PulmoLife Spirometer
Operating Manual

Federal (USA) law restricts this device to sale by or on the order of a physician or licensed practitioner.

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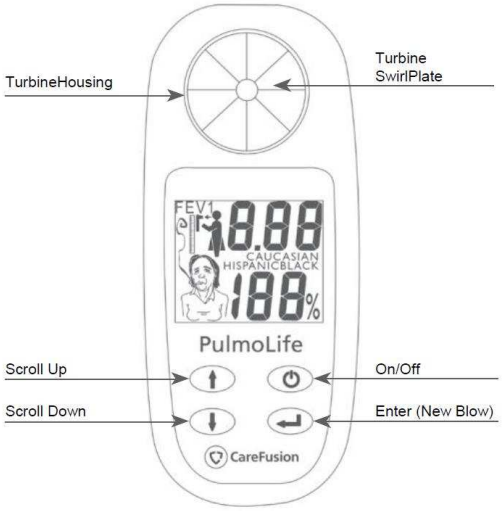

TurbineHousing
Turbine
SwirlPlate
FEV1
8.88
CAUCASIAN
HISPANICBLACK
188%
PulmoLife
Scroll Up
On/Off
Scroll Down
Enter (New Blow)
CareFusion

Introduction

The PulmoLife unit measures the Forced Expiratory Volume in the First Second of Expiration (FEV1) and the FEV1 as a Percentage of the Predicted Value (FEV1% predicted). The use of FEV1 is a useful diagnostic tool for early detection of COPD[1]. The results can also be used to calculate and display an equivalent 'Lung Age'[2]

BEFORE USING YOUR PULMOLIFE YOU MUST REMOVE THE BATTERY CONNECTION TAB

Contraindications

- Acute disorder affecting test performance (e.g. Vomiting, nausea, vertigo)
- Recent eye surgery (increases in intraocular pressure spirometry.
- Oral or facial pain exacerbated by mouthpiece
- Recent myocardial infarction

PLEASE NOTE: Extensive exhalation might lead to syncope

Warnings and Cautions

The following terms are used as follows in this manual

CAUTION: Possibility of injury or serious damage

WARNING: Conditions or practices that could result in personal injury

PLEASE NOTE: Important information for avoiding damage to the instrument or facilitating operation of the instrument.

 CAUTION: Read the manual before use
CAUTION: For batteries, do not attempt to charge, connect improperly, or dispose of in fire as there is possibility of leakage or explosion. Follow manufacturer's recommendation for proper disposal.
WARNING: The instrument is not suitable for use in the presence of explosive or flammable gases, flammable anesthetic mixtures or in oxygen rich environments.
PLEASE NOTE: The product and the battery you have purchased should not be disposed of as unsorted waste. Please utilize your local recycling facility for the disposal of this product.
PLEASE NOTE: Degree of protection against Ingress of Water is IPX0.

Intended Use

The intended use of PulmoLife is to quickly and easily screens smokers for early detection of Chronic Obstructive Pulmonary Disease (COPD). The effects of COPD in smokers are normally detectable from the age of 35.

The measurement taken from the unit can help in the diagnosis, management and treatment during the early stages of COPD development.

The use of 'Lung Age' provides an additional motivational tool that may help susceptible smokers to understand the physical damage caused by smoking

The PulmoLife is designed for use by clinicians and health care professional.

Entering Patient Details

Patients predicted values are based on their Sex, Height, Age and Race (default predicted value set shown on box, to change see Predicted Value Set Up)

Switch the unit On  to begin.

When entering the patient's, details use the Scroll Up  / Down  keys to change values and the Enter  key to accept and proceed.

Enter Sex (Male/Female) 

Enter Height (cm for ECCS and Asian, inches for NHANES III) 
Enter Age (Default is 45)
Enter Race (for ECCS and NHANES III only)

The display will show the blow symbol  and 0.00.

Performing a Test

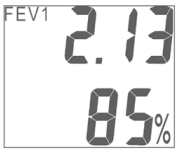
See further instructions on flap in the PulmoLife box.

Insert a new disposable one-way valve mouthpiece into the turbine holder. With the display showing the blow symbol  and 0.00.

Instruct the patient to breathe in until their lungs are completely full, seal their lips around the mouthpiece, and blast out as hard and as fast as possible for at least one second. After one second the unit will emit a beep to signal the end of the blow.

IMPORTANT NOTE: The rear of the turbine must not be obstructed during the blow.

The FEV1 and FEV1% predicted will be displayed.



If a blow is too slow at the beginning of the manuveur[3], the blow icon will flash assessing this test as poor quality and the test should be repeated. After a full inspiration, the patient should be encouraged to blast out the air as fast as possible without hesitation.

When FEV1% predicted is less than or equal to 80% of predicted, the FEV1% predicted value will flash indicating the possibility of airways obstruction.

Press the Scrolling Down key to display the 'Lung Age' (range 20-90 years) and smoker visual. A patient's 'Lung Age' is limited to 30 years over their chronological age up to a maximum age of 90.

PLEASE NOTE: If a patient's FEV1 %predicted is above 100% of predicted then their estimated 'Lung Age' would be lower than their chronological age.

Use the scrolling Up / Down keys to move back and forth between both results screens.

Press Enter to perform a new blow.

It is recommended that a spirometry result should be taken from the best of 3 technically correct blows.

To test another patient the unit must be switched off and on and then enter the new patient details.

Cleaning

Disinfection of contaminated parts is only effective after careful preliminary cleaning. Please follow the manufacturer's instructions for the solution you are using.

It is recommended that you use a MicroCheck one-way valve disposable mouthpiece (3395) with the PulmoLife unit. With the use of a new disposable mouthpiece for each patient, the transducer and must be sterilized once a week.

CAUTION: Switch off the device before cleaning.

The external housing of the PulmoLife may be wiped may be wiped with a disinfection wipe such as a Protex wipe (order #48-70). This should be performed after every patient.

To remove the turbine, simply press the turbine from the rear, without excessive force, and the turbine will pop out.

The turbine may now be immersed in warm soapy water for routine cleaning or immersed in cold disinfecting solutions for a maximum of 10 minutes (Alcohol and chlorine solutions MUST be avoided).

PLEASE NOTE: Do not use alcohol or chloride based solutions.

After cleaning/sterilizing, the turbine should be rinsed in distilled water and left to dry.

Do not use objects, such as pens or cotton buds, to clean or dry the turbine, as this may cause irreparable physical damage.

To replace the turbine, hold the unit and the turbine swirl plate facing you, put the turbine back into the turbine housing then push until the turbine is fully located, such that the back of the turbine is completely level with the back of the unit.

CAUTION: Do not attempt to wash or immerse the PulmoLife in water or cleaning fluid, as there are electronic components inside that will be permanently damaged.

PLEASE NOTE: Used cardboard mouthpieces must be disposed of immediately after each use.

If there are changes on the material surfaces (cracks, brittleness) the respective parts must be disposed of.

Calibration Check

To check the calibration, hold down the On  and Scrolling Up  keys together, and only release when ‘Ch’ is displayed.

When the blow symbol  and ‘0.00’ appear, empty the 3-litre syringe smoothly into the unit. The value will be displayed.

If the unit detects an error the blow symbol  and calibration value will flash. An acceptable calibration check is within +/-3.5% of the 3-litres entered (so between 2.90 and 3.10 liters).

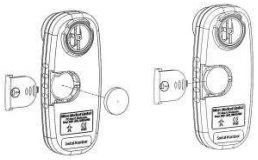
PLEASE NOTE: Calibration check failure is unusual but is most often due to malfunction of the turbine, either because it is physically damaged or dirty. Clean the turbine (see cleaning) and recheck the calibration. If the unit still fails calibration check, replace with a new turbine (see accessories for order number).

Service

This unit requires no routine servicing.

Battery

The PulmoLife is powered by a 3 Volt Lithium coin cell accessed via a slide cover on the rear of the instrument**.** If the battery level is low the unit will display the letters ‘bAt’. If switched on with a low battery level, the unit will beep three times and then turn off after 5 seconds. The battery is contained beneath the slide cover in the rear of the unit. For access to the battery first remove the battery cover by sliding sideways as indicated



Disassembly
Pry out the old coin cell using a suitable, non-metallic implement

Assembly
Replace the battery paying particular attention to its orientation. The part number etched on its outer face should be uppermost and visible when the battery is inserted. Press until clicked into place Slide the battery cover back into place, insert the screw and tighten it hand-tight.

PLEASE NOTE: If the battery is removed for any reason the unit will reset to factory predicted value settings.

Replacement 3V coin cell batteries are available at most major electrical outlets.

PLEASE NOTE: Please remove the battery if the meter is likely to be unused for some time.

CAUTION: Do not open the battery cover when the device is turned on.

CAUTION: The patient should not be allowed to remove the battery cover.

CAUTION: The operator should not touch the contacts of the battery and the patient at the same time.

PLEASE NOTE: Dispose of the waste battery in accordance with your local recycling facility.

Product Lifetime

The PulmoLife is designed for a product lifetime of 5 years.

Predicted Value Set Up

To change the Predicted Value Settings, from the default shown on the box, hold down the On and Enter keys together, and only release when 'Prd' is displayed**.** Use the Scrolling Up / Down keys to choose an alternative Predicted Value set.

1 ECCS[4]
2 NHANES III[5]
3 Asian (Chinese)[6]

When the desired number is selected press the Enter key to accept and save that predicted value set as default.

Version

To check the version number, hold down the On and Scrolling Down keys together, and only release when ‘rE’ is displayed. The version number will then be shown.

Troubleshooting Information

Should you encounter problems operating your PulmoLife unit, please consult the table below:

Problem	Possible Cause	Solution
Does not register a blow	Turbine incorrectly fitted	Ensure turbine is tightly pushed into the unit.
Unit does not turn on or Solid “bAt” indicator is displayed, while unit beeps three times and powers itself down after 5 seconds	Battery is exhausted	Replace battery
Calibration Check failed or cannot be completed	There are leaks in the syringe or connections	Check the syringe and connections for leaks
	Turbine may be faulty	Repeat calibration procedure, if problem still persists, replace turbine
	Shaft of the syringe being pushed down	The syringe should be emptied and filled with one smooth stroke, avoid pushing down on the shaft or banging at the end of each manoeuver.

Safety Designation Per IEC 60601-1

Type of protection against electrical shock	Internally powered Equipment
Degree of protection against electrical shock	Type B applied part
Power Equipment	Battery type: 3V Lithium Ion Coin Cell Battery (model no CR-2450)
Degree of Electrical connection between equipment and Patient	Equipment designed as non-electrical connection to the patient.
Degree of mobility	Transportable
Mode of operation	Continuous
Classifications according to IEC 60601-1	Applied part, type B

WARNING: No modification of this equipment is allowed.

WARNING: The user must not touch any voltage-carrying parts and the patient at the same time.

Electromagnetic Compatibility (EMC)

WARNING: use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation

The PulmoLife has been tested to EN60601-1-2:2007, regarding its ability to operate in an environment containing other electrical/electronic equipment (including other medical devices).

The purpose of this testing is to ensure that the PulmoLife is not likely to adversely affect the normal operation of other such equipment and that other such equipment is not likely to adversely affect the normal operation of the PulmoLife.

Despite the testing of the PulmoLife that has been undertaken, normal operation of the PulmoLife can be affected by other electrical/electronic equipment and portable and mobile RF communications equipment.

As the PulmoLife is medical equipment, special precautions are needed regarding EMC (electromagnetic compatibility).

It is important that the PulmoLife is configured and installed/put into service, in accordance with the instructions/guidance provided herein and is used only in the configuration as supplied.

Changes or modifications to the PulmoLife may result in increased emissions or decreased immunity of the PulmoLife in relation to EMC performance.

The PulmoLife should not be used adjacent to or stacked with other equipment. If adjacent or stacked use with other equipment is necessary, the PulmoLife and the other equipment should be observed/ monitored, to verify normal operation in the configuration in which it will be used.

For the purposes of EN60601-1-2 the PulmoLife has an essential performance (the PulmoLife must not begin to measure unintentionally during a test and should pass a posttest 3-liter calibration syringe measurement).

Guidance and Manufacturer's Declaration – Electromagnetic Immunity The PulmoLife is intended for use in the electromagnetic environment specified below. The customer or the user of the PulmoLife should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment -Guidance**
RF emissions CISPR 11	Group 1	The PulmoLife uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

RF emissions CISPR 11	Group B	The PulmoLife 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 (battery powered)	
Voltage fluctuations / flicker emissions IEC61000-3-3	Not Applicable (battery powered)	

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Immunity Test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic Environment -Guidance**
Electrostatic discharge (ESD) IEC61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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	Not Applicable (Battery Powered) and No Cables	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not Applicable (Battery Powered)	Mains power quality should be that of a typical commercial or hospital environment.

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Immunity Test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic Environment -Guidance**
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% UT (>95 % dip in UT) For 0.5 cycle 40% UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5% UT (>95 % dip in UT) For 5 s	Not Applicable (Battery Powered)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the PulmoLife requires continued operation during power mains interruptions, it is recommended that the PulmoLife be powered from an uninterruptable power supply or a battery.
Power frequency (50/60Hz) Magnetic field IEC61000-4-8	3 A/m	3 A/m	If incorrect operation occurs, it may be necessary to position the PulmoLife further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

NOTE UT is the a.c. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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Immunity Test	IEC 60601 test level	Compliance Level	Electromagnetic Environment -Guidance
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	Not Applicable (Battery Powered and No Cables) 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the PulmoLife, including any cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance (d)** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.5 GHz		$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Fields strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE [1] At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE [2] These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PulmoLife is used exceeds the applicable RF compliance level above, the PulmoLife should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the PulmoLife

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

Recommended separation distances between portable and mobile RF communications equipment and the PulmoLife

The PulmoLife is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PulmoLife can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PulmoLife as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter in Watts (W)	**Separation Distance in Meters (m) according to Frequency of Transmitter**		
	150 KHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz $d = 1.2\sqrt{P}$**	**800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures objects and people

Specifications

Measurement	Forced Expiratory Volume in 1 second (FEV1) Forced Expiratory volume in 1 second as a percentage of predicted (%FEV1) Lung Age
Transducer:	Digital Volume Transducer
Resolution:	0.01L
Accuracy:	+/-3% To ATS/ERS Taskforce Standardization of Spirometry, 2005
Volume Range:	0 - 8 L As per ATS/ERS Recommendations
Flow Range:	0-14 L/s as per ATS/ERS Recommendations
Predicted Values	1) ECCS 2) NHANES III 3) Asian (Chinese)
Display:	Custom Liquid Crystal
Power Supply:	3V Lithium Ion Coin Cell Battery (model no CR-2450)
Dimensions:	5” x 2” x 1”
Weight	Unit only: 3 ounces Unit complete with accessories: 9 ounces
Operating Temperature:	32°F to 104°F
Operating Humidity:	30% to 90% RH
Storage & Transport Temperature:	-20°C to + 70°C
Storage & Transport Humidity:	10% to 90% RH

Accessories

Product	Order Number
MicroCheck one-way valve mouthpieces (Box of 200)	3395
Adult Disposable Mouthpieces (200 per box)	3314SB
Adult Disposable Mouthpieces (500 per box)	3314B5
Pouch	CAS1048
Replacement Turbine	TDX1050
3 Liter Calibration Syringe	3325
Protex Disinfectant Wipe (100/canister)	48-70

Symbols

	Type B device
	In accordance with Directive 93/42/EEC
	Disposal in compliance with WEEE
	Consult the instructions for use
	Date of Manufacture
	Manufacturer
	Serial number
	Direct current
	Single patient use
Rx only	Federal U.S. law restricts this device to sale by or on the order of a physician.

To place an order for consumables / supporting products, for service/repair or for general questions please contact Micro Direct at:

Toll Free:	1-800-588-3381
Telephone:	207-786-7808
Fax:	207-786-7280
Email:	sales@mdspiro.com
	support@mdspiro.com
Website:	www.mdspiro.com

Or contact your local Micro Direct distributor.

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