KOROT V2 Doctor

User's Manual

KOROT

⚠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 near MRI equipment or in the EMC environment.
- Do not use in combination with defibrillator or hyperbaric oxygen therapy equipment.
- Except for the medical professionals, do not use the device 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.
- 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.
- Do not open or perform any internal modifications on V2 Doctor.
- If the patient feels severe pain or abnormalities during measurement, immediately stop measuring blood pressure.
- Do not use V2 Doctor on an injured arm or during arm treatment.
- Do not measure on an arm receiving an intravenous injection or blood transfusion.
- If this device has been modified, proper inspection and testing must be carried out to ensure its continued safe use.
- In case of an emergency during the measurement, press the Start/Stop button or unwrap the cuff.
- Do not use V2 Doctor along with HF SURGICAL EQUIPMENT.
- Too frequent measurements can cause injury to the patient due to the blood flow interference.
- By examining the affected limb, ensure that the device's operation does not result in a prolonged impairment of the patient's blood circulation.
- Pressurization of the cuff can temporarily cause loss of function of simultaneously used device on the same limb.
- Continuous cuff pressure due to connection tubing kinking can cause the effect of blood flow interference resulting harmful injury to the patient.
- If the air tube is wrapped around the neck, there is a risk of injury or death from suffocation.
- Do not use this product in places where the use of wireless devices is prohibited. Since this product emits radio frequency (RF) energy in the 2.4 GHz band, it is not recommended to use it in areas where high frequencies are restricted.
- Do not connect the unauthorized device via Bluetooth.

※Handling the Adapter

- Be sure to use only the Adapter supplied with V2 Doctor. Using an adapter other than the one provided could result in damage to V2 Doctor or malfunction.
- USB C-type port is for charging only.
- Do not connect the charger with wet hands.
- Do not use V2 Doctor when the cord or AC Adapter has been damaged.

메모 포함[조C2]: 전용 어댑터 제공하는 조건으로 수정

⚠Cautions - In general

- 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

- The device is not intended for infants.
- The cuff is not made of natural rubber latex.
- Only use dedicated cuffs manufactured by KOROT with this device.
- In the event of an incident related to cybersecurity, side effect or accident, contact KOROT Customer Service. It should be reported to the manufacturer and competent authority.
- Do not use without the arm in the cuff.
- Be careful not to allow foreign substances such as food or beverages to enter into the device.
- Do not wrap the cuff on the arm on the side of a mastectomy or lymph node clearance.
- Only use dedicated Li-ion battery with this device.

Cautions - Before taking a measurement

- Make sure whether the device is not dirty or wet.
- For proper blood pressure management, use the blood pressure monitor after setting the date/time.
- Install the device on a flat, vibration-free floor.
- If the battery level is low, connect the adapter and wait for 10 minutes before taking a measurement.
- Remove thick clothing and do not roll sleeves.
- Adjust the height of your chair so the cuff is leveled with your heart.
- Take a measurement when you are in a relaxed state. Sit and rest for about 5 minutes prior to taking the measurement.
- Wrap the cuff firmly so that KOROT sensor is pressed against the skin (If not, the measurement may not be accurate).

Cautions - When using V2 Doctor

- 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 KOROT sensor or cuff during the measurement.
- Press START/STOP button during the measurement if you encounter an error message on the monitor (Refer to QnA).
- Korotkoff sound may be temporarily inaudible if there is an electrical shock 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.
- Stop taking the measurement immediately if you feel pain or abnormality during the measurement.

Cautions - After using V2 Doctor

- Store the cuff in the holder located in the back of the device.
- Do not overly bend the cuff or the air tube when storing the unit.
- Consult experienced medical professionals for the measurement result.
- If you excessively repeat the measurement, temporary internal bleeding (bruising) may occur due to cuff compression.
- 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.
- For repackaging, the packaging protection material provided by KOROT Co., Ltd. must be used.
- The cuff cannot be washed. Be careful not to get water on the cuff.
- Do not overly bend the cuff or the air tube when storing the unit.
- Keep V2 Doctor out of reach of infants, children and pets.
- Dispose of packaging and other wastes in accordance with applicable laws and regulations.

V2 Doctor is verified in accordance with IEC 60601-1 and ISO 80601-2-30, international safety standards for electronic medical devices and produced under the quality control procedure of KOROT Co., Ltd. which complies with ISO 13485, an international quality management system standard.

V2 Doctor is clinically validated in accordance with the Association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization (AAMI/ESH/ISO) Universal Standard (ISO 81060-2:2018/A1:2020).

User's Manual Contents

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 15cm to 53cm (6-inch to 21-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 ocillometric 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 can be used in home environment.

메모 포함[조C3]: XS ~ XL

B. Measuring Blood Pressure Using V2 Doctor

메모 포함[이L4]: 여기 내용은 굳이 없어도 됨

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 KOROT sensor 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 one of the most traditional and well-recognized standard of blood pressure measuring method. 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.

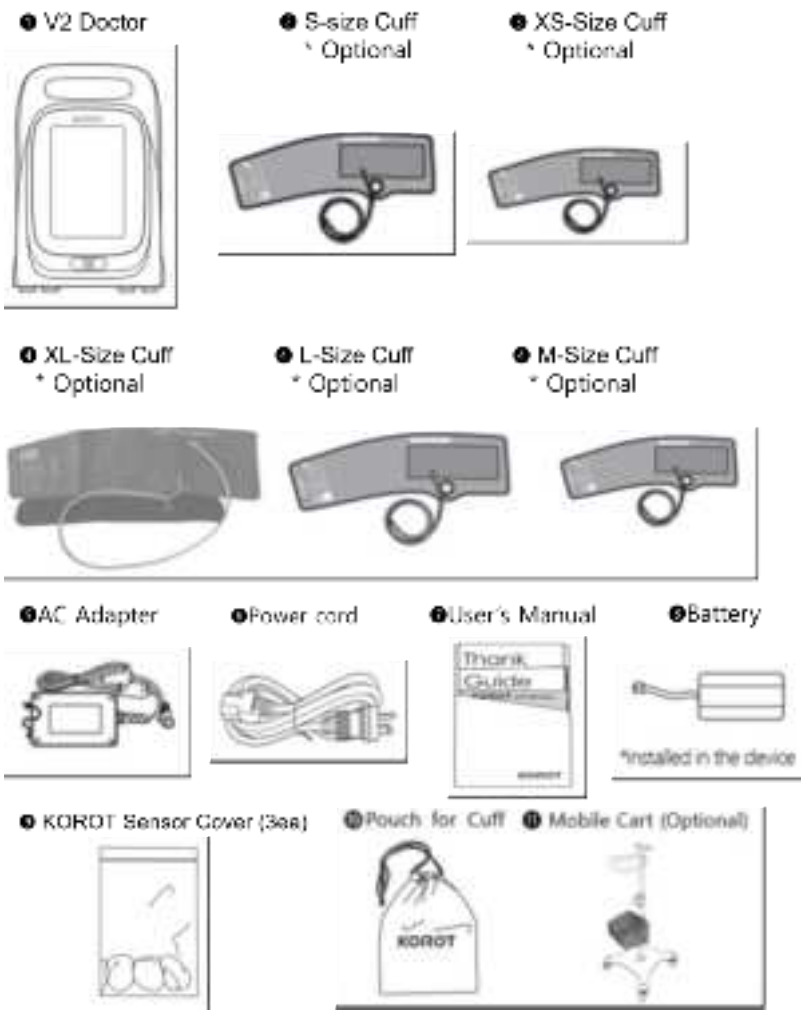
The resulting Korotkoff sound appears as shown in the figure above, marking the first sound heard with the systolic pressure (SYS) and the last sound heard with diastolic pressure (DIA).

C. Product Components

메모 포함[이L5]: User's manual 그림 바꿔야 하나? 퀵매뉴얼 들어가나?

메모 포함[성S6R5]: 양식 및 디자인은 퀵매뉴얼 형태로, 내용은 현재 검토중인 이 파일 내용으로 들어갑니다.

메모 포함[조C7]: 커프 및 구성품 업데이트
(어댑터는 브릿지파워 이미지인듯?)



NOTE

- Please check the product components when opening for the first time.

D. Exterior and Functions

※ KOROT Device

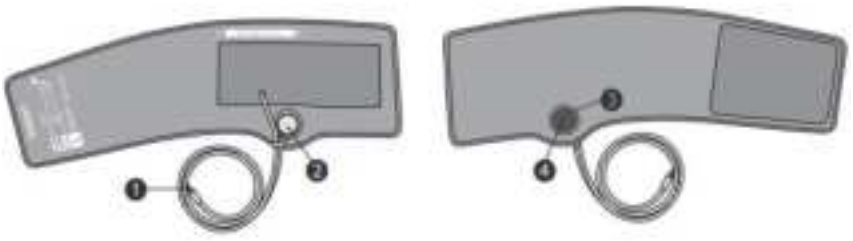
No.	Item	Function
①	User Interface Buttons	M1, M2, Menu and OK buttons
②	Cuff Connector	For connecting the dedicated cuff
③	Handle	Handle for carrying
④	Display	Displays measurement results and device status
⑤	Start/Stop Button	Button to start or stop measurement
⑥	USB 3.0 Connector	For connecting the 5V adapter for charging the battery
⑦	Anti-slip rubber	Rubber to support the device
⑧	Speaker	Speaker for sound output
⑨	Label	Label with basic device information

메모 포함[조C8]: 문구 일부 수정

※ KOROT Cuff

메모 포함[이L9]: D링으로 그림 교체 필요?

메모 포함[성S10R9]: M/L 커프는 D링 그림 넣어주세요



No.	Item	Function
①	Cuff connector	For connecting to the device
②	KOROT sensor (top side)	Collects KOROT signals (Korotkoff sound)
③	KOROT sensor (bottom side)	Collects KOROT signals (Korotkoff sound)
④	KOROT sensor cover	Protects KOROT sensor

2. Using V2 Doctor

A. Preparing to Use

메모 포함[조C11]: 문구 전용 어댑터 제공 하는 조건으로 수정

❶ Pull the device from the box using the handle on the top.

❷ Insert the AC adapter provided with the product into the AC adapter jack on the left side of the monitor.

❸ Plug the AC adapter into an outlet.

NOTE

- Remove the protection film before you use.

❹ Press the START/STOP button to power on the device.

⚠ Caution

- Use only the dedicated AC adapter that came with this monitor (5[V] 2.4[A])
- The battery level may be low when powering on the product for the first time. Please charge before use.
- Approximately 150 measurements can be taken on a full charge.
- If you try to measure at low battery, the following pop-up window will show up, and the measurement will be automatically stopped.
- While storing and not using the device, it is recommended to charge the battery to at least 50% every 6 months.
- The user can measure blood pressure while charging because the IEC 60601-1 test was conducted with the adapter connected.
- Last discharge capacity after 300th cycle is higher than 60% minimum capacity.
- For battery replacement, contact KOROT Customer Service center.

메모 포함[조C12]: 전용 어댑터 사양 문구로 수정

메모 포함[조C13]: IEC 60601-1-11 7.4.2 내용 적용, 전용 어댑터 제공하기에 충전 중 혈압 측정 가능

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

❶ Select Time setting and press  button.

❷ Press  button to change the date and time and press  button to move to the next.

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

※ Setting volume

❶ Select Volume setting and press  button.

❷ Press  button to control the volume.

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

Caution

- Loud noise can cause hearing loss.
- Korotkoff sounds may sound quiet even at maximum volume depending on the health status of the user..

※ Initializing the Device

❶ Select Reset and press  button.

❷ Press  button to decide whether to initialize the data.

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

C. Preparing for the Measurement

- It is recommended to take a break for 5 to 10 minutes before the measurement.
- Do not smoke and drink alcohols or caffeine 30 minutes before the measurement.
- During the measurement, please relax and take measurement in a stable state.
- Do not talk or move during the measurement.

❶ Connect the cuff with the triangle shape facing up.

NOTE

- Use the cuff that fits around your arm
  (XS: 6~7, S: 7~9, M: 9~13, L: 13~17, XL: 17~21 [in])
  (XS: 15~18, S: 17~22, M: 22~32, L: 32~42, XL: 42~53 [cm])

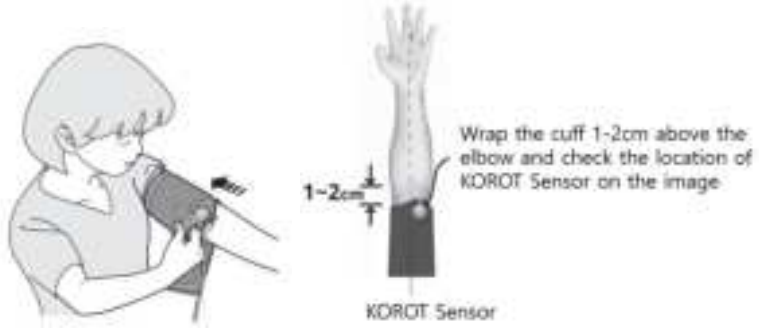
메모 포함[조C14]: XS ~ XL

⚠ Caution

- Measurements will not be performed if the cuff is not connected correctly

❷ Wrap the cuff on your upper arm.

메모 포함[성S15]: 일러스트에 1~2cm 옆에 (0.4~0.8 inch) 도 같이 써주세요.

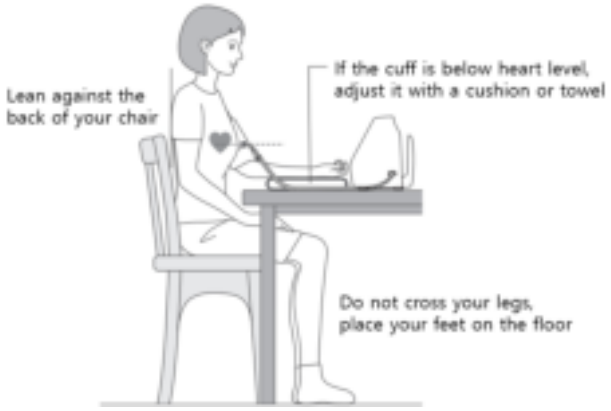


❸ After locating the KOROT sensor on the proper position, wrap the cuff and tighten it by using the Velcro.

*The result can vary between the left and the right arm. Always wrap the cuff on the same arm.

D. Taking Measurement

❶ Have a seat like the image below and the arm should be placed on the table, comfortable and in level with the heart.



❷ Press the Start/Stop button to turn on the screen and choose User1, User2 or guest by pushing button.

메모 포함[이L16]: 영문 화면 교체 필요 (한미숙K)

❸ Press the Start/Stop button to start KOROT test.

NOTE

- If the surroundings are noisy or you talk while measuring, the blood pressure value can be inaccurate.
- If you want to stop the measurement, press the Start/Stop button again.
- If you measured by guest, the data is not saved.
- If you are going to measure in a row, take at least one minute break between the tests.

⚠ Caution

- Wrap the cuff tightly enough for the KOROT sensor to be pressed against the skin.
- If the arm with the cuff is significantly higher or lower than the heart level, then the test results may be unreliable.
- If the KOROT sensor is incorrectly positioned, the measurement result can be inaccurate.

E. Measurement Result

※ Checking the result

❶ After the measurement, the following screen appears.

① ② ④ ③

No.	Content	
①	Displays the KOROT graph (Korotkoff and Oscillometric signal). The amplitude is different by person and the systolic/diastolic pressure points are marked.	
②	SYS	Displays Systolic pressure.
	DIA	Displays Diastolic pressure.
	Pulse	Displays pulse rate (heart rate per minute).
③	Can check the trend of your blood pressure.	
④	Displays the notification including normal blood pressure range (AHA).	

❷ The result screen is displayed for 120 seconds and the result is saved as history data.

❸ If KOROT App is connected, the result would be automatically saved in the app as well.

· 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 X SYS + 2/3 X DIA] * https://en.wikipedia.org/wiki/Mean_arterial_pressure

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

메모 포함[이L17]: 화면 영문으로 교체 필요 (한미숙K)

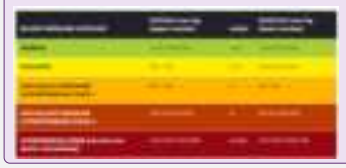
메모 포함[이L18]: 해외 기준에 맞게 수정 필요
현재 제품 내 기준은 WHO가 아님!
그저 예시로 WHO 넣었음

메모 포함[성S19R18]: 미국은 AHA 기준 따르고, 나머지 국가들은 보통 ESH/ISH 기준 따르는데, 미국향 매뉴얼엔 AHA를 쓰는 게 맞을 것 같습니다. 그리고 실제 정상 혈압을 정의하는 범위도 달라서 장비 내 확인을 해야할 것 같습니다.

메모 포함[이L20R18]: 현재 프로그램에 적용은 안되어 있지만, 기존 320 안내판넬이나 750 안내스티커는 ESC/ESH 기준으로 되어있습니다. 어디 기준으로 할지 정해서 개발팀에 전달하면 적용 가능합니다.

메모 포함[성S21R18]: 미국향 매뉴얼은 AHA 기준 적용 부탁드립니다. 내용은 아래와 같습니다. (표 내용과 텍스트 내용 동일합니다. 표에 있는 내용을 텍스트로 옮긴 것이며, 미국용 P3 결과지에도 아래 내용이 "혈압 범위"란에 적용되어 있습니다.

Normal <120 and <80
Elevated 120-129 and <80
Hypertension Stage 1 130-139 or 80-89
Hypertension Stage 2 ≥140 or ≥ 90
Hypertension Crisis >180 and/or >120
*Source: American Heart Association 2023

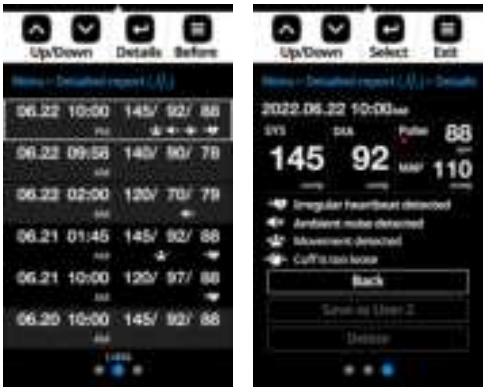


※ Checking the history data

❶ Press button, select History Data and press button to select the user.

❷ Press button to check the history data of the specific user.

❸ Press button to move to the record to manage and press button to see the data in detail.

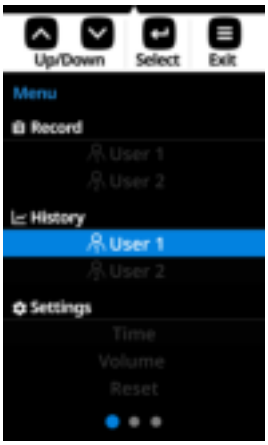


· Icons

	Appears when movement was detected while measuring. Do not move or talk during measurement.
	Appears when the noise is detected while measuring.
	Appears when an irregular pulse wave was detected. If this icon reappears, contact an expert.
	Appears when the cuff is wrapped loosely.

※ Checking the history graph

❶ Press button and press button to select the History Graph of the user.



❷ Press button and you can check your blood pressure history.

❸ Press button to go back to the menu.

3. Storing and Maintenance

A. Storing and maintenance

※ Storing V2 Doctor

❶ Always keep V2 Doctor clean using a soft, lint-free cloth.
❷ Unfold the cuff and put it in the holder behind the monitor body.

NOTE

- If not used for a long period of time, it is recommended to store it in the package provided.
- To store and transport V2 Doctor safely, you must meet the criteria below.
- It is recommended to get preventive inspection every 2 years to maintain its performance and safety.

· Environment Condition

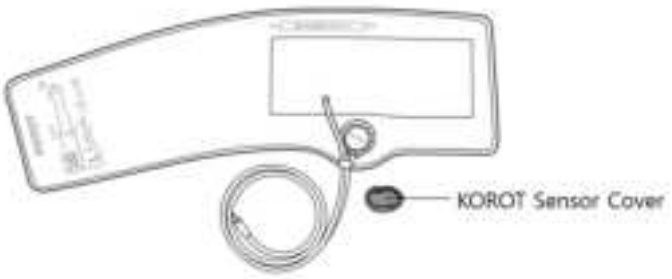
Item	Transport/Storage Condition	Operation Condition
Temperature	-20 ~ 60℃	0 ~ 40℃
Relative humidity	10 ~ 85% RH (No Condensation)	15 ~ 85% RH (No Condensation)
Air pressure	50 ~ 106 kPa	70 ~ 106 kPa

Caution

- 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.
- Do not detach the KOROT sensor from the cuff.

B. Replacing KOROT Sensor Cover

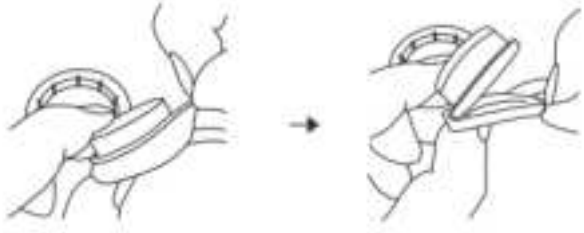
❶ Prepare the cuff and a spare KOROT sensor cover to replace.



❷ After turning the KOROT sensor case clockwise to unlock it, lift it up and separate it from the cuff.

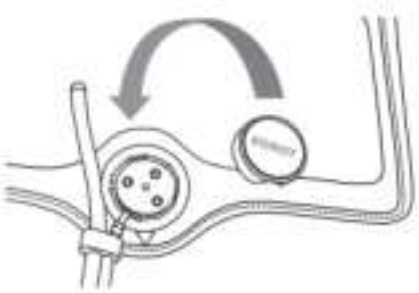
❸ Separate the microphone with the KOROT sensor cover from the cuff.

❹ Hold the band of the old KOROT sensor cover and remove it.



❺ Hold both sides of the new KOROT sensor cover and cover the microphone module all the way inside.
* Measurement may not be accurate if there is an empty gap.

❻ Arrange the microphone module with the KOROT sensor cover as shown below, and cover it with the case that was removed at the beginning.



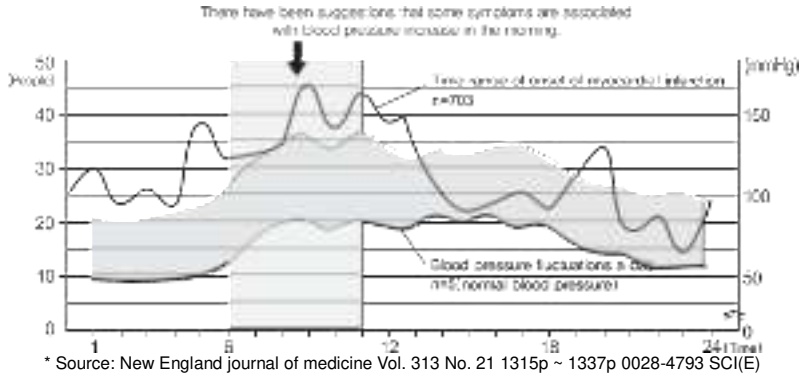
❼ Turn the case counterclockwise to lock it.

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, refer to the “Customer Service Information” on the page 1.

A. Measurement

Question 1: Measurement results appear different at each time



* Source: New England journal of medicine Vol. 313 No. 21 1315p ~ 1337p 0028-4793 SCI(E)

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 wrapped loosely, the cuff does not pressurize the pulse rate enough, so blood pressure is 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. Consult your doctor.

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 have 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 wrapped tightly on the arm, it can be deflated too fast. Wrap 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 a full charge.

Question 8: No sound

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

Question 9: How can I update V2 Doctor?

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

B. Errors

- Errors are shown on the screen. See descriptions below.
- If the error persists, contact KOROT Product Support with the code No.

Item	Error Code No.	Correction
Pressurization	11, 12, 13, 21, 31	• Connect or apply the cuff correctly. • Check the KOROT sensor is in touch with your skin.
Cuff	14, 22, 23, 24, 25, 26	• Check the connection of the monitor and apply the cuff correctly. • Take a measurement in a relaxed state.
Measurement	4, 8, 15	• Do not move and talk while measuring.
	3, 9	• Connect or apply the cuff correctly. • Check the KOROT sensor is in touch with your skin.

5. Others

A. Symbols

메모 포함[이22]: 추후 CE/EU REP 추가

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

B. Product Classification

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

C. Components Provided Separately

Adapter	• Dedicated adapter
Sensor Cover	• Dedicated KOROT Sensor Cover
Mobile Cart	• Dedicated Mobile Cart (Available for optional purchase)
Printing Program	• Dedicated Printing Program for PC/Tablet
Additional Cuff	• Dedicated cuff (XS/ML/XL size cuffs are available for optional purchase)

D. Specifications

Product Name (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: ±3mmHg, Pulse: Within ±2%
Minimum Scale Unit	1mmHg
Measurement Method	Auto Auscultation method + Oscillometric method
Measured Values	Systolic/Diastolic blood pressure, Pulse Rate, Mean Arterial Pressure
Pressurization time	Approx. 10 sec.
Test time	Approx. 30 seconds on average (20-50 seconds depending on the pulse and blood pressure value)
Cuff (0~300mmHg)	• XS-size cuff (Only for circumference 6~7in / 15~18cm / optional) • S-size cuff (Only for circumference 7~9in / 17~22cm) • M-size cuff (Only for circumference 9~13in / 22~32cm) • L-size cuff (Only for circumference 13~17in / 32~42cm) • ML-size cuff (Only for circumference 9~17in / 22~42cm / optional) • XL-size cuff (Only for circumference 17~21in / 42~53cm / optional) *Not made of natural rubber latex
Data Storage	User1/User2 1000 examinations each
USB Data Format	.csv
Wireless Communication	Bluetooth 5.1
Operating Environment	0 ~ 40℃, 15 ~ 85% RH, 70 ~ 106 kPa
Transport/Storage Environment	-20 ~ 60℃, 10 ~ 95% RH(No Condensation), 50 ~ 106 kPa
Rated voltage and power consumption	Input: 100-240 V a.c., 50/60 Hz, 0.5-0.25 A Battery: 3.6V, 3350mAh
Dimension	Approx: 130(W) x 197(H) x 150(L) mm
Device Weight	Approx: 0.7kg (1.54lb)
Package Weight	Approx: 1.5kg (3.3lb)
Manufacturing Country	Republic of Korea
Manufacturing Company	KOROT Co., Ltd.
Life Time	Device: 6 years Cuff: 1 year Battery : 6 years

메모 포함[조C23]: 커프 XS ~ XL

메모 포함[조C24]: 어댑터, 배터리 업데이트

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.

E. EMC Information

- The V2 Doctor is intended for use in the electromagnetic environment specified below. A V2 Doctor user must ensure that the product 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 +A1:2016+A2:2019 EN 55011:2016+A1:2017	Continuous operation mode	AC Mains	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 120 V, 60 Hz AC 220 V, 50 Hz AC 230 V, 50 Hz AC 240 V, 50 Hz	Group 1, Class B
Radiated disturbance	CISPR 11:2015 +A1:2016+A2:2019 EN 55011:2016+A1:2017	Continuous operation mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 120 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz Battery 3.83 V	Group 1, Class B
Harmonic Current Emission	IEC 61000-3-2:2018 +A1:2020 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 +A1:2017 EN 61000-3-3:2013 +A1:2019	Continuous operation mode	AC Mains	AC 230 V, 50 Hz	Plt: 1 Pst: 0.65 dmax: 4% dc: 3.3%
Electrostatic Discharge Immunity	IEC 61000-4-2:2008 EN 61000-4-2:2009	Continuous operation mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 120 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz Battery 3.83 V	± 8 kV/Contact ± 2, ± 4, ± 8, ± 15 kV/Air
Radiated RF Electromagnetic Field Immunity	IEC 61000-4-3:2020 EN 61000-4-3:2006 +A2:2010	Continuous operation mode	Enclosure	100 V, 60 Hz 100 V, 60 Hz 120 V, 60 Hz 230 V, 50 Hz 230 V, 50 Hz Battery 3.83 V	3 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz
Immunity to Proximity Fields from RF wireless Communications Equipment	IEC 61000-4-3:2020 EN 61000-4-3:2006 +A2:2010	Continuous operation mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 120 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz Battery 3.83 V	Table 9 in IEC 60601-1-2: 2014
Electrical Fast Transient/Burst Immunity	IEC 61000-4-4:2012 EN 61000-4-4:2012	Continuous operation mode	AC Mains	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 120 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	± 2 kV, 100 kHz repetition frequency ± 1 kV, 100 kHz repetition frequency
Surge Immunity	IEC 61000-4-5:2014 EN 61000-4-5:2014 +A1:2017	Continuous operation mode	AC Mains	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 120 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	Line to Line ± 0.5 kV, ± 1 kV Line to Ground ± 0.5 kV, ± 1 kV, ± 2 kV
Immunity to Conducted Disturbances Induced by RF fields	IEC 61000-4-6:2013 EN 61000-4-6:2014	Continuous operation mode	AC Mains	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 120 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	3 V 0.15-80 MHz 6 V in ISM bands Between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Power Frequency Magnetic Field Immunity	IEC 61000-4-8:2009 EN 61000-4-8:2010	Continuous operation mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 120 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz Battery 3.83 V	30 A/m 50 Hz & 60 Hz
Voltage dips	IEC 61000-4-11: 2020 EN 61000-4-11:2004 +A1:2017	Continuous operation mode	AC Mains	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 240 V, 50 Hz AC 240 V, 60 Hz	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°
Voltage interruptions	IEC 61000-4-11: 2020 EN 61000-4-11:2004 +A1:2017	Continuous operation mode	AC Mains	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 240 V, 50 Hz AC 240 V, 60 Hz	0 % U_T: 250/300 cycle

Immunity to proximity magnetic fields	IEC 61000-4-39: 2017	Continuous operation mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 120 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz Battery 3.63 V	30 kHz : 8 A/m 134.2 kHz : 65 A/m 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	Compli-ance level
Proximity fields from RF wireless Communica-tions IEC61000-4-3	380 - 390 MHz	TETRA 400	Pulse modula-tion b) 18Hz	27 V/m	27 V/m
	430 – 470 MHz	GMRS 460 FRS 460	FM c) ±5 kHz deviation 1 kHz sine	28 V/m	28V/m
	704 – 787 MHz	LTE Band13, 17	Pulse modula-tion b) 217 Hz	9 V/m	9 V/m
	800 – 960 MHz	GSM800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse modula-tion b) 18 Hz	28 V/m	28V/m
	1700 – 1990 MHz	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1,2,4,25 UMTS	Pulse modula-tion b) 217 Hz	28 V/m	28V/m
	2400 – 2570 MHz	Bluetooth WLAN 802.11b/g/n RFID 2450 LTE Band 7	Pulse modula-tion b) 217 Hz	28V/m	28V/m
	5100 – 5800 MHz	WLAN 802.11a/n	Pulse modula-tion 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.

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 product 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 to 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.

[47 CFR 15.21]Pursuant to Section 15.21 of the FCC rules, changes or modifications to a Product by the user that are not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. The device meets the FCC Radio Frequency Emission Guidelines. Information on the product is on file with the FCC and can be found by inputting such Product's FCC ID (which can be found on the device) into the FCC ID Search form available at https://www.fcc.gov/oet/ea/fccid.

Product : Blood Pressure Monitor
Model : KOROT V2 Doctor
Input : DC 3.6 V
FCC ID : 2BAK8-V2DOCTOR

Frequency : 2 402 ~ 2 480 MHz (BLE)