



REQUIREMENTS FOR A MEASUREMENT SYSTEM TO EVALUATE SAFETY AND ESSENTIAL PERFORMANCE OF ULTRASOUND DIAGNOSTIC EQUIPMENT

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Abstract: This work presents the main issues to be implemented for calibration of ultrasound diagnostic equipments in the Laboratory of Ultrasound/Inmetro. The International Electrotechnical Commission standards and technical reports were studied. As a result it will be presented the measurement system components that should be used, the main parameters to be measured and the methods involved.

Key words: ultrasound diagnostic equipment, calibration, pressure, intensity, power.

1. INTRODUCTION

Ultrasound diagnostic equipments (UDE) are widely used due to some benefits that they offer when compared with other diagnostic methods. Among them are the short time needed for diagnostic process, the relative simplicity of the method when compare whit other high-complexity techniques and, at first, the low aggressiveness. The last mentioned benefit is valid if, of course, the systems are working in safe conditions; it is, if the acoustic outputs are whiting the values range considered safe. Elsewhere, in many situations those conditions are not satisfied because either the equipments are not developed accordingly to the international standards, or the equipments' performance is not controlled along years of use in healthcare centers. When the UDS are not working in safe conditions, it can produce irreversible injuries in tissues, compromising the patients' good health. By the other side, when an images generated by UDE have not a appropriated performance, the results provided can be false or incomplete. So that, the patients could obtain an erroneous diagnostic and so that, an inappropriate treatment.

Up to now, in Brazil it has not been implemented legal control for the UDE, so that they are used without certainty about the patient safeness and the reliability of the results that they can provide. With the purpose of evaluate the conditions of the equipment commercialized and used in the country, Inmetro's Laboratory of Ultrasound is setting a measurement system to calibrate B-mode ultrasound medical equipments. In this manuscript, it is presented the first stage of the project, consisting on the study of the main measurement system characteristics, the most important acoustic parameters to be evaluated, and the measurement methods involved. The study was conducted based on international standards and technical reports specific for UDE.

2. MATERIAL AND METHODS

Along the development of the present work, they were analyzed in details several international standards and technical reports issued by the International Electrotechnical Commission (IEC). Firstly, the standard IEC 60601-2-37 [1] was analyzed, which refers to particular requirements for basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, in addition to the general standard IEC 60601-1 [2] for medical electrical equipment.

From the IEC 62127-1 [3], they were obtained guidelines for measurement and characterization of ultrasonic fields in medical systems (working up to 40 MHz). In this standard are considered pressure measurements using hydrophones, and other derives parameters that can be employed for field characterization. A number of important measurement system requirements and measurement procedures are depicted on it. For the particular case where the medical ultrasonic systems work with focalized transducers, as is the case of B-mode systems, the standard IEC 61828-1 [4] provides a theoretical description of the ultrasonic fields generated by these transducers, as well as the procedures that should be followed for determining them.

By the other side, in the technical report IEC 61390 [5], are depicted methods for evaluate the performance of images generated by UDE working in the pulse-echo mode at real time, between 0.5 MHz and 15 MHz. With this purpose, a number of test objects must be employed, and several requirements for them are presented in this report. Additional performance analysis using test objects were obtained from the technical report IEC 60854 [6], specific for pulse-echo systems consisting of single element transducers, at a frequency range between 0.5 MHz and 25 MHz; acoustic parameters and the corresponding methods for measurement are presented on it.

By the other side, for power measurement is common the use of radiation force balances, because they can provide more accurate results than deriving power parameters from pressure values measured by hydrophones. The measurement system characteristics and methods involved for different kinds of targets, are present in the standard IEC 61161 [7]. The effects that ultrasound can produce in the tissues are given by thermal and mechanical indexes, and their evaluation methods were studied from the standard IEC 62359 [8].

3. MEASURING SYSTEM COMPONENTS

3.1. Measurements with hydrophone

In the calibration procedure, the acoustic field emitted by a UDE's transducer is determined by mapping with a hydrophone, both of them immersed in a tank, and using water like a coupling medium. In our design, we select to positioning the hydrophone vertically at the bottom of the tank, and the transducer at the top of it (Figure 1), so that, only the active surface of the transducer is submerged in water. It is to avoid the water infiltration through the probe junctions, and consequent damages. The components' characteristics that must be used on the measuring system to be implemented are described to follow.

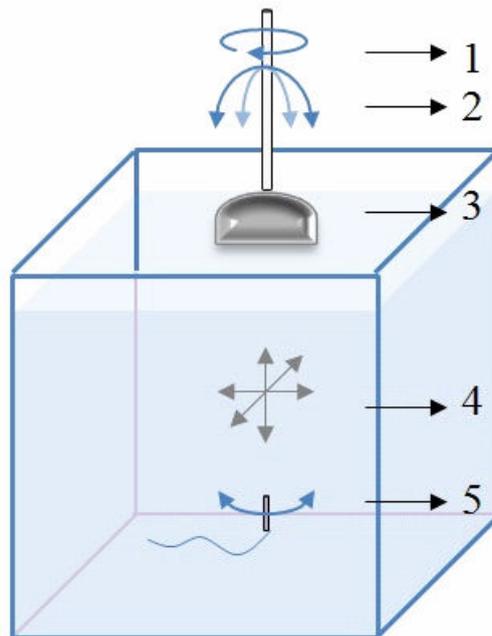


Fig. 1. Layout of the transducer and hydrophone positioned in the acoustic tank. 1: 360° circular movement of the transducer over the symmetry axis; 2: tilt of the transducer in two orthogonal axis; 3: UDE's transducer; 4: three linear movements between the transducer and the hydrophone, for three orthogonal axes; 5: hydrophone with a turn movement of about 180°.

The tank dimensions must be great enough to avoid interferences between the signal arriving directly from the transducer on the hydrophone, and that coming from reflections in the interfaces. For pulsed waves with pulse duration $<10 \mu\text{s}$, these dimensions must obey the following statement [2]. In a direction parallel to the beam axis, the interfaces must be between 30-100 % greater than the distance between the hydrophone and the transducer surface; in a direction perpendicular to the beam axis, the interfaces must be between 30-100% greater than the distance between the hydrophone and the beam axis (for no automatic scanners), or the distance between the hydrophone and the border scan line (for automatic scanners). Based on it, a water bath with 1 m x 1 m x 1 m was considered appropriated for most UDE. Moreover, lining absorber material will be used in the bath walls and base to diminish reflections risks.

The tank will be positioned over an anti-vibrating platform. To reduce electrical currents along the coupling medium, and to diminish cavitation risk, the tank should be filled with distilled and degassed water. Moreover, the water temperature must be controlled to be maintained between 23 ± 2 °C.

The relative positions between the hydrophone and the transducer will be controlled by an automatic positioning system of three orthogonal axis (X, Y, Z), with precision better than 1 μm (great enough when compared to standard recommendations); and the Z axis must coincide with the beam axis. Controls for rotate the hydrophone within $<180^\circ$ around an axis passing through the active element surface, will be introduced. Moreover, the transducer should have a rotation of 360° around their symmetry axis, and tilt controls on the other two axes will be implemented. The movements of the hydrophone and the transducer are represented in Figure 1.

A set of polyvinylidene fluoride (PVDF) hydrophone should be used, whose active area sizes must be chosen as function of transducer characteristics, and are established by the relation:

$$a_{\max} = \frac{\lambda}{8a_1} (l^2 + a_1^2)^{1/2} \quad (1)$$

being a_{\max} the maximum radius for the hydrophone, λ the wave length, a_1 the active element radius of the transducer (circular transducer), or half of their bigger dimension (for non circular transducers) and l the distance between the hydrophone and the transducer face. For cases where the maximum admissible dimension of the hydrophone is too small to provide enough sensitivity, a bigger one could be used, applying a subsequent correction for compensate face sensitivity [3]; nevertheless, a hydrophone with an active element radius $>0,5$ mm must not be used in any case. Another important hydrophone's characteristic is the bandwidth of the linear response; broadband hydrophones will be chosen to supply this requirement. Depending on the characteristics of a transducer being analyzed, a membrane or needle hydrophone type could be preferred. A pre-amplifier directly coupled to the hydrophone structure was also considered a better choice, because it can improve the measurement system response.

For trigger the acquisition system, a signal from the excitation pulse must be used, however in most UDE it is not available to be capture. An alternative way for trigger the acquisition is by positioning an additional hydrophone in the acoustic field, and connecting it to an external trigger input of the oscilloscope.

For signal acquisitions, an oscilloscope with sample frequency and bandwidth higher than 10^9 samples/s and 100 MHz respectively, should be used, which widely meet the signal requirements. The signals digitized in the oscilloscope will be transmitted through a GPIB plaque to a desktop.

For controlling the acquisitions procedure, visualizing the measurement results and computes the corresponding parameters; an interface will be developed with the LabVIEW software.

3.2. Power measurements with radiation force balance

Although the power values can be derived from hydrophone measurements, the use of radiation force balances can give more accurate results. In the latter case, a target (acoustically reflective or absorber) is positioned in front of the transducer face, and the displacement occasioned on it by the mechanical waves is measured like radiation force by a balance suspending the target, and subsequently converted to power values. The layout chosen for coupling the elements of the measurement system is presented in (Figure 2), however other configurations can be implemented [7].

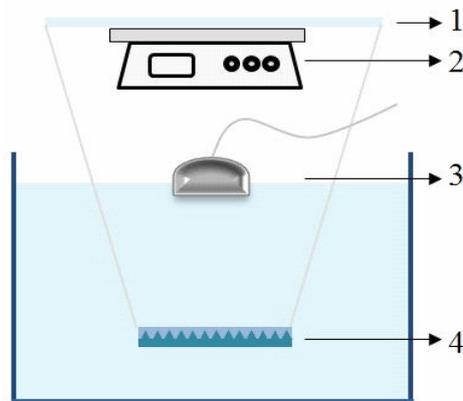


Fig. 2. Layout of the assembly for measurements of power using a force balance and an absorber target. 1: Support for target suspension; 2: force balance; 3: UDE transducer; 4: absorber target.

The balance should be gravimetric and provide an appropriated resolution for the UDE power range; considering it, a resolution = 10 μg could be enough for several cases. A load capacity of the balance is other characteristic to be considered, and must account by the target and coupling elements weight.

Absorber targets were selected for measurements in our work, to avoid problems generated by reflecting targets (like interferences from reflected waves or decentralization of targets position). The absorbing material will consist in elastic gum with serrated surface, and must have a reflection factor <3.5% and an absorbing factor >99%. Furthermore, in some procedures where the radiation area to be measured must be bounded, the use of an additional mask will be needed, consisting in an absorber material with a 1 cm x 1 cm window.

Both, the transducer surface and the target must be immersed in a tank of approximately 40 cm in size and 80 cm in height. To avoid electrical currents and cavitation effects, the tank must be filled with distilled and degassed water. Lining with absorber material should also be used for avoid reflections from the tank walls.

The relative position between the transducer and the target must be controlled with a high precision system, with at least 0.05 mm of resolution in the three orthogonal axes.

4. PARAMETERS COMPUTATION

From the number of parameters that can be computed for system performance evaluation, we selected a sub-set, considered the most representative, and are depicted bellow.

4.1. Pressure parameters

The output readings in the hydrophone terminals consist in voltage values, which can be converted in pressure parameters through mathematical equations.

The peak-rarefactional acoustic pressure (p_r [Pa]), is defined in [3] like a “maximum of the modulus of the negative instantaneous acoustic pressure in an acoustic field or in a specified plane during an acoustic repetition period”. In the practice is made a systematic search in the acoustic field, to find the point of minimum voltage in the hydrophone signal (V_-), being the p_r value obtained by:

$$P_r = \frac{V_-}{M}, \quad (2)$$

being M the hydrophone sensitivity [V/Pa].

The peak-compressional acoustic pressure (p_c [Pa]), is defined like a “maximum positive instantaneous acoustic pressure in an acoustic field or in a specified plane during an acoustic repetition period” [3]. As for p_r , the maximum voltage value (V_+) is found by a systematic search in the acoustic field, and the p_c value is obtained as:

$$P_c = \frac{V_+}{M}. \quad (3)$$

The pulse-pressure-squared integral (ppsi [$\text{Pa}^2 \cdot \text{s}$]) is defined in [3] like the “time integral of the square of the instantaneous acoustic pressure at a particular point in an acoustic field integrated over the acoustic pulse waveform”. In the practice, it is obtained by:

$$\text{ppsi} = \frac{1}{M^2} \int_{t_1}^{t_2} V^2(t) dt, \quad (4)$$

being V(t) the waveform voltage of the hydrophone [V], t_1 and t_2 [s] represent the on-set and end of the acoustic pulse waveform (the calculus is made over an entire number of acoustic pulses).

The root-mean-square acoustic pressure (p_{rms} [Pa]) is defined like a “root-mean-square of the instantaneous acoustic pressure at a particular point in an acoustic field” [3]. In the practice, is made a systematic search of maximum and minimum along the beam axis, and over an integer number of acoustic repetition periods.

4.2. Intensity parameters

In the cases where the UDE works with a focalized beam (like the case of B-mode systems), the intensity parameters can be derived from pressure measurements. The most important intensity parameters are described below.

The temporal-average intensity (I_{ta} [W/m²]), is defined in [3] like the “time-average of the instantaneous intensity at a particular point in an acoustic field”.

The spatial-peak temporal-peak intensity (I_{sptp}), is defined as “the maximum value of the temporal-peak intensity in an acoustic field or in a specified plane” [3]. In the practice it is computed from:

$$I_{sptp} = \frac{(p_{sptp})^2}{\rho \cdot c} , \quad (5)$$

being p_{sptp} the spatial-peak temporal-peak pressure (or the maximum between p_r and p_c), ρ the medium density and c the sound velocity in the medium.

The spatial-peak temporal-average intensity (I_{spta} [W/m²]), is defined in [3] as the “maximum value of the I_{ta} in an acoustic field or in a specified plane”. For no automatic scanner, it parameter can be obtained by:

$$I_{spta} = \frac{ppsi}{\rho \cdot c} \cdot prr , \quad (6)$$

where prr represent the pulse repetition rate. For automatic scanners, this parameter can be obtained from:

$$S_{ppsi} = \boxed{\square} + ppsi_{c-2} + ppsi_{c-1} + ppsi_c + ppsi_{c+1} + ppsi_{c+2} + \boxed{\square} . \quad (7)$$

Here the subscript c represents the central scan line, $c-i$ and $c+i$ represent the consecutive scan lines at the left and at the right of c , respectively.

The spatial-average temporal-average intensity (I_{sata}), is “equal to the temporal-average intensity averaged over the scan-area or beam area as appropriate” [3]. In the practice it is obtained like a mean value of I_{ta} inside the beam area (a_b).

4.3. Beam characteristics

Aspects of beam geometry are of interest in evaluating the system performance, and necessary for other parameters computation. They are obtained by mapping the pressure field, and the principal characteristics to be studied are mentioned below.

The beam axis is defined in [3] as the “straight line that passes through the beam centre points of two planes perpendicular to the line which connects the point of maximal pulse-pressure-squared integral with the centre of the external transducer aperture”. The centre points are located by mapping the acoustic field with a hydrophone, at two parallel planes; the first plane is located in the focal Fraunhofer zone, and the second one is as far as possible from the first.

The beam area (a_b) is defined as the area in a specified plane perpendicular to the beam axis consisting of all points at which the $ppsi$ is greater than a specified fraction of their maximum value in that plane [3]. Frequent used fractions for a_b establishments are -6 dB and -20 dB.

4.4. Power parameters

As mentioned before, the power will be obtained from measurements of radiation force using an appropriated balance. The power parameters of interest are:

Total power emitted by the transducer (P); it can be obtained by the expression:

$$P = c \cdot F \frac{2}{1 + \cos \gamma} \cdot 10^{-3} , \quad (8)$$

here, F represents the radiation force measured by the balance, $\tilde{a} = \arcsin(a/d)$ the focus angle, a the radius of the active element of the ultrasonic transducer, and d is the geometrical focal length [7].

A power emitted in an area of 1 cm x 1 cm (P_{1x1}), is measured by interposing a mask between the transducer and the target [8], as showing in Figure 3, and applying an equivalent equation to that shown in (8).

Fig. 3. Coupling for P_{1x1} measurement. 1: UDE transducer; 2: mask with a 1 cm x 1 cm window; 3: absorber target.

4.5. Others

Others parameters of interest to be analyzed are:

The acoustic working frequency (f_{awf}), defined in [3] as the “frequency of an acoustic signal based on the observation of the output of a hydrophone placed in an acoustic field at the position corresponding to the p_{sptp} ”. It can be determined by the zero crossing method [6] or by spectral analysis.

The non-linear propagation parameter ($\hat{\sigma}_m$) is an “index which permits the prediction of non-linear distortion of ultrasound for a specific ultrasonic transducer” [3], and can be obtained by the expression:

$$\sigma_m = \frac{\omega \cdot \beta \cdot l_1}{\rho \cdot c^3} p_m \frac{\ln \left((F_g - 1)^{1/2} + F_g \right)^{1/2}}{(F_g - 1)^{1/2}}, \quad (9)$$

in this expression, ω represents the angular frequency, $\hat{\sigma}_m$ is the non-linear parameter (equal to 3.5 for pure water at 20 °C), l_1 is the distance from the face of the ultrasonic transducer to the point containing the p_{sptp} , F_g is 0,69 times the ratio of the geometrical area of the ultrasonic transducer to the -6 dB a_b , p_m is the mean peak acoustic pressure at the point in the acoustic field corresponding to the p_{sptp} , \hat{n} and c as defined before.

4.6. Mechanical and thermal parameters

These parameters do not represent the beam characteristics themselves, but the effects that the ultrasonic beam could produce in the tissues, so that they are the main issue to be addressed.

The thermal indexes are determined as function of the tissue types, existing thermal index for soft tissue (TIS), for bone (TIB) and for cranial-bone (TIC). Moreover, in each case they can be classified as that measured at surface or below surface (subscript “as” or “bs” respectively), and for systems working at scanning mode or non-scanning mode (subscript “sc” or “ns” respectively). Then, for discrete scan modes, the thermal indexes are: $TIB_{as,sc}$, $TIB_{as,ns}$, $TIB_{bs,sc}$, $TIB_{bs,ns}$, TIC, $TIS_{as,sc}$, $TIS_{as,ns}$, $TIS_{bs,sc}$, $TIS_{bs,ns}$. Moreover, for combined scan modes the TI is obtained from specific combinations of the TIs mentioned before. In general sense, these parameters can be computed from values of pressure, power, intensity and frequency, previously explained. For simplicity, the equations used in their calculus are not depicted in this work, albeit more details can be found in [8].

The mechanical index (MI), for discrete mode operation, is obtained from the equation:

$$MI = \frac{p_{r,\hat{a}} \cdot f_{awf}^{-1/2}}{C_{MI}} \quad (10)$$

Here, the term C_{MI} is equal to $1 \text{ MPa} \cdot \text{MHz}^{-1/2}$, and $p_{r,\hat{a}}$ represent the p_r affected by an attenuation coefficient of 0,3 dB/cm·MHz, being measured at the location of the maximum attenuated pulse intensity integral [8]. For calculating the MI in combined modes, first is made the calculus for each discrete mode, and then selected that presenting the highest value.

5. DISCUSSION AND CONCLUSION

The most modern UDEs are constructed with beam patterns becoming more and more complex, being quite hard to synchronize signals, and making so the beam characterization extremely complex and difficult to implement. The latest suggestions are to put more attention in parameters that evaluate the effect of ultrasound in tissues, and so the risks involved, like mechanical and thermal indexes [3]. Elsewhere no specifics standards had yet been developed in this sense.

Some related articles were found in the literature [9-12], and them also will be used as reference along the project development.

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