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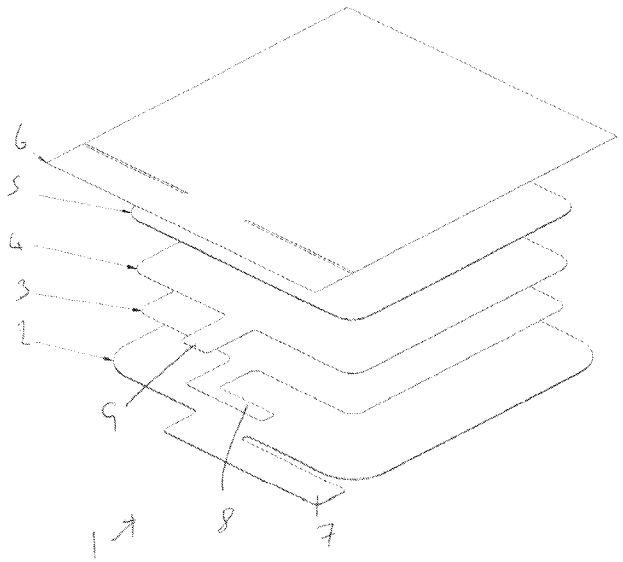
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(54) Title: CONDUCTIVE MEMBER FOR USE IN RADIOFREQUENCY ABLATION

Fig 1



(57) Abstract: A conductive member such as conductive pad (1) for use in radiofrequency ablation, the conductive member being flexible so as to conform to a subject's skin, the conductive member comprising a conductive skin contact layer (5) arranged for contact with the subject's skin and a conductive layer (4) over the conductive skin contact layer, in which the conductive skin contact layer (5) and the conductive layer (4) are both conductive to DC electrical signals.

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[Continued on next page]

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Declarations under Rule 4.17:

— *as to the identity of the inventor (Rule 4.17(i))*
— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

Published:

— *with international search report (Art. 21(3))*
— *in black and white; the international application as filed contained color or greyscale and is available for download from PATENTSCOPE*

CONDUCTIVE MEMBER FOR USE IN RADIOFREQUENCY ABLATION

This invention relates to a conductive member for use in radiofrequency ablation, a radiofrequency ablation system and a method of using such a system.

Radiofrequency ablation as a method of ablating tissues within a subject is known; a radiofrequency electric signal is applied to the tissues to be ablated using a (typically) pointed electrode, with return current typically being collected through a conductive member such as a pad applied to the subject's skin. For the subject's comfort and to avoid injury to the subject, it is desirable to keep the current per unit area passing through the conductive member as small as possible.

We are aware of the PCT patent application published as WO2006/082413, which discloses the use of such a radiofrequency ablation system with a DC offset applied to the radiofrequency signal to reduce the desiccating effect of radiofrequency ablation on the tissue to be ablated. That discusses using a conductive pad together with a separately applied (and "conventional") conductive gel. This can be referred to as "bimodal electric tissue ablation".

In accordance with a first aspect of the invention, we provide a conductive member for use in radiofrequency ablation, the conductive member being flexible so as to conform to a subject's skin, the conductive member comprising a conductive skin contact layer arranged for contact with the subject's skin and a conductive layer over the conductive skin contact layer, in which the conductive skin contact layer and the conductive layer are both conductive to DC electrical signals.

As such, by providing a conductive skin contact layer as part of a conductive member, this allows for improved contact with a subject's skin. Furthermore, making the conductive skin contact layer and the conductive layer conductive to DC signals is advantageous when using bimodal electric tissue ablation, where there is a DC component to the excitation signal. We have appreciated that prior art electrodes with prior art conductive gels are poor conductors of DC signals, and that transmission of the DC component is advantageous in bimodal electric tissue ablation. By reducing the resistance to DC signals, lower voltages are required to achieve a target DC

current, which reduces the potential risks (e.g. unintended electro-muscular stimulation) to the subject.

The conductive member may be a conductive pad, which may be arranged to adhere, typically by means of the conductive skin contact layer, to the subject's skin. Alternatively, the conductive member may not be adhesive to a user's skin; in such a case the conductive member may comprise attachment means, such as a resilient member, by means of which the conductive member (typically the conductive skin contact layer) can be held in use against the subject's skin.

In one embodiment, the conductive member may be arranged so as to be wearable. Typically, the conductive member would comprise a compression member which is wearable on a part of the subject (typically an arm or a leg) and which is placed in tension by being worn. The tension in the compression member may act to hold the conductive member, and in particular the conductive skin contact layer, against the subject's skin.

Typically, the conductive member would comprise an input for an electrical signal, coupled to the conductive layer. The input may comprise a conductive projection from the conductive layer.

The conductive skin contact layer may have a volume resistivity at a frequency less than 5Hz, or at zero frequency (i.e. DC) of a maximum of 2500 ohm cm, or 2000 ohm cm, or 1500 ohm cm, or 1000 ohm cm.

The conductive skin contact layer may comprise a gel layer, which may comprise a hydrogel which is conductive to DC signals. The conductive skin contact layer may be between 0.5 and 1mm thick.

The conductive layer will typically comprise a conductive plastic material, such as carbon-loaded polymer mix. In one embodiment, the conductive layer will comprise a carbon-loaded polyethylene film. The conductive layer may have a surface resistivity of at most 300, or 250, Ohms per square. The conductive layer may be between 0.1 and 0.5 mm thick. We have found that using such a conductive plastic material avoids any reaction between the conductive skin contact layer and a metallic conductive

layer, both during storage of the conductive member (where in particular a hydrogel could corrode a metal electrode) and during use (where gas can evolve at the interface between the conductive skin contact layer and a metallic conductive layer).

Additionally or alternatively, the conductive layer may comprise any of conductive fabrics, metal loaded substrates, sheet metal foils, conductive meshes, metallized fabric, or conductive silicones.

The conductive member may also comprise a removable release layer on the conductive skin contact layer, to protect and hold captive the conductive skin contact layer until it is applied to the subject's skin. Typically, the release layer will comprise silicone-coated polymer material, such as silicone-coated polyethylene terephthalate (PET).

The conductive member may also comprise a foam layer over the conductive layer, typically on the side of the conductive layer opposite to the conductive skin contact layer. This can provide support to the other layers and also provide insulation to protect medical operators from any electrical signals. The foam layer may comprise a medical foam, such as a closed cell polyethylene foam. The foam layer may be attached to the conductive layer by means of an intervening adhesive layer. The adhesive layer may comprise two layers of a conductive adhesive over a non-woven fabric core. The use of a fabric core can help avoid corrosion of a metallic substrate by the high salt content in the hydrogel where a hydrogel is used as the gel layer.

In accordance with a second aspect of the invention, there is provided a radiofrequency ablation system, comprising a conductive member in accordance with the first aspect of the invention, an electrode and a radiofrequency source arranged to generate a signal with a radiofrequency component, and coupled to the electrode and the conductive member to apply the signal between the electrode and the conductive member.

Typically, the signal will have a DC component; as such, the radiofrequency ablation system may be for use with bimodal electric tissue ablation.

The electrode may comprise a pointed needle, typically metal, in electrical communication with the radiofrequency source.

The radiofrequency component will typically have a frequency in the range of 300 to 600kHz (typically 400 to 500kHz). The signal will typically have a power of between 20 to 200 watts.

The DC component will typically have a voltage of a maximum of 40 volts, typically between 0 and 25 volts.

In accordance with a third aspect of the invention, there is provided a method of ablating a subject's tissue using the radiofrequency ablation system of the second aspect of the invention, the method comprising applying the conductive member to the subject's skin, positioning the electrode adjacent to the tissue to be ablated and passing the signal from the electrode through the tissue to be ablated, the signal returning to the conducting pad through the subject.

The signal may be applied to the tissue for at least 1 minute, 5 minutes, 10 minutes, 15 minutes or 20 minutes.

There now follows, by way of example, description of an embodiment of the invention, described with reference to the accompanying drawings, in which:

Figure 1 shows an exploded view of a conductive member in accordance with an embodiment of the invention;

Figure 2 shows a plan view of the conductive member of Figure 1, showing the internal arrangement of the components forming the conductive member;

Figure 3 shows a side elevation of the conductive member of Figure 1;

Figure 4 shows an enlargement of area A of Figure 3;

Figure 5 shows a plan view of the foam layer of the conductive member of Figure 1;

Figure 6 shows a plan view of the adhesive layer of the conductive member of Figure 1;

Figure 7 shows a plan view of the conductive layer of the conductive member of Figure 1;

Figure 8 shows a plan view of the gel layer of the conductive member of Figure 1;

Figure 9 shows a plan view of the release layer of the conductive member of Figure 1;

Figure 10 shows schematically a radiofrequency ablation system in accordance with the present invention, using the conductive member of Figure 1.

A conductive member of the form of a conductive pad 1 for use in radiofrequency ablation is shown in Figures 1 to 9 of the accompanying drawings; it is shown as part of a radiofrequency ablation system in Figure 10 of the accompanying drawings. The conductive pad 1 comprises a number of layers built into a flexible pad.

Taking the layers in turn, from the bottom of Figure 1 upwards:

- a foam layer 2;
- an adhesive layer 3;
- a conductive layer 4;
- a conductive skin contact layer, of the form of a gel layer 5; and
- a release layer 6.

The foam layer 2 provides structure to the conductive pad 1. It comprises a single-sided medical closed cell polyethylene foam, such as product 9776 from 3M Medical Specialities of St Paul, Minnesota, USA. The foam layer is 0.7mm thick. It is shaped as a rounded rectangle, with a tail portion 7 extending parallel to one side of the rectangle.

On the foam layer is provided the adhesive layer 3. This is provided as a layer of conductive non-woven fabric with conductive adhesive on both sides, such as the tape sold as HB350 from Hi-Bond Tapes Ltd of Corby, United Kingdom. Again, this is formed of rounded rectangular body, smaller than the foam layer 2, with a tail portion 8 that fits within tail portion 7 of the foam layer 2. The area around tail portion 7 connection needs to be fully covered by an insulating material (typically the backing layer) to avoid any risk of short circuit to the patient or operator. The adhesive layer is 0.1mm thick.

On top of the adhesive layer is the conductive layer 4. This comprises a polyethylene film loaded with carbon, such as the film available as LINQSTAT XVCF from Caplinq, Heemskirk, Netherlands. It is again of the form of a rounded rectangle, with a tab 9 for the connection to a signal generator (discussed below). The conductive layer 4 is larger than the adhesive layer, but smaller than the foam layer 2. The conductive layer 4 is 0.2mm thick.

On top of the conductive layer 4 is the gel layer 5. This comprises a hydrogel, such as that sold as AG625 from Axelgaard Manufacturing Co, Ltd of Fallbrook, California, USA. This allows the conductive pad 1 to conform to a subject's skin, and provides some adhesion to the subject's skin. The gel layer is provided as a rounded rectangle, larger than the conductive layer 4 but smaller than the foam layer 2. The gel layer is 0.7mm thick.

The conductive layer 4 and the gel layer 5 are together conductive to a range of frequencies from DC (zero frequency) up to at least 1MHz.

On top of the gel layer 5 is provided a release layer 6 of the form of silicone-coated polyethylene terephthalate. This protects and retains the gel layer 5 until it is ready to be used. The silicone coating allows for the easy removal of the release layer 6.

The use of the conductive pad 1 is shown in Figure 10 of the accompanying drawings. The conductive pad 1 is used as part of a radiofrequency ablation system along with a radiofrequency source 11 and a needle electrode 12.

The conductive pad 1 (with the release layer 6 removed) is applied to a subject's skin 10, so that the gel layer 5 adheres to the subject's skin 10. It is connected to the radiofrequency source 11, as is the needle electrode 12. The radiofrequency source 11 is used to create a signal applied as a voltage between the needle electrode 12 and the conductive pad 1. The signal has a radiofrequency component at around 460 kHz supplying between 20 and 200W. It also has a DC component of between 0 and 40 volts (with the conductive pad 1 as the anode), which will be transmitted by the conductive layer 4 and the gel layer 5 as they transmit DC signals.

Typically the resistance measured through the patient as a result of using the hydrogel will be less than 500ohm – the resistance is largely driven by the impedance of the stratum corneum which can be greater 1megaohm per cm^2. A sufficient area of hydrogel is used to overcome this.

As such, the needle electrode 12 can be introduced into an incision 13 in the user's skin 10 and used to ablate a tissue 14 of interest. The DC component will reduce the dehydrating effect of the tissue ablation.

CLAIMS

1. A conductive member for use in radiofrequency ablation, the conductive member being flexible so as to conform to a subject's skin, the conductive member comprising a conductive skin contact layer arranged for contact with the subject's skin and a conductive layer over the conductive skin contact layer, in which the conductive skin contact layer and the conductive layer are both conductive to DC electrical signals.

2. The conductive member of claim 1, being a conductive pad.

3. The conductive member of claim 1 or claim 2, which is arranged to adhere, typically by means of the conductive skin contact layer, to the subject's skin.

4. The conductive member of claim 1 or claim 2, in which the conductive member is not adhesive to a user's skin.

5. The conductive member of any preceding claim, comprising attachment means by means of which the conductive member (typically the conductive skin contact layer) can be held in use against the subject's skin.

6. The conductive member of any preceding claim, arranged so as to be wearable, and comprising a compression member which is wearable on a part of the subject and which is placed in tension by being worn, tension in the compression member acting to hold the conductive member, and in particular the conductive skin contact layer, against the subject's skin.

7. The conductive member of any preceding claim, in which the conductive skin contact layer has a volume resistivity at a frequency less than 5Hz, or at zero frequency (i.e. DC) of a maximum of 2500 ohm cm, or 2000 ohm cm, or 1500 ohm cm, or 1000 ohm cm.

8. The conductive member of any preceding claim, in which the conductive skin contact layer comprises a gel layer.

9. The conductive member of claim 8, in which the gel layer comprises a hydrogel which is conductive to DC signals.

10. The conductive member of any preceding claim, in which the conductive layer comprises a conductive plastic material, such as carbon-loaded polymer mix.

11. The conductive member of any preceding claim, comprising a removable release layer on the conductive skin contact layer.

12. The conductive member of any preceding claim, comprising a foam layer over the conductive layer on the side of the conductive layer opposite to the conductive skin contact layer.

13. The conductive member of claim 12, in which the foam layer is attached to the conductive layer by means of an intervening adhesive layer.

14. The conductive member of claim 13, in which the adhesive layer comprises two layers of a conductive adhesive over a non-woven fabric core.

15. A radiofrequency ablation system, comprising a conductive member in accordance with any preceding claim, an electrode and a radiofrequency source arranged to generate a signal with a radiofrequency component, and coupled to the electrode and the conductive member to apply the signal between the electrode and the conductive member.

16. The system of claim 15, in which the signal has a DC component.

17. The system of claim 15 or claim 16, in which the electrode comprises a pointed needle.

18. A method of ablating a subject's tissue using the radiofrequency ablation system of any of claims 15 to 17, the method comprising applying the conductive member to the subject's skin, positioning the electrode adjacent to the tissue to be ablated and passing the signal from the electrode through the tissue to be ablated, the signal returning to the conducting pad through the subject.

Fig 1

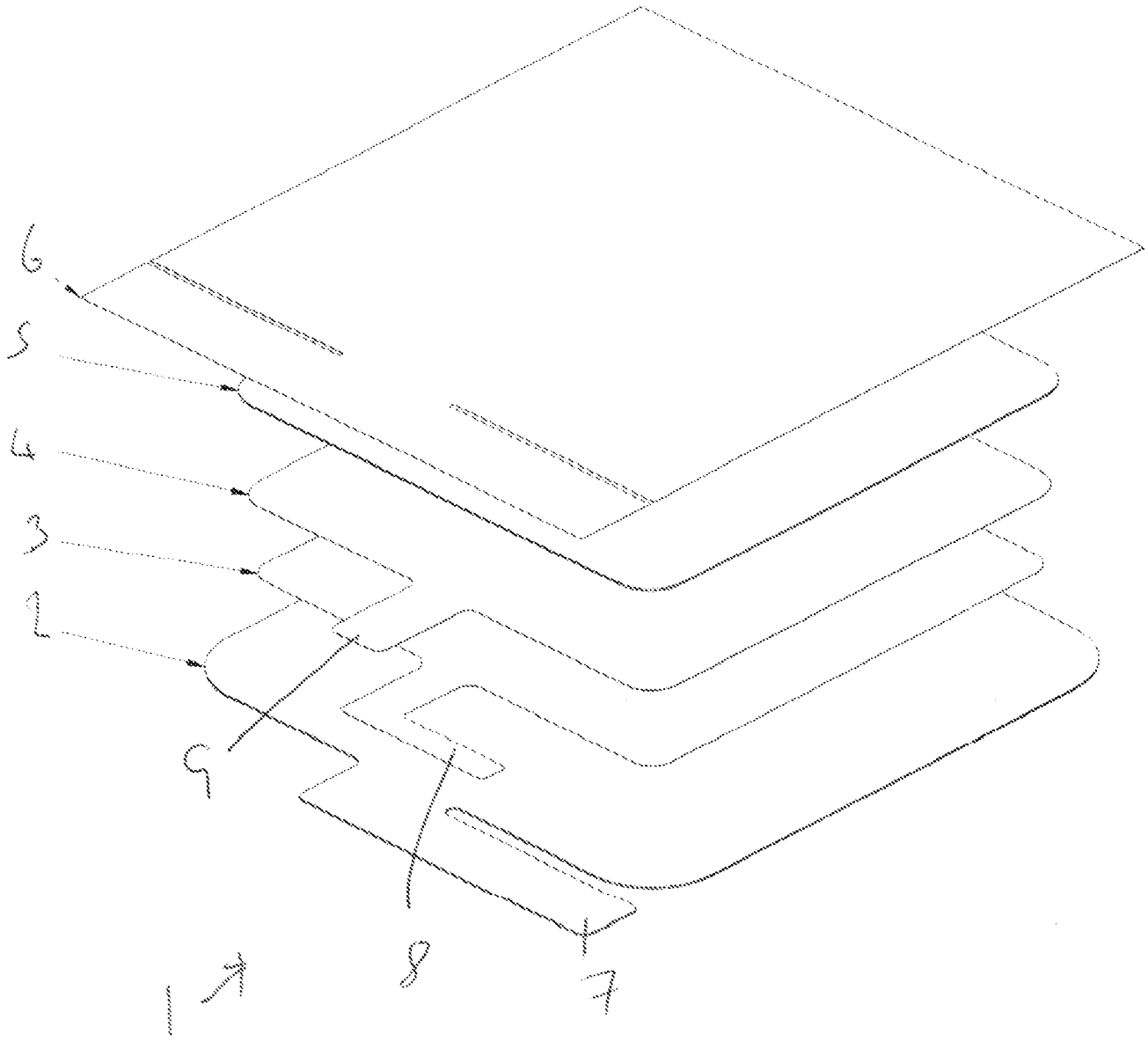


Fig 2

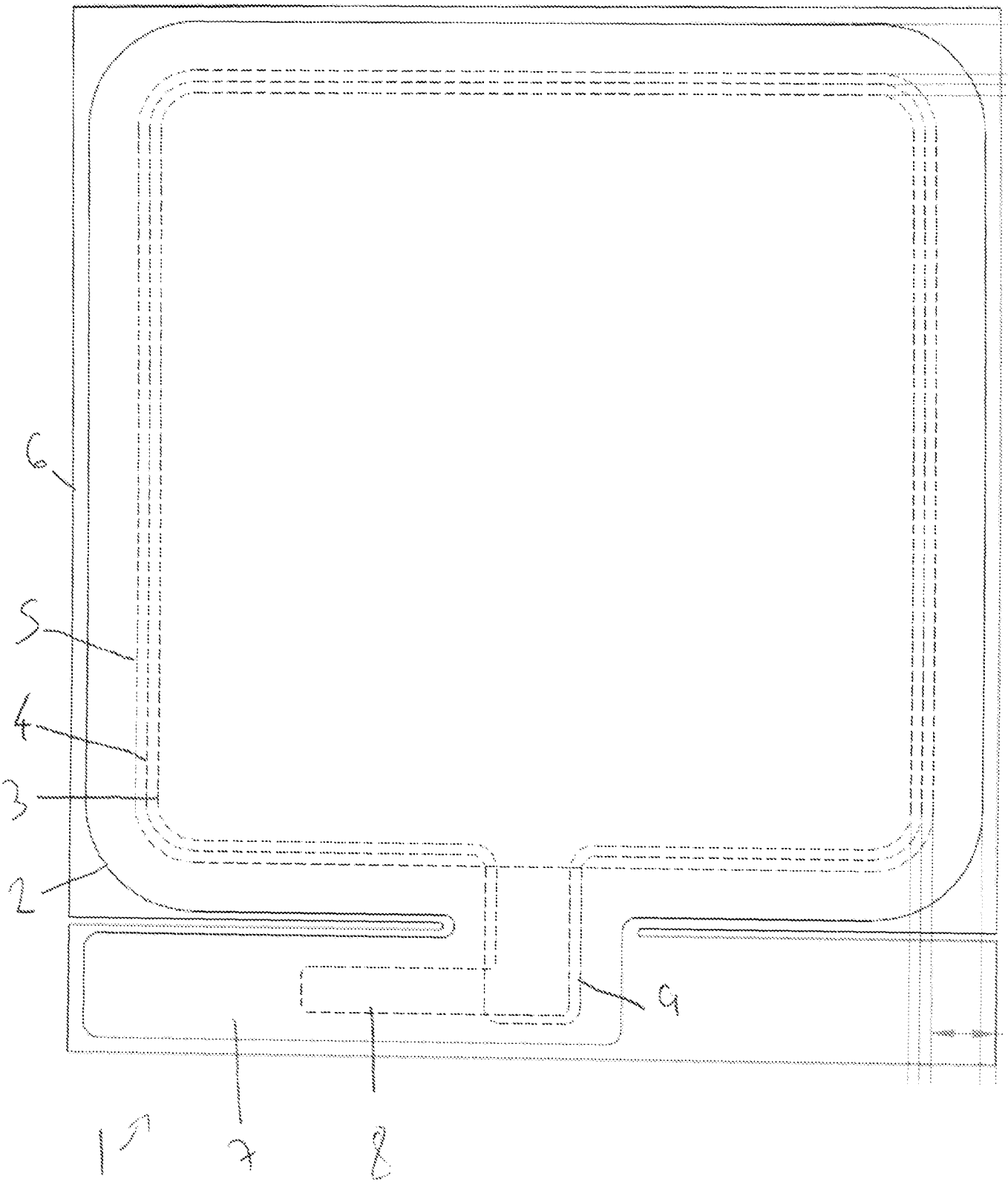


Fig 3

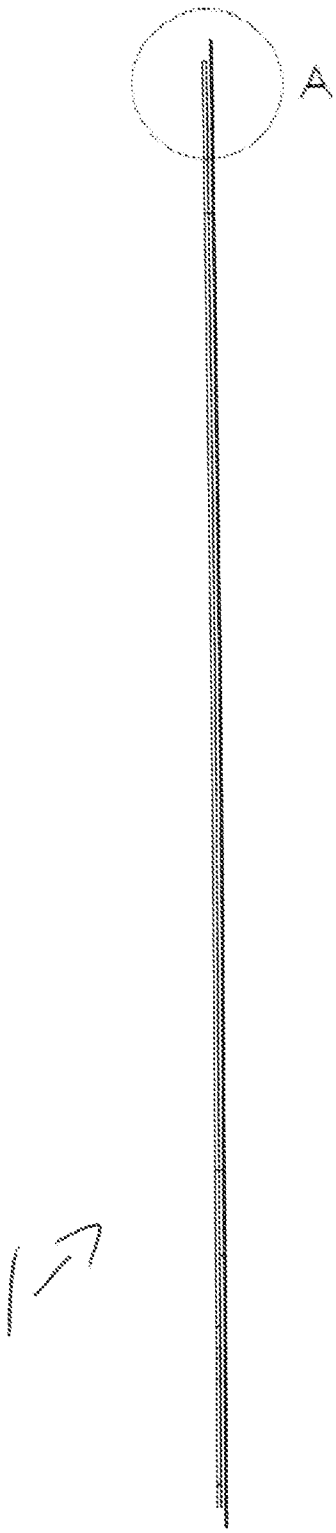


Fig 4

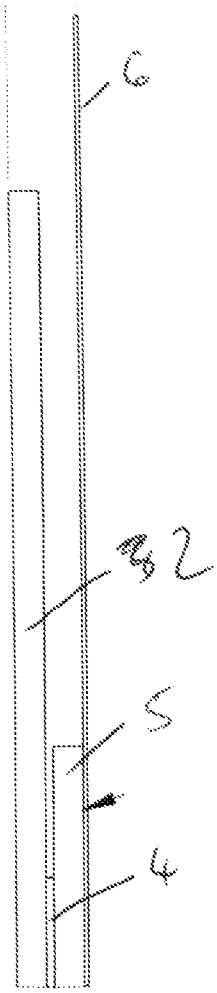


Fig 5

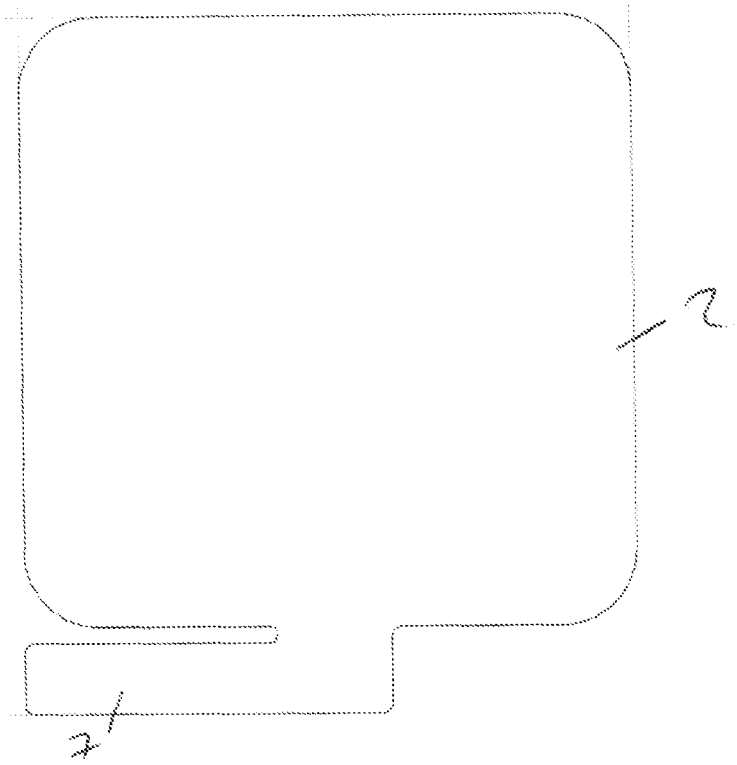


Fig 6

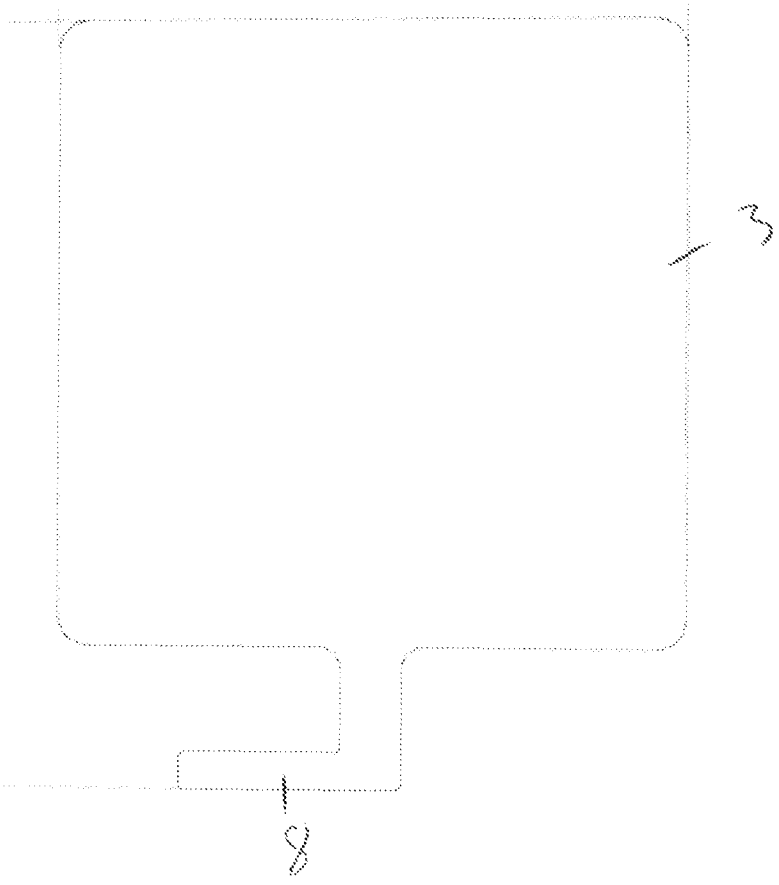


Fig 7

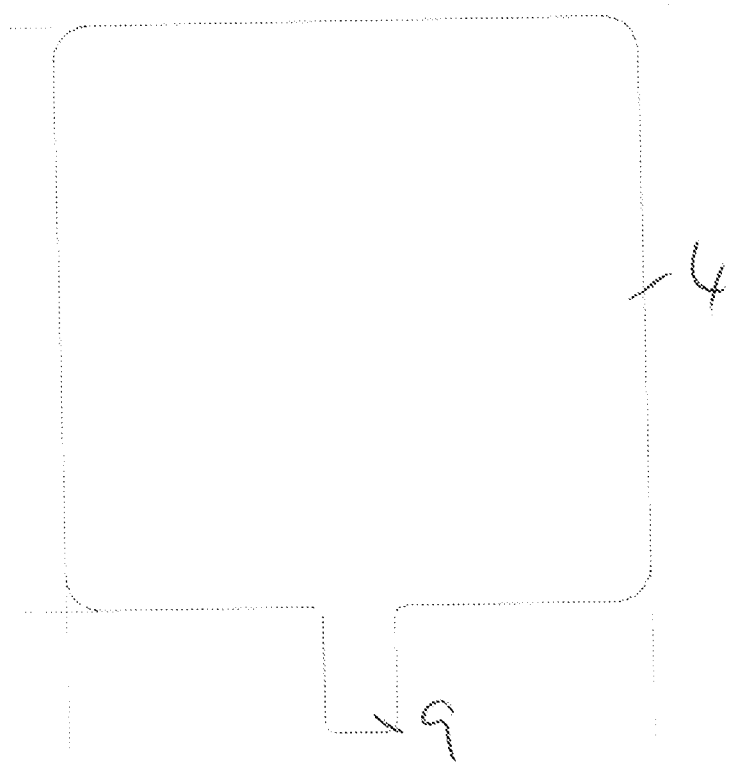
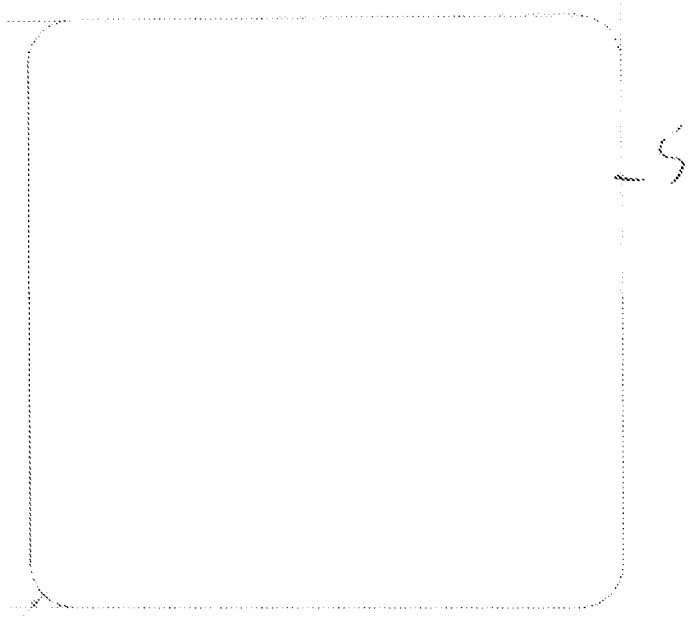


Fig 8



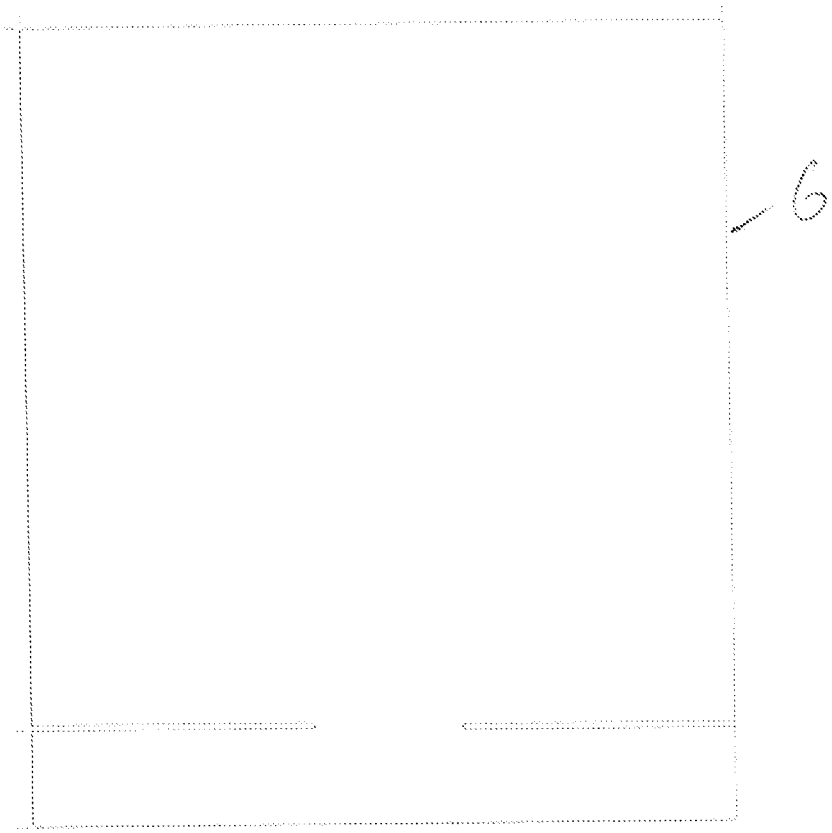
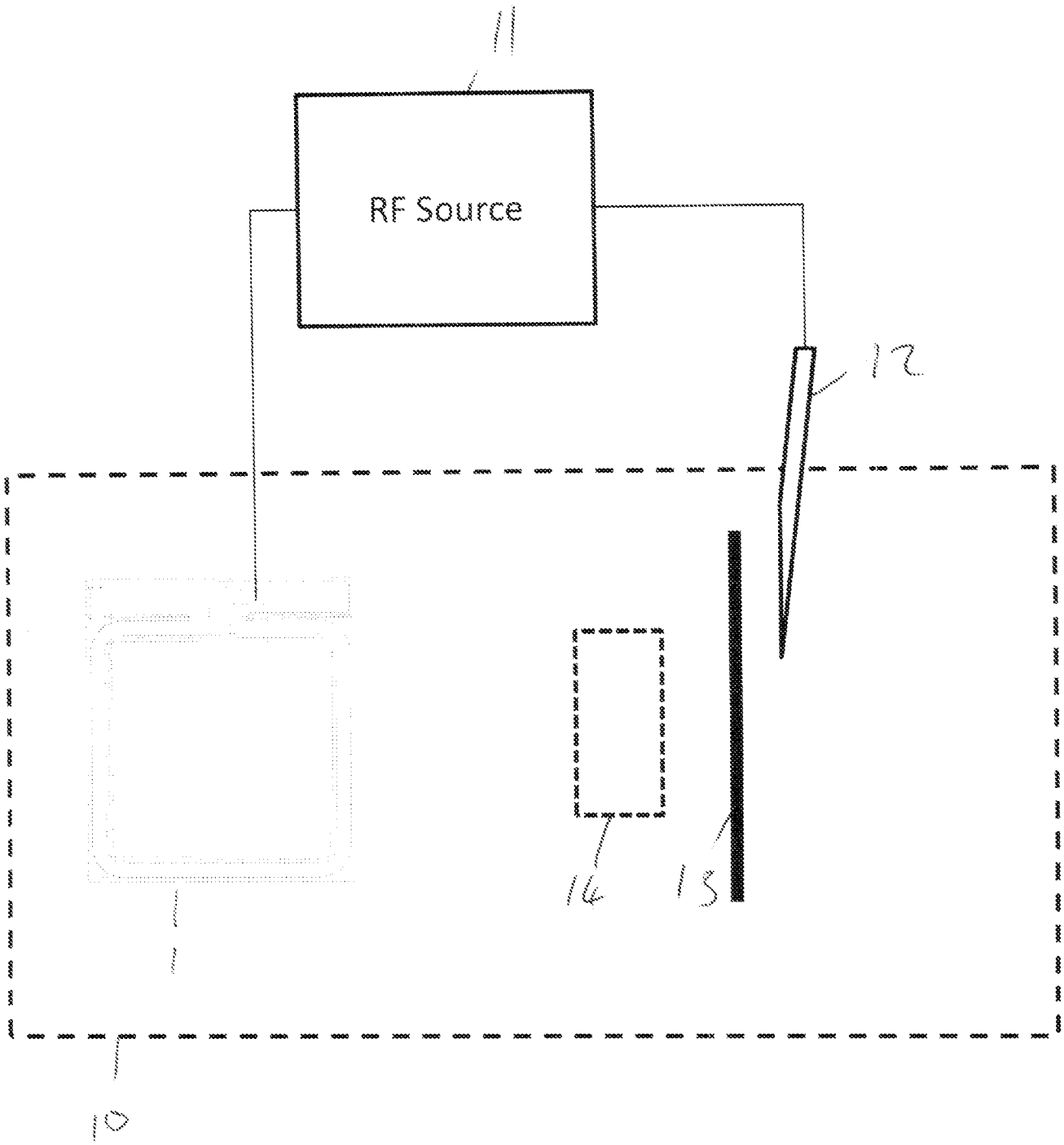


Fig 9

Fig 10



INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2020/054881

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B18/12 A61B18/14 A61B18/16
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 4 088 133 A (TWENTIER MAX E) 9 May 1978 (1978-05-09) figures 1,2,3,4 column 2, lines 30-36 -----	1-7,12, 15-17
X	US 5 733 324 A (FERRARI R KEITH [US]) 31 March 1998 (1998-03-31) figures 1,2 abstract column 3, lines 25-27,61-62 column 8, lines 52-55 ----- -/--	1-3,5, 8-13, 15-17

[X] Further documents are listed in the continuation of Box C.

[X] See patent family 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 application or patent 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	Date of mailing of the international search report
1 September 2020	09/09/2020

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Seon, Jean-Antoine

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INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2020/054881

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 722 761 A (CARTMELL JAMES V [US] ET AL) 2 February 1988 (1988-02-02) figure 1 column 1, lines 10-21 column 3, lines 22-26 column 4, lines 8-10	1-3,5, 8-13, 15-17
X	US 6 600 957 B2 (LUDLOW CO LP [US]) 29 July 2003 (2003-07-29) figure 4 column 6, lines 49-50 column 5, lines 61-63 column 8, line 65	1-3,5, 8-13
A	EP 2 942 023 A2 (COSMAN JR ERIC R [US]; COSMAN SR ERIC R [US]) 11 November 2015 (2015-11-11) figure 1 paragraph [0151]	15-17
A	DOBBINS ET AL: "Bimodal Electric Tissue Ablation-Modified Radiofrequency Ablation with a Le Veen Electrode in a Pig Model", JOURNAL OF SURGICAL RESEARCH, ACADEMIC PRESS INC., SAN DIEGO, CA, US, vol. 144, no. 1, 11 December 2007 (2007-12-11), pages 111-116, XP022385926, ISSN: 0022-4804, DOI: 10.1016/J.JSS.2007.03.066 the whole document	15-17
A	TOSHIHIRO TANAKA ET AL: "Optimization of Direct Current-Enhanced Radiofrequency Ablation: An Ex Vivo Study", CARDIOVASCULAR AND INTERVENTIONAL RADIOLOGY, SPRINGER-VERLAG, NE, vol. 33, no. 5, 22 January 2010 (2010-01-22), pages 1028-1032, XP019843021, ISSN: 1432-086X the whole document	15-17

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2020/054881

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 18
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 18

The subject matter of claim 18 relates to a surgical method. According to Rule 39.1 (iv) PCT the international search authority is not required to search subject matter falling under this category. The reasons are the following: The method of claim 18 relates to an ablation method. Ablating tissues on a body is considered as a surgical step and therefore the whole method is considered surgical.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2020/054881

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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