

Smart Watch Oscillometric BP Device BPW2



Tips:

- Please strictly follow the Instruction Manual to carry, store, operate and use, otherwise, the device might not meet the performance specifications, or even may cause serious accidents.
- Please avoid being pinched, e.g. do not let any third person to help wearing the device.
- The skin may have allergic reaction to device, do not wear the device for a long time to avoid skin irritation.
- Keep out of reach of children to avoid being hurt.
- The images shown here are indicative only. If there is inconsistency between the image and the actual product, the actual product shall govern.
- System crash: Please press and hold "START/STOP" button for at least 8 seconds to reset the device.
- Power on after over discharge: please charge the device for a period of time if the device is not able to start due to low battery.

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1 Before Using the Device

1.1 Brief introduction

The device is a smart watch which can be used stand-alone for measuring systolic and diastolic blood pressure / heart rate, and also can be used for Blood oxygen measuring, Step counting, Skin temperature measuring, and Sleep tracking for wellness.

The device is powered by a built-in rechargeable Lithium battery.

The device can also send out the data by Bluetooth.

1.2 Indications for use / Intended use

This device is intended to be used to measure blood pressure (systolic and diastolic) and heart rate from the wrist by using the oscillometric method. The device is intended for using in only adult population, not applied to the other populations such as neonatal baby. It can't be used while the wrist has bleeding or wound to avoid the blood flowing from the wound in pressurizing. The device has a "START" on screen or a "START/STOP" button for starting to measure blood pressure and the measuring can be stopped at any time by clicking on "STOP" on screen or pressing "START/STOP" button, or release the watchband at any time.

Measurable Circumference of Wrist is 13.5cm - 21.5cm.

1.3 Important Safety Information and Precautions

WARNING

- Contact your physician if you suspect you have a medical issue.
- Contact your physician for specific information about your blood pressure.
Self-diagnosis and treatment using measured results may be dangerous. Follow the instructions of your healthcare provider.
- Not for use by children, pregnant women, or pre-eclamptic patients.
- If you suffer from arrhythmia, diabetes, blood circulation problems, or apoplexy, only use the device under a physician's care.
- Prolonged over-inflation of the monitor will result in harmful injury to the patient.
- Do not use this device over a wound, as this can cause further injury.
- Too frequent measurements can cause injury due to blood flow interference.
- This device possible causes improper result due to external interference, such as acceleration during transport or transport in general.
- Do not attempt to modify this device in any way.

- Store this device in a cool, dry place. Do not subject this device to extreme temperatures, humidity, or sunlight. This device might not meet performance specifications, or even may cause serious accidents if stored or used outside the ranges specified in the "Specifications" section.
- Keep away from fire or rain.
- Do not immerse this device in water or clean with cleaning products, alcohol, or solvents. Carefully follow cleaning instructions provided.
- Ensure that the device is used in the environment specified in the EMC declaration in this IM, otherwise, may result in improper operation.
- Use of this device adjacent to or stacked with other device should be avoided because it could result in improper operation.
- This electrical medical equipment requires specific precautions regarding electromagnetic compatibility. It must be used according to the electromagnetic information.
- Please use only USB 5V / 1A or DC5V1A which complies with the standard of

IEC 60601-1, which provide 2 MOPP.

- Do not use this device where flammable gases or liquids are present.
- Never drop the device.
- Patient is the intended operator.

Maintenance and repair of the device are strictly prohibited during use.

- The expected service life of the device is 3 years, and the storage period is consistent with the service life.
- Patients could not be measured continuously, and the next measurement was taken at least 2 minutes apart.
- Clean after each measurement and disinfect before use. Multiple device machine parts need to be cleaned and disinfected before the next patient for use.
- When the device, or airbag is damaged, do not perform self maintenance.
- The manufacturer may provide the circuit diagrams, component list, drawing notes, calibration rules, or other information which can help maintenance personnel designated by the manufacturer to repair the device.

- The device shall not be used under the some conditions, such as magnetic field, pressure, thermal combustible source, etc. and needs to be used away from these conditions.
- The device needs waiting for 1 hour before use while moving from the lowest (or highest) storage temperature to the normal ambient temperature.
- The use of device should avoid the effects of the following conditions: cotton wool, dust, light (including sunlight); equipment or other interference sources that may cause interference; aging sensors that can reduce performance or cause other problems; the effects of pets, insects or children.
- The electromagnetic field may affect the product, causing the device not to be used normally, or the inaccurate measurement results. Therefore, blood pressure cannot be measured near the electromagnetic field.
- Warning and treatment for the following conditions: Do not remove the screws to prevent inhalation or swallowing.
- The skin may have allergic reaction to device, do not wear the device for a long time

to avoid skin irritation.

- Do not use accessories and other removable parts; do not use other power adapters to power or charge the device to avoid damage to the device or cause danger.
- Continuous airbag pressure may cause influence of blood flow interference and injury to the patient; application and pressurization of airbag on any limb undergoing vascular intervention or treatment, or arteriovenous shunt may temporarily disturb blood flow and can cause patient injury.

Application and pressurization of airbag on the wrist of the mastectomy or lymph node resection may cause temporary loss of monitoring equipment on the same limb; long-term damage to the limb due to patient's blood circulation due to the operation of the photometer.

- Please read the warnings carefully before use and follow the recommendations, otherwise it may cause physical harm.
- Spot check and monitoring of the blood oxygen saturation / heart rate, Step counting, Skin temperature measuring, and Sleep tracking are only for wellness.

- Date & time can be set manually if necessary, or be adjusted automatically while connecting with an application.
- Please adjust the folding buckle to an appropriate hole position so as not to pinch the wrist due to too tight wearing.
- Disposal of the device, accessories and packaging shall be carried out in accordance with national and local regulations for proper handling of waste.
- Please avoid being pinched when you wear the smart watch.
- Do not let any third person wear the device for the user to avoid being pinched.
- The device has a "START" on screen or a "START/STOP" button for starting to measure blood pressure and the measuring can be stopped at any time by clicking on "STOP" on screen or pressing "START/STOP" button, or release the watchband at any time.
- Keep out of reach of children to avoid being hurt.
- Reboot or restore the factory status if necessary.
- Switching voice call on will lead to stand-by time shorter.

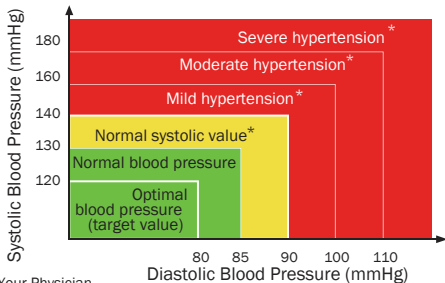
The instruction manual contains reference technical instructions.

Do not replace the wristband with the one not from the manufacturer, or may result in inaccurate measurement result.

The airbag fits wrist circumference ranging from 5.3 inches to 8.5 inches (approx. 13.5 cm to 21.5 cm), the user should confirm if the airbag fits the wrist before purchasing / using the device.

1.4 About Blood Pressure

BLOOD PRESSURE INDICATOR CHART
(World Health Organization (WHO) Blood Pressure Indicator)



*Consult Your Physician

When systolic and diastolic pressures fall into different categories, the higher pressure determines color code.

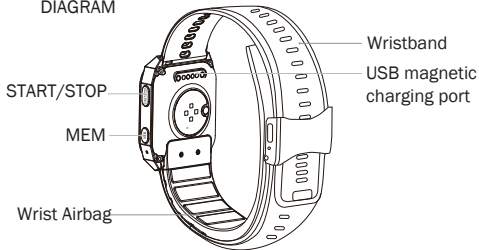
Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff / stethoscope auscultatory method, within the limits prescribed by European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults.

2 Device operation

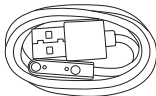
2.1 Before Using the Device

2.1.1 Know Your Device

DIAGRAM



Wrist sizing ruler



Magnetic charging cable

2.1.2 Device Charging

Put the head of the magnetic charging cable on the USB magnetic charging port of the smart watch as shown in Figure 1 to charge the smart watch.



Figure 1

The charging process is shown as Figure 2, and 100% means the charging finished.



Figure 2

Note: Please use only USB 5V / 1A or DC5V1A power adaptor which complies with the standard of IEC 60601-1 for charging, fast charging adaptor are prohibited.

Note: It takes about 2 hours to charge to 100%; the watch cannot be used while charging.

2.2 Operating the device

2.2.1 Button

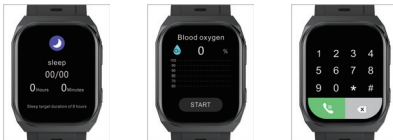
Button	Current Screen Status	Operate the button	Result
START/STOP button	Screen off	Press	Screen on
	Time interface	Press	Get into the blood pressure measurement interface
	Any other interface outside of the time interface	Press	Get into the time interface
	Power off	Press and hold at least 3 seconds	Power on
	Screen on	Press and hold at least 3 seconds	Get into the Restart & power off interface
	Power on	Press and hold at least 8 seconds	Forced restart

MEM button	Screen off	Press	Screen on
	Time interface、 Blood pressure measurement interface	Press	Get into the MEM interface
	MEM interface	Press	View the blood pressure readings
	Screen on	Press and hold at least 3 seconds	Get into the Menu interface

2.2.2 Touch panel

- In the time interface, slide up to get into "Message" interface.
- In the time interface, slide down to get into "drop-down menu" interface.
- In the time interface, sequence slide right to get into "Blood pressure" Interface, "Steps" interface, " Heart Rate " interface, " Sleep " interface, " Blood oxygen " interface, " Dialing " interface.





- d. In the time interface, press and hold the interface for at least 1 second to display Dial interface. Slide left or right to select the dial.

2.3 Blood pressure measurement

2.3.1 Wearing and wearing adjustment

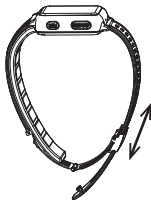
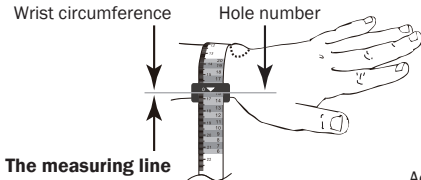
WARNING: Please strictly follow the wearing method below! Wearing the watch cannot be based on your comfort! Otherwise, loose wearing will cause the blood pressure reading too high or "warning wearing too loose " notice, and tight wearing will cause the blood pressure reading too low or "warning wearing too tight" notice!

2.3.1.1 Before wearing the device

- a. Remove your wristwatch and any other jewelry.
- b. The device should be used on the bare skin.
- c. Loosely roll up your sleeve to expose the wrist.

- d. Measure the wrist circumference, determine the hole number which the wristband will be locked

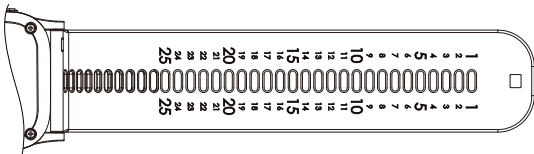
Measure the wrist circumference with a wrist sizing ruler and determine the hole number which the wristband will be locked according to the cross-reference on the wrist sizing ruler or as show below.



Adjust the position of the buckle on the watchband, and then lock.

wrist circumference (CM)	13.5~13.7	13.8~14.2	14.3~14.7	14.8~15.2	15.3~15.7	15.8~16.2	16.3~16.7	16.8~17.2	17.3~17.7
Hole number	22	21	20	19	18	17	16	15	14

wrist circumference (CM)	17.8~18.2	18.3~18.7	18.8~19.2	19.3~19.6	19.7~20.0	20.1~20.4	20.5~20.8	20.9~21.2	21.3~21.5
Hole number	13	12	11	10	9	8	7	6	5



2.3.1.2 Wear the device

Please keep the device on the dorsal side of left hand. The wrist skin should remain exposed, and the sleeves of the shirt should not wrap tightly around the wrist.



Note: The following situations may lead to inaccurate blood pressure reading!

- 1) The smart watch is in the wrong position on the wrist, such as the watch body is on the palm side.
- 2) The airbag is curled between the watchband and the wrist.
- 3) The airbag is not completely between the watchband and the wrist.
- 4) The watchband is too loose or too tight.

If you have any questions about wearing, please consult the customer service agent.

2.3.2 Before using the device

- a1. For most accurate results, measurements should be taken in the same circumstances and at the same time every day.
- a2. The device can be applied to either wrist, but preferably the left. Use the same wrist for each measurement.

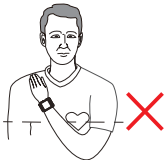
- a3. Any blood pressure recording can be affected by the position and physiological condition of the subject, as well as other factors such as background noise, stress, talking and body movement etc.
- a4. Avoid taking measurements while under stress.
- a5. Do not eat, drink alcohol, smoke, exercise, or bathe 30 minutes before using the device, as these activities may change blood pressure.
- a6. For an accurate blood pressure reading, take and record several measurements over a period of time.
- a7. Patients should have a 5-minute stop before the first measurement.
- a8. This device is used to monitor blood pressure. However, it cannot treat or prevent high blood pressure. If you suffer from high blood pressure, consult your doctor.
- a9. Correct measuring posture: Ensure the watch is at the heart height.
- a10. Relax, keep quiet and do not talk while measuring.
- a11. The time interval between two measurements should be at least 2 minutes.

◆ Measuring posture while seating

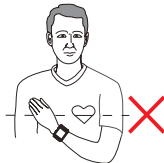
- Comfortably seated.
- Feet flat on the floor.
- Legs uncrossed.
- Back and arm supported.



Correct measuring posture

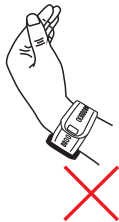
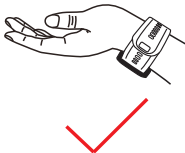
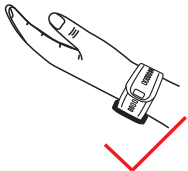


Higher than heart

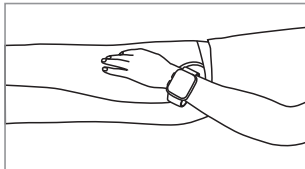


Lower than heart

Tip: Please keep your watch at the same level as your heart; otherwise it may result in inaccurate reading!



◆ Measuring posture while lying flat



Correct measuring posture
Please note that the airbag cannot be compressed

2.3.3 blood pressure measurement

- Method 1, Get into the time interface, slide right to get into the measurement interface, click on "START" to start measurement, pressure value on screen will increase and airbag will begin to inflate.



- Method 2, Get into the time interface, press and hold "MEM" button for at least 3 seconds to get into " Menu" interface, click on "Blood Pressure" to get into the measurement interface, and click on "START" to start measurement, pressure value on screen will increase and airbag will begin to inflate.



- Method 3, Get into the time interface, press "START/STOP" to start measurement (measurement process display as above image)

Note: The measuring can be stopped at any time by clicking on "STOP" on screen or pressing "START/STOP" button, or release the watchband at any time.

2.3.4. Measurement reading

When measurement is complete, the airbag deflates automatically and the systolic pressure, diastolic pressure, and pulse rate will display on screen.



“SYS” means Systolic Pressure;
“DIA” means Diastolic Pressure

Blood pressure unit:mmHg
Pulse unit: times / minute

2.3.5 View MEM (Memory)

This device will store up to 200 readings. When more than 200 readings are taken, the earliest reading will be replaced.

- Get into the time interface, press the "MEM" button to view the average of your three latest readings, indicated on screen as MEM AVERAGE(Measurement Average).



- Press the MEM button again to see the latest readings. and press the MEM button repeatedly to scroll towards the earliest readings. On screen, 001 indicates the latest readings, with higher numbers indicating earlier readings. Each slide will view a set of reading. a total of 200 sets.



Measurements
of MEM 001



Measurements
of MEM 002



Measurements
of MEM 200

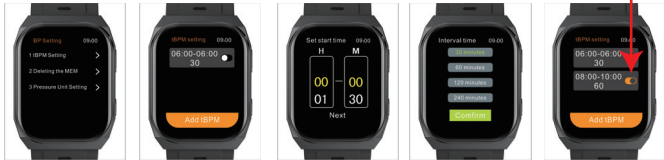
2.3.6 TBPM (Timing Blood Pressure Monitoring) setting

- Get into the time interface, slide down to get into " drop-down " interface, click on "Settings" icon to get into "Settings" interface.



- Click on "BP Settings(Blood Pressure Settings)" to get into the blood pressure setting interface; click on "1 tBPM Setting" to get into "tBPM Setting" interface, the default time period is displayed, and click on "Add tBPM" if you want to add, sequence set "Start time ", "End time "and " Interval time ", and light the button on the right to indicate that the settings have taken effect.

Light the button

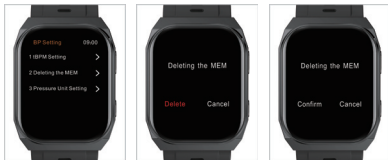


Note: When the right button is lit, the icon "tBPM" will appear in the drop-down interface, and measurement will automatically start at the set time point; if the right button is not lit, the icon "tBPM" will not appear, indicating that the tBPM is turned off.



2.3.7 Deleting the MEM

On "BP Settings" interface, click on "2 Deleting the MEM" to get into "Deleting the MEM" interface. Click on "Delete" to get into "Confirm" interface. Click on "Confirm" icon to delete MEM or "Cancel" to cancel the deleting and return to the "BP Settings" interface automatically.



2.4 Language change

In the time interface, slide down to get into "Setting" in the "drop-down menu" interface, and then click on "Select language" to change to the language you want.



2.5 Time setting

In the time interface, slide down to get into "drop-down menu" interface, and then click on the setting icon "⚙️" to get into "setting" interface, then click on "Time Setting" to get into "Time Setting" interface to set time manually; or, the time will be adjusted automatically while connecting with an application.



2.6 Restart

Please Restart the watch by pressing and holding START/STOP button at least 3 seconds when the screen status is screen on, or click on "Restart" in the System menu interface of Setting.

2.7 Resume factory

Please resume factory status by click on "Resume factory" in the System menu interface of Setting.

2.8 BT Voice Call

- In the time interface, slide down to get into "Setting" in the "drop-down menu" interface, and then click on "Bluetooth Settings" to switch on the bluetooth.
- Click on "settings" of smart phone to get into "Settings" interface, then switch on "Bluetooth" and click on BPW2 to pair.

3 Cleaning and Maintenance

- For regular maintenance, the device only needs to be wiped gently with a soft, dry cloth while it is not being used. Never immerse the device or any components in water.
- Do not carry out repairs of any kind yourself. If a defect occurs, please contact your local authorized distributor. Use only authorized parts and accessories.
- The device should be recharged periodically, even during storage, since the battery will self-discharge to an unacceptably low voltage, and even break.

4 Troubleshooting

If you see any of these symbols displayed on screen, perform the corresponding correction:

Symbol	Cause	Correction
Warning Wearing loose	wearing is too loose	Check if the cuff is leaking. Maintenance may be needed if leaking.
		Wrap the cuff properly.
Warning Body motion interference	body motion interference	Do not move your body, and keep quiet.
Warning wearing tight	wearing is too tight	Wrap the cuff properly.
Warning Improper wearing Position	Wearing is not appropriate	Wrap the cuff properly

	BLE cannot be connected automatically Note: The trouble is that the icon "📶" cannot get green while the watch is paired with an application via BLE and within the range that Bluetooth can cover.	Click on "Resume factory" in General interface of Setting to restore
Warning Battery low	The battery voltage is too low	Please charge in time
Warning Measurement timeout	Measurement timeout	Measure properly again

	System crash	Please press and hold "START/STOP" button for at least 8 seconds to reset the device.
	Unable to start due to low battery	Charge the device for a period of time before attempting to power on
	Unable to charge	Be sure to use only USB 5V / 1A or DC5V1A which complies with the standard of IEC60601-1, which provide 2 MOPP, fast charging adaptor are prohibited

5 EMC Declaration

Guidance and Manufacturer's Declaration - Electromagnetic Immunity the device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.

Immunity Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are 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 other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Not applicable	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at level characteristic of a typical location in a typical commercial or hospital environment.

NOTE: UT is the a.c. mains voltage prior to application of the test level.

Radiated RF IEC 61000-4-3	10V/m 80MHz to 2.7GHz 9V/m, 27V/m, 28V/m 385-5785 MHz	10V/m 80MHz to 2.7GHz 9V/m, 27V/m, 28V/m 385-5785 MHz	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 device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
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6 FCC 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.

FCC ID: 2AM6O-BPW1

Caution: 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.

7 Specifications

Model No.	BPW2
Regulation Number	21CFR 870.1130
Regulation Name	Noninvasive Blood Pressure Measurement System
Regulatory Class	Class II
Panel	Cardiovascular
Product Code	DXN
Display	TFT display
Measuring Principle	Oscillometric Method
Measurable Circumference of Wrist	13.5~21.5cm(5.3"~8.5")
Electric Shock Protection	Internal power supply appliance type BF
Airbag pressure	0 to 299 mmHg
Blood pressure measurement range	30 to 230 mmHg

Pulse measurement range	40 to 180 Pulses / min
Accuracy	Pressure: ± 0.4 kPa (± 3 mmHg)
	Pulse: $\pm 5\%$ of reading
LCD Indication	Pressure: Yes
	Pulse: Yes
Inflation	Automatic by Internal Air Pump
Rapid Air Release	Automatic by Air Valve
Power Source	Built-in 3.7V Li-ion Polymer Battery which should be charged by a charger of 5V $\overline{\text{---}}$ 1A
Charger	Magnetic charger
Bluetooth	Bluetooth 5.3 (data transmission), Frequency range: 2.4GHz (2402 – 2480MHz), Modulation: GFSK, Effective radiated power: < 20 dBm
Gross Weight	Approx. 68g
Device Life	3 Years

Operating Environment	Temperature	10~40°C (50 ~ 104°F)
	Humidity	15 ~ 90%RH(Noncondensing)
	Barometric Pressure	80~105 kPa
Transport Storage Environment	Pressure	-20~55°C (-4 ~ 131°F)
	Humidity	0 ~ 95% RH(Noncondensing)
Note: Subject to technical modification without prior notice.		

To improve performance, these specifications are subject to change without notice.

Disposal of the device, accessories and packaging shall be carried out in accordance with national and local regulations for proper handling of waste.

8 Calibration and Service

The accuracy of this device has been carefully tested and is designed for a long service life. It is generally recommended to have the device inspected and calibrated every two years to ensure correct functioning and accuracy.

Please contact the distributor.

9 Warranty Information

- The device is warranted to be free of manufacturing defects in workmanship and materials for a period of one year from the delivery date, when used in accordance with the instructions provided with the device.
- This warranty does not cover damage incurred by use of the device not in accordance with the instructions, accidental damage, or being tampered with or serviced by unauthorized service agents.
- For repair of manufacturing defect under this warranty, please contact your local distributor within the period of the warranty.

This warranty covers parts and labor only under normal operations.

A transportation fee or freight fee that may be incurred will be the owner's responsibility. Any defect resulting from natural causes, e.g., flood, hurricane etc., is not within this guarantee.

- Please note warranty does not cover damage caused by, including but not limited to: misuse or abuse; accident; the attachment of any unauthorized accessory; alteration to the product; improper installation; unauthorized repair or modification; improper use of electrical / power supply; dropped product; failure to follow required maintenance and safe-keeping; transportation damage.

This warranty specifically excludes expendables and consumables, for example batteries. All warranty claims must be directed to the distributor responsible for the sale of the device. The content of this warranty is subject to change without further notice.

The device complies with IEC 60601-1:2005+A1:2012+A 2:2020, IEC 60601-1-2:2014+A1:2020, IEC 60601-1-11:2015+A1:2020, IEC 80601-2-30:2018.

Note: To ensure accuracy, calibration by qualified technician is recommended every two years or after a repair. Please contact the distributor.

10 Symbols

SYMBOLS USED IN THIS INSTRUCTION MANUAL	
 WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
 CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property.
	Transport Package shall be kept away from rain.
	Refer to instruction manual / booklet
	Type BF applied part
	SERIAL NUMBER

MADE IN CHINA

VER: A00