(51) International Patent Classification 6 :		(11) International Publication Number:	**WO 99/32193**
A61N 5/06	**A1**	(43) International Publication Date:	1 July 1999 (01.07.99)

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(54) Title: APPARATUS FOR THERAPEUTIC ELECTROMAGNETIC TREATMENT
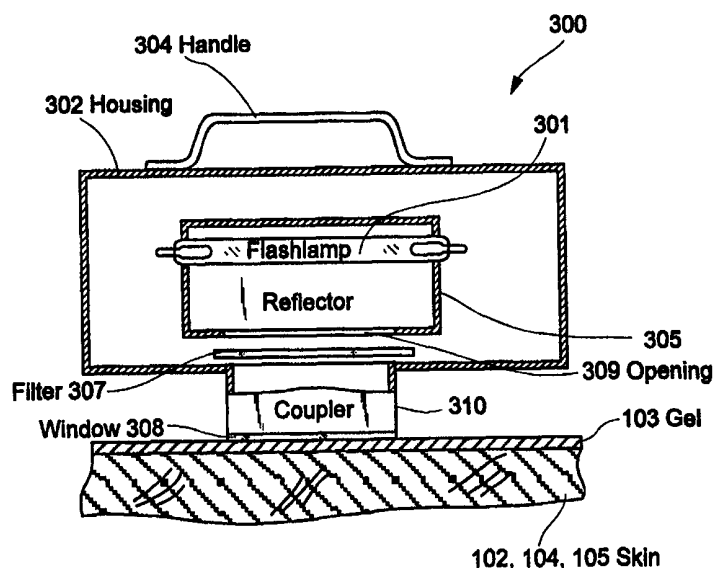
(57) Abstract

This invention is a combined therapeutic treatment apparatus for coagulating blood in blood vessels underlying a skin treatment site, and for the destruction of hair follicles at the skin treatment site. The combined apparatus includes a first device (10) including an incoherent light source (14) operable to provide a pulsed light output onto the treatment site, a driver circuit (121) including a switch (GTO1) capable of being electrically turned on and off to thereby provide a first interval of light connected to the light source to control the pulse width, and delay between pulses. The combined apparatus includes a second device (300) including a coherent radiation source (301) adapted to emit radiation at a wavelength between 800 nanometer and 1,200 nanometers over an irradiation time between 1 millisecond and 100 milliseconds, to provide a cumulative treatment dose of between 10 Joules and 200 Joules per square centimeter of radiation, as measured at the treatment site.

APPARATUS FOR THERAPEUTIC ELECTROMAGNETIC TREATMENT

FIELD AND BACKGROUND OF THE INVENTION

5   The present invention relates generally to the art of therapeutic electromagnetic treatment and more particularly to a combined apparatus for (i) utilizing a spatially extended pulsed light source such as a flashlamp (flash tube) for such a treatment and for (ii) irradiating for such a treatment with long pulses of radiation from a Nd: YAG laser.

10   It is known in the prior art to use electromagnetic radiation in medical application for therapeutic uses such as treatment of skin disorders. For example, U.S. Pat. No. 4,298,005 to Mutzhas describes a continuous ultraviolet lamp with cosmetic, photobiological, and photochemical applications. A treatment based on using the UV portion of the spectrum

15   and its photochemical interaction with the skin is described. The power delivered to the skin using Mutzhas' lamp is described as 150 W/m^2, which does not have a significant effect on skin temperature.

In addition to prior art treatment involving UV light, lasers have been used for dermatological procedures, including Argon lasers, CO_2 lasers,

20   Nd(Yag) lasers, Copper vapor lasers, ruby lasers and dye lasers. For example, U.S. Pat. No. 4,829,262 to Furumoto, describes a method of constructing a dye laser used in dermatology applications. Two skin conditions which may be treated by laser radiation are external skin irregularities such as local differences in the pigmentation or structure of the

25   skin, and vascular disorders lying deeper under the skin which cause a variety of skin abnormalities including port wine stains, telangiectasias, leg veins and cherry and spider angiomas. Laser treatment of these skin disorders generally includes localized heating of the treatment area by absorption of laser radiation. Heating the skin changes or corrects the skin

30   disorder and causes the full or partial disappearance of the skin abnormality.

Certain external disorders such as pigmented lesions can also be treated by heating the skin very fast to a high enough temperature to evaporate parts of the skin. Deeper-lying vascular disorders are more typically treated by heating the blood to a high enough temperature to cause

35   it to coagulate. The disorder will then eventually disappear. To control the treatment depth, a pulsed radiation source is often used. The depth the heat penetrates in the blood vessel is controlled by controlling the pulse width of the radiation source. The absorption and scattering coefficients of the skin

also affect the heat penetration. These coefficients are a function of the constituents of skin and the wavelength of the radiation. Specifically, the absorption coefficient of light in the epidermis and dermis tends to be a slowly varying, monotonically decreasing function of wavelength. Thus, the wavelength of the light should be chosen so that the absorption coefficient is optimized for the particular skin condition and vessel size being treated.

The effectiveness of lasers for applications such as tattoo removal and removal of birth and age marks is diminished because lasers are monochromatic. A laser of a given wavelength may be effectively used to treat a first type of skin pigmentation disorder, but, if the specific wavelength of the laser is not absorbed efficiently by skin having a second type of disorder, it will be ineffective for the second type of skin disorder. Also, lasers are usually complicated, expensive to manufacture, large for the amount of power delivered, unreliable and difficult to maintain.

The wavelength of the light also affects vascular disorder treatment because blood content in the vicinity of the vascular disorders varies, and blood content affects the absorption coefficient of the treatment area. Oxyhemoglobin is the main chromophore which controls the optical properties of blood and has strong absorption bands in the visible range. More particularly, the strongest absorption peak of oxyhemoglobin occurs at 418 nm and has a band-width of 60 nm. Two additional absorption peaks with lower absorption coefficients occur at 542 and 577 nm. The total band-width of these two peaks is on the order of 100 nm.

Additionally, light in the wavelength range of 500 to 600 nm is desirable for the treatment of blood vessel disorders of the skin since it is absorbed by the blood and penetrates through the skin. Longer wavelengths up to 1,000 nm are also effective since they can penetrate deeper into the skin, heat the surrounding tissue and, if the pulse-width is long enough, contribute to heating the blood vessel by thermal conductivity. Also, longer wavelengths are effective for treatment of larger diameter vessels because the lower absorption coefficient is compensated for by the longer path of light in the vessel.

Accordingly, a wide band electromagnetic radiation source that covers the near UV and the visible portion of the spectrum would be desirable for treatment of external skin and vascular disorders. The overall range of wavelengths of the light source should be sufficient to optimize treatment for any of a number of applications. Such a therapeutic

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electromagnetic radiation device should also be capable of providing an optimal wavelength range within the overall range for the specific disorder being treated. The intensity of the light should be sufficient to cause the required thermal effect by raising the temperature of the treatment area to the required temperature. Also, the pulse-width should be variable over a wide enough range so as to achieve the optimal penetration depth for each application. Therefore, it is desirable to provide a light source having a wide range of wavelengths, which can be selected according to the required skin treatment, with a controlled pulse-width and a high enough energy density for application to the affected area.

Pulsed non-laser type light sources such as linear flashlamps provide these benefits. The intensity of the emitted light can be made high enough to achieve the required thermal effects. The pulse-width can be varied over a wide range so that control of thermal depth penetration can be accomplished. The typical spectrum covers the visible and ultraviolet range and the optical bands most effective for specific applications can be selected, or enhanced using fluorescent materials. Moreover, non-laser type light sources such as flashlamps are much simpler and easier to manufacture than lasers, are significantly less expensive for the same output power and have the potential of being more efficient and more reliable. They have a wide spectral range that can be optimized for a variety of specific skin treatment applications. These sources also have a pulse length that can be varied over a wide range which is critical for the different types of skin treatments.

Although the above lists various shortcomings of laser systems with respect to treatment of vascular disorders lying deeper under the skin which cause a variety of skin abnormalities, for many such applications it is herein reported to have high effectiveness.

Hair can be removed permanently for cosmetic reasons by various methods, for example by heating the hair and the hair follicle to a high enough temperature that results in their coagulation. It is known that blood is coagulated when heated to temperatures of the order of 70 °C. Similarly, heating of the epidermis, the hair and the hair follicle to temperatures of the same order of magnitude will also cause their coagulation and will result in permanent removal of the hair.

One common method of hair removal, often called electrolysis, is based on the use of "electric needles" that are applied to each individual hair. An electrical current is applied to each hair through the needle. The

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current heats the hair, causes its carbonization and also causes coagulation of the tissue next to the hair and some coagulation of the micro-vessels that feed the hair follicle.

While the electrical needle method can remove hair permanently or
5   long term, its use is practically limited because the treatment is painful and the procedure is generally tedious and lengthy.

Light can also be used effectively to remove hair. For example, other prior art methods of hair removal involve the application of pulsed light, generally from coherent sources such as lasers. R. A. Harte, et al., in U.S.
10   Pat. No. 3,693,623, and C. Block, in U.S. Pat. No. 3,834,391, teach to remove hair by coagulating single hair with a light coupled to the individual hair by an optical fiber at the immediate vicinity of the hair.

Similarly, R. G. Meyer, in U.S. Pat. No. 3,538,919, removes hair on a hair by hair basis using energy from a pulsed laser. Similar inventions using
15   small fibers are described in U.S. Pat. Nos. 4,388,924 to H. Weissman, et al. and 4,617,926 to A. Sutton. Each of these teach to remove hair one hair at a time, and are thus slow and tedious.

U.S. Pat. No. 5,226,907, to N. Tankovich, describes a hair removal method based on the use of a material that coats the hair and hair follicle.
20   The coating material enhances absorption of energy by the follicles, either by matching the frequency of a light source to the absorption frequency of the material, or by photochemical reaction. In either case the light source is a laser. One deficiency of such a method and apparatus is that lasers can be expensive and subject to stringent regulations. Additionally, the coating
25   material must be applied only to the hair follicles, to insure proper hair removal and to prevent damage of other tissue.

Light (electromagnetic) energy used to remove hair must have a fluence such that sufficient energy will be absorbed by the hair and the hair follicle to raise the temperature to the desired value. However, if the light is
30   applied to the surface of the skin other than at the precise location of a hair follicle, the light will also heat the skin to coagulation temperature and induce a burn in the skin.

Accordingly, it is desirable to be able to effectively heat multiple follicles, without burning the surrounding skin. Such a method and
35   apparatus should be able to remove more than one hair at a time, and preferably over a wide area of skin, for example at least two square centimeters.

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Many of the shortcomings of laser systems are diminished when a specific application, such as hair removal, is concerned. As described, lasers have been used for many years to depilate the skin using the principle of selective photothermolysis. Light (or radiation, generally) is transmitted from a radiation source to the skin, is absorbed by the cells (or portions of the cells), heating is them. This heat causes the cells to lyse. A continuing problem for all such devices is how to damage hair follicles without damaging the surrounding tissue, In the early devices, small laser probes were used that directed the radiation to a single hair follicle at a time. In these devices, the doctor provided the device's selectivity, in effect. The major drawback is apparent: the requirement of moving a tiny easily damaged laser probe from follicle to follicle. This process was extremely slow. To be cost effective and efficient, entire areas of the skin would have to be treated with each pulse of laser light. Since relatively large area of the skin would have to be radiated however, the problem of healthy skin destruction, reappeared. Any apparatus and method for radiating large areas of skin would somehow have to selectively damage the hair follicles.

One such device is described in U.S. Pat. Nos. 5,226,907 and 5,425,728, to Tankovich. To provide the selectivity needed to destroy hair cells, the hair is treated with a "contaminant" that selectively absorbs the radiation emitted by the radiation source. This contaminant may be a carbon/oil suspension that penetrates between the hair shaft and the hair duct, or it may be a dye that penetrates into the hair shaft itself. In either case, a contaminant is provided to absorb radiation emitted by a laser light source applied externally to the surface of the contaminated skin. This energy passes through the skin and is absorbed by the contaminant, which then heats up. This heat is conducted into the tissue of the hair follicle surrounding the contaminant, which is then damaged. This process is an indirect photothermolysis, since the radiation does not heat the tissue directly, but heats an intermediate substance, which then conducts heat into the tissue to destroyed. Since the contaminant absorbs the radiation and tissue does not, a wavelength of radiation is chose to which tissue is particularly transparent and nonabsorptive.

The 5,226,907 and 5,425,728 patents describe two basic contaminants and tailored radiation sources. The first contaminant is a carbon/oil mixture rubbed into the space between the hair shaft and the hair duct. The second contaminant are dyes that penetrate the hair shaft itself. In an alternative

embodiment, briefly described, a contaminant is orally or intravenously administered.

Three radiation sources are proposed for the carbon/oil contaminant. One such device includes a CO_2 laser radiation source that provides a 10,600 nm ("10.6 microns") pulse of 275 ms duration at a pulse rate of 30 Hz that is focused to irradiate a spot on the skin of 1 cm^2 with an energy per pulse of 0.1 J at a scanning rate of 20 seconds per 10 cm^2 of treated area. The energy fluence per pulse is therefore 0.1 J/cm^2. The total energy per treatment is therefore 0.1 J/pulse x 30 pulses/second x 2 seconds/cm^2 of skin (assuming an even application of the energy aver the entire treated area) or 6 J/cm^2 of treated skin. Since each area of skin is irradiated for about two seconds in this embodiment, the average power density per treatment is 3/cm^2 of treated area. The power applied per each pulse is about 0.1 J/ (275 x 10^{-9} seconds) or 363 kW/cm^2.

In another embodiment, a CO_2 laser is disclosed emitting radiation at 10,600 nm having pulse lengths of 200 ns at a pulse repetition rate of 8 Hz, providing a spot size of 1 cm^2, with an energy per pulse of 0.2 J, and scanning the surface of the treatment area at a rate of 30 sec/10 cm^2 of skin. The energy fluence per pulse is therefore 0.2 J/cm^2. The total energy per treatment is therefore 0.2 J/pulse x 8 pulses/sec x 3 sec/ cm^2 of skin or 4.8 J/cm^2 of treated skin. Since each area is irradiated for about three seconds in this embodiment, the average power density per treatment is 4.8/3 or 1.6 W/cm^2 per treatment. The power applied per each pulse is about 0.2 J/(200 x 10^{-9} seconds) or 1 MW/cm^2.

To reduce the damage to the epidermis, a third embodiment is provided in which near-infrared (1060 nm) radiation is employed to radiate the carbon/oil mixture at an energy level that is significantly reduced from the examples provided above. As the inventor explains (col. 5, lines 50-58), the radiation energy applied to the skin can be reduced to one percent of the energy provided in the two 10,600 nm examples, since the skin does not absorb 1,060 nm radiation as well, and thus a greater percentage of energy penetrates the skin and thus reaches the carbon/oil mixture underneath the epidermis.

In this embodiment, a laser having a wavelength of 1,060 nm (1.06 microns). With a pulse duration of about 25-30 picoseconds (1/1,000 the time of the two previous examples) is applied to the skin. The energy per pulse is 3-6 mJ (1/100 the energy of the two previous examples), and the spot size is about 0.1 to 0.3 cm^2. As Tankovich states, the other treatment

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parameters are the same as in the "first embodiment" (col. 5, line 50). In that embodiment, 10 cm^2 of skin were treated at a pulse rate of 30 Hz for about 20 seconds (Table 1). This would provide a total energy fluence for the whole treatment of 30 pulses/sec x 20 sec x 0.1 cm^2 x 0.06 J/pulse, or 0.36 J/ cm^2. This is roughly one-twentieth the total energy fluence of the first embodiment. Thus, Tankovich teaches reducing the energy applied when radiating the skin at wavelengths that are not easily absorbed by the skin.

Several alternative contaminant/radiation source combinations are discussed for the dye method. In these alternative embodiments, summarily described, the hair is stained with particular dyes having high absorption characteristics at wavelengths preferably matching the wavelengths of laser radiation emitted by the laser radiation source. Tankovich recommends several laser/dye/wavelength combinations ranging between 531 nm and 785 nm, although a single tunable titanium/sapphire laser can be employed to cover this entire range.

By using a nonnaturally occurring contaminant is a radiation absorber, Tankovich is certainly able to tailor and enhance the thermal selectivity of the method. The contaminant method has significant drawbacks however. The contamination is unsightly and may cause an allergic reaction. A stain such as carbon that coats subcutaneous hair shafts using Tankovich's ultrasonic applicator is difficult to remove. The process may vaporize the skin. In the 1,060 nm embodiment, radiation is provided at energy levels insufficient to heat deep hair follicles and papillae.

Another class of depilation devices rely on the natural radiation absorptivity of human tissue and hair. In this class of devices, radiation is provided on the surface of the skin using a radiation wavelength to which naturally occurring substances in tissue or hair are particularly absorptive. The radiation heats the naturally occurring substances until the hair follicles or papillae are damaged. This process requires a more careful application of energy, and more careful selection of wavelength, since the process cannot rely on the extreme absorptivity of such substances as carbon particles.

One such commercial depilation device uses pulsed ruby laser emissions at 694 nm providing an energy density per pulse of between 30 and 40 J/cm^2. The 694 nm wavelength is used because it is absorbed more by melanin than by the hemoglobin in the surrounding tissue. Radiation applied to the skin is transmitted through the skin and heats melanin in hair shafts.

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The apparatus is complicated by a cooling system that is applied to the skin surface to prevent damage at the elevated energy levels provided by the device. The energy levels are significant since the energy is provided at a wavelength that melanin absorbs particularly well. The result is that more of the energy is absorbed in the epidermis causing significant heating of the skin, and relatively little energy penetrates the skin into deeper skin layers, such as the subcutaneous fat layers in which the deeper-lying hair papillae are located. The 694 nm wavelength does not provide for penetration deeper than about 2.5 mm.

Another single pulse device is described in U.S. Pat. No. 5,059,192, to Zaias. In this device melanin is also targeted, although the melanin targeted is in the papillae, and not in the hair shaft. By targeting the melanin in the papillae, the papillae are destroyed directly, rather than by thermal conduction from the hair shaft to the root as in the previous devices. It thereby destroys hair not only at the anagen stage of hair growth (when the papilla is attached to a hair shaft) but also at the catagen and telagen stages when no hair shaft is attached, and indeed when there may he no hair shaft at all. By attacking anagen and telagen stage hair papillae, regrowth of hair is inhibited, and the need for additional treatments is therefore reduced.

To kill the papillae, the radiation heats melanin in melanosomes in the papillae to the point of vaporization. The wavelength chosen is 694 nm. Melanin is particularly absorptive around 694 nm, and thus this new type of device emits near that wavelength and not at the 1,060 nm wavelength of the 5,226,907 and 5,425,728 patents which is not as readily absorbed by melanin.

Since the melanin in the melanosomes is heated to vaporization, a temperature well above ambient body temperature, the energy must be applied faster than it is removed by various heat transfer processes, such as conduction into surrounding tissues. As the Zaias patent indicates, a pulse should be shorter than the thermal relaxation time of the melanosomes. Zaias discloses that an acceptable energy density to be provided by the laser is an the order of 0.4 J/cm^2 to 10.0 J/cm^2 per pulse, with a pulse duration of 30-40 nanoseconds, but certainly less than the thermal relaxation time of the melanosomes, which is approximately 1 microsecond. Given an average pulse width of (30+40)/2 or 35 nanoseconds, and an average energy per pulse of (0.4-10)/2 or 5.2 J/cm^2, the radiated power required to vaporize the melanin is on the order of 140 MW/cm^2.

There are disadvantages to the Zaias device. Since the Zaias device directly irradiates melanosomes in the papillae, the power applied in the

treatment pulse must be quite high and have a very short duration to overcome the submicrosecond cooling time constant is ("thermal relaxation time") of the melanosomes. The advantage to this treatment is that it can damage papillae that are in a dormant state and not coupled to a hair shaft.

5   As with the Tankovich device, the 694 nm wavelength reduces the heating of deeper-lying skin layers, and thus does not sufficiently heat deeper hair bulbs, such as those located in subcutaneous fat layers greater than 2 mm deep.

The discussion above indicates that light source selection is of great

10   importance for effecting various applications. In some cases wherein lack of absorption homogeneity is evident, a wide band light source is the preferred choice, whereas, in other applications, wherein absorption homogeneity is evident, a laser source is the preferred choice.

Since all skin treatments, which are mainly cosmetic in nature,

15   including blood vessels coagulation and depilation, are typically effected in dedicated clinics, it will be advantageous to have a combined apparatus featuring both coherent (laser) and incoherent (wide band) light sources for effecting a variety of applications, since both light sources can be mutually controlled by a single control system, mounted onto a single mount, save

20   space and become cost effective.

There is thus a widely recognized need for and it would be highly advantageous to have a combined apparatus for (i) utilizing a spatially extended pulsed light source such as a flashlamp (flash tube) for skin treatment and for alternatively or additionally (ii) irradiating the skin with

25   long pulses of radiation from a Nd: YAG laser.

SUMMARY OF THE INVENTION

According to the present invention there is provided a combined therapeutic treatment apparatus for coagulating blood in blood vessels

30   underlying a skin treatment site and for the destruction of hair follicles at the skin treatment site.

According to further features in preferred embodiments of the invention described below, the combined apparatus comprising (a) a first device including an incoherent light source operable to provide a pulsed

35   light output onto the treatment site and a driver circuit, including a switch capable of being electrically turned on and being electrically turned off to thereby provide a first interval of light, connected to the light source to control the pulse width and delay between pulses; and (b) a second device

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including a coherent radiation source adapted to emit radiation at a wavelength of between 800 and 1,200 nanometers over an irradiation time of between 1 and 100 milliseconds, to provide a cumulative treatment dose of between 10 and 200 Joules per square centimeter of radiation, as measured at the treatment site.

According to still further features in the described preferred embodiments the first and second devices are integrated in a single operative unit.

According to still further features in the described preferred embodiments the first device further includes a housing with an opening, the light source being disposed in the housing, and the housing is adapted to be disposed adjacent a skin According to still further features in the described preferred embodiments the switch is a GTO.

According to still further features in the described preferred embodiments the switch and driver circuit limit the first interval to a predetermined duration of less than 100 milliseconds.

According to still further features in the described preferred embodiments the incoherent light source provides an incoherent light output having an energy fluence of between 6 and 300 J/cm^2 during the first interval.

According to still further features in the described preferred embodiments the incoherent light source provides an incoherent light output of between 6 and 20 J/cm^2 during the first interval.

According to still further features in the described preferred embodiments the first device further includes a light guide having a cross-sectional area of no less than 0.3 cm^2 which couples the light output to the treatment site.

According to still further features in the described preferred embodiments the light guide has a rectangular cross-section of between 3 and 30 millimeters in width and 10 and 100 millimeters in length.

According to still further features in the described preferred embodiments the incoherent light source provides an incoherent light output of between 30 and 100 J/cm^2 during the first interval.

According to still further features in the described preferred embodiments the light source is a flashtube, and the first device further includes a first capacitor According to still further features in the described preferred embodiments the switch electrically connects and disconnects the capacitor to the light source.

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According to still further features in the described preferred embodiments the first device further includes a second capacitor operable to be alternately coupled both in series and in parallel to the first capacitor.

According to still further features in the described preferred embodiments the coherent radiation source is a laser.

According to still further features in the described preferred embodiments the coherent radiation source is a Nd:YAG laser.

According to still further features in the described preferred embodiments the second device further includes a computer responsive to operator input coupled to and controlling the radiation source to provide a plurality of user-selectable irradiation times of between 1 and 100 milliseconds in length, and to provide a plurality of user-selectable cumulative treatment doses of between 10 and 200 Joules per square centimeter of radiation measured at the treatment site.

According to still further features in the described preferred embodiments the second device further includes an elongate flexible radiation delivery system having a proximal end and a distal end and adapted to transmit radiation from the proximal end to the distal end, wherein the distal end is optically coupled to the radiation source.

According to still further features in the described preferred embodiments the radiation delivery system is one of the group consisting of an optical fiber and an articulated arm.

According to still further features in the described preferred embodiments the second device further includes a hand piece having a proximal end and an aperture and adapted to transmit radiation from the proximal end to the aperture, wherein the proximal end is optically coupled to the distal end of the radiation delivery system, and wherein the aperture has a configuration selected from the group consisting of a circle, an oval or a rectangle.

According to still further features in the described preferred embodiments the second device further includes a solid transparent light guide having a proximal end and a distal end, wherein the light guide is adapted to transmit radiation from the distal end to the proximal end and wherein the proximal end is optically coupled to the aperture of the hand piece and the distal end has a first contact area adapted to be placed in contact with the treatment site.

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According to still further features in the described preferred embodiments the first contact area has a minimum cross-sectional distance of 2 mm.

According to another embodiment provided is a method of coagulating blood vessels underneath a skin treatment site.

According to still further features in the described preferred embodiments the method comprising the step of irradiating the treatment site with coherent radiation having a wavelength of between 600 and 1,200 nanometers over an irradiation time of between 1 and 100 milliseconds to provide a treatment dose of between 10 and 200 Joules per square centimeter of treatment site over the interval.

According to still further features in the described preferred embodiments the coherent radiation is generated by a laser radiation source.

According to still further features in the described preferred embodiments the laser radiation source is a Nd:YAG laser.

According to still further features in the described preferred embodiments the method further comprising the steps of (a) providing an operator with a plurality of user selectable irradiation times having a duration of between 1 and 100 milliseconds in length; and (b) providing an operator with a plurality of user-selectable treatment doses having an energy fluence of between 10 and 200 Joules per square centimeter of radiation measured at the treatment site.

According to still further features in the described preferred embodiments the step of irradiating includes the step of coupling the radiation to a spot on the treatment site having a diameter of at least 2 mm.

According to still further features in the described preferred embodiments the method further comprising the step of applying a gel transparent to the radiation to the treatment site.

According to still further features in the described preferred embodiments the step of irradiating the treatment site includes the step of irradiating the treatment site with two or more sequential pulses of radiation.

Other principal features and advantages of the invention will become apparent to those skilled in the art upon review of the following drawings, the detailed description and the appended claims.

The present invention successfully addresses the shortcomings of the presently known configurations by providing a combined apparatus for (i) utilizing a spatially extended pulsed light source such as a flashlamp (flash

tube) and for (ii) irradiating the skin with long pulses of radiation from a Nd: YAG laser.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention herein described, by way of example only, with reference to the accompanying drawings, wherein:

FIG. 1 is a cross-sectional view of an incoherent, pulsed light source skin treatment device (prior art);

FIG. 2 is a side view of the light source of Figure 1 (prior art);

FIG. 3 is a schematic diagram of a pulse forming network with a variable pulse width for use with the skin treatment device of Figures 1 and 2 (prior art);

FIG. 4 shows a light guide providing a large angular divergence (prior art);

FIG. 5 shows a light guide providing a narrow angular divergence (prior art);

FIG. 6 is a schematic configuration of a gel skin interface with a transparent plate (prior art);

FIG. 7 shows an angular distribution of photons penetrating without using a gel (prior art);

FIG. 8 shows a spectra produced with a flashlamp current of 200 amps (prior art);

FIG. 9 shows a spectra produced with a flashlamp current of 200 amps (prior art);

FIG. 10 shows a GTO driver circuit for a flashlamp (prior art);

FIG. 11 is a schematic drawing of a cross section of a hair follicle in the dermis and a gel applied to the epidermis;

FIG. 12 is a graph showing the optical properties of the skin;

FIG. 13 is a side view of a hair removal apparatus constructed having an incoherent, pulsed light source (prior art);

FIG. 14 is a front view of the apparatus of Figure 11;

FIG. 15 illustrates the absorptivity of red and black hair over a range of 500 to 1,000 nm;

FIG. 16 illustrates a portion of hirsute skin showing the general relationship of a deep hair follicle with respect to the epidermis, dermis and subcutaneous fat layer;

FIG. 17 illustrates a depilation apparatus;

FIG. 18 illustrates the hand piece of Figure 13 in contact with a treatment site; and

FIG. 19 schematically illustrates a combined apparatus according to the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is of a combined apparatus for (i) utilizing a spatially extended pulsed light source such as a flashlamp (flash tube) for skin treatment and for (ii) irradiating the skin with long pulses of radiation from a Nd: YAG laser. The present invention can be used to provide a combined apparatus featuring both coherent (laser) and incoherent (wide band) light sources for effecting a variety of applications.

The principles and operation of a combined apparatus according to the present invention may be better understood with reference to the drawings and accompanying descriptions.

Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of the components set forth in the following description or illustrated in the drawings. The invention is capable of other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

Figures 1-10 and their accompanying descriptions hereinbelow are reproduced from U.S. Pat. No. 5,626,631 to Eckhouse. Figures 11-14 and their accompanying descriptions are reproduced from U.S. Pat. No. 5,683,380. Figures 15-19 and their accompanying descriptions are reproduced from U.S. Pat. application No. 08/795,677.

The present invention concerns an integrated apparatus which includes combination of embodiments derived from U.S. Pat. Nos. 5,626,631 and 5,683,380 and U.S. Pat. application 08/795,677, all are incorporated by reference as if fully set forth herein. The invention further concerns a laser based method for treating disordered blood vessels underneath the skin.

Thus, referring now to Figures 1 and 2, cross-sectional and side views of an incoherent, pulsed light source skin treatment device **10** constructed and operated in accordance with the principles of the present

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invention are shown. Device **10** may be seen to include a housing **12**, having an opening therein, a handle **13** (Figure 2 only), a light source **14** having an outer glass tube **15**, an elliptical reflector **16**, a set of optical filters **18**, an iris **20** and a detector **22** (Figure 1 only).

5   Light source **14**, which is mounted in housing **12**, may be a typical incoherent light source such as a gas filled linear flashlamp Model No. L5568 available from ILC. The spectrum of light emitted by gas filled linear flashlamp **14** depends on current density, type of glass envelope material and gas mixture used in the tube. For large current densities (e.g.,

10   3000 A/Cm^2 or more) the spectrum is similar to a black body radiation spectrum. Typically, most of the energy is emitted in the 300 to 1,000 nm wavelength range.

        To treat a skin (or visible) disorder a required light density on the skin must be delivered. This light density can be achieved with the focusing

15   arrangement shown in Figures 1 and 2. Figure 1 shows a cross-section view of reflector **16**, also mounted in housing **12**. As shown in Figure 1, the cross-section of reflector **16** in a plane is perpendicular to the axis of flashlamp **14** is an ellipse. Linear flashlamp **14** is located at one focus of the ellipse and reflector **16** is positioned in such a way that the treatment

20   area of skin **21** is located at the other focus. The arrangement shown is similar to focusing arrangements used with lasers and efficiently couples light from flashlamp **14** to the skin. This arrangement should not, however, be considered limiting. Elliptical reflector **16** may be a metallic reflector, typically polished aluminum which is an easily machinable reflector and has

25   a very high reflectivity in the visible, and the UV range of the spectrum can be used. Other bare or coated metals can also be used for this purpose.

        Optical and neutral density filters **18** are mounted in housing **12** near the treatment area and may be moved into the beam or out of the beam to control the spectrum and intensity of the light. Typically, 50 to 100 nm

30   bandwidth filters, as well as low cutoff filters in the visible and ultraviolet portions of the spectrum, are used. In some procedures it is desirable to use most of the spectrum, with only the UV portion being cut off. In other applications, mainly for deeper penetration, it is preferable to use narrower bandwidths. The bandwidth filters and the cutoff filters are readily

35   available commercially.

        Glass tube **15** is located coaxially with flashlamp **14** and has fluorescent material deposited on it. Glass tube **15** will typically be used for treatment of coagulation of blood vessels to optimize the energy efficiency

of device **10**. The fluorescent material can be chosen to absorb the UV portion of the spectrum of flashlamp **14** and generate light in the 500 to 650 nm range that is optimized for absorption in the blood. Similar materials are coated on the inner walls of commercial fluorescent lamps. A typical material used to generate "warm" white light in fluorescent lamps has a conversion efficiency of 80%, has a peak emission wavelength of 570 nm and has a bandwidth of 70 nm and is useful for absorption in blood. The few millisecond decay time of these phosphors is consistent with long pulses that are required for the treatment of blood vessels.

Other shapes or configurations of flashlamp **14** such as circular, helical, short arc and multiple linear flashlamps may be used. Reflector **16** may have other designs such as parabolic or circular reflectors. The light source can also be used without a reflector and the required energy and power density may be achieved by locating light source **14** in close proximity to the treatment area.

Iris **20** is mounted in housing **12** between optical filters **18** and the treatment area and controls the length and the width of the exposed area, i.e., by collimating the output of flashlamp **14**. The length of flashlamp **14** controls the maximum length that can be exposed. Typically an 8 cm long (arc length) tube will be used and only the central 5 cm of the tube is exposed. Using the central 5 cm assures a high degree of uniformity of energy density in the exposed skin area. Thus, in this embodiment iris **20** (also called a collimator) will enable exposure of skin areas of a maximum length of 5 cm. Iris **20** may be closed to provide a minimum exposure length of one millimeter. Similarly, the width of the exposed skin area can be controlled in the range of 1 to 5 mm for a 5 mm wide flashlamp. Larger exposed areas can be easily achieved by using longer flash tubes or multiple tubes, and smaller exposure areas are obtainable with an iris that more completely collimates the beam. The present invention provides a larger exposure area compared to prior art lasers or point sources and is very effective in the coagulation of blood vessels since blood flow interruption over a longer section of the vessel is more effective in coagulating it. The larger area exposed simultaneously also reduces the required procedure time.

Detector **22** (Figure 1) is mounted outside housing **12** and monitors the light reflected from the skin. Detector **22** combined with optical filters **18** and neutral density filters can be used to achieve a quick estimate of the spectral reflection and absorption coefficients of the skin. This may be

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carried out at a low energy density level prior to the application of the main treatment pulse. Measurement of the optical properties of the skin prior to the application of the main pulse is useful to determine optimal treatment conditions. As stated above, the wide spectrum of the light emitted from the non-laser type source enables investigation of the skin over a wide spectral range and choice of optimal treatment wavelengths.

In an alternative embodiment, detector **22** or a second detector system may be used for real-time temperature measurement of the skin during its exposure to the pulsed light . This is useful for skin thermolysis applications with long pulses in which light is absorbed in the epidermis and dermis. When the external portion of the epidermis reaches too high a temperature, permanent scarring of the skin may result. Thus, the temperature of the skin should be measured. This can be realized using infrared emission of the heated skin, to prevent over-exposure.

A typical real-time detector system would measure the infrared emission of the skin at two specific wavelengths by using two detectors and filters. The ratio between the signals of the two detectors can be used to estimate the instantaneous skin temperature. The operation of the pulsed light source can be stopped if a preselected skin temperature is reached. This measurement is relatively easy since the temperature threshold for pulsed heating that may cause skin scarring is on the order of 50 °C, or more, which is easily measurable using infrared emission.

The depth of heat penetration depends on the light absorption and scattering in the different layers of the skin and the thermal properties of the skin. Another important parameter is pulse-width. For a pulsed light source, the energy of which is absorbed in an infinitesimally thin layer, the depth of heat penetration (d) by thermal conductivity during the pulse can be written as shown below:

$$d = 4[k\Delta t/C\rho]^{1/2}$$

where

k = heat conductivity of the material being illuminated;

Δt = the pulse-width of the light pulse;

C = the heat capacity of the material; and

ρ = density of the material.

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It is clear from the above equation that the depth of heat penetration can be controlled by the pulse-width of the light source. Thus, a variation of pulse-width in the range of 10^{-5} sec to 10^{-1} sec will result in a variation in the thermal penetration by a factor of 100.

5   Accordingly, flashlamp **14** provides a pulse width of from 10^{-5} sec to 10^{-1} sec. For treatment of vascular disorders in which coagulation of blood vessels in the skin is the objective the pulse length is chosen to uniformly heat as much of the entire thickness of the vessel as possible to achieve efficient coagulation. Typical blood vessels that need to be treated

10   in the skin have thicknesses in the range of 0.5 mm. Thus, the optimal pulse-width, taking into account the thermal properties of blood, is on the order of 100 msec. If shorter pulses are used, heat will still be conducted through the blood to cause

Coagulation, however, the instantaneous temperature of part of the

15   blood in the vessel and surrounding tissue will be higher than the temperature required for coagulation and may cause unwanted damage.

For treatment of external skin disorders in which evaporation of the skin is the objective, a very short pulse-width is used to provide for very shallow thermal penetration of the skin. For example, a 10^{-5} sec pulse will

20   penetrate (by thermal conductivity) a depth of the order of only 5 microns into the skin. Thus, only a thin layer of skin is heated, and a very high, instantaneous temperature is obtained so that the external mark on the skin is evaporated.

Figure 3 shows a variable pulse-width pulse forming circuit

25   comprised of a plurality of individual pulse forming networks (PFN's) that create the variation in pulse-widths of flashlamp **14**. The light pulse full width at half maximum (FWHM) of a flashlamp driven by a single element PFN with capacitance C and inductance L is approximately equal to:

30   $$\Delta t \approx 2[LC]^{1/2}$$

Flashlamp **14** may be driven by three different PFN's, as shown in Figure 3. The relay contacts **R1'**, **R2'** and **R3'** are used to select among three capacitors **C1**, **C2** and **C3** that are charged by the high voltage power

35   supply. Relays **R1**, **R2** and **R3** are used to select the PFN that will be connected to flashlamp **14**. The high voltage switches **S1**, **S2** and **S3** are used to discharge the energy stored in the capacitor of the PFN into flashlamp **14**. In one embodiment **L1**, **L2** and **L3** have values of 100 mH, 1

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mH and 5 mH, respectively, and C1, C2 and C3 have values of 100 mF, 1 mF and 10 mF, respectively.

In addition to the possibility of firing each PFN separately, which generates the basic variability in pulse-width, additional variation can be achieved by firing PFN's sequentially. If, for example, two PFN's having pulse-width $\Delta t1$ and $\Delta t2$ are fired, so that the second PFN is fired after the first pulse has decayed to half of its amplitude, then an effective light pulse-width of this operation of the system will be given by the relation: $\Delta t \approx \Delta t1 + \Delta t2$.

The charging power supply typically has a voltage range of 500 V to 5 kV. The relays should therefore be high voltage relays that can isolate these voltages reliably. The switches S are capable of carrying the current of flashlamp 14 and to isolate the reverse high voltage generated if the PFNs are sequentially fired. Solid-state switches, vacuum switches or gas switches can be used for this purpose.

A simmer power supply (not shown in Figure 3) may be used to keep the flashlamp in a low current conducting mode. Other configurations can be used to achieve pulse-width variation, such as the use of a single PFN and a crowbar switch, or use of a switch with closing and opening capabilities.

Typically, for operation of flashlamp 14 with an electrical pulse-width of 1 to 10 msec, a linear electrical energy density input of 100 to 300 J/cm can be used. An energy density of 30 to 100 J/cm^2 can be achieved on the skin for a typical flashlamp bore diameter of 5 mm. The use of a 500 to 650 nm bandwidth transmits 20 % of the incident energy. Thus, energy densities on the skin of 6 to 20 J/cm^2 are achieved. The incorporation of the fluorescent material will further extend the output radiation in the desired range, enabling the same exposure of the skin with a lower energy input into flashlamp 14.

Pulsed laser skin treatment shows that energy densities in the range of 0.5 to 10 J/cm^2 with pulse-widths in the range of 0.5 msec are generally effective for treating vascular related skin disorders. This range of parameters falls in the range of operation of pulsed non-laser type light sources such as the linear flashlamp. A few steps of neutral density glass filters 18 can also be used to control the energy density on the skin.

For external disorders a typical pulse-width of 5 microsecond is used. A 20 J/cm electrical energy density input into a 5 mm bore flashlamp results in an energy density on the skin of 10 J/cm^2. Cutting off the hard UV

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portion of the spectrum results in 90 % energy transmission, or skin exposure to an energy density of close to 10 J/cm^2. This energy density is high enough to evaporate external marks on the skin.

Device 10 can be provided as two units: a lightweight unit held by a physician using handle 13, with the hand-held unit containing flashlamp 14, filters 18 and iris 20 that together control the spectrum and the size of the exposed area and the detectors that measure the reflectivity and the instantaneous skin temperature. The power supply, the PFN's and the electrical controls are contained in a separate box (not shown) that is connected to the hand-held unit via a flexible cable. This enables ease of operation and easy access to the areas of the skin that need to be treated.

According to one embodiment of the invention rigid light guides are used to couple the light to the treatment area. Rigid light guides may be made from quartz, acrylic, glass, or other materials having a high degree of transparency. The material is generally highly polished on all sides.

For example, a typical cross section of a circular light guide useful for therapeutic treatment is one mm to ten mm in diameter. Alternatively, a rectangular light guide may be used having typical dimensions of 3 mm by 10 mm to 30 mm by 100 mm. In either case the length may be 20 to 300 mm, or as needed for the specific application.

According to another alternative embodiment a rectangular light guide is used to more efficiently couple the light. The rectangular light guide is chosen to have a shape that matches a rectangular linear flashlamp and to match the shape of the vessel being treated.

The light guides described above may be used in another alternative embodiment to control the spectrum of light delivered to the treatment area. Spectral control can be achieved by making the light guide from a material that has an absorbing dye dissolved therein. Thus, light transmitted by the light guide will have a spectrum as determined by the absorbing dye. Alternatively, a flat, discrete filter may be added to one end (preferably the input end) of the light guide. Both of these filters are absorbing filters. The inventors have found that absorbing filters produced by Schott, having Model Nos. OG515, OG550, OG570, and OG590 have suitable characteristics.

Additionally, interference filters or reflective coatings on the light guide may be used by applying a proper optical coating to the light guide. Again, a single discrete interference filter could also be used. Additionally, combinations of the various filters described herein, or other filters, may be

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used. The use of the filters described here may render the use of the filters described earlier with reference to Figure 1 redundant.

An alternative embodiment entails the use of application specific light guides. In this way the spectra of light for various treatments can be easily controlled. According to this alternative each type of treatment will be performed with a specific light guide.

The optical properties of the light guide will be chosen to optimize the particular treatment. The wavelengths below are particularly useful for the respective treatments:

arteries less than 0.1 mm in diameter--520-650 nm;

veins less than 0.1 mm in diameter--520-700 nm;

vessels between 0.1 and 1.0 mm in diameter--550-1,000 nm; and

larger vessels--600-1000 nm.

In each case if the skin is darker (higher pigmentation) longer wavelengths on the lower cut-off portion of the spectrum should be used.

Multiple spectra may be used for optimal penetration. This may be accomplished by illuminating with a few pulses, each having a different spectrum. For example, the first pulse can have a spectrum that is highly absorbed in blood. This pulse will coagulate the blood, thereby changing the optical properties of the blood, making it more absorbing in another wavelength range (preferably longer). A second pulse will be more efficiently absorbed since the blood absorbs energy of a greater wavelength range. This principle may be used with lasers or other light sources as well.

In addition to the features of the light guides discussed above, a light guide is used, in one alternative embodiment, to control the angular distribution of the light rays impinging on the skin. Light that impinges on the skin at large angles (relative to the perpendicular) will not penetrate very deeply into the tissue. Conversely, light that impinges perpendicularly to the skin will have a deeper penetration. Thus, it is desirable to provide a distribution of light rays that has a relatively wide angular divergence when the treatment requires shallow penetration. Alternatively, a narrow divergence is preferable for treatment requiring deep penetration is desired. Some treatment might require both shallow and deep penetration.

Figure 4 shows a light guide 115 having an exit beam with a greater angular divergence than that of the entrance beam. As shown in Figure 4, a beam 116 enters light guide 115 at a small angle, relative to the axis of light guide 115. When beam 116 exits light guide 115, the angle, relative to the

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axis, is much greater. The tapered shape of light guide **115** enhances this divergence.

Figure 5 shows a straight light guide **118** that maintains the angular distribution of the rays of light that enter into it. A beam **119** is shown entering and exiting light guide **118** with the same absolute angle. Alternate use of both light guides **115** and **118** can achieve the narrow and deep penetration discussed above.

One alternative embodiment includes the use of a gel to couple the light to the skin. This alternative reduces heating of the outer layer of the skin (the epidermis and upper layers of the dermis). The gel is preferably a high viscosity water based gel and is applied to the skin before treatment, although other gels that are not necessarily water based may be used. A gel having a relatively high heat capacity and thermal conductivity, such as a water based gel, is preferable to enable cooling of the outer skin (the epidermis in particular). Transparency is also desirable because during treatment light passes through the transparent gel and reaches the skin.

Referring now to Figure 6, a gel **110** is applied to the skin **21** prior to the treatment. A flat layer of gel on top of the skin is used since irregularities in the upper layer of the gel through which the light passes may cause scattering of the light and reduce its penetration into the skin. In order to achieve this flatness a solid, transparent, flat piece **111** may be applied on top of the skin. The configuration is shown schematically in Figure 6. The transparent plate can be made out of glass or other transparent materials. Either the flashlamp housing or the light guides discussed above may be placed in direct contact with the transparent plate or the gel.

The configuration of Figure 6 has the advantage of reducing the scattering of light (represented by arrows **113**) that enters into the skin due to irregularities in the surface of the skin. The skin has an index of refraction that is larger than that of the air. As a result, any photon that impinges on the air skin interface is deflected if it does not hit the skin at an incidence angle of 0 . Since the surface of the skin is irregular the angular distribution of the skin increases. This is shown schematically in Figure 7.

The use of gel addresses this problem since the gel can fill irregular voids that are created by the skin structure. The transparent plate that covers the gel and the gel itself will preferably have an index of refraction that is close to that of the skin. This is relatively easy since the index of refraction of the skin is of the order of 1.4 in the visible and the near

infrared. Most glasses and transparent plastics have indices of refraction that are of the order of 1.5 which is close enough. The index of refraction of water is of the order of 1.34 in this range. Water based gels will have similar indices of refraction. The index can be increased by proper additives. The plate and gel thus act as a flat surface for the light to impinge upon. Because the gel and plate have an index of refraction close to that of the skin there is very little scattering at the gel-plate and gel-skin interfaces.

The use of a gel has been experimentally successful in the treatment of leg veins and other benign vascular lesions of the skin. The treatments were carried out with the flashlamp described above. However, in alternative embodiments a different incoherent source, or a coherent source, may be used.

During operation light is typically applied to the skin in a sequence of three pulses with short delays between the pulses. This mode of operation is used in order to take advantage of the faster cooling of the superficial, thin (less than 0.1 mm thick) epidermis compared to the larger and deeper vessels typical of leg veins. The gel in contact with the skin cools the epidermis during the waiting period between the pulses. This cooling reduces significantly the damage to the epidermis.

In accordance with the invention, light is applied to the treated area in either a long pulse or in a sequence of pulses separated by a delay. The delay and/or pulse length is preferably controlled by the operator to provide enough heat to accomplish the desired treatment but not enough heat to damage the skin.

This concept was tested with large and deep vessels (of the order of 2 mm in diameter and 2 mm deep). A thin layer of commercial water based ultrasound gel (1 to 2 mm thick, "Aqua clear" gel made by Parker USA) was applied on the skin. A 1 mm thin glass window was used to generate a flat layer of the gel. The light from the device passed through the thin glass and the gel and into the skin. Care was taken to assure than no air bubbles exist in the gel. This configuration was tested with photon fluences of 30 to 50 J/cm^2. Coagulation and clearance of the vessels was obtained without causing damage to the skin. This is contrary to similar trials in which gel was not used and in which fluences of 20 J/cm^2 with the same pulse structure caused burns of the skin.

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The epidermis has a thickness of approximately 0.1 mm and a cooling time of about 5 msec. Thus, to avoid burning, delays greater than 5 msec are used.

In another alternative embodiment the spectrum of the light used for treatment is controlled by controlling the voltage and/or current applied to the flashlamp. As is well known in the art, the spectrum of light produced by a flashlamp is dependent on the voltage and current provided to the flashlamp. According to this embodiment the input voltage and current is selected to provide a desired treatment spectrum. The appropriate voltage and currents may be determined experimentally for each flashlamp used. For example, a flashlamp current of 200 amps produced the spectra shown in Figure 8. Similarly, the spectra of Figure 9 was produced using a flashlamp current of 380 amps. The spectra of Figure 8 shows a significant enhancement in the wavelength range of 800-1,000 nm. Such a spectra is particularly useful for treatment of large vessels.

The different currents and voltages used to control the output spectra may be obtained using a group or bank of capacitors that are capable of being connected in either series or parallel as part of the power source for the flashlamp. A series connection will provide a relatively high voltage and high current, thereby producing a spectra having energy in a shorter wavelength, such as 500-650 nm. Such a series connection will be more appropriate for generating shorter pulses (e.g., 1 to 10 msec) useful for treatment of smaller vessels.

A parallel connection provides a lower current and voltage, and thus produces an output spectra of a longer wavelength, such as 700-1,000 nm. Such a spectra is more appropriate for treatment of larger vessels and is suitable for producing longer pulses (e.g., in the range of 10-50 msec). The selection of series or parallel connections may be done using a relay or sets of relays.

In one alternative embodiment the pulse forming network of Figure 3 is replaced by a GTO driver circuit 121, such as that shown in Figure 10. The driver circuit of Figure 10 uses a switch capable of being turned both on and off to control the application of power to the flashlamp. While this alternative embodiment will be described with respect to a GTO being used as the switch, other switches capable of being turned both on and off, such as IGBTs, may also be used.

Referring now to Figure 10, driver circuit 121 includes a high voltage source 122, a capacitor bank C5, an inductor L5, a diode D5, a

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switch **GTO1**, a diode **D6**, a diode **D7**, a resistor **R5**, a capacitor **C6**, a GTO trigger generator **TR1**, a resistor **R7**, a capacitor **C7** and a flashtube trigger generator **TR2**. These components are connected to flashlamp **14** and serve to provide the power pulses to flashlamp **14**. The duration and timing of the pulses are provided in accordance with the description herein. Driver **121** operates in the manner described below.

High voltage source **122** is connected across capacitor bank **C5**, and charges capacitor bank **C5** to a voltage suitable for application to flashlamp **14**. Capacitor bank **C5** may be a comprised of one or more capacitors, and may be configured in the manner described above.

Prior to illumination of flashlamp **14** flashtube trigger generator **TR2** breaks down flashlamp **14** and creates a relatively low impedance channel therein. After the flashlamp breaks down, capacitor **C7** dumps current into flashlamp **14**, further creating a low impedance channel in flashlamp **14**. In this manner a pre-discharge is provided that prepares flashlamp **14** for the power pulse. Capacitor **C7** provides a small amount of current, relative to capacitor bank **C5**. Alternatively, driver circuit **121** may operate in a simmer mode, wherein the pre-discharge is not necessary.

Thereafter, switch **GTO1** is turned on via a pulse from GTO trigger generator **TR1**, completing the circuit between flashlamp **14** and capacitor bank **C5**. Thus, capacitor bank **C5** discharges through flashlamp **14**. An inductor **L5** may be provided to control the rise time of the current through flashlamp **14**. Inductor **L5** may include an inherent resistive component, not shown.

After a length of time determined by the desired pulse width has passed, GTO trigger generator **TR1** provides a pulse to switch **GTO1**, turning it off. A control circuit determines the timing of the trigger pulses and provides them in accordance with the desired pulse widths and delays.

A snubber circuit comprised of diode **D6**, resistor **R5**, and a capacitor **C6** is provided for switch **GTO1**. Also, diodes **D5** and **D7** are provided to protect switch **GTO1** from reverse voltages. Resistor **R7** is provided in parallel with flashlamp **14** to measure the leakage current of switch **GTO1**, which can in turn be used to make sure that switch **GTO1** is operating properly.

A possible addition to driver circuit **121** is to provide an SCR or other switch in parallel with capacitor bank **C5**. This allows the discharge or resetting of capacitor bank **C5** without turning on switch **GTO1**. Other modifications may be made, such as providing the circuit with a serial

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trigger, rather than the parallel trigger shown. Another modification is to use the driver circuit with a laser rather than flashlamp **14**.

Proper use of pulse widths and delays can aid in avoiding burning the epidermis. The epidermis has a cooling time of about 5 msec, while large vessels have a longer cooling time (a 1 mm vessel has cooling time of about 300 msec). Thus, during a pulse of duration longer than 5 msec the epidermis can cool down but the vessel will not. For example, for treatment of a large vessel (such as one having a diameter of about 1 mm) a pulse of 100 msec will allow the skin to cool, but the vessel will not cool.

The same effect may be achieved using trains of pulses. This is useful when it is not practical to provide a single long pulse to the flashlamp. The delays between pulses are selected to allow the skin to cool, but to be too short for the vessel to cool. Thus, larger vessels can be treated with longer delays because they have greater cooling times. Small vessels cool quickly and long delays are not effective. However, they also need less energy and can be treated effectively in a single pulse.

Typical delay times are in the range of 20 msec to 500 msec. More specifically, delays of between 100-500 msec are effective for vessels larger than 1 mm in diameter. Delays of between 20-100 msec are effective for vessels between 0.5 and 1 mm in diameter. Delays of between 10-50 msec are effective for vessels between 0.1 and 0.5 mm in diameter. A single pulse having a width in the range of 1 msec to 20 msec is effective for vessels less than 0.1 mm diameter.

Additionally, delays should be selected according to skin pigmentation. Darker skin absorbs more energy and needs more time to cool: thus longer delays are needed. Lighter skin absorbs less energy and can accommodate shorter delays.

It has been found that multiple pulses avoids "purpora" or the explosion of small vessels in or close to the skin. The use of pulses to avoid burning and provide cooling will be effective for light provided by lasers or other sources as well.

Another alternative embodiment includes the use of a microprocessor or personal computer to control the flashlamp. The microprocessor can be used to provide the timing functions and prompt the trigger signals described above.

Additionally, in one embodiment the microprocessor includes a user interface, such as a screen and keyboard, buttons, mouse, or other input

device. The microprocessors have information stored therein that aids in the selection of treatment parameters.

For example, if the condition being treated is a port wine stains skin type III, the physician inputs that condition into the microprocessor. The microprocessor responds with suggested treatment parameters, such as using a 570 nm cut-off filter, a double pulse with a delay of 50 msec and a fluence of 55 J/cm². The physician can alter these suggested parameters, but need not refer back to operating guidelines for suggested parameters.

The microprocessor or personal computer can also be used to create and store patient information in a database. Thus, past treatment information such as condition being treated, treatment parameters, number of treatments, etc., is stored and may be recalled when the patient is again treated. This aids in providing the proper treatment to the patient. Additionally, the database may include photographs of the patient's condition before and after each treatment. Again, this aids in record keeping and determining what treatments are most successful for given conditions.

In addition to the treatments described above the devices and methods described hereinabove may be used to treat other conditions. For example, psoriasis and warts have been successfully treated. Similarly, skin rejuvenation (treating wrinkles) should be effective.

As already mentioned, Figures 1-10 and their accompanying descriptions hereinabove are reproduced from U.S. Pat. No. 5,626,631 to Eckhouse.

Figures 11-14 described hereinafter are reproduced from U.S. Pat. No. 5,683,380, which describes a hair removal apparatus constructed having an incoherent, pulsed light source.

Generally, according to this embodiment of the present invention, hair is removed by exposing the "hairy" area to intense, wide area, pulsed electromagnetic (light) energy. The energy heats the hair and coagulates the tissue around the hair and follicle without damaging the healthy skin.

An optically transparent water based gel may be applied to the skin prior to treatment. As used herein gel means a viscous fluid that is preferably, but not necessarily water based. The gel is used to cool the epidermis which is the primary location of light absorption by tissue, due to the melanin content of the epidermis. The gel is applied so as not to penetrate into the cavity generated by the hair follicle, and thus does not

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cool the hair and the hair follicle. As a result the energy is selectively applied to coagulate the hair without damaging the skin.

A polychromatic light source, such as a high intensity pulsed flashlamp, is an example of a source suitable for the purposes described herein. One advantage of a polychromatic source such as a flashlamp is that energy having a wavelength in the range of 550 to 630 nm is heavily absorbed in blood and can be used to coagulate the vessel that feeds the hair. Additionally, longer wavelengths, in the range of 600 to 1100 nm have a very good penetration into non-pigmented skin. This wavelength range can be used to couple to the melanin of the hair. The higher pigmentation of the hair and the hair follicle can enhance the absorption of energy by the hair.

Flashlamps also have the advantage of being able to illuminate a large area, thus minimizing the treatment time. The flashlamp combined with a proper reflector can deliver the required fluences to areas on the order of a few square centimeters in a single application. However, other light sources, such as pulsed lasers can be used as well.

Referring now to Figure 11, a schematic drawing of a cross section of a hair follicle **100** in a dermis **102** is shown. As may be seen in Figure 11, a gel **103** applied to an epidermis **104**. In the present invention, water based transparent gel **103** is applied to a large section of the skin that is covered by hair, such as hair **105**. Gel **103** is applied to epidermis **104** and creates a thin layer on top of epidermis **104**. This layer is closely coupled to epidermis **104** and acts as a heat sink that cools epidermis **104** when light (electromagnetic energy) is applied to the area. As may also be seen in Figure 11, gel **103** does not penetrate into a cavity **106** formed by hair follicle **100** due to its surface tension properties and the fact that the hair is naturally covered by a thin layer of fatty material which makes it hydrophobic. The much higher heat diffusivity of gel **103** compared to that of air which fills cavity **106** enables fast cooling of epidermis **104**, represented by arrows **107**, while hair **105** is cooled at a much slower rate.

The cooling time, δt, of an object that has typical dimensions d and diffusivity α can be written as:

$$\delta t \approx d^2/16\alpha$$

The epidermis has typical cross dimensions of less than 0.1 mm, which is also the typical diameter of hair. The diffusivity of water is

approximately $\alpha= 3 \times 10^{-9}$ m^2 sec^{-1}. The gel is applied, in the manner shown in Figure 11, over a wide area.

When the gel is so applied the typical cooling time of the hair will be on the order of 200 msec and that of the epidermis will be on the order of 5 msec. This difference in cooling times is due to the fact that the gel does not penetrate into the hair follicles. It is preferable to use a transparent gel since the gel acts only as a cooling agent and should not be heated by the external illumination.

In accordance with the invention, light is applied to the treated area in either a long pulse or in a sequence of pulses separated by a delay. The delay and/or pulse length is preferably controlled by the operator to provide enough heat to remove the hair but not enough heat to damage the skin. For example, the pulse length or delay between the pulses should be more than the cooling time of the gel covered epidermis and less than the cooling time of the hair and follicle.   Thus, referring to the above discussion on cooling times, a pulse length of 50 msec if a single pulse is used or a delay of 50 msec between the pulses if a pulse sequence is used are appropriate values.

The spectrum of the light source may be selected with reference to the absorption by the skin, by the hair and by the blood vessels feeding the hair. For example, the hair follicle has typical a depth of 1 to 2 mm. It is preferable, therefore, to use a light wavelength range that can penetrate into this depth without very high attenuation.

Figure 12 is a graph showing the scattering, absorption and effective attenuation coefficients in fair skin dermis and the absorption coefficient of blood in the 400 to 1,000 nm range. Because a wide area is illuminated, rather than a single hair, it s preferable to use a wavelength range that penetrates into the skin without being highly attenuated. The skin attenuation coefficient controls the depth of penetration of light into the skin. As may be seen in Figure 12 wavelengths that are longer than 550 nm will be more effective to penetrate deep enough into the skin. Shorter wavelengths are less desirable because they will be highly attenuated before reaching the lower parts of the hair follicles.

Wavelengths significantly longer than 1,000 nm are also less effective due to high absorption of infrared in water which constitutes more than 70 % of skin. Wide area photo thermal hair removal of the present invention preferably uses light that can penetrate deep into the skin, since light is coupled to the hair and the hair follicles only after it penetrates

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through the skin. Most of the spectrum of light at wavelengths longer than 1,300 nm is heavily absorbed in water and will be less useful because it does not penetrate very deep into the skin. For example, CO_2 laser radiation in the 10,000 nm range penetrates only a few tens of microns into the skin.

Referring now to Figures 13 and 14, one preferred embodiment of hair remover 300 includes a flashlamp 301 located in a housing 302 having a handle. The flashlamp is shown adjacent gel 103 and hairy skin 102/104/105. The flashlamp provides a suitable fluence and it illuminates a large area in a single pulse (on the order of 10 x 50 mm²).

Such a flashlamp is driven by a variable pulse width power source. The flashlamp s contained in housing 302 and the light from the flashlamp is directed towards the skin by a reflector 305 that has a high reflectivity.

Also shown in Figures 13 and 14 is a filter 307, that is disposed between flashlamp 301 and gel 103. The filter, or in an alternative embodiment, multiple filters, are used to control the spectrum generated by the light source. As used herein filter, or band-pass filter, describes a device that allows electromagnetic energy (light) of certain wavelengths or frequencies to pass. The other wavelengths or frequencies are either partially or wholly removed.

The operator can select the filter according to the skin pigmentation of the person being treated. For the embodiment using a flashlamp, one can take advantage of the spectral range typically generated by such a lamp, which is in the range of 200 to 1,300 nm for high pressure xenon flashlamps operated at high current densities (on the order of 1,000 to 5,000 A/cm²). Since hair removal is mainly done for cosmetic reasons and is mostly important for cases of darker hair, the hair itself will absorb light in a wide spectral range in the visible and the near infrared. The shorter wavelengths generated by the flashlamp may be removed since they do not penetrate as deeply into the skin (as can be seen from Figure 12).

In one embodiment a long pass filter that transmits only wavelengths longer than the cut off wavelength of the filter is used. A cut off wavelength of 600 nm is used in a preferred embodiment when the person being treated has fair skin. A cut off wavelength in the range of 700 to 800 nm is used in the preferred embodiment to treat people with dark skin. According to the invention, the filters may be, for example, dichroic filters or absorbing filters. The desired spectrum can also be achieved by more than one filter or by band-pass filters.

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Light from flashlamp **301** is coupled to the skin through a transparent window **308** and a coupler **310**. As shown in Figures 13 and 14, window **308** is placed on transparent water based gel **103**. In use, the operator holds hair remover **300** by handle **304**, and places it on the area of skin where treatment is desired (and gel **103** has been applied). Transparent window **308** creates a well defined flat surface on gel **103**, through which light enters into gel **103** and into the skin.

The operator selects the pulse and energy fluence parameters on a control unit (not shown). The power and control unit are preferably housed in a separate box and will include power from a capacitor charged to a high voltage by a DC power supply, wherein the capacitor is discharged through the flashlamp. Hair remover **300** can be connected to the power and control unit via a flexible cable that allows easy aiming of the device when aiming it to the treatment area on the patient's skin.

Pulse length control can be achieved by using a few pulse forming networks that can generate different pulse widths. Alternatively, an opening **309** may include a solid state opening switch that can stop the discharge at a time preset by the operator, thus controlling the pulse width. These elements of the device are well known and can be easily constructed, or replaced by similar elements, as one skilled in the art will know.

After the parameters have been selected, the operator fires the unit by pressing a switch that can be located in a variety of locations.

A total fluence on the order of 10 to 100 J/cm² will successfully remove the hair. This fluence can be determined from the requirement of reaching a high enough temperature of the hair and hair follicle, and considering the penetration of light, through the skin and into the hair and hair follicle, absorption of light in he hair and hair follicle, specific heat capacity of the hair and the hair follicle, and the cooling of the hair during the pulse by heat conductivity to the surrounding skin.

Coupler **310** transmits light from flashlamp **301** to gel **103** and to the skin. The coupler can be comprised of a hollow box with internally reflecting walls that act as a light guide for the light generated by flashlamp **301**, to transmit the light (electromagnetic energy) to the skin. Coupler **310** may alternatively be made from other material, for example, a solid transparent material such as glass or acrylic in which light reflection from the walls is achieved by using total internal reflection on the side walls.

Coupler **310** is used, in one alternative embodiment, to control the angular distribution of the light rays impinging on the skin. Light rays will

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hit the hair or the hair follicle predominantly when they are traveling in a direction perpendicular to the plane of the skin. A distribution of light rays that has a relatively wide angular divergence when treating shallow hair is desirable to direct a large portion of the energy to the hairs and follicles.

5   Conversely, a narrow divergence is preferable when deep penetration is desired.

In one embodiment both shallow and deep penetration is obtained by using a two stage treatment process. A narrow divergence beam is used first to treat the deeper hair follicles, while a high divergence beam is used

10   to treat the top of the hair follicles. Suitable couplers having an exit beam with a greater or smaller angular divergence are shown in Figures 4 and 5 and are described hereinabove. The user can select the type of coupler according to the depth of hair being treated.

Clinical tests have been performed on hair on the legs of a few

15   patients. Hair was removed for at least two months without observing any hair growing back on the exposed areas during this period. The experiments were performed with high fluences, i.e., up to 45 J/cm^2 in each exposure. The spectrum used covered the range of 570 to 1,100 nm and the fluence was supplied in a triple pulse with delays of 50 to 100 msec between pulses.

20   The pulse sequence enabled hair removal with minimum pain and no damage to the skin. The transparent gel that was used in these experiments was a water based ultrasound gel, such as that commonly available.

Thus, as described herein with respect to Figures 1-14, an incoherent light source may be used both for depilation and coagulation of blood

25   vessels.

Figures 15-19 and their accompanying descriptions are reproduced from U.S. Pat. application 08/795,677. The present invention concerns an integrated apparatus which includes combination of embodiments derived from U.S. Pat. Nos. 5,626,631 and 5,683,380 and U.S. Pat. application No.

30   08/795,677.

The following is a description of the embodiments described in U.S. Pat. application 08/795,677, their uses and advantages.

In depilation devices prior to Tankovich each hair was individually treated by inserting a radiation probe into the hair duct and irradiating the

35   hair shaft and follicle directly. By directing energy at a single hair with not intermediate tissue, the selection of an appropriate wavelength was not a significant issue, since the radiation was focused at the actual hair to be treated. Tankovich improved this method by allowing a larger area of skin

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(and a plurality of hairs) to be treated at once. A drawback to this method is that significant portions of human tissue are irradiated together with the hair shafts causing skin overheating.

Tankovich addressed this over-heating problem by selectively heating individual hairs. This selectivity was provided by contaminating the hairs, typically by coating them with a carbon/oil (or other) mixture to make them especially good absorbers of radiation at particular wavelengths. The wavelengths were chosen such that the tissue surrounding the hair was relatively transparent (i.e., nonabsorbent) to those wavelengths. By providing an abnormally absorptive contaminant material, very low levels of radiation can be applied that are sufficient to heat the contaminant but not the surrounding tissue.

To reduce skin heating, Tankovich employed a source of 1,060 nm radiation (his "near infrared" embodiment) which would penetrate the skin more deeply, thus allowing more energy proportionately to penetrate the skin and be absorbed by the carbon coating on the hair shafts. By doing this, Tankovich was able to reduce the total energy fluence applied to the skin during a treatment by a factor of 20, since the absorber's (carbon) absorptivity was unaffected by the change in wavelength, and thus would be receiving and absorbing significantly more energy proportionately than the epidermis at the 1,060 nm wavelength. In this manner Tankovich could reduce the energy per pulse applied to the skin to less than 60 mJ/cm^2.

Such a method would not work to reduce or eliminate skin heating if the radiation absorber was melanin in the hair shaft, however, since the ratio of the absorption coefficient of hair and the absorption coefficient of skin remains substantially constant in the 1,060 nm range. This relationship was uncovered by the present inventors who calculated the absorption coefficient of hair using the method suggested in B. C. Wilson, and S. L. Jacques, Optical Reflectance and Transmittance of Tissue, Principles and Applications, IEEE Journal Of Quantum Electronics, Vol. 26, No. 12, 1990, pp. 2186-2199. The present inventors used the following equation to estimate the absorption of hair:

$$A= -\ln(T)/d$$

where A is the absorption coefficient, d is the thickness of the hair layer, and T is the transmission of a single layer of human hair. The Present inventors prepared a single layer of human hair and measured the

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transmission (T) of the hair using an integrating sphere and a spectrometer. The absorption coefficient over a range of wavelengths was calculated for a variety of wavelength and is plotted in Figure 15. The absorptivity of hair is about 200 cm^{-1} between 800 nm and 1,100 nm and about 400 cm^{-1} at 700 nm.

When one compares these curves with the absorptivity of epidermis and dermis (provided, for example, by M. J. C. van Gemert, A. J. Welch, A. P. Amin, Is There An Optimal Laser Treatment for Port Wine Stains? Lasers in Surgery and Medicine, Vol. 6, pp. 76-83, 1986), it can be seen that the absorption curves are quite similar, and in fact are in a constant proportion, regardless of the wavelength selected for wavelengths greater than 400 nm. The relatively high absorptivity of the epidermis is due largely to the absorptivity of melanin in the skin, which itself has absorption characteristics close to those of hair. Thus, the constant ratio of absorptivity is to be expected where absorption by melanin in both epidermis and hair is predominates.

To further enhance the subject depilation process, the relative cooling time constants of hair shafts and the epidermis can be factored into the depilation process to increase the heating of the deeper-lying hair shafts while limiting the heating of the epidermis. This is possible in the present application because the present treatment regime targets the hair shafts, which have a longer cooling time constant than the epidermis, unlike the Zaias reference, for example, in which the targeted structure -- melanosomes -- have an extremely short cooling time constant. By targeting the hair shafts instead of the papillae, however, the present inventors do not solve the Zaias problem (destruction of dormant hair papillae having no hair shafts at all) nor receive the Zaias benefits (more complete depilation in a single treatment).

To understand the advantages of using the relative cooling time constants of hair shafts and the epidermis, a cooling time constant, or "thermal relaxation time" is nothing more than the time required for a heated object that has been raised to a temperature T1 above an ambient temperature T2 to cool to a new temperature of (T1-T2)/e. In other words, the length of time required for the object to cool to a temperature that is about a third as far above ambient as its original temperature. The longer the time required for an object to cool, the better that object is insulated. The shorter the time constant, the less well-insulated that object is. This is true whether the object is a melanosome, a hair shaft, a planet or a piece of

toast. The subject method and apparatus is directed to depilation by targeting melanin in hair shafts, by heating the hair shafts and allowing the hair shafts to conduct heat into and destroy the surrounding tissue. It is critical, therefore, to supply energy to the hair shafts at least as fast as energy is removed by conduction or radiation into the surrounding tissue.

If the energy is not absorbed by the hair shafts at a rate greater than the rate at which it is removed, the hair shafts will never heat up significantly, and thus, they will never heat the surrounding tissue to a temperature sufficient to destroy them. This is the problem faced by Zaias. Since Zaias needed to heat melanosomes containing melanin, he was required to put energy into the melanosomes at least as fast as it was being removed by conduction into the surrounding tissue. The cooling time constant for the melanosomes was on the order of one microsecond. In effect, a melanosome heated to a temperature 100 degrees above ambient would cool to 36 degrees above ambient in about 1 microsecond; to 13 degrees above ambient in about 2 microseconds; to 5 degrees above ambient in about 3 microseconds; and to less than 1 degree above ambient in about five microseconds. A cooling time constant of less than a microsecond, as Zaias states, requires a pulse of radiation that will heat the melanosome within one micros.

The cooling time constant of the epidermis is several orders of magnitude greater than that of melanosomes. Depending upon the location and thickness of the epidermis, it can range from between 1 millisecond to perhaps 15 ms. This is over 1,000 times as long as the 1 microsecond cooling time constant of melanosomes noted by Zaias. Any energy that the Zaias device provides to melanosomes must pass through the epidermis before it can be absorbed by the melanosomes in the hair papillae, and thus the epidermis will be heated at the same time. Over a time interval of 10 microseconds, for example -- a rough estimate of the time required for a melanosome to cool to ambient temperature -- the epidermis will only cool by a small fraction of a degree. Given the greater than 1,000 to 1 ratio of time constants, the epidermis is almost perfectly insulated in comparison to the melanosomes. Given this perfect relative insulation, the Zaias system must heat the melanosomes in the shortest time possible at the highest possible rate to avoid overheating the skin.

Unlike the Zaias device, the present invention targets hair shafts which have substantially more mass and a much longer time constant than the Zaias melanosomes. Indeed, the time constant of the deep hair shafts

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lying in subcutaneous fat is substantially larger than the time constant of the epidermis itself, as the present inventors discovered by experimentation. This difference can be employed advantageously to significantly reduce epidermal overheating.

To determine the thermal time constant of hair shafts and hair papillae lying in subcutaneous fat, a series of experiments were performed. The thermal properties of hair and hair follicles are determined by the thermal properties of their various constituents. Figure 16 illustrates a typical cross-section of surface tissue and hair down to a depth of about 3 mm. An epidermal layer 210 is disposed at the surface of the skin, and typically has a depth of between 0.05 and 0.1 mm. Below thepidermis lies a dermal layer 212 which commonly extends to a depth of between 1 and 2 mm. Below the dermal layer 212 is a layer 214 of subcutaneous fat which may be several millimeters thick. A hair bulb or papilla 216 is embedded in the fat layer 214. The hair shaft 218 extends through the hair follicle 220 through the surface 222 of the skin.

The thermal properties of hair follicle 220 are very close to the thermal characteristics of the dermis is 212 itself. Heat conductivity of follicle 220 is about 0.6 W m^{-1} °C^{-1}. The specific heat of follicle 220 is about 3.5 x 10^3 J kg^{-1} °C^{-1}. Density of follicle 220 is very close to the density of water, or 1,000 kg m^3. Papilla 216 is usually located in the subcutaneous fat layer 214 at a depth of more than 2 mm. The thermal properties of fat were presented in L. O. Svaasand et al., Thermal conductivity of fat is about 0.3 W m^{-1} °C^{-1}. Its specific heat is 2,2 x 10^3 J kg^{-1} °C^{-1}. The density of fat is 815 kg m^3. The major part of the hair shaft consists of elongated cells that contain pigment granules in dark hair, and contain predominantly air in light hair. The thermal properties of hair cells are close to those of protein. The thermal conductivity of hair cells is about 0.3 W m^{-1} °C^{-1}, The specific heat of hair cells is about 1.09 x 10^3 J kg^{-1} °C^{-1}. The density of hair cells is about 1540 kg m^3.

On the basis of the above factors, the present inventors estimated the cooling time constant of hair shafts and follicles to which they are coupled. The following relationship was employed:

$$t = d^2/16a$$

where d is the diameter of the hair follicle, varying typically between 150 μm and 300 μm, t is the cooling time constant and a is thermal diffusivity.

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Using the equation above, a 150 m diameter hair follicle provides cooling time constant of about 10 ms, and a 300 m diameter follicle provides a thermal time constant of about 40 ms. The calculations were based upon the assumption that the follicle is surrounded by dermis, a relatively good conductor of heat.

To experimentally confirm the above estimations, the present inventors conducted an experiment on a single hair shaft and follicle embedded in a water-based gel medium. The water-based material models the dermis surrounding the hair and follicle. It was selected because it has a thermal capacity and thermal conductivity similar to that of dermis. A gel was used to eliminate any heat transfer from the hair and follicle due to convection currents which might occur if a liquid was used. There can be no convective heat transfer from the hair and follicle to the dermis since the dermis is a resilient solid.

The hair and follicle were heated using a radiation source emitting radiation at 600-1,200 nm. Water, like dermis, does not significantly absorb radiation at this wavelength, and thus the hair is heated in the gel much as hair would be heated in dermis. The radiation source emitted power at a level that met two conditions: (a) a single pulse of a predetermined duration t would not damage the hair, and (b) a pulse of duration 2t would damage the hair.

Once the appropriate time delay was determined, a series of test runs were carried out in which two sequential pulses of duration t were applied to a hair. A delay was provided between each sequential pulse in each experimental run. The delay had a duration of 1 ms in the initial test run, and was increased 1 ms at a time for each successive test run.

After each test run (i.e., two sequential pulses plus a variable delay between pulses), the irradiated hair and follicle were checked for damage. The hair and follicle showed damage until the delay between sequential pulses reached 6 ms, at which time no evidence of hair and follicle injury were indicated. This confirmed that the cooling time constant of hair in a predominately water-based medium was on the order of 4-8 ms.

Deeper-lying hair papillae and the shafts that extend into them are embedded in the subcutaneous fat layer, as shown in Figure 16. Since this layer has a lower thermal conductivity, it conducts less heat out of the hair shaft and follicle than the dermis does. This reduced conductivity means that the cooling time constant of that portion of a hair shaft or follicle

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surrounded by subcutaneous fat is longer than the cooling time constant of that portion of a hair shaft or follicle surrounded by dermis.

This assumption was experimentally confirmed in a series of experiments similar to those described above in which a hair was heated in a water-based gel. In these experiments, a black hair shaft and attached follicle were placed in corn oil and similarly heated with radiation. Corn oil was selected because it has thermal properties similar to those of subcutaneous fat.

A similar series of double pulse test runs were made varying the time delay between pulses to determine how long it takes for the hair and follicle to cool off. Damage to the hair and follicle could still be detected after a delay of 30-40 ms between sequential pulses, compared with the delay of 4-8 ms of the water-based medium. Oil (or fat) is therefore a superior insulator when compared with water (or dermis).

Epidermis has a relatively rapid cooling time constant when compared to either hair shafts and follicles in dermis or in subcutaneous fat. The cooling time for a typical epidermal layer cooling in air can be expressed by:

$$t = d^2/4a,$$

where t is the cooling time constant, d is the thickness of the epidermal layer, and a is the thermal diffusivity of the epidermis. For a typical epidermal layer, $d = 0.1$ mm, and $a = 3 \times 10^{-7}$ m^2sec^{-1}. Given these values, the thermal time constant for an epidermal layer is about 8 ms. This cooling time constant can be further reduced to a few milliseconds by applying a water-based gel to the surface of the epidermis (i.e., the surface of the skin prior to treatment).

By tailoring the radiation to target the deeper portions of the hair shaft and follicle, one can make use of the difference between the hair shaft and follicle cooling time constant and the epidermal cooling time constant to more effectively depilate. Since the cooling time constant of the epidermis is longer than the cooling time constant of the hair and follicle in subcutaneous fat, radiation that will heat both (e.g., radiation at 800-1,200 nm wavelengths) can be applied at a fairly low rate (e.g., 10-200 J/cm^2 distributed over a long interval of illumination of between 1-100 ms). This low rate of energy input to the skin will allow heat to be conducted away from the relatively short cooling time constant epidermis (e.g., 1-10 ms)

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while a greater portion of energy is retained by the relatively long cooling time constant subcutaneous fat layer (e.g., 20-40 ms). Conversely, if the skin is irradiated quickly in a fraction of a millisecond with a dose of radiation sufficient to heat the lower-lying hair bulbs to a damage temperature (e.g., Zaias), both the epidermis and the lower-lying hair bulbs will be damaged since the temperature of both will be increased much faster than either the epidermis or hair shafts will be cooled.

As mentioned above, the cooling time constant for the epidermis, the amount of melanin in the epidermis, hair shafts and follicles, the cross-sectional area of the hair shafts, and the depth of the subcutaneous fat layer can all vary. For this reason, the irradiation time for depilation must be at least 1 millisecond in length, although it may vary up to 100 ms or more. The "irradiation time", is the time interval during a treatment in which radiation is applied to elevate the temperature of the targeted hair and follicles. In the event a single long pulse is employed, it is the duration of that pulse, when a sequence of pulses is employed, it is the cumulative duration of the sequence of pulses. Similarly, the energy provided to the skin during a treatment may vary as well, from between 10 and 200 J/cm^2 of skin being irradiated.

If the degree of energy absorption of the epidermis is high or the epidermal cooling time constant relatively long with respect to the hair shafts, which would be the case with dark-skinned individuals, or individuals having relatively light hair, the radiation is preferably applied at a lower intensity (i.e., closer to 10 J/cm^2 than to 200 J/cm^2) with a longer irradiation time (i.e., closer to 100 ms than to 1 ms) to provide sufficient time for thermal energy to be conducted away from the epidermis. On the other hand, where the melanin in the epidermis is relatively low, thus reducing the absorption characteristics of the epidermis, and the hair being targeted are relatively dark, the irradiation time can be lowered and the energy per treatment increased. In any event, the radiation should have a wavelength of between 800 and 1,200 nm.

The radiation during a treatment need not be applied to the skin in a single long pulse having a constant radiation intensity over the entire irradiation time. The treatment can also consist of a series of pulses applied sequentially to the skin to be depilated with a time delay between each pulse of between 1 and 300 ms. This is especially useful when the intensity of the radiation source cannot easily be reduced for a particular low intensity treatment. By providing the treatment in a sequence of pulses, a single

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relatively high intensity radiation source can be adapted for use in depilating a variety of skin/hair combinations.

One embodiment of a device adapted to depilate the skin according to the previously described process is shown in block diagram form in Figure 17. Depilator 224 includes a computer 226, a radiation source 228, a display 230, a data entry device 232, a radiation delivery system 234, a hand piece 236, and a cooling system 238.

Computer 226 is coupled to radiation source 228 to regulate the emission of radiation by source 228. By selectively signaling source 228, computer 226 controls treatment parameters, such as pulse energy density (i.e., radiation intensity), radiation pulse duration, the number of pulses to be applied in a single treatment and the delay between the pulses. The computer is also coupled to data entry device 232, which is typically a keyboard. The operator, in turn, selects the pulse energy density, radiation pulse duration, the number of pulses to be applied in a single treatment and the delay between pulses via data entry device 232, to which the computer responds by selectively signaling source 228 during treatment. To have the widest performance range, the computer will preferably allow the operator to select between a plurality of irradiation times of between 1 and 100 ms, a plurality of pulse energy fluences that range between 10 and 200 J/cm^2 of treated skin per pulse (or per treatment), a plurality of delays between successive pulses during a treatment that range between 1 and 300 ms, and a plurality of different numbers of pulses during a treatment ranging between a single pulse and 10 pulses.

Radiation source 228 emits radiation having a wavelength between 800 and 1,200 nm. A preferred source is a Nd:YAG laser emitting at a wavelength of 1,064 nm.

Display 230 displays the radiation parameters, either default parameters that have been previously stored in computer 226, or parameters that have been selected by the operator using data entry device 232. In this manner the operator can determine the mode of operation of the depilator and verify that the computer has received the parameters selected by the operator using the data entry device.

Data entry device 232 is preferably a keyboard, although a track ball, mouse, digitizer pad or light pen (to be used in conjunction with display 230) may be provided. Data entered into the display device is communicated to computer 226 which controls radiation source 228.

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Radiation delivery system 234 couples light generated by radiation source 228 to the treatment site on the surface of the skin. It is preferably a jointed arm (shown here) or a flexible fiber optic fiber or bundle of fibers.

Referring to Figure 18, the radiation delivery system terminates in hand piece 236 which is coupled to the end of light delivery system 234, such that radiation produced by source 228 is conducted from the source through the radiation delivery system, through the hand piece to the treatment site. The hand piece preferably, has an enlarged aperture 240 to which light guide 242 is coupled. The aperture may he round, oval, or rectangular depending upon the application. For small treatment sites, a hand piece having a round or oval aperture is preferred. For larger treatment sites, a hand piece having a rectangular aperture is preferred. The hand piece couples radiation to the skin by transmitting it through the aperture and light guide, which itself is in contact with treatment site 244. The light guide is typically a solid, transparent to the wavelength or wavelengths that are transmitted to the skin for treatment. The light guide is preferably made of quartz or synthetic sapphire and is polished. The polished surface produces internal reflections that direct the radiation received from the light delivery system toward the treatment site. Since the present apparatus is directed to heating and damaging deeper-lying hair follicles, especially those rooted in the subcutaneous fat layer, the radiation has to travel through a significant depth of skin - on the order of 2-5 mm to reach these follicles. As the layer of skin through which the radiation travels increases, a greater proportion of that radiation is scattered. The effect of this scattering is to reduce the energy fluence impinging upon tissue at any particular depth. This reduction in energy fluence is particularly pronounced in deeper tissue underneath the lateral edges of the light guide. Thus, to achieve even heating of deep follicles embedded in subcutaneous fat, the smallest cross-sectional dimension of the light guide at the point it contacts the skin should be large, on the order of 2 mm.

A cooling system 238 may be coupled to the hand piece to further reduce the heating of the epidermis. The cooler may include a thermo electric heat pump, conduits through which coolant is circulated or the like. To further limit damage to the epidermis, a gel 246 may be disposed between the light guide and the treatment site before the light guide is pressed against the skin. The gel, which is preferably water-based, enhances heat conduction from the epidermis into the light guide.

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Thus, it should be apparent that there has be provided in accordance with the present invention a method and apparatus for hair removal using long pulse of Nd:YAG laser that fully satisfies the objectives and advantages set forth above.

In accordance with another embodiment of the present invention the Nd:YAG laser hereinabove described is employed for coagulation of blood vessels.

Using fluences of 60-150 Joules/cm^2 (by varying the laser's spot size from 6 to 3 mm^2) several deep vessels were treated. Each treatment was accompanied by pre and post Doppler ultrasound examinations to evaluate the results.

Vessels of 2-3 mm in diameter and depth of 5, 6 and even 9 mm underneath the skin surface were coagulated following a single treatment.

As already mentioned, the present invention is of a combined apparatus which integrates into a single operative unit the incoherent radiation devices described in U.S. Pat. Nos. 5,626,631 and/or 5,683,380, and the laser device described in U.S. Pat. application 08/795,677.

Such an operative unit **400**, which includes a first device **402** which may possess any of the configurations described with respect to the devices of Figures 1-14 and further includes a second device **402** which may possess any of the configurations described with respect to the device of Figures 15-18, is schematically depicted in Figure 19.

The combined apparatus thus includes both laser and incoherent light sources, each of which may be used for depilation or blood vessels coagulation, as hereinabove described in detail.

It will be appreciated that both the first and second devices feature common elements, such as but not limited to, a carrier to render the devices portable, and a computer to operate the devices, receive data of treatment options, record treatment actually applied, etc. Combining the devices into an integrative skin treatment unit offers the user with high versatility on one hand, and cost effectiveness on the other hand.

Thus, according to the present invention provided is a combined therapeutic treatment apparatus for coagulating blood in blood vessels underlying a skin treatment site and for the destruction of hair follicles at the skin treatment site.

According to a prefered embodiment the combined apparatus includes a first device including an incoherent light source operable to provide a pulsed light output onto the treatment site and a driver circuit,

including a switch capable of being electrically turned on and being electrically turned off to thereby provide a first interval of light, connected to the light source to control the pulse width and delay between pulses.

The combined apparatus further includes a second device including a coherent radiation source adapted to emit radiation at a wavelength of between 800 and 1,200 nanometers over an irradiation time of between 1 and 100 milliseconds, to provide a cumulative treatment dose of between 10 and 200 Joules per square centimeter as measured at the treatment site. The first and second devices are integrated in a single operative unit.

According to a preferred embodiment of the invention the first device further includes a housing with an opening, the light source being disposed in the housing, and the housing is adapted to be disposed adjacent a skin treatment site, and wherein the switch is a GTO.

According to another preferred embodiment of the invention the switch and driver circuit limit the first interval to a predetermined duration of less than 100 milliseconds.

According to yet another preferred embodiment of the invention the incoherent light source provides an incoherent light output having an energy fluence of between 6 and 300 J/cm^2 during the first interval.

According to still another a preferred embodiment of the invention the incoherent light source provides an incoherent light output of between 6 and 20 J/cm^2 during the first interval.

Preferably the first device further includes a light guide having a cross-sectional area of no less than 0.3 cm^2 which couples the light output to the treatment site.

Still preferably the light guide has a rectangular cross-section of between 3 and 30 millimeters in width and 10 and 100 millimeters in length.

Yet still preferably the incoherent light source provides an incoherent light output of between 30 and 100 J/cm^2 during the first interval.

According to a preferred embodiment the light source is a flashtube, and the first device further includes a first capacitor electrically coupled to the switch, wherein the switch electrically connects and disconnects the capacitor to the light source.

According to another preferred embodiment the first device further includes a second capacitor operable to be alternately coupled both in series and in parallel to the first capacitor.

According to yet another preferred embodiment the coherent radiation source is a laser.

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According to still another preferred embodiment the coherent radiation source is a Nd:YAG laser.

Preferably the second device further includes a computer responsive to operator input coupled to and controlling the radiation source to provide a

5   plurality of user-selectable irradiation times of between 1 and 100 milliseconds in length, and to provide a plurality of user-selectable cumulative treatment doses of between 10 and 200 Joules per square centimeter of radiation measured at the treatment site.

Still preferably the second device further includes an elongate

10   flexible radiation delivery system having a proximal end and a distal end and adapted to transmit radiation from the proximal end to the distal end, wherein the distal end is optically coupled to the radiation source.

Yet still preferably the radiation delivery system is one of the group consisting of an optical fiber and an articulated arm.

15   According to a preferred embodiment the second device further includes a hand piece having a proximal end and an aperture and adapted to transmit radiation from the proximal end to the aperture, wherein the proximal end is optically coupled to the distal end of the radiation delivery system, and wherein the aperture has a configuration selected from the

20   group consisting of a circle, an oval or a rectangle.

According to another preferred embodiment the second device further includes a solid transparent light guide having a proximal end and a distal end, wherein the light guide is adapted to transmit radiation from the distal end to the proximal end and wherein the proximal end is optically

25   coupled to the aperture of the hand piece and the distal end has a first contact area adapted to be placed in contact with the treatment site.

According to still another preferred embodiment the first contact area has a minimum cross-sectional distance of 2 mm.

According to another embodiment of the present invention provided

30   is a method of coagulating blood vessels underneath a skin treatment site. The method includes the step of irradiating the treatment site with coherent radiation having a wavelength of between 600 and 1,200 nanometers over an irradiation time of between 1 and 100 milliseconds to provide a treatment dose of between 10 and 200 Joules per square centimeter of treatment site

35   over the interval.

Preferably the coherent radiation is generated by a laser radiation source.

Still preferably the laser radiation source is a Nd:YAG laser.

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Yet still preferably the method further includes the steps of providing an operator with a plurality of user selectable irradiation times having a duration of between 1 and 100 milliseconds in length; and providing an operator with a plurality of user-selectable treatment doses having an energy fluence of between 10 and 200 Joules per square centimeter of radiation measured at the treatment site.

According to a prefered embodiment of the method of the present invention the step of irradiating includes the step of coupling the radiation to a spot on the treatment site having a diameter of at least 2 mm.

According to another prefered embodiment the method further includes the step of applying a gel transparent to the radiation to the treatment site.

According to yet another prefered embodiment the step of irradiating the treatment site includes the step of irradiating the treatment site with two or more sequential pulses of radiation.

While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications and other applications of the invention may be made.

WHAT IS CLAIMED IS:

1. A combined therapeutic treatment apparatus for coagulating deep blood vessels underlying a skin treatment site and for the destruction of hair follicles at the skin treatment site, the combined apparatus comprising:

(a) a first device including an incoherent light source operable to provide a pulsed light output onto the treatment site and a driver circuit, including a switch capable of being electrically turned on and being electrically turned off to thereby provide a pulse of light, connected to the light source to control the pulse width and delay between pulses; and

(b) a second device including a coherent Nd:YAG laser radiation source adapted to emit radiation over an irradiation time of between 1 and 100 milliseconds, to provide a cumulative treatment dose of between 10 and 200 Joules per square centimeter of radiation measured at the treatment site, said second device allowing said irradiation time and said dose to be selected such that a deep blood vessel, lying up to nine mm underneath the treatment site becomes coagulated upon treatment;

wherein said first and second devices are integrated in a single operative unit.

2. The combined apparatus of claim 1, wherein said first device further includes a housing with an opening, said light source being disposed in said housing, and said housing is adapted to be disposed adjacent a skin treatment site, and wherein the switch is a GTO.

3. The combined apparatus of claim 1, wherein the switch and driver circuit limit the pulse to a predetermined duration of less than 100 milliseconds.

4. The combined apparatus of claim 3, wherein the incoherent light source provides an incoherent light output having an energy fluence of between 6 and 300 J/cm^2 during the pulse.

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5.   (Amended)   The combined apparatus of claim 4, wherein the incoherent light source provides an incoherent light output of between 6 and 20 J/cm^2 during the pulse.

6.   The combined apparatus of claim 5, wherein said first device further includes a light guide having a cross-sectional area of no less than 0.3 cm^2 which couples the light output to the treatment site.

7.   The combined apparatus of claim 6, wherein the light guide has a rectangular cross-section of between 3 and 30 millimeters in width and 10 and 100 millimeters in length.

8.   The combined apparatus of claim 4, wherein the incoherent light source provides an incoherent light output of between 30 and 100 J/cm^2 during the pulse.

9.   The combined apparatus of claim 1, wherein the light source is a flashtube, and the first device further includes a first capacitor electrically coupled to the switch, wherein the switch electrically connects and disconnects the capacitor to the light source.

10.   The combined apparatus of claim 9, wherein said first device further includes a second capacitor operable to be alternately coupled both in series and in parallel to the first capacitor.

11.   The combined apparatus of claim 1, wherein said second device further includes a computer responsive to operator input coupled to and controlling the radiation source to provide a plurality of user-selectable irradiation times of between 1 and 100 milliseconds in length, and to provide a plurality of user-selectable cumulative treatment doses of between 10 and 200 Joules per square centimeter of radiation measured at the treatment site.

12.   The combined apparatus of claim 11, wherein said second device further includes an elongate flexible radiation delivery system having a proximal end and a distal end and adapted to transmit radiation from the proximal end to the distal end, wherein the distal end is optically coupled to the radiation source.

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13. The combined apparatus of claim 12, wherein the radiation delivery system is one of the group consisting of an optical fiber and an articulated arm.

14. The combined apparatus of claim 13, wherein said second device further includes a hand piece having a proximal end and an aperture and adapted to transmit radiation from the proximal end to the aperture, wherein the proximal end is optically coupled to the distal end of the radiation delivery system, and wherein the aperture has a configuration selected from the group consisting of a circle, an oval or a rectangle.

15. The combined apparatus of claim 14, wherein said second device further includes a solid transparent light guide having a proximal end and a distal end, wherein the light guide is adapted to transmit radiation from the distal end to the proximal end and wherein the proximal end is optically coupled to the aperture of the hand piece and the distal end has a first contact area adapted to be placed in contact with the treatment site.

16. The combined apparatus of claim 15, wherein the first contact area has a minimum cross-sectional distance of 2 mm.

17. A method of coagulating deep blood vessels lying up to nine mm underneath a skin treatment site comprising the step of irradiating the treatment site with coherent radiation of an Nd:YAG laser over an irradiation time of between 1 and 100 milliseconds to provide a treatment dose of between 10 and 200 Joules per square centimeter of treatment site over the interval, said irradiation time and said dose being selected such that the deep blood vessel, the blood vessel lying up to nine mm underneath the treatment site, becomes coagulated.

18. The method of claim 17, wherein the step of irradiating the treatment site includes the step of coupling the radiation to a spot on the treatment site having a diameter of at least 2 mm.

19. The method of claim 18, further comprising the step of applying a gel transparent to the radiation to the treatment site.

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20. The method of claim 17, wherein the step of irradiating the treatment site includes the step of irradiating the treatment site with two or more sequential pulses of radiation.
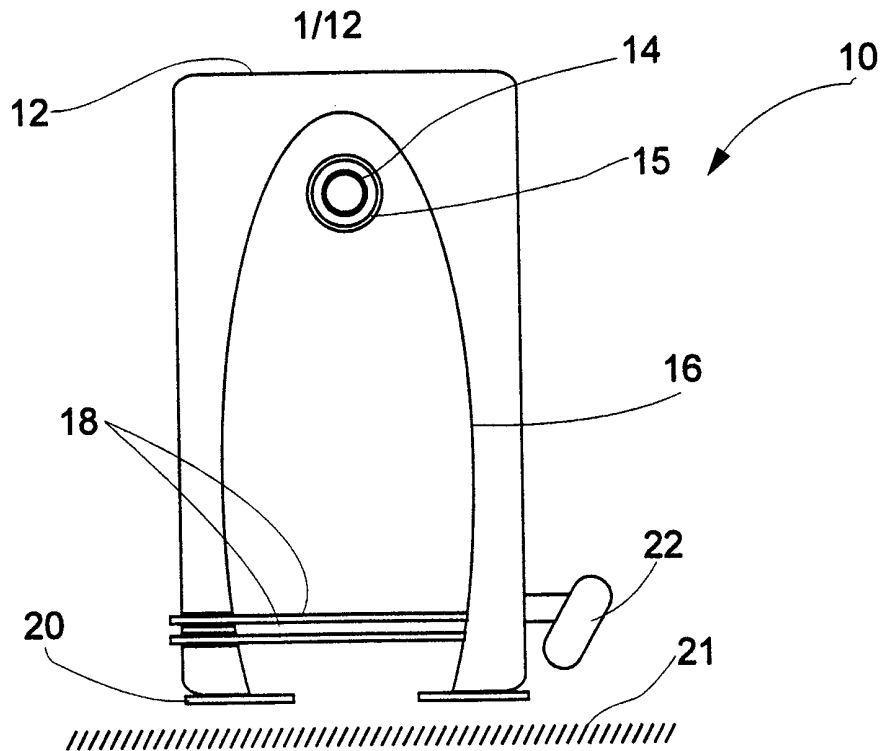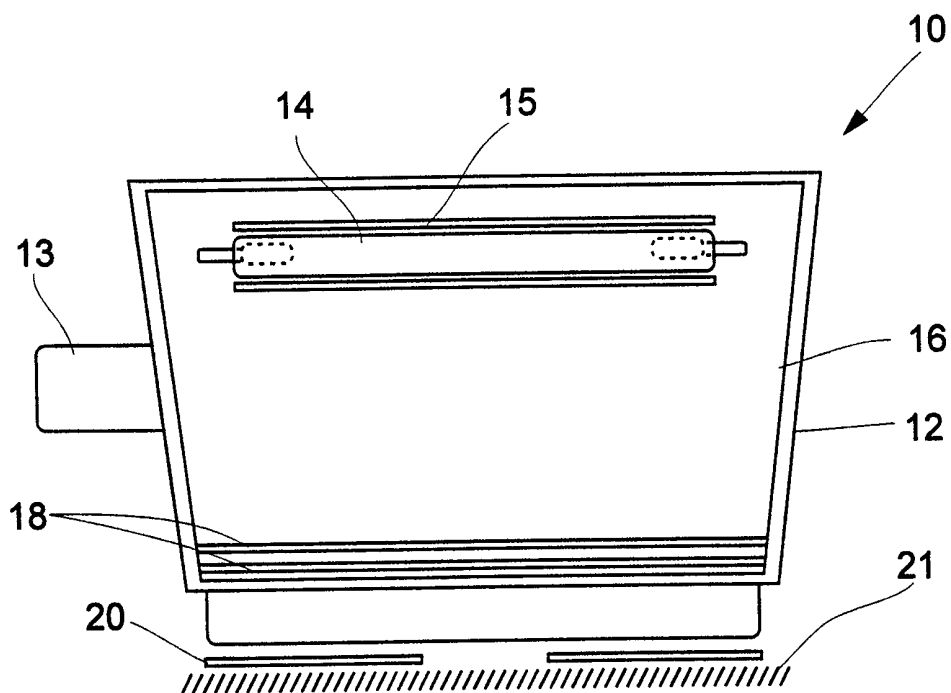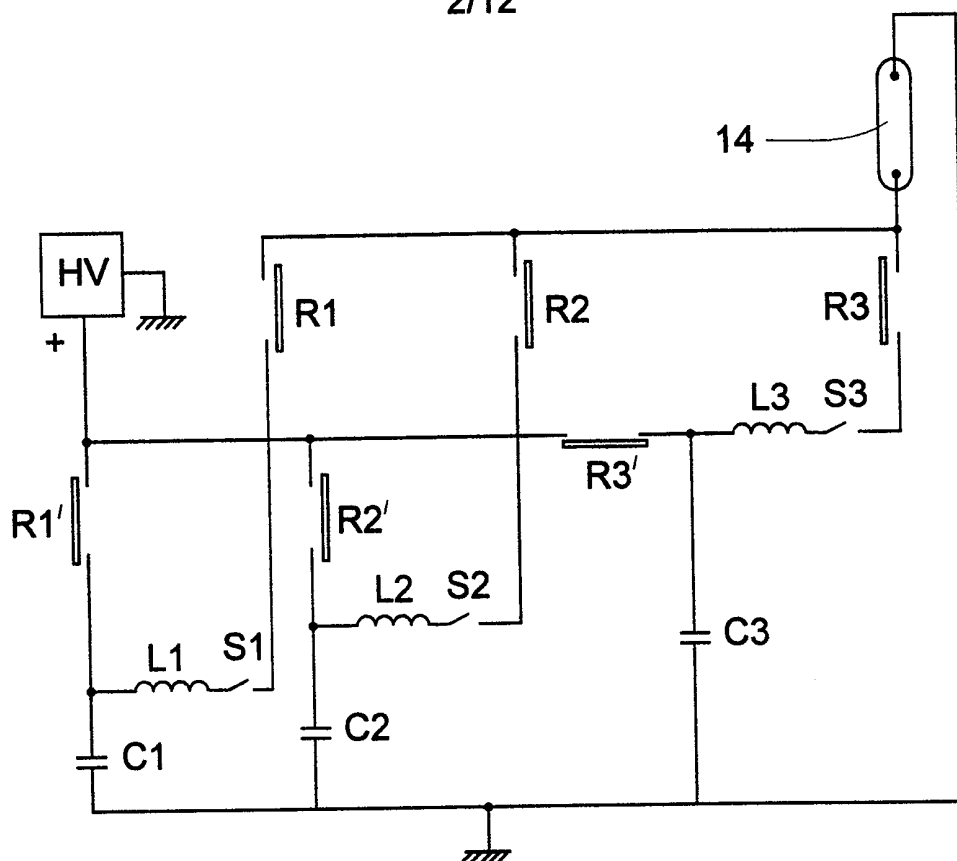
Fig. 1 (Prior Art)
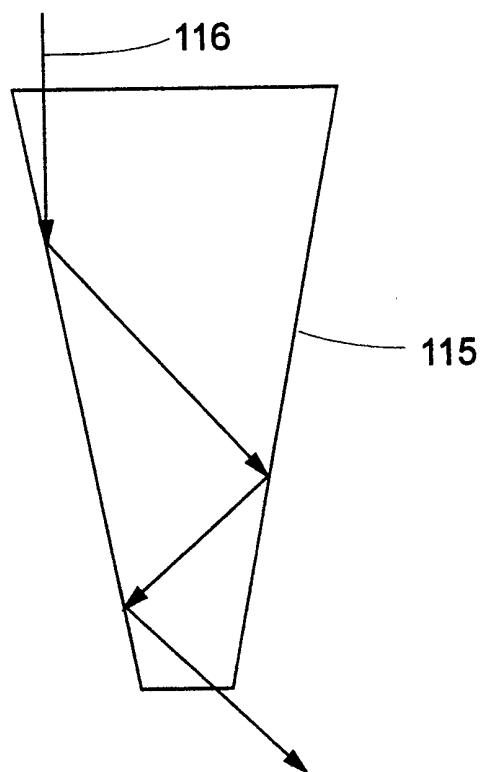
Fig. 2 (Prior Art)

Fig. 3 (Prior Art)

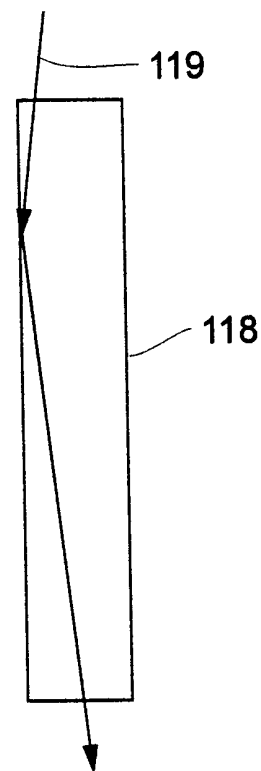Fig. 4 (Prior Art)   Fig. 5 (Prior Art)
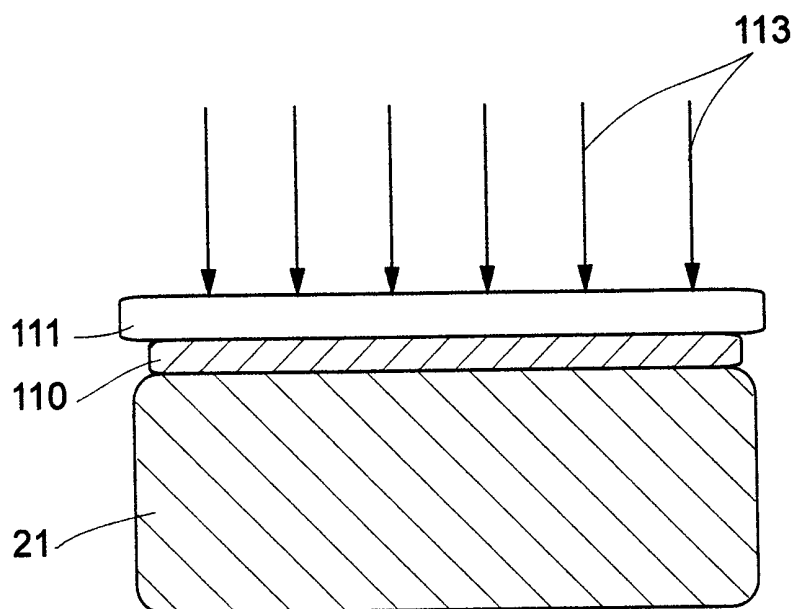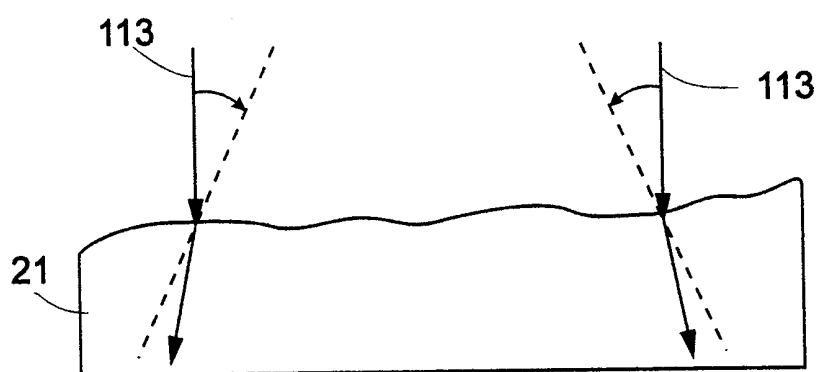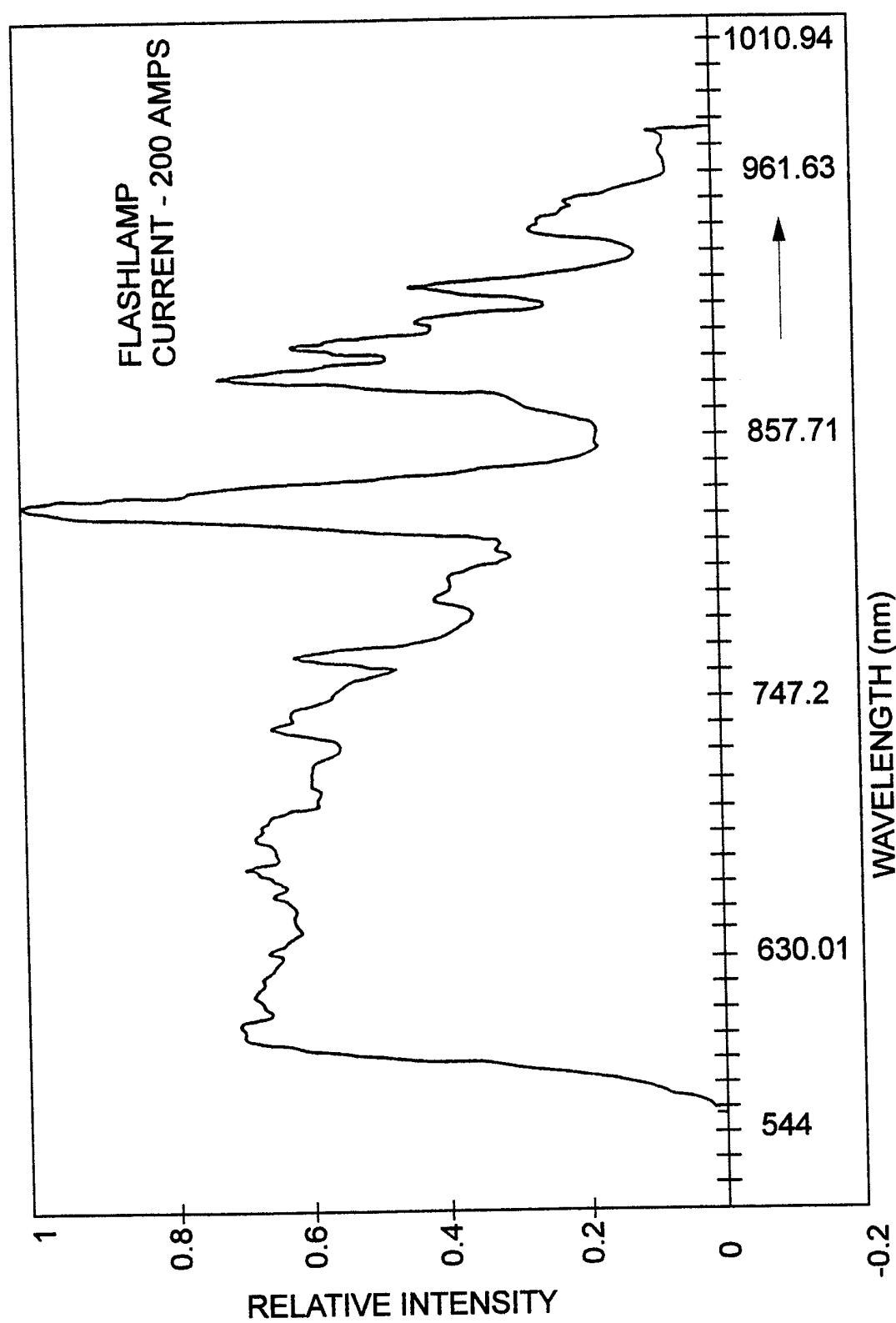
Fig. 6 (Prior Art)

Fig. 7 (Prior Art)

Fig. 8 (Prior Art)

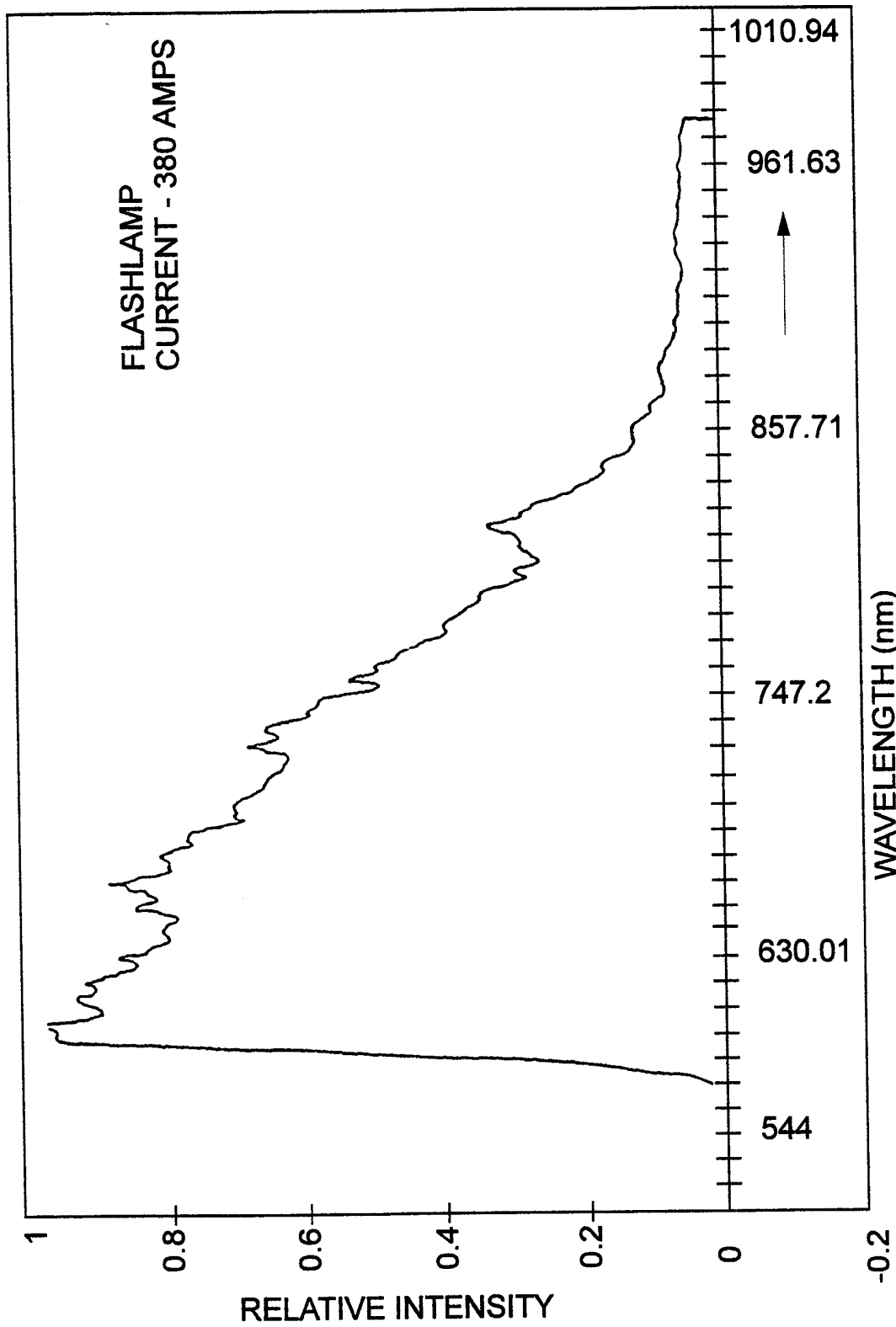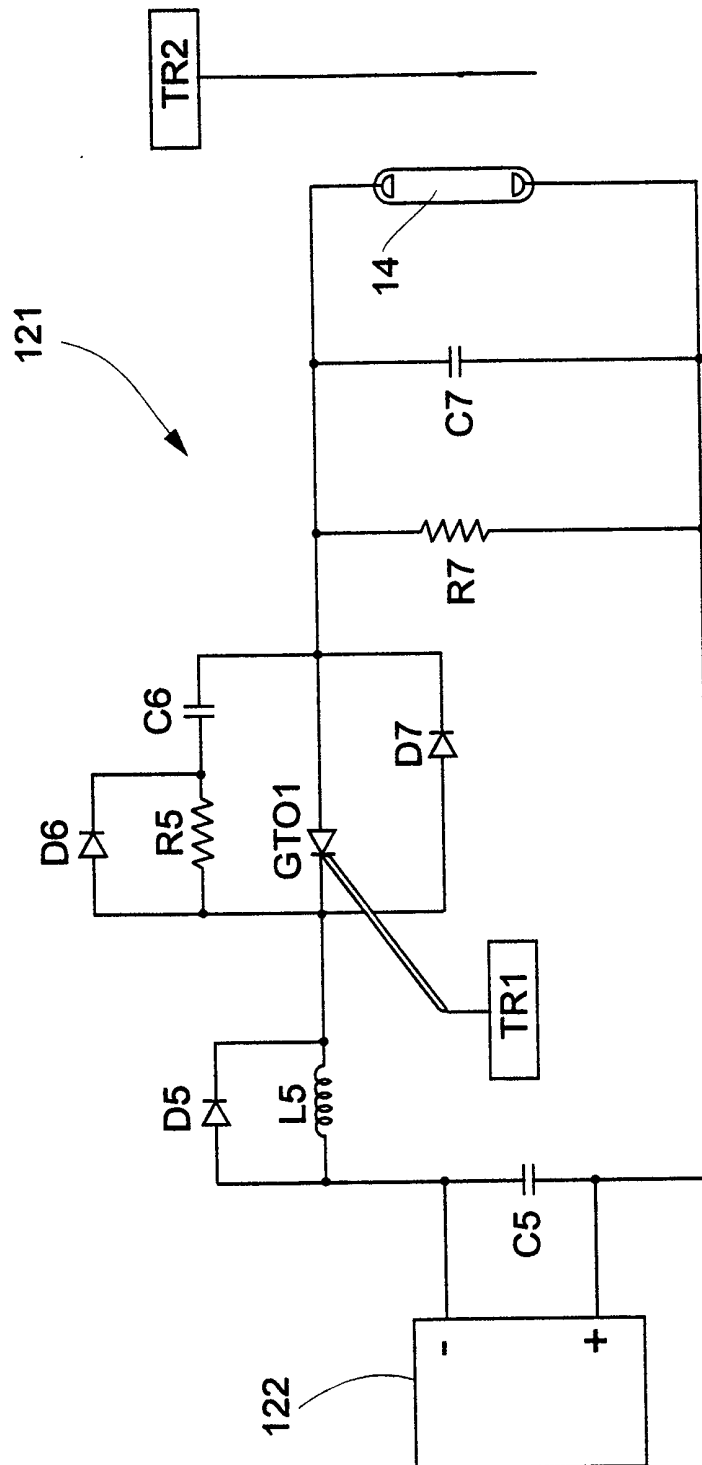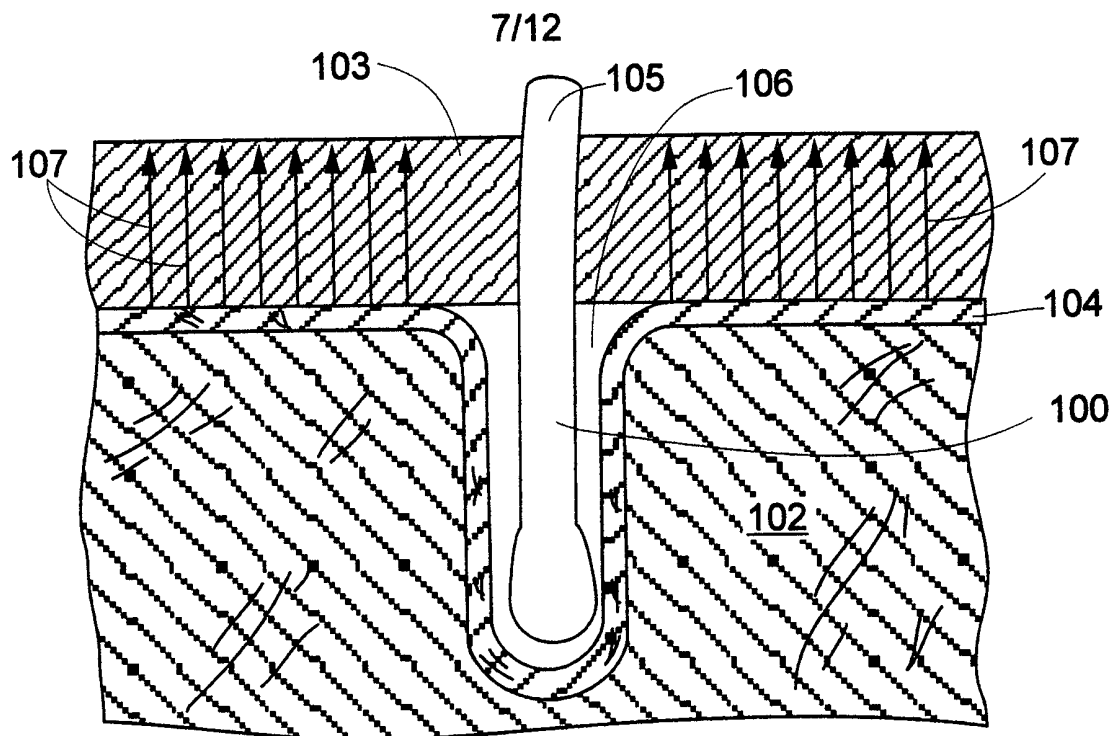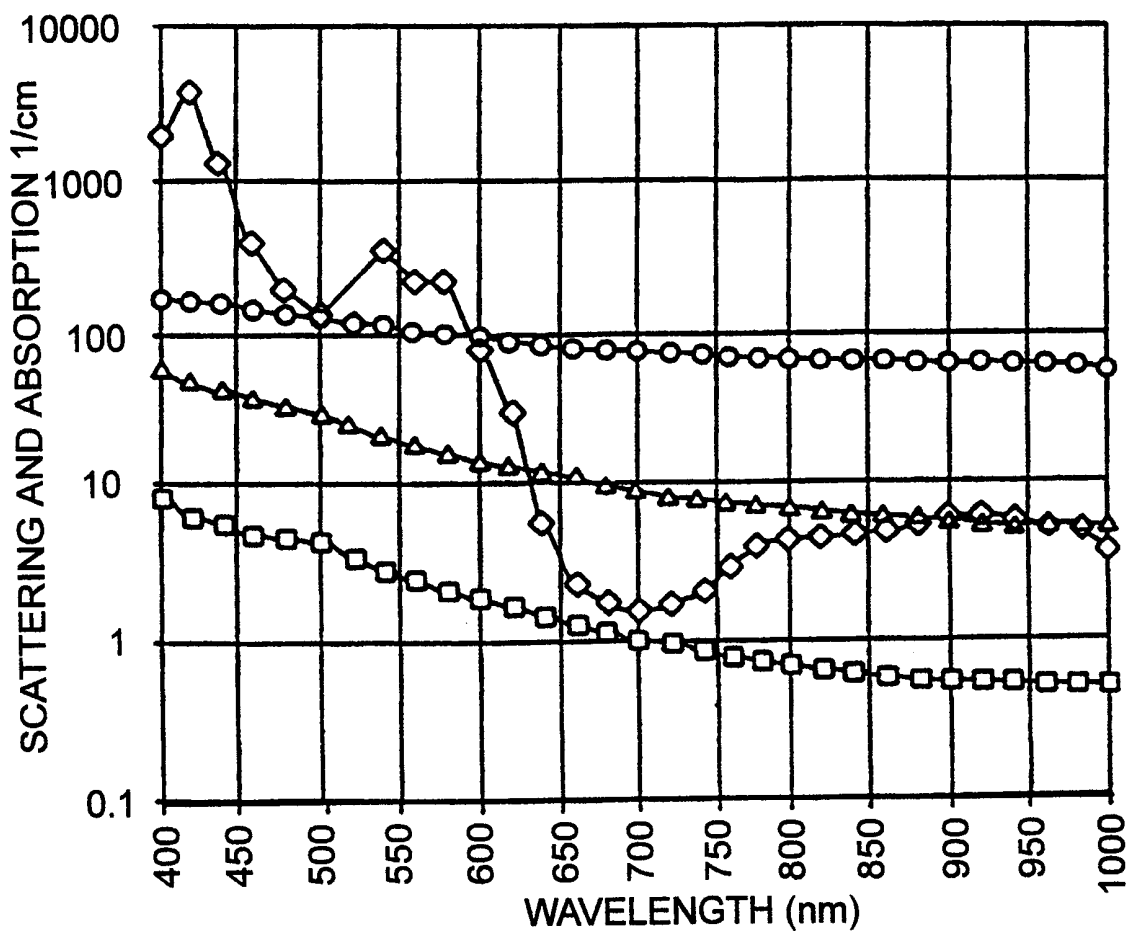Fig. 9 (Prior Art)

Fig. 10 (Prior Art)

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103   105   106

107   107

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100

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Fig. 11

SKIN ABSORPTION
BLOOD ABSORPTION
SKIN SCATTERING
EFFECTIVE SKIN ATTENUATION
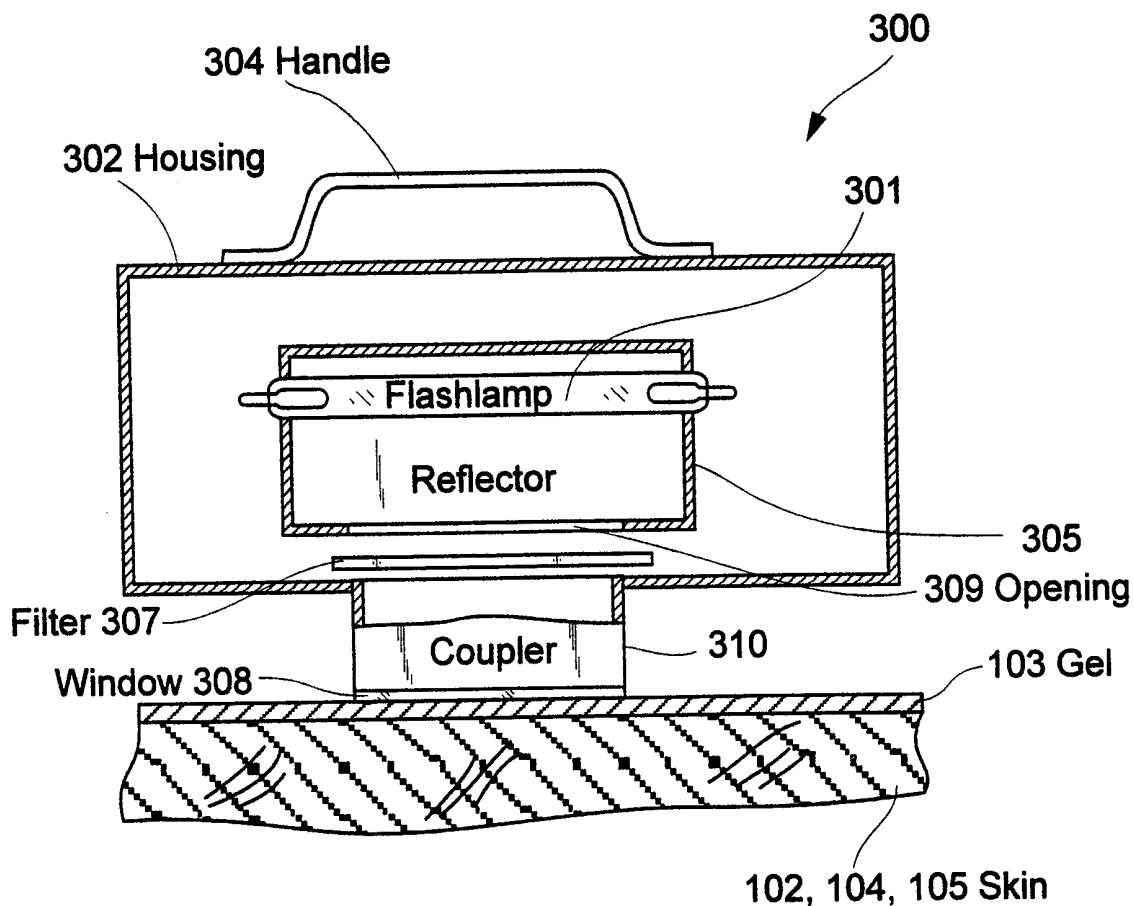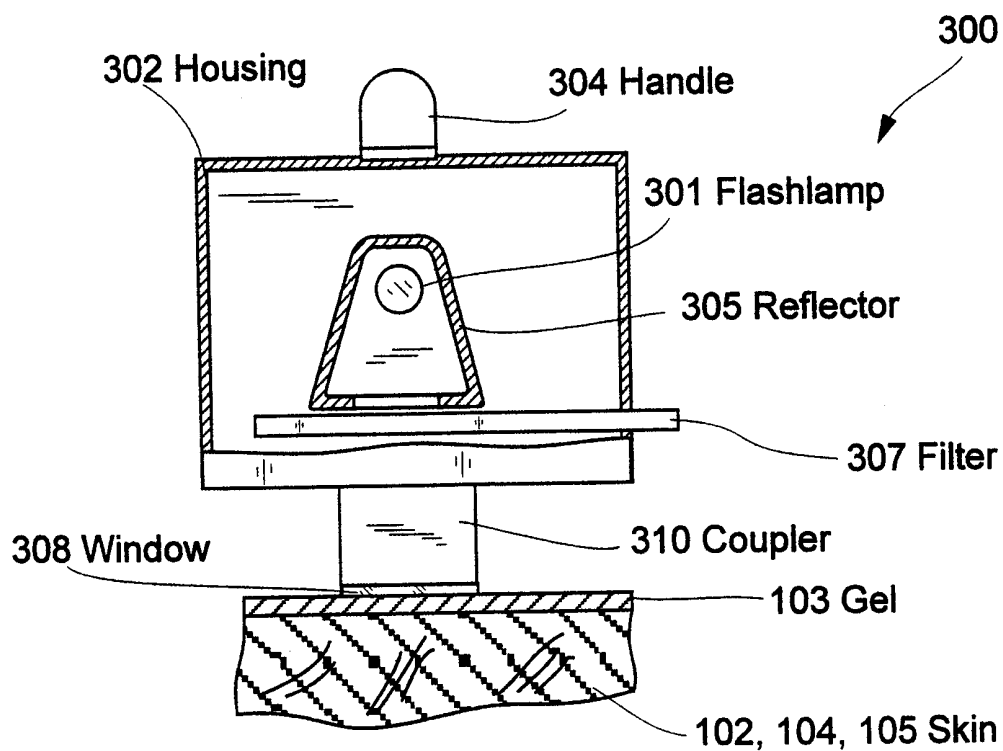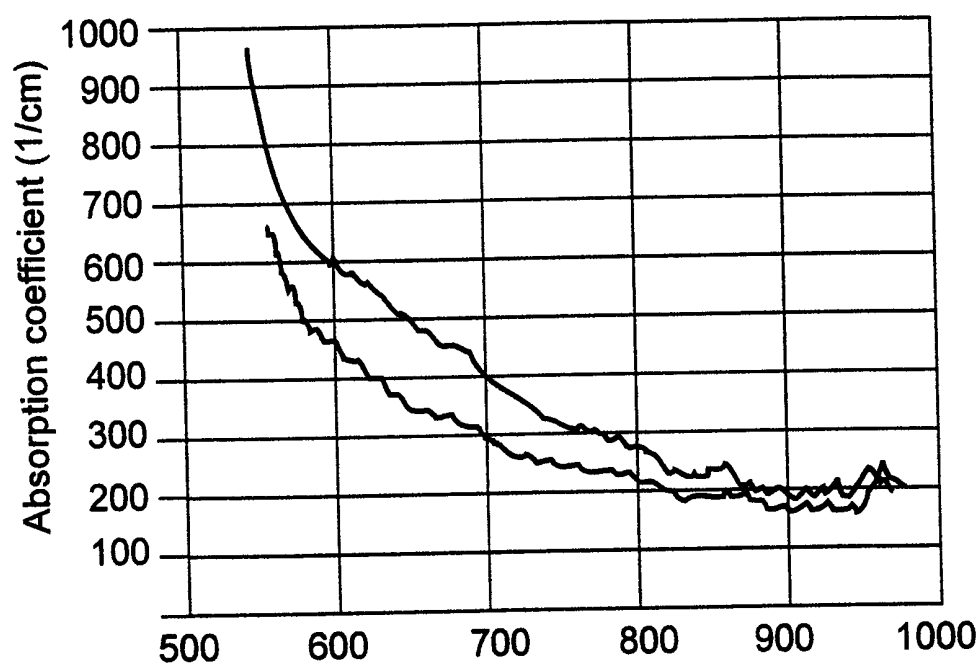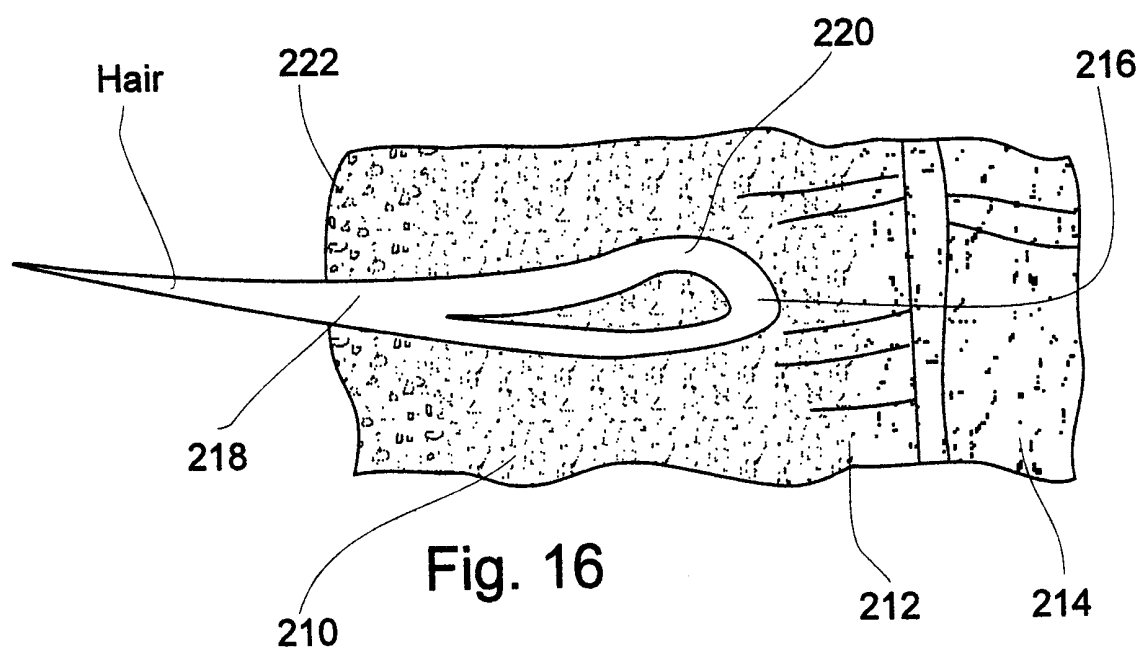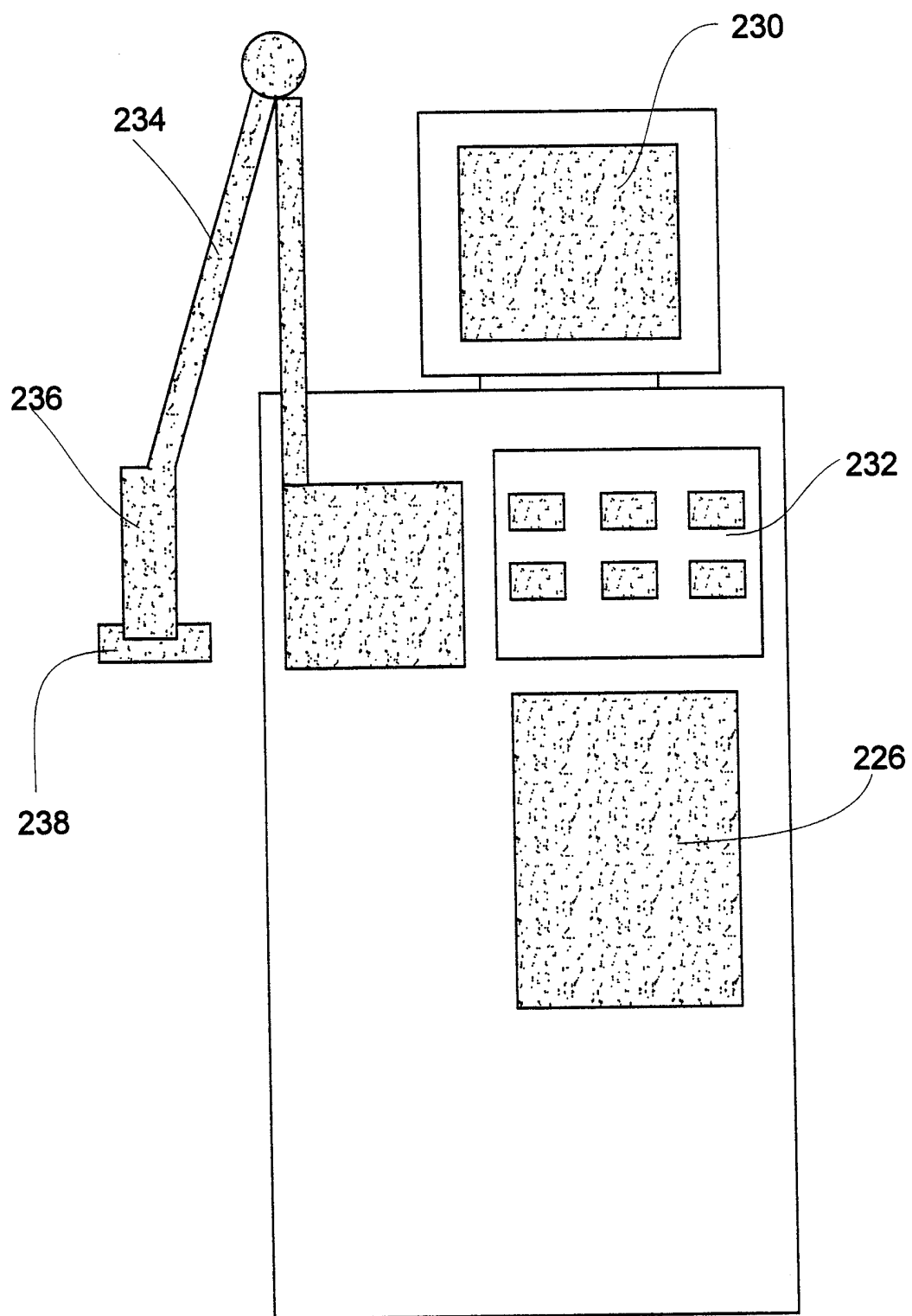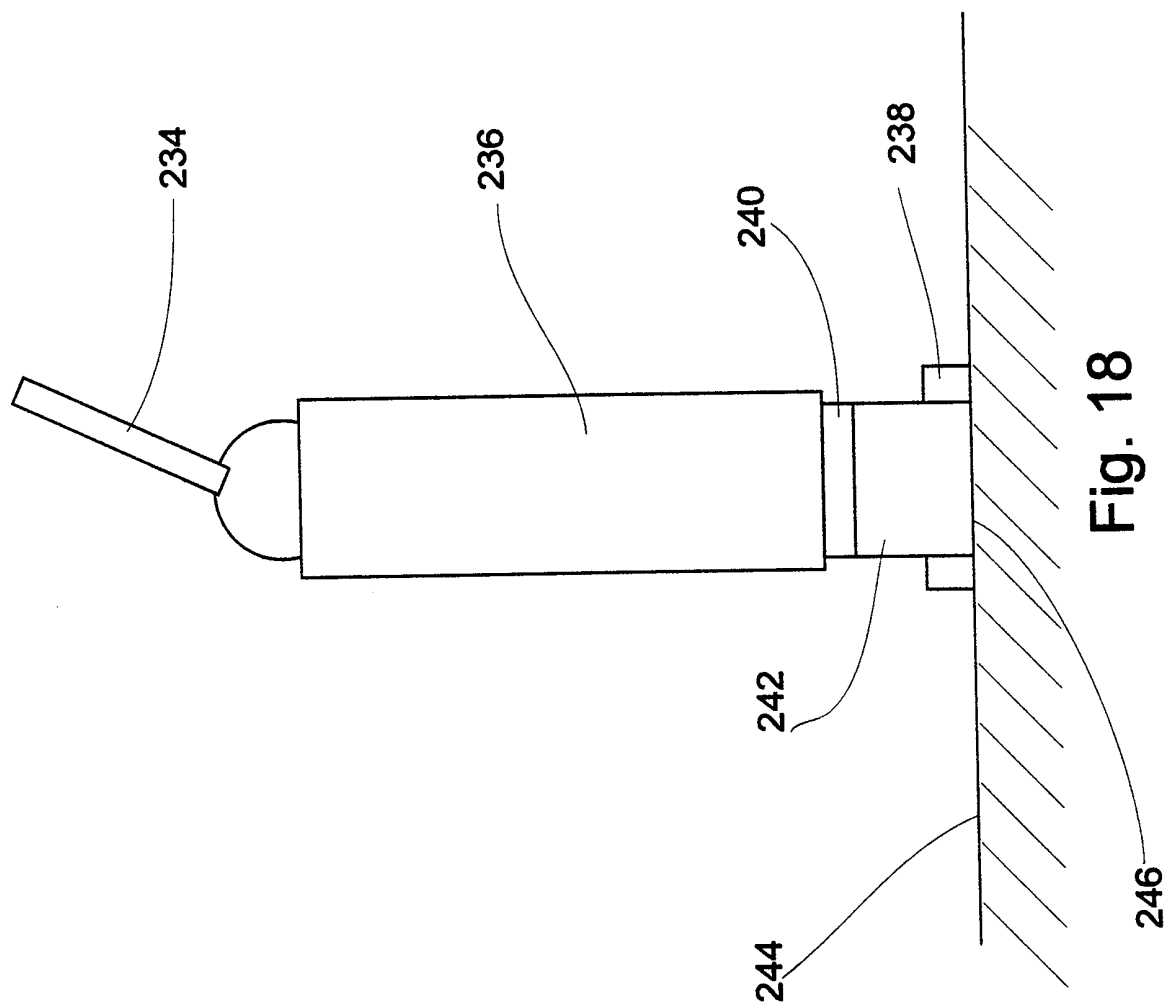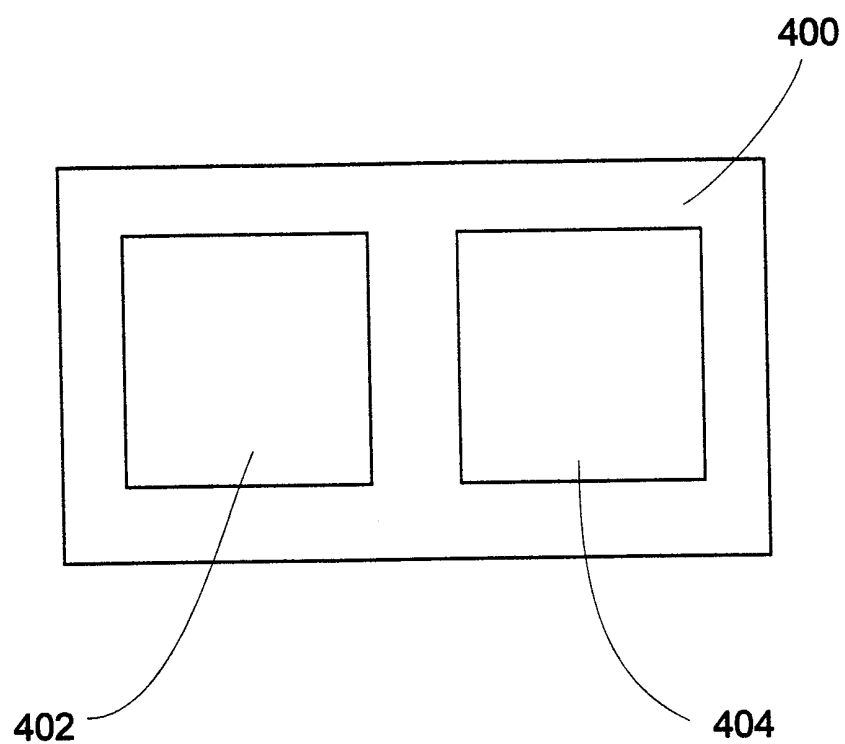
300

304 Handle

302 Housing

301

Flashlamp

Reflector

305

309 Opening

Filter 307

Coupler   310

103 Gel

Window 308

102, 104, 105 Skin

Fig. 13

300

302 Housing   304 Handle

301 Flashlamp

305 Reflector

307 Filter

308 Window   310 Coupler

103 Gel

102, 104, 105 Skin

Fig. 14

Fig. 15

Fig. 16

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Fig. 17

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Fig. 18

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Fig. 19

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61N 5/06
US CL :606/7
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/7, 10, 13-17

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,662,644 A (SWOR) 02 September 1997, entire document.	1-20
Y	US 5,683,380 A (ECKHOUSE et al) 04 November 1997, entire document.	1-20

☐ Further documents are listed in the continuation of Box C.   ☐   See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance		
"E"	earlier document published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed	"&"	document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
07 MAY 1999	07 JUN 1999

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Form PCT/ISA/210 (second sheet)(July 1992)★