United States Patent [19]

Freed

[11] **3,707,960**

[45] **Jan. 2, 1973**

[54] **BALLOON CARDIAC ASSISTING PUMP HAVING INTRAAORTIC ELECTROCARDIOGRAPHIC ELECTRODES**

[75] Inventor: **Paul S. Freed**, Brooklyn, N.Y.

[73] Assignee: **The United States of America as represented by the Secretary of the Department of Health**

[22] Filed: **Sept. 3, 1970**

[21] Appl. No.: **69,191**

[52] **U.S. Cl.** .....**128/2.06 E**, 128/1 D

[51] **Int. Cl.** **A61b 5/04**

[58] **Field of Search**...128/1 R, 2.05 R, 2.06 E, 2.1 E, 128/DIG. 4

[56] **References Cited**

UNITED STATES PATENTS

3,504,662	4/1970	Jones	128/1 R
3,585,983	6/1971	Kantrowitz et al.	128/1 R
3,533,403	10/1970	Woodson	128/2.06 E
3,187,745	6/1965	Baum et al.	128/2.06 E
3,547,105	12/1970	Paine	128/2.06 E

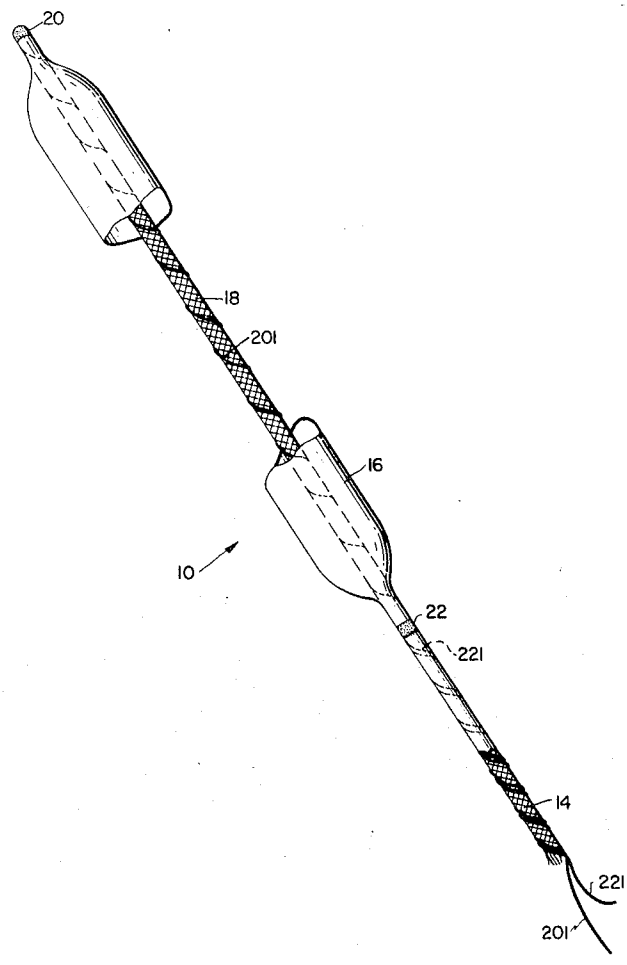
Primary Examiner—William E. Kamm

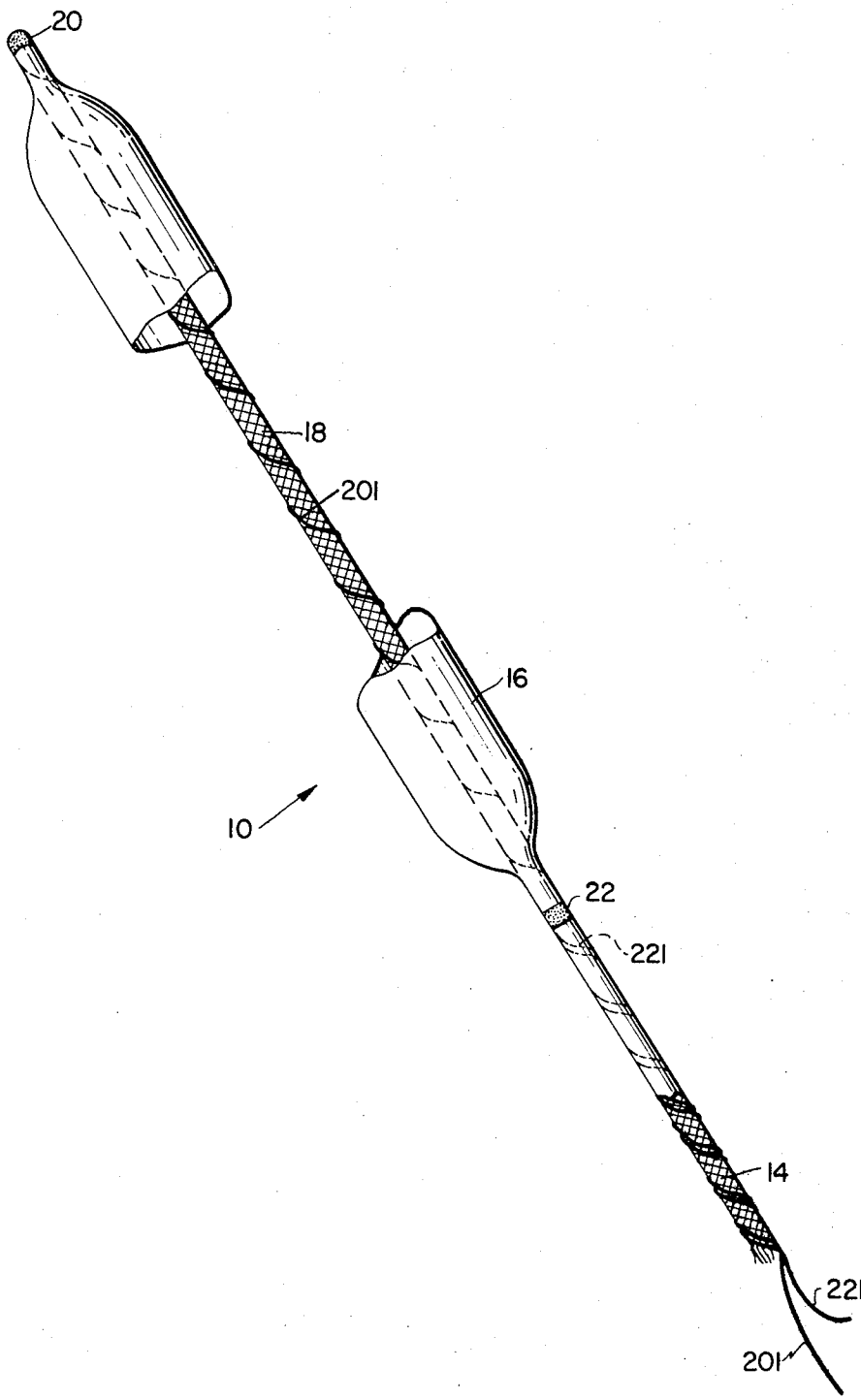
Attorney—Browdy and Neimark

[57] **ABSTRACT**

An intra-arterial cardiac assisting pump is provided with intraaortic electrocardiographic electrodes to improve the signal-to-noise ratio of the electrocardiogram and the reliability of trigger signal for phase-shift pumping.

4 Claims, 1 Drawing Figure





INVENTOR
Paul S. Freed
BY
Browdy and Neimark
ATTORNEYS

BALLOON CARDIAC ASSISTING PUMP HAVING INTRAAORTIC ELECTROCARDIOGRAPHIC ELECTRODES

The present invention relates to the provision of intraortic electrocardiographic electrodes for use in conjunction with driving a cardiac assisting balloon pump and, more particularly, to an auto-synchronous intra-arterial balloon pump incorporating intracorporeal electrodes for improving the reliability of the trigger signal for the balloon pumping.

As indicated in copending application Ser. No. 710,596, filed Mar. 5, 1968, now U.S. Pat. No. 3,585,983, a vital need has existed for quickly combating profound cardiogenic shock in those who suffer from acute myocardial infarction. The provision of intra-arterial balloon pumping has provided great promise in this area.

Among such devices has been described the phase-shift balloon pumping system of U.S. Pat., No. 3,585,983, for providing such circulatory assistance. In using such balloon pumps, it is conventional to obtain the electrocardiographic signal, used to control the phase-shift pumping procedure, from conventional electrocardiographic skin electrodes. The use of such conventional skin electrodes, however, has a number of disadvantages, one of the most important of which is the undesirably low signal-to-noise ratio. The low signal-to-noise ratio decreases the reliability of the triggering signal for phase-shift pumping, and this in turn reduces the reliability of the regulation of the inflation, deflation cycle of the balloon pumping chamber.

The above problem is increased in patients in whom the R-wave voltage, as recorded through the skin electrodes, is reduced. Most patients in cardiogenic shock have had myocardial infarctions, which generally are associated with reduced voltage of the R-wave. In addition, pulmonary edema, pericarditis, and other conditions which further reduce the amplitude of the R-wave are relatively frequent in patients in whom balloon pumping is performed.

It is, accordingly, an object of the present invention to overcome the above and other deficiences of the prior art.

It is another object of the present invention to provide for intra-arterial cardiac assistance in a new, improved and unobvious manner and to provide a novel intra-arterial cardiac assisting balloon pump.

It is another object of the present invention to provide for intracorporeal electrodes in a phase-shift balloon pumping system to improve the signal-to-noise ratio of the electrocardiogram, and thereby, the reliability of the trigger signal for phase-shift pumping.

It is another object of the present invention to provide an improvement on previous intracorporeal balloon pump units.

These and other objects and the nature and advantages of the instant invention will be more apparent from the following detailed description of an exemplification of the invention taken in conjunction with the drawing wherein:

The FIGURE is a perspective view, partly broken away, of an intracorporeal balloon pump unit.

An intra-arterial assisting device in which the present improvement is used comprises, in general, two major components, namely an extra-corporeal unit (not shown) such as that provided and described in U.S. Pat. No. 3,585,983, and an intracorporeal balloon pump unit **10**. Briefly, the intracorporeal unit comprises the balloon pump portion including a hollow elongated arterial catheter **14**, an inflatable non-elastic balloon portion **16**, and a perforated reinforcing portion **18** which constitutes an extension to the elongated arterial catheter portion **14**.

The extra-corporeal unit includes, very generally, a source of gas under pressure, valve means for periodically feeding the gas used to inflate the balloon portion **16** to the intracorporeal unit **10** through the hollow catheter **14**, and suitable electronic means for receiving a signal from the body in which the intra-arterial cardiac assisting device has been placed (such as an ECG signal) and using such signal for the opening and closing periodically of the valve means. In the past such signal has been provided from conventional electrocardiographic skin electrodes.

In the preferred embodiment of the present invention, the intracorporeal unit **10** is very similar to that disclosed in U.S. Pat. No. 3,585,983 in its details of construction. Among the important features of such a device is the provision of an arterial catheter **14** and perforated portion **18** of sufficiently small outer diameter to permit insertion thereof into an artery. The balloon **16**, which surrounds the perforated portion **18** of the catheter in gas-sealing relationship therewith, is of cylindrical configuration and is preferably very thin-walled; it is preferably formed of a non-elastic and very strong material, such as polyurethane rubber. The perforated reinforcing portion **18** preferably comprises a flexible braided tube of metal wires, such as copper braid, conventionally used as electrical shielding.

The intracorporeal unit **10** of the present invention differs from prior balloon pumps in the provision of intracorporeal electrodes and suitable leads to provide the electrocardiographic signal utilized in the extracorporeal unit to drive the balloon pump. While such electrodes and leads may be provided in various ways, it is preferred that the electrodes be primarily non-metallic. In the illustrated embodiment a first electrode **20** is provided at the leading end of the balloon pump and a second electrode **22** is located at the caudal end of the balloon **16**, in use preferably downstream from the balloon in the aorta. A first lead **201** passes from the first electrode **20** and a second lead **221** passes from the second electrode **22**, both along the length of the catheter **14** and to the extracorporeal unit.

The intracorporeal electrodes **20** and **22** are preferably provided by rendering suitable components of the balloon pump electrically conductive. As one illustration, a small amount of carbon black is mixed with the polyurethane used for the tips of the pumping chamber **16**, either during its fabrication, or subsequently thereto as a coating thereon. The leads are imbedded therein, respectively, and the lead **201** is woven through the copper mesh forming the body of the reinforcing portion **18**. If the entire length of the catheter **14** is lined with the mesh material, both leads **201** and **221** may be woven therein; if the catheter **14** is merely a hollow elongated tube, such as one formed of vinyl plastic, the leads may be either imbedded in the surface thereof in conjunction with a surface coating such as of polyurethane or polytetrafluoroethylene, or such leads may be carried within the interior of the

catheter **14**. In any event, the leads **201** and **221** are brought out at the terminal end of the catheter **14** to a suitable extracorporeal connector (not shown) such as shown in U.S. Pat. No. 3,585,983.

It will be understood that while the carbon black impregnated polyurethane electrodes are preferred, other electrodes may be utilized. For example, a biologically inert metal powder, such as titanium, stainless steel, nickel or chromium, may be used as a filler for the plastic forming the electrodes. Alternately, the electrodes may be formed of vacuum deposited metal of a biologically inert nature, or the electrodes may be electro-plated over an electroless coating in accordance with known techniques.

As pointed out above, the electrocardiographic signal obtained from the intracorporeal electrodes **20** and **22** are utilized in the same manner as that from conventional skin electrodes in the phase-shift pumping procedure. However, the signal obtained from the intracorporeal electrodes has a number of advantages, of which the most important is that the signal-to-noise ratio of the electrocardiogram is substantially improved. This benefit results from a number of factors: The cardiac voltage recorded at the sites of the intracorporeal electrodes is greater than that recorded at the skin. The potentials generated by movement of muscles between the heart and the skin are eliminated from the signal. And artifacts produced by movement of electrodes and by changes in the conductivity of electrode jelly, used on the skin, due to evaporation are avoided.

The improved signal-to-noise ratio in the electrocardiogram increases the reliability of the triggering signal for phase-shift pumping. In turn, the reliability of the regulation of the inflation-deflation cycle of the pumping chamber, which is critical for effective circulatory assistance, is enhanced. While these advantages accrue in every case, they are of especial importance in patients in whom the R wave voltage, as recorded through the skin electrodes, is reduced, such patients including those suffering from myocardial infarction, pulmonary edema, pericarditis, and other conditions which reduce the amplitude of the R wave, such patients forming a substantial portion of those in whom balloon pumping is performed.

Beside the primary importance of the intracorporeal electrodes, namely that they increase the capability of the system to pump with maximal effectiveness regardless of conditions which may render the trigger signal as recorded by external electrodes unsatisfactory, the use of intracorporeal electrodes provides other advantages. These include shortening the time needed to initiate balloon pumping, since external electrodes need not be applied as a separate step in the procedure. Furthermore, elimination of skin electrodes reduces by three the number of external restraints on the patient during pumping.

Also, the ability to achieve maximally effective pumping is improved in that the effectiveness of pumping is in part dependent upon the location of the pumping chamber in the aorta, which is reflected by the character of the electrocardiogram recorded from the internal electrodes; it is therefore possible to adjust the position of the pumping chamber as soon as it has been introduced, without waiting for X-rays to be obtained. Additionally, the diagnosis of certain cardiac abnormalities is facilitated by the use of internal electrodes; since the internal electrodes provide two additional sites from which potentials can be recorded and these locations are nearer to the heart than those of skin electrodes, more electrocardiographic information can be obtained than with the use of skin electrodes alone.

That other methods for incorporating electrodes in the phaseshift balloon pumping system are possible will be evident to anyone skilled in the art, and the scope of the present modification is not restricted to particular methods for achieving this result. The foregoing description of the specific embodiment will so fully reveal the general nature of the invention that others can, by applying current knowledge, readily modify such embodiment and/or adapt it without departing from the generic concept and, therefore, such adaptations and modifications should and are intended to be comprehended within the meaning and range of equivalents of the disclosed embodiment. It is to be further understood that the phraseology or terminology employed herein is for the purpose of description and not of limitation.

What is claimed is:

1. In an intra-arterial cardiac assisting pump comprising: a hollow elongated arterial catheter having an outer diameter sufficiently small to permit insertion thereof into an artery, and having a perforated portion; a thin-walled cylindrical, inflatable balloon surrounding the perforated portion of said catheter and in gas-sealing relationship therewith; and pumping means for periodically feeding gas to said balloon through said catheter in response to an electrocardiographic signal, the improvement comprising

means connected to said pumping means for simultaneously controlling balloon pumping and obtaining an electrocardiographic signal, comprising a pair of intracorporeal electrodes along the outer surface of said intraarterial pump in the vicinity of said balloon, and an electrical lead extending from each said electrode along the length of said catheter, wherein one said intracorporeal electrode is located at the leading end of said catheter adjacent the leading end of said balloon, and the other said intracorporeal electrode is located at the caudal end of said balloon.

2. A device in accordance with claim **1** wherein said arterial catheter is formed of a flexible mesh-material and wherein said leads from said electrodes are woven in said mesh.

3. A device in accordance with claim **2** wherein said electrodes consist essentially of a plastic material filled with electrically conductive particles.

4. A device in accordance with claim **3** wherein said electrically conductive particles consist of carbon black.

* * * * *