

SpiroConnect Spirometer

Operating Instructions

Issue 1.3

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1 Introduction

Thank you for choosing the SpiroConnect from MedChip Solutions. Please take a moment to familiarise yourself with the instructions for use detailed in this manual and for further information please refer to our website: www.medchipsolutions.com.

The SpiroConnect transmits real-time spirometric flow and volume data followed by diagnostic quality spirometry indices to a PC running SpiroConnect Data Manager software over a Bluetooth connection.

The spirometer is compact, battery operated, and fully portable.

The spirometer uses the MedChip Solutions turbine transducer. This is an extremely stable form of volume transducer, which measures expired air directly at B.T.P.S (Body Temperature and Pressure with Saturated water vapour) thus avoiding the inaccuracies of temperature corrections. This transducer is insensitive to the effects of condensation and temperature and avoids the need for individual calibration prior to performing a test.

The vertical turbine technology employed in the SpiroConnect ensures exceptional performance at low flows exceeding the ATS/ERS requirements to respond to flows as low as 0.025l/s.

2 Package Contents

- 1 SpiroConnect spirometer
- 2 SpiroConnect Data Manager software on USB flash drive memory stick
(May be supplied by distributor on alternative format)
- 3 SpiroConnect dongle
- 4 Carrying pouch
- 5 2 Alkaline AA cells
- 6 Nose Clip





3 Warnings and Cautions

Caution: Possibility of injury or serious damage

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

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

	CAUTION: Read the manual before use
	WARNING: The instrument is not suitable for use in the presence of explosive or flammable gases, flammable anaesthetic mixtures or in oxygen rich environments.
	WARNING: The use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation
	WARNING: Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents
	WARNING: Portable and mobile RF communications equipment can affect medical electrical equipment
	WARNING: Equipment should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation.
	WARNING: The USB socket on the device is for factory use only. Do not make any connection to this socket.
	PLEASE NOTE: The product you have purchased should not be disposed of as unsorted waste. Please utilise your local WEEE collection facilities for the disposal of this product.
	WARNING: No modification of this equipment is allowed

4 Contraindications

	WARNING: Do not use in the presence of a known or suspected respiratory infection
	WARNING: Do not use when haemoptysis (coughing up blood) of unknown origin is present
	WARNING: Do not use in the presence of pneumothorax (collapsed lung)
	WARNING: Do not use in the presence of unstable cardiovascular status: recent (within one month) myocardial infarction (heart attack), uncontrolled hypertension or pulmonary embolism
	WARNING: Do not use in the presence of uncontrolled hypertension or history of haemorrhagic cerebrovascular event (stroke)
	WARNING: Do not use in the presence of recent thoracic abdominal or eye surgery
	WARNING: Do not use in the presence of nausea, vomiting or pain
	WARNING: Do not use in the presence of confusion or dementia
	WARNING: Do not use in the presence of thoracic or abdominal aneurysms
	WARNING: Do not use on patients with a history of syncope (fainting) associated with forced exhalation

5 Intended Use

The intended use of the SpiroConnect is to provide spirometry measurements used for the diagnosis of common respiratory diseases such as asthma and COPD in adults and children over 5. The SpiroConnect is intended to be used in doctors' offices, hospitals and clinics.

6 Environment

The SpiroConnect is designed for routine clinical use in an office environment. Use in temperatures outside the range 10 to 40 °C should be avoided.

The environment should be free of excessive vibrations, and sources of electrical noise.

Obsolete

7 Getting Started

Open the battery cover by pressing the ridged area on the battery cover towards the front of the unit and simultaneously pulling outwards with your thumb, the lid will open like a door. Insert 2 AA size alkaline batteries as shown below taking care to observe the correct polarity:



WARNING: do not touch the patient when the battery cover is removed.

7.1 Installing SpiroConnect Data Manager Software

The SpiroConnect DM software is supplied on a USB flash drive memory stick together with this user manual.

Install the software as follows:

N.B. If the software is supplied by the distributor then follow their installation instructions

Run SpiroConnectDataManagerSetup_v1.00.exe. There is no need to run any of the other executable files on the drive, these will be automatically run during installation.

Please ensure the SpiroConnect Dongle is not plugged in to the USB port during installation. After installation completes, plug the SpiroConnect Dongle into a free USB port, and wait until Windows completes loading the correct drivers for the device and reports it as being ready for use.

At this point, installation is complete and the system is ready for use.

When the application is launched it will automatically check for an updated software version if the PC is connected to the internet. If an updated version is available, the operator will be taken to a download page where he can download the installer for the newer version. This file should be downloaded and then run to complete the update.

8 Operation

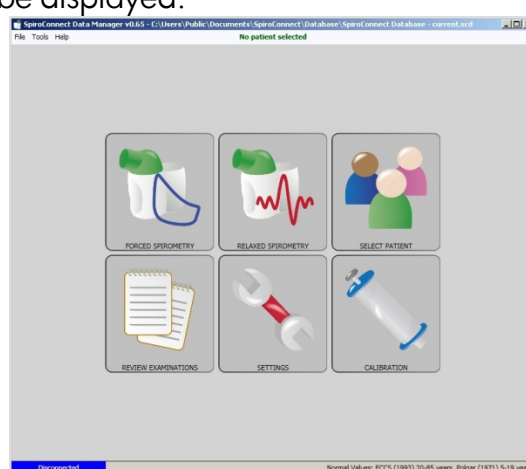
WARNING: Do not attempt to connect the SpiroConnect to the PC using the USB socket on the SpiroConnect device via USB cable.

WARNING: keep the patient away from the PC during use.


Start the SpiroConnect Data Manager software by clicking on the desktop icon, or from the Windows Start Menu under All Programs->Medchip Solutions Spirometry.





The Home Screen will then be displayed:



8.1 Patient Selection:

Before performing a test, click on  in order to open the Patient Selector. Select an existing patient, or click 'Create New' to create a new patient. Click 'Choose Selected' when the desired patient is selected. The program will return to the screen shown above.

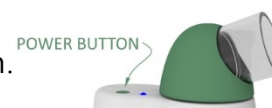
From this screen a forced spirometry test  or relaxed vital capacity test  may be selected.

8.2 Unit Connection:

Before 'Start' is clicked to initiate a test, the unit needs to be powered on and connected in order for tests to be performed.

Connect a disposable or clean reusable, CE-marked, mouthpiece onto the mouthpiece holder of the spirometer.

Turn the unit on at any point by pressing and releasing the power button.

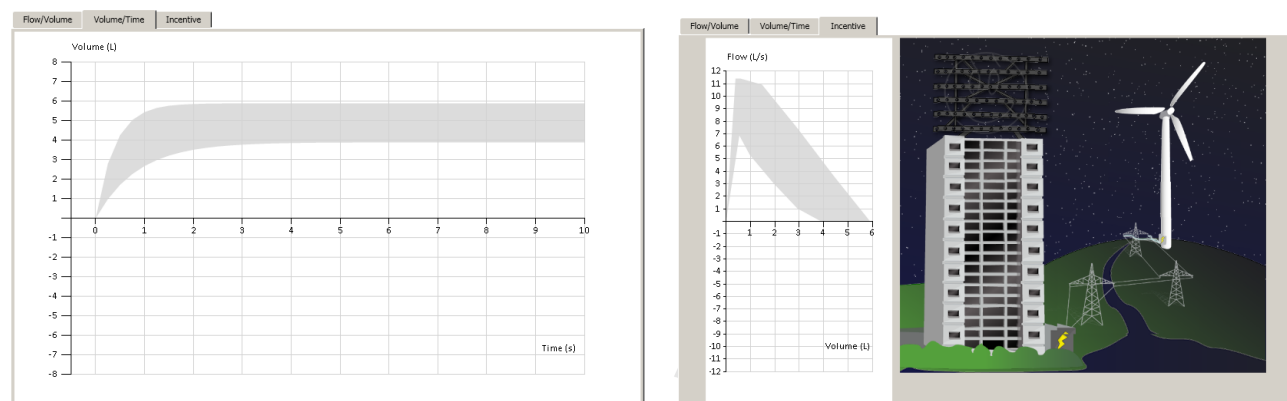


The LED indicator will flash blue at a fast rate for a few seconds whilst connection with SpiroConnect Dongle is established, and then change to a slow blue flash whilst connection with the SpiroConnect Data Manager application is established, finally displaying solid blue once ready. **Connected: BAT 100%** will also be displayed in the bottom left hand corner of the PC application, indicating successful connection and approximate remaining battery capacity.

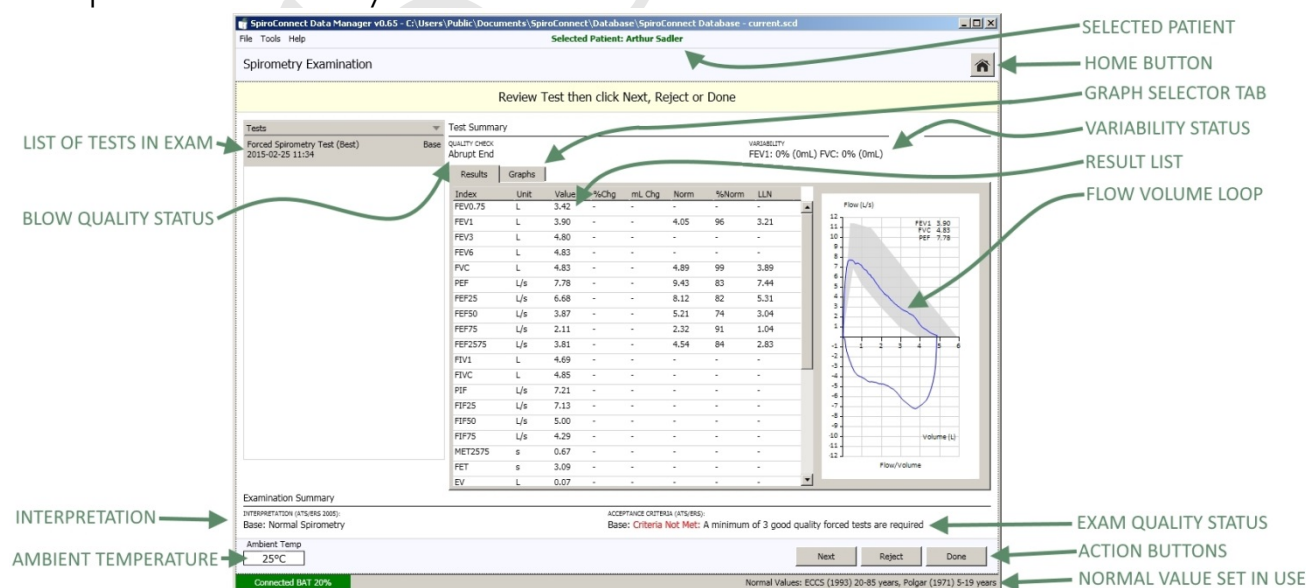
Once 'Start' is clicked to initiate a test, the LED shows solid green to show that the unit is ready for a blow.

8.3 Forced Spirometry:

Press **Start** in the bottom right corner of the Spirometry Examination screen to initiate the test. A flow-volume graph will be shown and the unit will beep to indicate that it is ready. At this point the operator can select the Volume/Time or Incentive tab, if he wishes to view the VT graph or Child Incentive graphic as an alternative to the default Flow Volume loop during the live blow.



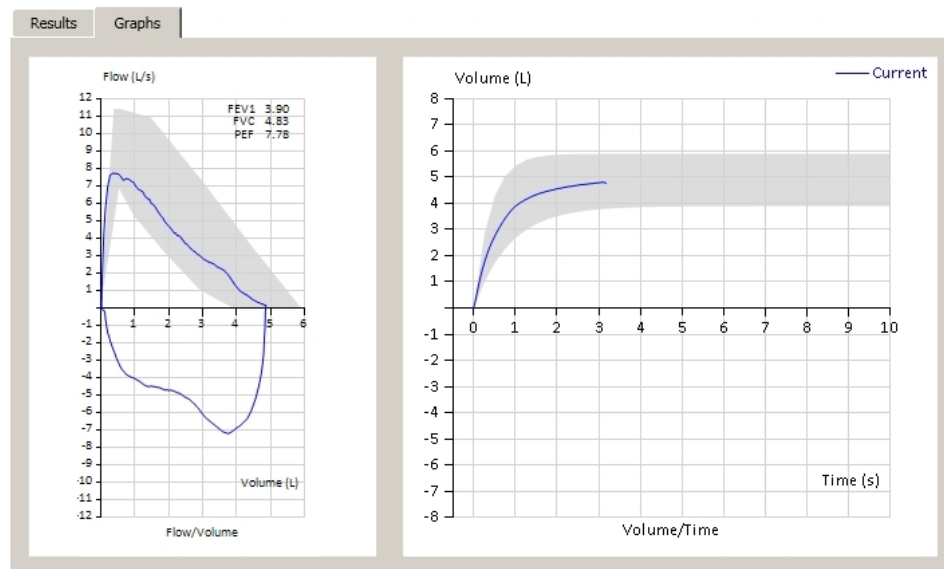
Instruct the patient to inhale as deeply as possible, then place the unit to their lips – ensuring a good seal – and blast out the air in their lungs as fast as they can and continue, until they cannot squeeze any more air out of their lungs. They should aim to exhale for at least 6 seconds – the graph border will turn green after 6 seconds as a visual aid to assist with this. They should then inhale as deeply and as rapidly as possible, before removing the unit from their lips. After two seconds has passed without the unit detecting any further flow, it will sound a beep and a test summary will be shown.



All parameters that have been selected for display in Settings are shown, along with the normal value (if available), percentage change from Best Base blow (if the blow is a Post blow), blow quality assessment, overall examination quality assessment and interpretation. If a Relaxed Spirometry test of the same stage already exists within the exam, the VC result for the

Relaxed test will be displayed within the Forced Spirometry results directly underneath FVC, for convenience sake.

Selecting the 'Results' tab will change the display to show detailed results, and an interpretation, if available.



NEXT can be clicked in order that the current blow is accepted into the exam stage and a new blow is initiated. REJECT can be clicked to initiate a new blow without adding the last blow to the exam. DONE can be clicked when all the desired blows have been added, and you wish to end the current exam stage and review results. After DONE is clicked, no further blows can be added to the current exam stage. Post1 or Post2 blows can be added at a later stage if they do not exist already.

A maximum of eight blows are allowed in any exam stage and the Next/Reject buttons should be used to disregard blows of poor quality and eventually end with an exam that conforms to the examination quality criteria. These are explained further below.

The QUALITY CHECK message for the blow can be seen above the Results tab. This reports the quality of an individual blow (as opposed to overall exam quality – see the next section below), and could be one of the three following messages:

- Slow Start:* The patient appeared to have paused slightly at the beginning of the manoeuvre. He/she should blast air out as hard as possible from the very beginning of test
- Abrupt End:* The patient appeared to stop blowing suddenly. The patient should continue to squeeze every last bit of air out of their lungs at the end of exhalation. A good guideline is that they should not stop before they have exhaled for 6 seconds at least (the graph border turns green after 6 seconds to indicate this time has elapsed)
- Possible Cough:* A possible cough has been detected.
- Good Blow:* The blow is of good quality

The ACCEPTANCE CRITERIA messages for the current exam are shown below the Results area. These messages report on the overall quality of the current and existing exam stages (Base, Post1, Post2) and may contain messages similar to those below:

Not Met: A minimum of 3 good quality tests are required

- An exam stage needs at least 3 blows that have a Quality Check of 'Good Blow'

Not Met: The two largest FEV1 values must not differ by more than 150mL

- The FEV1 result for the two largest blows vary too much

Not Met: The two largest FVV values must not differ by more than 150mL

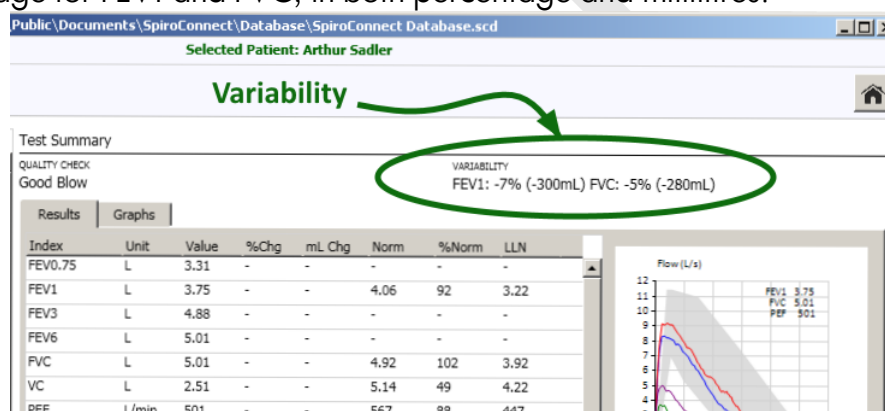
- The FVC result for the two largest blows vary too much

Criteria Met:

- This exam stage meets the acceptance quality criteria.

Please note that one can select either ATS/ERS or BTS acceptance criteria to be used for this assessment, see the Settings tab to select between the two.



Whilst seeking to attain 'Criteria Met' for the Acceptance Criteria summary, it is useful to know what the current variability status is. A VARIABILITY result is presented within the Test Summary section - this reports the variability between the blow being observed and the Best Blow in the same exam stage for FEV1 and FVC, in both percentage and millilitres.



After DONE is clicked examination notes can be added, a report can be printed, or a PDF report can be exported. The exam will automatically be saved into the database from where it can be reviewed in the future.

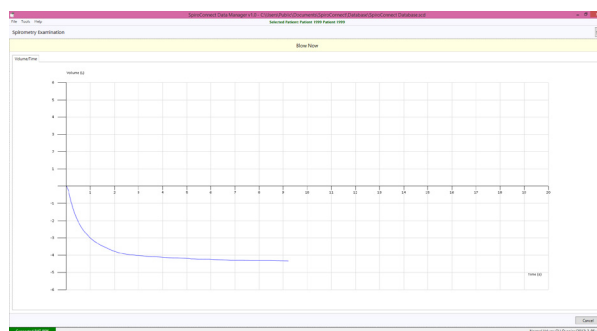
8.4 Relaxed Vital Capacity:

*Please note: Relaxed Vital Capacity tests MUST be added as the first test in any exam stage. If Forced Spirometry is performed first, there will be no option to add a Relaxed Spirometry test *

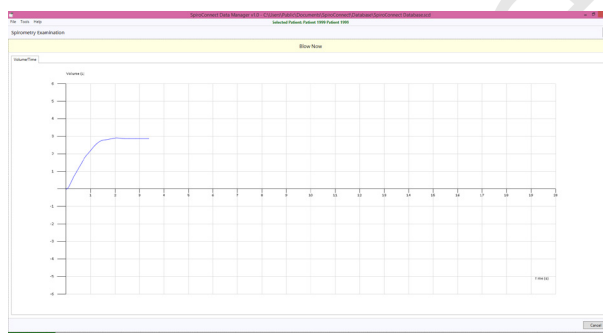
From the home screen, click on  to select Relaxed Spirometry. Press  in the bottom right corner of the Spirometry Examination screen to initiate the test. A volume-time graph will be shown and the unit will beep to indicate that it is ready.

The relaxed test may be performed with a single expiration, a single inspiration, or expiration and inspiration after tidal breathing. The latter is used to provide a number additional indices including Expiratory or Inspiratory Reserve Volume and tidal breathing indices if required.

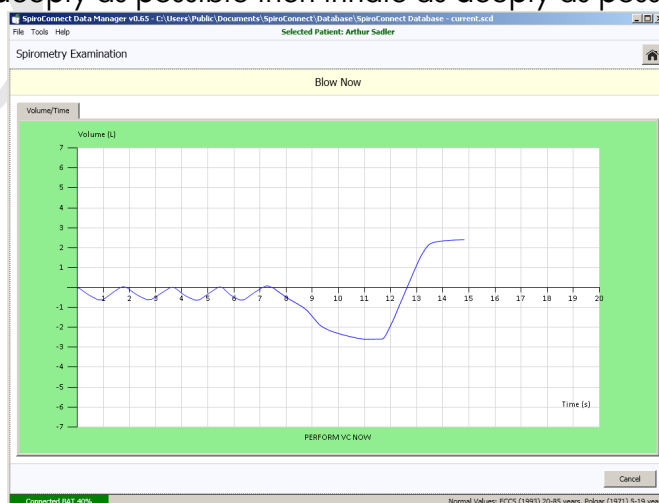
For Expiratory Vital capacity instruct the patient to fully inhale and then seal their lips around the mouthpiece and exhale at a comfortable rate until they have completely emptied their lungs. The expiratory volume/time curve will be displayed:



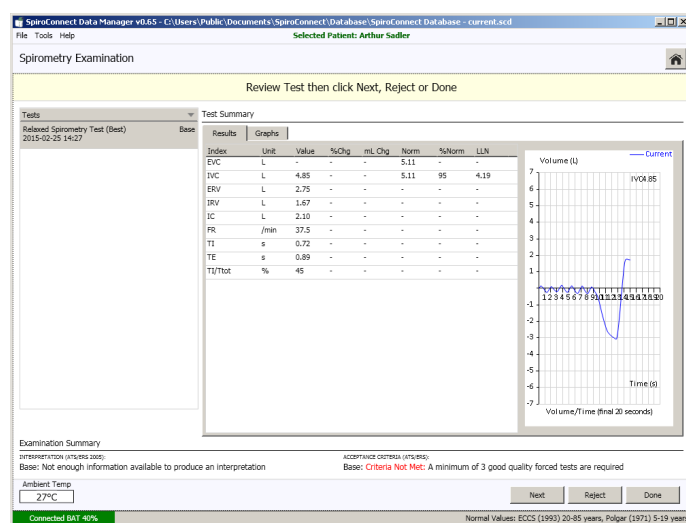
For Inspiratory Vital capacity instruct the patient to fully exhale and then seal their lips around the mouthpiece and inhale at a comfortable rate until they have completely filled their lungs. The inspiratory volume/time curve will be displayed:



For the tidal breathing method instruct the patient to seal their lips around the mouthpiece and breathe normally. The device will beep on each beginning of inhalation and monitor tidal breathing until it has determined a stable tidal pattern has been recognised. At this point the unit will beep three times in very quick succession as well as change the graph border to a green colour, indicating that it is ready for the vital capacity manoeuvre. At this point the patient should inhale as deeply as possible and then exhale as deeply as possible (if EVC is desired), or exhale as deeply as possible then inhale as deeply as possible (if IVC is desired).




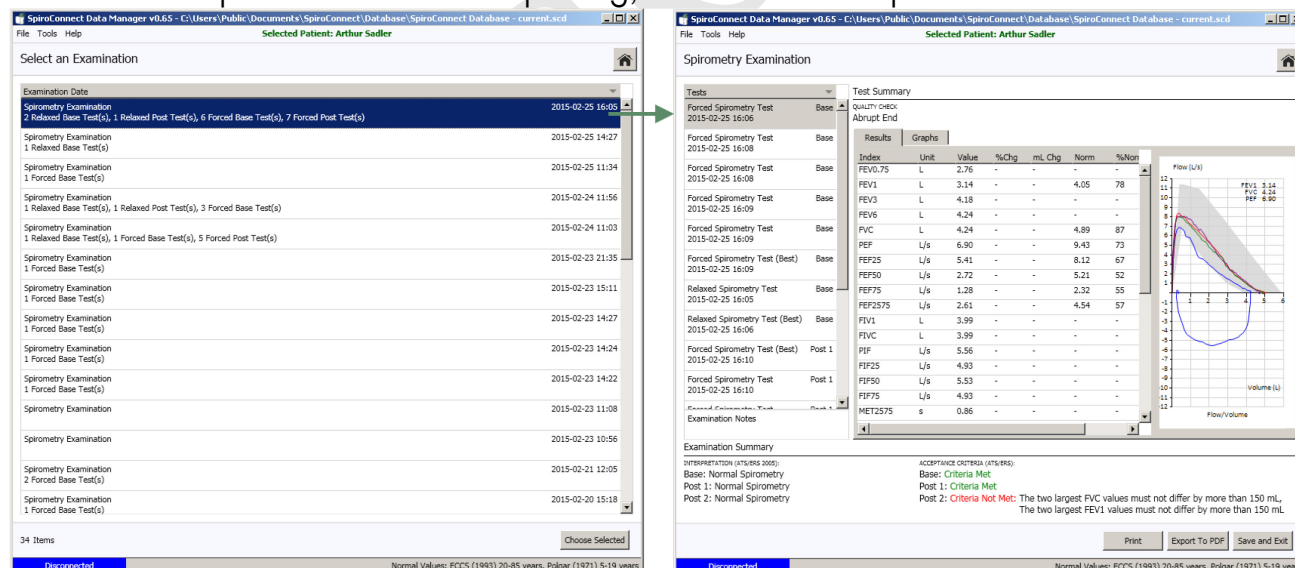
Once this has been done, the patient can remove the device from their lips and the results will be displayed.



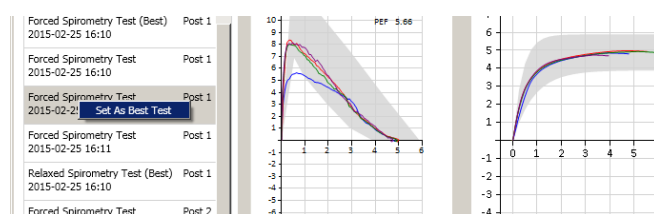
Forced tests (and subsequent post-BD tests) can be added using the buttons on the bottom right of the screen. When performing Relaxed Spirometry, Variability is shown on screen for VC.

8.5 Review Results:

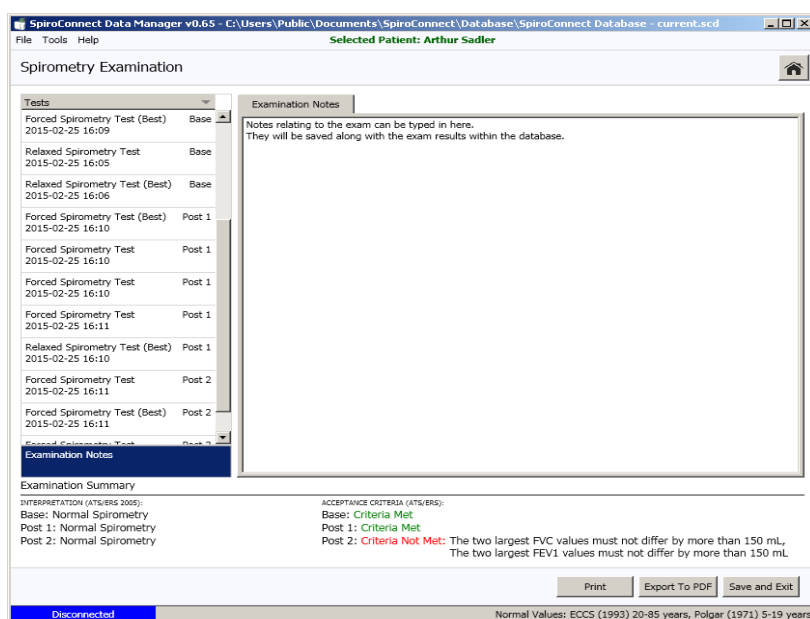
From the main window, clicking the Review Examinations button  will open the Exam Selector. This screen lists saved exams (the oldest exam at the top, newest at the bottom) which can be opened for review and printing, or the addition of post-BD tests.



When reviewing an exam, specific tests can also manually be selected as Best Tests (overriding the automatic Best Test selection) by right-clicking on the test in question and selecting 'Set as Best Test'.



Notes can also be added to the examination by clicking on the 'Examination Notes' panel at the bottom of the list of tests within an exam, and typing the notes into the Notes window:



8.6 General information pertaining to the reviewing of examinations:

Please note that when reviewing an existing exam, the patient details used for determination of normal values and interpretations are that of the patient when the base exam was conducted. The normal values therefore will not change with time, and even if SpiroConnect Data Manager has been configured to use a different Normal Value set to that used at the time the exam was created, the original Normal Value Set in use at the time of exam creation will always be used when reviewing or adding post bronchodilator blows to that exam.

There are things that this does not apply to: Best Blow Criteria, Interpretation and Acceptance Criteria. These are always based on whatever the currently selected settings are in Settings. Thus if Best blow criteria changes, the interpretation could change as the interpretation is based on the Best Blow.

Regarding Best Blow Criteria:

It may also be noticed that when Individual Best is selected as the Best Blow Criteria, a best blow is not marked as such until the DONE button is clicked after adding all desired blows to an exam stage. This is in contrast to other Best Blow settings, in which the best blow is updated after each blow. The reason for this is that in individual Best mode, the best blow is comprised of all the best parts of the other blows in the exam stage, and is therefore only calculated when all desired blows are present.

8.7 Calibration:



Calibration mode can be entered by clicking the  icon.

A 3 litre syringe should be connected to the device, and the plunger fully withdrawn prior to commencement of calibration. The unit should be in a vertical orientation or inverted by 180degrees – not orientated sideways. Once ‘Start’ is clicked, the syringe plunger should be pushed in at a controlled rate such that the waveform enters and remains within the green shaded area for the longest time possible, and upon reaching the end of the syringe discharge, the should pause for approximately one second before withdrawing the plunger, again at a pace such that the trace remains within the green shaded area.



Three consecutive cycles will be performed, each with a higher flow rate than the last. Once the final highest flow rate cycle has been performed, click ‘Done’ and the calibration check results dialog will be shown.

Spirometer details			
Spirometer model:	SpiroConnect		
Serial number:	000000000055		
Firmware revision:	1.57		
Last calibrated:	08/10/2013 12:02:07		
Last calibration check:	13/11/2013 21:10:15		

Calibration factor			
	Exp	Insp	
Last calibration	156.0	153.6	PPL
This calibration			PPL

Measured volumes			
	Exp	Insp	
Low flow	2.99	2.95	litres
Medium flow	2.97	2.96	litres
High flow	3.00	2.97	litres
Average	2.99	2.96	litres
Error	0.44	1.33	%

Calibration OK. Update anyway?

Yes No

The procedure just performed is considered a calibration check if the results are reported as ‘Calibration OK’, and ‘No’ (in response to ‘Calibrate Anyway?’) is clicked.

If 'No' is clicked, the calibration check results are saved. If 'Yes' is clicked, the calibration values are updated and the procedure is then deemed a calibration rather than a calibration check. In either case, the results are stored for record keeping purposes, and the option to print a report is displayed.

If the calibration values are unexpectedly large or small, the operator will be notified and calibration will not be allowed. This could indicate a faulty turbine or syringe.

8.8 Settings:

The settings pane is accessed by clicking the  icon. There are three tabs in the Settings pane:

Display - regional specific formats

Spirometry - best blow criteria, normal value set, and other spirometry related settings

Parameters - select which indices the user wishes to be displayed on the results screens

8.9 Menu Bar options:

Tools - 'Spirometer Details' displays data from the connected handheld unit, temperature reading, serial number, firmware version.
'Settings' as Settings above.

Help - 'About' displays the version number of the PC software
'Check for Updates' if the PC is connected to the Internet will check for a later version of software.

8.10 Patient Database:

The location of the currently used database is displayed in the SpiroConnect Data Manager title bar. The database can support thousands of patients (each with numerous exams) up to a maximum database size of 4GB. There may be occasions when the operator wishes to cease using an existing database and create a new, either due to a size limitation being reached, or to keep a database specific to a set of exams that has been conducted, or a time period over which the database has been used. The procedure for doing so is as follows:

Open SpiroConnect Data Manager, and take note of the database path and name as shown in the title bar. Close SpiroConnect Data Manager, and use Windows Explorer to navigate to the database file. Create a folder called 'Archive' in the database folder, and Move (don't copy, the original file must not exist in the database directory after this step is complete) the existing database file into it. You may wish to rename the file to something which describes it to make it easy to recognise should you ever wish to load it up again.

Run SpiroConnect Data Manager. Upon launch it will fail to find the recently moved database, and prompt the operator to create a new database. The same strategy can be employed to cease using the existing database and load up an existing database, simply select 'No' to browse to and select an existing database instead of 'Yes', which creates a new database.

The database file must not be located on a shared network location, or a folder that is accessed by file sharing/syncing software like SkyDrive, Dropbox or GoogleDrive.

It is the responsibility of the operator to provide a backup mechanism for the database if he wishes to have this function. SpiroConnect data Manager does not provide automatic database backups.

9 Battery Management

The SpiroConnect is designed to use 2 alkaline AA size primary cells.

Note:

To ensure maximum lifetime of the batteries the unit will automatically turn off approximately 5 minutes after a measurement is made. Remove the batteries if you do not intend to use the device for more than 3 months.

10 Looking after your SpiroConnect

Please observe the following precautions:

- * Avoid exposing the SpiroConnect to direct sunlight.
- * Avoid operating the spirometer in dusty conditions or near to heating appliances or radiators.
- * Do not keep the spirometer in a damp place or expose it to extremes of temperature.
- * Do not direct the transducer holder towards a strong light source whilst operating the spirometer.

11 Cleaning

The casing of the unit may be cleaned using a damp cloth. Take care that no water is allowed to enter the unit.

The transducer requires no routine maintenance or servicing. However, if you wish to sterilise or clean the transducer it may be removed by means of the following procedure:

- 1 Remove the transducer by rotating the mouthpiece holder assembly anti clockwise by 90° and gently pulling from the main body.



- 2 The transducer may now be immersed in warm soapy water for routine cleaning or immersed in cold sterilising solutions e.g. Perasafe for a period not exceeding 10 minutes. (Alcohol and chloride solutions should be avoided.) After cleaning/sterilising, the transducer should be rinsed in distilled water and dried.

- 3 Re-assemble the transducer into the main body by reversing the steps shown for disassembly.

12 Accessories

The following accessories are recommended for use with your spirometer.

- SpiroConnect Dongle (for Bluetooth communications)
- Replacement batteries (Energiser E91 x 2)
- USB memory stick (with Operators Manual and Software)
- Nose Clip
- Disposable Mouthpiece
- Pulmonary Filter

Please contact your distributor for pricing and purchasing options for the accessories above, or email sales@medchipsolutions.com to obtain the details of your local distributor.

13 Servicing

Routine maintenance consists of regular calibration checks and cleaning of the transducer. The SpiroConnect should be returned to the supplier every 2 years for transducer inspection and accuracy check unless local guidelines require a more frequent check.

Please contact service@medchipsolutions.com if your unit requires service or repair to obtain a Returned Goods Authorisation (RGA) number. No product should be returned to MedChip except in accordance with the MedChip Warranty and Return Goods Policy (for full details please visit www.medchipsolutions.com)

There are no user serviceable parts in the SpiroConnect.

14 Warranty and Liability

The SpiroConnect hardware is guaranteed against manufacturing defects for 2 years.

MedChip Solutions Ltd undertakes to ensure that the software meets the specification given in the product literature; it does not warrant that the software supplied in this package is suitable for your specific requirements or usage.

The warranty does not extend to any damage or corruption to the supplied media or documentation subsequent to your receipt of the product, however caused; nor does it extend to any damage or corruption of the program image on your computer subsequent to installation.

MedChip Solutions Ltd does not warrant the compatibility of the software on any computer other than that described in the product specification, and takes no responsibility for any incompatibility or problems arising from the use of other operating systems or application programs on your computer.

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15 Software License Agreement

Read carefully before use

The software included is subject to the following license terms and conditions. By installing the software onto your computer, you are signifying your acceptance of the terms of this agreement. If you do not agree in full with the terms of the agreement described below, please return the installation disk intact together with all accompanying manuals and packaging to your supplier.

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16 Trouble Shooting Information

Should you encounter problems operating the SpiroConnect consult the table below:


Problem	Possible cause	Solution
Unit does not turn on	Batteries flat	Replace batteries
Unit turns on, then beeps three times and turns off	Batteries flat	Replace Batteries
Blue light remains flashing (fast flash – 10 times per second).	Cannot connect to Wireless Dongle	Ensure SpiroConnect Dongle is plugged into PC
SpiroConnect Data Manager always reports unit as DISCONNECTED	Communications failure	Unplug dongle from PC, re-start SpiroConnect Data Manager, re-insert dongle then turn unit on
USB driver installation fails (SerialBallPoint error possibly reported)	Dongle must not be plugged in whilst software installation proceeds	Remove dongle from USB port, re-insert and proceed. There is no need to re-install.
Two seconds after performing a blow, the device does not beep and return results	Turbine is still rotating due to air currents	Ensure airflow in the room from a fan or air conditioner is not passing through the spirometer.

17 Electromagnetic Compatibility (EMC)

Guidance and manufacturer's declaration – electromagnetic emissions		
The SpiroConnect is intended for use in the electromagnetic environment specified below. The customer or the user of the SpiroConnect should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group2	The SpiroConnect must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. The SpiroConnect is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply networks that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-3	Not applicable	
Voltage fluctuations/flicker emissions	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The SpiroConnect is intended for use in the electromagnetic environment specified below. The customer or user of the SpiroConnect should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	- 6 kV contact - 8 kV air	- 6 kV contact - 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	- 2 kV for power supply lines - 1 kV for input/output lines	Not applicable	
Surge IEC 61000-4-5	- 1 kV line(s) to line(s) - 2 kV line(s) to earth	Not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_t (>95% dip in U_t for 0.5 cycle 40% U_t (60% dip in U_t) for 5 cycles 70% (30% dip in U_t) for 25 cycles. <5% (>95% dip in U_t) for 5 s	Not applicable	
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_t is the a.c. mains voltage prior to application of the test level			

SpiroConnect Instructions for Use









Guidance and manufacturer's declaration – electromagnetic immunity			
The SpiroConnect is intended for use in the electromagnetic environment specified below. The customer or user of the SpiroConnect should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V rms	3 V rms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the SpiroConnect, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3 \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	3 V/m	3 V/m	
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SpiroConnect is used exceeds the applicable RF compliance level above, the SpiroConnect should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SpiroConnect.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Recommended separation distances between portable and mobile RF communications equipment and the SpiroConnect			
The SpiroConnect is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SpiroConnect can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and SpiroConnect as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0.01	0,12	0,12	0,23
0.1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

Changes or modifications to the SpiroConnect that are not expressly approved by MedChip Solutions can cause EMC issues with this or other equipment.

The SpiroConnect is compliant with Directive 1999/5/EC and Standards EN 301 489-1 v1.8.1 and EN60601-1-2 electromagnetic compatibility but can be affected by cellular phones and by electromagnetic interference exceeding levels specified in EN 50082-1:1992

18 Symbols

	Type BF applied part. F-TYPE APPLIED PART complying with the specified requirements of EN60601-1:2006 to provide a higher degree of protection against electric shock than that provided by TYPE B APPLIED PARTS
 0120	In accordance with Directive 93/42/EEC
	Disposal in compliance with WEEE
	Consult the instructions for use
	Caution: consult the accompanying documents
	Date of manufacture
	Manufacturer
	Serial number

19 Classification

Protection against electric shock:
Internally powered equipment.

Mode of operation:
Continuous

20 Specifications

Transducer Type:
Bi-directional high sensitivity turbine

Measurements:

VC
FEV0.75
FEV1
FEV3
FEV6
FVC
PEF
FEF25 (MEF75)
FEF50 (MEF50)
FEF75 (MEF25)
FEF25-75 (MMEF)
FIV1
FIVC
PIF
FIF25 (MIF75)
FIF50 (MIF50)
FIF75 (MIF25)
MET25-75
FET
EVC
IVC
IC
VT (TV)
Ti
Te
IRV
ERV
Vext
FEV0.75/VC
FEV0.75/FVC
FEV1/VC
FEV1/FVC (FER)
FEV3/VC

FEV3/FVC
FEV0.75/FEV6
FEV1/FEV6
FEF50/VC
FEF50/FVC
MMEF/FVC (FEF25-75/FVC)
FIV1/FIVC (FIR)
R50 (FEF50/FIF50)
Ti/T_{tot}
VT/Ti (TV/Ti)
LUNG AGE**

** Please Note: Estimated Lung Age is limited to maximum age that a Normal Value Set supports, or the patient's age + 30 years, whichever is greater. Lung Age is not calculated for patients younger than 20 years old.

Accuracy:

To ISO26782 recommendations:

Volume to within $\pm 3\%$ of reading, or 0.05 litres, whichever is greater
Volume measurements are given referenced to BTPS conditions

Limits of Operation:

Volume: 8 litres maximum

Flow: 14 litres per second maximum

SpiroConnect Instructions for Use

Sensitivity:

Better than 0.025l/s

Dynamic Impedance:

137 pA(l/s), measured at 14lps

Power Supply:

2 x AA size Alkaline primary cells.

Operating current:

110 mA peak

Battery life:

Alkaline cells, greater than 100 measurement cycles

Dimensions:

55mm (W) x 100mm (D) x 110mm (H)

Weight, including batteries:

200 g

Operating Conditions:

10°C to 40°C, 15% to 95% RH, non condensing, Altitude up to 3000m

Transport and Storage Conditions:

-20°C to 70°C, 15% to 95% RH, non condensing

Lifetime:

5 years

NOTE: There are no user serviceable parts in the SpiroConnect.

WARNING: No modification of this equipment is allowed.

Issued: 14th May 2015

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This unit has been supplied by: