Preface

Welcome and thank you for choosing **UBREATH®** brand **Spirometer System** (Model PF280) from the **e-LinkCare**. This spirometer system is manufactured to test pulmonary function evaluation & data management, and calculate a series of parameters relating to human respiratory function. (Excluding infants and neonates).

The device is intended to test lung function and calculates a series of parameters relating to human respiratory function. (Excluding infants and neonates).

The **UBREATH®** brand **Spirometer System** (Model PF280) is intended for prescription use only to conduct spirometry testing for adults and pediatric patients over 4 years old. **UBREATH®** brand **Spirometer System** is used by general practitioners, specialists, and health care professionals, in hospitals and clinics, in pharmacies, and in clinical settings in occupational medicine, and also for patients self-monitoring at home after educated by Professionals. No person should attempt to use this device without the necessary knowledge and training to understand how this equipment is to be properly utilized and interpreted.

The measurement offered shall only be considered as a tool of screening but not to be treated as reference for diagnostic purposes.

We are dedicated to providing a safe product to our customers. It is the user's responsibility to follow the rules of safety as established for their protection and for the protection of their patients as described in this manual. Please take special note of the following to ensure an accurate test result is carried out:

- Read this entire instruction carefully before attempting use the product.
- Use only **UBREATH® Disposable Flow Transducer** with the **UBREATH® Spirometer**.
- Please consult with your physician or healthcare professional first if you are suitable for this testing.
- The flow transducer is disposable and for single patient use only. Do not clean or reuse it.
- Use rechargeable battery only which is provided by **e-LinkCare**.
- Do not immerse the unit with any fluids. See the maintenance and cleaning section for proper cleaning procedures.
- Keep out of reach of children.
- Use and store the device indoor only. Do not expose this device or its accessories to direct sunrays. Keep the temperature between 10-40 Celsius degrees when in use.

- Do not attempt to open or service the device on your own, return the device to distributor for all services. Opening the device case will void the warranty.

By following the instructions outlined in this User's Manual, you will be able to use your **UBREATH®** Spirometer System to see how well your lungs are working.

However, a spirometry test is not recommended to perform if the subject presents with following conditions:

- Pneumothorax;
- Hemoptysis of unknown origin (forced expiratory maneuver may aggravate the underlying condition);
- Unstable cardiovascular status such as angina (forced expiratory maneuver may worsen angina or cause changes in blood pressure) or recent myocardial infarction or pulmonary embolus;
- Thoracic, abdominal, or cerebral aneurysms (danger of rupture due to increased thoracic pressure);
- Cataracts or recent eye surgery;
- Recent thoracic or abdominal surgery;
- Nausea, vomiting, or acute illness;
- Recent or current viral infection;
- Undiagnosed hypertension;
- Presence of an acute disease process that might interfere with test performance (e.g., nausea, vomiting).

Table of Contents

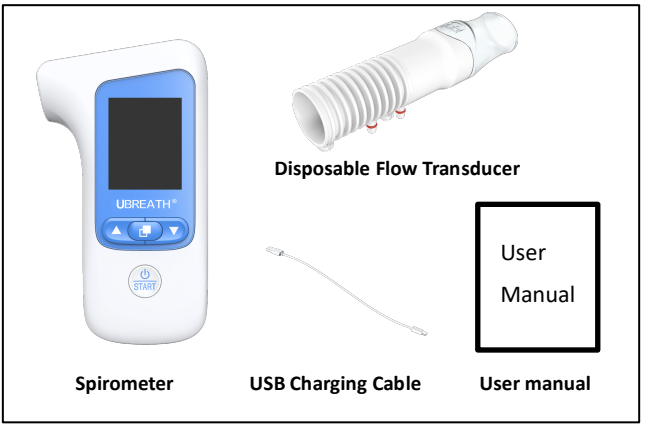
Getting Started

Your **UBREATH® Spirometer System** is carefully inspected and packed for shipping. However, it is a good practice to thoroughly inspect the outside of the package for damage. If any damage is noted, please notify the local distributor and return the damaged device back to them directly.

Carefully remove the package cover and Inspect the kit box and check device and accessories.

It is important to save all the original packing materials, so the device can be properly packed if it needs to be returned for service or repair.

Components Description



Please check the list below to ensure you have all accessories received in good condition.

1. **UBREATH®** Spirometer**:** measure a range of respiratory parameters.
2. **UBREATH®** Disposable Flow Transducer (Pouched): A disposable item that is used to connect user with spirometer. It's assembled by three parts: throttle pipe, mesh and mouthpiece.
3. **Micro USB cable:** Used to connect with power source to recharge or data transfer.

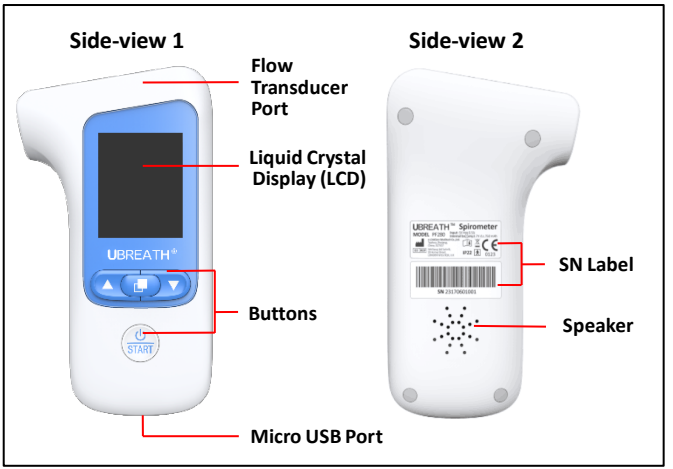
NOTE:

Contact your local distributor for purchasing alternative adaptor that is applicable in your country.

4. **User Manual (include warranty card):** Provides detailed instructions on using the spirometer system.

UBREATH® Spirometer

The **UBREATH® Spirometer** is the device calculates the result and display the pulmonary function parameter result. Please read below diagrams to become familiar with all the parts of **UBREATH®** Spirometer.



A. **Flow Transducer Port:** Flow Transducer is inserted into this area to perform a test.
B. **Liquid Crystal Display (LCD):** Shows your test results, and the instruction helps you through the testing process.
C. **Micro USB Port:** To recharge the power supply and Sends information to a computer via transfer cable to view, analyze and print stored data in the meter.
D. **Buttons:** Input orders to the device, see details on page 3 Section ***Function of Buttons.***
E. **Speaker:** Procedure instruction voice.

Function of Buttons:

Power Switch Button: To switch on/off power of the spirometer system.

Page Down Button: Selects time (e.g. year, month, date) and time (e.g. hour, minute) when setting the system time. Selects test results when viewing historical data.

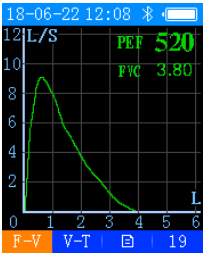
Toggle Button: Switches time (e.g. year, month, day) and time (e.g. hour, minute) when setting the system time. Long press to confirm.
Switches F-T/F-V/Tabular Display Interface when viewing historical data.

Page Up Button: Selects time (e.g. year, month, day) and time (e.g. hour, minute) when setting the system time. Selects test results when viewing historical data.

Start Button: Long press to switch between working mode and standby mode. Press once to begin the test at working mode.

LCD Display

The icons used in the various function screens and their meanings are shown in the following table:



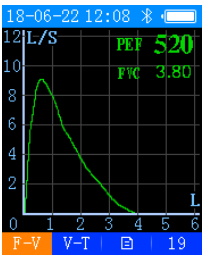
17-01-20	Current date in day-month-year format.
12:08	Current time in hour and minute format.
	The device is paired with another device through Bluetooth
	Status of current battery power.
F-V	Flow-volume curve of current or historical test.
V-T	Volume-time curve of current or historical test.
PEF	Peak expiratory flow
FVC	Forced vital capacity
FEV1	Forced expiratory volume in the first second
FEV1%	FEV1% = FEV1 / FVC
FEV50	Instantaneous forced expiratory flow when 50% of the FVC
FEV 75	Instantaneous forced expiratory flow when 75% of the FVC
	Results of current or historical test.
20	Show the number of stored historical test.

Power Supply (Rechargeable Li-ion Battery)

A rechargeable Li-ion battery is installed within the battery compartment when the device is being manufactured. We recommend recharging the battery before use for the first time.

You may not be able to use **UBREATH®** Spirometer System if the battery is running low, recharge your battery if battery power is low.

If the battery power drops below 10%, A "Lower Power! Can't Test "alert will show on the screen.



NOTE:

- The battery life is approximately 500 complete charge cycles. Contact your local distributor to replace your battery if the device consumes the power abnormally fast.
- The data saved in non-volatile memory will NOT lost when battery power is low, or batteries are removed.

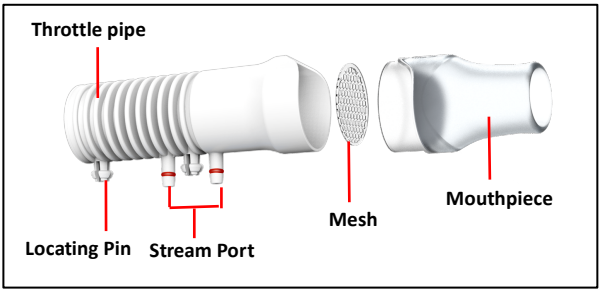
Accessory to Medical Equipment (IEC 60601-1)

Accessory equipment connected to this product must be certified according to the respective IEC standards (i.e.,60601-1) for medical equipment. Furthermore, all configurations shall comply with the system standard IEC 60601-1-1 and IEC 60601-1-11. Anyone, who connects additional equipment to the signal input part or signal output part configures a medical system, and it therefore responsible that the system complies with the requirements of system standard IEC 60601-1-1. Whoever is responsible for securing the unit to a system needs to ensure that the mounting equipment used with this product complies to IEC standard 60601-1. If in doubt, consult the technical services department or your local dealers.

UBREATH® Disposable Flow Transducer

To ensure the maximum level of hygiene and safety as well as accuracy, we suggest to always substitute the disposable flow transducer between each patient.

A disposable Flow Transducer included three parts: throttle pipe, mesh, and mouthpiece.



NOTE:

- Use disposable parts that are not from original manufacturer can cause measurement error and false results.
- You must only use **UBREATH®** Flow Transducer by the manufacturer to assure accuracy, and full warranty coverage. Contact your local distributor for purchasing disposable items.
- All disposable items included with the device are supplied only as a guide to the correct type and dimensions of the mouthpiece required for this device, they are clean but usually not sterile. To purchase appropriate item, we suggest that you contact your local distributor who supplied the **UBREATH®** Spirometer System.

Storage and Handling

Please review the following storage and handling instructions:

- **UBREATH®** Spirometer System together with its battery inside can be stored in a place with temperature ranges from -10 ℃ - 45 ℃. Store them away from heat and direct sunlight.
- Do not freeze or refrigerate.
- Do not store or use **UBREATH®** Spirometer System in a humid place such as a bathroom.
- Do not store the **UBREATH®** Spirometer System and the flow transducer near bleach or cleaners that contain bleach.

Information for Correct Use in an Electromagnetic Environment

As the **UBREATH®** Spirometer System is a medical equipment, special precautions are needed regarding EMC (electromagnetic compatibility).

It is important that the **UBREATH®** Spirometer System is properly configured in accordance with the User Manual provided herein and is used only in the configuration as supplied. Changes of modifications to the **UBREATH®** Spirometer System may result in increased emissions or decreased immunity of the device in relation to EMC performance.

The **UBREATH®** Spirometer System should be used only with the accessories (USB cables, adapter and flow transducer) supplied. None of the **UBREATH®** Spirometer System cables should be extended in length by the user.

If any cables are extended by the user or non-approved accessories are used, this may result in an increased level of emissions or decreased level of immunity, in relation to the **UBREATH®** Spirometer System EMC. None of the **UBREATH®** Spirometer System accessories should be used with other devices, as this may result in a n increased level of emissions or decreased level of immunity in relation to the other devices' EMC.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The **UBREATH®** Spirometer System is intended for use in the electromagnetic environment specified below. The customer or the user of the **UBREATH®** Spirometer System should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment -guidance
RF emissions CISPR 11	Group 1	The **UBREATH®** Spirometer System uses RF energy only for its internal unction. Therefore, its RF missions are very low and re not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Group B	The **UBREATH®** Spirometer System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Not applicable	Power input < 75W
Voltage fluctuations/flicker	Applicable	

emissions IEC61000-3-3		

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The **UBREATH®** Spirometer System is intended for use in the electromagnetic environment specified below. The customer or the user of the **UBREATH®** Spirometer System 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 +/-15 kV air	+/-8 kV contact +/-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%
Electrical fast transient /burst IEC61000-4-4	+/-2 kV for power supply lines +/-1 kV for input /output lines	+/-2 kV for power supply lines [Not Applicable]	Mains power quality should be that of atypical commercial or hospital environment
Surge IEC61000-4-5	+/-1 kV line(s) to line(s) +/-2 kV line(s) to earth	+/-1 kV line(s) to line(s) [Not Applicable]	Mains power quality should be that of atypical commercial or hospital environment

Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	< 5% U^T (> 95% dip in U^T) For 0.5 cycle 40% U^T (60% dip in U^T) for 5 cycles 70% U^T 30% dip in U^T)for 25 cycles<5% U^T(> 95% dip in U^T)for 5 s	< 5% U^T (> 95% dip in U^T) For 0.5 cycle 40% U^T (60% dip in UT) for 5 cycles 70% U^T (30% dip in U^T) for 25 cycles<5% U^T (> 95% dip in U^T) for 5 s	Mains power quality should be that of atypical commercial or hospital environment. If the user of the **UBREATH®** brand Spirometer System requires continued operation during power mains interruptions, it is recommended that the **UBREATH®** Spirometer System be powered from an uninterruptible power supply or a battery
Power frequency (50/60 Hz) Magnetic field EC61000-4-8	30 A / m	30 A / m	Power frequency magnetic fields should be at levels characteristics of atypical location in atypical commercial or hospital environment

No9: U^T is the AC mains voltage prior to application of the test level

Guidance and Manufacturer's Declaration –Electromagnetic Immunity

The **UBREATH®** Spirometer System is intended for use in the electromagnetic environment specified below. The customer or the user of the **UBREATH®** Spirometer System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment - guidance
Conducted RF IEC61000-4-6	3 Vrms 150kHz to 80MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the **UBREATH®** Spirometer System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d= 1.2√P 150kHz-80MHz

Radiated RFIEC61000-4-3	3 V/m 80 Mhz to 2.7 Ghz	3V/m	d= 1.2√P 80MHz-800MHz d= 2.3√P 800MHz-2.5GHz 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 meters(m). Fields strengths from fixed RF transmitters, as determined by an electromagnetic site survey*, should be less than the compliance level in each frequency range*. 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 propagation is affected by absorption and reflection from structures, objects and people.

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

*Field strengths from fixed transmitters, such as base stations for radio (cellular /cordless) telephones and land mobile radios, amateur radios, AM and FM radiobroadcast 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 the **UBREATH®** Spirometer System is used exceeds the applicable RF compliance level above, the **UBREATH®** Spirometer System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the **UBREATH®** Spirometer System.

Spirometer Setup before Testing

Switch on/off Power

The **UBREATH®** Spirometer System can be switched on or off power by sliding the power button located on the right-hand side of the device.

Sleeping Mode/Wake up

If your **UBREATH®** Spirometer System is left unattended for 10 minutes, the device will be automatically switched off then enter sleeping mode. Long press start button (⏻ START) can awake the device. However, with the Bluetooth being connected, the device will not enter sleeping mode but only LCD screen will be shut off. You can also Long press start button (⏻ START) to make the device enter standby mode.

Recharge the Battery

The battery comes with the product is a Li-Ion rechargeable battery with 750mAh.

Low battery power may cause incorrect result or unstable performance, please make sure that the battery is charged at all times.

By recharging the battery, simply connect the device to a power supply by a USB cable provided in the package. You can also use an adaptor to connect to Direct Current power source.

NOTE:

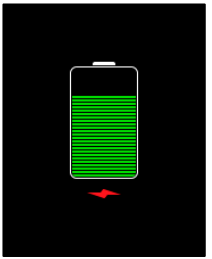
The user is responsible for evaluating the adaptor that is connected to **UBREATH®** Spirometer System for compliance to IEC60601-1 and IEC60601-1-1.

The power source must be a non-grounded receptacle with two slots.

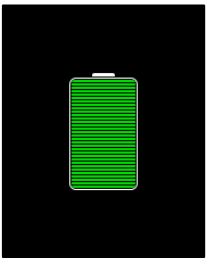
Depending on the power standard, you may need to purchase an additional and appropriate adaptor to fir in your own country.

You can't perform a test when the device is recharging, the below figures indicates the device is current recharging and recharging is finished respectively. The LCD screen will automatically turn off after 3 seconds while any key touch will turn on again.

Recharging



Battery is fully recharged



NOTE:

If the USB cord is connected to a power source when the device is swithed on, the device will automatically switch off and then start recharging.

Date & Time Settings

If it is your first time to turn on the device, after the welcome screen, you will be lead to date & time settings page, the screen will display "Please reset the date & time". Follow the procedure below to set your date and time correctly:

Date Setting

- The year will appear at the top of the display. Press the Page Up Button (△) or Page Down Button (▽) until the correct year is displayed. Once you have selected the correct year, press the Toggle Button (⏎) to save your choice and start setting the month.
- Press the Page Up Button (△) or Page Down Button (▽) until the correct month is displayed. Once you have selected the correct month, press the Toggle Button (⏎) to save your choice and start setting the date.
- Press the Page Up Button (△) or Page Down Button (▽) until the correct date is displayed. Once you have selected the correct date, press the Toggle Button (⏎) to save your choice and start setting the time.

Time Setting

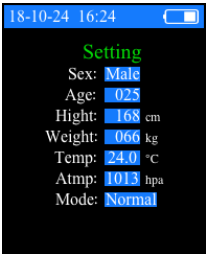
- The hour will appear at the top of the display. Adjust the hour with Page Up Button (△) or Page Down Button (▽) until the correct hour is displayed. Press the Toggle Button (⏎) to save your choice and start setting the minutes.
- Press the Page Up Button (△) or Page Down Button (▽) to change to the correct minute. Long press the Toggle Button (⏎) to save your choice and finish Date & Time settings.

NOTE:

Date & Time settings will not need to be configured when resume from sleeping mode. However, restart the device by sliding the power switcher will enter the Date & Time settings again.

Setting

Long press Page Up Button (△) and Page Down Button (▽) simultaneously for about 3 seconds, then a setting screen will be displayed. For certain patient, the Sex, Age, Hight, Weight, Temp, Atmp and Mode can be adjusted by press the Page Up Button (△) or Page Down Button (▽). It can help calculate the predicted value based on patient's profile. Once setting is completed, press the Toggle Button (⏎) to enter Spirometry Test.



Bluetooth

Bluetooth function is enabled by default and stays in standby mode until the device connects to another device which is compatible to **UBREATH®** Spirometer System. A Bluetooth symbol ( ) will appear on the top of the screen to indicate the device is connected through Bluetooth. For more information regarding Bluetooth data transmission, please contact your local distributor.

Performing a Spirometry Test

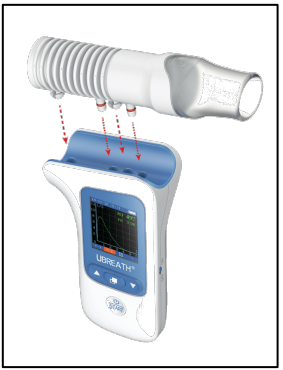
The following steps will show how to use the **UBREATH®** Spirometer System to measure your spirometry function parameters. However, before a test is conducted, you will need to connect the **UBREATH®** Flow Transducer onto the top of **UBREATH®** Spirometer System.

Step 1 – Install the Flow Transducer

1. The flow transducer usually comes with a transparent sterilized bag. Check the bag if it's leaking or damaged before use. Check the expiry dates of the disposable items.

2. Tear the pouch from the side with arrow direction in the pouch.

3. Push the locating pins and stream ports of the flow transducer vertically towards the corresponding ports on the top of handheld unit till they are locked.



4. Make sure the mouth piece side faces the patient, then the meter is ready to perform.

Step 2 – Prepare for a Test

Prepare the patient

It is recommended to explain the entire procedure for the type of effort which is expected to be performed. Remind subject that the test is painless. Demonstrate at least one effort for the subject.

The accuracy of a spirometry test is highly dependent on the subject's understanding and cooperation. So, be prepared to coach and encourage the subject with your “body language” and your words for example," Blow, blow, blow, keep blowing until you can't blow out any more” to ensure a good effort with reproducible results.

Instruct subjects to do the following to rehearse for a test:

1. Insert the mouthpiece into the protruding part of the flow transducer till it fits in perfectly and then hold **UBREATH®** Spirometer System handheld unit with one hand.

NOTE:

- Loosen any tight articles of clothing that might constrict lung function, for example, a tight belt, tie, vest, bra, girdle, or corset, if they will restrict maximal breathing
- Remove any foreign objects from the mouth, including loose dentures.

2. Place lips and teeth around a new flow transducer, sealing their lips tightly around the transducer. Grip slightly with teeth in the groove. The tongue and teeth must be positioned to not obstruct airflow.
3. Keep tongue away from the flow transducer to avoid blocking it.
4. Keep chin slightly elevated so as not to restrict the airway

NOTE:

- Do not touch the buttons of during the test to avoid switching off the system or stopping a test too soon.

5. When exhale use the other hand to hold on your nose and apply like a nose clip.

It’s preferable that following activities should be avoided before the test:

- Smoking within at least one hour before testing’
- Taking alcohol within 4 hours of testing
- Performing vigorous sports within 30 minutes of testing
- Eating a big meal within 2 hours of testing

Test posture

It is recommended to use the standing position during spirometry test unless the subject cannot do so because of a safety or health concern such as a history of fainting or an illness. Take the following safety precaution if the subject uses stand position:

- Place a sturdy chair without wheels behind the subject;
- Watch the subject during testing for signs of light-headedness;
- Place a hand on subject's arm or back if needed to steady them.

If the subject experiences light-headedness, fainting or any other signs of distress during the test, the subject should be conducted in the seated position or test should be terminated.

If the subject uses seated position to perform a test,

- The subject should sit upright
- The testing position should be documented and future test should be conducted in the same seating position.
- If a wheelchair is used, the wheels should be locked.

Step 3 – Take a Spirometry Test

Turn on spirometer

Sliding the Power Switch Button to turn on when power is off, or long press Start Button to wake up the device if it stays in sleeping mode. Be advised to wait for a minute to warm up the device when it was switched on just now.

Press the Start Button to begin test. The screen will show "Ready for breath", Now you are ready to perform a test.

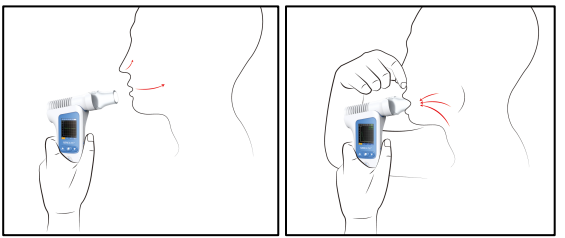
NOTE：

If the device is being switched off, Date & Time will need to be switched again. Follow the instructions on **Section Date & Time setting** to set Date & Time. If the device is awakened from sleeping mode, skip this step.

Perform a test

To make a correct spirometry test we recommend to following instructions carefully:

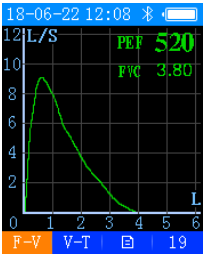
1. Hold **UBREATH®** Spirometer System up vertically with one hand.
2. Insert the mouthpiece well into the mouth beyond the teeth, being careful to ensure that air cannot escape from the sides of the mouth.
3. Once the spirometer beep and instruct to begin the test. Make a complete inspiration slowly as much air as possible and then exhale all the air with maximum effort as fast as possible. Use the other hand to hold on your nose and apply like a nose clip.

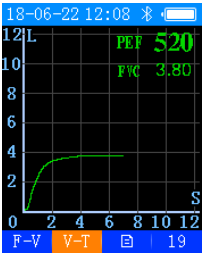


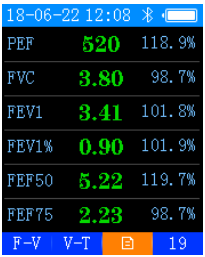
NOTE:
Do not touch the buttons during the test to avoid switching off the system or stopping a test too soon.
The performance of the Spirometer can be affected by the patient spitting or coughing into the Spirometer during expiration or by extremes of temperature, humidity and altitude.

Step 4 – Visualization of Spirometry Testing Data

The spirometer will beep after the test is done, the image below will describe the information which appears on the LCD screen:







The F-T curve (Flow against Time) and F–V curve (Flow against Volume) are the main parameters, interpretation is based on the Forced Vital Capacity (FVC) test and is based on the ERS standard. For a faster comprehension, this interpretation is illustrated by each test value showing with a traffic light color (green, yellow, red). For each test made, the color of the curve indicates level of interpretation of the test session.

The connection between the traffic light color and the test interpretation is shown below:

Red: PEF less than 40% of predicted.

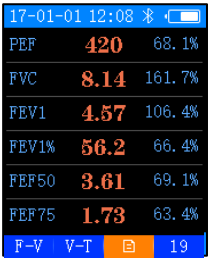
Yellow: PEF 40% to 79% of predicted.

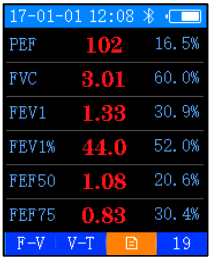
Green: PEF greater 80% of predicted.

NOTE:

During a spirometry test all flows and volumes are measured at ATP conditions (Ambient Temperature and Pressure).

By pressing toggle button, you will be able to jump to the third screen, which reflecting the rest of the available parameters, you will be able to know exact PEF, FVC, FEV1, FEV1%, FEF50, FEF75 values respectively, the percentage of the predicted values, as illustrated below:



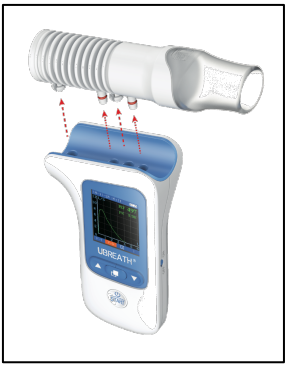


Again, the color of each test value feedbacks the summary of test.

Step 5 – Finish a Test

A pair of disposable gloves are encouraged to wear when Flow transducer is being removed from the **UBREATH®** Spirometer System. Follow the below procedure to finish a test:

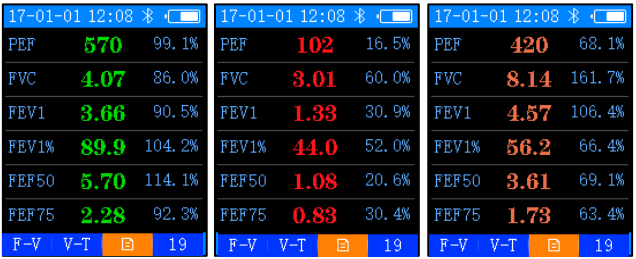
1. Pulling the Flow Transducer up vertically from the locating pins with care.



2. Discard the flow transducer directly into a waste container.

Review Historical Data

Switch on the **UBREATH®** Spirometer System or resume the device from sleeping mode. Or if it is already switched on/awaken, press toggle button to select type of data that you may want to review, then press up or down button to review historical data stored on this device. The number next to ( )button shows the number of data and it is sorted by the time of the testing.



There are up to 495 patients' data can be stored.

NOTE:

When reviewing historical data, the time showing on the status bar is the time when the test was taken. It will stay for 15 seconds before the ":" sign start blinking.

Once the ":" sign start blinking, it means the device is showing the systematic time.

Maintenance

Caring for Your UBREATH® Spirometer System

Your **UBREATH®** Spirometer System does not require special maintenance or cleaning. A cloth dampened with water and a mild detergent solution can be used to wipe the outside of the device. Take care to avoid getting liquids, dust or other foreign bodies into the device through the flow transducer or data ports. It is recommended that you store the device in the case after each use. **UBREATH®** Spirometer System is a device that requires very limited maintenance.

The operations to perform periodically are:

1. Changing the **UBREATH®** Disposable Flow Transducer between each test.
2. Charging the battery with safety.

The **UBREATH®** Spirometer System is a precision electronic instrument. Please handle it with care.

Charging the Battery of UBREATH® Spirometer System

The rechargeable battery of **UBREATH®** Spirometer System usually can last for an entire working day. To fully charge the battery after a day of work, it's recommends charging overnight. In addition, you can also charge multiple times during the day between spirometry tests. To charge **UBREATH®** Spirometer System, always use an original power supply component released by the manufacturer. For more information on charging the battery, refer to Page 11.

Reactivating the Meter after Storage

If you no need to use **UBREATH®** Spirometer System for a long while, slide the power supply button to off mode to save battery life. Make sure that spirometer has been stored under the specified storage conditions. If **UBREATH®** Spirometer System has not been stored under correct conditions, or if you cannot verify the conditions, do not proceed. Contact your dealer for further consulting.

Cleaning

Your **UBREATH®** Spirometer System does not require special maintenance or cleaning. A cloth dampened with water and a mild detergent solution can be used to wipe the outside of the device. Take care to avoid getting liquids, dust or other foreign bodies into the device through the flow sensor or data port. If flow sensor is partly blocked by dirt, it is suggested to use an air-blower to blow them away.

Troubleshooting Guide

The following table covers some of the issues that can possibly occur during the operations of **UBREATH®** Spirometer System, the useful trouble shooting guide can be found below to help you resolve an issue yourself.

Problem	Cause	Solution
The device does not switch on	The internal battery may be discharged.	Make sure that battery is fully charged and then turn the device on again.
The battery charging icon is not showing correctly	The USB cable may not be plugged firmly or the adaptor is not working properly	Make sure that the power supply cable of the charging unit is connected to the spirometer and that the plug is inserted correctly into the mains outlet. Or change the adaptor then proceed with charging
The device does not measure after expiration	The disposable flow transducer may not insert correctly	Readjust the position of flow transducer and make sure it's firmly inserted into the ports then repeat the test again
The measurement value is abnormally small	The mouthpiece may not be inserted tightly with the flow transducer	Check the mouthpiece again and make sure its inserted into the protruding part of the flow transducer perfectly

The maintenance operations described in the User's Manual must be carried out carefully. Failing to operate the instructions may cause errors in measurement or in the interpretation of measured values. Modifications, adjustments, repairs, and reconfiguration must be carried out by the manufacturer or by authorized persons. In case problems arise, never attempt to repair the unit.

Specifications

Feature	Specification
Size	Spirometer: about 132 × 76 x 38 mm Flow Transducer: about 135 x 34 x 43 mm
Weight	135g (including the Flow Transducer)
Measuring Sensitivity	0.025 L/s
Measuring Resolution	Volume: 0.01 L Flow: 1 L/s
Measuring Range	Volume: (0 - 8) L Flow:(0 - 14) L/s
Measurement Principle	Venturi principle
Dynamic Resistance at 14 L/s	< 0.35 kPa/(L/s)
LCD display	2.0“,176×220 pixels, 262K colors
Test Storage Capacity	Up to 495 records
Power Supply	3.7 V lithium battery
Input Power	≤ 2W
Battery life	Approximately 500 complete charge cycles
FVC	Range of measurement: (0.5 - 8) L Accuracy: ±3% or ±0.050 L (take the largest value) Repeatability: ≤ 3% or ≤ 0.050 L (take the largest value)
PEF	Range of measurement: (0 - 14) L/s Accuracy: ±10% or ± 0.17 L/s (take the largest value) Repeatability: ≤ 5% or ≤ 0.17 L/s
FEV1	Range of measurement:(0.2 - 8) L, Accuracy: ±3% or ±0.050 L (take the largest value)
Classification	IIa MDD 93/42/EEC Appendix IX Rule10
Classification according to the type of applied	Type BF Applied Parts

part	
Classification according to the type of protection against harmful ingress of water	IPX22
Operating Environment	10 - 35 ℃, 30% - 80% RH
Storage Environment	-10 - 45℃, ≤ 80%RH, storage in clean and ventilated room.
Operating altitude	0 - 1400 meters (1060 hPa - 850 hPa)

Index of Symbols

	Consult instructions for use
	Store between -10 ºC - 45 ºC (14 °F -113 °F)
	Use by
LOT	Lot Number
	Manufacturer
EC REP	Authorized Representative
STERILE EO	Sterilized using Ethylene oxide
MODEL	Model Number
REF	Catalog #
SN	Serial Number
	Do not dispose along with household waste
	Fragile, handle with care
	This Side Up
	Keep away from sunlight and heat
	Keep Dry
	Humidity Limitation between 10% - 80%
	Do not reuse (single-patient use)
IP22	Protected against access to hazardous parts with a finger and protected against vertically falling water drops when sensor titled up to 15 degrees
	Standing by mode and turn on/off
	Medical electric equipment that includes a radio frequency transmitter and emits non-ionizing radiation
	Instrument classification: Type BF applied part

Warranty Condition

UBREATH® Spirometer System (Model PF280) together with its standard accessories is guaranteed for a period of 3 years, while the battery is guaranteed for 1 year. The warranty is effective from the date of purchase shown on the relevant sales invoice or proof of purchase.

This device must be checked at the time of purchase, or upon delivery, and any claims must be made immediately in writing to the manufacturer.

This warranty covers the repair or the replacement (at the discretion of the manufacturer) of the product or of the defective parts without charge for the parts. All batteries and other consumable parts are specifically excluded from the terms of this guarantee.

This warranty is not valid, at the discretion of the manufacturer, in the following cases:

- If the fault is due to an improper installation or operation of the machine, or if the installation does not conform to the current safety norms in the country of installation.
- If the product is utilized differently from the use described in the User's Manual. If any alteration, adjustment, modification or repair has been carried out by personnel not authorized by the manufacturer.
- If the fault is caused by lack of or incorrect routine maintenance of the machine.
- If the machine has been dropped, damaged or subjected to physical or electrical stress.
- If the fault is caused by the mains, or by a product to which the instrument has been connected.
- If the serial number of the instrument is missing, tampered with and/or not clearly legible.

The customer is responsible for the transportation and for all transport and customs charges as well as for delivery charges of the goods both to and from the manufacturer or distributor. Any device or accessory returned must be accompanied by a warranty card with detailed explanation of the defect or problem found. If units are to be returned to the manufacturer then written or verbal permission must be received before any device are returned to the distributor.

Warranty Card

For records, also write the purchase date of your product here.

Date of purchase: _____

Model Number: _____

Device Serial Number: _____

The problem description: _____

_____

You expect:

☐ Replace a new device

☐ Return after maintaining

Note: This warranty applies only to the meter in the original purchase and does not apply to the battery supplied with the meter.

Local Dealer Information:

Contact Address：

Contact Name：_____

Contact Cellphone Number:_____

Address:_____

City:_____

State/Province/Region:_____

Postal Code:_____

Thanks so much for your kind support!

Effective Date: 2021-04-26