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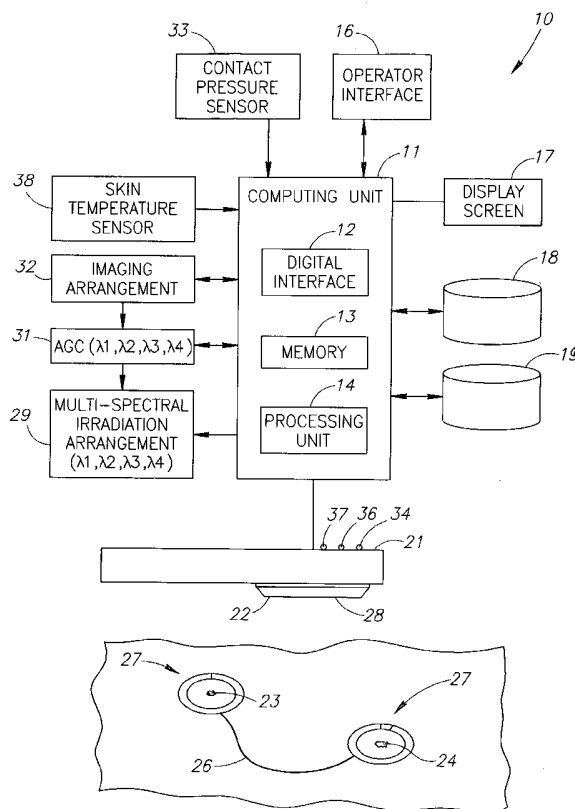
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(54) Title: DERMAL TISSUE INSPECTION APPARATUS AND SELF-ADHESIVE RING STICKERS WITH MACHINE  
READABLE IDENTIFICATION INFORMATION FOR USE THEREWITH



(57) Abstract: Dermal Tissue Inspection (DTI) apparatus including a contact face for intimate placement on a skin site, a multi-spectral irradiation arrangement for irradiating dermal tissue through an aperture in the contact face at at least two different wavelengths, a digital imaging arrangement for capturing digital images of irradiated dermal tissue through the aperture for imaging the dermal tissue at different imaging depths relative to the skin site's surface corresponding to the at least two different wavelengths, and a computing unit for processing the digital images for displaying clinical information on a display screen including clinical images at different imaging depths relative to the skin site's surface. The DTI apparatus is preferably used in conjunction with self-adhesive ring stickers for encircling skin patches at a skin site and having machine readable identification information for identification purposes.

**DERMAL TISSUE INSPECTION APPARATUS AND SELF-ADHESIVE  
RING STICKERS WITH MACHINE READABLE IDENTIFICATION  
INFORMATION FOR USE THEREWITH**

**Field of the Invention**

5           The invention pertains to dermal tissue inspection.

**Background of the Invention**

          Melanoma often is a fatal skin cancer unless it is detected and surgically removed at a relatively early stage. Melanoma starts when a regular mole evolves into a cancerous one. Such an evolvement is distinguished by pronounced changes in a mole's color and geometrical parameters which are both visible to the naked eye and its penetration into a skin's deeper dermal tissues which is hidden from the naked eye. Visible features are classified using the so-called ABCD rule where A=asymmetry, B=border irregularity, C=color variability and D=diameter greater than 6mm. Skin penetration is classified according to the Breslow skin penetration scale as follows: Stage I is defined as mole penetration of upto about 1mm into a skin's epidermis. Stage II is defined as mole penetration of upto about 2mm into a skin's deep dermis. And Stage III is defined as mole penetration greater than 3mm such that a melanoma can hit a lymph node enabling cancerous cells to migrate from the melanoma to the rest of the body, and therefore is the most critical life threatening stage.

          Imaging of human skin has long been recognized to be problematic since it is a non linear compressible biological optical medium whose optical properties are affected by internal and external conditions to such an extent that the same mole imaged under only slightly different conditions can often lead to pronouncedly different images. The theory of light transport in human skin is discussed in the following two papers: "Monte Carlo modeling of light transport in multi layered tissues" L. Wang, S. L. Jacques and L. Zhng, Computer Methods and Programs in Biomedicine 47 (1995), pgs. 131-146; and "A Study

on Skin Optics”, A. Krishnaswamy & G.V.G. Baranoski Technical Report CS-2004-01 Waterloo University, Canada.

Figure 1 shows the relationship between reflectance of human skin and contact pressure, and clearly demonstrates that a reasonably small change in contact pressure dramatically affects reflectance of visible light. Another phenomenon of human skin which has been investigated is the relationship between its reflectance and incident light intensity (see Figure 2). Reference is made to a paper entitled “Skin color detection under changing light conditions”, Störring, Andersen, and Granum, presented at a Conference on Intelligent Robotic Systems, Portugal, July 1999. Moreover, low ambient temperatures impart a bluish hue to human skin. Contrastingly, a body temperature higher than the normal 37°C body temperature imparts a reddish hue to human skin.

### Summary of the Invention

Generally speaking, the present invention is directed towards Dermal Tissue Inspection (DTI) apparatus designed to overcome the inherent difficulties in imaging human skin, and self-adhesive ring stickers for encircling skin patches at a skin site and having machine readable identification information for identification purposes for use therewith. The DTI apparatus of the present invention images dermal tissue at different imaging depths with respect to a skin site’s surface for determining clinical information otherwise invisible to the naked eye for diagnosis and follow-up purposes.

The DTI apparatus includes a probe with a contact face for intimate placement on a skin site, a multi-spectral irradiation arrangement for irradiating dermal tissue through an aperture in the contact face at at least two different wavelengths, a digital imaging arrangement for capturing digital images of dermal tissue through the aperture at the at least two different wavelengths for imaging dermal tissue at different imaging depths relative to the skin site’s surface, and a computing unit for processing the digital images for displaying

clinical information including clinical images at different imaging depths relative to the skin site's surface on a display screen.

The DTI apparatus preferably enables inspection of dermal tissue under a set of predetermined conditions for comparison with suitable case studies for diagnosis purposes, say, at a dermatology clinic, and the like. Moreover, the DTI apparatus enables repeated imaging of the same dermal tissue over an extended period of time for follow up purposes, say, in the home, at an out patient clinic, and the like. The most important predetermined conditions include contact pressure, incident light intensity, and skin temperature. Other conditions of lesser importance include ambient temperature, humidity, and the like.

The DTI apparatus can be implemented with different multi-spectral irradiation arrangements and digital imaging arrangements for imaging at different imaging depths relative to a skin site's surface for different clinical applications. For example, the DTI apparatus can irradiate dermal tissue with blue spectral light in the range of 455nm to 492nm and red spectral light in the range of 622nm to 770nm for imaging dermal tissue at imaging depths of about 0-0.2±0.1mm and about 1-3±0.4mm, respectively, suitable for imaging lesions and melanoma. In this case, the imaging arrangement can include a CCD, CMOS, and the like, monochrome or RGB color camera. Alternatively, the DTI apparatus can irradiate dermal tissue with Infra-Red (IR) radiation for inspecting healing of deep burns. In this case, the imaging arrangement includes a bolometer, for example, ULIS Model # UL 01 01 1 with a wavelength range 8000-14000 nm, commercially available from ULIS, France.

Different implementations of the DTI apparatus of the present invention are envisaged for different end users, say, patients, general medical practitioners, and dermatologists, as follows: First, a discrete camera module for intimate placing on a skin site and including a multi-spectral irradiation arrangement and a digital imaging arrangement for capturing digital images of dermal tissue for clinical information purposes. Such a camera module is intended for mounting on a handheld computing device with a built-in camera for displaying live video

on a display screen for facilitating convenient navigation of the camera module. The camera module preferably has a slim profile achieved by employing a camera behind a multi-spectral irradiation arrangement including an annular irradiation source. And second, a standalone DTI apparatus including a dedicated  
5 computing unit suitably implemented in hardware and/or software.

### **Brief Description of the Drawings**

In order to understand the invention and to see how it can be carried out in practice, preferred embodiments will now be described, by way of non-limiting examples only, with reference to the accompanying drawings in which similar  
10 parts are likewise numbered, and in which:

Fig. 1 is a graph showing reflectance of human skin as a function of contact pressure;

Fig. 2 is a graph showing reflectance of human skin as a function of incident light intensity;

15 Fig. 3 is a block diagram of Dermal Tissue Inspection (DTI) apparatus for inspecting dermal tissue having lesions encircled by ring stickers with machine readable identification information;

Fig. 4 is an optical ray diagram of a multi-spectral irradiation arrangement of the DTI apparatus prior to its intimate placement on a skin site for imaging  
20 purposes;

Fig. 5 is an optical ray diagram of Figure's 4 irradiation arrangement during imaging of dermal tissue;

Fig. 6 is a pictorial view of a display screen comparing a present image of a lesion to a base line image of the same lesion and changes in its ABCD values;

25 Fig. 7 is a pictorial view of a display screen simultaneously displaying three images of a lesion at different imaging depths relative to a skin site's surface;

Fig. 8 is a pictorial view of a packet of peel off self adhesive ring stickers with machine readable identification information for identification purposes;

Fig. 9A is a pictorial view of a dissembled DTI apparatus in accordance with a first preferred embodiment of the present invention;

Fig. 9B is a pictorial view of the DTI apparatus of Figure 9A after assembly; and

5 Fig. 10 is a pictorial view of a standalone DTI apparatus in accordance with a second preferred embodiment of the present invention.

### Detailed Description of Preferred Embodiments of the Present Invention

Figure 3 shows a Dermal Tissue Inspection (DTI) apparatus 10 including a computing unit 11 with a digital interface 12, a memory 13, a processing unit  
10 14, an operator interface 16 for operating the DTI apparatus 10, and a display screen 17 for displaying a Graphic User Interface (GUI) and clinical images of dermal tissue including lesions, melanoma, and the like. The computing unit 11 is connected to a database 18 including case study images of lesions, and a database 19 of patient medical records.

15 The DTI apparatus 10 includes a probe 21 with a contact face 22 for intimate placement on a skin site, say, having a new lesion 23 and an existing lesion 24. The lesions 23 and 24 are preferably encircled by self-adhesive ring stickers 26 having different machine readable identification information 27 for identification purposes. The contact face 22 has an aperture 28 for placing on a  
20 lesion or other skin site location, say, over scar tissue covering a burn, for imaging purposes. The DTI apparatus 10 includes a multi-spectral irradiation arrangement 29 for irradiating dermal tissue through the aperture 28. The irradiation arrangement 29 includes irradiation sources for irradiating  $\lambda_1$  blue spectral light for near surface imaging at imaging depths of about  $0-0.2\pm 0.1$ mm,  
25  $\lambda_2$  green spectral light for imaging at imaging depths of about  $0.3-0.7\pm 0.2$ mm,  $\lambda_3$  red spectral light for deep dermis imaging at imaging depths of about  $1-3\pm 0.4$ mm, and  $\lambda_4$  UV spectral light for photo-luminescence imaging. The multi-spectral irradiation arrangement 29 is under the control of an Automatic Gain Control (AGC) 31 for independently controlling the incident light intensity for

each color of the multi-spectral irradiation arrangement 29 to a predetermined average grey level of, say, 230 in the case of a 0-255 grey level scale.

The DTI apparatus 10 includes a digital imaging arrangement 32 having a live video mode for displaying live video on the display screen 17 and a snapshot mode for capturing digital images of irradiated dermal tissue. The digital imaging arrangement 32 can include a monochrome or RGB color camera. Deployment of a monochrome camera necessitates sequential irradiation of dermal tissue and capturing of a digital image of irradiated dermal tissue for each color to be imaged. Against this, deployment of a RGB color camera enables simultaneous capture of digital images at different colors. Deployment of a monochrome or RGB color camera also determines the use of the AGC 31 as follows: In the case of a monochrome camera, the incident light intensity of each color has to be controlled separately. In the case of a RGB color camera, the AGC 31 can independently control the incident light intensity for all the colors of the multi-spectral irradiation arrangement 29 energized simultaneously.

The contact face 22 is displaceable with respect to the probe 21 as a function of a prevailing contact pressure  $CP(t)$  of the contact face 22 on a skin site's surface. The DTI apparatus 10 includes a contact pressure sensor 33 for sensing the prevailing contact pressure  $CP(t)$ . The contact pressure sensor 33 can be implemented by Honeywell Catalogue No. FSL05N2C. The computing unit 11 selectively disables imaging of dermal tissue subject to the condition that  $CP(t) \neq CP_{base} \pm \Delta CP$  where  $CP_{base}$  is a baseline contact pressure of the contact face 22 on a skin site and  $\Delta CP$  is a preset contact pressure tolerance. A suitable baseline contact pressure is in the range of about 1000Pa to about 2000Pa. A preset contact pressure tolerance  $\Delta CP$  typically has a value of about 50Pa. The computing unit 11 preferably provides a visual indication to an operator that he is applying too little contact pressure, namely,  $CP(t) < CP_{base} - \Delta CP$ , acceptable contact pressure, namely,  $CP(t) = CP_{base} \pm \Delta CP$ , or too much contact pressure, namely,  $CP(t) > CP_{base} + \Delta CP$ . The visual indication can be implemented by, say,

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an orange LED 34 for indicating  $CP(t) < CP_{base} - \Delta CP$ , a green LED 36 for indicating  $CP(t) = CP_{base} \pm \Delta CP$ , and a red LED 37 for indicating  $CP(t) > CP_{base} + \Delta CP$ . Alternatively, a single LED can be employed which undergoes color changes corresponding to the three conditions. The visual indications can be accompanied by audible sound and/or suitable visual indications on the display screen 17.

The contact face 22 includes a skin temperature sensor 38 for sensing a prevailing skin temperature  $ST(t)$  at a skin site. The computing unit 11 selectively disables imaging of dermal tissue subject to the condition that  $ST(t) \neq 37^{\circ}\text{C} \pm \Delta ST$  where  $\Delta ST$  is a preset skin temperature tolerance with respect to normal  $37^{\circ}\text{C}$  body temperature. A preset skin temperature tolerance  $\Delta ST$  typically has a value of about  $1.5^{\circ}\text{C}$ .

Figures 4 and 5 show that the irradiation arrangement 29 includes an annular irradiation source 39 and a transparent disc shaped optical element 41. The annular radiation source 39 can be implemented by an annular array of LEDs 42, electroluminescent wires, and the like. The LEDs 42 includes LEDs for emitting blue light in the 455nm to 492nm blue spectral range, LEDs for emitting green light in the 492nm to 577nm green spectral range, LEDs for emitting red light in the 622nm to 770nm red spectral range, and LEDs for emitting UV light in the 300nm to 390nm UV spectral range. Mid-range LEDs with a narrow spectrum are preferably employed for facilitating imaging of dermal tissue at spaced apart imaging depths. Suitable LEDs having 40nm spectral widths are commercially available from Para Light Electronics Co. Ltd, Taiwan (see [www.para.com.tw](http://www.para.com.tw)).

The optical element 41 has an inside surface 43 and an outside surface 44 constituting the contact face 22. The optical element 41 is coated with reflective material 46 except for an inside circle 47 and an outside circle 48 constituting the aperture 28. The annular irradiation source 39 emits radially inwardly directed irradiation which undergoes total internal reflection in the optical element 41 (see Figure 4). Irradiation emanates outwardly from the aperture 28 on intimate



placement of the contact face 22 on a skin site and is partially reflected by dermal tissue for capture by the digital imaging arrangement 32 (see Figure 5).

The computing unit 11 processes digital images for determining clinical information for diagnosis and follow-up purposes: Figure 6 shows a display screen 49 comparing a present image 51 dated 20/6/05 of a lesion to a base line image 52 dated 20/7/04 of the same lesion imaged at the same imaging depth corresponding to 650nm irradiation. Figure 6 also shows a graphic depiction 53 of the changes in its ABCD values where A=asymmetry, B=border irregularity, C=color variability and D=diameter. Figure 7 shows a display screen 54 simultaneously displaying three images of a lesion at different imaging depths. The computing unit 11 can process digital images to display a reconstructed 3D image of a lesion on the display screen 17.

Figure 8 shows that ring stickers 26 are preferably packaged in packets 56 of 9 ring stickers numbered one through to nine. The ring stickers 26 can be manually peeled off a substrate 57 for removable adhering onto a skin site. The machine readable identification information 27 for lesion identification purposes can be implemented by radially directed lines 58, bar codes, and the like. The ring stickers 26 typically have an internal diameter D1 of about 18 mm and an external diameter D2 of about 25 mm but can be provided in different sizes.

Figures 9A and 9B show the DTI apparatus 10 implemented as a discrete camera module 61 for mounting on a handheld computing device 62 including a built-in camera 63 for displaying live video on a display screen 64. The camera module 61 includes the contact face 28, the multi-spectral irradiation arrangement 29, and the digital imaging arrangement 32 for capturing snap shot digital images of dermal tissue for clinical information purposes. A suitable handheld computing device 11 is the I-Mate Pocket PC or Samsung SCH-i730. The camera module 61 and the handheld computing device 62 preferably communicate over a wireless communication channel, for example, Bluetooth, and the like.

Figure 10 shows the DTI apparatus 10 implemented as a standalone medical device 66 including a dedicated computing unit suitably implemented in hardware and/or software.

The use of the DTI apparatus is now described with reference to dermal tissue imaging of a new lesion and an existing lesion as follows:

An operator places ring stickers on lesions at a skin site, say, a patient's back or one of his limbs which he wants to inspect. The operator holds the probe above the skin site and initiates a live video mode for displaying a distance shot of the skin site on the display screen. The computing unit reads the read stickers for identification purposes to avoid confusion between adjacent lesions. The operator places the probe over one of the ring stickers. The computing unit reads the ring sticker in a close-up shot for correlation with the distance shot. The operator presses the probe down such that the DTI apparatus' aperture overlies the selected lesion. The operator ensures that the green LED is illuminated confirming that he is pressing down with the appropriate contact pressure. The DTI apparatus also confirms that the local skin temperature is within the allowed range of  $37^{\circ}\text{C} \pm 1.5^{\circ}\text{C}$ .

The DTI apparatus is now ready to capture digital images of the selected lesion at different imaging depths relative to the skin site's surface. The DTI apparatus energizes the blue LEDs for irradiating the selected lesion. The DTI apparatus captures a digital image of the dermal tissue. The DTI apparatus determines the average grey level of the digital image. The DTI apparatus adjusts the incident light intensity of the blue LEDs to its predetermined average grey level. The DTI apparatus energizes the blue LEDs a second time. The DTI apparatus captures a digital image at the imaging depth corresponding to the blue spectral color of the blue LEDs. The DTI apparatus repeats the above steps for the remaining irradiation wavelengths, say, green, red, and UV.

In the case of a new lesion, the operator can compare the digital images to suitable case study images selected on the basis of criteria such as skin color, Body Mass Index (BMI), and the like. An operator may decide to open a new

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file for the selected lesion for future follow up. In the case of an existing lesion, present images can be compared to base line images or older images of the same lesion. The operator can decide future action based on his findings.

- 5           While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications, and other applications of the invention can be made within the scope of the appended claims. For example, the DTI apparatus can employ a so-called trans-illumination arrangement for irradiating dermal tissue.

**Claims:**

1. Dermal tissue inspection apparatus comprising:
  - (a) a probe having a contact face for intimate placement on a skin site;
  - 5 (b) a multi-spectral irradiation arrangement for irradiating dermal tissue through an aperture in said contact face at at least two different wavelengths;
  - (c) a digital imaging arrangement for imaging the irradiated dermal tissue through said aperture for capturing digital images at different imaging depths relative to the skin site's surface corresponding to the at least two different
  - 10 wavelengths; and
  - (d) a computing unit for processing said digital images for displaying clinical information on a display screen including clinical images at different imaging depths relative to the skin site's surface.
- 15 2. DTI apparatus according to Claim 1 wherein said contact face is displaceable with respect to said probe as a function of a prevailing contact pressure  $CP(t)$  of said contact face on a skin site's surface, and said computing unit selectively disables imaging of dermal tissue subject to the condition that  $CP(t) \neq CP_{base} \pm \Delta CP$  where  $CP_{base}$  is a baseline contact pressure of said contact
- 20 face on a skin site's surface and  $\Delta CP$  is a preset contact pressure tolerance.
3. DTI apparatus according to Claim 2 wherein said computing unit provides a visual indication that  $CP(t) < CP_{base} - \Delta CP$  or  $CP(t) = CP_{base} \pm \Delta CP$  or  $CP(t) > CP_{base} + \Delta CP$ .
- 25 4. DTI apparatus according to any one of Claims 1 to 3 wherein said contact face includes a skin temperature sensor for sensing a prevailing skin temperature  $ST(t)$  at a skin site and said computing unit selectively disables imaging dermal tissue subject to the condition that  $ST(t) \neq 37^{\circ}C \pm \Delta ST$  where  $\Delta ST$  is a preset
- 30 skin temperature tolerance.

5. DTI apparatus according to any one of Claims 1 to 4 and further comprising an Automatic Gain Control (AGC) for independently controlling the incident light intensity at each wavelength of said at least two different wavelengths such that said digital imaging arrangement captures digital images of dermal tissue at a predetermined average grey level for each wavelength of said at least two different wavelengths.

6. DTI apparatus according to any one of Claims 1 to 5 wherein said multi-spectral irradiation arrangement includes an annular irradiation source encircling said aperture and emitting radially inwardly directed irradiation undergoing total internal reflection within said multi-spectral irradiation arrangement and emanating through said aperture for irradiating the dermal tissue on said intimate placement of said contact face on a skin site.

15

7. DTI apparatus according to any one of Claims 1 to 6 wherein said digital imaging arrangement includes a monochrome digital camera whereupon said multi-spectral irradiation arrangement and said digital imaging arrangement sequentially irradiate dermal tissue and capture a digital image of the irradiated dermal tissue at each wavelength of the at least two different wavelengths.

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8. DTI apparatus according to any one of Claims 1 to 7 wherein a skin patch at a skin site is encircled by a ring sticker with machine readable identification information and said computing unit identifies said encircled skin patch by reading said ring sticker.

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9. DTI apparatus according to Claim 8 wherein said computing unit identifies said ring sticker in a distance shot of a skin site and a close-up shot of the skin site.

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10. DTI apparatus according to any one of Claims 1 to 9 wherein said computing unit simultaneously displays images of dermal tissue on said display screen at different imaging depths relative to the skin site's surface.
- 5 11. DTI apparatus according to any one of Claims 1 to 10 wherein said computing unit displays a reconstructed 3D image of dermal tissue on said display screen.
12. DTI apparatus according to any one of Claims 1 to 11 wherein said at least  
10 two wavelengths includes blue spectral light for near skin imaging of dermal tissue and red spectral light for deep dermis imaging.
13. DTI apparatus according to Claim 12 wherein said computing unit determines ABCD values of a lesion at different imaging depths relative to a skin  
15 site's surface where A=asymmetry, B=border irregularity, C=color variability and D=diameter.
14. DTI apparatus according to any one of Claim 1 to 13 wherein said at least two wavelengths are Infra-Red (IR) radiation.
- 20 15. DTI apparatus according to any one of Claims 1 to 14 implemented as a discrete camera module including said contact face, said multi-spectral irradiation arrangement and a digital imaging arrangement for capturing digital images of dermal tissue for clinical information purposes for use with a discrete handheld  
25 computing device including a built-in camera for displaying live video on a display screen.

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16. A packet of ring stickers for removably adhering on a skin site, the packet of ring stickers comprising a substrate with a plurality of self-adhesive ring stickers for encircling skin patches at a skin site, and having machine readable identification information for identification purposes.

5

17. The packet of ring stickers according to Claim 16 wherein said machine readable identification information is in the form of radially directed lines.

18. The packet of ring stickers according to Claim 16 or 17 wherein said ring  
10 stickers are annular.

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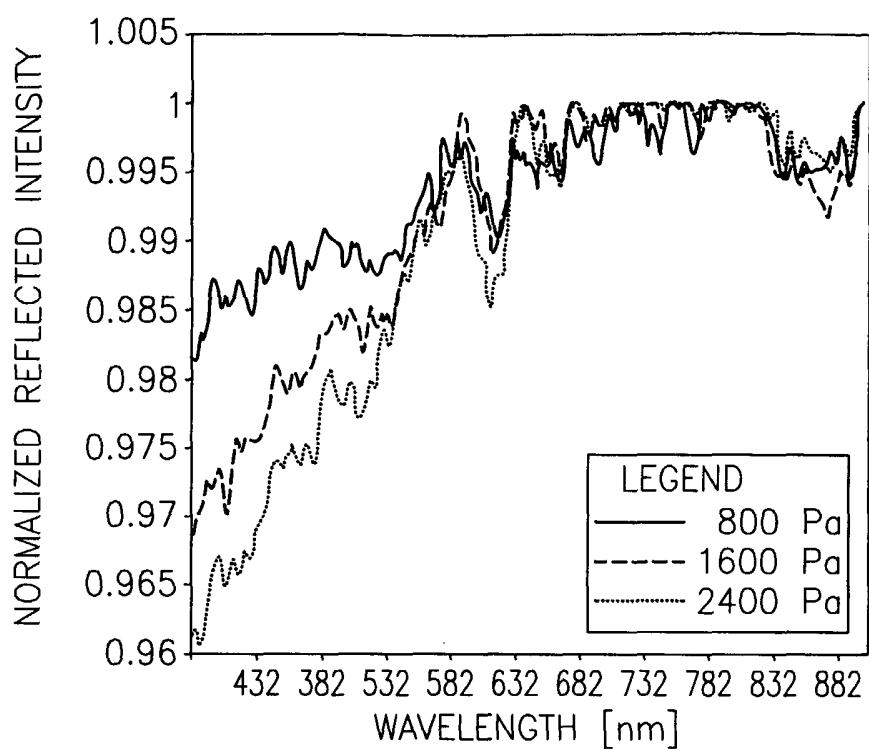


FIG.1

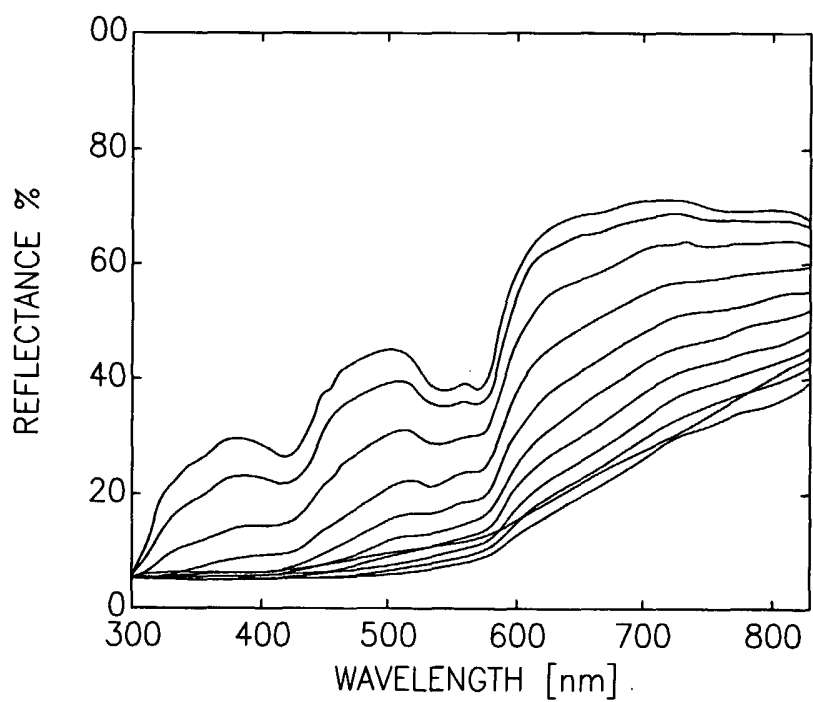


FIG.2



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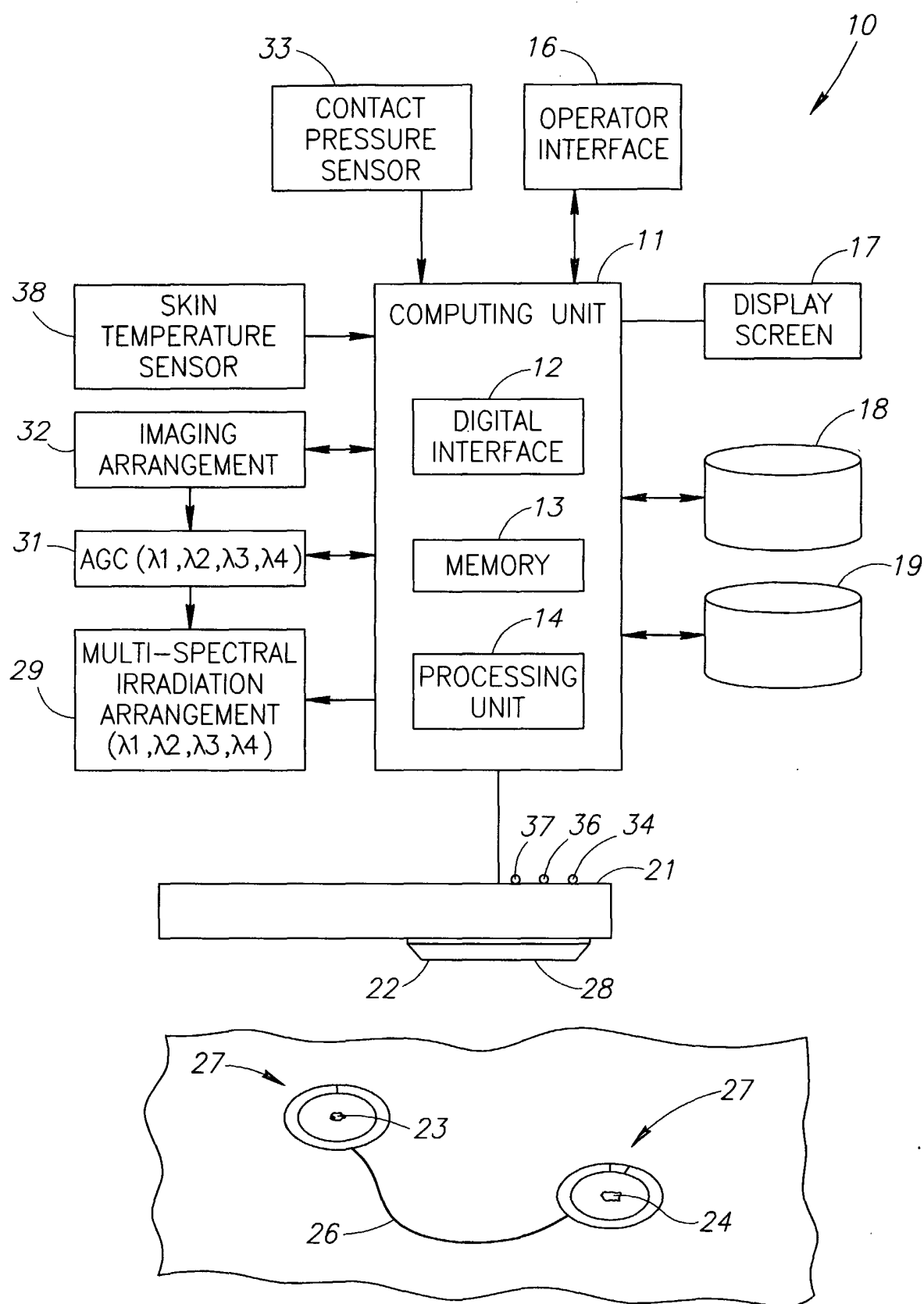
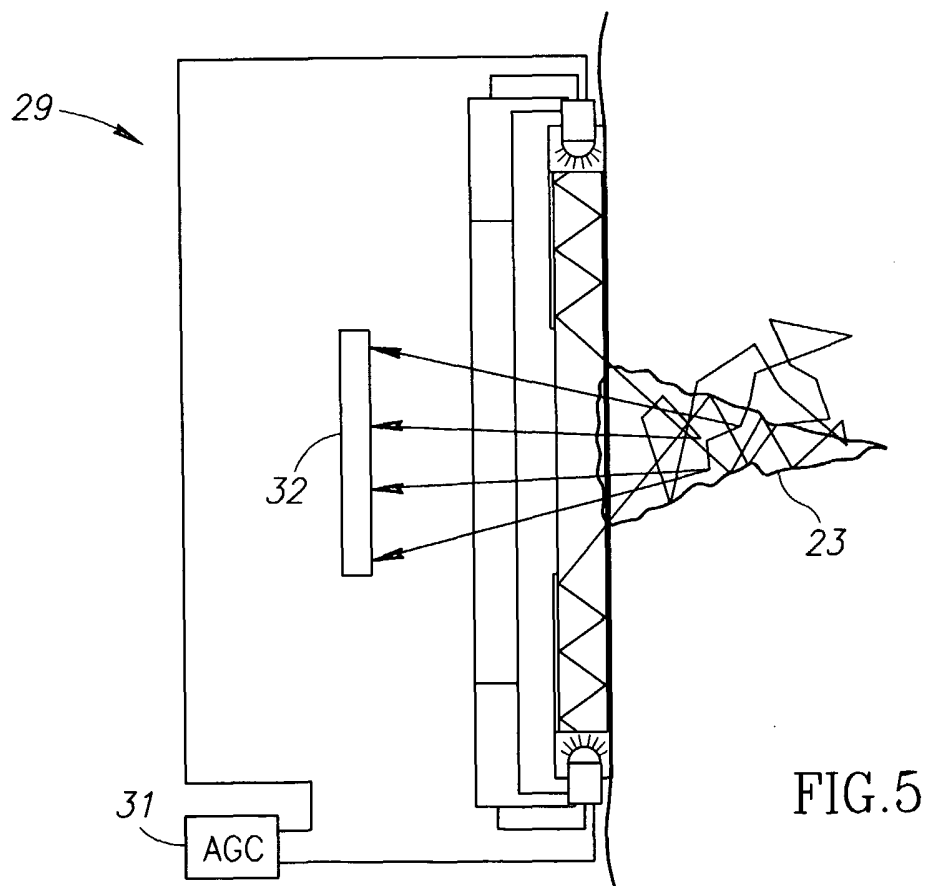
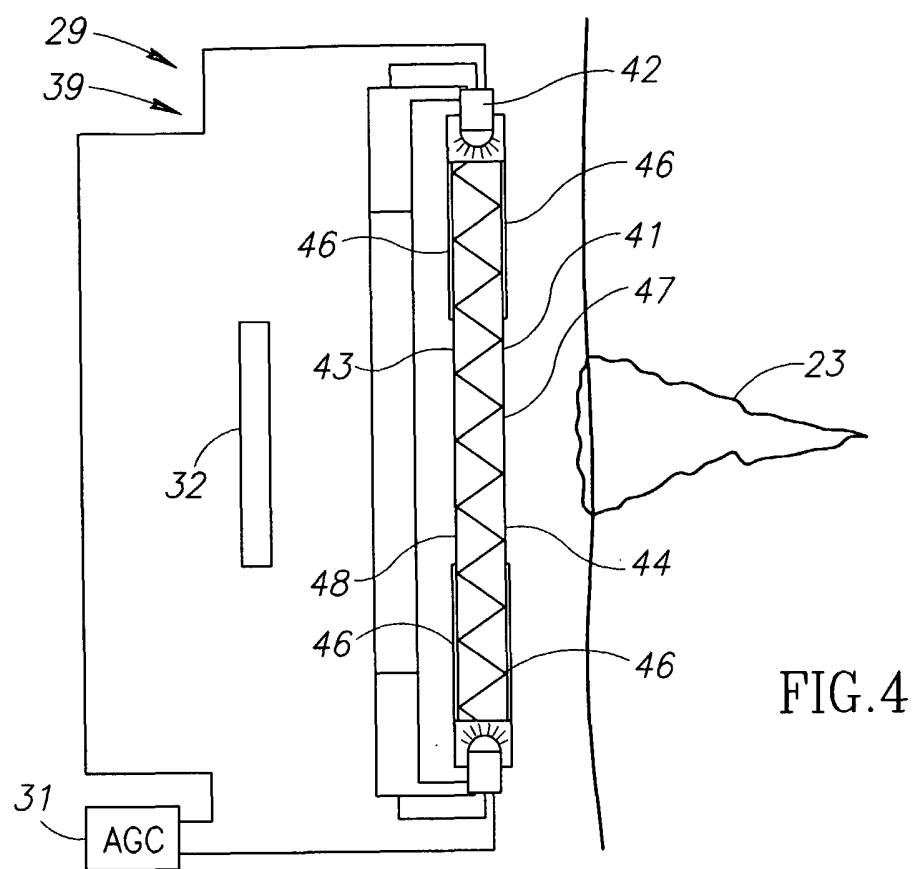


FIG.3

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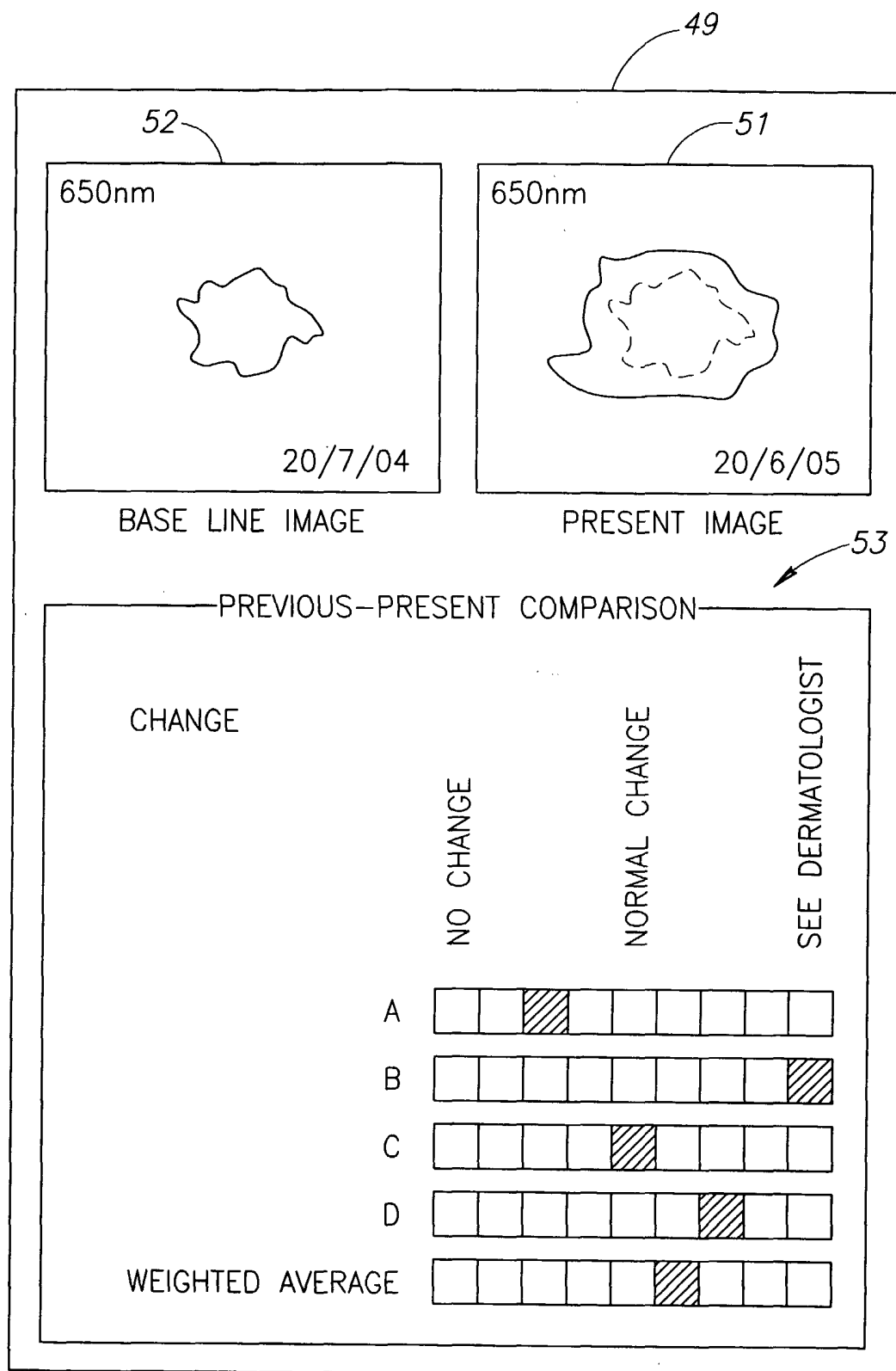


FIG.6

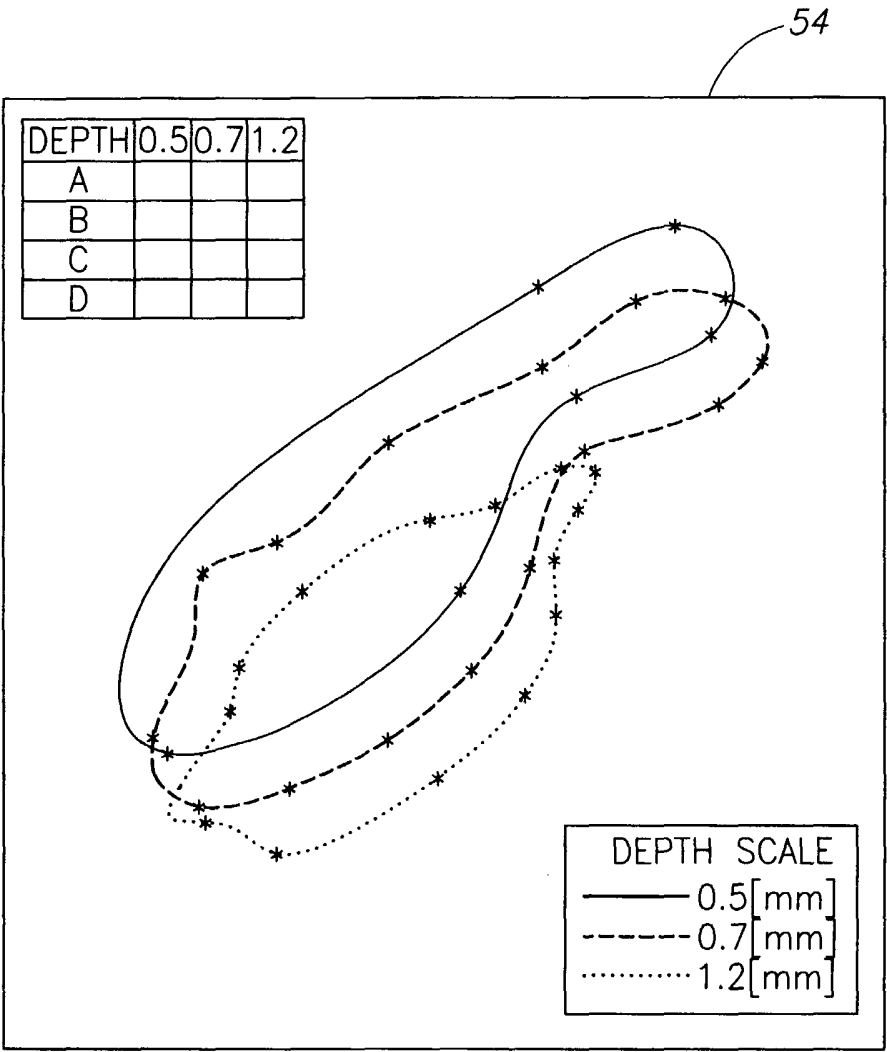


FIG.7

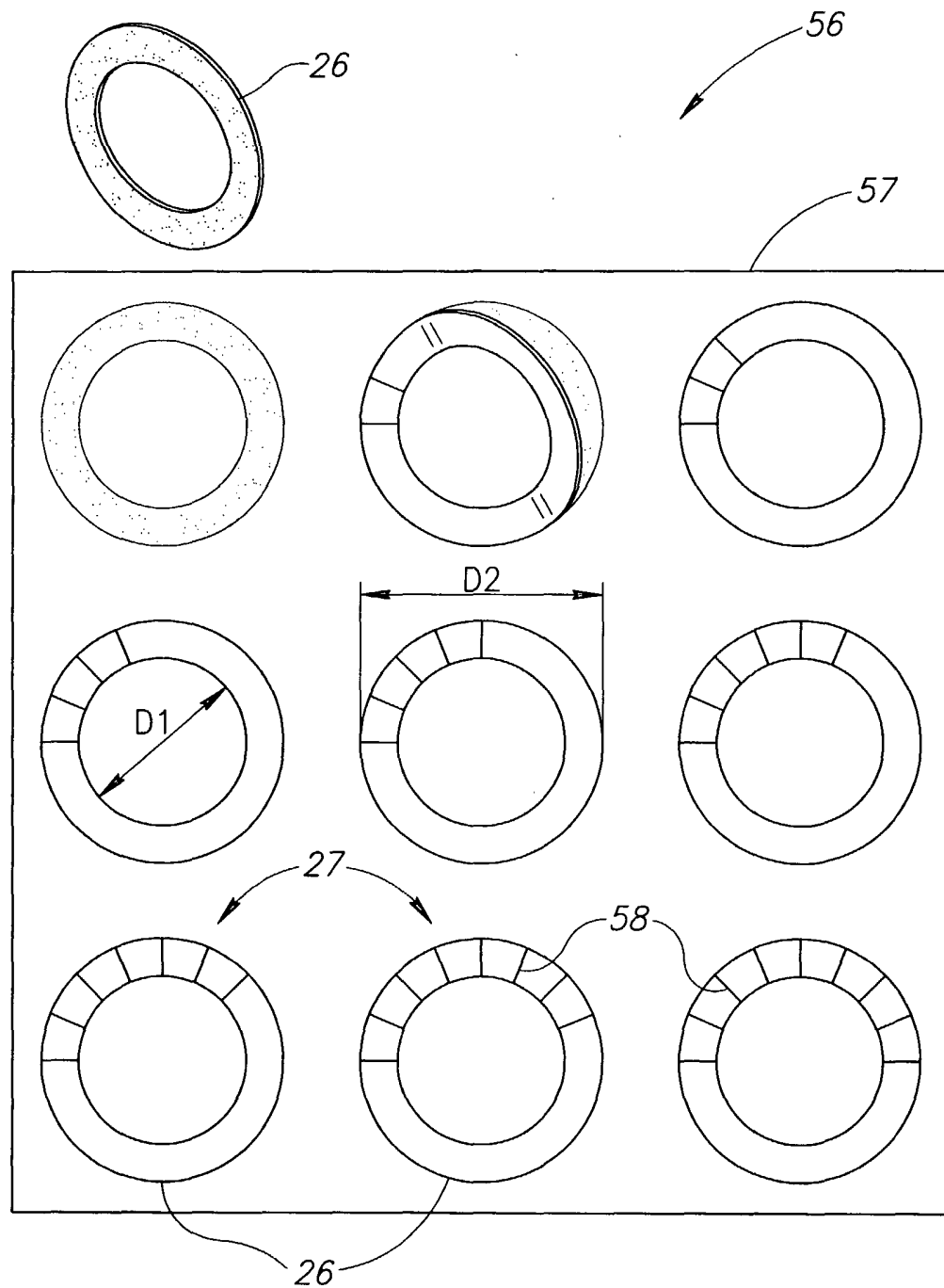


FIG. 8

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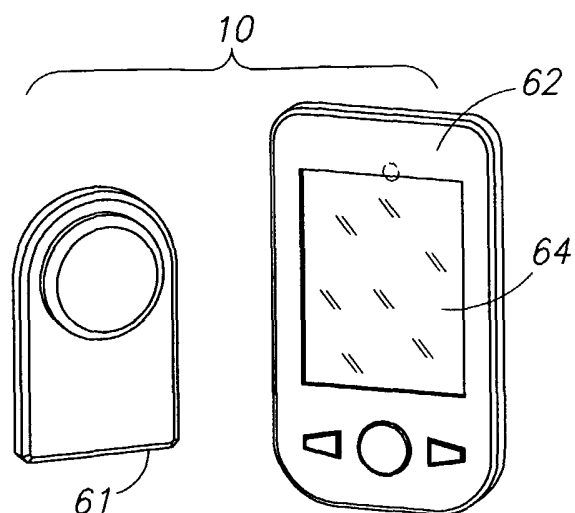


FIG. 9A

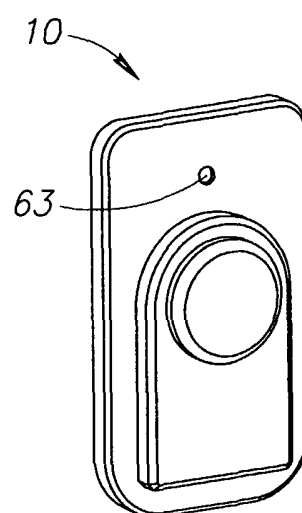


FIG. 9B

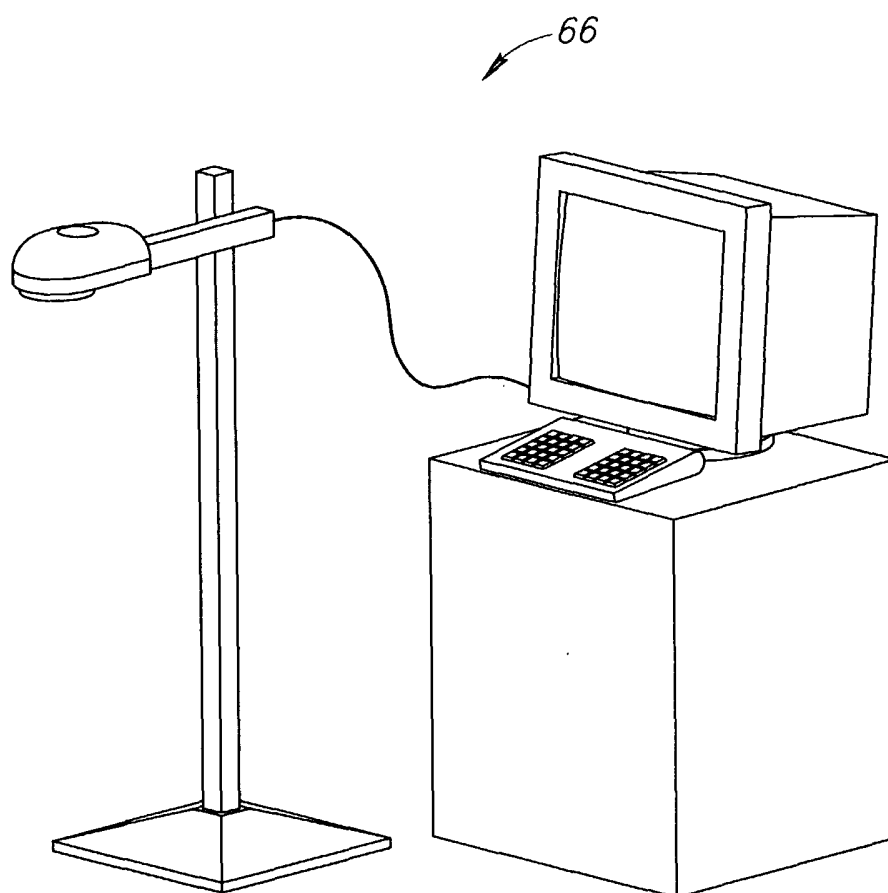


FIG. 10