This invention relates generally to electrical pulse generating devices, known as "pacemakers," for stimulation of the heart and more specifically to new and useful rate and amplitude controls for such devices. Various pacemaker devices have been developed for providing suitable stimulating current pulses to the heart. Some of these devices are external, some are suitable for complete implantation within the body, and some are partly external and operate by induction through the intact skin or a subcutaneous space. Implantable units have the advantage, over those which are entirely or partially external, that the patient need not carry about or be concerned with any external attachments or appliances. However, completely implantable pacemakers hereforeof have had the relative disadvantage that the rate and amplitude of the current pulse could not be adjusted. In addition, they had the further disadvantage that they commenced operation as soon as their manufacture was completed, and could not be turned off prior to use. For this reason, prolonged storage in sterile condition was not possible without encroaching upon some of the battery life.

Rate control is desirable for several reasons. In implanted battery powered pacemakers, for example, the pulse rate changes as the batteries near depletion, and it is desirable to be able to restore the basic pulse rate. In addition, it may in some patients be desirable to change the pulse rate, for example to deal with unusual situations such as intercurrent or coexisting disease requiring a temporary increase in cardiac output. Also, in the case of children, who normally require a higher pulse rate than adults, it is desirable to decrease the pulse rate as the child grows up.

Amplitude control is desirable to permit stimulation at levels just above the threshold requirements of the particular patient. Any greater amplitude merely reduces the total battery life, and may produce undesired physiological results.

Accordingly, a primary object of my invention is to provide rate and amplitude controls for implantable pacemaker devices, which controls are implantable with the pacemaker and can be actuated by making a simple percutaneous puncture.

Another object of my invention is to provide completely implantable rate and amplitude controls as aforementioned which can be located and identified, after implantation, by palpation through the intact skin.

Still another object of my invention is to provide an on-off control implantable with the pacemaker and which can be actuated by making a simple percutaneous puncture.

A pacemaker control constructed in accordance with my invention is characterized in one aspect thereof by the provision, in combination with an implantable cardiac pacemaker, of an adjustable component operable to vary an output characteristic of the pacemaker, and means for adjusting the component including means for receiving a skin puncturing instrument, the adjusting means being encased within a puncturable shield of material compatible with the human body as an environment for subcutaneous implantation of said control with said pacemaker.

In another aspect thereof, the control of my invention is characterized by the provision, in combination with an implantable cardiac pacemaker having a housing of an adjustable component operable to vary an output function of the pacemaker, and means for adjusting the component, wherein the adjusting means includes means for receiving a skin puncturing instrument, the control being implantable with the pacemaker and the instrument receiving means projecting beyond the main portion of the pacemaker housing for location by palpation.

The foregoing and other objects, advantages and characterizing features of my invention will become clearly apparent from the ensuing detailed description of a presently preferred embodiment of my invention, and one modification thereof, taken in conjunction with the accompanying drawing illustrating the same wherein like reference numerals denote like parts throughout and wherein:

FIG. 1 is a plan view of an implantable pacemaker incorporating the rate and amplitude controls of my invention, the electrode leads being broken away for convenience in illustration;

FIG. 2 is a view on an enlarged scale, partly in longitudinal section and partly in elevation, through one of the controls of FIG. 1;

FIG. 3 is a side elevational view of a standard bayonet type Keith skin needle, with which the rate and amplitude controls of my invention can be percutaneously actuated;

FIG. 4 is a side elevational view of an adaptor forming part of the control of FIG. 2;

FIG. 5 is an end elevation thereof;

FIG. 6 is a view similar to that of FIG. 2 but with certain parts omitted for ease of illustration and showing a modified construction; and

FIG. 7 is a diagrammatic view of a control portion of the pacemaker pulse producing circuit.

There is shown in FIG. 1 an implantable pacemaker having a housing generally denoted 1 and comprising, with the exception of the rate and amplitude controls to be described, a pacemaker of a type which is known per se. Such pacemakers have for some time been manufactured by Medtronic, Inc., Minneapolis, Minnesota, under the name "Chardack-Greatbatch Pacemaker," and are of the type described in detail in Patent 3,057,356 issued October 9, 1962 in the name of Wilson Greatbatch, to which reference is hereby made for such details. Accordingly, a detailed description thereof is not essential to an understanding of this invention, for purposes of which it is only necessary to say that pacemaker housing 1 comprises a pulse producing circuit in the form of a mercury cell driven, miniaturized blocking oscillator and amplifier, cast in a potting compound (such as the epoxy resin shown at 19 in FIG. 2) and enclosed in a thin envelope of suitable material, such as the inner silicone rubber layer 22' of FIG. 2. The rate and amplitude of the output pulse are controlled, in accordance with my invention, by adjustable components, such as the variable potentiometers generally denoted 2. The pulse is transmitted via leads 3 to a pair of electrodes, not shown, preferably of the type set forth in my pending application Serial No. 171,189 filed February 5, 1962.

While the circuit connections thereof will differ, so as to control rate on the one hand and amplitude on the other, the operation of potentiometers 2 otherwise is identical, and therefore only one thereof will be described in detail.

Referring now to FIG. 2, it is seen that each potentiometer 2 contains a worm wheel 4 or the like to which a movable potentiometer element 23' (FIG. 7) is connected for being driven across resistance 23 upon rotation of wheel 4 by worm 5. These parts are enclosed within a
chamber defining enclosure 6, from which extend leads 24 into the pacemaker circuit being controlled.

The potentiometer 2 shown in FIG. 2 is conventional, per se, and alternative types of potentiometers obviously can be used. Worm 5 extends through enclosure 6, terminating externally thereof in an enlarged head 7 slotted to receive a screwdriver bit. A locking key 8 engages a groove in the worm shaft, to hold worm 4 in axial position, and a seal 9, such as an O-ring of neoprene rubber, is carried by enclosure 6 in sealing engagement with the worm shaft.

It will be apparent that the resistance of potentiometer 2 can be varied by rotating head 7 and worm 4. The problem is to do this percutaneously, when the potentiometer is implanted with the pacemaker. This is accomplished as follows.

An adaptor 10 is provided, in the form of a cylinder having at one end a screwdriver bit 11 adapted to engage within the slot in worm head 7. At its opposite end, adaptor 10 is provided with a tapered, triangular recess 12, adapted to receive the triangular shaped head 13 of a standard, bayonet type Keith skin needle indicated at 14 in FIG. 3.

Adaptor 10 has a flat bottom surface, except for bit 11, and seats on the flat top wall of worm head 7. Also, it is larger in diameter than worm head 7, and the opposite ends of bit 11 are axially elongated, as indicated at 15, and extend downwardly along worm head 7 opposed sides thereof, below the bit receiving groove 10 and serves to more securely position adaptor 10 on the head 7.

The needle shaft is guided into engagement with adaptor slot 12 by an outer sleeve 16 having an enlarged bore receiving and containing the adaptor 10 for rotation thereon. Adjacent thereto, sleeve 16 has a finer contacting bore 18 tapering inwardly toward the adaptor recess 12. Thus, when needle shaft 13 is inserted in sleeve bore 18, it is guided thereby into the adaptor recess 12, for rotating the latter to turn worm 5 and needle 4 upon rotating needle 14 about its longitudinal axis. Sleeve 16 has a flat-sided extension 19 extending downwardly along one side of potentiometer enclosure 6 and abutting the same to prevent rotation of the sleeve thereon. Sleeve extension 19 is secured to enclosure 6 by an adhesive epoxy resin.

The pacemaker and its controls must be body fluid proof, and this presents a problem which is solved as follows. The sleeve bores 17 and 18, and adaptor recess 12, are filled with a sealing material 20 penetrable by needle shaft 13. Material 20 should be well tolerated by surrounding body tissue, and non-adherent to needle 14 so as not to be carried outwardly thereby when the needle is withdrawn. A suitable material is a siloxane high vacuum grease. Several layers 21 and 21' of a shielding material are then applied over the assembled potentiometer 2, adaptor 10 and sleeve 16. Material 21 and 21' must be non-toxic to surrounding body tissue and compatible with the human body as an environment.

Dow Corning silicone rubber compounds are suitable, and some of these have the added advantage of bonding to metal. The entire assembly then is sterilized by heat, prior to incorporation into the pacemaker.

In use, the rate and amplitude controls are completely implanted with the pacemaker. This poses the problem of locating and identifying the controls when adjustment is required. To accomplish this, sleeve 16 and the surrounding shielding layers are arranged to provide each control with a nubbin 22 projecting from the main portion of the pacemaker housing as shown in FIG. 1. Nubbins 22 are of sufficient diameter and length as to be readily palpable. Thus, the physician desiring to adjust either rate or amplitude can palpate the area and determine by feel alone the location of the two adjustment controls.

Further, to enable identification of one nubbin 22 from the other by palpation alone, one of the control nubbins 22 is positioned closer to the juncture of leads 3 with body than the other control nubbin 22. For example, assume that it is the amplitude control nubbin 22 which is closest to the juncture of electrode leads 3 and body 1, and which therefore is the left hand nubbin in FIG. 1. The physician, being also able to palpate the implantable pacemaker as described above 1, can determine by feel alone, through the intact skin, which control nubbin is the one he wants. He then can manipulate that control by inserting needle 14 through the skin, and through the shielding portion 21' overlying the outer end of sleeve bore 18. The needle will be guided by the sleeve 16 into the adaptor recess 12. Once it is received therein, as determined by the resistance to further insertion, the physician rotates the needle in the direction required to achieve the desired adjustment.

While the grease 20 is non-toxic to surrounding tissue, its escape through shielding material 21 and 21' nonetheless is not desired. Accordingly, the silicone shielding material, at least in the area of portion 21', is sufficiently resiliently yieldable to expand and thereby accommodate displacement of the silicone grease 20 upon insertion of needle 13. This prevents displacement of the grease along the needle shaft through the needle juncture in the shielding portion 21'.

FIG. 6 shows a modified arrangement in which potentiometer 2 is provided with a worm head 7' having a recess 12 for directly receiving the skin needle, in which case the separate adaptor 10 can be dispensed with. The operation being essentially that by which the grease 20 is displaced outwardly by the needle 13.

It will be appreciated that, in the case of rate control, potentiometer 23-23' can be substituted for resistor 22 in the timing circuit shown in the aforesaid Patent 3,057,356. For amplitude control, potentiometer 23-23' can be connected in series in the output circuit of said patent, as indicated at 24 (FIG. 7). Each potentiometer is provided with an "off" position, whereby the pacemaker can be turned on and off by percutaneous puncture.

Accordingly, it is seen that my invention fully accomplishes its intended objects, and provides completely implantable pacemaker rate and amplitude controls which can be activated by simple percutaneous puncture. While I have disclosed in detail only one embodiment of my invention, and a modification in a part thereof, that has been done by way of illustration only, it being my intention to be limited only by the scope of the appended claims.

Having fully disclosed and completely described my invention, and its mode of operation, what I claim as new is:

1. In combination with an implantable cardiac pacemaker compatible with the human body as an environment and having a housing and an electrode lead extending therefrom, percutaneously actuated controls implantable with said pacemaker beneath the skin of the human body for varying different output characteristics of said pacemaker comprising a first adjustable component in said housing operable to vary one output characteristic of said pacemaker, a second adjustable component in said housing operable to vary another output characteristic of said pacemaker, means for adjusting said first component including first means carried by said housing for receiving a skin puncturing instrument, means for adjusting said second component including second means carried by said housing for receiving a skin puncturing instrument, said first and second means projecting from the main portion of said pacemaker housing in spaced relation to each other and to the juncture of said lead and said housing, and one of said first and second means being positioned closer to said juncture than the other thereof, whereby said first and second adjusting means can be located and identified by palpation, said projecting adjusting means being encased within a shield of material puncturable by a skin puncturing instrument and compatible with the human body as an environment.

2. In combination with an implantable cardiac pace-
5. In combination with an implantable cardiac pacemaker compatible with the human body as an environment, a percutaneously actuated control implantable with said pacemaker beneath the skin of the human body for varying an output characteristic of said pacemaker comprising an adjustable component operable to vary such output characteristic, a member connected to said component and movable to adjust the same, and means connected to said member and engageable with a skin puncturing instrument for movement thereby to so move said member, said component, member and means being carried by said pacemaker and being encased within a puncturable shield of material compatible with the human body as an environment for subcutaneous implantation of said control with said pacemaker, wherein said component is enclosed within a chamber defining enclosure, said member being journaled in said enclosure and having a part exteriorly of said enclosure, said part having a first tool receiving formation, said means comprising an adaptor engaging said first tool receiving formation and having a second formation engageable with a skin puncturing instrument.

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