microlife PF200B Digital Peak Flow Meter Instruction Manual

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Introduction

Document Scope

Please read this Instructions for Use, the device label, and all other information provided with this product, before using the device.

This instruction of Use contains important information about the device safety, performance, and operation.

Disclaimers

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks on this device is under license.

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Important Information

Device Description

Microlife digital peak flow meter is a medical device that utilizes the principles of flow turbine with optical interruption detection and digital signal processing to compute and provide a measurement of peak expiratory flow and other pulmonary functional parameters. Measuring your pulmonary functions, as instructed by your physician or other qualified healthcare professionals, is useful for monitoring your airway and lung conditions or diseases.

ntended Purposes

This device is intended to measure the following pulmonary function parameters:

Peak Expiratory Flow (PEF): the maximum flow rate a person can exhale forcibly after taking a deep as possible breathe.

Forced Expiratory Volume 1-Second (FEV1): the air volume of forcible exhalation a person can exhale in 1 second after taking a deep as possible breathe

Intended User

The device is intended to be operated by adult users with the vision and motor functions as well as the literacy and basic educations capable of understanding the content of this instructions for use and operating general household electrical appliances, for use of self-monitoring or monitoring of other subjects.

Intended Patient

The device is intended for measurements of pediatric and adult subjects.

Intended Use Environment & Conditions

The device is intended for use in a home healthcare environment (for example general household) by patients (for self measurement) or by a care giver.

The device is intended for use by a single patient.

Indications

This device has the indications of:

- Asthma
- Chronic bronchitis
- Chronic Obstructive Pulmonary Disease (COPD)
- Other respiratory diseases or conditions affecting airway flow, as instructed by healthcare professionals.

Contra-Indications & Limitations
The device is not suitable for subjects who are unable to conduct the measurement correctly, for example:
Patients unconscious or in disabling conditions that does not allow correct self-measurement operating conditions.
Bedridden patients unable to stand or sit upright as required for correct measurement.
Patients whose mouth cannot cover the mouthpiece as required for correct measurement, for infants and neonates

 **WARNING**: Indicates a potentially hazardous situation, which if not avoided, could result in death or serious injury.

DO NOT use this device for purposes beyond described in this Instructions for Use. The manufacturer cannot be held liable for damage caused by incorrect application.

Inspect the device, cuff, and other parts for damage. DO NOT use the device, cuff or parts if they appear damaged or operating abnormally.

DO NOT use this device in oxygen rich environment or near flammable gas.

Keep the device away from children and people incapable of operating the device. Beware of the risks of accidental ingestion of small parts and of strangulation with the cables of this device and accessories. DO NOT let children operate the device alone

DO NOT use this device in proximity of equipment that may cause electromagnetic disturbance (EMD), such as high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment, and computerized tomography (CT) scanners. This may cause device malfunction and measurement inaccuracies.

 **CAUTION**: Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient, or cause damage to the device or other property

Protect the device & accessories from the following to avoid damaging the device:

- Water, other liquids, and moisture
- Extreme temperatures
- Impacts and vibrations
- Direct sunlight
- Contamination and dust

Stop using this device and consult with your doctor if you experience skin irritation or discomfort.

DO NOT use this device or parts after the expiration of its stated service life

DO NOT dissemble or attempt to service the device, accessory and parts, during use or in storage. Access to the device internal hardware and software is prohibited. Unauthorized access and servicing of the device, during use or in storage, may compromise the safety and performance of the device

Electromagnetic Compatibility Information

This device is compliant with EN60601-1-2: 2015 Electromagnetic Disturbances standard.

DO NOT use this device close to strong electromagnetic fields and portable radio frequency communication devices (for example microwave oven and mobile devices). Keep a minimum distance of 0.3 m from such devices when using this device.

This device features Bluetooth that emits radio frequency (RF) in the 2.4GHz band. Do not use this device in locations where RF is restricted (for example, on a aircraft). Turn off the device and remove the power source if necessary when in RF restricted locations.

This device operates in an unlicensed ISM band at 2.4GHz. In case this device is used near other wireless devices (for example wireless LAN) which operates on the same frequency band as this device, there is a possibility that interference may occur. If interference occurs, stop the operation of other devices or relocate this product away from other wireless devices before using it.

FCC Compliance Information

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. Changes or modifications to the product are not approved by Microlite USA and could void the user's authority to operate the equipment under FCC jurisdiction

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 recap ion, 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: 1) Reorient or relocate the receiving antenna. 2) Increase the separation between the equipment and receiver. 3) Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. 4) Consult the dealer or an experienced radio/TV technician for help

This device complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance

This device is not certified to be used in vicinity of medical equipment including high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) and computerized tomography (CT) instrument

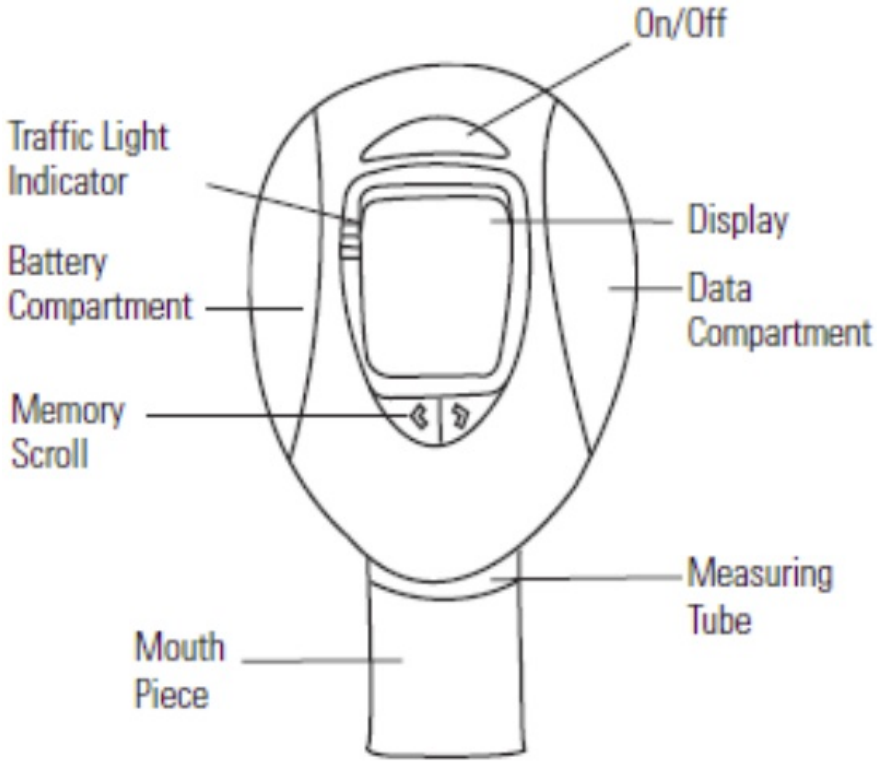
Adverse Events & Reporting

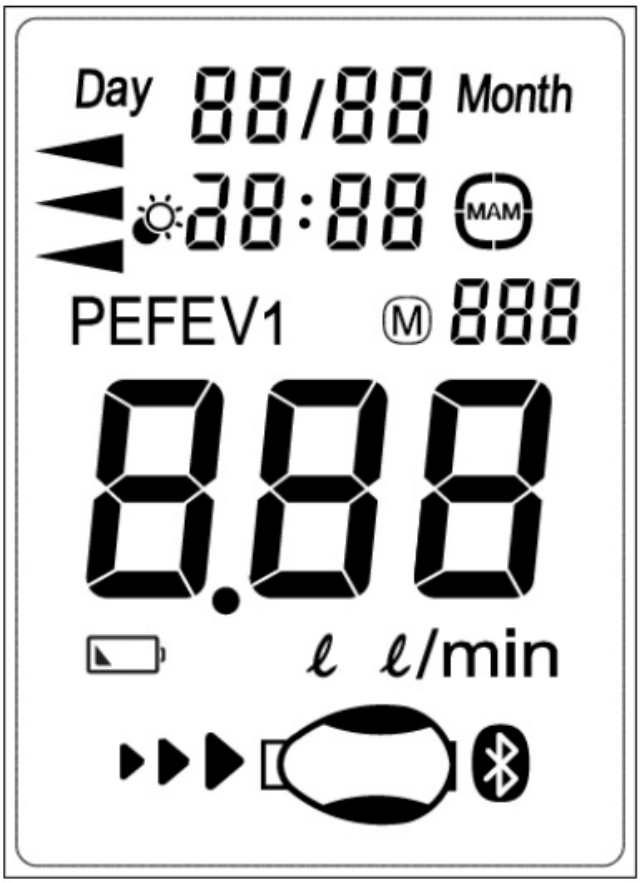
Device Information

Package Contents

1. Digital Peak Flow Meter device
2. AAA Batteries
3. Spare Mouthpiece
4. Data Cable: mini-USB to USB-A
5. Instructions for Use
6. Medication Card
7. Storage Bag

Device User Interface





Device Accessories

Mouthpiece

Device Optional Parts

Batteries: 1.5V, Size AAA.

NOTE: Device Optional Parts

The use of rechargeable batteries is NOT recommended

Device Installation & Setup

Mouthpiece Installation

The mouthpiece is snug fit in the measurement tube and can be inserted or removed with a gentle push or pull. Check if the mouthpiece is inserted all the way into the measurement tube prior to use

NOTE: Mouthpiece Installation
Prior to the initial use, it's recommended to disinfect the mouthpiece and flow tube.

Battery Installation

1. Open the battery compartment and remove the cover.
2. Insert two batteries (1.5V, size AAA) following polarity symbols in the compartment.
3. Reinstall the battery compartment cover.

Battery Replacement

When the battery low symbol appears in the display, the device is inoperable until the batteries have been replaced with two new batteries (1.5 V size AAA). If the device is left unused for longer periods, remove the batteries

NOTE: Battery Replacement
During a battery exchange the data stored in the device memory is saved and will NOT be lost

After battery replacement, the device date / time setting needs to be re-set.

Device Date & Time Setup

The device needs to be setup with the correct date & time to take measurements and record results in memory. After installing new batteries in the device, the device will enter date & time setting operation automatically, with the date & time display symbols blinking. Follow the steps to set the device date/time:

1. Open the data compartment and remove the cover

2. If the year is not blinking in the display, press the TIME button next to the clock symbol with a paper clip and the year will start blinking; release the switch.
3. Using the two arrow keys on the front of the device you can decrease (left arrow button) or increase (right arrow button) the number. Release the arrow button when the correct number is reached.
4. To confirm the year and then set the month, press the TIME button.
5. You can now set the month using the arrow buttons. (Example: pressing 2 times the right arrow button advances to 06 for June). To confirm and then set the day, press the TIME button.
6. Please follow the previous sequence to set the day, hour and minutes.
7. Once you have set the last minute and pressed the TIME button, the date and time are set, and the time is displayed.
8. Close the data compartment.
   The device date & time setting can be changed using the Settings Mode function manually or updated using compatible mobile or computer software.

NOTE: Device Date & Time Setup
If you hold down the arrow key for more than 2 seconds, it speeds up.

Date /time can also be set easily from computer when you run the Microlite Analyzer Software

Computer Software Installation

The device can transfer data to your personal computer (PC) using the USB data link function with the included USB data cable and compatible Microlite software.

The free downloadable Microlite Asthma Software allows you to transfer, store, and review measurement results on your Windows OS computers, and to customize your traffic light zones setting (if desired). Additionally, the software can generate reports of measurement results for share and review with your doctor

Before installing your Asthma Monitoring Software, be sure that your computer meets the minimum system requirements:

Microsoft Windows Operating System Software System Requirements		
System Requirements	**Minimum**	**Recommended**
Operating System	Microsoft Windows™ 8	Microsoft Windows™ 10 or 11
Microprocessor (CPU speed)	550 MHz	1 GHz or higher
RAM Memory Size	256 MB	512 MB
Available Hard Drive Size	500 MB	800 MB
USB Communications Port	USB 1.0	USB 1.0 or newer
Display Colors	256 colors	65536 colors
Display Resolution	800 × 600	1204 × 760 and above

Mobile Software Installation

The device can connect to compatible Microlite mobile application software on an Apple iOS smartphones via Bluetooth to take measurements in Connected Measurement Mode or to transfer data to the software via Bluetooth datalink mode.

The free downloadable Microlite mobile application software allows you to transfer, store, and review measurement results on your Apple iOS smartphones, and to customize your traffic light zones setting (if desired). Additionally, the software can generate reports of measurement results for share and review with your doctor

Please download the Microlite Connected Health App (referred to as App in this document) from Apple's App

Store before pairing your devices:

Apple iOS Operating System Software System Requirements		
System Requirements	**Minimum**	**Recommended**
Operating System	iOS14	iOS14 or above

Settings Mode Operation

Enter Settings Mode

1. Turn on device and wait for device to become ready for measurement.
2. Press TIME button to enter settings mode.
3. In settings mode, the following settings operations are available in the settings menu in the listed sequences:
    1. Connected Measurement Mode On / Off selection.
    2. PEF Traffic Light reference selection
    3. PEF Traffic Light reference value setup
    4. Device Date & Time setup

Connected Measurement Mode ON / OFF

1. The 1st setting in the Settings menu is On /OFF selection of Connected Measurement mode; "Set", Connected Measurement Mode symbol, and On / OFF will blink.
2. Press TIME button to turn Connected Measurement Mode ON or OFF.
3. Press TIME button to confirm selection and proceed to the next settings menu. Press O/I button to keep the current setting and exit Settings menu.

PEF Traffic Light Reference Selection

1. The second setting in Settings menu is the selection of reference maximum used for PEF traffic light. Device display will show "PEF", "rEF", "Set", memory symbol, with "On" or "OFF" blinking.
2. here are 2 reference methods available for selection, press Memory Scroll buttons to change selection:
    1. Select "On": Device automatically use the highest PEF measurement result (you personal best PEF) as the reference maximum PEF for the Traffic Light feature
    2. Select "OFF": Device uses customized PEF valve input by the user as the reference maximum PEF for the Traffic Light feature

3. Press Time button to confirm selection and proceed to the next settings menu. Press O/I button to keep the current setting and exit Settings menu

PEF Traffic Light Reference Value Setup

If customized PEF Traffic Light reference is selected, the device will enable adjustment of customized maximum PEF value. Device display will show “PEF” & “SEt” with the PEF value blinking.

Press Memory Scroll buttons to set the PEF value to be used as the reference maximum of PEF Traffic Light.

Press Time button to confirm selection and proceed to the next setting menu. Press O/I button to keep the current setting and exit Settings menu.

Device Date & Time Setup

The last setting in Settings menu is device date & time, the date & time display symbols will blink to allow adjustments, starting with year, then month, day, hour, and minute

Press Memory Scroll buttons to adjust the value. Press TIME button to confirm value and proceed to the next adjustment. Press O/I button to keep the current setting and exit Settings menu.

NOTE: Device Date & Time Setup
Device date & time can also be set using companion computer or mobile software.

Measurement Operation

Standalone Measurement Mode Operation

1. Press O/I button to turn the device on.
2. When device turns on, the previous measurement result will appear on the display (0 if there is no data). Then device will then sound two short beeps and show blinking arrows on display will blink to indicate it is ready for measurement.
3. Follow these steps to perform a measurement correctly.
    1. You can perform the measurement while standing or sitting upright. For better comparison of your data, you should always perform the measurement in a similar position.
    2. Hold the device with both hands on the two textured compartments.
    3. Inhale completely and hold your breath for a moment.
    4. Cover the mouthpiece tightly with your lips.
    5. Blow into the measuring tube as hard and as fast as you can.
    6. Device will sound a long beep to indicate the exhalation is measured; the PEF value is displayed for 3 seconds followed by FEV1 value. Then, the device will sound two short beeps to indicate that it is ready for a new measurement.
    7. Repeat measurement as needed – It is recommended to perform three or more measurements sequentially
4. After each measurement, the actual measurement result is shown followed by the highest reading of your current measurement session.
5. Press the O/I button to finish the measurement session and record the highest measurement value in the

device memory. The device will display the saved PEF & FEV1 values with the memory slot number MR XX.
6. After saving the measurement result, the device will activate Bluetooth datalink function. To Turn device off without Bluetooth data transfer, press O/I button again.
7. Clean the measuring tube and mouthpiece after use

Connected Measurement Mode Operation

1. Press O/I button to turn the device on.
2. When device turns on, the previous measurement result will appear on the display (0 if there is no data). Then device will then sound two short beeps and activate Bluetooth function with Bluetooth symbol blinking on the display.
3. Open the companion mobile application software (App) on the smartphone to connect to the device via Bluetooth (refer to the device Bluetooth ID shown on display as needed). When the device successfully connects to the App / smartphone, the Bluetooth symbol on display will stop blinking.
4. Operate the App to allow the App and device to become ready for measurement; the arrow symbols on device display will start blinking to indicate the device is ready for measurement.
5. Follow these steps to perform a measurement correctly.
    1. You can perform the measurement while standing or sitting upright. For better comparison of your data, you should always perform the measurement in a similar position.
    2. Hold the device with both hands on the two textured compartments.
    3. Inhale completely and hold your breath for a moment.
    4. Cover the mouthpiece tightly with your lips.
    5. Blow into the measuring tube as hard and as fast as you can.
    6. Device will sound a long beep to indicate the exhalation is measured; the PEF value is displayed for 3 seconds followed by FEV1 value. Device will transfer the measurement value to the App and await the App to become ready for the next measurement; when the App and device become ready for the next measurement, the device will sound two short beeps and the arrow symbols will blink.
    7. Repeat measurement as needed – It is recommended to perform three or more measurements sequentially.
6. To end the measurement session, operate the App to disable the device measurement function; device will turn off automatically.
7. Clean the measuring tube and mouthpiece after use.

NOTE: Connected Measurement Mode Operation

- The Connected Measurement Mode is designed to be used with the companion mobile application software (App) and suitable for a care-giver to take measurements of another patient (for example, pediatric subject) and monitor the process.
- Make sure Connected Measurement Mode is set to “On” in the Settings. Have the companion App open on the smartphone

Measurement Interpretation

Self-Assessment using the PEF Traffic Light Indicator

The colored bars on the left of the display is the PEF Traffic Light Indicator, which provides a quick visual reference comparing your PEF result versus a reference baseline value. As your PEF result raises or lowers, the arrow on the display will show the measurement as either within the normal (green), borderline (yellow) or danger (red) range.

Baseline Reference of the PEF Traffic Light Indicator

There are two different settings of baseline reference value available for the PEF Traffic Light Indicator:

- Default: Using your personal best PEF result in the device memory as the baseline for the Traffic Light Indicator zones
- Customized: Set a customized PEF value manually on the device or using the compatible software for the Traffic Light Indicator zones.

Default Baseline Reference for Traffic Light Indicator Zones

Device will automatically use your best (highest) PEF value recorded in the device memory as the baseline reference maximum (baseline MAX) to determine your traffic light zones.

- The green zone ranges between your personal best measurement (MAX) and 80% of that reading. To determine the yellow/green border zone, multiply the Baseline MAX by 0.8 [Example: 500 l/min x 0.8 = 400 l/min].
- The yellow zone ranges between your personal best measurement (MAX) and 60% of that reading. To determine the yellow/red border zone, multiply the Baseline MAX by 0.6. [Example: 500 l/min x 0.6 = 300 l/min].
- The red zone ranges below 50% of your best reading.

Customized Baseline Reference for Traffic Light Indicator Zones

Device can be setup to use a customized PEF value, for example one instructed by your prescribing doctor for your treatment plan, as the baseline reference maximum to determine your traffic light zones. The customized PEF value can be set manually in the Settings Mode operation of the device or set using compatible Microlite software or mobile application when connected to the device

- Green Zone – OK: If your measurement is in the green zone, your condition appears to be under control. Continue your treatment plan.
- Yellow Zone – Caution: If your measurement is in the yellow zone, measure more frequently and follow your treatment plan.
- Red Zone – Danger: If your measurement is in the red zone, your condition is serious. Act as discussed with your physician or seek emergency medical treatment

NOTE: Customized Baseline Reference for Traffic Light Indicator Zones

CAUTION: Setting area limits, creating a treatment plan and modifying your traffic light zone settings should only be done under direction of a physician (or other licensed health care practitioner). If you would like to use this feature, determine your customized zones with your doctor and record them on the traffic light card (enclosed).

Note: Once customized zones are programmed, default traffic light measurements will no longer be taken.

Memory Function Operation

During a measurement session, the device will measure multiple exhalation readings and automatically record the highest reading when the session ends (for example: 1 session is 1 on–off cycle). The device memory stores 240 readings.

Review Measurement Readings in Memory

To review the measurement readings in device memory, switch the device on and press Memory Scroll buttons. Press “<” of the Memory Scroll button to review the second latest readings; press “>” works in the opposite direction.

Memory Capacity Low

When the number of readings stored in the device memory reaches 230 sets or more, the device will display “MR XX” blinking after switched on to indicate that the device memory capacity is low

Memory Full

When the number of readings stored in the device memory reaches 240 sets, the device will beep and display “MR 240” blinking when switched on to indicate that the device memory is full. From this point on, any new measurement readings will replace and overwrite the oldest reading in the device memory.

Delete the Most Recent Reading in Memory

To delete the most recent data in the device memory, while the device is in memory function, press Memory Scroll (both “<” and “>”) buttons simultaneously for 5 seconds until the display shows “CLR” blinking. Press the Memory Scroll buttons again to delete the most recent reading in device memory. Wait until the “Cllr” message on the display elapses after 3 seconds to exit without change.

Delete All Readings in Memory

To delete all data in the device memory, while the device is in memory function, press Memory Scroll (both “<” and “>”) buttons simultaneously for 5 seconds until the display shows “CLR” blinking. Press O/I button to delete all readings in the device memory. Wait until the “Cllr” message on the display elapses after 3 seconds exit without change.

Bluetooth Datalink Function Operation

Turn On/Off the Bluetooth datalink function

1. Press O/I button for 4 seconds while device is off to activate the Bluetooth datalink function; device display will show a blinking Bluetooth symbol and the device identifier.
2. The Bluetooth will remain activated to scan for compatible Bluetooth mobile application to connect to; if no connection is made after 120 seconds, device will show rapidly blinking Bluetooth symbol to indicate that no connection made, then it will automatically deactivate.
3. Press O/I button while device Bluetooth is activated to turn off the Bluetooth function.

Software data transfer via Bluetooth datalink

1. While device Bluetooth function is activated, if a compatible mobile application is found over Bluetooth, device will automatically connect to the software. If a successful connection between device and software is established, the Bluetooth symbol on the device display will stop blinking and a 4-part circle animation will appear to indicate ongoing Bluetooth connection.
2. When connected, the device will execute data transfer from the device memory to the software via Bluetooth automatically.
3. After completion of successful data transfer, the device will automatically disconnect from the software and turn off the Bluetooth function.

USB Datalink Function Operation

Turn On/Off the USB datalink function

1. Connect the device to a computer via USB data cable while the device is turned off.
2. Press O/I button to turn the device on to activate USB datalink function. When USB datalink function is activated, the device will show “Subs” blinking on the display and automatically search for compatible software on the computer for data transfer.
3. Press O/I button to deactivate USB datalink function.

Software data transfer via USB datalink

1. While device ISB datalink function is activated, the compatible computer can communicate with the device and execute data transfer per user operation. The device will show the 4-part cycle animation on the display when communicating to the computer software.
2. After completion of data transfer on the computer software, you can turn off the USB datalink function and disconnect the device, computer and the USB data cable.

Errors/Issues & Troubleshooting

Device Errors & Troubleshooting

Error Message	Possible Cause	Solution
Er1	The result cannot be recorded in m emory because device date & timeo us not set.	Set device date & time.
no	There is no data stored in device m emory.	Set device date & time then takemeasurem ents.
Hi	The PEF value is higher than the Pe erage upper limit of 900 ml/min.	Please repeat the measurement.
Bluetooth symbol blinking r apidly	Bluetooth connection not establishe d successfully or Bluetooth connection ends abnormally	Turn off the device and the software, then r e- try connection in Bluetooth datalink funct ion.

Common Issues & Troubleshooting

Other possible errors and their solutions: If problems occur when using the device, the following points should be checked.

Issues	Possible Cause	Solution
The device display remains blank while batteries are installed.	Batteries are installed incorrectly or low in voltage.	1. Check the polarity (+/-) of the battery installation. 2. If the display is erratic or unusual, remove the batteries and re-install new batteries.
The devices fails to provide a reading during measurement, or the measurement reading appears abnormally low or high.	Device does not detect the turbine wind wheel rotation correctly, due to incorrect measurement, incorrect measuring tube installation, or wind wheel being stuck from foreign objects in the turbine.	1. Ensure the measurement is taken according the correct procedure. 2. Ensure that the measuring tube is correctly installed in the device. 3. Ensure that the wind wheel of the turbine in the measuring tube is rotating when air is blown through the tube. Any objects, dust, liquids or mucus may interfere with the wind wheel rotation – clean the turbine and measuring tube as needed. 4. Discuss the abnormal readings with your doctor as needed.
The unit fails to take admeasurement, year is blinking	Device date & time setting is not set.	1. Ensure the device date and time setting are set.

NOTE: Troubleshooting

If you get a low reading this could be an early warning sign your condition is getting worse. You must follow directions exactly as instructed to obtain accurate result

Contact Support

If you have questions call Microlite USA toll free at 866-934-1839 between 8:00am and 8:00pm Eastern Time, Monday through Friday (except holidays) or contact us at **custserv@microlifeusa.com.**

Device Maintenance & Disposal

Cleaning

Cleaning the Mouthpiece and the Measuring Tube

Your peak flow mouthpiece and measuring tube should be cleaned within 30 minutes after each use.

1. Separate the measuring tube and mouthpiece from the device's main body. Disconnect the mouthpiece from

the measuring tube by moving it in a forward direction.

2. Immerse the mouthpiece in a prepared soap solution of water and regular dishwashing soap. Thoroughly clean by swirling in the prepared soap solution. Thoroughly rinse the mouthpiece with water (distilled water is recommended). Allow the device to air dry.
   NOTE: Do not tap against hard surfaces to avoid damage.
3. Immerse the measuring tube in a prepared soap solution and thoroughly clean by swirling in the prepared soap solution. For cleaning the measuring tube it is best to use distilled water. Be careful not to damage the wind wheel or turbine assembly. Thoroughly rinse the measuring tube with water. Allow the device to air dry.
4. Visually inspect the measuring tube and mouthpiece after cleaning for residual mucus or debris inside – the measuring tube and mouthpiece should be free of any debris that may interfere with the turbine assembly inside the measuring tube.
   NOTE: DO NOT immerse the measuring tube in boiling water!
5. Reconnect the mouthpiece to the measuring tube and reassemble to the main unit as shown. When the tube is pushed completely into the fixed position, it will engage the tab on the body and click into place.

NOTE

- If you have “hard water”, mineral deposits may be visible on the mouthpiece or measuring tube. Rinse in distilled water, shake and place on a paper towel and allow to air dry before using.
- Please note temperatures lower than 50°F (10°C) and higher than 104°F (40°C) and humidity greater than 85%RH can affect the device measurement accuracy.

Cleaning the Device

Clean the device after use with a clean, damp cloth.

WARNING: DO NOT immerse the device in water or detergent.

Storage

Store the device in spaces away from direct exposure of sunlight, heat, humidity, and vibrations. For long term storage without use, remove the batteries before storage.

Service

The device is not designed to be serviced by the user. Contact device distributor for servicing by qualified personnel authorized by the manufacturer.

CAUTION: DO NOT open the device for service or repair.

Calibration

The device is pre-calibrated based on the measuring tube accompanying the device. The device does not require calibration by the user before use.

CAUTION: DO NOT interchange the measuring tubes between different devices.

Disposal

The device and its batteries are electronic waste that must be disposed of in accordance with the locally applicable regulations

CAUTION: DO NOT Dispose the device and its parts in household waste.

Specifications & Compliances

Technical Specifications

Measurement method: Flow turbine & optical detection
Measurement range: PEF: 50 to 900L/min, FEV1: 0.01 to 9.99L
Measurement resolution: PEF: 1L/min, FEV1: 0.01L

Measurement specifications: per ATS Standardization of Spirometry 1994 – Accuracy: ±25 L/min or ±12% of the reading, whichever is greater, FEV1: ±0.1L or ±5% of the reading, whichever is greater. **Dimensions (approximate):** 144 (L) × 77 (W) × 48 (H) mm
Weight: 115g (excluding batteries)
IP Rating: IP22: Protected against solid foreign objects of 12,5 mm ∅ and greater, protected against vertically falling water drops when enclosure tilted up to 15°.
Power source: AA size batteries × 2
Battery Life: Approx. 1000 measurement sessions (new batteries).
Power rating: DC 3V
Applied part: Type BF
Electrical Protection Type: Internally powered ME equipment.
Wireless Transmission method: Bluetooth Low Energy
Wireless communication: Operating Frequency Range: 2.4GHz, Modulation: GFSK, Power: +4dBm
Operation mode: Continuous operation
Operation Conditions: Temperature: +10 to +40℃ (50 to 104℉), Humidity: 10 to 85% relative humidity (non-condensing), 70 to 106kPa
Storage / **Transportation Conditions**: Temperature: -5 to +50℃ (50 to 104℉), Humidity: 10 to 85% relative humidity (noncondensing)
Service Life: 10,000 uses or 5 years, whichever earlier.

NOTE: Technical Specifications

Technical specifications are subject to change without notice

Compliance Information

Applicable standards:
IEC60601-1
IEC 60601-1-2
IEC 60601-1-11

Supplement Information for Users & Patients

Information about measurement and monitoring of peak flow values

A peak flow meter is used to measure a person's "peak expiratory flow," which is the fastest speed a person can blow air out of the lungs after taking in as big a breath as possible. "Peak expiratory flow" is a simple measure of airflow that can tell you how well you are breathing. It tells you how well air is moving through the airways in your lungs. Forced Expiratory Volume (FEV1) is a measure of the volume of air expelled in 1-second. Peak flow meter instructions must be followed carefully to get a correct measure of airflow.

If you have a breathing condition such as asthma or C.O.P.D., your physician (or other licensed health care professional) may recommend that you use a peak flow meter to watch for changes in your airflow. When the device is used to monitor lung conditions such as asthma and chronic obstructive pulmonary disease (COPD), the user should be under the care of a licensed health care professional. A licensed health care professional's advice is required to understand the meaning and importance of the measurements reported by the device and how to decide on an appropriate treatment plan that defines when to measure.

Your physician (or licensed health care professional) will give you a treatment plan that will tell you what actions to take when you have a change in airflow. In addition, you should record your peak flow measures as recommended by your physician (or other licensed health care professional). Reviewing peak flow measures can help you and your physician (or licensed health care professional) check closely on your asthma or C.O.P.D. to provide the best treatment for you. The treatment plan given to you by your physician or other licensed health care professional will tell you what action to take when there are changes in your peak flow number. No matter what your peak flow measures are, if you have signs and symptoms such as chest tightness, shortness of breath, coughing or wheezing you should follow your licensed health care professional's advice for contacting him or her.

Which PEF values are normal?

The PEF values listed are based on the population average from previous clinical literature, and may serve as a baseline reference of normal PEF values. Note that individuals will have different baseline PEF values which may differ from the population average. Consult with your doctor for guidance on your personal baseline PEF and FEV1 values.

Normal PEF values for males*

Age	Height				
(Years)	60"	65"	70"	75"	80"
20	554	602	649	693	740
25	543	590	636	679	725
30	532	577	622	664	710
35	521	565	609	651	695
40	509	552	596	636	680
45	498	540	583	622	665
50	486	527	569	607	649
55	475	515	556	593	634
60	463	502	542	578	618
65	452	490	529	564	603
70	440	477	515	550	587

Normal PEF values for females*

Age	Height				
(Years)	55"	60"	65"	70"	75"
20	390	423	460	496	529
25	385	418	454	490	523
30	380	413	448	483	516
35	375	408	442	476	509
40	370	402	436	470	502
45	365	397	430	464	495
50	360	391	424	457	488
55	355	386	418	451	482
60	350	380	412	445	475
65	345	375	406	439	468
70	340	369	400	432	461

Normal PEF values for children and adolescents**

Height (inches)	Males & Females
43"	147
44"	160
45"	173
46"	187
47"	200
48"	214
49"	227
50"	240
51"	254
52"	267
53"	280
54"	293
55"	307
56"	320
57"	334
58"	347
59"	360
60"	373
61"	387
62"	400
63"	413
64"	427
65"	440
66"	454

*Leaner GC. et al: Expiratory peak flow rate. AM Rev Respire Dis 88:644, 1963

**Polar G. Promadhat V: Pulmonary Function Testing in Children: Techniques and Standards. Philadelphia, W.B. Saunders Company, 1971

Limited Warranty

Your Digital Peak Flow Meter is warranted for 2 years by Microlite USA Inc, against manufacturer defects for the original purchaser only, from date of purchase.

The 2-year warranty applies to the device. Batteries are not covered by this warranty. There are no user serviceable parts inside

The warranty does not apply to consequential and incidental damages, or damage caused by batteries, improper handling, and accidents. Professional use, not following the operating instructions, and alterations made to the device or accessory by third parties, are also not included in this warranty. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you

Microlite USA Inc will investigate your concern. A device or accessory as defined by this warranty, determined to be out of specification, will be replaced and shipped to you at no cost. A device or accessory as defined by this

warranty, determined to be within specification, will be returned to you with a report of findings, at no cost.

Please use the customer service contact information to reach Microlite USA Inc. regarding any warranty concerns. Please contact us before sending any product back to better identify, and more quickly process, your concern

Symbols & Definitions

 Follow instructions of use.

 Type BF Applied Part

 Manufacturer

 Warning / Caution

 Temperature limitation

 Humidity limitation

 Atmospheric pressure limitation

Manufacturer & Certification

Manufacturer:
ONBO Electronic (Shenzhen) Co., Ltd.

Made in China

Distributed by:
Microlite USA Inc. 1617 Gulf to Bay Blvd, Clearwater, FL 33755

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Documents / Resources

	microlife PF200B Digital Peak Flow Meter [pdf] Instruction Manual PF200B Digital Peak Flow Meter, PF200B, Digital Peak Flow Meter, Peak Flow Meter, Flow Meter, Meter

References

- User Manual