MicroLab
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-10-CM Codes on back cover

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Introduction

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

The MicroLab 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 the optional Spirometry PC Software and patient details may be downloaded to the MicroLab.

Stored data may be printed to the integral thermal or uploaded to a PC using the optional Spirometry PC Software (SPCS).

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.

Indication for Use

The MicroLab 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.

 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.

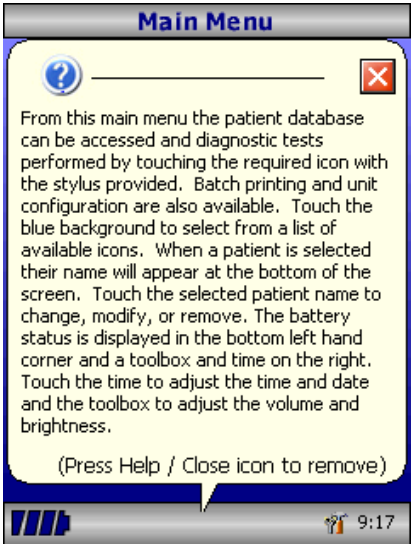
Overview

The MicroLab 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. Touch the toolbox icon to adjust volume and brightness.

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

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.



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The complete functionality is described on the help screen.

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

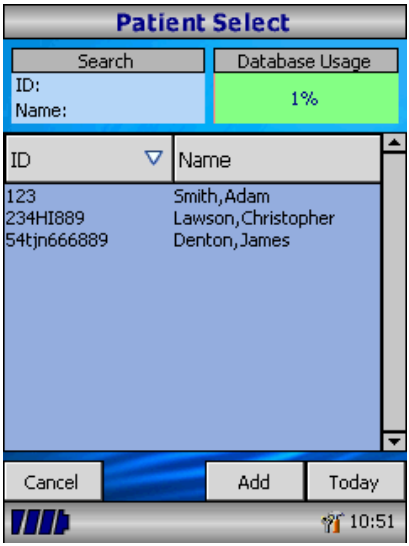
Help text exists for every screen viewed during the operation of the MicroLab.

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

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 right-hand side of the instrument.



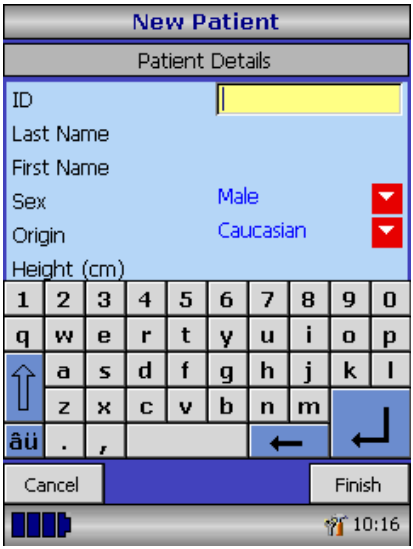
Select the 'Patients' icon to enter the patient database.

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

If the patient details have not been previously stored, select 'Add' to enter the new patient's details. The patient details may also be downloaded from the optional 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.

The following factors are recommended when using ECCS normal values:

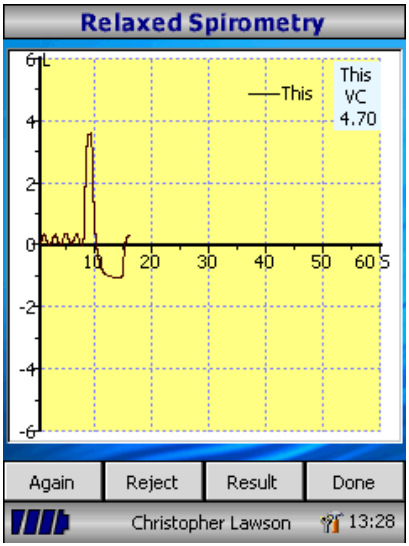
Hong Kong Chinese	100%
Japanese American	89%
Polynesians	90%
North Indians and Pakistanis	90%
South Indians and those of African descent	87%

Ref: Lung Volumes and Forced Ventilatory Flows. P.H. Quanjet et al. Eur Respir J, 1993, 6, Suppl. 16p5-40.

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.

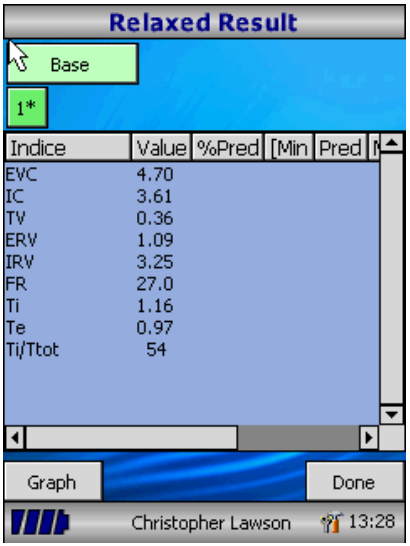
From the main menu select the required test, by touching the icon with the stylus.

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



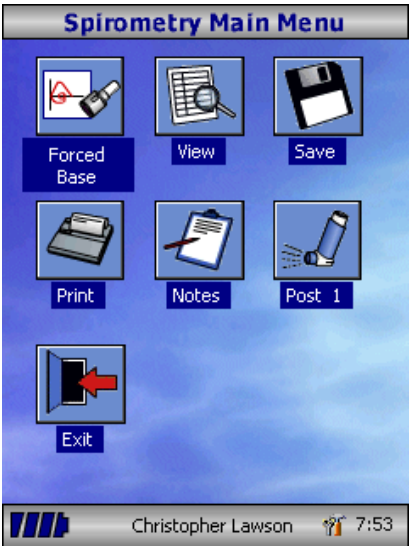
If Relaxed Spirometry is selected, a volume/time graph will be displayed. Note the unit may be customized to perform a relaxed Vital Capacity with tidal breathing or from a single expiration or single inspiration.

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.

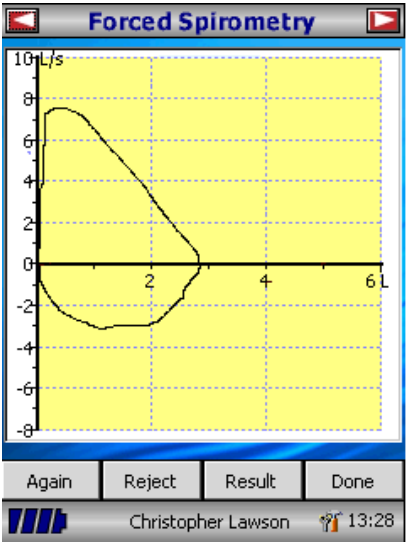
Select ‘Done’ to proceed to the Spirometry Main Menu.



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.

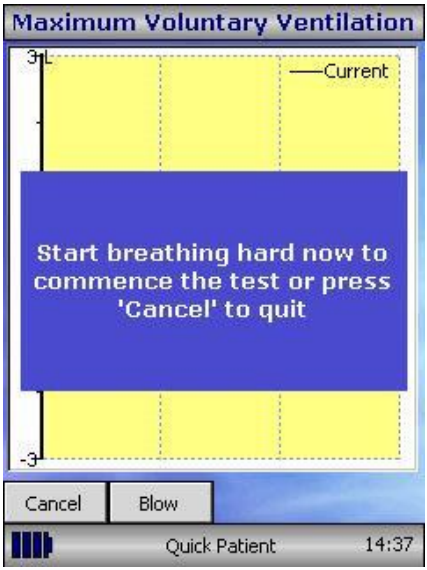
Select 'Exit' when all the required functions have been used.



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.

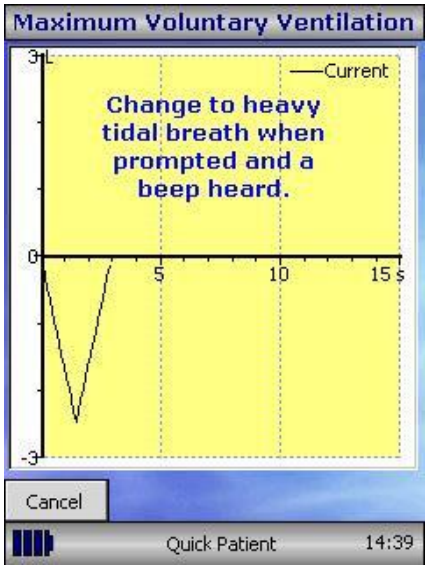
At the end of the test options to view results, save results, print results, and to add notes will be available from the spirometry main menu.



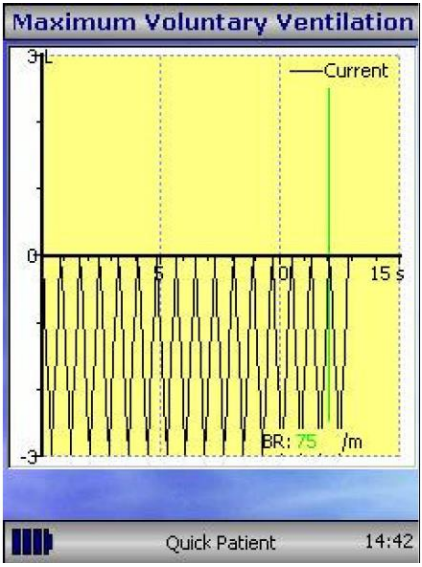
Select the MVV icon to select this mode of testing and the display will instruct the patient to start breathing hard to commence the test.

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.

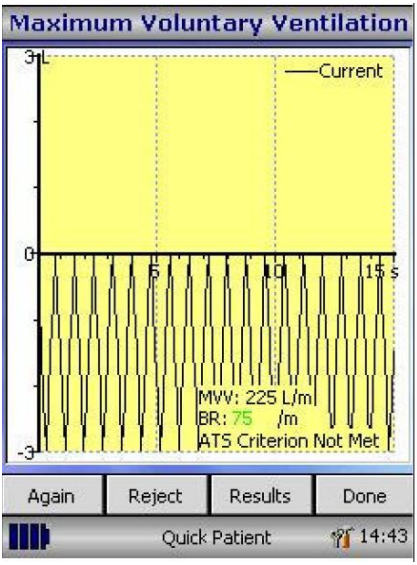


Once tidal breathing is complete, the display will change and an audible beep heard to instruct the patient to start rapid, fast breathing. The start button should be touched using the stylus to start registering the MVV maneuver.



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)

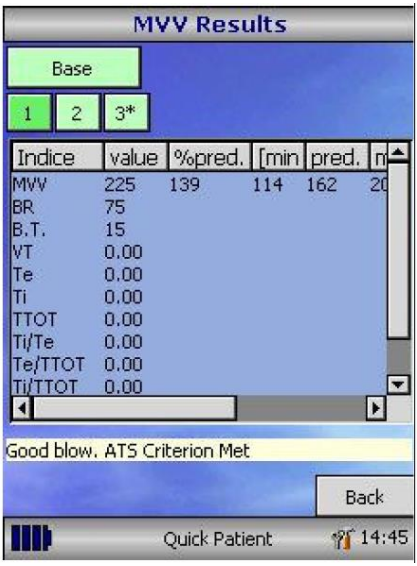


Once the test has finished, the display will show current test (shown in black – if more than one maneuver has been performed, the best maneuver will also be displayed in blue) the MVV rate, the % variation between maneuvers, the breath rate and the ATS quality warning for the test session.

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 a quality statement concerning the test session.

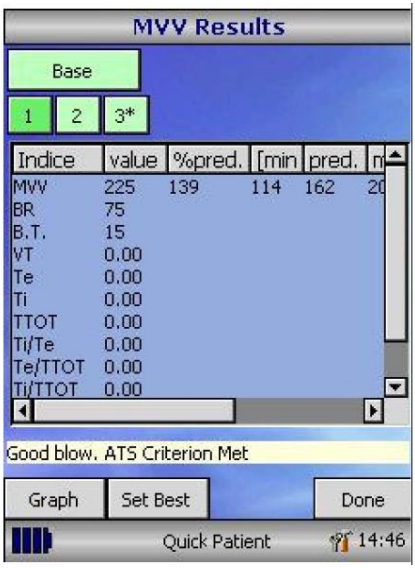
To meet the ATS quality criteria for a good blow, the maneuver should last 15 seconds with a breath rate greater than 65 breaths per minute. The ATS reproducibility criterion is two maneuvers with a good blow and the MVV variability between maneuvers should not exceed 20%.

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.

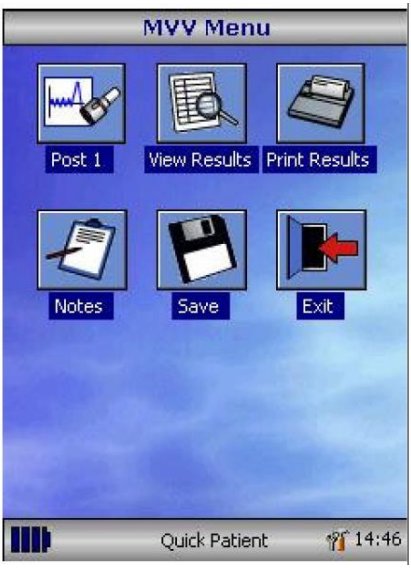


Select ‘Back’ to return to testing and the current maneuver.

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.

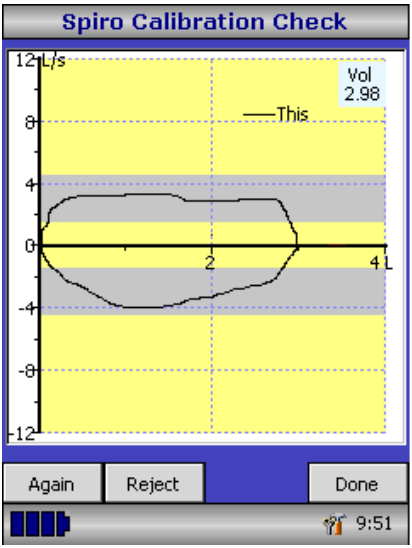


Once testing is complete the MVV main menu will be displayed Select the appropriate icon to allow a Post 1 MVV test to be performed, View Results, Print Results, add notes for the patient's examination, Save the tests or Exit to return to the main spirometer menu.

Calibration Check (Verification)

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, it is recommended that a calibration check (verification) is performed periodically and after the transducer was removed for cleaning.



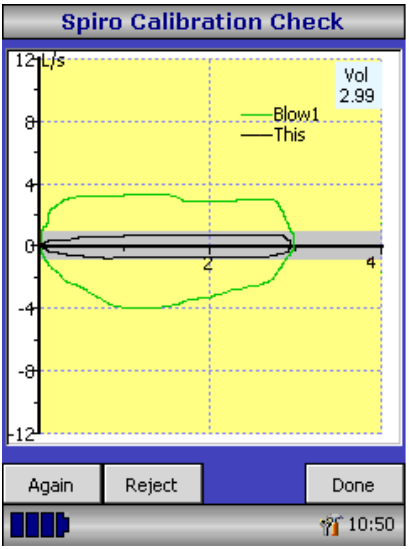
Connect a 3-liter syringe to the transducer with the minimum of adapters and empty by pushing the handle fully in.

Note: It is recommended that the transducer is disinfected prior to a calibration check (verification) 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.

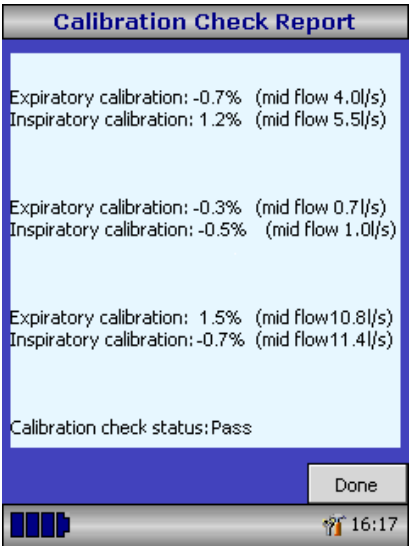
Select ‘Reject’ to retry the calibration check (verification) at the required flow rate.



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

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

When a calibration check (verification) at all three flow rates has been completed select ‘Done’ to view the calibration check (verification) 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 MicroLab and are divided into system, spirometry options and MVV options.

System options allow you to configure the following:

Language
Height and weight units
Date format
Date separator
Personalized printout heading

Spirometry options allow you to configure the following:

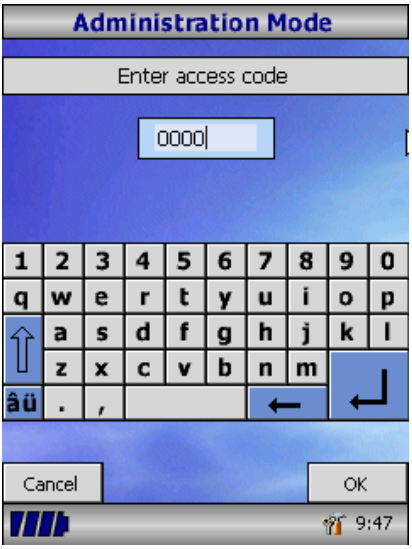
Relaxed spirometry mode (with or without tidal breathing)
Predicted value sets
Predicted area or line display
Display default
Incentive display type
Printed graphs
Best test criteria
Interpretation and Lung Age indication
Dyspnea score and smoking status
Daily calibration reminder
Manual temperature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

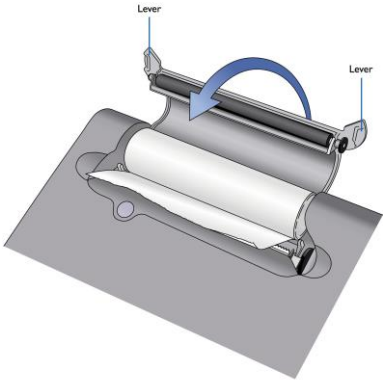
Select the 'Change Access Code' icon in order to enter your p

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.

Paper Loading

To load a new roll of thermal paper, lift the paper cover using the side levers, place the paper into the compartment as shown and close the cover firmly. It is recommended that only Micro Direct thermal printer paper (Cat No. 3327) be used with the MicroLab to avoid damage to the thermal printer head.



To tear off the paper pull the paper towards you and to the right as shown below:

Switching Off

The unit is switched off by pressing the On/Off button. The unit can be disconnected from the mains by unplugging the charger from the mains socket or unplugging the USB cable if no mains supply is connected.

Charging Procedure

The MicroLab's internal batteries are discharged when shipped from the factory and should be fully charged on first use. If the MicroLab is not for a few months, it must be recharged every three months to keep the battery alive. A fully charged device will hold the charge for a few months. Plug the AC adapter into the mains supply and plug the adapter output plug into the power input socket on the right-hand side of the instrument. The orange charging light next to the power input socket will flash to indicate charging and will turn on constantly to indicate full charge.

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 MicroLab and cause a fire or electrical hazard. Do not plug in and remove the power lead from the AC adapter repeatedly.

Please Note: Dispose of the waste battery in accordance with your local waste management regulations.

PC connection using SPCS

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

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

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 right-hand side of the instrument using the USB cable provided with the Spirometry PC Software.

Note: Always keep the PC and monitor out of reach of the patient.

It is recommended that while the unit is connected to a computer, the mains adapter is used.

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.

Product Lifetime

The MicroLab spirometer is designed for a product lifetime of 7 years.

Cleaning Instructions

Disinfection of contaminated parts is only effective after having them carefully pre-cleaned. Micro Direct recommends using a cold disinfectant solution that is NOT chlorine or alcohol based for pre-cleaning and disinfection. Please follow the 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 MicroLab before cleaning.

External Surfaces of the Spirometer

CAUTION: Do not attempt to wash or immerse the MicroLab 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 disinfecting wipes or a damp cloth that has been immersed in a cold disinfectant solution, when required.

CAUTION: Do not wipe the touch screen.

Cleaning the Accessories

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

When using the disposable cardboard mouthpiece (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 immediately 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:

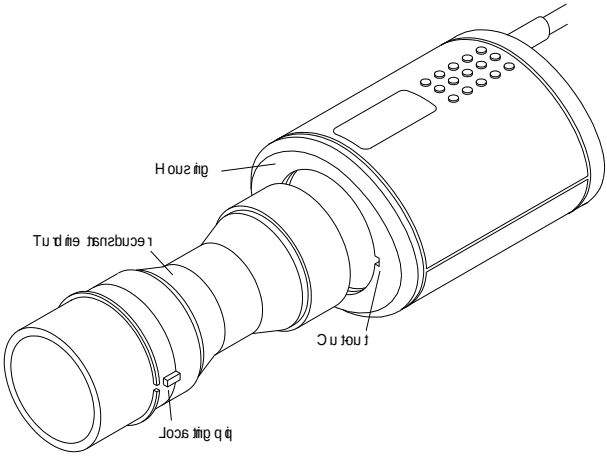
1. Rotating the turbine transducer anti-clockwise until the locating pip lines up with the small rectangular cut-out in the housing as shown below.

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 for a maximum of 10 minutes (Alcohol and chlorine solutions MUST be avoided).

4. After cleaning/disinfecting, the transducer should be immersed briefly in distilled water and left to dry.

5. Re-assemble the mouthpiece holder.



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

Servicing

There is no routine maintenance required for the MicroLab 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

Should you encounter problems operating your MicroLab meter, please consult the table below:

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 (approximately 10 seconds) 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 and leave unit to fully charge, 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 disinfecting solution; if problem continues, a replacement turbine may be required
Battery does not hold a charge	Exhausted battery	Replace the battery or return the unit for servicing
	Mains charger fault	Replace the mains charger
Paper not printing	Check paper is housed in printer compartment correctly	Refer to section "paper loading" of this manual and follow the instructions.
	Incorrect thermal paper being used	Ensure you are using Micro Direct recommended thermal paper (See Consumables/Accessories section).

Problem	Possible Cause	Solution
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: NiMH battery pack, 8.4V, 1100mAh
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	
MicroLab	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 MicroLab only to printers and 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.

During database upload, the MicroLab 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 (PSU1012 12V DC 2.5A). The adapter contains a transformer. Do not cut off the adapter to replace it with another plug as this causes a hazardous situation.

- The adapter transforms the mains voltage (100-240 Volts) to a safe voltage (12V DC)
- Make sure the adapter does not get wet
- Do not use a damaged adapter
- Always unplug your MicroLab 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.

Electromagnetic Compatibility (EMC) to IEC 60601-1-2

WARNING: use of portable phones or other radio frequency (RF) emitting equipment near the system (< 30cm) may cause unexpected or adverse operation.

The MicroLab has been tested to IEC 60601-1-2:2014, 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 MicroLab 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 MicroLab.

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

Keep a distance of about 2 meters from possible error sources when using the device.

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

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

The MicroLab should be used only with the accessories (USB cables, mains adapter and turbine transducer) supplied (which are referenced in the accessories section of this manual). None of the MicroLab 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 MicroLab's EMC. None of the MicroLabs 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.

List of EMC important cables. Do not exchange by other types

Part Number	Description
CAB7800	USB Lead (MicroLab to PC)
CAB1060	Power line US to mains adapter

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

Guidance and Manufacturer's Declaration – Electromagnetic Immunity The MicroLab is intended for use in the electromagnetic environment specified below. The customer or the user of the MicroLab should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC61000-4-2	Contact: +/- 8 kV Air: +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV	Contact: +/- 8 kV Air: +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV	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 100 kHz repetition frequency for power supply lines	+/- 2 kV 100 kHz repetition frequency for power supply lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC61000-4-5	+/- 0,5 kV, +/- 1 kV, +/- 2 kV	+/- 0,5 kV, +/- 1 kV, +/- 2 kV	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	0% U_T; 0,5 cycle At 0º, 45º, 90º, 135º, 180º, 225º, 270º and 315º 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0º and 0% U_T; 250/300 Cycle	0% U_T; 0,5 cycle At 0º, 45º, 90º, 135º, 180º, 225º, 270º and 315º 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0º and 0% U_T; 250/300 Cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MicroLab requires continued operation during power mains interruptions, it is recommended that the MicroLab be powered from an uninterruptible power supply or a battery

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Power frequency (50/60 Hz) Magnetic field IEC61000-4-8	30 A / m 50 & 60 Hz	30 A / m 50 & 60 Hz	If incorrect operation occurs, it may be necessary to position the MicroLab 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 MicroLab is intended for use in the electromagnetic environment specified below. The customer or the user of the MicroLab should assure that it is used in such an environment.		
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands Between 0,15 MHz and 80 MHz 80% MHz at 1 KHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands Between 0,15 MHz and 80 MHz 80% MHz at 1 KHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz
IMMUNITY to proximity fields from RF wireless communications equipment IEC 61000-4-3	28 V/m 450 MHz, 50% PM at 18 Hz 810 MHz, 50% PM at 18 Hz 870 MHz, 50% PM at 18 Hz 930 MHz, 50% PM at 18 Hz 1720 MHz, 50% PM at 217 Hz 1845 MHz, 50% PM at 217 Hz 1970 MHz, 50% PM at 217 Hz 2450 MHz, 50% PM at 217 Hz 27 V/m 385 MHz, 50% PM at 18 Hz 9 V/M 710 MHz, 50% PM at 217 Hz 745 MHz, 50% PM at 217 Hz 780 MHz, 50% PM at 217 Hz 5240 MHz, 50% PM at 217 Hz 5500 MHz, 50% PM at 217 Hz 5785 MHz, 50% PM at 217 Hz	28 V/m 450 MHz, 50% PM at 18 Hz 810 MHz, 50% PM at 18 Hz 870 MHz, 50% PM at 18 Hz 930 MHz, 50% PM at 18 Hz 1720 MHz, 50% PM at 217 Hz 1845 MHz, 50% PM at 217 Hz 1970 MHz, 50% PM at 217 Hz 2450 MHz, 50% PM at 217 Hz 27 V/m 385 MHz, 50% PM at 18 Hz 9 V/M 710 MHz, 50% PM at 217 Hz 745 MHz, 50% PM at 217 Hz 780 MHz, 50% PM at 217 Hz 5240 MHz, 50% PM at 217 Hz 5500 MHz, 50% PM at 217 Hz 5785 MHz, 50% PM at 217 Hz

Symbols

	Type B device
	In accordance with Directive 93/42/EEC
	Disposal in compliance with your local waste management facility
	Consult the instructions for use
	Manufacturer
	Date of Manufacture
	Serial Number
Rx only	Federal U.S. law restricts this device to sale by or on the order of a physician.
	Batch Code
	Reference Number
	Single Patient Use

Specifications

General

Storage:	>2000 tests including Flow/Volume loops and Volume/Time curves
Display:	Color 1/4VGA LCD.
Power supply:	Input 100 to 240V, 50 to 60Hz. Output 12V 2.5 A (Class 1) Type: ME30A1200F02 (PSU1012)
Battery Pack:	Rechargeable NiMH 8.4V 1A-hours
Battery Life:	Approximately 30 hours with a fully charged new battery
Dimensions:	1.4" x 10" x 4.7" - Transducer 2" x 2.4" x 3.5"
Weight:	Unit: 1.4 pounds
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
Transport and Storage Pressure:	650 to 1060 hPa

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:	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
3327	Thermal Printer Paper (10 rolls)
3314SB	Adult Disposable Mouthpieces (200 per box)
3314B5	Adult Disposable Mouthpieces (500 per box)
3395	MicroCheck One-way Cardboard Mouthpieces (200 per box)
3397	MicroCheck One-way Plastic Mouthpiece (200 per box)
3301	Pediatric Disposable Mouthpieces (100 per bag)
PSA1100	Pediatric Adaptor
3385	SpiroSafe Pulmonary Filters (100 per box)
3304	Nose Clips (20 per bag)
3325	3 Liter Calibration Syringe
SPC1000	Spirometry PC Software (Optional)
CAB7800	USB Lead (PC)
PSU1012	Mains Adapter
BAT1038	Battery
TDX1048	Turbine Transducer
ASS1206	Transducer Head Assembly
48-70	Protex Disinfectant Wipe

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-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

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