tenovì

Peak Flow Meter

Instructions For Use

TEN-PFM-01

Rev. 1.0 2022

1.Product introduction

【Tenovi】: Peak flow meter

【Specification】: TEN-PFM-01

【Intended use】: Measuring forced expiratory volume of 1 second (FEV1), peak expiratory 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) Aneurysm
3) Seizures require medication
4) Heart rate> 120 beats/min
5) Hemoptysis in the last 4 weeks
6) Pregnant women
7) Uncontrolled hypertension
8) Severe hyperthyroidism
9) Pneumothorax, huge lungs, and not ready for surgery
10) Tympanic membrane perforation (measured after the affected ear canal is first blocked)
11) Severe cardiac insufficiency, severe arrhythmia,unstable angina,in the last 4 weeks

⚠ Warning:

- Before using this product, please read this user manual carefully and keep the manual properly
- Measured results of vital capacity is for reference only, not for the diagnosis of disease
- For scrapped batteries, local laws should be used for recycling.
- In view of the test accuracy, the same user please don't test for more than 5 times
- Explosion danger: do not put any oxygen enrichment、flammable items in under the environment of using this product
- In the strong electromagnetic interference、the wind environment, please do not use
- Do not service or maintain while in use.

⚠ 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.

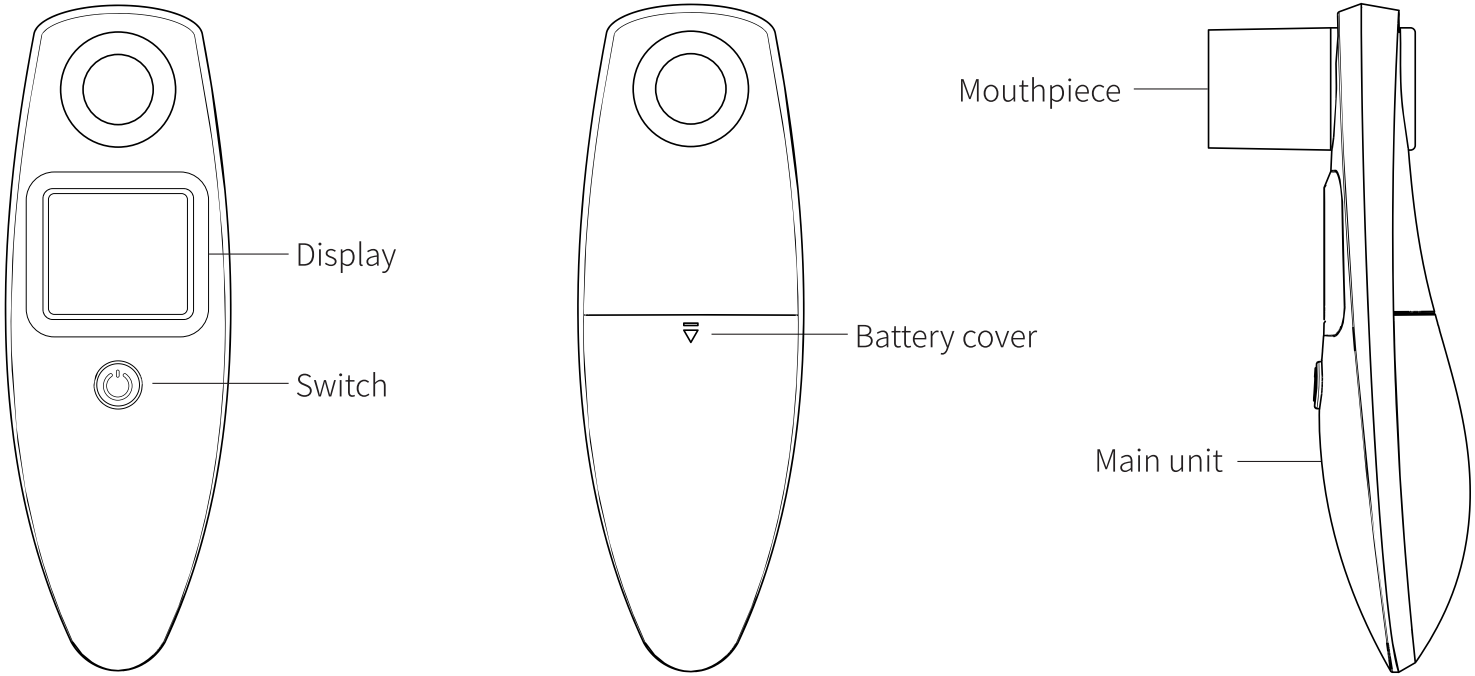

Figure 1 Peak Flow Meter

Screen display

Figure 2 Screen Display

① Low battery status indication ② PEF Measurements ③ FEV1 Measurements

Reflect lung function by measuring FEV1、PEF .

3.Instructions

⚠ Warning：Products for personal use only.

- The Peak Flow Meter (SMPF-1) 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.

3.1 Start

Hold the switch button (⏻) untill you heard a sound of tick , followed by on-screen message 888 on screen.

Figure 3 Boot screen

3.2 **Wait for Tenovi Gateway to connect**

Wait 2-3 seconds for the Tenovi gateway LED to start spinning yellow.

Figure 4 Wait for gateway LED to turn yellow

3.3 Measurement

Stand up straight, keep your head naturally or slightly up and hold both sides of the peak flow meter with both hands. Take a deep breath, blow out completely as fast as you can. In a few seconds, you will get the measurement result.

Figure 5 Measurement results display interface

Figure 6 Correct measurement posture

⚠ Note: In the following cases, remeasurement is required

① Cough

② Exhalation time is too short

③ Exhale too slow

④ Measured values deviate significantly from normal

3.4 Remeasurement

Press the button, the peak meter sends out a short ‘tick' tone, the screen will display the stand-by interface again. Repeat step 3.3 to perfume a remeasurement.
It is recommended to performe at least three consecutive measurements throughout the measurement, taking the maximum as the final result.

3.5 Shutdown

1) Shut down manually: Hold the button till the power switched off.
2) Automatic shutdown: The peak flow meter will shut down automatically in one minute without further operation.

3.6 Status Description

Low battery status indication ( ) : After Peak Flow Meter starts, when the battery power is low, the signal flashes, It is indicated to replace new batteries

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: using medical alcohol to clean. After clean wipe with a clean soft cloth,. To ensure the safety and hygiene during use, it must be cleaned after each use.

4.2 Replace the battery

When the low battery status indicator flash, please promptly replace the battery. Open the battery cover on both sides of the peak flow meter and load two 1.5 V [AAA] alkaline batteries according to the polarity indications in the battery compartment.

⚠ Warning：do not use rechargeable batteries

If the peak flow meter is not likely to be used for one month, please remove the battery.

4.3 Period of use

Peak flow meter life is three years.

4.4 Production date

See production date label in detail.

4.5 Maintenance

1) Before use, need to conduct a comprehensive inspection, to ensure that the equipment can normal operation and work.

- Check the equipment for any mechanical damage.
- Check the display is normal, and ensure that equipment is in good working condition

⚠ Note：equipment has been check before leaving the factory, during the term of use does not need to adjust again

2) Before use, please refer to the instructions the section (4.1) for cleaning

3) When the low battery status indicator flash，please refer to the instructions the section (4.2) for replace the batter.

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

4.6 Storage

Please put the peak flow meter in clean and dry place. Exposuring 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.

5.Definition

5.1 Term definition·

PEF：(unit：L/min) Peak expiratory flow rate

FEV1：(unit：L) One second forced expiratory volume

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

Refer to instruction manual

Applied part of type B

Warning, see the instructions for use

-10℃ +55℃ temperature

500 hPa 1060 hPa humidity

0% 95% pressure

Pollution control symbol of El electronic information products

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

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

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 specificationsition

Product Name	Peak Flow Meter
Model	SMPF-1
Power Supply	DC3V (2 AAA Alkaline batteries)
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 ±10L/min (whichever is greater)
Linearity	Volume：±3%　　Flow rate：⩽ 5%
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	0.006 kPa/L/min
Flow Rate Frequency response	±12% or ±15L/min (whichever is greater)
Working way	Continuous operation
Operating environment	+10°C ～ +40°C；⩽80%RH
Operating atmospheric pressure	700hPa～1060hPa
Transport, storage environment	-10°C ～ +55°C；⩽95%RH
Transport, storage of atmospheric pressure	500hPa～1060hPa
Weight	52g
Size	142*48*56mm

7.Features

The type of protection against electroshock	Internal power supply
The degree of protection against electroshock	Type B 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	Wrong inflatable posture	Blowing properly according to manual
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.

Emission test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Immunity test	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m
Radiated RF IEC 61000-4-3	10 V/m

Test frequency (MHz)	Service	Modulation	Compliance level (V/m)	Electromagnetic environmentguidance
385	TETRA 400	Pulse Modulation 18 Hz	27	WARNING: 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 peak flow meter. Otherwise, degradation of the performance of this equipment could result.
450	GMRS 460, FRS 460	FM [c] ±5 kHz deviation 1 kHz sine	28	
710	LTE Band 13,17	Pulse Modulation 217 Hz	9	
745				
780				
810	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation 18 Hz	28	
870				
930				

1720	GSM 1800; CDMA1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation 217 Hz	28	WARNING: 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 peak flow meter. Otherwise, degradation of the performance of this equipment could result.
1845				
1970				
2 450	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217 Hz	28	
5 240	5 800 WLAN 802.11 a/n	Pulse Modulation 217 Hz	9	
5 500				
5 785				

1720	GSM 1800; CDMA1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation 217 Hz	28	WARNING: 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 peak flow meter. Otherwise, degradation of the performance of this equipment could result.
1845				
1970				
2 450	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217 Hz	28	
5 240	5 800 WLAN 802.11 a/n	Pulse Modulation 217 Hz	9	
5 500				
5 785				

11.Manufacturer

Manufactured for:
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Irvina CA 92614
www.tenovi.com
FCC ID: OU9TMB2080-B
Made in China