SpiroConnect®
Mobile Application

Operators Manual

Issue 1.6.2

COVID-19 Update

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Contents

1 Operation Overview

Please read this manual before using the SpiroConnect.

The SpiroConnect Mobile App allows users to collect spirometry data, on an Android tablet or mobile phone and then upload the results to the patient database on the PC.

Both Relaxed VC and Forced VC tests may be performed as baseline or post bronchodilator tests.
The indices displayed are VC, FEV1, FVC, FEV1/FVC and PEF together with the predicted values and test quality information. However, all the spirometric indices are recorded and are uploaded for subsequent review on the PC.

Before using the SpiroConnect with a mobile device it must first be paired using the procedure in Section 7. This procedure is only performed once for each mobile device in use and only has to be repeated if a new mobile device is used.

Once paired, the SpiroConnect may be switched from PC mode to mobile mode. When in PC mode the indicator light is blue and for mobile mode it is yellow. The SpiroConnect is switched between the two modes by pressing the power button three times in quick succession when the unit is on

Patient details are downloaded from a SpiroConnect Data Manager to the mobile device. Alternatively, patient details may be entered directly on the mobile device if the patient's details have not been previously recorded on the PC.

Forced spirometry, Relaxed spirometry, calibration, examination review and patient data entry are all supported.
Patient note entry and printing are not supported, however, the addition of patient notes and printout facilities are available from the PC software after data upload.

The spirometer communicates with the mobile device using the mobile device's internal Bluetooth circuit rather than the Bluetooth dongle that is used when connecting to a PC.

The SpiroConnect transmits real-time spirometric flow and volume data followed by diagnostic quality spirometry indices to an Android device running the SpiroConnect Mobile App.

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.

For further information on the SpiroConnect, PC software and the App please refer to our website: www.medchipsolutions.com.

Note:
The Bluetooth dongle, supplied with the SpiroConnect, is not required for mobile use.

Note:
To ensure patient data security it is recommended that the mobile device remains in the user's possession at all times and that after uploading spirometry results into the PC database the patient record on the tablet are deleted.

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 case[1].

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 acquisition[2] 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 cleaners[2].

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 hour[1].

The MedChip Solutions Covid-19 Response is based on the ARTP document "Risk minimisation in spirometry re-start" by Martin Allen[3]. 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

As well as ATS guidance.

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.

<u>References</u>

[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 Further Information

For further information on the SpiroConnect, PC software and the App please refer to our website: www.medchipsolutions.com.

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.
PLEASE NOTE: Uninstalling the Spirometry Mobile App may remove all patient data from your phone. Please ensure results are uploaded to SDM first if you wish to keep the records.

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 Mobile App 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 Mobile App 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.
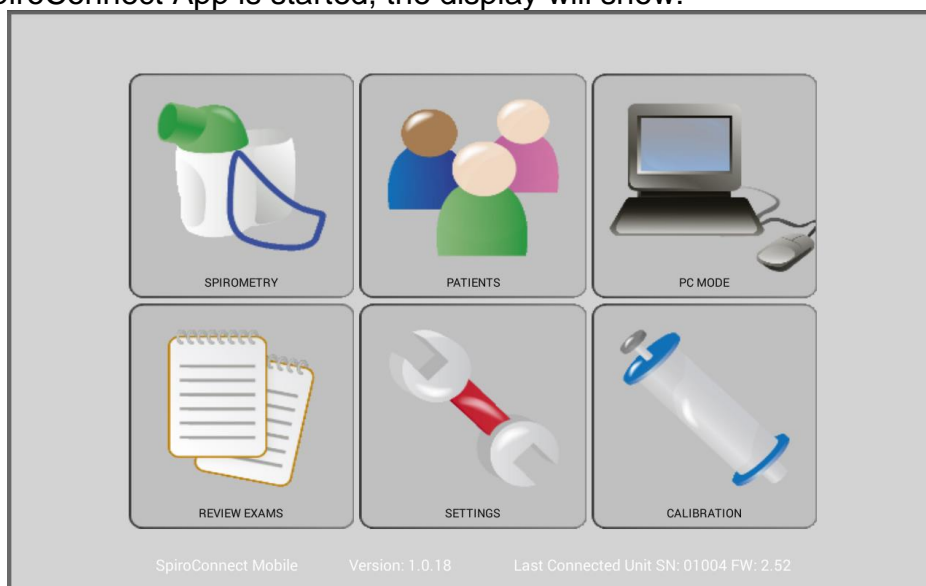Insert 2 AA size alkaline batteries as shown below taking care to observe the correct polarity:

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

8 Operation

8.1 Main Menu

When the SpiroConnect App is started, the display will show:

Note:
The screen is designed to work in landscape mode only and will not change to portrait mode when the device is rotated.

Function Overview
There are 6 buttons that have the following functionality:
SETTINGS - allows the SpiroConnect to be paired to the mobile device and adjust spirometry preferences.
PATIENTS - gives access to the patient database for entering new patient details or selecting a patient for testing.
SPIROMETRY – initiates a forced spirometry test with optional relaxed VC test
REVIEW EXAMS – allows stored tests to be reviewed.
PC MODE - establishes communications with SpiroConnect Data Manager for downloading patient details and uploading results.
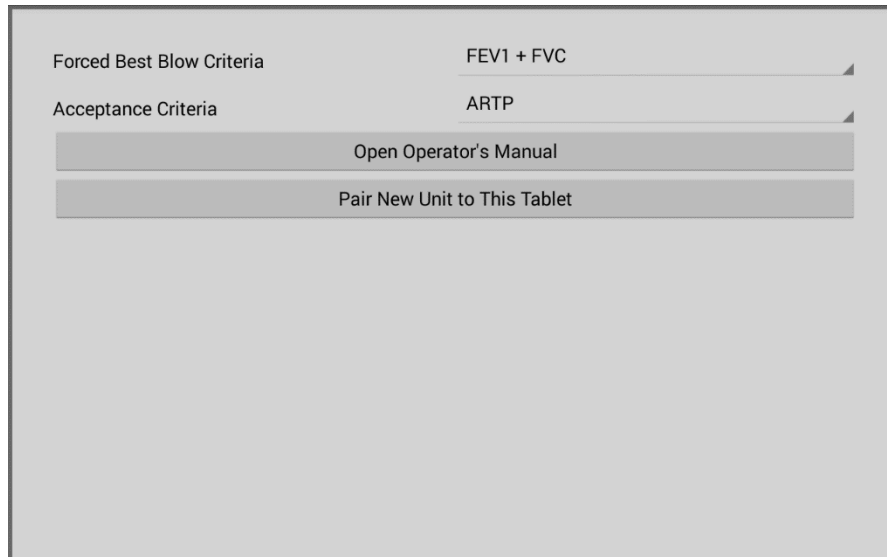CALIBRATION – allows the SpiroConnect calibration to be checked or updated.

Note:
The calibration data is stored in the SpiroConnect and not on the mobile device. If the SpiroConnect has been previously calibrated using SpiroConnect Data Manager then it is not necessary to repeat for use on the mobile device.
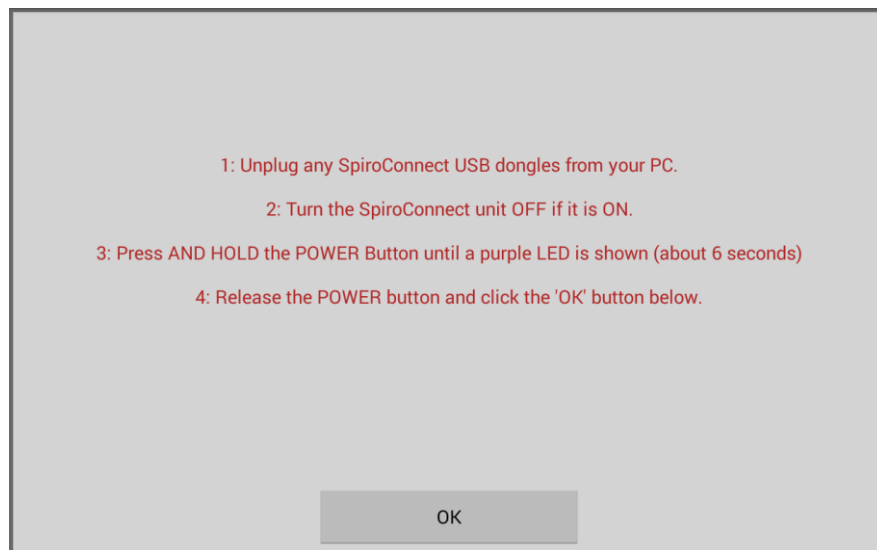
8.2 Pairing SpiroConnect to the mobile device

Before use the SpiroConnect must be paired to the mobile device.
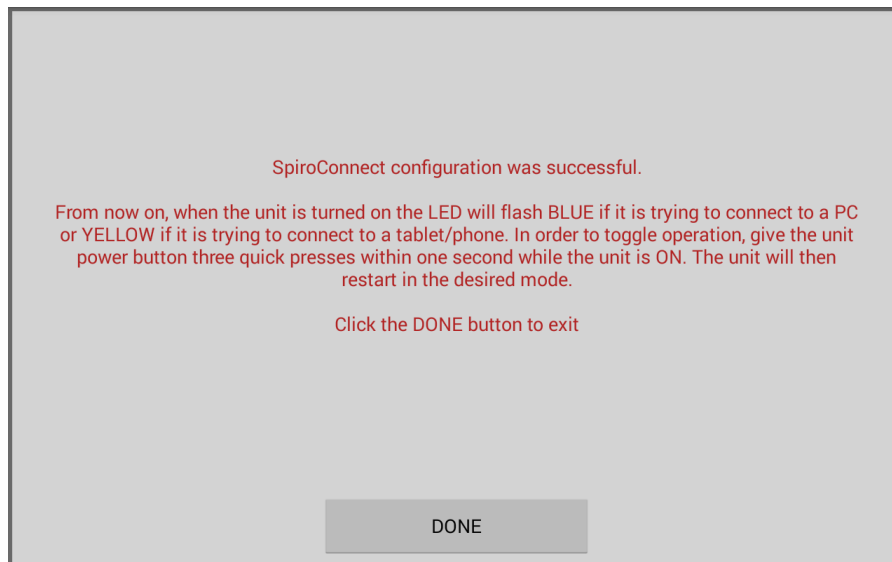Once this is done the SpiroConnect may be switched between mobile and PC use.

Touch the SETTINGS button and the display will show:

Forced Best Blow Criteria	FEV1 + FVC
Acceptance Criteria	ARTP
Open Operator's Manual	
Pair New Unit to This Tablet	

Touch 'Pair New Unit to This Tablet' and the following instructions will be displayed:

1: Unplug any SpiroConnect USB dongles from your PC.

2: Turn the SpiroConnect unit OFF if it is ON.

3: Press AND HOLD the POWER Button until a purple LED is shown (about 6 seconds)

4: Release the POWER button and click the 'OK' button below.

OK

Follow the onscreen instructions and touch OK. The mobile app will then search for the SpiroConnect and pair to the unit automatically.
Once paired, the instruction for switching the SpiroConnect between mobile use and PC use are displayed:

SpiroConnect configuration was successful.

From now on, when the unit is turned on the LED will flash BLUE if it is trying to connect to a PC or YELLOW if it is trying to connect to a tablet/phone. In order to toggle operation, give the unit power button three quick presses within one second while the unit is ON. The unit will then restart in the desired mode.

Click the DONE button to exit

DONE

Pairing devices facilitates quick communications between two Bluetooth devices to be established and once paired, the procedure does not need to be repeated unless a new mobile device or spirometer is used.

One paired, the SpiroConnect may be switched from PC mode to mobile mode. When in PC mode the indicator light is blue and for mobile mode it is yellow. The SpiroConnect is switched between the two modes by pressing the power button three times in quick succession when the unit is on.

Note:

When pairing a SpiroConnect to a tablet make sure that any other SpiroConnects are turned off and that all SpiroConnect Bluetooth dongles have been removed from any PCs in the vicinity. This will ensure that the tablet can quickly and easily connect to the required device.
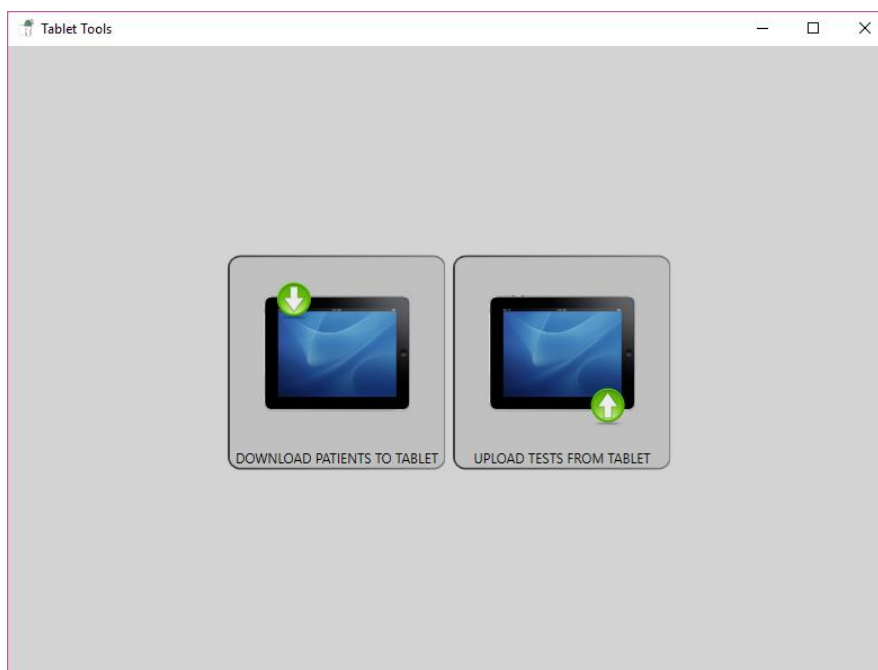
8.3 Connecting to PC

When connected to a PC patient details may be downloaded or spirometry results upload from the mobile device.
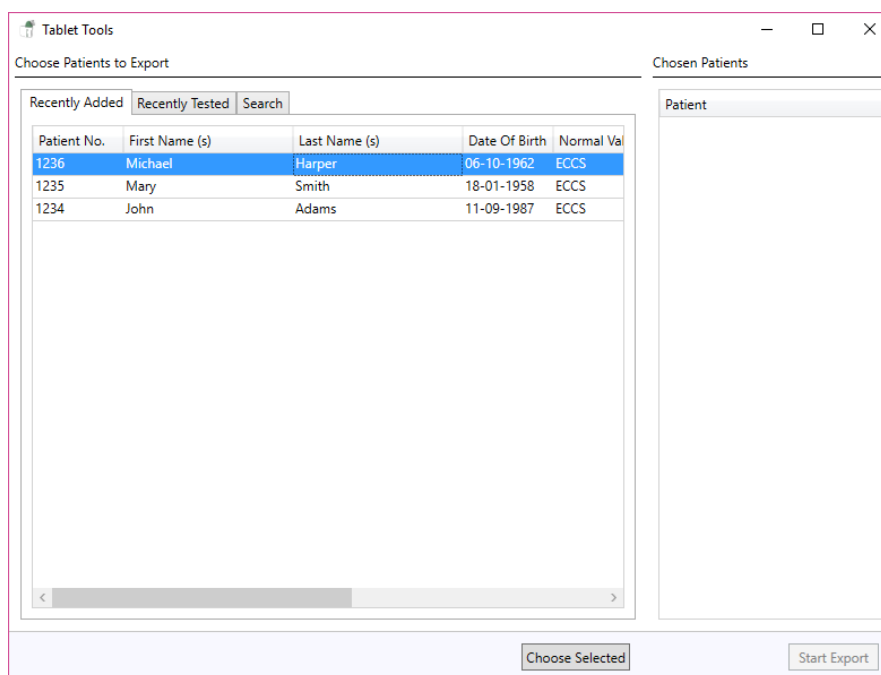
Run the SpiroConnect Data Manager software, ensuring that the dongle is connected to the PC, and then touch the PC MODE button. The mobile device display will show:
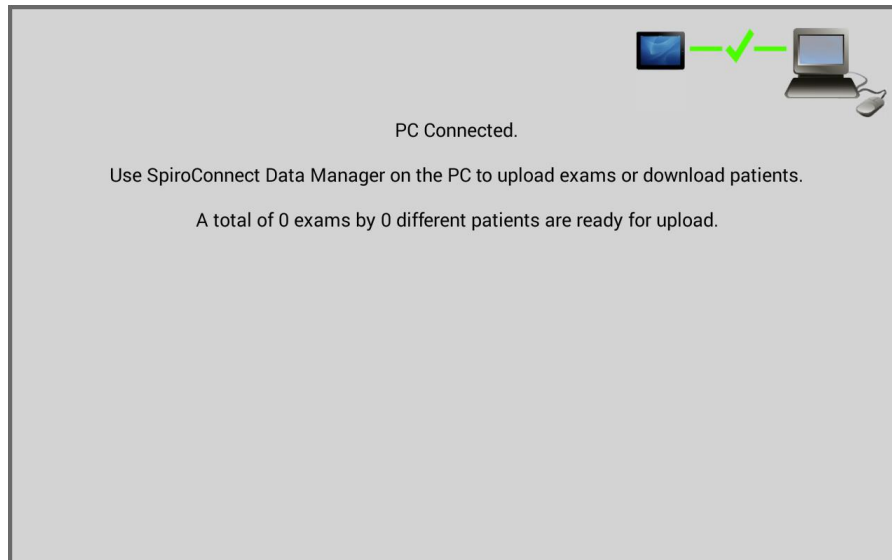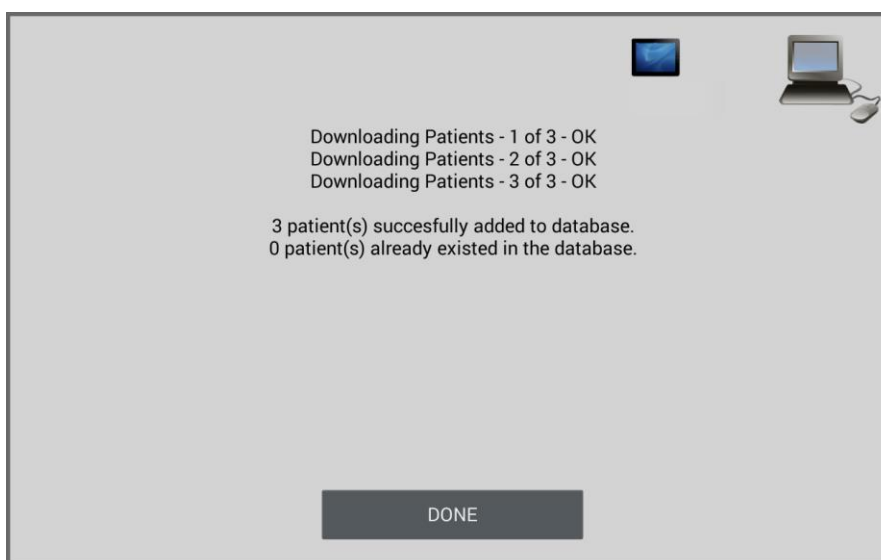

On the PC, the tablet tools will be displayed

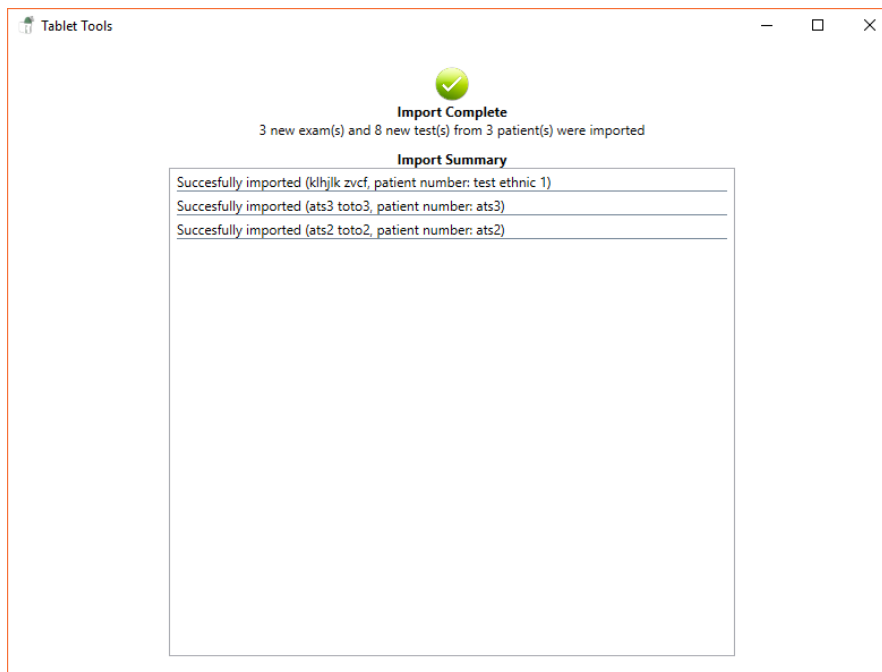Click DOWNLOAD PATIENTS TO TABLET and select the patients that you will be testing on the mobile device.

Once selected, click Start Export to download the patient details to the mobile device which will indicate the number of patients downloaded:

Note:
Patient details may also be entered directly into the mobile device, see Section 9 – Patient Selection. However, if a patient's details have been previously entered into the PC database then those details should be downloaded from the PC rather than entered directly on the mobile device. Spirometry results uploaded from a patient whose details have been entered on the mobile device may not be merged with the existing patient's results.

To upload results from the mobile device repeat the procedure above but click on the UPLOAD TESTS FROM TABLET button on the PC. When the upload is complete the following will be displayed on the PC.

8.4 Patient Selection

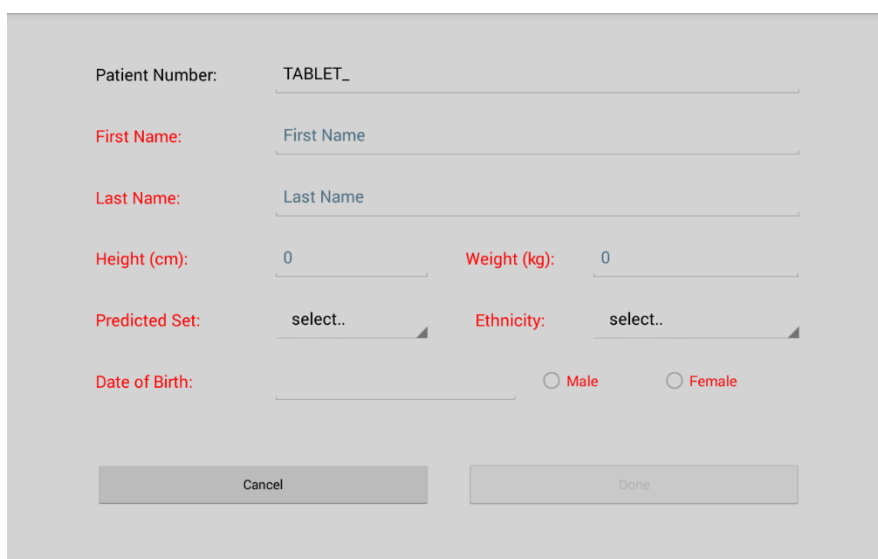Touch the PATIENTS button on the main menu and the following will be displayed:

Note:
For patients whose details have been entered on the mobile device TABLET prefixes the patient number. The others have been downloaded from SpiroConnect Data Manager.

From here you can add a new patient to the database, edit patient details, delete a patient from the database or select a patient for spirometry testing.

Create New is selected to enter a new patient's details:

Patient Number:	TABLET_
First Name:	First Name
Last Name:	Last Name
Height (cm):	0	Weight (kg):	0
Predicted Set:	select..	Ethnicity:	select..
Date of Birth:		○ Male	○ Female
Cancel	Done

Note:
If a patient's details have been previously entered into the PC database then those details should be downloaded from the PC rather than entered directly on the mobile device. Spirometry results uploaded from a patient whose details have been entered on the mobile device will not be merged with the existing patient's results.

Enter the new patient's details in all the fields and then select Done.

Edit Selected is used edit the highlighted patient's details.

Delete Selected is used to delete the highlighted patient's details and test results.

Choose Selected is used to select the highlighted patient for testing.

Note:
Only patients that have been created on the mobile device can be edited. These have the prefix TABLET on the patient number.

8.5 Spirometry Setup

Before performing a spirometry test for the first time set up the best blow and acceptance criteria by selecting the SETTINGS option from the main menu:
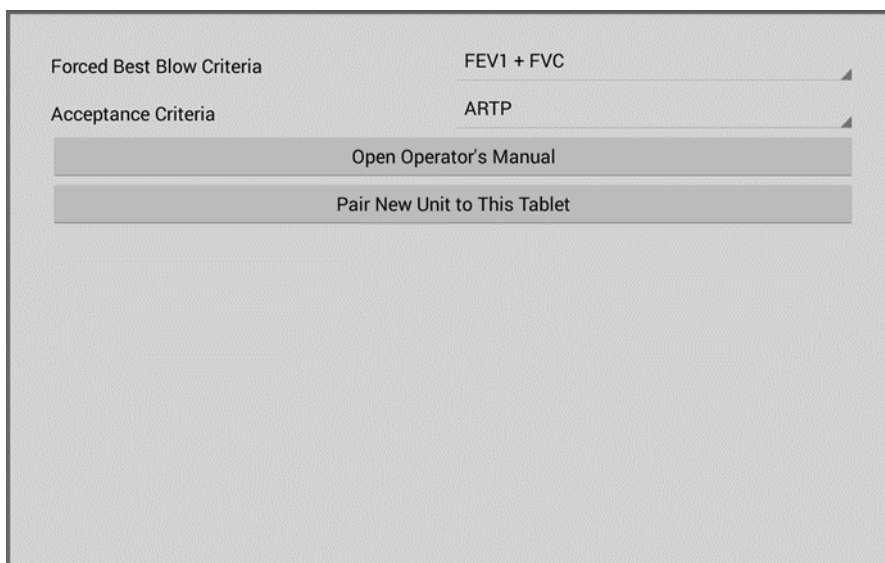
When performing a test the flow/volume loop and results of the best blow are displayed along with the flow/volume loop and results of the current blow. The criteria for choosing the best blow can be changed by touching the displayed Forced Best Blow Criteria.
The available options FEV1+FVC, FEV1, FVC and PEF will be displayed.

Note:
Only blows that have passed the quality checks will be used for the best blow selection

ATS/ERS, BTS or ARTP test acceptance criteria may be selected

8.6 Spirometry Testing

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

WARNING: Keep the patient away from the mobile device during use.

Before performing a test select a patient using the PATIENTS button on the main menu, see Section 9 – Patient Selection.

Once the patient is selected touch the SPIROMETRY button and the display will show:
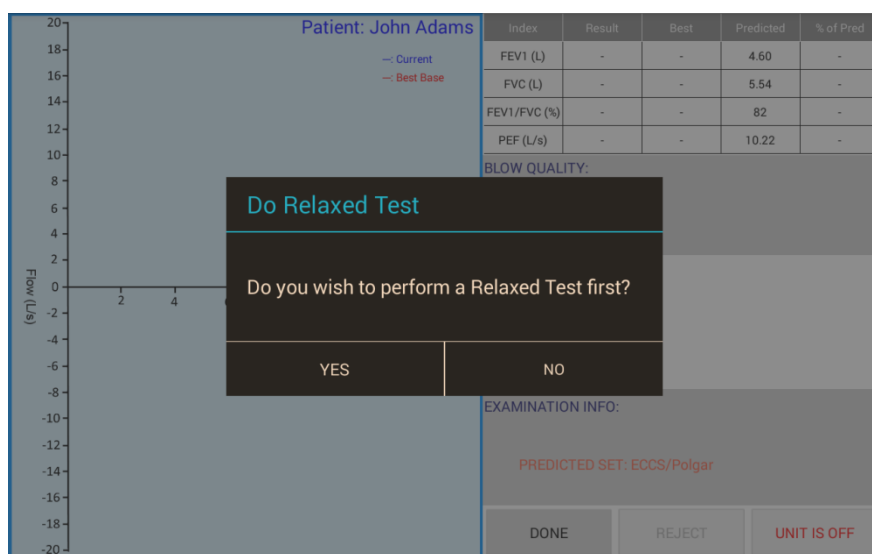
If a relaxed VC test is required touch Yes and the display will show:

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

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

Once connection has been made the UNIT IS OFF notification will change to START TEST. Touch this button to initiate a test.

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 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).
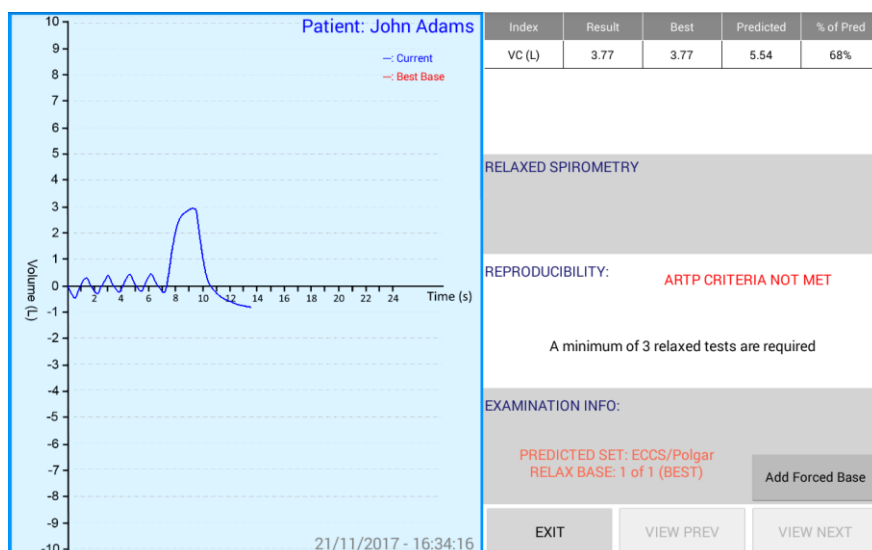
Once the test is completed, the following will be displayed:

After the relaxed VC tests have been completed touch Done and the display will change to:
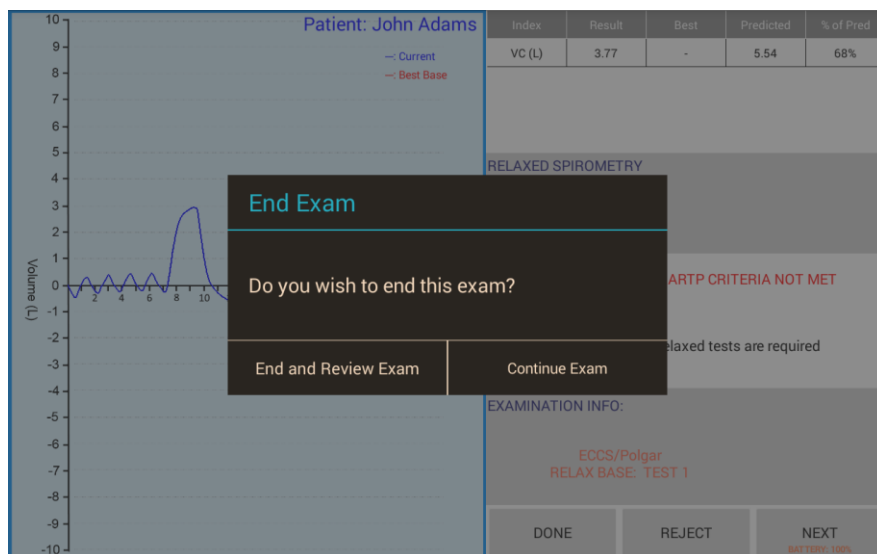
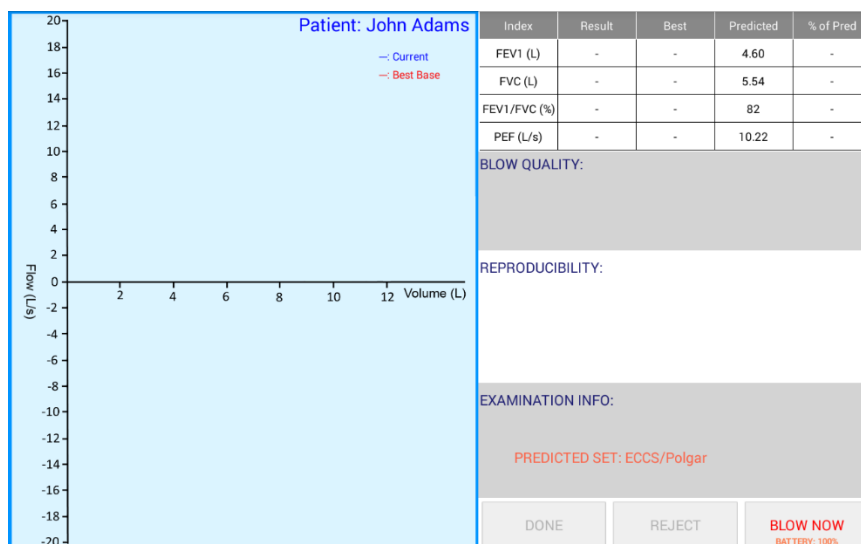Select end and Review Exam to continue onto a forced spirometry test:

Touch Add Forced Base to continue to a forced spirometry test

Note:
The option to perform a Post BD relaxed spirometry test is only available when a forced spirometry test has been added.

When a forced test is selected the display will show:

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 then inhale as deeply and as rapidly as possible, before removing the unit from their lips. They should aim to exhale for at least 6 seconds.

When no flow is detected for 2 seconds the unit will sound a beep and the test results will be shown:
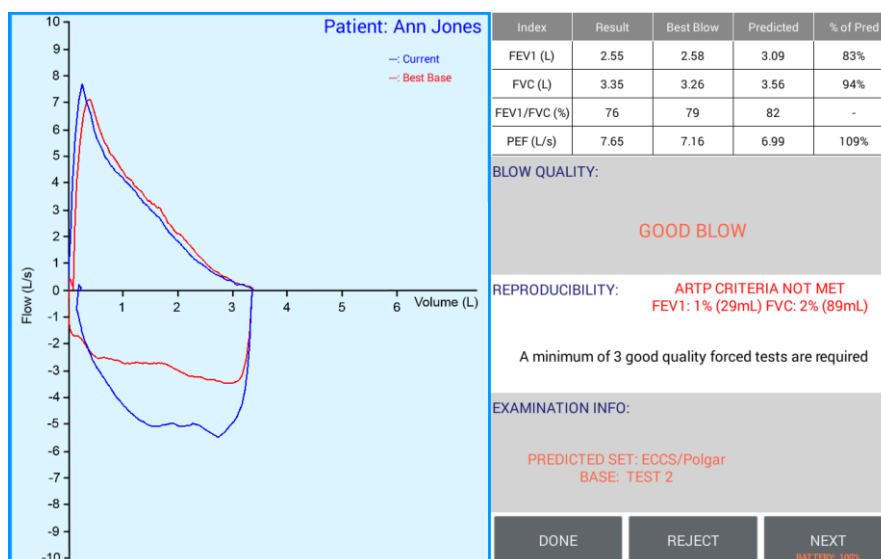
NEXT can be selected in order that the current blow is accepted into the exam stage and a new blow is initiated. REJECT can be selected to initiate a new blow without adding the last blow to the exam. DONE can be selected when all the desired blows have been added, and you wish to end the current exam stage and review results:

The left-hand side of the display will show the current and previous best flow/volume loops The right-hand side is divided into a result table together with blow quality, reproducibility, and examination information.

Note:
For mobile use the indicator light should flash yellow momentarily and then remain constant when Bluetooth communications have been established. If the light flashes blue, then the SpiroConnect is configured for PC use and must be switched to mobile use. To do this press the power button three times in quick succession when the unit is on

Results Table
The results for the current blow, best previous blow, predicted values, and percentage of predicted values are displayed.

Note:
The best results will be taken from individual blows

Blow Quality Information
The BLOW QUALITY message reports the quality of an individual blow (as opposed to overall exam quality – see the next section below), and could be one of the four 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.

Possible Cough: A possible cough has been detected.

Good Blow: The blow is of good quality

Reproducibility Information

The REPRODUCIBILITY messages report on the overall quality of the current stage (Baseline or PostBD) and will contain messages similar to those below depending upon the selected acceptance criteria:

ATS/ERS CRITERIA NOT MET: A minimum of 3 good quality tests are required
-        An exam stage needs at least 3 blows that have a Quality Check of 'Good Blow'

ATS/ERS CRITERIA NOT MET: The two largest FEV1 values must not differ by more than 150mL
-        The FEV1 result for the two largest blows vary too much

ATS/ERS CRITERIA NOT MET: The two largest FVC values must not differ by more than 150mL
-        The FVC result for the two largest blows vary too much

ATS/ERS CRITERIA MET:
-   This exam stage meets the acceptance quality and reproducibility criteria.

The variation between the FEV1 and FVC results of the two best blows will be displayed below one of the above messages after 3 good blows have been performed.
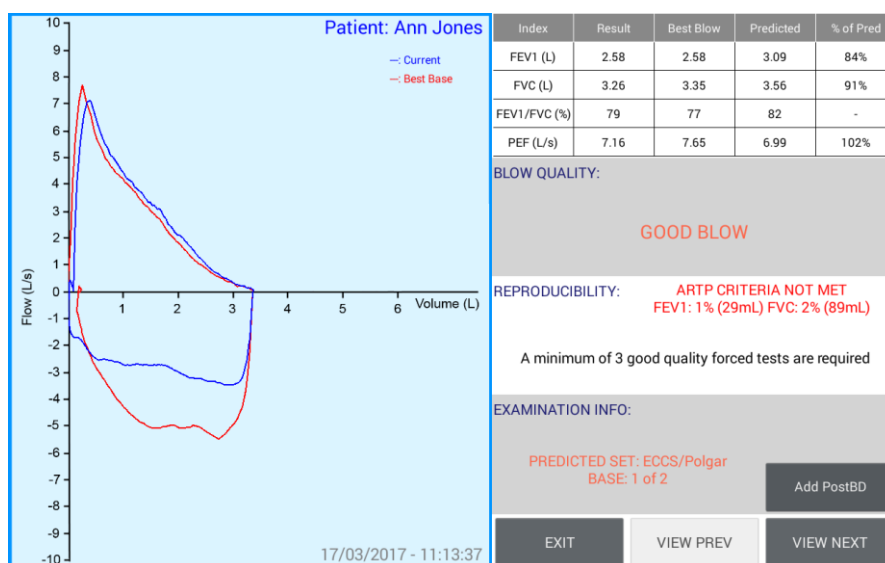
Examination Information

The predicted value set used and the current test number are displayed.

When the examination has been completed select DONE and the following will be displayed:
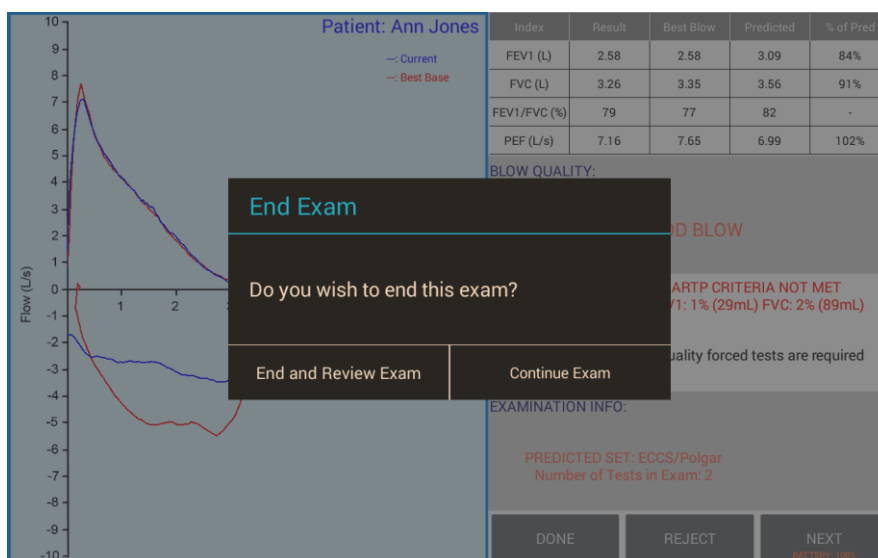
The examination may be continued, if required, or ended and the display will show:

The blows in the baseline test may be inspected by selecting VIEW NEXT or VIEW PREV. Post Bronchodilator testing may also be performed by selecting Add Post BD. The Post BD test is performed in an identical manner to the baseline test, however the results table displays the percentage change from the baseline result instead of the predicted value:
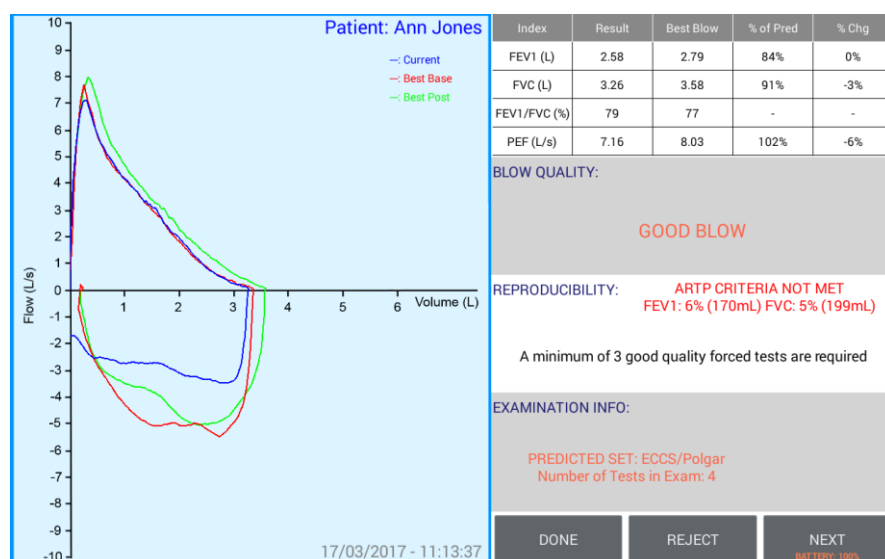
Note:
When a stored baseline test is reviewed, it is possible to append a post bronchodilator test, see Section 12 – Review Tests

Upon exit from a completed test session the display will show:
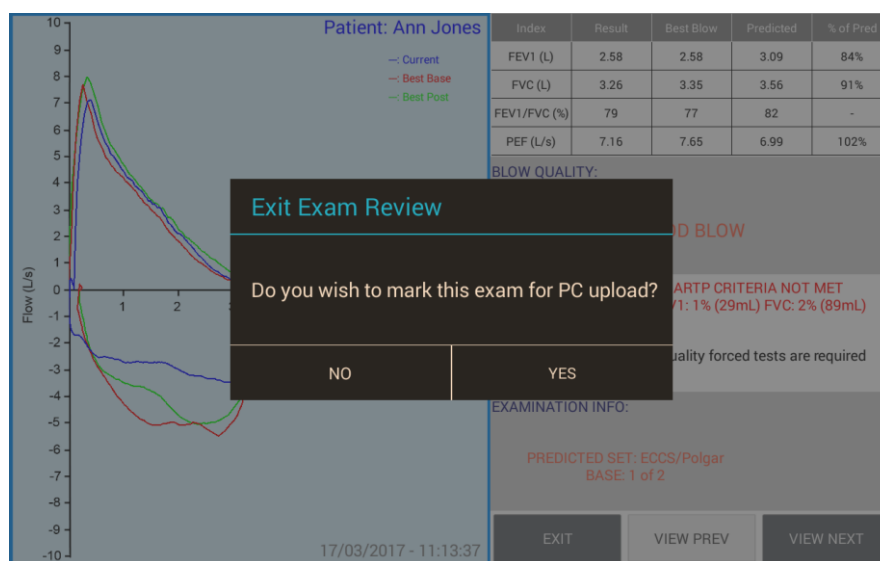
Tests marked for upload may be uploaded to SpiroConnect Data Manager PC software, see Section 8 – Connecting to PC.
Tests may also be marked for up load when they are reviewed.

Note:
For information on the spirometer's use and maintenance please refer to the operating manual accessible from the SpiroConnect Data Manager PC software and from www.medchipsolutions.com

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.

8.7 Review Tests

To review or delete a test, first select the required patient and then touch REVIEW EXAMS to display a list of all the tests performed by that patient:

Time of Exam / Number of Tests:
18/01/2017 - 19:23:20 (1 tests in exam)
18/01/2017 - 18:40:58 (6 tests in exam)
18/01/2017 - 18:39:32 (2 tests in exam)

Delete Selected	Choose Selected

Touch the required test to highlight and then either Chose Selected to review the test or Delete Selected to remove the test from the database.

When a test is selected for the review the test will be displayed:
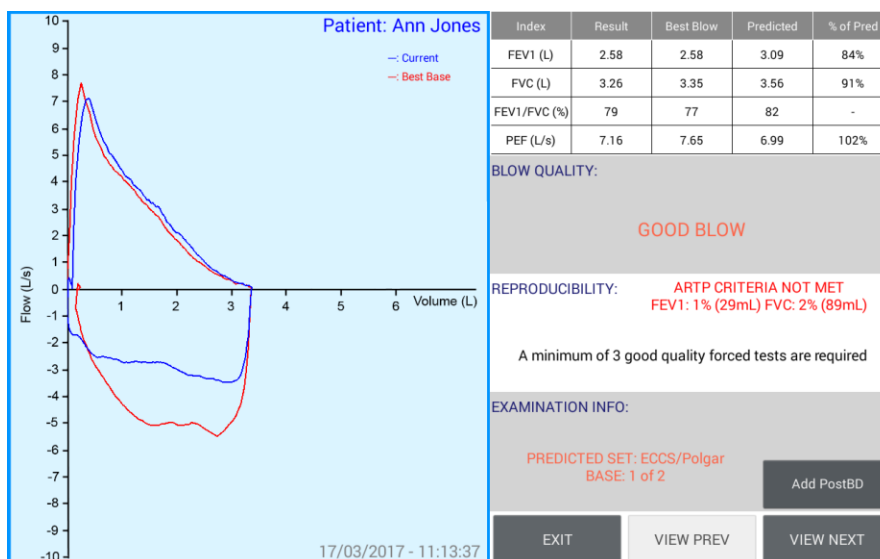
Note:
The Add Post button will only be displayed for saved tests that had only baseline tests performed.

8.8 Calibration

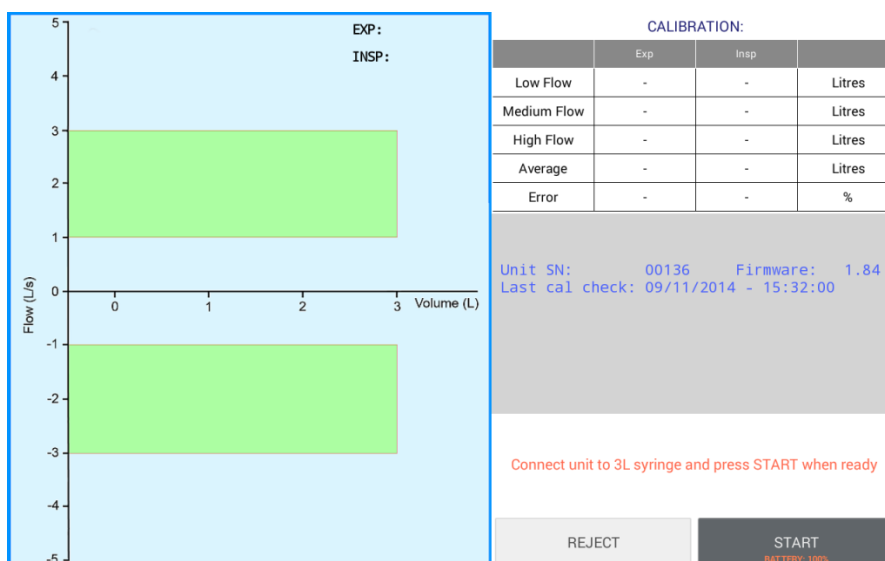Calibration performed by selecting the CALIBRATION option from the main menu:

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 selected, 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, touch 'Done' and the calibration check results dialog will be shown:
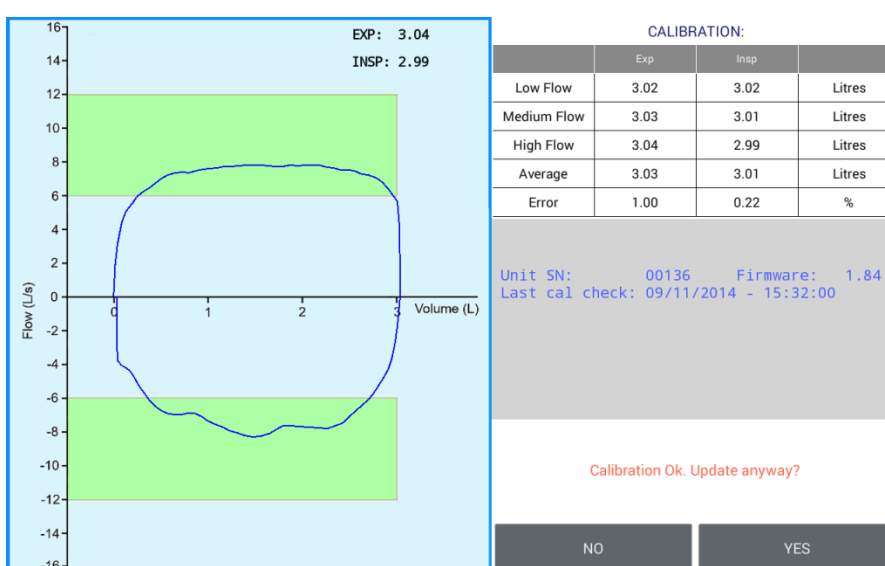
If NO is clicked, the calibration check results are saved. If YES is clicked, the calibration values stored inside the SpiroConnect are updated.

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 calibration data is stored in the SpiroConnect and not on the mobile device. If the SpiroConnect has been previously calibrated using SpiroConnect Data Manager then it is not necessary to repeat for use on the mobile device.

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 90º 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 you unit requires service or repair.
There are no user serviceable parts in the SpiroConnect.

14 Warranty and Liability

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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.

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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		If blue led is flashing or solid then SpiroConnect is configured for PC use	Switch to mobile use. To do this turn the unit off but with the on/off button held down for about 6 seconds until the red light changes to white.
4	SpiroConnect will not connect to Phone/Tablet	If yellow led is flashing or solid and you have just one SpiroConnect then it may be connected to a different Phone/Tablet.	Confirm this is the case. If so redo the pairing sequence with the Phone/Tablet you wish to use.
5		If yellow led is flashing and you have more than one SpiroConnect it may not be the one you paired to the Phone/Tablet.	Use the paired SpiroConnect or if not available you can pair this SpiroConnect to the Phone/Tablet you are using.
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	SDM Upload/Download screen does not appear on PC	It is hidden behind other windows.	Click on the SDM window. The Upload/Download screen should now appear.
8	Unusual Readings	Damaged Turbine	Visually inspect for damage. Check calibration with a 3L syringe. Refer to your distributor.

For trouble shooting with SpiroConnect Data Manager please see the SpiroConnect Operators manual.

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 and Standards EN 301 489-1 v1.8.1 and EN60601-1-2 electromagnetic compatibility but can be affected by cellular phones and by electromagnetic interference exceeding levels specified in EN 50082-1:1992

18 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

Symbol	Description
	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	Vext
FEV0.75	FEV0.75/FVC
FEV1	FEV1/FVC (FER)
FEV3	FEV3/FVC
FEV6	FEV0.75/FEV6
FVC	FEV1/FEV6
PEF	FEF50/FVC
FEF25 (MEF75)	MMEF/FVC (FEF25-75/FVC)
FEF50 (MEF50)	FIV1/FIVC (FIR)
FEF75 (MEF25)	R50 (FEF50/FIF50)
FEF25-75 (MMEF)	FIF75 (MIF25)
FIV1	MET25-75
FIVC	FET
PIF	MVV indirect (FEV1 X 35)
FIF25 (MIF75)	LUNG AGE**
FIF50 (MIF50)	

** Please Note: Estimated Lung Age is limited to maximum age that a Predicted 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:
Android tablets and phones with an Android 4.2 or greater and that have integral Bluetooth connectivity and a screen resolution of at least 480x800.

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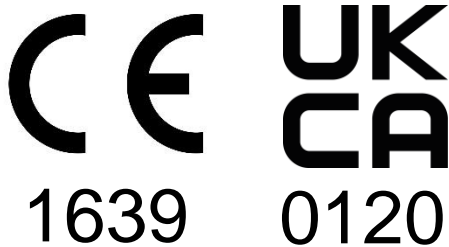Frequency Bands: 2.402 – 2.480 GHz
Maximum Power: 2 mW

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

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