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(54) **METHOD AND DEVICE FOR SKIN TREATMENT BY MUSCLE STIMULATION AND FEEDBACK THEREOF**

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(71) Applicant: **POLLOGEN LTD.**, Tel Aviv - Yafo (IL)

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(72) Inventors: **Pinchas Shalev**, Herzeliya (IL); **Zion Azar**, Shoham (IL)

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(63) Continuation of application No. 16/907,252, filed on Jun. 21, 2020, which is a continuation of application No. 15/587,487, filed on May 5, 2017, now abandoned, which is a continuation of application No. 13/510,062, filed on May 16, 2012, now abandoned, filed as application No. PCT/IL10/00947 on Nov. 16, 2010.

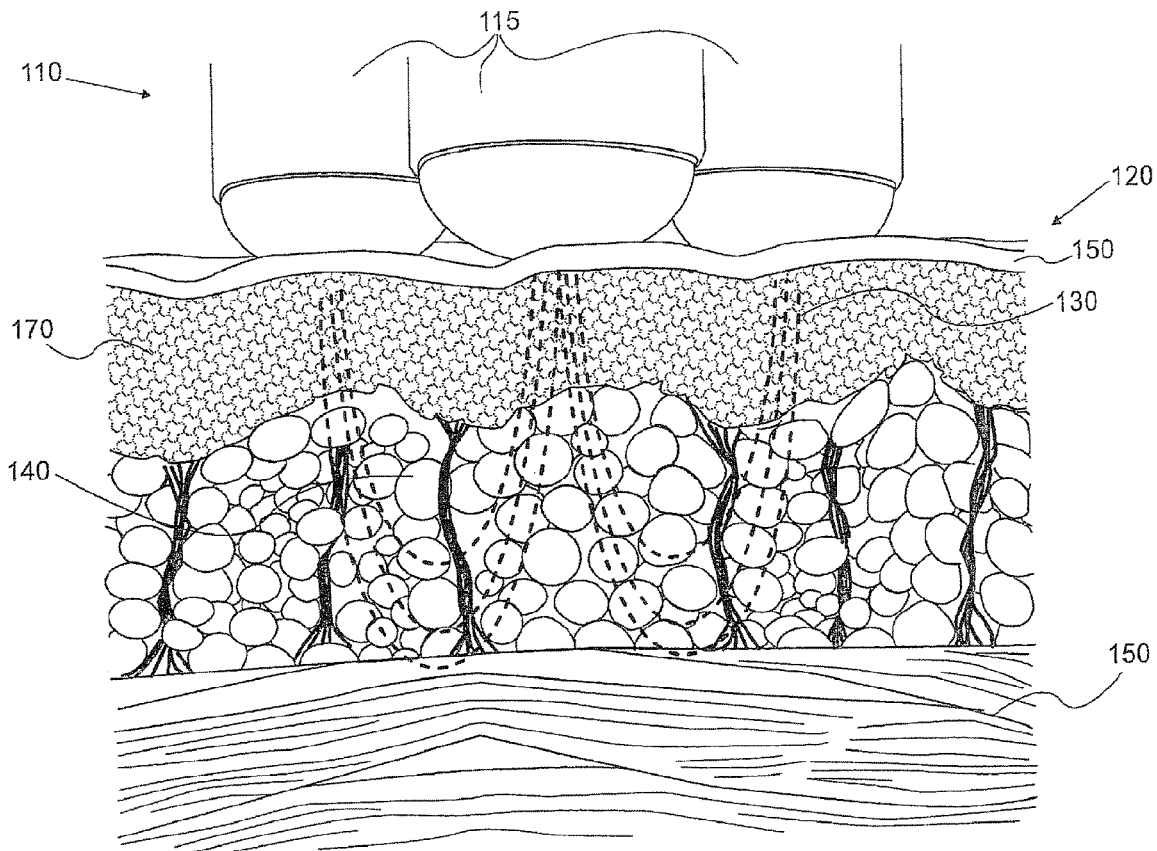
(60) Provisional application No. 61/261,381, filed on Nov. 16, 2009.

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A61H 9/00 (2006.01)

(57) **ABSTRACT**

A method and system for treating skin tissue are presented. A muscle stimulating element is configured to provide muscle stimulation to a muscle layer located below the skin tissue, a handheld applicator configured to be placed in vicinity of the skin tissue to deliver said muscle stimulation from said muscle stimulating element to the muscle layer located below the skin tissue, one or more sensors configured to provide measurements indicative of the muscle stimulation; and a control board configured and operable to activate the handheld applicator according to respective activation patterns; thereby providing one or more treatments to the skin tissue.



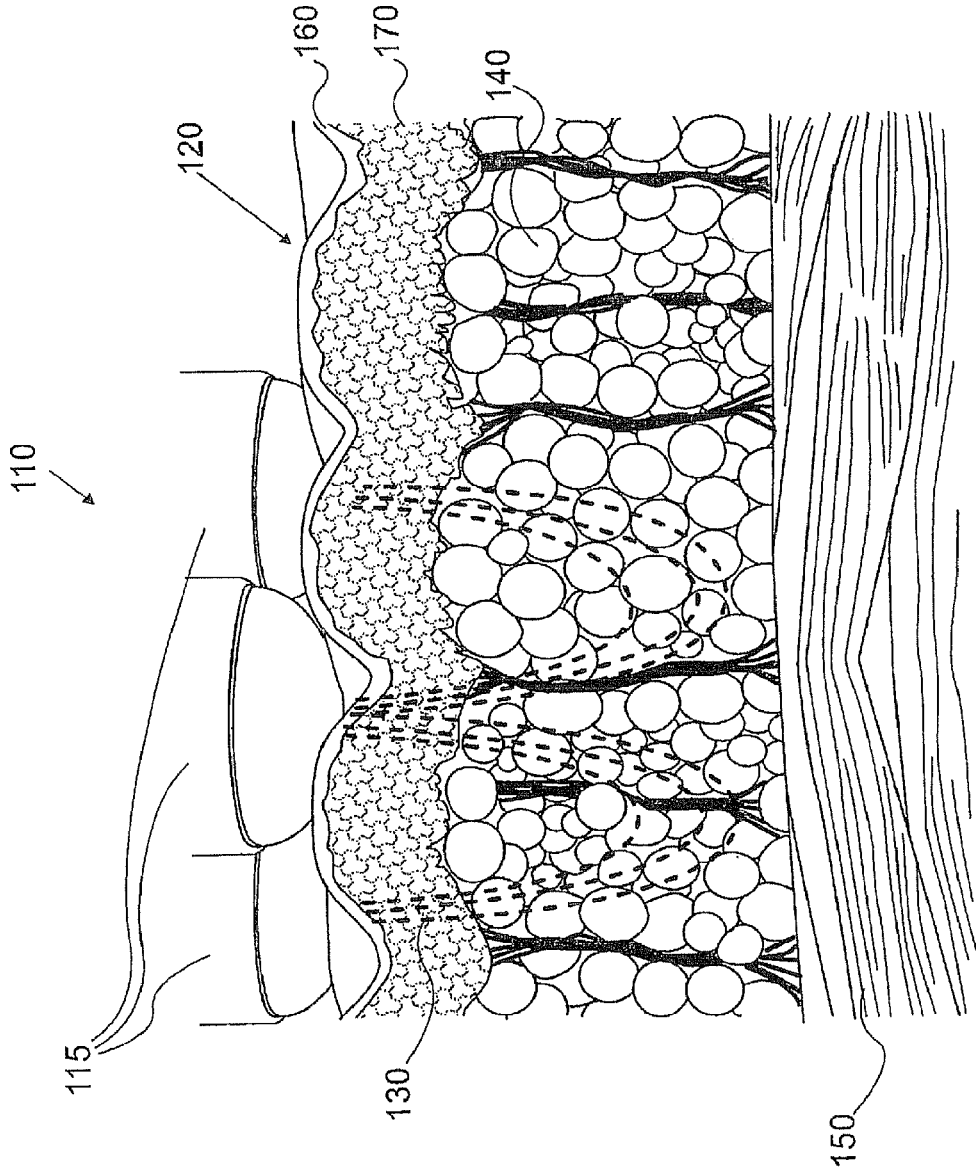


FIG. 1

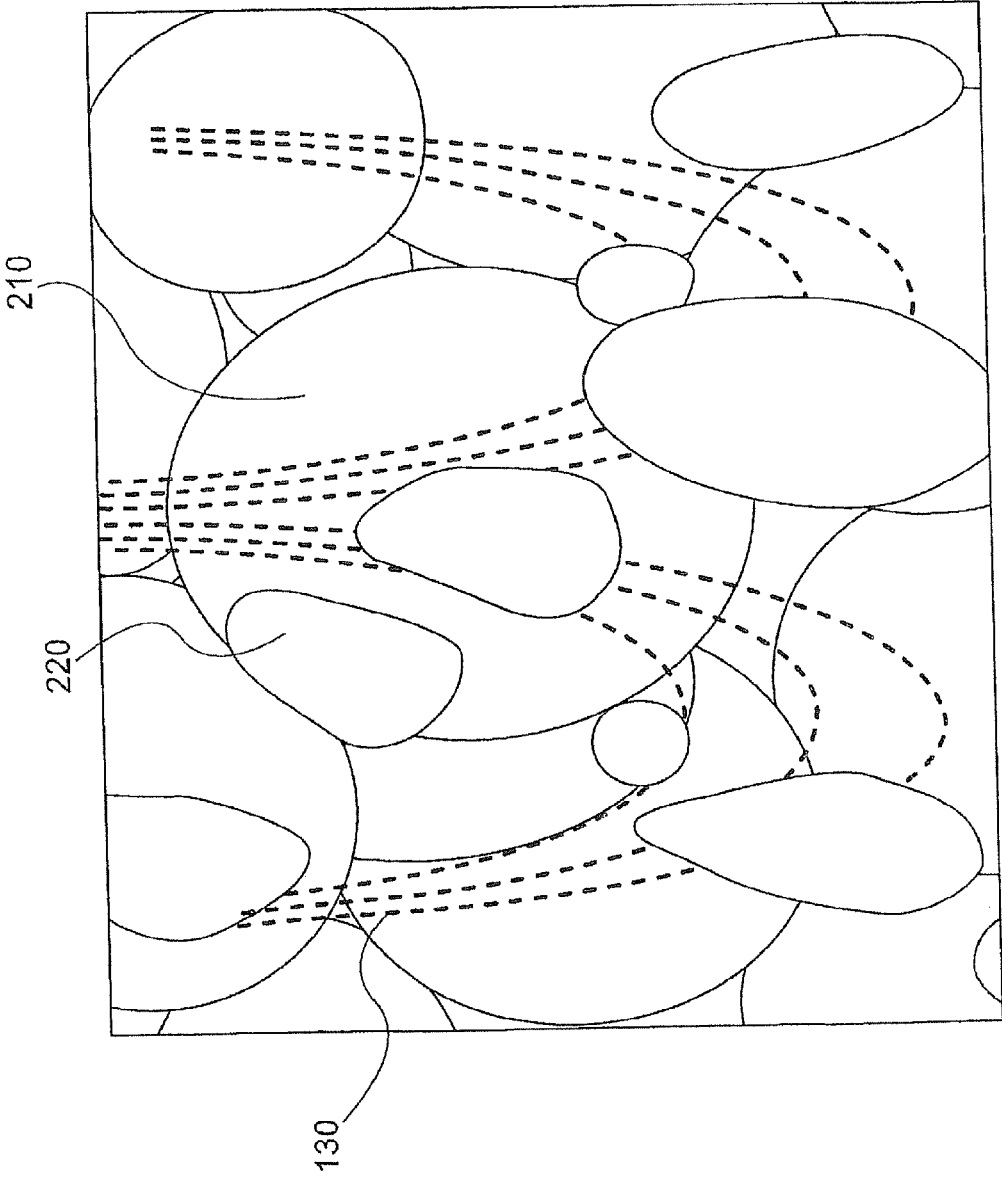


FIG. 2

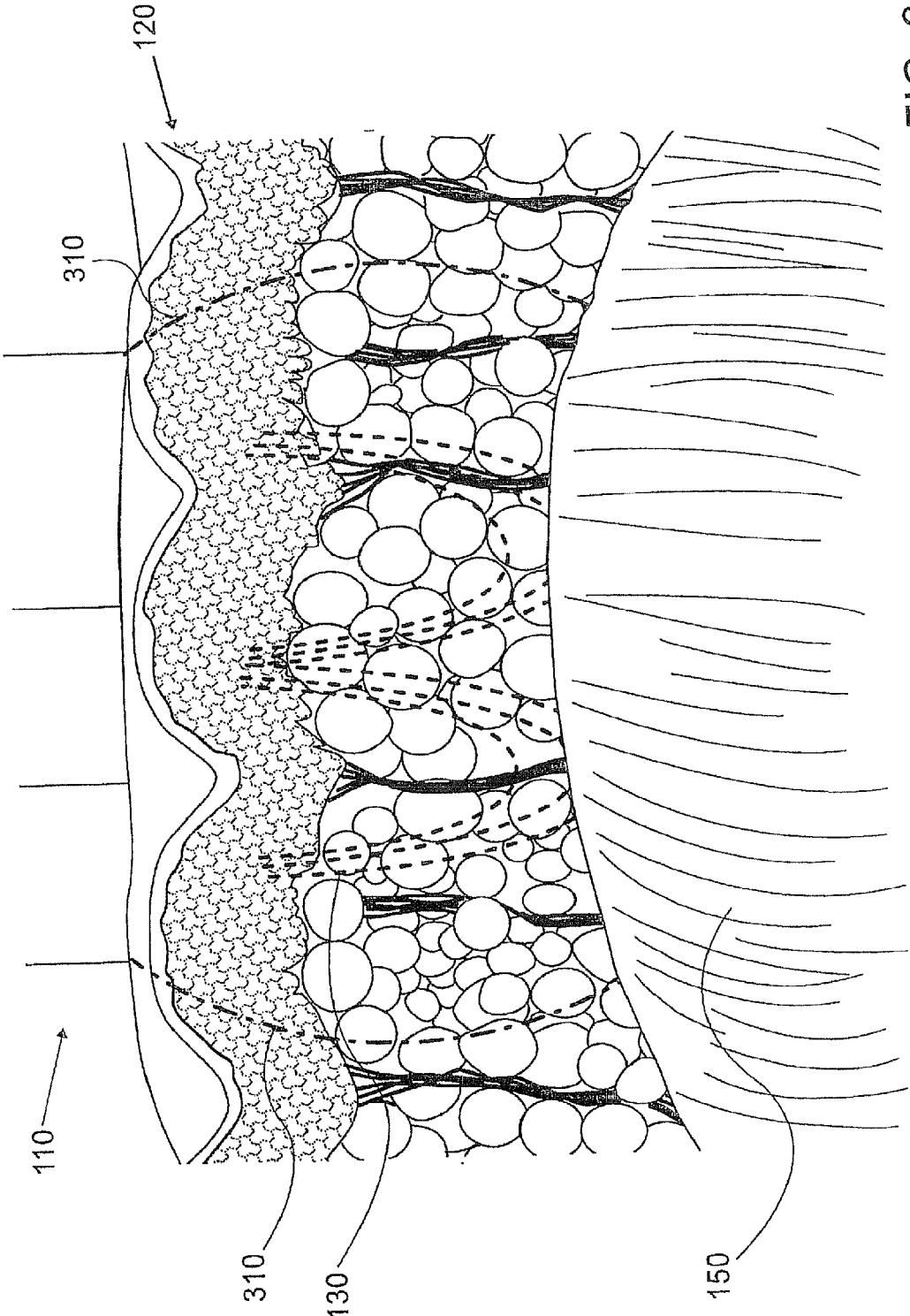


FIG 3

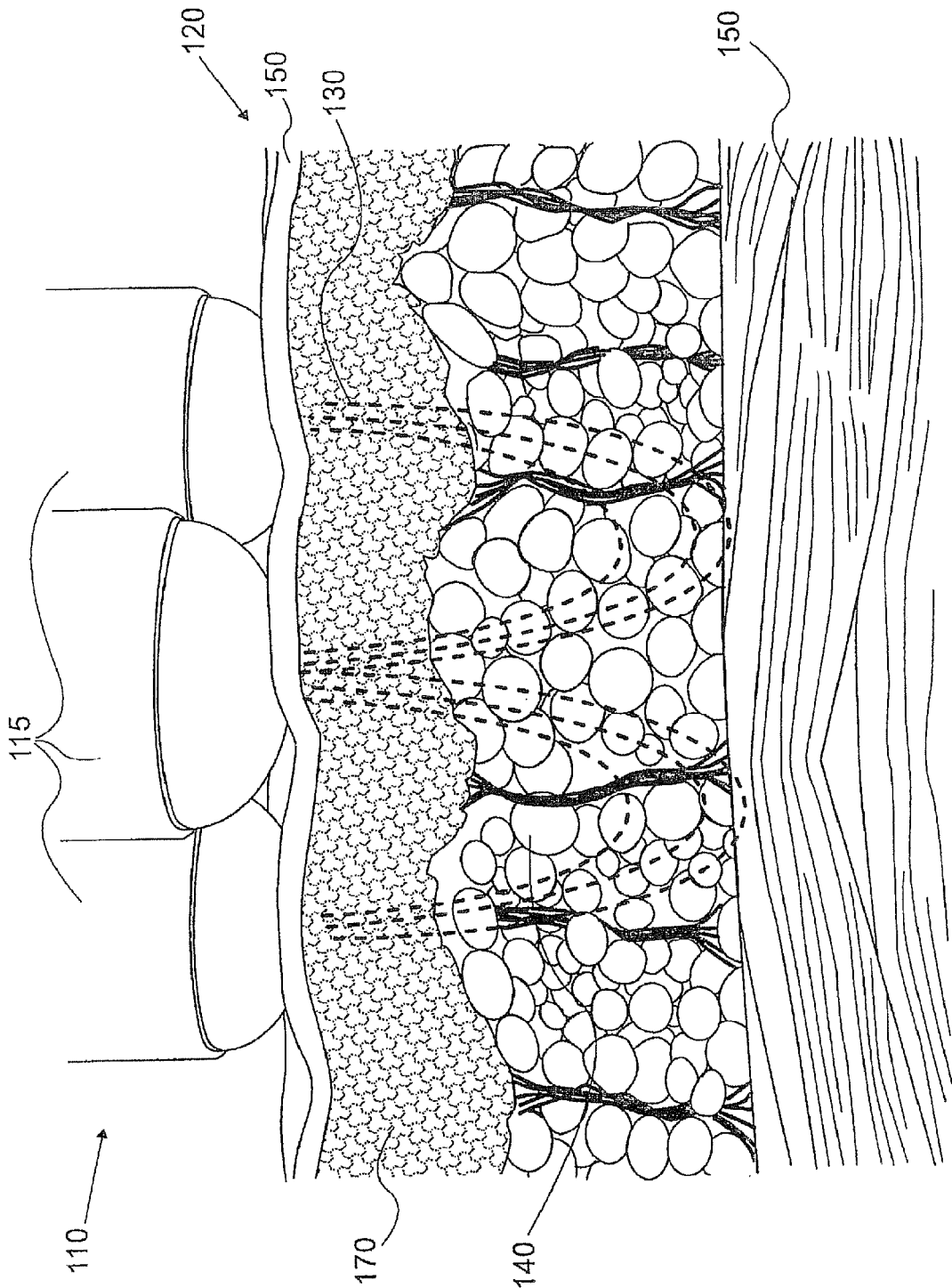


FIG. 4

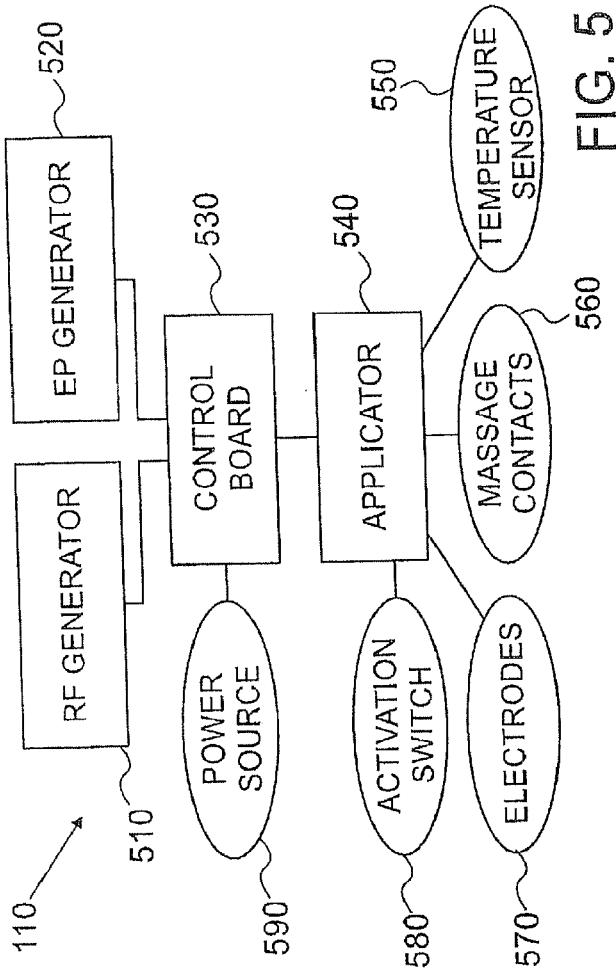


FIG. 5

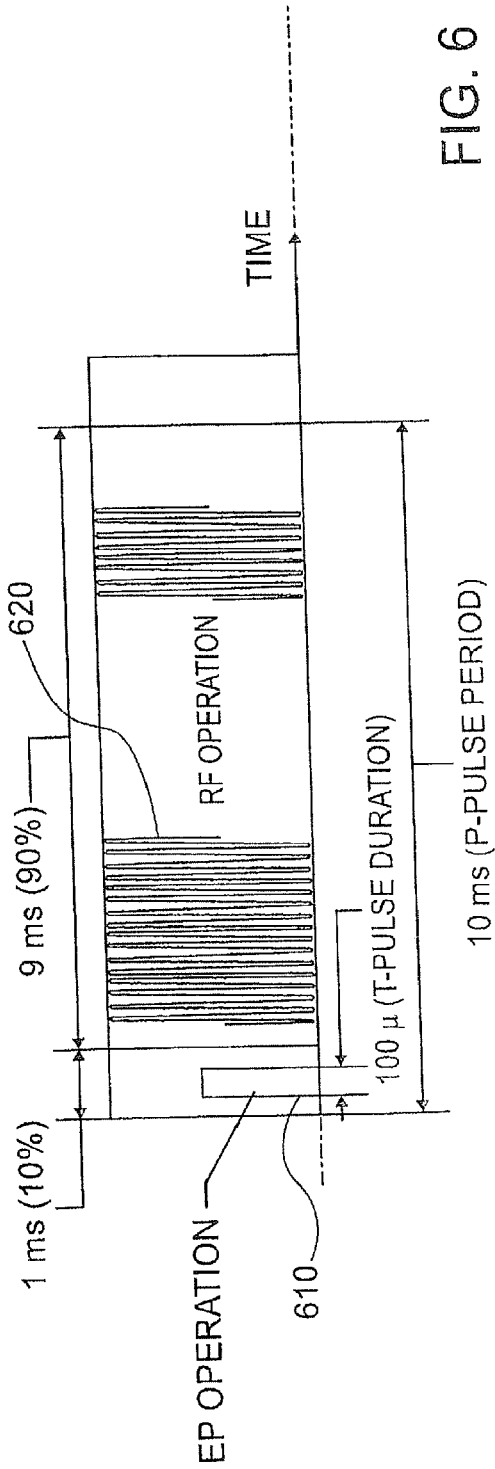


FIG. 6

**METHOD AND DEVICE FOR SKIN
TREATMENT BY MUSCLE STIMULATION
AND FEEDBACK THEREOF**

RELATED APPLICATIONS

[0001] This application is a continuation of and claims priority to U.S. application Ser. No. 16/907,252, filed Jun. 21, 2020, which is a continuation of and claims priority to U.S. application Ser. No. 15/587,487, filed May 5, 2017, now abandoned, which is a continuation of and claims priority to U.S. application Ser. No. 13/510,062, filed May 16, 2012, now abandoned, which is a U.S. National Stage application from and claims priority to PCT Application No. PCT/IL2010/00947, filed Nov. 16, 2010, which claims priority from U.S. provisional application No. 61/261,381 filed on Nov. 16, 2009, all of which disclosures are herein incorporated by reference.

FIELD OF THE INVENTION

[0002] The present invention relates generally to a device and method for treating skin tissue by using a radio frequency (RF) generator combined with muscle stimulation (MS), including electrical muscle stimulation (EMS).

BACKGROUND OF THE INVENTION

[0003] Skin tissue comprises an outer epidermal layer overlaying a dermal layer. The dermal layer is in contact with a subcutaneous adipose layer referred to as fatty tissue. Massaging the skin is known to improve blood circulation in the subcutaneous adipose tissue and help release fat from the cells of the fatty tissue into the surrounding cellular matrix. The fat is then removed by the body's lymphatic system.

[0004] U.S. Pat. No. 5,961,475 to Guitay discloses a massaging device in which negative pressure is applied to the user's skin while massaging. The combined treatment increases the blood circulation in the subcutaneous adipose tissue and breaks connections between adipose cells in the tissue.

[0005] U.S. Pat. No. 6,273,884 to Altshuler et al. discloses simultaneous application of optical energy and negative pressure to the user's skin for treating skin defects.

[0006] There is however a need for improved methods to enhance the release of fat from adipose tissue to increase lymphatic drainage.

SUMMARY OF THE INVENTION

[0007] An aspect of an embodiment of the invention, relates to an apparatus and method for accelerating lymphatic drainage. The method includes applying RF energy to heat the adipose layer. Additionally the method includes massaging the skin above the area that is heated by RF energy. Further additionally the method includes electrical muscle stimulation (EMS) to contract the muscles below the heated area thus providing pressure on the adipose layer from below. The apparatus is designed to apply the above three methods either separately or any combination of them simultaneously: namely, massaging the skin from above, causing electrical muscle stimulation from below, and heating the fatty tissue with RF radiation.

[0008] In an exemplary embodiment of the invention, the RF energy is provided by a high frequency AC current, and the EMS energy is provided by a low current DC pulse signal. Optionally, the electrical energies (RF and EMS) are

provided by a mono-polar configuration wherein the apparatus applied to the user's skin is provided with a first electrode of one polarity, and a second electrode of the opposite polarity is attached to the user or held by the user to form a closed circuit. Alternatively, the electrical energy may be provided by a bi-polar configuration wherein the apparatus applied to the user's skin includes two electrodes to form a closed circuit without attaching electrodes external to the apparatus to the body of the user. In some embodiments of the invention, the apparatus uses a multi-pole configuration wherein the apparatus includes multiple electrodes of both poles of the circuit.

[0009] In some embodiments of the invention, some electrodes provide RF energy and other electrodes provide EMS energy. Alternatively, the same electrodes are designed to synchronize the pulses and deliver any of the two currents by control of the apparatus.

[0010] In an exemplary embodiment of the invention, the skin massage may be performed by applying positive pressure, for example in the form of vibrations, pushing, pounding and the like. Alternatively or additionally, the skin massage may be performed by applying negative pressure, for example using a vacuum or suction and the like. Optionally, the element of the apparatus applying the pressure may be heated or cooled while applying the pressure.

[0011] In an exemplary embodiment of the invention, when the apparatus is placed in contact with the user's skin an electric circuit is formed and electric current flows automatically from the electrode to the user. Optionally, the RF energy may be coordinated with the EMS energy so that both will be activated simultaneously or separately by control of the apparatus.

[0012] In an exemplary embodiment of the invention, the frequency of the RF energy is selected to heat the user's skin mainly at the adipose layer positioned under the apparatus. The EMS flow is designed to contract the muscles below the adipose layer causing pressure on the fatty cells from below.

[0013] In some embodiments of the invention, parameters related to the RF energy are user selectable, for example signal intensity, frequency, duration and the like, to optimize usage of the apparatus for different users or different positions on the body of the user. Optionally, the parameters related to the EMS energy can be modified to fit the needs of the user, for example by selecting intensity, frequency, duration and the like.

[0014] In some embodiments of the invention, parameters related to massaging the skin are user selectable, for example the vibration rate, duration of vibrations, intensity, temperature of the massaging element and the like. Alternatively, the massaging may be performed by manually pressing the apparatus on the user's skin and moving it over a designated area.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] The present invention will be understood and better appreciated from the following detailed description taken in conjunction with the drawings. Identical structures, elements or parts, which appear in more than one figure, are generally labeled with the same or similar number in all the figures in which they appear, wherein:

[0016] FIG. 1 is a schematic illustration of a fat reduction device deployed upon a user's skin, according to an exemplary embodiment of the invention;

[0017] FIG. 2 is a schematic illustration of liquefied fat exiting from fat cells into the extra cellular matrix responsive to the use of the fat reduction device, according to an exemplary embodiment of the invention;

[0018] FIG. 3 is a schematic illustration of a fat reduction device applying an electrical current to stimulate a user's muscles, according to an exemplary embodiment of the invention;

[0019] FIG. 4 is a schematic illustration of a fat reduction device and the user's skin following use of the fat reduction device, according to an exemplary embodiment of the invention;

[0020] FIG. 5 is a schematic block diagram of the elements of a fat reduction device, according to an exemplary embodiment of the invention; and

[0021] FIG. 6 is a schematic illustration of an RF signal combined with an EMS signal, according to an exemplary embodiment of the invention.

DETAILED DESCRIPTION

[0022] FIG. 1 is a schematic illustration of a fat reduction device 110 deployed upon a user's skin 120, according to an exemplary embodiment of the invention. The skin 120 includes an upper epidermal layer 160, a lower dermal layer 170, and an adipose layer 140 (fat tissue layer). Muscles 150 are located below the adipose layer 140.

[0023] In an exemplary embodiment of the invention, fat reduction device 110 includes one or more heads 115 that serve as massage contacts and optionally also as electrodes for applying electrical energy. Optionally, fat reduction device 110 is adapted to perform at least three actions:

[0024] 1. Massaging the outer layer of skin 120;

[0025] 2. Heating the adipose layer 140 using RF energy 130 (e.g., with a frequency between 0.5 MHz to 2 MHz);

[0026] 3. Stimulating the muscles 150 below the adipose layer 140 with an electrical muscle stimulation (EMS) signal (e.g., with pulses of DC current between +/-500 ma).

[0027] In an exemplary embodiment of the invention, fat reduction device 110 is deployed upon the user's skin 120 and applies pressure with heads 115 to massage the skin 120. Optionally the pressure may be in the form of vibrations, pushing, pounding, or other tactile forms. Alternatively, or additionally, the massaging may be in a negative form, for example by applying a vacuum or suction or similar form. FIG. 1 demonstrates how the skin 120 takes an uneven form due to the physical pressure exerted upon it. In some embodiments of the invention, fat reduction device 110 includes an element that applies the pressure, for example a motor a piezoelectric chip or other devices known in the art. Alternatively, the pressure may be exerted by manually pressing heads 115 against the user's skin.

[0028] In an exemplary embodiment of the invention, the RF energy 130 is delivered through the skin to the adipose layer 140. The RF energy 130 accelerates natural fat cell metabolism causing the release of liquefied fat from the cells into the extra cellular matrix. Additionally, the RF energy 130 heats collagen fibers and stimulates fibroblast metabolism resulting in tightening of the skin 120 and an increase in new collagen production.

[0029] Optionally, the physical pressure loosens the ties between the fat cells and together with the heating from the RF energy 130 accelerates release of liquefied fat from the fat cells. The heating and massaging also increase blood

flow thus providing more nourishment to the area and removing dead cells and other impurities at all increased rate.

[0030] FIG. 2 is a schematic illustration of liquefied fat 220 exiting from fat cells 210 into the extra cellular matrix responsive to the use of the fat reduction device 110, according to an exemplary embodiment of the invention. In an exemplary embodiment of the invention, the RF energy is set to heat the fat cells 210 to a level wherein the temperature on the surface of the skin does not exceed 40° C.-45° C. to prevent skin damage. Optionally, higher temperature ranges may be possible for short durations.

[0031] FIG. 3 is a schematic illustration of fat reduction device 110 applying an electrical current 310 to stimulate the user's muscles 150, according to an exemplary embodiment of the invention. In an exemplary embodiment of the invention, electrical current 310 from the electrical muscle stimulation (EMS) pulse causes the muscles 150 to contract below the adipose layer 140, which causes a dual force to be applied to the fat cells 210. From above the adipose layer 140 is pressured physically by fat reduction device 110 and from below the EMS signals cause the muscles 150 to exert pressure on adipose layer 140. In some embodiments of the invention, the RF energy 130 and/or the EMS pulse may be activated by an activation switch on fat reduction device 110. Alternatively, they may be activated upon contact with the user's skin, for example by closing a circuit through the user's skin or by applying pressure on the head of fat reduction device 110.

[0032] FIG. 4 is a schematic illustration of fat reduction device 110 and the user's skin 120 following use of fat reduction device 110, according to an exemplary embodiment of the invention. Optionally, after applying fat reduction device 110 the distance between the muscles 150 and the epidermal layer 160 is reduced due to the exit of liquefied fat from the fat cells 210 of the adipose layer 140. Additionally, the epidermal layer 160 becomes smoother due to the tightening resulting from the collagen production as described above.

[0033] FIG. 5 is a schematic block diagram of the elements of fat reduction device 110, according to an exemplary embodiment of the invention. In an exemplary embodiment of the invention, fat reduction device 110 includes an RF generator 510 to provide an AC current in the form of a radio frequency (RF) electrical pulse for heating the user's skin 120. Optionally the AC signal is a low current signal, for example of about 1-10 ma, 24 VAC with a frequency between 0.5 MHz-2 MHz to prevent damage to the user's skin 120. In an exemplary embodiment of the invention, fat reduction device 110 also includes an electric pulse (EP) generator 520 that provides low current DC pulse signals, for example between +500 ma to -500 ma to cause the muscles 150 to expand and contract. In an exemplary embodiment of the invention, fat reduction device 110 includes a control board 530 that determines the actions of the device. Optionally, control board 530 may be a general purpose computer or a dedicated circuit. Control board 530 controls the duration, intensity, frequency and any other parameters of the electric pulses of the electrical current 310 for stimulating the muscles 150, and the RF energy 130 for heating the adipose layer 140. Additionally, the control board 530 determines the timing for applying the EP signal and the RF signal. In some embodiments of the invention,

control board **530** includes a CPU, a memory, and input/output devices, for example a keypad and a screen.

[0034] In some embodiments of the invention, the control board accepts measurements from various sensors and controls fat reduction device **110** responsive to the measurements, for example temperature readings from a temperature sensor **550**, which may include a thermistor or thermocouple monitoring the skin temperature. Optionally, the sensors may be placed in head **115**, for example adjacent to the electrodes.

[0035] In an exemplary embodiment of the invention, fat reduction device **110** includes an applicator **540** for applying the actions described above. In an exemplary embodiment of the invention, fat reduction device **110** is fed from a power source **590**. Optionally, the power source **590** may be an internal power source, for example a battery. Alternatively, power source **590** may be an external power source, for example by connecting a power cable to a standard household power outlet.

[0036] In an exemplary embodiment of the invention, applicator **540** includes one or more heads **115** that serve as massage contacts **560**, and electrodes **570**. In some embodiments of the invention, the applicator may include an activation switch **580** to turn on and off fat reduction device **110**. Optionally, activation switch **580** may be independently controlled by the user or may be automatically controlled, for example by placing fat reduction device **110** in contact with the user's body so that an electric circuit is formed or by pressing the fat reduction device **110** against the user's body causing the activation switch **580** to be depressed.

[0037] In some embodiments of the invention, fat reduction device **110** may use a mono-polar configuration wherein one pole of the circuit is represented by one or more electrodes on heads **115** and placed in contact with the user's skin. Optionally, the opposite pole is placed as a patch on the user's body or on a handle for grasping fat reduction device **110**, to form a closed circuit. Alternatively, fat reduction device **110** may use a bi-polar configuration wherein both poles are represented by electrodes on the head **115** of the device, and no external electrodes are required. In some embodiments of the invention, a multi-polar configuration is used, with multiple electrodes wherein some of the electrodes on head **115** represent a first pole of the circuit and some represent the opposite pole. Optionally, the polarity of the electrodes may be controlled by control board **530**, and their polarity may alternate during use of fat reduction device **110**.

[0038] In some embodiments of the invention, some of the electrodes deliver RF energy **130** and some deliver electrical current **310**. Alternatively, the same electrodes may deliver RF energy **130** and electrical current **310** intermittently. In some embodiments of the invention, electrical current **310** from the electrical muscle stimulation (EMS) signal is applied independent of the RF energy signal **130**.

[0039] In an exemplary embodiment of the invention, control **530** controls the actions of the massage contacts **560**. Optionally, the massage contacts **560** may include a motor, a piezoelectric element, a suction, a vacuum or other devices to massage the user's skin either positively or negatively. In an exemplary embodiment of the invention, the action of massage contacts **560** are synchronized with the electrical muscle stimulation (EMS) so that the adipose layer will be pressurized on both sides simultaneously. Alternatively, each function may act independently. In some embodiments

of the invention, the massage is applied manually by pressing massage contacts **560** against the user's skin **120**, and optionally moving them back and forth across the user's skin **120**. Optionally, massage contacts **560** may be made from a soft material or hard material selected for providing a comfortable feeling to the user while massaging the user's skin **120**. In some embodiments of the invention, the massage contacts **560** may include a heater to warm the contacts to enhance comfort and/or effectiveness of the massage.

[0040] FIG. 6 is a schematic illustration of an RF energy signal synchronized with an EMS signal, according to an exemplary embodiment of the invention. In an exemplary embodiment of the invention, an electric pulse **610** of for example **100** micro-seconds is provided during an interval of **1** ms after which a RF energy signal **620** is applied, for example for a duration of **9** ms. This sequence is applied repetitively while the fat reduction device is activated. Optionally, other duration may be used, for example the duration of electric pulse **610** may be longer than the duration of RF radiation signal **620** or vice versa.

[0041] It should be appreciated that the above-described methods and apparatus may be varied in many ways, including omitting or adding steps, changing the order of steps and the type of devices used. It should be appreciated that different features may be combined in different ways. In particular, not all the features shown above in a particular embodiment are necessary in every embodiment of the invention. Further combinations of the above features are also considered to be within the scope of some embodiments of the invention.

[0042] It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather the scope of the present invention is defined only by the claims, which follow.

1. A method of treating a person's skin tissue, comprising: providing a skin tissue treatment apparatus comprising:
 - a muscle stimulating element configured to provide muscle stimulation to a muscle layer located below the skin tissue,
 - a handheld applicator configured to be placed in vicinity of the skin tissue to deliver said muscle stimulation from said muscle stimulating element to the muscle layer located below the skin tissue,
 - one or more sensors configured to provide measurements indicative of the muscle stimulation;
 - and
 - providing a control board configured and operable to activate the handheld applicator according to respective activation patterns; thereby providing one or more treatments to the skin tissue.
2. The method according to claim 1, wherein said control board is configured to receive said measurements from the sensors and to determine parameters of the activation patterns based on the one or more sensors measurements.
3. The method according to claim 1, wherein said predetermined activation patterns provide a skin tissue treatment comprising one or more of the following: skin tightening, reducing distance between epidermis and the muscle layer.
4. The method according to claim 1, wherein said apparatus further comprising at least one heat generating element configured to modify temperature of the skin tissue.

5. The method according to claim 4, wherein one of said at least one heat generating element is configured to perform at least one of the following:

- decrease the temperature of the skin tissue, and
- increase the temperature of the skin tissue, optionally to a level of no more than 45 degrees C.

6. The method according to claim 4, wherein said handheld applicator comprises one or more heads configured to contact the skin tissue during said one or more treatments, wherein said one or more heads comprise one or more electrodes in electrical communication with said at least one heat generating element and/or said muscle stimulating element.

7. The method according to claim 6, wherein at least one electrode of the one or more electrodes is in electrical communication with said at least one heat generating element and said muscle stimulating element.

8. The method according to claim 6, wherein said muscle stimulating element comprises an electrical pulse generator configured to provide electrical muscle stimulation signal (EMS) to the muscles in the muscle layer located below the skin tissue, and wherein said one or more electrodes are configured to deliver the electrical muscle stimulation signal to the skin tissue.

9. The method according to claim 6, wherein said heat generating element comprises a radio frequency (RF) generator configured to generate RF energy to increase the temperature of the skin tissue, and wherein said one or more electrodes are configured to deliver the RF energy to the skin tissue.

10. The method according to claim 9, wherein said activation pattern of said EMS and said RF energy is user selectable and includes one or more of the following: signal intensity, frequency, and duration, thereby enabling to optimize the one or more treatments for different users or different positions on body of the treated person.

11. The method according to claim 4, wherein said control board is configured and operable to activate said at least one heat generating element and said muscle stimulating element in one or more of the following activation patterns: sequentially, intermittently and simultaneously.

12. A system of treating a person's skin tissue, comprising:

- a skin tissue treatment apparatus comprising:
 - a muscle stimulating element configured to provide muscle stimulation to a muscle layer located below the skin tissue,
 - a handheld applicator configured to be placed in vicinity of the skin tissue to deliver said muscle stimulation from said muscle stimulating element to the muscle layer located below the skin tissue,
 - one or more sensors configured to provide measurements indicative of the muscle stimulation;
- and
- a control board configured and operable to activate the handheld applicator according to respective activation patterns; thereby providing one or more treatments to the skin tissue.

13. The system according to claim 12, wherein said control board is configured to receive said measurements from the sensors and to determine parameters of the activation patterns based on the one or more sensors measurements.

14. The system according to claim 12, wherein said predetermined activation patterns provide a skin tissue treatment comprising one or more of the following: skin tightening, reducing distance between epidermis and the muscle layer.

15. The system according to claim 12, wherein said apparatus further comprising at least one heat generating element configured to modify temperature of the skin tissue.

16. The system according to claim 15, wherein one of said at least one heat generating element is configured to perform at least one of the following:

- decrease the temperature of the skin tissue, and
- increase the temperature of the skin tissue, optionally to a level of no more than 45 degrees C.

17. The system according to claim 15, wherein said handheld applicator comprises one or more heads configured to contact the skin tissue during said one or more treatments, wherein said one or more heads comprise one or more electrodes in electrical communication with said at least one heat generating element and/or said muscle stimulating element.

18. The system according to claim 17, wherein at least one electrode of the one or more electrodes is in electrical communication with said at least one heat generating element and said muscle stimulating element.

19. The system according to claim 17, wherein said muscle stimulating element comprises an electrical pulse generator configured to provide electrical muscle stimulation signal (EMS) to the muscles in the muscle layer located below the skin tissue, and wherein said one or more electrodes are configured to deliver the electrical muscle stimulation signal to the skin tissue.

20. The system according to claim 17, wherein said heat generating element comprises a radio frequency (RF) generator configured to generate RF energy to increase the temperature of the skin tissue, and wherein said one or more electrodes are configured to deliver the RF energy to the skin tissue.

21. The system according to claim 20, wherein said activation pattern of said EMS and said RF energy is user selectable and includes one or more of the following: signal intensity, frequency, and duration, thereby enabling to optimize the one or more treatments for different users or different positions on body of the treated person.

22. The system according to claim 15, wherein said control board is configured and operable to activate said at least one heat generating element and said muscle stimulating element in one or more of the following activation patterns: sequentially, intermittently and simultaneously.

23. A method of treating a person's skin tissue, comprising:

- providing a skin tissue treatment apparatus comprising:
 - a muscle stimulating element configured to provide muscle stimulation to a muscle layer located below the skin tissue,
 - a handheld applicator configured to be placed in vicinity of the skin tissue to deliver said muscle stimulation from said muscle stimulating element to the muscle layer located below the skin tissue,
 - one or more sensors configured to provide measurements while the person's skin tissue is treated by one or more treatments;

and
providing a control board configured and operable to
accept the measurements from the one or more sensors
and control the handheld applicator according to one or
more activation patterns, thereby providing the one or
more treatments to the skin tissue.

* * * * *