COMMISSION DE LA SÉCURITÉ DES CONSOMMATEURS

Paris, 3 July 2014

RECOMMENDATION

ON THE SAFETY OF PULSED LIGHT LAMPS FOR HAIR REMOVAL

THE CONSUMER SAFETY COMMISSION

HAVING REGARD TO *the Consumer Code and specifically Articles L. 534-4 to L. 534-6 and L. 534-8 to L 534-10 and R. 534-5 to R 534-8, R. 534-10 and R. 534-13 to R. 534-17*

HAVING REGARD TO *referral no. 12-047*

Whereas

I. THE OWN MOTION REFERRAL

Compliant with Article L. 534-6, paragraph 2 of the Consumer Code, the Consumer Safety Commission (CSC) used its power of own motion referral to address the safety issues raised by the design, operation and use of pulsed light lamps (commonly called Intense pulsed light [IPL] or flash lamps for hair removal. Aside from the long-standing method of shaving, various devices and products are available for long-lasting hair growth reduction. The devices and products can be broken down into two categories:

- Devices or products that pull the hair from its root sheath, such as tweezers, wax and electric epilators
- Devices or products that remove hairs by causing them to fall out, or that burn hairs, with or without destroying the hair bulbs, such as depilatory creams, laser or IPL hair removal devices[1]

As consumer IPL hair removal devices have only become available recently, until now consumers had to employ the services of a professional for the removal of body hair with IPL equipment. The hearings held for this report and the market study on hair removal identified numerous service suppliers in this field. A non-exhaustive list of the said suppliers comprise physicians, beauticians, nurses, physical therapists, hairdressers, pharmacists, fitness club operators as well as self-employed cosmetic service providers and franchisees. The paradox is that only physicians among all the stakeholders are authorised to use IPL equipment for hair removal according to legislation that has remained unchanged since 1962.

[1] In English, the generic term is hair removal; depilation is commonly used to designate the removal of hair using chemical (i.e. depilatory creams) or mechanical (i.e. shaving) methods and epilation to designate below skin hair removal (i.e. waxing, electric epilators, laser or IPL devices).

In a 13 June 2001 Recommendation on the use of laser equipment and other radiation sources for cosmetology, and given the knowledge at the time, the CSC recommended the possible introduction of pulsed light applications in beauty care facilities. At the same time, the CSC recommended making a distinction between the applications exclusively for the medical profession and the applications that could be delegated to non-medical personnel. According to the CSC, if it turned out that the applications could be used harmlessly in beauty care facilities without medical oversight, a regularly updated, detailed regulation would have to be drafted to govern the said applications and equipment.

The CSC also thought it would be appropriate to require that the persons using laser and flash lamp techniques acquire the relevant knowledge during training courses, which would be framed by regulations.

Have the CSC requisites for broadening the use of IPL equipment been met thirteen years after the publication of the recommendation? What do we know about radiation equipment effects on the human body? What level of qualification and training is available to non-medical practitioners for them to use the said equipment?

The discussion has changed in nature, and is far from over, as we will see. Actually, IPL consumer devices have been on the market for the past several years, hence consumers can remove body hair on their own without a professional's intervention. The devices are sold over the counter and consumers are increasingly using them because IPL epilators are affordable and incorporate new features inspired by professional equipment.

This report has set a priority of addressing the issues raised by the mass distribution of IPL devices without mediation. The immediate questions are:

- Do these devices provide safety assurances for home use, which may be very repetitive?
- Might not the search for efficiency lead to the design of devices that are as powerful as professional equipment?

This is why the rapporteur asked the LNE (French national testing laboratory) to take physical measurements and 'characterize' a representative sample of the products sold on the market and their accessories (protective eyewear and gels).

II. THE HEARINGS

Pursuant to Article L. 539-9 of the Consumer Code, the rapporteur assisted by technical advisors held hearings with representatives of:

- The Directorate-General for Health (DGS)
- The Directorate-General for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF)
- The Association of Dermatologists - Venereologists (SNDV)
- Representative bodies of the beauty care sector: *Confédération nationale artisanale des instituts de beauté* (CNAIB, the national artisanal confederation of beauty care centres) and *Confédération nationale de l'esthétique et de la parfumerie* (CNEP, national confederation of beauty care and perfumery)
- Manufacturers of IPL epilators: EUROFEEDBACK, DERMEO, E'ONE, PHILIPS and ELECTROPEM
- Franchised epilation facilities: RADICAL EPIL and DEPIL TECH
- Leading scientists specializing in laser and IPL technologies: Mr Serge MORDON, INSERM Research Supervisor, and Ms Evelyne SAGE, CNRS Research Supervisor and President of the European Society for Photobiology

A working meeting was held with representatives of the French Agency for Food, Environmental and Occupational Health & Safety (ANSES).

III. HAIRS AND HAIR REMOVAL

The entire human body except for the mucous membranes, soles of the feet and palms of the hand is covered with hair.

There are two types of hairs: terminal hair ranging in length from a few to several centimetres, comprising head hair, eyelashes, eyebrows and coarse body hair, and vellus hair that is typically short and fine, with low pigmentation. The human body is covered with anywhere from 500,000 to 5 million hairs.

The hair follicle is connected to one or several sebaceous glands and attached to a small smooth muscle called the arrector pili.

In different situations this muscle may contract causing body hair to stand out, for instance the formation of 'goose bumps' due to a drop in body temperature. Different types of stress, such as fear, may cause piloerection.

The protective role of body hairs is often overlooked when considering its removal.

Hairs preserve sweat longer, thus slowing evaporation, preventing dehydration and allowing the body to cool more efficiently. Hairs retain the little humidity available to maintain the proper temperature, thus preventing the body from sweating excessively. Hairs are important for skin sensitivity. They rapidly detect temperature variations and trigger body reactions, such as the withdrawal reflex from a heat source (sometimes the hairs are burnt but not the skin), or shivers when the body feels cold.

Hairs also soften the skin. Each hair is connected to one or several sebaceous glands producing the sebum that lubricates and softens the skin. The lack of leg hair promotes skin dryness skin and a depletion of the hydrolipidic film, and requires skin hydration to compensate.

Hair removal irritates the skin and permanent hair removal diminishes its sensitivity. People who have removed all their body hair are less sensitive to temperature changes in their environment.

The first traces of hair removal date back several millennia. Tools resembling tweezers have been uncovered in prehistoric graves.

In Mesopotamia, hairs were removed by rubbing the skin with vinegar. Another technique applied heating pads that promoted acid penetration, causing the hairs to fall out.

In Greece and Egypt, arsenic and lead-based ointments were used. In Rome, a session at the thermal baths ended with epilation and a massage.

In the Middle Age, natural wax was used; this will give birth to other methods similar to current waxes.

Hair threading (preferably with silk thread) for precision work comes from the Orient.

From the Renaissance to the mid-nineteenth century, some common practices used bat or frog blood, quicklime or arsenic.

A hair removal market with its different stakeholders – manufacturers of hair removal products and equipment, advertising, the media, beauty care and wellness businesses – was born in the early twentieth century. Hair removal then became scientific and advertising

touted depilatory methods and products that were classified as '*perfumery products for hygiene*'[2]. The target consumers were women.

Advertisements for underarm hair removal appeared in the twenties with the sleeveless dress fashion. The arrival of short skirts, bathing suits, bikinis and the tanning craze increased body exposure meaning that more and more body parts required hair removal.

In the 1950s, the advertisement for the new depilatory cream Taky stated that, "*the elegant, well-groomed woman always has smooth skin.*" Hairs were stigmatized and considered unsightly, unhygienic and unbeautiful. They were considered undesirable; having them was a sign of personal neglect and slovenliness.

Removing hair then became a social obligation to conform to standards. Every woman is plagued by the fear of rejection. This is especially true for very young women whose hairs begin to grow during adolescence, as they badly need to identify with their peer group.

Hair removal is widespread among athletes, for sports such as cycling, tennis, wrestling or swimming. Removing hair was already practised in Ancient Greece.

With these intimidating and guilt-creating methods and injunctions, the diktat of 'smooth skin' has won the day. The diktat, which has been gaining ground since the 1990s, now also affects men.

The hair removal industry is increasingly thriving, dynamic and creative, churning out products and devices for at-home hair removal, beauty care facilities, spas, eyebrow bars, Turkish baths and low-cost hair removal centres.

In magazines, the 'depilatory art' is regularly the subject of a 'special feature' with presentations of the latest trends and techniques. All the information is also available on the Internet, with beauty care websites specialized in hair removal, the brand websites, blogs and forums.

IV. THE OPERATING PRINCIPLE OF PHOTOEPILATION

IPL or laser photoepilation[3] is based on the principle of selective light absorption by the hair pigments, such as melanin, causing the thermal destruction of the hair bulb. Melanin is the primary determinant of hair pigmentation. The darker the hair, the more melanin it contains[4].

For pulsed light, high output bursts of light are produced by a xenon lamp. Laser epilator radiation has a fixed waved length and targets the hairs whereas IPL equipment flashes cover a wide spectrum of wavelengths (from 300 to 1,000 nm) in the ultraviolet, visible light and infrared spectra. The flashes are aimed at a spot framed by the device aperture, which may cover a hairy area of several square centimetres.

An optic filter between the xenon lamp and the skin cuts off the wavelengths emitted by the xenon lamp to filter out ultraviolet and violet light (< 400 nm) and lower the risk of erythema while promoting hair thermolysis, as melanin absorbs at high wavelengths. Two different types of filters[5] fitted onto the equipment and devices sold to professionals or consumers can be found on the market:

- Multiple layer filters
- Filters dyed in the mass

[2] Gillette invented the first safety razor with disposable blades in1908.
[3] Technique designed for dermatology in the 1970s; the first equipment appeared on the market in the 1990s.
[4] IPL for hair removal does not work on very light hairs (blonde, red, grey and white) that contain little melanin.
[5] 'Poorly filtered' light presents a risk of scattering wavelengths such as ultraviolet (wavelength < 400 nm). Ultraviolet propagation is hazardous to the skin and eyes. Aside from erythema, UV-generated free radicals may cause mutagenic DNA alterations.

IPL targets melanin that is also a skin pigment, the darker the skin, the more melanin it contains, therefore the contrast between skin and hair melanin is not as great. As IPL does not differentiate between hair and skin pigments, it produces a thermal action on the melanin rich epidermis and the skin, which may cause a burn. The so-called 'Fitzpatrick' scale, after the physician who developed it in 1976, is the reference for professionals and can be found in most of the user manuals of the consumer products. The scale breaks individuals down into six types according to the colour of the skin, head and body hair, and describes the reaction of their skin to the sun and tanning. The six phototypes have the following features:

- Phototype 1: never tans; pale white skin, freckles, blond or red hair;
- Phototype 2: tans minimally (sunburns); pale white skin, blond or light brown hair, freckles in the sun, light eye colour;
- Phototype 3: sunburns, tans gradually; creamy white skin, blond or light brown hair
- Phototype 4: rarely burns, always tans well; dark skin, light brown or brown hair, dark eye colour
- Phototype 5: very rarely burns, always tans well; dark brown skin, dark eye colour
- Phototype 6: deeply pigmented dark brown to black skin; never burns

Consequently, Phototypes 5 and 6 are not appropriate for IPL photoepilation.

The energy, or 'fluence', delivered by the device is measured in Joules per surface unit expressed in cm^2 (J/cm^2). Consumer products sold in stores usually have fluences with average amounts lower or equal to 10 J/cm^2. The light energy of the equipment used by beauticians for hair removal may reach 150 joules on a 7.5-cm^2 surface (area of the light guide), i.e. fluence of 20 J/cm^2. The 20 J/cm^2 threshold limiting the power of beauticians' equipment has been 'adopted' by numerous manufacturers. Physicians' equipment is programmed for a fluence of up to 32 J/cm^2.

When a hair absorbs light, the melanin heats. On professional equipment, hair bulb temperature may reach 70°C or even 100°C[6]. The thermolysis effect destroying the bulb and causing the hairs to fall out is produced at this temperature. If the operation is to be effective, it must be carried out during the hair growth stage (anagen)[7] when the hairs produce large amounts of melanin. On average, only 20% of the hairs are at the anagen stage at any given time, therefore, several sessions are required to produce noticeable hair removal.

The duration of light radiation, or 'pulse duration' (expressed in milliseconds, ms) is critical to raising melanin temperatures. However, the object is to heat the hair follicle without heating the skin, which may occur after excessively long pulses. Some professional equipment is fitted with a 'multi-pulse' or 'train of pulses' feature, so that the flashes are broken down into several micro-pulses. Each micro-pulse (from 2 to 5 ms) heats the follicle while the interval between two micro-pulses (from 15 to 50 ms) provides a brief respite allowing the skin to evacuate heat. Thermal relaxation time is defined as the time it takes for the skin to cool down (from 1 to 10 ms). Efficient hair destruction occurs at pulse durations of roughly 30 ms.

The devices have either water-cooling systems (professional equipment), or air-cooling systems (consumer devices) to lower temperatures.

---

[6] Importantly, lethal cell temperatures range from 45 to 60°C. The impacts of high temperatures on the healthy cells around a hair are not known.

[7] Hair roots are at about 4 mm under the skin. The life cycle of hair has three phases: the anagen phase (growth), the catagen phase (end of active hair growth) and the telagen phase (resting and death). Cycle length varies according to body part; for example, 6 to 7 months on the upper lip, 15 months on the chin, 9 months on the lower arms, 18 months on the bikini line and in the armpits, 18 to 22 months on the legs.

V. THE MARKET

A. THE PROFESSIONAL MARKET

Hair removal services account for about 30% of the sales figure of a beauty care centre. Notably, men's demand for hair removal is rising (nearly 30% of the market).

According to CNEP estimates, 20,000 pieces of equipment using new technologies (for hair removal, rejuvenation, slimming and 'anti-ageing' treatments) have been delivered to the 'Beauty Care & Wellness' sector, of which eight thousand IPL epilation machines, of which 4,500 operating in beauty care centres.

According to CNAIB, the estimated number of non-medical professionals with IPL equipment ranges from 5,000 to 10,000.

The main manufacturers or dealers of photoepilators for professional use are the following companies: EUROFEEDBACK, DERMEO, E'SWIN, CORPODERM, BVA TECHNOLOGIE and DERMASCIENTIFIQUE. The sales price for the products ranges from €15,000 to €40,000.

B. THE AT-HOME EPILATOR MARKET

According to GIFAM (*Groupement Interprofessionnel des Fabricants d'Equipements ménagers*, Inter-professional Group of Home Appliance Manufacturers), the French razor and epilator stock for women[8] amounts to 78 million devices in 26.8% of households in France, based on the results of a TNS SOFRES survey. One point nineteen million devices were sold in 2012. The IPL epilator market has skyrocketed from 8,000 to 9,000 devices sold in 2010 to 48,000 sold in 2012, i.e. €15 million in sales. According to some estimates, 75,000 devices may have been sold in 2013.

How can this sharp rise be explained?

After using available standard hair removal methods, i.e. dissolving hairs or pulling them out, hair will grow back three weeks after a depilatory cream or an electric epilator, and three to four weeks after waxing. The 'marketing' pitch of adverts for at-home IPL devices focuses on their similarities with professional equipment, touting that hair removal is long lasting, fast, easy and less painful. However, advertisers' main target is to reach the largest number of consumers, with a focus on those who cannot afford epilation clinics because of the high cost of hair removal sessions (roughly €1,300 per year).

Drawing on the momentum of home appliance professionalization (i.e. steam iron stations, coffee machines), manufacturers began tackling the design of portable photo-epilators, which are very different from the gigantic professional equipment.

IPL epilators arrived in the home device world in 2007 with E-One; a device created by E-Swin, a company specialized in IPL.

The major home appliance brands started launching their products in 2010: Philips, Rio, Remington and Babyliss followed by Beurer, Epilady, Braun and Calor the following years. Since the first product launches, new models have been created with altered power and efficiency features.

The goal, which is expressed differently for each brand, is to slow hair growth durably (not indefinitely). After testing, the publicized results range from 50 to 80% of zero hair growth for two months, after the fourth session.

[8] Including razors, hair clippers, at-home waxing kits, laser and IPL epilators

For their sales pitch, product manufacturers have chosen the adverb 'durably' and some make sure that any allegations that hair removal is permanent or definitive are not used, as they cannot be proven.

IPL technicians working with dermatologists created the consumer devices. *In vitro* tests and consumer tests were sometimes run to assess results before putting the products on the market.

The devices have a ventilated air-cooling system. They may be plugged into an electric outlet, or are powered by rechargeable batteries. The design varies with each brand. Their 'hair dryer' or revolver shape makes them easy to hold. Other devices have a base connected to the IPL hand piece with a cord.

Depending on the model, flash power ranges from 2 to 10 J/cm² and the treatment area ranges from 2 cm² (the face) to 6 cm².

Device prices range from €250 to €500, with one model costing less than €200 and another more than €1,000. The products are sold in large superstores, in the sales networks of the brands and on the Internet.

Product flash capacity is said to be from 5,400 flashes (Tanda Me Elos) for one cartridge, to 100,000 flashes, which would mean five years worth of hair removal (Philips). Usually only the bulbs have to be replaced but some models have to be completely changed once the finite number of flashes has run out (Philips).

The efficiency and safety of the operation depend on the light intensity setting that has to be adjusted according to skin type. Some devices (especially the most recent ones) have an automatic skin colour or phototype sensor that indicates the proper light intensity setting, or programs the setting automatically. The light intensity feature usually has five power settings adapted to the different phototypes.

The focus is also on the speed and ease of hair removal with the device. For optimized results, some brands provide an activating gel to apply before the session. The gel is also said to be skin soothing.

VI. THE CONDITIONS OF USE

A distinction should be made between the equipment used by professionals and the devices used by consumers.

A. BEAUTY CARE CENTRE EQUIPMENT

People who regularly go to a physician for IPL hair removal can be ensured of a virtually therapeutic protocol. Skin type and patient tolerance are taken into account when setting radiation doses. Physicians will systematically search for any contraindications. A diagnosis of skin condition (specifically to check for any cancerous or precancerous lesions) is performed before each session. The maximum number of safe sessions is set. The subject is constantly monitored during treatment. The physician oversees equipment checks and emitted radiation is measured at each session.

Settings and checks are performed on:

- The range of wavelengths
- Pulse duration
- Exposure time to the energy source
- The type of filter
- The ageing of the lamp

Do customers going to beauty care centres for hair removal enjoy the same assurances?

The following facts were ascertained after the hearings held with manufacturers, representatives of the professional associations and two IPL hair removal franchises.

1. The professionals recommend that beauticians with an official diploma, who have been trained to operate the equipment, should be allowed to use IPL equipment

A consequence of the 'illegality' of non-physicians practising IPL hair removal is that regulatory provisions requiring that only a qualified person having attended a IPL technique training course whose content would be defined by regulations may be allowed to operate IPL equipment for consumer hair removal do not exist.

However, the beauty care professional associations require that their members (who include franchise holders) ensure that the equipment operators have a beauty care diploma and training in IPL techniques[9].

To date, there are 66,000 beauticians with diplomas in France[10]. The Ministry in charge of Education designs the curricula for the beauticians' diploma-awarding training courses. The basic diploma is the CAP (certificate of professional competence) in 'beauty care and cosmetics' (Level V diploma), which is mandatory for anyone who intends to open a beauty care centre. However, an increasing number of beauticians have one of the following diplomas:

- A BP (professional certificate) in 'beauty care, cosmetics and perfumery' (Level IV diploma)
- A vocational baccalaureate in 'beauty care, cosmetics and perfumery' (Level IV diploma)
- A BTS (Advanced Technician's Certificate) in 'beauty care and cosmetics' (a Level III diploma available after the baccalaureate).

Actually, 20% of beauticians have a BTS. The curricula of the diploma-awarding training course for the 'Beauty Care-Cosmetics-Perfumery Occupations' BTS includes a theoretical approach to the characteristics and effects of electromagnetic radiation in visible light.

Furthermore, the OCPA (the accredited organisations that collect training funds) in the beauty care sector (OPCAREC and AGEFOS) finance diploma-awarding IPL training courses as part of adult education and DIF (individual training entitlement) programmes.

Some manufacturers have set the following prerequisites to the sale of their equipment: having a beauty care diploma and attending a training course.

Training courses on how to operate the equipment are usually designed by the manufacturer that pays the physician who teaches the course. The course comprises a theoretical and a practical part, and occasionally multiple-choice tests. At the end of the course, the physician delivers a training certificate to each beautician, which is sometimes posted at the hair removal centre for customers to see.

After the equipment is installed and during its life cycle, some manufacturers employ physicians to answer beauticians' questions on a hotline or on the Internet.

[9] Only a field survey can check whether these requirements are actually enforced.
[10] The French beauty care industry accounts for 39,700 businesses employing 37,000 people. The industry generates a 1.48 billion-euro sales figure (source CNAIB).

2. Beauty care centre customers must not have any contraindications to the practice of IPL hair removal

At the hearings, the professionals admitted that beauty care professionals do not have the required training to carry out 'medical' examinations of the skin such as the ones performed by physicians and specifically dermatologists.

Radiation may only be emitted into a 'healthy' body without any lesions or pathologies. Therefore, to avoid any adverse reactions, customers with certain disorders should not be admitted for hair removal treatment.

Some manufacturers have designed so-called 'enlightened consent' forms for their customers. The forms include the major principles of IPL hair removal (and its limits, if need be)[11], service prices and a health questionnaire[12] that all customers requesting hair removal must fill out and sign. The health questionnaire, which is absolutely not a medical diagnosis according to its authors, contains a limited list of diseases that preclude the use of pulsed light *a priori*, or at least require certain precautions. Customers must state whether they have one of the listed pathologies. The contraindications are usually the following[13]:

- Diseases of the adrenal gland or kidneys
- Chronic dermatological diseases
- Allergy to the sun, allergic skin reactions (i.e. hives, eczema), slight sensitivity or histamine reactions (rash, headaches, vomiting and diarrhoea)
- Blood coagulation diseases, such as thrombosis (blood clot, phlebitis, embolism)
- Endocrinal diseases such as diabetes
- Cardiac diseases (or excessively high blood pressure)
- All skin diseases such as herpes, psoriasis or eczema
- Immune diseases
- Infectious diseases
- Hormonal imbalance
- Nervous system diseases such as epilepsy
- Cancer

If one of the diseases on the list is checked, or another unlisted disease is provided, the customer is required to produce a medical certificate of no contraindication to IPL sessions, delivered by a physician.

3. IPL sessions are subject to the usual precautions

The equipment user manuals usually include the following instructions:

- The application must be done on untanned skin, meaning no exposure to the sun, tanning booth sessions, or use of self-tanning creams before and after IPL sessions.

---

[11] Some specialised centres offer their customers theoretical and practical presentations of IPL hair removal before a set of sessions. Pictures may be taken from one session to the next so the customer can appreciate the progression of hair removal.

[12] The preservation, automated processing and sorting of health data by persons, such as beauticians, who are not bound by doctor-patient confidentiality, is authorized subject to customer consent and to compliance by the 'data controller' with the provisions of the Act on Data Processing and the Protection of Privacy. On the other hand, the information is still governed by professional secrecy. Therefore, revealing the information to 'non-authorised' third parties, in any media whatsoever, is liable for penal sanctions (Article 226-13 of the French Penal Code). However the French Medical Association is against this practice when the type of the questionnaire is disproportionate compared to the treatment in question.

[13] It is not known whether the contraindications are actually founded, that is to say whether they have been clinically evaluated.

- Hairs must be shaved before the session to allow all the light energy to focus on the hair root, and to avoid burning the hairs on the skin surface, which may cause discomfort
- A cold (5°C) gel must be applied; a topical numbing cream (EMLA [14] or similar) is sometimes used
- Customers must wear protective eyewear. The eyewear is sometimes the standard small laser safety goggles. The practitioners wear glasses that are not as dark as the goggles because the former are not as close to the light beam as the patient/client.
- Tattoos, birthmarks and skin tumours, including melanomas, beauty marks with irregular edges and (or) raised birth marks must not be treated, or must have protective covering. Although they do not have the medical training required to examine a customer's skin, beauticians use their own power of discretion to determine which 'healthy' zones may be treated. During the hearings, the representatives of the Directorate General for Health said the protective measures against skin spot or beauty mark radiation were insufficient. A survey conducted in seven beauty care centres in Basse-Normandie showed that spots or beauty marks were protected with a white pencil. Other centres use small pieces of tape.
- Before every session, a flash-test has to be run to determine whether the person can stand pulsed light. The customer should not feel any stinging sensation for ten minutes.
- The recent intake of medicinal drugs or the application of photosensitiser creams, a recent vaccination and the application of essential oils are contraindicated, or entail waiting a sufficient lapse of time between sessions.
- The next session should only be scheduled after hair growth is in the ascending phase. The lapsed time is variable, from two to six weeks depending on the relevant body area. Some areas are usually not treated: around the eyes, cheeks and mucous membranes.
- Some consider that a 'precautionary principle' should be adopted for minors, that is to say wait until after puberty and the 'stabilisation of the pilous system'. Therefore, using the equipment on someone under the age of 15 is not recommended. Some centres require parental consent.
- Beauticians' equipment is pre-programmed to prevent any misuse. The beautician just has to select the phototype (skin colour) and hair diameter. Fluences, pulse duration and intervals are programmed into the equipment for each configuration.

B. THE DEVICES SOLD TO CONSUMERS

The operating principles of the devices and the instructions can be found in the user manuals.

Some manuals underscore that the devices have been clinically tested on a cohort of subjects, under dermatologists' supervision. The studies conclude that the devices are efficient and that the radiation causes no side effects.

Aside from one or two variables, the list of contraindications is the same as the list in the health questionnaires filled out by customers at beauty care centres.

VII. ACCIDENTOLOGY AND RISK ASSESSMENT

The French Institute for Public Health Surveillance (InVS, *Institut de veille sanitaire*) was consulted to find out if the EPAC database on everyday accidents had registered any hospital

[14] Cream with lidocaine, a local anaesthetic, also used to alleviate tattoo-induced pain.

emergency room admissions for various trauma caused by IPL, over the past years. InVS answered that, over the past eight years available in the EPAC database (2004 to 2011), none of the 132 reported accidents caused by an item for 'other individual hygiene care (specified or non specified)' involved an IPL device[15].

For the professionals (including CNEP and CNAIB) who were heard, photoepilation does not cause any skin punctures or blood flow. A bibliographical study by Dr. Daniel CANTALOUBE[16] commissioned by CNEP allegedly demonstrates the absence of any complications caused by the use of IPL lamps.

The professionals and their experts underscore that, in some cases, light rashes, oedemas or severe itching and a stinging sensation in the treated areas may be observed after radiation. The irritations allegedly clear up within a few days; they are less uncomfortable than the irritation occurring after the use of burning wax, especially in sensitive areas such as armpits.

However, during the hearings, DGS representatives said they had "*been informed of complications and secondary incidents after hair removal by equipment delivering pulsed light, by Regional Health Agencies (ARS). The complications were mainly deep burns over large areas, requiring several weeks of a healing treatment. Cases of paradoxical excessive hair growth, which causes a social handicap when it occurs on the face[17], were also reported. The incidents are hyper-pigmentation*."

What is the actual state of affairs? Burn cases do exist but are allegedly rare and the result of equipment operating 'mistakes'. The co-President of DEPIL TECH epilation centres deplored a first-degree burn accident after the customer did not comply with the safety instructions as he had neglected to say that he had splashed essential oil on his body. The Head of RADICAL EPIL only deplored two burn cases in six years due to the imprudence of a customer who had had a tanning session before her epilation and the other due to an operator error.

EUROFEEDBACK, a manufacturer of professional equipment, declared that only 10 to 15 first-degree burn cases per year had been reported for their entire fleet of 4,500 machines.

Undeniably, radiation causes short-term effects, such as immediate or delayed, visible and painful skin reactions sometimes, which are listed in product user manuals and available to customers.

International medical literature has reported second-degree burns after IPL epilation on tattooed skin (2013), cases of eye damage during a per ocular application causing iris transillumination and photophobia (2011).

Aside from the signs appearing at time of radiation, the existence of other less known but potentially serious events that may occur much later, are suspected. The public authorities have estimated that a scientific assessment of the effects of IPL equipment would be essential for the design of a supervisory framework based on risk control for users and professionals.

The assessment is part of a broader study on the health hazards incurred by using external physical agents for beauty care acts. The objective is to define the characteristics of the main types of physical agents used for beauty care acts, with a focus on electromagnetic radiation (i.e. wavelength, intensity), to assess their impacts on health over the mid to long term, and to draw up a comparative report of the regulations and standards for IPL equipment.

On 3 February 2012, the French Agency for Food, Environment and Health Safety (*Agence nationale de sécurité sanitaire, de l'alimentation, de l'environnement et du travail*, ANSES)

[15] However, it should be pointed out that only eleven hospital centres participate in the EPAC network.
[16] 'Hair removal with filtered IPL flash lamps' (26 November 2011)
[17] Growth of fine long hairs near the areas where the hair had been removed

was commissioned to conduct the study whose results should be transmitted to authorities[18] in late 2014.

Long term biological and health effects raise several questions:

- Do precancerous or cancerous lesions develop after radiation?
- What is the impact of chronic radiation on skin ageing
- Are there any irreversible effects on the stem cells of the hair follicle, i.e. the cells involved in the regeneration of the epidermis and sebaceous glands?

Several warnings have already been transmitted to CSC representatives about the photobiological effects of IPL equipment radiation by two distinguished scientists: Mr Serge MORDON, an INSERM researcher and recognised specialist of laser and pulsed light technologies, and Mrs Evelyne SAGE, President of the European Society for Photobiology.

Mr MORDON underscored the following points:

- *The importance of eye hazards*

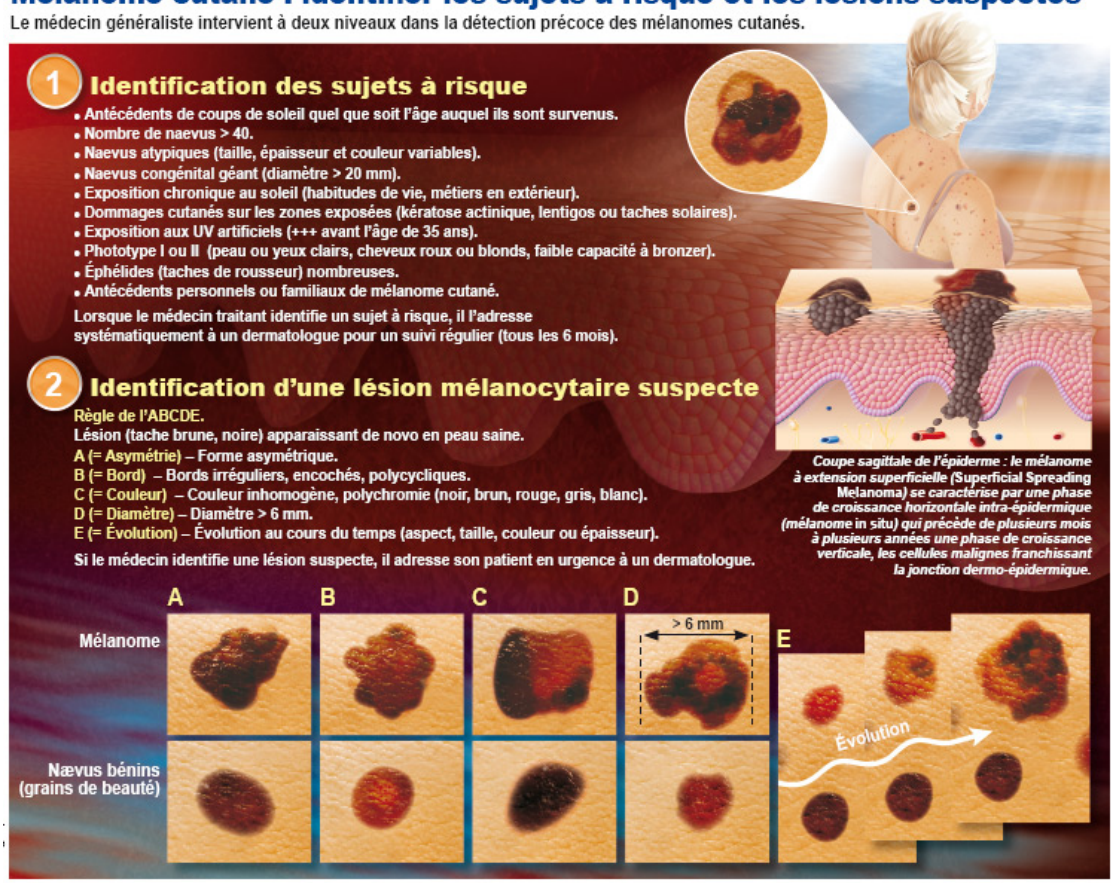
According to Mr MORDON, unlike laser that can be properly filtered as it emits over a precise wavelength, IPL emits over the entire visible light spectrum meaning that eyewear cannot protect against pulsed light. Mr MORDON believes that, to a certain extent, consumer devices are safer than professional equipment, because most are fitted with sensors that prevent them from powering up if they are not in direct contact with the skin. Therefore, in principle, radiation could not be emitted directly into the eyes. However, the fact that eyewear cannot protect user from the light output from IPL equipment will eventually lead to eye problems after repeated exposures. During an expertise for ANSES, the Director of an Ophthalmology Service stated that she was seeing a growing number of dermatologists using flash lamps who complained about eye problems.

- *The removal of cancerous lesions and specifically melanoma[19]*

According to Mr MORDON, in 70% of the cases, melanoma is formed on a previously unblemished skin and in 30% of the cases, on a pre-existing nevus, or raised beauty mark. Solar keratosis promotes the onset of this cancer. The dermatologist will be alerted to this development by the clinical aspect of the lesion characterised by a dark spot and will perform a biopsy. However, as was explained above, the operating principle of a photoepilator is based on absorbing the light of an optic target (melanin) in the hair and melanomas are lesions of melanin rich skin.

[18] DGS, DGCCRF, DGT (Directorate General for Labour) and DGPR (Directorate General for Risk Prevention) commissioned the study

[19] At the hearings, one manufacturer organised an unprecedented study to measure the impact of flashing melanomas with his equipment. The tests were conducted on two cohorts of mice that had been grafted with melanoma: one control batch and one treated batch. According to the manufacturer, the tests did not uncover any unfavourable impacts on melanoma growth in the batch of flashed mice. The results of the study should be published soon.



[Skin Melanoma: Identifying high-risk patients and suspicious lesions
The general physician plays a part in the early detection of skin melanomas, at two levels.
1- Identifying high-risk patients

- History of sunburns regardless of patient's age at time of burn
- Number of nevi > 40
- Atypical nevus (variable size, thickness and colour)
- Giant congenital nevus (diameter > 20 mms)
- Chronic exposure to the sun (lifestyle, outdoor jobs)
- Skin damage in the exposed areas (actinic keratosis, lentigos or sun spots)
- Exposure to artificial UV (+++ before age 35)
- Phototype I or II (light skin or eyes, red or blond hair, tans minimally)
- Numerous ephelides (freckles)
- Personal or family history of skin melanoma

When the attending physician identifies a high-risk patient, he or she will refer the patient to a dermatologist for regular follow-ups (every six months)

2- Identifying a suspicious melanocytic lesion
ABCDE Rule
Lesion (brown or black mole) appearing *de novo* on healthy skin
A – (Asymmetry): asymmetric shape
B – (Border): uneven, scalloped and polycyclic borders
C – (Colour)): Variety of shades and colours (black, brown, red, grey and white)
D – (Diameter): Diameter 6 mm
E – (Evolving): evolves over time (aspect, size, colour or thickness)

If the physician identifies a suspicious lesion, he or she will give the patient an emergency referral to a dermatologist

Melanoma
Benign nevi
(Beauty marks)

Evolving

When a melanoma is flashed, the melanin it contains will be destroyed, thus effacing any clinical signs of the lesion and preventing any opportunity to diagnose the mole. Mr MORDON suggested a solution consisting in increasing hair absorption by using an optical intensifier specific to the hair, or hair stalk. Consequently, low energy (under 1J/cm^2), which would only be efficient on the hair, without any risk to the skin, could be used.

Mrs SAGE also underscored the retinal thermal risk occurring when radiation temperature from the equipment heats the cells to over 45°C. Some retinal stem cells could be destroyed, which would be an irreversible loss. Temperatures exceeding 60°C present the risk of skin cell destruction. In the worst case, there is a risk of necrosis. However, unlike retinal lesions, not all lesions are irreversible because skin regenerates and skin graft options exist. Thermolysis may also destroy the stem cells of the hair follicle.

According to Mrs SAGE, irradiating beauty marks sharply increases thermal effects because the nevi are melanin rich. After repeated exposure to IPL, a beauty mark may change its aspect and become asymmetrical. In the mid to long term, it could become a melanoma. Similarly, irradiating a scar is not advisable because scar tissue skin is very fine.

VIII. REGULATIONS

The regulations applicable to the epilation act should be distinguished from the regulations applicable to IPL equipment and devices.

A. THE LEGAL SYSTEM FOR EPILATION

Specific regulations govern epilation, which is defined as a medical act. The amended Order of 6 January 1962 laying down the nomenclature of medical acts that may only be performed by physicians, medics, or non physician directors of medical screening laboratories provides for the following in Article 2°5:

> "*only the following medical acts: (…) all methods of epilation except for waxing or tweezing shall only be performed by medical doctors in compliance with Article L. 372-1 of the Public Health Code.*"

The safety issues involved in using non-ionizing electromagnetic radiation for beauty care are not new subjects for the CSC. For instance, on 31 May 2012, the Commission issued a recommendation for the modification of a Decree on the public availability of tanning booths.

Using IPL or laser equipment for hair removal by non-physicians constitutes the illegal practise of medicine. Pursuant to Article L. 4161-1 of the Public Health Code, persons who practise medicine illegally are:

> "*any individual, either on a regular basis, or under supervision even in the presence of a physician, who participates in establishing a diagnosis or treating congenital or acquired, real or imagined diseases, through personal acts, verbal or written consultations, or by any other means whatsoever, or practise one of the professional acts provided for in a nomenclature laid down by an Order of the Minister in charge of Health, issued after a recommendation by the National Academy of Medicine* (…)"

Pursuant to Article L. 4161-5 of the Public Health Code, the illegal exercise of the profession of physician is punishable by a two-year prison sentence and a €30,000 fine.

Interestingly, non-physicians are not forbidden to practice other applications, such as slimming, rejuvenation or the removal of skin or vascular spots with IPL equipment. However, as was explained by the DGS representatives at the hearing, "*the removal of spots by non-physicians who have not been trained to detect malignant lesions, raise the concern that spots which are a symptomatic presentation of cancer will be effaced, thus allowing them to develop quietly and lowering patient's chances.*" However, if it were proven that the said acts represented a serious

hazard, or the suspicion of a serious hazard to human health, Article L. 1151-3 of the Public Health Code[20] allows the DGS to issue a decree prohibiting this type of practice following a Recommendation of the French National Health Authority. There is a precedent in this area: Decree no. 2011-382 of 11 April 2011 on the prohibition of the practice of adipocyte lysis acts for cosmetic purposes.

Compliance with the provisions of Article 2.5 of the Order of 6 January 1962, drafted at a time when IPL equipment did not exist, is tightly controlled by civil and administrative jurisdictions.

In a Decision of 24 March 2013, the Supreme Administrative Court dismissed the appeal of a physician who had been forbidden by the Disciplinary Chamber of the French Medical Association to exercise medicine for three months (suspended sentence) for having non-physician assistants perform laser hair removal in his office. The physician was found guilty of complicity in the illegal exercise of medicine[21].

In a Ruling of 18 January 2012, the Criminal Court of Toulon, based on a complaint filed by the Association of Dermatologists – Venereologists, found 4 beauty care centres, a beautician and a self-employed nurse using IPL lamps for epilation, guilty of the illegal exercise of medicine.

The sentence was confirmed by an Order of the Court of Appeals of Aix en Provence, on 6 November 2012. The Court dismissed the argument of one of the defendants arguing that the amended Order of 6 January 1962 prohibited epilation by non-physicians but not depilation. "*This semantic argument shall be dismissed by the Court that, in the first instance, notes that the terms are synonymous as they both refer to the action of removing hairs from the skin, either by pulling them out or making them fall. In the second instance, the Court observes that the text of Article 2 of the Order is perfectly clear and does not leave room for any interpretation as it only authorises two types of epilation without medical control, i.e. waxing and tweezing. The spirit of the 1962 text is that only purely mechanical procedures, therefore harmless a priori, may be practised by persons with no medical competence, all other procedures must be exercised or performed by a physician.*"

Several formal notices to cease their IPL hair removal activity were sent to beauty care facilities by the lawyers of dermatologists. CNEP has recorded 87 ongoing lawsuits against beauticians.

Not long ago, on 12 March 2014, the Criminal Court of Orleans found three beauty care centres guilty of illicit photoepilation acts.

Furthermore, some professionals, who believe they have been misinformed about extant regulations, have sued IPL equipment manufacturers. A decision of the Court of Appeals of Angers of 15 December 2009 ruled in favour of a physical therapist that disputed the sale of the equipment because the seller had misled him by touting the alleged deregulation of the IPL technique used for phototherapy for cosmetic purposes.

The SNDV President would like French regulations to be enforced. He cannot keep suing beauticians indefinitely given the substantial legal fees.

Logically, beauticians practising IPL cannot be insured since they are legally prohibited from practising the IPL technique. However, some insurance companies have agreed to cover beauticians with diplomas either because they have signed agreements with the representative professional associations, or because the beauticians have agreed to use the brands of equipment recommended by the insurance companies.

---

[20] Stemming from the codification of Article 61 of the Act of 29 July 2009 reforming hospitals, and on patients, health and the regions

[21] Notably, in 2005, the Court of Cassation dismissed the appeal of a physician accused of the illegal exercise of medicine, not because he had delegated epilation acts but because he had not supervised his assistants at all.

According to the beauticians' associations, a widespread measure prohibiting beauticians from using IPL equipment would have serious consequences in terms of business shutdowns and job losses. The purchase of IPL hair removal equipment is a big investment. A machine costs about 30,000 to 50,000 euros and a filter 1,500 to 4,000 euros[22]. Beauty care centres would have to "mothball' the equipment, and ultimately close and fire personnel.

The SNDV President proposed a two-year moratorium before enacting a full prohibition banning non-physicians from using photoepilation equipment. The SNDV is also in favour of the set-up of a general regulation on equipment emitting radiation into the skin.

Both representative beauty care and cosmetic associations (CNEP and CNAIB) whose presidents were heard, as well as IPL equipment manufacturers demand that their members have the right to use a modern technique for treating hairs, such as photoepilation, and are very eager to see current regulations modified. They underscored that, in numerous European countries, beauticians use IPL equipment completely freely (Belgium, Ireland), or in compliance with national or local regulations that also govern other techniques, i.e. laser, radiofrequencies (United Kingdom, Finland, Spain and Italy).

In France, a bill on the modernisation of the occupation of beautician was filed with the Presidency of the French National Assembly on 26 November 2008. No proceedings for this Parliamentary bill have been forthcoming. Article 1 of the Bill provided for authorising beauticians to practise:

> "*all types of epilation and depilation, except for those found in Article 2 of the Order of 30 January 1974 on the regulations on the use of laser for medical purposes, provided they have received appropriate training in the use of each new technique*."

B. THE REGULATIONS GOVERNING THE EQUIPMENT AND DEVICES

Photoepilation equipment and devices for home and professional (including medical) use are not governed by any specific regulations. They are subject to the general regulations for home appliances i.e.:

- **Amended Directive 2001/95/EC** of 3 December 2001 on General Product Safety imposes a safety requirement for a product under normal or reasonably foreseeable conditions of use. The general safety requirement has been transposed into French law in Article L. 221-1 of the Consumer Code.
- **Directive 2004/108/EC** of 15 December 2004 on electromagnetic compatibility, called the EMC Directive. The Directive, which was transposed into French law by amended Decree no. 2006-1278 of 18 October 2006, states that the equipment must be designed and manufactured in such a way as to ensure that:
  - The electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment, or other equipment, cannot operate as intended (emission).
  - It has a level of immunity to the electromagnetic disturbance to be expected in its intended use, which allows it to operate without unacceptable degradation of its intended use (immunity).
- **Directive 2006/95/EC** of 12 December 2006 on electrical equipment designed for use within certain voltage limits, called the Low Voltage Directive. The Directive applies to electric equipment designed for use with a voltage rating of between 50 and 1000 V for alternating current, and between 75 and 1500 V for direct current. The electrical equipment must be constructed in accordance with good engineering practices so it does not endanger user safety. The manufacturer or representative is in charge of the conformity assessment

[22] A photoepilation session is billed about €200 whereas a waxing session is billed about €16.

procedure. CE marking must be affixed to the electrical equipment. The Directive was transposed into French law by amended Decree no. 95-1081 of 3 October 1995.

- **Directive 2012/19/EU** on waste electrical and electronic equipment (WEEE) requires that EEE manufacturers provide for selective collection, treatment and recovery of EEE. They must also inform consumers of collection requirements by affixing the symbol for marking EEE, indicating separate collection of the product pursuant to Annex IV of the Directive, and the pictogram in Standard NF EN 504-19 of June 2006 on the marking of electrical and electronic equipment.

- **Directive 2002/95/EC** (RoHS - Restriction of the use of certain Hazardous Substances in electrical and electronic equipment) completes Directive 2008/98/EC to limit the use of six hazardous substances: lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE). Maximum concentration values of the substances are 0.1% per unit weight of homogeneous substance, except for cadmium where the limit is 0.001%.

These requirements are not very demanding considering the health hazards incurred by using the equipment. As long as the equipment does not present any electrical hazard or electromagnetic disturbance, it can be placed on the market for consumers or professionals, beauticians or physicians. On the other hand, the literature included with the products must not have any medical allegations based on clinical trials or therapeutic protocols.

Only if the equipment claims to have one or several therapeutic purposes does it then become classified in the category of medical devices (MD) governed by amended Directive 93/42/EC on Medical Devices, even if the equipment claims to have other non-medical purposes. The main therapeutic function of epilation is the treatment of the consequences of hirsutism[23]. On the consumer product market, one device claims this application and other cosmetic functions, so it carries CE marking under the directive[24]. ANSM (*Agence nationale de sécurité du médicament*, French National Agency for Medicines and Health Products Safety) is the competent authority for classifying and controlling MD.

As CE 'medical' marking provides credibility, some professional equipment manufacturers have opted for this procedure for acts without therapeutic purposes, even if they are not legally obliged to do so.

The procedure for meeting the requirements of the abovementioned Directive 93/42/EC is more demanding, longer and more expensive that the mandatory procedure for home appliances. Medical devices are broken down into four classes corresponding to ascending risk levels (I, II a, II b and III). Manufacturers choose the method for proof of conformity with the requirements of the appropriate directive, according to the class of the device and their situation in terms of the organisation of their production and their quality assurance system. For devices with average, high or critical risks according to the manufacturer, the latter has to undergo a control by a notified body.

[23] It should be pointed out that the regulation on medical devices is being reviewed (draft regulation that will not be adopted before 2014). France has requested the strengthening of the provisions on MD, and the inclusion of the devices for cosmetic purposes, and a EU assessment for the very high risk MD before the delivery of CE marking.
[24]For products sold to consumers, the marking might lead consumers to confuse operations for cosmetic purposes with therapeutic care.

Notably, the regulation does not require clinical trials for MD. As underscored by the DGS representatives during the hearing:

> "*It requires clinical data from the manufacturer; the data can either be a critical evaluation of the available, relevant scientific literature demonstrating that the device is the same as the device for which the data was collected, or an evaluation of the results of all the clinical investigations, or a combination of both types of data.*"

The legal void surrounding the design of products, whether they are simple home appliances or medical devices, is detrimental to consumer safety.

1. None of the abovementioned texts set an energy density limit for the devices according to user status (physician and non-physician professionals, and consumers), nor do they require wearing personal protective equipment

Manufacturers set the power limits of photoepilation equipment and devices at their own discretion, taking account of user profile and an efficiency/risk ratio:

- From 2 to 10 J/cm² maximum for devices sold to consumers
- 20 J/cm² maximum for equipment sold to beauty care professionals along with recommendations, or the obligation to attend training to learn how to operate the equipment
- More than 20 J/cm² for the equipment for physicians

Therefore, nothing legally prevents a manufacturer from selling an device with an energy density of more than 30 J/cm² to a beauty care professional with a diploma (beauticians) or without one (franchise holders and others). On the other hand, as was said above, beauty care professionals may be liable for the illegal exercise of medicine, but the power of the equipment they use cannot be incriminated.

Yet, the situation is very different for laser epilators that physicians as well as manufacturers tend to place on the same level in terms of performance. Standard NF EN 60825-1 of January 2008 on the safety of laser devices breaks them down into seven different classes according to the hazards of their accessible radiation, ranging from the most harmless to the most hazardous: 1, 1M, 2, 2M, 3A, 3B, and 4. According to this classification, laser radiation is only hazardous at class 2M and above. Similar to class 2 lasers, if "*the eye is normally protected by a defence reaction (including the winking reflex), vision at beam output may be hazardous when using an optical instrument.*"[25]

The Act (Article 68 of Act 2011-267 of 14 March 2011 on direction and planning for the performance of domestic security, called the LOPPSI Act) incriminates the acquisition and sale of laser equipment with a given power, regardless of its intended use. Therefore, the fact of buying, owning or using, manufacturing, importing, distributing in consideration for a fee or free of charge, laser equipment that is not intended for a specific authorised use belonging to a class over Class 2 is punishable by six months in prison and a 7,500-euro fine.

Pursuant to Decree no. 2012-1303 of 26 November 2012 establishing the list of specific authorised uses for equipment belonging to classes above Class 2, manufacturers, importers or distributors, and consumers cannot manufacture, market, buy or use laser equipment from Class 2 M and above, i.e. equipment emitting visible radiation in the wavelengths ranging from

[25] The third version of Standard IEC 60825-1 published in 2014 amended this classification. The standard actually created a new class of devices (class 1 C) where devices, such as laser epilators, explicitly intended for skin or non-ocular tissue contact are classed. The laser device can only be ranked in Class IC if one of the standards in the series of IEC 60601 or IEC 60335 standards applies and details the methods of technical control that ensure that the eye is not exposed to laser radiation, among others.

400 to 700 nm. Equipment in a class equal to, or higher than 2 M can only be sold to professionals, to wit, for medical or cosmetic purposes[26].

The laser legislation explains why beauty care professionals prefer to use IPL rather than lasers for photoepilation.

Interestingly, in Italy, a Decree of 12 May 2011 limits the power of the IPL equipment beauticians are allowed to use, by distinguishing the equipment fitted with cooling systems from the machines that are not. Energy density must not exceed 26 J/cm² for the former and 13 J/cm² for the latter. In both cases, the wavelengths must range from 600 to 1000 mn; pulse duration from 2 to 50 ms and treatment area must not exceed 5 cm².

2. No text has established mandatory technical controls of currently operating epilation facilities by accredited third party organisations

Although the equipment coming out of the factory is controlled by manufacturers, and receives the required regulatory certifications, the viability of the equipment over time is not subject to mandatory periodical control by third parties. Specifically, this means that the stability and delivered energy density and its calibration, filter wear, the wear of the cooling and electrical systems, the conditions of use and hygiene, or the mandatory wearing of PPE are not controlled over time.

Yet this type of control is done for facilities that are very similar to epilation centres, i.e. tanning salons[27]. Accredited bodies conduct inspections of the facilities when they open, then every two years, according to the methods in a technical control guide drawn up by the administration. Every year, the bodies must transmit a report with the list of facilities that were controlled, a statistical presentation of the control results and the detail of compliance and non-compliance with regulations, to the Ministry of Health.

C. THE STANDARDS APPLICABLE TO THE EQUIPMENT

A draft good practises standards called 'Beauty Care and Wellness – The design and use of equipment for beauty care and wellness purposes; guidelines' has been drafted under the aegis of AFNOR (French standardisation agency), at the initiative of CNAIB and CNEP. Its purpose was to define the criteria for validating professional equipment for cosmetic purposes, without any medical or therapeutic purposes, using new technologies such as IPL flash lamps for 'depilation/epilation' purposes. The standards the equipment must meet and the conditions of use (content of the user manual, time of the warranty and after-sales service) are listed. The drafting of the guide has been suspended since December 2012 at the request of the DGS and DGCCRF, pending the results of an ongoing ANSES evaluation of the impact on health of the different technologies.

Home devices have to comply with home appliance standards providing presumption of conformity with the provisions of the abovementioned Low Voltage and EMC Directives. Standards NF EN 60335-1 and its amendments, NF EN 60335-2-8 and its amendments, NF EN 62233, NF EN 55014-1 and its amendment, NF EN 55014-2 and its amendments apply to electrical safety. Standards NF EN 6100 3-2 and NF EN 61000 3 apply to electromagnetic compatibility.

A draft standard (Standard IEC 60335-2-113), which is being designed at the International Electrical Commission (IEC), addresses the 'Specific requirements for cosmetic and beauty care devices with laser and intense light sources'. The standard concerns laser or pulsed light devices for consumer use and for service provision (specifically at beauty care centres). The Standard recommends that devices comply with the requirements of Standard

[26] Therefore, a 1 C class epilation device can be freely sold to consumers.

[27] See Decree no. 97-617 of 30 May 1997 on the sale and availability to the public of certain tanning equipment using ultraviolet rays and Order of 9 December 1997 on the approval conditions of the accredited organisations in charge of controlling tanning salons.

ISO 62471 of December 2008 on the photobiological safety of lamps and lamp systems. As it now stands, the standard does not define any energy density limit for the equipment and devices, whether they are used by consumers or by professional service providers.

Several manufacturers have tested their products against the Standards for electrical medical devices meeting the essential requirements of Directive 93/42/EC on medical devices:

- Standard NF EN 60601-1 *General Requirements for Basic Safety and Essential Performance*, NF EN 60601- 6 *Suitability for Use*
- Mainly Standard NF EN 60601-2-57 of April 2012 that adequately applies to pulsed light devices that can also be used by non-physicians, as it lays down the "*particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use*."

The Standard breaks down device classification into four groups, from the lowest (0) to the highest (3), according to the risks of ocular or skin lesions based on the criteria described in Standard ISO 62471 of December 2008, on the one hand. On the other hand, it defines requirements for the prevention of electrical hazards potentially generated by operating electrical medical devices: basic specifications of Standard NF EN 60601-1. It also adds recommendations about the cooling system, protection against hazards from unwanted radiation and excessive temperatures. This is why we considered it timely to have an accredited laboratory test a range of products sold to consumers against the recommendations of the standard.

IX. THE TEST RESULTS

After a call for tenders, the CSC asked the LNE (French national testing laboratory) to assess photoepilator safety. The study consisted in controlling the safety of IPL devices according to:

- Standard NF EN 60601-2-57 (April 2012) on the safety requirements for devices with a non laser light source, only on the aspects related to optic radiation safety
- Some tests of Standard NF EN 60601-1 (January2007) on the general requirements for basic safety and essential performance of medical electrical equipment

The LNE was also asked to analyse the different protective eyewear and two gels supplied with the devices.

The CSC defined the list of devices. The French National Testing Laboratory purchased the said devices. The tests were conducted during the second 2013 semester.

A. PRODUCT CHARACTERISTICS

1. The Devices

LNE Ref.	Description	Technical specifications[28]	Safety feature / Remarks
A	Multilayer filter Aperture: 30 x 13 mm² Flash: 30 x 4 mm² Bulb + replaceable filter	Spot size: 4 cm² Light energy: / Flash duration: / Wavelength: / Skin colour sensor	Shot possible only if the device is placed against the skin (metallic/magnetic loop inside the device) Skin colour detection before the first shot If skin is too dark or black, shot is impossible Once colour is detected, several shots may be fired at the same spot on the skin without skin colour control Skin colour detection mandatory with each change of energy setting
B	Multilayer filter Aperture: 30 x 13 mm² Flash: 30 x 4 mm²	Spot size: 4 cm² Light energy: / Flash duration: / Wavelength: / Skin colour sensor "*Device complying with international standards for eye safety**" *(*According to Standard IEC 60601-2-57 of 2011)*	Shot possible only if the device is placed against the skin (metallic/magnetic loop inside the device) Skin colour detection before the first shot If skin is too dark or black, shot is impossible Once colour is detected, several shots may be fired at the same spot on the skin without skin colour control Skin colour detection mandatory with each change of energy setting
C	Multilayer filter Aperture: 30 x 20 mm² 2 flash bulbs: 30 x 5 mm²	Spot size: / Light energy: / Flash duration: / Wavelength: / Skin colour sensor	Skin colour detection before each shot If skin is too dark or black, shot is impossible After skin colour detection, device does not have to be in contact with skin to fire a shot
D	Orangey filter dyed in the mass: 30 x 40 mm² Glass light guide: 20 x 30 mm² - 30 mm thick Flash lamp ∅ 10 mm x 30 mm Replaceable bulb cartridge	Spot size: 20 x 30 mm² Light energy: / Flash duration: / Wavelength: /	The device has to be fully depressed against the skin Repeated shots are not possible, the safety catch has to be released between each shot The light guide is in direct contact with the skin. The red filter is above the guide Protective eyewear supplied: "*They allow you to delineate the area where flashing is prohibited (i.e. eyelashes, eyebrows)"*
E	Multilayer filter Aperture: 25 x 12 mm² Flash bulb: 25 x 5 mm²	Spot size: / Light energy: / Flash duration: / Wavelength: /	Skin contact detection by 2 metallic contacts Automatic energy level according to the information supplied by the skin colour detection accessory

[28] The character/ means that the information was not in the user manuals.

LNE Ref.	Description	Technical specifications[28]	Safety feature / Remarks
			Repeat shots can be fired at the same spot Mandatory skin colour detection with each energy setting change
F	Multilayer filter Aperture: 30 x 9 mm² Flash blub: 30 x 4 mm	Spot size: / Light energy: / Flash duration: / Wavelength: /	Shot possible only if the device is placed against the skin (metallic/magnetic loop inside the device) If skin colour too light or too dark: shot is impossible Once skin colour is detected, several shots can be fired at the same spot on the skin without skin colour control Mandatory skin colour detection with each energy setting change
G	Multilayer filter Aperture: 32.5 x 12 mm² Precision accessory with filter Aperture 20 x 10 mm² Flash: 32.5 x 3 mm²	Spot size: / Light energy: / Flash duration: / Wavelength: > 570 nm > 600 nm (precision accessory)	System with 4 push-buttons around the aperture window Shot can only be fired when the four buttons are pushed Repeat shots can be fired at the same spot
H	Multilayer filter Aperture: 20 x 10 mm² 2 flash bulbs ∅ 6 mm x 20 mm Replaceable flash cartridge	Spot size: 10 x 20 mm² Light energy: / Flash duration: / Wavelength: / "*Compliant with Standard IEC 60335-1 & 60335-2-23*"	System with 2 push-buttons around the window Shot can only be fired when both buttons are pushed Repeat shots can be fired at the same spot The multilayer treatment filter is located next to the skin
I	Red filter dyed in the mass + Transparent filter 15 x 36 mm² Aperture: 35 x 13,5 mm² Flash bulb ∅ 4 mm x 35 mm	Spot size: 13 x 35 mm² Light energy: / Flash duration: / Wavelength: /	4 (resistive) electrical switches A shot at a lower energy setting must be fired before firing a shot at a higher energy setting Repeat shots are impossible, the safety catch has to be released between each shot
J	Multilayer filter Aperture: 33,5 x 10,5 mm² Flash: ∅ 5 mm x 33,5 mm	Spot size: 13 x 35 mm² Light energy: / Flash duration: / Wavelength: / "*Compliant with Standard 60601-1 and 60601-1-2*"	2 (resistive) electrical switches Several shots can be fired at the same spot

As can be seen, products B and J claim compliance with the abovementioned Standard 60601-1 and 2, and Standard 60601-2-57. Furthermore, information such as spot size, light energy, flash duration and wavelengths are not, or are but partially mentioned in the user manuals. Except for product C where firing shots is possible even if the device is not in direct contact with the skin, all the other devices only deliver radiation if they are fully depressed against the skin to avoid any risk of radiation output toward the eyes, among others.

Nevertheless, are these safety systems actually efficient?

The answer is no. Only one device (D) releases radiation output only if strong pressure is applied to the target body (the skin), which implies that a certain amount of mechanical resistance is a feature of the switch. All the other systems (magnetic metallic loop, system with two or four push buttons, system with two to four resistive electrical switches) only require

placing or merely pressing the device onto the target body. With these systems, light output toward the eyes could be triggered by a contact with a rigid body other than the skin targeted for the treatment. Pressure on the fingers of the cupped hand of a person removing hairs on someone else, or pressures of the device on the cheeks or temples are examples of contact. These are unwanted contacts but that are still reasonably foreseeable as they involve handling devices that have to be hand-squeezed and released repeatedly against the skin, to avoid removing hairs on the same spot. Other situations may also cancel out these safety features; for instance, children playing with the devices, although this comes under misuse of the device. The purpose of some provisions of Draft Standard IEC 60335-2-113 is to prevent these risks. The Standard introduces a new notion, i.e. devices "*incorporating an intense light source (ILS)*" defined as "*a source of intense light where eye exposure is prevented by a technical method, or more, intended for use in contact mode (for instance on human skin)*." The 'contact mode' is controlled with a test piece simulating the optic properties of the skin. Radiation output can only occur if the window of the device is correctly applied to the skin. When skin contact is lost, the device must lower output to drop under the limit of Risk Group 2 of ISO 62471. If the light 'leaks' from the target skin, the optic radiation must not exceed the limits of Risk Group 1. If these conditions are met, wearing protective eyewear becomes optional.

Only devices C and D provide protective eyewear with their devices: device C because the light output may be triggered without the device window being in contact with the skin; device D with the most efficient switches because the eyewear delineates the areas where flashing is prohibited (i.e. eyelashes, eyebrows).

The level of protection of the protective eyewear of devices C and D, and the gels supplied with devices D and E were also analysed.

B. THE ENERGY CHARACTERIZATION OF THE SOURCES

1. Light Energy Delivered by the Devices

Only the average values of minimum and maximum energy of the different configurations that were tested on each device can be found in the table below, with five measurements used to calculate standard deviation.

Maximum and minimum energy density was determined by taking account of the output area of the devices (subject to emission homogeneity).

	Maximum Energy			Minimum Energy		
	Average	Standard Deviation	Energy Density	Average	Standard Deviation	Energy Density
Devices	**J**	**J**	**J/cm²**	**J**	**J**	**J/cm²**
A	10.9	0.04	2.80	8.4	0.08	2.15
B	13.6	0.15	3.49	10.5	0.24	2.68
C	14.1	0.43	2.34	7.45	0.31	1.24
D	55.9	0.70	9.31	45.2	0.74	7.53
E	22.0	0.17	7.34	16.1	0.21	5.36
F	8.6	0.09	3.19	2.9	0.04	1.09
G	8.0 11.3	0.26 1.35	4.01 2.77	3.9 6.5	0.10 0.04	1.96 1.60
H	12.8	0.18	6.42	11.5	0.33	5.77
I	9.9	0.17	2.10	4.3	0.06	0.90
J	7.0	0.29	1.99	3.8	0.33	1.07

Two different window sizes are available on device G. The first line corresponds to the 'small' window and the second to the 'big' window.

Device D delivers the highest energy and energy density and device J the lowest energy and energy density.

2. The Temporal Characterization

The temporal shape of the emission was analysed with a polarized photodiode, for each emitted pulse during energy characterization. The table below provides a description of flash duration (width at mid-height), minimum repeat rate and measured pulse shape.

	Duration [ms]		Repeat rate	
Devices	**Maximum Energy**	**Minimum Energy**		**Shape description**
A	0.440	0.390	2 to 5 s	Relaxed
B	0.730	0.665	2 to 5 s	Relaxed
C	0.480	0.560	4 to 7 s	Relaxed
D	34.0	34.0	2 to 3 s	Rectangular
E	25.7	16.6	2 to 3 s	Rectangular
F	0.540	0.540	1 to 5 s	Relaxed
G	1.85	2.17	2 to 3 s	Relaxed
H	29.6	29.5	1 to 3 s	3.5 virtually contiguous rectangular pulses
I	1.035	0.830	2 to 3 s	Particular temporal shape
J	2.47	1.93	2 to 3 s	Relaxed

3. The Characterisation of the Spectral Transmission of the Filters

The optical filter or filters in the devices were characterised with a double beam spectrophotometer, in the 250-2500 nm spectral range.

The results can be found in the table below detailing the number of filters, type of filter (dyed in the mass / multilayer dielectric treatment), and the cut-off wavelength for the filter system.

Devices	Cut-off wavelength [nm]	Description
A	467	Dyed in the mass filter
B	470	Dyed in the mass filter
C	472	Dyed in the mass filter
D	583	Dyed in the mass filter+ glass block
E	520	Multilayer filter on glass block
F	470	Dyed in the mass filter
G	557 593	Multilayer filter
H	642	Multilayer filter
I	571	Dyed in the mass filter + protective window
J	546	Multilayer filter + protective window

It was observed that that filters of the devices properly absorb violet and UV radiation.

C. THE CONFORMITY OF THE DEVICES WITH THE REFERENCE STANDARD NF EN 60601-2-57

The conformity with the reference standard was checked in the following areas:

- Risk Groups
- ME equipment identification, marking and documents
- Protection against unwanted and excessive radiation hazards
- Accuracy of controls and instruments and protection against hazardous outputs
- Hazardous situations and fault conditions

1. The Risk Groups

Paragraph	Title
201-6	**Classification of ME equipment and ME systems**
201-6.1.101	*Classification responsibilities* The manufacturer shall provide the classification of LS equipment
201-6.1.102	*Classification rules* The classification is used to indicate the potential risk of adverse health effects
201-6.1.102.1	*Classification of continuous operation LS equipment*
201-6.1.102.2	*Classification of a pulsed LS equipment* Emission limits for pulsed LS equipment shall be calculated according to IEC 62471

The manufacturers did not indicate the risk group of any of the devices. Reference Standard NF EN 60601-2-57 (April 2012) is applicable to the devices according to their 'photobiological' risk group.

Based on the measured physical characteristics, the Laboratory determined the risk group of the different devices in compliance with the Standard.

The determination of the risk group was carried out at a 200-millimetre distance from the apparent source even if the radiation aperture is placed against the skin during normal use of the device. All the risks in the 200 to 3,000-nanometre fields were evaluated.

Given that the pulse duration of each device was shorter than 0.25 seconds, the classification into a risk group was done based on the conditions of the pulse sources.

The angle of acceptance for the evaluation was 1.7 mrad for luminance values, 1.4 rad for lighting values and 2π sr for lighting values in terms of the thermal hazard of skin burn.

The evaluation of accessible radiation according to the Reference Standard was established based on:

- Total energy
- The emission spectrum of the device (xenon source + filters)
- The geometric features (i.e. size of the flash bulb, aperture)

The results can be found in the Table in Annex I with the required parameters for the evaluation of limit values, exposure limit values and accessible radiation levels, for each type of risk. If one of the risk limits is exceeded, the device belongs to 'high' risk Group 3[29]. For all the devices, Risk Group 3 was 'high' for an evaluation at a 200-millimetre distance. Only the limit of the thermal eye hazard was systematically exceeded. For the lighting limits values, the evaluation was carried out at device outlet (area touching the skin). The evaluation showed the threshold of thermal eye and skin hazard was exceeded in all the consumer devices.

By way of comparison, the classification of an IPL device into Group 3 is the equivalent of class 3 R or 3 B for laser equipment.

2. The Identification, Marking and Documents of Electrical Medical Devices

The Accompanying Documents

Paragraph	Title
201.7	**Identification, marking and documents of the electrical medical devices Accompanying documents** *Instructions for use* *Specific information for LS equipment*
201.7.9.2.101.1	Manufacturers of LS equipment shall provide users with the following information:
	- Spectral irradiance or spectral radiant exposure for all intended configurations of LS equipment
	- Maximum output of optical radiation emission for all intended configurations of LS equipment, measured at the treatment area. If the LS equipment is designed for providing treatment in different treatment areas, these parameters shall be specified for each of the treatment areas
	- Spectral irradiance or spectral radiant exposure for all intended configurations of LS equipment
	- Maximum variation of the output from the mean value across the treatment areas for all intended configurations of the equipment
	- Ocular hazard distance and/or skin hazard distance, when the LS equipment is classified in excess of Risk Group I
	Information about the output (for pulsed LS equipment)
	- Pulse duration of individual pulses
	- Duration of a pulse train
	- Pulse interval
	- Repetition rate
	- Number of pulses in a pulse train
201.7.9.2.101.2	*Safety Information* Manufacturers of LS equipment shall provide the following safety information in the user instructions.
	- Instructions for installation, maintenance, check procedures and safe use, including clear warnings concerning precautions to avoid possible exposure to hazardous radiation or risk of fire
	- Recommendations for training
	- Legible reproductions (colour optional) of all required labels and hazard warnings affixed to the LS equipment
	- A clear indication of all locations of emission apertures

[29] The output of accessible radiation from the device was measured regardless of the conditions of use, and specifically even if the light was only activated when the device touched the skin.

Paragraph	Title
	- A list of controls, adjustments and procedures for operation and maintenance by the user, including the warning "Caution – Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure"
	- A note saying that LS equipment should be protected against unauthorised use, for example by removal of the key from the key switch
	- A recommendation for eye and skin protection for the User and for the Patient/client
201.7.101	*Labelling of LS Equipment*
201.7.101.1	*Labelling Requirements* The manufacturer of LS equipment shall provide product risk group marking. The label shall include the risk group number and wording according to Table 201.104 'Requirements for the labelling of LS equipment according to risk group classification'
201.7.101.2	*Information about product label design and labelling information* LS equipment classified in excess of the Exempt Group shall carry an explanatory label and warning label in accordance with the requirements of this standard. **RISK GROUP 3** **WARNING IR emitted from this device may cause eye injury.** **Avoid eye exposure** **CAUTION UV emitted from this device. Eye irritation may result** Explanatory indicator plate  Warning
	The labels shall be: - Durable and permanently affixed
	- Legible
	- Legible and clearly visible during operation, maintenance or service
	- Positioned so that they can be read without the necessity for human exposure to optical radiation in excess of the Exposure Limits
	Text, borders and symbols shall be black on a yellow background
	If the size or design of the product makes labelling impractical, the label shall be included with the user information or on the package
201.7.101.3	*Indicator plate of the aperture*
	Each LS equipment classified in excess of Risk Group 1 shall have a label affixed close to each Emission Aperture
	The label(s) shall bear the words: OPTICAL RADIATION APERTURE Or APERTURE FOR OPTICAL RADIATION Or AVOID EXPOSURE – OPTICAL RADIATION IS EMITTED FROM THIS APERTURE
201.7.101.4	*Information on the emitted radiation and the standards*
	The name and publication date of the standard to which the product was classified shall be included on the explanatory label or elsewhere in close proximity on the product.
	Each LS equipment shall be described on the explanatory label by a statement of the maximum output of optical radiation, the pulse duration range (if appropriate) and the emitted wavelength range

For each device, the instructions and markings on the device were examined to check its compliance with the above requirements.

The necessary precautions to avoid any exposure to hazardous radiation were in the user manuals of all the devices.

Device C had instructions in English. This is not compliant with the requirement of Clause 7.9.2.1 of the general standard (instructions must be in a language that is understood by the intended operator).

The majority of devices did not meet all the information and marking requirements defined in the Reference Standard, with the following exceptions:

- Device I had an aperture indicator plate compliant with § 201.7.101.3
- Device G specified that the output wavelengths from the large window were higher than 570 nm and higher than 600 nm from the small window

3. Protection against Unwanted and Excessive Radiation Hazards

Paragraph	Title
201.10	**Protection against unwanted and excessive radiation hazards**
201.10.101	*Disabling device*
	LS equipment may be fitted with a suitable system that disables the release of optical radiation in the absence of the target tissue
	If the LS equipment is classified into a lower risk group by implementing such a device, the following requirement shall be met: Once an exposure has been completed, the equipment shall not be capable of emitting optical radiation again until the device has been reactivated

This requirement is not mandatory. However, only devices D and I are compliant with this provision: shot can only be fired when device is in contact with the target tissue. The next shot is only possible after lifting the device off the skin, and placing it on the skin again.

For device C, the next shot can be fired if the device is in contact with the skin, after a mandatory check of skin colour between each shot.

Paragraph	Title
201.10.102	*Shield*
	Where the applicator is used in contact with the target area, LS equipment of Risk Group 3 shall incorporate a means which prevents radiation being emitted from the application in a direction other than intended for the treatment.
	LS equipment may additionally incorporate a removable or fixed means which prevents user exposure to radiation scattered from the target area

All the devices comply with this requirement. Radiation output is only possible through the aperture and in the direction of radiation propagation.

Paragraph	Title
201.10.104	*Controls and indicators* For the protection of the Patient, the Operator, and other persons present, LS equipment of Risk Group 3 shall incorporate:
	a) Key-operated master control. The key shall be removable and the optical radiation shall not be accessible when the key is removed.
	b) Visible or audible Ready Indicator, which shall be illuminated or audible when emission of the optical radiation is possible upon actuation of the control switch, to allow appropriate safety precautions to be taken
	c) Optical radiation indicator
	In addition to the Ready Indicator, LS equipment shall be equipped with a visible or an audible signal, which clearly indicates that emission of optical radiation is taking place
	If the indicators are of the visible type, the Ready Indicator and the optical radiation indicator shall be visible through protective eyewear recommended by the manufacturer.
	d) Stand-by/Ready control
	LS equipment shall be equipped with a Stand-by/Ready control. On initial switch-on, the LS equipment shall default to stand-by condition.

- 201.10.104.a) – Key-operated and code enabled master control: only device I complies with this requirement. It has both a key-operated and code enabled control: a sequence of buttons have to be selected to power up the device
- 201.10.104.b) – Visible or audible ready indicator: all the devices have a visible or audible ready indicator

- 201.10.104.c) – Optical radiation indicator (emission underway): only device I has an audible signal indicating that radiation is underway (two audible beeps) during the firing of radiation pulse
- 201.10.104.d) – Stand-by/ready control; only the following devices comply with this requirement:
  - Device D: Control 'II' / '▷'
  - Device I: Control 'I▷'
  - Device J: Control 'E…'

Paragraph	Title
201.10.105	*Exposure termination*
	When the exposure termination is by means of a timer, for LS equipment classified as Risk Group 3, protection against single fault conditions shall be provided by a safety device which is independent of the timer and is activated when the set time is exceeded by 20%. The safety device shall terminate the optical radiation output and shall prevent further operation of the equipment. (A second timer may be a means of achieving compliance with this requirement)

Not applicable: None of the devices has timers

4. Accuracy of controls and instruments and protection against hazardous outputs

Paragraph	Title
201.12	Accuracy of controls and instruments and protection against hazardous outputs
201.12.1	*Accuracy of controls and instruments*
201.12.1.101	*Indication of LS equipment output*
	LS equipment of Risk Group 3 shall display the user selected value of the output of the optical radiation in SI units
201.12.4.2	*Indication of parameters relevant to safety*
	The LS equipment output and, where applicable, pulse duration, emitted by the equipment shall not deviate from the pre-set indicated value by more than 20%.
	A measured quantity, electrical or optical, which is directly related to the LS equipment output and pulse duration, shall be monitored during operation.
	The monitoring shall be carried out at intervals shorter than the failure tolerance time.
	The indicated short wavelength boundary for the LS equipment shall not deviate from the set value by more than 5%.
	The LS equipment output emitted at the treatment area shall be checked each time the LS equipment is switched on. One possible option is that the User is able to perform this test according to instructions provided by the manufacturer.
	The LS equipment shall not be able to be put into the ready state before the LS equipment output has been checked and the check has been validated each time the LS equipment is switched to supply mains.
	Pulse duration and short wavelength boundary shall be checked at regular intervals. The test methods and the intervals shall be described in the instructions for use in accordance with 201.7.9.2.101.2.

- 201.12.1.101: Indication of radiation output in SI units. None of the devices has a display with output energy or energy density. The indicators on the devices have either 'bar graphs' or '1 to n' displays.
- 201.12.4.2: Due to the lack of information on radiation output and electronic diagrams, this requirement was not checked. However, the typical deviation from of the energy measurements is less than 20%.

The devices do not come with any means of controlling energy output.

Paragraph	Title
201.12.4.101	*Emergency Stop*
	LS equipment classified as Risk Group 3 shall incorporate an Emergency Stop.
	The emergency stop shall immediately stop the emission of optical radiation.

Paragraph	Title
	The emergency stop shall be designed so as to be independent of all other LS equipment stop systems.
	The switch shall be a red push-button device and be located in such a manner as to be readily visible and easily and quickly reached by the LS equipment operator from the operating position.
	'Emergency stop' or symbol 101 of Table EE.1 shall be marked on or near the push-button.
	If an emergency stop according to IEC 60947-3 is incorporated in the LS equipment, the emergency stop for optical radiation is not required.

None of the devices has an 'Emergency Stop'.

5. Hazardous situations and fault conditions

Paragraph	Title
201.13	**Hazardous situations and fault conditions**
201.13.1	*Specific hazardous situations*
201.13.1.101	*Optical radiation hazards*
	When applying the single fault conditions as described in 4.7 of the general standard and listed in 13.2 of the general standard and this particular standard, none of the hazardous situations described in 13.1 of the general standard and this particular standard (inclusive) shall occur in the LS equipment.
	For LS equipment of Risk Group 3, a single fault condition shall not result in an increase of accessible output greater than 100% above the nominal value, or in an unintended release of optical radiation.

The above items could not be checked as no risk management file for the devices (manufacturer's property) was provided.

The Table in Annex 2 provides a summary of the compliance or non-compliance of the devices.

D. THE COMPLIANCE OF THE DEVICES WITH ELECTRIC TESTS (STANDARDS NF EN 60601-2-57 OF APRIL 2012 AND NF EN 60601-1 OF JANUARY 2007)

The tests were performed in accordance with paragraphs 201-8-10.4 (cord-connected hand-held parts and cord-connected foot-operated control devices), 201.11 (protection against excessive temperatures and other hazards) and 201.13 (hazardous situations and fault conditions).

1. Clause 201.8.10.4: Cord-connected hand-held parts and cord-connected foot-operated control devices

Article 201.8.10.4 of specific Standard NF EN 60601-2-57 (April 2012) only applies to footswitches.

Checking compliance with Article 8.10.4.1 of general standard NF EN 60601-1 (January2007) could not be performed because the electric diagrams of the devices were not provided. Article 8.10.4.2 refers to Article 8.11.3 of General Standard NF EN 60601-1 (January2007).

Consequently, Article 8.11.3 of the General Standard requires running tests to check the anchorage (clause 8.11.3.5) and the protection against excessive bending (clause 8.11.3.6) of the power cords of non-stationary equipment.

a. <u>First test: clause 8.11.3.5: tests of cord anchorage</u>

The purpose is to test the mechanical robustness of the anchorage of the power cords connecting the hand pieces to the bases of the devices. The test was not run on devices without bases.

The pull test consisted in attaching a three-kilo weight to the ends of the power cords and pulling them for 1 second, 25 times in a row.

Immediately after the pull tests, a 0.1 N-m torque was applied to the cords.

No displacement of cord sheath was observed after the test. All the devices were compliant with this Article of the Standard.

b. Second test: clause 8.11.3.6: tests of protective systems of the power cords

The purpose is to test the mechanical robustness of the cord during bending. The risk is that excessive bending may cause the electric conductors to break.

Standard NF EN 60601-1 (January2007) requires one of the two following tests:

- The test in Clause 25.14 of Standard 60335-1:2001
- A test specific to the medical standard (third paragraph of Clause 8.11.3.6)

The second test was run. The test consisted in attaching a mass relative to power cord diameters and measuring the curvature of the radius during bending.

Test results can be found in the table below:

Products	**Wire diameter (mm)**	**Applied weight (g)**	**Measured radius (mm)**	**Results**	**Manufacturer's recommendations**
B	Inapplicable test (no cord)				Not necessary
F	Inapplicable test (no cord)				Not necessary
J	4.85	235	9.5	Compliant test result	Not necessary
G	Inapplicable test (no cable)				Not necessary
C	6.6	435	12	Compliant test result	Not necessary
A	Inapplicable test (no cord)				Not necessary
H	7.93	630	13	Compliant test result	Not necessary
E	8.1	660	9.5	Inconclusive test result	Page 53: Do not use the device if it is damaged, for instance: cracked glass (…), damaged device cord (exposed electric wires), device internal components have electrical charge levels that may be hazardous. Using a damaged device may cause an electric shock

I	8.4	706	7	Inconclusive test result	Page 25: in case of damage to the device, hand piece cord, hand piece or electric cord, stop using immediately
D	14.12	2000	17	Inconclusive test result	Page 18: Before each use, check the cord connecting the base to the hand piece (no visible deterioration)

Devices J, C, and H were compliant with the test required by the medical standard.

Devices E, I and D were not compliant with the specific test of the medical standard. However, this test result does not mean that there is a user hazard. Only the analysis of the actions planned by the manufacturer in the risk management file, the analysis of the electronic diagrams and the implementation of the test in Clause 25.14 of Standard 60335-1:2001 would make it possible to rule on the final compliance of the power cord and user hazard.

The manufacturers recommend not to use the device if a defect is observed, which limits the risk of injury from the power cord.

2. Clause 201.11: Protection against excessive temperatures and other hazards

Article 11 of the General Standard applies. The purpose of the test is to measure the operating temperatures on different spots of the different devices. The following spots were retained for the measurements:

- Hand piece power cord
- Upper shell of hand piece
- Lower shell of the hand piece
- Hand piece filter in contact with the skin during epilation
- Base power cord (where applicable)
- Upper shell of the base (where applicable)

The measurement spots were selected on the device shells to measure the temperatures of the parts likely to be touched during product use. The Standard classifies the parts of the devices according to the time of application in contact with the patient/client.

Use time of the devices and flash repeat rate vary according to the epilation area to treat, and according to the recommendations provided by the manufacturers in their user manuals.

A common protocol selected to compare one device to another included the following:

- Test duration for each device was 20 minutes
- Flash repeat rate was one flash every five seconds
- Device power level was set on maximum during the tests
- The devices were powered 110% of the maximum allowed voltage by manufacturer

The temperatures of the hand piece shells could not exceed a temperature of 43°C (according to Table 24 of the Standard, for a contact time > 10 minutes). Temperatures of the

base shells could not exceed a temperature of 71°C (according to Table 23 of the Standard, for a contact time ranging from 1 to 10 seconds).

The temperatures in the table are the maximum temperatures measured during the test.

a. The exploitation of the results measured on the shells (not including the temperature of the treatment spot)

As can be seen in the table below, by comparing the values between the different devices at a usage temperature of 30°C, devices J, E and D had operating temperatures in excess of 43°C (threshold required by the Standard for the parts in contact with the device during use). The other devices have operating temperatures under 43°C.

Maximum temperatures measured during a 20-minute usage cycle

Device	B	F	J	G	C	A	H	E	I	D
Lower shell	36.5	36.9	75.8	33.5	36.2	38	41.4	49.8	39.2	58.1
Power cord	39.9	40.7	34.8	N/A*	33.2	32.7	43.7	33.4	2.8	39.2
Upper shell	34	37	31.2	41.9	38.4	36.9	42	44.5	38.6	37.9
Base power cord	N/A*	N/A*	30.5	N/A*	33.7	N/A*	30.5	36.1	31.6	30.8
Base upper shell	N/A*	N/A*	30.5	N/A*	34.6	N/A*	33.7	37	31.5	34.8

* *N/A: Not applicable*

This table lists the measured then corrected values at an operating temperature of 30°C. The value of 30°C was selected as the common usage value for all the equipment. This common value was selected to allow for a comparison of maximum temperatures between all the devices. The values are in ° C.

Maximum temperature tolerance must be determined and documented by each manufacturer in the risk management files (according to Article 11.1.2.1 of ME equipment Standard NF EN 60601-1 (January2007). As these documents were not available for the tests, the selected maximum tolerance value was 43°C. This value corresponds to the maximum temperature of a plastic shell in contact with the patient/client for an application time longer than 10 minutes.

The temperatures measured on the different power cords and base shells were compliant with the requirements of the Standard.

b. Processing the results measured on the filters of the flash spots of each device

As can be seen in the table below, the temperatures measured on the flash spot reach higher temperatures than the tolerance thresholds required by the Standard. The values may cause a risk of user burns. The risk is controlled for all the devices via the recommendations in the user manuals (for instance, one manual explains that users must limit application time if redness appears. Another manual writes that users must adjust device power according to skin type). However, these warnings are insufficient according to the Standard. Temperatures and clinical effects must be documented in the risk management file (see Clause 11.1.2.1 NF EN 60601-1 (January2007). As the risk management files were not provided for the tests, the LNE report could not rule on the compliance of the different products with the Standard.

Maximum temperatures measured on the flash spot (values in °C, corrected at 30°C)

Device	B	F	J	G	C	A	H	E	I	D
Temperature on Flash Spot	153.6	141.3	129.5	254.1	190.8	153.6	221.7	107.9	116.2	229.1

The measurement was taken directly on the device. The temperatures are not the actual temperatures observed on user's skin. This temperature value may also be lower depending on the interface between the device and the skin (for instance, use of a gel, application distance between the filter and skin).

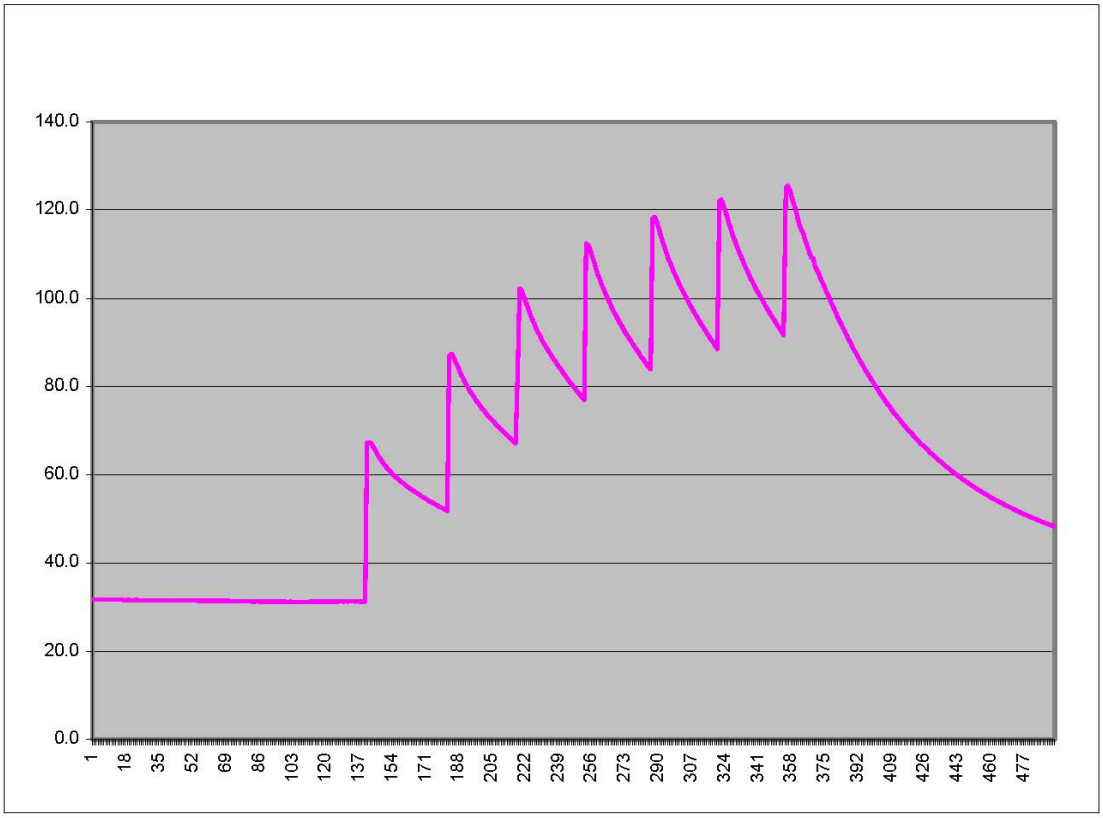
Accordingly, although the values are high, they are balanced by the very short application time of the device on the skin and the very short time it takes for the device to return to an acceptable temperature. (The observed order of magnitude is several dozen seconds).

The graphs below provide examples of the first flashes measured on devices A, J, D and G. The more flashes fired, the higher the temperature on the filter. The figures show that the temperature drops quickly after a flash. Only the repetition of flashes reaches the values in the table above.

Only the analysis of the clinical files or the risk management file supplied by the manufacturers would have allowed a ruling on the compliance of temperatures with the Standard and user risk.

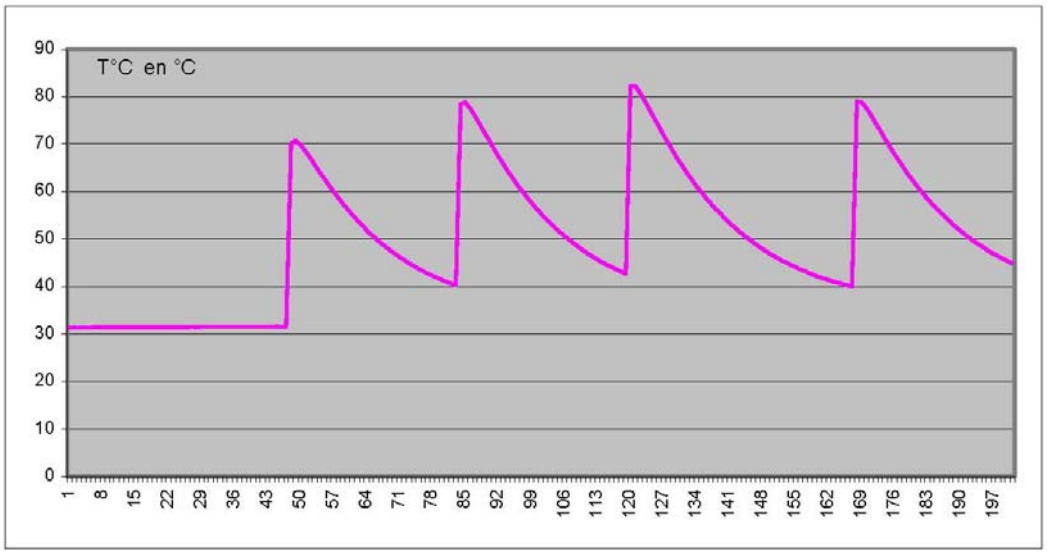
Nevertheless, the graph below shows that the temperature curves of devices A, D and G do not drop below 45°C whereas device D systematically exceeded a temperature of 60°C, which is hazardous to the skin.

Measurement of filter temperature on Device A



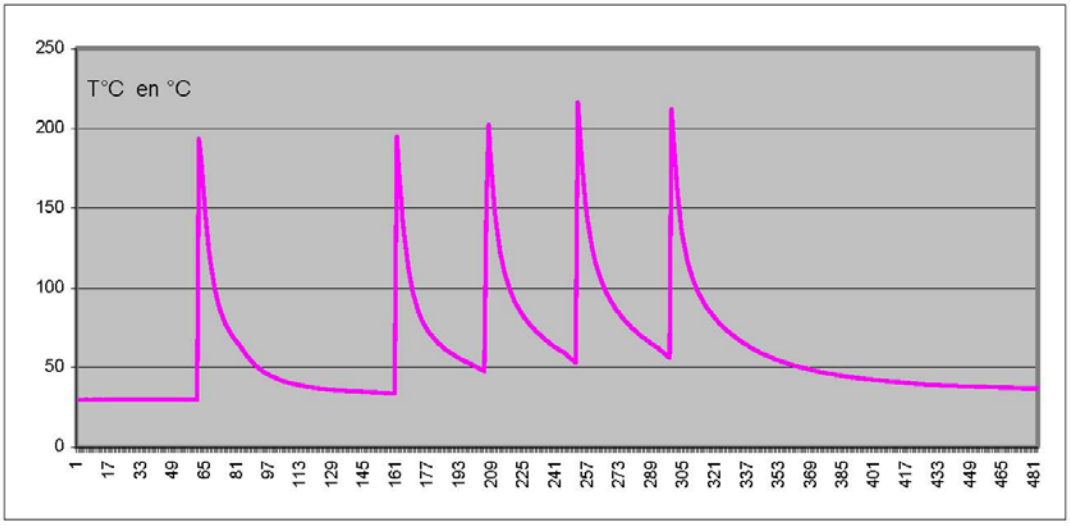
Abscise: acquisition number - Te = 100 ms - Ordinate: temperature in °C

Measurement of filter temperature on Device J



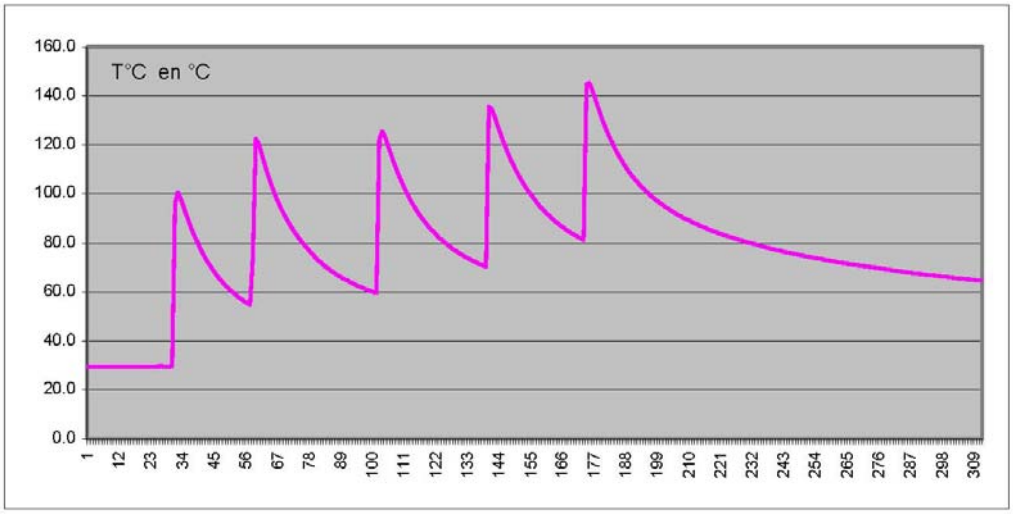
Abscise: acquisition number - Te = 100 ms - Ordinate: temperature in °C

Measurement of filter temperature on Device D



Abscise: acquisition number - Te = 100 ms - Ordinate: temperature in °C

Measurement of filter temperature on Device G



Abscise: acquisition number - Te = 100 ms - Ordinate: temperature in °C

All the manufacturers warn against the high risk of burns caused by excessive temperatures that will inevitably occur if user does not comply with certain recommendations[30]. The table below summarizes the recommendations found in the user manuals.

Products	Manufacturer's Recommendations regarding Burn Hazards
B	▪ Page 3: If you feel any pain, lower the intensity setting until the session feels comfortable. In this case, you may have to add one or two sessions for best results. Do not forget to take a tolerance test by emitting a light pulse on your skin at least 24 hours before the treatment a intensity setting I. ▪ Page 11: Caution: do not treat the same skin area more than once per hair removal session. Repeat treatment of the same spot may cause side effects.
F	▪ Page 38: Your skin may redden immediately after the use of G or within the next 24 hours. The redness usually clears up within 24 hours. Consult your physician if it lasts more than two or three days. ▪ Page 41: If burns or blisters appear, stop immediately. Avoid repeat pulses on the same spot.
J	▪ Page 1: if you feel discomfort, use a lower intensity setting. If the feeling is tolerable, increase the level of X for improved efficacy. ▪ Page 8: Do not use the system in case […] of burns ▪ Page 9: During the treatment, do not hold the hand piece against the same spot without moving! This may cause an excessive concentration of heat and damage your skin ▪ Page 10: Possible side effects: skin blisters or burns. Care instructions: cool the skin area down immediately and consult a doctor. ▪ Page 18: Be advised that the air outlet will release very hot air once the system is working ▪ Page 24: Temporary redness may appear on the skin during the 24 hours after the treatment. If the symptoms last longer than 24 hours and/or you experience severe discomfort and/or serious side effects, stop the treatment immediately and consult your doctor.
G	▪ Page 38: Do not use the device […] if you have […] burns ▪ Page 43: If at one point the device causes unbearable pain, lower the light intensity setting until you can use the product comfortably. If you notice skin reactions greater than light redness, stop the session immediately. ▪ Page 46: Do not flash the same area several times during the same session. This […] will increase the risk of skin reactions. ▪ Page 50: Possible side effects and common skin reactions: redness and/or […] a feeling of hot skin. This reaction is benign and temporary. ▪ Rare side effects: burns, excessive redness and swelling: these reactions very seldom occur. These effects are caused by using a light intensity that is too high for your skin colour. If these reactions last more than three days, consult your doctor. Wait until the skin is completely cured before starting another session and use a lower light intensity setting. ▪ Note: Pages 55, 56, 57 and 58 provide additional information
C	▪ Page 6: Do not overuse the device because the filter may overheat ▪ Note: Pages 7 and 11 tell user to use lower energy settings in case of discomfort ▪ Page 8: Do not treat the same skin area several times […] this may cause burns ▪ Note: Page 14 says to wait 24 hours if redness appears (the redness usually clears up after 24 hours).

[30] The definition of a photothermal injury of the skin cannot be established without independent studies, such as ANSES studies, defining whether skin lesions after radiation may occur within acceptable limits for human skin. The determination of a threshold of 'acceptable' photothermal injuries left to manufacturers' discretion may lead to abuses.

Products	Manufacturer's Recommendations regarding Burn Hazards
A	▪ Pages 12 and 23: Do not treat the same skin area more than once per session. If burns or blisters appear, stop immediately! ▪ Page 16: Your skin may redden immediately after using the epilator, or within the next 24 hours. The redness usually clears up within 24 hours. Consult your doctor if it lasts more than 2 to 3 days. ▪ In very rare cases, the skin may be injured or burned after an application. Several weeks may be necessary for a full cure, and in exceptional cases, there may be a scar.
H	▪ Page 57: Do not flash the same area more than once because this may cause burns. ▪ Page 65: if the treated area reddens after the treatment, this is normal and the redness should clear up. If it doesn't, use a lower light intensity.
E	▪ Page 55: Some people may feel mild discomfort (for example, skin reddens or heats) […] this is normal. This type of reaction will clear up within 24 hours. ▪ Possible side effects include: discomfort/pain in the treated area […] the skin remains hot or red after the first 24 hours ▪ If skin redness does not clear up within 24 to 48 hours after the treatment: stop using the device and consult your doctor before using it again. ▪ Pages 60 and 62: do not apply the hand piece on the same area more than once to avoid any adverse effects. If blisters or burns appear on your skin, stop immediately. Cool the area with a gel pack for cold therapy treatment.
I	▪ Page 4: Most users experience a feeling of heat during the treatment. Some people may see a slight redness on the skin. In most cases, side effects will clear up within 24 hours, but in rare cases, they might last for 72 hours. You must stop the treatment if you experience any of the effects listed below. In any case, cool the area, preferably with an aloe-based gel. If the symptoms last more than 48 hours, consult a doctor: pain in the treated area, itchiness in the treated area, redness. If the following symptoms appear, immediately consult a doctor (blister or burns). ▪ Page 24: are there any side effects? As for all epilators using light energy, spots of lighter skin or slight redness may occur after the treatments. This should clear up within 24 hours. ▪ Page 23: Avoid staying too long in the same area at all times. This may cause redness and swelling.
D	▪ Page 10: Do not use device D on injured, burnt or infected skin. ▪ Note: Page 23 recommends first adjusting the power on the lowest setting to avoid increasing the risk of redness, or even burns of skins with high pigmentation. ▪ Note: Page 25, the manufacturer recommends using the gel supplied with the device to avoid skin burns

3. Clause 201.13: Hazardous Situations and Fault Conditions

The Standard provides for several mechanical, electrical and thermal tests. As the electronic diagrams and risk management files for the equipment was not provided, not all the tests required by the Standard could be run. The following tests were conducted.

Clause13.1.4 concerns mechanical hazards. This article referred to Article 15.3. For portable devices, the Standard provides for the following tests:

- Clause 15.3.2: push test
- Clause 15.3.4.1: drop test

The purpose of the test is to check the mechanical robustness of the shells.

a. <u>First test: Clause 15.3.2: push test</u>

The compression test consisted in applying a 250 N force to the hand piece and base of the device for five seconds.

The post-test examination of the products showed that none of the devices was hazardous.

b. Second test: Clause 15.3.4: drop test

The drop test consisted in dropping the hand piece from a one-metre freefall height onto a 50-millimetre thick wooden board. The test was run three times on each device.

Devices B, E and F were destroyed by the tests.

Device E became hazardous, as electronic parts were exposed after the test.

Device B became hazardous, as the filter cracked after the last drop. However, the test is inconclusive regarding user hazard.

The manufacturer of device B has foreseen this hazard in the user manual where page 17 states, "*if the device is dropped, check that the UV filter is not broken or cracked. If so, replace the bulb before using.*"

Similarly, the manufacturer of device E has foreseen this hazard in the user manual where page 53 states, "*do not use the device if it is damaged, […] the internal components of the device have electric charge levels that may be hazardous. An electric discharge may be sparked when using a damaged device."*

The fourth column of the table below lists the manufacturers' recommendations in the user manuals.

Drop Test Results

Products	Observations	Results	Manufacturer's recommendation in case of impact
B	After the test, the device worked but the drop cracked the filter	Inconclusive test*	Page 17: if the device falls, check that the UV filter is not broken or cracked. If so, replace the bulb before using.
F	After the tests, the device no longer worked but did not present any apparent hazards	Compliant test	Page 36: if the device does not work properly, or has a defect, or is chipped, or the shell of the device is cracked or in pieces: stop using the device immediately and contact our customer service
J	After the tests, the device worked.	Compliant test	Page 9: Do not use the device if one of its components seems damaged. Do not use the device if the glass of the cartridge is cracked or broken. High voltage inside
G	After the tests, the device worked.	Compliant test	Page 36: Do not use the device or the AC adaptor if they are damaged. Do not use the device if the UV filter of the filtering glass is broken.
C	After the tests, the device worked.	Compliant test	Page 6: A replacement cartridge must be changed if the filter is broken. If your device is broken, damaged, […] please contact our customer service
A	After the tests, the device worked.	Compliant test	Page 25: A flash bulb must also be replaced […] if the application surface is broken. Page 14: Please contact our epilator customer service if your device is broken, damaged, or requires repairs.
H	After the tests, the device worked.	Compliant test	Page 64: if the window is cracked or broken, the device must not be used. Page 65: Do not use the device if it is damaged. If you are having trouble using the device, stop and contact our service centre.

Products	Observations	Results	Manufacturer's recommendation in case of impact
E	Live component exposed after the test. The device did not work after the tests	Inconclusive test*	Page 53: Do not use the device if it is damaged, for instance if the glass is cracked […], the power cord of the device is damaged (exposed electric wires); the inner components of the device have electric charge levels that may be hazardous. An electric discharge may be sparked by using a damaged device.
I	After the tests, the device worked.	Compliant test	Page 25: In case of damage to the device, the hand piece cord, the hand piece or the power cord, stop using immediately.
J	After the tests, the device worked.	Compliant test	Page 8: Never use if damaged, or if an operation anomaly is displayed on the touch screen, or after a fall (non visible damage may be a safety hazard). Page 19: The filter (flat part in red glass) should be intact, have no cracks and a regular flat surface.

** Inconclusive test due to the absence of risk management files and electronic diagrams (manufacturer's property)*

4. Clause 13.2.7: Impairment of cooling that could result in a hazard

The purpose of the test is to check that the device does not become hazardous when the cooling systems of the bases and hand pieces stop working. The ventilation slots were taped over for the test.

a. Third test: the exploitation of the results measured on the shells of the devices

The table below lists the maximum values measured during a 20-minute usage cycle with a fault condition. The values were corrected at a 30°C operating temperature. The values are in °C.

Device	B	F	J	G	C	A	H	E	I	D
Lower shell	45.9	38.5	82.4	35.8	43.5	49.8	45.6	53.7	44.2	71.9
Power cord	39.4	48.2	41.1	N/A*	36.5	38.1	45.8	34.9	36.6	42.0
Upper shell	43.1	38.7	37.2	65.1	44.7	50.3	45.9	51.0	43.1	45.1
Base power cord	N/A*	N/A*	31.3	N/A*	36.5	N/A*	32.8	37.2	33.3	31.1
Base upper shell	N/A*	N/A*	31.6	N/A*	37.9	N/A*	40.3	38.0	43.9	36.5

** N/A: Not applicable*

By comparing the temperatures between the different devices, only device F was compliant with the values required by the Standard (shell temperatures under 43°C) whereas devices J and D had operating temperatures higher than the other devices. The tests showed that all the devices presented burn hazards if they were over-used during a session.

E. THE TEST RESULTS OF THE PROTECTIVE EYEWEAR

The spectral transmission of the protective eyewear of devices C and D was measured with a double beam spectrophotometer in the 205-2500 nm spectral range.

Based on measurement results used to determine the risk group, the calculations were done taking account of the spectral transmission of the filters.

The results can be found in the table below with the parameters required to evaluate threshold values, exposure limit values and radiation output accessible through the protective eyewear, for each type of risk.

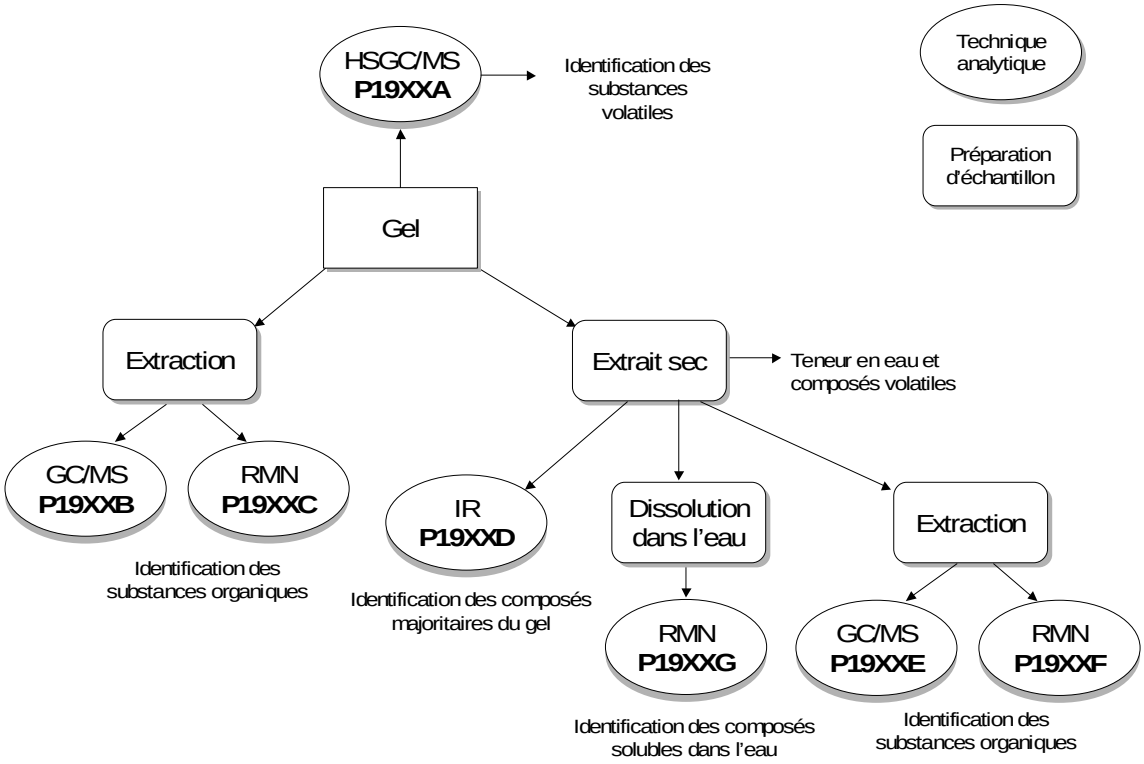
		C	D
	Maximum Energy [J]	14.1	55.9
	λ cut-off [nm]	472	583
	Pulse duration [ms]	0.480	34
Geometric characteristics	Flash bulb [mm]	30 x 5	30 x 12
	Aperture [mm]	30 x 20	30 x 20
	Apparent size [mrad]	100	105
Skin & eye hazard from exposure to actinic UV radiation 200 – 400 nm	Angle of acceptance [mrad]	1,400	
	E_S [J/m²]	/	/
	Limit [J/m²]	30	
	Limit exceeded	NO	NO
Eye hazard from exposure to near-UV 315 – 400 nm	Angle of acceptance [mrad]	1,400	
	E_{UVA} [J/m²]	/	/
	Limit [J/m²]	10,000	
	Limit exceeded	NO	NO
Retina hazard from exposure to blue light 300 – 700 nm	Angle of acceptance [mrad]	1.7	
	L_B [J/m²/sr]	29	2
	Limit [J/m²/sr]	1,000,000	
	Limit exceeded	NO	NO
Thermal retinal hazard from exposure to light 380 –1400 nm	Angle of acceptance [mrad]	1.7	
	L_R [W/m²/sr]	2,453	17,650
	Limit [W/m²/sr]	1,620	37,700
	Limit exceeded	YES	NO
Eye hazard from exposure to infrared 780 – 3000 nm	Angle of acceptance [mrad]	1,400	
	E_{IR} [W/m²]	117,000	23,900
	Limit [W/m²]	5, 550,000	227,300
	Limit exceeded	NO	NO
Thermal skin hazard from exposure to light 380 – 3000 nm	Angle of acceptance [sr]	2π	
	E_H [J/m²]	63	840
	Limit [J/m²]	2,960	8,600
	Limit exceeded	NO	NO
	Risk Group	3	0

For Device C protective eyewear, accessible radiation for a pulse exceeds the emission limit of the exempt group. Radiation with the protective eyewear is in 'high' Risk Group 3.

For Device D protective eyewear, accessible radiation for a pulse does not exceed the emission limit of the exempt group. Radiation with protective eyewear is in the zero, or 'exempt' risk group. One eyewear branch displays a reference to Standard NF EN 166 '*Personal eye protection - Specifications*'. The standard is applicable to all types of personal eyewear protecting against the various hazards occurring in industry, laboratories, schools, and DIY activities, that may damage the eye or impair vision, except for nuclear radiation, X-rays, laser emissions and infrared (IR) radiation emitted by low temperature sources.

F. THE TEST RESULTS FOR THE GELS OF DEVICES E AND D

1. The Analytical Approach



[Analytical Technique
Sample preparation

HSGC/MS
P19XXA=> Identification of volatile substances

GEL

Extraction — Dry extract => Water and volatile compound content

Extraction

GC/MS **P19XXB** — Identification of organic substances

NMR **P19XXC**

IR **P19XXD** — Identification of main gel ingredients

Dissolved in water

NMR **P19XXG** — Identification of water-soluble compounds

Extraction

GC/MS **P19XXE**

NMR **P19XXF** — Identification of organic substances]

The different sample preparations highlighted the molecules with different properties.

Gel extraction isolated the molecules that were sparingly soluble in water.

The main polar substances of the gel[31] were characterized by dissolving the dry extract in water.

[31] Acronyms of the techniques that were used:
- HSGC/MS: Headspace Gas Chromatography coupled with Mass Spectrometry detection
- GC/MS: Gas Chromatography coupled with Mass Spectrometry detection

2. Sample Preparation

a. Gel Extraction

The gel was diluted in an aqueous solution and extracted with an organic solvent at ambient temperature for one hour. The organic solution was filtered before analysis.

b. Gel Dry Extract

A given mass of the sample was placed in an oven heated to 105°C for sixteen hours.

c. Extraction of the Dry Extract

A given amount of the dry extract was extracted with a continuously stirred organic solvent at the ambient temperature of the laboratory, for sixteen hours.

The organic solution was filtered before analysis.

3. The Analytical Techniques

a. FTIR Analysis, Fourier Transform Infrared Spectrometry

The dry extract was analysed by Fourier Transform Infrared Spectrometry (ATR, Attenuated Total Reflectance, Mode).

b. HSGC/MS Screening, Headspace Gas Chromatography coupled with Mass Spectrometry detection

The gel was placed directly in a vial heated to 90°C. HSGC/MS was used for headspace analysis.

The chromatograms and mass spectra were compared to the LNE/HSGC database (32 substances) and the NIST database (165,000 substances).

c. GC/MS Screening, Gas Chromatography coupled with Mass Spectrometry detection

GC/MS was used to analyse the organic solutions resulting from the extraction.

The chromatograms and mass spectra were compared to the LNE/GC database (223 substances) and the NIST database (165,000 substances).

d. NMR (Nuclear Magnetic Resonance) Screening, ^{1}H and ^{13}C, 1D and 2D

The organic solutions resulting from extraction were evaporated to dryness. The residue was put in a deuterated solvent and analysed by 400 MHz NMR according to experiments 1D and 2D (coupling ^{1}H – ^{1}H and coupling ^{1}H – ^{13}C).

The dry extract was dissolved in deuterated water and analysed by 400 MHZ NMR according to experiments 1D and 2D (coupling ^{1}H – ^{1}H and coupling ^{1}H – ^{13}C).

The resulting NMR spectra were compared to the LNE/NMR spectra and chemical substructure database (338 substances and 41 chemical substructures).

NMR is not as specific as chromatography and substances with content higher than 0.01% can be detected.

- IR: Fourier Transform Infrared spectrometry
- NMR: Nuclear Magnetic Resonance

4. The Results

The analysis of the two gels showed that they were essentially composed of water at rate higher than 94.0%.

a. The Gel of Device E

The substances potentially contained in the gel sample of device E were:

Substances	IR	GC/MS	HSGC/MS	NMR
Polyacrylate	X			
Benzyl alcohol		X	X	X
Triethylene glycol		X		X
Triethanolamine		X		
Isopropyl alcohol				X

The chemical functions or structures potentially contained in the sample were:

Structures	IR	GC/MS	HSGC/MS	NMR 1 H
Alcohol	X			X
Carbonyl	X			
Carboxylate	X			
Alkane	X			
Long-chain-alcohol			X	
Glycol derivatives such as propanediol				X
Glycol function				X
X-CH2-CH2-X substructure where X = Oxygen or nitrogen				X
Propylene derivatives and ethylene glycol				X
Alkane function: propylene glycol methyl				X

The identified substances matched the substances described on the ingredients label. The identified chemical functions were compatible with the substances described on the ingredients label and with the substances used for cosmetic products.

The laboratory could not identify any molecules with light absorption properties or with any direct function in relation to PL technology.

b. The Gel of Device D

The substances potentially contained in the sample were:

Substances	IR	GC/MS	HSGC/MS	NMR
Polyacrylate	X			
Benzyl alcohol		X	X	X
Triethylene glycol		X		X
Triethanolamine		X		
Isopropyl alcohol				X

The chemical functions or structures potentially contained in the sample were:

Structures	IR	GC/MS	HSGC/MS	NMR 1 H
Alcohol	X			X
Carbonyl	X			
Carboxylate	X			

Alkane	X			
Long-chain-alcohol			X	
Glycol derivatives such as propanediol				X
Glycol function				X
X-CH2-CH2-X substructure where X = Oxygen or nitrogen				X
Propylene derivatives and ethylene glycol				X
Alkane function: propylene glycol methyl				X

The identified substances and chemical functions were compatible with the substances used for cosmetic products.

The laboratory could not identify any molecules with light absorption properties or with any direct function in relation to IPL technology.

BASED ON THIS DATA

A. THE GENERAL RECITALS

1. **Whereas** IPL equipment for hair removal is available to the public either as a service provided by professionals for cosmetic purposes, or through direct sales;
2. **Whereas** there are numerous contraindications to the use of the equipment by professionals and consumers;
3. **Whereas** the eye's direct or indirect exposure to pulsed light could cause the irreversible destruction of some retinal cells;
4. **Whereas** light flashes pointed at symptomatic spots of cancerous or precancerous lesions may cause a lost opportunity for a diagnosis since radiation partially erases the clinical signs of the said lesions;
5. **Whereas** there are no standardised protective systems for covering skin signs (i.e. beauty marks, scars, spots, redness);
6. **Whereas,** although the national InVS managed database does not have any records of accidents involving the use of the equipment, the database only relies on data transmitted by eleven volunteer hospitals;
7. **Whereas** complications and incidents subsequent to pulsed light hair removal have been reported to the Consumer Safety Commission, specifically during its hearings (burns, paradoxical hair growth and sweat gland disorders in regularly flashed areas);
8. **Whereas** the scientific data on the long-term effects of chronic exposure to the radiation from IPL equipment for hair removal is insufficient;
9. **Whereas** ANSES (French Agency for Food, Environmental and Occupational Health & Safety) has been mandated by the public authorities to conduct a study on the biological and health impacts of the said radiation;

B. RECITALS CONCERNING THE DEVICES USED BY NON-PHYSICIANS

10. **Whereas** the combination of Article L. 4165-1 of the Public Health Code and Article 2. 5° of amended Order of 6 January 1962 shows that hair removal, other than tweezing and waxing, constitutes the illegal exercise of medicine when it is not done by a medical doctor;
11. **Whereas** for many years the representative bodies of the cosmetic professions has been demanding unsuccessfully that they be legally approved to provide IPL hair removal services to consumers;
12. **Whereas** the public authorities will be reviewing the possible change of the legal framework for this type of act after the publication of the ANSES study results;

C. RECITALS CONCERNING THE DEVICES FOR CONSUMERS

13. **Whereas** the sales of consumer pulsed light devices are flourishing;

14. **Whereas** the devices are not governed by any specific regulations defining their characteristics and safety requirements, or mandatory consumer information and warnings;

15. **Whereas** the energy density of the devices currently sold to consumers is three times lower on average than the energy density of the equipment used by physicians, and that manufacturers have deliberately built this limitation into their devices;

16. **Whereas** the devices do, however, present recognised hazards from radiation exposure;

17. **Whereas** the 2013 study commissioned by CSC to LNE (French national testing laboratory) classified ten out of the ten consumer devices it tested in Risk Group 3, the high photobiological risk group for eyes and skin, which is defined in Standard NF EN 62471 on the photobiological safety of lamps and lamp systems;

18. **Whereas** nine out of the ten tested devices are fitted with safety systems designed to prevent radiation output if the device is not placed against the skin;

19. **Whereas** the safety systems in virtually all the devices do not, however, provide enough assurances to prevent a radiation leak toward the eyes;

20. **Whereas** only two out of the ten tested devices are delivered with eyewear said to ensure eye protection;

21. **Whereas** one pair of protective goggles provides enough attenuation to limit exposure to optical radiation at an exposure level equivalent to the zero risk group (exempt of photobiological risk) in compliance with Standard NF EN 166 *Personal Eye Protection – Specifications*;

22. **Whereas** the other pair of goggles does not provide appropriate eye protection even though it is delivered with the only device where radiation may be triggered without the device being placed against the skin;

23. **Whereas** the temperatures reached by the devices entail burn hazards, especially with repeat localised irradiation on the same spot;

24. **Whereas** the user manuals warn consumers about this hazard, but only two out of the ten tested devices prevent the device from flashing again and require users to lift the device off the skin between two flashes, thus avoiding irradiating the same area;

25. **Whereas** only two devices come with gels as an interface between the device and the skin;

26. **Whereas** both gels do not have any chemical properties rendering light output more efficient, or any light filtering properties to avoid burns;

27. **Whereas** certain contraindications, specifically the inadequacy of the devices for certain types of skin (phototypes), are not underscored sufficiently in the warnings on the outside packaging of the products, thus enabling consumers to appreciate the timeliness of the purchase;

28. **Whereas** a draft Standard IEC 60 335-2-113 dealing with the safety requirements for cosmetic and beauty care laser and pulsed light sources for home or professional use is being drafted.

After having heard the representatives of the following bodies in session:

- Directorate General for Health

- *Confédération Nationale Artisanale des Instituts de Beauté* (CNAIB, representative professional body)
- *Confédération Nationale de l'Esthétique Parfumerie* (CNEP, representative professional body)
- PHILIPS France
- BABYLISS

ISSUES THE FOLLOWING RECOMMENDATION:

The Commission recommends that:

1. The Public Authorities

1.1. Put an end to the incoherence consisting in the *de facto* tolerance of professionals who do not have a medical degree using IPL equipment whereas this practice is forbidden by law.

1.2. Design regulations to define what kind of device consumers may use and in what conditions

1.3. Promote research to gain a firmer grasp on the medium and long-term photobiological effects of the radiation from IPL devices

1.4. Improve the epidemiological knowledge about the causes of the accidents involving the use of cosmetic equipment, including IPL equipment, by compiling a documented collection of accident circumstance

2. The Bodies in charge of Standardisation

2.1. Accelerate the drafting process of Standard IEC 60 335-2-113 on the safety requirements for cosmetic and beauty care laser and IPL devices

3. The Manufacturers, Importers and Distributors of Consumer Devices

3.1. As unwanted activation, or radiation leaks are eye hazards, provide standardised protective eyewear with the devices sold on the market

3.2. Pending the publication of Standard IEC 60335-2-113, test their devices against the provisions in Standard NF EN 62471 of December 2008 on the photobiological safety of lamps and lamp systems and Standard NF EN 60601-1 of January 2007 (basic safety of electrical medical equipment) mentioned in the tests described in this recommendation

3.3. Refrain from using the high energy density of the devices as their sales pitch

3.4. Change their safety systems (skin contact) to avoid any light leak outside the flash area and any unwanted triggering of the light through contact with objects other than the targeted skin

3.5. On the outside packaging of the product, print a warning that the device is not appropriate for all types of skin and that medical contraindications exist

3.6. In the user's manual, draw consumers' attention to:

- The fact they must not point the radiation toward any skin signs (i.e. beauty marks, scars, tattoos, skin lesions)
- The risks of burns after repeat flashes on the same skin area
- The cleaning methods of the device so as not to damage the filter; and the fact that device must not be used when filter is damaged

4. Consumers

4.1 Take account that there is not enough scientific knowledge about the medium to long term health impacts of radiation from IPL epilation

4.2 Never flash skin signs such as lesions, redness, beauty marks and scars

4.3 Scrupulously comply with the list of contraindications in the user's manual; specifically: the device should not be used by:

- Pregnant or nursing women
- Any person who has first been exposed to natural or artificial UV
- Any person who has been recently vaccinated or taken certain photosensitisers (i.e. anti-inflammatory drugs, antihistamines, cough medicine, antibiotics, corticoids)
- Any person who has recently applied photosensitiser creams or essential oils
- Any person with skin signs (i.e. hives, eczema)

4.4 In case of doubt about the lack of any contraindications and the appropriateness of IPL hair removal according to skin type (i.e. light complexion, dark complexion, fragile skin), or about one's healthy or pathological condition, first consult a physician

4.5 Wear standardised protective eyewear

4.6 Demand protective eyewear from all professionals

4.7 Comply with precautions for use to avoid burns

4.8 Never flash the same skin area repeatedly and comply with the recommended time intervals between sessions, in the user's manual

4.9 Never use a device with a damaged filter

4.10 Keep the devices out of children's reach

ADOPTED AT THE SESSION OF 3 JULY 2014

BASED ON THE REPORT BY MR RICHARD ORTEGA

Assisted by Mrs Odile FINKELSTEIN and Mr Patrick MESNARD, Commission Technical Advisors, in accordance with Article R. 534-17 of the Consumer Code

MEASUREMENT UNITS

Unit	Abbreviation
Nanometre	nm
Time	T
Square centimetre	cm^2
Degree Celsius	°C
Diameter	Ø
Gram	g
Hour	hr
Joule	J
Joule per square centimetre	J/cm^2
Kilogramme	kg
Millimetre	mm
Square millimetre	mm^2
Milliradian	mrad
Millisecond	ms
Minute	min
Newton	N
Newton-metre	N-m
Radian	rad
Second	s
Steradian	sr
Volt	V
Watt per square metre	W/m^2
Watt per square metre and per steradian	$W/m^2/sr$

ANNEX I: RISK GROUP – RESULTS

		A	B	C	D	E	F	G	H	I	J
	Maximum Energy [J]	10.9	13.6	14.1	55.9	22.0	8.6	11.3	12.8	9.9	7.0
	λ Cut-off [nm]	467	470	472	583	520	470	557	642	571	546
	Pulse duration [ms]	0.440	0.730	0.480	34	26	0.540	1.84	29.6	1.035	2.47
Size	Flash bulb [mm]	30 x 4	30 x 4	30 x 5	30 x 12	25 x 5	30 x 4	32.5 x 3	20 x 6	35 x 4	33 x 5
	Aperture (mm)	30 x 13	30 x 13	30 x 20	30 x 20	25 x 12	30 x 9	32.5 x 12.5	20 x10	35 x 13.5	33.5 x 13
	Apparent aperture [mrad]	85	85	100	105	75	85	89	65	98	96
Eye & skin hazard from exposure to actinic UV radiation 200-400 nm	Acceptance angle	1,400									
	E_s [J/m^2]	/	/	/	/	/	/	/	/	/	/
	Limit [J/m^2]	30									
	Limit exceeded	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
Eye hazard from exposure to near-UV 315-400 nm	Acceptance angle [mrad]	1,400									
	E_{UVA} [J/m^2]	/	/	/	/	/	/	/	/	/	/
	Limit [J/m^2]	10,000									
	Limit exceeded	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
Retinal hazard from exposure to blue light 300-700 nm	Acceptance angle [mrad]	1.7									
	L_B [J/m^2/sr]	300	320	240	57	220	516	12	31	5	4
	Limit [J/m^2/sr]	1,000,000									
	Limit exceeded	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
Retinal thermal hazard from exposure to light 380-1400 nm	Acceptance angle [mrad]]	1.7									
	L_R [W/m^2/sr]	10,300	12,670	10,370	161,000	95,900	20,000	53,380	97,360	16,500	6,540
	Limit [W/m^2/sr]	1,800	2,620	1,620	37,700	43,170	2,080	5,000	55,450	2,880	5,630
	Limit exceeded	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Eye hazard from exposure to infrared radiation 780-3000 nm	Acceptance angle [mrad]	1,400									
	E_{IR} [W/m^2]	135,000	102,400	333,000	113,300	28,340	219,000	192,000	32,900	168,700	28,320
	Limit [W/m^2]	6,000,000	4,041,000	5,550,000	227,300	278,000	5,081,000	2,026,000	250,000	3,200,000	1,660,000
	Limit exceeded	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
Skin thermal hazard from exposure to light 380-3000 nm	Acceptance angle [sr]	2π									
	E_H [(J/m^2]	73	93	195	4,520	890	146	410	1,100	195	80
	Limit [(J/m^2]	2,900	3,290	2,960	8,600	8,000	3,050	4,140	8,320	3,560	4,430
	Limit exceeded	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
	Risk Group	**3**	**3**	**3**	**3**	**3**	**3**	**3**	**3**	**3**	**3**

ANNEX II: SUMMARY OF THE COMPLIANCE OF EACH DEVICE

Paragraph	Title	A	B	C	D	E	F	G	H	I	J
201-6	**Classification of ME Equipment**	**3**	**3**	**3**	**3**	**3**	**3**	**3**	**3**	**3**	**3**
201.7 201.7.9.2.101.1	**ME Equipment identification, marking and documents** **Accompanying documents** *Instructions for use* *Specific information for LS equipment* **Information on output**	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -
201.7.9.2.101.2	**Safety Information**	-	-	-	-	-	-	-	-	-	-
201.7.101 201.7.101.1	**Labelling of LS equipment** *Labelling requirements*	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -
201.7.101.2	*Product label design and labelling information*	-	-	-	-	-	-	-	-	-	-
201.7.101.3	*Emission aperture label*	-	-	-	-	-	-	-	-	**C**	-
201.7.101.4	*Radiation output and standards information*	-	-	-	-	-	-	-	-	-	-
201.10 201.10.101	**Protection against unwanted and excessive radiation hazards** *Disabling device*	- 	- 	- 	 **C**	- 	- 	- 	- 	 **C**	-
201.10.102	*Shield*	**C**	**C**	**C**	**C**	**C**	**C**	**C**	**C**	**C**	**C**
201.10.104	*Controls and indicators*	-	-	-	-	-	-	-	-	-	-
	a) Key-operated master control	-	-	-	-	-	-	-	-	**C**	-
	b) Visible or audible ready indicator	**C**	**C**	**C**	**C**	**C**	**C**	**C**	**C**	**C**	**C**
	c) Optical radiation indicator	-	-	-	-	-	-	-	-	**C**	-
	d) Stand-by/ready control	-	-	-	**C**	-	-	-	-	**C**	**C**
201.10.105	*Exposure termination*	**NA**	**NA**	**NA**	**NA**	**NA**	**NA**	**NA**	**NA**	**NA**	**NA**
201.12 201.12.1	**Accuracy of controls and instruments and protection against hazardous outputs** *Accuracy of controls and instruments*	 -	 -	 -	 -	 -	 -	 -	 -	 -	 -
201.12.1.101	*Indication of LS equipment output*	-	-	-	-	-	-	-	-	-	-
201.12.4.2	*Indication of parameters relevant to safety*	**NC**	**NC**	**NC**	**NC**	**NC**	**NC**	**NC**	**NC**	**NC**	**NC**
201.12.4.101	*Emergency stop*	-	-	-	-	-	-	-	-	-	-
201.13	**Hazardous situations and fault conditions**	**NC**	**NC**	**NC**	**NC**	**NC**	**NC**	**NC**	**NC**	**NC**	**NC**

Table 15 – Compliance Summary - Optical Radiation

Key:

- –: Non compliant
- C: Compliant
- NA: Not Applicable
- NC: Not Checked due to lack of information about the device and electric diagram