

# V2 Doctor

User's Manual



**KOROT**

Revision History

| Revision Number | Date       | Revision Contents |
|-----------------|------------|-------------------|
| 0               | 2023.03.20 | Initial Release.  |
|                 |            |                   |
|                 |            |                   |
|                 |            |                   |
|                 |            |                   |

Please note the important information below before reading this manual.



Warning

Failure to observe these precautions can result in personal injury or device damage.



Caution

Failure to comply with safety precautions can damage the device.

**NOTE**

Additional Information.

## Contact Information

**KOROT**

For any problems with V2 Doctor or any clinical questions, please contact us at:

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Visit our website ([www.korot.com](http://www.korot.com)) to view and download additional information about the V2 Doctor. KOROT Co., Ltd. reserves the right to modify the appearance, specifications, etc. of this product to improve its quality, without prior notice.

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.

**Note:**

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

**RF Exposure:**

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

**Part15.21 statement:**

Changes or modifications not expressly approved by the manufacturer (or party responsible) for compliance could void the user's authority to operate the equipment

## Warnings

### ※ In general

- Consult a doctor before using V2 Doctor if you have cardiovascular disease.
- V2 Doctor is a device to measure the blood pressure and pulse rate. Do not use it for any other purpose.
- Results can only be interpreted by experienced medical professionals, and cannot be used for diagnosis, medication, or other treatment by the consumer's arbitrary judgment without a doctor's prescription.
- Do not use V2 Doctor on an injured arm or during arm treatment.
- Do not open or perform any internal modifications on V2 Doctor.
- Do not use V2 Doctor along with HF SURGICAL EQUIPMENT.
- Do not use near MRI equipment or in the EMC environment.
- Do not use in combination with hyperbaric oxygen therapy equipment.
- Do not measure on an arm receiving an intravenous injection or blood transfusion.
- The application of the cuff and its pressurization on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt is present could result in injury to the patient because of the temporary interference with blood flow.
- Except for the experienced medical professionals, do not use V2 Doctor with other medical or electronic devices at the same time.
- Do not use in an environment where there is a risk of flame such as gas or chemical substances.
- Too frequent measurements can cause injury to the patient due to the blood flow interference.
- Pressurization of the cuff can temporarily cause loss of function of simultaneously used device on the same limb.
- There's the need to check that the operation of the device doesn't result in prolonged impairment of the circulation of the blood of the patient by observing the limb concerned.
- If the patient feels severe pain or abnormalities during measurement, immediately stop measuring blood pressure.
- If this device has been modified, proper inspection and testing must be carried out to ensure its continued safe use.
- If the air tube is wrapped around the neck, there is a risk of injury or death from suffocation.
- Continuous cuff pressure due to connection tubing kinking can cause the effect of blood flow interference resulting harmful injury to the patient.
- In case of an emergency during the measurement, press the Start/Stop button or unwrap the cuff.

### ※ Handling the Adapter

- Be sure to use the USB Type-C cable. Forcibly connecting a cable other than USB Type-C may damage V2 Doctor.
- USB C-type port is for charging only.
- Do not connect the charger with wet hands.
- Use a power outlet that meets the specifications.
- Do not use V2 Doctor when the cord or AC Adapter has been damaged.

## Cautions - In general

- It is recommended to get preventive inspection every 2 years to maintain its performance and safety.
- First, wrap the cuff firmly in place around your arm and wrap the cuff around so that the stethoscope is pressed against the skin (If not, measurement may not be accurate).
- Be in a relaxed state as much as possible and place your arm so the cuff is leveled with your heart.
- If the battery level is low, connect the adapter and wait for 10 minutes before taking a measurement.
- In the event of an incident related to cybersecurity, please contact KOROT Co., Ltd. Customer Service Center and wait for the administrator take action.
- If the battery level is low, start measuring after about 10 minutes after connecting the charger.
- For proper blood pressure management, use the blood pressure monitor after setting the date/time.
- The cuff is not made of natural rubber latex.
- Do not use without the arm in the cuff.
- Do not wrap the cuff on the arm on the side of a mastectomy or lymph node clearance.
- Measurements may be inaccurate in the following cases. Please check before use.
  - Patients with arrhythmias
  - Patients with aortic disease
  - Patients with tremor
  - Patients using an artificial heart or artificial lung
  - Patients with a marked drop in body temperature or poor blood circulation

- If another device is attached to the arm to which the cuff is connected
- If an improperly sized cuff is connected
- When measuring while wearing thick clothes
- When measuring with clothes rolled up
- Talking or moving while measuring
- If the position of the cuff is lower or higher than the heart
- Install the device on a flat, vibration-free floor.
- If it is not connected to a grounded power source, the device may be damaged or malfunction due to electric shock.
- Be careful not to allow foreign substances such as food or beverages to flow into the device.
- Check that the device is not deformed due to impact.
- Check if the device is dirty.
- Make sure whether the device is wet.
- Do not roll your arms and sleeves, and remove thick clothing.
- The device is not intended for infants and pregnant women.
- In the event of accident or side effect, report to national authorities or KOROT Customer Service.
- In the event of an incident related to cybersecurity, contact KOROT and wait for the administrator to take action.

### Cautions - Before taking a measurement

- Take a measurement when you are in a relaxed state. Sit and rest for about five minutes prior to taking the measurement.
- Be in a relaxed state as much as possible and place your arm so the cuff is leveled with your heart.
- If the battery level is low, connect the adapter and wait for 10 minutes before taking a measurement.

### Cautions - When using V2 Doctor

- Only use genuine KV cuffs with this monitor.
- Keep still and do not talk while taking a measurement. If you move or talk, the measurement may not be reliable.
- Perform the measurement in a quiet place. Noisy surroundings may affect the measurement results.
- Do not tap stethoscope or cuff during the measurement.
- Press START/STOP button during the measurement if you encounter an error message on the monitor (Refer to the QnA section).
- If air is not exhausted when the above button is pressed, turn off the machine.
- Korotkoff sound may be temporarily inaudible if there is an electrical shock on V2 Doctor during the measurement. It does not affect the measurement result, and the monitor should work properly if you perform the measurement again.
- Do not use V2 Doctor where physical or electrical shocks may occur.

### Cautions - After using V2 Doctor

- Store the cuff in the holder behind the monitor body.
- Do not overly bend the cuff or the air tube when storing the unit.
- Consult experienced medical professionals for the measurement result.
- Keep V2 Doctor out of reach of infants, children and pets.
- Do not use V2 Doctor in places with high humidity or water present. The monitor can be damaged.
- After use, keep it in a safe place where the unit will not be damaged.
- Once a week, gently wipe the exterior surfaces of the instrument with a lint-free cloth.
- Dispose of packaging and other wastes in accordance with applicable laws and regulations.
- For repackaging, the packaging protection material provided by KOROT must be used.
- The cuff cannot be washed. Be careful not to get water on the cuff.
- Do not bend the cuff or air tube forcibly and store it.

|                                                                                           |    |
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# 1. About V2 Doctor

## A. Intended Use

The V2 Doctor is a digital monitor intended for use in measuring blood pressure and pulse rate in user population with upper arm circumference ranging from 17cm to 42cm (7-inch to 16.5-inch). The systolic blood pressure and diastolic blood pressure are measured by non-invasive blood pressure ("NIBP") measuring method and also by utilizing the Auto auscultation method and Oscillometric method. The V2 Doctor may provide useful clinical information about the current health status of not only the users who are diagnosed with hypertension but also those who are not diagnosed with hypertension. Warnings and cautions described in the user's manual should be observed at all times.

\*This device is designed for use in home environment.

## B. Measuring blood pressure using V2 Doctor

Automated Auscultation is a method that combines the accuracy of auscultation, and the convenience of the Oscillometric method.

- ❶ To measure the blood pressure, wrap the cuff around the upper arm and inflate it to a pressure above the systolic pressure.
- ❷ Then slowly release the air to detect the Korotkoff sound signal and the pressure sensor signal, which you can listen with the stethoscope attached to the cuff, to measure the systolic and diastolic blood pressure.

The Automated Auscultation applied to V2 Doctor combines the accuracy of the auscultation method with the convenience of easy measurement. The signals are electronically processed to compensate for the possible errors in the auscultation method caused by movement, external noise, etc., enabling a more accurate blood pressure measurement.

### ※ What is Auscultation?

Auscultation is a method of measuring blood pressure directly using stethoscope, pressure gauge, and a cuff. It is the most traditional and a recognized standard. Wrap the upper arm with a cuff, inflate the cuff to pressurize the artery that passes under the skin to completely occlude the blood flow. Then release the air to reduce pressure, and use a stethoscope to listen to the sound from the pressed arteries when blood flows back into the pressed area. The sound generated at this moment is called the Korotkoff sound, and it is known to be caused by turbulence caused by the blood flow. As the pressure in the cuff falls to or below the patient's systolic blood pressure, some blood will be able to pass through the upper arm and the first Korotkoff sound is heard. Korotkoff sound continues to be heard as long as the pressure in the cuff is between the systolic and diastolic pressures, and it disappears altogether when the pressure in the cuff drops below the diastolic pressure. When the pressure in the cuff drops below the diastolic pressure, the cuff no longer interferes with blood flow, so there is no more audible sound as the blood flows without the turbulence.

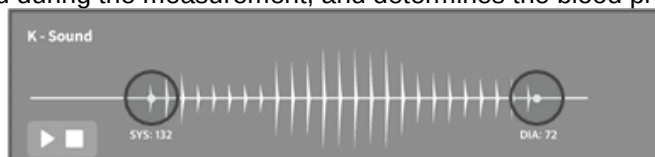
### ※ What is the Oscillometric method?

The Oscillometric method is similar to the auscultation method, where the cuff is inflated to reach above the systolic pressure and then deflated. The blood pressure is measured using the pressure change in the blood flow while the cuff is being deflated. Systolic, diastolic, and mean pressure are estimated based on Oscillometric waveforms generated by the pressure changes.

Compared to auscultation, it is convenient because it is easy to use and is less affected by external noise or movement, so it is widely used in automatic blood pressure monitors.

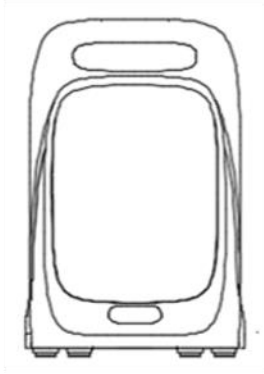
However, conventional automatic blood pressure monitors, which use their own estimation algorithms, have problems with different measurements and poor accuracy.

To perform a measurement, V2 Doctor inflates the cuff above the systolic pressure and then deflates it to obtain the cuff pressure value and Korotkoff sound. As the pressure falls to the patient's systolic blood pressure, the first Korotkoff sound is heard. When the pressure drops below the diastolic pressure, it disappears after the last Korotkoff sound is heard. V2 Doctor determines whether a Korotkoff sound is heard using the volume, distribution, Oscillometric signal, and filter of the sound acquired during the measurement, and determines the blood pressure value.

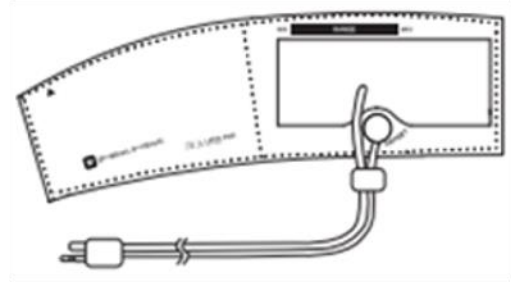


The resulting Korotkoff sound appears as shown in the figure above, marking the first sound heard with Systolic (SYS) and the missing sound with Diastolic (DIA).

### ❶ KOROT V2 Doctor



### ❷ M-size Cuff (S/L size are options)



### ❸ USB C type Cable



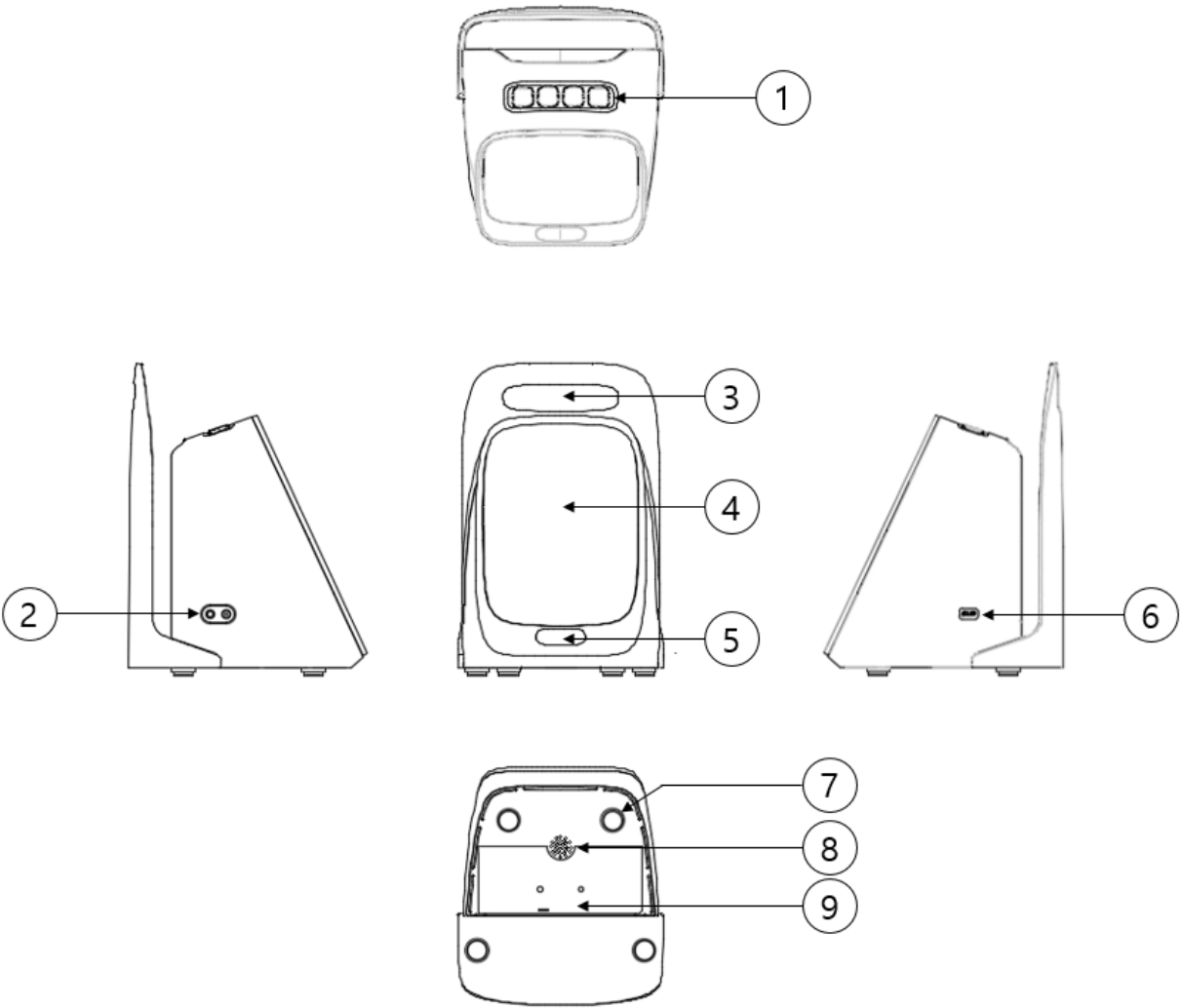
### ❹ User's Manual



#### NOTE

- Please check the product components when opening for the first time.
- USB adaptor and earphones are not provided.

D. Exterior and Functions



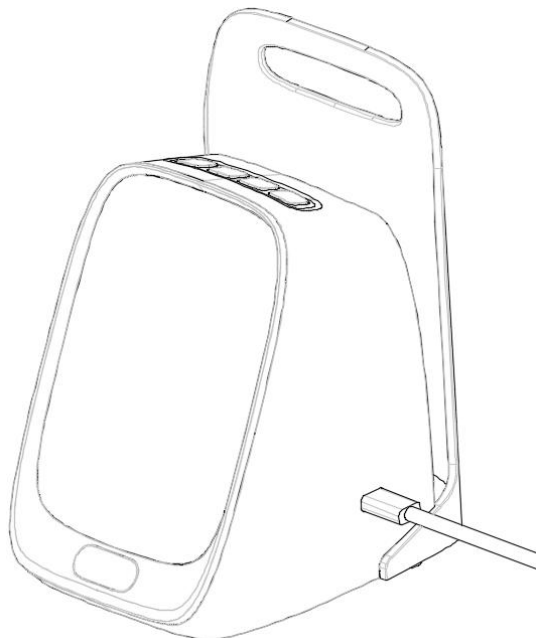
| No. | Item                   | Function                                                         |
|-----|------------------------|------------------------------------------------------------------|
| ①   | User Interface Buttons | M1, M2, Menu and OK buttons                                      |
| ②   | Cuff Connector         | Connector that connects the dedicated cuff                       |
| ③   | Handle                 | Handle for moving                                                |
| ④   | Display                | Display unit that displays measurement results and device status |
| ⑤   | Start/Stop Button      | Button to start or stop measurement                              |
| ⑥   | USB 3.0 Connector      | USB C Type charging connector                                    |
| ⑦   | Anti-slip rubber       | Rubber to support the device                                     |
| ⑧   | Speaker                | Speaker for sound output                                         |
| ⑨   | Label                  | Label with basic device information                              |

## 2. Using V2 Doctor

### A. Preparing to use

#### ※ How to Charge

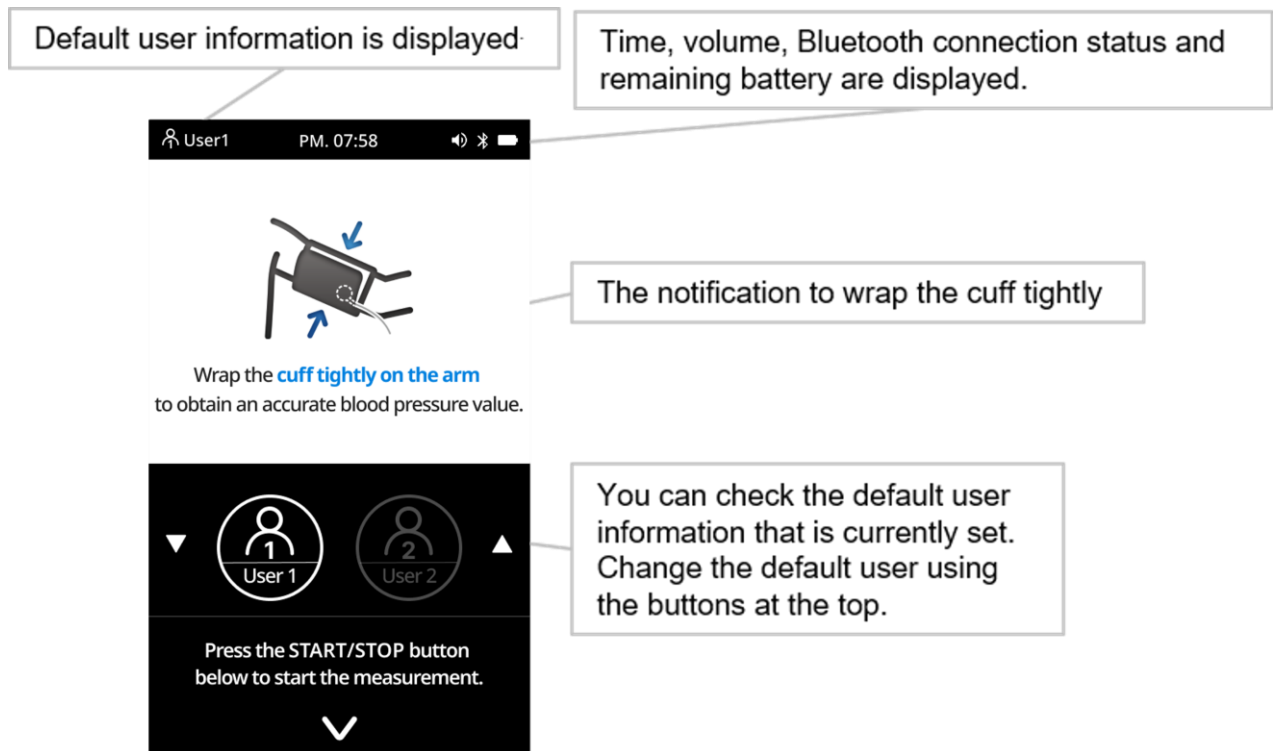
- 1 Connect the USB Type-C cable to the connector on the right side of V2 Doctor.



- 2 Press  Button to power on V2 Doctor



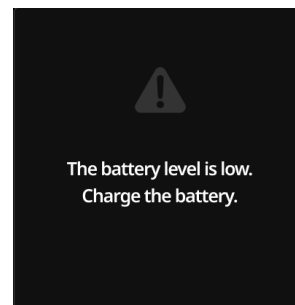
③ When V2 Doctor is turned on, the following home screen appears



### **Caution**

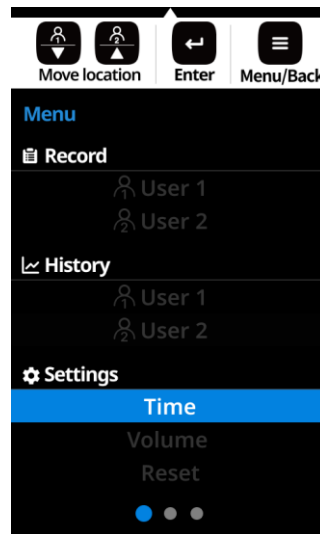
- Be sure to use the USB Type-C cable.
- The battery level may be low if it's the first time to use. Charge it fully before use.
- Check the battery level with the top icon on the right side of the screen.
- If you try to measure at low battery, the following pop-up window is displayed and the measurement is automatically stopped.
- While storing and not using the device, it is recommended to charge the battery to at least 50% every 6 months.
- For safety, the user can't charge the device while measuring the blood pressure.
- Last discharge capacity after 300th cycle is higher than 60% minimum capacity.
- For battery replacement, contact KOROT Customer Service center.

-  : Battery is full.
-  : Battery is low.
-  : Battery is depleted. Charge the battery



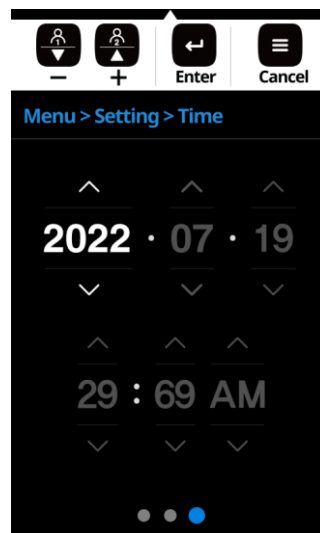
## B. Setting V2 Doctor

- Press  button at the top to move to the Menu screen.



### ※ Setting the date & time

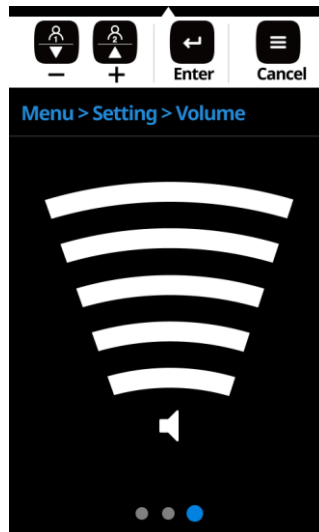
- 1 Select Time setting and press  button.
- 2 Press   button to change the date and time and press  button to move to the next.



- 3 When you are done, press  button to return to the previous screen.

## ※ Setting volume

- 1 Select Volume setting and press  button.
- 2 Press   button to control the volume.



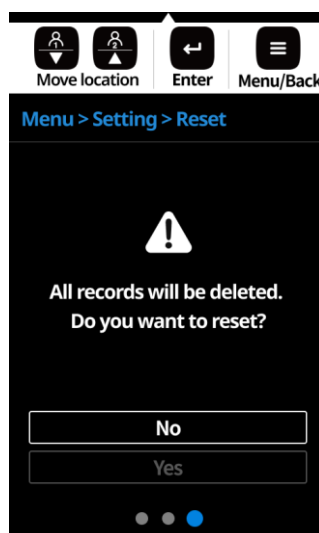
- 3 When you are done, press  button and return to the previous screen.

### Caution

- Loud noise can cause hearing loss.
- Korotkoff sounds can be muffled even at the maximum volume

## ※ Resetting the Device

- 1 Select Reset and press  button.
- 2 Press   button to decide whether to initialize the data.

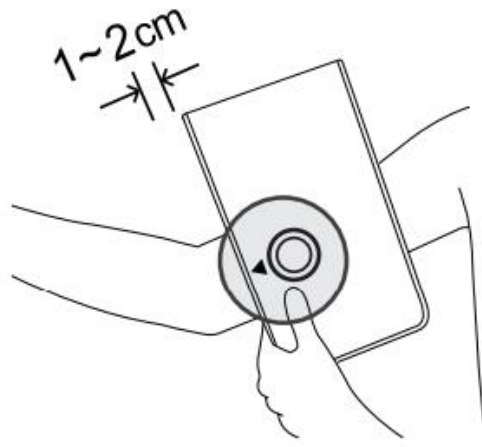


- 3 Press  button to start initializing.  
\* When initialized, all saved data and settings are deleted.

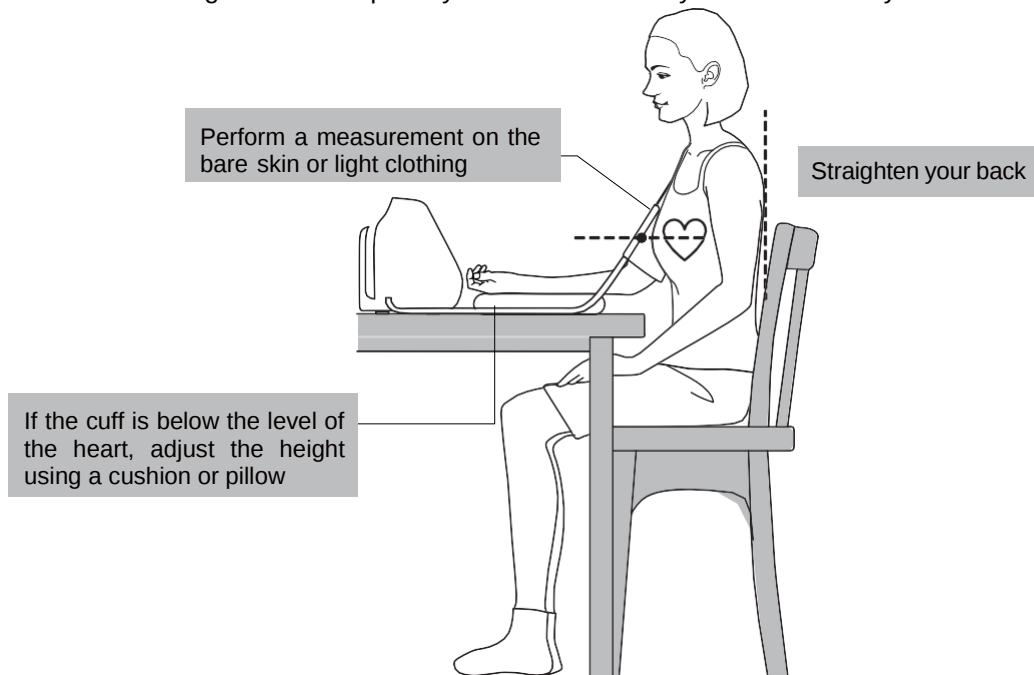
## C. Taking Measurement

### ※ Wrapping a cuff

- ❶ Wrap a cuff on your right arm (Apply the cuff to your arm so the ARTERY arrow mark is placed on the artery of your arm).



- ❷ Have a seat like the image below and place your arm comfortably to be level with your heart.



### ⚠ Caution

- Place your arm comfortably to be level with your heart.
- Wrap the cuff tightly enough for the stethoscope to be pressed against the skin.
- Remove thick clothing from the arm to acquire reliable measurement result.
- Use a cuff that fits around your arm.  
(S: 7~8.6 [in], M: 8.6~12.5 [in], L: 12.5~16.5[in]) / (S: 17~22 [cm], M: 22~32 [cm], L: 32~42[cm])
- If the cuffed arm is higher than or much lower than the level of the heart, the measurement can be unreliable.
- Place the stethoscope on the position of your artery. If the stethoscope is incorrectly positioned, the measurement result can be inaccurate.

## ✖ Taking measurement

- ① Press   to select the user and press  button to start measurement.

User1 PM. 07:58



Wrap the **cuff tightly on the arm** to obtain an accurate blood pressure value.



- ② Wait until the cuff is completely exhausted.

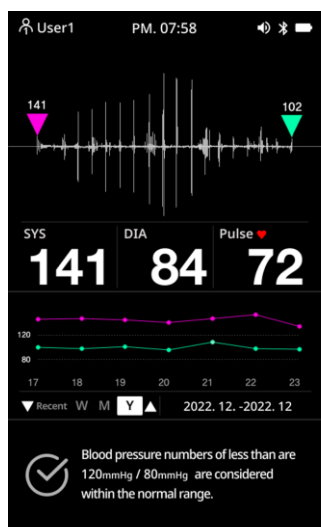


Korotkoff signal appears.  
The size varies from person to person.  
During the measurement, the highest and lowest blood pressure points are marked.

The current pressure of the cuff

Displays the guideline

- ③ After the measurement, the following result screen appears.



Korotkoff signal appears.  
The size varies from person to person.  
The highest and lowest blood pressure points are marked.

Blood pressure result  
From the left are high blood pressure, low blood pressure, and pulse.

Blood pressure trend  
(weekly, monthly, yearly)

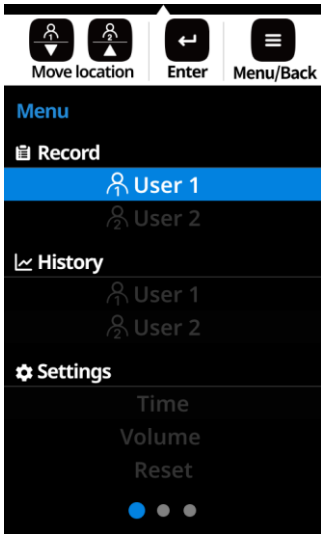
Common sense about the blood pressure and blood pressure measurement appears randomly.

- ④ The result screen is displayed for 12 seconds and the result value is saved in the Measurement record.

## D. Checking the Result

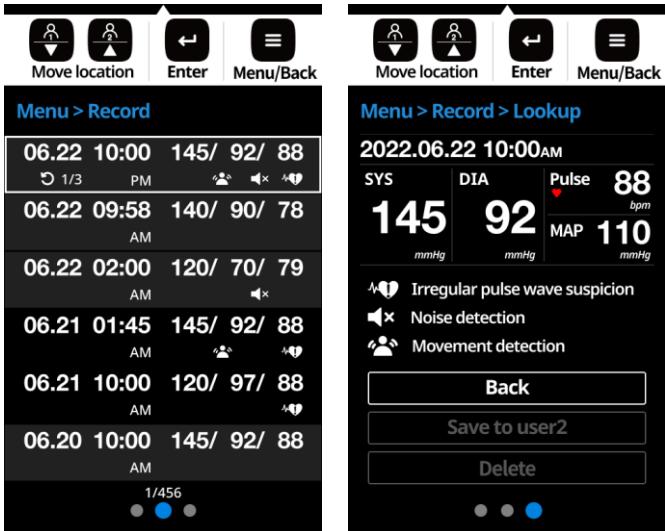
### ※ Measurement record

❶ Press  button, select Measurement record and press   button to select the user.



❷ Press  button to enter the record of the user.

❸ Press   button to move to the record to manage and press  button to select the record.



❹ Press   button to choose the option.



## ※ Reading the Measurement Record

- ❶ Check the measurement record. The measurement results were automatically saved.
- ❷ Icons shown in the result section are described below.



### • Icons

|  |                                |                                                                                                      |
|--|--------------------------------|------------------------------------------------------------------------------------------------------|
|  | Movement detection             | Appears when movement was detected during the measurement. Do not move or talk during a measurement. |
|  | Noise detection                | Appears when the noise is detected while taking a measurement.                                       |
|  | Irregular pulse wave detection | Appears when an irregular pulse wave was detected. If this icon reappears, contact an expert.        |

### • Explanation of the Measurement Result and the Method of Calculation

|     |                                                                                                                                                                                                              |
|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| SYS | Systolic Blood Pressure (SBP)                                                                                                                                                                                |
| DIA | Diastolic Blood Pressure (DBP)                                                                                                                                                                               |
| PR  | Pulse Rate [bpm]: Heart rate per minute / The heart rate per minute is displayed.                                                                                                                            |
| MAP | Mean Arterial Pressure [mmHg] $[1/3 \times \text{SYS} + 2/3 \times \text{DIA}]$<br>* <a href="https://en.wikipedia.org/wiki/Mean_arterial_pressure">https://en.wikipedia.org/wiki/Mean_arterial_pressure</a> |

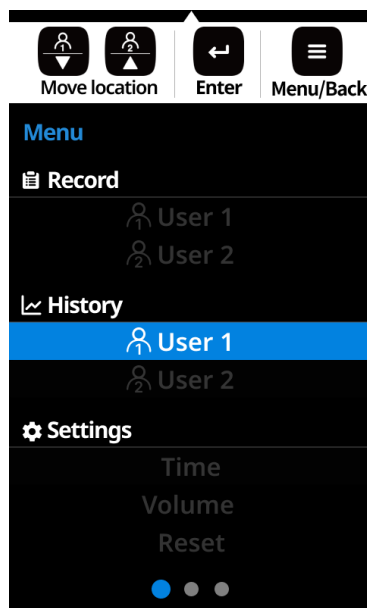


### Caution

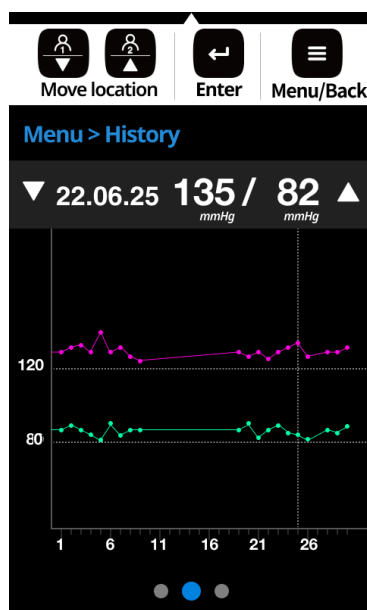
- Mean Arterial Pressure(MAP) is an ESTIMATED number.

## ※ Blood Pressure History Graph

- ① Press  button, select Measurement record and press   button to select the user.



- ② Press  button to check the user's history graph.



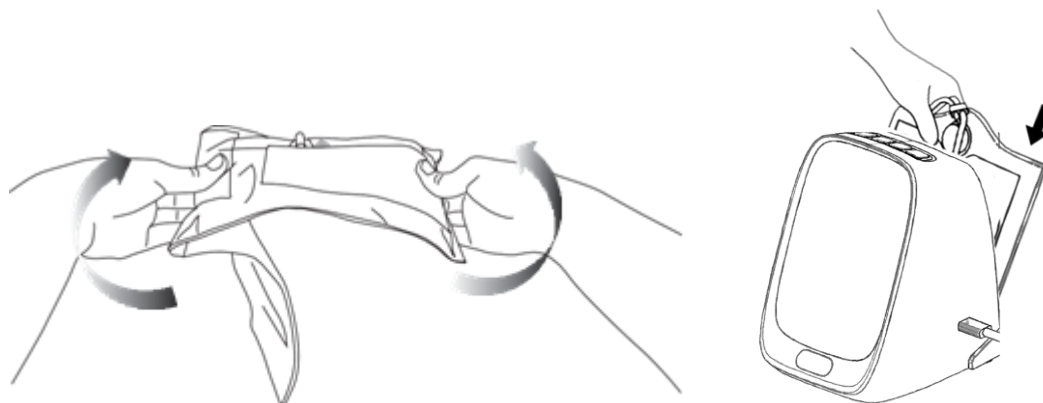
- ③ Press  button to go back to the menu.

## 3. Storing and Maintenance

### A. Storing and Maintenance

#### ※ Storing V2 Doctor and the Cuff

- ❶ Always keep V2 Doctor clean using a soft, lint-free cloth.
- ❷ Unfold the cuff and put it in the cuff box.
- ❸ Storing V2 Doctor in the package provided is recommended.



#### NOTE

- To unfold the cuff, hold it on both sides and unfold it in the opposite direction of the cuff rolling.
- To store and transport V2 Doctor safely, you must meet the criteria below.

#### • Environment Condition

| Item              | Transport/Storage Condition   | Operation Condition           |
|-------------------|-------------------------------|-------------------------------|
| Temperature       | -10 ~ 60°C                    | 10 ~ 40°C                     |
| Relative humidity | 10 ~ 85% RH (No Condensation) | 15 ~ 85% RH (No Condensation) |
| Air pressure      | 50 ~ 106 kPa                  | 70 ~ 106 kPa                  |

#### Caution

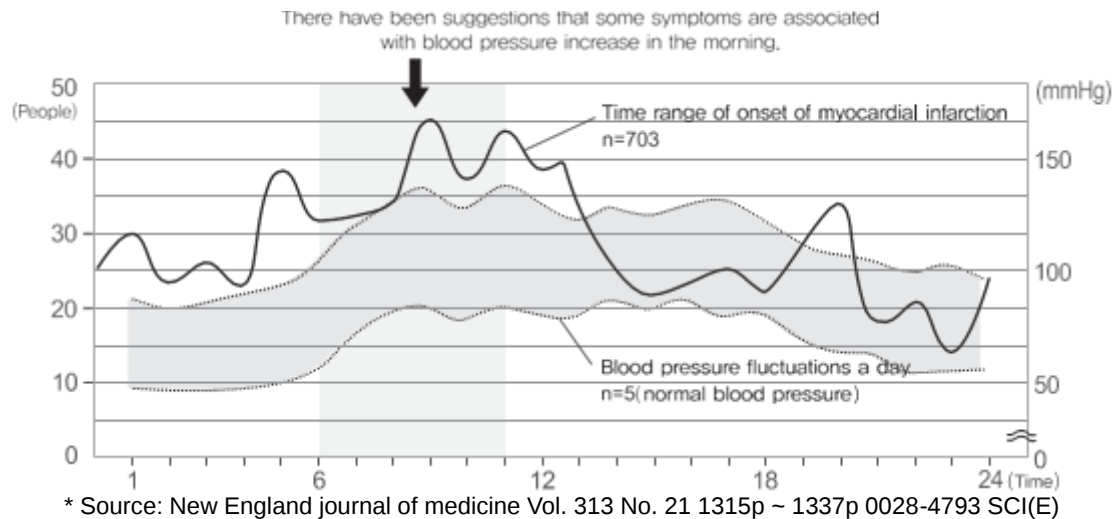
- Gently unfold the cuff so that it does not lose its ability to roll back.
- Do not put anything on V2 Doctor itself or on the box storing it.
- Keep V2 Doctor away from water.
- Do not subject the monitor to extreme hot or cold temperatures, humidity, direct sunlight, dust, bleach, or corrosive gas.
- Do not store V2 Doctor in a place subject to vibration or shock.
- Do not use flammable substances such as volatile liquids or benzene thinner to clean the monitor body or cuff.
- The cuff is not washable. Keep the cuff from water.
- Do not forcefully fold or press the cuff. It can cause the cuff to be damaged.
- The stethoscope is dedicated to V2 Doctor cuff and cannot be used alone. Do not detach the stethoscope from the cuff.
- It is recommended not to store the device over 60°C for more than a month. It can lower the battery performance.

## 4. Frequently Asked Questions and Answers

- Below are the frequently asked questions about the V2 Doctor.
- If you have any questions even after checking the information below, contact KOROT Customer Service.
- To contact KOROT customer service center, refer to the “Customer Service Information” on the page 1.

### A. Measurement

#### Question 1: Measurement results appear differently each time



##### Answer 1

- Blood pressure fluctuates throughout the day.
- Try to measure your blood pressure at about the same time each day for consistency.

##### Answer 2

- Blood pressure can change in the following cases.
  - Within one hour after meal
  - After you drink caffeinated beverages such as coffee or black tea, or consume alcohol
  - After smoking
  - After a bath
  - After urination or bowel movement
  - When you talk during a measurement
  - When you do not feel relaxed
  - When measuring in a different place or environment than usual

#### Question 2: The measurement result with V2 Doctor is lower than the blood pressure measured at the hospital.

##### Answer 1

- Because you are psychologically stable at home, result may appear 20-30mmHg lower than the measurement result at the hospital. It is important to know that the lower home blood pressure measured at home is in a relaxed state.

##### Answer 2

- If the cuff level is higher than the heart, the blood pressure result may appear lower. If so, adjust the height using a cushion or pillow.

**Question 3: The measurement result with V2 Doctor is higher than the blood pressure measured at the hospital.**

**Answer 1**

- If the cuff is loose, the cuff does not pressurize the pulse rate enough, so blood pressure measurement is higher. Wrap the cuff tightly so that there is no gap between the cuff and the arm.

**Answer 2**

- If the cuff level is lower than the heart, the blood pressure result may appear higher. If so, adjust the height using a cushion or pillow.

**Answer 3**

- Did you take a hypotensor at the hospital? Blood pressure may increase as the hypotensor wears off over time.

**Question 4: What time of the day is good for measurement?**

**Answer 1**

- It is recommended that you take a measurement after urinating especially in the morning and before breakfast. At night, try to measure before going to the bed.

**Answer 2**

- Because the blood pressure fluctuates as much as 30-50 mmHg throughout the day, try to measure your blood pressure at about the same time each day for consistency.

**Question 5: Measurement result is inconsistent.**

**Answer 1**

- If you experience severe arrhythmia, the measurement result may not be accurate. If you suffer from severe arrhythmia, measure the blood pressure at least three times and get the mean value of your blood pressure.

**Answer 2**

- Movement may affect the measurement result. Remain still and measure again.

**Answer 3**

- Measurement result may appear unreliable if you are not in a relaxed state.

**Question 6: Air is leaking from the cuff too fast.**

**Answer**

- If the cuff is not applied tightly on the arm, it can be deflated too fast. Apply it tightly and measure again.

**Question 7: Monitor is not working.**

**Answer 1**

- Check the adapter connection.

**Answer 2**

- The battery may have been depleted. If the battery level is not displayed at the top of the screen, connect the adapter and charge it. Contact Customer Service to change the battery if the battery level is still not displayed after charging.

**Question 8: No sound**

**Answer**

- Control the volume in the volume setting. If it doesn't work, please contact KOROT Customer Center.

**Question 9: How can I update V2 Doctor?**

**Answer**

- CS engineer will update the device if it is needed.

**Question 10: Can I transfer the blood pressure data to USB memory stick?**

**Answer**

- No. The USB port is only for the device firmware update and only CS engineer can access to the function.

## B. Errors

---

- Errors are displayed on the screen. See the descriptions below.

| Error Code No.        | Correction                                                                                                                                                |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1, 14, 23, 24         | <ul style="list-style-type: none"><li>• Tighten the cuff so that the stethoscope is in close contact with and measure again from the beginning.</li></ul> |
| 2, 11, 12, 13, 21, 22 | <ul style="list-style-type: none"><li>• Correct your posture, put the cuff back on, and measure again from the beginning.</li></ul>                       |
| 3                     | <ul style="list-style-type: none"><li>• The battery level is low. Please recharge.</li></ul>                                                              |

### NOTE

- If the problem repeats, please note the Code No. and contact Customer Service.

## 5. Others

### A. Symbols

|                                                                                     |                                                               |
|-------------------------------------------------------------------------------------|---------------------------------------------------------------|
|    | BF-type applied part                                          |
|    | Manufacturer                                                  |
|    | Date of manufacture                                           |
|    | EU-representative                                             |
|    | Serial number                                                 |
|    | Need for the user to consult the instruction manual           |
|    | Temperature limitation                                        |
|    | Humidity limitation                                           |
|   | Atmospheric pressure limitation                               |
|  | Medical device                                                |
|  | Unique device identifier                                      |
| IP21                                                                                | Classification of ingress of water or particulate matter info |
|  | WEEE mark                                                     |
|  | Importer                                                      |
|  | Federal Communications Commission mark                        |
|  | Direct current                                                |
|  | MR unsafe symbol                                              |

### B. Product Classification

- Type of protection against electric shock: Internally powered device
- Level of protection against flooding: IP21
- Level of protection against electric shock: BF-type applied part
- This device is not suitable for use in the presence of flammable anaesthetics or oxygen

## C. Components Sold Separately

|             |                                                                                                                     |
|-------------|---------------------------------------------------------------------------------------------------------------------|
| Cuff        | <ul style="list-style-type: none"><li>• S size(7~8.6in / 17~22cm)</li><li>• L size(12.5~16.5in / 32~42cm)</li></ul> |
| USB Adaptor | <ul style="list-style-type: none"><li>• General USB adaptor</li></ul>                                               |

## D. Specifications

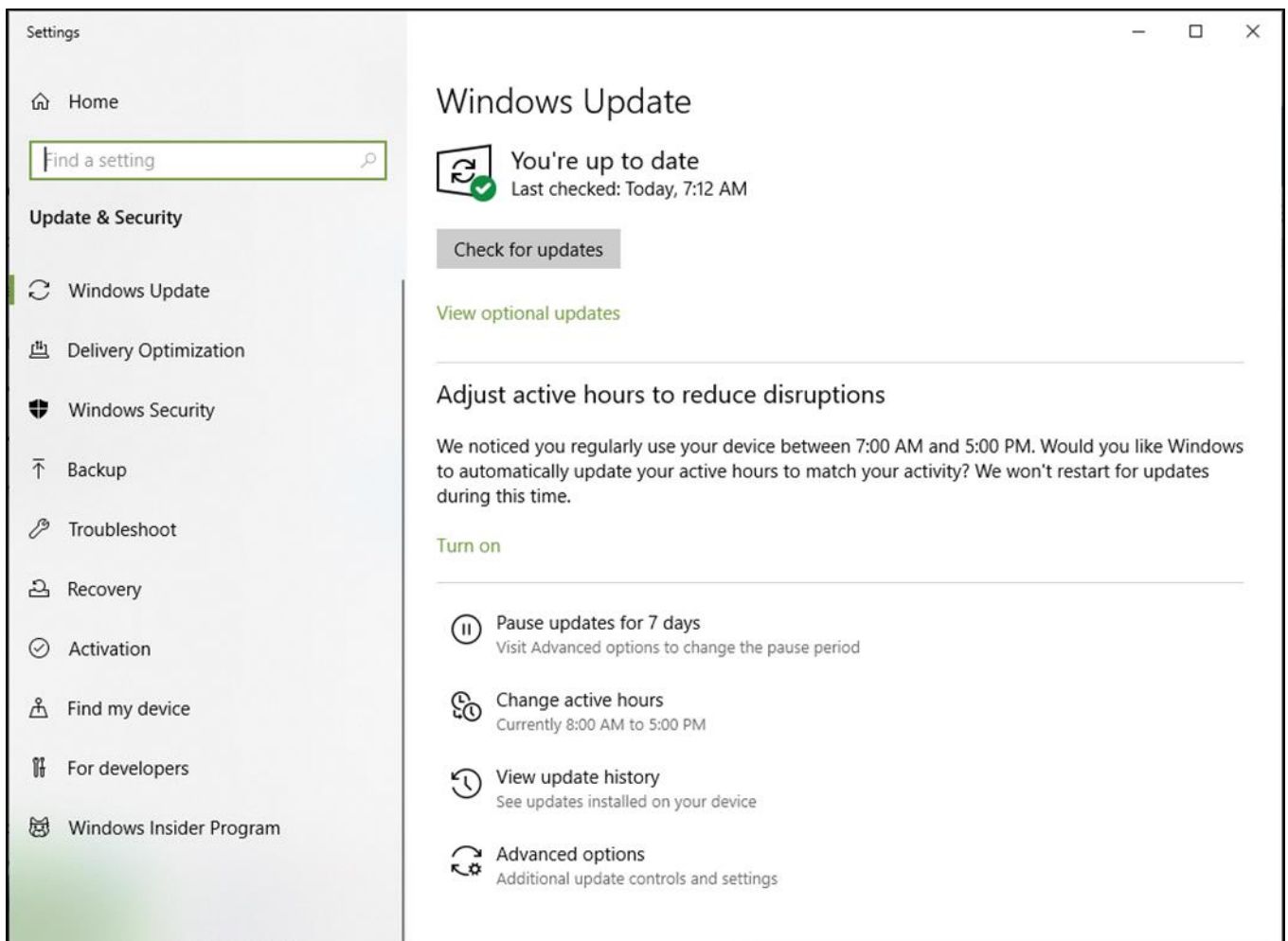
|                                     |                                                                                                                                                                                                                                                                                     |
|-------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name<br>(Model Name)        | Blood pressure monitor (KOROT V2 Doctor)                                                                                                                                                                                                                                            |
| Display Method                      | Digital display method (5 inch TFT LCD)                                                                                                                                                                                                                                             |
| Test Range                          | Pressure: 0~300mmHg, Pulse: 30~240bpm                                                                                                                                                                                                                                               |
| Degree of Precision                 | Pressure: $\pm 3$ mmHg, Pulse: Within $\pm 2\%$                                                                                                                                                                                                                                     |
| Minimum Scale Unit                  | 1mmHg                                                                                                                                                                                                                                                                               |
| Measurement Method                  | Auto Auscultation method + Oscillometric method                                                                                                                                                                                                                                     |
| Measured Values                     | Systolic/Diastolic blood pressure, Pulse Rate, Mean Arterial Pressure                                                                                                                                                                                                               |
| Pressurization method               | Automatic pressurization by air pump                                                                                                                                                                                                                                                |
| Depressurization method             | Automatic exhaust by linear solenoid valve                                                                                                                                                                                                                                          |
| Exhaust method                      | Automatic rapid exhaust                                                                                                                                                                                                                                                             |
| Cuff (0~300mmHg)                    | <ul style="list-style-type: none"><li>• S-size cuff (Only for circumference 7~8.6in / 17~22cm)</li><li>• M-size cuff (Only for circumference 8.6~12.5in / 22~32cm)</li><li>• L-size cuff (Only for circumference 12.5~16.5in / 32~42cm)</li></ul> *Not made of natural rubber latex |
| External Interface Connector        | USB, 3.5pi stereo                                                                                                                                                                                                                                                                   |
| Data Storage                        | 1000 examinations                                                                                                                                                                                                                                                                   |
| USB Data Format                     | .csv                                                                                                                                                                                                                                                                                |
| Wireless Communication              | Bluetooth 5.1                                                                                                                                                                                                                                                                       |
| Operating Environment               | 10 ~ 40°C, 15 ~ 85% RH, 70 ~ 106 kPa                                                                                                                                                                                                                                                |
| Transport/Storage Environment       | -10 ~ 70°C, 10 ~ 85% RH, 50 ~ 106 kPa (No Condensation)                                                                                                                                                                                                                             |
| Rated voltage and power consumption | USB C-Type: 5V/3A, 5V/2A<br>Battery: 3.63V, 2600mAh (min. 2550mAh)                                                                                                                                                                                                                  |
| Dimension                           | Approx: 130(W) x 197(H) x 150(L) mm                                                                                                                                                                                                                                                 |
| Device Weight                       | Approx: 0.7kg (1.54lb)                                                                                                                                                                                                                                                              |
| Package Weight                      | Approx: 1.4kg (3.07lb)                                                                                                                                                                                                                                                              |
| Manufacturing Country               | Republic of Korea                                                                                                                                                                                                                                                                   |
| Manufacturing Company               | KOROT Co., Ltd.                                                                                                                                                                                                                                                                     |
| Life Time                           | Device: 6 years<br>Cuff: 1 year                                                                                                                                                                                                                                                     |

### NOTE

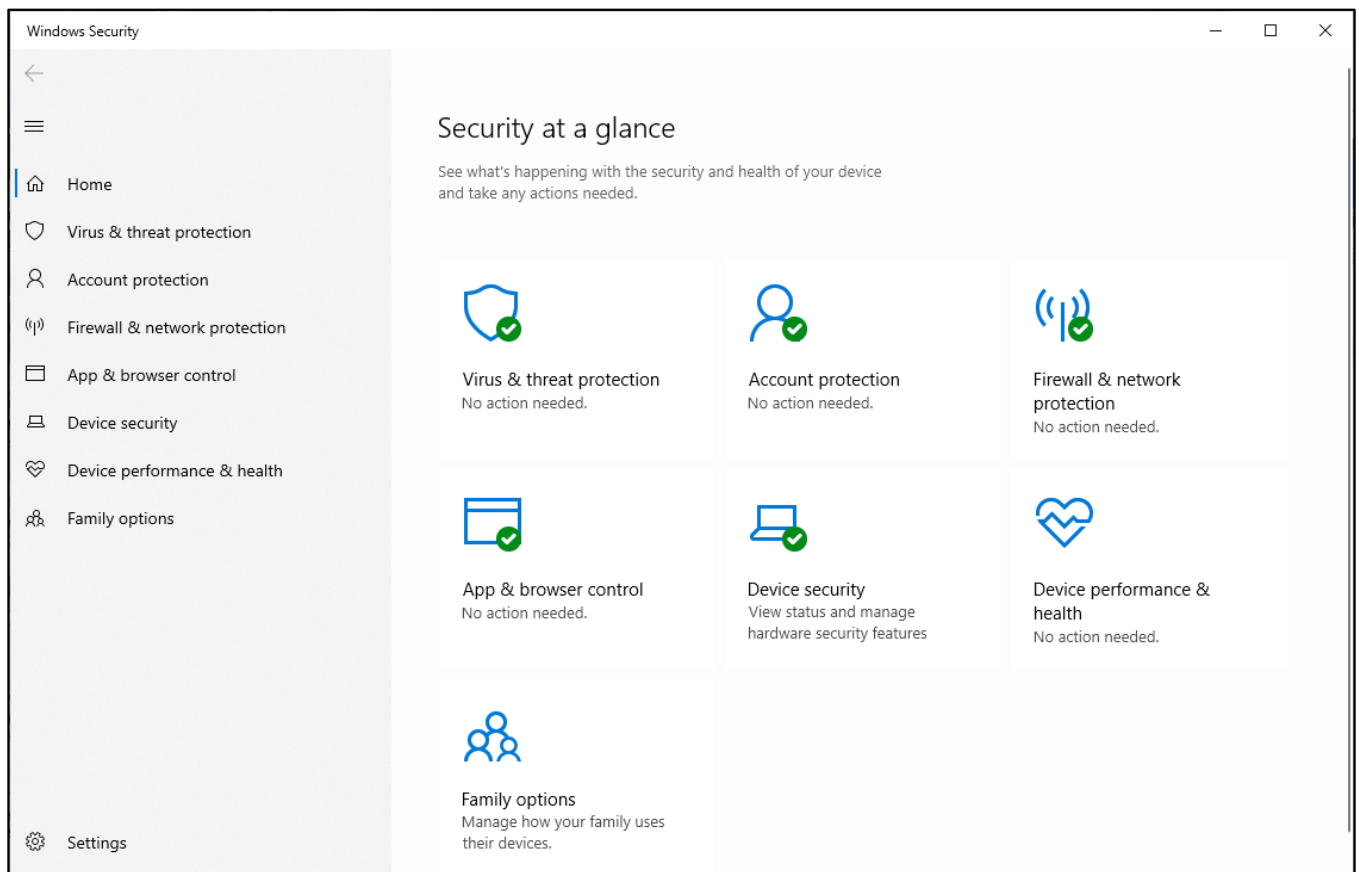
- The above information is subject to change without notice to improve appearance and product performance.
- This product is a Medical Device, and read the Precautions and Instructions carefully before you use.

### USER MANUAL SUPPLEMENT PROTECTING YOUR SYSTEM FROM CYBERSECURITY THREATS INTRODUCTION

Because the KOROT V2 Doctor has a USB port, and blood pressure data can be transferred to a USB data stick, it is possible that the data stick may carry malicious software, and the computer you connect the data stick to may connect by Wi-Fi or Ethernet to the Internet or via a hospital information system, cybersecurity may become an issue for you. Here are some tips to keep your system and your medical data secure. If your imaging system came with a Windows based computer system, it has had an anti-virus program installed on it. We request that you keep the operating system up to date with the operating system and anti-virus updates. You can view the status by typing Windows Update in the search box:



Also you can check the status of the anti-virus program by typing “Windows Security” in the search box:



### REQUIRED STRATEGIES: Your Responsibilities

Use antivirus programs such as:

- Microsoft Defender
- TotalAV
- ScanGuard Security Suite
- Norton by Symantec
- PCProtect
- McAfee Antivirus

Keep these products UP TO DATE.

**IMPORTANT:** WHEN YOU SELECT A USB DATA STICK TO TRANSFER YOUR BLOOD PRESSURE DATA, DO THIS FIRST: Plug the data stick into a free USB port on your computer and SCAN the data stick with your antivirus program. Only then can you use that data stick to transfer blood pressure data to it from your KOROT V2 Doctor. Furthermore if you are going to update the V2 Doctor software, use software provided by KOROT. Never use any other software.

Identify and Protect:

- Limit Access to Trusted Users Only: Limit access to devices through the authentication of users (e.g. user ID and password.)

Ensure Trusted Content:

- Restrict software or firmware updates to authenticated code. USE ONLY MATERIALS SUPPLIED BY US FOR YOUR SOFTWARE UPDATES.
- Use systematic procedures for authorized users to download version-identifiable software and firmware from the manufacturer.

Detect, Respond, Recover:

- Watch for on-screen warnings of possible virus infections
- Respond by scanning for and removing possible virus infections
- Recover from possible virus infections by having up to date BACKUPS of your host computer.

#### REQUIRED STRATEGIES: Our Responsibilities

We affirm our commitment to providing you with validated software updates and patches as needed throughout the lifecycle of the medical device to continue to assure its continued safety and effectiveness. Please promptly apply software updates and patches provided by us and never use software supplied by anyone else. Our development process utilizes the Microsoft Malware Defense Guide which can be found at:

<https://technet.microsoft.com/library/cc162791#E1F>

We are constantly scanning our development computers for malware. We hope you are doing the same.

#### A SUMMARY OF OUR INTEGRITY CONTROLS

- Our development computers are constantly being scanned for malware, and our supplier for anti-virus software automatically updates the software continuously as new threats are revealed.
- We perform daily backups to our external hard drives. These drives are then disconnected from the system after the backups.
- During software development we disconnect from the Internet to prevent external attacks.
- Our development process utilizes the Microsoft Malware Defense Guide.
- Copies of software updates we will be sending you are individually scanned for malware. **USE ONLY MATERIALS SUPPLIED BY US FOR YOUR UPDATES.**

#### CONCLUSION

It is our JOINT responsibility to ensure your medical software and data collection is safe and secure. We must both do our parts.

#### SUPPLEMENT FOR MAC COMPUTERS:

Although Apple MAC computers are generally less susceptible to viruses, they are NOT immune.

In short, yes you do need antivirus for your Mac. Mac computers are not immune to viruses and other malware and Mac-targeted attacks are increasingly prevalent. Following best practices for securing your device and using built-in security features can help, but antivirus software can protect your device even further.

## F. EMC Information

- The V2 Doctor is intended for use in the electromagnetic environment specified below. The customer or the user of V2 Doctor should assure that it is used in such an environment.

| Phenomenon                                                             | Basic EMC standard or test method                               | Operating mode            | Port tested | Test Voltage                                                                                                   | Test level/requirement                                                                           |
|------------------------------------------------------------------------|-----------------------------------------------------------------|---------------------------|-------------|----------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|
| Mains terminal disturbance voltage                                     | CISPR 11:2015<br>+A1:2016+A2:2019<br>EN 55011:2016+A1:2017      | Continuous operation mode | AC Mains    | AC 100 V, 50 Hz<br>AC 100 V, 60 Hz<br>AC 120 V, 60 Hz<br>AC 220 V, 60 Hz<br>AC 230 V, 50 Hz<br>AC 240 V, 50 Hz | Group 1, Class B                                                                                 |
| Radiated disturbance                                                   | CISPR 11:2015<br>+A1:2016+A2:2019<br>EN 55011:2016+A1:2017      | Continuous operation mode | Enclosure   | AC 100 V, 50 Hz<br>AC 100 V, 60 Hz<br>AC 120 V, 60 Hz<br>AC 220 V, 60 Hz<br>AC 230 V, 50 Hz<br>Battery 3.63 V  | Group 1, Class B                                                                                 |
| Harmonic Current Emission                                              | IEC 61000-3-2:2018<br>+A1:2020<br>EN 61000-3-2:2014             | Continuous operation mode | AC Mains    | AC 230 V, 50 Hz                                                                                                | Class A                                                                                          |
| Voltage change, Voltage fluctuations and Flicker Emission              | IEC 61000-3-3:2013<br>+A1:2017<br>EN 61000-3-3:2013<br>+A1:2019 | Continuous operation mode | AC Mains    | AC 230 V, 50 Hz                                                                                                | Pst: 1<br>Plt: 0.65<br>dmax: 4%<br>dc: 3.3%                                                      |
| Electrostatic Discharge Immunity                                       | IEC 61000-4-2:2008<br>EN 61000-4-2:2009                         | Continuous operation mode | Enclosure   | AC 100 V, 50 Hz<br>AC 100 V, 60 Hz<br>AC 120 V, 60 Hz<br>AC 220 V, 60 Hz<br>AC 230 V, 50 Hz<br>Battery 3.63 V  | ± 8 kV/Contact<br><br>± 2, ± 4, ± 8,<br>± 15 kV/Air                                              |
| Radiated RF Electromagnetic Field Immunity                             | IEC 61000-4-3:2020<br>EN 61000-4-3:2006<br>+A2:2010             | Continuous operation mode | Enclosure   | 100 V, 50 Hz<br>100 V, 60 Hz<br>120 V, 60 Hz<br>220 V, 60 Hz<br>230 V, 50 Hz<br>Battery 3.63 V                 | 3 V/m<br>80 MHz-2.7 GHz<br>80% AM at 1 kHz                                                       |
| Immunity to Proximity Fields from RF wireless Communications Equipment | IEC 61000-4-3:2020<br>EN 61000-4-3:2006<br>+A2:2010             | Continuous operation mode | Enclosure   | AC 100 V, 50 Hz<br>AC 100 V, 60 Hz<br>AC 120 V, 60 Hz<br>AC 220 V, 60 Hz<br>AC 230 V, 50 Hz<br>Battery 3.63 V  | Table 9 in<br>IEC 60601-1-2:<br>2014                                                             |
| Electrical Fast Transient/Burst Immunity                               | IEC 61000-4-4:2012<br>EN 61000-4-4:2012                         | Continuous operation mode | AC Mains    | AC 100 V, 50 Hz<br>AC 100 V, 60 Hz<br>AC 120 V, 60 Hz<br>AC 220 V, 60 Hz<br>AC 230 V, 50 Hz                    | ± 2 kV, 100 kHz repetition frequency                                                             |
|                                                                        |                                                                 |                           |             |                                                                                                                | ± 1 kV, 100 kHz repetition frequency                                                             |
| Surge Immunity                                                         | IEC 61000-4-5:2014<br>EN 61000-4-5:2014<br>+A1:2017             | Continuous operation mode | AC Mains    | AC 100 V, 50 Hz<br>AC 100 V, 60 Hz<br>AC 120 V, 60 Hz<br>AC 220 V, 60 Hz<br>AC 230 V, 50 Hz                    | Line to Line<br>± 0.5 kV, ± 1 kV<br><br>Line to Ground<br>± 0.5 kV, ± 1 kV, ± 2 kV               |
| Immunity to Conducted Disturbances Induced by RF fields                | IEC 61000-4-6:2013<br>EN 61000-4-6:2014                         | Continuous operation mode | AC Mains    | AC 100 V, 50 Hz<br>AC 100 V, 60 Hz<br>AC 120 V, 60 Hz<br>AC 220 V, 60 Hz<br>AC 230 V, 50 Hz                    | 3 V<br>0.15-80 MHz<br><br>6 V in ISM bands<br>Between 0.15 MHz and 80 MHz<br><br>80% AM at 1 kHz |
| Power Frequency Magnetic Field Immunity                                | IEC 61000-4-8:2009<br>EN 61000-4-8:2010                         | Continuous operation mode | Enclosure   | AC 100 V, 50 Hz<br>AC 100 V, 60 Hz<br>AC 120 V, 60 Hz<br>AC 220 V, 60 Hz<br>AC 230 V, 50 Hz<br>Battery 3.63 V  | 30 A/m<br>50 Hz & 60 Hz                                                                          |
| Voltage dips                                                           | IEC 61000-4-11: 2020<br>EN 61000-4-11:2004<br>+A1:2017          | Continuous operation mode | AC Mains    | AC 100 V, 50 Hz<br>AC 100 V, 60 Hz<br>AC 220 V, 60 Hz<br>AC 240 V, 50 Hz<br>AC 240 V, 60 Hz                    | 0 % U <sub>T</sub> : 0.5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°               |
|                                                                        |                                                                 |                           |             |                                                                                                                | 0 % U <sub>T</sub> : 1 cycle<br>and<br>70 % U <sub>T</sub> : 25/30 cycles<br>Single phase: at 0° |
| Voltage interruptions                                                  | IEC 61000-4-11: 2020<br>EN 61000-4-11:2004<br>+A1:2017          | Continuous operation mode | AC Mains    | AC 100 V, 50 Hz<br>AC 100 V, 60 Hz<br>AC 220 V, 60 Hz<br>AC 240 V, 50 Hz<br>AC 240 V, 60 Hz                    | 0 % U <sub>T</sub> : 250/300 cycle                                                               |

|                                       |                      |                           |           |                                                                         |                     |
|---------------------------------------|----------------------|---------------------------|-----------|-------------------------------------------------------------------------|---------------------|
| Immunity to proximity magnetic fields | IEC 61000-4-39: 2017 | Continuous operation mode | Enclosure | AC 100 V, 50 Hz                                                         | 30 kHz : 8 A/m      |
|                                       |                      |                           |           | AC 100 V, 60 Hz                                                         | 134.2 kHz : 65 A/m  |
|                                       |                      |                           |           | AC 120 V, 60 Hz<br>AC 220 V, 60 Hz<br>AC 230 V, 50 Hz<br>Battery 3.63 V | 13.56 MHz : 7.5 A/m |

### Electromagnetic immunity

The [Model name] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Portable RF communications equipment should be used no closer than 30 cm (12 inches) to any part of the [Model name]. Otherwise, degradation of the performance of this equipment could result.

| Immunity test                                                 | Band a)         | Service a)                                                             | Modulation b)                           | IEC60601 test level | Compliance level |
|---------------------------------------------------------------|-----------------|------------------------------------------------------------------------|-----------------------------------------|---------------------|------------------|
| Proximity fields from RF wireless Communications IEC61000-4-3 | 380 - 390 MHz   | TETRA 400                                                              | Pulse modulation b) 18Hz                | 27 V/m              | 27 V/m           |
|                                                               | 430 – 470 MHz   | GMRS 460<br>FRS 460                                                    | FM c)<br>±5 kHz deviation<br>1 kHz sine | 28 V/m              | 28V/m            |
|                                                               | 704 – 787 MHz   | LTE Band13, 17                                                         | Pulse modulation b) 217 Hz              | 9 V/m               | 9 V/m            |
|                                                               | 800 – 960 MHz   | GSM800:900<br>TETRA 800<br>iDEN 820<br>CDMA 850<br>LTE Band 5          | Pulse modulation b)<br>18 Hz            | 28 V/m              | 28V/m            |
|                                                               | 1700 – 1990 MHz | GSM 1800<br>CDMA 1900<br>GSM 1900<br>DECT<br>LTE Band 1,2,4,25<br>UMTS | Pulse modulation b) 217 Hz              | 28 V/m              | 28V/m            |
|                                                               | 2400 – 2570 MHz | Bluetooth<br>WLAN<br>802.11b/g/n<br>RFID 2450<br>LTE Band 7            | Pulse modulation b) 217 Hz              | 28V/m               | 28V/m            |
|                                                               | 5100 – 5800 MHz | WLAN 802.11a/n                                                         | Pulse modulation b) 217 Hz              | 9 V/m               | 9 V/m            |

NOTE : If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1m. The 1m 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 to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.