



BreathHome

Product user manual

Smart Peak Flow Meter Model: B1

Please read this user manual carefully before use.

Guangzhou Homesun Medical Technology Co., Ltd

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1. Product overview

1.1 Basic information

Product name: Smart Peak Flow Meter

Model: B1

1.2 Intended use

This device is intended for monitoring PEF (Peak Expired Flow Rate) and FEV1 (Forced Expiratory Volume in one second) for patient. The device is designed for pediatric to adult patients. The device is intended for monitoring respiratory conditions such as asthma.

1.3 Product performance and structure

1.3.1 Product introduction

Smart Peak Flow Meter B1 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). Regular measurement is beneficial to the controlling of pulmonary disease such as asthma.

The use of B1 is very simple, you can master it quickly after reading the product user manual. B1 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 transmission mode for permanent storage. You can check the previous measurement records on the smart phone App.

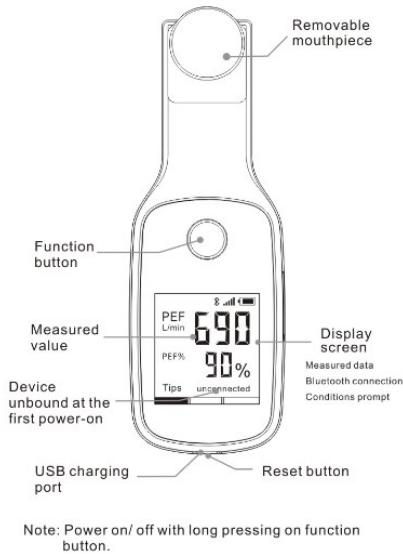
1.3.2 Package content

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

| Items | Quantity |
|-----------------------|----------|
| Smart Peak Flow Meter | 1 |
| USB data cable | 1 |
| User manual | 1 |
| Warranty card | 1 |
| Removable mouthpiece | 2 |

1.3.3 Product main structure

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



1.3.4 Measuring 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% |

1.3.5 What do the parameters mean?

| PEF% | Severity of asthma | FEV1% | Obstructive index |
|-------|--------------------|-------|-------------------|
| □ 80% | Normal | □ 80% | Normal |
| < 80% | Moderate | <80% | Mild |
| < 60% | Severe | <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

The following patients are prohibited from using this device:

- 1) Patients suffering from severe asthma;
- 2) Patients suffering from severe chronic obstructive pulmonary disease;
- 3) Patients suffering from uncontrolled high blood pressure;
- 4) Patients who have received chest, abdomen or ophthalmic surgery in the recent 3 months;
- 5) Patients who have had heart attack (such as angina, myocardial infarction, malignant arrhythmia) in the recent 3 months;
- 6) Patients who have been hospitalized due to heart disease in the recent 1 month;
- 7) Patients who have had massive hemoptysis in the recent 1 month;
- 8) Patients who have had cerebral apoplexy in the recent 1 month;
- 9) Patients suffering from aortic aneurysm;
- 10) Patients suffering from severe hyperthyreosis;
- 11) Patients suffering from epileptic seizure and in need of medication;
- 12) Patients who have a history of detached retina;
- 13) Patients suffering from facioplegia.

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.



- 1) Please operate strictly according to this user manual, or else there might be inaccurate measurement or device gets damaged.
- 2) Do not use while charging, otherwise it will lead to inaccurate measurement.
- 3) Lithium batteries are not replaceable. If lithium batteries are replaced, the measurement of equipment will be inaccurate.
- 4) Do not repair this device by yourself, it should only be done by qualified personnel appointed by the manufacturer.

- 5) Do not use this device in an environment that has anesthetics and other inflammables which may cause explosion.
- 6) Do not use this device in strong electromagnetic interference or direct wind source, cold source and heat source environment.
- 7) Do not immerse this device into liquid.
- 8) Do not spatter liquid onto this device which may cause damage.
- 9) Do not place this device in an mechanical vibration environment.
- 10) Do not drop this device from a high place.
- 11) Do not use sharp objects to press or scratch the device shell.
- 12) Do not disassemble the device without permission.
- 13) Do not place heavy objects on the device which may cause performance or mechanical damage.
- 14) Do not use high temperature high pressure or gas disinfection to disinfect the device.
- 15) Do not spatter liquid directly on the device when disinfect the device surface using medicinal alcohol.
- 16) The measurement results can only serve as a clinical reference which should be explained by professional medical personnel.

 Precaution

- 1) Regular maintenance to make sure there's no damage that affects safety and performance. It's advised to check at least once a week, if there's obvious damage, please stop using and contact customer service.
- 2) Please use the device in specified working environment, keep the working environment clean and avoid corrosive or flammable substance, too high or low temperature and humidity.
- 3) If the device continues to fail to display data or there's other abnormal conditions, press function button to remeasure, or power off the device and restart.
- 4) Please dispose of the device, its accessories and package (such as mouthpiece, plastic bag, foam and paper box) in accordance with the local laws and regulations.
- 5) When use the device, pay special attention to the user manual where this symbol  is

marked.

4. Installation and operation

When you use B1 for the first time, you should bond APP and input personal health information.

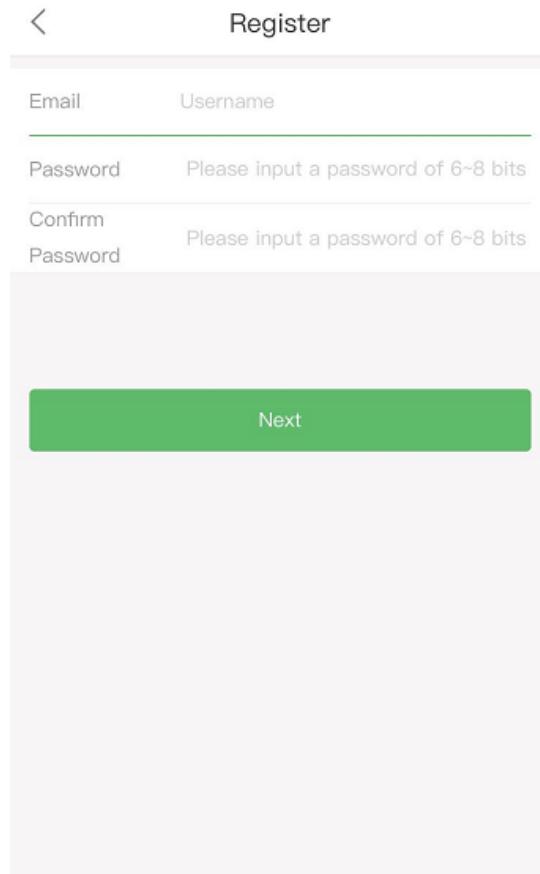
4.1 Download APP

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

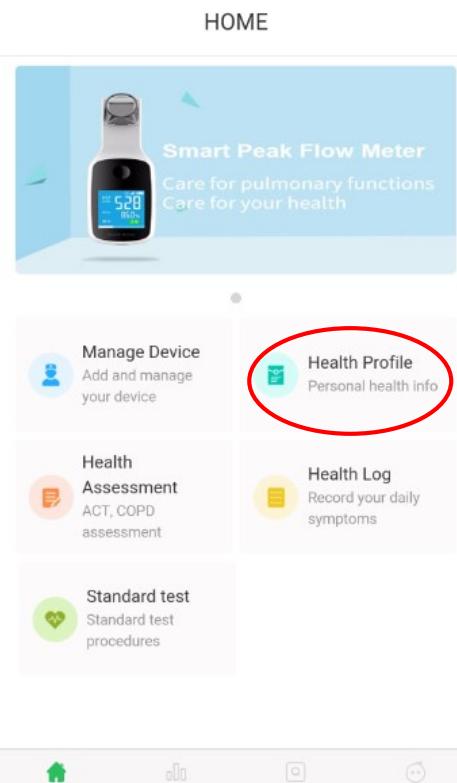


Note: This APP is supported by smart phone (all versions of iOS or Android 4.4-8.1 platform).

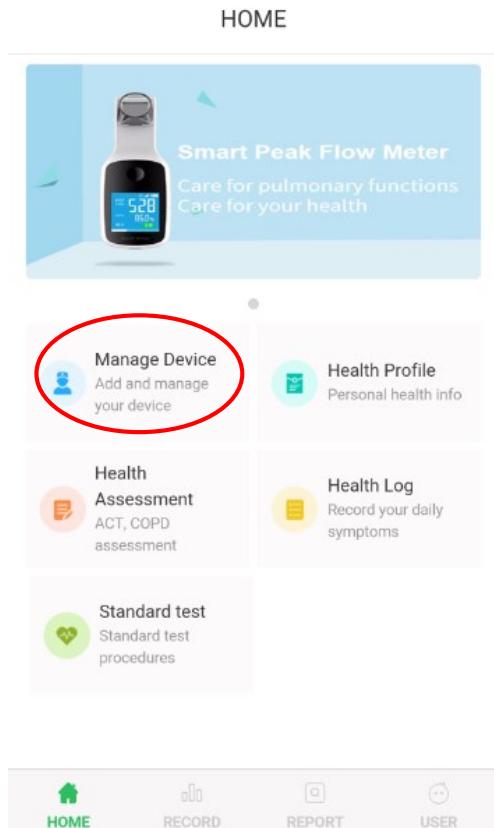
(2) Open the APP, register by email to create a new account, enter the APP HOME after registration.



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

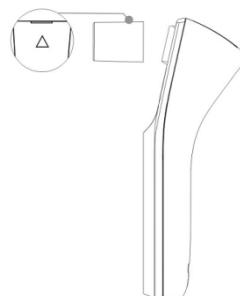


(4) Connect the device. Power on the device and place it near the smart phone, activate the bluetooth mode of the smart phone, click “Manage Device”, complete device bonding according to operation instruction.



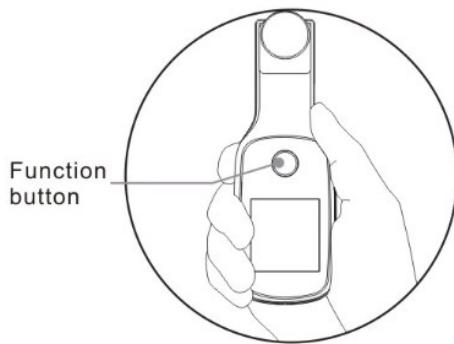
4.2 Device installation and preparation

Install the mouthpiece: Hold the device, make the side of the mouthpiece with this triangular symbol “△” face upward, insert the mouthpiece into air inlet with an angle of 30° upward, then press slightly, the mouthpiece would be firmly locked.



4.3 Start test

(1) Hold the product upright in the hand, long press the function button to start up.



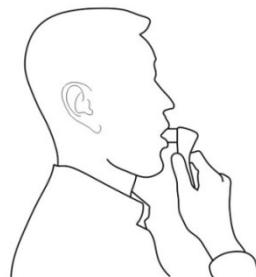
(2) Stand up.

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

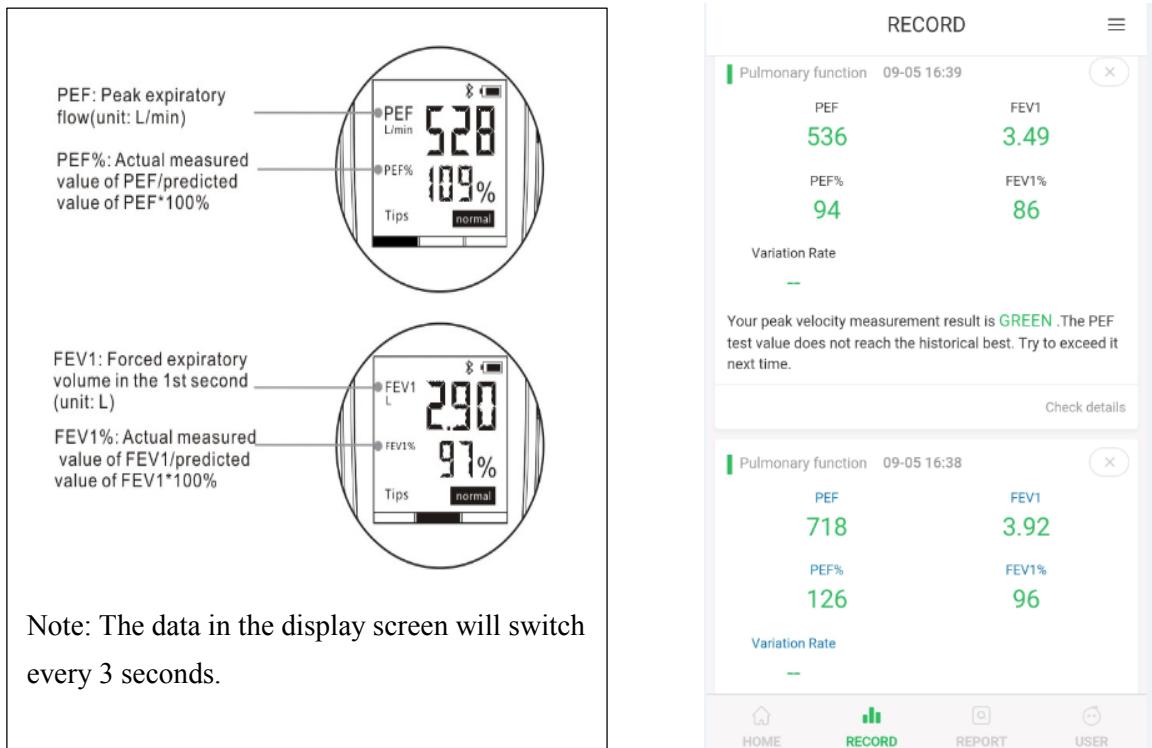
(4) Take a deep breath, hold your breath while put the mouthpiece into your mouth (the upper and lower teeth should nibble the front of the mouthpiece, and your lips should tightly cover the mouthpiece). Exhale quickly and forcefully, taking as much time as possible (the standard time is 6 seconds).

Note:

- ① Adjust your breath before the test (inhale and exhale for 3 rounds), keep your breath steady.
- 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.



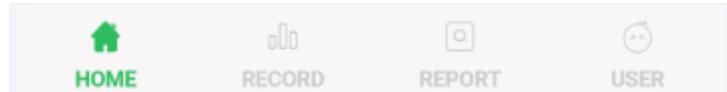
(5) After the test, there is a prompt tone, the results is shown in display screen (you can test multiple times and take the maximum value). Or you can check the results on the “RECORD” page of APP.



(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.

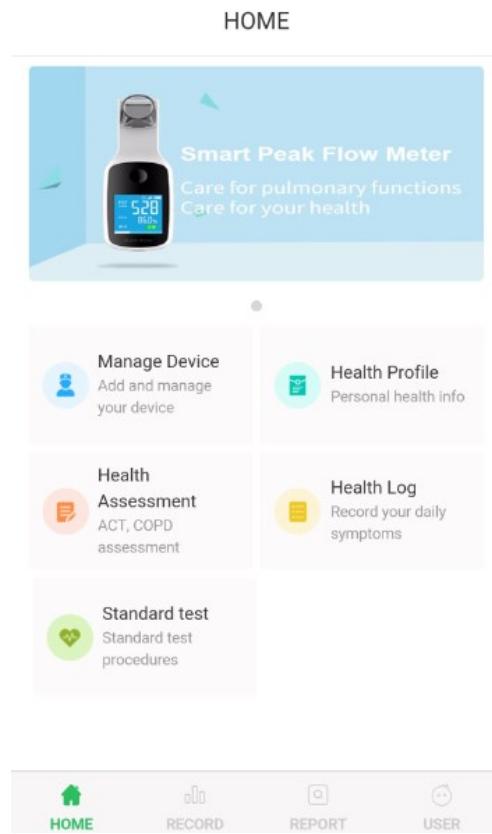
4.4 Introduction of APP

Log into the APP, it has the following functions:



(1) HOME

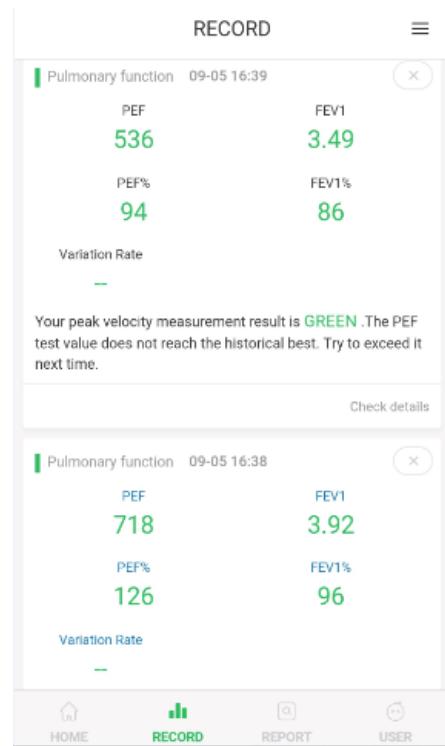
Click “HOME”, the following items will appear:



| 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. |

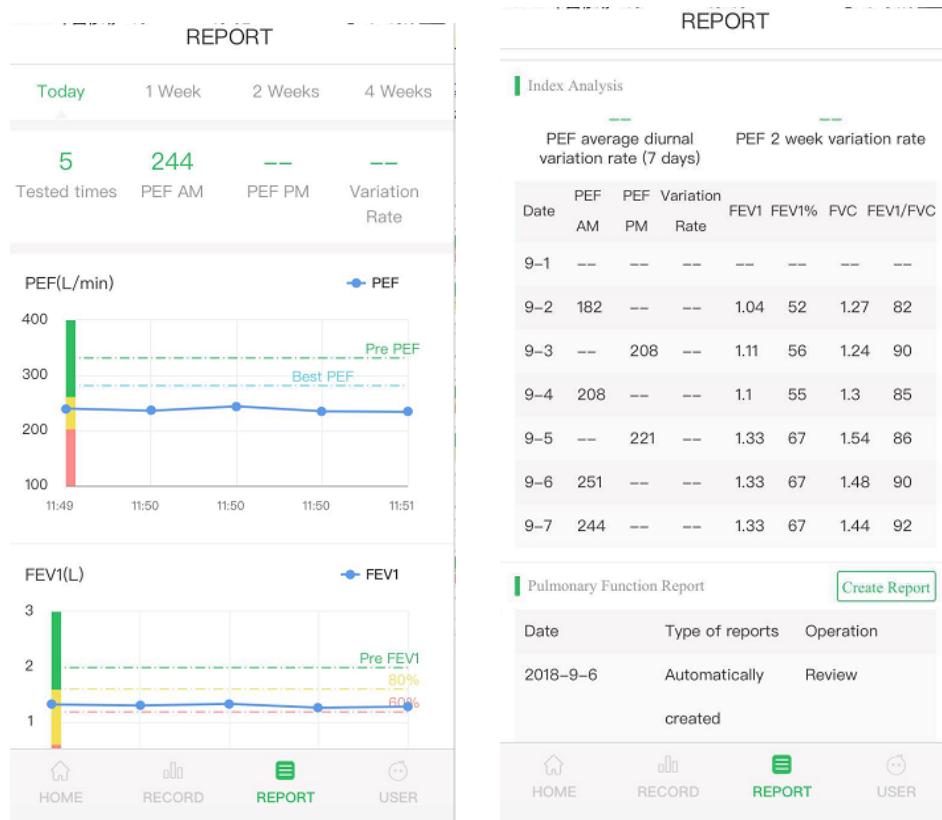
(2) RECORD

Display the historical records of measurement results:

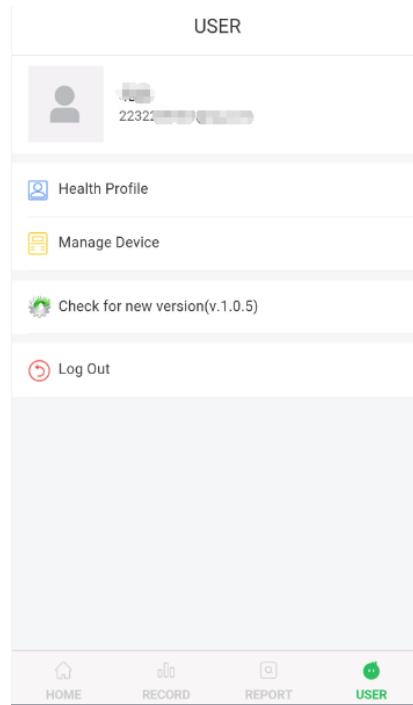


(3) REPORT

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 (v1.0.5) | Check the current version of APP. |
| 4 | Log Out | Log out |

5. Maintenance and storage

5.1 Cleaning and disinfection

- 1) Use medicinal alcohol to wipe the shell of the device, then use clean, soft cloth to dry it or dry by natural air.
- 2) Remove the mouthpiece regularly, rinse with clean water, use clean, soft dry cloth dipped in medicinal alcohol to wipe the inner and outer wall of the mouthpiece, then use soft dry cloth dipped in distilled water or drinking water to wipe, and dry by natural air; or dip the mouthpiece in medicinal alcohol for a Ten minutes, then take it out and dip it in distilled water or drinking water,

wipe it dry or dry by natural air.

- 3) Use cotton ball dipped in alcohol to gently wipe the spring strip to keep it clean.

 **Caution:**

- Only use wet cloth to wipe. It's prohibited to immerse the device shell into liquid.
- Do not flush the main unit with high pressure water.
- Do not wash or disinfect the device with strong alkali or strong acid.

5.2 Charging

When the device indicates low power, please charge as soon as possible. There are two charging methods:

- A. Use power adapter with an input power of 5VA to charge. Insert one end to power socket, the other end is connected with device through USB cable so as to charge the device.
- B. Connect to computer to charge. Insert one end of the USB cable to USB port on the computer, the other end is connected with device so as to charge it.

 **Caution:**

- You should use power adapter with an input power of 5VA and USB port, which conforms to IEC60601-1 standard.
- Do not use the device while charging.

5.3 Storage

Please store the device in a well-ventilated clean room with no corrosive gas, avoid direct sunlight and high temperature.

6. Product disposal

In order to avoid environmental pollution, please dispose this device according to local environmental requirements and do not discard casually.

7. Troubleshooting

| Failure | Cause analysis | Solutions |
|---------|----------------|-----------|
|---------|----------------|-----------|

| | | |
|--|--|--|
| Unable to turn on | Low battery | Please recharge |
| | Possible device damage | Please contact the local distributor |
| Unable to get the test data | Not in test status | Press again to measure or restart. |
| | Wrong blowing posture | Please refer to the user manual for the correct blowing posture. |
| Sudden disappearance of display | Automatically shut down without any operation for 6 minutes. | Normal phenomenon. |
| | Low battery | Please recharge |
| The device usage time is too short after recharging. | Low battery | Please recharge |
| | Battery damaged | Please contact the local distributor |
| Data transmission failure | Bluetooth unconnected | Turn on the blue-tooth in your smart phone |
| | | Start the APP and click “Unconnected” |
| | | Please contact the local distributor |

8. Technical parameters and specification

| Basic unit specifications | |
|--|---|
| Dimensions | 111*39*40mm |
| Weight | 50g |
| Power supply | 3.7V-300mAh, 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 |
| Safety category | BF type |
| Service life | 3 years |
| Measurement parameters | |
| Measurement parameters | PEF/FEV1 |
| Memory size | 100 |
| Measuring range of PEF | 50-840L/min |
| Measuring range of FEV1 | 0.01-9.99L |
| Accuracy | PEF: $\pm 10\%$ or $\pm 0.3\text{L/s}$ (Take the larger one) FEV1: $\pm 3\%$ or $\pm 0.05\text{L}$ (Take the larger one) Meet ATS 2005 Revision accuracy requirement. |
| Measuring resolution | PEF: 1L/min FEV1: 0.01L |
| Environmental conditions | |
| Working environment | Temperature: $10^\circ\text{C} \sim +40^\circ\text{C}$, Humidity: 0%RH~80%RH, Atmospheric pressure: 70KPa~106KPa |
| Storage environment | Temperature: $-20^\circ\text{C} \sim +55^\circ\text{C}$, Humidity: 0%RH~80%RH, Atmospheric pressure: 70KPa ~106KPa |
| About the bluetooth | |
| FCC ID | 2ASLFGZHX-B1 |
| Model | DX-BT05 4.0 |
| Operation Frequency Range | 2402-2480MHz |

| | |
|--------------------|-----------------------------------|
| Radio Power | -23 dBm < P _{AV} < 0 dBm |
| Type of Modulation | GFSK |
| Channel Bandwidth | 2 MHz |

9. EMC statement

- 1) Model B1 needs special precautions regarding EMC and need 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 B1.

Warning:

- 1) Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
- 2) Use of accessories, transducers and cables other than those specified or provided by the manufacturer of Model B1 could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- 3) Use of Model B1 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.

10. FCC declaration

This device complies with Part 15 of the FCC Rules. Operation is subject to the follow two conditions :

- (1) This device may not cause harmful interference, and
- (2) This device must accept any interference received, including interference that may cause undesired operation.

Note: This 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.

CAUTION: To comply with the limits of the Class B digital device, pursuant to Part 15 of the FCC Rules, this device is to comply with Class B limits. All peripherals must be shielded and grounded. Operation with non-certified peripherals or non-shielded cables my result in interference to radio or reception.

MODIFICATION: Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the device.

11. Symbols

| Graphic symbol | Meaning |
|----------------|---------------|
| LOT | Batch code |
| SN | Serial number |
| | Manufacturer |
| | Caution |
| | Keep dry |

| | |
|---|---|
|  | Type BF applied part |
|  | Low-frequency electromagnetic radiation |
|  | “WEEE (Waste Electrical and Electronic Equipment)”. The waste products should be handled legally. |
|  | Follow instructions for use |
| IP22 | Dustproof waterproof level. It can prevent solid object larger than 12mm from intruding, and when tilt for 15 degrees, it can still prevent water from intruding, so no harmful effect will be created. |
|  | CE mark and notified body code |

12. Quality warranty

12.1 Warranty

One year warranty since the purchasing date upon presentation of purchasing proof, but not include the following conditions:

- Failures caused by unauthorized disassembly;
- Failures caused by inappropriate transportation;
- Failures caused by the lack of reasonable maintenance;
- Failures caused by force majeure factors such as natural disasters.
- For faulty operation or problems caused by use with other device or accessory, our company assumes no responsibility.

12.2 After-sales maintenance

Please take this product to a professional service center for maintenance. If the maintenance is conducted by the user himself or unspecified service center, then this warranty is invalid.

To process your maintenance application faster, please provide the following information:

- Product number
- Batch code
- Detailed description of the problem

 ***Caution:***

- The service center has the right to reject contaminated product for safety reasons. Please pack the product in a way that does not contaminate the package.
- Please use appropriate and strong package (preferably the original package).
- Our company has the right to return contaminated product to the sender.

13. Contact information

Manufacturer: Guangzhou Homesun Medical Technology Co.,Ltd

Address:Floor 7th,TianxiangBusiness Building, No.28,Li Fu Road,Haizhu District, Guangzhou, GD .China (510250)

Tel.: +86 020 809 5414

Fax: +86 020 809 5414

Email:service@huxijia.cn

URL:https://www.huxijia.cn/index_english.html

Attachment:

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 | Compliance level |
| | Test 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 | 0 % UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 | 0 % UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; |

| | | |
|---|--|--|
| power supply input lines IEC 61000-4-11 | cycles; Single phase: at 0°. 0 % UT; 250/300 cycle | 25/30 cycles; Single phase: at 0°. 0 % UT; 250/300 cycle |
| Power frequency magnetic field IEC 61000-4-8 | 30 A/m 50Hz/60Hz | 30 A/m 50Hz/60Hz |
| Conduced RF IEC61000-4-6 | 3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz | 3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz |
| Radiated RF IEC61000-4-3 | 10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz | 10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz |
| NOTE UT is the a.c. mains 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 | Pulse | 0,2 | 0,3 | 9 |

| | | | | | | | |
|--|------|------------------|---|-------------------------------|-----|-----|----|
| | 745 | | 13, 17 | modulation 217 Hz | | | |
| | 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, 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulation 217 Hz | 2 | 0.3 | 28 |
| | 5240 | 5 100 – 5 800 | WLAN 802.11 a/n | Pulse modulation 217 Hz | 0,2 | 0.3 | 9 |
| | 5500 | | | | | | |
| | 5785 | | | | | | |