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Published:

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

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(54) Title: AN AIRWAY CARDIOVERTER-DEFIBRILLATOR SYSTEM

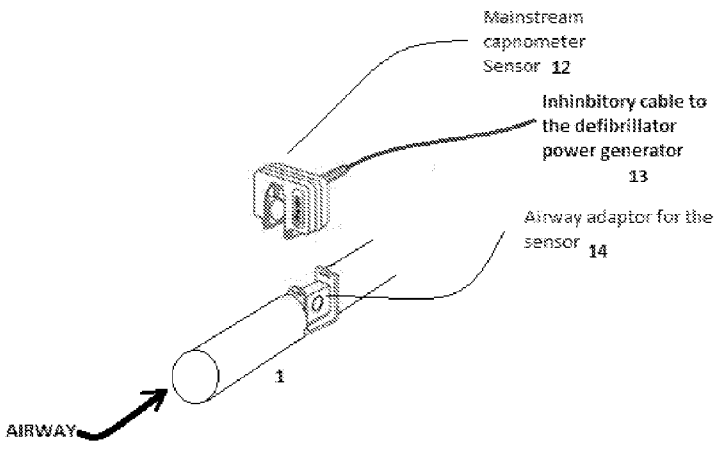

Figure 10 - Safety circuit with End Tidal capnographic sensor and circuit breaker connection.

(57) Abstract: An airway cardioverter-defibrillating system comprises a conductive Nano-balloon inserted to an airway tube. The airway cardioverter-defibrillating system functions either with unipolar or bipolar circuit configuration. The system is operatively arranged to supply safe continuous defibrillation pulses directly to the heart with simultaneous continuous external cardiac massage. The system also provides ventilation.

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An airway cardioverter-defibrillator system

Technical field

The present invention relates generally to a system for defibrillating a heart. More particularly for defibrillating the heart using an oro-pharyngeal path.

Background of the invention

Fibrillations cause the heart to stop pumping blood, leading to brain damage and/or cardiac arrest. About 10% of the ability to restart the heart is lost with every minute that the heart stays in fibrillation. Death can occur in minutes unless the normal heart rhythm is restored through defibrillation. Immediate defibrillation is crucial to the patient's survival. Defibrillators deliver a brief electric shock to the heart, which enables the heart's natural pacemaker to regain control and establish a normal heart rhythm.. During defibrillation, the paddles are placed on the patient's chest, caregivers stand back, and the electric shock is delivered. The patient's pulse and heart rhythm are continually monitored. Defibrillation continues until the patient's condition stabilizes or the procedure is ordered to be discontinued. Rapid detection, CPR and defibrillation are means to restore a normal heart rhythm and prevent death after sudden cardiac arrest (SCA) due to Ventricular Fibrillation (VF). If a patient is effectively defibrillated after the onset of SCA, survival rates are high. Therefore, the way to increase the chance of survival for an SCA victim through early detection, CPR and defibrillation.

The surface defibrillation needs high energy defibrillating current (100 to 200 joules biphasic or 360 joules monophasic). This amount of current is very dangerous for the rescuer. Defibrillation process requires rescuers to stand aside from the patient, which necessarily interrupts the chest compression activity. Interruption of the chest compressions stops the CPR-induced blood circulation and takes several compressions before the oxygenated blood regains the previous momentum. Flence, with the external defibrillation the patient gets an inconsistent and interrupted form of circulation and oxygen delivery. However, this dangerously high defibrillating current is inevitable to deliver successful external defibrillation due to the fact, that the skin impedes nearly 90% of the current energy.

Current invention aims to overcome this inconsistent CPR circulation and oxygen delivery by delivery the defibrillating current through the airways. Airway linings are moist, non-keratinized surfaces, which pose a very low impedance to the defibrillating energy. Furthermore, large blood vessels lie in juxtaposition to the airways. These blood vessels act as preferential conductor of electricity to the heart.

Thus by this invention a small amount of energy (15-20 Joules), which is harmless to the resuscitator, even when they are in contact with the patient, can be effective in

defibrillating/cardioverting the patient. This would make continuous, uninterrupted chest compression along with defibrillation and safe possibility that will improve the results of CPR.

SUMMARY OF THE INVENTION

The current invention is a combination of an airway tube and inflatable Nano-conductive balloon comprises defibrillating electrodes, bridging cables, and skin surface/subcutaneous electrodes. The said conductive balloon/s are placed along various airway tubes, e.g. Endotracheal tube, Combitubes, King's tube, Laryngeal mask airway & Oropharyngeal airway. Bridging cables are insulated electrical wires extending from the electrically conductive inflatable balloon/cuff to the Power generator and back to the said balloon/cuff or to the skin electrodes. The Aforementioned components together form a cardioverter-defibrillator system to be used in management of cardiac arrest.

Brief Description of Drawings

These and other objects and features of the present invention will be more fully disclosed or rendered obvious by the following detailed description of the preferred embodiments of the present invention, which are to be considered together with the accompanying drawings wherein like numbers refer to like elements and further wherein:

Figure 1: Schematic cross-sectional diagram of Bipolar Circuit with two halves of the electrically conductive balloon cathode and anode separated from each other by a non-conductive circumferential belt.

Figure 2: Bipolar electrically conductive balloon

Figure 3: Bipolar electrically conductive balloon over an endotracheal tube.

Figure 4: Bipolar electrically conductive balloon over an Oropharyngeal tube.

Figure 5: Unipolar electrically conductive balloon

Figure 6: Schematic cross-sectional diagram of Unipolar Circuit where the whole circumference of the electrically conductive balloon function as a Cathode electrode. The Anode electrode and cable, extend from the chest wall surface to the Defibrillator power generator.

Figure 7: Unipolar circuit with subcutaneous skin Electrode.

Figure 8: Unipolar electrically conductive balloon over an endotracheal tube.

Figure 9: Unipolar electrically conductive balloon over an Oropharyngeal tube.

Description of Related art

In the majority of cardiac arrests, the arrest is due to ventricular fibrillation, which causes the heart to immediately stop pumping blood. To treat ventricular fibrillation, defibrillation is administered which involves the delivery of a high energy electric shock to the thorax to depolarize the myocardium, and to allow a perusing rhythm to restart. If, however, more than few minutes pass between the onset of ventricular fibrillation and the delivery of the first defibrillation shock, the heart may be so deprived of metabolic substrates that defibrillation is unsuccessful.
The role of CPR is to restore the flow of oxygenated blood to the heart, which may allow defibrillation to occur.

Prior art

US application number 201 7304640 described (to SATO MASASHI) describes Automated external defibrillator (AED) which are easy to operate units that may be used by the layperson or healthcare personnel who only have basic training with color indications for the pads. These machines instruct the delivery of shocks when required or deliver them automatically. The drawbacks of this technology are that the AED systems can only be used to treat ventricular fibrillation and ventricular tachycardia and no other forms of cardiac arrhythmia. Furthermore, in order to allow the machine time to analyze the cardiac rhythm, chest compressions usually need to be stopped.

Application number WO201 5039591 that described the invention is based on a selective double-lumen endotracheal tube (ETT) made of rubber/ silicone or other plastic material and hence electrically nonconductive and sticking pieces of electrically conductive electrodes on the balloon with an interconnected circuit metal and wires are stuck to the balloon. The electrodes can become dislodged during insertion, or can produce injury to the inner lining of the bronchi. It will turn out the balloon to be rigid and not fully inflatable. On the other hand electrodes would generate heat and damage the tissues and/or the balloon itself, since heat generated by current is inversely related to the surface area of the electrode. That is why these electrode-mounted balloons did not succeed in defibrillation.

In US patent number 541 771 3 (to Todd J. Cohen) Transesophageal defibrillating system transesophageal defibrillating system includes a large area anterior patch electrode and a large area posterior patch electrode, as in some conventional exterior defibrillating systems.. The system is operatively arranged to supply either defibrillation pulses between the large anterior patch electrode and the distal electrode or the large posterior electrode, depending on which one of the latter two electrodes is connected or coupled by the clinician or paramedic to the defibrillating pulse source. The system includes a source of pacing pulses which may be supplied to the patient via the anterior patch electrode and at least one of the electrodes carried by the esophageal probe. The distal electrode is believed to be the more effective electrode to use for this purpose

DETAILED DESCRIPTION

This disclosure generally relates to medical devices and, more particularly, airway cardioverter-defibrillator. This invention relates to a method and system for expediting the rescue of victims experiencing sudden cardiac arrest (SCA) when used in conjunction with uninterrupted external cardiac massage. The system involves an airway tube, electrically conductive Nano coated balloon, bridging cables and sensor. Referring to the drawings in detail show an airway cardioverter- defibrillator system. The illustrated system comprises licensed technology Korean application number KR1 0-201 7-01 13174 “Balloon for catheter coated with multilayer electroconductive” 2,3&4, to function as means of receiving (sensing) and imparting (delivering) currents of biologically relevant magnitude. A high electrical conductive surface would be coated upon a biocompatible balloon (inflatable/ flexible/ foldable/ stretchable) with high biomechanical properties such as high adhesion strength, high fracture toughness and proper biocompatibility for biomedical application. The coating over the balloon would have suitable conductive conduits/wires 5, to carry the electrical current to and from the “conductive balloon” surface. The Nano-coated balloon is capable of passage of up to 60 watts energy, without thermal damage to the tissues or damage to the balloon due to the wide area of current transmission from the whole surface of the balloon. The completely Nano-coated balloon or cuff acts as one electrode while the other electrode is attached to the chest wall of the patient 4. Single conductive lead connects the single inflatable member (balloon/cuff) to the outside along various airway tubes, example endotracheal tube, Combitubes, King’s tube, Laryngeal mask airway & Oropharyngeal airway. Making the innovation practical in defibrillation during Cardio-Pulmonary Resuscitation (CPR) within general wards, hospital areas and even by emergency staff in out of the hospital places.

The illustrated embodiment further comprising combination of an airway tube 1 and inflatable Nano-conductive balloon 7 comprises defibrillating electrodes 2,3 electrically conductive inflatable balloon/cuff and skin surface/subcutaneous electrodes 11. The said conductive balloon/s 7 are placed along various airway tubes 1, e.g. endotracheal tube, Combitubes, King’s tube, Laryngeal mask airway & Oropharyngeal airway. Bridging cables 5, said cables are insulated, electrical wires extending from the electrically conductive inflatable balloon/cuff to the Power generator 6 and back to the said balloon/cuff or to the skin electrodes 11. An electrically inert belt 4 to separate between the cathode 3 and the anode 2 parts of the conductive balloon. Balloon inflation and deflation conduit 10.

One other preferred embodiment of the Airway cardiac Defibrillation system illustrated in figure 1 is the bipolar circuit. In the embodiment, the electrically conductive coating of the inflatable balloon/cuff 7 comprising two or more divided separate conductive surfaces named electrodes by a suitable widths non-conductive belt 4 thus permitting the inflatable balloon/cuff to function as two or more separate Cathode 3 & Anode 2 electrodes. Each one of these electrodes 2 & 3 being in connection with the Defibrillator power generator unit 6.

In another embodiment, more than one electrically conductive balloons 7 could be placed along the course of the airway tube. Whereby one distal balloon acts as a

cathode electrode while the proximal balloon acts as an anode electrode to complete the circuit.

In another embodiment Figure 5 clarified, the unipolar circuit of the airway defibrillator. In this embodiment, the completely electrically conductive coating of inflatable balloon/cuff, acts as a single cathode (negative terminal) electrode 3.

Figure 6, shed the light on one cathode bridging cable 9 extends from the electrically conductive inflatable balloon/cuff 7 to the power generator 6 and other single or multiple anode bridging cables lead 8, from the Power generator unit 6 to the chest wall of the person directly to the surface of the skin 11, Adhering to the chest wall via a bridge cable 5.

Figure 7, illustrates another embodiment of the unipolar circuitry; wherein the patient-end of the external anode terminal is an un-insulated conducting segment of the cable passing through the subcutaneous tissue, by means of an attached curved or straight needle, to the skin surface. Figure 8 illustrates such an arrangement over an endotracheal Tube while Figure 9 illustrates such an arrangement over an Oropharyngeal tube as examples for the aforementioned embodiment.

Figure 10, in an added safety embodiment to the airway cardioverter-defibrillator system comprises a breathing capnography sensor 12. It functions by appropriate electrical circuit and airway adaptor 14. The sensor functions either with unipolar or bipolar circuit configuration of the airway cardioverter-defibrillator system. Additional embodiment that it is activated by either mainstream &/or side stream end tidal level of carbon dioxide. It sends impulse through the inhibitory cable 13 to the defibrillator power generator 6. The sensor breaks the circuit off the defibrillator power generator 6 and hence stop defibrillation.

Brief Description of Drawings

These and other objects and features of the present invention will be more fully disclosed or rendered obvious by the following detailed description of the preferred embodiments of the present invention, which are to be considered together with the accompanying drawings wherein like numbers refer to like elements and further wherein:

Figure 1: Schematic cross-sectional diagram of Bipolar Circuit with two halves of the electrically conductive balloon cathode and anode separated from each other by a non-conductive circumferential belt.

Figure 2: Bipolar electrically conductive balloon

Figure 3: Bipolar electrically conductive balloon over an endotracheal tube.

Figure 4: Bipolar electrically conductive balloon over an Oropharyngeal tube.

Figure 5: Unipolar electrically conductive balloon

Figure 6: Schematic cross-sectional diagram of Unipolar Circuit where the whole circumference of the electrically conductive balloon function as a Cathode electrode. The Anode electrode and cable, extend from the chest wall surface to the Defibrillator power generator.

Figure 7: Unipolar circuit with subcutaneous skin Electrode.

Figure 8: Unipolar electrically conductive balloon over an endotracheal tube.

Figure 9: Unipolar electrically conductive balloon over an Oropharyngeal tube.

Drawings:

Claims

1. An airway cardioverter-defibrillator system, comprising:
an airway tube wherein the tube has a proximal end and a distal end at least a portion of said tube being positioned within the airway of the subject,

A power source connected to a first circuit ground;

An electrically conductive module;

Bridging cables;

A Skin surface electrode; and

A Mainstream capnometric sensor.

2. Airway cardioverter-defibrillator system according to claim 1, further comprising a bipolar circuit wherein the electrically conductive module is divided into two or more separate conductive surfaces named electrodes by having suitable widths of non-conductive belt thus permitting the module to effectively function as two or more separate cathode & anode connected to the defibrillator power generator unit.

3. Airway cardioverter-defibrillator system according to claim 1, wherein two electrically conductive modules could be placed along the course of the airway tube wherein one distal balloon acts as a cathode electrode while the proximal balloon acts as an anode electrode to complete the circuit.

4. Airway cardioverter-defibrillator system according to claim 1, further comprising unipolar circuit wherein the whole circumference of the electrically conductive module functions as a cathode electrode. The Anode electrode and cable extend from the chest wall surface to the defibrillator power generator.

5. The negative terminal electrode according to claim 4, comprising one cathode bridging cable extends from the electrically conductive module to the power generator and other single or multiple anode bridging cables lead, from the power generator unit to the chest wall of the person directly to the surface of the skin, adhering to the chest wall via a bridge cable.

6. The unipolar circuitry according to claim 4, where in the patient-end of the external Anode terminal is an un-insulated conducting segment of the cable passing through the subcutaneous tissue. The cable is attached to the skin by curved or straight needle.

7. A method performed by an Airway cardioverter-defibrillator system to induce a tachyarrhythmia, the method comprises:

Once cardiac arrest is confronted, the medical rescue team insert the airway cardioverter defibrillator system;

Connect to a power generator;

Wherein, impulses pass through the cathode and anode bridging cables to deliver the electrical current to an electrically conductive module;

The electrically conductive module sends out a controlled burst of impulses and shocks to the heart to restore a normal rhythm.

The sensor is activated by mainstream &/or side stream end tidal level of carbon dioxide. The sensor breaks the circuit off the defibrillator power generator and hence stop defibrillation.

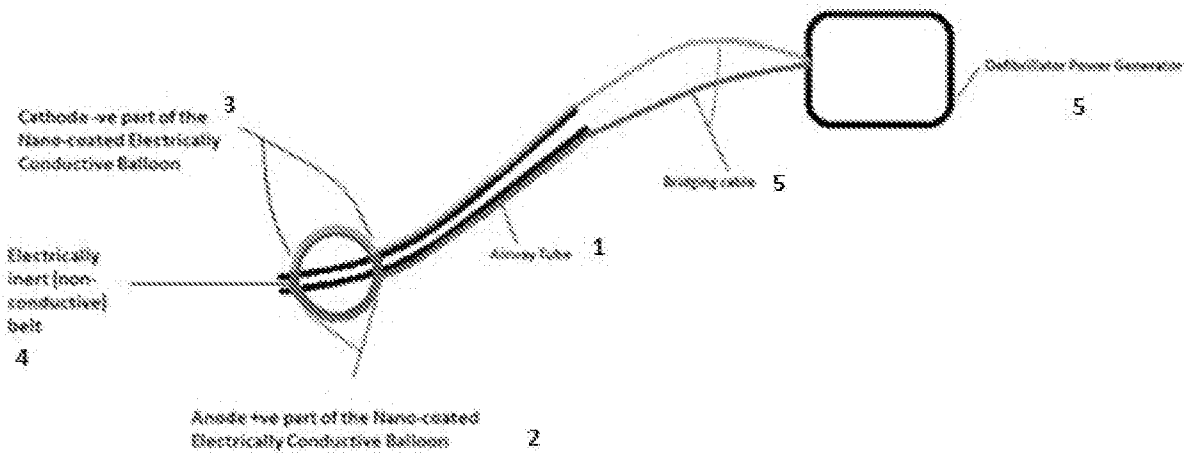

Figure 1– Schematic cross-sectional diagram of Bipolar Circuit with two halves of the electrically conductive balloon (Cathode and Anode, Orange & red colours, respectively), separated from each other by a non-conductive circumferential belt (blue colour) .

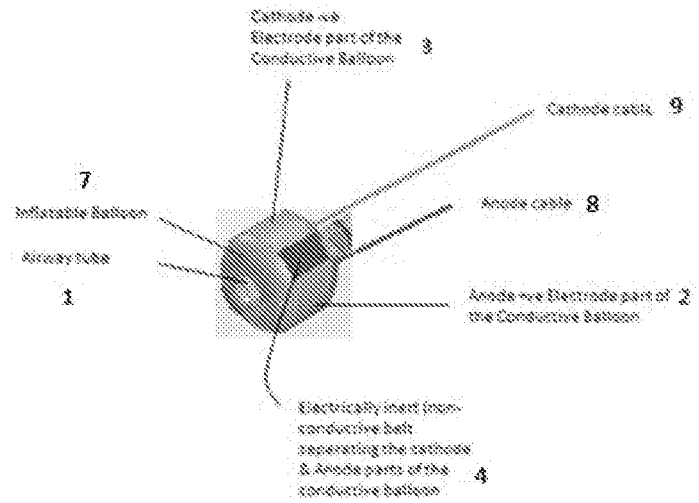

Figure 2: Bipolar electrically conductive balloon

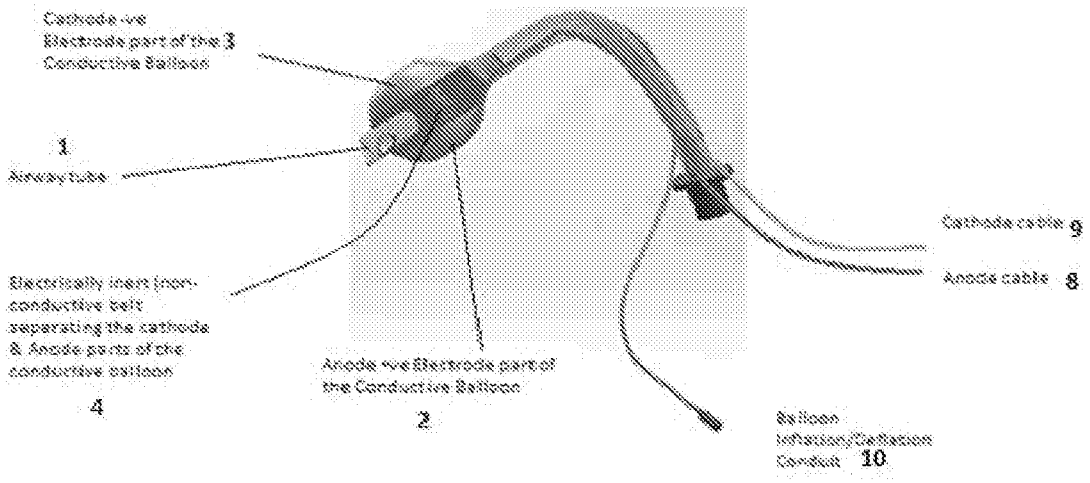

Figure 3: Bipolar electrically conductive balloon over an endotracheal tube.

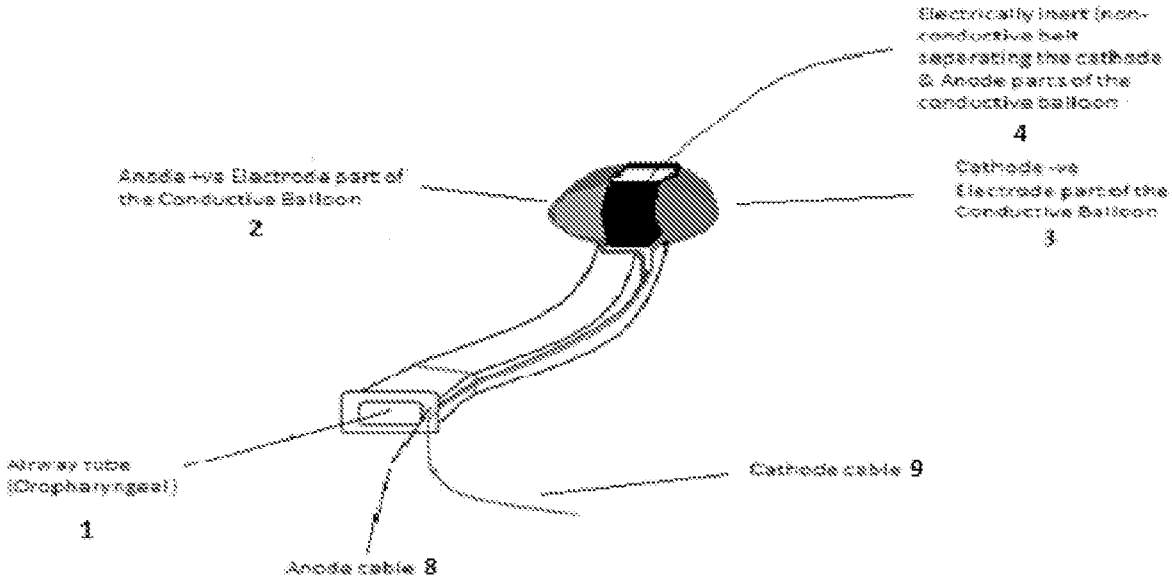

Figure 4: Bipolar electrically conductive balloon over an Oropharyngeal tube.

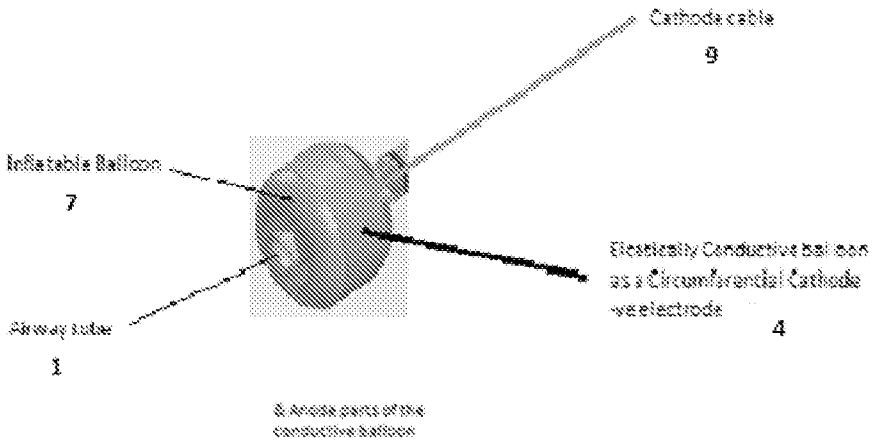

Figure 5: Unipolar electrically conductive balloon

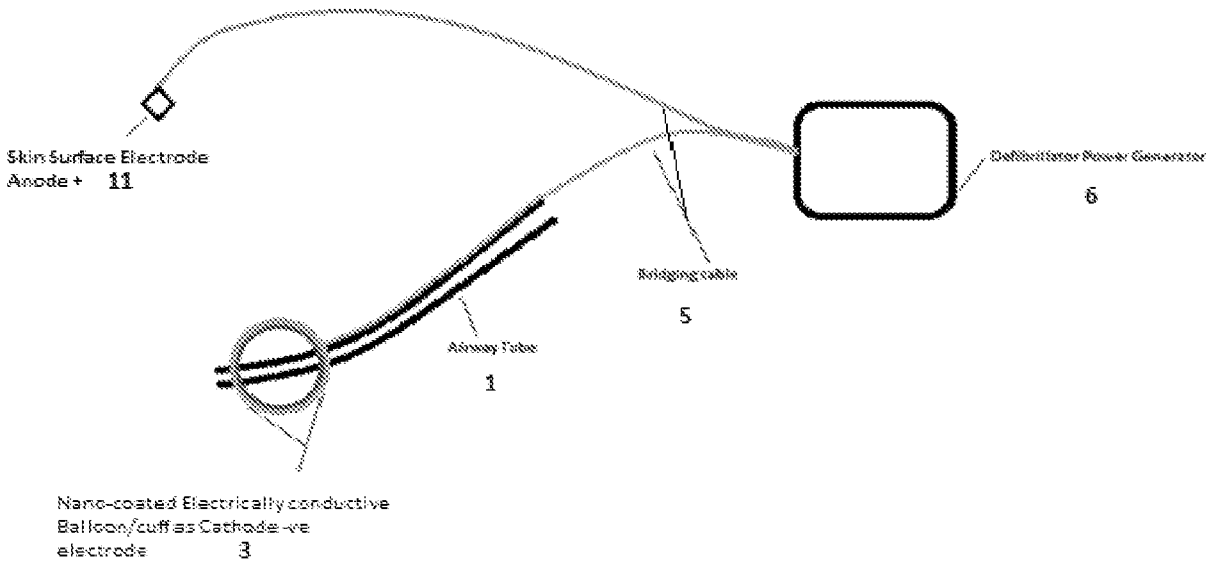

Figure 6– Schematic cross-sectional diagram of Unipolar Circuit where the whole circumference of the electrically conductive balloon function as a Cathode electrode (orange colour). The Anode electrode and cable (blue colour), extend from the chest wall surface to the Defibrillator power generator.

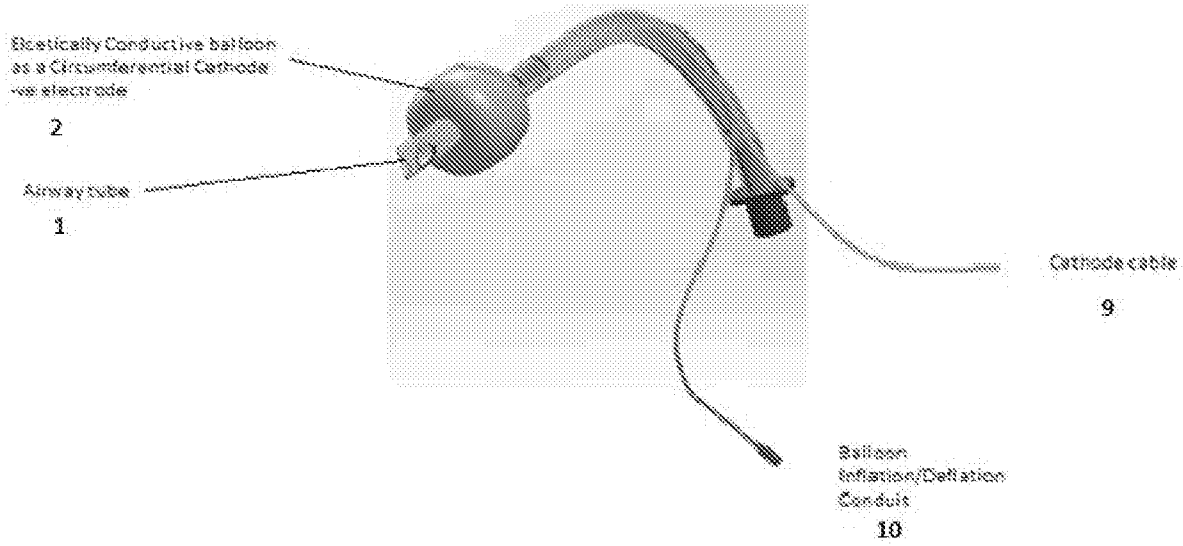

Figure 8: Unipolar electrically conductive balloon over an Endo-Tracheal tube.

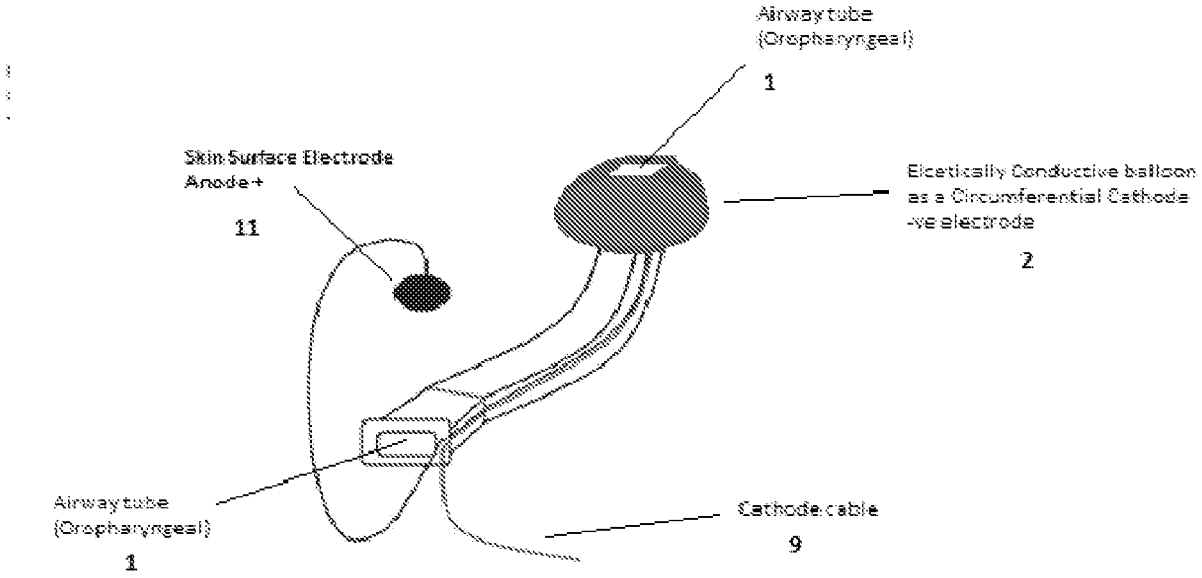

Figure 9: Unipolar electrically conductive balloon over an Oropharyngeal tube.

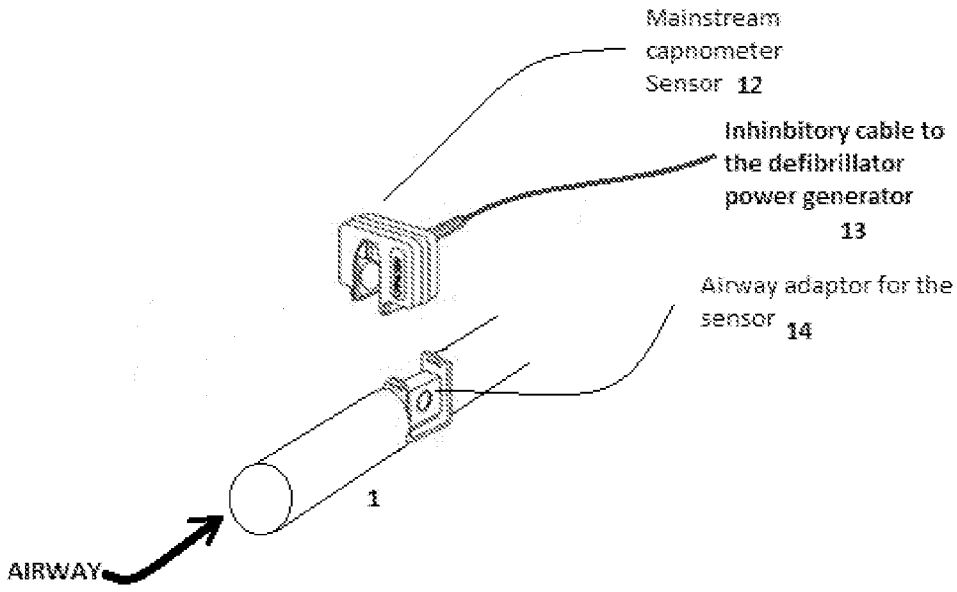

Figure 10 – Safety circuit with End Tidal capnographic sensor and circuit breaker connection.

INTERNATIONAL SEARCH REPORT

International application No
PCT/QA2017/000005

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/05 A61N1/39
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)
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 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 Y	US 2015/265790 A1 (NOLAN CLAY [US]) 24 September 2015 (2015-09-24) abstract; figures 1-11B paragraphs [0014] - [0176]	1,2 3-6
Y	US 4 198 963 A (BARKALOW C E; ELAM J O) 22 April 1980 (1980-04-22) the whole document	1-6
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Y	US 2002/032468 A1 (HILL MICHAEL R S [US] ET AL) 14 March 2002 (2002-03-14) the whole document	3-6

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[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) orwhich 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
4 April 2019	12/04/2019

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	Lins, Stephanie

INTERNATIONAL SEARCH REPORT

International application No
PCT/QA2017/000005

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2015/068164 A1 (INOVYTEC MEDICAL SOLUTIONS LTD [IL]) 14 May 2015 (2015-05-14) the whole document -----	1-6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/QA2017/000005

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.: 7
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

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.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/QA2017/000005

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