

FORM 1
COMMONWEALTH OF AUSTRALIA
PATENTS ACT 1952
APPLICATION FOR A STANDARD PATENT (OR DIVISIONAL)
OR A STANDARD PATENT OF ADDITION

We, CRITIKON, INC.
of, 4110 George Road, Tampa, FLORIDA 33614, U.S.A.

hereby apply for the grant of a standard patent for an invention entitled:

"AUTOMATED MEANS ARTERIAL BLOOD PRESSURE MONITOR WITH
DATA ENHANCEMENT"

which is described in the accompanying complete specification.

Number of original application 59708/86
Person by whom made CRITIKON, INC.

Our address for service is: GRIFFITH HACK & CO.
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DATED this 28th day of February, 1989

CRITIKON, INC.
By their Patent Attorneys



GRIFFITH HACK & CO.

TO: THE COMMISSIONER OF PATENTS
COMMONWEALTH OF AUSTRALIA

CKK73(2)

ASSIGNEE - APPLICANT

615263

COMMONWEALTH OF AUSTRALIA

PATENTS ACT 1952

DECLARATION IN SUPPORT OF AN APPLICATION FOR A PATENT

In support of an Application made by: CRITIKON, INC.

for a patent for an invention entitled: "AUTOMATED MEANS ARTERIAL BLOOD PRESSURE MONITOR WITH DATA ENHANCEMENT"

I, W. Brinton Yorks, Jr.

of, Critikon, Inc., 4110 George Road, Tampa, Florida 33631-3800

do solemnly and sincerely declare as follows:

1. I am authorised by the above mentioned applicant for the patent to make this Declaration on its behalf.
2. The name and address of each actual inventor of the invention is as follows:

MAYNARD RAMSEY, III; RICHARD MEDERO and RUSH W. HOOD, JR.

of 903 Golfview, Tampa, Florida 33609, U.S.A.; 2410 Blindpond Avenue, Lutz, Florida 33549, U.S.A. and 15615 Gardenside Lane, Tampa, Florida 33624, U.S.A. respectively.

and the fact(s) upon which the applicant is entitled to make this application are as follows:

The Applicant is the assignee of the said invention from the actual inventors.

Declared at New Brunswick this 25th day of April 1989.

Signed: W Brinton Yorks, Jr.

Position: W. Brinton Yorks, Jr.
Assistant Secretary

GRIFFITH HACK & CO., SYDNEY, AUSTRALIA

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(56) Prior Art Documents
AU 48076/85 A61B 5/02
AU 569244 89833/82 A61B 008/02
AU 552241 79640/82 A61B 008/02

(57) Claim

1. In combination in digital processor controlled automated blood pressure measuring apparatus operative in conjunction with a stored program:

(a) an inflatable cuff;

(b) means for inflating and deflating said cuff;

(c) pressure transducer means coupled to said cuff for signalling the pressure existing in said cuff;

(d) means responsive to the pressure signalled by said transducer for generating a signal representing blood pressure oscillation complexes sensed by said cuff and said transducer coupled thereto;

(e) complex peak storing means for storing values characterizing the peak amplitudes of said sensed oscillation complexes at different cuff pressures;

(f) cuff pressure storing means for storing the cuff pressures existing when said complex peak amplitudes arose; and

(g) mean arterial pressure determining means, said mean arterial pressure determining means comprising

(i) means for locating the maximum complex peak amplitude stored in said complex peak storing means;

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PATENTS ACT 1952

COMPLETE SPECIFICATION

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TO BE COMPLETED BY APPLICANT

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Complete Specification for the invention entitled:

"AUTOMATED MEANS ARTERIAL BLOOD PRESSURE MONITOR
WITH DATA ENHANCEMENT"

The following statement is a full description of this invention, including
the best method of performing it known to us:-

7929A/bm

Field of the Invention

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This invention relates to automated blood pressure measuring apparatus and, more particularly, to stored program controlled monitors employing the oscillometric method of detection characterized by data purification and enhanced systolic, diastolic and mean blood pressure determination.

10

Background of the Invention

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Automated blood pressure monitoring has rapidly become an accepted and, in many cases, essential aspect of human and veterinary treatment. Such monitors are now a conventional part of the patient environment in emergency rooms, intensive and critical care units, and in the operating theatre.

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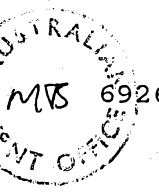
The so-called oscillometric method of measuring blood pressure is one of the most popular methods in commercially available systems. This method relies on measuring changes in arterial counterpressure, such as imposed by an inflatable cuff, which is controllably relaxed or inflated. In some cases the cuff pressure change is continuous, and in others it is incremental. In substantially all, a transducer monitors arterial counterpressure oscillations, and processing apparatus converts select parameters of these oscillations into blood pressure data.

Of particular interest with respect to the principles of the present invention are the concepts set forth in U.S. Patents 4,360,029 and 4,394,034 to M. Ramsey, III, which are commonly assigned with the instant invention. The Ramsey patents derive from common parentage, the former including apparatus claims and the latter including method claims, their division having been made in response to a restriction requirement during the prosecution. Both patents, however, carry common disclosures of apparatus and methods for artifact rejection in oscillometric systems, which have been in practice in the commercially successful DINAMAP brand monitors, which are manufactured and marketed by Critikon, Inc., of Tampa, Florida, the assignee hereof. In accordance with the Ramsey patents, an inflatable cuff is suitably located on the limb of a patient, and is pumped up to a predetermined pressure. Thereupon, the cuff pressure is reduced in predetermined fixed decrements, at each level of which pressure fluctuations are monitored. These typically consist of a DC voltage with a small superimposed variational component caused by arterial blood pressure pulsations (referred to herein as "oscillatory complexes"). Therefore, after suitable filtering to reject the DC component and to

provide amplification, pulse peak amplitudes above a given threshold are measured and stored. As the decrementing continues, the peak amplitudes will normally increase from a lower amount to a relative maximum, and thereafter will decrease. The lowest cuff pressure at which the oscillations have a maximum peak value is representative of mean arterial pressure. The cuff pressures obtaining when stored oscillatory complex pulse peak amplitudes bear predetermined fractional relationships with the largest stored peak corresponding to the subject's systolic and diastolic pressures.

The Ramsey patents devote considerable effort and disclosure to the rejection of artifact data to derive accurate blood pressure data. Indeed, as is apparent from Fig. 2 of the Ramsey patents, the most substantial portion of the measurement cycle (denominated "T3") is devoted to the execution of complex detection at the various pressure levels, measurement of signal peaks of true complexes, and processing those peaks in accordance with artifact rejection algorithms. Notwithstanding such efforts, the signal peak data collected sometimes incorporates data errors, ie, a data pattern inconsistent with the above described typical physiological response pattern of a subject as the artery occluding cuff pressure monotonically decreases.

Further, in a contemporaneous invention (Australian patent application no. 59810/86 for "OSCILLOMETRIC BLOOD PRESSURE MONITOR EMPLOYING NON-UNIFORM PRESSURE DECREMENTING STEPS", the disclosure of which is incorporated herein by reference) oscillometric blood pressure measurements are effected with non-uniform, cuff pressure-dependent pressure decrements between successive oscillatory complex peak measuring intervals. Such a method of effecting oscillometric blood pressure measurements is facilitated by systolic, diastolic and mean blood pressure determining algorithms not heretofore employed.



It is an aim of the present invention to provide improved
oscillometric blood pressure determining apparatus and
methodology. More specifically, an aim of the present
invention is to purify the oscillatory complex peak
5 amplitude data ensemble employed for blood pressure
determination.

An advantage of a preferred embodiment of the present
invention is that it has the provision of improved
10 algorithms, methodology and apparatus for determining
systolic, diastolic and mean arterial blood pressure.

Summary of the Invention

15 In a first aspect, the present invention provides in
combination in digital processor controlled automated blood
pressure measuring apparatus operative in conjunction with a
stored program:

(a) an inflatable cuff;
20 (b) means for inflating and deflating said cuff;
(c) pressure transducer means coupled to said cuff
for signalling the pressure existing in said cuff;

(d) means responsive to the pressure signalled by
said transducer for generating a signal representing blood
25 pressure oscillation complexes sensed by said cuff and said
transducer coupled thereto;

(e) complex peak storing means for storing values
characterizing the peak amplitudes of said sensed
oscillation complexes at different cuff pressures;

30 (f) cuff pressure storing means for storing the
cuff pressures existing when said complex peak amplitudes
arose; and

(g) mean arterial pressure determining means, said
mean arterial pressure determining means comprising

35 (i) means for locating the maximum complex peak
amplitude stored in said complex peak storing means;

(ii) means for locating a successor complex peak amplitude value stored in said complex peak storing means, said successor being the one next occurring after said maximum complex peak amplitude arose;

5 (iii) means, responsive to the value of said successor complex peak for selecting plural ones of the complex peak amplitudes which were generated at cuff pressures higher than that existing when said maximum complex peak arose; and

10 (iv) determining means for determining mean arterial pressure from

1. said selected plural ones of the complex peak amplitudes,

15 2. the cuff pressures stored in said cuff pressure storing means corresponding to said selected plural ones, and

3. the cuff pressure which corresponds to said successor complex peak amplitude.

20 In a further aspect, the present invention provides in an automated oscillometric blood pressure monitor employing a pressurized cuff, means for controllably changing pressure to distinct cuff pressure levels in predetermined cuff pressure decrements, and means for measuring arterial pressure oscillation complexes through
25 cuff pressure measurement, a method for measuring mean arterial pressure comprising the steps of:

30 (a) at each said level, detecting oscillation complexes, measuring and storing the peak thereof, and storing the identification of each associated prevailing cuff pressure level;

(b) finding the amplitude of the largest of said peaks, and recording the prevailing cuff pressure level stored in association therewith;

35 (c) identifying a cuff pressure level having a peak next following and smaller than said largest of said peaks;

(d) identifying, in response to the amplitude of said peak next following, plural peaks which occurred at cuff

pressure levels larger than the cuff pressure level of said largest of said peaks;

(e) interpolating the amplitude of said identified plural peaks; and

5 (f) developing mean arterial pressure as a predetermined weighted average of the cuff pressure corresponding to said interpolated amplitude and the cuff pressures corresponding to at least one of said largest and said next following peaks.

10 A blood pressure cuff is applied about a subject's artery, and inflated above the systolic level thus fully occluding the artery for a full heart cycle. The cuff pressure is thereafter reduced to permit an increasing flow through the progressively less occluded artery, and a
15 measure of the peak amplitudes of the successively encountered oscillatory complexes stored in memory. Also retained is the cuff pressure obtaining for each stored complex peak.

In accordance with a preferred embodiment of the
20 present invention, the stored complex peak-representing data set is corrected for aberrations; and improved data processing operates on the stored (and advantageously corrected) pulse peak data and the corresponding cuff
pressure

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information to determine the subject's systolic, diastolic and mean arterial pressure.

Description of the Drawings

5

The above and other objects and features of the present invention will be realized from the following detailed discussion of a specific, illustrative embodiment thereof, presented hereinbelow in conjunction with the accompanying drawing, in which:

10

Fig. 1 is a timing diagram illustrating data generation and correction during an illustrative measurement cycle for oscillometric blood pressure determination in accordance with the principles of the present invention;

15

Fig. 2 is a flow chart illustrating data purification for improved oscillometric blood pressure determination;

20

Fig. 3 depicts oscillation amplitude processing for a systolic blood pressure measurement in accordance with the present invention;

25

Fig. 4 is a program flow chart for the systolic blood pressure measurement typified in Fig. 3;

30

Fig. 5 illustrates blood pressure interpolation for the processing mode of Figs. 3 and 4 (and by analogy for Figs. 6-9 as well);

35

Fig. 6 depicts oscillatory complex measuring wave forms illustrating diastolic blood pressure determination in accordance with the present invention;

Fig. 7 is a program flow chart illustrating the diastolic blood pressure measurement typified by Fig. 6;

5 Fig. 8 is a timing diagram depicting oscillatory complex peak amplitude processing for mean arterial pressure measurements in accordance with the present invention; and

10 Fig. 9 is a program flow chart illustrating the mean arterial pressure determination typified by Fig. 8.

Best Mode For Carrying Out the Invention

U.S. Patent Nos. 4,360,029 and 4,349,034, each to Maynard Ramsey, III, and Maynard Ramsey, III et al U.S. Patent No. 15 4,543,962 for "IMPROVED METHOD OF AUTOMATED BLOOD PRESSURE DETECTION" issued October 1, 1985 are incorporated herein by reference, as is Australian Patent Application No. 59810/86. These patents and this patent application describe in detail the basic oscillometric method of 20 measuring blood pressure forming a background and a starting point for the instant invention.

To review only briefly, an artery-occluding cuff is disposed on the subject, e.g., about a subject's upper arm over the 25 brachial artery. At the inception of a measuring cycle, the cuff is inflated to a pressure which fully occludes the brachial artery, i.e., prevents blood from flowing therethrough at any point in the heart cycle. The cuff is then progressively deflated, as in discrete steps. A 30 pressure transducer is coupled to the internal cuff pressure and provides an analog signal characterizing the blood pressure oscillatory complexes when they begin to occur (i.e., when the maximum heart pressure corresponding to contraction of the heart's left ventricle

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exceeds the instantaneously obtaining artery-occluding cuff pressure). The peak values of the complex signals are determined in hardware or software.

5 As the measurement cycle progresses, the peak amplitude of the blood pressure complexes generally become monotonically larger to a maximum and then become monotonically smaller as the cuff pressure continues toward deflation. The peak amplitude of the cuff pressure
10 oscillation complexes, and the corresponding occluding-cuff pressure values are retained in computer memory. The aforementioned Ramsey patents and patent application illustrate previously employed algorithms for processing the stored blood pressure complex peak values
15 and concomitant pressure values to yield the subject's mean arterial pressure. These patents and applications also furnish detailed procedures for measuring oscillatory complex peaks; procedures for testing complexes and rejecting bad data associated with measurement-impeding
20 artifacts (such as motion) during a measuring cycle, and the like.

The oscillometric blood pressure measurements as typified by the aforementioned Ramsey disclosures are effected
25 under stored program control, as via a microprocessor operative in conjunction with a program containing read only memory (ROM or PROM), and a variable content random access memory (RAM) which stores the cuff pressures, oscillatory complex peak amplitudes, and other processing
30 operand variables. The microprocessor receives the cuff pressure readings generated by the pressure transducer, for example as processed by a peak detector, amplifier and analog-to-digital converter, and supplies all output control signals required, e.g., to open and close one or
35 more cuff deflating valves.



The oscillometric method above described and more fully discussed in the aforementioned Ramsey patents and application may be conducted with several variations.

5 Thus, for example, the cuff may be inflated directly by an air pump; and deflated in fixed, discrete steps under microprocessor control. Alternatively, the cuff may be principally or entirely inflated by the pressurized contents of an air reservoir; and/or deflation may proceed
10 in variable, cuff pressure-dependent steps via selected one or ones of plural deflating valves. These latter alternatives achieve the desideratum of condensing the time required for a composite measurement cycle of operation.

15 Also, there are alternative procedures for measuring the oscillatory complex peak amplitude at any prevailing cuff pressure. In one mode heretofore employed, plural (e.g., two) complex peaks are measured at each cuff pressure step during cuff deflation, and their average used as the peak
20 value. Since the peaks should be approximately equal, any marked disparity (e.g., > 20%) signals that some artifact error occurred and the data is rejected. In a fast ("stat") mode, after several intervals of qualifying (close or equal peak values) companion complexes are
25 detected to develop measurement confidence, only one pulse is required during succeeding cuff deflation intervals thus speeding the composite measurement period. Please see in this later regard US 4,543,962.

30

As alluded to above, it is sometimes the case when blood pressure complexes are being examined for peak amplitude at any occluding pressure level that improper data is
35 developed. There are varying causes for such

aberrations. Perhaps the most common is spurious motion
by the subject which generates an inadvertent pressure
impulse in the cuff which is sensed by the pressure
transducer which may be then incorrectly reflected in the
5 blood pressure measurement. Other causes include varying
sources of interfering electrical noise or internal
cardiac or respiratory changes in the subject. When a
false complex peak amplitude value is generated, it is
discarded by the composite measuring apparatus and a
10 discard-signalling value (e.g., +1) retained in its place
in memory.

A second form of spurious data occurs when the pattern of
stored pulse peak values departs from the physiologically
15 mandated sequence of values which progressively increase
to a peak and then progressively decrease.

Attention will now be directed to data processing under
stored program control for purifying the data collected by
20 the above-described blood pressure measuring apparatus.
Further, specific illustrative efficient algorithms are
discussed for in fact determining the subject's systolic,
diastolic and mean arterial blood pressures. Such data
processing may be effected on any computing equipment,
25 preferably digital microprocessors such as commercially
available from a number of vendors. The program
instructions and sequences presented below are for
illustrative purposes only. Such instructions may in fact
be implemented in any of diverse program languages and
30 sequences readily apparent to those skilled in the art.
In the signal processing below discussed, processing
variables have the following significance:

I. Variables Employed For All Data Processing Below Discussed

	<u>Variable</u>	<u>Functional Quantity Represented</u>
5		
	CP(I)	The cuff pressure, measured by the transducer pneumatically coupled to the artery occluding cuff, obtaining during the i-th deflation step. CP(I) is an indexed array, i.e., there exists a plurality of values for CP(I) characterizing each of the <u>i</u> deflation steps.
10		
	$\Phi A(I)$	The peak amplitude of the oscillometric oscillation (i.e., the complex peak amplitude) occurring at the i-th step. Where multiple complexes are measured during each prevailing deflation pressure, $\Phi A(I)$ is the average of two (or more) peak amplitudes during the i-th step. $\Phi A(I)$ is an indexed array.
15		
	$\Phi A(MAX)$	The peak value of the array of averaged oscillatory blood pressure complex amplitudes.
20		
	MAX	The time interval when the peak complex $\Phi A(MAX)$ occurred.
25		
30		
35		

II. Variables Specific To Systolic Pressure Measurement

	<u>Variable</u>	<u>Functional Quantity Represented</u>
5	LVL	An intermediate processing variable representing a predetermined fraction of $\Phi A(\text{MAX})$.
10	SYS	The subject's measured systolic pressure.

III. Diastolic Pressure Variables

	<u>Variable</u>	<u>Functional Quantity Represented</u>
15	UDLVL and LDLVL	Intermediate processing variables each representing a different fraction of $\Phi A(\text{MAX})$.
20	DIAU, DIAL	Intermediate processing variables representing upper and lower interpolated diastolic pressure computational variables.
25	DIA	The subject's measured diastolic pressure.

IV. Mean Arterial Pressure Processing Variables

	<u>Variable</u>	<u>Functional Quantity Represented</u>
30	AMP	The complex pulse peak for the deflation interval following that

35

for which the pressure oscillation amplitude was the maximum.

MAPL

5

An intermediate processing variable employed in the final mean arterial pressure computation.

MAP

10

The subject's mean arterial blood pressure.

Turning now to Fig. 1, there is depicted wave forms with associated data characterizing the generation of data for an oscillatory blood pressure measurement - and purging (overcoming) bad data constituents. In accordance with the above discussion, the cuff artery occluding pressure for a measurement cycle, as measured by the cuff-associated transducer, is characterized by a wave form 10. The cuff pressure rapidly increases to a maximum above the subject's systolic pressure, and is then deflated in a sequence of steps to a point below the diastolic pressure. The sequence of cuff deflation steps is indicated by the time interval signalling digits 1,2, ... , (lowest row 18 in the data table portion of Fig. 1). The internal pressure characterizing the cuff pressure at each step i is given by the data array $CP(1), CP(2), \dots$ (upper data table row 12).

Each step (time interval) is made sufficiently long to include at least two heart beats. Accordingly, at least two cuff pressure complex pulses 21_i and 22_i are measured during each interval after such pulses begin. Legends have been applied to pulses occurring during deflation steps 6 and 9 to avoid clutter and loss of clarity in Fig. 1. No pulses are measured during the first and second pressure steps (time intervals), it being

assumed that the cuff pressure [CP(1)=201 Torr., and CP(2)=194 Torr.] are sufficient during these periods to obviate blood flow through the subject's artery for the full heart cycle. During the following intervals 3,4
5 ... , two oscillometric complex pulses 21 and 22 are generated and measured, the two pulses having an average peak amplitude 23 (the processor variable array value initially stored in $\Phi A(I)$). The measured oscillation amplitude array ($\Phi A(I)$) is shown in the second row 14 of
10 the Fig. 1 data table for each time interval.

As above noted, assuming a perfect measurement, the oscillation pressure amplitude $\Phi A(I)$ data row would not contain any +1 values which signify an impeded
15 measurement. Further, the data pattern in the second row of the data table for the oscillation amplitudes would exhibit a pattern of successively increasing numbers to a peak value, followed by progressively decreasing values - all without adjacent equal $\Phi A(I)$ values. To the extent
20 that any $\Phi A(I)=1$ values are stored, or to the extent that the progressively increasing/decreasing pattern does not obtain, the data processing in accordance with the instant invention functions to compute appropriate corrected $\Phi A(I)$ values (the third data table row 15 in
25 Fig. 1) for the oscillation amplitude entries requiring correction.

In overview, where any $\Phi A(I)=1$ values exist, they are replaced by the average value of the oscillation amplitude
30 in the two contiguous storage cells, i.e.,

$$\Phi A(I) = (\Phi A(I-1) + \Phi A(I+1))/2. \quad \text{Eq. 1.}$$

Correspondingly, where two contiguous oscillation
35 amplitudes have the proscribed equal values, the first of

the contiguous equal pair is replaced by the average of the amplitudes of the complex peaks measured at the next lower and next higher occluding cuff pressures. See, for example, Eq. 1 and, more particularly, the comparable relationship in functional block 30 of Fig. 2.

10 Data flow effecting the data purification algorithm above-discussed is set forth in the program flow chart of Fig. 2. Fig. 2 operates on the measured average oscillation amplitudes (the second data table row 14 in Fig. 1) and generates the corrected $\Phi A(I)$ values shown in the third row 15 of Fig. 1. To this end, proceeding from a start block 10 (Fig. 2), step 15 reads the next value $\Phi A(I)$ (proceeding toward the right along the Fig. 1 data table row 14) and test 18 determines whether the value stored in $\Phi A(I)$ equals the error-signalling value +1. If as is the usual case it does not (indicating that the value measured was presumptively free of artifacts and the like), control passes to equality test 27. However, 15 if the contents of $\Phi A(I)$ did equal +1 ("YES" branch of test 18), functional block 23 implements Eq. 1, i.e., replaces the +1 former contents of memory cell $\Phi A(I)$ corresponding to cuff pressure $CP(I)$ with the average value of the oscillation amplitude measured at the next 20 lower ($\Phi A(I-1)$) and next higher non-plus one ($\Phi A(I+1)$) deflation steps. The processing steps 18 and 23 thus purge the measured pressure peak amplitude storage contents (the second row of the Fig. 1 data table) of all +1 values, replacing these by the average value of the 25 measurements made during immediately adjacent deflation steps (corrected $\Phi A(I)$ contents being illustrated in row 15).

35 Test 27 next examines the current operand $\Phi A(I)$ for the

proscribed equality with the previous value $\Phi A(I-1)$.
If, as is normally the case, the contents of $\Phi A(I)$ and
 $\Phi A(I-1)$ differ ("NO" branch from test 27), processing
flows to test 32 to determine whether each of the N
5 elements of $\Phi A(I)$ have been processed. If they have
not, control returns to block 15 to read in and process
the next $\Phi A(I)$ element of the array in the third row 15
of the Fig. 1 data table. When all elements have been
processed, control exits from the Fig. 2 data purification
10 routine to data processing point 33 to proceed with the
next (unrelated) task for the microprocessor.

If a data error has occurred ("YES" output of test 27
signalling that a data value $\Phi A(I)$ equaled the previous
15 value), control passes to step 30 which replaces the
assumed erroneous element $\Phi A(I-1)$ - (the value which
should differ from $\Phi A(I)$ but did not) with the average
of the two immediately contiguous elements, as by

$$20 \quad \Phi A(I-1) = (\Phi A(I) + \Phi A(I-2)) / 2. \quad \text{Eq. 2.}$$

Accordingly, the data purification routine depicted in
Fig. 2 and above-discussed replaces all error reading
signifying $\Phi A(I)=1$ values with an interpolated estimated
25 value; and purges the data table row 14 $\Phi A(I)$ array of
data of any contiguous equal values. The corrected set of
 $\Phi A(I)$ is shown in the third row 15 of the Fig. 1 data
table. Thus, for example, the oscillation amplitude value
during the cuff pressure step (time interval) "4" is
30 corrected from the error-signalling +1 value to a peak
amplitude 14, representing the average of measurements 4
and 25 at cuff pressures 187 Torr. and 153 Torr. during the
immediately contiguous time intervals 3 and 5. Similarly,
the first (pressure step 6) of two equal measured
35 oscillation amplitude pulses of value 63 during periods 6

and 7, corresponding to occluding cuff pressures of 140 Torr. and 128 Torr., is corrected to a value of 44 representing the average of the contiguous measured amplitudes of 63 and 25 units.

5

The corrected array $\Phi A(I)$ as represented by the third row 15 in Fig. 1 thus comprises value from which each of the systolic, diastolic and mean arterial blood pressures may be determined either in accordance with the improved algorithms below discussed or employing the algorithms of the above referenced patents and patent application. The data purification above discussed provides more accurate measurements than was heretofore the case; and also permits blood pressures to be determined more quickly, obviating the need for repeated deflation steps when unacceptable artifact or noise corrupted data is sensed.

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Attention will now be shifted to the particular method pursuant to which the stored cuff pressure $CP(I)$ and corrected blood pressure peak value $\Phi A(I)$ information in the first and third data rows of Fig. 1 is employed in accordance with other aspects of the present invention to measure a subject's systolic, diastolic and mean arterial blood pressures.

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Pulse complex wave form processing typifying systolic blood pressure determination is illustrated in Fig. 3, and a flow chart for the underlying data processing is set forth in Fig. 4. In overview, systolic pressure is determined by:

30

(a) Finding the amplitude ($\Phi A(MAX)$) of the largest blood pressure oscillatory complex (which occurs at the time interval MAX);

35



(b) Finding an amplitude level (LVL) equal to a predetermined fraction of the peak value $\Phi A(\text{MAX})$. We have found a value of 0.5 to be satisfactory for normal processing with something less (e.g., 0.45) for stat
5 (rapid deflation and/or single pulse) operation;

(c) Examining the corrected oscillation amplitude ($\Phi A(I)$) values (third row 15 in the Fig. 1 data table) starting at the MAX interval and proceeding toward the
10 higher cuff pressure direction (i.e., to the left in Figs. 1 and 3) to find the two contiguous oscillation amplitudes for which

$$\Phi A(L) < \text{MAX} * 0.5 < \Phi A(L+1); \quad \text{Eq. 3.}$$

15

(d) Computing the interpolated cuff pressure (between $\text{CP}(L)$ and $\text{CP}(L+1)$) assuming a linear variance in oscillation amplitude and cuff pressure between the intervals L and L+1. This per se well known linear
20 trapezoidal interpolation is graphically depicted in Fig. 5. The interpolated cuff pressure directly corresponds to the subject's systolic blood pressure (SYS).

Expanding upon the systolic pressure determining methodology set forth above, the cuff pressure interval
25 $I=\text{MAX}$ when the largest oscillation amplitude peak occurs is determined in any per se well known manner, (step 40 of the Fig. 4 flow chart corresponding to the interval MAX in Fig. 3).

30 Thus, for example, the following schematic BASIC sequence will suffice as illustrative to find the interval MAX:

$$\Phi \text{AMAX} = \Phi A(1) \quad \text{Eq. 4.}$$

$$\text{MAX} = 1 \quad \text{Eq. 5.}$$

35 $\text{F)R K} = 2 \text{ TO N} \quad \text{Eq. 6.}$

```
IF  $\Phi A(K) < \Phi A_{MAX}$  GOTO 70      Eq. 7.  
 $\Phi A_{MAX} = \Phi A(K)$                 Eq. 8.  
MAX = K                            Eq. 9.  
70 NEXT K                           Eq. 10.
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5

In brief, Equations 4 and 5 make an initial assumption that the peak value occurred during the first interval and load a provisional peak value storing variable ΦA_{MAX} with the value $\Phi A(1)$. For an assumed N-time interval measurement, the loop between Equations 6 and 10 sequentially examines every element of the $\Phi A(I)$ array from 2 to N, updating ΦA_{MAX} only when the value $\Phi A(K)$ - (K being the loop index) exceeds the previously assumed ΦA_{MAX} value. When the processing exits from the loop following instruction 70 in Equation 10 the variable MAX contains the value of I such that $\Phi A(MAX)$ is the largest value in the array.

10

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The next following step 42 sets a variable LVL equal to the predetermined fraction of the peak amplitude $\Phi A(MAX)$ as by

$$LVL = \Phi A(MAX) * 0.5. \quad \text{Eq. 11.}$$

25

The value LVL is shown by the dashed line 50 in Fig. 3.

30

The next following operation 45 finds the first time interval (L) preceding MAX for which the oscillation amplitude peak is less than LVL, i.e., less than one-half of the peak value $\Phi A(MAX)$, thereby finding the two contiguous values (L, L+1) having peak amplitudes which bound the value in LVL. Algorithms for conducting such a search are well known to those skilled in the art, e.g.,

35

```
FOR J=1 TO MAX                        Eq. 12.
```


IF ($\Phi A(\text{MAX}-J) - \text{LVL}$) < 0 GOTO 140 Eq. 13.
NEXT J Eq. 14.
140 L=MAX-J Eq. 15.

5 Equations 12-15 simply comprise a $D\Phi$ or $F\Phi R$ -NEXT loop progressing from MAX-1 toward L=1, exiting when the first sub-LVL value is obtained. The appropriate interval identification (MAX-J) is stored in the variable location L.

10

Finally, the value of the systolic pressure is estimated by assuming a linear variation in cuff pressure between the values CP(L) and CP(L+1), and a linear variation between the corresponding oscillation amplitude $\Phi A(L)$ and $\Phi A(L+1)$. Thus, in accordance with the per se well known trapezoidal interpolation equation, the systolic pressure SYS may be determined (step 47 of Fig. 4) by

15

$$\text{SYS} = \text{CP}(L) + \frac{(\text{CP})(L+1) - \text{CP}(L)}{\Phi A(L+1) - \Phi A(L)} * ((\text{LVL}) - \Phi A(L))$$

20 Eq. 16.

20

To illustrate employing the data of Fig. 1, 50% of the peak amplitude (70) is 35, and thus the pulse complex measurements of time intervals 5 and 6 are selected for systolic pressure computation. The Eq. 16 software interpolation implementation yields:

25

$$\text{SYS} = 153 + ((140 - 153) * (35 - 25) / (44 - 25));$$

30 =149 Torr. Eq. 17.
Eq. 18.

30

assuming three significant figures.

35

Pulse complex wave form processing characterizing diastolic blood pressure determination is illustrated in Fig. 6; and a flow chart for the underlying diastolic data

processing algorithm is depicted in Fig. 7. In overview, diastolic pressure is determined by:

(a) the amplitude ($\Phi A(\text{MAX})$) of the complex (which occurs at the time interval MAX);

5

(b) Finding an amplitude level (UDLVL) equal to a first predetermined fraction of the peak value $\Phi A(\text{MAX})$. We have found a value of 0.69 to be satisfactory for normal processing and 0.72 for rapid ("stat") processing;

10

(c) Examining the corrected oscillation amplitude ($\Phi A(I)$) buffer 15 (Fig. 1) starting at the MAX interval and proceeding toward the lower cuff pressure direction (i.e., to the right in Figs. 1 and 6) to find the two contiguous oscillation amplitudes for which

15

$$\Phi A(\text{UD}) \leq \text{MAX} * 0.69 \leq \Phi A(\text{UD}-1); \quad \text{Eq. 19.}$$

(d) Finding the interpolated cuff pressure (between $\text{CP}(\text{UD}-1)$ and $\text{CP}(\text{UD})$) assuming a linear variation in oscillation amplitude and cuff pressure between the intervals $\text{UD}-1$ and UD (processing variable DIAU in Fig. 7);

20

(e) Examining the stored $\Phi A(I)$ oscillation amplitude values at pressures starting at the lowest cuff pressure measured for a contiguous pair bounding the peak amplitude $\Phi A(\text{MAX})$ multiplied by a second factor lower than the first factor (e.g., 0.55), i.e., where

25

$$\Phi A(\text{LD}) \leq \text{MAX} * 0.55 \leq \Phi (\text{LD}-1); \quad \text{Eq. 20.}$$

30

(f) Computing the interpolated cuff pressure between $\text{CP}(\text{LD})$ and $\text{CP}(\text{LD}-1)$ corresponding to MAX times the 0.55 factor. This lower interpolated cuff pressure is associated with the variable designation DIAL ; and

35

(g) Determining the subject's diastolic pressure (DIA) as the average of the upper and lower interpolated values DIAU and DIAL, i.e.,

5

$$\text{DIA} = (\text{DIAU} + \text{DIAL}) / 2.$$

Eq. 21.

The above-described procedure is illustrated in the blood pressure complex depiction of Fig. 6 and the Fig. 7 flow chart. The peak $\Phi A(\text{MAX})$ is first located as by the processing of Equations 4-10. The upper and lower peak amplitude fractions DIAU and DIAL are next determined (steps 64 and 65 of Fig. 7 corresponding to the labeled horizontal dash lines in Fig. 6). Step 69 then finds the first time interval (UD) following MAX at which the peak amplitude $\Phi A(\text{UD})$ is lower than the value stored in DIAU (as by processing analogous to that of Equations 12 through 15 replacing "MAX-J" with "MAX+J"). Thereafter, step 72 performs the trapezoidal interpolation analogous to that of Fig. 5, determining the cuff pressure (DIAU) corresponding to the UDLVL complex amplitude value. It is observed that the time interval UD-1 coincides with the interval MAX when the peak complex value occurred since, for the data case illustrated, the first pulse complex following MAX less than $0.69 \times \Phi A(\text{MAX})$ occurred in the next time interval MAX+1.

The functional steps 73 and 74 of Fig. 7 perform in a manner directly analogous to operations 69 and 72, locating the cuff pressure DIAL by interpolation for the intervals when the peak complex amplitudes bound the LDLVL value equal $\Phi A(\text{MAX})$ times 0.55. This latter search is conducted from $\Phi A(i)$ at the lowest cuff pressure, then working toward higher cuff pressures. Finally, the subject's diastolic pressure (DIA) is computed as the

average of the contents stored in DIAU and DIAL (step 82).
To illustrate with a numerical example, again employing
the data portion of Fig. 1,

5 $DIAU=83+((93-83)\times(48-40))/(40-53)\approx 71.$ Eq. 22.

$DIAL=74+(83-74)\times(38-33)/(33-40)=67.$ Eq. 23.

$DIA=(71+67)/2 = 69.$ Eq. 24.

10

Finally, wave form processing illustrating mean arterial
blood pressure measurement is shown in Fig. 8, and in flow
chart form for the corresponding data processing in Fig.
9. In summary, mean arterial pressure is determined by:

15

(a) Finding the amplitude ($\Phi A(MAX)$) of the largest
blood complex (which occurs at the time interval MAX);

20

(b) Examining the cuff pressure values in the corrected
register 15 (Fig. 1) for the interval MN1 yielding the
first oscillation amplitude less than $\Phi A(MAX+1)$, i.e.,
the first cuff pressure to the left of the interval MAX
which was less than the complex peak amplitude $\Phi A(MAX+1)$
occurring in the first interval following the time MAX.

25

This satisfies the relationship

$\Phi A(MN1) \leq \Phi A(MAX+1) \leq \Phi A(MN1+1);$ Eq. 25.

30

(c) An interpolation is then conducted between the
intervals MN1 and MN1+1 for a cuff pressure MAPL
corresponding to the oscillation amplitude value
 $\Phi A(MAX+1)$; and

35

(d) Finally, the mean arterial pressure (MAP) is
determined by a weighting of the cuff pressures CP(MAX+1)

and MAPL, as by

$$\text{MAP} = (\text{CP}(\text{MAX}+1) + (2 * \text{MAPL})) / 2.9 \quad \text{Eq. 26.}$$

5 The denominator (2.9 in Eq. 26) may be somewhat lower for operation in a "stat" mode, e.g., 2.85.

The above-discussed algorithm for determining mean arterial pressure is illustrated in Figs. 8 and 9. Step 101 (Fig. 9) finds the peak interval MAX (for example, by execution comparable to Equations 4-10). A processing variable AMP is set equal to the peak value $\Phi A(\text{MAX}+1)$ of the complex following the interval MAX (step 105) and the interval MN1 is next determined (step 106) as the first occurring complex less than the value AMP (i.e., $\Phi A(\text{MAX}+1)$) to the left of time MAX in Fig. 8 (e.g., by processing comparable to Equations 12-15). An interpolation is then conducted to find the point MAPL (Fig. 8; step 111 in Fig. 9) and the final processing operation 113 finds the subject's mean arterial pressure by implementing Equation 26.

To again illustrate by numerical example from the Fig. 1 data

$$\text{MAPL} = 140 + ((128 - 140) \times (62 - 44)) / (63 - 44) = 129 \quad \text{Eq. 27.}$$

$$\text{MAP} = (104 + 2 * 129) / 2.9 = 124 \quad \text{Eq. 28.}$$

30 The foregoing discussion has thus demonstrated that measured data may be enhanced by replacing data lost through measurement artifacts or the like or deviations from a proper data pattern by approximated values. Specific data processing algorithms were presented and 35 discussed for the computation of a subject's measured

systolic, diastolic and mean arterial blood pressures.

5 The above-described arrangements are merely illustrative
of the principles of the present invention. Numerous
modifications and adaptations thereof will be readily
apparent to those skilled in the art without departing
from the spirit and scope of the present invention. For
10 example, the pressure measurement mode is described above
as stepped deflation from an initial inflation above the
subject's systolic pressure. The measurement of the
instant invention can alternatively be performed by
stepped inflation from an initial sub-diastolic cuff
15 pressure; or via continuous vis-a-vis discrete cuff
inflation or deflation.

20

25

30

35

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. In combination in digital processor controlled automated blood pressure measuring apparatus operative in conjunction with a stored program:

(a) an inflatable cuff;

(b) means for inflating and deflating said cuff;

(c) pressure transducer means coupled to said cuff for signalling the pressure existing in said cuff;

(d) means responsive to the pressure signalled by said transducer for generating a signal representing blood pressure oscillation complexes sensed by said cuff and said transducer coupled thereto;

(e) complex peak storing means for storing values characterizing the peak amplitudes of said sensed oscillation complexes at different cuff pressures;

(f) cuff pressure storing means for storing the cuff pressures existing when said complex peak amplitudes arose; and

(g) mean arterial pressure determining means, said mean arterial pressure determining means comprising

(i) means for locating the maximum complex peak amplitude stored in said complex peak storing means;

(ii) means for locating a successor complex peak amplitude value stored in said complex peak storing means, said successor being the one next occurring after said maximum complex peak amplitude arose;

(iii) means, responsive to the value of said successor complex peak for selecting plural ones of the complex peak amplitudes which were generated at cuff pressures higher than that existing when said maximum complex peak arose; and

(iv) determining means for determining mean arterial pressure from

(1) said selected plural ones of the complex peak amplitudes,

(2) the cuff pressures stored in said cuff pressure storing means corresponding to said selected plural ones, and

(3) the cuff pressure which corresponds to said successor complex peak amplitude.

2. A combination as in claim 1, wherein said determining
5 means comprises means for interpolating plural of the complex peak amplitudes and the cuff pressures corresponding thereto.

3. A combination as in claim 1, wherein said determining
10 means comprises means for computing a weighted average of the cuff pressure stored in said cuff pressure storing means corresponding to said successor complex peak signal and a function of the cuff pressures stored in said cuff pressure storing means corresponding to said selected plural complex
15 peak value.

4. A combination as in claim 1, and further including data purifying means, operative upon the complex peak amplitudes stored in said complex peak storing means, for correcting
20 data inaccuracies prior to operation of said mean arterial pressure determining means.

5. A combination as in claim 4, wherein a preselected character is stored in said complex peak storing means to
25 signal an unsuccessful pulse flow peak measurement, and wherein said data purifying means comprises means for examining the contents of said complex peak storing means and said means for examining being responsive to detecting said preselected character for replacing said character with
30 a function of plural stored complex peak values at least one of which was obtained at a cuff pressure higher than that associated with the preselected character and at least one of which was obtained at a cuff pressure lower than that associated with the preselected character.

35

6. A combination as in claim 4, wherein a preselected character is stored in said complex peak storing means to signal an unsuccessful pulse flow peak measurement, and

wherein said data purifying means comprises means for examining the contents of said complex peak storing means, the means for examining being responsive to detecting said preselected character for replacing said character with a
5 measure of plural stored complex peak values at least one of said stored values having been obtained by the average of the cuff pressures next higher and next lower than that associated with the preselected character.

10 7. A combination as in claim 4, wherein said data purifying means includes means for searching said complex storing means for the occurrence of two equal peak amplitude values arising at successive cuff deflation pressures, and means responsive to said searching means for replacing one
15 of the two stored equal values with a function of two other values stored in said complex peak storing means.

8. A combination as in claim 4, wherein said data purifying means includes means for searching said complex
20 storing means for the occurrence of two equal peak amplitude values arising at successive cuff deflation pressures, and means responsive to said searching means for replacing one of the two stored equal values with the average of the next higher and the next lower values stored in said complex peak
25 storing means.

9. In an automated oscillometric blood pressure monitor employing a pressurized cuff, means for controllably changing pressure to distinct cuff pressure levels in
30 predetermined cuff pressure decrements, and means for measuring arterial pressure oscillation complexes through cuff pressure measurement, a method for measuring mean arterial pressure comprising the steps of:

(a) at each said level, detecting oscillation
35 complexes, measuring and storing the peak thereof, and storing the identification of each associated prevailing cuff pressure level;

(b) finding the amplitude of the largest of said peaks, and recording the prevailing cuff pressure level stored in association therewith;

5 (c) identifying a cuff pressure level having a peak next following and smaller than said largest of said peaks;

(d) identifying, in response to the amplitude of said peak next following, plural peaks which occurred at cuff pressure levels larger than the cuff pressure level of said largest of said peaks;

10 (e) interpolating the amplitude of said identified plural peaks; and

(f) developing mean arterial pressure as a predetermined weighted average of the cuff pressure corresponding to said interpolated amplitude and the cuff pressures corresponding to at least one of said largest and
15 said next following peaks.

10. A method as described in claim 9 and further including the steps, prior to said finding step, of comparing said
20 stored peaks with predetermined standards, and of substituting corrected peak data for those peaks which depart from said standards.

25 DATED this 7th day of September 1990

CRITIKON, INC.

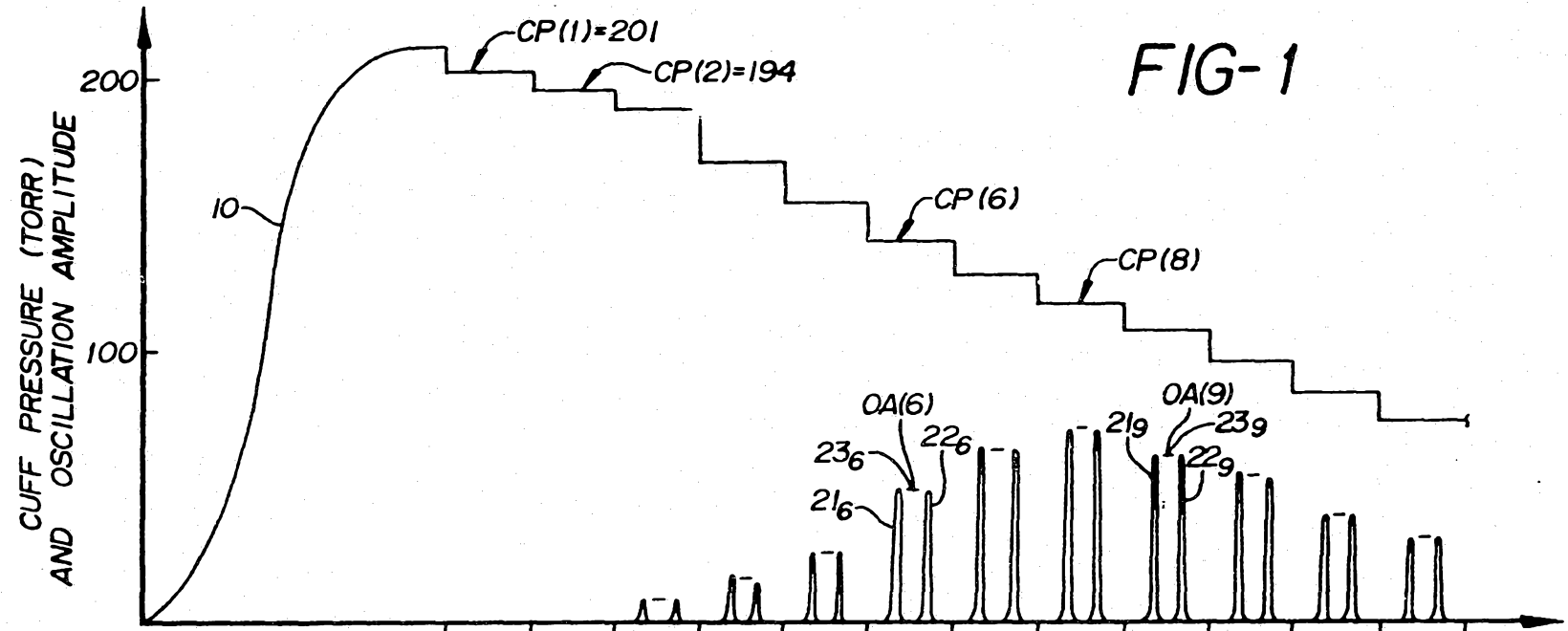
By their Patent Attorneys

30 GRIFFITH HACK & CO.

35

1 0 0 0 0 1

FIG-1



CUFF PRESS. CP(I)-12	201	194	187	168	153	140	128	116	104	93	83	74
MEAS. OSC. AMP. OA(I)-14	0	0	4	1	25	63	63	70	62	53	40	33
CORRECTED OA(I)-15	0	0	4	14	25	44	63	70	62	53	40	33
CUFF PRESS. STEP-18	1	2	3	4	5	6	7	8	9	10	11	12

ARTIFACT REPEATED
OA VALUES

30 881/89

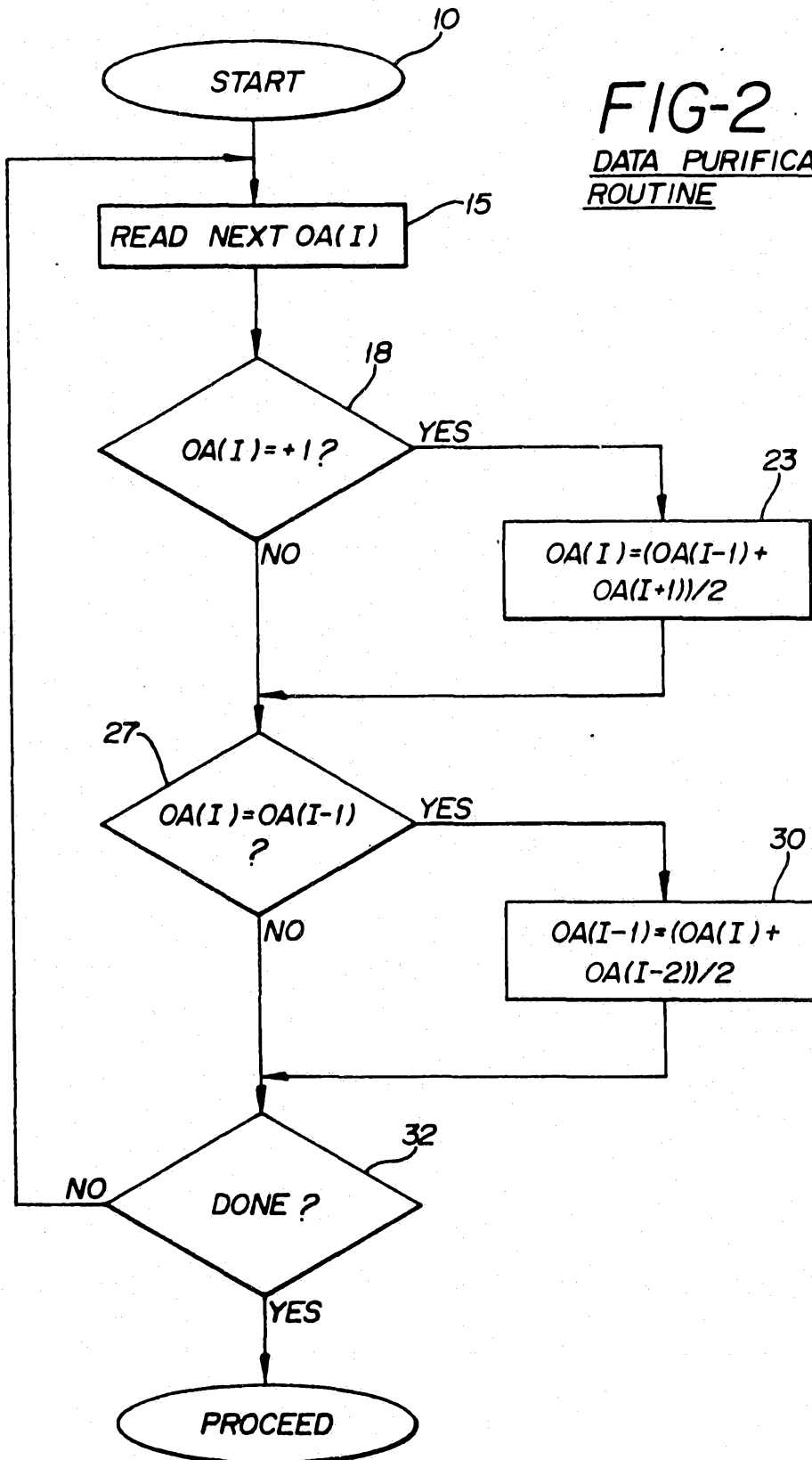


FIG-2
DATA PURIFICATION
ROUTINE

30881/89

FIG-3

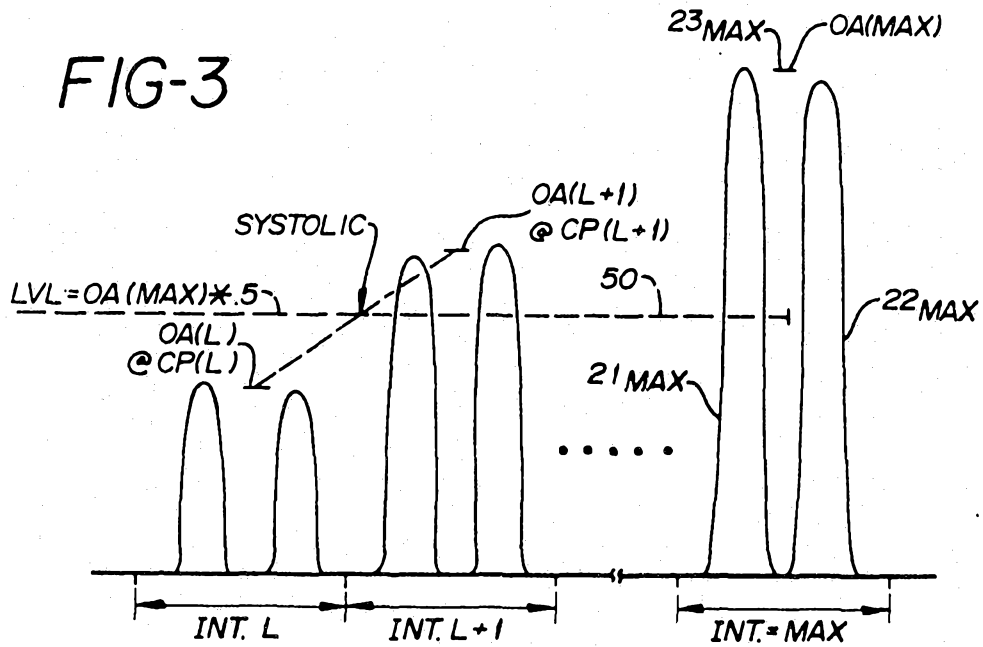


FIG-5

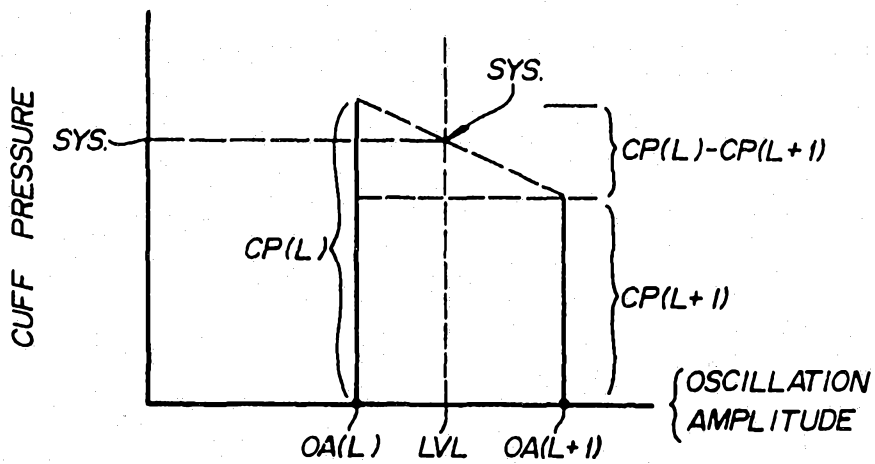


FIG-4

SYSTOLIC DETERMINATION

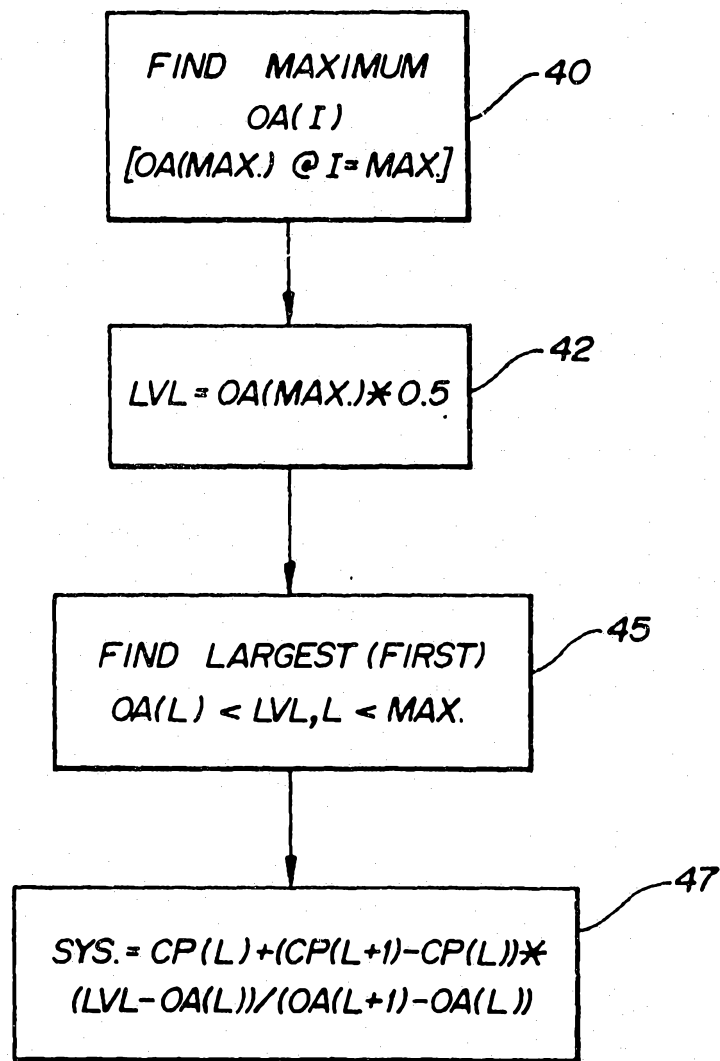
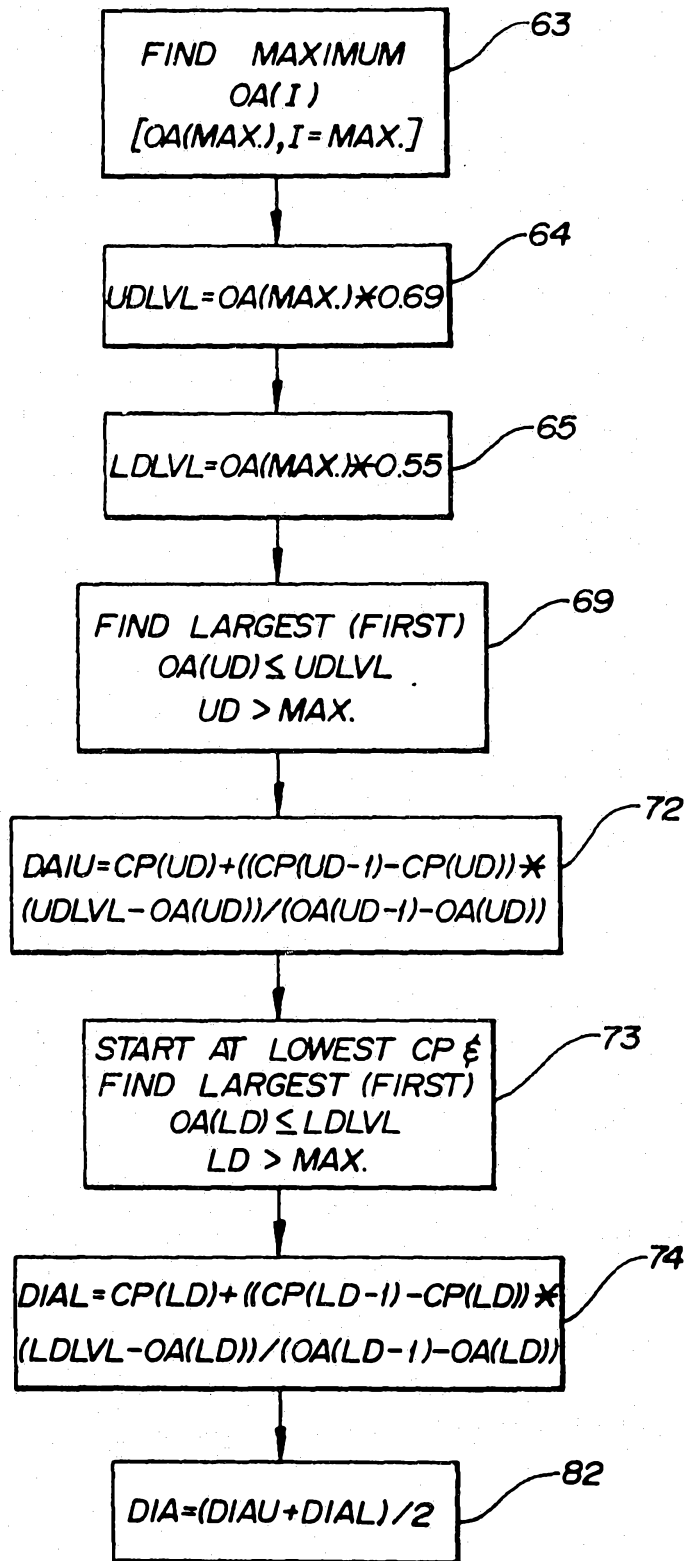


FIG-7 DIASTOLIC DETERMINATION



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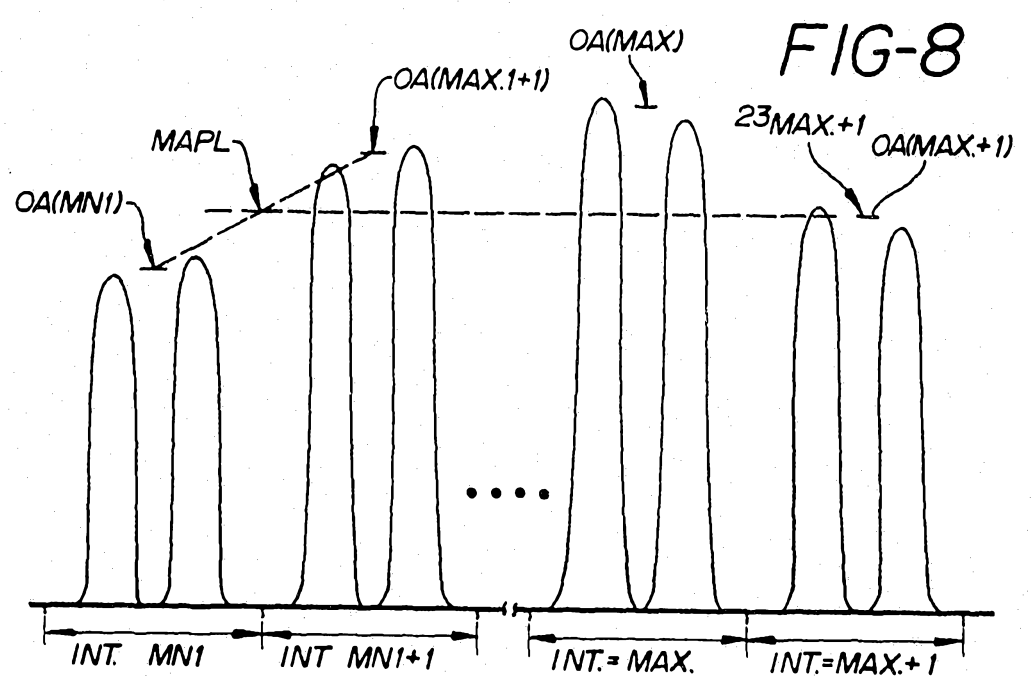
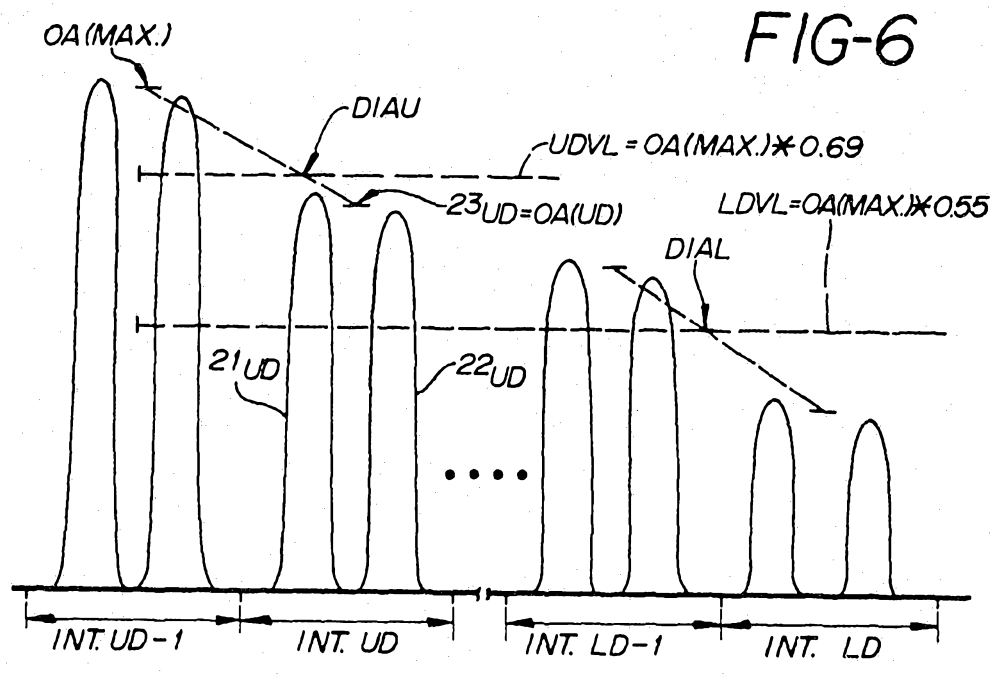


FIG-9

