



Minister for Economic Development

with the agreement of

the Minister for Health

IN VIEW OF Article 17.3 of Law 400 of 23 August 1988;

IN VIEW OF Law 1 of 4 January 1990 on the work undertaken by beauticians;

IN VIEW OF Articles 1 and 3 of the aforementioned Law 1/1990 in accordance with which work undertaken by beauticians includes services and treatments performed on the surface of the human body that are exclusively or predominantly intended to keep it in perfect condition, to improve or protect its aesthetic appearance, modifying it by removing or reducing any flaws present, and which may also be carried out using electromechanical beauty-treatment devices as provided for in the list attached to that law, subject to the professional qualification procedure provided for therein;

IN VIEW OF Article 10.1 of the aforementioned Law 1/1990 in particular, in accordance with which the Minister for Industry, Trade, and Craft, in conjunction with the Minister for Health and having consulted the national unions most representative of this economic sector, adopts a decree setting out direct standards determining the dynamic technical characteristics, adjustment mechanisms, implementing methods, and precautions to be taken during use of the electro-mechanical beauty-treatment devices provided for in the list attached to the aforementioned law, and updates that list in consideration of technological developments in the sector;

IN VIEW OF Decree Law 181 of 18 May 2006, as converted and amended by Law 233 of 17 July 2006, which among other things established the Ministry of Economic Development, and Article 1(376) and (377) of Law 244 of 24 December 2007, as well as Decree Law 85 of 16 May 2008, as converted and amended by Law 121 of 14 July 2008, as well as Law 172 of 13 November 2009, recently passed on the arrangement of the Ministries;

IN VIEW OF Law 791 of 18 October 1977 implementing Council Directive 73/23/EEC on safety assurances to be provided for electrical equipment designed for use within certain voltage limits, as amended and expanded;

IN VIEW OF Legislative Decree 194 of 6 November 2007 implementing Directive 2004/108/EC on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC;

IN VIEW OF Legislative Decree 206 of 6 September 2005, as amended, on the Consumer Code, and in particular Articles 102 to 112 of said code on provisions relating to the general safety of products, and implementing Directive 2001/95/EC;

WHEREAS consumer safety is ensured both by the duty of the manufacturer and the distributor to place safe goods on the market and by the requirement for electromechanical devices to comply with the standards applicable to them, as contained in the aforementioned legal provisions relating to product safety evaluation and performance, the safety guarantees to be provided by electrical hardware intended for use within certain voltage limits, and electromagnetic compatibility;

WHEREAS membership of the European Union prohibits any barrier to the free movement of goods legally manufactured or sold in another Member State of the Union or a signatory state to the European Economic Area Agreement, and that therefore no limitations or requirements may be imposed unless justified on the grounds indicated in Article 36 of the Treaty;

WHEREAS there is a need to identify European, international or national reference technical standards for each of the electromechanical beauty-treatment devices in the list attached to Law 1/1990;

HAVING CONSULTED the national unions most representative of this economic sector;

WHEREAS there is a need to update the list attached to the law, in consideration of the technological developments in the sector;

HAVING COMPLETED the notification procedure in the field of technical regulations and standards provided for in Directive 98/34/EC, as amended by Directive 98/48/EC that provides an information procedure in the field of technical regulations and rules relating to information society services;

HAVING HEARD the opinion of the Council of State expressed by the Advisory Section for Legal Acts at the Sitting of ...;

In view of the notification to the Prime Minister pursuant to Article 17.3 of Law 400 of 23 August 1988 reference ... protocol no. ...;

HEREBY ADOPTS
the following regulation

Article 1
(Identification of beauty-treatment devices)

1. Electromechanical beauty-treatment devices mean the devices included in the list attached to Law 1 of 4 January 1990 powered by low voltages or battery, built in accordance with prevailing safety standards and compliant with the technical specifications provided for in this decree.
2. The list of electromechanical beauty-treatment devices provided for in the annex to Law 1 of 4 January 1990 is replaced by Annex 1 to this decree, which is an integral part thereof.

Article 2
(General provisions)

1. The dynamic technical characteristics, adjustment mechanisms, implementing methods, and precautions to be taken during use of the electromechanical beauty-treatment devices provided for in Article 1 shall be determined by the general provisions set out below and, for each device, by the standards and specifications contained in the technical information sheets in Annex 2.

Article 3
(Safety level)

1. The electromechanical devices provided for in the list attached to Law 1 of 4 January 1990, as updated, may be used in Italy provided that they guarantee the safety level set out in Community directives and harmonised European standards.
2. National standards issued by national standardisation bodies may be used for devices for which no harmonised standard exists.

Article 4
(Update of list of electromechanical devices and adaptation of this decree)

1. If the list attached to Law 1 of 4 January 1990 is further updated, the resultant adaptations shall be made to Annex 2 of this decree using the procedure provided for in Article 10.1 of said law.
2. Annex 2 to this decree may be amended, following technical and scientific advancements, including separately from amendments made to the list attached to Law 1 of 4 January 1990.

Article 5
(Amendment of technical standards)

1. These provisions are intended to be automatically adapted to any amendments made by the relevant standardisation bodies to the technical standards for electromechanical beauty-treatment devices following adoption of this decree, for which suitable public notice shall be given in accordance with the provisions set out by the Ministry of Economic Development.

This decree, bearing the State seal, shall be included in the official collection of legal acts of the Italian Republic. All interested parties shall be bound to observe and ensure observance of this decree.

Rome,

Minister for Economic
Development

Minister for Health

Annex 1
(Article 1.2)

LIST OF ELECTROMECHANICAL BEAUTY-TREATMENT DEVICES (ANNEX TO LAW 1/90)

Vaporiser with unheated ionised and normal steam

Ultrasound stimulators and micro-current stimulators

Disincrusting device for cleaning with an intensity not exceeding 4 mA

Device for suctioning blackheads with pipes and a combined action to smooth the skin with mineral powders or fluids or equivalent materials

Atomising filiform shower at pressures no greater than 80 kPa

Appliances for skin-level mechanical massage, electrical massage with horizontal oscillation or rotation

Electrical and manual rollers

Oscillating electrical vibrators

Devices for mechanical or electrical patten massage

Tanning solariums with UVA lamps or combined or separate ultraviolet (UV) and infrared (IR) applications

Massage appliances using air or water with air at pressures up to 80 kPa

Heater for depilatory wax

Aesthetic gymnastics equipment

Manicure and pedicure equipment

Partial or total heat treatment appliances using resistive or capacitative radiofrequency

Suction massage device with different sized cups and moving, fixed, and rhythmic application with suction not exceeding 80 kPa

Iontophoresis beauty-treatment appliances on 1 mA per cm² plates

Electrical epilators using needles, tweezers or equivalent accessories or light pulses for photo-epilation

Devices for underwater massage

Pressure massage devices

Pulsed electrostimulator

Massage appliances using compressed air at pressures up to 80 kPa

Soft laser for relaxing and toning skin treatment or photostimulating the reflexogenic areas of the feet and hands

Defocused aesthetic lasers for epilation

Saunas and steam rooms

Annex 2
(Article 2)

TECHNICAL INFORMATION SHEETS SETTING OUT THE DYNAMIC TECHNICAL CHARACTERISTICS,
ADJUSTMENT MECHANISMS, IMPLEMENTING METHODS, AND PRECAUTIONS TO BE TAKEN DURING
USE OF ELECTROMECHANICAL BEAUTY-TREATMENT DEVICES

TECHNICAL INFORMATION SHEET 1

Category : VAPORISERS
Device list : Vaporiser with unheated ionised and normal steam
(as per Annex to Law 1 of
4 January 1990)

1) DYNAMIC TECHNICAL CHARACTERISTICS

- **Device description:**

Device used to produce water vapour at a temperature not exceeding boiling point in different environmental conditions with water boiling at atmospheric pressure, for beauty treatments for the face, body, and scalp.

The steam produced is discharged through a nozzle made of glass, metal, plastic or other suitable material.

It may be accompanied by steam ionising devices using ultraviolet lamps or ion generators. Such devices must be built such as to make them and their direct emissions inaccessible to the skin and eyes of the treatment recipient and/or the operator during normal operation.

The device must have an indicator of the maximum water level, which must not be exceeded.

The concentration of ozone produced by steam ionising devices must be below the levels indicated in Standard CEI-EN 60335-2-65 over a total operating time of 8 hours with cycles of 15 minutes on and 5 minutes off, in consideration of the time required to refill the water tank.

- **Mechanism of action (application):**

The flow of ionised steam, appropriately aimed at the body part to be treated, facilitates the dilation of skin pores and the consequent expulsion of any impurities present, having a toning and cleaning effect on the skin.

2) IMPLEMENTING METHODS AND USAGE PRECAUTIONS

- a) The steam flow must be aimed at the treatment recipient's face from a distance of at least 40–50 cm.
- b) The treatment may last between 10 and 20 minutes, and must not exceed 30 minutes.
- c) Use distilled water, unless otherwise indicated by the manufacturer.
- d) Contact with the heated nozzle may cause burns.
- e) Do not use on people with capillary fragility or telangiectasias (dilated capillaries).

WARNINGS

In addition to the above, carefully follow any instructions, warnings, and usage precautions given in the manual provided by the manufacturer.

3) APPLICABLE TECHNICAL STANDARDS including relating to adjustment mechanisms

Standard CEI EN 60335-1:2004 Safety of household and similar electrical appliances.
(CEI 61-150) Part 1: General requirements.
Third edition of 1 April 2004.
File 7286 C

ALTERNATIVE

Standard CEI EN 60335-1/A1/A11 of 1 January 2006 Classif. CEI 61-150; V1 File 8099

Standard CEI EN 60335-2-98:2005 Safety of household and similar electrical appliances.
(CEI 61-204) Part 2: Particular specifications for humidifiers.

Second edition of 1 August 2005.
File 7815 E

Standard CEI EN 60335-2-65:2005-08 Safety of household and similar electrical appliances.
Part 2: Particular requirements for air-purification devices.

These standards are not intended for devices used specifically in beauty treatment centres, although such products may be referenced against products covered by the aforementioned standards.

TECHNICAL INFORMATION SHEET 2A

Category:	STIMULTORS	
Device list:	ULTRASOUND STIMULATORS	
(as per Annex to Law 1 of 4 January 1990)	A1) Vibrating mechanical peel:	≥ 22 kHz – ≤ 28 kHz
	A2) Ultrasound for surface treatments:	> 0.8 MHz – ≤ 3.5 MHz

A1) Vibrating mechanical peel

DYNAMIC TECHNICAL CHARACTERISTICS

Device description:

Mains- and/or battery-powered device comprising a low-frequency current generator that triggers the contraction of a piezoelectric crystal applied to a metal plate (stainless steel) such as to produce vibrations at the same rate as the input frequency.

The hand piece comprises a plastic handle containing a stainless-steel plate, with a protruding part measuring about 4 cm. Two to six piezoelectric capsules are placed on the part of the plate inside the handle.

The handle of the application hand piece must be mechanically separated from the vibrating plate by means of a damping pad made of rubber or similar material so that no vibration is felt in the operator's hand.

The maximum power drawn by such devices must not exceed 70 W on a 230 VAC power line.

The maximum output power must not exceed 10 W in total.

The operating frequency must be between 22 and 28 kHz (typical frequency 25 kHz).

Mechanism of action (application):

A liquid or gel product must be applied to the area of skin to be treated. By applying the metal plate to the skin with the point inclined to about 30° to the skin, the vibration nebulises the product applied, which carries away dead cells and related impurities from the surface of the skin.

The end of the vibrating plate is typically, although not necessarily, curved. Curved-plate applicators may be used to speed up absorption of various cosmetic products and creams. To do so, the curved part of the plate should be placed flat on the skin.

USAGE PRECAUTIONS AND IMPLEMENTING METHODS

Usage precautions:

Read the usage manual carefully before use to prevent improper usage.

Do not treat people with sensitive skin.

Do not treat people who have already undergone a skin peel using other systems or mechanical-vibration or acid-based (glycolic, salicylic) systems in the past thirty days.

Suitable sterilisation and/or disinfecting of all elements coming into contact with the treatment recipient is recommended.

Perform applications quickly and in a manner suitable to the treatment to be performed.

Do not apply to red skin, open wounds or abrasions.

Apply only to unbroken skin.

Do not use on people with active hearing aids or hearing problems.

Implementation method:

Before each application, carefully check the condition of the applicator plate, which should be smooth, perfectly round, and free of any sharp edges or points.

Output may be continuous, pulsed or of adjustable intensity.

Treatment times depend on the intensity used.

Make quick and uniform movements throughout the area to be treated. Minimum pressure should be applied by the plate on the skin.

A2) High-frequency ultrasound

DYNAMIC TECHNICAL CHARACTERISTICS

Device description:

Mains- and/or battery-powered device comprising a high-frequency current generator that triggers the contraction of a piezoelectric crystal applied to an output head such as to produce vibrations at the same rate as the input frequency.

The mobile applicator comprises a handle made of plastic, rubber or similar with an output head made of steel, aluminium or other metal.

The handle of the application hand piece must be mechanically separated from the output head by means of a damping pad made of rubber or similar material such as to limit the transmission of ultrasound to the operator's hand.

The fixed applicator comprises a support made of rubber, fabric, plastic, aluminium or another material with one or more piezoelectric capsules. The maximum power of this applicator must comply with the table below.

The maximum output power depends on the frequency used in accordance with the values given in the table.

Frequency	Power in W per cm ²
≥ 0.8 ≤ 1.2 MHz	1.5 W Max
< 1.2 ≤ 3.5 MHz	3 W Max

The operating frequency must be between 0.8 MHz and 3.5 MHz.

The device must have circuits that guarantee against the unintentional emission of ultrasound.

The device must permit output power to be adjusted and include circuits to limit the maximum preset value.

The maximum output power must not exceed the table values. To measure the power emitted from 0.5 to 1 MHz, refer to Standard 60601-2-5. For higher frequencies, the method described in paragraphs 3.9, 3.10, and 3.11 should be used.

The intensity of unintentional ultrasound emissions to the hand piece handle must be less than 100 mW. Reference Standard CEI EN 60601-2-5

The output head must not reach temperatures that could cause damage to the skin. With regard to this, see technical standard CEI EN 60601-2-5:2001-11 - Set-up to test temperature of radiating surfaces (v. 42.3).

Mechanism of action:

Skin texture can be improved by applying high-frequency ultrasound. Mechanical micro-stressing boosts interstitial fluid levels and improves skin toning. The device may be used to treat moderate skin laxity and to reduce surface wrinkles.

USAGE PRECAUTIONS AND IMPLEMENTING METHODS

Usage precautions:

Read the usage manual carefully before use to prevent improper usage.

Do not treat people with sensitive skin or intolerance to conductive gel.

Suitable sterilisation and/or disinfecting of all elements coming into contact with the treatment recipient is recommended.

Apply only to unbroken skin.

Do not use on people with active hearing aids or hearing problems.

Use is not recommended in the following cases:

Metal joint replacement implants	Near to cartilage	Pregnancy
Current inflammations	Near to reproductive organs	Presence of varices
Skin lesions	Near to the cardiac zone	Near to bone
People with pacemakers	Neoplasia	

Implementation method:

Set the appropriate treatment time and power for the area to be treated in accordance with the instruction manual. Use low power initially.

To guarantee perfect contact between applicator and skin, apply gel to the area to be treated.

Rest the applicator on the area to be treated.

For the mobile applicator, activate ultrasound emissions and move it slowly, constantly, and uniformly. For the fixed applicator, ensure correct positioning and fixing. Check the constant presence of the appropriate gel.

APPLICABLE TECHNICAL STANDARDS including relating to adjustment mechanisms

Include three categories A1, A2, and A3

Italian Standard CEI 62-39:1998
File 3639 R

Electrical beauty-treatment devices
General safety guide

Standard CEI EN 60601-2-5
Second edition
Classification CEI 62-23:2001
Publication date: 1 November
2001
File 6298

Electrical medical devices.
Specific safety standards for neuromuscular stimulators (this standard shall only apply to build characteristics and adjustment mechanisms, since the intended use is not medical).

Standard CEI EN 60601-2-3:1998
(IEC 60601-2-3:1991
Classif. CEI 62.14
Amending A1:1998 to CEI EN60601-2-3

Electrical medical devices
Part 2: Particular requirements for the safety of short-wave therapy equipment.
1998; (IEC60601-2-3:1991/A1:1998)

Standard CEI EN 60601-2-5:2001-11
Standard CEI EN 62-23:1998-04

Set-up to test temperature of radiating surfaces (v. 42.3)
Set-up to test for unintentional radiation from treatment head (35.1).

TECHNICAL INFORMATION SHEET 2B

Category: STIMULTORS

Device list: MICROCURRENT STIMULATORS

(as per Annex to Law 1 of
4 January 1990)

1) DYNAMIC TECHNICAL CHARACTERISTICS

Device description:

Mains- and/or battery-powered device comprising a waveform micro-current pulse generator at fixed or variable frequencies and a handpiece to hold electrodes (bulbs) of different shapes and made of different appropriate materials, typically transparent or coloured glass. The handpiece includes a handle made of an insulating material.

Neither the frequency nor the intensity of the leakage current that passes from the electrode to the body of the treatment recipient must be such as to cause effects harmful to health. The maximum value is set at 200 micro-amps.

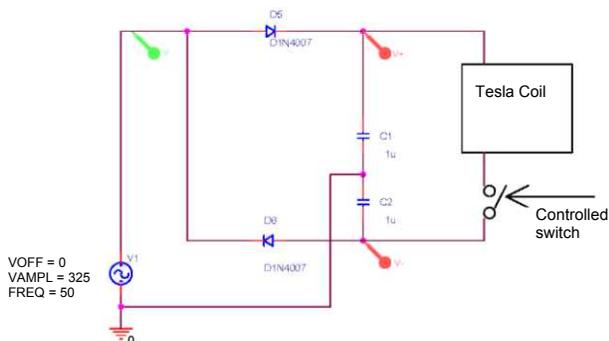
The device must have controls for adjusting the energy outputted with maximum limits within the limits set in the Standards.

The mains power used by the devices shall not exceed 50 W. The typical frequency shall be 100 Hz generated by rectifying the half wave to duplicate the 50 Hz mains supply. Other frequencies taken from static oscillators may be used, and in all cases the frequency must be between 50 and 400 Hz. The waveforms shall be sinusoidal.

The values given below by way of example relate to a 230 VAC/50 Hz mains supply.

Current drawn from the mains: 100 mA – Power drawn from the mains: 23 W

The electrical circuit comprises a voltage multiplier generating a voltage.



This voltage is applied to the equivalent condenser comprising C1 and C2 that accumulates 0.1 joule of energy.

The controlled switch is typically an SCR that closes at twice the mains frequency, i.e. 100 Hz.

When the switch is closed, it discharges the energy accumulated in the condenser to the Tesla coil primary that, having a turns ratio of 1:200, generates an overvoltage in the secondary. The capacitive discharge is of extremely low intensity. The discharge emitted is not applied directly to the treatment recipient but is attenuated and filtered by the glass bulb, where the discharge takes place. The dielectric strength of the glass is 25–100 kV/mm.

The overvoltage is synchronous at 100 Hz but comprises a damped-wave transient triggered by a voltage peak that decreases to zero (total transient duration about 3/5 millisecond).

Knowing the energy transferred to the primary, the voltage of the secondary and the repetition of the pulses gives a secondary current of around 100 micro-amps (0.1 mA).

Consequently, the micro-current delivered to the treatment recipient is a 100 Hz pulse with a maximum peak value of 100 micro-amps and a sinusoidal waveform decreasing to zero with around 5 half-waves. The event has a duration (per pulse) of around 3/5 milliseconds.

Light emissions:

During treatment, the electrode, which comprises a glass bulb filled with gas (argon, neon or other), assumes the colour of the gas enabling the electrical discharge. The gases contained in the bulbs are only intended to enable the electrical discharge, as with normal fluorescent domestic, industrial or street lights using sodium or mercury vapour.

Typically, the bulb assumes a very weak bluish colour. Measurements taken at maximum power have revealed values of less than 0.05 W. In consideration of the wavelengths and the low light output, the effect of such emissions is deemed to be zero, and therefore to have no positive or negative effects on the human body.

Mechanism of action (application):

Using the handpiece and the electrodes fitted to it, an action is performed on the skin to reactivate the skin surface microcirculation (by stimulation) and to remove dead cells on the stratum corneum, as in other desincrustation methods (exfoliating action).

The action is performed zonally. Concentrating on the chosen area triggers slight cutaneous hyperaemia, which encourages reactivation and improves the general appearance of the area. Reddening indicates correct operation. Reddening should normally disappear very quickly.

2) USAGE PRECAUTIONS AND IMPLEMENTING METHODS

Usage precautions:

Read the usage manual carefully before use to prevent improper usage.

Remove necklaces, earrings, piercings, and other metal objects before use.

Suitable sterilisation and/or disinfecting of all elements coming into contact with the treatment recipient is recommended.

For correct usage, users are recommended to insert the electrode correctly into the handpiece and to check that it is properly affixed. The electrode insertion force must be between 30 and 50 N.

If not securely inserted, the electrode may become dislodged, fall and break. Although there is no direct evidence of potential injury arising from the handpiece electrode becoming dislodged, the system should nonetheless not be used unless it complies with the aforementioned requirements. The device must be turned off to insert or remove the electrode.

Do not treat people with very sensitive skin, or reduce application times and output powers. Treatment tolerance should always be checked.

Do not apply to clothes, but directly to the skin.

Do not apply to red skin, open wounds, abrasions or moles that are not clearly identified.

Apply only to unbroken skin.

Do not apply to parts of the body that contain metal implants (fillings, dental implants, artificial limbs, etc.).

Do not apply to people with pacemakers, insulin pumps, hearing aids or active implantable devices.

Implementation method

Carefully check the integrity of the glass electrode before each application.

Do not use inflammable cosmetics before or during treatment.

Properly adjust the intensity of the micro-current emission in consideration of the fact that, even at maximum power, the treatment recipient must not suffer any discomfort.

Position the electrode on the area to be treated and then activate the micro-current emission.

A pre-treatment is recommended to assess the recipients tolerance of the treatment, as follows:

Apply the treatment at low power, about 30 % of maximum power.

After about one minute's treatment, check the condition of the skin treated. It should not show any reddening. If it does, stop the treatment and apply a soothing cosmetic cream. In any case, the reddening should disappear in a few minutes.

If no reddening occurs, increase the output power to the appropriate value and perform the treatment in consideration of the maximum times recommended.

Treatment times depend on the intensity used. In any case, it is advisable not to exceed 10 minutes' treatment for an area of about 25 cm by 25 cm, the approximate size of the face. Neck and chest treatment times should not exceed 10 minutes.

Make slow and uniform movements throughout the area to be treated. The electrode need not be pressed particularly hard against the skin.

During treatment, do not remove the electrode from the skin, but keep it in constant contact. Removing the electrode from the skin may cause discomfort to the treatment recipient.

3) APPLICABLE TECHNICAL STANDARDS *including relating to adjustment mechanisms*

Italian Standard CEI 62-39:1998
File 3639 R

Electrical beauty-treatment devices
General safety guide

Standard CEI EN 60601-2-10
Classification CEI 62-24
Second edition 1 November 2001
File 6296

Electrical medical devices.
Specific safety standards for neuromuscular stimulators (this standard shall only apply to build characteristics and adjustment mechanisms, since the intended use is not medical).

Alternative Standard CEI EN 60601-2-10/A1
Classif. CEI 62.24; V1 of 1 November 2002
File 6723

TECHNICAL INFORMATION SHEET 3

Category : DISINCRUSTATION DEVICE
Device list : Disincrusting device for cleaning with an intensity not exceeding 4 mA
(as per Annex to Law 1 of
4 January 1990)

1) **DYNAMIC TECHNICAL CHARACTERISTICS**

- **Device description:**

Mains- and/or battery-powered device having a direct-current generator with a maximum voltage of 24 V. The low direct current is applied by two electrodes touching the treatment recipient. This cleans the epidermis.

This includes a device for gradually adjusting the current intensity from 0 to 4 mA, and possibly a control indicator and a current limiter to prevent the output of currents over 4 mA.

Limiting the voltage of the direct-current generator and the current intensity limiter to 4 mA guarantees the safety of the treatment recipient.

The usage manual must state that the current intensity applied must be barely detectable.

During manufacture, the PERMANENT ADMISSIBLE LEAKAGE CURRENT VALUES set out in the applicable technical standards must be strictly observed.

The current density of each electrode must not exceed 0.1 mA/cm².

- **Mechanism of action (application):**

The disincrusting effect is obtained by the passage of a weak direct current that penetrates the area being treated and liquefies the sebum in the pores of the skin, facilitating the cleaning action.

2) **IMPLEMENTING METHODS AND USAGE PRECAUTIONS**

In addition to the instructions given in the technical standards, only apply this beauty treatment to healthy recipients with no on-going medical conditions.

Before using the device, carefully read the usage manual and, in particular, the following warnings:

- apply only to healthy, unbroken skin with no abrasions, lesions, irregularly shaped moles, boils, etc.
- do not apply the treatment to people with pacemakers or active electronic implantable devices;
- do not apply near metal artificial limbs;
- do not apply treatment to pregnant women;
- do not apply treatment to the abdominal area of women with inter-uterine devices implanted.

If mains-powered, the electrical equipment must comply with Law 46/90.

Adjust the intensity of the output current to a level that is not harmful to the health of the treatment recipient, in accordance with the thresholds provided for in the standards listed in point 3 below.

WARNINGS

Suitable sterilisation and/or disinfecting of all elements coming into contact with the treatment recipient is recommended.

In addition to the above, carefully follow any instructions, warnings, and usage precautions given in the manual provided by the manufacturer.

3) **APPLICABLE TECHNICAL STANDARDS** including relating to adjustment mechanisms

Italian Standard CEI 62-39:1998	Electrical beauty-treatment devices
File 3639 R	General safety guide
Standard CEI EN 60601-2-10	Electrical medical devices.
Classif. CEI 62-24:	Specific safety standards for neuromuscular stimulators (this standard shall only
Second edition	apply to build characteristics and adjustment mechanisms, since the intended use is
1 November 2001	not medical).
File 6296	

ALTERNATIVE

Standard CEI EN 60601-2-10/A1 Classif. CEI 62-24; V1 of 1 November 2002 File 6723

NB: These standards shall only apply to the build characteristics and adjustment mechanisms of the devices, since the intended use is not medical.

When considering the specific electromagnetic compatibility requirements set out in these standards, it should be noted that these requirements are related to Standard CEI EN 60601-1-2:2003+A1:2006 – Electrical medical devices – Part 1: General safety standards – Collateral standard: Electromagnetic compatibility – Requirements and tests (IEC 60601-1-2:2001+A1:2004).

TECHNICAL INFORMATION SHEET 4

Category	:	DEVICES FOR BLACKHEAD SUCTION AND FACE CLEANSING
Device list (as per Annex to Law 1 of 4 January 1990)	:	a) Device for suctioning blackheads using suction and pipes up to one centimetre in diameter b) Device for suctioning blackheads with a combined action to smooth the skin with mineral powders or fluids or equivalent materials

1) DYNAMIC TECHNICAL CHARACTERISTICS

- **Device description (a):**

Mains- and/or battery-powered device comprising a motor that drives an electrical pump connected to a flexible tube that does not conduct electricity, to a pipe made of glass, metal, plastic or another suitable material up to one centimetre in diameter.

The device may be fitted with a flow regulator and a pressure gauge. The suction pressure shall not exceed 80 kPa.

- **Device description (b):**

Suction device as described in point (a) above, having a pipe of suitable shape and material that enables the correct flow of therapeutic disposable mineral powders or fluids or equivalent materials suctioned from a suitable tank and ideally channelled and intended exclusively for cleaning and smoothing skin. The suction pressure shall not exceed 80 kPa.

- **Mechanism of action (application):**

Controlled suction applied to the skin by terminals of different shapes and sizes and, in certain cases, specific disposable mineral powders or fluids or equivalent materials are used to remove blackheads and to clean and smooth the skin.

2) IMPLEMENTING METHODS AND USAGE PRECAUTIONS

Pass the suction pipe over the treatment area, carefully checking the integrity of the pipe before using on the treatment recipient.

WARNINGS

Suitable sterilisation and/or disinfecting of all elements coming into contact with the treatment recipient is recommended.

In addition to the above, carefully follow any instructions, warnings, and usage precautions given in the manual provided by the manufacturer.

3) APPLICABLE TECHNICAL STANDARDS including relating to adjustment mechanisms

Standard CEI EN 60335-1:2004 Safety of household and similar electrical appliances.

(CEI 61-150) Part 1: General requirements.

Third edition of 1 April 2004

File 7286 C

ALTERNATIVE

Standard CEI EN 60335-1/A1/A11 of 1 January 2006 Classif. CEI 61-150; V1 File 8099

This standard is not intended for devices used specifically in beauty treatment centres, although such products may be referenced against products covered by the aforementioned standard.

TECHNICAL INFORMATION SHEET 5

Category : ATOMISING/FILIFORM SHOWER
Device list : Atomising/filiform shower at pressures no greater than one atmosphere
(as per Annex to Law 1 of
4 January 1990)

1) **DYNAMIC TECHNICAL CHARACTERISTICS**

- **Device description:**

Mains- and/or battery-powered device comprising a motor that drives a pump or a pressurised device supplying compressed air that is connected using a flexible tube to a container with a device for supplying a filiform or atomised jet (spray).

In some models, the airflow may be enriched with oxygen and/or toning substances to restore freshness, elasticity, and vitality to the skin.

The device may be fitted with a flow regulator.

- **Mechanism of action (application):**

This device is used to facilitate and encourage the uniform application of cosmetic products on the skin.

This is achieved by atomising, spraying or showering, at pressures no greater than one atmosphere.

2) **IMPLEMENTING METHODS AND USAGE PRECAUTIONS**

Aim the applicator jet at the treatment area.

Do not aim the applicator spray at the eyes or airways.

WARNINGS

In addition to the above, carefully follow any instructions, warnings, and usage precautions given in the manual provided by the manufacturer.

3) **APPLICABLE TECHNICAL STANDARDS** including relating to adjustment mechanisms

Standard CEI EN 60335-1:2004 Safety of household and similar electrical appliances.

(CEI 61-150) Part 1: General requirements.

Third edition of 1 April 2004

File 7286 C

ALTERNATIVE

Standard CEI EN 60335-1/A1/A11 of 1 January 2006 Classif. CEI 61-150; V1 File 8099

This standard is not intended for devices used specifically in beauty treatment centres, although such products may be referenced against products covered by the aforementioned standard.

TECHNICAL INFORMATION SHEET 6

Category

MESSAGE DEVICES

Device list

(as per Annex to Law 1 of
4 January 1990)

- a) Devices for mechanical massage at superficial, skin level
 - b) Devices for electrical massage, having only horizontal oscillation or rotation and only flat accessories or brushes
 - c) Electrical and manual rollers (including portable)
 - d) Oscillating electrical vibrators
 - e) Devices for mechanical padder massage (not electrical)
 - f) Devices for electrical padder massage
-

1) DYNAMIC TECHNICAL CHARACTERISTICS

- Device description:

Mechanical devices or devices with an electrical motor that are used to provide padder, roller, oscillating or vibrating massage via specific sphere-, roller-, cylinder-, plate- or other-shaped applicators suitable for providing the treatment that are made of wood, plastic, rubber, metal or any other suitable material.

- Mechanism of action (application):

The beauty-treatment devices covered by this category are intended to make traditional beauty-treatment massage easier and less tiring for the masseur.

2) IMPLEMENTING METHODS AND USAGE PRECAUTIONS

Before starting the treatment, check the integrity and functionality of the devices chosen for the treatment.

Do not use on recipients with capillary fragility, visible oedemas or bruising.

WARNINGS

Suitable sterilisation and/or disinfecting of all elements coming into contact with the treatment recipient is recommended.

In addition to the above, carefully follow any instructions, warnings, and usage precautions given in the manual provided by the manufacturer.

3) APPLICABLE TECHNICAL STANDARDS including relating to adjustment mechanisms

Standard CEI EN 60335-1:2004 Safety of household and similar electrical appliances.

(CEI 61-150) Part 1: General requirements.

Third edition of 1 April 2004

File 7286 C

ALTERNATIVE

Standard CEI EN 60335-1/A1/A11 of 1 January 2006 Classif. CEI 61-150; V1 File 8099

Standard CEI EN 60335-2-32:2005 Safety of household and similar electrical appliances.

(CEI 61-163) Part 2: Particular requirement for massage devices.

Third edition of 1 July 2005

File 7782 E

These standards are not intended for devices used specifically in beauty treatment centres, although such products may be referenced against products covered by the aforementioned standards.

TECHNICAL INFORMATION SHEET 7

Category	:	TANNING SOLARIUM
Device list (as per Annex to Law 1 of 4 January 1990)	:	a) UVA tanning lamps b) Quartz lamps with combined or separate ultraviolet (UV) and infrared (IR) applications

1) DYNAMIC TECHNICAL CHARACTERISTICS

- General introduction and device description:

Sources of ultraviolet (UV) radiation and the different devices in which they are fitted (solariums, sunbeds, etc.), whether type (a) or (b), are used to irradiate the skin in order to trigger various photochemical phenomena that result in the pigmentation of the exposed skin (photoinduced tanning using UV from artificial sources). The combined or separate use of infrared (IR) lamps is optional.

Artificial tanning devices have developed since they first appeared, in particular with regard to (a) the emission spectrums of the radiating source, (b) the radiation exposure or dosage per session, and (c) the maximum permitted irradiation, and this process is ongoing on account of the research intended to identify and reduce the risk of short- and long-term damage related to this type of beauty treatment.

The first lamps used emitted UVC, UVB, UVA, and visible light simultaneously. Their use in beauty treatments was related to the not infrequent risk of burns. Partially on account of this, in the 1980s they were replaced by other types of emitters, such as fluorescent lamps and properly filtered high-pressure metal-halide discharge lamps.

Use of these new types of lamps has had the following effects:

- a) UVC emissions have been almost completely eliminated;
- b) it is now possible to produce devices with different emission spectrums, i.e. different ratios between the intensities of the UVB and UVA components, up to the well known UVA device, which only emits in this spectral region.

The scientific community currently believes that the UV radiation sources most suitable for tanning skin are those in the spectrum most similar to the solar spectrum.

2) IMPLEMENTING METHODS AND USAGE PRECAUTIONS

Indoor tanning devices must be built in accordance with the reference standards and used strictly in accordance with the instructions given by the manufacturer and set out in the usage manual provided with each device model.

Ultraviolet radiation from the sun and UV devices may damage the skin and eyes. These biological effects depend on the quality and quantity of the radiation, as well as the sensitivity of the individual's skin and eyes.

Exposure to ultraviolet radiation from the sun or UV devices may cause premature ageing of the skin and increase the risk of developing cutaneous neoplasms. Indeed, in 2009 the International Agency for Research on Cancer (IARC) classified devices that emit UV radiation for artificial tanning as a Group 1 carcinogen for humans. For these reasons, the World Health Organisation advises against the use of artificial tanning devices by anyone.

Unprotected eyes may develop superficial inflammations and, in some cases, excessive exposure may result in retina damage following a cataract operation. Cataracts may develop after repeated exposure.

Special care should be taken by people who are particularly sensitive to ultraviolet radiation or if any medicines or cosmetics are used.

The following precautions should therefore be taken:

- always use suitable protective goggles, which must be provided to the client for use during tanning sessions;
- remove all types of cosmetic product and do not apply protective creams or products to accelerate tanning;
- do not undergo treatment while taking any drugs that increase sensitivity to ultraviolet radiation. If in doubt, consult a doctor;
- observe the recommended exposure times, exposure frequency and lamp distances;
- seek medical advice if the skin develops any pigmented lesions or irritation or any other relevant alteration. People who are particularly sensitive to the sun should notify the operator before undergoing tanning treatment.

People undergoing treatment are strongly advised to determine their own skin phototype and to familiarise themselves with the risks related to exposure.

Operators providing tanning services shall advise on the most suitable devices and exposure times on the basis of the user's skin phototype and the manufacturer's guidelines.

Before treatment, the recipient must be informed of the harmful effects of exposure to UV rays.

For the same reasons, signs must be displayed visibly in the immediate vicinity of the devices providing specific information on the risk of effects harmful to the user's health and that usage is not recommended, in particular for people in the following categories:

- People with lots of moles (> 25).
- People liable to have freckles.
- People with a history of frequent sunburn in childhood and adolescence.
- People taking medication. In this case, medical opinion should be sought to determine whether such medication may increase photosensitivity to UV.

These guidelines shall be clearly displayed along with the following recommendations:

- People who do not tan or who burn easily in natural sunlight (skin phototypes I and II) should not undergo treatment
- Treatment recipients must not be exposed to sunlight for 48 hours after a tanning session
- Wear protective goggles
- People with sun-damaged skin should not undergo treatment.
- People suffering from erythema should not undergo treatment
- People suffering, or who have suffered in the past, from cutaneous neoplasms, or people with a family history of cutaneous neoplasms.

The use of devices that also emit UVB requires particular usage precautions and assessment of the cumulative dosage to which the recipient is exposed.

The user must be given a personal form detailing all UVA and UVB doses received.

Do not treat people with skin diseases that may be aggravated by UV exposure.

Remove contact lenses before undergoing treatment.

As with any electrical device, exercise extreme caution around water.

Never use the device in extremely damp conditions.

Never allow skin to redden.

Tanning machines may not be used by:

- people under 18 years of age
- pregnant women
- people suffering from, or who have in the past suffered from, cutaneous neoplasms.
- People who do not tan or who burn easily when exposed to sunlight.

The device is used exclusively for beauty and not therapeutic purposes. Consequently, no beneficial effects may be claimed.

The effective erythral irradiance of the devices must not exceed 0.3 W/m².

- Device maintenance

The manufacturer shall issue a compliance statement for each device.

The operator must fulfil the schedule of periodic technical inspections specified by the manufacturer and relating to efficiency and safety.

In order to maintain initial safety conditions and to safeguard users against potential tampering with the device, replacement parts authorised for individual devices should only be defined by the manufacturer and/or the entity in charge of placing the product on the market.

It is advisable to place tanning devices in premises or areas that are suitable in consideration of hygiene factors and in a position that prevents potential accidental radiation.

- Guidelines and recommendations for correct usage:

The maximum duration of first and subsequent sessions should be indicated by the manufacturer on the basis of the spectrophotometric analyses carried out on the device and the skin phototype of the treatment recipient.

For people with sensitive skin, which is slightly dehydrated by the tanning treatment, specific cosmetic emollients may be applied on completion of the treatment, in accordance with the guidelines given by the beautician.

A gap of about one month is recommended between successive tanning treatments.

See the table provided by the manufacturer on exposure times and the duration of tanning treatment, as well as the minimum service life of the lamps.

- Warnings:

After the first application, recipients should wait 48 hours before the next treatment, after which the treatments must be applied no less than 24 hours apart.

Exposure to the sun following tanning treatment on the same day is dangerous.

Disinfecting of all elements coming into contact with the treatment recipient is recommended.

Use of tanning devices (UV) must be restricted to skilled staff with specific theoretical and practical training who are able to use the equipment correctly and to assess the treatment recipient's skin condition.

In addition to the above, carefully follow any instructions, warnings, and usage precautions given in the manual provided by the manufacturer.

3) APPLICABLE TECHNICAL STANDARDS including relating to adjustment mechanisms

Standard CEI EN 60335-1:2004

(CEI 61-150)

Third edition of 1 April 2004

File 7286 C

And subsequent

ALTERNATIVES

Safety of household and similar electrical appliances.

Part 1: General requirements

Standard CEI EN 60335-2-27:2005

(CEI 61-184)

Fourth edition

of 1 July 2005

File 7753

ALTERNATIVES

Safety of household and similar electrical appliances.

Part 2: Particular requirements for appliances for skin exposure to ultraviolet and infrared radiation.

1) Standard CEI EN 60335-2-27/A1:2009-03

2) Standard CEI EN 60335-2-27/A2:2009-03

TECHNICAL INFORMATION SHEET 8

Category	:	AIR MASSAGE DEVICES
Device list (as per Annex to Law 1 of 4 January 1990)	:	Air-massage devices at pressures up to one atmosphere

1) **DYNAMIC TECHNICAL CHARACTERISTICS**

- **Device description:**

Device driven by an electric motor to generate a continuous or pulsing airflow at pressures not exceeding one atmosphere, which is aimed at the area to be treated using a flexible tube with a suitable nozzle attached. The airflow may be regulated by changing the motor speed and/or the nozzle diameter. Mains- and/or battery-powered.

- **Mechanism of action (application):**

Using suitable pipes or cups of different shapes and sizes, the continuous or pulsing airflow is aimed at the treatment area. Doing this and moving the pipes correctly lightly massages the skin.

2) **IMPLEMENTING METHODS AND USAGE PRECAUTIONS**

Do not aim the airflow at or around the eyes or at the ears.

WARNINGS

Suitable sterilisation and/or disinfecting of all elements coming into contact with the treatment recipient is recommended. In addition to the above, carefully follow any instructions, warnings, and usage precautions given in the manual provided by the manufacturer.

3) **APPLICABLE TECHNICAL STANDARDS** including relating to adjustment mechanisms

Standard CEI EN 60335-1:2004 Safety of household and similar electrical appliances.
(CEI 61-150) Part 1: General requirements.
Third edition of 1 April 2004
File 7286 C

ALTERNATIVE

Standard CEI EN 60335-1/A1/A11 of 1 January 2006 Classif. CEI 61-150; V1 File 8099

This standard is not intended for devices used specifically in beauty treatment centres, although such products may be referenced against products covered by the aforementioned standard.

TECHNICAL INFORMATION SHEET 9

Category: WATER MASSAGE DEVICES

Device list: Water-massage device with **AIR** at pressures up to **100 kPa**
(as per Annex to Law 1 of
4 January 1990)

1) DYNAMIC TECHNICAL CHARACTERISTICS

- **Device description:**

Mains- and/or battery-powered device driven by an electric motor generating an airflow channelled along a tube to a special distributor immersed in water and having numerous holes emitting air bubbles that, in turn, provide a water massage.

The air produced, which may be heated, may be ionised using ultraviolet lamps or ion generators. Such devices must be built such as to make them and their direct emissions inaccessible to the skin and eyes of the treatment recipient and/or the operator during normal operation.

The concentration of ozone produced by steam ionising devices must be below the levels indicated in Standard CEI-EN 60335-2-65 with cycles of 50 minutes on and 10 minutes off over a total operating time of 8 hours.

The flow may be regulated by changing the motor speed and/or the diameter of the air outlets. The device may be fitted with a vibration device driven by the airflow.

- **Mechanism of action (application):**

The air bubbles produced and contained in the water that are aimed at the treatment area have a massaging effect on the skin known as a water massage.

2) IMPLEMENTING METHODS AND USAGE PRECAUTIONS

Having immersed the air distributor, place the treatment recipient in a technically suitable position.

Place the airflow generator in a safe place in consideration of the possibility of the generator accidentally falling into the water-filled tub.

WARNINGS

In addition to the above, carefully follow any instructions, warnings, and usage precautions given in the manual provided by the manufacturer.

The devices must provide at least IPX4-level protection against water.

3) APPLICABLE TECHNICAL STANDARDS including relating to adjustment mechanisms

Standard CEI EN 60335-1:2004 Safety of household and similar electrical appliances.
(CEI 61-150)

Part 1: General requirements.

Third edition of 1 April 2004

File 7286 C

ALTERNATIVE

Standard CEI EN 60335-1/A1/A11 of 1 January 2006 Classif. CEI 61-150; V1 File 8099

Standard CEI EN 60335-2-60:2006 Safety of household and similar electrical appliances.
(CEI 61-200)

Part 2: Particular requirements for whirlpool baths.

Third edition of 1 February 2006

File 8146

These standards are not intended for devices used specifically in beauty treatment centres, although such products may be referenced against products covered by the aforementioned standards.

TECHNICAL INFORMATION SHEET 10

Category

HEATER FOR DEPILATORY WAX

Device list:

Heater for depilatory wax

(as per Annex to Law 1 of
4 January 1990)

1) **DYNAMIC TECHNICAL CHARACTERISTICS**

- Device description:

Electrical device used to heat and melt cosmetic wax used for depilation. It may be mains- and/or battery-powered, and may be fitted with a temperature adjustment thermostat.

2) **IMPLEMENTING METHODS AND USAGE PRECAUTIONS**

Insert the cosmetic product to be heated, melted or thinned in the appropriate space until it reaches the required state.

Carefully check that the treated product is not too hot.

Turn off and unplug the device at the end of the day.

Do not reuse the same wax on different people.

Keep the space where the product to be heated is placed clean.

Do not treat people with venous insufficiency (varices), capillary fragility, telangiectasias or skin irritation.

WARNINGS

In addition to the above, carefully follow any instructions, warnings, and usage precautions given in the manual provided by the manufacturer.

3) **APPLICABLE TECHNICAL STANDARDS** including relating to adjustment mechanisms

Standard CEI EN 60335-1:2004 Safety of household and similar electrical appliances.

(CEI 61-150) Part 1: General requirements.

Third edition of 1 April 2004

File 7286 C

ALTERNATIVE

Standard CEI EN 60335-1/A1/A11 of 1 January 2006 Classif. CEI 61-150; V1 File 8099

Standard CEI EN 60335-2-15:2003 Safety of household and similar electrical appliances.

(CEI 61-157) Part 2: Particular requirements for appliances for heating liquids.

Third edition

Date of publication 1 August 2003

File 7011

ALTERNATIVE

Standard CEI EN 60335-2-15/A1 of 1 January 2006 Classif. CEI 61-157; V1 File 8108

These standards are not intended for devices used specifically in beauty treatment centres, although such products may be referenced against products covered by the aforementioned standards.

TECHNICAL INFORMATION SHEET 11

Category	:	AESTHETIC GYMNASTICS EQUIPMENT
Device list (as per Annex to Law 1 of 4 January 1990)	:	a) Aesthetic gymnastics equipment b) Equipment with vibrating platform for muscle toning

1) **DYNAMIC TECHNICAL CHARACTERISTICS**

- **Device description (a):**

Equipment made of wood, plastic, metal or other suitable material used to coordinate movements in aesthetic gymnastics (toning movements).

The movement of the equipment may be driven by a mains-powered motor or using mechanical and manual devices.

- **Device description (b):**

Equipment for muscle toning comprising a platform with a vibrating motor on which the user assumes the appropriate position to stimulate the muscle groups to be treated. A series of handles and specific supports ensures that the user is safely and correctly positioned throughout use.

2) **IMPLEMENTING METHODS AND USAGE PRECAUTIONS**

Carefully follow any instructions, warnings, and usage precautions given in the manual provided by the manufacturer.

Not to be used by people with joint, muscle or tendon complaints.

3) **APPLICABLE TECHNICAL STANDARDS** including relating to adjustment mechanisms

For electrical devices:

Standard CEI EN 60335-1:2004 Safety of household and similar electrical appliances.

(CEI 61-150) Part 1: General requirements.

Third edition of 1 April 2004

File 7286 C

ALTERNATIVE

Standard CEI EN 60335-1/A1/A11 of 1 January 2006 Classif. CEI 61-150; V1 File 8099

This standard is not intended for devices used specifically in beauty treatment centres, although such products may be referenced against products covered by the aforementioned standard.

TECHNICAL INFORMATION SHEET 12

Category	:	MANICURE AND PEDICURE EQUIPMENT
Device list (as per Annex to Law 1 of 4 January 1990)	:	Manicure and pedicure equipment

2) DYNAMIC TECHNICAL CHARACTERISTICS

- Device description:

Kit including scissors, files, gouges, burrs, and other devices, including mains- and battery-powered devices.

3) IMPLEMENTING METHODS AND USAGE PRECAUTIONS

Carefully follow any instructions, warnings, and usage precautions given in the manual provided by the manufacturer.

Preferably use disposable tools, or sterilise them after use and before reusing them on another person.

Use suitable means to protect the operator from potential contamination (for example: gloves, goggles, facemask, etc.).

WARNINGS

Suitable sterilisation and/or disinfecting of all elements coming into contact with the treatment recipient is recommended.

4) APPLICABLE TECHNICAL STANDARDS including relating to adjustment mechanisms

For electrical devices:

Standard CEI EN 60335-1:2004 Safety of household and similar electrical appliances.

(CEI 61-150) Part 1: General requirements.

Third edition of 1 April 2004

File 7286 C

ALTERNATIVE

Standard CEI EN 60335-1/A1/A11 of 1 January 2006 Classif. CEI 61-150; V1 File 8099

This standard is not intended for devices used specifically in beauty treatment centres, although such products may be referenced against products covered by the aforementioned standard.

TECHNICAL INFORMATION SHEET 13

Category : TOTAL OR PARTIAL HEAT TREATMENT DEVICES

Device list : a) Total or partial heat treatment device
(as per Annex to Law 1 of b) Partial heat treatment device using resistive
4 January 1990) radiofrequency
c) Partial heat treatment device using capacitive
radiofrequency

1) DYNAMIC TECHNICAL CHARACTERISTICS

- **Device description (a):**

Electrical devices used to generate heat using lamps, bandages, electric blankets, heating pads or other similar accessories applied to part or all of the body.

In devices that generate heat using infrared lamps, these lamps must be protected by grills or transparent screens or filters to prevent accidental contact by the treatment recipient or operator.

Such devices are made of a wood, plastic, metal or fabric structure with appropriate thermal and electrical insulation.

They must be fitted with temperature adjustment mechanisms.

Mains- and/or battery-powered.

If mains-powered, the equipment must comply with Law 46/90.

Devices that come into direct contact with the treatment recipient must be fitted with a device to limit the current and leakage current.

- **Device description (b):**

Mains- and/or battery-powered device comprising a unit to generate a radiofrequency current that is transmitted to the body via one or more applicators.

The applicator must be fitted with suitable conductive electrodes of a different shape, surface finish, and number, which are placed in direct contact with the body (resistance between applicator contact and the body must be very low).

The output power of the device must not exceed 25 W with a base frequency between 400 and 1 500 kHz.

If the system is mains-powered, the device must be fitted with safety insulation between the mains and the current-generator output.

- **Device description (c):**

Mains- and/or battery-powered device comprising a unit to generate a radiofrequency current that is transmitted to the body via one or more applicators.

The applicator must be fitted with suitable electrodes of a different shape, surface finish, and number, which shall be electrically isolated from the body by a dielectric element.

The output power of the device must not exceed 50 W with a base frequency between 400 and 1 500 kHz.

To improve safety for the treatment recipient, if the system is mains-powered, the device must be fitted with safety insulation between the mains and the current-generator output.

The exposure thresholds for electromagnetic fields provided for in prevailing standards in Italy for workers and the general public shall apply.

- **Mechanism of action (application):**

The heating action causes moderate perspiration and increases subcutaneous circulation.

2) IMPLEMENTING METHODS AND USAGE PRECAUTIONS

- **Device usage method (a):**

Carefully follow any instructions, warnings, and usage precautions given in the manual provided by the manufacturer.

Do not use on people with capillary fragility or telangiectasias.

Treatment times must not exceed 30 minutes.

In the case of lamp application, the treatment recipient and the operator must wear protective goggles.

The usage manual must set out the exposure thresholds provided by the ICNRP (2004) adopted in European Directive 2006/25/EC on protection against optical radiation in the workplace.

- **Device usage method (b):**

Carefully follow any instructions, warnings, and usage precautions given in the manual provided by the manufacturer.

Do not treat people with pacemakers or internal defibrillators.

To reduce contact resistance between electrode and skin and to reduce emissions, use a conductive liquid/gel/cream.

The parts that come into contact with the skin must be cleaned between treatments using the normal cleaning methods set out in the user manual provided by the manufacturer.

- **Device usage method (c):**

Carefully follow any instructions, warnings, and usage precautions given in the manual provided by the manufacturer.
Do not treat people with pacemakers or internal defibrillators.
To reduce contact resistance between electrode and skin and to reduce emissions, use a conductive liquid/gel/cream.
The parts that come into contact with the skin must be cleaned between treatments using the normal cleaning methods set out in the user manual provided by the manufacturer.

3) APPLICABLE TECHNICAL STANDARDS including relating to adjustment mechanisms

Standard CEI EN 60335-1:2004 Safety of household and similar electrical appliances.
(CEI 61-150) Part 1: General requirements.
Third edition of 1 April 2004
File 7286 C
ALTERNATIVE
Standard CEI EN 60335-1/A1/A11 of 1 January 2006 Classif. CEI 61-150; V1 File 8099

Standard CEI EN 60335-2-17:2003 Safety of household and similar electrical appliances.
(CEI 61-216) Part 2: Particular requirements for blankets, pads, and similar flexible heating appliances.
Second edition
of 1 September 2009
File 7160

with particular reference to point (a) only:

Standard CEI EN 60335-2-27 Particular requirements for devices for treating skin with ultraviolet and infrared radiation.

TECHNICAL INFORMATION SHEET 14

Category SUCTION MESSAGE DEVICES WITH SUCTION NOT EXCEEDING 80 kPa

Device list: Suction massage device with different sized cups and moving, fixed, and rhythmic application with suction not exceeding **80 kPa**
(as per Annex to Law 1 of 4 January 1990)

1) DYNAMIC TECHNICAL CHARACTERISTICS

- Device description:

Device comprising a motor driving a suction generator or an electric pump (not exceeding 80 kPa) with a device to provide constant and/or rhythmic suction.

The device shall have an adjustment mechanism and may have a pressure gauge.

Flexible tubes enable the differently sized cups to be attached to the body of the device.

Mains- and/or battery-powered.

- Mechanism of action (application):

Continuous or pulsed suction via the cups of different shapes and sizes has a beneficial draining and toning effect on subcutaneous tissue.

The operator applies the suction by moving the cups along the massage lines from the edges to the centre of the body.

Alternatively, the operator may achieve a rhythmic action by manipulating the cups in a fixed position, without moving them.

2) IMPLEMENTING METHODS AND USAGE PRECAUTIONS

Once the cups are properly attached to the device, position them on the treatment area.

The cups may be used in a fixed position or moving with constant or rhythmical suction.

Before treatment, check the integrity of the cups and strictly observe all instructions provided by the manufacturer concerning suction in consideration of the body parts being treated.

Do not use on people with capillary fragility or telangiectasias.

WARNINGS

Suitable sterilisation and/or disinfecting of all elements coming into contact with the treatment recipient is recommended.

In addition to the above, carefully follow any instructions, warnings, and usage precautions given in the manual provided by the manufacturer.

3) APPLICABLE TECHNICAL STANDARDS including relating to adjustment mechanisms

Standard CEI EN 60335-1:2004 Safety of household and similar electrical appliances.

(CEI 61-150) Part 1: General requirements.

Third edition of 1 April 2004

File 7286 C

ALTERNATIVE

Standard CEI EN 60335-1/A1/A11 of 1 January 2006 Classif. CEI 61-150; V1 File 8099

Standard CEI EN 60335-2-32:2005 Safety of household and similar electrical appliances.

(CEI 61-163) Part 2: Particular requirement for massage devices.

Third edition of 1 July 2005

File 7782 C

These standards are not intended for devices used specifically in beauty treatment centres, although such products may be referenced against products covered by the aforementioned standards.

TECHNICAL INFORMATION SHEET 15

Category	:	IONTOPHORESIS BEAUTY-TREATMENT DEVICES
Device list (as per Annex to Law 1 of 4 January 1990)	:	Iontophoresis beauty-treatment devices with maximum plate intensity of 1 mA per cm ²

1) DYNAMIC TECHNICAL CHARACTERISTICS

- **Device description:**

Mains- and/or battery-powered device having a low-voltage direct-current generator.

The treatment involves applying this low-intensity current to a person using metal plates or electrodes made of rubber, plastic or any other material providing good electric conductivity. When applied to the skin, a special spongy or similar material soaked in the cosmetic product to be applied is inserted.

Includes adjustment and control instruments and a current limiter to prevent the emission of current intensities that could be harmful to the health of the treatment recipient.

Limiting the voltage of the direct-current generator and the current intensity limiter guarantees the safety of the treatment recipient.

The usage manual must instruct the beautician to apply a current intensity that is barely detectable.

- **Mechanism of action (application):**

This device provides a beauty treatment that enables cosmetics applied to be absorbed more quickly.

It is therefore a method complementary to manual massage for applying cosmetics to the skin.

The products used must not contain active pharmaceutical ingredients.

2) IMPLEMENTING METHODS AND USAGE PRECAUTIONS

In addition to the instructions given in the technical standards, only apply this beauty treatment to healthy recipients with no on-going medical conditions.

Before using the device, carefully read the usage manual and, in particular, the following warnings:

- apply only to healthy, unbroken skin with no abrasions, lesions, irregularly shaped moles, boils, etc.;
- do not apply the treatment to people with pacemakers or active electronic implantable devices;
- do not apply near to metal artificial limbs;
- do not apply treatment to pregnant women;
- do not apply treatment to the abdominal area of women with inter-uterine devices implanted;
- moisten the sponge inserts;
- place the plates in the device slots and insert the spongy material between them and the areas to be treated.
- apply the plates to the areas to be treated;
- slowly adjust the intensity of each output channel to a value slightly above the sensitivity threshold;
- make sure the plates are kept far enough apart;
- check the integrity of the spongy inserts;
- adjust the intensity of the output current to a level that is not harmful to the health of the treatment recipient, in accordance with the thresholds provided for in the standards listed in point 3 below.

WARNINGS

In addition to the above, carefully follow any instructions, warnings, and usage precautions given in the manual provided by the manufacturer.

3) APPLICABLE TECHNICAL STANDARDS including relating to adjustment mechanisms

Italian Standard CEI 62-39:1998 File 3639 R	Electrical beauty-treatment devices General safety guide
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Standard CEI EN 60601-2-10 Classif. CEI 62-24: Second edition 1 November 2001 Fascicolo 6296	Electrical medical devices. Specific safety standards for neuromuscular stimulators (this standard shall only apply to build characteristics and adjustment mechanisms, since the intended use is not medical).
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ALTERNATIVE

CEI EN 60601-2-10/A1 of 1 November 2002 Classif. CEI 62-24; V1 File 6723

NB: These standards shall only apply to the build characteristics and adjustment mechanisms of the devices, since the intended use is not medical.

When considering the specific electromagnetic compatibility requirements set out in these standards, it should be noted that these requirements are related to Standard CEI EN 60601-1-2:2003+A1:2006 – Electrical medical devices – Part 1:

General safety requirements – Collateral standard: Electromagnetic compatibility – Requirements and tests (IEC 60601-1-2:2001+A1:2004).

TECHNICAL INFORMATION SHEET 16

Category	:	ELECTRICAL AND ELECTRONIC EPILATORS
Device list (as per Annex to Law 1 of 4 January 1990)	:	a) Electrical needle epilator b) Tweezer or equivalent (probe) electrical epilator c) Electronic light-pulse device for photo-epilation

1) DYNAMIC TECHNICAL CHARACTERISTICS

- **General device description (a + b):**

Device fitted with an oscillating current generator of limited power, possibly combined with a weak direct current. It may be applied by a handpiece made of an isolating material into which is inserted a fine, pointed metal electrode, or using tweezers or any other suitable electrode.

It may be combined with a timer to provide an automatic current output for a predetermined time.

Mains- and/or battery-powered.

If mains-powered, the electrical equipment must comply with Law 46/90.

The rated output power must not exceed 50 W.

- **Detailed description of electrical needle epilators (a):**

These devices use currents at a frequency below 30 MHz.

Some devices combine these frequencies with a direct current (known as “blending”) to obtain an electrolytic effect as well as the thermolytic effect.

In some devices, the current is generated at very high speed (thousandths of a second) on account of the thermolysis in order to speed up the action on individual hairs and facilitate the treatment.

- **Detailed description of electrical tweezer or probe epilators (b):**

These devices use currents at a frequency below 30 MHz.

- **Detailed description of electronic light-pulse devices for photo-epilation (c):**

Low-power pulsed-light device designed and built for use in the beauty-treatment sector for use exclusively for epilation.

To ensure that the treatment is effective and safe, if the system is fitted with a method for cooling the skin with skin temperatures of 10°C (including built into the system), the energy density must not exceed 26 J/cm², the wavelengths emitted must fall within the 600–1100 nanometre range, the pulse length must be between 2 and 50 ms and the treatment area must be larger than 5 cm².

If the device does not include a skin cooling system, notwithstanding other factors, the maximum admissible power density shall be 13 J/cm².

The tools must have a system that intrinsically limits the maximum emissions to the aforementioned levels and must have a power output meter. The system must be tamperproof.

The operator must be aware of the type of optical filter fitted to the handpiece.

The manufacturer must guarantee the repeatability of the filters provided and guarantee that the user is aware of the different skin reactions depending on the filter type used.

The device must be marked for use in epilation beauty treatment.

- **Mechanism of action (a + b):**

The epilatory action is effected directly on the skin for types (a) and (b).

- **Mechanism of action (c):**

The interaction between the pulsed light and the hair bulb is essentially thermal. The process, known as selective photothermolysis, requires a determined number of sessions (usually around ten).

Sessions must be taken approximately one month apart.

Specific tables provided by the manufacturer give instructions on how to optimise the results as a function of certain parameters, such as:

- hair colour;
- the body part to be treated;
- the growth “phase” of the hair at the time of treatment;
- the phototype of the treatment recipient;
- the hair thickness (fine, medium, thick).

2) IMPLEMENTING METHODS AND USAGE PRECAUTIONS

- **(a + b):**

Insert the electrode in the appropriate handpiece and then apply it to the follicle channel, or run it over the area to be treated, or grip the hair with the tweezers.

Actuate the manual control or pedal, and then remove the treated hair.

Sanitise the area to be treated and check the functional integrity of the electrode to be used.

Adjust the intensity of the current in accordance with the manufacturer’s instructions.

Use only disposable needles.

- (c):

The treatment must be performed by beauticians who have been properly trained, by the manufacturer or any other appropriate body, in both the safety aspects (also included in the usage manual) and the technical aspects of the treatments.

Sanitise the area to be treated and shave (shaving should preferably be done the day before treatment).

Where present, activate the skin cooling system, which may involve contact with a cold wall, either using air or a suitable layer of cold gel or similar product.

Place the handpiece on the area of skin to be epilated and then emit the test light pulse by pressing the appropriate pedal and/or button.

Wait at least 30 minutes to observe the reaction of the skin and to determine the optimum energy density in consideration of parameters (a) to (e) above.

Perform the entire treatment, taking care not to subject the same area to two or more successive pulses.

Do not aim the light directly at the eyes during treatment.

Treatment recipients and operators must wear protective goggles or equivalent protection (pads).

The part of the handpiece that touches the skin must be replaceable (disposable system) and/or cleanable using the means specified in the user manual provided by the manufacturer.

In all cases, carefully follow all instructions, warnings, and usage precautions set out in the manual provided by the manufacturer, as well as the precautions to be taken by the beautician.

WARNINGS

It is advisable to sterilise all electrodes, tweezers, and other epilation equipment that comes into contact with the treatment recipient.

The use of disposable sterilised epilation electrodes is recommended, where possible.

Epilation equipment may only be used by professionally qualified people with specific theoretical and practical training who are consequently able to evaluate suitable skin conditions before treatment.

Do not treat people with pacemakers or active electronic implantable devices.

In addition to the above, carefully follow any instructions, warnings, and usage precautions given in the manual provided by the manufacturer.

APPLICABLE TECHNICAL STANDARDS including relating to adjustment mechanisms

Italian Standard CEI 62-39:1998 Electrical beauty-treatment devices
File 3639 R General safety guide

Standard CEI EN 60601-2-2:2001 Electrical medical devices.
(CEI 62.11) Part 2: Particular requirements for the safety of high frequency surgical equipment
Third edition (this standard shall only apply to build characteristics and adjustment
of 1 November 2001 mechanisms, since the intended use is not medical).
File 6297

Guide CEI 62.39:1998 Beauty-treatment devices for beauty treatments.
General safety guide

Standard CEI EN 60601-1-1 Electrical medical devices.
General safety standards (this standard shall only apply to build characteristics
and adjustment mechanisms, since the intended use is not medical).

Standard CEI EN 60335-1:2004 Safety of household and similar electrical appliances.
(CEI 61-150) Part 1: General requirements.
Third edition of 1 April 2004
File 7286 C

ALTERNATIVE

Standard CEI EN 60335-1/A1/A11 of 1 January 2006 Classif. CEI 61-150; V1 File 8099

NB: These standards shall only apply to the build characteristics and adjustment mechanisms of the devices, since the intended use is not medical.

TECHNICAL INFORMATION SHEET 17

Category

DEVICES FOR UNDERWATER MASSAGE

Device list

Devices for underwater massage

(as per Annex to Law 1 of
4 January 1990)

1) DYNAMIC TECHNICAL CHARACTERISTICS

- **Device description:**

Mains-powered device fitted with an electric pump used to create a forced flow of water and air that is outputted from fixed or adjustable nozzles or from a handheld hose used by the operator.

This equipment may be moveable and/or built into tubs of different sizes for treating parts or all of the body.

- **Mechanism of action (application):**

These are usually bathtub-shaped devices, the sides and floor of which are fitted with special nozzles spraying out jets of water mixed with air.

These jets come into contact with the skin of the immersed treatment recipient, producing a skin massaging effect.

In some devices, the water and air are aimed at specific areas using a special "water hose" operated by the beautician.

In this device, the "water hose" used to aim the water jet is an accessory.

2) IMPLEMENTING METHODS AND USAGE PRECAUTIONS

Fill the bathtub with water at a suitable temperature.

Turn on the device and adjust the direction and intensity of the jets depending on the desired treatment.

Do not aim the jet from the water hose at the eyes, ears or airways.

The products must provide at least IPX5-level protection against water.

WARNINGS

In addition to the above, carefully follow any instructions, warnings, and usage precautions given in the manual provided by the manufacturer.

3) APPLICABLE TECHNICAL STANDARDS including relating to adjustment mechanisms

Standard CEI EN 60335-1:2004
(CEI 61-150)

Third edition of 1 April 2004
File 7286 C

Safety of household and similar electrical appliances.
Part 1: General requirements.

ALTERNATIVE

Standard CEI EN 60335-1/A1/A11 of 1 January 2006 Classif. CEI 61-150; V1 File 8099

Standard CEI EN 60335-2-60:2006
(CEI 61-200)

Third edition of 1 February 2006
File 8146

Safety of household and similar electrical appliances.
Part 2: Particular requirements for whirlpool baths.

These standards are not intended for devices used specifically in beauty treatment centres, although such products may be referenced against products covered by the aforementioned standards.

TECHNICAL INFORMATION SHEET 18

Category : PRESSURE MESSAGE DEVICES

Device list: : Pressure massage devices
(as per Annex to Law 1 of
4 January 1990)

1) **DYNAMIC TECHNICAL CHARACTERISTICS**

- **Device description:**

Device driven by an electrical pump that blows air into pads of different shapes and sizes that, in turn, are applied directly or inserted into suitable containers made of fabric, plastic or any other suitable material.

The massage pressure is adjusted using suitable devices and monitored using a measuring device and a safety device.

The device is also fitted with devices for adjusting the pressure emission and pause times, as well as programmed sequences for several pads.

Mains- and/or battery-powered.

- **Mechanism of action (application):**

This device provides a pressure massage.

2) **IMPLEMENTING METHODS AND USAGE PRECAUTIONS**

The pads are applied to the parts to be treated to carry out a massage using alternate, sequential or other pressure instead of manual massage.

Observe the treatment times, pressures, and frequencies given in the guidelines provided in the manufacturer's manual.

Do not treat people with capillary fragility, hypertension or heart disease.

WARNINGS

Suitable sterilisation and/or disinfecting of all elements coming into contact with the treatment recipient is recommended.

In addition to the above, carefully follow any instructions, warnings, and usage precautions given in the manual provided by the manufacturer.

3) **APPLICABLE TECHNICAL STANDARDS** including relating to adjustment mechanisms

Italian Standard CEI 62-39:1998 Electrical beauty-treatment devices
File 3639 R General safety guide

TECHNICAL INFORMATION SHEET 19

Category: PULSED ELECTROSTIMULATOR

Device list: PULSED ELECTROSTIMULATOR
(as per Annex to Law 1 of
4 January 1990)

1) DYNAMIC TECHNICAL CHARACTERISTICS

- Device description:

Device for generating a pulsed waveform current flow at variable frequencies applied to the areas to be treated using electrodes of different shapes and materials.

Moveable electrodes are typically, but not necessarily, metal spheres.

Fixed electrodes may be metal with soaked sponge inserts or conductive rubber or have conductive gel or paste.

The electrodes may be square, rectangular, and round and they may be of different sizes.

The current applied is weak and of variable frequency, depending on the model, ranging from 0.1 to 100 kHz, having different symmetrical and asymmetrical waveforms.

The appliance may have a device for adjusting the intensity of the current applied, the frequency, the application/pause times, and polarity switching.

It may have an intensity monitoring tool.

It must be fitted with a current limiter to prevent harmful current intensities being emitted.

The current density for each electrode must not exceed 1.5 mA/cm² (RMS). Maintaining 1.5 mA has been proposed.

Initial activation must only be possible at zero intensity.

If application is halted, the energy values gradually increased since activation must automatically drop down to zero.

The device is mains- and/or battery-powered.

The manufacturer must provide guidelines to ensure that it is not possible to place the electrode such that the current emitted affects the cardiac or reproductive areas.

Mechanism of action (application):

The physical principle of pulsed electrostimulators is based on low- and medium-frequency excitomotoric currents applied to electrodes, which stimulate the contraction and relaxation of the muscle in question. Furthermore, the "pump" effect obtained by muscle movement encourages lymphatic drainage in the treatment area.

This appliance provides pulsed electrostimulation treatments that act on muscle groups, generating positive reharmonising and toning effects on the face and body.

Muscle stimulation enables the firming of specific areas, improving cutaneous and subcutaneous tone.

To enhance the toning action, it may be used in conjunction with specific products that do not contain any active pharmaceutical ingredients to speed up their absorption.

2) USAGE PRECAUTIONS AND IMPLEMENTING METHODS

Usage precautions:

Read the usage manual carefully before use to prevent improper usage.

Suitable sterilisation and/or disinfecting of all elements coming into contact with the treatment recipient is recommended.

Do not treat:

people with active implants such as: pacemakers, insulin pumps or similar;

people with metal joint implants;

people with on-going inflammations, skin lesions or neoplasms;

pregnant women.

Do not treat people with sensitive skin, or limit power to very low output.

Apply only to unbroken skin.

Implementation method:

Carefully clean the area to be treated. The treatment area should be properly degreased to prevent the fixed or mobile electrodes from transmitting the energy inconsistently, which often causes discomfort.

Connect the electrodes to the appliance using the appropriate slots, in accordance with the instructions given in the usage manual.

The electrodes must be positioned on (fixed) or run over (mobile) the treatment area.

Observe the polarity and the application zones of the fixed electrodes, as specified in the usage manual.

Mobile electrodes must be moved slowly, consistently, and uniformly over the treatment area.

Application times vary depending on the treatment being applied, and are normally between 15 and 60 minutes.

Activation must not be possible unless the outputs are set to zero.

It is advisable to adjust the output current intensity by slowly manipulating the related controls, taking care to use values barely detectable by the treatment recipient, in accordance with the limits set in Standard CEI 62-24-1997 referred to in chapter 3). Where possible, intensity increases should be automatically gradual.

Reduce the output intensity if the treatment recipient feels any discomfort.

Once output is halted, the intensity setting shall automatically return to zero.

Always check the condition of the electrodes and carefully follow the instructions given in the usage manual. In addition to the above, carefully follow any instructions, warnings, and usage precautions given in the manual.

3) APPLICABLE TECHNICAL STANDARDS *including relating to adjustment mechanisms*

Italian Standard CEI 62-39:1998	Electrical beauty-treatment devices
File 3639 R	General safety guide
Standard CEI EN 60601-2-10	Electrical medical devices.
Classification CEI 62-24	Specific safety standards for neuromuscular stimulators (this standard shall only
Second edition of 1 November	apply to build characteristics and adjustment mechanisms, since the intended use is
2001	not medical).
File 6296	
Alternative	
CEI EN 60601-2-10/A1 of Classif. CEI 62-24; File 6723	
01.11.2002	

NB: This standard shall only apply to the build characteristics and adjustment mechanisms of the devices, since the intended use is not medical.

When considering the specific electromagnetic compatibility requirements set out in these standards, it should be noted that these requirements are related to Standard CEI EN 60601-1-2:2003+A1:2006 – Electrical medical devices – Part 1: General safety requirements – Collateral standard: Electromagnetic compatibility – Requirements and tests (IEC 60601 1-1:2001+A1:2004).

TECHNICAL INFORMATION SHEET 20

Category

AIR MESSAGE DEVICES

Device list

Air-massage device at pressures above one atmosphere

(as per Annex to Law 1 of
4 January 1990)

1) **DYNAMIC TECHNICAL CHARACTERISTICS**

- **Device description:**

Device driven by an electric motor to generate an airflow at pressures not exceeding one 4 bar, which is aimed at the area to be treated using a flexible tube with a nozzle attached.

The air flow may be regulated by changing the motor speed and/or the nozzle diameter.

Mains- and/or battery-powered.

- **Mechanism of action (application):**

Using a suitable terminal available in a range of sizes, the airflow is applied tangentially to the treatment area.

This flow creates slight pressure on the skin that, if properly and rhythmically applied by the beautician, provides a massaging effect complementing or replacing manual massage.

2) **IMPLEMENTING METHODS AND USAGE PRECAUTIONS**

Appliance used specifically to treat the body, excluding the face and delicate areas.

Pay careful attention to the airflow direction.

WARNINGS

In addition to the above, carefully follow any instructions, warnings, and usage precautions given in the manual provided by the manufacturer.

3) **APPLICABLE TECHNICAL STANDARDS** including relating to adjustment mechanisms

Standard CEI EN 60335-1:2004 Safety of household and similar electrical appliances.
(CEI 61-150) Part 1: General requirements.
Third edition of 1 April 2004
File 7286 C

ALTERNATIVE

Standard CEI EN 60335-1/A1/A11 of 1 January 2006 Classif. CEI 61-150; V1 File 8099

This standard is not intended for devices used specifically in beauty treatment centres, although such products may be referenced against products covered by the aforementioned standard.

TECHNICAL INFORMATION SHEET 21a

Category: SOFT LASER FOR RELAXING AND TONING SKIN TREATMENT –
PHOTOSTIMULANTS OF REFLEXOGENIC AREAS OF THE FEET AND HANDS

Device list Aesthetic laser
(as per Annex to Law 1 of
4 January 1990)

1) DYNAMIC TECHNICAL CHARACTERISTICS

- **Device description:**

Delicate beauty-treatment laser for relaxing, firming, and toning the skin, and photostimulating the reflexogenic areas of the feet and hands.

Appliances comprising one or more generators of consistent monochromatic light at a wavelength between 760 and 1200 nanometres (nm), near infrared, unfocused, and tamperproof with a maximum density of 10 milliwatts per cm² (mW/cm²).

Use of class 3B and class 4 laser devices is strictly prohibited in this type of appliance.

The maximum treatment application time is 1 200 (one thousand two hundred) seconds.

- **Mechanism of action:**

The aesthetic lasers act on the skin through various mechanisms. Depending on the wavelength, they can: tone, firm, and photostimulate specific areas of the body, such as feet or hands, or facilitate the absorption or distribution of products applied that do not contain any active pharmaceutical ingredients.

2) IMPLEMENTING METHODS AND USAGE PRECAUTIONS

- A. Pass the monochromatic light ray over the area to be treated, either manually or using automatic scanning. Each treatment may last up to 1 200 (one thousand two hundred) seconds. The operator and the treatment recipient must protect their eyes using goggles suitable to the light type, as provided by the appliance manufacturer. Rays should not be aimed at reflective surfaces or other people present.
- B. The instructions given in the manual must be followed, and staff must be properly trained to apply the treatment in accordance with the provisions of the usage manual provided by the manufacturer. Special care should be taken with class 3R as it is a wavelength outside the visible spectrum.
- C. Laser emission should preferably be triggered by a dual command.
- D. The qualified beautician shall be responsible for:
 - monitoring safety;
 - training any other staff working with the user;
 - providing specific information to people receiving laser beauty treatments.
- E. Checks, information, and specific training should be sought from the manufacturer-supplier, which may include the content of the technical-application manual.
- F. Users of laser appliances must understand:
 - the different laser class symbols;
 - the different safety and warning labels;
 - the risk to eyes and skin if used incorrectly;
 - the difference between different laser types and categories, so as to prevent any confusion with other types of laser or laser for other treatments;
 - the effectiveness of eye protection.

3) APPLICABLE TECHNICAL STANDARDS including relating to adjustment mechanisms

Standard CEI EN 60825-1:1998
(CEI 76-2)

Safety of laser products.

Part 1: Equipment classification, requirements, and user's guide (this standard shall only apply to laser-product safety, build characteristics, and adjustment mechanisms, since the intended use is not medical) – Aesthetic lasers may not be used for therapeutic purposes.

Standard CEI EN 60825-1:2003
(CEI 76-2)

Part 1: Equipment classification, requirements, and user's guide.

Consolidated standard comprising:

Alternative A1:2002 to EN 60825-1:1994; (IEC 60825-1:1993/A1:1997)

Alternative A2:2001 to EN 60825-1:1994; (IEC 60825-1:1993/A2:2001)

Important note: Standard CEI EN 60825-1:2003 must be applied in full to laser appliances in general, not specifically to those intended for medical use.

TECHNICAL REPORT CLC/TR 50448

Guide to levels of competence required in laser safety – August 2005".

Italian Standard CEI 62-39:1998

Electrical beauty-treatment devices General safety guide

NB: These standards shall only apply to the build characteristics and adjustment mechanisms of the devices, since the intended use is not medical.

When considering the specific electromagnetic compatibility requirements set out in these standards, it should be noted that these requirements are related to Standard CEI EN 60601-1-2:2003+A1:2006 – Electrical medical devices – Part 1: General safety requirements – Collateral standard: Electromagnetic compatibility – Requirements and tests (IEC 60601-1-2:2001+A1:2004).

TECHNICAL INFORMATION SHEET 21b

Category: DEFOCUSED AESTHETIC LASERS FOR EPILATION

Device list: LASER FOR AESTHETIC EPILATION

(as per Annex to Law 1 of
4 January 1990)

1) **DYNAMIC TECHNICAL CHARACTERISTICS**

- **Device description:**

Appropriately defocused pulsed-laser device designed and built for use in the beauty-treatment sector for use exclusively for epilation.

To ensure effective and safe treatment, the laser spot must not be smaller than 10 mm, the energy density must not exceed 40 J/cm², the maximum laser pulse duration shall be T=300 milliseconds, and the wavelength must be in the 800–1 200 nanometre range.

Tools must have a built-in power meter, and may have a system for checking the distance and treatment area.

The handpiece ensuring defocusing must not be removable by the operator and must prevent all radiation leakage outside the treatment area.

The device must be marked for use in epilation beauty treatment.

Appliances should preferably include:

- a) safety devices such as contact or proximity sensors to stop emissions when the handpiece is not touching the skin;
- b) an energy meter controlling the output level of the appliance from the optical fibre/handpiece;
- c) protective measures restricting emissions to the treatment area to prevent lateral or target-reflected emissions.

- **Mechanism of action:**

The interaction between the laser and the hair bulb is essentially thermal. The process, known as selective photothermolysis, requires a determined number of sessions (usually around ten).

Sessions must be taken approximately one month apart.

Specific tables provided by the manufacturer give instructions on how to optimise the results as a function of certain parameters, such as:

- a) hair colour;
- b) the body part to be treated;
- c) the growth "phase" of the hair at the time of treatment;
- d) the phototype of the treatment recipient;
- e) the hair thickness (fine, medium, thick).

2) **IMPLEMENTING METHODS AND USAGE PRECAUTIONS**

The treatment must be performed by beauticians who have been properly trained, by the manufacturer or any other appropriate body, in both the safety aspects (also included in the usage manual) and the technical aspects of the treatment.

Before treatment, carefully clean the skin and shave off hair.

Activate the machine using the setting suggested by the manufacturer in accordance with the elements listed in points a), b), c), d), and e) of the previous chapter.

Use a skin cooling system, which may involve contact with a cold wall, using air and/or cryogenic spray or a suitable layer of cold gel or similar product.

Emission should preferably be triggered by a dual hand or pedal command.

The qualified beautician shall be responsible for:

- monitoring safety (specific to laser appliances)
- providing training to any other staff using (or involved in using) the laser appliance
- providing information (specific to laser appliances) to people receiving the beauty treatment and any other visitors.

Checks, information, and training methods specific to the laser appliance shall depend on the laser class and should be obtained directly from the manufacturer-supplier of the laser appliance, in particular if not clearly specified in the usage manual.

Users of laser appliances must understand:

- laser classes;
- the entire content of the warning labels on the laser appliance;
- the risks to the eyes and skin posed by different laser types;
- the potential interaction of the laser with surrounding objects;
- the effectiveness of eye protection.

WARNINGS

In addition to the above, and before treatment begins, suitable goggles should be worn to protect the eyes.

Do not aim the ray at the eyes of the treatment recipient, the operator or anyone else present in the room where the laser is being used, or at reflective surfaces.

The appliance is for professional use only and must be used directly by the beautician.

All appliances shall be provided with a specific and complete usage manual including the technical phases of treatment and specific warnings and usage precautions for each part of the device, as well as references to standards relating to premises housing the appliances.

Signs must be clearly displayed in the usage manual and the area where the device is used with precise details of the specific biological damage caused (permanent epilation).

3) APPLICABLE TECHNICAL STANDARDS including relating to adjustment mechanisms

Directive 2002/96/EC WEEE (Waste Electrical and Electronic Equipment)

Standard CEI EN 60825-1:2003
(CEI 76-2)

Safety of laser products.

Part 1: Equipment classification, requirements, and user's guide.

Consolidated standard comprising:

Alternative A1:2002 to EN 60825-1:1994; (IEC 60825-1:1993/A1:1997)

Alternative A2:2001 to EN 60825-1:1994; (IEC 60825-1:1993/A2:2001)

Important note: Standard CEI EN 60825-1:2003 must be applied in full to laser appliances in general, not specifically to those intended for medical use.

TECHNICAL REPORT CLC/TR 50448

Guide to levels of competence required in laser safety – August 2005

Italian Standard CEI 62-39:1998

Electrical beauty-treatment devices

File 3639 R General safety guide

NB: These standards shall only apply to the build characteristics and adjustment mechanisms of the devices, since the intended use is not medical.

When considering the specific electromagnetic compatibility requirements set out in these standards, it should be noted that these requirements are related to Standard CEI EN 60601-1-2:2003+A1:2006 – Electrical medical devices – Part 1: General safety requirements – Collateral standard: Electromagnetic compatibility – Requirements and tests (IEC 60601-1-2:2001+A1:2004).

TECHNICAL INFORMATION SHEET 22

Category : SAUNAS AND STEAM ROOMS
Device list : Saunas
(as per Annex to Law 1 of
4 January 1990)

3) DYNAMIC TECHNICAL CHARACTERISTICS

- **Device description:**

SAUNAS: cabins made of wood or any other suitable material, with a door opening outwards, a safety aperture, and an electrical heat and steam generator.

Cabins can be of different sizes and for one or more people.

STEAM ROOM: appropriate built appliances producing heat and/or steam for partial or total "Turkish bath" treatments.

The operating temperature is controlled by a power regulator and/or an adjustable thermostat, depending on the model.

The appliance may be fitted with a thermometer, hygrometer, meter prover, humidifier, and bell for calling the operator.

Mains-powered.

4) IMPLEMENTING METHODS AND USAGE PRECAUTIONS

Turn on the heat generator before starting treatment in order to achieve the desired temperature.

The treatment recipient may be sitting or lying down for a period of 10 to 30 minutes.

Follow with a relaxation period of 10–15 minutes.

Before treatment, check that the treatment recipient is not wearing any metal jewellery.

Attach a sign with the following wording to the cabin:

INFORMATION FOR USERS

**You must be in good health to use the sauna.
It is advisable to seek medical advice before use.**

The operator must be trained in first aid in case of emergency.

The operator must monitor the treatment recipient constantly.

WARNINGS

In addition to the above, carefully follow any instructions, warnings, and usage precautions given in the manual provided by the manufacturer.

5) APPLICABLE TECHNICAL STANDARDS including relating to adjustment mechanisms

Standard CEI EN 60335-1:2004 Safety of household and similar electrical appliances.
(CEI 61-150) Part 1: General requirements.
Third edition of 1 April 2004
File 7286 C

ALTERNATIVE

Standard CEI EN 60335-1/A1/A11 of 1 January 2006 Classif. CEI 61-150; V1 File 8099

Standard CEI EN 60335-2-53:2004 Safety of household and similar electrical appliances.
(CEI 61-198) Part 2: Particular requirements for sauna heating appliances.
Third edition of 1 September 2004
File 7434

Standard CEI EN 60335-2-105:2006 Safety of household and similar electrical appliances.
(CEI 61-241) Part 2: Particular requirements for multifunctional shower cabinets.
First edition
File 8518

These standards are not intended for devices used specifically in beauty treatment centres, although such products may be referenced against products covered by the aforementioned standards.