrasound field, it is usual to try to find the "worst-case" values of the output quantities. These are the largest values that can be produced for any combination of control settings. It would be a mistake to consider them only as theoretical extremes of little relevance to clinical practice. They are values that are sometimes quite easy to achieve in clinical practice. Ensuring that the worst case values of an output quantity has been found and measured can be a difficult and time consuming task, and sometimes different values can be reported, say by manufacturers and independent physicists.

Protocols can be prepared to avoid the need to actually try every one of the millions of combinations of control settings that might conceivably affect the machine's output (Henderson et al 1993, 1994).

# 6. Machine control settings that give the highest output levels.

The most obvious example is setting the output power control to maximum. This increases the amplitude of the voltage oscillation applied to the transducer, and hence the energy and peak pressure in each pulse.

In all modes, selecting a deep transmission focus usually involves an increase in acoustic power. This is because a larger transmission aperture, and sometimes a larger drive voltage, is used to achieve a narrow beam width and good sensitivity in a deep focal region.

When operating in B-mode, the highest  $I_{SPTA}$  and power levels are usually produced when a deep and narrow write-zoom box is activated (*Fig 2*). This is because write-zoom involves a selected area being re-scanned at a higher line density. A deep box will mean a deep focus and hence a likely automatic increase in transmitted power, and therefore greater intensities at all depths. Selecting a narrow box also leads to higher temporal-average intensities at all depths, since the probe continues to transmit the same energy per second, but this is restricted to a narrower area. Note that attenuation in the tissue means that the site of greatest temporal average intensity (and hence possibly the greatest temperature rise) is not likely to be in the zoom box itself, but rather at some point much closer to the probe.

In Colour Flow Mapping (CFM) and Spectral Doppler imaging modes, the highest  $I_{\rm SPTA}$  and power levels are usually associated with a fairly deep and narrow colour box, for similar reasons.

In stationary beam modes, such as M-mode and Spectral Doppler, large p- and I<sub>SPTA</sub> values are usually produced if the operatorcontrolled focus is set close to the fixed lens focus, since these act in orthogonal planes (Fig 1) and thus concentrate the output power into the smallest cross-sectional area. However, as mentioned above, large  $\,\,p\text{-}\,\,and\,\,I_{\text{SPTA}}$  values may also be produced by a deep scan-plane focus (or range-gate in the case of Spectral Doppler). In Spectral Doppler mode, a high Doppler frequency scale setting, or the selection of "high prf" mode, is likely to produce a higher power and I<sub>SPTA</sub>. Controls can sometimes have quite unexpected effects, as manufacturers often arrange for drive voltages, pulse lengths or pulse repetition frequencies to change automatically when controls are set in way which would otherwise cause a particular safety parameter such as I<sub>SPTA</sub> or Thermal Index to exceed a regulatory limit. Whittingham (2000) gives a more detailed account of the effects of controls on acoustic output.

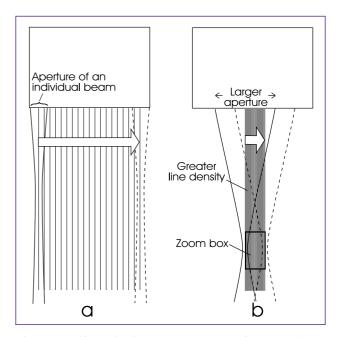
#### 7. Recent in-water measurements.

Table 1 gives a summary of median and maximum values of measurements made in the last few years.

p- values were found to be similar in all modes, with measurements being fairly symmetrically distributed around the median of approximately 2.5 MPa.

**Table 1:** Median and (maximum) values of worst case inwater output parameters for 100 probes, measured between 1995 and 1998 (Whittingham 2000). Power values based on 86 measurements made in 1999.

	M-mode Median (Max)	B-mode Median (Max)	CFM Median (Max)	Spectral Doppler Median (Max)
p- MPa	2.6 (4.9)	2.4 (4.6)	2.6 (4.9)	2.4 (5.5)
I <sub>SPTA</sub> mW cm <sup>-2</sup>	81 (604)	94 (1330)	328 (2030)	1420 (7500)
power mW	22 (213)	51 (256)	118 (295)	129 (324)



**Figure 2:** Effect of write zoom on temporal average intensity. Without a zoom box (a) the energy transmitted in one second is distributed over a wide field of view. If a zoom box is selected (b) the same energy per second is restricted to a narrower field, producing greater temporal average intensities at all depths. If the box is deep, a larger aperture (more elements transmitting) is likely to be used in order to achieve a narrow beam width in the box. This leads to even greater temporal average intensities at all depths.

 $I_{\text{SPTA}}$  varied considerably between modes. Spectral Doppler mode produced the highest  $I_{\text{SPTA}}$  values, partly because the beam is held stationary rather than being scanned, and partly because higher prfs are employed in an effort to avoid aliasing. CFM modes tended to have  $I_{\text{SPTA}}$  values intermediate between those of Spectral Doppler and B-mode since, although the beam is scanned across the "colour box", a sequence of several pulses are transmitted down each Doppler line at a high prf. In Spectral Doppler mode, higher  $I_{\text{SPTA}}$  values were found to be as common as lower values, but in the other modes the highest measurements came from only a few machines.

Acoustic power (W) is generally higher in CFM and Spectral Doppler modes although the maximum values were found to be similar in all modes. In CFM and Spectral Doppler modes, measurements were fairly evenly spread between low and high values, whereas in M-mode and B-mode the highest measured values were again from a relatively small number of machines.

Although the operating mode is an important factor for acoustic outputs, it is important to be aware of the large overlaps that exist between the ranges of measurements in the different modes. For any particular mode, the large range between the smallest and the largest worst-case measurements shows that differences between machines can be sometimes as significant as differences between modes. Many machines can produce B-mode power and I<sub>SPTA</sub> values above the median values for CFM mode, and substantially above the minimum values for Spectral Doppler mode. Similarly, many machines can produce I<sub>SPTA</sub> values in CFM mode above the median values for Spectral Doppler mode.

#### 8. In-water, in-situ and derated values.

Measurements are normally made in water for convenience. It is important to distinguish between such "in-water" or "free field" values and the "in-situ" values that would be measured in tissue, if that were possible. In-water values are sufficient to show any trends in outputs over the years (Section 10). In-situ values are likely to be of greater interest for those interested in in-vivo bioeffects.

The actual in-situ value of an acoustic output parameter at a particular point in a real subject would be difficult to determine precisely as it would be necessary to divide the in-water value by a series of attenuation factors, one for each layer of intervening tissue. Each of these factors would be dependent on the frequency as well as on the thickness and nature of the layer. In reality, the situation is even more complicated due to the fact that the waveform of an ultrasound pulse suffers non-linear (amplitude dependent) distortion it travels through water and, to a lesser extent, tissue (ECMUS Safety Tutorial No. 4, 1994).

"Derated" values are sometimes used as rough, but simple, estimates of in-situ values. These are obtained by reducing the inwater measurements by a factor representing the attenuation that would be introduced by a uniform medium with a specified attenuation coefficient. The attenuation coefficient of 0 3 dB cm-1 MHz-1 that is commonly specified in safety standards is somewhat less than that of most soft tissues. This low value is chosen in an attempt to allow for the frequent presence of low attenuation liquid layers in the ultrasound path. Derated values based on 0 3 dB cm-1 MHz-1 are specified in the regulations controlling acoustic outputs in the United States (FDA 1997).

Note that the depth at which an in-situ or derated output quantity is greatest will, in general, be different to that mentioned earlier (Section 3) for the in-water situation.

Reported in-water and derated values rarely include an allowance for the sometimes substantial distortion of the pulse that occurs when propagating in water (non-linear propagation), although new standards are planned that will address this problem.

# 9. In-situ estimates of worst case exposure.

In some circumstances, the difference between in-water and insitu worst case values may not be very great. Carson et al (1989) estimated how small the attenuation might be between the probe and a fetal skull in the third trimester of pregnancy. He proposed the figure of 0.5 dB MHz-1 as representing this worst case (i.e. minimum path) attenuation. This would mean in-situ I<sub>SPTA</sub> values would be 70–60 % of in-water values, depending on the frequency (assumed in the range 3–5 MHz). In-situ p- values would be 80–70% of in-water values, recalling that intensity is proportional to the square of pressure.

In the first and second trimesters there is likely to be more tissue between the probe and the embryo or fetus, and a figure of 1.0 dB MHz-1 may be more appropriate as an estimate of minimum path attenuation (Whittingham 2001). This would mean in-situ I<sub>SPTA</sub> values would be 50–30 % of in-water values, and insitu p- values would be 70–50% of in-water values, for the same frequency range. Low frequency exposures, such as in CFM and Spectral Doppler modes would be affected less.

More typically, the differences between in-water and in-situ values will be greater. An attenuation figure of 3.6 dB MHz-1 has been reported by Siddiqi et al (1995) as being more representative of "typical" trans-abdominal obstetric scanning in the first and second trimesters. This implies in-situ intensities will be lower than in-water values by a factor of between 10 and 60 for frequencies between 3 MHz and 5 MHz. p- values will be lower by a factor of between 3 and 8 over the same frequency range.

#### **10. Historical perspective.**

Awareness of the substantial increase in outputs since the early days of ultrasound is crucial for the interpretation of the results of epidemiological studies. *Figures 3, 4 and 5* show the changes in p-,  $I_{SPTA}$  and power, respectively, over the last three decades (Whittingham 2000). *[figures 3, 4, 5]* 

Reported p- measurements have not changed over the years as much as those of  $I_{SPTA}$  and output power, although a slow but steady increase is evident in *Figure 3*.

 $I_{SPTA}$  values in early reports were several orders of magnitude less than current levels. In B-mode, for example,  $I_{SPTA}$  values are now up to 1000 times greater than those reported in the 1970s, A rapid increase has been particularly evident since the mid 1980s. Acoustic powers are up to more than 300 times greater than in the early 1970s, again with the biggest increase coming after the mid 1980s.

The early 1980s was a time of rapid growth in the use of realtime B-mode and Doppler. The accompanying technical developments, aimed at improving image quality and Doppler performance, are almost certainly responsible for these increases. However, some of the increases in reported output levels over the years may be due to improvements in measurement equipment and techniques, and to procedures for finding worst-case values.

 $I_{\text{SPTA}}$  values in B-mode have continued to increase over the last decade and are now generally higher than those of M-mode. This has been a consequence of efforts to improve temporal and lateral resolution by interrogating tissue regions more intensively. It may be noted that, prior to 1993, application specific upper limits on temporal average intensity were imposed in the United States. Since then the limits for all applications, including obstetrics, have been relaxed (FDA 1997) to that previously permitted only for peripheral vascular applications (720 mW/cm<sup>2</sup> derated), provided that the machine displays TI and MI values (see next section). This relaxation has also contributed to the increase in outputs over the last decade.

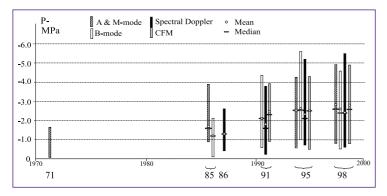
# 11. Thermal Index (TI) and Mechanical Index (MI) values.

These numbers are commonly displayed alongside the ultrasonic image or Doppler spectrum. They are not direct indicators of output pressures, intensities or powers, but rather guides to the physical consequences of the ultrasound exposure to the patient at the time. They are intended to assist the operator to make riskbenefit judgements and to apply the ALARA principle (As Low As Reasonably Achievable).

TI is intended to indicate the degree of tissue heating due to absorption of ultrasound energy. In effect it is an approximate estimate of the temperature rise that would be produced in a simple tissue model. It has three different forms according to the model assumed – TIS is for applications involving soft tissue only, TIB is for use where bone may be present, other than immediately below the surface, and TIC is for use where bone is very close to the probe. TI values of 6 or more can be generated by some equipment, particularly in Spectral Doppler mode, but more typical values are closer to 1.

TI values should be interpreted in the light of the recommendations on thermal effects published by WFUMB (1998) or the safety guidelines of other professional bodies (e.g. BMUS 2000). In so doing, operators should be aware that occasionally, for example where there is a low attenuation (e.g. liquid) path involved, the displayed TI value can underestimate the actual temperature rise by a factor of two or more. Furthermore, in practice, the probe itself can be a significant source of heat, and the TI takes no account of this.

The MI is an attempt to indicate the risk of cavitation. It is equal to the largest value of peak negative pressure (derated assuming a medium with an attenuation coefficient of 0.3 dB cm-1 MHz-1) divided by the square root of the frequency of the pulse. From theory, cavitation should not be possible if MI is less than 0.7 (Holland and Apfel 1989). The maximum value of MI that is allowed for machines seeking approval for sale in the United States is 1.9, irrespective of the application or the operating mode.



*Figure 3:* Reported worst-case values of peak negative pressure (p-) over the last three decades.

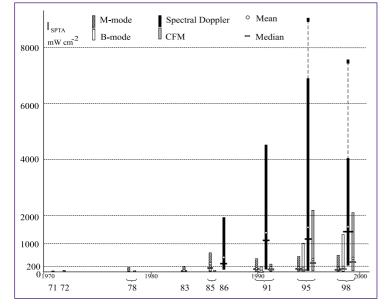
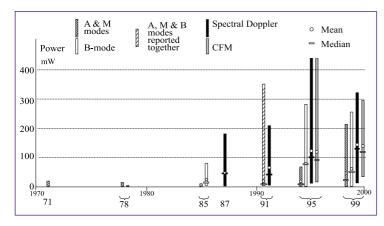


Figure 4: Reported values of worst-case ISPTA over the last three decades.



**Figure 5:** Reported values of worst-case acoustic power over the last three decades.

#### 12. Summary

The principal output parameters are peak negative pressure (p-), spatial peak temporal average intensity ( $I_{SPTA}$ ) and temporal average output power (W), The first is related to the risk of cavitation, while the other two are related to tissue heating.

Recent surveys of worst-case in-water measurements report p- values of around 2.5 MPa with maximum values of around 5 MPa, in all modes. Temporal average intensities and powers vary substantially between modes, being greatest for Spectral Doppler mode. However, there are large overlaps in the ranges for the different modes.

Measurements are made in water, but estimates of in-situ values can be made from these. In some circumstances the difference between in-situ and in-water values may be quite modest. "Derated" values give a rough estimate of in-situ values and are obtained by assuming a uniform medium, with a specified attenuation coefficient (often 0.3 dB cm-1 MHz-1).

In recent years, temporal average intensity and power values have been increasing most rapidly in B-mode. This is largely due to the more intensive interrogation associated with efforts to improve image quality.

Worst case  $I_{SPTA}$  and power values are now several orders of magnitude greater than in the 1970s, the most rapid increase occurring after the rapid growth of real-time scanning in the mid 1980s. Reported p- values have shown a more gradual increase. These large increases have important implications to the interpretation of the results of epidemiological surveys.

In the United States, and by implication elsewhere, there is a trend to relax limits on the basic acoustic output quantities and, instead, to transfer responsibility for limiting exposure to the operator. Onscreen TI and MI values are intended to assist in this regard, but it should be remembered that TI can underestimate the actual temperature rise by a factor of 2 or more in some circumstances.

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### **ECMUS LITERATURE REVIEWS**

Miller DL and Quddus J. Sonoporation of monolayer cells by diagnostic ultrasound activation of contrast-agent bodies. Ultrasound Med Biol 2000; 26: 661–7.

Miller DL and Quddus J. Lysis Sonoporation of epidermoid and phagocytic monolayer cells by diagnostic ultrasound activation of contrast agent gas bodies. Ultrasound Med Biol 2001; 27: 1107–13.

These two papers report in-vitro studies into the effects on human cells from exposure to pulsed ultrasound from a diagnostic scanner, in the prescence of the contrast agent Optoson<sup>™</sup>. Epidermoid A431 and phagocytic RAW-264.7 cells were grown as monolayers on 5 micrometer Mylar sheets. Optoson™, at concentrations up to 10%, was introduced into the exposure chamber, which was arranged with the cells on the upper surface. This allowed the contrast bubbles to rise and collect next to the cell monolayer. Sonoporation, that is a transient, non-lethal alteration in cell membrane permeability, was assessed using fluorescent dextran, and cell death was assessed using Trypan blue. Exposure was carried out using a clinical scanner with a 3.5 MHz transducer operating either in spectral pulsed Doppler mode, or in 2 D imaging mode. The rarefaction pressures ranged from 0.09 to 1.8 MPa, covering the normal diagnostic range. Exposure periods ranged from 4 s to 16 min. Cells were washed following exposure, and the percentage of fluorescent cells (or Trypan blue stained) were counted.

The reported threshold rarefaction pressure for significant lysis or sonoporation was 0.15 MPa, lying the range 0.09 to 0.23 MPa for all studies. For exposure at 3.5 MHz, this is equivalent to a Mechanical Index of 0.08 (range 0.05–0.12). For the highest exposure conditions, about 10% of the cell population were affected. The percentage related linearly to negative pressure up to about 1 MPa. The effect depended strongly on contrast concentration up to about 2%, with no obvious dependence above this concentration. Only weak dependence on pulse repetition and exposure duration was observed. The influence of phagocytic action of the RAW cells was investigated by first incubating and then rinsing the cells before exposure. Evidence for both increased sonoporesis and increased cell death was found, compared with results for epidermal cells, suggesting that phagocytic action can increase cell vulnerability.

These studies are significant because they report both sub-lethal and lethal effects on cells under exposure conditions, which lie well within the clinical range, including B-mode imaging, both for ultrasound exposure and contrast concentration. Extended sensitivity associated with phagocytic action is also noted. In order to relate these results to clinical practice, however, the usual caveats for relating in-vitro to in-vivo conditions must be considered. Nevertheless, all those using contrast agents clinically should be aware of the potential for cell membrane effects when contrast bubbles in contact with cells are activated by ultrasound. It should be noted that there is a wide range of contrast agents currently available, and any thresholds for lysis of sonoporation may be different from that reported here for Optoson<sup>™</sup>.

#### Herman B A and Harris G R. Theoretical Study of Steady-State Temperature Rise within the Eye due to Ultrasound Insonation. IEEE Transactions on Ultrasonics, Ferroelectrics and Frequency Control 1999; 46: 1566–1574.

This paper addresses the important question of whether the soft tissue thermal index TIS is appropriate for ultrasonic eye scanning. The authors used a simple model of a stationary ultrasound beam consisting of two cones aligned apex to apex, having uniform intensity within any cross-section. In the eye, curvature was ignored and a uniform thermal conductivity of 6.0 mW cm-1 oK-1 was assumed, as in the model used for the TIS formula. Attenuation coefficients were taken from published literature, and absorption coefficients were assumed to be equal to these. Perfusion was assumed to be negligible.

The maximum temperature rises that would be produced by a wide range of transducer output powers, diameters (2–10 mm), frequencies (7–40 MHz) and focal lengths (2–30 mm) were calculated. The acoustic output power from the transducer for each calculation was chosen such that the maximum derated spatialpeak temporal-average intensity ( $I_{SPTA}$ .3) was equal to the FDA regulatory limit of 720 mW cm-2. (In calculating  $I_{SPTA}$ .3, a uniform medium with an attenuation coefficient of 0.3 dB cm-1 MHz-1 is assumed.)

Calculated temperature rises ranged from 0.2 oC to 9.6 oC for exposures through the lens, and from 0.1 oC to 7.5 oC for exposures avoiding the lens. For each transducer, the calculated temperature rise was compared to the TIS value, calculated for the same output power and frequency, using the formula: TIS = Output power (mW) x frequency (MHz) / 210. The ratio of calculated temperature rise to TIS varied from 7.35 to 0.8 when the eye lens was included in the exposure, and from 4.1 to 0.4 when it was avoided.

As a special case, 2 MHz, 16 mm diameter, long focus (45–75 mm) transducers were also considered. These represented those sometimes used to measure intra-cranial blood flow via the eye and orbit. Intra-ocular temperature rises as high as 8.9 oC were calculated for exposure through the lens, and as high as 8.6 oC for exposures avoiding the lens. The ratio of maximum temperature rise to TIS covered a range from 7.3 to 7.6 via the lens and from 7.0 to 9.0 avoiding the lens.

The authors conclude that TIS is not adequate to predict temperature elevations in the eye. In consequence of these findings the Food and Drug Administration (FDA) in the USA, by whom both authors are employed, have modified their regulations for eye exposure. The 2 MHz results have led to a new regulation in the FDA guidance for ophthalmic use that TIS\_as must not exceed 1.0. TIS\_as is the same as TIS but uses the power through the central 1 cm of the transducer. The more general results have led to the introduction of a limit of 50 mW cm-2 for  $I_{\rm SPTA}$ . 3 for equipment intended for applications in the eye.

The analysis of the results is very comprehensive, perhaps overly so for the general reader. However, the paper is valuable on two counts. Firstly for the results on theoretical temperature elevation themselves; secondly for the insight it affords into the rationale behind the modifications to the FDA regulations. The choice of a stationary beam was sensible as this is the situation in Spectral Doppler mode, which is known to produce the greatest temperature rises. The assumption of continuous waves was also reasonable for the relatively long, narrow bandwidth pulses that are likely to be of interest. The assumption of a circular beam crosssection was not typical of clinical practice, since a linear array probe produces beams of rectangular cross-section close to the probe, the region where the authors found maximum temperature rises occurred. Real beams also have a non-uniform intensity profile across the beam cross-section.

It would be interesting to repeat this exercise with more realistic models for the beam and the eye, and to include scanning modes such as B-mode and colour Doppler imaging. However it would be surprising if the results changed the basic finding that TIS is not adequate to estimate temperature elevation in the eye. As the authors themselves suggest, there is a need for a new thermal index that would be more suitable for this application.

## **ECMUS LITERATURE REVIEWS**

Miller DL and Quddus J. Diagnostic ultrasound activation of contrast agent gas bodies induces capillary rupture in mice. Proc Nat Acad Sci 2000; 97: 10179–84.

The authors of this paper set out to confirm and extend an earlier study (1) reporting micro-vascular damage in mammalian tissue from pulsed ultrasound exposure in the prescence of a gasfilled contrast agent. The present authors exposed anaesthetised mice to 2.5 MHz pulses from a commercial scanner operating in imaging mode, after injection of a contrast agent (Optison<sup>™</sup>) and Evans blue dye. Subsequently abdominal muscle and intestine were examined for petechial haemorrhage and for evidence of Evans blue extravasation.

Robust evidence was obtained for both petechiae and haemorrhage at high contrast dosage (5 ml/kg) after 10 s imaging sequences. Petechiae formation depended on contrast dose, and was statistically significant above sham even at the lowest dose used, 0.05 ml/kg. The lowest level lies within the range that is used clinically. Petechiae formation in muscle depended approximately on acoustic pressure squared, and was statistically significant above 0.64 MPa. The threshold was slightly higher (1 MPa) for petechiae in intestine, and extravasation in muscle. All effects were essentially absent if exposure to ultrasound was delayed 5 minutes after contrast injection. There was evidence for petechiae in muscle following exposures of as little as a single frame.

This paper is very important in that it gives further clear documentary evidence confirming that pulsed ultrasound exposure of tissues in vivo in the prescence of contrast agents gives rise to micro-vascular damage. Furthermore, this can occur as a result of only a single frame of B-mode, and at pulse amplitudes well within the diagnostic range. No evidence is given for the dependence on frequency of the effect. Nevertheless, the MI threshold (about 0.4) is very close to that reported by Skyba et al (1) working at a slightly higher frequency (3.5 MHz). The extrapolation from animal studies to humans is uncertain. Nevertheless, prudent caution is advised for all those using contrast agents, who must consider the strong possibility that diffuse microvascular effects may be induced throughout the tissue examined.

1. Skyba DM, Price RJ, Linka AZ, Skalak TC, Kaul S. Direct in vivo visualization of intracellular destruction of microbubbles by ultrasound and its local effects on tissue. Circulation 1998; 98: 290–3.

#### Wouw PA, Brauns A, Bailey S, Powers JE. Premature ventricular contractions during triggered imaging with ultrasound contrast. J Am Soc Echocardiogr 2000; 13: 288–294.

In a phase I trial of a new ultrasonic contrast agent based on albumin coated air microbubbles, premature ventricular contractions (PVCs) had been observed during its continuous intravenous infusion. The present paper investigated the occurrence of PVCs further and conducted two studies in 19 young healthy male volunteers. A commercial ultrasound machine was used, with a frequency of 1.66 MHz. In the first study, three different doses of contrast agent were continuously infused over 20 minutes, containing between 25 x 106 and 750 x 106 microbubbles/min; no exact data are provided. Two different mechanical indices (MI) were used: 1.1 and 1.5. The latter was the maximum attainable in the machine. End-systolic and end-diastolic images were obtained and stored on tape to investigate the occurrence of PVCs. In the second study, volunteers received a continuous infusion of 500 x 106 microbubbles/min for 25 minutes. After the infusion, 3 boluses of 500 x 106 microbubbles/min were injected. Endsystolic and end-diastolic imaging were again used to detect the number of PVCs. Adequate controls were included in both studies to assess the base PVC rate and the occurrence of PVCs without contrast agent.

The major finding was the occurrence of premature ventricular contractions due to ultrasonic imaging in the presence of ultrasonic contrast agent. More specifically:

- 1. Almost all PVCs (944/967=97.6%) were recorded when performing end-systolic imaging with an MI of 1.5. There was no PVC increase over baseline with end-systolic imaging at an MI of 1.1, nor with end-diastolic imaging at either MI.
- 2. More PVCs were seen in the first study when a high dose of the contrast agent was infused.

In conclusion there was a clear causal role of contrast agent dose and MI in the generation of  $\ensuremath{\mathsf{PVCs}}$ 

#### Comment

The study has to be viewed in the context of the finding of several groups that ultrasonic contrast agents produce petechial bleedings. It is tempting to think that micro-vessel rupture in the heart may be associated with the reported PVC occurrences. Some future study should try to demonstrate this by re-transfer of the human to the animal situation. The authors discuss the contribution of cavitation as the most likely mechanism of PVC generation. They hypothesise that a threshold amount of cavitation or contrast agent microbubble destruction is needed to generate a PVC. It would have been valuable if they had explored this further by comparing the effects of different doses of contrast agents.

The impact of this study might be great. It is of note that the finding was obtained in a human study. It has been discussed for decades that transfer of findings obtained in animal models to humans is of unclear significance. The paper is a clear example that this is possible.

The finding is of concern and might have long term sequelae. One of these might be, for example, a recommendation that PVCs should not become a routine occurrence at echocardiography with an ultrasonic contrast agent. A more conservative approach could, perhaps, be taken by manufacturers – they might state in their product information whether there can be induction of PVCs in humans when used under defined conditions. This might be avoided by using a lower MI and a smaller dose.

#### Kramer JM, Waldrop TG, Frizzell LA, Zachary JF, O'Brien WD. Cardiopulmonary function in rats with lung haemorrhage induced by pulsed ultrasound exposure. J ultrasound Med 2001; 20: 1197–1206.

Lung haemorrhage was induced in rats by exposing the organ to high pressure ultrasonic pulses. Thirty minutes after sound exposure, the standard physiological parameters heart rate, blood pressure, respiratory rate and blood gases were determined and the experiment was terminated. The pulmonary volume affected by haemorrhage was quantified.

A 5 cm diameter, 3.1 MHz ultrasonic disc with -6 dB beamwidths of 610 micrometers on the rotational axis and 5.9 mm on the longitudinal axis was aimed through the chest wall to the lung surface. It generated pulses of 1.3 µs duration with a peak focal pressure of 45 MPa and a peak rarefactional pressure- of 20 MPa; these data were obtained with a PVDF hydrophone before derating. The MI was 5.8. In one group of rats, a single lung was exposed to five foci positioned along a line. At 1.7 kHz pulse repetition, each focus was exposed for 60 seconds. Haemorrhage comprised 3% of the volume of the lung, and there was no change of haemodynamic parameters. In another group of rats, both lungs were exposed according to this protocol. Haemorrhage comprised 8% of the lung volume, and there was a drop of blood pressure and change of blood gases.

Lung haemorrhage by diagnostic ultrasound has been reviewed in several previous ECMUS Literature Reviews during the last years. This study's exposure parameters are far beyond the values employed for diagnostic ultrasound; ultrasound safety was not a concern. One is tempted to doubt the output data of the transducer since today, the way the peak rarefactional pressure was determined has been replaced by a more accurate protocol. The authors do not explain why they performed this study. It is known for more than a century from tuberculous disease and miners' lung that structural lung damage leads to functional impairment. No exception from the rule was expected in this study.

# **REPORT FROM 14TH EUROSON'2002** AND 6TH CONGRESS OF POLISH ULTRASOUND SOCIETY

EUROSON'2002 took place from 4th–7th July 2002 in the Congress Venue "Gromada" in Warsaw, Poland. EUROSON Congresses usually take place jointly with Scientific Congresses of the host Ultrasound Society. EUROSON'2002 was organized together with 6th Congress of Polish Ultrasound Society. Over a thousand doctors from 39 countries from all continents participated in the Congress. A number of participants were from former Soviet Union Countries which was one success of the Congress. 250 papers were presented in plenary and poster sessions. Eight workshops in English were organized: Fetal Echocardiography, Endosonography, and Ultrasound in Male Infertility, Echocardiography, Ultrasound in Sports Medicine, Ultrasound of Carotid Arteries, Laparoscopic and Intraoperative Ultrasound, and Ultrasound in Menopausal Women.

4 workshop sessions in Polish were organized covering Abdominal Ultrasound, OB/GYN Ultrasound, Ultrasound in Laryngology, Pediatric Ultrasound, Genito-Urinary Ultrasound, Ultrasound Contrast Agents, and Ultrasound in Prenatal Care. Both plenary sessions and workshops had a high scientific content.

EUROSON'2002 hosted top ultrasonographers from Poland and the world.

The Congress was opened by Prof Michel Claudon, EFSUMB President and Prof Wieslaw Jakubowski, President of Polish Ultrasound Society in the presence of many distinguished guests.

The highest scientific level was represented by the Safety Session organized by EFSUMB together with World Federation for Ultrasound in Medicine and Biology (WFUMB).

The EUROSON Lecture "Working towards the Boundaries of Safety" was presented by Professor Francis Duck from United Kingdom.

The full day session on Breast Ultrasound was organized on 4th July, 2002 by International Breast Ultrasound School (IBUS) chaired by Professor Jack Jellins.

Over 400 doctors participated in IBUS. The lecturers were: Prof. Jack Jellins, Prof. Dominique Amy, Prof.Joachim Hackelöer, Prof. Michel Teboul, Prof. Ivo Drinkovic, Prof. Enzo Durante, Prof. Christian Weissmann, Kazimierz Szopinski MD, Ph.D.

50 firms and manufacturers were presented on EUROSON'2002 including the leaders of world markets.

The President of Poland Mr Aleksander Kwasniewski was Honorary Patron.

Honorary Memberships of Polish Ultrasound Society were presented during Opening Ceremony of the Congress to the following outstanding representatives of world ultrasound: Prof. Michel Teboul from France, Prof. Ivo Drinkovic from Croatia, Prof. Joachim Hackelöer from Germany, Prof. Jack Jellins from Australia, and Prof. Hiroki Watanabe from Japan.

The concert and show of Polish folk dances from Warsaw Technical University took place during Opening Ceremony of the Congress. An interesting social program was included in the Congress. A Garden Party in the gardens of Wilanow took place on the evening of 5th July, 2002. It was outstanding, with glorious weather, intelligent and skillful cabaret and delicious catering from the Restaurant Belvedere.

Restaurant Belvedere also hosted the Gala Dinner on the evening of 7th July, 2002. Exquisite atmosphere was added by the Operetta Star Grazyna Brodzinska. It was a most elegant evening.

At the EFSUMB Board of Director's meeting, Prof Kurt Jäger succeeded Prof Michel Claudon as President of EFSUMB.

In the opinion of the participants of the Congress, EUROSON'2002 was a most successful scientific and social meeting. Polish Ultrasound Society received many congratulations and words of thanks from all over Europe as well as Polish participants.

Dreams and tasks of the organizers were fulfilled by a scientific meeting with good organization, high scientific level and traditional Polish hospitality.

The Polish Ultrasound Society would like to thank all the firms and institutions for their help in the Congress.

Professor Wieslaw Jakubowski President of Polish Ultrasound Society

# MSc in Medical Ultrasound Full-time/Part-time

(specialising in echocardiography, general ultrasound, physics or vascular ultrasound) – Imperial College School of Medicine – Hammersmith Campus



Applications are invited for a full-time one year, or part-time two year course in diagnostic medical ultrasound, specialising in echocardiography, general ultrasound, physics or vascular ultrasound, and leading to the University of London MSc degree in Medical Ultrasound. The course will commence in October 2003, and will provide clinicians and medical scientists with intensive training in both the theoretical basis of the

subject and the required scanning and diagnostic skills. The faculty will include many internationally recognised experts in medical ultrasound.

The aim of the course is to provide a solid basis in the subject for a range of careers in medical ultrasound including research, investigative services or teaching.

The course comprises lectures, seminars, practical demonstrations and training and includes a research project, which will be designed to allow the student to make an original contribution in the chosen area of research. Current research studies are in the uses of contrast agents, three and four-dimensional imaging and image and signal processing. The course will be suitable for applicants with first degree or equivalent in medicine, biological, engineering or physical science or other appropriate subject. Previous experience in medical ultrasound would be an advantage.

Informal enquiries to Mr. K. Humphries (Tel. +44 (0)20 8383 2210; email: k.humphries@ic.ac.uk),

Professor D. Cosgrove (d.cosgrove@ic.ac.uk) (general ultrasound), Dr. P. Nihoyannopoulos (petros@ic.ac.uk) (echocardiography) or Dr. M. Aslam (maslam@hhnt.org) (vascular ultrasound) are welcomed. Applications for admission to the course should be made as soon as possible.

Application packs and further details are available from: Imperial College of Science, Technology & Medicine, Registry, South Kensington Campus, Level 3, Sherfield Building, Exhibition Road, London, SW7 2AZ, Tel: +44 (0)207 594 8089, Fax: +44 (0)207 594 8004, Email: pgmedreg@ic.ac.uk Further information on postgraduate study can be found on the ICSM web site at <u>http://www.med.ic.ac.uk</u> Application forms can also be downloaded from <u>http://www.ad.ic.ac.uk/registry/pgap</u>



# **16th EUROSON CONGRESS** 6 – 9 June 2004 – Zagreb / Croatia

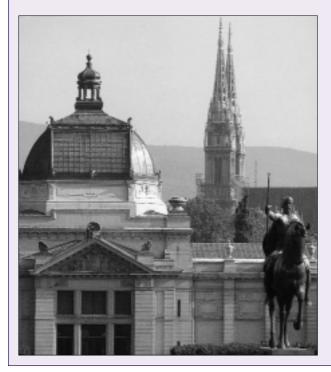
#### Dear Colleagues,

On behalf of The Croatian Society for Ultrasound in Medicine and Biology, I have the great pleasure in inviting all involved and interested ultrasound societies to Zagreb, the capital of the republic of Croatia, where we will host the XVIth Congress of the European Federation of Societies for Ultrasound in Medicine and Biology.

Zagreb, your host city, has developed out of the thousand year old medieval market place and ecclesiastical centre of North-western Croatia. Its geographical position at the cross-roads of trade routes and its turbulent past have made Zagreb an important cultural and scientific centre, an economic centre, a traffic cross-roads, and the capital of Croatia.

Come and share with us your recent research achievements, your clinical experiences, and the pleasure of your company. The local organizing committee, the University, and the City of Zagreb will be honoured to be able to provide you with Croatian hospitality and look forward to giving you a warm welcome and a memorable congress.

	Congress Presidents Kurt Jäger (EFSUMB) Ivo Drinković (CSUMB)	Honorary Presidents Vida Demorin Asim Kuriak
Congress Venue:		f the city combining luxury and style, and is an five-minute walk from the city centre and shop-
Call for Papers:		form, together with a call for papers and abstract uncement, which will also contain detailed in-
Scientific Programme:	Four days of parallel sessions, including satel forums and poster sessions.	lite symposia, educational meetings, discussions
Congress Language:	Official language will be English. No simulta	aneous interpretation will be provided.
Official Carrier:	Croatia Airlines will support EUROSON 2004 in flying to Zagreb on domestic and internation	n Zagreb and offers special rates to all delegates nal Flights





Appointed Congress Organiser HKQ\_MEDICAL SYSTEMS LASCINSKA CESTA 94 HR - 10000 ZAGREB TEL: 00 385 1 234 76 61 FAX: 00385 1 234 76 63 EMAIL: congress@hko.hr WEBSITE: http://www.euroson2004.com

# **EUROSON SCHOOL**

### **EUROSON SCHOOL** on 3D ULTRASOUND IMAGING 2 - 4 APRIL 2003

The British Medical Ultrasound Society and Imperial College Faculty of Medicine, Hammersmith Hospital are jointly running a three-day EUROSON SCHOOL on 3D Ultrasound Imaging. The course is a combination of lectures, demonstrations and practical sessions and is designed to cover both the basic principles of these techniques and a review of the current state of 3D & 4D applications and developments in Echocardiography, Abdominal/Small Parts, Obstetrics & Gynaecology and Vascular Ultrasound

#### **SCIENTIFIC PROGRAMME**

#### Wednesday, April 2nd.

- Basic Theory and Practice
- Welcome and Introduction 08.45
- Fundamentals of 3D imaging 08.50
- 09.30 Position sensing devices
  - Electromagnetic sensors
    - Mechanically driven arrays
  - Correlation techniques
- 10.45 3D Surface and volume rendering techniques
- 11.15 The Stradx 3D imaging system
- 11.40 Volume measurements
- 12.00 Practical Session I: System Demonstrations 13.00

#### Lunch/Exhibition Cardiovascular Applications

- 14.00 3- and 4D cardiovascular imaging techniques
- 14.45 Transoesophageal imaging
- 3D vascular ultrasound imaging 15.10
- 16.10
- 3D ultrasound in the Evaluation of Fetal malformations.
- 16.35 3D/4D Obstetric Imaging: Case studies Practical Session II: Cardiovascular 17.00
- 19.00 **Course Dinner**

### Thursday 3rd April.

- General
- 09.00 3D surgical applications 3D applications in Gasteroenterology 09.45
- 10.30
- 3D oral-maxillary imaging
- 11.30 Practical Session III: Abdominal and small parts 12.45 Lunch/Exhibition
- Small Parts
- 14.00 3D endoanal sonography
- 14.30 Prostate
- 15.30 Breast tumour neovascularization
- 16.15 Breast Imaging
- Practical Session IV: Abdominal and small parts 16.45

#### Friday 4th April.

#### Obstetrics

- 09.00 3D/4D Obstetric imaging
- 4D Fetal Echocardiography 10.00
- Volume sonography of fetoplacental vessels 11.00
- 11.30 Volume sonography of the pelvic floor after childbirth.
- 12.00 Practical Session V: General
- Lunch/Exhibition 13.00 Gynaecology
- 3D Gynaecological Imaging: Uterus & Fallopian tubes. 14.00
- Gynaecological malignancies: 14.30
- Diagnosis and Therapy Planning 15.15 Multiple Choice Examination
- 16.00 Course closes

#### For further details and registration forms please contact:

Secretariat: HITEC (Hammersmith Hospital), Du Cane Road, London W12 OHS, UK. Tel: +44 (0)20 8383 1601 Fax: +44 (0)20 8383 1610 E-mail: hitec@hhnt.org

#### EFSUMB – SRUMB

### **EUROSON SCHOOL** in INTERVENTIONAL ULTRASOUND **CONSTANJA – ROMANIA** 17-18 MAY 2003

#### Lecture topics include:

- · Percutaneous ultrasound guided biopsy of the liver and other organs (tumors, collections)
- · Percutaneous ultrasound guided treatment of liver diseases
- · Ultrasound guided maneuvres in urology
- · Complications of interventional ultrasound
- · Breast interventional ultrasound
- Musculo-skeletal interventional ultrasound

#### Contacts:

- For scientific information: isporea@excite.com
- Local organizing committee: edumitru@romhealth.ro

### **SONOGRAPHIE IN DER GASTROENTEROLOGIE** 3-5 JULY 2003 SIGMARINGEN, GERMANY

PD Dr. K. Seitz, Sigmaringen Prof. Dr. H. Lutz, Bayreuth

#### Applications to:

PD Dr. K. Seitz Kreiskrankenhaus Sigmaringen Hohenhollernstr. 40 D-72488 Sigmaringen Tel: (07571) 1 00-22 92 Fax: (07571) 1 00-22 83 klksiginn@t-online.de F-Mail: Information: http://www.sonoweb.de

# A CALL FOR HELP

## **ARE THERE ANY WEBMASTERS WILLING TO UPDATE THE EFSUMB WEBSITE?**

#### **VOLUNTEERS PLEASE CONTACT:**

Gianna Stanford, General Secretary EFSUMB, Carpenters Court, 4a Lewes Road, Bromley, Kent BR1 2RN, UK +44 (0)20 8402 8973, Tel: Fax: +44 (0)20 8402 9344 Email: efsumb@efsumb.org

#### "Vascular Medicine 2003"

Congress of the European Chapter of the International Union of Angiology, of the European Federation of Ultrasound in Medicine & Biology and of the French Society of Vascular Medicine.

Dates: October 8–10, 2003

Place: Toulouse, France, Centre de Congrès Pierre Baudis

#### Scientific organization:

Pr. BOCCALON H., Dr. LEGER Ph.CHU Rangueil, Dept of Vascular Medicine 1, Av. J. Poulhès, TSA 50032, 31059 TOULOUSE Cédex 9 (France) Tel: (33) 5-61-32-24-38 Fax: (33) 5-61-32-26-34 E-mail: cgvasc03@chu-toulouse.fr

#### General information:

EUROPA ORGANISATION 5, Rue Saint Pantaléon, BP 844, 31015 TOULOUSE Cédex 6 (France) Tel: (33) 5-34-45-26-45 Fax: (33) 5-34-45-26-46/47 E-mail: europa@europa-organisation.com Congress web site: http://www.medvasc-2003.com

#### Deadline for abstracts: April 30, 2003.

Topics:

- Quality control of ultrasound exams in vascular pathology at the level of peripheral arteries and veins, visceral arteries and veins, renal arteries, cerebro-vascular system.
- Vascular emergencies
- \* Education session on the haemorragic risk and biological supervision of anti-thrombotic drugs: antiagregants, anti-vitamins K, low molecular weight heparins, anti-thrombins.
- Pulmonary embolism.
- State of the art in imaging of aorta and its proximal branches.
- Stroke centers
- · Hormonal replacement treatment
- Therapeutic education
- Laser doppler: clinical applications
- Vascular centers
- Risk factors and secondary prevention of arteriopathy
- Diabète and Vascular Medicine
- Up-to-date in non invasive diagnosis: peripheral arteriopathies and diagnosis assessment.
- CoCaLis study
- Practical workshops of vascular technicians
- Pratical workshops of medical training for vascular physicians
- Eudcation program of patients with anti-vitamins K.
- Evaluation of arterial stiffness and role of echography
- Free papers
- Competition for the I.U.A. Prizes
- · Competition of the Poster Prizes.

#### **CONTENTS OF EJU** VOLUME 16 – ISSUE 1–2 NOVEMBER 20

Update in Transcranial Doppler Sonography and functional testing Transcranial Doppler Assessment of cerebral vasospasm R Aslid (USA) Clinical impact of patent foramen ovale diagnosis with transcranial Doppler G P Anzola (Italy) Microembolus detection by transcranial Doppler Sonography R Dittrich, M A Ritter, D W Droste (Germany) Cerebral autoregulation studies in clinical practice R R Diehl (Germany) Clinical applications of a non-invasive ICP monitoring method B Schmidt, J Klingelhöfer (Germany) Update in Transcranial Color-Coded Duplex Ultrasonography (TCCS) The axial imaging plane - the main domain of the transcranial color-coded duplex ultrasonograpy E Bartels (Germany) Transcranial ultrasonography of cerebral veins and sinuses S J Schreiber, E Stolz., J M Valdueza (Germany) Sonographic imaging of the brain parenchyma S Behnke, G Becker (Germany) Impact of ultrasound contrast agents in cerebrovascular diagnostics G Seidel, K Meyer (Germany) Brain perfusion and ultrasonic imaging techniques J Eyding, W Wilkening, T Postert (Germany) Neurosonology in Stroke prevention and diagnostics Clinical impact of intima media measurement P-J Touboul (France) Design of a multicentre study on neurosonology in acute ischaemic stroke: A Project of the Neurosonology Research Group of the World Federation of Neurosonology M Goertler, J Allendoerfer, G-M von Reuterns, The Neurosonology in Acute Ischaemic Stroke (NAIS) Study Group (Germany) Theraupetic ultrasound in ischemic stroke treatment:experimental evidence M Daffertshofer, M Fatar (Germany) Ultrasound-enhanced thrombolysis for stroke: clinical significance A V Alexandrov (USA) EJUS – Papers for Final Issue (Vol 16 issue 3) Incoherent imaging using continuous wave ultrasound. A preliminary study using bovine intervertebral discs. Dr. H-D Liang Heating caused by selected pulsed doppler and physiotherapy ultrasound beams measured using thermal test objectives. Dr T J Atkins The gender of the examiner, the state of the pregnancy and women's perception of transvaginal sonography in he first trimester. Dr. F.M. Salih Basama The diagnostic value of levovist in doppler imaging af visceral arteries in patients with abdominal angina before and after angioplasty. Dr. A. Drelich-Zbroja Sonographic diagnosis of hydatidosis: the sign of the cyst wall. Dr. M. Caremani The value of intraoperative ultrasound durning hepatic resection compared with improved preoperative magnetic resonance imaging. Dr. R. Conlon Reducing inter-observer variation in thyroid volume calculation using a new formula and technique. Dr. W. Shabana, Dr. E.Y. Peeters Diagnostic value of high-resolution B-mode and power-mode sonography in the follow-up of the thyroid cancer. Dr. R. Gorges Color doppler sonography in hypothyroidsm. Dr. S.L. Schulz Effect of hypertension and candesartan on the blood flow velocity of the extraocular vessels in hypertensive patients. Dr. A. Ahmetoglu Control ststem analysis of visually evoked blood flow regulation in humans under normocapnia and hypercapnia. Dr. B. Rosengarten, Dr. M. Kaps Ultrasonographic analysis plaques in the internal carotid artery. Dr. D. Christian, Prof. Dr. W. Lang The role of ultrasound in biliary and pancreatic diseases. Dr. L. Gandolfi

Case report: An unusual presentation of neonatal adrenal. Dr. J. O'Neill

# **15TH EUROPEAN CONGRESS OF** Ultrasound FIRST JOINT SCANDINAVIAN MEETING 27-30 April 2003 - Copenhagen

# CALL FOR PAPERS

# Pre-congress Courses and Workshops

DEADLINE FOR ABSTRACT

16 January 2003

Deadline for the Low Registration Fee: 16 January 2003

DEADLINE FOR THE LOW

PRESENTING AUTHORS:

1 April 2003

1 April 2003

CONGRESS DATES:

27-30 April 2003

Sunday 27 April 2003

CITY HALL RECEPTION

Monday 28 April 2003

CONGRESS DINNER Tuesday 29 April 2003

"IBUS - International Breast Ultrasound Seminar"

# MAIN SPONSORS



# **CONGRESS SECRETARIAT**

#### REGISTRATION FEES (IN EURO AND PER PERSON): Presenting authors Before 1 April 2003 € 300 Residents < 35 years, Sonographers, Midwives, Nurses EFSUMB-members Before 16 January 2003 € 300 Between 16 January and 1 April 2003 € 400 Non-momhor Refere 16 January 2002 £ 350

AULI-IIIGIIIDEI2	before to terrulary 2005	6 330
	Between 16 January and 1 April 2003	€ 450
Other Participants EFSUMB-members	Before 16 January 2003	€ 400
Non-members	Between 16 January and 1 April 2003 Before 16 January 2003 Between 16 January and 1 April 2003	€ 500 € 450 € 550
All Participants	After 1 April 2003/On site	€ 590
Accompanying pers	ons	€ 100

Accompanying persons

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