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### Skin treatment device with thermally modulated head

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#### Abstract

A skin treatment device is provided with a thermally modulated treatment head adapted for contact with a user or other subject's skin. The device includes one or more thermal elements adapted to modulate the temperature of the head, a power source adapted to provide current to the thermal elements, and a controller adapted to modulate the head temperature by controlling the current delivered to the thermal elements. A topical agent can be disposed between the treatment head and the subject's skin, where the temperature of the topical agent is modulated in response to the temperature thereof.

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## Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS (1) The application claims priority to U.S. Provisional Patent Application No. 63/209,916, SKIN TREATMENT DEVICE WITH THERMALLY MODULATED HEAD, filed Jun. 11, 2021, which is incorporated by reference herein, in the entirety and for all purposes.

### FIELD

(1) The application relates to skin treatment. More generally, the application relates to skin treatment systems, devices, and methods with a thermally modulated treatment head. Suitable applications include, but are not limited to, microcurrent devices for cosmetic skin care and skin treatment, skin treatment systems with a thermally modulated head adapted for heating a topical agent, and combinations thereof.

### BACKGROUND

(2) The skin is the largest organ of the human body, forming a physical barrier to the environment and providing important functions including insulation, temperature regulation and protection against microorganisms, as well as touch, heat sensitivity, and other forms of sensation. The skin also regulates the passage of water and electrolytes, and produces vitamin D.

(3) The outermost skin layer or epidermis covers the body's surface. Most of the epidermal cells are keratinocytes, which form an environmental barrier and synthesize vitamin D. The epidermis also includes melanocytes, which produce melanin to protect against harmful UV radiation, Merkel cells, which provide sensitivity to touch, and Langerhans cells, a type of white blood cell or macrophage that is part of the immune system, acting to protect the body against infection.

(4) The epidermis surrounds the dermis. The structure of the dermis is provided by fibroblasts, which synthesize collagen and elastin proteins to form the extracellular matrix, with collagen fibers to provide strength and toughness, and elastin threads or filaments to provide elasticity and flexibility. The fibroblasts also produce proteoglycans, viscous proteins that provide hydration and lubrication, and regulate ionic binding and molecular transport. The dermis also includes macrophages and mast cells, part of the immune system, as well as the hair follicles, sweat and oil glands, nerve cells, and blood vessels.

(5) The epidermis and dermis make up the cutis. Subcutaneous tissue connects the cutis to the underlying muscle and fascia, and to other connective tissue including the periosteum (covering the bones). The subcutis also includes elastin and adipose (fat) cells.

(6) Skin firmness and elasticity are often associated with the production of Type I collagen (typically the more abundant form), as well as elastin, proteoglycans, and other components of what is known as the extracellular matrix. A healthy extracellular matrix can also improve skin resilience and coloration, and promote immune response.

(7) A range of personal skin care products have been provided to help enhance these effects, including topical products and hand-held devices for cleansing, exfoliating and smoothing the outer skin layers. In galvanic systems, one or more anode or cathode electrodes are typically arranged to produce an electric potential across the skin, providing current flow through the epidermal and dermal layers. Advanced microcurrent based devices can include a control circuit operably connected to the electrodes, in order to carefully regulate the current to promote ion transport and other biological effects; e.g., as described in for example as described in U.S. Pat. No. 10,046,160 B1, U.S. Pat. No. 10,080,428 B2, U.S. Pat. No. 10,661,072 B2, and U.S. Pat. No. 10,772,473 B2, each of which is assigned to NSE (Nu Skin Enterprises) Products, Inc., of Provo Utah, and incorporated by reference herein.

(8) More generally, skin response to electric current flow involves a number of complex and interacting biological processes, and the full range of different effects have not all been recognized

in the prior art. There is an ongoing need more advanced approaches to skin care, including skin treatment techniques developed with a better understanding of the underlying biological response mechanisms of the skin, and how these mechanisms interact with different topical treatments and delivery techniques.

## SUMMARY

(9) A skin treatment device is provided with a thermally modulated treatment head adapted for contact with a user's skin. The device includes one or more thermal elements adapted to modulate the temperature of the head, a power source adapted to provide current to the thermal elements, and a controller adapted to modulate the head temperature by controlling the current delivered to the thermal elements. A topical agent can be disposed between the treatment head and the user's skin, where the temperature of the topical agent is modulated to have different temperatures in regions spaced from the skin surface, and proximate the skin surface.

(10) In some examples, the device can be provided with one or more emitters or electrodes configured for electrical communication with the surface of the subject's skin. A voltage or current source can be adapted to generate an electrical waveform for application to the skin surface, via the one or more emitters or electrodes. A controller can be configured for modulating the electrical waveform, so that the pulse width, pulse period, pulse frequency and/or pulse amplitude vary in a periodic, random, pseudorandom, non-repeating or aperiodic manner.

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## Description

### BRIEF DESCRIPTION OF THE DRAWINGS

(1) FIG. 1A is a sectional diagram illustrating representative components of human skin.

(2) FIG. 1B is a sectional diagram illustrating a topical skin treatment.

(3) FIG. 2 is a block diagram of a skin treatment device with thermally modulated treatment head.

(4) FIG. 3 is a plan view of a thermally modulated head for a skin treatment device.

(5) FIGS. 4A and 4B are isometric views of first and second contoured, thermally modulated skin contact elements for a treatment head.

(6) FIGS. 5A and 5B are plan views of representative thermal elements for a treatment head.

(7) FIG. 6 is a cross-sectional view of a thermally modulated skin treatment head, showing the thermal elements.

(8) FIGS. 7A and 7B are alternate plans view of a thermally modulated skin treatment head, illustrating alternative thermal element configurations.

(9) FIG. 8A is a thermal image or heat map of a thermally modulated skin treatment head.

(10) FIG. 8B is a thermal image or heat map of a thermally modulated skin contact element.

(11) FIG. 9A is a perspective view of an alternate skin treatment head.

(12) FIG. 9B is a thermal image or heat map of the skin treatment head in FIG. 9A.

(13) FIG. 10 is a cross sectional view of a thermally modulated skin treatment head, illustrating an alternate thermal element configuration.

### DETAILED DESCRIPTION

(14) FIG. 1A is a sectional diagram illustrating representative structural and functional components of human skin **100**. As shown in FIG. 1A, the skin (or “cutis”) **100** includes an upper epidermal layer (or epidermis) **105** extending from the skin surface **101** to a lower dermal layer (dermis) **110**. Together, the epidermis **105** and dermis **110** make up the cutaneous tissue or skin. The subcutaneous tissues comprise the subcutis (or hypodermis) **120**, underlying the cutis **100**.

(15) Collagen fibers **125** extend from the lower dermis **110** through the subcutis **120**, forming bands and sheets of connective tissue (fascia) connecting the skin (cutis) **100** to the underlying muscles and connective tissue. The dermis **110** also includes a papillary layer **111** and a reticular layer **112**, formed of more loosely arranged and denser collagen fibers, respectively.

(16) The subcutis **120** includes adipose tissues **130**, for example in the form of lipocytes (fat cells) and intracellular or intercellular lipids, which can form lobules and other structures between the collagen fibers **125**. A network of small blood vessels or capillaries **135** provide circulation, extending from the subcutis **120** into the dermis **110**.

(17) FIG. 1B is a sectional diagram illustrating an electrical stimulus S applied to a skin surface **101**, and propagating through different layers of the skin or cutis **100**. A fluid, paste, gel or other topical skin treatment agent **140** can be applied to the skin surface **101**; e.g., to improve conductivity, and to provide the skin **100** with moisturizers, nutrients and other beneficial agents.

(18) For example, in one embodiment a current or microcurrent stimulus S can be generated by a skin treatment device **150** with one or more emitters or electrodes **155** disposed along the skin surface **101**, either in direct contact with the skin surface **101**, or in electrical contact with the skin surface **101** via a conducting topical agent **140**. One or more thermal control components **160** can also be provided, in order to modulate the temperature of the topical agent **140** during application.

(19) A current source or waveform generator **170** can be configured to generate a potential (V) or current (I) waveform for application to the skin surface **101** via one or more of the emitters or electrodes **155**. It is also possible to use other forms of electromagnetic energy as a form of stimulus S to treat the skin **100**, for example in the form of radio frequency (RF), infrared (IR), optical or ultraviolet (UV) light (e.g., low-energy near UV light), or to provide an energetic stimulus S in the form of sonic, subsonic or ultrasonic acoustic energy.

(20) These energetic stimuli can be presented to the skin **100** as a modulated waveform, similar to the modulated waveforms provided in the form of an electrical or current stimulus S. Thus, electrical, electromagnetic and acoustic forms of energy are all within the teachings of the present disclosure, and any suitable combination of these energetic stimuli can be presented in the form of a modulated waveform.

(21) In particular examples, one or more resistive heating elements or thermal control component ("thermal components") **160** can be used to heat the topical agent **140**, adjacent the skin surface **101**. On a molecular scale, the transfer and movement of molecules within the topical agent **140** increases with temperature. Heating can also activate ingredients in the agent **140**, and allow active ingredients to more rapidly move through the agent **140**, across the skin surface **101**, and into the epidermis **105**, and/or the (upper) papillary layer **111** and (lower) reticular layer **112** of the dermis **110**. Heating may also reduce the viscosity of the topical agent **140** (e.g., in gel or fluid form), which will reduce the drag on the skin as the skin treatment device or head is moved over the skin. Using one or more thermal components **160** to modulate the temperature of the topical agent **140**, heat from the fluid can also be transferred across the skin surface **101**, increasing user comfort by providing a warming sensation, and opening pores in the skin to improve cleansing and absorption of active elements in the agent **140**.

(22) As shown in FIG. 1B, for example, an electrical stimulus S can be generated by applying a potential V (or current source I) between two or more emitters or electrodes **155**, spaced along the outer surface **101** of the skin **100**, either adjacent to or in direct contact with the skin surface **101**. Alternatively, one or more electrodes **155** may be disposed on or adjacent the skin surface **101** in a particular location, for example on the face, arm, torso or leg, with another electrode **155** coupled remotely, for example via contact with the hand of the user (or other treatment subject), or elsewhere on the subject's body. In other applications, the electrical stimulus S can be applied with a single electrode **155**; e.g., by applying an ungrounded (floating) potential waveform from one or more electrodes **155** to the skin surface **101**, or by forming a current loop through the subject's feet or other ground contact.

(23) Depending upon application, a potential V can be provided to the emitters or electrodes **155** to apply a current stimulus S to the top epidermal layer **105** of the skin **100**, or a current propagating through the epidermal layer **105** to one or both of the papillary and reticular layers **111**, **112** of the dermis **110**. The electrical stimulus may also propagate into or through the subcutis **120**,

promoting a favorable response from both cutaneous and subcutaneous tissues. The stimulus S can thus promote a range of biological responses in epidermal, dermal (cutaneous) and subcutaneous tissues. Alternatively one or more (or all) of the emitters or electrodes **155** can take the form of LEDs or laser light sources (or other electromagnetic emitters) configured to provide a stimulus in the form of RF, IR, optical or UV light energy, or one or more acoustic transducers configured to provide a subsonic, sonic, ultrasonic, or other acoustic stimulus, or any suitable combination of electrical, acoustic, and electromagnetic emitters **155**.

(24) Suitable waveforms and waveform modulation techniques are described, for example, in U.S. Publication No. 2021/0308452 A1, “Modulated Waveform Treatment Device and Method,” and in U.S. Provisional Patent Application No. 63/256,106, “Current Control System for Skin Treatment Device,” filed Oct. 15, 2021, each of which is incorporated by reference herein, in the entirety and for all purposes. In particular applications, for example, pulse width modulation (PWM) can be used to generate the stimulus S as a pulsed microcurrent waveform, or other energetic stimulus S, for example by applying a programmed, random or pseudorandom pulse width modulated (PRPWM) current or voltage waveform, or as a modulated electromagnetic or acoustic waveform, as described herein. The power output to the skin surface can also be modulated to reduce transients and increase user comfort, while maintaining treatment efficacy.

(25) In other examples, a DC (direct current) or pulsed DC potential V or current I is applied via the electrodes **155**, so that the electrical stimulus S propagates in a particular direction through the skin **100**. In other examples, an AC (alternating current) potential V of current I can be applied, so that the electrical stimulus S propagates back and forth, in alternating fashion.

(26) The potential V can be applied as a steady-state (constant or alternating) voltage signal, or using a modulated waveform. Depending on application, the pulse width, amplitude, period and frequency of the applied voltage V or current I can all be controlled, either individually or in combination, in order to generate the electrical stimulus S as an AC, DC or pulsed DC current treatment for the skin **100** of the user or other subject.

(27) FIG. 2 is a block diagram of a representative skin treatment apparatus, system or device **150** disposed within a housing **152**, with a treatment head **200** configured for thermal modulation during delivery of a microcurrent based skin treatment or other energetic stimulus S; e.g., according to FIG. 1B. As shown in FIG. 2, one or more electrodes or other emitters **155** are disposed on the treatment head **200**; e.g., extending from the bottom surface of the housing **152**. One or more thermal components **160** are provided to modulate the temperature of the treatment head **200** (and any adjacent topical) during delivery of the stimulus to the skin **100**, with a current or voltage waveform generator **170** and a power source or power supply **175** adapted for application of the stimulus S via one or more of the emitters or electrodes **155**, as described herein.

(28) Depending on application, device **150** can also a microprocessor ( $\mu$ P) based controller **180** with memory **185**, and a power supply (P/S) **175** adapted for operation of the electrodes **155**, thermal components **160**, waveform generator **170** and controller **180**. The microprocessor controller **180** is provided in data communication with memory **185**, which provides storage for control code **186** and operational data **188**.

(29) The power supply **175** can be provided in the form of a line connection or a rechargeable capacitor or battery system, for example with a power port or charger (C) **178** adapted for external wired or wireless (e.g., inductive) charging of the power supply **175**. A communications interface (UF) **190** can be adapted for data and control communications with the controller **180**, for example using a hard-wired or wireless communications port (P) **195**.

(30) In operation of device **150**, power supply **175** provides power to the electrodes **155** via the voltage or current waveform generator (or source) **170**, as well as the thermal components **160**, sensors **165**, controller **180**, memory **185**, interface **190**, and the other internal components of device **150**. Controller **180** is configured regulate the potential (V) or current (I) waveform generated by source **170**, for example by executing control code **186** stored in memory **185**.

Control parameters and other operational data **188** can be used for modulating the waveform provided to each selected emitter or electrode **155**, in order to deliver the desired amplitude, frequency, and pulse width modulation. One or more sensors **165** can also be provided in direct or indirect contact with the treatment head or skin surface, for example in direct physical contact with the treatment head or skin surface, or in inductive, conductive or thermal communication. Sensors **165** can be configured to measure treatment head and skin surface temperature and resistivity, and to determine other skin conditions such as hydration level, skin firmness, etc. Suitable sensors **165** can also be provided to measure or monitor environmental conditions such as ambient temperature and humidity, etc.

(31) The microprocessor controller **180** can also be adapted to monitor feedback signals from the emitters or electrodes **155**, and for regulating the applied potential (V) or current (I) responsive to the feedback. Feedback-based regulation allows the controller **180** to maintain the desired electrical stimulus S, taking into account the number and arrangement of electrodes **155** as well as the subject's skin type and related skin conditions such as resistivity, temperature, hydration, etc., for example as determined with additional data from one or more skin sensors and other environmental sensors **165**. The controller **180** can also be adapted to regulate the current stimulus S transmitted through the subject's skin via the electrodes **155**, based on the based the voltage (V) or current (I) waveform generated by the source **170**, and based on operational and environmental conditions such as the temperature of the skin surface (or topical agent disposed on the skin surface), the impedance of the skin between adjacent electrodes **155**, and other operational data include prior (recent or historical) treatment information recorded in the operational data **188**.

(32) Generally, this disclosure is directed to the value of heating technology in skin treatment devices, and more specifically to heating technology focused on the topical agent or composition applied to the subject's skin surface (e.g., as a fluid or gel medium). On a molecular scale, the warmer the topical composition, the more rapid the transfer and movement of molecules within the topical medium. Heating can allow active ingredients to more rapidly move through the fluid or gel medium, while reducing the medium's viscosity.

(33) Warming the topical agent to a suitable temperature thus reduces drag between the skin surface and the treatment device, as it moves over the subject's skin. A warmer topical composition can also transfer thermal energy to the skin, providing a beneficial warming sensation and opening pores in the skin surface, to increase penetration of active ingredients.

(34) This approach contrasts with existing technologies, including warming the topical fluid when pumped or otherwise dispensed from a reservoir. This approach requires combining a fluid pump with a heating element, and topical agents that are pre heated before application can quickly cool, and the benefits of heating can be lost within a few seconds. Heating the entire treatment surface, on the other hand, requires high amounts of energy, and can lead to discomfort.

(35) FIG. 3 is a plan view of a thermally modulated head **200** for a skin treatment device; e.g., according to device **150** of FIG. 2, or another suitable skin treatment system or apparatus. As shown in FIG. 3, head **200** include two skin contact elements **250**, which are provided with ridged, grooved or other textured or patterned application surfaces **255** adapted for application of a skin treatment or other topical fluid to the user's skin (or to the skin of another subject, by the user). In galvanic and microcurrent-based systems, contact elements **250** are typically provided in the form of emitters or electrodes **155**, as describe above with respect to device **150**, and adapted for application of the topical fluid by electro-osmosis electrophoresis, iontophoresis, and other electrochemical techniques, for example as described in U.S. Pat. No. 10,046,160 B1, which is incorporated by reference herein.

(36) As shown in FIG. 3, for example, skin contact elements **250** can be formed as heated metal plates, or other conducting elements, which also allow for a microcurrent treatment to be applied to the skin surface. The application surfaces **255** can also be heated to deliver the topical agent in a temperature range selected for use comfort, viscosity, and mobility of active agents, for example

from about 37 C to about 42 C, or up to a preselected maximum upper limit selected for user comfort; e.g. up to about 45 C.

(37) Simple, direct heating mechanisms can be used to heat the topical agent to the selected temperature range, as described herein, for example with a minimum power output of about 15.6 W, distributed over one or more treatment surfaces **250** with an area of about 60 to 80 cm.<sup>sup.2</sup> or more. Alternatively the thermal power output and treatment surface area may vary; e.g., from less than about 10 W to about 15-20 W, 20-25 W or more, over a treatment area up to about 50 cm.<sup>sup.2</sup>, from about 50-100 cm.<sup>sup.2</sup>, or more. The thermal power output can also be adapted to heat the topical to a desired temperature within a particular time, for example within a minute or less, when the agent is distributed over the treatment area with the device in a static location adjacent the subject's skin. The heating time may also vary, for example from about 30 seconds (or less) to about two minutes (or more), and the thermal power output can also be adapted to maintain the desired topical agent temperature when the device is subject to dynamic movement over the skin surface.

(38) FIGS. **4A** and **4B** are isometric views of first and second contoured, thermally modulated skin contact elements **250** for a treatment head. FIGS. **4A** and **4B** illustrate the grooved, ridged, or similarly textured or patterned application surfaces **255**, as adapted for distribution the topical fluid over the subject's skin.

(39) In some configurations, textured or patterned application surfaces **255** comprise a network of branching, intersecting, on interconnected groove or channel structures **260**, in a proximal position with respect to the contact element **250** (spaced from the subject's skin), and a complementary network or set of oblong pads, lands, or similar structures **265**, in a distal position with respect to the contact element **250** (adjacent the subject's skin). Alternatively, complementary ridged or grooved structures **260** and pads or lands **265** can be formed in parallel, intersecting, branched, concentric, or randomized patterns, or combinations thereof.

(40) Contact elements **250** of FIGS. **4A** and **4B** can be defined with first and second (e.g., opposing polarities), selected to provide a microcurrent treatment to the adjacent skin surface. The individual application surfaces **255** are defined within the circumference of the device body or treatment head **200** (see FIG. **3**), substantially flush with the bottom profile of the device, with textured features such as grooves **260** and lands **265** are adapted for spreading (distributing) a topical agent when moved across the skin surface.

(41) Contact elements **250** can be made from stainless steel, nickel, copper, chrome, silver, and alloys thereof, or other suitable conducting metals or metal alloys. The application surfaces **255** can be formed in a punch and die operation (e.g., from stamped metal plate contact elements **250**), or via a plating process, machining, or a combination thereof. Contact elements **250** can also be formed with substantially smooth application surfaces **255**, or with grooves or channels **260** and ridges or lands **265** defining rounded nodules, undulating ridges, crossed perpendicular bars, ovals, circles, rectangular or oblong features, triangles, stars, or other textured or patterned geometries, as adapted for a range of different skin treatments and topical applications.

(42) FIGS. **5A** and **5B** are plan views of a representative thermal control component **160** with individual thermal elements **360** for modulating the temperature of a skin treatment head, for example with first and second skin contact elements **250** according to FIGS. **4A** and **4B**. In this particular example, thermal elements **360** comprise a set of interconnected, substantially linear or lineal segments, conforming to the grooved structure of the skin contact surfaces on the opposite side of each respective contact element **250**. Connectors **380** are provided to connect the thermal elements **360** together with a rechargeable battery or other suitable power source.

(43) FIG. **6** is a cross-sectional view of a thermally modulated skin treatment head **200**, illustrating a thermal component **160** configured as a heating module **500** with one or more individual thermal elements **360**. In this configuration, the thermal elements **360** can be embedded in a polymer, polyimide, silicon or similar material **510**, forming a pad-like modular heater structure **500**. The



heating module **500** can also be provided with thermal insulation **520** and a foil reflector **530**, or other thermally reflective and insulating elements configured to direct heat generated by thermal elements **360** toward through the adjacent skin contact element **250**, and into the topical gel, fluid or other topical agent **140** adjacent the subject's skin **100**.

(44) In some configurations, thermal elements **360** are disposed adjacent and along the individual ridges, grooves or channel structures **260** making up the proximal portions of the patterned application surface **255**, spaced from the user's skin **100**. Air gaps or similar insulating spaces **540** are defined between the heating module **500** with thermal elements **360**, and the distal portions or lands **265** of the application surface **255**, adjacent the user's skin **100**.

(45) Thermal elements **360** are energized by a power supply and controlled by a microprocessor, for example a power supply **175** and a processor-based controller **180**, provided in combination with other components of a skin treatment device **150** according to FIG. 2. One or more thermocouple sensors or other suitable temperature-sensitive elements **165**, can be utilized to determine the temperature of the contact element **250** at any or all locations along the application surface **255**, in order to provide feedback to the controller **180**, and to maintain a desired temperature profile **256** along or across the contact surface **255**, defining a thermal grant **258** in the adjacent topical agent **140**.

(46) In some applications, thermal elements **360** comprise resistive heating elements adapted to modulate the temperature of the contact element **250** (e.g., a thermally conducting metal plate), adjacent the topical agent **140** being delivered to the user's skin along the ridged, grooved or channel structures **260**. Generally, increasing the temperature of the topical agent **140** will increase the fluid conductivity, and increased fluid conductivity can provide increased ability to deliver active components (e.g., molecular ions), in response to electrochemical effects such as iontophoresis, electro-osmosis and electrophoresis.

(47) In some examples, heating of the topical agent **140** can be concentrated in the grooves or channels **260** adjacent the thermal elements **360**, and through which the topical fluid flows for delivery to the subject's skin **100**. Limiting heating to the channels **260** can increase efficiency for heating the topical agent **140** (e.g., as opposed to the subject's skin **100**), resulting in lower energy demand on the power supply.

(48) Depending on skin type, topical composition, and individual preference, a typical comfort range for the temperature of a topical agent **140** when applied to a subject's skin **100** may be in the range of up to 37-42 C, or up to a comfort limit of about 45 C. Depending upon the design of thermal elements **360** and the size of the treatment head **200**, the may be achieved with a power output of about in the range of about 10-20 W, for example about 15.6 W, to produce a desired temperature range on the skin contact element **250**, for example after about one minute of operation, or after a few minutes of operation, or less than a minute of operation. In some examples, this power level range may also be suitable to maintain the desired head and fluid temperature ranges, as the topical agent **140** is delivered along channels **260** while the treatment head **200** is moved across the subject's skin **100**. In these applications, suitable rechargeable power sources are can provide a treatment cycle in the range of a few minutes or more, for example five to ten minutes, or more or less.

(49) In some examples, the contact surface **45** is formed of a metal or similar thermally and electrically conducting material, for example by stamping. In other examples, the head **200** can be built with a metal or similar thermally conductive material along the channels **260** adjacent the thermal elements **360**, and other portions of the contact element **250** adjacent the skin **100** may be formed of thermally and/or electrically insulating materials, for example using a two-piece metal/plastic or composite contact element **250**, or other suitable multi-component form.

(50) Suitable contact elements **250** can be formed with different components having different thermal conductivities, or with a substantially uniform conducting material. Suitable thermal elements **360** can be operated to modulate the temperature of the contact elements **250** at different

positions along the treatment head **200**; maintaining a temperature profile **256** between the individual thermal elements **360** disposed along the treatment surface **255**. For example, the temperature profile **256** can be controlled to define a thermal gradient **258** between the proximal ridge or groove structures **260**, spaced from the subject's skin **100**, and the lands or similar distal portions **265** of the textured or patterned treatment surface **255**, adjacent the subject's skin **100**. The temperature profile **256** can be controlled as the head **200** moves across the skin **100**, in response to heat absorption through the skin **100**, at the nominal skin temperature. Further, the thermal gradient **258** can be generated using a either one-component contact element **250** (e.g., with a metal contact surface **255**), or two-component design (e.g., a metal stamped channel structure **260**, with plastic or composite skin contact material in the distal or land portions **265**, adjacent the skin **100**).

(51) In some of these applications, the temperature of the topical agent **140** in channels **260** may increase to about 50-55 C, or up to 60 C, in order to increase activation chemistry in active treatment components of the agent **140**. Activation chemistry can be very sensitive to temperature, and the treatment components of topical agent **140** can be activated at higher temperature (e.g., up to 60 C) in the channels **260**, spaced from the skin **100**, then delivered to skin at lower (more comfortable) application temperature range, along the pads or lands **265** adjacent the skin **100**.

(52) In addition to ionization, increased fluid temperature can also affect molecular structure (e.g., resulting in the release of active ingredients in a "caged" molecular structure, or by releasing one or more active topical components that react readily at relative higher fluid temperature in the grooves **260**, adjacent the thermal elements **360** and spaced from the subject's skin **100**, and then are applied to the skin **100** at relatively lower fluid temperatures along the lands or pads **265**, adjacent the skin **100**).

(53) In other examples, thermal elements **360** can be provided as a combination or resistive heating and Peltier devices or similar elements **360** adapted to heat one or more skin contact elements **250**, or regions within a given element **250**, and to cool one or more other contact elements **250**, or other regions within a given element **250**. This arrangement can be used to enhance the thermal gradient **258** in the topical agent **140** between the subject's skin **100** and the channels **260**, spaced from the skin **100**. This arrangement can also be used to modulate the temperate of one or more contact elements **250**, or different regions within a given element **250**, so that the subject experiences different temperatures along or adjacent different pads or lands **265**, as the treatment head **200** moves across the skin **100**.

(54) Generally, the use of heating channels or other structures **260** to introduce a thermal gradient **258** in the topical agent **140** provides for a more advanced approach to topical skin treatment, defining an in-situ reaction chamber to activate the topical agent **140** at one temperature, and deliver agent **140** to the skin **100** at another temperature. The thermal gradient **258** can be defined to heat the agent **140** to a higher temperature for activation, and to lower the temperature of the agent **140** for application to the skin **100**.

(55) Single or multiple skin contact pads or similar elements **250** can be used in a given head **200**. The substantially linear or lineal thermal elements **360** can also be replaced with "buttons" or other discrete structures, or with a resistive plate. One or more regions of the treatment head **200** could also be uniform in temperature profile, or comprise a combination of different heated or temperature modulated regions and unheated or unmodulated regions, with textured, patterned or smooth application surfaces **255**. For example, the head **200** can be provided with regions of the contact element **250** heated to a temperature range selected to open pores and encourage vasodilation, and other regions cooling to a temperature range selected to close pores and encourage vasoconstriction, while promoting iontophoretic delivery and enhanced permeability for active skin treatment components in the topical agent **140**.

(56) FIGS. 7A and 7B are alternate plan views of a thermally modulated treatment head **200** for a skin treatment device **150**, illustrating different configurations for the thermal control components **160**. In the example of FIG. 7A, thermal components **160** are provided in the form of one or more

“buttons” or similar discrete elements **360**; e.g., disposed on the upper (interior) surface of the contact element **250**, inside the housing of device **205**, and opposite the textured or patterned application surface, which is adjacent the subject's skin. Alternatively, oblong, rectangular, oval, or continuous-plate elements **360** can be used.

(57) FIG. 7B shows a plan view illustrating the application surface **255** of a skin treatment device **150**, on the outer side of the contact element **250**, adjacent the skin surface, and opposite the view of FIG. 7A. As shown in FIG. 7B, application surface **250** can incorporate one or more substantially round, semi-spherical, or elongate, lobed emitters or electrodes **155**; e.g., as described in U.S. Design patent application Ser. No. 29/819,521, “Skin Treatment Device,” filed Dec. 15, 2021, which is incorporated by reference herein. In these examples, one, two or more pairs of electrodes **155** can be provided on contact element **250**, and operated at opposite polarities to deliver a microcurrent treatment to the adjacent skin surface.

(58) One or more thermal components **160** can be incorporated into the textured or patterned application surface **250** adjacent the electrodes **155**, for example in the form of discrete thermal elements **360** disposed on the opposite side of the application surface **250**, inside the housing of device **150**, as shown in FIG. 7A, and spaced from the skin surface with the respect to the electrodes **155**. Alternatively, one or more thermal components **160** can be disposed within the electrodes **155**, or in other locations along the contact surface **205**, in any of the other configurations described herein.

(59) FIG. 8A is a thermal image or heat map of a thermally modulated skin treatment head **200**, illustrating a three-dimensional temperature profile **256** defined along or across the textured or patterned application surface **255**. As shown in FIG. 8A, the temperature profile **256** is defined both between the two skin contact elements **250**, and between different textured or patterned regions of each individual application surface **255**. In this particular example, the temperature tends to be relatively higher in the front contact element **250** (right side of image), as compared to the back contact element **250** (left side of image).

(60) In addition, the temperate profile **256** may tend to be relatively higher proximate the grooved structures **260**, spaced from the skin surface, and relatively lower proximate the pads or lands **265**, adjacent the skin surface. This defines a thermal gradient in the adjacent topical agent; e.g., as achieved by selected placement of the thermal elements to increase temperature-dependent chemical activity for the topical agent in the grooves **260**, spaced from the skin surface, and a relatively lower temperature proximate the lands or **265**, where the topical agent is in contact with the subject's skin.

(61) FIG. 8B is an alternate thermal image or heat map of a skin treatment head **200** with a thermally modulated skin contact element **250**, illustrating the temperature profile **256** between different regions of the textured or patterned application surface **255**. In this example, the orientation of the skin contact element **250** is reversed, with heat distributed via a flat conducting plate (e.g. a solider copper plate or similar conducting element) disposed on the back side of the application surface **255**, opposite the surface shown in FIG. 8B. As a result, the temperature profile **256** typically defines relatively higher temperatures proximate the lands or valleys **265**, adjacent the heat plate, and relatively lower temperatures proximate the grooved or ridged structures **260**, spaced from the heat plate.

(62) FIG. 9A is a perspective view of an alternate skin treatment head **200**, in an oblong or rectangular configuration. In this example, the contact element **250** is disposed within a plastic, polymer or composite frame or housing **152**. The contact element **250** is formed of a conducting metal material, with textured or patterned application surface **255** defined by a series of generally parallel grooves **260** and lands **265**, with ridge-shaped lands **265** disposed between adjacent, complementary valleys or grooves **260**.

(63) In these examples, the contact element **250** can be formed as a corrugated metal stamping disposed within a plastic or composite frame **152**. A heating element can be provided in the form of

a laterally extended plate disposed on the opposite side of the contact element **250**, adjacent the grooves **260** (spaced from the lands **265**), or as a set of linear elements aligned along the grooves **260**. Suitable heating elements include a thermocouple plate adapted to the shape of the contact element **250**, and extending across the grooves **260**, or a set of linear thermocouple elements extending along the individual grooves **260**.

(64) FIG. **9B** is a thermal image or heat map of the skin treatment head **200** and application and contact element **250** in FIG. **9A**, illustrating a temperature profile **256** defining a thermal gradient between different regions of the textured or patterned application surface **255**. As shown in FIG. **9B**, the temperature profile **256** defines a thermal pattern across the application surface **255**; e.g. when the heating element is turned on and the surface **255** is allowed to come to an equilibrium temperature. In this example, the temperature profile is generally higher toward or adjacent the grooves **260**, which are proximate the heating element or elements on the back side, and spaced from the skin surface. The temperature profile is generally lower adjacent the ridges or lands **265**, which are spaced from the heating elements, and proximate the skin surface.

(65) Upon application of a topical agent, a thermal gradient is defined between portions of the topical agent adjacent the grooves **260**, as compared to the lands **265**. Generally, the heat pattern defines hotter spots (higher temperatures) along the grooves or channels **260**, forming a warmed reservoir of topical agent for delivery to the subject's skin, with cooler spots (lower temperatures) along the lands **265**, after the topical agent is applied the skin surface. The topical agent is applied by movement of the application surface **255** across the skin, distributing the topical by a wiping motion from which the topical flows from the grooves or channels **260** (warmer topical agent, spaced from the skin surface), and across the lands **265** (cooler topical agent, adjacent the skin surface).

(66) FIG. **10** is a cross sectional view of a thermally modulated skin treatment head **200**, illustrating an alternate configuration for the thermal control component **160**. In this example, Peltier thermoelectric elements **360** are disposed between adjacent thermal conductors **560**, with elongated configurations extending to the grooved portions **260** of the textured or patterned application surface **255**, spaced from the skin surface, and contact pads or lands **265** adjacent the user's skin. Thermal insulation **520** is provided on exposed portions of the application surface **255**, in order to direct heat toward the topical agent **140**.

(67) A topical agent **140** can be applied to the subject's skin **100**. The thermal elements **360** are controlled to alternately cool and heat the conductors **560** on the adjacent, opposing sides of each element **360**, providing a temperature differential adjacent the grooves **260** and lands **265**. For example, the thermal elements **360** can be oriented to transfer heat from a first conductor **560** extending to a grooved portion **260** of the application surface **255**, to another conductor **560** extending to a contact pad or land **265**.

(68) In this configuration, a temperature profile **256** is controlled along or across the application surface **255** to establish a thermal gradient **258** in the topical agent **140**; e.g., so that the topical agent **140** is relatively warmer in and adjacent the grooves **260**, spaced from the skin surface, and relatively cooler toward the contact pads or lands **265**, adjacent the skin surface. Alternatively the direction of heat flow via elements **360** may be reversed, from the grooves **260** to the lands **265**, so that the thermal gradient **258** defines the topical agent **140** at a relatively cooler temperature in and adjacent the grooves **260**, spaced from the skin surface, and at a relatively warmer temperature toward the contact pads or lands **265**, adjacent the skin surface.

(69) This disclosure is made with respect to representative examples and embodiments. Each can be used either alone or in combination with any other embodiment or example described or illustrated herein, and each may incorporate additional modifications, changes, equivalents, and alternatives that fall within the breadth of disclosure, as read and understood by a person of ordinary skill, and without departing from practice of the invention as claimed. These various examples and embodiments are provided by way of illustration, and should not be construed to

limit the scope of the invention, nor to limit the meets and bounds of coverage as defined by the language of the appended claims.

## Claims

1. A skin treatment device comprising: a thermally modulated treatment head coupled to a housing; one or more thermal elements adapted to generate a temperature profile across the treatment head; a power source adapted to provide current to the thermal elements; and a controller adapted to modulate the temperature profile by controlling the current delivered to the thermal elements; wherein the temperature profile defines different temperatures along different portions of the treatment head; and wherein the controller is adapted to modulate the temperature profile to define a relatively higher temperature along a first portion of the treatment head, spaced from an adjacent skin surface to which the treatment head is applied, and a relatively lower temperature along a second portion of the treatment head, proximate the skin surface.
2. The device of claim 1, where the temperature profile defines a thermal gradient for a topical agent disposed between the treatment head and an adjacent skin surface to which the treatment head is applied.
3. The device of claim 2, wherein the thermal gradient defines a relatively higher reaction temperature of the topical agent in a first region spaced from the skin surface, and a relatively lower application temperature of the topical agent in a second region proximate the skin surface.
4. The device of claim 1, further comprising one or more emitters or electrodes configured to apply an electromagnetic or current waveform to a skin surface adjacent the treatment head.
5. The device of claim 4, further comprising a voltage or current source adapted to generate the waveform for application to the skin surface via the one or more emitters or electrodes, wherein the controller is configured to modulate one or more of a pulse width, pulse period, pulse frequency or amplitude of the waveform in a periodic, random, pseudorandom, non-repeating or aperiodic manner.
6. The device of claim 4, wherein the one or more thermal elements are disposed adjacent the treatment surface inside the housing, spaced from the one or more emitters or electrodes along the treatment surface.
7. The device of claim 1, further comprising one or more thermal sensors adapted to generate temperature data responsive to the temperature profile at or along one or more locations on the treatment head, wherein the controller is configured to maintain or control the temperature profile responsive to the temperature data.
8. The device of claim 1, further comprising a textured or patterned application surface defined on the treatment head, and comprising one or more surface features adapted for application of a topical agent to an adjacent skin surface.
9. The device of claim 8, wherein the controller is adapted to modulate the temperature profile to maintain the topical agent at different temperatures in regions spaced from the skin surface, and proximate the skin surface.
10. The device of claim 8, wherein the thermal elements comprise one or more resistive elements disposed along or adjacent the textured or patterned application surface inside the housing, opposite the skin surface, and adapted to generate the temperature profile responsive to the current.
11. The device of claim 1, wherein the one or more thermal elements are disposed within the housing along or adjacent one or more grooves or recesses defined in the treatment head, and spaced from one or more ridges or lands defined adjacent or between the one or more grooves or recesses.
12. The device of claim 1, wherein the thermal elements comprise one or more Peltier devices configured to transfer heat from a first region of the treatment head to a second region of the treatment head, wherein: the first region is proximate a skin surface adjacent the treatment head and

the second region is spaced from the skin surface, or wherein the first and second regions successively contact a skin surface responsive to motion of the treatment head across the skin surface.

13. A skin treatment method comprising: disposing a thermally modulated treatment head adjacent a skin surface, wherein one or more thermal elements are adapted to generate a temperature profile across the treatment head; and moving the treatment head across the skin surface, wherein the temperature profile is modulated to define different temperatures along different portions of the treatment head; wherein the temperature profile is modulated to define a relatively higher temperature along a first portion of the treatment head, spaced from the skin surface, and a relatively lower temperature along a second portion of the treatment head, proximate the skin surface.

14. The method of claim 13, further comprising applying a topical agent to the skin surface, wherein the temperature profile defines a thermal gradient in the topical agent with a relatively higher temperature in a region spaced from the skin surface, and a relatively lower temperature in a region proximate the subject's skin surface.

15. The method of claim 13, wherein an electromagnetic or current waveform is applied to the skin surface via one or more emitters or electrodes disposed on the treatment head.

16. The method of claim 15, wherein one or more of a pulse width, pulse period, pulse frequency or amplitude of the waveform is modulated in a periodic, random, pseudorandom, non-repeating or aperiodic manner.

17. The method of claim 15, wherein the one or more thermal elements are disposed adjacent the treatment surface inside the housing, spaced from the one or more emitters or electrodes along the treatment surface.

18. The method of claim 13, wherein the treatment head defines a textured or patterned surface having one or more surface features adapted for application to the skin surface.

19. A device comprising: a thermally modulated treatment head coupled to a housing, the treatment head comprising a treatment surface adapted for application to a skin surface; a pattern of grooves, channels, lobes or lands defined in the treatment surface; one or more thermal elements adapted for generating heat adjacent the pattern, wherein a temperature profile is defined across the treatment head; a power source adapted to provide current to the thermal elements; and a controller configured for modulating the temperature profile defined across the treatment surface by controlling current delivered to thermal elements; wherein the temperature profile defines different temperatures along different portions of the treatment head, and along the pattern; and wherein the controller is adapted to modulate the temperature profile to define a relatively higher temperature along a first portion of the treatment head, spaced from an adjacent skin surface to which the treatment head is applied, and a relatively lower temperature along a second portion of the treatment head, proximate the skin surface.

20. The device of claim 19, wherein at least a portion of the skin contact surface is formed of an electrically conductive material adapted for current delivery to the skin surface.

21. The device of claim 19, wherein the pattern of grooves, channels, lobes or lands define flow structures adapted for application of a topical agent to the skin surface.

22. The device of claim 19, wherein the thermal elements comprise one or more resistive heating elements disposed along one or more of the grooves, channels, lobes or lands.

23. The device of claim 22, wherein the thermal elements are embedded in or disposed adjacent a layer of material configured to hold the resistive heating elements along the one or more of the grooves, channels lobes or lands, in spaced relation to one or more others of the grooves, channels, lobes or lands, said material being one or more of electrically insulating, thermally conductive, or thermally insulating.

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