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(71) Applicant: **UNIVERSITY OF FLORIDA RESEARCH FOUNDATION, INC.** [US/US]; 223 Grinter Hall, Gainesville, FL 32611 (US).

(72) Inventors: **MITTAUER, Kathryn Elizabeth**; c/o University of Florida Research Foundation, Inc., 223 Grinter Hall, Gainesville, FL 32611 (US). **YAN, Guanghua**; c/o University of Florida Research Foundation, Inc., 223 Grinter Hall, Gainesville, FL 32611 (US). **HELMIG, Richard**; c/o University of Florida Research Foundation, Inc., 223 Grinter Hall, Gainesville, FL 32611 (US). **LIU, Chihray**; c/o University of Florida Research Foundation, Inc., 223 Grinter Hall, Gainesville, FL 32611 (US). **LU, Bo**; c/o University of Florida Research Foundation, Inc., 223 Grinter Hall, Gainesville, FL 32611 (US).

(74) Agent: **BIANCO, Paul D.**; Fleit Gibbons Gutman Bongini & Bianco, 21355 East Dixie Highway, Suite 115, Miami, FL 33180 (US).

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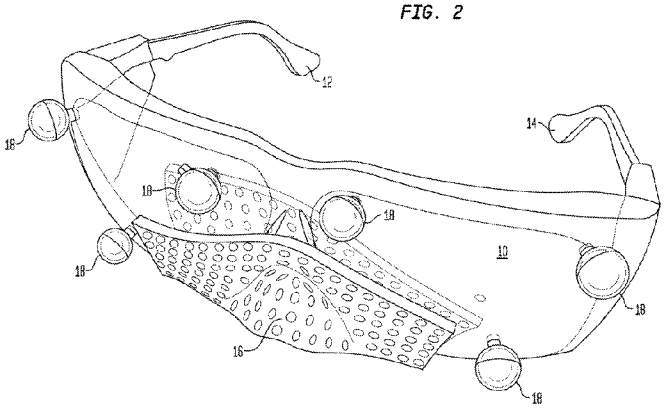
(54) Title: CRANIAL ALIGNMENT DEVICE FOR USE IN INTRACRANIAL STEREOTACTIC SURGERY

FIG. 2



(57) Abstract: A cranial alignment device for use in intracranial stereotactic radiotherapy includes a nosepiece that is custom shaped to mate with the dorsum and alae of the patient's nose application. It would be advantageous to provide a cranial alignment device for use in intracranial stereotactic radiotherapy that is comfortable, that does not require effort from the patient, and that operates with a high degree of repeatability even if the patient loses or gains weight, and even if the patient's hair pattern changes (hair loss occurs in patients who undergo chemotherapy).

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CRANIAL ALIGNMENT DEVICE FOR USE IN INTRACRANIAL STEREOTACTIC SURGERY

Background of the Invention

The invention relates to radiotherapy, and more particularly relates to stereotactic radiotherapy. In its most immediate sense, the invention relates to intracranial stereotactic radiotherapy.

In radiotherapy, a treatment beam of high-energy radiation is made incident on to a tumor that is to be destroyed. In intracranial stereotactic radiotherapy, an image-guided radiotherapy apparatus ("IGRT" apparatus) is used to destroy a brain tumor. An IGRT apparatus includes an imaging system such as a cone-beam computed tomography system (a "CBCT" system) and a linear accelerator. The imaging system is used to acquire an image of the tumor and the linear accelerator is used to produce the treatment beam, which is aimed at the tumor to destroy it.

In order to carry out intracranial stereotactic radiotherapy successfully, two localizations must occur. One of these localizations is carried out by the imaging modality; the e.g. CBCT image localizes the tumor within the patient's head. The other required localization is the localization of the patient's head within the coordinate system of the IGRT apparatus. This is carried out using an alignment device that is recognized by the IGRT apparatus or by equipment that is used together with it.

Before the patient's treatment begins, the alignment device is mounted to the patient and a computed tomography study (a "simulation") is carried out to acquire an image of the patient's head. During this image acquisition, the alignment device is used to register the precise location and orientation of the patient's head. Then, the information acquired during this simulation is used to develop a treatment plan for irradiating the tumor. To treat a patient who has been placed within the IGRT apparatus, the alignment device is used again to localize the patient's actual head position within the coordinate system of the IGRT apparatus and to place the patient's head in a location that precisely matches the position and orientation of the patient's head during the simulation procedure. And, since the position of the tumor within the patient's head is known from the image acquired during simulation, the treatment plan can be executed to destroy the tumor with little or no destruction of healthy tissue that surrounds the tumor.

The alignment device must operate with a high degree of repeatability because the localization of the patient within the IGRT apparatus must always be precise. If the alignment device works differently during patient imaging then during patient treatment, or if it works differently during successive treatments, the beam of ionizing radiation will be inaccurately aimed. This will cause unnecessary destruction of healthy tissue and insufficient destruction of tumor tissue.

In one category of alignment devices, a component with a known structure is physically attached to the patient's head and interacts with apparatus that registers the location of the component. This permits the location of the patient's head to be accurately determined. For example, the SonArray device manufactured by Varian has a bite plate that is held in the patient's mouth. Proper repeat positioning of the patient using the SonArray device requires the patient to bite with consistent pressure. This can be difficult. In addition, the SonArray device can be uncomfortable in use, especially with patients who have had teeth extracted (as is the case with many head and neck radiotherapy patients). Furthermore, if the patient swallows his or her saliva, the SonArray device can move with respect to the patient, causing the position of patient's head to be mis-registered within the coordinate system of the IGRT apparatus.

In the AlignRT device manufactured by Vision RT, the position of the patient is determined by image processing. The AlignRT device acquires images of the patient's head using two cameras whose locations and orientations are precisely known. After the two images are acquired, the device identifies patient features that appear in both images and then reconstructs 3D surface data to localize the patient's head using triangulation. If the patient loses weight or the pattern of the patient's facial hair changes (both conditions are often encountered with chemotherapy), the precision with which the patient's head is localized can be adversely affected.

Summary of the Invention

It would be advantageous to provide a cranial alignment device for use in intracranial stereotactic radiotherapy that is comfortable, that does not require effort from the patient, and that operates with a high degree of repeatability even if the patient loses or gains weight, and even if the patient's hair pattern changes (hair loss occurs in patients who undergo chemotherapy).

Disclosed herein are a method for reproducibly positioning a patient's head, and a cranial alignment device for use in intracranial stereotactic radiotherapy, that are comfortable

for the patient, that do not require the patient to exert effort, and that operate with a high degree of repeatability even if the patient's surface anatomy changes (as by gain or loss of weight or hair loss).

Also disclosed is, in general, improvement on known devices and methods of this general type.

The invention proceeds from the realization that for any patient, the shapes of the dorsum and alae of the patient's nose do not change when the patient gains or loses weight. Furthermore, these locations seldom have substantial hair growth. Thus, an alignment device that is mounted to the patient's head using a custom shaped nosepiece that mates with the dorsum and alae of the patient's nose will always fit on the patient's head in precisely the same way and in a rigid manner. This will be true whether the patient gains or loses weight or whether the patient loses hair.

A device in accordance with the invention has two earpieces and a front frame that is connected between them. These components are dimensioned to fit upon a patient's face with the front frame in front of the patient's eyes and each earpiece engaging behind one of the patient's ears. The device further has a nosepiece that is custom shaped to mate with the dorsum and alae of the patient's nose and that is detachably securable to the front frame. The device also has a plurality of infrared-reflecting markers mounted on the front frame.

A device in accordance with the invention is worn on the patient's head like a pair of eyeglasses. The patient is not required to exert any effort to keep the device in place, and changes in the patient's weight and hair patterns do not affect the way the device fits on the patient's head. A conventional optical tracking system such as is conventionally used with IGRT apparatus can be used to register with six-degrees-of-freedom (translation and rotation) the position of the device – and therefore the position of the patient's head – in the coordinate system of the IGRT apparatus.

A device in accordance with the invention is inexpensive and simple to make and to fit to a patient. And, no additional equipment is needed because an optical tracking system will likely be available anyway.

Advantageously, the infrared-reflecting markers are not coplanar and are positioned asymmetrically in two groups, each group being associated with one of the patient's eyes. Such a pattern minimizes the likelihood that the optical tracking system will improperly localize the device within the coordinate system of the IGRT apparatus.

In a method in accordance with the invention, a nosepiece that mates with the dorsum and alae of the patient's nose is created. The nosepiece is attached to a fixture that is adapted for mounting on the patient's head, and the fixture is mounted on the patient's head.

Brief Description of the Drawings

The invention will be better understood with reference to the following illustrative and non-limiting drawings, in which:

Fig. 1 shows a preferred embodiment of a device in accordance with the invention before assembly;

Fig. 2 shows a preferred embodiment of a device in accordance with the invention in the assembled state;

Fig. 3 illustrates a preferred embodiment of a device in accordance with the invention mounted on a patient; and

Fig. 4 is a flow chart of a preferred embodiment of a method in accordance with the invention.

Detailed Description of Preferred Embodiments

The drawings are not necessarily to scale, and individual parts may be enlarged or reduced for clarity.

Referring first to Fig. 1, a cranial alignment device for use in intracranial stereotactic radiotherapy generally indicated by reference numeral 2 has a front frame 10 connected between two earpieces 12 and 14. The front frame 10 and the earpieces 12 and 14 are dimensioned to fit upon the face of a patient 4 (Fig. 3) with the front frame in front of the eyes of the patient 4 and with each earpiece engaging behind one of the ears of the patient 4 (see Fig. 3). Advantageously, the front frame 10 and earpieces 14 are parts of a conventional pair of protective goggles.

A nosepiece 16 is formed from a sheet of thermoplastic. (Advantageously but not necessarily, the thermoplastic is available in sheet form from Klarity Medical as product number R-3242A.) The sheet is placed in hot water until it is appropriately pliable. Once the sheet has been withdrawn from the hot water, the sheet is folded into a U that encloses the nosepiece region 20 of the front frame 10. Then, the front frame 10 and earpieces 12 and 14 are placed on the patient's face, and the sheet is pressed over the dorsum and the two alae of a patient's nose. In this way, the sheet is made to conform to the patient 4 and to the nosepiece region 20 of the front frame 10 in a single operation. (The sheet may also be – and in the

preferred embodiment is - pressed over the radix of the patient's nose and onto the patient's forehead, but this is not required.) The sheet, after cooling, becomes rigid and forms the nosepiece 16. When the nosepiece region 20 of the front frame 10 has been slipped into the U of the nosepiece 16 as shown in Fig. 2 the device 2 fits securely on the head of the patient 4 in a consistently repeatable manner (see Fig. 3).

Six infrared-reflective markers 18 are mounted to the front frame 10 at locations that are known precisely. Such markers are used because an optical tracking system (not shown) of the type conventionally used with an IGRT apparatus uses such markers as fiducials. The markers 18 are not coplanar, no three of them are collinear, and they are positioned asymmetrically in two groups, each group being associated with one of the patient's eyes (see Fig. 3). This minimizes the likelihood that the optical tracking system will improperly localize the device 2.

In the initial step 50 of a method in accordance with a preferred embodiment of the invention, a sheet of thermoplastic material is heated so as to become plastic. In the next step 52, the sheet is folded into a U-shaped element that is sandwiched over the nosepiece region of a conventional pair of protective goggles. Subsequently, in step 54, the goggles are placed on the patient's head and the still-plastic sheet is placed over the dorsum and alae of the nose of a patient who is to undergo intracranial stereotactic radiotherapy. When the sheet cools (step 56), a nosepiece is formed; the nosepiece mates with the dorsum and alae of the patient's nose as well as with the nosepiece region of the protective goggles. This enables the resulting fixture made up of the goggles and the nosepiece to be mounted to a patient's head (step 58) in a highly repeatable manner.

Although a preferred embodiment has been described above, the scope of the invention is determined only by the following claims:

The Claims

What is claimed is:

1. A cranial alignment device for use in intracranial stereotactic radiotherapy, comprising:

a. two earpieces;

b. a front frame connected between the earpieces, the front frame and earpieces being dimensioned to fit upon a patient's face with the front frame in front of the patient's eyes and each earpiece engaging behind one of the patient's ears;

c. a nosepiece, the nosepiece being custom shaped to mate with the dorsum and alae of the patient's nose and being detachably securable to the front frame; and

d. a plurality of infrared-reflecting markers mounted on the front frame.

2. The device of claim 1, wherein the nosepiece is of a thermoplastic.

3. The device of claim 2, wherein the nosepiece is U-shaped and the front frame is fitted into the nosepiece.

4. The device of claim 1, wherein the infrared-reflecting markers are not co-planar.

5. The device of claim 4, wherein the infrared-reflecting markers are disposed in two groups, each group being associated with a one of the patient's eyes.

6. The device of claim 5, wherein the infrared-reflecting markers are positioned asymmetrically.

7. The device of claim 6, wherein no three of the infra-red reflecting markets are collinear.

8. The device of claim 1, wherein the earpieces and front frame are parts of a conventional pair of protective goggles.

9. A method of reproducibly positioning a patient's head, comprising the following steps:

a. creating a nosepiece that mates with the dorsum and alae of the patient's nose;

b. attaching the nosepiece to a fixture that is adapted for mounting on the patient's head; and

c. mounting the fixture on the patient's head.

10. The method of claim 9, wherein the creating step is carried out by molding a thermoplastic sheet.

11. The method of claim 9, further comprising the step of positioning the fixture at a predetermined location.

12. The method of claim 11, wherein the fixture has infrared-reflecting markers mounted upon it and the positioning step comprises the step of using a conventional optical tracking system.

13. The method of claim 9, wherein the creating step further comprises creating a nosepiece that mates with the radix of the patient's nose and the patient's forehead.

14. The method of claim 10, wherein the creating and attaching steps are carried out in a single operation.

FIG. 1

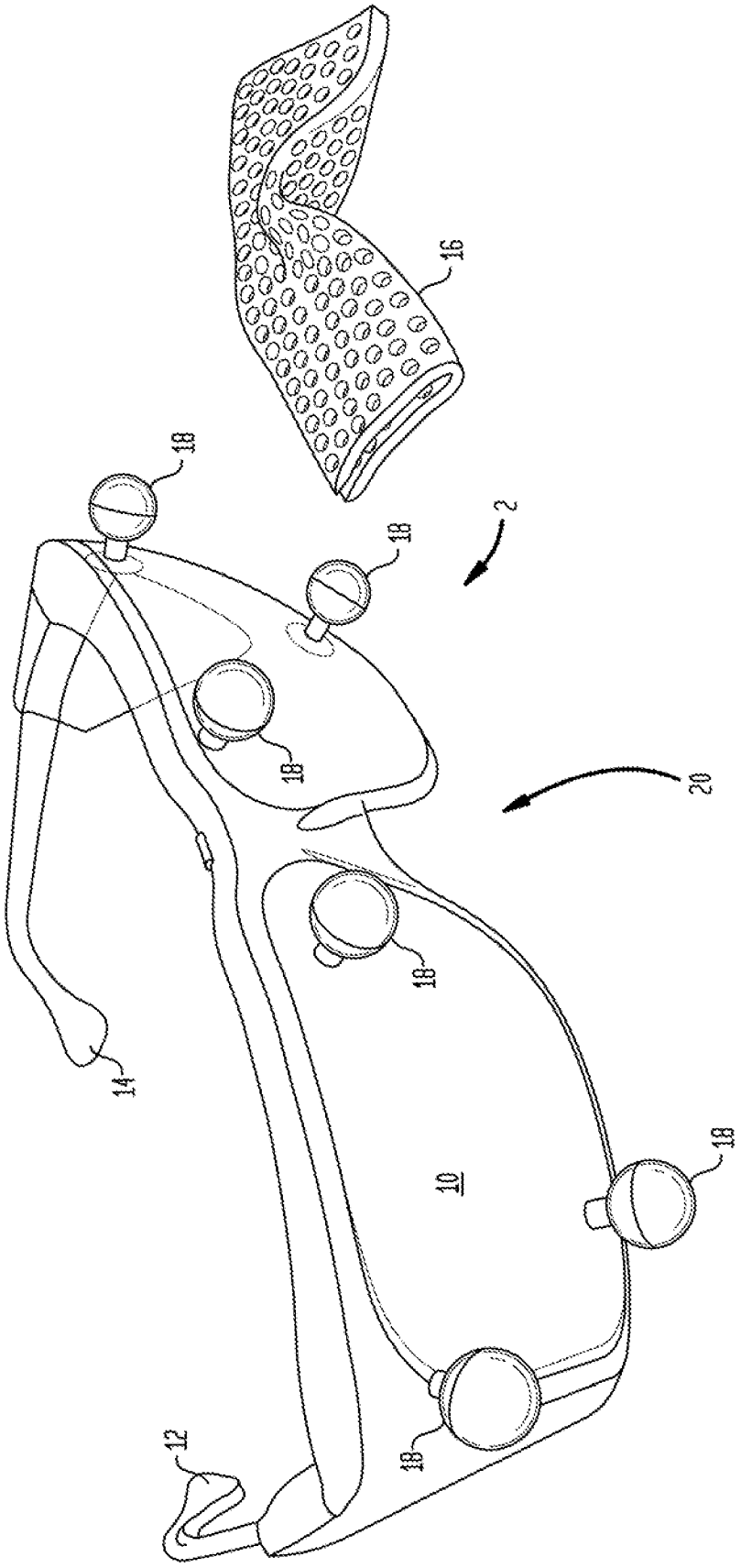


FIG. 2

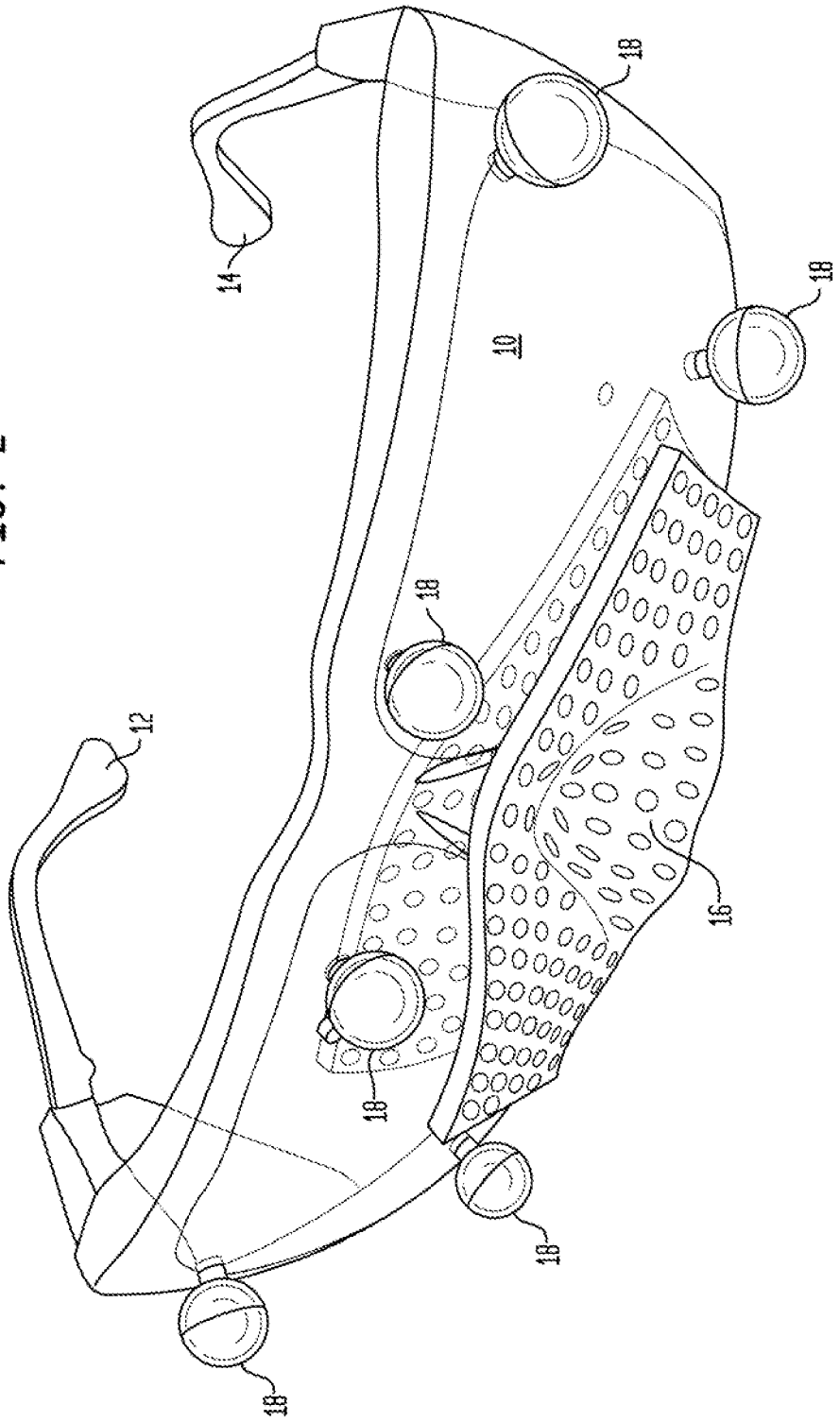


FIG. 3

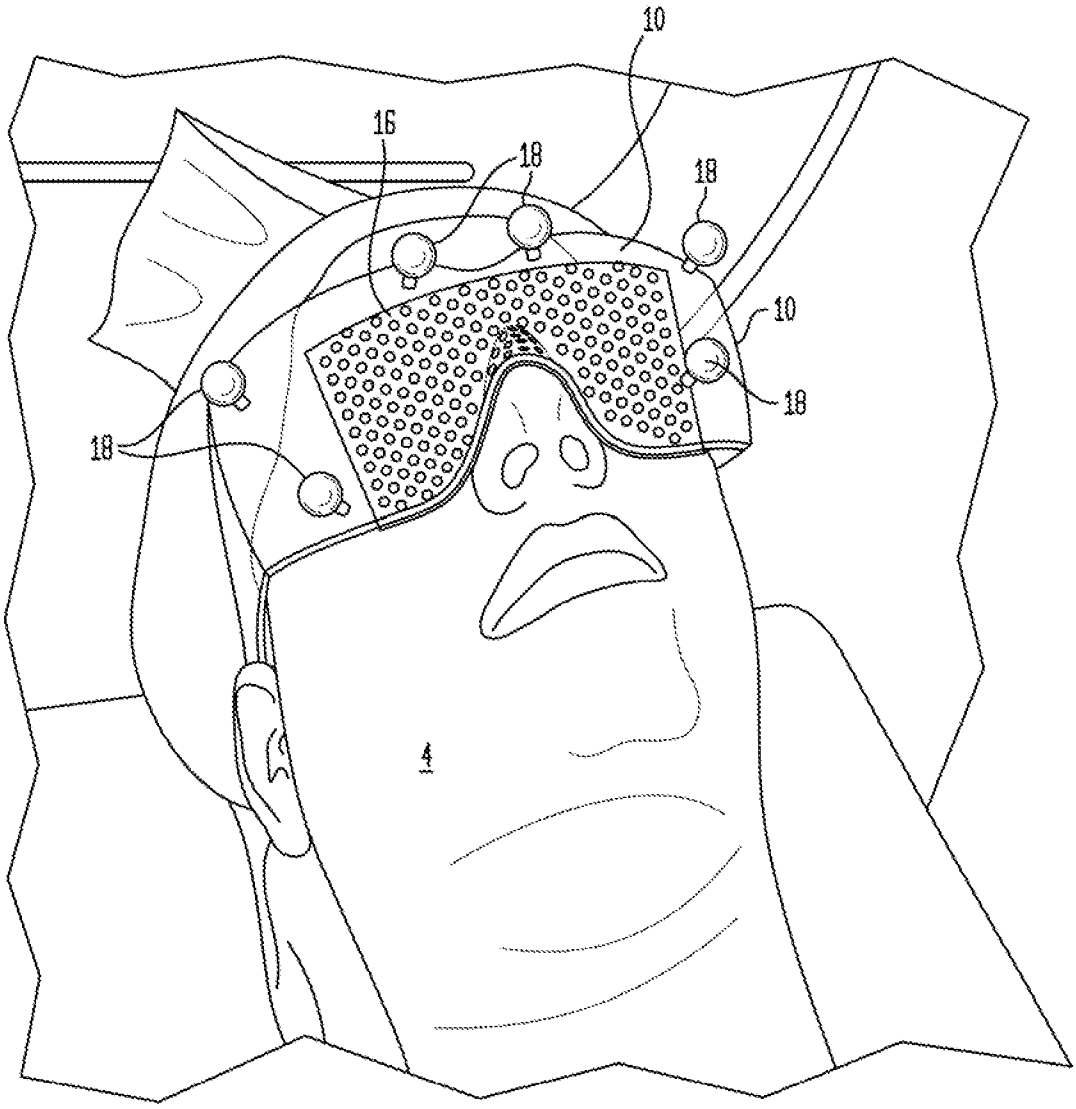
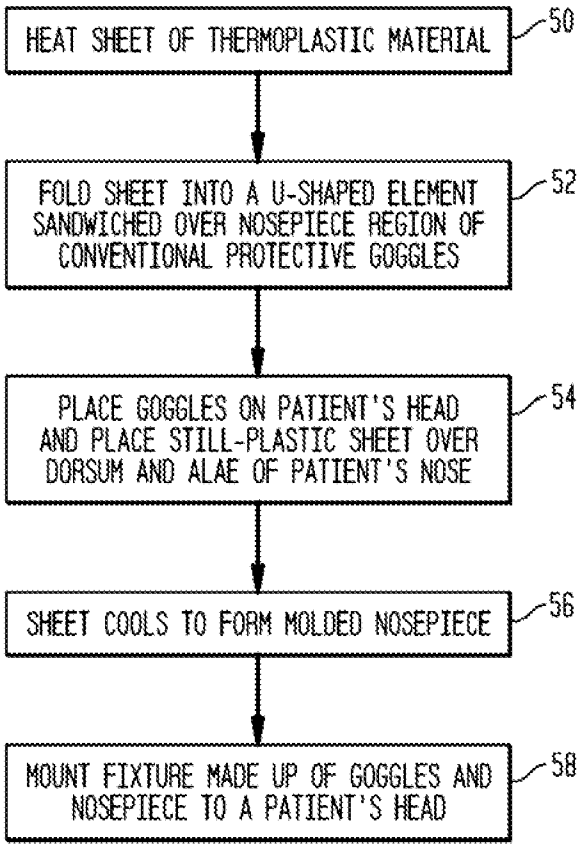


FIG. 4


HEAT SHEET OF THERMOPLASTIC MATERIAL
50
FOLD SHEET INTO A U-SHAPED ELEMENT SANDWICHED OVER NOSEPIECE REGION OF CONVENTIONAL PROTECTIVE GOGGLES
52
PLACE GOGGLES ON PATIENT'S HEAD AND PLACE STILL-PLASTIC SHEET OVER DORSUM AND ALAE OF PATIENT'S NOSE
54
SHEET COOLS TO FORM MOLDED NOSEPIECE
56
MOUNT FIXTURE MADE UP OF GOGGLES AND NOSEPIECE TO A PATIENT'S HEAD
58

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/037366

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 19/00 (2015.01)
CPC - A61B 19/203 (2015.09)
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)
IPC(8) - A61B 5/00, 6/00, 6/03, 18/00, 19/00 (2015.01) (keyword delimited)
USPC - 600/407, 417, 424, 425, 426, 427, 429; 606/130 (keyword delimited)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
CPC - A61B 5/6814, 19/20, 19/201, 19/203, 2019/206, 2019/262, 2019/507, 19/5244, 2019/5251, 2019/5272, 19/54, 2019/5483 (2015.09) (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase, Google Patents, Google.
Search terms used: stereotactic, image guided radiotherapy, IGRT, frame, eyewear, eyepiece, nose piece, radiation, cranial, intracranial, brain, head, eye, ear, tumor, marker, infrared, goggle, customized, personalized, thermoplastic, mold

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/0075560 A1 (HANNULA et al) 07 April 2005 (07.04.2005) entire document	1, 4-9, 11-13
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Y		2, 3, 10, 14
Y	US 2008/0006274 A1 (THORNTON) 10 January 2008 (10.01.2008) entire document	2, 3, 10, 14
A	US 2004/0064890 A1 (KIM et al) 08 April 2004 (08.04.2004) entire document	1-14
A	US 7,231,723 B1 (O'NEILL et al) 19 June 2007 (19.06.2007) entire document	1-14
A	US 6,132,437 A (OMURTAG et al) 17 October 2000 (17.10.2000) entire document	1-14

☐ 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
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"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
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
07 September 2015	30 SEP 2015
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774