SpiroConnect
Spirometer

Operators Manual

Issue 1.9

March 2020

Contents

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

Your SpiroConnect comes complete with 2 Alkaline AA (LR6) batteries, quick start guide, calibration certificate and the following items:

1 SpiroConnect spirometer
2 SpiroConnect Data Manager software on USB flash drive memory stick (May be supplied by distributor on alternative format)
3a SpiroConnect Bluetooth dongle (alternative dongle 3b may be supplied)
4 Nose Clip

3 Warnings and Cautions

Warning: Conditions or practices that could result in personal injury.
Caution: Possibility of injury or serious damage to the equipment
Please Note: Important information for avoiding damage to the instrument or facilitating operation of the instrument.

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
 **CAUTION:** Read the manual before use
CAUTION: Cleaning solutions containing alcohol or chlorine, e.g. bleach, must not be used.
CAUTION: When removing or replacing the turbine, the mouthpiece holder must be facing away from the SpiroConnect product name as shown above. Do not use excessive force.

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

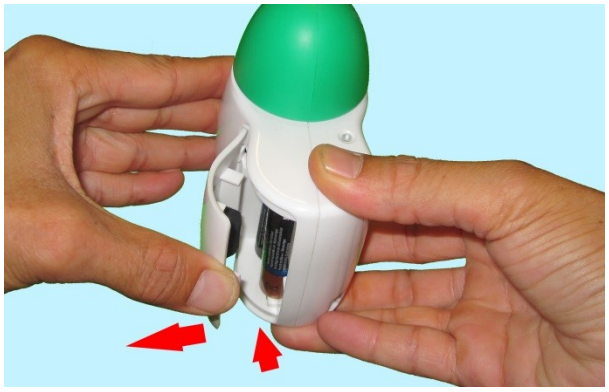
The intended use of the SpiroConnect is to provide spirometry measurements used for the diagnosis of common respiratory diseases such as asthma and COPD in adults and children aged 3 and older. The SpiroConnect is intended to be used in doctors' offices, hospitals and clinics.

6 Environment

The SpiroConnect is designed for routine clinical use in an office environment. Use in temperatures outside the range 10 to 38 ^{O}C should be avoided.
The environment should be free of excessive vibrations, and sources of electrical noise.

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:

NB: **- If the software is supplied by the distributor then follow their installation instructions**
- Administrative Rights is required for installation
- An installation is on a per-user basis. If a multiple users on the same PC wish to use SDM under their own login, it is necessary to run the installer for each user. The settings and database for each user will be unique to that user, however the database can be shared between users if it is configured to be in an accessible area for all users.

Run SpiroConnectDataManagerSetup_v1.XX.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.

Please note that PDF reader software needs to be installed on the system in order to view PDF reports that are generated by the software or the Operators Manual, which can be opened by clicking ‘Help’ and then ‘Open operators Manual’.

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.

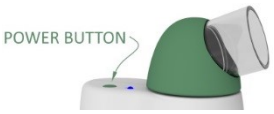
From this screen a forced spirometry test  or relaxed vital capacity test  may be selected.

8.2 Unit Connection:

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

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

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

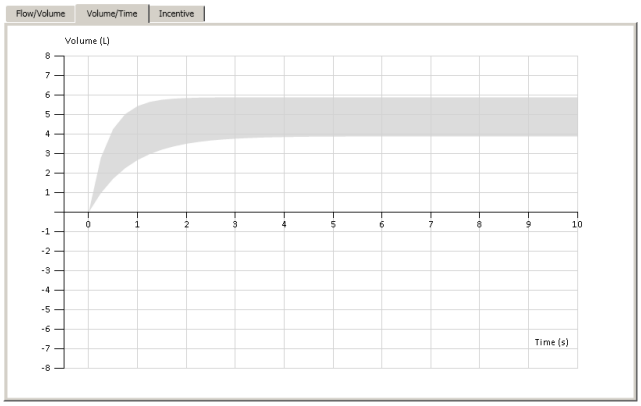


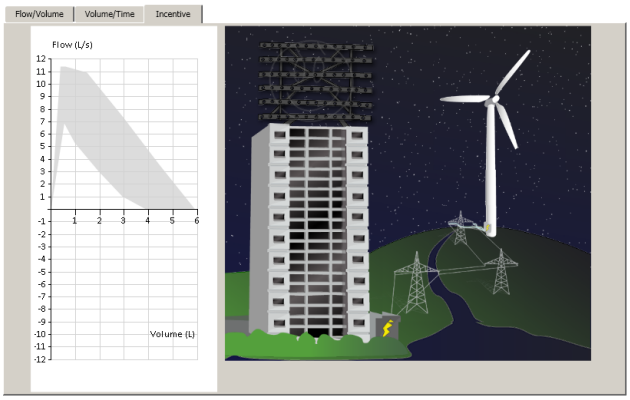
The LED indicator will flash blue at a fast rate for a few seconds whilst connection with SpiroConnect Dongle is established, and then change to a slow blue flash whilst connection with the SpiroConnect Data Manager application is established, finally displaying solid blue once ready. Connected: BAT 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:

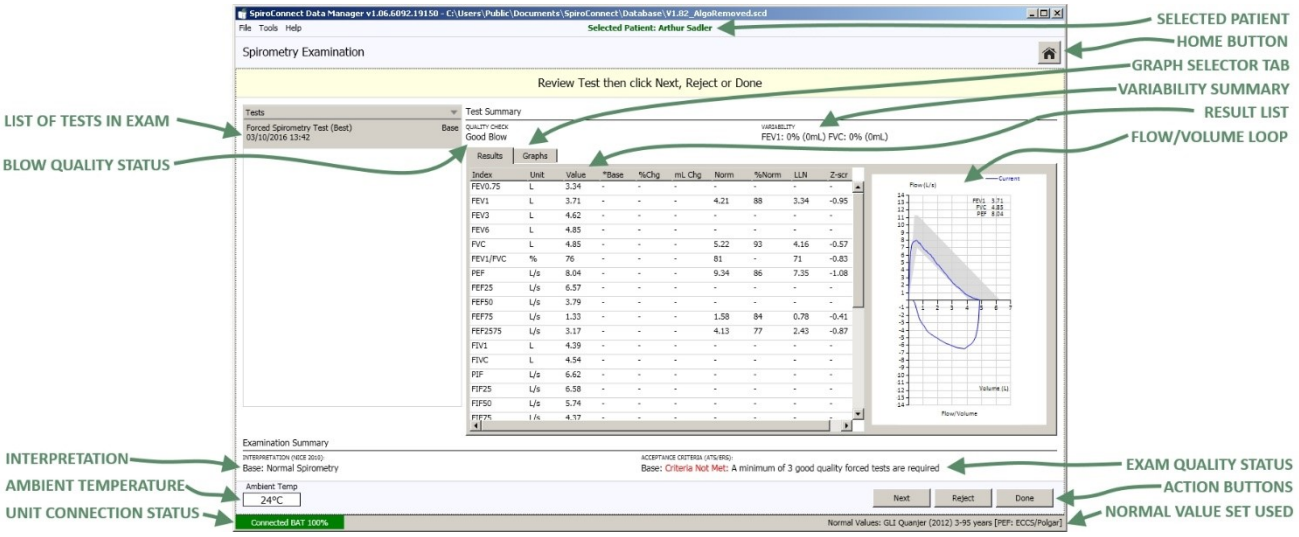
After clicking the Forced Spirometry icon on the main screen, a screen with a start button and temperature reading is displayed. This temperature reading is the ambient room temperature as measured by the unit. If the operator wishes to modify the temperature value, he may do so by clicking on the displayed temperature, and he will then be given the opportunity to enter a temperature to over-ride the automatic temperature. The ambient temperature is used for BTPS correction during inspiration. The same is true when conducting Relaxed Spirometry. The temperature can only be over-ridden before performing the first blow in a test sequence.

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.





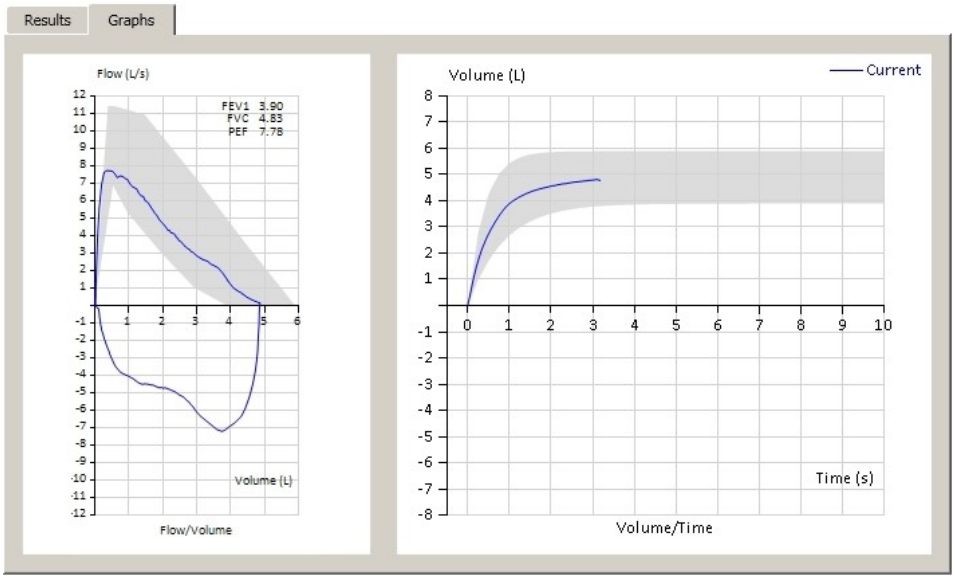
Instruct the patient to inhale as deeply as possible, hold the mouthpiece between the teeth, and then apply the lips for an airtight seal and blast out the air in their lungs as fast as they can and continue, until they cannot squeeze any more air out of their lungs. They should aim to exhale for at least 6 seconds – the graph border will turn green after 6 seconds as a visual aid to assist with this and will turn pink when a plateau in the volume/time curve is detected. 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), best baseline value (*Base) and 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 depend upon the criteria selected as follows:

ARTP (Association for Respiratory Technology and Physiology)

At least 3 good quality blows must exist within the exam stage
The two largest FVC values must be within 100mL of each other
The two largest FEV1 values must be within 100mL of each other

ATS/ERS

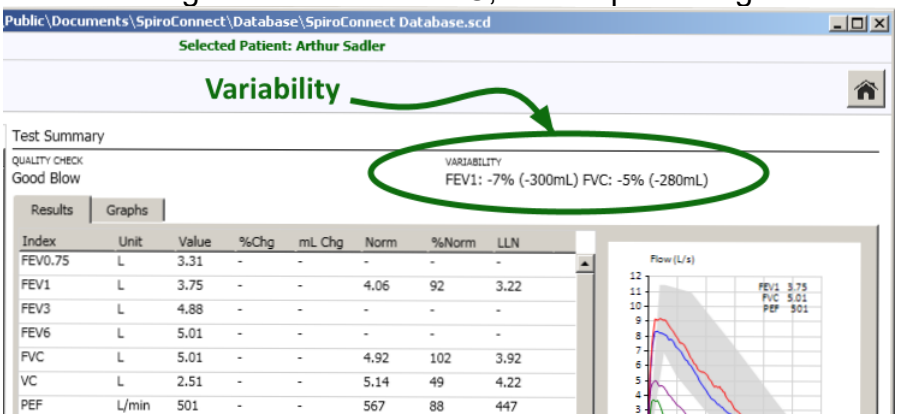
At least 3 good quality blows must exist within the exam stage
The two largest FVC values must be within 150mL (100mL if FVC<= 1L) of each other
The two largest FEV1 values must be within 150mL (100mL if FVC<= 1L) of each other

BTS

At least 3 good quality blows must exist within the exam stage
The two largest FVC values must be within 100mL or 5% (whichever is larger) of each other
The two largest FEV1 values must be within 100mL or 5% (whichever is larger) of each other

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

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.

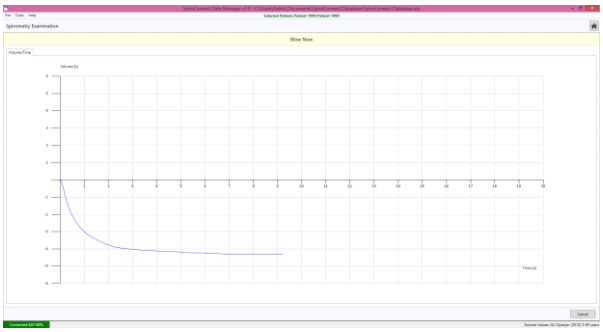
NOTE:
All timing calculations are performed with reference to Tzero, which is determined by locating the steepest rising point on the volume-time graph (which is the point of peak flow) and back extrapolating a line drawn through that point with an angle representative of the rate of change of volume at that point, and determining where in time that line intercepts with the point of zero flow. The point in time that the intercept occurred, represents Tzero.

8.4 Relaxed Vital Capacity:

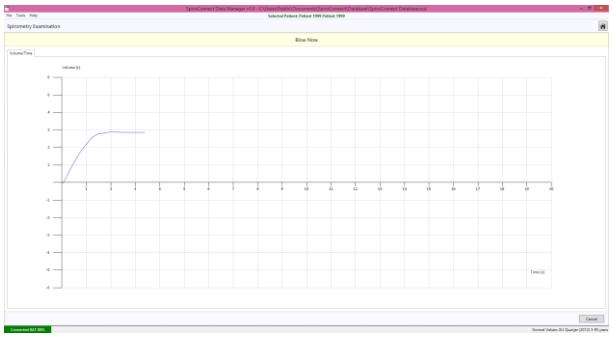
*Please note: Relaxed Vital Capacity tests MUST be added as the first test in any exam stage. If Forced Spirometry is performed first, there will be no option to add a Relaxed Spirometry test *

From the home screen, click on  to select Relaxed Spirometry. Press 

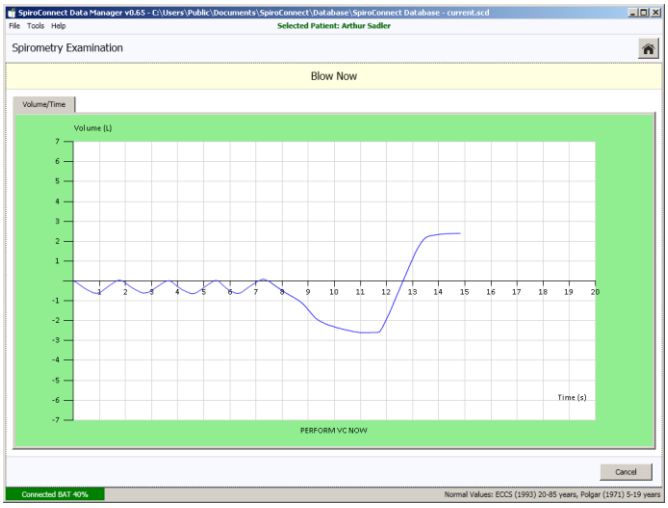
in the bottom right corner of the Spirometry Examination screen to initiate the test. A volume-time graph will be shown and the unit will beep to indicate that it is ready.
The relaxed test may be performed with a single expiration, a single inspiration, or expiration and inspiration after tidal breathing. 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:



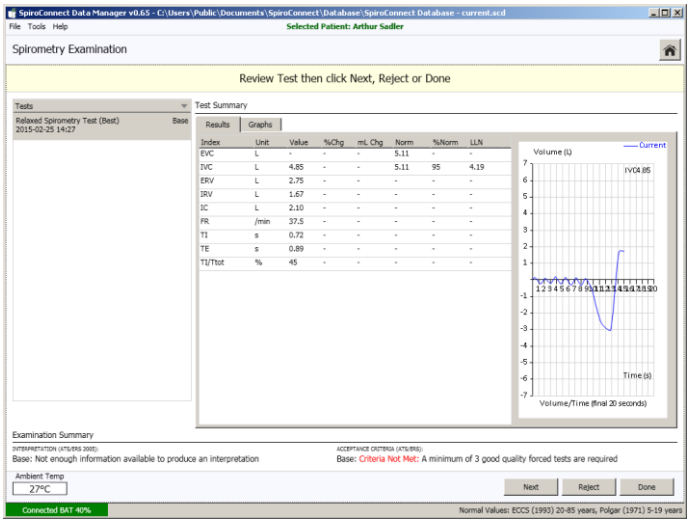
For Inspiratory Vital capacity instruct the patient to fully exhale and then seal their lips around the mouthpiece and inhale at a comfortable rate until they have completely filled their lungs. The inspiratory volume/time curve will be displayed:



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 and the graph border will turn green, indicating that it is ready for the vital capacity manoeuvre. At this point the patient should inhale as deeply as possible and then exhale completely (if EVC is desired), or exhale as deeply as possible then inhale completely (if IVC is desired).



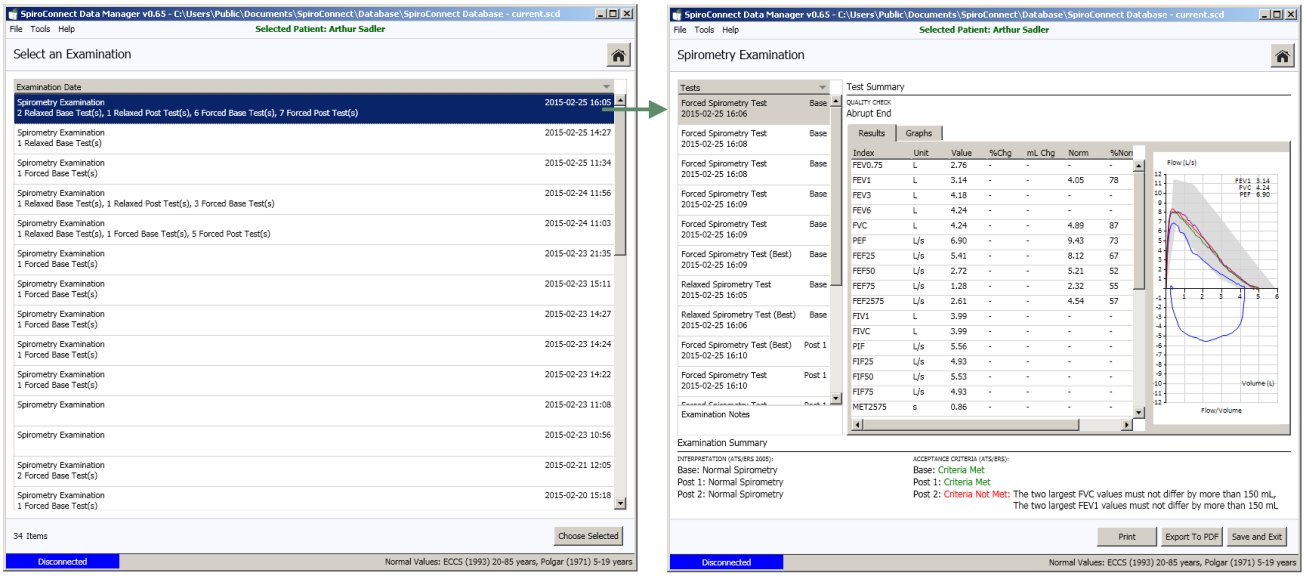
Once this has been done, the patient can remove the device from their lips and the results will be displayed.



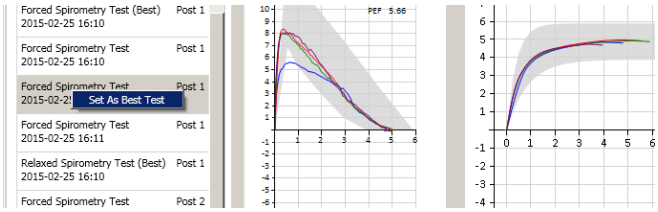
Forced tests (and subsequent post-BD tests) can be added using the buttons on the bottom right of the screen. When performing Relaxed Spirometry, Variability is shown on screen for VC.

8.5 Review Results:

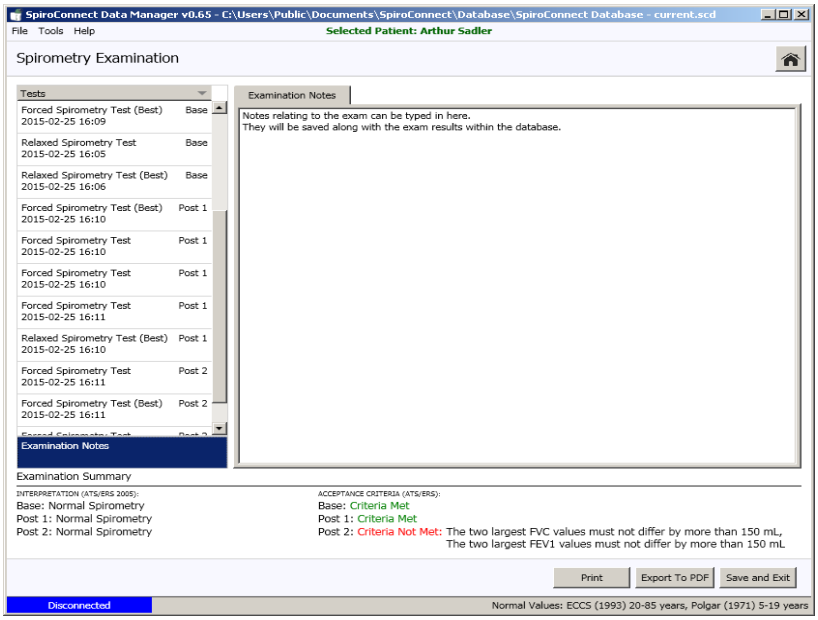
From the main window, clicking the Review Examinations button  will open the Exam Selector. This screen lists saved exams (the oldest exam at the top, newest at the bottom) which can be opened for review and printing, or the addition of post-BD tests.



When reviewing an exam, specific tests can also manually be selected as Best Tests (over-riding 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

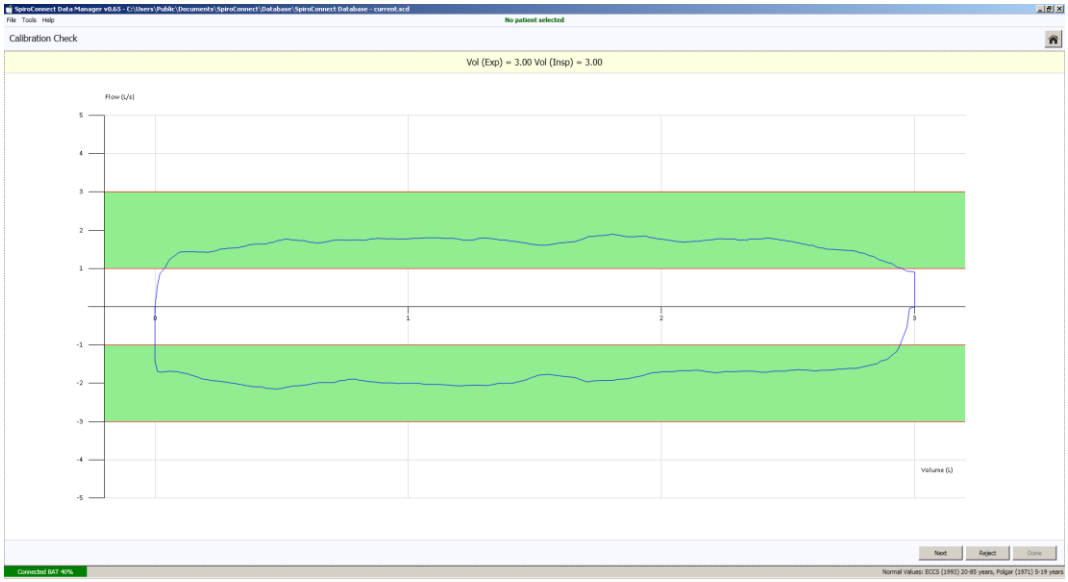
that used at the time the exam was created, the original Normal Value Set in use at the time of exam creation will always be used when reviewing or adding post bronchodilator blows to that exam.

There are exceptions to this: 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.

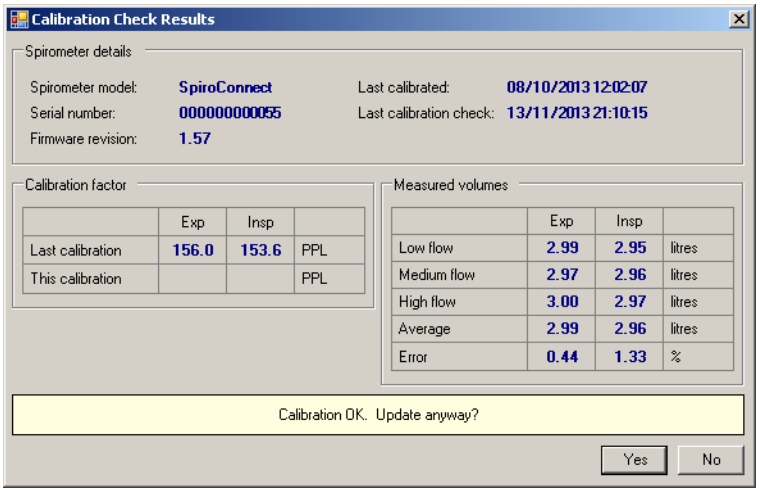
Regarding Best Blow Criteria:
It may also be noticed that when Individual Best is selected as the Best Blow Criteria, a best blow is not marked as such until the DONE button is clicked after adding all desired blows to an exam stage. This is in contrast to other Best Blow settings, in which the best 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 operator 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.



The procedure just performed is considered a calibration check if the results are reported as 'Calibration OK', and 'No' (in response to 'Update 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.
Note: The ATS/ERS spirometry guidelines state that calibration checks must be undertaken daily[1].

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

[1]SERIES "ATS/ERS TASK FORCE: STANDARDISATION OF LUNG FUNCTION TESTING" - Standardisation of spirometry Eur Respir J 2005; 26: 319–338.

a maximum database size that is limited only by the amount of disk space available. The operator may wish to maintain separate patient databases. The procedure for doing so is as follows:

Click ‘File’ and the ‘New Database’ in order to create a new database. You will be prompted to enter a new name for the database file, which will be saved in the default database location unless you choose to change the path. If you wish to switch between the currently used database and a new one, click ‘File’ and then ‘Open Database’. A window will open in which you will be able to browse and select an existing database.

The database file may be located on a shared network location e.g. a file server / NAS (that supports read/write access and file locking). A folder that is accessed by file sharing/syncing software like SkyDrive, Dropbox or GoogleDrive is NOT supported.

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.

It is the responsibility of the user to ensure the that patient records and the patient database are only accessed by those with authority to do so.

8.11 Android application:

Spirometry tests may be performed remotely from the PC by downloading the free SpiroConnect Android application onto a mobile phone or tablet. In Google Play search for “SpiroConnect Mobile”. This application is a simplified version of the full PC software and may be used, with your SpiroConnect, to collect spirometry results and upload to the PC. Patient details may also be downloaded from the PC to the mobile phone or tablet. Please refer to the Android application instruction manual for further details.

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.

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 clean or disinfect 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 Rely+On™ Perasafe™ solution for a period not exceeding 10 minutes. After cleaning/disinfection, the transducer should be rinsed in distilled water and dried.
CAUTION: Solutions containing alcohol or chlorine, e.g. bleach, must not be used.

3 Re-assemble the transducer into the main body by reversing the steps shown for disassembly.
CAUTION: When removing or replacing the turbine, the mouthpiece holder must be facing away from the SpiroConnect product name as shown above. Do not use excessive force.

12 Accessories

The following accessories are recommended for use with your spirometer.

- Replacement batteries (Energiser E91 x 2)
- 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 your authorised dealer if you unit requires service or repair.
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.

MEDCHIP SOLUTIONS LTD OR ITS SUPPLIERS SHALL, IN NO EVENT, BE LIABLE FOR SPECIAL, CONSEQUENTIAL, OR INDIRECT DAMAGES OR LOSS ARISING FROM THE USE OR MISUSE OF THIS PRODUCT, EVEN IF MEDCHIP SOLUTIONS LTD OR ITS SUPPLIERS HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN ANY CASE, THE ENTIRE LIABILITY OF MEDCHIP SOLUTIONS LTD UNDER THE PROVISION OF THIS AGREEMENT SHALL BE LIMITED TO THE AMOUNT PAID BY YOU FOR THE SOFTWARE LICENSE.

Should you need to request replacement or repair of the software or documentation under the terms of this warranty or if you have any questions regarding this license agreement, please email service@medchipsolutions.com quoting the date of purchase and the name of the supplier.

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.

COPYRIGHT

The enclosed software is owned by MedChip Solutions Ltd (and in parts by the Microsoft Corporation) and is protected by United Kingdom or copyright laws and international treaty provisions. Neither the software nor the accompanying manuals may be reproduced in whole or in part. You may not make changes or modifications to the licensed software, and you may not decompile, disassemble or otherwise reverse engineer the software.

The software may not be rented or leased to others, but you may transfer your rights under this agreement in full provided that all copies of the software and written manuals are transferred, and that the recipient agrees to the terms of this agreement and notifies MedChip Solutions Ltd of the transfer of license.

16 Trouble Shooting Information

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

	Problem	Possible cause	Solution
1	Unit does not turn on	Batteries flat	Replace batteries
2	Unit turns on, then beeps three times and turns off	Batteries flat	Replace Batteries
3	Blue light remains flashing (fast flash – 10 times per second).	Cannot connect to Wireless Dongle	Ensure SpiroConnect Dongle is plugged into PC
4	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
5	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.
6	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.
7	Unusual Readings	Damaged Turbine	Visually inspect for damage. Check calibration with a 3L syringe. Refer to your distributor.

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	Group 1	The SpiroConnect must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	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.
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			

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 Radiated RF IEC 61000-4-3	3 V rms 3 V/m	3 V rms 3 V/m	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. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz 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] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[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.			

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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
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. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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 (RTTE) 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

Hereby, MedChip Solutions Limited declares that the radio equipment type SpiroConnect is in compliance with Directive 2014/53/EU (RED). The full text of the EU declaration of conformity is available at the following internet address:
http://www.medchipsolutions.com/certificates

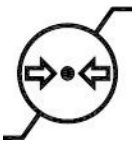
18 IT Network

The connection of the SpiroConnect to a PC running SDM software constitutes an IT Network.
The SpiroConnect transmits spirometry results to, and receives instructions from, a PC via a Bluetooth connection. The connection is between the SpiroConnect internal Bluetooth transceiver and a Bluetooth transceiver to USB converter (dongle) connected to a USB port on the PC. The Bluetooth connection offers security and encryption, and the packet protocol used for transport ensures data integrity.
The PC requirements are listed in the Specification section.
Failure of the Bluetooth link will result in the inability to perform a spirometry test.
It is the responsibility of the user to identify risks resulting from changes to the IT Network including changes to the IT Network configuration, connection or disconnection of additional items to or from the IT Network, and updating or upgrading equipment connected to the IT Network.

19 Applied Parts

SpiroConnect
Disposable mouthpiece or filter

20 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
CE 1639	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
SN	Serial number
	Range of humidity to which the instrument can be subjected to during transport
	Range of atmospheric pressure to which the instrument can be safely exposed to during transport

21 Classification

Protection against electric shock:
Internally powered equipment.

Mode of operation:
Continuous

22 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
MVV indirect (FEV1 X 35)
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/Ttot
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 and ATS 2005 standards:
Volume to within +-3% of reading, or 0.05 litres, whichever is greater

Limits of Operation:
Volume: 8 litres maximum
Flow: 14 litres per second maximum

Sensitivity:
Better than 0.025L/s

Dynamic Impedance:
137 $Pa.L^{-1}.s$, measured at $14L.s^{-1}$

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:
$10^{O}C$ to $38^{O}C$, 15% to 95% RH, non-condensing, Altitude up to 3000m

Transport and Storage Conditions:
$-20^{O}C$ to $70^{O}C$, 15% to 95% RH, non-condensing

Lifetime:
5 years

Supported Operating Systems:
A Microsoft Windows based PC is required, with hardware that meets the minimum specifications below:
Processor: 1 GHz or above
RAM: 512 MB or more
Free Disk Space: 100 MB
Video: 1024 x 768 minimum resolution
USB: One free USB port is required
OS: Win XP, Win 7, Win 8 and Win 10

BT Radio Equipment:
Frequency Bands: 2.402 – 2.480 GHz
Maximum Power: 2 mW

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

WARNING: No modification of this equipment is allowed.

MedChip Solutions Ltd.
Chislehurst Business Centre
1 Bromley Lane, Chislehurst
Kent, BR7 6LH, U.K.
email: sales@medchipsolutions.com
www.medchipsolutions.com

CE
1639

This unit has been supplied by:

[Released by CN315]