IEC 60335-2-113

Edition 1.0 2016-04

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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Household and similar electrical appliances – Safety – Part 2-113: Particular requirements for cosmetic and beauty care appliances incorporating lasers and intense light sources

Appareils électrodomestiques et analogues – Sécurité – Partie 2-113: Exigences particulières pour les appareils destinés aux soins cosmétiques et esthétiques comportant des lasers et des sources de lumière de forte intensité

IEC 60335-2-113:2016-04(en-fr)

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

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

HOUSEHOLD AND SIMILAR ELECTRICAL APPLIANCES – SAFETY –

Part 2-113: Particular requirements for cosmetic and beauty care appliances incorporating lasers and intense light sources

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

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

FDIS	Report on voting
61/5112/FDIS	61/5132/RVD

Full information on the voting for the approval of this 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.

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This part 2 is to be used in conjunction with the latest edition of IEC 60335-1 and its amendments. It was established on the basis of the fifth edition (2010) of that standard.

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: Safety requirements for cosmetic and beauty care appliances incorporating lasers and intense light sources.

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.

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.

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.

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 standard 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 publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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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.

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

NOTE 1 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 2 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 this part 2 standard. This does not apply to IEC 60825-1, except where specified in this part 2 standard.

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.

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HOUSEHOLD AND SIMILAR ELECTRICAL APPLIANCES – SAFETY –

Part 2-113: Particular requirements for cosmetic and beauty care appliances incorporating lasers and intense light sources

1 Scope

This clause of Part 1 is replaced by the following.

This International Standard deals with the safety of cosmetic and beauty care appliances incorporating lasers or **intense light sources** for household and similar purposes, where their operation relies on contact with the skin, their **rated voltage** being not more than 250 V.

NOTE 101 Battery-operated appliances and other d.c. supplied appliances are within the scope of this standard. Dual supply appliances, either mains-supplied or battery-operated, are regarded as **battery-operated appliances** when operated in the battery mode.

This standard covers appliances with a light emitting surface less than 25 cm^2. Appliances with a light emitting surface equal to or greater than 25 cm^2 are within the scope of IEC 60335-2-27.

Appliances not intended for normal household use but which nevertheless may be a source of danger to the public such as appliances intended to be used in beauty salons and similar premises are also within the scope of this standard.

Appliances covered by the scope of this standard include but are not limited to:

– appliances for control of hair growth;

– appliances for skin and beauty care incorporating lasers or intense light sources (ILS).

NOTE 102 Appliances incorporating lasers or **intense light sources** (**ILS**) either heat up hair follicles or skin tissue to produce thermal effects or to produce photo-biological effects from specific wavelengths.

As far as is practicable, this standard deals with the common hazards presented by appliances that are encountered by all persons in and around the home. However, in general, it does not take into account:

– persons (including children) whose physical, sensory or mental capabilities or lack of experience and knowledge prevents them from using the appliance safely without supervision or instruction;

– children playing with the appliance.

NOTE 103 Attention is drawn to the fact that in many countries additional requirements are specified by the national health authorities.

NOTE 104 This standard does not apply to

– appliances for medical purposes (IEC 60601);

– appliances for skin or hair care (IEC 60335-2-23);

– appliances for nail hardening;

– appliances for skin exposure to optical radiation with a light emitting surface equal to or greater than 25 cm^2 (IEC 60335-2-27).

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2 Normative references

This clause of Part 1 is applicable except as follows:

Addition:

IEC 60825-1:2014, *Safety of laser products – Part 1: Equipment classification and requirements*

IEC 62471:2006, *Photobiological safety of lamps and lamp systems*

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.

Addition:

Additional terms and definitions given in IEC 60825-1 and IEC 62471 are also applicable.

3.1.9 *Replacement:*
normal operation
use of the appliance applied in accordance with the manufacturer's instructions

3.101
accessible emission limit
AEL
maximum accessible emission permitted within a particular class of laser product or **ILS risk group**

Note 1 to entry: **Accessible emission limit** is hereinafter referred to as **AEL**.

Note 2 to entry: Wherever the text refers to "emission level not exceeding the **AEL**" or similar wording, it is implicit that the accessible emission is determined following the measurement criteria specified in Clause 5 of IEC 60825-1:2014 or Clause 5 of IEC 62471:2006.

3.102
Class 1C laser product
laser product that during operation does not permit **stray optical radiation** in excess of the **AEL** of Class 1 for applicable wavelengths and emission durations

3.103
embedded laser
laser that emits radiation within the **AEL** of **Class 3R laser products**, **Class 3B laser products** or **Class 4 laser products**, and that is incorporated in an appliance classified in a lower class

3.104
good contact
state that is established when the applicator is positioned at the target skin so that the skin acts to effectively prevent **stray optical radiation** exposure in excess of the ocular **MPE**

Note 1 to entry: Hazardous radiation emission refers to levels in excess of the ocular **MPE**.

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3.105
intense light source
source of intense broadband non-laser light which emits optical radiation exceeding that of the exempt group, and that is intended to cause a thermal or photo-chemical effect to the target tissue

Note 1 to entry: **Intense light sources** are hereinafter referred to as **ILS**.

Note 2 to entry: **ILS** may incorporate continuously emitting or pulsed xenon light bulbs, incandescent bulbs, LEDs or similar.

3.106
risk group
lamp classification according to IEC 62471

3.107
stray optical radiation
optical energy that is unintentionally emitted from the applicator, including scattered, reflected, and leakage radiation

3.108
maximum permissible exposure
level of optical radiation to which, under normal circumstances, persons may be exposed without suffering adverse effects

Note 1 to entry: **Maximum permissible exposure** is hereinafter referred to as **MPE**.

3.109
swivel connection
means for connecting the **supply cord** so that the appliance can be rotated continuously without twisting the cord

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.*

5.101 *Beauty care appliances are tested as a **motor-operated appliance**.*

5.102 *Where a test specification requires testing on skin or artificial skin, the artificial skin shall be similar in softness, heat capacity and reflection conditions of human skin.*

NOTE Suitable material for the artificial skin is silicone rubber with a thickness of 10 mm [e.g., (Wacker Chemie AG Elastosil RT 604, A/B) mix ratio = 9:1 with 0,6 % colour (Max Factor Creme Puff Compact Powder – 41 Medium Beige) and 6 % scattering material (Sigma Aldrich Chemical Co. AL203)][1].

[1] This information is given for the convenience of users of this document and does not constitute an endorsement by IEC of these products.

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For appliances with interlock system using a capacitive detection, the artificial skin shall also be similar in dielectric constant condition of human skin.

6 Classification

This clause of Part 1 is applicable.

7 Marking and instructions

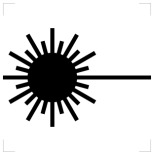
This clause of Part 1 is applicable except as follows.

7.1 *Addition:*

Appliances shall also be marked with the following, if applicable:

– a warning that intense visible and invisible optical radiation emitted from the device may cause eye injury;
– indication to avoid eye exposure;
– symbol ISO 7000-1329 (2004-01), for **Class 1C laser product** appliances;
– symbol ISO 7010-W027 (2011-05), for appliances incorporating an **ILS**;
– symbol ISO 7000-0790 (2004-01) to indicate the need to consult the user manual.

7.6 *Addition:*



[symbol ISO 7000-1329 (2004-01)] laser beam

[symbol ISO 7010-W027 (2011-05)] Warning; Optical radiation

7.12 *Addition:*

The instructions shall include the substance of the following warnings, if applicable:

WARNING. Possible eye injury (potentially leading to loss of vision) or skin injury if instructions are not followed. Read and follow the instructions.

WARNING. Only use disposable and consumable materials recommended by the manufacturer.

WARNING. Damage of the skin may occur after prolonged or repeated surface application on one site.

WARNING. Misuse can lead to eye damage. Protect the eye from exposure. Do not use the appliance over the eye lids or close to the eye.

WARNING. Do not override the safety mechanisms inherent to the device.

WARNING. If taking a photosensitizing medication or herbal remedy, seek medical advice prior to application of the appliance as use may harm the skin.

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The instructions shall include the substance of the following, if applicable:

– do not use the appliance in areas where skin integrity has been impaired (for example, in the presence of burns, lesions, blisters, scars, cuts, open wounds, active skin disease, recent sun tan or sun burn, and/ or infection);
– this appliance is not intended for the treatment of medical conditions. Medical advice should be sought to address, for example, moles, skin rash, itchy skin, skin fungus or infection, skin bumps, or skin tags;
– indications for how to use on various skin colour pigmentations, hair colours and hair thicknesses;
– these appliances are not to be used on children;
– avoid over-usage which includes excessive passes, stacking of pulses and/or increased frequency of use;
– verify that there is no visible damage to the emission optic or the appliance housing. If there is damage, do not use appliance;
– a description of how to test the skin reaction prior to the full area treatment;
– a description of how to prepare the skin before application, e.g. by applying lotions or removal of make-up;
– information concerning handling, disinfection, cleaning, care and storage of the device;
– information on use in the presence of injectable filler and toxins;
– a list of possible side effects, including blistering, pain, and scarring;
– when to seek medical advice prior to or during a use cycle;
– white or grey hair cannot be epilated;
– how to prepare the hair prior to use.

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

For appliance incorporating lasers, the instructions shall additionally provide specific information about:

– the maximum laser output delivered to the skin;
– the embedded laser class, wavelength/s, pulse duration, pulse repetition rate, output radiant power or radiant energy;
– irradiance in W/m^2 or radiant exposure in J/m^2 for each output setting of the device;
– the anticipated effects of the laser radiation on the skin, for a Class 1C laser product appliance that contains an embedded laser;
– repairs and, if applicable, recommended replacement components and accessories compatible with the product.

For appliances incorporating **ILS** the instructions shall additionally provide specific information about:

– the appliance optical output, wavelength range, pulse duration, pulse repetition rate, output irradiance or radiance;
– repairs and, if applicable, recommended replacement components and accessories that are compatible with the product, including lamps, timers, reflectors, and filters.

If symbol ISO 7000-1329 or symbol ISO 7010-W027 is used, its meaning shall be explained.

7.14 *Addition:*

The outer diameter of symbol ISO 7000-1329 and the height of the triangle in symbol ISO 7010-W027 shall be at least 10 mm.

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7.15 *Addition:*

Warnings on the housing shall be permanently fixed, legible, and clearly visible during use, maintenance, and service. They shall be so positioned that they can be read without the necessity for human exposure to laser radiation in excess of the **AEL** for **Class 1 laser product** or optical radiation in excess of the **AEL** of the exempt group.

8 Protection against access to live parts

This clause of Part 1 is applicable.

9 Starting of motor-operated appliances

This clause of Part 1 is not applicable.

10 Power input and current

This clause of Part 1 is applicable.

11 Heating

This clause of Part 1 is applicable except as follows.

11.2 *Addition:*

Appliances intended to be used on a stand or attached to a support are placed to give the most unfavourable results.

11.7 *Replacement:*

Appliances without a timer are operated

– *for 30 min, for **hand-held appliances** and appliances with hand-held applicators;*
– *until steady conditions are established, for other appliances.*

Appliances incorporating a timer are operated in cycles until steady conditions are established. Each cycle consists of the maximum operating time of the timer followed by either the programmed rest period, or a minimum rest period of 5 s.

11.8 *Addition:*

An appliance intended to be operated when in contact with the skin shall be tested using the artificial skin. All other appliances are tested in air. The maximum temperature rise of appliance parts intended to be in contact with the human body in normal use shall not exceed the following values:

– *if of metals and liquids*	*26 K*
– *if of glass, porcelain and vitreous material*	*31 K*
– *if of moulded material, plastics, rubber and wood*	*35 K*

The temperature rise of the artificial skin is not measured.

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12 Void

13 Leakage current and electric strength at operating temperature

This clause of Part 1 is applicable.

14 Transient overvoltages

This clause of Part 1 is applicable.

15 Moisture resistance

This clause of Part 1 is applicable.

16 Leakage current and electric strength

This clause of Part 1 is applicable.

17 Overload protection of transformers and associated circuits

This clause of Part 1 is applicable.

18 Endurance

This clause of Part 1 is applicable.

19 Abnormal operation

This clause of Part 1 is applicable except as follows.

19.13 *Addition:*

During and after the tests, if the appliance is operational, it shall comply with Clause 32.

20 Stability and mechanical hazards

This clause of Part 1 is applicable.

21 Mechanical strength

This clause of Part 1 is applicable except as follows.

21.1 *Addition:*

Hand-held appliances *and hand-held parts of the appliance are also subjected to the test of 21.101.*

21.101 *The appliance is placed on a horizontal surface positioned 700 mm above a rigidly supported hardwood board and operated while supplied at* ***rated voltage****.*

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