

STN	Ultrazvuk Zdroje nefokusovaných krátkých tlakových impulzov vrátane balistických zdrojov tlakových impulzov Charakteristiky polí	STN EN IEC 63045 34 0890
------------	---	--

Ultrasonics - Non-focusing short pressure pulse sources including ballistic pressure pulse sources - Characteristics of fields

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 10/20

Obsahuje: EN IEC 63045:2020, IEC 63045:2020

131781

EUROPEAN STANDARD

EN IEC 63045

NORME EUROPÉENNE

EUROPÄISCHE NORM

July 2020

ICS 17.140.50

English Version

**Ultrasonics - Non-focusing short pressure pulse sources
including ballistic pressure pulse sources - Characteristics of
fields
(IEC 63045:2020)**

Ultrasons - Sources d'impulsions de pression courtes sans focalisation, y compris les sources d'impulsions de pression balistiques - Caractéristiques des champs
(IEC 63045:2020)

Ultraschall - Quellen für nicht fokussierte kurze Druckimpulse einschließlich pneumatischen und ballistischen Druckpulsquellen - Feldcharakterisierung
(IEC 63045:2020)

This European Standard was approved by CENELEC on 2020-06-29. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.



European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

EN IEC 63045:2020 (E)**European foreword**

The text of document 87/741/FDIS, future edition 1 of IEC 63045, prepared by IEC/TC 87 "Ultrasonics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 63045:2020.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2021-03-29
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2023-06-29

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

Endorsement notice

The text of the International Standard IEC 63045:2020 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-2-62	NOTE	Harmonized as EN 60601-2-62
IEC 60601-2-36	NOTE	Harmonized as EN 60601-2-36
IEC 61689	NOTE	Harmonized as EN 61689
IEC 61828:2001	NOTE	Harmonized as EN 61828:2001 (not modified)
IEC 63009	NOTE	Harmonized as EN IEC 63009

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60565-1	-	Underwater acoustics - Hydrophones - Calibration of hydrophones - Part 1: Procedures for free-field calibration of hydrophones	EN IEC 60565-1	-
IEC 60565-2	-	Underwater acoustics - Hydrophones - Calibration of hydrophones - Part 2: Procedures for low frequency pressure calibration	EN IEC 60565-2	-
IEC 62127-1	2007	Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz	EN 62127-1	2007
IEC 62127-2	2007	Ultrasonics - Hydrophones - Part 2: Calibration for ultrasonic fields up to 40 MHz	EN 62127-2	2007
IEC 62127-3	-	Ultrasonics - Hydrophones - Part 3: Properties of hydrophones for ultrasonic fields up to 40 MHz	EN 62127-3	-



IEC 63045

Edition 1.0 2020-05

INTERNATIONAL STANDARD



Ultrasonics – Non-focusing short pressure pulse sources including ballistic pressure pulse sources – Characteristics of fields



**THIS PUBLICATION IS COPYRIGHT PROTECTED****Copyright © 2020 IEC, Geneva, Switzerland**

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform

The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,...). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished

Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

Electropedia - www.electropedia.org

The world's leading online dictionary on electrotechnology, containing more than 22 000 terminological entries in English and French, with equivalent terms in 16 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary

67 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.



IEC 63045

Edition 1.0 2020-05

INTERNATIONAL STANDARD



Ultrasonics – Non-focusing short pressure pulse sources including ballistic pressure pulse sources – Characteristics of fields

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 17.140.50

ISBN 978-2-8322-8340-0

Warning! Make sure that you obtained this publication from an authorized distributor.

CONTENTS

FOREWORD.....	5
INTRODUCTION.....	7
1 Scope.....	8
2 Normative references	8
3 Terms and definitions	9
4 List of symbols	20
5 Conditions of measurement	22
5.1 General.....	22
5.2 Measurements in the water test chamber	22
5.3 Measurements in the dry test bench.....	22
6 Test equipment.....	22
6.1 Water test chamber.....	22
6.1.1 Coordinate system.....	23
6.1.2 Hydrophone for water test chamber measurements	23
6.1.3 Hydrophone for pressure pulse measurements	23
6.2 Dry test bench	24
6.3 Voltage measurement	24
6.3.1 Oscilloscope or transient recorder	24
6.3.2 Pressure pulse waveform recording	25
7 Measurement procedure	25
7.1 Measurement procedure in the water test chamber	26
7.1.1 General	26
7.1.2 Spatial measurements	26
7.1.3 Non-focusing source	28
7.1.4 Weakly focusing source	29
7.1.5 Beam plots of peak-positive acoustic pressure	29
7.1.6 Beam plots of peak-negative acoustic pressure	29
7.1.7 Measurement centre point and beam axis.....	30
7.1.8 Beam width measurements.....	30
7.1.9 Beam pressure maximum extent measurements	31
7.1.10 Beam cross-sectional area and beam pressure maximum cross-sectional area.....	31
7.1.11 Beam pressure maximum volume measurements.....	31
7.1.12 Beam volume.....	31
7.2 Temporal measurements.....	31
7.3 Acoustic energy measurements	32
7.3.1 General	32
7.3.2 Pulse-pressure-squared integral	32
7.3.3 Derived pulse-intensity integral.....	32
7.3.4 Derived beam $-n$ dB pressure maximum acoustic pulse energy	32
7.3.5 Derived acoustic pulse energy	33
7.4 Dry test bench measurements.....	33
Annex A (informative) Acoustic pressure pulse therapy.....	34
A.1 Background.....	34
A.1.1 General	34
A.1.2 Development of relevant measurement standard	34

A.1.3	Current knowledge on biomedical effects	34
A.1.4	Availability of clinical and technical data	34
A.2	Other treatment devices and methods not subject to this document	35
A.2.1	Percutaneous continuous and modulated wave systems	35
A.2.2	Extracorporeal shock wave lithotripsy	35
A.2.3	Further exclusions	35
Annex B (informative)	Types of pressure pulse transducers	36
B.1	Overview	36
B.1.1	General	36
B.1.2	Principle of ballistic pressure pulse sources	36
B.1.3	Rail gun principle	36
B.1.4	Further generation principles	37
B.2	Non-focusing and focusing transducers	37
B.3	Examples of pressure pulse sources and their parameter sets	38
B.4	Positioning and targeting methods	43
Annex C (informative)	Field measurement	44
C.1	Measurement probes and hydrophones	44
C.2	Water test chamber	46
C.2.1	General	46
C.2.2	Degassing procedures	46
C.3	Dry test bench	46
C.3.1	General	46
C.3.2	Selection and attachment of the hydrophone	48
C.3.3	Attachment of the hand piece	49
C.3.4	Proof of the similarity of measurements in water and the dry test bench	49
C.3.5	Special measurements with the dry test bench	49
C.4	Acoustic pulse energy	50
C.4.1	General	50
C.4.2	Extrapolation of the applicator surface pressure value	51
Annex D (informative)	Lists of parameters	52
Bibliography	59
Figure 1	– Typical pressure pulse waveform at 2 mm distance from a ballistic pressure pulse source	25
Figure 2	– Typical pressure distribution along the beam axis of a non-focusing pressure pulse source	27
Figure 3	– Typical pressure distribution along the beam axis of a weakly focusing pressure pulse source	28
Figure 4	– Typical lateral pressure distributions of p_C at the beam pressure maximum of two ballistic pressure pulse sources	30
Figure B.1	– Applicator directly coupled to the patient	39
Figure B.2	– Pressure pulse source, non-symmetric (linear), directly coupled to the patient	39
Figure B.3	– Pressure pulse source, symmetric, distant from the patient	40
Figure B.4	– Applicator coupled to patient	40
Figure B.5	– Non-focused pressure pulse field	40
Figure B.6	– Non-focused pressure pulse field - n dB parameters (example: $n = 6$)	41
Figure B.7	– Non-focused pressure pulse field isobars	41

Figure B.8 – Weakly-focused pressure pulse field –6 dB contour and parameters	42
Figure B.9 – Weakly-focused pressure pulse field volume and isobar parameters	42
Figure B.10 – Weakly-focused pressure pulse field parameters	43
Figure C.1 – Design example of a dry test bench in two views	47
Figure C.2 – Detail of the measurement chamber item of the dry test bench	48
Table C.1 – Hydrophone types for pressure pulse measurements	45
Table C.2 – Measurement techniques and probes for quality assurance purposes	46
Table D.1 – List of device parameters	52
Table D.2 – Pressure pulse parameters	53
Table D.3 – Additional parameters useful for the correlation with biological effects	55
Table D.4 – Graphical representations of pressure pulse data	56
Table D.5 – Data of hydrophones and measurement conditions	57

INTERNATIONAL ELECTROTECHNICAL COMMISSION

**ULTRASONICS – NON-FOCUSING SHORT PRESSURE
PULSE SOURCES INCLUDING BALLISTIC
PRESSURE PULSE SOURCES – CHARACTERISTICS OF FIELDS**
FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as “IEC Publication(s)”). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 63045 has been prepared by IEC technical committee 87: Ultrasonics.

The text of this International Standard is based on the following documents:

FDIS	Report on voting
87/741/FDIS	87/743/RVD

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

Words in **bold** in the text are defined in Clause 3.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "<http://webstore.iec.ch>" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

In this document, **pressure pulses** are single pulses of ultrasonic energy of up to 25 μs duration which have only one significant positive and one negative peak carrying more than 95 % of the energy (see definitions). Focused **pressure pulses** (sometimes called "strongly focused") are characterized by a peak acoustic pressure in a point in the sound field distant from the **source aperture**. Parameters and measurement methods for focusing **pressure pulse** sources are described in IEC 61846. The parameters and measurement methods of any other types of **pressure pulses**, i.e. weakly focused and non-focused **pressure pulses**, are described in this document.

Devices with non-focusing/weakly focusing **pressure pulse** sources are used for the extracorporeal treatment of soft tissue pain situations in, for example, the shoulder, the heel spur or the tennis elbow and for trigger point therapy. Further, still under research are applications in orthopaedics, pain therapy, treatment of angina pectoris, stem cell therapy of infarcted cardiac areas, treatment of erectile dysfunction, of cellulitis, and wound repair.

The patients receive between 3 to 5 treatments of 10 min to 20 min duration with approximately or on average 1 000 pulses. Each **pressure pulse** consists of one significant compressional part and a trailing negative part and has an overall duration of less than 25 μs . In present devices, 1 to 35 pulses per second are released to the target tissue. The pulses are usually applied to the patient by a manually guided hand piece. Targeting is commonly done by asking the patient to direct the pulses to the point of maximum pain.

The first use of non-focused/weakly focused **pressure pulses** to treat soft tissue pain situations was described in 1999. The first devices used the ballistic principle for the generation of the **pressure pulses**, which is based on an "air-gun" like acceleration of a projectile by pressurized air. The projectile impinges on the rear side of a larger metal **applicator**, the front side of which instantly releases one fast **pressure pulse** to the patient. Today, most of the devices on the market use this design and often are called "radial shock wave devices" or "ballistic sources" although a true shock wave is not created. Also, other pulse generating principles are being applied including variations of common lithotripter sources (electromagnetic, piezoelectric, electrohydraulic).

Before this first occurrence, focused **pressure pulses** were used clinically beginning in 1993 for the treatment of shoulder calcifications, tennis elbow pain and heel spur pain, initially using lithotripter-like electrohydraulic, electromagnetic or piezoelectric sources. These focused **pressure pulses** can be characterized by IEC 61846, but the parameters described therein are not sufficiently applicable to characterize the parameters and fields of weakly focused and non-focused **pressure pulses** and their propagation characteristics.

This document specifies methods of measuring and characterizing the acoustic **pressure pulses** generated by non-focusing/weakly focusing **pressure pulse equipment** and their propagation characteristics.

ULTRASONICS – NON-FOCUSING SHORT PRESSURE PULSE SOURCES INCLUDING BALLISTIC PRESSURE PULSE SOURCES – CHARACTERISTICS OF FIELDS

1 Scope

This document is applicable to

- therapy equipment using extracorporeally induced non-focused or weakly focused **pressure pulses**;
- therapy equipment producing extracorporeally induced non-focused or weakly focused mechanical energy,

where the **pressure pulses** are released as single events of duration up to 25 μs .

This document does not apply to

- therapy equipment using focusing **pressure pulse** sources such as extracorporeal lithotripsy equipment;
- therapy equipment using other acoustic waveforms like physiotherapy equipment, low intensity ultrasound equipment and HIFU/HITU equipment.

This document specifies

- measurable parameters which are used in the declaration of the acoustic output of extracorporeal equipment producing a **non-focused** or **weakly focused pressure pulse field**,
- methods of measurement and characterization of **non-focused** or **weakly focused pressure pulse fields**.

NOTE 1 The parameters defined in this document do not – at the time of publication – allow quantitative statements to be made about clinical efficacy and possible hazard. In particular, it is not possible to make a statement about the limits for these effects.

NOTE 2 Figure B.1 to Figure B.10 and Figure 2 to Figure 4 are useful to understand the geometry of the field applied in this document.

This document has been developed for equipment intended for use in **pressure pulse** therapy, for example therapy of orthopaedic pain like shoulder pain, tennis elbow pain, heel spur pain, muscular trigger point therapy, lower back pain, etc. It is not intended to be used for extracorporeal lithotripsy equipment (as described in IEC 61846), physiotherapy equipment using other waveforms (as described in IEC 61689) and HIFU/HITU equipment (see IEC 60601-2-62 and IEC TR 62649).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60565-1, *Underwater acoustics – Hydrophones – Calibration of hydrophones – Part 1: Procedures for free-field calibration of hydrophones*

IEC 60565-2, *Underwater acoustics – Hydrophones – Calibration of hydrophones – Part 2: Procedures for low frequency pressure calibration*

IEC 63045:2020 © IEC 2020

– 9 –

IEC 62127-1:2007, *Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz*
IEC 62127-1:2007/AMD1:2013

IEC 62127-2:2007, *Ultrasonics – Hydrophones – Part 2: Calibration for ultrasonic fields up to 40 MHz*

IEC 62127-3, *Ultrasonics – Hydrophones – Part 3: Properties of hydrophones for ultrasonic fields up to 40 MHz*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN