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(71) Applicants (for all designated States except US): **UNIVERSIDADE DO PORTO** [PT/PT]; Gabinete UPIN, Praça Gomes Teixeira 4º andar, sala 419, P-4099-002 Porto (PT). **UNIVERSIDADE DE COIMBRA** [PT/PT]; Paço das Escolas, P-3004-535 Coimbra (PT). **UNIVERSIDADE DO MINHO** [PT/PT]; Largo do Paço, P-4700-320 Braga (PT).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **MAGALHÃES DUQUE DA FONSECA, José Carlos** [PT/PT]; Rua Das Artes Gráficas, Nº177, Hab.3.11, P-4100-092 Porto (PT). **DE AMORIM NOVAIS DA COSTA NÓBREGA, João Miguel** [PT/PT]; Rua José Sarmento, Nº27, 7º DTO., P-4710-103 Braga (PT). **ALVES MACHADO NÓBREGA, Ana Vera** [PT/PT]; Rua José Sarmento, Nº27, 7º DTO, P-4710-103 Braga (PT). **VILELA VAZ, José Filipe** [PT/PT]; Av. João XXI, Nº 1803, BL. A 1º DTO., Vila Nova De Famalicão, P-4770-754 Vermoim (PT).

FIGUEIREDO OLIVEIRA DUARTE, Luís Miguel [PT/PT]; Av. D. Nuno Álvares Pereira, Nº 158, 5º Esquerdo, P-4750-324 Barcelos (PT). **MACEDO DA MOTA, Armando Rafael** [PT/PT]; Lugar Da Gandra, Nº 93, Moure, Vila-Verde, P-4730-302 Moure VVD (PT).

(74) Agent: **VIEIRA PEREIRA FERREIRA, Maria Silvina**; Clarke, Modet & Co., Rua Castilho, 50-9º, P-1269-163 Lisboa (PT).

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(54) Title: POLYMER-BASED ELECTRODE FOR BIO-SIGNAL RECORDING

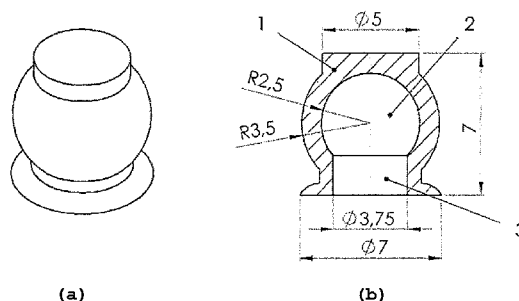


FIG. 3

(57) Abstract: A novel polymer-based pasteless electrode suitable for electroencephalogram (EEG) recording is described. This electrode is suitable for use in medicine, in particular for bio-signal recording, in particular for use in electroencephalogram (EEG), electrocardiogram (ECG) or electromyogram (EMG). The electrode is between the classic "wet" and "dry" electrodes. A localized skin hydration effect at the electrode/scalp contact point is achieved by the release of a small amount of a hydrating agent from a reservoir on the electrode itself, triggered by the electrode/scalp coupling pressure. The electrode functionality comprises polymer mechanical properties and the design of the electrode reservoir, whose volume decreases upon the application of the specified pressure. The electrode comprises a polymeric flexible body (1), a reservoir (2), within said body (1), and at least one orifice (3) in said reservoir (2), and a coating of conductive film on whole or part of the electrode body (1).



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DESCRIPTION**POLYMER-BASED ELECTRODE FOR BIO-SIGNAL RECORDING****Technical Field**

The present invention relates to electrodes for non-invasive bio-signal recording. Specifically the subject-matter comprises electrodes for use in medicine, for uses in electroencephalogram (EEG), electrocardiogram (ECG) or electromyogram (EMG).

Background of the invention

The silver/silver chloride (Ag/AgCl) electrodes have been the main choice of physicians for the non-invasive recording of electrophysiological signals like EEG (electroencephalographic), ECG (electrocardiographic) and EMG (electromyographic) signals. The main advantages of these electrodes for signal transduction are their electric potential reproducibility, excellent signal to noise ratio, reliability and biocompatibility [1,2]. However, they require a previous skin preparation and a conductive paste application in order to reduce the electric resistance at the scalp-electrode interface. Both operations, as well as the positioning of the electrodes themselves, require the intervention of trained personnel. In addition, the application of the gel is often the source of significant discomfort to the patient, may damage the hair and sometimes may even cause skin allergic reactions.

In order to solve these problems several solutions have been proposed. The closer to the classic Ag/AgCl electrode

solution consists of using a pre-amplifier coupled to each Ag/AgCl electrode. The active electronics improves the signal immunity to the interfacial impedance values, and thus the previous skin preparation can be skipped [3]. However, the gel paste is still essential. Furthermore, the electrodes are bulkier and have to be externally powered, which makes the set-up more complex and expensive.

In order to avoid the use of conductive pastes, several solutions have been proposed. Griss et al.[4] developed an electrode for EEG monitoring consisting in an array of micro-needles obtained by micro-machining, which penetrate the *stratum corneum* layer upon the application of a certain pressure, thus drastically decreasing the impedance for signal transfer. The patent US6.662035 refers to a device based on the same principle and Rufinni [6] proposed a similar solution based in carbon nanotubes. However Griss states that 5% of the needles break down during the exam and remain embedded in the outer skin layer. Because of its invasive nature this technology may generate inflammatory reactions and infections and therefore it is not expected to be well accepted by patients.

A radically different approach consists in the so-called dry electrodes, which do not require skin preparation or the use of any conductive paste. The sensor consists of an inert conductive material, which is mechanically coupled to the scalp for signal transfer. However, it requires the presence of local pre-amplification to compensate for the high interfacial impedance. The first prototypes appeared in the second half of the twentieth century for electrocardiogram (ECG) recording and were composed of a metallic substrate coated with a metal oxide (TiO_2 , Ta_2O_5 , etc.) [7,8]. Since then, several examples have been described in literature, varying primarily in the type of

metal and coating applied to the sensor [9-12]. It is noteworthy to mention, for its originality, the patent US4967038, based on an array of so-called flexible fingers that pass through the hair and establish an effective contact with the scalp. The fingers can be fabricated from a conductive material or just have a conductive tip. The main disadvantages of dry electrodes are the higher complexity and price, motivated by the presence of the pre-amplifier, and the higher sensitivity to movement artefacts, due to the absence of a liquid contact. It is important to remark that up to the present no system was commercialized for EEG based in dry electrode technology.

The Company Electrical Geodesics Incorporated (EGI) commercializes a sensor net system, which is abrasion free and where the electrodes rely on sponges, embedded in a moistener solution to locally hydrate the scalp. This system has been reported to be very reliable, however it relies on bulk silver electrodes and the sponges have to be replaced quite often. The price of the EGI system is higher than that of common EEG systems.

US2002/0173710 describes an electrode solution, lying between the common wet and the dry electrodes, which consists in using a group of elastomeric bristles to penetrate through the hair layer. Each bristle is filled with a wick material saturated with an electrically conductive liquid for local skin hydration. A reservoir located at the electrode top supplies the fluid to the bristles by a capillary/gravity action. The electric sensors may be either the wick material itself or metal electrodes immersed in the reservoir. According with this invention the hydrating solution is thus supplied by an electrode concept but certainly difficult to fabricate. The polymers pointed out by the authors for the wick material

are hydrophobic and thus will not display wicking properties with water based fluids without a specific surface modification.

In the present invention the hydrating fluid is also kept within the electrode reservoir, but it is fed to the electrode tip all at once just before the starting of the exam. These are two different concepts to achieve the same effect, except that in the case of the present invention the hydration effect will be achieved in a faster way. It is also to note that the present solution will work with fluids of any viscosity, whereas the bristles based solution, relying on capillary forces to drive the fluid through the bristles, will not work with viscous solutions. Finally, the presently proposed solution is simpler (only one part), and certainly cheaper to fabricate than the one proposed in patent US2002/0173710, where multiple parts need to be assembled to assure the hydration effect.

US6201982B1 refers to a complex multi-part electrode that fixes to patient's head by trapping the hair. A sponge swollen with the electrolytic gel is used to achieve a liquid contact when it is compressed. This solution has the main disadvantage of dispensing a quite large amount of liquid that spreads and eventually short-circuits adjacent electrodes. The present electrode solution, as well as the one of patent US2002/0173710, rely on the local delivery of very small amounts of the electrolytic solution in order to overcome this problem.

The hydrating solution aims at creating low resistance electrical path through the skin, in a safe, fast and reversible way. Multiple formulations are possible, like the one of US2007/0282188 A1. The presently proposed

electrode may work with any electrolytic solution or gel paste.

Description of the Invention

The disclosure comprises a bio-electrode suitable for EEG signal monitoring that achieves a reliable skin contact by locally releasing a small amount of a hydrating fluid. The electrode has a built-in internal liquid cavity that, upon the application of the electrode coupling pressure, shrinks and releases a controlled amount of a moistening fluid to the electrode/skin contact point. The flexible polymeric electrode body is coated with a conductive film for bio-signal transmission. Such an electrode is also suitable for other skin contact applications, namely.

The present invention consists in a new electrode which, under the application of a 1-15N load (electrode/scalp coupling force), releases 0.01-2ml, in particular 0.01-1 mL, in particular about 30 μ L, or in particular 1-2mL of an hydrating fluid from a built-in reservoir so the underneath skin layer is hydrated and an effective electrode/scalp electrical path is established. Consequently, the interfacial impedance to signal transfer is substantially reduced. Being half-way between the commercial wet and the dry electrodes, this electrode can be referred as a *quasi-dry* electrode. A scheme of the electrode working principle is depicted in Fig.1 and possible realizations of the invention are depicted in Figs.2 and 3.

With the quasi-dry electrode the 1-2 mL/electrode of the tacky gel paste commonly used with the silver/silver

chloride electrodes can be replaced by a considerably lower fluid volume that will be easily absorbed by the skin, without damaging the hair or dirtying the scalp. The wet contact is achieved by the releasing of a moistener solution contained in the electrode reservoir.

The moistener may be any aqueous solution chemically compatible with the electrode body material and the skin and including a dissolved salt, in order to improve the electrical conductivity, e.g. sodium chloride, potassium chloride or sodium bicarbonate. A surfactant may also be added to improve the hydrating effect. Possible surfactants already used as skin permeation enhancers are the polisorbates, polyoxyethylene alkyl ethers or polyoxyethylene alkyl esters.

The hydrating solution is kept within its reservoir by a suction effect, the communication with the outside being made through a single or multiple orifice(s). The diameter of such orifice(s) must be adapted to the viscosity and specific weight of the hydrating solution, so the suction effect retains the solution inside the reservoir. In general terms, the lower the viscosity and/or the higher the specific weight of the liquid, the smaller the orifice diameter should be.

In order to obtain a functional device the Young modulus of the electrode material, preferentially a polymer, is preferentially in the 2-50 MPa range. The electrode body is partially or totally coated with a conductive layer to ensure an efficient bio-signal transmission. The electrode conductive layer is essential to provide a conductive path to the signal. The coating material is:

- (i) conductive enough to minimize any electric effects on the signal.

- (ii) resistant to wear and tear induced by normal manipulation and cleaning.
- (iii) chemically inert in contact with the hydrating fluid and body fluids, as well as biocompatible.
- (iv) able to withstand the electrode deformation needed for liquid release without fracturing.

The coating may be any conductive material with appropriate conductivity and biocompatibility. Possible coating techniques include (but not restricted to) those of thin film technologies, as these are usually known in the art, like physical vapour deposition (PVD) technologies, chemical vapour deposition (CVD) technologies and electroless plating. Good results were obtained with titanium nitride layers deposited by PVD and silver/silver chloride layers deposited by electroless plating.

As can be observed in Fig.2, the exact shape of the electrode is not critical to achieving the obtained effects. A bracelet, while practical in a number of uses, also comprises the electrode body comprising a reservoir covered, partially or fully, by a conductive film such that a conductive connection is obtained to a skin contact area where conductivity-improving fluid is present flowing from said reservoir.

Production Process

Production of the electrode body

The electrode body production process can be divided into four main phases: (i) electrode specifications (ii) electrode geometry, (iii) production tools design and (iv) electrode production, which are briefly described hereinafter.

Electrode specifications

To establish the electrode body specifications the load applied by the electrode cap (device that fits to the patient's head and where the electrodes are assembled for proper coupling to the scalp) was measured using a universal testing machine (Zwick/Roell Z005). This study allowed concluding that, in most situations, the electrode should be able to deform and expel the moistener solution when a compression load of about 3 N is applied.

In order to promote the required effect, the cavity of the electrode should be able to hold and expel, at least 0,01ml as above mentioned, in particular at least a volume of about 30 μ l of the moistener solution.

Electrode format

During this phase, using the previously defined specifications, it was possible to set both the electrode geometry and the required mechanical properties of the material, to be employed for the production of the electrodes. For this purpose numerical modelling software was used, which allowed to obtain the geometry illustrated in Figure 3 and to define the adequate range of the material elastic modulus (2-50 MPa). As Shown in Figure 3, the geometry comprises a body (1), a spherical reservoir (2), where the hydrating solution is stored at rest. After the deformation imposed by a suitable pressure on the cap, the solution is expelled through the orifice (3) and is kept between the skin and the electrode, thus reducing the contact impedance.

Based on the above mentioned material properties, amongst several alternatives of flexible materials, two polymeric materials can be employed to produce the electrode body: a Thermoplastic Vulcanizate (TPV) or a thermoset polyurethane (PU).

Production Tools Design

There are two suggested alternatives for the production of the electrode body, which should be selected in function of the selected raw material.

For the case of the TPV, since it is a thermoplastic, a conventional injection moulding processing technique is envisaged. This option is adequate for large production scales.

Initially, the raw material PU was selected to produce the electrode prototype, since it allows to obtain the required geometry with a simple, swift and cost-effective manner. The mould designed and used to produce the electrode body is illustrated in Figure 4. A exploded view of the mould components is shown in Figure 4(i). The mould comprises the following main parts: "a" plate, "b" piston, "c" hopper, "d1" and "d2" mould cavity, "e1" and "e2" piston support and "f" piston. A cross section and a general overview of the mounted mould, are shown in Figures 4(ii) and 4(iii), respectively. When mounted, the parts "d1", "d2", "e1", "e2" and "f" form the mould cavity, that should be filled the raw material used to produce the electrode. Prior to the mould filling, the material is placed in the cavity of the hopper "c", and is subsequently forced to the mould cavity by the action of piston "b". The plate "a" is used to apply the load required to force the mould cavity filling.

Electrode production

The PU electrode body was produced using a mixture of a diisocyanate and a diol, a two component polyurethane (PU) from BMP Europe Ltd (refs DIPRANE* 5278 Prepolymer and Phoenix Polyester blended Polyol). The mixture is prepared using a percentage of 48% of polyol and 52% of prepolymer, at a temperature of 45 °C. Subsequently, the mixture is injected in the mould, that should preferably be at around 100°C. Finally the mould is placed in a vacuum heater during approximately 20 min, kept at around 100°C and near -1 bar, which promotes the PU curing. The prototypes obtained are illustrated in Figure 5.

For the case of the raw material TPV, since it is a thermoplastic, the production process should follow the conventional injection moulding methodology.

The electrode after a silver coating procedure is illustrated in Figure 6.

An embodiment of the electrode for non-invasive skin-contact bio-signal recording comprises:

- a polymeric flexible body (1);
- a reservoir (2), within said body (1), for containing a conductivity-improving fluid;
- one orifice (3) in said reservoir (2) through which the fluid is able to flow to a skin contact point, where the bio-signal is to be monitored;
- a coating of conductive film applied to the whole or part of the electrode body (1), such that an electric

connection is established between said skin contact point and a part of the electrode body (1) suitable to be connected to equipment for recording of the bio-signal.

A further embodiment comprises an electrode according to any one of the previously described for use in medicine.

A further embodiment comprises an electrode according to any one of the previously described for use in medicine in electroencephalogram - EEG, electrocardiogram - ECG or electromyogram - EMG.

The following claims set out particular embodiments of the invention. The described embodiments are combinable. The invention is of course not in any way restricted to the embodiments described and a person with ordinary skill in the art will foresee many possibilities to modifications thereof without departing from the basic idea of the invention as defined in the appended claims.

Brief description of the figures

The following figures provide preferred embodiments for illustrating the description and should not be seen as limiting the scope of invention.

Fig.1 - quasi-dry electrode wherein (1) represents the electrode's body; (2) represents the reservoir and (3) represents the electrode bottom orifice through which the

hydrating fluid is released to the skin, upon the application of the electrode coupling pressure.

Fig.2 - quasi-dry electrode bracelet for ECG signal monitoring. The bracelet has a fluid cavity that may be pressed for skin moisturization. The whole or part of the bracelet is coated with a conductive layer for bio-signal transmission to the acquisition apparatus.

Fig. 3 - Electrode geometry: (a) general overview, (b) Section view showing the main electrode dimensions (in mm), wherein (1) is the electrode's body; (2) is the reservoir and (3) is the electrode orifice.

Fig.4 - Mould manufactured for the production of PU electrodes: (i) exploded view, (ii) mounted section view and (iii) mounted overview.

Fig.5 - PU electrode prototypes.

Fig.6 - Silver-plated PU electrode prototype.

Fig.7 - Overlay plot of the EEG data containing eye blinking artifacts in time domain, clearly showing the almost complete overlap of the measurements between a prior art electrode and the present electrode. A set of four EEG electrode prototypes similar to those of Figure 7 were assembled with a Nihon-Kohden commercial device on the scalp of a volunteer, and the EEG signals monitored in parallel with commercial bridge electrodes, fixed in the

Fp1, Fp2, O1 and O2 positions, according with the international 10-20 system.

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CLAIMS

1. Electrode for non-invasive skin-contact bio-signal recording comprising:
 - a polymeric flexible body (1);
 - a reservoir (2), within said body (1), for containing a conductivity-improving fluid;
 - one orifice (3) in said reservoir (2) through which the fluid is able to flow to a skin contact point, where the bio-signal is to be monitored;
 - a coating of conductive film applied to the whole or part of the electrode body (1), such that an electric connection is established between said skin contact point and a part of the electrode body (1) suitable to be connected to equipment for recording of the bio-signal.
2. Electrode according to the previous claim wherein the elasticity of the polymeric flexible body (1) is such that an amount of the conductivity-improving fluid is expelled when manual or cap compression is applied to the electrode.
3. Electrode according to any one of previous claims wherein the elasticity of the polymeric flexible body (1) is such that after manual compression of the electrode enough suction is maintained to keep the electrode in skin contact under its own weight.
4. Electrode according to any one of previous claims wherein the coating of conductive film is 100 nanometers - 5 micrometers thick.

5. Electrode according to any one of previous claims, wherein the polymer material of the polymeric flexible body (1) is selected from the group of polymers comprising polyurethanes, polydimethylsiloxanes, thermoplastic vulcanizates and/or rubbers.
6. Electrode according to any one of previous claims comprising a plurality of orifices (3) in said reservoir (2) through which the fluid is able to flow to a skin contact point, where the bio-signal is to be monitored.
7. Electrode according to any one of previous claims wherein the viscosity and specific weight of the conductivity-improving fluid and the size of the orifice or orifices (3) are such that the reservoir (2) is able to retain the fluid when no manual or cap compression is applied to the electrode.
8. Electrode according to any one of previous claims wherein the reservoir (2) has a capacity of 0.01-2 mL of a fluid; in particular 0.01-1 mL, more in particular about 30 μ L; or in particular 1-2mL.
9. Electrode according to any one of previous claims wherein the conductivity-improving fluid is a hydrating fluid.
10. Electrode according to the previous claim wherein the hydrating fluid is an aqueous solution with a dissolved salt, in particular sodium or potassium chloride.
11. Electrode according to the previous claim wherein the hydrating fluid comprises a surfactant agent.

12. Electrode according to any one of the previous claims wherein the coating of conductive film is a thin film coating.
13. Electrode according to any one of the previous claims wherein the coating of conductive film is obtained by electroless plating, physical vapor deposition and/or chemical vapor deposition.
14. Electrode according to any one of the previous claims wherein the coating of conductive film is obtained by electroless plating, physical vapor deposition and/or chemical vapor deposition.
15. Electrode according to any one of the previous claims wherein the reservoir (2) is substantially spherical.
16. Electrode according to the previous claim wherein the electrode is mushroom-shaped.
17. Electrode according to any one of the claims 1 - 14 wherein the electrode is bracelet-shaped.
18. Electrode according to any one of the previous claims comprising a protrusion with a substantially circular cross-section suitable for receiving an electrical signal connector to said equipment for recording of the bio-signal.
19. Electrode according to any one of the previous claims for use in medicine.
20. Electrode according to any one of the previous claims for use in medicine in electroencephalogram - EEG, electrocardiogram - ECG or electromyogram - EMG.

DRAWINGS

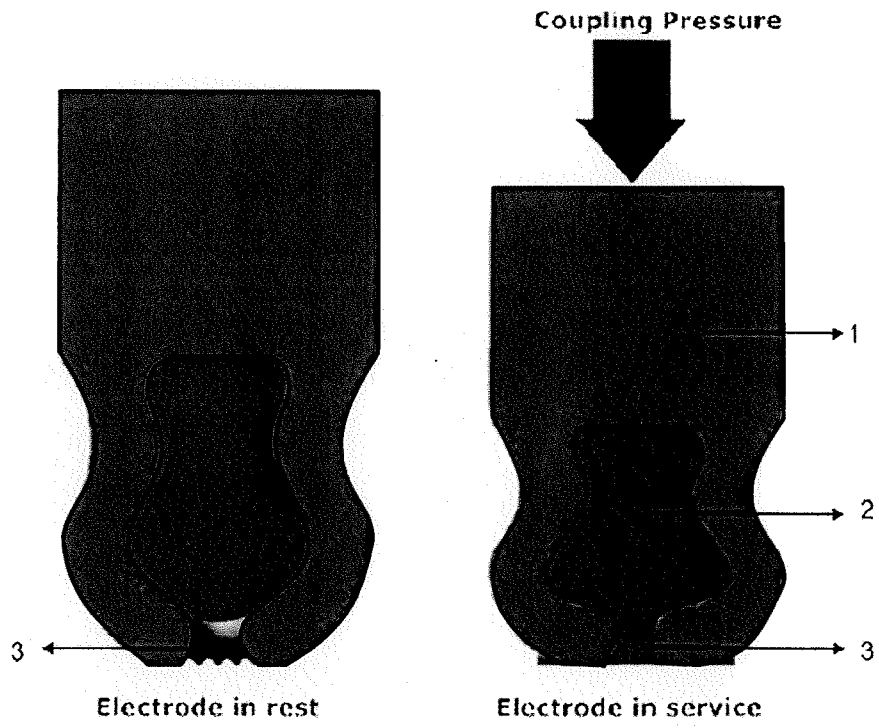


FIG. 1

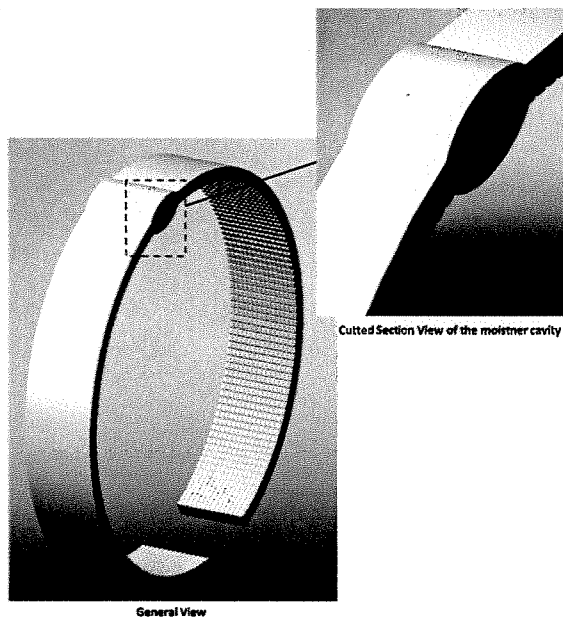
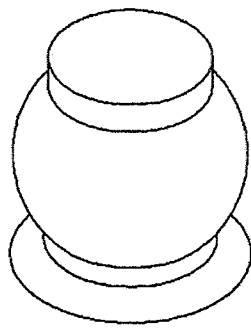
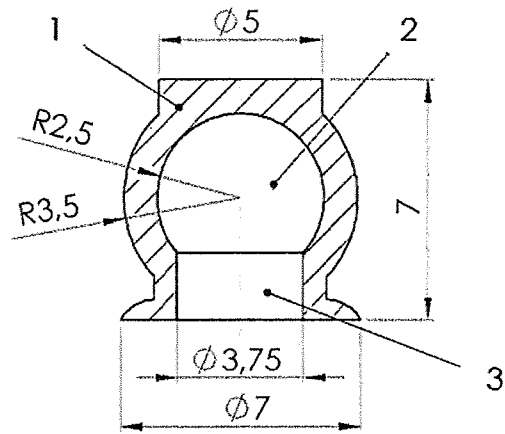


Fig. 2



(a)



(b)

FIG. 3

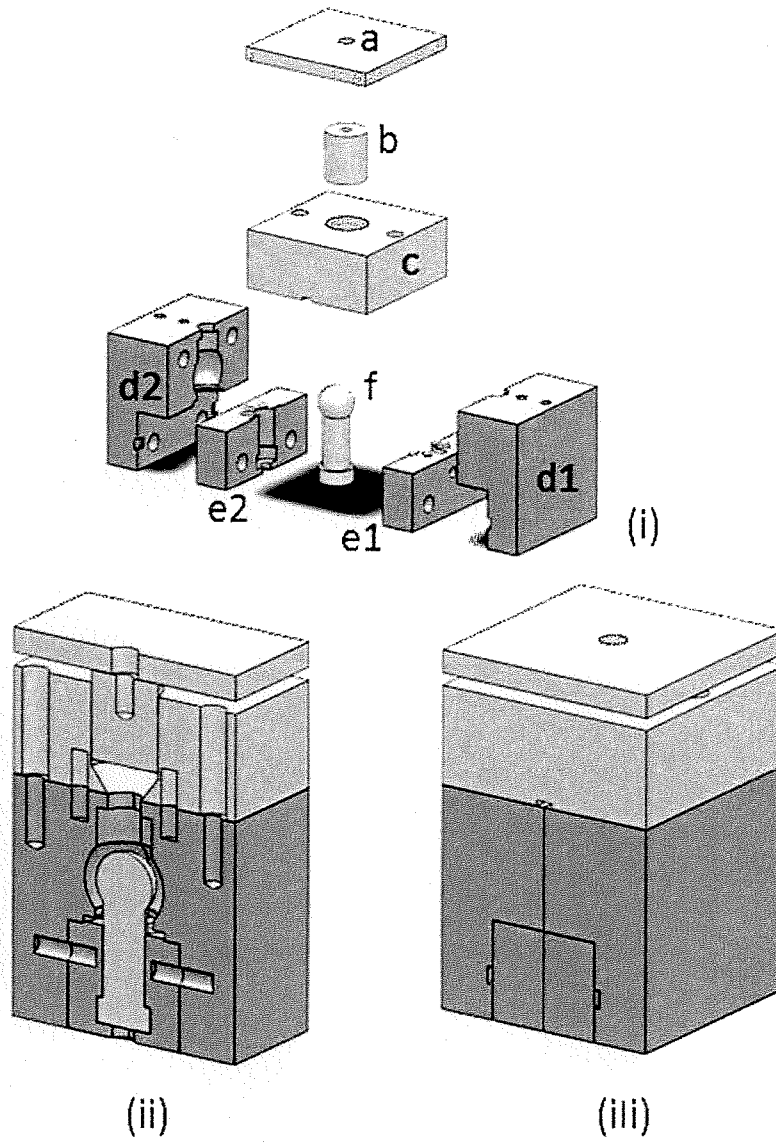


FIG. 4

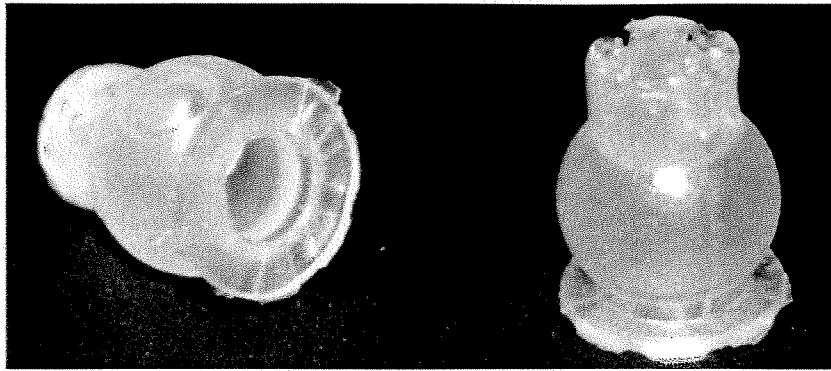


FIG. 5



FIG. 6

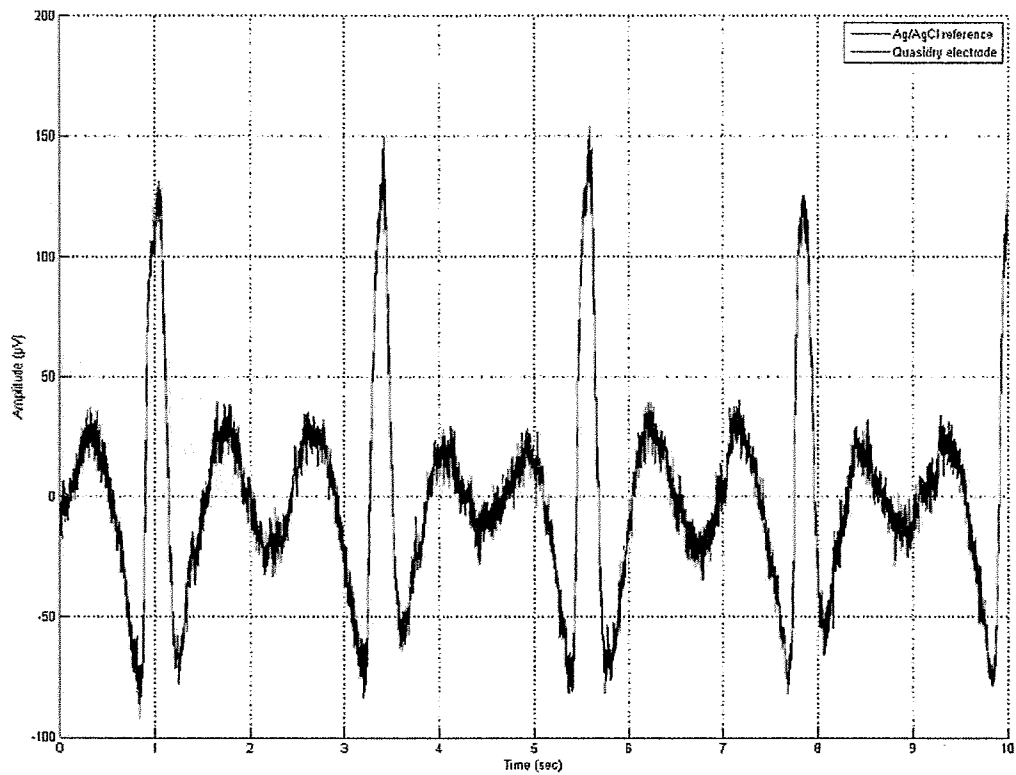


FIG. 7

INTERNATIONAL SEARCH REPORT

International application No PCT/IB2012/051880
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A. CLASSIFICATION OF SUBJECT MATTER INV. A61B5/0408 A61B5/0478 A61B5/0492 ADD.				
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) A61B				
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched				
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPO-Internal, WPI Data				
C. DOCUMENTS CONSIDERED TO BE RELEVANT				
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.		
X	US 4 559 950 A (VAUGHAN RAYMOND C [US] ET AL) 24 December 1985 (1985-12-24) column 1, lines 7-11,38-50 column 3, lines 35-62 column 4, lines 3-27 column 4, line 64 - column 5, line 6 figures 1-4	1-16, 18-20 17		
Y	----- US 2001/044573 A1 (MANOLI SAMIR [US] ET AL) 22 November 2001 (2001-11-22) paragraphs [0035], [0036], [0039]; figures 4-11	1-16, 18-20		
X	----- US 2010/069735 A1 (BERKNER LIOR [IL]) 18 March 2010 (2010-03-18) paragraphs [0068], [0204] - [0207]; figures 2F-2I	17		
Y	----- US 2010/069735 A1 (BERKNER LIOR [IL]) 18 March 2010 (2010-03-18) paragraphs [0068], [0204] - [0207]; figures 2F-2I	1		
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Date of the actual completion of the international search	Date of mailing of the international search report			
30 August 2012	10/09/2012			
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Mecking, Nikolai			

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2012/051880

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