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(54) **SKIN TREATMENT APPARATUS AND METHOD**

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(57) **ABSTRACT**

A method of treating skin including the application of a treatment gas to a surface of the skin and simultaneous neuro-muscular stimulation of the skin. The increased blood flow resulting from the neuro-muscular stimulation improves the effectiveness of the treatment gas. The treatment gas applicator used to deliver the oxygen to the wound may further be used to provide repeatable measurements of the size of the wound over time. Other beneficial skin effects, such as hair growth and age retardation, may be achieved by applying treatment gas simultaneously with neuro-muscular stimulation.

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(63) Continuation-in-part of application No. 09/376,916, filed on Aug. 18, 1999, now Pat. No. 6,179,804.

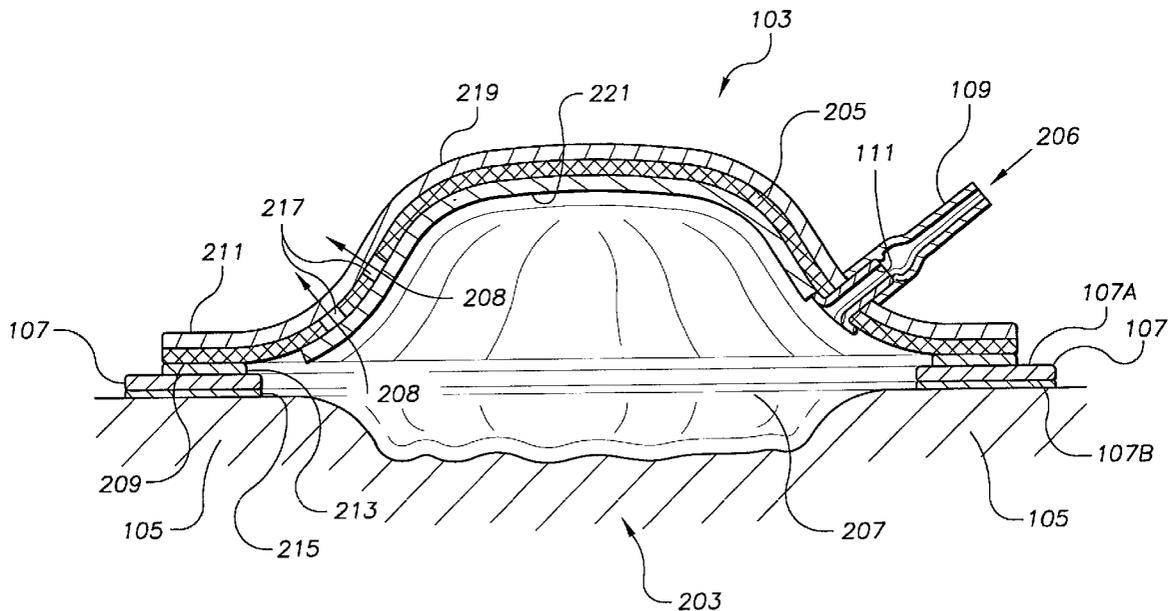


FIG. 2

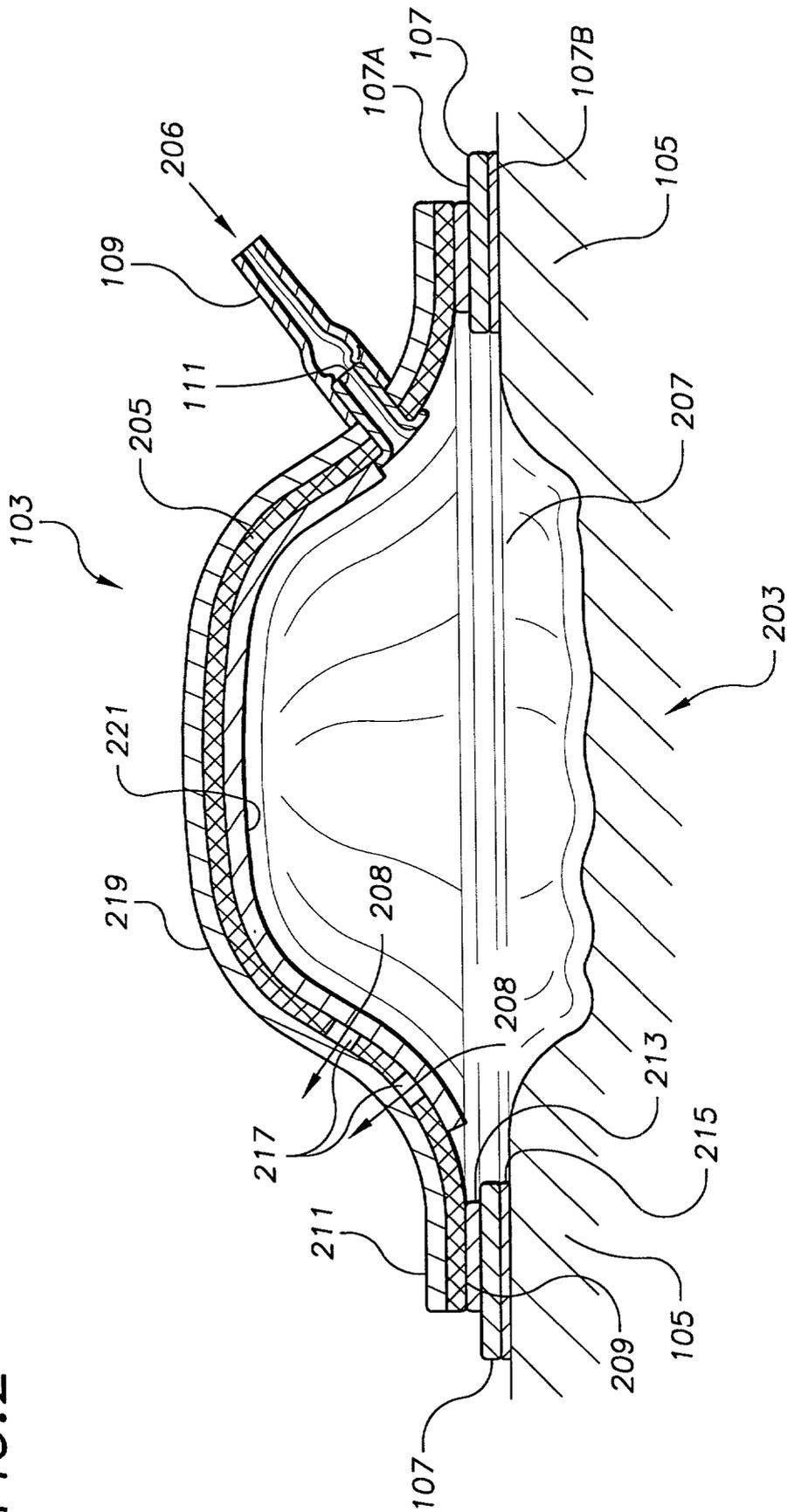


FIG. 3

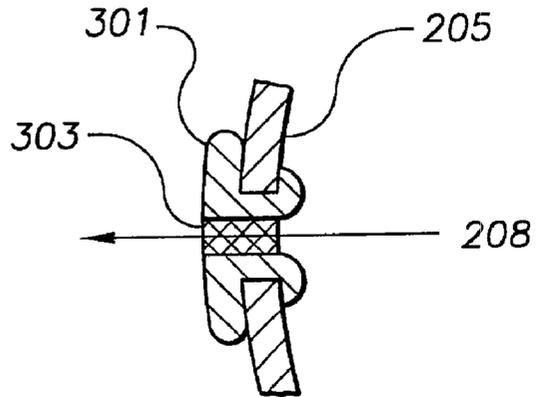
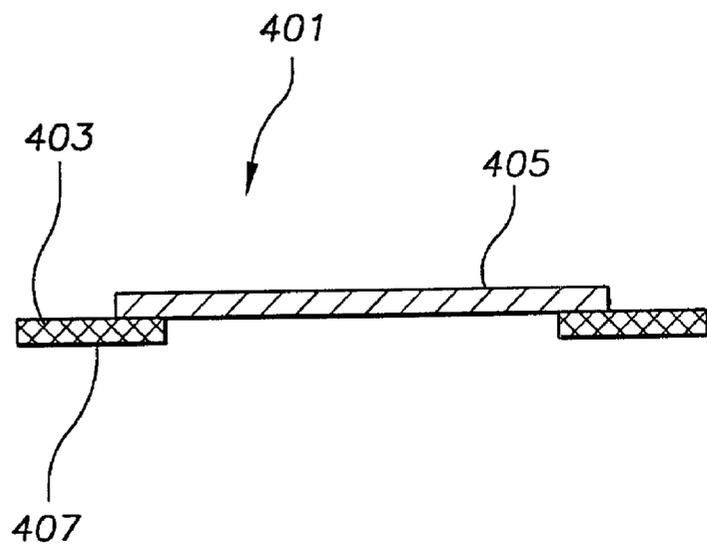


FIG. 4



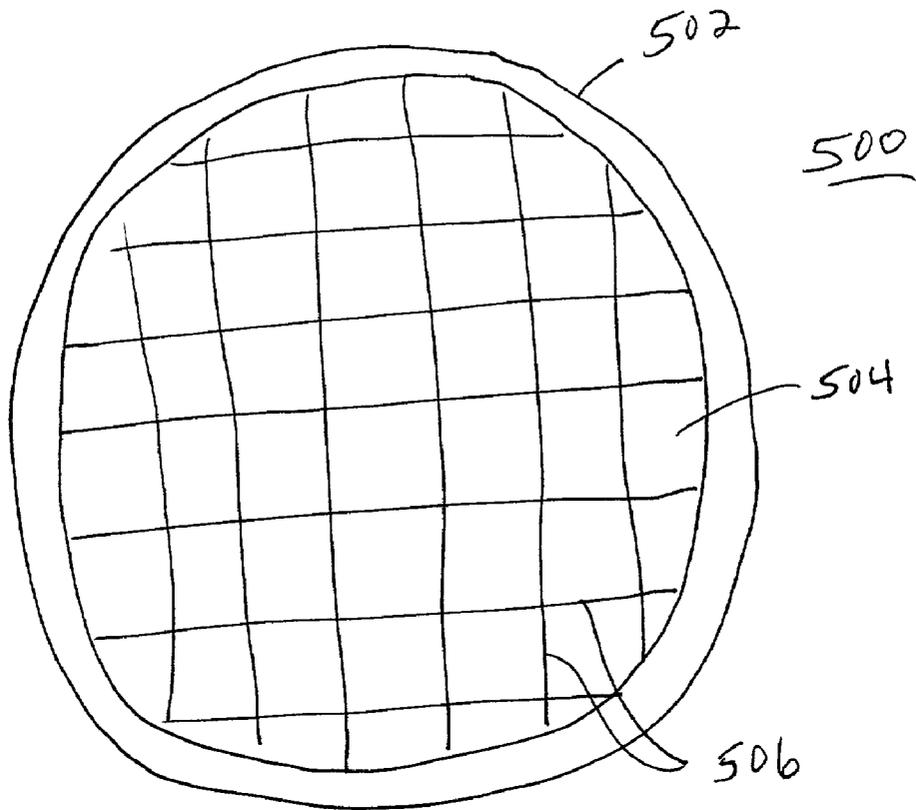


FIG. 5

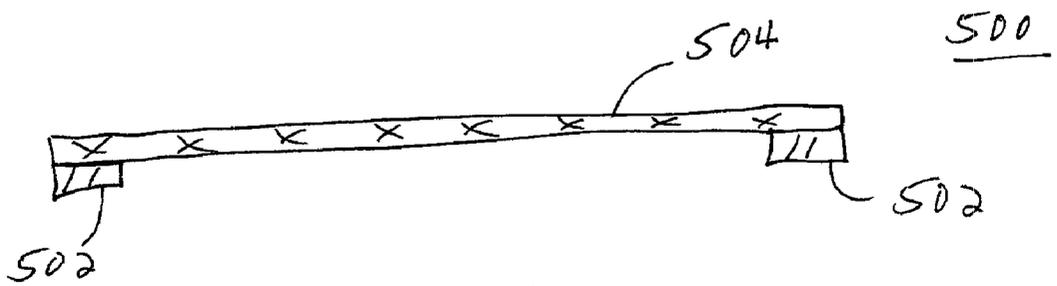


FIG. 6

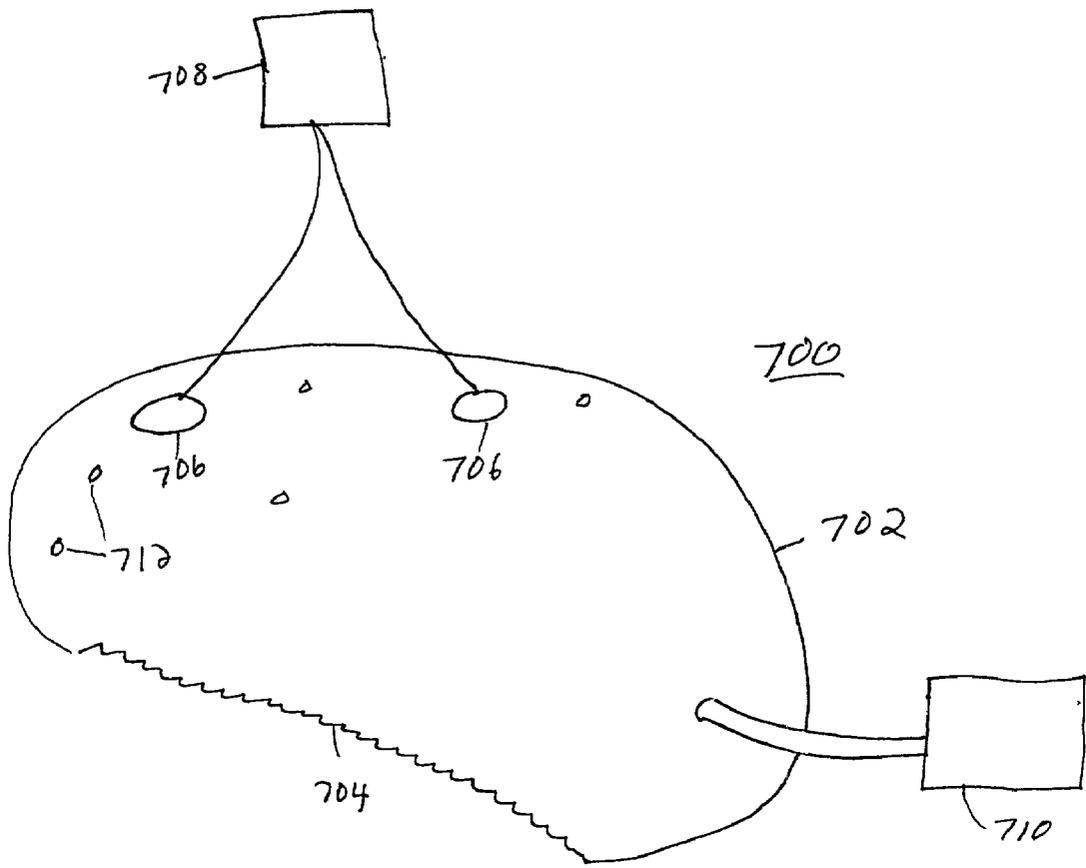


FIG. 7

SKIN TREATMENT APPARATUS AND METHOD

[0001] This application is a continuation-in-part of application Ser. No. 09/376,916 filed on Aug. 18, 1999, and issued as U.S. Pat. No. 6,179,804 on Jan. 30, 2001.

FIELD OF THE INVENTION

[0002] The present invention relates generally to the field of skin care, and, more particularly, to devices and methods for treating skin with a combination of a treatment gas and simultaneous neuro-muscular electrical stimulation.

BACKGROUND OF THE INVENTION

[0003] The use of oxygen to promote healing of wounds, burns, and infections has been documented. Nielsen discloses a device for treatment of wounds by exposure to jets in U.S. Pat. No. 4,608,041. A series of inlet and outlet openings ventilate a space between the device and the wound area. The device is fixed over the area of the wound by means of plaster or tape.

[0004] Loori discloses a collapsible topical hyperbaric apparatus in U.S. Pat. No. 5,154,697. A gas inlet tube introduces oxygen to a shell covering the treated area. An adhesive sealing ring on the bottom of the unit secures the device to the affected area in conjunction with a belt.

[0005] These and other devices, while providing a chamber to apply oxygen to a wound, are difficult to apply, remove and re-apply. The previous devices are sometimes ineffective in particularly difficult-to-heal wounds.

[0006] Neuro-muscular electrical stimulation is the known technique of applying an electrical current to the skin to stimulate the contraction of muscles. One known device for performing neuro-muscular electrical stimulation is the RS-2 Muscle Stimulator provided by RS Medical, Inc. of Vancouver, Wash. Neuro-muscular stimulation is used to stimulate the flow of blood to an area of the skin by repeated contraction and relaxation of nearby muscles.

SUMMARY OF THE INVENTION

[0007] It has been found that the simultaneous application of a treatment gas such as oxygen to the skin while simultaneously providing electrical stimulus to the same area of skin promotes beneficial effects such as wound healing, hair growth, pain relief and generally improved health of the skin tissues. The improved circulation generated by the neuro-muscular stimulation results in the efficient absorption of the oxygen into the body. The method promotes healing of wound areas not responsive to other forms of treatment. Wounds, burns and infections which have been unresponsive to treatment gas application alone are responsive when subjected to both treatment gas and electrical stimulation in adjacent areas.

[0008] A method of treating a wound is described herein as including providing a flow of oxygen to the wound while applying an electrical current to the skin proximate the wound. The oxygen may be provided through a treatment gas applicator adhered to or positioned proximate the skin. The electrical current may be provided through at least one electrode attached to the skin proximate the wound.

[0009] A variety of benefits may be obtained by a method of treating skin including the steps of providing a flow of a treatment gas to a skin surface and applying an electrical current to the skin surface during the step of providing a flow of treatment gas. Such benefits may include retarding the aging of skin, reducing wrinkles, stimulating hair growth and improved healing of wounds. The application of electrical current to the skin increases the circulation of blood near the skin surface, thereby facilitating the absorption of the treatment gas components into the skin and blood stream.

[0010] A device for delivering a treatment gas to a wound may include a seal gasket adhered to the skin with an age-degradable adhesive. The seal gasket may also be used as a base for the repeated application of a grid pattern for photographically measuring the size of a wound over a plurality of time periods. By disposing the grid pattern very close to the wound, the accuracy of the wound measurements is made less sensitive to changes in the height of the camera used to photograph the grid/wound.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] These and other features, aspects and advantages of the present invention will become better understood with regard to the following description, appended claims and accompanying drawings where:

[0012] **FIG. 1** is a perspective drawing of an embodiment of oxygen application apparatus showing an inflatable dome attached to a skin portion surrounding a wound by a seal gasket, and two stimulation electrodes attached to an oxygen supply hose;

[0013] **FIG. 2** is a cross section of the inflatable dome and seal gasket taken along lines 2-2 of **FIG. 1**;

[0014] **FIG. 3** is a detail cross section of a vent installed in the membrane of the inflatable dome of the apparatus; and

[0015] **FIG. 4** is a cross section drawing of a dressing cover used in conjunction with the seal gasket of **FIG. 1**.

[0016] **FIG. 5** is a top view of a wound measuring device that may be used with the apparatus of **FIG. 1**.

[0017] **FIG. 6** is a side sectional view of the wound measuring device of **FIG. 5**.

[0018] **FIG. 7** is a device for applying treatment gas and neuromuscular stimulation to the scalp.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0019] **FIG. 1** is a perspective drawing of treatment apparatus **101** covering a wound area (**203** of **FIG. 2**). The apparatus consists of an inflatable dome portion **103** attached to surrounding skin portion **105** by seal gasket **107**. Oxygen supply hose **109** supplies oxygen to inflatable dome **103** through fitting or nozzle **111**. Gas vents **113** vent gasses inside dome **103** to atmosphere. Tab **115** promotes removal of dome portion **103** from seal gasket **107**.

[0020] Neuro-muscular stimulation electrodes such as electrode patches **117** provide electrical connections to surrounding skin portion **105A** to promote blood supply to the wound area and further promote healing. A power supply **118** supplies electric current to electrode patch **117** through

plugs **119** and current carrying conductors or wires **121**. Plugs **119** are attached to oxygen supply hose **109** by adhesives, welding, or mechanical connectors. Alternatively, plugs **119** are connected to dome portion **103**. A contact adhesive attached to the bottom **117A** of electrode patches **117** attaches the patches to surrounding skin portion **105A**. The electrodes **117** may be integrated into the seal gasket assembly **107**.

[**0021**] **FIG. 2** is a cross section drawing of inflatable dome portion **103** taken along lines **2-2** of **FIG. 1**. Membrane **205** is a flexible gas barrier providing the structure of dome portion **103** when inflated by a gas such as oxygen, air, an inert gas, nitrogen or other gas appropriate for a specific treatment. In the preferred embodiment, membrane **205** is made of a polymeric sheet or film such as polyolefin film. Other materials include PVC, fluoropolymers, and natural and synthetic rubber sheets and films. In alternative embodiments, membrane **205** is a rigid or semi-rigid material such as plastic, formed in a dome shape. Dome peripheral portion **211** may be the peripheral portion of membrane **205**, or it may be a ring-shaped element bonded by adhesives, welding, or fasteners to membrane **205**. In the preferred embodiments, peripheral portion **211** is flexible to provide sealing with seal gasket **107** on uneven portions of the body.

[**0022**] Oxygen supply hose **109** provides oxygen flow **206** to dome interior portion **207** through nozzle **111** inserted through an aperture in membrane **205**. Nozzle **111** is sealed and attached to membrane **205** by adhesives, welding or mechanical fasteners. Gasket **107** seals interior portion **207** of inflatable dome **103** against wound area **203** and surrounding skin portion **105**. In the preferred embodiments, gasket **107** is a ring-shaped flexible member made of a hypoallergenic polymer material such as MicroSkin available from Cymed.

[**0023**] In the preferred embodiments, upper gasket surface **107A** of seal gasket **107** and lower dome seal surface **209** of dome peripheral portion **211** are releasable and re-sealable with respect to each other. In one preferred embodiment, the releasable and re-sealable feature of surfaces **107A** and **209** are provided by a releasable and re-sealable contact adhesive **213** fixed to surface **107A**. Lower dome seal surface **209** is a smooth seal surface to which adhesive **213** releasably seals surface **107A**. Alternatively, adhesive **213** is fixed to lower dome seal surface **209** and adhesive **213** is releasable and re-sealable to surface **107A**. Adhesive **213** may be a pressure sensitive adhesive. The releasable (non-adhesive) surface may be treated to promote release from the releasable adhesive.

[**0024**] A second adhesive **215** attaches seal gasket **107** to surrounding skin portion **105**. Adhesive **213** is a controlled degradable adhesive. In the preferred embodiments, second adhesive **215** is an age-degradable, septic and hypoallergenic adhesive. For the purposes of this disclosure, and age-degradable adhesive is one in which the adhesive capability with the skin decreases with time, either from a direct time dependent process, or a process in which time not an direct, but rather a substantial indirect, factor in the adhesive degradation process. The preferred time periods of degradability are those typical for wound healing, i.e. 3-14 days.

[**0025**] The age-degradable feature may be provided by a hydrocolloid adhesive such as Duoderm, available from ConvaTec. Hydrocolloid-based adhesives maintain adhesion

to the skin until moisture saturation of the hydrocolloid component (typically 3-12 days, depending on hydrocolloid content and skin, wound and environmental conditions). The moisture saturation is age or time dependent in that moisture provided to the hydrocolloid component from the wound portion, the surrounding portion, and atmospheric moisture is cumulative with time.

[**0026**] Utilization of an age-degradable adhesive permits secure fastening of seal gasket **107** to surrounding skin portion **105** for a substantial period of time and sufficient for normal use of the apparatus. Upon age degradation of the adhesive, removal of seal gasket **107** is simple and painless, and completed without damage to the surrounding skin portion. In the preferred embodiments, adhesive **215** is attached to lower surface **107B** of seal gasket **107**.

[**0027**] Restricted discharge of gasses **208** through vents **217** of membrane **205** maintains inflation of interior portion **207** and provides ventilation of gasses discharged from wound area **203**. Vents **217** provide restriction of gas entrapped in interior portion **207**, resulting in a positive pressure in portion **207**. Positive pressure provides the dome shape of membrane **205**. Vents **217** may comprise one or more apertures in membrane **205** such as holes, slots, or perforations. Outer layer **219**, made of a fabric, mesh or perforated material such as a fine polymeric mesh material, prevents introduction of foreign material into vents **217** while allowing escape of gasses exiting the vents. Outer layer **219** may be bonded to membrane **205** by adhesives, welding or fasteners.

[**0028**] **FIG. 3** is a detail drawing of an alternative vent utilizing vent insert **301** attached to membrane **205**. Vent **301** may be made of a polymeric, ceramic or metallic material. A contamination barrier or vent filter **303** allows venting of gasses **208** inside membrane **205** while preventing foreign material from entering vent **301**. Filter **303** may be made of natural or synthetic fiber material, or sintered metal or ceramic materials.

[**0029**] Referring back to **FIG. 2**, an inner layer **221** of a sterile material such as sterile gauze may be bonded to the inner side of membrane **205**. Inner layer **221** may be a natural or synthetic woven, non-woven or mesh material, or, other dressing materials known in the art. Inner layer **221** prevents membrane **205** from sticking to wound area **203**. In the preferred embodiments, inner layer **221** is a breathable material, allowing covering of vents **217** and/or nozzle **111** and yet permitting flow of treatment gas into interior portion **207** and gasses out of interior portion **207**. In other embodiments, cutouts or positioning of inner layer **221** prevents covering of vents **217** and/or nozzle **111**. In one embodiment, dome portion **103** may be a single layer of material, preferably a material that will transmit electromagnetic radiation so that the condition of the underlying wound may be viewed.

[**0030**] In use, seal gasket **107** is attached to surrounding skin portion **105** surrounding wound area **203**, utilizing an adhesive such as age-degradable adhesive **215**. A skin preparation agent may be used to remove contaminants from the skin and provide a thin protective film before application of the age-degradable adhesive. Removal of a peel strip (not shown) exposes releasable adhesive **213** on upper gasket surface **107A**. Releasable adhesive **213** bonds lower dome seal surface **209** of inflatable dome **103** to seal gasket **107**.

Alternatively, this may be a mechanical connection. The user removes peel strips (not shown) from electrode patches **117** and applies to surrounding skin portion **105A**. Surrounding skin portion **105A** is preferably upstream from a blood supply in relation to the wound so that the electrode patches will promote blood supply to wound area **203** upon energizing the patches.

[**0031**] Attachment of plugs **119** to supply hose **119** promotes correct use of the electrode patches since the physical attachment of the patches to the apparatus reminds the user to use and connect them. The placement of plugs **119** and the length of wire **121** promotes placement of the patches near the wound area where they are most effective. In alternative embodiments, additional electrode patches are attached to the apparatus.

[**0032**] Once dome portion **103** and electrode patches **117** are in place, the operator attaches oxygen hose **109** to a supply of oxygen, and stimulator power supply **118** to plugs **119**. The operator then activates the oxygen supply and stimulator power supply **118**.

[**0033**] Upon completion of the therapy, the operator may remove the dome portion by separating lower seal surface **209** of dome portion **103** from upper seal surface **107A**. Tab **115** eases removal of dome portion **103**. Re-sealable adhesive **213** allows removal and replacement of dome portion **103** without damage to the seal. In an alternative embodiment, a peel strip protects upper seal surface **107A** when dome portion **103** is removed. Seal gasket **107** remains in place for several installations and removals of dome portion **103**. Upon removal of dome portion **103**, the wound may be cleaned or dressed or treated as directed.

[**0034**] The wound may be covered by conventional dressings, or a dressing cover as shown in **FIG. 4**. Dressing cover **401** comprises a peripheral portion **403** of flexible material such as a polyolefin ring. A sterile dressing **405** covers the opening in peripheral portion **403**. An adhesive bonds sterile dressing **405** to peripheral portion **403**. Lower dressing seal surface **407** is sealable to upper seal gasket surface **107A**.

[**0035**] In other embodiments, re-sealable adhesive **213** is fixed to dome lower seal surface **209** and lower dressing seal surface **407**. The adhesive may be protected by a peel strip. In still other embodiments, oxygen nozzle **111** position provides physical stimulation of the wound by direct impingement of the gas on the wound area. Several nozzles placed to direct gas on the wound area provide additional stimulation. In still other embodiments, inflatable dome **103** may have other shapes such as rectangular, oval or octagonal.

[**0036**] Accordingly the reader will see that the treatment apparatus for wounds disclosed and claimed provides improved apparatus and methods for treating wounds. The apparatus provides the following additional advantages:

[**0037**] Simultaneous application of a treatment gas such as oxygen to the wound and promotion of circulation afforded by the electrode patches provides an apparent synergistic effect to rapidly heal difficult wounds;

[**0038**] Use of a re-sealable adhesive on the seal gasket allows the inflatable dome to be removed and replaced frequently and easily, and with low cost;

[**0039**] Placement of the electrode patches on the device reminds the user to connect them and place them correctly; and

[**0040**] Use of an age-degradable adhesive on the seal gasket allows simple and painless removal upon completion of use.

[**0041**] Although the description above contains many specifications, these should not be construed as limiting the scope of the invention but as merely providing illustrations of some of the presently preferred embodiments of this invention. For example, mechanical fasteners may attach the dome portion to the seal gasket, a re-sealable adhesive may be used on the lower dome seal surface and the device used without a seal gasket, or the inflatable dome may be made of a rigid material.

[**0042**] The simultaneous application of neuro-muscular stimulation and oxygen is believed to have a generally beneficial effect on the health of the treated skin, including the skin of humans and animals. Skin is an aerobic organism and the improved supply of oxygen provided by the present invention may have many beneficial effects. In one example, a treatment of oxygen and neuro-muscular electrical stimulation was applied periodically to the head of a bald man for between 2-3 hours daily. A standard RS Medical, Inc. Model RS-2 stimulator was used at a setting of Grade 6 to provide the electrical stimulation. In less than about 3 months, new hair began growing from the previously bald skin. It is believed that this effect resulted from the improved blood supply provided by the neuro-muscular stimulation in combination with the augmented oxygen made available to support the chemical reactions necessary to produce hair.

[**0043**] In a further aspect of this invention, treatment apparatus **101** may be used to assist in determining the rate of healing of a wound. In particular, seal gasket **107** may serve as a fixed base upon which a measuring grid may be repeatedly positioned in the same measuring position for periodically measuring the dimensions of a wound over a period of time. It is known that accurate recording of the size of a wound is important for evaluating the effectiveness of the therapy being used on the wound. The prior art technique for sizing a wound involves placing a grid over the lens of a camera, taking a series of pictures of the wound over time, and using the interposed grid pattern to estimate the size of the wound over time. The size of the wound is estimated by counting the number of grid spaces through which the wound is visible in the picture. The accuracy of this process is very sensitive to the distance of the camera lens/grid from the wound when each picture is taken. If the camera is moved away from the wound, the estimated wound size will be inaccurately small. Conversely, if the camera is moved closer to the wound, the estimated wound size will be inaccurately large. To keep the camera/grid a fixed distance from the wound, it is known to use a string attached to the camera to set the position of the camera for each picture. Not only is the accuracy of such a process less than desired, it also give rise to the possibility of the wound site being contaminated by touching the string.

[**0044**] A wound measuring device adapted for use with treatment apparatus **101** is illustrated in **FIGS. 5 and 6**. Wound measuring device **500** includes a frame portion **502** and a window portion **504**. Frame portion **502** is may be round, rectangular or other desired shape for fitting around

a wound or onto a particular portion of a body. Window portion **504** is made of a translucent or preferably transparent material such as a polymeric sheet or film such as polyolefin film. Printed on or otherwise disposed on or in the window portion **504** is a patterns of lines defining a grid pattern **506**. Grid **506** may be opaque or of sufficient color density so that it is visible in contrast to the underlying skin when measuring device **600** is disposed over a wound. Grid **506** may take any shape or size as appropriate, and in one embodiment is a $\frac{1}{4}$ inch square pattern defining a plurality of transparent areas each having an area of approximately 0.0625 square inches. Preferably, frame portion **502** is sized or otherwise deigned to align precisely and repeatedly over the seal gasket **107** of treatment apparatus **101**. In such a measurement position, grid **506** is disposed a fixed distance from the underlying skin and wound. The thickness of a seal gasket **107** may be, for example, from 0.1 inch to 0.5 inch, thus placing the grid very near to, but not touching the underlying wound. Because the grid **506** is positioned a fixed, small distance from the wound each time it is applied for a picture, the accuracy of the measurement of the size of the wound over a period of time becomes relatively insensitive to the distance of the camera lens from the grid/wound. The treatment gas containment portion **103** and the wound measuring device **500** are alternately attached to the seal gasket **107** in order to alternately treat the wound with a treatment gas and to measure the wound. Frame portion **502** may be made from a flexible material such as plastic in order to bend over curved portions of the skin. Frame portion **502** should also have sufficient rigidity to support window portion **504** taut so as to maintain the grid pattern **506** in its predetermined shape. In one embodiment, a bottom surface **508** of the frame portion **502** and a top surface **107A** of the seal gasket **107** may be formed with mating loop and hook type re-sealable fastening material. In an alternative embodiment, measuring device **500** may be used independent of treatment apparatus **101** by simply placing the frame portion **502** against the skin surrounding a wound when no seal gasket **107** is applied to the skin. In this embodiment, the thickness of frame portion **502** will determine the distance of the grid **506** from the skin/wound. With this embodiment, the position of the grid is not held constant in the plane of the skin from picture to picture. However, even in this embodiment, the distance between the wound and the grid **506** is held constant, thereby providing an improved method and apparatus for measuring a wound using photography when compared to the prior art technique.

[0045] FIG. 7 illustrates a device **700** for stimulating the growth of hair on a portion of skin on the head of a patient where hair growth is desired. The device **700** includes a gas containment cap portion **702** adapted for placement on the head of a patient. The containment **702** may be formed of plastic or other appropriate material and may have an elastic band **704** around an opening through which the patient's head is placed. One or more electrodes **706** are attached to the containment **702** in position to make contact with the scalp when the containment **702** is worn as a cap. The electrodes **706** are attached to a neuromuscular stimulation device **708** for applying an electrical current to the scalp. A supply of oxygen or other treatment gas **710** is connected to the containment, with the gas being directed over the scalp and out of the containment **702** through one or more vent openings **712**. In this manner, both the treatment gas and electrical current may be applied simultaneously or in a

predetermined pattern to the scalp in order to stimulate the growth of hair. While the preferred embodiments of the present invention have been shown and described herein, it will be obvious that such embodiments are provided by way of example only. Numerous variations, changes and substitutions will occur to those of skill in the art without departing from the invention herein. Accordingly, it is intended that the invention be limited only by the spirit and scope of the appended claims.

What is claimed is:

1. A method for treating a wound, the method comprising:
 - providing a flow of oxygen to a wound; and
 - applying an electrical current to a skin portion proximate the wound during the step of providing a flow of oxygen.
2. The method of claim 1, further comprising:
 - positioning a treatment gas applicator proximate the wound;
 - placing at least one electrode in contact with the skin portion proximate the wound;
 - providing the flow of oxygen to the treatment gas applicator while providing electrical current to the at least one electrode.
3. A method of treating skin, the method comprising:
 - providing a flow of a treatment gas to a skin surface; and
 - applying an electrical current to the skin surface during the step of providing a flow of treatment gas.
4. The method of claim 3, further comprising:
 - positioning a treatment gas applicator proximate the wound;
 - placing at least one electrode in contact with the skin portion proximate the wound;
 - providing the flow of treatment gas to the treatment gas applicator while providing electrical current to the at least one electrode.
5. A method of stimulating the growth of hair on skin, the method comprising:
 - providing a flow of oxygen to a skin surface;
 - applying an electrical current to the skin surface during the step of providing a flow of oxygen; and
 - periodically repeating the steps of providing a flow of oxygen to the skin surface and applying an electrical current to the skin surface during the step of providing a flow of oxygen.
6. The method of claim 5, further comprising:
 - providing a gas containment adapted to be worn around a portion of skin on the head of a patient where hair growth is desired;
 - attaching at least one electrode to the containment;
 - placing the gas containment on the head of the patient with the at least one electrode in contact with the head of the patient;
 - providing the flow of oxygen to the containment; and
 - applying the electrical current via the at least one electrode.

7. A method of treating a wound, the method comprising:
adhering a seal gasket to skin surrounding a wound;
providing a treatment gas containment removably attachable to the seal gasket;
providing a wound measuring device removably attachable to the seal gasket in a repeatable measuring position; and
attaching alternate ones of the treatment gas containment and the wound measuring device to the seal gasket for alternately treating the wound with a treatment gas and measuring the wound.

8. The method of claim 7, further comprising:
providing a grid pattern on the wound measuring device; and
wherein measuring the wound comprises photographing the wound and the grid pattern.

9. The method of claim 7, further comprising providing an electrical current to the skin surrounding the wound while treating the wound with a treatment gas.

10. A device for treating wounds, the device comprising:
a frame portion having a central opening;
a window portion disposed across the central opening of the frame portion; and
a grid pattern on the window portion.

11. The device of claim 10, further comprising a seal gasket portion adapted to be adhered to skin surrounding a wound, the frame portion adapted for repeated releasable engagement with the seal gasket in a repeatable predetermined position.

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