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(54) **Positioning devices for patients**

(57) It has been suggested that it is very important to position patients reproducibly at different stages of radiotherapy treatment planning and treatment, or similar procedures. Devices have been described for positioning a patient's upper and lower thorax. This invention provides reproducible positioning for a female patient's breasts, for example in planning treatment of and treating breast tumours (4). The patient (1) is placed prone, using for example an upper thorax device (14). A support device (8) is placed central to and beneath her breasts to partially displace them outwards. The device may be triangular in section with one apex 9 contacting the chest wall at the sternum. Restraining straps (11) may be provided to hold the breasts against the support device. Means (15) may be provided to take a healthy breast (at 16) from the path (13) of radiation through the tumour (4).

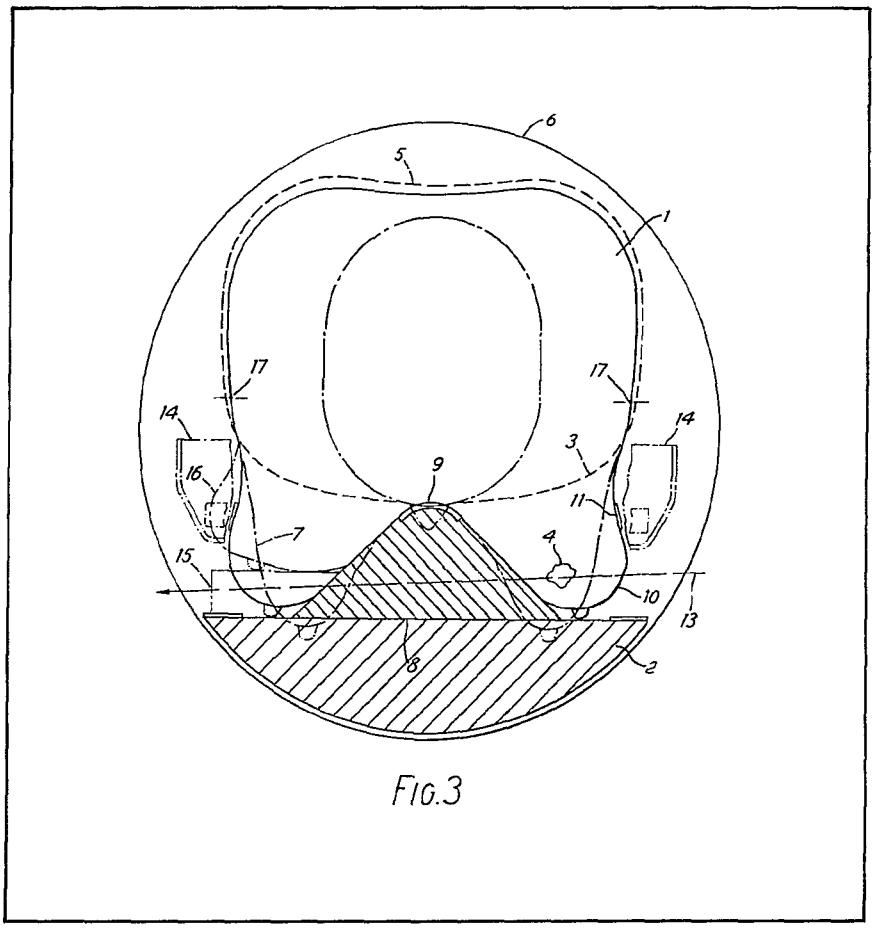

FIG.3

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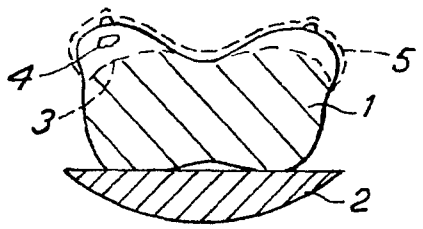

FIG. 1

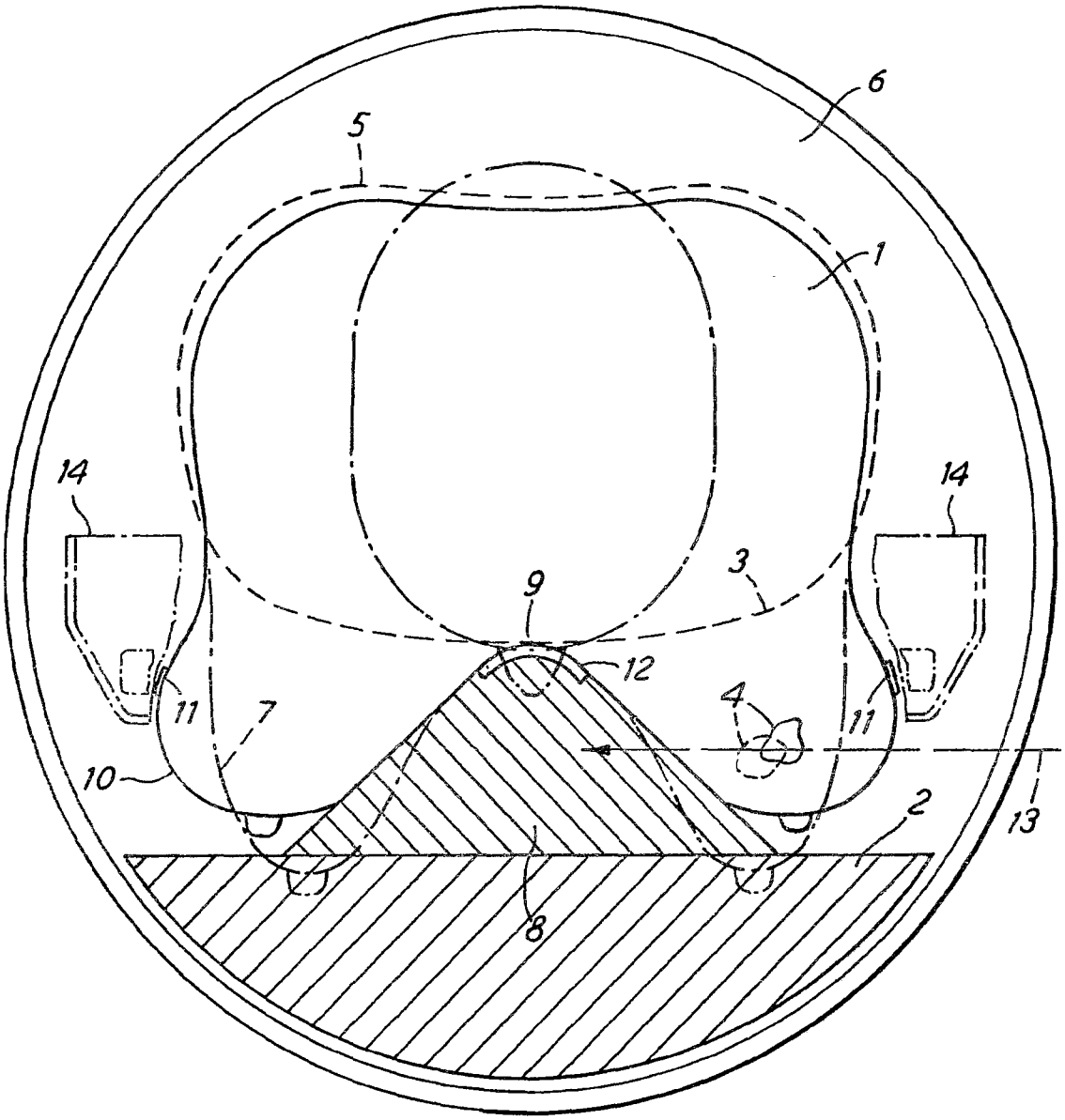

FIG. 2

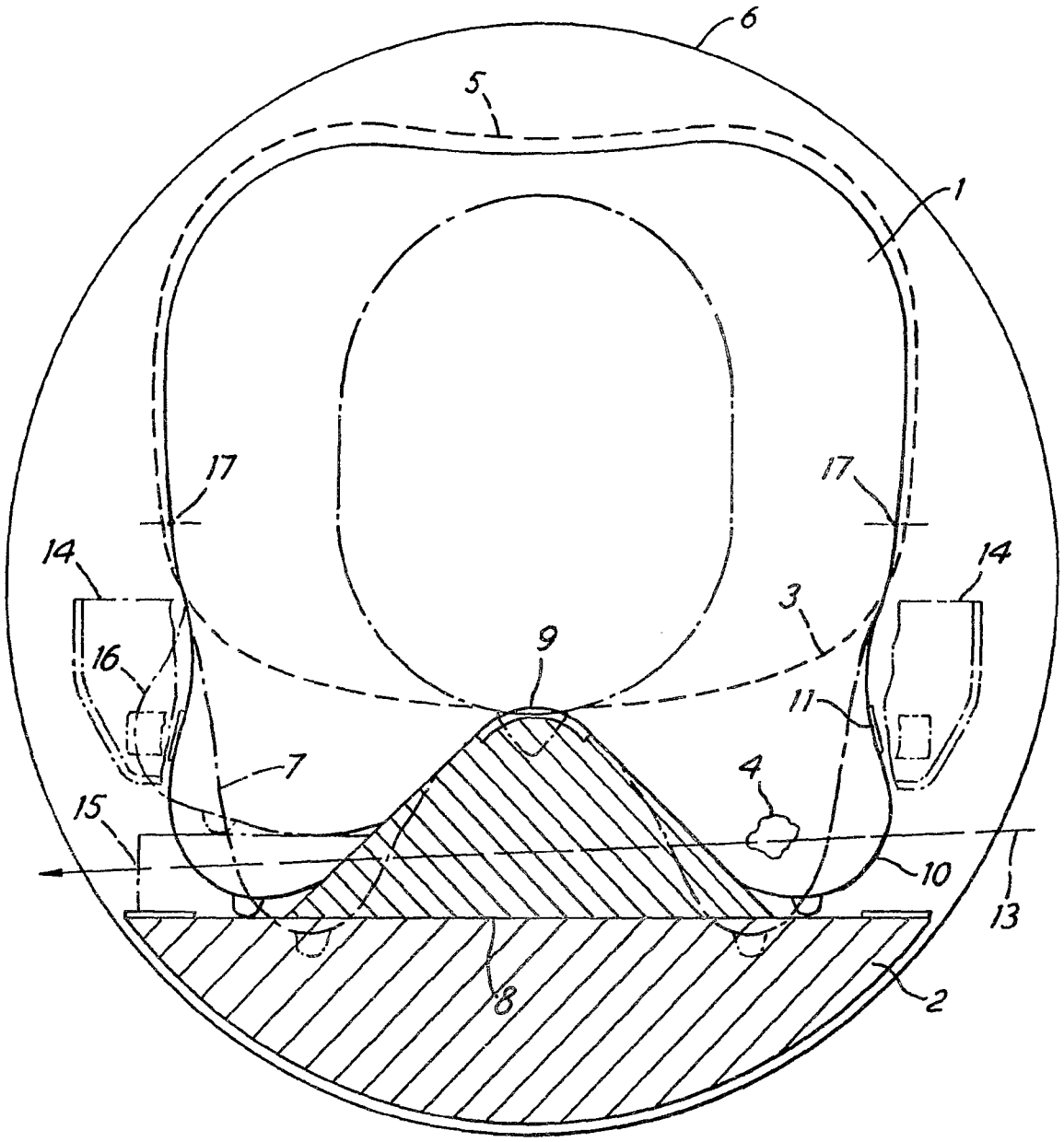

FIG.3

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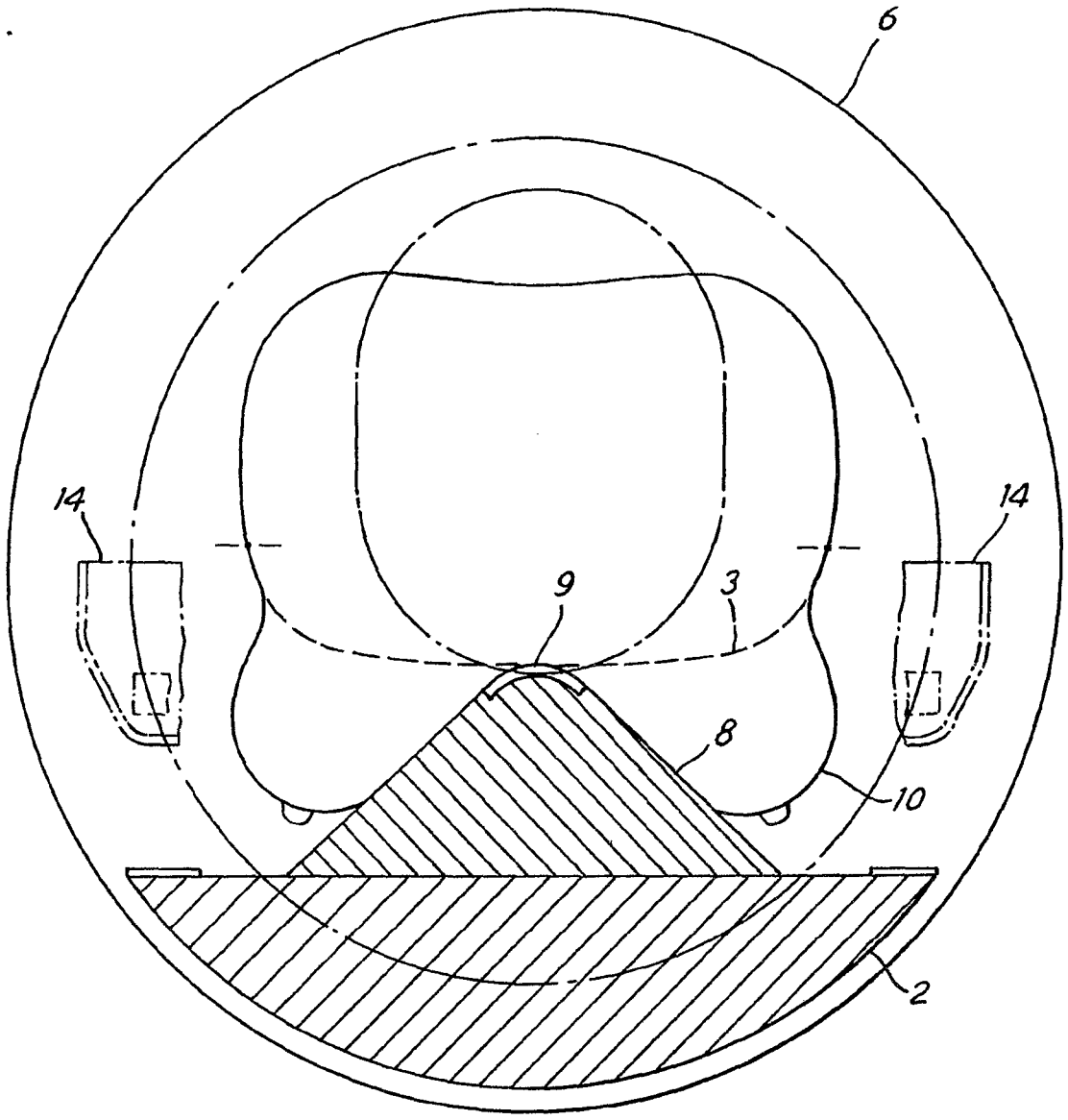
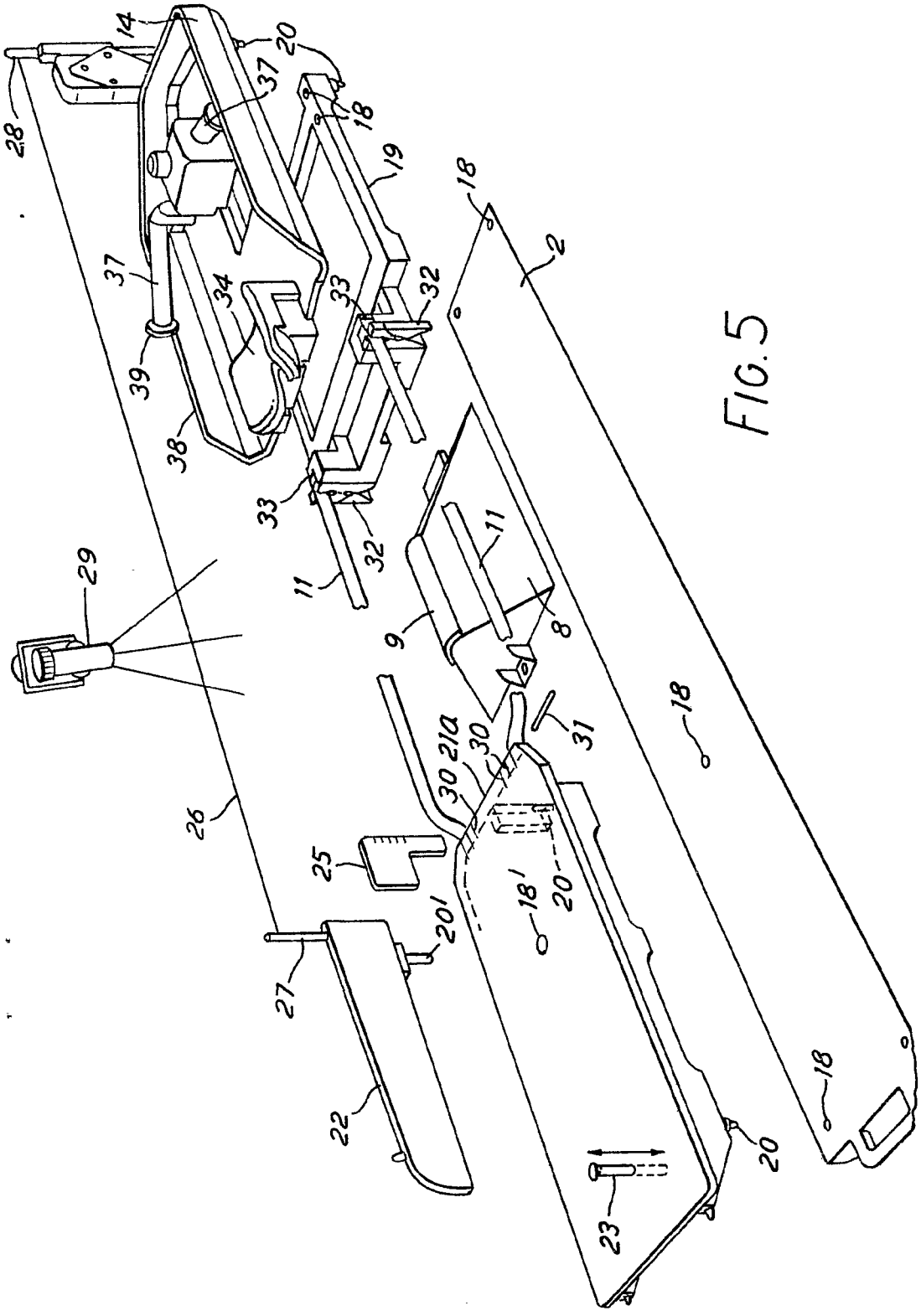


FIG. 4


14
20
28
37
18
19
18
2
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34
33
32
39
38
33
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11
11
29
9
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31
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21a
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26
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18'
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201
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23

FIG. 5

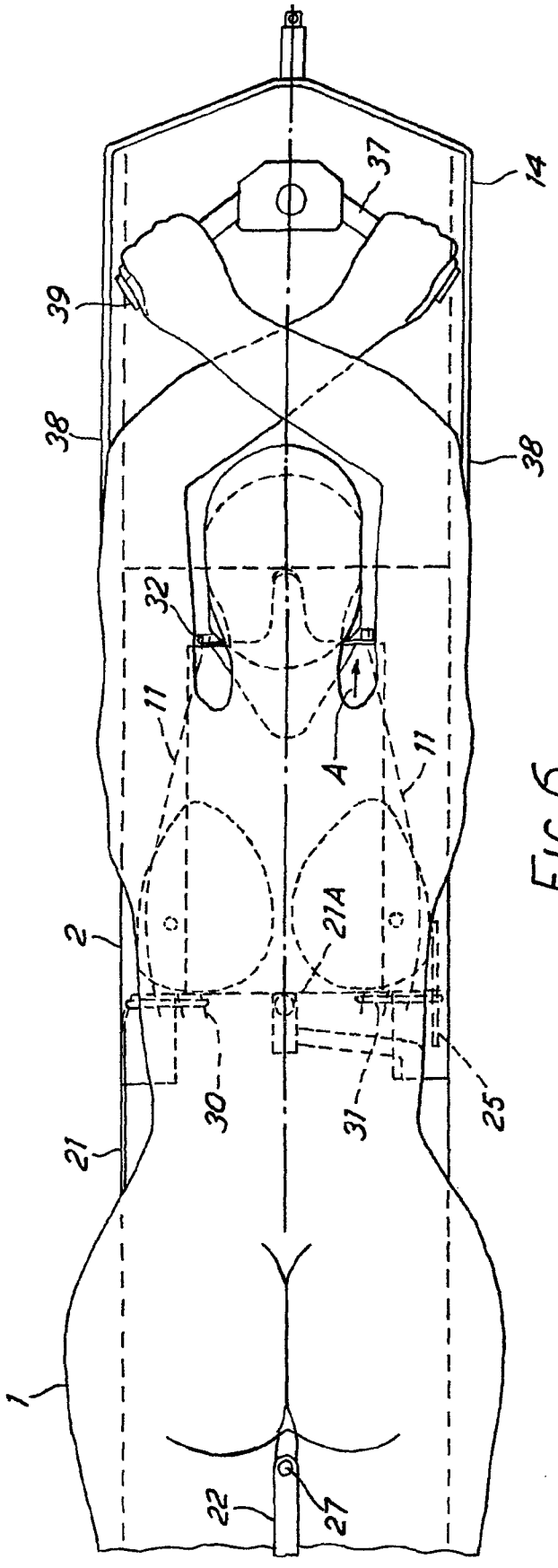
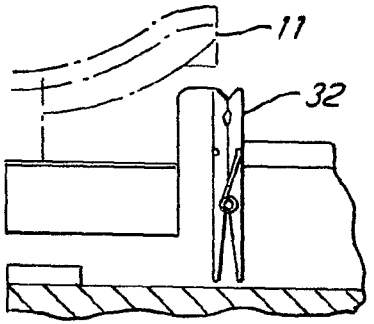


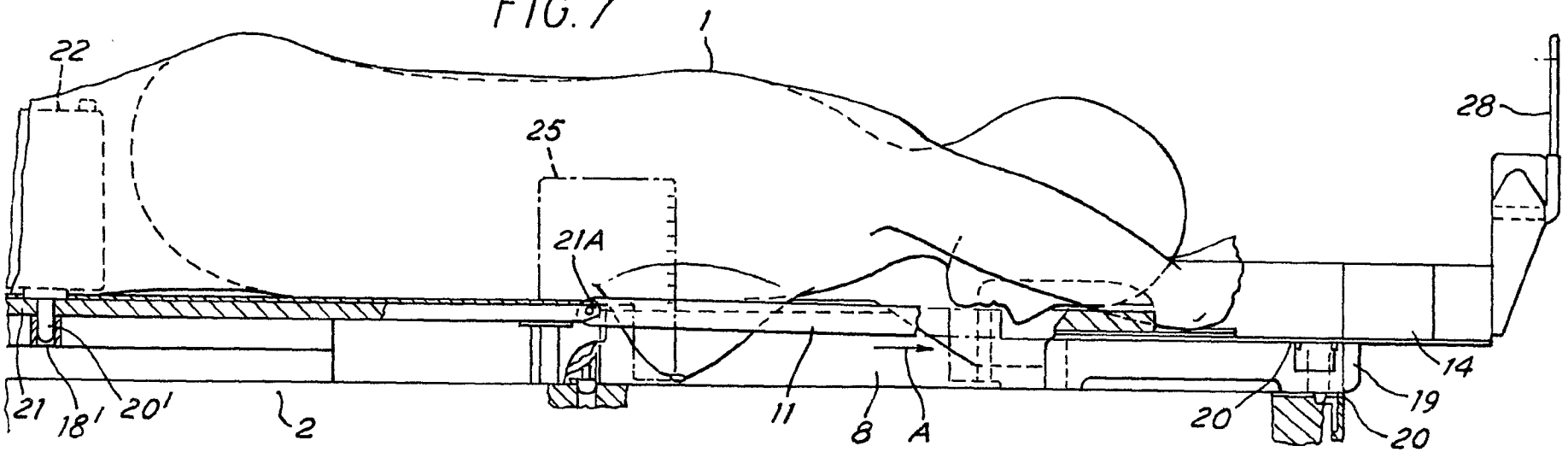
FIG.6

FIG. 7a



VIEW IN DIRECTION OF ARROW 'A'

FIG. 7



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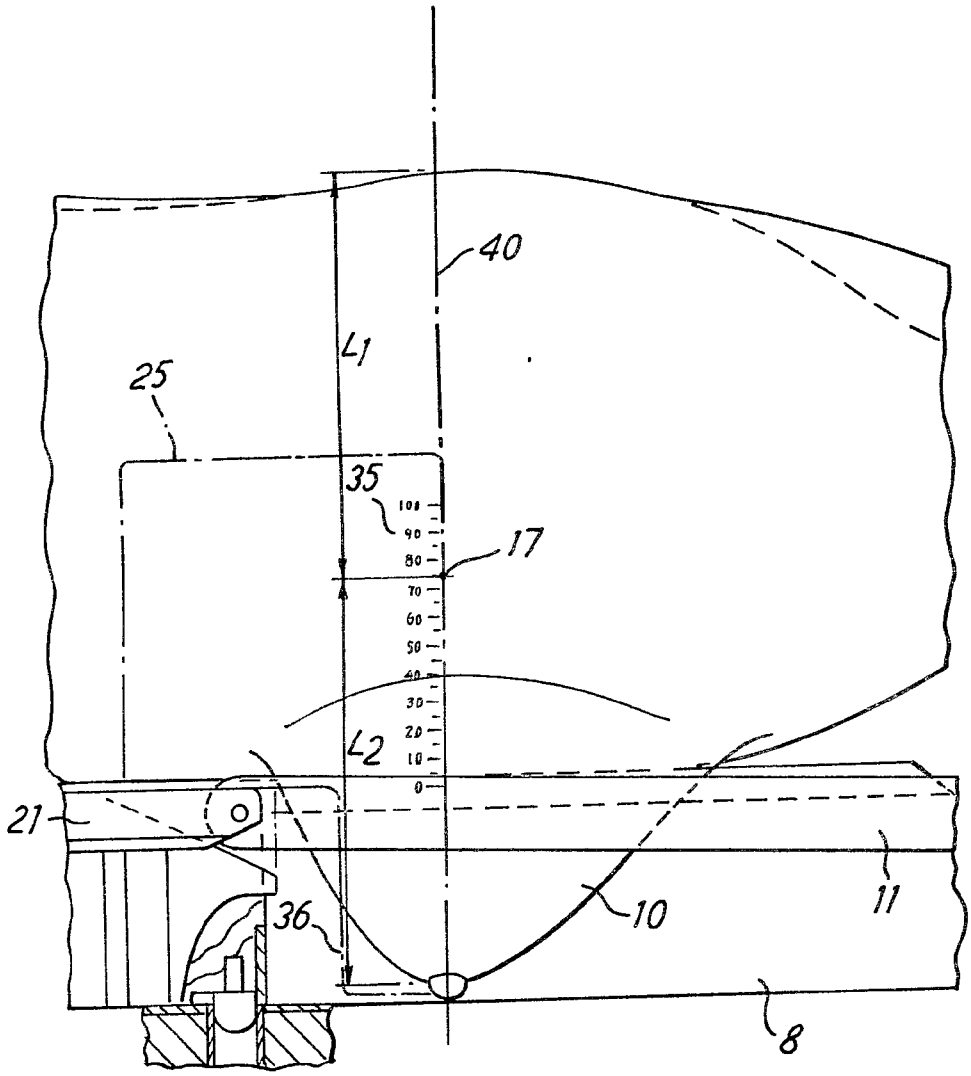

FIG. 8

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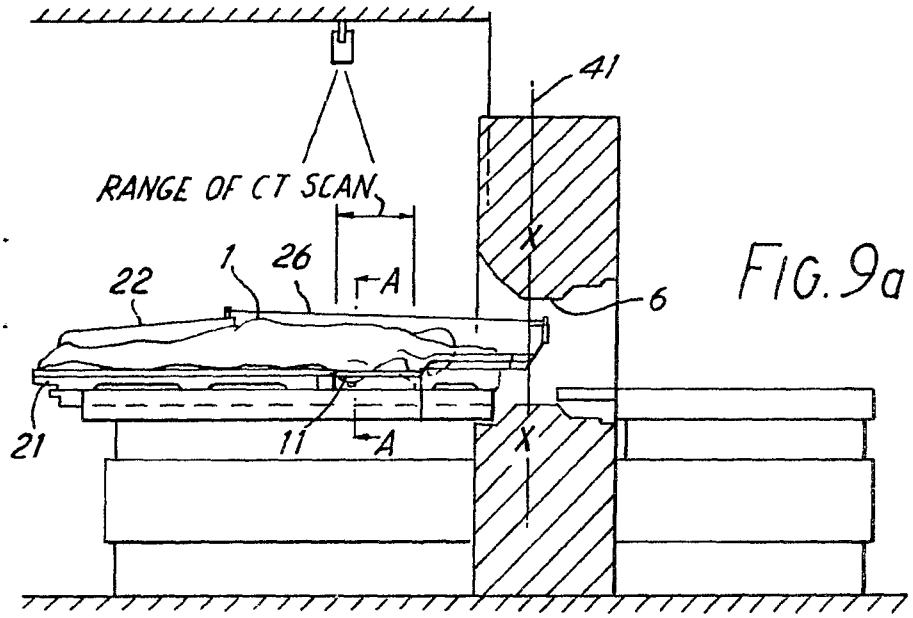

FIG. 9a

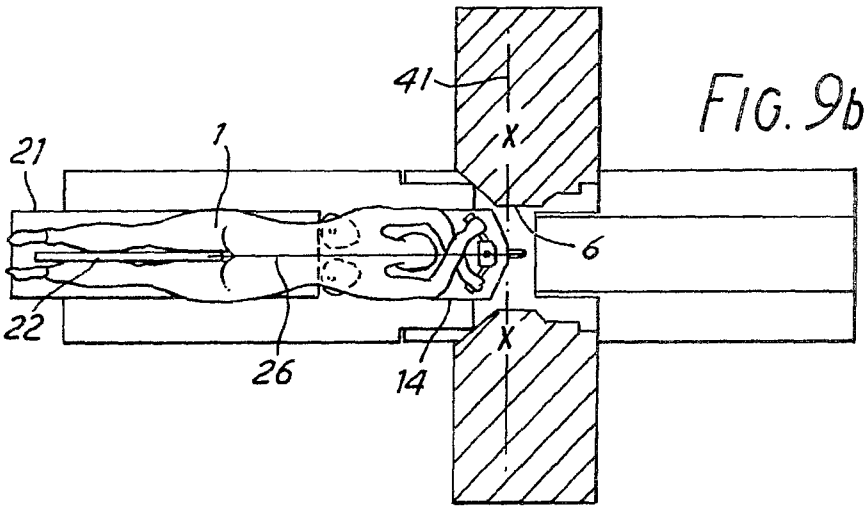

FIG. 9b

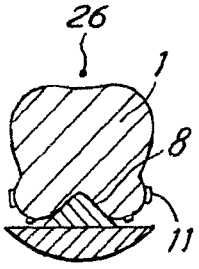

FIG. 9c

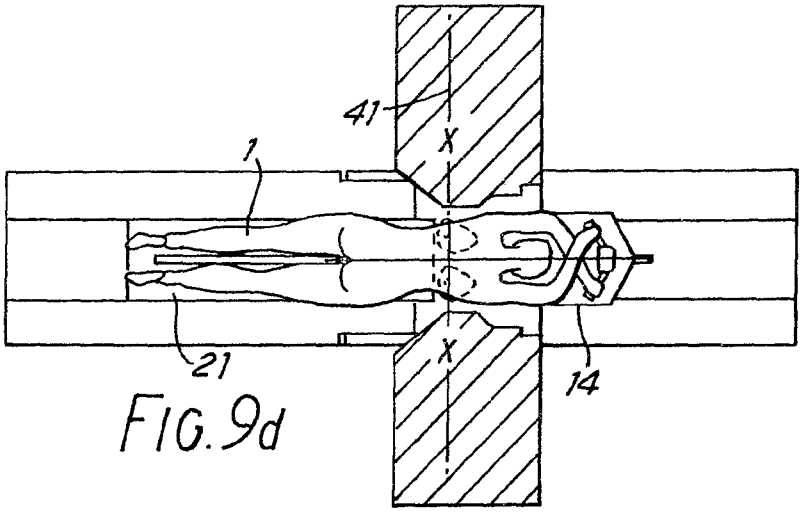

FIG. 9d

SPECIFICATION

Improvements in or relating to positioning devices

The present invention relates to devices for positioning a female human patient undergoing medical treatment, to maintain her breasts in a reproducible position. The invention is particularly, though not exclusively, related to devices for reproducibly positioning the breasts in different stages of the radiotherapy treatment planning (RTP) procedure, including the treatment itself.

One well known method of treating malignant tumours is by irradiation by beams of x-rays, electrons or other particles, care being taken to reduce irradiation of surrounding healthy tissue to a minimum. This method of radiotherapy generally involves irradiating the tumour tissue many times over an extended period and from many different directions so as to ensure a significantly greater dose in the tumour than in surrounding tissue. It will be apparent that to be successful such treatment should be carefully controlled and meticulously planned and it is the practice to draw up detailed treatment plans before irradiation is begun.

Radiotherapy treatment planning takes into account information of different kinds including diagnostic radiography. Conventional shadowgraph x-ray pictures can be used to indicate the position of a tumour, although they are not ideal. Recently there has been made available a diagnostic x-ray technique invented by G. N. Hounsfield (British Patent No. 1283915) and known as computerised tomography (CT). This technique is embodied in equipment such as the CT7020 and CT7070 scanners made by EMI Medical and provides detailed cross-sectional x-ray pictures which are not obscured by shadows of adjacent features.

Such pictures are extremely valuable for radiotherapy planning and have been used to determine the exact position and extent of tumours prior to therapy.

It is even possible to use the pictures to plan the treatment automatically, determining which paths the beams should follow and what their intensities should be. This facility is provided by the EMIPLAN (Registered Trade Mark) equipment made by EMI-Medical.

It has recently been realised (as disclosed in our co-pending British Patent Application No. 7938326) that for maximum success of radiotherapy it is essential for the patient's body to be as closely as possible in a corresponding position at different stages of the planning and treatment (x-rays, CT, therapy etc.) so that the tumour is in the same position relative to body landmarks used to align the respective equipment.

Clearly if the treatment beams are planned relative to a CT picture the tumour and surrounding tissue must be in the same relative position when the treatment is carried out.

To that end the said Patent Application No. 7938326 discloses and claims equipment which in different embodiments is designed to reproducibly position the patient's upper thorax or lower thorax and also to further aid reproducibility by positioning the lega and torso.

It is generally known that one form of cancer which is a significant problem for the female population is cancer of the breast. In very many cases where a malignant tumour has been found in a woman's breast the preferred treatment is mastectomy, usually accompanied by irradiation to ensure that no tumours remain. This is clearly a very drastic procedure both in terms of medical considerations and in terms of the very considerable psychological shock to a woman losing a breast.

The almost routine use of this operation has recently given rise to growing concern in the medical profession that the treatment is too drastic for many smaller tumours. It has been suggested that in many cases radiotherapy may successfully be employed with mastectomy being resorted to only in more serious cases.

It is therefore an object of this invention to provide an arrangement for reproducibly positioning the breast for medical procedures in particular radiotherapy treatment planning and treatment.

According to the invention there is provided apparatus for positioning a female patient to place her breasts in a reproducible position the apparatus including means for supporting the patient in a substantially prone position, with an aperture through which the breasts are suspended and a support device placed beneath and central to the breasts so that they are partially supported and partially displaced outwards of said patient.

The said support device is preferably substantially triangular in cross-section.

The apparatus is particularly suitable for reproducible positioning of a patient's breasts for radiotherapy treatment planning.

In order that the invention may be clearly understood and readily carried into effect it will now be described by way of example with reference to the accompanying drawings of which,

Figure 1 shows in cross section a supine female patient with unsupported breasts,

Figure 2 shows in cross section a prone average size female patient with breast shown both unsupported and supported by the device of this invention,

Figure 3 shows the device of Figure 2 supporting a female patient of larger than average size,

Figure 4 shows the device of this invention supporting a female patient of smaller than average size,

Figure 5 shows an exploded perspective view of an example of the positioning apparatus of this invention,

Figure 6 is a plan view of the apparatus of Figure 5 with a patient in place,

Figure 7 is a side elevation of the apparatus of Figure 5 with a patient in place,

Figure 7a is a view of arrow A in Figures 6 and 7,

Figure 8 is an enlarged detail of Figure 7 and

Figure 9 shows views of a patient positioned with the apparatus of Figure 5 for a CT scanner.

As for any radiotherapy treatment, for irradiation of a woman's breasts it is desirable to place her body in a reproducible position for each stage of the planning and treatment. For this purpose the upper thorax positioning device and the leg positioning attachment in combination with a spot light directed at the patient, as described in the said Patent Application No. 7938326, are particularly suitable. However it will be apparent that positioning the breasts is a more difficult problem since they comprise soft and mobile tissue outside the rib cage and therefore not restrained by bone structure. Nevertheless one possible procedure is to place the patient's thorax reproducibly and to expect that the breasts will fall in the same position each time. The most apparently comfortable position for the patient is supine and Figure 1 shows in cross section a supine patient 1 on a flat radiotherapy platter 2. The rib cage is indicated at 3 and a breast tumour at 4.

As can be seen the breasts in this position fall outward and retract to the chest wall. This would be especially marked for less firm breasts. As a result the tumour 4 is brought closer to the chest wall reducing the available treatment beam paths which do not pass through the patient's torso. Furthermore, since the patient's back is the fixed surface two other problems arise. First the breasts and therefore the tumour, being above the chest wall, are subject to the maximum change of position on breathing, as may be seen from the expanded chest profile shown in broken line at 5 in Figure 1. Second the moment of the tumour from the mounting face is large and errors in positioning will be amplified.

It has been known to position a patient prone for breast examination. In one specialised CT apparatus for examining the breasts the patient is placed prone with the breasts suspended freely in a water bath. Examination is then by x-ray beams in a horizontal plane, i.e. parallel to the chest wall. (See Gisvold et. al., Am J. Rad. *133,* 1143-1149, 1979). This equipment is of course intended purely for examination and unless therapy treatment is envisaged the problem of repeatability does not arise.

Figure 2 shows a view similar to Figure 1 of a prone patient placed in the vertical aperture 6 of a typical CT scanner. This patient is a 50 percentile U.S. female, i.e. the average of the US population.

Leaving aside the practical problems of attaining the required position, the broken line 7 shows the position of the patients breasts if they are allowed to hang unsupported. It will be apparent that this position provides the maximum separation between tumour 4 and the chest wall thus allowing irradiation beam paths to be well clear of the chest. Further, if the patient can be supported with the chest wall in a fixed position the breasts are not subject to significant motion in breathing. This position is still not ideal, however. If allowed to hang unsupported the breasts may take the same position on each occasion but that very much depends on the chest wall position being totally invariant and it is also very difficult to place them relative to fixed references. This problem may be eased by placing the breasts in moulded shells such as are often used for the head. However assembly of the shells and insertion of the breasts is not straightforward and it should be noted that the nipples should not be enclosed as they vary in size under certain conditions. Another, although less significant, disadvantage is that in this position the distance between the patient's back and nipples is a maximum, increasing clearance problems particularly in CT scanners with smaller apertures.

It is proposed in this arrangement to place on the platter 2 a support 8 of triangular cross-section placed symmetrically of the breasts with one apex 9 in contact with the chest wall at the sternum. This separates and partly supports the breasts to take the position shown in solid line at 10. The support 8 retains the advantages of the prone position, in fact providing the required firm positioning for the chest wall and including shallow breathing. It provides a positive centering of the patient relative to the platter 2 and, if made of a suitable material, has a bolus effect improving the dynamic range of beam paths through the breasts for CT examination (that is it fills the otherwise unavoidable air space between the breasts). Reproducible positioning and minimum breathing motion are further aided by the use of breast motion control straps 11 which pass longitudinally of the patients body to hold the breasts firmly against support 8. In this example support 8 is made of expanded polystyrene and has inset a small 7mm thick foam pad 12 for maximum comfort at the region of contact with the sternum.

It will be apparent that the support 8 needs to be of identical size for each planning and treatment stage for one patient, although it may be of different size for other patients. It need not, however, be of the same material for each stage. Thus for the radiotherapy stage the support 8 could be made of or include lead to attenuate treatment beams following paths such as 13 and to prevent unnecessary irradiation of the healthy breast.

Also shown in Figure 2 are the extremes of the position of the upper thorax device 14 supporting the patients' head and shoulders. As can be seen this is sufficiently higher than the platter 2 to allow adequate clearance for the breasts.

Figure 3 shows a 97.5 percentile U.S. female; considerably larger than average. It can be seen that the platter and support used for the 50 percentile is still suitable for this larger woman. Also shown is an alternative arrangement for protecting the healthy breast from unnecessary irradiation, namely a polystyrene block 15 moving that breast to take the raised position 16.

Marks 17 on the patients sides are tattoo marks for aiding positioning and will be further described hereinafter.

For comparison Figure 4 shows a 2.5 percentile U.S. female; smaller than average.

In Figure 5 there is shown an exploded perspective view of the complete arrangement used to position the patient 1 for radiotherapy treatment planning. The major part of the arrangement is also shown in plan and side elevation, in Figures 6 and 7 respectively, assembled with the patient placed on it and reference may be made to those Figures in the fol-

lowing description.

Referring to Figure 5 there is shown at 2 the basic radiotherapy platter 2 seen in section in the preceding Figures. Unlike the platter which is commonly used for radiotherapy, the platter 2 is provided with holes 18 to take other equipment by dowel fixings. Other fixings may, of course, be used and may be necesary for use with a linear accelerator and its simulator. Provision is made to plug holes 18 with material of suitable x-ray absorption.

Fitted at one end of platter 2 is the upper thorax and shoulder alignment device 14. This is essentially as described in the said application No. 7938326 except that there is inserted an intermediate frame 19 whose primary purpose is to provide additional height for the patient's head above the platter and thereby to provide clearance thereabove for her breasts. The alignment device and intermediate frame are both in this example placed by dowel fixing 20.

At the opposite end of the platter 2 there is a torso and leg support platform 21 to provide the same additional height for the torso and legs as was provided by frame 19 for the head and shoulders. This is covered with a 7mm thick rubber cushion such as is generally allowed on radiotherapy platters for patient comfort. Platform 21 is provided also with a torso and legs alignment attachment 22, which is also essentially as described in said application No. 7938326. This is mounted by a dowel fixing 20' and a pillar 23, which is retractable to allow the patient to be placed without obstruction. Also fitted to platform 21, in detachable manner in a suitable socket, is a breast alignment gauge 25 which will be described hereinafter. There should preferably be a socket at each side for this gauge although two gauges can be used.

As described in the said application No. 7938326 an elasticated centre line cord 26 may be stretched between posts 27 and 28 on the torso and legs alignment attachment 22 and upper thorax alignment device 14 respectively. This aids lateral alignment of the patient, particularly if assisted by a ceiling mounted spotlight as illustrated at 29.

Between frame 19 and plaform 21 there is mounted on the platter 2 the breast support wedge 8. At either side of wedge 8 there are the breast motion control straps 11 which pass outside the patient's breast to reduce involuntary motion of this relatively mobile tissue. These are of 25mm wide by 0.5mm long thick clear PVC and are inserted into opposing sides of platform 21 in slots 30 of which there are a plurality on each side to allow for variations in width of individual patients. They are held in the chosen slots by nylon retaining pins 31.

At the frame 19 the straps 11 are held by clamps 32 and may be aligned against repeatability datum marks 33. Figure 7a shows an enlarged detail of the view of arrow A in Figures 6 and 7. The upper thorax device 14 also includes a head support 34. This is capable of a longitudinal adjustment sufficient for the 2.8" variation in the distance from the base of the breasts to the crown of the head found between 2.5 percentile and 97.5 percentile U.S. females. However the intermediate frame 19 is provided with two holes 18 for upper thorax device fixing dowels 20 to give a further adjustment.

The breast positioning gauge 25 is shown in more detail in Figure 8 which is an enlarged part of Figure 7. In this Figure there can more clearly be seen a tattoo 17, on the patient's side, the position of which can be determined against a scale 35 on gauge 25. Although other marks could be used for reference, it is common in radiotherapy to use small marks tattooed onto the patient's skin since these can not be accidentally removed between treatment stages. They are not obtrusive and in the present case should be acceptable to most women since their positions are such that they would be concealed by a brassiere. The tattoos are on both sides of the patient for optimum reference and it is suggested that for avoidance of error that on the side of the diseased breast could be red. It will be appreciated that the repeatibility of patient positioning using devices such as that of this invention is much improved if a well ordered positioning procedure is followed at each stage at which the device is used. For the device of this invention the preferred positioning procedure is as follows, with reference to Figures 5 to 8.

Initially the patient is placed prone with her legs and lower torso on platform 21 and head on support 34 of attachment 14 so that her breasts are suspended in the opening therebetween. Leg alignment attachment 22 and cord 26 are put in place and then, using the narrow end of the breast alignment gauge 25, the patient's position is adjusted so that the base of each breast is close to (say 5mm from) the leading edge 21A of the torso and legs support platform. This is a first datum which will probably be used as a reference for CT scans with the platter being withdrawn fixed amounts from the initial position. The patient should then always be referred to this leading edge and the distance of the base of the breasts from it should be recorded in the patient's file for setting in future stages of the procedure.

The breast support wedge 8 is placed so that its apex is in contact with the patient's sternum over the largest possible distance.

The patient is placed with her arms above her head and crossed to grip handles 37 of the upper thorax alignment device 14. The position of the handles are then adjusted to ensure that:

a) the patient's shoulders are placed as low as possible consistant with her comfort;

b) her elbows are in contact with the side flanges 38 of the tray of device 14; and

c) the handles are fully grasped so that her thumbs are against the end stops 39.

After this has been done the hand grips are firmly secured by suitable fixings (not shown) and the relevant positions are noted against appropriate scales or reference marks. The positions are recorded in the patient's file.

The patient's head is then positioned on the headrest 34 ensuring that:

a) her face is parallel to platter 2;

b) her head is in line with her body; and

c) her neck is as full extended as is comfortably possible. Her heels (or ankles), calves (or knee-caps)

and thighs are positioned comfortably against the torso and legs alignment attachment 22. Her torso is then centred against the centre line provided by cord 26 using the division between her buttocks (or a tattoo above a lumbar vertebra or both) and a tattoo positioned above a thoracic vertebra.

It is then necessary to ensure that the patient's torso is laterally positioned to be parallel to the platter. For this purpose the breast alignment gauge 25 is used in conjuction with the lateral tattoos 17 which should be at the same height for the gauge at each side. These tattoos are preferably placed on the patient on the first occasion on which the equipment is used so that each tattoo lies on a line (40 in Figure 8) which is vertically through the centre of the patient's nipple when she is prone. They are also preferably placed so that the vertical distances L_1 from the tattoo to the patient's shoulders and L_2 from the tattoo to the base of the nipple are equal. Using these prepared marks each breast is positioned in the longitudinal direction so that the nipple is in vertical alignment with tattoos 17 using the edge of gauge 25.

As mentioned hereinbefore, breast shells may be used and these would then be attached to wedge 8 instead of making this longitudinal alignment.

Finally a suitably prepared (radiused and pierced) end of each breast motion control strap 11 is attached to platform 21, in a slot suitable for the patient's size, by a respective rod 31. These straps are passed around her breasts and through the clamps 32 on the intermediate frame 19 where they are tightened until the desired amount of breast compression is achieved and firmly clamped. The strap is cut to length at the datum mark 33, preferably by marking the position of the datum on the transparent strap with a pen and cutting after removal. These straps are then personal to the particular patient and should be appropriately identified and retained in her file where the slots 30 used in platform 21 should also be recorded. These straps will be used each time the patient is positioned and will always apply the same degree of breast compression if the end of the strap is aligned with datum 33. If the details then recorded in the patient's file are used on each subsequent planning or treatment stage then reproducible positioning will be significantly improved. It should be noted that if the breast reduces in size as the tumour regresses the degree of compression may be increased by further shortening as the treatment plan is modified.

As it is the practice in radiotherapy to irradiate the patient with beams from many different directions, subject to clinical requirements for avoiding sensitive tissue, it may be desirable to cut away the leading corners of platform 21 to a greater extent than indicated. This permissible provided attention is paid to the integrity of the structure and may be aided by the choice of material such as carbon fibre reinforced materials.

The end of platform 21 closest to the patient's breasts should also be made of material as transparent as possible to x-rays, consistent with strength to permit scannograms and other x-ray pictures to be taken for determination (among other things) of required lead shields for sensitive organs during treatment.

Figures 9a and 9b show in side elevation and plan respectively the patient 1 placed with the apparatus of this invention for examination on a CT scanner (as illustrated an EMI CT 7020). Figure 9c is a view on arrows AA of Figure 9a particularly noteworthy is the position of cord 26 in this view. This will appear on the CT scan and provide an artefact free datum relative to the platter 2. The patient so placed may then be introduced into the scanner aperture 6 head first, as shown in Figure 6 so that the x-ray plane 41 is the desired distance from datum face 21A. It will be understood that it is not necessary for the patient to be introduced head first but since the 97.5 percentile U.S. female hip width is greater than the aperture diameter of some scanners, this mode may be required in practice.

It will be apparent that variation may be made to the detailed arrangement described hereinbefore consistent with the basic principles of the invention. In particular specific dimensions and alignment devices may be varied provided the alternatives allow reproducible positions to be determined and recorded.

Furthermore the invention is not limited to breast positioning for radiotherapy but may be used, for example, for ultrasound examination, nuclear medicine examination, nuclear magnetic resonance examination, diagnostic examination by conventional x-rays or CT chest wall treatment following mastectomy or the treatment of Hodgekins disease.

Other variations or uses of the invention will be apparent to those with the appropriate skills. For example for the EMI-Medical CT 7070 scanner which has a 600mm aperture, and on which the gantry can be slewed, the upper thorax tray width can be increased but platform 21 may need to be further cut away to avoid interfacing with a slewed CT examination plane.

CLAIMS

1. An apparatus for positioning a female patient to place her breasts in a reproducible position, the apparatus including: means for supporting the patient in a substantially prone position and having an aperture through which breasts are suspended; and a support device placed beneath and central to the breasts so that they are partially supported and partially laterally displaced outward of said patient.

2. An apparatus according to claim 1 in which the support device is substantially triangular in cross-section.

3. An apparatus according to claim 2 in which the support device is disposed relative to the means for supporting the patient so that one apex thereof contacts the chest wall, of a patient in position, at the sternum.

4. An apparatus according to claim 3 in which the support device includes a resilient pad at said one apex to contact the patient's sternum.

5. An apparatus according to any preceding claim in which the support device is made of expanded polystyrene.

6. An apparatus according to any preceding claim in which the support device includes lead.

7. An apparatus according to any one of claim 1-4 in which the support device is made of lead.

8. An apparatus according to any preceding claim further including motion control means to pass outwards of one or both breasts to hold the respective breast against the support device.

9. An apparatus according to claim 8 in which the motion control means comprise one or two restraining straps.

10. An apparatus according to claim 9 in which the retaining straps are made of PVC.

11. An apparatus according to any preceding claim including means for further displacing a healthy breast not to be irradiated to avoid radiation to be directed at the other breast.

12. An apparatus according to claim 11 in which the means for further displacing is an expanded polystyrene block.

13. An apparatus according to any preceding claim including means for reproducibly positioning the patient's upper or lower thorax or both.

14. An apparatus according to any preceding claim including gauge means for positioning the breasts relative to the support device.

15. An apparatus for positioning a female human to place her breasts in a reproducible position, the apparatus being substantially as herein described with reference to the accompanying drawings.

16. A radiotherapy apparatus including positioning apparatus according to any of the preceding claims.

17. A radiotherapy apparatus including positioning apparatus according to any of claims 1-15.

18. A patient supporting apparatus arranged to be used interchangeably in diagnostic or treatment parts of a radiotherapy and radiotherapy planning facility, the supporting apparatus including a positioning apparatus according to any of the preceding claims.

19. A method of positioning a female human such that when positioned on different occasions her breasts take substantially the same position, the method including: placing the patient in a substantially prone position; placing a support device beneath and central to the breasts so that they are partially supported and partially laterally displaced outward of said patient and adjusting the position of at least one of the breasts relative to a reference associated with the support device.

20. A method according to claim 19 including pressing the breasts inwardly against the support device.

21. A method of positioning a female human such that when positioned on different occasions her breasts take substantially the same position, the method being substantially as herein described with reference to the accompanying drawings.

22. The method of any of claims 19-21 used for positioning a female patient for radiotherapy treatment planning and treatment.

23. The method of claim 22 used for radiotherapy treatment planning including diagnostic radiotherapy.

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