

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO	
RAD: 14-49585- -5	FECHA: 2015-05-16 23:33:07
DEP: 2020 DIRECCION DE NUEVAS CREACIONES	EVE: 378 FASE NACIONAL INCLUIDO CAPITULO I
TRA: 11 PCT-PATENTE DE INVENCION CAPITULOS I Y II	FOLIOS: 7
ACT: 430 REQUERSOLICITA	

DIRECCIÓN DE NUEVAS CREACIONES

2020
Bogotá, D.C.,

Abogado(a)/Señor(a)
LUZ CLEMENCIA DE PÁEZ

Asunto: Radicación: 14-49585- -5
 Trámite: 11
 Evento: 378
 Actuación: 430
 Oficio: 5380
 Folios: 7

Patente de Invención	X			Patente de Modelo de Utilidad	
Vía Nacional					
Vía PCT (Fase Nacional)	X	Capítulo I	X	Capítulo II	
No. Solicitud Internacional	PCT/US2012/053838				
Fecha de Presentación Internacional	06/09/2012				

Como resultado del examen de fondo realizado, con fundamento en el Artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se comunica:

1. Documentos estudiados

Descripción:	Rad. N° 14-049585-00000-0000	07/marzo/2014
Reivindicaciones:	Rad. N° 14-049585-00000-0000	07/marzo/2014
	Rad. N° 14-049585-00004-0000	28/Noviembre/2014
Dibujos:	Rad. N° 14-049585-00000-0000	07/marzo/2014
Prioridades:	US 61/532,140	08/Septiembre/2011
	US 13/604,012	05/Septiembre/2012

2. Análisis de la Prioridad

Se acepta la reivindicación de prioridad porque ésta solicitud fue presentada dentro del plazo establecido (Art. 9 D 486) y su contenido técnico corresponde con el de la prioridad reivindicada.

3. Objeto de la invención

De acuerdo con lo establecido en el numeral 1.2.2.2 del Capítulo Primero del Título X de la Circular Única para efectos del examen de patentabilidad, se tendrá en cuenta la tasa pagada por el solicitante al momento de comenzar el examen para las reivindicaciones adicionales; esto es que cuando la solicitud contenga más de diez (10) reivindicaciones y no se haya pagado la tasa complementaria, sólo se estudiarán las cubiertas por la tasa pagada. Por lo tanto, se estudiarán las reivindicaciones 1 a 17.

Título de la solicitud: “Sistema de plataforma de terapia de luz” (Fl. 1).

El problema planteado en esta solicitud, consiste en lograr una plataforma de terapia de luz que evite su manipulación continua por parte del usuario y que se adapte a las superficies receptoras de su cara.

Para resolver este problema técnico, la solicitud en estudio propone un dispositivo de fototerapia que comprende una máscara con una configuración parabólica cóncava, con una pluralidad de lámparas radiantes, además de un marco para apoyar la máscara en el usuario.

El objeto de la presente solicitud se relaciona con la Clasificación Internacional de Patentes (CIP): A 61 N 5/06.

4. De la solicitud de patente

Título

El título no define en forma precisa el objeto de la invención ya que el término “*plataforma*” no refleja la configuración del dispositivo. Se sugiere al solicitante modificar el título por uno que exponga dicho objeto, refiriéndose a las características constructivas de la invención, por ejemplo, “Máscara para fototerapia con marco para apoyar el dispositivo en el usuario”.

Reivindicaciones (Art 30 D 486, Art 22 PCT)

El capítulo reivindicatorio no es claro porque:

- Las reivindicaciones 4 y 12, y las expresiones: “...y dispuestos para comunicar (...) de un usuario...”, “...para comunicar la radiación de energía radiante al área de tratamiento (...) tratamiento.”, “...para apoyar la máscara en el usuario...”, “...para proteger los ojos en donde al momento (...) un tamaño del usuario.” (reivindicación 1), “...para separar la máscara del área (...) terapéutico adecuado” (reivindicación 5), “... para el usuario dispuestos para guiar (...) deseada.” (reivindicación 6), “...que se puede usar...”, “y dispuesta para comunicar la energía (...) tratamiento...”, “...para apoyar la plataforma en el usuario.” (reivindicación 9), “...para la dispersión de energía radiante (...) tratamiento del usuario.” (reivindicación 14), describen funciones, efectos, ventajas o resultados a alcanzar, los cuales no son aspectos susceptibles de patente. El producto reclamado se debe definir técnicamente mediante sus características estructurales. Se sugiere al solicitante eliminar las reivindicaciones y expresiones citadas.

- Las reivindicaciones 5 y 7, incluyen la expresión: “...el marco tiene un tamaño...” y “...están empotradas en relación con la pared reflectante.”, las cuales son de carácter general y sugieren de forma imprecisa que la protección se extiende a otras posibles variaciones o modificaciones, lo que no permite compararlas con el estado de la técnica. En cuanto a la reivindicación 5, no se especifica el tamaño del marco o se exponen características constructivas adicionales que permitan comprender mejor la configuración del dispositivo, por el contrario, la reivindicación está redactada en términos de funciones y ventajas, lo cual no puede ser susceptible de patente. Por su parte, la reivindicación 7 no describe a que se refiere la expresión “...en relación con la pared reflectante...” o que características hacen que dichas lámparas estén empotradas en dicha relación. En consecuencia, se sugiere eliminar las reivindicaciones citadas.
- La reivindicación 6 no están debidamente soportada en la descripción, toda vez que los puntos de contacto reclamados en ésta, no están incluidos en el capítulo descriptivo. Se sugiere al solicitante incluir dichas características en la descripción.

5. Determinación del Estado de la Técnica

El estado de la técnica se determinó con base en la fecha de presentación de la solicitud de prioridad: septiembre 08 de 2011, y se encontraron los siguientes documentos que anticipan el objeto de esta solicitud:

Ítem	Documento	Título	Fecha de Publicación
D1	US 2005/0070977	'Light and magnetic emitting mask'	31/Marzo/2005
D2	US 2006/0217787	'Light therapy device'	28/Septiembre/2006

El documento D1¹ divulga una máscara terapéutica que incluye diodos emisores de luz y electroimanes embebidos en la máscara. Luz pulsada y energía magnética pulsada es emitida a la región facial del usuario (resumen).

El documento D2² divulga un dispositivo de terapia de luz (40) para entregar energía lumínica a una porción del cuerpo del paciente, que comprende una fuente de luz (115). La fuente de luz comprende uno o más emisores de luz (122) para proveer la luz (resumen).

6. Examen de Patentabilidad (Art 14 D486)

Novedad (Art 16 D486)

La reivindicación 9 consiste en: “Un dispositivo de fototerapia que comprende: una plataforma de lámpara terapéutica que se puede usar...” (Ver página 5 del radicado N° 14-049585-00004-0000).

1 <https://www.google.ca/patents/US20050070977?dq=us20050070977&hl=es&sa=X&ei=bR0xVcVZiuWwBf6egdGK&ved=0CB0Q6AEwAA>

2 https://www.google.ca/patents/US20060217787?dq=US2006/0217787&hl=es-419&sa=X&ei=_cwyVaj4ApffsATj_YHIDw&ved=0CB4Q6AEwAA

Comparación de las características técnicas esenciales, con las del estado de la técnica:

Características esenciales	D1
Dispositivo de fototerapia caracterizado por:	Mascara emisora de luz y magnetismo caracterizada por:
Una plataforma de lámpara terapéutica.	Una máscara emisora de luz (Figs. 1 y 2)
Una pluralidad de lámparas radiantes que tienen una combinación mixta de diferentes longitudes de onda.	Una pluralidad de lámparas radiantes (36) y (66) (Párr. [0060]) que tienen una combinación mixta de diferentes longitudes de onda (Tablas 1 y 2).
Una pared reflectante con una pluralidad de aberturas alineadas con las lámparas radiantes.	Una máscara interna (26) que comprende los agujeros (20) para que los LEDs puedan pasar hacia el usuario (Párr. [0056]).
Un marco.	Dispositivo de apoyo de la máscara (Párr. [0055]) y un parche de protección (46) (Párr. [0058]).

Asimismo, el documento D1 divulga las características de las reivindicaciones dependientes así:

- Reivindicación 10: Incluye una pared exterior separada de la pared reflectante, a una distancia predeterminada (Párr. [0056]), donde las lámparas (36) y (66) se interponen entre la pared exterior (40) y la pared interior (26) (Fig. 2).
- Reivindicación 11: En donde as diferentes longitudes de onda de energía radiante comprenden al menos dos de rojo, azul o infrarrojo (Tablas 1 y 2).
- Reivindicación 13: En donde la pared reflectante tiene una configuración parabólica cóncava (Figs. 1 y 2).
- Reivindicaciones 14 y 15: Dispositivo de apoyo de la máscara (Párr. [0055]) y un parche de protección (46) (Párr. [0058]).

Nivel inventivo (Art18 D486)

La reivindicación 1 consiste en: “*Un dispositivo de fototerapia que comprende: una plataforma de lámpara terapéutica que comprende una máscara.*” (Ver página 4 del radicado N° 14-049585-00004-0000).

Comparación de las características técnicas esenciales, con las del estado de la técnica:

Características esenciales	D1	D2
Dispositivo de fototerapia caracterizado por:	Mascara emisora de luz y magnetismo caracterizada por:	Dispositivo para terapia de luz caracterizado por:
Una plataforma de lámpara terapéutica que comprende una máscara que tiene una configuración parabólica cóncava.	Una máscara emisora de luz que tiene una configuración parabólica cóncava (Figs. 1 y 2)	Una máscara emisora de luz que tiene una configuración parabólica cóncava (Fig. 9)
Máscara con una rigidez maleable.	No menciona.	El sustrato guía de luz (50) es una lámina de un elastómero flexible transparente poliuretano, entre otros (Párr. [0040])

Una pluralidad de lámparas radiantes que tienen una combinación mixta de diferentes longitudes de onda.	Una pluralidad de lámparas radiantes (36) y (66) (Párr. [0060]) que tienen una combinación mixta de diferentes longitudes de onda (Tablas 1 y 2).	Una pluralidad de lámparas radiantes (122), las longitudes de onda pueden ser variables dependiendo de la condición tratada (Párr. [0063]).
Una primera pared y una pared reflectante.	Una máscara exterior (Párr. [0058]) y una máscara interna (26) que comprende los agujeros (20) (Párr. [0056]).	Un sustrato guía de luz (50) y una capa de extracción de luz (75) (Párr. [0040]).
La pared reflectante comprende aberturas.		No menciona.
Un marco que incluye un lente.	Dispositivo de apoyo de la máscara (Párr. [0055]) y un parche de protección (46) (Párr. [0058]).	No menciona.

Los documentos D1 y D2 se consideran el estado de la técnica cercano a la invención definida en la reivindicación 1 porque divulgan una máscara emisora de luz y magnetismo y un dispositivo de terapia de luz, respectivamente.

La diferencia entre la invención, definida en la reivindicación 1 y el dispositivo de D1 consiste en la máscara de rigidez maleable.

La diferencia entre la invención, definida en la reivindicación 1 y el dispositivo de D2 consiste en la pared reflectante que comprende aberturas y un marco que incluye un lente.

El efecto que logra el incluir la máscara de rigidez maleable es que permite ser inclinada o desviada durante su uso, por comodidad del usuario.

Por lo tanto, el problema técnico objetivo que pretende resolver esta invención se puede formular así: “cómo modificar el dispositivo conocido en D1 para que permita ser inclinada o desviada durante su uso, por comodidad del usuario.

Sin embargo, la máscara de rigidez maleable para que permita ser inclinada o desviada durante su uso, por comodidad del usuario, ya está divulgada en el documento D2 enseña una máscara que comprende un sustrato guía de luz (50) de una lámina de un elastómero flexible transparente poliuretano (Párr. [0040]).

En consecuencia, la persona del oficio normalmente versada en la materia, incluiría la máscara que comprende un sustrato guía de luz (50) de una lámina de un elastómero flexible transparente poliuretano (Párr. [0040]) del documento D2 en el dispositivo divulgado en el documento D1 para llegar así al objeto de la reivindicación 1 de la solicitud. Por lo cual se considera obvia.

Asimismo, el documento D1 divulga las características de las reivindicaciones dependientes así:

- Reivindicación 2: Donde las lámparas (36) y (66) se interponen entre la pared exterior (40) y la pared interior (26) (Fig. 2).
- Reivindicación 3: En donde las lámparas se montan en la pared exterior (40) (Fig. 2).
- Reivindicación 6: Dispositivo de apoyo de la máscara que puede incluir ganchos,

bandas elásticas, cuerdas, estructuras de alambre, cascos moldeados y similares (Párr. [0055]).

- Reivindicación 8: En donde as diferentes longitudes de onda de energía radiante comprenden al menos dos de rojo, azul infrarrojo (Tablas 1 y 2).
- Reivindicaciones 16 y 17: Dispositivo de apoyo de la máscara (Párr. [0055]) y un parche de protección (46) (Párr. [0058]).

Por su parte, las reivindicaciones 4 a 7 y 12 están afectadas en el numeral 4 de la presente solicitud.

7. Conclusión

Los requisitos de Patentabilidad de la presente solicitud están afectados así:

Ítem	Documento	Reivindicaciones afectadas	Requisito que afecta
D1	US 2005/0070977	1, 2, 3, 6, 8, 9 a 17	Novedad/Nivel Inventivo
D2	US 2006/0217787	1	Novedad/Nivel Inventivo

En cumplimiento del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del término de sesenta (60) días contados a partir del día siguiente de la fecha de notificación de la presente comunicación. En caso de no dar respuesta al presente requerimiento, o si a pesar de la respuesta subsistieran los impedimentos para la concesión, se denegará la patente.

Se invita al solicitante se sirva indicar, si así lo considera, su renuncia al término faltante de sesenta (60) días para dar respuesta a este requerimiento y presentarla por escrito.

Finalmente, se le recuerda al solicitante que si como respuesta a este requerimiento llegara a modificar el capítulo reivindicatorio y éste contenga más de diez (10) reivindicaciones, no pagará la tasa de modificación voluntaria pero sí la correspondiente al pago por reivindicación adicional.

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal e), del capítulo quinto del título primero de la Circular Única No. 10 de 2001.



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Director de Nuevas Creaciones (c)

El anterior requerimiento fue notificado por fijación en lista, de fecha 2015-05-19

Elaboró: Monica Andrea Gutierrez Almonacid
Revisó: Sonia Andrea Diaz Pirazan



US 20050070977A1

(19) **United States**(12) **Patent Application Publication**
Molina(10) **Pub. No.: US 2005/0070977 A1**(43) **Pub. Date: Mar. 31, 2005**(54) **LIGHT AND MAGNETIC EMITTING MASK**(52) **U.S. Cl. 607/88; 607/100**(76) **Inventor: Sherry L. Molina, Charlotte, NC (US)**

Correspondence Address:

MORGAN & FINNEGAN, L.L.P.**3 WORLD FINANCIAL CENTER****NEW YORK, NY 10281-2101 (US)**(21) **Appl. No.: 10/835,618**(22) **Filed: Apr. 28, 2004****Related U.S. Application Data**(60) **Provisional application No. 60/465,984, filed on Apr. 28, 2003. Provisional application No. 60/480,266, filed on Jun. 20, 2003.****Publication Classification**(51) **Int. Cl.⁷ A61N 5/06**(57) **ABSTRACT**

A therapeutic mask includes light emitting diodes and electromagnets imbedded in the mask. Pulsed light and pulsed magnetic energy is emitted to a user's facial region. Facial therapy is performed with the mask simultaneously or separately using magnetic therapy and light therapy. The electro-pulsed magnets are imbedded in the mask at appropriate locations based on acupressure and acupuncture therapy. Diodes in the mask are located about the center of the electro-magnetics to maximize therapeutic results. Light therapy is added to the eye area by a removable eye patch that contains light emitting diodes mounted in front of each eye. The mask can be used with a face serum-cream and an oral supplement both containing pycnogenol.

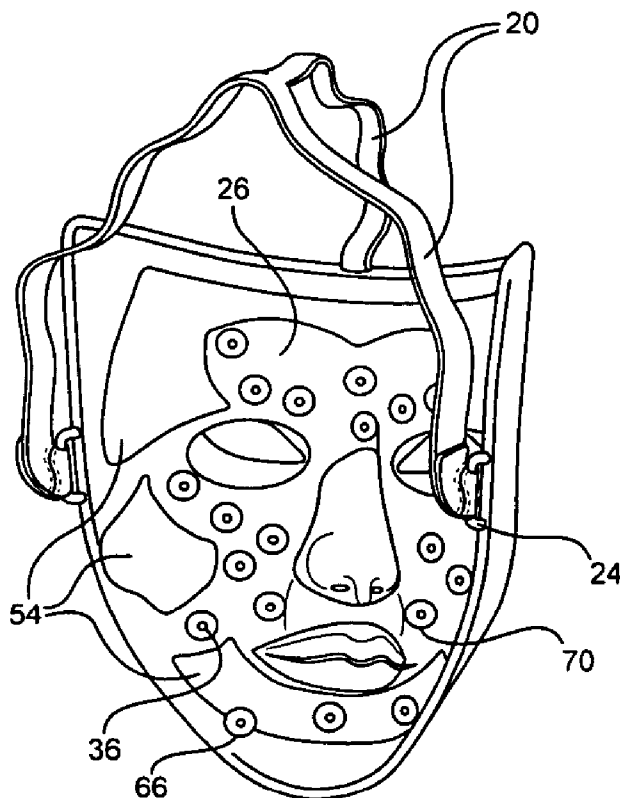


FIG. 1

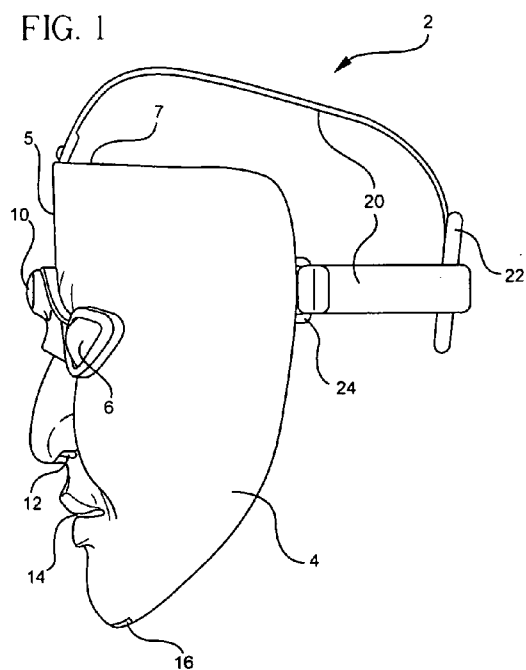


FIG. 2

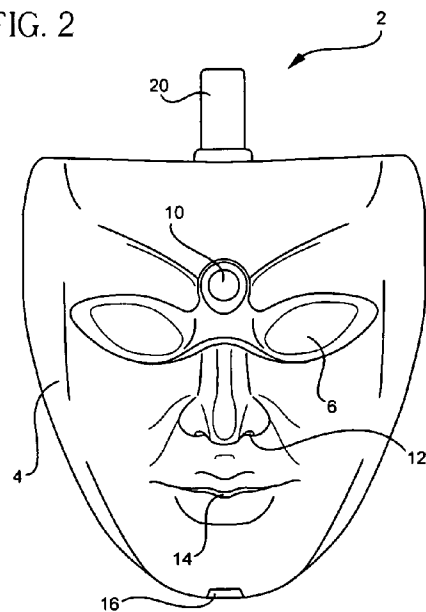


FIG. 2

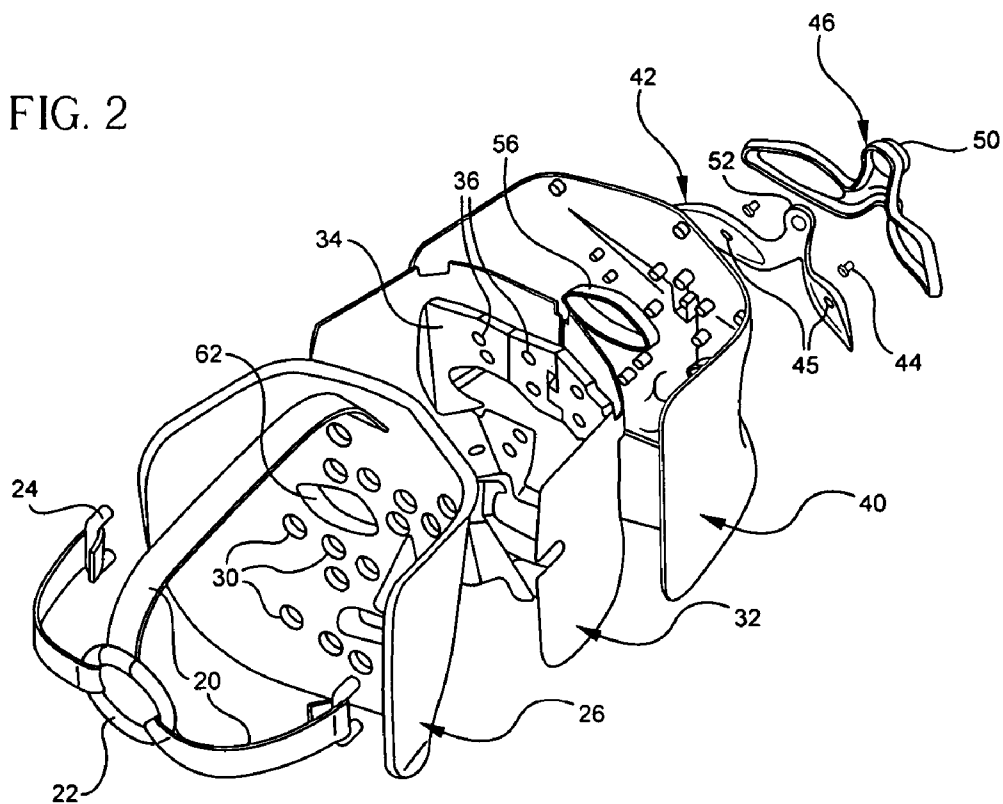


FIG. 3

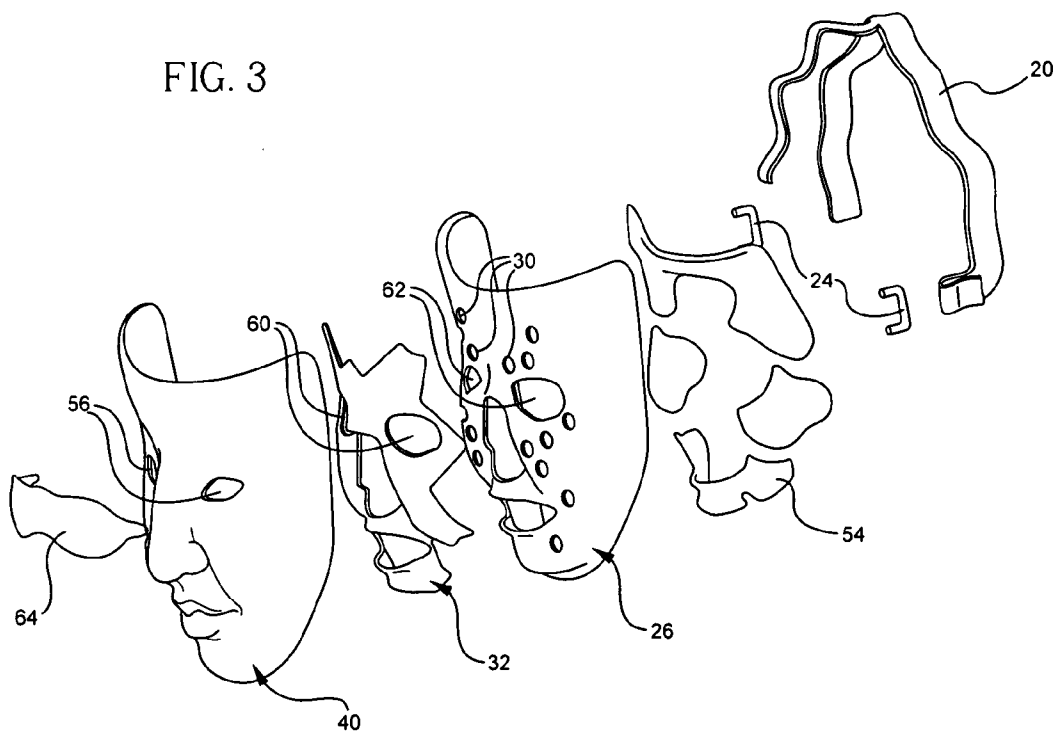


FIG. 4A

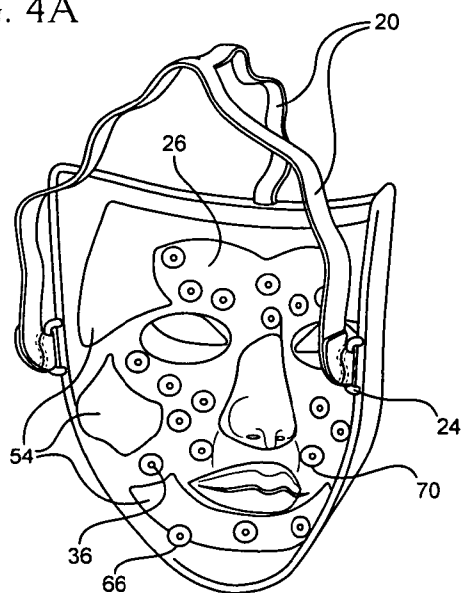


FIG. 4b

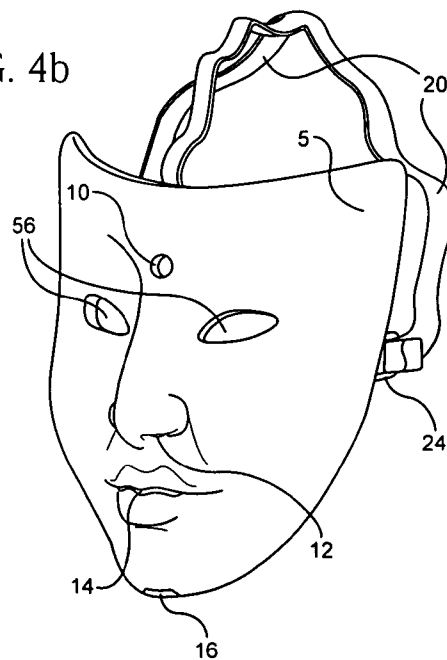


FIG. 5A

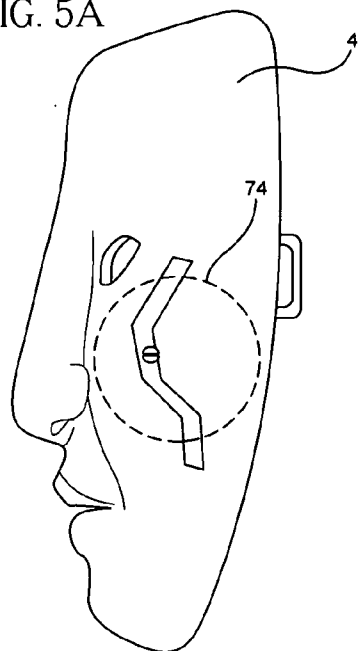
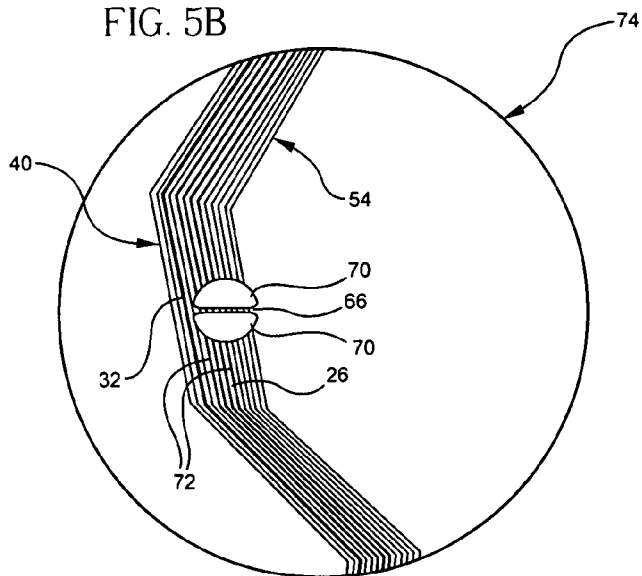


FIG. 5B



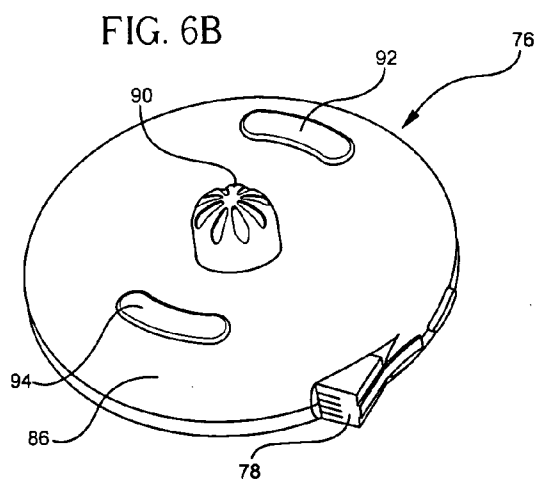
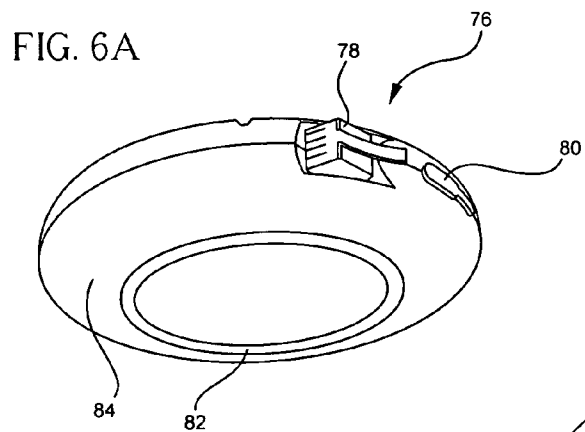


FIG. 7A

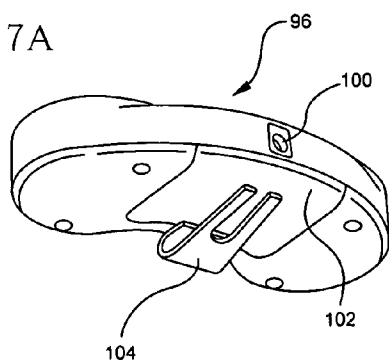


FIG. 7B

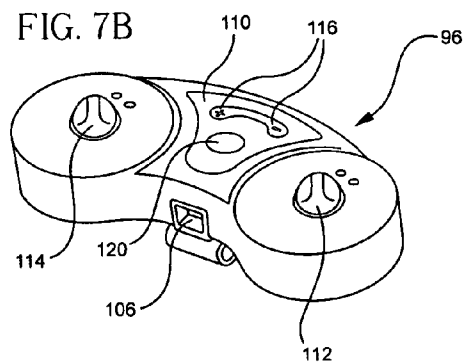


FIG. 7C

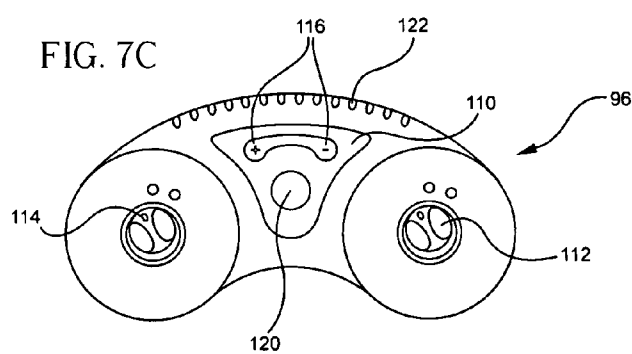


FIG. 8A

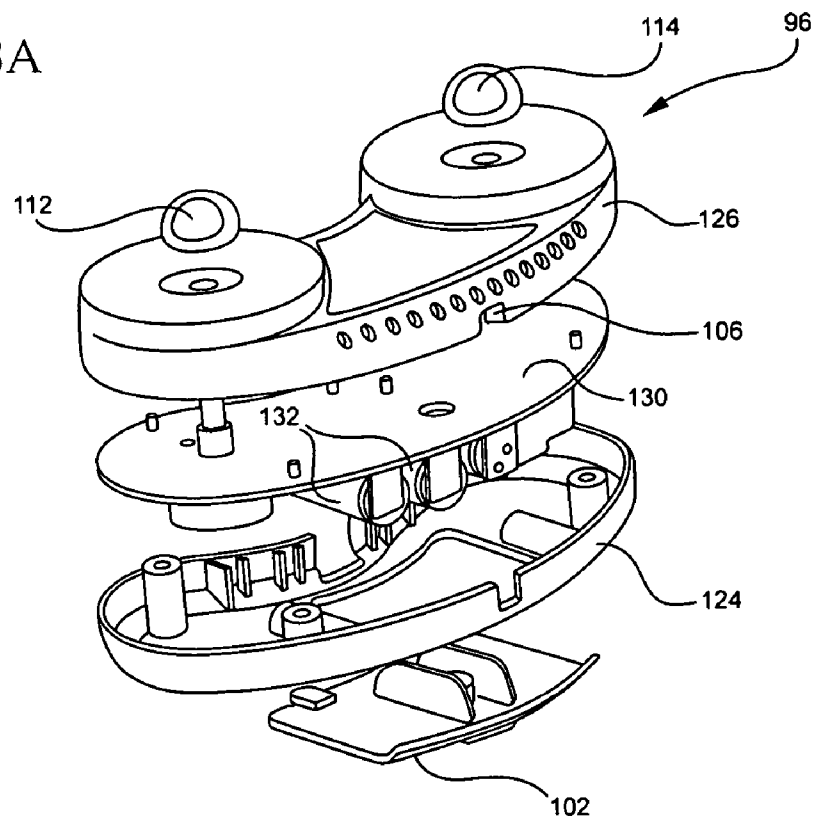
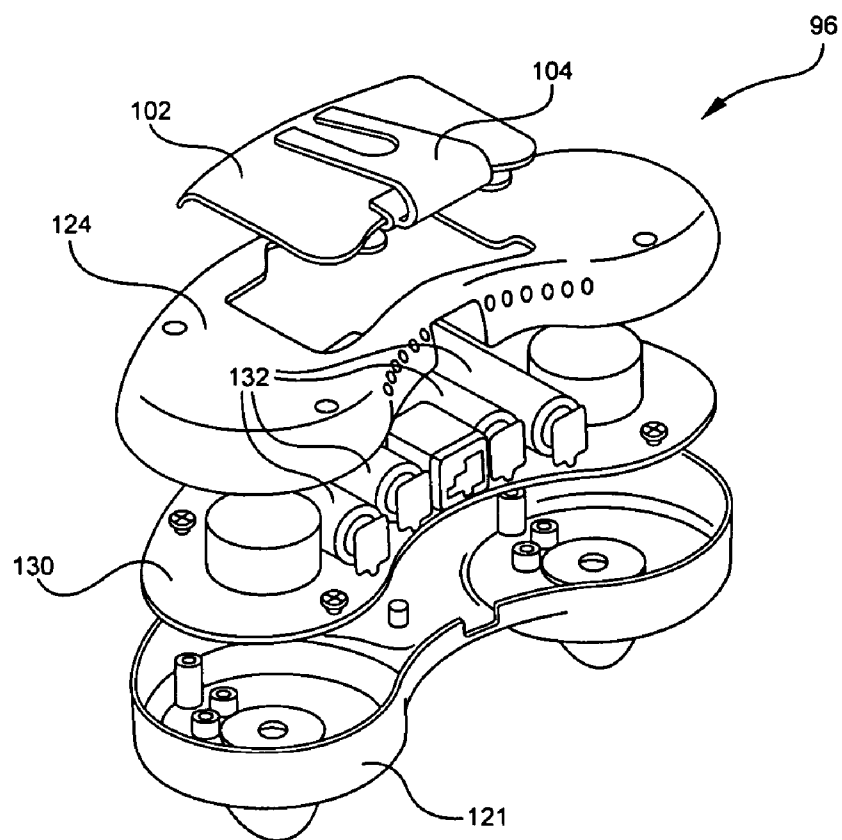


FIG. 8B



LIGHT AND MAGNETIC EMITTING MASK

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional application Ser. No. 60/465,984 filed on Apr. 28, 2003 and U.S. Provisional application Ser. No. 60/480,266 filed on Jun. 20, 2003.

FIELD OF THE INVENTION

[0002] This invention generally relates to a medical device that delivers light and magnetic energy for therapeutic responses. More particularly, the present invention is directed to a mask that contains light emitting diodes and magnetics that deliver energy to a user's facial region for the treatment of various medical conditions.

BACKGROUND

[0003] There are many devices for administering treatment to organic tissues for therapeutic, repair, or beauty treatment purposes. It is widely accepted that the use of light energy enhances the characteristics of the skin and provides beneficial biological and/or therapeutic results. In addition, the use of magnetic energy is also widely accepted as a therapeutic and restorative treatment to limbs, organs and other parts of the human body. However, the various therapeutic apparatus available for applying these types of energies to the skin suffer from significant structural and functional shortcomings thereby necessitating certain new and useful improvements.

[0004] For example, in U.S. Pat. No. 5,913,883 to Alexander et al., a therapeutic facial mask uniformly and totally floods light to a user's facial area using light emitting diodes. Totally flooding the skin with light can irritate the skin. This device lacks control over delivering specific energy to certain area's of treatment without irritation to the skin. The Alexander et al. device also lacks the ability to supply light therapy to the eye region. In addition, this device lacks the ability to supply magnetic energy to the skin.

[0005] In U.S. Pat. No. 6,293,900 to Bove et al. a magnetic face mask provides magneto-therapy to the eyes and/or face using static magnetic fields. Alternating magnetic fields is achieved through alternating magnetics in different patterns. Use of this device is cumbersome when therapy of various amounts of magnetic energy is desired. Different intensities and polarities of magnetic field are controlled by physically removing magnetics from the mask and replacing them with magnetics that contain the desired properties. In addition to this lack of control of the magnetic field, this device lacks the ability to supply light energy therapy.

[0006] In U.S. Pat. No. 6,520,903 to Yamashiro, an electromagnetic device generates plasma to simultaneously discharge light and magnetic energy pulses for the promotion of energy and pain relief in the human body. Again, this device lacks the control of the energy to either alternate or simultaneously direct different types of energy to the skin as desired. The device provides localized treatment and only provides treatment in one area of the body at a time. Selected treatment over a wider area is unavailable. In addition, this device lacks the ability to supply light energy to the eye region.

[0007] There remains a need for an apparatus that uses both light and electromagnetic energies in a controlled manner for therapeutic uses to the skin and eye regions. In addition, there is a need for an apparatus that offers a range of modalities and can treat multiple areas at one time without being too cumbersome or difficult to use.

SUMMARY

[0008] The present invention provides an apparatus that uses both light and electro-magnetic energies in a controlled manner for therapeutic uses to facial skin and eye regions. The present invention is portable and easy to use. It offers a range of modalities and can treat multiple areas at one time.

[0009] A mask of the present invention includes an exterior portion and an interior portion. A plurality of light emitting diodes and a plurality of electro-magnetics are disposed about the interior portion. A control unit is coupled to the mask, either physically by a cable or wireless, for selectively controlling the light emitting diodes and the electro-magnetics.

[0010] The light emitting diodes includes white diodes, blue diodes, ruby red diodes, infra-red diodes to provide various therapeutic benefits to the skin and eyes. Different wavelengths are used for some diodes as well as different frequencies to provide the user with various options of use. The light emitting diodes are positioned about the center of the electro-magnetics for maximum therapeutic response. The light emitting diodes and electro-magnetics pulse when activated by the controller. The controller allows alternating pulses when desired by the user.

[0011] Light therapy is added to the eye area by a removable eye patch that contains light emitting diodes mounted in front of each eye. The mask can be used with a face serum-cream and an oral supplement both containing pycnogenol.

[0012] These, and other aspects of the apparatus of the present invention, are described in the following brief and detailed description of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] FIG. 1A is a side view of a light and magnetic emitting mask.

[0014] FIG. 1B is a front view of the mask in FIG. 1A.

[0015] FIG. 2 is an exploded perspective view of the mask in FIG. 1A.

[0016] FIG. 3 is an exploded perspective view of the mask in FIG. 1A with the addition of a gel inlay and an alternate embodiment of a strap.

[0017] FIG. 4A is a perspective interior view of the mask in FIG. 3 without the eye patch.

[0018] FIG. 4B is a perspective exterior view of the mask in FIG. 3 without the eye patch.

[0019] FIG. 5A is a partial cross-sectional view of the mask in FIG. 1A without the eye patch and strap.

[0020] FIG. 5B is an enlarged cross-sectional view of FIG. 5A.

[0021] FIG. 6A is a bottom perspective view of a controller for the mask in FIG. 1A.

[0022] FIG. 6B is a top perspective view of the controller in 6A.

[0023] FIG. 7A is a bottom perspective view of a controller for the mask in FIG. 1A.

[0024] FIG. 7B is a top perspective view of the controller in 7A.

[0025] FIG. 7C is a top view of the controller in 7A.

[0026] FIG. 8A is a top perspective and exploded view of the controller in 7A.

[0027] FIG. 8B is a bottom perspective and exploded view of the controller in 7A.

DETAILED DESCRIPTION

[0028] This invention relates to an apparatus that includes a mask. The mask can be used for several wellness modalities. The present invention thereby provides a single structured product that can be utilized for multiple purposes. The present invention gives the user the ability to perform facial therapy with pulsed magnetic therapy and light therapy/color therapy that can be used simultaneously or separately. Typically, a user is permitted to wear the mask for about 20 minutes for each treatment and about three to four times per week.

[0029] The electro-pulsed magnets can be embedded in the mask, or protruding out from the interior of the mask. The magnets are situated at appropriate locations based on acupressure and acupuncture therapy. By activating the mask through a controller, magnetic pulses stimulate the acupuncture points which provide gateways to influence, redirect, increase, or decrease the body's vital substance, (Qi). Thus, improvements of many related conditions are possible. For example, acupuncture has been shown to stimulate the immune system. It also affects the circulation, blood pressure rhythm and stroke volume of the heart and the production of red and white cells. It also stimulates the release of a variety of hormones that helps the body respond to injury and stress. The body continually generates tiny but detectable electrical discharges. This electrical field influences the growth, maturation and functioning of some types of cells. Acupuncture points are concentrated in regions of low electrical resistance.

[0030] Acupuncture Points have certain electrical properties and stimulating these points alters chemical neurotransmitters in the body. Some theorize that individuals are affected by a so-called Magnetic Field Syndrome. Under this theory, the human body is under the influence of the earth's magnetic field and is kept in some sort of balance with it. The theory speculates that under today's living conditions the effects of this field have decreased. Consequently, we can assume that for the human body, this lack of magnetism can cause abnormalities.

[0031] By using pulsed magnetic therapy, the mask apparatus can supplement this deficiency of magnetism and abnormal conditions can improve. There is some support for this theory for a direct relationship between magnetism and improvement of abnormal conditions experienced by the human body. When NASA astronauts began getting sick on

Shuttles missions from their lack of the earth's magnetic field, magnets were placed on the shuttles. After placement of the magnets, the astronauts recovered more quickly.

[0032] There are basically two types of magnetic therapy: stationary and pulse. Preferably, pulse magnetism is used. Pulse magnetism can be further divided into alternately pulsating, rotating and traveling fields. Invisible magnetic field lines permeate all the cells in the body simultaneously, down to the last molecular level, reaching parts of the body that cannot be influenced efficiently with other methods. Using pulsed magnetic therapy on acupuncture points need not be exact due to its ability to permeate the area in depth and width. There are also light emitting diodes positioned about the center of each magnet to stimulate the acupoints and further maximize the therapeutic response.

[0033] Light therapy that enters the facial skin is through the placement of light emitting diodes (LEDs) placed throughout the mask that will be further discussed. This therapy is also known as photo-modulation or photo-stimulation light therapy. The technology behind light therapy is well known by those skilled in the art and can be used for hard to heal wounds, such as diabetic skin ulcers, severe oral sores cause by chemotherapy and radiation. This process is thought to activate skin cells, thus renewing the skin. Light passes through the skin, stimulating cells directly, and the cells function more like younger cells.

[0034] The mask of the present invention also provides light therapy to the eye area. This therapy is preferably done using pulsed light therapy or photo stimulation. The light device covers the eyes and has an LED light mounted in front of each eye. Pulsed light directed in the eyes is shown to be effective against various conditions. For example, such conditions include, but are not limited to, premenstrual syndrome, headaches, seasonal affect disorder, labor, jet lag, sleep disorders and eating disorder such as bulimia nervosa. Many new light therapies have been developed. However, these devices use intense or fully flood the area of treatment. In contrast, in photo stimulation, gentle pulsed light is shone in the eyes.

[0035] The mask of the present invention covers the eyes by utilizing an eye patch that is removable. The eye patch shuts out external light. When daylight enters the eye, it reaches a gland known as the pineal gland (also known as the third eye). This daylight activates our endocrine system, which is connected to our immune systems, and can affect such systems.

[0036] Furthermore, the balance of melatonin is well known to be a crucial element in many health related conditions. Stimulating proper production of melatonin from the pineal gland is very important to good health. When the retina is stimulated with light, the light becomes a vital nutrient. At the beginning of the 20th century, approximately 70% of the Western world's population worked outdoors and benefited from exposure of natural outdoor light. Today, most people in the Western culture spend their time indoors and as a result, are missing that portion of the sun's spectrum, which is important to trigger proper melatonin secretion. It is estimated that millions of people feel the effects of malillumination (light starvation).

[0037] A lack of sunlight can lead to ill health with a variety of mental and emotional and physical symptoms.

Working and living indoors, poorly illuminated environments with inappropriate artificial lighting could have serious health implications. Most artificial indoor lights lack ultraviolet light, which at the proper intensity is essential to the production of vitamin D and metabolism of calcium. Unhealthy artificial light (indoor light) lacks the requisite full color range distribution and the proper intensity to sustain health and certain functions, such as vitamin D and hormone production.

[0038] Even though light therapy is well known, light's effect on human mind and body health has been largely ignored. Both fluorescent and incandescent have lots of red, but lack green, blue and violet and indoor light generally is not bright enough, amounting to only 1/20th the intensity of outdoor lighting in the shade on a sunny day. The amount of light we receive from 16 hours indoors is dramatically less than the amount we receive outdoors. Even in locations that receive a significant amount of sun, the average person receives little sunlight in a 24 hour period. Other interferences such as, tinted glasses, tinted windows, contact lenses, do not allow in the health given properties of the entire spectrum of light. Light is a vital nutrient much like food we eat, the wrong kind can make us ill and the right kind can keep us well. Light also regulates the human body's internal biological clock. Without it our daily, monthly and annual rhythms become disrupted. Light regulates and stabilizes our physiology and emotions. Light through the eyes affects the brain and every cell in the body. Humans have biological requirements for light and it is currently unclear on how much we need of the other colors of the spectrum. Evidence points to the fact that we all can benefit from a greater supply of natural light, particularly in the winter months. Light enables us to see and plays several vital roles as it enters our eyes and skin.

[0039] Light enters the pineal gland (the body's light meter) via the retina and influences the hypothalamus. The hypothalamus is responsible for maintaining the body's status quo (the existing condition); i.e., blood pressure, body temperature, fluids and electrolyte balance and body weight. Light therapy can beneficially affect conditions related to these areas. Thus, both light therapy and magnetic therapy are desirable to deliver in a single therapeutic apparatus.

[0040] To further the benefit of these therapies, the present invention further includes a face serum-cream (for cell renewal) and an oral supplement that both contain Pycnogenol as the main ingredient. Pycnogenol, French Maritime Pine Bark extract, is a plant extract made from the bark of the European coastal pine, (*pinus maritime*). Pycnogenol contains approximately 40 natural ingredients, including proanthocyanidins, organic acids and other biologically active components. It has been shown to have free radical scavenging activity.

[0041] Free radicals, the normal by-products of metabolism, can accumulate and cause damage to cells and tissues. This may lead to degenerative health and skin conditions, which are associated with the acceleration of the normal aging process. Pycnogenol has potent antioxidant properties that protect against free radical damage. If left unchecked, free radicals, also called oxidants, can break down cells and tissue to unleash a variety of health problems. When the body is healthy, it is better able to fight off illnesses, recover from injury and put off the aging process.

[0042] Pycnogenol also has the ability to bond collagen fibers. Cells in the human body are bonded together with collagen. Pycnogenol helps these fibers rebuild their cross-links and reverse some of the damage done due to free radicals. It also inhibits the body's enzymes that break down collagen and helps return flexibility to the skin, arteries, capillaries, joints and other tissues by restoring collagen. Pycnogenol activates vitamin C and helps it work faster, continuing to work long after Vitamin C passes out of the body. Pycnogenol works to maintain the integrity of the blood vessels, particularly the capillaries and exerts a powerful anti-inflammatory and anti-aging effect. Pycnogenol, improves skin elasticity and smoothness during the aging process, as well as protecting the skin against harmful effects of the sun. It has been shown to prevent LDL oxidation and to have protective action against UV radiation. Pycnogenol has also been shown to be beneficial in cases of psoriasis. It has added value of working synergistically with many other essential nutrients.

[0043] Another element in these creams is minerals. Minerals are the regulator and activators of many cellular functions. As we age, eat poorly, experience pollution and stress, our bodies lose minerals. Without minerals we age faster, lack hydration, are prone to infections and have a sluggish metabolic energy. Minerals can cause a dramatic skin, muscular, immune and circulatory healing effects. Since minerals are small in molecular size, they are able to penetrate the skin's basal layer to replenishes de-vitalize cells. Without minerals there is no way to re-hydrate, reestablish and slow down the aging process. The skin will absorb substances that it recognizes as similar components to its own cells, like minerals.

[0044] To accomplish these benefits of light and magnetic therapies, the following example is given. This example is merely illustrative of the principles of the present invention and is not meant to limit the invention to embodiments given in this example.

TABLE 1

Description of Light Sources	
Face Therapy Light source-LED lamps	Eye Therapy Light source-LED lamps
Quantity: 128	Quantity: 2, one per eye
Colors: blue, ruby red, 2 different wavelength of Infra Red (4 total colors)	Color: White
Intensity: adjusted by user	Intensity: adjusted by user, 8 levels of selection
LED drive frequencies: 73, 146, 292, 584, 1168 Hertz, 25% Duty Cycle square wave Driving method: in 4 groups, time division multiplexed	LED drive frequencies: 9.8, 29, 48 Hertz, Driving method: 50% Duty Cycle square wave, alternating left right.

[0045] The above example demonstrates that the facial area is treated with at least four different types of light treatment. Typically, the red light treatment is directed to destroying acne and other related skin maladies. The blue light treatment is directed to destroying harmful bacteria. The infra red light treatment provides benefits already discussed as does the white light treatment for the eyes. Pulsed light energy is used to reduce irritation to the skin and eyes during application of the treatment.

[0046] The following is an illustrative example of the specifications of LEDs that can be used in the present invention. Again, this example is given as a mere illustration, and is not intended to limit the invention to this particular embodiment.

[0050] As illustrated in the above example, 1 magnet is disposed per each LED disposed in the interior of the mask. Preferably, the LED is about in the center of the electro-magnet to maximize the therapeutic response of the light and magnetic therapy.

TABLE 2

Examples of LEDs for Facial Treatment				
Infrared LED	Infrared LED option 2	Ruby Red LED	Ruby Red LED option 2	Blue LED
Device: Stanley DNP1105W	Device: Unity Opto Technology MSE-1542H2	Device: Fema LRF2SC-R	Device: LITEON C930KFKT	Device: Fema LRF2BC-R
Wavelength: 880 nm	Wavelength: 850 nm	Wavelength: 639 nm	Wavelength: 611 nm	Wavelength: 467 nm
Light source distance to skin: 0.6 cm	Light source distance to skin: 0.6 cm	Light source distance to skin: 0.6 cm	Light source distance to skin: 0.6 cm	Light source distance to skin: 0.6 cm
Treatment time: = 375 seconds	Treatment time: = 375 seconds	Treatment time: = 375 seconds	Treatment time: = 375 seconds	Treatment time: = 375 seconds
Light output energy density = 4.166 Joule/cm ²	Light output energy density = 8.3325 Joule/cm ²	Light output energy density = 1.562 Joule/cm ²	Light output energy density = 3.645 Joule/cm ²	Light output energy density = 1.177 Joule/cm ²

[0047] As indicated in the above example, various wavelengths are possible to use with the light treatment of the present invention. In the above example the wavelengths ranged from about 467 nm to about 880 nm. The above example used a test time of 375 seconds and a distance to skin of 0.6 cm. As stated before, the LEDs used in the present invention are not so limited to such a distance from skin. The calculated light out put energy density for the above example was up to about 8.5 Joule/cm². It was further noted that the use of (32) Ruby Red LED and (32) Blue LEDs yielded an average light output energy density of 2.767 Joule/cm² and the use of (64) Infrared. (32) Red, (32) Blue LEDs yielded an average light output energy density of 5.372 Joule/cm² as determined by the below equations:

$$\frac{Ee_{avg}((2 \times Ee_{IR}) + Ee_{ep} + Ee_{BLUE})}{4} = \frac{((2 \times 4.166) + 1.562 + 1.177)}{4} = 2.767 \text{ Joule/cm}^2 \quad (\text{Equation 1})$$

$$\frac{Ee_{avg}((2 \times Ee_{IR}) + Ee_{RED} + Ee_{BLUE})}{4} = \frac{((2 \times 8.3325) + 3.645 + 1.177)}{4} = 5.372 \text{ Joule/cm}^2 \quad (\text{Equation 2})$$

[0048] In these equations, Ee_{avg} is the average light output energy density, Ee_{IR} , Ee_{ep} , Ee_{BLUE} , Ee_{RED} are light out put density from the above Table 2 for LEDs of infra-red, ruby red, blue, and ruby red option 2, respectively.

[0049] The following is an example of the electromagnets. Again, these examples are merely given for illustrative purposes. The present invention is not limited to the embodiments illustrated.

TABLE 3

Description of Electro-magnets
Face Therapy Electro-Magnet per Light source-LED lamps
Quantity: 1
Construction: air core
Intensity: adjusted by user
Drive method: 50% Duty Cycle 16 Hz square wave

[0051] Adverting to the drawings, FIGS. 1A & 1B illustrates a side view and a front view, respectively, of mask 2. The mask includes an exterior portion 5 and an interior portion 7. The mask can be made of many layers or made of a single unitary layer, depending on the implementation. As shown in FIG. 1A, mask 2 has an exterior layer 4 that includes exterior portion 5.

[0052] An eye patch 6 is provided to deliver light therapy to the eyes if the user so desires. The eye path is removably attached to the exterior portion 5 by an eye therapy connection port 10.

[0053] Breathing holes 12, allow the user to wear the mask comfortably for an extended period of time. In addition the breathing holes permit the use of aroma therapy with the light and magnetic therapy. Voice through hole 14 allows the user to communicate while wearing the mask. Users of the mask can essentially continue their daily routine while the mask is delivering therapy.

[0054] A control unit connection port 16 allows the mask 2 to be connected to a controller. The connection can be by a cable (not shown fully extended) or by a wireless connection know to those skilled in the art. This flexibility in connection to a controller allows the user to be mobile while receiving therapy from the mask.

[0055] Straps 20 are shown to fix the mask on a user's facial region. However, any type of fixing apparatus can be used with the invention. These types of fixing apparatus include but are not limited to hoods, elastic bands, string, rope, wire frames, a unitary molded helmet, and the like. In the illustrative example of FIG. 1A, straps 20 are attached to the mask by a metal loop 24 and contain a strap ring 22. The strap is adjustable by the strap loop and/or ring. Again any means of fixing the mask about the user can be used with the present invention.

[0056] FIG. 2 illustrates an exploded view of the mask. Inner mask 26 faces the user and is attached to strap 20. The inner mask defines through holes 30 for the magnetics and

LEDs to pass through to the user. The distance from the LEDs and magnetics to the user's skin is typically a predetermined distance. However, it is within the purview of this invention that the distance can be adjusted if so desired by the user by simply adjusting the straps to pull the mask closer or farther away. Inner mask **26** also includes through holes **62** for the user's eyes and eye light therapy.

[0057] Attached to the inner mask is a flexible printed circuit board **32**. Flexible Printed circuit board **32** includes a printed circuit board (PCB) **34**. The PCB contains the LEDs and magnetics used in the therapy. Additionally, depending on the implementation the PCB may be configured to control the LEDs and the magnetics such that the controller is integral with the mask. For example, the controller port **16** may be a control console for the control of the LEDs and magnetics disposed on the PCB.

[0058] Typically attached to the flexible printed circuit board **32** is an exterior mask **40** to provide protection. The exterior mask **40** includes through holes **56** for eye light therapy/Eye light therapy is delivered by LEDs **44**. Preferably, LEDs **44** are white pulse LEDs as previously described to prevent irritation to the eyes. LEDs **44** are attached to inner eye patch **42** through holes **45**. An exterior eye patch **46** may cover the assembly and provide protection. Attachment of the eye patch to the mask is done by an eye connection port **50** or eye connection port **52**. It should be understood that the eye patch can be a single unitary and integral component that does not require interior and exterior layers as previously described.

[0059] FIG. 3 illustrates another exploded view of the mask from its front. Illustrated in FIG. 3 is a gel inlay that is typically attached to the back of inner mask **26** or a similar structure. The gel inlay provides comfort for the user and may contain trans-dermal medication to further the therapy of the skin. Also illustrated in FIG. 3 is the removal of the strap ring **22**. Adjustments to the strap can be done through loops **24**, or by any other suitable means. Also illustrated in FIG. 3 is a single piece eye patch **64** that contains LEDs **44** (not shown in FIG. 3). The flexible printed circuit board **32** defines eye through holes **60** for facilitating eye light therapy from the eye patch LED's.

[0060] FIG. 4A illustrates the back of the mask. Shown is the gel inlay **54** interior portion **7** of the mask and LED/magnetic **36**. Again, preferably LED **66** of the facial mask is positioned about the center of magnet **70** to maximize the therapeutic response. FIG. 4B illustrates the front portion of the mask in 4A, and demonstrates the mask without the eye patch attachment that connects to port **10** on exterior mask **4**.

[0061] As shown in FIG. 5A, cross section **74** of the assembled mask can consist of several layers. Again, depending on the implementation, the mask may be comprised of an integral layer containing components from each previously described layer. In FIG. 5b, LED **66** is disposed about the center of magnet **70**. Typically one LED is utilized in the mask per one magnet, however, many variations can be used in the present invention, and the mask of the present invention is not limited to the illustrations shown. Through holes **72** allows space for the LEDs and magnetics to pass through each successive layer without hindrance.

[0062] Averting to the control unit, shown in FIG. 6A is one embodiment of control unit **76**. In this illustration a

cable (not shown) is retracted within the housing of the control unit. A release button **80** can release the cable from the control unit housing. The communication plug **78** is attached to the cable. Alternatively, communication plug **78** can be a wireless communication device known to those skilled in the art to communicate with the mask. As previously stated the control unit may be integrally made part of the mask and place on any portion of the mask. A power source **82** can be part of the control unit **76** or an external power source can be utilized. For example, DC batteries such (4) AA battery could last for 2-3 hours. Alternatively, an externally powered (DC or AC jack) can be used or a LAN jack (R345) can be used for the mask's electrical connections.

[0063] Controller **76** has a bottom **84** and a top **86**. The control panel illustrated in FIG. 6B is on top **86**. A start/intensity magnetic pulse adjustment knob **90** is disposed about the center of controller **76**. This knob adjusts the intensity of the magnetic pulse and starts the magnetic therapy, whether it is magnetic therapy alone or both magnetic and light therapy. A light therapy start button **94** allows the user to activate the facial LEDs, either alone or in conjunction with the magnetics. An eye light start button **92** allows the eye light therapy to be activated. There is an automatic shut off control feature in the controller that allows the user with added safety in using the mask.

[0064] FIGS. 7A-7C illustrate a controller **96** embodiment. Controller **96** has a DC or AC optional connector for external power. A battery cover **102** protects a battery compartment for an internal power source. The cover may also include a clip **104** so that the controller can be attached to the user's belt or clothing further making the mask easy to use and allowing the user to be mobile while receiving therapy from the mask. The mask communication port can attach to a cable (not shown) to the port **16** of the mask. Alternatively there can be a wireless connection between port **106** and port **16** as previously discussed.

[0065] Controller **96** has a general control pad **110**. Intensity control **116** allows control of the intensity of the therapy chosen. A mode control button **120** allows control over what type of therapy the user wants delivered. For example, the user can have the following exemplary options for therapy. Therapy options include, but are not limited to, 1. light therapy to the face region only, 2. magnetic therapy to the face region only, 3. light therapy to the face region and magnetic therapy to the face region together, and alternating, 4. light therapy to the eye region only, and 5. magnetic therapy to the face region and eye light therapy together (simultaneously).

[0066] Individual control to the magnetic light therapies can be given by magnetic therapy control knob **112**, and light therapy control knob **114**. These control knobs control the intensity and duration of each respective type of therapy. The eye light control is controlled by control **116** and mode control **120**. In addition, it is within the scope of the present invention that the controller can choose through user input what frequency of light or magnetic energy the user will receive, what intensity and duration. Air vents **122** can be provide to assist in cooling the controller. Optionally or in addition to, a heat sink can be place within the controller.

[0067] FIGS. 8A and 8B illustrate an exploded view of controller **96**. Shown is a bottom cover **124**, a top cover **126**,

and a printed circuit board **130**. Power can be external or internal as shown by batteries **132**. The printed circuit board **130** can be configured to control the mask's delivery of light and magnetic therapies so that the user has selective control over all aspects of these therapies and over what areas the user wants exposed to the specific therapy. For example, a user may have acne on the chin. The user could program the controller to apply light energy only to the chin area. Alternatively, the user may want high energy in one area, and low energy in another. In addition, the user may want just eye light therapy. The user may desire facial magnetic therapy and eye light therapy. The user may desire facial light therapy, eye light therapy, and facial magnetic therapy. All of these variations are possible with use of the controller. Several more and different variations are available and are all within the scope of the present invention.

[0068] The following is an exemplary description of the operation of the mask. Again, this description is meant as an example, and does not limit the invention to such operation sequences. The present invention can utilize many different operating sequences to deliver the desired therapy to the user of the mask.

[0069] The description of operation includes turning either the face/eye or magnetic therapy rotary switch from off position to the on position. The mask through the controller unit will enter into a very low power, standby mode after about 25 minutes, in magnetic/face therapy mode, and after about 16 minutes in the eye therapy mode.

[0070] After sleep mode, the unit restarts by repositioning either switch. The eye therapy module wakes up from sleep mode by pressing the mode button. It's possible to change therapy modes during sessions while not affecting the remaining time, however only turning both knobs to power off position, for at least 20 seconds, will reset the unit.

[0071] To de-energize the unit, both rotary switches should be in off position. There are four indicator lights showing the activity of each therapy options. If only "face therapy" is selected, 32 LEDs will be active at the time for 11.76 seconds in a 1 to 4 time division multiplex mode. The duty cycle therefore is 25% (128 LEDs). There are four groups of LEDs, 32 of them in each group (128 total LEDs). Every group is active for 11.76 seconds then the program rotates the four groups by 255 times, for a total of 25 minutes. The LEDs are also driven at five different frequencies (73, 146, 292, 584, 1168 Hz), each active for 5 minutes.

[0072] If only "magnetic pulse" therapy is selected the program drives the coil for 25 minutes, at 16 Hz, 50% duty cycle, with the pre-selected polarity. If both the magnetic and the face light therapy are selected, the program will alternate between the two modes. Each mode is active for about 5.88 seconds at the time, for 255 times (total 25 min). The coil and LEDs are driven the same way as described before.

[0073] The "eye light" therapy can be selected alone or only together with "magnetic pulse" therapy. The "eye light" with "magnetic pulse" therapy will run simultaneously without any interaction. The eye light therapy is enabled in the last position of "face/eye" rotary switch. This time the three pushbuttons are active. The "mode" button will cycle between the three different frequencies (9.8, 29, 49 Hz) and the "brightness up"/"brightness down" buttons select the eight of light output levels.

[0074] It should be understood that the above description is only representative of illustrative examples of embodiments. For the reader's convenience, the above description has focused on a representative sample of all possible embodiments, a sample that teaches the principles of the invention. Other embodiments may result from a different combination of portions of different embodiments. The description has not attempted to exhaustively enumerate all possible variations.

[0075] Furthermore, since numerous modifications and variations will readily occur to those skilled in the art, it is not desired that the present invention be limited to the exact construction and operation illustrated. Accordingly, all suitable modifications and equivalents that may be resorted to are intended to fall within the scope of the claims.

What is claimed is:

1. An apparatus for producing a therapeutic response, comprising:

a mask having an exterior portion and an interior portion,
a plurality of light emitting diodes and a plurality of electro-magnetics disposed about the interior portion,
and

a control unit coupled to the mask for selectively controlling the light emitting diodes and the electro-magnetics.

2. The apparatus of claim 1, wherein the light emitting diodes further includes blue diodes, ruby red diodes, infra-red diodes or any combination thereof.

3. The apparatus of claim 2, wherein the infrared diodes have at least two different wavelengths.

4. The apparatus of claim 3, wherein all the light emitting diodes are driven at five different frequencies.

5. The apparatus of claim 1, wherein the light emitting diodes are positioned about the center of the electro-magnetics for maximum therapeutic response.

6. The apparatus of claim 1, wherein the light emitting diodes and electro-magnetics pulse when activated by the controller.

7. The apparatus of claim 6, wherein the light emitting diodes and electro-magnetics alternately pulse when activated by the controller.

8. An apparatus for producing a therapeutic response, comprising:

a mask having an exterior portion and an interior portion,

a plurality of light emitting diodes positioned about centers of a plurality of electro-magnetics, the diodes and the electro-magnetics disposed about the interior portion,

an eye patch removably attached to the exterior of the mask, the eye patch further including at least two light emitting diodes that provides light to eyes of a user, and

a control unit coupled to the mask for selectively controlling the light emitting diodes, the electro-magnetics, and the light emitting diodes of the eye patch.

9. The apparatus of claim 8, wherein the light emitting diodes of the interior portion of the mask includes blue diodes, ruby red diodes and infra-red diodes of at least two different wavelengths, and the light emitting diodes of the eye patch are white diodes.

10. The apparatus of claim 8, wherein the control unit is configured to allow activation of only the light emitting diodes in the interior portion of the mask.

11. The apparatus of claim 8, wherein the control unit is configured to allow only activation of only the electro-magnetics in the interior portion of the mask.

12. The apparatus of claim 8, wherein the control unit is configured to allow activation of only the light emitting diodes and the electro-magnetics in the interior portion of the mask together.

13. The apparatus of claim 12, wherein the light emitting diodes and electro-magnetics pulse and are alternately activated.

14. The apparatus of claim 8, wherein the control unit is configured to allow activation of only the light emitting diodes of the eye patch.

15. The apparatus of claim 8, wherein the control unit is configured to allow activation of the light emitting diodes of the eye patch and the electro-magnetics in the interior portion of the mask.

16. The apparatus of claim 15, wherein the light emitting diodes of the eye patch and the electro-magnetics are simultaneously activated together.

17. The apparatus of claim 8, wherein the control unit is configured to allow activation of the light emitting diodes of the eye patch and the interior portion of the mask together.

18. The apparatus of claim 8, wherein the control unit is configured to allow activation of the light emitting diodes of the eye patch, the interior portion of the mask, and the electro-magnetics in the interior portion of the mask together.

19. The apparatus of claim 8, wherein the controller is configured to allow preset energy delivery from the light emitting diodes of the interior portion of the mask and the eye patch and the electro-magnetics.

20. The apparatus of claim 19 wherein the controller further includes an automatic shut off that terminates energy delivery after a predetermined time period.

21. An apparatus for producing a therapeutic response, comprising:

an external mask portion having a mask having an exterior portion and an interior portion, the exterior portion having an eye therapy connection port and a controller connection port,

a flexible circuit board attached to the interior portion of the external mask and in communication with the controller connection port, the flexible circuit board having a plurality of light emitting diodes positioned about centers of a plurality of electro-magnetics, the diodes and the electro-magnetics disposed about the flexible circuit board,

an internal mask attached to the flexible circuit board to provide support to the circuit board, the diodes, and the electro-magnetics,

a gel inlay attached to the internal mask and positioned opposite the flexible circuit board for providing facial comfort to a user,

an eye patch removably attached to the eye therapy connection port, the eye patch further including at least two light emitting diodes that provides light to eyes of the user, and

a control unit coupled to the controller connection port of the external mask for selectively controlling the light emitting diodes, the electro-magnetics, and the light emitting diodes of the eye patch.

22. The apparatus of claim 21, wherein the control unit is coupled to the controller connection port of the external mask by wireless connection.

23. The apparatus of claim 21, wherein the control unit is coupled to the controller connection port of the external mask by a cable.

24. The apparatus of claim 23, wherein the cable is retractable within the control unit.

25. The apparatus of claim 21, wherein the external mask further defines a nasal aperture for breathing and a mouth aperture for speaking by the user.

26. The apparatus of claim 21, wherein the external mask further includes a strap for adjustably securing the apparatus over a facial area of the user.

27. The apparatus of claim 21, wherein the controller further includes a printed circuit board that is configured to adjust the intensity of the light emitting diodes of the eye patch, the diodes of the interior portion of the external mask, and the electro-magnetics.

28. The apparatus of claim 21, wherein the light emitting diodes of the interior portion are blue diodes, ruby red diodes, and two different wavelength infra-red diodes.

29. The apparatus of claim 21, wherein the diodes of the eye patch are white diodes.

30. The apparatus of claim 21, wherein the average light output energy density of the light emitting diodes of the interior portion is up to about 8.5 Joule/cm².

31. A kit containing an apparatus for producing a therapeutic response, comprising:

a face serum-cream,

a mask having an exterior portion and an interior portion,

a plurality of light emitting diodes and a plurality of electro-magnetics disposed about the interior portion, and

a control unit coupled to the mask for selectively controlling the light emitting diodes and the electro-magnetics.

32. The kit of claim 31, wherein the face serum-cream is pycnogenol.

33. The kit of claim 31, further including an oral supplement containing at least pycnogenol.

34. An apparatus for producing a therapeutic response, comprising:

a mask having an exterior portion and an interior portion,

a plurality of light emitting diodes disposed about the interior portion that releases pulsed light energy, the light emitting diodes consisting of blue diodes, ruby red diodes, and infra-red diodes of at least two different wavelengths and any combination thereof, and

a control unit coupled to the mask for selectively controlling the light emitting diodes and configured to drive the diodes at least at five different frequencies.

35. The apparatus of claim 34, further including a plurality of pulsed electro-magnetics disposed around the diodes.

36. An apparatus for producing a therapeutic response, comprising:

a mask having an exterior portion and an interior portion,
a plurality of pulsed electro-magnetics disposed about the interior portion, the electro-magnetics arranged at specific acupuncture and acupressure points to facilitate a therapeutic response, and

a control unit coupled to the mask for selectively controlling the electro-magnetics and configured to drive the electro-magnetics for a predetermined time period.

37. The apparatus of claim 36, further including pulsed light emitting diodes disposed about the center of the electro-magnetics for facilitating light therapy.

38. The apparatus of claim 36, further including a gel inlay attached to the interior portion, the gel inlay containing a trans-dermal medication for delivery of medication to a treatment site.

39. The apparatus of claim 36, wherein the mask further defines a breathing hole to allow the use of aroma therapy.

* * * * *



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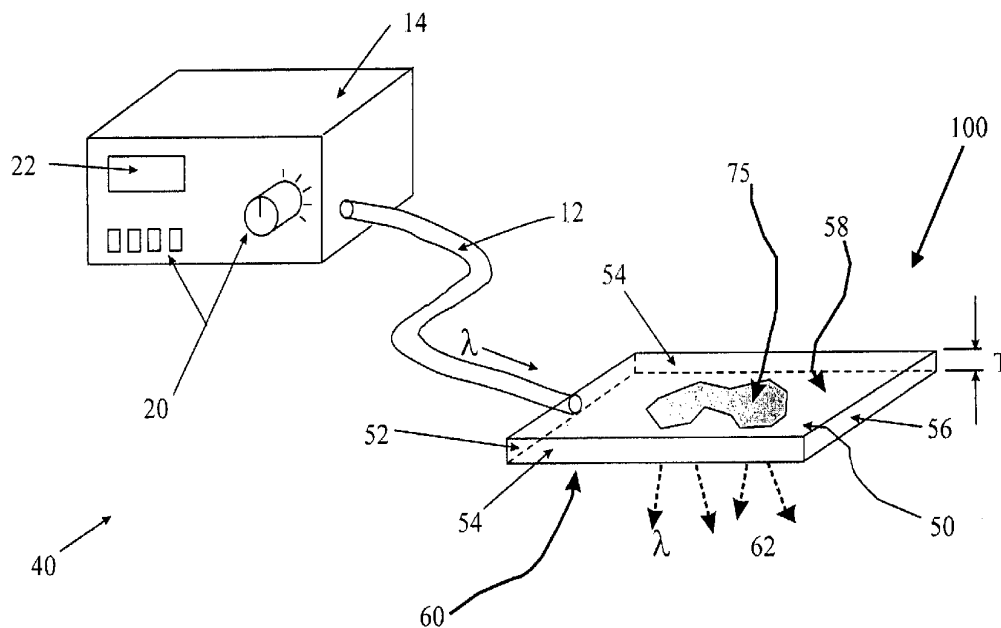
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(52) **U.S. Cl.** **607/88; 607/89**

(57) **ABSTRACT**

A light therapy device (40) for delivering light energy to a portion of a patient's body comprises a light source (115). The light source comprises one or more light emitters (122) for providing input light. A light coupling means (80) directs the input light into a light guide (140). A flexible optically transparent light guide material comprises the light guide. A light extraction means (75) is applied to a surface of the light guide material. The light extraction means is positioned to provide light therapy treatment to one or more localized areas of the patient's body. A control means controls a light dosage relative to intensity, wavelength, modulation frequency, repetition, and timing of treatments.

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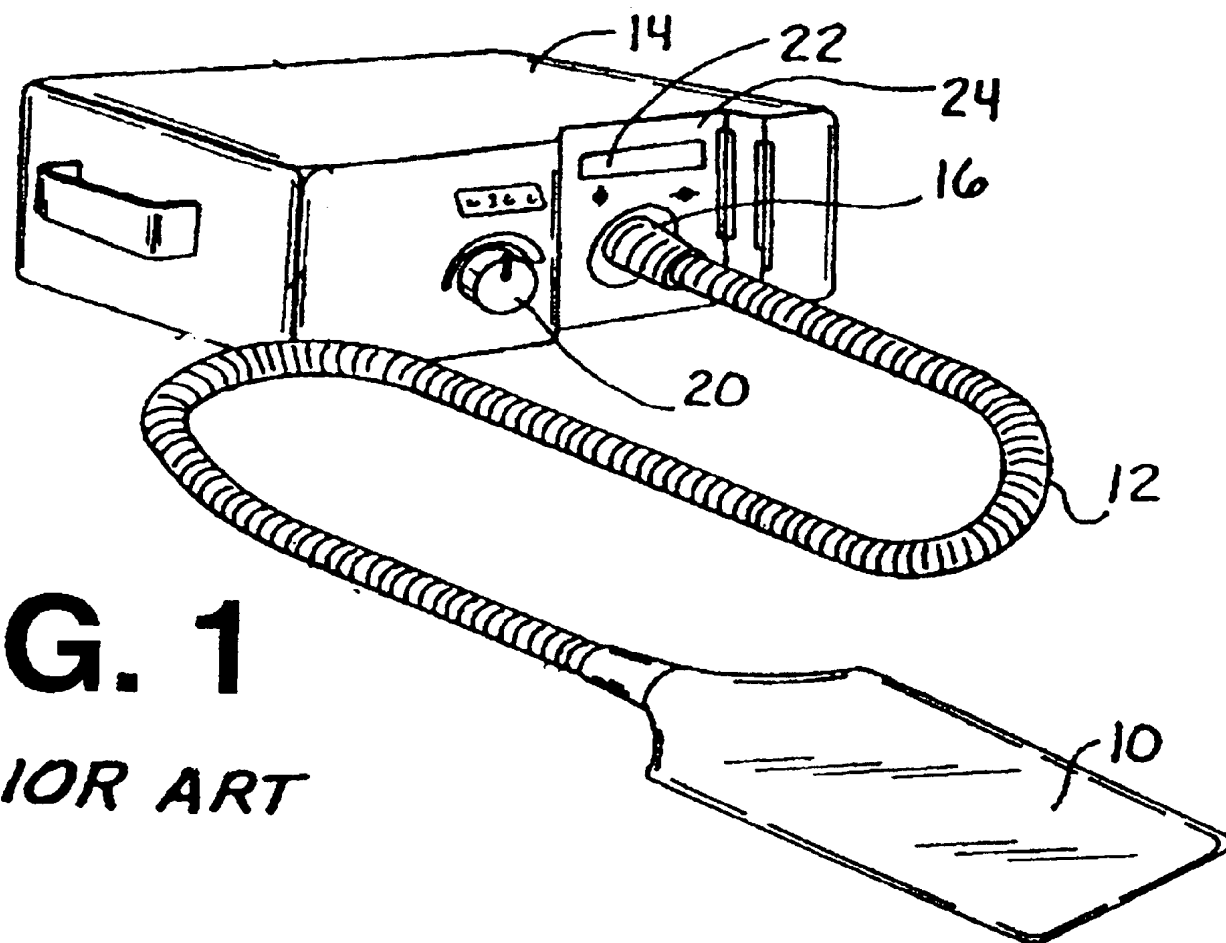


FIG. 1
PRIOR ART

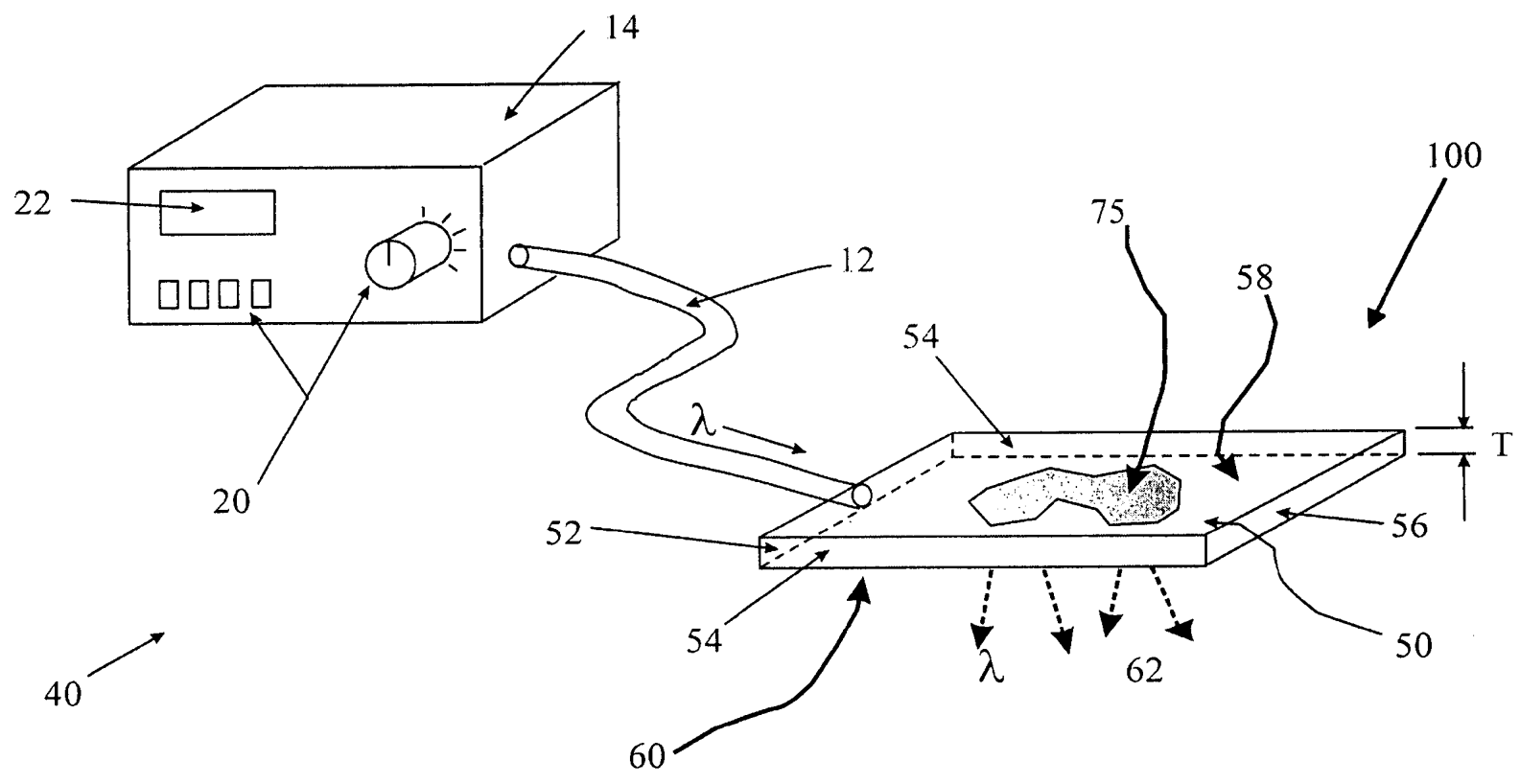


Figure 2

Figure 3a

100

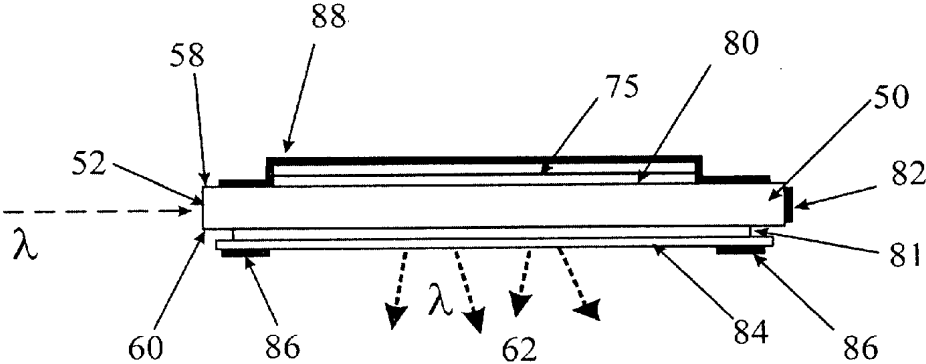
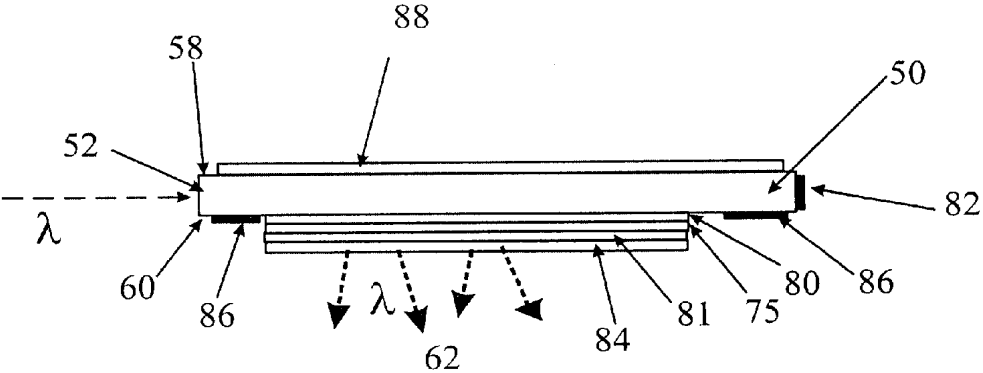


Figure 3b

100



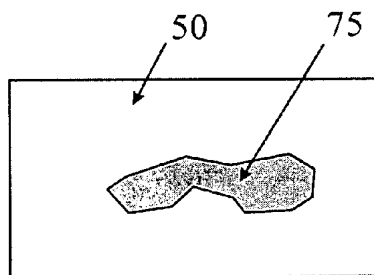


Figure 4a

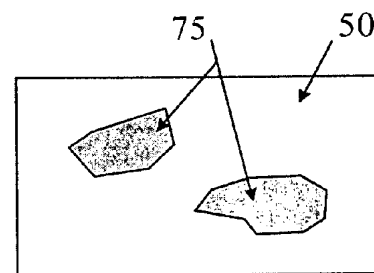


Figure 4b

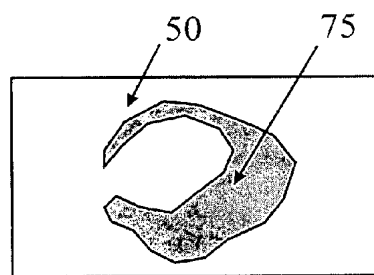


Figure 4c

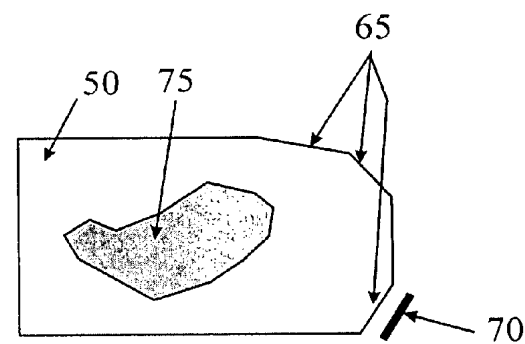


Figure 4d

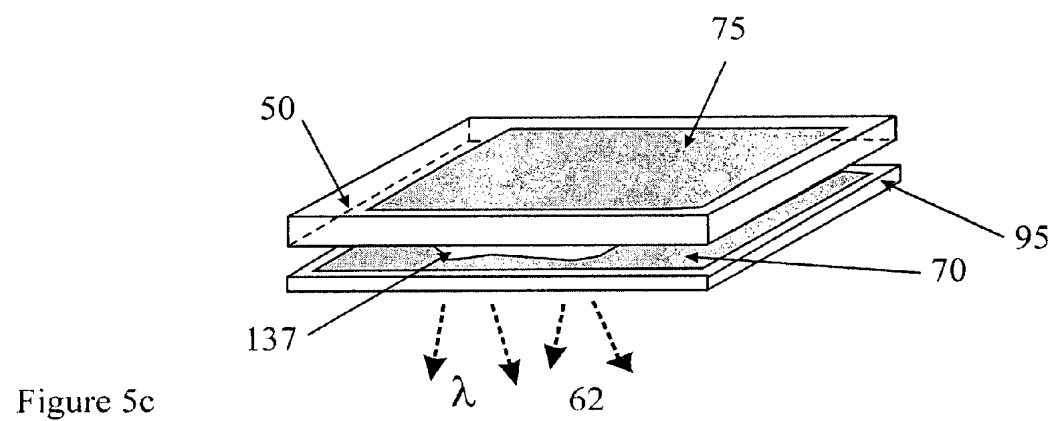
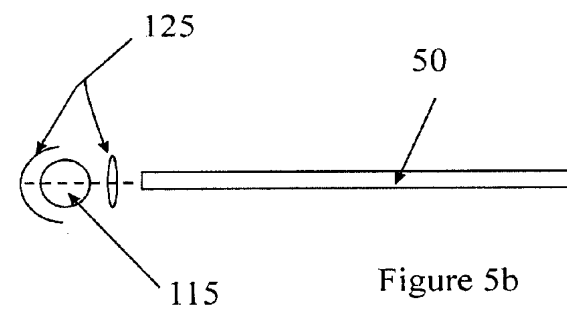
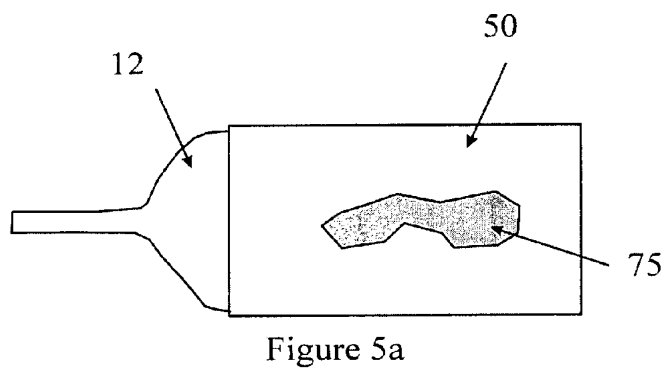


Figure 6a

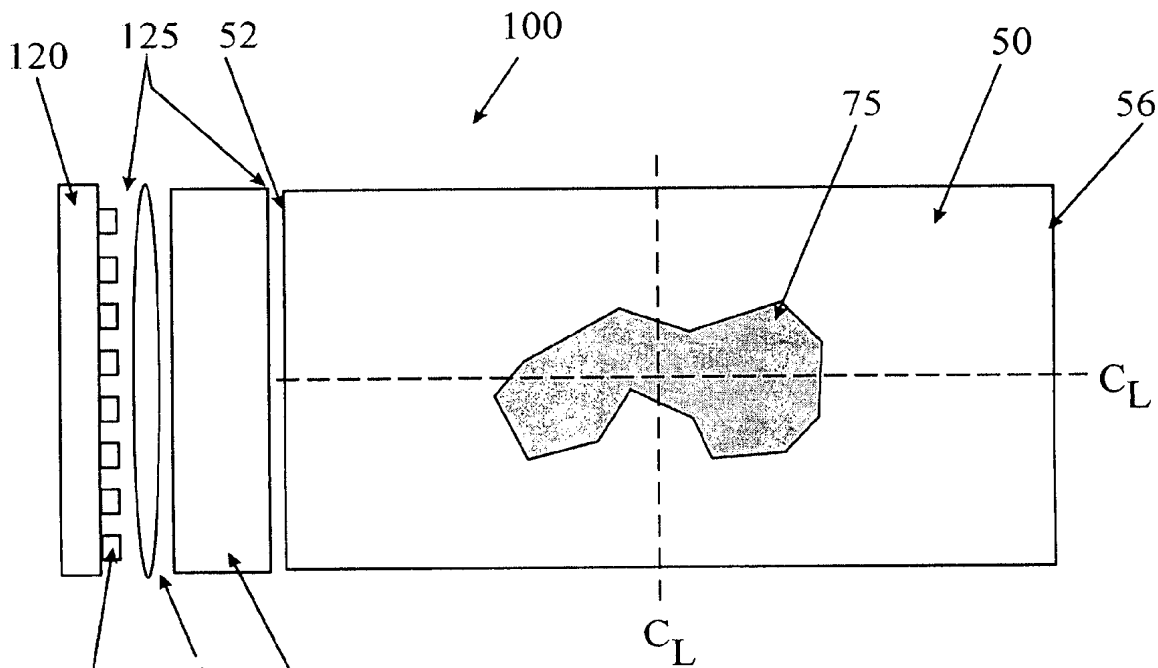
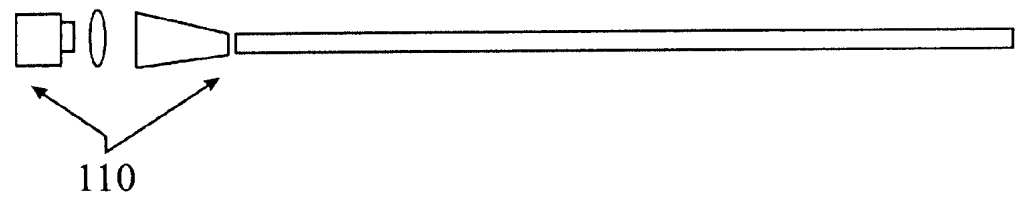


Figure 6b



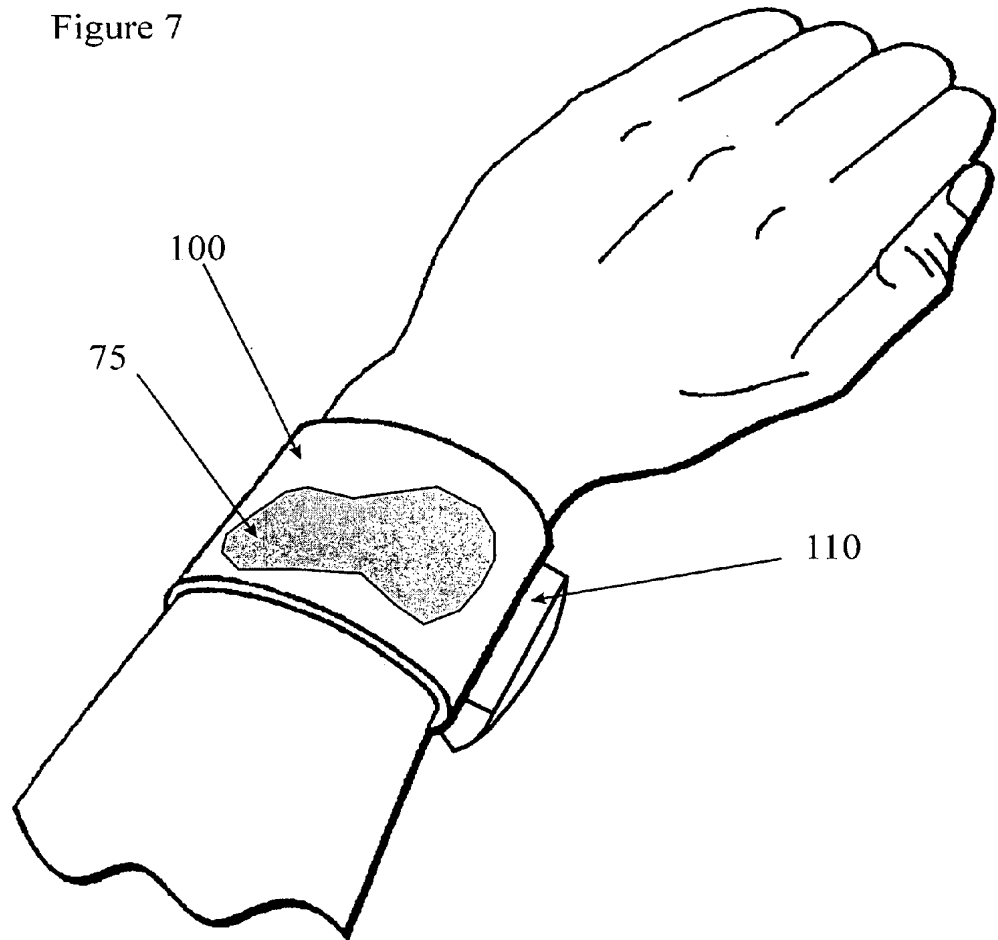


Figure 8a

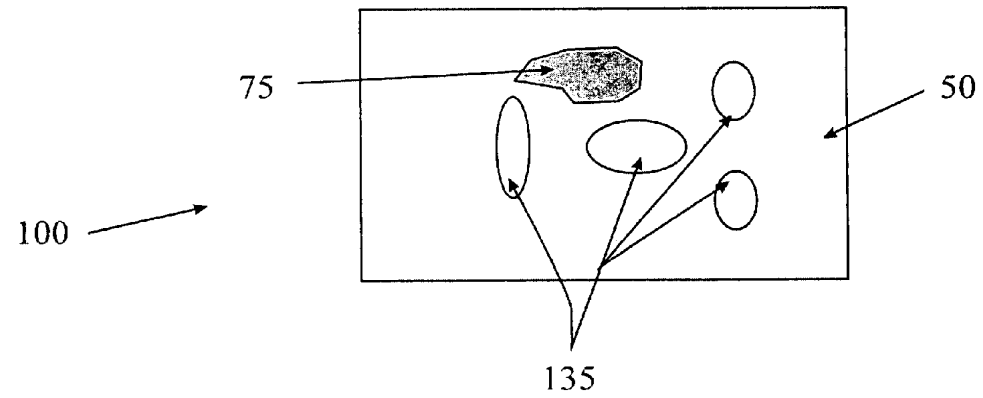
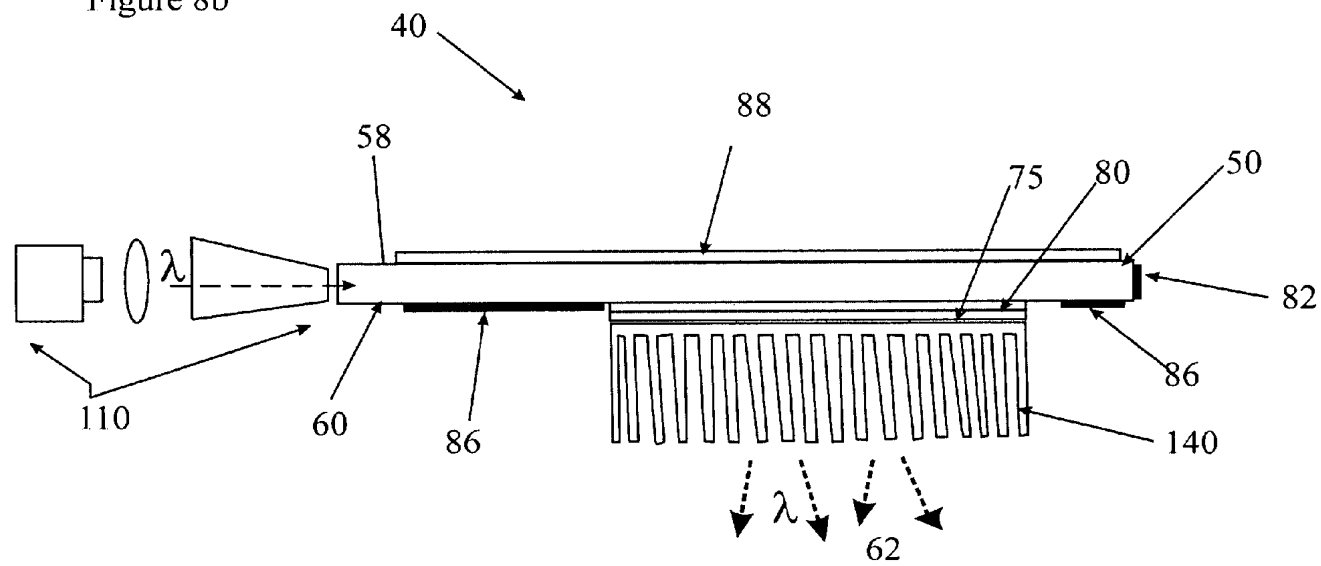


Figure 8b



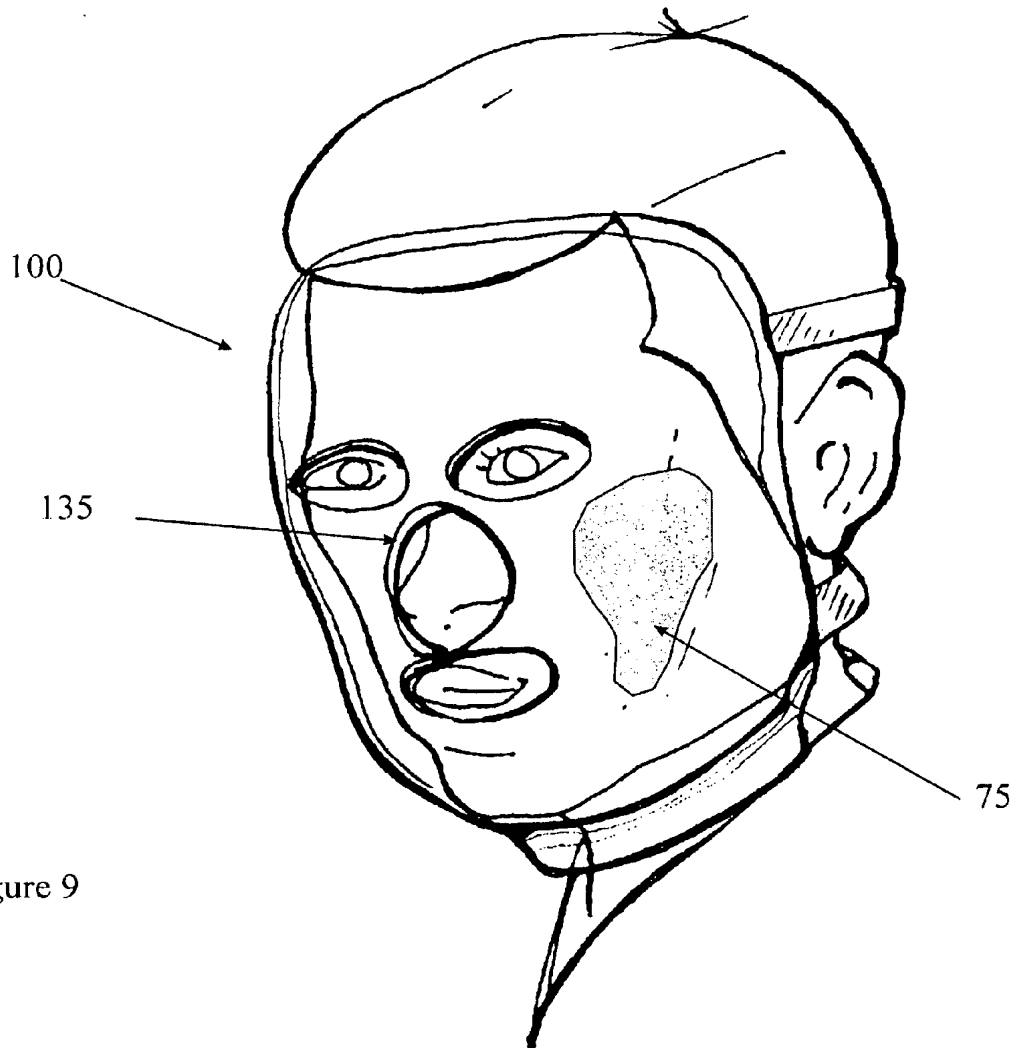


Figure 9

LIGHT THERAPY DEVICE

FIELD OF THE INVENTION

[0001] The invention relates generally to a light therapy device and in particular, to a light therapy device for use in close proximity, or in contact with, the skin or a patient.

BACKGROUND OF THE INVENTION

[0002] The term “phototherapy” relates to the therapeutic use of light, and the term “illuminator” or “light therapy device” or “phototherapy device” refers to a device that is generally intended to be used externally to administer light to the skin of a patient for therapeutic purposes.

[0003] External light therapy has been shown to be effective in treating various medical conditions, for example, seasonal affective disorder, psoriasis, acne, and hyperbilirubinemia common in newborn infants. Light therapy has also been employed for the treatment of wounds, burns, and other skin surface (or near skin surface) ailments. As one well-known example, light therapy can be used to modify biological rhythms in humans, such as circadian (daily) cycles that affect a variety of physiologic, cognitive, and behavioral functions. Light therapy has also been used for other biological treatments that are less recognized. For example, in the late 1800's, Dr. Niels Finsen found that exposure to ultraviolet radiation aggravated smallpox lesions. Thus, he illuminated his patients with light with the UV filtered out. Dr. Finsen further discovered that exposure with the residual red light sped healing in recovering smallpox victims. Finsen also determined that ultraviolet radiation could be used to heal tuberculosis lesions. As a result, in 1903, Dr. Finsen was awarded a Nobel Prize for his use of red light therapy to successfully treat smallpox and tuberculosis.

[0004] In the 1960's and 1970's researchers in Eastern Europe undertook the initial studies that launched modern light therapy. One such pioneer was Endre Mester (Semmelweis Hospital, Budapest, Hungary), who in 1966, published the first scientific report on the stimulatory effects of non-thermal ruby laser light (694 nm) exposure on the skin of rats. Professor Mester found that a specific range of exposure conditions stimulated cell growth and wound healing, while lesser doses were ineffective and larger doses were inhibitory. In the late 1960's, Professor Mester reported the use of laser light to treat non-healing wounds and ulcers in diabetic patients. Mester's 70% success rate in treating these wounds led to the development of the science of what he called “laser biostimulation.”

[0005] Photodynamic therapy (PDT) is one specific well-known example of light therapy, in which cancerous conditions are treated by a combination of a chemical photosensitizer and light. Typically in this instance, several days before the light treatment, a patient is given the chemical sensitizer, which generally accumulates in the cancerous cells. Once the sensitizer concentrations in the adjacent non-cancerous cells falls below certain threshold levels, the tumor can be treated by light exposure to destroy the cancer while leaving the non-cancerous cells intact.

[0006] As compared to PDT, light therapy, as exemplified by Professor Mester's pioneering work, involves a therapeutic light treatment that provides a direct benefit without the use of enabling external photo-chemicals. Presently,

there are over 30 companies world wide that are offering light therapy devices for a variety of treatment applications. These devices vary considerably, with a range of wavelengths, power levels, modulation frequencies, and design features being available. In many instances, the exposure device is a handheld probe, comprising multitude light emitters; that can be directed at the patient during treatment. The light emitters, which typically are laser diodes, light emitting diodes (LEDs), or combinations thereof, usually provide light in the red-IR (~600-1200 nm) spectrum, because the tissue penetration is best at those wavelengths. In general, both laser light and incoherent (LED) light seem to provide therapeutic benefit, although some have suggested that lasers may be more efficacious. Light therapy is recognized by a variety of terms, including low-level-laser therapy (LLLT), low-energy-photon therapy (LEPT), and low-intensity-light therapy (LILT). Despite the emphasis on “low” in the naming, in actuality, many of the products marketed today output relatively high power levels, of up to 1-2 optical watts. Companies that presently offer light therapy devices include Thor Laser (United Kingdom), Omega Laser Systems (United Kingdom), MedX Health (Canada), Quantum Devices (United States) and Lumen Photon Therapy (United States).

[0007] Many different examples of light therapy and PDT devices are known in the patent art. Early examples include U.S. Pat. No. 4,316,467 (Muckerheide) and U.S. Pat. No. 4,672,969 (Dew). The most common device design, which comprises a hand held probe, comprising at least one light emitter, but typically dozens (or even 100) emitters, that is attached to a separate drive controller, is described in numerous patents, including U.S. Pat. No. 4,930,504 (Diamantapoulos et al.); U.S. Pat. No. 5,259,380 (Mendes et al.); U.S. Pat. No. 5,464,436 (Smith); U.S. Pat. No. 5,634,711 (Kennedy et al.); U.S. Pat. No. 5,660,461 (Ignatius et al.); U.S. Pat. No. 5,766,233 (Thiberg); and U.S. Pat. No. 6,238,424 (Thiberg).

[0008] One shortcoming of the probe type laser therapy device is that it requires the clinician, or perhaps the patient, to actively apply the laser light to the tissue. Typically, the clinician holds the light therapy probe, aims the light at the tissue, and operates the device according to a treatment protocol. As a result, the laser therapy devices are often designed to emit high light levels, in order to reduce the time a clinician spends treating an individual patient to a few minutes or less, whether the application conditions are optimal or not. Additionally, in many such cases, the patient is required to travel to the clinician's facility to receive the treatment. Because of this inconvenience, patients are typically treated only 1-3 times/week, even if more frequent treatments would be more efficacious.

[0009] Certainly, these shortcomings with the handheld probes have been previously identified. For example, Laser Force Therapy (Elizabeth, Colo.) offers a disk-shaped probe (the “Super Nova”) that can be strapped onto the patient. While this is a potential improvement, the device does not conform to the shape of the tissue being treated. As an alternate approach, a variety of self-emissive light bandages have been suggested, in which a conformal pad having a light emitting inner surface is strapped directly on the patient. Since the patient can wear the device, perhaps under their clothes for a prolonged period of time, the convenience limitations of the handheld probe may be overcome.

[0010] As a first example, U.S. Pat. No. 6,569,189 (Augustine et al.) provides a heat therapy bandage that uses IR blackbody radiation generated from electrical resistance in circuit trace within the bandage. In this case, since the emitted light is broadband IR (nominally 3-30 microns), this bandage does not enable the use of specific illumination optical wavelengths that have been suggested to be optimal for treating various conditions. In particular, the wavelengths provided by this device may not advantageously activate the known photo-acceptor molecules in cells. Moreover, this device does not offer a means to vary the light spectrum in any useful way.

[0011] As an example, Omnilight (Albuquerque, N. Mex.) offers the Versalight pads, which combine a controller (such as the VL3000) with a pad, where the pads comprise a multitude of discrete LEDs imbedded in a neoprene-covered foam. Bioscan Inc. (Albuquerque, N. Mex.) offers a similar suite of products for veterinary applications. In both cases, the products typically comprise a mix of IR and red LED emitters, arranged in a pattern across the pad. These devices are described in U.S. Pat. No. 4,646,743 (Parris), which teaches conformational pad light therapy devices in which an array of diodes is imbedded in pliable foam. Several other similar devices are known in the prior art, including:

[0012] U.S. Pat. No. 5,358,503 (Bertwell et al.), which provides a conformational pad utilizing tightly packed LEDs, which is placed in contact with the tissue, so as to provide both light and thermal treatments.

[0013] U.S. Pat. Nos. 5,616,140 and 5,989,245 (both to Prescott), which provides a conformational bandage comprising laser diodes and flexible circuitry fabricated within a multi-layer pad.

[0014] U.S. Pat. No. 5,913,883 (Alexander et al.), which provides a conformational therapeutic facial mask comprising a plurality of LEDs held off of the tissue by spacer pads.

[0015] Other prior art patents that provide for conformational light therapy pads with discrete light emitters mounted to a pad substrate include U.S. Pat. No. 6,187,029 (Shapiro et al.); U.S. Pat. No. 6,290,713 (Russell); U.S. Pat. No. 6,443,978 (Zharov); and U.S. Pat. No. 6,743,249 (Alden).

[0016] While these various patents provide designs for conformational light therapy pads, these devices are disadvantaged by their awkward construction, which typically involves mounting some number of rigid discrete diodes (lasers or LEDs) within a conformational pad, accompanied by the required drive circuitry and thermal management means. As a result, these devices are encumbered by some manufacturing difficulties that affect unit cost, and likely limit the potential that these devices could become ubiquitous, if not disposable.

[0017] As an alternate approach, there are a variety of technologies being developed for self emissive devices, such as organic light emitting diodes (OLEDs), polymer light emitting diodes (P-LEDs), and thin film flexible electroluminescent sources (TFELs), which could readily enable volume production. As an example, U.S. Pat. No. 6,096,066 (Chen et al.) teaches a flexible LED array on a thin polymer substrate, with addressable control circuitry, slits for perspiration, and the use of LEDs, which could be replaced with

OLEDs. Similarly, U.S. Patent Application Publication No. 2004/0111132 (Shenderova) discloses a thin film electroluminescent (TFEL) phototherapy device based on high field electroluminescence (HFEL) or OLED technologies. Certainly, light therapy bandages based on these technologies have several potential advantages, including volume production and customizable temporal and spatial control from the addressing circuitry. However, even in the target display markets (laptop computers, television, etc.) OLED technologies are not yet sufficiently mature to support volume production. Also, while self emissive light bandages will not be encumbered by lifetime issues and the resolution requirements imposed on the display market, such bandage type devices will have their own issues (minimizing toxicity, providing sufficient output power or IR output light) that will likely effect the appearance of such devices in health markets.

[0018] Therapeutic light pads have also been developed using woven bundles of optical fibers. Such devices are typically marketed for use in treating jaundice in infants. One example is the Biliblanket Plus, offered by Ohmeda Medical (Baltimore, Md.), which uses a high intensity halogen lamp, mounted in a controller and light coupled into a fiber bundle. The fiber bundle, nominally comprising 2400 individual optical fibers, is configured into a woven pad, in which the bends in the optical fibers cause local breakdown in total internal reflection, so that light is coupled out of the fiber over the full surface area of the pad. Another company, Respiroics (Murrysville, Pa.), offers a similar system, the Wallaby Phototherapy System, for neonatal care of jaundice. The basic concept for a woven fiber-optic illuminator is described in U.S. Pat. No. 4,234,907 (Daniel).

[0019] This type of medical light therapy pad, using an illuminator comprising a woven mat of optical fibers, is described in prior art patents U.S. Pat. No. 5,339,223 (Kremenchugsky et al.) and U.S. Pat. No. 5,400,425 (Nicholas et al.), both assigned to Ohmeda Inc. For example, the prior art light therapy device of U.S. Pat. No. 5,400,425, shown in FIG. 1, comprises a woven fiber-optic pad 10 connected by a fiber-optic cable 12 to a drive unit 14 that houses a source of light. The fiber-optic cable 12 has a protective coating of a plastic material such as vinyl and contains a plurality of individual optical fibers, not shown in FIG. 1, which transmit the light from the drive unit 14 to the woven fiber-optic pad 10 for emission toward the infant. A connector 16, affixed to an end of fiber-optic cable 12, positions the cable to receive light energy from a light source (internal to the drive unit 14 and not shown). The light source is typically a quartz halogen lamp, although xenon lamps, tungsten halogen lamps, LEDs, and other light sources can be used. Also within the drive unit 14 are the various electrical components and optical components, the latter including optical filters to obtain the desired wavelength of the light radiation delivered to the fiber-optic cable 12 in the range of about 400 to 550 nanometers. Other filters may filter out infrared and UV radiation spectrums from the light radiation delivered. The drive unit 14 is also shown equipped with a controller 20 and a display 22 mounted on the front panel 24, which may facilitate intensity and frequency modulation of the light. In combination with the drive unit 14, fiber-optic pad 10 comprises a plurality of optical fibers woven so as to emit light energy for phototherapy. U.S. Pat. No. 6,494,899 (Griffin et al.), assigned to

Respironics Inc., provides an improved device in which the lamp source can be automatically changed after a lamp failure.

[0020] U.S. Pat. No. 4,907,132 (Parker) provides an improved woven fiber-optic light therapy device where the pad is designed for improved light efficiency and controlled output. Accordingly, the uniformity of illumination of a pad may be varied by varying the shape of the optical fiber disruptions or bends and/or the spacing between such disruptions or bends as by varying the pattern and tightness of the weave or by varying the proportion of optical fibers to other material in the weave. U.S. Pat. No. 4,907,132 also provides that the fiber-optic pad may have a transparent coating laminated applied to the outer surfaces of the disruptions or bends on one or both sides of each optical fiber layer. The coating is intended to cause changes in the attenuation of light being emitted from the pad. The coating increases the overall optical efficiency of the pad by causing attenuation changes only where the light normally escapes from the disruptions or bends of the woven optical fiber panel. While control of the pattern and tightness weave certainly will effect light emission over the pad, such customization likely occurs at the factory, rather than at a clinic or even in the home. The other approach, with the transparent overcoat layers, may lend itself to customization at the treatment facility. However, while the over coat seems to offer effective control of the light output, fiber-optic light emission at the bends is largely controlled by the radius of the bends and the core and cladding refractive indices, and applying a transparent coating onto the cladding may only have a secondary effect on the light emission characteristics.

[0021] While such systems may have achieved certain degrees of success in their particular applications, there is yet a need for a low cost flexible light therapy device that can be safely, readily, and comfortably used. In particular, it would be desirable if a clinician could modify the output of a light therapy bandage device to provide light at a desired treatment area, but not elsewhere. As an example, a pressure ulcer is typically a localized wound that affects several square inches of tissue. An overlaying bandage, whether a light therapy device, an alginate based bandage, a hydrocolloid dressing, or some other type of dressing, tend to extend over large areas of the surrounding tissue. While a clinician may want some illumination of the surrounding area, that desired illumination area may still be much smaller than the overall bandage size. Moreover, it would be desirable to allow a clinician to customize the light therapy treatment area to follow the typically irregular shape of the treatment area (a pressure ulcer, a burn, etc.). In particular, it would be desirable if the clinician can customize the light emission area to match the wound area during a given visit to the patient, rather than having to make a return trip. Additionally, it would be desirable if the customized light therapy treatment device can be readily changed upon subsequent visits to the patient. Finally, it would be desirable if such a light therapy device could be fabricated using high volume manufacturing technologies that are already in place today.

SUMMARY OF THE INVENTION

[0022] Briefly, according to one aspect of the present invention a light therapy device for delivering light energy to a portion of a patient's body comprises a light source. The

light source comprises one or more light emitters for providing input light. A light coupling means directs the input light into a light guide. A flexible optically transparent light guide material comprises the light guide. A light extraction means is applied to a surface of the light guide material. The light extraction means is positioned to provide light therapy treatment to one or more localized areas of the patient's body. A control means controls a light dosage relative to intensity, wavelength, modulation frequency, repetition, and timing of treatments.

[0023] These objects are given only by way of illustrative example, and such objects may be exemplary of one or more embodiments of the invention. Other desirable objectives and advantages inherently achieved by the disclosed invention may occur or become apparent to those skilled in the art. The invention is defined by the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] The foregoing and other objects, features, and advantages of the invention will be apparent from the following more particular description of the embodiments of the invention, as illustrated in the accompanying drawings. The elements of the drawings are not necessarily to scale relative to each other.

[0025] FIG. 1 shows a perspective view of a prior art light therapy device comprising a fiber-optic mat type illuminator and a drive unit.

[0026] FIG. 2 shows a diagrammatic view of a light therapy device in accordance with the present invention.

[0027] FIGS. 3a and 3b show side views of the light therapy device of FIG. 2 showing application of a light extraction layer.

[0028] FIGS. 4a, 4b, 4c and 4d show top views of the light guide substrate of the light therapy device of the present invention, with different configurations of light extraction layers.

[0029] FIG. 5a shows a top view of an alternate embodiment of a portion of the light therapy device of the present invention.

[0030] FIG. 5b shows a side view of an alternate embodiment of a portion of the light therapy device of the present invention.

[0031] FIG. 5c shows a perspective view of an alternate embodiment of a portion of the light therapy device of the present invention.

[0032] FIG. 6a shows a top view of an alternate embodiment of the light therapy device of FIG. 2 of the present invention.

[0033] FIG. 6b shows a side view of the FIG. 6a alternate embodiment of the light therapy device of the present invention.

[0034] FIG. 7 shows a perspective view of a light therapy device of the present invention in position to apply treatment to a limb of a patient.

[0035] FIGS. 8a and 8b show views of alternate configurations for portions of the light therapy device of the present invention.

[0036] FIG. 9 shows a perspective view of a light therapy device of the present invention in position to apply treatment to the face of a patient.

DETAILED DESCRIPTION OF THE INVENTION

[0037] The following is a detailed description of the preferred embodiments of the invention, reference being made to the drawings in which the same reference numerals identify the same elements of structure in each of the several figures.

[0038] The present invention provides a flexible light therapy device having a plurality of applications, including but not limited to, the treatment of seasonal affective disorder, psoriasis, acne, diabetic skin ulcers, pressure ulcers, and hyperbilirubinemia common in newborn infants. The present invention delivers light energy by means of a flexible member that can be placed in contact with the skin of a patient. The present invention comprises a light guide bandage, in which light is input coupled into the light guide, trapped within by reflection, and emitted in accordance with a light extraction layer. The light extraction layer can be custom applied, such that the light is emitted nominally onto the area requiring treatment but not elsewhere over the output face of the bandage. The device is nominally designed to be readily worn by the patient for a prolonged time period, and is potentially disposable thereafter.

[0039] FIG. 2 generally illustrates a diagrammatic view of a first embodiment of a light therapy device 40 in accordance with the present invention. As illustrated in FIG. 2, light therapy device 40 comprises a drive unit 14 with an internal light source (not shown), a fiber-optic cable 12 to couple light from the light source into the light therapy pad. The drive unit 14 can be equipped with a display 22 and a controller 20, which facilitates setting of treatment parameters such as light intensity, frequency, wavelength, modulation, and repeat treatment timing. While fiber-optic cable 12 is nominally identified as containing a fiber-optic bundle, other flexible light piping means can be used, such as liquid light pipe or solid dielectric light pipe.

[0040] The light guide therapy pad 100 depicted in FIG. 2 is nominally a transparent optical sheet, wherein light is input coupled at input surface 52. Light is then trapped within the light guide substrate by reflections off of outer surface 58, inner surface 60, side surfaces 54, and end surface 56. A portion of the light trapped within the light guide substrate 50 encounters light extraction layer 75, which re-directs the light, so that it is coupled out of the light guide substrate 50 as therapeutic light 62. Light guide substrate 50 is nominally a non-woven sheet material, such as a flexible transparent elastomeric polymer polyurethane. Other polymers could be used, such as acetate sheets, although the substrate could also be made with a thin optical glass. The light is nominally trapped within the light guide substrate 50 by total internal reflection off of outer surface 58, inner surface 60, and side surfaces 54. End surface 56 will likely utilize a reflective layer as mirror layer 82. This reflective layer could be a dielectric (MgF₂, for example) or a metal (aluminum, for example) layer to reflect the incident light back into the light guide substrate 50. More likely a commercial reflectance film, such as 3M Vikuiti enhanced specular reflection film (ESR) would be used, with an

intermediate adhesive layer used to attach the film to light guide substrate 50. Light guide therapy pad 100 is nominally a wave-guide, with a thickness T that supports multi-mode light guiding along its length and across its width. Light extraction layer 75, can for example, be an optical diffuser such as a sheet white matte reflective beads which can be cut to a shape corresponding to the treatment area and then externally applied to the light guide substrate 50.

[0041] Although to the casual observer, light guide therapy pad 100 of FIG. 2 may appear similar to the prior art fiber-optic pad 10 discussed with respect to FIG. 1, there are several important differences. Light guide therapy pad (or bandage) 100 is not constructed from a multitude of woven optical fibers, but instead comprises a substrate that is a nominally homogeneous optical sheet material. The distribution of the therapeutic light emerging from the prior art fiber-optic pad 10 largely relies on the optical coupling into the individual optical fibers, the distribution of those optical fibers, and the manner and frequency in which bends are imparted to the optical fibers when they are woven. In the case of the light guide therapy pad 100 of the present invention, the distribution of the therapeutic light 62 emerging from the light guide substrate 50 largely depends on the light coupling at the input surface 52, the use of any beam shaping optics at the input surface, and the properties and dimensions of the light extraction layer 75. These differences will become more apparent during the subsequent descriptions of the present invention.

[0042] FIGS. 3a and 3b depict cross sectional views of two basic constructions for the light guide therapy pad 100. In the case of FIG. 3a, light guide therapy pad 100 comprises light guide substrate 50, with a light extraction layer 75 mounted on outer surface 58. Light extraction layer 75 is nominally a reflective optical diffuser, such as the white reflective diffusers commonly used in the manufacture of laptop computer displays. An exemplary optical diffuser that might be used for light extraction layer 75 is the LTO series reflective diffuser from Tsujiden Co. Ltd. (Japan). In this case, light that incident into the light guide substrate 50 reflects internally until it encounters the diffusing light extraction layer 75. Most of this incident light then diffusely reflects from the light extraction layer 75, back towards the light guide substrate 50, through the thickness T of the light guide substrate 50, and exits out the inner surface 60 as therapeutic light 62. Of course, some of the diffusely reflected light will be reflected such that it remains trapped within the light guide substrate 50. After multiple reflections, a portion of that light will again encounter the light extraction layer 75, where it will again be diffusely reflected, and may yet contribute to the therapeutic light 62 emerging from the device. FIG. 3a also depicts light guide therapy pad 100 as constructed with an optional optical coupling layer 80 between light extraction layer 75 and substrate 50. This layer could have both refractive index matching properties and adhesive properties to enhance the efficiency and uniformity of the optical diffusion.

[0043] Other properties of a light guide therapy pad 100 are depicted in FIG. 3a. For example, end surface 56 can be coated with a mirror layer 82 to prevent the light from spilling out the ends of the light guide substrate 50. Side surfaces 54 could also be provided with a mirror layer (such as 3M ESR film) rather than relying on total internal reflection to provide the light trapping. Surfaces 54, 58, and

60 could also be coated with scattered matte beads to provide miniature standoffs, so that other applied layers and materials could be kept from defeating the total internal reflection of the light guide outside the treatment area. Input surface **52** could likewise have a mirror coating, aside from any clear apertures that are provided for the input light to enter the light guide substrate **50**. A cover **88** can be provided on the outer surface **58**. Cover **88** could be a coating or a sleeve, made of gauze or some other material. It could serve several functions, including to protect the light guide therapy pad **100** from damage and contamination (from pathogens; and optically (to prevent degradation of the reflecting and diffusing properties of the bandage surfaces), or to fasten the therapy bandage to other bandage elements (such as straps), etc. Cover **88** could have multiple properties and functions; for example on the outer edges of outer surface **58**, it could comprise one or more Velcro strips for attaching light guide bandage **100** to other bandage elements. Cover **88** could also have localized properties elsewhere relative to outer surface **58**, such as for protection of the optical properties of the light guide, etc. Cover **88** could also provide a non-stick surface, so the light guide therapy pad **100** does not catch on clothing the patient may wear over the pad. Prior art patents, such as U.S. Pat. No. 5,759,570 (Arnold) and U.S. Pat. No. 6,528,697 (Knutson et al.) suggest approaches for constructing composite modular bandages that might be appropriate for the light therapy bandage of the present invention.

[0044] Light guide substrate **50** may also have layers and coatings on the inner surface **60**. For example, a tissue interface layer **84** can be provided, which could have anti-biotic properties or bio-sensing capabilities. For example, tissue interface layer **84** could have topical agents that fight infection (including anti-biotic silver), encourage epithelialization or other tissue healing activities, or amplify the effects of light therapy. In the case of bio-sensing, the bio-sensor features might detect a bio-physical or bio-chemical condition of the treatment area, which can then be used as input to guide further treatments. For example, the biosensors might detect the presence or absence of certain pathogens or enzymes associated with infections, or other enzymes and proteins associated with healing. Light guide bandage **100** could also be equipped with a sensing means that changes color relative to time to indicate the time (or amount of exposure) and thereby indicates an end to a given therapy session. For example, biosensors could be used to look for bio-chemical indications of the effective dosage applied. Alternately, optical sensors could detect the back-scattered light as measure of the optical dosage delivered. The end of session control could then be manual or automatic.

[0045] Light guide substrate **50** may also have adhesive layers **86** on the inner surface **60**, which might help to attach the light guide therapy pad **100** directly onto the tissue, or to other bandage elements. Alternately, adhesive layers **86** could represent other types of attachment means, such as Velcro, which could be used to fasten the light guide therapy pad **100** to other bandage elements. Other cover layers (not shown) could also be provided, to aid in assembly of a composite bandage, incorporating other bandage technologies, such as hydrocolloidal or alginate type dressings, silver based anti-biotic dressings, etc. Obviously, the addition of such dressings should minimally interfere with the use of the light therapy bandage. Also, contact with the patient's body

can require disposing device **40** within a hygienic enclosure/sheath/sleeve. That is, it is recognized that there may be applications (e.g., instances of potential infections) wherein it may be desired to reduce the potential spread of germs. As such, it may be desirable to employ a hygienic sleeve, as known to those skilled in the art (e.g., as used with digital thermometers), for example, a transparent material such as a polymer sheet or bag. The sleeve might then be comprised of an anti-bacterial material. Alternatively, light guide bandage **100** might include an anti-bacterial layer disposed on the surface intended for contact with the patient's skin. The adhesive layer **86** could also be spongy, to provide better comfort for the patient when the light therapy bandage is worn.

[0046] An alternate cross-sectional construction of light guide therapy pad **100** is shown in FIG. 3b. In this case, a transmissive light extraction layer **75** is provided on the inner surface **60** of light guide substrate **50**. Light extraction layer **75** could have a micro-structured optical surface, with micro-prisms, micro-lenses, or other features, which will cause incident light (from internal to light guide substrate **50**) to refract, diffract, and/or scatter out of the light guide substrate **50** and emerge as therapeutic light **62**. An exemplary light extraction layer could be a brightness enhancement film (BEF) from 3M. Potentially, extraction layer **75** could be formed with micro-structured light extraction features that are directly embossed or patterned into either outer surface **58** or inner surface **60** of the light guide substrate **50**. Other complementary layers, such as cover **88**, mirror layer **82**, adhesive layers **86**, and tissue interface layer **84** are shown for completeness.

[0047] Ongoing research into light therapy has also suggested that it can be advantageous to illuminate the tissue being treated with polarized light, as compared to non-polarized light. Therefore it may be beneficial to equip the light guide therapy device **100** of the present invention with the ability to polarize light. To exemplify this, the conceptual devices of FIGS. 3a and 3b are shown to possibly comprise other optical layers **81**. For example, other optical layers **81** could comprise a polarizing film or a polarization conversion film, as are used in the display industry to build laptop and television displays. Other optical layers **81** could have other desirable properties; and for example be optical filters or be photo-chemically active, and react (change color) in response to bio-chemically emitted light emerging from the tissue in connection to some ongoing biological process. As such, other optical layers **81** could serve as a diagnostic device, similar to the previously mentioned biosensors. The clinician could be equipped with light guide substrates lacking such other optical layers **81**, and apply them as needed, or the dielectric substrates could be pre-fabricated with such layers, and the clinician could be offered a range of light guides with different properties, and choose accordingly.

[0048] It should be understood that the cross-sectional views of FIGS. 3a and 3b are meant to be illustrative of the general concepts, and do not represent the actual relative physical size of the various constituent layers and components. Other figures are intended to be similarly illustrative.

[0049] Another aspect of light guide therapy pad **100** is depicted in FIGS. 4a-4c. In particular, these figures illustrate the intention that light extraction layer **75** can be

optimized to illuminate a given treatment area or areas, even if they are irregular in shape. In particular, **FIG. 4b** depicts a light guide therapy pad **100** with two light extraction layers **75** disposed on a surface. It is generally preferable to pattern light extraction layer **75** in the general shape of the treatment area, and to illuminate the wounded tissue or an area somewhat larger, rather than to illuminate the tissue over the entire surface area of the light guide therapy pad **100**, as there will then be greater efficiency in delivering light to the wounded area. In some cases, depending on the size of the wound and the available bandages, or the type of wound, the light extraction layer **75** could cover nearly the entire surface of light guide therapy pad **100**.

[0050] Considering **FIGS. 4a-4c**, a clinician might measure directly, or via a digital camera, the boundary regions of a wound. This data would then be transferred over to a sheet of light extraction layer **75** material, where the pattern of the boundary regions would be generally replicated. Depending on the construction of the light guide therapy pad **100**, the location of the patient (in a clinic or hospital, or at home) and the capabilities of the clinician, the pattern transfer to the light extraction layer **75** might happen in situ with the patient, or remotely. For example, in the remote case the digital image data for a wound might be transferred to another location, where the light extraction layer **75** could be printed or cut from a material. The final assembly of the bandage could then occur at that location. If the patterning of the light extraction layer **75**, and the attachment thereof to the light guide substrate **50**, is a simple process, the customized light guide therapy pad **100** could be completed by the clinician in the field.

[0051] Although it may be optimal for a clinician to customize the light extraction layer **75** to the wound area, using a digital camera (for example), it may also be that the practicalities of image capture and transfer, and completion of the bandage **100** may prove too cumbersome for some circumstances. Thus, it should be understood that a clinician could be provided with a set of pre-shaped and pre-sized light extraction layers **75** (for example, with round and/or oval shapes). The clinician could then choose the light extraction layer **75** that most closely resembles the desired treatment area. The clinician could then apply the light extraction layer **75** to light guide substrate by the appropriate methods to complete the bandage preparation. Alternately, a range of bandages **100** could be pre-assembled at the factory, comprising a range of differently shaped and sized light extraction layers **75**. The clinician could then select the most appropriate bandage **100** from the selection available. Assuming that the bandage cost is sufficiently low, then the burden of having a selection of pre-fabricated bandages available to one or more clinicians could be manageable.

[0052] In the prior discussions, it was assumed that the light therapy device of the present invention would be used by applying a light extraction layer **75** to a surface of the light guide substrate, such as a reflective diffuser on the outer surface **58** or a transmissive micro-structured layer on the inner surface **60**, where the shape, size, and position of the light extractor can be optimized relative to the treatment area. However, an alternate construction can be used, as depicted in **FIG. 5c**, in which the light extraction layer **75** covers all or most of a surface of the light guide substrate **58**, and in which a mask **95** is applied between the inner surface and the tissue. In this case, mask **95** nominally includes an

internal patterned aperture **137** that corresponds to the treatment area, through which the therapeutic light travels. Mask **95** can be light absorptive or light reflective. As shown in **FIG. 5c**, mask **95** has a reflective material **70** applied to the surface facing the light guide substrate. Mask **95** is shown offset from light guide substrate **50** for illustrative purposes, but in general, these two items would be held together in close proximity.

[0053] The coupling of the input light into light guide substrate **50** can be accomplished by a variety of means. For example, in **FIG. 2**, a fiber-optic cable **12** is shown, attaching to light guide substrate **50** at the center of input surface **52**.

[0054] In this case, while light trapping within light guide substrate **50** will tend to homogenize the light, there will likely be a "hot spot" (an area of higher intensity) near the center of the light guide substrate **50**. As most wound patterned light extraction layers **75** would likely be positioned near the center of the bandage **100**, it may be desirable to have an intensity hot spot in the center region of the light guide substrate **50**. On the other hand, the light guide substrate **50** can be more uniformly filled with light if need be. For example, in the top view of **FIG. 5a**, fiber-optic cable **12** is a "circle to line converter", with the ensemble of individual optical fibers at the output end of fiber-optic cable **12** distributed over a long linear region. As another example, depicted in the cross sectional view of **FIG. 5b**, light source **115** is a linear light source (extending into the paper), complemented by beam shaping optics **125**, which couple the output light into the light guide substrate **50**. Light source **115**, for example, might be a cold cathode fluorescent lamp (CCFL), a neon type tube lamp, or an elongated tungsten halogen filament lamp. Beam shaping optics **125** could include a reflector and a lens, as well as optical filtering (not shown).

[0055] Another embodiment of light guide therapy pad (or bandage) **100** is depicted in **FIGS. 6a-6b**. Light therapy device **40** nominally comprises a light source module **110** and light guide substrate **50**, whereas bandage **100** includes light guide substrate **50** and perhaps a portion of the light source module **110**, depending on how design modularity is accomplished. Light source module **110** nominally comprises light source array **120** and beam shaping optics **125**. Mounting means (not shown) would be provided to hold these various components in their proper relationships with respect to each other.

[0056] For this device, a light source array **120** is shown, which could comprise 1 to N individual light emitters **122**. For example, if a fiber-optic cable **12** were branched into N smaller fiber bundles, then light emitters **122** would represent the output end of these fiber-optic bundles. More likely, the plurality of light emitters **122** represent a series of laser diodes, or light emitting diodes (LEDs), or combinations thereof. As such, the lasers or LEDs could be discretely packaged semiconductor type devices. Molded-in LEDs on flex circuits could also be used, as is done in the display industry (for example, by Global Lighting Technologies Inc.). Discrete laser diodes and LEDs are available from numerous companies, including Spectra-Physics, Coherent, SuperLum Diodes Ltd. Lumileds, Cree, Osram, or Nichia. The ensemble of laser emitters **122** could also represent a monolithic array, such as a laser diode array (although such

an array would not likely extend the full width of the light guide substrate 50). The plurality of light emitters 122 could also be provided by other light source technologies, such as organic LEDs (OLEDs), polymer LEDs (P-LEDs), or thin film electroluminescent (TFEL) emitters.

[0057] Considering again FIGS. 6a-6b, the light emitted from light emitters 122 can be coupled into light guide substrate 50 by beam shaping optics 125, which are shown as comprising lens 127 and optical coupler 130. Lens 127 may represent a single lens, a lens system, or other optical elements with optical power. For example, lens 127 could represent a field lens, such as Fresnel lens. Lens 127 would have a focal length determined by the preferential light distribution sought within light guide 50. For example, lens 127 could have a focal length that would cause light to be focused towards the intersection of the two light guide center lines (CL), or a focal length that would correspond to the far end (end surface 56) of the light guide substrate 50. Lens 127 could also include optical power, for example from a cylinder lens, which would help to couple light into the near end (input surface 52) of light guide substrate 50. Beam shaping optics 125 could also include an optical coupler 130, such as a non-imaging optical light concentrator such as a tapered bar or a compound parabolic concentrator (CPC) for enhancing the efficiency of coupling input light into the light guide substrate 50. Beam shaping optics 125 could also comprise a lenslet array, where there may be a lenslet for a light emitter 122 or for a group of light emitters 122. It should be understood that beam shaping optics could also further comprise other optical elements such as spectral filters and optical polarizers.

[0058] The light guide therapy device 40 depicted in FIG. 6a-6b represents an alternate embodiment to the device shown in FIG. 2 in other ways than just the configuration of the light source and the means for optical coupling into the substrate 50. Considering again the light therapy device 40 of FIG. 2, the drive unit 14 (which includes the light source) is separate and distinct from the light guide bandage 100, with the two joined by fiber-optic cable 12. In order to facilitate ease of use by the clinician and the patient, it would be optimal if the light guide bandage 100 could be disconnected from the drive unit 14. This modularity could be provided numerous ways, but optimally, the fiber-optic cable 12 has an interface connector (not shown). Preferably this connector would be located at the juncture of the fiber-optic cable 12 and the light guide substrate 50, or alternately at some short distance (~25 mm, for example) prior to the juncture of the fiber-optic cable 12 and the light guide substrate 50. In that latter case, light guide bandage 100 would be assembled with a short length of fiber-optic cable 12 protruding from it, which would then mate to the longer cable extending from the drive unit 14.

[0059] In this context, the light guide therapy device 40 of FIGS. 6a-b can represent another approach to modularity. Certainly this light therapy device 40 can include a separate drive unit 14, much as depicted in FIG. 2. However, as the light therapy device 40 in FIGS. 6a-6b is designed to be compact, and preferably utilize small light sources such as LEDs, then the drive unit could be incorporated somewhere within light source module 100. For example, the functions of controller 20 could be provided by a small circuit board or a flexible thin film circuit could be included in the assembly for light source array 120. Presumably battery

power would also be included. If this assembly is sufficiently small and light, it could be an integral permanent assembly with light guide substrate 50. However, as the goal is to provide a low cost light therapy bandage which is easy for the patient to wear for prolonged periods of time, and which further may have the portion that is in contact with the treatment area replaceable, if not disposable, then the various further concepts for modularity may be utilized. For example, the light therapy bandage 100 could comprise light guide substrate 50 and the various coatings and layers (per FIGS. 3a-b) and little else. In that case, modularity could be enabled by having the bandage separate from the light source module 110 at the juncture of the light coupling means 130 and the light guide substrate 50. This has the advantage that light guide substrate 50 is nominally a sheet material which can be readily fabricated. On the other hand, changing the light guide substrate 50 could require a clinician to align the flexible sheet light guide substrate 50 to the light source module 110. Attaining that alignment over the width of the substrate 50, while providing efficient light coupling, could be difficult, particularly in the field.

[0060] Alternately, modularity could be provided by having light therapy bandage 100 include both substrate 50 and light coupling means 130. Light coupling means 130 could be fabricated separately, and then adhered or fused to the light guide substrate 50. Alternately, bandage 100 could be partially made using an extrusion process, where light coupling means 130 is formed at the end of substrate 50 as one contiguous piece. Light coupling means 130 would still be part of the beam shaping optics 125, but not part of the light source module 110, as it was originally defined. In this case, the alignment of the bandage 100 to the incident light from the light source module would be significantly easier, because the incoming light beam would still be relatively large, as would the light coupling means 130. This would also likely simplify the design of the mechanical mounting interface structures provided for light source module 110 and bandage 100, as well as improving the robustness of the mechanical design. Certainly other design variations can be considered as means to provide modularity for the light therapy device 40 of the present invention.

[0061] It is noted that light guide substrate 50 is shown in the figures as having a constant nominal thickness T over the length and width of the sheet. Alternately, substrate 50 can have a wedged profile, with the thicker end corresponding to input surface 52. If the input end is sufficiently thicker, the potential need for a light coupling means 130 may be obviated. Alternately, providing a wedge in the sheet material towards the input surface 52 may ease the mechanical interface to the optical coupling means 130.

[0062] Certainly the light guide therapy device 40 would be designed to be adaptable to facilitate treatment of a variety of conditions. For example, the bandage 100 could have a square form factor, as small as 2.5 in.×2.5 in., or as large as 10 in.×10 in., or a rectangular form factor, such as 8 in.×20 in. The thickness T of substrate 50 would nominally be ~1-2 mm, although it could be as little as 0.1-0.5 mm, as long as the required flexibility is achieved. It may also be desirable that the light guide substrate 50 be fabricated from a material that is extensible, so that the bandage can be stretched and wrapped (for example around a limb). The clinician may also encounter circumstances where it would be desirable to modify the outward shape of the light guide

substrate, as wrapping the bandage, even if flexible and conformal, around some portion of a patient's body, may not be an adequate solution. With respect to this issue, **FIG. 4d** depicts a light guide substrate that has been modified with cut edges **65**. Unfortunately, cutting the edges in this manner will likely cause light to leak out the new edge surfaces. Potentially the clinician could stop this light leak by applying a reflective layer, such as the previously mentioned 3M ESR film, to the edges. This could be an awkward activity for the clinician to undertake, particularly in the field. Alternately, an easy to apply reflective material **70**, such as a quick curing metal (silver, for example) impregnated epoxy or adhesive could be applied along the edges. Although light guide bandage **100** has been generally depicted in the various figures as comprising a substrate **50** with sharp corners, it should be understood that the devices could be initially fabricated with rounded corners, which might aid comfortable application onto a patient.

[0063] The operational wavelength could be variable, depending on the condition being treated. For example, the bandages could emit blue light for treating jaundice in infants. Alternately, the bandages could be designed to emit red light (such as 632 nm or 670 nm) or infra-red light (such as 840 nm), or the combination thereof. Numerous academic studies have demonstrated enhanced healing effects for conditions such as burns, pressure ulcers, and chronic pain, with application of red and/or IR light. This is partially because most human tissue has a transmission window, from ~630 nm to ~1200 nm where light can penetrate ~3-4 mm into the tissue. Furthermore, various bio-chemicals, such as cytochrome oxidase, have been shown to be particularly photo-reactive to incident light in that spectral range. The energy received by such photo-chemicals can then be used in various ways to enhance healing. Also, as some studies have suggested that laser light may provide more efficacious healing than does incoherent light (such as that from LEDs), it is emphasized that the light source can comprise one or more lasers (such as laser diodes), which can be used by themselves or in combination with incoherent light sources. It is also noted, that in many of the published light therapy studies, the applied optical intensity ranges between 5-100 mw/cm². The light guide bandage of the present invention is generally intended to meet these apparent optical power needs. However, given that the light guide bandage is intended to stay on a patient for a prolonged duration, then it is intended to employ longer exposure times at lower power levels. The lower power levels do need to fall within a range where reciprocity applies, and lower power levels still provide a beneficial effect, rather than little or no effect. For example, biological time constants or threshold effects may limit the lower level of light exposure.

[0064] Controller **20** nominally provides intensity control, as well as light modulation (nominally at frequencies in the 5 Hz-5 kHz range) and repeat treatment programming capability. Controller **20** could also include intensity calibration functionality, as well as data management for any feedback or bio-sensing capabilities that might be built into the bandage. Depending on the circumstances, it may or may not be desirable to allow the consumer or patient to control the operation of the light therapy bandage of the present invention. It should be understood that the light therapy device of the present invention could be used not only for light therapy, but also for photodynamic therapy (PDT).

[0065] To illustrate the general concept of the light therapy device **40** of the present invention, **FIG. 7** is provided, in which a light guide bandage **100** is shown wrapped around a patient's arm. Light guide bandage **100** may also be equipped with apertures **135** (see **FIG. 8a**) to allow the passage of air flow and perspiration, or to allow clearance for appendages (fingers, for example). The inside edges of apertures **135** could be coated with a reflective layer, such as the metallized epoxy that was mentioned previously. **FIG. 9** then shows a general concept of the light guide bandage **100** as a facial mask attached to a patient's head with straps. In this instance, the apertures **135** more readily allow the patient to breathe, talk, see, and smell while wearing the mask. For example, the clinician could use a digital camera to capture an image of the patient's face, then download the image onto a light guide template, which would determine how the apertures **135** should be shaped and positioned. In this case, light guide bandage **100** may not only be flexible and conformal, but may also be molded to better follow the complex features of the tissue it is applied to. **FIG. 8b** shows another alternative concept where the light guide therapy device **40** is equipped with a light guide adaptor **140** that protrudes from the inner surface **60** of the substrate **50**. For example, a light guide adaptor **140** might facilitate treatment in circumstances where there is dense hair, such as a cranial treatment or a veterinary treatment (where there is fur), in which a goal is to avoid shaving the hair off while still allowing treatment.

[0066] The conceptual designs for the light therapy device of the present invention have been discussed with emphasis on providing a low cost, customizable, light therapy bandage that is modular. In part, the modularity is emphasized as an enabling means to allow the clinician to adapt the bandage to the changing characteristics of the wound over time. In part also, the emphasis on modularity and low cost is also to enable the clinician to readily change and adapt the bandage in the field. In this latter context, it needs to be understood that a clinician may change normal bandages on a wound 2-3 times per week. Thus the light therapy bandage needs to have sufficient ease of use, as well as well as a low enough cost, that its use is economically feasible. If the cost of the entire device was sufficiently low, then the entire bandage, light source included, could be discarded after use. But as the light source module **110** or the drive unit **14** will likely have some significant costs associated with them, it is likely desirable to have a modular design, where the light guide bandage can be separated from the light source. Alternately, the light source emitters, can be formed directly onto the substrate **50**. For example, either patterned organic LEDs (O-LEDs) or polymer LEDs (P-LEDs) could be fabricated at an edge or side of substrate **50**, so that the emitted light is directly coupled into the substrate. Perhaps, the molded-in LEDs on flex circuits, integrated directly on an edge of the substrate **50**, could also be used. In such instances, the modularity of light therapy bandage **100** could be compromised in order to have a fully integrated light source and light guide, provided that the cost of the combination unit was still sufficiently low, that the bandage **100** could be cost effective. The advantage in this case, is that with the light source module **100** effectively integrated into the bandage with a very low profile, the thickness and rigidity of the bandage **100** at the light input might be minimized, potentially making the device usage easier for both the patient and the clinician.

[0067] The light therapy bandage **100** of the present invention is generally conceived to have a combination of adaptability, physical flexibility, modularity, and low cost, that a clinician would readily apply it to a patient for an extended period of time (for example, several days), during which the device would likely operate according to some predetermined protocol. For the light therapy bandage of the present invention to have the greatest utility, it should be integrated with other bandage elements. Preferably, bandage **100** could be combined with other types of bandages or dressings, such as hydro-colloids, alginates, or anti-biotic silver bandages. In such a case, these other bandages or dressings would provide required functions to keep the wound moist and suppress infections, and bandage **100** could slip into a sleeve or pocket in one of the other bandages. Attachment feature **86**, which could be an adhesive or Velcro, could be used to assist such combinations. In such instances, it would likely be required that any bandages or dressings that are intervening between bandage **100** and the wounded tissue be sufficiently transparent at the treatment wavelengths, that the treatment light can effectively reach the tissue. Of course, exudates (fluid, cells or other substances that have been slowly exuded, or discharged, from cells or blood vessels) may be present and reduce the effectiveness of the light therapy from the bandage **100**. Thus, it is generally preferable that bandage **100** can be cleaned. Therefore, bandage **100** may be combined with other types of dressings, such as vacuum sponges, that help remove exudates. Additionally, bandage **100** may be equipped directly with the previously mentioned tissue interface layers **84** (preferably transparent) that provide the needed features of modern bandages or dressings, such as alginate or anti-bacterial silver functionality. In that case, bandage **100** may include a foam or gel that contacts the tissue. Preferentially, bandage **100** can be cleaned and re-used on the patient. Light guide bandage **100** likely also needs to be waterproof and crushable, as well as non-allergenic. Some portion of the bandage or dressing including bandage **100** needs to be moisture permeable and breathable. The light source and associated drive electronics could be re-used, perhaps rented or leased, or sold to the clinician or consumer for ongoing use.

[0068] It is noted that light guide therapy pad **100** is also generally similar to the light guides used in backlights for laptop computer and mobile phone displays. Display backlighting systems typically comprise a light source, a light guide member, and a light extraction means. For example, the light source is typically a cold cathode fluorescent lamp or an array of LEDs that are coupled into one end of the thin sheet light guide. The light guide substrate can likewise be equipped with a light extraction layer, such as a light diffusion layer, or a prismatic sheet. In many cases, the light extraction means comprises a volume diffusion mechanism, such as beads or bubbles that act as light scatterers, and which are imbedded in the light guide itself. There are numerous prior art patents known in the art for display backlights, including U.S. Pat. No. 5,005,108 (Pristah et al.); U.S. Pat. No. 6,079,838 (Parker et al.) and U.S. Pat. No. 6,712,481 (Parker et al.). The most important difference for the present invention, and in particular light guide therapy pad **100**, as compared to the prior art known from display backlighting, is that the display backlights designs are motivated to provide uniform spatial and uniform angular light output over nearly the full length and width of the light

guide panel. In particular, in the backlight applications, the goal is to reduce the spatial non-uniformity over the display to a few percent, so that the user is nominally unaware of any residual variation within the viewing area. Many backlight display designs employ spatially variant or patterned diffusers, micro-structures, or deformities, but with the goal to transform a non-uniform light input (often at one end) into a spatially uniform light output over nearly the full area of the light guide. Likewise, the goals in backlight design often include control the horizontal and vertical angular directionality of the output light, to maximize light efficiency within the likely viewing angles (for example $\pm 15^\circ$ vertically and $\pm 30^\circ$ horizontally) to allow the user to view the screen with minimal change over some angular range, as for example, the user turns his or her head. The display backlights, which are usually illuminating a liquid crystal panel, are also usually equipped with other layers, such as color filters (and particularly color filter arrays) and contrast enhancement layers, so that the display provides high contrast full color illumination. As the light guide therapy device of the present invention does not employ addressed modulated high-resolution pixels, neither color registered color filter arrays nor contrast enhancement layers are needed.

[0069] The light guide therapy pad **100** of the present invention is different and distinct from the display backlights in several regards. In particular, the light extraction means (light extraction layer **75** or mask **95**) of the present invention is not nominally applied to the entire surface area of the light guide, but is only applied to a smaller portion corresponding to one or more treatment areas. Therefore, spatial uniformity of the light distribution exiting the light guide **100** is not a priority, and may not even be desirable (per FIGS. 4a, 4b). Likewise, the light guide **100** of the present invention is not designed with an emphasis on controlling the angular spread of the exiting light. In general, the design goal would be to have the therapeutic light **62** emerge over some range of angles, from normal incidence out to $\theta_{\max}$, where $\theta_{\max}$ is likely between $20-45^\circ$. However, separate control of angular emissions in the two meridians ("horizontal" and "vertical") is not required. Importantly also, the light guide therapy pad of the present invention is designed to facilitate customization of the light extraction to match the treatment area, as well as to facilitate the potential disposability or reusability of all or a portion of the light guide therapy pad **100**. In this context, the pad **100** is designed so that the clinician can apply a light extraction layer **75** or mask **95** to the light guide substrate **50**, as well as remove and replace the light guide bandage **100** relative to the light source module **110** or the drive unit **14**. In contrast, display backlights are designed as factory integrated packages, with the light source (such as the CCFL) and the light guide held in a fixed relationship, without any intent for user modification. The user is not expected to change the light guide relative to the light source, or to alter the light extraction capabilities of the light guide. Additionally, while the light guide therapy pad **100** of the present invention may be equipped with secondary layers and functions, such as anti-biotic layers, adhesive layers (to the tissue), non-stick layers, or bio-sensing layers, these layers are functionally different than the color filter and contrast enhancement layers provided in display backlights.

[0070] Throughout the previous discussions in which the present invention has been described, the focus has been

directed towards the treatment of wounds, such as chronic wounds, as exemplified by pressure ulcers. Certainly the device of the present invention can be used to treat other types of chronic wounds (such as diabetic ulcers or venous stasis ulcers), as well as acute wounds (such as cuts and incisions), burns, jaundice, and various skin conditions (acne, psoriasis, fine lines and wrinkles, etc.), as well as other conditions not listed here. Under the appropriate circumstances, the device of the present invention might even be used for internal (such as body cavity) treatment applications.

[0071] The invention has been described in detail with particular reference to a presently preferred embodiment, but it will be understood that variations and modifications can be effected within the scope of the invention. The presently disclosed embodiments are therefore considered in all respects to be illustrative and not restrictive. The scope of the invention is indicated by the appended claims, and all changes that come within the meaning and range of equivalents thereof are intended to be embraced therein.

PARTS LIST

[0072] 10 fiber-optic pad
 [0073] 12 fiber-optic cable
 [0074] 14 drive unit
 [0075] 16 connector
 [0076] 20 controller
 [0077] 22 display
 [0078] 24 front panel
 [0079] 40 light therapy device
 [0080] 50 light guide substrate
 [0081] 52 input surface
 [0082] 54 side surface
 [0083] 56 end surface
 [0084] 58 outer surface
 [0085] 60 inner surface
 [0086] 62 therapeutic light
 [0087] 65 cut edges
 [0088] 70 reflective material
 [0089] 75 light extraction layer
 [0090] 80 optical coupling layer
 [0091] 81 other optical layers
 [0092] 82 mirror layer
 [0093] 84 tissue interface layer
 [0094] 86 adhesive layer
 [0095] 88 cover
 [0096] 95 mask
 [0097] 100 light guide therapy pad
 [0098] 110 light source module
 [0099] 115 light source

[0100] 120 light source array
 [0101] 122 light emitters
 [0102] 125 beam shaping optics
 [0103] 127 lens
 [0104] 130 optical coupler
 [0105] 135 apertures
 [0106] 137 patterned aperture
 [0107] 140 light guide adaptor

1. A light therapy device for delivering light energy to a portion of a patient's body, comprising:

- a) a light source, comprising one or more light emitters for providing input light;
- b) a light coupling means for directing said input light into a light guide;
- c) a flexible optically transparent light guide material, which comprises said light guide;
- d) a light extraction means which is applied to a surface of said light guide material; wherein said light extraction means is positioned to provide light therapy treatment to one or more localized areas of said patient's body; and
- e) a control means, which controls a light dosage relative to intensity, wavelength, modulation frequency, repetition, and timing of treatments.

2. A light therapy device as in claim 1 wherein said light extraction means is a reflective optical diffuser layer.

3. A light therapy device as in claim 1 wherein said light extraction means comprises a micro-structured transmissive optical layer.

4. A light therapy device as in claim 1 wherein said light extraction means includes a light extraction layer and a mask.

5. A light therapy device as in claim 1 wherein said light extraction means is customizable to generally conform to the size and shape of the areas to be treated.

6. A light therapy device as in claim 1 wherein a clinician examines the wounds and transfers the shape and size information to said light extraction layer, and modifies said light extraction layer to aid illumination of the wound area, and then attaches the customized light extraction layer to said light guide.

7. A light therapy device as in claim 6 wherein a digital camera is used to customize said light extraction means.

8. A light therapy device as in claim 1 wherein said light guide has apertures to conform said light guide to body structures.

9. A light therapy device as in claim 1 wherein edges or corners of said light guide are modified to conform to local features of said patients' body.

10. A light therapy device as in claim 9 wherein a reflective epoxy or adhesive, such as a silver impregnated epoxy, is applied to said edges.

11. A light therapy device as in claim 1 wherein the device comprises polarization layers to irradiate said localized areas with polarized light.

12. A light therapy device as in claim 1 wherein said light source comprises one or more LEDs, lasers, lamps.

13. A light therapy device as in claim 1 wherein said light source emits light within a spectral range of 400-1500 nm.

14. A light therapy device as in claim 1 wherein said light source emits red or IR light.

15. A light therapy device as in claim 1 wherein said light guide material comprises a non-woven polymer material, such as a polyurethane, elastomer, or acetate.

16. A light therapy device as in claim 1 wherein said light source is temporally modulated within a frequency range encompassing 5 Hz to 5 kHz.

17. A light therapy device as in claim 1 wherein said light coupling means comprises beam shaping optics comprising a tapered light guide, a Fresnel lens, a cylinder lens, a lenslet array, or other appropriate optical components.

18. A light therapy device as in claim 1 wherein said light guide can be removed from said light source and replaced by another light guide.

19. A light therapy device as in claim 1 wherein said light extraction means includes an adaptor for hair.

20. A light therapy device as in claim 1 wherein said light source includes spectral filters.

21. A light therapy device as in claim 1 wherein said light guide is coated with hygienic layers, antibiotic layers, biochemical marker, or anti-tacky outermost surface.

22. A light therapy device as in claim 1 wherein light guide is a sheet, which can be of uniform thickness or wedged, with the thick end towards said light source.

23. A light therapy device as in claim 1 wherein said light guide has a pre-formed or pre-molded shape.

24. A light therapy device as in claim 1 wherein said light guide is shaped like a face.

25. A light therapy device as in claim 1 wherein said light therapy device is modular, and can be disassembled between said light source and said light guide.

26. A light therapy device as in claim 1 wherein said light therapy device provides bio-sensors.

27. A light therapy device for delivering light energy to a portion of a patient's body comprising:

- a) a light source, comprising one or more light emitters for providing input light;
- b) a coupler for directing said input light into a light guide;
- c) a flexible, optically transparent, light guide material, which comprises said light guide;
- d) a light extraction layer which is applied to a surface of said light guide material, such that light exits said light guide; wherein said light extraction layer is customized for shape, size, and position to provide light therapy treatment to one or more localized areas of said patient's body;
- e) a controller, which controls the light dosage relative to intensity, wavelength, modulation frequency, repetition and timing of treatments; and

wherein said light therapy device is modular, and can be disassembled between the light source and the light guide.

28. A light therapy bandage device for delivering light energy to a portion of a patient's body, comprising:

- a) a light source, comprises an array of light emitters for providing input light;

- b) a light coupler for directing said input light into a light guide;

- c) a flexible optically transparent light guide material, which comprises said light guide;

- d) a light extraction layer which is applied to a surface of said light guide material, such that light exits said light guide and is available for a light therapy; wherein said light extraction layer is customized for shape, size, and position to provide light therapy treatment to one or more localized areas of said patient's body;

- e) a controller, which controls the light dosage relative to intensity, wavelength, modulation frequency, repetition and timing of treatments, and other parameters; and

wherein said light therapy device is modular, and can be disassembled between the light source and the light guide.

29. A light therapy bandage device for delivering light energy to a portion of a patient's body, comprising:

- a) a light source, comprises an array of light emitters for providing input light;

- b) a light coupler for directing said input light into a light guide;

- c) a flexible optically transparent light guide material, which comprises said light guide;

- d) a light extraction layer which is applied to a surface of said light guide material, such that light exits said light guide and is available for a light therapy;

- e) a controller, which controls the light dosage relative to intensity, wavelength, modulation frequency, repetition and timing of treatments, and other parameters;

wherein said light extraction layer is pre-assembled onto said light guide; and

wherein said light therapy bandage is applied to said patient's body such that said light extraction layer is positioned to provide light therapy treatment to one or more localized areas of said patient's body.

30. A light therapy bandage device for delivering light energy to a portion of a patient's body, comprising:

- a) a light source, comprises one or more light emitters for providing input light;

- b) a light coupler for directing said input light into a light guide;

- c) a flexible optically transparent light guide material, which comprises said light guide;

- d) a light extraction layer which is a reflective optical diffuser applied to the outer surface of said light guide material, such that light exits said light guide and is available for a light therapy; wherein said light extraction layer is customized for shape, size, and position to provide light therapy treatment to one or more localized areas of said patient's body; and

- e) a control means, which controls the light dosage relative to intensity, wavelength, modulation frequency, repetition and timing of treatments, and other parameters.

31. A light therapy bandage device for delivering light energy to a portion of a patient's body, comprising:

- a) a light source, comprises one or more light emitters for providing input light;
- b) a light coupler for directing said input light into a light guide;
- c) a flexible optically transparent light guide material, which comprises said light guide;
- d) a light extractor which is a transparent micro-structured optical layer applied to a surface of said light guide material, such that light exits said light guide and is available for a light therapy; wherein said light extractor is customized for shape, size, and position to provide light therapy treatment to one or more localized areas of said patient's body; and
- e) a controller, which controls the light dosage relative to intensity, wavelength, modulation frequency, repetition and timing of treatments, and other parameters.

32. A light therapy bandage device for delivering light energy to a portion of a patient's body, comprising:

- a) a light source, comprises one or more light emitters for providing input light;
- b) a light coupler for directing said input light into a light guide;
- c) a flexible optically transparent light guide material, which comprises said light guide;
- d) a light extractor which comprises a micro-structured optical layer applied to a surface of said light guide material, and a mask, such that light exits said light guide and is available for a light therapy; wherein said mask portion of said light extractor is customized for shape, size, and position to provide light therapy treatment to one or more localized areas of said patient's body; and
- e) a controller, which controls the light dosage relative to intensity, wavelength, modulation frequency, repetition and timing of treatments, and other parameters.

33. A method for providing light therapy using a light guide bandage for treatment of one or more areas of a patient, comprising:

- a) examining the treatment areas to determine the condition of the tissues therein;
- b) determining the size and extent of the treatment areas to be treated with light therapy;
- c) customizing a light extraction layer onto a light guide bandage in accordance with the treatment areas;
- d) combining said light guide bandage with a light source and a controller;
- e) assembling the light guide bandage with other bandage elements; and
- f) setting control parameters for the light therapy.

34. A method for providing light therapy using a light guide bandage for treatment of one or more areas of a patient, comprising:

- a) examining the treatment areas to determine the condition of patient tissues;

- b) determining the size and shape of the treatment areas to be treated with light therapy;

- c) providing a light guide bandage, which includes a light source and a controller, with a light extraction layer that generally corresponds to said treatment areas;

- d) assembling said light guide bandage with other bandage elements; and

- e) setting control parameters for the light therapy.

35. A method for providing light therapy as in claim 34, wherein said light guide therapy device delivers repeated controlled treatments over a course of time.

36. A method for providing light therapy as in claim 34, wherein at least part of said light guide bandage is modified or replaced during treatment of said patient.

37. A light therapy device for delivering light energy to a portion of a patient's body, comprising a light source that consisting of one or more light emitters for providing input light to a light guide, wherein said light guide comprises a flexible optically transparent light guide material, wherein said light guide material is provided with a light extraction means that is spatially patterned across one or more portions of said light guide so as to direct light out of said light guide to then provide light therapy treatment to one or more localized areas of said patient's body.

38. A light therapy device for delivering light energy to tissues requiring treatment, comprising a light source consisting of one or more light emitters for providing input light to a flexible transparent optical substrate material, wherein said light therapy device is provided with a light extraction means that is spatially patterned across one or more portions of said device so as to direct light out of said device to then provide light therapy treatment to one or more localized areas of said tissues.

39. A light therapy device for delivering light energy to a portion of a patient's body, comprising:

- a) a light source, comprising one or more light emitters for providing input light for a light guide;
- b) a flexible optically transparent light guide material, which comprises said light guide; and
- c) a controller means, which controls a light dosage emitted from said light therapy device;

wherein said light guide material is provided with a light extraction means that is spatially patterned across one or more portions of said light guide so as to direct light out of said light guide to provide light therapy treatment to one or more localized areas of said patient's body.

40. A light therapy device for delivering light energy to tissues requiring treatment, comprising:

- a) a light source, comprising one or more light emitters for providing input light for a light guide;
- b) a flexible optically transparent light guide material, which comprises said light guide;
- c) a tissue interface layer, which is attached to a surface of said light guide, and which is proximate to tissues; and
- d) a controller means, which controls a light dosage emitted from said light therapy device;

wherein said light guide material is provided with a light extraction means that is spatially patterned across one or more portions of said light guide so as to direct light out of said light guide to provide light therapy treatment to one or more localized areas of said tissues.

41. A light therapy device for delivering light energy to a portion of a patient's body, comprising:

- a) a light source, comprising one or more light emitters;
- b) a light coupling means comprising one or more optical fibers for coupling said input light from said light source into a light guide;
- c) a flexible optically transparent light guide material, which comprises said light guide; and

d) a controller means, which controls a light dosage emitted from said light therapy device;

wherein said light guide material is provided with a light extraction means that is spatially patterned across one or more portions of said light guide so as to direct light out of said light guide to provide light therapy treatment to one or more localized areas of said patient's body.

42. A light therapy device as in claim 1 wherein said light coupling means comprises one or more optical fibers for coupling said input light from said light source into said light guide.

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