THE RECENT RAPID DEVELOPMENT OF THE DIRECTED-ENERGY, HOME-USE DEVICE SECTOR

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Disclosure: G.T. is a consultant of Unilever, Trumball, USA, from whom he received honoraria. Other authors have no conflicts of interest.
Received: 07.07.14 **Accepted:** 19.08.14
Citation: EMJ Dermatol. 2014;2:50-55.

ABSTRACT

This article presents an overview of this exciting new technology category, the development of the industry, and future trends in at-home cutaneous therapy using 'directed energy'. New equipment directed at unwanted hair removal, traditional skin blemishes, and new targets are being developed using novel Class 1C lasers and intense light sources. Other directed energy devices include electromagnetic energy sources beyond those in the visible light and infrared spectrum, such as microwaves, radio frequency, and high frequency focused ultrasound. Both cosmetic and medical applications are being exploited to provide efficacy and specificity of treatment at the consumer-use level. Future applications will combine different directed energy sources to optimise results. Early clinical data following the use of home-use devices (HUDs) is indicative of at least temporary hair reduction and skin improvements, and several safety studies have shown most devices to be safe for consumer use. The HUD category is a new and fast emerging market, worth multimillions of dollars annually, and the emergence of consumer use devices reflects the needs of an ageing, wealthy, and wellness-oriented population. The new miniaturised products and appliances entering the market employing powerful and complex technology do, however, raise some health concerns. Safety standardisation and national regulation, however, seem to be somewhat behind the market development.

Keywords: Home-use device (HUD), quantified self, laser Class 1C, regulatory, standards.

INTRODUCTION

From the safety razor to home waxing and electrolysis kits, the advent of light-based home-use devices (HUDs) marks the latest development in the consumer hair-removal market. But this is just one example of many technology-led developments occurring in the overall HUD category, which is set to boom in the coming years. Other than hair removal technology devices, which are currently the largest group of HUD products, consumers can already choose from anti-ageing, body shaping, cleansing, and anti-acne devices. By definition, cosmetic use of energy-based therapy by consumers is primarily directed at the skin surface where unwanted body and facial hair, acneiform eruptions, age-related wrinkles, sun and wind damage, as well as topographic changes to the skin caused by skin dimpling and excess fat deposits, arise. The high demand for hair removal amongst darker skin types demands a careful evaluation of the risks associated with light therapy in skin with high levels of melanin, and the uncontrolled nature of the consumer market also requires a precise assessment of ocular and dermal hazards associated with the application of HUDs. In the future, multi-functional devices may well become the norm, and HUD designers are also developing solutions to treat medical skin conditions such as eczema and actinic keratosis. Even the potential for diagnostic and 'quantified self' capabilities (daily self-monitoring of body metabolism, skin, nutrition, sleep, calorie consumption, etc.) is well advanced.

HUD INDUSTRY HISTORY

The announcement late last year of Unilever Ventures $25 million investment into a joint venture with Syneron Beauty, marks a turning point in the HUD industry. A brief overview of the historical progress of at-home device companies during the past decade may be seen in Table 1.

A recent Kline & Company report showed 'steady growth' (+20%) in the global HUD market in 2012, taking the total annual value up to $1.3 billion.[1] To put this figure into context, the global skincare market (excluding hygiene) is estimated at $130 billion, so at a mere 1% the potential for HUD growth looks substantial (Figure 1). The US currently tops global HUD sales with a 40% share, followed by Asia (35%) and Europe (15%). A mix of global, regional, and local brands are currently battling for dominance across existing categories, but it is likely that, with the odd exception, the global companies will prevail in the majority of geographies and categories over time. In Asia, for example, Japan currently commands more than two-thirds of market value with the top two brands provided by local companies MTG and Ya-man. China, however, is experiencing exceptional market growth (+100% in 2012), being led by the established global player Nu Skin.

Table 1: Overview of the historical development of home-use energy-based device companies.

Year	Historical Development of Home-Use Energy-Based Device Companies
2003	Palomar, exploiting its professional laser hair removal patent portfolio, signed a $7 million development agreement with Gillette® to build a home-use hair removal device. In 2013, Palomar was acquired by Cynosure, Inc.
2003	Tria Beauty, Inc. It launched its home-use hair removal device in Japan in 2005 and gained FDA clearance in 2008
2003	The medically approved E-One home-use hair removal device was developed by Vincent Brottier in France and launched on French TV in 2007
2006	Dezac Group Ltd. launched its first home-use laser hair removal device in Europe
2006	Home Skinovations Ltd. founded. Silk'n® hair removal system launched
2007	Syneron® Medical Ltd. developed a home-use hair removal device - launched under the 'MeMyElos' brand and signed an 'exclusive' agreement with P&G, aimed at developing home-use skin rejuvenation devices
2008	Philips launched its Lumea hair removal device and the RéAura skin rejuvenation device followed in 2010/11. Philips has since formed a new, dedicated unit (Philips Light & Health) to develop new light-based technology
2008	Radiancy, Inc launched the no!no! 'hot wire' device in 2008. It rapidly became a direct response TV shopping sensation with sales of >5 million units worldwide
2009	Unilever signed a long-term deal with Cynosure, Inc. to develop a home-use wrinkle reduction device
2009	Remington launched its home hair removal system
2009	CyDen Ltd. launched the co-branded Boots SmoothSkin hair removal IPL capturing the attention of P&G and leading to a worldwide exclusive distribution agreement
2011	Photomedex, Inc., a NASDAQ-listed US company, acquired Radiancy, Inc. in a merger that has made Radiancy a global player in this category
2012	Groupe SEB (France) entered the market with a hair removal IPL
2014	Unilever Ventures, Ltd. announced the formation of a joint venture with Syneron, called Iluminage, Inc. All of Syneron's home-use products will be sold through this venture starting with the Skin Smoothing Laser launched in March 2014

NASDAQ: National Association of Securities Dealers Automated Quotation System; P&G: Procter & Gamble; IPL: intense pulsed light.

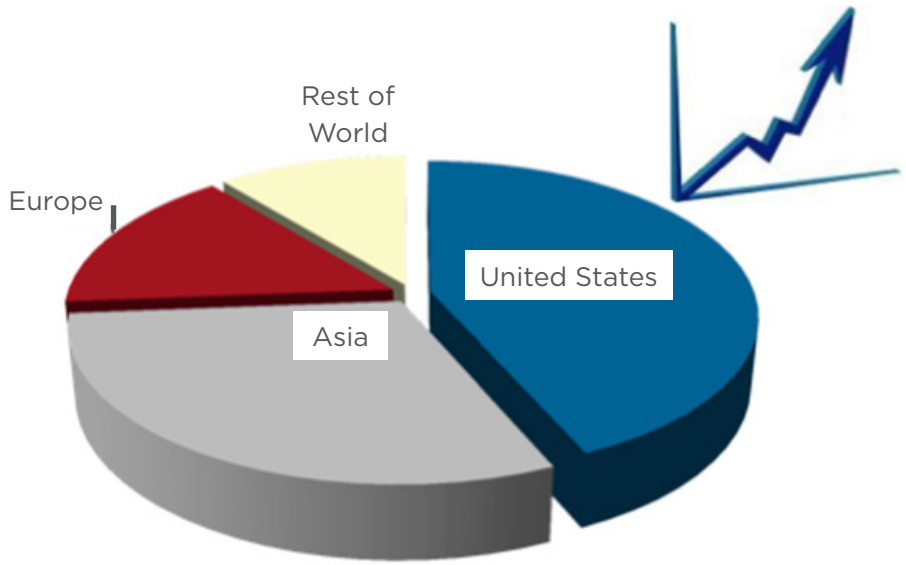

Figure 1: HUD Market Development: the global market for beauty devices showed steady growth in 2012, reaching $1.3 billion, up by over 20%.
Adapted from Kline & Co.[1]

Figure 2: Example home-use, broadband intense-pulsed light hair removal device sold in retail outlets to consumers.
This product includes safety interlocks, to ensure skin contact before energy is released, and an integrated skin tone detector to control output energy (Smooth Skin Gold, Ipulse Ltd., Swansea, UK).

While the overall skincare market continues to achieve solid growth, higher-priced luxury brands are making the largest gains. It therefore seems appropriate for HUD manufacturers to focus on innovation and quality to develop the market while simultaneously establishing efficacy and safety credentials; the latter being the route to long-term success when borne out in practice. Example modern HUDs may be seen in Figures 2 and 3. New product offerings can be expected to be the key market driver for some time, with an almost endless array of aesthetic indications to satisfy. Up and coming trends to follow include: developments for treating specific medical conditions, the emergence of multi-benefit devices, and the opportunity for growth in the male market category. Longer term, 'quantified self', and the fashion aspect of devices are likely to help to sustain growth as brands mature. An effective digital strategy to maintain a direct link with consumers, a large distribution network with a mix of trade presence and web availability, and ultimately professional endorsement, will contribute to retail success.

What do the Professionals say?

Many leading dermatologists with an interest in aesthetics see the rising popularity of HUDs as a valuable 'door opener' to their aesthetic business. Rather than being seen as competing with office-based procedures, the use of HUDs may prove to be a stepping-stone for many consumers to seek medical help when otherwise it would have been a leap too far. What's more, the possibility of HUDs acting as a companion to procedures between visits may help physicians to maintain long-term relationships with patients. However, reasonable concern is being voiced about the lack of specific safety standards and appropriate regulations for HUDs, primarily motivated by the potential risk of eye and skin damage with device misuse.

Figure 3: Example home-use, non-ablative fractional skin rejuvenation laser (1,435 nm) for wrinkle reduction. (RéAura, Philips, Amsterdam, the Netherlands).

The European Society for Laser Dermatology recently published guidelines on the safety of light-based hair removal HUDs, in part to encourage manufacturers to adopt best practices.[2] This interim measure highlights an urgent need for regulators to catch up with market developments and pin down suitable safety standards that apply to the breadth of devices currently available and in development. Once these are in place, the need for sufficient clinical evidence of safety and efficacy will predominate before solid professional endorsement can become a reality.

Clinical Efficacy and Safety

To date, the majority of published clinical studies have focused on hair reduction using low fluence, home-use laser, and intense pulsed light (IPL) devices. Amongst these, the following results have been reported in international, peer reviewed journals:

- Alster and Tanzi[3] reported 40-75% hair reduction over 1, 3, and 6 months in 20 subjects following three consecutive bi-weekly treatments (skin phototypes 1-5) in a supervised self-treated study using <5 J/cm^2 IPL (Silk'n®, Home Skinovations Ltd., Yokneam, Israel).
- Nuijs et al.[4] reported steady state hair reduction percentages of 70% or more on axilla and bikini line and >85% on legs in all skin types using a professional IPL at between 2 and 15 J/cm^2 fluence with a 15 ms pulse duration and a wavelength band 600-950 nm at 2-week intervals. Hair reduction rates were achieved after an initial phase of 4-6 weeks without side-effects, and treatments were scored as perceptible but not painful. Parallel *in vitro* studies revealed a highly localised trauma in the matrix of the anagen follicles leading to a catagen-like transition.
- Wheeland[5] reported hair reduction rates of 40%, 35%, and 33% at 6, 9, and 12 months, respectively, after the third treatment in 77 users of a home-use 810 nm diode laser,[1] in a simulated consumer use study in phototypes 1-4, when applied three times over a 6-week period. Wheeland[6] also described 'permanent' hair reduction at 1 year follow-up in 13 adult subjects (Fitzpatrick Skin Types 1-4) who received 8 monthly treatments at 3 different home-use laser diode fluences of 7, 12, and 20 J/cm^2, with mean percentage hair count reduction rates of 44%, 49%, and 69%, respectively (Tria, Tria Beauty Ltd., Pleasanton, CA, USA).
- Emerson and Town[7] reported mean reduction in terminal hair counts of 41% at 6-month follow-up after completing three sequential weekly treatments in 29 subjects in skin phototypes 1-3 using IPL at 11 J/cm^2 and a pulse duration of 25 ms (Boots Smooth Skin, CyDen Ltd., Swansea, UK).

However, a recent systematic review of published trials of light-based HUDs for hair removal found only seven prospective studies, of which only one was controlled and none were randomised.[8] The data so far indicate that the devices tested provided short-term efficacy but further studies will be required to confirm and extend the results and to establish the incidence of adverse events in selected cohorts of patients. Longer-term surveillance studies will then be required to demonstrate the safety profile of HUDs in real-world use. Manufacturers are strongly motivated to provide safe products in order to make products available to as wide a consumer

base as possible, and to avoid negative press coverage and expensive litigation. To date, several safety studies have appeared in international, peer reviewed journals examining measurement and safety issues.[9-12]

The Regulatory Environment

Since their introduction, manufacturers of home-use lasers and IPL devices have relied upon existing international standards and national regulations covering household electrical appliances to achieve safety compliance. In the absence of specific national regulations, in the European Union this would typically include: compliance with the General Product Safety Directive, Electromagnetic Compatibility legislation, and international standards covering household and similar electrical appliances such as the International Electrotechnical Commission (IEC) 60335 family of standards. In order to obtain FDA marketing clearance for sale in the US for HUDs for over-the-counter sale, some consumer device manufacturers have sought to comply with existing laser and lamp standards as far as they could be reasonably applied. These have included the current IEC 'parent' standard for lasers, 60825-1 and the IEC 60601 family of standards, which were largely formulated for professional medical, dental, diagnostic, and cosmetic electrical equipment.

Embedded Lasers – Class 1C

Home-use laser products have 'accessible emission limits' from 'embedded' lasers that would result ordinarily in laser hazard classifications of Class 3R, 3B, or 4, but because of interlocks and design features, cannot emit hazardous radiation when the product is not in contact with the skin. With no 'free' emission, control measures in current standards do not make much sense. The IEC has therefore defined a new laser category, Class 1C, in its latest revisions to IEC standard 60825-1 Edition 3, '*Safety of laser products - Part 1: Equipment classification and requirements*' (published in May 2014), which may be applied to laser products that are being marketed for skin treatments in the home. The most recent IEC 60825-1 ed3.0: 2014 'parent' standard, whilst specifying the requirements for a Class 1C laser, clearly states that if an applicable IEC ('daughter') standard specifying engineering controls to prevent emission into the surrounding space or to the eye does not exist, then classification to laser Class 1C is not permitted. Typical Class 1C laser products would embrace those intended for home-use hair removal, skin wrinkle reduction, and acne reduction. The IEC has also commenced drafting a vertical standard IEC 60335-2-xx, '*Household and Similar Electrical Appliances – Safety – Part 2-xx Particular requirements for cosmetic and beauty therapy appliances incorporating lasers and intense light sources*,' which incorporates the new laser classification wording contained in IEC 60825-1 ed.3.0: 2014 and provides the necessary design features, engineering controls, interlocks, skin pigment detection, and suitable user instructions to ensure safe use by a consumer.

The invention of the laser Class 1C and acceptance of the definition of Class 1C in the new IEC 60825-1 ed3.0: 2014 opens the market for new products being offered by manufacturers of cosmetic light-based appliances. This seems to make sense since the laser appliances otherwise classified laser Class 3B or 4 would be regarded as being very hazardous to the eyes (which they are not when interlocked) and hence suffer from strong regulation of their usage. In similar cases, such as ultraviolet (UV)-emitting devices, national regulation comes into play in some countries. However, lasers and intense light sources discharging in the visible and infrared spectrum present no risk of cancer as compared with malignancy-provoking UV sources. The worst effect of visible and infrared light is skin burns, which might include blistering and possibly scarring as seen in a number of reported cases following professional laser and IPL treatments. Notwithstanding that other side-effects such as triggering of skin infections, photoallergic reactions, leucotrichia, hair growth induction, photosensitive drug interaction, etc., might arise with HUDs, these are likely to be considerably less common than with professional treatments owing to the built-in limitations on treatable skin phototypes, skin colour sensors, conservative energy settings, small aperture size, comparatively low pulse energy, etc., inherent in HUDs.

Although some adverse event cases that might arise following incorrect or inappropriate use of HUDs may require medical care, most of them will heal over time. Permanent effects may consist of scarring and hyper/hypo-pigmentation. Although this risk seems tolerable, eye injury due to non-functioning of safeguards or due to misuse of the equipment is a serious concern. Apparently, there are only a few reports available about incidents of

any type in the home-use area, although several million units have already been sold. This should not prevent those who are concerned from collecting data and evaluating the true risks.

Regulation Outside the European Union and USA

International efforts continue to develop consistency in regulatory frameworks, and in the EU and the USA regulatory controls usually include a three-tiered approach:

- pre-market assessment, assuring quality and safety for sale;
- in-market monitoring of advertising, claims, and labelling;
- post-market surveillance, to check adverse events and ensure continuing safety in use.

While Australia and New Zealand treat home-use light-based devices in a similar way to other household electrical appliances as in the EU, no clear pattern is seen in most other world markets.

Japanese manufacturers produce significant numbers of home-use lasers and intense light devices which are both exported and actively sold in the domestic market. However, the regulatory position of such devices in Japan is at best ambiguous, with strong opinions expressed by professional interest groups about who should use light-based devices such as lasers, but are not backed by any visible statutory framework or guidelines from government ministries. Despite many anecdotal reports of adverse events in the media and at national medical conferences, between 1999 and 2003 there were only seven complaints to the Consumers' Centre of the Tokyo Metropolitan Government about home laser hair removal devices.

CONCLUSIONS

The HUD category is a new and fast emerging market, worth millions of dollars annually. The emergence of HUDs reflects the needs of an ageing, wealthy, and wellness-oriented population. The new miniaturised products and appliances entering the market employing powerful and complex technology do, however, raise some health concerns. Safety standardisation and national regulation, however, seem to be somewhat behind market development.

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