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FEATURE ARTICLE

CE Marking of Lasers & IPLS

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Introduction

This article is concerned with laser equipment and intense pulsed light (IPL) equipment. Treatment modalities for such equipment range from major surgical interventions such as laser lipolysis (laser fat reduction), through laser skin resurfacing, to “minimally invasive” procedures such as IPL hair reduction. In this review we are concentrating on the equipment itself, rather than issues of how the service is provided - such as who is allowed to use the laser or IPL, with what level of training, and in what type of premises etc.

In particular we are looking at the process of the equipment being granted a CE mark, which stands for “Conformité Européenne”. In order to be legally sold in Europe lasers must be CE marked. The same applies to IPL equipment. The granting of a CE mark is dependent on the equipment meeting the relevant European Directive(s). For lasers and IPLs designed for "medical use", one of the Directives that needs to be met is the Medical Devices Directive, “MDD”.

But what if the devices are only being marketed for "aesthetic use"? That is the main subject of this article, and is based on our practical experience over many years as certificated Laser Protection Advisers. We expect that many readers of the Consulting Room Newsletters will already be aware of much of what we have to say, and / or they will have in any case bought their equipment from reputable suppliers who are fully conversant with the necessary requirements. We certainly don't wish to point the finger at any particular manufacturer or Test House. Rather we would like to share some of our experiences and pose a few questions.

Overview of laser and IPL treatment modalities

Knowledge of light interaction with human tissue provides an explanation for observed therapeutic efficacy and treatment related side effects in the fields of surgery and dermatology and applies equally to the action of lasers and intense light sources in purely cosmetic applications. Understanding the biological effect of light penetration or transfer of optical radiation within skin, its location and the absorption depth of optical radiation in tissue is strongly dependent on the wavelength of the light and is important in the development of new therapies.

Absorption of light in tissue is strongly wavelength dependent and absorbing molecules, called chromophores, absorb in different wavelength regions. In order for light to produce any biological effect in skin it must first be absorbed, where transformation of radiant 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 optical radiation: 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 injury to the surrounding tissue.

For example, in the case of a terminal hair follicle, irradiative energy is absorbed selectively by the melanin-rich hair shaft and surrounding follicular matrix. The temperature of the chromophore increases and thermally-induced biological changes take place to damage or destroy the follicle and adjacent cellular structures and induce a change in normal hair cycling i.e. telogen induction / hair regrowth inhibition.

European and international standards bodies

One of the standards that we talk about in this article is EN 60602-1-22 the medical laser product standard. This standard is published in Europe by CENELEC, the European Committee for Electrotechnical Standardization. Much of the actual technical work in producing such standards is however done at a "higher" (international) level, by the IEC, the International Electrotechnical Commission. Another standard that we will talk about, the medical standard covering IPLs, EN 60601-2-57 has also come via the same route, i.e. IEC did most of the drafting of the standard, with CENELEC publishing it in Europe.

At the international level a parallel organization to the IEC is ISO, the International Organization for Standardization. In Europe ISO standards are published by CEN, the European Committee for Standardisation. The main ISO / CEN standard that we will mention later on in this article is the EN 207 laser eyewear product standard. It might seem a little confusing that the eyewear product standard has come via the ISO / CEN route, whereas the laser product standard itself has come via the IEC / CENELEC route. The reasoning, in the case of those two standards anyway, is that lasers are "electronic" in nature, and are therefore the responsibility of the IEC and CENELEC (note the word "electrotechnical" in each acronym); whereas the optical filters fitted in laser safety eyewear (being of a "non-electronic" form) are the responsibility of ISO and CEN.

Another ISO standard that we mention in this article is the well-known ISO 9001 standard, which deals with quality management. It should be noted however that this standard is of very general applicability, being relevant to more or less any product at all, whereas e.g. the EN 60601-2-22 and EN 207 standards are very specific to lasers and laser eyewear respectively.

Lasers and IPLs for "medical use"

We now consider in more detail the specific testing and CE marking requirements for medical lasers. The way a Test House (or to use a more formal term the "Notified Body") will actually check that a laser meets the MDD is by running suitable tests on the equipment, as well as looking at the user guide, labelling and so on. However the MDD - like most Directives - is written in legalese, whereas Test Houses generally need something rather more technical. So the Test Houses will usually base their tests on the relevant European Standards, or ENs - European Norms as they are called.

The ENs are written by engineers and clinical experts, and are much more amenable to being translated into practical tests and inspections that the Test Houses can then carry out. But still the legal requirement is that it is the Directive that must be met whilst the ENs themselves are, in a sense, "not mandatory". However, for all practical purposes, and via a process known as "Presumption of Conformity", if a laser meets the relevant ENs then it is presumed to thereby meet the applicable Directive, in this case the MDD.

A key standard for medical lasers is EN 60601-2-22, entitled, "Medical electrical equipment. Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment". An important aspect of EN 60601-2-22 is that it is "harmonised" with the MDD. This means that if a Test House tests a laser against the requirements of EN 60601-2-22, and the tests are passed, then by the process of Presumption of Conformity the equipment can be deemed to have satisfied the related parts of the MDD.

So there is a lot that the equipment manufacturers need to consider, and it is also best that prospective buyers and users of such equipment have some insight into the process whereby CE marking of the equipment is granted.

Lasers and IPLs for "aesthetic use"

Thus far we have mainly considered lasers (and IPLs) that are being marketed specifically for "medical use". To some extent though, the dividing line between medical and aesthetic use isn't really all that clear. For example some lasers and IPLs can be used for acne treatment, which a lot of beauty salons in the UK are offering. It is difficult to see acne treatment as being always purely aesthetic. Similarly, cosmetic hair reduction treatment provided by IPLs can be used in the medical treatment of unwanted hair such as for patients suffering from polycystic ovarian syndrome, hirsutism connected with conditions such as ingrowing hair in the natal cleft requiring surgical intervention, pseudofolliculitis barabae (folliculitis affecting the beard area caused by ingrown facial hair), unwanted hair growing on surgical skin grafts, etc.

At present there is therefore something of an issue with lasers and IPLs which are marketed solely for "aesthetic use". Manufacturers could in principle claim that, because such devices are only for aesthetic treatments, they don't need to meet the requirements of the MDD. This matter is being looked at as part of an overall review of medical device regulation throughout Europe. It may however be several years before that review is completed, and obviously the results cannot be predicted. (In the meantime the authors of this article have made their concerns known to the MHRA). At the end of the day what will matter is the law in individual sovereign states, and that is indeed a complex matter.

For now the authors of this present article would just like to give a couple of examples which we feel are representative of some of our concerns in this area, from a purely technical and engineering viewpoint. We have mentioned the laser product standard EN 60601-2-22, which as we have said is harmonised with the MDD. There is another standard however, one might say the equivalent standard, for IPLs - although in its full detail it actually covers other non-laser intense light sources as well, such as LED arrays used in photodynamic therapy, post cosmetic laser surgery wound healing and in skin rejuvenation. This standard is EN 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". Note the words "cosmetic / aesthetic use" in the title even though strictly speaking the Part 2-57 standard (being part of the overall IEC 60601 medical series of standards) is for "Medical electrical equipment".

Now suppose a manufacturer of an IPL markets their device as being purely for aesthetic use, and thereby claims exemption from the need to comply with the MDD. Imagine in particular the device isn't tested against the requirements of EN 60601-2-57. Many concerns would arise from this from an engineering point of view. The particular (and rather straightforward) example we have in mind is to do with the avoidance of hotspots over the treatment area on the skin. EN 60601-2-57 has specific requirements on this "output uniformity" issue. We would expect that reputable manufacturers will have built all of their current IPL range to comply with every relevant requirement in the EN 60601-2-57 standard, even if the IPL is being marketed solely for aesthetic use. But if a manufacturer hasn't taken such an approach, the question might be asked: where precisely will they have taken their design and manufacturing requirements from, and what will the Test House use as a basis for its tests?

We would therefore advise people considering buying lasers or IPLs to check precisely which standards the equipment has been tested against, and in particular that compliance with the MDD is not being claimed solely on the basis e.g. of the (very generic) ISO 9001 standard. From a legal and ethical point of view there should be a completely level playing field with regard to the testing and certification of products. But of course Test Houses - like any commercial organization - have to compete on the open market, providing CE testing and marking services to their customers, i.e. the laser and IPL manufacturers. Nevertheless, it is the primary responsibility of the manufacturer to comply with those standards for those applications for which their device is intended.

In Wales and Northern Ireland the use of specific technology including Class 3B or Class 4 lasers as described in British Standard EN 60825-1 and intense light is defined in regulations so the devices themselves must comply with the relevant medical device standards. Where other specific unitary regulation exists, such as under the Special Treatments Licensing provisions of the London Local Authorities Act 1991, establishments seeking a licence in London boroughs must use laser and IPL equipment that meets the British Standards EN 60601-2-22 for lasers and EN 60601-2-57 for intense light devices.

It's all in the detail

The specific issue of hotspots that we have mentioned above is just a single example, of which many more could probably be quoted, both for IPLs and also for lasers. In this article we are not claiming or even attempting to give a full list of such issues. We just want to give some anecdotal examples of why we have some concerns. In many ways "it's all in the detail", and that is why it is so important that these products are only granted CE marking after thorough evaluation and testing. It is sometimes difficult to put one's finger on a specific issue in advance and say - that will cause a problem. Sometimes (the IPL hotspot issue mentioned above excepted, because it is clearly a potential issue it its own right) problems may arise as a result of a combination of issues.

Take for example tattoo removal lasers. As readers will be aware these lasers typically need to be of the "Q-switched" type, which means that they work by emitting extremely short pulses - usually in the nanosecond region. Even though the amount of optical energy each such pulse delivers is not great, the energy is delivered so quickly that the effect on the skin (or more specifically on the tattoo dye pigment) is that it effectively shatters the dye molecules. Phrased more technically this is a photo acoustic effect, which causes a shock wave in the dye.

Anyone who has seen the effect that such a pulse has on tattooed skin will know that it is by no means a trivial treatment modality! But of course the skin will heal, provided the power (and the wavelength) were chosen correctly. Generally speaking it is indeed skin hazards that we are most concerned about in aesthetic laser treatments, because it is the skin that is intentionally being exposing - to sometimes very high levels of optical power. But of course we also have a big concern about (inadvertent) eye exposure. Now it might seem rather obvious to point out that one shouldn't get one's eye in the way of the type of laser beam we have just been talking about, or indeed any laser beam. But what is perhaps not so obvious is that such beams are often also a hazard even at some considerable distance from the laser aperture. This distance is technically known as the NOHD, the nominal ocular hazard distance. For the type of lasers used in tattoo removal the NOHD can be tens of metres, e.g. 20 or 30 metres or more. Hence there is a need for suitable laser blocking blinds on any treatment room windows. The laser standards say that the manufacturer should indicate what the NOHD is in the supporting documentation. Does your user manual provide this information?

Within the treatment room great care must be taken in the selection and use of appropriate protective eyewear, be it of the occlusive / total blocking type (e.g. eye caps made of alloy), or the spectacle type. In the latter case the filters need to be CE marked according to EN 207. The title of EN 207 is: "Personal eye-protection equipment. Filters and eye-protectors against laser radiation (laser eye-protectors)". But many times the authors of this article have seen

filters that are only marked (in accordance with the US standards) with their OD, i.e. optical density, not the scale numbers mandated (in Europe) by EN 207. Sometimes clinics might have a mix of laser safety glasses and IPL safety glasses on site. But it must be recognised that IPL filters are manufactured to a different standard to the EN 207 laser standard and cannot be considered suitable for protection against laser radiation. And conversely, laser safety glasses cannot be considered suitable for protection against IPL beams. And so it goes on . . .

The end result is that, if all these things (and many more) are not carefully taken into account, then the patient is seriously at risk, of both skin and eye injury. Also the clinician is at risk, primarily of eye injury. And even (due to the large hazard distance of some lasers) members of the public outside the treatment room may also be at risk of eye injury.

Disclaimer: The views expressed in this article are the personal views of the authors, and do not necessarily represent the position of any of the organisations referred to either directly or indirectly, e.g. BSI, CEN, CENELEC, IEC, ISO, MHRA etc. Address for correspondence: ***info@bla-online.co.uk***

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Dr Godfrey Town Ph.D. is a clinical technologist and scientist specialising in the comparative measurement of IPL and laser devices. He is a regular invited speaker at international aesthetic laser meetings and has published numerous scientific and clinical papers in international peer-reviewed journals on the use of laser and intense pulsed light (IPL) devices. Godfrey was awarded his Ph.D. for original research in light-based skin therapy as an Innovation Scholar at The Global Academy, University of Wales Trinity Saint David, Swansea, UK.

He holds a Certificate of Competence in the fields of Medical and Research issued by the Board of RPA2000 an Assessing Body recognised by the UK Health & Safety Executive (Certificate No: L00101), is a registered clinical technologist and provides consultancy services to several laser and IPL manufacturers.

He has authored comprehensive Laser Hair Removal & Skin Rejuvenation training manuals and book chapters and has directly assisted in the staff training and commissioning of numerous laser skin care clinics. His technical knowledge is supported by over five years' practical experience as an owner-manager of a successful UK private laser & IPL clinic.

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Mike Regan is a joint Director of Bioptica Laser Aesthetics Ltd. His work involves carrying out practical laser / IPL risk assessments and providing Local Rules for aesthetic clinics and salons, and presenting Core of Knowledge training in accordance with the Department of Health MHRA DB2008(03) Syllabus. Mike also provides safety consultancy to laser and IPL manufacturers.

He holds the position of Chair to the Association of Laser Safety Professionals, and has been actively involved in the national and international laser safety standards sector since 2001. Mike is also Chair to the BSI CH403 Committee: "*Aesthetic surgery & non-surgical medical services*". The CH403 committee, and its parent European organisation CEN TC403, have the truly vast aim of producing new pan European Standards seeking to improve the safety and quality of aesthetic healthcare services across all CEN Member States. He was recognised with a BSI Leadership Award for his outstanding work guiding the production of the standard on aesthetic surgical services at an award ceremony at the end of 2015. In addition, Mike serves as an Adviser to The Consulting Room and is also on the Save Face Advisory Board.

Mike has in depth technical knowledge and experience of laser and IPL safety as it applies to the medical / cosmetic sector. In addition, he has a firm grasp of the principles of a wide range of other laser safety applications as well, enabling him to take a wide perspective when presented with problems and issues as they arise.