Micro I Diagnostic Spirometer

Operating Manual

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

Micro Direct, Inc.
803 Webster Street
Lewiston, ME 04240
1-800-588-3381
www.mdspiro.com

122-14
Issue 1.8 MD
February 2019

CONTENTS

Introduction

The Micro I is a compact, rechargeable battery operated and fully portable diagnostic spirometer. It is accurate to the requirements of the ATS/ERS TASK FORCE: STANDARDIZATION OF LUNG FUNCTION TESTING 2005. Its ergonomic and user-friendly design allows diagnostic spirometry measurements, including predicted values and automatic interpretation, to be made quickly and simply.

The Micro I features include:

- ✓ Measures FEV_1, FVC(FEV_6), FEV_1/FVC, FEV_1/FEV_6, PEF, FEF_{25}, FEF_{75} and FEF_{25-75}
- ✓ Fully configurable using software supplied
- ✓ ECCS, Asian, NHANES III Kainu (2016) Finnish, Quanjer GLI (2012) or Quanjer GLI (2012) + ECCS predicted values
- ✓ Variation from norm as a percentage or Z-score
- ✓ NLHEP, NICE or the ATS/ERS interpretation
- ✓ Spirometry maneuver quality checks
- ✓ Post bronchodilator comparison
- ✓ NLHEP compliant mode
- ✓ Upload of the last patient tested for report generation either to be printed directly or saved as a PDF document and printed or stored in the patient's electronic medical records.

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

Micro Direct can supply spirometers to fulfil all your diagnostic and monitoring spirometry needs.

Package Contents

The Micro I is packaged in a convenient carrying case and comes complete with the following items:

1 Micro I Spirometer

2 Digital Volume Transducer with disposable cardboard mouthpieces and instruction manual.

3 Universal power supply (PSU1017 5VDC 1.2A)

4 Cardboard mouthpiece adapter

5 USB/charging cable

Contraindications, Warnings and Cautions

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

The following terms are used as follows in this manual:

Caution: Possibility of injury or serious damage

Warning: Conditions or practices that could result in personal injury.

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

Note: The device should only 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.
WARNING: With any other use as described in cleaning instructions, the volume transducer, mouthpiece adapter and the pediatric adapter must be cleaned between patients.
WARNING: Use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation.
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 also increase air resistance and lead to an incorrect measurement.
CAUTION: Do not allow the patient to handle the spirometer when connected to either the power supply for charging or to a PC when configuring the unit.
WARNING: The user must not touch any voltage-carrying parts and the patient at the same time.
 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.

Intended Use

The Micro I Spirometer is intended to measure the maximal volume and flow of air that can be moved out of a patient's lungs. The system is intended for use with pediatric and adult patients over the age of 3 years in hospitals, physician offices, laboratories and occupational testing environments.

Environment

Please observe the following precautions:

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

Getting Started

It is recommended that the Micro I spirometer be fully charged before use. The power supply is provided with separate UK, USA and European plugs. Connect the required plug to the power supply and plug into an electrical outlet. Connect the Micro I to the power supply using the USB/charging cable and the charging symbol will appear on the screen.

Fully charge for a minimum of five (5) hours when used for the first time.

NOTE: When disconnecting the USB cable from the Micro I, make sure to squeeze both sides of the jack to unlock the cable from the unit.

Remove the protective film from the display screen before use.

Configuration

When the unit is first turned on, it may be configured for your region. This will set the language, height and weight units, date format and predicted values set appropriate for your region. It will also configure the indices to be displayed and whether a percent predicted, or Z-score is to be used to show variation from the norm. However, all these setting may be customized using the PC software supplied.

Turn the unit on by pressing the on/off button located at the top of the device and the following will be displayed:

Use the up and down arrow keys to highlight the required country and then press 'Enter' (↵). This procedure is only required when the unit is first switched on and the selection will be stored for future use.

It is recommended that the PC software be used to adjust these settings, if required. Connect Micro I to the PC using the USB cable supplied. Run the software and turn on the Micro I. The PC software will detect when the Micro I is connected. Follow the onscreen instructions to configure your unit.

Micro I PC Software

This software allows you to customize the settings on your Micro I spirometer and allows full spirometry reports containing patient demographics, indices and flow volume and volume time graphs to be generated and saved as a PDF file or printed. Once

successfully installed, comprehensive help is available through the Help menu when using the application.

System Requirements

Micro I PC Software requires certain hardware and software components in order to run properly.

PC Requirements

An IBM-compatible PC is required with hardware that meets or exceeds the following minimum requirements.

Processor: 800 MHz or above

RAM: 256 MB

Free Disk Space: 50 MB

Video: 800x600, 256 colors. It is recommended that a resolution of at least 1280x1024 be used to enable the full benefits of the multi-window interface.

At least one free USB port.

Operating System Requirements

Micro I PC Software will run on the following operating systems:

Windows 7 32/64 bit
Windows 8.1 64 bit
Windows 10 64 bit

Installing Micro I PC Software

Before you begin, please ensure your computer meets the minimum system requirements and the user installing the software has administrative user rights.

Close any other applications that are running.

Insert the installation CD into your CD-Rom drive.

The setup program should launch automatically, displaying the welcome dialog box, click ‘Next’ to continue. If the setup program does not launch automatically use Windows Explorer to manually select the CD drive, then open the file named Micro I PC Software.exe.

The license agreement will be displayed. Please read the complete document and ensure you understand fully before accepting the terms of the license. Click ‘Next’ to continue.

The select destination location dialog box will be displayed showing the directory where the Micro I PC Software will be installed. The default location is:

C:\Program Files\Vyaire\Micro I PC Software

To change this location, select ‘Browse’.

Click ‘Next’ to display the Select program manager group dialog box. This will be the location where the Micro I PC Software launch icon will be placed under the Start Menu. Either a new location can be entered, or an existing location used.

Click ‘Next’ to display the installation option dialog box containing the following option:

Add Micro I PC Software icon to the desktop.

Click ‘Next’ to start copying the files to your system.

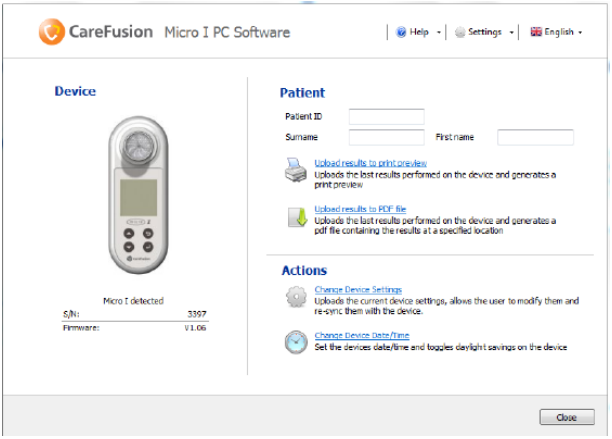
Once the files have finished copying to your system, you will be advised that the Micro I PC Software has been successfully installed and it would be advisable to restart your PC before using the application. Click ‘Finish’ to complete the installation process.

Running Micro I PC Software

Connect your Micro I to a USB port on the PC using the cable provided. The Micro I will take power from the USB port on the PC. Please be advised that the Micro I requires a high current USB port and if connected to a lower power USB port the device will turn itself off and fail to respond to any key presses until disconnected. Low power USB ports are commonly found on keyboards and unpowered USB hubs and should not be used. While connected to the PC, the Micro I will display:

Do not allow the patient to handle the spirometer during this procedure.

The Micro I PC software will automatically be launched when a Micro I unit is connected to the PC, the first screen will show:



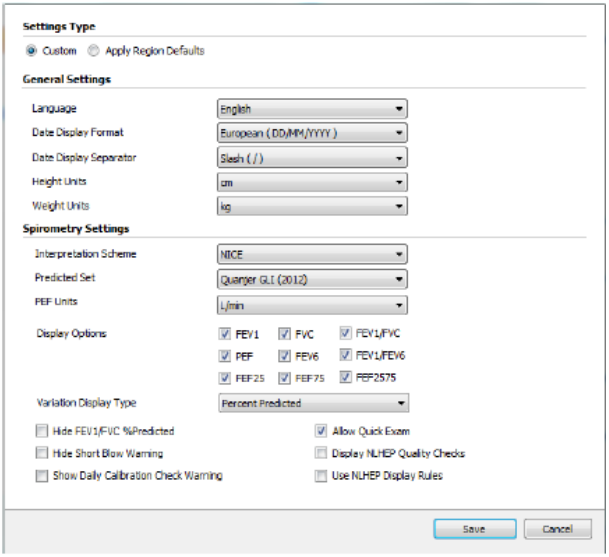
From this screen you can enter an ID and the patient's name to generate a report. The patient options allow the last results to be uploaded from the Micro I and print preview of the report can be view in preparation of printing or alternatively a PDF of the report can be generated for saving to a specified location.

Please note: The patient ID can contain a maximum of 20 characters.

Please note: If Quanjer-GLI (2012) predicted values are selected, the number of indices are limited to those of the published set, it is also not possible on the printed report to have a predicted area on the flow volume or volume time graphs.

In the Actions section the user has the choice of two options either change the device settings or adjust the Micro I internal clock.

When the settings option is used, the display will change to:



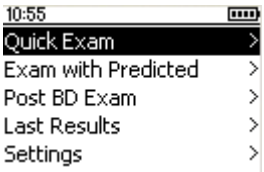
By selecting the 'Custom' option at the top of the screen, all of the Micro I features may be tailored to your specific requirements.

NOTE: When disconnecting the USB cable from the Micro I, make sure to squeeze both sides of the jack to unlock the cable from the unit.

Operation

The Micro I is designed to suit a range of applications from the very simplest spirometry test where only a few indices are required to be displayed to more complex operation where deviation from the norm, bronchodilator response and interpretation of results are required.

The main menu is displayed after the initial configuration and subsequently when the unit is turned on:



Main Menu Overview

Quick Exam

Use this function to take an immediate spirometry measurement with no predicted values or interpretation.

Exam with Predicted

This function requires the entry of the patient's demographics so that predicted values and interpretation may be calculated and displayed.

Post BD Exam

This function allows the post bronchodilator response to be measured. The response is measured with respect to the previously measured baseline obtained using either the Quick Exam or the Exam with Predicted options. The last recorded

baseline examination is automatically stored when the unit is turned off and will be available for a post bronchodilator comparison when the unit is turned on.

Last Results

This option is used to view the results of the last stored examination.

Settings

This option allows the user to adjust various settings including date, time and language and to perform a calibration check.

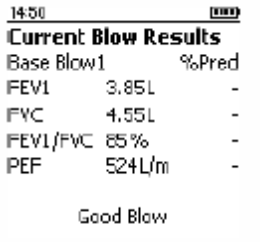
Quick Exam

After selecting this option, the display will change to:

The Micro I may be used with a SpiroSafe filter or a MicroCheck disposable cardboard mouthpiece with the adapter supplied. Insert mouthpiece or SpiroSafe filter into the mouthpiece holder of the spirometer.

Instruct the patient to inhale as deeply as possible, seal their lips around the mouthpiece and exhale as hard, as fast and as long as possible until no more air can be exhaled.

The spirometry results for that blow are then displayed together with the maneuver quality check based upon ATS/ERS guidelines:



Further indices, if configured and the best results from a sequence of blows may be displayed by pressing the down key.

Each maneuver is quality checked for a slow start, abrupt end, short blow, poor effort or cough according to ATS/ERS 2005 guidelines.

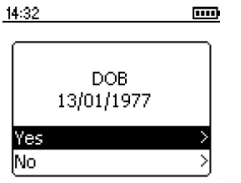
Please note the percentage of predicted value and the interpretation is not available for the Quick Exam option.

Press ‘Enter’ (↵) to display:

To repeat the test, select ‘Blow Again’ and press ‘Enter’ (↵).

Exam with Predicted Values

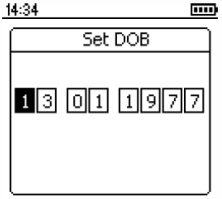
When this option is selected, the following is displayed:



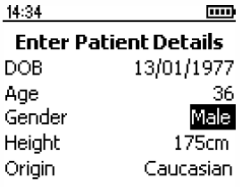
The date of the birth displayed will be the last patient tested (in the case of a new unit, the last test performed was a calibration test), select ‘No’ to enter the date of the birth of the patient to be tested or ‘Yes’ to confirm the date of birth is correct.

If ‘No’ is selected, the screen will change to allow the correct date of birth to be entered. Use the up and down keys to enter the date

of birth and press ‘Enter’ (↵) key after each correct entry has been made.



If ‘Yes’ is selected and the date of birth is correct, the patient details screen will be displayed.



The up and down keys should also be used to adjust the patient’s age and then press ‘Enter’ (↵). Repeat for gender, height (will be configured to accept height in inches) and racial origin. If a mistake is made, simply touch the ‘Back’ (⮌) key to go back to the previous entry.

The racial origin selected applies a percentage drop to the volumetric predicted values to be applied for the patient.

These ethnic corrections for ECCS are as follows:

Population	Percentage drop
Caucasian	0
Non-Specified	0
Polynesian	10
Asian	10
Afro Caribbean	13

Press ‘Enter’ (↵) when the required correction has been selected.

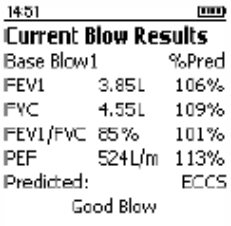
If NHANES III or Quanjer-GLI (2012) predicted values are used, the ethnic origin will be used according to the author's equations.

Please note the Micro I may be configured to accept height in centimeters.

If a mistake is made, simply touch the back key to go back to the previous entry.

When all the patient data has been entered, the following screen will be displayed, and a spirometry test may be performed:

After performing a test, the results are displayed:

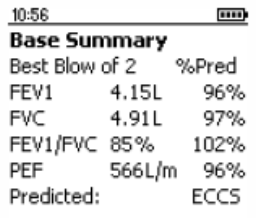


Each maneuver is quality checked for a slow start, abrupt end, short blow, poor effort or cough according to ATS/ERS 2005 guidelines. An asterisk (*) at the end of the line denotes a result below the lower limit of normality.

If additional indices were chosen during configuration, press the down key to view these.

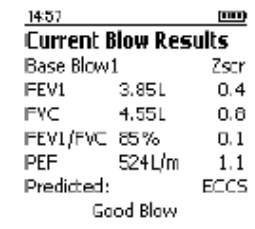
When a sequence of blows is recorded, the results and the quality check refer to the current blow but the interpretation is based upon the best result of the sequence.

Use the down arrow to see further indices, if configured, and the best results from a sequence of blows:



At any time when the results are displayed another spirometer test may be performed by touching the 'Enter' (↵) key. If the enter key is touched accidently, simply press the back (⮌) key to return to the results screen.

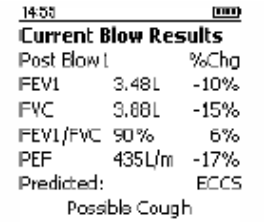
The Micro I may be configured to display the Z score instead of the percentage of predicted values where data from the predicted value sets are available:



The Z score is the number of standard deviations that the results are above (positive Z score) or below (negative Z score) the predicted value.

Post BD Exam

Once satisfactory baseline tests have been recorded, a post bronchodilator examination may be performed by selecting the Post BD Exam option from the main menu. When these tests are performed, the percentage of predicted value is replaced by the percentage change from the best baseline result for each index:

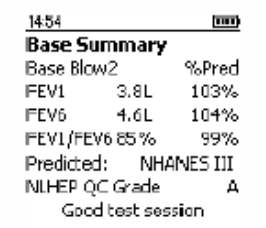


Using the down key will display the other indices and the best results as with the baseline blows.

NLHEP Mode

This mode of operation is obtained by selecting the USA (NLHEP) option from the configuration menu when the unit is first turned on or subsequently from the settings option on the main menu.
In this mode the functionality of the Micro I becomes fully compliant with the National Lung Health Education Program requirements.

Only FEV_1, FEV_6 and FEV_1/FEV_6 are displayed and stored, quality checks are applied to every maneuver and a quality grading score for the test session is displayed:



NLHEP Quality Checks

For the interpretation to be displayed, a maneuver must pass a set of enhanced quality checks. After the patient has performed a poor-quality maneuver, one of the three following messages will appear:

Message	Criteria	Recommended action
Don't hesitate	Back-extrapolated volume (BEV) greater than 150 ml	The patient should blast out the air more quickly and evenly and without hesitation at the beginning of the maneuver
Blast out faster	Time until peak flow (PEFT) greater than 120 msec	The patient must exhale more explosively at the beginning of the maneuver
Blow out longer	Expiration time less than 6 seconds or volume accumulation has not dropped below 100 ml per 0.5 seconds	The patient stopped exhaling too early. The patient must exhale until their lungs are completely empty.

Once an acceptable maneuver has been performed, the following consistency checks will also be applied to subsequent maneuvers		
Blast out harder	Peak flow not reproducible. The best previous maneuvers do not match within 1.0 L/sec indicating that the patient is giving an inconsistent effort	The patient must give their maximum effort for each maneuver
Deeper breath	FEV1 or FEV6 not reproducible. Difference with respect to best test greater than 150 ml	The patient must inhale until their lungs are completely full before each maneuver

When two maneuvers fail either of the consistency checks, the best individual results of the two are saved (FEV1, FEV6 and PEF individually).

When any of the above messages appear, instruct the patient on how to improve their maneuver and demonstrate the correct maneuver yourself.

NLHEP QC Grades

The quality of each session is graded according to the following criteria:

QC Grade	Criteria
A	At least two acceptable maneuvers, with the largest two FEV_1's matching better than 100 ml and the largest two FEV_6's matching better than 100 ml
B	At least two acceptable maneuvers, with the largest two FEV_1's matching better than 150 ml
C	At least two acceptable maneuvers, with the largest two FEV_1's matching between 200 ml and 150 ml
D	Only one acceptable maneuver or two with the largest two FEV_1's matching less than 200 ml
F	No acceptable maneuvers

NLHEP Interpretation

The interpretation is performed on the best spirometry results and is based upon the predicted values for the force expiratory ratio, FEV_1/FEV_6, and FEV_1. If airways obstruction is detected, the level of severity is reported in accordance with the NLHEP guidelines.

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.

Maintenance

Battery Management

The Micro I is powered by a rechargeable battery pack.

The Micro I's internal batteries should be fully charged on first use.

A fully charged device will hold a charge for a few months. If the Micro I is not used for longer then this, it must be recharged every few months to keep the battery alive.

Battery Status Icons

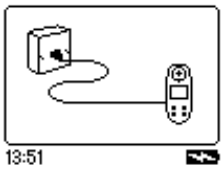
Battery nearly exhausted. Recharge as soon as possible to avoid running out of charge.

Battery fully charged.

The battery is not required to hold the internal memory and stored results will be lost when the battery becomes exhausted.

To recharge the battery, connect the Micro I to the charger provided and then plug the charger into a suitable wall socket ensuring that access to the charger is not restricted so that it may easily be removed.

The Micro I will display:



Do not allow the patient to handle the spirometer during this procedure.

The charging icon ( ) will display to indicate that the device is charging.

Once the charging icon has switched off (up to five hours) it will be replaced by the battery fully charged icon ( ). Remove the power adapter from the wall socket and from the base of the unit. Micro I is now ready for portable use.

Note: Micro I may also be charged from a PC or laptop using the USB cable provided.

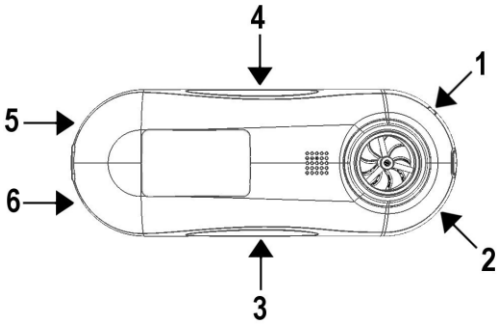
NOTE: When disconnecting the USB cable from the Micro I, make sure to squeeze both sides of the jack to unlock the cable from the unit.

Battery Replacement

The lifetime of all rechargeable batteries is limited and the battery pack will need to be replaced after a few years, depending upon usage. As the battery nears the end of its life, you will notice that fewer test can be be performed between charges.

For access to the battery, the rear of the device requires careful removal.

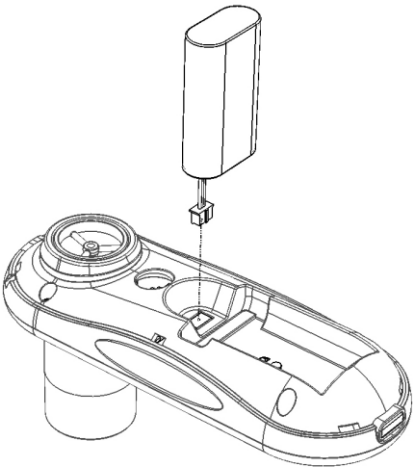
Clips are molded into the rear cover in the positions indicated and should be carefully pryed undone in the sequence shown.

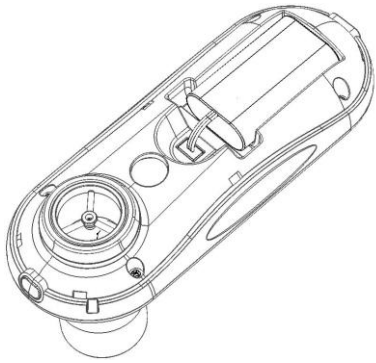


To aid this process, clip 1 has a recess molded into the device body to allow a small flat bladed screwdriver to be carefully slid under the clip to release it.

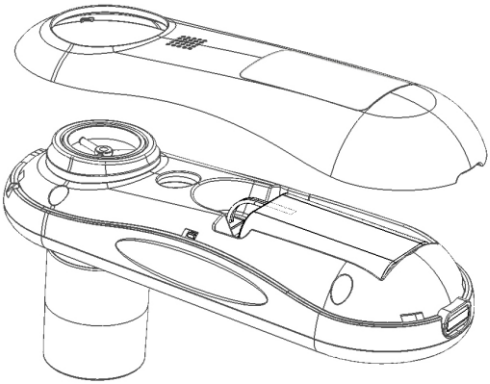
Once released, work the screwdriver around to clips 2, 3 and 4. Finally slide the cover off the bottom of the unit which in turn releases clips 5 and 6.

Replace the battery paying attention to the orientation of the connector in its socket and of the battery itself in the case. Note the leads coming from the battery should exit from the upper face of the pack when installed.





Replace the rear cover by attaching the securing clips in the reverse order.



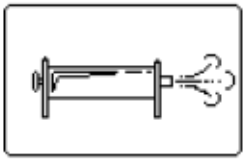
Dispose of the waste battery in line with your local waste management regulations.

Calibration Check

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

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

To perform a calibration check, select the calibration check option from the setting menu and the display will show:



Connect a 3-liter syringe to the Micro I with the minimum of adapters and inject the syringe volume into the transducer evenly without pausing. When complete, the display will show:

The acceptable calibration accuracy is +/- 3.5%. If the calibration accuracy is outside of this range, the check mark will be replaced by a cross. If this happens, check the syringe and the connections for leaks and repeat the check. If the Micro I is repeatedly outside the calibration range, the unit will have to be returned to Micro Direct for servicing.

Cleaning Instructions

With the use of a SpiroSafe filter or MicroCheck one-way valve mouthpiece for each patient, cleaning for the components in the patients' gas path is recommended once a month.

When using a pediatric/adult disposable mouthpiece without a filter under the prerequisite that the patient was instructed only to exhale into the Micro I device, the following parts must be cleaned once a day: volume transducer, mouthpiece adapter and pediatric adapter.

WARNING: With any other use as described in cleaning instructions, the volume transducer, mouthpiece adapter and pediatric adapter must be cleaned between patients.

The cleaning of the transducer, mouthpiece adapter and pediatric adapter is equal for all the components in the patient gas path and is described in the below section "Cleaning the Transducer".

Cleaning the Transducer

The transducer requires no routine maintenance or servicing.

To disinfect or clean the transducer, it may be removed by means of the following procedure:

1. Remove the transducer by gently rotating the transducer counterclockwise and then pulling from the main body.
2. The transducer may now be immersed in warm soapy water for routine cleaning or immersed in cold disinfectant solution for a period not exceeding 10 minutes. (Alcohol and chlorine solutions MUST be avoided) After cleaning/disinfecting, the transducer should be rinsed in distilled water and air dried.
3. Re-assemble the transducer into the Micro I.

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

Servicing

If your unit requires service or repair, please see page 34 for contact details.

There are no user serviceable parts in the Micro I.

Product Lifetime

The Micro I meter is designed for a product lifetime of 5 years.

Troubleshooting Information

Should you encounter problems operating your Micro I spirometer, please consult the table below:

Problem	Possible Cause	Solution
Micro I cannot be switch on	Batteries are flat	Recharge batteries
Every time you switch the instrument on, the time is shown as 00:00	The internal battery is defective	Contact Micro Direct
Micro I is outside of range when conducting the calibration check	There are leaks in the syringe or connection	Check the syringe and connections for leaks

Safety Designation per IEC 60601-1

Type of protection against electrical shock	Class II
Degree of protection against electrical shock	Type B applied part
Supply connection	100-240 VAC, 50/60Hz
Power Equipment	Adapter and rechargeable internal NiMH battery
Battery Life	Approximately 30 hours with a fully charged new battery
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

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. When connecting to a PC with the supplied USB lead then the PC must be EN 60601-1 / ANSI/AAMI ES60601-1:2005 compliant.

IMPORTANT: Only use the mains adapter supplied (PSU1017 5V DC 1.2A). 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 (5V DC)
- Make sure the adapter does not get wet
- Do not use a damaged adapter
- Always unplug your Micro I before cleaning

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

WARNING: No modification of this equipment is allowed.

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 (<30 cm) may cause unexpected or adverse operation

The Micro I has been tested to IEC60601-1-2:2014 regarding its ability to operate in an environment containing other electrical/electronic equipment (including other medical devices).

The purposes of this testing is to ensure the Micro I 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 Micro I.

Despite the testing of the Micro I that has been undertaken, normal operation of the Micro I 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 Micro I is medical equipment, special precautions are needed regarding EMC (electromagnetic compatibility).

It is important that the Micro I 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 of modifications to the Micro I may result in increased emissions or decreased immunity of the Micro I in relation to EMC performance.

The Micro I 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 Micro I 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 Micro I EMC. None of the Micro I 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 devices' EMC.

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

Part Number	Description
CAB1098	USB Cable (Micro 1 to PC or to PSU)

The Micro I has an essential performance – when verified with a 3 liter syringe the readings remain within a tolerance of +/- 3.5% and unit firmware must not cease operating. In the unlikely event of a Fast Transient / ESD event occurring, the device should be reset and located away from the source of interference.

Note: In the very unlikely event of a high ESD event occurring to the device connector, the device could be damaged.

WARNING: The Micro I should not be used adjacent to or stacked with other equipment. If adjacent or stacked use with other equipment is necessary, the Micro I 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 Micro I is intended for use in the electromagnetic environment specified below. The customer or the user of the Micro I should assure that it is used in such an environment

Emission Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The Micro I 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 Micro I 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 Micro I is intended for use in the electromagnetic environment specified below. The customer or the user of the Micro I 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 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0° and 0% U_T; 250/300 Cycle	0% U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0° 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 Micro I requires continued operation during power mains interruptions, it is recommended that the Micro I be powered from an uninterruptible power supply or a battery

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 Micro 1 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 Micro I is intended for use in the electromagnetic environment specified below. The customer or the user of the Micro I 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

Please Note: Information in this manual is subject to change without notice and does not represent commitment on the part of the manufacture. The software may be used or copied only in accordance with the terms of that agreement. No part of the manual may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying and recording for any purpose without the written permission of the manufacturer.

Specifications of the Micro I

Measurements:

Forced Expiratory Volume in 1 second (FEV_1)
Forced Expiratory Volume in 6 seconds (FEV_6)
Forced Vital Capacity (FVC)
Forced Expiratory Ratio (FEV_1/FEV_6)
Forced Expiratory Ratio (FEV_1/FVC)
Peak Expiratory Flow Rate (PEF)
Mid Expiratory Flow (FEF_{25-75})
Expiratory Flow at 75% of volume remaining (FEF_{75})
Expiratory Flow at 25% of volume remaining (FEF_{25})

Display:	128 x 128-pixel graphic backlit monochrome LCD
Transducer type:	Uni-directional digital volume
Accuracy:	To the requirements of the ATS/ERS Task Force: Standardization of Lung Function Testing 2005 (Eur Respir J 2005; 26:319-338 Table 6)
Power supply:	2 x AA size NiMH rechargeable cells
Battery life:	Approximately 30 hours with a fully charged new battery
Operating current:	Less than 90mA
Charging current:	Less than 500mA
Dimensions:	6.4” x 2.4” x 1.2”
Weight:	5.4 ounces
Lifetime:	5 years
Operating temperature:	50 to +95^o F
Operating humidity:	20% to 80% RH
Operating pressure:	650 to 1060 hPa
Storage & transport temperature:	-4 to +158^o F
Storage & transport humidity:	30% to 90% RH
Storage & transport pressure:	650 to 1060 hPa

Accessories

Catalog #	Description
3314SB	Adult Mouthpieces (Box of 200)
3314B5	Adult Mouthpieces (Box of 500)
3395	MicroCheck, one-way mouthpieces (Box of 200)
3385	SpiroSafe, Viral/Bacterial Filter (Box of 100)
3301	Pediatric Mouthpieces (Bag of 100)
PSA1100	Pediatric Adapter
3304	Nose Clips (Pack of 20)
3325	3-Liter Calibration Syringe
MLD1621	Mouthpiece Adapter
BAT1043	Battery Pack (NiMH AA 2.4V, 1600 mAh)
PSU1017	5V DC 1.2A (GlobTek WR9QA1200USBNR-G2267)
CON1195	PSU Adapter Set - UK, Euro, USA, Australia
48-70	Protex Disinfectant Wipe

Customer Contact Information

For all sales order processing for products, training and spare parts, service and technical support inquiries, please contact the following:

Micro Direct, Inc.
803 Webster Street
Lewiston, ME 04240

Telephone: 207-786-7808

Toll Free: 800-588-3381

Fax: 207-786-7280

Website: www.mdspiro.com

Sales Email: sales@mdspiro.com

Service Email: support@mdspiro.com