July 7, 1970 T. C. WOODS ET AL 3,518,986

PATIENT MONITORING SAFETY SYSTEM

Filed Nov. 20, 1967

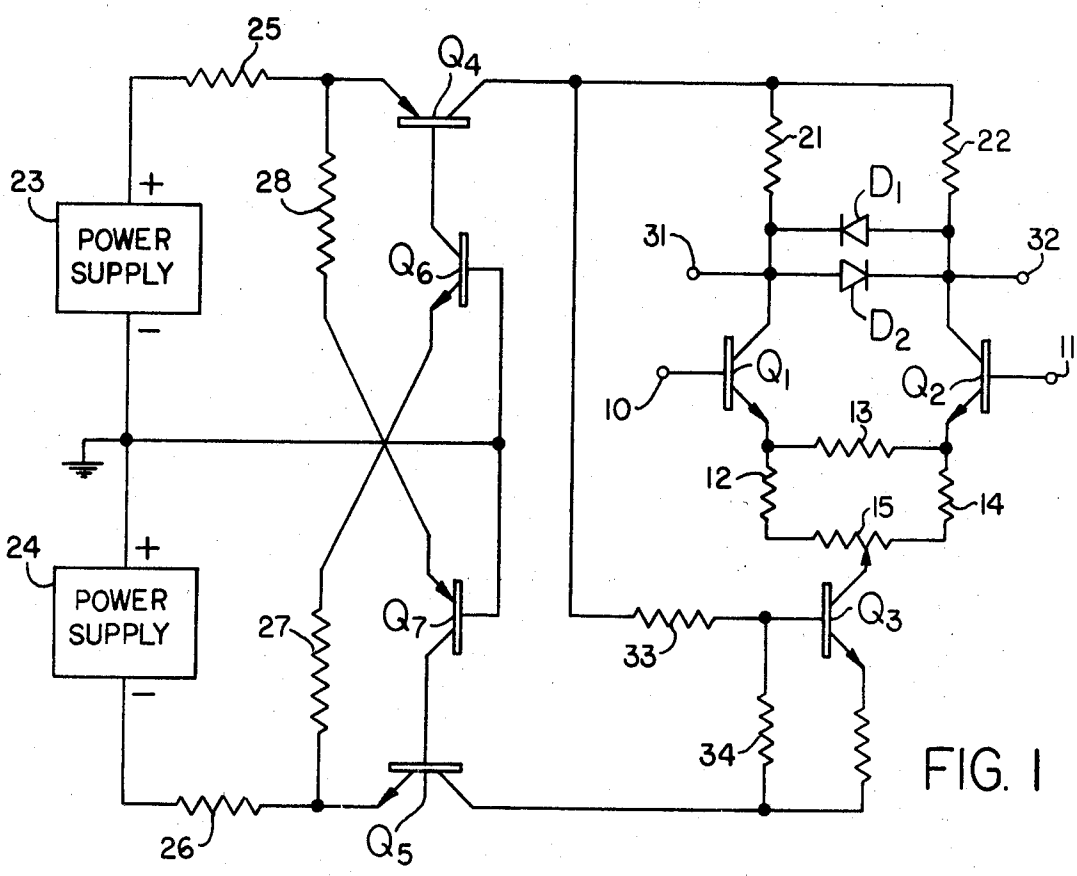


FIG. 1

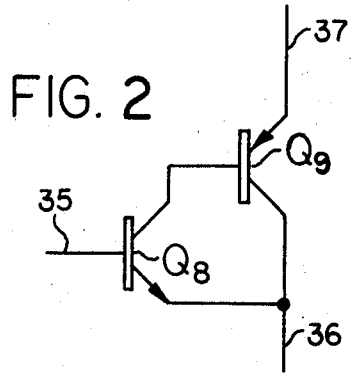


FIG. 2

INVENTORS:

ALLAN F. PACELA
DONALD W. ROLAND
THOMAS C. WOODS

BY A. M. Fernandez
ATTORNEY

United States Patent Office 3,518,986 Patented July 7, 1970

3,518,986

PATIENT MONITORING SAFETY SYSTEM

Thomas C. Woods, Diamond Bar, Donald W. Roland, Orange, and Allan F. Pacela, Diamond Bar, Calif., assignors to Beckman Instruments, Inc., a corporation of California

Filed Nov. 20, 1967, Ser. No. 684,432
Int. Cl. A61b 5/04
U.S. Cl. 128—2.1 8 Claims

ABSTRACT OF THE DISCLOSURE

A system for insuring against hazardous current flow between a patient and monitoring apparatus having power supply sources connected to the electronic circuits of the apparatus, and in particular to the input amplifying stage thereof is provided by connecting each source through a separate current transmitting means. A first control means for detecting the presence of power supply to one of the current transmitting means is employed to enable the other current transmitting means, and a second control means for detecting the presence of power supply to the other current transmitting means is employed to enable the current transmitting means, whereby failure of either power supply to provide current to its associated current transmitting means will cause the other to interrupt transmission of current therethrough. The input amplifying stage consists of a differential amplifier having a pair of oppositely poled diodes connected in parallel between output electrodes thereof to prevent either side of the differential amplifier from being driven into saturation upon the disconnection from the patient of the base electrode of the other transistor, thereby preventing a dangerous increase or transient of current through the remaining connection to the patient.

This invention relates to a system for preventing hazardous currents from flowing between an electronic monitoring apparatus and a patient connected thereto.

Patient safety must always be the first consideration in the design of medical electronic instruments. One of the greatest problems in the design of such instruments is to insure that hazardous currents may not flow between the patient and electronic monitoring apparatus.

The use of electronic amplifiers to monitor biopotential or bioimpedance signals requires a direct connection between sensing electrodes attached to the patient and the amplifier. In direct-coupled amplifiers, hazardous currents may flow directly through the patient in the event of a partial power failure where two power supplies of opposite polarity with respect to a point of reference potential are employed or in the event of an electrode connected to the patient becoming disconnected where two electrodes are connected to input terminals of a differential amplifier.

Although there are no absolute limits to define the physiological results of excessive currents through a patient, it is known that at frequencies from 0 Hz. to 2 kHz., currents of 20 to 200 milliamperes can produce ventricular fibrillation in the heart, while currents of 5 to 25 milliamperes can produce painful to violent muscular contractions and currents of 500 microamperes to 2 milliamperes produce the threshold of sensation. These values of current are for superficial thoracic electrical shocks to an adult. Should a catheter be present in the body and particularly in the heart, fibrillation may be produced by currents as small as 20 microamperes. This could occur, for example, during cardiac catheterization, thoracic surgery, and the like. From the standpoint of safety, the maximum allowable shock currents are accepted to be approximately 200 microamperes for a body shock, but only 1 to 2 microamperes for a direct cardiac shock. Consequently, it is extremely important to design electronic patient monitoring apparatus such that hazardous currents through the subject will not result due to some failure in the monitoring apparatus, particularly when the monitoring apparatus is being employed during cardiac catheterization, thoracic surgery, and the like.

An object of this invention is to provide an improved power supply system for electronic patient monitoring apparatus of the type which employ two power supply sources. A further object of this invention is to provide an improved electronic patient monitoring apparatus of the type employing a differential amplifier having input terminals thereof directly connected to the patient.

These and other objects of the invention are provided in patient monitoring apparatus by coupling power supplies to at least the input amplifier thereof through separate current transmitting means and providing a first current control means for detecting the flow of current to one transmitting means and in response thereto for enabling the other current transmitting means to transmit current therethrough. A second current control means is provided for detecting the flow of current to the other current transmitting means and in response thereto for enabling the first current transmitting means to transmit current therethrough. In that manner, failure of either power supply will result in the other being disconnected from the patient monitoring apparatus. Otherwise, the patient monitoring apparatus, and in particular the input stage thereof directly connected to the patient, may fail to operate properly and thereby cause hazardous current to flow between the patient and the monitoring apparatus. If the input stage is a differential amplifier, a pair of oppositely poled, parallel diodes are connected between the output terminals thereof in order that, should the connection from the patient to the input terminal on one side of the differential amplifier become disconnected, the remaining side of the differential amplifier still having its input terminal connected to the patient, will not cause hazardous current to flow between the patient and the monitoring apparatus.

The manner in which these and other objects and advantages are achieved in one illustrative embodiment is described with reference to the drawings in which:

FIG. 1 discloses a circuit diagram of a preferred embodiment of the invention; and

FIG. 2 discloses a circuit diagram of a pair of transistors which may be substituted for each of two transistors in a differential amplifier of FIG. 1.

Referring now to the drawings, a differential amplifier comprising transistors Q_1 and Q_2 is shown having a pair of input terminals **10** and **11** adapted to be connected to, for example, skin electrodes attached to a patient for monitoring biopotentials or bioimpedances. A transistor Q_3 is connected to the emitters of the transistors Q_1 and Q_2 to provide a constant current thereto in a manner well known to those skilled in the art. A network comprising resistors **12**, **13** and **14** is provided together with a potentiometer **15** to properly balance the differential amplifier in order to avoid having to select exactly matched transistors Q_1 and Q_2. Load resistors **21** and **22** are connected to the collectors of the transistors Q_1 and Q_2.

Power for the operation of the differential amplifier is provided by sources **23** and **24** through current transmitting transistors Q_4 and Q_5. For a differential amplifier employing npn transistors, the potential source **23** is connected with its negative terminal connected to a point of reference potential, or ground, and its positive terminal to the emitter of the pnp transistor Q_4. The source of

potential **24** is then connected to the emitter of the npn transistor Q_3 with the positive terminal connected to the point of reference potential and the negative terminal connected to the emitter of the npn transistor Q_5. Current limiting resistors **25** and **26** are connected in series with the emitters of the transistors Q_4 and Q_5, and are optional in the illustrated embodiment.

The current transmitting transistors Q_4 and Q_5 are enabled, or biased on, by transistors Q_6 and Q_7. The npn transistor Q_6 has its collector connected directly to the base of the transistor Q_4 and its base connected to the point of reference potential. In that manner, the current transmitting transistor Q_4 is enabled only while the control transistor Q_6 is also biased on. Since it is an npn transistor, and has its emitter connected to the emitter of the transistor Q_5 by a current limiting resistor **27**, it will be biased on only as long as the negative potential source **24** is operating to provide a negative potential and therefore current to the emitter of the transistor Q_5 to thereby bias the base-emitter junction of the transistor Q_6 in the forward direction. The emitter of the pnp transistor Q_7 is connected to the emitter of the pnp transistor Q_4 through a current limiting resistor **28**. While the source of potential **23** is operating to provide a positive potential at the emitter of the transistor Q_4, and therefore current thereto, the base-emitter junction of the transistor Q_7 is biased in the forward direction.

While both sources of potential **23** and **24** are operating, both control transistors Q_6 and Q_7 are turned on and the current transmitting transistors Q_4 and Q_5 are therefore also enabled or turned on. Should either source of potential **23** or **24** fail, the control transistor associated with the current transmitting transistor connected to the other source of potential will detect the failure by having its base-emitter junction zero biased, thereby interrupting base currents to the current transmitting transistor controlled thereby. For example, if the source of potential **23** fails, the base-emitter junction of the transistor Q_7 is then no longer sufficiently forward biased for it to conduct base current to the current transmitting transistor Q_5. Accordingly, the current supplied to the collector of the transistor Q_5 is cut off. Similarly if the source of potential **24** fails, the control transistor Q_6 detects the failure and interrupts base current to the transistor Q_4 so that current transmitted through the transistor Q_4 is interrupted. In that manner, the failure of either source of potential **23** or **24** to provide current to the differential amplifier will cause the current from the remaining source of potential to be interrupted.

If both positive and negative sources of potential to the differential amplifier are not shut down when one source of potential fails, a transient, or step change of current can occur in the input terminals or base electrodes of the transistors Q_1 and Q_2 resulting in potentially hazardous current being supplied to the patient connected thereto for the reason that the transistors Q_1 and Q_2 then function simply as junction diodes between the base elecrodes and collector or emitter electrodes, depending upon whether the positive or negative power supply fails.

The constant current source (transistor Q_3 and its associated biasing network) supplies the necessary bias current through both halves of the differential amplifier into the two identical load resistors **21** and **22**. The current normally divides equally between the two load resistors such that the voltage between two output terminals **31** and **32** is zero. The potentiometer **15** is adjusted to realize this zero output voltage between the output terminals in the absence of an input signal at the input terminals **10** and **11**. In the presence of an input signal, the currents through the two load resistors become unequal and a differential output voltage is developed at the output terminals **31** and **32** in the usual manner.

It should be noted that the two halves of the amplifier are operating in their linear regions, and that their respective forward current-transfer ratios β are high. If either side were allowed to saturate, its current-transfer ratio would drop to a low value and a large base current would result. That could occur, for example, if the input terminal **11** should become disconnected from the patient while the input terminal **10** remains connected such that the transistor Q_2 would be cut off and the transistor Q_1 driven toward saturation. For instance, assuming a constant current of two milliamperes from the transistor Q_3, the load resistors **21** and **22** conduct substantially equal currents of one milliampere. In the absence of an input signal, the current through each resistor would be equal to exactly one milliampere. The value selected for each of the resistors **21** and **22** is such that the output terminal connected to each remains at zero volts with respect to the other in the absence of any input signal. Assuming a β for the transistors Q_1 and Q_2 of 100 while they are operating in their linear regions, and an input signal of 10 to 20 nanoamperes, at, for example, the input terminal **11**, the current through the resistor **22** will increase correspondingly from 1000 to 2000 nanoamperes.

If either of the input terminals **10** and **11** should become disconnected from the patient, or should either of the transistors Q_1 and Q_2 fail, all of the current carried by the two halves of the amplifier must be carried by the remaining half of the amplifier having its input terminal still connected to the patient thereby causing that half of the differential amplifier to saturate. For instance, if the connection between the patient and the input terminal **11** were to become disconnected or the transistor Q_2 were to otherwise be caused to cease conduction, the current normally flowing therethrough would be diverted to the remaining transistor Q_1. The current transfer ratio β of the transistor Q_1 would then drop toward zero owing to the large drop in collector potential, which would result in a large increase in the base current. The result would be a large increase in current between the amplifier input terminal **10** and the patient. That increased current is commonly referred to as "ejection" current since the amplifier is then functioning as a current source for the connection to the patient.

To prevent ejection current from flowing through the patient, it is necessary to prevent a given transistor of a differential amplifier from being driven toward saturation when the other transistor fails or conduction therethrough is otherwise cut off. That is accomplished in accordance with the present invention by connecting a pair of oppositely poled diodes D_1 and D_2 in parallel between the collector electrodes of the transistors Q_1 and Q_2. If, as in the previous example, the transistor Q_2 should cease to conduct for any reason, the collector current normally flowing therethrough is shunted by the diode D_1 such that the current through the resistor **21** remains substantially the same after the failure as before at a level approximately equal to half the current supplied by the current source transistor Q_3, depending upon the value of the input signal at the input terminnal **10**. The current transfer ratio of the transistor Q_1 then remains substantially the same because the collector voltage of transistor Q_1 remains substantially the same and an ejection current is not caused to flow through the patient.

Since the input signals at the terminals **10** and **11** are in the low millivolt range, the diodes D_1 and D_2 do not become sufficiently forward biased to conduct during the normal operation of the differential amplifier, which is with both transistors Q_1 and Q_2 functioning properly with connections to their respective base electrodes. Junction diodes preferably of silicon are employed for this purpose.

FIG. 2 illustrates a pair of transistors Q_8 and Q_9 which, connected in the manner shown, function as a single transistor with a higher current transfer ratio equal to the product of the current transfer ratios of the two individual transistors. The terminal **35** functions as the base electrode while the terminals **36** and **37** function as the emitter

and collector electrodes of the pair commonly referred to as a pnp/npn compound block.

While the principles of the invention have now been made clear in an illustrative embodiment, there will be immediately obvious to those skilled in the art many modifications which are particularly adapted for specific environments and operating requirements, without departing from those principles. The appended claims are therefore intended to cover and embrace any such modifications, within the limits only of the true spirit and scope of the invention.

What is claimed is:

1. In electronic patient monitoring apparatus, a system for insuring against hazardous current flow between the patient and the apparatus comprising

first and second power supply sources connected in circuit,

first and second current transmitting means in series with said first and second sources, respectively,

first control means for detecting the absence of power supply voltage to said first transmitting means and in response thereto for disabling said second current transmitting means to prevent current from being transmitted therethrough, and

second control means for detecting the absence of power supply voltage to said second current transmitting means and in response thereto for disabling said first current transmitting means to prevent current from being transmitted therethrough.

2. In electronic patient montoring apparatus, the combination defined by claim 1 wherein said first and second power supply sources are of opposite polarity with respect to a point of reference potential common to both sources,

said first and second current transmitting means comprise first and second transistors, respectively, the first transistor being of one conductivity type, and the second transistor of the opposite conductivity type, said first and second transistors each having its respective emitter connected to said first and second sources of potential,

said first control means comprises a third transistor of the same conductivity type as said second transistor, said third transistor having its emitter electrode connected to the emitter electrode of said second transistor, its collector electrode connected to the base electrode of said first transistor, and its base electrode connected to said point of reference potential, and

said second control means comprises a fourth transistor of the same conductivity type as said first transistor, said fourth transistor having its emitter electrode connected to the emitter electrode of said first transistor, its collector electrode connected to the base electrode of said second transistor, and its base electrode connected to said point of reference potential.

3. In electronic patient monitoring apparatus, the combination defined by claim 1 including an input differential amplifier comprising

means connected in series with said first current transmitting means for producing a constant current,

a pair of active elements, each having a first electrode connected to said constant current means, a second electrode and a control electrode,

means for deriving an output signal from each of said active elements including first and second resistors connected in series with the second electrodes of said first and second active elements, respectively, and said second current transmitting means,

first and second means for connecting the control electrodes of said first and second active elements to said patient, and

a pair of oppositely poled diodes connected in parallel between the second electrodes of said first and second active elements, whereby said input differential amplifier is effective to amplify normal biopotentials, but prevented by said diodes from ejecting hazardous current to the patient.

4. In electronic patient monitoring apparatus, the combination as defined by claim 3 wherein said active elements are transistors.

5. In electronic patient monitoring apparatus, the combination defined by claim 3 wherein said first and second power supply sources are of opposite polarity with respect to a point of reference potential common to both sources,

said first and second current transmitting means comprise first and second transistors, respectively, the first transistor being of one conductivity type, and the second transistor of the opposite conductivity type, said first and second transistors each having its respective emitter connected to said first and second sources of potential by a resistor,

said first control means comprises a third transistor of the same conductivity type as said second transistor, said third transistor having its emitter electrode connected to the emitter electrode of said second transistor, its collector electrode connected to the base electrode of said first transistor, and its base electrode connected to said point of reference potenial and

said second control means comprises a fourth transistor of the same conductivity type as said first transistor, said fourth transistor having its emitter electrode connected to the emitter electrode of said first transistor, its collector electrode connected to the base electrode of said second transistor, and its base electrode connected to said point of reference potential

6. In electronic patient monitoring apparatus, an input differential amplifier comprising

a power supply,

a pair of active elements, each having a first electrode connected to one side of said power supply, a second electrode and a control electrode,

means for deriving an output signal from each of said active elements including first and second resistors connected in series with the second electrodes of said first and second active elements, respectively, and the other side of said power supply,

first and second means for connecting the control electrodes of said first and second active elements to said patient, and

a pair of oppositely poled diodes connected in parallel between the second electrodes of said first and second active elements, whereby said input differential amplifier is effective to amplify normal biopotentials, but prevented by said diodes from ejecting hazardous current to the patient.

7. In electronic patient monitoring apparatus, the combination as defined by claim 6 wherein said active elements are transistors.

8. In electronic patient monitoring apparatus, the combination as defined by claim 6 comprising in addition a constant current source connected in circuit between the one side of said power supply and said first electrodes of each of said active elements.

References Cited

UNITED STATES PATENTS

3,029,808	4/1962	Kagan	128—2.06
3,213,290	10/1965	Klein et al.	

FOREIGN PATENTS

764,813	1/1957	Great Britain.

WILLIAM E. KAMM, Primary Examiner

U.S. Cl. X.R.

307—86, 93, 131; 317—27; 330—69