

INTERNATIONAL STANDARD

NORME INTERNATIONALE



Medical electrical equipment –
Part 2-62: Particular requirements for the basic safety and essential performance
of high intensity therapeutic ultrasound (HITU) equipment

Appareils électromédicaux –
Partie 2-62: Exigences particulières pour la sécurité de base et les performances
essentiels des appareils ultrasonores thérapeutiques de haute intensité (HITU)



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Medical electrical equipment –

Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment

IEC 60601-2-62:2013

Appareils électromédicaux –

Partie 2-62: Exigences particulières pour la sécurité de base et les performances essentielles des appareils ultrasonores thérapeutiques de haute intensité (HITU)

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International standard IEC 60601-2-62 has been prepared by IEC subcommittee 62D: [Therapy equipment] Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice. It has been prepared in close co-operation with TC 87 (Ultrasonics).

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/1069/FDIS	62D/1076/RVD

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

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

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

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

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

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INTRODUCTION

In this particular standard, safety requirements additional to those in the general standard are specified for HIGH INTENSITY THERAPEUTIC ULTRASOUND (HITU) EQUIPMENT.

This particular standard takes into account IEC 62555 and IEC/TS 62556.

The requirements are followed by specifications for the relevant tests.

A rationale for the more important requirements, where appropriate, is given in Annex AA. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of the particular standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However this annex does not form part of the requirements of this standard.

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment

201.1 Scope, object and related standards

Clause 1 of the general standard¹⁾ applies, except as follows:

201.1.1 Scope

Addition:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of HIGH INTENSITY THERAPEUTIC ULTRASOUND EQUIPMENT as defined in 201.3.218, hereafter referred to as ME EQUIPMENT.

This International Standard adds or replaces clauses listed in the IEC 60601-1 that are specific for HIGH INTENSITY THERAPEUTIC ULTRASOUND EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE 1 See also 4.2 of the general standard.

NOTE 2 As, in HITU fields, the acoustic waveform is expected to be extremely distorted due to non-linear propagation effects, the ultrasonic measurements are to be made under quasi linear conditions and then extrapolated following procedures given in IEC/TS 62556. See also IEC/TS 61949

This standard can also be applied to:

- therapeutic equipment for thrombolysis through exposure to high-intensity therapeutic ultrasound;
- therapeutic equipment for the treatment of occluding feeding vessels through exposure to high-intensity focused ultrasound;
- equipment intended to be used for relieving cancer pain due to bone metastases.

This particular standard does not apply to:

- ULTRASOUND EQUIPMENT intended to be used for physiotherapy (use: IEC 60601-2-5 [1]²⁾ and IEC 61689);
- ULTRASOUND EQUIPMENT intended to be used for lithotripsy (use: IEC 60601-2-36 [2]);
- ULTRASOUND EQUIPMENT intended to be used for dedicated hyperthermia devices;
- ULTRASOUND EQUIPMENT intended to be used for phacoemulsification.

¹⁾ The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

²⁾ Numbers in square brackets refer to the Bibliography.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for HIGH INTENSITY THERAPEUTIC ULTRASOUND (HITU) EQUIPMENT [as defined in 201.3.218.]

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2:2007 applies as modified in Clause 202. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this particular standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

Clause 2 of the general standard applies, except as follows:

NOTE Informative references [3,4,5,6,7,8,9,10] are listed in the bibliography beginning on page 61.

Replacement:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

Addition:

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IEC 61689:2013, *Ultrasonics – Physiotherapy systems – Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz*

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IEC/TS 61949, *Ultrasonics – Field characterization – In-situ exposure estimation in finite amplitude ultrasonic beams*

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

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

IEC 62359, *Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields*

IEC 62555³⁾, *Ultrasonics – Power measurement – High intensity therapeutic ultrasound (HITU) transducers and systems*

IEC/TS 62556⁴⁾, *Ultrasonics – Field characterization – Specification and measurement of field parameters for high intensity therapeutic ultrasound (HITU) transducers and systems*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1, IEC 62359, IEC 62127-1 and IEC 61689, as well as the following additional terms and definitions apply:

³⁾ To be published.

⁴⁾ To be published.

NOTE 1 An index of defined terms is found after the Bibliography.

NOTE 2 A list of symbols used in this particular standard is found in Table 201.101

201.3.201

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 is intended for pulse-wave equipment only.

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 3dB below the peak magnitude.

Note 4 to entry: See IEC 62127-1 for methods of determining the ARITHMETIC-MEAN ACOUSTIC-WORKING FREQUENCY.

[SOURCE: IEC 62127-1:2007 + Am1:2013, 3.3.2, modified – a note to entry has been added.]

201.3.202

BEAM AREA

A_{b6}, A_{b20}

area in a specified plane perpendicular to the BEAM AXIS consisting of all points at which the PULSE-PRESSURE-SQUARED INTEGRAL is greater than a specified fraction of the maximum value of the PULSE-PRESSURE-SQUARED INTEGRAL in that plane

Note 1 to entry: If the position of the plane is not specified, it is the plane passing through the point corresponding to the maximum value of the PULSE-PRESSURE-SQUARED INTEGRAL in the whole acoustic field.

Note 2 to entry: In a number of cases, the term PULSE-PRESSURE-SQUARED INTEGRAL is replaced everywhere in the above definition by any linearly related quantity, e.g.:

- in the case of a continuous wave signal the term PULSE-PRESSURE-SQUARED INTEGRAL is replaced by mean square acoustic pressure as defined in IEC 61689,
- in cases where signal synchronisation with the scanframe is not available, the term PULSE-PRESSURE-SQUARED INTEGRAL may be replaced by TEMPORAL AVERAGE INTENSITY.

Note 3 to entry: Some specified fractions are 0,25 and 0,01 for the -6 dB and -20 dB beam areas, respectively.

Note 4 to entry: Beam area is expressed in square metres (m²).

[SOURCE: IEC 62127-1:2007 + Am1:2013, 3.7, modified – the symbol has been changed]

201.3.203

BEAM AXIS

straight line that passes through the BEAM CENTREPOINTS of two planes perpendicular to the line which connects the point of maximal PULSE-PRESSURE-SQUARED INTEGRAL with the centre of the TRANSDUCER OUTPUT FACE

Note 1 to entry: The location of the first plane is the location of the plane containing the maximum PULSE-PRESSURE-SQUARED INTEGRAL or, alternatively, is one containing a single main lobe which is in the focal Fraunhofer zone. The location of the second plane is as far as is practicable from the first plane and parallel to the first with the same two orthogonal scan lines (x and y axes) used for the first plane.

Note 2 to entry: In a number of cases, the term PULSE-PRESSURE-SQUARED INTEGRAL is replaced in the above definition by any linearly related quantity, e.g.:

- in the case of a continuous wave signal the term PULSE-PRESSURE-SQUARED INTEGRAL is replaced by mean square acoustic pressure as defined in IEC 61689,
- in cases where signal synchronisation with the scanframe is not available the term PULSE-PRESSURE-SQUARED INTEGRAL may be replaced by TEMPORAL AVERAGE INTENSITY.

[SOURCE: IEC 62127-1: 2007, 3.8, modified – EXTERNAL TRANSDUCER APERTURE replaced by TRANSDUCER OUTPUT FACE in the definition].

201.3.204

BEAM CENTREPOINT

position determined by the intersection of two lines passing through the BEAM WIDTH MIDPOINTS of two orthogonal planes, xz and yz

[SOURCE: IEC 61828:2001, 4.2.13]

201.3.205

*BEAM WIDTH AT FOCUS

BEAM WIDTH AT BEAM MAXIMUM

w_{6m}

greatest distance between two points on a specified axis, perpendicular to the BEAM AXIS and at z_{spta} where the PULSE-PRESSURE-SQUARED INTEGRAL falls below its maximum on the specified axis by 6 dB

Note 1 to entry: In a number of cases, the term PULSE-PRESSURE-SQUARED INTEGRAL is replaced in the above definition by any linearly related quantity, e.g.: in the case of a continuous wave signal the term PULSE-PRESSURE-SQUARED INTEGRAL is replaced by mean square acoustic pressure as defined in IEC 61689,

Note 2 to entry: BEAM WIDTH AT FOCUS or BEAM WIDTH AT BEAM MAXIMUM is expressed in metres (m).

[SOURCE: IEC 62127-1: 2007, 3.11, modified – here it concerns the -6dB beamwidth as defined in IEC62127-1]

201.3.206

BEAMWIDTH MIDPOINT

linear average of the location of the centres of BEAMWIDTHS in a plane

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Note 1 to entry: The average is taken over as many BEAMWIDTH levels given in Table B.2 in IEC 61828 as signal level permits.

[SOURCE: IEC 61828:2001, 4.2.17, modified – the second sentence of the definition has been transformed into a note to entry.].

201.3.207

DISTANCE z_{spta}

z_{spta}

distance along the BEAM AXIS between the plane containing the SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY and the TRANSDUCER OUTPUT FACE

Note 1 to entry: In practice DISTANCE z_{spta} is equal to the distance where the maximum PULSE-PRESSURE SQUARED INTEGRAL occurs. In a number of cases, the term PULSE-PRESSURE-SQUARED INTEGRAL is replaced by any linearly related quantity, e.g.: in the case of a continuous wave signal the term PULSE-PRESSURE-SQUARED INTEGRAL is replaced by mean square acoustic pressure as defined in IEC 61689,

Note 2 to entry: The DISTANCE z_{spta} is expressed in metres (m).

[SOURCE: IEC 62127-1: 2007, 3.18, modified – EXTERNAL TRANSDUCER APERTURE has been replaced by TRANSDUCER OUTPUT FACE in the definition and the first note to entry has been expanded.]

201.3.208

DISTANCE z_{slpta}

z_{slpta}

distance along the BEAM AXIS between the plane containing the SIDE-LOBE PEAK TEMPORAL-AVERAGE INTENSITY and the TRANSDUCER OUTPUT FACE

Note 1 to entry: The DISTANCE z_{slpta} is expressed in metres (m).

[SOURCE: IEC/TS 62556:----, 3.19 SOURCE APERTURE PLANE has been replaced by TRANSDUCER OUTPUT FACE]

201.3.209

DISTANCE z_E

z_E

distance along the BEAM AXIS between the PATIENT ENTRY PLANE and the TRANSDUCER OUTPUT FACE

Note 1 to entry: The DISTANCE z_E is expressed in metres (m).

[SOURCE: IEC/TS 62556:----, 3.14, modified – EXTERNAL TRANSDUCER APERTURE PLANE has been replaced by TRANSDUCER OUTPUT FACE.]

201.3.210

DISTANCE z_r

z_r

distance along the BEAM AXIS between the plane containing the PEAK-RAREFACTIONAL ACOUSTIC PRESSURE and the TRANSDUCER OUTPUT FACE

Note 1 to entry: The DISTANCE z_r is expressed in metres (m).

[SOURCE: IEC 62127-1: 2007, 3.15, modified – EXTERNAL TRANSDUCER APERTURE has been replaced by TRANSDUCER OUTPUT FACE]

201.3.211

DISTANCE z_T

TRANSITION DISTANCE

z_T

for a given LONGITUDINAL PLANE, the TRANSITION DISTANCE is defined based on the transducer design (when known) or from measurement:

- from design: the TRANSITION DISTANCE is the equivalent area of the ultrasonic TRANSDUCER APERTURE WIDTH divided by π times the EFFECTIVE WAVELENGTH, λ ;
- for measurements, the TRANSITION DISTANCE is the equivalent area of the TRANSDUCER APERTURE WIDTH divided by π times the EFFECTIVE WAVELENGTH.

Note 1 to entry: Using method a), an unapodized ULTRASONIC TRANSDUCER with circular symmetry about the BEAM AXIS, the equivalent area is πa^2 , where a is the radius. Therefore the TRANSITION DISTANCE is $z_T = a^2/\lambda$. For the first example of a square ULTRASONIC TRANSDUCER, the equivalent area is $(L_{TA})^2$, where L_{TA} is the TRANSDUCER APERTURE WIDTH in the LONGITUDINAL PLANE. Therefore, the TRANSITION DISTANCE for both orthogonal LONGITUDINAL PLANES containing the sides or TRANSDUCER APERTURE WIDTHS, is $z_T = (L_{TA})^2 / (\pi\lambda)$. For the second example, for a rectangular ULTRASONIC TRANSDUCER with TRANSDUCER APERTURE WIDTHS L_{TA1} and L_{TA2} , the equivalent area for the first linear transducer aperture width for the purpose of calculating the TRANSITION DISTANCE for the associated LONGITUDINAL PLANE is $(L_{TA1})^2$, where L_{TA1} is the TRANSDUCER APERTURE WIDTH in this LONGITUDINAL PLANE. Therefore, the TRANSITION DISTANCE for this plane is $z_{T1} = (L_{TA1})^2 / (\pi\lambda)$. For the orthogonal LONGITUDINAL PLANE that contains the other TRANSDUCER APERTURE WIDTH, L_{TA2} , the equivalent area for the other for the purpose of calculating the transition distance for the associated LONGITUDINAL PLANE is $(L_{TA2})^2$, where L_{TA2} is the TRANSDUCER APERTURE WIDTH in this LONGITUDINAL PLANE. Therefore, the TRANSITION DISTANCE for this plane is $z_{T2} = (L_{TA2})^2 / (\pi\lambda)$.

Note 2 to entry: Using method b) for measurements in a longitudinal plane, the TRANSDUCER APERTURE WIDTH, L_{SA} , in the same plane is used in $z_T = (L_{SA})^2 / (\pi\lambda)$.

Note 3 to entry: TRANSITION DISTANCE is expressed in metres (m).

[SOURCE: IEC 62127-1:2007, Am1:2013, 3.88, modified – in Note 2 to entry, SOURCE APERTURE WIDTH has been replaced by TRANSDUCER APERTURE WIDTH.]

201.3.212

ENTRY POWER

$P_E(z_E)$

time-average ultrasonic power measured under approximate free field conditions at the DISTANCE z_E of the PATIENT ENTRY PLANE in a specified medium, preferably in water

Note 1 to entry: For measurement purposes the PATIENT ENTRY PLANE is the position along the BEAM AXIS where ultrasound in normal use enters the PATIENT

Note 2 to entry: ENTRY POWER is expressed in watt (W),

Note 3 to entry: OUTPUT POWER is defined in 201.3.223.

201.3.213

ENTRY EFFECTIVE INTENSITY

I_{Eeff}
intensity given by $I_{\text{Eeff}} = P_{\text{E}}/A_{\text{EB}}$ where P_{E} is the ENTRY POWER and A_{EB} is the ENTRY BEAM AREA

Note 1 to entry: ENTRY EFFECTIVE INTENSITY is expressed in watts per square metre (W/m^2)

201.3.214

ENTRY BEAM AREA

A_{EB}
area of the ultrasonic beam equal to the -12 dB BEAM AREA at the PATIENT ENTRY PLANE

Note 1 to entry: For reasons of measurement accuracy, the -12 dB ENTRY BEAM AREA may be derived from measurements at a distance chosen to be as close as possible to the face of the transducer or PATIENT ENTRY PLANE, if different, and, if possible, no more than 1 mm from the face or PATIENT ENTRY PLANE, if different,

Note 2 to entry: For contact transducers, this area can be taken as the geometrical area of the ULTRASONIC TRANSDUCER or ULTRASONIC TRANSDUCER ELEMENT GROUP,

Note 3 to entry: The ENTRY BEAM AREA is expressed in square metres (m^2).

201.3.215

*FOCAL DEPTH

BEAM MAXIMUM DEPTH

L_6
greatest distance between two points on the BEAM AXIS where the PULSE-PRESSURE-SQUARED INTEGRAL falls below its maximum on the BEAM AXIS by 6 dB

Note 1 to entry: In a number of cases, the term PULSE-PRESSURE-SQUARED INTEGRAL is replaced in the above definition by any linearly related quantity, e.g.: in the case of a continuous wave signal the term PULSE-PRESSURE-SQUARED INTEGRAL is replaced by mean square acoustic pressure as defined in IEC 61689,

Note 2 to entry: FOCAL DEPTH or BEAM MAXIMUM DEPTH is expressed in metres (m).

[SOURCE: IEC/TS 62556:----, 3.15, modified – the term, the definition and the notes to entry have all been modified.]

201.3.216

*FOCAL POINT

BEAM MAXIMUM POINT

position on the BEAM AXIS where the maximum PULSE-PRESSURE-SQUARED INTEGRAL is measured

Note 1 to entry: In a number of cases, the term PULSE-PRESSURE-SQUARED INTEGRAL is replaced in the above definition by any linearly related quantity, e.g.: in the case of a continuous wave signal the term PULSE-PRESSURE-SQUARED INTEGRAL is replaced by mean square acoustic pressure as defined in IEC 61689.

[SOURCE: IEC/TS 62556:----, 3.12]

201.3.217

*FOCAL VOLUME

BEAM MAXIMUM VOLUME

V_{foc}
volume in a specified space consisting of all points at which the PULSE-PRESSURE-SQUARED INTEGRAL is greater than - 6 dB of the PULSE-PRESSURE-SQUARED INTEGRAL value in the FOCAL POINT or BEAM MAXIMUM POINT