Instructions for use

File No.	MF/TCF-CE03-017-2S
Version.	A/0
Product Name:	Peak flow meter
Specification	SMPF-2S

Chongqing Moffy Innovation Technology Co.,Ltd.

Instructions For Use

1. Product introduction

Product Name: Peak flow meter

Specification：SMPF-2S

Intended use：Measuring forced expiratory volume of 1 second (FEV1), peak flow rate（PEF）

The scope of application: Apply to the test of forced vital capacity.

Contraindications:

1) Myocardial infarction, stroke, shock in the past 3 months
2) Severe cardiac insufficiency, severe arrhythmia, unstable angina, in the last 4 weeks
3) Hemoptysis in the last 4 weeks
4) Seizures require medication
5) Uncontrolled hypertension
6) Aneurysm
7) Severe hyperthyroidism
8) Heart rate> 120 beats/min
9) Pneumothorax, huge lungs, and not ready for surgery
10) Pregnant women
11) Tympanic membrane perforation (measured after the affected ear canal is first blocked)

⚠ Warning：

- Patients are expected user
- To ensure proper use of the product, please read the user manual thoroughly and store it safely
- Measured results of vital capacity is for reference only, not for the diagnosis of disease
- Dispose of used batteries in accordance with local regulations
- For accurate testing, do not perform more than 5 consecutive tests as a single user
- Explosion danger: do not put any oxygen enrichment、flammable items in under the environment of using this product
- Avoid usage in areas with strong electromagnetic interference or excessive wind.
- Do not service or maintain while in use
- Do not modify this equipment without authorization of the manufacturer

⚠ Note：

- Keep environment clean operation, no vibration, no corrosion or flammable materials, not too high or too low temperature and humidity
- When the instrument from cold to warm、moist environment, don't use immediately
- When measuring process, cannot display data or have other anomalies, please turn off to restart
- Users need to have the basic knowledge of asthma

2. Product structure and components

The Peak flow meter is composed of Main Unit and Mouthpiece.

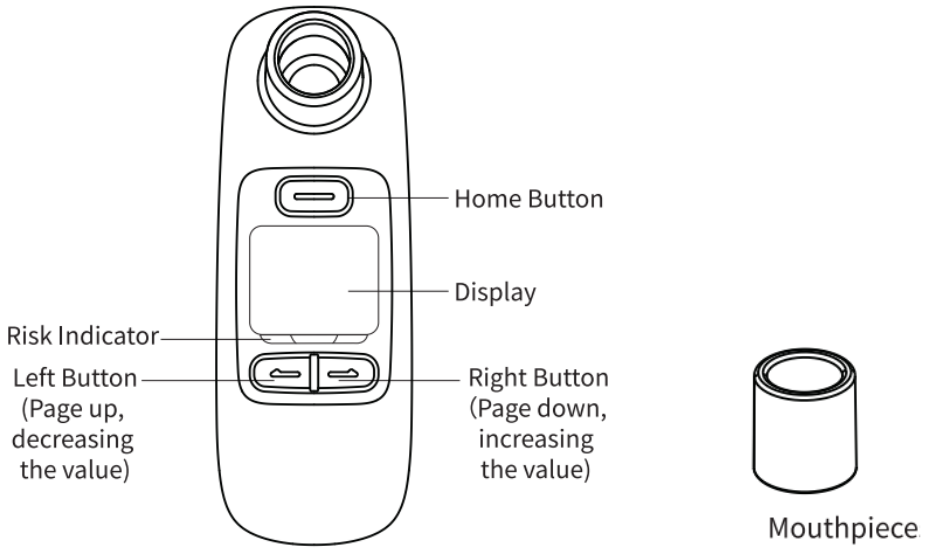

Figure 1 **Peak Flow Meter**

Figure 2 Screen Display

① FEV1 Measurements

② PEF Measurements

③ Current Month

④ Current date

⑤ Current Year

⑥ Current Time

⑦ Low battery status indication

⑧ Records

⑨ Unit of PEF

⑩ Unit of FEV1

⑪ Risk Indicator

⑫ Bluetooth status indication

Reflect lung function by measuring FEV1、PEF .

3. Instructions

⚠Warning：For personal use only.

The Peak Flow Meter（SMPF-2S）is a hand-held equipment for examining lung function，it's only required that the user operates it according to user manual, no need for specialized training.

When the equipment is taken out of storage under extreme temperature conditions, it should be allowed to acclimate for atleast half an hour before use.

3.1 Power on

Press the Home Button"-", the device is properly turned on with " 90- " shows on the screen.

Figure 3 stand-by Interface

3.2 Prepare

Sit straight/ stand up, take a deep breath with your mouth, then cover the Mouthpiece with your mouth completely. Please don't place your tongue or teeth against the Mouthpiece. Also please do not cover the back of the Mouthpiece with your hand.

Figure 4 Correct measurement posture

3.3 Start

Blow as fast as you can, wait for 2 beeps from the device before you can read the result.

⚠ Note: Remeasurement is required in the following cases

① Cough

② Exhalation time is too short

③ Exhale too slow

④ Measured values deviate significantly from normal

3.4 Remeasurement

Press the Home Button again， and repeat step 3.2 and step 3.3.

It is recommended to perform at least three consecutive measurements throughout the measurement, taking the maximum as the final result.

3.5 Shutdown

1) Press and then hold the Home Button for 2 to 3 seconds until the device is turned off.
2) Also the device will be automatically powered off after approximately 1 minute of inactivity.

3.6 Time setting

1) Press the Home Button, the screen will be "fully bright" first, then it will display "go-"
2) Press and hold the Home Button and the Left Button "◄" at the same time for about 5 seconds. and you will see the year figure starts to flash at the top of the screen. Adjust the value through the Left Button "◄"and Right Button "►".
3) Press the Home Button to confirm, and then set the month, date and time in turn.
4) Press and hold the Home Button about 3 seconds to save the date and time settings.

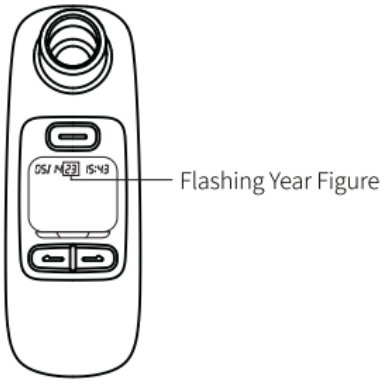

Figure 5 Enter time setting

3.7 Setup your expected PEF value

The expected value affects the asthma control assessment results and needs to be set in advance before the test. It is recommended to update the expected value once a year due to changes in age, height, etc.

1) Make sure the device is powered off, press and hold the Home Button (ignore the " go-" page) for about 5 seconds. The display will show " PEF 000 L/MIN" indicating the parameter setting mode is properly activated, and the flashing figure indicates that the value can be edited.
2) In the parameter setting mode, press the Right Button "►" to increase the value of the current digit, press the Left Button "◄" to decrease the value, press the Home Button to switch the next dight.
3) Press and hold the Home Button about 3s to save the current value as your expected PEF value.

Note:

- The maximum setting value is "999L/MIN", and the minimum is "60L/MIN".
- No red, yellow and green Risk Indicators will be displayed on the device without properly setting the expected value.

4) How can I know my expected PEF value?

You can get your personal prediction value from your doctor.

3.8 About battery

When the Low battery status indication ( ) stay on continuously, it indicates a low battery, a 5V power adapter is required for charging.

"..." flashes sequentially, indicating that it is charging, and "..." stays on, indicating that it is fully charged.

3.9 What do the parameters mean?

After the measurement, by comparing the real-time measured value with the predicted value get percentage values, and then you can know the extent of the disease.

PEF%：PEF real-time measured value / PEF predicted value * 100%

FEV1%：FEV1 real-time measured value / FEV1 predicted value * 100%

You can get your personal prediction value from your doctor.

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.

3.10 Data transmission

1) Scan the QR code to download

2) Launch app, press the product icon on your phone to connect with the Peak Flow Meter turned on. The icon will turn into green once the Bluetooth connection is successfully established. All data stored in the Peak Flow Meter can be synced to your smart phone within one Bluetooth connection progress

3) Data can be recorded manually or via Bluetooth connection between the device and your smart phone.

4. Maintenance

4.1 Cleaning

Main unit: Wipe with a soft dry cloth, do not put it in water. Cleaning once a week is recommended.

Mouthpiece: To clean the Mouthpiece internal and external, a meidcal alcohol cotton of 75% concentration and larger than 30*60mm is recommanded. To ensure the safety and hygiene during use, it must be cleaned after each use.

4.2 Period of use

Peak flow meter life is five years.

4.3 Maintenance

1) Before use, it is essential to perform a comprehensive inspection to ensure the equipment can operate normally. Please follow these steps.
   - Confirm that the display is functioning correctly, ensuring the equipment is in excellent working condition.
   - Confirm that the display is functioning correctly, ensuring the equipment is in excellent working condition

   ⚠ Note：The equipment undergoes a thorough inspection at the factory before shipping, and during its intended period of use, no further calibrations are necessary
2) Before use, please refer to the instructions in section (4.1) for cleaning
3) When the low battery indicator lights up，please refer to the instructions in section (4.2) for replace the battery.
4) The maintenance of this product is limited to the qualified maintenance personnel designated by the manufacturer. The user cannot disassemble and repair. At the same time the manufacturer can provide the circuit diagram, components list, rectification rules, or necessary information to help qualified technical personnel for maintenance.

⚠ Warning :Do not modify this equipment without authorization of the manufacturer

4.4 Storage

Please put the Peak Flow Meter in clean and dry place. Exposure to direct sun light or extreme high and low temperature, or violent impact may result in work failure of the Peak Flow Meter or even damage the device.

4.5 Production date

Please refer to the production date label in detail.

5. Definition

5.1 Term definition

1) PEF：（unit：L/min ）Peak Expiratory Flow (PEF), also called Peak Expiratory Flow Rate (PEFR), is a person's maximum speed of expiration, as measured with a Peak Flow Meter. It measures the airflow through the bronchi of the lungs and shows the degree of obstruction in the airway
2) FEV1：（unit：L）Forced Expiratory Volume (FEV1) calculates the amount of air that a person can force out of their lungs in 1 second. It is an indicator of the reversibility of airway obstruction and the primary indicator of impaired lung function
3) PEF%：Measured PEF/ Expected PEF*100% * 100%
4) FEV1%：Measured FEV1/ Expected FEV1 * 100%
5) Expected value

The expected value (target value) is usually calculated based on statistics. It varies according to race, gender, age, and height.

According to the variation between the actual tested value and the expected value, your PEF readings are classified into three measurement

zones: green, yellow, and red. The device will show these colors with results accordingly.

- Green: PEF%≥80%, a peak flow reading in the green zone indicates that the lung function management is under good control.
- Yellow: 50%≤PEF%＜80%, your peak flow reading indicates caution. It may mean respiratory airways are narrowing, and additional medication may be required.
- Red: PEF%＜50%, your peak flow reading indicates a medical emergency. Severe airway narrowing may occur, and immediate action must be taken. This would usually involve contacting a doctor or hospital.

Note:

Recommendation from: National Institutes of Health (NIH)

FEV1 is generally used as an indicator to measure airway obstruction. Its measurement, evaluation, and interpretation are complicated. It is recommended to consult a doctor or consult professional publications.

5.2 Environmental protection instructions

 From an environmental and resource standpoint, environmental disposal for batteries should be in accordance with local regulations.

The equipment in life end should be handled in accordance with local laws and regulations

5.3 Key of Symbols

 After the use of waste, please follow the regulations of local health or environmental protection agencies

 Applied part of type BF

 Refer to instruction manual/ booklet

 Warning, see the instructions for use

 Pollution control symbol of El electronic information products

Indicating that this product is environmentally friendly for 10 years and is recyclable and should not be discarded

 Do not use if package is damaged

 Fragile, handle with care

 Keep dry

 Keep away from sunlight

5.4 Precautions and warnings

Adverse reactions during use are mostly mild, repeated deep breathing force, hyperventilation may appear dizziness, hand and foot fingertips and facial perioral numbness or acupuncture, slight hand tremor and other symptoms, severe syncope may occur. At this point, the subject should be resting quietly, and care should be taken to protect the subject from fall injuries.

6. Technical specifications

Product Name	Peak Flow Meter
Model	SMPF-2S
Power Supply	DC 3.7V
Display	Segment LCD
Test method	Pressure Sensor
Measurement range	Volume：0.5L ～ 8L Flow rate：60L/min ～ 840 L/min
Accuracy	Volume：±3% or ±0.05L (whichever is greater) Flow rate：±10% or ±18L/min (whichever is greater)
Repeatability	Volume：±3% or ±0.05L of reading (whichever is greater) Flow rate：±5% or ±10 L/min of reading (whichever is greater)
Airflow resistance	0.25kPa/L/s (600 L/min)
Working way	Continuous operation

Operating environment	+10℃ ～ +40℃； ≤80%RH
Operating atmospheric pressure	700hPa～1060hPa
Transport, storage environment	-10℃ ～ +55℃； ≤95%RH
Transport, storage of atmospheric pressure	500hPa～1060hPa
Software version	V2

7. Features

The type of protection against electroshock	Internal power supply
The degree of protection against electroshock	Type BF applied part
The degree of protection against ingress of water	IP22
According to the degree of safely of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Non-AP / APG device
According to the mode of operation	Continuous
Disinfect and sterilize according to the manufacturer's recommendations	No special disinfection and sterilization methods

8. Troubleshooting

Troubles	Possible Reasons	Solutions
Display E1	Initialization error	Turn off and restart
Display H1	The result is higher than 840L/min	Extremely high measurement
The device cannot be powered on	Anti-loaded with the positive and negative of battery The battery is drained away	Reinstall the battery Replace batteries
No data while blowing	Not enter the test mode	Press the function button again or restart
	Wrong inflatable posture	Refer to manual and blow properly
Sudden display disappearance	shut down naturally while no operation for one minute	Normal phenomenon

9. EMC Declaration

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

Guidance and manufacturer´s declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

Guidance and manufacturer´s declaration – electromagnetic emission		
The **SMPF-2S Peak flow meter** is intended for use in the electromagnetic environment specified below. The customer or the user of **SMPF-2S Peak flow meter** should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The **SMPF-2S Peak flow meter** uses RF energy only for its internal function. There for, 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 **SMPF-2S Peak flow meter** 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	N/A	
Voltage fluctuations flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacturer´s declaration – electromagnetic immunity			
The **SMPF-2S Peak flow meter** is intended for use in the electromagnetic environment specified below. The customer or the user of the **SMPF-2S Peak flow meter** should assure that it is used in such an environment.			
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 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.

	± 2 kV common mode		
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle g) 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	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **SMPF-2S Peak flow meter** requires continued operation during power mains interruptions, it is recommended that the **SMPF-2S Peak flow meter** be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE	U_T is the a. c. mains voltage prior to application of the test level.		

Guidance and manufacturer´s declaration – electromagnetic immunity –for EQUIPMENT and SYSTEM

Guidance and manufacturer´s declaration – electromagnetic immunity

The **SMPF-2S Peak flow meter** is intended for use in the electromagnetic environment specified below. The customer or the user of the **SMPF-2S Peak flow meter** should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the **SMPF-2S Peak flow meter**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. 1.1.1 Recommended separation distance $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{12}{V_2}]\sqrt{P}$

Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	$d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.7 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).[b] 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 is affected by absorption and reflection from structures, objects and people.

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

[b] 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 th **SMPF-2S Peak flow meter** is used exceeds the applicable RF compliance level above, the **SMPF-2S Peak flow meter** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **SMPF-2S Peak flow meter**.

[c] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM -for EQUIPMENT and SYSTEMS

Recommended separation distances between portable and mobile RF communications equipment and the SMPF-2S Peak flow meter
The **SMPF-2S Peak flow meter** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **SMPF-2S Peak flow meter** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **SMPF-2S Peak**

flow meter as recommended below, according to the maximum output power of the communications equipment				
Rated maximum output of transmitter W	**Separation distance according to frequency of transmitterm**			
	150 kHz to 80 MHz outside ISM and amateur radio bands $d=[\frac{3.5}{V_1}]\sqrt{P}$	150 kHz to 80 MHz in ISM and amateur radio bands $d=[\frac{12}{V_2}]\sqrt{P}$	80 MHz to 800 MHz $d=[\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d=[\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.20	0.035	0.07
0.1	0.38	0.63	0.11	0.22
1	1.2	2.00	0.35	0.70
10	3.8	6.32	1.10	2.21
100	12	20.00	35	70
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.				

10. Manufacturer

Company: CHONGQING MOFFY INNOVATION TECHNOLOGY CO., LTD.
Address: No.292 Jingdongfang Rd. Beibei Dist, Chongqing, 400714, CHINA
Email: liyongxu@healthcare-inc.com
Website: https://www.ibreathcare.com

FCC Warning

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.

NOTE 1: 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.

NOTE 2: Any changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.