

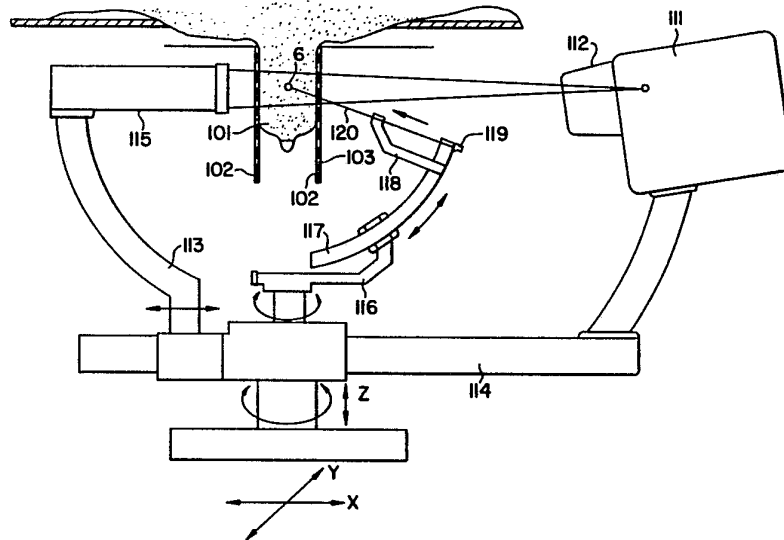


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/US93/02308 (22) International Filing Date: 12 March 1993 (12.03.93) (30) Priority data: 851,683 12 March 1992 (12.03.92) US (60) Parent Application or Grant (63) Related by Continuation US 07/851,683 (CON) Filed on 12 March 1992 (12.03.92) (71) Applicant (for all designated States except US): FISCHER IMAGING CORPORATION [US/US]; 12300 North Grant Street, Denver, CO 80241 (US).</p>	<p>(72) Inventors; and (75) Inventors/Applicants (for US only) : SICZEK, Bernard, W. [US/US]; SICZEK, Aldona, A. [US/US]; 1252 Chinook Way, Boulder, CO 80303-1411 (US). (74) Agent: FISCHMANN, Kent, A.; Sheridan Ross & McIntosh, 1700 Lincoln Street, 35th Floor, Denver, CO 80203 (US). (81) Designated States: CA, JP, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>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.</i></p>
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(54) Title: ISOCENTRIC PUNCTURE INSTRUMENT AIMING DEVICE



(57) Abstract

A device for aiming a puncture instrument to an area of interest within a patient's body, such as a suspicious breast lesion, is disclosed. The device includes an imaging system (111, 112, 115) and a movable puncture instrument (120) which are isocentric with respect to a common isocenter. An initial calibration process can be performed without the patient to ensure that the puncture instrument (120) is aimed at the isocenter. This is accomplished by positioning the puncture instrument such that a tip thereof does not move when the puncture instrument and/or the imaging system change positions. The patient is then positioned so that the area of interest is located at the isocenter. Proper positioning is achieved when the area of interest does not move as viewed with the imaging equipment in two different positions. The invention allows for real time aiming of the puncture instrument and selection of a puncture instrument penetration path without the need for realignment, re-imaging of the patient, or repeating calculations.

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ISOCENTRIC PUNCTURE INSTRUMENT AIMING DEVICE

FIELD OF THE INVENTION

The present invention relates to medical instruments
5 used in diagnostic penetration of a body to collect a cell
or tissue sample and, more particularly, to such an
instrument incorporating an aiming device for aiming a
puncture instrument to an isocenter of the instrument
wherein a targeted object or area of interest is
10 positioned. The present invention is particularly useful
for sampling, excising or treating suspicious breast
lesions.

BACKGROUND OF THE INVENTION

15 The use of puncture instruments for collecting cell or
tissue samples, e.g., from suspicious breast lesions, in
diagnostic examinations is well known. Also well known is
the use of imaging systems such as fluoroscopic imaging
systems for locating an area of interest within a body and
20 for aiming and guiding a needle. Since such systems
ordinarily provide two dimensional images, two views are
normally required for three-dimensional orientation.

Based on the two views, the spatial coordinates of an
area of interest, e.g., a suspicious breast lesion, can be
25 determined for use in aiming the puncture instrument.
However, the penetration path of the puncture instrument
thus defined is often obstructed by equipment or body
parts, thereby necessitating selection of a different
penetration path. Conventionally, selection of a different

path entails re-imaging the area of interest and/or repeating calculations or alignment processes for aiming the puncture instrument. Such processes are time consuming, subject the patient to great stress and can
5 result in errors due to fatigue or patient movement.

SUMMARY OF THE INVENTION

The present invention discloses an apparatus for aiming a puncture instrument to an area of interest within
10 a patient's body and is particularly suitable for aiming a puncture instrument to an area of interest within the patient's breast. The present invention allows for real time, three-dimensional aiming of the puncture instrument to the area of interest, such as a suspicious breast
15 lesion, by obtaining appropriate initial alignment of the area of interest in two imaging views. In addition, the present invention thereafter allows for real time selecting of the puncture instrument penetration path by pivoting the puncture instrument about the area of interest and
20 observing the instrument on an imaging monitor or screen without the need for re-alignment, re-imaging or repeating calculations.

According to one aspect of the present invention, an apparatus for aiming a puncture instrument includes an
25 isocentric imaging system. The imaging system includes an imaging signal source such as an x-ray imaging source, magnetic resonance imaging source or the like and an imaging signal receiver such as an x-ray film tray or a

radiation sensitive device for substantially real time imaging. The imaging signal source and imaging signal receiver define an imaging signal axis which coincides with a center line of the radiation signal. The imaging system
5 is constructed such that there is a point on the imaging signal axis, the isocenter, which does not move in space when the isocentric imaging means is moved between a first imaging position and a second imaging position. For example, the imaging system can be moved between the first
10 and second imaging positions by rotating the imaging signal source and imaging signal receiver about an axis extending through the isocenter. Preferably, the imaging system is isocentric with respect to at least one such rotational axis.

15 According to another aspect of the present invention, the apparatus for aiming a puncture instrument supports a puncture instrument so that the puncture instrument is movable between at least a first position and a second position wherein the puncture instrument is aimed at the
20 isocenter in each of the first and second positions. It will thus be appreciated that the puncture instrument, like the imaging system, is isocentric and that the puncture instrument and imaging system share a common isocenter, i.e., there is a point on an aiming axis of the puncture
25 instrument, the isocenter, which does not move in space when the puncture instrument is moved between the first and second positions. In this regard, for example, the puncture instrument can be orbitally moved relative to the

isocenter so that the puncture instrument pivots thereabout within a single plane (defined by movement of the aiming axis) and/or the puncture instrument can be rotationally moved relative to the isocenter so that the puncture
5 instrument pivots thereabout in three-dimensions.

In one embodiment, the apparatus for aiming a puncture instrument comprises a table having an opening therein through which a patient's breast is permitted to pendulantly protrude. The imaging signal source, imaging
10 signal receiver and puncture instrument are disposed beneath the table and are movable around the patient's breast. At least one compression paddle is provided to immobilize the breast during the procedure. Preferably, a pair of paddles formed to substantially match a contour of
15 the patient's breast are provided. A biasing assembly, such as a spring or pneumatic device, is employed to urge the paddles together such that the patient's breast is compressingly engaged therebetween. At least one of the paddles has openings, of any shape, to permit passage of
20 the puncture instrument.

In operation, an initial calibration procedure is performed without the patient to ensure that the puncture instrument is aimed at the isocenter. This can be accomplished by simply viewing the alignment of the
25 instrument tip with the instrument in a number of different positions. It will be appreciated that, when the tip is located at the isocenter, the puncture instrument can be moved to different positions without movement of the tip.

The puncture instrument is then withdrawn or removed to allow the patient to be situated on the table. The table and/or the isocenter are then moved until the area of interest is located at the isocenter. An operator knows
5 that the area of interest is located at the isocenter when the area of interest does not move when the imaging equipment is moved from one position to another. Three-dimensional, real time aiming can thus be achieved if real time imaging equipment is employed. Additionally, a
10 penetration path to an area of interest within the patient's breast via an opening in a paddle can be rapidly selected by simply pivoting the puncture instrument. It will thus be appreciated that the apparatus is well suited for use in biopsy procedures to obtain a cell or tissue
15 sample from a suspicious breast lesion.

In another embodiment, the apparatus for aiming a puncture instrument includes a table for supporting the patient. An x-ray tube and an x-ray image receptor (for example, an x-ray film tray or a charge-coupled device for
20 providing substantially real-time imaging via a monitor) are disposed at opposite ends of a "C" shaped or "U" shaped arm, or are otherwise disposed in a movable, opposing relationship for imaging an area of interest within the patient's body. One of the x-ray tube and x-ray image
25 receptor is positioned above the table and the other is positioned below. The x-ray tube and x-ray image receptor are rotatable or otherwise movable such that the isocenter

located on the imaging signal axis remains fixed, i.e., the radiation axis is rotatable about the isocenter.

The puncture instrument is mounted on the apparatus such that the instrument is pivotally movable about the isocenter. That is, the instrument remains pointed at the isocenter as the instrument is moved from one position to another. Conveniently, the puncture instrument, x-ray tube and x-ray image receptor can be mounted on a common arm which is rotatable about the isocenter. Additionally, the puncture instrument is mounted such that it is rotatable about a second axis, which extends through the isocenter, and is movable on an arcuate rail assembly or the like for further pivotal movement about the isocenter. The puncture instrument can be a biopsy needle, a cannula for providing access to the area of interest for other medical instruments, a needle for delivering a medicament or other instruments depending on the particular application. The puncture instrument can be retained in a guide for manual insertion or in an automatic delivery system such as a biopsy gun. The apparatus operates in a manner substantially identical to that described above. The puncture instrument penetration path can be changed, for example, to avoid vital organs or ribs, by simply pivoting the puncture instrument.

25

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a pictorial view of an apparatus constructed in accordance with the present invention including C-arm fluoroscopic equipment;

5 Fig. 2 is a pictorial view of a further apparatus constructed in accordance with the present invention including U-arm fluoroscopic equipment;

Fig. 3 is an elevation view of the apparatus of Fig. 1;

10 Fig. 4 is a side view of a still further apparatus constructed in accordance with the present invention; and

Fig. 5 is a bottom view of the apparatus of Fig. 4 showing mammo compression paddles compressing a patient's breast, a targeted object overlying an isocenter of the
15 radiation axis and a puncturing needle aiming at the targeted object.

DETAILED DESCRIPTION

The present invention discloses an isocentric puncture
20 instrument aiming device. The device includes an imaging system and a movable puncture instrument which share a common isocenter. The present invention thus takes advantage of built-in isocentric device geometry to provide for real-time aiming and selection of a puncture instrument
25 penetration path without the need for realignment, re-imaging of the patient or repeating calculations. The invention will first be described with respect to embodiments generally applicable for use in connection with

various body regions. Thereafter, the invention will be described with respect to embodiments which are particularly adaptable for use in connection with the breast.

5 Referring to Fig. 3, the orbital aiming device comprises a C-arm 1 carrying an x-ray tube 2 with a collimator 3 having cross-hairs in the center of the beam and an image receptor 4. The C-arm is isocentric about two rotational axes with the isocenter at point O on the
10 radiation axis defined by the x-ray tube and the image receptor. The isocenter remains at the same point O in space when the radiation axis is rotated about the two rotational axes.

The orbital aiming device further comprises an
15 elongated member 5 having a biopsy gun 6 with a needle 7 movably mounted thereon so that the needle aims at the isocenter O; the biopsy gun with the needle is linearly displaceable to a manually adjusted stop 8 which controls the depth of the needle penetration. The elongated member
20 5 is mounted on an arcuate rail system 9 for a relative orbital movement therebetween and, hence, for pivotal movement of the needle tip about the isocenter O. The arcuate rail system 9 is shown to include two arcuate components coupled in a telescopic relationship for
25 providing an extended orbital travel of the elongated member 5 without compromising compactness of the device. The arcuate rail system 9 is rotatably attached to a rotational means 10 and rotatable about an axis R for

pivotal movement of the needle tip about the isocenter. The rotational means is attached, for example, to the C-arm or U-arm (Fig. 2) by a connecting means providing for prompt attachment and detachment of the device if desirable to gain more access to a patient. The connecting means provides for attachment such that the isocenter of the rotational puncture device overlies the isocenter of the fluoroscopic imaging system.

An initial calibration of the orbital aiming device is carried out without a patient by viewing the needle on the fluoroscopic screen to align it to the cross-hair in one view and to adjust the stop 8 in the second view so that the needle points to the cross-hairs.

Then, the patient is positioned on a movable table top 11 and the table top is moved in three directions so that the targeted object overlies the isocenter, that is, overlies the cross-hairs in at least two views. The needle tip is now pivoted for selecting a path of penetration, so that vital organs are avoided and the needle aims between ribs.

Referring to Figs. 4-5, the orbital aiming device for breast biopsy comprises mammo fluoro x-ray equipment including an x-ray tube 111 with a collimator 112 and an image receptor 115, which x-ray tube and image receptor define the radiation axis.

Cross-hairs indicating the center of the beam are placed either on the collimator or the image receptor to assist in the alignment.

A patient breast 101 is compressed between lens shaped compression paddles 102 translucent to the x-rays, which have holes 103 for inserting the biopsy needle 120.

The compression paddles are rotatable around the breast and displaceable relative to the breast, away from the breast by means of arms 105 and toward compressing the breast by action of springs 104.

An elongated arm 114 supporting diametrically the x-ray tube at one end and a fluoro image receptor at the other by means of the arm 113 slidably mounted thereon, is linearly displaceable along the x,y,z orthogonal coordinates and rotatable around the z-coordinate, wherein the z-coordinate passes through the isocenter.

The fluoro image receptor can be a tubular image intensifier or a fiber optics reducer with a TV camera having a vacuum tube or being solid state.

The orbital aiming device comprises a guide member 118 having a puncture instrument 120 movably mounted thereon so that the needle aims at the isocenter; the needle is linearly displaceable to a manually adjusted stop 119 which controls the depth of its penetration. The guide member 118 is affixed to an arcuate member 117, which member is mounted on a swivel arm 116 and adapted for a relative orbital movement therebetween and, hence, for pivotal movement of the needle tip about the isocenter. The swivel arm 116 is rotatably mounted on the elongated arm 114 and rotatable about the z axis for pivotal movement of the needle tip about the isocenter.

Again, an initial calibration of the orbital aiming device is carried out by viewing the alignment of the tip of the needle to the cross-hairs in a number of angulated positions of the needle and of the image receptor; the stop
5 119 is adjusted at that time.

To overlie the isocenter and the targeted object, the targeted object is aligned to the cross-hairs in at least two views by rotating and linearly displacing the arm 114. By swiveling the arm 116 and orbitally displacing the
10 arcuate member 117, a penetration path passing through either of the compression paddles is selected.

What is claimed is:

1. An apparatus for aiming a puncture instrument to an area of interest within a patient's breast, comprising:

immobilization means for immobilizing said patient's breast relative to a predetermined frame of reference;

5 isocentric imaging means, disposed in predetermined relation to and moveable relative to said predetermined frame of reference, for imaging said area of interest within said patient's breast including an imaging signal source and an imaging signal receiver, the imaging signal
10 source and imaging signal receiver defining an imaging signal axis wherein there is a point on the imaging signal axis, the isocenter, which point does not move in space when the isocentric imaging means is moved between a first imaging position and a second imaging position relative to
15 said predetermined frame of interest;

support means, disposed in predetermined relation to and movable relative to said predetermined frame of reference, for movably supporting said puncture instrument so that said instrument is movable between a first aiming
20 position and a second aiming position, wherein said puncture instrument is aimed at said isocenter in each of said first and second aiming positions; and

positioning means for providing relative movement between said area of interest within said patient's breast
25 and said isocenter so that said area of interest is located at said isocenter.

2. The apparatus of Claim 1, further comprising:
table means for supporting said patient including an
opening through which said patient's breast is permitted to
5 pendulantly protrude.

3. The apparatus of Claim 1, further comprising:
arm means for supporting said imaging signal source
and said imaging signal receiver for relative movement
therebetween, wherein a distance between said imaging
5 signal source and said imaging signal receiver can be
changed by moving at least one of said imaging signal
source and said imaging signal receiver.

4. The apparatus of Claim 1, wherein said
immobilization means comprises a paddle for compressing
said patient's breast, the paddle having at least one
opening therein for allowing passage of said puncture
5 instrument therethrough.

5. The apparatus of Claim 1, wherein said
immobilization means comprises:
first and second paddles disposed in an opposing
relationship and defining a breast receiving space
5 therebetween; and

biasing means for urging said first and second paddles
together so as to compressingly engage said patient's
breast.

6. The apparatus of Claim 1, wherein said
immobilization means comprises at least one paddle formed
to substantially match a contour of said patient's breast.

7. The apparatus of Claim 1, wherein said positioning means is operative for orbitally moving said puncture instrument across a range of positions relative to said isocenter, the range of positions defining a
5 substantially planar region.

8. The apparatus of Claim 1, wherein said positioning means is operative for rotationally moving said puncture instrument across a range of positions relative to said isocenter, the range of positions defining a three
5 dimensional region.

9. An apparatus for aiming a puncture instrument to an area of interest within a patient's body, comprising:

isocentric imaging means for imaging said area of interest including an imaging signal source and an imaging signal receiver, the imaging signal source and imaging signal receiver defining an imaging signal axis wherein there is a point on the imaging signal axis, the isocenter, which point does not move in space when the isocentric imaging means is moved between a first imaging position and a second imaging position;

support means, interconnected to said isocentric imaging means, for movably supporting said puncture instrument so that said puncture instrument is moveable between a first aiming position and a second aiming position, wherein said puncture instrument is aimed at said isocenter in each of said first and second aiming positions; and

positioning means for providing relative movement between said area of interest and said isocenter so that said area of interest is located at said isocenter.

10. The apparatus of Claim 9, wherein said apparatus further comprises table means for supporting said patient, and said positioning means comprises means for moving the table means.

11. The apparatus of Claim 9, wherein said apparatus further comprises arm means for supporting said imaging signal source, imaging signal receiver and said support

means, and said positioning means comprises means for
5 moving the arm means.

12. The apparatus of Claim 9, further comprising:
table means for supporting said patient; and
arm means for supporting said imaging signal source
and said imaging signal receiver so that said imaging
5 signal source and said imaging signal receiver are disposed
on the same side of said table means.

13. The apparatus of Claim 9, further comprising:
table means for supporting said patient including an
opening through which a breast of said patient is permitted
to pendulantly protrude; and
5 arm means for supporting said imaging signal source
and said imaging signal receiver relative to said pendant
breast so as to permit imaging of said pendant breast.

14. The apparatus of Claim 9, further comprising:
arm means for supporting said imaging signal source
and said imaging signal receiver for relative movement
therebetween, wherein a distance between said imaging
5 signal source and said imaging signal receiver can be
changed by moving at least one of said imaging signal
source and said imaging signal receiver.

15. The apparatus of Claim 9, wherein said area of
interest is within said patient's breast and said apparatus
further comprises immobilization means for immobilizing
said patient's breast.

16. The apparatus of Claim 15, wherein said
immobilization means comprises a paddle for compressing

said patient's breast, the paddle having at least one opening therein for allowing passage of said puncture instrument therethrough.

17. The apparatus of Claim 15, wherein said immobilization means comprises:

first and second paddles disposed in an opposing relationship and defining a breast receiving space therebetween; and

biasing means for urging said first and second paddles together so as to compressingly engage said patient's breast.

18. The apparatus of Claim 15, wherein said immobilization means comprises at least one paddle formed to substantially match a contour of said patient's breast.

19. The apparatus of Claim 9, wherein said isocentric imaging system comprises a monitor associated with said imaging signal receiver to provide substantially real time imaging.

20. The apparatus of Claim 9, wherein said positioning means is operative for orbitally moving said puncture instrument across a range of positions relative to said isocenter, the range of positions defining a substantially planar region.

21. The apparatus of Claim 9, wherein said positioning means is operative for rotationally moving said puncture instrument across a range of positions relative to said isocenter, the range of positions defining a three dimensional region.

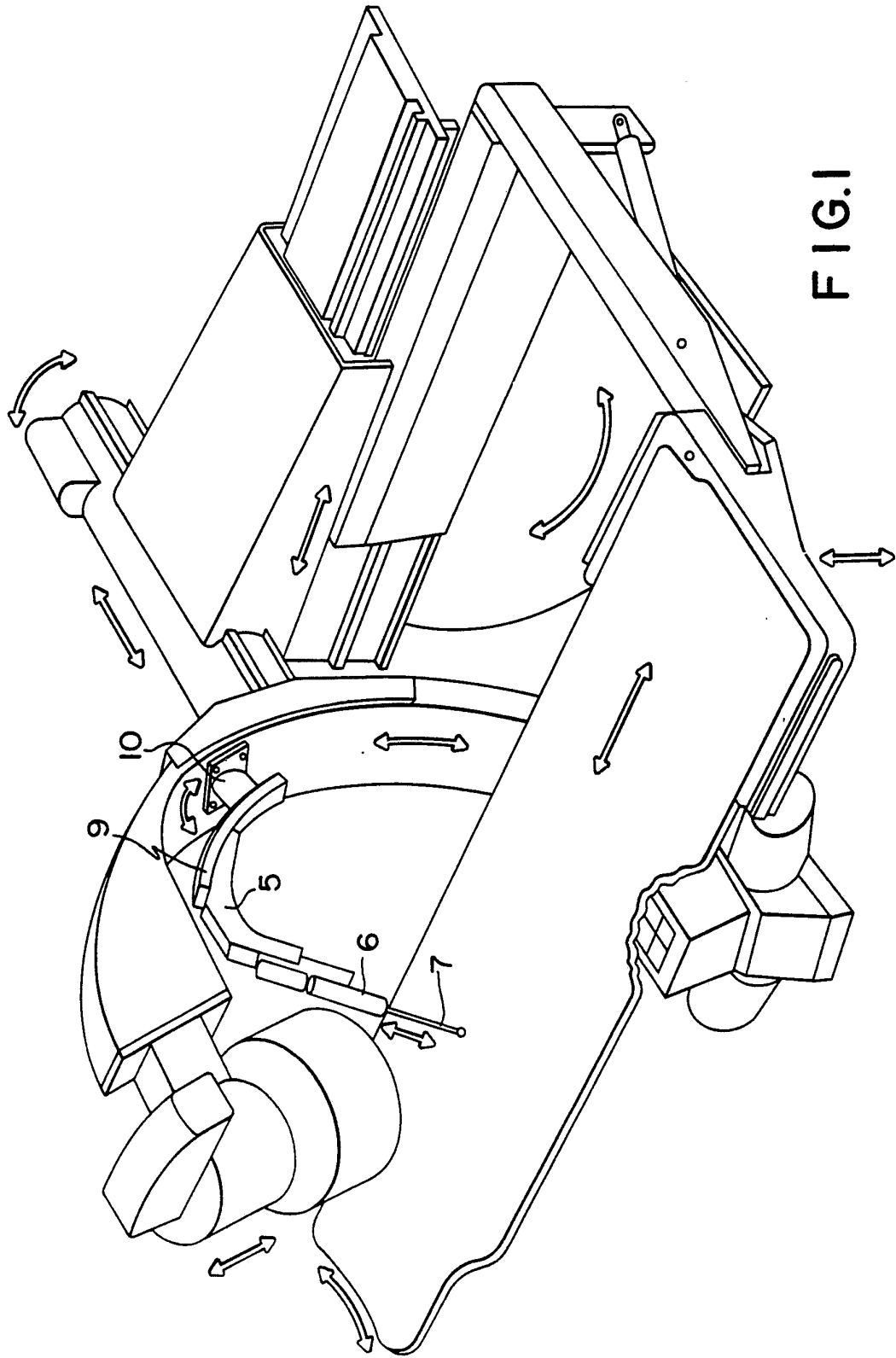


FIG.1

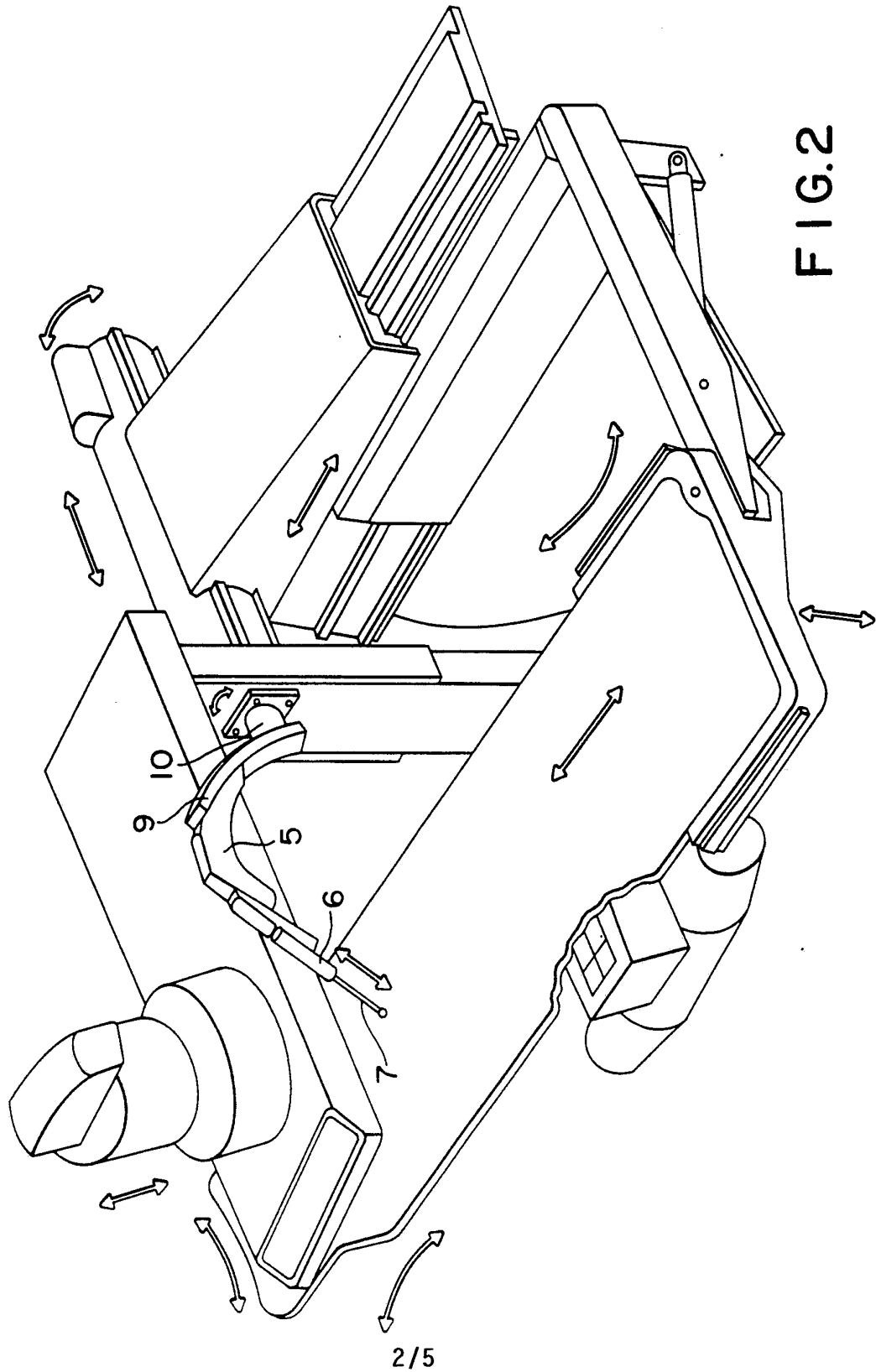


FIG. 2

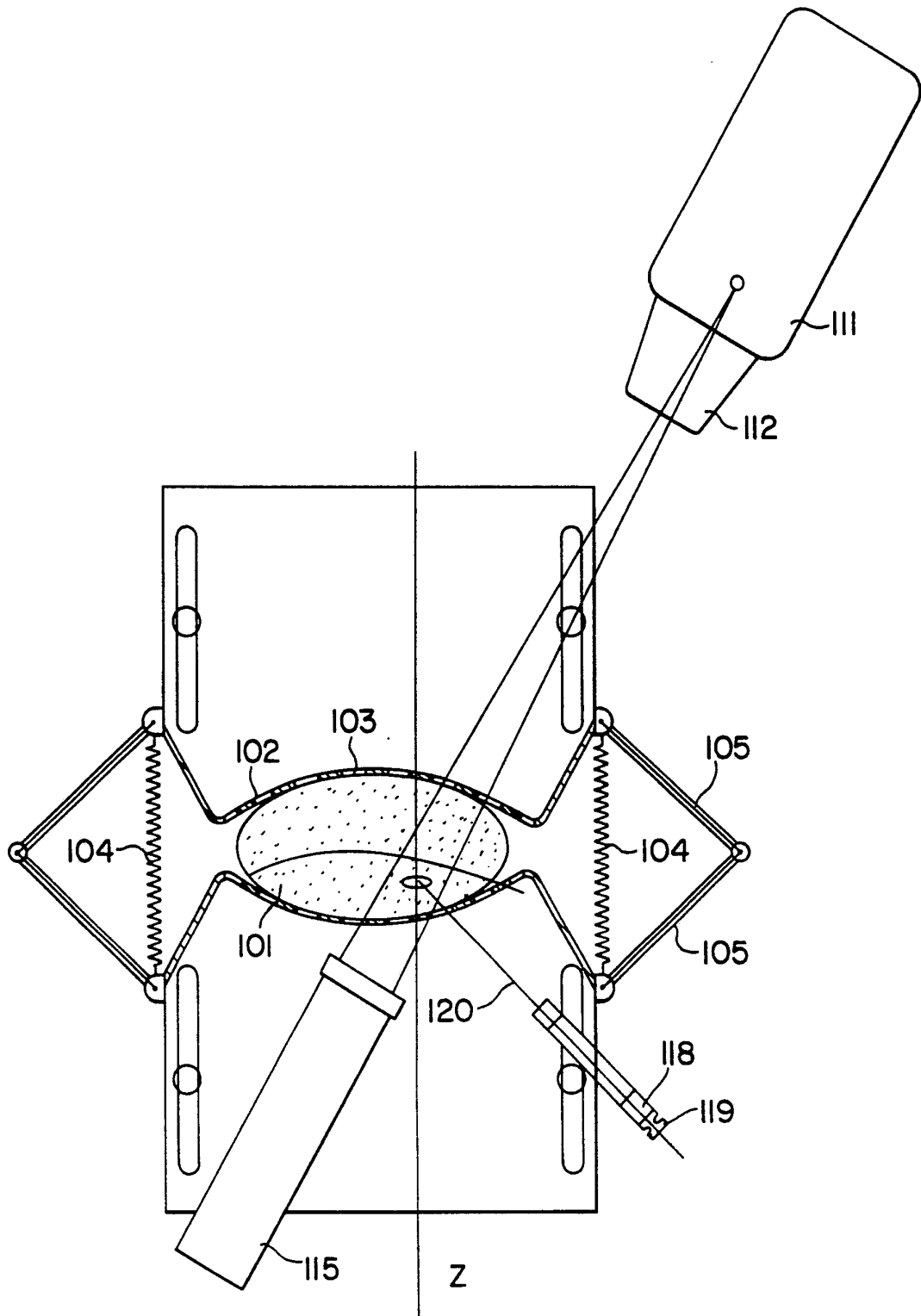


FIG. 4

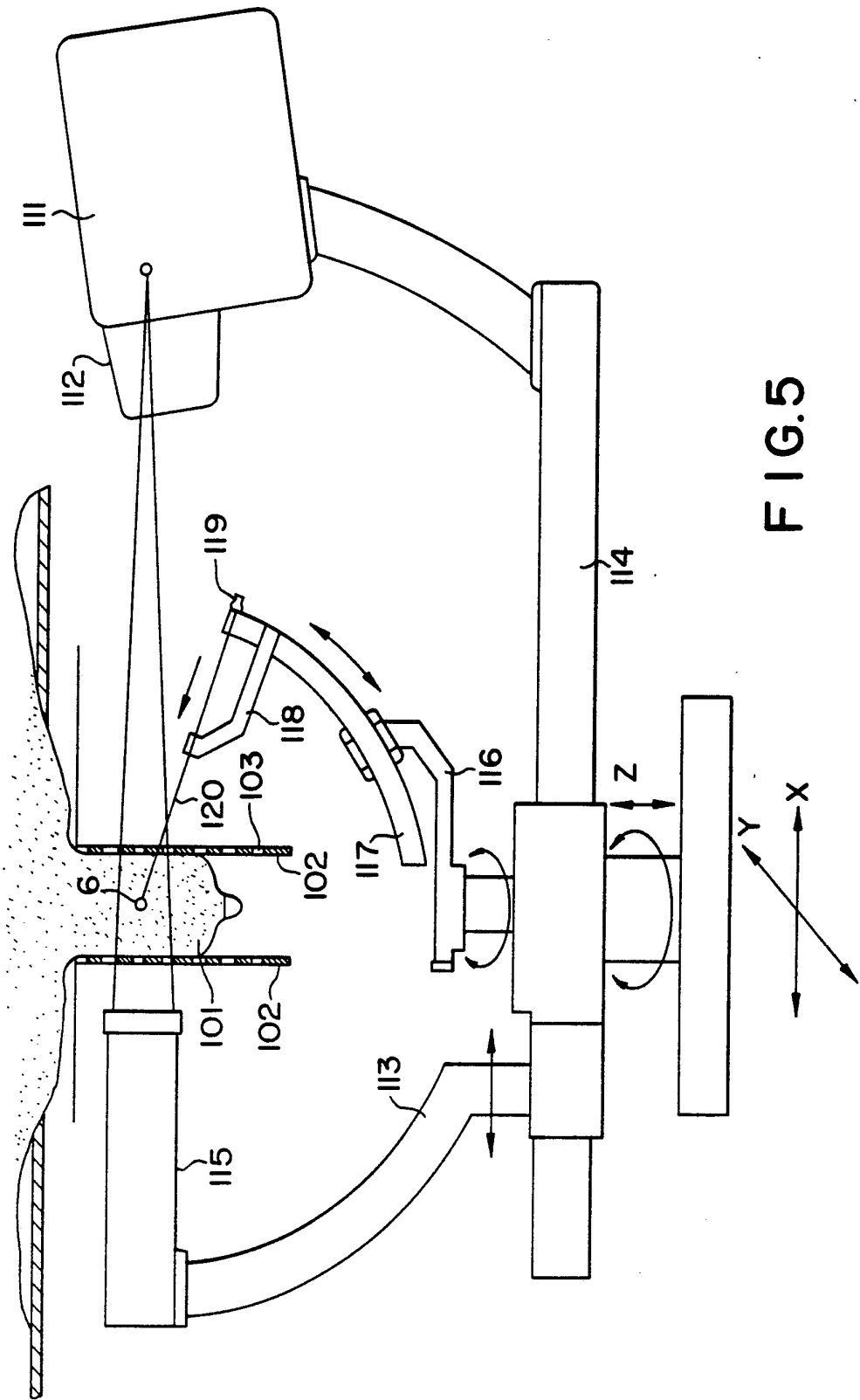


FIG.5

INTERNATIONAL SEARCH REPORT

PCT/US93/02308

A. CLASSIFICATION OF SUBJECT MATTERIPC(5) :A61B 6/12; A61B 10/00; A61B 19/10
US CL :128/653.1; 378/37

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)

U.S. : 128/653.1; 378/37 128/653.2,653.5,749,915; 606/130; 378/68-69,195-198,208-209

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
<u>X</u> P Y	US,A, 5,129,911 (Siczek et al.) 14 July 1992 See the entire document.	9-12,14 <u>19-21</u> 1-8,13,15-18
<u>X</u> Y	US,A, 4,821,727 (Levene et al.) 18 April 1989 See the entire document.	1,3-5,9,11 <u>14-17 and 19</u> 2,6,18
Y	US,A, 5,078,142 (Siczek et al.) 07 January 1992 See the entire document.	1-5,13,15-17
Y	US,A, 4,943,986 (Barbarisi) 24 July 1990 See the entire document.	6,18
A	US,A, 5,056,523 (Hotchkiss et al.) 15 October 1991 See the entire document.	1-21

 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 22 JUNE 1993	Date of mailing of the international search report 23 JUL 1993
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INTERNATIONAL SEARCH REPORT

International application No.
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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A, 4,750,487 (Zanetti) 14 June 1988 See the entire document.	1-21
A	US,A, 4,727,565 (Ericson) 23 February 1988 See the entire document.	1-21
A	US,A, 4,722,336 (Kim et al.) 02 February 1988 See the entire document.	1-21
A	GB,A, 2,239,605 (Koorosh) 10 July 1991 See the entire document.	1-21
A	EP,A, 0,390,653 (Romeas et al.) 03 October 1990 See the entire document.	1-21