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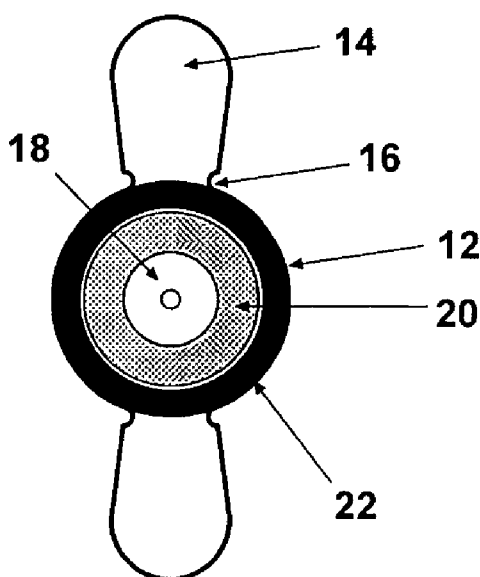
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[Continued on next page]

(54) Title: SKIN MARKER

Figure 1



(57) Abstract: A skin marker for providing a reference point for a plurality of different medical imaging procedures, said marker incorporating one or more substances having one or more of radiance and/or hydration and/or radiopaque and/or radio luminescent and/or radioactive properties for detection by X-ray and/or Computer Tomography (CT) and/or MRI and/or Ultrasonic scanning processes and/or Positron Emission Tomography (PET), and one or more markings recognisable by an optical imaging process such as 3D surface scanning.

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Skin Marker

This invention relates to a skin/body marker and in particular to a trans-modal/multi-modal skin marker for use as a reference marker for mapping anatomical landmarks when using a range of
5 invasive and non-invasive imaging methods. Applications may include medical imaging processes for measurement, diagnostic and therapeutic procedures, posture mapping for spinal analysis and biomechanics purposes and as a measurement reference for anthropometrics, sports science, fitness and fashion industries.

10 A variety of imaging techniques are available for imaging different anatomical structures of the body, such as X-ray imaging, typically used for imaging bones, Computer Tomography (CT), typically used for generating a three-dimensional image of the inside of an object from a large series of two-dimensional X-ray images taken around a single axis of rotation, Magnetic Resonance Imaging (MRI), or Nuclear Magnetic Resonance Imaging (NMRI), used most commonly to visualize the
15 internal structure and function of the body, including soft tissues as well as bones, Diagnostic sonography (ultrasound scanning), used to visualize subcutaneous body structures including tendons, muscles, joints, vessels and internal organs for possible pathology or lesions and Positron Emission Tomography (PET), where a three-dimensional image or picture of functional processes in the body is produced by creating images of the passage of a radioactive tracer through the body.

20

It is often desirable to register images produced by such modalities, for example for full spine imaging, and there is an emerging trend to register images produced by different techniques to each other. To do this, reference points are required to register the various images. Different skin markers are available to suit each imaging technique. However, these markers are all different and
25 may not be transferable between modalities, meaning that they need to be removed and alternative ones replaced between different scanning operations, leading to a risk of placement error and mis-registration of the various images produced.

Many markers also have difficulty in attaching to the skin, due to hair and moisture, and some have
30 very small surface areas, increasing this problem. Furthermore, none of the known markers are suitable for reliable recognition by 3D surface scanning technologies, which are increasingly used in volumetric analysis and surface profiling/measurement operations.

It is an object of the present invention to alleviate these disadvantages.

35

According to the present invention there is provided a skin marker for providing a reference point for a plurality of different medical imaging procedures, said marker incorporating one or more substances having one or more of radiance and/or hydration and/or radiopaque and/or radio
40 luminescent and/or radioactive properties for detection by X-ray and/or Computer Tomography (CT) and/or MRI and/or Ultrasonic scanning processes and/or Positron Emission Tomography (PET), and one or more markings recognisable by an optical imaging process such as 3D surface scanning.

In one embodiment said substance may comprise a radiopaque material having a radiographic density sufficient to produce a discernable shadow on a radiographic image.

5 In one embodiment said markings may comprise at least one first marking recognisable by Moiré Fringe 3D scanning processes or other optical scanning processes and at least one second marking recognisable by a colour recognition imaging process. Said first marking may comprise a substantially non-reflective image, such as a matt black printed image. Said second marking may comprise a coloured image, for example a blue or green image.

10

The marker may include a 3D surface formation. Such surface formation may be adapted to be recognisable by ultrasound and 3D surface scanning processes, including photogrammetry and laser scanning, or other optical imaging processes and/or may comprise a chamber or reservoir within which said one or more substances may be located.

15

Preferably said one or more substances are encapsulated within said 3D surface formation. In one embodiment said 3D surface formation comprises a hollow body containing a liquid, semi-liquid or solid material, said material containing and/or comprising said one or more substances. The material may comprise an oil based liquid (such as vitamin E fish oils), an oil-based semi-solid material or a gelled material. Such gelled material may comprise either an oil or aqueous base having a rheological structure, which may be achieved by way of high polymeric concentration, incorporation of stiffening agents, induced hydrogen bonding or covalent cross-linking using molecular or ionic species. One suitable material may be a hydrogel, such as a PVA (poly vinyl alcohol) hydrogel.

20

In one embodiment said 3D surface formation comprises a dome shaped member defining a substantially hemi-spherical surface formation. Preferably said dome shaped member is located on a central portion of the marker. At least a portion of the dome shaped member may be optically transparent to define a magnifying lens to assist correct location of the marker on the skin.

25

Alternatively the dome may be coloured and/or possess markings to provide enhanced visibility.

Said one or more markings may comprise one or more concentric rings located around said dome shaped member.

35 Preferably the skin marker further comprises two or more tabs or wings, preferably extending radially from said central portion of the marker, to enable the marker to be attached to the body. Said tabs or wings may be provided with a suitable adhesive, which may be covered by a releasable cover material, and/or may define locations or carriers for the attachment of surgical tape to enable the marker to be affixed to the skin. Each tab may have a semi-circular indent at their respective hinge point to allow better flexion and positioning over the human anatomy.

40

An embodiment of the present invention will now be described, by way of example only, with reference to the accompanying drawings, in which:-

Figure 1 is a plan view of a skin marker according to a first embodiment of the present invention;

5 Figure 2 is a side view of the skin marker of Figure 1;

Figure 3 is a plan view of a skin marker according to an alternative embodiment of the present invention;

Figures 4a and 4b are plan views of a skin marker according to a further alternative embodiment of the present invention, with various surface patterns;

10 Figure 5 is a plan view of a skin marker according to a further embodiment of the present invention; and

Figure 6 is a sectional view through the skin marker of Figure 5 on line A-A.

The skin marker 10 is made from 0.125mm thick polycarbonate (PC) or polyester (PET) film (or a
15 comparable flexible carrier suitable for graphic printing) comprising a circular central portion 12 and having two or more radially extending attachment wings or tabs 14 provided to allow the marker to be attached to the skin. The tabs 14 may be coated with a suitable adhesive, such as a hypoallergenic pressure sensitive adhesive (for example Duplomed 2806), which may be covered by a protective releasable covering, or may simply be used to receive surgical tape to secure the
20 marker to the skin, particularly in areas of excessive hair. As shown in Figures 1, 3, 4a and 4b, different versions of the marker 10 may be produced having a different number of tabs 14 to suit different anatomical locations on the body of the patient. The tri-form shape shown in Figure 4 may provide the best adhesion on most locations. However, any other number or arrangement of tabs may be provided to suit the location to which the marker is to be attached. Unevenly spaced or odd
25 numbered tabs may be provided to provide a better distribution of forces at particular locations.

The width of each tab 14 is reduced at the junction of the tab 14 with the central portion 12 of the marker by means of cut-outs 16 to provide a hinge joint for flexion. This assists the central circular portion 12 of the marker 10 to retain its profile and provides enhanced adhesion at this area. The
30 distal ends of the tabs 14 are wider to provide a greater surface area for adhesion.

A raised hemispherical dome 18 is formed in the centre of the marker 10. The dome 18 may have a diameter of between 5mm and 25mm, although a prototype has been made with a 10mm diameter dome. The dome 18 comprises a hollow body encapsulating an oil based liquid or PVA hydrogel
35 containing substances or additives which have a desired combination of radiance and/or hydration and/or radiopaque and/or radio luminescent properties and/or radioactive properties. These substances can be imaged using ionizing radiation, electro-magnetic fields and the hemispherical form of the dome can be recognised by ultrasound and/or 3D surface scanning processes, including photogrammetry and laser scanning. For example, such substances may comprise Barium Sulphate
40 to be recognisable by X-Ray techniques and/or all forms of gadolinium, such as a salt, a covalently bound compound, lattice or co-ordination complex, a chelate or ionic solution, to be recognised by

MRI techniques. Chelates may be utilised (e.g. Gadolinium III Chelate) to enhance the water solubility and reduce toxicity of such substances. The oil based liquid may comprise a mineral oil or any other liquid hydrocarbon oil of synthetic or natural origin, which may be cross-linked or thickened with styrenic copolymer, such as polystyrene blocks and/or rubber blocks (comprising polybutadiene, polyisoprene or their hydrogenated equivalents). In a particular example the liquid within the dome
5 may comprise a paraffin based cross-linked hydrogel.

The dome 18, containing a liquid/gel, may have an embodiment where both are (at least in part) transparent whereby the dome may function as a lens, magnifying the skin location upon which the
10 marker 10 is placed. For example, such magnifying effect may assist in locating the marker over a cross or other mark previously placed on the skin to assist accurate placement of the marker.

In a modified embodiment shown in Figures 5 and 6, to preserve the lens effect with the use of radiopaque substances within the dome 18 (which are visually opaque), a conical section 24 of the
15 dome 18 may be moulded with a non-radiopaque transparent material, as shown in Figure 6. This maintains the sphere-like reference of radiopaque substance 26.

In an alternative embodiment the dome 18 may be coloured or patterned to enhance its visibility. For example, the surface of the dome may be black, preferably matt black, to provide enhanced contrast
20 and thus visibility.

A coloured graphic surface image 20 (preferably blue or green) is formed on the central portion 12 of the marker 10 around the dome 18 for recognition by colour imaging processes, such as Red, Green and Blue (RGB) or Cyan, Yellow, Magenta and Key (CYMK) colour recognition algorithms. Using
25 pixel recognition methods similar to "blue screen technology", the coloured graphic image 20, in a colour absent from the human body, can be isolated using video and still image processing systems. In the embodiment shown, the coloured graphic image 20 comprises a coloured ring arranged concentrically around the dome 18.

30 A further printed surface image 22, in the preferred embodiment in the form of a matt black ring surrounding the coloured graphic image 20, is provided on the central portion of the marker for recognition by Moiré Fringe 3D scanning processes or other optical scanning processes. The substantially non-reflective black pattern of the image 22 absorbs the light from an optical scanning process, resulting in a gap/blank on the surface model geometry. This gap clearly highlights the
35 location of the 3D dome of the marker, which may also be detected as a 3D surface feature. The geometric centre of the dome 18 can thereby be easily calculated using simple algorithms.

Thus the present invention provides a skin reference marker that can be recognised by multi-modal imaging processes to assist diagnosis and operative planning. The skin markers may be used to
40 identify regions for reference purposes and for image registration (for example for registering or aligning multiple images produced by different imaging techniques). The skin marker in accordance

with the present invention allows a more seamless workflow and better image registration across a wider range of modalities than presently available.

5 The present invention also provides a skin marker that can be more easily, reliably and accurately placed on the skin of the patient by means of the radially extending attachment wings. This design does not depress the skin surface.

10 The invention is not limited to the embodiment(s) described herein but can be amended or modified without departing from the scope of the present invention. The present invention is not limited to the imaging modalities described above and encompasses other substances recognisable by other imaging modalities beyond the aforementioned modalities.

Claims

1. A skin marker for providing a reference point for a plurality of different medical imaging procedures, said marker incorporating one or more substances having one or more of radiance
5 and/or hydration and/or radiopaque and/or radio luminescent and/or radioactive properties for detection by X-ray and/or Computer Tomography (CT) and/or MRI, and/or Ultrasonic scanning processes and/or Positron Emission Tomography (PET), and one or more markings recognisable by an optical imaging process.
- 10 2. A skin marker as claimed in claim 1, wherein said substance may comprise a radiopaque material having a radiographic density sufficient to produce a discernable pattern on a radiographic image.
3. A skin marker as claimed in claim 1 or claim 2, wherein said markings comprise at least one
15 first marking recognisable by Moiré Fringe 3D scanning processes or other optical scanning processes and at least one second marking recognisable by a colour recognition imaging process.
4. A skin marker as claimed in claim 3 wherein said first marking comprises a substantially non-reflective image, such as a matt black printed image.
20
5. A skin marker as claimed in claim 3 or claim 4, wherein said second marking comprises a coloured image, for example a blue or green image.
6. A skin marker as claimed in any preceding claim, wherein the marker includes a 3D surface
25 formation.
7. A skin marker as claimed in claim 6, wherein said one or more substances are encapsulated within said 3D surface formation.
- 30 8. A skin marker as claimed in claim 6 or claim 7, wherein said 3D surface formation comprises a dome shaped member defining a substantially hemi-spherical surface formation.
9. A skin marker as claimed in claim 7 or claim 8, wherein said dome shaped member is located on a central portion of the marker.
35
10. A skin marker as claimed in any of claims 6 to 9, wherein at least a portion of the dome shaped member is optically transparent to define a magnifying lens to assist correct location of the marker on the skin.
- 40 11. A skin marker as claimed in any of claims 6 to 9, wherein the 3D surface formation is coloured and/or is provided with markings to provide enhanced visibility.

12. A skin marker as claimed in any of claims 6 to 11, wherein said 3D surface formation comprises a hollow body containing a liquid, semi-liquid or solid material, said material containing and/or comprising said one or more substances.

5

13. A skin marker as claimed in claim 12, wherein said material comprises one or more of an oil based liquid, an oil-based semi-solid material or a gelled material.

14. A skin marker as claimed in claim 13, wherein said gelled material comprises either an oil or aqueous base having a rheological structure, achieved by way of high polymeric concentration, incorporation of stiffening agents, induced hydrogen bonding or covalent cross-linking using molecular or ionic species.

15

15. A skin marker as claimed in any of claims 6 to 14, wherein said one or more markings comprise one or more concentric rings or similar markings located around said 3D surface formation.

20 16. A skin marker as claimed in any preceding claim, wherein the skin marker further comprises two or more tabs or wings to enable the marker to be attached to the body.

17. A skin marker as claimed in claim 16, wherein said tabs or wings extending radially from said central portion of the marker.

25

18. A skin marker as claimed in claim 16 or claim 17, wherein said tabs or wings are provided with a suitable adhesive to enable the marker to be affixed to the skin.

30 19. A skin marker as claimed in claim 18, wherein said adhesive is covered by a releasable cover material.

20. A skin marker as claimed in claim 16 or claim 17, wherein said tabs or wings define locations or carriers for the attachment of surgical tape to enable the marker to be affixed to the skin.

35 21. A skin marker as claimed in any of claims 16 to 18, wherein each tab comprises an indent or reduced width region at the neck of the tab to increase flexion.

Figure 1

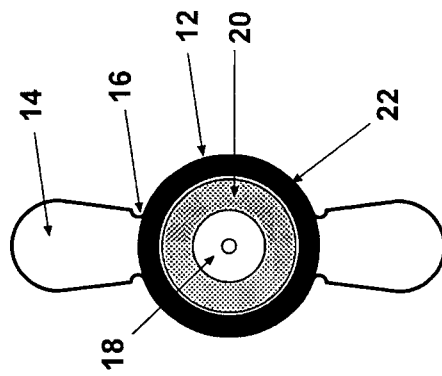


Figure 3

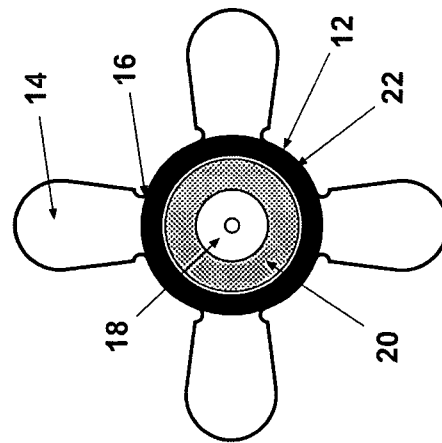


Figure 4

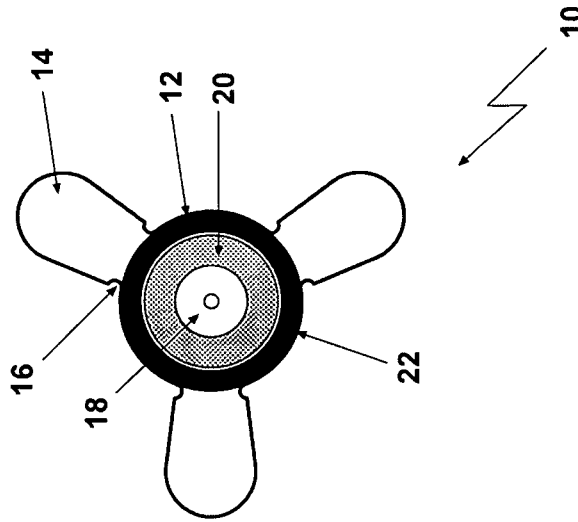


Figure 2

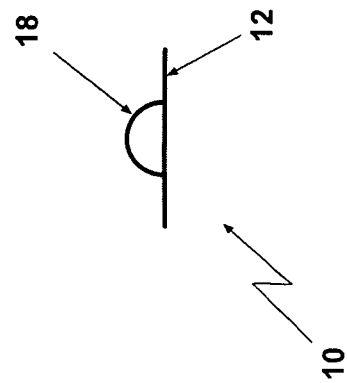


Figure 5

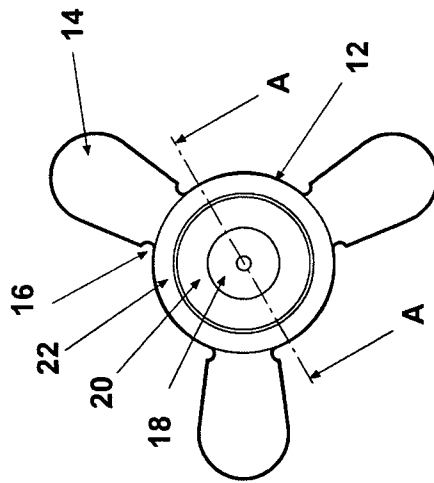
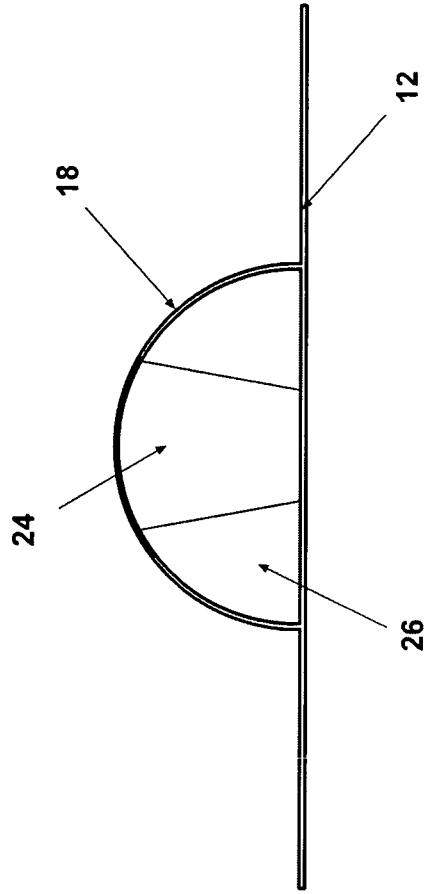


Figure 6



Section A-A

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2010/002814

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B6/12 A61B19/00
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

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 practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/116802 A1 (JESSOP WAYNE G [US] ET AL) 17 June 2004 (2004-06-17) paragraphs [0032] - [0038], [0047]; figures 1-3	1-15
X	US 5 469 847 A (ZINREICH SIMION J [US] ET AL) 28 November 1995 (1995-11-28) column 3, line 61 - column 5, line 15; figures 1-6	1-7, 11-15
X	US 2009/022272 A1 (JOSEPH KAREN [US] ET AL) 22 January 2009 (2009-01-22) paragraphs [0031] - [0046]; figures 2A-2C, 4A, 4B, 6	1-5, 16-21
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Further documents are listed in the continuation of Box C.

See patent family annex.

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Date of the actual completion of the international search

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INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2010/002814

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 368 030 A (ZINREICH SIMION J [US] ET AL) 29 November 1994 (1994-11-29) column 3, line 27 - column 6, line 24; figures 1-7 -----	1-7, 11-14, 16,17,20
A	EP 0 228 692 A2 (NIPPON OIL CO LTD [JP]) 15 July 1987 (1987-07-15) the whole document -----	1-21

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No PCT/EP2010/002814
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