

# Safety Issues for HIFU Transducer Design

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**Abstract.** In contrast with most ultrasound modalities for medical applications, (especially ultrasound imaging), High Intensity Focused Ultrasound (HIFU) involves technologies and procedures which may present risk to the patient. These risks, resulting from the high power levels required for effective therapy, should be taken into account at the earliest stages in the design of a system dedicated to HIFU treatment. An understanding of these risks must thus be shared amongst the many players in the field of therapy using high power ultrasound. Moreover, since the number of applications of HIFU has increased appreciably over recent years and the technology is ready to move from the research to the industrial level, it is worth now considering solutions that should be put in place to guarantee the safety of the patient during HIFU treatment. This paper reports thoughts on this, and identifies some risks to the patient that must be taken into consideration in the design of HIFU transducers, and proposes some solutions that could prevent the deleterious consequences of transducer misuse or failure. For the main risks identified, such as exceeding the desired acoustic power or poor control of tissue targeting, a description of transducer performance that could potentially result in problems is systematically sought. This allows proposals for precautions to be taken during operation to be made. Parameters which should be monitored to ensure safe use are also suggested.

This type of approach, which should be undertaken for the different components of a therapeutic system, highlights the challenges that must be faced in the immediate future for the development and safe exploitation of HIFU systems. The necessity for standard definitions of the parameters to be checked or monitored during HIFU treatments is crucial in this approach, as is the availability of reliable dedicated measurement devices. Co-ordinated action on these topics in the HIFU community would contribute to the demonstration of the safe use of high power ultrasound in therapy, thus enhancing the chance of its recognition by medical and institutional organisations.

## INTRODUCTION

HIFU has proven to be a very promising method for treating many cancers [1], including those of prostate [2][3], breast [4] and liver [5]. However, compared with ultrasound modalities such as medical imaging, the deleterious consequences of improper use of HIFU are much greater due to the energy levels necessary for effective treatment.

Today HIFU moves from research to industrial level: precautions usually taken into account in research applications have to be translated into industrial and medical

tools/requirements (devices, procedures,...) to prevent risks and to guarantee safe widespread medical practice. So far, in order to reduce the risks inherent in HIFU treatments, research has been aimed at better understanding the interactions between HIFU and biological tissues. For examples, the roles on lesion development of non linearity, cavitation or temperature related variation of acoustic properties of tissues have been studied [6], [7] and [8]. In this paper, we focus on transducer design aspects and safety considerations which are specifically linked to the ability of HIFU transducers to generate high power density [9]. These are important for all HIFU users from the technologist to the clinician.

Our approach is to use the methodology of Failure Modes and Effects Analysis (FMEA [10], [11]) to analyse, prioritize and mitigate potential failures and to ensure that any failure that could occur will not injure the patient. FMEA is structured as follows: 1) failure identification and description (what might go wrong? what might cause it to go wrong?), 2) analyse of the risk (what effect would it have?), 3) definition of a prevention plan (what can be done?).

In the case of HIFU transducer design, the following failure modes are considered: over- (or under-) estimation of acoustic power, lack of control of the acoustic beam, lack of localization of the targets to be treated, transducer damage or failure, and error in operation. For each mode of failure, possible causes are sought out and suggestions are made for their prevention. The important challenges for the prevention of risks in HIFU system development are then summarized.

## **1/ OVER- (OR UNDER-) ESTIMATION OF ACOUSTIC POWER**

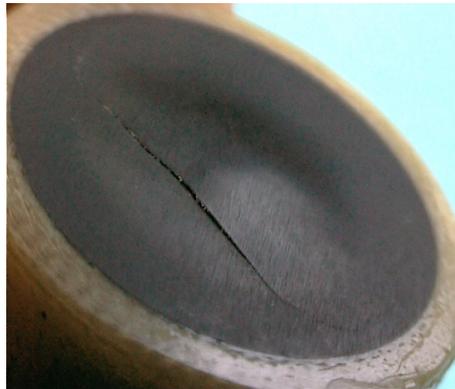
### **Excessive Acoustic Power**

A major risk in HIFU treatment is the over-exposure of the patient to ultrasonic power with the possible creation of lesions larger than expected, and of cavitation occurrence making lesions difficult to predict, and burns at interfaces.

When the unpredicted high acoustic power is due to an excess of electrical power input to the transducer, this may also lead to transducer overheating and thus its possible destruction (see Fig.1 for instance). This may happen if the current, voltage, or overall transmitted electrical power is not controlled during the treatment for each transducer used. For instance a defective channel in an array driven only with global control of electrical power may cause an increase in the electrical power applied on the other elements. Another risk is offered by inefficient control of the variation of the duty cycle (ON/OFF ratio). This may lead to longer or shorter excitation times for the transducer.

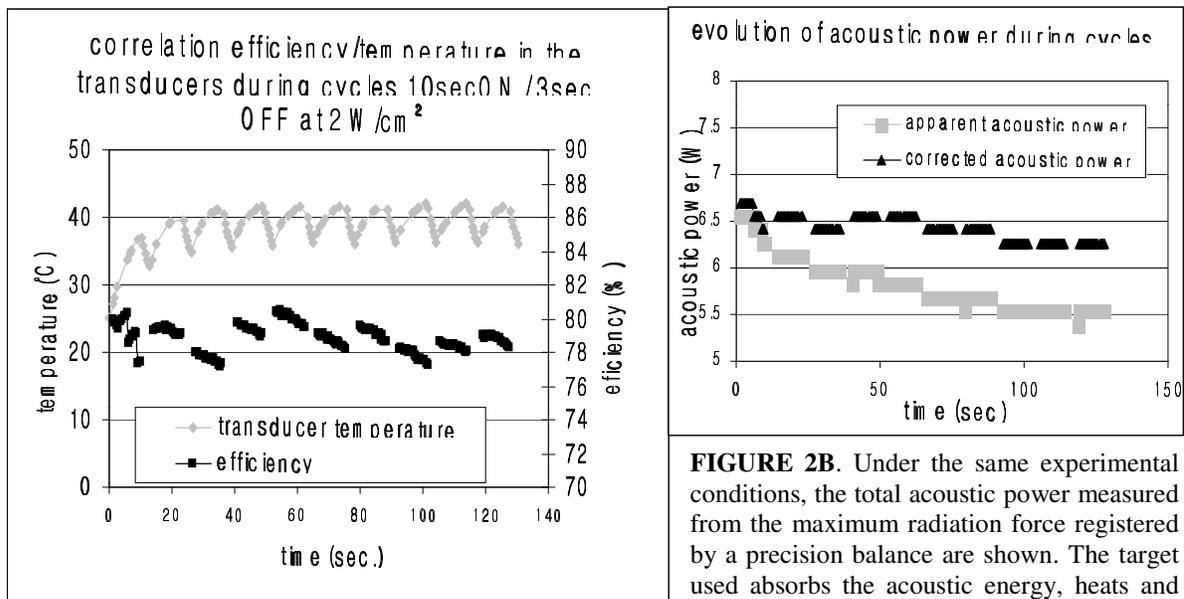
Excessive production of acoustic power can also arise from a failure to appreciate the efficiency of the transducer. This can result from initial measurement errors during the calibration of the system. Acoustic power is often difficult to estimate especially in high overall power (some hundreds of Watts) situations. Another source of error might be a change in the electrical impedance due to the transducer heating which might result in better electrical matching of the transducer with the transmitter. This would

mean that more acoustic power than predicted would be produced for a given available electrical power out of the emitter. This is particularly risky when the impedance, or the transmitted electrical power, is not controlled during operation.



**FIGURE 1.** Cracked transducer front face due to an excessive applied power (about twice the maximal acceptable excitation level)

There are many solutions to mitigate the risks of over-exposure. At a general level, the first requirement is the development of more traceable means and methods for acoustic power measurement (Fig.2b) at high intensity levels. More specifically it seems essential to control the temperature rise in and around the transducer and to define a threshold to guarantee a safe operation (Fig.2a). Solutions to limit heating can also help the control of the therapy. A cooling system for the transducer and its



**FIGURE 2A.** Variation of transducer temperature and efficiency during 10 excitation cycles at 2 W/cm<sup>2</sup> with a duty cycle of 77% (10secON / 3secOFF). This test was performed on a non focused 20mm diameter transducer. The variations of the efficiency during excitation periods are correlated with the variations in temperature. Neglecting these variations leads to uncertainty in estimating the acoustic power produced.

**FIGURE 2B.** Under the same experimental conditions, the total acoustic power measured from the maximum radiation force registered by a precision balance are shown. The target used absorbs the acoustic energy, heats and expands. The values obtained can be corrected by taking into account the effect of the expansion (black curve). This shows the stability of the output power during an excitation period (the variation is less than measurement precision) and the slight variation during the test, correlated with the transducer temperature increase.

environment should be considered. Other parameters to be controlled during a HIFU session are the reflected or (preferably) the transmitted electrical power on each channel of the system or the variation in electrical impedance of each transducer.

### Reduced Acoustic Power

There is also risk associated with the required power levels not being reached, leading to the failure of treatment.

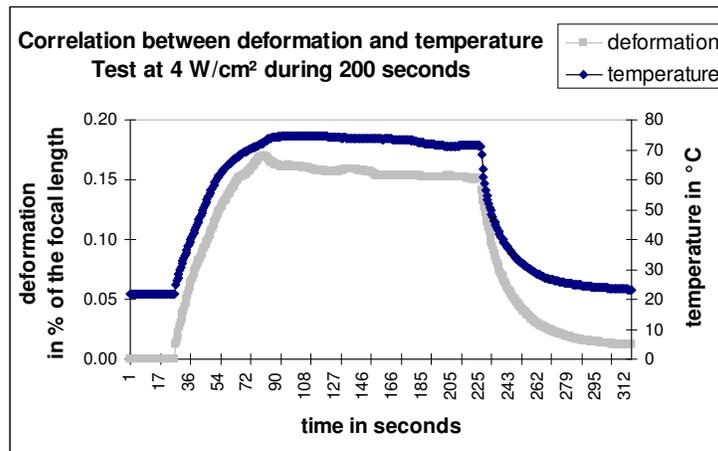
The reasons for this are the same as those for excessive power. In addition, transducer ageing may result in a loss of efficiency. Furthermore, deficient coupling of the transducer with the medium can create reflections at the interface and thus reduce the amount of acoustic power available in the treated area.

Among the potential solutions for reducing these kinds of risk are those described above for the risk of excessive power, but also regular verification of the equipment, including the periodic calibration of the transducer. Procedures must be defined and equipment developed to enable efficient, easy and cost effective verification, preferably on site and, when possible, before each therapy session.

## 2/ CONTROL OF THE ACOUSTIC BEAM

Once the acoustic power level of the transducer is controlled, it is essential to ensure that the generated power is used to deliver the required treatment. Lack of control of the energy distribution and location of the acoustic beam can lead to tissue destruction in unwanted locations or can reduce the efficacy of treatment. Different sources of error cause this.

Firstly, reversible or irreversible deformation of the active surface, due for instance to thermal expansion or thermo-mechanical distortion following excessive heating of the transducer can modify the focal distance, and thus the location where tissues are destroyed (see Fig.3). The energy density at focus is also changed and thus the time necessary to initiate a lesion in tissue as well as the appearance of cavitation bubbles.



**FIGURE 3.** Variation of temperature and deformation of the front face of a focused transducer (Fnumber close to 1) measured at 4 W/cm<sup>2</sup> during 200sec. The maximum deformation results in a change of 1.2% in the focal distance.

This contributes to lower the efficiency of a treatment. A potential solution to this problem is the thermal management of the transducer and of its environment, especially the acoustic coupling media. Another solution is to regularly check the transducer surface and acoustic beam geometries. It is important that the geometry of the beam at the focus is carefully measured (-6 dB focal area for instance) and not only at low power levels as is usually done. Precise methods of characterizing beams at high level are still not available despite the requirement for such methods to guarantee the safety of HIFU.

Errors in beam control can also be seen with phased array systems. Poor control of element contributions in phase or amplitude, for instance caused by differences in impedance values between elements, results in asymmetry or wrong orientation of the beam. This situation is avoided when electrical impedance or electrical power and phase for each channel are efficiently monitored. Refraction effects in the coupling media (water bath, membrane,...) between the transducer and the patient also have an impact on the control of the acoustic beam. A potential cause for this is the presence of thermal inhomogeneities in coupling media. Here again, temperature control at critical points and optimised circulation of coupling liquid offer solutions for detecting and solving this problem.

### **3/ ERRORS IN REGISTRATION OF THE BEAM LOCATION WITH RESPECT TO THE TARGET**

The potential for creating damage in unintended locations may also be linked with errors of interpretation of the imaging used to monitor the therapy.

When monitoring is done by means of ultrasound imaging, the acoustic axis of therapeutic and imaging transducers are generally different. Any modification in the mechanical system linking the transducers together results in a loss of reference points, and potentially of energy deposition in wrong location.

Imaging may also be realized using MRI (Fig.4). In this situation a lack of compatibility of the transducer with its MRI environment causes distortion of the images used for monitoring. Careful choice of materials for the transducers and of other components close to the MRI coil must be made during the design phase. Compatibility and reproducibility tests of components ensure valid choices.

Regular checking in 3D of the position of the sonicated volume with respect to that targeted allows the detection of any problem related to beam location or geometry.

### **4/ TRANSDUCER FAILURE OR DAMAGE AND ERRORS IN OPERATION**

In addition to the main risks identified in preceding paragraphs, there are risks related to the manipulation and the operating conditions of the transducer in its therapeutic environment, as well as possible transducer failure, which must also be taken into account. The potential effects of these are of various types: in addition to those previously discussed electrical hazards, potential for mechanical injury,

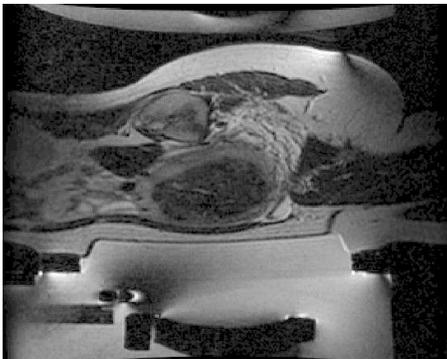
chemical contamination or simply the inability to perform the treatment that was planned must be considered.

The following examples illustrate different situations:

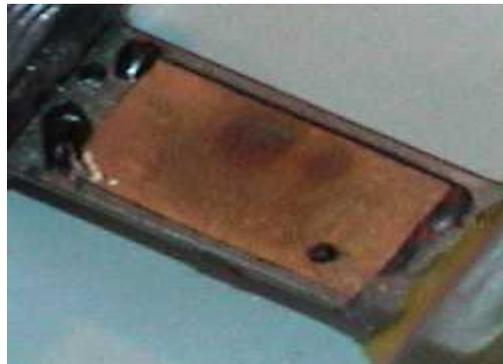
During the preparation of the setup the front face of the transducer may be subject to shock or excessive mechanical pressure. This is of course to be avoided for any kind of transducer since this can partly or even totally damage the active area of the transducer. Shocks and high pressure can be particularly detrimental in the case of large transducers which are designed to be without backing material in order to optimise the generation of acoustic energy. However, some solutions already exist to limit this risk. As early as in the design phase, all predictable mechanical requirements, including hydraulic pressure must be specified and taken into account in the design of the transducer's mechanical structure. Furthermore, the precise procedure for handling the transducer during use must be defined for operators. This means, for instance, the use of a protective cover for the front face whenever the transducer is not in use.

Poor acoustic coupling of the transducer with the patient or with acoustic coupling elements gives rise to the risk of destructive reverberation inside the transducer or on its front face (Fig.5). A critical situation is typically encountered with power transducer when the electrical power to the transducer is applied while its front face is in air. In this case the power cannot be transmitted away from the transducer which can then be rapidly damaged by overheating. The absence of coupling can easily be detected electrically. It is possible to couple this detection with an alarm or, better, with a controlled power cut-off system.

Lastly, the risk of contamination of the patient through direct contact with the transducer exists with both therapeutic transducers and imaging transducers, and especially for the case of endo-cavitary applications. To avoid this, materials incorporated in the transducer must be of biomedical grade and compatible with other acoustic and thermal constraints in relation with the electro-acoustic design of the transducer.



**FIGURE 4.** MR image showing the transducer in place for the treatment (bottom of image). In this case, no perturbation of the image is seen. (courtesy of Insightec)



**FIGURE 5.** 4 MHz plane ceramic transducer (laboratory prototype) after a destructive test. The creation of a bubble on the front face of the transducer during a test at 30 W/cm<sup>2</sup> for 1 minute resulted in a local loss of acoustic coupling, overheating and damage of the transducer (dark areas on the front electrode). The transducer was no longer usable.

## **5/ CHALLENGES IN THE SEARCH FOR SOLUTIONS TO PREVENT FAILURE AND MISUSE OF HIFU TRANSDUCERS**

Starting from the above observations of specific problems and solutions, we can try to define some directions to address the challenges related to safety issues in the design and use of HIFU transducers.

The first is to make people aware of risks and possible failure modes. On the basis of a collective awareness of the problems, the following objectives should be considered.

The mitigation of risks begins in the development of transducers and systems with early and consistent use of FMEA methodology in the design process to allow engineers to design reliable and safe devices. This means that simulation tools and the experimental checking of models should be used to improve the predictability of tissue effects and to improve the predictability of the power transducer behaviour. Furthermore collaboration is necessary at the design phase between medical teams, system developers and transducer manufacturers, with the aim of defining common specifications for the devices and for their characterisation tests.

An essential step in this process is the definition of checking procedures for the transducer and the system to prevent uncontrolled ageing changes in the transducer or other components in the system. Regular checking of output power and radiated field with reproducible instruments is necessary and should preferably be performed on site. This implies the improvement of measurement techniques and the development of standards and traceable measurement tools to characterize radiated fields at high power (measurement of power level and beam pattern). As far as we know, existing methods must be significantly improved in order to become precise enough, reliable and non destructive at the required power levels, ie. acceptable from both the medical and industrial points of view.

Another challenge in HIFU today is the availability of efficient monitoring methods which are able to localize tumours with sufficient resolution and are able to demonstrate the effect of ultrasound on tissues [12]. New imaging methods need to be considered which are not disturbed by and themselves do not disturb the HIFU acoustic field.

On a more general level medical ultrasound safety standards need to be defined specifically for HIFU applications, leading to specific requirements for the different elements of the systems including the transducer.

## **CONCLUSION**

Given the high energy density delivered by HIFU transducers it is necessary to avoid adverse events that could potentially cause harm to patients. This requires appropriate methodology, and early collaboration in the design of HIFU devices.

FMEA is a standard and proactive method used to identify, prioritise and eliminate potential failures from systems and components. The diffusion and use of such a method with complete specifications defining the application and the detailed implementation conditions, including excitation conditions, environment, and thermal

management aspects is highly recommended. Moreover the identification of needs on both short and long term levels helps in defining efficient development steps and risk management solutions.

At a more general level, collaborative work is also required in the definition of standard procedures and associated devices for characterizing transducers and systems and regularly checking devices.

For all above reasons and related challenges there is a great need for collaborative projects with public funding in order to demonstrate that HIFU can be a safe, efficient and inexpensive method for many cancer treatments.

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