MD SPIRO
a Micro Direct company

Micro

Model MD6300

Instruction for Use

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Indications for Spirometry

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

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

Diagnosis and ICD-10-CM Codes on back cover

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1. Indications for Use

The device is a spirometer which measures a subjects respiratory parameters including FVC, FEV1, FEV6, PEF, MVV and VC. The Micro Spirometer is a handheld spirometer designed for lung function testing for use on adults and pediatrics, 5 years and older, in a variety of environments such as hospital wards, health centers and private homes under the supervision of a healthcare provider.

2. Contraindications, Warnings, Precautions and Adverse Reactions

1. No modification of this equipment is allowed. Any unauthorized changes to the device 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. 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.
4. Spirometry may support or exclude diagnosis but it cannot make one (ATS/ERS 2019[1]).
5. The device is marked as “Rx Only” and therefore may only be sold in the USA by or on the order of a physician.
6. When using the remote flowhead ensure that the flowhead connecting tube is not pinched or trapped as spirometry results may be affected, or a false reading may be detected.
7. The USB cable supplied with the device has the potential to be a strangulation hazard and therefore should be kept out of the reach of children and pets.
8. The device is rated to IP22 which protects it from solids >12.5 mm and dripping water however it is not designed to be waterproof. Do not get the device wet or use it in a wet environment (e.g., in the rain, in the shower). If the device does get wet, it may cease to function however there is no safety risk or potential harm to the user. If the device does get wet, contact the device manufacturer.

[1] ATS/ERS Standardization of Spirometry Eur Respir J2019

9. Take care not to block the flowhead cone with tongue or teeth during testing. A ‘spitting’ action or cough will give a false reading.
10. 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. The maximum number of efforts for each of the test modules (SVC, FVC and Post) on the Micro Spirometer is 20 maneuvers.
11. All values displayed are expressed as BTPS values.
12. Time zero is determined using the back-extrapolated method, from the steepest part of the curve.
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 completing a calibration verification 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. A calibration verification should be completed after cleaning or disassembling the spirometer, 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. Do not disconnect the device or USB cable from the computer running the software during data transfer or printing.
18. The device contains a lithium coin cell battery which is not accessible by the user. Any suspected battery faults should be reported to the manufacturer.
19. The device uses 4x 1.5V non-rechargeable IEC60086 certified AAA alkaline batteries.
20. The AAA batteries should be removed if the Micro Spirometer is intended to be stored, without use, for an extended period.
21. When replacing the batteries all four should be replaced together, use batteries from the same manufacturer, never mix new and old batteries, make sure all four batteries are inserted in the correct orientation.

22. If the flowhead is removed from the Micro Spirometer (when disassembling for cleaning and/or to attach the remote flowhead adapter), care should be taken with the exposed edges. During normal use, these edges are covered, are not accessible by the user or subject.
23. Use of accessories and cables other than those specified or provided by the manufacturer for this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of the device and result in improper operation.
24. 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.
25. 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 device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
26. 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.
27. Avoid exposure to known sources of EMI (Electromagnetic Interference) such as diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as anti-theft/electronic article surveillance systems, metal detectors. Note that the presence of RFID devices may not be obviously. If such interference is suspected, reposition the equipment, if possible, to maximize distances.
28. This device is ‘MR Unsafe’ do not use it in an MRI environment.
29. The applied part is the flowhead and device body. These, along with the SpiroSafe Filter, are the contact points for the subject during a spirometry session. There are no adverse effects if the subject comes into contact with any other part of the device.

3. Main Components of the Micro Spirometer

The Micro is a standalone spirometer. Device Studio software allows the Micro Spirometer to generate reports to a computer after testing is complete but is not required for the device to function.

The main components of the Micro Spirometer are:

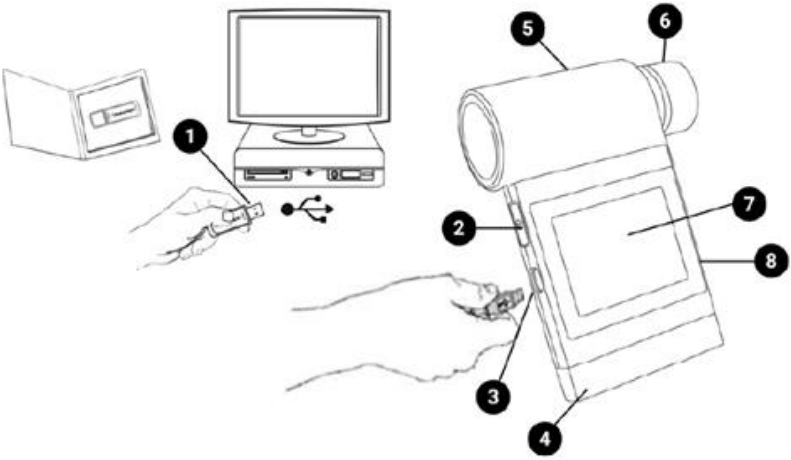


Figure 1 The main components of the Micro Spirometer

1	USB Flash Drive containing Device Studio Software
2	Power (On/Off) Button
3	Micro USB Port
4	Plinth
5	Flowhead
6	Flowhead Cone
7	LCD/Touch Panel Display
8	Battery Compartment (4 x 1.5V AAA Batteries)

Note: *Computer Shown for illustration purposes only and not supplied.*

3.1 Features of the Micro Spirometer

The features include:

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

4. Setting Up the Micro Spirometer

1. Insert 4 x 1.5V AAA batteries into the battery compartment.
2. Alternatively, the device may be powered using the USB cable supplied. Connect one end of the USB cable into a USB port on a computer and the other end into the micro-USB connector on the device.
3. Press the On/Off switch to turn the device on.
4. Install Device Studio on the computer following instructions supplied with the software.
5. To use Device Studio, the Micro Spirometer must be connected 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 and is at room temperature prior to testing.

Ensure a calibration verification is completed on each testing day, prior to using the device (see Section 5.4 Calibration Verification).

If using with the with the remote flowhead (not included as standard):

1. Remove the flowhead from the main body of the device by gripping and sliding it firmly in the direction of the flowhead cone (6).
2. Connect the remote flowhead adapter (4) to the base of the flowhead (5), connect the device cap (2) to the device (1).
3. Unwrap the flowhead connection tubing (3) and connect one end to device cap (2) and the other end to the remote flowhead adapter (4). See Figure 2. The tubing is keyed, so it will only connect one way.

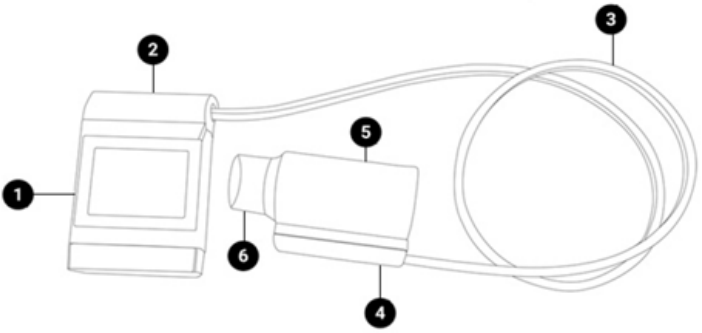


Figure 2 Micro with remote flowhead

1	Micro Device
2	Device Cap
3	Flowhead Connection Tubing
4	Remote Flowhead Adaptor
5	Flowhead
6	Flowhead Cone

3. Operating Instructions

On first time use, the Micro opens on the Setup screen for Date and Time. Enter the current date and time.

Press the forward icon to save.

Continue to the temperature entry screen . Enter the temperature.

Press the forward icon to save.

Continue to the Maine Menu screen which including the following options:

New Subject 

VC Test 

FVC Test 

Post Test 

The test icons will appear greyed out and can't be selected until a subject is created. The Post Test icon becomes active when an FVC pre-test is performed.

The status bar at the top on the screen shows the following after tests have been completed:

1. V – indicates a VC test has been performed
2. F – indicates an FVC has been performed
3. P – indicates a Post test has been performed.

5.1 Entering Subject Data

1. Select New Subject  on the Main Menu.
2. The available information fields available are: Date of Birth  , Height  , Birth Sex , Weight , Population . Weight and Population Group are on the second screen and may be enabled in the Configuration Menu (Subject Options ).
3. To enter the information for Date of Birth, Height and Weight, touch the blank field on the screen to open the touchscreen keyboard. Use the keyboard to enter the information. Units will automatically switch between cm/kg and in/lbs.
4. Select Birth Sex by pressing the male or female  icon.
5. Select Population Group by pressing the appropriate option on the screen. Use the select arrow on the right of the screen to access additional Population Groups.
6. Press the forward button  to save the subjects details.
7. If a value is not entered for Birth Sex, Height or Date of Birth, an Error Icon  will appear next to the empty field. If the information is not entered then the predicted values will not appear in test results.

8. To exit the new subject screen, press the forward button.

5.2 Conducting a Test[2]

To prepare for a test session:

1. Ensure the accuracy of the device has been checked. (Refer to the section 5.4 on Calibration Verification).
2. Ensure the subject's details have been entered on the Micro Spirometer. A test session can be performed without filling in any details for the subject but this is not recommended.
3. Fit a new disposable SpiroSafe filter to the flowhead. A disposable noseclip may also be used.
4. Select the test option 'VC' or 'FVC'. Instruct and demonstrate the test as detailed below.
5. Testing may begin when the 'Exhale to Begin' icon appears.  .
6. The subject should:
   - Sit upright and maintain this posture throughout the test.
   - Fit the noseclip and relax.
   - Place SpiroSafe Filter in mouth and close lips around the mouthpiece.
   - Seal lips around the mouthpiece and keep the tongue down.

5.2.1 VC Testing

To perform a VC test  (ensure Volume/time (V/t) is selected):

1. Instruct the subject to breath normally.
2. The subject should inhale completely, with a brief pause when lungs are completely full (≤ 2 secs).
3. Then exhale in a relaxed manner with no hesitation until no more air can be expelled. It is vital the operator encourages the subject to keep exhaling to ensure all air is expelled (when a plateau has been reached or expiration time reaches 15 seconds).

[2] Derived from terminology and guidance taken from ATS/ERS Standardization of Spirometry 2019 Update Am J Respir Crit Care Med 2019 Vol 200, Iss 8 pp e-70-e88

4. Results may be viewed as either: Volume/time (V/t)  or Volume Bar graph  by pressing the icon on the side menu. These are not enabled during test.

5. View a full screen graph by using the zoom button  at the side of the test screen. Zoom in  to return to normal mode. These are not enabled during test.

6. The results summary at the top of the screen shows the VC of the last blow. The number of blows is shown next to the last test VC.

7. The best three tests are shown on the graph in order of rank (best 1, 2, 3 etc.). A legend at the top of the graph explains the order of the tests.

8. Select results  from the side menu to view results.
   - Use the left/right arrows to select which test results to view.
   - The tests are shown in order of rank (best is ranked number 1, then 2, 3 etc.).

9. To delete the current blow:
   - Select the Delete option from the side menu. Two delete icons will appear:

     Delete (green)  Press to confirm the deletion.

     Delete (red)  : Press to cancel the deletion.

     To clear/delete all the sessions on the device, connect to Device Studio as outlined in section 5.3 and move all the data to Device Studio to clear if from the device.

10. After performing the VC tests, press the enter button  to exit the **VC Test** screen and return to the **Main Menu**.

Note: Single breath technique may also be performed.

5.2.2. FVC Test

To perform an FVC test  :

1. Instruct the subject to breathe normally.
2. The subject should inhale completely and rapidly, with a brief pause when lungs are completely full (≤ 2 secs).

3. Then exhale with maximal effort until no more air can be expelled (when a plateau has been reached or forced expiratory time (FET) reaches 15 seconds).
4. It is vital the operator encourages the subject to keep exhaling to ensure all air is expelled. The operator should repeat instructions as necessary, with enthusiasm.
5. Breathe in with maximal effort until completely full. The maneuver is now complete, remove the mouthpiece from the mouth.
6. Listen for two beeps. The device is ready for the next blow.
7. Repeat for a minimum of three maneuvers, up to a maximum of 20.
8. The results may be viewed as either a Volume/time (V/t)  or Flow/Volume (F/V)  by pressing the icons on the side menu. These are not enabled during the test.
9. The graph may be changed to a full screen graph by using the zoom button  on the side menu. Zoom in  to return to normal mode. These are not enabled during test.
10. The results summary at the top of the screen shows the FVC and FEV1 of the last blow.
11. The number of tests (for VC) or the number of usable tests or bad blow '!' indicator (for FVC) is shown next to the last test results.
12. The best three tests are shown on the graph in order of rank (best 1, 2, 3 etc.). A legend on the top of the graph explains the order of the tests.
13. Select results  from the side menu to view results.
    - Use the left/right arrows to select which test results to view.
    - Scroll through the results for each test using the up/down arrows. The number of parameters displayed will depend on the configured parameters.
    - The tests are shown in order of rank (best is ranked number 1, then 2, 3 etc.).
    - The results screen has several columns, arranged in a similar manner to the printout. The first column displays the parameter name, the second displays the units, the third the test value and the fourth column shows the %Pred or Z-value, depending on the configuration.

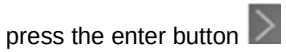
14. To delete the current blow:

    - Select the Delete option from the side menu. Two delete icons will appear:

      Delete (green)  Press to confirm the deletion.

      Delete (red)  : Press to cancel the deletion.

      To clear/delete all the sessions on the device, connect to Device Studio as outlined in section 5.3 and move all the data to Device Studio to clear if from the device.

15. After performing the FVC tests, press the enter button  to exit the FVC Test

***Note**: Single breath technique may also be performed.*

***Note**: Different tests conducted during the same session i.e., VC and FVC, will be treated as a single session, with a report for that session. A Post test will be treated as a single session, with a report for that session. If more than one test is required for the same subject, the device should be switched off and on again between tests so they are registered as separate sessions and separate reports can be generated.*

***Note**: A session ends and is saved when one of the following occur: the device is turned off, a new subject is created or the device is connected to Device Studio.*

5.2.3 Post Bronchodilator (Post) Test

A Post test session may be performed on the last FVC pre-test session performed. The device will retain the last pre-bronchodilator test (pre-test) even when it is turned off and on again and/or the data has been transmitted to Device Studio.

To perform a Post-test  :

1. Select 'Post Mode' from the **Main Menu**.
2. Perform the Post FVC test as outlined in section 5.2.2 Performing an FVC Test.

Note: A Post Test may only be selected if an FVC pre-test has been completed. When leaving the Post FVC test screen and returning to the main menu, the user will not be able to select either the VC or FVC test (they will be greyed out) as the Micro is still in Post mode, unless the pre-FVC contains VC data in which case the VC will still be available.

5.2.4. Saving the Test Session

The Micro Spirometer has the capacity to store 325 subject entries with corresponding session data. Only the best three blows will be stored with

each session. The session information will also include the subject details entered and the best pre-test if there is a Post-test session.

The Micro Spirometer is intended to be used as a temporary storage device. It may be connected to Device Studio to produce pdf reports of the session data, this will move all subject/sessions to the Device Studio application and flag them as deleted on the device except for the last FVC Pre-test.

***Note**: If more than the maximum 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).*

5.3 Reporting

The Micro Spirometer prints reports to an external printer through the Device Studio application.

To generate PDF reports:

1. Connect the Micro Spirometer to a computer running Device Studio.
2. The Device Studio application should be open, the Micro Spirometer switched on and in the Main Menu.
3. When connected, the remote mode icon will display on the Micro Spirometer.
4. Device Studio will search for assessments on the device. The user will be presented with the download screen for each report.
5. Additional information may be added such as name, user interpretation and comments.
6. Device Studio may also be used to print/save calibration verification reports and download/print all assessments.

The settings option on Device Studio allows the user to configure information displayed on the session report.

Additional guidance on using Device Studio can be found in the Instructions for Use supplied on the Device Studio USB flash drive and in the software help menu.

Note: Do not disconnect the device or USB cable from the computer during data transfer or printing.

Note: When the Micro Spirometer is connected to Device Studio, it will move, not copy, the stored sessions, except for the latest FVC Pre-session.

Note: Different tests conducted during the same session i.e., VC and FVC, will be treated as a single session, with a report for that session. A Post test will be treated as a single session, with a report for that session.

If more than one test is required for the same subject, the Micro Spirometer should be switched off and on again between tests so they are registered as separate sessions and separate reports can be generated.

5.4 Calibration Verification

The Micro Spirometer should never be outside accuracy limits unless damaged or in a fault condition. In normal use, it is recommended that a daily calibration verification is performed on the device. ISO 26782 recommendations require that the difference between the volume measured by the spirometer and the volume pumped into the spirometer from a syringe is within 3%.

To complete a calibration verification:

1. Select the Configuration icon on the Main Menu screen.
2. Select the calibration verification icon .
3. Enter the syringe volume , serial number SN and ambient temperature using the touchscreen keypad.
4. Connect the flowhead to the syringe and pump air through the flowhead to bring it to ambient temperature. If the flowhead has recently been used for testing or has come from a cold environment, pump air through it several times to equilibrate its temperature.

Figure 3: Micro Spirometer connected to a 3L syringe

5. Pres the 'Forward' key to move to the Calibration Verification screen, follow the on-screen instructions.

6. The result of each stroke, expiratory (E) and inspiratory (I) displays on the top of the screen with the number of strokes shown in between. If they are reproducible and within 3%, this

will be displayed on the top of the screen and a syringe with a green tick pass  will display. Pressing the forward key  will return to the Main Configuration menu and the calibration verification is recorded.

In the unlikely event the result is outside 3% or nonreproducible, an error icon will display.

	Successful verification (green syringe with a tick).
	Non-reproducible syringe strokes (red syringe with 'information' in center, after the 5th stroke). Outside 25% (poor technique, repeat verification or an issue with the flowhead/device, contact technical support).
	Outside 3%, 6% (purple syringe and shows >3%, >6% on the top of the screen). The higher the %, the more severe the issue. Over 3%, repeat calibration verification. Over 6% may indicate the device requires cleaning or maintenance.

The following icons display after the calibration update:

	Calibration update (purple syringe with purple tick in a circle, % shown on top of screen).
	Non-reproducible syringe strokes (red syringe with 'information' in center, after the 5th stroke). Outside 25%.

The following displays on power on if the previous calibration verification has failed:

	Calibration verification has failed (orange syringe with triangular warning symbol).

A calibration verification report may be printed or saved if required, see section 5.3 Reporting

If the procedure was followed correctly and the error icon is showing, the calibration verification should be repeated. If the error continues to show, contact the manufacturer using the contact information in this document.

***Note**: To exit the Calibration Verification screen without performing a check, press the forward key*  *to return to the Configuration Menu screen. The calibration verification will not be logged to the device memory in this case.*

***Note**: A calibration verification is recommended daily, if the device has been stored or transported, if the flowhead is dropped or replaced and if EMI (Electromagnetic Interference) is suspected or possible.*

5.5 Configuration Options

To access the Configuration menu, press the  icon on the Main Menu screen.

There are four configuration options:

1. The Subject option  to configure:
    a. Posture: set the posture for the session to sitting  or standing  .
    b. Weight: turn on  to enter the subject's weight or off  if not required.
    c. Population Group: turn on  to enter the subject's population group or off  if not required.
2. The Device setting option  to configure:
    a. The device  which includes:
        - Selecting between % Predicted or Z-score . The parameter selected will them be displayed in the results screen.
        - Audio: turn audio off  and put the Micro Spirometer into silent mode.
        - User Passcode: use  to lock the device so that any user will be prompted for a passcode on start up.

- Temperature: enter the temperature, up to 2 decimal places. The default setting is 23°C.

b. Parameters: Choose to select which parameters to display on the results screen, use the left/right arrows to navigate between screens. A maximum of 8 parameters can be selected.

The following are all available parameters:

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
PEF L/s	Peak Expiratory Flow (L/sec)
PEF L/min	Peak Expiratory Flow (L/min)
FEF25-75	Forced Expiratory Flow: the mean FEF in the time interval between 25% and 75% of the FVC (L/sec).
FEF75-85	Forced 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
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 FIVC (L/sec)

FIF50	Forced Inspiratory Flow at 50% of the FIVC (L/sec)
FIF75	Forced Inspiratory Flow at 75% of the FIVC (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
FEV1/EVC	Ratio FEV1 to EVC
BEV/FVC	Ratio BEV to FVC
BEV	Back Extrapolated Volume
EOTV	End of Test Volume
tRise	Rise Time
tHes	Hesitation Time

c. Date/Time: Select to set or change the date and/or time. Use the up/down arrows to edit fields.

d. Service mode/Technician. This option is for servicing and technicians, a passcode is required to activate.

3. Calibration Verification : See section 5.4 for details on performing a Calibration Verification.

4. About : Contains information about the software which should be used if making inquiries to the manufacturer or a service agent. This information includes the model number (MD6300), serial number of the device, the software reference number, date of last calibration verification and date of service completion.

6. Power Management

The Micro Spirometer may be powered from a computer via the USB cable or from internal batteries. The battery icon shows the power status of the device.

The device uses 4 x 1.5 non-rechargeable IEC60086 certified AAA alkaline batteries.

***Note**: When replacing the batteries, all 4 should be replaced together. Use batteries from the same manufacturer, never mix new and old batteries and make sure the batteries are in the correct orientation.*

6.1 Batteries

	Battery Full – a white battery icon.
	Battery Low – half-filled white battery icon.

	Battery Depleted – an orange depleted battery icon. Continued use is allowed, however prepare to change the batteries, or connect via USB cable to a computer to continue testing.
	Battery Discharged – the Battery Discharged icon displays on full screen on power up and a red empty battery icon displays on the status bar. Batteries should be changed immediately or the device connected to a computer via USB cable to continue testing.

When the USB power is connected, this icon  displays instead of the battery icon.

6.2 Power Save Mode

To improve battery life, when powered by batteries, the Micro Spirometer will auto power down if left unused for 5 minutes.

When running of the USB, the device screen will go blank if left unused for 5 minutes. The device will not auto power down if powered by USB.

Press the screen or on/off button will bring the device out of power save mode.

7. Cleaning & Hygiene

7.1 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.

Where the user suspects the flowhead has become contaminated or where local 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).

Table of Cleaning/Disinfection Methods

Part	Clean/Low Level Disinfection	Recommended Cleaning/Low Level Disinfection
Case Exterior	Clean	Wiping with a 70% isopropyl alcohol impregnated cloth provides a suitable form of cleaning. The exposure time for low level disinfection using 70% IPA wipes is ≥ 1minute.[3]
Screen	Clean	For the screen, lightly wipe the surface with cotton pad or other soft material. **NOTE: DO NOT wipe in a circular motion. Strokes should be either up/down or over/back**.

3 Rutala, W. A. 2017 “Back to the Basics” accessed from disinfection&sterilization.org, June 2020.

7.2 Inspection of the Micro Spirometer

A visual inspection is recommended on a routine basis. Examine cone and flow conditioning mesh filter for damage or contamination. If damaged or blocked, it should be replaced with a new part. Examine the Fleisch element and replace if damaged.

If it is suspected that the flowhead has become contaminated or where user risk assessment identifies a need for higher level of decontamination, then it should be cleaned as per the instructions in ‘Cleaning and Hygiene’ on the Micro Direct website.

It is recommended a calibration verification is carried out following cleaning and re-assembly as recommended by the ATS/ERS 2019 guidelines.[4]

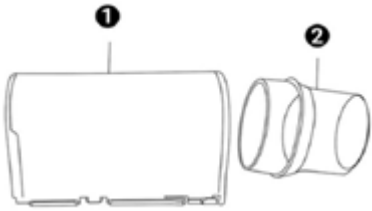


Figure 4. Flowhead Assembly

1	Flowhead containing Fleisch
2	Flowhead Cone

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

8. 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. Slide the flowhead away from the device from left to right. You may need to push firmly to get it to move.
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.
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.

9. Fault Finding Guide

Problem Fault Symptoms:	• **Calibration verification variations > ± 3%.** • **False readings suspected.**
Possible Solutions: (In probable order)	• The % error indicates the severity of the issue. Over 3%, repeat the calibration verification. Over 25%, the user should contact technical support. • Was the correct syringe volume selected? • Flowhead pressure tapping holes blocked. Contact support. • Flowhead Fleisch element assembly sealing 'O' rings damaged. Contact support. • Flowhead Fleisch element assembly blocked. Contact support. • Cold syringe. Ensure syringe is in its test environment for at least an hour before use. • EMI (Electromagnetic Interference) that exceeds EN60601-1-2 EMC standard. Turn off offending device or move the Micro Spirometer to another location and repeat. • Internal tubing from pressure ports on device is blocked. Contact support.
Problem Fault Symptoms:	• **Cannot print to external printer**
Possible Solutions: (In	• Check device is connected to the computer and Device Studio is installed on the computer.

probable order)	• Ensure the device is in the Main Menu screen. • Electronics 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)	• Device (or if using remote flowhead, the flowhead) is not stationary at the start of test. Hold it steady until the 'Ready to Blow' prompt appears. • Return to previous menu and re-enter the test.
Problem Fault Symptoms:	• **Cannot read screen**
Possible Solutions: (In probable order)	• Ensure the on/off button was pressed. • The batteries may be low, plug in USB cable attached to a computer or replace the batteries. • Electronics failure. Contact Support.
Problem Fault Symptoms:	• **Reversed or no volume measurements.**
Possible Solutions: (In probable order)	• Ensure flowhead is properly connected/seated on device (if using the remote flowhead also check the tubing is connected correctly). • Electronics failure. Contact support.

9.1 Software Check

Information about the device may be obtained from the About option  in the Configuration Menu. This information may be used when inquiries are made to Micro Direct or a service agent.

9.2 Product Useful Life Checks

To ascertain whether the device has exceeded its useful life, Micro Direct recommends checking the flowhead and the real time clock.

The flowhead may be checked with the daily calibration verification, to be completed by the clinician/healthcare professional and during the periodic inspection of the device. Reference section 5.4. Calibration Verification for details on how to check the device flowhead.

The clock will reset if the 3V coin cell battery has depleted. This will be evident as the Time-Date option will be displayed every time the device is turned on until the battery is replaced and the time/date is set again.

The coin cell has an expected battery life of 15 years+ which exceeds the devices product life; therefore, a service is recommended at 10 years or when product useful life checks dictate it is required.

10. 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 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
69131	Flowhead Cone (5)
41653	USB Cable
83157	Flowhead Spare
83200	Flowhead Adapter Kit
48-70	Protex Disinfectant Wipe

10. Disposal

The device is marked with the WEEE symbol and must be taken to separate collection at the product end-of-life. Do not dispose of these products as unsorted municipal waste. They should be disposed of in line with local requirements.

- 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 BF equipment
	Class II
VA	Power Rating
	Voltage DC Batt V for battery DC for power supply
	Instructions for Use; operating instructions
	Manufacturer
	Date of Manufacture (Date format yyyy-mm-dd)
	USB connector
	On/Off
	The device must be taken to separate collection at the product end-of-life. Do not dispose of these products as unsorted municipal waste.
	Operating Temperature Limits
	Operating Relative Humidity Limits
	Operating Atmospheric Pressure Limits
	Nonsterile

	Recycle
	Keep Dry
	QR Code – matrix bar code
Rx Only	Restricted to sale by or on the order of a physician.
	MR Unsafe – Do not use this device in an MRI environment.

12. Description of the Micro Spirometer

The Micro Spirometer is a handheld spirometer which measures subject respiratory parameters. It is designed for portable spirometry but may be connected to the associated Device Studio application to view and print reports. The Fleisch flowhead is used for testing and is integral to the device.

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	± 2.5%
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 2019)
Operating Temperature Range	ISO 26782 Limits: 62.6 – 95° F

	Design Limits: 50 – 104° 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
Electrical Safety Standards	EN 60601-1:2006 + A1:2013
EMC Standards	EN 60601-1-2:2015 + A1:2021
Home Use Standard	EN 60601-1-11:2015
Coexistence Standard	ANSI C63.27-2017
QA/GMP Standards	EN ISO 13485, FDA 21 CFR 820, CMDR SOR/98-282 & JPAL
Dimensions	~ 5.6” x 3.2” x 1”
Weight	~ 9 ounces (device only, no batteries, packaging or accessories)
Communications	USB 2.0 Bluetooth 2/4
Power Supply	5V DC via USB 4 x 1.5V AAA batteries (6V)
Essential Performance	Flow measurement output
Essential Performance Test Limits	Flow accuracy ±10% or ±10 L/min with ±3% or 3 L/min allowed for test apparatus (ISO 23747)
Service Life	The recommended service life of the device is 10 years+ or when the product life checks dictate it is required. The battery life of the RTC battery is expected to exceed the device product life. Reference section 8.2 Product Useful Life Checks.
Product Life	10 years+ when maintenance procedures are adhered to. Reference section 8.2 Product Useful Life checks’ for information on how to ascertain whether the device or parts on the device have exceeded their useful life and a service is required.
Minimum PC System Requirements	Processor Speed: 2GHz or greater RAM: 2GB (min), 4GB (recommended) Disk Space: 1GB or greater Operating Systems: Windows® 10 or above Monitor: 1280 x 800 pixel

	Other: • .Net Framework 4.6.1 • USB Port • Bluetooth Support • PDF Viewer

Notes:

- All values displayed are expressed as BTPS values.
- Take care not to block the mouthpiece with tongue or teeth. A 'spitting' action or coughing will give false readings.
- Time zero is determined using the back-extrapolated method, from the steepest part of the curve. The operating conditions specified apply to the device plus accessories.
- The device, flowhead and SpiroSafe filter are classified as type BF applied parts.
- 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. CE Notice

Marking by the symbol CE 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 healthcare environments, e.g., primary care, hospital wards and private homes, 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 + A1:2021 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.

EN60601-1-11:2015 – Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – collateral standard: Requirement for medical electrical equipment and medical electrical systems used in the home healthcare environment.

Coexistence: ANSI C63.27-2017 American National Standard for Evaluation of Wireless Coexistence

EN 60601-1-2:2015 + A1:2021 - Emissions tests **During the immunity testing below the device continued to operate within specification**		
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 + A1:2021 - Immunity tests		
Immunity test	Test level	Compliance level reached
Electrostatic discharge (ESD) EN 61000-4-2	Contact: ± 8kv Air: ± 2 kV, ± 4 kV ± 8kV, ± 15kV	Contact: +8kv Air: ± 2 kV, ± 4 kV ± 8kV, ± 15kV
Radiated RF EN 61000-4-3	10 V/m 80MHz to 2700MHz 3V 2700 to 6000MHz	10 V/m 80MHz to 2700MHz 3V 2700 to 6000MHz

EN 60601-1-2:2015 + A1:2021 - Immunity tests (continued)		
Immunity test	Test level	Compliance level reached
Power Frequency	30A/m	30A/m

Magnetic Field Immunity EN61000-4-8		
Power Magnetic Field Immunity EN61000-4-8	8A/m 30kHz 65A/m 134.2 k Hz (2.1 kHz PM) 7.5A/m 13.56 M Hz (50 kHz PM)	8A/m 30kHz 65A/m 134.2 k Hz (2.1 kHz PM) 7.5A/m 13.56 M Hz (50 kHz PM)

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 standard and to check before use that no interference is evident or possible. Loss or degraded performance due to EMI that exceeds the test levels in immunity test tables above will result in a failed calibration verification on the Micro Spirometer. If interference is suspected or possible, move the Micro Spirometer to a new location and repeat the calibration verification.

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided.

The Model MD6300 is a spirometer and so the performance deemed to be essential is the output of the flow transducer.

***WARNING**: No modification of this equipment is allowed.*

15. FDA Notice

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

16. 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, MD 82182
Signed on behalf of Vitalograph (Ireland) Ltd.

Frank Keane.
CEO, Vitalograph Ltd.

17. 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 opinion of the Company is faulty or below standards as result of inferior workmanship or materials.

The conditions of this Guarantee are:

1. This Guarantee shall only apply to hardware defects which are notified to the Company or to its accredited distributor within two years of the date of purchase of the equipment, unless otherwise agreed in writing by the Company. Registration is not required for this base two-year guarantee.
2. An extended five-year warranty from date of purchase is available by registering the products serial number at www.vitalograph.com/warranty within 30 days of purchase.
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	J84.89

Pulmonary Disease	
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