

INTERNATIONAL STANDARD

NORME INTERNATIONALE



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

Appareils électrodomestiques et analogues – Sécurité –
Partie 2-115: Exigences particulières pour les appareils destinés aux soins
esthétiques de la peau



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

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esthétiques de la peau**

INTERNATIONAL
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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

STANDARD PREVIEW
(standards.iteh.ai)

[IEC 60335-2-115:2021](https://standards.iteh.ai/catalog/standards/sist/8c6ac722-f4fa-4755-bd99-65c7df05d179/iec-60335-2-115-2021)

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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

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(standards.iteh.ai)

[IEC 60335-2-115:2021](https://standards.iteh.ai/catalog/standards/sist/8c6ac722-f4fa-4755-bd99-65c7df05d179/iec-60335-2-115-2021)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

HOUSEHOLD AND SIMILAR ELECTRICAL APPLIANCES – SAFETY –**Part 2-115: Particular requirements for skin beauty care appliances**

FOREWORD

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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
61/6132/FDIS	61/6178/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.

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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 skin 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

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This clause of Part 1 is applicable except as follows:

Addition: <https://standards.iteh.ai/catalog/standards/sist/8c6ac722-f4fa-4755-bd99-65c7df05d179/iec-60335-2-115-2021>
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*

3 Terms and definitions

This clause of Part 1 is applicable except as follows.

3.1 Definitions relating to physical characteristics

3.1.9 Replacement:

normal operation

conditions under which the appliance is operated as in normal use in accordance with the manufacturer's instructions

Note 1 to entry: Appliances also producing vapour are operated in the normal position of use and filled with liquid. Liquid is added, when necessary, to maintain the vapour output

3.1.101

local specific absorption rate

local SAR

amount of radio frequency power absorbed by cubical tissue with a mass of 10 g

Note 1 to entry: Unit: W/kg.

3.2 Definitions relating to means of connection

3.2.101

swivel connection

means for connecting the **supply cord** so that the appliance can be rotated continuously without twisting the cord

3.5 Definitions relating to types of appliances

3.5.101

electrical stimulator

appliance intended to stimulate skin or muscle by using current going through the skin surface

3.5.102

pressurised appliance

appliance in which vapour or liquid is produced at a pressure exceeding 50 kPa and in which the pressure does not drop to atmospheric pressure when the vapour or liquid is not supplied

3.5.103

radio frequency appliance

appliance intended to produce radiofrequency current, an electric field, magnetic field, or electromagnetic field for application to the human body

3.5.104

ultrasound appliance

appliance intended to produce ultrasound for application to the human body

3.5.105

plasma pen

appliance intended to target the upper skin layer tissue by an electrical discharge without skin contact

3.5.106

micro-needling appliance

appliance with an array of needles intended to penetrate the skin in a stamping motion

3.6 Definitions relating to parts of an appliance

3.6.101

applied part

part of an appliance that in normal use necessarily comes into physical contact with the skin to perform its function

3.6.102

biased-off switch

switch that automatically returns to the off position when its actuating member is released

3.6.103

isolating transformer

transformer, the input winding of which is electrically separated from the output winding by an insulation at least equivalent to **double insulation** or **reinforced insulation**, that is intended to supply an appliance or circuit at a voltage greater than **safety extra-low voltage**

4 General requirement

This clause of Part 1 is applicable.

5 General conditions for the tests

This clause of Part 1 is applicable except as follows.

5.2 Addition:

The additional test of 25.14 for **hand-held appliances** is carried out on a separate appliance.

5.10 Addition:

If the appliance cannot operate as intended when applying the load resistance specified for the tests of 10.101 and 10.102, the manufacturer or responsible agent shall provide details of a different method to achieve the required input power or current.

5.101 Unless otherwise specified, skin beauty care appliances are tested as **motor-operated appliances**, except wax-melting appliances and appliances with a liquid heating function.

5.102 For **ultrasound appliances**, the artificial skin used shall be based on Table BB.1 in IEC 60601-2-5: 2009. For other appliances, 10 mm thick solidified agar shall be used for the artificial skin. The agar to be used for the test is prepared by mixing 6 g food grade powdered agar with 100 ml of water.

6 Classification

This clause of Part 1 is applicable except as follows.

6.1 Modification:

Hand-held appliances, appliances incorporating vapour-producing devices or spray-producing devices and appliances that are washable according to the instructions shall be **class II** or **class III**.

Appliances incorporating vapour-producing devices or spray-producing devices may be **class I** if they are for use in beauty parlours and similar premises only.

6.2 Modification:

Appliances that are washable according to the instructions shall be at least IPX7. Parts that are intended to be fixed, **detachable power supply parts** fitted in flexible cords or provided with pins for insertion into socket-outlets shall be at least IPX4.

This classification does not apply to parts of **class III construction**.

6.101 Appliances shall be one of the following types:

- appliances suitable for household use;
- appliances for use in beauty parlours only.

NOTE Appliances for household use can also be used in beauty parlours and similar premises.

Micro-needling appliances shall be appliances for use in beauty parlours and similar premises only.

Compliance is checked by inspection and by the relevant tests.

7 Marking and instructions

This clause of Part 1 is applicable except as follows.

7.1 Addition:

Appliances intended to deliver current to the human body shall be marked with symbol ISO 7000-0790 (2004-01).

Wax-melting appliances that are filled manually shall be marked with the maximum and minimum wax levels.

Appliances, that are not suitable for use in a bath or shower shall be marked with the prohibition sign ISO 7010-P026 (2011-05) or with the substance of the following:

WARNING: Do not use this appliance in a bathtub, shower, or water filled reservoir

Electrical stimulators capable of delivering output values in excess of 10 mA or 10 V shall be marked near the **applied part** connections with symbol ISO 7000-0434A (2004-01).

If **ultrasound appliances** have replaceable ultrasound probes, the beam non-uniformity ratio (BNR) shall be marked on the probe. For **ultrasound appliances** that have non-replaceable ultrasound probes, the BNR shall be marked on the appliance.

If the appliance is intended to be only used in beauty parlours and similar premises, it shall be marked with the prohibition sign “Not for household use” or with the substance of the following:

WARNING: This appliance is not for household use

NOTE For certain types of appliances, there can be national regulations regarding their use by appropriately trained persons.

7.6 Addition:



[prohibition sign (2011-05)]

sign

ISO 7010-P026

Do not use this device in a bathtub, shower, or water-filled reservoir



[prohibition sign]

Not for household use

7.10 Addition:

For appliances delivering current to the human body, timing controls used to regulate the duration of operation shall be clearly and indelibly marked at regular intervals over the complete timing range to indicate time settings. Time settings may also be indicated using digital displays.

For **radio frequency appliances**, controls used to regulate the maximum output power or maximum output energy shall be clearly and indelibly marked at regular intervals over the complete output range to indicate the output settings levels. The output levels shall be in the same units as the maximum values or as a percentage of the maximum values.

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7.12 Addition:

If prohibition sign ISO 7010-P026 (2011-05) is used, its meaning shall be explained using the substance of the following:

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WARNING: Do not use this appliance near bathtubs, showers or water-filled reservoirs

If the prohibition sign “Not for household use” is used, its meaning shall be explained using the substance of the following:

WARNING: This appliance is not for household use

As applicable, the instructions shall state the substance of the following:

- use of this appliance may cause discomfort or adverse effect to, persons suffering from skin disease or inflammation of the skin, persons with sensitive skin and persons having an allergic constitution. Stop using it if any discomfort occurs;
- this appliance is not to be used on the parts where the integrity of the skin is damaged (such as burns, blisters, lesions, incision, wounds, active skin disease or infection);
- this appliance shall not be used by, or on, persons wearing implants not compatible with its use;
- this appliance shall not be used by or on persons up to and including 14 years of age;
- WARNING: Adverse effects may occur if the instructions are not followed;
- WARNING: Prolonged or repeated application on one site may potentially damage the skin;
- WARNING: Do not bypass or remove the inherent safety device of the appliance.

As applicable, the instructions shall include the following:

- information with regard to the proper use of the appliance;
- a caution to the user when the appliance is not suitable to treat certain parts of the human body such as eyes and genital areas;

- information for cleaning and when necessary, disinfection of the appliance or parts of it;
- information on how to get the skin ready, such as smearing cream, before the application;
- indication of the application time (application time may be a fixed time value multiplied by the number of cycles).

The instructions for appliances that use disposable parts or consumable materials shall list these products and give advice on the safe disposal of them after use. The instructions shall also include the substance of the following:

Only use disposable and consumable materials recommended by the manufacturer.

The instructions for **micro-needling appliances** shall include the following:

- the needle cartridge shall not be used more than once and shall be replaced after use;
- before application first clean the skin;
- an application of an inert cream/gel/liquid applied on the skin may help the gliding process and prevent scratches;

The instructions for **electrical stimulators** shall contain the substance of the following:

- deactivate the output of the appliance before placing or removing the electrodes to or from the skin (not applicable if in normal use the appliance is moved continuously over the surface of the skin);
- do not use the appliance in conjunction with flammable based cosmetic products, unless they are recommended by the manufacturer;
- do not use the appliance near the eyes of the person on whom the appliance is used (not applicable for appliances having a maximum output current not exceeding 50 μA);
- do not use the appliance on persons with an implanted electronic device (for example a cardiac pacemaker);
- do not use the appliance close to the region of the heart.

The instructions for **electrical stimulators** shall contain:

- information on the type (such as the shape and size) of the **applied part** to be used;
- information on the method of application for each particular type of operation for which the appliance is intended.

For appliances capable of delivering output values in excess of 10 mA or 10 V, the instructions shall contain the maximum output values allowed for each type of **applied part** to be used.

The instructions for wax-melting appliances shall include the following:

- information on the highest temperature of wax after melting;
- indication of the maximum load of wax allowed.

For appliances capable of producing vapour, the instructions shall contain the substance of the following:

WARNING: In order to avoid scalding, maintain a safe distance between body parts and the vapour outlet in normal use

- the minimum distance between human body parts and the vapour outlet in normal use;
- do not apply vapour to the eyes unless the eyes are covered by towelling or similar material.

The instructions for **radio frequency appliances** producing a continuous power output or a continuous pulse train shall specify the maximum output power (W).