



(43) International Publication Date  
20 February 2014 (20.02.2014)

(10) International Publication Number  
**WO 2014/028885 A1**

- (51) **International Patent Classification:**  
*A61B 17/22* (2006.01) *G10K 15/06* (2006.01)
- (21) **International Application Number:**  
PCT/US2013/055431
- (22) **International Filing Date:**  
16 August 2013 (16.08.2013)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**  
61/684,398 17 August 2012 (17.08.2012) US  
13/777,807 26 February 2013 (26.02.2013) US
- (71) **Applicant:** SHOCKWAVE MEDICAL, INC. [US/US];  
48531 Warm Springs Boulevard, Suite 416, Fremont, CA  
94539 (US).
- (72) **Inventors:** ADAMS, John; 18023 Fales Road, Snohom-  
ish, WA 98296 (US). HOLMBERG, Randy; 24005 30th  
Drive SE, Bothell, WA 98021 (US).
- (74) **Agents:** YANG, Hain-ann, Hsueh et al.; Morrison & Fo-  
erster LLP, 755 Page Mill Road, Palo Alto, CA 94304-  
1018 (US).

(81) **Designated States** (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) **Designated States** (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

**Published:**

— with international search report (Art. 21(3))

(54) **Title:** SHOCK WAVE CATHETER SYSTEM WITH ARC PRECONDITIONING

(57) **Abstract:** A shock wave catheter system and method produces a shock wave with reduced energy. The system includes a catheter and a power source. The catheter has an elongated carrier and a balloon about the carrier in sealed relation thereto. The balloon is arranged to receive a fluid therein that inflates the balloon. The catheter further includes an arc generator including at least two electrodes within the balloon. The power source is coupled to the at least two electrodes and is configured to grow a bubble at one of the at least two electrodes and then thereafter to rapidly expand the bubble to form a shock wave within the balloon.



WO 2014/028885 A1

## SHOCK WAVE CATHETER SYSTEM WITH ARC PRECONDITIONING

### PRIORITY CLAIM

**[0001]** The present application claims the benefit of United States Provisional Patent Application Serial No. 61/684,398, filed August 17, 2012, and United States Patent Application Serial No. 13/777,807, filed February 26, 2013, the disclosures of each of which are hereby incorporated by reference in their entirety.

### BACKGROUND

**[0002]** The present invention relates to a treatment system for percutaneous coronary angioplasty or peripheral angioplasty in which a dilation catheter is used to cross a lesion in order to dilate the lesion and restore normal blood flow in the artery. It is particularly useful when the lesion is a calcified lesion in the wall of the artery.

**[0003]** Calcified lesions, currently treated with angioplasty balloons, require high pressures (sometimes as high as 10-15 or even 30 atmospheres) to break the calcified plaque and push it back into the vessel wall. With such pressures comes trauma to the vessel wall which can contribute to vessel rebound, dissection, thrombus formation, and a high level of restenosis. Non-concentric calcified lesions can result in undue stress to the free wall of the vessel when exposed to high pressures. An angioplasty balloon when inflated to high pressures can have a specific maximum diameter to which it will expand but the opening in the vessel under a concentric lesion will typically be much smaller. As the pressure is increased to open the passage way for blood the balloon will be confined to the size of the opening in the calcified lesion (before it is broken open). As the pressure builds a tremendous amount of energy is stored in the balloon until the calcified lesion breaks or cracks. That energy is then released and results in the rapid expansion of the balloon to its maximum dimension and may stress and injure the vessel walls.

**[0004]** Recently, a new system and method has been contemplated for breaking up calcium deposits in, for example, arteries and veins. Such a system is described, for example in U.S. Patent Publication No. 2009/0312768, Published December 17, 2009. Embodiments described therein include a catheter having balloon, such as an angioplasty balloon, at the distal end thereof, arranged to be inflated with a fluid. Disposed within the balloon is a shock wave

generator that may take the form of, for example, a pair of electrodes, which are coupled to a high voltage source at the proximal end of the catheter through a connector. When the balloon is placed adjacent a calcified region of a vein or artery and a high voltage pulse is applied across the electrodes, a shock wave is formed that propagates through the fluid and impinges upon the wall of the balloon and the calcified region. Repeated pulses break up the calcium without damaging surrounding soft tissue.

[0005] Each high voltage pulse causes an arc to form across the electrodes. The arc in turn causes a steam bubble to form. Each arc results in intense heat and energy for a brief period of time. Inside the small confines of tiny angioplasty balloons the fluid can warm up and become hot enough to damage tissue unless steps are taken to control the amount of energy released into the fluid. Just a two degree Celsius elevation in temperature above body temperature can result in tissue damage.

[0006] The amount of energy to assure the formation of the steam bubble and arc can be highly variable from arc to arc. Therefore, if the same amount of energy is used to assure the formation of each bubble and arc, more energy than is necessary will be used to form many of the bubbles and arcs. Excessive heating of the fluid within the balloon may result. Also, because greater applied energies create larger bubbles at the electrodes, the excessive energy will produce a larger bubble than required which can unduly stress the balloon walls.

[0007] Another consideration is the amount of energy represented by the high voltage applied to the electrodes. Each high voltage pulse removes a portion of the electrode material. Since the size of the electrodes must be small in order to fit into the calcified vein or artery, they are only capable of sustaining a limited numbers of high voltage pulses sufficient to form the shock wave resulting electrical arc.

[0008] Hence, there is a need in the art to be able to control the amount of energy required to produce the bubbles and arcs. It would also be desirable to be able to produce the bubbles and arcs with less energy than hereto for possible. The present invention addresses these and other issues.

## BRIEF SUMMARY

[0009] In one embodiment, a shock wave catheter system includes a catheter and a power source. The catheter has an elongated carrier and a balloon about the carrier in sealed relation thereto. The balloon is arranged to receive a fluid therein that inflates the balloon. The catheter further includes an arc generator including at least two electrodes within the balloon. The power source is configured to deliver a first electrical voltage across the at least two electrodes that grows a bubble at one of the at least two electrodes and then thereafter delivers a second electrical voltage across the at least two electrodes to create an arc across the at least two electrodes to rapidly expand the bubble to form a shock wave within the balloon.

[0010] The second electrical voltage is significantly greater than the first electrical voltage. The first electrical voltage is on the order of 50 volts and the second electrical voltage is between 300 and 10,000 volts.

[0011] The power source may be configured to hold the first electrical voltage for a first time period and to hold the second electrical voltage for a second time period, the first time period being significantly longer in length than the second time period. The first time period may be on the order of two milliseconds and the second time period may be on the order of one-half microsecond.

[0012] The balloon may be an angioplasty balloon.

[0013] According to other embodiments, a shock wave catheter system includes a catheter and a power source. The catheter has an elongated carrier and a balloon about the carrier in sealed relation thereto. The balloon is arranged to receive a fluid therein that inflates the balloon. The catheter further has an arc generator including at least two electrodes within the balloon. The power source is coupled to the at least two electrodes and is configured to grow a bubble at one of the at least two electrodes and then thereafter to rapidly expand the bubble to form a shock wave within the balloon.

[0014] In another embodiment, a method of producing an electrohydraulic shock wave includes growing a bubble within a fluid during a first time period and thereafter, rapidly expanding the bubble during a second time period.

[0015] The growing step may include providing at least two electrodes within the fluid and delivering a first voltage to the at least two electrodes during a first time period.

[0016] The expanding step may include delivering a second voltage to the at least two electrodes during a second time period. The second voltage may be greater than the first voltage and the first time period may be longer than the second time period. The second voltage may be between 300 and 10,000 volts. The first time period may be on the order of two milliseconds and the second time period may be on the order of one-half microsecond.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0017] The features of the present invention which are believed to be novel are set forth with particularity in the appended claims. The invention, together with further features and advantages thereof, may best be understood by making reference to the following description taken in conjunction with the accompanying drawings, in the several figures of which like reference numerals identify identical elements, and wherein:

[0018] **FIG. 1** is a simplified side view of an a shock wave catheter system embodying various embodiments of the invention to advantage;

[0019] **FIG. 2** is a simplified view, partly in perspective, of the electrode structure and power source employed in the catheter of **FIG. 1**;

[0020] **FIG. 3** is a graph illustrating typical voltage and current waveforms of voltage and current to form an electrohydraulic shock wave between a pair of electrodes as practiced in the prior art;

[0021] **FIG. 4** is a simplified view, to an enlarged scale, illustrating the growth of a large bubble at an electrode;

[0022] **FIG. 5** is a simplified view, to an enlarged scale, illustrating the growth of a small bubble at an electrode;

[0023] **FIG. 6** is a schematic diagram of a power source for use in an angioplasty electrical arc shock wave angioplasty catheter system according to an embodiment of the invention; and

[0024] **FIG. 7** is a graph illustrating voltage and current waveforms of voltage and current which may be derived from the power circuit of **FIG. 6** to form an electrohydraulic shock wave between a pair of electrodes as practiced according to an embodiment of the invention.

#### DETAILED DESCRIPTION

[0025] **FIG. 1** is a simplified side view of an angioplasty balloon catheter system **10** of the type that may utilize various embodiments of the invention to advantage. The system **10** includes a catheter **11** and a power source **30**.

[0026] The catheter **11** includes an elongated carrier, such as a hollow sheath **12** and a dilating balloon **14** formed about the sheath **12** in sealed relation thereto at a seal **16**. The balloon **14** has a tubular extension **18** which forms with the sheath **12** a channel **20** for admitting a fluid into the balloon **14**. The sheath **12** has a longitudinal lumen **22** through which a guide wire (not shown) may be received for directing the catheter **11** to a desired location within a vein or artery, for example.

[0027] The catheter **11** further includes an arc generator **24** within the balloon **14**. The arc generator, as may be best seen in **FIG. 2**, includes a lead **25** having a coaxially configured electrode pair including electrodes **26** and **28**. As may be seen in **FIG. 2**, electrode **26** forms a center electrode and electrode **28** forms a ring shaped electrode concentrically disposed about the center electrode **26**. As mentioned above, the sheath **12** forms with the balloon extension **18** a channel **20** through which fluid, such as saline, may be admitted into the balloon to inflate the balloon. The channel **20** further permits the electrodes **26** and **28** of lead **25** to be fed into the balloon **14**.

[0028] As may be seen in **FIGS. 1 and 2**, the electrodes **26** and **28** are attached to a source **30** of high voltage pulses. As may be seen in **FIG. 2**, the center electrode **26** is coupled to a positive terminal **34** of source **30** and the ring electrode **28** is coupled to a negative terminal **36** of the source **30**. The electrodes **26** and **28** may be formed of metal, such as stainless steel, and are maintained a controlled distance apart to allow a reproducible arc to form for a given applied voltage and current.

[0029] The electrical arcs between electrodes **26** and **28** in the fluid are used to generate shock waves in the fluid. Each pulse of high voltage applied to the electrodes **26** and **28** forms an arc

across the electrodes. The voltage pulses may have amplitudes as low as 500 volts, but preferably, the voltage amplitudes are in the range of 1000 volts to 10,000 volts. The balloon **14** may be filled with water or saline in order to gently fix the balloon in the walls of the artery or vein, for example, in direct proximity with the calcified lesion. The fluid may also contain an x-ray contrast to permit fluoroscopic viewing of the catheter during use. Once the catheter **11** is positioned with the guide wire (not shown), the physician or operator can start applying the high voltage pulses to the electrodes to form a plurality of discrete shock waves that crack the calcified plaque. Such shock waves will be conducted through the fluid, through the balloon, through the blood and vessel wall to the calcified lesion where the energy will break the hardened plaque without the application of excessive pressure by the balloon on the walls of the artery.

**[0030]** **FIG. 3** is a graph illustrating typical voltage (solid line) and current (dashed line) waveforms of voltage and current if traditional prior art techniques are employed to form an electrohydraulic shock wave between a pair of electrodes, such as electrodes **26** and **28**. Here it may be seen by reference character **40** that a voltage of 3,000 volts is applied between the electrodes. A low level current **42** flows through the water creating a bubble on the electrodes. After a delay **D**, for example one microsecond, at **44**, an arc jumps across the bubble. In this example, the arc is 200 amperes and jumps between the electrodes. When the arc starts, the voltage drops quickly and when the voltage pulse is terminated at **46**, it drops to zero. In this prior art methodology, the delay **D** is highly variable and has been measured to be as short as ninety nanoseconds to as long as 1000 nanoseconds. The delay **D** is also unpredictable from pulse to pulse. The shock wave is generated when the arc current occurs at **44**. Since the delay **D** is unpredictable, the voltage pulse must be have a duration long enough to assure an arc will form. In the example, that duration is about 1.8 microseconds. The net result of a fixed long voltage is that more energy is applied to each pulse than is needed to assure the occurrence of an arc. The excess energy needlessly heats the fluid in the balloon.

**[0031]** **FIGS. 4 and 5** illustrate the cause of the variable delay **D**. Sometimes, as shown in **FIG. 4**, a large bubble **50** is formed before the arc **60** occurs. However, at other times, a small bubble **52** is formed before the arc **60** occurs causing the arc to occur more quickly. The bubbles are formed by electrolysis of the fluid and a large bubble takes longer to form than a small

bubble. The arc occurs when the voltage across the bubble is sufficient to arc the gap and is highly variable.

[0032] **FIG. 6** is a schematic diagram of a power source **30** for use in an angioplasty electrical arc shock wave angioplasty catheter system according to an embodiment of the invention. As will be seen, the power source delivers a first low voltage across the electrodes to pre-grow the bubble at one of the electrodes and thereafter delivers a second higher voltage across the electrodes to rapidly expand the pre-grown bubble to cause the arc and the shock wave in a time controlled manner.

[0033] The source **30** includes control logic **70**, a first transistor **72**, a second transistor **74**, and output terminals **76** and **78**. Output terminal **76** is arranged to coupled through a connector **38** (**FIG. 1**) to the center electrode **26** (**FIG. 2**) of the shock wave generator **24** and output **78** is arranged to be coupled through the connector to the outer electrode **28** of the shock wave generator. The output terminal is connected to a 3,000 volts source.

[0034] Initially, the control logic **70** delivers a two millisecond (2 ms) control pulse **80** to the gate of transistor **72**. This causes a low (for example, 25ma) current through the electrodes and a resistor **73**. The low current applied for 2 ms forms a bubble on one of the electrodes of a predictable size. After the 2 ms, the control logic **70** turns transistor **74** on hard for 500 nanoseconds (500 ns). This applies the full 3,000 volts to the electrodes. The control logic **70** may turn transistor **74** on hard immediately after the 2 ms period or a short time thereafter, as for example, 10 microseconds after the 2 ms period. An arc and shock wave will occur essentially immediately. Since the high voltage is applied for only a short time, here 500 ns, a reduced amount of energy is delivered to the fluid within the balloon for generating each shock wave. As a result, much less heat is generated in the fluid within the balloon.

[0035] **FIG. 7** is a graph illustrating voltage and current waveforms of voltage (solid line) and current (dashed line) which may be derived from the power source **30** of **FIG. 6** to form an electrohydraulic shock wave between the pair of electrodes **26** and **28** as practiced according to the embodiment of **FIG. 6**. First, a low voltage **90** is applied across the electrodes when transistor **72** is turned on for 2 ms. The low voltage assures that an arc will not occur across the electrodes. However, the low voltage does produce a low current **92** (25 ma) to flow through the electrodes. During this 2 ms period, a bubble of predictable size is grown on one of the



electrodes. The bubble size may be controlled by the amount of current and the length of time the low current is applied. After the 2 ms period, the transistor **74** is turned on hard to apply a narrow pulse (500 ns) of the full 3,000 volt high voltage **94** across the electrodes. During this short time, a current of 250 amperes may flow between the electrodes. The high voltage and current rapidly expands the pre-grown bubble and within a short delay time **DT** causes the arc and shock wave to be produced at **96**. The arc and shock wave are produced quickly because the bubble had already been pre-grown by the low voltage **90**. The voltage and current fall quickly to zero at **98**.

[0036] As may be seen from the foregoing, the high voltage pulse is applied for a much shorter period of time to produce the arc and shock wave because the bubble had already been pre-grown by the preceding low voltage and current. The overall arc energy is lower and the steam bubble will be smaller. This results in less energy being applied to the fluid within the balloon for each generated shock wave. The fluid is therefore heated less and there is less stress on the wall of the balloon.

[0037] While particular embodiments of the present invention have been shown and described, modifications may be made. It is therefore intended in the appended claims to cover all such changes and modifications which fall within the true spirit and scope of the invention as defined by those claims.

What is claimed is:

1. A shock wave catheter system, comprising:  
a catheter having an elongated carrier, a balloon about the carrier in sealed relation thereto, the balloon being arranged to receive a fluid therein that inflates the balloon, and an arc generator including at least two electrodes within the balloon; and  
a power source that delivers a first electrical voltage across the at least two electrodes that grows a bubble at one of the at least two electrodes and then thereafter delivers a second electrical voltage across the at least two electrodes to create an arc across the at least two electrodes and to rapidly expand the bubble to form a shock wave within the balloon.
2. The shock wave catheter system of claim 1, wherein the second electrical voltage is significantly greater than the first electrical voltage.
3. The shock wave catheter system of claim 2, wherein the first electrical voltage is on the order of 50 volts and the second electrical voltage is between 300 and 10,000 volts.
4. The shock wave catheter system of claim 1, wherein the power source is configured to hold the first electrical voltage for a first time period and to hold the second electrical voltage for a second time period, the first time period being significantly longer in length than the second time period.
5. The shock wave catheter system of claim 4, wherein the first time period is on the order of two milliseconds and the second time period is on the order of one-half microsecond.
6. The shock wave catheter system of claim 1, wherein the balloon is an angioplasty balloon.
7. A shock wave catheter system, comprising:  
a catheter having an elongated carrier, a balloon about the carrier in sealed relation thereto, the balloon being arranged to receive a fluid therein that inflates the balloon, and an arc generator including at least two electrodes within the balloon; and

a power source coupled to the at least two electrodes configured to grow a bubble at one of the at least two electrodes and then thereafter to rapidly expand the bubble to form a shock wave within the balloon.

8. The shock wave catheter system of claim 7, wherein the power source is arranged to grow the bubble during a first time period and to expand the bubble during a second time period, the first time period being longer than the second time period.

9. The shock wave catheter system of claim 8, wherein the power source is arranged to deliver a first voltage to the arc generator during the first time period to grow the bubble and to deliver a second voltage to the arc generator during the second time period to rapidly expand the bubble.

10. The shock wave catheter system of claim 9, wherein the second voltage is greater in magnitude than the first voltage.

11. A method of producing an electrohydraulic shock wave, comprising:  
growing a bubble within a fluid during a first time period; and thereafter, and  
rapidly expanding the bubble during a second time period.

12. The method of claim 11, wherein the growing step includes providing at least two electrodes within the fluid and delivering a first voltage to the at least two electrodes during a first time period.

13. The method of claim 12, wherein the expanding step includes delivering a second voltage to the at least two electrodes during a second time period.

14. The method of claim 13 wherein the second voltage is greater than the first voltage and wherein the first time period is longer than the second time period.

15. The method of claim 14, wherein the second voltage is between 300 and 10,000 volts.

16. The method of claim 14 wherein the first time period is on the order of two milliseconds and the second time period is on the order of one-half microsecond.

1/3

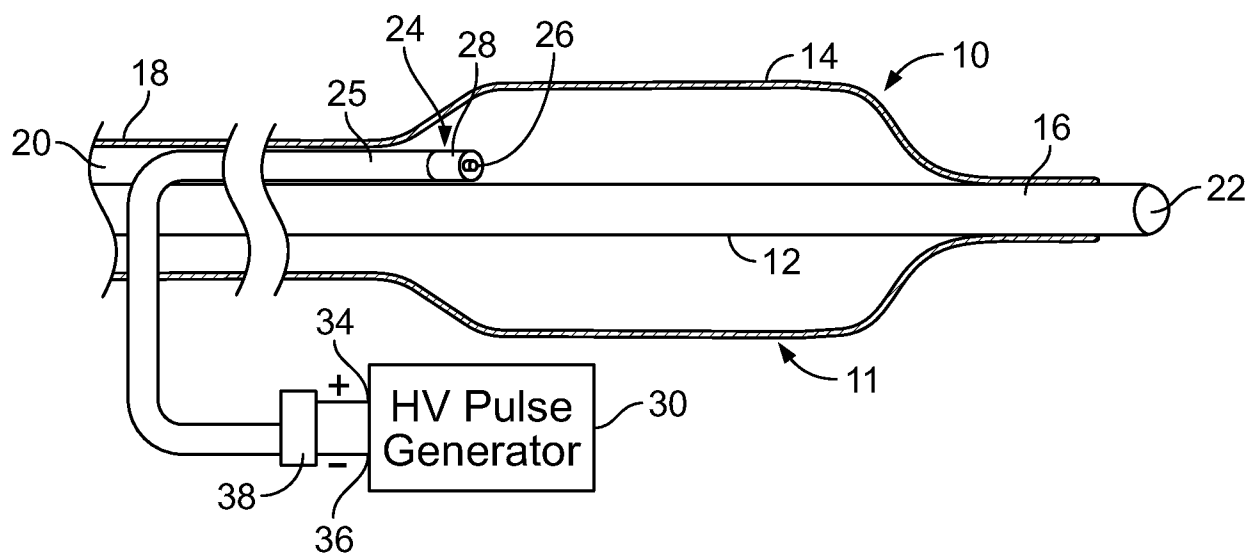


FIG. 1

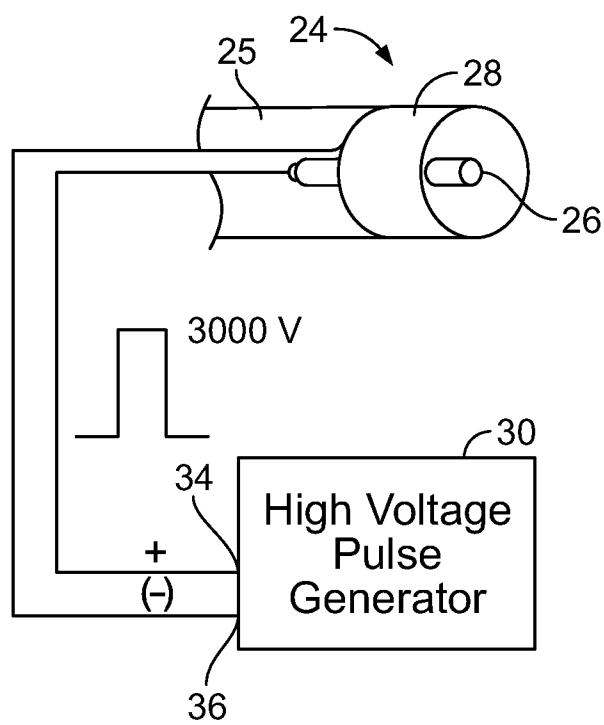
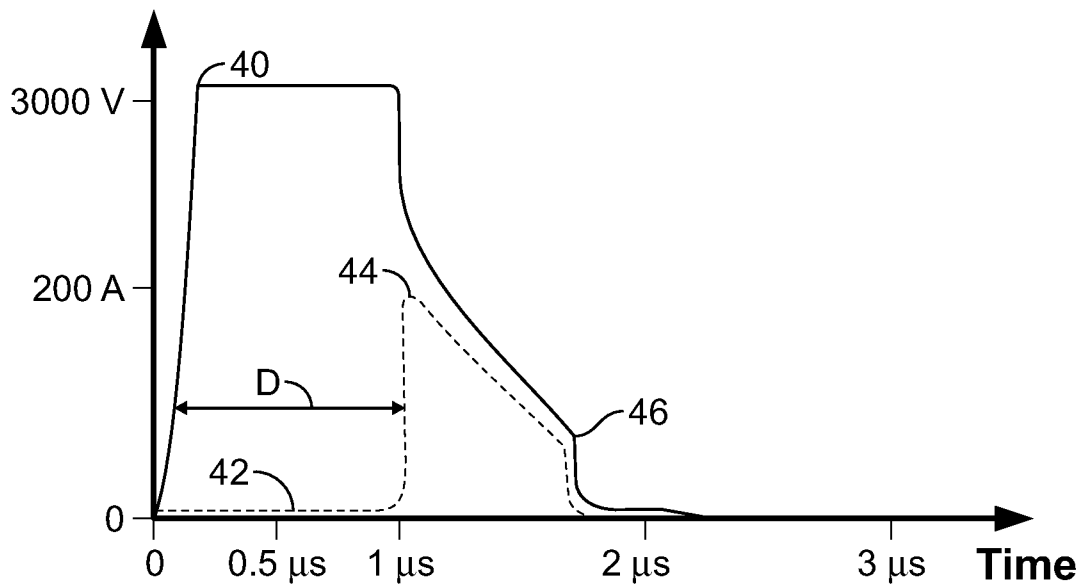
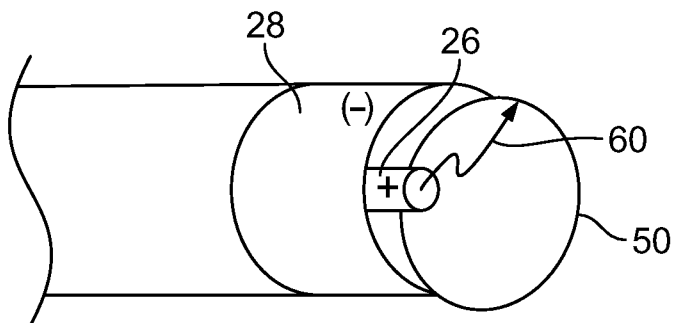


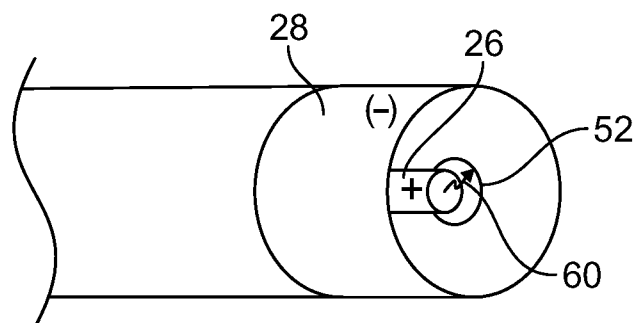
FIG. 2



**FIG. 3**  
**(Prior Art)**



**FIG. 4**



**FIG. 5**

3/3

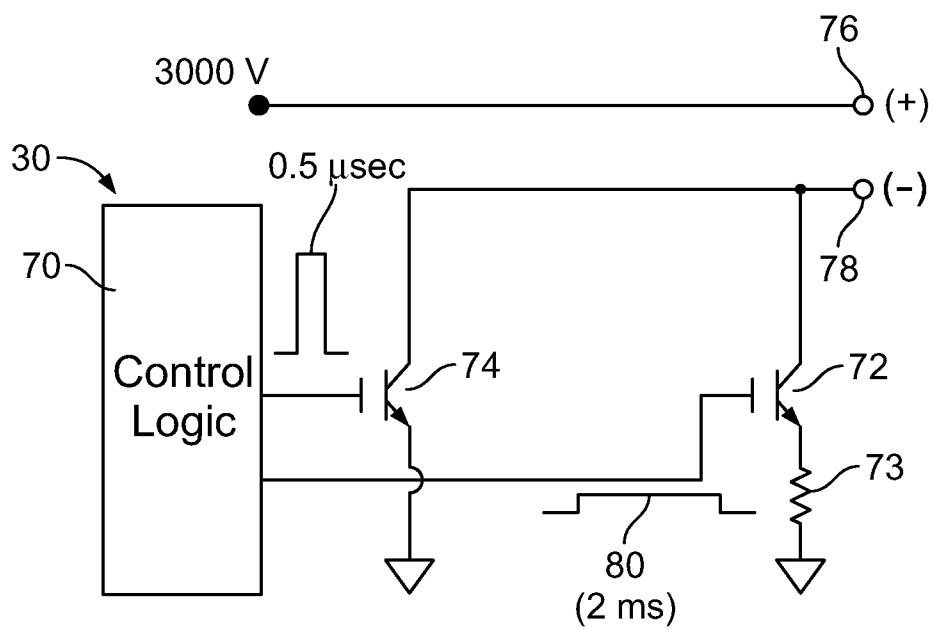


FIG. 6

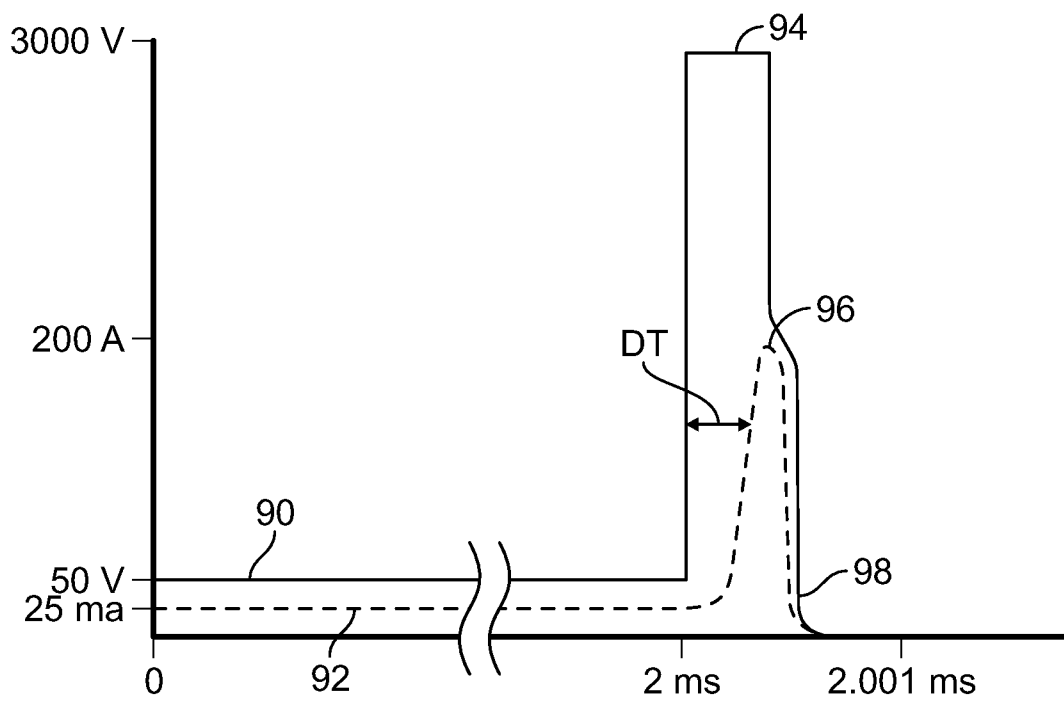


FIG. 7

## INTERNATIONAL SEARCH REPORT

International application No

PCT/US2013/055431

## A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B17/22 G10K15/06  
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 G10K

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.
A	US 2009/312768 A1 (HAWKINS DANIEL [US] ET AL) 17 December 2009 (2009-12-17) cited in the application paragraph [0052]; figures 2-4 -----	1,7,11
A	US 5 009 232 A (HASSLER DIETRICH [DE] ET AL) 23 April 1991 (1991-04-23) column 7, line 12 - line 40; figure 2 -----	1,7,11
A	US 2012/071889 A1 (MANTELL ROBERT [US] ET AL) 22 March 2012 (2012-03-22) paragraph [0029]; figure 2 -----	1,7,11



Further documents are listed in the continuation of Box C.



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

4 November 2013

Date of mailing of the international search report

12/11/2013

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

Moers, Roelof



# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2013/055431

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2009312768	A1	17-12-2009	AU 2009257368 A1 17-12-2009
			CA 2727429 A1 17-12-2009
			EP 2300091 A2 30-03-2011
			JP 2011524203 A 01-09-2011
			US 2009312768 A1 17-12-2009
			US 2011166570 A1 07-07-2011
			US 2013030447 A1 31-01-2013
			WO 2009152352 A2 17-12-2009
US 5009232	A	23-04-1991	EP 0355177 A1 28-02-1990
			JP H0228214 U 23-02-1990
			US 5009232 A 23-04-1991
US 2012071889	A1	22-03-2012	EP 2285296 A2 23-02-2011
			US 2010036294 A1 11-02-2010
			US 2012071889 A1 22-03-2012
			WO 2009136268 A2 12-11-2009