

Do Home-use Hair Removal Lasers & Intense Light Devices Deliver What They Promise?

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ABSTRACT

Background *In the past two years since their first introduction, there has been a rapid proliferation of light-based hair removal devices intended for home use. In Europe, sales already run into several tens of thousands of units, with multinational companies such as Phillips, Remington and Alliance Boots entering the market.*

Objectives *This study expands on a preliminary study and investigates the technical performance of a wider range of devices tested with particular focus on recognised critical parameters for the safe and effective use of light-based technology in hair removal. The study also catalogues measured values against manufacturers' stated claims and examines likely suitability for different skin types.*

Materials and methods *Previously published standard test methods were used to evaluate the devices tested.*

Results *Some of the devices measured in this study showed significant discrepancies between claims made by the manufacturers and the parameters measured.*

Discussion and conclusions *There is an urgent need for regulation of intense pulsed light devices, which will include manufacturing standards for both professional and home-use hair removal devices.*

Keywords

Home use device, hair removal, optical hazard, spectral output, square pulse

INTRODUCTION

Several leading laser and intense pulsed light (IPL) manufacturers have developed miniaturised systems to meet the needs of the domestic consumer wishing to undertake depilation in the privacy of their own home and at a price cheaper than a professional service. This has required manufacturers to focus on safety measures for home-use devices to limit the risk of accidental injury to the skin and eyes of the user.

The cost reduction needed to bring retail prices into the range of middle class consumers necessarily results in treatments with these systems being slower to use, having smaller spot sizes on tissue and delivering lower power than professional systems.

The lack of any current legislation controlling required performance parameters of non-medical consumer laser and IPL devices has resulted in a number of products being offered for sale without evidence-based data on safety and clinical efficacy. Moreover, the training ethos found in professional clinics has to be mirrored in the adequate provision of information to consumers and safety restrictions to prevent accidents or abuse.

While 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, DVDs and web-based consumer care support are necessary features of the successful marketing of such devices to the general public who are otherwise unaware of the potential implications of solar-induced post-inflammatory hyperpigmentation¹ and the use of some photosensitive drugs and herbal remedies, which can lead to side effects. Professional providers are able to accommodate safely 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 among the general public unable or unwilling to pay for professional treatments.

Although the popularity of laser hair removal has grown rapidly over the past decade, the majority of women are reluctant to try other methods than those used traditionally, such as plucking, shaving, waxing, 'sugaring', chemical depilatory creams, threading and electrolysis.

MATERIALS AND METHODS

The measurement methods used in this study were those reported in previously published studies on the evaluation of professional IPLs² and home-use hair removal devices³. The five key technical parameters being: (i) radiant exposure (fluence); (ii) pulse duration (or sub-pulse durations in a pulse train); (iii) spectral emission; (iv) electrical discharge shape across the xenon lamp and/or time-resolved spectral “footprint” (IPL); and (v) spatial distribution of energy over the device output aperture on tissue. The devices were purchased through distributors or public websites or borrowed from users to ensure normal production quality and performance.

The following general information was recorded and checked in this study:

- Device identity (manufacturer, name, model, serial number, manufacturing date);

- CE classification (eg, medical device or consumer electrical safety) / labeling details;
- Lifetime output claimed in the company literature, web site, user manual, etc;
- Treatment area (dimensions of glass transmission block or output aperture);
- Repetition rate between emission of pulses;
- Details of application technique.

The systems evaluated in this report included: Tria (Tria Beauty Inc, CA, USA), Rio Salon Laser, IPL 8000 (Dezac Ltd, UK), Rio Scanning Laser (Dezac Ltd, UK), iPulse Personal (CyDen Ltd, UK), Silk'n and SensEpil (HomeSkinovations, Yokneam, Israel), Viss (Vissbeauty, Korea), i-Light/LumaSmooth (Remington, USA), Teny Epil Flash (GHT Innovation, France), E-One (E-Swin, France) and Lumea (Philips, Eindhoven, Netherlands).



Fig 1. Home-use hair removal devices measured in this study. From top left: Tria (Tria Beauty Inc, CA, USA), Rio Salon Laser, 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).

DEVICE-RELATED FACTORS AFFECTING TREATMENT EFFICIENCY

Fluence IPL and laser fluence (or more correctly “radiant exposure”) is the amount of light energy delivered per unit area and is measured in Joules per cm². In effective hair removal using lasers and IPL devices, optical energy is absorbed principally by melanin in the hair shaft and hair bulb and converted into thermal energy. The optimum fluence will raise the temperature of the chromophore (melanin) to a level that causes irreversible damage to the hair follicle and adjacent structures but will not produce adverse side effects such as burns or blisters. Too low energy may result in under-treatment and user dissatisfaction and has been associated with stimulation of hair growth⁴.

Pulse duration Although the precise mechanism of hair removal is not fully

understood, with long-pulsed lasers and IPL devices it is thought to be caused by selective thermal damage to the hair follicles. According to Anderson and Parrish, the optimum pulse duration should be less than or equivalent to the thermal relaxation time (TRT) of the target chromophore⁵.

If the pulse duration is considerably shorter than the TRT of the hair follicle, as in the case of Q-Switched Nd:YAG with pulse durations below 50ns, complete regrowth of hair at three months can be expected⁶. If the pulse duration is too long, the heat diffuses to surrounding tissue rendering hair removal ineffective and increasing the risk of adverse side effects⁷. High photon density occurring during short IPL pulse durations at high fluence also increases discomfort for the patient and the risk of collateral tissue damage.

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Spectral footprint (IPLs) The time-resolved spectrum of light delivered throughout the pulse, confirms the biologically effective duration of an IPL pulse during which, the desired wavelengths are delivered in the optimum intensity. The time-resolved spectra were produced in this study using an Ocean Optics HR2000+ spectrometer (Ocean Optics, Dunedin, FL 34698, USA) and its counterpart Spectra Suite software, to provide 3-D visualisation of the pulse structure by time and wavelength distribution⁸.

Spectral emission The optimum wavelengths for the treatment of adult androgenic terminal hair is 590-900nm, which provides both adequate melanin absorption and sufficient penetration into the dermis to achieve selective heating of the hair shaft, hair follicle epithelium and hair matrix including pluripotential stem cells in the region of the bulge at depths of approximately 2-4.75mm⁹. Measurement of the spectral output also provides information on any undesirable wavelengths, such as ultraviolet and infrared radiation, which can present immediate and long-term health risks^{10,11}.

Spatial distribution of energy 'Hot spots' of over-treatment resulting in pain, blisters, crusting or hyperpigmentation, and areas of under-treatment resulting in early hair regrowth or leukotrichia are a common occurrence when reviewing different devices and side-effects after professional IPL depilation^{1,3,12,13}.

Optical alignment, polarity of flashlamps, light transmission materials and surface finishing of the glass medium used to conduct broadband light to the skin surface can all affect homogeneity of energy delivered across a treatment spot on tissue.

For the purposes of this investigation, it was considered adequate to record energy distribution patterns on laser alignment paper (Zap-It Corp., Salisbury, NH 03268, USA) and analyse them using custom software to produce assessable histograms to determine the approximate energy distribution pattern.

TEST RESULTS

Manufacturers' general device information is recorded in Table 1.

Table 2 records radiant exposure (fluence) and wavelength data, both claimed and verified,

showing a significant difference between stated and measured values for the GHT Epil-Flash.

Table 3 shows the variation in stated and confirmed pulse durations as measured by a reversed biased photodiode, spot size, repetition rate and calculated coverage rates per 30cm² (claimed and verified). The different devices show a great variation in the pulse duration to deliver optical radiation for hair removal and widely varying total treatment times.

As a result of the very wide variation in the results recorded for the GHT Epil-Flash versus the manufacturer's claims, a second device was purchased from another vendor and retested. The measured data for the second device was found to be identical to the first.

In notes to the data on Table 3 an explanation is given where the calculated coverage rates per 30cm² are at variance with the coverage rates attained in accordance with the manufacturer's instructions for use.

The spectral distribution graphs confirm the wavelength of the diode lasers and show the cut-on filter position for each of the IPLs. Only the GHT Epil-Flash recorded a significant UV component indicating absence of any effective filtering below 500nm.

Time-resolved 3D spectral images of each IPL permitted a more accurate visual assessment of the "biologically effective" pulse duration. There is a clear contrast between the free discharge devices (HomeSkinovations Silk'n/Sensepil, Philips Satinlux/Lumea and Dezac Rio IPL 8000) and the "managed" discharge systems (iPulse Personal, E-One and i-Light/LumaSmooth).

Spatial profile images confirm that the diode lasers have relatively small treatment areas on tissue and the histograms indicate a poor energy distribution for some of the IPL devices measured.

Safety Features All of the devices tested featured primary optical safety systems including: (i) small mechanical spring switches used to activate the discharge of energy to the user's skin; (ii) switches that make contact when the handpiece is pressed against the user's skin and a trigger button on the rear of the handpiece is depressed simultaneously; (iii) skin-sensitive electrical conductance safety systems comprising contact pins, which all must be in contact with coupling gel and/or

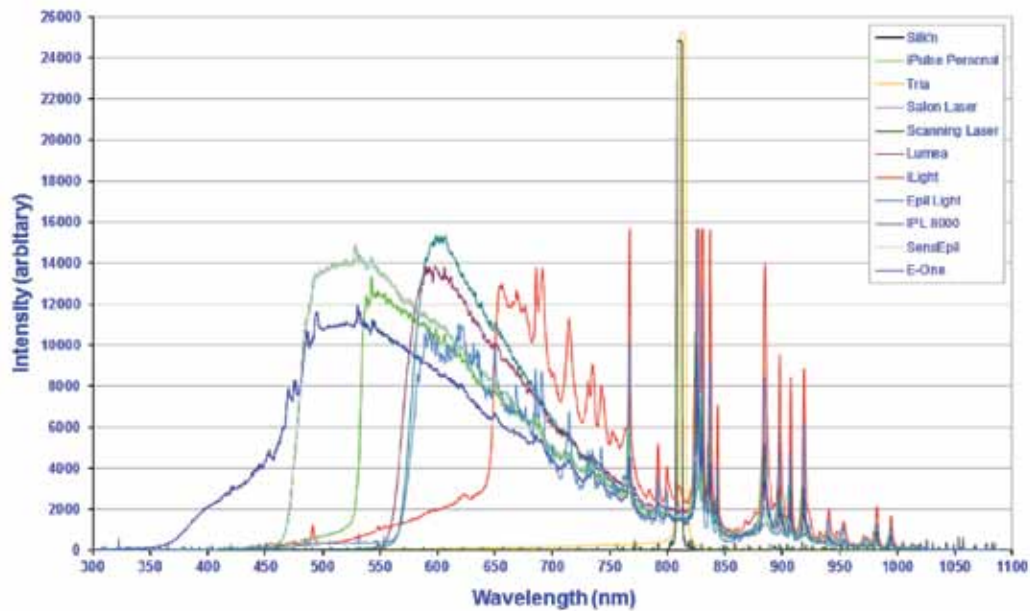


Fig 2. Spectral distribution of tested systems taken at maximum fluence showing the varying degrees of UV filtering by the IPL systems and the spectral position of the monochromatic lasers (810nm).

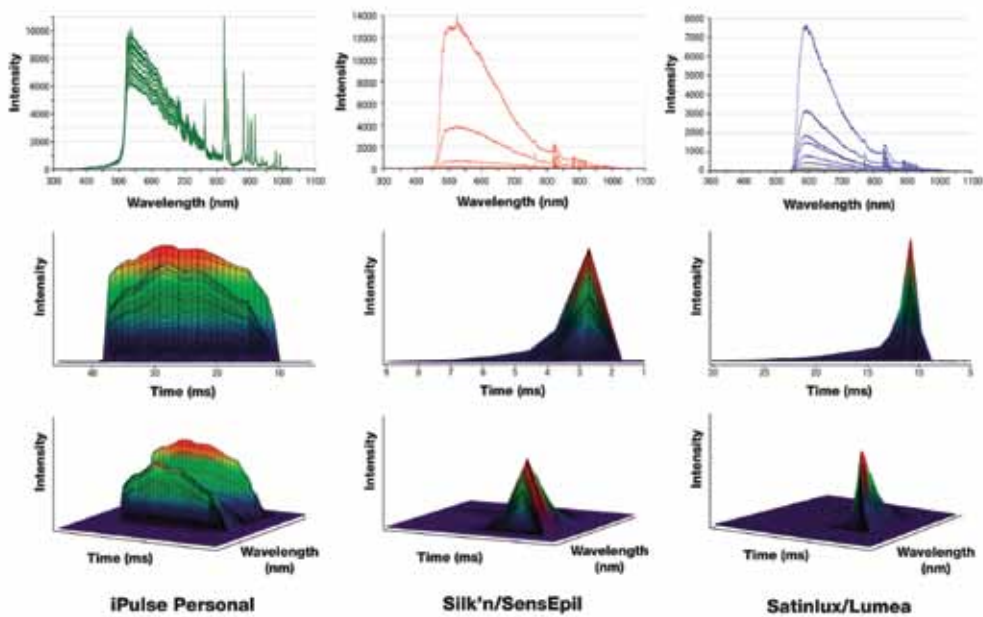


Fig 3. Example of time-resolved spectral footprint images of three IPL systems of 25ms, 3ms and 2ms pulse duration. The Silk'n and Philips devices are free-discharge IPL systems with a correspondingly more marked spectral shift during their short pulse (3).



Fig 4. Spatial profile of measured systems (top left to right: Philips SatinLux Lumea, Dezak Rio IPL8000, HomeSkinovations Silk'n, HomeSkinovations Sensepil, Remington i-Light/LumaSmooth, CyDen iPulse Personal; Bottom left to right: Dezac Rio Scanning Laser Hair Remover, Dezac Rio Laser Hair Remover, Tria Beauty, Tria) showing the diode lasers have relatively small treatment areas and the histograms indicate poor energy distribution for some of the IPL devices.

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skin for the device to be active and discharge energy; (iv) devices which require entry of a security code to activate the system to prevent misuse by children; and (v) an electrical contact system close to the laser aperture, which has to be broken and re-made before each discharge.

Lasers and LEDs should be tested under current international standard IEC 60825-1:2001 to ensure that emissions are below Exposure Limit Values for a Class 1 or Class 1M laser, ie, "eye-safe". In the absence of an internationally recognised standard for intense light sources, manufacturers of home-use IPL devices should test to the national safety standard BS 8497-2:2008 to calculate retinal thermal hazard of IPL devices in the event of failure of skin contact sensors or failure of safety pressure switches designed to prevent accidental emission of optical radiation¹⁴.

All manufacturers of such home-use devices must ensure the Weighted Radiance Values are less than the Exposure Limit Values for retinal thermal hazard. In this study these safety values were only calculated for one of the IPL devices to establish the feasibility of producing a table of Exposure Limit Values and Weighted Radiance Values for each device setting. The Weighted Radiance Values for the CyDen iPulse Personal were found to be below the Exposure Limit Values for all settings. Thus, with this device, there is no requirement for the use of safety eyewear¹⁵.

DISCUSSION

The comparative measurements presented here show all systems to be different in radiant exposure, pulse duration and spectral distribution characteristics. The manufacturers have chosen methods to deliver optical energy from their devices with the intention of disabling hair follicles while producing a profitable and robust product that can be mass produced. While trying to satisfy these parameters, clinical efficacy compared with professional systems may be sacrificed.

Domestic optical hair removal systems operate under the same principle of selective photothermolysis as professional IPL/laser systems with several peer-reviewed articles confirming efficacy¹⁶⁻²⁰. The optical energy of suitable wavelengths is emitted and absorbed by melanin and other chromophores in the

user's skin within a time constant that heats the actively growing hair shaft and hair bulb to temperatures of 65-70°C, causing sufficient damage to the hair follicle and adjacent structures to prevent or delay its regrowth.

The progression of professional hair removal from the clinic or beauty centre into the home for use by the consumer, brings with it a risk of injury to the skin and eyes of consumers through misuse or failing to follow instructions properly. Such risks in clinics and salons are reduced by sufficient training, support and advice from experienced professionals who are also able to screen-out unsuitable individuals or skin types. Evaluation by the authors of the safety mechanisms employed in the devices shows they are not too complex, and simple mechanical switches are sufficient to show the device is in good contact with the skin and reduce the risk of eye exposure, misuse or accidental injury.

All systems are attractively packaged with clear educational material for the customer concerning contraindications to treatment such as too dark skin types, active suntan and contraindicated medications. However, what cannot be so easily accommodated is the inappropriate purchase and use of such devices by darker skin types than those advised by the manufacturer. There is also scope for misjudgment of skin tone when selecting output settings and consequential unpleasant skin reactions caused by excessive radiant exposure for that skin type or under-treatment resulting in poor efficacy in reducing hair and ensuing disappointment for the consumer.

Attempts have been made by some manufacturers, particularly in the USA, to address these problems such as shipping units to customers that then require an activation code from the manufacturer before the device can be used. This gives the manufacturer the chance to attempt to check the user is of the correct skin tone to use the device.

The US FDA has also taken a lead by initially restricting the sale of some home-use light-based hair removal devices to be used under the direction of a physician, after training by a healthcare professional. Moreover, future devices intended for over-the-counter sale to consumers may have to be equipped with skin sensor technology to ensure they cannot

be used on unsuitable dark skin types or on tanned or inappropriate pigmented skin areas.

In the absence of any recognised international standard, the UK national safety standard (BS 8497-2: 2008) should be used by manufacturers to calculate eye hazard of IPL devices in the event of failure of contact or safety pressure switches designed to prevent accidental emission of optical radiation. Until a dedicated standard for home-use lasers and IPL devices is produced, all manufacturers should test self-use products against this standard and ensure the Weighted Radiance Values are less than the Exposure Limit Values for retinal thermal hazard.

The arrival of trusted brands of home-use hair removal laser and IPL devices from multinational consumer companies may expand public awareness and acceptance of aesthetic light-based technologies and lead to an increase in demand for professionally delivered therapy rather than to a decline in clinic-based treatments.

CONCLUSIONS

For optimum hair reduction, the user should choose a device that delivers sufficient energy within each pulse or pulse train that is within the thermal relaxation time (TRT) of the entire terminal hair follicle including stem cells (20-100ms) and that is adequate to achieve histologically evident hair bulb damage or at least prevent any regrowth for an extended period²⁰. Only the iPulse Personal, E-one and the Tria laser had settings that met both of these criteria while the Philips Lumea and Remington i-Light/LumaSmooth only included fluence settings that exceeded the required threshold for permanent photo epilation.

The measured pulse durations and fluence settings of the three devices tested, GHT Epil-Flash (<3ms/max 0.18J/cm²), Vissbeauty, Viss (5-7ms/max 3.64J/cm²) and the Rio Salon/Scanning Laser (3.5ms/max 0.3J/cm²) and Rio IPL8000 (3.5ms/max 3.05 J/cm²) did not meet the criteria as set down by Manstein et al²¹.

The ability to vary the energy density on home-use hair removal devices will better allow the user control and flexibility of treating different Fitzpatrick skin types.

It is clear the design of some of the devices measured for this study have had to compromise product performance with reducing manufacturing costs. Inefficiency of a home-use device may well cause frustration and dissatisfaction to the user, due to long treatment times and greater frequency of use.

While all of the devices included adequate safety features to prevent accidental eye exposure, additional safety measures are needed to ensure that home-use hair removal systems are not used on recently suntanned skin and that treatment is restricted to body areas of the appropriate skin tone.

There is an urgent need for dedicated standards for home-use laser and IPL devices, which could be developed under the IEC 60335 series (Household and similar electrical appliances, Safety – Part 1: General requirements). Meanwhile, home-use lasers should be tested as far as possible to the published IEC 60601-2-22 standard (Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment) and home-use IPL devices should be tested to the draft international IEC 60601-2-57 intense light standard (Medical electrical equipment – Part 2-57: Particular requirements for the safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use), which encompass manufacturing standards. Home-use IPL devices should also be tested to BS 8497-2: 2008 (BS 8497-2: 2008 Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical application. Part 2: Guidance on use.) to ensure eye safety.

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DISCLOSURES

Godfrey Town is a PhD student at the University of Wales and receives consultancy fees and travel grants from CyDen Ltd, Swansea, SA1 8PH, UK and Unilever, Trumbull, CT 06611, USA.

Caerwyn Ash, is a PhD Graduate at University of Wales and receives travel grants from the university. He also receives salary from Cyden Ltd, Swansea, SA1 8PH, UK and has a minor stock holding in the company.

Device	Manufacturer	Safety Feature	Clinical Data	Number of Shots	Time to Recharge	Treat on face
TRIA Laser	Triia Beauty	YES	R. Wheeland, <i>Lasers Surg Med</i> 2007	>250	2-8 hrs	No
Salon Scanning Laser	Rio	YES	None Published	n/a	n/a	Yes
SatinLux / Lumea IPL	Philips	YES	Nuijs et al, <i>Lasers Surg Med</i> 2008	160-520	3 hrs	Yes
Silk'n / SensEpil IPL	Home Skinovations	YES	Alster & Tanzi, <i>Dermatol Surg</i> 2009	750	n/a	No
iPulse Personal IPL	CyDen	YES	Emerson & Town, <i>J. Cos Laser Ther</i> 2009	10,000	n/a	Yes
Epil-Flash IPL	GHT	YES	None Published	20,000	n/a	Yes
IPL 8000 (2011 model)	Rio	YES	None Published	ad 40,000	n/a	No
i-Light / LumaSmooth IPL	Remington	YES	None Published	1,500	n/a	No
E-One IPL	E-Swin	YES	None Published	3,000	n/a	Yes
Viss IPL	Vissbeauty	YES	None Published	4,000	n/a	No

Table 1: Table records general information about the home-use hair removal devices evaluated.

Device Manufacturer	Fluence (Radiant Exposure)		Wavelength (Cut-on filter)	
	Claimed (J/cm ²)	Measured (J/cm ²)	Claimed (nm)	Measured (nm)
TRIA Laser Tria Beauty	13-22	4.9-18.8	810	810
Salon Scanning Laser Rio	Not Stated	0.02 - 0.15	810	810
SatinLux / Lumea IPL Philips	2 - 6.5	2.5 - 6.8	575	575
Silk'n / SensEpil IPL Home Skinovations	< 5	2.8 - 4.2	475	475
iPulse Personal IPL CyDen	7.0 - 10.0	7.1 - 9.98	530	530
Epil-Flash IPL GHT	20	0.18	600	465
IPL 8000 Rio	Not given	1.3 - 3.05	Not given	575
i-Light / LumaSmooth IPL Remington	Not given	7.18 - 8.52	Not given	645
E-One IPL E-Swin	Not given	9.5 - 12.7	575	575
Viss IPL Vissbeauty	23 Joules	2.5 - 3.64	530	495

Table 2: Table records manufacturers' device information with fluence and wavelength data, both claimed and verified showing a significant difference between stated and measured values for the GHT Epil-Flash.

Device Manufacturer	Pulse Duration Claimed (ms)	Pulse Duration Measured (ms)	Spot Size (cm ²)	Rep Rate (sec)	Coverage Rate Sec/30cm ²
TRIA Tria Beauty	1. 300 ms	330 ms	0.793 cm ² (1 cm dia)	2.26	171 ^x
	2. 400 ms	210 ms		2.12	160
	3. 600 ms	345 ms		2.24	169
Salon Laser Rio	1. Not given	6 Pulses of 100 ms, 600 ms off	0.0019 cm ²	6.32	1264 (assumes 200 hairs per 30cm ²)
	2. Not given	4 Pulses of 500 ms, 600 ms off		6.37	1274 (assumes 200 hairs per 30cm ²)
	3. Not given	3 Pulses 1 s on, 600 ms off, 1 s on, 600 ms off, 0.8 s on		6.45	1290 (assumes 200 hairs per 30cm ²)
	4. Not given	2 Pulses 2.5 s on, 600 ms off, 0.9 s on		6.47	1294 (assumes 200 hairs per 30cm ²)
	5. Not given	1 Pulse 3.45 s on		6.32	1264 (assumes 200 hairs per 30cm ²)
Lumea Philips	1. Not given	<7 ms	3.0 cm ² (30 x 10 mm)	1.86	19
	2. Not given	<7 ms		2.54	25
	3. Not given	<7 ms		3.27	33
	4. Not given	<7 ms		4.25	43
	5. Not given	<7 ms		4.42	44
Silk'n / SensEpil IPL Home Skinovations	1. Not given	5.05 ms	6.0 cm ² (30 x 20 mm)	3.96	20
	2. Not given	5.05 ms		4.12	21
	3. Not given	5.01 ms		4.23	21
	4. Not given	5.01 ms		4.06	20
	5. Not given	5.01 ms		4.10	21
iPulse Personal CyDen	Fair: 25 ms	25 ms	3.0 cm ² (12 x 25 mm)	6.00	60
	Medium: 40 ms	40 ms		6.00	60
	Dark: 60 ms	62.5 ms		6.00	60
Epil-Flash GHT	1. 24 ms	1.6 ms	2.64 cm ² (8 x 33 mm)	6.90	157
	2. 33 ms	3.0 ms		8.30	189
Salon Scanning Laser Rio	1. Not given	9 seconds in duration	0.35 cm ² (7 x 5 mm)	9.00	771
	2. Not given	19 seconds in duration		19.00	1629
	3. Not given	29 seconds in duration		29.00	2486
	4. Not given	37 seconds in duration		37.00	3171
	5. Not given	46 seconds in duration		46.00	3943
IPL 8000 Rio	1. Not given	3.5 ms	4.69 cm ² (13.6 x 34.5 mm)	5.21	33
	2. Not given	3.5 ms		5.21	33
	3. Not given	3.5 ms		5.21	33
	4. Not given	3.5 ms		5.26	34
	5. Not given	3.5 ms		5.27	34
i-Light / LumaSmooth IPL Remington	1. Not given	Triple Pulse 7.5 ms on, 2.5 ms off	2 cm ² (10 x 20 mm)	2.31	35
	2. Not given	Triple Pulse 7.5 ms on, 2.5 ms off		2.31	35
	3. Not given	Triple Pulse 7.5 ms on, 2.5 ms off		2.32	35
	4. Not given	Triple Pulse 7.5 ms on, 2.5 ms off		2.31	35
	5. Not given	Triple Pulse 7.5 ms on, 2.5 ms off		2.31	35
E-One IPL E-Swin	Not given	30 ms	6.0 cm ² (30 x 20 mm)	6.35	31
Viss IPL Vissbeauty	1. Not given	5 - 7.5 ms	6.0 cm ² (30 x 20 cm)	2.86	143
	2. Not given			3.15	157.5
	3. Not given			3.33	166.4
	4. Not given			3.51	175.6
	5. Not given			3.64	181.0
	6. Not given			3.76	187.8
	7. Not given			3.93	196.5
	8. Not given			4.12	206
StarLux Palomar	Typical	20-40 ms (typical)	7.47 cm ² (16.2 x 46.1 mm)	8.60	35

Table 3: Table shows the variation in stated and measured pulse duration as verified by a reversed biased photodiode, spot size, repetition rate and calculated coverage rates per cm² (claimed and measured). The different devices show a great variation in the pulse duration to deliver optical radiation for hair removal and widely varying total treatment times.

* 12.2 sec/cm² using recommendations in Instructions for Use (pages 40-44).