

SpiroConnect Spirometer

**Operating Instructions** 

Issue 1.4

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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: <u>www.medchipsolutions.com</u>.

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 0.0251/s.

## 2 Package Contents

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



## **3** Warnings and Cautions

Caution: Possibility of injury or serious damage

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

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

CAUTION: Read the manual before use

WARNING: The instrument is not suitable for use in the presence of explosive or flammable gases, flammable anaesthetic mixtures or in oxygen rich environments.

WARNING: The use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation

WARNING: Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents

WARNING: Portable and mobile RF communications equipment can affect medical electrical equipment

WARNING: Equipment should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation.

WARNING: The USB socket on the device is for factory use only. Do not make any connection to this socket.

PLEASE NOTE: The product you have purchased should not be disposed of as unsorted waste. Please utilise your local WEEE collection facilities for the disposal of this product.

WARNING: No modification of this equipment is allowed

### 4 Contraindications

WARNING: Do not use in the presence of a known or suspected respiratory infection

WARNING: Do not use when haemoptysis (coughing up blood) of unknown origin is present

WARNING: Do not use in the presence of pneumothorax (collapsed lung)

WARNING: Do not use in the presence of unstable cardiovascular status: recent (within one month) myocardial infarction (heart attack), uncontrolled hypertension or pulmonary embolism

WARNING: Do not use in the presence of uncontrolled hypertension or history of haemorrhagic cerebrovascular event (stroke)

WARNING: Do not use in the presence of recent thoracic abdominal or eye surgery

WARNING: Do not use in the presence of nausea, vomiting or pain

WARNING: Do not use in the presence of confusion or dementia

WARNING: Do not use in the presence of thoracic or abdominal aneurysms

WARNING: Do not use on patients with a history of syncope (fainting) associated with forced exhalation

# 5 Intended Use

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

### 6 Environment

The SpiroConnect is designed for routine clinical use in an office environment. Use in temperatures outside the range 10 to 40  $^{\circ}$ 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:

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

Run SpiroConnectDataManagerSetup\_v1.00.exe. There is no need to run any of the other executable files on the drive, these will be automatically run during installation.

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

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

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

# 8 Operation

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

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

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

SpiroConnect Data Manager

The Home Screen will then be displayed:

### 8.1 Patient Selection:

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

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

### 8.2 Unit Connection:

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

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

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

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

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

### 8.3 Forced Spirometry:

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



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



All parameters that have been selected for display in Settings are shown, along with the normal value (if available), percentage change from Best Base blow (if the blow is a Post blow), blow quality assessment, overall examination quality assessment and interpretation. If a Relaxed Spirometry test of the same stage already exists within the exam, the VC result for the MedChip Solutions Ltd. Page 9 of 25 001.105 Issue 1.4

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

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



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

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

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

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

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

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

- An exam stage needs at least 3 blows that have a Quality Check of 'Good Blow' Not Met : The two largest FEV1 values must not differ by more than 150mL

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

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

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

Criteria Met:

- This exam stage meets the acceptance quality criteria.

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

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



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

### 8.4 Relaxed Vital Capacity:

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

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

The relaxed test may be performed with a single expiration, a single inspiration, or expiration and inspiration after tidal breathing. The latter is used to provide a number additional indices including Expiratory or Inspiratory Reserve Volume and tidal breathing indices if required. For Expiratory Vital capacity instruct the patient to fully inhale and then seal their lips around the mouthpiece and exhale at a comfortable rate until they have completely emptied their lungs. The expiratory volume/time curve will be displayed:



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



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



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

SpiroConnect Data Manager v0.6	5 - C:\Users'	Public\Docu	iments\Spi	roConne	:t\Databa	ase\Spiro(	ionnect E	atabase -	current.sci	ta j
Tools Help				Selecte	d Patient	: Arthur Sa	dler			
pirometry Examination										
			Review -	Test the	en click	Next, R	eject or	Done		
ests	Ŧ	Test Summa	ary							
elaxed Spirometry Test (Best) 015-02-25 14:27	Base	Results	Graphs							
		Index	Unit	Value	%Chg	mL Chg	Norm	%Norm	LLN	Curr
		EVC	L	-	-	-	5.11			Volume (L)
		IVC	L	4.85			5.11	95	4.19	1\04.85
		ERV	L	2.75	-	-	-	-	•	D -
		IRV	L	1.67						5 -
		IC	L	2.10	-	-	-	-	-	4.
		FR	/min	37.5	-	-	-	-	-	3.
		П	s	0.72		•		•	•	
		TE	s	0.89	-	-	-	-	-	ſ
		10100								-1 -2
										-3
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mination Summary										
expertation (ats/ess 2005): se: Not enough information availab	ole to produc	e an interpre	tation		Bas	e: Criteria	RIA (ATS/BRS) Not Met:	A minimum	of 3 good	I quality forced tests are required
bient Temp 27°C										Next Reject Don
Connected BAT 40%								1	formal Value	es: ECCS (1993) 20-85 years, Polgar (1971) 5

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.

🔮 SpiroConnect Data Manager v0.65 - C:\Users\Public\Documents\SpiroConnect\D	atabase\SpiroConnect Database - current.scd	💣 SpiroConnect Data Manag	ger v0.65 - I	C:\Users\Pub	lic\Docume	ents\Spire	oConnec	\Databas	e∖SpiroCo	nnect Data	base - current.scd	
File Tools Help Selected Patient: Arthur Si	adler	File Tools Help			Selec	ted Patie	nt: Arthu	r Sadler				
Select an Examination	Â	Spirometry Examinati	on									ñ
Examination Date	v	Tests	~	Test Summa	ary							
Spirometry Examination 2 Relaxed Base Test(s), 1 Relaxed Post Test(s), 6 Forced Base Test(s), 7 Forced Post Test(s)	2015-02-25 16:05 💻	Forced Spirometry Test 2015-02-25 16:06	Base 🔺	QUALITY CHECK Abrupt End								
Spirometry Examination 1 Relaxed Base Test(s)	2015-02-25 14:27	Forced Spirometry Test 2015-02-25 16:08	Base	Results	Graphs	14-bas	auch-	and the	Marrie	AL 1. 1. 1.		
Spirometry Examination	2015-02-25 11:34	Forced Spirometry Test	Base	FEV0.75	L	2.76	%Cng	- mL Chg	-	76NON	Flow (L/s)	
1 Forced Base Test(s)		2015-02-25 16:08		FEV1	L	3.14	-		4.05	78	12	FEV1 3.14
Spirometry Examination	2015-02-24 11:56	Forced Spirometry Test	Base	FEV3	L	4.18		-	-	· .	10-	PEF 6.90
1 Kelaxed base Test(s), 1 Kelaxed Post Test(s), 5 Forced base Test(s)		2015-02-25 16:09		FEV6	L	4.24			-	•	1	
Spirometry Examination 1 Palavad Base Test(e) 1 Formad Base Test(e) 5 Formad Post Test(e)	2015-02-24 11:03	Forced Spirometry Test	Base	FVC	L	4.24	-		4.89	87	in	
		2013-02-23 10:09	_	PEF	L/s	6.90	-	-	9.43	73		
Spirometry Examination 1 Forced Base Test(s)	2015-02-23 21:35	Forced Spirometry Test (Best) 2015-02-25 16:09	Base	FEF25	L/s	5.41	-	-	8.12	67		
Colomato Develoption	2015 02 22 15 11			FEF50	L/s	2.72	-	-	5.21	52	1	
1 Forced Base Test(s)	2015-02-25 15:11	2015-02-25 16:05	Dase -	FEF/5	L/s	1.28	-	-	2.32	55		
Spirometry Examination	2015-02-23 14:27	Relayed Solromator Test (Rest	) Pace	PEP2575	L/s	2.61	-	-	4.54	57	-2 -	
1 Forced Base Test(s)		2015-02-25 16:06	,	FIVE		3.99					4	
Spirometry Examination	2015-02-23 14:24	Forced Spirometry Test (Best)	Post 1	PIE	1/5	5.56						
1 Forced Base Test(s)		2015-02-25 16:10		FIF25	L/s	4.93					-7 -	
Spirometry Examination	2015-02-23 14:22	Forced Spirometry Test	Post 1	FIF50	L/s	5.53						
1 Forced Base Test(s)		2015-02-25 16:10		FIF75	L/s	4.93	-		-		10-	Volume (L)
Spirometry Examination	2015-02-23 11:08	Connel Colormates, Tast	Deat 1	MET2575	s	0.86		-	-	· •	-12 J Flow/Vol	me
		Examination Notes		•						•		
Spirometry Examination	2015-02-23 10:56	Examination Summary										
		INTERPRETATION (ATS/ERS 2005):			ACCEPTAN	CE CRITERIA (	(ATS/ERS):					
Spirometry Examination 2 Forced Base Test(s)	2015-02-21 12:05	Base: Normal Spirometry			Base: C	Criteria Me	et					
Palana das Resolucións	2015 02 20 15 10	Post 1: Normal Spirometry			Post 1:	Criteria N	Met Motor	the two lar	and D/C	oluce must	pat differ by more th	an 150 ml
1 Forced Base Test(s)	2015-02-20 15:18	Post 2. normal spirometry			r USL 2.	Critical la la	NUC PIEL	The two lar	gest FEV1	values mus	t not differ by more 1	han 150 mL
34 Items	Choose Selected									Print	Export To PDF	Save and Exit
Disconnected	Normal Values: ECCS (1993) 20-85 years, Polgar (1971) 5-19 years	Disconnected						No	rmal Value	s: ECCS (199	3) 20-85 years, Polgar	(1971) 5-19 years

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



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

le Tools Help		Selected Patient: Arthur Sadler	
pirometry Examination	n		1
lests .	Ŧ	Examination Notes	
Forced Spirometry Test (Best) 2015-02-25 16:09	Base 🔺	Notes relating to the exam can be typed in here. They will be saved along with the exam results within the database.	
elaxed Spirometry Test 015-02-25 16:05	Base		
elaxed Spirometry Test (Best) 015-02-25 16:06	Base		
orced Spirometry Test (Best) 015-02-25 16:10	Post 1		
prced Spirometry Test 015-02-25 16:10	Post 1		
prced Spirometry Test 015-02-25 16:10	Post 1		
prced Spirometry Test 015-02-25 16:11	Post 1		
elaxed Spirometry Test (Best) 015-02-25 16:10	Post 1		
prced Spirometry Test 015-02-25 16:11	Post 2		
orced Spirometry Test (Best) 015-02-25 16:11	Post 2		
need Colonantes Tast	Dant D		
kamination Notes			
amination Summary		,	
FERPRETATION (ATS/ERS 2005):		ACCEPTANCE CRITERIA (ATS/ERS):	
se: Normal Spirometry		Base: Criteria Met	
ost 1: Normal Spirometry		Post 1: Criteria Met Dest 2: Oritoria Net Met: The hue largest D/C unlines must not differ by more than 150	-
st 2: Normal spirometry		The two largest FVC values must not differ by more than 150 The two largest FEV1 values must not differ by more than 150	0 mL
		Print Event To DDE Save a	nd Evi
		Pline Export to PDI Save a	ING EXI
Disconnected		Normal Values: ECCS (1993) 20-85 years, Polgar (1971)	5-19 v

### 8.6 General information pertaining to the reviewing of examinations:

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

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

#### Regarding Best Blow Criteria:

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

#### 8.7 Calibration:

Calibration mode can be entered by clicking the *icon*.

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



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

Spirometer details — Spirometer model: Serial number: Firmware revision:	SpiroC 00000 1.57	onnect D000055		Last Last	calibrated: calibration check:	08/10/20131 13/11/20132	12:02:07 21:10:15	
Calibration factor —					Measured volume	·s		
	Exp	Insp				Exp	Insp	
Last calibration	156.0	153.6	PPL		Low flow	2.99	2.95	litres
This calibration			PPL		Medium flow	2.97	2.96	litres
	1				High flow	3.00	2.97	litres
					Average	2.99	2.96	litres
					Error	0.44	1.33	%
		C	alibration	OK. L	pdate anyway?			

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

SpiroConnect Instructions for Use

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

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

#### 8.8 Settings:

The settings pane is accessed by clicking the pane:

Display – regional specific formats

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

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

#### 8.9 Menu Bar options:

- Tools 'Spirometer Details' displays data from the connected handheld unit, temperature reading, serial number, firmware version. 'Settings' as Settings above.
- Help 'About' displays the version number of the PC software 'Check for Updates' if the PC is connected to the Internet will check for a later version of software.

### 8.10 Patient Database:

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

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

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

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

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

## 9 Battery Management

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

Note:

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

# 10 Looking after your SpiroConnect

Please observe the following precautions:

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

# 11 Cleaning

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

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

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



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

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

# **12 Accessories**

The following accessories are recommended for use with your spirometer.

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

Please contact your distributor for pricing and purchasing options for the accessories above, or email <u>sales@medchipsolutions.com</u> 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 <u>service@medchipsolutions.com</u> if you unit requires service or repair to obtain a Returned Goods Authorisation (RGA) number. No product should be returned to MedChip except in accordance with the MedChip Warranty and Return Goods Policy (for full details please visit www.medchipsolutions.com)

There are no user serviceable parts in the SpiroConnect.

### **14 Warranty and Liability**

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

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

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

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

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

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

# **15 Software License Agreement**

Read carefully before use

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

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

### **16 Trouble Shooting Information**

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

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

# **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	Group 1	The SpiroConnect must emit electromagnetic energy in order to perform its			
CISPR 11		intended function. Nearby electronic equipment may be affected.			
RF emissions	Class B	The SpiroConnect is suitable for use in all establishments, including domestic			
CISPR 11		establishments and those directly connected to the public low-voltage power			
Harmonic emissions	Not	supply networks that supplies buildings used for domestic purposes.			
IEC 61000-3-3	applicable				
Voltage fluctuations/flicker	Not				
emissions	applicable				

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

	Guida	ance and manuf	acturer's	declaration - electromagnetic	: immunity		
The SpiroConnect is intended for use in the electromagnetic environment specified below. The customer or user of the							
SpiroConnect shou	uld assure that	it is used in such	an envir	ronment.			
Immunity test	IEC 60601	Compliance	Electro	magnetic environment - guidar	nce		
,	test level	level		5 5			
-			Portab	le and mobile RF communicatio	ns equipment should be used no		
			closer t	to any part of the SpiroConnec	t, including cables, than the		
			recomr	mended separation distance cc	lculated from the equation		
			applica	able to the frequency of the trai	nsmitter.		
				, ,			
			Recom	mended separation distance			
Conducted RF	3 V rms	3 V rms	d=1.2	2ffl <i>P</i>			
IEC 61000-4-6			d-10				
			<i>u</i> = 1.2				
Radiated RF	3 V/m	3 V/m	<i>d</i> = 2.3	3ffl P 800 MHz to 2,5 GHz			
IEC 01000-4-3			where	<i>P</i> is the maximum output power	r rating of the transmitter in watts (W)		
			accord	ing to the transmitter manufact	ure and d is the recommended		
			separa	ition distance in metres (m). Fiel	d strengths from fixed RF		
			transmi	itters, as determined by an elec	ctromagnetic site survey," should be		
			less the	an the compliance level in each	frequency range		
			Interter	ence may occur in the vicinity o	of equipment marked with the		
			TOHOWI	ng symbol:			
			((t <u>-</u> ))	)			
NOTE 1 At 80 MH	z and 800 MH	z, the higher tre	equency	range applies.	<b>"</b>		
NOTE 2 These gui	delines may no	of apply in all sif	uations.	Electromagnetic propagation is	s attected by absorption and		
reflection from stru	ctures, objects						
Field strengths fro	om fixed fransn	niffers, such as k	ase stati	ions for radio (cellular/cordless	b) felephones and land mobile		
radios, amateur ra	alo, Alvi and F		cast ana	Iv brodacast cannot be preak	cted theoretically with accuracy. To		
the measured field	strongth in the	location in whi	ch tha Sr	ansimillers, an electromagnetic	applicable PE compliance level		
above the Spire	onnoct should	he observed to	vorify no	smal operation. If apportal pe	orformance is observed additional		
measures may be		h as re-orienting	a or reloc	cating the SpiroConnect			
<sup>b</sup> Over the frequen	cv range 150 k	Hz to 80 MHz	field stre	enaths should be less than 3 V/	m		
	ey range leer						
Recommended s	separation dist	ances between	portable	and mobile RF communication	s equipment and the SpiroConnect		
The SpiroConnect	is intended for	use in an electr	omagnet	tic environment in which radiate	ed RF disturbances are controlled.		
The customer or th	e user of the Sp	piroConnect car	n help pre	event electromagnetic interfere	nce by maintaining a minimum		
distance between	, portable and r	nobile RF comm	unicatior	ns equipment (transmitters) and	SpiroConnect as recommended		
below, according	to the maximur	n output power	of the co	ommunications equipment.			
Rated maximum o	utput	S	eparatio	n distance according to freque	ncy of transmitter		
power of transm	itter			m			
	15	0 kHz to 80 MI	Ηz	80 MHz to 800 MHz	800 MHz to 2,5 GHz		
W		<i>d</i> =1.2ffl <i>P</i>		d=1.2∰P	d=2.3₩P		
0.01		0,12		0,12	0,23		
0.1		0,38		0,38	0,73		
I I,2		1,2		1,2	2,3		
IU 3,8			3,8	/,3			
IUU For transmittors re	ated at a mavir		ver not li	IZ	d separation distance d in motres		
(m) can be estima	ited using the	equation applic	able to th	he frequency of the transmitte	r where $P$ is the maximum output		
power rating of the	e transmitter ir	watts (W) acc	ording to	the transmitter manufacturer.			
NOTE 1 At 80 MH	Iz and 800 MH	z, the separation	on distar	nce for the higher frequency ra	inge applies.		
NOTE 2 These gu	idelines may i	not apply in all	situations	s. Electromagnetic propagatio	n is affected by absorption and		
renection from str		s 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 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
<b>CE</b> 0120	In accordance with Directive 93/42/EEC
X	Disposal in compliance with WEEE
i	Consult the instructions for use
$\triangle$	Caution: consult the accompanying documents
$\sim 1$	Date of manufacture
	Manufacturer
SN	Serial number

SpiroConnect Instructions for Use

### **19** Classification

Protection against electric shock: Internally powered equipment.

Mode of operation: Continuous

# **20 Specifications**

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

\*\* 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:

FEV3/FVC

FEF50/VC FEF50/FVC

Ti/Ttot

FEV0.75/FEV6 FEV1/FEV6

FIV1/FIVC (FIR)

VT/Ti (TV/Ti)

LUNG AGE\*\*

R50 (FEF50/FIF50)

MMEF/FVC (FEF25-75/FVC)

To ISO26782 recommendations: Volume to within +-3% of reading, or 0.05 litres, whichever is greater Volume measurements are given referenced to BTPS conditions Limits of Operation: Volume: 8 litres maximum Flow: 14 litres per second maximum

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#### SpiroConnect Instructions for Use

Sensitivity: Better than 0.025l/s Dynamic Impedance: 137 pA(l/s), measured at 14lps Power Supply: 2 x AA size Alkaline primary cells. Operating current: 110 mA peak Battery life: Alkaline cells, greater than 100 measurement cycles Dimensions: 55mm (W) x 100mm (D) x 110mm (H) Weight, including batteries: 200 g **Operating Conditions:** 10°C to 40°C, 15% to 95% RH, non condensing, Altitude up to 3000m Transport and Storage Conditions:  $-20^{\circ}C$  to  $70^{\circ}C$ ,  $15\overline{$ % to 95% RH, non condensing Lifetime: 5 years

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

WARNING: No modification of this equipment is allowed.

Issued: 14<sup>th</sup> May 2015

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**CE** 0120

This unit has been supplied by: