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IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

3GEN, INC., a California corporation, Plaintiff vs. CANFIELD SCIENTIFIC, INC., a New Jersey corporation; and DOES 1 through 10, inclusive, Defendants	Case No. 13-CV-00631 DOC (JPRx) **FIRST AMENDED COMPLAINT FOR INJUCTION AND DAMAGES FOR:** **1. PATENT INFRINGEMENT OF U.S. PATENT NO. 7,167,243** **2. PATENT INFRINGEMENT OF U.S. PATENT NO. 7,167,244** **DEMAND FOR JURY TRIAL**

AMENDED COMPLAINT

Plaintiff 3GEN, INC. ("3GEN" or "Plaintiff"), for its First Amended Complaint against CANFIELD SCIENTIFIC, INC. ("Canfield") and DOES 1 through 10, inclusive (collectively Canfield and DOES 1 through 10 referred to as "Defendants") states and alleges as follows:

PARTIES

1. 3GEN is a corporation organized and existing under the laws of the state

of California, and having a principal place of business at 31521 Rancho Viejo Rd., # 104, San Juan Capistrano, California 92675.

2. Upon information and belief, Defendant Canfield, is a corporation organized and existing under the laws of the state of New Jersey, and having a principal place of business at 253 Passaic Avenue, Fairfield, New Jersey 07004.

3. The true names and capacities of the Defendants named herein as DOES 1 through 10, whether individual, corporate, associate, or otherwise, are unknown to Plaintiff, who therefore sues said Defendants by said fictitious names. Plaintiff is informed and believes, and thereon alleges, that each of the Defendants designated herein as DOE is legally responsible for the events and happenings hereinafter alleged and legally caused injury and damages proximately thereby to Plaintiff as herein alleged. Plaintiff will seek leave to amend the Complaint when the true names and capacities of said DOE Defendants have been ascertained.

4. Plaintiff is informed and believes, and on that basis alleges, that each of the Defendants participated in and is in some manner responsible for the acts described in this Complaint and any damages resulting therefrom.

5. Plaintiff is informed and believes, and on that basis alleges, that each of the Defendants has acted in concert and participation with each other concerning each of the claims in this Complaint.

6. Plaintiff is informed and believes, and on that basis alleges, that each of the Defendants were empowered to act as the agent, servant and/or employees of each of the other Defendants, and that all the acts alleged to have been done by each of them were authorized, approved and/or ratified by each of the other Defendants.

JURISDICTION AND VENUE

7. This action, as hereinafter more fully appears, arises under the patent laws of the United States of America, namely under Title 35, United States Code (35 U.S.C. §§1, *et seq.*), and is for patent infringement. Jurisdiction for all counts is based upon 28 U.S.C. §§1331, 1338(a).

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8. Venue is proper with this Court pursuant to 28 U.S.C. §§1391(b) and (c) and/or 28 U.S.C. §1400(b) as Defendants reside in this judicial district, and/or a substantial part of the events, omissions or acts which are the subject matter of this action occurred within this judicial district and/or a substantial part of the property that is the subject of this action is located in this judicial district.

BACKGROUND OF THE CONTROVERSY

9. Plaintiff is an industry leader and innovator of hand held dermoscopy devices used in dermatological examinations. Plaintiff is the owner, with the right to sue for infringement, of United States Patent Nos. 7,167,243 and 7,167,244, both related to hand held dermoscopy devices. Copies of such patents are attached hereto as Exhibits 1-2, respectively.

10. Upon information and belief, Defendants have been making, selling, using, importing and/or offering for sale in the United States the product identified as the "VEOS HD2" Polarized and Non-Polarized Light Dermatoscope. A printout of a page of Canfield's website showing Canfield's VEOS HD2 product (hereinafter the "VEOS HD2") is attached hereto as Exhibit 3. Canfield's VEOS HD2 product infringes Plaintiff's United States Patent Nos. 7,167,243 and 7,167,244.

11. Upon information and belief, Defendants have been making, selling, using, importing and/or offering for sale in the United States the product or products identified as the "DermScope" Dermoscopy Attachment for iPhone 4 and/or iPhone 4S. Attached hereto as Exhibits 4-5 are copies of the covers of product inserts of two iterations of Defendant's DermScope products (hereinafter the "DermScope Products"). Canfield's DermScope Products infringe Plaintiff's United States Patent Nos. 7,167,243 and 7,167,244.

12. Upon information and belief, Defendants have been making, selling, using, importing, and/or offering for sale in the United States the product or products identified as the "VEOS DS3" Digital Dermatoscope with Integrated iPod Touch. A printout of a page of Canfield's website showing Canfield's VEOS DS3 product

(hereinafter the "VEOS DS3") is attached hereto as Exhibit 6.

13. Upon information and belief, Canfield manufactures all VEOS HD2 products in the United States.

14. Upon information and belief, Canfield manufactures all DermScope Products in the United States.

15. Upon information and belief, Canfield manufactures all VEOS DS3 products in the United States.

FIRST CLAIM FOR RELIEF

(Patent Infringement of U.S. Patent No. 7,167,243)

16. Plaintiff realleges and repeats the allegations set forth in paragraphs 1-15, inclusive, and incorporates such allegations herein by reference.

17. Plaintiff is the owner of all right, title and interest in and to United States Patent No. 7,167,243 entitled "Dermoscopy Epiluminescence Device Employing Cross and Parallel Polarization" (hereinafter "the '243 Patent"). A true and correct copy of the '243 Patent is attached hereto as Exhibit 1. The '243 Patent was duly and lawfully issued on January 23, 2007 and is presently valid and in full effect.

18. Upon information and belief, Defendants have been and are infringing the '243 Patent in the United States by making, using, selling, importing, distributing and/or offering for sale products that contain each and all of the elements of one or more claims of the '243 Patent. In particular, at least the Canfield VEOS HD2 products, the Canfield DermScope products, and the Canfield VEOS DS3 products infringe one or more of the claims of the '243 Patent.

19. Upon information and belief, Defendants are contributorily infringing the '243 Patent in the United States by making, using, selling, importing, distributing or offering for sale in the United States materials and/or apparatus for use in practicing the inventions set forth in the '243 Patent, that they know to be especially made or especially adapted for use in infringement of the invention embodied in the '243 Patent. Upon information and belief, these materials and/or apparatus have no

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substantial non-infringing use in commerce.

20. Upon information and belief, Defendants are inducing infringement of the '243 Patent in the United States by instructing in the use of materials and/or apparatus that infringe one or more of the claims of the '243 Patent.

21. Upon information and belief, by the acts of patent infringement herein complained of, the Defendants have made substantial profits to which they are not equitably entitled.

22. By reason of the aforementioned acts of the Defendants, the Plaintiff has suffered great detriment in a sum which exceeds this Court's jurisdictional amount, but which cannot be ascertained at this time.

23. Upon information and belief, Defendants continue to infringe Plaintiff's '243 Patent, and will continue to infringe Plaintiff's '243 Patent, and will continue to infringe Plaintiff's '243 Patent to Plaintiff's irreparable harm, unless enjoined by this Court.

24. Any continuing infringement of the '243 Patent by Defendants after receiving notice of the '243 Patent will be willful, entitling Plaintiff to enhanced damages.

SECOND CLAIM FOR RELIEF

(Patent Infringement of U.S. Patent No. 7,167,244)

25. Plaintiff realleges and repeats the allegations set forth in paragraphs 1-24, inclusive, and incorporates such allegations by reference.

26. Plaintiff is the owner of all right, title and interest in and to United States Patent No. 7,167,244 entitled "Dermoscopy Epiluminescence Device Employing Multiple Color Illumination Sources" (hereinafter "the '244 Patent"). A true and correct copy of the '244 Patent is attached hereto as Exhibit 2. The '244 Patent was duly and lawfully issued on January 23, 2007, and is presently valid and in full effect.

27. Upon information and belief, Defendants have been and are infringing the '244 Patent in the United States by making, using, selling, importing, distributing

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and/or offering for sale products that contain each and all of the elements of one or more claims of the '244 Patent. In particular, at least the Canfield VEOS HD2 products, the Canfield DermScope products, and the Canfield VEOS DS3 products infringe one or more of the claims of the '244 Patent.

28. Upon information and belief, Defendants are contributorily infringing the '244 Patent in the United States by making, using, selling, importing, distributing or offering for sale in the United States materials and/or apparatus for use in practicing the inventions set forth in the '244 Patent, that they know to be especially made or especially adapted for use in infringement of the invention embodied in the '244 Patent. Upon information and belief, these materials and/or apparatus have no substantial non-infringing use in commerce.

29. Upon information and belief, Defendants are inducing infringement of the '244 Patent in the United States by instructing in the use of materials and/or apparatus that infringe one or more of the claims of the '244 Patent.

30. Upon information and belief, by the acts of patent infringement herein complained of, the Defendants have made substantial profits to which they are not equitably entitled.

31. By reason of the aforementioned acts of the Defendants, the Plaintiff has suffered great detriment in a sum which exceeds this Court's jurisdictional amount, but which cannot be ascertained at this time.

32. Upon information and belief, Defendants continue to infringe Plaintiff's '597 Patent, and will continue to infringe Plaintiff's '244 Patent to Plaintiff's irreparable harm, unless enjoined by this Court.

33. Any continuing infringing of the '244 Patent by Defendants after receiving notice of the '244 Patent will be willful, entitling Plaintiff to enhanced damages.

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PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendants as follows:

A. A judgment that Defendants have infringed, contributorily infringed, and/or induced infringement of the patents-in-suit.

B. A judgment that Defendants' infringement of the patents-in-suit has been willful.

C. A preliminary and permanent injunction, pursuant to 35 U.S.C. §283, enjoining Defendants, and all persons in active concert or participation with them, from any further acts of infringement, contributory infringement or inducement of infringement of the patents-in-suit.

D. A preliminary and permanent injunction enjoining Defendants, and all persons in active concert or participation with them, from any and all making, using, selling, offering of sale or importing of the following Canfield Scientific, Inc. products: the VEOS HD2 products; the DermScope products; and the VEOS DS3 products.

E. An order, pursuant to 35 U.S.C. §284, awarding Plaintiff damages adequate to compensate Plaintiff for Defendants' infringement of the patents-in-suit, in an amount to be determined at trial, but in no event less than a reasonable royalty.

F. An order, pursuant to 35 U.S.C. §284, trebling all damages awarded to Plaintiff based on Defendants' willful infringement of the patents-in-suit.

G. An order, pursuant to 35 U.S.C. §285, finding that this is an exceptional case and awarding to Plaintiff its reasonable attorneys' fees incurred in this action.

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H. That Plaintiff have such other and further relief that the Court may deem just and proper.

Dated: August 21, 2013

STETINA BRUNDA GARRED & BRUCKER

By: _____

William J. Brucker
Attorney for Plaintiff
3GEN, INC.

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DEMAND FOR JURY TRIAL

Plaintiff 3Gen, Inc. hereby demands a jury trial in this action.

Dated: August 21, 2013

STETINA BRUNDA GARRED & BRUCKER

By: _____
William J. Brucker
Attorney for Plaintiff
3GEN, INC.

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US007167243B2

(12) **United States Patent**
Mullani

(10) **Patent No.: US 7,167,243 B2**
(45) **Date of Patent: *Jan. 23, 2007**

(54) **DERMOSCOPY EPILUMINESCENCE DEVICE EMPLOYING CROSS AND PARALLEL POLARIZATION**

(75) Inventor: **Nizar A. Mullani**, Sugar Land, TX (US)

(73) Assignee: **3gen, LLC.**, Dana Point, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **11/345,142**

(22) Filed: **Feb. 1, 2006**

(65) **Prior Publication Data**

US 2006/0132774 A1 Jun. 22, 2006

Related U.S. Application Data

(63) Continuation of application No. 10/384,110, filed on Mar. 7, 2003, now Pat. No. 7,006,223.

(51) **Int. Cl.**
G01J 4/00 (2006.01)

(52) **U.S. Cl.** **356/369**; 600/476; 606/9

(58) **Field of Classification Search** 356/364–369, 356/445–448, 39; 600/9, 306, 340, 476, 600/477; 362/19, 138–140; 359/501, 493, 359/368, 385, 390
See application file for complete search history.

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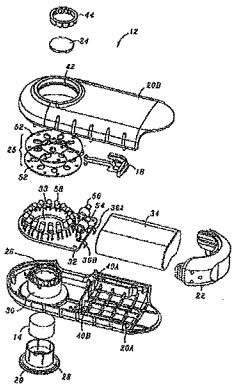
Primary Examiner—Hoa Q. Pham
(74) *Attorney, Agent, or Firm*—Stetina Brunda Garred & Brucker

(57) **ABSTRACT**

The present invention is a hand held dermoscopy epiluminescense device with a magnification lens and an associated ring of luminous diodes powered by an on board battery. Every other diode in the ring operates as first and second light sources. The even diodes are filtered by a first polarization ring and the odd diodes are filtered by a second polarization ring. Each polarization ring has an open center for the lens and openings sized and positioned to correspond to the even or odd diodes to only filter one set. A viewing polarizer is provided and is cross-polarized relative to the first polarization ring and is parallel-polarized with the second polarization ring. A three way switch which provides on demand cross-polarized, parallel-polarized and a combination thereof for epiluminescence. A second embodiment provides even diodes of a first color and odd diodes of a second color. A third embodiment employs the alternating colored diodes of the second embodiment as well as the cross and parallel polarization of the light from the diodes as found in the first embodiment.

26 Claims, 6 Drawing Sheets



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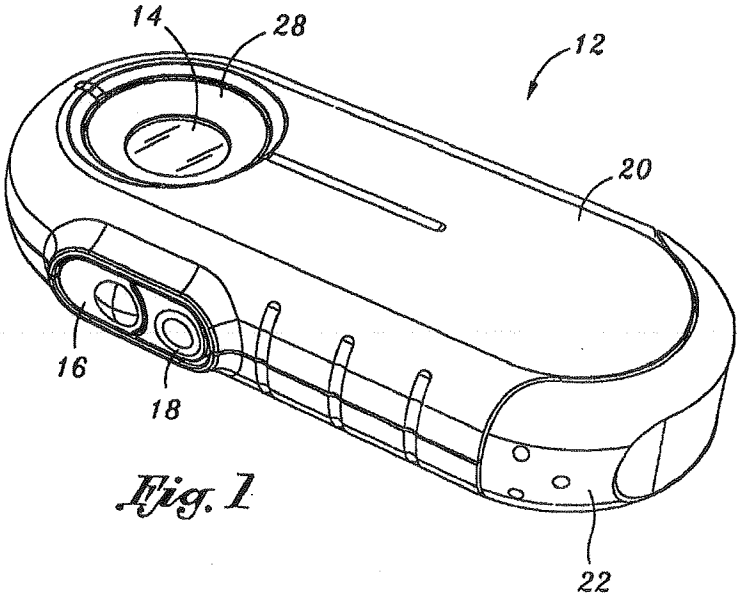

Fig. 1

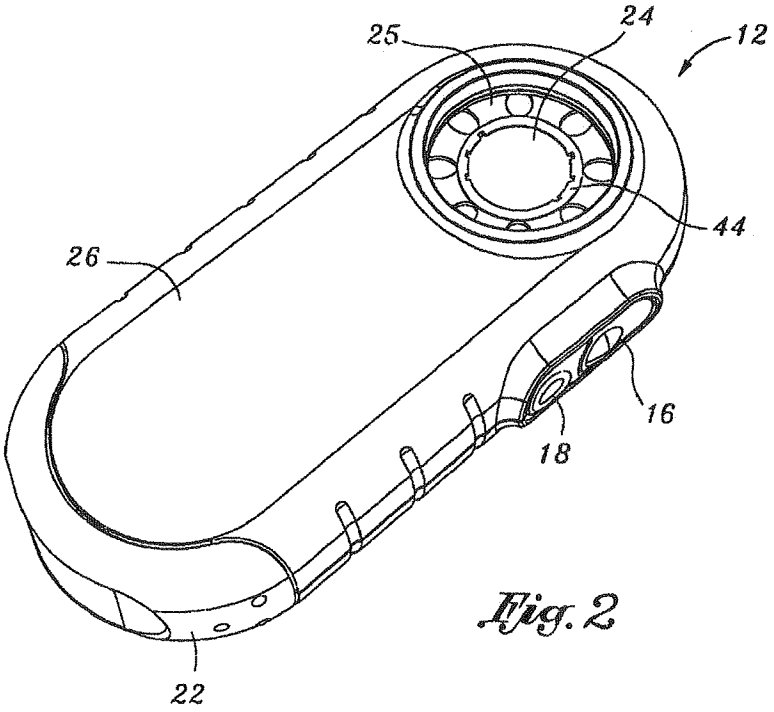

Fig. 2

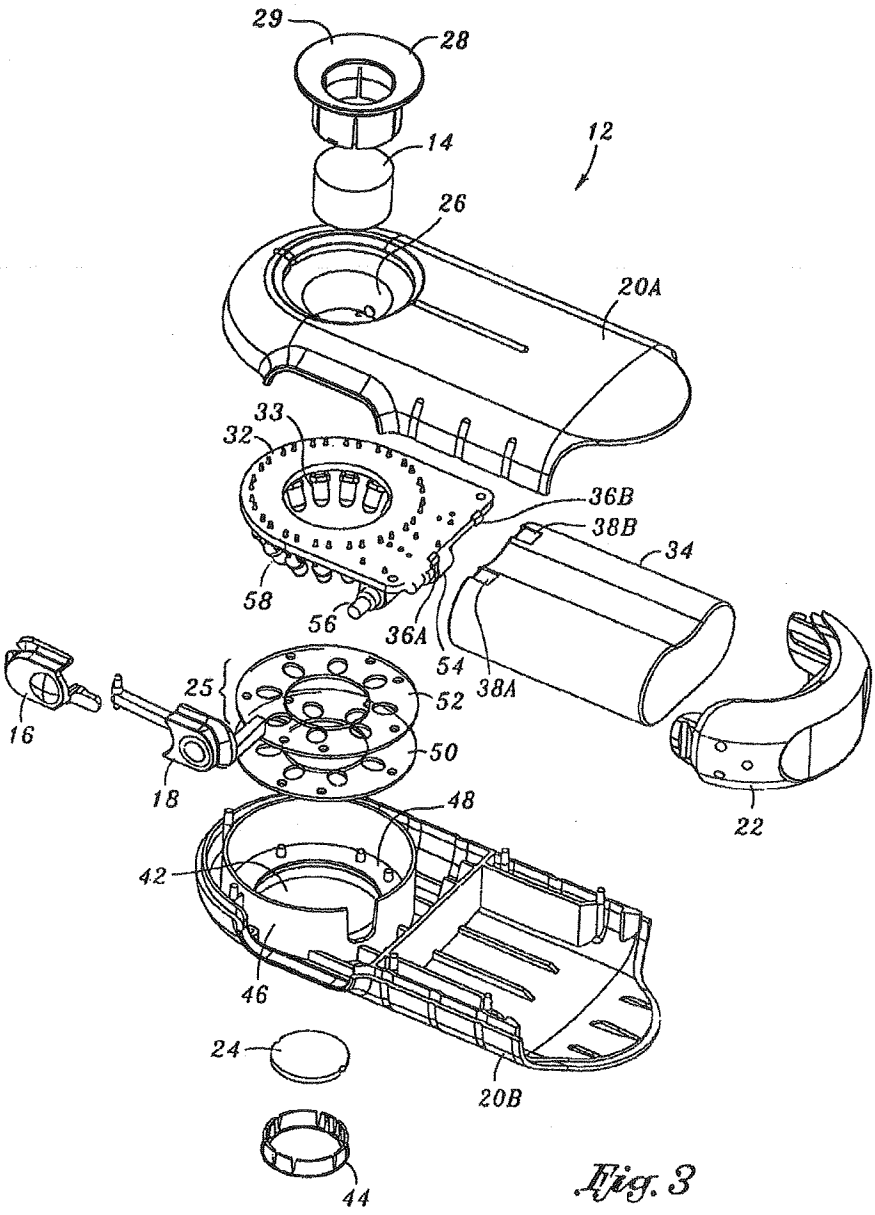
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Fig. 3

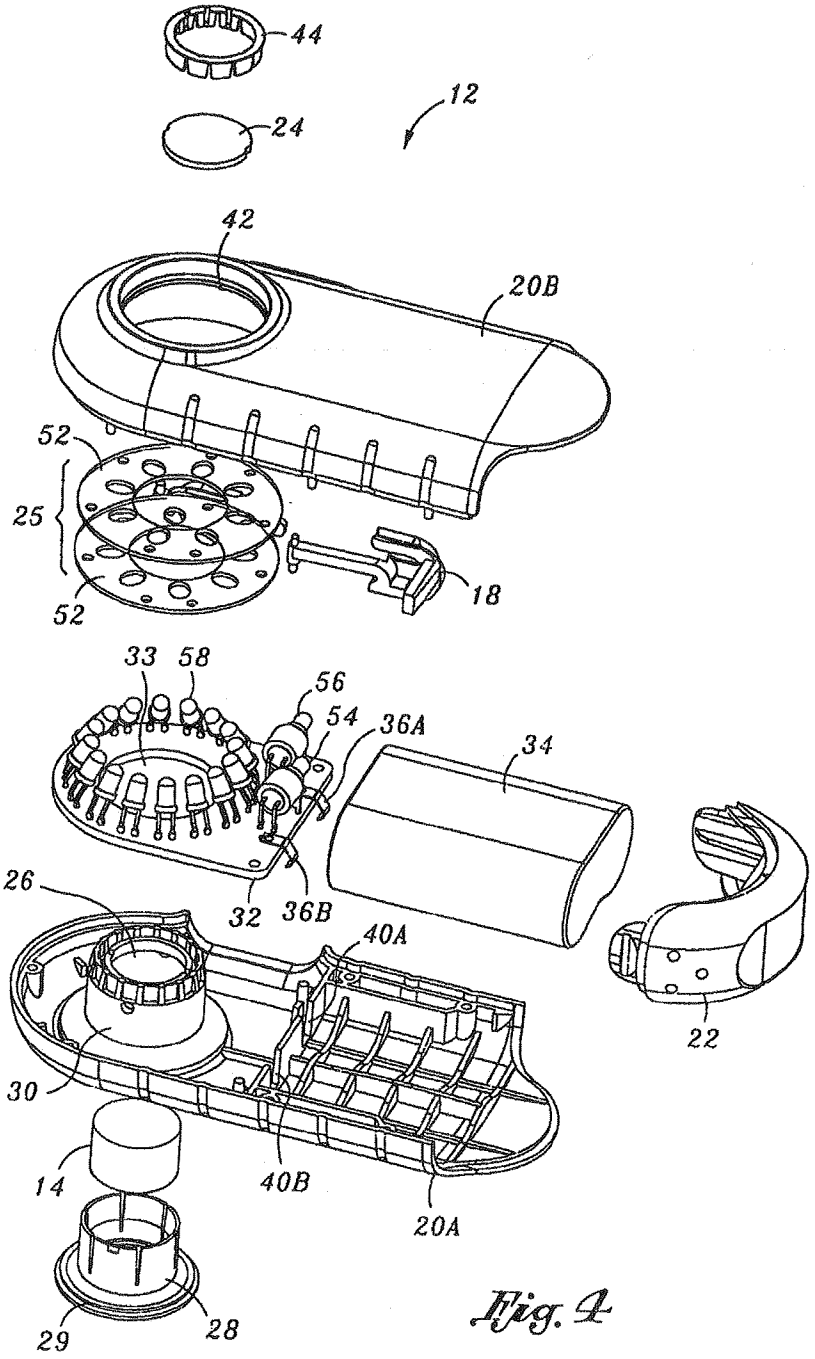
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Fig. 4

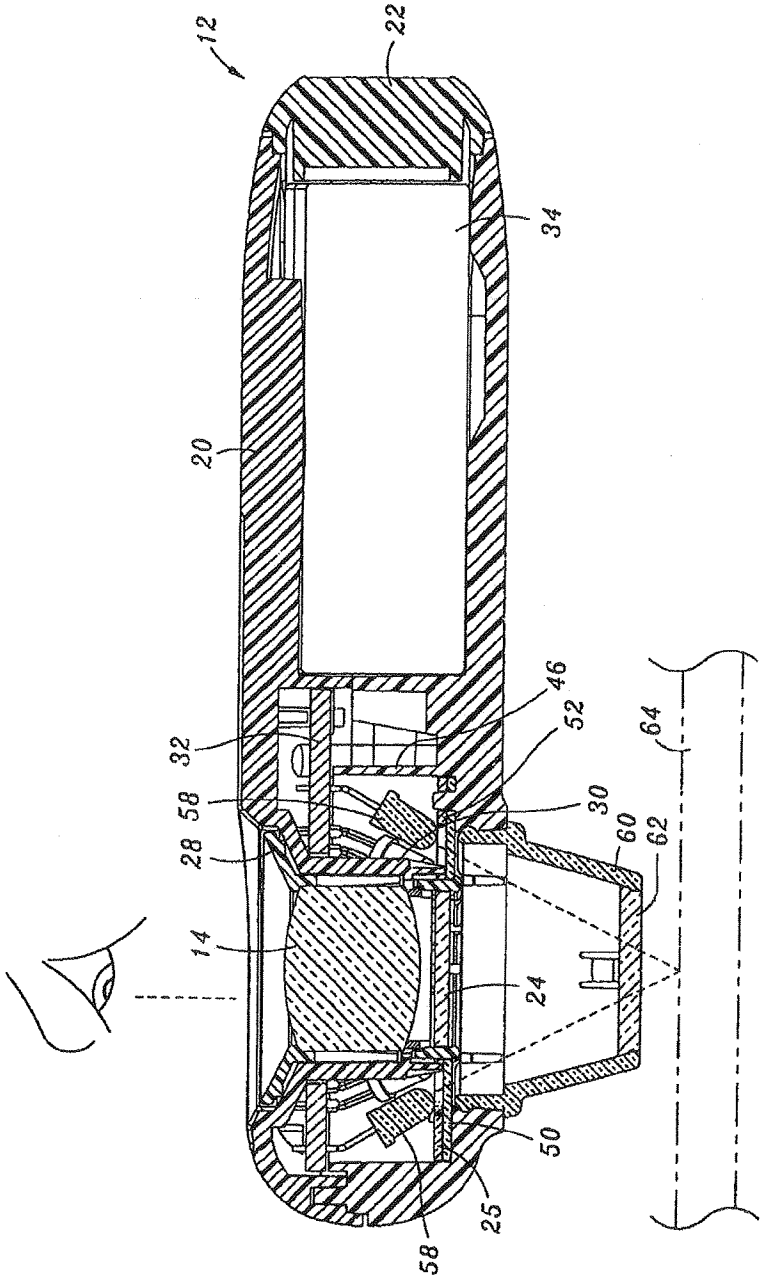

Fig. 5

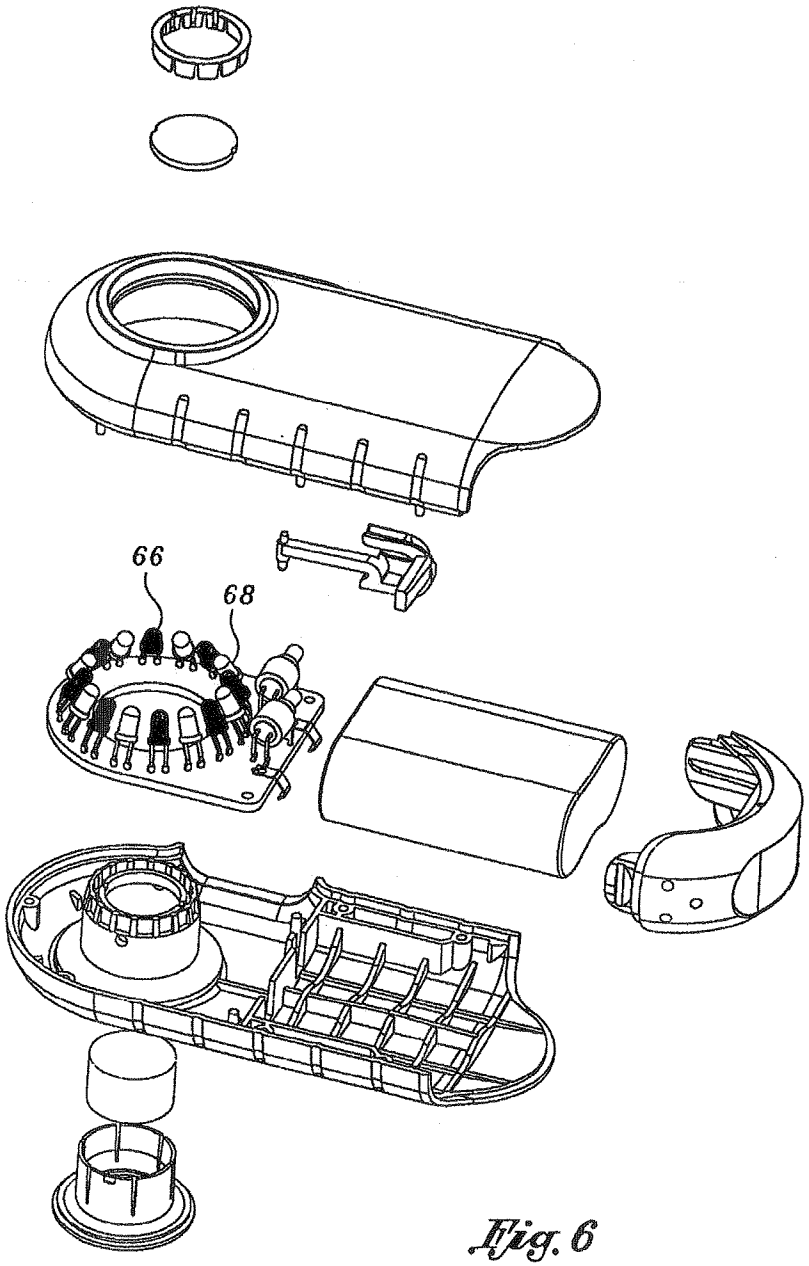

Fig. 6

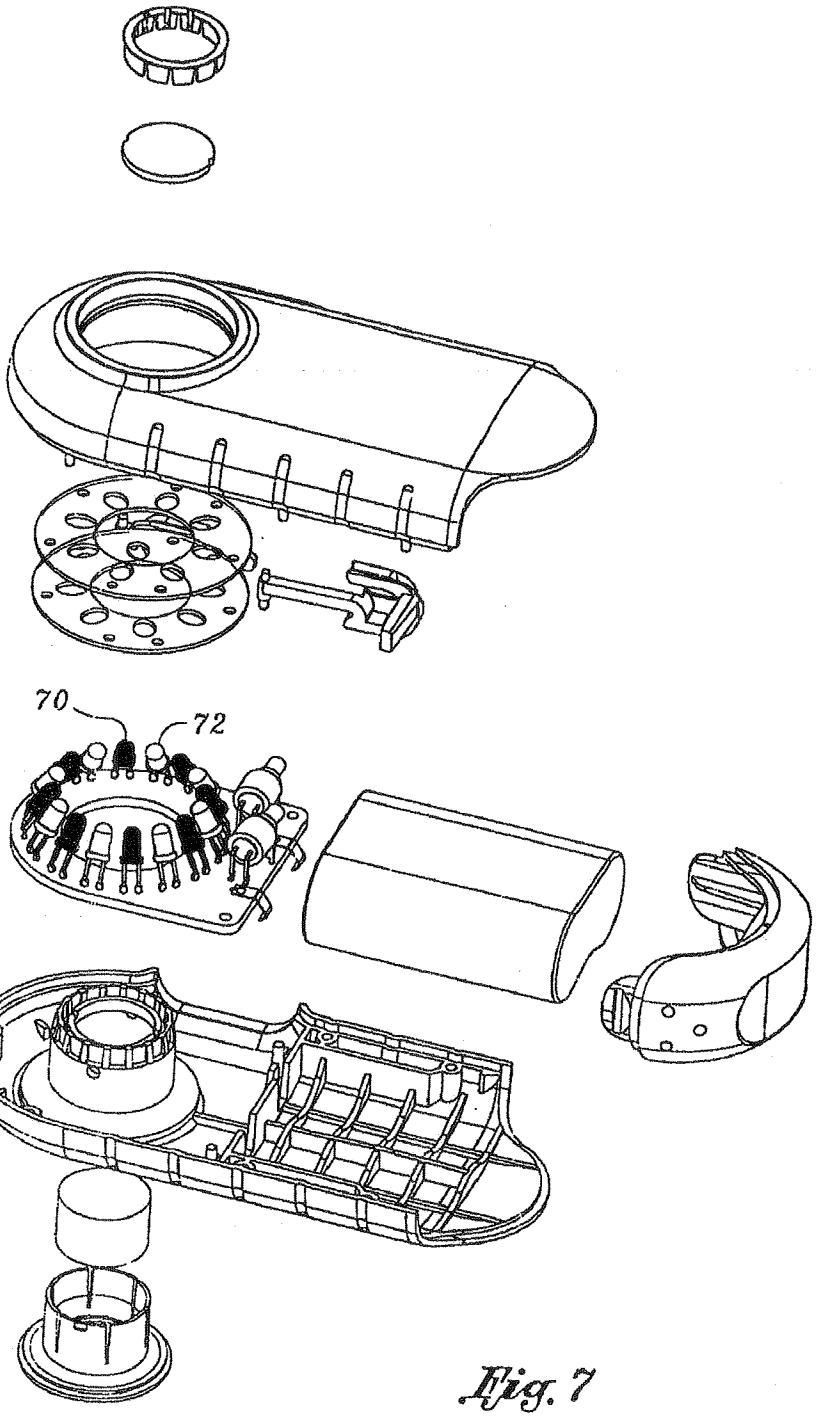

Fig. 7

DERMOSCOPY EPILUMINESCENCE DEVICE EMPLOYING CROSS AND PARALLEL POLARIZATION

CROSS-REFERENCE TO RELATED APPLICATIONS

This is a continuation application of U.S. patent application Ser. No. 10/384,110 filed on Mar. 7, 2003 and issued Feb. 28, 2006 as U.S. Pat. No. 7,006,223 entitled Dermoscopy Epiluminescence Device Employing Cross and Parallel Polarization, the substance of which is relied upon and incorporated herein by reference.

STATEMENT RE: FEDERALLY SPONSORED RESEARCH/DEVELOPMENT

(Not Applicable)

FIELD OF THE INVENTION

The present invention relates generally to an epiluminescence device used in dermoscopy. More particularly, the invention comprises an improved apparatus for illuminating the skin for medical examination by providing cross-polarized and parallel-polarized light to aid in viewing internal structures as well as the skin surface.

BACKGROUND OF THE INVENTION

Dermoscopy is the term used to describe methods of imaging skin lesions. Skin is the largest organ in the body and it is the most easily accessible organ for external optical imaging. For early detection of cancers, it is important that the skin be medically examined for lesions.

With over forty (40%) percent of the cancers occurring on the skin (American Cancer Society Statistics 2001, Perelman 1995), and incidence of skin cancer increasing each year, tools and methods of imaging skin lesions are becoming increasingly important. Most of the cancers detected on the skin are Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SSC), which are differentiated from melanoma, a more deadly form of skin cancer. The early detection of skin cancer allows for inexpensive treatment before the cancer causes more severe medical conditions. Thus, there is a great need in the art for simple inexpensive instruments that allow for the early screening for skin cancer.

Because skin is partially translucent, dermoscopy utilizes tools for visualization of the pigmentation of the skin below the surface. In this regard, when attempting to visualize the deeper structure of the skin, it is important to reduce the reflection of light from the skin which may obscure the underlying structures. Methods used to reduce the surface reflection from the skin are referred to as epiluminescence imaging. There are three known methods for epiluminescence imaging of the skin, oil-immersion, cross-polarization, and side-transillumination. Oil-immersion and cross-polarization methods have been extensively validated for early skin cancer detection while side transillumination methods are currently undergoing study and clinical validation.

Oil-immersion devices are generally referred to as Dermatoscopes. Dermatoscopes permit increased visualization of sub surface pigmentation by using a magnification device in association with a light source. In operation, oil is placed between the skin and a glass faceplate. The placement of oil and a glass interface between the eye and the surface of the skin reduces the reflected light from the skin, resulting in deeper visualization of the underlying skin structure.

While oil-immersion has proved to be an excellent method of epiluminescence imaging of the skin, demonstrating improved sensitivity for melanoma detection, it is messy and time consuming for the physician. As a result, the Dermatoscope is used mostly by physicians that specialize in pigmented lesions and for evaluation of suspicious lesions that cannot be diagnosed visually. Also, the oil-immersion of the Dermatoscope has been found to be less effective for BCC and SCC imaging. The pressure created by the compression of the glass faceplate causes blanching of blood vessels in the skin resulting in reduced capability of the Dermatoscope for imaging the telangiectesia that is often associated with BCC or other malignent lesions.

Cross-polarization or orthogonal polarization is another method of reducing the reflection of the light from the surface of the skin to aid in the medical examination of the skin. Light emanating from a light source is first linearly polarized, so that the orientation of the light falling on the skin surface is in the same plane of polarization. As the light enters the skin, its polarization angle changes such that the light is reflected from a deeper structure. However, the light reflected from the surface of the skin is still polarized in the same plane as the incident light. By including a second polarizer in the path of the reflected light from the skin, a selective filtering of light can be achieved.

Most of the light directed to the skin's surface is reflected as the refractive index of skin is higher than that of air. The reflection of light, off of the skin, is analogous to the reflection of light off of the surface of water. Accordingly, the information received by the eye carries mostly information about the contour of the skin surface rather than the deeper structures. Remaining light enters the skin and is absorbed or is reflected back in a scattered fashion. By polarizing the incident light with a second of polarizer, the specular component of the reflected light is blocked by the viewing polarizer, thus producing an enhanced view below the skin surface. Accordingly, inflammation, color, pigmentation, hair follicles and blood vessels may be viewed.

When the incident light and the second polarizer are parallel, the surface topography and properties of the skin are highlighted and enhanced. In this regard, if the polarizer in the path of the light from the skin to the eye is polarized in the same orientation of the incident light, only the light from its polarization angle will be allowed to pass through the lens. Cross-polarization imaging of the body was originally described by R. R. Anderson ("Polarized light examination and photography of the skin." Archives Dermatology 1991; 127; 1000–1005). Later, Binder introduced the MoleMax manufactured by Derma Instruments (Vienna, Austria) for the examination and mapping of pigmented lesions. Binder further developed the no-oil cross-polarization epiluminescence method. MoleMax, however, while validating clinically the improved diagnosis and accuracy without the use of oil, still used a glass faceplate and video imaging system to execute skin examinations.

In light of many of the difficulties associated with prior dermoscopy systems, a simple and cost-effective diagnostic systems remained unavailable for general dermatologists to use on a routine clinical basis. Dermoscopy, until recently, remained generally a research tool utilized in special clinical cases.

More recently, however, a substantial advancement in skin cancer detection occurred through a simple device identified as DermLite®, manufactured and marketed by

3Gen, LLC. of Monarch Beach, Calif. With this low cost and easy to use DermLite® Device, screening for cancer by dermatologists in routine clinical examination of skin disease has become a reality. The DermLite® device uses cross-polarization epiluminescence imaging through use of white light emitting diodes (LEDs), a high magnification lens (10×), and a lithium ion battery contained in a small lightweight device.

In the DermLite® device, a window is incorporated into a compact housing, and a plurality of white light LEDs encircle a magnifying lens. The DermLite® device incorporates cross-polarization filters that reduce the reflection of light from the surface of the skin and permits visualization of the deeper skin structures. Light from eight (8) LEDs is polarized linearly by a polarizer, which is annular in shape and located in front of the LEDs. The imaging viewed through the magnifying lens is also linearly polarized by using a polarizer that is located in front of the lens. The LEDs have a narrow beam angle that concentrates the light into a small area, pointing the incident light to the center to increase the brightness of the area being viewed. Thus, light from the LEDs passes through the polarizer which enters the skin and reflects back through the viewing polarizer to create cross-polarization allowing examination to look deeper within the skin structure. Although, the DermLite® product has been recognized as a major advancement in the art of routing clinical diagnosis and analysis of skin cancer lesions, DermLite® device does not provide a mechanism for enabling the user to additionally view parallel-polarized light, or a combination of cross-polarized light and parallel-polarized light.

The DermLite® Platinum® product, also manufactured by 3Gen, LLC. was developed to provide variable polarization. Variable polarization is achieved by a rotating dial. Rotation of the polarizer to a cross-polarization cancels out the surface reflection for an in-depth look at the deeper pigmentation in lesion structure. Rotation to parallel polarization allows a clear view of the skin surface. The DermLite® Platinum® product requires manual manipulation of the dial which may cause user to lose the viewing spot, or otherwise interfere with examination. Further, DermLite Platinum® does not provide a user the ability to view the skin with an instantaneous switch over from cross-polarization to parallel polarization.

Recent discoveries in optical fluorescence imaging have identified several molecules having fluorescence properties that are useful in medicine. In dermatology, simple applications such as delta-aminolaevulinic acid (ALA) applied topically have been found to enhance the visualization of basal cell cancer from normal tissue, when illuminated with UV/Blue light. Fluorescein is another fluorescent compound that has been in clinical use in opthamology for several years and has great potential for use in dermatological applications. Indocyanine green (ICG), Methylene Blue, and ethyl nile blue are contrast agents that are used to increase light absorption in blood vessels. There are several FDA approved optical fluorescence tracers already approved for clinical use, and several more new probes may be applicable in the future. However, the use of fluorescence imaging of the skin has been illusive for clinical dermatologist because of the complexity and costs of the associated equipment.

In current applications, such as in the application of ALA topically to a basal cell carcinoma to a BCC, conventional white light visual images of the BCC are displayed next to the fluorescence excited images of ALA in the BCC. The ALA is taken up by the active areas of cancer, converted to porphyrin IX, and fluoresces when exposed to UV/Blue light. It becomes apparent that the fluorescent areas of the BCC may not coincide with the anatomical features of the BCC as shown in white light. Currently the side-by-side comparison is only available by taking two separate images and co-registering these images later in the computer.

Thus, there is a great need in the art for a device that will allow clinical viewing of skin lesions which provides on demand switching from cross-polarized imaging to parallel-polarized imaging and a combination of both. Further there is a great need in the art for a clinical viewing of skin lesions that can toggle back and forth from a white light to a colored or UV light in order to contrast and compare images.

BRIEF SUMMARY OF THE INVENTION

The present invention relates to a dermoscopy epiluminescence device used in the medical diagnosis of skin lesions. The device is a hand held modular housing incorporating a magnification lens and associated lighting scheme for examining the epidermis on humans. The light sources of the lighting scheme are powered by an on board lithium battery and are controlled by a three way switch which provides on demand cross-polarized, parallel-polarized and a combination thereof for epiluminescence.

More particularly, a first embodiment of the present invention comprises a generally circular optical lens incorporated into the housing of the device. The lens produces a magnified image of the skin to be observed by a viewer. In the first embodiment the lens is a 15 mm diameter Hastings lens with a 10× optical gain. The viewer observes the magnified skin through the lens window of the housing. The viewing is aided by a plurality of luminous diodes positioned within the housing and about the circumference of the lens. The diodes direct light upon the skin to be viewed. The LEDs are white high light output Indium Gallium Nitride LEDs. Two light circuits form first and second illumination sources forming a ring of alternating diodes about the lens. A switch is provided that when not in operation has a normal OFF mode. In operation the switch has a first ON mode for initiating the first illumination source (i.e. every other diode on the first light circuit), a second ON mode for initiating the second illumination source (i.e. every other diode on the second light circuit) and a third ON mode for initiating both said first and second illumination sources simultaneously (i.e. all diodes).

A first polarizer filter comprises a planar annular ring defining a generally circular center opening and an outer ring. The center opening of the annular ring of the first polarizer is positioned in alignment with the circular optical lens to provide an unobstructed view of the skin through the lens and the housing. The outer ring of the first polarizer includes a plurality of openings sized and positioned to correspond to the diodes of the second illumination source (i.e. every other diode of the second light circuit) such that light emitted from the diodes of the second illumination source passes through the openings unfiltered by the first polarizer. Because there are no corresponding openings for the diodes of the first illumination source (i.e. every other diode on the first light circuit) light emitted from first source diodes is polarized by the outer ring of the first polarizer filter.

A second polarizer filter comprises a planar annular ring defining a generally circular center opening and an outer ring. The center opening of said annular ring of the second polarizer is positioned in alignment with the circular optical lens to provide an unobstructed view of the skin through the lens and housing. The second polarizer is 90 degrees out of

phase with the first polarizer. The outer ring of the second polarizer has a plurality of openings sized and positioned to correspond to the diodes of the first illumination source (i.e. every other diode on the first light circuit) such that light emitted from the diodes of the first illumination source passes through the openings unfiltered by the second polarizer. Because there are no corresponding openings for the diodes of the second illumination source (i.e. every other diode on the second light circuit) light emitted from second source diodes is polarized by the outer ring of the second polarizer filter.

A viewing polarizer is also provided positioned in the housing in line with viewing corridor of the optical lens. The viewing polarizer filters light reflected back from the skin and is cross-polarized relative to said first polarizer and is parallel-polarized relative to said second illumination source. The cross-polarization aids the examiner in viewing deeper structures of the skin while the parallel polarization aids in viewing the topography of the skin.

In a second embodiment of the invention, the ring of diodes that surround the lens incorporate alternating light wavelengths of differing colors. In operation, a user initiates the first light circuit by operating the first ON mode of the housing switch to light every other diode of a first color. The user then can initiate the second ON mode to light every other diode of a second color. Finally the user can initiate a third ON mode and light both sets of diodes to emit both colors simultaneously. For example, one set of lights could be white light LEDs and the second set of light can be a UV/Blue LEDs. Fluorescence imaging provides functional information about the disease, while the standard white light epiluminescence imaging provides the anatomical information that the physician is familiar with in viewing skin disease. Combining the UV/Blue light image with the standard white light image, into a device that is simple and easy to use can be achieved by using a "flicker" method of image integration in the eye, whereby two sets of images are presented one after the other. Switching back and forth between the two sets of images allows the brain to "co-register" the two different images without the need for computers. A third embodiment employs the alternating colored diodes of the second embodiment as well as the cross and parallel polarization of the light from the diodes as found in the first embodiment.

BRIEF DESCRIPTION OF THE DRAWINGS

These as well as other features of the present invention will become more apparent upon reference to the drawings wherein:

FIG. **1** is a is a top perspective view of the device of the present invention;

FIG. **2** is a bottom perspective view of the device of the present invention;

FIG. **3** is an exploded top view of a first embodiment of the present invention;

FIG. **4** is and exploded bottom view of a first embodiment of the present invention;

FIG. **5** is a cross-sectional view of the device of a first embodiment of the present invention;

FIG. **6** is and exploded bottom view of a second embodiment of the present invention; and

FIG. **7** is and exploded bottom view of a third embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The detailed description as set forth below in connection with the appended drawings is intended as a description of the presently preferred embodiments of the present invention, and does not represent the only embodiment of the present invention. It is understood that various modifications to the invention may be comprised by different embodiments and are also encompassed within the spirit and scope of the present invention.

Referring particularly to FIGS. **1** and **2**, there are shown a top and bottom perspective views, respectively, of the dermoscopy epiluminescence device **12** of the present invention. The device **12** is lightweight and compact, and can easily fit within the shirt pocket of a user. The outer structure of the device **12** can be utilized in association with the first embodiment (FIGS. **3**–**5**), the second embodiment (FIG. **6**) and third embodiment (FIG. **7**). The exterior appearance of the device for each of the first, second and third embodiments would be identical as shown in FIGS. **1** and **2**.

FIG. **1** shows the top perspective view of the device **12** showing the viewing port of the lens **14** incorporated into a housing **20**. A battery cover **22** may be removeably secured to the housing **20** to provide access to an interior compartment for insertion and removal of a battery.

Also shown is a switch **16** for initiating a first light source and a switch **18** for initiating the second light source.

Referring particularly to FIG. **2**, a bottom perspective view of the device **12** is shown. A light portal is incorporated into the housing **20** to expose a viewing polarizer **24**. A plurality of diodes (not shown) encircle the viewing polarizer within the housing **20** and direct light though a multiple layer filter ring **25**. Light from the diodes (not shown) is directed onto the skin surface to aid lighting the magnified area to be viewed.

Referring particularly to FIGS. **3** and **4**, there is shown a first embodiment of the present invention. FIG. **3** is an exploded top view of the device **12** and FIG. **4** is an exploded bottom view of the device **12**. The housing **20** includes top component **20***a* and bottom component **20***b*. The top component **20***a*, bottom component **20***b* and battery cover **22** are formed from molded lightweight durable plastic. The plastic is a PVC derivative material and may be formed from acrylic or lexan. Additionally, the housing may be formed from metal such as aluminum. Components **20***a*, **20***b* and cover **22** are interconnected to form the outer housing **20** as shown in FIGS. **1** and **2**.

The top housing component **20***a* includes an aperture **26** for receiving the combination of the optical lens **14** inserted within the lens sleeve **28**. Shown best in FIG. **4**, the underside of the top housing component **20***a* is shown wherein the aperture **26** incorporates a downwardly protruding collar for receiving the lens **14** within the lens sleeve **28**. The lens sleeve **28** incorporates an annular lip **29** which engages the sloped sides of the aperture **26** to complete the exterior of the viewing port of the housing **20**. The lens sleeve **28** operates to securely hold the lens **14** in place within the aperture **26**. The lens **14** in the first embodiment is preferably a 15 mm diameter Hastings lens with a 10× optical gain. Although the first embodiment employs a Hastings lens, the lens may be a single convex lens, a combination of two or more lenses, a double achromat lens, or a combination of double achromat lenses. In addition, the lens may incorporate aspherical lenses to accommodate better optics and lower distortion. The lenses coated with an

antireflection coating may be used and may additionally include a color filter to selectively filter light passing through the lens.

Although the invention shows a hand held unit without imaging equipment attached, it is contemplated by the present invention that the same could be used with a camera, and that the size and shape of the lens would be modified to accommodate the same.

The protruding collar **30** is part of the unitary structure of the upper housing component **20***a*. The cylinder **30** protrudes through the interior components of the housing **20**, including a printed circuit board (PCB) **32** having an opening **33** to extend to the light portal of bottom component **20***b*. A battery **34** nests within a battery chamber formed by the top component **20***a* and bottom component **20***b*. PCB **32** includes electrical contacts **36***a* and **36***b* for interfacing with the battery **34** contacts **38***a* and **38***b*. The upper housing **20***a* includes slots **40***a* and **40***b* to allow the PCB contacts **36***a* and **36***b* to protrude from the circuit board **32** into the battery chamber and contact the battery leads **38***a* and **38***b*. In all embodiments of the present invention, the battery **34** is an extended charge lithium battery, however, it is understood and contemplated by the present invention that the battery could be any suitable battery package such as a one-time lithium battery or rechargeable lithium battery. The invention additionally contemplates use of a DC power supply that may have a suitable DC output to drive the LEDs.

The bottom component **20***b* includes a viewing aperture **42**. The viewing polarizer **24** and sleeve **44** cap off the opening of the collar **30**. Viewing polarizer **24** is composed of acrylic plastic with polarization material embedded within the polarizer. It is contemplated by the invention that the viewing polarizer **24** may be constructed of glass, also with material embedded or coated on the glass. In addition, the viewing polarizer **24** may be coated with a filter material that can selectively filter out some of the light frequencies emanating from the object. Alternatively, the secondary filter assembly made of plastic or glass with the capability of filtering the light may be placed in the path of the viewing lens to filter out some of the light. Bottom housing component **20***b* includes a bottom collar **46** formed therein. A lip **48** incorporating a plurality of guide tabs, is formed between the collar **46** and the aperture **42**. The lip **48** and guide tabs are adapted to engage bottom annular polarizer **50** and a top annular polarizer **52**. The top **52** and bottom **50** polarizers are 90 degrees out of phase. The bottom **50** polarizer is in cross polarization with the viewing polarizer **24** and top polarizer **52** is in parallel polarization with the viewing polarizer **24**. The top **52** and bottom **50** polarizers are composed of acrylic plastic and include polarization at different angles. The polarizers **50** and **52** may also be coated with a special material to filter out some of the light emanating from the LEDs, or alternatively the annular polarizer **50** and **52** may be sandwiched with a color filter acrylic material. The aperture **42** is wide enough to permit a viewing corridor from the lens sleeve **28** through the housing **20** to the aperture **42** while allowing portions of the top **52** and bottom **50** polarizers to be exposed and to filter light emitting diodes inside the housing **20**.

Sixteen light emitting diodes **58** ring the circuit board. The diodes are preferably white high light output Indium Gallium Nitride LEDs, however any suitable lighting diodes are appropriate. The even diodes are on a single circuit and the odd diodes are an a separate single circuit. In the shown embodiment, the LEDs **58** are a standard white LED made with phosphorescence phosphors to create white light. It is additionally contemplated by the present invention that tri-colored LEDs, with individual red, green and blue LEDs that can combine form white light may be utilized. It is contemplated by the present invention that the LEDs may have focusing lenses to concentrate the light into a smaller and tighter beam. The LEDs may additionally be comprised of indium gallium arsenide material, or any other like semiconductor material. The PCB board **42** incorporates switch contacts **54** and **56**. The polarizing parallel switch **16** engages switch contact **56** and the parallel-polarizing switch **18** engages with contact **54**. Thus, engaging switch **16** initiates a first light source, which are the eight even diodes **58** and the switch **18** initiates the second light source, which are the other eight odd diodes. Both switches **56** and **54** may be operated simultaneously to light all sixteen diodes **58** simultaneously. It is contemplated by the present invention that the device may employ three or more switches operative to initiate three or more sets of diodes.

A first polarizer filter **50** comprises a planar annular ring defining a generally circular center opening and an outer ring. The center opening of the annular ring of the first polarizer **50** is positioned in alignment with the circular optical lens **14** to provide an unobstructed view of the skin through the lens **14** and the housing **20**. The outer ring of the first polarizer **50** includes a plurality of openings sized and positioned to correspond to the diodes **58** of the second illumination source (i.e. every other diode **58** of the second light circuit) such that light emitted from the diodes **58** of the second illumination source passes through the openings unfiltered by the first polarizer **50**. Because there are no corresponding openings for the diodes of the first illumination source (i.e. every other diode on the first light circuit) light emitted from first source diodes is polarized by the outer ring of the first polarizer filter **50**.

A second polarizer filter **52** comprises a planar annular ring defining a generally circular center opening and an outer ring. The center opening of said annular ring of the second polarizer **52** is positioned in alignment with the circular optical lens **14** to provide an unobstructed view of the skin through the lens **14** and housing **20**. The second polarizer **52** is 90 degrees out of phase with the first polarizer **50**. The outer ring of the second polarizer **52**, like the first polarizer **50**, has a plurality of openings sized and positioned to correspond to the diodes of the first illumination source (i.e. every other diode on the first light circuit) such that light emitted from the diodes of the first illumination source passes through the openings unfiltered by the second polarizer **52**. Because there are no corresponding openings for the diodes **58** of the second illumination source (i.e. every other diode on the second light circuit) light emitted from second source diodes is polarized by the outer ring of the second polarizer **52**. While the switches of the first embodiment 16 and 18 shows only two light sources (i.e. two sets of diodes) three are more sets of diodes are contemplated by the present invention.

Referring particularly to FIG. **5**, there is shown a cross-sectional view of the device **12** of the first embodiment of the present invention. FIG. **5** shows an optional spacer **60** which can engage the viewing portal of the housing **20**. The spacer includes glass **62** to provide a transparent barrier. The spacer can aid in achieving the optimal viewing distance between the device **12** and the skin **64**. Also, the spacer **60** can prevent contamination of the lens **14** during examination.

FIG. **5** illustrates the angle of mounting of the LEDs **58** upon the PCB **32**. The light from the LEDs **58** is angled to concentrate the light onto a focused area are represented by the angled lines shown in phantom. The light from the LEDs

58 is focused into a smaller area, so as to increase the brightness of the LEDs. All of the LEDs **58** in the circle are pointed toward the central area of the region of interest, so as to increase multifold the amount of light directed into the region. It is additionally contemplated by the present invention that some of the LEDs may be directed slightly off center to enlarge the viewing field and to make for uniform lighting.

FIG. **6** is a bottom exploded view of a second embodiment of the present invention. The assembly and structure of the device shown in FIG. **6** is identical to that shown in FIGS. **1**–**5** of the first embodiment of the present invention (and thus the description is not repeated herein), except that the device shown in FIG. **6** does not include two annular filters **50** and **52** and the LEDs **66** and **68** are of different colors. Preferably, the even diodes **66** are of a particular green wavelength and odd diodes **68** are white diodes. The colored LEDs may be different LEDs available at the time such as 370 nm UV, 470 nm blue, 500 nm aqua, 525 nm green, 570 nm orange, 630 nm red, etc. The combination of different colors will provide different imaging capabilities. As an example, the blue light is more absorbed in skin pigmentation and therefore better visualization of pigmentation is achieved with the blue light. Similarly, the green light is more absorbed by the blood and so it is better for visualizing blood vessels. Some compounds also fluoresce at different wavelength light. An example of this is the multiple fluorescence compounds used in research and medicine such as fluorescein, which fluoresces green when illuminated with a blue light. While the second embodiment herein shows green and white diodes, it is understood that the second embodiment could employ any desirable combinations of colors. Likewise, while the switch contemplates only two light sources (i.e. two sets of diodes) three are more sets of diodes are contemplated by the present invention, employing multiple combinations of colors.

FIG. **7** is a bottom exploded view of a third embodiment of the present invention. The assembly and structure of the device shown in FIG. **7** is identical to that shown in FIGS. **1**–**5** of the first embodiment of the present invention (and thus the description is not repeated herein), except that the device shown in FIG. **7** includes LEDs **70** and **72** are of different colors. Preferably, the even diodes **70** are of a particular green wavelength and odd diodes **72** are white diodes. The two annular polarizers provide cross polarization and parallel polarization identical to that described with respect to the first embodiment. While the third embodiment herein contemplates green and white diodes, it is understood that the third embodiment could employ any desirable combinations of colors. Likewise, while the switches may only initiate two light sources (i.e. two sets of diodes), three are more sets of diodes are contemplated by the present invention, employing multiple combinations of colors.

It should be noted and understood that with respect to the embodiments of the present invention, the materials suggested may be modified or substituted to achieve the general overall resultant high efficiency. The substitution of materials or dimensions remains within the spirit and scope of the present invention.

I claim:

1. A dermoscopy epiluminescence device comprising:

a) a generally circular optical lens defining an outer circumference to produce a magnified image of an object to be observed by a viewer;

b) an illumination source comprising a plurality of luminous diodes spaced about the circumference of said optical lens to direct light upon the object;

c) at least one polarizer comprising a planar annular ring filter defining a generally circular center opening and an outer ring, said center opening of said annular ring is positioned in corresponding alignment with the circular optical lens to provide an open view of the object through the lens, said outer ring having at least one opening sized and positioned to correspond to at least one of the diodes of the illumination source such that light emitted from said at least one diode of the illumination source is passed through said at least one opening toward the object and light emitted from remaining diodes of the illumination source is polarized by the polarizer;

d) a viewing polarizer positioned between a viewer and the object to polarize light reflected from the object wherein said viewing polarizer is cross-polarized relative to polarized light emitted from said remaining diodes.

2. The dermoscopy epiluminescence device of claim **1** further comprising a switch having a first mode for initiating diodes that emit light through said polarizer, and a second mode for initiating the diodes that emit light through said at least one polarizer openings.

3. The dermoscopy epiluminescence device of claim **1** wherein diodes that emit filtered light through said polarizer and diodes that emit light through said at least one polarizer opening have different color wavelengths.

4. The dermoscopy epiluminescence device of claim **1** further comprising a power source to power said illumination sources.

5. The dermoscopy epiluminescence device of claim **4** wherein said power source is a battery.

6. The dermoscopy epiluminescence device of claim **4** wherein said power source is a lithium battery.

7. The dermoscopy epiluminescence device of claim **4** wherein said switch has a third mode for initiating the diodes that emit filtered light through said polarizer and diodes that emit light through said at least one polarizer openings simultaneously.

8. The dermoscopy epiluminescence device of claim **1** wherein said luminous diodes are white light emitting diodes.

9. The dermoscopy epiluminescence device of claim **1** wherein said luminous diodes are high light output Indium Gallium Nitride light emitting diodes.

10. The dermoscopy epiluminescence device of claim **1** wherein said optical lens is a Hastings Triplet lens.

11. The dermoscopy epiluminescence device of claim **1** wherein said optical lens is a 15 mm diameter Hastings lens with a 10× optical gain.

12. The dermoscopy epiluminescence device of claim **1** wherein said viewing polarizer linearly polarizes light emitted from said at least one diodes positioned in alignment with said at least one polarizer openings.

13. The dermoscopy epiluminescence device of claim **1** further comprising a spacer positioned between said viewing polarizer and the object to be viewed.

14. The device of claim **1** wherein said luminous diodes are pointed inwardly from said circumference with the light emitted therefrom being directed toward said object to be viewed.

15. The device of claim **14** further comprising a spacer positioned between said viewing polarizer and the object to be viewed.

16. The device of claim **14** wherein said polarizer is a planar ring.

17. The device of claim 14 further comprising a switch having a first mode for initiating said first diodes, a second mode for initiating said second diodes and a third mode for initiating said first and second diodes simultaneously.

18. The device of claim 14 wherein said first and second diodes have different color wavelengths.

19. The device of claim 14 wherein said pluralities of first and second diodes are pointed inwardly from said outer circumference with the light emitted therefrom being directed toward said object.

20. The dermoscopy epiluminescence device of claim 14 wherein said first and second diodes have different color wavelengths.

21. The dermoscopy epiluminescence device of claim 20 wherein said power source is a battery.

22. The dermoscopy epiluminescence device of claim 20 wherein said power source is a lithium battery.

23. The dermoscopy epiluminescence device of claim 14 further comprising a power source to power said first and second luminous diodes.

24. The dermoscopy epiluminescence device of claim 14 wherein said optical lens is a Hastings Triplet lens.

25. The dermoscopy epiluminescence device of claim 14 wherein said optical lens is a 15 mm diameter Hastings lens with a 10× optical gain.

26. A selective polarization device for producing a polarized view of an object to be observed by a viewer, the device comprising:

a) an optical lens defining an outer circumference;

b) a plurality of first and second luminous diodes being alternately spaced about said outer circumference to form a ring of diodes;

c) at least one polarizer comprising an annular ring filter defining a generally circular center opening, an outer ring and a plurality of openings, said center opening corresponding with the optical lens to provide an open view of the object through the lens, said outer ring substantially corresponding to said outer circumference, said plurality of openings being sized and positioned corresponding to said second diodes with light emitted therefrom being transmittable through the openings toward the object and light emitted from said first diodes being polarized by the first polarizer filter; and

d) a viewing polarizer being positioned between said viewer and being cross-polarized relative to said polarizer.

* * * * *

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(12) **United States Patent**
Mullani

(10) **Patent No.: US 7,167,244 B2**
(45) **Date of Patent: *Jan. 23, 2007**

(54) **DERMOSCOPY EPILUMINESCENCE DEVICE EMPLOYING MULTIPLE COLOR ILLUMINATION SOURCES**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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Related U.S. Application Data

(63) Continuation of application No. 10/773,003, filed on Feb. 5, 2004, now Pat. No. 7,027,153, which is a continuation-in-part of application No. 10/384,110, filed on Mar. 7, 2003, now Pat. No. 7,006,223.

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G01J 4/00 (2006.01)

(52) **U.S. Cl.** **356/369**; 600/476; 606/9

(58) **Field of Classification Search** 356/364–369, 356/445–448, 39; 600/9, 306, 340, 476, 600/477; 362/19, 138–140; 359/501, 493, 359/368, 385, 390
See application file for complete search history.

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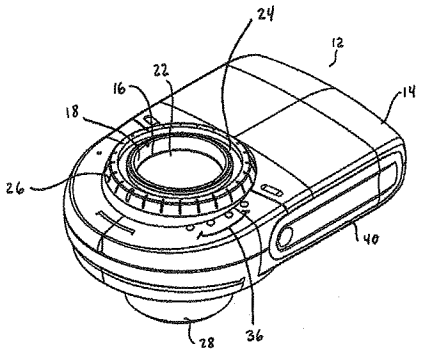
(57) **ABSTRACT**

The present invention provides a hand held dermoscopy epiluminescense device having a generally circular optical magnification lens incorporated into the housing of the device. A lighting array provides the light necessary for medical examination of the skin. The lighting array comprises a ring of LEDs comprising four different colored sets of LEDs each on a different lighting circuit. The four colors comprise White, UV/Blue (405 nm), green/yellow (565 nm) and orange/red (630 nm). A second embodiment provides a hand held dermoscopy epiluminescense device with a magnification lens and an associated ring of luminous diodes powered by an on board battery. Every other diode in the ring operates as first and second light sources. The even diodes are filtered by a first polarization ring and the odd diodes are filtered by a second polarization ring. Each polarization ring has an open center for the lens and openings sized and positioned to correspond to the even or odd diodes to only filter one set. A viewing polarizer is provided and is cross-polarized relative to the first polarization ring and is parallel-polarized with the second polarization ring. The device is threaded to mate with a camera or camera lens.

24 Claims, 12 Drawing Sheets



Exh 2

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(Internet Literature) www.syrissscientific.com, "Technical", 1 page, (Unknown publication date).

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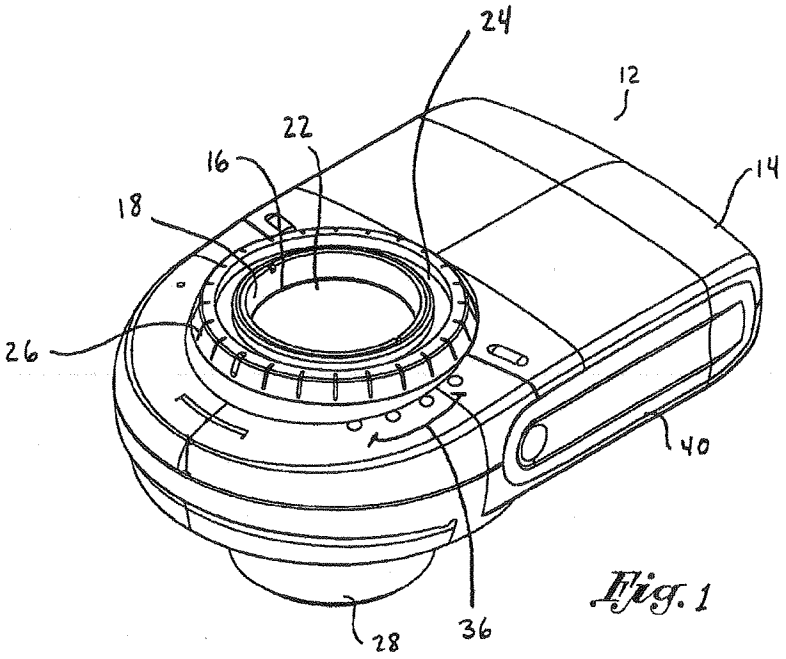


Fig. 1

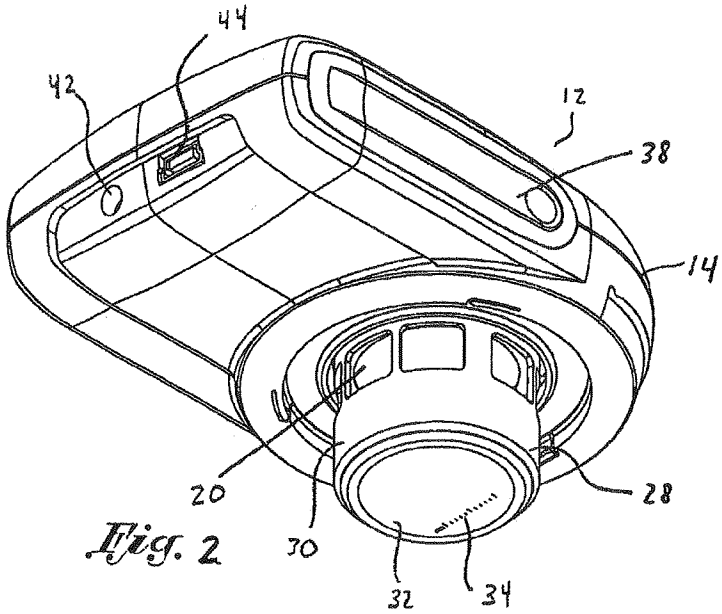


Fig. 2

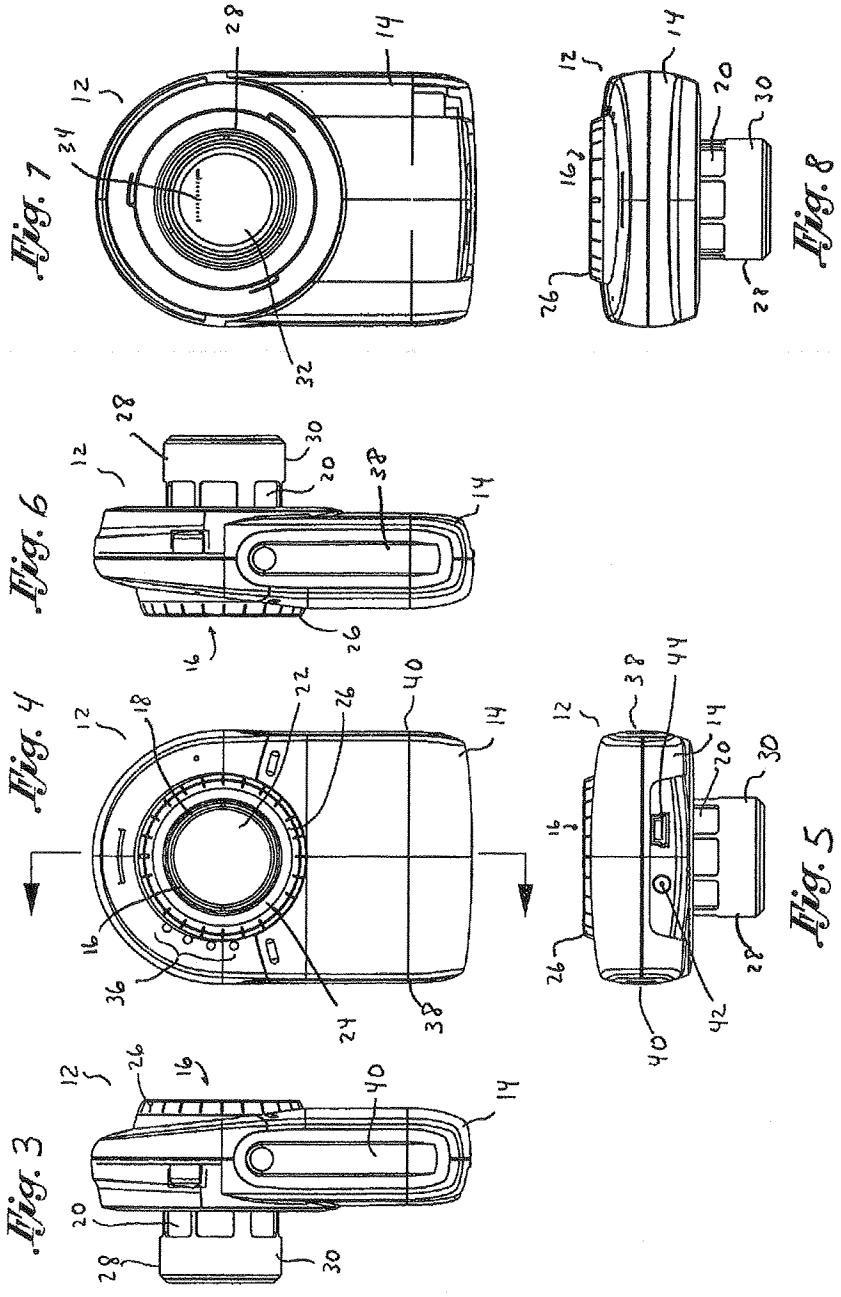


Fig. 7
Fig. 8
Fig. 6
Fig. 4
Fig. 5
Fig. 3

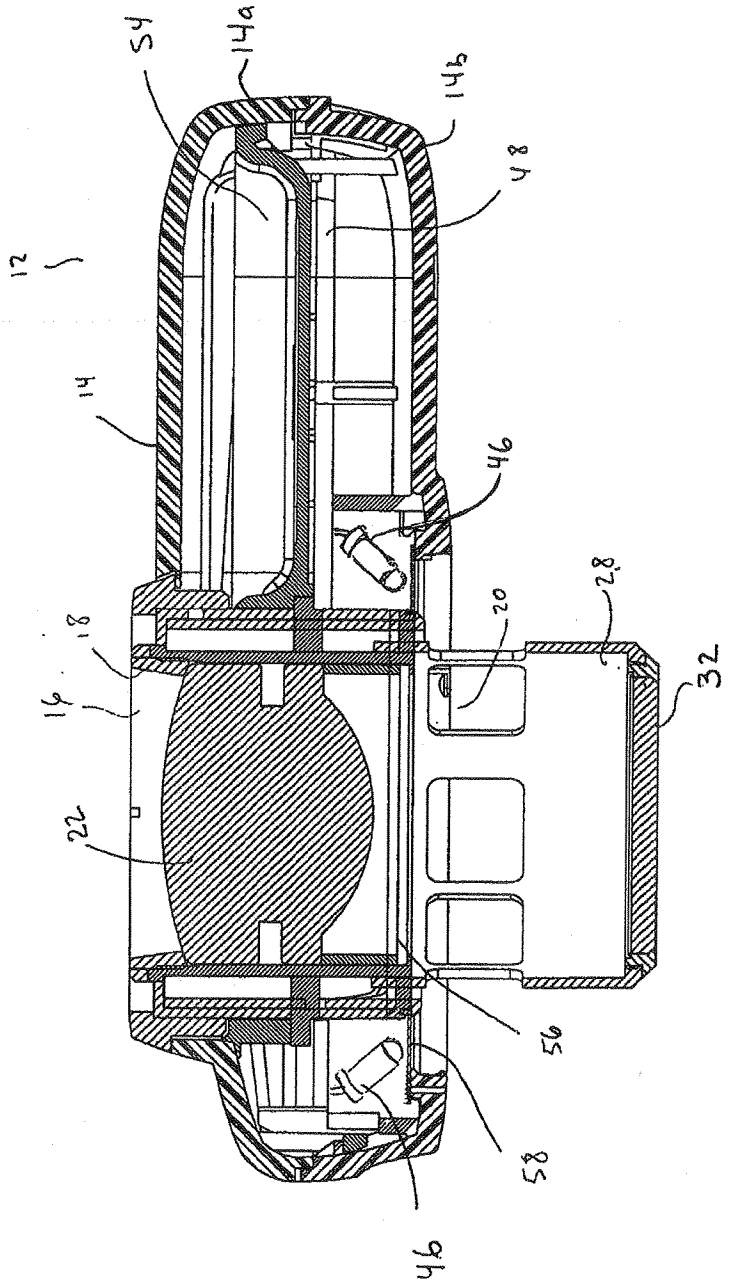
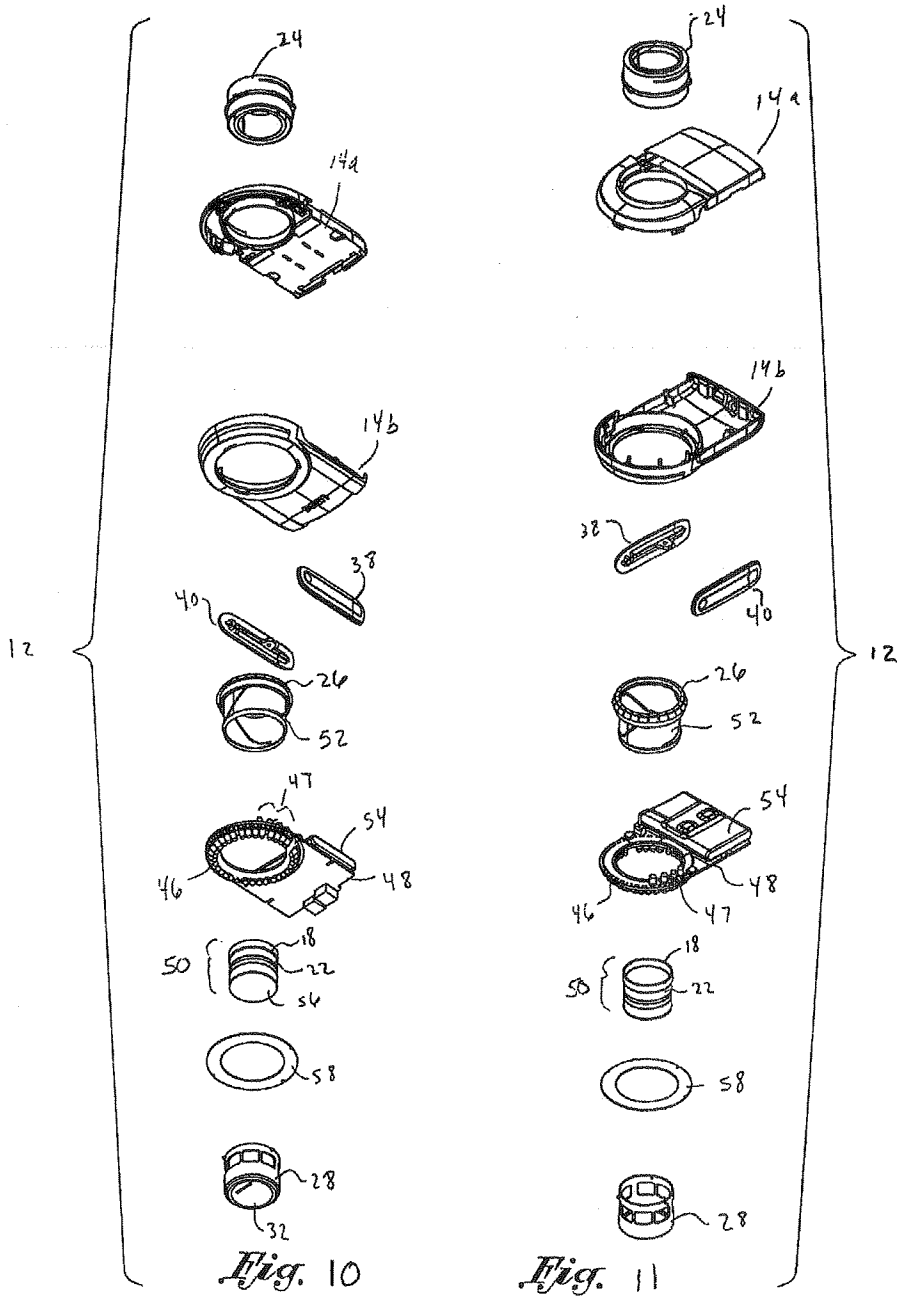


Fig. 9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14b
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40
26
52
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54
46
48
50
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58
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32
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14b
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28

Fig. 10 Fig. 11

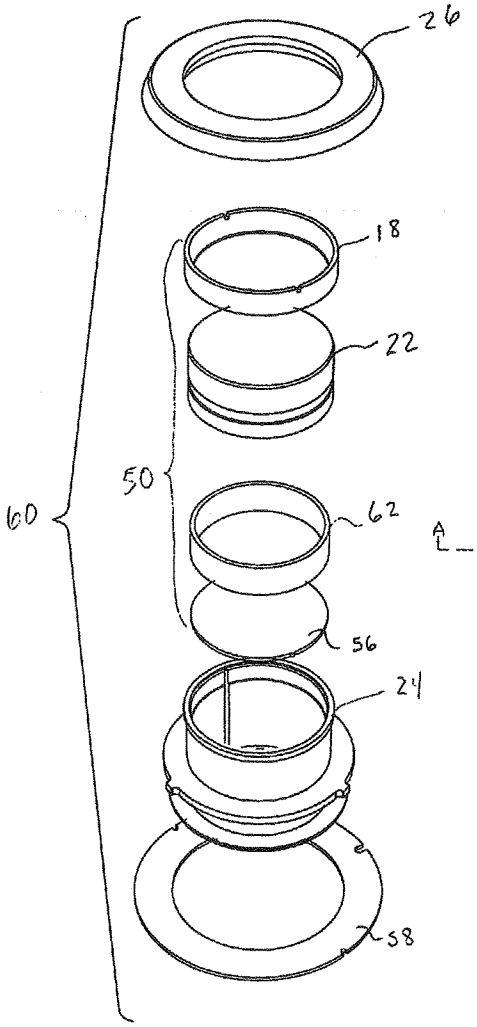


Fig. 13

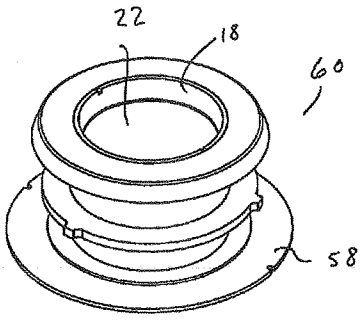


Fig. 12

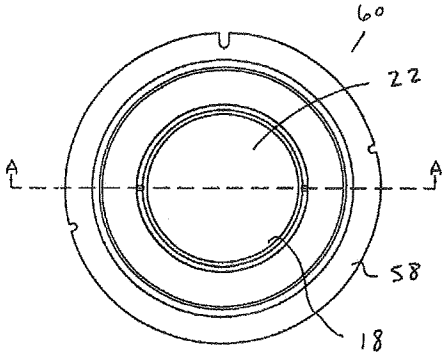


Fig. 14

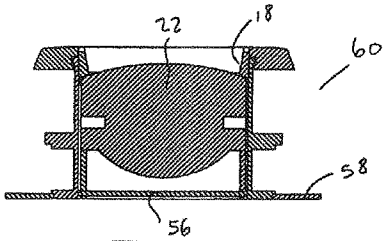
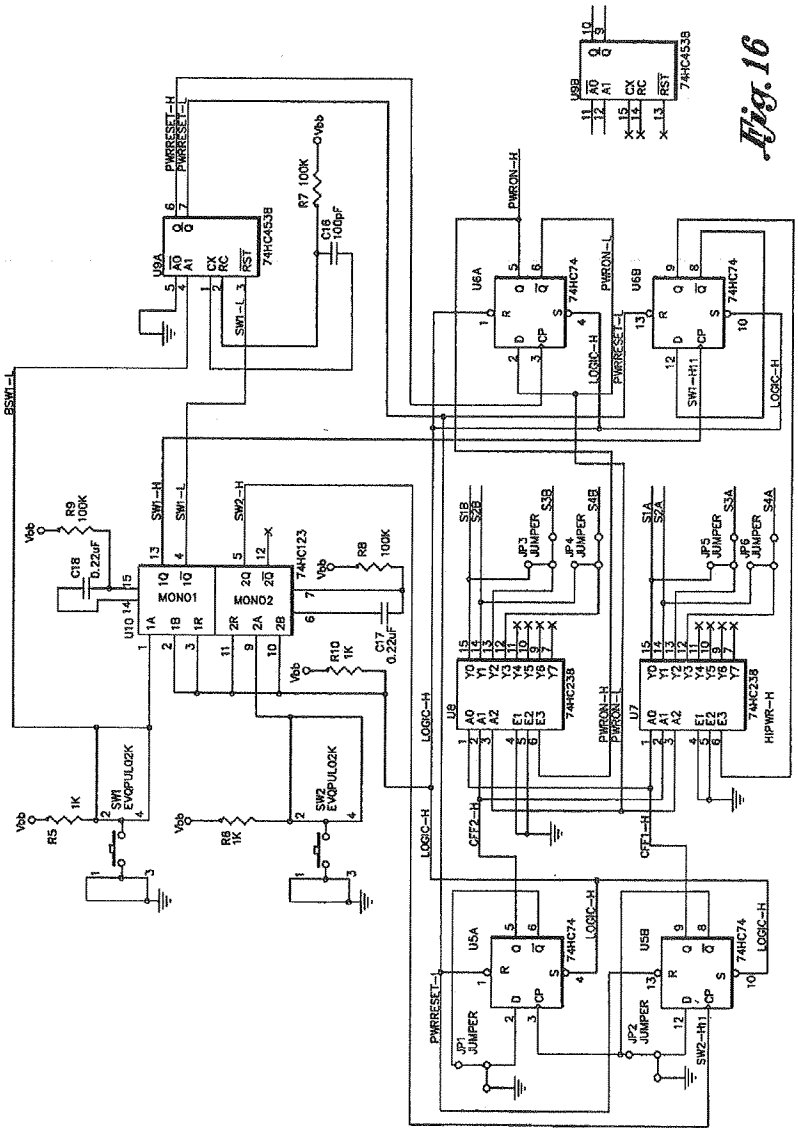


Fig. 15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74HC4538
U9A
74HC4538
R7 100K
C18 100pF
Vbb
PWRRESET-H
PWRRESET-L
PWRON-H
PWRON-L
U6A
74HC74
U6B
74HC74
LOGIC-H
SW1-H11
BSW1-L
SW1-H
SW1-L
SW2-H
R9 100K
C18 0.22uF
MONO1
MONO2
74HC123
U10
R8 100K
C17 0.22uF
R10 1K
S1B
S2B
S3B
S4B
S1A
S2A
S3A
S4A
JP3 JUMPER
JP4 JUMPER
JP5 JUMPER
JP6 JUMPER
U8
U7
74HC238
PWRON-H
PWRON-L
HIPWR-H
CFF2-H
CFF1-H
R5 1K
R6 1K
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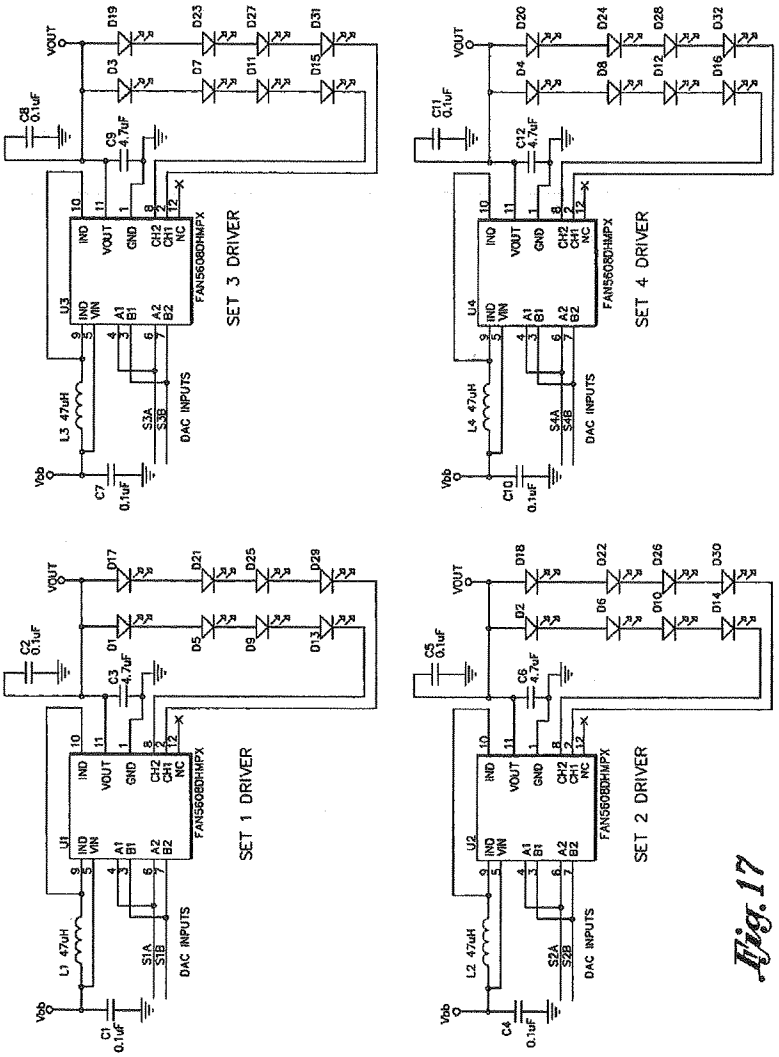
SW2-H11

Fig. 16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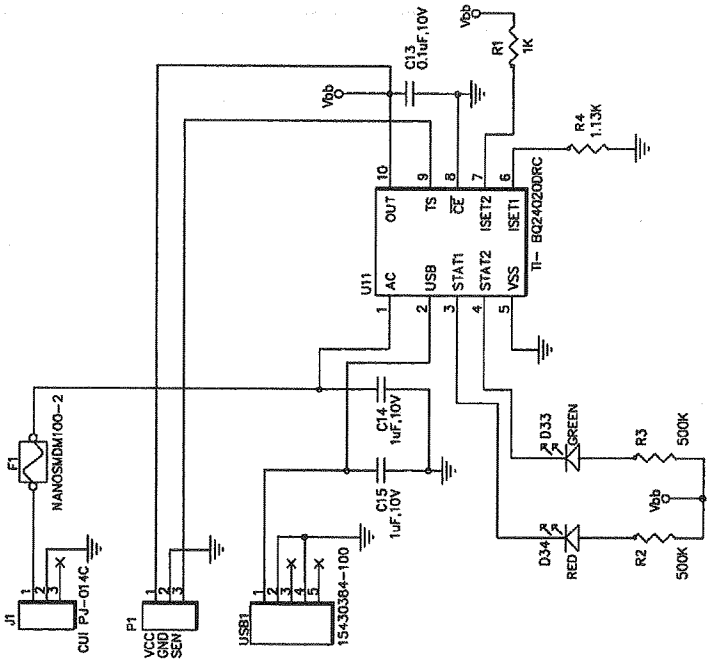
SET 4 DRIVER
SET 1 DRIVER
SET 2 DRIVER
FAN5608DHMPX
DAC INPUTS
VOUT
Vbb

Fig. 17


C13
0.1uF,10V
Vbb
R1
1K
R4
1.13K
U11
AC
USB
STAT1
STAT2
VSS
OUT
TS
CE
ISET2
ISET1
TI- BQ24020DRC
C14
1uF,10V
C15
1uF,10V
F1
NANOSMDM100-2
J1
CUI PJ-014C
P1
VCC
GND
SEN
USB1
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D33
GREEN
D34
RED
R3
500K
R2
500K

Fig. 18

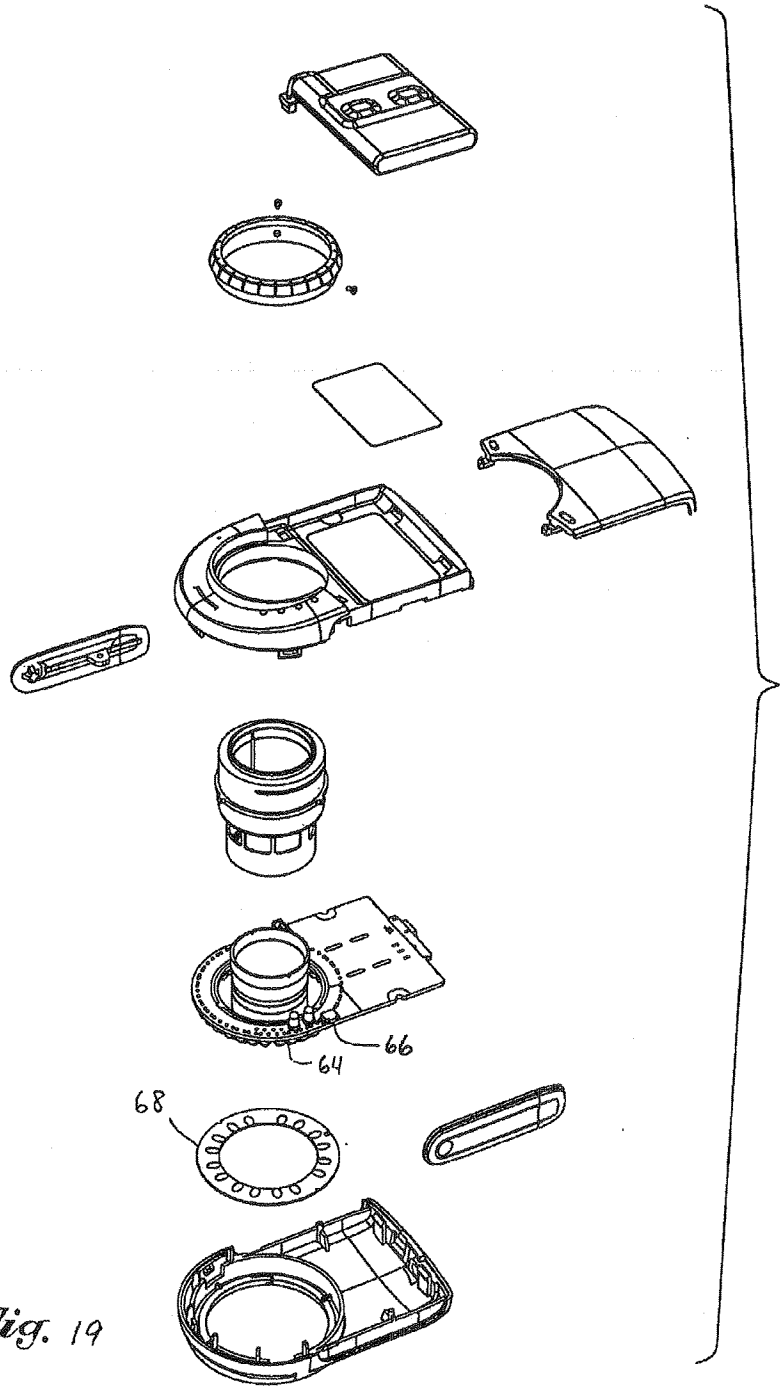


Fig. 19

Fig. 20

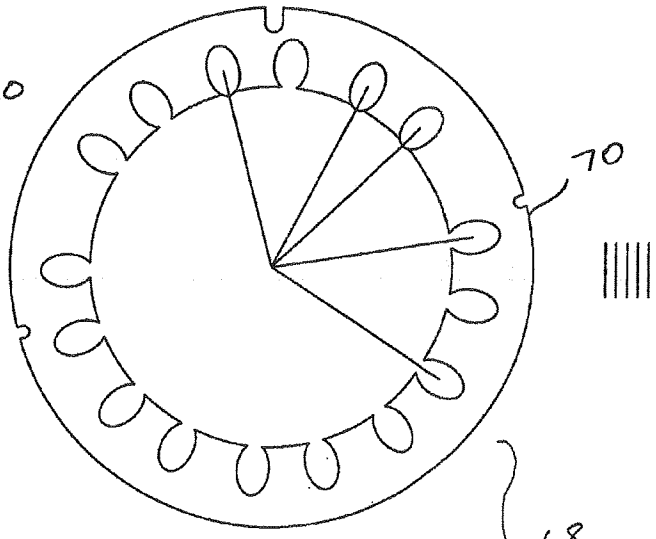
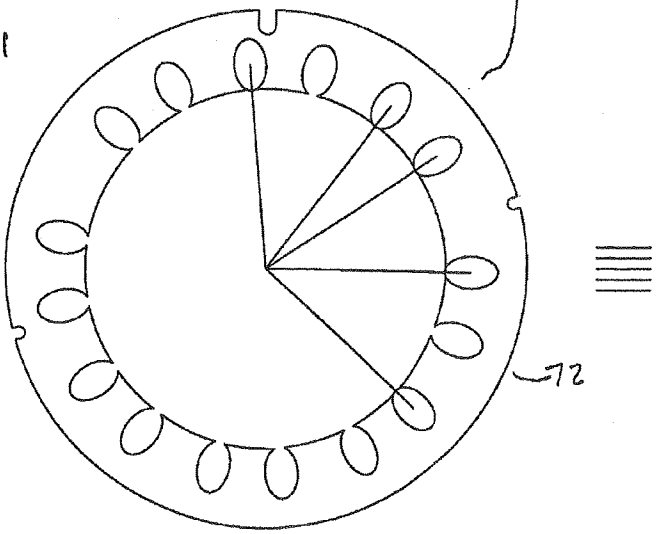


Fig. 21



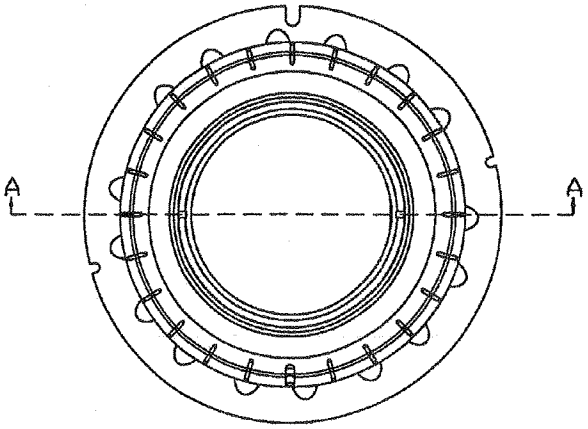


Fig. 22

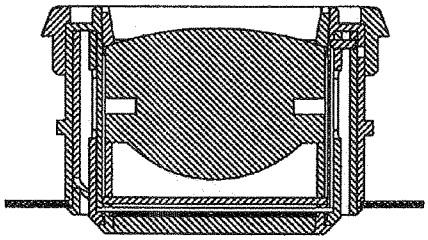


Fig. 23

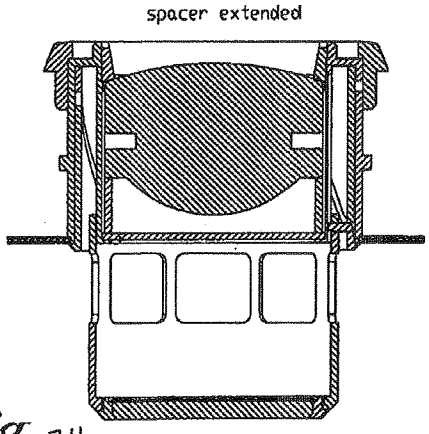


Fig. 24

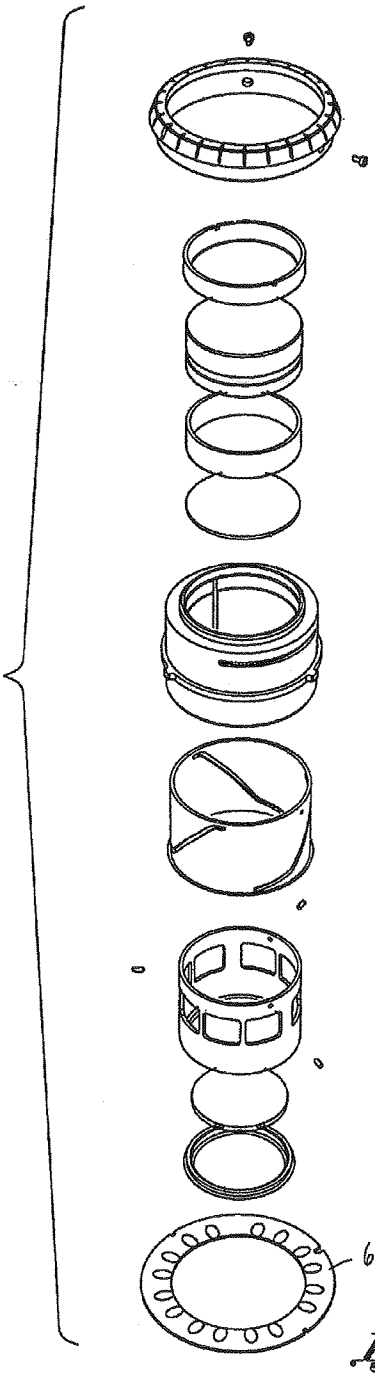


Fig. 27

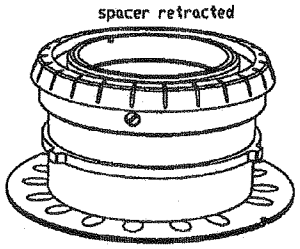


Fig. 25

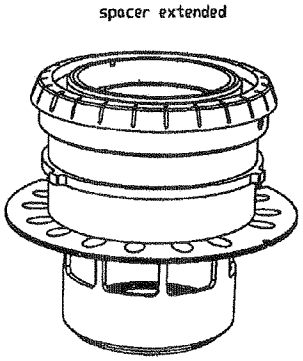


Fig. 26

DERMOSCOPY EPILUMINESCENCE DEVICE EMPLOYING MULTIPLE COLOR ILLUMINATION SOURCES

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a continuation application of U.S. patent application Ser. No. 10/773,003 filed Feb. 5, 2004 and issued Apr. 11, 2006 as U.S. Pat. No. 7,027,153,the substance of which is incorporated herein by reference, which is a continuation-in-part of U.S. patent application Ser. No. 10/384,110 filed Mar. 7, 2003 and issued Feb. 28, 2006 as U.S. Pat. No. 7,006,223 entitled Dermoscopy Epiluminescence Device Employing Cross and Parallel Polarization, the substance of which is relied upon and incorporated herein by reference.

STATEMENT RE: FEDERALLY SPONSORED RESEARCH/DEVELOPMENT

Not Applicable.

FIELD OF THE INVENTION

The present invention relates generally to an epiluminescence device used in dermoscopy. More particularly, the invention comprises an improved apparatus for illuminating the skin for medical examination by providing multiple colored light sources to aid in viewing and treatment of the skin.

BACKGROUND OF THE INVENTION

Dermoscopy is the term used to describe methods of imaging skin lesions. Skin is the largest organ in the body and it is the most easily accessible organ for external optical imaging. For early detection of cancers, it is important that the skin be medically examined for lesions.

With over forty (40%) percent of the cancers occurring on the skin (American Cancer Society Statistics 2001, Perelman 1995), and incidence of skin cancer increasing each year, tools and methods of imaging skin lesions are becoming increasingly important. Most of the cancers detected on the skin are Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SSC), which are differentiated from melanoma, a more deadly form of skin cancer. The early detection of skin cancer allows for inexpensive treatment before the cancer causes more severe medical conditions. Thus, there is a great need in the art for simple inexpensive instruments that allow for the early screening for skin cancer.

Because skin is partially translucent, dermoscopy utilizes tools for visualization of the pigmentation of the skin below the surface. In this regard, when attempting to visualize the deeper structure of the skin, it is important to reduce the reflection of light from the skin that may obscure the underlying structures. Methods used to reduce the surface reflection from the skin are referred to as epiluminescence imaging. There are three known methods for epiluminescence imaging of the skin, oil-immersion, cross-polarization, and side-transillumination. Oil-immersion and cross-polarization methods have been extensively validated for early skin cancer detection while side transillumination methods are currently undergoing study and clinical validation.

Oil-immersion devices are generally referred to as Dermatoscopes. Dermatoscopes permit increased visualization of subsurface pigmentation by using a magnification device in association with a light source. In operation, oil is placed between the skin and a glass faceplate. The placement of oil and a glass interface between the eye and the surface of the skin reduces the reflected light from the skin, resulting in deeper visualization of the underlying skin structure.

While oil-immersion has proved to be an excellent method of epiluminescence imaging of the skin, demonstrating improved sensitivity for melanoma detection, it is messy and time consuming for the physician. As a result, the Dermatoscope is used mostly by physicians that specialize in pigmented lesions and for evaluation of suspicious lesions that cannot be diagnosed visually. Also, the oil-immersion of the Dermatoscope has been found to be less effective for BCC and SCC imaging. The pressure created by the compression of the glass faceplate causes blanching of blood vessels in the skin resulting in reduced capability of the Dermatoscope for imaging the telangiectesia that is often associated with BCC or other malignent lesions.

Cross-polarization or orthogonal polarization is another method of reducing the reflection of the light from the surface of the skin to aid in the medical examination of the skin. Light emanating from a light source is first linearly polarized, so that the orientation of the light falling on the skin surface is in the same plane of polarization. As the light enters the skin, its polarization angle changes such that the light is reflected from a deeper structure. However, the light reflected from the surface of the skin is still polarized in the same plane as the incident light. By including a second polarizer in the path of the reflected light from the skin, a selective filtering of light can be achieved.

Most of the light directed to the skin's surface is reflected, as the refractive index of skin is higher than that of air. The reflection of light, off of the skin, is analogous to the reflection of light off of the surface of water. Accordingly, the information received by the eye carries mostly information about the contour of the skin surface rather than the deeper structures. Remaining light enters the skin and is absorbed or is reflected back in a scattered fashion. By polarizing the incident light with a second polarizer, the specular component of the reflected light is blocked by the viewing polarizer, thus producing an enhanced view below the skin surface. Accordingly, inflammation, color, pigmentation, hair follicles, blood vessels and other structures may be viewed.

When the incident light and the second polarizer are parallel, the surface topography and properties of the skin are highlighted and enhanced. In this regard, if the polarizer in the path of the light from the skin to the eye is polarized in the same orientation of the incident light, only the light from its polarization angle will be allowed to pass through the lens. Cross-polarization imaging of the body was originally described by R. R. Anderson ("Polarized light examination and photography of the skin." Archives Dermatology 1991; 127; 1000–1005). Later, Binder introduced the MoleMax manufactured by Derma Instruments (Vienna, Austria) for the examination and mapping of pigmented lesions. Binder further developed the no-oil cross-polarization epiluminescence method. MoleMax, however, while validating clinically the improved diagnosis and accuracy without the use of oil, still used a glass faceplate and video imaging system to execute skin examinations.

In light of many of the difficulties associated with prior dermoscopy systems, simple and cost-effective diagnostic systems remained unavailable for general dermatologists to

use on a routine clinical basis. Dermoscopy, until recently, remained generally a research tool utilized in special clinical cases. More recently, however, a substantial advancement in skin cancer detection occurred through a simple device identified as DermLite®, manufactured and marketed by 3Gen, LLC, Monarch Beach, Calif. With the low cost and ease of use of the DermLite® Device, screening for cancer by dermatologists, in routine clinical examination of skin disease, has become a reality. The DermLite® device uses cross-polarization epiluminescence imaging through use of white light emitting diodes (LEDs), a high magnification lens (10×), and a lithium ion battery contained in a small lightweight device.

In the DermLite® device, a window is incorporated into a compact housing, and a plurality of white light LEDs encircle a magnifying lens. The DermLite® device incorporates cross-polarization filters that reduce the reflection of light from the surface of the skin and permits visualization of the deeper skin structures. Light from eight (8) LEDs is polarized linearly by a polarizer, which is annular in shape and located in front of the LEDs. The imaging viewed through the magnifying lens is also linearly polarized by using a polarizer that is located in front of the lens. The LEDs have a narrow beam angle that concentrates the light into a small area, pointing the incident light to the center to increase the brightness of the area being viewed. Thus, light from the LEDs passes through the polarizer which enters the skin and reflects back through the viewing polarizer to create cross-polarization allowing examination to look deeper within the skin structure. Although, the DermLite® product has been recognized as a major advancement in the art of routing clinical diagnosis and analysis of skin cancer lesions, DermLite® device does not provide a mechanism for enabling the user to additionally view parallel-polarized light, or a combination of cross-polarized light and parallel-polarized light. The DermLite® Platinum™ product, also manufactured by 3Gen, LLC., was developed to provide variable polarization. In the Dermlite® Platinum™, a rotating dial achieves variable polarization. Rotation of the polarizer to a cross-polarization cancels out the surface reflection for an in-depth look at the deeper pigmentation in lesion structure. Rotation to parallel polarization allows a clear view of the skin surface. The DermLite® Platinum™ product requires manual manipulation of the dial which may cause user to lose the viewing spot, or otherwise interfere with examination. Further, DermLite®Platinum™ does not provide a user the ability to view the skin with an instantaneous switch over from cross-polarization to parallel polarization.

The DermLite®Pro DP-R™ also manufactured by 3gen, LLC, was developed to provide instant, button activated, polarization control. Embodiments of the DermLite® Pro DP-R™ are disclosed in U.S. patent application Ser. No. 10/384,110 filed Mar. 7, 2003, the substance of which is incorporated by reference. Variable mode polarization is provided by a toggle switch that allows the viewer to view the surface of the skin using a polarizing mode, and a switch mode, and a switch creates a cross-polarization which cancels out surface reflection for a view of the deeper pigmentation and structures of the skin.

While existing devices have been proven for effectiveness in detecting melanomas, non-melanoma skin cancers (NMSC) such as BCC and SSC have little or no melanin and therefore are very hard to detect by classical dermoscopy methods. Detection of NMSC is usually carried out by visually examining the suspected reddish areas of skin eruptions with a magnifying lens. Early NMSC are usually detected by looking for the presence of abnormal blood vessels, which are best seen with an epiluminescence device that does not use a glass faceplate and oil. The presence of a glass faceplate and oil blanches the blood vessels and makes it difficult to see the increased vascularity. In addition, NMSC excision boundaries are very difficult to estimate without the information about the subsurface extension of the lesion. Kumar et al (2002) [inset cite] examined 757 BCC that were excised in a British hospital and found positive margins in 3.1% to 7.5% of the excisions, depending on the location of the lesion. Another study by Hallock et al (2001) [Hallock G G, Lutz D A, 2001, A Prospective Study of the Accuracy of the Surgeon's Diagnosis and Significance of Positive Margins in Non-Melanoma Skin Cancers. Plast Reconstr Surg 107:942–7]examined the incidence of positive margins in excised lesions from a private clinic. They found that 20% of all the excisions were malignant (98% were NMSC) and that within the malignant group, 15.7% of the NMSC had positive margins. In this study, 80% of all the excisions were not malignant. Both studies show a significant percentage of excisions with positive margins using present methods.

The presence of positive margins could contribute in part to the recurrence of NMSC. In Australia, where the incidence of BCC and SCC is extremely high (3% as reported by Diepgen et al (2002)), recurrence of NMSC, as reported in a three (3) year study by Czarnecki et al (1996), is 8%. The incidence of multiple NMSC in Australian population was found to be 38.5%, as published in a large study by Raasch et al (2002). And, in a 10 years study by Czarnecki et al (2002), the incidence of second skin cancer occurred in 67.8% of the study population with very high odds for malignant melanoma in the NMSC patients. Incomplete excision can result in recurrence of disease at the same site. And, once the skin lesion becomes larger and is located on the face, normal excisions cannot be performed. Instead, a costly procedure called Mohs Microsurgery (MMS) needs to be performed to remove only the minimum amount of normal tissue. Welch et al (1996) studied the incidence of MMS in 5193 NMSC over a five years period. They found that 32.7% of the NMSC had MMS surgery during the five-year period.

NMSC are characterized by reddish fleshy (nodular) or flat (sclerosing) areas on the skin. These skin lesions usually grow from a pinpoint-sized object, that looks like a pimple, to as large as several mm in size. NMSC are usually found on the head and the neck areas. Ceylan et al (2003) [Ceylan C., Ozturk G, Alpers S., 2003 Non-melanoma Skin Cancers Between the Years of 1990 and 1999 in Izmir, Turkey: Demographic and Clinicopathological Charactoristics. J. Dermaol 30:123–31] showed, in a Turkish population, that 46.6% of the NMSC were located on the face, and that 78.4% of the lesions were between 11 and 20 mm in size at the time of diagnosis.

The visual features that make NMSC different from surrounding normal skin are the abnormal blood vessels and increased vascularity of the lesion. Bedlow et al (2003) [Bedlow A J, Stanton A W, Cliff S., Mortimer P S. Basal Cell Carcinoma and In-vivo Model of Human Tumor Microcirculation? Exp Dermatol 1999, 8:222-6], using video capillaroscopy for the examination of blood vessels in situ, showed that the superficial blood vessels in the BCC are larger and longer than normal blood vessels. They computed the ratio of BCC vessels to normal vessels and found that the area of the BCC vessel was 4.9 times larger and the length was 5.9 times longer than for normal vessels. Weninger et al (1997) [Weninger W, Rendl M, Pammer J, Grin W, et al

1997. Differences in Tumor Microvessel Density Between Squamous Cell Carcinomas and Basal Cell Carcinomas May Relate to Their Different Biological Behavior. J Cutan Pathol 24:364–9] found that SCC had larger vascularity than normal tissue in a study that examined microvessel density (MVD) in excised tissue. Stanton et al (2003) [Stanton A W, Drysdale S B, Patel R, Mellor R H et al. 2003. Expansion of Microvascular Bed and Increased Solute Flux in Human Basal Cell Carcinoma In-Vivo, Measured by Fluorescein Video Angiography. Cancer Res 63:3969–79] used laser Doppler flow and video microscopy with injections of fluorescein to study BCC in vivo. They found increased vasculature and blood flow in BCC. Increased number of blood vessels and larger sized blood vessels means a larger blood volume, which is usually associated with increased blood flow in malignant lesions. Accordingly, finding an inexpensive means to view and analyze these features is therefore important in the field.

Recent discoveries in optical fluorescence imaging have identified several molecules having fluorescence properties that are useful in medicine and in particular, dermatology. Simple applications such as delta-aminolaevulinic acid (ALA) applied topically have been found to enhance the visualization of basal cell cancer from normal tissue, when illuminated with UV/Blue light. Fluorescein is another fluorescent compound that has been in clinical use in opthamology for several years and has great potential for use in dermatological applications. Indocyanine green (ICG), Methylene Blue, and ethyl nile blue are contrast agents that are used to increase light absorption in blood vessels. There are several FDA approved optical fluorescence tracers already approved for clinical use, and several more new probes may be applicable in the future. However, the use of fluorescence imaging of the skin has been illusive for clinical dermatologist because of the complexity and costs of the associated equipment.

In current applications, such as in the application of ALA topically to a basal cell carcinoma to a BCC, conventional white light visual images of the BCC are displayed next to the fluorescence excited images of ALA in the BCC. The ALA is taken up by the active areas of cancer, converted to porphyrin IX, and fluoresces when exposed to UV/Blue light. It becomes apparent that the fluorescent areas of the BCC may not coincide with the anatomical features of the BCC as shown in white light. Currently the side-by-side comparison is only available by taking two separate images and co-registering these images later in the computer.

Thus, there is a great need in the art for a device that will allow clinical viewing of skin lesions which provides on demand switching that can toggle back and forth from a white light to a colored or UV light in order to contrast and compare images. Further there is a great need in the art for a device to allow the clinical viewing of skin lesions that provides on demand switching that can toggle between from lights of differing wavelengths or colors. Further there is a great need in the art to allow the on-demand comparison images of the skin illuminated by differing wavelengths viewed in combination with cross and parallel polarization.

BRIEF SUMMARY OF THE INVENTION

The present invention relates to a dermoscopy epiluminescence device used in the medical diagnosis of skin lesions. The device is a hand held modular housing incorporating a magnification lens and associated lighting scheme for examining the epidermis on humans. The light sources of the lighting scheme are powered by an on board lithium battery and are controlled by a switches that provide on demand use of four differently colored cross-polarized light sources for epiluminescence. The switching of the light colors can also be controlled remotely using a USB connection and an onboard microprocessor.

More particularly, a first embodiment of the present invention comprises a generally circular optical lens incorporated into the housing of the device. The lens produces a magnified image of the skin to be observed by a viewer. In the first embodiment the lens is a 25 mm diameter lens with a 10x optical gain. The viewer observes the magnified skin through the lens window of the housing. The viewing is aided by a plurality of luminous diodes positioned within the housing and about the circumference of the lens. The diodes direct light upon the skin to be viewed. The LEDs are staggered into four sets with each set having a differing color wavelength. There are a total of 32 LEDs, grouped in four sets of eight LEDs each. Four light circuits form first, second, third and fourth illumination sources forming a ring of staggered diodes about the lens. Two switches are provided that when not in operation have a normal OFF mode. In operation, a first switch powers ON/OFF the device, and a second switch selects between the one of the four LED groups. The first switch also can select between high and low settings of the lights.

A first polarizer filter comprises a planar annular ring defining a generally circular center opening and an outer ring. The center opening of the annular ring of the first polarizer is positioned in alignment with the circular optical lens to provide an unobstructed view of the skin through the lens and the housing. The outer ring of the first polarizer filter polarizes light emitted from each of the LEDs.

A viewing polarizer is also provided positioned in the housing in line with viewing corridor of the optical lens. The viewing polarizer filters light reflected back from the skin and is cross-polarized relative to said first polarizer and is parallel-polarized relative to said second illumination source. The cross-polarization aids the examiner in viewing deeper structures of the skin while the parallel polarization aids in viewing the topography of the skin.

In a second embodiment of the invention, the device comprises a generally circular optical lens incorporated into the housing of the device. The lens produces a magnified image of the skin to be observed by a viewer. The viewer observes the magnified skin through the lens window of the housing. The viewing is aided by a plurality of luminous diodes positioned within the housing and about the circumference of the lens. The diodes direct light upon the skin to be viewed. Two light circuits form first and second illumination sources forming a ring of alternating diodes about the lens. A first polarizer filter comprises a planar annular ring defining a generally circular center opening and an outer ring. The center opening of the annular ring of the first polarizer is positioned in alignment with the circular optical lens to provide an unobstructed view of the skin through the lens and the housing. The outer ring of the first polarizer includes a plurality of openings sized and positioned to correspond to the diodes of the second illumination source (i.e. every other diode of the second light circuit) such that light emitted from the diodes of the second illumination source passes through the openings unfiltered by the first polarizer. Because there are no corresponding openings for the diodes of the first illumination source (i.e. every other diode on the first light circuit) light emitted from first source diodes is polarized by the outer ring of the first polarizer filter.

A second polarizer filter comprises a planar annular ring defining a generally circular center opening and an outer ring. The center opening of said annular ring of the second polarizer is positioned in alignment with the circular optical lens to provide an unobstructed view of the skin through the lens and housing. The second polarizer is 90 degrees out of phase with the first polarizer. The outer ring of the second polarizer has a plurality of openings sized and positioned to correspond to the diodes of the first illumination source (i.e. every other diode on the first light circuit) such that light emitted from the diodes of the first illumination source passes through the openings unfiltered by the second polarizer. Because there are no corresponding openings for the diodes of the second illumination source (i.e. every other diode on the second light circuit) light emitted from second source diodes is polarized by the outer ring of the second polarizer filter.

A viewing polarizer is also provided positioned in the housing in line with viewing corridor of the optical lens. The viewing polarizer filters light reflected back from the skin and is cross-polarized relative to said first polarizer and is parallel-polarized relative to said second illumination source. Also, the housing in both embodiments is adapted to engage and be affixed to a camera body such that the lens of the camera can capture images of the object to be observed through said optical lens and viewing polarizer. A threaded recess in the viewing port of the device allows the device to mate with a standard camera lens to attach the device to the camera so that images of the examined skin can be captured. An adapter is additionally provided to mate the device with a camera where required. Also, both the second embodiments include a retractable spacer with a removable face plate with scale. In this regard the invention provides a user a choice between free-floating dry skin imaging and oil immersion to be used with the spacer.

BRIEF DESCRIPTION OF THE DRAWINGS

These as well as other features of the present invention will become more apparent upon reference to the drawings wherein:

FIG. **1** is a is a front (proximal to the viewer) perspective view of the device of the present invention;

FIG. **2** is a back (proximal to the subject) perspective view of the device of the present invention;

FIG. **3** is a left side plan view of the device of the present invention;

FIG. **4** is a front plan view of the device of the present invention;

FIG. **5** is a bottom plan view of the device of the present invention;

FIG. **6** is a right side plan view of the device of the present invention;

FIG. **7** is a back plan view of the device of the present invention;

FIG. **8** is a top plan view of the device of the present invention;

FIG. **9** is a cross-sectional view of the device of the present invention along the A—A axis as shown in FIG. **4**;

FIG. **10** is an exploded back view of a first embodiment of the present invention;

FIG. **11** is an exploded front of a first embodiment of the present invention;

FIG. **12** is perspective view of the lens assembly of the first embodiment of the present invention;

FIG. **13** is an exploded view of the lens assembly shown in FIG. **12**;

FIG. **14** is a top plan view of the lens assembly shown in FIG. **12**;

FIG. **15** is a cross-sectional view of the lens assembly along the A—A axis of FIG. **14**;

FIGS. **16–18** are circuit diagrams of the various lighting and switch components of first embodiment of the present invention;

FIG. **19** is an exploded view of a second embodiment of the present invention;

FIG. **20** is a plan view of a first polarizing filter of the second embodiment of the present invention showing the angle of polarization;

FIG. **21** is a plan view of a second polarizing filter of the second embodiment of the present invention showing the out of phase polarization as compared to the first polarizing filter;

FIG. **22** is a top plan view of the lens assembly of the second embodiment of the present invention;

FIG. **23** is a cross-sectional view of the lens assembly along the A—A axis as shown in FIG. **22**;

FIG. **24** is a cross-sectional view of the lens assembly along the A—A axis as shown in FIG. **22** with the spacer extended;

FIG. **25** is a perspective view of the lens assembly of the device of the second embodiment;

FIG. **26** is a perspective view of the lens assembly of the device of the second embodiment, with the spacer extended; and

FIG. **27** is an exploded view of the lens assembly as shown in FIGS. **25–26**.

DETAILED DESCRIPTION OF THE INVENTION

The detailed description as set forth below in connection with the appended drawings is intended as a description of the presently preferred embodiments of the present invention, and does not represent the only embodiment of the present invention. It is understood that various modifications to the invention may be comprised by different embodiments and are also encompassed within the spirit and scope of the present invention.

Referring particularly to FIGS. **1** and **2**, there are shown top and bottom perspective views, respectively, of the dermoscopy epiluminescence device **12** of the present invention. The device **12** is lightweight and compact. The outer structure of the device **12** can be utilized in association with the first embodiment (FIGS. **9–18**), the second embodiment (FIGS. **19–27**). The exterior appearance of the device for each of the first and second embodiments is identical as shown in FIGS. **1** through **8**.

Referring collectively to FIGS. **1** through **8**, the device **12** is shown with a housing **14** that encases the working components of the device. Preferably, the housing **14** is formed of assembled pieces of injection molded polycarbonate and polyurethane. It will be recognized by one skilled in the art that the housing **14** can be formed form other suitable rigid lightweight material, including, but not limited to plastic, composite materials, fiberglass, aluminum, PVC, acetate and or lexan. A distal viewing port **16** includes a lens retainer **18** for securing the lens and other internal components within the housing **14**. The distal viewing port **16** is visually connected with the proximal viewing port **20** creating a line of sight through the housing **14** through lens **22** and polarizing filters (not shown). The view corridor through

ports **16** and **20** allows a user to view with the skin with a naked eye to view subject skin placed below proximal viewing port **20**.

A lens tube **24** secures the lens **22** and the entire lens assembly (not shown) within the housing **14**. The exposed rim of the lens tube **24** includes threads (not shown) for engaging a standard cameral lens or a lens adaptor. In this regard, the device may be securely affixed to a camera, and the cameral can capture images through the corridor formed by the ports **16** and **20**.

A circular dial **26** is exposed and is accessible about the perimeter of the distal viewing port **16**. The dial may be manually rotated to effect a rotation of a spacer assembly (not shown) to extend or retract the spacer **28**. With the spacer **28** retracted, the user can effect a dry examination of the skin. With the spacer **28** extended, a user can complete a direct contact skin examination, typically employing oil emersion. The spacer **28** includes a circular sidewall **30** that is retracted within the device when not in use, but extends outwardly and locks into place when extended. The sidewalls **30** support a glass faceplate **32**. The glass faceplate **32** contacts the skin to be examined. The glass faceplate **32** also incorporates a scale **34** to provide the user with information regarding size of a lesion, blood vessel or other object to be viewed. The face plate **32** is removable from the spacer **28**. The sidewalls **30** of the spacer **28** includes a plurality of openings to allow light projected from the illumination sources (not shown) to light the area to be examined.

Status LEDs **36** provide the user with information about the light set being used or the relative intensity of the lights. Side switches **38** and **40** provide the means to operate different sets of illumination sources (not shown) and to activate and deactivate light circuits. A power port **42** is provided as a means of powering the device or recharging on-board batteries (not shown). A USB port is provided as means of powering the device.

Referring particularly to FIGS. **9**–**11**, the device of a first embodiment of the present invention is shown. In FIG. **10** the device **12** is shown from a bottom perspective exploded view, and in FIG. **11** the device **12** is shown from a top perspective exploded view. The housing **14** is formed from top housing component **14***a* and bottom housing component **14***b*. Both components **14***a* and **14***b* include apertures for receiving a lens assembly **50**, and accommodating a lighting array **46**. The lighting array comprises a ring of LEDs affixed to an circuit board **48**. The circuit board **48** is secured within the housing **14**. The LEDs comprise four different colored sets of LEDs each on a different lighting circuit. The four colors comprise White, UV/Blue (405 nm), green/yellow (565 nm) and orange/red (630 nm). White is contemplated for normal epiluminescence imaging, U/Blue for ALA florescence and autoflouresence imaging an, green/yellow for superficial blood vessel imaging and orange/red for deeper blood vessel imaging. Although the invention contemplates use of the forgoing colors for the LEDs it is understood that other colors and combinations of colors are contemplated. For example, 480 nm, 580 nm and/or 660 nm may be used together or in combination with previously identified colors or in combination with colors not identified herein. Indicator LEDs provide the user information about the set of LEDs operating.

In the first embodiment, the LEDs of the lighting array **46** are four different colors, eight of each color for a total of 32 LEDs. The LEDs, are a repeating pattern of the four different colors, fore example, white, UV/blue, green-yellow and orange/red repeating around the perimeter, with all like colors interconnected on a single circuit. In operation, a user initiates a switch to light all of one color, which would comprise eight LEDs. The user can then immediately switch to a second colored set, and so forth. The user can compare and contrast images by toggling between colors. Although the first embodiment contemplates a repeating series of four different colored lights, it is also contemplated that other combinations and arrangements may be utilized. It is also contemplated that as few as two different colors may be used, or as many as thirty two sets of colors, or possibly more if a different number of LEDs are used. A battery **54** is selectively removable from the device **12** and the battery **54** electrically contacts the electrical board **48** and provides power to the device **12**. The battery **54** is Lithium rechargeable battery is contemplated with greater than 600 mAh capability. The battery **54** is adapted for at least four hours of continuous use with 8 LEDs. A typical single lesion examination lasts one minute, and as such the battery life is expected to cover approximately 240 skin lesion examinations. Side switches **38** and **40** also interconnect with the board **48** and provide a user with the ability to selective operate the LEDs. The selection of the color of the LEDs of the light array **46** is done by switch **38** and the selection of the brightness of illumination is controlled by the swith **40**. Power ON/OFF is controlled by depressing swich **40**.

The lens **22** in the first embodiment is preferably a 25 mm diameter aspherical lens with a 10× optical gain. The aspherical design minimizes distortions. The lens is optimized to allow both visual viewing and also allow attachment of a digital camera for capturing images. A lens retainer **18** secures the lens **22** within the housing **14**. Although the first embodiment employs a aspherical lens, the lens may be a single convex lens, a combination of two or more lenses, a double achromat lens, or a combination of double achromat lenses. In addition, the lens may incorporate Hastings lenses. The lenses are coated with an antireflection coating may be used and may additionally include a color filter to selectively filter light passing through the lens.

A lens assembly **50** is held within the lens tube **24**. The lens tube **24** is received within the spacer mover **52**. The spacer **28** is received over the spacer mover **52**, such that the rotation of the spacer mover **52** within the housing **14** causes the spacer **28** to extend and retract. Rotation of the spacer mover **52** is manually operated by the dial **26**.

A center polarizer **56** is integrated with the lens assembly **50**, and provides polarization to the eye of the user (or to a camera lens). An outside ring polarizer **58** provides polarization to of light from the lighting array **46**, and such ring polarizer **58** is 90 degrees out of phase with the center polarizer **5** The center polarizer **56** and outer ring polarizer **58** are composed of acrylic plastic with polarization material embedded within the polarizer. It is contemplated by the invention that the polarizers **56** and **58** may be constructed of glass, also with material embedded or coated on the glass. In addition, the polarizers **56** and **58** may be coated with a filter material that can selectively filter out some of the light frequencies emanating from the object. Alternatively, the secondary filter assembly made of plastic or glass with the capability of filtering the light may be placed in the path of the lens **22** to filter out some of the light. **6** such that the light that reaches the eye of the user (or the camera lens) is cross-polarized. It is contemplated by the present invention that the center polarizer **56** and ring polarizer may be selectively removable, to aid in viewing certain oil immersion dermoscopy examinations. It is also contemplated that device of the present invention can be produced without any polarizing filters.

Referring particularly to FIGS. **13–15**, there is shown the lens assembly **50** combined with the spacer components to form the lens-spacer assembly **60**. The lens assembly comprises a lens retainer **18**, to retain the lens **22**. A polarizer spacer **62** is provided below the lens **22**. A center polarizer **56** is placed over the circular polarizer spacer **62**. The lens assembly **50** is placed within the lens sleeve **24**. At the base, an outside polarizer **58** is provided to provide polarization to the lighting array **46**.

FIGS. **16–18** represent the lighting circuits used to power the lighting array **46** of the device **12**. It is contemplated that the lighting circuits may be comprised of any different number of circuit designs and the circuits represented in FIGS. **16–18** are one way of completing the function of the lighting circuits. Other schemes and designs are contemplated for controlling the lights and selection of color, including, but not limited to, remote control by a USB connector and an on-board microprocessor, control by embedded software in on-board electronics and computer controlled by the USB connector.

FIGS. **19–27** represent the second embodiment of the present invention and are referred hereto collectively. The design of the second embodiment is nearly identical to the first embodiment (and thus the description of common elements are not repeated herein) except for the following differences. In the second embodiment, the lighting array **64** comprises two sets of LEDs, both sets white light. In this regard only two indicator LEDs **66** are required. Also, the outside filter **68** comprises two ring filters **70** and **72**, each filter 90 degrees out of phase with the other. In conformance with two sets of lights, the lighting circuits (not shown) are modified for the second embodiment.

The top **70** and bottom **72** polarizers are 90 degrees out of phase. The bottom **72** polarizer is in cross polarization with the center polarizer **56** and top polarizer **70** is in parallel polarization with the center polarizer **56**. The top **70** and bottom **72** polarizers are composed of acrylic plastic and include polarization at different angles. The polarizers **70** and **72** may also be coated with a special material to filter out some of the light emanating from the LEDs, or alternatively the annular polarizer **70** and **72** may be sandwiched with a color filter acrylic material. The aperture of the polarizer **58** is wide enough to permit a viewing corridor from the lens **22** through the housing **14** while allowing portions of the top **70** and bottom **72** polarizers to be exposed and to filter light emitting diodes inside the housing **20**.

Thirty two light emitting diodes of the array **46** ring the circuit board. The diodes are preferably white high light output Indium Gallium Nitride LEDs, however any suitable lighting diodes are appropriate. The even diodes are on a single circuit and the odd diodes are on a separate single circuit. In the second embodiment, the LEDs are a standard white LED made with phosphorescence phosphors to create white light. It is additionally contemplated by the present invention that tricolored LEDs, with individual red, green and blue LEDs that can combine form white light may be utilized. It is contemplated by the present invention that the LEDs may have focusing lenses to concentrate the light into a smaller and tighter beam. The LEDs may additionally be comprised of indium gallium arsenide material, or any other like semiconductor material. A switch may initiates half of the every other light source, which are the eight even diodes and the switch also initiates the second light source, which are the other sixteen odd diodes. All 32 diodes of the array **46** may be simultaneously

A first polarizer filter **70** comprises a planar annular ring defining a generally circular center opening and an outer ring. The center opening of the annular ring of the first polarizer **70** is positioned in alignment with the circular optical lens **22** to provide an unobstructed view of the skin through the lens **22** and the housing **14**. The outer ring of the first polarizer **70** includes a plurality of openings sized and positioned to correspond to the diodes of the second illumination source (i.e. every other diode **58** of the second light circuit) such that light emitted from the diodes of the second illumination source passes through the openings unfiltered by the first polarizer **70**. Because there are no corresponding openings for the diodes of the first illumination source (i.e. every other diode on the first light circuit) light emitted from first source diodes is polarized by the outer ring of the first polarizer filter **50**.

A second polarizer filter **72** comprises a planar annular ring defining a generally circular center opening and an outer ring. The center opening of said annular ring of the second polarizer **72** is positioned in alignment with the circular optical lens **22** to provide an unobstructed view of the skin through the lens **22** and housing **14**. The second polarizer **72** is 90 degrees out of phase with the first polarizer **70**. The outer ring of the second polarizer **52**, like the first polarizer **50**, has a plurality of openings sized and positioned to correspond to the diodes of the first illumination source (i.e. every other diode on the first light circuit) such that light emitted from the diodes of the first illumination source passes through the openings unfiltered by the second polarizer **72**. Because there are no corresponding openings for the diodes **58** of the second illumination source (i.e. every other diode on the second light circuit) light emitted from second source diodes is polarized by the outer ring of the second polarizer **72**. While the only two light sources (i.e. two sets of diodes) are contemplated three or more sets of diodes are contemplated by the second embodiment of the present invention.

It should be noted and understood that with respect to the embodiments of the present invention, the materials suggested may be modified or substituted to achieve the general overall resultant high efficiency. The substitution of materials or dimensions remains within the spirit and scope of the present invention.

What is claimed is:

1. A dermoscopy epiluminescence device comprising:

a) a generally circular optical lens defining an outer circumference to produce a magnified image of an object to be observed by a viewer;

b) an illumination source comprising a plurality of luminous diodes spaced about the circumference of said optical lens to direct light upon the object;

c) at least one polarizer comprising a planar annular ring filter defining a generally circular center opening and an outer ring, said center opening of said annular ring is positioned in corresponding alignment with the circular optical lens to provide an open view of the object through the lens, said outer ring having at least one opening sized and positioned to correspond to at least one of the diodes of the illumination source of a first colored wavelength such that light emitted from said at least one diode of the illumination source is passed through said at least one opening toward the object and light emitted from remaining diodes of a second colored wavelength of the illumination source is polarized by the polarizer;

d) a viewing polarizer positioned between a viewer and the object to polarize light reflected from the object

wherein said viewing polarizer is cross-polarized relative to polarized light emitted from said remaining diodes; and

e) at least one switch for initiating diodes of a first colored wavelength at a first position and for initiating diodes of a second wavelength at a second position.

2. The dermoscopy epiluminescence device of claim **1** further comprising a power source to power said illumination sources.

3. The dermoscopy epiluminescence device of claim **2** wherein said power source is a battery.

4. The dermoscopy epiluminescence device of claim **2** wherein said power source is a lithium battery.

5. The dermoscopy epiluminescence device of claim **2** wherein said power source is a USB connection.

6. The dermoscopy epiluminescence device of claim **1** wherein at least one of said luminous diodes are white light emitting diodes.

7. The dermoscopy epiluminescence device of claim **1** wherein at least one of said luminous diodes are high light output Indium Gallium Nitride light emitting diodes.

8. The dermoscopy epiluminescence device of claim **1** wherein said optical lens is a Hastings Triplet lens.

9. The dermoscopy epiluminescence device of claim **1** wherein said optical lens is a 15 mm diameter Hastings lens with a 10× optical gain.

10. The dermoscopy epiluminescence of claim **1** further comprising, a housing for integrating the optical lens, illumination source, polarizer and viewing polarizer and wherein said housing is adapted to selectively employ a spacer between the housing and the object to be viewed allowing a user to conduct direct contact examination with the spacer employed and non-contact examination when the spacer is not employed.

11. A dermoscopy epiluminescence device comprising:

a) a generally circular optical lens defining an outer circumference to produce a magnified image of an object to be observed by a viewer;

b) an illumination source comprising a plurality of luminous diodes spaced about the circumference of said optical lens to direct light upon the object;

c) at least one a polarizer comprising a planar annular ring filter defining a generally circular center opening and an outer ring, said center opening of said annular ring is positioned in corresponding alignment with the circular optical lens to provide an open view of the object through the lens, said outer ring having at least one opening sized and positioned to correspond to at least one of the diodes of the illumination source such that light emitted from said at least one diode of the illumination source is passed through said at least one opening toward the object and light emitted from remaining diodes of the illumination source is polarized by the polarizer;

d) a viewing polarizer positioned between a viewer and the object to polarize light reflected from the object wherein said viewing polarizer is cross-polarized relative to polarized light emitted from said remaining diodes; and

e) a housing for integrating the optical lens, illumination source, polarizer and viewing polarizer and wherein said housing is adapted to selectively employ a spacer between the housing and the object to be viewed allowing a user to conduct direct contact examination with the spacer employed and non-contact examination when the spacer is not employed.

12. The device of claim **11** wherein said direct contact examination utilizes oil emersion.

13. The device of claim **11** wherein said device is adapted to interface with a USB connection.

14. The device of claim **13** wherein said housing further incorporates a USB port.

15. The device of claim **11** wherein said housing further incorporates an on-board microprocessor.

16. The device of claim **11** wherein said housing is further adapted to engage and be affixed to a camera body.

17. The device of claim **11** where said spacer is affixed to said housing and is retractable to conduct non-contact examination and extendable to a locked position for direct contact examination.

18. A selective polarization device for producing a polarized view of an object to be observed by a viewer, the device comprising:

a) an optical lens defining an outer circumference;

b) a plurality of first and second luminous diodes being alternately spaced about said outer circumference to form a ring of diodes;

c) at least one a polarizer comprising an annular ring filter defining a generally circular center opening, an outer ring and a plurality of openings, said center opening corresponding with the optical lens to provide an open view of the object through the lens, said outer ring substantially corresponding to said outer circumference, said plurality of openings being sized and positioned corresponding to said second diodes with light emitted therefrom being transmittable through the openings toward the object and light emitted from said first diodes being polarized by the polarizer;

d) a viewing polarizer being positioned between said viewer and being cross-polarized relative to said polarizer; and

e) a housing for integrating the optical lens, said plurality of first and second luminous diodes, polarizer and viewing polarizer and wherein said housing is adapted to selectively employ a spacer between the housing and the object to be viewed allowing a user to conduct direct contact examination with the spacer employed and non-contact examination when the spacer is not employed.

19. The device of claim **18** wherein said direct contact examination utilizes oil emersion.

20. The device of claim **18** wherein said device is adapted to interface with a USB connection.

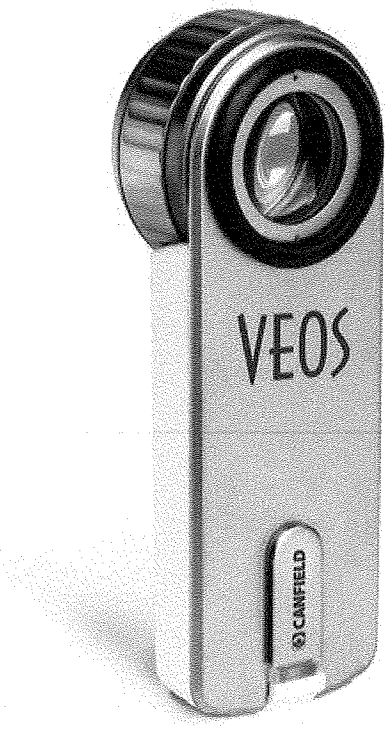
21. The device of claim **18** wherein said housing further incorporates a USB port.

22. The device of claim **18** wherein said housing further incorporates an on-board microprocessor.

23. The device of claim **18** wherein said housing is further adapted to engage and be affixed to a camera body.

24. The device of claim **18** where said spacer is affixed to said housing and is retractable to conduct non-contact examination and extendable to a locked position for direct contact examination.

* * * * *



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Exh 3

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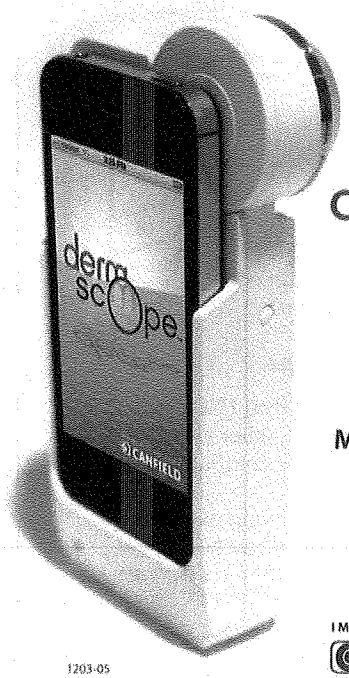

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Exh 4

viewing & capture

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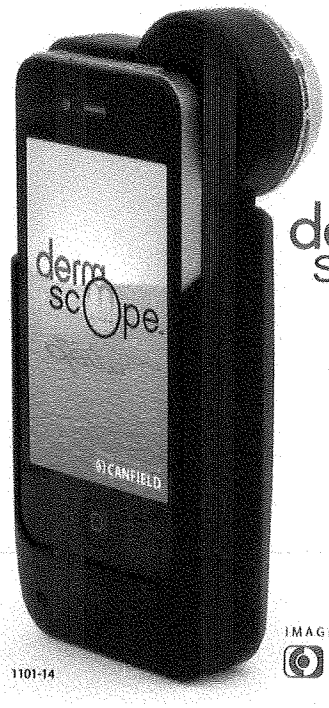

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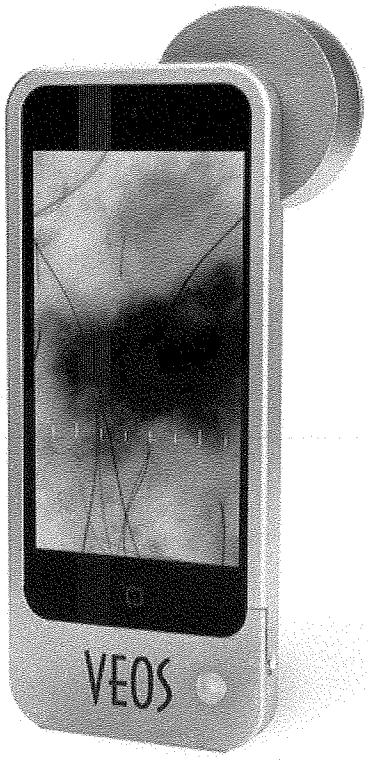

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STETINA BRUNDA GARRED & BRUCKER
75 ENTERPRISE, SUITE 250
ALISO VIEJO, CALIFORNIA 92656
PHONE: (949) 855-1246; FACSIMILE: (949) 855-6371

PROOF OF SERVICE

State of California)
) ss.
County of Orange)

I am over the age of 18 and not a party to the within action; my business address is 75 Enterprise, Suite 250, Aliso Viejo, California 92656. On **August 23, 2013**, the attached **FIRST AMENDED COMPLAINT FOR INJUNCTION AND DAMAGES FOR: (1) PATENT INFRINGEMENT OF US PATENT NO. 7,167,243; (2) PATENT INFRINGEMENT OF US PATENT NO. 7,167,244** was served on all interested parties in this action via U.S. Mail, postage prepaid, at the address as follows:

Chris Kolefas
Brosemer, Kolefas & Associates, LLC
1 Bethany Road, Bldg. 4, Suite 58
Hazlet, New Jersey 07730

Executed on **August 23, 2013** at Aliso Viejo, California. I declare under penalty of perjury that the above is true and correct. I declare that I am employed in the office of STETINA BRUNDA GARRED & BRUCKER at whose direction service was made.

Tara Hamilton