



PRE-RELEASE VERSION (FDIS)



Household and similar electrical appliances – Safety – Part 2-115: Particular requirements for skin beauty care appliances

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 13.120; 97.170

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



FINAL DRAFT INTERNATIONAL STANDARD (FDIS)

PROJECT NUMBER: IEC 60335-2-115 ED1	
DATE OF CIRCULATION: 2020-10-23	CLOSING DATE FOR VOTING: 2020-12-04
SUPERSEDES DOCUMENTS: 61/5947/CDV, 61/6010A/RVC	

IEC TC 61 : SAFETY OF HOUSEHOLD AND SIMILAR ELECTRICAL APPLIANCES	
SECRETARIAT: United States of America	SECRETARY: Ms Randi Myers
OF INTEREST TO THE FOLLOWING COMMITTEES: TC 87	HORIZONTAL STANDARD: <input type="checkbox"/>
FUNCTIONS CONCERNED: <input type="checkbox"/> EMC <input type="checkbox"/> ENVIRONMENT <input type="checkbox"/> QUALITY ASSURANCE <input checked="" type="checkbox"/> SAFETY	
<input type="checkbox"/> SUBMITTED FOR CENELEC PARALLEL VOTING	<input checked="" type="checkbox"/> NOT SUBMITTED FOR CENELEC PARALLEL VOTING

This document is a draft distributed for approval. It may not be referred to as an International Standard until published as such.

In addition to their evaluation as being acceptable for industrial, technological, commercial and user purposes, Final Draft International Standards may on occasion have to be considered in the light of their potential to become standards to which reference may be made in national regulations.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:
Household and similar electrical appliances – Safety – Part 2-115: Particular requirements for skin beauty care appliances

PROPOSED STABILITY DATE: 2024

NOTE FROM TC/SC OFFICERS:
This document is circulated according to the decisions taken at the meetings of TC 61 in Vladivostok – 61/5578/RM, Busan – see 61/5737/RM, Bled - see 61/5848/RM, Shanghai – see 61/5948/RM and

CONTENTS

FOREWORD	4
INTRODUCTION	6
1 Scope	7
2 Normative references	8
3 Terms and definitions	9
4 General requirement	10
5 General conditions for the tests	10
6 Classification	10
7 Marking and instructions	11
8 Protection against access to live parts	14
9 Starting of motor-operated appliances	14
10 Power input and current	15
11 Heating	15
12 Void	19
13 Leakage current and electric strength at operating temperature	19
14 Transient overvoltages	19
15 Moisture resistance	19
16 Leakage current and electric strength	19
17 Overload protection of transformers and associated circuits	20
18 Endurance	20
19 Abnormal operation	20
20 Stability and mechanical hazards	20
21 Mechanical strength	21
22 Construction	22
23 Internal wiring	27
24 Components	27
25 Supply connection and external flexible cords	28
26 Terminals for external conductors	28
27 Provision for earthing	29
28 Screws and connections	29
29 Clearances, creepage distances and solid insulation	29
30 Resistance to heat and fire	29
31 Resistance to rusting	29
32 Radiation, toxicity and similar hazards	29
Annexes	34
Annex R (normative) Software evaluation	34
Annex AA (normative) Estimation of the local specific absorption rate (local SAR)	35
Annex BB (informative) Guidance to measure the dimensions of the treatment head of a radio frequency appliance	41
Annex CC (normative) Isolating transformers	44
Bibliography	45

Figure 101 – Probe for measuring surface temperatures	31
Figure 102 – Burn threshold spread when the skin is in contact with a hot smooth surface made of bare (uncoated) metal.....	31
Figure 103 – Burn threshold spread when the skin is in contact with a hot smooth surface made of ceramics, glass and stone materials	32
Figure 104 – Burn threshold spread when the skin is in contact with a hot smooth surface made of plastics	32
Figure 105 – Circuit for testing leakage current from applied parts.....	33
Figure AA.1 – Examples of radio frequency appliance output types.....	40
Figure BB.1 – Use of the smallest distance between electrodes for treatment heads of type 7	43
Table 101 – Maximum temperature rises for specified external accessible surfaces other than the applied parts under normal operating conditions.....	17
Table 102 – Maximum temperature rise of applied parts	18
Table 103 – Logarithmic interpolation equations	18
Table 104 – Output current limits for application below the neck	24
Table 105 – Local SAR limits	25
Table BB.1 – Dimensions and volume calculations for various types of RF treatment heads	41

INTERNATIONAL ELECTROTECHNICAL COMMISSION

HOUSEHOLD AND SIMILAR ELECTRICAL APPLIANCES – SAFETY –

Part 2-115: Particular requirements for skin beauty care appliances

FOREWORD

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

International Standard IEC 60335-2-115 has been prepared by IEC technical committee 61: Safety of household and similar electrical appliances.

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

FDIS	Report on voting
61/XX/FDIS	61/XX/RVD

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

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

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

A list of all parts of the IEC 60335 series, under the general title: *Household and similar electrical appliances – Safety*, can be found on the IEC website.

This part 2 is to be used in conjunction with the fifth edition of IEC 60335-1:2010 and its amendments.

NOTE 1 When “Part 1” is mentioned in this standard, it refers to IEC 60335-1.

This part 2 supplements or modifies the corresponding clauses in IEC 60335-1, so as to convert that publication into the IEC standard: Particular requirements for skin beauty care appliances.

When a particular subclause of Part 1 is not mentioned in this part 2, that subclause applies as far as is reasonable. When this standard states “addition”, “modification” or “replacement”, the relevant text in Part 1 is to be adapted accordingly.

NOTE 2 The following numbering system is used:

- subclauses, tables and figures that are numbered starting from 101 are additional to those in Part 1;
- unless notes are in a new subclause or involve notes in Part 1, they are numbered starting from 101, including those in a replaced clause or subclause;
- additional annexes are lettered AA, BB, etc.

NOTE 3 The following print types are used:

- requirements: in roman type;
- *test specifications: in italic type;*
- notes: in small roman type.

Words in **bold** in the text are defined in Clause 3. When a definition concerns an adjective, the adjective and the associated noun are also in bold.

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

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

NOTE 4 The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests.

It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 12 months or later than 36 months from the date of publication.

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

INTRODUCTION

It has been assumed in the drafting of this International Standard that the execution of its provisions is entrusted to appropriately qualified and experienced persons.

This standard recognizes the internationally accepted level of protection against hazards such as electrical, mechanical, thermal, fire and radiation of appliances when operated as in normal use taking into account the manufacturer's instructions. It also covers abnormal situations that can be expected in practice and takes into account the way in which electromagnetic phenomena can affect the safe operation of appliances.

This standard takes into account the requirements of IEC 60364 as far as possible so that there is compatibility with the wiring rules when the appliance is connected to the supply mains. However, national wiring rules may differ.

If an appliance within the scope of this standard also incorporates functions that are covered by another part 2 of IEC 60335, the relevant part 2 is applied to each function separately, as far as is reasonable. If applicable, the influence of one function on the other is taken into account.

NOTE 1 For example, if appliances within the scope of this part 2 include an ion generator, then IEC 60335-2-65 is applicable as far as is reasonable.

When a part 2 standard does not include additional requirements to cover hazards dealt with in Part 1, Part 1 applies.

NOTE 2 This means that the technical committees responsible for the part 2 standards have determined that it is not necessary to specify particular requirements for the appliance in question over and above the general requirements.

This standard is a product family standard dealing with the safety of appliances and takes precedence over horizontal and generic standards covering the same subject.

NOTE 3 Horizontal and generic standards covering a hazard are not applicable since they have been taken into consideration when developing the general and particular requirements for the IEC 60335 series of standards. For example, in the case of temperature requirements for surfaces on many appliances, generic standards, such as ISO 13732-1 for hot surfaces, are not applicable in addition to Part 1 or part 2 standards.

An appliance that complies with the text of this standard will not necessarily be considered to comply with the safety principles of the standard if, when examined and tested, it is found to have other features that impair the level of safety covered by these requirements.

An appliance employing materials or having forms of construction differing from those detailed in the requirements of this standard may be examined and tested according to the intent of the requirements and, if found to be substantially equivalent, may be considered to comply with the standard.

HOUSEHOLD AND SIMILAR ELECTRICAL APPLIANCES – SAFETY –

Part 2-115: Particular requirements for skin beauty care appliances

1 Scope

This clause of Part 1 is replaced by the following.

This part of IEC 60335 deals with the safety of electric appliances for skin beauty care of persons and intended for household, commercial and similar purposes, their **rated voltage** being not more than 250 V.

NOTE 101 Dual supply appliances, either mains-supplied or battery-operated, are regarded as **battery-operated appliances** when operated in the battery mode.

Examples of appliances that are within the scope of this standard are

- **battery-operated appliances** and other DC supplied appliances for beauty care;
- appliances with high frequency outputs including equipment for heat-producing effects on the skin;
- appliances with medium frequency outputs including interferential outputs, for skin stimulation or muscle stimulation;
- appliances with low frequency outputs (e.g. faradic currents) for application such as skin stimulation or muscle stimulation;
- appliances with extra-low voltage DC outputs (e.g. galvanic currents), such as electro-epilation (hair removal);
- skin beauty care appliances with ultrasonic outputs;
- appliances having vacuum-pressure functions;
- skin beauty care appliances for melting wax;
- appliances intended to produce surface cooling effect on the skin;
- facial cleaning appliances;
- micro-needling appliances;
- plasma pens.

NOTE 102 Appliances covered by this standard can incorporate vapour-producing devices or spray-producing devices.

This standard deals with the common hazards presented by appliances that are encountered by all persons. However, in general, it does not take into account

- persons (including children) whose
 - physical, sensory or mental capabilities; or
 - lack of experience and knowledgeprevents them from using the appliance safely without supervision or instruction;
- children playing with the appliance.

NOTE 103 Attention is drawn to the fact that

- it is recognized that persons having very extensive and complex disabilities can have needs beyond the level addressed in this standard.
- for appliances intended to be used in vehicles or on board ships or aircraft, additional requirements can be necessary;

- in many countries, additional requirements can be specified by the national health authorities, the national authorities responsible for the protection of labour and similar authorities.

This standard does not apply to

- appliances intended exclusively for industrial purposes;
- appliances intended to be used in locations where special conditions prevail, such as the presence of a corrosive or explosive atmosphere (dust, vapour or gas);
- shavers, hair clippers and similar appliances (IEC 60335-2-8);
- blankets, pads, clothing and similar flexible heating appliances (IEC 60335-2-17);
- appliances for skin or hair care such as facial saunas, hand dryers, foot care appliances (IEC 60335-2-23);
- spray tanning appliances;
- appliances for skin exposure to optical radiation (IEC 60335-2-27);
- sauna heating appliances and infrared cabins (IEC 60335-2-53);
- cosmetic and beauty care appliances incorporating lasers and intense light sources (IEC 60335-2-113);
- appliances intended for medical purposes (IEC 60601);
- **radio frequency appliances** without contact to the skin;
- **ultrasound appliances** provided with focusing ultrasound transducers.

2 Normative references

This clause of Part 1 is applicable except as follows:

Addition:

IEC 60584-1, *Thermocouples – Part 1: EMF specifications and tolerances*

IEC 60601-2-5:2009, *Medical electrical equipment – Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment*

IEC 61558-2-4:2009, *Safety of transformers, reactors, power supply units and similar products for supply voltages up to 1 100 V – Part 2-4: Particular requirements and tests for isolating transformers and power supply units incorporating isolating transformers*

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

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

IEC 63009:2019, *Ultrasonics – Physiotherapy systems – Field specifications and methods of measurement in the frequency range 20 kHz to 500 kHz*

ISO 7010, *Graphical symbols – Safety colours and safety signs – Registered safety signs*

ISO 14155, *Clinical investigation of medical devices for human subjects – Good clinical practice*