

SA-3000P

Operation Manual

Ver.2.0.0



TABLE OF CONTENTS

General	3
Service Request.....	5
How to contact for customer service	6
How to use this manual.....	7
1.1 Contents of Manual	7
1.2 Manual Construction	8
1.3 Meaning of Symbols used in this Manual	9
Operational Dos and Don'ts.....	10
2.1 Don'ts in Operational Environment	10
2.2 Cautions for Electrical Safety.....	12
2.3 Maintenance and Cleaning	13
2.4 Cautions for Measurement.....	15
Description of SA-3000P	17
3.1 The features of SA-3000P.....	17
3.2 Theoretical background of SA-3000P	17
3.4 Description of Equipment symbols.....	19
Installation of SA-3000P	20
4.1 Installation	20
Operation.....	22
5.1 Before use SA-3000P	22
5.2 Use the SA-3000P	22
5.3 Main window of software.....	23
5.4 Data Backup.....	26
5.6 RSA TRAINING	36
Trouble shooting.....	43
6.1 System malfunction	43
Use of Finger Sensor	44
7.1 Attachment of the PPG Probe	44
7.2 Treatment and Checks.....	44
Description of Terms	45
Certificate of quality and warranty	46

Introduction

General

Thank you for using SA-3000P. Please read this User's Manual carefully before operating this equipment for proper handling and maintenance, and get familiar with all the functions and features of this equipment for safe handling and reliable performance.

Please, try to fully understand the features and operation and maintenance methods of this equipment prior to actual operation by thoroughly and carefully reading this manual. This is the only way to insure safe operation and reliable performance of the equipment for a long time.

Medicore Co., Ltd. only provides the reliable products to our customers.

- All of assembling, extending, adjusting or repairing of this equipment shall be carried out only by the service personnel authorized by our Company or Medicore Co., Ltd.
- Electrical connection or installation location has to comply with relevant regulations.
- Operate the equipment as directed by this manual.

This equipment has to be operated under the supervision of licensed medical professionals.

This equipment is used to monitor the conditions of patients. You are strongly requested to use accessories that are recommended in manual for safety of your patients.

In the event this equipment needs to be used by connecting with other equipment that is not listed in this manual, be sure to notify us, or our authorized dealers for proper measurement.

This is operation instruction, and the products are protected by the Copyright Act.

No part of this instruction and the products may be reproduced or transmitted in any form

or by any means, electronic or mechanical recording, or any information storage and retrieval system, without permission in writing from Medcore Co., Ltd. This operation instruction and the products may contain printing or technical errors, and are subject to change without notice.

This manual includes operation instructions for the best use of the product. Please read the manual carefully and keep it in a safe place.

Do not alter or modify the products. Do not use the product other than normal purpose. Medcore Co., Ltd. is not liable for damage caused by the use of the persons without appropriate medical license or education.

Service Request

Only people of Medcore Service Center or authorized distributor can carry out warranty repair or after-sales-service. If an unauthorized person tries to warranty repair, warranty is void.

Medcore Service Center or authorized distributor is obligated to perform warranty repair or after-sales service for the service requested by user.

Hospital or user must ask early and adequate maintenance if there is the risk or possibility of harming to human body in its equipment usage.

If there are any problems with the equipment, please take the following steps.

- Contact to the authorized distributor or Medcore Co., Ltd. immediately.
- Advise the model name, serial number, date of purchase, and description of the problem.
- Resolve the problem on the phone or online communication at first, and in case it's difficult to resolve on the phone or online communication, you can ask visit of service person.

How to contact for customer service

In the event of a malfunction or failure, contact Service Dept. of Medicores Co., Ltd along with the model name, serial number, date of purchase and the detail description of technical failure.

Tel No.	Overseas department of Medicores Co., Ltd. +82-2-2056-2650
----------------	---

E-mail	bkyoo@medi-core.com
---------------	--

Website	http://www.medi-core.com
----------------	---

Authorized distributor	Contact to our distributor in your local market
-------------------------------	---

Chapter 1

How to use this manual

1.1 Contents of Manual

- This manual contains all the information needed to operate our SA-3000P and it further provides exact information on the conditions of the patients including the measured parameter analysis.
- As this manual is constructed by independent chapter, some contents may appear in more than one chapter.
- This manual is a guideline for the efficient use of SA-3000P.
You can understand clinical significance and pathology of the feature for each function better if you refer to the documentations of medical-related literature. The user can expect to use effectively as seen as the clinical literature with this manual.
- In this manual, the method of operation is described for proper using the equipment. Read the instruction manual carefully before operating and keep it.
- In case you have some questions on the operation of the equipment while operating, please contact to our Overseas Sales Department or our local distributor.

1.2 Manual Construction

- Users have to carefully read this Manual before operating the Equipment.
- This Manual consists of various Chapters as follows.

Chapter 1	How to use this Manual.
Chapter 2	Operational Dos and Don'ts
Chapter 3	Description of SA-3000P
Chapter 4	Installation of SA-3000P
Chapter 5	Operation
Chapter 6	Handing and check point
Chapter 7	Trouble shooting
Chapter 8	Description of terms
Chapter 9	Certificate of Warranty

1.3 Meaning of Symbols used in this Manual

- Symbols are used to specially emphasize the agreed details as follows. Users need to follow all the cautions and notes listed in this manual.
- In the event that the product is damaged to misuse or negligence by a user, the manufacturer or the authorized dealers shall not be responsible for any damage or system failure thereof.

Warning

- The title “Warning” is used to inform the users of possible causes that could inflict the injury, death, or property damage to the patients.

Caution

- The title “Caution” is used to inform the users of possible causes that could inflict the injury on the patients although it might not be severe to cause deaths.

NOTE

- The title “Note” is used to inform the users of items that are of importance in terms of installation, operation, or maintenance of the equipment although the failure does not do the physical harm to the patients.

Chapter 2

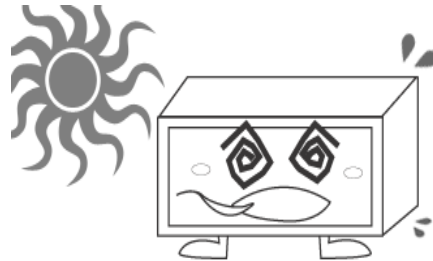
Operational Dos and Don'ts

2.1 Don'ts in Operational Environment

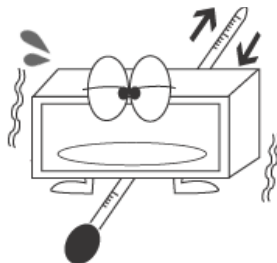
- Do not operate or store the equipment under the following environments.



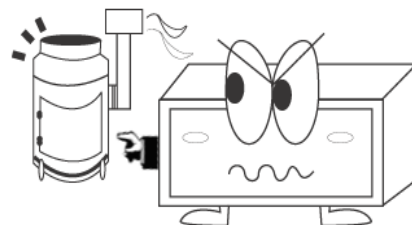
Avoid the damp locations, and do not operate the equipment with wet hands.



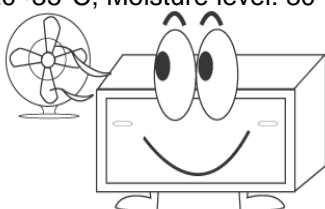
Location where exposed to direct sunlight.



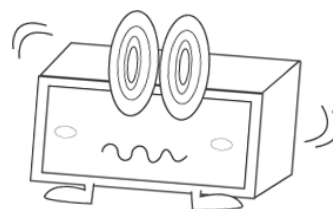
Locations where the temperature fluctuation is rather big (Operational temperature range: 20~35°C, Moisture level: 30~75%)



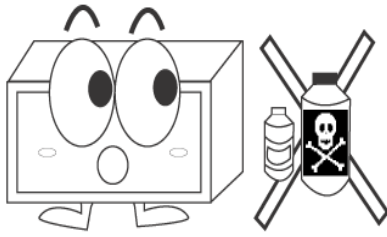
Locations close to electrical heating apparatus.



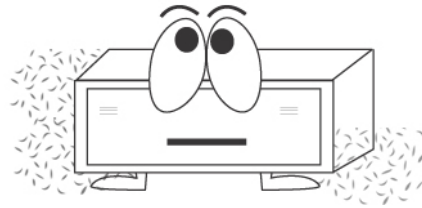
Locations where moisture level could go up considerably or where air is not ventilated.



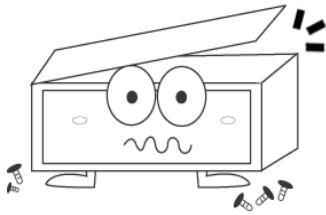
Locations where sudden impact or vibration could occur.



Locations exposed to chemical or explosive gas.



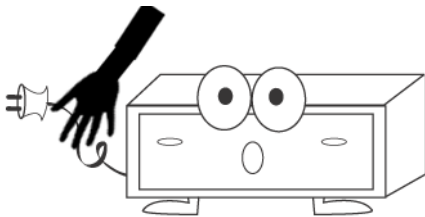
Make sure to prevent dust and especially metal debris.



The disassembling of equipment should be done by the authorized personnel. Otherwise, we will not be liable for any system failure or malfunction.



Do not plug in the power, until the installation is completed. Otherwise, it can cause damage to the equipment.



When pulling out the power cord, be sure to grab the plug, not the cord.

Standard operational conditions are as follows.

- Temperature : 10°C ~ 40°C(50°F ~ 104°F)
- Humidity : 80% RH max @40°C(104°F)
- Atmospheric pressure: 700hPa ~ 1060hPa

Standard storage conditions are as follows.

- Temperature : -20°C ~ 60°C(-4°F ~ 140°F)
- Humidity : 95% RH max @50°C(122°F)
- Atmospheric pressure: 700hPa ~ 1060hPa

2.2 Cautions for Electrical Safety

Prior to operation of the equipment, make sure to check following items:

- Whether power supply is appropriate. (100 – 240VAC).
- Whether connections (power line or selected equipment) are properly made to the equipment.
- Whether the equipment is properly grounded. (If not, some noises could be generated.)
- Whether a right kind of measuring accessory made for measuring of that desired parameter is connected to the equipment prior to turning on the equipment.

Classifications

Protection Class	Class I
Degree of Protection	Type BF: Heart Rate Monitor, BCA

NOTE

- The equipment should be placed far from generator, X-ray equipment, broadcasting equipment, or transmitting wires to prevent the electrical noises from being generated during the operation. When these devices are placed close to the equipment, it can produce inaccurate measurements. For SA-3000P, both independent circuit and stable grounding are essentially required. In the event that same power source is shared with other electronic equipment, it can also produce inaccurate output.

NOTE

- It is not proper to operate this equipment around combustible anesthetic or dissolvent.

Caution

- Although SA-3000P has been manufactured in compliance with existing EMI/EMC requirements, use of this system in the presence of an electromagnetic field can cause momentary degradation of the SA-3000P. If this occurs often, Medcore suggests a review of the environment in which the system is being used, to identify possible sources of radiated emissions. These emissions could be from other electrical devices used within the same room or an adjacent room. Communication devices such as cellular phones and pagers can cause these emissions. The existence of radio, TV, or microwave transmission equipment located nearby can cause emissions. If EMI causes disturbances, it may be necessary to relocate your system.
- Electrostatic discharge (ESD), commonly referred to as a static shock, is a naturally occurring phenomenon. ESD is most prevalent during conditions of low humidity, which can be caused by heating or air conditioning. During low humidity conditions, electrical charges naturally build up on individuals and can create static shocks. An ESD condition occurs when an individual with an electrical energy build-up comes in contact with objects such as metal doorknobs, file cabinets, computer equipment, and even other individuals. The static shock or ESD is a discharge of the electrical energy build-up from a charged individual to a lesser or non-charged individual or object. The level of electrical energy discharged from a system user or patient to the SA-3000P can be significant enough to cause damage to the system or probes. The following precautions can help to reduce ESD: anti-static spray on carpets; anti-static spray on linoleum; anti-static mats; or a ground wire connection between the system and the patient table or bed.

2.3 Maintenance and Cleaning

SA-3000P and its accessories can be cleaned using various methods. Please follow the methods mentioned below to avoid unnecessary damage or contamination to the equipment.

In the event that harmful (NOT allowed) materials are used for cleaning the damaged, contaminated equipment shall not be serviced without charges regardless of warranty period.

Caution

- **When you finish cleaning up the device, please check the main body and the sensor.**
- **If the device is outworn or damaged, please do not use it.**

At least once a month, clean and wipe off the frame by using the soft cloth after wetting it in lukewarm water or alcohol. Do not use lacquer, thinner, ethylene, or oxides, which could be harmful to the equipment.

Make sure both cables and accessories are free of dust or contaminants, and wipe them off with soft cloth wetted with lukewarm water (40°C/104°F), and at least once a week, clean them. Do not submerge the accessories under any liquid or detergent. Also, make sure ant liquid not to penetrate into the equipment or accessories.

Caution

- If you have using substances that could damage the product (unauthorized substance), the warranty period of the product is not even valid.
- Please check carefully both frame and sensor, after cleaning the equipment.
- Do not use the equipment that is worn out or damaged.

2.4 Cautions for Measurement

2.4.1 Things to remember in measurement

Please do not behave to cause the fluctuation of heartbeat just before measuring. For example, taking a significant workload, taking drugs or smoking shall be refrained.

2.4.2 Preparation of the patient before measuring

Patient shall maintain the fully stable condition to allow it to reflect the condition of the patient as much as possible.

Please consult with the doctor in case of taking drug.

2.4.3 Preparation of patient on the testing day

Please refrain from smoking or drinking, or taking drug or beverage that may stimulate the nervous system.

Please refrain from wearing accessory (ring, watch, and necklace) that may interfere with measuring.

Please relax for about 15 minutes in measuring room before taking the measurement in physically and mentally calm condition.

The measurement shall be taken in supine or sitting position of relaxed with eyes open.

Please do not move or speak but breathe regularly during the measurement.

2.4.4 Things to remember during testing

The people with difficulty in walking including the elderly and the psychosomatic patient, especially the stroke patient, shall require the presence of a guardian in the testing room.

2.4.5 Why to get different result when testing multiple times

In general, a healthy person has a large change in heart rate, and conversely, a person with a disease (diabetes, myocardial infarction, arteriosclerosis, obesity, etc.) or older people has less change in heart rate.

In other words, a large change in heart rate means that the autonomic nervous system functions and the resistant to stress are good, thus lowering the incidence risk of stress-related diseases.

The cycle of heartbeat changes by affecting the autonomic nervous system (Sinus

Arterial Node).

In other words, repeatedly testing effected of internal and external environmental factors (mental stress, emotional changes, breathing, blood pressure, body temperature or hormone, etc.) make a change of result value.

People with diseases or older people are not able to respond immediately to changes in internal and external environments. Therefore, the difference of the result value is small in the continuous measurement, but the difference in the result value for the health person is large because of quick response to the changes of internal and external environment.

In addition, since vital signs are very sensitive, the following points should be carefully taken for the measurement.

If there is a lot of change, it is recommended to read the average after 2 to 3 measurements.

- 1) After exercise, you should measure after 10 minutes stabilization.
- 2) Do not move or talk during testing.
- 3) Maintain most comfortable and normal breathing. (Coughing, sneezing, sighing, yawning and abdominal breathing are not allowed during the measurement)
- 4) Avoid 8 hours before drinking and at least 2 hours before smoking or coffee.
- 5) When measuring, do not apply pressure with sensor finger.
- 6) The proper temperature should be maintained. (Room temperature 22 to 25 ° C)
Higher room temperature causes expansion of the peripheral blood vessels, resulting in higher wave height. Lower temperature causes contraction of blood vessel, resulting lower wave height.
In particular, measurement with cold finger may be fail.
- 7) Measure with the left index finger (measurement standard).
- 8) Nail polish must be removed for the measurement (a cause of measurement error)
- 9) There is a difference between the results in the morning and afternoon, but the measurement in the morning is recommended for periodic test.
- 10) In case of hypertension, high fever or tachycardia, the result value tend to get better because of rapid blood flow in artery.
Even after drinking, the result value tend to get better due to increased blood flow.
- 11) In the case of arrhythmia, heart disease or asthma, the result value is unreliable.

Chapter 3

Description of SA-3000P

3.1 The features of SA-3000P

HRV is aims to quantitatively assess the overall health forecasting and autonomic nervous system activity by measuring heart rate variability for a certain period time, and used to determine the physical/mental stress level and autonomic balance through it.

The simple and fundamental theory is that heart rate variation is larger for a healthy adult. To show quantitative data, both of the time-domain analysis and the frequency domain analysis are used.

3.2 Theoretical background of SA-3000P

SA-3000P HRV quantify the full extent of the patient's heart rate variability during the measurement time. The healthy individual with excellent ability to regulate autonomic function has bigger variability of heart rate but a person under any disease or stressed state has reduced variability. There are two method for analyzing heart rate variability, the one is a statistical analyzing including the RR intervals, the mean heart rate and its standard deviation in a time domain and the other is the frequency domain analysis which is a way to quantify the relative strength of each frequency band. Especially through frequency domain analysis, it can evaluate the activities of two branches, sympathetic and parasympathetic nerve of the autonomic nervous system.

SA-3000P TRAINING is a respiratory training program through the RSA.

RSA (Respiratory Sinus Arrhythmia) is a normal arrhythmia rhythm influenced by breathing on the signal of the sympathetic and vagus nerve that affect the sinus node. In other words, the variation of heart rate caused by breathing. Through this respiratory training, we can develop the ability to lead a balanced biological rhythms, and get the stress relaxation effect. You can increase the training effect by selecting respiratory rate and expiratory-inspiratory ratio for the patient.

3.3 Composition of Equipment

Be sure to check the following product and accessories are available:

- The list of components

- | | |
|----------------------|--------|
| ① SE-3000P Main Unit | : 1 EA |
| ② Operation Manual | : 1 EA |
| ③ PPG Sensor | : 1 EA |
| ④ Power Cable | : 1 EA |
| ⑤ Fuse(250V/2A) | : 4 EA |

3.4 Description of Equipment symbols



Type BF



Type CF



Power "ON"



Power "OFF"



Attention

PPG

Photo-PlethysmoGraphy

HRV

Heart Rate Variability



Ground



LAN/USB

Chapter 4

Installation of SA-3000P

4.1 Installation

▣ Check point for installation

While installing SA-3000P, observe the following points.

- SA-3000P has to be used under the ambient temperature of 10°C~40°C and humidity of 80%.
- Check the connection with power cord.
- Do not plug in the cords into the same port of other equipment.
- Place the frame on the horizontal surface.
- Be sure to ground the equipment.
- Do not use the electrical cord that generates the connection noise
- Handle the equipment with care, because the equipment can be easily damaged by sudden impacts.
- Place it in a clean place without dust or combustible materials

4.1.1 Power Connection

- Plug the power cable into power port of SA-3000P.
- Please check if each signal input and output is properly connected.
- If the connection is not correct, problems may occur.

4.1.2 The connection of accessories

- Connect the accessories required for measuring into the outlets.

Caution

- The sensor and cable should be handled with caution. Careless use of them may cause damage, as they are very delicate. The cable should be protected against anything sharp.

Warning

- Do not use this equipment with any other medical device. Otherwise it may be dangerous in user.

Chapter 5

Operation

5.1 Before use SA-3000P

Check the followings before measuring a patient.

- Make sure there are no mechanical risk.
- Check the power plug, lead and accessories that are connected to the outside.
- Check all the devices necessary to monitor the patient.

5.2 Use the SA-3000P

5.1.1 Turning on SA-3000P

5.1.2 In case a user changes the setting values during the test, use the menu and then alter the setting.

5.1.3 If you connect the sensor with patient, SA-3000P indicates the patient's data with figure and wave shape on the screen.

5.3 Main window of software

FIG 5.1 is the Main Window of the SA-3000P. The functions and settings of each button is as follows:

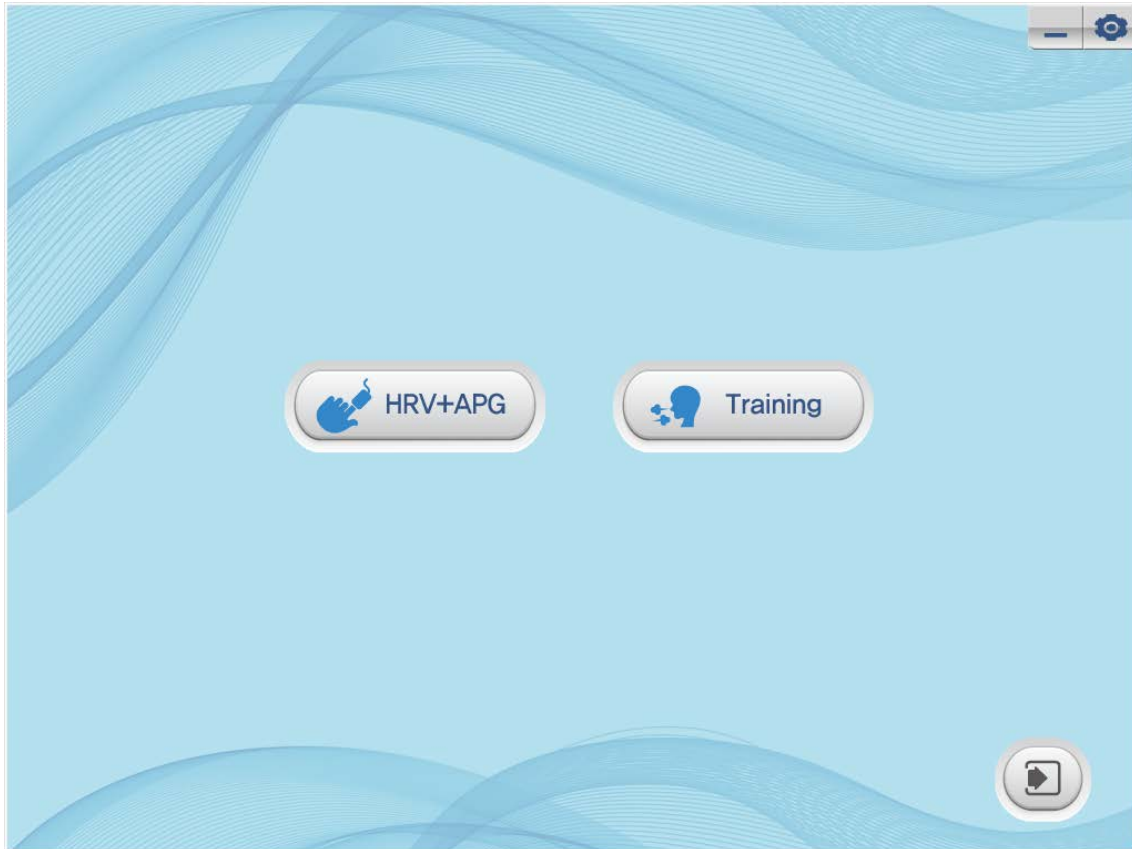





FIG 5.1 MAIN WINDOW OF SA-3000P

HRV+APG	: Perform the program for HRV & APG measurement.
TRAINING	: Perform the program for respiration training.
Minimize ()	: Minimize SA-3000P Software.
Setting ()	: Set up user information, Reference and the name of saved image.
Exit ()	: Exit SA-3000P program.

The figures below are initial screen after executing each function of SA-3000P program.

SETUP

Information

User Name: Medicore

Telephone: 02-1234-5678

User Language: English

Reference Type

East West

File Name Setting

ChartID Date Report - -

FileName : ChartID_Date_Report

OK CANCEL

FIG 5.2 Setup Window of Program

HRV Test Report MEDICORE

HRV Tachogram

Heart Rate

Pulse Wave (PPG) HR Variability

1min 2min 3min

Patient Print Delete Setup Exit Chart ID Name Preview Start Stop

FIG 5.3 HRV INITIAL SCREEN (3M, 5M)

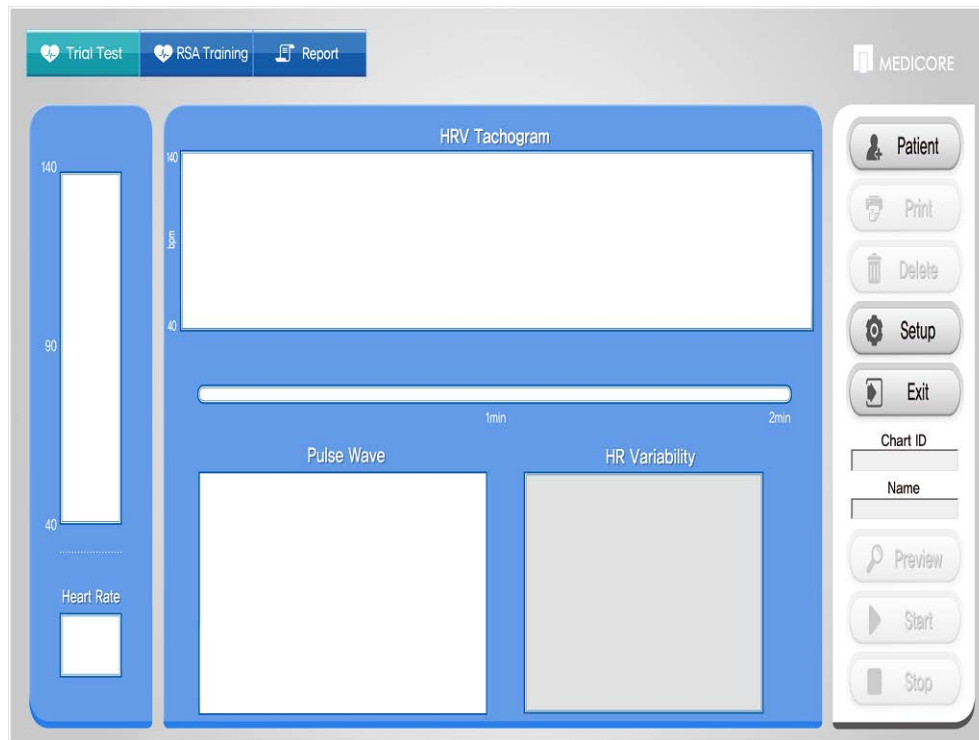


FIG 5.4 INITIAL SCREEN FOR TRAINING

5.5 HRV+APG

5.5.1 HRV+APG Initial Screen

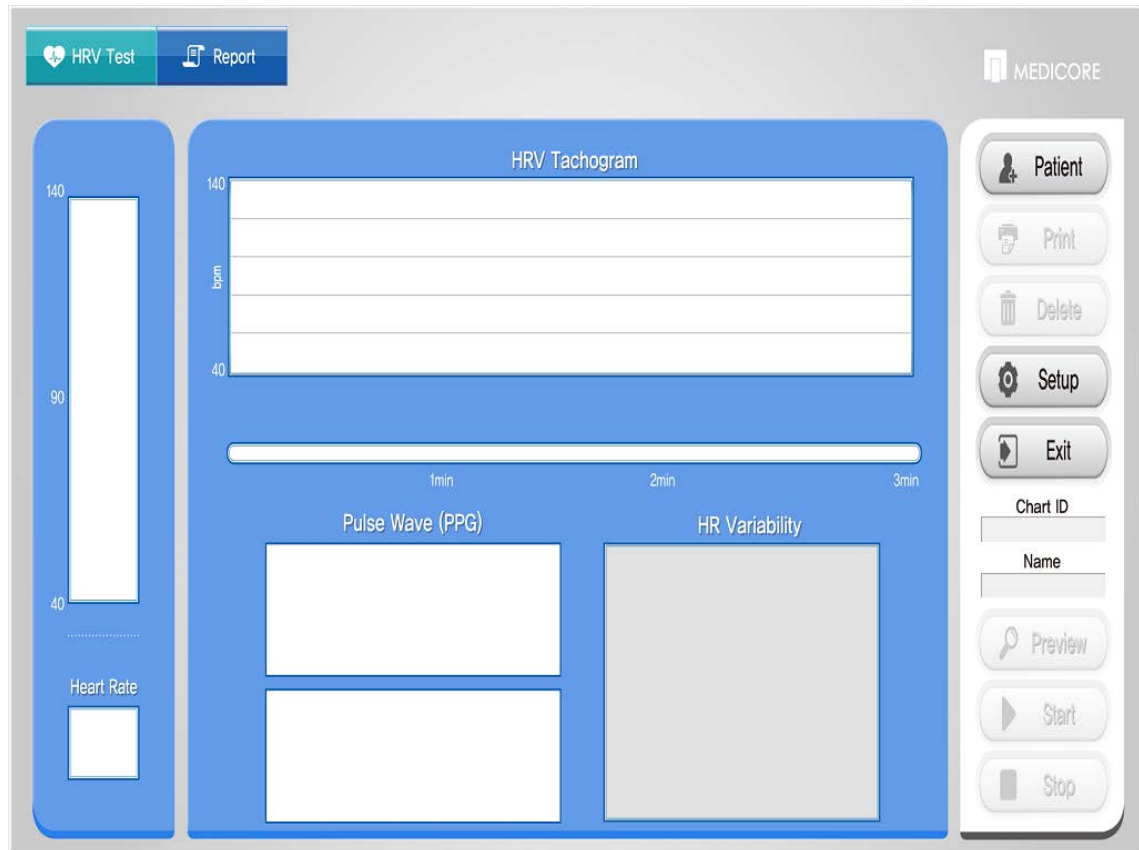


FIG 5.6 HRV INITIAL SCREEN

- Patient : Insert the new patient or import the current data from the list.
- Print : Print the result after the measurement or saved data.
- Delete : Delete of the data.
- Setup : Set up the measurement time (3M, 5M), sound and printing mode (Sheet, Image).
- Exit : Shut down the program.
- Preview : Display the waveforms receiving from the finger sensor.
- Start : Display the HR Variability and HR Distribution at real time.
- Stop : Stop the measurement and initialize the all circumstance.

5.5.2 SETUP Mode

When you click the “SETUP” button on HRV+APG (PPG) screen, the popup as below will be appeared.

The SETUP screen is a light blue dialog box with a title bar labeled "SETUP". It contains several sections with dashed borders:

- Acq.Time**: Four radio buttons for selection: "25beat", "1'30", "3'" (selected), and "5'".
- Open Patient**: Two radio buttons: "General" (selected) and "PACS".
- System**: A "Sound" label followed by a horizontal slider bar with a yellow indicator and a circular mute button.
- Result**: A section containing:
 - A checked checkbox for "Printer".
 - Unchecked checkboxes for "Image" and "E-Mail".
 - A text field showing "C:\SA-3000NEW\Image" with a browse button ("...") next to it.
 - An unchecked checkbox for "File".
 - A text field showing "C:\SA-3000NEW\Image" with a browse button ("...") next to it.

At the bottom are two blue buttons: "OK" and "CANCEL".

FIG. 5.7 SETUP

On SETUP screen, you can make the setting as follows.

- ① Measurement time has 4 modes to be selected such as 25beat, 1M 30S, 3M and 5M.
- ② When the PACS is set like “ON”, the program related to the PACS will be appeared when you click the “Registration” button.
- ③ You can adjust the sound by controlling the sound bar. If you move the slide bar to the left end, the sound will be off.
- ④ You can set up the printing method. If the printer were marked with “V”, you can print out the report and if the Image were marked with “V”, the image in JPG will be saved on this folder. If you mark on E-Mail, you can send the image of result by e-mail.

- ⑤ When you finish all marks, you shall press “OK” button while, if you click “CANCEL”, it will not be saved.

5.5.3 Measurement with HRV +APG (PPG) Mode

1) Patient Registration & Import of Current Patient.

PATIENT INFORMATION

NECESSARY INFORMATION

CHART ID: abcd1234 AGE: 30

NAME: test GENDER: Male Female

BIRTH DATE (MM/DD/YYYY): 08/23/1985 REG / DATE: 2016-06-16

ADDITIONAL INFORMATION

DEPARTMENT: REFERRED BY DR.: LatestDate: Today E:00 P:01 T:00

No.	Chart ID	Name	Age	Sex	Latest Date
1	abcd1234	test	30	Male	2016-06-16

EDIT DELETE OK CANCEL

FIG. 5.8 SELECTION FROM THE CURRENT PATIENT DB

2) Measurement for Patient

- ① After making the patient comfortable at resting, put the probe into the left index finger. (The side where is the cable should be located on the top of the finger.)
- ② Press “Preview” button. (After clicking “Preview” button, the “Start” button will be activated to start in 10 seconds.)
- ③ Please check the Pulse wave if it is stable and also the heart rate is changing stably.
- ④ Click “Start” button.
- ⑤ During your measurement, maintain the position stable without moving and talking.
- ⑥ When the measurement is completed, the result will be automatically analyzed and display the result.
- ⑦ According to the time at SETUP mode, the measurement screen and the report will

be different.

- 25Beat, 1M 30S (APG Screen): APG Report only available
- 3M, 5M (HRV Screen): APG Report, HRV Report available



FIG. 5.9 MEASUREMENT SCREEN (1M 30S, 3M)

3) Storage of Measured Data

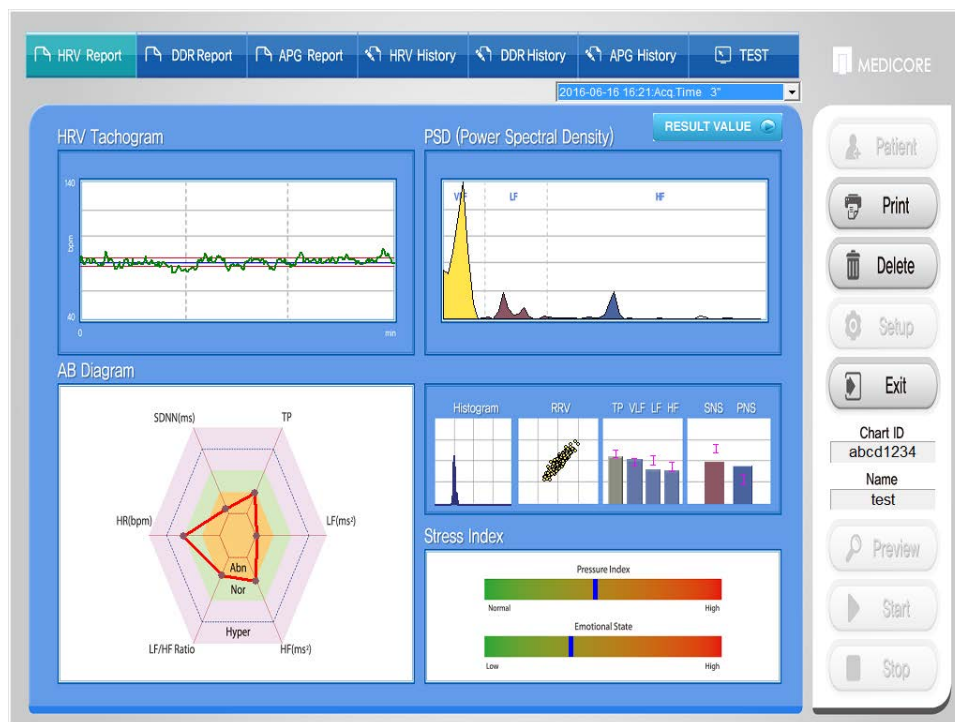
- ① When the measurement is completed, the result will be automatically analyzed and it will be saved in the DB.

5.5.4 Management of Patient and Result Data

You can manage the patient list and measured data conveniently.

1) Selection of Result Data

- ① You can select the patient as the same process mentioned above.
- ② On the top TAB buttons, click one of HRV REPORT, DDR REPORT, APG REPORT, HRV History, DDR History and APG History.



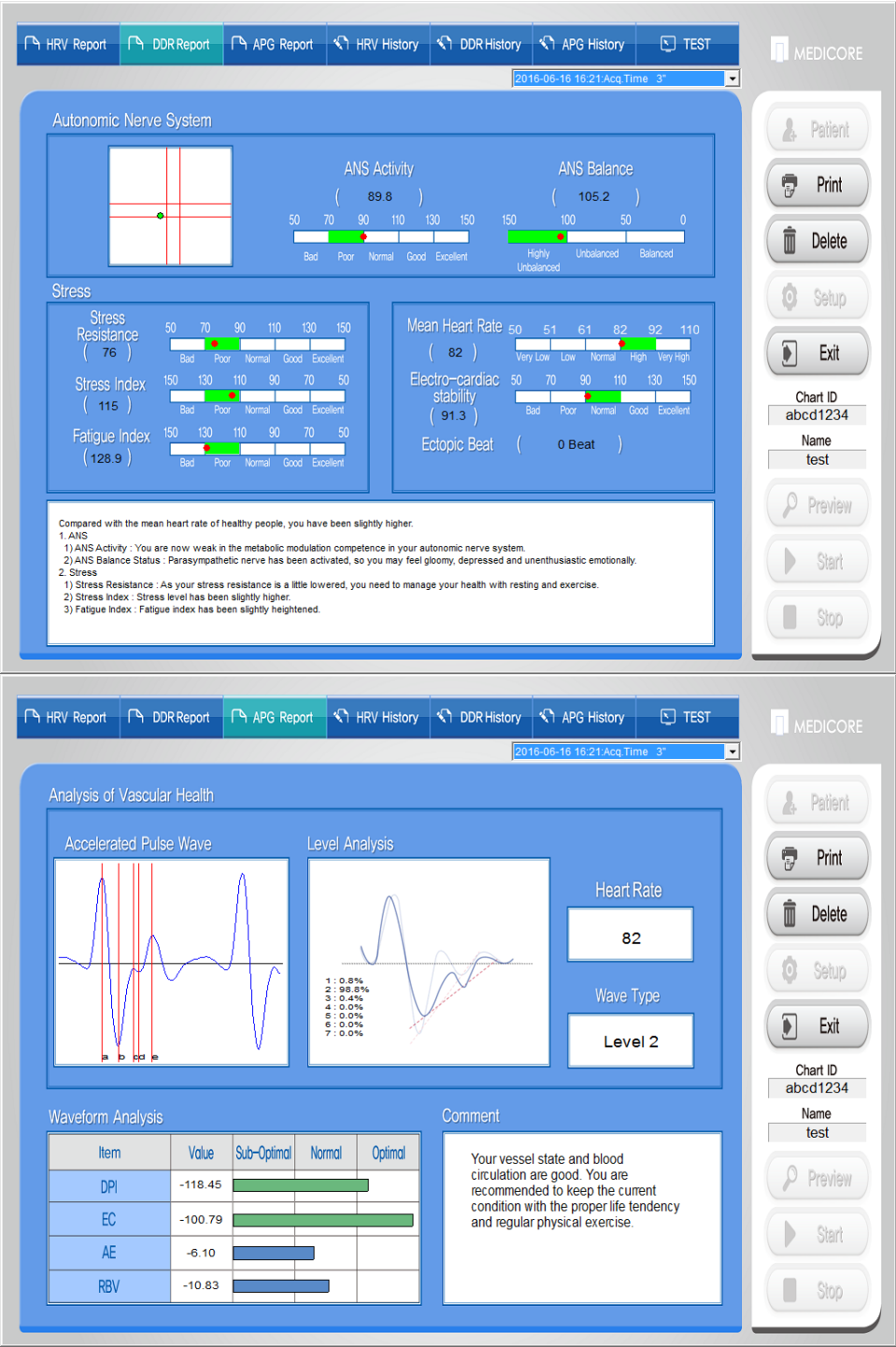


FIG. 5.10 RESULET SCREEN (3M Mode)

- ③ You can see the activated box at the top of right side on REPORT screen. Data will be displayed as following the Measurement Date and Time.
You can select one of them to see the result.
- ④ When you click the button for HRV, DDR and APG Report button, you can

see the result.

- ⑤ When you click the button for HRV, DDR, APG History, you can see the result history for each data.

The image displays two screenshots of the MEDICORE software interface, showing the history of HRV and DDR data. The interface includes a menu bar at the top with options: HRV Report, DDR Report, APG Report, HRV History (selected), DDR History, APG History, and TEST. The main area shows a table of data for two time periods: 2016-04-25 20:55(1) and 2016-06-16 16:21(2). The right sidebar contains buttons for Patient, Print, Delete, Setup, Exit, Chart ID (abcd1234), Name (test), Preview, Start, and Stop.

HRV History Data:

	2016-04-25 20:55(1)	2016-06-16 16:21(2)			
HR(bpm)	88.30	81.80			
SDNN(ms)	21.96	29.51			
RMSSD(ms)	16.35	21.07			
PSI	103.32	63.42			
TP(ms ²)	5.89	6.93			
VLF(ms ²)	5.38	6.58			
LF(ms ²)	4.27	5.04			
HF(ms ²)	4.30	4.96			
LF Norm(n.u.)	49.20	51.87			
HF Norm(n.u.)	50.80	48.13			
LF/HF Ratio	0.97	1.08			
SRD	0.87	0.94			
Artifact	1	0			

DDR History Data:

	2016-04-25 20:55(1)	2016-06-16 16:21(2)			
ANS Activity	64.6	89.8			
ANS Balance	107.6	105.2			
Stress Resistance	67	76			
Stress Index	136	115			
Fatigue Index	139.6	128.9			
Mean Heart Rate	88	82			
Electro-Cardiac Stability	76.3	91.3			
Ectopic Beat	1	0			



FIG. 5.11 RESULT HISTORY

2) Delete the Measured Result of Patient

- ① Select the date of result record and time on HRV Report/ DDR Report screen from the top right side.
- ② Click “Delete” button at the right side.
- ③ When the small window of “Do you want to remove current record permanently?” is appeared, you can click “Y” to delete the data.
- ④ When the window of “Measured data was deleted.” is appeared on the screen, click “Y” button to delete the data.

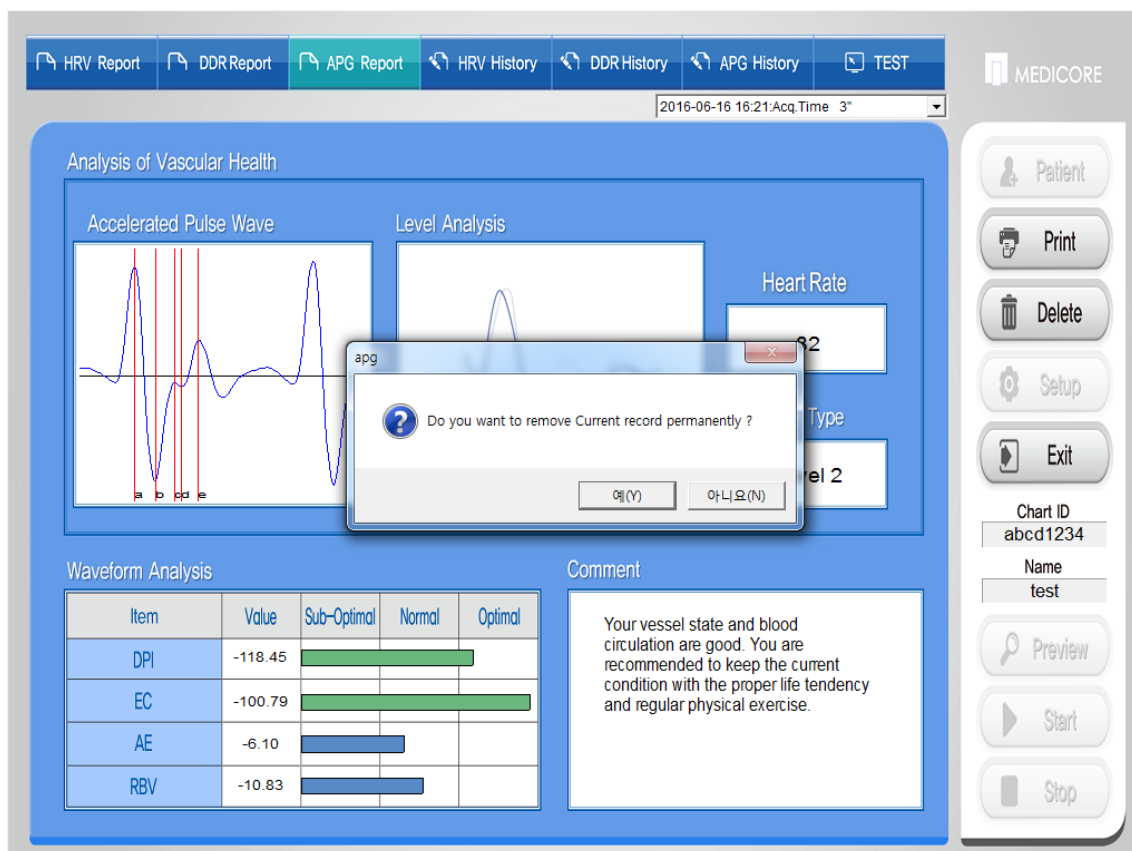


FIG. 5.12 DELETE OF PATIENTDATA (PPG)

5.6 RSA TRAINING

5.6.1 Initial Screen of RSA TRAINING

Below is the main screen when you click the “TRAINING” button.

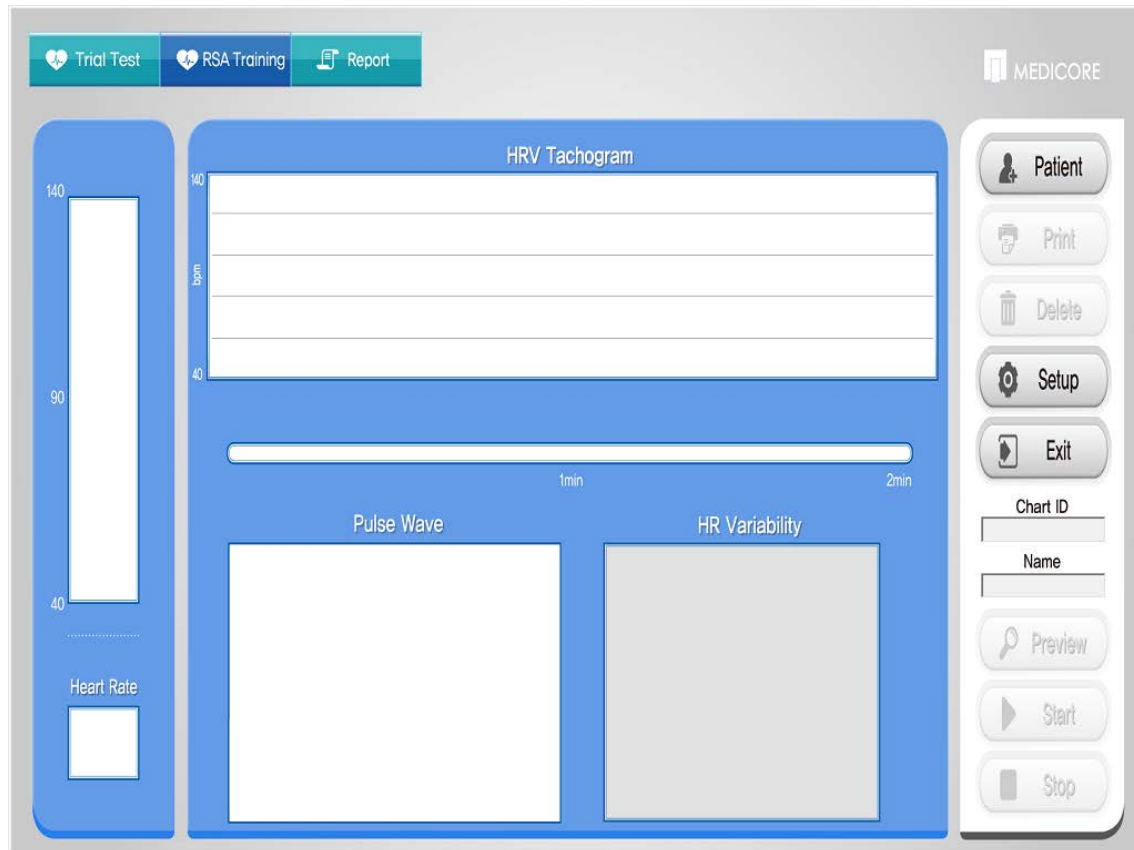


FIG. 5.13 INITIAL SCREEN OF TRAINING

- **REGISTRATION** : Insert the new patient or import the current data from the list.
- **PRINTING** : Print the result after the measurement or saved data.
- **DELETE** : Delete the current data
- **SETUP** : After selecting the measurement time (3M, 5M), set up the sound and printing mode (Sheet, Image).
- **FINISH** : Finish the program.
- **PREVIEW** : Display the waveforms receiving from the finger sensor.
- **START** : Display the HR Variability and HR Distribution at real time.
- **STOP** : Stop the measurement and initialize the all circumstance.

5.6.2 CIRCUMSTANCES

When you click the SETUP button on the TRAINING screen, it will be seen as below screen.



FIG 5.14 CIRCUMSTANCES (Left: Biofeedback, Right: Free)

It is possible to set the function on SETUP as seen below.

- ① Select the training mode (Biofeedback, Free) at your option.
- ② Also can select the Training Time for 3M, 5M, or 10M.
- ③ When you move the sound bar to the end of left, the sound will be mute.
- ④ At the Biofeedback mode, the user can set the targeted breathing difficulties.
- ⑤ The user can set up the targeted breathing number and RSA Image at the Free mode.
- ⑥ When you click “OK” button, all setting will be saved and if you cancel it, it will be returned to the previous SETUP mode.

5.6.3 Breathing Training Method

After selecting the patient, the user can measure the test as following process.

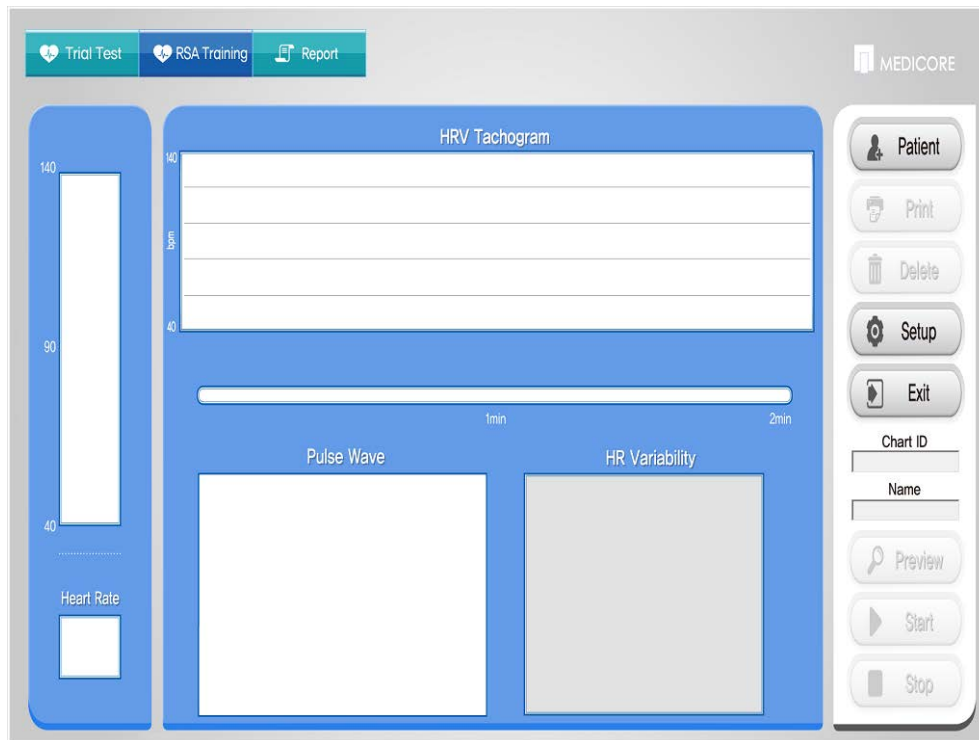


FIG 5.15 MEASUREMENT SCREEN OF TRAINING (Trial Test)

- ① Make the patient comfortable and wear the PPG finger sensor.
- ② Click "Preview". (After clicking Preview button, it will be activated in 10 seconds.)
- ③ Check if the Pulse wave is stable and HR is stable at the left bottom.
- ④ Click "Start" button.
- ⑤ Maintain the patient condition stable during the measurement time.

1) Trial Test

- ① It is the test to calculate how many are breathing numbers of the patient.
- ② Measurement time is 2M and the HRV test should be performed at stable status after wearing the sensor.
(You can select the range of target breathing numbers through the RSA Grade.)

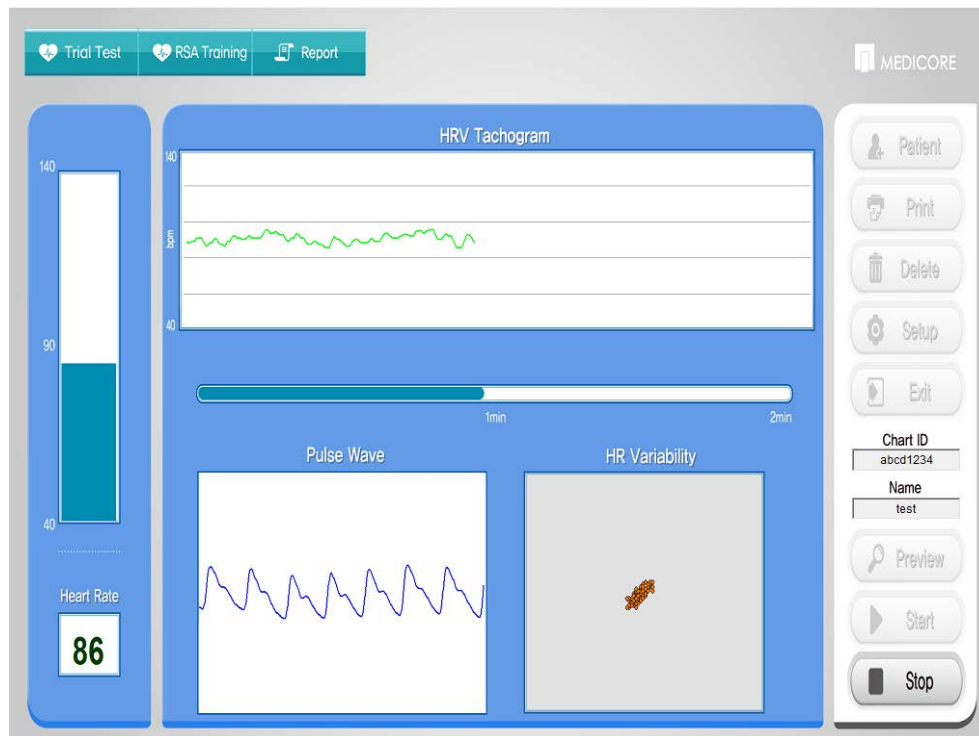


FIG 5.16 TRIAL TEST SCREEN OF TRAINING

2) Biofeedback Mode

- ① The Biofeedback is to do training with the target breathing numbers obtained by the Trial Test.
(Without self-targeting breathing number, it cannot start the Biofeedback.)
- ② After wearing the sensor in comfort, follow the training method as above **5.7.3 Breathing Training method**.
- ③ If the user feels hard to follow the breathing training for 5M, you can adjust the training for 2M and break the time for 30 seconds and then, do training again for 2M.

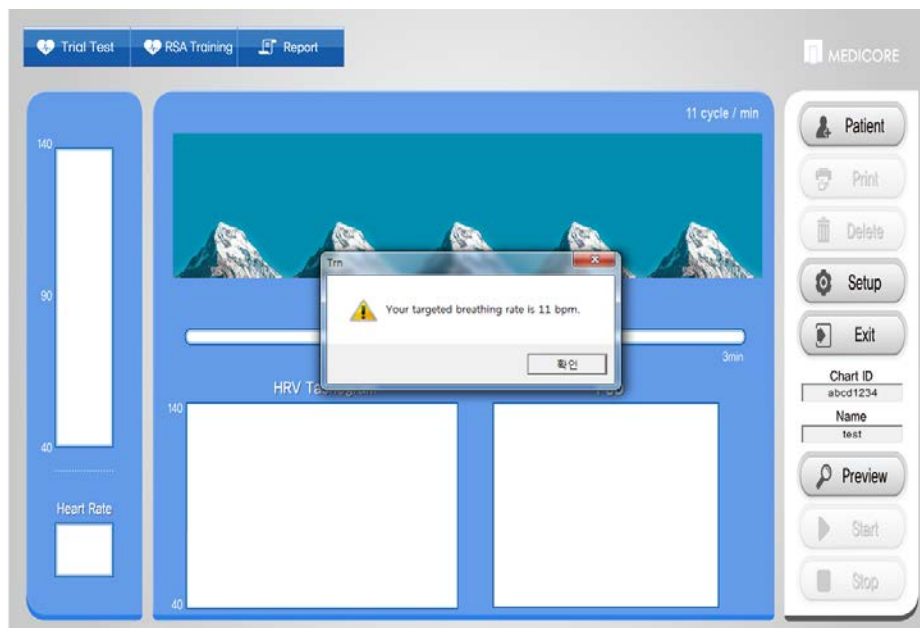


FIG 5.17 TRAINING SCREEN OF TRAINING (Biofeedback)

3) Free Mode

- ① At this mode, it is to do training by selecting the free target breathing numbers at the SETUP. (In this case, without the Trial Test, you can do training.)
- ② RSA Image can be selected at the SETUP screen.
- ③ Follow the training method of ②~④ at the stable status after wearing the sensor.
- ④ If the breathing training were hard to follow for 5M, you could do training for 2M and then, break the time for 30 seconds. Do training again for 2M.

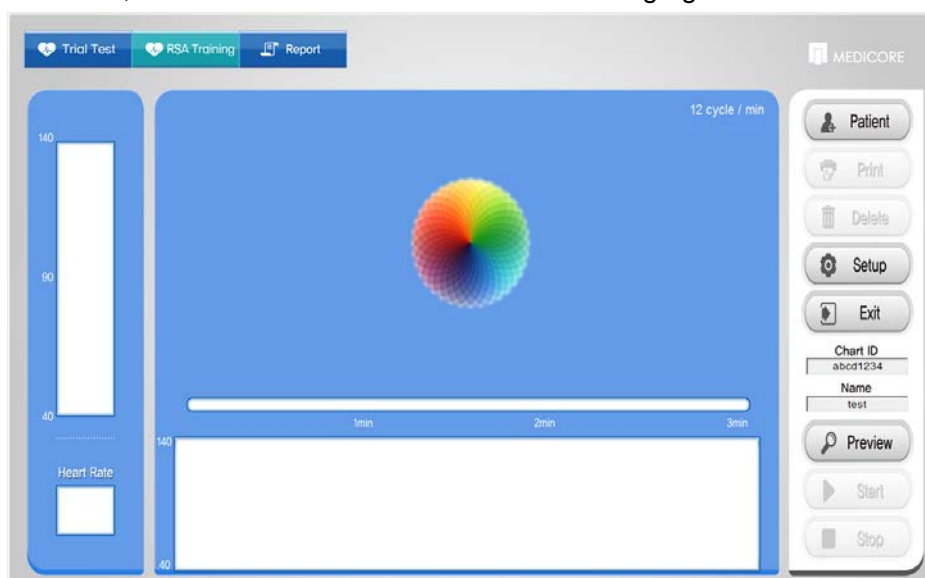


FIG 5.18 TRAINING SCREEN OF TRAINING (Free MODE)

5.6.4 Management Method of Patient & Data

1) Management Method

5.5.3 Patient's measurement method & Management – As same as 2).

2) When the data is selected

- ① Select the patient.
- ② Click "Report" at the top of TAB button. At the initial screen, all TABs are already pressed. In this case, you will see the following screen.



FIG 5.19 RESULT SCREEN OF TRAINING

3) Delete Measured Data of Patient

- ① Select the date or time to be deleted that was measured from the top right side of HRV Report/ DDR Report.
- ② Click “Delete” button at the right side.
- ③ If the message of “Do you want to remove current record permanently?” were appeared, would click “Y” button.
- ④ If the data were deleted, would see the “Data was completely deleted.”. Then, click “Y” to delete the data.

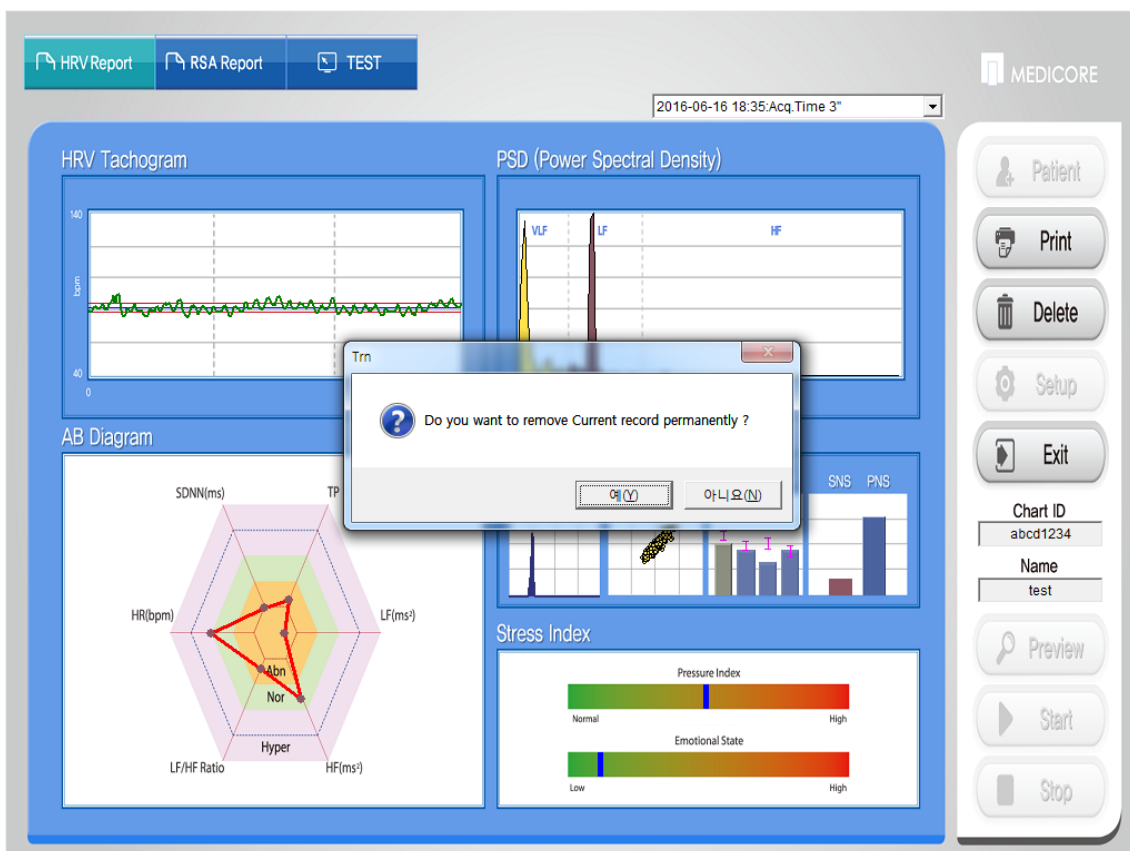


FIG 5.20 DELETE OF PATIENT DATA

Chapter 6

Trouble shooting

6.1 System malfunction

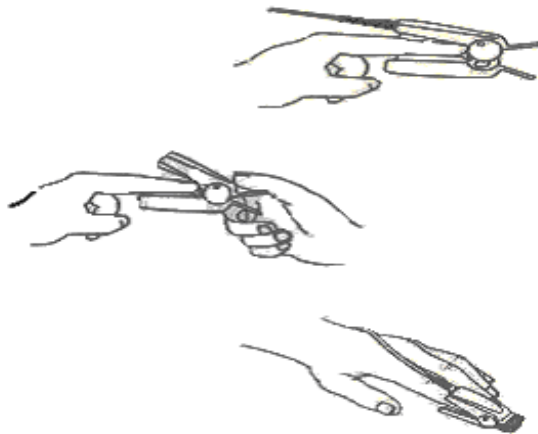
- ① Pulse wave is not shown during preview.
→ Check the connection between the probe and main body.
- ② Do not measuring during executing print-out; SA-3000P shows and records the real-time data, so if operator performs measurement and print at the same time, serious malfunction occurs.
- ③ Do not execute any other program during SA-3000P program performed.

Chapter 7

Use of Finger Sensor

7.1 Attachment of the PPG Probe

- ① Clean the applicable areas with alcohol.
- ② Place probe to the index finger (2nd finger) of left hand as illustrated in the picture below.



7.2 Treatment and Checks

- ① After putting the PPG Probe, check the waveform with the button “Preview” and if the heart rate is changing stably, it works properly.
- ② If the waveform is not displayed properly or the heart rate is shown abnormally, check the connection of sensor.

Chapter 8

Description of Terms

Bio-Signal processing: Bio-signal refers to all signals we can get from a body. Medcore Co., Ltd. Co., Ltd. device is interested in obtaining signal through blood volume in the capillary vessel of tip of fingers. Analysis of above waveform is possible, but to obtain more specific and precise information we process signals. These are called Bio-Signal processing.

HRV (Heart Rate Variability): Heart Rate is the speed of the heartbeat measured by the number of poundings of the heart per unit of time — typically beats per minute (BPM). For the normal people, the heart rate is continuously changed within specific range. And, it is called “HRV (Heart Rate Variability)”. (Generally, the healthy people have a much wider range of the variation of heart rate.)

Time-domain method: It is one of the ways to analyze the degree of HRV by statistic analyzing of R-R interval.

Frequency-domain method: It is one of the ways to analyze the degree of HRV by evaluating the power of each frequency bands. It is used as an index of analyzing the activation degree of Sympathetic & Parasympathetic nervous system.



MEDICORE

Certificate of Quality and Warranty

- This product is manufactured with the thorough quality control and strict inspection. Medicore Co., Ltd. warrants its product against defects in material and workmanship for one year. During the warranty period, Medicore will, at its option, repair or replace product which proves to be defective. Product that is installed by Medicore or its authorized distributor carries a warranty from the installation date, all others from the shipment date.

- Medicore Co., Ltd. warrants the product for a period of one year.

- The warranty shall not be applied to defects resulting from:

1. Improper or inadequate maintenance, adjustment, calibration, or operation by buyer.
2. Buyer-supplied software, hardware, interfacing apparatus, kits or consumables without Medicore's approval.
3. Indirect defects which do not affect main function and performance such as appearance.

Medicore may require the appropriate service charge for buyer's service call, if the defects occurred from the above cases.

- When you contact us to request product service, please have some information handy including the description of troubles and product's model number, serial number.
- Medicore has no responsibility or liabilities for the products out of warranty.