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REVIEW ARTICLE

Guidelines on the safety of light-based home-use hair removal devices from the European Society for Laser Dermatology

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Abstract

In the past 5 years since their US introduction, there has been a rapid proliferation of light-based hair removal devices intended for home-use. In the last 2 years in Europe, sales already run into many tens of thousands of units with well-known multi-national companies entering the market. These guidelines provide a definition of light-based home-use technology, to inform healthcare professionals about home-use light-based technology and encourage manufacturers wishing to sell in Europe to adopt 'best practice'. The review presents the current status on standards and regulation issues and considers home-use safety issues, encompassing human, device and electrical safety, given risks to the eyes and skin from optical radiation both to the consumer and persons in the vicinity. Proposed technical measurement methodology is considered with focus on recognized critical parameters for the safe use of light-based hair removal technology including recording the technical performance and safety claims of a range of home-use hair removal devices. The literature review emphasizes potential adverse incidents and safety aspects of treating cosmetic conditions, such as unwanted hair growth. Although some regulations exist, they differ from region to region and there is a specific need for international common principles and guidelines relating to the manufacture, marketing and use of intense pulsed light and laser devices, including manufacturing standards for home-use products intended, amongst others, for cosmetic hair removal and photo-rejuvenation procedures. In these guidelines, the European Society for Laser Dermatology (ESLD) provides a professional view of what 'best practice' may imply for manufacturers and consumers alike.

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Conflict of interest

Godfrey Town receives consultancy fees and travel grants from CyDen Ltd., SA1 8PH, Swansea, UK and Unilever HPC, Trumball, USA. Caerwyn Ash receives salary from Cyden Ltd., SA1 8PH, Swansea, Wales, UK. Christine Dierickx receives consultancy fees from Procter & Gamble, Cincinnati, Ohio 45202, United States. Klaus Fritz is remunerated for presentations and hands-on training with other devices manufactured by one of the companies mentioned but not related to this technology. Peter Bjerring has received consultancy fees from CyDen Ltd., SA1 8PH, Swansea, Wales. Merete Haedersdal receives consultancy fees from Procter & Gamble, Cincinnati, Ohio 45202, United States.

Introduction

Ever since a Frenchman, Jean-Jaques Perrett, invented the first safety razor in the late eighteenth century, the race has been underway for companies to exploit the consumer market for safe, home-use personal hair removal devices. With recent advances in technology, device manufacturers have been expanding device-marketing categories to include treatments for acne, wrinkles, cellulite, alopecia and skin rejuvenation as well as tooth bleaching and all manner of body and podiatry treatments.

Several leading laser and intense pulsed light (IPL) manufacturers have developed low-powered, miniaturized systems to meet the needs of the domestic consumer wishing to undertake

Figure 1 Home-use hair removal devices identified in this study. From top left: Tria (Tria Beauty Inc, CA, USA), Rio Scanning Laser (Dezac Ltd., UK), iPulse Personal (CyDen Ltd., UK), Silk'n and SensEpil (HomeSkinovations, Yokneam, Israel), i-Light/LumaSmooth (Remington, USA), Teny Epil Flash (GHT Innovation, France), IPL 8000 (Dezac Ltd., UK), E-One (E-Swin, France), Lumea (Philips, Eindhoven, Netherlands) and Viss (Vissbeauty, Korea).

depilation and other cosmetic treatments in the privacy of their own home and at a price cheaper than a professional service Fig. 1. This movement from professional oversight to consumer use has meant that home-use devices must be 'smart' to minimize adverse events and has given manufacturers the challenge of focusing on specific safety measures to limit the risk of accidental injury to the eyes and skin of the consumer and those in the vicinity of the user.

The lack of any specific current standards controlling required performance parameters of light-based devices for home-use has allowed a number of such products to be offered for sale in some international markets without reliable evidence-based data on safety and efficacy.

Although home-use devices may offer greater privacy and personal convenience to the consumer than professionally delivered hair removal treatments and a reduction in the cost of maintaining hair free skin for extended periods, education of the consumer in light-based treatments is more difficult than traditional methods of consumer depilation. Comprehensive education materials, detailed instructions for use, DVDs and consumer care support should be mandatory as part of the comprehensive safety plan for the sale of such devices to the general public who are otherwise unaware of potential safety issues. Other consumer education strategies may include physician-directed use of home-use devices, in-store trained sales consultants and web-based tutorials. The consumer should be informed of safety issues in general and specifically about the potential implications of light-induced post-inflammatory hyperpigmentation following treatment on sun tanned skin.[1]

Although professional providers are able to accommodate a wider range of skin types and provide faster and possibly longer-lasting treatments than are attainable with home-use systems, domestic devices may still play a significant part in removing unwanted body and facial hair, stimulating hair growth, as well as rejuvenating aged and photodamaged skin amongst a general public unable or unwilling to pay for professional treatments.

This review article focuses on home-use devices for hair removal and intends to inform healthcare professionals about home-use light-based technology and influence manufacturers and distributors wishing to sell in Europe to adopt 'best practice'. In particular, attention is given to human safety issues and the risks to the eyes and skin from optical radiation, both to the self-treating consumer and persons in the vicinity of the user. The published technical performance of a range of home-use devices is included with discussion of recognized critical parameters for the safe and effective use of light-based technology in hair removal.[2]

Definitions of a light-based home-use device

In these guidelines, the authors define home-use light-based devices as products intended by design and intention for beauty treatments and not medical products for diagnosis or treatment of any disease, disorder or injury to a person or animal.

The authors will consider laser and IPL devices being sold legitimately 'over-the-counter' to end users in Europe through department stores, pharmacies, internet on-line stores, mail-order catalogues and TV shopping channels for the purpose of treating unwanted hair. To date, lasers and IPL devices are the only light-based devices shown clinically to have sufficient energy to remove hair and appear to offer a real alternative to conventional methods

Table 1 Table listing manufacturers' device data for fluence, pulse duration and wavelength, illustrating that only three manufacturers publish claimed values for these three key technical parameters.

Manufacturer/ Device	Claimed fluence (pulse energy) J/cm^2	Claimed pulse duration ms	Claimed wavelength (spectral range) nm
CyDen iPulse Personal IPL	7.0–10.0	25–74	530–1100
E-Swin E-One IPL*	Max 12.5	Not given	575–1100
GHT Teny Epil-Flash IPL	20	24–33	600–950
Home Skinovations Silk'n IPL	Not given	Not given	475–1100
Home Skinovations SensEpil IPL	Not given	Not given	475–1100
Philips SatinLux/Lumea IPL	2–6.5	<2	>570
Remington i-Light/LumaSmooth IPL	Not given	Not given	Not given
Rio Dezac Salon Scanning Laser	Not given	Not given	808
Rio Dezac IPL 8000	Not given	Not given	Not given
Tria Beauty TRIA Laser	6–24	125–600	800
Vissbeauty Viss IPL	(23 Joules)	Not given	530–930

IPL, intense pulsed light.

*Independently published technical data on the E-One IPL (E-Swin, France), which is a CE-marked medical device, but sold for home use, indicates a maximum pulse energy of 72 J and should therefore be considered equivalent to other professional medical devices on the market.

of epilation. A total of nine currently available IPL devices and two laser devices for hair removal procedures were identified in this study Table 1.

Although unwanted body and facial hair can be caused by specific medical conditions, such as hypertrichosis (excess hair at any body site) and hirsutism (excess hair in androgen-dependent sites in women) it can also be secondary to endocrine disorders, malnutrition, medication and virilising tumours.[3] However, these are medical conditions requiring advice and treatment from a healthcare professional and the authors believe that home-use devices should be considered purely for cosmetic conditions with no underlying medical abnormalities and exclusively for improving cosmetic appearance.

From a technical standpoint, the maximum pulse energy available from a home-use IPL is typically in the range 7.5–30 J delivered over at least 2.5–60 ms pulse duration in the spectral range 450–1200 nm and over treatment areas (spot sizes) of 2–6 cm^2. Only the E-One IPL (E-Swin, France), which is a CE-marked medical device, but sold for home-use, exceeds this range with a maximum pulse energy of 72 J and should probably therefore be treated as equivalent to other professional medical devices on the market. Home-use hair removal lasers considered in this review operate at a nominal 800–808 nm wavelength and one device, the Tria laser (Tria Beauty, Dublin, CA 94568, USA) claims to deliver up to 22 J/cm^2 with pulse durations up to 600 ms and a treatment area on tissue of 0.79 cm^2.

Principles of photobiology

Light produces a biological effect in skin via three mechanisms of interaction between light and tissue: photochemical, photothermal and photomechanical effects. Lasers and intense pulsed light sources utilize photothermal interaction in skin to achieve hair removal, where incident light at the skin surface is either reflected (approximately 5% of photon energy is directly reflected) or refracted and absorbed or scattered within the layers of the epidermis and dermis (95% of photons). If light is reflected from the surface of the skin or transmitted completely through it without absorption, there will be no effect.

In order for light to produce any biological effect in skin it must first be absorbed, where transformation of radiative optical energy into a different form of energy (usually heat) occurs by specific interaction with tissue. There are only four main components (or 'chromophores') in the skin that absorb visible and near infrared light energy: melanin, haemoglobin, porphyrin and intracellular or extra-cellular water, and their absorption spectra and absorption and scattering coefficients have been well investigated. Manufacturers of light-based equipment have taken this information and designed technological devices that produce light, which have the correct

wavelengths to be precisely absorbed by one or more of these components of skin, while minimizing collateral thermal injury to the surrounding tissue.

This mechanism, called 'selective photothermolysis', employs a knowledge of the rate of heat loss from specific targets, such as the melanin in hair follicles, whereby carefully selected wavelengths, optical energy density and pulse duration precisely damage an absorbing biological target without causing injury to surrounding structures.[4] In the case of a terminal hair follicle, energy is absorbed by the melanin-rich hair shaft and follicular matrix, the temperature of the chromophore increases and thermally induced biological changes take place to damage or destroy the follicle and induce a change in normal hair cycling e.g. telogen induction.

Going from professional to home-use employs the same mode of action, so it is reasonable to anticipate a similar adverse event profile, although the use of considerably lower energy delivery in home-use devices would suggest a lower quantitative side effect response in tissue. It is also possible that the typical adverse event profile of high power professional systems, which could 'overwhelm' some potential tissue responses, may emerge in home-use products with greater prevalence. The thermal events associated with the mode of action therefore still drive safety concerns with this type of technology for home-use and serve as a framework for presenting the ocular and dermal hazards in these guidelines.

Standards & regulation

It is important to acknowledge the difference between the US and European Union (EU) countries with respect to medical vs. non-medical classification of devices for hair removal. In the US, home-use hair removal devices are treated as medical devices for premarketing permission by the Food and Drug Administration (FDA) for sale over-the-counter (OTC) to consumers. In the EU, such devices are treated as cosmetic products. It follows that different regulations control the manufacture and sale of these products in different geographical areas.

Table 2 Table listing manufacturers' device FDA pre-marketing 510(k) clearance for hair removal and CE-Mark status.

Manufacturer/ Device	FDA 510(k) cleared	CE-mark
CyDen iPulse Personal IPL	Pending	Yes
E-Swin E-One IPL	Yes	Yes (medical)
GHT Teny Epil-Flash IPL	No	Yes
Home Skinovations Silk'n IPL	Yes	Yes
Home Skinovations SensEpil IPL	Yes	Yes
Philips SatinLux/Lumea IPL	No	Yes
Remington i-Light/LumaSmooth IPL	Not known	Yes
Rio Dezac Salon Scanning Laser	Pending	Yes
Rio Dezac IPL 8000	Pending	Yes
Tria Beauty TRIA Laser	Yes	Yes
Vissbeauty Viss IPL	Not known	Yes

IPL, intense pulsed light; FDA, Food and Drug Administration.

In the USA, the FDA controls OTC market licencing of light-based home-use hair removal devices and there are already a number of precedents Table 2. It should be remembered, however, that strict Premarket Approval (PMA) requirements to market a device for consumer use and rigorous obligations in respect of applying human usability factors to optimize safety are imposed on manufacturers by the FDA[5].

Which laser standards apply in the USA?

The FDA has affirmed its commitment to harmonize selected provisions of the International Electrotechnical Commission (IEC) Laser Standards in a guidance document issued in June 2007. For most of the world, the applicable laser safety standard is the international standard set by the IEC, and known as IEC 60825 (previously IEC 825). The USA user standard is American National Standards Institute (ANSI) Z136.1, whereas the manufacturer's standard is CDRH 21 Code of Federal Regulations (CFR) parts 1040.10 and 1040.11.

Recently, FDA's Center for Devices and Radiological Health (CDRH) has decided to accept certain conformance standards of IEC 60825-1 and IEC 60601-2-22 standards in lieu of those required by 21 CFR §1040.10 and §1040.11. This FDA recognition of the IEC standards has not yet been codified and in the interim, so as to reduce the regulatory burden on industry and the CDRH agency, FDA has released 'Laser Notice No.50′ that explains which of the IEC standards will be accepted in the USA. This industry guidance allows some IEC standards for lasers to be accepted within the USA. Further information on CDRH requirements can be found at http://www.fda.gov/cdrh/radhealth/products/lasers.html.

Laser manufacturers intending to distribute OTC light-based home-use hair removal devices in USA should consider that the FDA will treat these as medical devices and compliance will be required with IEC 60825-1 (*Safety of laser products – Part 1: Equipment classification and requirements*) and IEC 60601-1-11:2010 (*Medical electrical equipment Part 1–11: General requirements for basic safety and essential performance. Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*). The requirement for compliance with this latter standard holds irrespective of whether the device is used by a consumer or healthcare professional. Certain codified regulations outlined in 21 CFR §1040.10 and §1040.11 remain in effect and therefore strict compliance with the IEC standards alone is not sufficient for complying with all US laser requirements.

In Europe, domestic (i.e. household) electrical appliances are normally manufactured under national legislation to comply with standards issued (originally) by the International Electrotechnical Commission (IEC) and subsequently ratified by CENELEC. The IEC is the international standards and conformity assessment body, for all fields of electro-technology. CENELEC is the European Committee for Electrotechnical Standardization, based in Brussels.

Which laser standards apply in Europe?

Existing IEC laser standards control the manufacture of lasers, and these have been ratified by CENELEC. The recently published standard IEC 60601-2-57 for intense light devices (*Medical electrical equipment – Part 2–57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use*) was ratified by CENELEC in April 2011. In the opinion of the authors of this present article, until a suitable, dedicated standard for home-use laser and intense light devices is developed, the applicable parts of the following general standards and guidelines (inasmuch as they apply to home-use devices) should be followed by manufacturers. Strictly speaking, these standards carry more legal weight in Europe once they are recognized as being 'harmonized standards' and are listed in the Official Journal of the EU enabling the manufacturer to claim presumption of conformity with the associated European Directives, e.g. Low Voltage Directive, Medical Devices Directive, etc. In short, these standards are adopted and mandatory, and currently represent the best way forward for manufacturers of devices intended for the home-use sector:

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

In 2000, there was a major revision of the fundamental International and European laser safety standards IEC 60825-1 and EN 60825-1 (which are word identical) and these versions came into effect on 1st January 2001. New laser classes were introduced and Maximum Permissible Exposure (MPE) and Accessible Emission Limit (AEL) tables were changed as well as revisions to measurement aperture requirements and changes to the user section and appendices.

IEC 60601-1 (*Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*)

This is the General Standard containing requirements for basic safety and essential performance that are generally applicable to medical equipment and are either supplemented or modified as Particular Requirements standards. Where particular standards exist, they should be used in conjunction with the General Standard.

IEC 60601-2-22 (*Medical electrical equipment – Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment*)

IEC 60601-2-22 applies to the safety and essential technical performance of laser equipment for either cosmetic, surgical, therapeutic, medical diagnostic or veterinary applications, intended for its use on humans or animals, classified as a class 3B or class 4 laser product as defined in IEC 60825-1. This edition constitutes a technical revision and takes account of the new editions of the General Standard IEC 60601-1 and publication IEC 60825-1. Throughout this International Standard, light emitting diodes (LED) are included whenever the word 'laser' is used.

IEC 60601-2-57 (*Medical electrical equipment – Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use*)

IEC 60601-2-57:2011 and EN 60601-2-57:2011 applies to basic safety and essential performance of light source equipment consisting of a single or multiple sources of optical radiation, with or without power supply in the wavelength range 200 nm to 3000 nm, with the exception of laser radiation, and intended to create non-visual photo-biological effects in humans or animals for therapeutic, diagnostic, monitoring, cosmetic/aesthetic or veterinary applications.

ICNIRP *Guidelines on exposure to broadband incoherent optical radiation*. *Health Physics 1997; 73:4:539–554*

These guidelines from the International Commission on Non-Ionizing Radiation Protection (ICNIRP) establish the basic principles of protection against visible and infrared radiation emitted by broadband, non-laser sources, including LEDs. They are intended for use by experts and regulatory bodies who are responsible for developing controls, recommendations, guidelines or codes of practice to protect workers and the public from the potentially adverse effects of optical radiation.

Review of Thresholds and Recommendations for Revised Exposure Limits for Laser and Optical Radiation for Thermally Induced Retinal Injury. *Schulmeister K, Stuck BE, Lund DJ, Sliney DH. Health Physics 2011; Volume 100, Number 2:210–220.*

This publication reviews and makes recommendations to update ICNIRP Guidelines on exposure limits for broadband incoherent optical radiation, which will come into effect in 2012 and be adopted into IEC 62471 (Photobiological safety of lamps and lamp systems). The changes are quite relevant since exposure limits for pulsed devices will increase quite significantly.

IEC 60335-1 (*Household and similar electrical appliances – Safety – Part 1: General requirements*)

IEC 60335-1 deals with the safety of electrical appliances for household and similar purposes, their rated voltage being not more than 250 V for single-phase appliances and 480 V for other appliances. Battery-operated appliances and other d.c.-supplied appliances are within the scope of this standard. Appliances not intended for normal household use, but which nevertheless may be a source of danger to the public, such as appliances intended to be used by laymen in shops, in light industry and on farms, are within the scope of this standard.

The above standards include CE-marking and compliance with low-voltage regulations, electro-magnetic compatibility EMC requirements and the Medical Devices Directive.[6,7]

Non-medical consumer products (including light-based cosmetic home-use devices) are generally governed by national General Product Safety (GPS) regulations, which transpose EU regulations on general product safety into national law.[8] In the United Kingdom for example, as long as a device is marketed for cosmetic applications and no medical claims are made, the regulatory authorities (MHRA* and HPA†) have no interest except in reported adverse events. "Products" within the meaning of the regulations can best be described as all goods that are (or could be) placed on the market, or supplied or made available (including in the course of providing a service) to consumers for their private use and UK Department of Trade and Industry (DTI) has overall responsibility for safety issues concerning these products.[9] The DTI normally exercises enforcement control through the local authorities (Environmental Health Division/Trading Standards). There are no specific requirements for home-use light-based hair removal or other cosmetic devices.

Generally in Europe, in the absence of specific product regulations or national standards, the GPS regulations will normally apply.

Compliance by manufacturers must show engineered solutions that prevent accidental discharge and hinder potential misuse. For this reason, home-use lasers and IPLs are provided with skin contact switches or sensors to ensure that the device can only be activated in full occlusion on the skin surface. This has led some manufacturers of home-use lasers to claim that their devices fall into the Class I laser category and do not require the user to wear safety glasses. As an additional safeguard, several manufacturers state in their instructions for use that the device should not be used on the face (or above the chin).

A proposal is under discussion within the international standards bodies to introduce a new optical classification category for light-based equipment, whereby although the system or device could cause biological ocular damage if accidentally viewed directly, with a sequence of internal safety checks prior to discharge, the device is considered a lower risk to the user. This potential solution is currently being considered by the IEC technical committee TC76 WG1 with a view to introduce a new laser Class 1C. Concern about the ocular safety of home-use IPL devices has led the IEC technical committee TC76 WG4 to consider a similar classification scheme for IPLs using skin contact switches or sensors, as the proposed Class 1C for lasers.

At an IEC meeting in Bali in June 2011, it was decided to set up an IEC/TC61 Working Group with suitable experts to develop a new Part 2 standard under the IEC 60335 series for the safety of Beauty Care Appliances. The new standard will build on work already done by CENELEC TC61/WG5 and the current Australian Standard for these kinds of products (AS/NZS 3130:1995). The goal will be to come to one global IEC standard.

*MHRA; Medicines and Healthcare products Regulatory Agency; a UK Government agency with responsibility for standards of safety, quality and performance.

†HPA; Health Protection Agency; an independent UK body that protects the health and well-being of the population.

Proposed technical measurement methodology

Knowledge of the optical dosimetry characteristics of a laser or an IPL device is essential to establish a scientific basis for applications involving light–tissue interaction. Previously, published studies have identified five key measurement parameters for laser and IPL output: energy measurement (fluence), pulse duration (exposure time on tissue), spatial distribution (homogeneity on tissue), spectral output (wavelength or band of wavelengths), and in the case of IPL devices, time-resolved spectral output. Standardization of measurement introduces consistency into a system, lowering the risk of adverse reactions from device malfunction and improving treatment efficacy and reliability.

Practical measurement methodology suitable for use with IPL and laser light sources is required to ensure quality control and to validate manufacturers' claims and the following proposed methods have been published.[2,10,11]

Energy measurement (fluence)

The optical energy density generated by home-use devices (also called fluence or radiant exposure) is the amount of light energy delivered per unit area and is measured in Joules/cm^2. The ideal energy density will raise the temperature of the chromophore to a level that causes damage to the target, but does not produce adverse side effects, such as burns or blisters. Excessive fluence may increase the frequency and severity of side effects and low energy may result in under-treatment and user dissatisfaction.

Previous trials showed repeatable and consistent energy measurements of IPLs from Ophir power and energy meters Ophir L50 (300) IPL Absorber Head (Ophir Optronics Ltd, Jerusalem 91450, Israel) in comparison with radiometric analysis traceable to national standards. However, the exact model should be selected with support from the power meters and absorber head manufacturer to encompass the device wavelength range, pulse/exposure time and its energy range.

Pulse duration (exposure time on tissue)

According to Anderson and Parrish, the measurement of pulse duration is important because the optimum pulse duration should be close to the thermal relaxation time (TRT) of the target chromophore[4] Numerous studies have confirmed this, proving that higher hair clearance rates occur when the pulse duration is close to, or longer than, the thermal relaxation time of the hair follicle. However, if the pulse duration is too long the heat diffuses to surrounding tissue, increasing the risk of adverse side effects; at the same time, the side effect risk is also increased if the pulse duration is too short and the fluence too high.

The duration of the discharged laser or IPL pulse or sub-pulses can be measured using a reversed biased fibre optic photodiode detector (BPW32, 200–2000 nm) and amplifier, acting as a light-

dependent switch. The pulse duration can be captured on an oscilloscope. The pulse duration can differ considerably between IPL and laser systems from different manufacturers: some use true single pulses or utilize two or more sub-pulses to extend overall pulse duration to allow intra-pulse epidermal thermal relaxation. Ideally, the pulse durations should be adjustable as various chromophores have differing thermal relaxation times (TRT) and therefore the device should match such times to target the correct chromophore.

Spatial distribution (homogeneity on tissue)

Inhomogeneity in the spatial profile of the laser or IPL output on skin, such as a 'hot spot' in the centre, can cause over treatment of the skin centrally and/or under treatment peripherally. This may, in part, explain side effects, such as burning, hypopigmentation, hyperpigmentation and/or patchy increased hair growth, despite the device being of a suitable average energy. If the region of treatment is not uniform, then overlapping treatments are required which, as well as increasing the time taken for the procedure, can also cause burns.

Traditionally, the spatial distribution of laser and IPL outputs has been assessed by reviewing the burn pattern on black laser alignment paper. Although this method highlights major discrepancies in the spatial profile and gives an overview of the energy distribution, it does not quantify the results. A recent study by Thomas *et al.* has provided a new technique for measuring spatial distribution of IPL systems and such methodology can be adapted for laser and LED devices. Using a CCD camera and a phosphorescent screen to extend the pulse duration, averaged time frames can be analysed using Matlab modelling software where dark reference frames are also taken to minimize noise.[12]

Spectral emission measurement (IPLs)

The chromophores in the skin, which are important for many light-based treatments, have individual absorption spectra. This means that, depending on the target chromophore, certain wavelengths will be more effective in treating certain conditions than others. Therefore, each treatment type will be best suited to a particular wavelength or range of wavelengths. However, the wavelength or range used should take into account the absorption spectra of all chromophores, because heating a non-target chromophore can damage the skin. Knowledge of the spectral output of IPLs also provides information of emitted wavelengths, such as ultraviolet and infrared radiation, which can present immediate and long-term health risks.

With each device, a photo-spectrometer apparatus can be set up to produce accurate results with minimal experimental error. Using a USB spectrometer (Ocean Optics, Dunedin, FL 34698, USA) the device optical output is directed at the spectrometer probe from a distance to avoid saturation of the apparatus. The spectrometer probe may be held with a retort clamp fixed to a laboratory stand to ensure no movement of the probe. The spectral output can be saved digitally and presented in a MICROSOFT EXCEL GRAPH for analysis.

Proposed minimum safety & efficacy testing

It has to be assumed that manufacturers and suppliers of home-use light-based devices in Europe will comply with statutory safety requirements listed above under 'Standards & Regulation'.

In addition, manufacturers should test devices to the latest guidelines and draft international standards awaiting national ratification as these contain ocular hazard testing requirements including home-use devices (e.g. IEC 60601-2-57 *Medical electrical equipment – Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use* – published 31st January 2011 has been ratified by CENELEC (and in the UK) published as BS EN 60601-2-57).

Moreover, manufacturers and healthcare professionals should not rely upon clinical data from published studies using professional laser and IPL systems as the operating parameters and user regimes are quite different and may produce dissimilar outcomes in terms of efficacy and adverse event responses.

Human safety

The overall safety of a product is assessed having regard to the product's characteristics including electrical safety; packaging; instructions for assembly, maintenance and disposal; effects on other products with which it might be used; labelling[13] and other information provided for the consumer as well as categories of consumer at risk when using the product e.g. children. The focus of this human safety review will be on ocular and dermal hazards.

Risk of ocular damage

The mechanisms by which light could produce ocular damage include photochemical, photomechanical and photothermal effects. The latter is the most likely event associated with near IR (laser) and IPL emissions, but photochemical effect is also possible with IPL. This review considers the current approach to eye safety by manufacturers of home-use devices and describes what could occur.

Several, but not all home-use laser and IPL manufacturers supply safety eyewear, but there is of course no guarantee that the consumer will use the protective spectacles if provided. Currently, while there are standards for manufacturers to follow in providing suitable protective goggles or glasses for different laser classes, there is no international safety eyewear standard for IPL devices. Most professional IPL manufacturers supply optical density (OD) 3, 4 or 5 safety eyewear according to the harmonized American and European welding eyewear standards (EN 166/EN 169 – Optical Class I, Directive for Personal Protective Equipment (PPE), 89/686/EEC). However, in the absence of any internation-

ally ratified standards for intense light safety eyewear, suppliers may elect to follow the specific British national standard BS 8497-2 '*Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications*', published in 2008.[14]

If someone is treating their face or underarm and fires a home-use laser or IPL close to or directly into the eye either because of a faulty safety switch or because the safety mechanism is defeated accidentally or intentionally, what are the effects to the eye? Are they permanent or reversible?

Retina, cornea & lens

The human eye is a critical organ with only the 'blink reflex' to provide limited protection against excess light exposure of delicate optical tissues including the highly vascularised retina, cornea, lens and pigmented iris. In the case of non-cosmetic domestic laser products that produce parallel light in the wavelength range 400–1400 nm (visible to near infrared), even a laser pointer with an output greater than 5 mW has the potential to produce permanent retinal damage because of the risk of such laser energy being focused by the cornea and the lens to a small point on the retina i.e. low-power concentrated into a small area equates to a high power density and probable thermal damage to the highly pigmented and vascularised retinal tissues. Retinal injury may include a peripheral blind spot to partial or even total blindness. Above 1400 nm, laser exposure to the eye may cause a corneal burn whereas wavelengths above 750 nm and below 400 nm can cause lens cataracts and photochemical damage to the cornea.

The light from an IPL, however, is highly divergent and therefore cannot be focused by the lens in the eye to a small point on the retinal epithelium. The filtered IPL output should not include any ultra-violet (UV) light, which is a primary source of eye damage through prolonged exposure. UV light causes breakdown of the DNA over time resulting in cataracts and permanent damage to the cornea and lens.

The amount of light in the region 400–550 nm (blue/green light) produced by most home-use IPLs is minimal, only a relatively small percentage of the filtered IPL output is below 550 nm and usually none below 500 nm. Under normal ambient conditions, this blue/green region of the spectrum may be transmitted to the back of the eye and absorbed by the retinal pigments, this absorption leads to a temperature rise in the retina and has the highest probability to induce permanent ocular damage.

There is potential for blue light hazard to the retina, particularly at shorter wavelengths between 400 nm and 500 nm and longer wavelength infrared hazard to the cornea and lens in lasers and IPLs producing wavelengths in this higher wavelength region of the spectrum. Most home-use IPLs do not include any water filter that would reduce emissions from a xenon flash lamp at higher wavelengths above 900 nm so IPL manufacturers should measure irradiance and calculate exposure limit values (ELVs) to ensure that published safety thresholds are not exceeded.

In the absence of any specific international IPL standards, Eadie *et al.*, tested the iPulse Personal IPL (CyDen Ltd, Swansea, UK) for ocular hazard,[15] in accordance with IEC TR 60825-9 and the International Committee on Non-Ionizing Radiation Protection (ICNIRP) Guidelines on Limits of Exposure to Broad-band Incoherent Optical Radiation.[16] The conclusions of this testing showed that the device was within the prescribed international limits for ocular exposure. Data reported in a study by Ash and Town measured three popular home-use IPL devices, one of which generated emissions at the two highest settings of the device which exceeded the MPE threshold for retinal thermal hazard as set down in the current ICNIRP guidelines on exposure to broad-band incoherent optical radiation.[17] However, it should be noted that this hazard could only occur in the event that the skin contact safety mechanism failed or was accidentally or intentionally defeated.

Iris

The iris, like the retina is rich in melanin and contains small amounts of haemoglobin and absorbs incident light, which in the case of a narrow beam laser or highly divergent IPL may cause damage to the iris sphincter muscle used to control the amount of light hitting the retina. If this muscle is partially damaged then ocular hypertension, a long-term condition that can cause visual distortion (glaucoma) and migraine, may occur.

The degree of thermal absorption that may occur (assuming the eye is open and unprotected by the skin of the eyelid) is dependent upon the amount of melanin pigment (chromophore) available in the iris as the cornea and anterior chamber are essentially clear and refracted light will pass through with only a minimal loss of energy. However, the iris acts not only as an optical filter but it also acts as a very efficient diffuser of the light beam. Pigment layers in the iris dilator muscle (radial sphincter muscle) are found primarily in the posterior layer (closest to the lens of the eye). For light to be absorbed in these layers, the light first has to pass through the thin eyelid skin, the cornea, anterior chamber of the eye and the anterior surface of the iris muscle. The natural blink reflex alone (about ¼ second) will not shield the unprotected eye from an IPL flash or laser beam, as the pulse duration is shorter than the blink reflex and the spectral range and energy delivered within the flash lamp or laser pulse may be sufficient to cause an injury. Although no cases of eye injury have been reported following home-use laser or IPL treatments, several cases of iris damage following professional IPL treatments have been recorded in the literature.[18,19]

In one of these few reported cases in the reviewed literature of iris injury following professional IPL treatment, Sutter and Landau described an ocular injury to the iris of a 2-year-old patient treated for a facial port wine stain using a high-powered medical IPL system with a 550–1000 nm filter, which delivered 14 000 Watts of pulse power using a free-discharge pulse i.e. with a very high peak

of photon energy, where the IPL used delivered 70 J of pulse energy over 5 ms pulse duration.[20] As these are rare recorded cases showing ocular injury and the use of IPL technology is so widely used, it can be concluded that the incidence of documented professional IPL ocular injury is very low. Although the home-use devices described in these guidelines typically employ pulse power at least five times less than the high-power IPL systems in the above reports, the possibility of ocular injury in the home-use setting still remains. Even taking into consideration that the IPL is a highly divergent light source, the risk to the pigmented iris of the eye remains in the event of a home-use IPL device being discharged close to the eye with the safety mechanism impaired or defeated. Unless a light-based device manufacturer can demonstrate compliance with current standards specifying 'exempt group' status for ocular hazard, protective eyewear is essential to prevent ocular damage.

More case reports of iris injury by lasers using high fluence and short pulse duration following professional cosmetic eyebrow hair removal treatments have been recorded in the literature.[21–26] Adverse events have included anterior uveitis, pupillary distortion, posterior synechiae, iris atrophy, nuclear cataract, visual field defect, macular hole and retinal scarring. Chi-Chung Lin *et al.* (2010) observed that Caucasians with green-blue iris colour were more prone to iris injury in the event of laser exposure owing to the increased possibility of absorbed light energy at the anterior border layer and more prominent trabeculae than those with a brown iris.

To avoid the risk of permanent damage to the retina, lens or cornea of the human eye through accidental or intentional misuse of home-use devices, manufacturers should test their devices to all available standards and guidelines, and implement them even where they have not been ratified and adopted into national law.

Longer-term, manufacturers should collaborate with IEC working groups to create a new standard for home-use devices, which will, amongst other important parameters, define energy output, pulse characteristics, wavelengths and the requirement for safety sensors.

Risk of skin damage vs efficacy

It is well established in the literature that side effects, ranging from discomfort and pain, transient erythema and hyperpigmentation to blisters, burns and scars, can occur in the professional delivery of effective laser and IPL hair reduction and other cutaneous treatments, where operators should have received training and for the most part are qualified healthcare professionals.[27–30] It is therefore to be expected that home-use devices that deliver positive treatment results using selective photothermolysis are also inherently likely to produce some adverse incidents.

In respect of light-based hair reduction and extended hair regrowth delay, threshold values for efficacy have been presented by Manstein *et al.*[31] and several early studies have been published in peer-reviewed journals reporting positively on extended hair growth delay using home-use or simulated home-use treatments. In these studies, mean terminal hair reduction at 6 months after as few as three sequential weekly or bi-weekly treatments was >40%.[32–37]

In these simulated home-use hair removal clinical trials mild to moderate transient erythema was the most consistently reported adverse effect followed by varying levels of discomfort or pain, ranging from 'a feeling of warmth' to slight to moderate pain. However, in one study, where the device was used on a subgroup of unsuitable skin types, Wheeland reported that the incidence and severity of adverse effects increased significantly.[38]

As with any treatment using a device or chemical compound, there are side or adverse effects; the issue is the incidence and severity of these effects. Given the lower energy produced by light-based home-use hair removal devices compared with professional high-power systems, such side effects following correct use should be less severe than with professional devices although the incidence of side effects is likely to be more pronounced in darker Fitzpatrick skin types.

Even if a home-use device is used correctly, but especially if it is used on wrong settings, if it is used excessively or the user does not follow pre- or post-treatment instructions, the following are possible and may be referred to a general medical practitioner or dermatologist:

Temporary side effects

- Temporary side effects, such as soreness, edema, redness or irritation, which can be dealt with by appropriate patient advice and medication if indicated. Hyperpigmentation is usually transient, but further self-treatment should be deferred and the user advised to check correct device settings for their skin type before any further home treatments. If the device does not offer different treatment settings and there is no other obvious cause of the adverse reaction (such as direct sun exposure pre- or post-use, which could have irritated the skin) look for other causes of the reaction, such as spray tan use, concomitant use of other depilatory methods that may have irritated the skin area treated and use of photosensitive drugs or herbal remedies (e.g. St. John's Wort). The user should also consider returning the device to the supplier for fault inspection.
- Crusting – suitable healing ointments should be recommended if this occurs.
- Mild to moderate pruritus – this will normally settle over 1–3 days, but may require medication to relieve the itching.
- Skin pigment changes – both hyperpigmentation and hypopigmentation are possible, however, this should be temporary, but may take weeks or months to resolve completely.
- Leukotrichia or 'vellus change' – temporary or long-term bleaching of melanin from hair follicles has been reported

in the literature, where previously brown or black terminal hair changes colour to yellow or white. This rare side effect is normally associated with use of professional high-energy devices where the effect was temporary, normal hair colour returning in 1–4 months.[39,40]
- Herpes simplex activation – suitable medication should be prescribed.
- If the user has had any adverse side effects from self-treatment this should be discussed and an assessment made of whether this was due to the treatment or subsequent activities.

At some stage after a course of home treatments, either if there has been less improvement of the condition than expected by the home-use device user or because no further clearing is likely to occur with additional treatments, leading them to seek medical advice, the user should be advised accordingly and a professional treatment recommended if appropriate.

Paradoxical hair growth

In some patients, optical hair removal treatment has a paradoxical effect of stimulating hair growth: new terminal hair growth has been observed in areas untreated, but in close proximity to the treated ones. The incidence of paradoxical hair growth, usually associated with polycystic ovarian syndrome (PCOS) and ovarian hyperandrogenism, in professional treatments has been reported to range from 0.6% to 10%. Although listed as a contraindication by several home-use device manufacturers, it is likely that PCOS sufferers will seek relief from unwanted body and facial hair by using light-based consumer devices leading to activation of dormant hair follicles in untreated areas close to hirsute-treated areas.[41] Such users may seek professional medical advice or further professional treatments.

The most susceptible patients are female individuals with darker skin types (III–VI) and receiving facial treatments. In most cases, this paradoxical hair growth occurs at a site that has a high vellus count and is relatively free of terminal hairs, such as adjacent to untreated facial areas or neck. All laser and light sources have the potential to cause hair induction, as there has been no clear relationship established between the types of hair removal device or the fluence used and the incidence of paradoxical hair growth. Possible causes include the effect of inflammatory mediators and sub-therapeutic thermal injury causing induction of the hair cycle.

In two case reports, hair growth has also been reported to occur after professional IPL treatment for removal of a port wine stain and a tattoo: terminal hair, not present before treatment, developed in treated areas of both indications.[42–47] Based on clinical experience, it is recommended in this subset of users not to start laser treatment to prevent paradoxical hair growth or in cases where it occurs, to stop further laser treatment and revert to traditional hair removal methods, such as waxing.

Hair removal and pigmented skin lesions

Exposure of melanin-containing skin lesions, especially congenital melanocytic nevi and dysplastic nevi to laser and IPL, should be avoided because of the risk of burn and potential scarring. Moreover, there has been a report of the appearance of clinically atypical nevi when nevus cells were treated in areas previously treated for hair removal. This should be kept in mind, especially in patients with a history of dysplastic nevi or with a personal or family history of malignant melanoma.[48] It is therefore advisable to avoid treating skin for hair removal when melanocytic nevi are present in this area.

Hair removal and tattoos

Today, more than 10% of the Western population has at least one tattoo. It is therefore conceivable that permanent hair removal is desired at the location of a tattoo. However, this poses a problem when the subject has no intention of removing or altering existing tattoos, but requires hair removal on the area in question. The concern is two-fold: (i) optical treatment of a tattoo might result in fading of the tattoo and (ii) absorption of the photons by tattoo ink could reduce the efficacy of hair removal and/or cause adverse effects of burning, pigment changes or scarring because of the inappropriate use of laser or IPL parameters, such as insufficiently short pulse duration (milliseconds). It is therefore advisable to avoid treating skin for hair removal when a tattoo is present in this area.[49–51]

Hair removal and pregnancy

Laser and IPL hair removal targets dark pigment in the hair and causes thermal and/or mechanical damage to the hair follicle. There are no studies that evaluate the safety of laser or IPL hair removal during pregnancy. There is no evidence or technical rationale that treatment would have any effect on fetal development or pregnancy.

Hair removal and sun exposure

Patients seeking advice should be instructed to avoid sun-exposure before their laser or IPL treatment and to use a broad-spectrum (UVA/UVB) sunscreen with SPF 15 or greater after laser or IPL treatments.[52]

Hair removal and compromised skin

Common sense should apply when using laser or other light-based devices for hair removal on compromised or damaged skin. However, users should be told that treatment with home-use lasers or IPLs should be avoided till healing of the damaged or compromised skin has occurred.

Hair removal and drug intake

The vast majority of pharmaceuticals that have the ability to develop abnormally heightened sensitivity to sunlight of the eyes

or the skin absorb in the long UV wavelength range (UVA). There are a very small number of botanicals and drugs, which have phototoxic potential in visible wavelengths. It is therefore possible that an ingested herbal supplement or exogenously administered drug or cosmetic might potentiate adverse effects after light-based therapy.

Phototoxic potential is less likely with a single wavelength laser than a broadband IPL. Current home-use hair removal lasers operate in the near infrared at 810 nm where phototoxicity is largely irrelevant. However, for IPL, with spectral emissions in the range 450–550 nm, there is a clear potential for phototoxicity. Photoxic side effects could happen in two ways: (i) drugs/cosmetic absorb the light resulting in a phototoxic reaction or (ii) the drug/cosmetic changes the structure or function of the skin.

1 There are few, if any, reports of a phototoxic response at the wavelengths of the lasers and IPLs in question (600–1200 nm) besides intentional photodynamic therapy. This is related to the absorption profile of chemicals where the majority of photosensitizers are activated by wavelengths in the UVA (320–400 nm) and to a lesser extent in the UVB region (290–320 nm). A direct phototoxic reaction is therefore unlikely if not negligible since current drugs/cosmetics do not absorb wavelengths emitted by visible/IR lasers or IPL.
2 The second possible contraindication is the change in structure or function of the skin by a drug or cosmetic. Increased skin sensitivity is consistent with the effects of isotretinoin and other retinoic acid derivatives on skin. This potential interaction is of concern, as female patients with androgen hormone profiles, where severe acne and hirsutism tend to coexist, seek treatment for hair removal while taking isotretinoin.

Katri followed seven female patients undergoing isotretinoin therapy for acne, who were treated with a diode laser for hair removal. In this study, the patients showed mild erythema consistently following hair removal, but no other side effects. Cassano reported similar findings in six patients treated with diode laser, four patients undergoing isotretinoin therapy and the remaining two had just completed the isotretinoin therapy. These studies, although limited, suggest that diode laser hair removal is safe in patients undergoing isotretinoin therapy. However, these data should not be applied to all lasers in patients using isotretinoin. For example, treatment of severe acne with isotretinoin has been reported to result in keloid formation and to reduce the wound healing response following laser treatment.[53–58]

Long-term side effects

In rare cases, long-term (permanent) hypopigmentation and possible scarring may occur. If this is observed, no further home treatment should be performed and the patient should be given appropriate professional medical advice.

With the exception of work by Haedersdal *et al.*, looking at IPL and UV-induced skin tumours in hairless mice, long-term side effects have not been studied.[59]

Conclusions

Safe and effective home-use hair removal laser and IPL usage depends on integration of several key elements:

The training ethos found in professional establishments has to be mirrored in the adequate provision of information and advice to consumers and safety mechanisms must be in place to prevent accidents or abuse.

The end user (consumer) needs to be well informed about the capability of modern, miniaturized light-based technology to provide cosmetic hair management and improvements to photodamaged skin in the home environment.

The consumer also needs to be encouraged to take advantage of multi-media training options and indirect supervision (e.g. DVDs, internet, telephone helpline support, user manuals, charts, etc.) in the use of these high-tech products that have hitherto only been available from professional providers.

Manufacturers and suppliers of home-use light-based therapy devices need to implement a total quality (TQ) approach to ensure that sufficient resources are made available from the design stage through to post-marketing vigilance to ensure that 'best practice' is adopted in this emerging market category. 'Best practice' for manufacturers might be:

1 Incorporate contact switches and/or sensors to ensure full contact with skin and not fired in open air.
2 Warnings against treating eyebrows and to avoid direct exposure to the eye.
3 Warnings against use on the face…(not true for all, but could be used to reduce risk of eye exposure)…
4 Routine use of safety eyewear to lessen glare discomfort (IPL).
5 Routine use of safety eyewear unless the manufacturer can demonstrate compliance with current standards specifying 'exempt group' status for ocular hazard.

Manufacturers should adopt all relevant national and international safety standards, published new standards and recommendations governing light-based therapy devices before adoption into national legislation. 'Best Practice' goes beyond this to include incorporating contact sensors to ensure full contact of devices with skin and not fired in open air and warnings against treating eyebrows and avoiding direct exposure to the eye. Depending on levels of independent safety testing achieved, warnings against use on the face (not applicable for all, but could be used to reduce risk of eye exposure).

Longer-term, manufacturers should work with national and international standards bodies to create a new category for home-use devices, which will define energy and sensor systems needed.

Manufacturers must publish clear technical information about products in their user guides to assist users and clinicians from

whom users may seek advice in making informed choices about treatment and to assist in resolving any adverse incidents.

Epilogue

Evidence-based guidelines on light-based, home-use hair removal devices do not so far exist for this new category. No national, European or international guidelines have been established for the treatment of unwanted body and facial hair.

In the preparation of these guidelines an informal European Consensus Group was built, consisting of members from different countries (Belgium, Denmark, Germany and United Kingdom), organizations (manufacturers, university design and engineering faculty, university hospitals, private hospitals, private clinics and a technical consultancy) specialties (dermatology, toxicology, physics, opto-electronics and non-ionizing radiation safety) and interest groups (standards and professional societies).

Based on the literature available, statements in these guidelines were developed by an expert subgroup of this European Consensus Group consisting of the six authors of these guidelines who consider that this work fulfils the requirements of S2 Guideline status under the German Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF) recognized in the EU. A leading independent toxicologist and a standards specialist undertook external review. These guidelines were unfunded and are therefore independent.

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