MD SPIRO
a Micro Direct company

Micro

Model MD6300

Instruction for Use

Current Edition (Issue 2, 22-May-2020) Cat. No. 09200

Micro Direct, Inc. 803 Webster Street Lewiston, ME 04240
Toll Free: 800-588-3381 Email: support@mdspiro.com

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.

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
- ✓ To support or exclude an 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

Table of Contents

1. Main Components

The main components are:

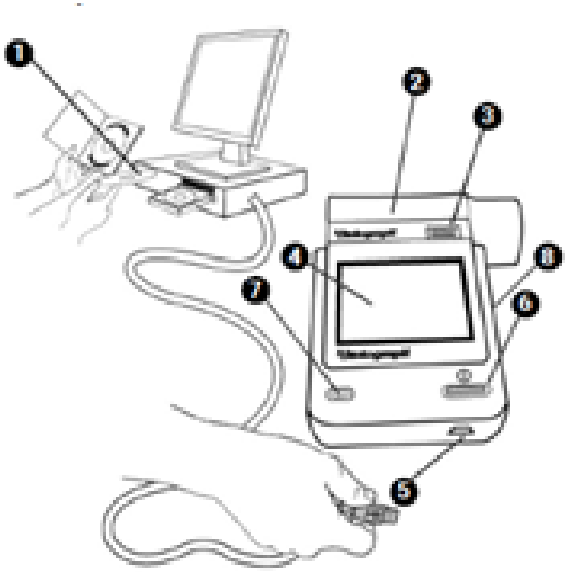


Figure 1 The main components of the Micro Spirometer

1	PC Software
2	Flowhead
3	Flowhead Release Button
4	LCD/Touch Panel Display
5	Mini USB Port
6	On/Off Button
7	LED
8	Battery Compartment (4 x 1.5V AAA Batteries)

Note: *Computer is not supplied.*

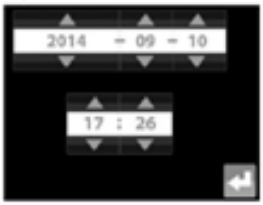
1.1 Features

The features include:

- Fleisch type pneumotachograph
- Removable flowhead
- Touch screen color display
- Choice of predicted values
- Report generation through Reports software
- Storage of test and demographic information

2. Setting Up

1. Insert 4 x 1.5V AAA batteries into the battery compartment. Alternatively, the Micro may be powered from the user's computer via the mini-USB port on the bottom of the device using the USB cable supplied. Press the On/Off button on the front face of the instrument.
2. When first turned on, the date and time setup screen is presented. Use the up/down buttons to enter the current date and time and press enter  to save these settings.



3. The Micro Spirometer is now ready for use.
4. To use with the Reports Application, install the software provided with the Micro Spirometer following the instructions supplied with the software.
5. Connect the Micro Spirometer to the computer using the USB cable (via ports marked with the  symbol).

If the device has just been unpacked or transported, ensure it is left sitting, fully powered so that it is at room temperature prior to testing.

3. Operating the Micro Spirometer

The Main Menu screen includes the following options – New Subject, VC Test, FVC Test and Post Test (for bronchodilator responsiveness testing).

When turning the device on for the first time, the test screen icons will appear greyed out and can't be selected until a subject is created. The Post Test icon will stay greyed out until an FVC pre-test is performed.

In addition to displaying the time and the battery icon, the status bar at the top on the screen will show various icons to indicate the following:

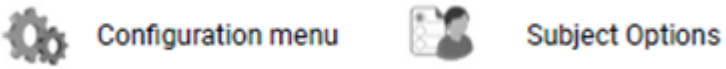
1. V – indicates a VC test has been performed
2. F – indicates an FVC has been performed
3. P – indicates post mode (for bronchodilator responsiveness testing).

The icons will only appear after the test has been completed.

3.1 Entering Subject Data

1. Select the  New Subject button on the Main Menu to open the New Subject screen.
2. The Subject information fields available are as follows:

3. Age, Height and Gender are on the first screen and are enabled by default. Weight and Ethnicity are on the second screen and are not enabled by default. Enable by selecting:



4. To enter information for Age, Height and Weight, select the appropriate icon and type in the information using the touch panel keypad.

    - Units automatically switch between cm/in and kg/lbs.
    - Gender is select by pressing either

    - Ethnicity is selected from a list by pressing the appropriate option on screen. To access additional Ethnicities, select the arrow on the right of the screen.

5. To save the subject details and return to the Main Menu, press the  Enter button.

6. If a value is not entered for Age, Height or Gender, an Error Icon  will appear next to the empty field when the enter button is pressed. This is to indicate the predicted values will not appear in the results of any testing done.

7. To exit the new subject screen, press the enter button again.

    Note: *The Micro retains data for the last subject until a new subject is created. Therefore, except for the first use of the device or after clearing the memory, when the user enters the new Subject Screen, the fields appear greyed out to indicate data is retained. Selecting age, height or weight boxes will move the last subject data to the device memory to allow the user to enter new subject information. All subject details need to be completed to continue.*

3.2 Conducting a Test

Before starting a test session:

1. Ensure the accuracy of the device was checked recently. (Refer to the section on Calibration Verification).
2. Select a subject and ensure the required demographic information is entered.
3. Wash hands (operator and subject).
4. Fit a new SpiroSafe filter to the flowhead for each test subject. The use of a disposable nose clip is recommended.
5. Instruct and demonstrate the test.

3.2.1 Testing

1. From the Main Menu select either

VC Test or

FVC Test

2. Wait for the 'Blow Now' icon to appear. The device is now ready to accept a blow.

Example Script[1]:

- Sit upright with back straight and feet flat on the floor. Fit the nose clip and relax.
- Place SpiroSafe filter in mouth and close lips around the mouthpiece.
- Seal your lips around the mouthpiece and keep your tongue down.
- Breath normally.

VC Test Session (with V/T graph display selected):

1. Inhale completely with a brief pause when your lungs are completely full (≤ 2 secs).
2. Exhale with no hesitation until no more air can be expelled while maintaining an upright posture.

It is vital the operator encourages the subject to keep exhaling to ensure all air is expelled (when a plateau has been reached or forced expiratory time (FET) reaches 15 seconds). The operator should repeat instructions as necessary, coaching vigorously.

3. Listen for two beeps. This indicates the device is ready for the next blow.
4. Repeat for a minimum of three maneuvers, usually no more than eight for an adult.
5. Check VC repeatability and perform more maneuvers as necessary.

***Note**: A single-breath VC technique may also be performed on the device.*

1 Derived from terminology and guidance take from ATS/ERS Standardization of Spirometry 2019 Update Am J Respir Crit Care Med 2019 Vol 200, Issue 8 pp e70-e88

FVC Test Session:

1. Inhale completely and rapidly with a brief pause when your lungs are completely full (≤ 2 secs).
2. Exhale with a maximal effort until no more air can be expelled while mainlining an upright posture

It is vital the operator encourages the subject to keep exhaling to ensure all air is expelled (when a plateau has been reached or forced expiratory time (FET) reaches 15 seconds). The operator should repeat instructions as necessary, coaching vigorously.

3. Breathe in with maximal effort until completely full. The maneuver is now complete and the SpiroSafe filter is removed from the mouth.
4. Listen for two beeps. This indicates the device is ready for the next blow.
5. Repeat for a minimum of three maneuvers, usually no more than eight for adults.
6. Check FEV_1 and FVC repeatability and perform more maneuvers as necessary.

Note: *A single-breath FVC technique may also be performed on the device.*

When testing is complete, press the enter button to exit the screen and return to the Main Menu.

3.2.2 Saving the Test Session

The Micro Spirometer has the capacity to store 750 subject entries with corresponding session data. Only the best three blows will be stored with each session. Stored session information includes subject details and best pre-test if it is a bronchodilator responsiveness testing session.

The Micro Spirometer is intended to be used to store test data temporarily. When the device is connected to the Reports Software to product pdf reports of the session data, all subject/sessions are moved to the software and cleared from the device except for the last FVC Pre-test performed.

If more than 750 subject/session entries are stored on the device, the existing subject/sessions entries will be deleted on a First In First Out (FIFO) basis (i.e. the first session entered will be the first to be deleted).

3.2.3 Bronchodilator Responsiveness Testing

Bronchodilator responsiveness testing can be performed on the most recent FVC pre-test session performed. The device will retain the last pre-test even when it is turned off and on again and/or the data has been transmitted to the Reports software. To perform a bronchodilator responsiveness test:

1. From the Main Menu, select 'Post Mode' 

2. Perform the Post FVC Test Session following the example script for 'FVC test session' in section 3.2.1.

***Note**: Post Mode may only be selected if a FVC Pre-Test has been completed. When returning to the Main Menu from the Post FVC test screen, it is not possible to select either the VC or FVC test as the device is still in Post Mode. These options will be greyed out.*

3.2.4 View VC Test Results

Results may be viewed as either a Volume/time (V/t) or Volume Bar graph by pressing the graph button on the side of the test screen. It is not possible to change the view of results during testing.

 Volume/time (V/t)  Volume bar graph

1. The graph may be changed to a full screen graph by using the zoom button on the side of the test screen. To return to normal mode, select the zoom in button.

2. The results summary on the bottom of the screen shows the VC of the last blow. The number of blows is shown in a separate box next to the last test VC.

3.2.5 View FVC Test Results

The results may be viewed as either a Volume/time (V/t) or Flow/Volume (F/V) graph by pressing the graph button on the side of the test screen. It is not possible to change the view of results during testing.

 Volume/time (V/t)  Flow/Volume (F/V)

1. The graph may be changed to a full screen graph by using the zoom button on the side of the test screen. To return to normal mode, select the zoom in button.

2. The results summary on the bottom of the screen shows the FVC and FEV1 of the last blow.
3. The number of usable blows and bad blow indicator (!) are shown in a separate box next to the last test FVC and FEV1.

4. The best three tests are shown on the graph in order of rank (best 1, 2, 3….). A key is shown at the top of the graph to help identify the tests.
5. To view results as a table, select the button on the side of the test screen 
    a. Select the test results for viewing by using the left/right arrows.
    b. Scroll through the results for each test by using the up/down arrows. The number of parameters displayed will depend on the configured parameters.
    c. Tests are shown in order of rank (best is ranked number 1 then 2, 3….).
6. The results screen has several different columns:
    - Parameter name
    - Units
    - Test value (Pre and Post for bronchodilator responsiveness testing).
    - %Pred or Z-value (depending on the configuration)

3.2.6 Deleting Test Results

To delete the current blow:

1. From the menu on the side of the test screen, select the delete button.

2. To confirm the deletion of the blow, press the Delete icon with the green tick. ✓

3. To cancel the deletion, select the Delete icon with a red cross X

3.2.7 Ending a Test Session

A session ends and is saved when one of the following occur:

- The device is turn off
- A new subject is created
- The device is connected to the Reports Software

3.3 Reporting

Generating PDF reports from the Micro Spirometer requires a computer running the Reports Software. Different tests conducted during the same session i.e. VC, FVC

Post tests are treated as a single session and are printed as one report. If more than one test report is required for the same subject, the device should be switched on and on again between tests so they can be registered as separate sessions and separate reports can be generated.

1. To produce PDF reports from the Micro, connect it to a computer using the USB cable supplied with the device.
2. Run the Reports software on the computer.
3. Ensure the Micro is switched on and in the home screen.
4. Guidance on using the Reports software can be found in the Reports Instruction for Use and in the software help menu.
5. Connect to Reports and select to move all data to clear/delete all the sessions from the device.

***Note**: When the Micro is connected to the Reports software, it will move, not copy, the stored sessions except for the latest FVC pre-session.*

3.4 Calibration Verification

1. Select Configuration button at the top right corner of the Main Menu.

2. Select Calibration Verification

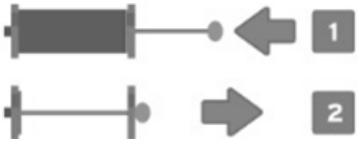
3. Enter the syringe volume and reference using the touch panel keypad.
4. Enter the ambient temperature using the touch panel keypad.

5. Attached the flowhead to the syringe with a SpiroSafe fitted as shown in Figure 2.

Figure 2 Calibration Verification

6. Pump air through the flowhead to bring it to ambient temperature. If the flowhead has very recently been used for testing or has come from a cold environment, its temperature should be equilibrated by pumping air through it from the syringe several times.

7. Press the Enter key to open the Calibration Verification screen and follow the on-screen instructions.



8. The calibration verification result is shown in % in the top right corner of the screen. If it is reproducible and within 3% a green tick will show. Press Enter to return to the main configuration menu. The verification pass is recorded.

9. If the calibration verification results are outside 3%, the error icon will show. Consult the Micro fault-finding guide in Section 7. Press the Enter key to proceed to the calibration update routine.

10. The Calibration Update screen shows the volume (L) at the top left corner of the screen next to the number of strokes.

11. The procedure is the same as for the Accuracy Check. If two strokes are within 3% of the reference volume, press Enter to return to the Configuration Menu. The calibration factor is not updated and a pass is recorded. If outside 3%, the error icon is shown. Press Enter to return to the Configuration Menu. The calibration factor is updated and the calibration update is recorded.

Note: To exit the Calibration Verification screen without performing a check, press the Enter key to return to the Configuration Menu screen. The calibration verification will not be logged where the calibration verification routine has not been completed.

When to check accuracy:

- In accordance with establishment procedures
- After service checks
- After cleaning or disassembling spirometer for any reason
- After adjusting calibration
- If the flowhead or device has been dropped
- If a new flowhead has been fitted

3.5 Setting up a New Flowhead

After fitting a new flowhead to the Micro Spirometer, it is necessary to set up the flowhead with the device.

Follow these steps when setting up a new flowhead.

1. Perform a full calibration verification as per section 3.4 above.
2. Select the Accuracy/Calibration icon again and repeat steps from section 3.4 up to step 7.
3. Instead of continuing to follow on-screen instructions, withdraw the syringe fully and follow instructions below:
4. Select the New Flowhead icon.

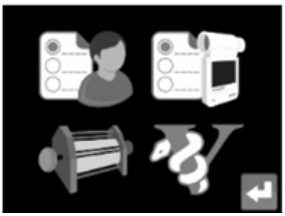
5. Slowly push the syringe fully and then withdraw fully, keep the flow rate below the 0.75 L/sec limit lines on the graph. If this is performed correctly, new limit lines of 2.50 L/sec will appear.
6. Using a medium speed, push in the syringe fully and then withdraw fully, keeping the flow rate between the 0.75 L/sec and 2.50 L/sec limit lines on the graph. If this is performed correctly, new limit lines of 10.00 L/sec will appear.
7. Using a fast stroke, push in the syringe fully and then withdraw fully, keeping the flow rate between the 2.50 L/sec and 10.00 L/sec limit lines on the graph.
8. The result is shown in % on the bottom of the screen. If it is within 3%, a green tick icon will be shown to indicate successful setup of the new flowhead. Press the Enter key to return to the Main Configuration Menu.
9. If the result is outside 3%, the error icon will be shown. Press Enter to proceed to the new flowhead set-up screen.

Only complete the next step where result is outside 3%

10. Repeat steps 5-8. At the end of the procedure, a green tick will appear. Press the Enter key to return to the Configuration Menu.

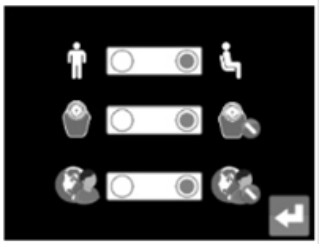
3.6 Configuration Options

To access the Configuration Menu, select the configuration icon on the top right corner of the main screen.

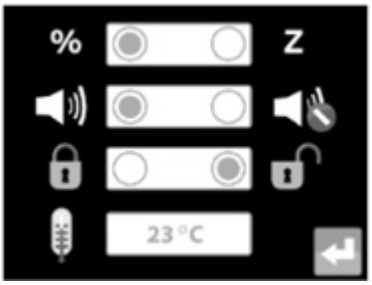


In the Configuration Menu there are four options:

- Subject options (top left icon)
- Device settings (top right icon)
- Accuracy and Calibration (bottom left icon)
- About box (bottom right icon)

1. Subject Options	
• **Posture** - sets posture to be recorded as sitting or standing. • **Weight** - turn on to enable the option to enter weight in the subject screen. • **Population Group** - turn on to enable the option to enter ethnicity in the subject screen.	

***Note**: Default Posture is sitting. Default for Weight and Ethnicity is Off.*

2. Device Settings	
Results Options	
• Display % predicted or Z-score in the results screen. • Turn sounds on or off. • Device lock on or off. Turning on requires the user to enter a passcode. • Set temperature (up to 2 decimal places). The default setting is 23° C.	
Parameters **(See Parameters section)**	
• Select the parameters to be displayed in results. • Use the left/right arrow to navigate between the screens. • A maximum of 8 parameters can be selected.	
Date/Time	
• Select this option to set or change the Date and/or Time. • Use the up/down arrows to edit these fields. • Date format is YYYY/MM/DD, Time is in 24 hour format.	
Service/Technician Mode	
• An 8 digit passcode is required to enter this mode.	

3. Accuracy / Calibration	
• The user may perform calibration verification and calibration by selecting this option (See calibration verification section for detail). • Spirometry standards recommend checking the accuracy of lung function measuring devices at least daily with a 3-L syringe to validate the instrument is measuring accurately.	

4. About Box	
• Information about the software can be obtained from the About Box. This information is required for queries to the manufacturer or a service agent. • Information includes the model number, serial number, the software reference number, date of the last calibration verification and the service date due.	

3.6.1 Parameters

Parameters available in the Micro Spirometer:

Parameter	Definition
VC	Vital Capacity (L)
FVC	Forced Vital Capacity (L)
FEV1	Forced Expiratory Volume after 1 second (L)
FEV1R	FEV1 divided by the largest VC from the VC or FVC maneuver
PEF L/s	Peak Expiratory Flow (L/sec)
PEF L/m	Peak Expiratory Flow (L/min)
FEF25-75	Maximal Mid Expiratory Flow: the mean FEF in the time interval between 25% and 75% of the FVC (L/sec)
FEF75-85	Forced Late Expiratory Flow: the mean FEF in the time interval between 75% and 85% of the FVC (L/sec)
EVC	Expiratory Vital Capacity (L)
IVC	Inspiratory Vital Capacity (L)
FIVC	Forced Inspiratory Vital Capacity (L)
FIVC/FVC	Ratio FIVC of FVC
FEV.5	Forced Expiratory Volume after 0.5 seconds (L)
PIF L/s	Peak Inspiratory Flow (L/sec)
FMFT	Forced Mid-Expiratory Flow Time (sec)
FET	Forced Expiratory Time (sec)
FEV.5/FVC	Ratio FEV 0.5 of FVC
FEV.75	Forced Expiratory Volume after 0.75 seconds (L)
FEV.75/FVC	Ratio FEV 0.75 of FVC
FEV1/VC	Ratio FEV1 of VC
FEV1/IVC	Ratio FEV1 of IVC
FEV1/FVC	Ratio FEV1 of FVC
Parameter	Definition
FEV1/FIVC	Ratio FEV1 of FIVC
FEV1/FEV6	Ratio FEV1 of FEV6
FEV1/PEF	Ratio FEV1 of PEF
FEV3	Forced Expiratory Volume after 3 seconds (L)
FEV3/VC	Ratio FEV3 of VC

FEV3/FVC	Ratio FEV3 of FVC
FEV6	Forced Expiratory Volume after 6 seconds (L)
FEF25	Forced Expiratory Flow at 25% of the FVC (L/sec)
FEF50	Forced Expiratory Flow at 50% of the FVC (L/sec)
FEF75	Forced Expiratory Flow at 75% of the FVC (L/sec)
FEF0.2-1.2	Mean Forced Expiratory Flow in the volume interval between 0.2 and 1.2 L of the test (L/sec)
FEF25-75/FVC	Ratio FEF25-75 of FVC
FIV1	Forced Expiratory Volume after 1 second (L)
FIV1/FVC	Ratio FIV1 of FVC
FIV1/FIVC	Ratio FIV1 of FIVC
PIF L/min	Peak Inspiratory Flow (L/min)
FIF25	Forced Inspiratory Flow at 25% of the FVC (L/sec)
FIF50	Forced Inspiratory Flow at 50% of the FVC (L/sec)
FIF75	Forced Inspiratory Flow at 75% of the FVC (L/sec)
FIF50/FEF50	Ratio FIF 50% of FEF 50%
FEF50/FIF50	Ratio FEF 50% of FIF 50%
MVVind	Maximum Voluntary Ventilation indirectly calculated from the FEV1 (L/min)
Rind	Airways Resistance indirect measurement
Vext	Extrapolated Volume (L)
Vext/FVC	Ratio Vext to FVC
FEV1/EVC	Ratio FEV1 to EVC

4. Power Management in the Micro Spirometer

The Micro Spirometer can be powered from a computer via the USB cable or from its internal batteries. The LED on the front face of the device and the battery power icon show the power status of the device.

When powered from USB power, a power supply icon will be displayed on the status bar at the top of the screen and the LED on the device shows green.

4.1 Batteries

	When the batteries are full, a Green “Battery Full” icon is displayed on the Main Menu screen device. The LED will show green when the device battery is full.
	When the batteries start to run low, an orange “Battery Low” icon is displayed and the LED will show orange. It is possible to continue to use the device. It is advised the batteries are changed or USB cable is connected to a computer to continue testing.

	When the batteries are approaching fully discharged the “Battery Discharged” icon will be displayed on the full screen on power up and on the main screen status bar and both it and the LED will turn red. It is advised you change the batteries or attach to a PC using a USB cable to continue testing.

The Micro Spirometer uses 4 x 1.5V non-rechargeable IEC60086 certified AAA alkaline batteries. This allows the device to be used without the USB cable connected to the device.

4.2 Power Save Mode

During battery only use, the screen on the Micro Spirometer will dim after 30 seconds, go blank after 60 seconds and the device will automatically power down after 2 minutes if left unused.

When powered via USB, the screen on the Micro Spirometer will go blank if left unused for 5 minutes. The device will not automatically power down if powered by the USB. Pressing the On/Off button will bring the device out of the power save mode.

5. Cleaning & Hygiene

5.1 Preventing Cross-Contamination of Subjects

A spirometer is not designed or supplied as a ‘sterile’ device. Micro Direct intends that a new SpiroSafe filter be used for every subject to prevent cross contamination. Using a new SpiroSafe provides a significant level of protection for the subject, the device and the user against cross contamination during spirometry maneuvers.

The interior of the Micro flowhead does not require decontamination where a new SpiroSafe filter is used for each subject. The outside surfaces of the device and the flowhead tube may be cleaned with a 70% isopropyl alcohol impregnated cloth to remove any visible soiling and for low level disinfection.

If you suspect the flowhead has become contaminated or where user risk assessment identifies the need for higher level of decontamination, then it should be cleaned as per the instructions on ‘Cleaning and Hygiene’ on the Micro Direct website (www.mdspiro.com).

5.2 Inspection of the Micro Spirometer

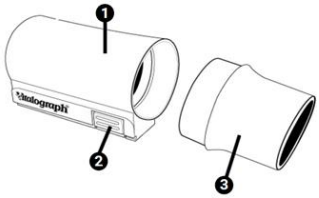


Figure 3. Flowhead Assembly

1	Flowhead Body containing Fleisch
2	Flowhead Release Button
3	Flowhead Cone

A visual inspection is recommended on a routine basis. Remove the flowhead cone from the flowhead. Examine the mesh part of the flowhead cone for damage or contamination. If it is damaged or blocked, discard and replace with a new part. Re-assemble the cone and flowhead body.

It is recommended that a calibration verification be carried out following cleaning and re-assembly as recommended by the ATS/ERS 2019 guidelines[2]

6. Remote Flowhead

The Micro flowhead can be set up to work remotely from the device. This may be useful if the display needs to be monitored while the subject uses the device.

1. Press and hold the flowhead release button and slide the flowhead away from the device from left to right.
2. From the remote flowhead adapter kit, attach the device cap in the space that was occupied by the flowhead.
3. Attach the remote flowhead adapter to the flowhead. This is done by sliding the flow head into the grooves in the remote flowhead adapter. Ensure this is fully pushed in.
4. Attach the remote flowhead to the port on the Micro Spirometer cap using the flowhead connection tube.

2 ATS/ERS Standardization of Spirometry 2019 Update Am J Respir Crit Care Med 2019 Vol 200, Iss 8 pp e70-e88

5. It is recommended that an accuracy check is carried out before the flowhead is used remotely or refitted to verify correct operation and accuracy.

7. Fault Finding Guide

Problem Fault Symptoms:	• **Calibration verification variations > ± 3%.** • **Error at last calibration verification.** • **Accuracy / Calibration Fail.**  • **False readings suspected.**
Possible Solutions: (In probable order)	• Recheck Accuracy / Calibration. • Was the correct syringe volume selected? • Calibration verification is required after cleaning/disinfecting the flowhead assembly. • Flowhead body pressure port holes/grommets blocked. • Flowhead Fleisch element not dried thoroughly. • Flowhead Fleisch element assembly blocked. • Main PCB failure – contact support.
Problem Fault Symptoms:	• **Test begins automatically.** • **Volume accumulates automatically without the subject blowing.** • **Very small VC or FVC test displayed.**
Possible Solutions: (In probable order)	• Flowhead and/or tubing when using remote flowhead not stationary at the start of the test. Hold them steady until the 'Blow Icon' appears. • Return to Main Menu and re-enter the test routine.
Problem Fault Symptoms:	• **No volume measurements.**
Possible Solutions: (In probable order)	• Ensure the grommets on flowhead are not pinched or trapped.

Problem Fault Symptoms:	• **Cannot print to PC (Reports Application).** • **Corrupt or missing data on printout.**
Possible Solutions: (In probable order)	• Check USB cable is connected between Micro Spirometer and the PC. • Check to ensure the Reports application is correctly installed. • Check to ensure the required software drivers are installed on the PC. • Main PCB failure – contact support.
Problem Fault Symptoms:	• **Cannot read screen.**
Possible Solutions: (In probable order)	• The batteries may be low. Plug in the USB cable and switch on the device. • LCD failure – contact support. • Main PCB failure – contact support.

1. Medical Devices may be affected by mobile RF communications equipment including cellular telephones and other personal or household devices not intended for medical facilities. It is recommended that all equipment used near the Micro Spirometer comply with the medical electromagnetic compatibility standards and to check before use that no interference is evident or possible. If interference is suspected or possible, switching off the offending device is the normal solution, as is required in aircraft and medical facilities.
2. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Micro, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
3. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify they are operating normally.

8. Customer Service

Service and repairs should be carried out only by the manufacturer or by Service Agents specifically approved by the manufacturer. The manufacturer makes instructions and parts available to designated service agents as required.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer or Micro Direct and the Regulatory Authorities of the country. Refer to the contact information listed below.

Toll Free:	1-800-588-3381
Telephone:	207-786-7808
Fax:	207-786-7280
Email:	orders@mdspiro.com
	sales@mdspiro.com
	support@mdspiro.com
Website:	www.mdspiro.com

9. Consumables and Accessories

Cat. No.	Description
3385	SpiroSafe Viral/Bacterial Filters (100)
3304	Nose Clips (20)
3325	3-Liter Calibration Syringe
79158	Flow Cone (10)
79191	Flowhead Complete
79192	Flowhead Connection Tube
79163	Remote Flowhead Adapter Kit
41421	USB Cable
65030SPR	Reports Application Software
48-70	Protex Disinfectant Wipe

10. Disposal

The device must be taken to separate collection at the product end-of-life. Do not dispose of these products as unsorted municipal waste.

Used SpiroSafe filters constitute minimally soiled waste from human healthcare. SpiroSafe filters are made from recyclable material and should be disposed of in line with local requirements.

11. Explanation of Symbols

	Type B equipment
	Class II
VA	Power Rating
	Direct Current
	Instructions for Use; operating instructions
	Manufacturer
	Date of Manufacture (include date in format yyyy-mm-dd)
	USB connection
	The device must be taken to separate collection at the product end-of-life. Do not dispose of these products as unsorted municipal waste.
	Fragile, handle with care
	Keep Dry
	Do Not Re-Use

	Nonsterile
	Recycle
	QR code - matrix bar code. All information in the bar code is included in the text under it
	Use by Date (Date Format yyyy-mm-dd)
	Device Order Number
	Lot/Batch Number
	Serial Number
	On/Off Button
+	Battery Positive

11.1 Icons Used in the Micro Spirometer

	Subject		VC Test
	FVC Test		Post Test
	Settings		Enter
	Subject Options		Device Settings
	Accuracy/Calibration		Device and Software Information
	Age		Height
	Gender – Male		Gender – Female
	Posture – Sitting		Posture – Standing

	Weight On		Weight Off
	Population Group – On		Population Group – Off
	Results Options		Parameters
	Time/Date		Service Mode
	VC Volume-Time Graph		VC Volume Graph
	Zoom Out		Zoom In
	Test Results		Blow Now
	FVC Volume-Time Graph		FVC Flow-Volume Graph
	Delete		Error or Invalid Entry (re-enter field)
	Serial Number		Software Number
	Syringe Volume		Micro Device
	USB Power		Battery Full
	Battery Low		Battery Empty
	Z Score		% Predicted
	Sound On		Sound Off
	User Passcode – On/Off Locked		User Passcode – Off/Unlocked
	Temperature		Bluetooth
	Accuracy/Calibration Fail		Error/Invalid Entry
	Strokes Not Repeatable		Syringe In Stroke Syringe Out Stroke
	Error at Last Accuracy Check (shown on startup)		New Flowhead

12. Description of the Micro Spirometer

The Micro Spirometer is a handheld spirometer which measures subject respiratory parameters including but not limited to VC, FVC, FEV1, PEF and MVV. The Micro Spirometer is designed for portable spirometry. The Fleisch flowhead is used for testing and is integral to the device, although it may be removed to use with an adapter for remote testing.

12.1 Indications for Use

The indications for use of the Micro Spirometer is in the assessment of lung function through the measurement of dynamic lung volumes, i.e. spirometry.

The Micro Spirometer is designed to be operated by medical professionals trained in respiratory and lung function testing on adults and pediatrics, 2.5 years and older, in a variety of environments, e.g., primary care, hospitals, occupational health centers and private homes under the supervision of a healthcare provider. The measurements obtained from a lung function test provide objective information used in the diagnosis of lung disease and monitoring lung health.

13. Technical Specifications

Product	Micro Spirometer, Model MD6300
Flow Detection Principal	Fleisch Type Pneumotachograph
Volume Detection	Flow Integration Sampling at 100 Hz
Maximum Test Duration	90 Seconds
Maximum Displayed Volume	10 Liters
Volume Accuracy	Better than ±3% or ±0.05 L of the reading (ISO 26782:2009)
Flow Measurement Range	Max. Flow Rate ±960 L/min (±16 L/s) Min. Flow Rate ±1.2 L/min (±0.02 L/s)
PEF Accuracy	±10% or ±10 L/min of the reading (ISO 23747:2015)
Back Pressure	Less than 0.1 kPa/L/sec at 14 L/sec (ATS/ERS 2005)
Operating Temperature Range	ISO 26782 limits: 62.6 - 95° F
Operating Humidity Range	30% - 75%
Ambient Pressure Range	850hPa – 1060hPa
Performance Standards the Micro Spirometer meets or exceeds	ATS/ERS 2019, ISO 23747:2015 & ISO 26782:20009

Safety Standards	EN 60601-1:2006 + A1:2013
EMC Standards	EN 60601-1-2:2015
QA/GMP Standards	EN ISO 13485, FDA 21 CFR 820, CMDR SOR/98-282 & JPAL, MDSAP
Dimensions	~ 3.25” x 3.50” x 1.25”
Weight	~ 9 ounces
Communications	USB & Bluetooth option available. (***Note**: The Reports Application is not enabled for Bluetooth communications with this device)*
Power Supply	4 x 1.5V AAA batteries (6V) 5V DC via USB 2.0/3.0
Minimum PC System Requirements to run the Reports Software	Processor: Pentium, Celeron CPU, 1.73 GHz or better Operating Systems: Windows® 7 or higher Memory: 128 MB of RAM, 256 MB recommended Hard Disk: 40 MB for the application, 280 MB for the .NET framework Display: A display supporting a resolution of 1280 x 800 pixels, higher recommended. Other: • Installation of the .NET Framework 3.5 • CD-Rom Drive • USB Port (to connect device) • Install the application as System Administrator and provide full read/write access rights to the folder and sub-folders where the application has been installed for all applicable users. • Internet Explorer 8.0 or above required.

Notes:

Class II device when powered by USB. Otherwise, is internally powered device.

- ME system is created when the device is connected to a supporting PC via USB. This system made from the following parts: Supporting PC, USB Cable and Micro Device.
- The SpiroSafe filter, flowhead and device body are type BF applied part.

An applied part is a part of the equipment, that in normal use necessarily comes into physical contact with the subject for equipment or system to perform its function.

14. Contraindications, Warnings, Precautions and Adverse Reactions

1. No modification of this ME equipment or ME system is allowed, except for connecting and disconnecting of the USB interface. Any unauthorized changes to the Micro Spirometer may compromise product safety and/or data and as such the manufacturer cannot be held responsible and the device will no longer be supported.
2. The Micro Spirometer is not designed as a sterile device. Always follow the safety guidelines given by the manufacturer of cleaning and disinfectant chemicals.
3. For the device to be used as intended, there is no requirement to clean any supporting computer. If cleaning is required to remove any visible soiling, this should be done as per the computer manufacturer's instructions.
4. Micro Direct intends a new SpiroSafe Filter be used for every subject to prevent cross contamination. Using a new SpiroSafe filter provides a significant level of protection of the subject, the device and the user against cross contamination during spirometry maneuvers. A SpiroSafe filter is for single use only.
5. Spirometry is a valuable tool that provides important information to clinicians which is used together with other physical findings, symptoms, and history to reach a diagnosis (ATS/ERS 2019).
6. When using the Micro Spirometer with a remote flowhead adaptor ensure that the flowhead connecting tube is not pinched or trapped as spirometry results may appear to be inverted.
7. Take care not to block the mouthpiece with tongue or teeth during testing. A 'spitting' action or cough will give false readings.
8. Subject fatigue may occur during spirometry testing depending on the subject's characteristics e.g., age, health status. For

safety reasons, testing should be preferably done in the sitting position, using a chair with arms and without wheels. Subject may also take a break between tests. A subject fatigue warning will appear after 8 maneuvers and the maximum number of allowed maneuvers in one session is 20.

9. All values displayed are expressed as BTPS values.
10. Time zero is determined using the back-extrapolated method from the steepest part of the curve.
11. After fitting a new flowhead to the Micro Spirometer, it is necessary to set-up the flowhead with the device. The procedure is outlined in section 3.6.
12. Do not expose the Micro Spirometer to liquids, except for 70% Isopropyl wipes for cleaning as detailed in Section 5 Cleaning & Hygiene.
13. The Micro Spirometer should not be used in the presence of flammable liquids or gases, dust, sand or any other chemical substances.
14. All spirometry standards recommend checking the accuracy of lung function measuring devices daily with a 3-L syringe to validate the instrument is measuring accurately. The Micro Spirometer should never be outside accuracy limits. Accuracy should be checked after cleaning or disassembling the spirometer for any reason, after adjusting calibration or if the flowhead or device has been dropped.
15. Service and repairs should be carried out only by the manufacturer or by Service Agents specifically approved by the manufacturer.
16. Maintenance must not be performed while the device is in use by a subject.
17. The device uses 4x 1.5V non-rechargeable IEC60086 certified AAA alkaline batteries.
18. Use of accessories, parts and cables other than those specified or provided by the manufacturer for this equipment is not recommended.
19. Non-medical equipment must be kept outside the subject environment i.e., any area in which intentional or unintentional contact between the subject and parts of the system, or some other persons touching part of the system, can occur.
20. Including the SpiroSafe Filter, the subject may contact any part of the device during a spirometry session. There are no adverse

effects if the subject comes into contact with any part of the Micro Spirometer.

21. The AAA batteries should be removed, if the device is intended to be stored, without use, for an extended period.
22. Reprocessing of single use devices is not permitted.
23. Non-ME equipment used with the device, should comply with its relevant IEC or ISO standard and supplied via a suitably approved PSU.
24. The operator should not contact to patient while simultaneously contacting any of the following: batteries, components within battery compartment and USB connector (whilst the USB cable is connected to the supporting PC) or supporting PC's connectors

15. CE Notice

Marking by the symbol  indicates compliance of the Model MD6300 Micro Spirometer to the Medical Devices Directive of the European Community.

The Model MD6300 Micro Spirometer is intended for use in a variety of professional healthcare environments, e.g., primary care, hospital wards and occupational health centers, except for near active high frequency surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high. The customer or the user of the Micro Spirometer should assure that it is not used in such an environment.

The Model MD6300 Micro Spirometer has been tested in accordance with:

EN 60601-1:2006 + A1:2013 Medical electrical equipment. General requirements for basic safety and essential performance.

EN 60601-1-2:2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral

Standard: Electromagnetic disturbances - Requirements and tests.

EN 60601-1-2:2015- Emissions tests		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Model MD6300 micro 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	Class B	The Model MD6300 micro is suitable for use in all establishments, including domestic establishments and those connected to the public mains network (e.g., at home and doctor's offices in residential areas)

EN 60601-1-2:2015 - Immunity tests		
Immunity test	Test level	Compliance level reached
Electrostatic discharge (ESD) EN 61000-4-2	Contact: +8kv Air: +15kv	Contact: +8kv Air: +15kv
Power frequency (60 Hz) magnetic field EN 61000-4-8	30A/m	30A/m
Radiated RF EN 61000-4-3	3 V/m 80MHz to 2700MHZ	3 V/m 80MHz to 2700 MHZ

16. FDA Notice

Caution: Federal law restricts this device to sale by or on the order of a physician.

17. EU Declaration of Conformity

Product: MD6300 Micro Spirometer

The manufacturer hereby ensures and declares the above product associated with these instructions for use, is designed and manufactured in accordance with the following QMS regulations and standards.

- European Medical Devices Directive {MDD} 93/42/EEC, as amended.

  This device is classified as IIa per Annex IX of the MDD also meets the provision of the Essential Requirements, Annex I, via compliance with Annex II of the Medical Devices Directive as per Article 11, section 3a, excluding point 4 of Annex II.

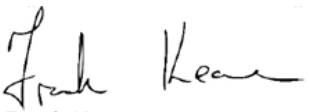
- Canadian Medical Device Regulation {CMDR SOR/98-282}.
- FDA Quality System Regulation {QSR} 21 CFR 820.
- EN ISO 13485 Medical devices. Quality management systems. Requirements for regulatory purposes

Certifying Body: British Standards Institute {BSI}.

BSI Notified Body #: 2797

Certificate Nos. CE 00772, CE 85553, MD 82182

Signed on behalf of Vitalograph (Ireland) Ltd.



Frank Keane.
CEO, Vitalograph Ltd.

18. Guarantee

Subject to the conditions listed below, the manufacturer and its associated companies (hereinafter called the Company) guarantee to repair or at its option replace any component thereof, which in the option of the Company is faulty or below standards as result of inferior workmanship or materials.

1. The conditions of this Guarantee are:
2. This Guarantee shall only apply to hardware defects which are notified to the Company or to its accredited distributor within 1 year of the date of purchase of the equipment, unless otherwise agreed in writing by the Company.
3. Software (meaning computer software, or user installable modules) is guaranteed for 90 days from the date of purchase.
4. The Company warrants the software when correctly used in conjunction with the hardware will perform in the manner described in the Company's literature and user manuals. The Company undertakes to rectify at no expense to the customer any software failure notified within the period stated above, provided the failure can be recreated and the software has been installed and used in accordance with the user manual. Notwithstanding this clause, the software is not warranted to be free of errors.
5. This Guarantee does not cover any faults caused by accident, misuse, neglect, tampering with the equipment, use of consumable items or parts not approved by the Company, or any attempt at adjustment or repair other than by personnel accredited by the Company, nor does it cover reinstatement of any configuration changes caused by the installation of any software.
6. If a defect occurs, please contact the supplier from it was purchased for advice. The Company does not authorize any person to create for it any other obligation or liability in connection with the manufacturer’s equipment.
7. This Guarantee is not transferable and no person, firm or company has any authority to vary the terms or conditions of this guarantee.
8. To the maximum extent permitted by law, the Company does not accept liability for any consequential damages arising out of the use of, or inability to use any of the manufacturer’s equipment.
9. This Guarantee is offered as an additional benefit to the Consumer's statutory rights and does not affect these rights in any way.

CD-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