MicroLoop
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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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

94150 - Vital Capacity
Total (separate procedure)

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-9-CM Codes on back cover

Contents

Introduction

The MicroLoop is a mains/battery operated portable spirometer with the unique combination of ease of use and sophistication. Ease of use is assured through the use of context sensitive help screens, accessed at a touch of a button, that explain every MicroLoop feature.

The MicroLoop is supplied with a cradle that may be connected with the USB cables supplied, to either a PC or a printer. The cradle also connects to the mains adapter so that the MicroLoop's batteries may be charged while it is placed in the cradle. The blue lights on the cradle indicate that it is being powered either by a PC connection or by the mains adapter. When either of these sources of power is connected to the cradle, it is ready to charge your MicroLoop.

The MicroLoop utilizes a **single patient use** disposable mouthpiece or filter that must be disposed of after use.

The MicroLoop provides a suggested interpretation **that must be supported by clinical judgment.**

The MicroLoop uses a 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. The transducer is insensitive to the effects of condensation and temperature and avoids the need for individual calibration prior to performing a test.

Test results may be uploaded to a PC using Spirometry PC Software and patient details may be downloaded to the MicroLoop.

Contraindications

- Acute disorders affecting test performance (e.g. vomiting, nausea, vertigo)
- Recent eye surgery (increases in intraocular pressure during spirometry)
- Oral or facial pain exacerbated by a mouthpiece
- Recent myocardial infarction
- Post-operative thoracic surgery
- Hyperventilation syndrome

Note: Extensive exhalation might lead to syncope.

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

Overview

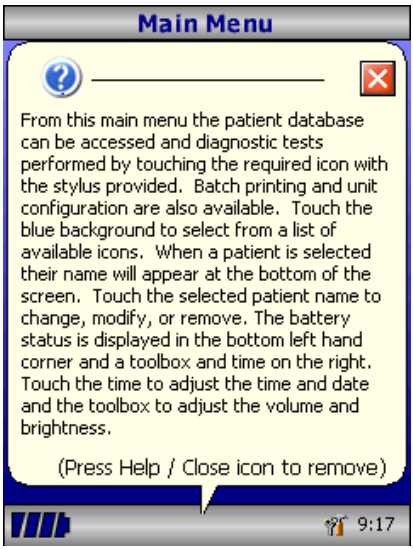
The MicroLoop uses a touch screen with icons representing each function available. A stylus, housed in the left hand side of the unit, is provided for icon screen activation.

Touch the displayed time to adjust time and date.

Unused icons may be disabled by touching the blue background and selecting from the list displayed.

Touch the toolbox icon to adjust volume and brightness.

Four levels of battery charge are indicated by the segmented battery icon.



When this icon turns red the battery is nearly exhausted and the batteries must be charged – see Charging Procedure. The complete functionality is described on the help screen.

This is obtained by pressing the help button (?).

Help text exists for every screen viewed during the operation of the MicroLoop.

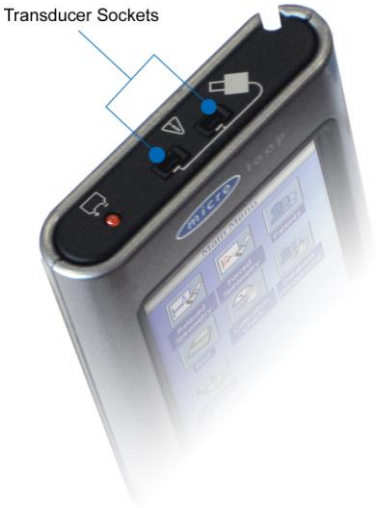
You are recommended to make full use of the extensive Help screens provided.

Intended Use

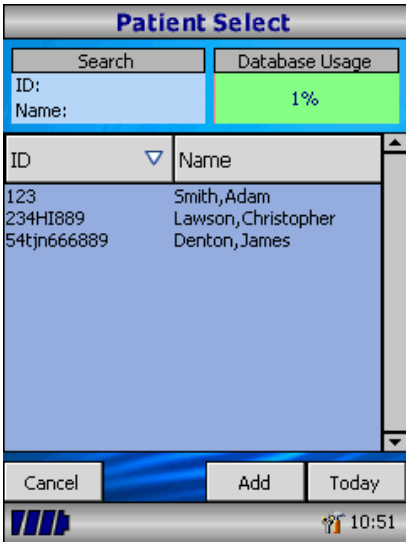
The MicroLoop spirometer is intended for prescription use only, to measure the maximal volume and flow of air that can be moved in and out of a patient's lungs. The system is intended for use with pediatric (4 to 17 years of age) and adult (18 to 99 years of age) patients in hospitals, physician offices,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

Getting Started

When performing a spirometry test the recommended workflow is to enter the patient's details, or retrieve them from memory, perform the required test and then print and save the results.



Please ensure that the turbine transducer is plugged in to either of the two sockets on the top of the instrument.



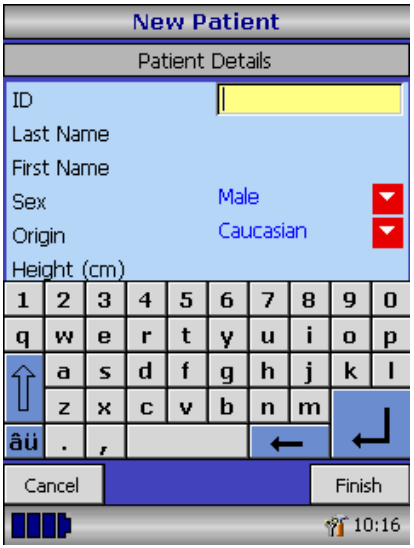
Select the 'Patients' icon to enter the patient database.

The required patient may be selected from the stored patient list.

If the patient details have not been previously stored then select 'Add' to enter the new patient's details. The patient details may also be downloaded from the Spirometry PC Software.

Once selected, the patient's name will appear at the bottom of the screen.

Use the help button to obtain further information.

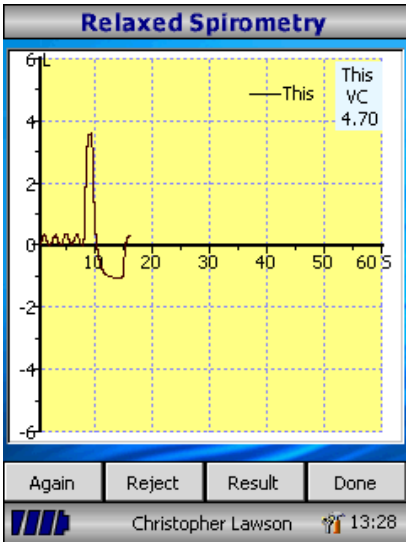


To add a patient to the database, use the on screen keyboard to type a unique patient ID and then touch the enter key. You will then be prompted for Last Name, First Name, Sex, Ethnic Origin, Height, Weight, date of Birth and Factor.

A factor can be applied when testing individuals of other ethnic origins who would not normally be tested against the countries set of predicted values. The factor alters the predicted value set on volume indices by the percentage applied. If NHANES predicted values are selected, then the ethnic origin field should be chosen but a factor correction is not required.

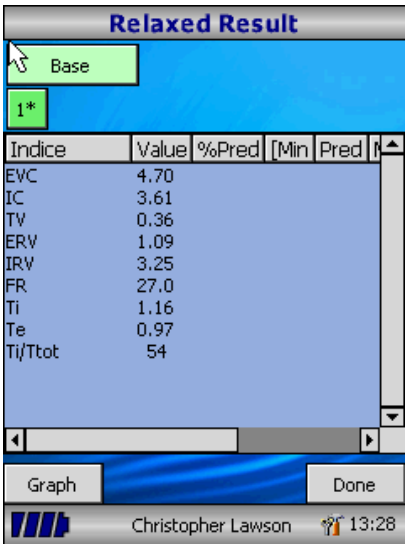
Once all the patient details are added, the patient is added to the database and the main menu is displayed with the patient name displayed at the bottom of the screen. From the main menu select the required test, by touching the icon with the stylus.

If the displayed patient is not required for testing then touch the patients name and options to change or remove the current patient will become available.



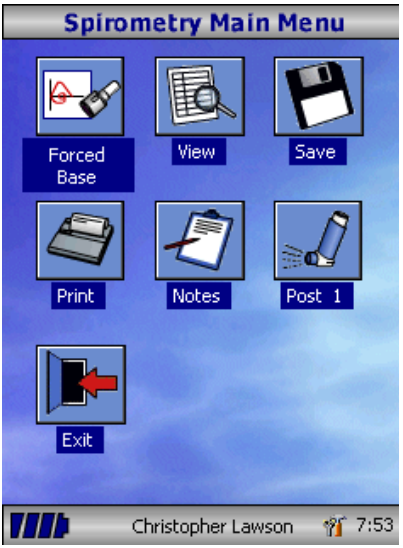
If Relaxed Spirometry is selected then a volume/time graph will be displayed. Note the unit may be customized to perform a relaxed Vital Capacity with tidal breathing or from a single expiration or single inspiration.

When a maneuver has been obtained select 'Results' to view the indices, 'Again' to repeat the maneuver, 'Reject' to delete the maneuver or 'Done' to end the test.



All the active indices are displayed for any of the maneuvers selected together with an option to review the volume/ time curves. The active indices listed can be changed by using the customization option.

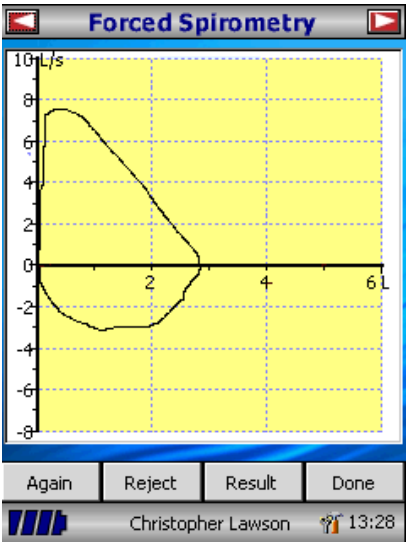
Select 'Done' to proceed to the Spirometry Main Menu.



From this menu the results of the test may be viewed, saved, or printed and notes may be added.

It is also possible to proceed to a forced baseline spirometry test, or a post medication relaxed spirometry test.

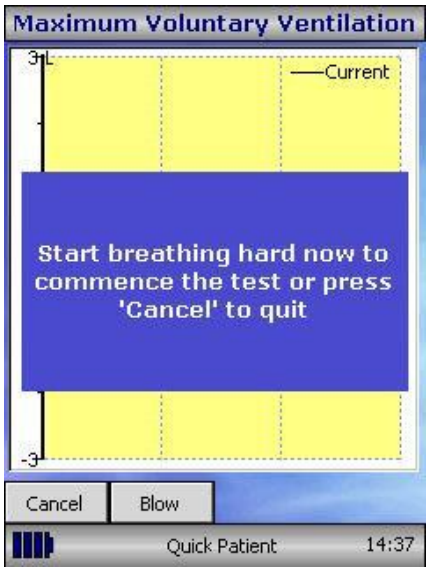
Select 'Exit' when all the required functions have been used.



If forced spirometry is selected the default graph will be displayed. This may be changed by touching the arrows at the top of the screen. Flow/Volume, Volume/time or child incentive default displays may be selected using the customize option from the main menu.

When the spirometry maneuver has been completed options to repeat the test, reject the test, and view results will be available.

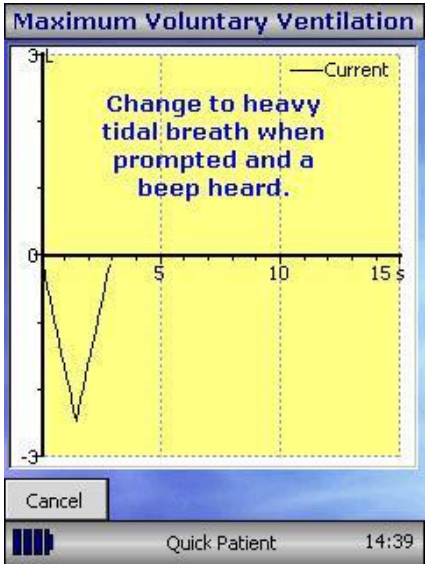
At the end of the test options to view results, save results, print results, and to add notes will be available from the spirometry main menu.



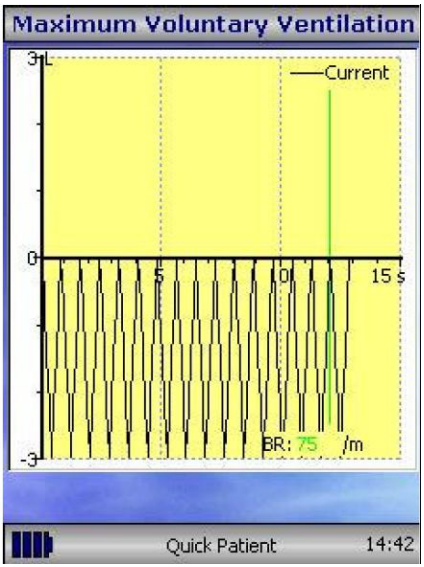
Select the MVV icon to select this mode of testing and the display will instruct the patient to start breathing hard to commence the test.

It is recommended that the patient perform 3 tidal breathing maneuvers prior to performing hard and fast rapid breathing (required for the MVV maneuver).

The patient should be instructed to tidal breath. The tidal breaths are automatically detected prior to commencing the MVV maneuver.

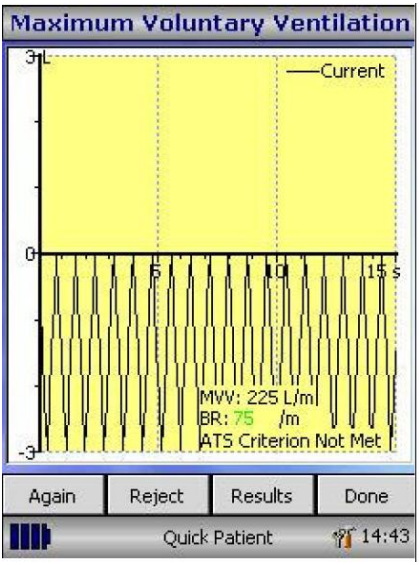


Once tidal breathing is complete, the display will change and an audible beep heard to instruct the patient to start rapid, fast breathing. The start button should be touched using the stylus to start registering the MVV maneuver.



The current maneuver will be displayed in black. During the maneuver, the breath rate (BR) will be displayed in green if the breath rate is acceptable (> 65 breaths per minute). If the breath rate falls below this level, it will be displayed in red to show the operator that the patient needs to be instructed to breathe harder and faster during the maneuver. After 12 seconds of hard, fast and rapid breathing, the display will show a green line indicating 12 seconds of the maneuver have elapsed – the patient should be encouraged to continue until the display changes to signify the end of the test. The MVV rate, the % variation between maneuvers, the breath rate and an ATS quality warning for the maneuver will be displayed.

Note: The patient's effort is acceptable when patient made a maximum effort indicated to the user by the breath rate being displayed in green (> 65 breaths per minute); and the maneuver lasted a full 12 seconds indicated by a green line being displayed. The patient should ideally continue until the test is automatically terminated at 15 seconds with no interruption (i.e. did not cough)

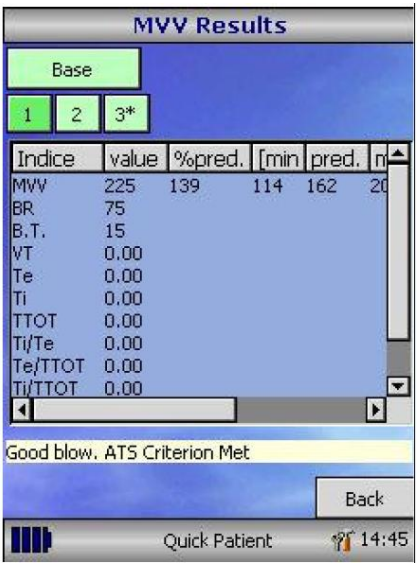


Once the test has finished, the display will show current test (shown in black – if more than one maneuver has been performed, the best maneuver will also be displayed in blue) the MVV rate, the % variation between maneuvers, the breath rate and the ATS quality warning for the test session.

Select ‘Again’ to repeat the maneuver, ‘Reject’ to reject the current maneuver, ‘Results’ to display a list of indices, the values obtained, % predicted where applicable and also a quality statement concerning the test session.

To meet the ATS quality criteria for a good blow, the maneuver should last 15 seconds with a breath rate greater than 65 breaths per minute. The ATS reproducibility criterion is two maneuvers with a good blow and the MVV variability between maneuvers should not exceed 20%.

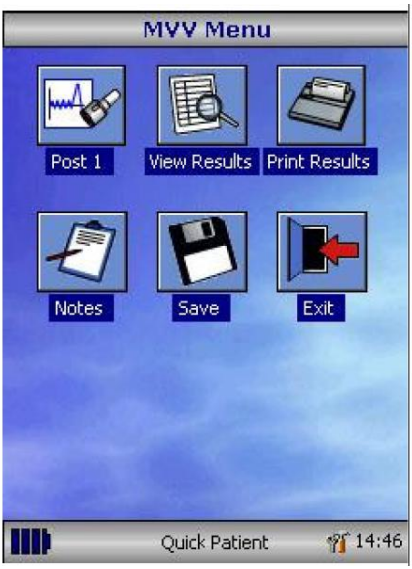
Note: The MVV test is an exhausting test. It should not be repeated without a rest period. Some elderly or ill people cannot repeat this test even after the rest period.



Select ‘Back’ to return to testing and the current maneuver.

NOTE: If the breathing rate is insufficient (less than 65 breaths per minute) then the BR value will be displayed in red – an MVV value will be calculated and a message displayed that the MVV results was extrapolated from a maneuver with a poor breath rate.

Once the number of maneuvers has been completed and the test session has finished, select ‘Done’ and the results with selected indices will be displayed. Each maneuver will be numbered and the best maneuver highlighted with an asterisk (*). Select ‘Graphs’ to view the graphs of the currently selected maneuver and best maneuver. Select ‘Set Best’ to manually select the best maneuver. Select ‘Done’ to return to the main MVV menu.

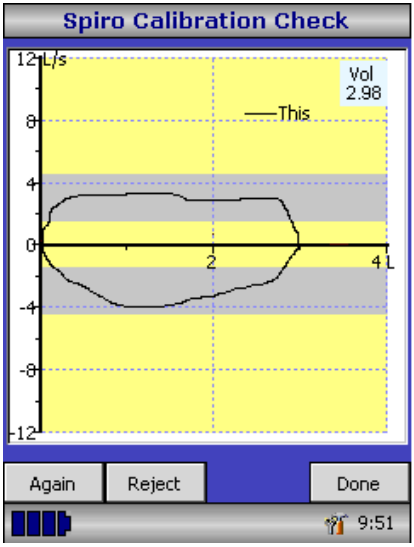


Once testing is complete, the MVV main menu will be displayed. Select ‘Post 1’ to perform a post medication test following the same procedures as the pre test. You are also able to ‘View Results’, ‘Print Results’, add ‘Notes’ and “Save’ the results by touching the appropriate icon. Select ‘Exit’ to return to the main menu.

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 that a calibration check is performed periodically and after the transducer was removed for cleaning.



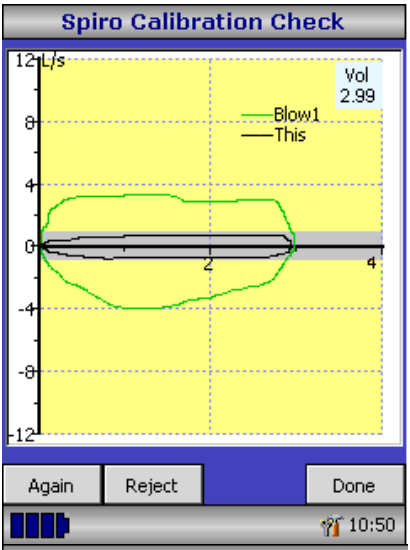
Connect a 3 liter syringe to the transducer with the minimum of adapters and empty by pushing the handle fully in.

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

Select ‘Calibration Check’ from the main menu and then select ‘Check Calibration’.

Fill the syringe by pulling the handle at a constant rate until the end stop is reached and then immediately empty the syringe completely. Try to maintain a flow rate that keeps the trace within the grey bands on the display.

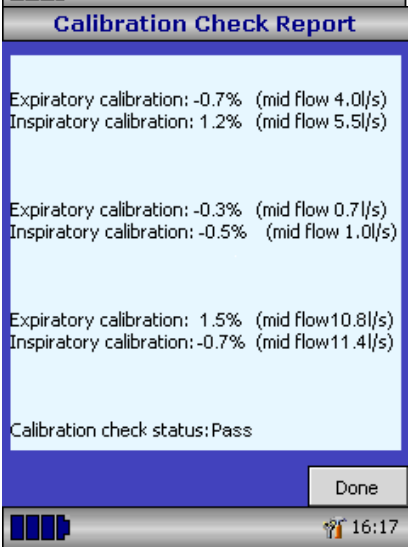
Select ‘Reject’ to retry the calibration check at the required flow rate.



Select ‘Again’ to repeat the calibration check at a low flow rate.

Select ‘Again’ to repeat the calibration check at a high flow rate.

When a calibration check at all three flow rates has been completed select ‘Done’ to view the calibration check report screen.



The calibration error for expiration and inspiration at each flow rate are displayed. The calibration error should be less than 3.5%. If a greater error is shown, repeat the procedure ensuring that the syringe is emptied and filled in a smooth manner without jerking the handle. If an error greater than 3.5% is still shown, inspect the turbine transducer and clean if necessary.

Customization

The ‘Customize’ option from the main menu may be used to configure many of the features of your MicroLoop and are divided into system and spirometry options.

System options allow you to configure the following:

Language
Height and weight units
Date format
Date separator
Color or monochrome printing (on external printer)
Personalized printout heading

Spirometry options allow you to configure the following:

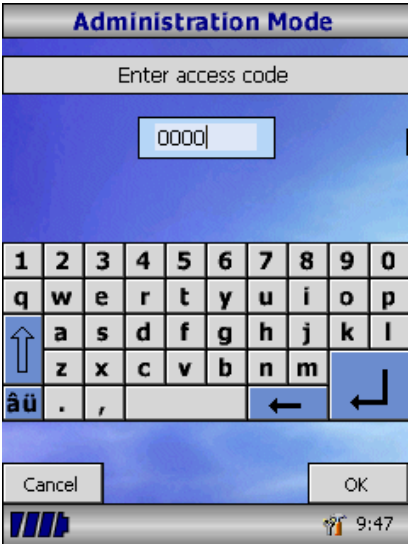
Relaxed spirometry mode (with or without tidal breathing)
Predicted value sets
Predicted area or line display
Display default
Incentive display type
Printed graphs
Best test criteria
Interpretation and Lung Age indication
Dyspnea score and smoking status
Daily calibration reminder
Manual temperature adjustment
Indices selection

MVV options allow you to configure the following:

Choice of predicted values
Display ambient temperature during MVV test
Include graph of MVV maneuver in the final printout

Note: that when the language is selected, the height and weight units, date format, and date separator will be automatically changed. However this automatic selection may be overridden manually.

Administration Mode



Administration mode allows the administrator to restrict the availability of functions to the user by disabling icons on the main menu. For example, after the unit has been configured to the administrator's requirements, disabling of the 'Customize' icon will prevent any further adjustment by the user. Similarly, disabling of the 'Database Management' icon will prevent the user from deleting any patient details or test results.

To enter administration mode, turn the unit on while holding down the help key. The default access code is 0000. Type this number in using the on-screen keyboard. A number of functions are now available.

Please note: if you change the access code, make sure you document the number in case you forget it.

Press the help button to obtain a full description of the functions.

Printing

Using the cables provided, connect the mini USB A/B socket on the back of MicroLoop cradle to the input socket on the printer. For a list of compatible printers refer to the web site www.micro-direct.com or call Micro Direct customer service at 1-800-588-3381.

It is recommended that during printing, the batteries are placed on charge with the cradle connected to the mains adapter.

NOTE: Keep the printer out of reach of the patient at all times.

NOTE: Disconnect the printer during live measurements.

Charging Procedure

The MicroLoop should be fully charged before first use. Plug the AC adapter into the mains supply and plug the adapter output plug into the power input socket on the cradle. The orange charging light on top of the unit will flash to indicate charging and will turn on constantly to indicate full charge. The blue lights on the cradle will also be illuminated.

The batteries will take approximately 4 hours to become fully charged.

Note: Use only the AC adapter supplied. Use of any other type may cause permanent damage to the MicroLoop and cause a fire or electrical hazard. Do not plug in and remove the power lead from the AC adapter repeatedly.

Note: To ensure maximum battery life, remove MicroLoop from cradle once fully charged.

PC connection using SPCS

The Spirometry PC Software (SPCS) is an easy to use PC based windows application that interfaces to the MicroLoop via the USB port. It incorporates a database into which patient details can be entered and downloaded to the MicroLoop or test results may be uploaded from the MicroLoop to the PC.

Using SPCS and the MicroLoop, live blows can be performed with the PC directly controlling the operation of the MicroLoop.

The results and graphs produced are displayed directly on the PC screen.

The spirometer is connected from the USB port on the PC, to the USB port on the cradle using the USB cable provided with the Spirometry PC Software.

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

It is recommended that while the unit is connected to a computer, the MicroLoop remains in the cradle.

Looking after your Spirometer

Please observe the following precautions:

- Do not touch the screen with fingers. Use only the stylus provided.
- Use only a damp, lint free, cloth to clean the screen.
- Do not keep the spirometer in a damp place or expose it to extremes of temperature.
- Do not direct the transducer holder towards a strong light source while operating the spirometer.
- Check the AC charger for compatibility with local power rating.

Cleaning Instructions

Disinfection of contaminated parts is only effective after having them carefully pre-cleaned. Micro Direct recommends the tested solution of PeraSafe sterilizing power (#SSC5000) for pre-cleaning and disinfection. If a different solution is used, please follow the given manufacturer's instructions.

The device must not be wiped with any aqueous solutions and must not be exposed to solvents i.e. alcohol or chloride solutions as there are electronic components inside that will be permanently damaged.

CAUTION: Switch off the device and always unplug the MicroLoop before cleaning.

External Surfaces of the Spirometer

CAUTION: Do not attempt to wash or immerse the MicroLoop 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 wipe with sterile wipes or a damp cloth that has been immersed in a cold sterilizing solution.

CAUTION: Do not wipe the touch screen.

Cleaning Accessories

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

When using the disposable cardboard mouthpieces (adult: #3314SB or #3314B5, pediatric: #3301) without a filter and under the prerequisite that the patient was instructed only to exhale into the transducer, the following parts have to be cleaned once a day: transducer and pediatric adapter (if one was used).

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 after 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:

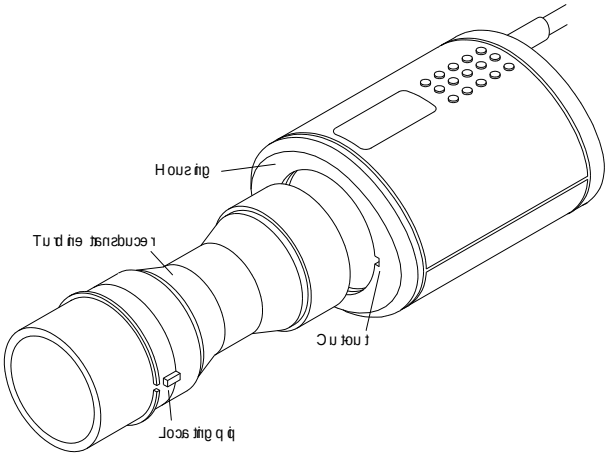
1. Rotating the turbine transducer anti-clockwise until the locating pip lines up with the small rectangular cut-out in the housing as shown below.

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 cold disinfecting solutions e.g. PeraSafe (#SSC5000) for a maximum of 10 minutes (Alcohol and chloride 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.



Servicing

There is no routine maintenance required for the MicroLoop and there are no user serviceable parts in this instrument. Please return the unit to Micro Direct or an authorized agent if servicing is required.

If your unit requires service or repair, please see page 35 for contact details

Troubleshooting Information

Problem	Possible Cause	Solution
Display 'freezes' and the unit does not respond to any key presses	Multiple icons have selected or accidently pressed	Hold the on/off button down until the unit switches off and then turn on again
No display present	Charger not connected or battery is exhausted	Connect charger to the mains or return the unit for servicing
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 unit for servicing
Blows tracking ends abruptly although patient is still exhaling	Turbine sticking	Clean turbine in warm soapy water or sterilizing solution; if problem continues, a replacement turbine may be required
Battery does not hold a charge	Exhausted battery	
	Mains charger fault	Replace the mains charger
	MicroLoop not seated in cradle correctly	Reposition unit in the cradle correctly, when charging the orange light will be illuminated

Stylus does not register icons on the display	Touch screen display requires calibration	Select the calibration check icon and choose touch screen and follow the instructions
Icons missing from the display	Icon has been de-selected	Hold stylus on the blue area of the display, a list will appear, ensure required icon is selected
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 necessary
	Calibration syringe does not have an inspiratory seal or seal is leaking	Ensure you are using manufacturers recommended syringe
	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	Internally powered Equipment and Class I
Degree of protection against electrical shock	Type B applied part
Power Equipment	Battery type: Lithium ion polymer LP385085, 3.7V, 1600mAh
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	
MicroLoop	Applied part, type B
Volume Transducer	Applied part, type B

WARNING: No modification of this equipment is allowed.

Note: 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 MicroLoop only to printers and computers that comply with IEC/EN 60601-1 / UL 60601-1.

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

During database upload, the MicroLoop may be connected to a computer that complies with EN 60950 – 'Information technology equipment – Safety – Part 1: General requirements'.

IMPORTANT: Only use the mains adapter supplied (PSU1013 5V DC 2.0A). The adapter contains a transformer. Do not cut off the adapter to replace it with another plug as this causes a hazardous situation. Turn off the mains supply or remove the MicroLoop from the charger once the battery display shows fully charged.

- The adapter transforms the mains voltage (100-240 Volts) to a safe voltage (5V DC)
- Make sure the adapter does not get wet
- Do not use a damaged adapter
- Always unplug your MicroLoop before cleaning

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

Note: If an MPSO (Multiple Portable Socket Outlet) is used with the system, the maximum permitted load should not be exceeded. Do not connect electrical equipment that has not been supplied 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 MicroLoop 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 MicroLoop 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 MicroLoop.

Despite the testing of the MicroLoop that has been undertaken, normal operation of the MicroLoop can be affected by other electrical/electronic equipment and portable and mobile RF communications equipment.
As the MicroLoop is medical equipment, special precautions are needed regarding EMC (electromagnetic compatibility).

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

The MicroLoop should be used only with the accessories (USB cables, mains adapter, cradle and turbine transducer) supplied (which are referenced in the accessories section of this manual). None of the MicroLoop 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 MicroLoop's EMC. None of the MicroLoops accessories should be used with other devices, as this may result in an increased level of emissions or decreased level of immunity, in relation to the other device's EMC.

The MicroLoop 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 MicroLoop should not be used adjacent to or stacked with other equipment. If adjacent or stacked use with other equipment is necessary, the MicroLoop 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 MicroLoop is intended for use in the electromagnetic environment specified below. The customer or the user of the MicroLoop should assure that it is used in such an environment		
Emission Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The MicroLoop 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 MicroLoop 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	Class A	
Voltage fluctuations / flicker emissions IEC61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity The MicroLoop is intended for use in the electromagnetic environment specified below. The customer or the user of the MicroLoop 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	+/- 2 kV for power supply lines Input/output line tests not applicable (< 3 m)	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	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment

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% 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 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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MicroLoop requires continued operation during power mains interruptions, it is recommended that the MicroLoop 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 MicroLoop 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 MicroLoop is intended for use in the electromagnetic environment specified below. The customer or the user of the MicroLoop 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 MicroLoop, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance (d)** $d = 1.2\sqrt{P}$

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
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 strengths 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 MicroLoop is used exceeds the applicable RF compliance level above, the MicroLoop should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the MicroLoop			
[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 MicroLoop

The MicroLoop is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MicroLoop can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MicroLoop 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 equipment 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

Caution: Consult the accompanying document

Manufacturer

Date of Manufacture

Serial Number

Direct Current

Single Patient Use

Federal U.S. law restricts this device to sale by or on the order of a physician (Rx only)

Medical Device listing mark for US and Canada by SGS Testing Services recognized by the American Occupational Safety and Health Administration (OSHA) for electrical safety and compliance

Specifications

General

Storage :	>2000 tests including Flow/Volume loops and Volume/Time curves
Printer Output:	PLC3 compatible Hewlett Packard USB printers.
Display:	Color 1/4VGA LCD.
Power supply:	Input 100 to 240V, 50 to 60Hz. Output 5V 2.0A (Class 1) Type:MENB1010A0500F02
Battery Pack:	Rechargeable Lithium Ion Polymer 3.7V 1600mA-hours.
Battery Life:	Approximately 30 hours with a fully charged new battery
Dimensions:	4.7” x 3.1” x <1” - Transducer 2” x 2.4” x 3.5”
Weight:	Unit: 7.1 ounces
Operating Temperature:	32 to 104 degrees Fahrenheit
Operating Humidity:	30% to 90% RH
Transport and Storage Temperature:	-4 to 158 degrees Fahrenheit
Transport and Storage Humidity:	10% to 90% RH

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:	Micro Medical 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.

Consumables / Supporting Products

Cat. No.	Description
3314SB	Adult Disposable Mouthpieces (200 per box)
3314B5	Adult Disposable Mouthpieces (500 per box)
3395	MicroCheck One-way Mouthpieces (200 per box)
3301	Pediatric Disposable Mouthpieces (100 per bag)
PSA1100	Pediatric Adaptor
3385PG	SpiroSafe Pulmonary Filters (50 per box)
3385	SpiroSafe Pulmonary Filters (100 per box)
SSC5000	PeraSafe Sterilizing Powder 81g (to make up 5 liters of solution)
3304	Nose Clips (20 per bag)
3325	3 Liter Calibration Syringe
SPC1000	Spirometry PC Software
CAB7800	USB Lead (PC)
CAB7801	USB Lead (Printer)
ASS1244	Cradle
PSU1013	Mains Adapter
ASS1280	Battery
TDX1048	Turbine Transducer
ASS1206	Transducer Head Assembly

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.

ICD-9 Codes for Spirometry

Diagnosis	ICD-9-CM Codes
Smokers over 40	491.0
Shortness of Breath	518.82
Chronic Cough	464.4, 493.9
Frequent Coughs	460 or 465, 465.0, 465.8, 465.9
Allergic Rhinitis	506, 506.0, 506.1, 506.2, 506.3, 506.4, 506.9
Occupational Exposure to Dust or Chemicals	506, 506.0, 506.1, 506.2, 506.3, 506.4, 506.9
Scoliosis	737, 737.0, 737.1, 737.10, 737,12, 737.19, 737.2, 737.20, 737.21, 737.22, 737.29, 737.3, 737.30, 737.31, 737.32, 737.33, 737.34, 737.39, 737.4, 737.40, 737.41, 737.42, 737.43, 737.8, 737.9
Pigeon Chest	738.3, 754.82
Barrel Chest	783.3
Diagnosis of Asthma	493, 493.0, 493.1, 493.2, 493.9
Diagnosis of Bronchitis	491, 491.0, 491.1, 491.2, 491.8, 491.9
Diagnosis of other COPD	496
Pre-Operative Evaluation	518.5
Wheezing	786.09
High Risk Medication	V58.69