

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Ultrasonics – Physiotherapy systems – Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz

Ultrasons – Systèmes de physiothérapie – Spécifications des champs et méthodes de mesure dans la plage de fréquences de 0,5 MHz à 5 MHz



THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2022 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.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de l'IEC ou du Comité national de l'IEC du pays du demandeur. Si vous avez des questions sur le copyright de l'IEC ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de l'IEC de votre pays de résidence.

IEC Secretariat
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 It also gives information on projects, replaced and withdrawn publications.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.

IEC Products & Services Portal - products.iec.ch

Discover our powerful search engine and read freely all the publications previews. With a subscription you will always have access to up to date content tailored to your needs.

Electropedia - www.electropedia.org

The world's leading online dictionary on electrotechnology, containing more than 22 300 terminological entries in English and French, with equivalent terms in 19 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

A propos de l'IEC

La Commission Electrotechnique Internationale (IEC) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications IEC

Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

Recherche de publications IEC -

webstore.iec.ch/advsearchform

La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études, ...). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

IEC Just Published - webstore.iec.ch/justpublished

Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et une fois par mois par email.

Service Clients - webstore.iec.ch/csc

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: sales@iec.ch.

IEC Products & Services Portal - products.iec.ch

Découvrez notre puissant moteur de recherche et consultez gratuitement tous les aperçus des publications. Avec un abonnement, vous aurez toujours accès à un contenu à jour adapté à vos besoins.

Electropedia - www.electropedia.org

Le premier dictionnaire d'électrotechnologie en ligne au monde, avec plus de 22 300 articles terminologiques en anglais et en français, ainsi que les termes équivalents dans 19 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

INTERNATIONAL STANDARD

NORME INTERNATIONALE

**Ultrasonics – Physiotherapy systems – Field specifications and methods
of measurement in the frequency range 0,5 MHz to 5 MHz**

**Ultrasons – Systèmes de physiothérapie – Spécifications des champs
et méthodes de mesure dans la plage de fréquences de 0,5 MHz à 5 MHz**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.60

ISBN 978-2-8322-1080-0

**Warning! Make sure that you obtained this publication from an authorized distributor.
Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.**

CONTENTS

FOREWORD	5
INTRODUCTION	7
1 Scope	8
2 Normative references	8
3 Terms and definitions	9
4 Symbols	18
5 Ultrasonic field specifications	19
6 Conditions of measurement and test equipment used	20
6.1 General	20
6.2 Test vessel	20
6.3 Hydrophone	21
6.4 RMS peak signal measurement	22
7 Type testing reference procedures and measurements	22
7.1 General	22
7.2 Rated output power	23
7.3 Hydrophone measurements	23
7.4 Effective radiating area	24
7.4.1 Effective radiating area measurements	24
7.4.2 Hydrophone positioning	24
7.4.3 Beam cross-sectional area determination	24
7.4.4 Active area gradient determination	24
7.4.5 Beam type determination	25
7.4.6 Effective radiating area calculation	25
7.4.7 Beam non-uniformity ratio calculation	25
7.4.8 Testing requirements	25
7.5 Reference type testing parameters	26
7.6 Acceptance criteria for reference type testing	26
8 Routine measurement procedure	27
8.1 General	27
8.2 Rated output power	27
8.3 Effective radiating area	27
8.4 Beam non-uniformity ratio	27
8.5 Effective intensity	28
8.6 Acceptance criteria for routine testing	28
9 Sampling and uncertainty determination	28
9.1 Reference type testing measurements	28
9.2 Routine measurements	28
9.3 Uncertainty determination	29
Annex A (normative) Guidance for performance and safety	30
A.1 General	30
A.2 Rated output power	30
A.3 Effective intensity	30
A.4 Beam non-uniformity ratio	30
A.4.1 General	30

A.4.2	Rationale behind using a limiting value for the beam non-uniformity ratio (R_{BN})	30
Annex B (normative)	Raster scan measurement and analysis procedures	35
B.1	General.....	35
B.2	Requirements for raster scans	35
B.3	Requirements for analysis of raster scan data.....	36
B.3.1	General	36
B.3.2	Total mean square acoustic pressure	36
B.3.3	Calculation of the beam cross-sectional area, A_{BCS}	36
Annex C (normative)	Diametrical or line scan measurement and analysis procedures.....	37
C.1	General.....	37
C.2	Requirements for line scans	37
C.3	Analysis of scans	37
Annex D (informative)	Rationale concerning the beam cross-sectional area definition.....	41
Annex E (informative)	Factor used to convert the beam cross-sectional area (A_{BCS}) at the face of the treatment head to the effective radiating area (A_{ER}).....	42
Annex F (informative)	Determining acoustic power through radiation force measurements	44
Annex G (informative)	Validity of low-power measurements of the beam cross-sectional area (A_{BCS}).....	46
Annex H (informative)	Influence of hydrophone effective diameter	47
Annex I (informative)	Effective radiating area measurements using a radiation force balance and absorbing apertures	49
I.1	General.....	49
I.2	Concept of aperture method.....	49
I.3	Requirements for the aperture method	50
I.3.1	Radiation force balance	50
I.3.2	Apertures.....	50
I.4	Measurement procedure for determining the effective radiating area.....	51
I.5	Analysis of raw data to derive the effective radiating area.....	52
I.6	Implementation of the aperture technique	58
I.7	Relationship of results to reference testing method	59
Annex J (informative)	Guidance on uncertainty determination	60
Annex K (informative)	Examples of pulse duration and pulse repetition period of amplitude modulated waves	62
Bibliography		64

Figure A.1 – Normalized, time-averaged values of acoustic intensity (solid line) and of one of its plane-wave approximations (broken line), existing on the axis of a circular piston source of $ka = 30$, plotted against the normalized distance s_n , where $s_n = \lambda z/a^2$ 33

Figure A.2 – Histogram of R_{BN} values for 37 treatment heads of various diameters and frequencies..... 34

Figure E.1 – Conversion factor F_{ac} as a function of the ka product for ka product between 40 and 160

Figure I.1 – Schematic representation of aperture measurement set-up

Figure I.2 – Measured power as a function of aperture diameter for commercially available 1 MHz physiotherapy treatment heads

Figure I.3 – Cumulative sum of annular power contributions, previously sorted in descending order of intensity contributions, plotted against the cumulative sum of their respective annular areas	58
Figure K.1 – Example 1: Tone-burst (i.e. rectangular modulation waveform)	62
Figure K.2 – Example 2: Half-wave modulation with no filtering of the AC mains voltage.....	62
Figure K.3 – Example 3: Full-wave modulation with no filtering of the AC mains voltage	62
Figure K.4 – Example 4: Half-wave modulation with filtering of the AC mains voltage; filtering insufficient to define the wave as continuous wave (3.17).....	63
Figure K.5 – Example 5: Full-wave modulation with filtering of the AC mains voltage; filtering insufficient to define the wave as continuous wave (3.17).....	63
Table C.1 – Constitution of the transformed array [B] used for the analysis of half-line scans	39
Table F.1 – Necessary target size, expressed as the minimum target radius b , as a function of the ultrasonic frequency, f , the effective radius of the treatment head, a_1 , and the target distance, z , calculated in accordance with A.5.3.1 of IEC 61161:2013 (see [8])	45
Table G.1 – Variation of the beam cross-sectional area $A_{BCS}(z)$ with the indicated output power from two transducers	46
Table H.1 – Comparison of measurements of the beam cross-sectional area $A_{BCS}(z)$ made using hydrophones of geometrical active element radii 0,3 mm, 0,5 mm and 2,0 mm	48
Table I.1 – Aperture measurement check sheet	53
Table I.2 – Annular power contributions	55
Table I.3 – Annular intensity contributions.....	55
Table I.4 – Annular intensity contributions, sorted in descending order	56
Table I.5 – Annular power contributions, sorted in descending order of intensity contribution.....	56
Table I.6 – Cumulative sum of annular power contributions, previously sorted in descending order of intensity contribution, and the cumulative sum of their respective annular areas.....	57

INTERNATIONAL ELECTROTECHNICAL COMMISSION

**ULTRASONICS – PHYSIOTHERAPY SYSTEMS –
FIELD SPECIFICATIONS AND METHODS OF MEASUREMENT
IN THE FREQUENCY RANGE 0,5 MHz TO 5 MHz**

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.

IEC 61689 has been prepared by IEC technical committee 87: Ultrasonics. It is an International Standard.

This fourth edition cancels and replaces the third edition published in 2013. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition.

- a) The requirement on water oxygen content is specified in 6.1.
- b) Former recommendations in 6.2 have been changed to become requirements.
- c) Several definitions in Clause 3 have been updated in line with other TC 87 documents.
- d) The formerly informative Annex A has been changed to become normative, and now contains details on how conformance with IEC 60601-2-5 requirements is checked.
- e) Annex D has been considerably shortened and reference to a now withdrawn regulatory document has been removed.

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

Draft	Report on voting
87/784/FDIS	87/789/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

NOTE The following print types are used:

- Requirements: in Arial 10 point
- Notes: in Arial 8 point
- Words in **bold** in the text are defined in Clause 3
- Symbols and formulae: *Times New Roman + Italic*
- Compliance clauses: in *Arial Italic*

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under 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.

INTRODUCTION

Ultrasound at low megahertz frequencies is widely used in medicine for the purposes of physiotherapy. Such equipment consists of a generator of high frequency electrical energy and usually a hand-held **treatment head**, often referred to as an applicator. The **treatment head** contains a transducer, usually a disc of piezoelectric material, for converting the electrical energy to **ultrasound** and is often designed for contact with the human body.

ULTRASONICS – PHYSIOTHERAPY SYSTEMS – FIELD SPECIFICATIONS AND METHODS OF MEASUREMENT IN THE FREQUENCY RANGE 0,5 MHz TO 5 MHz

1 Scope

This document is applicable to ultrasonic equipment designed for physiotherapy containing an **ultrasonic transducer** generating continuous or quasi-continuous (e.g. tone burst) wave **ultrasound** in the frequency range 0,5 MHz to 5 MHz. This document only relates to **ultrasonic physiotherapy equipment** employing a single plane non-focusing circular transducer per **treatment head**, producing static beams perpendicular to the face of the **treatment head**.

This document specifies:

- methods of measurement and characterization of the output of **ultrasonic physiotherapy equipment** based on reference testing methods;
- characteristics to be specified by manufacturers of **ultrasonic physiotherapy equipment** based on reference testing methods;
- guidelines for safety of the ultrasonic field generated by **ultrasonic physiotherapy equipment**;
- methods of measurement and characterization of the output of **ultrasonic physiotherapy equipment** based on routine testing methods;
- acceptance criteria for aspects of the output of **ultrasonic physiotherapy equipment** based on routine testing methods.

Therapeutic value and methods of use of **ultrasonic physiotherapy equipment** are not within the scope of this document.

Ultrasonic physiotherapy equipment using **ultrasound** in the frequency range from 20 kHz to 500 kHz is dealt with in IEC 63009.

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 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-2-5, *Medical electrical equipment – Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment*

IEC 61161, *Ultrasonics – Power measurement – Radiation force balances and performance requirements*

IEC 62127-1, *Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

3.1

absolute maximum rated output power

sum of the **rated output power**, the 95 % confidence overall uncertainty in the **rated output power**, and the maximum increase in the **rated output power** for a ± 10 % variation in the rated value of the mains voltage

Note 1 to entry: The possibility of variation in the **rated output power** resulting from ± 10 % variation in the rated value of the mains voltage should be checked by using a variable output transformer between the mains voltage supply and the **ultrasonic physiotherapy equipment**. See Clause A.2 for further guidance.

Note 2 to entry: **Absolute maximum rated output power** is expressed in watts (W).

3.2

active area coefficient

Q

quotient of the **active area gradient**, m , and the **beam cross-sectional area** at 0,3 cm from the face of the **treatment head**, $A_{\text{BCS}}(0,3 \text{ cm})$

Note 1 to entry: **Active area coefficient** is expressed in units of one per metre (m^{-1}).

3.3

active area gradient

m

ratio of the difference of the **beam cross-sectional area** at z_N , $A_{\text{BCS}}(z_N)$, and the **beam cross-sectional area** at 0,3 cm from the face of the **treatment head**, $A_{\text{BCS}}(0,3 \text{ cm})$, divided by the difference of the respective distances

$$m = \frac{A_{\text{BCS}}(z_N) - A_{\text{BCS}}(0,3 \text{ cm})}{z_N - 0,3 \text{ cm}} \quad (1)$$

where

A_{BCS} is the **beam cross-sectional area**;

z_N is the distance from the face of the **treatment head** to the last maximum of the **RMS acoustic pressure** on the **beam alignment axis**

Note 1 to entry: **Active area gradient** is expressed in metres (m).

[SOURCE: IEC 61689:2013, 3.3, modified – The calculation scheme of the gradient was added to the definition, and the formula was added.]

3.4

absolute maximum beam non-uniformity ratio

beam non-uniformity ratio plus the 95 % confidence overall uncertainty in the **beam non-uniformity ratio**

3.5

absolute maximum effective intensity

value of the **effective intensity** corresponding to the **absolute maximum rated output power** and the **absolute minimum effective radiating area** from the **equipment**

3.6

absolute minimum effective radiating area

effective radiating area minus the 95 % confidence overall uncertainty in the **effective radiating area**

3.7

acoustic-working frequency

acoustic frequency

f_{awf}

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 **spatial-peak temporal-peak acoustic pressure**

Note 1 to entry: The signal is analysed using either the **zero-crossing acoustic-working frequency** technique or a spectrum analysis method. Acoustic-working frequencies are defined in 3.7.1 and 3.7.2.

Note 2 to entry: In a number of cases the present definition is not very helpful or convenient, especially for broadband **transducers**. In that case a full description of the frequency spectrum should be given in order to enable any frequency-dependent correction to the signal.

Note 3 to entry: **Acoustic frequency** is expressed in hertz (Hz).

[SOURCE: IEC 62127-1:2007, 3.3]

3.7.1

arithmetic-mean acoustic-working frequency

f_{awf}

arithmetic mean of the most widely separated frequencies f_1 and f_2 , within the range of three times f_1 , at which the magnitude of the acoustic pressure spectrum is 3 dB below the peak magnitude

Note 1 to entry: This frequency definition usually is intended for systems that produce short pulses containing only a few cycles, but it could be used for tone bursts.

Note 2 to entry: It is assumed that $f_1 < f_2$.

Note 3 to entry: If f_2 is not found within the range $< 3f_1$, f_2 is to be understood as the lowest frequency above this range at which the spectrum magnitude is 3 dB below the peak magnitude.

[SOURCE: IEC 62127-1:2007 and IEC 62127-1:2007/AMD1:2013, 3.3.2, modified – Note 1 to entry has been modified.]

3.7.2

zero-crossing acoustic-working frequency

f_{awf}

number, n , of consecutive half-cycles (irrespective of polarity) divided by twice the time between the commencement of the first half-cycle and the end of the n -th half-cycle

Note 1 to entry: None of the n consecutive half-cycles should show evidence of phase change.

Note 2 to entry: The measurement should be performed at terminals in the receiver that are as close as possible to the receiving transducer (**hydrophone**) and, in all cases, before rectification.

Note 3 to entry: This frequency is determined in accordance with the procedure specified in IEC TR 60854.

Note 4 to entry: This frequency is intended for **continuous wave** or quasi-continuous-wave (e.g. tone-burst) systems only.

[SOURCE: IEC 62127-1:2007/AMD1:2013, 3.3.1, modified – In Note 4 to entry, "or quasi-continuous-wave (e.g. tone-burst)" has been added.]

3.8

acoustic pulse waveform

temporal waveform of the **instantaneous acoustic pressure** at a specified position in an acoustic field and displayed over a period sufficiently long to include all significant acoustic information in a single pulse or tone-burst, or one or more cycles in a **continuous wave**

Note 1 to entry: Temporal waveform is a representation (e.g. oscilloscope presentation or equation) of the **instantaneous acoustic pressure**.

[SOURCE: IEC 62127-1:2007 and IEC 62127-1:2007/AMD1:2013, 3.1]

3.9

acoustic repetition period

arp

pulse repetition period equal to the time interval between corresponding points of consecutive cycles for **continuous wave** systems

Note 1 to entry: **Acoustic repetition period** is expressed in seconds (s).

[SOURCE: IEC 62127-1:2007, 3.2, modified – The definition has been made more specific for non-scanning systems.]

3.10

amplitude modulated wave

wave in which the ratio $p_{tp}/(\sqrt{2}p_{RMS})$ at any point in the **far field** on the **beam alignment axis** is greater than 1,05, where p_{tp} is the **temporal-peak acoustic pressure** and p_{RMS} is the **RMS acoustic pressure**

3.11

attachment head

accessory intended to be attached to the **treatment head** for the purpose of modifying the ultrasonic beam characteristics

[SOURCE: IEC 60601-2-5:2009, 201-3-202]

3.12

beam alignment axis

straight line joining two points of **maximum RMS acoustic pressure** on two plane surfaces parallel to the faces of the **treatment head** at specific distances

Note 1 to entry: One plane is at a distance of approximately a^2/λ where a is the geometrical radius of the active element of the **treatment head**. The second plane surface is at a distance of either $2a^2/\lambda$ or $a^2/(3\lambda)$, whichever is the more appropriate. For the purposes of alignment, this line may be projected to the face of the **treatment head**.

Note 2 to entry: As the **beam alignment axis** is used purely for the purposes of alignment, the definitions of specific distances may be relaxed slightly to reflect the constraints of the measurement system employed. For example, some **treatment heads** will have a^2/λ considerably greater than 12 cm, in which case a maximum distance of 12 cm may be used to define the first plane. General guidelines for determining the **beam alignment axis** are given in 7.3.

3.13**beam cross-sectional area** A_{BCS}

minimum area in a specified plane perpendicular to the **beam alignment axis** for which the sum of the **mean square acoustic pressure** is 75 % of the **total mean square acoustic pressure**

Note 1 to entry: **Beam cross-sectional area** is expressed in units of square metre (m²).

Note 2 to entry: The rationale supporting the definition is described in Annex D.

3.14**beam maximum intensity**

product of the **beam non-uniformity ratio** and **effective intensity**

Note 1 to entry: **Beam maximum intensity** is expressed in units of watt per square metre (W/m²).

3.15**beam non-uniformity ratio** R_{BN}

ratio of the square of the **maximum RMS acoustic pressure** to the spatial average of the square of the **RMS acoustic pressure**, where the spatial average is taken over the **effective radiating area**

$$R_{\text{BN}} = \frac{p_{\text{max,RMS}}^2 A_{\text{ER}}}{pms_{\text{t}} A_0} \quad (2)$$

where

$p_{\text{max,RMS}}$ is the **maximum RMS acoustic pressure**;

A_{ER} is the **effective radiating area**;

pms_{t} is the **total mean square acoustic pressure**;

A_0 is the unit area for the raster scan.

3.16**beam type**

descriptive classification of the ultrasonic beam

Note 1 to entry: There are three beam types: **collimated** (3.18), **convergent** (3.19) and **divergent** (3.20).

3.17**continuous wave**

wave in which the ratio $p_{\text{tp}}/(\sqrt{2} p_{\text{RMS}})$, at any point in the **far field** on the **beam alignment axis**, is less than or equal to 1,05, where p_{tp} is the **temporal-peak acoustic pressure** and p_{RMS} is the **RMS acoustic pressure**

3.18**collimated**

<beam> having an **active area coefficient**, Q , that obeys the following inequality

$$-0,05 \text{ cm}^{-1} \leq Q \leq 0,1 \text{ cm}^{-1}$$

3.19**convergent**

<beam> having an **active area coefficient**, Q , that obeys the following inequality

$$Q < -0,05 \text{ cm}^{-1}$$

3.20**divergent**

<beam> having an **active area coefficient**, Q , that obeys the following inequality

$$Q > 0,1 \text{ cm}^{-1}$$

3.21**duty factor**

ratio of the **pulse duration** to the **pulse repetition period**

3.22**effective intensity**

I_e

intensity given by $I_e = P/A_{ER}$ where P is the **output power** and A_{ER} is the **effective radiating area**

Note 1 to entry: **Effective intensity** is expressed in units of watt per square metre (W/m^2).

3.23**effective radiating area**

A_{ER}

beam cross-sectional area determined at a distance of 0,3 cm from the front of the **treatment head**, $A_{BCS}(0,3 \text{ cm})$, multiplied by a dimensionless factor F_{ac} equal to 1,333

Note 1 to entry: The conversion factor F_{ac} is used here in order to derive the area close to the **treatment head** which contains 100 % of the **total mean square acoustic pressure**. The origin of the value of F_{ac} is described in Annex E.

Note 2 to entry: **Effective radiating area** is expressed in units of square metre (m^2).

3.24**end-of-cable loaded sensitivity**

$\underline{M}_L(f)$

<of a **hydrophone** or hydrophone assembly> quotient of the Fourier transformed **hydrophone** voltage-time signal $\mathcal{F}(u_L(t))$ at the end of any integral cable or output connector of a **hydrophone** or hydrophone assembly, when connected to a specified electric load impedance, to the Fourier transformed **acoustic pulse waveform** $\mathcal{F}(p(t))$ in the undisturbed free field of a plane wave in the position of the reference centre of the **hydrophone** if the **hydrophone** were removed

$$\underline{M}_L(f) = \frac{\mathcal{F}(u_L(t))}{\mathcal{F}(p(t))} \quad (3)$$

Note 1 to entry: The **end-of-cable loaded sensitivity** is a complex-valued parameter. Its modulus is expressed in units of volt per pascal (V/Pa), its phase angle is expressed in degrees, and represents the phase difference between the electrical voltage and the sound pressure.

[SOURCE: IEC 61828:2020, 3.50]

3.25

far field

region of the field where $z > z_T$ aligned along the beam axis for planar non-focusing transducers where z is the distance from the face of the **treatment head** to a specified point on the **beam alignment axis**

Note 1 to entry: In the **far field**, the sound pressure appears to be spherically **divergent** from a point on or near the radiating surface. Hence the pressure produced by the sound source is approximately inversely proportional to the distance from the source.

Note 2 to entry: The term "**far field**" is used in this document only in connection with non-focusing source transducers. For focusing transducers a different terminology for the various parts of the transmitted field applies (see IEC 61828).

Note 3 to entry: For the purposes of this document, the **far field** starts at a distance where $z_T = A_{ERN}/(\pi\lambda)$, where A_{ERN} is the nominal value of the **effective radiating area** of the **treatment head** and λ is the wavelength of the **ultrasound** corresponding to the **acoustic working frequency**.

[SOURCE: IEC 62127-1:2007/AMD1:2013, 3.28, modified – In the definition, specification of z has been added and Note 3 to entry has been replaced to provide specific information on z_T]

3.26

hydrophone

transducer that produces electrical signals in response to pressure fluctuations in water

Note 1 to entry: A **hydrophone** is principally a passive device designed and built to respond to sound pressure.

Note 2 to entry: In some applications, a **hydrophone** is used as an active device to transmit sound.

[SOURCE: IEC 60050-801:2021, 801-32-26]

3.27

instantaneous acoustic pressure

$p(t)$

pressure at a particular instant in time and at a particular point in an acoustic field, minus the ambient pressure

Note 1 to entry: **Instantaneous acoustic pressure** is expressed in pascals (Pa).

[SOURCE: IEC 60050-802:2011, 802-01-03]

3.28

maximum RMS acoustic pressure

$p_{\max, \text{RMS}}$

maximum value over the entire acoustic field of the **RMS acoustic pressure**

Note 1 to entry: **Maximum RMS acoustic pressure** is expressed in pascals (Pa).

3.29

mean square acoustic pressure

mean square of the **instantaneous acoustic pressure** at a particular point in the acoustic field, taken over an integral number of **acoustic repetition periods**

Note 1 to entry: In practice, the mean value is often derived from RMS measurements.

Note 2 to entry: **Mean square acoustic pressure** is expressed in units of pascal squared (Pa^2).

3.30**modulation waveform**

temporal envelope waveform of the **amplitude modulated wave** at the point of **peak RMS acoustic pressure** on the **beam alignment axis** and displayed over a period sufficiently long to include all significant acoustic information in the **amplitude modulated wave**

Note 1 to entry: See Annex K for examples.

3.31**output power***P*

time-average ultrasonic power emitted by a **treatment head** of **ultrasonic physiotherapy equipment** into an approximately free field under specified conditions in a specified medium, preferably in water

Note 1 to entry: **Output power** is expressed in watts (W).

[SOURCE: IEC 61161:2013, 3.3, modified – In the definition, "ultrasonic transducer" has been replaced by "treatment head of ultrasonic physiotherapy equipment".]

3.32**peak RMS acoustic pressure**

maximum value of the **RMS acoustic pressure** over a specified region, line or plane in an acoustic field

Note 1 to entry: **Peak RMS acoustic pressure** is expressed in pascals (Pa).

3.33**pulse duration**

time interval beginning when the **modulation waveform** exceeds a reference value and ending at the next time the **modulation waveform** returns to that value

Note 1 to entry: The reference value is equal to the sum of the minimum value of the **modulation waveform** and 10 % of the difference between the maximum and minimum value of the **modulation waveform**.

Note 2 to entry: This definition differs from that in IEC 62127-1:2007 to be applicable to **amplitude modulated waves**.

Note 3 to entry: See Annex K for examples.

Note 4 to entry: **Pulse duration** is expressed in seconds (s).

3.34**pulse repetition period***prp*

time interval between equivalent points on the **modulation waveform** for an **amplitude modulated wave**

Note 1 to entry: See Annex K for examples.

Note 2 to entry: **Pulse repetition period** is expressed in seconds (s).

3.35**pulse repetition rate***prf*

reciprocal of the **pulse repetition period**

Note 1 to entry: The **pulse repetition rate** is equal to the repetition frequency of the modulated waveform.

Note 2 to entry: The **pulse repetition rate** is expressed in hertz (Hz)

[SOURCE: IEC 62127-1:2007, 3.52, modified – Note 1 to entry differs from the original NOTE 1.]

3.36

rated output power

maximum **output power** of the **ultrasonic physiotherapy equipment** at the rated value of the mains voltage, with control settings configured to deliver maximum **output power**

Note 1 to entry: **Rated output power** is expressed in watts (W).

3.37

RMS acoustic pressure

p_{RMS}

root-mean-square (RMS) of the **instantaneous acoustic pressure** at a particular point in an acoustic field

Note 1 to entry: The mean should be taken over an integral number of **acoustic repetition periods** unless otherwise specified.

Note 2 to entry: **RMS acoustic pressure** is expressed in pascals (Pa).

[SOURCE: IEC 62127-1:2007, 3.53]

3.38

spatial-peak temporal-peak acoustic pressure

p_{sptp}

larger of the peak-compressional acoustic pressure or the peak-rarefactional acoustic pressure

Note 1 to entry: **Spatial-peak temporal-peak acoustic pressure** is expressed in pascals (Pa).

[SOURCE: IEC 62127-1:2007, 3.63]

3.39

temporal-maximum output power

P_{tm}

<for an **amplitude modulated wave**> actual **output power** scaled by half of the squared ratio of the **temporal-peak acoustic pressure** and the **RMS acoustic pressure**

$$P_{\text{tm}} = \frac{1}{2} \left(\frac{p_{\text{tp}}}{p_{\text{RMS}}} \right)^2 \times P \quad (4)$$

where

P is the actual **output power** under **amplitude modulated wave** conditions;

p_{tp} is the **temporal-peak acoustic pressure**;

p_{RMS} is the **RMS acoustic pressure**.

Note 1 to entry: Both p_{tp} and p_{RMS} are measured at a specified point on the **beam alignment axis**.

Note 2 to entry: **Temporal-maximum output power** is expressed in watts (W).

3.40

total mean square acoustic pressure

pms_t

sum of the **mean square acoustic pressure** values, each with a specified incremental area, in a specified plane over specified limits of summation

Note 1 to entry: **Total mean square acoustic pressure** is expressed in units of pascal squared (Pa²).

3.41**temporal-maximum intensity** I_m

<for an **amplitude modulated wave**> quotient of the **temporal-maximum output power** and the **effective radiating area**

$$I_m = \frac{P_{tm}}{A_{ER}} \quad (5)$$

where

P_{tm} is the **temporal-maximum output power**;

A_{ER} is the **effective radiating area**.

Note 1 to entry: **Temporal-maximum intensity** is expressed in units of watt per square metre (W/m²).

3.42**temporal-peak acoustic pressure** p_{tp}

maximum value of the modulus of the **instantaneous acoustic pressure** at a particular point in an acoustic field

Note 1 to entry: **Temporal-peak acoustic pressure** is expressed in pascals (Pa).

[SOURCE: IEC 62127-1:2007, 3.67]

3.43**treatment head**

assembly comprising one **ultrasonic transducer** and associated parts for local application of **ultrasound** to the patient

[SOURCE: IEC 60601-2-5:2009, 201.3.214, modified – The NOTE has not been included.]

3.44**ultrasonic transducer**

device capable of converting electrical energy to mechanical energy within the ultrasonic frequency range and/or reciprocally of converting mechanical energy to electrical energy

[SOURCE: IEC 62127-1:2007, 3.73]

3.45**ultrasound**

acoustic oscillation whose frequency is above the high-frequency limit of audible sound (about 20 kHz)

[SOURCE: IEC 60050-802:2011, 802-01-01]

3.46**ultrasonic physiotherapy equipment**

equipment

equipment for the generation and application of **ultrasound** to a patient for therapeutic purposes

Note 1 to entry: Excluded equipment includes, but is not limited to:

- equipment in which **ultrasound** waves are intended to destroy conglomerates (for example stones in the kidneys or the bladder) or tissue of any type;

- equipment in which a tool is driven by **ultrasound** (for example surgical scalpels, phacoemulsifiers, dental scalers or intracorporeal lithotripters);
- equipment in which **ultrasound** waves are intended to sensitize tissue to further therapies (for example radiation or chemotherapy);
- equipment in which **ultrasound** waves are intended to treat cancerous (i.e. malignant) or pre-cancerous tissue, or benign masses, such as high intensity focused ultrasound (HIFU) or high intensity therapeutic ultrasound (HITU).

[SOURCE: IEC 60601-2-5:2009, 201.3.216, modified – The NOTE has been modified to give some examples of excluded equipment.]

4 Symbols

a	geometrical radius of the active element of a treatment head
A_{BCS}	beam cross-sectional area
$A_{\text{BCS}}(0,3 \text{ cm})$	beam cross-sectional area evaluated at 0,3 cm from the front face of the treatment head
$A_{\text{BCS}}(z_N)$	beam cross-sectional area evaluated at the position of the last axial maximum, z_N
A_{ER}	effective radiating area of a treatment head
a_g	geometrical radius of the active element of a hydrophone
a_{max}	maximum effective hydrophone size, defined in IEC 62127-1
A_o	unit area for a raster scan
arp	acoustic repetition period
b	minimum radius of a target for a radiation force balance
c	speed of sound in water
ERD	echo reduction
f_{awf}	acoustic working frequency
F_{ac}	conversion factor to convert $A_{\text{BCS}}(0,3 \text{ cm})$ to A_{ER}
I_e	effective intensity
I_m	temporal maximum intensity
k	($= 2\pi/\lambda$) circular wave number
m	active area gradient
$\underline{M_L}$	end-of-cable loaded sensitivity of a hydrophone
P	output power of a treatment head
P_{tm}	temporal-maximum output power
$p(t)$	instantaneous acoustic pressure
p_{tp}	temporal-peak acoustic pressure
p_{sptp}	spatial-peak temporal-peak acoustic pressure
$p_{\text{max,RMS}}$	maximum RMS acoustic pressure
p_{RMS}	RMS acoustic pressure
pms_t	total mean square acoustic pressure
prp	pulse repetition period
prr	pulse repetition rate
Q	active area coefficient

R	ratio of the peak RMS acoustic pressure to the RMS acoustic pressure averaged over the beam cross-sectional area in a specified plane
R_{BN}	beam non-uniformity ratio
s	step size for a raster scan
s_n	normalized distance from the face of the transducer to a specified point on the beam alignment axis
u	end-of-cable voltage for a hydrophone
u_i	hydrophone signal for the i -th scan point
u_n	RMS noise voltage
z	distance from the face of the treatment head to a specified point on the beam alignment axis
z_j	distance from the face of the treatment head to the measurement plane (perpendicular to the beam alignment axis) of interest
z_N	distance from the face of the treatment head to the last maximum of the RMS acoustic pressure on the beam alignment axis
z_p	distance from the face of the treatment head to the peak RMS acoustic pressure on the beam alignment axis
λ	ultrasonic wavelength
ρ	density of water

5 Ultrasonic field specifications

In addition to the general requirements specified in IEC 60601-1 and specific requirements specified in IEC 60601-2-5, manufacturers shall specify nominal values for the following parameters in the accompanying literature for each type of **treatment head**:

- **rated output power** (± 20 %);
- **effective radiating area** (A_{ERN}) of the **treatment head** (± 20 %);
- **effective intensity** (I_e) at the same equipment settings as the nominal value of the **rated output power** (± 30 %);
- **acoustic working frequency** (f_{awf}) (± 10 %);
- **beam non-uniformity ratio** (R_{BN}) (± 30 %);
- **beam maximum intensity** (± 30 %);
- **beam type**;
- **pulse duration, pulse repetition period** (prp), **duty factor** and the ratio of the **temporal maximum output power** to the **output power** for each modulation setting (± 5 %);
- **modulation waveform** for each modulation setting.

The numbers given in brackets are the tolerances defining the range of acceptable values for the results of either the type testing reference measurements specified in Clause 7 or the routine measurements specified in Clause 8. If the published tolerance requirement cannot be met, then the 95 % confidence level that is achievable should be reported. It shall then be demonstrated that the reported value, when incorporated with the tolerance so as to produce the "worst case" value, remains within the range of acceptable values, as specified in IEC 60601-2-5, and on which more details are provided in Annex A.

The temperature range shall be specified for the parameters specified above. The range of line voltages shall also be specified.

For **ultrasonic physiotherapy equipment** using a **treatment head** capable of operating at more than one nominal value of **acoustic working frequency**, the parameters listed above shall be specified for each nominal value of **acoustic working frequency**.

In addition, for **ultrasonic physiotherapy equipment** which can use an **attachment head**, the parameters listed above shall be specified for each combination of **attachment head** and **treatment head**.

NOTE This document does not contain requirements relating to safety: these are covered in IEC 60601-2-5. However, the requirements of IEC 60601-2-5 on parameters of this document, as well as guidance on performance and safety, can be found in Annex A.

6 Conditions of measurement and test equipment used

6.1 General

All measurements undertaken in water shall be under approximately free-field conditions at a temperature of $22\text{ °C} \pm 3\text{ °C}$.

If measurements are carried out at any other temperature, a test shall be undertaken to show that the results, determined in accordance with 7.6 and 8.6, are not dependent on the temperature at which the tests were undertaken.

Degassed water shall be used for the measurement of ultrasonic power, see Clause 7. The amount of dissolved oxygen in the degassed water shall be $< 4\text{ mg/l}$ during all measurements.

NOTE Degassed water is essential to avoid cavitation when the physiotherapy units are operated at or near full **output power**. Information on preparation of water suitable for physiotherapy measurements can be found in IEC 61161, IEC TR 62781 and in [1]¹.

All measurements shall be made after the warm-up period specified by the manufacturer. If no such period is specified, a period of 30 min shall be used.

6.2 Test vessel

The test vessel used for all **hydrophone** measurements shall be large enough to allow the immersion of both the **treatment head** and the **hydrophone**. The tank size should conform to IEC 62127-1.

The relative position and angular orientation of the **treatment head** and **hydrophone** shall be adjustable for the purposes of alignment in accordance with IEC 62127-1. Full degrees of freedom of movement of both may be provided, although the minimum requirement is that either the **treatment head** or the **hydrophone** shall possess three independent degrees of translational movement. The measurements shall be performed under free-field conditions. To achieve these conditions, it may be necessary to line the walls of the test vessel as well as the mounts used to hold the **treatment head** and the **hydrophone** with absorbers or angled reflector(s) and absorber(s) of higher absorption and lower scatter. The free-field conditions will be met sufficiently when the overall echo is reduced by more than 25 dB. Various methods can be used to check the compliance for echo reduction of the tank lining materials used.

¹ Numbers in square brackets refer to the Bibliography.

Compliance for overall echo reduction of an acoustic absorber may be checked using the procedure from IEC TS 63081. If echo reduction is determined it shall be measured at the **acoustic working frequency** of the **treatment head** under test using tone-burst **ultrasound**, with the acoustic absorber located in the **far field** of the separately driven **ultrasonic transducer**. The pressure amplitude of the reflection from the front surface of the acoustic absorber, p_{absorber} is compared to that from a perfect planar reflector, $p_{\text{reflector}}$. The acoustic absorber and the reference reflector shall be aligned near normal to the **beam alignment axis** but angled so that the reflected signal can be intercepted by the **hydrophone**. Given that the amplitude reflection coefficient of a reference reflector $R_{p,\text{reflector}}$ such as a stainless-steel reflector ($R_{p,\text{reflector}} = 0,938\ 9$) is slightly less than that of a perfect reflector ($R_{p,\text{reflector}} = 1$), the measured reflection pressure amplitude p_{absorber} can be adjusted to account for the imperfect reflection in accordance with

$$\hat{p}_{\text{absorber}}(f) = p_{\text{absorber}}(f) \cdot R_{p,\text{reflector}} \quad (6)$$

The echo reduction ERD in decibels (dB) is then calculated using

$$ERD = -20 \log_{10} \left[\frac{\hat{p}_{\text{absorber}}}{p_{\text{reflector}}} \right] \text{dB} \quad (7)$$

When a reference reflector is used, its thickness shall be sufficient that reflections from its rear surface do not introduce unwanted measurement artefacts.

Compliance of the test vessel to free-field conditions is checked by noting the invariance of the product $p_{\text{rms}_t} \cdot s^2$ (see 7.4.7) after completing the measurements specified in Clause 7.

NOTE For some **treatment heads**, **ultrasound** reflected back to the **treatment head** can affect **output power**, particularly in the case of coherent reflections from absorbers with planar smooth surfaces. In these instances, an improved approximation to free-field conditions can be obtained by using acoustic absorbers with textured surfaces.

6.3 Hydrophone

All pressure measurements shall be made with a **hydrophone**, for example, with either a piezoelectric polymer or ceramic active element. The electrical signal from the **hydrophone** may be amplified for adequate measurement accuracy. The maximum effective radius of the **hydrophone** used for the measurements shall be a_{max} so that:

$$a_{\text{max}} / \lambda \leq 0,4 \quad (8)$$

NOTE 1 For more information on the use of **hydrophones** see IEC 62127-1.

NOTE 2 The influence of effective **hydrophone** radius on measurement is described in Annex H.

NOTE 3 Information on the frequency-dependent effective **hydrophone** radius or size and its derivation from directional response measurements can be found in IEC 62127-3.

6.4 RMS peak signal measurement

The measured end-of-cable voltage $u_L(t)$ at the **hydrophone** shall be related to the **instantaneous acoustic pressure** p applying the **end-of-cable loaded sensitivity** $\underline{M}_L$ of the **hydrophone** in accordance with IEC 62127-1. If distortion caused by nonlinear propagation effects is negligible, the narrow-band approximation can be applied, and the **instantaneous acoustic pressure** can be determined from

$$p(t) = u_L(t) / |\underline{M}_L(f_{\text{awf}})| \quad (9)$$

where $|\underline{M}_L(f_{\text{awf}})|$ is the modulus of the **end-of-cable loaded sensitivity** of the **hydrophone** at the **acoustic-working frequency**. However, in practice, the absolute values of the acoustic pressure are not required as the analysis of measured data throughout this document is based on relative **hydrophone** measurements.

NOTE 1 For more information on criteria for the narrow-band approximation, and alternatives for broadband measurements using the frequency-dependent sensitivity of the **hydrophone**, see IEC 62127-1.

NOTE 2 For more information on the determination of the **hydrophone** sensitivities see IEC 62127-2.

Subsequent reference to acoustic pressure will refer to the **RMS acoustic pressure** for convenience. In fact, if distortion caused by nonlinear propagation effects is negligible, in which case the **temporal-peak acoustic pressure** is proportional to the **RMS acoustic pressure** as the excitation voltage to the **ultrasonic transducer** is increased, **temporal-peak acoustic pressure** may as well be chosen. All measurements need to be based on the same method.

The linearity of the response of the combination of **hydrophone**, **hydrophone/amplifier** and the RMS or peak detection system shall be determined and, if appropriate, corrections shall be made to the measured data.

*Compliance for linearity shall be checked using a well-characterized linear **ultrasonic transducer** and measuring the signal received by the **hydrophone** and measuring system as a function of voltage excitation applied to the **ultrasonic transducer**.*

7 Type testing reference procedures and measurements

7.1 General

The procedures specified in 7.2 to 7.4 shall be used for the determination of type testing reference values for the parameters specified in 7.5.

Any **ultrasonic physiotherapy equipment** that includes circuits that control the acoustic output of the **ultrasonic transducer** in response to changes in the acoustic impedance of the propagation medium shall be configured so that the control circuitry is switched off, if possible.

7.2 Rated output power

Output power of the **ultrasonic physiotherapy equipment** shall be determined in accordance with IEC 61161. **Rated output power** shall be determined by setting all controls of the equipment to yield the maximum **output power**. To avoid cavitation, degassed water shall be used between the output face of the **treatment head** and the entrance of the power measurement system. The amount of dissolved oxygen in the degassed water shall be < 4 mg/l during all measurements. Overall uncertainty of measurement expressed at the 95 % confidence level shall be determined (see 9.3) and shall be better than ± 15 %. Measurements shall be traceable to national measurement standards. The **absolute maximum rated output power** shall be determined from the sum of the **rated output power** and the overall uncertainty in the mean value of the measured **rated output power** and the maximum increase in the **rated output power** for a ± 10 % variation in the nominal line voltage. (See Annex F.)

7.3 Hydrophone measurements

The **treatment head** shall be set up in the test vessel in accordance with Clause 6.

All measurements of **effective radiating area** shall be undertaken with the equipment set in **continuous wave** mode at intensities low enough to avoid cavitation. Using degassed water in the measurement system is good practice to ensure that air bubbles are not present on the face of the **treatment head** or on the **hydrophone**.

NOTE 1 Measurements of beam **cross-sectional area** are performed at low powers to protect the needle **hydrophones** used. The validity of extrapolating these values to higher power levels more typical of therapeutic treatment is demonstrated in Annex G.

NOTE 2 **Treatment heads** with $a \leq 10$ mm, when compared with **treatment heads** of larger dimensions operating at similar **equipment** output settings, have been observed to produce higher **temporal-peak acoustic pressure** levels. For **treatment heads** with an **acoustic-working frequency** of 1 MHz or less, this increases the risk of cavitation occurring. The lower limit of $0,2 \text{ W/cm}^2$ for these small **ka treatment heads** minimizes this likelihood.

To reduce the likely effects of acoustic reflections on the received **hydrophone** signal, it is permissible to make **hydrophone** measurements with the **ultrasonic physiotherapy equipment** operating in tone-burst mode producing an **amplitude modulated wave**. If measurements are carried out in this way, it shall be demonstrated that the derivation of the measured parameters from the **amplitude modulated wave** acoustic field are equivalent to those determined in the **continuous wave** case. The effect of making measurements in the **amplitude modulated wave** acoustic field case on the uncertainties in the nominal values of the parameters listed in Clause 5 should also be assessed.

The **beam alignment axis** of the **treatment head** shall be established by **hydrophone** scanning in accordance with IEC 62127-1. The second plane surface (see 3.12) shall initially be chosen as $A_{ERN}/(3\pi\lambda)$. If it is not possible to locate a single peak at or close to this distance, the larger distance of $2A_{ERN}/(\pi\lambda)$ shall be chosen. If this latter distance is too large, locate another measurement plane sufficiently far from the first in order to establish reliably the **beam alignment axis**. Once aligned, an axial plot shall be performed along the **beam alignment axis** and the distance of the **maximum RMS acoustic pressure**, z_p , and the position of the last axial maximum, z_N , shall be determined. It may occur that z_p and z_N are equal.

The step size of the axial plot shall be typically between 0,5 mm and 1,0 mm, and shall not be greater than 2 mm.

The **acoustic-working frequency** shall be determined with the **hydrophone** at a distance z_p from the **treatment head**.

With the **hydrophone** positioned at the same place, the **pulse duration**, **pulse repetition period** and **duty factor** shall be determined, and the **modulation waveform** shall be recorded for the different modulation settings of the **equipment**. The quotient of the **temporal-peak acoustic pressure** to the **RMS acoustic pressure** shall be determined for each modulation setting. The **temporal-maximum output power** shall then be determined using the **output power** determined from 7.2.

7.4 Effective radiating area

7.4.1 Effective radiating area measurements

Effective radiating area, A_{ER} , of the **treatment head** shall be determined by undertaking a raster scan of the acoustic field in a plane perpendicular to the **beam alignment axis** at a distance of 0,3 cm from the output face of the **treatment head**, using a **hydrophone**. From this scan, the **effective radiating area** of the **treatment head** shall be derived from the **beam cross-sectional area**, A_{BCS} . The general requirements for raster scans are given in Clauses B.1 and B.2. The actual procedure for the reference measurements and the analysis of the results are given in 7.4.2 to 7.4.7. Under normal test conditions, the results using the test methods described shall produce an overall uncertainty in the determination of **effective radiating area** (at the 95 % confidence level) of ± 10 %.

For the determination of the **beam non-uniformity ratio**, R_{BN} , under normal test conditions, the test methods shall achieve a measurement uncertainty (at the 95 % confidence level) of less than ± 15 %.

7.4.2 Hydrophone positioning

With the **hydrophone** at distance z_p , the position of the **hydrophone** shall be adjusted in the plane perpendicular to the **beam alignment axis** to determine the **maximum RMS acoustic pressure**, $p_{max,RMS}$, in the field.

This shall be done either by carrying out a raster scan over a limited region of the acoustic field or by manual translation.

7.4.3 Beam cross-sectional area determination

The **beam cross-sectional area** shall be determined at 0,3 cm from the output face of the **treatment head**, and at the position of the last axial maximum, z_N . The analysis of the raster scans shall be carried out in accordance with Clause B.3. The analysis yields the **beam cross-sectional areas**, $A_{BCS}(0,3 \text{ cm})$ and $A_{BCS}(z_N)$ and the **total mean square acoustic pressure**, pms_t , at each measurement plane.

7.4.4 Active area gradient determination

The **active area gradient**, m , and the **active area coefficient**, Q , [$Q = m/A_{BCS}(0,3 \text{ cm})$] shall be determined.

7.4.5 Beam type determination

The **beam type** shall be determined from:

$$\begin{aligned}
 Q &\geq 0,1 \text{ cm}^{-1} && \text{divergent} \\
 -0,05 \text{ cm}^{-1} &\leq Q \leq 0,1 \text{ cm}^{-1} && \text{collimated} \\
 Q &< -0,05 \text{ cm}^{-1} && \text{convergent}
 \end{aligned} \tag{10}$$

7.4.6 Effective radiating area calculation

The **effective radiating area**, A_{ER} , of the **treatment head** shall be determined as follows:

$$A_{\text{ER}} = F_{\text{ac}} A_{\text{BCS}}(0,3 \text{ cm}) = 1,333 A_{\text{BCS}}(0,3 \text{ cm}) \tag{11}$$

NOTE Studies have shown that physically unrealistic values for **treatment head effective radiating area** can occur when applying linear extrapolation procedures to scans carried out in four planes on small *ka* **treatment heads**. The analysis described above, in which the **effective radiating area** is determined from measurements made in a plane at a distance of 0,3 cm from the output face of the **treatment head**, produces physically realistic data.

7.4.7 Beam non-uniformity ratio calculation

The **beam non-uniformity ratio**, R_{BN} , shall be calculated from:

$$R_{\text{BN}} = \frac{p_{\text{max}}^2 \cdot A_{\text{ER}}}{pms_t \cdot s^2} \tag{12}$$

where

$$\overline{pms_t \cdot s^2} = \frac{1}{2} \left\{ \left[pms_t(0,3) \cdot s^2(0,3) \right] + \left[pms_t(z_N) \cdot s^2(z_N) \right] \right\} \tag{13}$$

NOTE 1 Although $p_{\text{max,RMS}}$ and pms_t are referred to as acoustic pressure or pressure-squared parameters, only their ratio is used for the determination of R_{BN} , hence the **end-of-cable loaded sensitivity** of the **hydrophone** is not needed.

NOTE 2 The product $pms_t \cdot s^2$ is related to the acoustic power and is calculated by summation of the pressure-squared values over the area of the raster scans in the plane at 0,3 cm from the **treatment head**, and also the plane at z_N . In ideal cases, it is invariant with distance from the **treatment head**.

7.4.8 Testing requirements

The procedures given in 7.4.1 to 7.4.7 refer to measurements made on one **treatment head**. After measurements have been completed on the group of **treatment heads** in accordance with the sampling requirements of 9.1, mean values of the various parameters specified in 7.5 shall be determined.

7.5 Reference type testing parameters

For the purposes of reference type testing, values for the following parameters shall be determined and recorded:

- **rated output power**;
- **effective radiating area** (A_{ER}) of the **treatment head**;
- **effective intensity** (I_e) at the same equipment settings as the **rated output power**;
- **acoustic-working frequency** (f_{awf});
- the distance from the face of the **treatment head** to the **peak RMS acoustic pressure** on the **beam alignment axis** (z_p);
- **beam non-uniformity ratio** (R_{BN});
- **beam type**;
- **pulse duration, pulse repetition period** (prp) and **duty factor** for each modulation setting;
- **modulation waveform** for each modulation setting.

NOTE This set of parameters could be used for the purposes of recording the performance of a single piece of ultrasonic physiotherapy equipment.

The values shall be the mean values based on sampling specified in 9.1. The overall uncertainty at the 95 % confidence level shall also be determined based on the methods specified in Annex J.

In addition, absolute maximum or absolute minimum values for certain parameters shall be determined as follows.

The **absolute minimum effective radiating area** shall be determined by subtracting the 95 % confidence overall uncertainty in the **effective radiating area** from the mean value of the **effective radiating area**.

The **absolute maximum beam non-uniformity ratio** shall be determined by adding the 95 % confidence overall uncertainty in the determination of the **beam non-uniformity ratio** to the mean value of the **beam non-uniformity ratio**.

7.6 Acceptance criteria for reference type testing

For the parameters listed below, the acceptance criteria for each **treatment head** shall be that the measured values plus and minus the 95 % confidence overall uncertainty in the measured values shall be entirely within the range defined by the nominal values and their tolerances specified in Clause 5. The parameters are as follows:

- **rated output power**;
- **effective radiating area** (A_{ER}) of the **treatment head**;
- **acoustic-working frequency** (f_{awf});
- **pulse duration, pulse repetition period** (prp) and **duty factor** for each modulation setting.

For **beam type**, the acceptance criterion shall be that the **beam type** shall be the same as the nominal **beam type** specified in Clause 5.

For **effective intensity** and **beam non-uniformity ratio**, acceptance criteria are specified in IEC 60601-2-5. Guidance on these parameters can be found in Annex A.

Compliance is checked by measurement in accordance with 7.2 to 7.4.

8 Routine measurement procedure

8.1 General

These procedures shall be used as the basis of tests that may be undertaken on a routine basis, possibly for each unit of **ultrasonic physiotherapy equipment**, but more typically for a certain percentage of the production. This could form the basis of good manufacturing practice or quality assurance procedures.

The routine tests specified here involve the determination of the values of certain acoustical parameters, which shall then be compared with the manufacturer's declared values (nominal values) and their tolerances, where appropriate, given in Clause 5.

8.2 Rated output power

The **rated output power** of the **equipment** shall be determined in accordance with 7.2.

NOTE Although not a requirement of this document, ascertaining accuracy of indicated power is an integral part of calibration: see IEC 60601-2-5.

8.3 Effective radiating area

8.3.1 The **treatment head** shall be set up in the test vessel in accordance with Clause 6. However, alignment of the **treatment head** shall be achieved by using a mount designed to hold the **treatment head** under test in an orientation similar to that used for the reference type testing. An appropriate mechanical alignment device may be used that accepts the **treatment head** and always defines the orientation of the front face in relation to the translational axes of the **hydrophone**.

NOTE The aim here is to allow all **treatment heads** to be set up using a jig or alignment method in such a way that the orientation of each **treatment head** is the same as that used for the reference measurements.

8.3.2 A full axial plot of the acoustic pressure distribution shall be completed to locate the positions of z_p and z_N for each **treatment head**, such that $p_{\text{RMS,max}}$ may be determined. It may occur that z_p and z_N are equal.

8.3.3 The **beam cross-sectional area** shall be determined in the plane at a distance of 0,3 cm from the face of the **treatment head** by carrying out a raster scan as described in 7.4. The **beam cross-sectional area** at z_N shall also be determined and may be derived from a raster scan in accordance with the requirements of Annex B, or by using four line or diametrical scans. The measurement and analysis procedures used for determination of **beam cross-sectional area** using diametrical scans shall be in accordance with Annex C.

8.3.4 The **effective radiating area**, A_{ER} , can be estimated on a routine evaluation basis through an alternative experimental method that uses a radiation force balance in conjunction with circular apertures, formed by an **ultrasound** absorbing material with low reflection loss. An example of such an implementation, and a worked example of the calculations required to derive the **effective radiating area** from the measurements made using a range of aperture diameters, is described in detail in Annex I.

NOTE The value derived for the **effective radiating area** using the aperture technique is considered an approximation to the true **effective radiating area** that would be derived when carrying out the procedures described in 7.4.

8.4 Beam non-uniformity ratio

The **beam non-uniformity ratio**, R_{BN} , shall be determined in accordance with 7.4.7.

8.5 Effective intensity

The **effective intensity** shall be determined in accordance with 3.22.

8.6 Acceptance criteria for routine testing

The range of **rated output power**, defined by the measured **rated output power** plus and minus the 95 % confidence overall uncertainty for the routine measurement of **rated output power** (see 9.3), shall be entirely within the range of values defined by the manufacturer's nominal value for the **rated output power** and its tolerances specified in accordance with Clause 5.

Compliance is checked by measurement in accordance with 7.2.

The range of **effective radiating area**, defined by the measured **effective radiating area** plus and minus the 95 % confidence overall uncertainty for the routine measurement of **effective radiating area**, shall be entirely within the range of values defined by the manufacturer's nominal value of the **effective radiating area** and its tolerances specified in accordance with Clause 5.

Compliance is checked by measurement in accordance with 7.4 and 8.3.

The range of **effective intensity**, defined by the measured **effective intensity** plus and minus the 95 % confidence overall uncertainty for the routine measurement of **effective intensity**, shall be entirely within the range of values defined by the manufacturer's nominal value of the **effective intensity** and its tolerances specified in accordance with Clause 5.

Compliance is checked by measurement in accordance with 7.2 and 8.3.

The value of the **beam non-uniformity ratio** plus the 95 % confidence overall uncertainty in the routine measurement of **beam non-uniformity ratio** shall be less than or equal to the nominal value of the **beam non-uniformity ratio** specified in accordance with Clause 5.

Compliance is checked by measurement in accordance with 7.4.7.

9 Sampling and uncertainty determination

9.1 Reference type testing measurements

The mean values for reference type testing specified in 7.5 shall be based on a sample batch of nominally identical units of the **ultrasonic physiotherapy equipment**.

9.2 Routine measurements

The routine measurements shall be undertaken as the basis of good manufacturing practice. Normally, they shall be undertaken as the basis for testing batch production or at any time when there may be reason to suspect changes may have occurred. Typically, they shall be undertaken on a certain percentage of production but, exceptionally, could be undertaken on each manufactured unit of **ultrasonic physiotherapy equipment**.

For the purpose of carrying out the Type A uncertainty evaluation (see Annex J) for routine measurements when full repeat measurements are impractical, partial repeat measurements may be carried out (by repeating those aspects of the measurement process which can be undertaken simply and quickly) and a prior knowledge for the type of measurement being undertaken then used to carry out an estimated Type A uncertainty evaluation.

NOTE An example of this would be to carry out two line scan measurements on a type of **treatment head**, and to use the outcome from a Type A uncertainty evaluation carried out previously on a raster scan on a **treatment head** of the same type to produce an overall uncertainty in **effective radiating area**.

9.3 Uncertainty determination

Where it is necessary to determine the 95 % confidence overall uncertainty of the measurement, or any parameter, for the purposes of this document, normal uncertainty analysis and estimation methods shall be used (see Annex J for guidance).

Annex A (normative)

Guidance for performance and safety

A.1 General

Clauses A.2 to A.4 reflect the established approach on acceptable values of a few safety related parameters.

A.2 Rated output power

According to IEC 60601-2-5, the **rated output power** shall not vary by more than $\pm 20\%$ for variations of the mains voltage of $\pm 10\%$. Manual readjustment of the equipment for compliance with this requirement is not permitted.

*Compliance is checked by measurement of the **rated output power** in accordance with 7.2 at 90 %, 100 % and 110 % of the rated value of the mains voltage. For example, if the physiotherapy unit has a rated mains voltage of 230 V, the **rated output power** shall be checked at mains voltages of 230 ($\pm 10\%$) V.*

The term "rated" is defined in IEC 60601-1 as the "value assigned by the manufacturer to a quantity characteristic of the equipment". This means that when a manufacturer specifies a useable voltage on the back of a therapy unit, this is a "rated" value; so, from IEC 60601-2-5, the power output needs to be checked for variation at 90 %, 100 % and 110 % of the declared value even when there is a range.

A.3 Effective intensity

According to IEC 60601-2-5, the **absolute maximum effective intensity** shall be less than or equal to $3,0 \text{ W/cm}^2$.

*Compliance is checked by determination of the **absolute maximum rated output power** in accordance with 7.2 and **absolute minimum effective radiating area** in accordance with 7.4.*

A.4 Beam non-uniformity ratio

A.4.1 General

According to IEC 60601-2-5, the **absolute maximum beam non-uniformity ratio** shall be less than or equal to 8,0.

Compliance is checked by measurement in accordance with 7.4.

A.4.2 Rationale behind using a limiting value for the beam non-uniformity ratio (R_{BN})

The ultrasonic beam distribution produced by a therapeutic **treatment head** is non-uniform by nature. Besides this natural character, details of the construction and operation of the **treatment head** can produce regions of very high local pressure, also referred to as "hot spots". These can result in excessive heating in small regions of the tissue being treated, resulting in potential harmful effects to the patient.

Transducers of **ultrasonic physiotherapy equipment** are not designed to provide highly localized tissue treatment. Consequently, the transducers addressed in this document are planar. The characterization of focusing transducers capable of generating high intensity beams which are being used in therapeutic applications is the subject of other documents (see IEC 62555 and IEC TS 62556).

Alongside the safety aspects and the increased possibility of thermal injury, localized peaking of the pressure distribution resulting in a "hot spot" may also be considered as an adverse indicator of **transducer** quality. For these reasons, the therapist should have knowledge of the sound field distribution in order to apply therapeutic **ultrasound** judiciously. A measure of this non-uniformity is provided by the **beam non-uniformity ratio** (R_{BN}). The R_{BN} parameter represents the ratio of the highest intensity in the field to the average intensity, as indicated on the physiotherapy device.

If, as in a plane wave, the intensity is derived from the acoustic pressure alone, the ratio between the time-average intensity distribution (I_p) in a field and average intensity of the piston source (I_0) is given in Figure A.1 [2]. Following on from the previous discussion, this relation also represents the R_{BN} , and it follows that, on theoretical grounds, the maximum value will be four. Even in the correct treatment where the true intensity (I) is given by the product of acoustic pressure and particle velocity, the maximum is four and will be found at one near-field length ($s_n = 1$ in Figure A.1). From the distance of about one transducer element radius, ($z/a = 1$), back to the element itself, the maximum ratio will decrease typically to a value of the order of two.

The actual determination of the R_{BN} may be performed using a **hydrophone**. In the following it will be shown that a calibrated **hydrophone** is not needed, which will simplify the method of determination.

In a plane wave approximation, the relation between intensity and pressure p is given by $I = p^2/\rho c$, where ρc is the characteristic acoustic impedance. This formula cannot strictly be used at distances closer than one transducer element radius of the **treatment head**. In most cases, the maximum pressure is found at greater distances than the **treatment head** radius and the error in using the expression $I = p^2/\rho c$ results in relatively small inaccuracies as illustrated in Figure A.1.

As it may be assumed that the **hydrophone** output voltage is linearly related to the received acoustic pressure, the formula of the R_{BN} can be simplified as stated in this document as follows.

The highest intensity in the beam, **spatial-peak temporal-average**, I_{spta} , is given by:

$$I_{spta} = \frac{u_p^2}{|\underline{M}_L|^2 \rho c} \quad (\text{A.1})$$

The quantity pms_t , used in the main body of this document, is given by:

$$pms_t = \sum_{i=1}^N \frac{u_i^2}{|\underline{M}_L|^2} \quad (\text{A.2})$$

and is known as the **total mean square acoustic pressure**. It represents a summation of the acquired voltages squared during the raster scan. Using pms_t , the **spatial-average temporal-average intensity** is given by:

$$I_{sata} = \frac{P}{A_{ER}} = \frac{A_0 \cdot pms_t}{\rho \cdot c \cdot A_{ER}} \quad (A.3)$$

The expression for the R_{BN} , given as the ratio I_{spta}/I_{sata} , may then be derived as:

$$R_{BN} = \frac{u_p^2 A_{ER}}{A_0(z_j) \sum_{i=1}^N u_i^2(z_j)} \quad (A.4)$$

The denominator is related to an approximation of the total **output power**, derived by a summation of the intensities over the acoustic beam.

In the above formulae, the parameters are as follows:

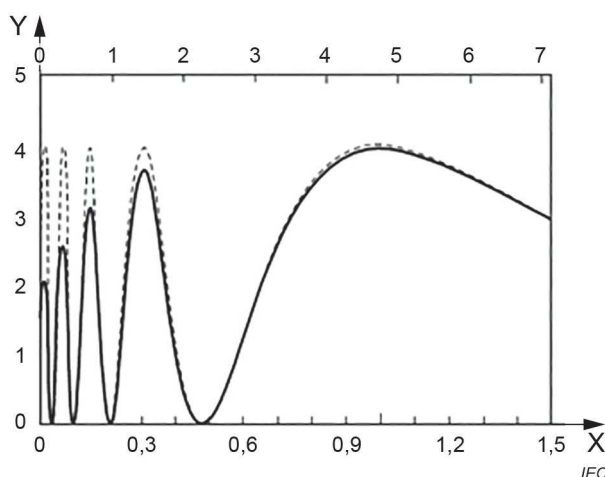
- u_p is the maximum value of u_i ;
- u_i is the RMS **hydrophone** voltage at the i -th point of measurement;
- M_L is the **end-of-cable loaded sensitivity** of the **hydrophone**;
- P is the acoustic power;
- pms_t is the **total mean square acoustic pressure**;
- ρ is the density of water;
- c is the speed of sound in water;
- A_0 is the unit area of the scan ($A_0 = s^2$ for a raster scan where s is the step size);
- N is the total number of measurement points in the scan;
- A_{ER} is the **effective radiating area**;
- z_j is the distance from the **treatment head** to the measurement plane of interest.

Figure A.2 illustrates a histogram in which the R_{BN} values calculated using Formula (A.4) are presented for 37 different **treatment heads**, along with the frequency with which these values occurred when the values of R_{BN} are separated into bands of 0,5. Normally, the R_{BN} appears to be in the range three to seven, but some transducers having a R_{BN} greater than eight are shown and these may be considered to have a high R_{BN} .

The limiting value of eight has been identified in this document for the following reasons.

- In **ultrasound** physiotherapy the treatment protocol (output, duration and frequency) used is based on an ultrasonic beam behaving normally, following theoretical expectations. Evaluating the dose for a treatment is currently difficult to define. Accordingly, a relaxation of the ideal R_{BN} value of four is appropriate. Relaxing the theoretical value of R_{BN} by a factor of two seems to be quite reasonable. As can be seen in Figure A.2, for normal behaving practical transducers, R_{BN} values less than eight can readily be attained.

- Physiotherapists have no current requirement for a focusing transducer. If a transducer is focusing, the R_{BN} will easily exceed the value eight.
- From a quality point of view, taking the theory into account, there is no justification at all in having a R_{BN} greater than eight.
- It can be calculated that a R_{BN} value of 8,0 (limiting value) results in a maximum pressure at the maximum allowed output setting (3 W/cm^2) in the range of 1 MPa, a **spatial-peak temporal-peak intensity** (I_{sptp}) of 48 W/cm^2 and a **spatial-peak temporal-average intensity** (I_{spta}) of 24 W/cm^2 . It can be expected that higher values cause unwanted biological effects.



Key

X bottom axis: s_n

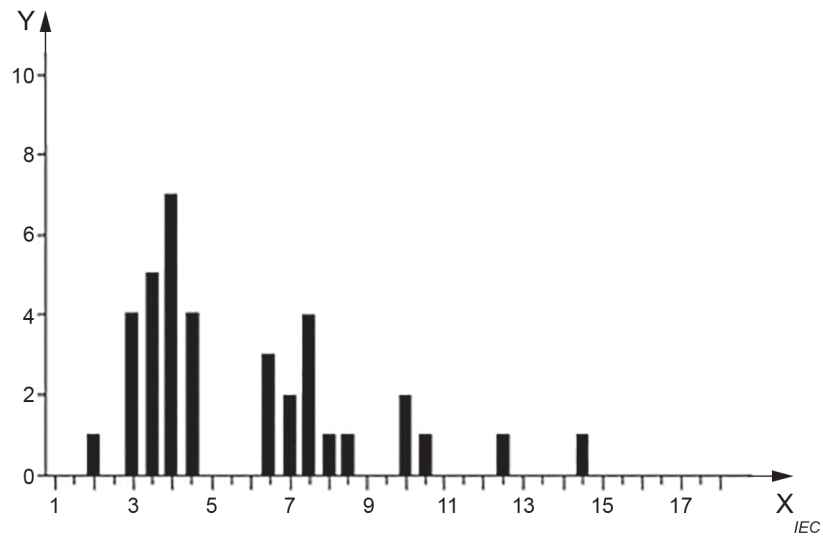
X top axis: z/a

Y solid line: I/I

Y broken line: I_p/I_p

NOTE In [2], the symbol "s" is used to describe the normalized distance. To avoid confusion with the raster scan step size definition used in this document, the normalized distance symbol here has been changed to s_n .

Figure A.1 – Normalized, time-averaged values of acoustic intensity (solid line) and of one of its plane-wave approximations (broken line), existing on the axis of a circular piston source of $ka = 30$, plotted against the normalized distance s_n , where $s_n = \lambda z/a^2$



Key

X R_{BN}

Y Number of transducers

NOTE The R_{BN} value (in bands of 0,5) has been displayed against its frequency of occurrence.

Figure A.2 – Histogram of R_{BN} values for 37 treatment heads of various diameters and frequencies

Annex B (normative)

Raster scan measurement and analysis procedures

B.1 General

The determination of the **effective radiating area** of the **treatment head** for the purposes of reference measurements shall be performed using raster scans at 0,3 cm from the face of the **treatment head**. These procedures may also be used for routine measurements in accordance with Clause 8.

B.2 Requirements for raster scans

B.2.1 All raster scans shall be square grids with the central point on the **beam alignment axis** and in a plane perpendicular to the **beam alignment axis**. The scan shall not be a continuous motion but shall be performed in discrete steps with the values of RMS or peak voltage measured at each point.

NOTE With the central point being on the **beam alignment axis**, there are necessarily an odd number of measured points on each line.

B.2.2 The boundaries of the raster scan shall be large enough to ensure that the signal level at any part outside the scanned boundary is at least 26 dB below the peak signal. However, for **treatment heads** having $z_N \leq 13$ cm, the level beyond the limits of the raster scan should be at least 32 dB below the peak signal.

NOTE Initial measurements are usually necessary to identify the size of the raster scan, and care needs to be taken to ensure that local diffraction minima do not lead to spuriously small scan areas.

B.2.3 The spacing between measurement points (step size) should be small enough such that there are at least 31 measurements across the full width of the raster scan (the raster scan will therefore constitute a square grid of at least 31×31 points). See also B.3.2.

B.2.4 During the raster scan, the **hydrophone** may be scanned to a distance from the centre of the ultrasonic beam where no signal is obtained above the noise. To apply a correction to the integral of the square of the **hydrophone** signal to account for the contribution from the noise, the RMS noise voltage u_n shall be subtracted from the measured signals in the following manner. If the **hydrophone** signal at each measurement point is u_i , then the **hydrophone** signal after correcting for the contribution from noise, u_i' is:

$$u_i' = (u_i^2 - u_n^2)^{1/2} \quad (\text{B.1})$$

The noise level shall be determined, as in IEC 62127-1, by moving the **hydrophone** to a position sufficiently far from the ultrasonic field that no direct acoustic signal is detected. In general, this shall be at a distance in the direction perpendicular to the **beam alignment axis** equal to at least twice the distance from the beam centre to the limit used for the raster scanning process.

B.3 Requirements for analysis of raster scan data

B.3.1 General

The two-dimensional array of data values obtained from the raster scan shall be analysed in the following way.

B.3.2 Total mean square acoustic pressure

The summation of the squares of the voltages obtained over the raster scan is related to the **total mean square acoustic pressure**, pms_t , given by:

$$pms_t = \sum_{i=1}^N u_i'^2 / |\underline{M}_L|^2 \quad (B.2)$$

where

N is the total number of points in the scan;

u_i' is the noise-corrected voltage (either peak or RMS) of the i -th point in the scan;

$\underline{M}_L$ is the **end-of-cable loaded sensitivity** of the **hydrophone**.

NOTE The **end-of-cable loaded sensitivity** of the **hydrophone** has been introduced for convenience in Equation (B.2) to convert the measured voltage to acoustic pressure. However, due to cancellation, when pms_t is introduced into Equation (B.3), its absolute value is not needed.

B.3.3 Calculation of the beam cross-sectional area, A_{BCS}

The values u_i' are sorted into a set in descending order (either RMS or temporal peak) in the scan. A second summation shall be performed to find the value of n that satisfies the following two relationships:

$$\frac{1}{|\underline{M}_L|^2} \sum_{i=1}^n u_i'^2 \leq 0,75 pms_t \quad (B.3)$$

$$\frac{1}{|\underline{M}_L|^2} \sum_{i=1}^{n+1} u_i'^2 > 0,75 pms_t$$

The value of A_{BCS} is then given by $A_0 \cdot n$, where A_0 is the unit area of the raster scan ($A_0 = s^2$ where s is the distance between successive points in the scan, i.e. the step size). This procedure provides a value for the **beam cross-sectional area** in the measurement plane of interest.

For reliable determination of A_{BCS} , the number of points, n , included in the determination of A_{BCS} , should be at least 100.

Annex C (normative)

Diametrical or line scan measurement and analysis procedures

C.1 General

The determination of the **beam cross-sectional area** at a specified distance from the **treatment head** for the purposes of routine measurements in accordance with Clause 8 may be performed using diametrical or line scans. The term line scan is used within Annex C. If line scans are used, then the procedures and analysis methods specified in Clauses C.2 and C.3 shall be used.

C.2 Requirements for line scans

C.2.1 The central or common point of the four line scans shall lie on the **beam alignment axis**. The relative angle of the scans shall be 45° and the four line scans shall divide the plane perpendicular to the **beam alignment axis** into eight equal areas.

C.2.2 The scan shall not be a continuous motion but shall consist of a series of discrete steps perpendicular to the **beam alignment axis** with the RMS or peak voltage generated by the **hydrophone** being measured at each position.

C.2.3 The boundaries of each full-line scan shall be sufficiently large such that the **hydrophone** signal level at the edge of the line scan, relative to the peak level obtained, shall be at least 32 dB below the peak level.

C.2.4 The step size used during the line scan shall be sufficiently small such that the line scan consists of at least 50 points.

NOTE Each of the four line scans can be of different step size. Here, for ease of analysis, they are assumed to be identical.

C.2.5 The noise level shall be determined, and measurements corrected for the influence of noise in accordance with B.2.4.

C.2.6 For simplicity, it is assumed that the four line scans are of identical size, each containing N_1 measurements. This will be true for analysis of raster scan data but not generally true for line scan measurements.

C.3 Analysis of scans

C.3.1 The individual line scans will be analysed in the following way.

NOTE In the steps described in Clause C.3, the symbols [A] and [B] refer to data arrays and are not references to publications in the bibliography.

C.3.2 The four line scans shall be further sub-divided into a pair of radial scans (half-line scans). Each of these half-line scans consists of one-dimensional arrays, [A], of data points sharing a common point on the **beam alignment axis** and having $(N_1 - 1)/2$ other points.

C.3.3 To calculate the **beam cross-sectional area** for each of the half-line scans, the one-dimensional sampling of the acoustic beam profile is transformed into a two-dimensional description of the beam assuming cylindrical symmetry.

C.3.4 For the measurement point which lies on the **beam alignment axis** (designated the $j = 0$ point) the contribution to such an area will be A_0 , given in centimetres squared, by:

$$A_0 = \frac{\pi \cdot s^2}{4} \quad (\text{C.1})$$

where s is the step size (for diagonal radial scans derived from raster scan measurements the step size will be $s\sqrt{2}$).

C.3.5 For all of the other elements of the half-line scan, from $j = 1$ to $(N_1 - 1)/2$, the contribution to the scan area will be annuli of thickness s . For the j -th measurement the corresponding annulus area, A_j , will be given by the expression:

$$A_j = \pi \cdot s^2 \left[\left(j + \frac{1}{2} \right)^2 - \left(j - \frac{1}{2} \right)^2 \right]$$

$$A_j = 2\pi \cdot j \cdot s^2 \quad (\text{C.2})$$

C.3.6 To calculate the **beam cross-sectional area**, the area of each of the annuli from $j = 1$ to $(N_1 - 1)/2$ shall be broken down into multiples of the smallest unit area A_0 . By dividing A_j given in Equation (C.2) by A_0 given in Equation (C.1), it may be seen that the j -th annulus is comprised of n_j units of the smaller area, such that:

$$n_j = 8j \quad (\text{C.3})$$

C.3.7 Using this expression, the original one-dimensional array representing the line scan shall be transformed into a new one-dimensional array [B], the elements of which are shown in Table C.1.

Table C.1 – Constitution of the transformed array [B] used for the analysis of half-line scans

Measurement point	Voltage squared u_j^2	Number of elements in array [B] of value u_j^2
$j = 0$ (point on beam alignment axis)	u_0^2	1
$j = 1$ (first point off-axis)	u_1^2	8
$j = 2$ (second point off-axis)	u_2^2	16
•	•	•
•	•	•
•	•	•
$j = (N_1 - 1)/2$ (last point in scan)	$u_{(N_1-1)/2}^2$	$4(N_1 - 1)$
NOTE The j -th ($j > 0$) point in the half-line scan array [A] is represented in the new array by $8j$ elements of the original voltage-squared values. The new array will contain N_1^2 elements.		

C.3.8 In a similar manner to the analysis undertaken using the raster scan data in B.2.4, the RMS noise level u_n shall be subtracted from each line-scan data point, to account for the contribution of noise. If the **hydrophone** signal at each point in the line scan is u_j , then the **hydrophone** signal after correcting for the contribution from noise, u_j' is:

$$u_j' = (u_j^2 - u_n^2)^{1/2} \quad (\text{C.4})$$

C.3.9 To evaluate the **beam cross-sectional area** the **total mean square acoustic pressure**, pms_t , of the half-line scan is required. This is given by:

$$pms_t = \frac{1}{|\underline{M}_L|^2} u_0'^2 + \frac{1}{|\underline{M}_L|^2} \sum_{j=1}^{(N_1-1)/2} 8j u_j'^2 \quad (\text{C.5})$$

C.3.10 The new array [B] is sorted into descending order and a second summation performed as described in Equations (B.3), leading to the determination of the value of n .

NOTE Performing the sorting process on the original n values will lead to the same result if the correct weighting is applied during the summation process.

C.3.11 The **beam cross-sectional area**, A_{BCS} , of the half-line scan is given by $A_{BCS} = \frac{n \cdot \pi \cdot s^2}{4}$, where s is the step size.

C.3.12 The analysis shall be completed for all eight half-line scans and the results averaged to determine the mean value along with the standard deviation.