Delivering the right dose

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Abstract. For treatment with high intensity focused ultrasound (HIFU), delivering the correct amount of energy to the patient is critical. This paper describes a novel design of sensor based on the pyroelectric principle for monitoring the output power from HIFU transducers of the type used for tissue ablation. The sensor is intended to be minimally perturbing to the ultrasound field, so that it can remain in the ultrasound field throughout treatment and provide a constant monitor of ultrasound power. The main advantages of the technique are: power can be measured or monitored without dismantling the HIFU system, thus reducing equipment downtime; power can be measured immediately before or during every patient treatment, thus ensuring accurate dosimetry; power can be measured at the output levels used for treatment (whereas a radiation force balance may be damaged by overheating); the method uses components which are robust and simple to use compared to radiation force balances or hydrophone scanning systems.

1. Introduction

This paper describes a novel, patented sensor[1] whose application relates initially to the determination of the amount of ultrasound power generated by a High Intensity Focused Ultrasound (HIFU) system. It is considered likely that the same principle could also be used to measure the ultrasound power generated by other medical and non-medical ultrasound systems.

HIFU is a small but growing application for ultrasound in medicine. Several companies are seeking FDA approval in the USA; in Europe, HIFU is used routinely in about 30 centres, with more than 4000 patients treated to date [2]; in China several thousand patients have been treated over the past 5 years for a range of abdominal cancers [3]. In Europe, clinical trials are most advanced for the treatment of prostate conditions [4]: treatment is not limited to treatment of life-threatening cancer; uterine fibroids and benign prostate hypoplasia (BPH) are much more common conditions which can benefit from treatment with HIFU [5]. Another potential application for HIFU is haemostasis [6] to cauterise and seal internal blood vessels at an accident scene. During ablative surgical procedures like these deep in the body, the surgical site is not exposed and cannot be seen by the surgeon.

Effective treatment requires that the tissue reaches an adequate temperature and this requires that the ultrasound transducer generates at least the amount of power which is anticipated; conversely, safe treatment requires that the output power does not exceed the expected level. It is therefore of prime importance to ensure that the correct amount of ultrasound power is delivered to a patient during treatment with HIFU. There are currently no techniques used that allow the ultrasound power to be monitored or measured directly at the time of clinical treatment. With some HIFU systems, it is
possible to measure the ultrasound power using a radiation force balance; but this cannot be done while the patient is being treated. Generally, HIFU systems are complex (often with integrated imaging systems) and it is extremely difficult to measure the acoustic output without disassembling the system, which the user is not normally able to do. Even when this is possible, the strongly focused, very high intensity ultrasound fields cannot be measured accurately with conventional ultrasound QA equipment. Instead, the electrical drive to the transducer is monitored in an attempt to detect changes in the expected output level. This method is very indirect for such a safety critical application. It is also known that more general therapeutic ultrasound equipment is of relatively poor quality in the sense that the output may be substantially higher or lower than anticipated and may even be zero.

The proposed solution is to place a nearly acoustically transparent membrane (either permanently or temporarily) in the beam of the ultrasound transducer and to determine the amount of heating caused by ultrasonic absorption in the membrane; the amount of heating can be related quantitatively to the ultrasound power. It is intended that the membrane will be minimally perturbing to the transmitted ultrasound field.

2. Principle of operation

The active part of the sensor is made from polyvinylidene difluoride (PVdF) and operates on the pyroelectric principle. A small fraction of the power in the ultrasound beam is absorbed by the sensor, resulting in a temperature increase. Due to the pyroelectric properties of the membrane, there is a separation of electrical charge which, when connected to an appropriate electrical circuit, can be measured.

A schematic diagram of the membrane of the prototype sensor is shown in Figure 1. It is a bilaminar construction of overall thickness 120 µm with the live electrode in the centre and the outside electrodes on each side connected together and acting as signal return. A prototype sensor (Figure 2) was made by Precision Acoustics Ltd (Dorchester, UK) and mounted in the same way as a membrane hydrophone; the diameter of the membrane is 80 mm. This sensor is closely related to an existing NPL design for an ultrasound power meter [7].

When the HIFU transducer is energised, an ultrasound wave is generated which propagates through the membrane. A small part of the ultrasound energy is absorbed by the membrane resulting a change of temperature which varies from point to point across the membrane, depending on the local ultrasound intensity. The total charge generated on the membrane by the change in temperature can be measured by an appropriate the electronic circuit. Pyroelectric detectors can operate in voltage mode (where the open circuit voltage into a high impedance load is measured) or current mode (where the short circuit current into a low impedance

![Figure 1. Schematic diagram of the active membrane of the HIFU power sensor.](image1.png)

![Figure 2. Photograph of the prototype HIFU power sensor.](image2.png)
load is measured). Current mode has been mostly used during the evaluation, with the sensor connected to a Bruel & Kjaer type 2651 charge amplifier which is intended for use with pyroelectric accelerometers. For some tests, voltage mode was also used with the sensor connected to an oscilloscope with a 1 MΩ input impedance set to dc-coupled. The optimum arrangement for this application has not yet been decided.

3. Evaluation

The purpose of the evaluation was to investigate the potential of the sensor for measuring HIFU or other ultrasound fields and to establish whether further development is warranted. A number of factors were identified as being important: the signal must be reproducible and of sufficient amplitude to be readily measurable; the sensor should not be damaged by the ultrasound field; the amplitude should preferably be linearly related to the incident power; the amplitude should not be overly sensitive to the position of the sensor in the field; and the amplitude should not be overly sensitive to the angle of incidence of the ultrasound.

Unless otherwise stated, all tests were carried out in freshly degassed water using a 7 cm diameter, 1.7 MHz transducer with a focal length of 15 cm which belonged to the Institute for Cancer Research (ICR); the sensor was tilted by 5° to 10° to avoid standing waves and connected to a B&K 2651 charge amplifier set to ‘Acceleration’ with 1 mV pC⁻¹ sensitivity and a 1 Hz low frequency roll-off.

3.1. Signal shape and reproducibility

Repeatability was assessed with the B&K 2651 set to ‘Acceleration’. Four nominally identical measurements were made (shown in Figure 3) with a mean value for the peak negative voltage of 1.259 V and a standard deviation of 0.012 V. The negative peak in these signals corresponds to heating caused by the turn-on of the transducer; the positive peak (which is more-or-less a mirror-image of the first) is caused by cooling of the membrane when the transducer is turned off. The rise time of the output signal was approximately 50 ms but this is actually governed by the low frequency roll-off of the charge amplifier. Selecting a lower roll-off frequency (0.03 Hz instead of 1 Hz) with the same gain, shows a time response which has a shape similar to a typical temperature-time variation in ultrasound fields, suggesting that the output signal in this mode is proportional to temperature.

In voltage-mode, the output signal is proportional to the rate of change of temperature and is characterised by a sharp rising edge (rise time typically 30 ms) when the ultrasound is turned on or off, which then decays towards zero with a 1/e time of approximately 0.25 s. There was also a component at the driving frequency of the transducer due to the piezoelectric response of the film; this
is not seen in current mode due to the upper frequency cut-off of around 30 kHz in the charge amplifier.

3.2. Linearity with respect to applied power

Operating in current mode, the dependence of the peak output voltage from the charge amplifier on applied power was assessed from 3.5 W to 60 W; the sensitivity is plotted in Figure 5. The values for power were provided by ICR based on measurements with a radiation force balance (RFB) fitted with a reflecting target. Measurements in these types of ultrasound fields are extremely demanding and the accuracy of these measurements is currently unknown. Clearly the sensitivity determined in this way is not constant and increases with power; however, it is possible that this is related to slew-rate issues or other electrical nonlinearities introduced by the 1 Hz low frequency roll-off of the charge amplifier. A separate evaluation also shown on Figure 5 of linearity using a different transducer up to 125 W also at a frequency of 1.7 MHz but with the sensor operating in voltage mode, demonstrated better linearity. The presence of the piezoelectric component to the signal made it difficult to evaluate the peak pyroelectric voltage accurately which may explain the apparent reduced sensitivity at lower applied powers. Even at 125 W, the only damage to the sensor occurred at the focus of the field and appears to have been caused by cavitation rather than thermal mechanisms. The sensor continued to work with an unchanged sensitivity after this damage.
3.3. Dependence on position in the field

The pyroelectric sensor was placed at different positions relative to the beam focus and the peak negative voltage measured as shown in Figure 6. There is a variation with position: the signal at the focus is approximately 20% larger than the signal closer to the transducer. The reason for this needs to be investigated; one possibility is that, due to nonlinear propagation, there is more power in the higher harmonics at the focus. Since the sensitivity increases with frequency (see section 3.5), this would cause a larger output signal at the focus.

3.4. Directional response

The directional response was measured by tilting the pyroelectric sensor over a range of angles up to 35° at two positions in the field – at the focus of the field and 2 cm before the focus. The peak-negative voltage over this range is shown in Figure 7, showing that the signal is nearly independent of angle up to approximately 25°. The increase above this angle may be related to mode conversion at the membrane.

3.5. Frequency response

The variation of sensitivity with frequency was investigated using a 25 mm diameter, circularly focused 2.25 MHz Panametrics transducer driven by an HP 8116a signal generator and an ENI 240L power amplifier. The output power (approximately 1.2 W at 2.25 MHz) was measured as a function of frequency from 1.25 MHz to 4.05 MHz at a constant amplitude setting for the signal generator. Subsequently, the peak negative output voltage produced at each frequency by insonating the pyroelectric sensor under the same driving conditions was measured. The ratio of output voltage to applied power is plotted in Figure 8 in 0.1 MHz intervals and shows a smooth but rather rapid change with frequency (the apparent ripple around 4 MHz is probably due to low output power and poor signal-to-noise). The sensitivity at 1.7 MHz is approximately 0.2 V W⁻¹, which agrees with the intercept value for current mode sensitivity in Figure 5.

4. Discussion and conclusions

The prototype sensor described here appears to be promising for use in HIFU fields. The output signal when operating in current mode through a B&K 2651 charge amplifier is very reproducible and sensitivity is high (approximately 0.2 V W⁻¹). The sensor is robust: the only damage appears to be caused by cavitation and occurred when the sensor was placed at the focus and the transducer driven at its maximum power setting (approximately 125 W). In practice, the sensor would never be placed at the focus since this is where the treated tissue will lie; the sensor will always be in the near-field of the transducer, where pressures and intensities are lower. There is some dependence of the sensitivity on position in the field but this appears to be limited to the region around the focus; some further investigation with a larger diameter sensor is required close to the transducer, where the sensor will typically be placed. The sensor output does not appear to depend on the angle of incidence provided this is less than approximately 25°, but there is a rather strong dependence on acoustic frequency. This will require that the acoustic frequency is known or that the sensor is calibrated for use with the specific ultrasound system. It may be possible to improve the frequency response by using a thinner sensor; this will move the thickness resonance (currently around 10 MHz) further away from the acoustic frequency. A thinner membrane will give lower sensitivity but the sensitivity is so high that this will not be a problem and may even be a benefit to the attached preamplifier. A further important advantage of a thinner sensor is that it will be less perturbing to the ultrasound field. Further investigation is required into whether the pyroelectric charge is actually proportional to the applied power or not. Operating in voltage mode, the sensor response appeared to be linear up to 125 W however, in current mode, a distinct nonlinearity was observed. This is not necessarily a problem provided the sensor can be calibrated appropriately and it may, in any case, be caused by the slew-rate limitations or other electrical nonlinearities introduced by the charge amplifier used for the test.
In terms of the practical application of this type of sensor in clinical use, we can consider extracorporeal HIFU systems (like the Chongqing HAIFU system - http://www.haifu.com.cn) and intracavity systems (like the EDAP Sonablate - http://www.edap-hifu.com/). In the former, the transducer is outside the body and the ultrasound propagates through a water path to the patient; here, the sensor could be simply placed between the transducer and the patient or it could be fixed to the transducer. Implementation on intracavity systems will be more complicated: and the sensor would have to be incorporated into the acoustic window of the housing of the transducer. An alternative would be build the sensor into a test object which could be used to validate the power output before and after use. This does not give the same degree of confidence as monitoring the power actually during treatment, but it may be a useful compromise.

The main advantages of the technique are:

- a) Power measured without dismantling the HIFU system, thus reducing equipment downtime.
- b) Power measured before or during every treatment, thus ensuring accurate dosimetry.
- c) Power measured at the output levels used for treatment (whereas a radiation force balance may be damaged by overheating).
- d) Device is robust and simple compared to RFBs or hydrophone scanning systems.

In conclusion, this type of sensor seems to offer a valuable method for monitoring the output power of HIFU or other types of ultrasound transducer. Further work is required to understand the operation of the device and to identify the most appropriate mode of operation along with any required preamplification or signal processing. Factors affecting the relationship between the applied power and the output signal also require further research and will give a better understanding of how to configure and calibrate the sensor for use in a clinical environment.

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