SPIROLINK

User Manual

Model: B1

CMI Health Inc

1. Product overview

1.1 Basic information

Product name: SpiroLink
Model: B1
Data Transmission: Bluetooth BLE

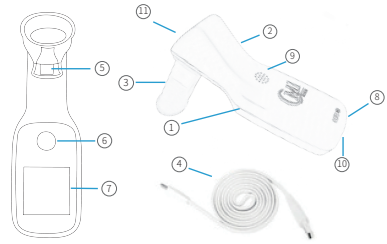
1.2 Intended use

This device is intended for monitoring PEF (Peak Expiratory Flow) and FEV1 (Forced Expiratory Volume in 1 second). The device is designed for pediatric and adult patients. The device is intended for monitoring respiratory conditions such as asthma and COPD.

1.3 Product structure

The product is composed of the device, mouthpiece and USB cable as shown below:

1-Front Housing	2-Rear Housing	3- Mouthpiece
4-USB Cable	5- Air Inlet	6-Power button
7-Display	8-Reset Keyhole	9-Speaker
10-USB port	11- Air Vent	



1.4 Product performance

1.4.1 Measure parameters

PEF	Peak Expiratory Flow
FEV1	Forced Expiratory Volume in 1 Second
*FVC	*Forced Vital Capacity

1.4.2 Technical parameters

Measuring range	PPEF:(0～14) L/s FEV1:(0.5～8) L *FVC:(0.5～8) L
Accuracy	PEF: ±10% or ±18L/min (whichever is greater) FEV1: ±3% or ±0.05L (whichever is greater) *FVC: ±3% or ±0.05L (whichever is greater)
Power supply	3.7V DC

Anti-shock	Internal power supply
Safety category	BF type
Water resistance	IPX0
Operating mode	Consecutive
EMC compatibility	Group 1 Class B

* FVC is provided for wellness use only

1.5 Contraindications

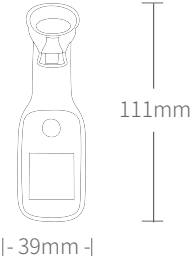
1) Patients with severe asthma
2) Patients with severe COPD
3) Uncontrolled hypertension patients
4) Patients who had chest, abdominal or eye surgery in the past 3 months
5) Patients who had heart disease (angina pectoris, myocardial infarction, malignant arrhythmia, etc.) in the past 3 months
6) Patients hospitalized for heart disease in the last 1 month
7) Patients with massive hemoptysis in the last 1 month
8) Patients with stroke in the last 1month
9) Patients with aortic aneurysms
10) Patients with severe hyperthyroidism

11) Patients with seizures and in need of medication
12) Patients with a history of retinal detachment
13) Patients with facial paralysis

1.6 Product content

Main unit	1
USB data cable	1
Quick Guide	1
User manual	1
Removable mouthpiece	2

1.7 Specifications



2. Symbols

Graphic Symbol	Meaning
	Please refer to the user manual and follow the instructions
	Keep Dry
	Type BF applied part, can contact patient isolate from other parts
	Low-frequency electromagnetic radiation
	Caution! View accompanying documents
	“WEEE (Waste Electrical and Electronic Equipment)”. The waste products should be handled legally.
IPX0	Waterproof rating is 0

3. Safety precautions

1) Please operate strictly according to this user manual, otherwise, there might be inaccurate measurement, or damage to device.
2) Do not use while charging, otherwise it will lead to inaccurate measurement.
3) Regular maintenance to make sure there’ s no damage that affects safety and performance. It is advised to check at least once a week, if there’ s obvious damage, please stop using and contact customer service.
4) Do not repair this device by yourself, it should only be done by qualified personnel appointed by the manufacturer.
5) Do not use this device in an environment that has anesthetics and other inflammables which may cause explosion.
6) Do not use this device in strong electromagnetic interference or direct wind source, cold source and heat source environment.
7) Do not immerse this device into liquid.
8) Do not spatter liquid onto this device which may cause damage.
9) Do not place this device in a mechanical vibration environment.

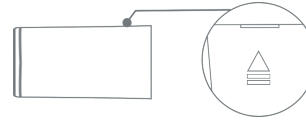
10) Do not drop this device from a high place.
11) Do not use sharp objects to press or scratch the device shell.
12) Do not disassemble the device without permission.
13) Do not place heavy objects on the device which may cause performance or mechanical damage.
14) Please use the device in specified working environment, keep the working environment clean and avoid corrosive or flammable substance, too high or low temperature and humidity.
15) Do not use high temperature high pressure or gas disinfection to disinfect the device.
16) Do not spatter liquid directly on the device when disinfect the device surface using rubbing alcohol.
17) If the device continues to fail to display data or there' s other abnormal conditions, press power button to remeasure, or power off the device and restart.
18) Please dispose of the device, its accessories and package (such as mouthpiece, plastic bag, foam and paper box) in accordance with the local laws and regulations.

19) The measurement results serve as a clinical reference which should be explained by professional medical personnel.
20) When using the device, pay special attention to the user manual where this symbol "!" is marked.

4. Installation and operation

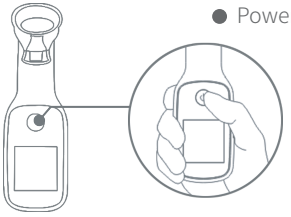
4.1 Device installation and preparation

Install the mouthpiece: Hold the device, make the side of the mouthpiece with this triangular symbol "△" face upward, insert the mouthpiece into air inlet, then press slightly, the mouthpiece will be firmly locked.

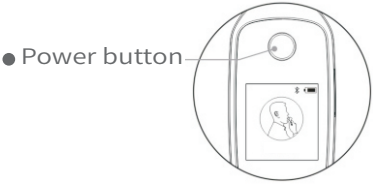


4.2 Testing procedure

Step 1: Hold the product upright in the hand, press and hold the power button to start up, you will see a device startup screen.



Step 2：Wait for the device to finish booting, then short press power button, you will hear “Please blow”.



Step 3：After hearing “Please blow”, Take a deep breath, hold your breath while put the mouthpiece into your mouth and close lips around the mouthpiece. (the upper and lower teeth should nibble the front of the mouthpiece, and your lips should tightly cover the mouthpiece), blow air out as fast and as far as possible (the standard time is 6 seconds, while blowing, you will hear “Come on, come on, 3, 2, 1, stop”.

⚠ Note:

- Adjust your breath before the test (inhale and exhale for 3 rounds), keep your breath steady.
- Keep the standing posture during the test and keep your body stable.
- Do not shake your head downward with your body violently while blowing, since this may affect test result.

Step 4: After the test, there will be a prompt tone, the results are shown in display screen (you can test multiple times and take the maximum value).

⚠	CAUTION: 1) The measurement results serve as a clinical reference which should be explained by professional medical personnel. 2) No matter what your reading is, if you have signs and symptoms such as chest tightness, shortness of breath, coughing or wheezing, please seek medical assistance.

4.3 Shutting down

1) When device is powered on, long press power button to power off. The device will display shutdown interface (LOGO gradually zoom out), while the device prompt “Device shutting down”. After the above actions are completed, the device is powered off.
2) The device will automatically power off after 6 minutes of inactivity.

4.4 Charging

There are two charging methods:

1) Use power adapter with a 5V-1A power adapter to charge. Insert the standard USB to the power adapter and the microUSB to the device using included USB cable.
2) Insert the standard USB to a USB port on a running computer and the microUSB to the device.

5. Maintenance

5.1 Cleaning and disinfection

1) Use rubbing alcohol to wipe the shell of the device, then use clean, soft cloth to dry it or dry by natural air.
2) Remove and clean the mouthpiece regularly. Rinse with clean water, or use clean, soft dry cloth dipped in rubbing alcohol to wipe the inner and outer wall of the mouthpiece and dry by natural air. Alternatively dip the mouth piece in rubbing alcohol for a while, wipe it dry or dry by natural air.
3) Use cotton ball dipped in rubbing alcohol to gently wipe the metal plate to keep it clean.

⚠	CAUTION: 1) Only use wet cloth to wipe (Wipe disinfection). 2) It’s prohibited to immerse the device shell into liquid. 3) Do not flush the main unit with high pressure water. 4) Do not wash or disinfect the device with strong alkali or strong acid.

5.2 Maintenance

1) Please read the "Safety precautions" section carefully and implement strictly.
2) When the display shows low charge, charge the battery in time.
3) When the device is not in used for a long period of time, it shall be recharged every 6 months.
4) We recommend performing quarterly check if the device is used by Healthcare Professionals. Please contact CMI customer service for device calibration and repair.

5.3 Storage and transportation requirements

1) Storage environment
- Temperature: -4 F to 131 F
- Relative humidity: 0%RH to 80%RH
- Atmospheric pressure: 0.7 ATM to 105 ATM
- Environment: non-corrosive gases and well-ventilated clean rooms

2) Work environment
- Temperature: 50 F to 104 F
- Relative humidity: 0%RH to 80%RH
- Atmospheric pressure: 0.7 ATM to 105 ATM

3) Transportation requirements
The product should be protected from heavy pressure, direct sunlight and rain during transportation. It should be in accordance with the order contract.

⚠	CAUTION: 1) Avoid falling or strong impact 2) Avoid high temperature or direct sunlight.

6. Troubleshooting

Problem	Cause analysis	Solutions
Unable to turn on	Low battery	Please recharge
	Possible device damage	Please contact Customer Service
Unable connect to network after turned on	Bluetooth on phone not turned on	Turn on the Bluetooth in phone setting
Unable to get the test data	Device not in test mode	Press the power button to start test
	Incorrect exhalation posture	Please refer to Chapter 4 for the correct blowing posture

Sudden disappearance of display	Automatically shut down without any operation for 6 minutes	Normal phenomenon
	Low battery	Please recharge
The device usage time is too short after recharging	Low battery	Please recharge
	Battery damaged	Please contact Customer Service
Data transmission failure	Bluetooth disconnected	Turn on Bluetooth on your smartphone
		Open the APP and retry connection
		Please contact Customer Service

7. Warranty

7.1 Duration and exceptions

One-year warranty from the purchasing date upon presentation of proof of purchase. Warranty does not include the following failure conditions; unauthorized disassembly, inappropriate transportation, lack of reasonable maintenance, force majeure factors such as natural disasters.

CMI Health assumes no responsibility for faulty operation or problems caused by improper use with other unapproved device, or accessory.

7.2 Maintenance and repair

Please contact CMI Health Customer Service at 888-985-1125 or info@cmihealth.com for detailed instructions.

Warranty will be void if maintenance is conducted by the user, or unauthorized personnel.

To process your maintenance request faster, please provide the following information to our Customer Service:

- Product number
- Detailed description of the problem

⚠	WARNING: The service center has the right to reject contaminated product for safety reasons. Please pack the product in a way that does not contaminate the package.
⚠	Caution: Please use proper packaging (preferably the original package) when shipping. Our company has the right to return contaminated product to the sender.

7.3 Production date and expiration date

Product production date: see product label
Product expiration date: three years

8. Network Security Description

The device can upload data to the mobile app via Bluetooth.

8.1 Operating environment requirements

Device	Hardware requirement	Software requirement	Network requirement
B1	Android or iOS phone with Bluetooth BLE	SpiroLink APP	Bluetooth ON; device within 15 feet from phone

8.2 Data and device interface

The spirometer (B1) complies with the BLE protocol, enabling the embedded device to communicate with other Bluetooth devices.

8.3 User Access

User Type	User Authority	User authentication method	Password strength settings
General user	Access device Measure data	The user's personal account is bound to the device code, and device data can only be obtained after the device is bound.	Personal account: The account name and password match, and the password length is not less than 6 digits. Device ID: Each device has a unique ID, which serves as a unique identity. Device ID is encrypted.
Device Administrator CMI authorized service personell	Access device data and perform software updates	Via account and password	The password must be in English uppercase and lowercase, and the length must be at least 6 digits.

9. EMC statement

9.1 Parameter Description

Spirometer B1	Modulation type: GFSK
	Operation Frequency: 2.4 GHz ISM band
	Radio Power: 12dbm

9.2 Precautions statement

⚠ ATTENTION:

- The SpiroLink complies with the relevant EMC requirements of the YY0505-2012 standard; users should install and use the electromagnetic compatibility information
- provided in the accompanying documents. Portable and mobile RF communication equipment may affect the performance of the pulmonary function testing device. Avoid strong electromagnetic interference while using it, such mobile phones, microwave ovens, etc.
- Guidance and manufacturer's declaration are detailed in the accessories.
- USB cable length is about 2.6 feet

⚠ WARNNING:

- The SpiroLink should not be operated near, or stacked, with other equipment. If must be stacked, it should be verified that it can operate normally in the configuration in which it is used.
- Except for cables sold by the CMI Health Inc. as spare parts for internal components, the use of accessories and cables other than those specified may result in increased EM emissions or reduced immunity to interference.
- Even if other equipment meets the emission requirements of the corresponding national standard, the SpiroLink may still be susceptible to interference by other equipment.

9.3 Declaration of conformity

Manufacturer declaration - Electromagnetic Emissions		
The SpiroLink is intended for use in the electromagnetic environment specified below. The purchaser or user of the spirometer should ensure that it is used in this electromagnetic environment:		
Emission tests	Compliance	Electromagnetic Environment Guide
RF emission GB 4824	Group 1	The spirometer uses radio frequency energy only for its internal functions. As a result, its RF emissions are low and there is little chance of interference with nearby electronic equipment
RF emission GB 4824	CAT B	The spirometer is suitable for use in all facilities, including domestic facilities and public low-voltage power grids that are directly connected to the home
Harmonic emission GB17625.1	Not applicable	
Voltage fluctuation / flicker emission GB17625.2	Not applicable	

Manufacturer Declarations – Electromagnetic Immunity			
The spirometer is intended for use in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment:			
Immunity test	IEC 60601 test level	Coincidence level	Electromagnetic Environment Guide
Electrostatic discharge GB / T17626.2	± 6KV contact discharge ± 8KV air discharge		The floor should be wood, concrete or tile, and if the floor is covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient Burst GB / T17626.4	± 2KV to power line ± 1KV to input / output	Not applicable	Not applicable
Surge GB / T17626.5	± 1KV differential mode ± 2KV common mode	Not applicable	Not applicable

Voltage sag, short-term interruption and voltage change on the power input line GB / T17626.11	<5% UT for 0.5 cycles (on UT, >95% dip) 40% UT for 5 cycles (60% sag on UT) 70% UT for 25 cycles (30% sag on UT) <5% UT for 5s (on UT, > 95% dip)	Not applicable	Not applicable
Frequency magnetic field (50 / 60Hz) GB / T17626.8	3A/m	3A/m 50/ 60Hz	Power frequency magnetic fields should have power frequency magnetic field levels typical of typical locations in a typical commercial or hospital environment.
Note: UT refers to the AC network voltage before the test voltage is applied			

Manufacturer's Declarations - Electromagnetic Immunity			
The spirometer is intended for use in the electromagnetic environment specified below. User should ensure that it is operate in this electromagnetic environment:			
Immunity test	IEC60601 Test level	Coincidence level	Electromagnetic Environment Guide
RF conduction GB/T 17626.6	3V (Effective value) 150kHz – 80MHz	3V/m	Portable and mobile RF communications device should not be used closer to any part of the handheld lung function tester A1 than the recommended isolation distance, including cables. This distance should be calculated by the formula corresponding to the frequency of the transmitter Recommended isolation distance:
RF radiation GB/T 17626.3	3V/m 80MHz – 2.5GHz	3V/m	

	d = 1.2√P d = 1.2√P 80MHz~800MHz d = 2.3√P 800MHz~2.5GHzd In formula: P: the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer. d: recommended isolation distance in meters (m)The field strength of the fixed RF transmitter is determined by surveying the electromagnetic field c, and in each frequency range d should be lower than the compliance level. Interference may occur near equipment marked with the following symbol. “!”
NOTE 1: At 80MHz and 800MHz frequencies, the higher frequency band formula is used. NOTE 2 These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and people	

1. The field strength of fixed transmitters, such as base stations for wireless (cellular / cordless) phones and terrestrial mobile radios, amateur radios, AM and FM radio broadcasts, and television broadcasts, cannot be accurately predicted theoretically. To assess the electromagnetic environment of fixed RF transmitters, surveys of electromagnetic sites should be considered. If the measured field strength of the hand-held pulmonary function tester A1 is higher than the applicable radio frequency compliance level above, the hand-held pulmonary function tester A1 should be observed to verify its normal operation.
If abnormal performance is observed, supplementary measures may be necessary, such as reorienting or repositioning the handheld lung function tester A1.
2. In the entire frequency range from 150KHz to 80MHz, the field strength should be lower than 3V/m.

Recommended distance between RF devices and spirometers

Spirometry is expected to be operate in an electromagnetic environment where RF radiation disturbances are controlled. Depending on the rated maximum output power of the communication device, user can prevent electromagnetic interference by maintaining a minimum distance between mobile RF communication device (transmitters) and (equipment or system) as recommended below.

Transmitter rated maximum output power (W)	Isolation distance corresponding to frequencies (m)		
	150kHz~ 80MHz $d = 1.2\sqrt{P}$	80MHz~ 800MHz $d = 1.2\sqrt{P}$	800MHz~2.5GHz $d = 2.3\sqrt{P}$
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

For the rated maximum output power of the transmitters not listed in the table above, the recommended isolation distance d in meters (m) can be determined using the formula in the corresponding to frequency, where P is provided by the transmitter manufacturer Transmitter maximum output power in watts (W).

Note 1: At 80 MHz and 800 MHz, the higher frequency range formula is used.
NOTE 2 These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

10. Manufacturer information

Manufacturer name: CMI Health Inc.
Manufacturer address:
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Alpharetta, GA 30005
Toll-Free Customer Service: 888-985-1125
Website: www.cmihealth.com
Email: info@cmihealth.com