Guangdong Transtek Medical Electronics Co., Ltd.
Zone B, No.105 ,Dongli Road, Torch Development District,
Zhongshan,528437,Guangdong,China

Distributed by JOICOM CORPORATION
14129 The Merge Street, Building 3 Unit A, Eastvale, CA 92880

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RENPHO

User Manual

Blood Pressure Monitor

Model: RP-BPM001S

Arm Type

- Thank you very much for selecting RENPHO Blood Pressure Monitor RP-BPM001S.
- Please read the user manual carefully and thoroughly to ensure the safe usage of this product, Keep the manual well for further reference in case you have problems.

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FCC ID: 2APXU-RP-BPM001S
FCC Regulatory Compliance
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.
Warning: changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
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 Compliance
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

ISED Regulatory compliance
This device contains licence-exempt transmitters that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s).
Operation is subject to the following two conditions:
(1)This device may not cause interference.
(2)This device must accept any interference, including interference that may cause undesired operation of the device.
Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:
(1) l'appareil ne doit pas produire de brouillage, et
(2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.
This equipment complies with IC RSS-102 radiation exposure limits set forth for an uncontrolled environment.
Cet équipement est conforme aux limites d'exposition aux radiations IC CNR-102 établies pour un environnement non contrôlé.

General Description

Thank you for selecting RENPHO arm type blood pressure monitor (RP-BPM001S). The monitor features blood pressure measurement, pulse rate measurement and the result storage. The design provides you with two years of reliable service.

Readings taken by the RP-BPM001S are equivalent to those obtained by a trained observer using the cuff and stethoscope auscultation method.

This manual contains important safety and care information, and provides step-by-step usage instructions for using the product.

Read the manual thoroughly before using the product.

Features:

- 60*74mm Digital LCD display
- Maximum 60 records per each user
- Measuring during inflation technology

Indications for Use

The RENPHO Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and heartbeat rate with arm circumference ranging from 22cm to 42cm (about 8¾″-16½″). It's intended for indoor use by adult only.

Contraindications

1. The device should not be used by any person who may be suspected of, or is pregnant .
2. The device is not suitable for patients with implanted, electrical devices, such as cardiac pacemakers, defibrillators.

Measurement Principle

This product uses the Oscillometric Measuring method to detect blood pressure. Before every measurement, the unit establishes a “zero pressure” equivalent to the atmospheric pressure. Then it starts inflating the arm cuff, meanwhile, the unit detects pressure oscillations generated by beat-to-beat pulsatile, which is used to determine the systolic and diastolic pressure, and also pulse rate.

Safety Information

The signs below might be in the user manual, labeling or other component. They are the requirement of standard and using.

	Symbol for “THE OPERATION GUIDE MUST BE READ”		Symbol for “TYPE BF APPLIED PARTS”
	Symbol for “MANUFACTURER”		Symbol for “ENVIRONMENT PROTECTION - Electrical waste products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice”
	Symbol for “SERIAL NUMBER”		
	Symbol for “DIRECT CURRENT”		
	Symbol for “RECYCLE”		Symbol for “MANUFACTURE DATE”
	Caution: These notes must be observed to prevent any damage to the device.		

⚠ CAUTION

* This device is intended for adult use in homes only.
* The device is not suitable for neonatal patients, pregnant women, patients with implanted, electronical devices, patients with pre-eclampsia, premature ventricular beats, atrial fibrillation, peripheral, arterial disease and patients undergoing intravascular therapy or arterio-venous shunt or people who received a mastectomy. Please consult your doctor prior to using the unit if you suffer from illnesses.
* The device is not suitable for measuring the blood pressure of children. Ask your doctor before using it on older children.
* The device is not intended for patient transport outside a healthcare facility.
* The device is not intended for public use.
* This device is intended for no-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the arm or for functions other than obtaining a blood pressure measurement.
* Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure.Do not begin or end medical treatment without asking a physician for treatment advice.
* If you are taking medication, consult your physician to determine the most appropriate time to measure your blood pressure. Never change a prescribed medication without consulting your physician.
* Do not take any therapeutic measures on the basis of a self measurement. Never alter the dose of a medicine prescribed by a doctor. Consult your doctor if you have any question about your blood pressure.

⚠ CAUTION

* When the device is used to measure patients who have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, the best result may occur with deviation. Please consult your physician about the result.
* Don't kink the connection tube during use, otherwise, the cuff pressure may continuously increase which can prevent blood flow and result in harmful injury to the PATIENT.
* When using this device, please pay attention to the following situation which may interrupt blood flow and influence blood circulation of the patient, thus cause harmful injury to the patient: connection tubing kinking too frequent and consecutive multiple measurements; the application of the cuff and its pressurization on any arm where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present; inflating the cuff on the side of a mastectomy.
* Warning: Do not apply the cuff over a wound;otherwise it can cause further injury.
*Do not inflate the cuff on the same limb which other monitoring ME equipment is applied around simultaneously, because this could cause temporary loss of function of those simultaneously-used monitoring ME equipment.
*On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, open the cuff immediately. Prolonged high pressure (cuff pressure $>$ 300mmHg or constant pressure $>$ 15mmHg for more than 3 minutes) applied to the arm may lead to an ecchymosis.
*Please check that operation of the device does not result in prolonged impairment of patient blood circulation.

⚠ CAUTION

* When measurement, please avoid compression or restriction of the connection tubing.
* The device cannot be used with HF surgical equipment at the same time.
* The ACCOMPANYING DOCUMENT shall disclose that the SPHYGMOMANOMETER was clinically investigated according to the requirements of ISO 81060-2:2013.
* To verify the calibration of the AUTOMATED SPHYGMOMANOMETER, please contact the manufacturer.
* This device is contraindicated for any female who may be suspected of, or is pregnant. Besides providing inaccurate readings, the effects of this device on the fetus are unknown.
* Too frequent and consecutive measurements could cause disturbances in blood circulation and injuries.
* This unit is not suitable for continuous monitoring during medical emergencies or operations.Otherwise, the patient's arm and fingers will become anaesthetic, swollen and even purple due to a lack of blood.
* When not in use, store the device in a dry room and protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on the storage case.
* This device may be used only for the purpose described in this booklet. The manufacturer cannot be held liable for damage caused by incorrect application.
*This device comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in this booklet.

⚠ CAUTION

* The equipment is not AP/APG equipment and not suitable for use in the presence of a flammable anesthetic mixture with air of with oxygen or nitrous oxide.
* Warning: No servicing/maintenance while the ME equipment is in use.
* The patient is an intended operator.
* The patient can measure data and change batteries under normal circumstances and maintain the device and its accessories according to the user manual.
* To avoid measurement errors, please avoid the condition of strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.
* The blood pressure monitor and the cuff are suitable for use within the patient environment. If you are allergic to polyester, nylon or plastic, please don't use this device.
* During use, the patient will be in contact with the cuff. The materials of the cuff have been tested and found to comply with requirements of ISO 10993-5:2009 and ISO 10993-10:2010. It will not cause any potential sensation or irritation reaction.
* Adaptor is specified as a part of ME EQUIPMENT.
* If you experience discomfort during a measurement, such as pain in the arm or other complaints, press the START/STOP button to release the air immediately from the cuff. Loosen the cuff and remove it from your arm.
* If the cuff pressure reaches 40 kPa (300 mmHg), the unit will automatically deflate. Should the cuff not deflate when pressure reaches 40 kPa (300 mmHg), detach the cuff from the arm and press the START/STOP button to stop inflation.

⚠ CAUTION

* Before use, make sure the device functions safely and is in proper working condition. Check the device, do not use the device if it is damaged in any way. The continuous use of a damaged unit may cause injury, improper results, or serious danger.
* Do not wash the cuff in a washing machine or dishwasher!
* The service life of the cuff may vary by the frequency of washing, skin condition, and storage state. The typical service life is 10000 times.
* It is recommended that the performance should be checked every 2 years and after maintenance and repair, by retesting at least the requirements in limits of the error of the cuff pressure indication and air leakage (testing at least at 50mmHg and 200mmHg).
* Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines.
* Manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, etc., to assist to service personnel in parts repair.
* The plug/adapter plug pins insulate the device from the main supply. Do not position the device in a position where it is difficult to disconnect from the supply mains to safely terminate operation of ME equipment.
* The operator shall not touch output of batteries/adapter and the patient simultaneously.
* Cleaning: Dust environment may affect the performance of the unit. Please use the soft cloth to clean the whole unit before and after use. Don't use any abrasive or volatile cleaners.
* The device doesn't need to be calibrated within two years of reliable service.

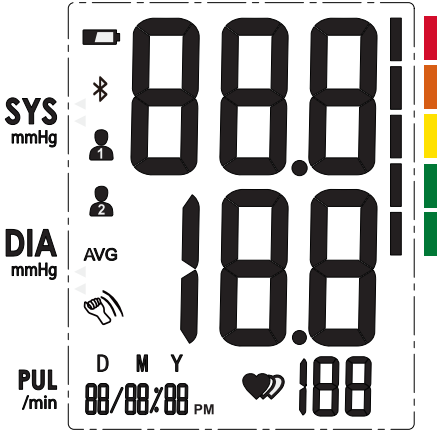
⚠ CAUTION

* If you have any problems with this device, such as setting up, maintaining or using, please contact the SERVICE PERSONNEL of RENPHO. Don't open or repair the device by yourself in the event of malfunctions. The device must only be serviced, repaired and opened by individuals at authorized sales/service centers.
* Please report to RENPHO if any unexpected operation or events occur.
* Keep the unit out of reach of infants, young children or pets to avoid inhalation or swallowing of small parts. It is dangerous or even fatal.
* Be careful to strangulation due to cables and hoses, particularly due to excessive length.
* At least 30 min required for ME equipment to warm from the minimum storage temperature between uses until it is ready for intended use. At least 30 min required for ME equipment to cool from the maximum storage temperature between uses until it is ready for intended use.
* This equipment needs to be installed and put into service in accordance with the information provided in the ACCOMPANYING DOCUMENTS;
* Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d away from the equipment. The distance is calculated by the MANUFACTURER from the 80MHz to 5.8 GHz column of Table 4 and Table 9 of IEC 60601-1-2:2014, as appropriate.

⚠ CAUTION

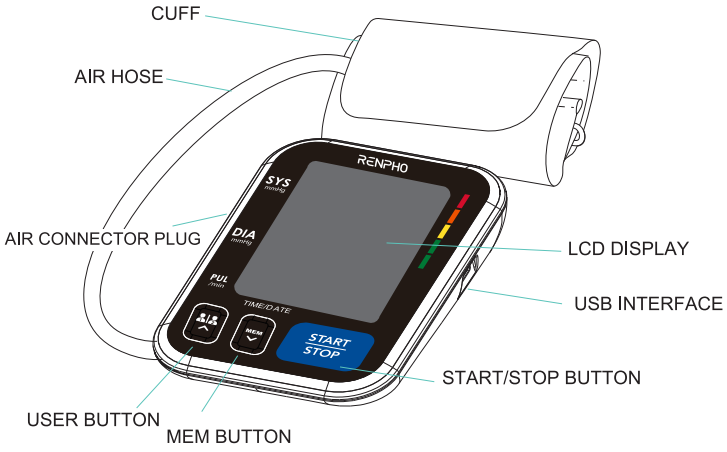
* Please use ACCESSORIES and detachable parts specified/ authorised by MANUFACTURE. Otherwise, it may cause damage to the unit or danger to the user/patients.
* There are no luer lock connectors in the construction of tubing. There is a possibility that they might be inadvertently connected to intravascular fluid systems, allowing air to be pumped into a blood vessel.
* Please use the device under the environment which is indicated in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced.

• LCD Display Signal



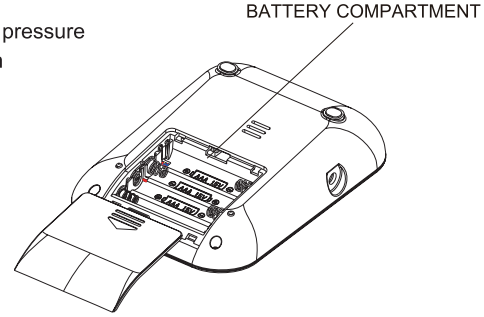
SYMBOL	DESCRIPTION	EXPLANATION
	Bluetooth	When flashing, it means Bluetooth is pairing
		When it is always on, it means that Bluetooth is connected to Bluetooth
SYS	Systolic blood pressure	High blood pressure
DIA	Diastolic blood pressure	Low blood pressure
PUL /min	Pulse display	Pulse in beats per minute
AVG	Average value	The average value of blood pressure
	Memory	Indicate it is in memory mode and which group of memory it is.
	Motion indicator	Motion may result in an inaccurate measurement
mmHg	mmHg	Measurement Unit of the blood pressure (1mmHg=0.133kPa)
Lo +	Low battery	Batteries are low and need to be replaced
	Irregular heartbeat	Blood pressure monitor is detecting an irregular heartbeat during measurement.
	Blood pressure level indicator	Indicate the blood pressure level
D M Y PM	Current Time	Day/Month/Year, Hour/Minute
	Heartbeat	Blood pressure monitor is detecting a heartbeat during measurement.
	User 1	Start measurement for User 1
	User 2	Start measurement for User 2

Monitor Components



Component list of pressure measuring system

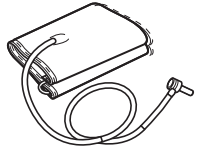
1. Cuff
2. Air pipe
3. PCBA
4. Pump
5. Valve



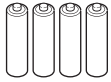
List

1. Blood Pressure Monitor (RP-BPM001S)

2. Cuff (Type BF applied part) (22~42cm)



3. 4*AAA batteries



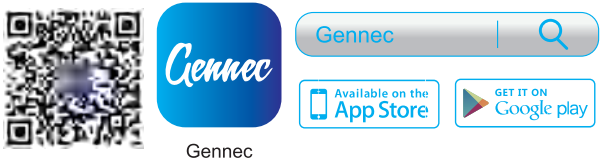
4. User manual

5. USB Cable

6. Carry bag

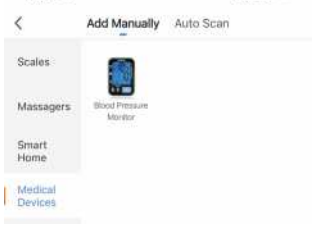
Download

1. Search and download Gennec APP from Apple Store / Google Play or scan the QR code below to download the app.



2. Open the Gennec app. To create a new account, tap Register. If you already have an account, tap Login.

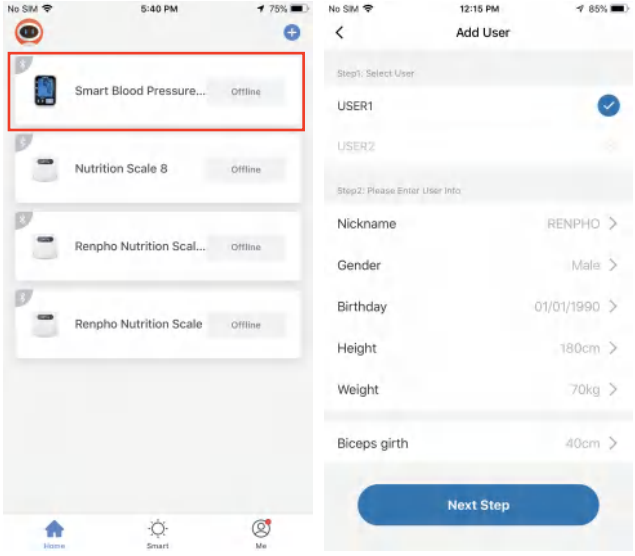
1. Add device



Note:

1. Turn on Bluetooth on the phone and open the APP, enter “add device page”, press the User button to turn on the Renpho device to pair with APP. Tick to confirm, choose User1 or User2, then click “Next” to enter the homepage.

2. Add user on homepage

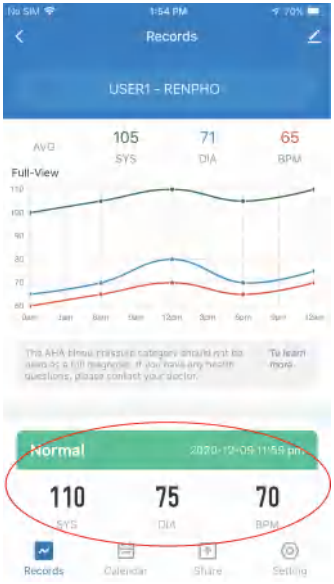


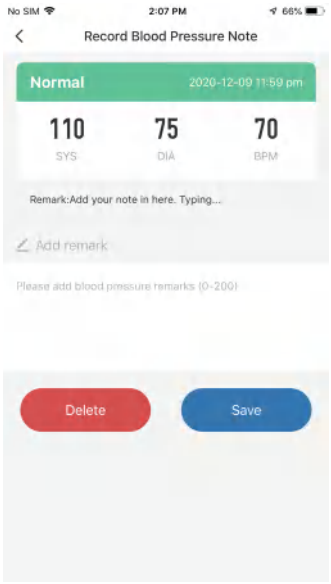
Note:

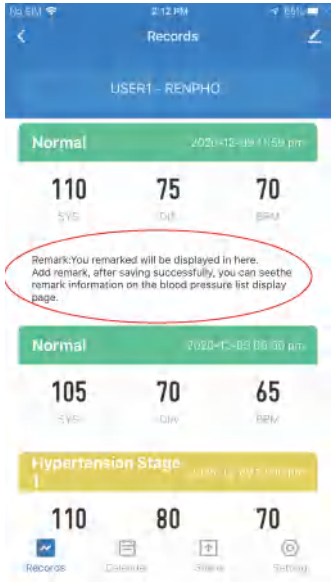
1. You need to add a user if you use the APP for the first time. You can press the User button on the device to choose User1 or User2. After filling in the user information, click Next step to save and enter the main menu.
2. User1or User2, you can only choose one.
3. Enter height in cm or inch, weight in kg or lb.
4. Enter arm circumference in cm or inch.

3. Measurement Record

A: The data is displayed on a daily, weekly, monthly, and yearly basis. Select the period, the trend chart below will auto-populate, slide down to view all historical measurement records.
Note: The date and time settings of your device will automatically sync with the smartphone when paired.





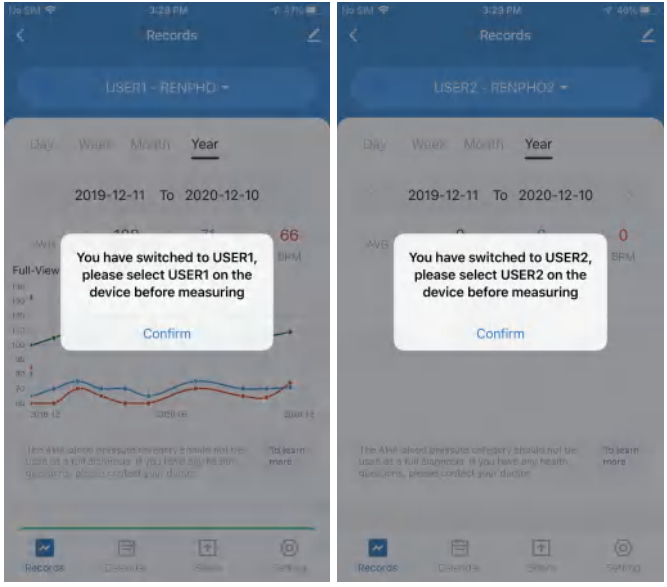


B: Click any data to jump to the blood pressure record remark page, and you can add remark. After saving successfully, you can see the remark information on the blood pressure list display page. Click the delete button on the blood pressure remarks page to delete the remarks.

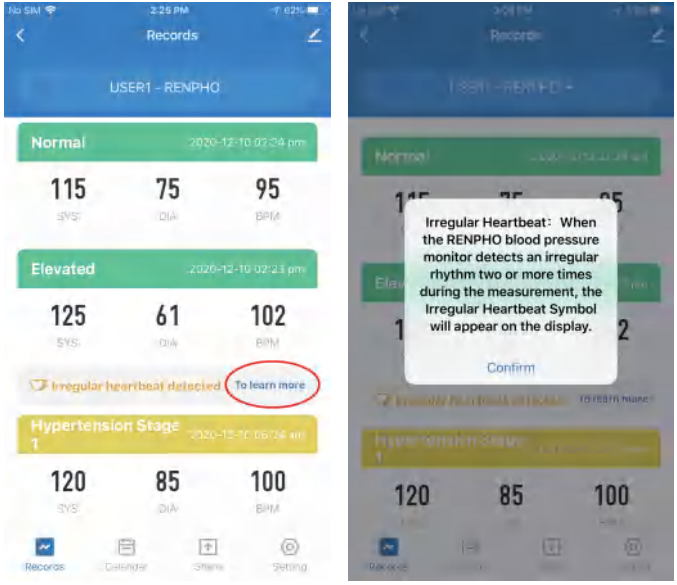
C. Any data can be deleted by sliding the list from right to left.

D. Click the icon on the right side of the title to enter the "More" interface to view device information.

E. Click on the user name to switch User1 or User2 (As shown on the left picture below).

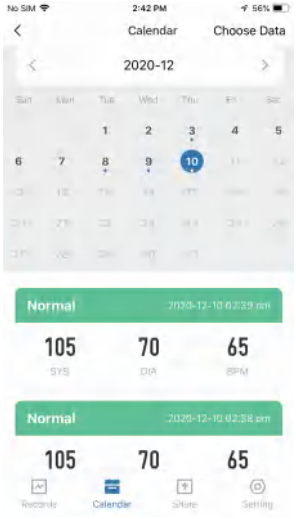


F. Click "Learn More" in the list, and an irregular heartbeat prompt will pop up. (As shown on the right picture below)



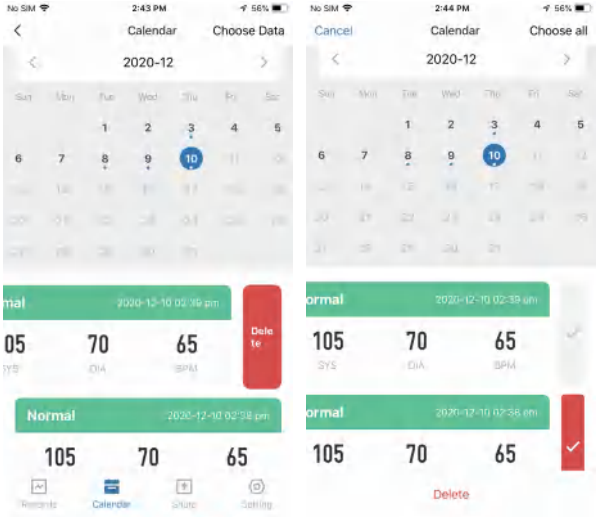
G. The average value of the trend graph is calculated based on the time range shown in the trend graph.

4. Blood Pressure Calendar



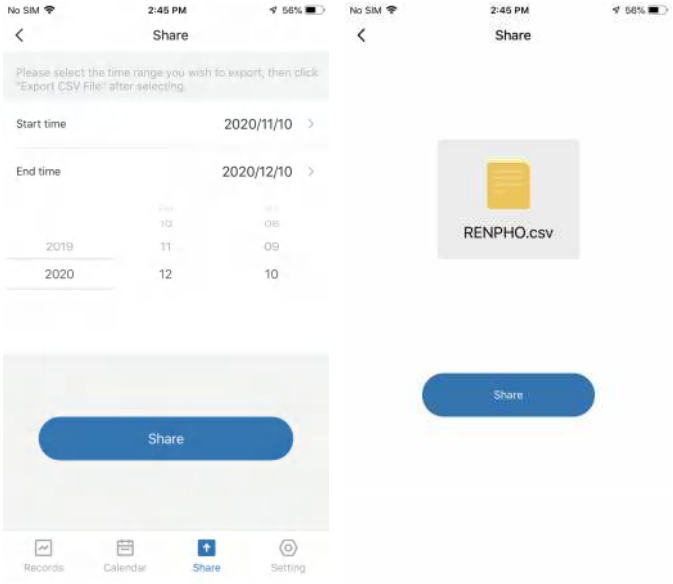
Note:

1. Select any day in the calendar (as shown in the picture above: 10th, Dec for example), you can track the blood pressure records of that day, and the records will be presented in the following list.
2. The small blue dot indicates that there is measurement data on that day (as shown in the figure below: 9th, Dec).
3. Click on the list data to jump to the add blood pressure remarks menu.



4. Slide left in the list below to delete a single data. If you click “Select all” in the upper right corner, the list data can be deleted in batches (As shown in the figure below).

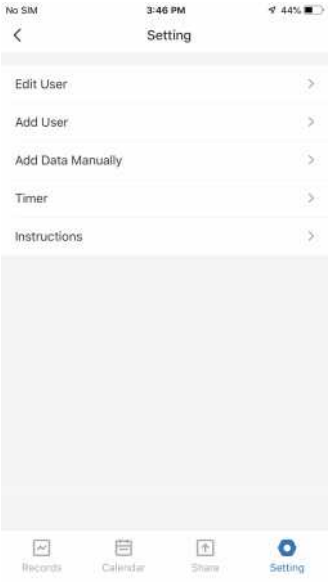
5. Share



Note:

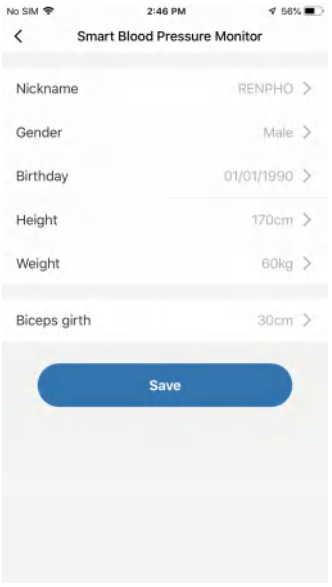
1. Click “Starting time” to pop up the date selection control and select the starting time.
2. Click “Ending time” to pop up the date selection control and select the ending time.
3. Click “Share” to share CSV file. (As shown below)

6. Setting



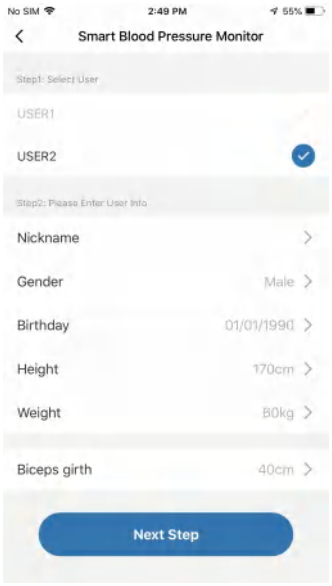
Note:
You can modify the current user information, add new users, manually add blood pressure records and measurement timing reminders, and you can also view the FAQ and blood pressure standards.

7. Modify user information



Note:
1. Height and arm circumference unit: cm or inch, weight unit: kg or lb.
2. Click “Save”, return to personal setting.

8. Add user



Note:

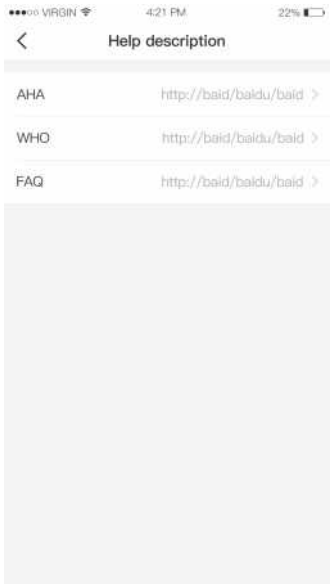
1. Each APP can have two users, User1 and User2. If the user is bound to User1, it will be grayed out by default and only User2 can be selected.
2. To add a new user, the monitor must be in pairing status. Press the User button on the device to turn on the pairing mode.

9. Manually add blood pressure records

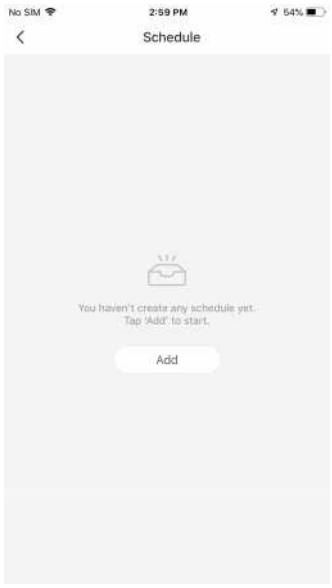
Note:

1. High pressure, low pressure, and heart rate verification must be specific data, not range.
2. After saving successfully, return to the main menu of measurement record.

10. Operating instructions

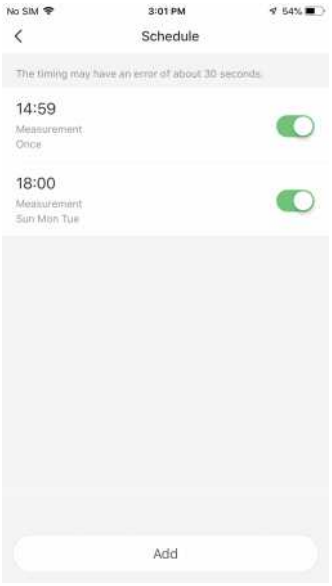


11. Timing reminder

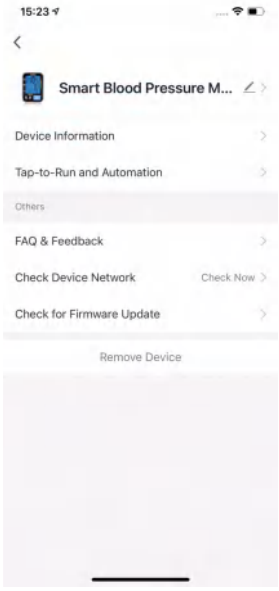


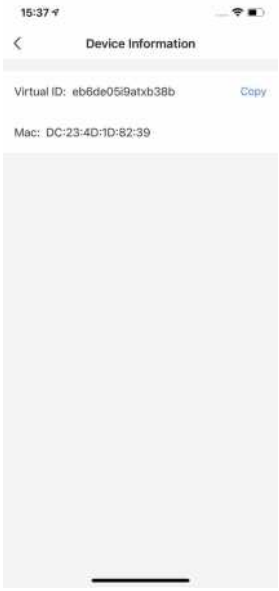
Note:

1. Click the “Add ” button in the middle of the page to enter the add reminder interface as shown on the right.
2. Turn on the switch to use schedule function. (As shown below)
3. You can set the reminder according to the timing period.



12. More

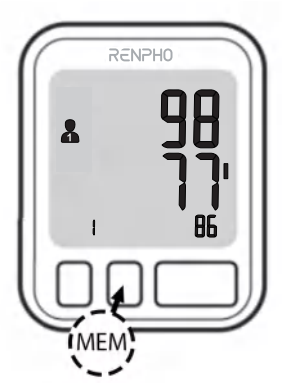




Note:

1. Click “Device information” to enter the device information interface.
2. Click “Remove Device” to remove the current device from the homepage.
3. After the device is successfully removed, you will return to the main menu.

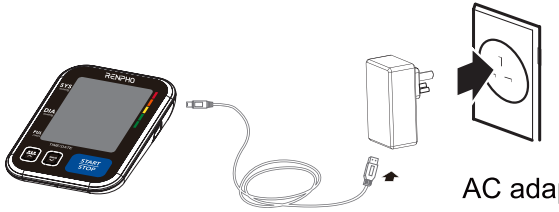
Transfer the existing data



1. Recall your readings on the screen by pressing the "MEM" button on your device.
2. Next, open the Gennec app and then enter the Records interface, the data will automatically be transferred.
   * When you have existing measurement data on RENPHO smart BP monitor and haven't connected with Gennec APP during previous measurement.

The Choice of Power Supply

1. Battery powered mode:
   6VDC 4*AAA batteries
2. AC adaptor powered mode: 5V⎓1A
   Please use the AC adaptor (not included) and USB cable just like the following picture:

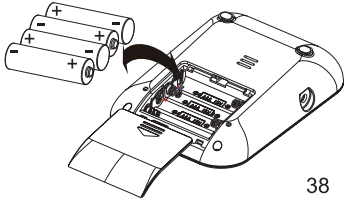


⚠ CAUTION

In order to get the best effect and protect your monitor, please use the right battery and special power adaptor which complies with local safety standard.

Installing and Replacing the Batteries

- Slide off the battery cover.
- Install the batteries by matching the correct polarity, as shown.
- Replace the battery cover.



Replace the batteries whenever the below happens

- The Lo+ shows
- The display is dim
- The display does not light up

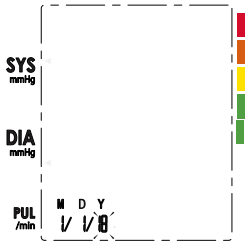
⚠ CAUTION

- Do not use new and used batteries together.
- Do not use different types of batteries together.
- Do not dispose of the batteries in fire. Batteries may explode or leak.
- Remove batteries if the device is not likely to be used for some time.
- Worn batteries are harmful to the environment. Do not dispose with daily garbage.
- Remove the old batteries from the device following your local recycling guidelines.

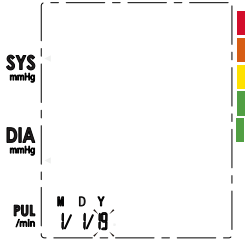
• Setting Date, Time

It is important to set the clock before using your blood pressure monitor, so that a time stamp can be assigned to each record that is stored in the memory. (The setting range of the year: 2020--2060 time: 12 H)

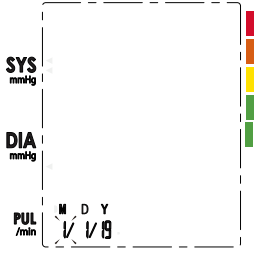
1. When the monitor is off, press and hold “START/STOP” button for 3 seconds to enter the mode for year setting.



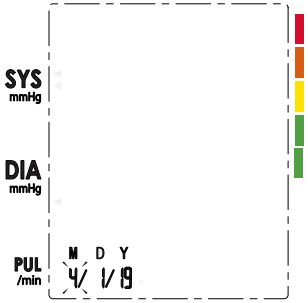
2. Press “USER” button or “MEM” button to change the [YEAR]. Each press will increase or decrease the numeral by one in a cycling manner.



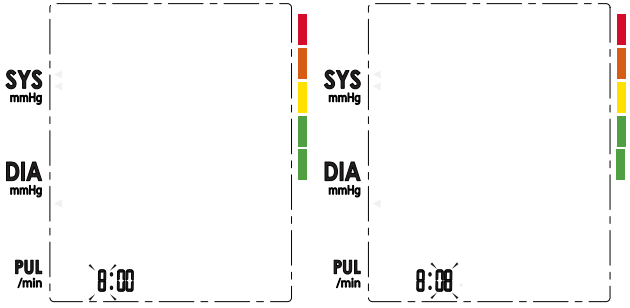
3. When you get the right year, press “START/STOP” button to set down and turn to next step.



4. Repeat step 2 and 3 to set the [MONTH] and [DAY].



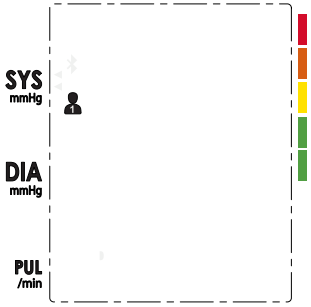
5. Repeat step 2 and 3 to set the [HOUR] and [MINUTE].



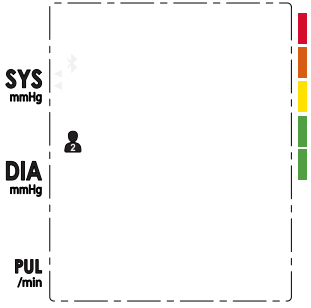
6. After the [MINUTE] is set, the LCD will display “donE” first, then display all the settings you have done and then it will turn off.

Select the User

1. When the monitor is off, press “USER ” button shortly to enter user setting mode.



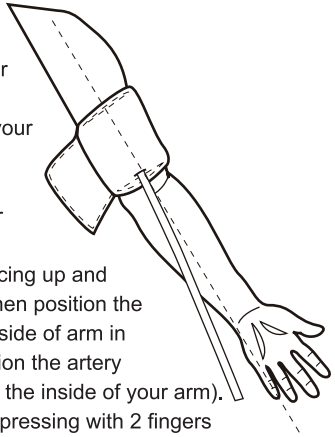
2. Then press “ USER ” button again to select the user ID between user 1 and user 2.

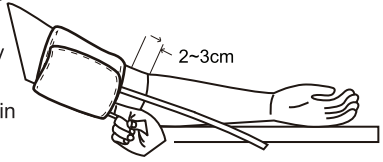


3. After selecting the suitable user ID, press “START/STOP” button to confirm and it will start to measure.

♥ Tie the Cuff

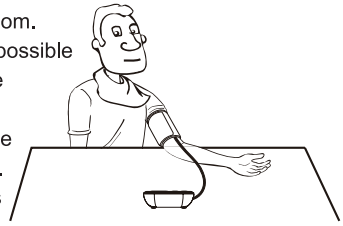
1. Remove all jewelry, such as watches and bracelets from your left arm. Note: If your doctor has diagnosed you with poor circulation in your left arm, use your right arm.
2. Roll or push up your sleeve to expose the skin. Make sure your sleeve is not too tight.
3. Hold your arm with your palm facing up and tie the cuff on your upper arm, then position the tube off-center toward the inner side of arm in line with the little finger. Or position the artery mark ϕ over the main artery (on the inside of your arm). Note: Locate the main artery by pressing with 2 fingers approximately 2 cm above the bend of your elbow on the inside of your left arm. Identify where the pulse can be felt the strongest. This is your main artery.





4. The cuff should be snug but not too tight. You should be able to insert one finger between the cuff and your arm.

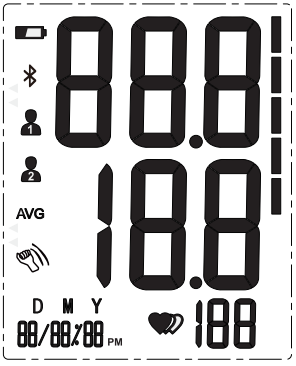
5. Sit comfortably with your tested arm resting on a flat surface. Place your elbow on a table so that the cuff is at the same level as your heart. Turn your palm upwards. Sit upright in a chair, and take 5-6 deep breaths.
6. Helpful tips for Patients, especially for Patients with Hypertension:
   - Rest for 5 minutes before first measurement.
   - Wait at least 3 minutes between measurements. This allows your blood circulation to recover.
   - Take the measurement in a silent room.
   - The patient must relax as much as possible and do not move and talk during the measurement procedure.
   - The cuff should maintain at the same level as the right atrium of the heart.
   - Please sit comfortably. Do not cross your legs and keep your feet flat on the ground.
   - Keep your back against the backrest of the chair.
   - For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, on the same arm, or as directed by a physician.



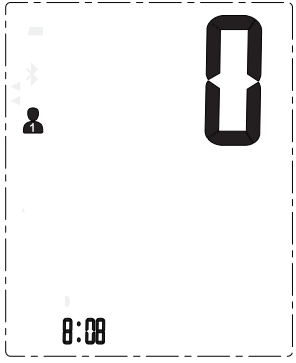
• Start the Measurement

1. When the monitor is off, press “START/ STOP” button to turn on the monitor, and it will finish the whole measurement.

LCD display

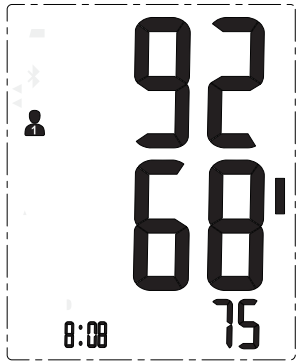


Adjust the zero.



Inflating and measuring.

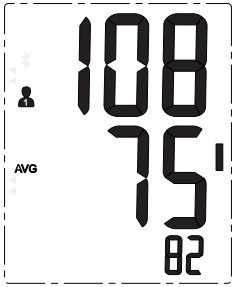
Display and save the results.



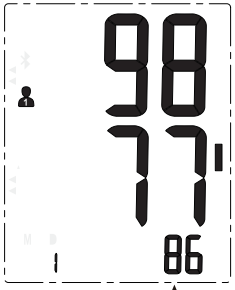
2. Press “Start/Stop” button to power off, otherwise it will turn off within 1 minute.

Recall the Records

1. When the monitor is off, please press “MEM” button to show the recent record. If the records are less than 3 groups, it will display the latest record instead. Take user 1 for example.



2. Press “MEM” button to get the record you want.



The date and time of the record will be shown alternately.

⚠ CAUTION

The most recent record (1) is shown first. Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (e.g., 2 becomes 3, and so on), and the last record (120) is dropped from the list.

Delete the Records

If you did not get the correct measurement, you can delete results by following steps below.

A: Delete one record

1. Hold pressing “MEM” button for 3 seconds when the monitor is in the memory recall mode, the flash display “dELy 1 +USER ID” will show.

2. Press “USER” button or “MEM” button and the flash displays “dEL n” or “dEL y”.

3. Press “START/STOP” button shortly to confirm deleting this group result when it shows “dEL y” and display “USER ID + dEL donE”, then the device will show the latest record.

Tips: Press “START/STOP” when it shows “dEL n” , it will drop out.

B: Delete all records

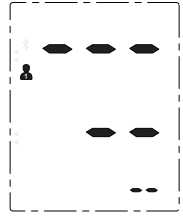
1. Hold pressing “MEM” button and “USER” button for 3 seconds when the monitor is in the memory recall mode, and the flash display “USER ID+dELy U5Er” will show.

2. Press “USER” button or “MEM” button and the flash displays “dEL n” or “dEL y”.

3. Press “START/STOP” button shortly to confirm deleting this group result when it shows “dEL y” and display “USER ID + dEL donE”, then the device will turn off.

Tips: Press “START/STOP” when it shows “dEL n” , it will drop out.

4. If there is no record, it will display like the right picture.



♥ Tips for Measurement

Measurements may be inaccurate if taken under the following circumstances.


Within 1 hour after dinner or drinking


Immediate measurement after tea, coffee, smoking


Within 20 minutes after taking a bath


When talking or moving your fingers


In a very cold environment


When you want to discharge urine

Maintenance

Please calibrate the blood pressure monitor in specific institute once every two years to ensure the precise measurement. In order to get the best performance, please follow the instructions below for storage.

Put in a dry place and avoid the sunshine

Avoid touching water, clean it with a dry cloth in case.

Avoid intense shaking and collisions

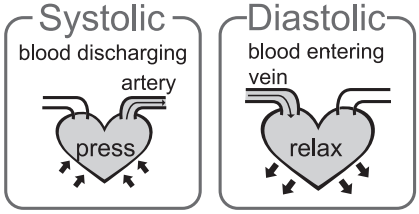
Avoid dusty and unstable temperature environment

Using wet cloths to remove dirt

Do not attempt to clean the reusable cuff with water and never immerse the cuff in water

What are systolic pressure and diastolic pressure?

When ventricles contract and pump blood out of the heart, the blood pressure reaches its maximum value in the cycle, which is called systolic pressure. When the ventricles relax, the blood pressure reaches its minimum value in the cycle, which is called diastolic pressure.



What is the standard blood pressure classification?

The chart on the right is the standard blood pressure classification published by American Heart Association (AHA).

This chart reflects blood pressure categories defined by American Heart Association.

Blood Pressure Category	Systolic mmHg (upper#)		Diastolic mmHg (lower#)
Normal	less than 120	and	less than 80
Elevated	120-129	and	less than 80
High Blood Pressure (Hypertension) Stage 1	130-139	or	80-89
High Blood Pressure (Hypertension) Stage 2	140 or higher	or	90 or higher
Hypertensive Crisis (Consult your doctor immediately)	Higher than 180	and/or	Higher than 120

⚠ CAUTION

Please consult a physician if your measuring result falls outside the range. Please note that only a physician can tell whether your blood pressure value has reached a dangerous point.

Irregular Heartbeat Detector

An irregular heartbeat is detected when a heartbeat rhythm varies while the device is measuring systolic pressure and diastolic pressure. During each measurement, blood pressure monitor will keep a record of all the pulse intervals and calculate the average value of them. If there are two or more pulse intervals, the difference between each interval and the average is more than the average value of ±25%, or there are four or more pulse intervals, the difference between each interval and the average is more than the average value of ±15%, then the irregular heartbeat symbol will appear on the display with the measurement result.

⚠ CAUTION

The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heart-beat was detected during measurement. Usually this is NOT a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that the device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

Why does my blood pressure fluctuate throughout the day?

1. Individual blood pressure varies multiple times everyday. It is also affected by the way you tie your cuff and your measurement position, so please take the measurement under the same conditions.
2. If the person takes medicine, the pressure will vary more.
3. Wait at least 3 minutes for another measurement.

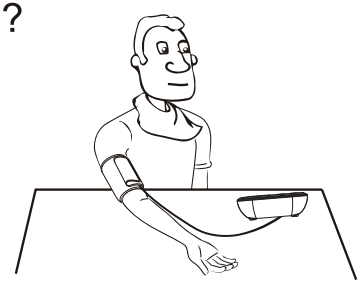
Why do I get a different blood pressure at home compared to the hospital?

The blood pressure is different even throughout the day due to weather, emotion, exercise, etc. Also, there is the “white coat” effect, which means blood pressure usually increases in clinical settings.

What you need to pay attention to when you measure your blood pressure at home:
If the cuff is tied properly. If the cuff is too tight or too loose. If the cuff is tied on the upper arm. If you feel anxious. Taking 2-3 deep breaths before beginning will be better for measuring.
Advice: Relax yourself for 4-5 minutes until you calm down.

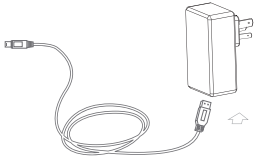
Is the result the same if measuring on the right arm?

It is ok for both arms, but there will be some different results for different people. We suggest you measure the same arm every time.



Authorized Components

1. Please use the manufacturer authorized AC adaptor (Not included)



Adapter
Input: 100~240V, 50~60Hz, 0.2Amax
Output: 5V ⎓ 1000mA
BLJ06L050100U-U

Contact Information

Please feel free to contact us if there anything we can help. We’ll try our best to improve the product quality and service. All products come with warranty and lifetime support.

Tel: +1(844) 417-0149
PST 9:00am-4:30pm Mon-Fri
Email: support@renpho.com

TROUBLESHOOTING

PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display will not light up	Batteries are exhausted	Replace with new batteries
		Batteries are inserted incorrectly	Insert the batteries correctly
		AC adaptor is inserted incorrectly	Insert the AC adaptor tightly
Low batteries	Display is dim or show Lo+	Batteries are low	Replace with new batteries
Error Display will not message	E 01 shows	The cuff is too tight or too loose	Refasten the cuff and then measure again
	E 02 shows	The monitor detected motion, talking,or the pulse is too poor while measuring	Relax for a moment and then measure again
	E 03 shows	The measurement process does not detect the pulse signal	Loosen the clothing on the arm and then measure again
	E 04 shows	The treatment of the measurement failed	Relax for a moment and then measure again
	EExx shows	A calibration error occurred	Retake the measurement. If the problem persists, contact the retailer or our customer service department for further assistance. Refer to the warranty for contact information and return instructions
Warning message	"out" shows	Out of measurement range	Relax for a moment. Refasten the cuff and then measure again. If the problem persists, contact your physician

SPECIFICATION

Power supply	Battery powered mode: 6VDC 4*AAA batteries AC adaptor powered mode: 5V⎓1A (Not included) (Please only use the recommended AC adaptor model).
Display mode	Digital LCD display V.A.2.36"X2.91" (60mm*74mm)
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0mmHg~299mmHg(0kPa ~ 39.9kPa) Measurement pressure: SYS: 60mmHg~230mmHg (8.0kPa~30.7kPa) DIA: 40mmHg~130mmHg (5.3kPa~17.3kPa) Pulse value: (40-199)beat/minute
Accuracy	Pressure: 41°F-104°F (5°C-40°C) within±3mmHg (0.4kPa) Pulse value: ±5%
Normal working condition	A temperature range of : 41°F to +104°F(+5°C to +40°C) A relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa An atmospheric pressure range of: 700 hPa to 1060 hPa
Storage & transportation condition	Temperature: -4°F to +140°F (-20°C to +60°C) A relative humidity range of ≤ 93%, non-condensing, at a water vapour pressure up to 50hPa

Measurement perimeter of the upper arm	About 8.66"~16.53" (22cm~42cm)
Net Weight	Approx.187g(Excluding the batteries)
External dimensions	Approx.3.66"X5.12"X1.28" (93mm*130mm*32.5mm)
Attachment	4*AAA batteries, user manual, USB Cable, Carry bag, Warranty card
Mode of operation	Continuous operation
Device Classification	Battery Powered Mode: Internally Powered ME Equipment AC Adaptor Powered Mode: Class II ME Equipment
Degree of protection	Type BF applied part
Protection against ingress of water	IP21 It means the device could protected against solid foreign objects of 12.5mm and greater, and protect against vertically falling water drops.
Software Version	A01
Bluetooth Module NO.	LS8261
RF Frequency Range	2400 MHz to 2483.5 MHz
Output Power Range	≤8dBm
Supply Voltage	1.9-3.6 V
Transmitting Distance	10 meters

WARNING: No modification of this equipment is allowed.

• Complied Standards List

Risk management	EN ISO1497: 2012/ISO 14971; 2019 Medical devices - Application of risk management to medical devices
Labeling	EN ISO 15223-1:2016 / ISO 15223-1:2016 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements
User manual	EN 1041:2008 +A1:2013 Information supplied by the manufacturer of medical devices
General Requirements for Safety	EN 60601-1:2006+A1:2013+A12:2014/ IEC 60601- 1:2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance EN 60601-1-11:2015/ IEC 60601-1-11:2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
Electromagnetic compatibility	EN 60601-1-2:2015/ IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
Performance requirements	EN ISO 81060-1:2012 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type IEC 80601-2-30:2018 Medical electrical equipment- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

Clinical investigation	EN 1060-4:2004 Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers ISO 81060-2:2013 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type
Usability	EN 60601-1-6:2010+A1:2015/IEC 60601-1-6:2010+A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
Software life-cycle processes	EN 62304:2006 + A1:2015/IEC 62304: 2006+A1:2015 Medical device software - Software life-cycle processes
Bio-compatibility	ISO 10993-1:2018 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

EMC Guidance

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments

Warning: Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment RP-BPM001S, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Technical description:

1. all necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.
2. Guidance and manufacturer's declaration -electromagnetic emissions and Immunity

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class [B]
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Comply

Table 2

Guidance and manufacturer's declaration – electromagnetic Immunity		
Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency
Surge IEC61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV,±2 kV common mode	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV,±2 kV common mode

Immunity Test	IEC 60601-1-2 Test level	Compliance level
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°.0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°.0 % UT; 250/300 cycle	0 % UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0 % UT; 250/300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE U T is the a.c. mains voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity							
	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modulation (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380-390	TETRA 400	Pulse modulation b) 18Hz	1.8	0.3	27
	450	430-470	GMRS 460, FRS 460	FM c) ± 5kHz deviation 1kHz sine	2	0.3	28
	710	704-787	LTE Band 13, 17	Pulse modulation b) 217Hz	0.2	0.3	9
	745						
	780						
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18Hz	2	0.3	28
	870						
	930						

	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modulation (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation b) 217Hz	2	0.3	28
	1845						
	1970						
	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
	5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
	5500						
	5785						

Federal Communications Commission (FCC) Statement. This device complies with part 15 of the FCC Rules. Operation is subject to the following twoconditions:

(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 ormore 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.

Warning: Changes or modifications made to this device not expressly approved by **REESTAR INTERNATIONAL LIMITED** may void the FCC authorization to operate this device.Note: The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate the equipment.

RF exposure statement:

The device compliance RF exposure requirement and can installed and used without restriction