



DPC: 25 / 30507460 DC

BSI Group Headquarters

389 Chiswick High Road London W4 4AL

Tel: +44 (0)20 8996 9000

Fax: +44 (0)20 8996 7400

www.bsigroup.com

Date: 06 January 2025

Origin: International

Latest date for receipt of comments: 31 January 2025

Project No. 2025/00114

Responsible committee: CPL/61 Safety of household and similar electrical appliances

Interested committees:

Title: BS EN IEC 60335-2-115 Household and similar electrical appliances - Safety

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

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

- i) has any issues related to 3rd party IPR, patent or copyright
- ii) affects other national standard(s)
- iii) requires additional national guidance or information

**WARNING: THIS IS A DRAFT AND MUST NOT BE REGARDED OR USED AS A BRITISH STANDARD.
THIS DRAFT IS NOT CURRENT BEYOND 31 January 2025**

This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

No copying is allowed, in any form, without prior written permission from BSI except as permitted under the Copyright, Designs and Patent Act 1988 or for circulation within a nominating organization for briefing purposes. Electronic circulation is limited to dissemination by e-mail within such an organization by committee members.

Further copies of this draft may be purchased from BSI Shop <http://shop.bsigroup.com> or from BSI Customer Services, Tel: +44(0) 20 8996 9001 or email cservices@bsigroup.com. British, International and foreign standards are also available from BSI Customer Services.

Information on the co-operating organizations represented on the committees referenced above may be obtained from <http://standardsdevelopment.bsigroup.com>

Responsible Committee Secretary: **Mrs Geraldine D Salt (BSI)**
Direct tel: **020 8996 7273**
E-mail: geraldine.salt@bsigroup.com

Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
------------------	------------------------

1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/Figure/ Table/Note	Type of comment	Commend (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



61/7371/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER: IEC 60335-2-115 ED2	
DATE OF CIRCULATION: 2024-12-27	CLOSING DATE FOR COMMENTS: 2025-02-21
SUPERSEDES DOCUMENTS: 61/7367/RR	

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 FUNCTION(S):	
ASPECTS CONCERNED: Safety		

This document is still under study and subject to change. It should not be used for reference purposes.

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.

Recipients of this document are invited to submit, with their comments, notification of any local regulations or technical reasons that may exist and should be considered should this proposal proceed, recognizing that failure to address such requirements could result in the need for new or existing "In Some Countries" clauses. (SEE AC/22/2007 OR NEW GUIDANCE DOC).

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

NOTE FROM TC/SC OFFICERS:

Copyright © 2024 International Electrotechnical Commission, IEC. All rights reserved. It is permitted to download this electronic file, to make a copy and to print out the content for the sole purpose of preparing National Committee positions. You may not copy or "mirror" the file or printed version of the document, or any part of it, for any other purpose without permission in writing from IEC.

CONTENTS

1		
2	FOREWORD.....	5
3	INTRODUCTION.....	7
4	1 Scope.....	9
5	2 Normative references	10
6	3 Terms and definitions	11
7	4 General requirement.....	12
8	5 General conditions for the tests	12
9	6 Classification.....	13
10	7 Marking and instructions.....	14
11	8 Protection against access to live parts.....	17
12	9 Starting of motor-operated appliances	18
13	10 Power input and current.....	18
14	11 Heating.....	19
15	12 Charging of metal-ion batteries.....	23
16	13 Leakage current and electric strength at operating temperature	23
17	14 Transient overvoltages	23
18	15 Moisture resistance	23
19	16 Leakage current and electric strength	24
20	17 Overload protection of transformers and associated circuits	24
21	18 Endurance.....	24
22	19 Abnormal operation	24
23	20 Stability and mechanical hazards.....	25
24	21 Mechanical strength	26
25	22 Construction	27
26	23 Internal wiring.....	33
27	24 Components	33
28	25 Supply connection and external flexible cords	34
29	26 Terminals for external conductors.....	35
30	27 Provision for earthing	35
31	28 Screws and connections	35
32	29 Clearances, creepage distances and solid insulation	35
33	30 Resistance to heat and fire	35
34	31 Resistance to rusting	36
35	32 Radiation, toxicity and similar hazards.....	36
36	Annexes	40
37	Annex R (normative) Software evaluation	42
38	Annex AA (normative) Estimation of the local specific absorption rate (local SAR)	43
39	Annex BB (informative) Guidance to measure the dimensions of the treatment head of	
40	a radio frequency appliance	49
41	Annex CC (normative) Isolating transformers	52
42	Bibliography.....	53

44	Figure 101 – Probe for measuring surface temperatures	37
45	Figure 102 – Burn threshold spread when the skin is in contact with a hot smooth	
46	surface made of bare (uncoated) metal	37
47	Figure 103 – Burn threshold spread when the skin is in contact with a hot smooth	
48	surface made of ceramics, glass and stone materials	38
49	Figure 104 – Burn threshold spread when the skin is in contact with a hot smooth	
50	surface made of plastics	38
51	Figure 105 – Circuit for testing leakage current from applied parts	39
52	Figure AA.1 – Examples of radio frequency appliance output types	48
53	Figure BB.1 – Use of the smallest distance between electrodes for treatment heads of	
54	type 7	51
55		
56	Table 101 – Maximum temperature rises for specified external accessible surfaces	
57	other than the applied parts under normal operating conditions	21
58	Table 102 – Maximum temperature rise of applied parts	22
59	Table 103 – Logarithmic interpolation equations	22
60	Table 104 – Output current limits for application below the neck	30
61	Table 105 – Local SAR limits	31
62	Table BB.1 – Dimensions and volume calculations for various types of RF treatment	
63	heads	49
64		

Note 1 of MT 53: This CD incorporates the following documents:

- 61/6846/DC with 61/6912B/INF
- 61/6361C/INF, Guidance for Updating Part 2 Standards to be Aligned to IEC 60335-1 Edition 6
- 61/6845/DC with 61/6913B/INF
- Relocation of part 2-23 products (based on comment 3 in 61/6920A/RVC)
- AG23 "Remote operation" proposal
- MT53's clarification for 5.2, 10.1 and 10.2

The changes from these documents are shown in the highlight colours above.

Note 2 of MT 53:

AG23 "Remote operation" proposal

Background:

As agreed in the plenary meeting of IEC TC61 Web Series II 2021, MT 23 (now named AG23) took the task to review several parts 2 for aligning them to Part 1 of Ed.6.0 with regards to modifications for remote operation of appliances via public networks. MT23 prepared a guidance document integrated in the TC61 guidance document 61/6361/INF explaining the approach that will be taken for considering all relevant aspects and clauses of part 1 that might need adaptation in specific parts 2 to cover safety related risks raising by use of appliances without user presence which is implied if remote control was enabled via public networks. The approach taken by MT23 was agreed by TC61 and will therefore be applied to all parts 2 under revision.

Based on 61/6769/CDV and 61/6920A/RVC for Part 2-23 and the aforementioned guidance document, MT53 sought direct guidance from MT23 on the approach for Part 2-115, which was discussed in the AG23 meeting in Hangzhou (D833). This proposal has been prepared by AG23 based on the outcome of that discussion (item 6.12 of 61/AG23(Secretary)854B).

Rationale:

AG23 has determined that almost all of the appliances within the scope of this standard should not be operated remotely, not allow remote communication nor use a delayed start timer. Other than facial saunas and water filled foot care appliances without massage function, the range of different, potentially hazardous, technologies used for appliances in direct contact with the skin are considered to be able to give rise to a hazard if operated continuously, automatically or remotely or if the operation data is remotely communicated and not reliable for safety.

For commercial skin beauty care appliances, since the operation of a hand-held part is intended to be by a trained operator who is intended to be in sight of the appliance, any communication between the beauty care part in contact with the skin and hand-held part for commercial use is not intended to be remote communication. However, an error or delay in the remote monitoring data may lead to a hazard in the operation of the appliance. Therefore remote communication shall not be allowed for this kind of appliance.

Additionally, Part 2-115 is written for attended (hand-held and body worn) appliances, so other clauses outside of the scope of AG23 would also be impacted if remote functions were allowed.

65

66

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/xxxx/FDIS	61/xxxx/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.

**Documents**

Document Sharing Hub

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

This part 2 is to be used in conjunction with the latest edition of IEC 60335-1 and its amendments unless that edition precludes it; in that case, the latest edition that does not preclude it is used. It was established on the basis of the sixth edition (2020) 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: 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.

Guidance documents concerning the application of the safety requirements for appliances can be accessed via TC 61 supporting documents on the IEC website

<https://www.iec.ch/tc61/supportingdocuments>

This information is given for the convenience of users of this International Standard and does not constitute a replacement for the normative text in this standard.

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 can 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 21 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~~

~~NOTE 2 Horizontal publications, basic safety publications and group safety publications 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.~~

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.

- 198 NOTE 3 Standards dealing with non-safety aspects of household appliances are:
- 199 – IEC standards published by TC 59 concerning methods of measuring performance;
- 200 – CISPR 11, CISPR 14-1 and relevant IEC 61000-3 series standards concerning electromagnetic emissions;
- 201 – CISPR 14-2 concerning electromagnetic immunity;
- 202 – IEC standards published by TC 111 concerning environmental matters.

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 **including direct current (DC) supplied appliances and battery-operated appliances.**

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 **and facial saunas**;
- micro-needling appliances;
- plasma pens.
- **water filled foot care appliances** without massage function;

NOTE A water filled **foot care appliance** with water jets is not considered to have a massage function

NOTE 102101 Appliances covered by this standard can incorporate vapour-producing devices or spray-producing devices.

This standard deals with the **reasonably foreseeable hazards 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.

- 246 NOTE 103-102 Attention is drawn to the fact that
- 247 – it is recognized that persons having very extensive and complex disabilities can have needs beyond the level
- 248 addressed in this standard.
- 249 – for appliances intended to be used in vehicles or on board ships or aircraft, additional requirements can be
- 250 necessary;
- 251 – in many countries, additional requirements can be specified by the national health authorities, the national
- 252 authorities responsible for the protection of labour and similar authorities.

253 This standard does not apply to

- 254 – appliances intended exclusively for industrial purposes;
- 255 – appliances intended to be used in locations where special conditions prevail, such as the
- 256 presence of a corrosive or explosive atmosphere (dust, vapour or gas);
- 257 – shavers, hair clippers and similar appliances (IEC 60335-2-8);
- 258 – blankets, pads, clothing and similar flexible heating appliances (IEC 60335-2-17);
- 259 – appliances for skin or hair care and similar such as facial saunas, hand dryers, foot care
- 260 appliances (IEC 60335-2-23);
- 261 – spray tanning appliances;
- 262 – appliances for skin exposure to optical radiation (IEC 60335-2-27);
- 263 – wafer filled foot massagers (IEC 60335-2-32);
- 264 – sauna heating appliances and infrared cabins (IEC 60335-2-53);
- 265 – cosmetic and beauty care appliances incorporating lasers and intense light sources
- 266 (IEC 60335-2-113);
- 267 – appliances intended for medical purposes (IEC 60601);
- 268 – **radio frequency appliances** without contact to the skin;
- 269 – **ultrasound appliances** provided with focusing ultrasound transducers.

270 2 Normative references

271 This clause of Part 1 is applicable except as follows:

272 *Addition:*

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

274 IEC 60601-2-5:2009, *Medical electrical equipment – Part 2-5: Particular requirements for the*

275 *basic safety and essential performance of ultrasonic physiotherapy equipment*

276 IEC 61558-2-4:2009, *Safety of transformers, reactors, power supply units and similar products*

277 *for supply voltages up to 1 100 V – Part 2-4: Particular requirements and tests for isolating*

278 *transformers and power supply units incorporating isolating transformers*

279 IEC 61689:2013-2022, *Ultrasonics – Physiotherapy systems – Field specifications and methods*

280 *of measurement in the frequency range 0,5 MHz to 5 MHz*

281 IEC 62127-1, *Ultrasonics – Hydrophones – Part 1: Measurement and characterization of*

282 *medical ultrasonic fields up to 40 MHz*

283 IEC 63009:2019, *Ultrasonics – Physiotherapy systems – Field specifications and methods of*

284 *measurement in the frequency range 20 kHz to 500 kHz*

285 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:~~ **Modification:**

~~normal operation~~

Replace the first paragraph with the following:

Facial saunas and appliances also producing vapour are operated in the normal position of use and filled with water. Water is added, when necessary, to maintain the steam or vapour output.

The liquid container of water filled foot care appliances is filled with water at a temperature of $40\text{ °C} \pm 2\text{ °C}$ up to the rated capacity as marked on the appliance or specified in the instructions, if no rated capacity is marked or specified in the instructions, then the liquid container is filled with the maximum water capacity, and then loaded with an additional mass of 10 kg evenly distributed over an area of 100 mm × 300 mm.

For other skin care appliances covered by this standard, 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 in the frequency range from >0 Hz to 100 kHz, to go 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 treat face and body by using produce radiofrequency current, an electric field, magnetic field, or electromagnetic field in the frequency range from 100kHz to 300GHz 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 **a single or** an array of needles intended to penetrate the skin **in a stamping motion**

3.5.107**foot care appliance**

appliance for softening the feet skin or relaxing the feet

3.5.108**facial sauna**

appliance intended to use steam to provide deep cleaning of the pores.

3.5.109**wax melting appliances**

appliance intended to melt the wax for hair removal.

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 without a swivel connection** 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.

If a specially prepared sample is required to apply the different method, then this shall be provided by the manufacturer.

5.101 Unless otherwise specified, ~~s~~ 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:

Replace the first paragraph with the following:

Appliances shall be of one of the following classes with respect to protection against electric shock:

- **Hand-held appliances**, appliances incorporating vapour-producing devices, ~~steam-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.
- **water filled foot care appliances** shall be class II or class III.
- **other appliances** shall be **class I, class II** or **class III**.

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

7.6 Addition:



[prohibition
(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.

7.12 Addition:

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

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 **can** 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 **can** occur if the instructions are not followed;
- WARNING: Prolonged or repeated application on one site **can** potentially damage the skin;
- WARNING: Do not bypass or remove the inherent safety device of the appliance.
- **before use visually inspect the appliance to ensure it is not damaged.**

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 substance of** 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 **can** help the gliding process and prevent scratches;

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