A system for evaluation of a cardiac stimulator connected to a patient, the system having means for detecting and differentiating between stimulation pulses and cardiac response pulses, means for determining rate of stimulation pulses and whether such rate falls within a predetermined calibration, and means for determining whether heart capture results from the stimulation pulses, all such means operative when the cardiac stimulator is in an asynchronous mode; the means being operative to determine whether the patient is dependent on cardiac stimulation pulses when the stimulator is in the demand mode. Also provided are means for transmitting the information to a remote receiver.

23 Claims, 1 Drawing Figure
EVALUATION SYSTEM FOR CARDIAC STIMULATORS

This application is a continuation of application Ser. No. 235,252, filed Mar. 16, 1972 and now abandoned.

BACKGROUND OF THE INVENTION

Cardiac stimulators, or pacemakers, are well-known in the art. Such devices are most often implanted in the bodies of patients with heart problems, and may work in an asynchronous mode to constantly provide heart stimulation pulses, or in a demand mode to supply heart stimulation pulses only when required. Implantable cardiac stimulators have a useful life time measured in terms of years.

It is apparent that it is necessary to make tests during the lifetime of the stimulators to determine whether they are functioning properly. These tests are normally conducted by a doctor or his staff and usually necessitate travel by the patient to the doctor's surroundings where the proper equipment is located. Obviously, the time and cost involved in such travels and tests are highly significant. The apparatus of this invention eliminates the need for travel and greatly decreases the time involved in the tests, by enabling the patient to use a localized evaluation system to determine by visual indication the status of operation of the stimulator, and to transmit, in the preferred embodiment by telephone, all necessary information to the physician or his staff at a remote location. The apparatus of this invention has the additional feature of enabling a remote recording on an electrocardiogram (EKG) machine of pulses representative of the patient's QRS complex, and of pacing rate, if desired.

SUMMARY OF THE INVENTION

Briefly described, the apparatus of this invention comprises a system adapted to be connected to electrodes which are in turn adapted to pick-up the electrical signals representing cardiac stimulation pulses and cardiac beats. The signals are amplified and filtered for detection purposes. The system has a switch which enables it to evaluate either asynchronous or demand mode operation of the stimulator. When evaluating the asynchronous mode, the system will count the number of stimulation pulses occurring in a predetermined period of time and compare the count to a predetermined rate calibration. Also, when operating in the asynchronous mode, the evaluation system will determine if heart capture is achieved by the stimulation pulses by counting the number of heart beat responses to the stimulation pulses occurring within a predetermined period of time. An indicator is provided which is actuated to visually display when the rate is within the calibrated setting and heart capture is achieved. The indicator will also provide a visual display when either the rate is not within the calibrated setting or heart capture is not achieved, or both rate and capture are not satisfactory. When operating in the demand mode, the system will determine whether any heart stimulation pulses are present, and if a predetermined number of such pulses occur within a set period of time, a visual indication is provided to indicate whether or not the patient is pacemaker dependent. The information can be transmitted to a remote location.

In the preferred embodiment, a frequency modulation device and acoustic coupler are provided to enable the evaluation information to be sent over a standard telephone hand-set. At a remote location, a receiver is provided, also connected to a standard telephone hand-set, which provides for demodulation of the transmitted signals and display of the same information provided to the patient. The remote station is also provided with outputs which may be connected to an electrocardiogram machine for recording pulses representative of the pacemaker artifacts and the QRS complexes of the patient, and a rate interval computer for determining the pacemaker rate, the EKG rate and the corresponding intervals between stimulation pulses and cardiac response pulses. The outputs may also be connected to other analyzing and recording devices, such as a computer.

BRIEF DESCRIPTION OF THE DRAWING

The single FIGURE of the drawing comprises a block diagram of the system of this invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to the single FIGURE of the drawing, there is shown a complete system including the evaluation device, the transmission apparatus, and the receiver apparatus. It will be apparent that the evaluation device may be advantageously used without connection to the transmitter and receiver. Thus, the patient may use the evaluation device without transmission of the information to the physician, or may use it in the presence of the physician without need for the transmission and reception apparatus.

In the single FIGURE of the drawing there are shown a pair of terminals 10 and 11 adapted to be connected to electrodes which are in turn adapted to be placed to pick up the desired signals. These electrodes may comprise a hand-held bipolar pick-up module which can be held over the patient's chest; a non-disposable bipolar electrode system for use on limbs, for example; and a disposable bipolar electrode system pasted onto the patient's body. These or other electrode systems may be connected to the apparatus of the single FIGURE of the drawing by means such as a cable.

Terminals 10 and 11 are connected to a preamplifier 12, which may be of a type well-known to those skilled in the art, for the purpose of amplification of the pick-up signals. Preamplifier 12 has an output connected to a high bandpass filter 13 and another output connected to a low bandpass filter 14. The output of high bandpass filter 13 is connected to the inputs of a transmission modulator 15, a rate detector 16, a capture detector and counter 17 and a timer 18. The output of low bandpass filter 14 is connected to the inputs of transmission modulator 15 and capture detector and counter 17.

Transmission modulator 15 has an output connected to the input of an acoustic coupler 19, which is in turn connected to a phone 20. Rate detector 16 has an output connected to the input of a rate comparator 23 which has a calibration setting circuit indicated in schematic form as a potentiometer 24. The output of rate comparator 23 is connected to the input of an indicator logic circuit 25. Capture detector and counter 17 has an output also connected to the input of indicator logic circuit 25. Timer 18 has an output connected to capture and detector counter 17, and another output connected to the input of a patient dependency detector 26.
Indicator logic circuitry 25 has an output connected to an asynchronous mode indicator 27, and an output connected to an indicator oscillator control 29. Indicator oscillator control 29 has an output connected to the input of an indicator oscillator 31, which in turn has an output connected to transmission modulator 15. Patient dependency detector 26 has an output connected to a demand mode indicator 28, and an output connected to indicator oscillator control 29.

A mode switch 33 has an output connected to each of timer 18, patient dependency detector 26, demand mode indicator 28 and asynchronous mode indicator 27. The output of mode switch 33 is also connected to a mode oscillator 34, which in turn has an output connected to acoustic coupler 19.

Phone 20 is connected to a transmission line 30, and is also connected back through acoustic coupler 19 to a call back receiver 36, which is in turn connected to a call back indicator 37.

Transmission line 30 is also connected to a phone 40. Phone 40 is connected to another acoustic coupler 41 which has an output connected to a tone demodulator 42. Demodulator 42 has an output connected to an indicator bandpass filter 43. The output of demodulator 42 is also adapted to be connected to an electrocardiogram machine 46 and a rate interval computer 47. Indicator bandpass filter 43 is connected to another indicator logic circuitry 44, which has a pair of outputs connected to, respectively, another asynchronous mode indicator 56 and another demand mode indicator 57.

The output of acoustic coupler 41 is also connected to the input of a mode bandpass filter 51 and a phone carrier detector 52. The output of mode bandpass filter 51 is connected to indicator logic circuitry 44. The output of phone carrier detector 52 is connected to another call back indicator 53. A call back oscillator 58 is connected through acoustic coupler 41 to phone 40.

In operation, the apparatus of the single FIGURE of the drawing will initially be calibrated to a predetermined window range of cardiac stimulation pulse rate, in the asynchronous mode, by adjustment of potentiometer 24 on rate comparator 23. In this preferred embodiment, it has been found desirable to provide a calibration window of ±5 pulses. This calibration will normally be performed by a physician or his staff when the system is first provided to the patient.

For purposes of explanation of the operation of the apparatus of this invention, assume that mode switch 33 has been placed in position to select the asynchronous mode. In the preferred embodiment of this invention, mode switch 33 includes a magnet which is placed on or taken off of the evaluation device to actuate the switch 33 as desired. With switch 33 in the asynchronous mode, patient dependency detector 26 and demand mode indicator 28 will be locked out. Asynchronous mode indicator 27 will be turned on, and timer 18 will be set to provide a predetermined timed pulse upon receiving a trigger, which predetermined time in the preferred embodiment has been selected to be 15 seconds.

As previously described, terminals 10 and 11 are connected to a signal pick-up system. The signals are then amplified in preamplifier 12 and passed to high bandpass filter 13 and low bandpass filter 14. Filter 13 is centered around 1 KHz so that only the energy associated with the cardiac beats (QRS complex) appears at its output.

The output of high bandpass filter 13, which represents cardiac stimulation pulses, will be felt at rate detector 16, where the interval between pacemaker artifacts is determined. This information is fed to rate comparator 23 and compared to the preset intervals corresponding to the calibration window originally set into comparator 23 through potentiometer 24.

The output of filter 13 is also fed to timer 18 where it acts as a trigger for a pulse of a predetermined period, in the preferred embodiment 15 seconds. The output of timer 18 is fed to capture detector and counter 17. The output of high bandpass filter 13 is also fed to capture detector and counter 17, as is the output of low bandpass filter 14 which represents cardiac beats. Detector 17 is therefore enabled for a period of 15 seconds to determine the time relationship between stimulation pulses and cardiac response. In the preferred embodiment of this invention, if a cardiac stimulation pulse is followed within 50 milliseconds by a cardiac response, this is considered to be one capture. The number of captures occurring within the 15 second period is counted in capture detector and counter 17. Detector 17 will provide an output signal indicating satisfactory capture if a predetermined number of captures occur during the 15 second timing of asynchronous operation. In the preferred embodiment of this invention it has been determined that a signal representing satisfactory capture will occur if three or more captures are detected and counted during the 15 second time interval.

The outputs of both capture detector and counter 17 and rate comparator 23 are fed to indicator logic circuitry 25. If both the rate and capture signals are satisfactory, indicator logic circuitry 25 will provide a signal to asynchronous mode indicator 27 to visually indicate satisfactory asynchronous operation of the cardiac stimulator. If either capture or rate or both are not satisfactory, logic circuitry 25 will provide a different signal to asynchronous mode indicator 27 to visually show unsatisfactory operation.

For operation in the demand mode, switch 33 is changed to the demand position to lock out asynchronous mode indicator 27, to enable demand mode indicator 28 and patient dependency detector 26, and to provide a signal to timer 18 such that it is set for a maximum 15 seconds by an input from high bandpass filter 13 and is immediately reset by the next input from filter 13. The turn off of asynchronous mode indicator 27 will effectively remove capture detector and counter 17, rate detector 16 and rate comparator 23 from the circuitry.

In the demand mode operation, any cardiac stimulation pulses called for when the heart fails to have a natural beat will be picked up by the above described electrode system, and provided to terminals 10 and 11. These stimulation signals will pass through filter 13 to set timer 18, which then commences its 15 second output pulse. The 15 second output pulse is detected by patient dependency detector 26, and if a second demand cardiac stimulation pulse occurs during the 15 second interval, timer 18 will be immediately reset, which will also be detected in patient dependency detector 26. A signal will then be provided to demand mode indicator 28 from detector 26 to visually indicate that the patient is pacemaker dependent. Thus, in the preferred embodiment of this apparatus, it has been de-
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determined that a minimum of two demand cardiac stimulation pulses within a 15 second interval will be considered to place the patient in a dependency status. Should the apparatus of this invention fail to sense the second pacemaker pulse during the 15 second interval, the signal from detector 26 to demand indicator 28 will be such as to give visual indication of non-dependency.

The apparatus of this invention has the distinct advantage of being able to transmit the evaluation information garnered in the above described manner to a remote location, such as a doctor's office. Referring again to the single FIGURE of the drawing, this transmission is effected in the following manner. The outputs of both of filters 13 and 14 are fed to transmission modulator 15. There they modulate a carrier, in this preferred embodiment a telephone carrier of 1988HZ. The output of filter 13, which represents the cardiac stimulation pulses, modulates the carrier upward, in the preferred embodiment to a frequency of 2240HZ. The output of filter 14, which represents the QRS complexes, modulates the carrier downward, in this preferred embodiment to a frequency of 1726HZ. These modulated tones are fed to acoustic coupler 19 which couples them to a transmitter, in this embodiment a standard telephone handset 20. The information is transmitted, in this preferred embodiment, over a phone line 30 to a receiver at the remote location, shown in this preferred embodiment to be another standard telephone handset 40. The information from phone 40 is connected through acoustic coupler 41 to tone demodulator 42. As shown in the single FIGURE of the drawing, the information from tone demodulator 42, which represents the pacemaker pulses and the QRS complexes, can be fed directly to an EKG machine 46 or to a rate interval computer 47.

The remote station is also provided with information concerning the state of mode switch 33. This is done by turning on or off mode oscillator 34 dependent on the position of switch 33. The output of mode oscillator 34 is connected through acoustic coupler 19 to phone 20, and is transmitted through line 30 to phone 40 at the remote station. Acoustic coupler 41 receives the information from mode oscillator 34 and presents it to mode bandpass filter 51. Dependent on the information received, filter 51 provides a signal to indicator logic 44 at the remote station, which is responsive to the information received to turn on either asynchronous mode indicator 56 or demand mode indicator 57. Thus, the remote station provides a visual indication of whether mode switch 33 is in the asynchronous or demand mode.

Depending on whether the mode switch 33 is in the demand or asynchronous position, the evaluation information is transmitted to the remote station through the connections of patient dependency detector 26 and indicator logic circuitry 25 to indicator oscillator control 29. A signal from either detector 26 or circuitry 25 will be felt at oscillator control 29 to turn on indicator oscillator 31. The output of oscillator 31 may be caused, for example, to turn on only when the signals from detector 26 or circuitry 25 is such as to indicate, respectively, patient pacemaker dependency or satisfactory capture. The output of indicator oscillator 31 is fed to transmission modulator 15 where it again modulates the carrier frequency by yet another tone, and is thereafter coupled through acoustic coupler 19 and phone 20 to line 30. In this preferred embodiment a low frequency oscillator is used as indicator oscillator 31.

The presence or absence of the signal from indicator oscillator 31 is detected at the remote station through phone 40, coupler 41 and tone demodulator 42. The output of tone demodulator 42 is then passed through filter 43 to indicator logic 44 to affect the visual indications in the selected of indicators 56 or 57.

Thus, it is apparent that the remote station receives information as to the mode of operation and the same evaluation information available at the local transmitter. In addition, the remote station has the advantage of providing information to a selected EKG machine or rate interval computer which would be useful for displaying stimulation pulse rate, EKG rate, and the corresponding intervals between stimulation pulses and QRS complex responses.

In addition, apparatus is provided in the form of call back circuitry by which the party at the local or remote transmitter may contact the other party, and by which system integrity can be indicated. Should the transmission circuitry not be completed, such as the handset of phone 20 being improperly positioned, the normal phone carrier frequency will not pass through line 30, phone 40 and acoustic coupler 41 to be presented to phone carrier detector 52. When detector 52 senses a lack of system integrity a signal is provided to a call back indicator 53 to provide visual notice. Call back oscillator 58 is normally on, if the physician wishes to call the patient, he may deactivate call back oscillator 58 which is coupled to phone 40 through acoustic coupler 41, and the signal which normally passes through line 30 and phone 20 to acoustic coupler 19 will be interrupted. Call back receiver 36, when it senses the interruption, will turn on a visual indicator in call back indicator 37.

From the above description of the preferred embodiment of this invention, it is apparent that there has been provided a unique cardiac stimulator evaluation system which not only can provide immediate evaluation information to a patient, but which has the facility of transmitting the information to a remote station for review by a physician or his staff.

What is claimed is:

1. A system for cardiac stimulator evaluation, the system adapted to be connected to means for sensing stimulation pulses and cardiac pulses, comprising: input means for receiving said sensed pulses; first means for differentiating between stimulation pulses and cardiac pulses and including high bandpass filter means and low bandpass filter means each connected to the input means, the high bandpass filter means including means for passing frequencies in the range of stimulation pulses and the low bandpass filter means including means for passing frequencies in the range of cardiac pulses; second means for detecting the rate of the stimulation pulses; third means for detecting heart captures due to stimulation pulses; means connecting the input means to the first means; means connecting the first means to the second and third means; and fourth means connected to the second and third means and responsive to signals therefrom for indicating the status of operation of the stimulator being evaluated.

2. The apparatus of claim 1 in which: the means for passing frequencies in the high bandpass filter means is centered around 1Khz; and the means for passing frequencies in the low bandpass filter means is centered around 10Hz.

3. The apparatus of claim 1 in which the input means includes: amplifier means connected to the filter
The apparatus of claim 1 including: modulation means connected to the first means and including means for providing a carrier frequency modulated to a first frequency in response to a stimulation pulse and modulated to a second frequency in response to a cardiac pulse; first transmission means connected to the modulation means for transmitting the carrier frequency and the first and second modulated frequencies; second transmission means connected to receive the carrier frequency and the first and second modulated frequencies; demodulator means connected to the second transmission means and having means for detecting the first and second modulated frequencies for providing first and second output signals representative of, respectively, stimulation pulses and cardiac pulses; and means connected to the demodulator means for receiving the output signals therefrom, and selectively connectable to electrocardiogram means and rate interval counter means.

The apparatus of claim 4 including: oscillator means connected to the fourth means and responsive to signals therefrom indicative of the status of operation of the stimulator being evaluated; means connecting the oscillator means to the modulation means; the modulation means including means for modulating the carrier frequency to a third frequency in response to an input from the oscillator means representative of the status of operation of the stimulator being evaluated; the first and second transmission means including means for, respectively, transmitting and receiving the third modulated frequency; the demodulator means including means for detecting the third modulated frequency for providing third output signals representative of the status of the stimulator being evaluated; and indicator means connected to the demodulator means and responsive to signals therefrom for indicating the status of the stimulator being evaluated.

The apparatus of claim 4 including: carrier frequency detecting means connected to the second transmission means for detecting and indicating the presence and absence of the carrier frequency.

The apparatus of claim 4 including: selectively operable call back oscillator means; means connecting the call back oscillator means to the second transmission means for transmission of a call back signal to the first transmission means; and call back receiver means connected to the first transmission means for detecting and indicating the presence or absence of a call back signal.

A system for cardiac stimulator evaluation, the system adapted to be connected to means for sensing stimulation pulses and cardiac pulses, comprising: input means for receiving said sensed pulses; first means for differentiating between stimulation pulses and cardiac pulses and including high bandpass filter means and low bandpass filter means each connected to the input means; the high bandpass filter means including means for passing frequencies in the range of stimulation pulses and the low bandpass filter means including means for passing frequencies in the range of cardiac pulses; second means for detecting the rate of the stimulation pulses; third means for detecting heart captures due to stimulation pulses; means connecting the input means to the first means; means connecting the first means to the second and third means; and fourth means connected to the second and third means and responsive to signals therefrom for indicating the status of operation of the stimulator being evaluated; said second means including rate detection means for detecting the time intervals between succeeding stimulation pulses; adjustable calibration means for providing a calibration window for a desired stimulation pulse rate, means connected to the rate detection means and the calibration means for comparing the time intervals to the calibration window and including means for providing a signal to the fourth means.

A system for cardiac stimulator evaluation, the system adapted to be connected to means for sensing stimulation pulses and cardiac pulses, comprising: input means for receiving said sensed pulses; first means for differentiating between stimulation pulses and cardiac pulses; second means for detecting the rate of the stimulation pulses; third means for detecting heart captures due to stimulation pulses; means connecting the input means to the first means; means connecting the first means to the second and third means and responsive to signals therefrom for indicating the status of operation of the stimulator being evaluated; switch means having first and second switch positions; means operative when the switch means is in the first switch position for disabling the fifth and sixth means and en-
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15. The apparatus of claim 14 including: modulation means connected to the first means and including means for providing a carrier frequency modulated to a first frequency in response to a stimulation pulse and modulated to a second frequency in response to a cardiac pulse; oscillator means connected to the fourth means and responsive to signals therefrom indicative of the status of operation of the stimulator being evaluated; means connecting the sixth means to the oscillator means; means connecting the oscillator means to the modulation means; and means for modulating the carrier frequency to a third frequency in response to an input from the oscillator means representative of the status of operation of the stimulator being evaluated; first transmission means connected to the modulation means for transmitting the carrier frequency and the first, second and third modulated frequencies; second transmission means connected to receive the carrier frequency and the first, second and third modulated frequencies; demodulator means connected to the second transmission means and having means for detecting the first, second and third modulated frequencies for providing first and second output signals representative respectively, stimulation pulses and cardiac pulses and for providing third output signals representative of the stimulator being evaluated; indicator means connected to the demodulator means and responsive to signals therefrom for indicating the status of the stimulator being evaluated; and further means connected to the demodulator means for receiving the output signals therefrom and selectively connectable to electrocardiogram means and rate interval counter means.

16. The apparatus of claim 15 including; mode oscillator means connected between the switch means and the transmission means and operable to provide an output to the transmission means when the switch means is in one of the first or second switch positions; mode detection means connected between the second transmission means and the indicator means for providing mode information to the indicator means.

17. The apparatus of claim 14 in which: the predetermined period of time is 15 seconds.

18. The apparatus of claim 14 in which: the predetermined minimum number is two.

19. A system for evaluating a cardiac stimulator operating in an asynchronous mode or a demand mode, the system adapted to be connected to means for sensing stimulation pulses and cardiac pulses, comprising: input means for receiving said sensed pulses; first frequency filter means for passing frequency signals from stimulation pulses; second frequency filter means for passing frequency signals from cardiac pulses; rate detector means connected to the first filter means for detecting the rate of stimulation pulses; capture detector means connected to the first and second filter means for detecting captures that comprise a cardiac pulse which follows a stimulation pulse within a first predetermined period of time; counter means connected to the capture detector means for counting the captures which occur within a second predetermined period of time; first indicator means connected to the rate detector means and the counter means and including means responsive to signals therefrom for providing visual stimulator status indications; timer means connected to the capture detector means and the first filter means, and responsive to a stimulation pulse for enabling the capture detector means for the second predetermined period of time; further detector means connected to the timer means; second indicator means connected to the further detector means and including means responsive to signals therefrom during said second predetermined period of time for providing visual stimulator status indications; switch means selectively adjustable to an asynchronous mode position and a demand mode position, the switch means including means operable in the asynchronous mode position for enabling the first indicator means and disabling the second indicator means and the further detector means, and the switch means including means operable in the demand mode position for disabling the first indicator means and enabling the second indicator means, the further detector means and means in the timer means for allowing stimulation pulses to reset the timer means during the second predetermined time period.

20. The system of claim 19 including: modulation means connected to the first and second filter means; indicator oscillator means connected to the first indicator means, the further detector means and the modulation means; first transmission means; first acoustic coupler means connected between the modulation means and the transmission means; mode oscillator means connected between the switch means and the first coupler means; second transmission means connected to the first transmission means; demodulation means; second acoustic coupler means connected between the second transmission means and the demodulation means; remote indicator means responsive to demodulated signals from the demodulator means for providing visual stimulator status indications; indicator filter means connected between the demodulation means and the remote indicator means; and mode filter means connected between the second coupler means and the remote indicator means.

21. The apparatus of claim 20 including: first call back indicator means; and carrier frequency detection means connected between the second acoustic coupler and the first call back indicator means.

22. The apparatus of claim 20 including: selectively operable call back oscillator means connected to the second acoustic coupler means; second call back indicator means; and call back receiver means connected between the first acoustic coupler means and the second call back indicator means.

23. The apparatus of claim 20 including: means connected to the demodulator means and selectively connectable to electrocardiogram means and rate interval computer means.