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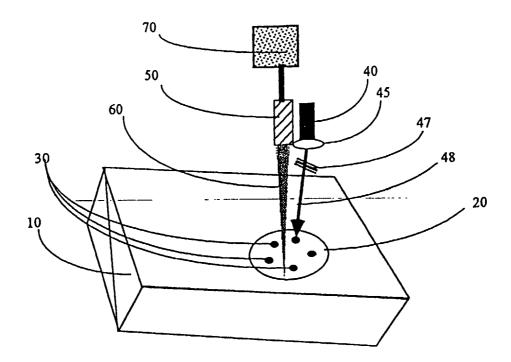
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(54) Title: OPTO-THERMAL MATERIAL MODIFICATION



(57) Abstract: A device and a method for removing or modifying a material substance, comprising: applying energy (60) to an intermediate material, said intermediate material subsequently delivering said energy to the target material (30). The device and the method also utilize active energy removal schemes in order to minimize pain, and/or protect some tissue and/or control tissue modification and removal effects.



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### **OPTO-THERMAL MATERIAL MODIFICATION**

#### **BACKGROUND OF THE INVENTION**

Recent studies of tissue healing process have demonstrated that an injury to the upper layers of a person skin will result in collagen regeneration and the growth of a more elastic, younger looking skin.

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Several methods for generating this effect have been attempted. A mild photodamage will cause some blistering followed by a natural removal of a few outer layers of the skin. Such a process usually results in a younger looking skin. Similar results can be obtained from a mechanical or opto-mechanical removal of a few surface layers by an abrasive or ablative processes. One such process is known as micro-dermabarasion and involves the removal of skin by a stream of Aluminum oxide particles aimed at the surface of the skin. Alternatively, a mechanical scraping of the skin outer surface layers with an abrasive material such as fine sand paper is also deployed to achieve such abrasive effects. A more sophisticate yet expensive method involves Er:YAG laser sources of relatively short pulse duration (for example a few hundreds microseconds long) and a highly water-absorbed wavelength of 2.94 micrometer (Or, alternatively 2.79 micrometer of the Er:YSGG free-running lasers). Other methods involve somewhat longer exposure to somewhat more deeply water-penetrating beams such as those of the 9.6 micrometer and 10.64 micrometer CO<sub>2</sub> laser beams to generate a layer of thermally damaged surface a few hundred micrometer thick. Such deeper skin tissue coagulation usually results in the most aggressive tissue damage and the longest healing time but also in the most effective removal of wrinkles and most effective "Skin rejuvenation" and younger-appearing skin.

These prior art procedures represent some beneficial results but also provide potential risk to the patients in the form of excessive damage and danger of scarring. Abrasive processes often result in excessive cutting, bleeding and pain and sometimes lead to infection, and scarring. Laser treatments are expensive and often result in significant pain excessive thermal tissue damage and lead to permanent scarring.

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### SUMMARY OF THE INVENTION

The present invention provides a method and apparatus for the removal and modification of target material and in particular the removal and modification of the human skin and underlying tissue layers.

A substance which absorbs electromagnetic radiation well in at least a portion of the incident beam electromagnetic spectrum is applied to the surface of the target material. The target material is exposed to electromagnetic radiation, which includes the portion of the spectrum that is absorbed by the substance applied to the surface. At least some of the absorbed energy of the electromagnetic radiation source is absorbed by the substance of high absorption and is converted thermal energy at the surface of the target material. The thermal energy thus generated is then responsible for vaporizing and ablating part of the skin and for irreversibly thermally modifying portion of the target material. A preferred embodiment envisions the use of carbon-based pigments in suspension within a host material and a continuous emitting electromagnetic radiation source.

The device described in this invention allows effective, safe and easy-to-use applications of the high absorbing material to the target material surface for the purpose of converting optical energy into thermal energy and affecting a change in the target material using said thermal energy.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Figure is a simplified pictorial illustration showing an apparatus for modifying a target material, in accordance with a preferred embodiment of the present invention;

Figure 2 is a graphic illustration of an exemplary intermediary energy absorbing material that can be mounted on two revolving mounts designed to advance the intermediate material following each use;

Figure 3 shows a heater embedded in the intermediate material. The Energy removal source is either acting through the intermediate medium or is external to the intermediate medium (IM) and effect energy removal. The energy removal can also act directly on the target material;

Figure 4 shows a heater embedded in the intermediate material. The Energy removal source is also embedded in the intermediate material and consist of a coolant

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coming from a coolant reservoir and circulating in a tube in contact with the intermediate material, thus capable of cooling the intermediate material;

Figure 5 by creating cuts in the intermediate material and creating an alternating series of high conducting material strips and insulating material strips, one can create a series of selected tissue modification. Alternatively, one can have the entire intermediate material made of high conducting material, while only a certain region is covered with high absorbing substance. This will ensure selective heating while uniform cooling;

Figure 6 is a graphic illustration of an intermediary energy absorbing material can be mounted on a revolving disk;

Figure 7 is a heater/cooling combination where the cooling mechanism cools both the target tissue and the energy source during operation of the energy source;

Figure 8 is a simplified pictorial illustration of an apparatus for modifying and removal material and biological tissue, in accordance with a preferred embodiment of the present invention;

Figure 9 is a simplified pictorial illustration of an exemplary pattern for depositing High Absorption Substance (HAS) on the intermediate material of the apparatus for modifying material and removal of biological tissue, in accordance with a preferred embodiment of the present invention;

Figure 10 illustrates the pattern and direction of heat diffusion following the energy deposition in the pattern of HAS of Figure 1B;

Figure 11 illustrates an exemplary pattern for High absorbing substance placed on the intermediate material;

Figure 12 illustrates the extent of thermal diffusion of the energy in the target material in response to the energy deposition in the high absorbing substance pattern in the intermediate material as shown in Figure 1B;

Figure 13 illustrates an exemplary pattern for High absorbing substance placed on the intermediate material and the corresponding thermal energy deposition in the target material;

Figure 14 is a simplified pictorial illustration showing an apparatus for modifying a target material, in accordance with a preferred embodiment of the present invention;

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Figure 15 is a simplified pictorial illustration showing an apparatus for modifying a target material, allowing the intermediate material to be lifted to allow energy removal directly from the target material;

Figure 16 is a simplified pictorial illustration showing an apparatus for modifying a target material;

Figure 17 is a simplified pictorial illustration of possible patterns and shapes of the high energy absorbing substance;

Figure 18 is a simplified pictorial illustration showing additional possible patterns and shapes of the high energy absorbing substance;

Figure 19 is a simplified pictorial illustration showing an exemplary device for material removal and modification and the device related controls;

Figure 20 is a simplified pictorial illustration showing in greater details an exemplary control box for the device for material removal and modification;

Figure 21 is a simplified pictorial illustration showing in greater details an exemplary device for material removal and modification;

Figure 22 is a simplified pictorial illustration showing an exemplary method for material removal and modification using a stationary beam method;

Figure 23 is a simplified pictorial illustration showing an exemplary method for material removal and modification using a moving beam method;

Figure 24 is a simplified pictorial illustration showing an exemplary method for material removal and modification using a broad beam method;

Figure 25 is a simplified pictorial illustration showing an exemplary cap with an exemplary intermediate material used in a device for material removal and modification;

Figure 26 is a simplified pictorial illustration showing an exemplary cap with an exemplary intermediate material mounted on a box containing the energy source and energy removal element used in a device for material removal and modification;

Figure 27 is a simplified pictorial illustration showing a time-sequence of energy deposition, energy removal and additional energy deposition as practiced by a preferred embodiment of the present invention;

Figure 28 is a simplified pictorial illustration showing the method of peeling intermediate material used in the present invention for target material removal and modification;

Figure 29 is a simplified pictorial illustration showing the method of peeling intermediate material used in the present invention for target material removal and modification allowing use of a variety of lenses;

Figure 30 is a simplified pictorial illustration showing the method of detecting perforation in the intermediate material substance;

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Figure 31 is a simplified pictorial illustration showing the intermediate material substance ability to partially transmit and partially absorb portions of the incoming energy thus creating dual heating effects;

Figure 32 is a simplified pictorial illustration showing an actual handpiece with intermediate material designed for the use with the present invention;

Figure 1A is a cross-sectional representation of human skin with a substance of high absorption applied in the form of a cream or lotion;

Figure 2A is a cross-sectional representation of human skin with a thin film containing the substance of high absorption, attached to the skin;

Figure 3A is a schematic representation showing the pattern of application of electromagnetic radiation and a cooling spray;

Figure 4A illustrates the two zones of target modification including zone of ablative material removal and zone of thermal material modification;

Figure 5A illustrates the four-parameter regimes that interact together to bring about the desired target modification effect;

Figure 6A illustrates experimental data showing tissue modification depth as a function of source's power and other relevant parameters;

Figure 7A illustrates the effect of the density of particles of high absorbing substance on the amount of energy coupled to the target surface;

Figure 8A illustrates an apparatus for a high absorbing substance film;

Figure 9A illustrates a telescopic attachment for adjusting the distance of the high absorbing substance film from the energy-focusing element; and

Figure 10A is a schematic representation showing an apparatus for the enhanced delivery of drug and other substance through a material barrier.

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### DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

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Figure 1 is a simplified pictorial illustration showing an apparatus 22 for modifying a target material, in accordance with a preferred embodiment of the present invention. Apparatus 22 comprises an energy source 32, which delivers energy to a target material 62, so as to remove or modify a layer of the target material. The apparatus consist of an energy source 32, an energy coupling element 52 coupling the source of energy to the target material, and an energy-removing element 72. Preferably, the energy-removing element is coupled to the energy source so that the energy deposition and energy removal are synchronized.

Alternatively, in another preferred embodiment, an intermediate material made of thermally conducting material (for example, Aluminum) is patterned to so that heating occurs only in one area. That heat travels very fast to all other locations and so that heat travels along conduits to specific areas for heating and modification of the target material and then cooling quickly removes the heat from the target. The high absorbing substance on an intermediate conducting material can indicate how deep the thermal effect in the target material has reached

In another preferred embodiment, the energy source beam can rotated along a circle made of spots of high absorbing substance. Much like a drum gun the beam is shifted each time it fires. This we can allow the user, a precise, predetermined number of uses and no more. Once the high absorbing substance on the spots in the circle is consumed no further interaction can occur. This is illustrated in Figure 8. Here an energy source 40 passes through a focusing element 45 and a steering mechanisms 47 and focuses onto a spot of high absorbing material 30 on an intermediate material 20 in contact with the target material 10. In addition, a substance capable of removing the energy from the intermediate material in a reservoir 70 is dispensed through the coolant control valve 50 to remove energy from the intermediate material 20. The energy beam does not have to be steered, in modification to the present preferred embodiment, the beam 48, is absorbed by the high absorbing substance 30 and then conducted throughout the intermediate material 20 if it is made of a thermally conducting substance. The result is rapid spreading of the thermal energy throughout the intermediate substance to allow a thermal energy distribution throughout the intermediate material.

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In another preferred embodiment, the energy intermediary absorbing material can be mounted on two counter-revolving mounts 126 as shown in Figure 2, which can be adjusted (either manually or automatically) to replace the high absorbing substance strips 136 as they are being consumed by the interaction. Here the intermediate material substance attachment 116, attached to the output port in the handpiece, consists of two rotating mounts 126, which are both rotating in the same sense in order to advance a film of high absorbing substance 156. The High absorbing substance is deposited in "frames" 136 which are deposited on the film band 156 capable of conducting the thermal energy forward towards the target material which is then advanced, frame by frame to place a fresh frame before each new area treatment. The spot 146 represent an exemplary energy beam from a light source interacting with the high absorbance substance.

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An additional preferred embodiment is illustrated by Figure 1 is a simplified pictorial illustration showing an apparatus 22 for modifying a target material, in accordance with a preferred embodiment of the present invention. Apparatus 22 comprises an energy source 32, which delivers energy to a target material 62, so as to remove or modify a layer of the target material. The apparatus consist of an energy source 32, an energy coupling element 52 coupling the source of energy to the target material, and an energy-removing element 72. Preferably, the energy-removing element is coupled to the energy source so that the energy deposition and energy removal are synchronized.

Alternatively, in another preferred embodiment, an intermediate material made of thermally conducting material (for example, Aluminum) is patterned so that heating occurs only in one area. The heat travels rapidly to all other designated locations along the manufacturer-designed thermal conduits to specific areas for heating and modification of the target material. Controlled cooling is then activated and quickly removes the heat from the target. A high absorbing substance on an intermediate conducting material can control how deep the thermal effect in the target material has reached

In another preferred embodiment, the energy source beam can be rotated along a circle made of spots of high absorbing substance. Much like a drum-gun, the beam is shifted each time it fires. This we can allow the user, a precise, predetermined number of uses and no more. Once the high absorbing substance on the spots in the circle is consumed no further interaction can occur. This is illustrated in Figure 8.

In another preferred embodiment, the intermediary energy absorbing material can be mounted on two counter-revolving mounts as shown in Figure 2, which can be adjusted (either manually or automatically) to replace the high absorbing substance as it is being consumed by the interaction. Here the attachment 116, attached to the output port in the handpiece, consists of two rotating mounts 126, which are both rotating in the same sense in order to advance a film of high absorbing substance 156. The High absorbing substance is deposited in "frames" 136 which are deposited on the film band 156 which is then advanced frame by frame to place a fresh frame before each new area treatment. The spot 146 represent an exemplary energy beam from a light source interacting with the high absorbance substance.

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In an alternative preferred embodiment the intermediate medium is replaced at the required interval by rotating a carousel, or a rotating wheel at the required interval to a new "fresh" HAS-coated, location. This is shown in Figure 6. Here, the apparatus is identical to the attachment Figure 2 except that instead of the rollers one use a wheel 226, where the high absorbing substance is deposited on the surface of the wheel facing the energy beam, 146 as shown in Figure 6. The wheel is then rotated before each interaction to allow new and un-used high absorbing substance surface to be placed between the energy beam 146 and the target material

In yet another exemplary preferred embodiment, the energy can be delivered to the target material 1160, in an energy source 1130 embedded in the intermediate material 1140. Figure 3 shows a heater 1130 embedded in the intermediate material 1140. The Energy removal element 1150 is then either embedded in the intermediate medium as shown in Figure 4, or is external to the intermediate medium (as shown in Figure 1.3) and allows energy removal. Energy removal can then be generated either through the intermediate material as shown in Figure 4 or by direct application of energy removal substance to the intermediate medium as is shown in Figure 4. In both cases the reservoir 1155 containing the energy removal substance is also shown. Alternatively, in yet another preferred embodiment, the energy removal substance may also be applied to directly to the target material 1160 thus removing energy directly from the target material.

The use of a highly controlled heating and cooling is contemplated. For example, one preferred embodiments is illustrated in Figure 8: A thin, highly conducing

intermediate material (HCM, for example a thin sheet of Aluminum) 20 is attached to a target material such as the skin 10. The high conducting material (HCM) is coated at specific points with high absorbing substance 30 high absorbing material (HAS). The laser beam is directed towards one such location of high absorbing substance - coated material. The heat is absorbed by the HAS and conducted through the layer of highly conducting material. For example we calculate that in a circular area of 1 cm<sup>2</sup> heat will be diffuse to a depth of about 600um in about 0.36 sec or 360 ms, in water-like substance. The energy source 40 is on for the duration of time corresponding to power of the energy source allowing sufficient energy to be deposited. Immediately following the interaction a coolant spray 60 from a coolant ejector 50 is discharged allowing immediate cooling of the target area through the HCM film. One can design the film thickness and size so that the resultant energy per unit time is sufficient to achieve the desired effect.

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In 360 ms the thermal diffusion in a water-like tissue target material is on the order of 600 um. On the other hand a circular area of 3 mm<sup>2</sup> will be evenly heated up by a scanned energy source contemplated in one preferred embodiments of this invention, in about 36 ms by an exemplary scanning of the optical light. During this time, heat diffuses only a ~ 200 um. This will be more in line with the thermal tissue damage that we wish to take place. Such a small volume, small size intermediate material will allow the use of a single stationary beam. One can then use a mechanical device (for example a drum-like switcher (much like in a revolver pistol) that will move small, mirrored faces 47 to move the beam 48 around to the various spots of high absorbing substance 30.

Alternatively the intermediate material 20 in Figure 8 can be made of a thermally non-conducting thin intermediate medium. The highly absorbing substance 30 is deposited on the intermediate material and the process continues as described above. The main difference between the two methods is that very little lateral conduction occurs with the intermediate material 20 made of non-conducting material. On the other hand, efficient transfer of thermal energy from the HAS spots 30 to the target material is ensured by using a very thin layer of 20. This has the advantage that while no photons or high absorbing substance comes in direct contact with the target material, the heat is quickly and efficiently transferred to the target and can then be just as efficiently and quickly eliminated.

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In either one of the above preferred embodiments, the intermediate substance can be made so there is no direct contact or interaction of the energy from the energy source (for example, photons from an electromagnetic energy source) NOR direct contact of the HAS with the material. For example, only the sterile outer surface of the intermediate material makes direct contact or has direct interaction with the target material.

In the embodiment that envisions a non-conducting intermediate material, the highly absorbing substance, HAS, can be precisely deposited at the selected locations on top of the intermediate material. Since thermal diffusion in the lateral direction is very limited the interaction is confined to substantially the area where the HAS is exposed to the energy beam. For example, if the non thermally-conducting intermediate material is a water-like material with water-like thermal properties, with approximately 100 um thickness, it will conduct thermal energy through in about 10 ms. The thermal interaction with the target material will start within less then 10ms and the lateral heat diffusion, if, for example, we deploy the energy removal system within 40 ms, will be confined to boundary of 200um from the energy deposition zone (i.e., the lateral distance from the zone where the HAS is deposited).

In fact, by controlling the lateral spatial separation between the HAS zones one can create a continuum of thermal deposition. This is shown in Figure 13 where the pattern 82 of highly absorbing substance 30 deposited on the intermediate medium 20, becomes after thermal energy diffusion, a substantially uniform target-material modification pattern, 85, on the target material 10.

Similarly the process can contain sources other then light (for example a broad band light source, a xenon or halogen lamp) in synchronized use with the coolant.

In one such preferred embodiment, a thermo-electric cooler (TEC) can be employed. Here the TEC is off during the energy deposition phase. The TEC is then turned on to remove energy and quench the interaction at a precisely desired moment. Alternatively, in another preferred embodiment, the TEC can also act as an energy source and heat up the targets material, then the electric current polarity is reverse and the TEC can then acts as an energy removal element and rapidly cool the target material.

However, cryogen spray is more easily and rapidly controlled. In yet another preferred embodiment, the TEC polarity may be reversed rapidly and in a controlled manner upon the generation of a signal from the user or a controller unit. In this

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embodiment, the TEC acts as both the energy source and as an intermediate material. Heating of the target material takes place and modification of the target material follows. The TEC controller then causes heating of the target material to stop at a desired moment in time, and the removal of energy and / or cooling to follow in order to quench the interaction.

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In yet another preferred embodiment a thermoelectric cooler can be combined with the process of coblation or electric-cautery or electric-surgery to achieve rapid energy removal following energy deposition in order to minimize pain and control damage and control target material modification. The same process can also be applied to the process of coblation where energy removal and minimization of pain can be achieved by application of energy removing to the target material after any and all plasma mediated interactions. In this embodiment, the energy removing can be achieved by using thermo-electric cooler, a peltier cooler, coolant spray, cryogen spray as well as a host of other energy removal mechanism. All of these will work provided that the user allow the modifying interaction to take place and then, at a predetermined point in time, the user activate one of the above energy removal methods. This applies to the processes of ablation that can be envisioned as well except that ablation takes place by electrosurgery or Coblation or plasma generation, or plasma-mediated material removal, or rapid generation of heat. Again, cooling occurs either through the highly conducting material (for example if aluminum is used), or if electrodes are used for delivering electric, electromagnetic, irradiative, or chemical energy. And it will also work if one raises the intermediate material to allow directed application of the energy removing substance (or coolant) to the target material as shown in Figure 9 where the intermediate material 340 is lifted up to allow the energy removal substance to be applied directly to the targeted tissue 10 following the interaction. This also ensures minimization of pain with all methods including electro-cautery/hyfercator.

In yet another preferred embodiment, the intermediate medium consists of an electrical heater in contact with the target material. The electrical heater may be pulsed or may be on continuously. If it is on continuously, a pulsed energy removal system is employed. For example, a sufficiently think intermediate material, said intermediate material is also a heater or capable of heating the target material, which is then sprayed by a cryogen spray or cooled by other coolant or energy removal means in order to

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modulate both intermediate material and target material temperature and thermal energy content. The cryogen spray will also remove thermal energy from the target material through the intermediate medium. This will allow reduction of the target material temperature at the desired times.

With the above methods we can also aid in the removal of pigmented skin blemishes that can also be affected. This can be done much like the CO<sub>2</sub> only much less expensive, pain-free, and with a much better control of spatial targeting because of the high absorption substance deposition.

Another advantage of the embodiment envisioning the depositing of high absorbing substance (HAS) on a paper or thermally mediating medium but on the side-away from the skin is that the intermediate material or intermediate paper block any debris from the ablated target material. In addition, the high absorbing substance is not allowed to come in contact with the skin.

Attached below is an exemplary list of possible intermediate papers and or material that can serve as intermediate material:

A. The intermediate material can be prepared with the high absorbing substance embedded in it: colored paper, toilet paper, tissue paper, paper matrix with the HAS embedded in its matrix.

B. Good conductors which may for example be shaped into a foil:

Stainless steel

Steel

Aluminum

Copper

Gold

Other metals

- B. The above method means containing both light and HAS within the device. The target material or skin is never in direct contact with the material and is never exposed the photons from an energy source.
- C. An intermediate material for the delivery of energy may be devices such as hyfercator or electrical coaguluator with Cooling apparatus for energy removal
  - D. Coblation with Cooling

- E. An alternative method may be a thermoelectric cooler with a laser acting as an energy source. The laser radiation may be activated in a pulsating mode while the energy removal (e.g., cooling) is synchronized with the heat source.
- F. Energy may be pumped into the intermediate material using high resistance electrical wires. The intermediate material can then be cooled rapidly with a loop of thermally conducting tube containing a circulating cryogen or other water flow, or through the use of cryogen spray.

Another preferred embodiment is shown in Figure 14.

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The energy source (for example a laser source) 300 and the coolant source 310 are mounted inside the handpiece 320. The cap 330 is made of a conducting material or from a material thin enough to allow significant heat conduction from the inside part of the cap 330 to the outside part 335 in a short time, substantially shorter then about 0.5 second. The power supply 340 powers the instrument's energy source and cooling source.

The light from the energy source, (e.g., a laser or a broadband light source) is absorbed by a high absorbing substance (HAS) 350. The HAS 350 transfers its energy to the conducting part 355 which stretches throughout the intermediate material cap volume 370 is in contact with the target material 10. The rest of the intermediate material cap volume 370 is made of insulating material. Thus, by controlling the size and volume of the high conductive substance area = the high thermal conductivity area size 340, one determines how the size of the area to be affected. By controlling the power and the on time duration of the energy source, one determines how much energy will be delivered to what size area. By controlling the coolant, one determines the duration of time for which the interaction is allowed to go on. Thus, this embodiment allow for elimination of scanners, no moving parts, no contact of the HAS with the skin, and no exposure of the skin to photons or any energy other then highly controlled thermal energy. There is also no microprocessors or programs to control this. It can all be made with hardwired design.

The high absorbing substance 350 is consumed within a given amount of time and thus allows a finite amount of time for use. The Size of the high conductive material (HCM) 355 is adjustable to treat different areas shape and sizes. Each HCM 355 is packed within its own cap 330 making it a disposable cap. The Energy source power and duration are presets and corresponds to the size of the HCM size and design.

Figure 8 illustrates one of the preferred embodiments:

A source of energy 40

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Deliver a dose of energy to an intermediate material 20.

The intermediate substance absorbs this energy and conducts it to the target material 10.

It is also possible that the intermediate substance 20 may have on it a few absorbing locations 30 where a substance of high absorbance with respect to the energy of the source 40 has been applied. This energy is then absorbed by the high absorbing substance locations 30 which then transfer them to the intermediate material 30 which then transfer the energy to the target material 10. There, said energy modifies or ablate the target material 10. Subsequent to the interaction, (or, in some preferred embodiments during) a substance capable of energy removal 70 is directed by the ejector/director 50 to the intermediate material 20 which is in contact with the target material 10. The substance capable of energy removal so directed 60, then remove at least some of the energy from the intermediate material 20 and thus also from the target material. This procedure allows, among other things minimization of pain in human tissue interaction and greater control of damage.

In further elaboration of this embodiment, the high absorption substance (HAS) 30 may be located at several different points thus allowing efficient delivery of energy to various locals on the intermediate material and target material. This too is illustrated in Figure 8.

In a further elaboration of this embodiment, the high absorption substance (HAS) 30 may be located at several different points 30 thus allowing efficient delivery of energy to various locals on the intermediate material and target material. This will also spread out the energy deposition effect and will allow simultaneous deposition of energy in one location AND removal of energy in a second, adjacent location. Of course the energy source 40, in this embodiment has to be stirred from one location 30 to the next in a predetermined pattern. The stirring of the energy source can be accomplished by means of an energy-stirring device 45. The energy removal substance ejector/director 50 can be synchronized with the beam stirring device 45 to accomplished the above mentioned simultaneous energy deposition in one location and energy removal in a second location.

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In a further embodiment the intermediate material 20 may be made of a conductor or an insulator. If a conductor – then depending on the thickness, of the plate, it may conduct well within a given interaction time (i.e., before the energy removing substance ERS is applied) to all region of the plate 20. However if the plate is very thin, the flow of energy is limited by the cross section and is limited in the lateral direction. Energy flow will be efficient in the Z-direction (i.e., towards the target material) i.e., most of the energy shall be conducted directly, in the Z-direction towards the target material and very little energy shall be conducted laterally and then into the targeted material. The energy distribution in the intermediate material will be that shown by 65 in Figure 9. Then, due to the finite thermal conduction in the intermediate material the final thermal energy distribution in the target material, will be that shown by 70 in Figure 10 where the concentric arrows indicate the direction diminishing thermal effect.

In another preferred embodiment, the intermediate material is made of a substantially thin thermal insulator. The energy from the energy source is then applied to the intermediate material via a high absorbing substance 30 applied at any desired pattern as shown in Figure 11. Since the absorbed source energy is now converted to thermal energy but remains confined substantially to the shape of the HAS spots 30 on the intermediate material 20, at least some of this energy will be transferred to the target material 10 below, shown in Figure 12 and diffuse further down towards the target material. If said target material is composed, for example, of tissue or water-like material, the thermal diffusion will be rather slow (for example it takes about 10 ms in such water-like material for thermal energy to diffuse a distance 100 um) and the thermal effect at the target by the time the energy removal system (or coolant) is activated, will be more confined, for example, to within the second ring, 75, in Figure 12.

An additional preferred embodiment envisions the energy source as a rapid heater embedded within confining caps. These heaters may be made of electrical heaters. Alternatively, these heaters may be made of thermoelectric cooler with switchable polarity.

An alternative embodiment is shown in Figure 14: The energy source (for example, a laser) 300 and the energy removal source (for example a coolant) 310 are mounted inside a handpiece 320. The intermediate material 330 is shaped like a cap and is made of a conducting material or from a material thin enough to allow sufficient

amount of heat to be conducted from the inside surface of the cap 330 to the outside surface of the cap in contact with the target material 335. Preferably this conduction is completed in a short time for example shorter then about 0.5 second. The power supply 340 powers the instrument's energy source and cooling source.

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The light from the energy source (e.g., a laser or a broadband light source) is absorbed by a high absorbing substance 350. The high absorbing substance 350 transfers its energy to the conducting part 340 which is in contact with the skin 360. The rest of the cap area 370 is made of an insulating material, which does not conduct thermal energy well. Thus, by controlling the size of the material of high thermal conductivity (HCS) 340, one can determine how the size of the area to be affected. By controlling the power and the "on" time duration of the energy source, one determines how much energy will be delivered to a desired area size. By controlling the coolant duration and timing, one determines the duration of time for which the interaction is allowed to go on.

There are no scanners, no moving parts, no contact of the high absorbing substance with the skin, and no exposure of the skin to photons or any energy other then highly controlled thermal energy. There are also no microprocessors or programs needed to control the process. All operations are hardwired.

The highly absorbing substance 350 in Figure 14, is consumed within a given amount of time and thus allows only a well-defined finite length of time for use.

The Size of the highly conducting material 355 is adjustable to treat different areas, shapes, and sizes. Each highly conducting material 355 is packed within its own cap 370, and since the highly absorbing material is at least partly consumed by during operation, the caps are disposable caps. The Energy source power and duration settings are presets and are designed to correspond to the size and shape of the highly conductive material.

Figure 16 illustrates a replaceable cap that can be attached to an exemplary device for modification of target material 3030. The caps 3035 constitute the intermediate material that absorbs the source's radiation and conduct it to the targeted surface. The cups may be arranged so that a certain portion of them is highly conductive and a certain portion of them is highly insulating. Further, part of the conductive portion of the cup may be coated with capable of absorbing well the energy from the source. For example in Figure 16, the energy from the source is scanned across the cup's surface 3040 that is

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facing the energy source 300. The regions that contain the high energy absorbing substance 350 however, only absorb the energy. The regions that are made of high energy absorbing substance 350 can be made in different shapes as shown in Figure 17 (see for example in pattern 3070), or pattern 3080 in Figure 3C. Of course, a person skilled in the art will easily recognize that the patterns illustrated in Figure 3B are merely very few representative examples and many other patterns of high absorbing material can be envisioned.

In Figure 16, a person skilled in the art will recognize that a beam from the energy source scanned across a portion of the cap 350 and encountering the portion of the cup with a high absorbing substance will deposit its energy in said area according to the rate equation:

Fluence =  $F_0$  \* Alpha = P / (L \* Nu \* Diameter) \* Alpha

Where  $F_0$  is the energy delivering rate from a scanned source of power P, with a length of scan L, and scanned frequency Nu, and beam diameter Dia. The Absorption coefficient Alpha characterizes the high absorbing substance and determines what fraction of the delivered energy is actually absorbed and removed from the beam by the highly absorbing substance.

Said energy will rapidly be conducted downwards to the outside surface of the cap 335 (i.e., the surface in contact with the target material).

The outside surface of the cap 335 is in contact with the target material and will be rapidly heated. Aluminum, for example, may conduct heat across 1 mm distance in 1 ms. Thus a cap with a thickness of for example 100 um may be conducted within 10 us.

Conduction in the lateral dimension is more difficult since it is more difficult to conduct heat in the lateral dimension through a very thin cup. Thermal conduction is accomplished most efficiently through energetic free electron motion and it is clearly more difficult to cram many electrons though a finite narrow passage.

In Figure 17 we show an additional embodiment using an exemplary cup 3035 with the intermediate material made mostly of a substance of high thermal conductivity, and with an inner surface made with an element that are coated with a high absorbing substance. When the sources beam is scanned across the high absorbing substance its energy is quickly conducted to the outside surface in contact with the target material. On its periphery, the high absorbing substance (HAS)-coated surface may encircled with a

thin ring of material of low thermal conductivity. This ring ensures confinement of the thermal effect only to the desired area of HAS coating. Except for the ring of thermal insulator, the entire cap is made of a substance of high thermal conductivity. Thus, when the energy removal substance comes in contact with the inner surface, the entire surface is rapidly cools, thus both quenching the hot thermal area and adjacent regions which may have been effect by thermal energy conduction through the target material itself. This is illustrated in Figure 18 where the intermediate material 3035 is made of a high conducting substance (HCS) 395. The high absorbing substance area 370, is thermally isolated from the rest of the HCS 395 by the ring of insulator material 390. when the energy source beam is scanned across the cap of intermediate material, 3035, only the area 370 is heated. Heat is confined by the insulating ring to the HAS area 370. However, when the energy removal substance is activated, all the intermediate material area and the target material area in contact with it are cooled.

A complete device and its control box and knobs envisioned by a preferred embodiment of the present invention are illustrated in Figure 19.

A typical preferred embodiment for a device 4010 consists of five components: a handpiece assembly, a connector cable, power cord, power supply console, and the footswitch.

Within the handpiece assembly are several sub-components:

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- Diode laser4 4020: Emits laser radiation towards the scanning mirrors.
- Thermoelectric cooler 4030: Cools the diode laser, 4020 to prevent overheating.
- Photodiode detector 4040: The photodiode detector is used to measure total output power. It compares the amount of photons detected from 4% of the reflected power from the beam splitter to the power output determined by the preset modes.
- Scanning unit 4050: The sub-components of the scanning unit consist of mirrors, a lens, and a beam splitter. The mirrors are used to scan the laser emission across a section of the target. The window in the scanning unit is used as a beam splitter where it reflects 4% of the total output beam towards the photodiode detector 4040. This allows for 96% transmission of total energy towards the target tissue. A detailed picture of the scanning unit can be seen in Figure 19.

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- Coolant ejector 4060: The coolant ejector sprays the contents in the coolant reservoir 4070 onto the target tissue. The rate and duration at which the coolant is ejected is predetermined by the different preset modes. The ejector sprays once every three scanned lines for a period time period determined by the mode that the device is operating in.
- Coolant reservoir 4070: The coolant reservoir houses the coolant that is used by the coolant ejector, 4060.
- Focus guard 4080: The focus guard is mounted on the outside of the handpiece. Its length is used to determine to optimal distance from the end of the handpiece to the target tissue. Resting the focus guard on the target tissue does this.
- Manual shutter, 4090: The manual shutter is used to prevent accidental firing of the laser. In its open position, it allows transmission of the laser beam to the target tissue. In its closed position, it allows no transmission of laser radiation outside of the handpiece.

The connector cable 4100 is used to connect the handpiece to the power supply console 4110.

The power supply console 4110 contains the control panel, 4120 and houses the power supply 4140. The power supply console is plugged into wall via the power cord 4150. The control panel 4120 is used for turning the device on or off, selecting one of the presets, and displays the system status. The control panel is better illustrated and described in Figure 20.

The footswitch 4130 is used to operate the device. When depressed, power is supplied to the handpiece that allows the laser diode and all systems within the handpiece assembly to operate.

An exemplary device control box is shown in Figure 20. The components of such an exemplary device control box are as follows. The push button 510 represent an exemplary present button which, using an exemplary, preprogrammed microprocessor, allow the user to select a predetermined set of scanning, energy source power, and coolant parameters. Four exemplary preset buttons are shown in this example. Above the present buttons 510 an exemplary light emitting diodes (LED) 500 is shown. Such LEDs indicate which settings have been selected. An on/off button is shown by 520. The LED shown by 540 is a standby indicator that lights up when the device is idle. The

LED shown by 550 indicates that the energy source is on and interaction with the intermediate and target material is occurring. The LED illustrated by 530 lights up whenever the energy removal components are activated.

As Figure 21 shows, one preferred embodiment envisioned utilizing a diode laser 120 as an exemplary energy source that is mounted on an thermoelectric cooler. A collimating lens 130 ensures a collimated beam, which then passes through the two scanner mirrors. From the scanner the beam is directed to a focusing lens 140 which directs the laser beam energy to the target tissue. Before emerging from the handpiece a small portion of the beam is directed by the beam splitter 205 to a photodiode detector. The photodiode detector 200 ensures that the system is operated at a proper power level. The coolant reservoir 160 is also mounted within the handpiece. The coolant is ejected via the ejector 170, and directed towards the treated target tissue area. The focus guard 225, ensures proper positioning of the handpiece with respect to the target skin tissue. The manual shutter, 240, prevents accidental firing of the laser. Another possible embodiment makes use of a broadband light source as the source of energy (for example, a halogen lamp or a xenon lamp). Of course, in general, this invention contemplates many energy sources as a possible source.

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The laser beam is emitted from the diode laser as a collimated beam, and is reflected from the first scanning mirror, 140, onto the second scanning mirror, 150. From there, the beam passes through the focusing lens, 190. Once the beam reaches the beam splitter 205, 4% of the laser output power 210, is reflected by the beam splitter 205, to the photodiode detector 200, which is used to measure the total amount of power emitted by the diode laser. The photodiode detector 200, ensures that the system is operated at a proper power level. The remaining 96% of the laser output passes through the beam splitter and focuses onto the target tissue.

The coolant reservoir 160, is also mounted within the handpiece. The coolant is ejected via the ejector and directed towards the treated target tissue area 180. A manual shutter 240 prevents accidental firing of the laser. The focus guard 225, acts as the positioning device that allows the user to properly determine the optimal distance to the target tissue that will allow for optimal performance of the device.

If the manual shutter 240 is not displaced, the shutter will block all transmission of the beam. Only when the shutter is disengaged from its normal position will the beam be transmitted out of the handpiece and onto the target tissue.

Figures 22 through 27 illustrate several other preferred embodiment of the present invention including the patterns of good heat conductors on the intermediate material.

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Figure 22 shows a high thermal conductor 'heaters' 720 which comprises part of the intermediate material (which we sometimes also designate at "caps") and the entire cap structure. The High thermal conductors heaters are separated by the insulator margin 750. Only the HTC 720, are heated due to the High absorbing substance HAS 730, deposited in one end. Heat is conducted throughout the heaters 720 in the direction of the arrows 740. The HASs 730 is heated by the stationary elongated BEAM 710. Thus, Figure 22 illustrates the high thermally conducting 'heaters' 720. The heaters, 720 are covered with the high absorbing substance (HAS) 730. The beam 710 is elongated and its long axis is aligned with that of the long axis of the heaters. The beam is then scanned across the intermediate material and get absorbed every time it crosses each one of the HAS 730 covered heater 720. The rest of the intermediate material 760 is a conductor as well. Heat does not flow from the heaters to the rest of the intermediate material because it is insulated from the rest of the intermediate material conductor by the insulator brackets (750). Upon a predetermined timing an energy removal is activated and quenches the heating of the cell.

Figure 23 shows the heating process completed by a scanning beam. Here, the entire length of a heater-strip of heaters 720 on the intermediate material 760, is coated by a high absorbing substance 730 and is heated by an elongated beam 710 which is then scanned across the surface and heat each one of the heater as it passes over it.

The entire process can also be made, in another preferred embodiment, by illuminating an entire pattern, as shown in Figure 24. The energy source in this case would be a large diameter, large area beam which will irradiate and heat all heater at once. In this preferred embodiment, all the heater-strips 720 on the intermediate material 760, are coated by a high absorbing substance 730 and are heated by a broad beam, 710, which covers and heat all heater-strips at the same time for the duration of time for which the energy source is on.

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Both of the above can be made, in another preferred embodiment, using an insulating intermediate substance as the intermediate material 760, said intermediate/ insulating material, however, is thin enough to allow quick transfer of heat to the underlying target material. In this case, the High absorbing substance (HAS) is deposited on the insulator-intermediate material in whatever pattern is desired. The energy source can then be scanned across the absorbers as in 7B, or can be large area as in Figure 24. The regions covered with HAS will heat up and transfer their energy to the target material and then, at a predetermined time, the device will activate an energy removing substance, for example a coolant spray, or a cryogen clay, to quench the heating and eliminate some of the pain and control the extent of the interaction and the tissue modification.

Figure 25 illustrates an exemplary cap 776 comprising of an intermediate material 777 on which a High absorbing substance can be deposited, and a holder 779 that can be attached, via the guiding tube 783, to the handpiece containing the energy source and the energy removing substance.

Figure 26 shows that cap 776 attached with an intermediate material 777 on which a High absorbing substance can be deposited, with its holder 779, attached, via the guiding tube 783, to the handpiece 781 containing the energy source and the energy removing substance.

In a further preferred embodiment the effect of the energy removal substance interacting directly with the target material or interacting with the intermediate substance absorbing the source's energy can be further controlled through the action of an auxiliary source of energy (or the same energy source activated again for additional periods and acting in coordination with the energy removal substance) in order to mitigate excessive energy removal effect or excessive cooling (which may cause harm to the target material.) For example, in Figure 27 if the time axis is represented by the line 7035. Then a burst of energy 7005 at time 7006 may be followed by the application of the energy removal substance 7015 at time 7016. Then, in order to control or mitigate the effect of the energy removal substance, the burst 7015 is followed by a second application of a burst of energy pulse 7025 at time 7026. If the target material removal or modification process occur repetitively, then the energy/energy-removal/energy

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application cycle is repetitive as well as shown by the additional sequences 7040 and 7050 Figure 27.

Figure 28. Another preferred embodiment contemplates "The peeling system" shown in Figure 28 is made of layers of paper of different color. As Figure 28 illustrates, one preferred embodiment employed a multileveled high absorbing substance (HAS) system composed of several layers of high absorbing substance. Further, each individual layer may be composed of a different color. The idea is to make use of the fact that

- 1. The high absorbing substance is consumed during the interaction.
- 2. The longer the total interaction time is, the deeper the thermal damage and modification to the target material below.

Thus, by employing multilevel system of high absorbing substance, where each layer is composed of a different color, one can calibrate precisely the amount of heat deposited in the tissue. In particular, if one design the thermal conduction properties of the HAS layer, and if one knows how much energy per unit time is required to remove a given thickness of HAS, one can predetermine the amount of thermal energy deposited in the target material.

As Figure 28 shows, an energy source beam 810 is impinging upon the multi-layer system of high absorbing substance films, 820. The first layer to interact with the beam is layer 830 of a green color, which, for example, can be design so that a given beam/scan parameter set completely removes it in a single path. In doing so, it deposit an amount of X.X W/Cm2 of which y.y W/Cm<sup>2</sup> is actually deposited in the target material leading to Z1 depth of thermal damage and A1 depth of ablatively removed material.

A second path may be designed to remove the second layer 840 of yellow color, thus depositing Z.Z W/W/Cm<sup>2</sup> additional power density in the targeted tissue.

One can see that by controlling the interaction parameters and the properties of the high absorbing substance, the manufacturer can allow the user to select a predetermined effect with desired outcome and well known endpoint corresponding to a given color of the exposed layer. Such color selection will tell the user the end treatment end point.

Alternatively in another preferred embodiment, the device may be made of an intermediate material that is capable of absorbing the sources' energy and transmit it to the target material on the other side of the intermediate material in contact with the target

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tissue. The intermediate target material possesses the property whereby each pass removes some of the intermediate material and exposes a new color or shade. Each such consecutive exposure corresponds do a deeper tissue modification effect.

Alternatively, the intermediate material changes its color with each consecutive application.

Alternatively, the intermediate material is capable of changing its color as a function of cumulative applied.

Alternatively, the intermediate material ability to absorb energy from the source is diminished with consecutive application of energy. Said diminishing ability to absorb is calibrated to allow a known amount of total energy to be absorbed by the intermediate material.

Another embodiment contemplates the intermediate material being able to absorb only a certain amount of energy per time. In other word, its absorbing ability is eliminated after the absorption of a known quantity of energy and then restored after a certain length of recovery time.

In a further embodiment, the above intermediate material is a key to activating the device.

The device cannot be activated and the energy source will not work unless the cup is in place. This is an important safety feature.

It will be appreciated that although preferred embodiments of the present invention are described with respect to the application of energy to skin and the cooling of skin, typically for purposes such as treatment or removal of skin lesions or wrinkles, it is within the scope of the present invention to apply energy to and cool substantially any type of biological tissue. For example, tumors, polyps, hemangiomas, ectasias, arteriovenous malformations, esophageal varices, coronary arteries, hemorrhoids and cellulite deposits are appropriate sites for application of the principles of the present invention. Additionally, non-biological materials may be processed in accordance with some embodiments of the present invention, as described hereinabove. It will be further appreciated that, although preferred embodiments of the present invention are described herein with respect to an electromagnetic energy source, other heating devices are suitable in many applications. For example, these other heating devices may include an

ultrasound energy source or a heating element, which is placed in contact with the target area.

Persons skilled in the art will understand that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and sub-combinations of the various features described hereinabove, as well as variations and modifications thereof that are not in the prior art which would occur to persons skilled in the art upon reading the foregoing description.

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In another preferred embodiment the device for modifying material at both the surface level and deeper into the material bulk, as figure 29 shows the device comprises of an energy source 1005, said energy 1007 can penetrate the martial and gradually (with respect to depth) can be deposited within it, yet said energy is also being capable of being absorbed by a substance capable of high absorption of said sources energy, said high absorbing substance (HAS) 1020, is place at some location on the surface closer to the energy source and further from the material to be modified 1030 of an intermediate material medium (IMM) 1010. Part of the energy 1007 is absorbed by the HAS on the surface of the window or intermediate material medium (IMM) 1010, and part of the energy 1057 is able to pass through a transmitting portion 1047 of the intermediate material 1010 into the material to be modified 1030. In the there it is scattered and propagates inward 1057 towards deeper tissue. As the energy 1057 (for example, optical energy) is penetrating inward into the material, it is being gradually absorbed in the material and converted to heat and thermal energy, interacting with the material to be modified and modifying and conditioning it. At the same time the portion of the energy from the energy source encountering the HAS 1020 is substantially completely absorbed by the HAS and then thermally conducted 1067 to the surface of the material to be modified below it. If the IMM or window is made of a thermally conducting substance, for example, sapphire, then said thermal energy diffusion out of the HAS region, also diffuses laterally and substantially creating a uniform surface layer (blanket) of thermal energy over the modified material surface, said blanket of thermal energy diffuses and modifies the surface of the modified material.

Said modification of surface region may be accomplished more rapidly and with higher temperatures, since the entire absorbed surface may be concentrated in a narrow surface area.

After a predetermined length of time (determined by the operator/designer to be sufficient to generate enough thermal energy and enough thermal energy penetration and enough thermal energy interaction with the material to be modified, an energy removal source is activated to discharge and energy removal substance, said energy removal substance remove the energy from the HAS, and from the IMM. The removed energy allow the IMM temperature to drop and the new thermal gradient thus generated cause thermal energy flow BACK from the material to be modified to the IMM, thus removing material from the material to be modified, and quenching the interaction.

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Said IMM may also be hollow so that energy-removing-substance may circulate through it, thus achieving more rapid and efficient energy removal from the material to be modified. Alternatively, the energy removal substance may be sprayed on the IMM surface closer to the energy source and further from the material to be modified. Alternatively, the energy removal substance may be applied directly to the surface for the material to be modified, thus allowing a very efficient energy removal.

In further development of the preferred embodiment the device incorporate an intermediate material substance which is composed of (See Figure 30) partially reflecting substance 1110 so that partial perforation of the High absorbing substance film or High absorbing substance cap or High absorbing substance cartridge results in detectable drop in the backscattered radiation level. This backscattered light is detected by a detector substantially feedback the signal to the source, automatically stopping the source from emitting energy if said signal level drops below a predetermined level. If, following or during the interaction, perforation of the High absorbing substance takes place, backscattered light level drops and a feedback mechanism forces the energy source to stop operating. See Figure 30 Below.

In yet additional preferred embodiment an intermediate material substance is highly absorbing and not thermally conducting but a few reflecting substance element are dispersed on the surface of the intermediate material substance facing the energy source. The reflected energy is then detected by a photo-detector. If said reflected energy drops below a certain level, thus indicating possible perforation of the High absorbing

substance cap, the energy source is immediately disabled. This will ensure that no energy comes out of the cap if said High absorbing substance cap is perforated or otherwise allows energy leakage.

In yet another preferred embodiment a device for controlling the distribution of energy in a target material where in the surface is heated by energy of the source absorbed by the high absorbing substance (1100 in Figure 31) is diffused to the surface of the material to be modified 1105. This source energy absorption at the surface by the high absorbing substance (HAS) is then converted to thermal energy 1120 and diffuses as thermal energy 1120 into the material to be modified material in the direction of the arrows 1115. On the other hand, some of the source energy is allowed to pass through the intermediate material substance 1005.

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#### Preferred embodiment - layered intermediate material/high absorbing substance

Figure 28 shows another preferred embodiment of the present invention. In this embodiment, a grid 810 made of a rigid material is attached to a film of a substance of high absorption 820 to form an interface between the impinging source's energy and the target material. The film of substance of high absorption 820 is in contact with the target material, while the grid 810 is facing the energy source. The grid 810 can be made of aluminum or any other substance. Preferably it is made of material that does not absorb the source energy very well. The energy from the source, passes through the openings in the grid and is then absorbed by the film of high absorbing substance 820 and is then transferred to the target tissue. The energy is either not absorbed well by the grid or if absorbed, is not sufficiently damage the grid. The grid 810 may also serves as a active cooling to cool the target material and the high absorbing substance film. The grid 810 may, for example, function as a thermoelectric cooler where each line on the grid is triggered at a different time (for example, cooling can be triggered so that cooling a line on the grid is triggered to follow an energy scan along or in the vicinity of that line. This phased cooling can assure efficient interaction at, for example, the region parallel to grid line 840 while the region parallel to the area 840 is being infused with energy from the energy source. One exemplary way to prepare such a grid 810 is to use a metallic thin sheet cut out to the desired dimensions, create a perforation pattern in said thin sheet of metal and then, attach the film of high absorbing substance to the sheet of metal.

In another preferred embodiment, shown in Figure 29 an apparatus is contemplated by the invention to allow different focusing lenses to create different spot sizes at the high absorbing substance. In this embodiment, a telescopic attachment 910 to which a high absorbing substance intermediate material cap 920, is capable of being extended or folded to the desired length from a position, 930 to which a corresponding lens can be attached. The Operator can thus insert a variety of lenses with different focal lengths (thereby creating a range of target effects) and adjust the telescopic attachment 910 to the corresponding proper length. The lenses 950 can either be inserted one by one to a lens holder position 930, or they can be all mounting on an exemplary revolving carrousel or drum 960, said revolving carrousel or drum 960 is placed at the lens holding position 930. The operator can then rotate the revolving carousel or drum to the position where the desire lens is engaged and adjust the telescopic attachment 910 to the proper position. Of course the entire process can be automated and driven by a motor so that the operator can select the target or tissue effect he wish, the drum is automatically rotated to the proper position with the proper lens selection, and the telescopic attachment 910 is automatically adjusted by motor to the appropriate extended length. Also shown in Figure 29 is an optional energy removal system 970. Such energy removal system can consist, for example, of a coolant reservoir and ejection control, 970, which, for example, on demand, allow an exemplary jet of coolant spray 980 to discharge and be directed toward the intermediate material medium 920 with the high absorbing substance. The cooling of the intermediate material medium also remove energy from the target material and thus the cooling of the both the intermediate material as well as the cooling of the target material is achieved.

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In yet another preferred method for controlling the distribution of energy in a target material where in the surface is heated by energy of the source absorbed by the high absorbing substance (1100 in Figure 31) is conducted to the surface of the material to be modified 1105. This source energy absorption at the surface of the intermediate material 1005 is then converted to thermal energy 1115 by the high absorbing substance and is then conducted as thermal energy 1115 into the material to be modified in the direction of the arrows 1117. On the other hand, some of the source energy is allowed to pass through less absorbing windows1110 within the intermediate material substance 1005, and are scattered as optical 1130 within the target material 1105. This optical

energy is ultimately absorbed by sites in the target material and is converted to heat as well.

Finally, in yet another preferred embodiment shown in figure 32 a source of diode laser energy 3210 emit beam 3230 collimated by the collimating lenses 3220, which is then deflected by the scanning mirrors 3240 and focused by the focusing lens 3250. A small portion of the beam 3260 (typically less than about 4%) is deflected by a beam splitter 3270 towards a detector 3280 which measure power as well as motion. The rest of the beam 3290 continues through a manual shutter 3300 to the disposable tip 3310 and the intermediate material 3320. The disposable tip contain the high absorbing substance film 3320 which may have some partially transmitting ability. The device also contain a coolant reservoir 3330 and a coolant ejector 3340 which direct the coolant spray output 3350 towards the side of the high absorbing substance film facing the inside of the device. The High absorbing substance is able to both conduct the laser energy to the target material 3360 as well as remove energy from the target material 3360 through the action of the coolant spray3350.

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It will be appreciated that although preferred embodiments of the present invention are described with respect to the application of energy to a target material with an intermediate material and the use of cooling of skin, typically for purposes such as treatment or removal of skin lesions or wrinkles or treating skin diseases, it is within the scope of the present invention to apply energy to and cool substantially any type of biological tissue. For example, tumors, polyps, hemangiomas, ectasias, arterio-venous malformations, esophageal varices, coronary arteries, hemorrhoids and cellulite deposits are appropriate sites for application of the principles of the present invention. Additionally, non-biological materials may be processed in accordance with some embodiments of the present invention, as described hereinabove. It will be further appreciated that, although preferred embodiments of the present invention are described herein with respect to an electromagnetic energy source, other heating devices are suitable in many applications. For example, these other heating devices may include an ultrasound energy source or a heating element, which is placed in contact with the target area.

Persons skilled in the art will understand that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the

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present invention includes both combinations and sub-combinations of the various features described hereinabove, as well as variations and modifications thereof that are not in the prior art which would occur to persons skilled in the art upon reading the foregoing description.

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An embodiment of the present invention can be described by reference to Figure. 1A. Figure 1A shows a cross section of a target tissue such as the human skin. A layer of high absorbing substance 10 is placed on top of the epidermis 20 which in turn is overlying the dermis 30 and fat 40 layers. The layer of high absorbing substance is contained within a lotion or liquid which is applied to the target material. This method has the disadvantage of being harder to apply and of accidentally contaminating other location on the target material. On the other hand, the method is simple because the high absorbing substance is at least partly in direct contact with the target material thus leading to the most efficient transfer of the optically absorbed thermal energy to the tissue.

Figure 2A shows a preferred embodiment of the invention. A layer of high absorbing substance is now placed in the form of thin film 100 containing particles of the high absorbing substance, on top of the epidermis 20. The epidermis 20 in turn is overlying the dermis 30 and fat 40 layers. The layer of high absorbing substance is contained within a lotion or liquid, which is applied to the target material. This method has the disadvantage whereby is a cross-sectional representation of human skin with a thin film containing the substance of high absorption, attached to the skin.

As Figure 3A shows, a light source 130 emits energy 120 towards the high absorbing substance 10. The high absorbing substance 10 is capable of absorbing at least some of the energy 120. The energy is subsequently thermally conducted towards the deeper portion of the epidermis 20, the dermis 30 and the deeper fat layer 40. As figure 4A shows if sufficient energy is deposited in the tissue, an ablative zone, 300, where target material has been physically removed, is formed at the outer target layer. In the case of a human skin portion of the epidermis, and, in case of more aggressive interaction, the entire epidermis and even parts of the dermis, may be ablatively removed. Further thermal diffusion and deposition of energy will also lead to the formation of a zone of irreversible damage, 320. Here target material has been thermally altered but not physically removed or ablated. In the specific case of human skin, the tissue in the zone 320 will usually be thermally coagulated.

Such thermal coagulation and thermal injury to the skin tissue will lead to collagen regeneration and the appearance of younger looking skin.

Topically applying a thin layer of high absorbing substance such as carbon particles, Indochina green, graphite, black food coloring, china ink, acrylic tattoo inks, and black pigments among others, will result in an efficient conversion of electromagnetic source energy to thermal energy.

As is shown in Figure 5A, the conversion efficiency (i.e., how much of the incident energy has been converted to thermal energy) depends strongly on the interaction between four factors: The energy source parameters (Lp) 500, the energy manipulating components parameters (OSp) 510, the Energy removing parameters (ER p) 520 and the high absorbing substance parameters (HAS<sub>p</sub>) 530. The present invention contemplates four interacting parameter regimes that yield to the final target modification effect.

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The first parameter group to be considered 500, is the source parameter. These include the source energy, the source power, the pulse duration (if pulsed) and Pulse repetition rate (if pulsed), and the source wavelength, if the energy is radiated.

The second 510 group of parameters is the optical/scanning parameters. These define the beam spot size and the motion of the energy along the intermediate material.

The third group 520 is intermediate material parameters. These define the rate of conversion of energy from the source energy to the type of energy that interacts with the target. The final group of parameters 530 is the energy removal parameters. These define when, how and temporal nature of the energy removal from the intermediate material, target material or both. The interaction of these parameters amongst themselves is illustrated schematically in figure 5A.

The interaction between these four components, illustrated symbolically in figure 5A by the circle 540, will determine how much of the source's energy is converted to thermal energy.

For example, I have tested a 1 W source scanning a 1 Cm<sup>2</sup> area of at a rate of about 6 seconds. Assuming that all the energy is absorbed by the layer of high absorbing substance, we have 6 Joule deposited over the 1 Cm<sup>2</sup> area.

Assume now that the energy absorbed E is thermally conducted to the underlying target area. In the case of human skin, for example, water molecules dominate the

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$$E = C \square T \tag{1}$$

Where E is the energy required and  $\Box$ T is the increase in temperature.

To take water from  $20^{\circ}$ C to  $60^{\circ}$ C and with the specific heat of water given by approximately Cs=1 cal/g\*°C, we get from the relation above E ~ 1.6J.

To vaporize this amount of tissue would require bringing the tissue (or in our simplified thermal model – the water volume,  $1 \text{ cm}^2 100 \text{ }\square\text{m}$  thick) to boiling temperature, and then, further vaporizing that volume. From the relationship of Equation 1 above, the temperature rise of 80°C, would require about 3.2 J.

The heat of vaporization of water at 100°C and 1 atmosphere pressure is 539.6 Cal/gm.

Thus, to vaporize the 100 um thick volume discussed above will require bout 21.6J, clearly much more than the total incident source energy in our experiment of about 6J. On the other hand, a 10 mm thick layer of tissue (approximated as water) will require only approximately 0.32 J to raise its temperature from 20°C to 100°C, and 2.16 J to vaporize. With our above calculations show that to raise an addition volume of (100  $\Box$ m x 1 cm<sup>2</sup>) to 60°C coagulation temperature is about 1.6 J, we see that with a total of about (2.16 J + 0.32 J + 1.68 J = 4.16 J) we can vaporize about 10  $\Box$ m of tissue and coagulate an additional 100  $\Box$ m thick layer.

This simplified analysis agrees with the order of magnitude of our experiments as illustrated in figure 6A. The experimental results of figure 6A shows the depth of tissue ablated 620 and thermally damaged 630 in pig skin tissue. The figure shows ablation and thermal damage depth on the tissue depth dimension axis 610, as a function of laser diode fluence, 600, (power = 1 W, scan rate is 1 cm $^2$ /sec, and wavelength = 810 nm absorbed by a high absorbing substance composed of carbon suspension).

We can clearly see that both the depth of ablation and depth of tissue thermal damage are on the order of magnitude predicted by the above analysis.

#### <u>Preferred embodiment - controlling tissue effects</u>

1) From the above analysis we can conclude that coupling of X Joule of energy with temporal T(t) and spatially R(r) of energy will lead to the ablation of a layer of thinness Xabl and leave behind a layer of thickness Xtd of thermally modified tissue. The present invention contemplate four parameter groups responsible for a given energy distribution E(t,r) = F[T(t) R(r)]

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The four parameter group are illustrated schematically in Figure 5A. These include the laser parameters, 500, the beam-modifier parameters (including the optical beam modification apparatus and scanning parameters) 510, the Energy Removal parameters, 520 and the high absorbing substance parameters, 530.

The example above showed that a given parameter combination with 1 W of 810 nm radiation, allows, for example, the generation of 10 um deep ablation zone and a subsequent thermal modification zone of approximately 100 um deep. Such an exemplary combination generated 6 J of energy, of which, according to the above analysis, about 4.2 J was needed to generated these effect. If we define this energy as Eth, or threshold energy for interaction, which when applied in conjunction with the parameter combination 540 of figure 5A, will result in the Zabl=10 um and Ztd = 100 um.

Clearly, when considering the parameter involved in the substance of high absorption (HAS) 530, if a single layer of absorbing particles is involved, the surface density of absorber will correspond to the amount of energy coupled to the substance of high absorption and the total amount of incident energy converted into thermal energy.

For the parameters in the incident power 1W, 810 nm, with scan rate of 1cm<sup>2</sup> per six seconds, described above, a single layer HAS with particle density such that only, for example, 1/3 of the target area is cover, will not provide sufficient energy to achieve the effect of vaporizing 10um of tissue and thermally modifying 100 um. While thermal diffusion will provide thermal effect even through the gaps in the surface coverage, (for example, if a heat-removing substance is applied every 250 ms, heat diffusion of about 500 um within this time, would essentially assure complete coverage of the target surface by energy) the total amount of energy deposited in the tissue will be 2/3 less then in a uniformly covered surface as the portion of the beam that does not encounter HAS particles, continues to propagate through the skin unimpeded.

2) On the other hand, if E > Eth, then one can compensate for the high absorbing substance, HAS, lower particle density, with a higher source power.

For example, if in the experiment discussed above we employ a power source of, for example, 3 W, the sources now deliver 18J in 6 sec, and while 1/3 of the particles will couple approximately 1/3 of the energy, the same total quantity of energy will be coupled to the targeted. Heat diffusion will then assure that this same overall quantity of coupled energy will be distributed to the entire area.

With a spot size of, for example, about 200 um and a dwell time of about 10 ms, even small, roughly single micron size particles, will allow heat diffusion to roughly the same area on the same time scale. Thus a uniform HAS particle coat with a 1W beam dwell time of about 10 ms will cover about he area with thermal energy as a coat with 1/3 the particle density but with a 3W power.

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The above discussion thus demonstrate that the parameters combination 540 of Figure 6A, allow compensation of sources power by varying the High absorbing substance concentration and vice versa.

- The thickness of the high absorbing substance is another components of the parameter group 530 of Figure 6A that plays an important part in determining the target (or tissue) effects. If the absorbing particles are poor thermal conductors, depositing a multiplayer absorbers on top of the target will result in significant source's energy being absorbed in the upper layers but never making it to the lower layers before the heat remover is applied. On the other hand, applying a high absorbing particles in suspension in a substance with improved thermal conductivity will assure that the above energy is conducted to the target material. One can then allow gradual thermal energy application to the target as sequential scan passes are stacked and add their thermal energy to the tissue. The present invention contemplates ablatively removing portion of the high absorbing substance coat with each pass resulting in a self-limiting scheme allowing only a finite number of passes and thus only a finite amount of energy deposited in the target material before the high absorbing coat has been completely removed and no more sources energy can be coupled to the target.
  - 4) Controlling tissue effects through the heat-removal mechanism.

The energy removal mechanism 520, illustrated in Figure 5A also plays a multiple role in controlling the tissue effect. As was pointed in the discussion above, it effectively

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ends a heating cycle by effectively removing the heat from the outer surface of a target. For example, if a single line 1cm long and 0.7 mm wide is scanned in, for example, 100 ms, then heat diffuses about 300 um from the impacted zone. Activation of the heat-removing mechanism (according to the pattern shown, for example, in figure 3A) allows control of spatial distribution and synchronized termination of the thermal effect (by effectively removing the heat source from the surface). In fact, the action of the heat removal mechanism goes even further, because by allowing the operator to very rapidly readjust the surface temperature to even below normal ambient temperature, heat can now be forced to flow out of deeper layers in the tissue. The net effect is creating a spatially and temporally controlled thermal pulse that propagates into the material bulk from the high absorbing substance in contact with the material surface layer and then, upon instruction from the operator, the heat reverses direction and flows out of the bulk.

An analogy to the behavior of the flow of thermal energy in the material and the time and space dependence of the distribution of thermal energy density (thermal energy per unit volume) is the behavior of an electric charge density (for example electrons density) under the influence of alternating positive and negative electrodes outside a conducting medium. The thermal energy density under the influence of the deposited light energy (effect of 530 in figure 5A) and the heat removing mechanism 520 (such as freon like spray or other cryogen spray or controlled air flow, or temporary contact with cold plates or thermoelectric coolers or other such methods to induce transient heat removal), is much like an oscillating or direction-reversing electron cloud movement.

The following are additional preferred embodiments contemplated by the present invention. The discussion below will also demonstrate the relationship between the various parameter groups of figure 5A.

Preferred embodiment 1: Optical heating, no high absorbing substance and no heat removal mechanism is used. Heat transfer amounts substantially to diffusion.

In this case, initial thermal energy distribution mirrors that of the optical deposition. Heating due to optical scattering is maximal just below the surface.

Preferred embodiment 2. Heating with a heat removal applied before and or during irradiation, resulting in peak power and thermal energy distribution below the surface.

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Preferred embodiment 3: Heating the target surface optically resulting in initial thermal distribution which mirror the initial optical distribution. Heat removal is then applied to the surface resulting in modification of thermal distribution below the surface as well as heat begins to redistribute itself and diffuse back upward towards the now cooler surface. Thermal modification thus does not allow enough time for surface to get fully heated and damaged. Thermal distribution below the surface is temporally and spatially modified according to intended operator design.

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Preferred embodiment 4: Application of a highly absorbing substances to the target surface prior to external energy deposition. This leads to initial heating confined to the thickness of surface high absorbing substance alone. The operator thus has full control over the deposition layer and the initial heating zone.

Preferred embodiment 5: Initial heating with high absorbing substance allowing heat to propagate ahead a predetermined distance. A heat removal mechanism is then applied to the surface quenching the surface heating. The heat then continues to diffuse deeper into the tissue but the thermal energy below the surface also flows back out and flows back towards surface where it is used to reheat surface. The net effect of this process is to limit the effect of the heating, the amount of heat available for tissue modification and the extent of the damaged tissue and the depth location of damaged tissue.

Preferred embodiment 6: The high absorbing substance is applied and subsequently wiped off so it remains substantially mostly in the pores, depressions and troughs of the skin. In these location it absorbs radiation causing localized points of thermal heating spatially distributed on the target surface. Subsequent illumination but the external energy source, results in some of the radiation being absorbed by the localized points containing high absorption substance while the rest of the radiation propagates deeper and heating – to a much lower degree – much deeper into the tissue.

The net effect is rapid heating and expansion of the pores combined with heating of lower/deeper region of the skin to allow expansion of the lower parts which, in turn, expel through the pores, undesired material which may reside in the skin.

Preferred embodiment 7: The preferred embodiment above (Preferred embodiment 6) followed by the removal of heat which stops the expansion on the surface

(and begins generation of contraction of the target material) while heating of deeper regions by Optical deposition allows an efficient deeper target expansion.

Preferred embodiment 8: The process of application a high absorbing substance can be modified through a high absorbing substance applicator device to achieve the following effects:

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- Heating of a very thin layer of high absorbing substance. Heat is transferred to the skin.
- 2 Heating of a "diluted" high absorbing substance suspended in a layer of other material
- Wherein other material is an insulator thereby mitigating the amount of heat transferred but also maintaining heat in that layer for a longer time.
  - Wherein the other material is an insulator thereby mitigating the amount of heat transferred down to the lower tissue but allowing accumulation of heat in the surface layer lowing to material removal through explosive ablation of the applied surface layer.
  - Wherein other material is a conductor—thereby enhancing heat transfer to the tissue.
  - Whereby the above method is followed by surface heat removal.
  - Where the high absorbing substance is also insulating thus resulting in ablation of surface with substantially mostly mechanical shock to tissue.
  - Wherein the high absorbing substance is partially transmitting resulting in BOTH deeper "Optical" heating AND intense surface heating.
  - 9 The device and method of 8 above wherein the heating phase is followed by heat removal resulting in intense heating at below surface but a more delicate spatially larger heating at the surface.

# Additional preferred embodiment Application Technologies – Application of high absorbing substance using a thin film

Another way to create a precise effect with the disposable is to create a film. For example one can create a uniform suspension of high absorbing substance in a host material such as paraffin, paper, metallic matrix, insulator matrix, thermal insulator or

plastic matrix, thermally conducting matrix, jelly, agar or other hosting material. The operator can then slice it to a precise thickness (for example from a preferred thickness of about 10 micrometer to as much as about a 100 micrometer thick, although many other thickness can be contemplated). The process is much like that used in histological slides preparation. A slice with the desired particle size and the desired concentration is prepared and is coated with adhesive to allow it be attached to the targeted area of the skin.

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Such a film of high absorbing substance can be packaged in a sterile packaging and can come in various sizes and shapes. Such a package can then be opened prior to use, and the operator can cut it with sterile scissors to the desired shape. The film is then attached over the desired targeted area creating a precise special localization of concentration and density and particle size and thickness of layers.

Light traveling through the film containing the high absorbing substance, activates the product in order to cause thermal injury to tissue and/or the high absorbing substance itself for the purpose of causing thermal injury to tissue. The solid film become adhesive upon contact with moist target and adheres to a given location. The adhered film allows high spatial control and eliminates the more messy cream or lotion method of applying a substance of high absorption. The film visually changes in color as the high absorbing substance interacts with the incident energy. Some portions of the film are consumed by the applied light source.

The consumption of the film shows the operators where they have treated, and how long and when the product has expired.

With the film or cream of high absorbing substance in place, an site undergoing interaction is visually altered and the handpiece may be used in a free hand motion to cover a larger area. The film will change in appearance, showing the area treated and confirming the product has been consumed. The operator continues to move the handpiece over the target area until the film changed its appearance uniformly to the one indicating proper treatment.

The film may be designed to be thin enough so it does diminish the effectiveness of thermal energy conduction due to the energy source or heat removing source that are heating or cooling the skin. The film may incorporate anesthetics drugs nutrients and coolants that could allow the film to have it own cooling mechanism built into it.

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In yet another preferred embodiment, the device contemplated include an energy source which emit radiation which, in turn, is absorbed by the an intermediate material made of thin layer. One surface of the intermediate layer contains an absorbing substance, which is capable of absorbing the radiation of the energy source inside the handpiece. A second property of the intermediate substance is that it is capable of transmitting said absorbed energy from the side facing the energy source to the side in contact with the target material (the material to be modified). A third property of the intermediate material is that all the absorbing substance is contain in a region of the intermediate material, which is accessible to the radiation from the energy source but which is, in a preferred embodiment, not in contact direct contact with the target material.

In an alternative embodiment, the intermediate material contains absorber that IS in contact with the target material. However, said intermediate material and the high absorbing substance of this embodiment are made of bio-compatible material which can be used in contact with an animal skin without causing adverse effect. In the more general case, said high absorbing substance and intermediate material can be in contact with the target material but are made of material which does not have adverse effect on the target material. For example, High absorbing material can consist of carbon particle in solution as in Higgins Black Magic ink. A paper matrix can be a 0.05 mm thin paper with the carbon solution capable of adhering to the surface of the paper film.

Further preferred embodiments for the application of high absorbing substance:

A) The composition of the high absorption substance can be adjusted for an optimal tissue modification. The matching to optimize the interaction 540 in Figure 5A is accomplished by adjusting the source parameters  $P_L$  500 and Optical/scanner parameters Po/s 510 in figure 5A, to that of the high absorption substance parameters  $P_{HAS}$ , 530.

Settings for Laser/Optical/scanner –

The fluence F at a given point and time on the target surface is given by

$$F=P/(L_x NU_x D)$$

Where P is the source's power in Watts, Lx is the length of scan in the X direction (the horizontal direction), NU<sub>x</sub> is the scan frequency in the X direction and D is the spot size diameter.

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The actual energy in the tissue is determined by a combination of the effect of the energy absorbed by the high absorbing substance and its conduction coefficient (CC) responsible for transferring the thermal energy to the tissue.

Thus, the thermal energy transferred to the tissue (recall that the fluence is simply the energy per unit area) is proportional to

Now if we use an absorber which also acts as an insulator in the medium, the conduction coefficient then becomes a function of the high absorption substance density:

$$(\tilde{\square} \square abs = FUN(\square$$

If we design the high absorbing substance (HAS) as a good insulator, material conduction will in general decrease as a function of HAS density  $\tilde{\Box}$ .

With these considerations we have effectively designed a system such that incident energy conversion to thermal energy is increase with the HAS density but the transfer of this thermal energy from the layer of HAS to the targeted material surface is diminished with increase HAS density. This situation is depicted by Figure 7A below.

As shown in Figure 7A, the absorbed energy 710 increase with HAS density 700, while the transferred thermal energy to the tissue 720 is decreased as a function of HAS particle density. The total amount of energy transferred to the targeted material surface, 730, is thus, a combination of these two effects and is demonstrated in figure 7A by the curve 740. Optimal and maximum thermal energy deposition in the targeted tissue surface is corresponds to the location 750 shown in Figure 7A. The curve 720 shows the tendency to decrease coupling due to increase HAS particle density and the associated decrease thermal conduction. The curve 710 shows the tendency to increase energy coupling with increase HAS particle density and increased absorption. The curve 740 shows the actual effective energy coupling to the target material surface due to the combined effect of curve 710 and 720

The correct calculation of the amount of energy deposited in the target material should thus be:

$$F_{\text{effective}} = P_{\text{effective}} / (L NU_x Diamter)$$

Where  $F_{\text{effective}}$  is given by:

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To calculate a manipulation of the beam power as a function of HAS particle density we follow the procedure below:

We assume a uniform complete absorption in tissue when  $\Box = \Box_{ideal}$ 

We then assume that when  $F = F_{ideal}$  one gets the desired tissue effect.

We set laser/optic/scan parameters - Power, Lx, NUx and beam diameter at the target so that to  $F >> F_{ideal}$ , so we are certain that a thermal damage to the target material will occur.

We then reduce  $\square$  to  $\square$   $\square$   $\square$  ideal so that less power is absorbed and the incident fluence is again in the close of the "ideal" fluence  $F_{ideal}$ .

Obviously the dependence of high absorbing substance particle density on Laser/optical/scanner parameters to achieve a desired tissue or target effect allow a large number of permutation and large number of combinations to be selected.

If a different high absorbing substance (HAS) particle density  $\Box$  is provided and if the high absorbing substance particle density is too low, no effective interaction occurs. On the other hand, if the high absorbing substance particle density is too high, a burn might occur.

If high absorbing substance particle and the host substance are maintained at a constant conductance level, the deposited energy density will increase monotonically as a function of the HAS particle density until the surface is completely covered with HAS.

Such a situation in combination with the increasing source power levels will result in increased thermal loading and ultimately burn and blister.

In an additional preferred embodiment, the film is designed to be thin enough so it does not affect the cryogen that is cooling the skin. The film can incorporate anesthetics drugs nutrients and coolants that could allow the film to have it own cooling mechanism built into it.

One way of creating such a film that adheres to the surface is using a starch paper such as rice paper or potato starch paper. High absorption substance particles according to the correct composition proportions and design described above may be incorporated into the starch papers or may be added after the paper has been form. The method allow precise control of the thickness of the film or paper sheet, as well as precise control of the paper composition and HAS particle density, particle size and chemical content. The thin film or paper is then, in a preferred embodiment, being consumed with successive paths

so at the end of a pre-determined number of passes, substantially very little HAS particles are left behind and the interaction is self-suspended adding to the safety of the device.

# <u>Preparation of a film comprising of a Potato Starch film with high absorbing</u> <u>particles suspended within it can be accomplished via the following procedure</u>

1.5 cup of water

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1 spoon of potato starch

Mix starch in Cold water first

Stir thoroughly and make sure all is dissolved. Place mixture in pot and bring to a boil (1/2 way). Mix in HAS into liquid (food coloring carbon particles). Bring again to a boil allowing liquid to rise close to the top of the pot. (Stir regularly to make sure no clumps form). Remove/turn off heat and allow to dry on the side of the pot. Approximately 15 minutes depending on thickness. If it is too thin redo but at lower temperatures. It is very important that the liquid and starch concentration determine how thickly the side of the pots will be coated. The process can be repeated a few times to make a thicker coat.

Another way to create a precise effect with the disposable is to create a film by other means. For example one can create a uniform suspension in a paraffin, or in a Jelly or agar. Then slice it to a precise thickness (e.g., 5 micrometer) much like we do in histology slides preparation. A slice with the desired particle size and the desired concentration is prepared and is coated with adhesive to allow it be attached to the targeted area of the skin

Such a film of HAS can be packaged in a sterile packaging and can come in various sizes and shapes. Such a package can then be opened prior to use, and the operator can cut it with sterile scissors to the desired shape. The film is then attached over the desired targeted area creating a precise special localization of concentration and density and particle size and thickness of layers.

# **Additional Embodiments:**

6. In an additional preferred embodiment, the high absorption substance is deposited in a thin film containing high absorbing particles of density which assures that at least 60% of the light energy is intercepted and absorbed by the particles.

- 7. In an additional preferred embodiment the high absorption substance is deposited in a thin film containing high absorbing particles of density which assures that at least 40% of the light energy is intercepted and absorbed by the particles.
- 8. In an additional preferred embodiment said high absorption substance is deposited in a thin film containing high absorbing particles of density which assures that at least 20% of the light energy is intercepted and absorbed by the particles.
- 9. In an additional preferred embodiment the high absorption substance is deposited in a thin film containing high absorbing particles of density corresponding to the rate of energy deposition per unit area so that the energy deposited in the skin is sufficient for the removal of at no more than 70% of the epidermis and the energy deposited in the skin allows permanent modification of the skin to a depth of no more than 100 micrometer below said depth of tissue removal.

# Embodiment set #2

1. In an additional preferred embodiment the a superficial layer of a material while thermally modifying deeper layers, comprising the steps of:

mixing a substance having a high absorption of at least one frequency band of electromagnetic radiation in a host substance, host substance has the properties that after mixing it can be formed into thin films or stripes, and

said stripes are capable of adhering to the surface of the target material thus becoming cohesive stripes, and

applying said stripes to the target material,

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applying electromagnetic radiation to the area covered by the stripes with the substance having a high absorption of at least one frequency band of electromagnetic radiation being applied.

### Embodiment set #3

1. In an additional preferred embodiment the method applying energy to biological tissue, comprising: directing an electromagnetic energy source to apply the energy to a region of the tissue, so as to ablate a portion of the tissue in the region; and applying the energy to the region of the tissue comprises placing a material on the tissue to increase the absorption into the tissue of energy applied by the source.

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- 2. In an additional preferred embodiment the material comprises: Water, glycerin, Stearic Acid, Aloe Vera Gel, Isoparapffin Glycol Stearate, Mineral Oil, Lanolin, Cetyl acetate, Glycerl Stearate, Cetyl Alcohol, Dimenthicone, DEACetyl Phosphate, Magnesium Aluminum Silicate, Acetyulated Lanolin Alcohol, Strearamide, AMP, Methylparaben, Propylpaaben, Fragrance, Cabomer 934, Disodium EDTA, Butylene Glycol, DMDM Hydantoin with a suspension of graphite powder.
- 3. In an additional preferred embodiment the graphite powder particles are larger than any pore in the human body.
- 4. In an additional preferred embodiment the graphite powder particles are larger than about 30 micrometer.
  - 5. In an additional preferred embodiment the graphite powder particles are larger than about 60 micrometer.
  - 6. In an additional preferred embodiment the graphite powder particles are larger than about 1 micrometer.
- 7. In an additional preferred embodiment the biological tissue, comprising: directing an electromagnetic energy source to apply the energy to a region of the tissue, so as to ablate a portion of the tissue in the region; and applying the energy to the region of the tissue comprises placing a material on the tissue to increase the absorption into the tissue of energy applied by the source.
- 20 8. In an additional preferred embodiment the absorption-enhancing material comprises graphite powder particles suspended in mineral oil.
  - 9. In an additional preferred embodiment the absorption-enhancing material comprises graphite powder particles are suspended at a density of yyy particle per cm3.
  - 10. In an additional preferred embodiment the graphite powder particles are suspended in K-Y Jelly.
  - In an additional preferred embodiment the material comprises: Water, glycerin, Stearic Acid, C11-13, Triethnolamine, Petrlatum, Sunflower See Oil, Soy Sterol, Lecithin, Sodium Stearoyl Lactylate, Tocopheryl Acetate (Vitamin E Acetate) Tetinayl Palmitate (Vitamin A Palmitate) Potassium Lactate, Urea, Colleagen Amino Acids, Sodium PCA, Lactic Acid, Zinc Oxide, Isoparapffin Glycol Stearate, Mineral Oil, Lanolin, Cetyl acetate, Glycerl Stearate, Cetyl Alchohol, Dimenthicone, DEACetyl Phosphate, Magnesium Aluminum Silicate, Acetyulated Lanolin Alcohol, Strearamide,

AMP, Methylparaben, Propylpaaben, Fragrance, Cabomer 934, Disodium EDTA, Butylene Glycol, DMDM Hydantoin with a suspension of graphite powder

- 12. In an additional preferred embodiment the material comprises: Novocain and graphite powder suspension.
- 5 13. In an additional preferred embodiment the material comprises: Antioxidant and graphite powder suspension.
  - In an additional preferred embodiment the system, comprising: directing an electromagnetic energy source to apply the energy to a region of the tissue, so as to ablate a portion of the tissue in the region; and applying the energy to the region of the tissue comprises placing a material on the tissue to increase the absorption into the tissue of energy applied by the source, said material is dispensed in such a concentration so as to allow approximately 100% of the incident energy to be converted to heat within the first interaction, followed by: 60% within the second interaction, 30% within the third interaction, and less then 5% within the forth interaction.

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In general the present method contemplates an apparatus for the ablation of a superficial layer of a tissue while thermally modifying deeper layers, comprising the steps of:

Mixing a substance having a high absorption of at least one frequency band of electromagnetic radiation in host substance, host substance has the properties that after mixing it can be formed into thin films or stripes, forming adhesive stripes of said host substance, applying said stripes to the target tissue, applying electromagnetic radiation to the area covered by the stripes with the substance having a high absorption of at least one frequency band of electromagnetic radiation being applied.

However, those skilled in the art would recognize that the embodiments described above are only examples of the present invention and the scope of the present invention should not be limited to these examples only.

In a further preferred embodiment, the present invention contemplates a method for enhancing the transport of a substance through a barrier, comprising: applying the substance to be transported to the surface of the barrier, and exposing the barrier to energy capable of driving said applied substance across the barrier. The invention of further contemplates said energy capable of driving said substance across the barrier is also capable of modifying the barrier characteristics which enhance the penetration of

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said barrier by said substance. This embodiment also contemplates the use of electromagnetic energy to allow modification of the barrier characteristics which enhance the penetration of said barrier by the substance one wishes to drive across the barrier.

In a further preferred embodiment the energy capable of driving said substance across the barrier is also capable of modifying the barrier characteristics which enhance the penetration of the barrier by the substance one wishes to drive across the barrier, said energy is generated by an electromagnetic radiation source and said electromagnetic radiation is subsequently absorbed by an intermediate material capable of absorbing said emitted EM energy.

The energy capable of driving said substance across the barrier is also capable of modifying the barrier characteristics. For example, if the source energy is absorbed by the barrier material or a substance in contact with the barrier material it may generate heat and rapid expansion of pores and perforation (or for example, voids between cells in the skin) which enhance the penetration of the barrier by the substance one wants to drive across the barrier.

The energy is generated by an electromagnetic radiation source and said electromagnetic radiation is subsequently absorbed by an intermediate material capable of absorbing said emitted electromagnetic energy, the absorbed electromagnetic cause rapid expansion in at least a portion of said intermediate material. The rapid expansion due to heat build up build up stress in the material and drives the substance into and through the barrier. The rapid expansion also cause modification of the barrier properties and the modification enhance the delivery of the substance through the barrier.

In further variation of this preferred embodiment, the energy from the source is focused down to a small spot on an intermediate substance capable of absorbing the source energy. The spot may be as small as a about a few microns to as large as about a mm. The peak power density thus may reach as high as 10 E7 or even about 10E8 W/cm2 (i.e., as high as about  $10^9$  W/cm²) even with a moderate continuous wave source of energy with about 1W to about few tens of a W of power. Such power densities are sufficient to create significant stress waves. The focused energy point location can be changed with the use of a scanner composed of mirrors that moves the beam to cover a larger treatment area. Alternatively, the laser and lens combination can be mounted on a

small track that allow the targeted interaction spot to be changed and move across the target skin.

This embodiment can be better understood with the help of Figure 10A. In this Figure, the apparatus contain a power source (for example, a laser) 10A10 which emits a laser beam 10a20, the beam is manipulated thorough a scanner 10a30, and a lens 10a40 and is focused on a layer of substance capable of absorbing the energy 10a50.

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The stress wave generated by the interaction of the energy with the high absorbing substance propagate to a reservoir of medicine or other product one wishes to deliver across a barrier surface to the target material 10a70. An optional coolant 10a80 can be discharged to cause rapid contraction in the membrane of high absorbing substance 10a50.

Alternatively, in a preferred embodiment also shown in figure 10A, a track 10A100 can carry the mounted energy source 10a10 and the lens 10a40 thus replacing and eliminating the need for the scanners 10A30. In this embodiment, the energy source and lens are scanned as one across the high absorbing substance membrane 10a50 to move the interaction point and create a much larger treatment area.

In yet another preferred embodiment the energy capable of driving said substance across the barrier is also capable of modifying the barrier characteristics which enhance the penetration of the barrier by the substance, said energy is generated by an electromagnetic radiation source and said electromagnetic energy is subsequently absorbed by an intermediate material capable of absorbing said emitted EM energy, the absorbed EM cause rapid expansion in at least a portion of said intermediate material, the rapid expansion drives said substance into and through the barrier, the rapid expansion also cause modification of the barrier properties, the modification enhance the delivery of said substance through the barrier, and the EM energy is focused from the source onto the intermediate substance and said focal spot is scanned across the intermediate substance surface, and, scanning rate and scanning pattern determine the characteristics of the spatial and temporal modification of the barrier characteristics, and also determine the spatial and temporal driving effect on the substance being delivered across the barrier.

In yet another preferred embodiment the method above can be enhanced as the energy capable of driving said substance across the barrier is also capable of modifying the barrier characteristics which enhance the penetration of said barrier by said substance,

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said energy is generated by an electromagnetic energy source and said electromagnetic energy is subsequently absorbed by an intermediate material capable of absorbing said emitted EM energy, said absorbed EM cause rapid expansion in at least a portion of said intermediate material, said rapid expansion drives said substance into and through the barrier, the rapid expansion also cause modification of the barrier properties, the modification enhance the delivery of said substance through the barrier, and the EM energy is focused from the source onto the intermediate substance and said focal spot is scanned across the intermediate substance surface, and, scanning rate and scanning pattern determine the characteristics of the spatial and temporal modification of the barrier characteristics, and also determine the spatial and temporal driving effect on the substance being delivered across the barrier, and, said intermediate medium is shaped so when it interacts with said EM energy, said interaction enhances the modification of the barrier to allow better delivery of said substance across the barrier, and said interaction also enhances the driving and delivery of substance across the barrier.

In yet another preferred embodiment enhancing the transport of a substance across a barrier, the device comprising: a dispenser for applying the substance to be transported to the barrier surface, an energy source, a conduit capable of directing energy from the energy source to said barrier's surface leading to enhancement of the delivery of said applied substance across said surface barrier.

In yet another preferred embodiment the device above can be enhance by using the energy capable of driving said substance across the barrier is also capable of modifying the barrier characteristics which enhance the penetration of said barrier by said substance.

In yet another preferred embodiment the said energy enhancing the delivery of said substance across a barrier is also capable of modifying the barrier characteristics so that said modifications enhance the penetration of said barrier by said substance, wherein said energy is generated by an electromagnetic (EM) energy source.

In yet another preferred embodiment the device above can use the energy enhancing the delivery of said substance across a barrier is also capable of modifying the barrier characteristics so that said modifications enhance the penetration of said barrier by said substance, wherein said energy is generated by an electromagnetic (EM) energy

source, and wherein said electromagnetic energy is subsequently absorbed by an intermediate material capable of absorbing said emitted EM energy.

In yet another preferred embodiment the device above can use the energy enhancing the delivery of said substance across a barrier is also capable of modifying the barrier characteristics so that said modifications enhance the penetration of said barrier by said substance, wherein said energy is generated by an electromagnetic (EM) energy source, and wherein said electromagnetic energy is subsequently absorbed by an intermediate material capable of absorbing said emitted EM energy, said absorbed EM energy causes rapid expansion in at least a portion of said intermediate material, said rapid expansion drives said substance into the barrier, said rapid expansion also cause modification of the barrier properties, wherein said effects of modification and driving of substance enhance the delivery of said substance through the barrier.

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In yet another preferred embodiment The device above can use the energy enhancing the delivery of said substance across a barrier is also capable of modifying the barrier characteristics so that said modifications enhance the penetration of said barrier by said substance, wherein said energy is generated by an electromagnetic (EM) energy source, and wherein said electromagnetic energy is subsequently absorbed by an intermediate material capable of absorbing said emitted EM energy, said absorbed EM energy causes rapid expansion in at least a portion of said intermediate material, said rapid expansion drives said substance into the barrier, said rapid expansion also cause modification of the barrier properties, wherein said effects of modification and driving of substance enhance the delivery of said substance through the barrier, and, wherein, said source EM energy is focused onto the intermediate substance while said focal spot is scanned across the intermediate substance surface.

In yet another preferred embodiment the device above can use the energy enhancing the delivery of said substance across a barrier is also capable of modifying the barrier characteristics so that said modifications enhance the penetration of said barrier by said substance, wherein said energy is generated by an electromagnetic (EM) energy source, and wherein said electromagnetic energy is subsequently absorbed by an intermediate material capable of absorbing said emitted EM energy, said absorbed EM energy causes rapid expansion in at least a portion of said intermediate material, said rapid expansion drives said substance into the barrier, said rapid expansion also cause

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modification of the barrier properties, wherein said effects of modification and driving of substance enhance the delivery of said substance through the barrier, and, wherein, said source EM energy is focused onto the intermediate substance while said focal spot is scanned across the intermediate substance surface, wherein scanning rate and scanning pattern determine the characteristics of the spatial and temporal modification of the barrier characteristics, and also determine the spatial and temporal driving effect on the substance being delivered across the barrier.

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In yet another preferred embodiment the device above can use the energy enhancing the delivery of said substance across a barrier is also capable of modifying the barrier characteristics so that said modifications enhance the penetration of said barrier by said substance, wherein said energy is generated by an electromagnetic (EM) energy source, and wherein said electromagnetic energy is subsequently absorbed by an intermediate material capable of absorbing said emitted EM energy, said absorbed EM energy causes rapid expansion in at least a portion of said intermediate material, said rapid expansion drives said substance into the barrier, said rapid expansion also cause modification of the barrier properties, wherein said effects of modification and driving of substance enhance the delivery of said substance through the barrier, and, wherein, said source EM energy is focused onto the intermediate substance while said focal spot is scanned across the intermediate substance surface, wherein scanning rate and scanning pattern determine the characteristics of the spatial and temporal modification of the barrier characteristics, and also determine the spatial and temporal driving effect on the substance being delivered across the barrier and, wherein, said intermediate medium is shaped so when it interacts with said EM energy, said interaction enhances the modification of the barrier to allow better delivery of said substance across the barrier, and said interaction also enhances the driving of said substance across the barrier.

In yet another preferred embodiment for the transport of a substance across a barrier, the device comprising: a dispenser for applying the substance to be transported to the barrier surface, a continuous wave electromagnetic energy source, a conduit capable of directing and scanning said electromagnetic energy from the EM energy source to said barrier's surface and moving it about said barrier surface thus leading to enhancement of the delivery and transport of said applied substance across said barrier.

In yet another preferred embodiment the device above can use the energy from the EM energy source by focusing it onto an intermediate material comprised of at least two distinct surfaces, a first surface containing at least some high absorbing substance capable of absorbing at least some of said source energy and facing the energy source and, a second surface made of peeks and troughs, said peaks form the "legs" which make contact with the surface of the barrier across which the substance is to be delivery, while the troughs contain the substance to be delivered and wherein the energy from the beam of EM energy source is scanned across the high absorbing substance surface generating rapid expansion in said high absorbing substance surface which drives the substance within each trough below said high absorbing surface into the barrier.

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In yet another preferred embodiment of the device above the sources energy per unit area at the high absorbing substance is at least 10<sup>2</sup> W/CM<sup>2</sup> and a dwell time of on the order of 0.1 second to 0.01 seconds.

In yet another preferred embodiment of the device above can be improved by using the sources energy per unit area at the high absorbing substance is at least  $10^4$  W/CM<sup>2</sup> and a dwell time of on the order of 1 ms to 0.1 ms.

6. The device of claim 34 wherein said sources energy per unit area at the high absorbing substance is at least  $10^6$  W/CM<sup>2</sup> to  $10^8$  W/CM<sup>2</sup> and a dwell time of on the order of 0.01 ms to 0.01 microsecond.

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#### **CLAIMS**

# What Is Claimed Is:

- 1 1. A device for the modification of a layer of a tissue comprising:
- a source of electromagnetic radiation;
- an intermediate substance having a high absorption of at least one frequency band emerging from said source of electromagnetic radiation;
- said intermediate substance having a high absorption of at least one frequency
- band emerging from said source of electromagnetic radiation is positioned between the
- 7 target material and said light source; and
- said intermediate substance is irradiated by said electromagnetic source whereby
- 9 at least one frequency band of electromagnetic radiation, and is thereby converted to
- thermal energy sufficient to bring about modification in the target properties.
- 1 2. The device as in claim 1 wherein said intermediate substance having a high
- 2 absorption of at least one frequency band emerging from said source of electromagnetic
- 3 radiation is a thin film containing high absorbing substance.
- 1 3. The device of claim 1 wherein said intermediate substance having a high
- 2 absorption of at least one frequency band emerging from said source of electromagnetic
- 3 radiation is a paper containing highly absorbing substance.
- 1 4. The device of claim 1 where said intermediate substance having a high absorption
- of at least one frequency band emerging from said source of electromagnetic radiation is
- a 40 wt tracing paper containing highly absorbing particles.
- 1 5. The device of claim 1 where said intermediate substance having a high absorption
- of at least one frequency band emerging from said source of electromagnetic radiation is
- a thermal insulator containing highly absorbing particles.
- 1 6. The device of claim 1 where said intermediate substance having a high absorption
- of at least one frequency band emerging from said source of electromagnetic radiation is
- a layer of thermal conductor containing highly absorbing particles.

- 1 7. The device of claim 1 wherein said intermediate substance having a high
- absorption of at least one frequency band emerging from said source of electromagnetic
- 3 radiation is applied to said substance of high absorption on the side facing the energy
- 4 source and not to the side which is in contact with the target material.
- 1 8. The device of claim 1 wherein said intermediate substance having a high
- 2 absorption of at least one frequency band emerging from said source of electromagnetic
- radiation is applied to a film of material on the side facing the energy source and not to
- 4 the side which is in contact with the target material, and, The film is made of thermally
- 5 insulating material.
- 1 9. The device of claim 1 wherein said intermediate substance having a high
- absorption of at least one frequency band emerging from said source of electromagnetic
- 3 radiation is mixed with grains of conducting material to form a film of thermally
- 4 conducting, optically absorbing mix.
- 1 10. A method for removing or modifying a material, comprising: applying energy to a
- 2 material so as to remove or modify a portion of a target material; and, initiating removal
- 3 of energy from the same material in coordination with the energy deposition phase
- 4 wherein the target material comprises the surface region of the material substance and
- 5 some of the area below the surface.
- 1 11. A method according to claim 9, wherein applying energy comprises applying
- 2 energy which is absorbed by an intermediate substance which is in contact with the target
- material to be modified or removed, said intermediate substance is capable of absorbing
- 4 said energy, converting it to thermal energy and conducting the thermal energy to the
- 5 target material.
- 1 12. The method of claim 9 wherein the intermediate substance in contact with the
- 2 target material and capable of absorbing energy, converting it to thermal energy and
- 3 conducting said thermal energy to the target material, is cooled after transferring at least
- 4 part of the absorbed energy to the target material.

13. 1 A method for controlling the distribution of energy in a target material wherein in the surface is heated by energy of the source absorbed by the high absorbing substance is 2 conducted to the surface of the target material to be modified, wherein the energy 3 absorbed at the surface by the high absorbing substance is further converted to thermal 4 5 energy and diffuses as thermal energy into the target material to be modified while some of the source energy is allowed to pass through windows the intermediate material 6 substance and are scattered as optical energy within the target material, wherein said 7 8 optical energy is ultimately absorbed by sites in the target material and is converted to heat. 9

- 1 14. The method of claim 12 for controlling the distribution of energy in a target material wherein the energy source of diode laser energy emitting a beam which is then 2 collimated by the collimating lenses, said beam is further deflected by scanning mirrors 3 4 and focused by the focusing lens, a small portion of the beam is further deflected by said beam splitter towards a detector which measure power as well as motion, the rest of the 5 beam continues through a manual shutter to a substance of high absorption mounted on a 6 7 disposable tip of said intermediate material, said disposable tip contain the high absorbing substance film which have the ability to partially transmit some of the source 8 energy to the target material, said device also contain a coolant reservoir and a coolant 9 ejector said ejector direct the coolant spray output towards the side of the high absorbing 10 substance film facing the inside of the device, said high absorbing substance is also able 11 to both conduct the laser energy to the target material as well as remove energy from the 12 13 target material through the action of the coolant spray.
- 1 15. A device for modifying and removing material comprising: an energy source and an intermediate material, said energy source is capable of imparting energy to said intermediate material; said intermediate material is capable of absorbing said energy and transferring said energy further to the target material to achieve modification or removal of said target material;
- 1 16. The device of claim 14 wherein the substance in the intermediate medium capable of absorbing said source energy is located on the side farther away from the target material and said absorbing substance is gradually consume by the interaction thus

- 4 gradually exposing deeper and deeper layers of the absorbing substance, said different
- 5 layers possess different colors, and said different layers' color corresponds to different
- tissue modification effect, wherein said energy source is a laser source which is directed
- towards a stirring mechanism capable of moving the beam in a predetermined pattern
- 8 over absorbing substance in the intermediate medium capable of absorbing said laser
- 9 source energy, wherein parts of said intermediate substance are capable of conducting
- said absorbed energy to the target surface and part of said intermediate medium are
- 11 insulators.
- 1 17. A device for modifying the condition of a target material, comprising: A source of
- 2 optical energy for irradiating an intermediate material with electromagnetic radiation said
- 3 intermediate material is substantially a strong absorber of said electromagnetic radiation;
- 4 cooling element coupled to said source of energy for cooling the surface of the target
- 5 material immediately after the irradiation period, said cooling means comprising: a
- 6 thermally conducting intermediate material having one side in contact with the target
- 7 material, wherein said conducting intermediate material is comprised of a material that is
- opaque to the source's optical energy and has a high thermal conductivity; and means for
- 9 circulating a cooling gas in contact with said intermediate material.
- 1 18. A method for enhancing the transport of a substance through a barrier,
- 2 comprising: applying the substance to be transported to the surface of the barrier, and
- 3 exposing the barrier to energy capable of driving said applied substance across the
- 4 barrier.
- 1 19. The method of claim 17, wherein said energy capable of driving said substance
- 2 across the barrier is also capable of modifying the barrier characteristics which enhance
- 3 the penetration of said barrier by said substance.
- 1 20. The method of claim 17, wherein said energy capable of driving said substance
- 2 across the barrier is also capable of modifying the barrier characteristics which enhance
- 3 the penetration of said barrier by said substance, said energy is generated by an
- 4 electromagnetic radiation source.

- 1 21. The method of claim 17, wherein said energy capable of driving said substance
- 2 across the barrier is also capable of modifying the barrier characteristics which enhance
- 3 the penetration of said barrier by said substance, said energy is generated by an
- 4 electromagnetic radiation source and said electromagnetic radiation is subsequently
- 5 absorbed by an intermediate material capable of absorbing said emitted EM energy.
- 1 22. The method of claim 17, wherein said energy capable of driving said substance
- 2 across the barrier is also capable of modifying the barrier characteristics which enhance
- 3 the penetration of said barrier by said substance, said energy is generated by an
- 4 electromagnetic radiation source and said electromagnetic radiation is subsequently
- absorbed by an intermediate material capable of absorbing said emitted EM energy, said
- absorbed EM cause rapid expansion in at least a portion of said intermediate material,
- 7 said rapid expansion drives said substance into and through the barrier, said rapid
- 8 expansion also cause modification of the barrier properties, said modification enhance the
- 9 delivery of said substance through the barrier.
- 1 23. The method of claim 17, wherein said energy capable of driving said substance
- 2 across the barrier is also capable of modifying the barrier characteristics which enhance
- 3 the penetration of said barrier by said substance, said energy is generated by an
- 4 electromagnetic radiation source and said electromagnetic radiation is subsequently
- 5 absorbed by an intermediate material capable of absorbing said emitted EM energy, said
- 6 absorbed EM cause rapid expansion in at least a portion of said intermediate material,
- 7 said rapid expansion drives said substance into and through the barrier, said rapid
- 8 expansion also cause modification of the barrier properties, said modification enhance the
- 9 delivery of said substance through the barrier, and, said EM energy is focused from the
- source onto the intermediate substance and said focal spot is scanned across the
- intermediate substance surface.
  - 1 24. The method of claim 17, wherein said energy capable of driving said substance
- 2 across the barrier is also capable of modifying the barrier characteristics which enhance
- 3 the penetration of said barrier by said substance, said energy is generated by an
- 4 electromagnetic radiation source and said electromagnetic energy is subsequently
- absorbed by an intermediate material capable of absorbing said emitted EM energy, said

absorbed EM cause rapid expansion in at least a portion of said intermediate material, said rapid expansion drives said substance into and through the barrier, said rapid expansion also cause modification of the barrier properties, said modification enhance the delivery of said substance through the barrier, and said EM energy is focused from the source onto the intermediate substance and said focal spot is scanned across the intermediate substance surface, and, scanning rate and scanning pattern determine the characteristics of the spatial and temporal modification of the barrier characteristics, and

- also determine the spatial and temporal driving effect on the substance being delivered
- 14 across the barrier.
- 25. The method of claim 17, wherein said energy capable of driving said substance 1 2 across the barrier is also capable of modifying the barrier characteristics which enhance the penetration of said barrier by said substance, said energy is generated by an 3 electromagnetic energy source and said electromagnetic energy is subsequently absorbed 4 by an intermediate material capable of absorbing said emitted EM energy, said absorbed 5 EM cause rapid expansion in at least a portion of said intermediate material, said rapid 6 7 expansion drives said substance into and through the barrier, said rapid expansion also 8 cause modification of the barrier properties, said modification enhance the delivery of said substance through the barrier, and said EM energy is focused from the source onto 9 the intermediate substance and said focal spot is scanned across the intermediate 10 11 substance surface, and, scanning rate and scanning pattern determine the characteristics 12 of the spatial and temporal modification of the barrier characteristics, and also determine the spatial and temporal driving effect on the substance being delivered across the barrier, 13 and, said intermediate medium is shaped so when it interacts with said EM energy, said 14 interaction enhances the modification of the barrier to allow better delivery of said 15 substance across the barrier, and said interaction also enhances the driving and delivery 16 of substance across the barrier. 17
- 1 26. For enhancing the transport of a substance across a barrier, the device comprising:
- a dispenser for applying the substance to be transported to the barrier surface, an energy
- 3 source, a conduit capable of directing energy from the energy source to said barrier's
- 4 surface leading to enhancement of the delivery of said applied substance across said
- 5 surface barrier.

- 1 27. The device of claim 25, wherein said energy capable of driving said substance
- 2 across the barrier is also capable of modifying the barrier characteristics which enhance
- 3 the penetration of said barrier by said substance.
- 1 28. The device of claim 25, wherein said energy enhancing the delivery of said
- 2 substance across a barrier is also capable of modifying the barrier characteristics so that
- said modifications enhance the penetration of said barrier by said substance, wherein said
- 4 energy is generated by an electromagnetic (EM) energy source.
- 1 29. The device of claim 25, wherein said energy enhancing the delivery of said
- substance across a barrier is also capable of modifying the barrier characteristics so that
- 3 said modifications enhance the penetration of said barrier by said substance, wherein said
- 4 energy is generated by an electromagnetic (EM) energy source, and wherein said
- 5 electromagnetic energy is subsequently absorbed by an intermediate material capable of
- 6 absorbing said emitted EM energy.
- 1 30. The device of claim 25, wherein said energy enhancing the delivery of said
- 2 substance across a barrier is also capable of modifying the barrier characteristics so that
- 3 said modifications enhance the penetration of said barrier by said substance, wherein said
- 4 energy is generated by an electromagnetic (EM) energy source, and wherein said
- 5 electromagnetic energy is subsequently absorbed by an intermediate material capable of
- absorbing said emitted EM energy, said absorbed EM energy causes rapid expansion in at
- 7 least a portion of said intermediate material, said rapid expansion drives said substance
- 8 into the barrier, said rapid expansion also cause modification of the barrier properties,
- 9 wherein said effects of modification and driving of substance enhance the delivery of said
- substance through the barrier.
- 1 31. The device of claim 25, wherein said energy enhancing the delivery of said
- 2 substance across a barrier is also capable of modifying the barrier characteristics so that
- 3 said modifications enhance the penetration of said barrier by said substance, wherein said
- 4 energy is generated by an electromagnetic (EM) energy source, and wherein said
- 5 electromagnetic energy is subsequently absorbed by an intermediate material capable of
- absorbing said emitted EM energy, said absorbed EM energy causes rapid expansion in at

7 least a portion of said intermediate material, said rapid expansion drives said substance

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8 into the barrier, said rapid expansion also cause modification of the barrier properties,

wherein said effects of modification and driving of substance enhance the delivery of said

substance through the barrier, and, wherein, said source EM energy is focused onto the

intermediate substance while said focal spot is scanned across the intermediate substance

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- 32. The device of claim 25, wherein said energy enhancing the delivery of said substance across a barrier is also capable of modifying the barrier characteristics so that said modifications enhance the penetration of said barrier by said substance, wherein said energy is generated by an electromagnetic (EM) energy source, and wherein said electromagnetic energy is subsequently absorbed by an intermediate material capable of absorbing said emitted EM energy, said absorbed EM energy causes rapid expansion in at least a portion of said intermediate material, said rapid expansion drives said substance into the barrier, said rapid expansion also cause modification of the barrier properties, wherein said effects of modification and driving of substance enhance the delivery of said substance through the barrier, and, wherein, said source EM energy is focused onto the intermediate substance while said focal spot is scanned across the intermediate substance surface, wherein scanning rate and scanning pattern determine the characteristics of the spatial and temporal modification of the barrier characteristics, and also determine the spatial and temporal driving effect on the substance being delivered across the barrier.
- 33. The device of claim 25, wherein said energy enhancing the delivery of said 1 substance across a barrier is also capable of modifying the barrier characteristics so that 2 3 said modifications enhance the penetration of said barrier by said substance, wherein said energy is generated by an electromagnetic (EM) energy source, and wherein said 4 electromagnetic energy is subsequently absorbed by an intermediate material capable of 5 absorbing said emitted EM energy, said absorbed EM energy causes rapid expansion in at 6 least a portion of said intermediate material, said rapid expansion drives said substance 7 into the barrier, said rapid expansion also cause modification of the barrier properties, 8 wherein said effects of modification and driving of substance enhance the delivery of said 9 10 substance through the barrier, and, wherein, said source EM energy is focused onto the intermediate substance while said focal spot is scanned across the intermediate substance 11

surface, wherein scanning rate and scanning pattern determine the characteristics of the spatial and temporal modification of the barrier characteristics, and also determine the spatial and temporal driving effect on the substance being delivered across the barrier and, wherein, said intermediate medium is shaped so when it interacts with said EM energy, said interaction enhances the modification of the barrier to allow better delivery of said substance across the barrier, and said interaction also enhances the driving of said substance across the barrier.

- 34. A device for enhancing the transport of a substance across a barrier, the device comprising: a dispenser for applying the substance to be transported to the barrier surface, a continuous wave electromagnetic energy source, a conduit capable of directing and scanning said electromagnetic energy from the EM energy source to said barrier's surface and moving it about said barrier surface thus leading to enhancement of the delivery and transport of said applied substance across said barrier.
- 35. 1 The device of claim 33 wherein said energy from the EM energy source is focused onto an intermediate material comprised of at least two distinct surfaces, a first 2 surface containing at least some high absorbing substance capable of absorbing at least 3 some of said source energy and facing the energy source and, a second surface made of 4 peeks and troughs, said peaks form the "legs" which make contact with the surface of the 5 barrier across which the substance is to be delivery, while the troughs contain the 6 7 substance to be delivered and wherein the energy from the beam of EM energy source is scanned across the high absorbing substance surface generating rapid expansion in said 8 high absorbing substance surface which drives the substance within each trough below 9 said high absorbing surface into the barrier. 10
- 1 36. The device of claim 34 wherein said sources energy per unit area at the high absorbing substance is at least 10<sup>2</sup> W/CM<sup>2</sup> and a dwell time of on the order of 0.1 second to 0.01 seconds.
- The device of claim 34 wherein said sources energy per unit area at the high absorbing substance is at least 10<sup>4</sup> W/CM<sup>2</sup> and a dwell time of on the order of 1 ms to 0.1 ms.

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- 1 38. The device of claim 34 wherein said sources energy per unit area at the high
- 2 absorbing substance is at least 10<sup>6</sup> W/CM<sup>2</sup> to 10<sup>8</sup> W/CM<sup>2</sup> and a dwell time of on the order
- of 0.01 ms to 0.01 microsecond.

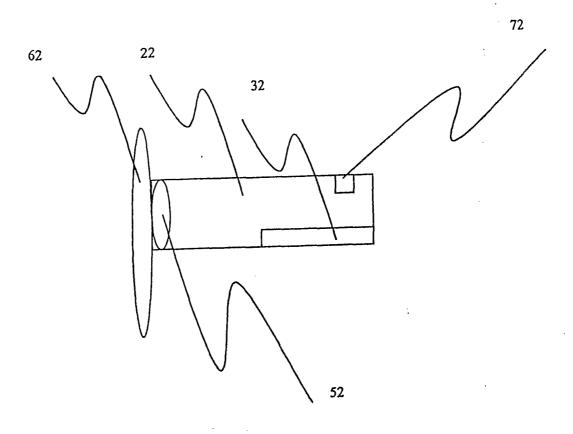


Figure 1

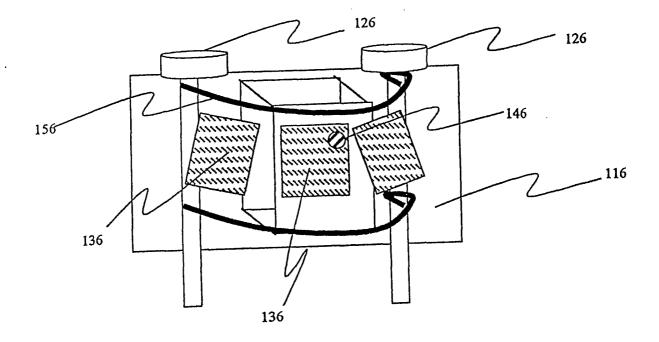


Figure 2

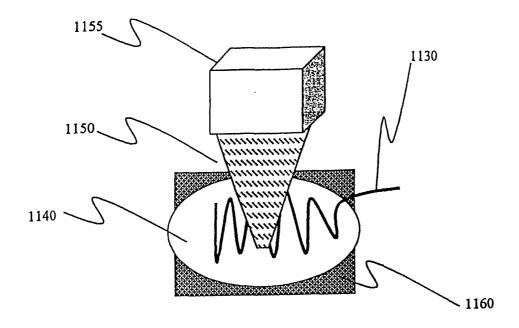


Figure 3

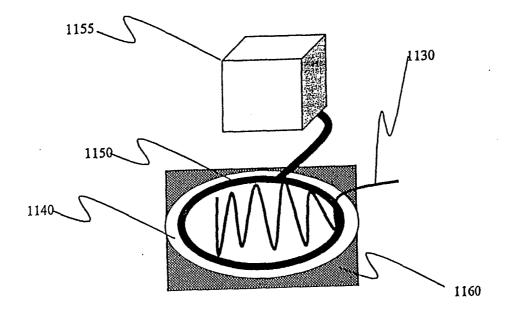


Figure 4

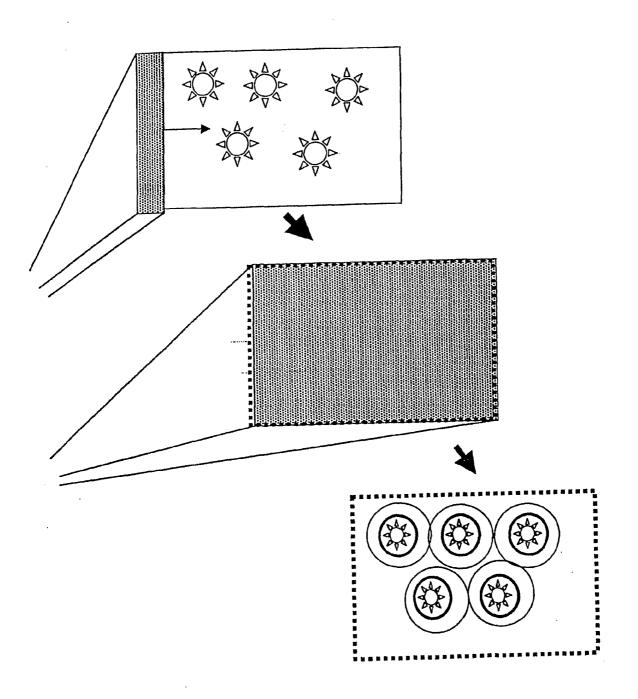


Figure 5

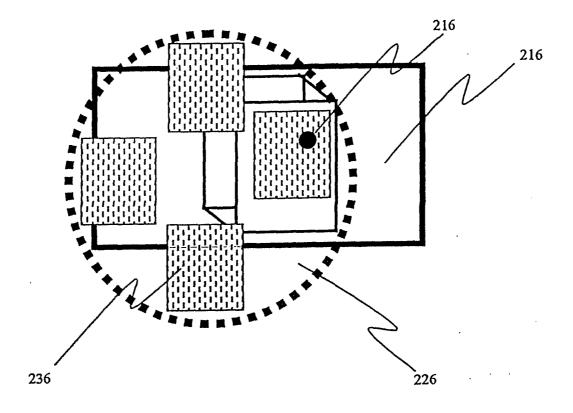


Figure 6

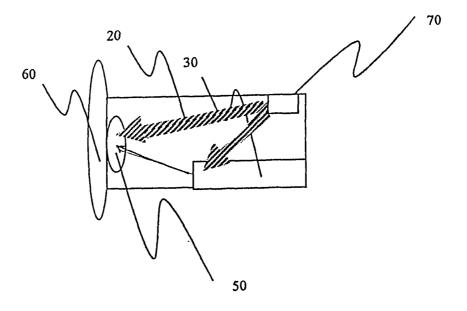


Figure 7

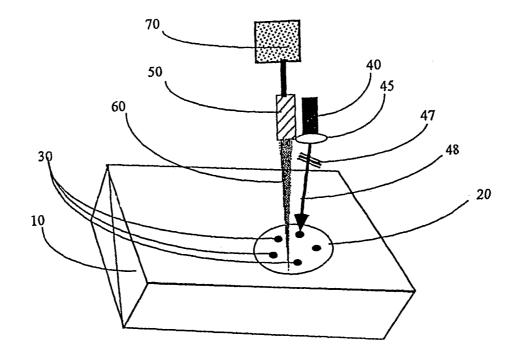
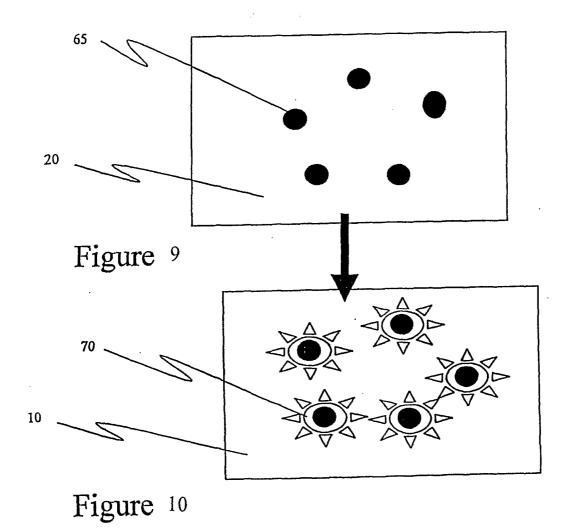
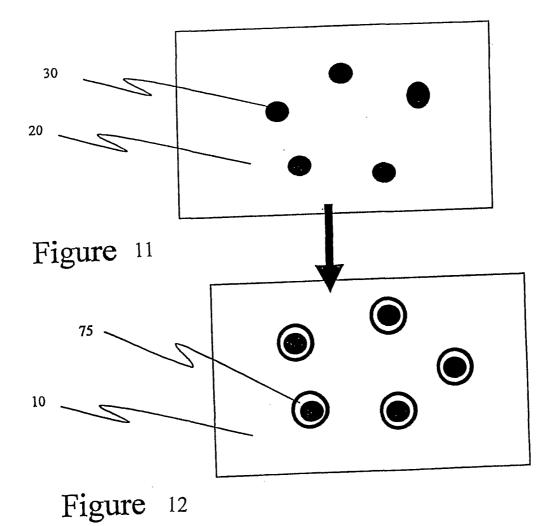


FIGURE 8





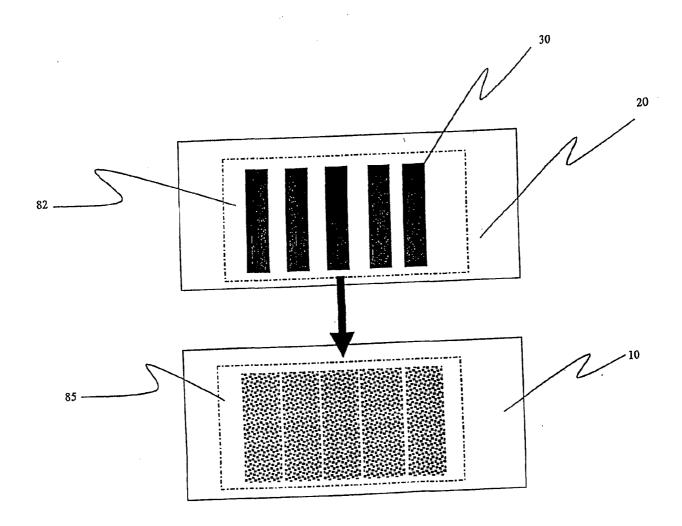


Figure 13

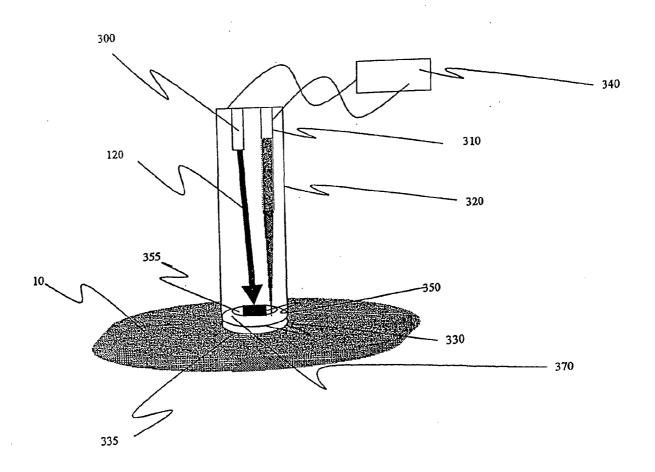


Figure 14

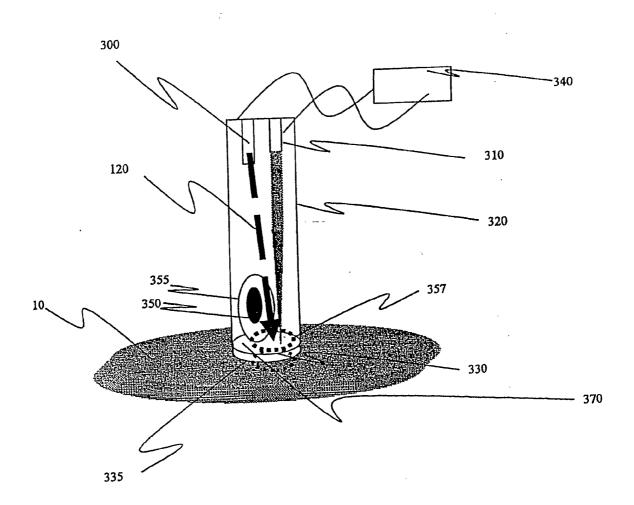
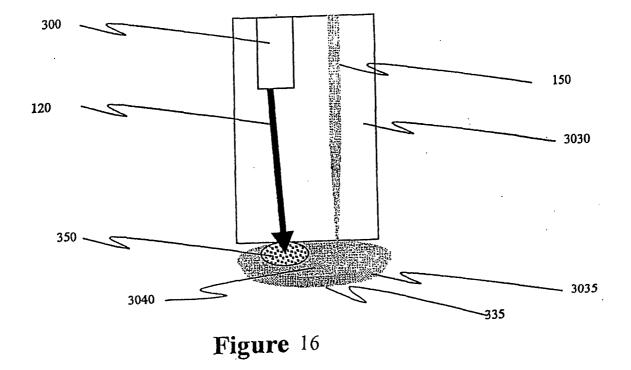


Figure 15



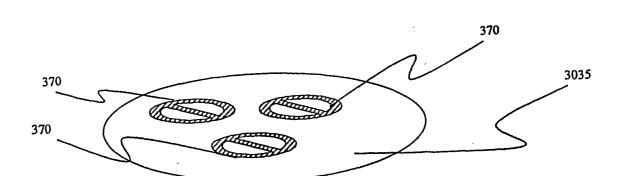


Figure 17

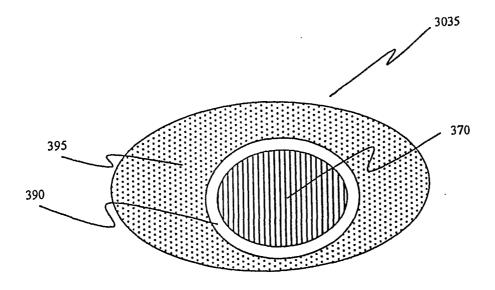


Figure 18

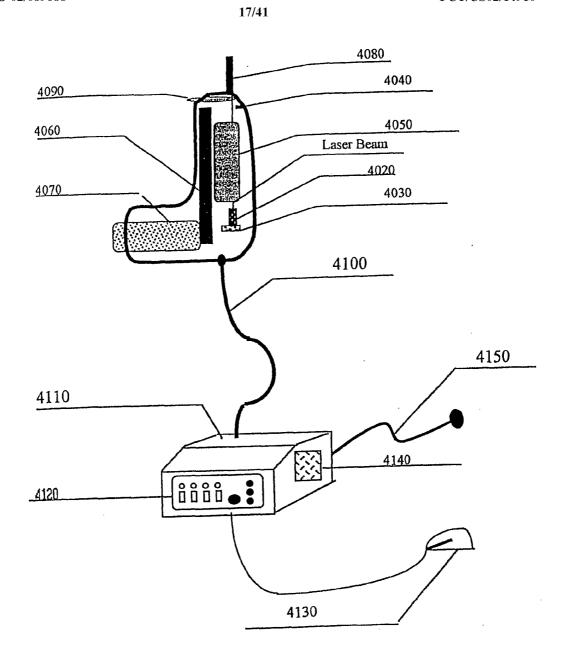


Figure 19

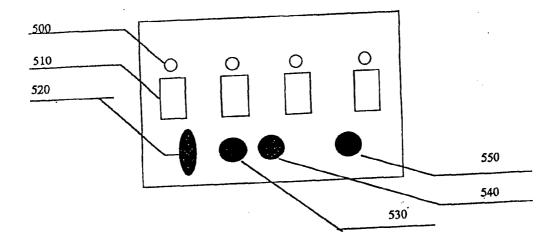


Figure 20

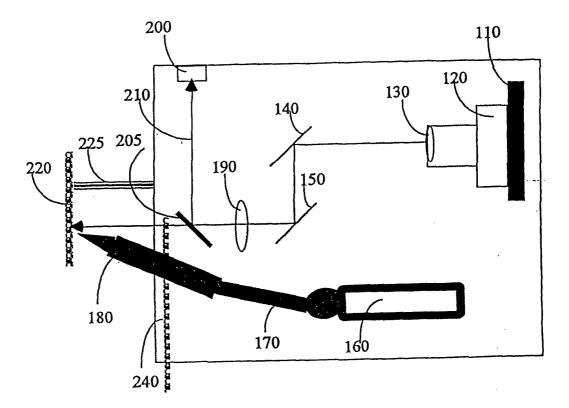


Figure 21

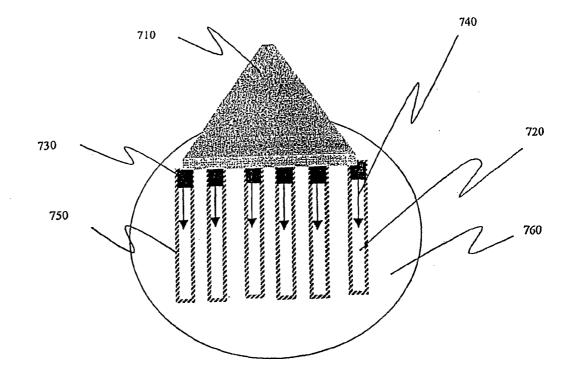


Figure 22

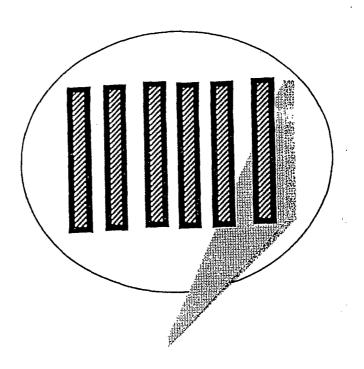


Figure 23

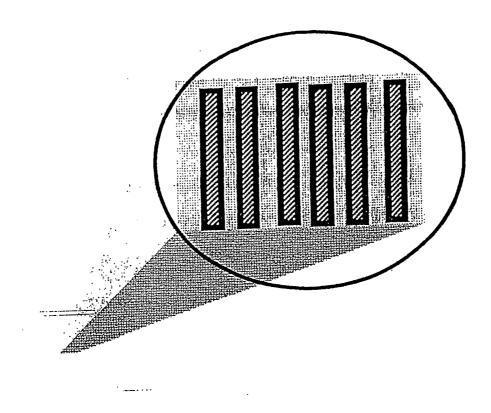


Figure 24

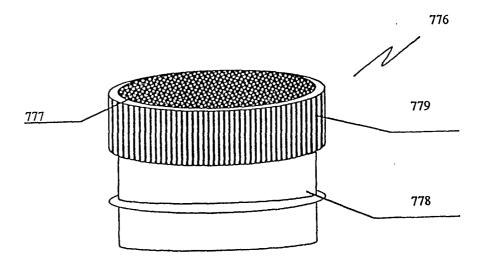


Figure 25

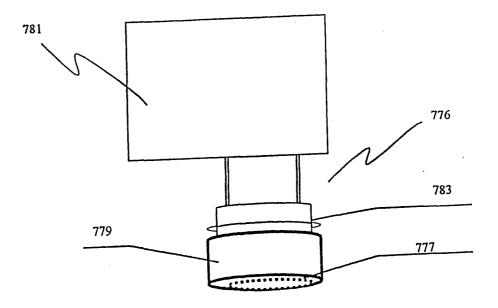


Figure 26

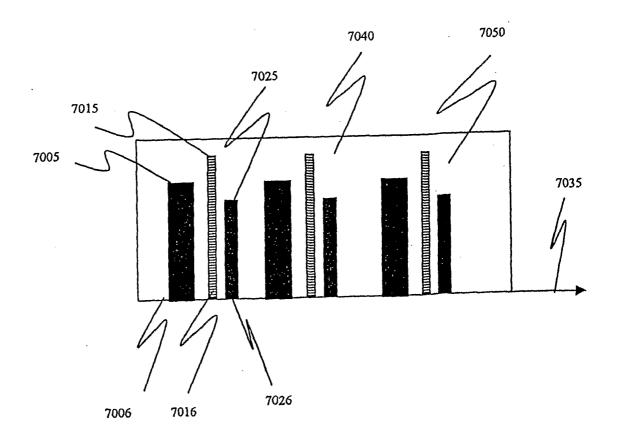


Figure 27

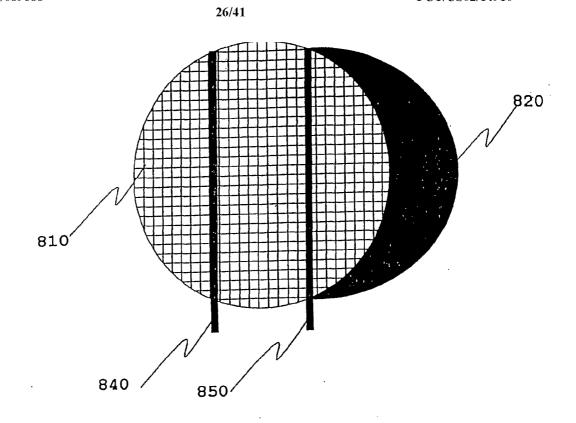


Figure 28

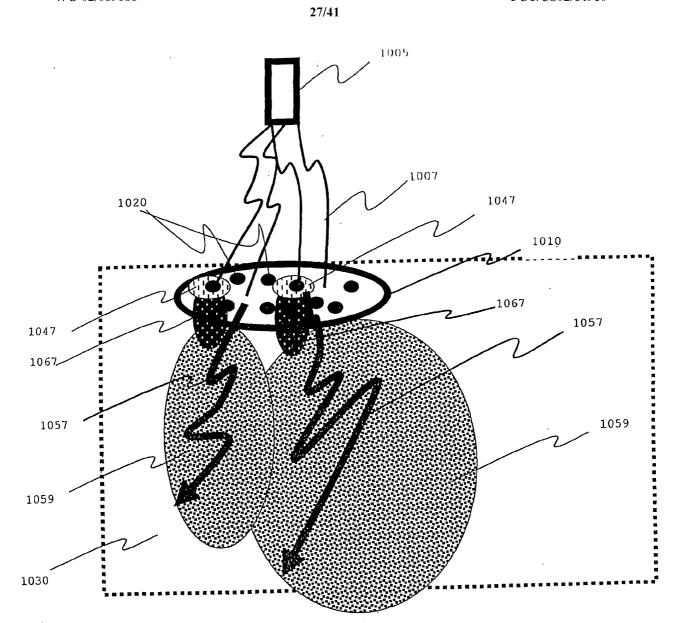


Figure 29

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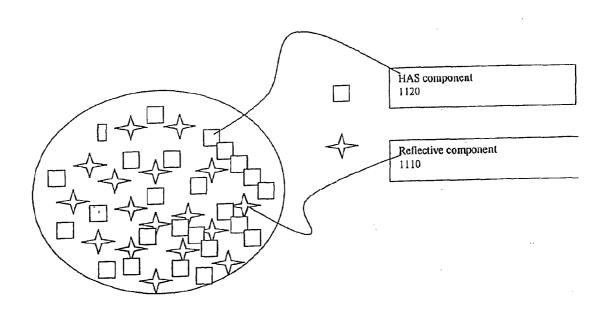
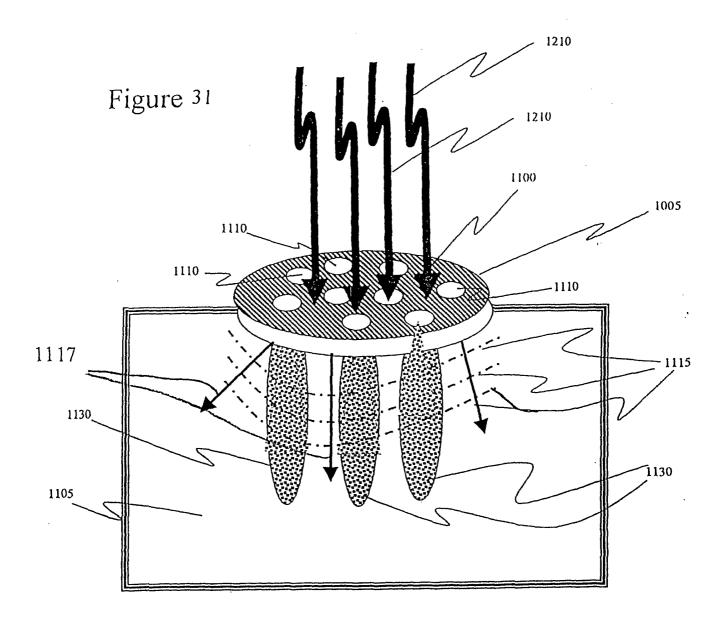
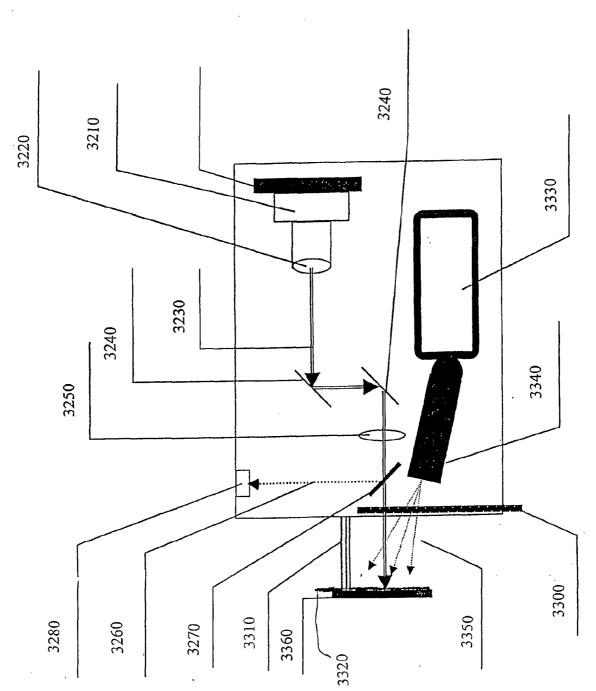


Figure 30







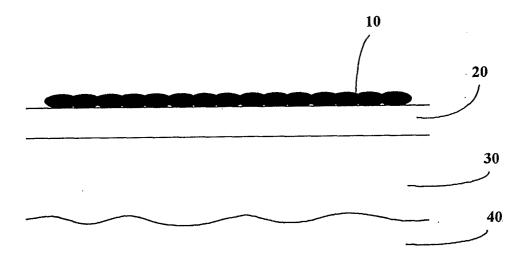


Figure 1A

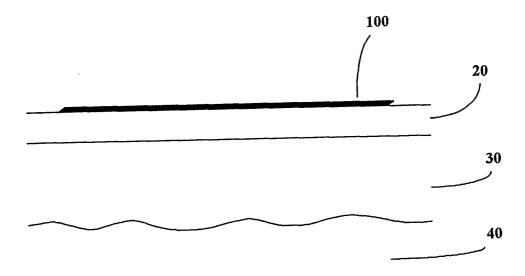


Figure 2A

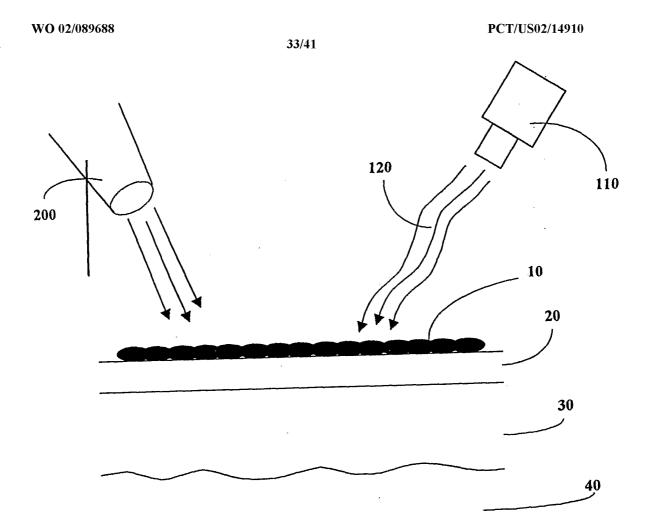


Figure 3A

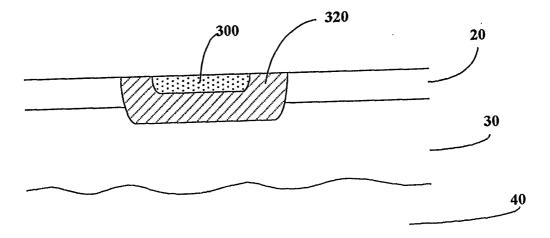


Figure 4A

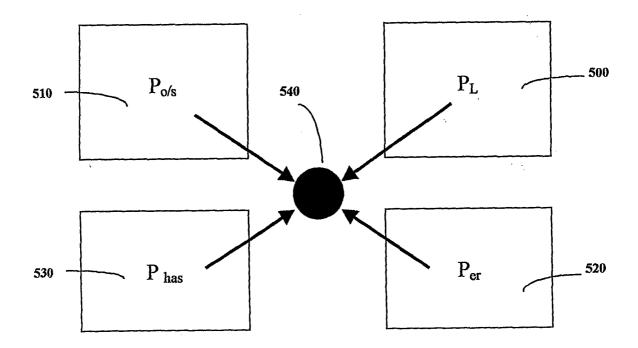
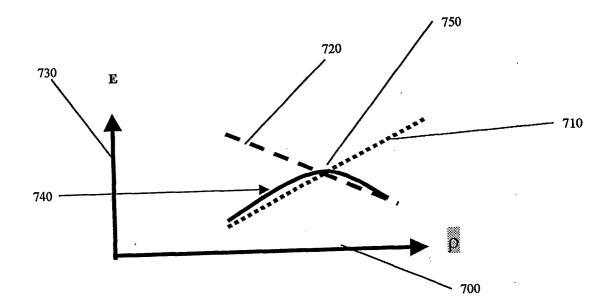


Figure 5A

300,00 630 250.00 200.00 Ablation Rate (um) **510** Thermal Damage 100.00 620 50.00 Abiation Rate 0.00 50.00 100.00 150.00 200.00 250.00 300.00 0.00 Fluence (J/cm2) 600 Figure 6A

Figure 7A



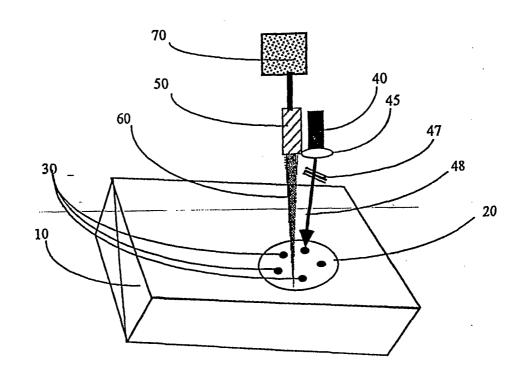


Figure 8A

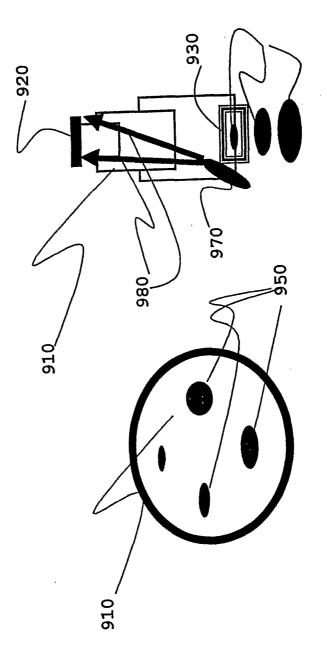


Figure 9A

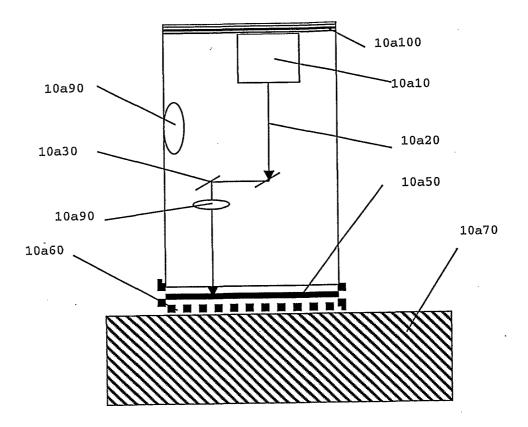


Figure 10A

WO 02/089688 PCT/US02/14910

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/14910

| A. CLASSIFICATION OF SUBJECT MATTER   |   |                           |
|---|---|---------------------------|
| IPC(7) : A61B 18/18<br>US CL : 606/9  |   |                           |
| 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.: 606/3, 9-17; 604/20, 21   |   |                           |
|   |   |                           |
| Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched NONE  |   |                           |
| Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) NONE   |   |                           |
| C. DOCUMENTS CONSIDERED TO BE RELEVANT  |   |                           |
| Category * Citation of document, with indication, where ap  | phropriate of the relevant passages Rele  | vant to claim No.         |
| X US 6,156,030 A (NEEV) 05 December 2000 (05.12   |   | 1-38                      |
|   |   |                           |
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| Further documents are listed in the continuation of Box C.  | See patent family annex.  |                           |
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| Date of the actual completion of the international search 27 July 2002 (27.07.2002)   | Date of mailing of the international search re  | port                      |
| Name and mailing address of the ISA/US  | Authorized officer  |                           |
| Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231   | David Shay  |                           |
| Facsimile No. (703)305-3230   | Telephone No. (703) 308-0858  |                           |
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