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- (81) **Designated States** (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,

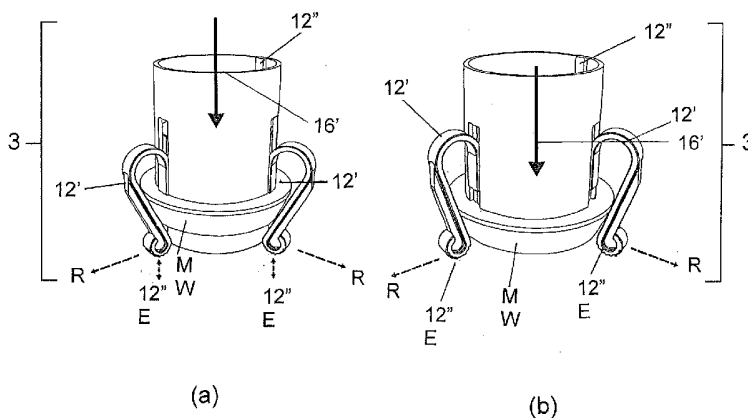
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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(54) Title: A SYSTEM AND METHOD FOR IMAGING BODY AREAS

FIG. 3



(57) **Abstract:** The invention relates to a system for imaging one or more external human body areas comprising a photographic device configured to acquire, store and output an image or images of the one or more body areas. The invention also relates to a method for determining a probable disease state of an external human body area.

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A system and method for imaging body areas

The invention relates to a system for imaging one or more external human body areas with a photographic device  
5 mounted or mountable thereon and configured to acquire, store and output an image or images of the one or more body areas, wherein the system further comprises a stretching element to transversally stretch at least a proportion of each of the one or more body areas, which stretching element has an expandable  
10 body surface engaging portion and means to define a degree of expansion of the expandable body surface engaging portion to a predefined value.

Such a system is known from US2003/0045799 and from DE 197 19 336 A.

15 The system of US2003/0045799 concerns a portable device with means for capturing an image or images from a body skin, which device can be used in combination with a separate tool for creasing or stretching the skin. This tool has portions which must be provided with double-sided adhesive tape in  
20 order to attach to the skin. The system of US2003/0045799 is relatively cumbersome in use and probably less reliable in taking images because it requires separate handling of the tool and the portable device to be used after stretching or creasing the skin with the tool. A definite disadvantage is that the  
25 system of this prior art involves the handling of separate independent parts.

The device of DE 197 19 336 A is a unitary device but is of complicated construction and applies sensors to monitor the amount of stretching applied to the skin. Considering its  
30 complicated construction it appears that this device is less suited for home use.

It is one of the objects of the invention to provide a system for monitoring people with a risk of developing cutaneous melanoma, which is usable in a home environment. It is  
35 noted that the system could also be used by people without an elevated risk of developing cutaneous melanoma, but who are very anxious about their skin, consequently making regular "false-alarm" visits to their doctor which may be prevented by

having these people use the system of the invention on their own.

Cutaneous melanoma is a cancer of the skin in which melanocytes (pigment forming cells) develop malignantly. Of the total number of deaths that occur each year as a result of skin cancer, approximately 75 % (global average) of these are due to cutaneous melanoma.

A common symptom of cutaneous melanoma is a change in appearance of a skin nevus. Nevus (plural nevi) is a term used to describe pigmented spots on the skin including moles, birthmarks, lentiges and freckles.

To be able to identify a change it is convenient to have a system that is able to acquire, output and store images of the nevi for later comparison.

Systems for imaging external human body areas are known in the prior art. One further example of such is provided in US 2011/0040192.

US 2011/0040192 recites: a mole monitoring system including: (a) a calibration fixture including an illuminator that is operational to illuminate a skin area that includes a mole; (b) a digital camera operational to acquire at least one image of a body area that is included in the illuminated skin area and which includes the mole and its environment; and (c) a processor operational to analyze the at least one image of the mole and to determine values for parameters of the mole.

A disadvantage of such a system is that the mole being imaged can become distorted by contacting the calibration fixture with the skin area, which includes the mole, such as in a manner that is dependent on the pressure applied; thus if multiple images of a mole must be recorded at different points in time, consistency of imaging can be problematic. A further disadvantage is that determined parameters outputted by the system are not meaningful to any person other than a trained dermatologist.

It is a further object of the invention to provide a system for imaging one or more external human body area(s) that overcomes one or more disadvantages of systems of the prior art.

It is still a further object of the invention to pro-

vide a method for collecting data enabling the later determination of a probable disease state of an external human body area, such as by using the system of the invention.

It is still a further object of the invention to provide a system which provides consistency in lighting conditions, distance from observer to object and skin stretch uniformity.

These and other objectives that may become apparent from the following disclosure are at least in part achieved with a system and method according to one or more of the appended claims.

In a first aspect, the invention relates to a system for imaging one or more external human body areas with a photographic device mounted or mountable thereon and configured to acquire, store and output an image or images of the one or more body areas, wherein the system further comprises a stretching element to transversally stretch at least a proportion of each of the one or more body areas, which stretching element has an expandable body surface engaging portion and means to define a degree of expansion of the expandable body surface engaging portion to a predefined value, and which is provided with the specific features that the stretching element comprises three or more legs that are resilient or are resiliently mounted to a main body of the stretching element, each of the legs having a lowest point with a preferential position adjacent to said main body, wherein the combination of all such lowest points of the legs together forms the expandable body surface engaging portion, and wherein the main body of the stretching element is further provided with one or more wedge-shaped elements around the circumference of said main body which provide an increasing diameter to the main body as seen in a direction from the expandable body surface engaging portion towards the photographic device, wherein the main body is movable towards the expandable body surface engaging portion to cause that the wedge-shaped elements provided on said main body drive the three or more legs and their lowest points in a radial direction away from their preferential position adjacent to said main body resulting in expansion of the expandable body surface engaging portion.

This enables that in use, with the body surface engaging portion being in contact with a body area, expansion of the body surface engaging portion results in transverse stretching of the body area being imaged. According to this system it is possible for people in their home environment to take images in a consistent way so as to allow meaningful comparison to be undertaken between images of the same body area recorded at different time points. All that is required is pressing the main body of the stretching element towards the skin to be observed; the construction of the stretching element with the surrounding legs and the wedges acting on said legs ensures that the pressing action always results in uniform and the same amount of stretching of the skin. In this way reproducibility in obtaining the images is ensured.

The form of the body surface engaging portion and/or the material from which the body surface engaging portion is constructed are chosen such that stretching is achievable through said expansion: the coefficient of friction between the body surface engaging portion and the external human body area should be sufficient to prevent the body surface engaging portion from simply sliding over the body area rather than stretching it.

The wedge-shaped elements are designed such to determine a degree of expansion of the expandable body surface engaging portion to a predefined value so as to prevent that the force exerted by the body surface engaging portion on the external human body area becomes larger than the frictional force between this body surface engaging portion and the external human body area.

In a particularly preferred embodiment, the stretching element comprises three or more legs wherein a lowest point of each leg, together forming the expandable body surface engaging portion, is in a horizontal plane equally spaced around the circumference of an imaginary circle, wherein the lowest point of each leg is moveable in a radial direction relative to the imaginary circle.

Research by the inventor has shown that optimum stretching, in particular of areas of a body that are curved, can be achieved by having as few legs as possible. The minimum

number of legs necessary to be able to achieve stretching in two dimensions is three.

A portion of each of the three or more legs is preferably elastically deformable. This promotes the legs to follow the curvature of the body surface.

The stretching element could be made by e.g. 3D printing or by injection molding at low cost. Other suitable techniques are known to a person of skill in the art. The finished product will preferably retail for less than 150 euros, such as between 100 and 150 euros.

Furthermore, the legs are preferably mounted to, or are integral to a main body of the stretching element and/or the legs are elastically coupled to the main body.

Wherein the system further comprises means to determine a degree of expansion of the expandable body surface engaging portion to a predefined value, the degree of expansion could be limited such that above a certain applied pressure the degree of expansion would be independent of stretching of at least a portion of the one or more body areas and thus facilitate a user to consistently reproduce the same extent of stretching. The applied wedge-shaped elements constitute a simple means for establishing a degree of expansion of the expandable body surface engaging portion at a predefined value i.e. determined by the length of the wedges and its angle relative to an imaginary axis running the length of the stretching element (when the system is in use with the expandable body surface engaging portion in contact with a horizontal surface, the imaginary axis would be a vertical axis). In other words, a point is reached at which no further expansion is actuable by the wedges.

In a preferred embodiment, the system further comprises, or is arranged, to provide a fixed spacing between the photographic device and the body area being imaged at least during capture of an image. This may be through provision of an additional component on the system, but may also be achieved as an effect of the combination of components making up the system, e.g. by mounting the photographic device directly on top of the stretching element. The system may then be pushed against a body area during image capture and the rigidity of

the system as a whole ensures the fixed spacing. A person of skill in the art can envisage many other ways in which such an effect can be achieved.

5 The photographic device is any device that is suitable for recording close-up photographs or videos of a body area. Close-up is defined as with a sensor, e.g. a CCD (charge coupled device), of the photographic device being within 20 cm of the body area, such as within 10 cm of the body area, e.g. within 5 cm of the body area.

10 The photographic device preferably comprises: a sensor e.g. a CCD (charge coupled device); a power source; a lense; a memory, such as a removable memory card; means to output images stored on the memory to a computer, such as via a USB cable; means to illuminate the body area, preferably uniformly, and; a screen for visualising images stored on the  
15 memory.

As already mentioned desirably the photographic device is mounted on top of the stretching element. In a suitable embodiment of the stretching element this can provide fixed  
20 spacing between observer and object, and provides the conditions enabling the exclusion of ambient light.

The one or more human external body areas (also abbreviated to body areas or one or more body areas) are areas on the skin, typically areas containing a nevus or nevi: applica-  
25 tions can be envisaged where the system could be used to monitor e.g. areas of skin suffering from other skin disorders and which do not contain a nevus or nevi.

In a preferred embodiment, the system further comprises a memory, or online data storage means, storing a historical database comprising sequences of images of reference  
30 body areas.

Each sequence of images of the sequences of images of reference body areas preferably further comprises a label relating to a disease state that has been identified for the body  
35 area to which the sequence of images relates, e.g. whether a feature of that body area e.g. a mole was identified to be malignant or benign. By providing a memory, or online data storage means, storing a historical database that comprises sequences of images of reference body areas, and by performing a

comparison (preferably by pattern recognition) between the reference images and images captured by the user, the system could alert a user of the need to seek further help e.g. from a dermatologist or other specialist.

5           In a preferred embodiment, the sequences of images of reference body areas relate to body areas of multiple patients. The database preferably contains a large number of reference images.

10           In a second aspect, the invention relates to a method to collect data pertaining to an external human body area which can (later) be used to determine a probable disease state of an external human body area. In this method a comparison is done how the nevus evolves over time. The method comprises: (i) imaging one or more body areas over time, e.g. weekly or monthly,  
15           to obtain a sequence of images; (ii) comparing said images with an initial image or images (e.g. a first image in the sequence) of the one or more body areas, and; (iii) identifying differences occurring over time (e.g. appearance of new colors, a change in shape (in asymmetric manner) and appearance of a local, irregular pigment network), such as using pattern recognition (such techniques are known to a person of skill in the art). The method further comprises: (iv) comparing sequences of images obtained in step (i) with a historical database comprising sequences of images of reference body areas. The data may  
20           be used for determining a probable disease state e.g. by relating a characteristic of the sequences of images of reference body areas to those obtained in step (i); examples of characteristics to compare include appearance of new colors, a change in shape (in asymmetric manner) and appearance of a local, irregular pigment network etc. By reference to the historical database, a statistical probability that the presence of a particular characteristic signals a particular disease state can be assigned. Wherein the probability is above a certain threshold value a user can be warned by the system to see a specialist.  
35

          Preferably a current recording of images is compared to an initial recording of images to establish an absolute evolution of the images over the time elapsed between the initial recording and the current recording of images, and comparing



this absolute evolution of images with a normalized evolution of such images pertaining to the elapsed time. This will reveal the rate of change of the parameters of the nevus, and provides the advantage that a very aggressive melanoma which might initially not result in an alarm will still be detected.

The invention will hereinafter be further elucidated with reference to the Drawing of Figures 1-3 showing an exemplary embodiment of the system of the invention. This exemplary embodiment is provided for merely illustrative purposes and is not be considered limiting of the claims.

Figures 1(a) and 1(b) show alternative views of a preferred embodiment of the system of the invention;

Figure 2 shows constituent parts of the system of the invention;

Figure 3(a) and 3(b) show a preferred embodiment of the stretching element in non-expanded and expanded states respectively.

Where in the Figures the same reference numerals or characters are used, these reference numerals or characters refer to the same parts.

With reference first to Figure 1; Figure 1 shows a preferred embodiment of the system 1 for imaging one or more external human body areas comprising a photographic device 2 (components 1'-11' and 13'-15' of Figure 2) configured to acquire, store and output an image or images of the one or more body areas, wherein the system 1 further comprises a stretching element 3 (components 12' and 16' of Figure 2) to transversally stretch at least a portion of each of the one or more body areas.

Figure 2 shows constituent parts of the system 1. The system 1 comprises: a casing topshell 1'; a casing bottom shell 2'; a mini USB port 3' (for outputting an image or images acquired by the system); a battery 4'; flash memory 5'; buttons 6' (to operate the device); a CPU 7'; a display 8'; a buzzer 9' (to signal the user e.g. that a measurement is complete); an image sensor 10' (for capturing an image or images e.g. a CCD); a source of illumination 11' (e.g. a ring of light emitting diodes for illuminating a body area being imaged by the system); legs 12' (which make up part of the stretching element, ex-

plained with reference to Figure 3); a lens 13'; a linear polarizer 14' (to minimize the amount of scattered and reflected light reaching the sensor 10'); a faceplate 15' (to contain the indicated elements and to flatten a body area of interest, including the mole, thus providing a flat, illuminated surface at fixed distance); a main body 16' of the stretching element 3.

Figure 3(a) and 3(b) show a preferred embodiment of the stretching element 3. The stretching element 3 has an expandable body surface engaging portion E and is shown in a non-expanded and an expanded state in Figures 3(a) and 3(b) respectively. The stretching element 3 of the system 1 further comprises means M to define a degree of expansion of the expandable body surface engaging portion E to a predetermined value. The stretching element 3 comprises three legs 10' wherein a lowest point 12'' of each leg 12', together forming the expandable body surface engaging portion E, is in a horizontal plane equally spaced around the circumference of an imaginary circle, wherein the lowest point 12'' of each leg 10' is moveable in a radial direction R relative to the imaginary circle. Each of the three legs 12' is elastically deformable and is mounted to a main body 16' of the stretching element 3. The stretching element is arranged such that lateral movement of the body surface engaging portion relative to the main body of the stretching element accompanies expansion of the expandable body surface engaging portion (as shown in Figure 3). The system 1 further comprises a wedge-shaped element W around the main body 16' of the stretching element 3 arranged such that lateral motion of the three or more legs 12' relative to the wedge-shaped element W results in expansion of the expandable body surface engaging portion E i.e. the lowest point 12'' of each of the legs 12' moves in the direction R upon pushing the expandable body surface engaging portion E against a body area. The wedge shaped element W embodies the means M to determine a degree of expansion of the expandable body surface engaging portion E to a predefined value. The legs 12' are prevented from passing a highest point of the wedge.

The system 1 further comprises a memory, or online data storage means (not shown), storing a historical database comprising sequences of images of reference body areas. The se-

quences of images of reference body areas relate to body areas of multiple patients, e.g. containing various types of nevi and melanoma, thus serving to improve the diagnostic accuracy of the system.

CLAIMS

1. A system (1) for imaging one or more external human body areas with a photographic device (2) mounted or mountable thereon and configured to acquire, store and output an image or images of the one or more body areas, wherein the system  
5 (1) further comprises a stretching element (3) to transversally stretch at least a proportion of each of the one or more body areas, which stretching element (3) has an expandable body surface engaging portion (E) and means (M) to define a degree of expansion of the expandable body surface engaging portion (E)  
10 to a predefined value, **characterised in that** the stretching element (3) comprises three or more legs (12') that are resilient or are resiliently mounted to a main body (16') of the stretching element (3), each of the legs (12') having a lowest point (12'') with a preferential position adjacent to said main body (16'), wherein the combination of all such lowest points (12'')  
15 of the legs (12') together forms the expandable body surface engaging portion (E), and wherein the main body (16') of the stretching element (3) is further provided with one or more wedge-shaped elements (W) around the circumference of said main  
20 body (16') which provide an increasing diameter to the main body (16') as seen in a direction from the expandable body surface engaging portion (E) towards the photographic device, wherein the main body (16') is movable towards the expandable body surface engaging portion (E) to cause that the wedge-shaped elements (W) provided on said main body (16') drive the  
25 three or more legs (12') and their lowest points (12'') in a radial direction (R) away from their preferential position adjacent to said main body (16') resulting in expansion of the expandable body surface engaging portion (E).

30 2. A system (1) according to claim 1, **characterised in that** the photographic device (2) is mounted on top of the stretching element (3).

3. A system (1) according to claim 1 or 2, **characterised in that** at least a portion of each of the three or more  
35 legs (12') is elastically deformable.

4. A system (1) according to one or more of the preceding claims, **characterised in that** the system (1) further

comprises a memory, or online data storage means, storing a historical database comprising sequences of images of reference body areas.

5       5. A system (1) according to claim 4, **characterized in that** the sequences of images of reference body areas relate to body areas of multiple patients.

10       6. A method to collect data pertaining to an external human body area comprising: (i) imaging one or more body areas over time to obtain a sequence of images; (ii) comparing said images with an initial image or images of the one or more body areas, and; (iii) identifying differences occurring over time, **characterized in that** the method further comprises: (iv) comparing sequences of images obtained in step (i) with a historical database comprising sequences of images of reference body areas.

15       7. A method according to claim 6, **characterized in that** a current recording of images is compared to an initial recording of images to establish an absolute evolution of the images over an elapsed time between the initial and the current recording of images, and comparing said absolute evolution of images with a normalized evolution of such images pertaining to the elapsed time.

FIG. 1

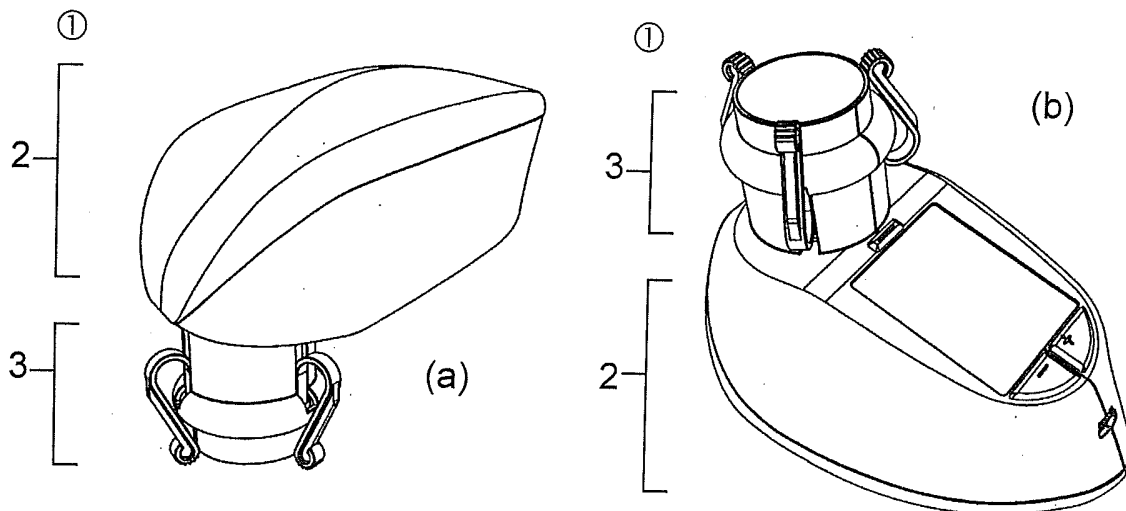


FIG. 2

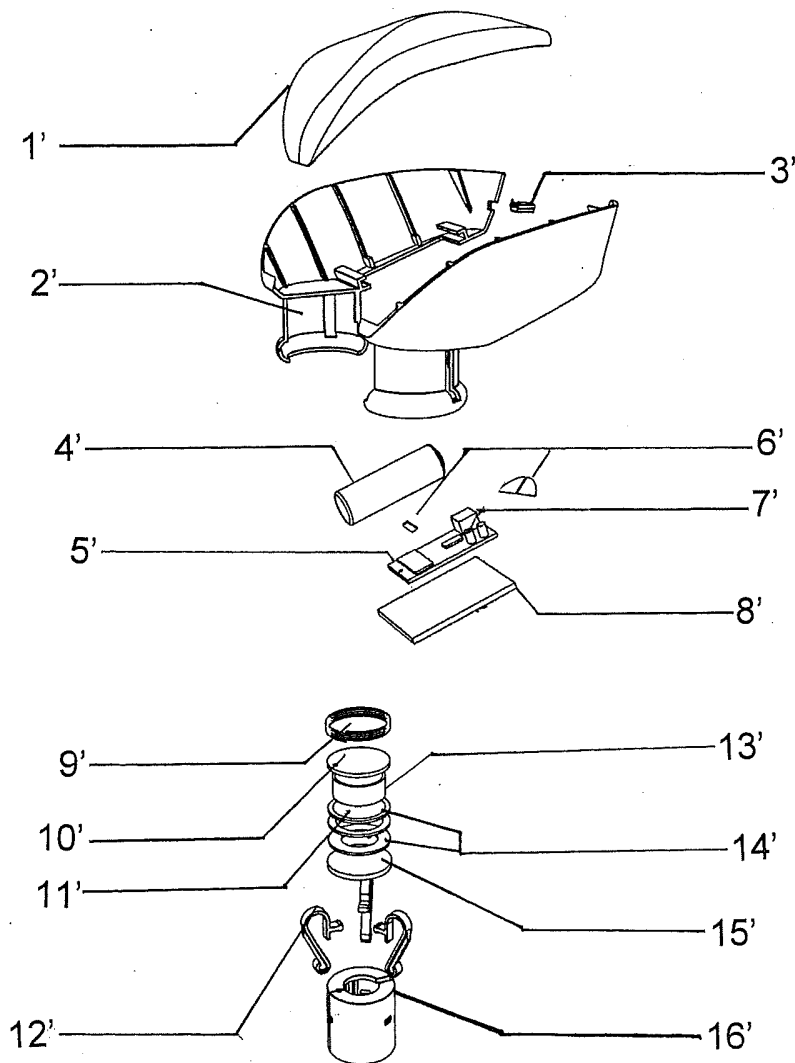
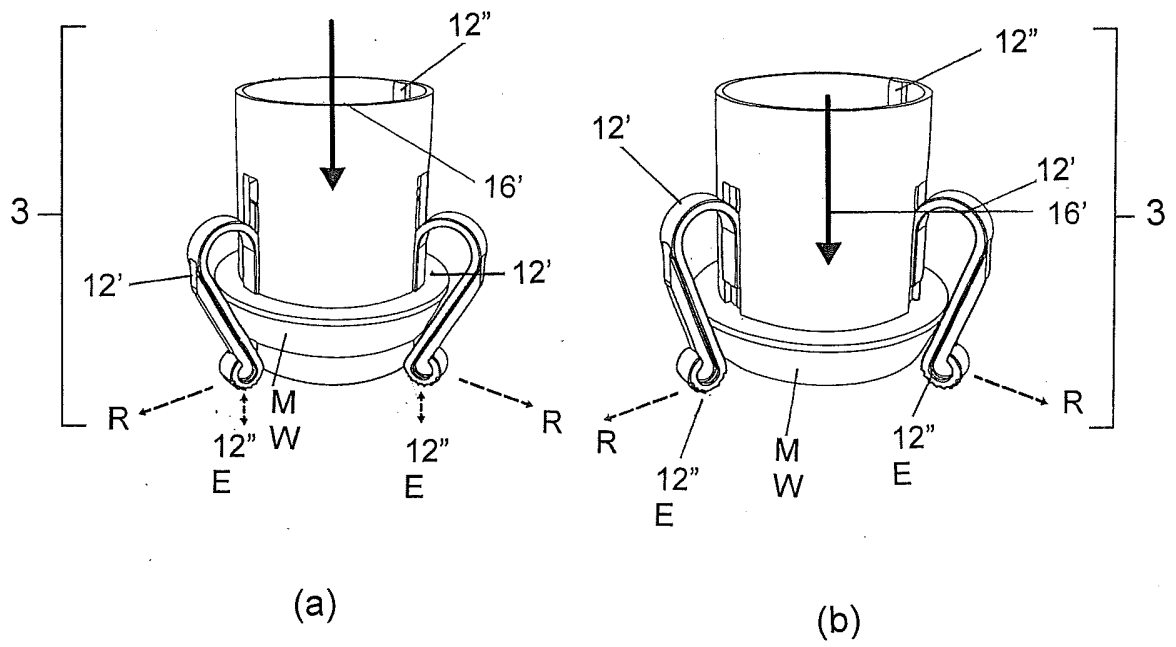


FIG. 3



## INTERNATIONAL SEARCH REPORT

International application No

PCT/NL2013/050298

A. CLASSIFICATION OF SUBJECT MATTER  
 INV. A61B5/00 G06T7/00  
 ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B G06T

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, INSPEC

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2003/045799 A1 (BAZIN ROLAND [FR] ET AL) 6 March 2003 (2003-03-06) paragraphs [0021] - [0023], [0027], [0028], [0094] - [0104] -----	1-5
A	DE 197 19 336 A1 (BEIERSDORF AG [DE]) 12 November 1998 (1998-11-12) column 3, line 65 - column 4, line 3 column 4, line 40 - line 53 column 5, line 8 - line 37 ----- -/--	1-5

 Further documents are listed in the continuation of Box C. See patent family annex.

\* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&amp;" document member of the same patent family

Date of the actual completion of the international search

2 July 2013

Date of mailing of the international search report

11/07/2013

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2  
 NL - 2280 HV Rijswijk  
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 Fax: (+31-70) 340-3016

Authorized officer

Knüpling, Moritz



## INTERNATIONAL SEARCH REPORT

International application No

PCT/NL2013/050298

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	MOFID Y ET AL: "Mechanical skin thinning-to-thickening transition observed in vivo through 2D high frequency elastography", JOURNAL OF BIOMECHANICS, PERGAMON PRESS, NEW YORK, NY, US, vol. 43, no. 15, 16 November 2010 (2010-11-16), pages 2954-2962, XP027472955, ISSN: 0021-9290, DOI: 10.1016/J.JBIOMECH.2010.07.014 [retrieved on 2010-11-04] abstract -----	1-5
A	MICHAEL I. MIGA ET AL: "An elastography framework for use in dermoscopy", PROCEEDINGS OF SPIE, 8 March 2007 (2007-03-08), page 65111C-1, XP055046082, ISSN: 0277-786X, DOI: 10.1117/12.708959 pages 65111C-6 - pages 65111C-7 -----	1-5
X	US 2011/026768 A1 (CHARI SUJAI [US] ET AL) 3 February 2011 (2011-02-03) paragraphs [0027], [0028], [0042], [0062] -----	6,7
X	US 2011/124987 A1 (PAPAZOGLU ELISABETH S [US] ET AL) 26 May 2011 (2011-05-26) paragraphs [0068], [0075] -----	6,7
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A	US 6 238 337 B1 (KAMBHATLA NANDA [US] ET AL) 29 May 2001 (2001-05-29) column 7, line 8 - line 20 -----	7

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/NL2013/050298

## Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2.  Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
  
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1.  As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-5

System for imaging body areas comprising stretching elements  
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2. claims: 6, 7

Method of collecting data comprising comparing images with  
historical database  
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**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No

PCT/NL2013/050298

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