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DEVELOPMENT OF AN EXPERIMENTAL SETUP FOR SAFETY ASSESSMENTS OF NEW ULTRASOUND IMAGING MODES

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ABSTRACT

Thanks to the availability of ultrasound imaging open platforms developed for the research community, numerous new ultrasound transmission (e.g. unfocused waves, multi focus waves...) and imaging techniques like 3D imaging with matrix probe have been developed. While research scanners are mainly used for *in-vitro* acquisition and do not have the CE-marked, it is mandatory to prove that before any *in-vivo* acquisition, the whole research platform (ultrasound scanner, probes and imaging sequences) is safe and is compliant with safety regulations similar to the conventional clinical ultrasound systems. To evaluate the safety of the ultrasound imaging modes, commercial solutions exist however they may be unsuitable for unfocused sequences and 3D imaging or expensive. In this work, a home-made experimental setup that allows the acquisition of pressure fields to calculate the safety indexes (Thermal Index, Mechanical Index) is presented. It has been validated for plane-wave and focused imaging in 2D, where the safety indexes calculated are below the thresholds gives by the FDA for a clinical application targeted by laboratory researchers, the peripheral vessels. A pressure field acquired of a 3D imaging is also presented. A discussion about the improvements of our setup and the different strategies for acquiring data in order to calculate safety indexes is proposed.

1. INTRODUCTION

Since the 2000s, several ultrasound imaging open platforms have been available to the research community [1]. They have enabled the development of new imaging techniques such as synthetic aperture imaging, ultrafast plane wave imaging, transient elastography, vector flow imaging and 3D imaging [2]. For these new techniques to be tested on animal models, healthy volunteers or patients, it is necessary to prove that the whole acquisition platform (ultrasound scanner, probes and imaging sequences) is safe and is compliant with safety regulations. In some cases, it is also important to know only the sound power delivered by the sequence used.

There are two main risks in ultrasound imaging related to sound pressure [3]: (i) thermal effects which are monitored by the Thermal Index (TI), calculated from the Intensity Spatial Peak Temporal Average (ISPTA) and (ii) mechanical effects in particular cavitation which are monitored by the Mechanical Index (MI).

Commercial solutions are available and follow standards for the protocol of measurement of the emitted pressures and the calculation of the safety indexes. Three of the main calibration models are [AIM III](#) (Onda corporation, USA), [AMT](#) (Acertara, USA) and [UMS3](#) (Precision Acoustics, UK). All these systems have a similar architecture in a single block: a tank with linear 3D motor stages on top (Fig. 1).

The comparison between their different characteristics is given in Tab. 1.

Typical price is about 50 k€/system. As far as automatic safety indexes calculations are concerned, even if the number given by each manufacturer is different, all deliver ISPTA, pulse duration and MI. They do not use the same standard but FDA 510 (k), premarket submission made to FDA, and NEMA UD2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, are mentioned each time by two manufacturers. The minimum step size of their linear stages is a few μm and the travel range of the three axes is on average 30 cm. Options are also available to improve acquisition: rotational axes to aid alignment, water conditioner and temperature measurement. Some systems offer source code or external controls via Ethernet or software libraries and give access to the pressure fields.

³The first author apart, all the authors have contributed in an equivalent manner.

However, as mentioned above, for new specific ultrasound imaging modes developed in research, these commercial solutions may not well adapted. This may be the case for 2D and 3D unfocused imaging (i.e. plane or diverging wave) for medical applications such as vessels, heart or brain imaging. For these applications, it is necessary to go through a well resolved pressure field in order to calculate the ISPTA, TI and MI and check if they are below the standard thresholds. Unlike standard focused sequences, where the maximum pressure is easily measurable at the depth of focus, unfocused wave sequences insonify the medium more uniformly (Fig. 2). It is therefore more difficult to find the position of the maximum pressure. For 3D imaging, matrix probes may not have an elevation focusing lens, so it is necessary to look for the maximum in a 3D space and not only in the elevation focusing plane.

Although some of the commercial platforms offer source code or external controls via Ethernet or software libraries and give access to the pressure fields, in this paper, we proposed our pressure field platform as we, like several research groups, like to have a perfect control over all possible measurements and calculations and coupled with the abilities to continuously improve our setup according to new standards/requirements. Our experimental setup should allow greater flexibility in measuring the pressures emitted by the new ultrasound imaging modes.

In this paper, we detail our experimental setup and the methods we use to evaluate the safety parameters in Section II. The 2D and 3D unfocused imaging results obtained with our setup are described in Section III.

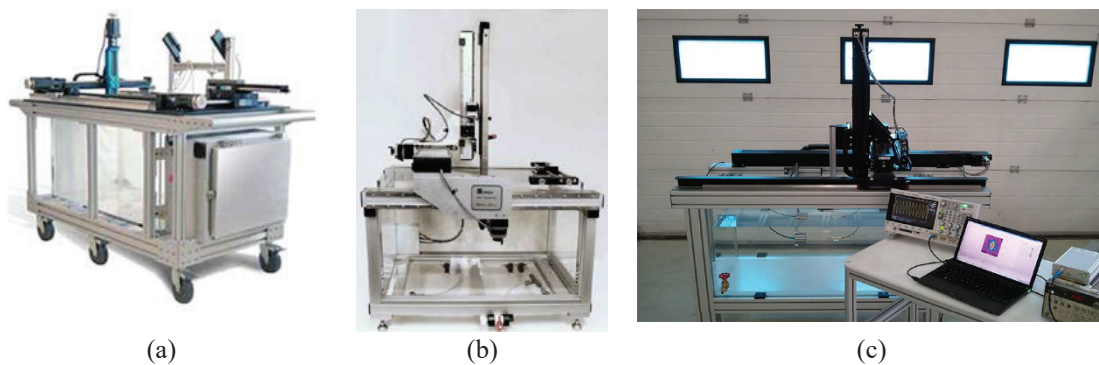


Figure 1. Photographs of three commercially solutions. (a) AMT (b) AIM III (c) UMS3.

	AMT	AIM III	UMS3
Price without options (k€)	48 (quotation in 2020)	57 (quotation in 2020)	46 (quotation in 2018)
Automatic calculation of safety indexes	Gold standard	ISPTA, pulse duration, MI (derated value)	ISPTA, pulse duration, MI + others
Regulatory requirements	IEC60601-2-5 et -2-37, EN45502-1, IEC 61847, NEMA UD2/3 , ISO 14708-1	FDA 510(k)	FDA 510(k) , NEMA UD2 IEC62127-1, IEC61157
Minimum step size in μm	X : 0.635, Y : 1.25 et Z : 0.198	5.5	1
Dimension of the travel: X x Y x Z in cm	Not found	38 x 26.5x33	30x30x30 (for the littlest model)
Programming language	access to the source code possible	External Control via Ethernet or DLL	labview + source code for developments
Options	Integrated Thermocouple	Temperature Probe, rotational axes, water conditioning system	rotational axes, water conditioning system

Table 1. Main specifications of the commercially solutions, “not found” means that the information is not available on datasheets from the provider’s website. The same characteristics found in the different models have been bolded.

2. MATERIALS AND METHODS

2.1 Description of our experimental setup

The experimental setup, composed of several parts, is presented in Fig. 3:

- An optical breadboard of 1000 x 400 x 33 mm, weight 32 kg
- Three 750 mm profiles mounted in an inverted U-shape

For the measurements in all three spatial directions, a DC motor-driven translation (Owis, Staufen im Breisgau, Germany) is used.

A controller drives the three axes via USB with the OWISOFT software. Libraries for C++ and Labview are also implemented.

Because of the huge total weight, the whole acquisition platform is installed on a solid bench.

2.2 Comparison with commercial solutions

In the Tab. 2, we compare our system with the synthesis of the three commercial solutions studied above.

As our setup is composed of several parts (tank, motors ...) and can be connected or disconnected as required, it is also easier to move it or adapted it for a more specific application.

Without taking into account the time spent to develop the system, the investment cost is roughly 1/5 time less than for the acquisition of a commercial solution. It should be noted that the quotations for commercial systems are at least 5 years more recent than our system and that we do not have any certification, which can lead to a significant cost for commercial systems.

Our work is based on the IEC60601-2-37 [4] and IEC61102 standard [5].

We have chosen to calculate three indexes: ISPTA, TI, in particular the soft tissue index (TIS) and the bone-at-focus thermal index (TIB) and MI, linked to this standard, but new parameters can be easily calculated, if needed. For the moment, the results are given with in-water measurements, in-situ attenuation has not been applied.

The minimum step size of our setup, 1.25 μm , is included in the range of the commercial solutions.

Our home-made solution is more compact than commercial systems. Its main constraint is the limitation

of in-depth acquisition but different setup configurations can improve this limit, if needed.

The acquisition platform is triggered by the ultrasound scanner, to acquire the signal at the right time.

The other devices required for the pressure measurement are described in the following paragraphs.

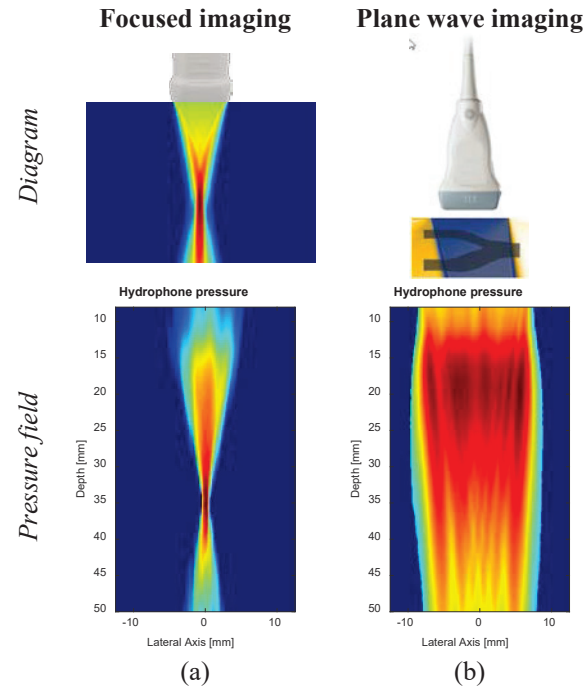


Figure 2. Column a : focused imaging, column b : plane wave imaging – 2nd line: imaging diagram made by MATLAB Ultrasound Toolbox MUST [6] – 3rd line : example of 2D pressure field obtained with our Setup [4].

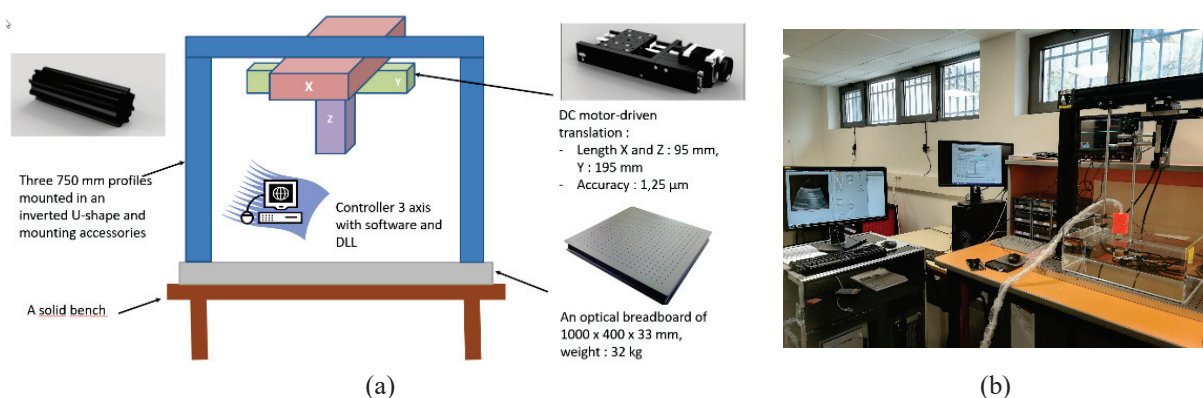


Figure 3. (a): Schematic of our experimental setup, (b): photo of our experimental setup.

2.3 Others devices required

2.3.1 Hydrophones

This experimental setup can be used with any hydrophone. For this setup, a calibrated capsule hydrophone from Onda (Sunnyvale, USA) – diameter 200 μm – band pass: 1 MHz to 20 MHz, is used. Capsule hydrophone is more interesting than needle or membrane hydrophone as it is more ruggedness and thanks to the 200 μm diameter, it allows to have: :

- A sensitivity around -265 [dB] re 1V/ μPa

- A high directivity: to measure the maximum of elements contribution (See Fig. 4)
- A precision inferior to the pitch of probes elements we have tested

The large band-pass allowed testing a large panel of frequencies.

2.3.2 . Software

A software developed in Labview [7] allows to control the hydrophone displacements and the acquisition of the hydrophone signals by an oscilloscope.

	Our setup	Synthesis of commercial solutions
Architecture	Composed of several parts	One block
Price without options (k€)	10 (in 2013)	50 (in average, quotation in 2018-2019)
Automatic calculation of safety indexes	ISPTA, MI and TI	ISPTA, pulse duration, MI + others
Regulatory requirements	IEC60601-2-37, IEC61102	IEC62127-1, IEC61157, IEC60601-2-37 + others
Minimum step size in μm	1.25	Between 0.198 and 5.5
Dimension of the travel: X x Y x Z in cm	9.5 x 19.5 x 9.5	34 x 28 x 32
Programming language	Labview and Matlab	Labview, External Control via Ethernet or Libraries, source code for developments
Options	None	Temperature Probe, rotational axes, water conditioning system

Table 2. Main specifications of our system compared to the commercially solutions.

A MATLAB program was developed to evaluate the safety indexes from the data acquired.

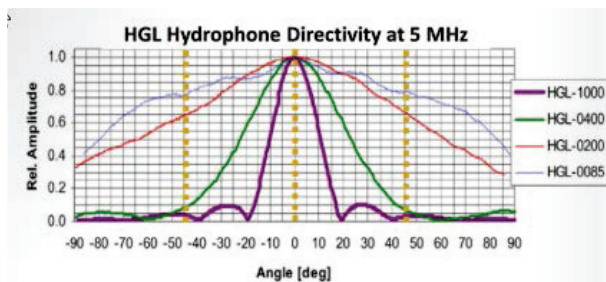


Figure 4. Directivity of several reference of capsule hydrophone : we can see our reference (HGL-0200) has an acceptance angle of 100° (-6 dB at 5 MHz).

2.3.3 Probes' holders

To optimize the alignment between the US probe and the hydrophone, probe holders printed with a 3D printer were used (Fig. 5):

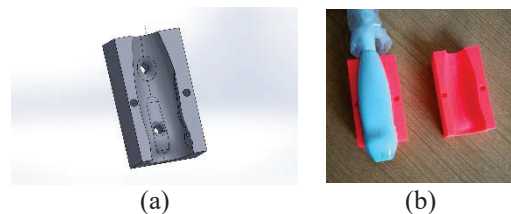


Figure 5. Example of probe's holder. (a) CAO file and (b) the holder printed.

2.4 Method

2.4.1 Procedure according to standards

The logigram of the procedure to calculate the safety indexes is presented in Fig. 6. It is composed by six steps.

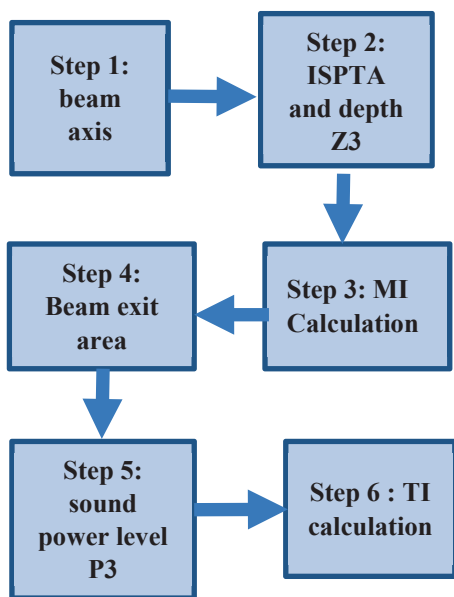


Figure 6. Logigram of the procedure to measure and to calculate the safety indexes.

In the step 1 the ultrasound beam axis is found from three 1D scans in the lateral dimension at three depths: near-field, depth of interest and far-field, we find the axis of the ultrasound beam. The step 2 corresponds to the calculation, along the axis, of the ISPTA for each depth. The Z3 value corresponds to the depth where the ISPTA is maximum. MI is calculated at the depth Z3 in step 3. In the step 4, close to the probe, two 1D scan, in lateral and elevation, are carried out. Only the values higher than 12 dB are kept. With the 2 lengths an area and an associated depth Zbp are calculated. Then, at depth Zbp, a 2D scan parallel to the surface of the probe is performed in step 5. At each point the intensity is calculated and the intensities are integrated in the two dimensions of space to obtain the acoustic power P. The power P3 is then calculated as a function of the depth. To finish, at the step 6, TI is calculated as a function of P3.

2.4.2 Alignment

After installing the probe with its support above the water tank and positioning the hydrophone underneath it, in a first step the hydrophone was visualized on the ultrasound scanner and can thus have a first placement in the center of the probe in lateral and elevation directions and place it as close as possible to it (about 5 mm).

A 1D scan is then performed in the lateral and elevation directions to check the alignment in these two directions and add, if necessary, an additional length of acquisition in either direction. We also use these measurements for the step 4 described in Fig. 6.

A C-scan near the probe and at 35 mm is then realized to visualize and control the third misalignment angle. An example of misalignment is presented in Fig.7.

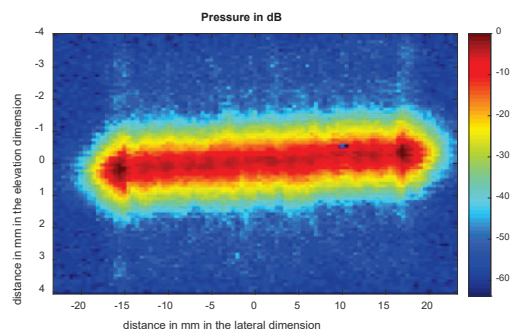


Figure 7. C-scan at 35 mm depth in a plane wave transmission, when using the L7-4 US probe.

The misalignment will be compensated by the acquisition of the complete field whose dimensions are: in axial of 45 mm from 5 mm from the probe surface, in lateral of 46 mm centred in relation to the centre of the probe and in elevation of 8 mm also centred in relation to the height of the probe elements. There is no risk of not acquiring the areas of interest.

2.4.3 Data acquisition

Once the alignment is completed, we acquire the time signals received by the hydrophone. We have chosen here to acquire the complete pressure field (Fig.8) with a step of 0.5 mm in the axial and lateral dimensions and 1 mm in the elevation direction. We use an ultrasound scanner Vantage 256 from Verasonics (Kirkland, USA) with the linear probe L7-4 to transmit a plane wave sequence at the center frequency of the probe 5.2 MHz with one pulse. A voltage of 50 V and a frame rate of 500 Hz were used.

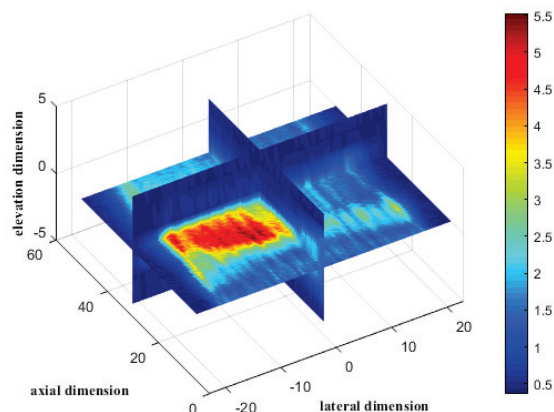


Figure 8. Pressure field of the plane wave sequence in MPa and distance in mm.

3. RESULTS

3.1 Safety index measured and calculation

We present two different results (see Tab. 3): (i) the first, “standard” column, correspond to the results found following the procedure according to the standard (see Fig.6) where ISPTA and MI are calculated along the beam axis, (ii) the second, “complete field”, correspond to the ISPTA (i.e. MI) calculated by the maximum (i.e. the minimum) pressure found in the whole acquired 3D field.

	Standard	Complete Field
ISPTA in mW/cm ²	44	47
MI	1.1	0.8
TIS / TIB	0.1/ 0.5	

Table 3. Safety index found for a focused and a plane wave sequence.

The results are different because the place of the maximum and minimum pressure in the whole 3D pressure field is not located on the beam axis, like it is shown in Fig. 9. In this figure, the map of the maximum of pressure with a plane wave sequence in the 5th elevation plan is presented, in red the beam axis calculated by the standard, and the position of the place of the ISPTA max found with the complete field (left arrow) and the ISPTA found following the standard (right arrow).

3.2 Comparison with standard thresholds

Additional guidelines can be found in the FDA regulation [8]:

1. The derated time-averaged intensity integral ISPTA₃ should not exceed 720 mW/cm² when used on peripheral vessels, 430 mW/cm² when used in cardiac imaging, and 94 mW/cm² for the rest of applications (fetal, abdominal, intra-operative, pediatric, small organ, cephalic).

2. The MI should not exceed 1.9 for non-ophthalmic use, and 0.23 for ophthalmic use.

Then, our ultrasound sequence present MI and ISPTA value below these thresholds for the clinical application targeted, peripheral vessels.

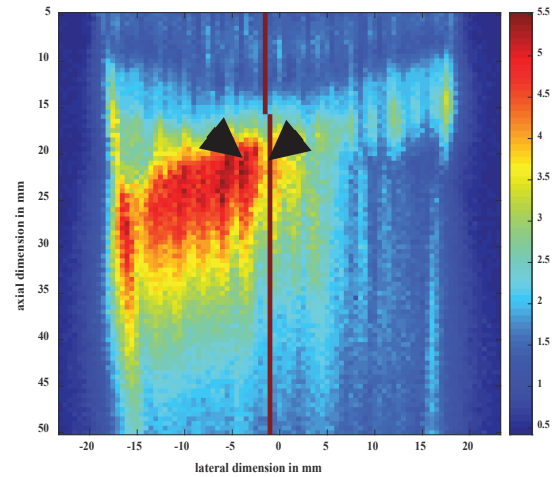


Figure 9. Beam axis represented on the max Pressure field of the plane wave sequence in MPa : left arrow place of the maximum pressure 5.5 MPa of which gives an ISPTA of 47 mW/cm² found with the max of the complete field, right arrow : place of the maximum pressure of 4,5 MPa which gives an ISPTA of 44 mW/cm² on the beam axis.

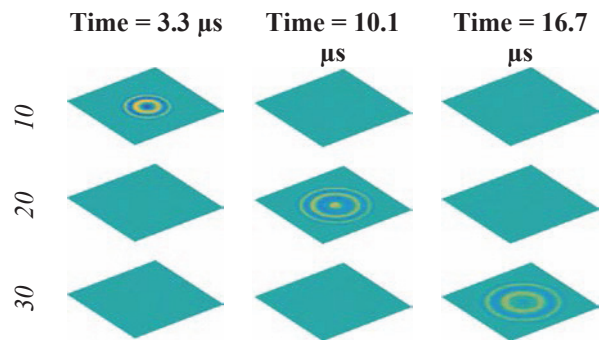


Figure 10. Pressure evolution at 3 different depths in mm (rows) for three time of the propagation (columns).

3.3 Uncertainties

With the Ishikawa diagram, the following sources of error have been identified:

- Hydrophone measures uncertainty in the range of frequency we use ± 1 dB
- Oscilloscope measures uncertainty
- BNC cable error is neglected
- Error positioning of the motor stage : $<25\mu\text{m} / 100$ mm
- The quality of the water that is not filtered and degassed : for pressure superior at 1MPa there is a risk of cavitation
- Integral calculation under MATLAB software by the trapezium method

The two first uncertainties are added directly during the conversion between voltage and pressure to have the worst case. To take account of the others, the measurement should be repeated several times in order to know the overall error percentage.

Commercial systems must certainly present the same sources of error.

3.4 Pressure field of 3D ultrasound imaging

We will also extend the measurement of safety indexes for the 3D ultrasound imaging. In Fig. 10, a pressure field acquired for a 2D probe from Vermon (Tours, France), 32 x 32 elements, for three depths [9] is presented.

4. DISCUSSION

Our setup, which is compact and less expensive than commercial systems, allows us to acquire ultrasonic pressure signals and calculate safety indexes. It is also flexible to adapt the way in which these data are measured. Despite the many advantages of our system, some improvements remain of course possible.

We need to improve our system concerning the quality of our water. That is currently not filtered or degassed and yet we sometimes reach more than 1 MPa which can lead to cavitation. The fact that the water temperature is also not monitored means that we have to constantly adapt in our calculations the values of the velocity and impedance of the water and the temperature at the beginning of the acquisition may be different from that at the end.

Sometimes the standard are not reached because 7 samples above -12 dB have not been acquired. Acquisitions with a smaller step are then required.

Moreover, acquiring the complete pressure field takes a lot of time (seven 2D planes in six hours). We do this over several days with the risk of a misalignment.

Several solutions could be explored :

- program a procedure that only acquires the necessary data according to Fig. 7. But we saw in the paragraph 3.1 that this implies not taking into account the real maximum of the pressure field.
- optimise the size of the pressure field acquired, in an iterative process: first a large field with a large acquisition step, then a smaller field with a finer step when the area of interest has been located.
- find the maximum pressure using a gradient algorithm.

It is also necessary to check why other manufacturers do not use IEC 61102 and the consequences for the acquisition and calculation of safety indices.

5. CONCLUSION

We have designed a setup to acquire and visualize pressure fields available to the scientific community. From the acquired data, we can calculate the safety indexes of new ultrasonic sequences.

Our setup needs to be improved, in particular by investing in a water conditioning module.

6. ACKNOWLEDGEMENT

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