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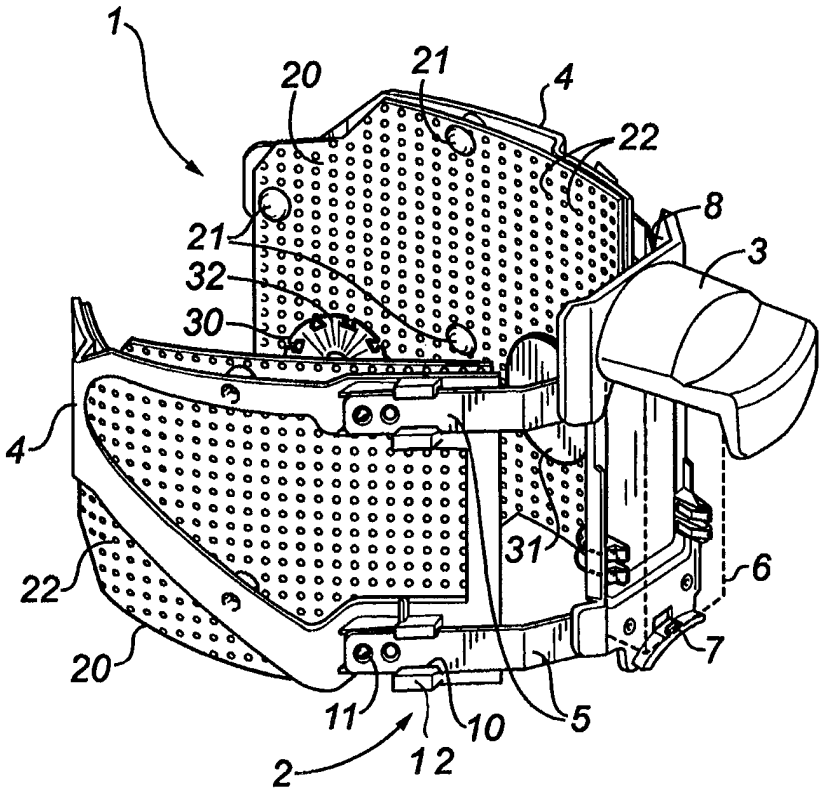
(54) Title: ASSEMBLY FOR HOLDING ELECTRODES OF A FUNCTIONAL ELECTRICAL STIMULATION DEVICE

(57) Abstract

A grid (20) forming a regular pattern of holes (22) provides a substrate on which to mount electrical stimulation electrodes. The electrodes are carried by two part receptacles (30, 31). One receptacle part has fingers which extend through the holes – the other part has locking means which disengageably lock with the fingers. Thus the parts can be locked together across the grid, but they can be disengaged and moved to another location on the grid (20). The parts form a conductive path between an external current–carrying wire lead (60) and the electrode (70). The grid is mounted to a frame forming a cuff. The frame is shaped to provide a locator which conforms to a bony protrusion on the limb to be stimulated. Thus, a clinician can move the electrodes around on the grid to optimally position them. When the user dons the cuff, the locator automatically positions the electrodes over the desired stimulation sites.



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ASSEMBLY FOR HOLDING ELECTRODES OF A FUNCTIONAL ELECTRICAL STIMULATION DEVICE

FIELD OF THE INVENTION

The invention relates to an assembly for holding an electrode of a functional electrical stimulation ("FES") device in contact with an anatomical part.

BACKGROUND OF THE INVENTION

FES devices are commonly used to electrically stimulate the body at optimal sites and cause muscle contraction. For example, an individual who has had a stroke may have difficulty in raising one foot as he walks. This is referred to as a "foot drop". By stimulating the peroneal nerve in the leg electrically, an involuntary muscle contraction can assist in better raising the foot.

A major limitation with these devices is repeatable and reliable localization of the electrodes over the optimal stimulation sites when donning the device. The problem is exemplified by the commercially available prior art peroneal nerve stimulators used to address the aforementioned foot drop. These stimulators rely on the user to check and re-find the stimulation sites. The electrodes are usually held to the body by a tensor band, to which the electrodes are mounted. Usually no electrode locating system is provided. The users typically have difficulty in locating the site and positioning the device so that the electrode overlies it. In addition, the band or garment tends to wear and stretch with use, thereby altering the relative position of the electrode and making it more difficult for the user to coincide the electrode with the stimulation site.

SUMMARY OF THE INVENTION

With this background in mind, the present invention has been directed toward providing a system in which:

- The clinician would accurately identify the optimal stimulation sites;
- The clinician would precisely mount the electrodes on a support substrate which would resist stretching; and
- The assembly would be provided with a locator for automatically referencing the electrodes to a bony protrusion in the limb.

The invention will now be described in connection with a specific preferred embodiment for holding the positive and negative electrodes of on FES device in contact with predetermined sites on an anatomical limb such as a user's leg. The embodiment comprises:

- A stiff, generally U-shaped frame. This frame comprises a pair of curved plastic wing members resiliently and flexibly connected at their front ends by bent steel bands with a central plastic bracket. The wings are open to the rear. The bracket carries a battery and suitable control electronics, for supplying appropriate current pulses – this current-supplying stimulator is of conventional design. The frame is adapted to conform in shape to the limb of the user, in the form of a cuff;

- A pair of plane or sheeted grids, each having a regular pattern of holes extending transversely therethrough. The grids provide the support substrate to which the electrodes are mounted. One grid is mounted to each wing member. Each grid is flexible into or out of its plane, so that it can conform to the shape of the wing members and the leg. However the grid is rigid in its plane, so that the location and spacing of the holes will remain constant;
- A movable negative receptacle is mounted to one of the grids. The receptacle comprises external and internal (or body side) parts. One part has projecting fingers which can extend through the grid holes. The other part has means for disengagably locking with the fingers. Thus the two receptacle parts can be snapped together to lock across the grid. The external receptacle part has contact means for connecting with wiring leading from the negative terminal of the stimulator, through which stimulating electrical pulses are transmitted. The internal receptacle part has means for mechanically and electrically engaging and holding an electrode. The two parts together incorporate means forming a conductive path for electrically connecting the contact means and the electrode so that the pulses can reach the electrode;

- A movable positive receptacle is also mounted to the grid. The positive receptacle is identical to the negative receptacle, except that the contact means is connected with wiring leading back to the positive terminal of the stimulator, to complete the stimulation circuit;
- A locator is carried or formed by the frame. The locator is shaped to fit a bony protrusion (e.g. the tibia) to thereby reference or locate the assembly so that the electrodes overlie the predetermined stimulation sites, when the locator is positioned over the protrusion; and
- A fabric garment jackets the assembly to protect the skin of the user.

In one broad aspect then, the invention is directed to selecting a grid to provide the electrode-supporting substrate and uniting the grid with interlocking, movable receptacle parts and providing a conductive path therethrough, all in the context of an FES device having a locator.

The grid covers a relatively broad expanse of the limb – localized groups of grid holes provide many relatively small areas where an electrode can be precisely positioned over a stimulation site. The grid is accurately referenced to the bony protrusion, as are its electrodes. Each receptacle is movable on the grid to any one of multiple locations. The receptacles can be fixed on the grid by a clinician so that the electrodes are optimally positioned. The user can then slip the assembly onto the limb. The locator automatically correctly positions the unit around the limb by mating with the bony protrusion. The grid is not susceptible to stretching over time with use – therefore the positioning of the grid holes and the receptacles remains constant.

Broadly stated, in this aspect the invention comprises an assembly for holding an electrode of a functional electrical stimulation ("FES") device, comprising: a sheeted grid having a regular pattern of holes extending transversly therethrough, the grid being flexible into and out of its plane but being substantially rigid in its plane, so that the grid may generally conform to the shape of an anatomical part but the location and spacing of the holes remain constant, said grid forming a suppport substrate for an electrode; a pair of receptacles for supporting a pair of electrodes, each said receptacle comprising external and internal parts, one of the parts having fingers for extending through grid holes, the other part having means for disengagably locking with the fingers so that the two parts can be locked together across the grid at a predetermined location, the internal part having means for mechanically and electrically engaging and holding an electrode, said external part having a contact for connection with a lead for supplying FES stimulation pulses, and said parts having means forming a conductive path for electrically connecting the contact with the electrode.

In another aspect, the invention comprises an electrode for use with a functional electrical stimulation ("FES") device comprising: a conductive snap stud; a first layer of electrically insulating foam supporting the stud, said layer having adhesive on its underside; a snap eyelet securing the foam layer to the stud; a conductive second layer having a film of silver on its upper surface for distributing current laterally, said second layer being attached to the first layer by

the adhesive; and a low tack conductive third layer of hydrogel attached to the second layer.

DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view from one angle showing an FES foot drop device incorporating the assembly of the invention, but without a fabric cover – one of the receptacles holds an electrode, the other does not;

Figure 2 is a perspective view from another angle showing the FES foot drop device of Figure 1;

Figure 3 is a perspective view showing a grid with a receptacle external part locked thereto;

Figure 4 is a perspective view showing a grid with a receptacle internal part locked thereto;

Figure 7 is a plan view of the outer side of the external part;

Figure 8 is a plan view of the inner side of the external part;

Figure 9 is a sectional side view showing the receptacle parts locked across the grid with the internal part uppermost and an electrode attached to the internal part;

Figure 10 is a sectional side view taken at 90° through the assembly of Figure 9; and

Figure 11 is an exploded side view of an electrode.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The invention will be described in connection with an FES device 1 for use on a leg to assist with foot drop.

The device 1 comprises a frame 2 formed by a central plastic bracket 3, a pair of rearwardly extending, arcuate, plastic wings 4 and a pair of steel bands 5 connecting the wings 4 with the bracket 3. The frame 2 forms a cuff operative to fit around the leg.

A battery/stimulation control assembly or stimulator 6 snaps into the tabs 7 of the bracket 3 and is supported thereby.

The back surface 8 of the bracket 3 and the bands 5 combine to form a locator 9 which fits and conforms to the tibia of the user's leg.

The wings 4 form a channel 10, locking pin 11 and tabs 12 for sliding and locking engagement with the bands 5 – thus the wings 4 can be adjusted toward or away from the bracket 3.

A grid 20 is attached to each wing 4 by plastic rivets 21. The grids 20 are sheet-like in form and have a regular pattern of small holes 22 extending transversely therethrough. The grids 20 are formed of low density polyethylene plastic and can flex in and out of their main plane. However they are quite strong and rigid in the direction of the main plane.

Positive and negative receptacles 30, 31 are shown mounted to one of the grids 4. These receptacles 30, 31 are identical in structure. Each comprises internal (body side) and external parts 32,33.

The dish-shaped internal part 32 comprises a plastic circular body 34 having a transverse wall 35 and an outwardly or rearwardly projecting circular side wall 36. The side wall 36 forms a recess 37. The transverse wall 35 forms a central opening 38 for receiving an electrode stud 71. A stainless steel S-shaped spring 40 is positioned in the bottom of the recess 37. The spring 40 crosses the prong opening 38 and provides contact points 41. A ring contact 42 overlies the outer side of the spring 40 and is retained in place in the part 32 by snap tabs 43. A plastic retainer 44 holds the spring 40 over the prong opening 38. The ring contact 42 has a plurality of outwardly or rearwardly projecting conductive fingers 45 for extending through the grid 20 and establishing electrical contact with the crown 50 of the external part 33. A plurality of locking fingers 46 extend outwardly from the side wall 36 for projecting through the grid 20 and engaging the outer part 33 to lock the parts 32,33 together across the grid 20. Support members 47 extend radially out from the inner periphery of the body 34, for providing support to the electrode 70.

The external part 33 comprises a circular member 51 having a transverse wall 52 and a side wall 53 forming inner and outer recesses 54, 55. The transverse wall 52 has a central post 56 projecting inwardly. An electrically conductive crown 50 is positioned on the post 56. When the parts 32, 33 are locked together, the conductive fingers 45 of the internal part contact the crown 50, to complete a conductive path through the two parts 32, 33.

T-shaped posts 57 project radially out from the side wall 53 of the external part 33, to define slots 58 into which the locking fingers 46 of the internal part 32 can slide to lock the parts 32, 33 together.

A pair of wire leads 60, 61 extend from the stimulator terminals 62,63 on the bracket 3. The leads 60,61 are each welded to the crown 50 of one of the electrodes 64,65. The FES device 1 has negative and positive electrodes – current flows through the user's body between the electrodes. So one wire lead 60 connects the negative stimulator terminal 62 with the receptacle 31 of the negative electrode 64 and the other wire lead 61 connects the positive stimulator terminal 63 with the receptacle 30 of the positive electrode 65.

The multi-layer electrode 70 comprises: a conductive snap stud 71 including the prong 29; a layer 72 of electrically insulating foam (available from Scapa Tapes, Windsor, Connecticut, identified by designation P.N. RX 23, 2V-42) supported by a stiffening layer 72a of polyethylene coated with adhesive on its bottom surface, a conductive snap eyelet 73 securing the foam layer 72 to the stud 71; a conductive layer 74 (available from Rexam Graphics, South Hadley, Maine, identified by designation 2252M) having a film 75 of silver on its upper

surface for distributing current laterally, the layer 74 being secured to the foam layer 72 by the adhesive; a tacky conductive layer 76 of hydrogel having a high tack upper surface and a low tack bottom or skin surface (available from Uni-Patch, Wabasha, Maine, identified by designation RG62D); and a removable release liner 77 (used to protect the hydrogel).

The layers 72, 74, 76 have the following functions.

The stud 71 contacts the silver film 75, which distributes the current uniformly across the conductive layer 74. The foam layer 72 protects and insulates the silver film 75. The film 75 and conductive layer 74 conduct the current to the hydrogel layer 76, which provides a good electrical contact to the user's skin. The inner or lower surface of the hydrogel layer 76 is low tack, so that the electrodes can be moved around as required.

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. An assembly for holding an electrode of a functional electrical stimulation ("FES") device, comprising:

a sheeted grid having a regular pattern of holes extending transversly therethrough, the grid being flexible into and out of its plane but being substantially rigid in its plane, so that the grid may generally conform to the shape of an anatomical part but the location and spacing of the holes remain constant, said grid forming a suppport substrate for an electrode;

a pair of receptacles for supporting a pair of electrodes, each said receptacle comprising external and internal parts, one of the parts having fingers for extending through grid holes, the other part having means for disengagably locking with the fingers so that the two parts can be locked together across the grid at a predetermined location, the internal part having means for mechanically and electrically engaging and holding an electode, said external part having a contact for connection with a lead for supplying FES stimulation electrical pulses, and said parts having means forming a conductive path for electrically connecting the contact with the electrode.

2. The assembly as set forth in claim 1 comprising;

a pair of electrodes held by the inner parts of the receptacles.

3. An assembly for holding the positive and negative electrodes of a functional electrical stimulation ("FES") device in contact with an anatomical part, comprising:

a frame shaped to embrace and conform to the anatomical part;

at least one sheeted grid carried by the frame, said grid having a regular pattern of holes extending transversly therethrough, the grid being flexible into and out of its plane but being substantially rigid in its plane, so that the grid may generally conform to the shape of the anatomical part but the location and spacing of the holes remain constant, said grid forming a support substrate for an electrode;

movable pairs of positive and negative electrode receptacles, each receptacle comprising external and internal parts, one of the parts having fingers for extending through grid holes, the other part having means for disengagably locking with the fingers, so that the two parts can be locked together across the grid at a predetermined location and the fingers and locking means can be disengaged to allow the receptacle to be moved to a new location;

the internal part of each receptacle having means for mechanically and electrically engaging and holding an electrode;

the external part of each receptacle having a contact for connection with a lead for supplying FES stimulation electrical pulses; and

means, carried by the parts of each receptacle, for electically connecting the contact with the electrode.

4. An assembly as set forth in claim 3 comprising:

a pair of electrodes held by the inner parts of the receptacles.

5. An electrode for use with a functional electrical stimulation ("FES") device comprising:

a conductive snap stud;

a first layer of electrically insulating foam supporting the stud, said layer having adhesive on its underside;

a snap eyelet securing the foam layer to the stud;

a conductive second layer having a film of silver on its upper surface for distributing current laterally, said second layer being attached to the first layer by the adhesive; and

a low tack conductive third layer of hydrogel attached to the second layer.

Fig. 2

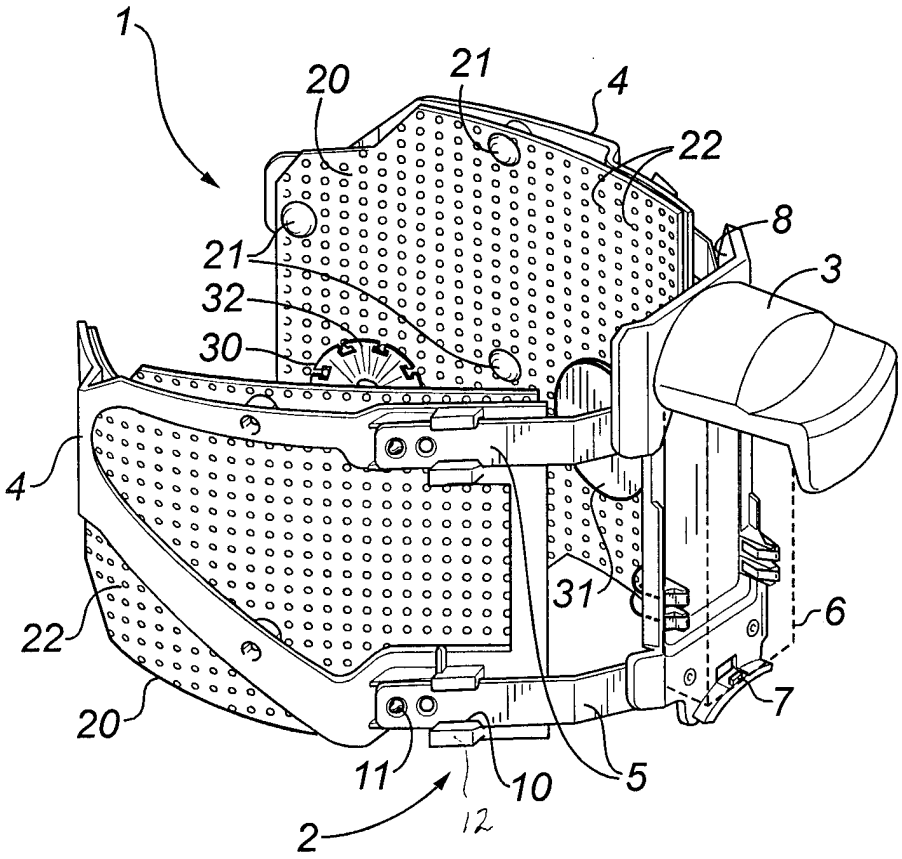
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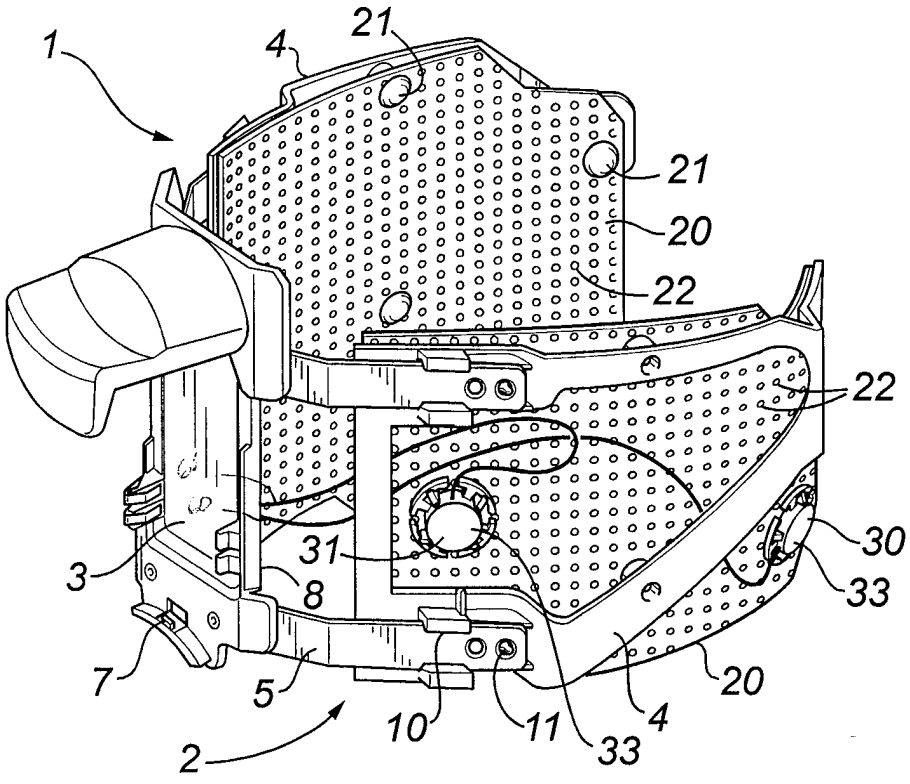
Fig. 1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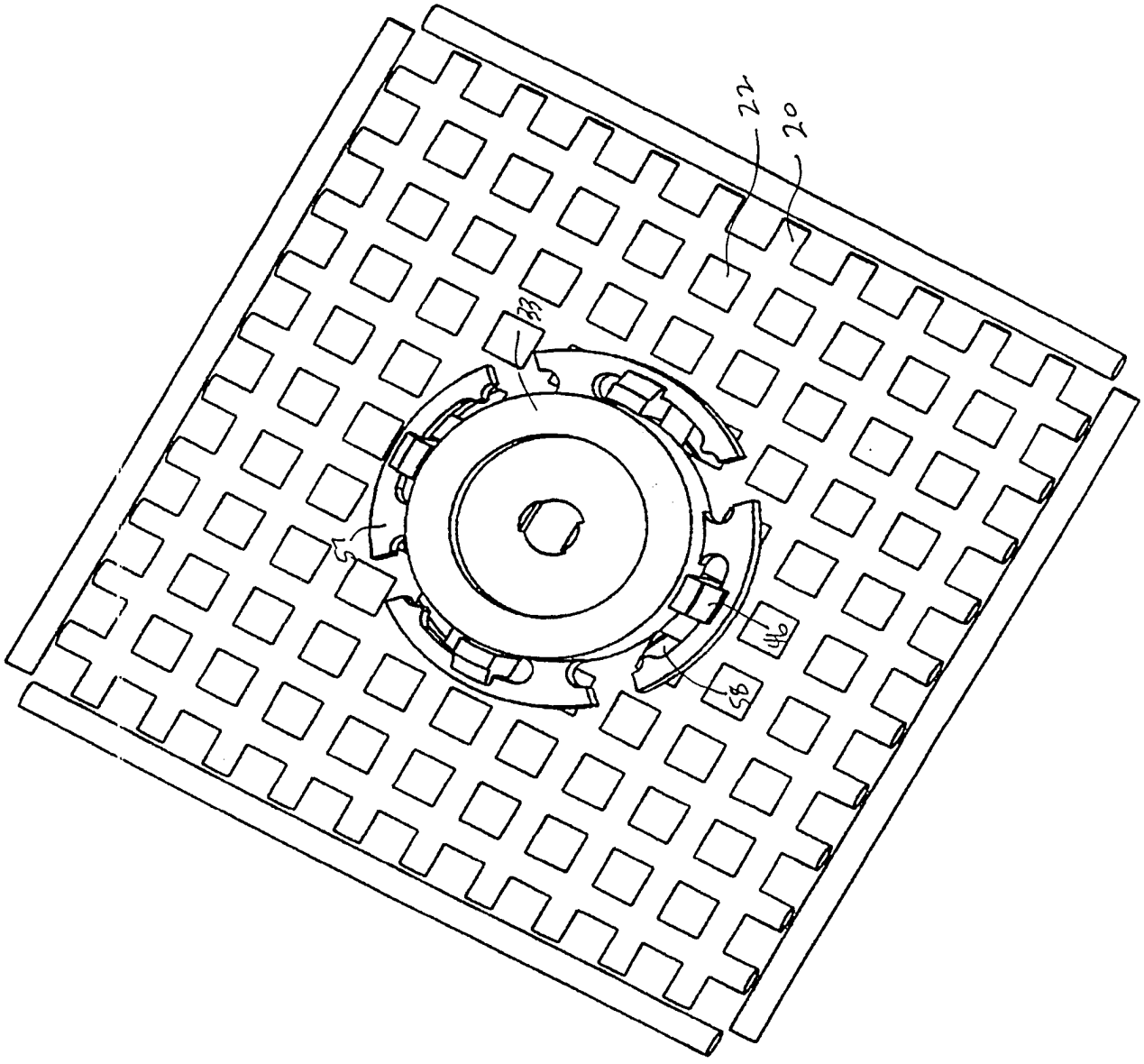
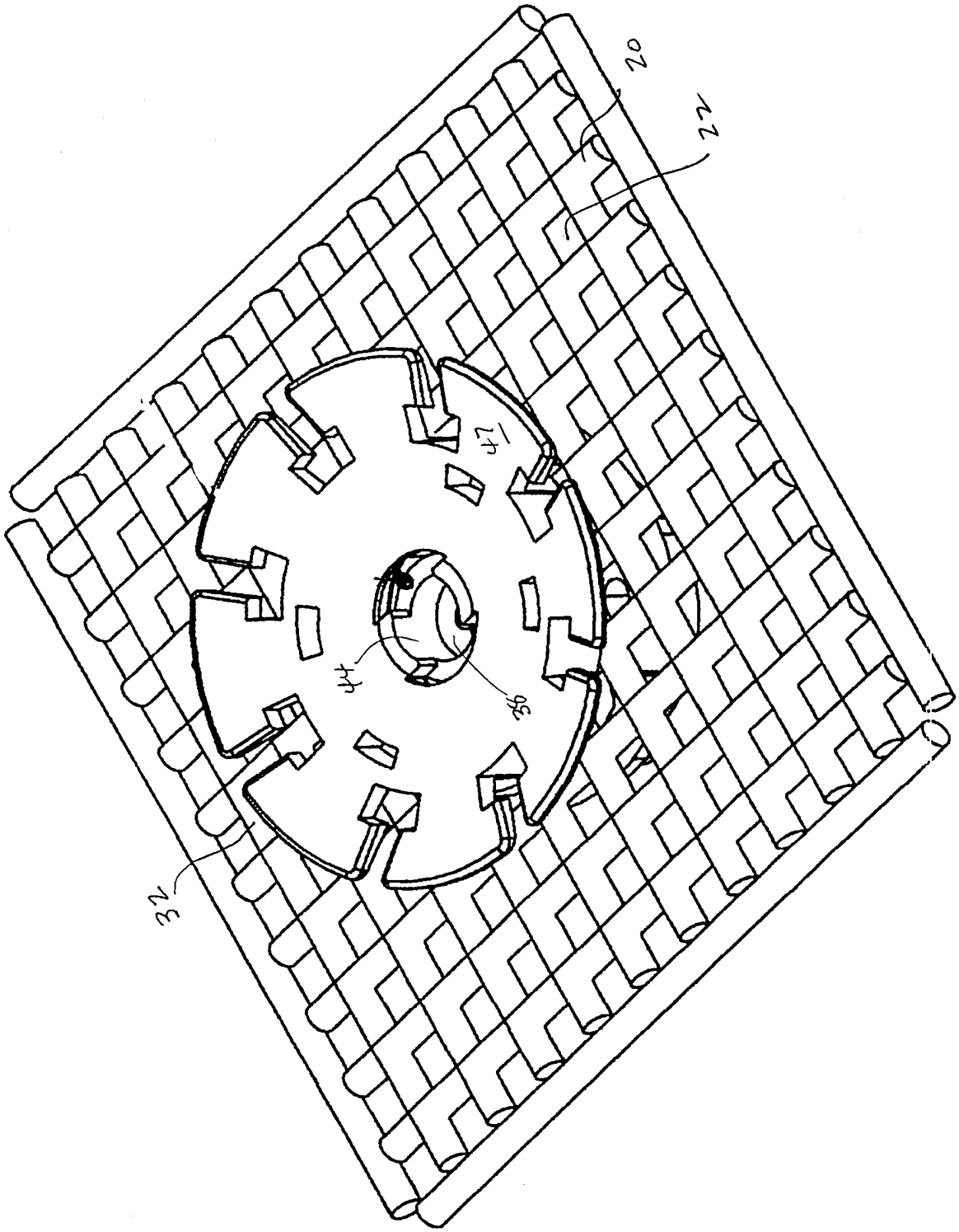


Figure 3

Fig. 4



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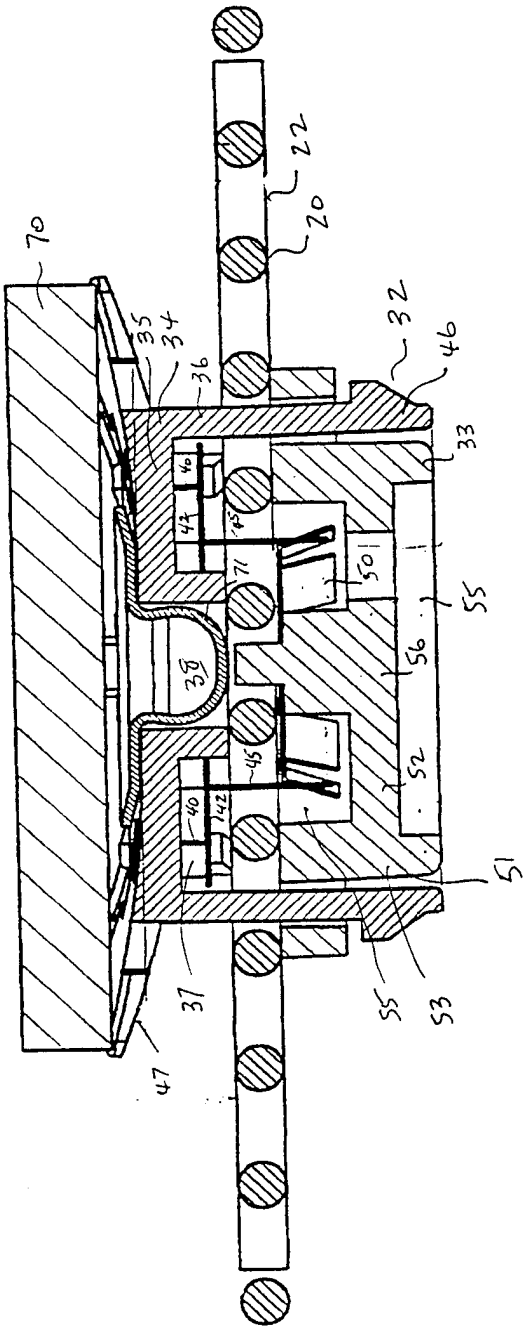
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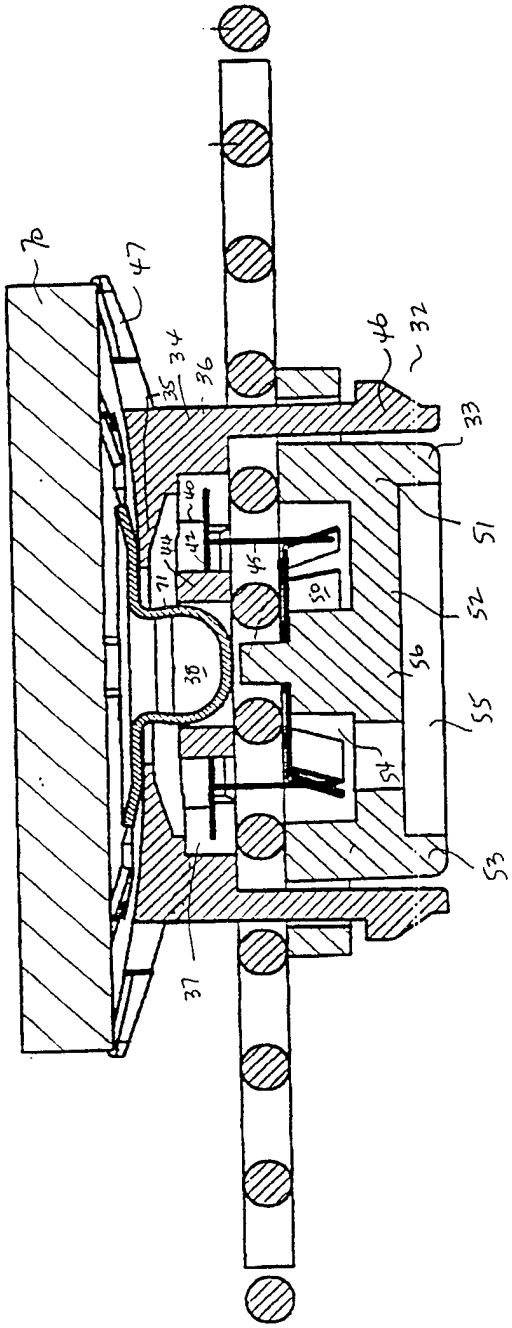
Fig 8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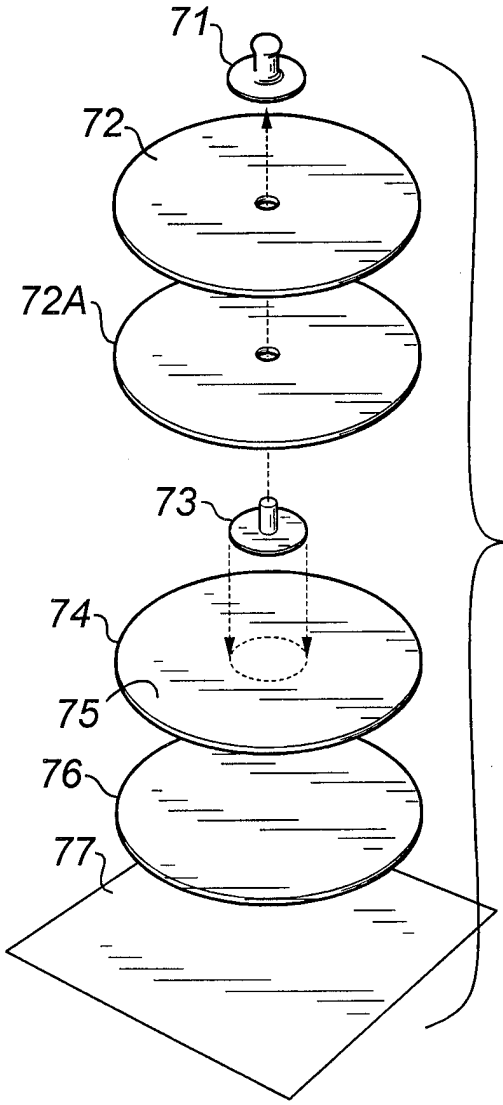

FIG. 9

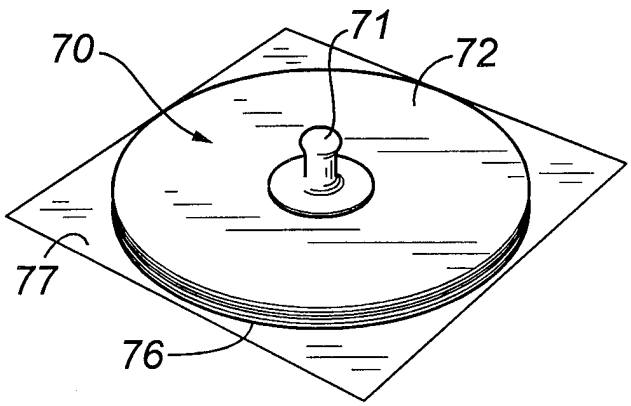

FIG. 10

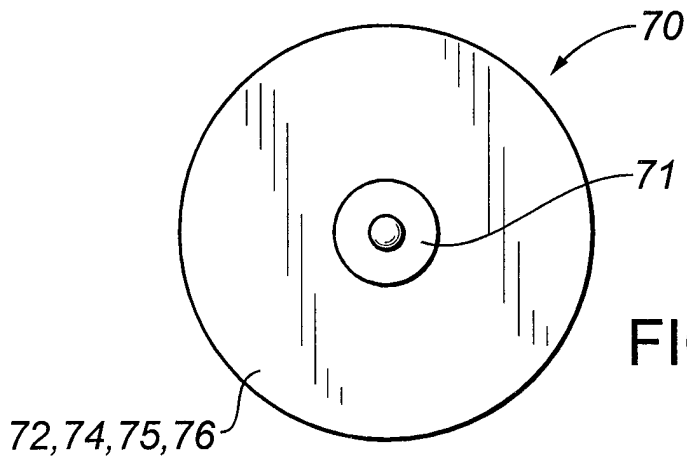

FIG. 11

INTERNATIONAL SEARCH REPORT

Internatio. Application No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61N1/04

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B. FIELDS SEARCHED

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IPC 6 A61N

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

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	WO 82 00951 A (WALLANT INT TRADE INC) 1 April 1982 see page 4, line 8 - page 5, line 19; figures ---	1,3,5
A	US 4 736 752 A (MUNCK GARY ET AL) 12 April 1988 see column 4, line 20 - column 6, line 16; figures ---	1,3
A	US 4 919 148 A (MUCCIO PHILIP E) 24 April 1990 see column 5, line 66 - column 7, line 47; figures ---	1,3

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Date of the actual completion of the international search	Date of mailing of the international search report
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Name and mailing address of the ISA	Authorized officer
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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A	EP 0 128 103 A (BIO STIMU TREND CORP) 12 December 1984 see page 2, line 10 - page 3, line 11; figures	1,3
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