

SA Series

Ambulatory Blood Pressure Monitor
Version 1.2

User Manual

CE₀₁₂₃



About this Manual

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Statement

This manual will help you understand the operation and maintenance of the product better. It is reminded that the product shall be used strictly complying with this manual. User's operation failing to comply with this manual may result in malfunction or accident for which EDAN INSTRUMENTS, INC. (hereinafter called EDAN) cannot be held liable.

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Product Information

Product Name: Ambulatory Blood Pressure Monitor

Model: SA-10, SA-05, SA-06, SA-08, and SA-09

Responsibility of the Manufacturer

EDAN only considers itself responsible for any effect on safety, reliability and performance of the equipment if:

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by EDAN, and

The electrical installation of the relevant room complies with national standards, and
The instrument is used in accordance with the instructions for use.

Terms Used in this Manual

This guide is designed to give key concepts on safety precautions.

WARNING

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

CAUTION

A **CAUTION** label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

NOTE

A **NOTE** provides useful information regarding a function or a procedure.

Table of Contents

Chapter 1 Safety Guidance	1
1.1 Indications for Use/Intended Use.....	1
1.2 Warnings and Cautions	1
1.2.1 General Warnings	1
1.2.2 Protecting Personal Information	4
1.2.3 Battery Care Warnings	6
1.2.4 General Cautions.....	6
1.2.5 Contraindications	7
1.3 List of Symbols	8
Chapter 2 Introduction.....	11
2.1 About ABPM	11
2.2 ABP Monitor at a Glance.....	12
Chapter 3 Setting up ABPM.....	14
3.1 Powering the Monitor for Use.....	14
3.2 Installing Analysis Software	14
3.3 Logging in to Analysis Software	14
3.4 Connecting the Monitor to PC	15
Chapter 4 Main Screen of Analysis Software	17
Chapter 5 Conducting an Ambulatory BP Study	19
5.1 Programming the Monitor.....	19
5.2 Fitting Patient with the Monitor and Cuff.....	20
5.3 Preparing the Patient	22
5.4 Measurement Limitations	22
5.5 Starting the Study.....	23
5.6 Finishing the Study	23
Chapter 6 Retrieving ABP Data.....	24
Chapter 7 Analyzing and Editing ABP Data.....	25
7.1 Editing Patient Information.....	25
7.2 Data Table	25
7.3 Day & Night BP Profile	25
7.4 Correlation.....	27
7.5 Histogram.....	27
7.6 Pie Chart.....	27
7.7 Variability	27
7.8 Statistics	28
7.9 Conclusion	28
Chapter 8 Creating Reports	29
Chapter 9 System Setting	30

9.1 General Setting	30
9.2 Patient Information Setting	30
9.3 Security Setting	31
9.4 Communications Setting	31
9.5 Report Setting	32
9.6 Barcode Setting	32
9.7 GDT	33
Chapter 10 Error Codes	35
Chapter 11 Cleaning, Care and Maintenance	37
11.1 General Points	37
11.2 Cleaning	37
11.2.1 Cleaning the Monitor and Carrying Pouch	38
11.2.2 Cleaning the Cuff Sleeve, Bladder, and Hose	38
11.3 Disinfection	39
11.4 Care and Maintenance	40
Chapter 12 Accessories	44
Chapter 13 Warranty and Service	45
13.1 Warranty	45
13.2 Contact information	45
Appendix 1 Technical Specifications	46
A1.1 Safety Specifications	46
A1.2 Environment Specifications	47
A1.3 Physical Specifications	47
A1.4 Power Supply Specifications	47
A1.5 Performance Specifications	47
A1.6 Configuration Difference	48
Appendix 2 EMC Information	49
Appendix 3 Abbreviation	55

Chapter 1 Safety Guidance

This chapter provides important safety information related to the use of SA series ambulatory blood pressure monitor (as referred to below as ABPM).

1.1 Indications for Use/Intended Use

The Ambulatory Blood Pressure Monitor is capable of measuring systolic and diastolic blood pressures, and pulse of adults and pediatrics (> 12 years) over a preprogrammed period of time. These measurements are stored in the monitor and can be transferred to analysis system via wire or wireless transmission. It is intended for use as an aid or adjunct to diagnosis and treatment.

WARNING

1. This device is not intended for treatment or monitoring.
 2. This device is not intended for use with pregnant women, including preeclamptic patients, and neonates.
 3. The device is intended to be used in hospitals and clinics.
 4. The results given by the system should be examined based on the overall clinical condition of the patient, and they cannot substitute for regular checking.
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1.2 Warnings and Cautions

In order to use the Ambulatory Blood Pressure Monitor (ABPM) safely and effectively, and avoid possible dangers caused by improper operation, please read through the user manual and be sure to be familiar with all functions of the device and proper operation procedures before use. The following warnings and cautions must be paid more attention to during the operation of the system.

1.2.1 General Warnings

WARNING

1. The device is intended to be used by qualified physicians or personnel professionally trained. They should be familiar with the contents of this user manual before operation.
2. The monitor must be used in its carrying pouch to protect it from liquid splash or solid

- foreign objects.
3. Do not measure ambulatory blood pressure on patients with sickle-cell disease or any condition where skin damage has occurred or is expected.
 4. Do not measure ambulatory blood pressure on the arm of the same side with a mastectomy. Too frequent measurements can cause injury to the PATIENT due to blood flow interference.
 5. Use clinical judgment to decide whether to perform frequent blood pressure measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.
 6. Do not apply the cuff to a limb that has an intravenous infusion or catheter in place. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.
 7. Do not attach the cuff to a limb being used for IV infusions as the cuff inflation can block the infusion, potentially causing harm to patient. Do not apply the CUFF over a wound, as this can cause further injury.
 8. Do not apply the cuff to a limb where intravascular access or therapy, or an arterio-venous (A-V) shunt is present, otherwise, it may result in injury to the patient.
 9. Using an incorrect cuff size could result in erroneous and misleading blood pressure measurement results and even harm due to over-pressure.
 10. Make sure that the air conduit connecting the blood pressure cuff and the monitor is neither blocked nor tangled.
 11. Measuring of blood pressure can temporarily cause malfunctioning of other medical monitoring devices on the same limb.
 12. Ambulatory blood pressure readings can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic conditions.
 13. Continuous cuff pressure due to connection tubing kinking can block the blood flow, and may result in injury to the patient.
 14. Do not use the monitor on patients who are using cardiopulmonary devices and defibrillators and patients who are severely ill or in the intensive care unit (ICU).
 15. Check (for example, by observation of the limb concerned) that operation of the ABPM does not result in prolonged impairment of the circulation of the blood of the PATIENT.
 16. The monitor provides over-pressure protection and thus will not inflate excessively.

17. Only service engineers authorized by the manufacturer can open the shell. Otherwise, safety hazards may happen.
 18. **EXPLOSION HAZARD** - Do not use the system in the presence of flammable anesthetic mixtures with oxygen or other flammable agents.
 19. If multiple instruments are connected to a patient, the sum of the leakage currents may exceed the limits given in the IEC/EN 60601-1 and may pose a safety hazard. Consult your service personnel.
 20. Only the cuff and other accessories supplied by the manufacturer can be used. Or else, the performance and electric shock protection cannot be guaranteed. The system has been safety tested with the recommended accessories, peripherals, and no hazard is found when the system is operated with cardiac pacemakers or other stimulators.
 21. Do not use the device in strong magnetic and electrostatic environments.
 22. Do not use the device together with the high frequency surgical equipment.
 23. Do not touch patients with the device when defibrillators are discharging because it will damage the monitor and result in incorrect readings.
 24. The use of equipment that applies high frequency voltages to the patient (including electrosurgical equipment and some respiration transducers) is not supported and may produce undesired results. Take off the monitor or cuff from the patient prior to performing any procedure that uses high frequency surgical equipment.
 25. The operation or use of non-approved equipment or accessories with the device is not tested or supported, and system operation and safety are not guaranteed.
 26. Continuous automatic measuring mode for short intervals may lead to the discomfort of patient.
 27. Prevent babies or children from swallowing small components, e.g. the batteries.
 28. SA series ABPM are precision instruments. Prevent babies or children from playing them.
 29. The equipment should not be used adjacent to or stacked with other equipment, refer to the recommended separation distances provided in Appendix 2 EMC Information.
 30. The use of monitor and other accessories not supplied by the manufacturer may result in increased emissions or decreased immunity of the equipment.
 31. Do not perform service or maintenance of the equipment while it is in use with the patient.
-

32. Assembly of the ABPM and modifications during actual service life shall be evaluated based on the requirements of IEC60601-1.
33. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
- 1) This device may not cause harmful interference, and
 - 2) this device must accept any interference received, including interference that may cause undesired operation.

CAUTION

1. Do not use the monitor if it displays a greater than zero pressure with no cuff attached. The values displayed by such a monitor may be inaccurate.
 2. Ambulatory blood pressure measurement can be affected by extremes of temperature, humidity and altitude.
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NOTE:

- 1 It is suggested that the user should not start ambulatory BP measuring when the low battery displays, or the monitor may be turned off automatically.
- 2 If you spill liquid onto the equipment or accessories, particularly if there is a chance that it can get inside the tubing or the measurement device, contact your service personnel.
- 3 BP measurement value should be explained by qualified professionals.
- 4 The pulse rate based on the ambulatory BP measurement may differ from the heart rate based on the ECG waveform. Ambulatory BP measures the number of peripheral pulse pulsations, and the heart rate is measured by the electrical signal of the heart. When the electrical signals of the heart occasionally fail to cause the peripheral blood vessels to pulse or the patient's peripheral perfusion is poor, the difference happens.
- 5 Pay attention to the surrounding environment when entering passwords.

1.2.2 Protecting Personal Information

Protecting personal health information is a major component of security strategy. To protect the personal information and ensure the proper device performance, the user should take necessary precautions in accordance with local laws and regulations and institution's policies. EDAN recommends health care organizations or medical institutions to implement a comprehensive and multifaceted strategy to protect the information and systems from internal and external security threats.

To ensure the patients' safety and protect their personal health information, the user should implement practices or measures that include:

1. Physical safeguards - physical safety measures to ensure that unauthorized personnel do not have access to the ABPM.
2. Operational safeguards - safety measures during operation.
3. Administrative safeguards - safety measures in management.
4. Technical safeguards - safety measures in technical field.

CAUTION

- 1 The access/operation of the ABPM is restricted to authorized personnel only. Assign only staff with a specific role the right to use the ABPM.
- 2 Ensure that all device components maintaining personal information (other than removable media) are physically secure (i.e. cannot remove without tools).
- 3 Ensure that the ABPM is connected only to the device authorized/approved by EDAN. Users should operate all EDAN deployed and supported ABPMs within EDAN authorized specifications, including EDAN approved software, software configuration, security configuration, etc.
- 4 Protect all the passwords to prevent unauthorized changes.
- 5 Anti-virus measures such as USB device virus scanning should be carried out prior to using USB flash drive.
- 6 Firewalls and/or other security devices should be in place between the medical system and any externally accessible systems. Firewalls and/or other security devices should be in place between the medical system and any externally accessible systems. It's recommended to use Windows defender firewall or any other firewall that can defend against Dos and DDos attacks, and keep it up to date.
- 7 When the ABPM is returned for maintenance, disposed of, or removed from the medical institution for other reasons, it is necessary to ensure that all patient data are removed from the ABPM.
- 8 Please protect the privacy of the information and data displayed on the screen, and those information and the data stored in the monitor.
- 9 It is recommended that you activate Windows password strategy.
- 10 Users should make a backup of data on a periodic basis.
- 11 Install security software, anti-virus software, and activate firewall and auto updates. Run the anti-virus software on a regular basis. Add the master computer software to the whitelist.
- 12 Disable unnecessary services from the operating system and reduce vulnerabilities.

- 13 Close the default services of remote desktop, Telnet, file sharing of Windows.
 - 14 It is recommended that you disable the Administrator and Guest accounts.
 - 15 Destroy the sensitive information in the idle or scrapped device.
-

1.2.3 Battery Care Warnings

WARNING

1. Improper operation may cause the internal battery to be hot, ignited or exploded, and it may lead to the decrease of the battery capacity. It is necessary to read the user manual carefully and pay more attention to warning messages.
 2. Batteries of the same model and specification as manufacture configuration should be used.
 3. **DANGER OF EXPLOSION** -- Do not reverse the anode and the cathode when installing the battery.
 4. Do not heat or splash the battery or throw it into fire or water.
 5. Do not destroy the battery; do not pierce battery with a sharp object such as a needle; do not hit with a hammer, step on or throw or drop to cause strong shock; do not disassemble or modify the battery.
 6. When leakage or foul smell is found, stop using the battery immediately. If your skin or cloth comes into contact with the leakage liquid, cleanse it with clean water at once. If the leakage liquid splashes into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.
 7. Properly dispose of or recycle the depleted battery according to local regulations.
 8. Remove the battery from the monitor when the monitor is not in use for long periods of time to prevent possible battery leakage and product damage.
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1.2.4 General Cautions

CAUTION

1. Avoid liquid splash and excessive temperature. The temperature must be kept between 5 °C and 40 °C during operation, and it should be kept between -20 °C and 55 °C during transportation and storage.

2. Do not use the equipment in a dusty environment with bad ventilation or in the presence of corrosive.
 3. Make sure that there is no intense electromagnetic interference source around the equipment, such as radio transmitters or mobile phones etc. Attention: large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment etc. is likely to bring electromagnetic interference.
 4. The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Batteries are hazardous waste. Do NOT dispose of them together with house-hold garbage. At the end of their lives hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office, or the shop where you purchased the product.
 5. The time required for the ABPM to warm from the minimum storage temperature between uses until it is ready for intended use is at least 2 hours; and the time required for the ABPM to cool from the maximum storage temperature between uses until it is ready for intended use is at least 2 hours.
 6. The monitor should not be modified in any way.
 7. Federal (U.S.) law restricts this device to sale by or on the order of a physician.
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1.2.5 Contraindications

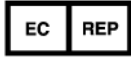





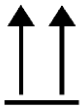





Do not use on patients with erratic, accelerated or mechanically controlled irregular heart rhythms, including patient with arrhythmias.


Due to the strangulation risk posed by the cuff and hose, the SA series ABPM must not be within reach of unsupervised children, and must not be used on unsupervised patients with limited cognitive abilities.

The SA series ABPM is not intended for alarm triggering monitoring purposes in intensive care units, and must not be used for blood pressure monitoring purposes in intensive care units or during surgery.

1.3 List of Symbols

No.	Symbol	Description
1		DEFIBRILLATION-PROOF TYPE BF APPLIED PART
2		USB socket
3		On/Off button
4		Start/Stop button
5	IP 22	Protected against solid foreign objects of 12.5 mm Ø and greater Protected against vertically falling water drops when enclosure tilted up to 15°
6		Caution
7		Consult instruction for use
8		General symbol for recovery/recyclable
9	P/N	Part Number
10		SERIAL NUMBER
11		Date of manufacture
12		MANUFACTURER

13		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
14		CE marking
15		Disposal method
16	Rx Only	Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.
17		Refer to instruction manual/booklet (Background: Blue; Symbol: White)
18		General warning sign (Background: Yellow; Symbol & Outline: Black)
19		Non- ionizing electromagnetic radiation
20		This way up
21		Fragile, handle with care
22		Keep away from rain
23		Stacking limit by number
24		Handle with care
25		Do not step on

26	<p style="text-align: center;">Front</p> 	Front
27	FCC ID: SMQSAEDAN	Federal Communications Commission: FCC ID: SMQSAEDAN

NOTE: The user manual is printed in black and white.

Chapter 2 Introduction

2.1 About ABPM

The Ambulatory Blood Pressure Monitor consists of a blood pressure monitor (as referred to below as monitor) and analysis software. The monitor inflates and deflates the cuff on the upper arm to measure blood pressure by the oscillometric method and stores the measurement. The stored measurements are transferred to a PC via wired or wireless transmission and analyzed by the analysis software.

The ABPM is used to measure systolic and diastolic blood pressures, and pulse of adult patients and store the measurement data for clinical diagnosis.

Oscillometric devices measure the amplitude of pressure changes in the occluding cuff as the cuff deflates from above systolic pressure. The amplitude suddenly increases as the pulse breaks through the occlusion in the artery. As the cuff pressure decreases further, the pulsations increase in amplitude, reach a maximum (which approximates to the mean pressure), and then diminish.

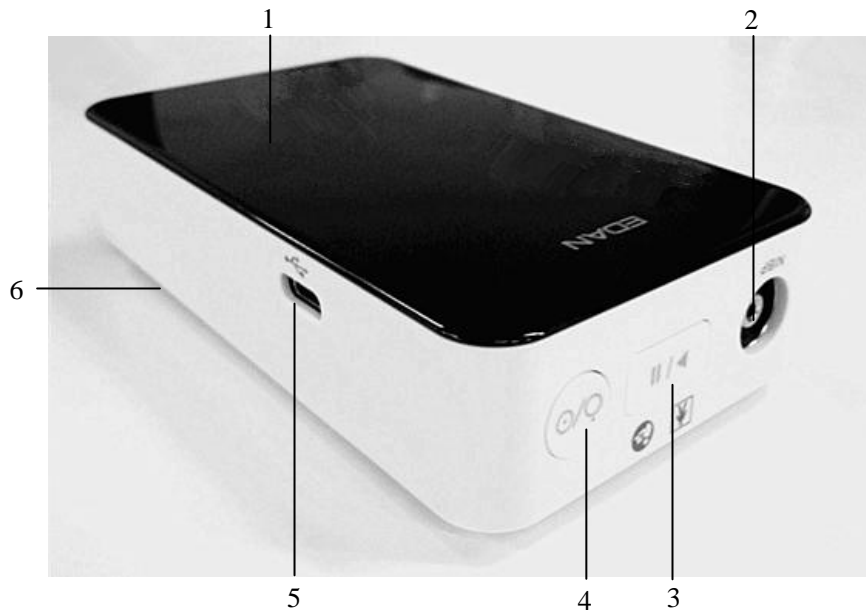
The blood pressure measurements determined with this device comply with the American National Standard for Electronic or Automated Sphygmomanometers (ISO 81060-2) in relation to mean error and standard deviation. In clinical investigation method with a reference sphygmomanometer, the fifth Korotkoff sound was used to determine adult diastolic pressure.




The ABPM is useful for:

- ◆ Showing 24-hour BP profile
- ◆ BP data storage and query
- ◆ Comparing two studies conducted on the same patient
- ◆ Bluetooth module for wireless transmission (optional)
- ◆ BP data loading and retrieving, and statistical analysis of the ABP study
- ◆ Report preview, printing, and configuration

NOTE: The pictures and windows in this manual are for reference only.




2.2 ABP Monitor at a Glance



1	/	OLED screen	Displaying time, automatic or manual BP readings.
2	/	Hose connection	To connect the extension hose from the cuff to monitor for an ambulatory BP study.
3		Start/Stop button	To start a programmed ABP study: when 24-hour time is displayed, press this button to take first reading. To abort a measurement: press this button any time during a reading. To start a manual BP reading: Press this button before/after an auto reading. To mark an event: Press and hold this button for 3 seconds when not reading.
4		On/Off button	To power on, when the monitor is properly loaded with batteries, the monitor will be automatically powered on. If the display is not illuminated, press the On/Off button. To power off, when not taking a reading, press and hold the button till the display turns off, then release.
5		Type-C interface	To connect the monitor to a PC by a USB cable for the purpose of monitor programming and BP data transmission.
6	/	Battery compartment	To place two AA batteries for power supply.

CAUTION

The ABP monitor cannot be charged. DO NOT use the type-C interface for charging.

Keys/Icons	Description
	Bluetooth connection If this icon is not seen on the display, you need to match the device manually.
	Event mark When this icon flashes, it indicates you can enter a patient activity.
	When this icon flashes, it indicates low battery.

Chapter 3 Setting up ABPM

Setting up the ABPM involves powering on the BP monitor, installing the analysis software on a personal computer (PC), and connecting the BP monitor to the PC.

The ABPM is packaged with everything you need to start. See Accessories for complete contents.

3.1 Powering the Monitor for Use

Install two AA batteries in the bay located at the back of the monitor. The bay shows the orientation in which the batteries should be placed. When batteries are properly loaded, the monitor will automatically start up and its display will show the model type and version. When you see the 24-hour time, the monitor is ready to be used.

NOTE:

1. Always use fully charged batteries for a new measurement.
2. When installing the batteries, please ensure correct orientation.
3. Please remove the batteries if the device has not been used for a long period.
4. Different battery types may have different capacities and characteristics, so their service life and the battery level indicated on the display may vary.

3.2 Installing Analysis Software

PC System Requirement

Operating System	Windows XP, Windows 7, Windows 8, or Windows 10
CPU	Dual core 2 GHZ or above
System Memory (RAM)	>2G, 4G recommended
Hard Disk	>128G, 256G recommended
Resolution	1024*768, 1366*768, 1280*1024, 1440*900, and 1920*1080

Insert the CD to your PC and follow the instructions to install the analysis software.

3.3 Logging in to Analysis Software

Double click the ABPM icon. If you have set password, you must enter it to log in. For the setting and change of passwords, see Section 9.4 *Communications Setting*.

3.4 Connecting the Monitor to PC

When the analysis software is installed and logged in, you can connect the ABP monitor to your PC by a USB cable.

1. Connect the Type-C end of the cable to the Type-C interface of the ABP monitor.
2. Connect the USB end of the cable to the USB port on your PC.

Wireless Communication

The ABPM may be equipped with an optional Bluetooth module that will allow communications with your PC for monitor programming and BP data transmission.

The steps are as follows:

1. Connect the Bluetooth adapter to a USB port in your PC.
2. Establish Bluetooth pairing in two ways: auto and manual.
 - Auto: when you power on the ABP monitor, it automatically enters the pairing mode and starts pairing with a Bluetooth host.
 - Manual: Press the On/Off button and hold on. Then press the Start/Stop button to start pairing with a Bluetooth host.
3. The Bluetooth icon on the monitor display flashes which means entering the pairing mode.
4. Select System Setting > Communications Setting > Bluetooth and click **Bluetooth search** in your PC. The devices ready for Bluetooth connection are displayed.
5. Select the device to connect. Click **Connect**.
6. Enter “1234” to the PIN text box. Click **OK**. If pairing is not finished in 3 minutes, the monitor automatically exits the pairing mode. If pairing is successful, the Bluetooth icon on the monitor display will light up constantly.

NOTE:

1. The distance for barrier-free data transmission via Bluetooth is 5 meters.
2. Please use the connection method that you configure in the Communications Setting.

WARNING

1. Using devices of other companies may cause software incompatibility. If necessary, contact your local distributor.
 2. Use the accessories not supplied by the manufacturer may damage the equipment and compromise equipment performance and safety.
 3. Batteries of the same model and specification as manufacture configuration should be used.
 4. When the batteries are exhausted, they needs to be replaced.
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5. If the Bluetooth adapter provided by the manufacturer is lost, the UGREEN Bluetooth 4.0 adapters are recommended.
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Chapter 4 Main Screen of Analysis Software

The analysis software allows you to program the monitor, collect and retrieve important test data, and analyze the data. After login to the software, you enter the main screen (BP data screen).

The screenshot shows the 'Smart ABPM View' software interface. At the top, there is a menu bar with icons for Program, BP Data, Retrieve, Setting, Help, About, and Exit. On the left side, there is a folder structure with 'Register DB', 'Recorder DB', and 'Recycle'. The main area contains a search bar and a table of patient data. At the bottom, there are buttons for Import, Export, and Delete. Red annotations point to the Menu, Folder, Patient query, Patient list, and Button areas.

Patient ID	Name	Gender	Age	Department	Inpatient Area	Room No.	Exam. Time	Study duration
000	DEMO	M	30				12-08-2019 09:00:00	24:00
000	DEMO	M	30				10-08-2019 09:00:00	24:00
000	DEMO	M	30				10-08-2019 09:00:00	24:00
000	DEMO	M	30				10-08-2019 09:00:00	24:00
000	DEMO	M	30				10-08-2019 09:00:00	24:00

Menu

Program: Enter patient information and set the BP study program

BP data: Opens the main screen above.

Retrieve: Initiates data retrieval from the monitor

Setting: Opens the system setting window.

Help: Opens the electronic user manual.

About: Views the basic information about the software

Exit: Exits the software.

Folder

- Recorder DB: Stores test data from the monitor. Click **Recorder DB**, a list of test data is shown. Double click a line of the data, you will enter the Data Analysis screen.
- Register DB: Stores registered patient information. Click **Register DB**, a list of patients to be studied is shown. Double click a line of patient information, you will enter the Program screen.
- Recycle: Stores data deleted from the Recorder DB.

Patient query

Enter patient ID or names, fully or partially, for searching from the patient list.

Patient list

A list that shows patient's personal information and measurement readings.

Button

- **Import:** Imports single or multiple BP files that were exported before from your PC.
- **Export:** Exports single or multiple BP files to your PC.
- **Delete:** Deletes data from the patient list. Select a line of data, and click **Delete**.

Chapter 5 Conducting an Ambulatory BP Study

5.1 Programming the Monitor

Before an ambulatory BP study, you need to set the parameters for your study to be programmed into the monitor as below.

1. Click **Program** in the main screen.
2. Enter patient ID, name, gender, age, and accession number. For the generation of patient ID, see section 9.1 General Setting. Patient information can be customized. For more information, see section 9.2 Patient Information Setting.
3. Select the desired measuring time and intervals in the form. Two additional measurement periods are available. Select a start time, an end time, and intervals from the pull-down list.
4. Click **Register**. The above patient information and measuring program are sent to the monitor.

NOTE: Besides measuring program setup, a default measuring program is available in the monitor: Awake portion starts from 7:00 am with a measuring interval of 30 min; asleep portion starts from 22:00 pm with a measuring interval of 60 min. To run the default program, click **Restore Default Program**.

Register before conducting a study

In the Program screen, enter patient information and measuring program before conducting a BP study.

1. Enter patient information.
2. Enter the desired measuring time and intervals in the form.
3. Click **Save**. The patient information and measuring program is saved to the Register DB folder.

Starting study in 5 min

- If selected, the study will automatically start in 5 minutes after programming.
- If not selected, the study will be started with the first press of the **Start/Stop** button when the monitor is powered on.

Display off

- If selected, the OLED display of monitor turns itself off in the Auto measurements.
- If not selected, the OLED display never turns itself off in the Auto measurements.

Note:

1. You can use a barcode reader to enter the patient information if barcode scanning is activated. The recommended readers are Motorola LS4208 for one dimension and Honeywell Xenon 1500GSR for two dimensions.
2. You can also retrieve patient information via GDT in the Program screen. Select Setting > GDT > Enable GDT.
3. Patient information with an asterisk * is mandatory, for example, patient name and ID. Patient name allows for up to 60 English letters for entry. Patient ID allows for up to 30 letters or numbers for entry if generated manually or automatically, and 10 numbers if accumulated from zero.

5.2 Fitting Patient with the Monitor and Cuff

After you have successfully programmed the monitor, you may begin fitting the patient with the BP monitor and a blood pressure cuff. Cuffs may be used on either arm.

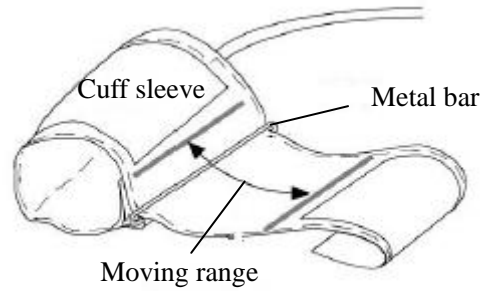
1. Choose the proper cuff size. This is very important for BP measurements.

CAUTION

Using an incorrect cuff size could result in erroneous and misleading blood pressure measurements.

2. Apply the ABPM cuff. Simply slide the sleeve up the patient's arm. Align the cuff so that the lower edge of the cuff is approximately 2 cm above the inside of the patient's elbow. Tighten the cuff around the upper arm until one finger can be introduced under the cuff. It is imperative that the artery symbol ⇨ is positioned on the brachial artery. If you have aligned the cuff correctly, the metal bar will lie on the outside of the upper arm (on the elbow side), whereby the cuff sleeve must cover the skin under the metal bar.





3. Connect the hose. Connect the hose from the cuff and monitor by twisting the fittings together until you hear a snap. Drape the hose over the patient's shoulder, behind the neck and across to the opposite side of the body.
4. Attach to patient. Put the monitor into its pouch. Attach the pouch to the patient using a pouch strap. By varying the length of the strap, it can be worn around the shoulders.

The patient should take the following position during blood pressure measurement:

- ◆ Comfortable seated or lie flat, legs uncrossed
- ◆ Feet flat on the floor
- ◆ Back and arm supported
- ◆ Middle of the cuff at the level of the right atrium of the heart
- ◆ During the measurement, relax as much as possible, neither talking nor applying external pressure on the cuff.

NOTE:

- 1 The width of the cuff is either approximately 40% of the limb circumference or 2/3 of the upper arm length. The inflatable part of the cuff should be long enough to encircle 80%-100% of the limb. The wrong size of cuff can cause erroneous readings. If the cuff size is in question, use another cuff with suitable size to avoid errors.
- 2 Please make sure that no part of the hose is kinked. Carefully observe the cuff pressure to avoid over-pressure and inflate time-out.
- 3 Please make sure the cuff is well connected. A leak of air may cause measurement error.
- 4 Avoid incursion of liquid into the cuff. If this happens, please desiccate the cuff completely.
- 5 During measurement, the patient should be as relaxed as possible and may not speak unless he wants to report any discomfort.
- 6 Allow for 5 minutes of relaxation before recording the first measurement value.

WARNING

Prolonged non-invasive blood pressure measurements in Auto mode may be associated with purpura, ischemia and neuropathy in the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop the blood pressure measurements.

5.3 Preparing the Patient

To ensure measurement readings are valid, provide your patient with the following instructions.

- ◆ When the pressure in the cuff increases, the patient should avoid excess movement during measurements. Let the cuffed arm hang loosely, slightly away from the body with the middle of the cuff at heart level. It is better to lie flat when asleep.
- ◆ It is expected that the patient may experience some mild to moderate discomfort during a blood pressure measurement. Instruct the patient to turn off the device, remove the cuff, and notify the doctor if they are experiencing pain, swelling, redness or numbness in the limb where the cuff is placed.
- ◆ Wear a loose and comfortable shirt for the ABP study. Do not go swimming or bathing.
- ◆ Do not operate heavy machinery or power tools. Vibration may compromise the performance of monitor.
- ◆ Avoid car driving or bus taking. Try to keep the monitor dry and do not drop it.
- ◆ Do not use the monitor if accidental wetting, drop or damage occurs to it or its parts. Please power off and return it to EDAN.
- ◆ Before sleeping, the patient should make sure that the hose is not and will not become kinked.
- ◆ The patient can stop a measurement in progress by pressing the Start/Stop button.
- ◆ The batteries can be replaced during a study without the data being lost or interrupting the monitor's program. Alternatively, the monitor can be turned off without losing its data. The study will go on as programmed.
- ◆ If cuff fails to deflate within two and a half minutes, instruct the patient on manual removal of cuff.

5.4 Measurement Limitations

Measurements are impossible with pulse rate extremes of less than 40 bpm or greater than 240 bpm, or if the patient is on a heart-lung machine.

The measurement may be inaccurate or impossible in the following situations:


- ◆ A regular arterial pressure pulse is hard to detect.
- ◆ Patients with cardiac arrhythmias.

- ◆ Patients with excessive and continuous movement such as shivering or convulsions.
- ◆ Patients with rapid blood pressure changes.
- ◆ Patients with severe shock or hypothermia that reduces blood flow to the peripheries.
- ◆ Patients with obesity, where a thick layer of fat surrounding a limb dampens the oscillations coming from the artery.
- ◆ Patients on an edematous extremity.

5.5 Starting the Study

The monitor is on and start the first BP reading automatically or by pressing the Start/Stop button. The cuff will inflate and complete the BP measurement. The cuff will then be fully deflated. When measurement is in progress, real-time BP readings should appear on the display of the monitor. When measurement is completed, the results of systolic BP, diastolic BP, pulse rate and “Auto” are shown. This indicates that the first measurement succeeds. The monitor now runs in the auto mode and the study is in progress as programmed. The first measurement readings are saved as data of the study.

To record an event:

Press and hold the Start/Stop button for 3 seconds. The event mark  appears.

To stop a measurement in progress:

Press the Start/Stop button. The monitor will stop a measurement in-progress.

To manually start a measurement:

Press the Start/Stop button before an auto measurement. The readings of such a measurement are saved.

Auto restarting measurement:

In the auto mode, if a measurement fails, the monitor will re-start the measurement in 3 min. The subsequent measurements will not be affected.

To light up the display

After the 24-hour time is shown for 20s, the display of the monitor turns itself off. Press any button to light up the display prior to operation.

5.6 Finishing the Study

When the study is finished, the patient returns. Take the monitor, cuff, and pouch strap off and download the captured data to the analysis software.

The monitor displays “24:00” when one-day study is completed. You can retrieve the data to your PC, exit the study, or set up a new measuring program. .

Chapter 6 Retrieving ABP Data

BP readings can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic conditions.

To retrieve the data:

1. Connect the ABP monitor to your PC. For operations, see section 3.4 *Connecting the Monitor to PC*.
2. In the Main Screen of analysis software, click **Retrieve**. The Retrieve window opens. Click **OK**.
3. When retrieval is finished, the Analysis screen will open. If the retrieved data does not contain patient name and ID, the patient information screen will appear for entry.
 - If **Enter the analysis screen directly** is not selected in the Retrieve window, the Main screen will open when retrieval is finished. The data is saved to the Recorder DB folder.

NOTE:

Please retrieve data from the monitor right after the study is finished.

CAUTION

1. Sharing patient data or data storage folders on the network is not supported by the ABPM analysis system and may cause irreversible data lost or corruption.
 2. You should make a backup of data on a periodic basis.
-

Chapter 7 Analyzing and Editing ABP Data


When data is successfully transferred to your PC, the data analysis screen will open automatically. To manually access this screen:

1. Open the Recorder DB. A patient list is displayed.
2. Enter patient ID or name in the search bar. If more than one study is conducted on this patient, the studies are listed in chronological order.
3. Double click the study you want. The data analysis screen is displayed. You have the following options.

7.1 Editing Patient Information


Patient information can be entered before or after data retrieval.

To edit patient information:

1. Click . Patient Info tab opens.
2. Edit any patient information except patient ID. Your modification is automatically saved when you exit.

7.2 Data Table

You can delete or restore data in the data table.

- To automatically delete abnormal data: Open the Day & Night BP Profile tab. Click **Threshold Setting**. Reset the auto elimination threshold. Click **OK**. Your setting is saved. The data exceeding the threshold will be deleted automatically.
- To manually delete abnormal data: Double click the data. The data is marked with  and turns yellow. It will be excluded from the statistical analysis. Double click the data again to restore it.

The systolic and diastolic BP that exceed the threshold will be displayed in red.

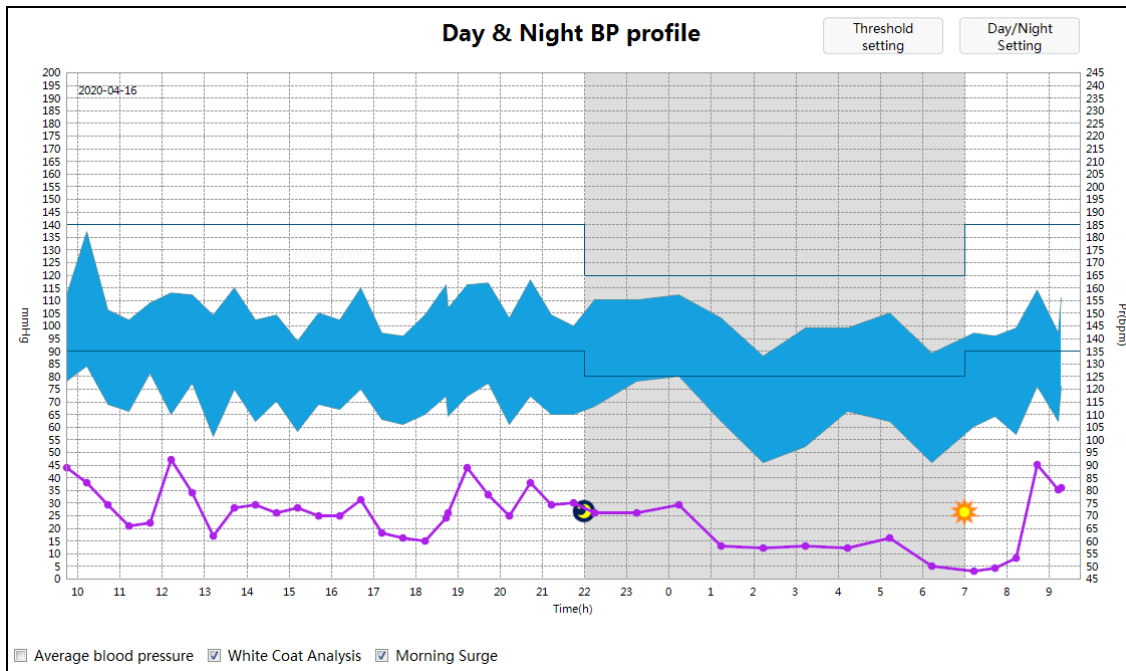
To customize the data table, click your right mouse button, and tick the item you want to show in the table.

To see the posture of patient, click **Posture** in the upper right corner. Patient's posture will also be shown in the printout of data table.

To make a remark, double click the text box and type in.

7.3 Day & Night BP Profile

Display BP profile throughout the day and night. Additional parameter such as pulse rate is recognized.



In this profile, X axis displays the time in clock hours. Y axis represents the blood pressure (mmHg) in the left and pulse rate (bpm) in the right.

24-hour BP curve: consists of 24-hour systolic and diastolic BP curves.

- Threshold curves: drawn based on the threshold setting.
- Vertical line: click any point in the profile. A vertical line goes through this point and displays the SYS, DIA, and pulse rate at this point of time.
- Pulse rate curve: a line that connects all the pulse rates.

Day/Night setting

Set the awake time and sleep time of patient:

1. Click **Day/Night Setting**.
2. Slide the button to set the awake time and sleep time.
3. Click **OK**.

The awake period starts from 07:00 and asleep period from 22:00 by default.

Threshold setting

Set the BP thresholds and data elimination thresholds. When you change the setting, click **OK** to save.

White coat analysis

Data collected during the first hour of the study. This appears in the graph if enabled.

Morning surge

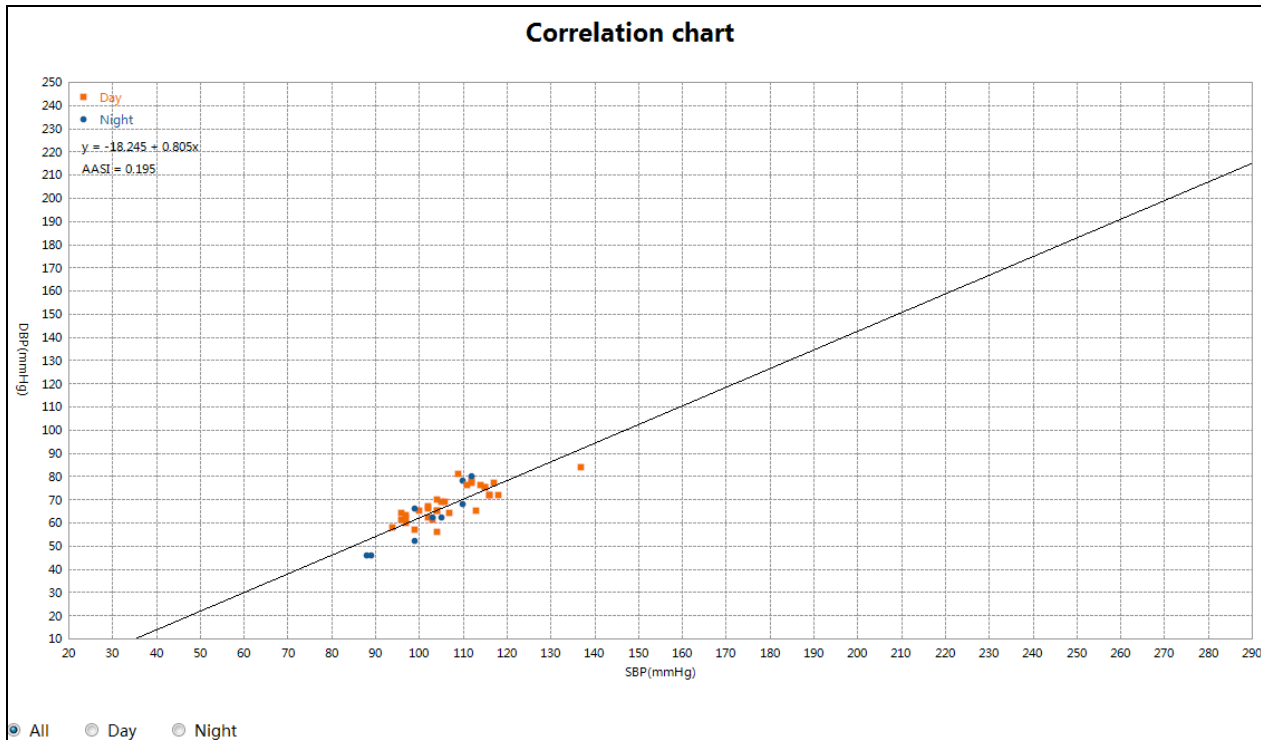
A 2-hour period after wakeup is used to calculate Morning Surge. This calculation can help to identify cases in which the morning BP increase is unusually high and presents a potential cardiovascular risk or a risk of stroke. This appears in the graph if enabled.

The curve of average blood pressure appears if Average blood pressure is enabled.

Compare: compares the BP studies of one patient conducted in different periods.

7.4 Correlation

The graph on this tab plots the diastolic on systolic BP values for each measurement captured in the study. Additionally, this tab lists the calculated AASI (ambulatory arterial stiffness index) value and linear regression equation. The user can specify which BP values to use in the graph and calculations by selecting all, day, and night at the bottom of the graph.



7.5 Histogram

This tab shows SYS, DIA, and pulse in histograms. You can choose the time periods of all, day, and night. X axis represents the blood pressure (mmHg) and pulse rate (bpm). Y axis represents the frequency (in percentage) for SYS, DIA, and pulse rate.

7.6 Pie Chart

This tab shows pie chart for Overall, Awake, Asleep periods. Illustrate values above the established high thresholds in red, below the established low thresholds in yellow, and values within the two thresholds in green.

7.7 Variability

Curves are drawn to show the blood pressure and MAP (mean arterial pressure) variability. The horizontal axis shows the time of measurement from its start to the end. The vertical axis shows the true blood pressure on the left and blood pressure variability on the right. Vertical lines shows the greatest variability and the time it occurs.

7.8 Statistics

To view the statistical analysis for the displayed study, click on the Statistics tab. This window initially shows the following tables:

- Overall: Data for the complete ABPM study.
- Day: Data collected while the patient is awake.
- Night: Data collected while the patient is asleep.

The Statistics tab can also show the additional time periods, which show tables with data collected during other time periods as programmed.

In the Statistics tab, each table includes the calculation of valid data, the mean values, standard deviation, maximum values, minimum values, coefficient of variation (CV), BP load, asleep dip, morning surge, morning BP, and AASI.

- Coefficient of variation: The coefficient of variation (CV) can be used as a measure of BP variability, which can be a determinant of end-organ damage.
- AASI (ambulatory arterial stiffness index): This index has been used to measure arterial stiffness and has been shown to help predict target organ damage, cardiovascular mortality, and stroke.

7.9 Conclusion

This tab provides an interpretative summary according to the official guidance and statistics. Select the following guideline you want from the drop-down list:

- 2017 ACC/AHA hypertension guidelines
- 2018 ESC/ESH Guidelines for the Management of Arterial Hypertension
- Chinese Guidelines for Prevention and Treatment of Hypertension

The summary provides normal or hypertensive results for the 24-hour average, day, and night systolic and diastolic pressure readings if the data collected is adequate.

To draw a conclusion, you can manually enter a conclusion to the text box, or choose from the diagnosis list on the left. Double click the diagnostic statement you want. It appears in the conclusion. You can add, edit, and delete the statements in this diagnosis list.

To sign on the report, type your name in the text box beside **Physician**. You can also predefine a name list by selecting **Edit** from the drop-down list. In the pop-up window, click **Add** to add physician's name to this list. With this name list, you can also delete or modify the names.

Chapter 8 Creating Reports

On the Data Analysis screen, you can configure or customize, preview, and print your report.

The following preconfigured report formats are provided:

- Simple report
- Standard report
- Full report

You can choose from the pages available to customize your report. For more details, see section 9.5 *Report Setting*. For patient demographics to be included in the report, you can configure System Setting > Patient Information Setting.

To save the report as a PDF, click the **PDF** tab. The system creates the PDF and saves the file to the location you specify.

SA series provides you with flexibility in printing the report. You can either:

- Print the configured report by clicking the Print tab. The Print dialog box is displayed where you can choose the preferred printer.
- Print the report page corresponding to the current tab that is being displayed by clicking the Preview tab. You can configure your report by clicking the **Report Setting** button. Print the report page by clicking **Print current page**. Print the configured report by clicking the **Print** button.

Note: It's necessary to install a printer before printing a report. If you need more information about installation, please contact the manufacturer or your local distributor.

Chapter 9 System Setting

To open the system setting, tap **Setting** on the main screen. To save your changes in setting, click **OK**. You have the following options. The options with an underline are default settings.

9.1 General Setting

Item	Description
ID Generation Mode	Choose from: Manual , <u>Auto</u> , or Accumulate . Select Auto , the patient ID can be automatically generated according to the study date. ID is the study date plus 4 serial numbers which start from 0001. Select Manual , you should enter the patient ID manually in the New Patient dialog box. Select Accumulate, the ID increases from 0 to 9999999999 by one.
Language	Choose from: Chinese , <u>English</u> .
Date Format	Choose from: YYYY-MM-DD , <u>DD-MM-YYYY</u> , or MM-DD-YYYY .
Blood Pressure Unit	Choose from: <u>mmHg</u> , kPa .
Height	Choose from: <u>cm</u> , inch .
Weight	Choose from: <u>Kg</u> , lb .
File Exporting Path	BP file is by default exported to the Export folder under the installation path. You are allowed to change the path by clicking Browse .
Data Storage Path	The data is by default saved to the Data folder under the installation path. You are allowed to change the path by clicking Browse .
File Name	File name consists of patient ID, patient name, exam time (date-hhmmss), age, gender, and accession number. They are separated by a dash. The default setting is last name + first name + exam time. You can customize your file name by selecting the above portions.

9.2 Patient Information Setting

You can configure the patient information as displayed on the Program screen and in the BP report. Gender, age, and accession number are displayed by default. More options are last/first name, date of birth, telephone, address, height, weight, race, office BP, measurement site, technician, department, inpatient area, room No., Inp/Outp/PE ID, patient source, clinical

diagnosis, medical history, medication, customize 1, and customize 2. You need to input the content for customize 1 and customize 2 if selected.

9.3 Security Setting

Item	Description
Login password	Allows for up to 30 numbers and letters for entry. Blank by default.
System setting password	Allows for up to 30 numbers and letters for entry. Blank by default.
Export password	Allows for up to 30 numbers and letters for entry. Blank by default.
Patient name hiding	If selected, patient name becomes invisible to protect personal privacy. Not selected by default.
Backup Path	Define the directory for data backup.
Recovery Path	Define the directory for data recovery.

9.4 Communications Setting

Item	Description
USB	If selected, the monitor can communicate with the PC only through the USB cable.
Bluetooth	If selected, the monitor can communicate with the PC only via Bluetooth.
Demo	If selected, only the DEMO data can be retrieved. Such data is named DEMO with 000 as patient ID.
Bluetooth search	This functions only when Bluetooth is enabled. Insert a Bluetooth adapter to the USB port of your PC. Click this button. A paring list which includes device name, status, and MAC address is displayed.
Connect	Connects the monitor to your PC via Bluetooth. Select the device from the paring list. Click Connect . Or alternatively, double click the device to connect. Prior to connection, enter the PIN code which is 123456 by default. Click OK . When connected, change the device name by double clicking it. The device name is not longer than 30 numbers and letters. Click OK to save your change. The device name is now stored in the monitor.
Clear	Clears the list of devices that have ever been connected.

9.5 Report Setting

You can configure or customize your report.

Item	Description
Hospital name	You can enter up to 40 characters. After setting, the name is displayed on the printed report.
Logo	Click Browse to upload an image. The image must be in the format of JPG, BMP, and PNG. After setting, the image is displayed on the printed report.
Template list	<p>This templates by default are simple report, standard report, and full report.</p> <ul style="list-style-type: none"> • Simple report contains patient information, BP profile, statistics, and conclusion. • Standard report contains simple report and 24-hour BP data table. • Full report contains simple report, 24-hour BP data table, histogram, pie chart, correlation analysis, study comparison, and variability analysis. <p>To configure or customize your report, do one of the following:</p> <ul style="list-style-type: none"> • Choose one of the templates listed in the left pane. When you select a template, the pages included in that template are selected in the Report List. • Create a new custom report template by clicking Add. Enter the template name. Select the pages from the Report List on the right. <p>You can also delete the customized templates or restore the default setting of templates.</p>
Report List	The pages that are included in the report templates. From here you can control the pages for printing reports.

9.6 Barcode Setting

Item	Description
Enable Barcode scanning	If this is enabled, you can use a barcode reader to scan patient information when establishing a new study or retrieving ABP data.

Two-dimensional barcode scanning is also supported.

Patient ID	Enter a number from 0 to 255. The default number is 1 to 12. When using a barcode reader, the first 12 characters of the bar code will be scanned to the ID dialog box.
Last name	Enter a number from 0 to 255. The default number is 0.
First name	Enter a number from 0 to 255. The default number is 0.
Gender	Enter a number from 0 to 255. The default number is 13.
Birth year	Enter a number from 0 to 255. The default number is 14 to 17.
Birth month	Enter a number from 0 to 255. The default number is 18 to 19.
Birth date	Enter a number from 0 to 255. The default number is 20 to 21.
Customize 1	Enter a number from 0 to 255. The default number is 22 to 25.
Customize 2	Enter a number from 0 to 255. The default number is 26 to 29.
Male code	Enter a number from 0 to 99. The default number is 1.
Female code	Enter a number from 0 to 99. The default number is 2.
Device port	Choose from COM1 to COM29. The default setting is COM3.
Initialize the reader	Initialize the barcode reader and automatically get the COM port of the reader.

9.7 GDT

Item	Description
Enable GDT	If this is enabled, the GDT communication is activated. Disabled by default.
GDT path	The default is C:\gdt. You can enter the path for storing GDT files. Or alternatively select the path by clicking Browse .
Suffix	Choose from .GDT and .001 . If .GDT is selected, the files with this suffix will be exported. If .001 is selected, the files with this suffix will be exported.
Input file name	Set the name of BP data files delivered from the GDT server. EDP-ABPMD by default.
Output file name	Set the name of BP data files exported from the ABPM analysis software. EDP-ABPME by default.

ABPM ID	Set the name of local device. ABPM by default.
EDP ID	Set the name of GDT server. EDP by default.
Encoding format	Choose from <u>ANSI</u> , IBM437 , and 7Bit .
Export PDF file	Create files as PDF when exporting GDT files. Disabled by default.

Chapter 10 Error Codes

Error codes appear when abnormality occurs during the operation of ABPM. Error codes do not automatically indicate that a reading is invalid. They serve only as guides to help you use the ABPM.

Table 10-1 Error codes and description

Error code	Description	Cause	Action Taken
Er02	Self-Test Error	Transducer or other hardware failure	Measure again, if failure persists, stop measuring and notify biomedical engineer or manufacturer's service staff.
Er03	Over-Pressure Protection	Pressure exceeded the specified upper safety limit.	
Er05	Initial Pressure High	The initial pressure was too high during measuring.	
Er06	Loose cuff or disconnected	Cuff was loose or not applied.	Properly wrap the cuff.
Er07	Air Leakage	Failed to deflate normally during the leak test, so leak test could not be finished.	Test again. If the problem still exists, contact your service personnel.
Er08	System Pressure Abnormality	ABPM failed to deflate, so the system pressure is unchanged.	Check whether the airway is occluded or pressure sensor works properly. If the problem still exists, contact your service personnel.
Er09	Weak Oscillometric Signal	Cuff was too loose or patient pulse was too weak.	Use other methods to measure blood pressure.
Er10	Results outside of published range	The BP was out of the published range.	
Er11	Artifact/erratic oscillometric signal	Signal noise was too large or pulse rate was irregular due to the patient movement.	Make sure that the patient under monitoring is motionless.
Er12	Auxiliary Over-Pressure Protection	Pressure exceeded the first or second auxiliary safety limit as specified.	Notify biomedical engineer or manufacturer's service staff.
Er15	System Failure	Transducer was faulty or ABPM was not calibrated.	Contact your service personnel.
Er19	Measurement time-out	Measuring time exceeded the specified time limit.	Measure again or use other measuring method.

Er20	User Aborted	User himself stopped measurement.	/
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Chapter 11 Cleaning, Care and Maintenance

Use only the EDAN-approved substances and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by using unapproved substances or methods.

Edan Instruments has validated the cleaning and disinfection instructions provided in this User Manual. It is the responsibility of the healthcare professional to ensure that the instructions are followed so as to ensure adequate cleaning and disinfection.

11.1 General Points

Keep your device and accessories free of dust and dirt. To prevent the device from damage, please follow the instructions:

- Use only the recommended cleaning agents and disinfectants listed in this manual. Others may cause damage (not covered by warranty), reduce product lifetime or cause safety hazards.
- Always dilute according to the manufacturer's instructions.
- Unless otherwise specified, do not immerse any part of the equipment or any accessories in liquid.
- Do not pour liquid onto the equipment.
- Do not allow liquid to enter the case.
- Never use abrasive material (such as steel wool or silver polish).
- Inspect the monitor and reusable accessories after they are cleaned and disinfected.

CAUTION

1. If you spill liquid on the monitor, or it is accidentally immersed in water, do not use; contact your service personnel or EDAN service engineer.
 2. Clean and disinfect the device and reusable accessories when the patient changes.
 3. The equipment is chemically resistant to most cleaning agents, disinfectants and non-caustic detergents used in hospital, but cleaning agents or disinfectants that are not listed in this manual are not recommended. For example, didecyl dimethyl ammonium bromide, which contains quaternary ammonium salt, may corrode the equipment and accessories.
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11.2 Cleaning

If the device or accessory has been in contact with the patient, then cleaning and disinfection is required after every use. If there has been no patient contact and there is no visible contamination then daily cleaning and disinfection is appropriate.

The validated cleaning agents for cleaning the monitor, hose, and cuff sleeve are:

- Mild near neutral detergent
- Ethanol (75%)
- Isopropanol (70%)

Cleaning agents should be applied or removed using a clean, soft, non-abrasive cloth or paper towel each time.

11.2.1 Cleaning the Monitor

1. Power off the monitor, take out the battery and disconnect the hose.
2. Wipe the exterior surface of the equipment and the pouch using a soft, damp cloth until no visible contaminants remain.
3. Wipe off the cleaning solution with a fresh cloth or towel dampened with tap water after cleaning until no visible cleaning agent remains.
4. Dry the monitor and the pouch in a ventilated and cool place.

CAUTION

1. Take out batteries and disconnect the hose prior to cleaning.
 2. Do not use alcohol to clean the carrying pouch. It can only be wiped using the mild near neutral detergent.
 3. Ensure that no fluid enters the device.
 4. Any remainder of cleaning solution should be removed from the monitor after cleaning.
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11.2.2 Cleaning the Cuff Sleeve

1. Carefully remove the bladder and hose from the cuff sleeve.
2. Hand wash the cuff with the cleaning solution; clean the air bladder with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
3. Rinse the cuff and after cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
4. Wipe off residual moisture with a dry cloth. If the cuff sleeve is contaminated, replace it.

Replacing the Air Bladder

After cleaning, the bladder needs to be inserted back into the cuff sleeve so the pneumatic hose portion of the bladder goes through the tube opening on the cuff. Please note that the pneumatic hose connection should face upward when using the ABPM cuff on either the right or the left arm.

CAUTION

1. Always close the Velcro strip before cleaning.
 2. Do not use fabric softener or other washing aids (e.g. hygiene rinses, textile deodorants). These agents can leave residues and damage the material.
 3. The cuff sleeve is not suitable for drying in a dryer. Line dry is recommended.
 4. Do not machine wash the bladder.
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11.3 Disinfection

To avoid permanent damage to the equipment, it is recommended that disinfection is performed only when it is considered as necessary according to your hospital's regulations.

Clean the equipment and reusable accessories before they are disinfected. The validated disinfectants for disinfecting the monitor and cuff sleeve are:

- Ethanol (75%)
- Isopropanol (70%)

If Ethanol or Isopropanol is used for both cleaning and disinfecting, then a new cloth is required to be used for the disinfection step.

CAUTION

1. Intolerances caused by the use of disinfectants. Some patients may display intolerance (e.g. allergies) to disinfectants or their components. Never use disinfectants which leave residues on the product or which are not suitable for contact with the skin. Carefully wash the cuff to remove residues.
 2. Do not use high-temperature, high-pressure vapor or ionizing radiation as disinfection methods.
 3. Do not use chloric disinfectant such as chloride, sodium hypochlorite etc.
 4. To prevent corrosion of the device and its accessories, do not use disinfectants that contain additional active ingredients not mentioned above, for example, didecyl dimethyl ammonium bromide, which contains quaternary ammonium salts.
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11.3.1 Disinfecting the Monitor

WARNING

Before disinfecting the monitor, make sure that the monitor is powered off and disconnected from any power supply including batteries and USB connection.

To disinfect the monitor, follow these steps:

1. Switch off the monitor. Take out the batteries or disconnect it from other power supply.
2. Disconnect the hose.
3. Clean and dry the monitor, including the hose and carrying pouch, according to the methods in section 11.2.1 prior to disinfection.
4. Prepare the disinfectant solution.
5. Use a clean cotton swab dampened with the disinfectant solution to wipe the surface of the equipment, including the carrying pouch. Follow the disinfectant manufacturer's recommended contact time and mode.
6. Use a soft clean cloth dampened with the disinfectant solution to wipe the entire exterior surface of the equipment, including the carrying pouch. Follow the disinfectant manufacturer's recommended contact time and mode.
7. After disinfection, wipe off the disinfecting agent with a new sterile cloth dampened with sterile water.
8. Dry the hose and carrying pouch for at least 30 minutes in a ventilated and cool place.
9. Inspect the hose and carrying pouch to ensure that there is no damage.

11.3.2 Disinfecting the Cuff Sleeve

Disinfecting the Cuff Sleeve:

1. Disassemble the cuff sleeve and hose from the monitor and take out the bladder.
2. Clean and dry the cuff sleeve, bladder, and hose according to the methods in section 11.2.2 prior to disinfection.
3. Prepare the disinfectant solution.
4. Wipe the cuff sleeve, bladder, and hose with a soft cloth dampened with the disinfectant solution.
5. Leave the cuff sleeve, bladder, and hose to air dry for at least 30 minutes.

6. Inspect the cuff sleeve, bladder, and hose to ensure that there is no damage.

Replacing the Air Bladder

After disinfection, the bladder needs to be inserted back into the cuff sleeve. Refer to section 11.2.2 for operation.

NOTE:

Prolonged use of disinfectant may cause discoloration of the cuff.

11.4 After Reprocessing

- After reprocessing, the monitor and cuff sleeve should be checked to ensure there are no signs of aging, wear, cracks, deformation, discoloration or peeling, etc. Replacement should be taken or contact the service personal of the manufacturer if necessary.
- Assembling and connecting device-specific components.

Prerequisite:

All components have been reprocessed and are dry.

- Preparation before next use of device

Assembling and fitting patient-specific accessories and consumables, i.e. cuff sleeve.

11.5 Care and Maintenance

CAUTION

1. Besides the maintenance requirements recommended in this manual, comply with local regulations on maintenance and measurement.
2. Do not open the casing. Once the device is opened, all warranties will lapse.
3. The maintenance operations like software upgrade of the device can only be completed by EDAN-qualified service personnel.

The monitor will automatically perform auto-zero adjustment when powered on. This is to eliminate the impact of atmospheric pressure on blood pressure. It also supports periodic auto-zero to eliminate the impact of temperature drift on ABP study.

11.5.1 Inspection

Perform regular visual inspection to see if there is any dirt or dust on the device, hose, and cuff sleeve. Follow the instructions for cleaning. Visually inspect cables, materials, pneumatic hoses,

and the monitor cases for cracks, fraying, or kinks. Do not use the monitor or cuff if there are any signs of damage. Please contact our service department if any damage or defects are identified.

11.5.2 Calibration

The accuracy of the ABPM should be checked at least once every year. If needed, an authorized service center may recalibrate the pressure transducers in the monitor. To check accuracy, the SA series ABPM must first be placed into the proper mode. Follow the steps below:

1. Retrieve data from the monitor so as to exit the monitoring program.
2. Power off and then on the monitor.
3. You see the 24-hour time displayed and no “Auto”, press and hold the **Start/Stop** button for 3 seconds. You will now see “0 mmHg”.

The monitor’s accuracy can now be checked against a calibrated mercury column.

1. Place a t-tube between the hoses connecting the monitor and the cuff.
2. Wrap the cuff around a suitably sized can or bottle. This acts as the reservoir for the unit.
3. Attach the third end of the “T” tube into a calibrated mercury column, which gives you access to the bulb and a reference.
4. Using the bulb of the calibrated mercury column, inflate the cuff to 250 mmHg.
5. Once the pressure has stabilized at this level, the monitor should match the mercury column by ± 3 mmHg.
6. Check the unit against the column every 100 mmHg from 250 to 50 mmHg. The monitor should be within ± 3 mmHg. If it is not, the monitor needs to be returned to the service department for recalibration or repair.

NOTE: To return the SA series ABPM to its normal operating mode, power off and on the monitor.

11.5.3 Maintenance

WARNING

1. Failure on the part of the responsible individual hospital or institution employing this equipment to implement a satisfactory maintenance schedule may cause undue equipment failures and possible health hazards.
 2. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
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1) PC and Monitor

- ◆ Avoid excessive temperature, sunshine, humidity and dirt.
- ◆ Put the dustproof coat on the monitor after use and prevent shaking it violently when moving it to another place.
- ◆ Prevent any liquid from seeping into the equipment; otherwise the safety and the performance of the monitor cannot be guaranteed.

2) Hose

- ◆ Integrity of the pneumatic hose should be checked regularly. Make sure that it is conductible.
- ◆ Do not drag or twist the hose with excessive stress while using it...
- ◆ Align the hose to avoid twisting, knotting or crooking in a closed angle while using it.
- ◆ Once damage or aging of the hose is found, replace it with a new one immediately.

While usage will have an impact, it is expected the monitor will be in service for 10 years.

Replace the hose, cuff sleeve and other accessories according to your actual use. It is recommended that you replace them once every year.

EDAN will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair those parts of the equipment that are designated by EDAN as repairable by service personnel.

CAUTION

The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal.

Chapter 12 Accessories

WARNING

Only the cuff and other accessories supplied by the manufacturer can be used. Or else, the performance and electric shock protection cannot be guaranteed.

Table 12-1 Accessory list

Accessory	Part Number
Cuff sleeve (L)	01.57.472007
Cuff sleeve (M)	01.57.472006
Cuff sleeve (S)	01.57.472008
Cuff sleeve (XS)	01.57.472009
Carrying pouch	01.56.466767
Belt	01.56.465781
USB cable	01.13.037903
Extension hose	01.57.472010
Installation CD	02.01.215368
Alkaline batteries	01.21.064086
Bluetooth adapter	01.48.099220

NOTE:

The part name may vary depending on context, but the part number is unchanged.

Chapter 13 Warranty and Service

13.1 Warranty

EDAN warrants that EDAN's products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period.

The warranty is void in cases of:

- a) Damage caused by mishandling during shipping.
- b) Subsequent damage caused by improper use or maintenance.
- c) Damage caused by alteration or repair by anyone not authorized by EDAN.
- d) Damage caused by accidents.
- e) Replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, EDAN will, at its discretion, repair or replace the defective part(s) free of charge. EDAN will not provide a substitute product for use when the defective product is being repaired.

13.2 Contact information

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor.

Alternatively, you can send an email to EDAN service department at: support@edan.com.

Appendix 1 Technical Specifications

A1.1 Safety Specifications

Comply with	IEC 60601-1:2005+A1:2012 EN 60601-1:2006+A1:2013 IEC 60601-1-2:2014 EN 60601-1-2:2015 EN/IEC 60601-1-11 EN/ISO 80601-2-30 EN/ISO 81060-2	
Anti-electric-shock type	Internally powered equipment	
Anti-electric-shock degree	DEFIBRILLATION-PROOF Type BF	
Degree of protection against solid foreign objects and harmful ingress of water	IP22 (with carrying pouch)	
Disinfection/sterilization method	Refer to the user manual for details	
Degree of safety of application in the presence of flammable gas	Equipment not suitable for use in the presence of flammable gas	
Working mode	Continuous operation	
EMC	CISPR 11, Group 1, Class B	
Patient Leakage Current:	NC	<10 μ A (AC) / <10 μ A (DC)
	SFC	<50 μ A (AC) / <50 μ A (DC)
Patient Auxiliary Current:	NC	<10 μ A (AC) / <10 μ A (DC)
	SFC	<50 μ A (AC) / <50 μ A (DC)

A1.2 Environment Specifications

	Transport & Storage	Working
Temperature	-20 °C (-4 °F)~+55 °C (+131 °F)	+5 °C (+41 °F) ~ +40 °C (+104 °F)
Relative Humidity	15%RH~95%RH Non-Condensing	15%RH~95%RH Non-Condensing
Atmospheric Pressure	70 kPa ~106 kPa	70 kPa ~106 kPa

A1.3 Physical Specifications

Dimensions	106.5 mm × 62 mm × 27 mm, ±1 mm
Weight	160g ± 10g (excluding battery and cuff)
Display	0.96" screen

A1.4 Power Supply Specifications

Battery type	Two AA alkaline batteries
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A1.5 Performance Specifications

ABP monitor	
Method of measurement	Oscillometric
Static pressure range	0 to 300 mmHg (0 to 40 kPa), ±3 mmHg (±0.4 kPa)
Measurement pressure range	Systolic: 25 to 290 mmHg (3.3 to 38.6 kPa) Diastolic: 10 to 250 mmHg (1.3 to 33.2 kPa) Mean error: ±5 mmHg (±0.67 kPa) Standard deviation: Max. 8 mmHg (1.07 kPa)
Pulse range	40 to 240 bpm, accurate within ±3 bpm or ±3.5%, whichever is greater.

Resolution	Blood pressure: 1 mmHg (0.133kPa) Pulse: 1 bpm
Over-pressure protection	The cuff will be deflated when the measurement pressure reaches 297 ± 3 mmHg (39.6 ± 0.4 kPa).
Data memory	Flash memory stores up to 300 readings.
Sampling duration	24 hours (Time interval options are: 5, 10, 15, 20, 30, 45, 60, 90, 120 minutes)
Safety system	Maximum inflation pressure limited to 300 mmHg; Maximum measurement time limited to 120 seconds
Bluetooth (configurable)	
Transmitting Frequency	2400 MHz to 2483.5 MHz
Frequency Band	≤ 2 MHz
Modulation Type	GFSK, DPSK, PSK
Transmitting Power	≤ 20 dBm (EIRP)

A1.6 Configuration Difference

The table below shows the configuration difference between models of ABPM.

Models	Configuration		
	Feature 1	Feature 2	Feature 3
	Starting study in 5 min	Event recording	Study comparison
SA-10	√	√	√
SA-05	√	×	√
SA-06	×	√	√
SA-08	√	√	×
SA-09	√	×	×
Note: "√" = Standard "×" = Not Available			

Appendix 2 EMC Information

Electromagnetic Emissions

Guidance and manufacture's declaration - electromagnetic emission		
The SA series device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The SA series device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The SA series device is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC/EN 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC/EN 61000-3-3	Not applicable	

Electromagnetic Immunity

Guidance and manufacture's declaration - electromagnetic immunity			
The SA series device is intended for use in the electromagnetic environment specified below. The customer or the user of the SA SERIES DEVICE should assure that it is used in such an environment.			
Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC/EN 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.

Electrical fast transient/burst IEC/EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	Not applicable
Surge IEC/EN 61000-4-5	± 1 kV line to line ± 2 kV line to ground	Not applicable	Not applicable
Power frequency (50Hz/60Hz) magnetic field IEC/EN 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	0 % U_T ; 0.5 cycle At 0 °, 45 °, 90 °, 135 °, 180 °, 225 °, 270 ° and 315 ° 0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycles) Single phase: at 0 ° 0 % U_T ; 250/300 cycle	Not applicable	Not applicable
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Electromagnetic Immunity

Guidance and manufacture's declaration - electromagnetic immunity			
The SA series device is intended for use in the electromagnetic environment specified below. The customer or the user of the SA series device should assure that it is used in such an environment.			
Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC/EN 61000-4-6	3 V _{rms} 150 kHz to 80 MHz 6V _{rms} ^{c)} in ISM bands between 0.15 MHz and 80 MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the SA series device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC/EN 61000-4-3	3 V/m 80 MHz to 2.7 GHz See Table 1.	3 V/m 80 MHz to 2.7 GHz See Table 1.	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz $d = 6\sqrt{P}/E$ at RF wireless communications equipment bands (Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SA series device, including cables specified by the manufacturer). Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the


		<p>recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>		
<p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SA series device is used exceeds the applicable RF compliance level above, the SA series device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SA series device.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p> <p>^c The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.</p>		

Table 1 Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test Frequency (MHz)	Brand ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum Power(W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse modulation ^{b)} 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM ^{c)} ±5 kHz deviation 1kHz sine	2	0.3	28
710	704-787	LTE Brand 13, 17	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900,TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN,802.11 b/g/n, RFID 2450, LTE Brand 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9
5500						
5785						
Note: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM maybe reduce to 1m. The 1 m test distance is permitted by IEC 61000-4-3.						

- a) For some services, only the uplink frequencies are included.
- b) The carrier shall be modulated using a 50% duty cycle square wave signal.
- c) As an alternative FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM

Recommended separation distances between portable and mobile RF communications equipment and the SA series device			
The SA series device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SA series device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SA series device as recommended below, according to the maximum output power of the communications equipment.			
Maximum output power rating of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance <i>d</i> in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Appendix 3 Abbreviation

Abbreviation	Full Description
BP	Blood Pressure
HR	Heart Rate
OLED	Organic Light-Emitting Diode
SYS	Systolic Blood Pressure
DIA	Diastolic Blood Pressure
AASI	Ambulatory Arterial Stiffness Index
ID	Identification
PDF	Portable Document Format
AC	Alternating Current
USB	Universal Serial Bus
NC	Normal Condition
SFC	Single Fault Condition

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