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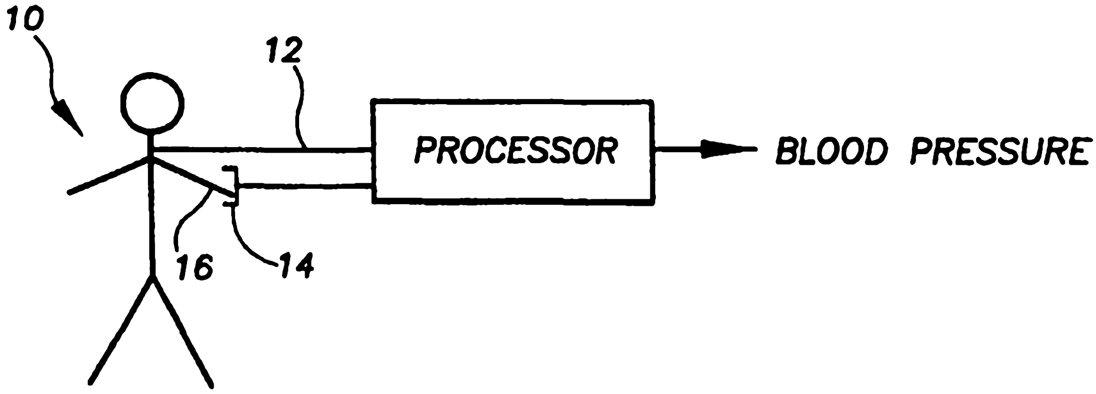

(57) Abstract

Arterial blood pressure of a subject (10) is determined by detecting the EKG (12) and selecting a fiducial point thereof, preferably the R-wave. Apparatus, preferably a photoplethysmograph (14) is provided for monitoring blood volume versus time at a selected location on the subject's body such as a fingertip (16). A time difference between the occurrence of the selected fiducial point on the EKG and a selected change in blood in volume at the selected body location is determined. This time difference depends on the arrival time of the pulse at the distal location in addition to the shape of the blood volume versus time curve. Heart rate is determined from the EKG. The arterial pressure is computed from pulse arrival time, volumetric wave shape and instantaneous heart rate for each pulse. Methods are disclosed for determining diastolic pressure, systolic and mean arterial pressure. In another aspect, artifact detection and rejection are enabled. The invention provides for a continuous measure of blood pressure in a non-invasive, cuffless manner.

NON-INVASIVE CUFFLESS DETERMINATION OF BLOOD PRESSURE

Background of the Invention

Several distinct arterial blood-pressure parameters yield medically useful information, among them pressure at systole, pressure at diastole, mean arterial pressure, pulse pressure, and continuous arterial pressure. The traditional ways of measuring these may be categorized as follows: sphygmomanometry (cuff measurement), automated sphygmomanometry, and indwelling arterial-line transduction (A-line).

The importance of continuous arterial blood pressure as a medical indicator has spurred the development of new methods of measuring it. These include external pressure transduction, photoplethysmography, and pulse-wave transit timing. To date these latter methods have been used mainly experimentally.

Sphygmomanometry, the most widely used traditional method, gives pressure at systole and pressure at diastole. The automated cuff uses a machine-actuated pump for cuff inflation, and algorithms and sensors to listen for initial and unrestricted arterial flow. However the cuff methods restrict blood flow during each measurement so they are unsuited to continuous use, and the determinations of blood pressure made by many automatic cuff systems fail to meet accuracy standards. The cuff also produces discomfort to the patient, which can influence blood pressure readings.

A-lines, which are used when continuous measurement is necessary, are reasonably accurate during periods free from signal artifact, from sources such as line-crimping, blood-clotting, and contact between the indwelling transducer and the arterial wall. However the transducer needs to be inserted surgically, and can cause thrombosis and infection. Because the method necessitates a surgical procedure, it is used sparingly, and frequently not recommended for use even when continuous pressure measurement would otherwise be desirable.

The experimental methods noted all attempt to circumvent the drawbacks of the A-line by measuring continuous blood pressure externally. Both direct external pressure sensing and indirect calculation methods have been devised.

The direct non-invasive methods use external pressure transduction. A pressure transducer is placed against an artery that lies just beneath the skin, such as the radial artery, and by pushing against the arterial wall senses pressure mechanically. However, because the transducer is sensing force, it is extremely subject to mechanical noise and motion artifact. Continuous measurement is problematical in that the transducer impedes blood flow. Difficulty also arises in keeping the transducer positioned properly over the artery. Thus, indirect-measurement methods have been considered.

Pulse-wave transit-time measurement is an indirect way of inferring arterial blood pressure from the velocity of the pulse wave produced at each heart cycle. however, though the velocity is related to blood pressure, the methods devised to date assume that the relationship is linear, and even if that were the case, it is probable that transit time by itself provides too little information about the pulse wave to permit the determination of blood pressure accurately. Another shortcoming of the method is that it is incapable of giving pressures at both systole and diastole, which many medical practitioners find useful.

Photoplethysmography, a technique of tracking arterial blood-volume and blood oxygen content, gives rise to the other indirect way of inferring blood pressure continuously. However, the methods based on it derive information from the volumetric data as though it were the same as blood pressure; that is, they assume that blood-pressure and blood-volume curves are similar -- which is true sometimes but not in general. Furthermore, photoplethysmographic measurements are made at bodily extremities such as the earlobe or finger, and blood pressure observed at the body's periphery is not generally the same as from more central measurements.

Because the insertion of an A-line is frequently judged to be too invasive a procedure to undertake in order to determine blood pressure, and no practical non-surgical method of continuous measurement has yet supplanted it, the need for one remains.

Summary of the Invention

In one aspect, the method according to the invention for determining arterial blood pressure in a subject includes detecting an EKG signal for the subject. A fiducial point on the EKG signal is selected and the blood volume versus time wave shape at a selected location on the subject's body is monitored. Instantaneous heart rate is determined from the EKG signal and arterial pressure is calculated from the instantaneous heart rate and the blood volume versus time wave shape. In one embodiment, the fiducial point is the R-wave and arterial pressure is calculated utilizing a selected change in blood volume from the blood volume versus time wave shape. It is preferred that the selected change in blood volume be in the range of 20% to 80% on the upslope on the wave shape. It is more preferred that the selected change in blood volume is in the range of 40% to 60%. The most preferred selected change in blood volume is approximately 50% on the upslope of the volume waveform. It is preferred that the selected body portion is a distal location such as a fingertip.

In another aspect, the method according to the invention for determining arterial blood pressure in a subject includes detecting an EKG for the subject and selecting a fiducial point on the EKG during the pulse period. Blood volume versus time is monitored at a selected location on the subject's body. The time difference between occurrence of the selected fiducial point on the EKG and occurrence of a selected change in blood volume at the selected body location is determined. Heart rate is determined from the EKG and arterial pressure is computed based on the time difference and heart rate. In a preferred embodiment, the fiducial point is the R-wave and the body portion is a distal location such as a fingertip. A preferred method for monitoring blood volume utilizes photoplethysmography. The computed arterial pressure may be diastolic pressure, systolic pressure, or mean arterial pressure.

In another aspect, apparatus according to the invention for determining arterial blood pressure includes EKG apparatus for detecting electrical activity of the heart. Apparatus responsive to change in blood volume may include photoplethysmography apparatus. Outputs from the EKG apparatus and the blood volume monitoring apparatus are introduced into a signal processor or computer which computes arterial blood pressure.

The present invention provides an improved method and apparatus for measuring arterial blood pressure continuously, non-invasively, and without the use of a blood pressure cuff.

Brief Description of the Drawing

Fig. 1 is a schematic illustration of the apparatus of the present invention.

Fig. 2 is a graph of EKG and blood volume versus time.

Description of the Preferred Embodiment

The physics of wave propagation in elastic tubes is an important factor to understand the underlying concept of the present invention. The simplest equation for the velocity of propagation of a pressure pulse in an elastic tube was first described by Moens-Kortweg who from experimental evidence and theoretical grounds established the formula

$$c = \sqrt{\frac{Eh}{2R\delta}}$$

where c is the wave velocity, E and h are Young's modulus and thickness of the arterial wall, δ the density of the fluid and R the mean radius of the tube.

To eliminate the experimental difficulties of measuring the wall thickness and Young's modulus the Moens-Kortweg equation was modified by Bramwell and Hill

(1922) so that the elastic behavior of the tube was expressed in terms of its pressure-volume distensibility. The formula can then be reduced to

$$c = \sqrt{\frac{V}{\delta(\partial V / \partial P)}} = \sqrt{\frac{V \partial P}{\delta \, \partial V}}$$

or

$$\Delta P \; \alpha \; c^2 \left(\frac{\Delta V}{V}\right)$$

where V is the initial volume of the artery, ΔV is the change in volume resulting in the pressure pulse ΔP and c is the pulse wave velocity.

The problem then involves determining a non-invasive way of measuring both the pulse wave velocity, and percent change in arterial volume. In order to accomplish this, we have chosen to use the standard EKG signal and any stable measure of blood volume versus time (such as photoplethysmography in the preferred embodiment).

The method of utilizing the EKG signal and blood volume versus time signals include first measuring the $T_{R\_50(i)}$ (duration of R-wave on EKG to 50% point on volume versus time up-slope) for the i'th pulse. This duration is the sum of the time between the R-wave and the arrival of the pulse 0% point ($T_{R\_0(i)}$) added to the duration of the pulse 0% point to the 50% point on the up-slope ($T_{0\_50(i)}$). The inverse of $T_{R\_0(i)}$ is proportional to the pulse velocity as defined above (or $c \alpha 1/T_{R\_50(1)}$) and $T_{0\_50(i)}$ is more related to ΔV and V. Therefore the measure $T_{R\_50(i)}$ is a measure that is related to c, ΔV and V.

Then, the combined pulse velocity measure for the i'th pulse ($v_{p(i)}$) is therefore defined as the inverse of $T_{R\_50(i)}$ and the combined pulse velocity squared ($v_{p(i)}^2$) is obtained by simply squaring $v_{p(i)}$. Also the instantaneous R-R interval and thereby instantaneous heart rate for the i'th pressure pulse (RR_i and $IHR_{(i)}$ respectively) are determined and used in the calculation of diastolic, systolic and mean pressures for the i'th pulse ($P_{D(i)}$, $P_{S(i)}$ and $P_{M(i)}$ respectively). The theoretical basis for the importance of the R-R interval or IHR in the calculation of diastolic pressure can be summarized as follows. The diastolic pressure is defined as that arterial pressure that exists at the end of the diastolic pressure decay. This exponential diastolic pressure decay starts at the closure of the aortic valve, and ends at the opening of the aortic valve. The pressure decay rate depends on a variety of factors, including the aortic pressure built up during systole, and the systemic arterial impedance (related to the stiffness of the walls of the arterial system, especially the arteriole). For a given individual, the pressure to which this decay falls for any given heart beat (or diastolic pressure) is therefore related to the duration this decay is allowed to continue. This duration of decay for any given pulse is directly proportional to the instantaneous R-R interval or inversely proportional to the IHR of that pulse. Therefore, the shorter the decay duration (higher IHR), the higher the diastolic pressure is expected to be, and the longer the decay duration (lower IHR), the lower the diastolic pressure is expected to be. In summary the equations for the calculation of pressures for the i'th pressure pulse are as follows:

$$IHR_{(i)} = 1/RR_{(i)}$$

$$v_{p(i)}^2 = (1/T_{R\_50(i)}) * (1/T_{R\_50(i)})$$

$$P_{D(i)} = (K_{Dv} * v_{p(i)}^2) + (K_{Dihr} * IHR_{(i)}) + K_{Dcal}$$

$$P_{S(i)} = (K_{Scal} * v_{p(i)}^2) + K_{Sconst}$$

$$P_{M(i)} = (P_{S(i)} - P_{D(i)}) * 1/3 + P_{D(i)}$$

In these equations, K_{Dv}, K_{Dihr} and K_{Sconst} are constants that in the preferred embodiment are equal to 2.5, 0.5 and 35 respectively, and where K_{Dcal} and K_{Scal} are calibration constants. $P_{D(i)}$, $P_{S(i)}$ and $P_{M(i)}$ are diastolic, systolic and mean arterial pressure respectively.

The practice of the present invention will be described in conjunction with the figures. In Fig. 1 a human subject 10 is monitored by EKG leads represented generally at 12. Those skilled in the art recognize that multiple leads are typically utilized for measuring the EKG. Photoplethysmography apparatus 14 monitors blood volume at a fingertip 16 of the subject 10. The outputs from the EKG apparatus 12 and photoplethysmography apparatus 14 are processed in a computer or signal processor 18 and produces as an output blood pressure which, as discussed above, may be diastolic pressure, systolic pressure or mean arterial pressure for each pulse. With reference to Fig. 2, the processor 18 detects the R-wave arrival.

Thereafter, the blood volume measuring apparatus 14 detects the onset of a change in volume at time $T_{R\_0(i)}$ and determines the time when volume has reached the 50% ($T_{0\_50(i)}$) point on the volume versus time upslope. As can be seen in Fig. 2, the time from the arrival of the pulse zero percent point ($T_{R\_0(i)}$) to the 50% point on the upslope ($T_{0\_50(i)}$) depends on the shape of the volume versus time curve. Because the present invention utilizes both the time from R-wave arrival to the zero percent volume change point, and from the zero percent volume change point to the 50% point, pressure determinations are more accurate than in the prior art in which either pulse arrival time or wave shape was utilized but not both in combination as in the present invention.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. Method for determining arterial blood pressure in a subject comprising:

detecting an EKG signal for the subject for a series of pulses in a time window;

selecting a fiducial point for each pulse on the EKG signal;

monitoring blood volume versus time waveshape at a selected location on the subject's body for the series of pulses;

determining instantaneous heart rate for each pulse from the EKG signal;

calculating arterial pressure from the instantaneous heart rate and the blood volume versus time waveshape for each pulse;

sorting by value a function of at least one of the EKG signal and the blood volume versus time waveshape for each pulse over the series of pulses

calculating a parameter based on the sorted values; and

detecting artifacts from the calculated parameter.

2. The method of claim 1 wherein the fiducial point is a point on an R-wave.

3. The method of claim 2 wherein the fiducial point is the peak of the R-wave.

4. The method of claim 1 wherein the calculating step includes utilizing a selected change in blood volume on the blood volume versus time waveshape.

5. The method of claim 4 wherein the selected change in blood volume is in the range of 20% to 80% on an upslope on the wave shape.

6. The method of claim 4 wherein the selected change in blood volume is in the range of 40% to 60% on an upslope on the wave shape.

7. The method of claim 4 wherein the selected change in blood volume is approximately 50% on an upslope on the wave shape.

8. The method of claim 1 wherein the selected body portion is a distal location.

9. The method of claim 8 wherein the distal location is a fingertip.

10. The method of claim 1 wherein monitoring blood volume versus time comprises utilizing photoplethysmography.

11. Method for determining arterial blood pressure in a subject comprising:

detecting an EKG for the subject for a series of pulses in a time window;

selecting a fiducial point for each pulse on the EKG signal;

monitoring blood volume versus time at a selected location on the subject's body for the series of pulses;

determining time difference between occurrence of the selected fiducial point and occurrence of a selected change in blood volume at the selected body location for each pulse;

determining heart rate for each pulse from the EKG;

computing arterial pressure based on the time difference and heart rate for each pulse;

sorting by value a function of at least one of the EKG signal and the blood volume versus time waveshape for each pulse over the series of pulses

calculating a parameter based on the sorted values; and

detecting artifacts from the calculated parameter.

12. The method of claim 11 wherein the fiducial point is a point on an R-wave.

13. The method of claim 12 wherein the fiducial point is the peak of the R-wave.

14. The method of claim 11 wherein selected change in blood volume is in the range of 20% to 80%.

15. The method of claim 11 wherein selected change in blood volume is in the range of 40% to 60%.

16. The method of claim 11 wherein selected change in blood volume is approximately 50%.

17. The method of claim 11 wherein the selected body portion is a distal location.

18. The method of claim 17 wherein the distal location is a fingertip.

19. The method of claim 11 wherein monitoring blood volume versus time comprises utilizing photoplethysmography.

20. The method of claim 11 wherein arterial pressure is diastolic pressure.

21. The method of claim 11 wherein arterial pressure is systolic pressure.

22. The method of claim 11 wherein arterial pressure is mean arterial pressure.

23. Method for determining diastolic blood pressure in a subject comprising:

detecting an EKG for the subject;

selecting a fiducial point on the EKG during a pulse;

monitoring blood volume versus time at a selected location on the subject's body;

determining time difference between occurrence of the selected fiducial point and occurrence of a selected change in blood volume at the selected body location;

determining heart rate from the EKG; and

computing diastolic pressure based on the time difference and heart rate, wherein diastolic pressure, $P_{D(i)}$, is determined by computing

$$P_{D(i)} = (K_{Dv} * v_{p(i)}^2) + (K_{Dihr} * IHR_{(i)}) + K_{Dcal}$$

$$v_{p(i)}^2 = (1/T_{R\_50(i)}) * (1/T_{R\_50(i)})$$

where $T_{R\_50(i)}$ is the time difference between occurrence of the selected fiducial point and a change in blood volume at the selected body location; K_{Dv} and K_{Dihr} are constants and K_{Dcal} is a calibration constant; $IHR_{(i)}$ is the instantaneous heart rate; $v_{p(i)}$ is the pulse velocity; and i refers to the ith pulse.

24. The method of claim 23 wherein K_{Dv} is approximately 2.5 and K_{Dihr} is approximately 0.5.

25. Method for determining systolic blood pressure in a subject comprising:

detecting an EKG for the subject;

selecting a fiducial point on the EKG during a pulse;

monitoring blood volume versus time at a selected location on the subject's body;

determining time difference between occurrence of the selected fiducial point and occurrence of a selected change in blood volume at the selected body location;

determining heart rate from the EKG; and

computing systolic pressure based on the time difference and heart rate, wherein systolic pressure, $P_{S(i)}$, is determined by computing

$$P_{S(i)} = (K_{Scal} * v_{p(i)}^2) + K_{Sconst}$$

wherein K_{Sconst} is a constant; K_{Scal} is a calibration constant; $v_{p(i)}$ is the pulse velocity; and i refers to the ith pulse.

26. The method of claim 25 wherein K_{Sconst} is approximately 35.

27. The method of claim 22 wherein mean arterial pressure, $P_{M(i)}$, is determined by computing

$$P_{M(i)} = (P_{S(i)} - P_{D(i)}) * 1/3 + P_{D(i)}$$

where $P_{S(i)}$ is systolic pressure, $P_{D(i)}$ is diastolic pressure, and i refers to the ith pulse.

28. A method for determining arterial blood pressure in a subject comprising:

detecting an EKG for the subject;

selecting a fiducial point on the EKG during a pulse;

monitoring blood volume versus time at a selected location on the subject's body;

determining a time difference between occurrence of the selected fiducial point and the sum of time to beginning of a volume change and the time to a selected change in blood volume which is a function of blood volume waveshape;

calculating arterial blood pressure; and

detecting artifacts by determining whether any of the calculated arterial blood pressure and the determined time difference lie outside of a selected range.

29. The method of claim 28 wherein the selected change in blood volume is approximately 50%.

30. The method of claim 29 wherein the selected fiducial point is an R-wave and the selected location of a subject's body is a fingertip.

31. The method of claim 28 wherein monitoring blood volume versus time utilizes photoplethysmography.

32. Method for determining mean arterial blood pressure in a subject, comprising:

detecting an EKG for the subject;

selecting a fiducial point on the EKG during a pulse;

monitoring blood volume versus time at a selected location on the subject's body;

determining time difference between occurrence of the selected fiducial point and occurrence of a selected change in blood volume at the selected body location;

determining heart rate from the EKG; and

computing mean arterial pressure based on the time difference and heart rate, wherein mean arterial pressure, $P_{M(i)}$, is determined by computing

$$P_{M(i)} = ((K_{Scal} * v_{p(i)}^2) + K_{Sconst} - (K_{Dv} * v_{p(i)}^2) + (K_{Dihr} * IHR_{(i)}) + K_{Dcal}) * 1/3 + (K_{Dv} * v_{p(i)}^2) + (K_{Dihr} * IHR_{(i)}) + K_{Dcal} .$$

wherein $T_{R\_50(i)}$ is the time difference between occurrence of the selected fiducial point and a change in blood volume at the selected body location; K_{Dv}, K_{Dihr} and K_{Sconst} are constants and K_{Dcal} and K_{Scal} are calibration constants; $IHR_{(i)}$ is the instantaneous heart rate; $v_{p(i)}$ is the pulse velocity; and i refers to the i_{th} pulse.

33. The method of claim 32 wherein K_{Dv} is approximately 2.5, K_{Dihr} is approximately 0.5, and K_{Sconst} is approximately 35.

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FIG. 1

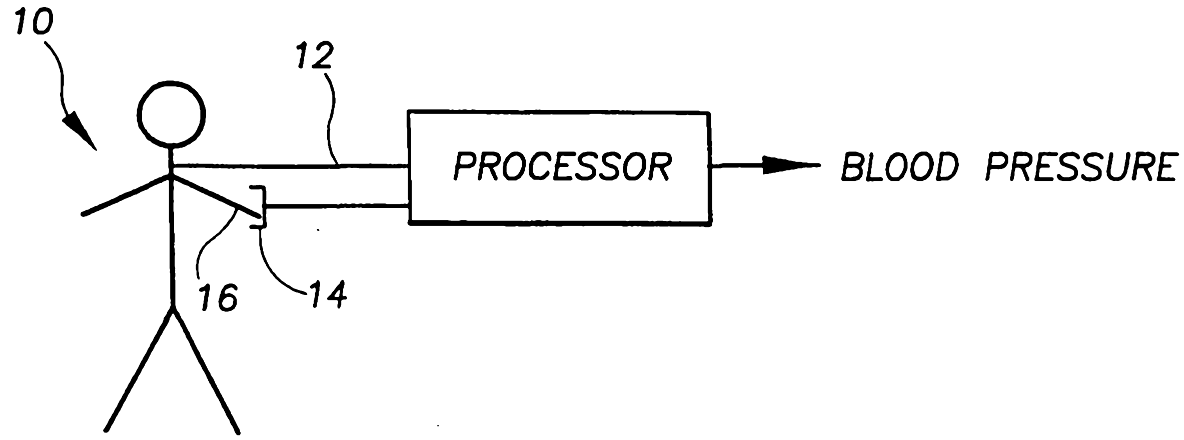
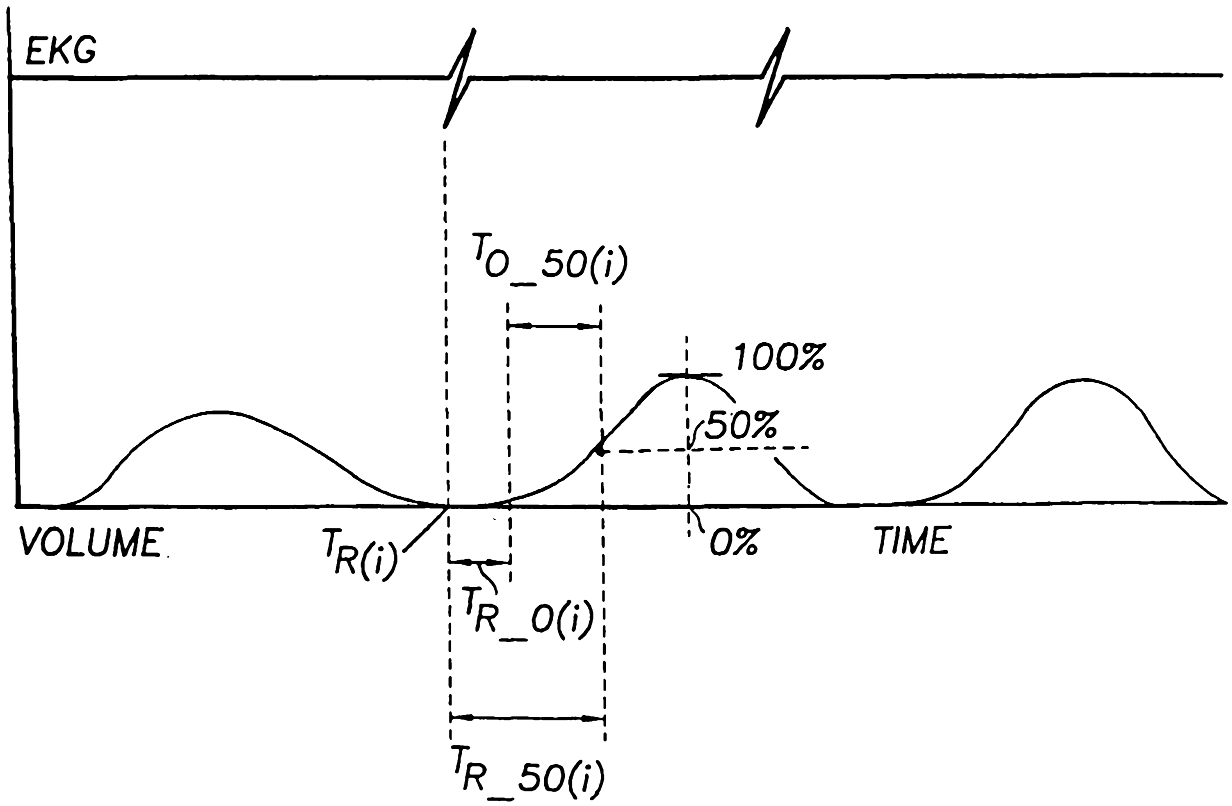

10
12
PROCESSOR
BLOOD PRESSURE
16
14

FIG. 2


EKG
$T_{O\_50(i)}$
100%
50%
VOLUME
$T_{R(i)}$
0%
TIME
$T_{R\_O(i)}$
$T_{R\_50(i)}$