

(19) World Intellectual Property Organization  
International Bureau



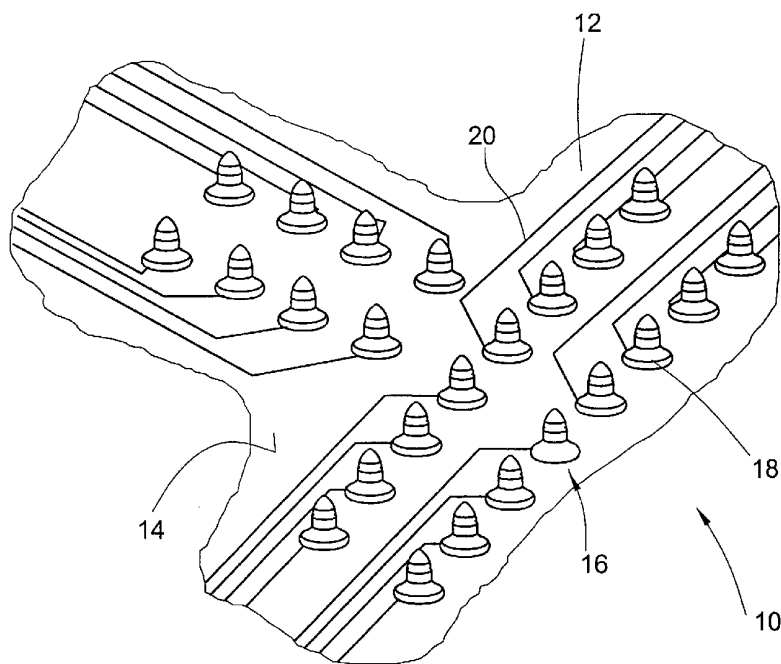
(43) International Publication Date  
10 May 2002 (10.05.2002)

PCT

(10) International Publication Number  
**WO 02/36002 A1**

- (51) International Patent Classification<sup>7</sup>: **A61B 5/04778**, 5/0408, A61N 1/04 (74) Agents: **HILLERINGMANN, Jochen** et al.; Deichmannhaus, Bahnhofsvorplatz 1, 50667 Köln (DE).
- (21) International Application Number: PCT/EP00/10775 (81) Designated States (*national*): CA, JP, SG, US.
- (22) International Filing Date: 1 November 2000 (01.11.2000) (84) Designated States (*regional*): European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).
- (25) Filing Language: English (84) Designated States (*regional*): European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).
- (26) Publication Language: English Published: — with international search report
- (71) Applicant (*for all designated States except US*): **3M INNOVATIVE PROPERTIES COMPANY** [US/US]; O.I.P.C., 3M Center, P.O. 33427, Saint Paul, MN 55133-3427 (US). *For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*
- (72) Inventor; and (75) Inventor/Applicant (*for US only*): **SIEBURG, Willi** [DE/DE]; Auengrund 14, 22113 Oststeinbek (DE).

(54) Title: ELECTRICAL SENSING AND/OR SIGNAL APPLICATION DEVICE



(57) Abstract: The electrical signal sensing and/or signal application device for sensing electrical signals on a surface and/or for applying electrical signals to a surface, particularly of human or animal skin or other organs or tissues, comprises a substrate (12) having first and second major surfaces (14), and a plurality of electrodes (16) arranged on the first major surface (14) of the substrate (12) and projecting therefrom, each of the electrodes (16) comprising a pointed contact end (36) facing away from the substrate (12) for contacting the surface, and a base end (26) facing towards the substrate (12). On the first or second or both major surfaces (14) of the substrate (12) there is arranged a plurality of first contact pads (22) for electrical connection to contact elements of an evaluation and/or driving means for evaluating the sensed electric signals and/or applying signals to the electrodes (16), the first contact pads (22) being electrically

connected to the electrodes (16). The first major surface (14) of the substrate (12) comprises, for each electrode (16), a second contact pad (18) the base ends (26) of the electrodes electrically and mechanically connected to the second contact pads (18). Each electrode (18) is generated by bonding an electrically conductive bonding wire to a second contact pad (18) for generating a thickened socket portion (24) of the electrode comprising its base end (26), and by tearing the bonded bonding wire off the socket portion (24) so as to generate a pointed portion (34) of the electrode (16) comprising its pointed contact end (36) and projecting from the socket portion (24) thereof.



WO 02/36002 A1

5

**Electrical sensing and/or signal application device****Field of the Invention**

10 The invention relates to an electrical signal sensing and/or signal application device for sensing electrical signals on a surface and/or for applying an electrical signal to a surface. Such a device in particular is used for sensing electrical signals on and/or for applying electrical to human or animal skin and most preferably are used in therapy and diagnostic methods. For example a signal sensing device can be used to record impedances or other  
15 electrical images of tissues and other components or objects to which the sensing device can be electrically attached. On the other side the device can be used to apply electric current or voltage for stimulating tissues or other components or objects.

20 Moreover, the invention relates to a method for manufacturing a device as described above. Finally, the invention also relates to the use of such a device for therapy and diagnostic methods.

**Background of the Invention**

25

Medical diagnosis is utilizing diverse approaches of obtaining images of humans and animals such as X-ray, computer tomography, nuclear-spin-resonance and ultrasonics. The straight forward photography is of lesser importance as it merely records the external appearance of skin portions of  
30 humans and animals while the other methods present specific views especially of the inner portions of the body which are more suitable for the diagnosis.

- 2 -

More recently the recording of impedance and other electrical images was developed. The use of single electrodes including the independent handling of several electrodes for the recording of the electrical properties such as the impedance typically as a function of time is well known for many decades, especially in the fields of electro-cardiography (ECG or EKG) and electro-encephalography (EEG). In these cases typically the individual electrodes are attached to the skin by some means such as suction devices or adhesives. Furthermore, these electrodes are provided with a relatively large surface having the order of magnitude of about 1 sq. cm which consists of metals, conductive gels or conductive adhesives. Typically the electrical properties are recorded as a function of time. However, the recent developments utilizes arrays of these electrodes where each of them records the electrical properties such as the impedance or conductivity in a manner that all these values are simultaneously recorded and for example brought onto a display like a monitor. This then provides images yielding information which is significantly different from the images of the other diagnostic methods as stated above. The known specific configurations will be referred to in more detail below.

A particular area of interest is the diagnosis of cancer where it is of interest to investigate the skin primarily related to breast cancer and skin cancer. The article "Overview of Skin Cancer Detection and Prevention for the Primary Care Physician" by A.J. Bruce et al. of the Mayo Clin. Proc. 2000; 75; 491-500 describes the diagnostic possibilities for a primary evaluation of the skin with respect to the detection of specific cancers. This article states that the initial visual inspection by the physician is a meaningful first step in order to decide whether or not further investigations will be necessary. However, it is desirable after the immediate first visual inspection to develop another rather simple method for identifying whether or not cancer can be diagnosed.

WO-A-97/47235 provides a method of a dermal diagnostic analysis through the use of a digital camera which allows a somewhat more sophisticated approach through the recording of the critical portions of the skin.

5 WO-A-98/09155 shows a step further, it includes to apply a chemical to the critical skin area and after several hours this area is illuminated with ultraviolet light and the fluorescent irradiation can be recorded through picturing spectroscopy. This allows to identify cancerous portions of the skin. This method, however, is time consuming and cumbersome and still  
10 requires additional diagnostic methods in most of the cases.

A number of possibilities have become known which utilize the determination of the electrical properties of the skin.

15 US-A-5,928,159 describes an apparatus and methods utilizing a probe provided with several electrodes which is applied to a skin portion that might be cancerous and the electrical data of these portions are recorded in comparison with a normal neighbour portion of skin.

20 US-A-5,143,079 describes an apparatus for the detection of tumors in tissues. It utilizes a probe with a fixed arrangement of electrodes, e.g. 64 elements arranged in an 8x8 array. These electrodes have a hexagonal form, the electrodes being of gold plated printed copper for example. The hexagons typically have sides of 10 mm. These electrodes by themselves  
25 are still rather large so that only a fairly small number of them can be utilized in the probe and, therefore, a real image cannot be generated.

A further development is described in US-A-5,810,742 and the article "T-SCAN™ as a Diagnostic Tool for Breast Cancer" by M. Assenheimer et al.  
30 accessible in the Internet through [www.transscan.co.il/publication1.html](http://www.transscan.co.il/publication1.html). The described systems have a fairly large number of individual electrodes allowing to generate an image of having a reasonable resolution. The

- 4 -

electrodes described are typically in a rectangular array with a multiplicity of wells which are separated by dividers consisting of insulating material. These wells are filled with a hydro-gel or conductive gel and the wells themselves are provided with a metal electrode which projects to the  
5 portion below the electrode so that the entire configuration can be applied onto a printed circuit board (PCB) which has a corresponding array of electrodes. In this manner a discardable article is generated. This is of importance as for well known reasons it is not advisable to use electrode configurations for more than a single patient. The PCB as such has an array  
10 of conductive paths which are guided to a multi-pin connector which then is connected through a cable to the evaluation computer which is capable of recording the electrical characteristics of each individual electrode so that the desired image can be generated in the computer and displayed on the monitor. The use of wells filled with a conductive gel has the disadvantage  
15 of being difficult to manufacture thus being expensive which is critical for such a discardable article. Furthermore, the spacing between these wells is limited which reduces the resolution of the desired image. This is of particular importance as critical skin portions which might be cancerous only have dimensions of a few millimeters and, therefore, for obtaining a good  
20 resolution pitches of the wells in the order of several tenths of a millimeter are required.

The use of multiple electrodes or arrays of electrodes is well known and described in a large number of publications.

25

US-A-3,490,439 describes an assembly of electrodes used for electroencephalography. The electrodes as such are small foam balls coated with a conductive cloth piece.

30

US-A-5,452,718 presents an electrode configuration in which a conductive material having a tip is embedded in a plastic ferrule.

US-A-3,896,790 relates to a brain wave sensor in which a single electrode is used which consists of several prongs which ensure a good electrical contact, even in the presence of hair.

5 In the above cited references all these electrodes essentially are still separate from each other. Configurations are also known in which a multiplicity of electrodes is arranged in a fixed mutual configuration. This is described for example in US-A-5,184,620, US-A-4,353,372 and US-A-6,055,448. In all these cases the electrodes are embedded into a common  
10 carrier, however, they are still used for the typical ECG or EEG application which means that despite their fixed spacial relationship they are individually used and usually only their time dependence is recorded.

In all electrodes and electrode arrays described above configurations are  
15 shown in which the electrodes themselves have a relatively large surface and they are typically directly applied to the outer surface of the skin. There are alternative methods of utilizing electrodes which essentially consist of individual needles. These needles operate in a somewhat different manner. If properly applied they allow to penetrate the outermost portion of the skin  
20 and provide a more valuable determination of the electrical properties which for the recording of the image appears to be advantageous.

A needle electrode is described in US-A-5,482,038 where an individual sharp  
25 needle is inserted into a special holding device which allows to establish a defined pressure. Needles of this type are used for example in neurological examinations using an electro-myograph (EMG).

Similar configurations can be taken from the references US-A-5,509,822  
and EP-A-0 533 487 which are either used for electro-myography or for  
30 electro-cardiography. These needles are either a multiplicity of several components that are handled independently but connected to a common monitoring system or configurations in which a pair of needles is used.

EP-A-0 538 739 describes an array of needles, the number ranging between 50 and 150. These needles are brought into a common plastic holder. The needles themselves have a solid configuration with a relatively sharp pin similar to those used in acupuncture. Each needle is provided with a spring  
5 allowing to apply all needles with a given pressure. The array is a pre-determined geometrical configuration typically having an overall circular circumference. The data, however, are collected individually from each electrode and utilized in some kind of a statistical evaluation. There is no intention to record an image. Furthermore, the reference is silent with  
10 respect to the establishment of the electrical contacts between these needles and the cable leading to the electronic evaluation unit.

DE-U-92 18 879 relates to an array of electrodes for the determination of the distribution of electrical potentials on the skin of a patient. It shows  
15 multiplicities of electrodes for the above described purpose and the object of this reference is to replace this multiplicity of electrodes by a foil having semi-conductive layers which is scanned for example by a laser beam causing a temporary conductivity of a small portion of the foil thus replacing a multiplicity of electrodes by such a foil which is scanned through point by  
20 point. No reference is made at all to the type of electrode configurations used.

DE-U-85 02 291 describes arrays of needle electrodes for biomedical applications where each electrode is individually connected to a cable so  
25 that a multiplicity of signals can be recorded. No reference is made to the possibility of recording an electrical image.

WO-A-78/07825 describes an electrode and the related method of manufacture. A base carrier contains an arrangement of conducting  
30 protuberances arising from the base serving as the electrodes. These electrodes are individually connected to an electrical path that is leading to an array of contact areas which allow to transfer the signal to a recording

unit. The protuberances or needles have the shape of cones. These cones are grown on a multi-layer configuration and typically have dimensions up to 25 microns. This means that they are relatively small and their primary use is in the area of neurology. The needles allow to penetrate the surface of the tissue to be diagnosed.

US-A-5,215,088 describes a three-dimensional multi-electrode device especially useful as a neuron interface. The electrodes are electrically isolated from each other, the signals are typically transmitted using a multiplexing circuitry. The needles typically consist of semi-conductive material on the basis of silicon. In a block of such material sequences of cuts are obtained using a saw utilized in the microelectronic industry. This is performed in two directions so that an array of pins is obtained having a rectangular or square cross-section. In a subsequent etching process material is taken away from the upper portions of these columns so that they obtain a needle-like form. This is particularly suitable for neuron-type applications e.g. a prosthesis for a blind person. The process is rather complicated and thus expensive, needle arrays of this configuration do not appear to be suitable as single use throw-away articles because of the high cost.

Arrays of needles as electrodes require to bring them into a defined array by simultaneously electrically isolating them from each other. For instance this could be performed by bringing a multiplicity of contact pins into a plastic body, for example through an injection molding or casting method. The use of these techniques, however, is cumbersome and not very cost effective which is critical for an article that preferably should be discardable. The problem becomes even more critical when moving in the direction of smaller pitches, for example well below 1 mm. The handling of individual needles or pins will be increasingly difficult thus resulting in unacceptably high manufacturing cost.



Arrays of needles or needle-like configurations are of primary interest for the medical diagnosis and therapy of the skin or other organs and tissues of humans and animals. Such an array of electrodes, however, might also be useful for other configurations whenever it is possible to establish electrical contact with the component to be investigated and when the determination of an impedance or electrical image provides meaningful information. This typically applies to components which do not have a hard outer surface because in this case only individual electrodes would establish an electrical contact. Therefore, components of interest are typically softer on their surface like elastomeric and similar components.

### **Summary of the Invention**

Accordingly, there is a need for an electrical signal sensing and/or signal application device for sensing electrical signals on a surface and/or for applying electrical signals to a surface, particular human or animal skin or other organs or tissues which device is provided with an array of electrodes which can be reliably manufactured with a very small pitch in a cost efficient manner.

In a first aspect of the invention there is provided an electrical signal sensing and/or signal application device for sensing electrical signals on a surface and/or for applying electrical signals to a surface, particularly of human or animal skin or other organs or tissues, wherein the device comprises

- a substrate having first and second major surfaces,
- a plurality of electrodes arranged on the first major surface of the substrate and projecting therefrom, each of the electrodes comprising a pointed contact end facing away from the substrate for contacting the surface, and a base end facing towards the substrate, and
- a plurality of first contact pads arranged on said first or second or both major surfaces of said substrate for electrical connection to contact

elements of an evaluation and/or driving means for evaluating the sensed electric signals and/or applying signals to said electrodes, said first contact pads being electrically connected to said electrodes,

- wherein said first major surface of said substrate comprises, for each electrode, a second contact pad said base ends of said electrodes being electrically and mechanically connected to said second contact pads, and

- wherein each electrode is generated by bonding an electrically conductive bonding wire to a second contact pad for generating a thickened socket portion of said electrode comprising its base end, and by tearing the bonded bonding wire off the socket portion so as to generate a pointed portion of said electrode comprising its pointed contact end and projecting from the socket portion thereof.

15 On the first or second or both major surface of the substrate there is arranged a plurality of first contact pads for electrical connection to contact elements of an evaluation and/or driving means for evaluating the sensed electric signals and/or applying signals to the electrodes, the first contact pads being electrically connected to the electrodes.

20 The first major surface of the substrate comprises, for each electrode, a second contact pad the base ends of the electrodes electrically and mechanically connected to the second contact pads.

25 Each electrode is generated by bonding an electrically conductive bonding wire to a second contact pad for generating a thickened socket portion of the electrode comprising its base end, and by tearing the bonded bonding wire off the socket portion so as to generate a pointed portion of the electrode comprising its pointed contact end and projecting from the socket  
30 portion thereof.

- 10 -

According to the invention, for the electrodes it is suggested to utilize a technology which is known from the electronic industry, namely to use so-called ball bumps. Electronic chips and especially flip chips are provided with external contact areas which by some means have to be connected to a printed circuit board (PCB) and one way to achieve this is to utilize these ball bumps. These are generated from extremely thin wires consisting of gold or gold alloys that have a diameter below 50 microns, typically 25 microns. Through the use of a special equipment the ends of these wires are pressed on one of the components to be connected, either the contact area in the chip or the corresponding contact area in the PCB. Heat is applied electrically sufficient to deform the end of the thin wire and establish a mechanical and electrical connection. Subsequently the wire is torn apart which creates a needle-like pointed configuration. After having provided all contact areas with these ball bumps the other component, either the flip chip or the PCB, is then pressed onto the arrangement of the bumps. This pressure is so high that the needle-like tips of the bumps are deformed so that also an electrical and mechanical connection is established. Needle-like configurations are not considered to be ideal and there are approaches where it is attempted to avoid them or at least flatten them.

20

In contrary to the use of ball bumps in the electronic industry it is now suggested to take advantage of the needle-like pointed tips of the ball bumps. In the invention these bumps are created in exactly the same manner as for the application in the electronic industry and in particular are thermally or ultrasonically or both bonded to second contact pads of a flexible or rigid substrate. By this procedure an electrode in the form of a so-called ball bump is generated on a second contact pad of the substrate wherein the ball bump electrode comprises a thickened socket portion comprising the base end for electrically and mechanically contacting the second contact pad and a needle-like pointed portion comprising the pointed contact end of the electrode projecting from the socket portion. In the invention, the ball bumps are applied to e.g. a (rigid) printed circuit board or

30

- 11 -

flexible circuit (i.e. the substrate) that has a pre-determined array of conductive paths or traces whereby, however, the board or carrier could be any other configuration that includes these paths. The bumps are attached to the end areas of these conductive paths and it is ensured that the  
5 pointed configuration is created without deformation for flattening them which in this case is a desired feature. It is advantageous to increase the size of the ball bumps which, however, depends on the practical application.

The substrate with the conductive paths may be mechanically relatively  
10 unstable. For example it could consist of a flexible circuit, i.e. of a flexible layer having electrically conductive traces and pads on it and may also comprise electric or electronic components for some reason. Therefore, it is advantageous to provide the system with additional mechanical stability and, for example, the substrate of the conductive traces with the ball bumps  
15 applied onto could be supported by a plate which is appropriately attached to it providing the necessary mechanical stability. The plate can consist of plastic or metal provided that the electrical circuits are not irritated. Instead of a plate also a completely solid component preferably consisting of plastic could be used.

20 The substrate can be rigid (e.g. PCB), flexible (e.g. flexible circuit layer) or a ceramic material. The conductive traces or paths may extend over the surface of or through the substrate or both. In case that the electrodes and the contact pads for connecting the substrate to a processing device are on  
25 different major surfaces of the substrate, the contact pads most preferably are aligned or flush with the electrodes wherein the conductive paths directly extend through the substrate.

In another configuration a hand-held device could be used which comprises  
30 a handle that is provided at its distal end with an array of electrical contacts which for example could be a ball grid array (BGA). The handle at the other end is provided with the cable which is electrically connected to the contact

array, the cable guiding the electrical information onto the evaluation unit consisting of a computer and a display.

5 Preferably, a discardable unit is created. This unit includes the configuration with the conductive traces like a PCB onto which the ball bumps are attached with means for providing the sufficient mechanical stability and contact means for the electrical and mechanical connection to a processing unit. This is particularly useful for the typical applications in the medical field where it is strongly advised to use such an electrode array for a single  
10 patient only. Therefore the discardable portion should only contain the absolute minimum of components to fulfil the task.

In another aspect of the invention there is provided a method for manufacturing an electrical signal sensing and/or signal application device  
15 for sensing electrical signals to a surface and/or for applying an electrical signal to a surface, particularly of human and animal skin or other organs or tissues, the method comprising the steps of

- providing a substrate having first and second major surfaces,
- forming first and second contact pads on the first or the second or both  
20 major surfaces of the substrate,
- providing electrically conductive traces at the substrate for electrically connecting the first and second contact pads,
- forming protruding electrodes onto the second contact pads by bonding a bonding wire to each of the second contact pads for generating a  
25 socket portion of the respective electrode bonded to the second contact pad, and by tearing the bonded bonding wire off the respective socket portion so as to generate pointed portions of the electrodes protruding from the socket portions thereof.

30 According to a third aspect of the invention the device as described above is used for biomedical applications, in particular for dermal diagnostic and for sensing and/or stimulating biologic tissue or organs or cells.

According to the invention there are provided an array of pointed electrodes and a method of producing the same which are electrically insulated with respect to each other and which simultaneously are connected to conductive traces of a substrate such as a printed circuit board or a flexible circuit, whereby the manufacture of such an electrode array including the connection means can be achieved in a cost efficient manner.

### **Brief Description of the drawing**

10

The invention will be described in more detail referring to the drawing in which

15

Fig. 1 is a plan view onto a substrate having an array of ball bump electrodes according to a first embodiment of the invention,

Fig. 2 is a perspective view of a portion of the ball bump electrode array according to Fig. 1,

20

Fig. 3 is a perspective view onto a ball bump like electrode on a larger scale for illustrating the overall shape of the electrode,

Fig. 4 is a elevational view of the electrode of Fig. 3,

25

Fig. 5 shows an second embodiment of the device according to the invention,

Fig. 6 shows an alternative embodiment of a device according to the invention,

30

Fig. 7 shows a further embodiment of the device of the invention, and

Fig. 8 shows still another alternative embodiment according to the invention.

### **Detailed description of preferred embodiments**

5 Figure 1 shows a device 10 according to the invention and represents a view onto a circuit substrate 12 which can be a solid printed circuit board or a flexible circuitry. On one of the major surfaces 14 of the substrate 12 an array of e.g. 8x8 electrodes 16 and electrode contact pads 18 of the substrate 12 can be identified, each of them being connected with its own  
10 conductive trace 20. It is to be noted that an array of 8x8 electrodes is just a specific example and that it is advantageous and desirable to increase the number of electrodes to, for example, 16x16 corresponding to 256 individual electrodes. Even a higher number could be used. This is possible and also realistic in view of the low manufacturing cost when using the  
15 technology as suggested in the invention. The electrodes 16 as such are provided as so-called ball bumps as described hereinbelow and used in the micro-electronic industry for connecting chips using the flip chip technology.

In Figure 2 a perspective view of a part of the electrode array on a larger  
20 scale is shown. Each conductive trace 20 leads to a first contact pad 22 (see Figure 1) which by some connection means is connectable to an electronic device for generating and evaluating electrical signals to be applied to or sensed by the individual electrodes 16. These electrical signals can represent impedances, currents, voltages, potentials, AC or DC or impulse  
25 signals. The connection means can comprise a ball grid array (BGA), a land grid array (LGA) or contact pins and the like.

Figures 3 and 4 show in more detail the design and construction of a ball bump electrode 16. This electrode 16 comprises a thickened socket portion  
30 24 having a base end 26 for electrically and mechanically connecting the socket portion 24 to an electrode contact pad 18. The shape of the socket portion 24 looks like a flattened ball having a rounded periphery 28, wherein

- 15 -

the lower side 30 of the socket portion 24 being flat so as to contact the second contact pad 18. In the middle from the upper side 32 of the socket portion 24 there protrudes a pointed portion 34 having a pointed end 36. This pointed portion 34 contacts the surface (human or animal skin or organ  
5 or tissue or cell) to be measured or investigated.

It is to be noted that Figures 3 and 4 schematically show the ball bump which as of yet is used in the flip chip technology for connecting chips to a circuitry layer with the structured side of the chip facing the circuitry layer.  
10 In particular the pointed portion 34 can be longer and more needle-like or sharper or both than depicted. The related technology for generating such bumps and the typical use is described in a number of articles, for example "Flip Chip Attachment Using Mechanical Bumps" by J. Eldring et al., 1994, ITAP & Flip Chip Proceedings, pages 74-81, "Flip Chip Attachment Using  
15 Non-Conductive Adhesives and Gold Ball Bumps" by R. Aschenbrenner et al. from the Technische Universität Berlin, Forschungsschwerpunkt Technologien der Mikroperipherik, TIB 4/2-1, or "Single Chip Bumping" by Matthias Klein et al., Technical University of Berlin, Center of Microperipheric Technologies. The latter article describes the typical technology in more  
20 detail. Thin wires of Au98Pd for example, with diameters between 18 and 33 micrometers are grabbed by a wire clamp and pressed on the contact area to be connected. These contact areas can either be located on the flip chip or the component comprising the conductive paths such as a PCB. This can be done utilizing a conventional ball-wedge bumping process, namely a wire  
25 bonder, for example available from F&K Delvotech Bondtechnik GmbH, Germany. The wire is passed through a capillary tube which forms the wire clamp and an electrical discharge is applied which forms a ball establishing the electrical and mechanical connection to the contact area to be connected. This is identical to the well known wire bonding technique. In a  
30 second step, however, the wire is torn off whereby it is ensured that this rupture occurs within the heat effective zone where the grain structure of the wire is coarser compared to the non-affected state. The rupture causes



- 16 -

a lengthening of the wire with a significant simultaneous reduction of its diameter until it becomes so thin that it ruptures. In this way a pointed configuration is obtained which actually for the intended purpose of the electrical connection is undesirable.

5

The effect of such a process can be seen from Figure 3 which shows a perspective view of such a mechanically applied gold stud bump on an aluminium pad. Figure 4 shows a cross-sectional view showing the typical dimensions. The overall diameter  $D$  of the ball bump ranges between 40 and 105 microns. The actual contact area  $B$  (base end 26) on the contact pad 18 to be contacted is typically 80 percent of the dimension  $D$ . The height  $h$  of the socket portion 24 as shown in Figure 4 typically ranges between 12 and 65 microns. The height  $H$  is about 10 microns larger. The overall height  $h'$  of the ball bump typically corresponds to the diameter  $D$  of the entire ball bump. In this application heights of 100-200 microns are advantageous for an optimum penetration of the pointed portion 34 and the pointed end 36 into the skin. Namely, the outermost portion of the skin typically has a thickness of around 100 microns which should be penetrated to establish a good electrical contact. The actual pointed end 36 occurs in the upper part, namely in that part of the overall height  $h'$  that exceeds  $H$ . The dimension  $b$  is around half to  $1/3$  of the height  $h$  of the socket portion 24. The above mentioned article refers to specific details of the ball bump in flip chip technology application. For example it has been shown that the connection to the contact pad 18 is sufficiently stable. Shear values in the area of 43-60 cN/bump have been observed. Alternative alloys are PbSn<sub>2</sub>, PbSn<sub>61</sub>, and SnAg<sub>3</sub> and relatively pure gold itself.

30

Figure 5 shows another embodiment of the device according to the invention. This embodiment is rather similar to that of Figures 1 and 2. The difference between these embodiments can be seen in the fact that in the embodiment of Figure 5 the conductive traces 20 extend through the substrate 12 in the thickness direction thereof with the end surfaces of the

- 17 -

conductive traces 20 laying in the first and second major surfaces 14 of the substrate 12 forming the second contact pads 18 and the first contact pads 22.

5 Figure 6 shows an alternative embodiment having is a configuration that in principle is similar to the one depicted in Figures 1 and 2, however, arranged in a non-flat configuration. Also here ball bump electrodes 16 have been applied to contact pads of the flexible substrate 12. The substrate 12 is supported by a metal 38 stiffener which is arranged so that the  
10 conductive traces 20 cannot be irritated as they are on the side 14 of the substrate 12 facing away from the metal stiffener 38. The contact area with the contact pads 22 can be a zebra strip, a ball grid array (BGA), or a land grid array (LGA) 40.

15 Figure 7 shows an embodiment which is very similar to the one shown in Figure 6 with the essential difference that instead of providing a metal plate as a stiffener a plastic body 42 is applied which is solid in itself the whole system, however, being essentially identical to the one shown in Figure 6.

20 Figure 8 shows an alternative embodiment in which the component with the ball bump electrodes 16 is configured in a way to be discardable. The ball bump electrodes 16 are applied to a flexible circuit layer substrate 12 having BGA or LGA contact areas 44. The substrate 12 is fixed onto a plastic or metal support part 46. The discardable component 48 can be attached to a  
25 hand-held device 50. Accordingly this device 50 has to comprise mechanical features like snapping means and the like (not shown) which allow to fix the discardable component 48 onto the hand-held device 50 keeping it in a position stable enough for the intended evaluation such as the generation of an electrical or impedance image of a skin portion of a patient. The hand-  
30 held device 50 includes the handle 52 as such which can be of a pistol type. Furthermore, it includes a cable 54 connected to the connecting means 56 of the hand-held device 50 for connection to the BGA or LGA contact areas

44 of the discardable component 48. At its other end (not shown) the cable 54 is connected or connectable to an evaluation unit, typically a computer and a display unit.

**CLAIMS**

1. An electrical signal sensing and/or signal application device for sensing electrical signals on a surface and/or for applying electrical signals to a surface, particularly of human or animal skin or other biological organs or tissues, comprising
  - a substrate (12) having first and second major surfaces (14),
  - a plurality of electrodes (16) arranged on the first major surface (14) of said substrate (12) and projecting therefrom, each of said electrodes (16) comprising a pointed contact end (36) facing away from said substrate (12) for contacting the surface, and a base end (26) facing towards said substrate (12), and
  - a plurality of first contact pads (22) arranged on said first or second or both major surfaces (14) of said substrate (12) for electrical connection to contact elements of an evaluation and/or driving means for evaluating the sensed electric signals and/or applying signals to said electrodes (16), said first contact pads (22) being electrically connected to said electrodes (16),
  - wherein said first major surface (14) of said substrate (12) comprises, for each electrode (16), a second contact pad (18) said base ends (26) of said electrodes being electrically and mechanically connected to said second contact pads (18), and
  - wherein each electrode (16) is generated by bonding an electrically conductive bonding wire to a second contact pad (18) for generating a thickened socket portion (24) of said electrode comprising its base end (26), and by tearing the bonded bonding wire off the socket portion (24) so as to generate a pointed portion (34) of said electrode (16) comprising its pointed contact end (36) and projecting from the socket portion (24) thereof.
  
2. The electrical signal sensing and/or signal application device according to claim 1, wherein said substrate (12) is flexible.

- 20 -

3. The electrical signal sensing and/or signal application device according to claim 1, wherein said substrate (12) is rigid.
4. The electrical signal sensing and/or signal application device according to any one of claims 1 to 3, wherein said second contact pads (18) are electrically connected to the first contact pads (18) of said substrate (12) via electrically conductive traces (20) arranged on said substrate (12).
5. The electrical signal sensing and/or signal application device according to any one of claims 1 to 3, wherein said first contact pads (22) are arranged on said second major surface of said substrate (12) and flush with the second contact pads (18) and are electrically connected to said second contact pads (18) by conductor portions extending through said substrate (12).
6. The electrical signal sensing and/or signal application device according to any one of claims 1 to 5, wherein said socket portions (24) of said electrodes (16) are connected to said electrode contact pads (18) by thermal bonding or ultrasonic bonding or both.
7. A method for manufacturing an electrical signal sensing and/or signal application device for sensing electrical signals to a surface and/or for applying an electrical signal to a surface, particularly of human or animal skin or other biological organs or tissues, said method comprising the steps of
  - providing a substrate (12) having first and second major surfaces (14),
  - forming first and second contact pads (22,18) on said first or said second or both major surface (14) of said substrate (12),

- 21 -

- providing electrically conductive traces (20) at said substrate (12) for electrically connecting said first and second contact pads (22,18),
  - forming protruding electrodes (16) onto said second contact pads (18) by bonding a bonding wire to each of said second contact pads (18) for generating a socket portion (24) of the respective electrode (16) bonded to said second contact pad (18), and by tearing said bonded bonding wire off said respective socket portion (24) so as to generate pointed portions (34) of said electrodes (16) protruding from said socket portions (24) thereof.
8. The method according to claim 7, wherein said bonding wire is thermally bonded or ultrasonically bonded or both to said second contact pads (18) of said substrate (12).
9. Use of the device of any one of claims 1 to 6 or the device manufactured according to claim 7 or 8 for biomedical applications, in particular for dermal diagnostic and for sensing and/or stimulating biological tissue or organs or cells.

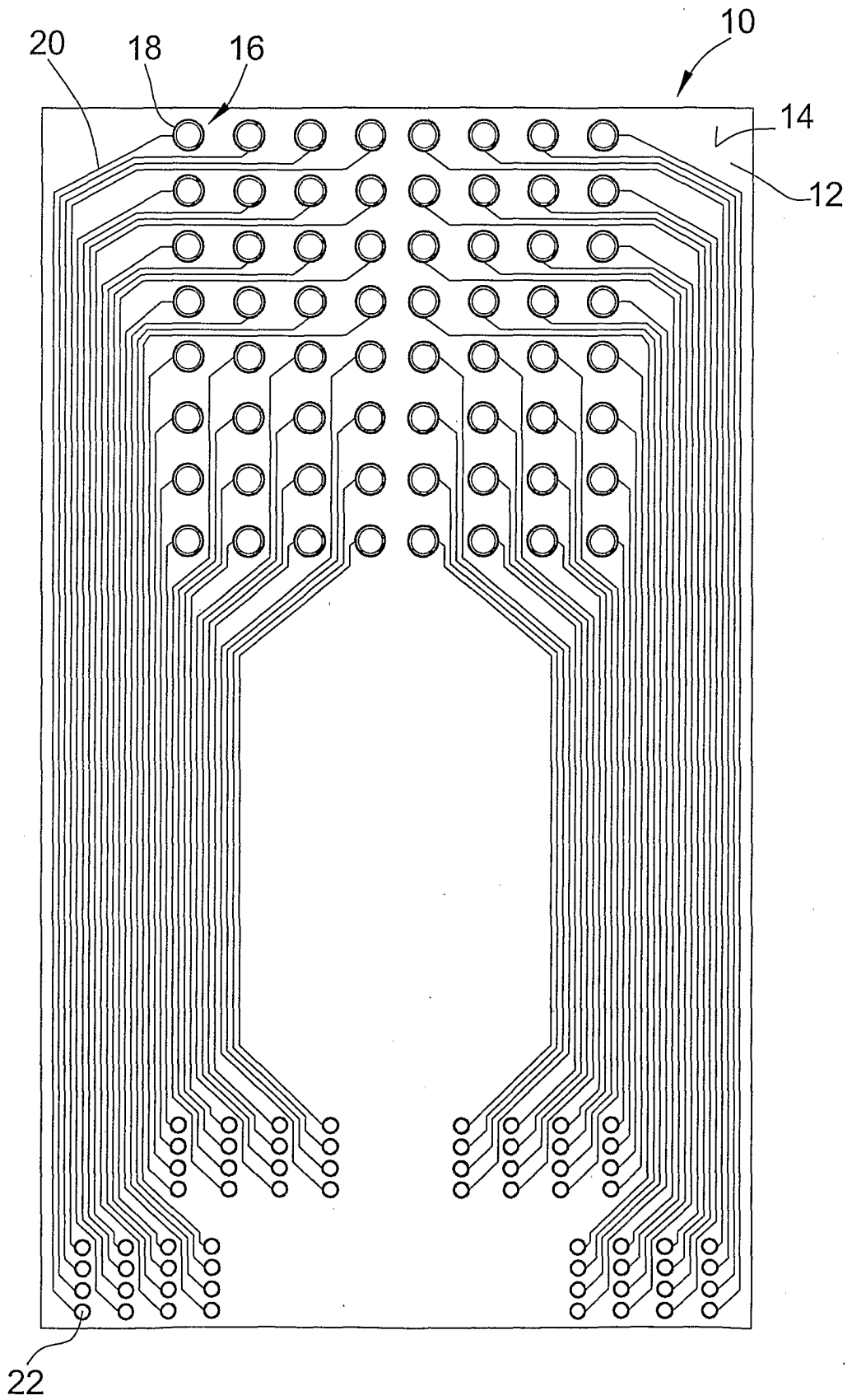


FIG.1

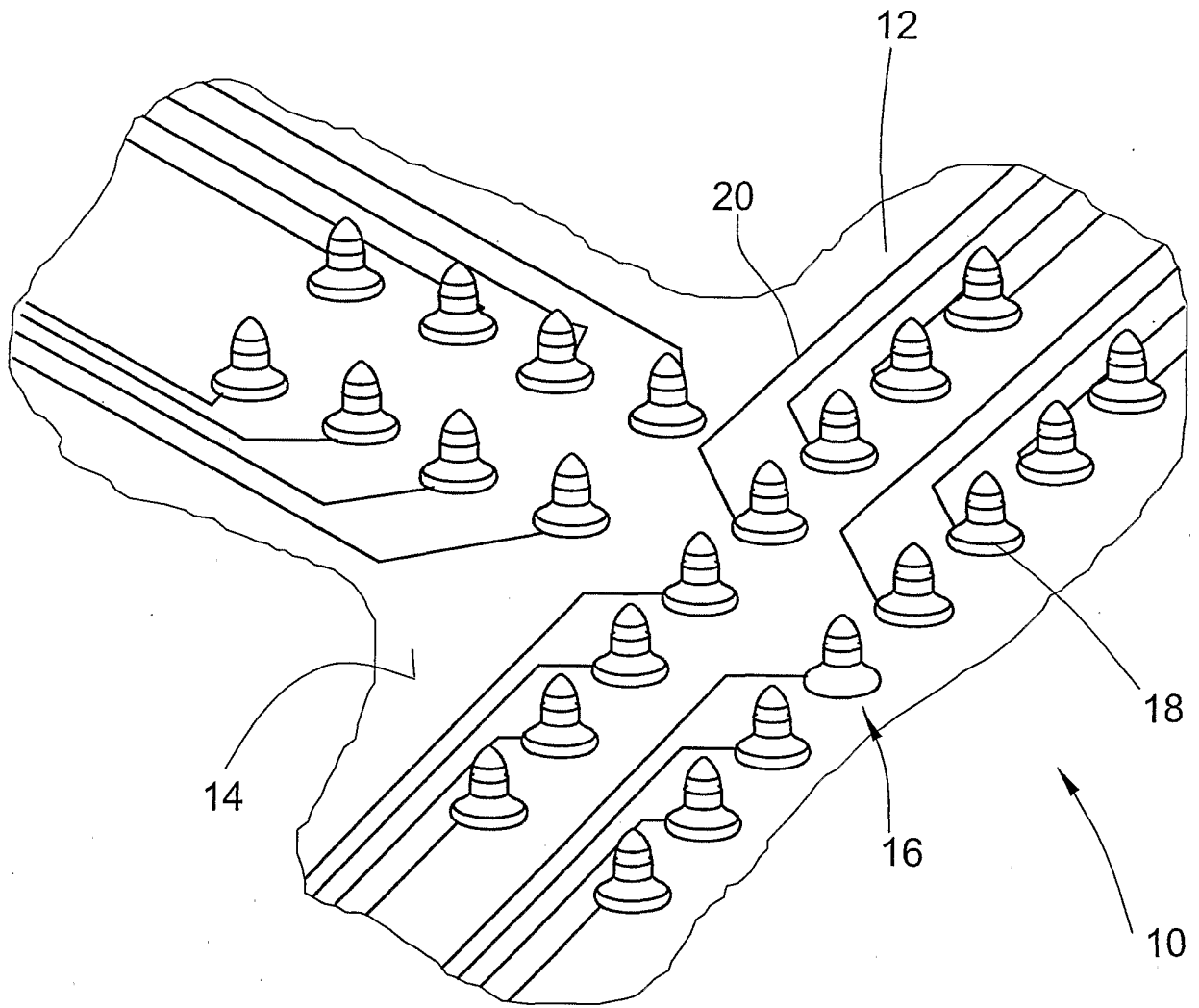


FIG.2



- 3/6 - 16

FIG.3

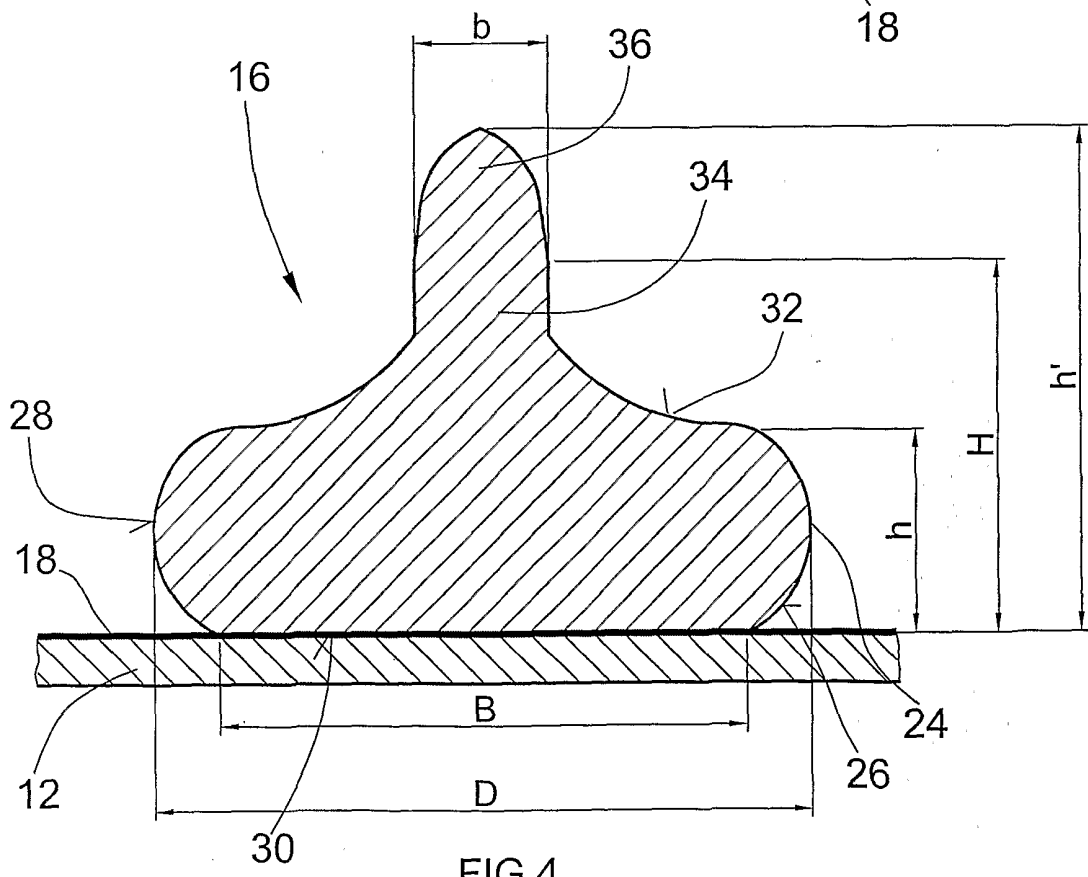
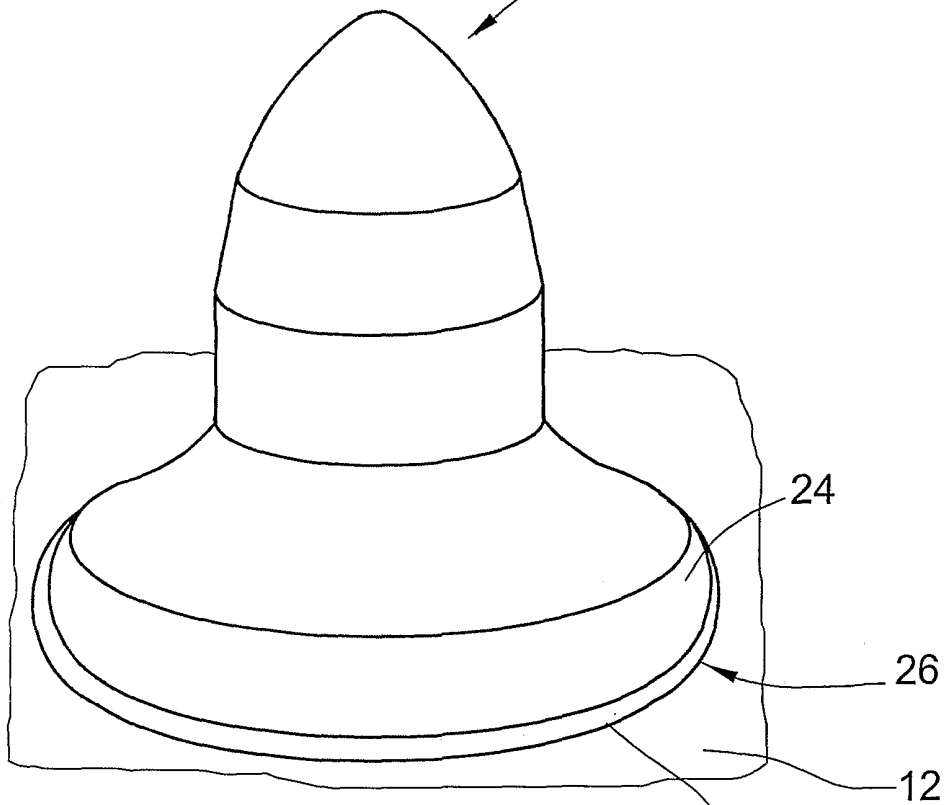


FIG.4

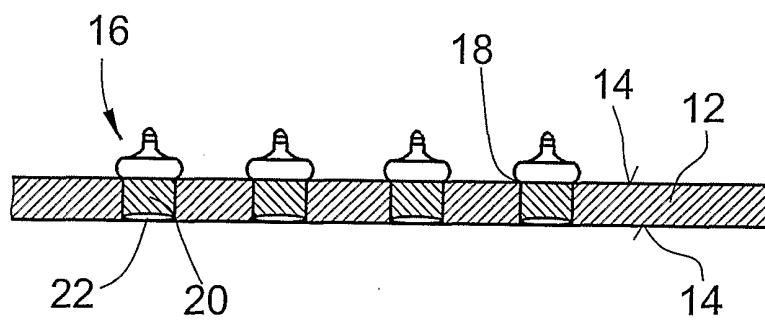


FIG.5

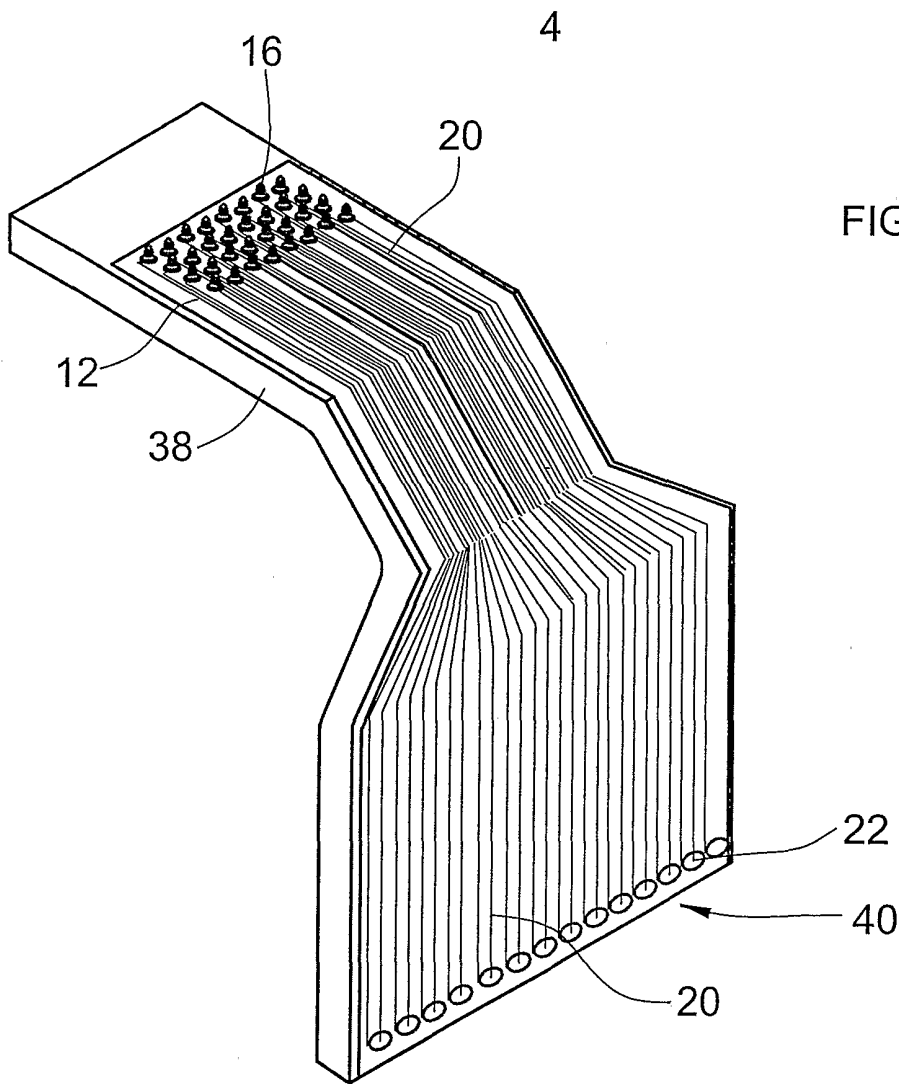


FIG. 6

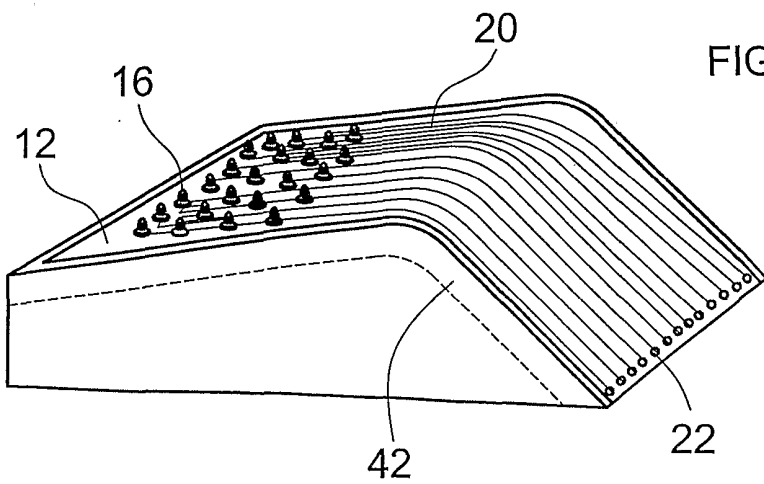


FIG. 7

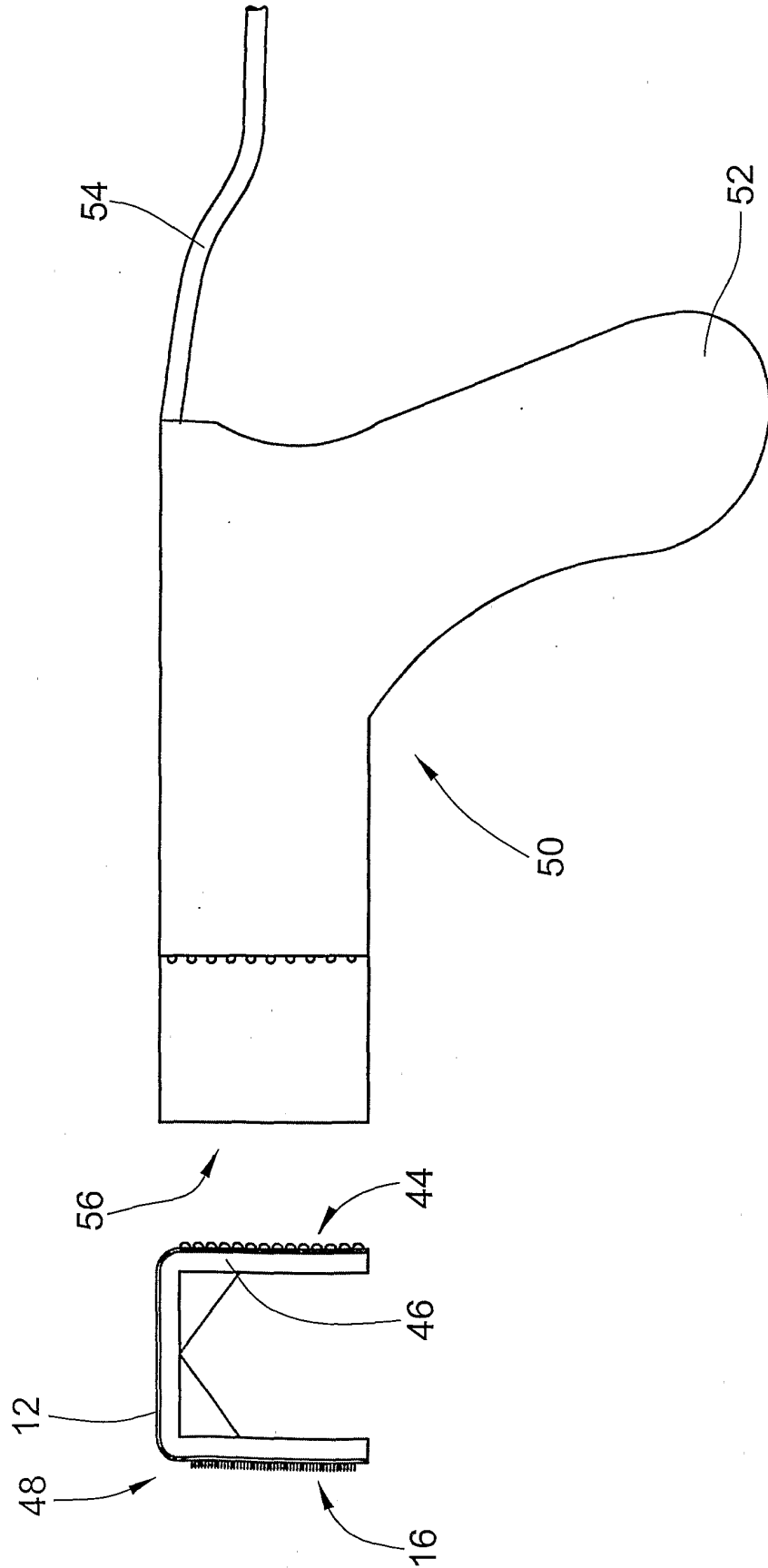


FIG.8

INTERNATIONAL SEARCH REPORT

International Application No  
PCT/EP 00/10775

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61B5/0478 A61B5/0408 A61N1/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61B A61N

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6 128 521 A (PHYSIOMETRIX) 3 October 2000 (2000-10-03) column 7, line 20 -column 9, line 4 ---	1-9
Y	US 5 928 458 A (FRAUNHOFER) 27 July 1999 (1999-07-27) column 2, line 51 -column 3, line 19; figures 2A,3A -----	1-9

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*&\* document member of the same patent family

Date of the actual completion of the international search

29 June 2001

Date of mailing of the international search report

05/07/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Lemercier, D

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP 00/10775

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6128521 A	03-10-2000	AU 5095399 A EP 1096878 A WO 0002484 A	01-02-2000 09-05-2001 20-01-2000
US 5928458 A	27-07-1999	WO 9605614 A EP 0803132 A	22-02-1996 29-10-1997