UL 60335-2-113

STANDARD FOR SAFETY

Household and Similar Electrical Appliances – Safety – Part 2-113: Particular Requirements for Beauty Care Appliances Incorporating Lasers and Intense Light Sources

UL Standard for Safety for Household and Similar Electrical Appliances – Safety – Part 2-113: Particular Requirements for Beauty Care Appliances Incorporating Lasers and Intense Light Sources, UL 60335-2-113

First Edition, Dated January 27, 2023

Summary of Topics

First Edition of the UL IEC-Based Standard for Household and Similar Electrical Appliances – Safety – Part 2-113: Particular Requirements for Beauty Care Appliances Incorporating Lasers and Intense Light Sources, ANSI/UL 60335-2-113, dated January 27, 2023.

UL 60335-2-113 is an adoption of IEC 60335-2-113 (Edition 1.1, issued November 2021). Please note that the National Difference document incorporates all of the U.S. national differences for UL 60335-2-113.

The new requirements are substantially in accordance with Proposal(s) on this subject dated December 2, 2022.

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UL 60335-2-113

Standard for Household and Similar Electrical Appliances – Safety – Part 2-113: Particular Requirements for Beauty Care Appliances Incorporating Lasers and Intense Light Sources

First Edition

January 27, 2023

This ANSI/UL Standard for Safety consists of the First Edition.

The most recent designation of ANSI/UL 60335-2-113 as an American National Standard (ANSI) occurred on January 27, 2023. ANSI approval for a standard does not include the Cover Page, Transmittal Pages, Title Page, or Preface. The National Difference Page and IEC Foreword are also excluded from the ANSI approval of IEC-based standards.

Comments or proposals for revisions on any part of the Standard may be submitted to UL at any time. Proposals should be submitted via a Proposal Request in UL's On-Line Collaborative Standards Development System (CSDS) at https://csds.ul.com.

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PREFACE

This UL Standard is based on IEC Publication 60335-2-113: first edition, Household and similar electrical appliances – Safety – Part 2-113: Particular requirements for beauty care appliances incorporating lasers and intense light sources, as revised by Amendment 1. IEC publication 60335-2-113 is copyrighted by the IEC.

This UL Standard 60335-2-113 Standard for Safety for Household and Similar Electrical Appliances – Safety – Part 2-113: Particular Requirements for Beauty Care Appliances Incorporating Lasers and Intense Light Sources, is to be used in conjunction with the latest edition of UL 60335-1. The Safety requirements for cosmetic and beauty care appliances incorporating lasers and intense light sources are contained in this Part 2 Standard and UL 60335-1.

Requirements of this Part 2 Standard, where stated, amend the requirements of UL 60335-1.

Where a particular subclause of UL 60335-1 is not mentioned in UL 60335-2-113, the UL 60335-1 subclause applies.

Note – Although the intended primary application of this Standard is stated in its Scope, it is important to note that it remains the responsibility of the users of the Standard to judge its suitability for their particular purpose.

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NATIONAL DIFFERENCES

National Differences from the text of International Electrotechnical Commission (IEC) Publication 60335-2-113, Household and Similar Electrical Appliances – Safety – Part 2-113: Particular Requirements for Beauty Care Appliances Incorporating Lasers and Intense Light Sources, copyright 2021, are indicated by notations (differences) and are presented in bold text.

There are five types of National Differences as noted below. The difference type is noted on the first line of the National Difference in the standard. The standard may not include all types of these National Differences.

DR – These are National Differences based on the **national regulatory requirements**.

D1 – These are National Differences which are based on **basic safety principles and requirements**, elimination of which would compromise safety for consumers and users of products.

D2 – These are National Differences from IEC requirements based on existing **safety practices**. These requirements reflect national safety practices, where empirical substantiation (for the IEC or national requirement) is not available or the text has not been included in the IEC standard.

DC – These are National Differences based on the **component standards** and will not be deleted until a particular component standard is harmonized with the IEC component standard.

DE – These are National Differences based on **editorial comments or corrections**.

Each national difference contains a description of what the national difference entails. Typically one of the following words is used to explain how the text of the national difference is to be applied to the base IEC text:

Addition / Add - An addition entails adding a complete new numbered clause, subclause, table, figure, or annex. Addition is not meant to include adding select words to the base IEC text.

Modification / Modify - A modification is an altering of the existing base IEC text such as the addition, replacement or deletion of certain words or the replacement of an entire clause, subclause, table, figure, or annex of the base IEC text.

Deletion / Delete - A deletion entails complete deletion of an entire numbered clause, subclause, table, figure, or annex without any replacement text.

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FOREWORD

INTERNATIONAL ELECTROTECHNICAL COMMISSION

HOUSEHOLD AND SIMILAR ELECTRICAL APPLIANCES – SAFETY – Part 2-113: Particular requirements for beauty care appliances incorporating lasers and intense light sources

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.

This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.

IEC 60335-2-113 edition 1.1 contains the first edition (2016-04) [documents 61/5112/FDIS and 61/5132/RVD] and its amendment 1 (2021-11) [documents 61/6367/FDIS and 61/6417/RVD].

IEC 60335-2-113 has been prepared by IEC technical committee 61: Safety of household and similar electrical appliances.

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

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 the base publication and its amendment will remain unchanged until the stability date indicated on the IEC web site under 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.

101DV D2 ***Modification to replace the sixth paragraph and NOTE 1 of the Foreword with the following:***

This Part 2-113 is to be used in conjunction with the latest edition of UL 60335-1.

NOTE 1 When "Part 1" is mentioned in this standard, it refers to UL 60335-1.

102DV DE ***Modification of NOTE 2 by adding the following:***

– The numbering system in the standard uses a space instead of a comma to indicate thousands and uses a comma instead of a period to indicate a decimal point. For example, 1 000 means 1,000 and 1,01 means 1.01.

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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 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 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).

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 7010:2019, *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 60825-1:2014 and IEC 62471:2006 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
maximum accessible emission permitted within a particular class of laser product

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.

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 **Void**

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** emission in excess of the **AEL** for Class 1 laser products or the emission limits for the exempt group for intense light sources

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 **Void**

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].

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

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

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;

– for **Class 1C laser product** appliances;

- sign shown in Figure 101; or
- warning sign ISO 7010-W004 (2019-07) and the substance of the following:

  Laser radiation. Follow instructions. Class 1C laser product.

– warning sign 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:*

[warning sign ISO 7010-W004 (2019-07)]

Warning: Laser beam

[warning sign ISO 7010-W027 (2019-07)]

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.

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 laser product 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;

– 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 warning sign ISO 7010-W004, sign shown in Figure 101 or warning sign ISO 7010-W027 (2019-07) is used, its meaning shall be explained.

7.14 *Addition:*

The height of the triangle in warning sign ISO 7010-W004, height of the sign shown in Figure 101, and the height of the triangle in warning sign ISO 7010-W027 (2019-07) shall be at least 10 mm.

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 emission limits 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.

12 Void

13 Leakage current and electric strength at operating temperature

This clause of Part 1 is applicable except as follows:

13.1 *Addition:*

Compliance is also checked by the test of 13.101.

13.2 *Addition:*

For an applicator intended to make contact with the human body, the allowable limit for leakage current is 0,1 mA.

13.101 *The leakage current for the applicator intended to make contact with the human body shall also be measured between the part in contact with the human body and the poles of the supply with each supply conductor interrupted one at a time and shall not exceed 0,5 mA.*

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****.*

It is pulled from the surface by its ***supply cord*** *and allowed to drop freely. The test is carried out five times, the appliance being placed on the horizontal surface in different positions likely to occur.*

The appliance shall not be damaged to such an extent that compliance with this standard is impaired. In particular, the requirements of Clauses 8 and 29 shall be fulfilled.

21.102 The enclosure of a **detachable power supply part** used in a flexible cord shall have adequate mechanical strength against crushing.

Compliance is checked by the following test.

The appliance is operated under the conditions of Clause 11 with the ***detachable power supply part*** *placed on the floor of the test corner.*

After steady conditions are established, a compression force of 1 350 N is applied to the ***detachable power supply part*** *enclosure. The compression force is applied for one minute using a flat surface 100 mm × 250 mm and repeated with the* ***detachable power supply part*** *placed in all possible different orientations.*

The ***detachable power supply part*** *shall not be damaged to such an extent that compliance with 8.1 and Clause 29 is impaired and it shall not emit flames or molten metal.*

21.103 The enclosure of a **detachable power supply part** used in a flexible cord shall have adequate mechanical strength against dropping.

Compliance is checked by the following test.

*The **detachable power supply part** is placed in a sling that is constructed by tying together the four corners of a single layer of cheesecloth. The lowest point of the sling is suspended at a height of 900 mm above a concrete or similar hard surface.*

*The **detachable power supply part** in the sling is dropped from a stationary position. The test is carried out a total of five times with the **detachable power supply part** being positioned so that it falls onto the concrete surface in five different orientations.*

*The **detachable power supply part** shall not be damaged to such an extent that compliance with 8.1 and Clause 29 is impaired.*

22 Construction

This clause of Part 1 is applicable except as follows.

22.7 *Addition:*

This requirement also applies to negative pressure.

22.101 Appliances incorporating rechargeable non-sealed batteries shall be ventilated.

Compliance is checked by inspection.

22.102 Appliances incorporating parts that are suspended or intended to be raised and lowered over a person shall incorporate a safety device to prevent injury if the suspension means fails or there is excessive travel of the part.

Compliance is checked by inspection and by manual test.

22.103 Foot-operated control devices shall be able to support the weight of a person.

Compliance is checked by applying to the foot-operated control device, in its position of normal use, an actuating force of 1 350 N for 1 min. The force is applied over an area of 625 mm^2. There shall be no damage to the device that is likely to cause a hazard.

22.104 Foot-operated control devices and hand-held control devices shall not change their control setting when inadvertently placed in an unintended position.

Compliance is checked by turning the device in all positions where the control device can be activated or kept activated under the weight of the control and placing it on a supporting surface. There shall not be any inadvertent change of control setting that is likely to cause a hazard.

22.105 Appliances using vacuum or pressure aperture shall be constructed so that

– gas flow, by means of cooling gas supply, shall not exceed an output pressure of 20 kPa;

– the suction applicators or probes shall not induce a vacuum exceeding 75 kPa.

Compliance is checked by inspection and measurement.

22.106 Any appliance incorporating

– a laser product, other than a **Class 1 laser product**, **Class 1M laser product**, **Class 2 laser product**, **Class 2M laser product**; or

– an **ILS** other than those classified as exempt group in 6.1.1 of IEC 62471:2006 or classified as **risk group 1** in 6.1.2 of IEC 62471:2006

shall give a visible, audible or tactile signal when the interlock system senses **good contact** with the skin and enables the appliance for emission.

*If a tactile signal is used, the indication of **good contact** shall be other than the sense of pressure on the skin. An example of an acceptable tactile signal is vibration.*

Compliance is checked by inspection and by functional tests.

22.107 If an appliance incorporates

– a laser product that emits above the **AEL** of a Class 3B laser product in IEC 60825-1:2014; or

– an **ILS** classified as **risk group** 3 as defined in 6.1.4 of IEC 62471:2006 (continuous wave light source) or in 6.2 of IEC 62471:2006 (pulsed light source),

it shall have means to assess the skin pigmentation level and means to adjust the output according to the skin pigmentation level so that damage to the bulk tissue is avoided.

NOTE The means to assess the skin pigmentation level can be via a colour chart.

Means of assessing the pigmentation level is not required if the appliance is not capable of damaging the bulk tissue of any skin type when set at the maximum output.

Compliance is checked by inspection. For devices without means to adjust the output, the manufacturer shall supply a validation study on human skin showing that damage to the bulk tissue does not occur. The study shall be a registered clinical study in accordance with good clinical practice as described in ISO 14155.

*If compliance relies on an **electronic circuit** that is programmable, the software shall contain measures to control the fault/error conditions specified in Table R.1 and it is evaluated in accordance with the relevant requirements of Annex R.*

22.108 Appliances incorporating a laser product other than a **Class 1 laser product** shall be equipped with an interlock system which is capable of detecting whether **good contact** with the human skin is established.

If continuous action by the user is required to maintain the enabled status (for example an activation button is continuously depressed) the appliance shall keep emitting, unless **good contact** with the skin is lost. While this continuous action is maintained by the user, any loss of **good contact** shall be detected by the interlock system and the laser emission shall shut off.

The time interval between loss of **good contact** with the skin and disabling the triggering of laser emission shall not exceed 0,1 s. For pulsed systems, the time between loss of **good contact** and disabling of emissions shall be less than the minimum pulse interval.

The emission may resume automatically if **good contact** is re-established within 10 s. When the loss of **good contact** exceeds 10 s the appliance shall require active retriggering by the user in order to resume emission.

Compliance is checked by the following tests.

The function of the interlock system shall be tested with a cylindrical test specimen, designed to simulate human skin, with the following properties:

– a cylindrical rod with an outer diameter exceeding the maximal dimension of the applicator footprint by 40 mm and having a smooth surface, made of a flexible material with a Shore hardness not exceeding 25;

*– the material shall simulate the optical properties of the skin with regard to absorption, reflection and scattering, in order to assess the **stray optical radiation**;*

– the surface of the artificial skin used for detecting the skin contact is modified in turn as follows:

- *dry skin is simulated using the artificial skin without any modification;*
- *the presence of dried sweat is simulated by using a 0,9 g/l saline solution on the artificial skin surface, that is then air dried;*
- *the presence of sebum is simulated by using petroleum jelly on the artificial skin surface.*

*For appliances using an auxiliary material such as a gel as specified in the instructions as the contact means for **normal operation**, the test shall be performed with and without this material.*

The reaction time of the interlock system is tested by placing the output window of the appliance applicator on the test specimen, subsequently removing the applicator from the test specimen and the emission of light shall cease within a time interval of 0,1 s.

*The output window of the appliance applicator shall be placed on the test specimen and rotated, tilted and raised to test whether the sensors in the interlock system correctly detect **good contact** with the test specimen.*

*If **stray optical radiation** from the target skin occurs it shall be measured by placing the appliance applicator in contact with the test specimen at varying positions of orientation. The **stray optical radiation** shall not exceed the **AEL** of Class 1 as specified in Table 3 and Table 4 of IEC 60825-1:2014 for an emission duration of 10 s, unless the appliance emission is limited to a shorter emission duration.*

*If compliance with the requirement of this subclause relies on the operation of an **electronic circuit**, the appliance is further tested as follows.*

*a) The appliance is supplied at **rated voltage** and operated under **normal operation**.*

The electromagnetic phenomena tests of 19.11.4.1 to 19.11.4.7 are then applied. The tests are carried out with surface protective devices disconnected, unless they incorporate spark gaps.

*The **stray optical radiation** shall not exceed the **AEL** of Class 1 as specified in Table 3 and Table 4 of IEC 60825-1:2014 for an emission duration of 10 s, unless the appliance emission is limited to a shorter emission duration, after the loss of **good contact** with the skin.*

*b) The appliance is supplied at **rated voltage** and operated under **normal operation**.*

*The fault conditions in a) to g) of 19.11.2 are then considered and, if necessary, applied one at a time to the **electronic circuit** monitoring the interlock.*

*The **stray optical radiation** shall not exceed the **AEL** of Class 1 as specified in Table 3 and Table 4 of IEC 60825-1:2014 for an emission duration of 10 s, unless the appliance emission is limited to a shorter emission duration, after the loss of **good contact** with the skin.*

*If the **electronic circuit** is programmable, the software shall contain measures to control the fault/error conditions specified in Table R.1 and it is evaluated in accordance with the relevant requirements of Annex R.*

22.109 For appliances incorporating **ILS**, other than those classified as exempt group in 6.1.1 of IEC 62471:2006 or classified as **risk group 1** in 6.1.2 of IEC 62471:2006, the appliance shall be equipped with an interlock system, which is capable of detecting whether **good contact** with the human skin is established.

If continuous action by the user is required to maintain the enabled status (for example, an activation button is continuously depressed) the appliance shall keep emitting, unless **good contact** with the skin is lost. While this continuous action is maintained by the user, any loss of **good contact** shall be detected by the interlock system and the emission from the **ILS** shall shut off.

The time interval between loss of **good contact** with the skin and disabling the triggering of **ILS** shall not exceed 0,1 s. For pulsed systems, the time between loss of **good contact** and disabling of emissions shall be less than the minimum pulse interval. For gas discharge lamps, the time between loss of **good contact** and disabling of emissions shall be less than one pulse interval.

The emission may resume automatically if **good contact** is re-established within 10 s. When the loss of **good contact** exceeds 10 s, the appliance shall require active retriggering by the user in order to resume emission.

Compliance is checked by the following tests.

The function of the interlock system is tested with a cylindrical test specimen, designed to simulate human skin, with the following properties:

– a cylindrical rod with an outer diameter exceeding the maximal dimension of the applicator footprint by 40 mm and having a smooth surface, made of a flexible material with a Shore hardness not exceeding 25;

*– the material shall simulate the optical properties of the skin with regard to absorption, reflection and scattering, in order to assess the **stray optical radiation**;*

– the surface of the artificial skin used for detecting the skin contact is modified in turn as follows:

- *dry skin is simulated using the artificial skin without any modification;*
- *the presence of dried sweat is simulated by using 0,9 g/l saline solution on the artificial skin surface, that is then air dried;*