BreathHome

Product user manual

Smart Peak Flow Meter
Model: B300

Please read this user manual carefully before use.

Guangzhou Homesun Medical Technology Co., Ltd

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Content

1. Product overview

1.1 Basic information

Product name: Smart Peak Flow Meter

Model: B300

FCC ID: 2ASLFGZHX-B300

1.2 Intended use

This device is intended to monitor a patient's Peak Expiratory Flow (PEF) and Forced Expiratory Volume in one second (FEV1) at home. The device is designed for adults and children over 5 years of age with caregiver supervision. The device is intended for monitoring respiratory conditions such as asthma. The device is for Over-The-Counter Use.

1.3 Product performance and structure

1.3.1Product introduction

Smart Peak Flow Meter (Model: B300) is a new type of hand-held pulmonary function testing device that measures your peak expiratory flow (PEF) and forced expiratory volume in 1 second (FEV1).

The use of B300 is very simple, you can master it quickly after reading the product user manual. B300 can be used by pediatric (≥5 years old) and adult patient. The device can store 100 sets of data which can be transmitted to smart phone APP through Bluetooth or LTE transmission mode for permanent storage. You can check the previous measurement records on the smart phone APP.

1.3.2Package content

Upon opening the product package, you will find the following contents inside:

Items	Quantity
Smart Peak Flow Meter	1
Mouthpiece	1
USB cable	1
User manual	1
Warranty card	1
Quality certificate	1

1.3.3Product main structure

The product is mainly composed of the main unit and removable mouthpiece as shown below:

Figure 1 Product structure composition

1.3.4Measuring parameters

PEF	Peak Expiratory Flow (Unit: L/min)
PEF%	PEF real-time measured value / PEF predicted value * 100%
FEV1	Forced Expiratory Volume in 1 Second (Unit: L)
FEV1%	FEV1 real-time measured value / FEV1 predicted value * 100%

1.3.5What do the parameters mean?

PEF%	Severity of asthma		FEV1%	Obstructive index
≧80%	Normal		≧80%	Normal
< 80%	Moderate			
< 60%	Severe		<80%	Mild
			<50%	Moderate
			<30%	Severe

Note: This measurement result is only an evaluation method, which cannot serve as a standard for disease diagnosis. You should consult your doctor for the meaning and importance of the measured values who will make a diagnosis.

If you experience symptoms such as chest distress, short of breath and cough, no matter what the measured value is, please contact your doctor and act according to his/her suggestions.

2. Contraindications

2.1 Absolute contraindications

1) Suffered from myocardial infarction, stroke, and shock in the past 3 months;

2) Severe cardiac insufficiency, severe arrhythmia, and unstable angina in the past 4 weeks;

3) Large hemoptysis in the past 4 weeks;

4) Seizures need treatment;

5) Uncontrolled hypertension (systolic blood pressure > 200mmHg, diastolic blood pressure > 100mmHg);

6) Aortic aneurysm;

7) Severe hyperthyroidism.

2.2 Relative contraindications

1) Resting heart rate >120 beats /min;

2) Pneumothorax, giant bullae, and those who are not prepared for surgical treatment;

3) Pregnant women;

4) Tympanic membrane perforation (need to be measured after the affected ear canal is blocked);

5) Respiratory tract infection in the past 4 weeks;

6) People with low immunity and susceptible to infection;

7) Infectious diseases of the respiratory tract (such as tuberculosis, influenza, etc.);

8) Children with critical illnesses and children with blood oxygen saturation lower than 92% require oxygen therapy.

The contraindications for the operation and use of the equipment include but are not limited to the above symptoms.

3. Safety precautions

As a medical device manufacturer, our company is dedicated to ensuring the safety, reliability and performance of the device. To use the device correctly, please read and follow the precautions below and keep this user manual in a convenient place for reference at any time.

⚠ Warning
● In order to reduce cross infection, it is recommended that customers purchase general accessories detachable mouthpiece for smart peak flow meter. ● Please use within the temperature, humidity and atmospheric pressure range specified by the manufacturer, otherwise the equipment may not reach the claimed performance. ● Please operate strictly according to this user manual, or else there might be inaccurate measurements or device gets damaged.

- Please clean and disinfect the pressure taking structure according to the method specified in the product manual.
- Please connect the device to the designated device, otherwise the device will be unusable or the measurement data will be wrong.
- Please test according to the method specified in the product manual, and confirm that the current measurement mode and the blowing method are correctly matched, otherwise the measurement results will be inaccurate.
- Do not use this device in an environment that has anesthetics and other inflammables which may cause an explosion.
- Do not use this device in strong electromagnetic interference or direct wind source, and heat source environment.
- Do not spatter liquid onto this device which may cause damage.
- Do not place the equipment in a mechanically vibrating environment.
- Do not drop this device from a high place.
- Do not use sharp objects to press or scratch the equipment shell.
- Do not disassemble the device without permission. No part of the medical device may be replaced by the customer. Use only Homesun approved accessories and spare parts for this medical device.
- Keep accessories, packing material, cleaning and disinfection substances out of the reach of children.
- Do not place heavy objects on the device which may cause performance or mechanical damage.
- Do not use high temperature, high pressure or gas disinfection to disinfect the device.
- If the device continues to fail to display data or there are other abnormal conditions, press function button to remeasure, or power off the device and restart; please contact the after-sales customer service in time.
- After use, the device will produce some wastes such as disposable parts or vulnerable parts and when discarding the equipment itself. Disposing of these wastes arbitrarily will pollute the environment or cause cross-infection. It should be dealt with per laws, regulations and other relevant regulations.
- The measurement results can only serve as a clinical reference which should be explained by professional medical personnel. A qualified physician must reassess all measurements. An interpretation by the medical device is significant only when considered together with other clinical findings.
- When using the device, pay special attention to the user manual where this symbol  is marked.

4. Installation and operation

When you use B300 for the first time, you should bond APP and input personal health

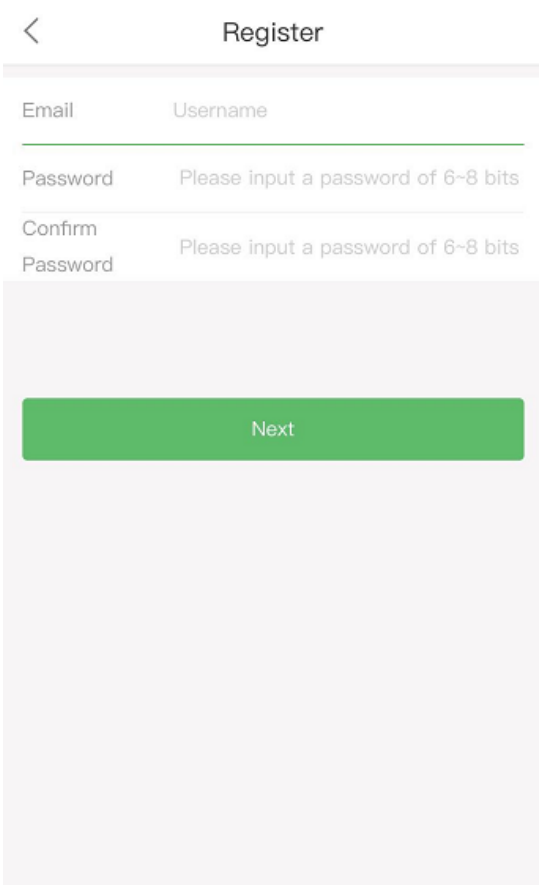
information.

4.1 Download APP

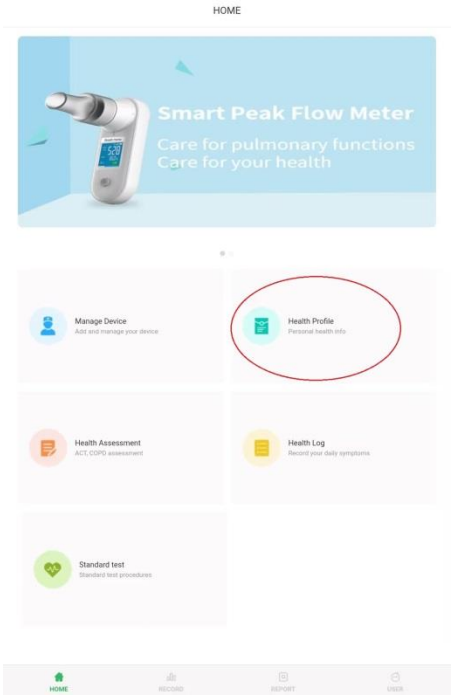
(1) Scan the QR code ,or search name “breathhome” from “App Store” or “Google Play Store” to download and install the APP.

Note: This APP is supported by smart phone (all versions of iOS or Android 4.4-11 platform).

(2) Open the APP, register by email to create a new account, enter the APP HOME after registration.

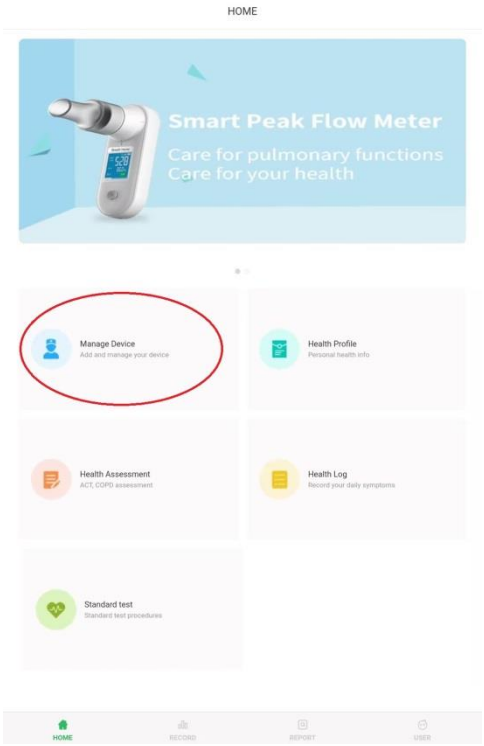


(3) Click “Health Profile” to complete personal information input and change.



(4) Connect the device. Power on the device and place it near the smart phone, activate the bluetooth mode of the smart phone, click “Manage Device”, complete device bonding according to operation instruction. If the device is not connected, you will hear “Device

not bond".



4.2 Device installation and preparation

Put the round end of the detachable mouthpiece into the flow sensor head, then connect the flow sensor head to the breathing hole of the Smart Peak Flow Meter, applying a little pressure so that the flow sensor head is tightly attached to the breathing hole of the device.

4.3 Start test

(1) Hold the product upright in the hand, long press the function button to start up, you will hear "Welcome to breath home".

(2) Stand up.

(3) Short press function button, you will hear “Please blow ”.

(4) Take a deep breath, hold your breath while put the mouthpiece into your mouth (the upper and lower teeth should nibble the front of the mouthpiece, and your lips should tightly cover the mouthpiece). Exhale quickly and forcefully, taking as much time as possible (the standard time is 6 seconds). While blowing, you will hear “Come on, come on, 3, 2, 1, stop”. When blowing is not correct, you will hear “Please blow again”.

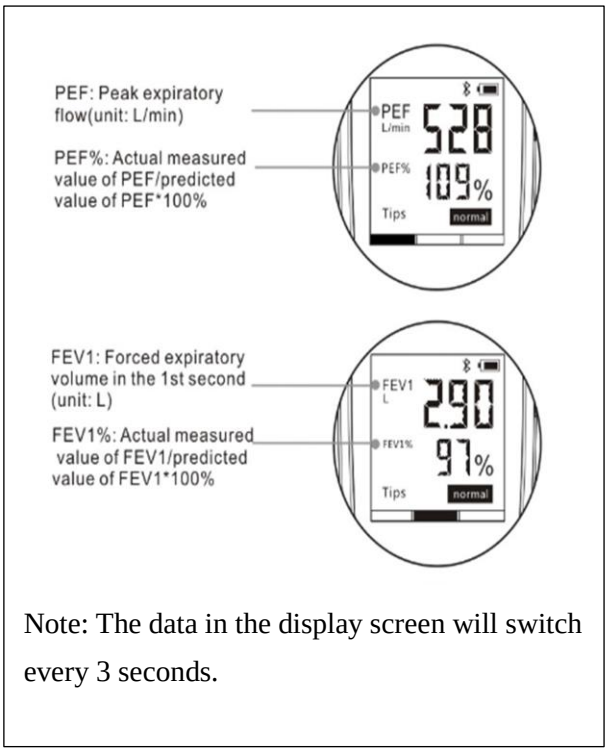
Note:

① In order to ensure the accuracy of measurement results, users are required to understand and master the blowing method of each measurement mode.

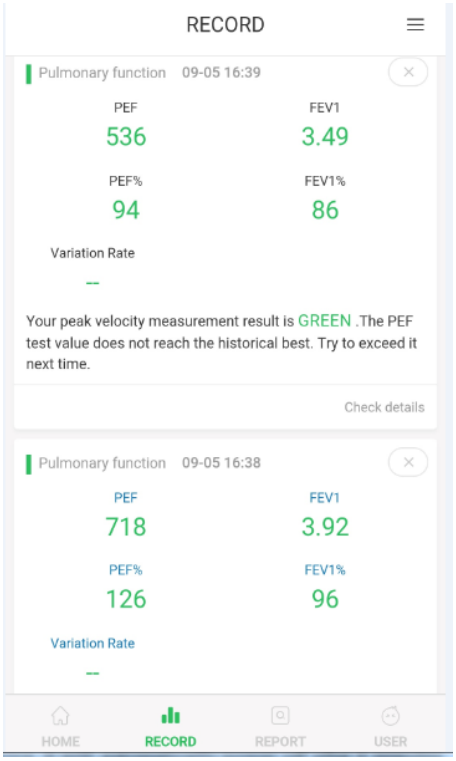
② Keep the standing posture during the test and keep your body stable.

③ Do not shake your head downward with your body violently while blowing, since this may affect test result.

(5) After the test, there is a prompt tone, you will hear “Your peak flow is XXX litres per minute”, the results is shown in display screen (you can test multiple times and take the maximum value). Or you can check the results on the “RECORD” page of APP.



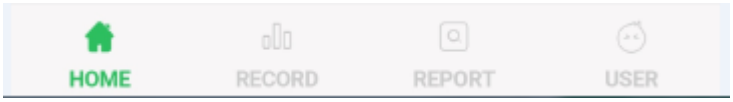
Note: The data in the display screen will switch every 3 seconds.



(6) When test is completed, long press function button to power off; when there's no operation conducted to the device, it will automatically power off after 6 minutes, you will hear "Device shutting down".

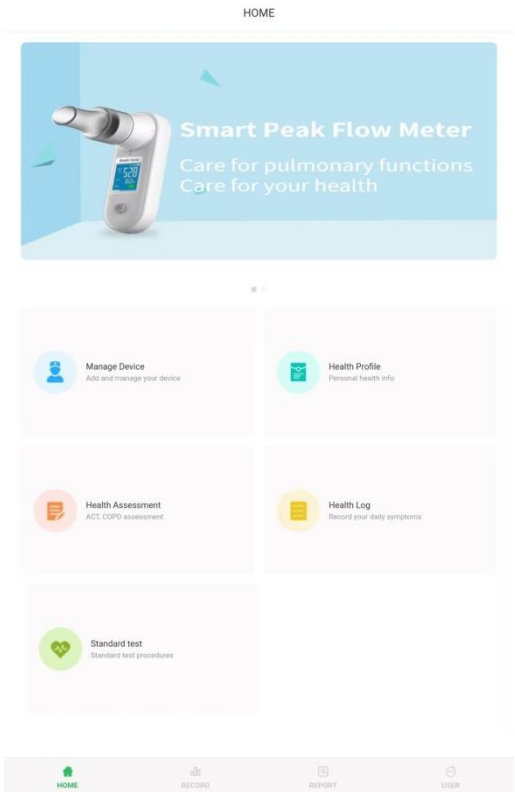
4.4 Introduction of APP

Log into the APP, it has the following functions:



（1）HOME

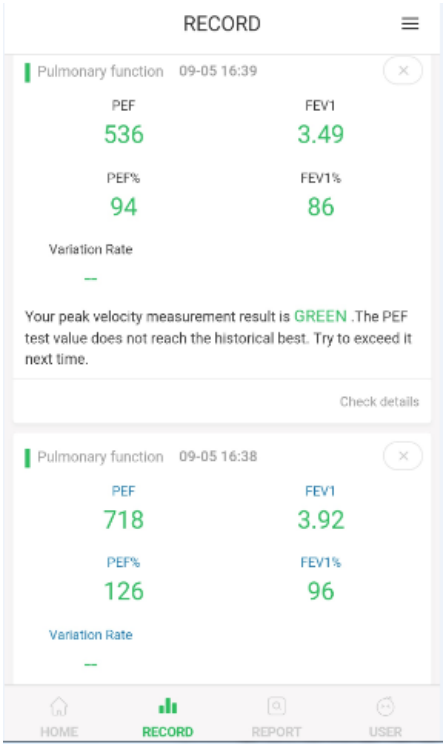
Click "HOME"， the following items will appear:



No	Item	Function
1	Manage Device	Check device information, bind or unbind the device to APP.
2	Health Profile	Fill in, modify or check personal information.
3	Health Assessment	Fill in questionnaire, APP will conduct an assessment to your asthma control results based on the answers in the questionnaire.
4	Health Log	Record and check the daily Peak flow rate, Medication records (Manually choose) and Records of symptoms (Manually choose).
5	Standard test	Open this page while blowing, it will display the blowing curve and measured values, and make a judgment on whether the blowing manner meets standard.

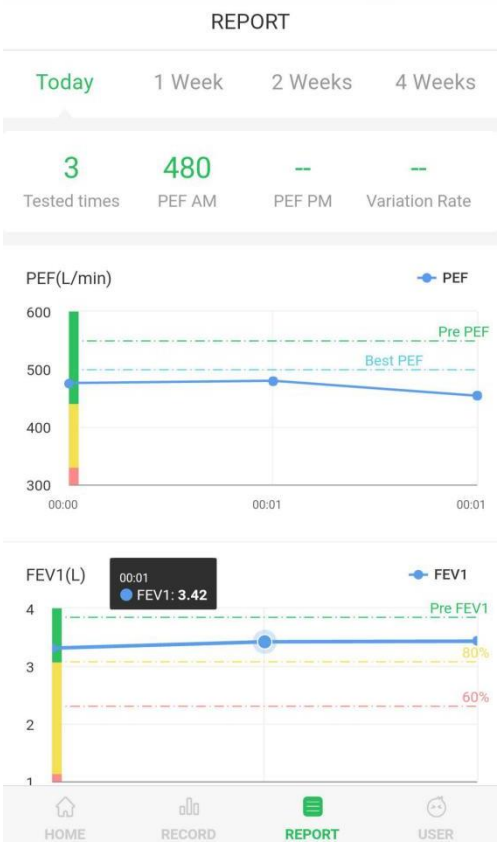
（2）RECORD

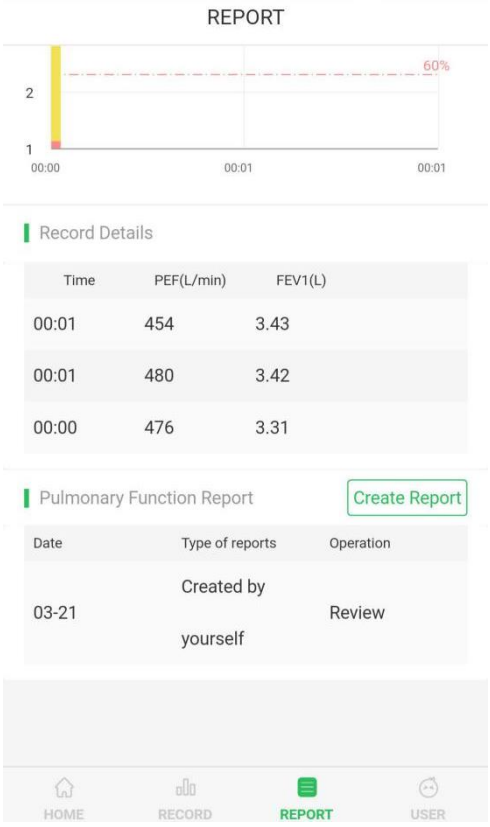
Display the historical records of measurement results:



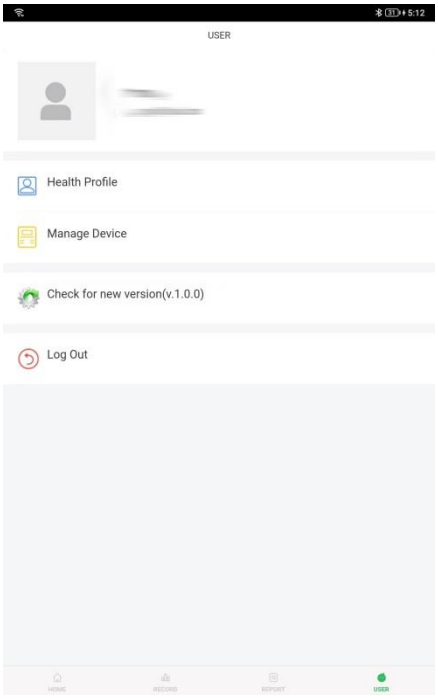
（3）REPORT

Record the best measurement results of “Today”, “1 Week”, “2 Weeks”, “4 Weeks” and generate a line chart. It also has functions of “Index Analysis” and “Create Report”.





（4）USER



No	Item	Function
1	Health Profile	Fill in, modify or check personal information.
2	Manage Device	Check device information, bind or unbind the device to APP.
3	Check for new version (v.1.0.0)	Check the current version of APP.
4	Log Out	Log out

5. Cleaning and disinfection methods

During the pulmonary function test, some parts of the equipment will be contaminated with bacteria. Therefore, the next subject may be at risk of bacterial infection.

Thorough disinfection of all contaminated parts can avoid potential risks of infection. Therefore, all parts should be disinfected regularly. See the table below.

	Disposable pulmonary function mouthpiece Discarded immediately after use in each patient

Special reminder: Disposable products must be discarded.

The following parts must be cleaned and disinfected once a day, see the following table：

	Flow sensor head is cleaned and disinfected once a day

⚠ ***Caution:***

Thorough disinfection of all contaminated parts can avoid potential risks of infection. Therefore, all parts should be disinfected regularly, and disposable products must be discarded!

5.1 Removal steps of flow sensor head

Press the button on the back of the device， rotate the flow sensor head and pull it out forcefully at the same time；

5.2 Cleaning and disinfection of the parts of the flow sensor head

1) Cleaning and disinfection of the parts of the flow sensor head and the screen under normal temperature and pressure:

① Pre-rinse with running distilled water immediately after use to remove residual saliva, dirt and other stains.

② Soak all the cleaned sensor head parts in 2% glutaraldehyde disinfectant solution for about 15 minutes, and add 0.3% sodium bicarbonate to enhance its sterilization and disinfection effect. If there are dirt deposits, do not use hard objects directly scraping, but should increase the soaking time and disinfectant concentration.

③ After disinfection, rinse all parts with a large amount of distilled water and place them in a clean place to dry thoroughly.

It is recommended that all patients be cleaned and disinfected after the test on the same day, so that they can be dried naturally and used next time.

2) Cleaning and disinfection of the main body:

① Use clean gauze dipped in the appropriate amount of 75% medical alcohol (the gauze does not drip), and wipe the outside of the fuselage;

② Wait for natural air drying or use clean dry gauze to wipe dry.

3) Assemble and restore the disassembled parts according to their original positions.

⚠ ***Caution:***

❖ **cleaning and disinfecting the equipment, it is forbidden to immerse the main body in liquid!**

❖ **Do not use cloth, paper, or hard objects to clean the screen, if necessary, use the**

special brush provided by the company for cleaning!

⚠ ***Warning:***

Failure to follow the steps of the cleaning and disinfection methods mentioned above may result in cross-infection.

⚠ ***Caution***

After cleaning and disinfecting and before starting to use the equipment, complete the capacity calibration and 3 flow verification of the equipment in accordance with the description of the calibration in the APP.

6. Equipment maintenance

6.1 Maintenance

1) Regular inspections to ensure that the equipment has no obvious damage that affects safety or detection performance. It is recommended to inspect at least once a week. If there is obvious damage, stop using the equipment and contact after-sales customer service.

2) The maintenance of this equipment is limited to qualified personnel designated by the manufacturer. Users should not repair the equipment by themselves.

3) When the device prompts that the battery is low, use a power source that meets the USB specification to charge in time. If the battery is found to be used for too short a time, you should stop using the device and contact after-sales customer service.

4) Please use it in the specified working environment, keep the operating environment clean, free of corrosive or combustible substances, and free of excessively high or low temperature and humidity.

6.2 Work, storage and transportation requirements

6.2.1 Working environment

The device needs to work under the following environmental conditions:

Temperature:10℃～+40℃,

Humidity: 0％RH～80％RH,

Atmospheric pressure: 70KPa ～106KPa

If it exceeds the above working environment, it will affect the measurement performance of the product.

6.2.2 Transport and storage environment

The device should be transported and stored under the following environmental conditions:

Temperature:-20℃ ～+55℃,

Humidity: 0％RH～80％RH,

Atmospheric pressure:

70KPa ～106KPa

Clean room without corrosive gas and well ventilated.

6.2.3 Transportation requirements

The following requirements must be met when transporting the device:

1) Avoid heavy objects squeezed;
2) Avoid direct sunlight;
3) Avoid getting wet from the rain;
4) Handle with care during the moving process.

7. Troubleshooting

Failure phenomenon	Cause Analysis	Solution
Can not boot	Low battery	Please connect the charger to charge.
	Possible equipment damage	Please contact the after-sales customer service center.
The LTE network connection fails after the device is powered on	There is no LTE network signal in the use area or the network signal is weak	Please move to the LTE network signal strong location to use the device
	The LTE communication module may be damaged	Please contact the customer service center
Bluetooth network connection failed after power on	The Bluetooth function of the mobile phone is not turned on	Please turn on the Bluetooth function of the mobile phone.
	The distance between the device and the phone is too large	Please keep the distance between other Bluetooth and the device less than 5 meters.
	The Bluetooth communication module may be damaged	Please contact the after-sales customer service center.
The device successfully connects to the network but fails to upload data	There is a strong electromagnetic interference around	Please use this product under electromagnetic compatibility conditions as specified in the product manual
No data can be detected for blowing	The instrument does not enter the detection state	Press the key again to measure or shut down and restart.
	Incorrect blowing posture	Please use the correct blowing method.
The flight time after charging is too short	Battery is damaged	Please contact the after-sales customer service center.
Data lost (software)	data lost	You can find the information under the backup in the software catalog or use the data recovery function of the system to find the lost data.

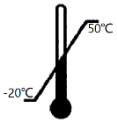
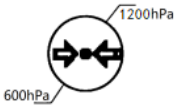
	Software crashes	During use, the logic of the application itself may be wrong, and the system may cause the software to crash. At this time, the software can be restarted to continue running.

8. Technical parameters and specification

Basic unit specifications	
Dimensions	120×44×52mm
Weight	85g
Power supply	3.7V-500mAh, rechargeable Lithium polymer battery
Input power	5VA
Working electricity	100mA
Maximum battery life with one full charge	6 days
Maximum stand-by time with one full charge	30 days
Display	1.44" TFT LCD display
Sensor type	Pressure sensor
Transmission mode	Bluetooth, LTE Cat M, LTE Cat NB
Safety category	BF type
Service life	5 years
Measurement parameters	
Measurement parameters	PEF/FEV1
Memory size	100
Measuring range of PEF	30-840L/min
Measuring range of FEV1	0.01-9.99L
Accuracy	PEF: ±10% or ±10L/min (Take the larger one) FEV1: ±3% or ±0.05L (Take the larger one) Meet ATS 2005 Revision accuracy requirement.
Measuring resolution	PEF: 1L/min FEV1: 0.01L
Environmental conditions	
Working environment	Temperature:10℃～+40℃, Humidity: 0％RH～80％RH, Atmospheric pressure: 70KPa ～106KPa
Storage environment	Temperature:-20℃～+55℃, Humidity: 0％RH～80％RH, Atmospheric pressure:70KPa ～106KPa

About the bluetooth	
Support Bluetooth type:	Bluetooth-LE
Type of Modulation	GFSK
Channel Bandwidth	2 MHz
About the LTE	
Support LTE type:	Cat M, Cat NB
Operation Band	2, 4, 12, 13, 66

9. Symbols

Graphics Symbols	Meaning
	Refer to the instruction manual / booklet
	Keep away from rain
	Keep away from sunlight
	Fragile, handle with care
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Stacking limit by 5
	Type BF applied part

	Low-frequency electromagnetic radiation
	“WEEE (Waste Electrical and Electronic Equipment)”. The waste products should be handled legally.
	Caution
	Serial number
	Manufacturer
	Class II equipment
	Recyclable
	Unique device identifier
IP22	Dustproof waterproof level. It can prevent solid object larger than12mm from intruding, and when tilt for 15 degrees, it can still prevent water from intruding, so no harmful effect will be created.

10. Product quality information

10.1 Warranty service

From the date of purchase, the product enjoys a free warranty within one year with the purchase invoice, but does not include the following failures caused by the user's personal reasons.

Such as unauthorized disassembly and assembly, malfunctions caused by product modification, malfunctions caused by accidental drops during handling, malfunctions caused by lack of reasonable maintenance, malfunctions caused by force majeure factors such as natural disasters.

The manufacturer does not assume any responsibility for problems caused by incorrect operation or use with other equipment or accessories.

10.2 Post-maintenance

If you need to apply for warranty and repair services, please contact after-sales customer

service, fill in the warranty card, and take this product to a professional service point for repair.

If the product is repaired by the user or by a non-designated repair center, the warranty statement is invalid. If the equipment needs maintenance, the above requirements also apply.

In order to process your repair application more quickly, please provide the following product information:

1) Product number.

2) Detailed description of the fault.

⚠ ***warning:***

For safety reasons, maintenance center personnel have the right to reject products that have been contaminated. Products should be packaged in non-polluting packaging.

⚠ ***Caution:***

Please choose appropriate and strong packaging when sending it for repair (original packaging is best).

The manufacturer has the right to return the contaminated product to the shipper

10.3 Production date and expiry date

Product production date: see product label

Product expiration date: three years

11. Electromagnetic compatibility instructions

11.1 Parameter description

Serial number	name	Cable length (m)	Whether to block	Remark
1	USB Cable	1.0	Yes	/

⚠ ***Warning***

Even if other equipment meets the emission requirements of the corresponding national standards, the equipment or system may still be interfered by other equipment.

11.2 EMC statement

1） Model B300 needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying document;

2） Portable and mobile RF communications equipment can affect model B300.

⚠ **Warning:**

1） Don’t be 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.

2）Use of accessories, transducers and cables other than those specified or provided by the manufacturer of Model B300 could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

3） Use of Model B300 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.

11.3 FCC declaration

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 Caution:

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

This radio is designed for and classified as “General population/uncontrolled Use”, the guidelines are based on standards that were developed by independent scientific organizations through periodic and thorough evaluation of scientific studies. The standards include a substantial safety margin designed to assure the safety of all persons regardless of age or health.

The device complies with RF specifications when the device used at 15mm from your front face and 0mm from your limbs.

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.

11.4 Declaration of conformity

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, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±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 N/A 100 kHz repetition frequency
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode N/A
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	10 V/m 80 MHz – 2,7 GHz

	80 % AM at 1 kHz	80 % AM at 1 kHz
NOTE U_T is the a.c. mians voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity							
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	**Test Frequency** (MHz)	**Band** (MHz)	**Service**	**Modulation**	**Modulation** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)
	385	380 –390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27
	450	430 –470	GMRS 460, FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0.3	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0.3	9
	745						
	780						
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
	870						
	930						
	1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
	1845						
	1970						
	2450	2 400 – 2 570	Bluetooth, WLAN,	Pulse modulation	2	0.3	28

			802.11 b/g/n, RFID 2450, LTE Band 7	217 Hz			
	5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0.3	9
	5500						
	5785						

12. Contact information

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