

Wearable Multi-parameter Patient Monitor

Elegant-1010

User Manual

Version: 2.0

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North-Vision Tech. Inc.

This Manual is written for the current Elegant-1010 Monitor.

The Manual describes, in accordance with the Elegant-1010 Monitor's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.

The Manual is published in English and we have the ultimate right to explain the Manual.

Marks in the Manual:

-  **Caution: must be followed to avoid endangering the operator and the patient.**
-  **Attention: must be followed to avoid causing damage to the Elegant-1010 monitor.**
-  **Note: contains some important information and tips about operations and application.**

Instruction to User

Dear Customers,

Thank you for purchasing this quality product. Please read the following information very carefully before using this device. Read these instructions carefully before using this Elegant-1010 Monitor. These instructions describe the operating procedures to be followed strictly. Failure to follow these instructions can cause monitoring abnormality, equipment damage and personal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, personal injury and equipment damage due to user's negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

Contraindication: NO.

Cautions:

- ⚠ This device is used for measurement. Do not use for self-diagnose and it is not a treatment device. This device is applicable to adult.
- ⚠ This device is not designed to be used in movable vehicle (such as a car, airplane).
- ⚠ To avoid any harm during charging, it is recommended that the device shall not be in use while the battery is charging.
- ⚠ Check the device, accessories including cable and cuff before use. Stop use if any damage and aging is found.
- ⚠ Please check the monitor completely to verify that the accessories can function safely and normally.
- ⚠ Do NOT use the device under the flammable gas condition or in any environment that may lead to explosion.
- ⚠ The device is forbidden to be used together with other equipment not specified in this Manual.
- ⚠ All combinations of equipment must be in compliance with standard of IEC 60601-1-1 medical and electric system requirements.
- ⚠ Do not modify or disassemble this device and the cuff without authorization of the manufacturer.
- ⚠ Although biocompatibility tests have been performed on all the applied parts, some exceptional allergic patients may still have anaphylaxis. Do NOT apply to those who have anaphylaxis.
- ⚠ When disposing of the monitor and its accessories, the local law should be followed.

Attentions:

- 🔔 Please store and operate the device in specified temperature, humidity and atmospheric pressure. The excessive ambient environment may affect the measuring result.
- 🔔 To avoid damaging device, if the monitor gets wet, please do not start it until it is air-dry.
- 🔔 ONLY monitor one person at a time.

Note:

- 🖱 In this Manual, "long press" means press and hold key for about 3 seconds; "short press" means press key for less than 1 second.

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CHAPTER 1 OVERVIEW

1.1 Features

- ✧ Blood pressure, oxygen saturation and pulse rate can be measured;
- ✧ A wearable device, and convenient to measure;
- ✧ Small in size, light in weight, easy to carry and operate;
- ✧ It's intended to use in homes;
- ✧ The measurement result can be set to the host device via wireless communication.
- ✧ The measured data can be displayed, stored and managed by APP software installed on the host device, such as smart phone, tablet, and computer.

1.2 Application and Scope

The Elegant-1010 Monitor is applicable for measuring adult's physiological parameters, such as non-invasive blood pressure (NIBP), functional oxygen saturation (SpO₂), and pulse rate (PR).

1.3 Conformation

The Elegant-1010 Monitor consists of the main unit, functional accessories (cuff, SpO₂ sensor) and the software package running on the host system.

1.4 Product Name and Model

Product Name: North-vision Wearable Multi-parameter Patient Monitor

Model Name: Elegant-1010 Monitor

1.5 Working Environment and Power Supply

1. Operating temperature: 5°C ~ 40°C;

Operating humidity: 15% ~ 93% ;

Atmospheric pressure: 70.0kPa ~ 106.0kPa

2. Power Supply:

Internal power supply by built-in battery: d.c. 3.7V (lithium battery) with capacity 1000mAh.

When the device is charging, the icon "" will be displayed on the screen (in scroll status), when the device is full charged, the icon turns to be "". Normally, it will take 3 hours to be fully charged to the capacity for use of 150 times of NIBP measurement.

CHAPTER 2 APPEARANCE

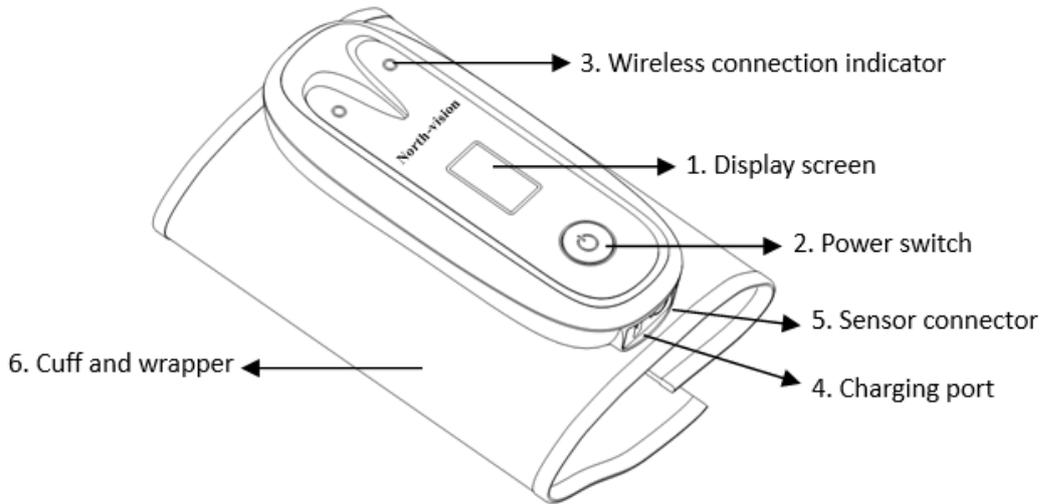


Figure 2.1 Demonstration

1. "☐": display screen.
2. "⏻": power switch. Long pressing to turn on/off the device; Short pressing to start/cancel NIBP measurement.
3. "◎◎": wireless connection indicator. Indicator flashing means the host device is connecting to the device; Indicator light means the host device is successfully connected with the device.
4. "🔌": external DC power input socket (Micro USB interface).
5. "🔌": sensor connector. It is used to connect SpO₂ probe.
6. Cuff: it is used for wrapping patient's upper arm for NIBP measurement. It is self-bound to the device and cannot be disassembled.
7. Symbols and description

Symbol	Description	Symbol	Description
North-vision	Brand name	SN	Serial number
	Type BF applied parts		Class II device
	"Attention!"--please refer to the User Manual	 (rolling bar)	Battery is charging
	Battery is fully charged		

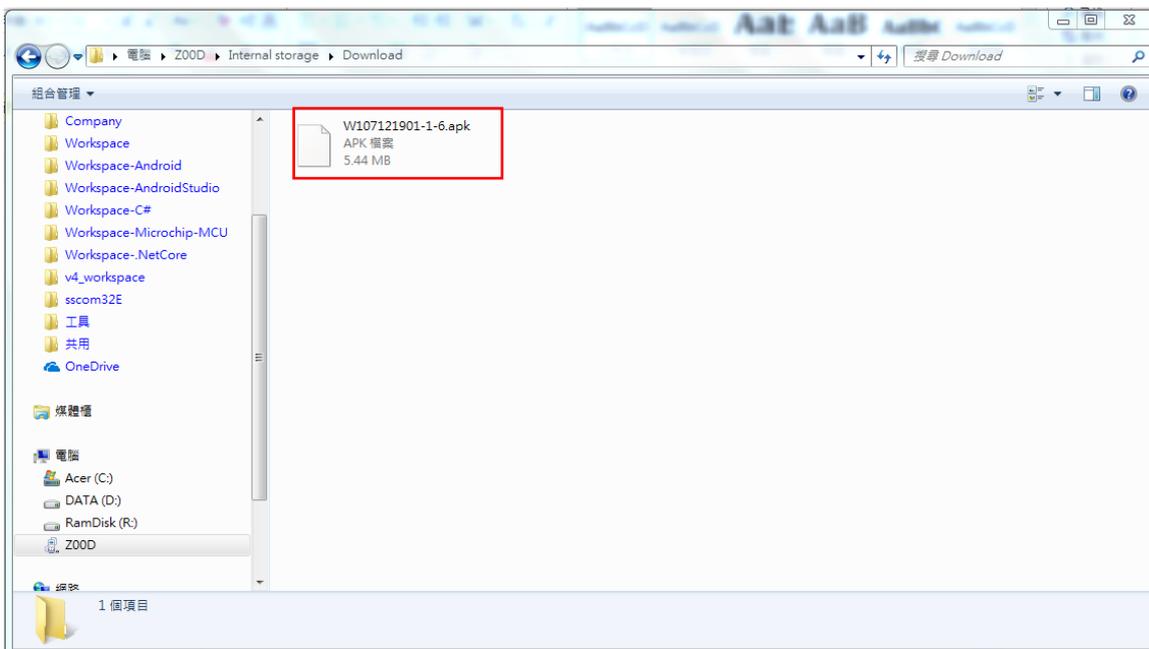
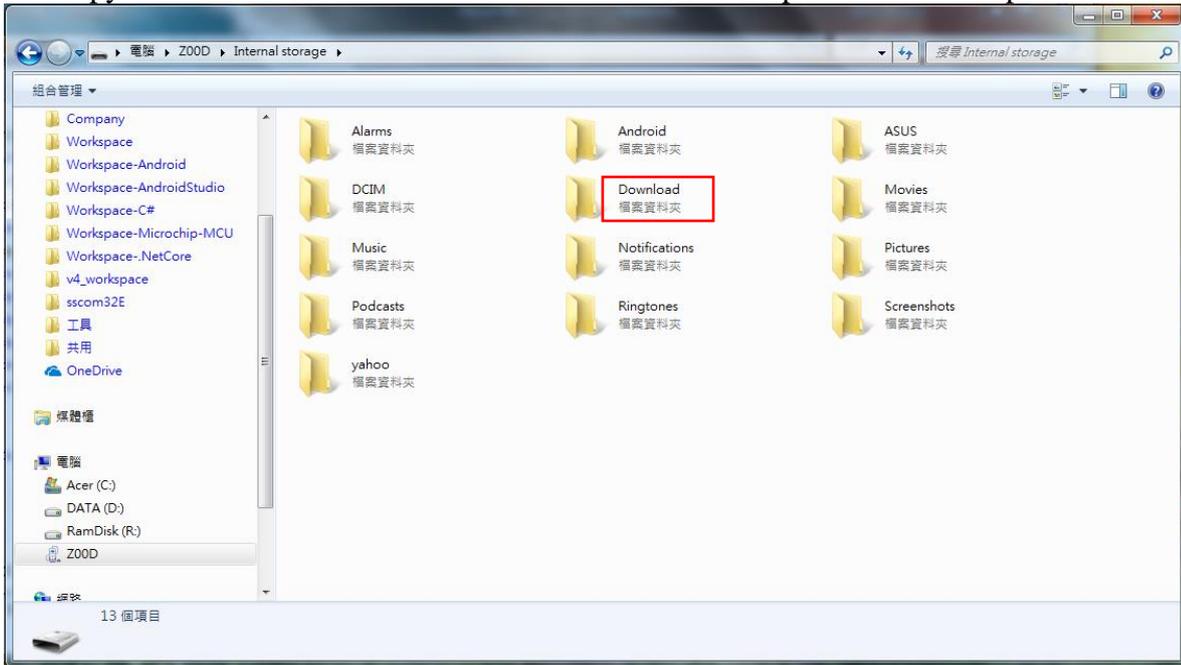
Note: the above signs and symbols may appear on your device.

CHAPTER 3 INSTALLATION AND CONNECTION

The measurement result of Elegant-1010 Monitor can be also displayed, stored and managed via the APP software installed in a host device (such as smart phone, tablet, and etc.), so before making measurement, please install APP software first and make sure the APP software connects to the Elegant-1010 Monitor via wireless of Blue-tooth successfully.

The APP software is installed in the following procedure:

1. Copy the APK file to the folder of “Download” in smart phone's internal space as shown below.

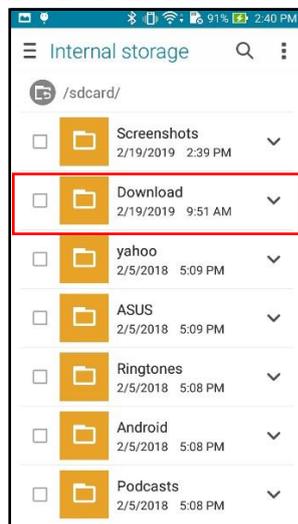


2. Run the APK execution file.

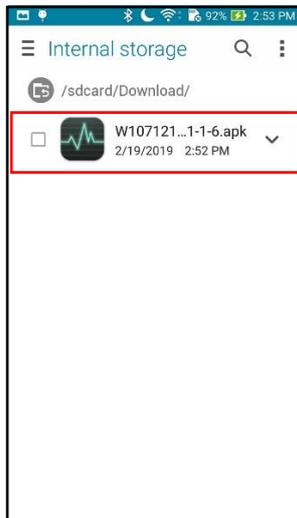
(1) Enter the menu screen



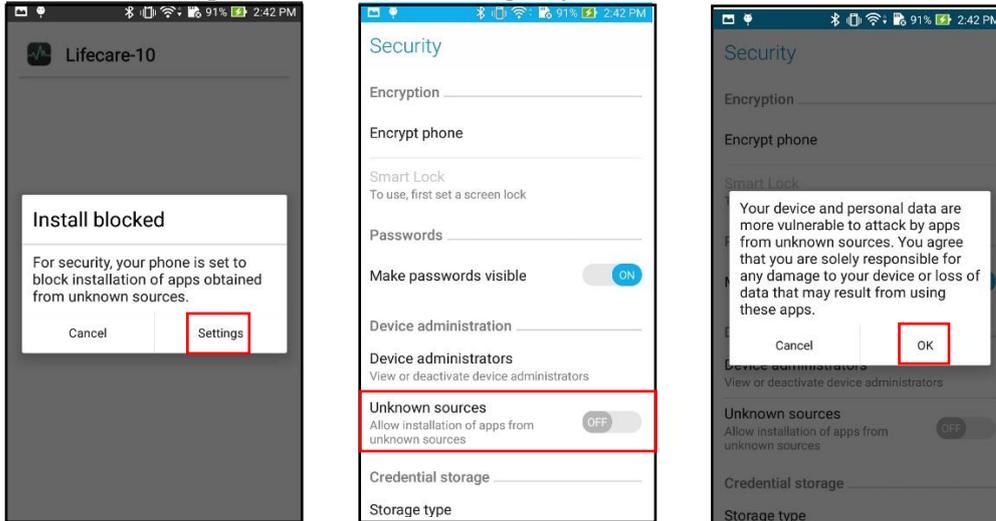
(2) Open the "File Manager" and enter the folder of "Download".



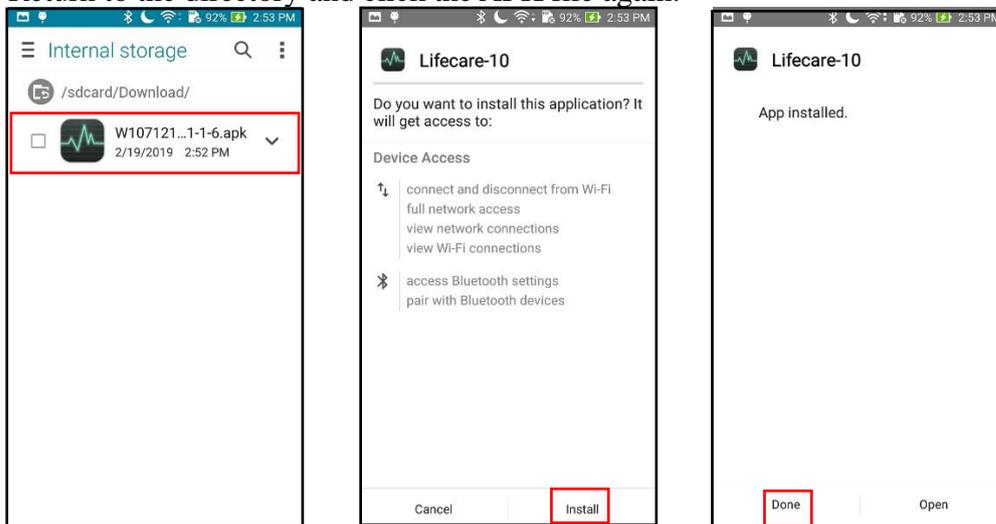
(3) Click the APK file.



(4) If your smartphone is not allowed to install any apps obtained from unknown sources, please confirm to accept it for normal working in your device.



(5) Return to the directory and click the APK file again.



- Go back to the menu screen, then press and hold the "Elegant-1010" software icon to place it on the desktop.

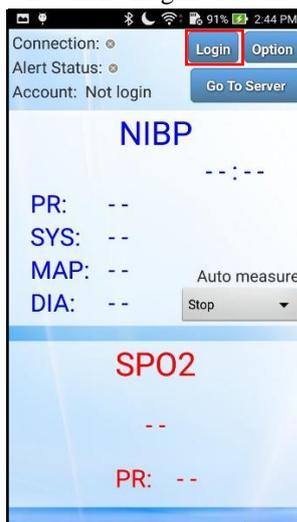


- Create User Account:
You can just login directly if you have an account, otherwise, please create a user account first

1. Click the icon of "Elegant-1010".



2. Click "Login" button.



3. Click "Signup" button.



4. Key-in account's information.



5. Input the account and password.



6. Login successfully



CHAPTER 4 MEASUREMENT

4.1 Blood Pressure Measurement

Long pressing power switch "⏻", the device displays software version number, and then enters into the default screen, as shown in figure 4.1.

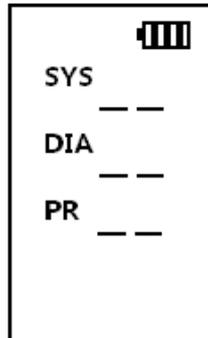


Figure 4.1 Default screen (NIBP measurement screen)

Description:

1. "▢▢▢": battery capacity.
2. "SYS__DIA__PR__": it displays the measured value of systolic pressure, diastolic pressure and pulse rate.

Note: on default screen, if there is no signal or no operation for 5 minutes, then the device will power off automatically.

Safety instruction before making measurement:

- Take off the sweater or the thick cloth to make the arm is uncovered or only one thin cloth left.
- Before making measurement, do not eat, drink, smoke, take exercise or have a bath.

Operating procedure:

1. When putting on the cuff, spread the cuff and wrap it around the upper arm evenly to appropriate tightness. The correct cuff position refers to figure 4.2. Note: locate the cuff in such a way that direction mark "▼" directs to the lower arm.

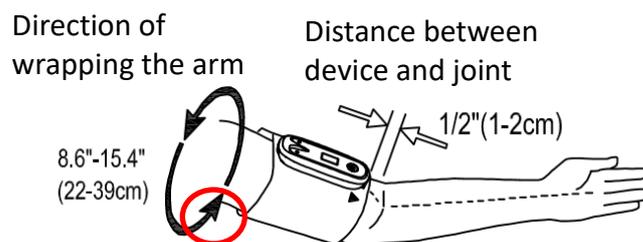


Figure 4.2 Cuff placement

2. Adjust the testee's position. Right position: the testee should stand, sit or lay down with calm condition and make the cuff and the testee's heart on the same level to get accurate measurement.
3. Short pressing power key to start NIBP measurement.
4. When the measurement is finished, the measured result and pressure level description will be displayed on the screen, refer to Form 4-1 for the detailed description. Please refer to the appendix for detailed blood pressure level.

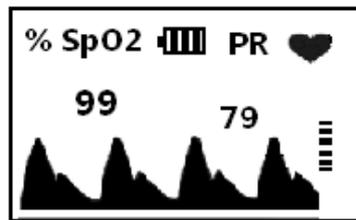
Message	Description
"Optimal"	Optimal blood pressure
"Normal"	Normal blood pressure
"Hi Normal"	High normal blood pressure
"HTN G1"	Hypertension grade 1
"HTN G2"	Hypertension grade 2
"HTN G3"	Hypertension grade 3

Form 4-1

Safety Instructions for blood pressure measurement

- ☞ During measurement, the testee should not talk, move the device, shake body or arm.
- ☞ For the same testee, the testee should wait for 3 minutes for another NIBP measurement.

4.2 SpO₂ Measurement

Figure 4.3 SpO₂ measurement screen

Screen description:

1. "%SpO₂ 99": mark and value of oxygen saturation.
2. "PR 79": mark and value of pulse rate.
3. "♥": heart beat icon.
4. "PPG": photoplethysmogram.
5. "Pulse Bar": pulse bar graph.

Operation procedure:

1. Connect the SpO₂ probe to the connector on the sensor connector.
2. When the device is powered on, insert one finger (index finger is preferred, the nail should be not too long) into the clip of the probe.
3. Wait for 2 seconds, the device will auto begin to make measurement.
4. The measured result will be displayed on the screen, as shown in figure 4.3. If the host device is connected to the device, then the measured result can be displayed on the screen of the host device by running APP software.
5. Remove the finger, the device will auto turn to the default screen (NIBP measurement screen).

Note: 1. PR and SpO₂ over-limit indication are available for the device (if the PR and SpO₂ options are selected).

2. If NIBP and SpO₂ are measured simultaneously, then the NIBP measured result will be prior to be displayed for 10 seconds.

CHAPTER 5 TECHNICAL SPECIFICATIONS

5.1 Blood Pressure Measurement

1. Blood pressure measuring range:
Systolic pressure: 60mmHg~240mmHg
Diastolic pressure: 30mmHg~180mmHg
2. Blood pressure measuring accuracy: mean difference \leq 5mmHg, standard deviation \leq 8mmHg
3. Pneumatic system error: \pm 3mmHg
4. Pressure display resolution: 1mmHg

5.2 SpO₂ Measurement (Optional)

1. SpO₂ measuring range: 35%~100%
2. SpO₂ measuring accuracy: Arms is not greater than 3% for SpO₂ range from 70% to 100%
Note: Arms is defined as root-mean-square value of deviation according to ISO 9919
3. Resolution: 1%
4. Low limit alarm value for SpO₂: 90%.
Note: when the measured SpO₂ \leq 90%, then the over-limit SpO₂ value blinks.

5.3 Pulse Rate Measurement (Optional)

1. Pulse Rate measuring range: 30bpm~240bpm
2. Pulse rate measuring accuracy: \pm 2bpm or \pm 2% of reading, whichever is greater
3. Resolution: 1bpm
Note: when the measured PR \geq 120bpm or PR \leq 50bpm, then the over-limit PR value blinks.

5.4 Dimension and Weight

Dimension: 140.5mm(L) \times 60.0mm(W) \times 24.5mm(H)
Gross Weight: 260g

CHAPTER 6 MAINTENANCE AND SERVICE

The Elegant-1010 Monitor is designed to serve for 5 years, it should be properly maintained to ensure its maximum performance and long service life. In addition to the warranty period, the manufacturer also offers long-term service for customers. It is important that the user read and follow the operating instructions, important information and maintenance measures.

6.1 Technical Maintenance

6.1.1 Daily Examination

Before using the device, the following checks should be carried out:

- Check the device for any mechanical damage;
- Inspect the exposed parts and the connected parts for all the cables, and the accessories;
- Examine all the functions of the device that are likely to be used for measuring, and ensure that it is in good working condition.

In case of any indication of damage about the function of the device is detected and proven, it is not allowed to use. Please contact the local dealer or the manufacturer.

6.1.2 Battery Maintenance

- ⚡ Only use the provided AC adapter to charge the built-in battery, if the other charger is used, the device may be damaged.
- 🔔 Whether the monitor is on or off, the built-in battery will be charged as long as the monitor is connected to the provided AC adapter and AC power is on. When the battery is full, it will stop charging for protecting the battery from damage.
- 🔔 In order to maintain battery power and prolong battery lifetime, please charge the battery routinely. Generally, charge the battery every 3 months if the device has not been used for more than 3 months.

6.2 Cleaning and Disinfection of the Main Unit

- ⚡ Switch off the device and disconnect the power adapter before cleaning.
- Do NOT let any cleanser and disinfectant flow into the connector or any parts of the device.
- Do NOT put any parts of the monitor or its accessories in the liquid.
- Do NOT pour the disinfectant on its surface while disinfecting.

6.3 Cleaning and Disinfection of Accessories

- The accessories can not be entirely immersed into water, liquid or cleanser.
- Wipe the accessories clean with a mild cloth if it is dirtied.
- Wipe the accessories clean and keep it in the packaging for maintenance after using.

6.4 Storage

If the device will not be used for long period of time, wipe it clean and keep it in the package, which shall be kept in a dry good ventilation place free from dust and corrosive gases.

Storage environment: Ambient temperature: -20°C~60°C

Relative humidity: ≤93%

Atmospheric pressure: 53.0kPa~106.0kPa

CHAPTER 7 TROUBLESHOOTING

Trouble	Possible reason	Solution
Cannot turn on the device	The built-in battery is exhausted	Recharge it by connecting the power supply adapter
	Incompatible accessories are mis-connected to this device	Remove the mis-connected parts and try again.
No blood pressure result	The cuff is wrapped around the arm incorrectly	Wrap the cuff around the arm correctly
No SpO ₂ result	SpO ₂ probe is not inserted to the sensor connector or the finger is out of probe	Plug SpO ₂ probe to the sensor connector and check if the finger is inserted into the probe properly.
Can not connect to the host device	1. Bluetooth version is not compatible; 2. Low battery	1. Use the host device with Bluetooth Ver 2.0 and try again. 2. Recharging the battery

CHAPTER 8 ERROR MESSAGE INTERPRETING

Error Code	Description
ERR 01	The cuff is not well-wrapped
ERR 02	Overpressure protection
ERR 03	No valid pulse is detected
ERR 04	Excessive motion artifact
ERR 05	The measurement fails
ERR 06	Air leakage
ERR 07	Self-test fail
ERR 08	Pneumatic system error
ERR 09	Signal saturation
ERR 10	Air leakage
ERR 11	Hardware fault
ERR 12	Measurement timeout
ERR 15	Low battery

Note: the above error codes appear when the NIBP measurement fails.

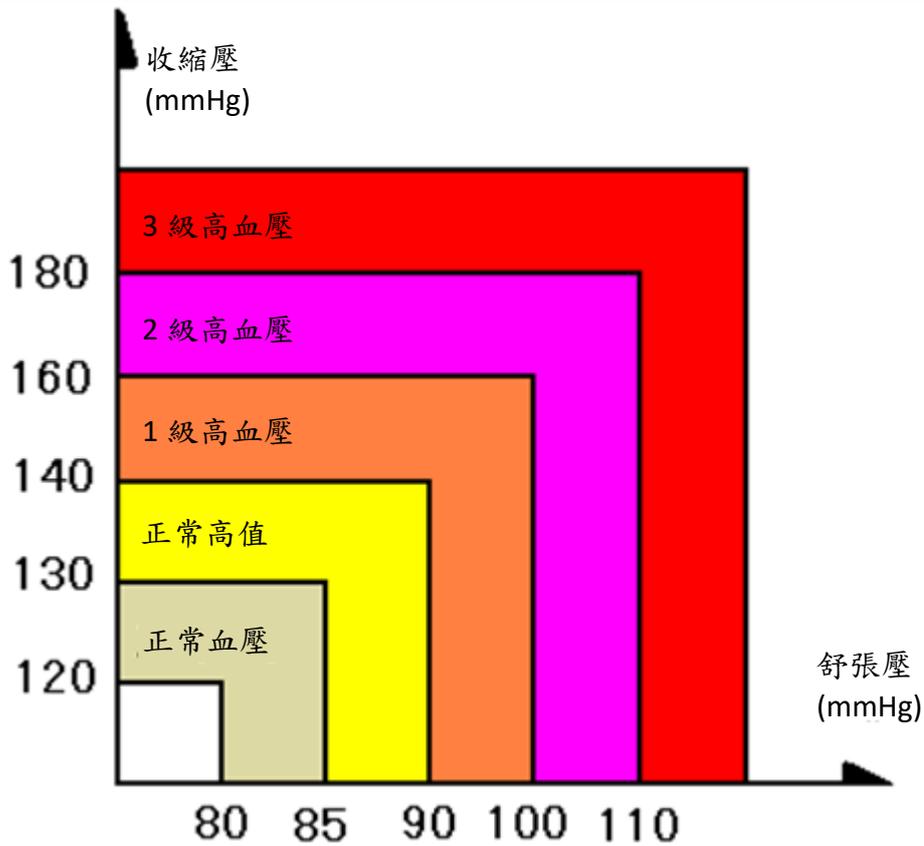
CHAPTER 9 PACKING LIST

Item	Description	Quantity	Check
1	Elegant-1010 Monitor	One piece	OK
2	User Manual	One piece	OK
3	AC power adapter (charger)	One piece	OK
4	SpO ₂ probe	One piece	Optional
5	Charging cable	One piece	OK
6	Handbag	One piece	OK

Appendix: Classification of Blood Pressure Level

The below form is applicable to adult with age over 18 years.

Blood Pressure Level	SYS(mmHg)	DIA(mmHg)
Optimal blood pressure	<120	<80
Normal blood pressure	<130	<85
High normal blood pressure	130~139	85~89
Hypertension Grade 1	140~159	90~99
Hypertension Grade 2	160~179	100~109
Hypertension Grade 3	>180	>110



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