



SpiroConnect Spirometer

Operators Manual

Issue 1.12.2

Note: This issue of the Operators Manual, Issue 1.12.1, is applicable to SDM 1.12 when used with FW 3.02.

October 2022

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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.

The SpiroConnect turbine is a precision sensor and to avoid damage the following precautions should be taken:

- Clean or sterilise the turbine in accordance with the instructions – See section 11
- Do not immerse the turbine in sterilising solution for more than 10 minutes
- The turbine should be dried in air, do not insert anything into the turbine to dry or clean
- Do not apply undue force when removing or inserting the turbine into the housing

1.1 MedChip Solutions COVID-19 Response

Spirometry should not be performed if the patient has any symptoms of COVID-19 infection at the time of the test, or if they are known to have recently been in contact (within previous 10 days) with a confirmed case¹.

MedChip Solutions recommends that a spirometry test using the SpiroConnect, should only be performed using a bacterial/viral spirometry filter. These should be purchased from an authorised SpiroConnect distributor to ensure they fit the device correctly.

After each use the unit should be wiped down with an alcohol infused wipe or other medically approved anti-viral wipes such as Clinell wipes as per section “11.1 Case Cleaning COVID-19 Update”.

The single use pulmonary filter should be safely disposed of immediately after the test by a clinician wearing medical gloves.

Even though the SpiroConnect directs air downwards away from the clinician's face, it is recommended that a clinician is wearing personal protective equipment (PPE) that limits aerosolized droplet acquisition² as the patient may cough after performing spirometry.

The Bluetooth connectivity allows the clinician to remain at a safe distance from the patient throughout the test and to be isolated from the patient, preferably behind a screen, in case of a coughing event. Enhanced cleaning of the testing space should be carried out such as wiping down surfaces with appropriate cleaners².

If available, a room with mechanical air circulation should be used or a room where other ways of ventilation are possible (e.g. opening windows). Ideally this should be in the region of 6 room air changes per hour¹.

The MedChip Solutions Covid-19 Response is based ATS guidance and on the ARTP document "Risk minimisation in spirometry re-start" by Martin Allen³. Which includes:

- PCRS Spirometry in Primary Care - Guidance on reinstating spirometry in England
- ARTP Statement for the NHS NATIONAL RESPIRATORY PROGRAMME Task and Finish Group Recommendations for undertaking risk-managed spirometry

Covid19 advice may be updated by the Medical Bodies and Governments. It is always vital to act in line with the latest advice and any local Risk Assessment.

References

¹ ARTP (Association for Respiratory Technology & Physiology) Statement for the NHS NATIONAL RESPIRATORY PROGRAMME Task and Finish Group Recommendations for undertaking risk-managed spirometry.

² Meredith C. McCormack, MD MHS, David A. Kaminsky, MD, 2020 members of the ATS Proficiency Standards for Pulmonary Function Testing Committee.

³ https://www.artp.org.uk/write/MediaUploads/Standards/COVID19/ARTP_PCRS_spiro_re-start_FINAL2.pdf

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 on the turbine transducer. See section 11.2 on how to clean the turbine.
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.
 CAUTION: The turbine must be orientated to the unlock position when removing or replacing and turned to the lock position for use as shown on the label on top of the device. Do not use excessive force.
WARNING: If you use multiple turbines in the same SpiroConnect then the calibration should be checked each time the turbine is swapped and the calibration updated in line with the recommendations on screen.
PLEASE NOTE: Activities That Should Be Avoided before Lung Function Testing <ul style="list-style-type: none"> • Smoking and/or vaping and/or water pipe use within 1 h before testing (to avoid acute bronchoconstriction due to smoke inhalation) • Consuming intoxicants within 8 h before testing (to avoid problems in coordination, comprehension, and physical ability) • Performing vigorous exercise within 1 h before testing (to avoid potential exercise-induced bronchoconstriction) • Wearing clothing that substantially restricts full chest and abdominal expansion (to avoid external restrictions on lung function)

4 Relative Contraindications for Spirometry

WARNING: Due to increases in myocardial demand or changes in blood pressure: Acute myocardial infarction within 1 wk Systemic hypotension or severe hypertension Significant atrial/ventricular arrhythmia Noncompensated heart failure Uncontrolled pulmonary hypertension Acute cor pulmonale Clinically unstable pulmonary embolism History of syncope related to forced expiration/cough
WARNING: Due to increases in intracranial/intraocular pressure: Cerebral aneurysm Brain surgery within 4 wk Recent concussion with continuing symptoms Eye surgery within 1 wk
WARNING: Due to increases in sinus and middle ear pressures: Sinus surgery or middle ear surgery or infection within 1 wk
WARNING: Due to increases in intrathoracic and intraabdominal pressure: Presence of pneumothorax Thoracic surgery within 4 wk Abdominal surgery within 4 wk Late-term pregnancy
WARNING: Infection control issues: Active or suspected transmissible respiratory or systemic infection, including tuberculosis Physical conditions predisposing to transmission of infections, such as hemoptysis, significant secretions, or oral lesions or oral bleeding

Spirometry should be discontinued if the patient experiences pain during the maneuver. Relative contraindications do not preclude spirometry but should be considered when ordering spirometry.

The decision to conduct spirometry is determined by the ordering healthcare professional on the basis of their evaluation of the risks and benefits of spirometry for the particular patient. Potential contraindications should be included in the request form for spirometry.

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 °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 are required for installation
- An installation is on a per-user basis. If 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

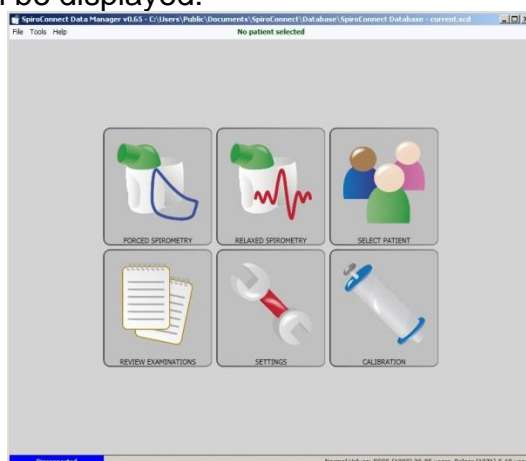
WARNING: Do not attempt to connect the SpiroConnect to the PC using the USB socket on the SpiroConnect device via USB cable.

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.



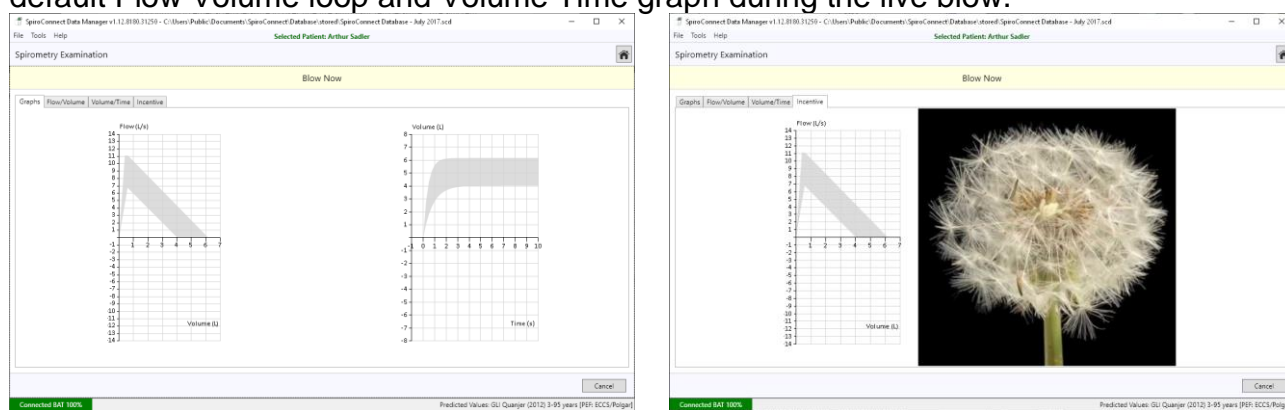
The LED indicator will flash blue at a fast rate for a few seconds whilst connection with SpiroConnect Dongle is established, and then change to a slow blue flash whilst connection with the SpiroConnect Data Manager application is established, finally displaying solid blue once ready. **Connected: BAT 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  in the bottom right corner of the Spirometry Examination screen to initiate the test.

Both flow-volume and volume-time graphs are shown and the unit will beep to indicate that it is ready. At this point the operator can select a tab for a single graph or the Incentive tab, if he wishes to view the FV graph, VT graph or Child Incentive graphic as an alternative to the default Flow Volume loop and Volume Time graph during the live blow.



Instruct the patient to hold the mouthpiece between the teeth, and then apply the lips for an airtight seal and breathe normally through the device. The patient should then be instructed to breathe in rapidly until their lungs are completely full and then without delay, 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 until the graph border turns pink when a plateau in the volume/time curve is detected, or to the point where they simply cannot squeeze any more air out. They should then inhale as deeply and as rapidly as possible back to full lung capacity, before removing the unit from their lips. After four seconds has passed without the unit detecting any further flow, it will sound a beep and a test summary will be shown.

Labels and UI Elements:

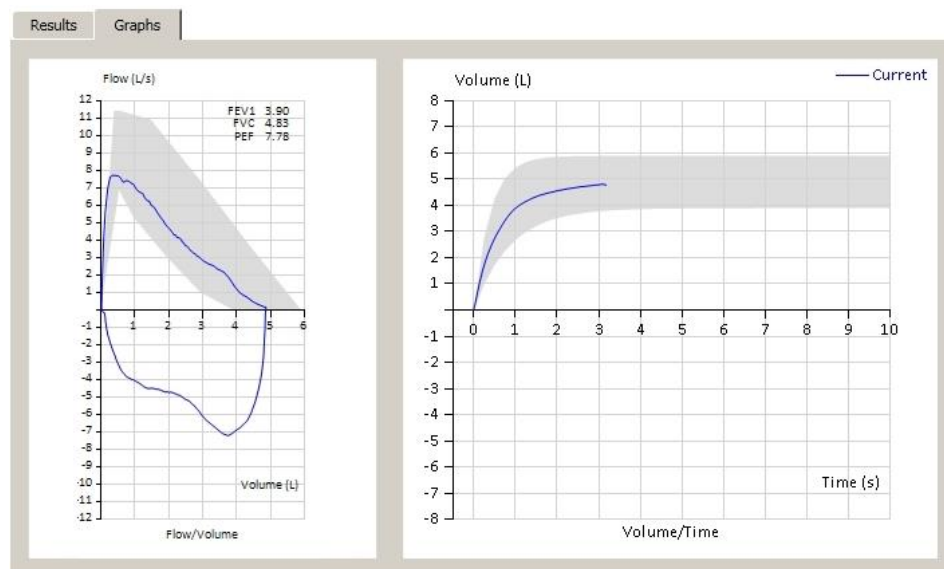
- OPERATOR GUIDANCE:** Review Test then click Next, Reject or Done
- LIST OF TESTS IN EXAM:** Tests list (Forced Spirometry Test (Best), 2022-05-30 15:20)
- TEST QUALITY STATUS:** QUALITY CHECK: Good Blow
- VARIABILITY SUMMARY:** VARIABILITY: FEV1: -% (-mL) FVC: -% (-mL)
- ACCEPTABLE/USABLE:** ACCEPTABLE/USABLE: FEV1: A FVC: A
- ATRS/ERS 2019 TEST ACCEPTABILITY GRAPH/TREND TAB SELECTOR:** Results | Graphs | Trend
- PREDICTED VALUES TEST RESULTS:** Graph showing Flow (L/s) vs Volume (L) with a shaded normal range.
- EXAM ACCEPTANCE STATUS:** EXAM GRADE: Base: FEV1 E, FVC E
- ATRS/ERS 2019 EXAM GRADE:** ACCEPTANCE CRITERIA (ATRS/ERS 2019): Base: Criteria Not Met: A minimum of 3 acceptable results for both FEV1 and FVC are required
- ACTION BUTTONS:** Next | Reject | Done
- NORMAL VALUE SET USED:** Predicted Values: GLI Quanjer (2012) 3-95 years (PEF: ECCS/Polgar)
- MEASURED AMBIENT TEMP:** Ambient Temp: 24°C
- UNIT CONNECTION STATUS:** Connected BAT 100%
- INTERPRETATION:** INTERPRETATION (ATRS/ERS 2019): Base: Normal Spirometry

Index	Unit	Measured Value	Best	Best Base	%Chg	mL Chg	Pred	%Pred	LLN
FVC	L	5.03	5.03	-	-	5.10	99	4.03	-
FEV1	L	3.63	3.63	-	-	4.07	89	3.21	-
FEV1/FVC	%	72	72	-	-	80	-	70	-
PEF	L/s	8.28	8.28	-	-	9.13	91	7.14	-
Lung Age	Years	58	-	-	-	-	-	-	-

All parameters that have been selected for display in Settings are shown, along with the predicted value (if available), best baseline value (*Base) and percentage change from Best Base blow (if the blow is a Post blow), blow quality assessment, ATRS/ERS 2019 FEV1 and FVC acceptability status for this blow, ATRS/ERS 2019 exam grade for the exam as a whole, 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.

Note: The values used for the interpretation are always the values in the 'Best' column. These values comprise the best results for each parameter, taken from all tests of acceptable quality from the current exam stage, in accordance with ATRS/ERS guidelines.

Selecting the 'Graphs' tab will change the display to show both the flow-volume and volume-time graphs.



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

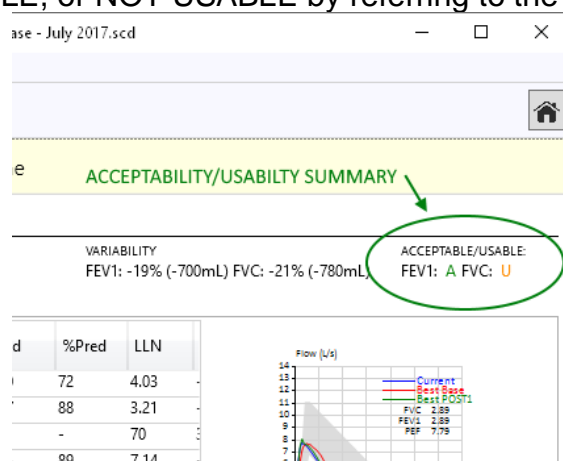
you wish to end the current exam stage and review results. After DONE is clicked, no further blows can be added to the current exam stage. Post1 or Post2 blows can be added at a later stage if they do not exist already.

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 ten following messages:

Hesitant Start: [BEV exceeds limit] - Blast out immediately when completely full
Slow Start: [PEF rise time > 150ms] Blast out immediately when completely full
No Plateau: [No plateau and expiration < 15 s] Keep going until completely empty
Hesitation at Max Vol: [Hesitation time > 2s] Blast out immediately when completely full
Low Volume: [FVC less than max previous FVC] Take the deepest breath possible and keep going until completely empty
Incomplete Insp before Exp: [(FIVC after FVC) > FVC] Fill your lungs completely before blasting out – take the deepest breath possible
Low Final Insp: [(FIVC after FVC) < 90% FVC] After completely emptying your lungs, remember to breathe in – back to the top
Slow Filling: [Mean Inspiratory Flow of inhalation prior to FVC < 2 LPS] Breathe in faster before blasting out
Cough in first second: [Suspected cough in first second of expiration] Try having a sip of water before the next blow
Good Blow: The blow is of good quality

With many of the new ATS/ERS 2019 quality checks, a failure does not necessarily mean that the test is ineligible for taking acceptable results from. The software automatically determines whether the FEV1 and FVC from each specific test should be used for interpretation or not, in accordance with rules published in the ATS/ERS 2019 update. You can see whether the FVC and the FEV1 measurements in each blow have been categorised as ACCEPTABLE, USABLE, or NOT USABLE by referring to the information on screen:



In the case above, the FEV1 was ACCEPTABLE and the FVC was USABLE. If either parameter happened to be NOT USABLE, a dash would have been displayed instead of the 'A' or 'U'.

Note: If an older exam is being reviewed and it was conducted with SDM software < 1.12 or unit firmware < V3.02, the exam will be presented with quality messages from ATS/ERS 2005 guidelines instead of ATS/ERS 2019, and could be one of the following messages:

<i>Slow Start:</i>	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
<i>Abrupt End:</i>	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)
<i>Possible Cough:</i>	A possible cough has been detected.
<i>Good Blow:</i>	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 150mL (100mL if $FVC \leq 1L$) of each other

The two largest FEV1 values must be within 150mL (100mL if $FVC \leq 1L$) of each other

The two largest VC values must be within 150mL of each other

ATS/ERS 2019

At least 3 acceptable FEV1 and 3 acceptable FVC must exist within the exam stage

The two largest FVC values must be within 150mL of each other, or for patients aged 6 or younger, 100mL or 10% of largest FVC, whichever is greater.

The two largest FEV1 values must be within 150mL of each other, or for patients aged 6 or younger, 100mL or 10% of largest FEV1, whichever is greater.

The two largest VC values must be within 150mL of each other or 10% VC (whichever is smaller) for patients older than 6 years; and 100mL or 10% of largest FVC, whichever is smaller (for patients aged 6 or younger).

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

The two largest VC values must be within 100mL or 5% (whichever is larger) of each other

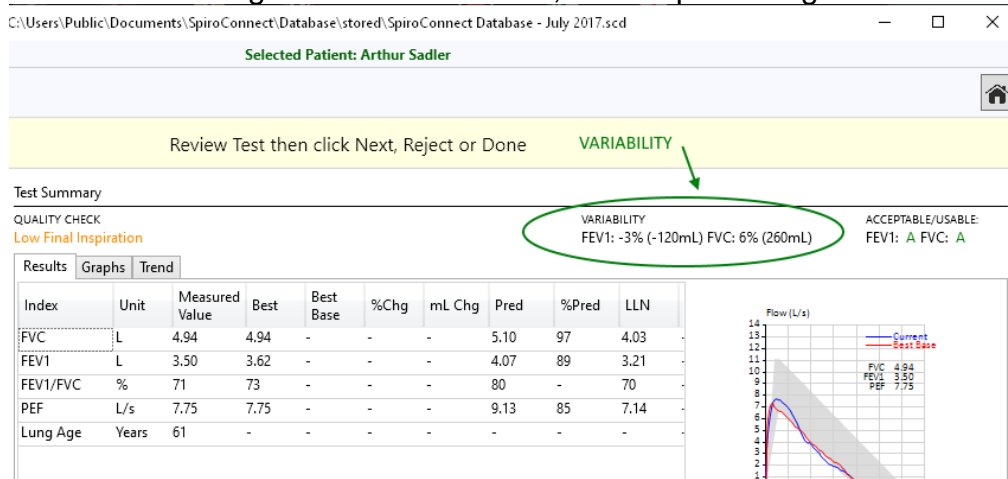
CUSTOM

You can select CUSTOM and set up your own set of acceptance criteria if desired

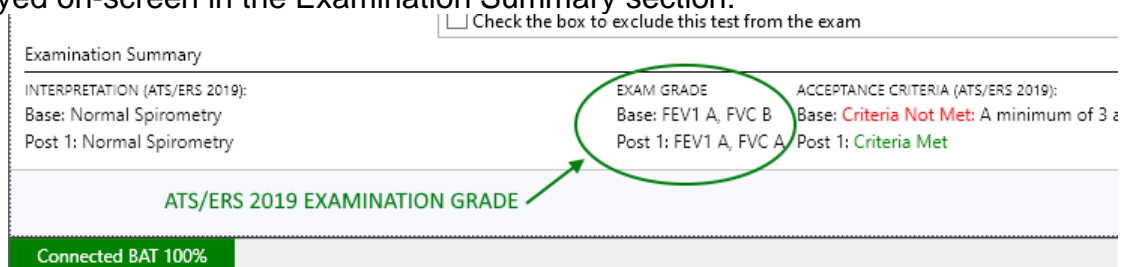
Please note that one can select either ATS/ERS 2019, BTS, ARTP or CUSTOM acceptance criteria to be used for this assessment, from the Settings tab.

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.



The ATS/ERS 2019 update also introduces the concept of Exam Grade. This is an overall grade that is given to an exam based upon how many FEV1 and FVCs were acceptable/usable/not usable and what the reproducibility between the best values was. The operator should always aim to get the highest exam grade possible. The grading system goes as follows (from best to worst): A, B, C, D, E, U, F. The Exam Grade is displayed on-screen in the Examination Summary section:



Once the operator is satisfied that the exam is at the best quality level attainable, the DONE button can be clicked to finalise the exam.

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.

The EXAMINATION NOTES feature can be accessed by clicking on the pane at bottom of the list of tests:

SpiroConnect Data Manager v1.12.8186.30352 - C:\Users\Public\Documents\SpiroConnect\Database\stored\SpiroConnect Database - July 2017.scd

File Tools Help

Selected Patient: Arthur Sadler

Spirometry Examination

Tests	Base
Forced Spirometry Test (Best)	Base
2022-05-31 15:56	
Forced Spirometry Test	Base
2022-05-31 15:56	
Forced Spirometry Test	Base
2022-05-31 15:57	
Forced Spirometry Test (Best)	Post 1
2022-05-31 15:59	
Forced Spirometry Test	Post 1
2022-05-31 15:59	
Forced Spirometry Test	Post 1
2022-05-31 15:59	
Forced Spirometry Test	Post 1
2022-05-31 16:00	
Forced Spirometry Test	Post 1
2022-05-31 16:00	

CLICK HERE TO SHOW EXAMINATION NOTES

Examination Notes

Examination Notes Standardised Operator Comments

Forced Base: Serial Number SN01003 Last Calibration Check: 31 May 2022 10:10:57 - Calibration OK
Forced Post1: Serial Number SN01003 Last Calibration Check: 31 May 2022 10:10:57 - Calibration OK

Type new notes in here..

Save Exam Notes

CLICK HERE TO ADD STANDARD NOTES

TYPE NEW NOTES IN HERE

AUTOMATICALLY GENERATED NOTES

Standardised Operator Comments can be elected for addition to Exam Notes by selecting the 'Standardised Operator Comments' tab:

Examination Notes Standardised Operator Comments

Patient Condition:

- ☐ No comments
- ☒ First attempt at spirometry
- ☐ Reference values are based on ethnicity that may not be suitable for this patient
- ☐ Patient used bronchodilator(s) prior to test [record drugs, doses and times used in Notes]
- ☐ Patient smoked < 1 hr prior to test
- ☐ Patient had difficulty understanding directions
- ☐ Patient reported consumption of an intoxicant
- ☐ Observed symptoms e.g. cough, wheeze, dyspnea or cyanosis [record symptoms in Notes]

Manoeuvre Quality:

- ☐ No comments
- ☐ Cough during the first second of expiration
- ☐ Glottis closure
- ☐ Early termination
- ☒ Hesitant start of test
- ☐ Obstructed mouthpiece or breathing tube
- ☐ Leak around mouthpiece
- ☐ Not at TLC prior to expiration
- ☐ Operator changed manoeuvre designation from acceptable to unacceptable

Bronchodilator Responsiveness:

- ☐ Facility bronchodilator responsiveness protocol followed for type, dose and delivery method of bronchodilator and wait time before post-BD testing
- ☐ Post-BD measurements obtained using other bronchodilator(s), dose(s), delivery method or wait time

Quality of Testing Session:

- ☐ No comments
- ☐ Acceptability and/or repeatability criteria not met despite patient's best efforts
- ☐ Spirometry induced bronchospasm
- ☒ Patient was too tired to continue
- ☐ FEV1 dropped more than 20% from baseline
- ☐ Motivation difficulties
- ☐ Coordination difficulties



Add Selected Comments

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.

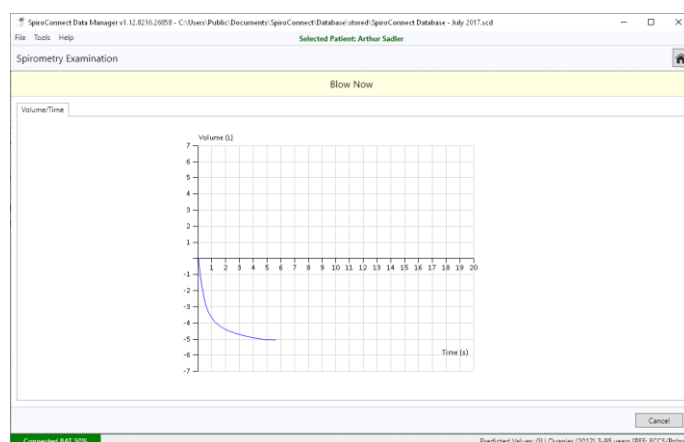
8.4 Relaxed Vital Capacity:

*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 *

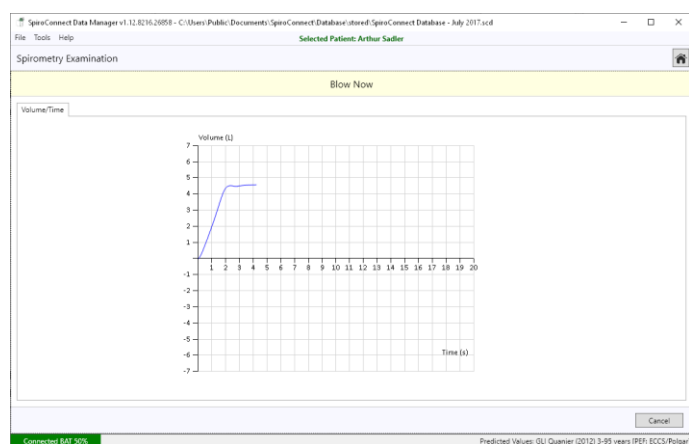
From the home screen, click on  to select Relaxed Spirometry. Press  in the bottom right corner of the Spirometry Examination screen to initiate the test. A volume-time graph will be shown and the unit will beep to indicate that it is ready.

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.

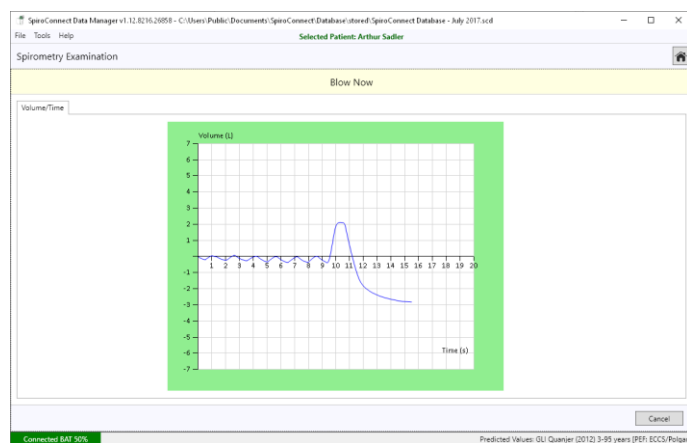
For Expiratory Vital capacity instruct the patient to fully inhale and then seal their lips around the mouthpiece and exhale at a comfortable rate until they have completely emptied their lungs. The expiratory volume/time curve will be displayed:



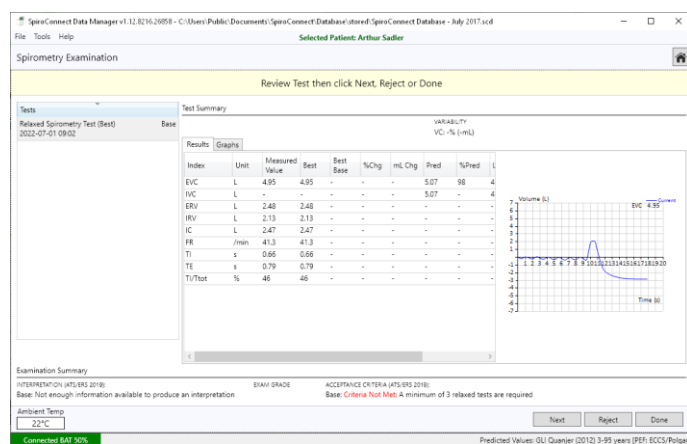
For Inspiratory Vital capacity instruct the patient to fully exhale and then seal their lips around the mouthpiece and inhale at a comfortable rate until they have completely filled their lungs. The inspiratory volume/time curve will be displayed:



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 once 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). If an EVC is being performed and a plateau is detected at the end of expiration, the unit will emit a double beep to signal that the patient can stop exhaling.




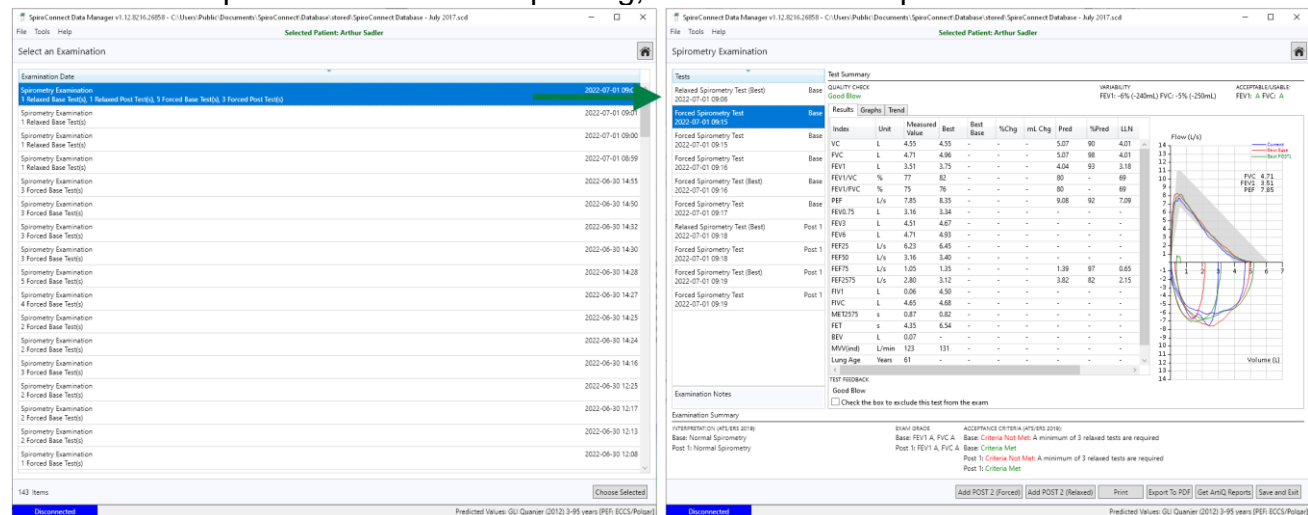
Once this has been done, the patient can remove the device from their lips and the results will be displayed.



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.



A report can be printed or exported to PDF by using the relevant buttons on the lower button bar.



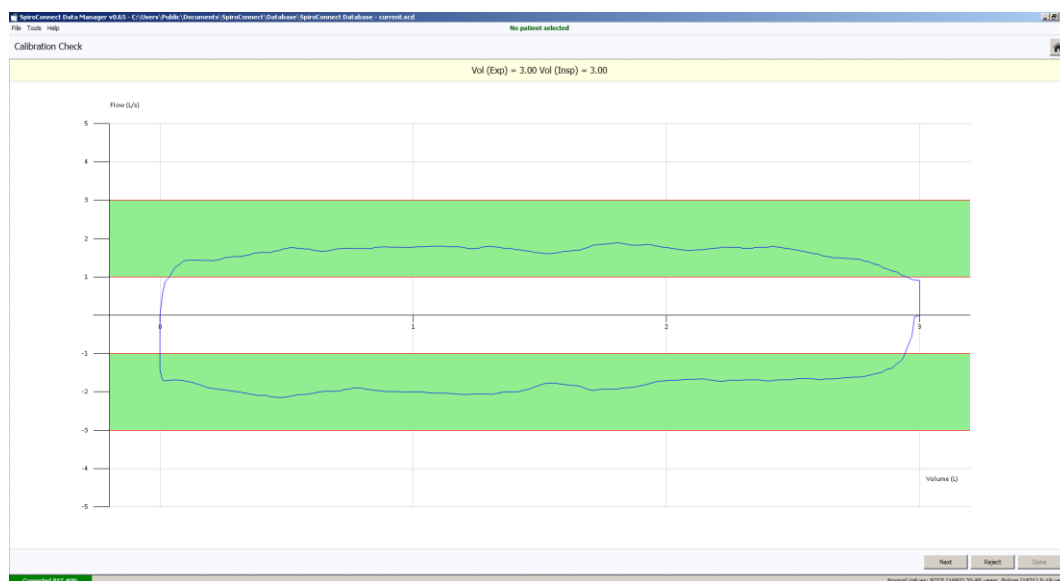
Please note that when reviewing an existing exam, the patient details used for determination of normal values and interpretations are that of the patient when the base exam was conducted. The normal values therefore will not change with time, and even if SpiroConnect Data Manager has been configured 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: Interpretation and Acceptance Criteria. These are always based on whatever the currently selected settings are in Settings

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, possible outcomes of the Calibration Check are:

PASS	No change to the stored calibration is required.
PASS	Accuracy is within the ATS/ERS $\pm 3\%$ requirement. Accuracy can nonetheless be improved by updating the calibration.
FAIL	Outside of ATS/ERS $\pm 3\%$. If any doubts about the calibration being performed correctly then redo the calibration check, else update the calibration.
FAIL >6% Change	If any doubts about the calibration being performed correctly then redo the calibration check. If it still fails check the turbine for damage. If turbine is good then update the calibration.
FAIL Out of Range	This could indicate a faulty turbine or syringe. Check both and repeat. If Calibration Check continues to fail out of range do not use the turbine and contact supplier for technical support.

If the calibration values are updated the procedure is then deemed a calibration rather than a calibration check.

The results are stored for record keeping purposes, and the option to print a report is displayed.

*Note: The calibration must be checked when switching to a different turbine, using the calibration procedure within the SpiroConnect Data Manager PC software. To update the calibration the user simply clicks the 'Update' button at the end of the calibration routine. If on checking the turbine had a calibration factor very similar to the previous one then it will display as **PASS** and the 'Update' option not given.*

Note: The ATS/ERS spirometry guidelines state that calibration checks must be undertaken daily¹.

8.8 Settings:

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

- Display – regional specific formats
- Spirometry 1/2 – normal value set, interpretation and other spirometry related settings
- Spirometry 2/2 – quality check selection
- Parameters – select which indices the user wishes to be displayed on the results screens
- Spirometry Printout – Report customisation
- ArtiQ – Add or delete API credentials

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.
 - 'Export Calibration History' exports a listing of all calibrations done on this PC
- 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.
 - 'Check for Firmware Update' will guide the user through the process of checking whether their unit firmware is up to date.

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 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.

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

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 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.

8.12 ArtiQ AI Functionality:

ArtiQ provides artificial intelligence based report generation for quality control of an examination as well as a report that presents their interpretation of a lung function test. These reports can be presented alongside SpiroConnect Data Manager's own quality feedback and interpretation as additional information if the user has a set of valid ArtiQ credentials.

In order to enable ArtiQ functionality, click on the Settings icon on the main screen and then select the ArtiQ tab. Enter the ‘ArtiQ Key ID’ and ‘ArtiQ Key Secret’ into the relevant boxes then click OK and restart the software.

Once enabled, if you review an existing exam that has not previously fetched ArtiQ reports and select any of the Forced Spirometry tests, you will notice a ‘Get ArtiQ Reports’ button along the bottom button bar. Clicking this button will result in the software sending examination data to the ArtiQ portal and retrieving the reports, which will be displayed onscreen in new ArtiQ QC and ArtiQ PFT tabs:

The image displays two side-by-side screenshots of the SpiroConnect Data Manager software interface, showing the integration of ArtiQ reports. Both screenshots are for a patient named 'Selected Patient: Arthur Sadler'.

Left Screenshot (ArtiQ Report):

- Session ID:** PRE
- Analyzed on:** 2022-07-01 14:43:07
- Session Evaluation:** FEV1 Acceptable (Grade A), PFC Acceptable (Grade A)
- Best Trial Results:** Unit Trial: 4, FEV1: 3.74 L, PFC: 4.97 L
- Trial Overview Table:**

	FEV1		PFC	
	Acceptable	Usable	Acceptable	Usable
Trial 1	Yes	-	No	Yes
Trial 2	Yes	-	Yes	-
Trial 3	Yes	-	Yes	-
Trial 4	Yes	-	Yes	-
Trial 5	Yes	-	Yes	-

Right Screenshot (ArtiQ Report):

- Report ID:** 361
- Age:** 45, **Gender:** Male, **Current Smoker:** Stopped, **Pack-Years:** 15
- Protocol:** Normal spirometry. Tendency towards obstructive spirometry. Borderline significant reversibility after postbronchodilator test. Change in FEV1 of -90ml or -2.4%, and PFC of 270ml or 5.4%.
- Disease probability:**
 - Asthma: 63.6%
 - COPD: 12.8%
 - Normal: 8.1%
 - Unidentified: 15.5%
- Conclusions and suggestions:** Highest disease probability based on lung function: asthma. The following tests may help determine a final diagnosis: Perform screening laboratory (including allergy and eosinophilia). Consider inhaled corticosteroids with or without bronchodilator therapy. Consider exhaled NO or histamine challenge when doubt.

These reports will also be appended to SpiroConnect Data Manager's standard report when the Print or Export PDF buttons are clicked.

From this point onwards when performing spirometry testing, when an exam stage is complete and the 'Done' button is pressed, a popup window will prompt the user to retrieve ArtiQ reports. These reports are only downloaded once and saved alongside the examination in the database so that they can be automatically displayed the next time the exam is reviewed without requiring a connection to the internet.

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

11.1 Unit Case Cleaning COVID-19 Update

After each use the unit should be wiped down with an alcohol infused wipe or other medically approved anti-viral wipes such as Clinell wipes.

See also section “1.1 MedChip Solutions Covid-19 Response”.

Take care that no liquid is allowed to enter the unit.

11.2 Turbine/Transducer Cleaning

The transducer requires no routine maintenance or servicing. 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.

11.3 Soft Carry Case Cleaning

Local infection control guidance should be followed. Alcohol infused wipe or other medically approved anti-viral wipes may be used.

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 your 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.

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Read carefully before use

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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	
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	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>			

^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.











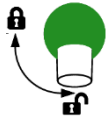
It is the responsibility of the user to identify risks resulting from changes to the IT Network including changes to the IT Network configuration, connection or disconnection of additional items to or from the IT Network, and updating or upgrading equipment connected to the IT Network.

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
	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
	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
	The symbol indicates the orientation of the turbine for removal/replacement and use: Unlocked – the turbine can be removed and replaced Locked – the SpiroConnect can be used

21 Classification

Protection against electric shock:

Internally powered equipment.

Mode of operation:

Continuous

22 Specifications

Transducer Type:

Bi-directional high sensitivity turbine

Measurements:

VC	VT (TV)
FEV0.75	Ti
FEV1	Te
FEV3	IRV
FEV6	ERV
FVC	Vext
PEF	FEV0.75/VC
FEF25 (MEF75)	FEV0.75/FVC
FEF50 (MEF50)	FEV1/VC
FEF75 (MEF25)	FEV1/FVC (FER)
FEF25-75 (MMEF)	FEV3/VC
FIV1	FEV3/FVC
FIVC	FEV0.75/FEV6
PIF	FEV1/FEV6
FIF25 (MIF75)	FEF50/VC
FIF50 (MIF50)	FEF50/FVC
FIF75 (MIF25)	MMEF/FVC (FEF25-75/FVC)
MET25-75	FIV1/FIVC (FIR)
FET	R50 (FEF50/FIF50)
EVC	Ti/Ttot
IVC	VT/Ti (TV/Ti)
IC	LUNG AGE**
MVV indirect (FEV1 X 35)	

** 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°C to 38°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

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, Recommended 1280x800 or greater.

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



1639



0120

This unit has been supplied by:

[Released by CN472]

Notes: