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(54) **Title:** DEVICE AND METHOD FOR TREATING SKIN WITH TEMPERATURE CONTROL

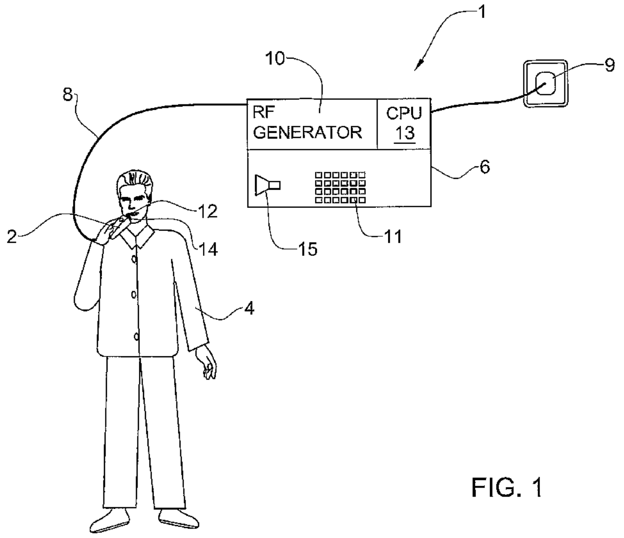

FIG. 1

(57) **Abstract:** A method and system for heating a skin area surface of an individual from an initial temperature to a treatment temperature in a treatment time period exceeding 0.5 sec, where the treatment temperature is in the range of 40 -60 C. An RF generator provides a continuous wave RF voltage energy or a quasi-continuous wave RF voltage across first and second electrode, where at least the first electrode is associated with an applicator that is displaced over the skin surface. The system further includes a skin temperature measuring device or an applicator displacement speed measuring device; and a CPU that monitors a skin temperature or an applicator displacement speed. The CPU turns off the RF energy when the skin temperature is above a predetermined temperature or the displacement speed of the applicator is below a predetermined speed, in order to prevent overheating of the skin.

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DEVICE AND METHOD FOR TREATING SKIN WITH TEMPERATURE CONTROL

FIELD OF THE INVENTION

This invention relates to methods and devices for treating skin.

BACKGROUND OF THE INVENTION

There are many medical and cosmetic treatments of skin that utilize heating a region of skin to be treated. Among these are hair removal, treatment of vascular lesions and skin rejuvenation. In these treatments, a volume of skin tissue to be treated is heated to a temperature sufficiently high to achieve a desired effect, which is typically in the range of 45-60°C. One method that has been used for heating the epidermal and dermal layers of the skin is pulsed radio-frequency (RF) energy. In this method, electrodes are applied to the skin and an RF voltage pulse is applied across the electrodes. The properties of the voltage pulse are selected so as to generate an RF current pulse in the tissue to be treated that heats the tissue to the required temperature. For example, US Patent No. 6,749,626 discloses use of pulsed RF energy for inducing collagen formation in the dermis.

When an RF current pulse is used to heat a volume of tissue, the temperature of the tissue volume rises from body temperature to the required temperature within the duration of the pulse, which is typically of the order of 100 msec. The temperature of the tissue volume thus rises vary rapidly. Since the final temperature will actually depend on the electrical properties of the tissue volume which vary from individual to individual, the rapid rise in temperature of the tissue volume limits control of the tissue heating. Moreover, the rapid rise in temperature prevents the user from stopping the treatment should the tissue volume become overheated. Thus, using an RF pulse to heat the skin carries a risk of overheating the skin which could result in permanent scarring or other damage to the skin surface. Such damage to the skin includes, for example, a first degree or higher burn, blisters, or blood coagulation.

SUMMARY OF THE INVENTION

The present invention provides a method and system for heating a sub-dermal tissue volume. In accordance with the invention an RF current is generated in a tissue volume to be treated that raises the temperature of the tissue volume to a desired temperature above its initial temperature in a period of time that exceeds 0.5 sec. The slow rise in temperature allows the user to control the skin temperature and to avoid overheating of the skin. The invention is particularly useful for skin treatments requiring the tissue volume to be heated to a temperature in the range of 45°C to 60°C. Such treatments include, for example, skin rejuvenation, collagen remodeling and contraction, skin tightening, wrinkle treatment, subcutaneous tissue treatment, cellulite treatment, pore size reduction, skin texture and tone improvement, acne treatment and hair removal.

In one embodiment of the invention, a pair of RF electrodes is applied to the skin surface, and an RF energy pulse is applied to the skin surface having a duration and power selected so as to heat the skin surface to a predetermined temperature within an amount of time exceeding 0.5 sec. For example, an RF energy pulse having a power range of 1-10 Watts could be used. In this case application of RF energy would heat the tissue volume to a temperature in the range of 40°-60°C within 0.5-10 sec. The electrodes could be positioned at a first location in a skin region to be treated and the RF energy pulse applied to the first location. The electrode pair could then be repositioned on the skin surface at another location in the region to be treated and the procedure repeated. In another embodiment of the invention, continuous wave (CW) RF energy is applied to the skin surface and by a pair of electrodes which is displaced over the skin surface at a displacement speed that sequentially heats a tissue volume adjacent to the electrodes to the predetermined temperature in a time that exceeds 0.5 sec. For example, CW RF energy having a power range of 2-10 Watts could be used. In this case, a displacement speed of about 0.5 -1.0 cm/sec would heat the tissue volume to a temperature in the range of 45°-60°C in a time that exceeds 0.5 sec. Quasi-CW RF energy may also be used in which a train of RF pulses is applied to the skin surface, where the train has a frequency and the pulses have durations and powers, so as to heat the tissue volume to be treated to a predetermined temperature in a period of time that exceeds 0.5 sec.

The system of the invention comprises two or more RF electrodes and an RF generator configured to apply an RF voltage across at least a pair of electrodes, where the RF voltage has a power selected to heat a tissue volume to a predetermined temperature in a time period that exceeds 0.5 sec., when an electrode pair is applied to the skin surface over the tissue volume. The RF generator may be configured to deliver a pulse of RF energy having a duration exceeding 0.5 sec. Alternatively, the RF generator could be configured to deliver CW or quasi-CW RF energy to the electrodes, in which case, the electrodes are displaced over the skin surface during delivery of the RF energy. In a preferred embodiment of the system, a pair of RF electrodes is included in a hand held applicator. A user treating his own skin with the system of the invention may simply displace the applicator over the skin surface in the region to be treated at a speed at which the user feels that the skin is heated but not to an extent that causes pain to the user.

The slow heating of the skin volume by the method and system of the invention permits greater control of the tissue heating, and thus reduces the risk of overheating, and hence damaging, the tissue.

Damage to the skin may include, for example, a first degree or higher burn, blisters, or blood coagulation. The appropriate displacement speed of the applicator over the skin is thus a function of the RF power. As the RF power increases, the movement of the applicator over the skin surface should be faster in order to avoid skin damage due to overheating of the skin.

The system includes a control mechanism that turns off or reduces the RF energy when a condition indicative of skin overheating occurs, in order to prevent overheating of the skin that could otherwise occur if the applicator were to be displaced over the skin by the user too slowly or not at all during delivery of RF energy to the skin. In one embodiment, the control system includes a temperature sensor, such as a thermistor or thermocouple that measures the skin temperature during delivery of RF energy. The skin temperature is monitored by the system which automatically turns off the RF energy when the skin temperature exceeds a predetermined threshold.

In another embodiment, the system includes a motion detector that continuously monitors the movement of the applicator over the skin. An optical or mechanical device can be used for the motion detection. An acceleromenter may also be used for motion detection. In this embodiment, the system turns off the RF energy when the speed of the applicator is below a predetermined threshold or when the applicator is applied to the skin and not moved for a period of time which is longer than a predetermined time period. In a preferred embodiment, the control mechanism involves measuring the electrical impedance of the skin between a pair of RF electrodes. A processor continuously calculates the skin temperature from the impedance measurements and turns off the RF energy when the calculated temperature is above a predetermined threshold.

Thus, in one of its aspects, the invention provides a system for heating a tissue volume under the skin surface of an individual from an initial temperature to a treatment temperature in a treatment time period exceeding 0.5 sec, the treatment temperature being in the range of 40°-60°C, comprising:

(a) an applicator;

(b) an RF generator configured to provide a continuous wave RF voltage energy or a quasi-continuous wave RF voltage across a first electrode and a second electrode, at least one electrode being associated with the applicator;

(c) A skin temperature measuring device or an applicator motion sensor; and

(d) a CPU configured to monitor a skin temperature or an applicator displacement speed and to turn off or reduce the RF energy when the skin temperature is above a predetermined temperature or the displacement speed of the applicator is below a predetermined speed.

In another of its aspects, the invention provides a method for heating a tissue volume under the skin surface of an individual from an initial temperature to a treatment temperature in a treatment time period exceeding 0.5 sec, the treatment temperature being in the range of 40°-60°C, comprising:

(a) providing a continuous wave RF voltage energy or a quasi-continuous wave RF energy across a first electrode and a second electrode, at least one of the electrodes being associated with an applicator;

(b) displacing the applicator over the skin surface;

(c) monitoring a skin temperature or an applicator motion; and

(d) turning off or reducing the RF energy when the skin temperature is above a predetermined temperature or the displacement speed of the applicator is below a predetermined speed.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be carried out in practice, a preferred embodiment will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

Fig. 1 shows a system for treating skin in accordance with one embodiment of the invention;

Fig. 2 shows an applicator for use in the system of Fig. 1;

Fig. 3 shows the electrodes of the applicator of Fig. 2; and

Fig. 4 shows another applicator for use in the system of Fig. 1.

DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 shows a system **1** for treating skin in accordance with one embodiment of the invention. The system **1** includes a hand held applicator **2** that is used to apply RF energy to the skin of an individual **4**. The applicator **2** is connected to a control unit **6** via a harness **8**. The control unit **6** includes an RF generator **10** that generates a continuous wave or quasi-continuous RF voltage across a pair of electrodes **12** and **14** in the applicator **2**. The control unit **10** also includes a CPU **13** and an input device such as a key pad **11** for inputting to the CPU **13** the wavelength and amplitude of the RF voltage generated by the RF generator **10** as required in any particular skin treatment. The RF generator is connected to the electrodes **12** and **14** by a pair of wires in the harness **8**. The system **1** may be plugged into a wall electrical socket **9**, as shown in Fig.1 or use batteries (not shown) that are preferably rechargeable.

Figs. 2 and 3 show an applicator **2a** in accordance with one embodiment of the applicator **2**. The applicator **2a** contains a push-button on-off switch **16**. The switch **16** is spring biased in an open position, so that no voltage is applied to the electrodes **12** and **14** when the switch **16** is released. When the applicator **2** is held by a user, as shown in Fig. 1, the switch **16** is depressed and a continuous or quasi-continuous wave RF voltage (train of repetitive pulses) is applied between the electrodes **12** and **14**. The electrodes **12** and **14** preferably have rounded edges in order to avoid hot spots on the skin surface in the vicinity of the edges of the electrodes. Rounded electrodes also allow smooth moving of the applicator over the skin surface.

The applicator **2a** preferably, though not necessarily, includes a light source **21** which is located between the electrodes **12** and **14** that generates optical energy that is directed to the skin **25** surface by a reflector **24**. Optical energy directed to the skin surface from the light source **21** is used to specifically heat pigmented targets at the skin surface. Such skin targets include vascular lesions, varicose veins, acne, and mole marks. The optical energy may have a single wavelength or several wavelengths. The wavelengths are selected to be optimal for the color of the contrasted component of the target, and are typically in the range of 400 to 1800 nm. A filament lamp or gas filled lamp can be used as the light source **21**. Light from a laser or LED also can be used for skin irradiation.

In use, the applicator **2** is held by the user and the electrodes **12** and **14** are applied to the skin. The switch **16** is then depressed so as to deliver a continuous wave RF current to a section **17** of the skin between the electrodes **12** and **14**. The applicator **2** is displaced over the skin in a skin region **15** to be treated so as to heat the skin region to a temperature that produces the desired treatment of the skin.

When the applicator **2a** is used, the CPU **13** continuously monitors the electrical impedance of the skin between the electrodes **12** and **14**. Increasing skin temperature leads to a change in impedance, monitoring the skin impedance allows the temperature in the skin between the electrodes to be followed, as is known in the art. The CPU **13** is configured to continuously calculate a skin temperature from the impedance measurements and to turn off the RF energy when the calculated skin temperature is above a predetermined threshold.

Fig. 4 shows an applicator **2b** in accordance with another embodiment of the applicator **2.** The applicator **2b** has several elements in common with the applicator **2a** shown in Figs. 2 and 3, and similar elements are indicated by the same reference numeral in Figs. 2, 3, and 4 without further comment.

The applicator **2b** has roller **20** adjacent to the electrode pair that is positioned and dimensioned to contact the skin surface and to roll over the skin surface as the applicator is displaced over the skin surface. The roller **20** has a plurality of evenly spaced radial markers **22** on its edge **24**. The edge **24** is illuminated by light from a laser **26**. Light reflected from the edge **24** is detected by a photo cell **28** that generates an electric signal indicative of the intensity of the reflected light. Due to the presence of the radial markers **22** the intensity of the reflected light, and hence the intensity of the electric signal, varies cyclically as the roller rolls over the skin surface. The electrical signal is continuously monitored by the CPU **13** which is configured to calculate a displacement speed of the applicator **2b** over the skin surface from the periodicity of the electrical signal which is proportional to the displacement speed of the applicator. The CPU **13** in this embodiment is configured to turn off the RF energy when the displacement speed is below a predetermined value.

When the CPU determines that the skin temperature is above the predetermined temperature, the processor may generate a sensible signal, such as sounding an alarm **15** at a pitch indicating to the user that the displacement speed is too low and that the RF energy has been turned off. Similarly, if the CPU **13** determines that the skin temperature is below a second predetermined value that is required to produce the desired skin treatment (for example, 45°C to 60°C, which maybe input to the CPU **13** prior to the treatment), the processor may generate a sensible signal, such as sounding the alarm **15** at another pitch indicating to the user that the displacement speed should be increased.

The displacement velocity of the applicator **2** over the skin is determined so that the skin section between the electrodes is heated to a temperature that produces the desired skin treatment, but does not damage the skin. The desired displacement speed can be determined, for example, using the equation $V = \frac{P}{L\, d\, c\rho \Delta T}$, where P is the power of the continuous RF current, L is the spacing of the electrodes, d is the penetration depth of the RF energy, c is the specific heat of the treated tissue, ρ is the mass density of the tissue, and ΔT is the required temperature increase. Thus, for example, if the RF power is P=5W, the spacing of the electrodes is L=1cm, the RF penetration depth is d=0.25cm, $c\rho$=4J/cm^3/°K and ΔT=10°C, the applicator displacement speed should be about 0.5cm/sec. in order to achieve the desired heating in amount of time in slightly more than 0.5 sec. If a mono-polar electrode system is used, the power should be lower to avoid damage to sub-dermal tissue.

The system **1** may be used with the following exemplary parameter values:

An RF power in the range of 2-10W.

An energy delivery mode that is CW or Quasi-CW.

An RF frequency in the range of 0.2-10MHz.

An optical energy spectrum in the range of 400-1800nm.

Optical energy power in the range of 1 to 20W/cm^2.

CLAIMS:

1. A system for heating a tissue volume under the skin surface of an individual from an initial temperature to a treatment temperature in a treatment time period exceeding 0.5 sec, the treatment temperature being in the range of 40°-60°C, comprising:

(a) an applicator;

(b) an RF generator configured to provide a continuous wave RF voltage energy or a quasi-continuous wave RF voltage across a first electrode and a second electrode, at least one electrode being associated with the applicator;

(c) A skin temperature measuring device or an applicator motion sensor; and

(d) a CPU configured to monitor a skin temperature or an applicator displacement speed and to turn off or reduce the RF energy when the skin temperature is above a predetermined temperature or the displacement speed of the applicator is below a predetermined speed.

2. The system according to Claim 1 comprising a skin temperature measuring device.

3. The system according to Claim 2 wherein the skin temperature monitoring device is an electronic device.

4. The system according to Claim 2 wherein the temperature measuring device includes an impedance meter measuring skin impedance.

5. The system according to Claim 1 comprising an applicator motion sensor.

6. The system according to Claim 5 where motion sensor measures an applicator displacement speed.

7. The system according to Claim 5 wherein the applicator motion sensor is accelerometer.

8. The system according to Claim 5 wherein the applicator motion sensor is an optical device.

9. The system according to Claim 1 wherein the first and second electrodes are associated with the applicator.

10. The system according to Claim 1 wherein the RF voltage has a power in the range of 1-50W.

11. The system according to Claim 1 wherein the RF voltage has a frequency in the range of 0.2-100MHz.

12. The system according to Claim 1 wherein the applicator further comprises a light source configured to direct optical energy to the skin region.

13. The system according to Claim 12 wherein at least a portion of the optical energy is in the range of 400-1800nm.

14. The system according to Claim 12 wherein the optical energy has an energy power density in the range of 0.01 to $10W/cm^2$

15. The system according to Claim 12 wherein the light source is selected from an incandescent lamp, a gas filled lamp, a LED and a laser.

16. The system according to Claim 4 wherein the CPU is configured to determine a heat distribution in the skin based upon one or more impedance measurements.

17. The system according to Claim 1 wherein the processor is configured to generate a sensible signal if the skin temperature is below a predetermined temperature.

18. The system according to Claim 17 wherein the sensible signal is sounding an alarm at a first pitch.

19. The system according to Claim 1 wherein the processor is configured to generate a sensible signal if the skin temperature is above a predetermined temperature.

20. The system according to Claim 17 wherein the sensible signal is sounding an alarm at a second pitch or a visible signal.

21. A method for heating a tissue volume under the skin surface of an individual from an initial temperature to a treatment temperature in a treatment time period exceeding 0.5 sec, the treatment temperature being in the range of 40°-60°C, comprising:

(a) providing a continuous wave RF voltage energy or a quasi-continuous wave RF energy across a first electrode and a second electrode, at least one of the electrodes being associated with an applicator;

(b) displacing the applicator over the skin surface;

(c) monitoring a skin temperature or an applicator motion; and

(d) turning off or reducing the RF energy when the skin temperature is above a predetermined temperature or the displacement speed of the applicator is below a predetermined speed.

22. The method according to Claim 21 comprising monitoring a skin temperature.

23. The method according to Claim 22 wherein the skin temperature is monitored using an electronic or optical device.

24. The method according to Claim 21 wherein the temperature is monitored using an impedance meter measuring a skin impedance.

25. The method according to Claim 21 comprising monitoring an applicator motion.

26. The method according to Claim 25 wherein the applicator motion is measured using a roller rolling over the skin surface when the applicator is displaced over the skin surface.

27. The method according to Claim 25 wherein the applicator motion is measured by measuring the acceleration of applicator.

28. The method according to Claim 25 wherein the applicator motion is measured using an optical device.

29. The method according to Claim 21 wherein two or more electrodes are associated with the applicator.

30. The method according to Claim 21 wherein the RF voltage has a power in the range of 1-50W.

31. The method according to Claim 21 wherein the RF voltage has a frequency in the range of 0.2-50MHz.

32. The method according to Claim 21 further comprising directing optical energy to the skin surface.

33. The method according to Claim 32 wherein at least part of the optical energy has a spectrum in the range of 400-1800nm.

34. The method according to Claim 32 wherein the optical energy has an energy power density in the range of 0.01 to $10W/cm^2$

35. The method according to Claim 32 wherein a light source is selected from an incandescent lamp, a gas filled lamp, a LED and a laser.

36. The method according to Claim 22 further comprising determining a heat distribution in the skin based upon one or more impedance measurements.

37. The method according to Claim 22 further comprising generating a sensible signal if the skin temperature is below a predetermined temperature.

38. The method according to Claim 33 wherein the sensible signal is sounding an alarm at a first pitch.

39. The method according to Claim 22 further comprising generating a sensible signal if the skin temperature is above a predetermined temperature.

40. The method according to Claim 35 wherein the sensible signal is sounding an alarm at a second pitch or a visible signal.

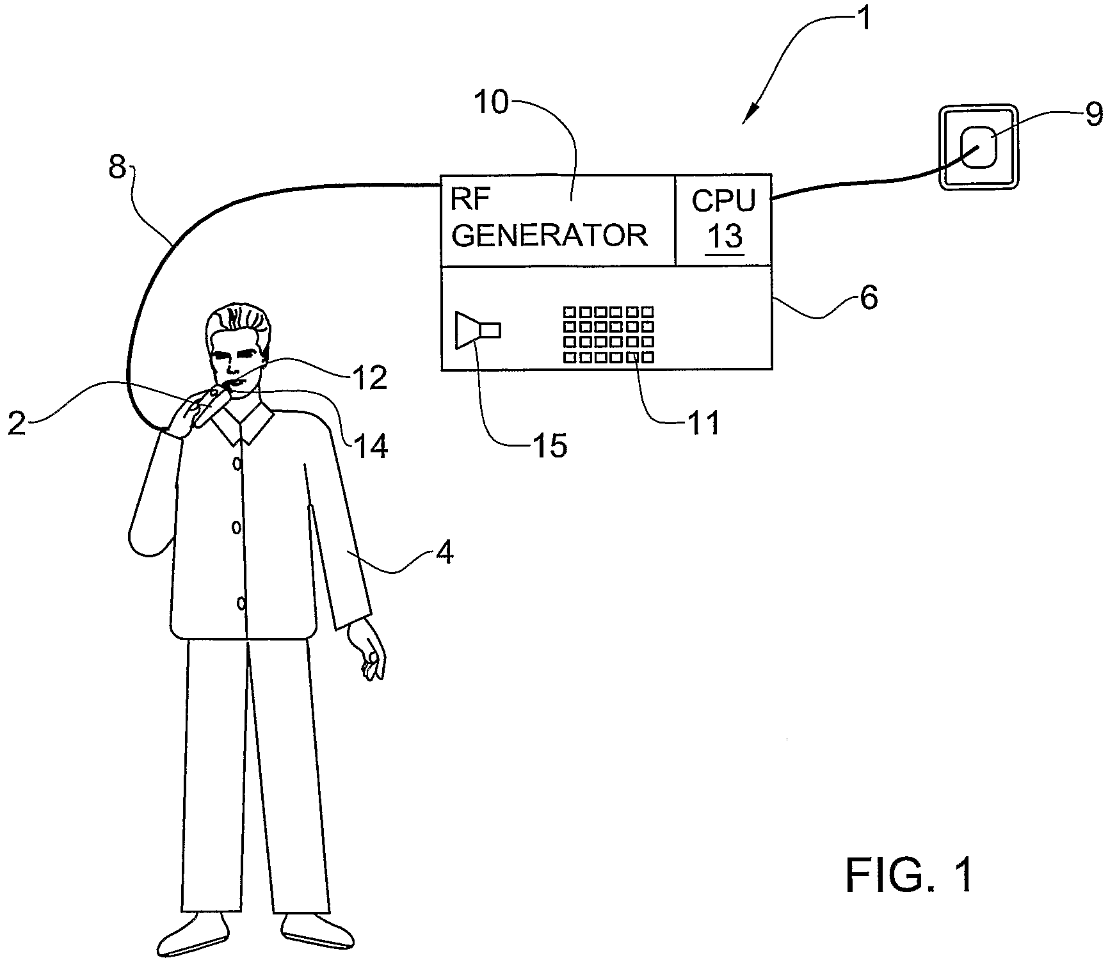

FIG. 1

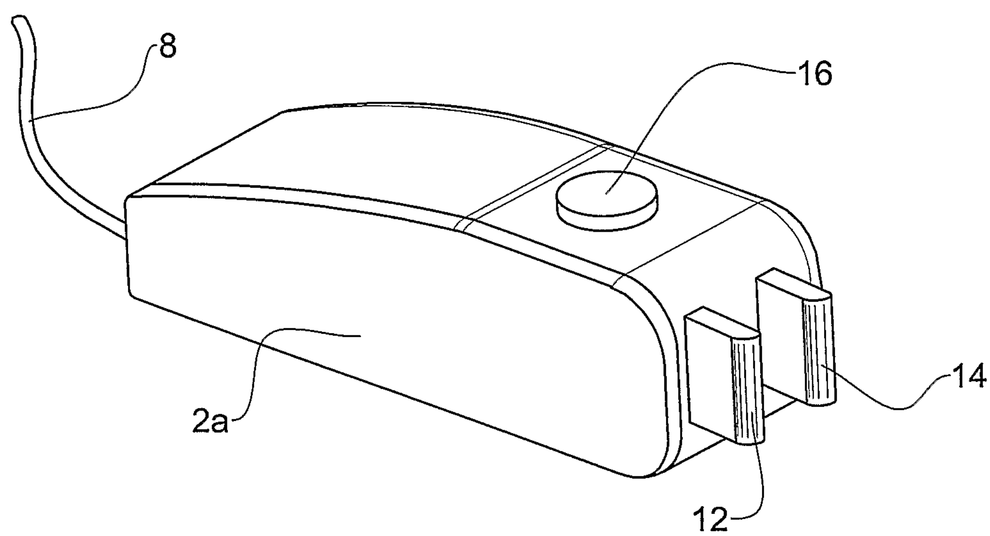

FIG. 2

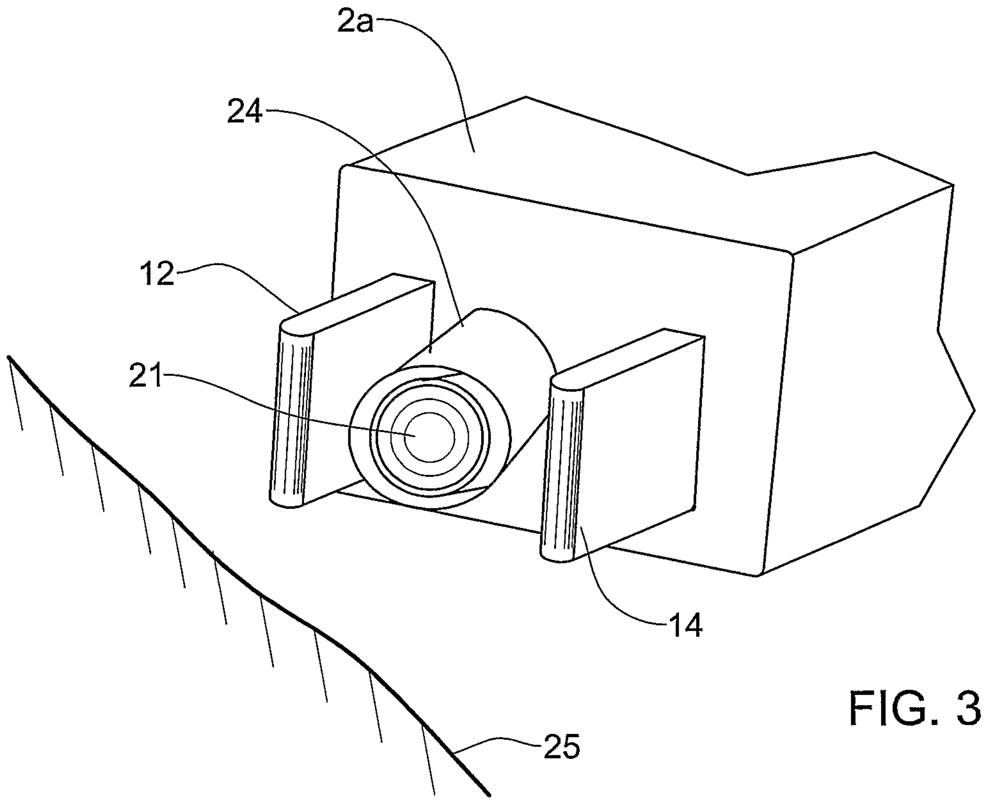

FIG. 3

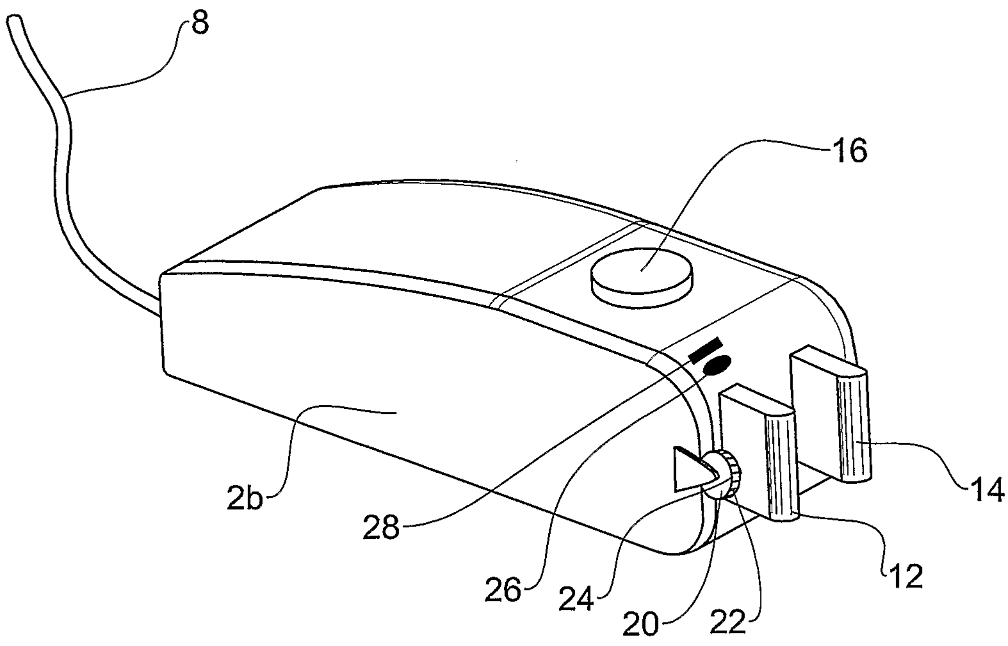

FIG. 4