

uBioMacpa User Guide



Biosense Creative Co.,LTD

#425 Seoul Technopark 232, Gongreung-ro, Nowon-gu, Seoul, Korea

www.ubionet.com

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01. About uBioMacpa

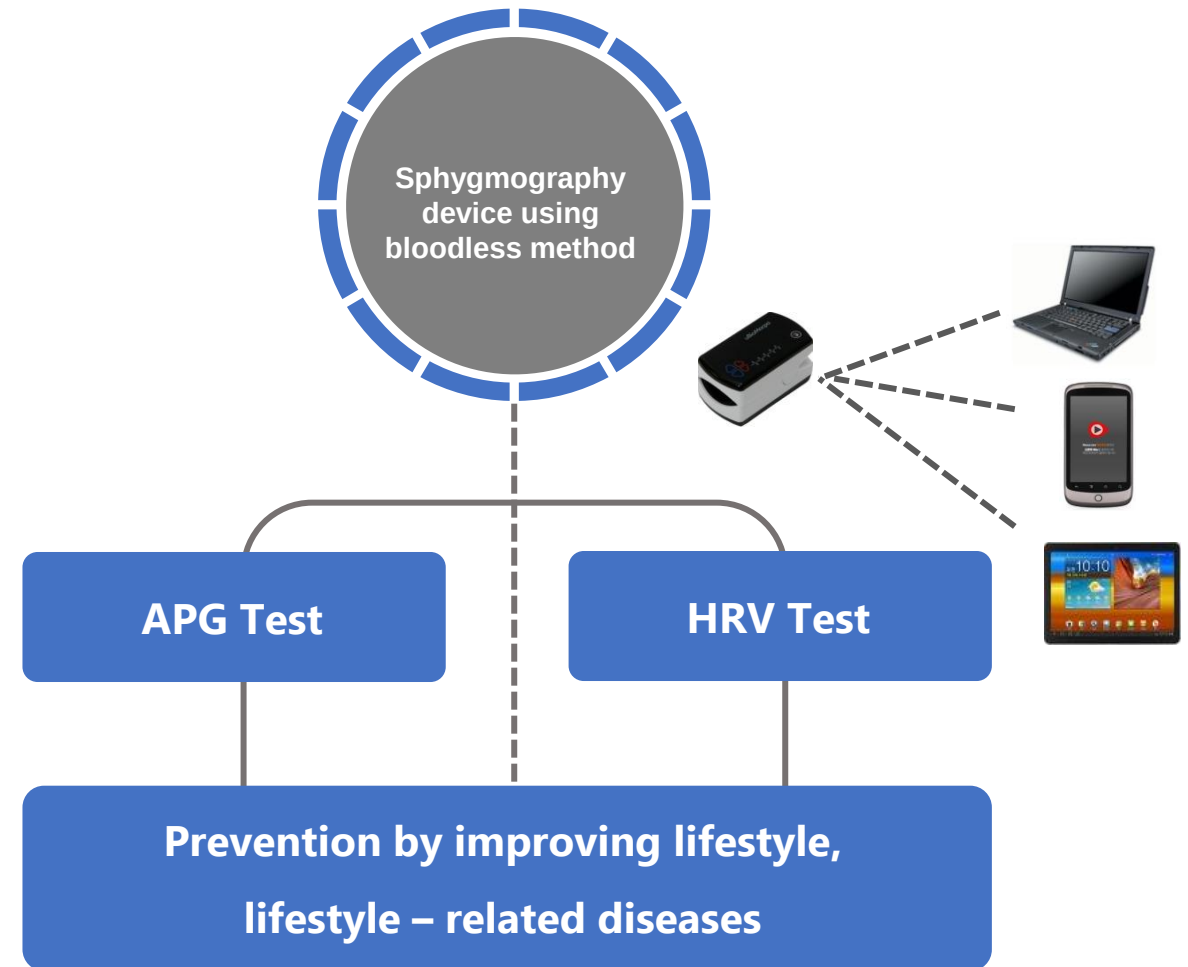
uBioMacpa can help to check our blood circulation status and accumulated stress easily by measuring HRV(Heart Rate Variability) through pulse wave analysis of capillary.

Anybody can easily test accumulated stress and vascular health status at home using uBioMacpa device to prevent further development of disease.

Prevention of cardiovascular disorder or accumulated stress using easy-to-use test device



01. About uBioMacpa

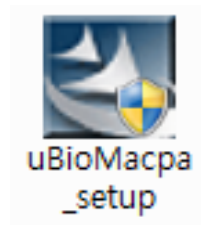


02. Installation and Operation

01 Product Includes



uBioMacpa
Measuring Probe



uBioMacpa
Software



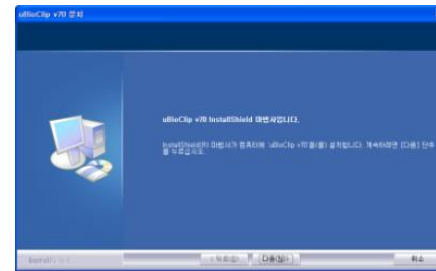
USB Cable & Gender



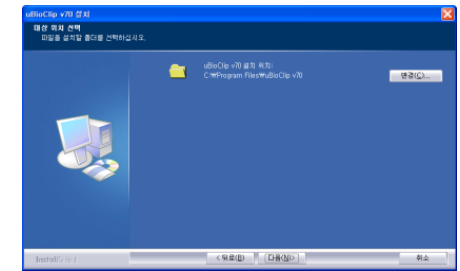
Installation and
User Manual

02 Software installation

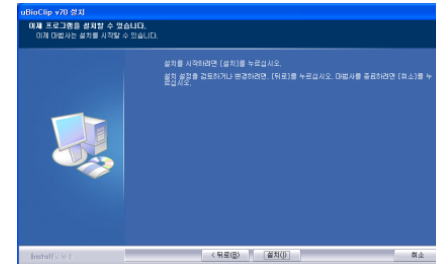
Install the uBioMacpa software. Then it will start installation automatically and will follow the procedure as below.



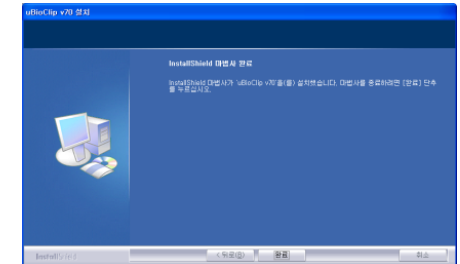
Click "Next[n]" and proceed.



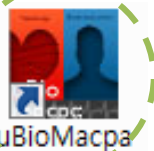
(If you want to change the path, click "Change[C]".)
Click "Next[n]" and proceed.



Click "Install [I]" and proceed.



When installation is completed, click "Finish". Make sure the icon is generated on the desktop.

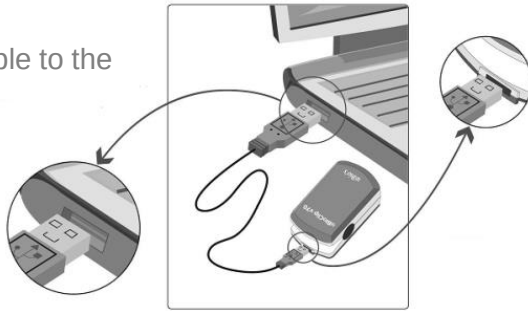


02. Installation and Operation

03

Connecting the device to the computer

1) Connect the USB cable to the computer.

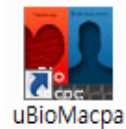


2) Then connect the USB cable to the device.

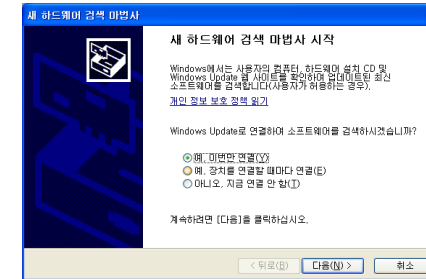
04

Running

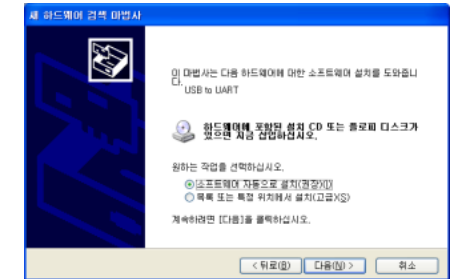
When you click the icon on the desktop, uBioMacpa will start running.



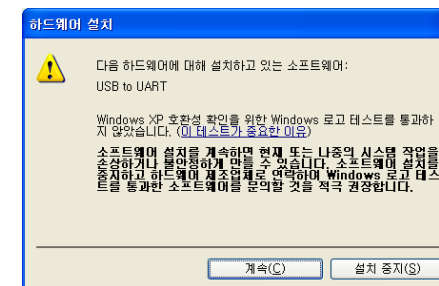
* When you connect this to a computer USB port for the first time, follow the procedure below.



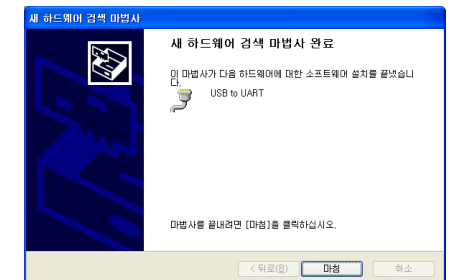
Click “Yes, connect this time only (Y)” and click “Next (N)”.



Click “Automatic installation (recommended)” and click “Next (N)”.



Click “Continue (C)” and proceed”.



Click “Finish” and finish the connection process.

03. User Registration

When you click the icon on the desktop, the main screen will be displayed, Click 5 to register the user for testing.

- Register the user for testing
- Enter name, date of birth, and sex, 1 and click “OK”, You will see the data below. 3
- Once you have a test, you can select the user in the list from next time. 2
- There is no limit on the number of the users
- Users have their own records only.
- Viewing previous test result shows only the records for the user.



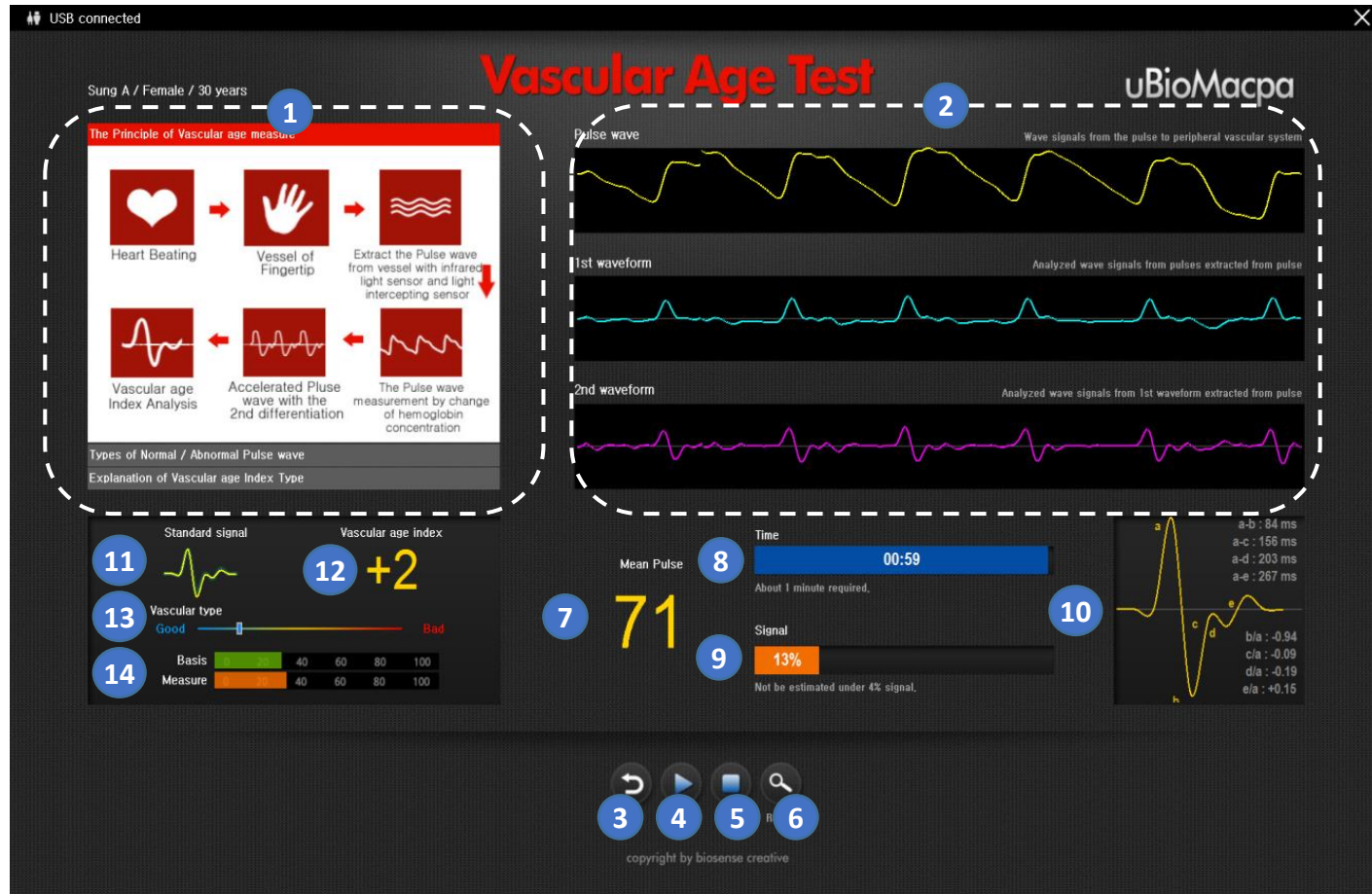
Design of main screen

- Testing vascular health
- Testing accumulated stress
- Viewing records per user
- How to use
- Selecting the user
- Analyzing the test result
- Showing product version
- Finishing the program

04. Testing Vascular Health

It gets vascular health level from vascular health type and calculated vascular health age. (Test time = 1 minute)

It moves to analysis screen when the test is finished.



1 Basis of test and vascular health types

- Basis of testing vascular health level
- Distinguishing normal/abnormal pulse wave
- Meaning of vascular health type

2 Basis of test and vascular health types

- Pulse wave (wave form of pulsing on peripheral blood vessel)
- Extracted wave from pulsing (wave form from which number of pulse is extracted)
- Wave for analysis from pulsing (wave form from which vascular health index is analyzed)

3 Move to main screen

4 Start testing

5 Finish testing

6 If you click "Viewing test result" before the test is finished, the analysis screen uses only the tested data.

- The data is not saved
- You may do it for fast testing but it is not recommended
- We recommend normal finish of testing and moving for analysis

7 Measured pulse rate per minute

13 Type of vascular health There are 7 levels between Good and Bad

14 Average index - age of tested person Tested index - Vascular health age compared to the age of tested person

8 Show test time (process time)

9 Reception sensitivity of bio-signal

10 Average from the start of test Accelerated pulse wave graph

11 Comparison of average accelerated pulse wave for the age group and measured accelerated pulse wave

12 Vascular health calculated from accelerated pulse wave

05. Analysis of test result of vascular health (1)

1

Summary

Testing vascular health level is a **screening test** of vessel age and blood circulation level in a noninvasive way.

2

Signal Level : 24%

Classification	Safe	Caution	Dangerous	Note
Vascular Age Index	●			-30 ~ +5 : Safe (Healthy Lifestyle) +6 ~ +20 : Caution (Attention to Lifestyle) +20 ~ : Danger (Need for Diagnosis)
Vascular Age Type	●			A ~ B type : Safe C ~ D type : Caution E ~ G type : Danger

3

If the reception signal is 4% or better, it can be tested.
Higher reception signal does not mean it is better (5% or better is enough).
When you have cold hands or bad blood circulation, the reception signal may be low and is unable to test.

4

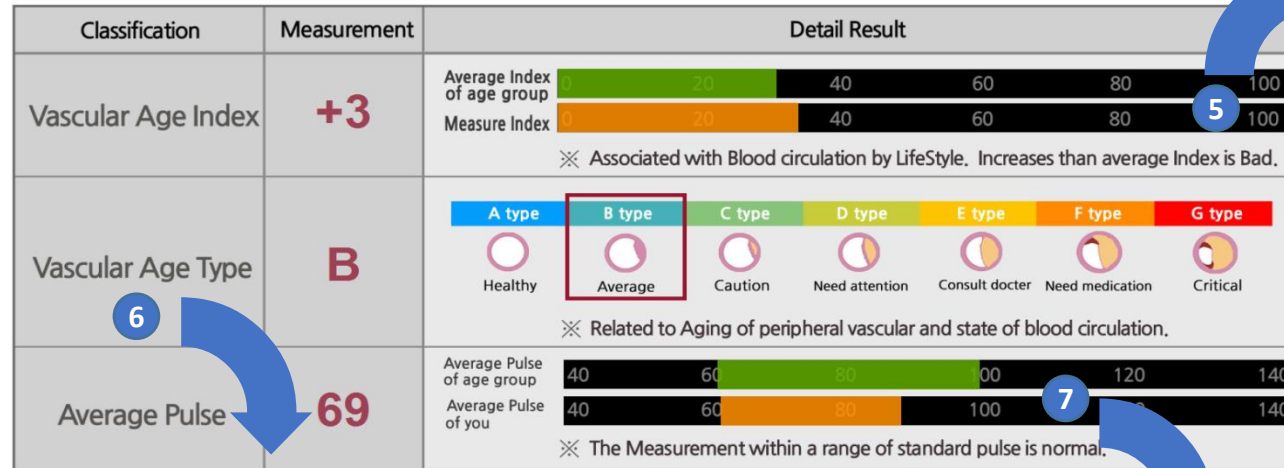
There are 7 levels (A – G) in **vascular health** level depending on its Resilience.
The resilience gets worse **as you get older**.
Healthy adults are usually in B level. But they could be in C or D level if they have high blood pressure or diabetes.
A person who is 60 years old could be in level B if he keeps a good lifestyle.

Diabetes, high blood pressure, stroke, and obesity were considered as adult disease before. But they are considered as **lifestyle disease** these days because they come from irregular eating habit, pollution, and stress. Those diseases can be prevented if you change the lifestyle. **So regular checking of vascular health level is important.**

Vascular health index is related to vascular health but it is also closely **related to lifestyle which affects blood circulation**.
Eating too much meat, lack of exercise, irregular eating habit, too much drinking, smoking, and frequent instant food cause higher vascular health index.

05. Analysis of test result of vascular health (2)

Result of Measurement



Average age index in vascular health level means the age of testing person.

When you take away the age of testing person from vascular health age, it becomes vascular health level.

Lower value means it is healthier and a good lifestyle is kept.

There are 7 levels (A – G) in vascular health level.

It is related to resilience of vessel tube.

Healthy people who are 10 – 29 years old are in A level.

Healthy people who are 30 – 59 years old are in B level.

If you are 30 – 59 years old and are in C level, you need to be careful.

If you have adult disease, you may be in C level or worse.

Elderly people are usually in C level or higher but if you are in good health, you could be in B level.

Average pulse is average heart rate and green stripe is the range of average pulse per age group.

Yellow stripe is the average pulse of the testing person and the width is min/max variation. If the variation is more than 1/3 of green stripe, it is good.

If the width is narrow, test the stress level.

Pulse variation during measuring stress is related.

05. Analysis of test result of vascular health (3)

This shows the last five test results. Average index is the average of final tests.

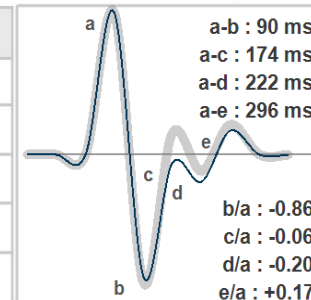
Blood circulation in peripheral blood vessel is affected by oxygen, nutrition, emotion, and hormone. **So you need to test several times and get the average for vascular health level.**

8

Previous Test Results (Last 4 times) Average Index : +0

번호	Test Date	Vascular Age Type	Vascular Age Index
1	2014-06-26 11:05:32	B type	+2
2	2014-06-26 11:13:52	A type	-4
3	2014-06-26 11:28:19	B type	+0
4	2014-06-26 11:29:29	B type	+3

Detail Analysis



This shows the average of accelerated pulse wave during the test.

Points of a, b, c, d, and e are inflection points.

a-b, a-c, a-d, and a-e are the time taken to reach the inflection points and they are not used during analysis.

b/a, c/a, d/a, and e/a are used during analysis and they are the ratios of length.



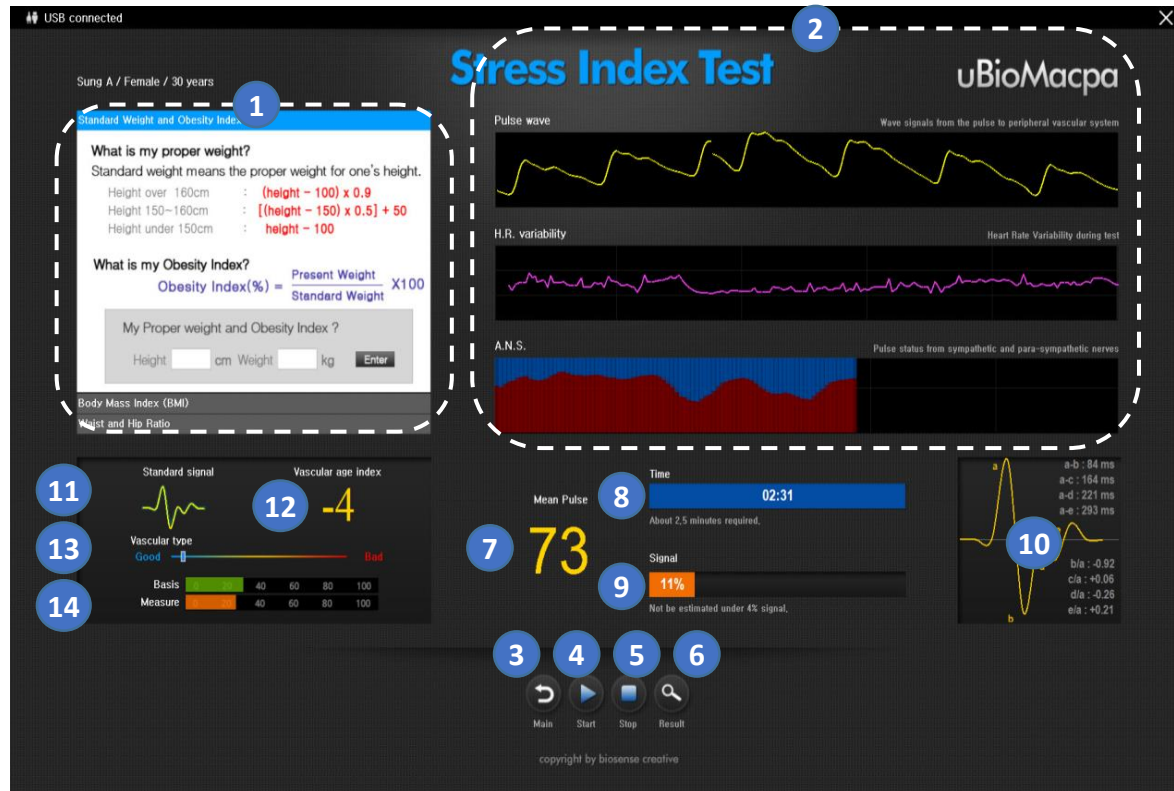
You may experience sharp change of vascular health level. This happens when there is sudden change of blood pressure or resilience of blood vessel. If that happens **try again after 5 minutes.** This happens more to **unhealthy person.**

o6. Testing Accumulated Stress



This tests accumulated stress of the body (test time = 2.5 minutes).

- uBioMacpa tests vascular health and accumulated stress levels at the same time. You can view the test result of vascular health level using “Viewing previous test result”.
 - It analyzes accumulated stress level by getting heart rate variability from pulse wave.
- It moves to analysis screen when the test is finished.



- 7 Measured pulse rate per minute
- 8 Show test time (process time)
- 9 Reception sensitivity of bio-signal
- 10 Average from the start of test Accelerated pulse wave graph
- 11 Comparison of average accelerated pulse wave for the age group and measured accelerated pulse wave
- 12 Vascular health calculated from accelerated pulse wave
- 13 Type of vascular health There are 7 levels between Good and Bad

1 Calculating 3 types of health-related data

- Standard weight and obesity level
- Getting BMI (body mass index)
- Ratio of waist size and bottom size

2 Showing pulse wave and analysis data

- Pulse wave (wave form of pulsing on peripheral blood vessel)
- Heart rate variability (shows the change of pulsing)
- Automatic nerves (shows the change of sympathetic nerve and parasympathetic nerve in real time; starts showing it after 1 minute)

3 Finish the test and move to main screen

4 Start testing

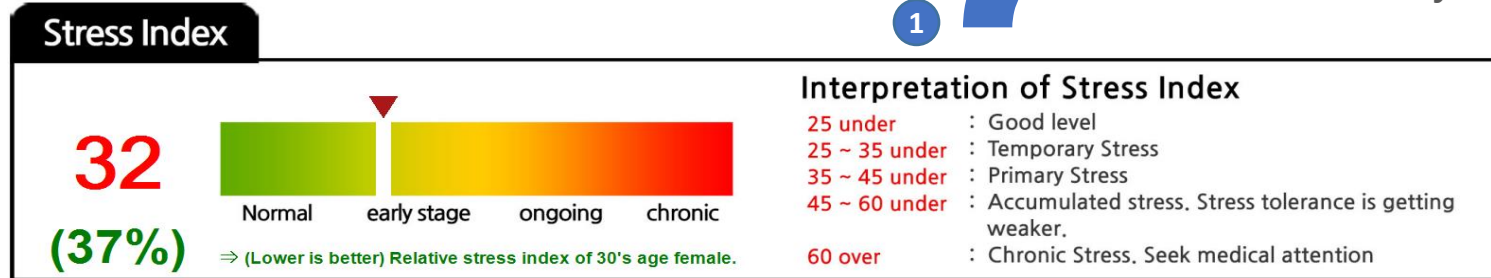
5 Finish testing

- 6 If you click “Viewing test result” before the test is finished, the analysis screen uses only the tested data.
 - The data is not saved
 - You may do it for fast testing but it is not recommended
 - We recommend normal finish of testing and moving for analysis

- 14 Average index - age of tested person
Tested index - Vascular health age compared to the age of tested person

07. Analyzing test data of accumulated stress (1)

Stress index is obtained considering all the data (pulse variation, heart rate distribution, balance of automatic nerve, and detailed analysis) below



Hans Selye, an endocrinologist in Canada and Nobel Prize winner, first used the term stress while he was researching **the biological response when animals are in extreme situation.**

Stress is the response of the body (human being, animal, plant) **to any demand placed upon it internally or externally.** Sympathetic nerve works when you are in danger. For example, it opens pupil wide for better recognition and to get more lights, makes body hairs stand to sense vibration, makes heart beat faster for more blood circulation to arms and legs, tightens muscles to fight or to run away, shrinks peripheral blood vessels to provide more blood where needed, minimizes blood circulation to digestive organs, and make breathe fast for more oxygen. If you stay in such situation for long, sympathetic nerve becomes inactivated.

When you are in stress, automatic nerve works to overcome the situation. But **if this situation goes for long or repeats, body becomes to be used to it and it develops to chronic stress.**

For testing stress, European Society of Cardiology and The North American Society of Pacing and Electrophysiology prepared a guideline on the standards of measurement and interpretation of HRV (Heart Rate Variability). Most medical devices today follow this standard. uBioMacpa is also based on this standard.

07. Analyzing test data of accumulated stress (2)



Data Analysis

Pulse Variability (Complexity = 83.65) Adults average is 30~40, under 20 are in excess stress level. ²



What is Variability ?

Graph showing changes HRV, More Variety of graph line is healthier.

What is Complexity?

Complex pulse index in various forms that defines immunization against stress and environment.

Pulse Distributional Map ³



Graphed the distributions of heart rate variability. Slim triangle shaped distribution refers to the excess stress. The standard shape means healthy.

Autonomic nerve system balance Map ⁴



It means the type of stress, Medium domain refers to 'healthy' condition.

It is healthier if there is more pulse variation. If there are more little sawtooth-like curves, the variation is higher. And if it becomes a straight line, it is less sensitive to stimulus.

- The horizontal axis represents the **pulse rate**, and the vertical axis represents the **pulse rate frequency**. It is better if heart rate distribution fills the triangle area in an equilateral triangle shape. If it becomes an **an isosceles triangle** indicates **low variability in heart rate**. This indicates a state where accumulated stress has **dulled responsiveness to external stimuli**.
- Balance of automatic nerve shows accumulated stress level through the rate between activation of sympathetic nerve and activation of parasympathetic nerve. The closer it is to the center of red box, it is more balanced. Depending on the accumulated stress level, **the green square dot moves to chronic stress area on the left**. If you do not solve it at this stage, it moves to chronic area below.

07. Analyzing test data of accumulated stress (3)

5 Activation of sympathetic nerve, activation of parasympathetic nerve, and standard pulse deviation affect stress index in detailed analysis.

5 Testing data analysis

Sympathetic Activity (Average age)

- High when excited or nervous (Better to be low within the green range)



Para-sympathetic Activity (Average age)

- Low when feeling anger/worry/fear (Better to be high within the green range)



Autonomic nerve system balance (Average age)

- Autonomic nerve system balance (Normal within the green range)



Average Pulse

- Average pulse per minute (Better to be low within green range)



Pulse Standard Deviation

- Immunization against environment (Better to be high within green range)



Root Mean Square Standard Deviation

- Low when anxious/worry/fear (Better to be high within green range)



8 Balance of automatic nerve shows the rate between activation of sympathetic nerve and activation of parasympathetic nerve. If it is in the green stripe, it is normal. If it goes to the right or left end after several tests, **the function of automatic nerve is low.**

9 Average pulse is average heart rate. If it is in green area (standard area per age group), it is normal. Heart beat is automatically controlled to provide oxygen to all body parts through blood. If it is always fast, it is called frequent pulse and you may consult with a doctor. If it is out of green area and is on the left, it is called infrequent pulse. it may cause fatigue and dizziness but it can happen to people like marathoners who have large lung capacity.

6 When you are **tense or excited**, the activation of the **sympathetic nervous system increases**. If you are **under continuous stress**, the responsiveness of the sympathetic nervous system dulls, often causing it to move out of the green stripe (standard range per age group) and **shift to the left**.

7 Activation of parasympathetic nerve is higher when you are relaxed. But when you are in **anger, worry, or fear**, it gets out of green stripe (standard area per age group) and **moves to left**. If the state of low activation of sympathetic nerve goes for long, activation of parasympathetic nerve is affect by it and it becomes low and more stress is accumulated.

10 Pulse standard deviation is known as index of body adaptability to environment. If this gets out of green stripe (standard area per age group) and moves to left, **the immunity to stress becomes weaker.**

11 Mean deviation is another way of checking activation of parasympathetic nerve. When you are relaxed, it is higher. But when you are in anger, worry, or fear, it gets out of green stripe (standard area per age group) and moves to left.

o8. Viewing previous test result

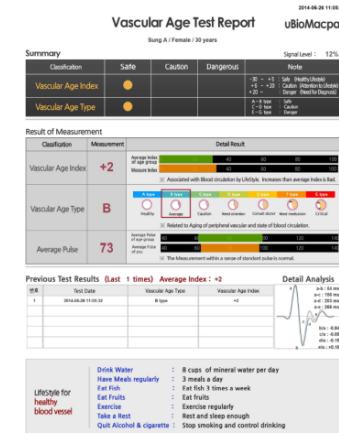
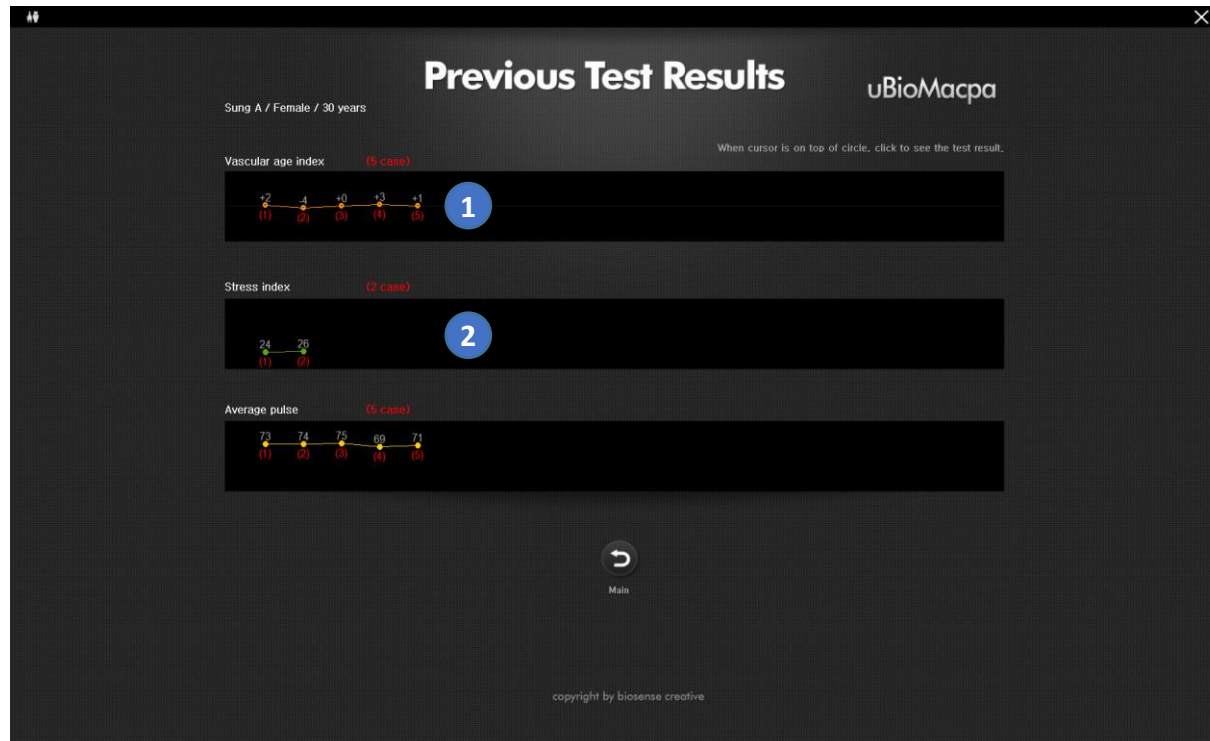


It allows viewing previous test results by test date.

- It shows the test result of vascular health level.
- It shows the test result of accumulated stress.
- It shows the average heart rate records.
- You can delete test records one by one

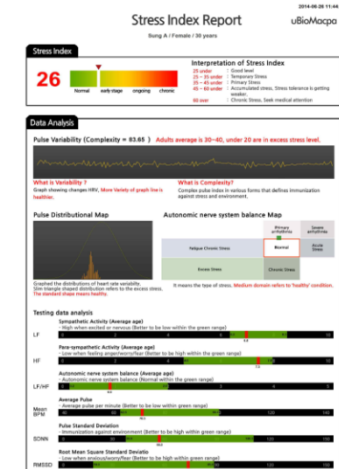
1

Click the point and load the record.

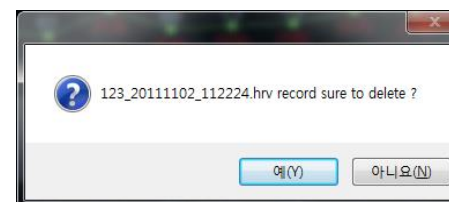


2

Click the point and load the record.



If you place the mouse pointer on the point and right-click it, **you can delete only the record.** If you click "Yes (Y)", the record gets deleted.



09. Deleting all records of a user



You can delete all records of a user by selecting “User Registration/Change” at the initial screen.

- “Delete” deletes all test records of the user.
- You cannot recover the deleted records. So be careful.

User Registration/change

User list 1 List hide

Name	Birth year	Gender
David 2	1980	Male
Sung A	1984	Female

User

Birth

Phone ☒ Male ☐ Female

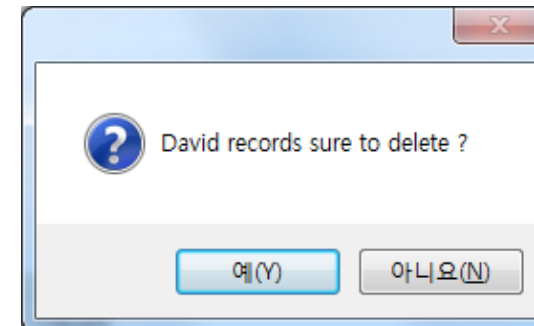
Confirm Cancel

1

Open the list by selecting “Viewing the list”.

2

If you select a user and right-click it, “[Record Deletion]” menu pops up.



If you click “Yes (Y)”, **all records of the user get deleted.**
(vascular health record + accumulated stress record)

10. Data storage path (PC – Windows 7 64bit)



Windows 7 64bit : You can follow the data storage path.

(My computer or File Explorer -> (C:)Drive -> Users -> User name -> AppData -> Local -> VirtualStore -> Program Files(x86) -> uBioMacpa -> work)

구성 | 열기 | 공유 대상 | 굵기 | 새 폴더

work 검색

이름	수정된 날짜	유형	크기
David_20140626_120050.ppg	2014-06-26 오후...	PPG 파일	24KB
Sung_A_20140626_110532.ppg	2014-06-26 오전...	PPG 파일	24KB
Sung_A_20140626_111352.hrv	2014-06-26 오전...	HRV 파일	7KB
Sung_A_20140626_111352.ppg	2014-06-26 오전...	PPG 파일	24KB
Sung_A_20140626_112819.ppg	2014-06-26 오전...	PPG 파일	24KB
Sung_A_20140626_112929.ppg	2014-06-26 오전...	PPG 파일	24KB
Sung_A_20140626_114438.hrv	2014-06-26 오전...	HRV 파일	7KB
Sung_A_20140626_114438.ppg	2014-06-26 오전...	PPG 파일	24KB

폴더 옵션

일반 보기 검색

폴더 보기

이 폴더의 보기(자세히 또는 아이콘 등)를 같은 종류의 모든 폴더에 적용할 수 있습니다.

모든 폴더에 적용(L) 모든 폴더를 원래대로(R)

고급 설정:

- 목록 보기에 입력할 때
 - ☐ 검색 상자에 자동 입력
 - ☒ 보기에서 입력한 항목 선택
- ☒ 미리 보기 창에 미리 보기 처리기 표시
- ☒ 미리 보기에 파일 아이콘 표시
- ☒ 보호된 운영 체제 파일 숨기기(권장)
- ☒ 숨김 파일 및 폴더
 - ☒ 숨김 파일, 폴더 또는 드라이브 표시
 - ☐ 숨김 파일, 폴더 또는 드라이브 숨기기
- ☒ 알려진 파일 형식의 파일 확장명 숨기기
- ☒ 암호화되거나 압축된 NTFS 파일을 컬러로 표시
- ☐ 새로 표시됨에 대해 새로 표시(클릭시 나타남)

기본값 복원(D)

확인 취소 적용(A)

* If you can not see the files, please check the folder options.

* XP or window 7 32bit : (C:)Drive → Program Files → uBioMacpa → work

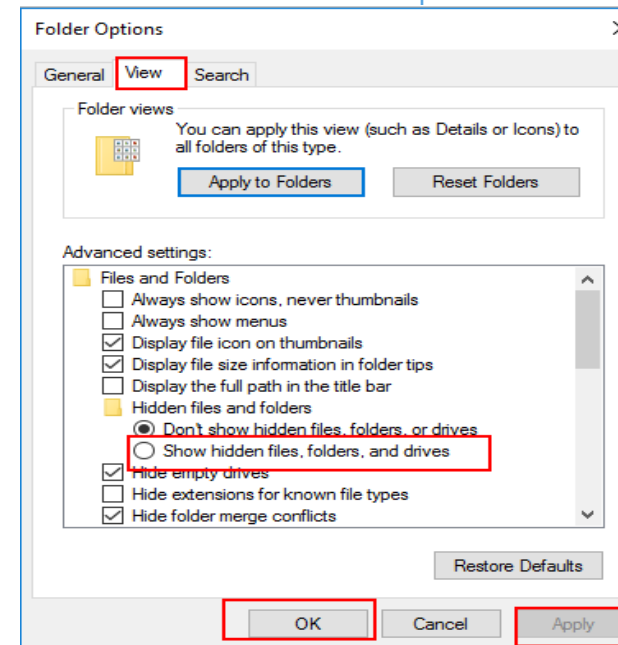
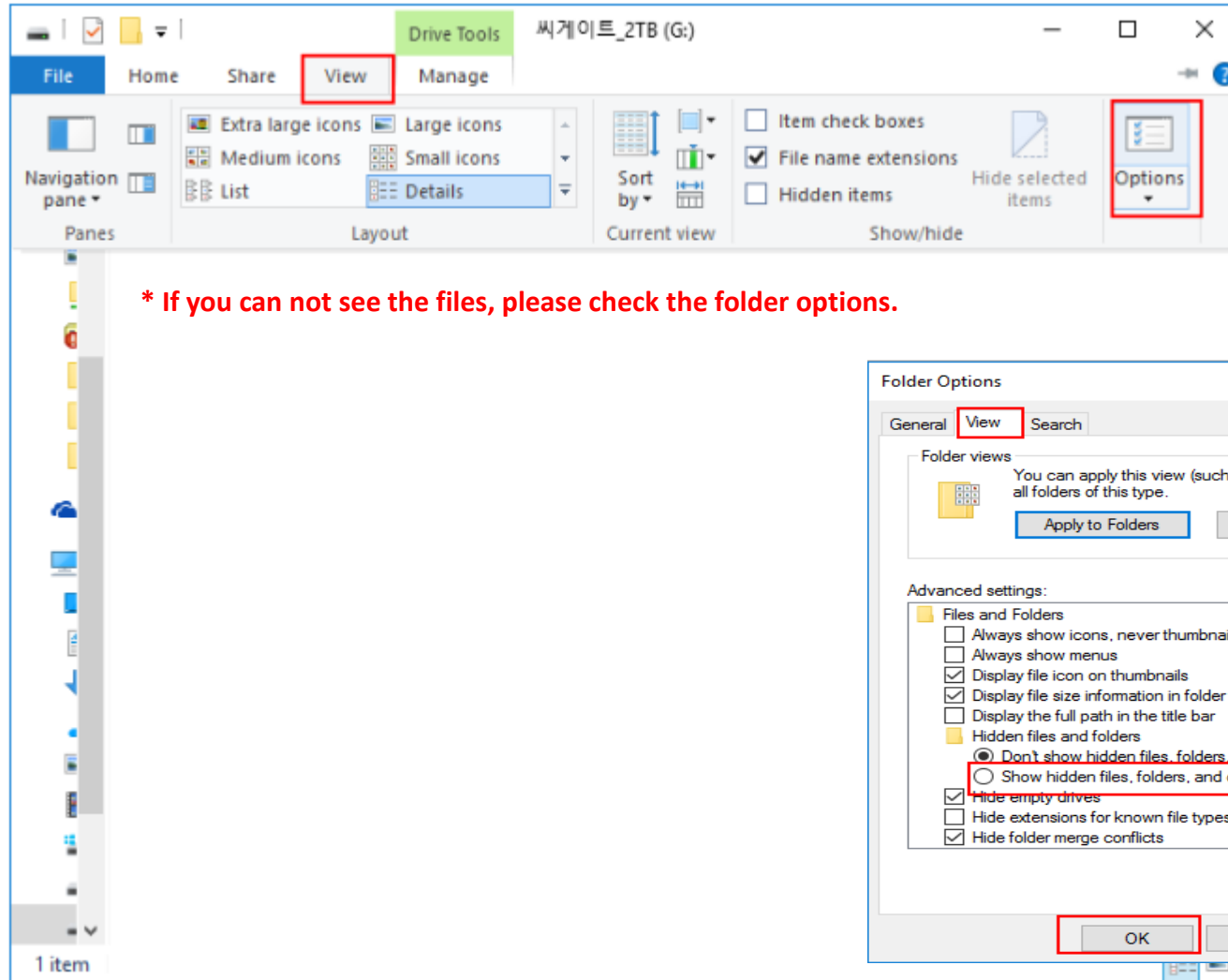
8개 항목을 선택했습니다. 수정된 날짜: 2014-06-26 오후 12:01 만든 날짜: 2014-06-26 오후 12:01
크기: 154KB

10. Data storage path (PC – Windows 8 or 10)



Windows 8 or 10 : You can follow the data storage path.

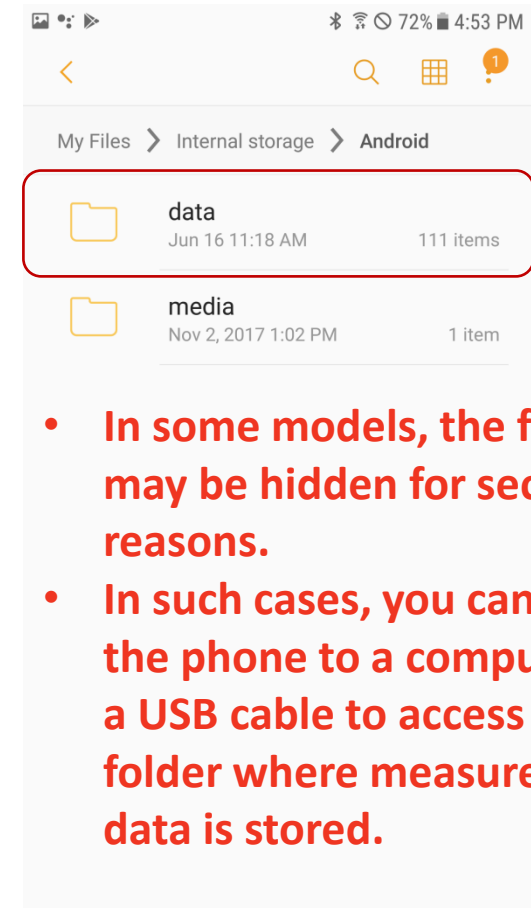
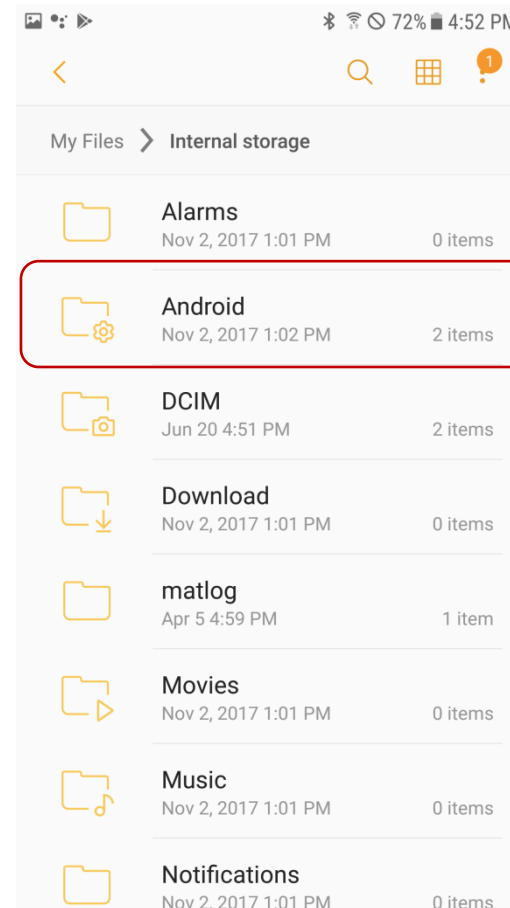
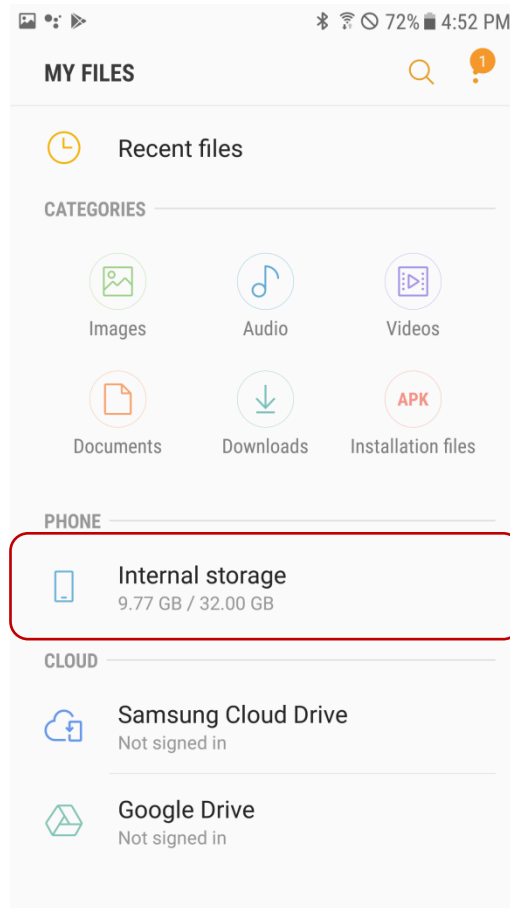
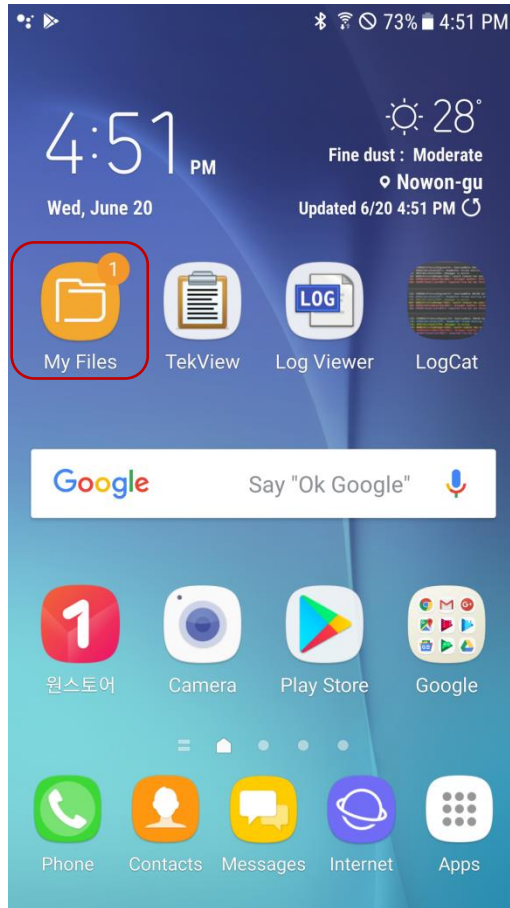
(My computer or File Explorer -> (C:)Drive -> Users -> User name -> AppData -> Local -> VirtualStore -> Program Files(x86)
-> uBioMacpa -> work)



10. Data storage path(Mobile Phone or Tablet)



My Files -> Internal or Other storage -> Android -> data -> com.biosense.ubiomacpa -> files -> work -> test report files



- In some models, the folders may be hidden for security reasons.
- In such cases, you can connect the phone to a computer using a USB cable to access the folder where measurement data is stored.

10. Data storage path (Mobile Phone or Tablet)



My Files -> Internal or Other storage -> Android -> data -> com.biosense.ubiomacpa -> files -> work -> test report files

The following table summarizes the file structure shown in the screenshots:

Path	Item Name	Created	Count / Size
My Files > Internal storage > Android > data	com.android.phone	Jan 1, 2015 9:01 PM	1 item
	com.android.providers.media	Nov 2, 2017 1:01 PM	1 item
	com.android.systemui	Jan 7, 2015 4:02 PM	1 item
	com.android.vending	Apr 5 2:32 PM	1 item
	com.apptiva.logviewer	Apr 7 1:53 PM	1 item
	com.biosense.ubiomacpa	May 16 4:32 PM	2 items
	com.biosense.u...acpa.chinese	May 16 12:12 PM	2 items
My Files > data > com.biosense.ubiomacpa	cache	May 16 4:32 PM	0 items
	files	Jun 7 4:14 PM	2 items
My Files > com.biosense.ubiomacpa > files	work	Jun 7 5:13 PM	5 items
	config.txt	Jun 7 4:14 PM	54 B
My Files > biosense.ubiomacpa > files > work	chk_20180607_161117.hrv	Jun 7 4:13 PM	6.48 KB
	chk_20180607_161117.ppg	Jun 7 4:12 PM	23.70 KB
	chk_20180607_164105.ppg	Jun 7 4:42 PM	23.70 KB
	mk	Jun 7 5:01 PM	23.70 KB
	park_20180607_171233.ppg	Jun 7 5:13 PM	23.70 KB

11. About the device

Size: Width(W)×Depth(D)×Height(H) = 58.3×32.84×27.46(mm)

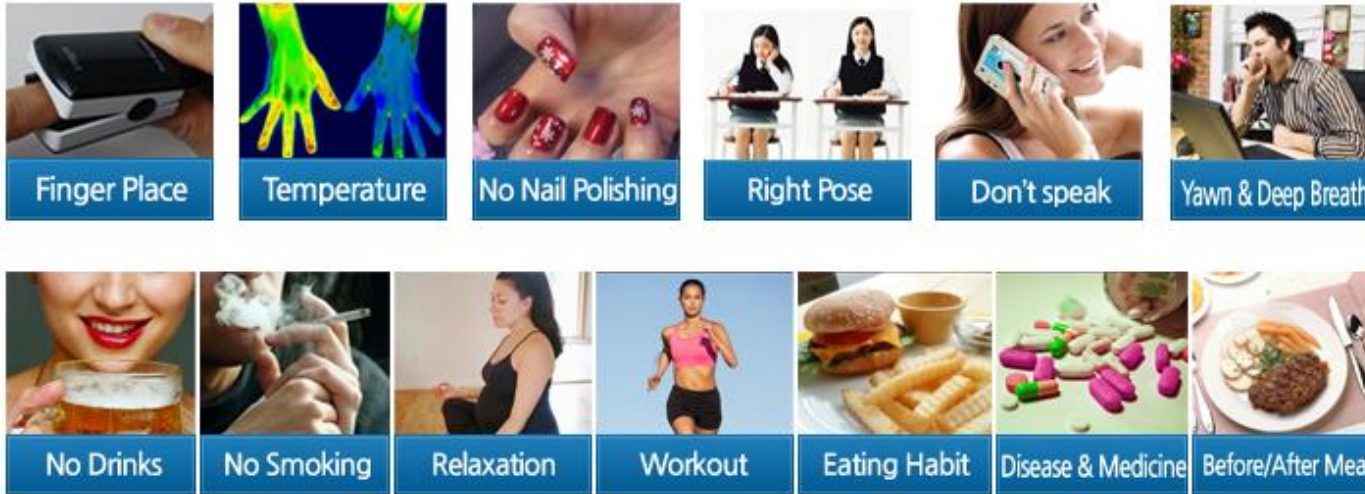
Weight: 25g

Material: ABS resin



Features	Description
1) USB cord	This connects to the computer. It is used for data communication.
2) Test probe	a test probe to measure pulse wave using infrared rays
3) Light emitting part	This emits infrared rays to fingers.
4) Light reception part	A sensor which receives light through fingers
5) Computer	universal PC, notebook Windows XP/Vista/7 CPU : 1GHz, RAM : 512MB HDD : 120GB

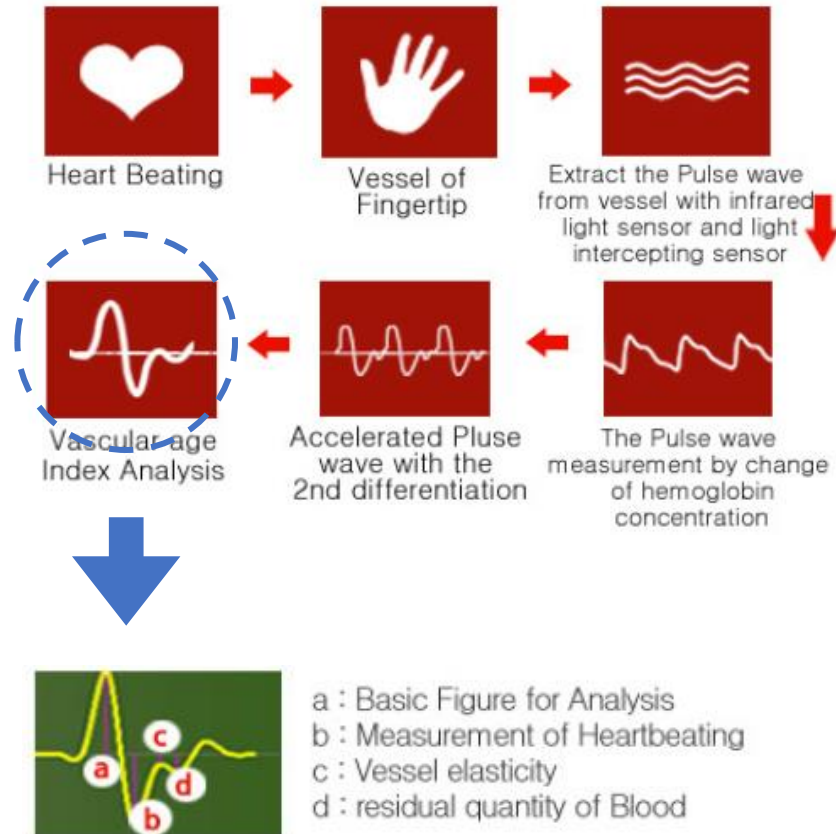
12. Caution



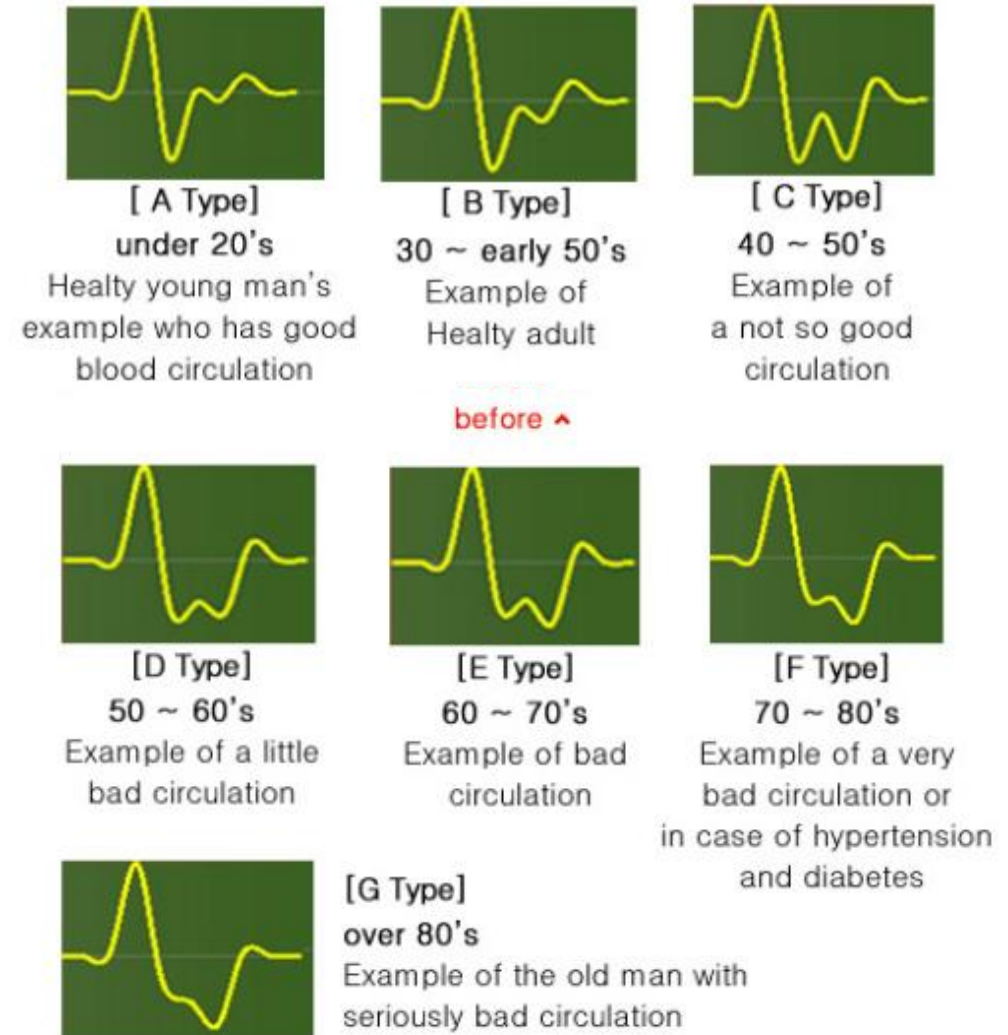
- Calm down for 5 minutes before testing.
- The testing for kids who are 12 years old or younger is not reliable because their fingers are too thin to test.
- If the test result is not what you expected, calm down and try again after 30 minutes
- It is best to use average of 5 test results.
- For better test, the finger in the probe should be placed horizontally with the rubber band for even light reflection.
- Do not test after drinking or smoking. The test may not be reliable.
- When you test during the winter or in cold weather, warm the fingers first.
- Do not yawn or take deep breaths during the test. It may affect automatic nerves.
- When you test outdoors, cover your hand with a tower. The light may affect the test.

13. Basis of the test

< Basis of testing Vascular Health >



< Type of pulse wave means that the Acceleration >



14. Checking pulse wave

< Distinct pulse wave of the human eye >

[Normal Pulse wave – healthy young man]



It has a sharp curve.

If you test after drinking, it has this shape.

[Normal Pulse wave – healthy middle aged man]



It has a smoother turn compared to that of a healthy young person.

[Normal Pulse wave – old man]

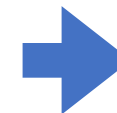


The cycle of pulse wave is triangle.

If this happens for people who are not elderly, try again after 5 minutes.

If it consists, consult with a doctor.

[Arrhythmia Pulse wave]



The cycle of pulse wave is not regular. It skips a cycle and gets shorter or longer.

There are many reasons for irregular pulse. Consult with a doctor for electrocardiogram.

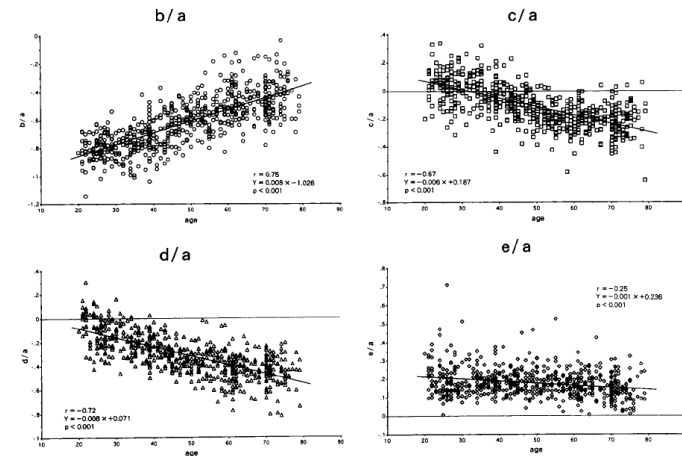
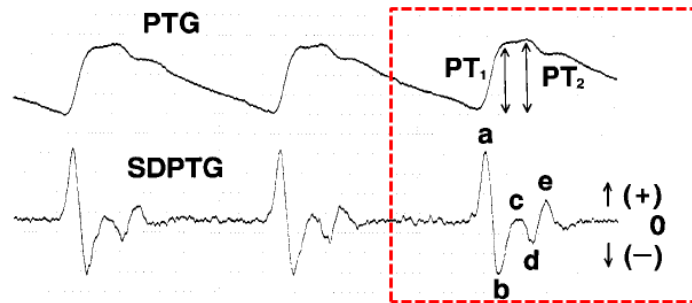
15. Basis of testing Vascular Health (1)

Hypertension
JOURNAL OF THE AMERICAN HEART ASSOCIATION

American Heart
Association
Learn and Live

Assessment of Vasoactive Agents and Vascular Aging by the Second Derivative of
Photoplethysmogram Waveform
Kenji Takazawa, Nobuhito Tanaka, Masami Fujita, Osamu Matsuoka, Tokuyuki Saiki,
Masaru Aikawa, Simobu Tanura and Chiharu Ito
Hypertension 1998;32:365-370
Hypertension is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX
75214
Copyright © 1998 American Heart Association. All rights reserved. Print ISSN: 0194-911X. Online
ISSN: 1524-4563

- Hypertension by **American Heart Association**, 1998; 32; 365-370
- Assessment of Vasoactive Agents and Vascular Aging by the Second Derivative of Photoplethysmogram Waveform
- Assessment of vascular age by analysis of pulse waveform in a noninvasive way
- Analysis of PTG Wave by the second derivative based on 400 males and females with age between 30 and 89 found that the size of peak a, b, c, d, and e is related to age. It is assessing vascular age based on that.



15. Basis of testing Vascular Health (2)

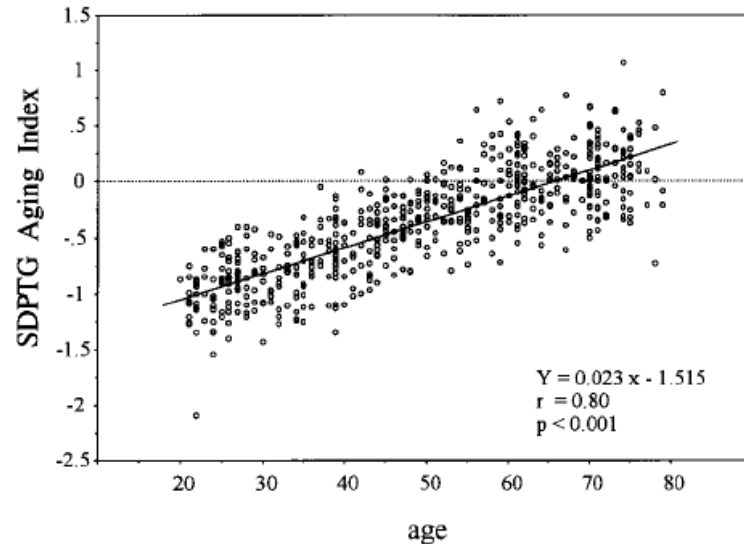


Figure 5. Relationship between SDPTG aging index and age. SDPTG aging index (b-c-d-e/a) (Y) increased with age (X); $Y = 0.023X - 1.515$ ($P < 0.001$, $r = 0.80$).

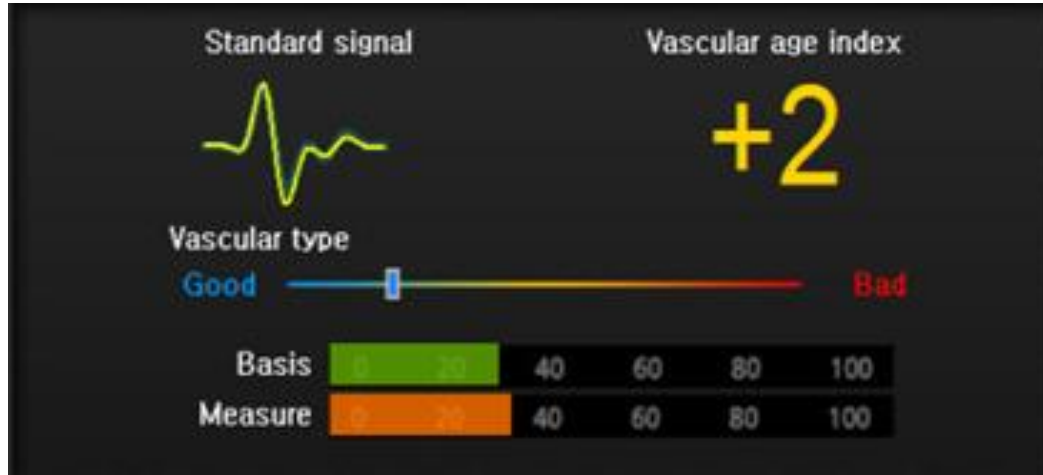
TABLE 2. Demographics of Study 2 Subjects With Results of Student's Unpaired *t* Test

Demographic	3rd Decade		4th Decade		5th Decade		6th Decade	
	M	F	M	F	M	F	M	F
Subjects, n	50	50	50	50	50	50	50	50
Age, y	26.0±2.2	24.4±2.6*	34.7±3.2	35.9±2.5‡	44.7±2.8	44.7±2.7	54.6±2.8	54.5±3.2
Height, m	1.72±0.05	1.57±0.07*	1.72±0.05	1.58±0.04*	1.70±0.06	1.56±0.06*	1.66±0.06	1.56±0.05*
Weight, kg	65±9	48±7*	69±10	53±7	68±8	53±8*	64±9	54±7*
SBP, mm Hg	113±10	98±8*	114±13	102±9*	116±11	104±10*	116±13	108±16‡
DBP, mm Hg	61±8	59±5	69±10	63±7*	74±11	67±8*	77±8	70±10*
PP, mm Hg	52±11	40±8*	45±11	39±8‡	42±8	37±8*	39±10	38±10
MBP, mm Hg	79±7	72±5*	84±10	76±7*	88±10	79±8*	90±9	83±11*
PR, bpm	70±12	73±10	68±10	73±10‡	68±11	69±11	66±10	69±10
b/a	-0.79±0.08	-0.80±0.11	-0.81±0.11	-0.72±0.11*	-0.72±0.11	-0.60±0.11*	-0.57±0.13	-0.54±0.11
c/a	0.01±0.13	0.07±0.10‡	0.01±0.12	-0.01±0.12	-0.08±0.13	-0.10±0.07	-0.18±0.11	-0.20±0.08
d/a	-0.10±0.13	-0.10±0.16	-0.17±0.15	-0.24±0.09‡	-0.29±0.11	-0.30±0.08	-0.38±0.14	-0.36±0.12
e/a	0.21±0.12	0.19±0.08	0.21±0.09	0.17±0.05‡	0.22±0.08	0.17±0.05*	0.19±0.08	0.17±0.05
SDPTG AI	-0.91±0.23	-0.95±0.31	-0.86±0.28	-0.64±0.26*	-0.57±0.28	-0.36±0.23*	-0.20±0.30	-0.16±0.27
PTG AI	0.87±0.14	0.88±0.18	0.92±0.14	1.02±0.14*	1.03±0.12	1.12±0.16‡	1.16±0.19	1.13±0.13

TABLE 2. Continued

7th Decade		8th Decade		All Decades	
M	F	M	F	M	F
50	50	50	50	300	300
63.3±2.6	63.5±2.6	73.0±2.8	72.3±2.1	49.4±16.4	49.2±1.5
1.66±0.05	1.53±0.05*	1.63±0.06	1.50±0.05*	1.68±0.06	1.55±0.06*
64±8	54±7*	62±9	50±7*	65±9	52±7*
126±20	119±22	124±17	118±16‡	118±15	108±16*
77±12	74±12	73±7	70±8	72±11	67±10*
49±13	45±14	51±14	47±15	46±12	41±11*
93±14	89±15	90±10	86±9‡	87±11	81±11*
64±9	72±12*	64±11	71±11‡	67±11	71±11*
-0.48±0.12	-0.45±0.13	-0.48±0.13	-0.40±0.12*	-0.64±0.18	-0.59±0.18*
-0.20±0.10	-0.20±0.07	-0.20±0.14	-0.24±0.09	-0.10±0.15	-0.12±0.14
-0.44±0.11	-0.43±0.12	-0.45±0.13	-0.46±0.13	-0.30±0.18	-0.32±0.17
0.17±0.07	0.16±0.06	0.16±0.07	0.12±0.07‡	0.19±0.09	0.16±0.07*
-0.01±0.27	0.03±0.26	0.00±0.32	0.18±0.29‡	-0.43±0.47	-0.32±0.47‡
1.20±0.15	1.26±0.24	1.25±0.20	1.27±0.20	1.07±0.21	1.11±0.22‡

15. Basis of testing Vascular Health (3)



Test value of uBioMacpa

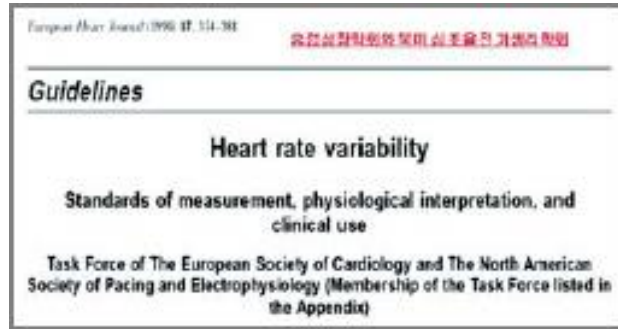
Vascular health index = vascular age - age

$$\text{Vascular age} = \left(\left(\frac{b - c - d - e}{a = 1} + 1.515 \right) / 0.023 \right)$$

$$\text{Vascular age (32)} = ((-0.94 - (-0.09) - (-0.19) - 0.15) + 1.515) / 0.023$$

$$\text{Vascular health index} = 32 - 30 = +2$$

16. Basis of testing Accumulated Stress (1)



- **European Society of Cardiology and The North American Society of Pacing and Electrophysiology prepared** a guideline on the standards of measurement and interpretation of HRV (Heart Rate Variability). Most medical devices today follow this standard.
- **uBioMacpa** is also based on this standard.

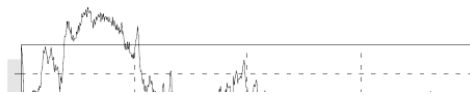
구분	파라메타	내 용
시간영역	SDNN	Standard deviation of all NN intervals
	RMSSD	The square root of the mean of the sum of the squares of differences between adjacent NN intervals
	SDSD	Standard deviation of differences between adjacent NN intervals
	NN50 count	Number of pairs of adjacent NN intervals differing by more than 50 ms in the entire recording
	pNN50	NN50 count divided by the total number of all NN intervals
주파수영역	TP	5 min total power
	VLF	Power in very low frequency range
	LF	Power in low frequency range
	HF	Power in high frequency range
	LFnorm	LF power in normalised units
	HFnorm	HF power in normalised units
	LF/HF	Ratio LF [ms ²] / HF [ms ²]

16. Basis of testing Accumulated Stress (2)

HEARTMATH Research Center

Autonomic Assessment Report

A Comprehensive Heart Rate Variability Analysis



- Autonomic Assessment Report Interpretation Guide and Instructions(Heartmath Research Center, U.S., 1996)
- **A guideline prepared by Heartmath Lab. in America for autonomic assessment and interpretation** (Heartmath Lab. was founded in 1991 to research and teach cardiology. It is a non-profit organization in California, U.S.)
- **Suggests standard value per age group of each item such as LF, HF, LF/HF, mean BPM, SDNN, and RMSSD**

< Range per age group for time and frequency analysis value >

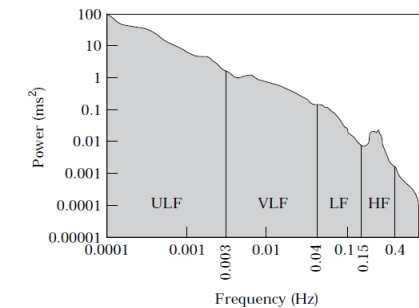
Table 2. Age Ranges and Cutoff Values for Time Domain Variables

Range	Heart Rate		SDNN		SDANN		SDNN index		Ln rMSSD	
	Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper
10-20	64.01	99.99	94.39	265.65	78.99	247.28	42.42	112.17	3.06	4.56
21-30	62.52	98.50	88.71	249.67	74.24	232.41	36.79	106.54	2.93	4.44
31-40	61.03	97.01	83.37	234.66	69.78	218.43	31.16	100.91	2.80	4.31
41-50	59.54	95.53	78.36	220.54	65.58	205.30	25.53	95.28	2.68	4.18
51-60	58.06	94.04	73.64	207.27	61.64	192.95	19.90	89.65	2.55	4.05
61-70	56.57	92.55	69.21	194.81	57.93	181.35	14.26	84.01	2.42	3.93

Table 3. Age Ranges and Cutoff Values for Frequency Domain Variables

Range	Ln Total power		Ln ULF		Ln 5-min Total power		Ln 5-min VLF		Ln 5-min LF		Ln 5-min HF		Ln LF/HF	
	Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper
21-30	9.12	11.05	8.80	10.88	7.57	9.47	7.04	8.98	6.24	8.30	4.56	7.79	0.20	1.99
31-40	8.97	10.90	8.67	10.74	7.36	9.27	6.84	8.77	6.08	8.14	4.19	7.42	0.41	2.21
41-50	8.82	10.75	8.53	10.60	7.16	9.07	6.64	8.57	5.93	7.99	3.82	7.05	0.63	2.42
51-60	8.67	10.60	8.39	10.47	6.96	8.87	6.43	8.37	5.77	7.83	3.45	6.68	0.84	2.64

< Area for each frequency range >



17. Certificates for the product (1)

Item	Detail description
Patent	• Testing device of vascular health and stress level by analyzing pulse wave signal (Registration number: 10-0954817)
KFDA Certificate	• Medical Device Product Manufacturer (#3447) • Medical Device Product Permit (#13-262) • KGMP(KTL-AA-110168)
Other Certificate	• CE(KES-E1-13T0070) • RoHS(CTS130617-01A1)

 특 허 증 CERTIFICATE OF PATENT		
특 허 제 10-0954487 호 (PATENT NUMBER)	출원번호 NUMBER 2009년 03월 13일 출원일자 FILING DATE 2010년 04월 19일	제 2009-00012377 호 2009년 03월 13일 2010년 04월 19일
발명의명칭 (TITLE OF THE INVENTION) 핵발전소보통치를 이용한 핵안전감 및 스트레스 감지시스템 및 방법		
특허권자 (PATENTEE) (주)비오메스소프트테크닉 (110113-000000-) 서울 성북구 회원동길 30-1 한국과학기술원전원빈전차운 951 A호		
발명자 (INVENTOR) 문득시행원내 기제		
위의 발명은 「특허법」에 의하여 특허등록원부에 등록되었음을 증명합니다. (THIS IS TO CERTIFY THAT THE PATENT IS REGISTERED ON THE REGISTER OF THE KOREAN INTELLECTUAL PROPERTY OFFICE.)		
2010년 04월 19일		

KTL-AA-110168

No. 1 - 00135

의뢰기기 제조 및 품질관리기준 적합인정서 (Certificate of GMP)

• 법 도 명 (Name of Manufacturer) / 제과간호(호)코스노

(주)비오엔소크라에티브 / 제3447호

BioSense Creative

• 소 재 지 (Address of Manufacturer)

서울특별시 성북구 화왕로길 39-1 한국과학기술연구개발센터동 951 A
39-1, KIST Venture Town, Hawolgok-dong, Seongbuk-gu, Seoul,
Korea

• 대 표 자 명 (Representative of Manufacturer)

권기철 (Kwon, Ki-Chul)

• 분 류 코 드 / 품 목 명 (분류 코드)

(Name of Category / Name of Classification) (See attached list)

의뢰기기 제조 및 품질관리기준에 적합함을 인정합니다.

(We hereby certify that the above manufacturer complies with Korea
Good Manufacturing Practices for the product(s) listed above.)

발행일자 (Date of Issue) :

2011. 07. 22

유효기간 (Date of Expiration) :

2014. 07. 21.

식품의약품안전청

Korea Food & Drug Administration

한국산업기술시험원

Korea Testing Laboratory

[illegible]

MSA Certification Co., Ltd.
Quality Management System Certificate

㈜바이오센스크리에티브

사용목적 : 식탁용 화물자동차 20-1 한국과학기술연구원 벤처타운 B51A호

평가시스템인증을 위해 회사와 검사관과 인증담당자 이외의 불공정영향이나 다른 당사자를 모두 배제하고 일정한 절차를 준공하여 인증을 승인하였음(사).
ISO 9001:2008

인증범위
생체활성 오일기기의 설계, 개발, 제조 및 분포서비스 / 생체활성 오일기기의 소프트웨어 개발

인증번호 : KQC-1210807
인증시 유효기간 : 2012년 12월 11일 ~ 2015년 12월 10일

대표 : 안동철	2012년 12월 11일
MQA 담당자 :	2012년 12월 11일
인증 담당자 :	2012년 12월 30일

Scheme Manager

IAF DAKKS

ISO 9001

MSA CERTIFICATION

MSA QUALITY MANAGEMENT SYSTEM

의료기기 제조 허가증		
발령기관번호 제 2447호		
구분	제조	종류/종목/품목
제품명 (상용명, 등록명, 모델명)	세손도매용, 폐쇄회로, ultrasonic	분쇄기(30분용)
모양 및 구조	별첨	420040(51)(2)
원재료	별첨	
제조방법	별첨	
사용 목적	생체조직의 분쇄, 분쇄물 생성	
사용방법	별첨	
사용시 주의사항	별첨	
포장단위	별첨	
저장방법 및 사용기한	악아프아정정	
시험규격	제 463기 2015-01-01(2013-06-06호(2013.05.10))	
제조(수입)업체 정보	제5호(수입업체) : (주)비이비이테크(주)비이비이테크, 제5호(제조업체) : (주)비이비이테크(주)비이비이테크	
허가조건	제조명 : 없음	
비고	없음	

『의료기기법』 제6조 및 같은 법 시행규칙 제5조 제2항에 따라 하위 확인이 허가됩니다.

2013년 01월 24일

서울지방식품의약품안전청장 (인)

 EC Declaration of Conformity According to EC EMC Directive 2004/108/EC	
Applicant's Name	: BioSense Creative CO., LTD
Applicant's Address	: 39-1, KIST Venture valley, Hwasong-dong, Seongbuk-gu, Seoul, Korea
Manufacturer's Name	: Same as Above
Manufacturer's Address	: Same as Above
<i>Declares that the product:</i>	
Product Name	: ulloB-facpa
Base Model	: ulloB-facpa
Variant Model	: ulloB-facpa Pro
To which this declaration relates is in conformity with the following standard(s) or other normative document(s);	
EN50222:2010	Information technology equipment: Radio disturbance characteristics: Limits and methods of measurement
EN50244:2010	Information technology equipment - Immunity characteristics - Limits and methods of measurement
EN50100-5-2:2006+A2:2009	Electromagnetic compatibility (EMC) - Part 5-2: Limits and methods for harmonic current emissions (equipment with current ≤ 16 A per phase)
EN50100-3-3:2008	Electromagnetic compatibility (EMC) - Part 3-3: Limits and methods of voltage changes, voltage fluctuations and flicker in public low voltage supply systems for equipment with current ≤ 16 A per phase and not subject to continuous connection
Following the provisions of Directive(s):	
2004/108/EC Council Directive on the approximation of laws of the Member States relating to electromagnetic compatibility (OJ L31 1923 5 89; amended by Directive: 92/31/EEC (OJ L126 12 3 92) and 93/68/EEC(OJ L220 30 8 93)	
KOREA: 07/04 0141	
(Place and date of issue) (name and signature or equivalent making of authorized person)	
European Contact (for regulatory bodies only)	

 CTS Laboratory Co. #2130 A-Dong, 784-1, Seibang-dong, Cheonan-City, Chungcheongnam-do, Korea TEL : 070-418-8379	
RoHS Verification Test Report	
1. Receipt No. : CTS130617-01A1	
2. Applicant : - o Company name : Biosense Creative Co., Ltd. - o Address : #951A, KST Venture town, 39-1, Hawolgok-dong, Sungbuk-gu Seoul city, South, Korea	
3. Product name : ulioMaeca	
4. Model No.: ulioMaeca, ulioMaeca Pro	
5. Date of receipt : June, 19, 2013	
6. Test Method : IEC 62321-2008	
7. Test result : Refer to the following page(s)	
8. Directive : Directive 2011/65/EU on restriction of hazardous substances in electrical and electronic equipment.	
Tested by Title : Sample research Name : J.W. Park 	Reviewed by Title : Director Name : Smith Jo 
This report is the result of tests performed for the samples submitted to the applicant	
CTS Inc. 	
Issue No. : CTS130617-01A1 (01. 08. 2013) 00191 : 17 16	
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