

(19) AUSTRALIAN PATENT OFFICE

- (54) Title
Reinforced thermoplastic patient restraints for radiation therapy
- (51) ⁶ International Patent Classification(s)
A61B 19/00 060101BHAU
(2006.01) PCT/US2002/03
A61B 19/00 1816
20060101AFI20
- (21) Application No: 2002330237 (22) Application Date: 2002.10.04
- (87) WIPO No: W004/032781
- (43) Publication Date : 2004.05.04
(43) Publication Journal Date : 2004.06.03
- (71) Applicant(s)
Med-Tec Iowa, Inc.
- (72) Inventor(s)
Nibbelink, Jeff; Ungemach, Robert
- (74) Agent/Attorney
Davies Collison Cave, Level 15 1 Nicholson Street, MELBOURNE,
VIC, 3000
- (56) Related Art
US 559591
WO 1997/002942

DAVIES COLLISON CAVE

Patent Attorneys

1 Nicholson Street, Melbourne, 3000, Australia
Telephone 03 9254 2777 Facsimile +61 3 9254 2770

25 February 2005
Our Ref: 12574320/RSH



The Commissioner of Patents
WODEN ACT 2606

Sir

Re: International Patent Application PCT/US02/031816
(WO 04/032781)
Applicant: Med-Tec Iowa, Inc.

In order to enter the National Phase in Australia, we enclose:

National fee - \$320.00

Request for examination

Examination fee - \$340.00

Amendments have been made under Article 34

TOTAL: \$660.00

Subject to any subsequent request, we hereby request the deferral of acceptance under the provisions of Section 49(3) until the last day of the period specified in Regulation 13.4(1)(a).

The address for service is care of DAVIES COLLISON CAVE, Patent Attorneys, of 1 Nicholson Street, Melbourne, 3000, Australia.

A handwritten signature in black ink, appearing to read "Keith Hoshino".

A member of the firm of DAVIES COLLISON CAVE
for and on behalf of the Applicant



5202

2002330237 27 Jan 2006

REINFORCED THERMOPLASTIC PATIENT RESTRAINTS FOR RADIATION THERAPY

BACKGROUND OF THE INVENTION

5 Thermoplastic sheets are well known for use in the field of radiation therapy treatment, including Intensity Modulated Radiation Therapy (IMRT). Typically, such thermoplastic sheets are heated and then formed to a shape corresponding to the body part to be restrained, such as a mask for restraining a patient's head. The sheet is mounted on a frame which can be secured to a treatment table to facilitate proper positioning of the patient on the table for radiation treatment.

10 The prior art thermoplastic sheets are solid sheets or perforated sheets. Solid thermoplastic sheets require much higher forces to form, retain much more heat and tend to have excess shrinkage when formed to the body shape, all of which leads to patient discomfort. The perforations serve to reduce the force necessary to form, minimise the heat transferred to the patient, and minimise shrinkage of the thermoplastic material. When the sheet is formed into a facemask, the holes permit a patient to see and breathe through the sheet, and thereby minimise or eliminate claustrophobic feelings. The holes can be punched into the sheet, or formed when the sheet is made in an injection molding process. However, totally perforated sheets do not offer the necessary rigidity which is present in a solid or non-perforated sheet.

20 An objective of the present invention is the provision of an improved thermoplastic sheet, which is comfortable when used on a patient for medical procedures.

BRIEF SUMMARY OF THE INVENTION

25 According to the present invention there is provided a patient restraint member for use in medical procedures, comprising: a sheet of thermoplastic material that can be softened upon heating so as to be formable into a shape corresponding to a patient's body part to be restrained and setting upon cooling to retain the shape; spaced apart groups of perforations punched or molded in the sheets to reduce the force necessary to form, to minimise the heat transferred to the patient, and to minimise the shrinkage of the thermoplastic material; and solid bands extending between the groups of perforations.

30 The improved thermoplastic sheet defined above, is intended for use as a patient restraint member in medical procedures such as radiation therapy treatment, including

2002330237 27 Jan 2006

5 IMRT. The sheet may take various forms and shapes to restrain various body parts, including the head, neck, breasts, and hips/pelvic area. The groups of perforations increase patient comfort, with non-perforated bands extending between the groups of perforation to provide enhanced rigidity. The perimeter edge of the sheet is preferably free from perforations. The solid bands may extend inwardly from the perimeter edge of the sheet. The bands may extend completely or partially across the sheet. The solid bands are preferably placed in strategic areas to provide increased rigidity while the perforations minimize shrinkage. The perforations may be punched or formed during injection molding.

10 BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side elevation view of a thermoplastic sheet formed into a mask for restraining a patient's head and mounted onto a radiation treatment table.

15 Figures 2 - 5 are each a top plan view of a sheet adapted to be formed into a head restraint, and showing various alternative embodiments of the perforation groupings and solid reinforcing bands, according to the present invention.

Figure 6 is a top plan view of a thermoplastic sheet adapted to be formed into a head and shoulder restraint with the perforations and reinforcing bands of the present invention.

20 Figure 7 is a top plan of a thermoplastic sheet adapted to be formed into a breast restraint with the perforations and reinforcing band of the present invention.

Figure 8 is a top plan view of a thermoplastic sheet adapted to be formed into a hip/pelvic restraint and having the perforations and reinforcing bands of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

In Figure 1 a patient 10 as shown on a treatment table 12 in preparation for radiation therapy on his/her head. The patient's head is restrained by a thermoplastic mask 14, which has been formed to fit the patient's head. The mask 14 is mounted on a frame 16, which is adapted to be secured to the treatment table 12 in any convenient manner. For example, the table 12 may include a plurality of indexing notches adapted to receive an indexing member 18 extending from the frame 16, as described in the U.S. patent 6,161,237.

The mask 14 is formed from one of the thermoplastic sheets 20A-20D shown in figures 2-5, respectively. Each sheet 20 includes spaced apart groups of perforations or holes 22 extending through, or partially through, the sheets 20A-20D. The spacing between the groups of the holes define solid bands 24 which increase the rigidity of the sheets 20A-20D, and thus the mask 14. The holes 22 minimize shrinkage of the sheets during the mask formation process. Each of the sheets 20A-D has a non-perforated perimeter edge 26 for securement of the sheet to the U-shaped frame 16. Alternatively, the groups of holes 22 may extend to the edge of the sheet 20A-D, which facilitates bonding of the sheet 20A-D to the frame 16, for example using adhesives or heat. The non-perforated bands 24 extend inwardly from the perimeter edge 26 of the sheets 20A-D. Some bands 24 may extend completely across the sheets 20a-d while other bands 24 extend partially across the sheets. Also, the bands 24 may extend perpendicularly to the opposite side edges, top edge, or bottom edge, or angularly thereto in a non-perpendicular orientation. As seen in Figure 5, some of the bands may criss-cross the sheet 20D. The holes 22 may be formed by punching or during an injection process used to make the sheets 20A-D.

Figure 6 shows another sheet 28 adapted to be formed for restraining the head and shoulders of a patient. The holes 22 in the sheet 28 minimize shrinkage, while the solid bands 24 provide increased rigidity for the sheet 28 after it is heated, formed, and cooled to the set shape.

Figure 7 shows another embodiment of the present invention where in a sheet 30 having holes 22 and a solid band 24 is adapted for formation and use in restraining the upper torso of a patient, for example, in breast radiation treatment. Similarly, Figure 8 shows a thermoplastic sheet 32 with holes 22 and solid bands 24 according to the present invention. The sheet 32 is adapted to be formed and used as a hip/pelvic restraint. The

2002330237 27 Jan 2006

enlarged holes 34 along the edges of the sheets 30 and 32 are used for attaching the sheets 30, 32 to a frame (not shown) which is then mounted to the treatment table.

Whereas the invention has been shown and described in connection with the preferred embodiment thereof, it will be understood that any modifications, substitutions, and additions may be made which are within the intended broad scope of the following claims. From the foregoing, it can be seen that the present invention accomplishes at least all of the stated objectives.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

The reference to any prior art in this specification is not, and should not be taken as, an acknowledgment or any form of suggestion that that prior art forms part of the common general knowledge in Australia.

What is claimed is:

1. A patient restraint member for use in medical procedures, comprising:
a sheet of thermoplastic material that can be softened upon heating so as to be formable
into a shape corresponding to a patient's body part to be restrained and setting upon
5 cooling to retain the shape;
spaced apart groups of perforations in the sheets; and
solid bands extending between the groups of perforations.
2. The patient restraint member of claim 1 wherein the sheet has a perimeter edge and
10 the bands extend inwardly from the edge.
3. The patient restraint member of claim 2 wherein the bands intersect at a location
spaced inwardly from the edge.
- 15 4. The patient restraint member of claim 2 wherein the bands extend perpendicular to
the edge.
5. The patient restraint member of claim 2 wherein the bands extend in a non-
perpendicular angle from the edge.
20
6. The patient restraint member of claim 2 wherein the bands extend completely
across the sheet.
7. The patient restraint member of claim 1 wherein the sheet has a perimeter edge
25 without perforations.
8. The patient restraint member of claim 1 wherein the solid bands extend across the
sheet.
- 30 9. The patient restraint member of claim 1 wherein the spaces between the groups of
perforations define the solid bands.

2002330237 27 Jan 2006

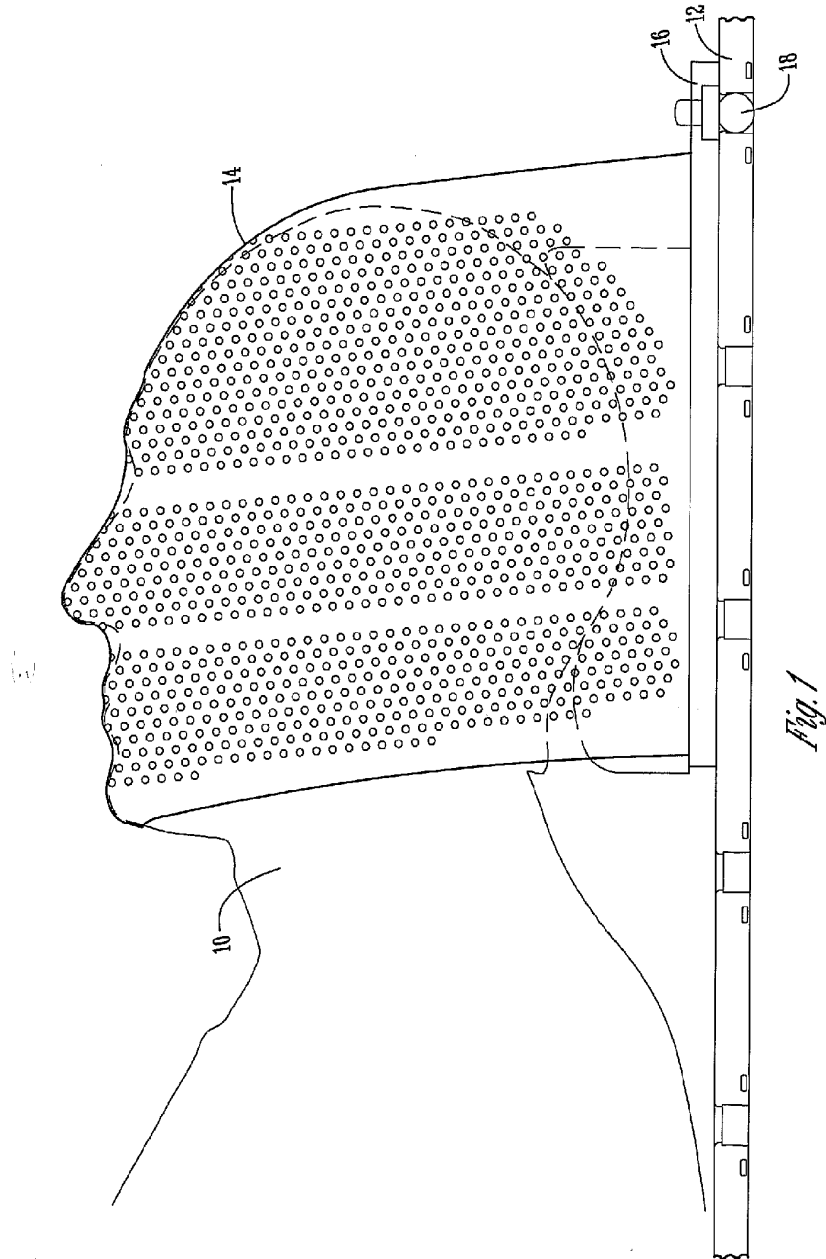
9. The patient restraint member of claim 1 wherein the spaces between the groups of perforations define the solid bands.
10. A patient restraint member for use in medical procedures, substantially as hereinbefore described with reference to the accompanying drawings.

Dated this 25th day of January, 2006.

Med-Tec Iowa, Inc.

By their Patent Attorneys:

DAVIES COLLISON CAVE



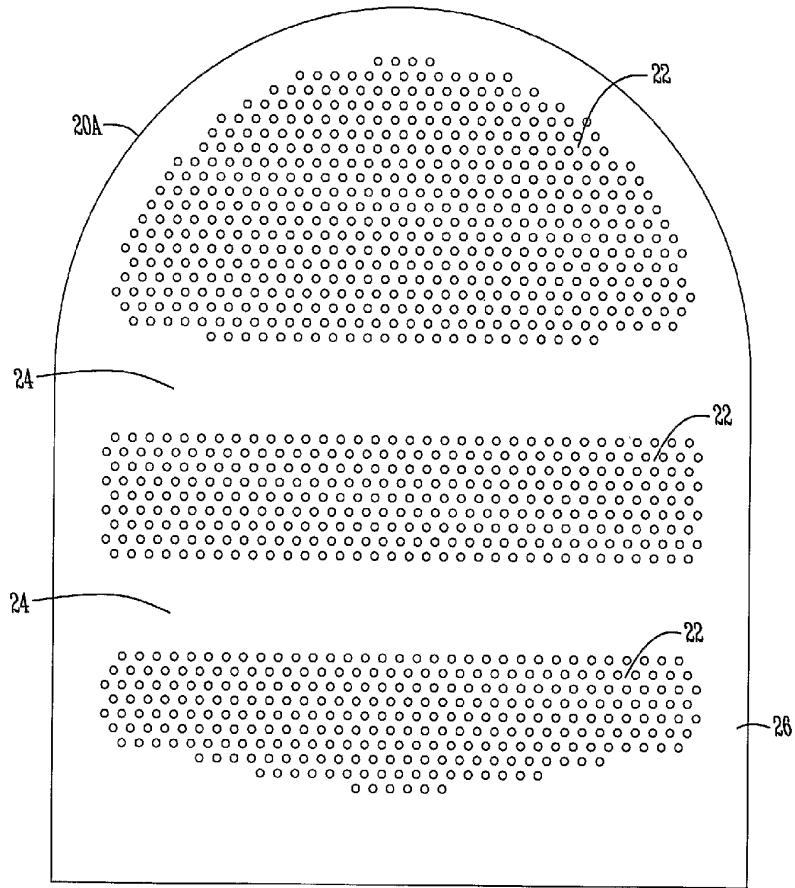


Fig. 2

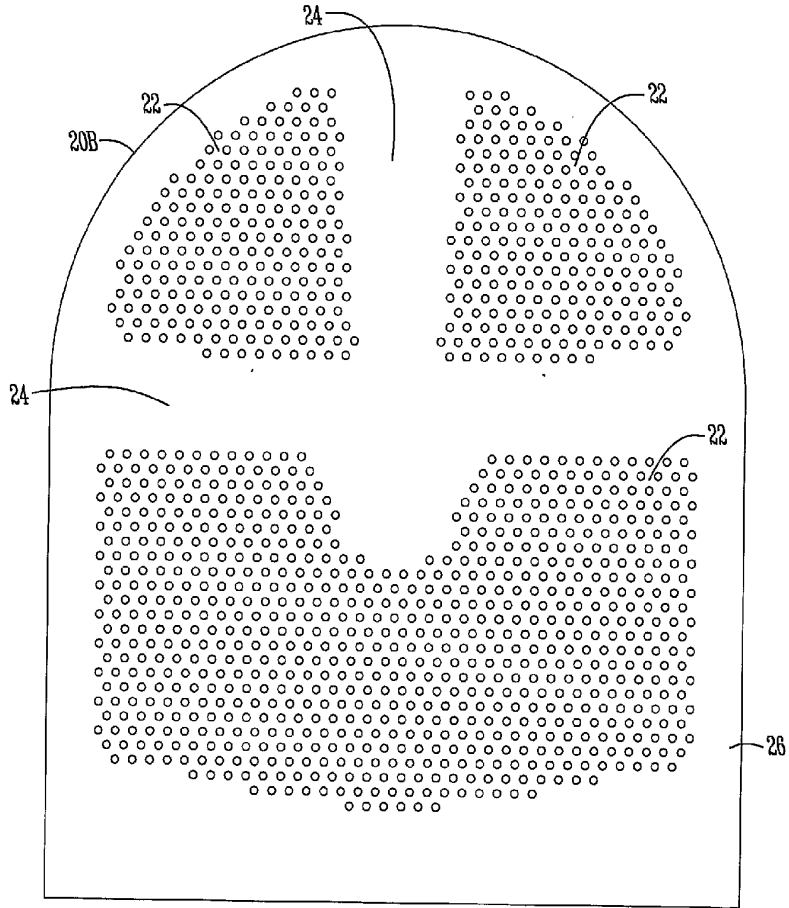


Fig. 3

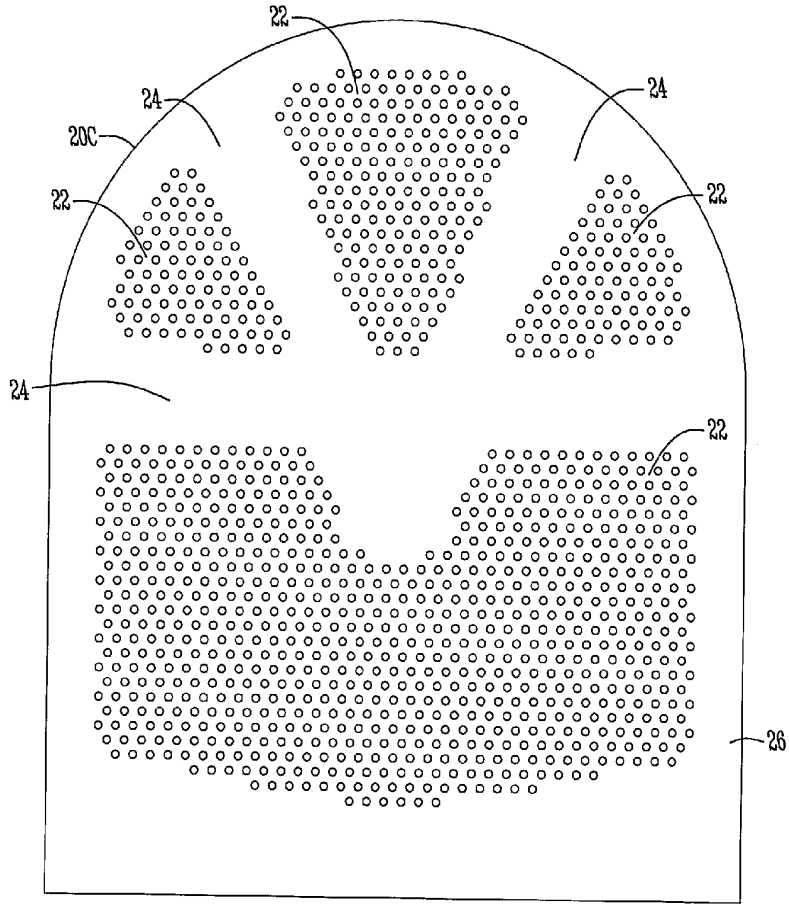


Fig. 4

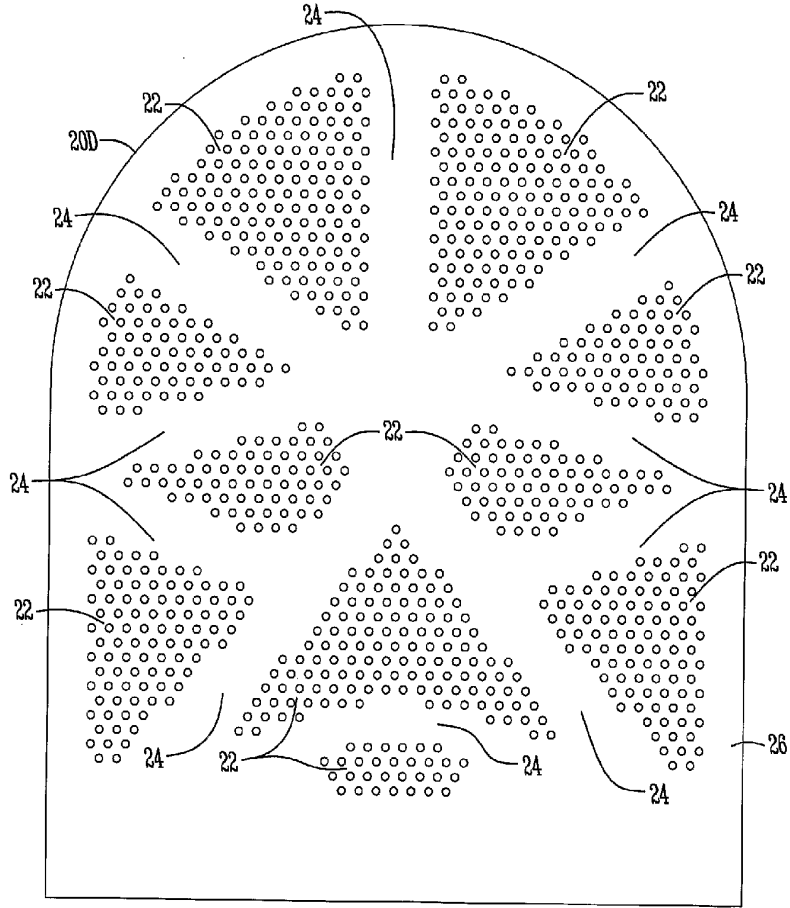


Fig. 5

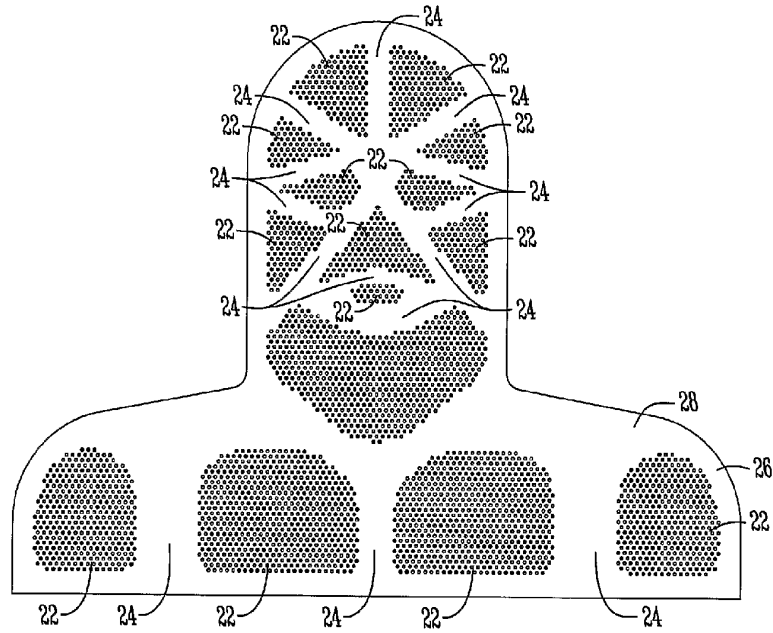


Fig. 6

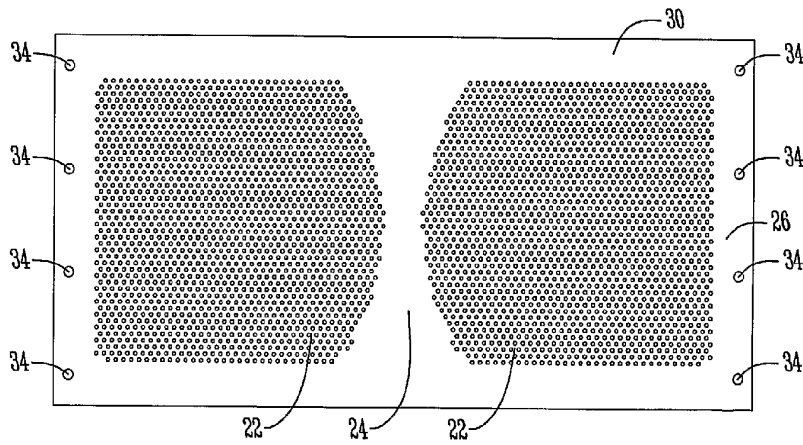


Fig. 7

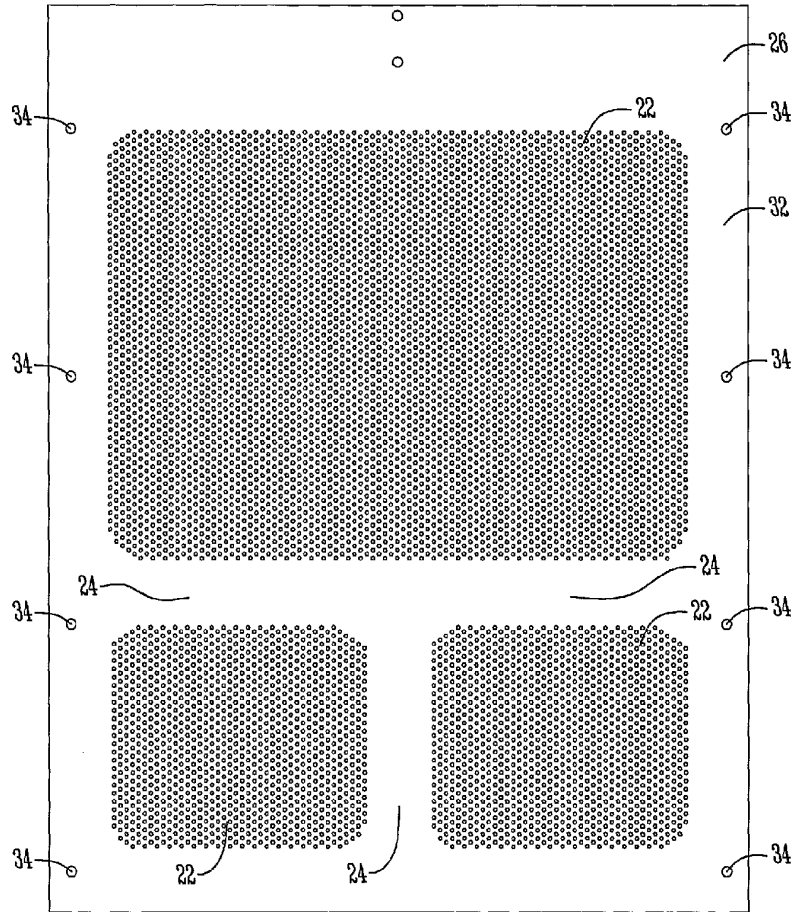


Fig. 8