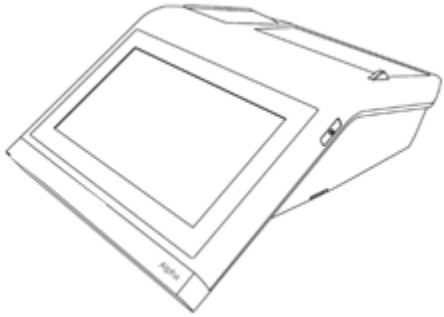
MD SPIRO
a Micro Direct company

Alpha

Model MD6000



Instruction for Use

Current Edition (Issue 1, 27-Jan-2021) Cat. No. 09060

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Indications for Spirometry

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

Generally speaking, spirometry is a simple diagnostic tool used to define a subject's lung condition. The major indications for spirometry are:

- ✓ Dyspnea (shortness of breath)
- ✓ Exercise induced coughing
- ✓ Chest tightness
- ✓ Smokers over 45 years of age (NLHEP recommendations)
- ✓ Obesity
- ✓ Pre-operative testing
- ✓ Occupational exposure to dust and/or chemicals
- ✓ Ongoing assessment of patients receiving bronchodilator treatments
- ✓ Determination and/or documentation of pulmonary disability
- ✓ 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

Table of Contents

1. Main Components

The main components are:

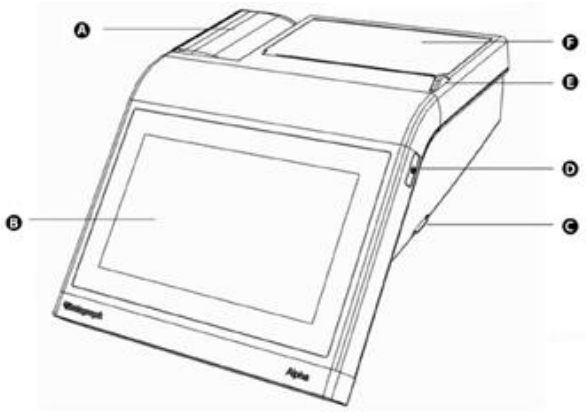


Figure 1.a

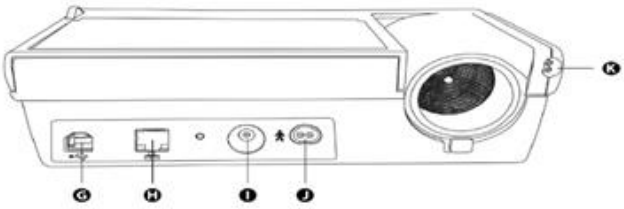


Figure 1.b

A	Flowhead
B	Touchscreen Display
C	Micro SD Card Connector
D	On/Off Button
E	Printer Door Release Button
F	Printer
G	USB Connector
H	Ethernet Connector
I	Power Supply Input
J	Flowhead Tubing Connector (Device)
K	Flowhead Tubing Connector (Flowhead)

1.1 Features

The features include:

- Fleisch type pneumotachograph
- Ambient temperature sensor
- Color touchscreen display
- Sounds for audio feedback
- Integral 4” thermal printer

2. Setting up the Device

The Alpha Spirometer is supplied with the following items:

Alpha Unit	Ethernet Cable
Fleisch Flowhead	Connect & Device Studio Software
Double Tubing	Instructions for Use
12V Power Supply	Carry Case
Kit of 3 Input Modules (EU,AU,US)	Thermal Printer Rolls x2
USB Cable	

Preparing for use:

1. Unwrap flowhead connection tubing and connect one end to the device base. The tubing is keyed so it will only connect one way.
2. Connect the other end of flowhead tubing to the flowhead.
3. Open the printer door and check a roll of thermal paper is present.
4. Only use the device with the purpose-built low voltage power supply unit with which it is supplied. Attempted use with other power sources may cause irreparable damage and invalidate the warranty. The output from the power supply is 12 volts DC.
5. Connect the power supply into the socket on the rear of the device. Plug the mains plug into a suitable socket, press the On/Off switch on the side of the instrument. The device is ready for use.
6. The device is fitted with rechargeable batteries, which allows the device to be used without the power supply connected.
7. On first use, the internal battery pack will require a full charge, this may be completed overnight and will take a minimum of 12 hours.

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 at least once daily, prior to using the device (see Section 3.4 Calibration Verification).

3. Operating Instructions

On all screens:

The (blue) arrow  at the top left goes back one step,

the (green)  at the top right moves forward one step.

1. After turning on the device for the first time, the Start-up Wizard opens giving two options:

   Device Config allows the user to change audio level, haptic feedback, screen brightness, units and language.

   Date/Time allows the user to update the Date/Time.

2. If defaults are acceptable, press the green arrow  to move to the main menu.

3. The Main Menu offers three standard options – Subject, Quick Test and Configuration – and a fourth option Connect, if Connect is configured.

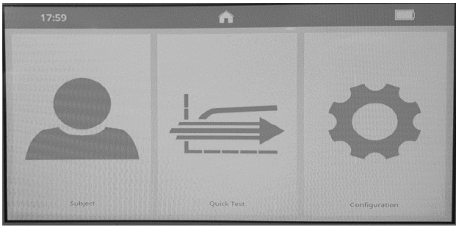


Figure 2.a

Figure 2.b

The Calibration Verification prompt  displays in the center of the screen when the device has just been powered on if a calibration verification has not been completed that day. To complete a calibration verification, press the green  button (see Section 3.4 Calibration Verification).

If a calibration verification is not required, press .

4. Subject allows the user to select a current subject by ID, first name (Forename) or last name (Surname) (see section 3.2 Conducting a Test) or add/create a new subject (see Section 3.1 Entering Subject Data).

   All subject demographics may be added in the add subject screen.

5. **Quick Test** allows the user to select Spirometry or Reports. Reports will always be blank for the Quick Test.

Figure 3

   Spirometry option includes VC, FVC and Post (see Section 3.2 Conducting a Test).

   Report option allows printing of a subject's report to the internal printer (see Section 3.3 Reporting).

6. Configuration – allows user to:

   - carry out a calibration verification (Section 3.4),
   - configure reports (Section 3.3),
   - configure parameters for test (Section 3.2),
   - configure device including audio level, hepatic feedback and screen brightness level, setting the date and time population groups (Section 3.1) and has the About box

 containing details of the device, including software revision number (Section 6.1).

3.1 Entering Subject Data

1. Select ‘Subject’ from the Main Menu.
2. Select ‘Add Subject’  . Subject information fields are divided into primary and secondary, on two separate pages. Enter details in subject information fields:

   Primary: ID  , Date of Birth  , Height  , Birth Sex  , Population  .

   Secondary: Alternative ID  , First Name (Forename)  , Last Name (Surname)  , Weight  , Smoker and Pack Years  .

   On the comments page, comments may be freeform or selected from a pre-defined list.
3. Press the green forward arrow to save subject details and return to the main menu. A warning will appear on screen that no predicted values will be generated if a required field is missing.

3.2 Conducting a Test

1. Before starting a test session ensure a calibration verification of the device was completed recently (refer to Section 3.4 Calibration Verification).
2. Select a subject  and ensure details are entered.
3. Wash hands (operator and subject).
4. Fit a disposable SpiroSafe filter to the flowhead. The use of a disposable nose clip is recommended.
5. Instruct and demonstrate the test.

3.2.1 Testing

1. Select ‘VC Test’  or ‘FVC Test’  from ‘Spirometry’ in the Main Menu.
2. Select how the results should be presented by scrolling across the screens or pressing the circles  at the top of the screen:

- VC Test – Volume/Time (V/T) graph or Volume (Bar Chart).
- FVC Test – Volume/Time (V/T) graph or Flow/Volume (F/V) graph.

3. When the 'Exhale to Begin' icon appears  the device is ready to accept a blow.

- Sit upright, fit the nose clip and relax.
- Place SpiroSafe filter in mouth and close lips around the filter.
- Seal lips around the filter and keep the tongue down.
- Breathe normally.

VC Test Session

a. Breathe normally until the end-expiratory lung volume is stable.

b. Inhale completely, with a brief pause when lungs are completely full (≤ 2 secs).

c. While maintaining an upright posture, exhale in a relaxed manner with no hesitation until no more air can be expelled.

d. 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).

e. The operator should repeat instructions as necessary, with enthusiasm.

f. When prompted by the device, a satisfactory expiratory flow plateau has been achieved or expiration time > 15 seconds, inhale maximally and return to normal breathing.

g. The maneuver is now complete. Remove the SpiroSafe filter from the mouth.

h. Listen for two beeps. The device is now ready for the next blow.

i. Repeat for a minimum of three maneuvers, up to a maximum of eight.

j. Check VC repeatability and perform more maneuvers as necessary.

k. Click on  for quality information and test acceptability.

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

FVC Test Session

- Inhale completely and rapidly with a brief pause when lungs are completely full (≤ 2 secs).
- While maintaining an upright posture, exhale with maximal effort 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 forced expiratory time (FET) reaches 15 seconds).
- The operator should repeat instructions as necessary with enthusiasm.
- Breathe in with maximal effort until completely full. The maneuver is now complete, remove the SpiroSafe filter from the mouth.
- Listen for two beeps. The device is now ready for the next blow.
- Repeat for a minimum of three maneuvers up to a maximum of eight.
- Check FEV1 and FVC repeatability and perform more maneuvers as necessary.
- Click on  for quality information and test acceptability.

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

Results grading for FEV1 and FVC is shown below in Table 1.

Grade	Number of Measurements	Repeatability: Age > 6 yr	Repeatability: Age ≤ 6 yr
A	≥ 3 acceptable	Within 0.150 L	Within 0.100 L*
B	2 acceptable	Within 0.150 L	Within 0.100 L*
C	≥ 2 acceptable	Within 0.200 L	Within 0.150 L*
D	≥ 2 acceptable	Within 0.250 L	Within 0.200 L*
E	≥ 2 acceptable OR 1 acceptable	> 0.250 L N/A	> 0.200 L* N/A
U	0 acceptable AND ≥ 1 usable	N/A	N/A
F	0 acceptable and 0 usable	N/A	N/A

Table 1: Grades

*Or 10% of the highest value, whichever is greater; applies for ages 6 years or younger only.

3.2.2 Bronchodilator Responsiveness Testing

Bronchodilator responsiveness testing can be performed on any pre-test session performed.

1. Select ‘Spirometry’ from the Menu, then select ‘Post’  .
2. Select the relevant pre-test from the list and perform the post-test as outlined in section 3.2.1 Testing.

Note: *A Post-test may only be completed if an existing Pre-test is available.*

3.2.3 View FVC Test Results

Results may be viewed as either a Volume/Time (V/T) or Flow/Volume (F/V) graph by scrolling across the screens or pressing the circles  at the top of the screen. Screens viewed in order: F/V graph, V/T graph, Results screen.

The Results screen displays Best, %Pred, Pred values, z-score, LLN by pressing the tabs 

.

There are additional options to add comments and information on session quality and session interpretation.

The user may add comments of up to 250 characters to the results by clicking  in the top right corner. Select again to save and close.

The icons  and  in the bottom right corner allow the user to select from pre-defined comments as per ATS/ERS 2019. Select again to save and close.

The icon  in the top right corner displays the session information, quality and interpretation. Select again to close.

3.2.4 Viewing VC Test Results

VC test results may be viewed as either a Volume/Time (V/T) or Volume Bar graph by scrolling across the screens. First screen is the bar graph, second is the V/T graph, third is the Results screen. All other viewing is as per section 3.2.3.

3.2.5 Saving and Ending the Test Session

The device has capacity to store at least 20,000 tests with a maximum of 8 blows allowed for each test session. Stored session information includes subject details and best pre-test if it is a bronchodilator responsiveness test session.

A session ends and is saved when the user exits the test screen by pressing the green arrow on the top right.

A session also ends and is saved if any of the following occur:

- The device is turned off.
- A new subject is created.
- The device is connected to Device Studio.

3.3 Reporting

To print the current subject test session:

1. Select the green forward arrow to go to the print screen.
2. Select the 'Print' icon on screen.
3. Alternatively returning to the main menu and selecting the 'Reports' option will display a list of the sessions available for print. Clicking on a session will allow it to be reviewed, a long press will print.

Report Configuration: Select in 'Configuration' of the Main Menu to configure reports. Options include enable/disable predicted shading, predicted I-bars, test graphs, report % predicted, session comments, environmental data, auto acceptability and posture.

3.3.1 Internal Printer

The device has an internal 4" thermal printer.

To load paper to the internal printer: with the device facing forward, press the printer button to open the door. Remove the tape from the new paper roll, unroll a small amount of paper and load it into the paper holder with the paper coming from under the paper roll. Close the printer door.

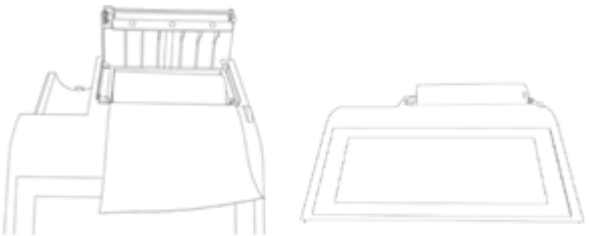


Figure 4

***Note**: The internal (thermal) printout will fade over time when exposed to light or heat. If a permanent record is required, photocopy the thermal printout or send the report to the Device Studio Utility.*

3.3.2 External Printer via Vitalograph Device Studio

The device can print to an external printer using the Device Studio application.

To generate PDF reports from the device:

1. Use the USB cable supplied to connect the device to a computer running Device Studio.
2. Ensure Device Studio application is open, the device is switched on and on the main menu screen. If the device is not already connected, click on the 'Connect Device' option in the menu.

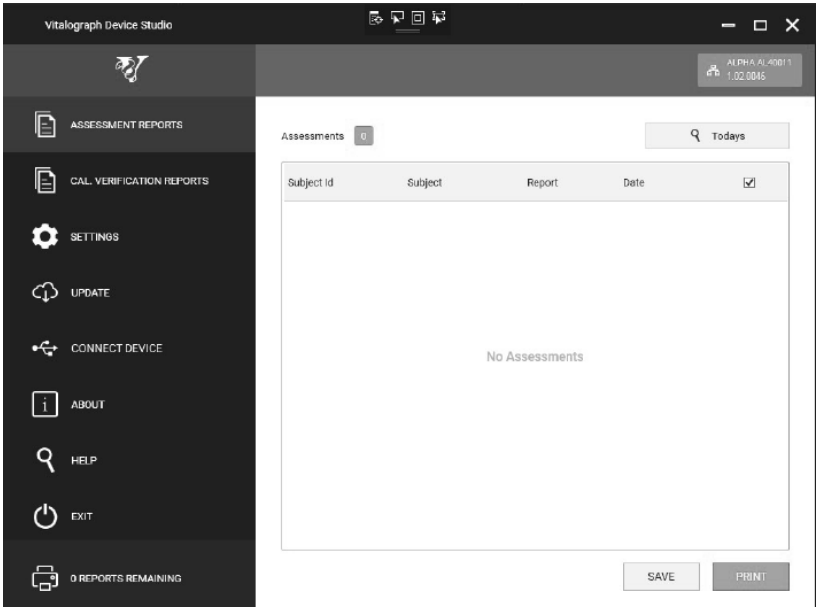


Figure 5.a

3. Device Studio will search for assessments on the device (see Fig. 5.a). Available assessments are shown on screen and may be selected and printed and/or saved (see Fig 5.b).

Figure 5.b

4. Device Studio may also be used to print/save calibration verification reports and to update device firmware.
5. When finished with Device Studio click on the ‘Disconnect Device’ option in the application menu before disconnecting the USB cable/device.

***Note**: If the USB cable/device is disconnected prior to clicking the ‘Disconnect Device’ option, the device will restart.*

Additional guidance on using Device Studio can be found in the Instruction for Use PN 09550 supplied on the USB flash drive PN93002 and in the software help menu of the application.

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

3.4 Calibration Verification

ISO 26782 recommendations require the difference between the volume measured by the spirometer and the volume pumped into the spirometer from a syringe is within 3% (2.5% for the device with an additional 0.5% allowed for the syringe.

1. Attach the flow head to the syringe as per figure 6.

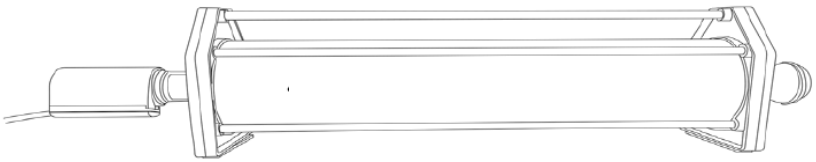


Figure 6

2. Select ‘Configuration’ on the main menu, select ‘Calibration Verification’  option.

3. Enter syringe details: serial number, syringe volume (will default to 3L), pressure, altitude and humidity %. At a minimum the serial number, syringe volume and temperature must be entered. The temperature auto fills from the internal temperature sensor but may be changed if required. If a calibration verification was performed previously this will pre-populate with the details of last syringe used. Press 'Continue'.
4. Complete three (3) full strokes as per onscreen instructions.
5. If the reproducibility between the three consecutive syringe strokes is less than 3% of 3 L, the calibration verification has passed and a green tick displays on the syringe icon and <3% is displayed in the top right corner.

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

	Successful verification check with tick in syringe indicating a pass.
	Non-reproducible syringe strokes (red syringe after the 5th stroke). Repeat calibration verification.
	Outside 3%, 6% or 25% (purple syringe and shows >3%, >6% or >25% in top right corner of screen). The % it is out by indicates the severity of the issue. Over 3%, repeat calibration verification. Over 6%, may indicate the device requires cleaning or maintenance. Over 25%, the user should contact technical support.

A report may be printed or saved for the calibration verification if required, see Section 3.3 Reporting.

If the procedure was followed correctly and the error icon is showing, the calibration verification may be repeated. If the error continues to show, contact MDSpiro using contact information found on page 23.

3.5. Connection to Electronic Medical Records (EMR) via Vitalograph Connect

Connection to an EMR system may be achieved using the Connect service. This is available on the Flash Drive PN 93002 supplied with the device. Refer to the Connect Instruction for Use PN 09570 for information on installing and running connect.

3.5.1. Connect Configuration

On the main menu, select ‘Connect Config’  .

The following information is required:

- Address: URL for the Connect Service – http://{host}[:{port}]/connect
- Network information: Three options – disabled, wired or wireless.

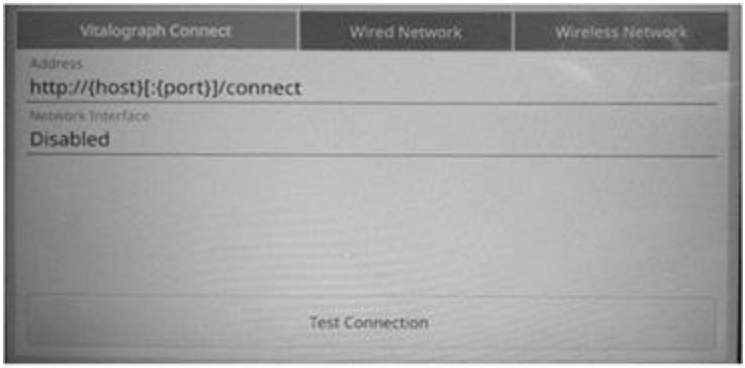


Figure 7 – Example set up for Connect

Once the information is entered, select the appropriate tab: wireless or wired.

a) Wireless Network

1. When the wireless tab is selected, the device searches all available networks.

2. Select the required network and enter passkey. The ‘Advanced’ option allows the user to add/edit the advanced network details if required.
3. Press the green forward button to save.
4. To test the connection, re-select the ‘Connect Config’ option and press the ‘Test Connection’ button at the bottom of the screen (see Figure 7).
5. This message confirms if there is a good connection.

6. When connected, a WiFi symbol  displays in the status bar, top left.

b) Wired Network

1. For a wired connection complete the required information in the ‘Wired Network’ tab including:

- MAC address
- Connection method (DHCP or Static)
- IP address
- Netmask

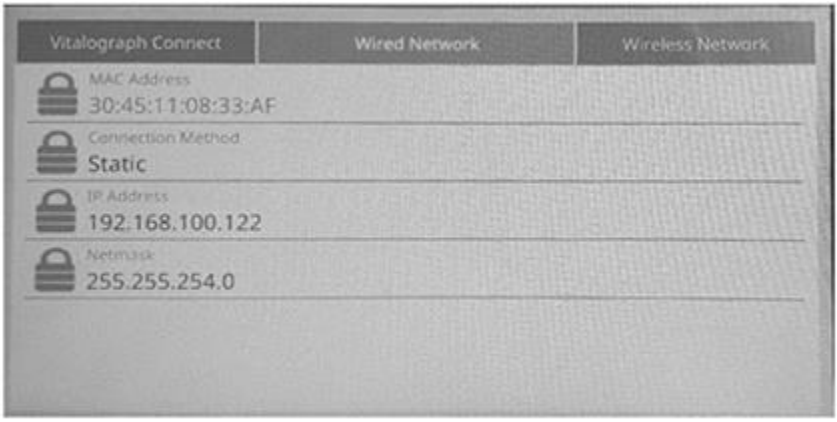


Figure 8 – Example set up for Connect (wired)

2. When connected, a wired Ethernet symbol displays in the status bar, top left.

Once Connect is configured, the Main Menu offers Subject, Quick Test, Configuration and Connect options. (See section 3, Figures 2.a and 2.b above).

Scroll right to access the Connect option.

The Connect screen has three tabs (see Figure 9).

- New Orders
- Open Order
- Return Orders

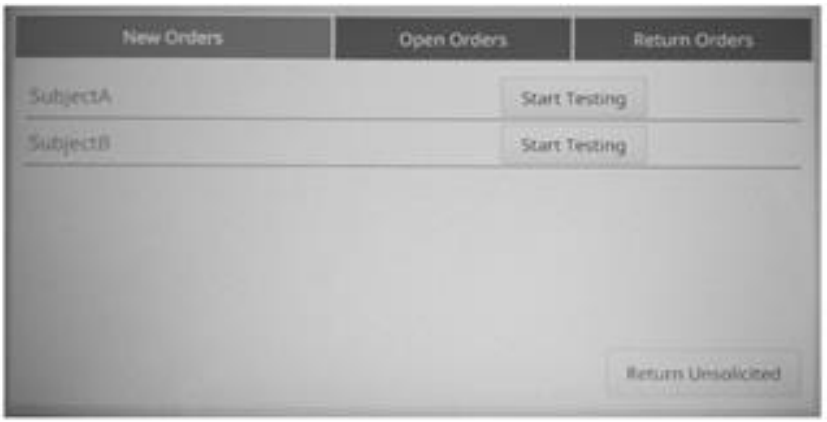


Figure 9

3.5.2 New Orders

To process a new order, go to the ‘New Orders’ tab, select the order required and press the ‘Start Testing’ button (see Figure 9). The subject information displays. Review and press the green forward button to proceed with a test. The main test menu displays. Select ‘Spirometry’ and complete a test (see section 3.2.1 Testing). When complete, select the green forward button to exit and close the session.

3.5.3 Open Order

The ‘Open Orders’ tab shows a list of orders allocated to the device which have not yet had a test completed. These remain on the list until they are processed. To process an open order, select it from the list and follow the same instructions as for new orders in section 3.5.2 New Orders above.

3.5.4 Return an Order

To return an order to the EMR, go to the ‘Return Orders’ tab, select the order required. All available sessions for that order will be shown. **If the order is complete**, ensure the required sessions are selected and press the ‘Return’ button (see Figure 10). **If additional testing is required**, select the ‘Start Testing’ button first (see Figure 10) and press the green forward button to proceed with a test (see section 3.5.2 New Orders). When complete, select the green forward button to return and complete the order.

Figure 10

3.5.5 Return Unsolicited

Unsolicited Orders are tests that were not allocated by the EMR. If the EMR is configured for unsolicited orders the user may select the ‘Return Unsolicited’ button 

, complete a test and return it to the EMR.

The ‘Return Unsolicited’ button does not show if the EMR is not configured for unsolicited orders.

4. Cybersecurity Consideration

4.1 Specification

The device employs an Operating System (OS) that is not accessible under normal use. The application runs on top of the OS and is the only user interface to the device. The OS has a configured firewall to protect against any unauthorized access over the communications ports, only Vitalograph PC based applications can access the device over a secure connection. No further controls are required to be applied by users to secure the device. The device will timeout and auto power down after five minutes of inactivity.

4.2 Security Recommendations

When connecting to a PC, it is recommended the PC has the following cybersecurity in place:

- **Up to Date Operating System**: the Operating System should be configured for automatic update for security patches and have all the latest patches applied.
- **Antivirus/Antimalware**: the PC should have a reputable antivirus or antimalware application installed and all updated virus definitions in place.
- **Secure Login**: the PC should be password protected via industry standard user access controls, via active directory or other methods.
- **Firewall**: if the PC is connected to the internet ensure a reputable firewall or equivalent protection is in place to protect against unauthorized access.

4.3 Interfaces

Communications interfaces – USB, WiFi, Ethernet: The device will communicate with Vitalograph PC based applications for:

- Back-ups and restore
- Software updates
- Printing to external printer
- Transfer of test data

SD Card: Only used for encrypted backup of stored data.

5. Power Management

The device can be powered using the 12V low voltage power supply with which it is supplied or from the internal battery pack.

5.1 Battery Pack

The device is fitted with a rechargeable battery pack which allows it to be used without the 12V power supply connected. To fully recharge, switch off the device and leave the power supply plugged in overnight. A full charge will allow five hours testing with five reports from the internal printer.

Note: *With the power supply plugged in, the device will continue to charge even if it auto powers down after five minutes of inactivity*. The recommended battery pack replacement interval is three years. Battery replacement should be carried out only by the manufacturer, the approved importer or by Service Agents approved by the manufacturer.

Note: *Powering the device or recharging the battery pack from the USB is not possible.*

5.2 Battery Power Indications

The device has several battery power indications:

	When the battery is fully charged, a white 'Battery Full' icon displays on the status bar at the top of the screen. Disconnect the device from external power source when it is fully charged.
	When the battery is at less than 20% capacity, an orange 'Battery Low' icon displays on the status bar at the top of the screen. You may continue to use the device but it is advisable to connect to an external power source.
	When the battery is approaching fully discharged, the red 'Battery Discharged' icon displays on the status bar at the top of the screen. If the battery is less than 5% capacity, the device powers down. Connect to an external power source to recharge the battery before attempting to use the device again.

5.3 Power Save Mode

The device will auto power down after five minutes whether the power is plugged in or not. Pressing the On/Off button will turn the device back on.

6. Cleaning & Hygiene

6.1 Preventing Cross-Contamination of Subjects

A spirometer is not designed or supplied as a 'sterile' device. We intend that a new SpiroSafe, viral/bacterial filter, be used for every patient to prevent cross contamination. Using a new SpiroSafe provides a significant level of protection of the patient, the device and the user against cross contamination during spirometry maneuvers. The interior of the pneumotachograph does not require decontamination where a new SpiroSafe filter is used for each patient. The outside surfaces of the device and flowhead tube may be cleaned with a 70% isopropyl alcohol impregnated cloth to remove any visible soiling and for low level disinfection. There are no special temperature requirements for cleaning which may be carried out at room temperature. After cleaning, the device should be inspected for residual soiling and repeat cleaning carried out if required.

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 is ≥ 1 minute.[1]
Screen	Clean	For the screen, lightly wipe the surface with cotton pad or other soft material. **Note**: *DO NOT use any chemicals. DO NOT wipe in a circular motion. Strokes should be either up/down or over/back.*

Where the user suspects the flowhead has become contaminated or where local risk assessment identifies a need for higher level of decontamination, then it should be cleaned as per the instructions on 'Cleaning and Hygiene' on the MDSpiro website.

6.2 Inspection of the MD6000 Alpha

No inspection of the device is required by the subject. The device is used under the supervision of a healthcare professional. For the healthcare professional, a visual inspection is recommended on a routine basis. Examine cone and flow conditioning mesh filter for damage or contamination. If it is damaged or blocked, it should be replaced with a new part. Examine the Fleisch element and replace if damaged.

1. Rutala, W. A. 2017 "Back to Basics" access from disinfection&sterilization.org June 2020

If you suspect 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 on “Cleaning and Hygiene’ on the MDSpiro website.

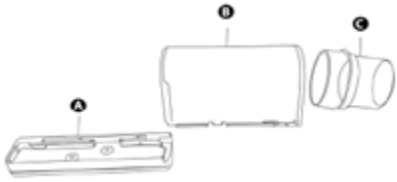


Figure 11: Flowhead Assembly

A	Flowhead Base
B	Flowhead Containing Fleisch
C	Flowhead Cone

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

2. Derived from terminology and guidance taken from ATS/ERS Standardisation of Spirometry 2019 Update Am J Respir Crit Care Med 2019 Vol 200, Iss 8 pp e70-e88.

7. Fault Finding Guide

Problem Fault Symptoms:	• **Calibration verification variations > +/- 3%** • **False reading suspected**
Possible Cause / Solution: (In Probable Order)	• The % error indicates the severity of the issue. Over 3%, repeat calibration verification. Over 6% may indicate the device requires cleaning or maintenance. Over 25%, the user should contact technical support. • Was the correct syringe volume selected? • Flowhead pressure tapping holes blocked. • Flowhead Fleisch element assembly sealing 'O' rings damaged. • Flowhead Fleisch element assembly blocked. • Cold syringe. Ensure syringe is in its test environment for at least an hour before use. • Internal tubing from pressure ports on device is blocked. Contact support. • Electronics failure. Contact support.
Problem Fault Symptoms:	• **Printout is blank** • **Cannot print to internal printer**
Possible Cause / Solution: (In Probable Order)	• Check paper is loaded correctly and not reversed. • Internal printer failure. Contact Support.
Problem Fault Symptoms:	• **Tests begin automatically** • **Volume accumulates automatically without the subject blowing** • **Very small VC or FVC test displayed**
Possible Cause / Solution: (In Probable Order)	• Flowhead and/or tubing not stationary at the start of test. Hold them steady until the 'Ready to Blow' prompts appear. • Return to previous menu and re-enter the test.
Problem Fault Symptoms:	• **Rocking device**
Possible Cause / Solution: (In Probable Order)	• Ensure device is on a flat surface. • Check for damaged or missing feet. • If any of the feet are damaged or missing, replace both feet.

Problem Fault Symptoms	• **Cannot read screen**
Possible Cause / Solution: (In Probable Order)	• Ensure the on/off button was pressed. • If running off battery, ensure the device is charged and/or the power supply is connected. • Electronics failure. Contact support.
Problem Fault Symptoms:	• **Reversed or no volume measurements**
Possible Cause / Solution: (In Probable Order)	• Ensure tubing is connected correctly. • Ensure flowhead connecting tube is not pinched or trapped.

7.1 Software Check

Information about the device can be obtained from the About box. This information can be used if any queries are made to MDSpiro or a service agent.

To access the About box  , select 'Configuration' on the Main Menu and go to the second screen of options.

7.2 Product Useful Life Checks

To ascertain whether the device has exceeded its useful life, the manufacturer recommends checking the flowhead and the batteries.

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 3.4 Calibration Verification for details on how to check the device flowhead.

As the main battery pack ages, the required charging frequency will increase, and the battery life will decrease. MDSpiro recommends changing the battery pack every three (3) years.

The clock may reset to a default time and date on power down if the 3V coin battery has depleted. MDSpiro recommends changing the battery during routine service every three (3) years.

8. Customer Service

Service and repairs should be carried out only by the manufacturer or by Service Agents approved by the manufacturer.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer or MDSpiro and the Regulatory Authorities of the country. Refer to the contact information listed on the next page.

9. Consumables and Accessories

Cat. No.	Description
3385	SpiroSafe Viral/Bacterial Filters (100)
3329	Printer Paper (3/Rolls)
3304	Nose Clips (20)
3325	3-Liter Calibration Syringe
42175	Flowhead Connection Tube
69130	Flowhead
69131	Flowhead cone (5)
48-70	Protex Disinfectant Wipe

To place an order for consumables and accessories, for service/repair or for general questions please contact Micro Direct at:

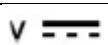
Toll Free:	1-800-588-3381
Telephone:	207-786-7808
Fax:	207-786-7280
Email:	orders@mdspiro.com
	sales@mdspiro.com
	support@mdspiro.com
Website:	www.mdspiro.com

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
	Ethernet 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
Rx Only	Restricted to sale by or on the order of a physician

11. Description of the Model MD6000 Alpha

The model MD6000 Alpha is a spirometer designed for lung function testing in a variety of professional healthcare environments, e.g., primary care, hospitals and occupational health centers. The device is designed for desktop use. The Fleisch flowhead is used for testing and has a resting location on the device.

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). And as such, spirometry may support or exclude diagnosis, but it cannot make one.

Spirometers are also used in non-clinical settings such as occupational health screening where no clinical judgment is made, suspect findings leading to a referral to a clinician. The device is intended for use by medical professionals trained in respiratory and lung function testing. Apart from this instruction manual, there are no other training requirements for the medical professional.

12.1 Indications for Use

The intended use of the Model MD6000 Alpha Spirometer is in the simple assessment of respiratory function through the measurement of dynamic lung volumes i.e. spirometry. The device measures patient respiratory parameters including FVC, FEV1, FEV6, PEF, MVV and VC. The device is designed to be operated by medical professionals trained in respiratory and lung function testing on

adults and pediatrics, 5 years and older, in a variety of professional healthcare environments, e.g. primary care, hospitals and occupational health centers.

13. Technical Specification

Product	Alpha Spirometer
Model	MD6000
Flow Detection Principal	Fleisch type pneumotachograph
Essential Performance	Flow measurement output
Essential Performance Test Limits	Flow accuracy ± 10% or ± 20 L/M, whichever is greater
Back Pressure	Less than 0.1 kPa/L/sec @ 14 L/sec
Volume Detection	Flow integration sampling @ 100 Hz
Maximum Test Duration	90 seconds
Volume Accuracy	± 2.5%
Voltage/Frequency	Power Supply: Input 100-240V, 50/60Hz, 0.5A Output 12V, 1.5A Battery: 7.2V, 2.2Ahr
Accuracy when Operated in Operating Temperature Range Conditions	Flow ± 10% Maximum flow rate ±16 L/sec Minimum flow rate ±0.02 L/sec
Operating Temperature Range	ISO 26782 limits: 62.6 - 98.6^{o} F Design limits: 50 - 104^{o} F
Operating Humidity Range	30% - 75%
Ambient Pressure Range	850hPa - 1060hPa
Performance Standards the Device Meets or Exceeds	ATS/ERS 2019, ISO 23747:2015 & ISO 26782:2009
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 program
Dimensions	8” (length) x 10” (width)
Weight	3 Pounds 5 Ounces
Communications	USB, Ethernet, Wi-Fi

Power Supply	12V, 1.5A DC power supply 7.2V, 2.2Ahr NiMh battery
Service Life	The recommended service life of the device is 3 years
Product Life	10 years+ when maintenance and servicing (every 3 years) procedures are adhered to. Reference section 7.2 'Product Useful Life Checks' for information on how to ascertain whether the device has exceeded its useful life.
Minimum PC System Requirements	Processor Speed: 2GHz or greater RAM: 2GB (Minimum), 4GB (Recommended) Disk Space: 1GB or greater Operating System: Windows 7 or above Monitor: 1280 x 800 pixel or above Other: Net Framework 4.5.1 and USB port

Notes:

- All values displayed are expressed as BTPS values.
- Take care not to block the cone with the 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 flowhead and SpiroSafe filter are classified as type B applied parts. The device body or other accessories are not 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 it function.

14. 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 device 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 patient to prevent cross contamination. Using a new SpiroSafe

provides a significant level of protection of the patient, the device and the user against cross contamination during spirometry maneuvers. A SpiroSafe is for single use only.

4. Spirometry may support or exclude diagnosis but it cannot make one (ATS/ERS 2019[3]).
5. The Alpha is marked as 'Rx Only' and as such is restricted to sale by or on the order of a physician.
6. When using the device, ensure the flowhead connecting tube is not pinched or trapped as spirometry results may be affected or a false reading may be detected.
7. Take care not to block the flowhead with tongue or teeth during testing. A 'spitting' action or cough will give false readings.
8. Patient fatigue may occur during spirometry testing depending on the patient'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. Patient may also take a break between tests. A max test completed message will appear after eight maneuvers.
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. Do not expose the device to liquids.
12. The device should not be used in the presence of flammable liquids or gases, dust, sand or any other chemical substances.
13. All spirometry standards recommend completing a calibration verification of lung function measuring devices daily with a 3-liter syringe to verify the instrument is measuring accurately. The device should never be outside accuracy limits. A calibration verification should also be completed after cleaning or disassembling the spirometer for any reason, after adjusting calibration or if the flowhead or device has been dropped.
14. Service and repairs should be carried out only by the manufacturer or authorized Service Agents.
15. Maintenance must not be performed while the device is in use by a patient.
16. The device contains a lithium coin cell battery and an NiMH main battery which are not accessible by the user. Any suspected battery faults should be reported to the manufacturer.

[3] ATS/ERS Standardization of Spirometry Eur Respir J 2019

17. The internal NiMH battery is not user accessible or user replaceable. In the unlikely event that any issues are noted with the

power or battery such as swelling or leaking, stop using the device immediately, do not charge the device and contact Micro Direct support. In case of leaking, ensure the electrolyte does not get in the eyes or touch skin. If electrolyte gets into the eyes, flush the area immediately with water for 15 minutes and seek medical attention. Do not inhale the leaked material, leave the area immediately and allow the battery to cool and any material to dissipate.

18. To isolate the device from the mains supply, remove the 12V power supply from the mains wall socket. When charging the device via the 12V power supply, do not position the power supply where it is difficult to unplug from the socket.

19. The paper tear bar has sharp edges to allow the printouts to be removed cleanly. Once the printer door is closed, the paper tear bar is covered. Users should take care with their fingers when replacing the paper roll. When disassembled for cleaning the flowhead and base have exposed edges. Once assembled the edges are covered. The user should take care with their fingers when assembling or disassembling the flowhead.

20. The internal (thermal) printout will fade over time when exposed to light or heat. If a permanent record is required, photocopy the thermal printout or send the report to the Device Studio Utility.

21. 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.

22. Non-medical equipment must be kept outside the patient environment i.e., any area in which intentional or unintentional contact between the patient and parts of the system, or some other persons touching part of the system, can occur.

23. 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.

24. 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.

25. The applied part is the Flowhead. This along with the SpiroSafe filter, are the contact points for the patient during a spirometry session. There are no adverse effects if the patient encounters any other part of the device.

15. CE Notice

Marking by the symbol CE 2797 indicates compliance of the Model MD6000 Alpha to the Medical Devices Directive of the European Community.

The device is intended for and suitable for use in a variety of professional healthcare environments, e.g. primary care, hospital wards, occupational health centers and clinics, 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 device should assure it is used in such an environment.

The device was tested in accordance with:

EN60601-1:2006 + A1:2013 with US deviations – Medical electrical equipment – Part 1: 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 device 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 device is suitable for use in all establishments, including those connected to the public mains network (e.g. at 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: ± 8 kV Air: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	Contact: ± 8 kV Air: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV
Electrical fast transient / burst EN 61000-4-4	± 2 kV for power supply lines	± 2 kV
Surge EN61000-4-5	± 0.5 kV, ± 1 kV differential mode Device is identified as Class II unearthed equipment therefore common mode testing is omitted	± 0.5 kV, 1 kV
Voltage dips, short interruptions on power supply input lines EN 61000-4-11	100% drop, 0.5 cycles, 0°, 45°, 90°, 135°, 180°, 225°, 270° 315° 100% dip, 1 cycle 30% dips, 25/30 cycles 240V AC, 50Hz 100V AC, 50Hz	100% drop 0.5 cycles, 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 100% dip, 1 cycle 30% dip, 25/30 cycles 240V AC, 50Hz 100V AC, 50Hz
Conducted RF EN 61000-4-6	3V/m 0.15-80MHz 6V/m ISM/amateur radios bands 0.15-80MHz 80% AM at 1kHz	3V/m 0.15-80MHz 6V/m ISM/amateur radios bands 0.15-80MHz 80% AM at 1kHz
Radiated RF EN61000-4-3	3V/m (professional healthcare) 80MHz to 2700MHz	3V/m (professional healthcare) 80MHz to 2700MHz
Proximity fields from RF devices EN 61000-4-3	9 to 28V/m 385 to 5785MHz As per Table 9 EN60601-1-2:2015	9 to 28V/m 385 to 5785MHz As per Table 9 EN60601-1-2:2015
Power frequency (120V, 60Hz and 240V, 50Hz) magnetic field	30A/m	30A/m

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.

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.

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

16. FDA Notice

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

17. EU Declaration of Conformity

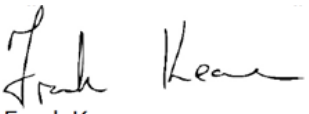
Product: MD6000 Alpha

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.

18. Guarantee & Free Five Year Warranty

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 standard as a 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 two-year base 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 with 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 consumables 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 whom it was purchased for advice. The Company does not authorize any person to create for it any other obligation or liability in connection with Vitalograph 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 of the law, the Company does not accept liability for any consequential damages arising out of the use of, or inability to use any Vitalograph 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