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(54) **METHOD AND APPARATUS FOR HYPERTENSION CLASSIFICATION**

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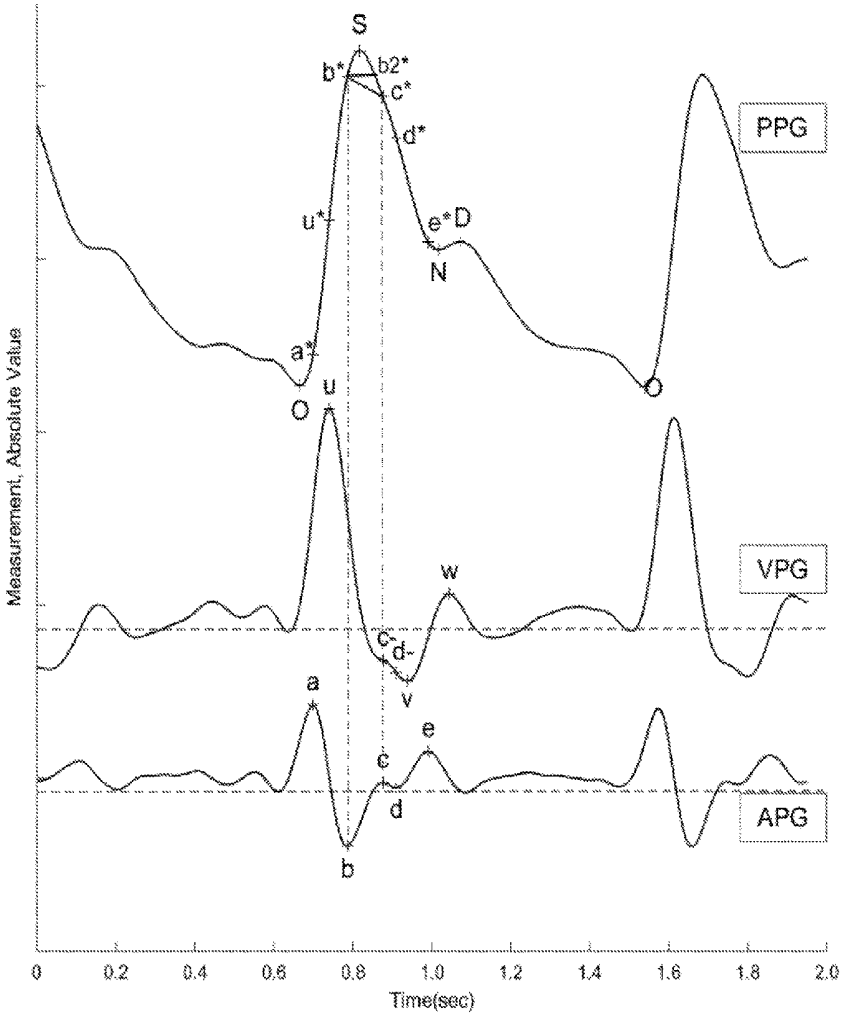
(57) **ABSTRACT**

This patent provides a system for screening and management of hypertension, which includes the following characteristics: High precision fingertip photoplethysmography (PPG) acquisition device and the application software of hypertension screening and management in a smartphone. The former includes 905 nm wavelength infrared light emitting sensor, photoelectric receiving sensor, and Bluetooth transmission module. The latter includes PPG signal configuration and acquisition module, automatic hypertension classification and screening module and hypertension management module. The system can process the real-time PPG signal and can classify and evaluate the blood pressure level, and carry on the long-term management and the hypertension health instruction.



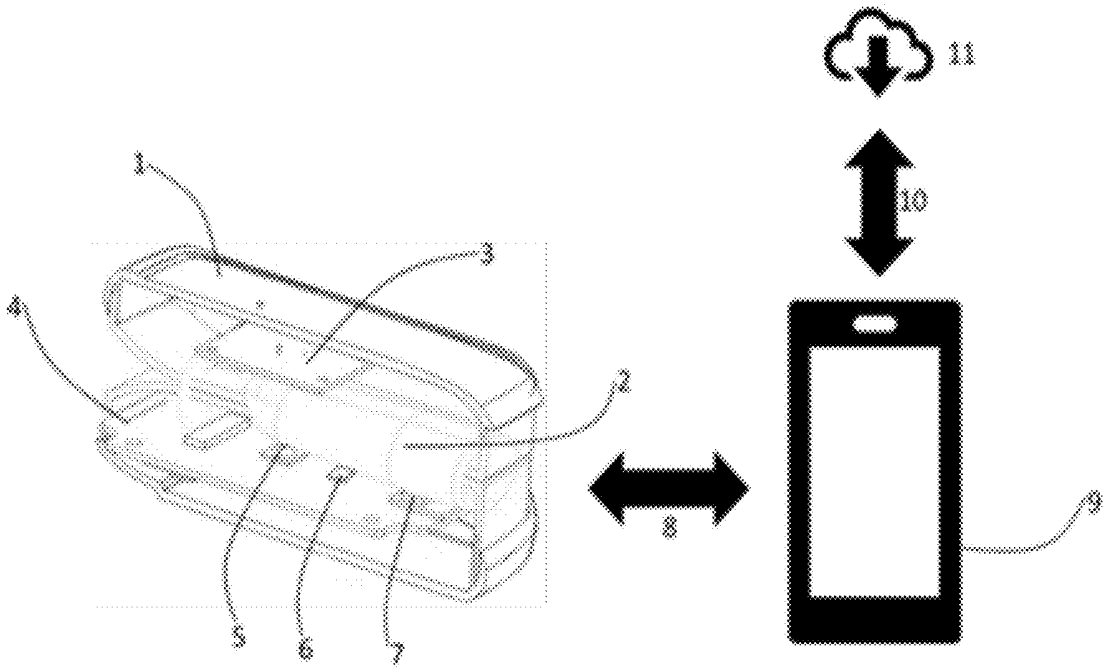


FIG. 1

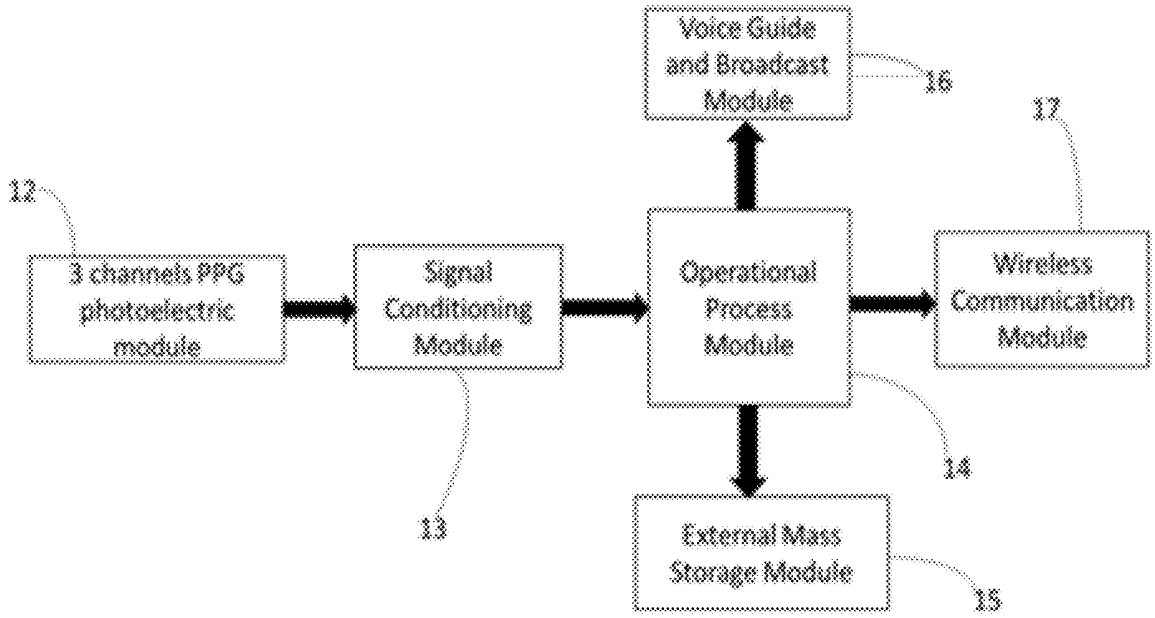

Voice Guide and Broadcast Module
16
17
12
3 channels PPG photoelectric module
Signal Conditioning Module
Operational Process Module
Wireless Communication Module
13
14
External Mass Storage Module
15

FIG. 2

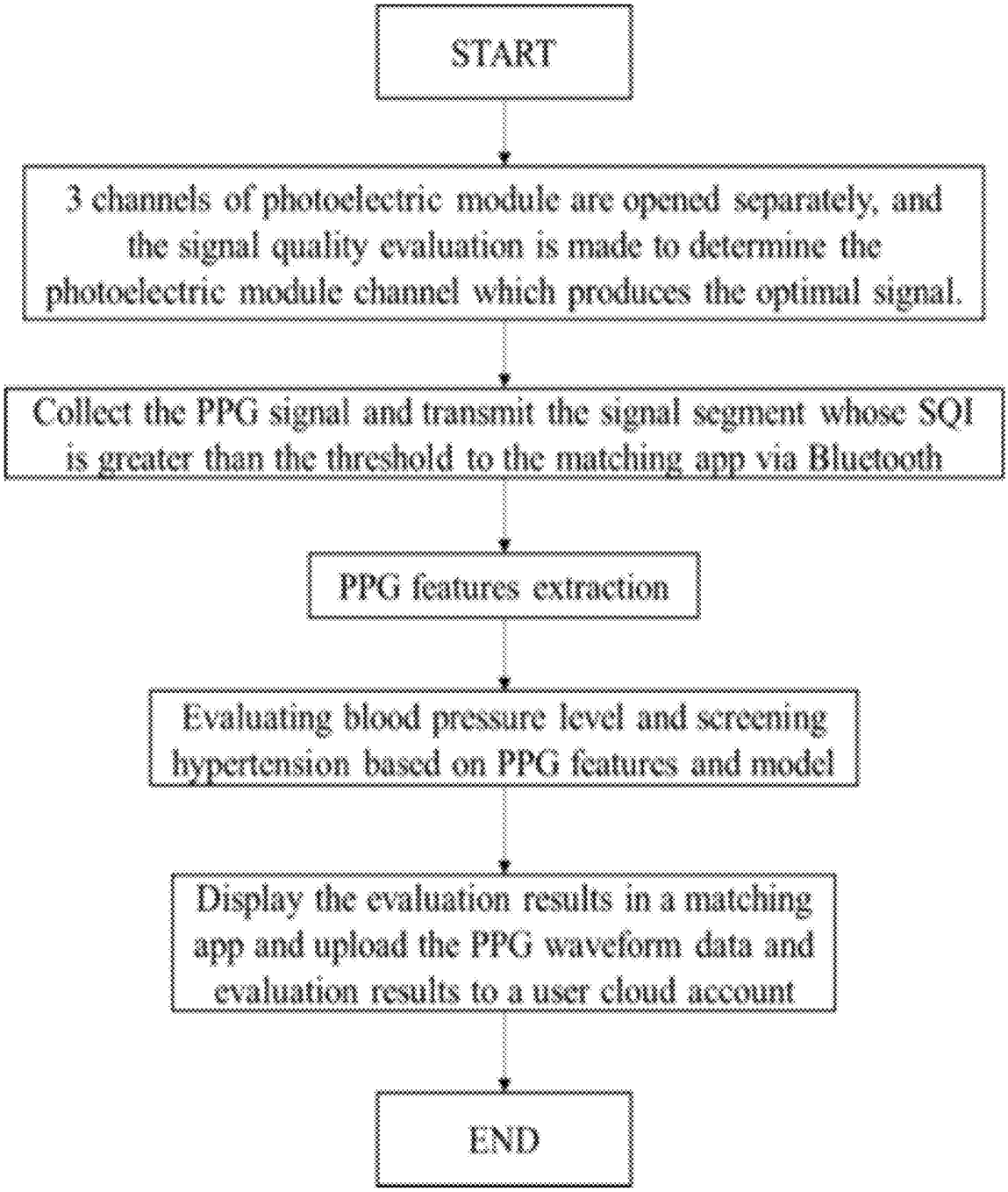

START
3 channels of photoelectric module are opened separately, and the signal quality evaluation is made to determine the photoelectric module channel which produces the optimal signal.
Collect the PPG signal and transmit the signal segment whose SQI is greater than the threshold to the matching app via Bluetooth
PPG features extraction
Evaluating blood pressure level and screening hypertension based on PPG features and model
Display the evaluation results in a matching app and upload the PPG waveform data and evaluation results to a user cloud account
END

FIG. 3

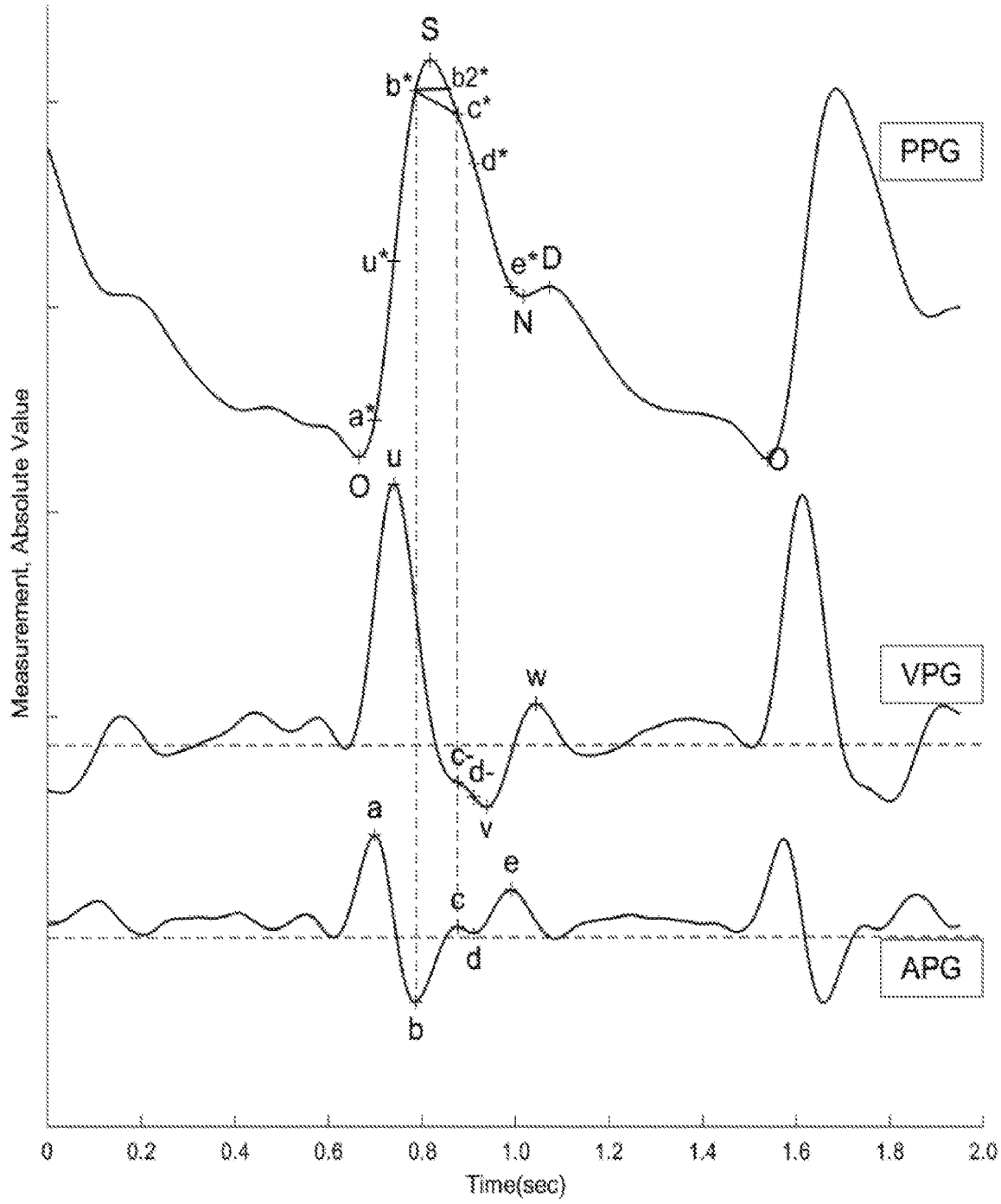

S
b*
b2*
c*
d*
u*
e*
D
N
a*
O
u
O
PPG
VPG
w
c
d
v
a
e
c
d
b
APG
Measurement, Absolute Value
0
0.2
0.4
0.6
0.8
1.0
1.2
1.4
1.6
1.8
2.0
Time(sec)

FIG. 4

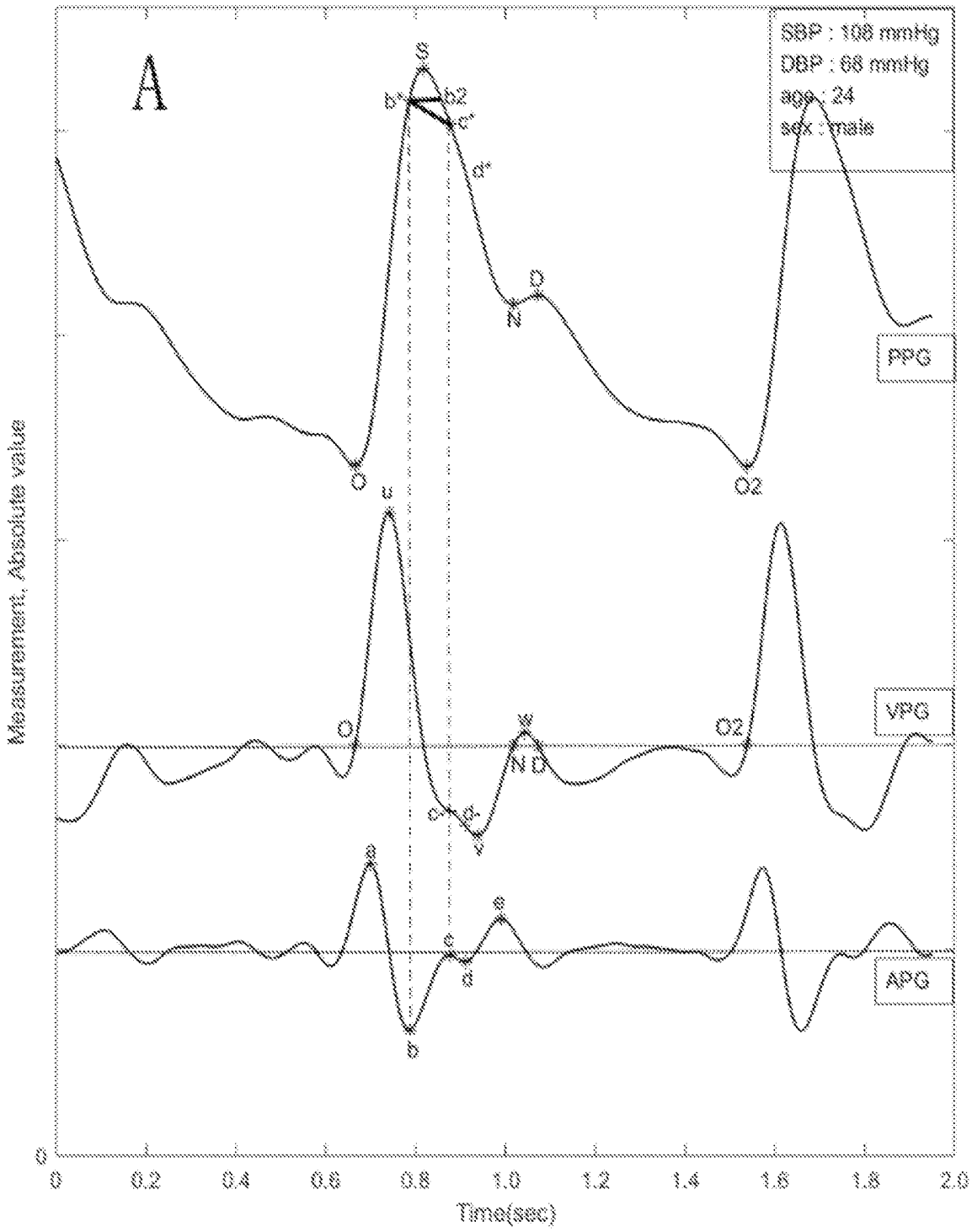

A
SBP : 108 mmHg
DBP : 68 mmHg
age : 24
sex : male
PPG
VPG
APG
Measurement, Absolute value
Time(sec)
0
0.2
0.4
0.6
0.8
1.0
1.2
1.4
1.6
1.8
2.0

FIG. 5A

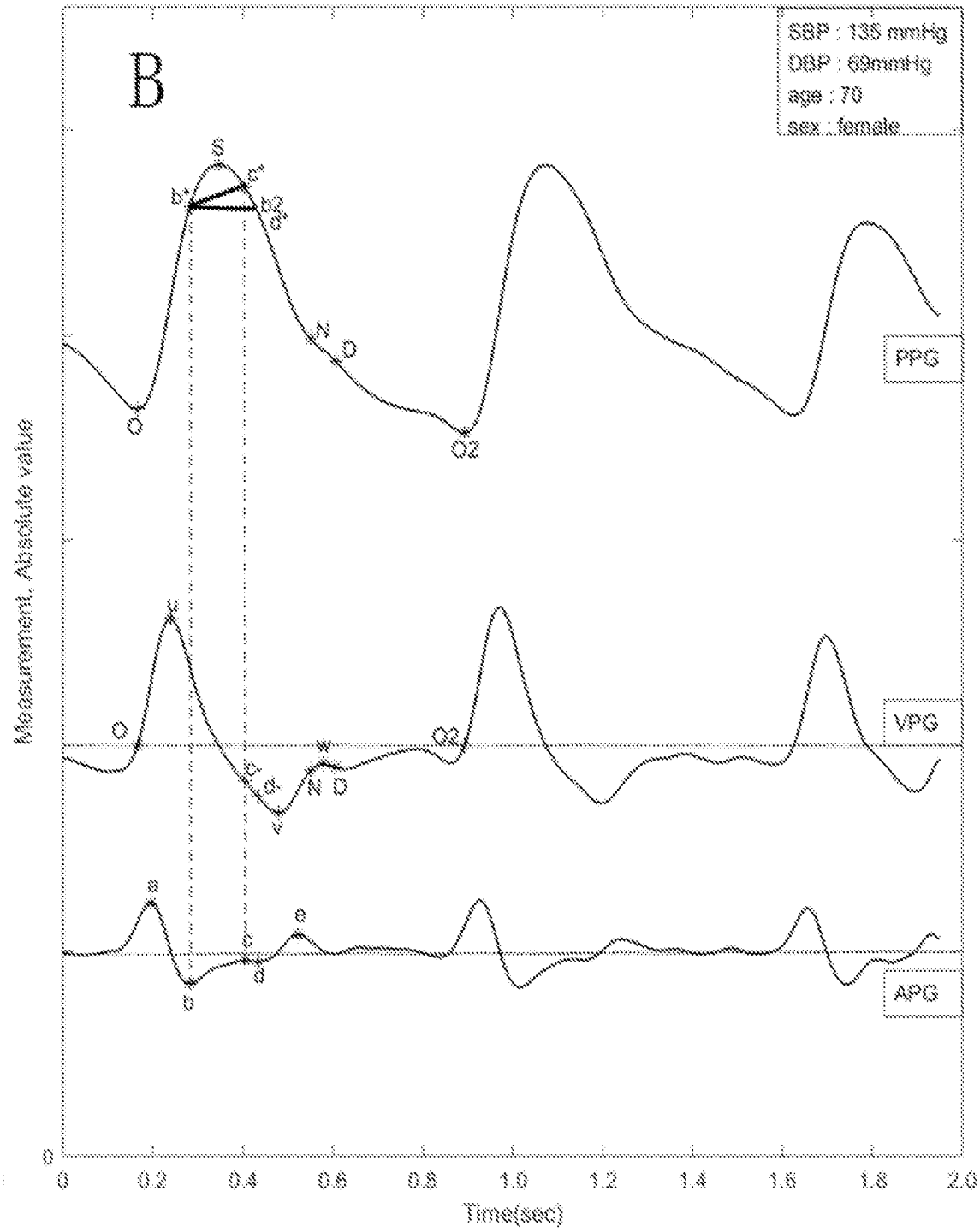

B
SBP : 135 mmHg
DBP : 69mmHg
age : 70
sex : female
PPG
VPG
APG
Measurement, Absolute value
Time(sec)
0
0.2
0.4
0.6
0.8
1.0
1.2
1.4
1.6
1.8
2.0

FIG. 5B

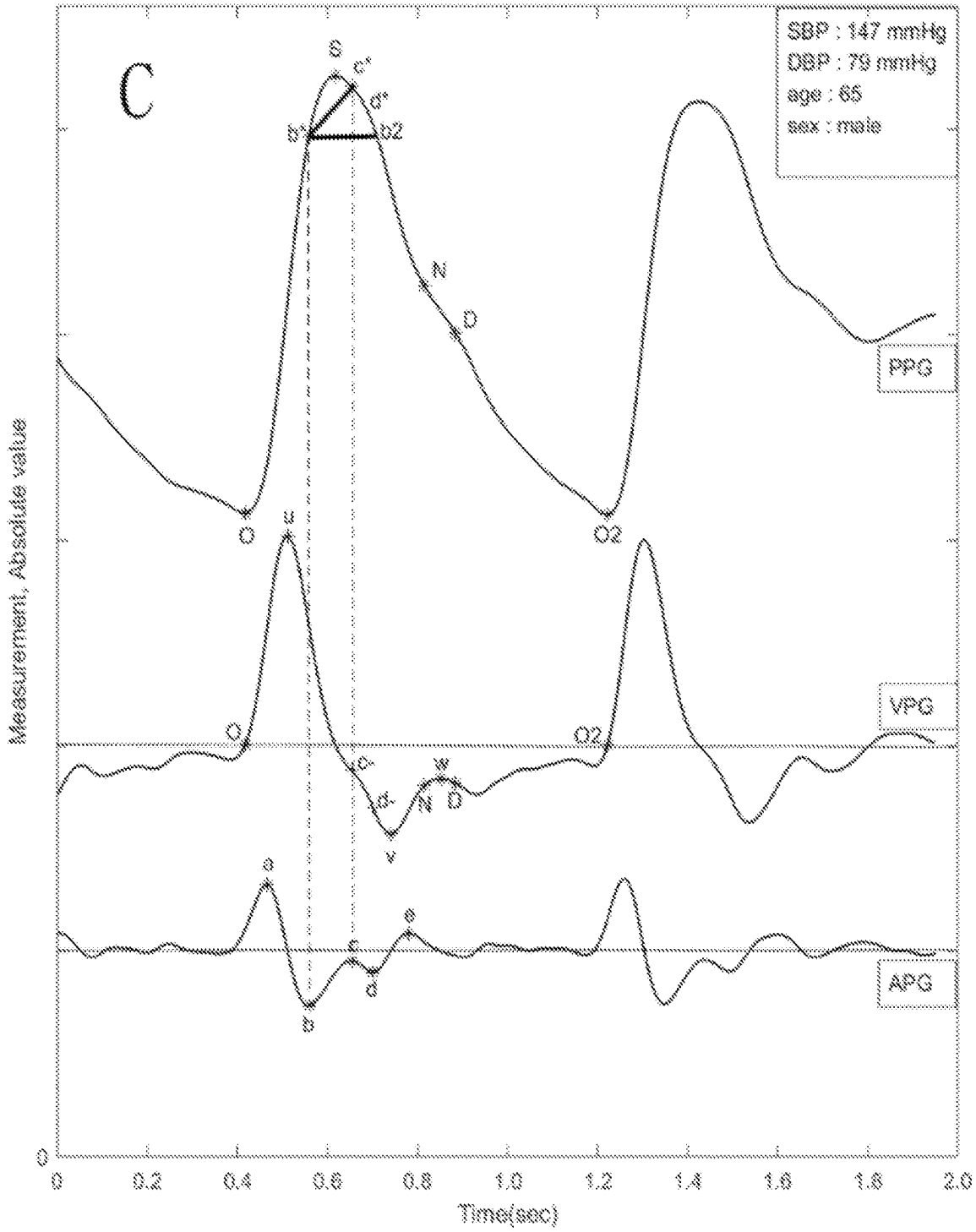

C
SBP : 147 mmHg
DBP : 79 mmHg
age : 65
sex : male
PPG
VPG
APG
Measurement, Absolute value
Time(sec)
0
0.2
0.4
0.6
0.8
1.0
1.2
1.4
1.6
1.8
2.0

FIG. 5C

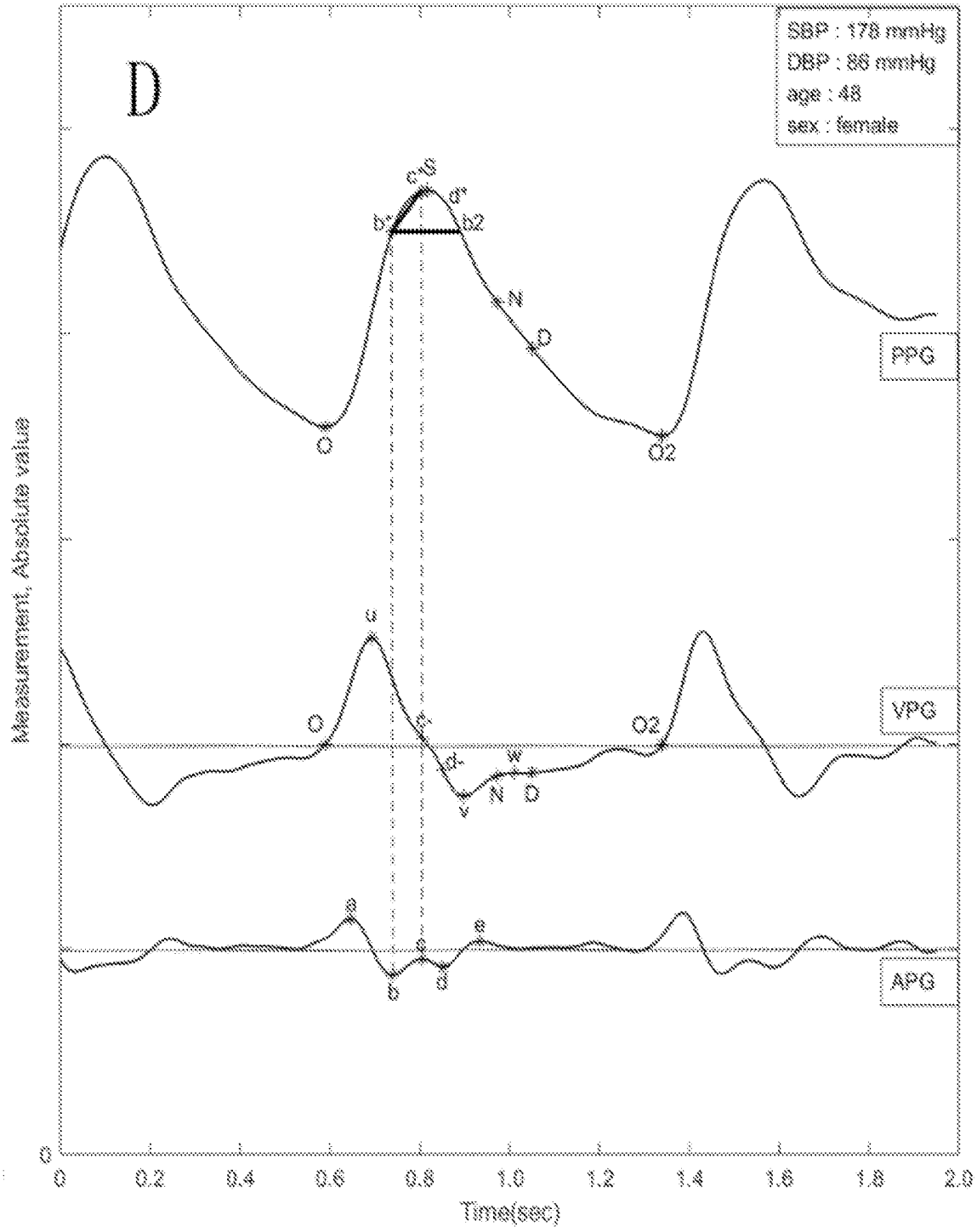

D
SBP : 178 mmHg
DBP : 86 mmHg
age : 48
sex : female
PPG
VPG
APG
Measurement, Absolute value
Time(sec)
0
0.2
0.4
0.6
0.8
1.0
1.2
1.4
1.6
1.8
2.0

FIG. 5D

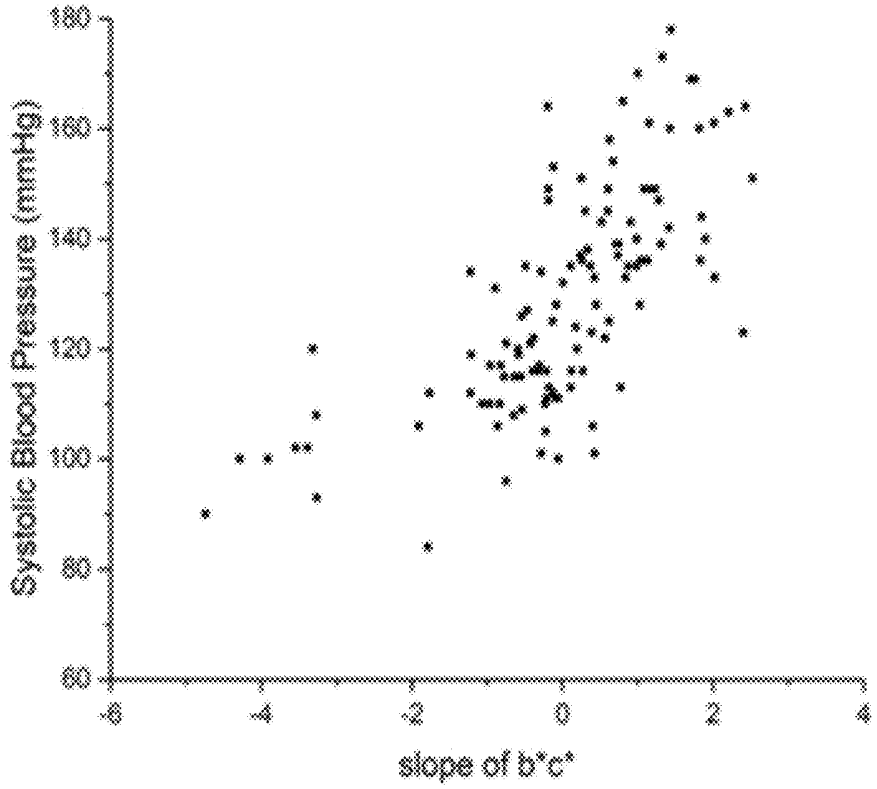

Systolic Blood Pressure (mmHg)
180
160
140
120
100
80
60
-6
-4
-2
0
2
4
slope of b*c*

Fig.6.A

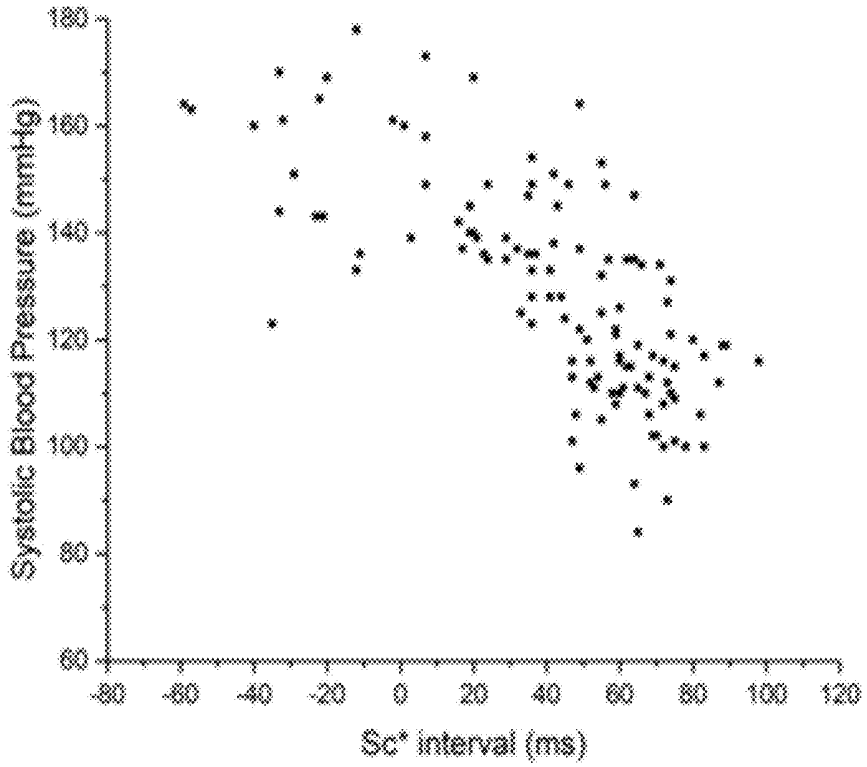

Systolic Blood Pressure (mmHg)
180
160
140
120
100
80
60
-80
-60
-40
-20
0
20
40
60
80
100
120
Sc° interval (ms)

Fig. 6.B

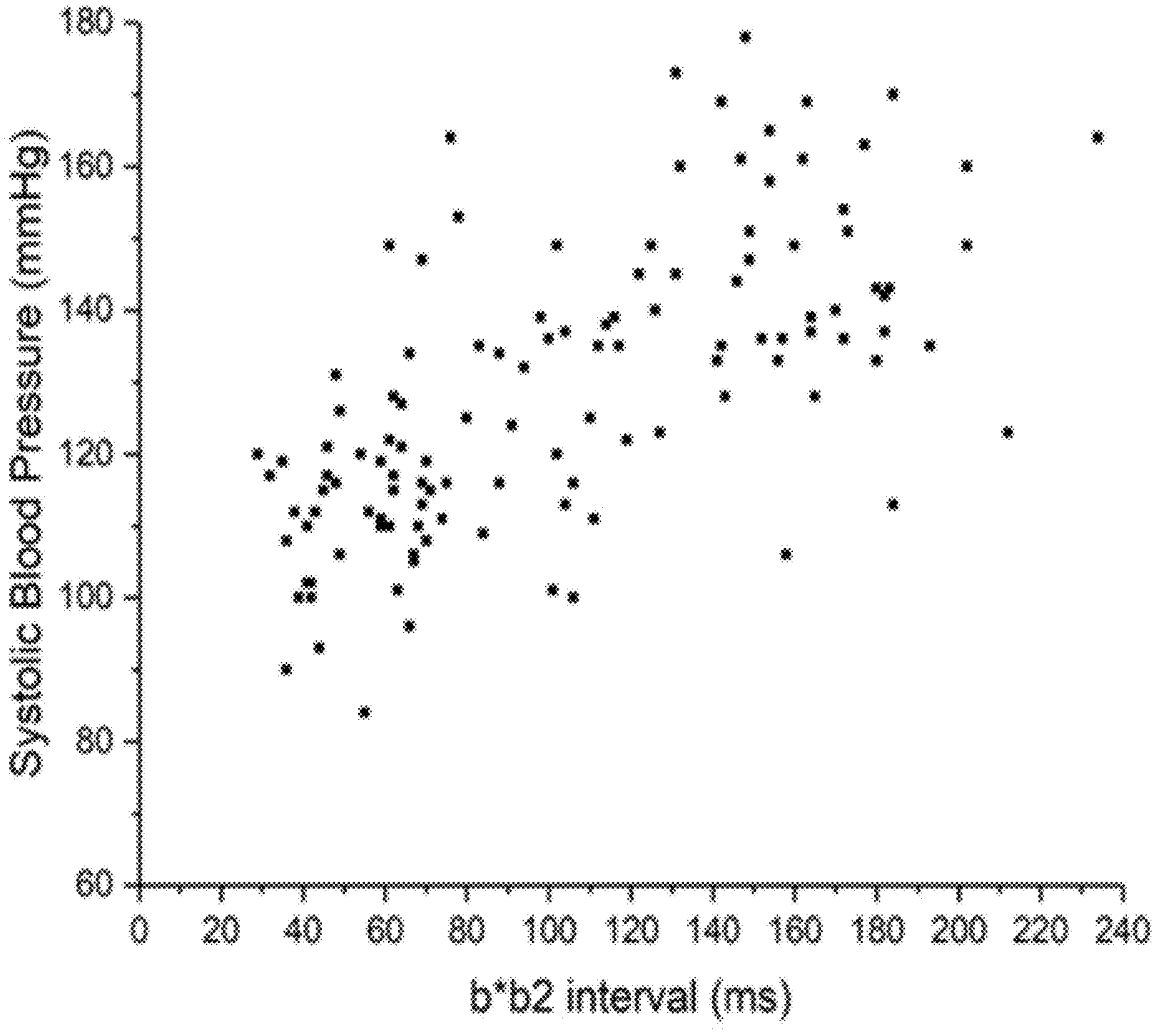

Systolic Blood Pressure (mmHg)
180
160
140
120
100
80
60
0
20
40
60
80
100
120
140
160
180
200
220
240
b*b2 interval (ms)

FIG. 6C

Table 1 Classification result of Normal group and Hypertension group

	F1 score
Normal vs Prehypertension	0.72
Normal vs Stage 1 Hypertension	0.8421
Normal vs Stage 2 Hypertension	0.9286
Normal vs Hypertension	0.8955
Normal + Prehypertension vs Hypertension	0.6984

METHOD AND APPARATUS FOR HYPERTENSION CLASSIFICATION

BACKGROUND

Field of the Invention

[0001] The invention relates to a medical and health equipment and method for screening and management of hypertension, which can be used for the screening and evaluation of hypertension for individuals or family and for the management and guidance of different stage hypertension.

Description of the Related Art

[0002] As an important physiological index of the cardiovascular system, blood pressure (BP) plays an important role in predicting the occurrence of acute and chronic CVDs. Therefore, the early screening and evaluation of patients with hypertension (HT) or prehypertension are of great practical significance. At present, the blood pressure measurement uses the cuff mercury or electronic sphygmomanometer, this measurement method has been widely recognized and popularized after hundred years of development, and it has played a major role in the control of CVDs. However, both the Korotkoff Sound method and the Oscillometric method need to use cuff and pressure to the forearm when the blood pressure is measured, and the measurement is very easy to be affected by the operation and use conditions, such as the operation of the cuff, sitting posture, exercise and so on. In addition, it also has a certain white coat phenomenon for some patients. Therefore, in current severe CVDs prevention and control situation, its role has been greatly limited, the cuff-less hypertension screening technology and blood pressure detection technology in the new situation of cardiovascular health management is forming an urgent need. At present, with the increasing demand for personal health equipment, more and more health information measuring or evaluating equipment and systems are being researched and developed.

[0003] Photoplethysmography (PPG) contains very abundant physiological information about the operation of the cardiovascular circulation system, and it has the characteristics of low-cost and convenient signal acquisition, therefore, it is widely concerned by researchers, and a series of investigations and research are carried out in-depth. PPG signal is extracted by the use of an LED transmit section to generate the red or infrared light to illuminate the skin of fingertip or earlobe or forehead and a photosensitive diode to measure the time-varying light absorption by the tissue which can reflect the changes in the blood volume and the common PPG acquisition methods are divided into transmission and reflection. Therefore, it is the external manifestation and aggregated expression of many physiological processes in the cardiovascular circulation system. The PPG signal is a high fusion signal which covers the activity of heart's systolic and diastolic period, hemodynamic, hemorheology and network information of human peripheral microcirculation system.

[0004] The invention is based on PPG morphological theory, quantitatively analyses the characteristic of PPG, establishes the intrinsic relation between PPG characteristic and cardiovascular cycle physiology process, and realizes the accurate classification and early screening of hypertension.

SUMMARY

[0005] The technical problem to be solved by the invention is to provide a non-invasive convenient, accurate and reliable evaluation and screening methods of hypertension and its measuring instruments, the method requires less input signal, the relationship between input signal and blood pressure level is stable, the measuring instrument also has the characteristics of small size, simple operation, inexpensive price, suitable for personal and family use. In order to solve the technical problem, the specific technical plan of the invention is as follows.

[0006] A method for real-time evaluation and screening of hypertension using fingertip photoplethysmograph (PPG) signal, including the following steps:

[0007] a. Obtain the original infrared PPG signal of the subject;

[0008] b. Obtain the high-quality PPG signal after the signal conditioning and the signal quality evaluation;

[0009] c. Obtain velocity of plethysmograph (VPG), acceleration of plethysmograph (APG), third derivative waveform (3^{rd} Derivative) and fourth derivative waveform (4^{th} Derivative) through four times differential process using the processed PPG signal;

[0010] d. Based on the PPG signal and its derivative waves, the waveform characteristics are defined and extracted, which can include time interval, amplitude, area, ratio, slope, energy parameter and so on. The physiological significance of PPG features is analyzed and the top 3 optimal features are selected;

[0011] e. Based on the above selected feature, the classification model of hypertension was established, and the evaluation and screening of hypertension based on the morphological characteristics of the PPG signal were realized.

[0012] After signal processing and signal quality evaluation, the raw PPG signal obtained by the acquisition probe (**1**) will be transferred to the app application software in the smartphone through the wireless transmission module, wherein, the acquisition probe set up 3 pairs of infrared transmission photoelectric module distributed in the front, middle, root of the acquisition probe.

[0013] Firstly, the signal quality of PPG waveform acquired from different photoelectric modules is compared and the photoelectric module which produces the optimal signal quality is selected as the working module of subsequent signal acquisition. The setting of three photoelectric modules is mainly used to solve the poor PPG signal caused by the different peripheral circulatory system condition which is different because of gender, age, blood perfusion and other factors.

[0014] The application software can display the received PPG signal in real time. The PPG signal is processed as 0.5 hz-8 hz bandpass filtering and then its derivative waveforms are acquired as the forward difference process. The PPG, VPG, APG, 3^{rd} Derivative and 4^{th} Derivative waves are used to obtain the PPG features.

[0015] Based on these features, the cubic SVM blood pressure classification model is established, and the evaluation of blood pressure level and the screening of hyperten-

sion are realized, and the results of blood pressure level can be displayed in real-time in the application software.

[0016] PPG signal data, its features, and evaluation of blood pressure level can be stored in the user-specific cloud space, for long-term blood pressure level management and health guidance.

[0017] An instrument to realize the real-time evaluation and screening of hypertension, including PPG acquisition probe (**1**), matching app application software in smartphone (**9**), cloud storage space (**11**);

[0018] The PPG acquisition probe (**1**) includes a sequential connection 3 channel PPG photoelectric module (**12**), a signal conditioning module (**13**), an operational processing module (**14**), an external mass storage module (**15**), a voice guide and broadcast module (**16**), a wireless communication module (**17**).

[0019] The 3 channel PPG photoelectric module (**12**) comprises an infrared photoelectric emitting and receiving module located in the front (**7**), middle (**6**) and root (**5**) section of the probe, wherein, 3 sections are spaced 10 mm respectively.

[0020] The output of the operation module (**14**) is connected to an external mass storage module (**15**), a voice guide and broadcast module (**16**), a wireless communication module (**17**) respectively.

[0021] The signal conditioning module (**13**) comprises a two-stage amplifying circuit, a bandpass filter circuit and a baseline drift suppression circuit, which is used to amplify, filter and signal conditioning the faint PPG signal, and its output connects the operation module (**14**).

[0022] The operation module (**14**) includes the functions of PPG acquisition, 3 channel photoelectric module function evaluation and selection, data compression and transmission, etc.

[0023] The external mass Storage module (**15**) includes the data of the operation result, the photoelectric working mode and other information storage.

[0024] The wireless communication module (**17**) includes receiving commands and sending data to achieve information interaction with the application software in the smartphone.

[0025] Compared with the existing technology, the instrument is portable and convenient for the family and community health care use and provides important reference physiological information for the early prevention of hypertension. At the same time, the instrument is easy to operate and only needs to hold the fingertip to collect PPG signal in order to realize the evaluation of blood pressure level and classification of hypertension. In addition, it reduces the pain and the psychological burden of diagnosis and detection.

BRIEF DESCRIPTION OF THE DRAWING

[0026] The disclosure may be more completely understood in consideration of the detailed description of various embodiments of the disclosure that follows in connection with the accompanying drawings, in which:

[0027] FIG. **1** depicts a diagram of hypertension evaluation system that can capture photoplethysmograph (PPG) signal and conducts the hypertension evaluation, consistent with embodiments of the present disclosure;

[0028] FIG. **2** depicts a function module diagram of hardware device that can capture PPG signal and transit the PPG data to the matching app in the mobile phone, consistent with embodiments of the present disclosure;

[0029] FIG. **3** illustrates a flowchart of PPG signal processing and hypertension evaluation that are conducted in the hardware device and matching app.

[0030] FIG. **4** depicts the definition of the PPG waveform, its derivatives and the PPG features.

[0031] FIG. **5** shows the different waveform and feature in normal (FIG. **5**.A), prehypertension (FIG. **5**.B), stage **1** hypertension (FIG. **5**.C) and stage **2** hypertension (FIG. **5**.D).

[0032] FIG. **6** shows the scatter between systolic blood pressure and PPG feature (**6**.A slope of b*c* vs SBP, **6**.B Sc* interval vs SBP, **6**.C b*b2 interval vs SBP).

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0033] The system and method of hypertension screening and classification disclosed in the invention can be used to evaluate blood pressure level and to screen for hypertension, it can also be used to evaluate vascular health, such as vascular aging, arteriosclerosis, and vascular compliance, and the following illustration illustrates the specific realization of the measurement method. FIG. **1** is the overall block diagram of the instrument.

[0034] The apparatus of the invention comprises a PPG photoelectric module (**12**), signal conditioning module (**13**), operation module (**14**), external mass storage module (**15**), wireless communication module (**17**), voice guidance and broadcast module (**18**), the real-time waveform display module in the matching app application software of smartphone (**9**), PPG acquisition probe function configuration module, hypertension classification and screening module, hypertension management and health guidance module and cloud platform storage module (**11**).

[0035] Among them, PPG photoelectric module (**12**), signal conditioning module (**13**) and operation module (**14**) are the sequential connection to complete the PPG signal acquisition. Operation Module (**14**) includes sequential execution of PPG signal acquisition, 3 channel photoelectric module function evaluation and selection, data compression and transmission. The output of the operation module (**14**) respectively connects the external mass storage module (**15**), the wireless communication module (**17**), the voice guidance and broadcast module (**16**), which realizes the storage, communication and voice guide function of PPG signal and partial result respectively.

[0036] When the instrument is working, it follows these steps:

[0037] 1. Because the human finger will have different traits due to sex, age, blood overall volume, skin roughness and other factors, the device is designed as 3 infrared photoelectric transmission and receiving pathway in the front (**7**), middle (**6**) and root (**5**) of the probe groove. When the infrared light emitted by the IR tube (**3**) shines on the human finger, the blood of the human finger blood can absorb part of infrared light, and the effect of the heart periodic beat makes the light absorption process periodic, this periodic change process is converted by the photoelectric receiving tube into the electrical signal to form the original faint PPG signal. In addition, the instrument conducts the PPG signal quality evaluation under the 3 different photoelectric modules at first. And the photoelectric module

that it acquires the best signal quality is selected as a working photoelectric module, and then the other two photoelectric modules are closed.

[0038] 2. The PPG signal obtained by the photoelectric module is very weak and is accompanied with a lot of interference signals, which must be amplified, filtered and disturbed. The raw PPG signal is amplified by an amplification circuit and then passed through 0.5 hz-12 hz bandpass filter to obtain a smooth and effective PPG signal. For the processed PPG signal, the digital conversion of the signal is carried out through the A/D converter inside the operation module, and the data is encoded and compressed through the Microprogrammed Control Unit (MCU). The compressed data (**8**) is sent to the smartphone (**9**) through the wireless transmission module (**17**). In the process, partial configuration information and temporary calculation results are stored in the external mass storage module (**15**).

[0039] 3. The real-time PPG signal data received by the smartphone, after further denoising and optimized processing, is carried on the multiple forward difference operation to obtains VPG, APG, 3^{rd} Derivative and 4^{th} Derivative wave. A lot PPG features are defined and extracted based on the PPG and its derivative waveforms. And the top 3 optimal features which are slope of b*c*, Sc* interval and b*b2 interval are selected. The cubic SVM model is established and used to classify and screen hypertension using these features. The result is shown in the display window of the application software (**9**) and uploaded to the user-specific cloud storage space (**11**).

[0040] 4. The hypertension classification and screening module is the core module of the whole system, responsible for including data analysis and model establishment, the results of storage and real-time display control, and more importantly, PPG characteristic waves recognition and features extraction, data classification model implementation, the operation process mainly includes the following steps:

[0041] (a) After filtering and the differential process of PPG signal, the smooth PPG and VPG, APG, 3rd Derivative, 4th Derivative waveforms are obtained.

[0042] (b) The features defined based on the PPG and its derivative waves include time span, amplitude, area, ratio, slope and so on. These features show different states according to different blood pressure levels and have a good quantitative expression of blood pressure, and they are related to the formation process of systolic pressure in arterial blood pressure.

[0043] (c) The systolic blood pressure (SBP) of the human arterial pressure is the maximum value formed the in the middle of the systolic period under the action of the propulsion and reflection fusion of the blood from the heart. Therefore, the propulsion and reflection fusion process of the blood in the arteries during the systolic period plays an important role in the formation of SBP. PPG signal reflects the physical changes of blood volume in the blood vessel during cardiac activity and blood transmission, and it is the direct show of blood volume state. The VPG signal reflects the blood volume change extent in the peripheral blood vessels, and it is the manifestation of the blood change. The APG signal reflects the ability of the speed change for the blood volume, and this ability largely reflects the systolic and diastolic ability of the heart. The features of strong correlation with systolic pressure and greater contribution weight are with BP label concentrated in the position of systolic wave and reflection wave, specifically in the interval between b wave and c wave. We find that some features reflect the details of the fusion process of the main propulsion wave and the reflected wave such as slope of b*c*, Sc* interval, and b*b2 interval. FIG. **5** shows four subjects' PPG and their derivatives, and the four subjects have different blood pressure levels and represent normal, prehypertension, stage 1 hypertension and stage 2 hypertension respectively. In these figures we find that systolic peak and tidal wave have different fusion in different blood pressure stage. This different fusion has generality and some features in this period (b*--c* period) have strong correlation with SBP.

[0044] (d) The features have a good expression for the condition of main propulsion wave and reflected wave. FIG. **6**.A, FIG. **6**.B and FIG. **6.0** show the scatter figures between SBP and slope $b_{-2}c_{-2}$, Sc* interval and b*b2 interval respectively and the spearman correlation coefficients are 0.73, 0.71, 0.66 respectively.

[0045] (e) The hypertension classification model is established based on the Cubic SVM. The F1 score of the model is shown in Table 1.

What is claimed is:

1. A method for real-time evaluation and screening of hypertension of a subject using a fingertip photoplethysmograph (PPG) signal, comprising the steps of:

a) obtaining an original infrared PPG signal of the subject;

b) obtaining a high-quality PPG signal after a signal conditioning and a signal quality evaluation;

c) obtaining a velocity of plethysmograph (VPG), acceleration of plethysmograph (APG), third derivative waveform (3^{rd} Derivative) and fourth derivative waveform (4^{th} Derivative) through a four times differential process using the processed PPG signal;

d) based on the PPG signal and its derivative waveforms, defining and extracting waveforms, comprising at least a time interval, an amplitude, an area, a ratio, a slope, and an energy parameter;

e) analyzing the physiological significance of PPG features;

f) selecting the top three optimal features; and

g) based on the selected features, establishing a classification model of hypertension,

whereby the evaluation and screening of hypertension based on the morphological characteristics of the PPG signal are realized.

* * * * *

专利名称(译)	高血压分类的方法和装置		
公开(公告)号	US20200107737A1	公开(公告)日	2020-04-09
申请号	US16/589612	申请日	2019-10-01
[标]申请(专利权)人(译)	霍华德NEWTON 梁永波 陈真诚 病房转移		
申请(专利权)人(译)	霍华德，牛顿 梁，李永波 陈，振成		
当前申请(专利权)人(译)	霍华德，牛顿 梁，李永波 陈，振成		
[标]发明人	HOWARD NEWTON LIANG YONGBO CHEN ZHENCHENG WARD RABAB		
发明人	HOWARD, NEWTON ELGENDI, MOHAMED LIANG, YONGBO CHEN, ZHENCHENG WARD, RABAB		
IPC分类号	A61B5/024 A61B5/021 A61B5/00		
CPC分类号	A61B5/6826 A61B5/7239 A61B5/02125 A61B5/02116 A61B5/7221 A61B5/02427 A61B5/7264 A61B5/02108 A61B5/02416 G16H50/20		
优先权	62/740578 2018-10-03 US		
外部链接	Espacenet USPTO		

摘要(译)

该专利提供了一种用于高血压的筛查和管理的系统，该系统包括以下特征：高精度指尖光电容积描记（PPG）采集设备以及智能手机中的高血压筛查和管理的应用软件。 前者包括905 nm波长的红外发光传感器，光电接收传感器和蓝牙传输模块。 后者包括PPG信号配置和采集模块，自动高血压分类和筛查模块以及高血压管理模块。 该系统可以处理实时PPG信号并可以对血压水平进行分类和评估，并进行长期管理和高血压健康指导。