

Instruction Manual

Bluetooth Automatic Upper Arm Blood Pressure Monitor

Model No. SFBP01



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Medical Disclaimer

This manual and product are not meant as a substitute for advice provided by your doctor.

You are not to use the information contained herein, or this product for diagnosing or treating a health problem or prescribing any medication. If you have or suspect that you have a medical problem, promptly consult your healthcare provider.

Intended Use

This device uses the oscillometric method to automatically measure systolic and diastolic blood pressure as well as heart rate.

The measurement position is at human being's arm.

All values can be read out in one LCD panel.

The device is designed for home use and recommended for use by adults aged 18 years and older with upper arm circumference ranging from $9 \sim 13$ " (approx. $23 \sim 33$ cm).

About Blood Pressure

1. What is blood pressure?

Blood pressure is the measurement of the force of blood pushing against the walls of the arteries. Arterial blood pressure is constantly fluctuating during the course of the cardiac cycle. The highest pressure in the cycle is called the systolic blood pressure, and represents the pressure in the artery when the heart is beating. The lowest pressure is the diastolic blood pressure, and represents the pressure in the artery when the heart is at rest. Both the systolic and the diastolic pressure are necessary for a physician to evaluate the status of a patient's blood pressure.

Many factors such as physical activity, anxiety or the time of day, can influence your blood pressure. Blood pressure is typically low in the mornings and increases from the afternoon to the evening.

It is on average lower in the summer and higher in the winter.

2. Why is it useful to measure blood pressure at home?

Having one's blood pressure measured by a doctor in a hospital or a clinic, is often associated with a phenomenon called "White Coat Hypertension" where the patient becomes nervous or anxious, thus raising his blood pressure. There are also numerous other factors that might cause your blood pressure to be raised at a specific time of day. This is why medical practitioners recommend home monitoring as it is important to get readings of blood pressure during different times of the day to really get an idea of your real blood pressure.

Medical practitioners generally recommend the "Rule of 3", where you are encouraged to take your blood pressure three times in a row (at 3 \sim 5 minute interval), three times a day for three days.

After three days you can average all the results and this will give you an accurate idea of what your blood pressure really is.



About Blood Pressure

A. WHO blood pressure classifications :

Standards for assessment of high or low blood pressure without regard to age, have been established by the World Health Organization (WHO), as shown in the chart.

However this chart is not exact for classification of blood pressure and it's intended to be used as a guide in understanding non-invasive blood pressure measurements. Please consult with your physician for proper diagnosis.

B. Variations in blood pressure :

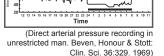
Individual blood pressures vary greatly both on a daily and a seasonal basis. These variations are even more pronounced in hyper tense patients. Normally the blood pressure rises while at work and is at its lowest during sleeping period.

(hyper tense: means a person who has high blood pressure symptom.)

The graph below illustrated the variations in blood pressure over a whole day with measurement taken every five minutes.

The thick line represents sleep.

The rise in blood pressure at 4 PM (A in the graph) and 12 PM (B in the graph) correspond to an attack of pain.





Precautions

- * Do not use this manual and product as a substitute for advice, diagnosing or treating a health problem or prescribing any medication by your doctor. If you have a medical problem, promptly consult your healthcare provider.
- * Read the Instruction Manual thoroughly before measuring and keep it at hand for your reference at any time.
- * This device uses the oscillometric method to measure systolic and diastolic blood pressure as well as your heart rate. It's recommended for use by people over the age of 18 and not to be used on infant or children.
- * The device is designed for home use and not suitable for clinical use.
- * This monitor is not intended for use in the MR environment.
 - -----
- Do not take a measurement in a low (less than 41°F /5°C) and high (more than 104°F /40°C) temperature, nor in a place outside humidity ranges (15 % ~ 93 % R.H.), and atmospheric pressure ranges (700 ~ 1060 hPa), or you may get inaccurate readings.
- Wait 30 ~ 45 minutes before measurement if you've just consumed caffeinated beverages or smoked cigarettes.
- Rest at least 5 ~ 10 minutes before taking a measurement.
- To allow your blood vessels to return to the condition prior to taking the measurement, please wait at least 3 ~ 5 minutes in between measurements. You may need to adjust the wait time according to your personal physiological situation.
- We recommend you using the same arm (preferably the left arm) and measuring around the same time each day.
- Sit down comfortably and place your elbow on the table with your feet flat on the floor. Please do not cross your legs during measurements.

Precautions

- Keep the cuff at heart level. Relax your hand with the palm facing up.
- Perform measurements in a quiet and relaxed environment at room temperature.
- Do not move or shake the device during a measurement. Please keep quiet and do not talk during measurements.
- This product is not suitable for:
 - Pregnant women
 - People with arrhythmias
 - Undergoing intravenous injection on any limb
 - Currently in a dialysis treatment
 - In pre-eclampsia condition
- For those who have had mastectomy surgery (especially whose' lymph nodes removed), it's recommend take a measurement on the unaffected side.
- When used among medical electronic equipments on the same limb, pressurization of the cuff may cause temporarily malfunction to other devices.
- Keep in mind that blood pressure naturally varies from time to time throughout the day and is affected by lots of different factors such as stress, eating, smoking, alcohol consumption, medication, and physical activity, etc.
- Normally the blood pressure rises while at work and is at its lowest during sleeping period.
- Blood pressure measurements should be interpreted by a physician or a trained health professional who is familiar with your medical history. Using the unit and recording the results regularly for your physician to interpret, you will keep your physician informed of the continuing changes in your blood pressure.



Precautions

- If you have one of the circulatory problems as arteriosclerosis, diabetes, liver disease, kidney disease, severe hypertension, peripheral circulation...., please consult your healthcare professional before using the device.
- Results are not intended for direct diagnosis. Please consult with a physician if you have any questions or concerns about your results.
- Blood pressure measurements taken with this device are equivalent to those obtained by a trained observer using the cuff / stethoscope auscultation method and are within the accuracy limits prescribed by the Standard of EN 1060-4.

*Attention !

- 1. Do not use the device on infants, children, or those who cannot express their own intention. To avoid accidental strangulation, keep this product away from children and do not drape tube around neck.
- 2. The medical device should not used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary. The medical device should be observed to verify normal operation in the configuration in which it will be used.
- 3. Consider the electromagnetic compatibility of the device (ex. power disturbance, radio frequency interference etc.) Please use it indoor only.
- 4. Over high frequency measurements may result in blood flow interference, which is likely to cause uncomfortable sensations, such as partial subcutaneous hemorrhage, or temporary numbness to your arm. In general, these symptoms should not last long. However, if you do not recover in time, please seek your medical practitioners for help.



Device Overview

Part names and product components



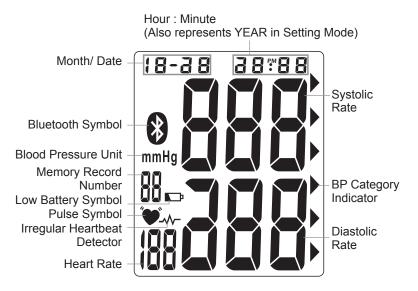
*Caution !

Substitution of a component different from that supplied might result in measurement error.



Device Overview

Unit display



Symbol Definitions

SYMBOLS	Definitions
Low Battery Symbol	This symbol appears when the battery power is excessively low or the polarity reverses. →We suggest you replace all batteries with new ones, and make sure the +/- polarities are properly positioned.
Pulse Symbol	Once pulse is detected, the symbol flashes with each pulse beat. →Our suggestion: Please do not talk or move during measurements.
الاتون Irregular Heartbeat Detector	This symbol appears for 1 minute when the user was talking, moving, shaking, or an irregular heart beat was detected during measurements. →Our suggestion: Please do not talk or move during measurements. Repeat the measurement after resting for at least 5 minutes, and restart your measurement while sitting down comfortably and quietly.
Bluetooth Symbol	LCD displays this symbol when Bluetooth Function turns ON.
BP Category Indicator	The arrowhead points out the specific BP Category that your measurement reading fits in.

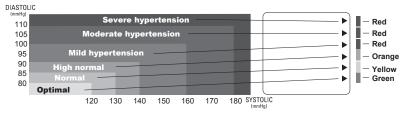
BP Category Indicator

This device is equipped with BP Category Indicator which classifies your blood pressure measurements into six stages (Optimal to Severe hypertension) as shown in below chart:

Stage Press	es of Blood ure Levels	Systolic (mmHg)	Diastolic (mmHg)	Color	Recommendations by SIGN 49: Hypertension in older people	
Grade 3	Severe Hypertension	≥180	≥110	Red	Confirm immediately and repeat BP in one day and again within one week depending on clinical situation.	
Grade 2	Moderate Hypertension	160~179	100~109	Red	Serial blood pressures repeated within one month.	
Grade 1	Mild Hypertension	140~159	90~99	Red	Provide advice about lifestyle modification and confirm within two months.	
High	n-Normal	130~139	85~89	Orange	Provide advice about lifestyle modification and recheck in one year.	
N	lormal	120~129	80~84	Yellow	Recheck in 2 - 5 vears.	
0	ptimal	<120	<80	Green	Recheck in 2 - 5 years. (patients aged > 75 years offered annual health check	

*Source: WHO, 1999

After each measurement is completed, LCD display will show your position automatically on the six segments of the bar indicator which corresponds to BP Category Indicator.



*Note!

When a person's systolic and diastolic pressures fall into different categories, the higher category should apply.

- e.g. systolic rate 181 & diastolic rate 99 => Red category (Severe Hypertension)
- e.g. systolic rate 110 & diastolic rate 95 => Red category (Mild Hypertension)

*Note!

The above table is not exact for classification of blood pressure and it's intended to be used as a guide in understanding non-invasive blood pressure measurements.

Usually this is not a cause for concern; however we recommend you consult with your physician for proper diagnosis or seek medical advice according to our recommendation mentioned above. Please note that the device does not appropriate to diagnose hypertension, and it is only for user reference on blood pressure monitoring.

Irregular Heartbeat Detector -

The symbol will appear on screen indicating a certain heartbeat irregularity was detected during measurement.

The heartbeat rhythm that is more than or less than 25% from the average rhythm is usually defined as an irregular heartbeat rhythm. Talking, moving, shaking or an irregular pulse during the measurement can result in the appearance of this symbol.

Usually this is not a cause for concern, however if the symbol appears often, we recommend you seek medical advice.

And please note that the device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

*Note !

- The pulse display is not suitable for checking the frequency of heart pacemakers. If a certain pulse irregularity is detected during measurement often, we recommend you seek medical advice.
- As a safeguard, we recommend that if you have arrhythmias such as atrial or ventricular premature beats and atrial fibrillation or any other special conditions you should check with your physician before using your device.
- The IHB function is not designed for use by people with arrhythmias nor for diagnosing or treating an arrhythmic problem. In order to filter the unstable status of user and avoid affecting the detection of heart rate from any movement, shaking or talking in the beginning of measurement, the method of averaging heart beat intervals of subject device is calculated with the three proper heart beat pulses detected in the beginning of measurement and that is different from a strict mathematical averaging of all recorded intervals.
- At least 3 beats with at least 25% difference from the average heart beat interval will generate the IHB icon on the screen.

Bluetooth Communication Function

SFBP01 features a built-in Bluetooth Communication function, which enables the device to automatically transmit results to paired Smartphone. After connection is established, device will transmit memory data such as Measure Date, Systolic Pressure, Diastolic Pressure and Pulse Rate to the Smartphone via MedCheck App.

For step-by-step guide on how to use the MedCheck App, please visit www.getmedcheck.com.

If paired Bluetooth device is not working or is not within RF range of this device, the measuring results will be stored in the blood pressure monitor's memory. For more details, please refer to "Bluetooth Communication" page.

Bluetooth compatibility with blood pressure monitor for Bluetooth-enabled device is:

- Bluetooth 4.0 for Android 4.4 or above,
- Bluetooth 4.0 for iOS 8.0 or above

*Note !

- SFBP01 is subject to and complies with electromagnetic compatibility (EMC) standard of EN 60601-1-2, EN 301 489-1, EN 301 489-17, EN 300 328 and U.S. federal guidelines, Part 15 of the FCC (Federal Communications Commission) rules for devices with RF capability. These guidelines help ensure that your device will not affect the operation of other nearby devices. Additionally, other devices should not affect the use of your device.
- Other wireless devices that are in use nearby, such as a cell or mobile phone, or a wireless network, may prevent or delay the transmission of data from your device to paired Bluetooth device. Moving away from the source of the interference or turning off these devices will resolve the problem.
- Make sure SFBP01 and paired Bluetooth device are within acceptable distance (no more than 10 meters) with each other. If not, put them closer.
- If you plan to transmit test results to paired Bluetooth device, be sure to select User 1, 2, or 3 before measurements, in case other people's results may be transmitted to your paired Bluetooth device or included in your past results.

About Bluetooth Communication Function

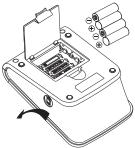
The Bluetooth communication function might not be workable to some Bluetooth devices because of the compatibility of Android system.

Installing Batteries

When Low Battery Symbol **1** appears on the display, or if there is no response, please change batteries.

Replace all worn-out batteries with new ones and do not mix new and used batteries. Do not mix alkaline, standard (carbon-zinc) or rechargeable (cadmium) batteries either. Such action may shorten he battery life or cause the device to malfunction.

Slide the battery cover and insert 4 AAA (LR03) alkaline batteries into the battery compartment as shown on the figure below. Make sure the polarities "+" and "-" ` ends are coinciding with similar markings engraved on the battery housing.



*Attention !

- Batteries are hazardous waste. Do not dispose of them together with the household garbage. Please discard worn-out batteries to the recycling site according to local regulations.
- Keep the battery away from children in case they choke on it.
- To prolong the battery life and prevent damage caused by leakage, remove the batteries from the device if the device is not to be used for a long period.
- The device will keep the last measuring results after changing batteries, please reset date and time.
- Please replace all worn-out batteries with new ones when you are operating the Bluetooth communication function, and the LOW BATTERY SYMBOL 1 appears on the display.

Installing Batteries

Using the AC Adaptor

This monitor is also designed for operation with AC/DC adapter. Please use only a compatible AC/DC adapter with required voltage and current as indicated in this manual.

*Note !

- No batteries are needed when operating with an AC adapter.
- Please unload the batteries when operating with an AC adapter for an extended period of time.
- Leaving the batteries in the compartment for a long time may cause leakage, which may lead to damage of the unit.

*Note !

When you use the blood pressure monitor with AC adapter, do not position the device to make it difficult to disconnect the adapter plug.

Applying the Cuff

- Press your brachial artery approximately 1 inch (2 ~ 3 cm) above the elbow on the inside of your left arm to determine where your strongest pulse is.
- Slide the end of arm cuff furthest from the tube through the metal ring to a loop. The smooth cloth should be on the inside of the cuff.
- If the cuff is located correctly, the velcro will be on the outside of the cuff and metal ring will not touch your skin.
- Put left arm through the cuff loop. The bottom of the cuff should be approximately 1 inch (2 ~ 3 cm) above the inner elbow. The tube should lie over the brachial artery on the inner part of the arm.
- Pull the cuff so that the top and bottom edges are tightened around your arm.
- When the cuff is positioned properly, press the velcro firmly against the pile side of the cuff.
- Sit on a chair and lay your forearm on the table so that the cuff is at the same level as your heart.
- Relax your arm and turn your arm upward.
- Make sure there are no kinks in the air tube.

*Note !

- Fit the cuff snugly, leaving enough space for 1 inch (2 ~ 3 cm) between the inner elbow and the lower edge of the cuff, or the measurement may not be accurate.
- \bullet This monitor comes with one size of arm cuff: 9" \sim 13" (23 \sim 33 cm).
- In case the cuff kept pumping up non-stop, open the cuff at once.
- Do not wrap the cuff around any body part other than your arm.
- The device is not supposed to be used when your arm is wounded or injured.



Measurement Procedure

Switch on the Monitor

- A. Press 0 button to switch on the monitor.
- B. All segments appear on the screen.

Setting Year, Date and Time

- A. Press () button ("YEAR" flashes). Press < or > button to adjust YEAR value.
- B. Press () button ("MONTH" flashes). Use < or > button to adjust MONTH (1, 2, 3,....., 12).
- C. Adjust DATE (1, 2, 3,..., 31), HOUR (1, 2, 3,.....12PM,1 PM,..., 12) and MINUTE (00,01,02,03,.....59) as described in Step A above.
- D. When settings are done, press () button to confirm the settings. The device turns to standby mode.

Turning Bluetooth Feature ON/OFF

User can press and hold (J) button 3 seconds to turn the Bluetooth feature ON/ OFF in Standby Mode.







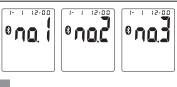
Bluetooth feature OFF

*Note !

- The Bluetooth Feature Switch default setting is ON
- Once Bluetooth Feature turns ON, the LCD appears Bluetooth symbol in any mode.

Taking a Measurement

A. Before measurement, press < or > button to select User 1, 2, or 3.







Measurement Procedure

B. With the cuff wrapped around your upper arm, press () button to start measurement. All display units appear on the screen.

*Note !

Do not inflate the cuff until it is wrapped around your upper arm.

After all symbols disappear, the display will show "00". The monitor is "Ready to Measure" and will automatically inflate to the level that is right for vou.

C. After inflation of the cuff. the pressure will slowly decrease. When pulse is detected, PULSE SYMBOL • flashes.

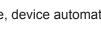
*Note !

- If the cuff does not stop inflating, remove the cuff at once.
- To stop measurement, press ⁽¹⁾ button. The cuff will deflate immediately after the button is pressed.
- D. LCD screen displays your systolic rate, diastolic rate, pulse, BP Category Indicator, and Irregular Heartbeat Detector symbol (if any) with date and time for 1 minute. (Year and Date / Time display alternate automatically)
- E. Without any operation for 1 minute, device automatically shuts off











Memory Function

Storing data

After each measurement, the systolic and diastolic pressure, heart rate, pulse, BP Category Indicator, and Irregular Heartbeat Detector symbol (if any) with date and time will be automatically stored.

The monitor can store up to 120 memories for 3 users, and automatically replace the oldest data with new one.

Recalling data

A. Press < or > button to select User 1, 2, or 3.

- B. Press M button to enter Memory Mode. LCD displays average of last 3 measuring results first.
- C. Press M button again, LCD displays the latest measuring result. Use < or > button to scroll through all stored measuring results. (Year and Date / Time display
- D. To stop reading memories, press button, and switch to Standby Mode.



8 **[]]**

Erasing data

- A. Press < or > button to select User 1, 2, or 3.
- B. Press M button to enter Memory Mode.
- C. Press > and () hold and buttons at the same time, the data will be erased automatically.
- D. To confirm the data in the selected user has been erased, press M button and no data should appear.

Note: Once deleted, your data can NOT be restored.

Bluetooth Communication

To perform the Bluetooth Communication, please follow these steps:

- 1. To activate Bluetooth function, please make sure you have downloaded MedCheck App on your Android or iOS Smartphone.
- 2. Turn on Bluetooth in your Smartphone.
- 3. When connection is established, SFBP01 will light Bluetooth indicator if it's in a reachable range (no more than 10 meters) with each other.



Bluetooth Indicator lit constantly

For all features of MedCheck App and step-by-step guide, please visit www.getmedcheck.com.

*Note !

- Without any operation in 1 minute, the device shuts off automatically and Bluetooth Connection OFF.
- Standby Mode: Press 🕛 button under Date/Time, Measuring, or Memory Mode, and the device will turn to Standby Mode.
- SFBP01 can only pair up with one Bluetooth device at a time.

Storage and Maintenance

General Use

- Do not in any way twist the cuff.
- Do not press 🕛 button if the cuff is not wrapped around your upper arm.
- Do not drop the product and avoid any strong impacts.

Maintenance

- Use a piece of cloth with water or mild cleansing agent to wipe the device and dry it immediately with a dry cloth.
- Do not use detergent or any strong chemicals to clean the device.
- Disinfection Use a piece of cloth with 75% alcohol to wipe the surface of the cuff for 10 seconds.
- Make sure the cuff is completely dry before using.
- Do not attempt to disassemble or change any parts of the monitor, including arm cuff, due to substitution of a component different from that supplied might result in measurement error.
- If any suggestion or service is requested, please contact Smartfuture Pte Ltd.
- Do not implement the maintenance procedures for equipment during measurement.
- Only trained technicians are allowed to repair and dissemble the device, including software upgrades, patches and maintenance.

*Note ! Water quality required for cleaning: Tap water.

Storage

- If the device is not to be used for a long time, please remove the batteries from the device (leaking of battery acid can cause the device to malfunction).
- Always store the unit in the storage case after use. It is intended to be transported or stored in a carrying case between uses.
- Do not place the device directly under sunlight, in high temperature, or in humid or dusty places.
- Do not store the device in extremely low (less than –13 °F /–25 °C) and high (more than 158 °F /70 °C) temperature, nor in a place where humidity exceeds 93% R.H.

Troubleshooting

SYMBOLS/ SYMPTOMS	CONDITIONS/ CAUSES	INDICATION/ CORRECTION	
Unit does not turn on when	Worn-out batteries.	Replace them with 4 new AAA (LR03) alkaline batteries.	
ம் button is pushed.	Battery polarities have been positioned incorrectly.	Re-insert the batteries in the correct positions.	
EE Measuring Error Symbol	Cuff has been placed incorrectly.	Wrap the cuff properly so that it is positioned correctly.	
appears when blood pressure	Did you talk or move during measurement?	Measure again. Keep arm steady during measurement.	
value displayed is excessively low or high.	Shaking of the arm with the cuff on.		
E Measuring Error Symbol	Air circuit abnormality. Cuff tube may not be plugged into monitor correctly.	Check cuff connection. Measure again.	
E2 Measuring Error Symbol	Inflation pressure exceeding 300 mmHg.	Switch the unit off, then measure again.	
E3 Measuring Error Symbol	Can't determine blood pressure measurement data.	Wrap the cuff properly and keep steady. Measure again.	

Troubleshooting

SYMBOLS/ SYMPTOMS	CONDITIONS/ CAUSES	INDICATION/ CORRECTION	
BPM cannot communicate with Bluetooth	Paring has not been completed.	Please try to pair BPM and Bluetooth device with each other	
device	Bluetooth function is not turn on.	Please refer to Page 19 "Measurement Procedure" and Page 22 "Bluetooth Communication" to turn on the Bluetooth function.	
	The distance between BPM and Bluetooth device is out of transmitting range.	Please make sure the devices are within 10 meters of each other.	
	Use an incompatible Bluetooth device.	Please refer to Page 15 "Bluetooth compatibility" &	
	Use non-Bluetooth device.	Page 28 "RF Specification"	
	Unexpected loss of electrical/ mechanical	Re-insert the batteries and try again.	
	integrity.	Return the device to local distributor or Smartfuture Pte Ltd.	
Note: If "EP" appears on the display, just return the device to your local distributor.			

Limited Warranty

To ensure continued measurement precision, all digital blood pressure monitors require recalibration regularly.

After 2 years from the manufacturing date, we recommend you have your monitor recalibrated at the local distributor.

Please contact your distributor for the details about the recalibration service and the charge of shipping and handling.

Please also note that this service does not cover damage caused by misuse or abuse; accident; the attachment of any unauthorized alteration to the product; improper installation; accessorv: unauthorized repairs or modifications; improper use of dropped electrical/power supply; loss of power: product: malfunction or damage of an operating part from failure to provide recommended maintenance: manufacturer's transportation damage; theft; neglect; vandalism; or environmental conditions; loss of use during the period the product is at a repair facility or otherwise awaiting parts or repair; or any other conditions whatsoever that are beyond the control of distributors.

Specifications

Model Number	SFBP01
Measurement Method	Oscillometric
Rated Range of Cuff Pressure	0 ~ 300 mmHg
Rated Range of Determination	40 ~ 280 mmHg
Measurement Range of Heart Rate	40 ~ 199 Beats/Minute
Accuracy	Pressure: ± 3 mmHg Pulse: ± 5 % Max.
Inflation	Automatic Inflation (Air Pump)
Deflation	Automatic Air Release Control Valve
Display	Liquid Crystal Display
Memory	120 Memory Total for 3 Users
Unit Dimensions	97.92 X 139.95 X 56.75 mm (L X W X H) 3.86 X 5.51 X 2.23 inch (L X W X H)
Unit Weight	291 g ± 10 g (10.26 oz ± 0.35 oz) (Cuff & Batteries Excluded)
Cuff Size	23 ~ 33 cm (approx. 9 ~ 13 inch)
Storage/ Transportation Environment	Temperature: -25 °C ~ 70 °C (-13 °F ~ 158 °F) Humidity: ≤ 93 % R.H.
Operation Environment	Temperature: 5 °C ~ 40 °C (41 °F ~ 104 °F) Humidity: 15 % ~ 93 % R.H. Atmospheric pressure: 700hPa ~ 1060hPa
Power Supply	1. AAA "LR03" (1.5V) alkaline battery x 4 2. 6V 1A AC/DC adapter (Excluded)
Battery Life	Approx. 200 Measurements (Bluetooth ON)
Product Life	5 Years (4 times per day)
Sleeping Mode	Without any operation for 1 minute, device automatically shuts off.
Accessories	4 AAA (LR03) Alkaline Batteries, Arm Cuff with Tube, Instruction Manual, Storage Pouch

*The contents of this manual and the specifications of the device covered by this manual are subject to change for improvement without notice.

Specifications

RF Type	Bluetooth 4.0 BLE
RF Modulation	GFSK
Effective Radiated Power	0dBm
Data Throughput	0.2Mbps
Expected Delay (Latency Range) in Wireless (RF) Communication	The latency time is less than 0.3ms second from sender to receiver.
Integrity	Channel Quality-Driven Data Rate (CQDDR) technology increases the effective data rate and integrity in noisy environments.
Security	AES-128 and application layer user defined
Wireless Operation Distance	Class 2 (Maximum: 10 meter)
RF Frequency / Need for Spectrum Management	2402 - 2480 MHz (allowing for guard bands)
Maximum Limitation	Unlimited
Maximum Permitted Power	2.5 mW
Proximity of Other In-band Transmitters Used in Vicinity	Up to 40 bands (2 MHz spacing; centered from 2402 to 2480 MHz)
Wireless Communication Profile	GATT – Client and Server
Wireless Coexistence	Support for 802.11 Coexistence
System requirement of the Bluetooth device	Bluetooth 4.0 for Android 4.4 or above Bluetooth 4.0 for iOS 8.0 or above

Note

C E 0197

This blood pressure monitor complies with the EC Directive (93/42/EEC) and bears the CE mark. This blood pressure monitor also complies with mainly following standards (included but not limited):

Safety standard:

EN 60601-1 Medical electrical equipment part 1: General requirements for safety EMC standard:

EN 60601-1-2 Medical electrical equipment part 1-2: General requirements for safety-Collateral standard: Electromagnetic compatibility- Requirements and tests

Performance standards:

- EN 1060-1 Non-invasive sphygmomanometers General requirements
- EN 1060-3 Non-invasive sphygmomanometers Supplementary requirements for electromechanical blood pressure measuring systems
- EN 1060-4 Non-invasive sphygmomanometers Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers

Symbol	Explanation	Details
CE	CE conformity marking	-
0197	Notified Body (NB) number	-
8	Refer to instruction manual/ booklet	-
*	TYPE BF Applied Part	-
Ø	To avoid inaccurate results caused by electromagnetic interference	Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the SFBP01, Otherwise, degradation of the performance of this equipment could result.
X	Waste of electrical and electronic equipment (WEEE)	-

Explanation of symbols :

Note

Symbol	Explanation	Health & Life Information	
	Manufacturer	HEALTH & LIFE Co., Ltd. 9F, No. 186, Jian Yi Road, Zhonghe District, New Taipei City, Taiwan www.healthandlife.com.tw	
M	Date of manufacture	M YYYY-MM	
EC REP	Authorized representative in the European Community	ECIREP EMERGO EUROPE Prinsessegracht 20, 2514 AP The Hague, The Netherlands	
SN	Serial number	SN YYMMXXXXXX	
IP22	Ingress Protection Rating	First characteristic numeral- Degree of protection against access to hazardous parts and against solid foreign objects N1=2 (Protected against solid foreign objects of 12.5 mm Ø and greater) Second characteristic numeral- Degree of protection against ingress of water N2=2 (Protected against vertically falling water drops when ENCLOSURE tilted up to 15°)	
700 hPa	Atmospheric pressure limitation	Atmospheric pressure: 700hPa~1060hPa	
15 % ^{93 %}	Humidity limitation	Humidity limitation: R.H.: 15 % ~ 93 %	
+5 °C (41 °F)	Temperature limit	Temperature: 5°C ~40°C	



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Guidance and manufacturer's declaration - electromagnetic emissions

The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	RF energy is used only to maintain device's operation. Therefore, its RF emissions are so low that it's not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic
Harmonic emissions IEC 61000-3-2	Class A	establishments, and those directly connected to the public low-voltage power supply network that supplies buildings used
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	for domestic purposes.

Guidance and manufacturer's declaration - electromagnetic immunity

The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	The relative humidity should be at least 5 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 or 60 Hz	30 A/m 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. Recommended separation distance $r = \frac{I}{188}$ (m) where I is the current in amperes in a power bus or an appliance wire and r is the recommended separation distance between your device and the power bus or appliance wire, in meters (m).

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 2 kV Power lines	±2 kV Power lines	Mains power quality should be that of a typical commercial or hospital environment.
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 cycles 70 % UT; 25/30 cycles 0 % UT; 250/300 cycle	0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycles 70 % UT; 25/30 cycles 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.

Recommended separation distances between portable and mobile RF communication equipment and the device.

The device is intended for use in an electromagnetic environment where radiated RF disturbances are under control. User can help prevent electromagnetic interference by keeping the device at a minimum distance from portable and mobile RF communications equipment (transmitters). Below table details the maximum output power of transmitter:

Rated maximum output power	Separation distance according to frequency of transmitter m			
of transmitter W	150 kHz to 80 MHz d = 1.2 √ <i>P</i>	80 MHz to 800 MHz d = 1.2 √ <i>P</i>	800 MHz to 2.5 GHz d = 2.3 √P	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration – electromagnetic immunity							
The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:							
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance				
Conducted RF IEC 61000-4-6	3V rms At 0.15-80 MHz	Not Applicable	Portable and mobile RF communications equipment should be used no closer to				
Radiated RF IEC 61000-4-3	6V rms At ISM & Radio Amateur Freq.		any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance				
	3 V/m at 80-2700 MHz (10V/m	3 V/m at 80-2700 MHz (10V/m Home Healthcare) AM Modulation And 9-28V/m at 385-6000MHz,Pul se Mode and other Modulation					
	Home Healthcare) AM Modulation And 9-28V/m at 385-6000MHz, Pul se Mode and other Modulation		d = 1.2 \sqrt{P} d = 1.2 \sqrt{P} 80 MHz to 800 MHz d = 2.3 \sqrt{P} 800 MHz to 2.5 GHz				
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol:				
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.							
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.							

Blood Pressure Diary

Date	Time	Systolic/ Diastolic	Pulse
	☐Before ☐After Meal	1	
	□Before □After Meal	1	
	☐ Before ☐ After Meal	1	
	□Before □After Meal	1	
	☐ Before ☐ After Meal	1	
	□Before □After Meal	1	
	☐Before ☐After Meal	1	
	□Before □After Meal	1	
	☐Before ☐After Meal	1	
	□Before □After Meal	1	
	☐Before ☐After Meal	1	
	☐ Before ☐ After Meal	1	
	☐ Before ☐ After Meal	1	
	☐ Before ☐ After Meal	Ι	
	☐ Before ☐ After Meal	1	
	☐Before ☐After Meal	1	
	☐Before ☐After Meal	/	



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