PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 :		(11) International Publication Number:	WO 00/13571
A61B 3/00	A1	(43) International Publication Date:	16 March 2000 (16.03.00)

(21) International Application Number: PCT/US99/20034

(22) International Filing Date: 1 September 1999 (01.09.99)

(30) Priority Data:
09/148,108 4 September 1998 (04.09.98) US

(71) Applicant: SUNRISE TECHNOLOGIES INTERNATIONAL, INC. [US/US]; 3400 West Warren Avenue, Fremont, CA 94538 (US).

(72) Inventors: HEREKAR, Satish, V.; 411 College Avenue, Palo Alto, CA 94306 (US). McFARLAND, Michael, S.; 200 Sparling Road, Hotsprings, AR 71913 (US).

(74) Agents: DE RUNTZ, K., Alison et al.; Majestic, Parsons, Siebert & Hsue P.C., Suite 1100, Four Embarcadero Center, San Francisco, CA 94111–4106 (US).

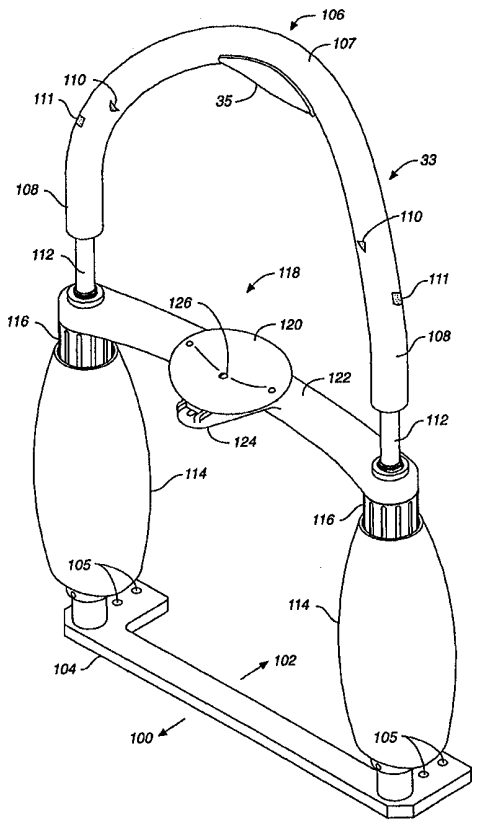
(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: APPARATUS AND METHOD FOR RECEIVING THE HEAD OF A SUBJECT

(57) Abstract

The present invention provides a headrest apparatus (33) (and associated method), which includes a means for sensing a degree of contact (35) between a subject's head and the headrest and means for providing sensory feedback (150) based on the degree of contact. The apparatus includes a means for receiving at least one portion of the head (106) of the subject or patient, such as the forehead, and may include additional means for receiving another portion of the head, such as the chin. The apparatus (33) is adjustable in multiple directions to accommodate physical characteristics of the patient's head or to place the patient's head in a desirable position for observation or treatment. In use, the contact–sensing means (35) is used to determine whether or not the patient has moved his or her head away from the head–receiving means (106), and the sensory feedback means (150) is used to alert the patient of his or her movement out of contact with the head–receiving means (106) so that the patient may respond by re–establishing and maintaining the necessary contact. The present invention also provides a treatment system (15) (and associated method) which includes the headrest apparatus (33) and a means for irradiating tissue within a region of the head of the patient, such as ocular or corneal tissue.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

APPARATUS AND METHOD FOR RECEIVING THE HEAD OF A SUBJECT

FIELD OF THE INVENTION

The invention relates generally to a headrest for a subject and a method of using same. More particularly, this invention relates to a headrest which is useful to receive the head of a patient in preparation for and during medical treatment, especially medical treatment of the eye. The headrest and method of using same are particularly useful in a system which directs a defined pattern of electromagnetic radiation to a cornea in a controlled manner for the purpose of reshaping the cornea and a method associated with such apparatus.

BACKGROUND OF THE INVENTION

Apparatus for performing laser surgery, which include a variety of patient headrests, and methods of using same, are known. For convenience and patient comfort, the headrests employed in such apparatus are often designed to accommodate a patient who is placed in an upright, seated position before the treatment apparatus. These headrests may include rests for the forehead and chin of the patient, the latter of which may be adjustable to accommodate the configuration of the patient's head.

By way of example, in the Published International Patent Cooperation Treaty Application WO 98/22055, Clapham discloses a laser surgery station for treating a patient who is positioned in an upright, seated position. The station includes a head support unit which retains the patient's head in a fixed, predetermined position relative to laser beam. The head support unit includes a forehead rest and a chin rest, the latter of which is said to be adjustable (in an

unspecified manner). The laser surgery station of Clapham is disclosed as being useful for performing refractive surgery by corneal photoablation.

Further by way of example, in U.S. Patent No. 5,000,563, Gisel *et al.* disclose an apparatus for observation and/or treatment of a patient, which accommodates both seated and recumbent positions of a patient. The apparatus includes a headrest system which immobilizes the head of the patient. The headrest includes a forehead rest and a chin rest, the latter of which may be adjusted by means such as a bellows. The headrest system further includes two handles to diminish patient fatigue. The apparatus of Gisel *et al.* is disclosed as being useful for carrying out ophthalmological laser surgery.

In a further example, namely, U.S. Patent No. 5,098,426, Sklar *et al.* disclose a work station for performing laser surgery on a patient seated in an upright position. The work station includes a rest unit which is adjustable (in an unspecified manner) as a unit and includes rests for the forehead and chin of the patient. The work station of Sklar *et al.* is disclosed as being useful for ophthalmological laser surgery.

There is a need for a headrest, usefully employed in the observation or treatment of patients, which is conveniently adjustable in a multi-dimensional manner to accommodate the various configurations of patients' heads. Additionally, there is a need for a headrest which allows the head of a patient preparing for and/or undergoing observation or treatment to be unrestrained, while providing the patient with sensory feedback when patient's head is making insufficient contact with the headrest, so that the patient may resume headrest contact appropriate to the observation or treatment. There is a particular need for such a headrest which is useful in ophthalmological treatment, such as photothermal keratoplasty.

Although there are many specific treatment procedures which involve directing a highly controlled beam of electromagnetic radiation to an eye, keratoplasty procedures are currently receiving a great deal of attention because of their ability to correct an eye for near-sightedness, far-sightedness and/or astigmatism. In one surgical procedure, a radiation beam is used to cut controlled portions of the cornea by ablation of tissue in its path. One specific application of this procedure is in the performance of a radial keratotomy procedure which does not require use of a knife to make radial cuts in the cornea. In another specific application, an outside surface of the cornea is removed by an excimer laser in order to reshape it.

In an alternative procedure, which avoids cutting the cornea, at least one focused beam of electromagnetic radiation within the infrared portion of the spectrum is directed into the eye to shrink collagen tissue within the cornea in order to cause corrective changes in the cornea curvature. This technique, often termed photothermal keratoplasty, is the subject of U.S. Patent Nos. 4,976,709 and 5,618,284 to Bruce J. Sand (hereinafter, "the Sand Patents"), which patents are expressly incorporated herein in their entirety by this reference. This collagen shrinkage technique promises to provide permanent changes to the optical characteristics of the human cornea with a higher degree of safety and patient comfort than is the case with techniques that involve physically cutting and removing portions of the cornea.

One way to deliver a desired electromagnetic radiation pattern to the cornea is by projection from a short distance removed from the cornea. One instrument for doing so is described in the Published International Patent Cooperation Treaty Application WO 94/03134 (hereinafter, "the PCT Publication"), which publication is hereby incorporated herein in its entirety by this reference. This instrument allows an ophthalmologist, or other attending physician or practitioner, to select and to deliver a specific pattern and amount of electromagnetic radiation to each patient in accordance with the condition to be corrected. It is desirable for such an instrument to perform efficiently corrective photothermal keratoplasty procedures on a large number of patients with a high degree of accuracy, effectiveness, safety and convenience.

There remains a need for a treatment system, usefully employed in the ophthalmological treatment of patients, which includes a patient headrest that is adjustable in a multi-dimensional manner to accommodate the various configurations of patients' heads. Additionally, there remains a need for a such a system which includes a headrest that allows the head of a patient preparing for and/or undergoing such treatment to be unrestrained, while providing the patient with sensory feedback when patient's head is making insufficient contact with the headrest, so that the patient may resume headrest contact appropriate to the treatment.

SUMMARY OF THE INVENTION

The present invention provides a headrest apparatus (and associated method), which includes a means for sensing a degree of contact between a

subject's head and the headrest and a means for providing sensory feedback based on the degree of contact.

Briefly, the apparatus includes a means for receiving at least one portion of the head of the subject or patient, such as the forehead, and may include additional means for receiving another portion of the head, such as the chin. The apparatus is adjustable in multiple directions to accommodate physical characteristics of the patient's head or to place the patient's head in a desirable position for observation or treatment. This adjustability is important for both patient comfort and versatility in observation or treatment.

Preferably, the patient's head is not immobilized, but merely received by the apparatus. For many patients, this lack of restraint is important for comfort and/or mitigation of anxiety, as some treatment procedures are lengthy and/or anxiety-provoking. For the observing or treating physician, the lack of head restraint may be less desirable, as certain movements of the head may interfere with a particular observation or treatment. Thus, in the present apparatus, a contact sensor is used to determine whether or not the patient has moved his or her head away from the head-receiving means, so that contact is re-established or observation or treatment of the patient is interrupted pending the re-establishment of contact suitable for observation or treatment. Further, a sensory feedback means is used to alert the patient of his or her movement out of contact with the head-receiving means, of which an inattentive, fatigued or anxious patient may be unaware, so that the patient may respond by re-establishing and maintaining the necessary contact. Preferably, the sensory feedback is variable, such as a sound of variable frequency, tone, or volume, according to the degree of the lapse in contact, so that the patient is encouraged to respond with an appropriate level of attention, movement and speed.

The present invention further provides a treatment system (and associated method), which includes the headrest apparatus and a means for irradiating tissue in a region of the head of a patient, such as the eye region. The system is usefully employed in any of a wide variety of tissue treatment applications for which a headrest is desirable, for example, cosmetic or substantive treatment of facial tissue.

According to a particularly preferred embodiment, this treatment system is used to receive a patient's head and to irradiate the corneal tissue of a patient with electromagnetic radiation in order to reshape the cornea, for example, in the manner of the Sand Patents, the PCT Publication, and a co-pending U.S.

Patent Application Serial No. _/__/__ of Herekar *et al.*, entitled "METHOD AND APPARATUS FOR EXPOSING A HUMAN EYE TO A CONTROLLED PATTERN OF RADIATION", filed concurrently with the present application, which co-pending application (hereinafter, "the co-pending application") is hereby incorporated herein in its entirety by this reference. That is, the treatment system of this preferred embodiment is usefully employed to receive the patient's head in a manner suitable for irradiation of sensitive corneal tissue and to irradiate such tissue. The treatment system provides adjustment capability, positioning versatility, and sensing and feedback capability appropriate for ophthalmologic treatments such as photothermal keratoplasty, as well as many patient-comfort features which facilitate such treatment.

Additional objects, advantages and features of the present invention will become apparent from the description of preferred embodiments, set forth below, which should be taken in conjunction with the accompanying drawings, a brief description of which follows.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of an ophthalmic treatment instrument, including a headrest for a patient, from a side that faces an attending physician.

Figure 2 is a perspective view of the instrument of Figure 1 from an opposite side that faces a patient.

Figure 3 is a side view of the instrument of Figures 1 and 2 with typical positions of a patient and attending physician being outlined.

Figure 4 is a perspective view of a headrest for a patient, such as a headrest shown in any of Figures 1-3, from a side that faces a patient. The headrest is enlarged (relative to that shown in Figures 1-3) in this view.

Figure 5 is a straight-on view of the headrest of Figure 4 from an opposite side that faces an attending physician.

Figure 6 is a side view of the headrest of Figures 4 and 5.

Figure 7 is a schematic illustration of a sensing and feedback system employed in a headrest for a patient, such as a headrest shown in any of Figures 1-6, according to an embodiment of the present invention. The portion of the headrest shown is enlarged in this schematic illustration.

DESCRIPTION OF PREFERRED EMBODIMENTS

The various aspects of the present invention, those summarized above and others, are illustrated herein in relation to a system that corrects vision by photothermal keratoplasty. Such a system is described in greater detail in the above-mentioned, co-pending application of Herekar *et al.*. The system is easily configured to generate precisely a desired pattern of electromagnetic radiation to correct a vision deficiency, such as far-sightedness, of a particular patient. The specific type or amount of vision correction required by the particular patient determines the specific configuration appropriate for that patient.

Many aspects of the present invention are also applicable to other techniques of vision correction, wherein certain parameters are different, such as the radiation wavelengths, patterns, exposure times, and the like. Further, many aspects of the present invention are applicable to the generation of radiation patterns for uses other than vision correction. Additionally, many aspects of the present invention are applicable to operation of a wide variety of medical treatment or diagnosis systems.

An example of a system according to the present invention is now generally described with respect to Figures 1-3. By way of convenience, the system is described herein with reference to terms which correspond to a representation 80 of a three-dimensional Cartesian coordinate system, including an x-axis, a y-axis, and a z-axis, such that rightward, leftward, lateral, horizontal, or like movement is in a direction (x-direction) substantially parallel to the x-axis; upward, downward, elevational, vertical, or like movement is in a direction (y-direction) substantially parallel to the y-axis; and forward, backward, proximity-adjusting, or like movement is in a direction (z-direction) substantially parallel to the z-axis.

The system is specifically designed for use in an office of an ophthalmologist, other physician or medical service provider, where reliability and ease of use are important since technical assistance is not on site or very close to the office. A base 11 is provided with casters for ease of movement of the system within the office. A table assembly 13 is carried by the base in a manner such that it is adjustable in an upward and downward direction with respect to the base. A motor (not shown in Figures 1-3) within the base is used to facilitate such adjustment. This allows vertical adjustment of an optical radiation delivery instrument 15 to suit a physician 17 who is performing the procedure and a particular patient 19 who is having his or her vision corrected. This adjustment, along with a typically independent adjustment of physician and patient chairs 21 and 23, permits comfortable positioning of both the physician and patient with

respect to the instrument 15. Handles 20 and 22 on opposite sides of a top 25 of the table of the assembly 13 make it easy to move the system by rolling it on its casters.

The radiation delivery instrument 15 is carried on the top 25. During the procedure, the physician looks through binoculars 27 on one side of the instrument 15 and a treatment optical radiation pattern exits the other side of the instrument at opening 29. This radiation is directed through a few inches of air to a patient eye 31 being treated. Only one eye is treated at a time in one procedure. In order to place the treated eye in a fixed position with respect to the table assembly 13, a headrest assembly 33 is attached to the table top 25. This headrest assembly 33 is described in greater detail below in connection with Figures 4-7. Generally, in one operational embodiment, the patient's head is placed in contact with this assembly 33 in preparation for or during treatment, and optionally urged against it or strapped against it. A transducer 35 is built into a top of the headrest assembly 33 in a position to be contacted by the forehead of the patient. This transducer provides an electrical signal with a magnitude related to a degree of contact between the patient's forehead and the assembly. By way of example, the degree of contact, and thus, the electrical signal, may be related to an amount of pressure or force applied to the assembly 33 when the patient's forehead contacts the assembly. The resulting electrical signal is used to confirm an appropriate level of contact or to indicate an inappropriate level of contact between the patient's forehead and the headrest assembly. Thus, this electrical signal is usefully fed into an electronic control portion of the system that, for example, may provide a desired safety response, such as shutdown of the radiation delivery system or provision of physician or patient feedback.

Once the patient's head is placed against the headrest assembly 33, the radiation pattern from opening 29 is manually aligned with the eye 31 by movement of the optical instrument with respect to the table top 25. The physician so moves the instrument by manipulating a joystick type of handle control 37 on a base 39 of the instrument. The handle 37 operates a mechanism (not shown) positioned under the base 39 of the instrument 15 that, in response to movement of the handle 37 to the left or right by the physician 17, moves the projected radiation pattern between the patient's right and left eyes and horizontally adjusts the pattern on the selected eye 31 being treated. Movement of the handle 37 forward and backward by the physician 17 moves the instrument 15 toward and away from the patient, respectively, to control the focus of the radiation pattern on the eye 31 being treated. Vertical motion of the instrument 15 with respect to the table top 25 is not

provided in this example, but could also be provided. Rather than moving the instrument 15 up and down with respect to the table top 25, the vertical position of the patient eye 31 being treated is controlled by a mechanical adjustment of the headrest assembly 33, as further described below in relation to Figures 4-7, in combination with an adjustment of the patient's chair, if and as necessary.

Included as part of the optical instrument 15 is an illuminator 41 that directs light through a top prism 43 to the patient eye being treated from a side of the eye. This illuminates the eye so that the physician 17 may have a clear view of it through the binoculars 27 when carrying out the treatment procedure. The illuminator 41 is rotatable by hand with respect to the instrument 15 about an axis (not shown), as shown and described in more detail in the co-pending application. The attending physician may easily adjust the angle of the eye illumination, while looking through the binoculars, in order to obtain a good view of the eye being treated. The illuminator 41 will generally be rotated to one side or the other, depending upon whether the right or left eye of the patient is being treated. Since the prism 43 directs light from about the same height as the treatment radiation output opening 29, it is rotated out of the way when treatment radiation is directed against the patient eye 31. The intensity of light from the illuminator 41 is adjusted by the physician through rotation of a knob 47 on the base 39 of the instrument.

The base 11 includes a number of electrical receptacles for connection to power and communications systems. Included are a receptacle 49 for a power cord, a receptacle 51 for a telephone line and a receptacle 53 for a local-area network (LAN). Several controls and devices are provided on the physician's side of the table assembly 13. These include a key-operated power switch 55 and an emergency button 57 that turns off the treatment radiation source. A floppy-disk drive 59 is also positioned on a side of the table facing the physician. A compact-disk (CD) drive 61, a high- capacity, removable-disk drive 63 and a slot 65 for receiving a smart card are also provided. Many of the radiation sources used in the system and a controlling computer are installed in the base unit 11. A foot switch 67 is provided for the physician to use to start treatment after the system is adjusted for a particular patient eye.

A primary input/output device to the system's controlling computer system is a touch-sensitive screen 69. It can be mounted to the table top 25 on either the right (as shown) or left side of the physician, by attachment to respective receptacles 71 and 73. Thus, the attending physician may select whichever side is the most convenient. A typical computer keyboard may also be connected to the

internal computer system through a receptacle 75 in the base unit 13, although it is unlikely that it will be used by the physician to perform treatments since the touch screen 69 is usually preferred. A tray (not shown) can be added to extend the table top 25 to support a keyboard. A keyboard will be useful when a significant amount of data is input or retrieved through the treatment system, rather than though another computer connected in a LAN with the treatment system. Standard computer-peripheral receptacles 76 and 78 are also provided for connection to an external printer and monitor, respectively.

The headrest assembly 33 is now described in greater detail in relation to Figures 4-7. In Figure 4, the headrest assembly 33 is shown in a perspective view from a side 100 which faces a patient. In Figure 5, the headrest assembly is shown in a straight-on view from the opposite side 102 which faces a physician. A side view of the headrest assembly is shown in Figure 6.

Generally, the headrest assembly 33 is an apparatus for receiving the head of a subject which is typically used when it is desired to observe or to treat the subject's head, or a region thereof. Thus, the headrest assembly 33 is usefully employed by a physician 17 to receive the head of a patient 19 for the observation and/or treatment of tissue in a particular region of the head, as depicted in Figure 3. As described above, the headrest assembly is desirably employed in system including means for irradiating tissue, particularly such a system that corrects vision by photothermal keratoplasty, as described in greater detail in the co-pending application.

The headrest assembly 33 includes a base 104 which supports a means 106 for receiving the patient's head (Figure 3). The base 104 may be of any construction sufficient to support means 106, and preferably, is constructed for attachment to a table top, such as table top 25 of Figures 1-3. The base may include means 105 for attaching the base to a table top, such as holes 105 for receiving conventional screws or bolts (not shown) therethrough, to be secured in a known manner in corresponding screw- or bolt-receiving means (not shown) in the table top, as may be seen from Figure 4, or base pegs 107 to be received in peg receptacles (not shown) in the table top, as may be seen from Figures 5 and 6.

The receiving means 106 is of a substantially open construction to allow the physician to observe the head of the patient. Preferably, the receiving means 106 is constructed to frame the patient's head where the patient's head contacts the receiving means and at least one side, and preferably both sides, of the patient's head. Thus, as shown in Figure 3, the receiving means 106 of the headrest

assembly 33 may include a top, bar-like portion 107 to frame the patient's head along the forehead and at least one side, bar-like portion 108 along at least one side of the face, allowing the physician 17 to observe the facial region of the head of the patient 19, in particular the eye region, therethrough. Naturally, the receiving means is of a construction sufficient to facilitate the physicians's unobstructed observation of the region of interest, and thus, may be constructed for receiving not only the forehead, as described above, but any other appropriate region of the patient's head, such as the temples, the cheeks, the jaws, the chin, or a portion of the back of the head, including the nape of the neck, should a rest, or cradle, for the back of the head (not shown) be employed.

In order to facilitate appropriate placement of the patient's head in relation to the receiving means 106 for isolation of the region to be observed or treated, the receiving means 106 may include markers 110 which correspond to a desired positioning of the region of interest. For example, the receiving means 106 may include a side element 108, or two such side elements, having a marker 110 thereon corresponding to a desired position of an eye of the patient when the head of the patient is received in the receiving means. The receiving means 106 may be adjustable relative to the base 104 to accommodate a dimension or proportion of the patient's head. For example, the receiving means 106 may be slidingly moved along posts 112 in an upward or downward direction, according to the vertical dimension of the patient's head, so that the region of interest is appropriately positioned for observation or treatment when the patient's head is received by the receiving means. Any other appropriate means for vertical adjustment of the receiving means relative to the base could also be employed.

As previously described, the headrest assembly 33 includes a means 35 for sensing a degree of contact between the contacting portion of the patient's head, such as the forehead, and the receiving means. As shown, the sensing means 35 is disposed on the receiving means 106 at an appropriate location for contact, such as the top portion 107 of the receiving means 106 for receiving the patient's forehead.

The sensing means 35 may be any means appropriate for sensing a degree of contact or an amount of pressure or force, including any appropriate optical, semiconductor, electrical, ultrasonic, or hydraulic sensor. For example, the sensor 35 may include a material, such as a piezoelectric material, or in the case of a hydraulic sensor, a fluid-filled cavity, which is responsive to an amount of force or pressure applied thereto when the patient's head is received in the receiving

means 106 and contacts the sensor 35 Preferably, the sensor 35 includes a transducer, particularly a piezoelectric transducer, which provides a signal 140 (Figure 7) having a magnitude related to the degree of contact between the patient's head and the receiving means 106, or an amount of force or pressure applied to the sensor when the patient's head contacts the sensor.

The signal 140 from the sensing means 35, schematically shown in Figure 7, is used to confirm an appropriate level of contact or to indicate an inappropriate level of contact between the patient's head and the receiving means 106, particularly the latter. This feedback concerning the level of patient contact is important, as often a patient moves his or her head during or after placement on the receiving means, for example, because of inattention, fatigue, discomfort, or anticipation or fear of the procedure, such that the patient is in a position which is non-optimal, inappropriate, or unsafe for the planned procedure. Any movement which reduces contact with the headrest is of interest. Often such movement will be back and away from the treatment system, such as the optical radiation delivery instrument 15, for example, when the patient fears irradiation of sensitive tissue such as his or her ocular tissue. Other movements of particular interest are lateral movement with respect to the receiving means and forward movement toward the treatment system and away from a headrest receiving the back of the head. When the procedure is the irradiation of tissue, any such movement can have undesirable consequences, for example, the irradiation of tissue other than the tissue of interest. Thus, the signal 140 may be used to alert the physician to the movement of the patient, and perhaps more importantly, since the physician's reaction time may be too slow, to interrupt treatment or to shut down the treatment system automatically to prevent any undesired consequences, as further described in the co-pending application.

The signal 140, which may be an electrical signal, either analog or digital, travels through any appropriate communication means 130, such as electrical wires, from the sensing means 35 (which is preferably non-metallic or electrically non-conductive) to a feedback system 150. The communication means 130 may be channeled from the sensor 35 through any hollow interior portions of the headrest assembly 33, such as any hollow interior of the receiving means 106, the side elements 108, the posts 112, and/or the base 104, or may be otherwise configured. The feedback system provides sensory feedback to the patient, to a heads-up display 200 which provides feedback to the physician, and/or to an electronic control system 300 for the treatment instrument for treatment interruption

or shut down, as schematically shown in Figure 7. The heads-up display 200 should be located in the physician's field of view so as not to interfere with the field of view of the patient's eye undergoing observation or treatment. Typically, the electronic control system 300 will be located in proximity to the treatment instrument, such as the radiation delivery instrument 15.

While the patient's head may be secured against the receiving means 106 to prevent undesired movement, such as by use of an adjustable strap or an adjustable band (not shown) attached to the side portions 108 of the receiving means via attachment means 111, this is not always conducive to the mental or physical comfort of the patient. For example, a patient who may be fearful of a procedure may find being immovably held in front of the treatment instrument anxiety-provoking. Further, unless the securing means is adjusted to secure the patient's head rather tightly, which may be physically uncomfortable for the patient, the level of contact may still be insufficient for appropriate positioning or securing of the patient's head. Thus, it is desirable to involve the patient in placing his or her head securely on the receiving means 106, or even urging his or her head thereagainst, such that restraining means are optional.

The headrest assembly 33 provides patient feedback to facilitate a patient's involvement in placing or maintaining his or her head on the receiving means 106 in an appropriate position for observation or treatment. That is, as schematically shown in Figure 7, the headrest assembly 33 includes a means 150, operably connected to the sensing means 35, for providing sensory feedback to the patient when the signal 140 indicates that the degree of contact is below a predetermined value. The feedback means 150 includes means 142 for generating a sensory signal 144, preferably an analog signal, such that when the degree of contact is below the predetermined value, the patient receives the sensory signal. The sensory signal 144 may be any signal that may be perceivable by the senses of a patient, such as an auditory signal, a visual signal, and a tactile signal. Preferably, when the treatment to be performed concerns a patient's eye, the sensory signal is non-visual or at least not visible to the eye undergoing treatment. When the patient senses the sensory signal, he or she is thereby informed that contact with the headrest assembly is decreased or insufficient, so that contact should be increased or resumed.

By way of example, the signal-generating means 142 may be an oscillator. The feedback means 150 may further include an amplifier 146, operably connected to the signal-generating means 142, for amplifying any signal 144 that

is too weak to be perceived with relative ease by the patient. The feedback means 150 may also include a means 148, operably connected to the signal-generating means 142 or the amplifier 146, for conveying the sensory signal 144 to the patient, such as a speaker, a lighting device, a vibrating device, and the like. If a vibrating device is used, the conveying means 148, such as a vibratory paging device, should be in close proximity to or touching the patient to facilitate tactile sensing. Preferably, the output from the feedback means varies according to the degree of contact detected by the sensor 35. For example, if the level of contact has fallen off slightly, moderately, or greatly, preferably, the signal would vary accordingly to be of low, medium, or great intensity, so that the patient would respond with an appropriate level of attention and speed. When the treatment concerns the eye of a patient, preferably, the signal is auditory, such as a sound which varies in tone or pitch or a sound which varies in intensity or volume.

The predetermined value for the desired degree of contact between the patient's head and the receiving means 106 may be based on a number of factors, such as the margin of error for the observation or treatment procedure, patient capability and comfort, and physical constraints of the sensor or headrest apparatus. By way of example, when an amount of pressure is being sensed, this predetermined may be in a range of about one to about two pounds of pressure. When the headrest assembly is being used in tissue treatment applications, preferably, the sensing and feedback means are employed during the placement of the patient's head and up to the time of treatment, and not just during the actual treatment procedure. This pre-treatment sensing and feedback exercise is important to allow the patient to become accustomed to the feedback operation of the system, such that the patient may act accordingly during the actual treatment procedure, when proper head contact and positioning may be critical.

While mechanical securing of the patient's head is optional, it is desirable to aid the patient as much as possible in placing and positioning his or her head appropriately in relation to the headrest assembly 33. Such aid may be in the form of at least one hand rest 114 or handle for receiving a hand, and preferably, two such hand rests are provided, as shown in Figures 4-6. The hand rests 114 should be positioned for patient comfort, such as near the base 104 and attached to the posts 112 of the headrest assembly, as shown. These hand rests 114 should be designed for patient comfort, as well, and thus, may include comfortable grips 160, of any desirable shape, textured 162 and/or smooth 164, for the patient's hands, as detailed in Figures 5 and 6. The patient may use these hand rests 114 to assist him

or her in establishing and maintaining the necessary degree of contact with or pressure against the headrest assembly and to reduce fatigue.

Another aid may be in the form of an additional means 118, supported by base 104, for receiving a portion of the patient's head. That is, while means 106 receives a portion of the patient's head, such as the forehead, means 118 receives another, lower portion of the patient's head, such as the chin, to aid the patient in placing and maintaining an appropriate position. Any appropriate head portions may be selected for being received in receiving means 118, such as the temples, the cheeks, the jaws, the chin, or a portion of the back of the head, such as the nape of the neck, should a rest, or cradle, for the back of the head (not shown) be employed, provided the selected portion is lower than that received in the receiving means 106. When the treatment concerns the eye, preferably the forehead is received by the receiving means 106 and the chin is received by the receiving means 118.

The headrest assembly 33 shown in Figures 4-6 includes receiving means 106, having a forehead rest 107 and side elements 108 as described above, and receiving means 118, including a chin rest 120 and support means 122. The chin rest 120 may be in the form of a cup, as shown, to provide good support for the weight of the patient's head, as well as additional patient comfort. The chin rest 120 may also accommodate disposable tissues and have wipe-down capability. The support means 122 is attached to the posts 112 of the headrest assembly and serves as a base for the chin rest 120.

Preferably, the chin rest 120 is adjustable to conform to a dimension or proportion of the patient's head or to achieve a desired angular or leaning position of the head. For vertical adjustment (in the y-direction), adjusting means 116 may be manipulated to move the chin rest 120 up or down relative to the receiving means 106. The adjusting means 116 may be any appropriate means, such as the two knobs which are simply turned in one direction or the other for the desired upward or downward movement of the support means 120 along posts 112. The adjusting means 116 may provide for any desired extent of adjustment, such as an adjustment of approximately two inches, as schematically detailed by the dotted line configurations shown in Figure 6. Adjustment in the y-direction is useful to accommodate a vertical dimension or length of a patient's head, for example, from forehead to chin.

Adjustment of the chin rest 120 relative to the receiving means 106 is also possible in the z-direction, for example, to accommodate a patient having a

chin set forward or backward relative to his or her forehead or to achieve an angled head position, such as a forward-leaning position in which the patient's forehead closer to the treatment instrument than the patient's chin or a backward-leaning position. Any appropriate adjustment means 124 may be provided for this adjustment, such as a track-type adjustment means, as shown in Figure 4, where the chin rest 120 is moved back and forth along a track 124 and then secured in the proper position by any appropriate means, such as a screw or bolt to be received through a hole 126 and secured therebelow in a screw- or bolt-securing means (not shown) in the track 124. Adjustment of the chin rest 120 relative to the receiving means 106 is also possible in the x-direction, for example, to accommodate a patient having a chin set to the right or left relative to the center of his or her forehead, or to achieve an angled or side-leaning head position, using any appropriate means (not shown), such as a track-type adjustment means running in an x-direction.

Alternatively, adjustments to accommodate a dimension or proportion of the patient's head or to achieve a desired angular or leaning position of the head may be facilitated by adjusting the receiving means 106 relative to the chin rest 120. For example, vertical adjustment of the receiving means 106 may be accomplished by moving the side elements 108 of the receiving means up or down on posts 112, as previously described. Additionally, adjustments in the z- and x-directions may be facilitated by the use of means therefor (not shown), such as the track-type means described above, attached to the sensing means 35 or the receiving means 106. Thus, at least one of the receiving means 106 and the receiving means 118 is adjustable relative to the other to conform to at least one dimension of the patient's head or to position the head in an angled or leaning position.

A further aid to the patient may be a sensing means 35 in the form of a pad across the top portion 107 of the receiving means 106 where the forehead, or other portion of the head contacts the headrest assembly, as shown in Figure 6. Additionally, the chin rest 120 may be padded for patient comfort. For tissue treatments as short as those sufficient for photothermal keratoplasty, as further described in the co-pending application, such aids may still be desirable for patient comfort, as the pre-operative procedures (such as patient orientation, alignment, calibration, and safety procedures) may be lengthy enough to affect patient comfort.

The headrest assembly 33 described herein is usefully employed in a system for treating tissue in a region of the patient's head which includes a means for irradiating the tissue when the degree of contact between the patient's head and the receiving means 106 is of at least the predetermined value previously described.

The irradiating means is preferably a means for irradiating the tissue with infrared radiation to shrink collagen within the tissue. Such a system may be used in the treatment of a variety of tissue, such as corneal tissue, as well as non-corneal tissue containing collagen. The system may also be used in a variety of treatments, such as the photothermal keratoplasty treatment further described in the co-pending application and various treatments for correcting an undesirable condition of selected tissue, whether medically substantive, structurally substantive, functionally substantive, or cosmetic, which modify a shape or structure of the tissue being treated.

Preferably, the irradiating means used in the system is a laser. For photothermal keratoplasty applications, where the wavelength of the treatment radiation is in the infrared region of the electromagnetic spectrum, a holmium-doped, yttrium-aluminum-garnet (YAG) crystal laser having a coherent radiation output with a wavelength of about 2.1 microns is preferred. Preferably, the system includes means 300, operably connected to the sensing means 35, for interrupting tissue treatment when the degree of contact is below the predetermined value, to avoid any undesirable consequences. Many of these preferred features are described in greater detail in the co-pending application.

Although the various aspects of the present invention have been described with respect to the preferred embodiments thereof, it will be understood that the invention is entitled to protection within the full scope of the appended claims.

IT IS CLAIMED:

1. An apparatus for receiving a head of a subject for observation or treatment of tissue in a region thereof, comprising:

a base;

first means for receiving a first portion of the head, said first receiving means supported by said base;

means for sensing a degree of contact between the first portion and said first receiving means, said sensing means disposed on said first receiving means; and

means, operably connected to said sensing means, for providing sensory feedback to the subject based on the degree of contact.

2. The apparatus of claim 1, wherein said first receiving means is of a construction sufficient for receiving a forehead of the subject.

3. The apparatus of claim 1, wherein said first receiving means is adjustable relative to the base.

4. The apparatus of claim 1, wherein said sensing means comprises a material responsive to force or pressure.

5. The apparatus of 4, wherein said material is a piezoelectric material.

6. The apparatus of claim 1, wherein said sensing means comprises a transducer.

7. The apparatus of claim 6, wherein said sensing means comprises a piezoelectric transducer.

8. The apparatus of claim 1, wherein said feedback means comprises a generator of a sensory signal.

9. The apparatus of claim 8, wherein said feedback means comprises an oscillator.

10. The apparatus of claim 1, wherein said feedback means comprises an amplifier.

11. The apparatus of claim 1, wherein the feedback means provides sensory feedback to the subject when the degree of contact is below a predetermined value.

12. The apparatus of claim 1, wherein said feedback means provides an analog signal corresponding to the degree of contact sensed by said sensing means.

13. The apparatus of claim 1, wherein said feedback means provides an analog signal corresponding to an amount of force or pressure sensed by said sensing means.

14. The apparatus of claim 1, wherein said feedback means provides audible feedback.

15. The apparatus of claim 1, wherein said feedback means provides tactile feedback.

16. The apparatus of claim 1, wherein said feedback means provides variable sensory feedback which corresponds to variations in the degree of contact.

17. The apparatus of claim 1, further comprising second means for receiving a second portion of the head which is lower than the first portion, said second receiving means supported by said base.

18. The apparatus of claim 1, wherein said second receiving means is of a construction sufficient for receiving a chin of the subject.

19. The apparatus of claim 18, wherein said second receiving means is of a construction sufficient for supporting the chin.

20. The apparatus of claim 17, wherein at least one of said first receiving means and said second receiving means is adjustable relative to another of said first receiving means and said second receiving means.

21. The apparatus of claim 20, wherein said one adjustable receiving means is adjustable in a y-direction.

22. The apparatus of claim 20, wherein said one adjustable receiving means is adjustable in a z-direction.

23. The apparatus of claim 1, further comprising a means, attached to said first receiving means, for securing the head.

24. The apparatus of claim 23, wherein said securing means is a strap or band.

25. The apparatus of claim 1, further comprising at least one means attached to said first receiving means for receiving a hand of the subject.

26. The apparatus of claim 1, wherein said first receiving means is of a construction sufficient to frame the first portion and at least one side of the head.

27. The apparatus of claim 26, wherein said first receiving means comprises at least one side element for framing the at least one side of the head, said side element having at least one marker thereon corresponding to a desired position of an eye of the subject when the first portion is received in said first receiving means.

28. A system for treating tissue in a region of a head of a subject, comprising:

the apparatus of any one of claims 1, 17 and 20; and

means, opposing said first receiving means, for irradiating the tissue with electromagnetic radiation.

29. The system of claim 28, wherein said feedback means provides sensory feedback to the subject when the degree of contact below a predetermined value.

30. The system of claim 28, wherein said irradiating means irradiates the tissue when the degree of contact is of at least a predetermined value.

31. The system of claim 28, wherein said irradiating means comprises means for irradiating the tissue with infrared radiation to shrink collagen within the tissue.

32. The system of claim 28, wherein the tissue is corneal tissue and said irradiating means comprises means for irradiating the corneal tissue with infrared radiation to shrink collagen within the corneal tissue.

33. The system of claim 28, wherein the irradiating means comprises a laser.

34. The system of claim 28, further comprising means, operably connected to said sensing means, for interrupting tissue treatment when the degree of contact is below the predetermined value.

35. A method of receiving a head of a subject for observation or treatment of tissue in a region thereof, comprising:

receiving a first portion of the head on a first receiving means therefor;

sensing a degree of contact between the first portion and the receiving means; and

providing sensory feedback to the subject based on the degree of contact.

36. The method of claim 35, wherein said receiving of the first portion comprises receiving a forehead of the subject on the first receiving means.

37. The method of claim 35, further comprising adjusting the first receiving means to position the head.

38. The method of claim 35, further comprising adjusting the first receiving means to conform to at least one dimension of the head.

39. The method of claim 35, wherein said sensing comprises sensing an amount of force or pressure.

40. The method of claim 35, wherein said providing feedback comprises providing sensory feedback to the subject when the degree of contact is below a predetermined value.

41. The method of claim 35, wherein said providing feedback comprises providing an analog signal corresponding to the degree of contact sensed by said sensing means.

42. The method of claim 35, wherein said providing feedback means comprises providing an analog signal corresponding to an amount of force or pressure sensed by said sensing means.

43. The method of claim 35, wherein said providing feedback comprises providing audible feedback.

44. The method of claim 35, wherein said providing feedback comprises providing tactile feedback.

45. The method of claim 35, wherein said providing feedback comprises providing variable sensory feedback corresponding to variations in the degree of contact.

46. The method of claim 35, further comprising receiving a second portion of the head which is lower than the first portion on a second receiving means therefor.

47. The method of claim 46, wherein said receiving of the second portion comprises receiving a chin of the subject on the second receiving means.

48. The method of claim 47, wherein said receiving of the second portion comprises supporting the chin.

49. The method of claim 47, further comprising adjusting at least one of the first receiving means and the second receiving means relative to another of the first receiving means and the second receiving means.

50. The method of claim 49, wherein said adjusting comprises adjusting the at least one receiving means in a y-direction.

51. The method of claim 49, wherein said adjusting comprises adjusting the at least one receiving means in a z-direction.

52. The method of claim 35, further comprising securing the head.

53. The method of claim 35, further comprising receiving at least one hand of the subject on a third receiving means therefor.

54. The method of claim 35, wherein said receiving of the first portion comprises framing the first portion and at least one side of the head with the first receiving means.

55. The method of claim 35, further comprising providing a reference for a desired position of an eye of the subject when the first portion is received in the first receiving means.

56. A method for treating tissue in a region of a head of a subject, comprising:

the method of any one of claims 35, 46 and 49; and

irradiating the tissue with electromagnetic radiation.

57. The system of claim 56, wherein said providing feedback comprises providing sensory feedback to the subject when the degree of contact is below a predetermined value.

58. The method of claim 56, wherein said irradiating the tissue comprises irradiating the tissue when the degree of contact is of at least a predetermined value.

59. The method of claim 56, wherein said irradiating comprises irradiating the tissue with infrared radiation to shrink collagen within the tissue.

60. The method of claim 56, wherein said irradiating comprises irradiating corneal tissue with infrared radiation to shrink collagen within the corneal tissue.

61. The method of claim 56, wherein said irradiating comprises irradiating the tissue with laser-generated radiation.

62. The system of claim 56, further comprising interrupting tissue treatment when the degree of contact is below the predetermined value.

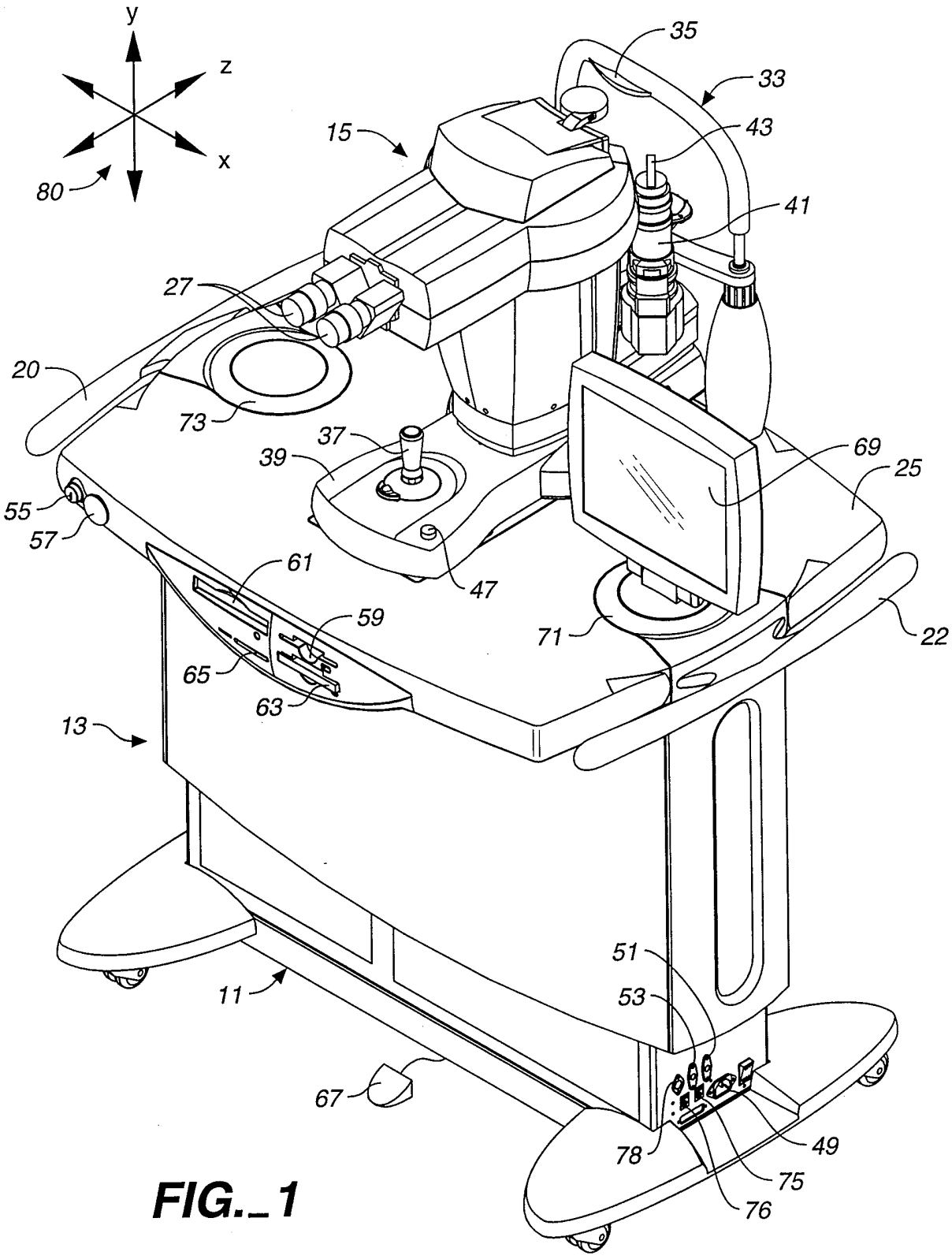

y
z
x
80
35
33
15
43
41
27
20
73
37
39
69
25
55
57
61
47
59
71
22
65
63
13
51
53
11
67
78
49
75
76

FIG._1

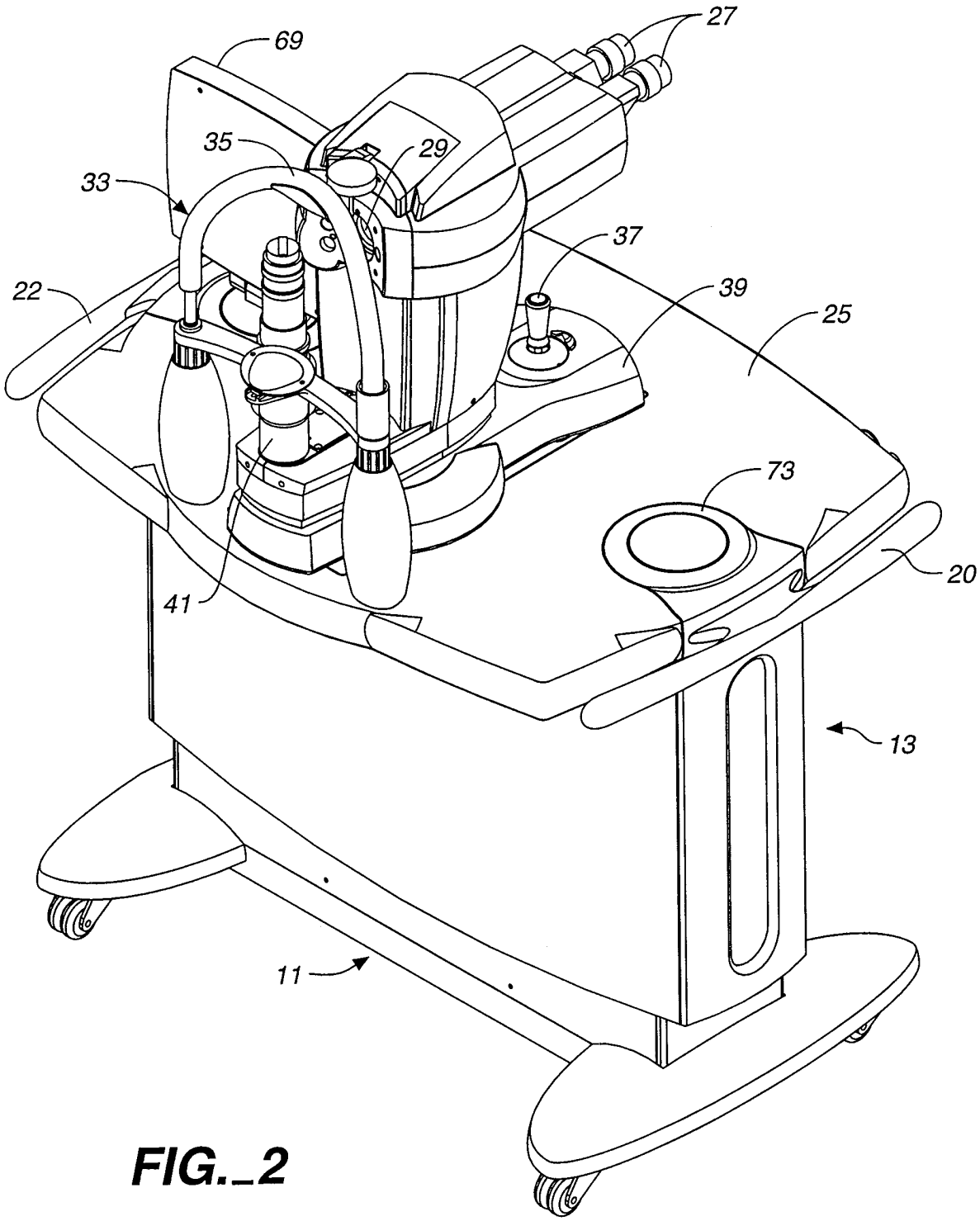


FIG._2

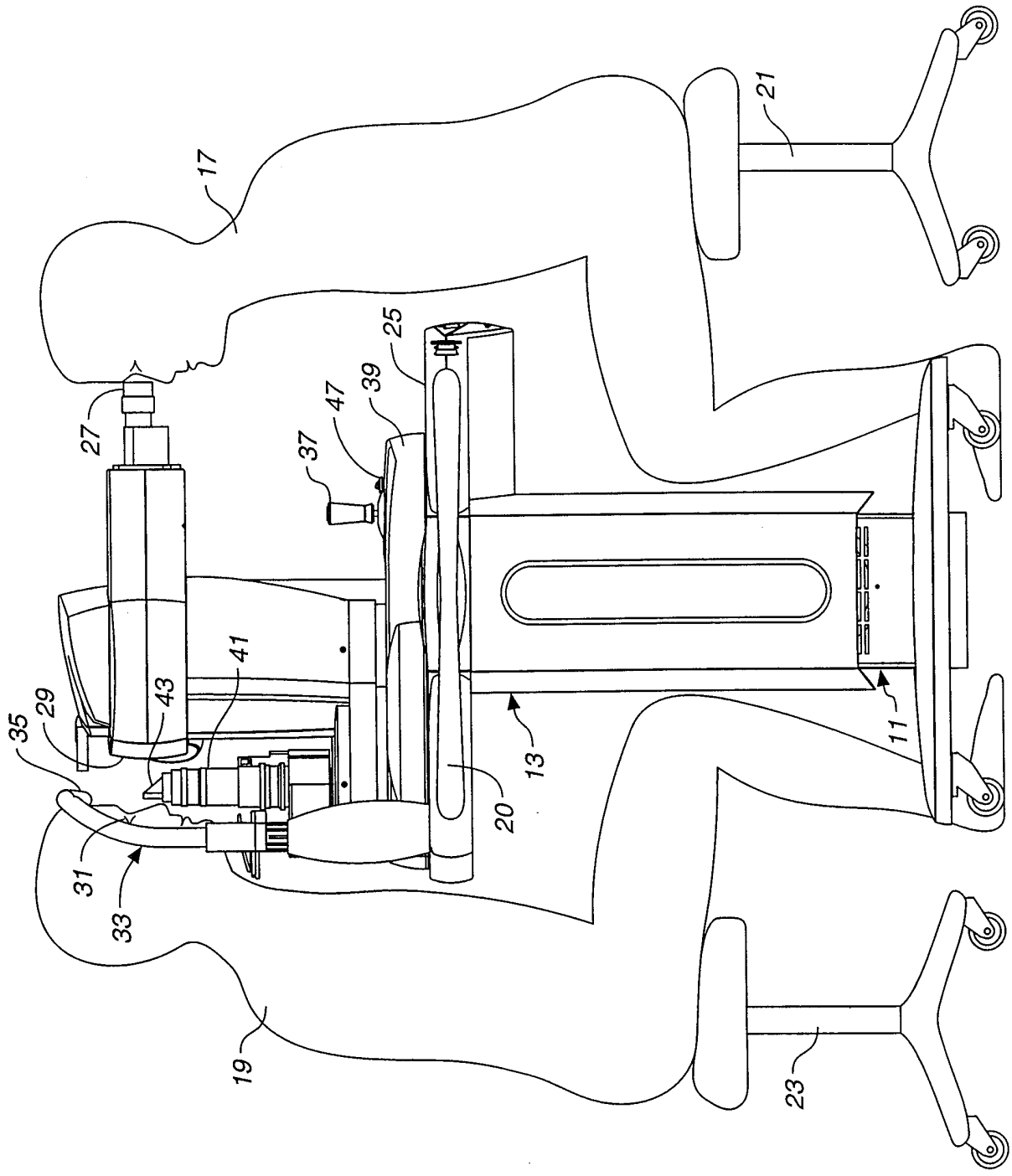


FIG._3

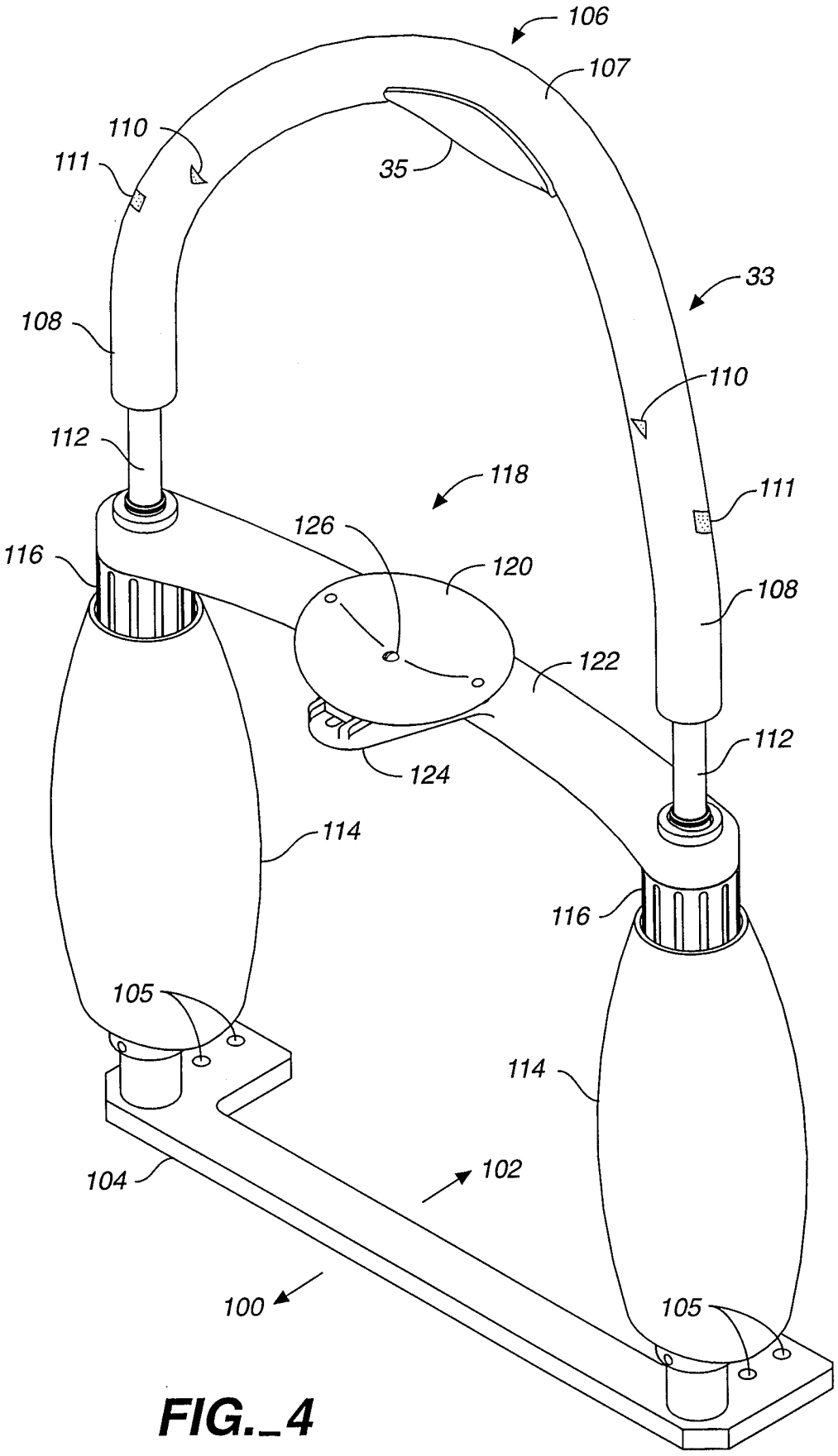

106
107
110
111
35
33
108
110
112
118
111
126
116
120
108
122
112
124
114
116
105
114
104
102
100
105

FIG._4

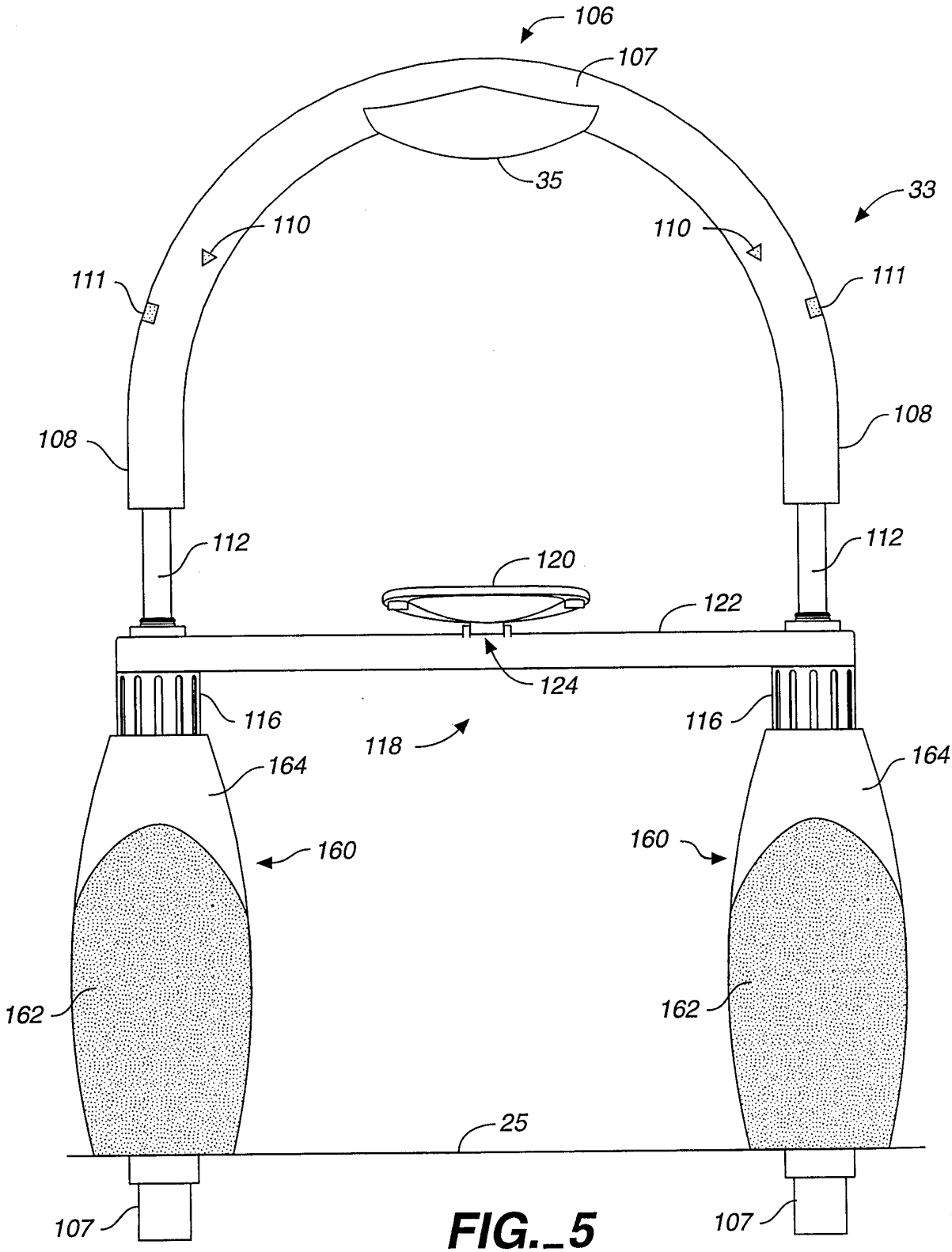

106
107
35
33
110
110
111
111
108
108
112
112
120
122
124
116
116
118
164
164
160
160
162
162
25
107
107

FIG._5

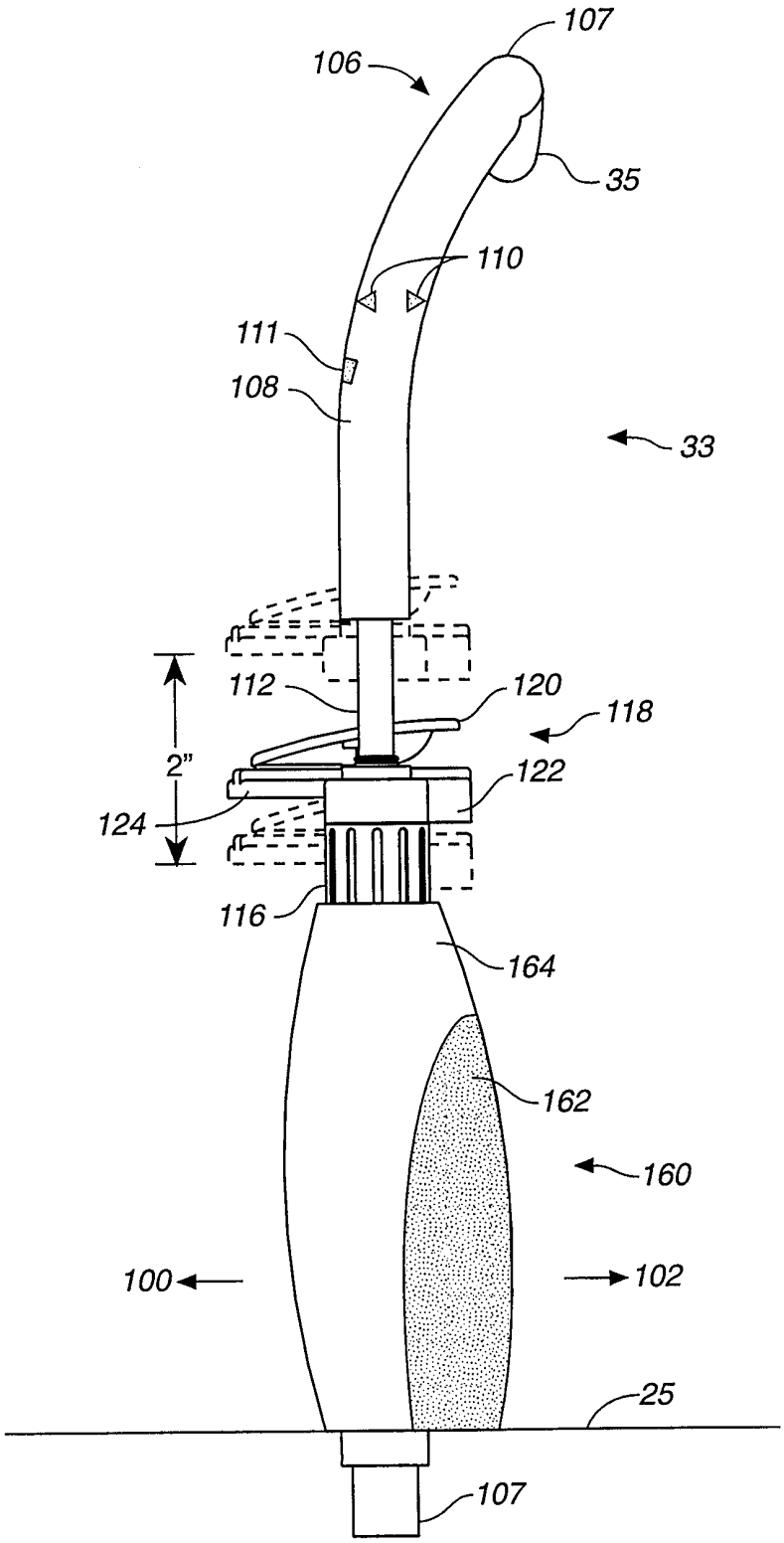

107
106
35
110
111
108
33
112
120
118
2"
122
124
116
164
162
160
100
102
25
107

FIG._6

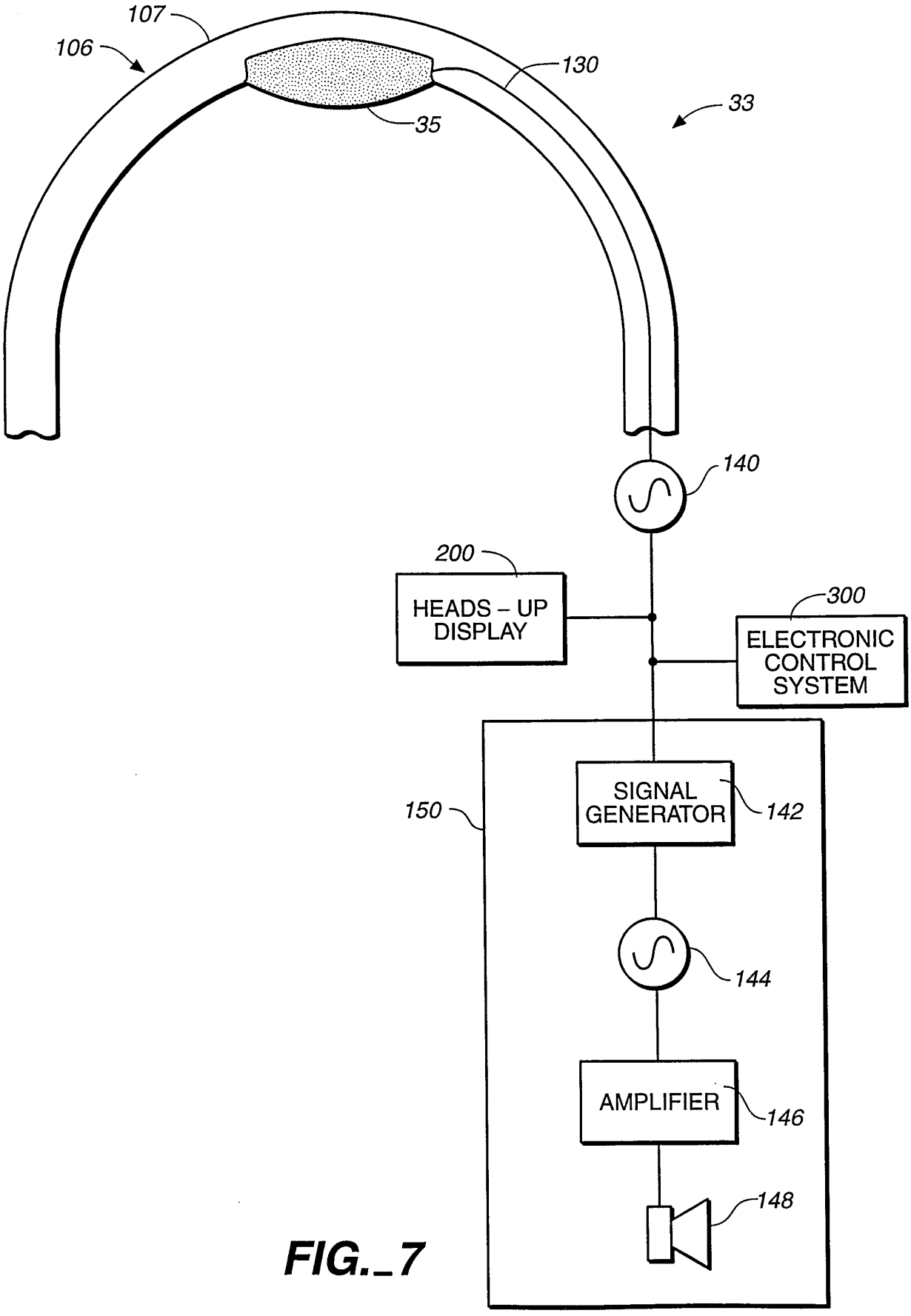

107
106
130
33
35
140
200
HEADS – UP DISPLAY
300
ELECTRONIC CONTROL SYSTEM
150
SIGNAL GENERATOR
142
144
AMPLIFIER
146
148

FIG._7

INTERNATIONAL SEARCH REPORT

Intern ıal Application No
PCT/US 99/20034

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B3/00

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 7 A61B A61F G01L

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 387 952 A (BYER) 7 February 1995 (1995-02-07) column 4, line 41 -column 6, line 25 column 6, line 60 -column 7, line 48 figures 1,2,4	1,35
Y		28
A		2,4,6,8, 9,11-15, 17-19, 23,24, 29,30, 37,38, 40-44, 46-48,52
	--- -/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in 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 document 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.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 December 1999	13/01/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Chen, A

1

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Interr ıal Application No
PCT/US 99/20034

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 098 426 A (SKLAR ET AL.) 24 March 1992 (1992-03-24) cited in the application column 6, line 1 - line 11 column 11, line 62 -column 12, line 2 figure 1	28
A		30,33,34
X	WO 94 04076 A (JUTO) 3 March 1994 (1994-03-03) page 2, line 19 -page 4, line 15 figures	1,35
A		2-4,6,8, 11-13, 17-21, 23,24, 26, 28-30, 36-42, 46-50, 52-54
A	US 4 873 994 A (ANGER ET AL.) 17 October 1989 (1989-10-17) column 6, line 55 -column 7, line 11 column 9, line 4 - line 25 figures 1,8	4-7
A	EP 0 362 768 A (LASAG AG) 11 April 1990 (1990-04-11) column 2, line 40 -column 4, line 21	1,2, 17-21, 23-26, 35,36, 46-50, 52-54
A	US 4 128 317 A (LE COVER) 5 December 1978 (1978-12-05) the whole document	1,2, 17-20, 22-24, 26, 46-49, 51,52, 54,55
A	US 4 976 709 A (SAND) 11 December 1990 (1990-12-11) cited in the application column 1, line 62 -column 2, line 7	28,31-33

1

INTERNATIONAL SEARCH REPORT

Int. ational application No.
PCT/US 99/20034

Box I Observations where certain claims were found unsearchable (Continuation of item 1 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. [X] Claims Nos.: 56-62
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery or therapy. Claims 56-62 describe a method of treating tissue by irradiation with electromagnetic energy.

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 II Observations where unity of invention is lacking (Continuation of item 2 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. [X] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

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.

[ ] 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: 1-27 and 35-55

   Method and apparatus for receiving the head of a subject.

2. Claims: 28-34

   System for treating tissue in a region of the head.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Interr ıal Application No
PCT/US 99/20034

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5387952 A	07-02-1995	NONE	
US 5098426 A	24-03-1992	AU 651313 B	21-07-1994
		AU 5161290 A	05-09-1990
		CA 2009368 A	06-08-1990
		CN 1045028 A	05-09-1990
		EP 0426779 A	15-05-1991
		JP 4503913 T	16-07-1992
		WO 9009141 A	23-08-1990
WO 9404076 A	03-03-1994	SE 501167 C	28-11-1994
		AU 4766893 A	15-03-1994
		DE 69324686 D	02-06-1999
		DE 69324686 T	25-11-1999
		EP 0654974 A	31-05-1995
		JP 8500497 T	23-01-1996
		SE 9202334 A	13-02-1994
		US 5591175 A	07-01-1997
US 4873994 A	17-10-1989	DE 3610897 A	08-10-1987
		EP 0240599 A	14-10-1987
		JP 6023673 B	30-03-1994
		JP 62235534 A	15-10-1987
EP 362768 A	11-04-1990	CH 676421 A	31-01-1991
		FR 2638959 A	18-05-1990
		AU 4252889 A	12-04-1990
		JP 2218331 A	31-08-1990
US 4128317 A	05-12-1978	NONE	
US 4976709 A	11-12-1990	AT 112950 T	15-11-1994
		AU 673235 B	31-10-1996
		AU 5935094 A	16-06-1994
		AU 645513 B	20-01-1994
		AU 6034290 A	17-01-1991
		CA 2063245 A	31-12-1990
		DE 69013508 D	24-11-1994
		DE 69013508 T	24-05-1995
		DK 480995 T	27-03-1995
		EP 0480995 A	22-04-1992
		EP 0581339 A	02-02-1994
		ES 2064745 T	01-02-1995
		HK 1006802 A	19-03-1999
		JP 4506312 T	05-11-1992
		SG 48899 A	18-05-1998
		WO 9100063 A	10-01-1991
		US 5484432 A	16-01-1996
		US 5618284 A	08-04-1997
		US 5137530 A	11-08-1992
		US 5374265 A	20-12-1994
		US 5304169 A	19-04-1994