

# CHARACTERIZATION OF UNFOCUSED / WEAKLY FOCUSED PRESSURE PULSE SOURCES FOR EXTRACORPOREAL PAIN THERAPY (“RADIAL SHOCK WAVE THERAPY” SOURCES)

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**Abstract:** Extracorporeal “Shock Wave” Therapy (ESWT) is widely and successfully used for the treatment of orthopedic pain situations. Based on measurements of different pressure pulse devices, a set of parameters for the characterization of unfocused / weakly focused pressure pulse sources is proposed, which may be used to initiate an internationally harmonized (IEC) standard for the measurement and characterization of these devices and to further develop an appropriate safety standard.

**Keywords:** Pressure Pulses, Pain Therapy, Unfocused / Weakly Focused Source, Measurement Parameters

## Introduction

Extracorporeal “Shock Wave” Therapy (ESWT) is widely and successfully used for the treatment of orthopedic pain situations, e.g. in the shoulder, the tennis elbow, or heel spur. ESWT was first developed using focused lithotripsy pressure pulse sources [1].

In 1999, an alternative technology, called “Radial Shock Waves” was introduced (“RESWT” devices). These types of sources are significantly smaller in diameter and therefore emit non-focused or weakly focused pressure pulses. First designs used pressurized air driven pistons impinging on a 15 mm (6..30 mm) circular steel “applicator” to create short pulses of 4.5  $\mu$ s duration with 2..10 MPa amplitudes [2], more recent devices drive the pistons by electromagnetic forces.

Although there is an increasing number of RESWT devices from different manufacturers on the market, there is no international standard for the characterization of the acoustic properties and for the safety available, which is fitted to these types of devices. Therefore, the data for the approval by notified bodies and public authorities (e.g. FDA) are usually measured on the basis of IEC 61846 [3], which was written for the characterization of *focused* lithotripter pressure pulses.

Thus only a subset of the parameters apply for the unfocused or weakly focused RESWT sources. More open issues occur due to the difference both in the mechanical structures and working principles as well in the application parameters (e.g. pulse generation principles, pulse amplitudes, energy and time parameters, pulse repeat rates, targeting, handling) of unfocused “radial” sources versus focused lithotripter(like) sources.

## Methods

Based on measurements of different pressure pulse devices [2], a set of parameters for the characterization of unfocused / weakly focused pressure pulse sources is proposed, which may be used to initiate an internationally harmonized (IEC – International Electrotechnical Committee, Geneva, Suisse) standard for the measurement and characterization of these devices and to further develop an appropriate safety standard.

4 different hand pieces of air pressure-driven ballistic pressure pulse sources were used for measurements both in water and in a “dry” test bench using a silicon coupling spacer of 5 mm thickness between applicator and hydrophone [2]. The devices were coupled to a pressurized (6 bar) air source. The driving pressure was adjusted at the device controls between 1,4 and 4..5 Bar. Measurements were made with single pulse (ca. 0,5 Hz) and at 1, 2, 5, 10,12, 15 and 20..21) Hz repeat rates. Applicators had 10 and 15 mm diameter.

Both piezoelectric hydrophones (Onda HGL 200: 200 $\mu$ m active diameter, <1,5MHz to >20MHz: -265,5dB(1V/ $\mu$ Pa.)  $\pm$ 1,5dB, with preamplifier AH-2010 (+20dB) and optical hydrophones (LSHD, 9,6mV/MPa) were used for the water measurements. In the water free test bench, both the HGL 200 and a piezoelectric pressure transducer (PCB, ICP type WS113B22, Ser.No. 22338, sensitivity 146,3 mV/MPa at 0,6% linearity up to 5000 mV = 34 MPa) were used.

The time domain pulse parameters, in particular the pulse intensity integral PII+ (Also termed “Energy Flux Density ED+) were evaluated using the definitions of the lithotripsy measurement standard IEC 61846 [3].

## Results

The spatial pressure distributions along and perpendicular to the axis of pulse propagation measured in degassed water give a set of parameters, which describe the sites and values of peak positive and negative pressure and pulse intensity (“Energy flux density”) and the axial and radial decay of these quantities (Table 2).

Due to cavitation, which frequently occurs at higher driving settings, measurements at higher repeat rates (e.g. 2 to >20 Hz) are often not feasible in water. In order to characterize the variation of the sources (pulse-to-pulse variations, long term variations), but also for fast and nevertheless precise measurement of pulse timing parameters at a fixed distance from the applicator, the “dry” test bench can be used with advantage. At the given pulse shapes and peak pressures, both pressure-time curves and the behavior of the hand pieces when changing parameters

like the pulse repeat rate can be measured with the same accuracy as in water, completely avoiding cavitation, although the negative pressure amplitude reaches the same levels as in water. Therefore, the parameters of pulses at higher repeat rates (Table 3) can be studied with high reliability, when appropriate hydrophones with sufficiently broad bandwidth and linearity are used.

Although the pressure-time curve of the pulse shape suffers from a low pass characteristics of the rigid ICP sensor, it could be shown that positive pressure amplitudes and the pulse intensity integral values  $ED^+$  over the positive signal portion were in good agreement to the values measured in water and in silicone with a precision hydrophone [2]. In contrast, the negative pressure portions are obviously limited by this probe type and cannot be used to describe the rarefaction parts of the signals.

Measurements with different devices revealed that the pressure-time curves of different types of applicators show significant differences. The detail structure of the pressure pulses depend on the geometry of the applicators. Applicators with an almost equal front and anterior areas support different patterns of internal reflections, which e.g. lead to double positive peaks in the signals. Measurements of the inertial motion of the applicators are also possible using the dry test bench. First results suggest, that there is a slower oscillation of the applicator, caused by its inertia and the mechanical construction of the devices. The measured amplitudes were significantly lower than those of the fast pressure pulse, but they still may be of medical importance and should therefore be documented (Table 3).  $Z=5$  mm proved as a safe distance to avoid damage to the hydrophones.

## Discussion

A set of parameters, which can be measured at minimum, typical and maximum driving energy settings either in water or – more easily and also at higher pulse repeat rates– in the dry test bench is proposed in Table 1. Typical pressure-time-curves should be documented additionally which includes the positive and negative pulse parts.

Table 1: Measurement parameters in water or in the dry test bench with 5 mm silicon [2] at min., typ. and max. setting

Symbol	Unit	Description
$P^+_{5mm}$	MPa	Peak positive pressure at $Z=5$ mm
$P^-_{5mm}$	MPa	Peak negative pressure at $Z=5$ mm
$ED^+_{5mm}$	mJ/mm <sup>2</sup>	Pulse intensity integral of the positive pulse portion at $Z=5$ mm (see [3])
Tr	μs	Rise time of the positive portion of the pressure pulse (10..90% of $P^+$ )
Tw	μs	Pulse width of the positive portion of the pressure pulse (10% amplitudes)

The field parameters as proposed in Table 2 need to be measured in water at slow pulse rates because of the need to move the hydrophone in the field. In unfocused and weakly focused devices, the values at 5 mm will give the  $E_{max}$  values due to the diverging nature of the pressure pulse field. 5 mm distance is a good compromise to safe

the hydrophones from damage due to possible inertial motion of the applicator but give enough data for extrapolation of the pulse parameters at the applicator surface.

It is advisable to define a limit of focusing, which will restrict the use of this standard. For stronger focusing fields, the existing lithotripsy standards [3] may be used.

Table 2: Parameters of unfocused / weakly focused RESWT devices measured in water in single pulse mode (to avoid cavitation). Propagation axis (Z) is defined in the direction normal to the surface of the transducer, starting in its center (of gravity), X, Y and Z form a Cartesian coordinate system. Measurements at min., typ. and max. drive energy settings.

Symbol	Unit	Description
$P^+_{max}$	MPa	Spatial peak positive pressure
$P^-_{max}$	MPa	Spatial peak negative pressure
$ED^+_{max}$	mJ/mm <sup>2</sup>	Pulse intensity integral of the positive pulse portion and the complete pulse
$ED_{max}$		
$W_{X10dB}$	Mm	$P^+$ Pressure field extension (-10dB) perpendicular to the propagation axis Z
$W_{Y10dB}$		
$W_{Z10dB}$	Mm	$P^-$ Pressure field extension (-10dB) along the propagation axis Z
$E^+_{5mm}$	mJ	Energy per pulse in $[W_{X5mm}+W_{Y5mm}]/2$ (positive defined by Tw and total)
$E_{5mm}$		
$E^+_{max}$	mJ	Energies per pulse in $[W_{Xmax}+W_{Ymax}]/2$ (positive defined by Tw and total) [3]
$E_{max}$		

These two sets of parameters should be completed by measurements of the maximum displacement of the applicator, e.g. by optically monitoring the motion shadow, and by parameters describing the change in output at different repeat rates (Table 3).

Tables 1 to 3 state a reasonable minimum set of parameters. It may be extended with growing experience in RESWT measurements and requirements for more clinically significant parameters.

Table 3: Measurement parameters evaluated in the dry test bench with 5mm silicon, at min., typ. and max. setting,  $single \rightarrow$  single pulse release,  $maxHz \rightarrow$  maximum pulse release rate

Symbol	Unit	Description
$DP^+_{5mm}$	%	$100(P^+_{5mm(single)} - P^+_{5mm(maxHz)})/P^+_{5mm(single)}$
$DED^+_{5mm}$	%	Equivalent for the Pulse Intensity Integral
$S_{max,PR}$	mm	Maximum displacement of the applicator due to inertial pulse at pulse rate PR
$TS_{maxHz,100}$	°C	Surface temperature of the applicator in the dry test bench after 100 pulses (or at equilibrium) at maximum rate

## Bibliography

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