SpiroUSB 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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075-11 US
Issue 1.6
February 2019

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Indications for Spirometry

Spirometry has been used extensively to measure lung function capability and to recognize and treat many diseases associated with the impairment of healthy lung functions. Spirometry today provides great insight into the status of any person's health.

Generally speaking, spirometry is a simple diagnostic tool used to define a subject's lung condition. The major indications for spirometry are:

- ✓ Dyspnea (shortness of breath)
- ✓ Exercise induced coughing
- ✓ Chest tightness
- ✓ Smokers over 45 years of age (NLHEP recommendations)
- ✓ Obesity
- ✓ Pre-operative testing
- ✓ Occupational exposure to dust and/or chemicals
- ✓ Ongoing assessment of patients receiving bronchodilator treatments
- ✓ Determination and/or documentation of pulmonary disability
- ✓ Asthma diagnosis
- ✓ Pre-existing pulmonary disease
- ✓ Frequent colds
- ✓ Assessment of congestive heart failure

CPT Codes for Spirometry

94010 - Spirometry Complete
Includes graphic record total and timed vital capacity, expiratory flow rate measurement (s) with or without maximal voluntary ventilation

94060 - Bronchodilation Responsiveness
Spirometry as in 94010, pre and post-bronchodilator or exercise

94070 - Bronchospasm Provocation Evaluation
Multiple spirometric determinations after bronchodilator with spirometry as in 94010

94200 - Maximal Voluntary Ventilation
Maximum breath capacity

94375 - Flow Volume Loop
Respiratory Flow Volume Loop

95070 - Inhalation Bronchial Challenge Testing
(Not including necessary pulmonary function tests), with histamine, methacholine or similar compounds.

94464 - Bronchodilator Administration
Demonstration and/or evaluation of patient utilization of an aerosol generator, nebulizer and meter dose inhaler or IPPB device

Diagnosis and ICD-10-CM Codes on back cover

Contents

Introduction

The SpiroUSB is a PC connected spirometer dedicated to work with the comprehensive Spirometry PC Software (SPCS).

SPCS is a fully Windows™ compatible spirometry system that interfaces seamlessly with the SpiroUSB providing many display options and includes powerful reporting and database facilities.

SPCS has many advanced features including display of real time respiratory traces, predicted values, patient database, and the ability to carry out pre and post bronchodilator and post steroid testing.

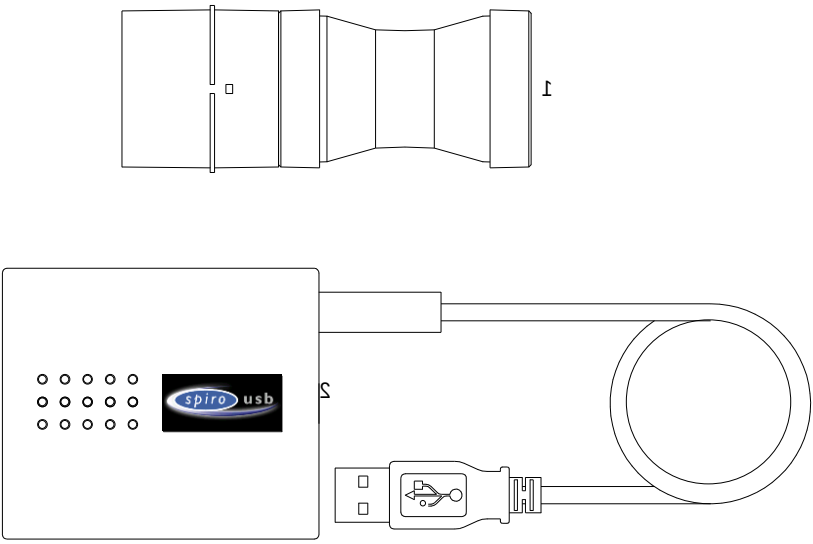
The SpiroUSB uses a Gold Standard Digital Volume Transducer, an extremely stable form of volume transducer, which measures expired air directly at B.T.P.S (Body Temperature and Pressure with Saturated water vapor) thus, avoiding the inaccuracies of temperature corrections. This transducer is insensitive to the effects of condensation and temperature and avoids the need for individual calibration prior to performing a test.

Package Contents

The SpiroUSB is packaged in a sturdy carrying case containing this manual and the following items (Fig.1):

1. Digital Volume Transducer
2. SpiroUSB transducer housing.

Together with SPCS, extension cable, disposable cardboard mouthpieces and nose clip.



Contraindications

Contraindications: It is recommended that patients should not be tested within one month of a myocardial infarction.

Conditions where suboptimal spirometry are likely:

- chest or abdominal pain
- oral or facial pain exacerbated by a mouthpiece
- stress incontinence
- dementia or confused state

Ref: ATS/ERS Task Force: Standardization of Lung Function Testing. General considerations for lung function testing.

M. Miller et al. Eur Resp J 2005:26. 153-161

Warning 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

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

Note: Patients below the age of four (4) may struggle to perform spirometry correctly and reproducibly.

Note: The device should be used by trained and qualified personnel.

 CAUTION: Read the manual before use.
WARNING: The instrument is not suitable for use in the presence of explosive or flammable gases, flammable anesthetic mixtures or in oxygen rich environments.
CAUTION: Mouthpieces are single patient use. If used on more than one patient, there is a risk of cross-infection. Repeat use may degrade materials and lead to an incorrect measurement.
CAUTION: Pulmonary filters are single patient use. If used on more than one patient, there is a risk of cross-infection. Repeat use may increase air resistance and lead to an incorrect measurement.
 PLEASE NOTE: The product 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.
WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
CAUTION: When you connect the SpiroUSB to other equipment, always make sure that the whole combination complies with the international safety standard IEC 60601-1 for medical electrical systems. During measurements, connect the SpiroUSB only to printers and computers that comply with IEC 60601-1 / ANSI/AAMI ES60601-1:2005 / CAN/CSA-C22.2 No. 60601-1:14.

Indications for Use

The SpiroUSB spirometer is intended for prescription use only, to measure the maximal volume and flow of air that can be moved in and out of a patient's lungs. The system is intended for use with pediatric (4 to 17 years) and adult (18 to 99 years) patients in hospitals, physician offices, laboratories and occupational health testing environments.

Installing SPCS

SPCS is supplied on the CD ROM with your SpiroUSB. Install SPCS according to the instructions in the SPCS quick start guide.

Installing SpiroUSB Device Driver

The driver enables the SpiroUSB devices to work with USB enabled PC software on Windows based machines.

Compatibility Status

There are two versions of the USB driver. The driver used depends on the Operating System you are using. There is a driver for Windows 32 bit Operating Systems and for 64 bit.

The following operating systems are supported:

- Windows 7 32 & 64-bit Operating Systems
- Windows 8.1 32 & 64-bit Operating Systems
- Windows 10 64-bit Operating System

The driver will not be supported under older Windows Operating Systems.

Driver installation

If software is installed that provides support for USB, the drivers may be pre-installed, allowing automatic installation of the drivers when the device is connected to the USB port. If the device does not install automatically, contact Micro Direct at 800-588-3381 to request a link for the drivers.

Operation

Simply connect the SpiroUSB to a spare USB port on your PC with the supplied SPCS installed. SPCS will automatically detect the SpiroUSB has been connected to a USB port and will run, ready for you to start your spirometry session. There is no need to remove the SpiroUSB between sessions.

Please note that with certain PC configurations, even if a compatible operating system is being used, SPCS may not be launched automatically when the SpiroUSB is plugged in. In this case, SPCS may be run in the usual way using the Windows on-screen Start button.

The SpiroUSB transducer is supplied with a 6.5-foot cable. If this length is insufficient then a remote USB hub should be used. Remote USB hubs are readily available from computer accessory suppliers. For some recent computers, the USB signal will work over a longer distance using an extension cable. An extension cable has been supplied for your convenience. If communication problems are

encountered using the extension cable, then a remote USB hub must be used.

Note: Keep the PC and monitor out of reach of the patient at all times.

Looking after your SpiroUSB Spirometer

Please observe the following precautions:

- Avoid exposing the SpiroUSB to direct sunlight during use.
- Avoid operating the spirometer in dusty conditions or near to heating appliances or radiators.
- Do not keep the spirometer in a damp place or expose it to extreme temperatures.
- Do not direct the transducer holder towards a strong light source while operating the spirometer.

Calibration Check

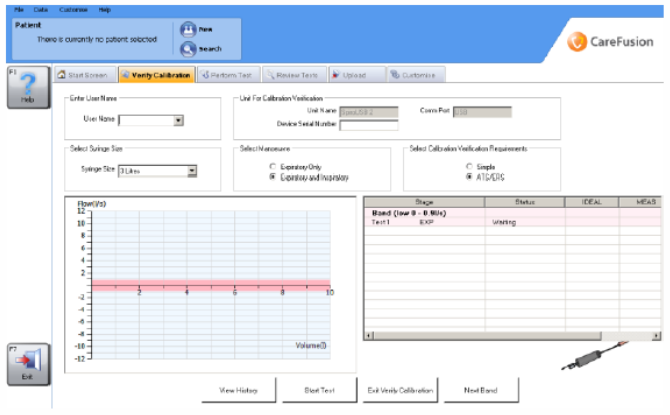
The spirometer is calibrated to read in liters at body temperature, barometric pressure saturated with water vapor (BTPS).

The calibration should remain stable indefinitely unless the transducer is physically damaged, and the unit should not require re-calibration. However, to ensure the correct functioning of the unit, we do recommend a calibration check is performed after the transducer is removed for cleaning.

Pressing the ‘Verify Calibration’ button in the SPCS invokes the start of a device search and the option Calibration Check. The device search effectively scans the PC’s com/usb ports for any attached device. On finding a device, the screen will change to the main verify calibration test screen. The option to perform an expiratory only or an expiratory and inspiratory calibration check and a single volume calibration or more advanced calibration check at three separate flow rates can be chosen in the calibration screen.

Connect a 3-liter syringe to the transducer with the minimum of adapters and empty it by pushing the handle fully in.

Note: It is recommended that the transducer is disinfected prior to a calibration check or a SpiroSafe filter is used during the procedure.



Cleaning Instructions

Disinfection of contaminated parts is only effective after having them carefully pre-cleaned. Please follow the solution manufacturer's instructions.

The device must not be exposed to solvents e.g. alcohol, chlorine

CAUTION: Unplug your SpiroUSB before cleaning.

External Surfaces of the Spirometer

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

The external housing of the spirometer may be wiped with sterile wipes or a damp cloth that has been immersed in a cold sterilizing solution when required. We recommend the Protex Disinfectant wipe (see consumables / supporting products)

Cleaning Accessories

With the use of a SpiroSafe filter (#3385) or a MicroCheck one-way valve mouthpieces (#3395) for each patient, cleaning for the components in patient's gas path is recommended once a month.

When using the disposable cardboard mouthpiece (adult #3314SB/#3314B5 or pediatric #3301) without a filter under the prerequisite that the patient was instructed only to exhale into the transducer, the

following parts must be cleaned once a day: adapter (pediatric/adult) and the transducer.

With any other use as described above all contaminated parts must be disinfected between patients.

Important Note: Used single patient nose clips, mouthpieces and SpiroSafe filters must be disposed of immediately after the use.

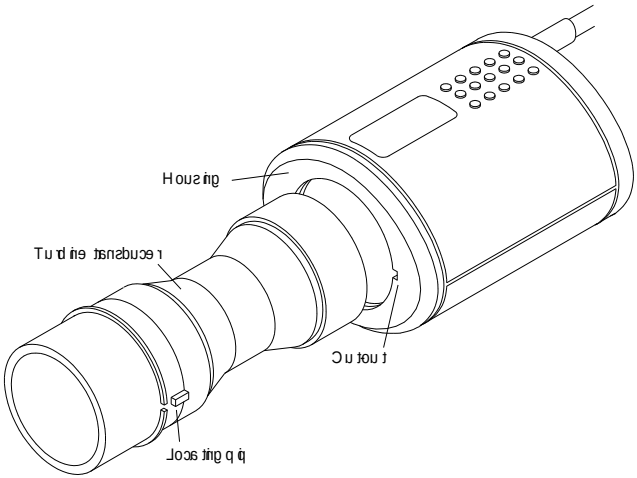
If there are changes on the material surfaces (cracks, brittleness), the respective parts must be disposed of.

Cleaning the Transducer

The transducer requires no routine maintenance or servicing. However, if you wish to disinfect or clean the transducer it may be removed by means of the following procedure:

1. Rotating the turbine transducer anti-clockwise until the locating pip lines up with the small rectangular cut-out in the housing as on the next page.
2. Gently pull the transducer away from the housing.
3. The transducer may now be immersed in warm soapy water for routine cleaning or immersed in a cold disinfectant solution for a maximum of 10 minutes (Alcohol and chlorine solutions should be avoided).
4. After cleaning/disinfecting, the transducer should be rinsed briefly in distilled water and dried.

5. Re-assemble the mouthpiece holder.



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

Servicing

A full-service manual including circuit diagrams and parts list is available upon request.

If your unit requires service or repair, please see page 23 for contact details.

Product Lifetime

The SpiroUSB spirometer is designed for a product lifetime of 5 years.

Trouble Shooting Information

Should you encounter problems operating your SpiroUSB Spirometer, please consult the table below:

Problem	Possible Cause	Solution
Does not register a blow	Head assembly or cable broken	Replacement of head assembly or return the unit for servicing
Blows are inverted on the display	Head assembly or cable broken	Replacement of head assembly or return the unit for servicing
Blows tracking ends abruptly although patient is still exhaling	Turbine sticking	Clean turbine in warm soapy water or disinfecting solution, if problem continues a replacement turbine may be required
Calibration procedure failed or cannot be completed	Turbine may be faulty	Repeat calibration procedure, if problem persists, replace turbine or return unit for servicing
	Turbine not fitted tightly to calibration syringe	Ensure the syringe is fitted to the turbine using an adapter if needed
	Calibration syringe does not have an inspiratory seal or seal is leaking	Check with syringe manufacturer to confirm syringe is operating properly
	Shaft of the syringe is 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 maneuver.

Safety Designation per IEC 60601-1

Type of protection against electrical shock	Powered by computers that comply with IEC 60601-1 / ANSI/AAMI ES60601-1:2005 / CAN/CSA-C22.2 No. 60601-1:14.
Degree of protection against electrical shock	Type B applied part
Power Equipment	Powered by computers that comply with IEC 60601-1 / ANSI/AAMI ES60601-1:2005 / CAN/CSA-C22.2 No. 60601-1:14.
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	
SpiroUSB	Applied part, type B
Volume Transducer	Applied part, type B

WARNING: No modification of this equipment is allowed.

CAUTION: When you connect other equipment to the unit, always make sure that the whole combination complies with the international safety standard IEC 60601-1 for medical electrical systems. During measurements, connect the SpiroUSB only to computers that comply with IEC 60601-1 / ANSI/AAMI ES60601-1:2005 / CAN/CSA-C22.2 No. 60601-1:14.

WARNING: The user must not touch any voltage carrying parts and the patient at the same time or the operator must not create a “bridge” between the device I/O ports and the patient by simultaneously touching both.

WARNING: Do not connect devices that are not specified as part of the system.

WARNING: To avoid risk of electric shock, this equipment must only be connected to supply mains with protective earth.

Electromagnetic Compatibility (EMC) to EN60601-1:2007

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

The SpiroUSB has been tested to EN60606-1-2:2007, regarding the 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 SpiroUSB 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 SpiroUSB.

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

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

It is important that the SpiroUSB 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 SpiroUSB may results in increased emissions or decreased immunity of the SpiroUSB in relation to EMC performance.

The SpiroUSB should be used only with the USB extension cable provided by Micro Direct, which is referenced in the accessories section of this manual. This cable should not be used with devices other than the SpiroUSB. If the cable is extended by the user using non-approved cables, this may result in an increased level of emissions or decreased level of immunity, in relation to the SpiroUSB’s EMC. Use of the USB extension cables with devices other than the SpiroUSB, may result in an increased level of

emissions or decreased level of immunity, in relation to the other devices' EMC.

The SpiroUSB has an essential performance – the product should continue to operate correctly. In the unlikely event of a Fast Transient / ESD event occurring, the device should be reset and located away from the source of interference.

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

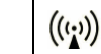
Guidance and Manufacturer's Declaration – Electromagnetic Emissions
The SpiroUSB is intended for use in the electromagnetic environment specified below. The customer or the user of the SpiroUSB should assure that it is used in such an environment

Emission Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The SpiroUSB 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 SpiroUSB 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 (USB powered)	
Voltage fluctuations / flicker emissions IEC61000-3-3	Not Applicable (USB powered)	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity
The SpiroUSB is intended for use in the electromagnetic environment specified below. The customer or the user of the SpiroUSB should assure that it is used in such an environment.

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Gudiance**
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	Supply line tests not applicable +/- 1 kV for USB Lead	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 (USB Powered)	Mains power quality should be that of a typical 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	Not Applicable (USB Powered)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SpiroUSB requires continued operation during power mains interruptions, it is recommended that the SpiroUSB be powered from an uninterruptible power supply or a battery
Power frequency (50/60 Hz) Magnetic field IEC61000-4-8	3 A / m	3 A / m	If incorrect operation occurs, it may be necessary to position the SpiroUSB 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 U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity
The SpiroUSB is intended for use in the electromagnetic environment specified below. The customer or the user of the SpiroUSB 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 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the SpiroUSB, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance (d)** $d = 1.2\sqrt{P}$
Radiated RF IEC61000-4-3	3 V/m 80 Mhz to 2.5 Ghz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 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 strength from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radios, 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 SpiroUSB is used exceeds the applicable RF compliance level above, the SpiroUSB should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the SpiroUSB

[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 SpiroUSB

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

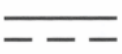
Rated Maximum Output Power of Transmitter in Watts (W)	**Separation Distance in Meters (m) according to Frequency of Transmitter**		
	150 KHz to 80 MHz ***d* = 1.2** √ P	**80 MHz to 800 MHz** ***d* = 1.2** √ P	**800 MHz to 2.5 GHz** ***d* = 2.3** √ P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
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.

Symbols

	Type B device
	In accordance with Directive 93/42/EEC
	Disposal in compliance with WEEE
	Consult the instructions for use
	Manufacturer
	Date of Manufacture
	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 (Rx only)
	Batch Code
	Reference Number

Specification of the SpiroUSB

Power supply:	Input 5V 0.1A
Dimensions:	2” x 2.4” x 3.5”
Weight:	4.6 ounces
Operating Temperature:	32 to 104^{O} F
Operating Humidity:	30% to 90% RH
Storage & Transport Pressure:	650 – 1060 hPa
Storage Temperature:	-4 to 158^{O} F
Storage Humidity:	10% to 90% RH
Predicted Values:	Various – depends upon national preference.
Transducer:	Gold Standard Bi-Directional Digital Volume.
Resolution:	10ml volume 0.03l/s flow
Accuracy:	+/-3%. To ATS recommendations – Standardization of spirometry 1994 update for flows and volumes.
Measurements:	See SPCS manual for details of all the spirometry measurements available.

Spirometry Measurements

Relaxed Expiratory Vital Capacity (VC)
Forced Expired Volume in 0.75 seconds (FEV.75)
Forced Expired Volume in 1 second (FEV1)
Forced Expired Volume in 3 second (FEV3)
Forced Expired Volume in 6 seconds (FEV6)
Forced Vital Capacity (FVC)
Peak Expiratory Flow Rate (PEF)
$FEV_{0.75}$ as a percentage of VC (FEV.75/VC)
$FEV_{0.75\ as}$ a percentage of FVC (FEV.75/FVC)
FEV_1 as a percentage of VC (FEV1/VC)
FEV_1 as a percentage of FVC (FEV1/FVC)
FEV_3 as a percentage of VC (FEV3/VC)
FEV_3 as a percentage of FVC (FEV3/FVC)
$FEV_{0.75}$ as a percentage of FEV6 (FEV.75/FEV6)
FEV1 as a percentage of FEV6 (FEV1/FEV6)
Maximum Expired Flow at 75% of FVC remaining (MEF75)
Maximum Expired Flow at 50% of FVC remaining (MEF50)
Maximum Expired Flow at 25% of FVC remaining (MEF25)
Mean Mid-Expiratory Flow Rate (MMEF)
Forced expiratory flow at 50% of volume as a percentage of VC (FEF50/VC)
Forced expiratory flow at 50% of volume as a percentage of FVC (FEF50/FVC)
Maximal voluntary ventilation indicated ($MVV_{(ind)}$)
Forced inspired volume in 1 second (FIV1)
Forced inspiratory Vital Capacity (FIVC)
Peak Inspiratory Flow Rate (PIF)
FIV_1 as a percentage of FIVC (FIV1/FIVC)
Forced inspiratory flow at 25% of inhaled volume (FIF25)
Forced inspiratory flow at 50% of inhaled volume (FIF50)
Forced inspiratory flow at 75% of inhaled volume (FIF75)
Forced expiratory flow at 50% of volume as a percentage of FIF50 (FEF50/FIF50)
The time taken between 25% and 75% of the forced expired volume (MET2575)
Forced Expiratory Time (FET)
Tidal Volume (TV)
Expiratory reserve volume (ERV)
Inspiratory reserve volume (IRV)
Inspiratory capacity (IC)
Expiratory Relaxed vital capacity (EVC)
Inspiratory vital capacity (IVC)
Breathing frequency rate (FR)
Inspiratory time (Ti)
Expiratory time (Te)
Ti as a % of total breath time (Ti/Ttot)
Tidal volume as a % of Ti (TV/Ti)

Breath Rate	BR
Breathing Time	B.T
Volume Tidal	VT
Expiratory Time – average time of expiration per breaths in seconds	Te
Inspiratory Time – average time of inspiration per breath in seconds	Ti
Total Tidal Breath Time in Seconds	TTOT=Ti + Te
Ratio of Average Expiratory and Inspiratory Breaths	Ti/Te
Average Time of Expiration per Breath as a ratio to The Total Tidal Breath Time	Ti/TTOT

Tests per subject:	5 VC maneuver 8 FVC maneuvers
Predicted Values:	Various – depends upon national preference
Transducer:	Gold Standard Bi-Directional Digital Volume

Consumables / Supporting Products

Cat. No.	Description
3314SB	Mouthpieces, Disposable Cardboard (box of 200)
3314B5	Mouthpieces, Disposable Cardboard (box of 500)
3395	Mouthpieces, Disposable Cardboard, One-way (box of 200)
3385	SpiroSafe Filter (bag of 100)
3397	Mouthpiece, Plastic, One-way (box of 200)
PSA1100	Pediatric adapter (30mm - 22mm)
3301	Mouthpieces, Disposable Cardboard (bag of 100)
3304	Nose Clips (pack of 20)
48-70	Protex Disinfectant Wipes
3325	3 Liter Calibration Syringe
ASS1041	SpiroUSB Desktop Stand
CAB1047	USB Extension Cable
TDX1043	Turbine Transducer

Customer Contact Information

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@micro-direct.com
Website:	www.mdspiro.com

Or contact your local Micro Direct distributor.

ICD-10 Codes for Spirometry

Diagnosis	Code
Acute Bronchitis	J20.0-J20.9
Allergic Rhinitis, Other	J30.81-J30.89
Allergic Rhinitis, Unspecified	J30.9
Vasomotor and Allergic Rhinitis	J30.0-J30.5
Asthma, Mild, Intermittent	J45.20-J45.22
Asthma, Mild, Persistent	J45.30-J45.32
Asthma, Moderate, Persistent	J45.40-J45.42
Asthma, Severe, Persistent	J45.50-J45.52
Asthma, Unspecified	J45.901-J45.909
Cough Variant Asthma	J45.991
Other Asthma	J45.998
Cystic Fibrosis with Pulmonary Manifestations	E84.10
Bronchiectasis	J47.0-J47.9
Encounter for Preprocedural Respiratory Examination	Z01.811
Other Interstitial Pulmonary Disease with Fibrosis in diseases classified elsewhere	J84.17
Other Specified Interstitial Pulmonary Disease	J84.89
Interstitial Pulmonary Diseases, Unspecified	J84.9
Pneumoconiosis Due to Asbestos and Other Mineral Fibers	J61

Pneumonitis	J67.0-J67.9
Pulmonary, Fibrosis	J84.10
Respiratory conditions due to inhalation of chemicals, gases, fumes and vapors	J68.0-J68.9
Respiratory conditions due to unspecified external agent	J70.9
Sarcoidosis of the Lung	D86.0
Sarcoidosis of the Lung with sarcoidosis of the lymph nodes	D86.2
Bronchiolitis, Acute	J21.0-J21.9
Bronchitis, Not Specified as Acute or Chronic	J40
Bronchospasm, Acute	J98.01
Bronchospasm, Exercised Induced	J45.990
Chronic Bronchitis, Simple	J41.0-J41.8
Chronic Bronchitis, Unspecified	J42
COPD	J44.0-J44.9
Cough	R05
Emphysema	J43.0-J43.9
Other Long Term (Current) Drug Therapy	Z79.899
Shortness of Breath	R06.02
Systemic Sclerosis with lung involvement	M34.81
Contact with and (suspected) exposure to environmental tobacco smoke (acute) (chronic)**	Z77.22

Nicotine Dependence**	F17.200-F17.299
Tobacco Use (NOS)**	Z72.0
Occupational exposure to environmental tobacco smoke**	Z57.31
Personal history of nicotine dependence**	Z87.891
Smoking (tobacco) complicating pregnancy, childbirth, and the puerperium**	O99.330-O99.335
Wheezing	R06.2

**Use additional code after the primary diagnosis to identify any tobacco use, dependence or exposure to tobacco smoke