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Measurement Parameters for the characterization of unfocused Extracorporeal Pressure Pulse Sources - Standardization of Biomedical Equipment

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ABSTRACT

Extracorporeal Pressure Pulse Sources (EPPS) are in regular clinical use to treat a growing variety of tissue and pain therapy conditions. Since 1999, second-generation devices mostly using ballistic generation methods are available, often claiming to provide “radial shock waves”. A Chinese national standard from 2015 describes few measurement methods for ballistic EPPS, mainly overall energy and impulse of the sources, but no field parameters. Up to now, no international standard for the characterization of the signals and the acoustic fields of EPPS is in place. Clinical trial reports of EPPS therapies reveal contradictory results, which seems connected to a lack of knowledge on the physical EPPS signal and field parameters. Even worse, measurements for the certification process are carried out according to the IEC standard 61846, which was originally developed for the characterization of *focused* shockwave-lithotripters. Aside from lacking the characteristics of physical shock waves, many of those parameters are not applicable or even misleading when used to characterize *non-focused* (“radial”) EPPS. As a result, there is a significant lack of knowledge how to relate reported parameters to observed tissue and health effects and how to apply the devices properly for optimum treatment results. This paper reports on the development of the international standard on acoustic EPPS measurements, IEC 63045.

Keywords: Pressure Pulse, Biomedical Equipment, Standardization, Shockwave

1. INTRODUCTION

Extracorporeal Pressure Pulse Sources (EPPS) are in use in a variety of tissue and pain therapy applications, e.g. for the treatment of shoulder, heel spur and elbow pain, erectile dysfunction, cardiac pain, cellulitis etc. Today, a variety of second-generation devices, mostly using ballistic generation methods and claiming to provide “radial shock waves”, is available. Nevertheless, a review of the publications on the EPPS shows that neither the characteristics of the sound field nor the therapeutic effects in biological tissue are fully understood. Furthermore, clinical trial reports of EPPS therapies reveal contradictory results, mainly connected to a lack of knowledge on the physical properties of the pressure pulse EPPS field. As a proper measurement standard for unfocused EPPS devices is not in place, measurements for the certification process are carried out according to the IEC standard 61846, which was originally developed for the characterization of focused shockwave-lithotripters. Many of the parameters standardized in IEC 61846 are not applicable or even misleading for the characterization of non-focused EPPS.

A Chinese national standard YY 0950-2015 [1] describes measurement methods for ballistic EPPS driven by air pressure, and mainly overall energy and impulse of the sources, but no field parameters.

This paper reports on the development of IEC 63045 [2], the international standard on acoustic EPPS measurements.

2. PARAMETERS IN IEC 63045

2.1 Background

The IEC technical committee TC87 has the scope to create measurement standards for ultrasonic

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instrumentation. Thus, IEC 63045 is designed as a measurement standard, where the main scope is to describe measurement parameters and methods how to measure them in a reliable and repeatable way. It is not intended to serve as a safety standard for pressure pulse therapy, this task may be assigned by an international voting to a different technical committee, IEC SC62D, which is responsible for the creation and maintenance of biomedical equipment safety standards.

During the drafting of 63045, concerns were raised that "too many parameters were defined, which leads to a large number of required measurements". It needs to be stressed that the intent of a measurement standard is to state definitions and measurement methods for all technical parameters which might be useful to characterize the parameters of a device according to best technical knowledge. This may also include requirements necessary to gain proper measurement results, e.g. the definition of minimal technical specifications for measurement probes and instruments and methods for calibrating those, material parameters and important construction details of test benches and consumables (like using degassed water), and minimal requirements for proper technical documentation of the results. In contrast, it is not intended to define which ones of the given parameters need to be measured. These requirements can be given in appropriate safety standards, or they need to be assessed during the development process of the device according to the rules of national and international regulations and standards, namely the medical device directives, usually pointing to the IEC 601 series of safety standards. It is usual practice, that the devices need to be approved by notified bodies and / or governmental authorities for the clinical use. The necessary steps also include a risk management process, which considers all possible hazards for the patient and the user. If no sufficient previous experience, e.g. documented by literature, is available, this risk management process may also require clinical studies. During this process, all parameters necessary to provide the safe use of the device needs to be stated by the manufacturers. IEC 63045 gives a firm base of the internationally accepted technical state-of-the art.

2.2 Scope

IEC 63045 is applicable to therapy equipment using or producing extracorporeally induced **non-focused** or **weakly focused** mechanical energy (pressure pulses), where the pressure pulses are released as single events of duration up to25 microseconds.

The application to therapy equipment using **focused** pressure pulse sources and to extracorporeal lithotripsy equipment (to which IEC 61846 is dedicated), or to therapy equipment using other acoustic waveforms like physiotherapy equipment, low intensity ultrasound equipment and HIFU / HITU equipment is not in the scope.

IEC 63045 specifies measurable parameters which should be used in the declaration of the acoustic output of extracorporeal non-focused or weakly focused pressure pulse sources, and methods of measurement and characterization of the pressure field generated by non-focused or weakly focused pressure pulse equipment.

The parameters do not – at the present time – allow quantitative statements to be made about clinical efficacy and possible hazard. Particularly it is not possible to make a statement about the limits for these effects.

2.3 Pressure pulse sources

Pressure pulse sources were originally developed for the extracorporeally induced disintegration of kidney stones. Since the first successful treatment in 1980 kidney lithotripsy is the standard treatment for a wide variety of stones. The first pressure pulse source used the electrohydraulic principle, which employs a spark gap, which is placed at one focus of an elliptical mirror. The stones to be treated are placed in the other focus of this mirror by ultrasound or x-ray imaging. Since 1984, electromagnetic sources are applied, which use a flat or cylindrical coil and a metal membrane, which is repelled by the interaction of a pulsed primary magnetic field created by the coil, and a secondary field in the membrane, generated by the eddy current due to the primary field. The third type of pressure pulse source employs large numbers of piezoelectric elements, which are arranged on a spherical surface, and emit an ultrasonic wave when excited by a high voltage impulse. In general, the first devices for pressure pulse (pain) therapy were smaller versions of the lithotripter sources, so the pressure pulse fields were generally focused.

Since 1999, many devices on the market use the ballistic source technology, which is based on accelerating a projectile (e.g. of 30 g mass) in a tube of e.g. 20…30 mm length towards the rear side of a metallic block (e.g. …. g mass, typical diameter 6 to 15, up to 30 mm), which is called *applicator* [3] [4]. The other (front) side of the applicator is in contact with the patient. When the projectile hits

the rear side of the applicator, a longitudinal density wave propagates through the block and is transmitted at the front side into the patient. The manufacturers claimed that these sources were generating “radial” pressure pulses, thus implying that the devices were non-focused. Today, besides the ballistic source type, there are also non-focused or weakly focused designs for the “classical” electrohydraulic, electromagnetic or piezoelectric sources available.

2.4 Non-focused, Weakly Focused and Focused Fields

In this paper, only a few aspects shall be discussed in detail, starting with the definitions of focusing.

“In a non-focused pressure pulse field, the pressure pulse amplitude in the field is nowhere larger than the peak-positive pressure pulse amplitude at any place at the source aperture, and the pressure pulse amplitude is decreasing with increasing distance from the source aperture…” (Fig. 1a; 4a). “…in a weakly focused pressure pulse field, a local acoustic pressure maximum occurs, which has an amplitude less than the peak-positive pressure amplitude at the source aperture” (Fig. 1b,c; 4b,c).

“In a focused pressure pulse field, a beam pressure maximum point occurs, which is more distant from the source aperture than the beam pressure maximum -6 dB extent. In a focused pressure pulse field, the pressure pulse amplitude adjacent to the beam pressure maximum is larger than the pressure pulse amplitude at any place at the source aperture” [2].

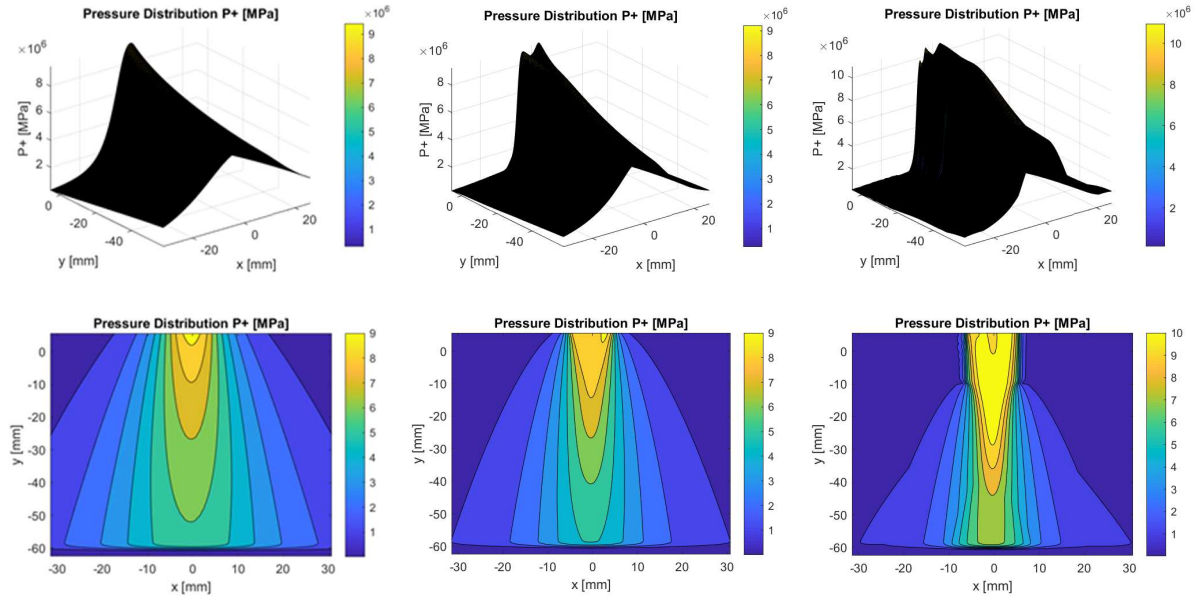


Figure 1: a) unfocused field, b) c) weakly focused fields (drawings start 19 mm from applicator), source aperture at +20 mm

2.5 Applicator, Source Aperture, Measurement Center Point and Target Location

The concept of the source aperture enables the unambiguous application of all definitions of 63045, independent from the physical nature and the mechanical construction of the source (e.g. ballistic, electrohydraulic, electromagnetic, piezoelectric etc.).

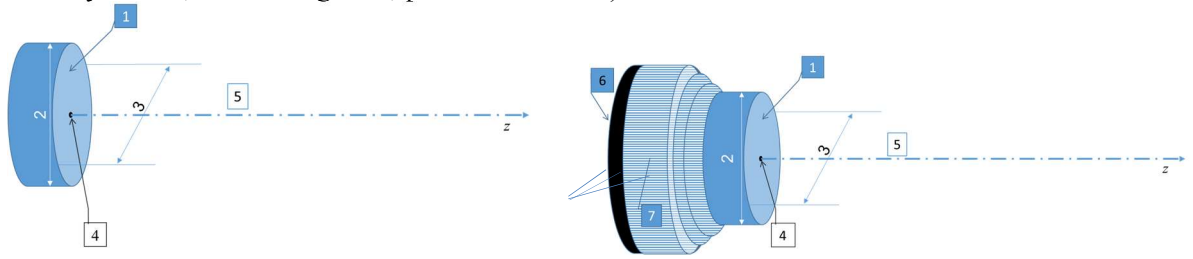


Figure 2: Left: Applicator, directly coupled to the patient. Right: Pressure pulse source, distant from the patient, 1 - source aperture, 2 - source aperture width D_x, 3 - source aperture width, orthogonal D_y, 4 - measurement center point O where (x, y, z) = (0, 0, 0), 5 - beam axis (z), 6 - pressure pulse source, 7 - acoustic standoff, e.g. coupling pad or water [2]

The *source aperture* is not necessarily the front of the applicator, it is the area where the wave propagates into the patient. It is characterized by its width in both directions x- and y- perpendicular to the beam axis z (Fig. 2). Depending on the design of the source, there may be a fluid filled space or another coupling means between the source emitting the pressure pulses and the source aperture. The center-of-mass of the source aperture is the *measurement center point*, which is the origin of the coordinate system used to describe positions inside the pressure pulse field. The z-axis is perpendicular to the source aperture at the measurement center point, x- and y- axes are orthogonal to the z-axis.

For each intended therapy, the *target location* describes the location in space of the biological tissue to be treated[2]. It differs depending on the therapy (e.g. superficial structures like tendons, or deeper positions like trigger points etc.), but also on the size and body mass of the patient. The manufacturer shall state the intended target locations as three-dimensional position vectors relative to the measurement center point.

2.6 Pulse and Field Parameters

For the description of focused sources (IEC 61846) many field parameters were linked to the peak positive pressure at the focus[3]. In a weakly focused field, there is a local maximum (called *beam pressure maximum*) lower than the peak pressure at the source, which defines the *beam pressure maximum point.* In the field of an unfocused source, the beam pressure maximum point is located at the source aperture and is usually identical to the measurement center point.

In order to give the user reliable knowledge on the possible locations of intended and unintended effects, both area and beam widths in x- and y- as well as beam extensions in the z- directions need to be stated. Up today, the correlation between physical values (e.g. positive pressure p_c, rarefactional pressure p_r, “energy flux density” or derived pulse intensity integral PII etc.) and the observed biomedical effects is not commonly known. IEC 63045 calls upon manufacturers to define and communicate limits of regions by an appropriate risk assessment process, which may e.g. be based on literature or own clinical studies. Limits can be defined based on absolute values (e.g. *n* MPa, *n* mJ/mm² etc.) or relative values (e.g. –*n* dB relative to the beam pressure maximum etc.). These values then are used to describe the boundaries and positions of relevant areas and volumes and calculate the respective beam extents, areas, or energies.

If a calculation requires time limits for integration, the same procedure for the definition of limit values is used (positive temporal MPa threshold integration limits, total temporal MPa threshold integration limits etc.). Other parameters are based on commonly established scientific definitions, e.g. rise time (10%...90%).

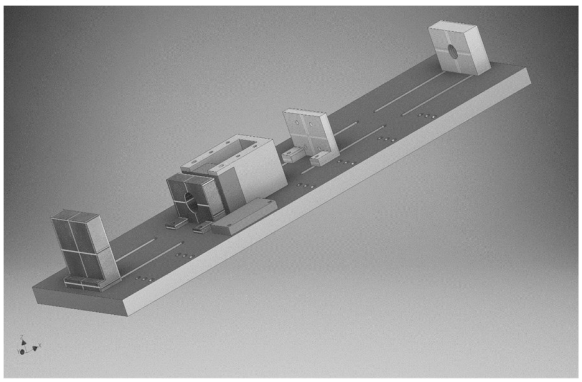


Figure 3: Dry test bench, including: Hydrophone and tissue-mimicking pad chamber, hand-piece holder, rear holder including (adjustable) retention-force spring, are fixed to a base plate [2]

[2] Usually the position of the target tissue’s center-of-mass if larger areas are treated

[3] Since the first standard IEC 61846 on the measurement of pressure pulse parameters was published, a constant point of discussion was the large uncertainty of those parameters directly linked to the peak focus pressure. This uncertainty both is heavily influenced by source fluctuations (Pulse-to-pulse variation) and positional errors of the focus determination.

2.7 Test Benches and Measurement Conditions

Measurements of the pressure pulse temporal (Table 1) and field parameters (Tables 2, 3) mostly require a water tank, filled with degassed water. A well-known problem of high intensity sources measurements in water is the development of cavitation, which makes measurements at higher repeat rates prone to error. As the EPPS devices for pain therapy are working at pulse repeat rates of more than 2 to 20 per second, important parameters like the pulse-to-pulse stability cannot be measured reliably in water. Therefore IEC 63045 also proposes a dry test bench for some measurements (Fig. 3). It can also be used as a quick measurement tool for quality control and service. With the dry test bench, measurements on the beam axis at a fixed distance from the source aperture can be made at higher pulse-repetition rates. Parameters which can be measured in the dry test bench are given in Table 1, where L_p is the thickness of a silicon pad mimicking patient tissue. L_p should be 5 mm, which was chosen as typical measurement distance from the source aperture.

Table 1 – Temporal pressure pulse parameters [2] (Figure 6)

Parameter	Water measurement	Dry test bench measurement	Unfoc. Source	WeakF Source	Unit
Instantaneous acoustic pressure	$p\ (x,y,z,t)$	$p(0,0,L_p,t)$	*Fig. 6a*	*Fig. 6c*	MPa,µs
peak-positive acoustic pressure	$p_c(x,y,z)$	$p_c(0,0,L_p)$	*13*	*11*	MPa
peak-negative acoustic pressure	$p_r(x,y,z)$	$p_r(0,0,L_p)$	*-11*	*-11*	MPa
compressional pulse duration	$t_{FWHMpc}(x,y,z)$	$t_{FWHMpc}(0,0,L_p)$	*0,74*	*0,66*	µs
rise time	$t_r(x,y,z)$	$t_r(0,0,L_p)$	*0,46*	*0,52*	µs
pulse-pressure-squared integral	$ppsi(x,y,z,t)$	$ppsi(0,0,L_p)$	-	-	MPa^2s
(derived) instantaneous intensity	$pi(x,y,z,t)$	$I(0,0,L_p,t)$	*Fig. 6a*	*Fig. 6c*	mW/mm^2
derived pulse-intensity integral	$PII(x,y)$	$PII(x,y,L_p)$	*0,4*	*0,31*	mJ/mm^2

In the water tank, all pressure pulse (see Table 1) and field parameters (see Table 2) can be measured at single pulse setting with sufficient pauses between pulses to allow for complete cavitation recess.

The integrated parameters relating to intensity at any position (x,y,z) are calculated from the measured pressure-time signal $p(t)$ The temporal limits T over which integration is performed shall be stated and can be either the duration of the positive signal $t_{Pt,lim}$, the total signal duration $t_{Tot,lim}$ (used in the PII in Table 1), or signal durations delimited by n MPa threshold $t_{Pt\,n\,MPa,lim}$ or $t_{Tot,n\,MPa,lim}$.

From these parameters the energy parameters in the field (Tables 2,3; Fig. 5) can be calculated.

Beam areas, volumes and extents are stated either as -n dB re. beam pressure maximum value at the indexed z position, or as isobar values based on n MPa limits. The choice of appropriate values for n is left to the risk analysis of the manufacturer. Besides a required position of z = 5 mm, other z positions can be chosen depending on different target locations.

3. APPLYING THE PARAMETERS

3.1 Materials and methods

In order to demonstrate how to derive the parameters from a practical measurement, a ballistic pressure pulse source was simulated using MatLab® and the k-Wave toolbox [5]. This allows the creation of a hypothetical EPPS with a 13 mm diameter applicator, independent of actual manufacturers. From the simulations, parameters were retrieved as from a real source. In order to mimic real measurements as close as possible, pressure-time signals were calculated at pre-defined positions in the pressure pulse field, i.e. at 1 and 5 mm from the source aperture. As replacement for the mechanical projectile, a velocity signal shaped as exponentially decaying sinusoid was generated at the rear end of the applicator. During the simulation runs, the propagation of waves in the simulated fluid can be observed as a video.

As weakly focused fields, strictly speaking, do not have a focus, but local maxima, there is an equivalent parameter “beam pressure maximum”, for weakly focusing sources only (Table 3)

Table 2 – Parameters for non-focused and weakly focused fields [2] (Figures 1a,1c,4a,4c,5)

Parameter	Symbol	Comment	Unfoc. Source	WeakF Source	Unit
beam -n dB cross-sectional area	$A_{z,n\mathrm{dB}}$	-*n* dB re.beam pressure, *n*=6dB, *z*=5mm	162	88	mm²
beam -n dB extent	$z_{\mathrm{b},n\mathrm{dB}}$	maximum value at *x*=0 (see Fig. 4)	~ 60	~ 60	mm
beam -n dB volume	$V_{\mathrm{b},n\mathrm{dB}}$	-*n* dB re. b.press *n*=6dB	9720	4999	mm³
beam -n dB width, maximum	$w_{\mathrm{max,x},z,n\mathrm{dB}}$	largest -6dB *z*= 5mm: largest -6dB *z*= 15mm:	14,4 10,5	10,3 -	mm
beam -n dB width, orthogonal	$w_{\mathrm{max,y},z,n\mathrm{dB}}$	orth. -6dB *z*= 5mm: orth. -6dB *z*= 15mm:	14,4 10,5	9,0 -	mm
beam isobar cross-sectional area	$A_{n\mathrm{MPa},z}$	*n* MPa delimited, *z*=5, *n*=6	98,5	95	mm²
beam isobar extent	$z_{\mathrm{be},n\mathrm{MPa}}$	*n* MPa delimited, *n*=6	52	n.a.	mm
beam isobar volume	$V_{\mathrm{b},n\mathrm{MPa}}$	*n* MPa delimited *n*=6	5123	n.a.	mm³
beam isobar width, maximum	$w_{\mathrm{max,x},z,n\mathrm{MPa}}$	*n* MPa isobar delimited, largest extent, *z*=5, *n*=6	11,2	11,0	mm
beam isobar width, maximum	$w_{\mathrm{max,x},z,n\mathrm{MPa}}$	*n* MPa isobar delimited, largest extent, *z*=5, *n*=2		13,4	mm
beam isobar width, orthogonal	$w_{\mathrm{max,y},z,n\mathrm{MPa}}$	*n* MPa isobar delim *n*=6	11,2	11,0	mm
derived acoustic pulse energy[4]	E_R	PII integrated over radius *R* (*R*=20, *z*=5)	12	14	mJ

Table 3 – Additional parameters for weakly focused fields and equivalences to focused fields [2] (Figures 1c, 4c, 5b)

Parameter weakly focused[5]	Weakly Foc.	Unit	Focused sources
beam pressure maximum point (bpm)	(0,0,17,5)	mm	focus
beam pressure maximum … extent (here: only 9,8 MPa, see Fig. 4c)	33,2	mm	focal extent
beam pressure max… cross-sectional area at[6] z (here: z_{bpm}=17,5mm)	-6dB: 71 9,8MPa:27 6MPa: 64 2MPa: 230	mm²	focal cross-sectional area
beam pressure maximum … volume	9,8MPa:907	mm³	focal volume
beam pressure maximum … width, maximum (here: z_{bpm}=17,5mm)	-6dB: 9,5 9,8MPa:5,9 6MPa: 9,0 2MPa:17,1	mm	focal width, maximum
bpm … width, orthogonal	Dto.	mm	focal width, orthogonal
derived beam –n dB pressure maximum acoustic pulse energy[7] $E_{\mathrm{bpm},-n\mathrm{dB}}$ (here: *n*=-6dB)	12,5	mJ	focal energy in FWHM

[4] S is a circular cross-sectional area of radius R around a z position on the beam axis
[5] The "…" stands for *n* MPa or –*n* dB
[6] (0,0,z) is the coordinate of the beam pressure maximum point on the beam axis
[7] Derived from the beam pressure maximum –*n* dB cross-sectional area

4. RESULTS

Results of the simulations are shown in the Figures 1 and 2. Tables 1 to 3 contain the values derived from the simulated measurements.

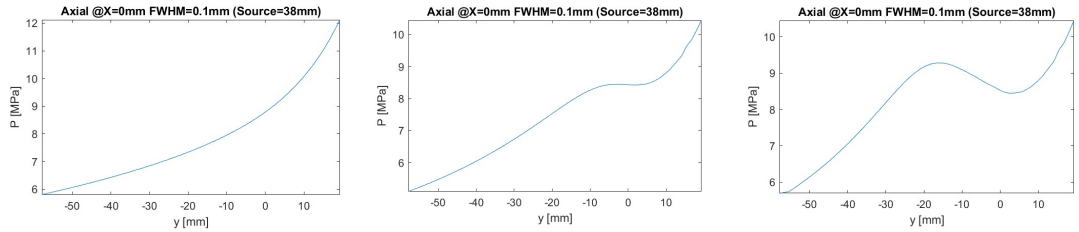
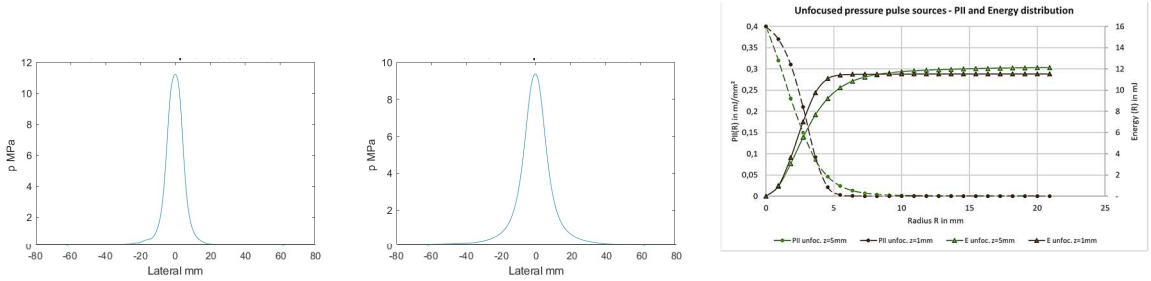
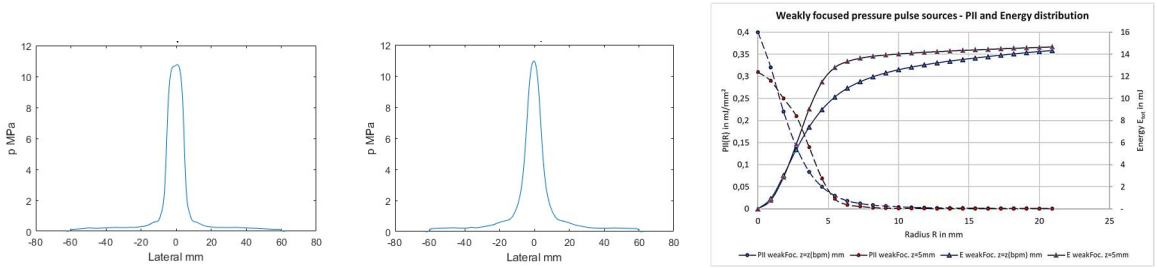


Figure 4: Axial distributions of simulated ballistic sources with 13 mm source aperture

a) unfocused field, b), c) weakly focused fields (drawings start at applicator), source aperture (0,0,0) at +21 mm



a) unfocused field at z = L_p = 5 mm and 15 mm, pressure distributions, and PII and energy E_R at z = 1 mm and z = L_p = 5 mm



b) weakly focused field, z=L_p=5 and z_{bpm}=17 mm, pressure and PII distributions and energy E_R

Figure 5: Lateral distributions , z=L_p=5 mm and z_2 mm from source aperture

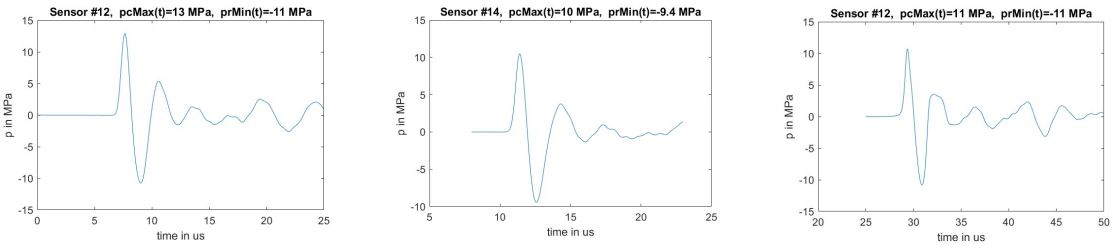


Figure 6: Pressure signals on axis: a) unfocused source signal at z = L_p = 5 mm; b) unfocused source signal at z = 15 mm; c) weakly focused source signal at z = L_p = 5 mm distance from source aperture

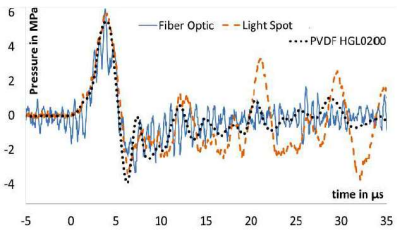


Figure 7: Measured pressure pulse signal of an unfocused EPPS, at z = L_p = 5 mm (from [4])

5. CONCLUSIONS

The standard IEC 63045 is intended to cover today's state-of-scientific measurement methods and parameters for unfocused and weakly focused pressure pulse sources. It could be shown by the application to simulated sources, that the parameters can be applied both to unfocused and to weakly focused EPPS sources.

The simulation of the sources with k-Wave was chosen to check the applicability of the draft standard IEC 63045, independent from any commercial products. Figure 7 proves the close similarity of the simulated pressure pulse $p(t)$ signals to measured signals at 5 mm from the source aperture from a 15 mm diameter ballistic EPPS [4] with three different types of hydrophones: fiberoptic, light spot and piezoelectric.

Once introduced, IEC 63045 will likely serve as a flexible basis for reliable, traceable reporting of the properties and fields of biomedical pressure pulse equipment to notified bodies, customers, users and researchers. It can be expected that, based on these parameters, the knowledge about the links and correlations between physical parameters, and the observed biomedical effects can be further clarified. This will lead to more dependable and reproducible therapy results and further new, efficient applications of pressure pulses.

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