MIR
MEDICAL INTERNATIONAL RESEARCH

spirolab

UK Version | User Manual

spirolab standard package

Available with disposable turbines or re-usable turbine

Complete with:

- Spirolab main unit
- MiniFlowmeter sensor
- Re-usable turbine or disposable turbines
- Power supply unit
- Mouthpiece
- Single use nose clip
- Durable carrying case

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WARNING: READ BEFORE USE

All the maintenance operations described in the user manual must be carried out with great care. Failure to follow these instructions may lead to incorrect readings or the incorrect interpretation of readings that have been taken.

Do not modify the device without authorisation from the manufacturer.
All modifications, adjustments, repairs and reconfigurations must be performed by the manufacturer or by personnel authorised by the manufacturer. In the event of problems, do not attempt to make repairs. The setting of configurable parameters must be performed by qualified staff. The incorrect setting of parameters, however, will not compromise a patient's state of health. On request, the manufacturer can provide electrical diagrams, parts lists, descriptions and calibration instructions to assist the technicians with repairs.

The high frequencies emitted by an "electronic" device can interfere with the functioning of the device. For this reason, a minimum distance (of several metres), must be observed if there are other devices in operation in the same area. Examples of such devices include TVs, radios, domestic appliances, mobile phones, cordless phones etc. The device may provide inaccurate readings in the presence of strong electromagnetic sources such as electrosurgical scalpels or medical devices such as CT equipment. Do not use the device in the presence of MRI equipment that can generate an induced current in the oximetry sensor and harm the patient.

The use of accessories and cables other than those specified by the manufacturer may result in increased emissions or decreased device immunity.

The Spirolab device should not be used close to or stacked with other equipment; if it must be used close to or stacked with other equipment, Spirolab should be observed to verify normal operation in the configuration in which it will be used.
If the device is used in conjunction with other items of equipment, only equipment that complies with current safety regulations can be used so as meet the safety standards laid down by IEC EN 6060160601-1; consequently, the PC or printer to which Spirolab is connected should comply with IEC EN 60601-1.

As regards the disposal of Spirolab devices, accessories, plastic consumables (mouthpieces), removable components and items that are subject to ageing (e.g. the battery pack), only use suitable containers or, better, send the materials to the device retailer or an approved disposal centre. Local legal requirements in force must be complied with in all cases.
Failure to comply with the above mentioned regulations will relieve MIR of all responsibility from any direct or indirect claim for damages.

Use only the battery pack specified in § Technical Specifications.

The device can also be powered using a USB cable connected to a computer, thus also allowing online operation.

Keep the device out of the reach of children and differently-able persons.


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8
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intermedical
CARDIO RESPIRATORY
spirolab
MIR Spirolab
Patients

Product Description

Spirolab is a portable spirometer that can also feature a pulse oximeter feature (optional). The device can operate completely autonomously or can be connected to a personal computer or printer by means of USB or Bluetooth connections.
The device is intended for measuring respiratory parameters and monitoring oxygen saturation and pulse rate.

The device carries out a control test on the quality of the readings taken and can save the results of approximately 2,000 spirometric tests or a maximum of 900 hours of oximetry data.

Spirolab is intended for use by medical specialists and it provides them with a powerful but compact tool that can process approximately 30 functional parameters. The device also provides a pharmacodynamic response, i.e. the % comparison of spirometric data measured before and after (PRE/POST) administration of a drug for bronchial provocation or bronchodilation. The POST data measured after administering the drug is compared with the PRE data obtained before administration.

A turbine inside the device that uses the interruption of infra-red light as its operating principle, measures volume and flow rate of expired air directly at B.T.P.S. (Body Temperature and Pressure with Saturated water vapour).

Product Description

This operating principle ensures accurate, reproducible results without needing periodic recalibration although, routine verification as per local guidelines is recommended.

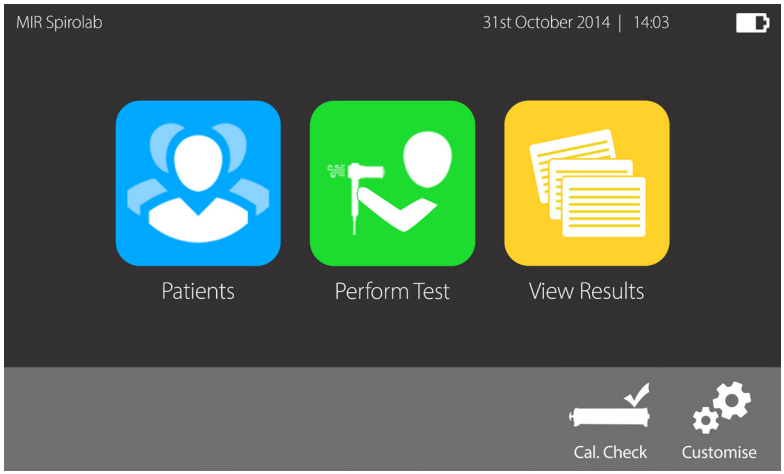
The key features of this type of sensor are as follows:

- Accurate readings even with low air flow rates (end of exhalation)
- Not affected by humidity and gas density
- Inexpensive to replace

The turbine volume and flow sensor is available in disposable and reusable versions.

Overview

The Spirolab uses a high resolution touch screen with individual icons to represent each function available.



When the Spirolab device is turned on, the battery icon located in the top right-hand corner of the screen shows the charge remaining.

The maximum charge level is reached when the battery symbol is completely white.

Charging the Spirolab

The Spirolab is shipped with the battery fully discharged. Prior to first use, it is highly recommended that the Spirolab is fully charged to obtain optimum battery performance. Charging the battery takes approximately 4 hours.

Connect the Spirolab to the mains power supply with the AC adaptor provided.

Power supply port at rear of device

Power charge status light on main interface

Getting Started

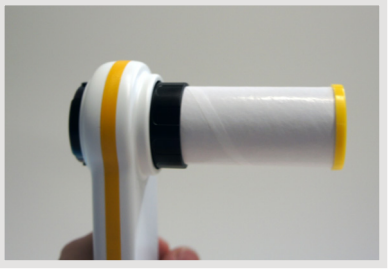
Once connected, a blue LED will illuminate in the lower right hand corner to indicate the Spirolab is charging. The LED indicator will illuminate green once charging is complete.

The Spirolab can be used on mains power supply whilst the battery is being charged providing that the battery has sufficient charge for it to operate. The battery will continue to charge even when in use.

Connecting the sensor

To correctly perform a spirometry test, observe the following instructions.

Slide the turbine fully into position in the MiniFlowmeter then turn it clockwise until it clicks into place.



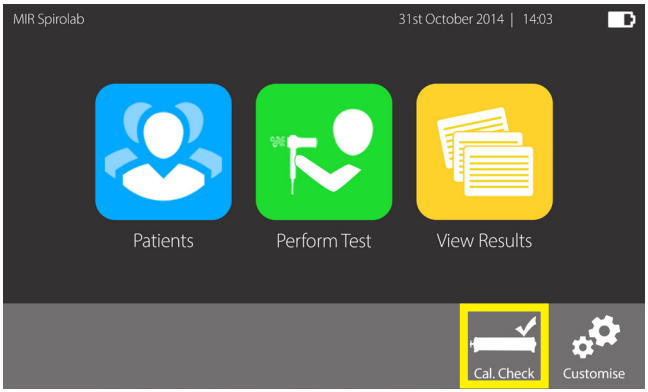
Insert a cardboard mouthpiece or bacterial filter.

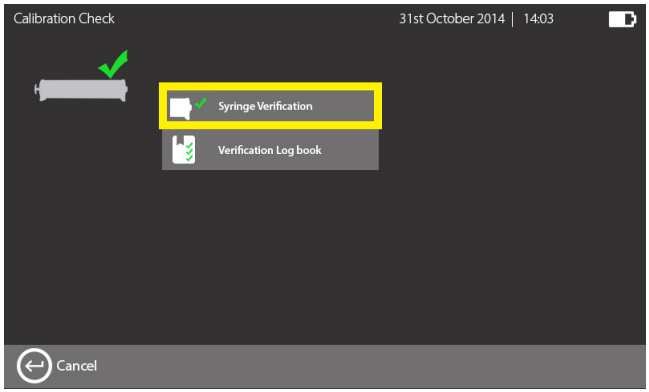
Connect the MiniFlowmeter to Spirolab as shown in the image.

Calibration Check

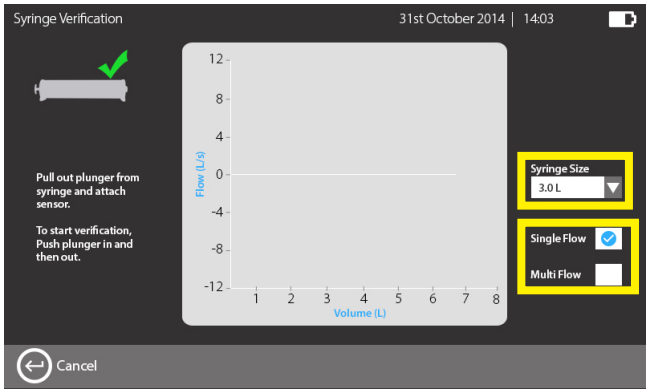
The Spirolab can be verified as per local guidelines using a single flow or calibrated using a multi flow.

Tap the "Cal. Check" icon from the home screen.
Tap the "Syringe Verification" icon to enter the verification screen.

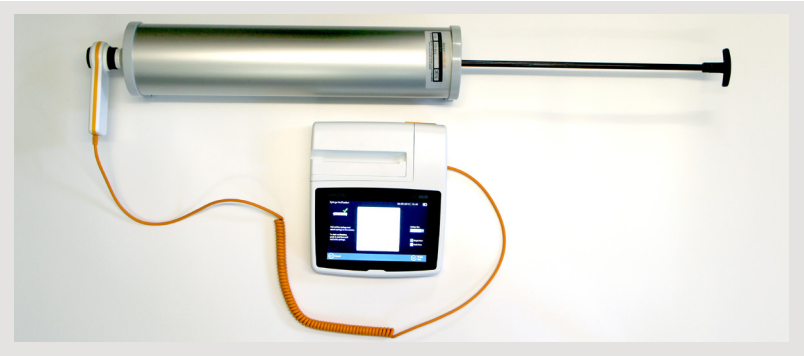




You have the option to perform a single flow or multi flow verification by tapping on the desired icon. You can also choose the syringe size by tapping on the drop down arrow.



Calibration Check



Connect the calibration syringe with the plunger fully out.

To start the verification, push in then pull out the syringe.

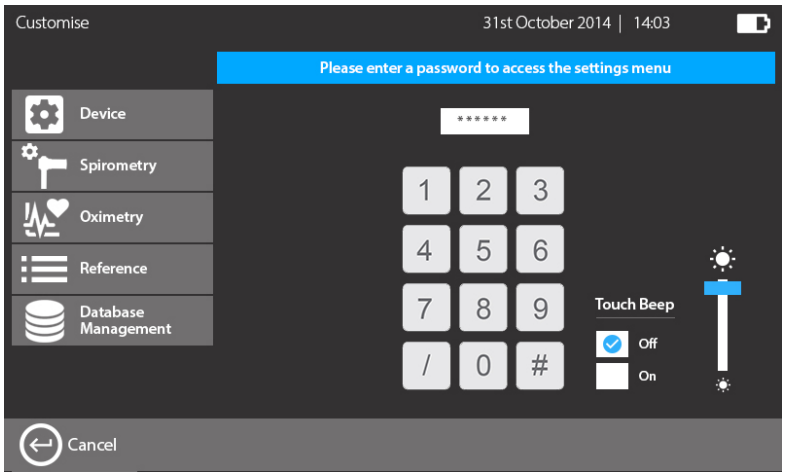
Verifying using single flow

For single flow verification push in and then pull out the syringe at a steady flow rate. The results are then displayed on screen and a pass or fail is indicated. You have the option to repeat the verification, save or print. The single flow verification is based on the memorised multiflow calibration data. All verification data can be viewed in the verification log book.

Calibrating using multi flow

For multi flow 'calibration' push in and pull out the syringe at the different flow rates as indicated by the lines and red dots. When the correct flow and volume has been achieved then the red dot will turn green. Each flow and volume has to be achieved 3 times. The average results are then displayed on screen and a pass or fail is indicated. If the volume is within 3.5% of the syringe volume then the calibration is unchanged. If the volume is over 3.5% of the syringe volume then the Spirolab is recalibrated to these new values.

Customise



The Spirolab can be fully configured to the users own specification.
Tap the "Customise" icon from the home screen. Enter the password (1223) to access the settings menu which is divided into the following sections. Each section has sub-sections which allow the user to navigate easily through the options.

The options available are:

Device — Language, turbine used, auto power off, Bluetooth off, height/weight, format, touch beep, brightness, date and time, device information, printer header and factory reset

Customise

Spirometry	Parameter selection, test type, test beep, print curves, interpretation, units of measurement, incentive
Oximetry	Min/Max SpO2, Min/Max BPM
Reference	Predicted value selection
Database Management	Memory used, format database

INFORMATION

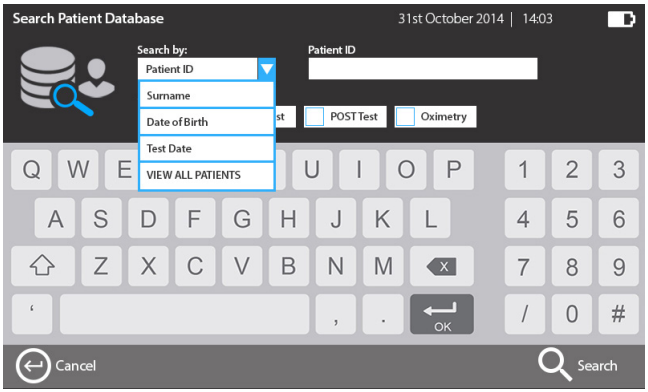
The default password is 1223

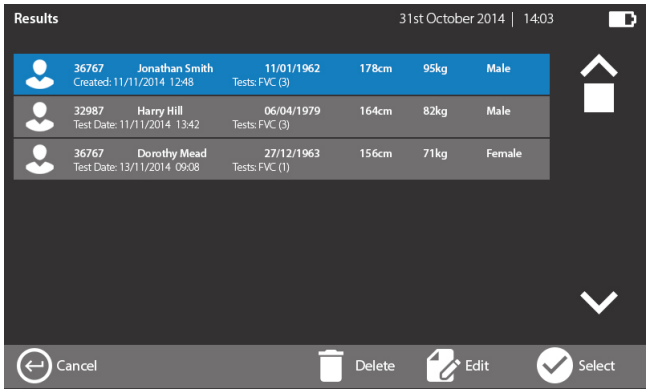
View Results

From the home screen you have the option to view the results from previous tests.

Tap on "View results". You can configure the search criteria by tapping on the drop down menu and choosing to search by patient ID, surname, date of birth, test date or view all patients.

You can also choose to view FVC, VC, POST or Oximetry tests. Type in the desired patient details and tap the "Search" or "OK" button. You will see all of the patients with that ID, surname etc.





Tap on the desired patient and tap "Select" and you will see all of the patient details as well as their previous results. By highlighting the desired result the option to view results, perform a test or perform a POST test becomes available.

Patients

From the home screen you have the option to search for patient details or adding new patient details.

Tap on the "Patient" icon. Search for an existing patient by either patient ID or surname. View the patient entered today by tapping on the "View patients entered today" icon.

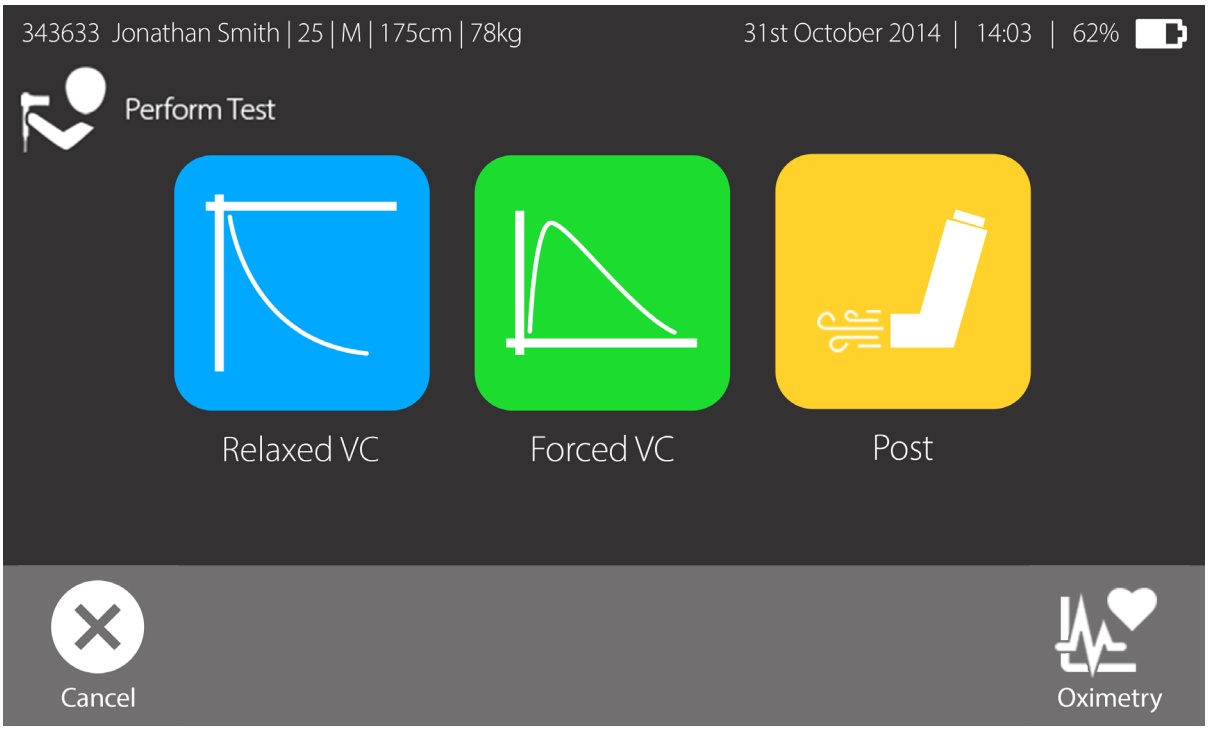
Add a new patient by tapping "Add a new patient" icon. You will be prompted to enter a unique ID number, first name, surname, DOB, height, weight, sex and ethnic group.

Any fields which have an asterisk next to them are required fields so they have to be filled in to obtain predicted values for the patient.

When the patient details are complete you have the option to either save them for use at a later date/time or tap "Perform test" to continue to the test screen.

Perform Test

From the home screen (or after entering patient details) you can perform a test. If no patient details have been entered or selected then you will be asked to enter the details or search for a patient as above. You will then have the options displayed below:



Note: Oximetry is available as an optional add-on. Button will display if installed.

Perform Test

Relaxed VC

To perform a relaxed VC test tap on the "Relaxed VC" icon. You can then perform the relaxed test as required. When the trial is complete all of the active indices are shown with the graphical interpretation.

Tap on "Add Trial" to perform another trial, "Reject Trial" if the trial isn't acceptable, or "Finish Test" to end the test. With each subsequent trial performed the previous best trial and the current trial will be shown for comparison and repeatability.

At the end of the test the results screen will be shown. The best result will be shown with % predicted as well as the graph. Options to add notes, print results, finish test or perform a forced VC test will be available.

Perform Test

Forced VC

To perform a Forced VC test tap on the "Forced VC" icon. You can then perform a Forced test as required. During the test you can see both the Flow Volume and Volume Time graphs. You have the option to choose the incentive if desired.

When the trial is complete the four main parameters of FEV1, FVC, PEF and FEV/FVC are shown along with the graphical interpretation. With each subsequent trial performed the previous best trial and the current trial will be shown for comparison and repeatability.

A quality message for the individual trial will also be shown i.e. Good blow, Abrupt end etc. Variance for both FEV1 and FVC will be shown in litres and %. At the end of the test the results screen will be shown. The best results of the active indices will be shown with % predicted. Interpretation is shown and is based on the ATS/ERS guidelines.

Options to add notes, print results, finish test or perform a post test will be available.

Perform Test

POST

To perform a POST test tap on the POST icon. A base test can be selected from the list as required. The test can be performed in the usual way but you will be able to see the baseline graph for comparison.

At the end of the test the results screen will be shown displaying the PRE and POST best indices for comparison.

Options to add notes, print results, finish test or perform an additional POST test will be available.

Oximetry

The Spirolab allows the user to perform oximetry (optional extra).

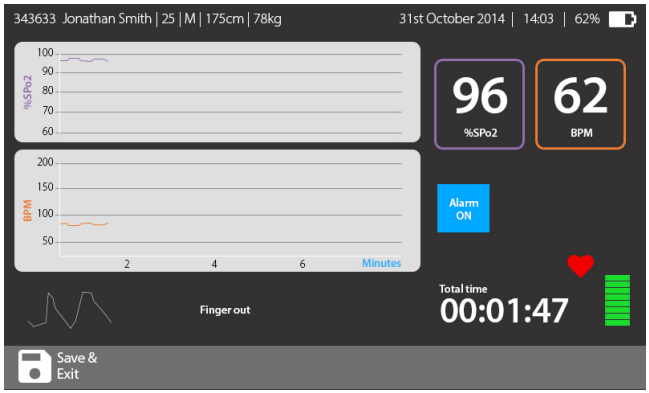
Perform Test

Preparation for oximetry

Choose a site with a good blood flow that is suitable for the sensor. Insert the finger all the way into the sensor. Make sure that the under part of the finger completely covers the detector. If you cannot position the finger properly use a different finger. Position the sensor so that the cable runs over the back of the hand. This ensures that the light source stays on the same side as the nails while the detector remains under the finger.

Performing an oximeter test

Select a patient and from the perform test screen tap the "Oximetry" icon in the bottom right hand corner. The oximetry test screen will appear.



Perform Test

The first few seconds of a test are used for finding the strongest signal. Once this has been found, the timer resets itself and the Spirolab starts recording data. If the sensor is not inserted correctly, icon transforms into and the icon appears alongside it. At the same time the Spirolab will beep (if set to do so in the customise menu).

If the sensor has been inserted but the finger is not positioned correctly, the icon transforms into and the icon appears alongside it. At the same time the Spirolab will beep (if set to do so in the customise menu). By tapping the icon you can pause the alarm for a few minutes.

If the alert situation persists then the beep will return after a few minutes
If the signal is received properly by the sensor, after a few seconds the device will begin to beep and display readings on the screen.

During the test if the %SpO2 or HR rate goes above or below the threshold as set in the customise menu then the Spirolab emits a beep (if set to do so in the customise menu) for as long as this anomaly continues.

When the test ends then the results are displayed and the minimum, maximum and average %SPO2 and HR is shown. The results can be saved and printed.

Maintainance

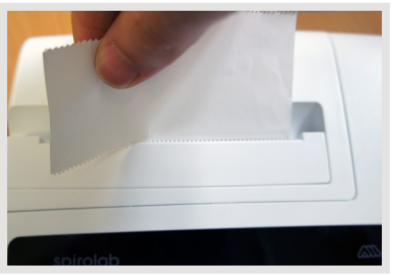
Changing the printer roll

To load a new roll of thermal printer paper, slide the paper cover from the top of the Spirolab.

Insert the spindel into the new roll of paper.

Place the roll inside the device and feed the paper end under the roller.

The paper will automatically feed through the roller. You will have the option to manually adjust the roll as required.



Replace the paper cover firmly. To tear off the excess paper pull towards you and to the right or left as shown

Maintainance

WARNING

It is recommended that only MIR thermal printer paper is used with the Spirolab to avoid damage to the printer head.
Please contact Intermedical (UK) Ltd to re-order on 01732 522444

Cleaning the turbine

To clean a reusable turbine, remove it from its housing in the MiniFlowmeter by turning it anti-clockwise and pulling gently.

Soak the turbine in a cold liquid detergent and shake it so as to remove any impurities that have deposited inside; leave to soak for the period of time recommended by the detergent manufacturer that is shown in the instructions for use.

MIR recommends the use of Dupont Perasafe that has been tested on all MIR sensors. Rinse the turbine by immersing it in clean luke warm water. Shake off any excess water from the turbine. Leave the turbine to dry by placing it in an upright position on a dry surface.

WARNING

To avoid irreparable damage to the turbine, do not use alcohol or oil based detergent solutions. Never place the turbine in an autoclave.
Never clean the turbine under running water or spray with other liquids.

Maintainance

Servicing

The Spirolab does not require any routine servicing as standard. If the Spirolab is damaged or requires servicing please contact Intermedical (UK) Ltd on 01732 522444.

Consumables/Supporting Products

PART NUMBER	DESCRIPTION
MR-911082E1	MIR Intermedical Spirolab Spirometer with re-usable turbine
MR-910002	Replacement re-usable turbine
MR-910004	Disposable turbines (Box of 50)
881002	One-way valve adult mouthpieces for re-usable turbine (Box of 200)
MR-910350	Thermal printer roll (Box of 10)
1690000	3 Litre calibration syringe

INFORMATION

Please call 01732 522444 to re-order consumables

Technical Specification

Labels and symbols

The label shows:

- Device serial number (SN)
- Product name (REF)
- Antenna symbol for devices that include RF transmitters
- Manufacturer's name and address
- Electrical safety symbol
- CE mark as per Council Directive 93/42 CEE
- WEEE symbol
- FCC Identification code (FCC ID)
- Reference to US FDA regulations (Rx Only)
- Degree of protection against penetration by external agents (IPX1)

CE 0476

CE mark for medical devices
This product is a Class IIa medical device that is certified and in compliance with the requirements of Council Directive 93/42/EEC

Electrical safety symbol
As per IEC601-1, the product and its component parts are type BF and therefore offer protection against electrical shocks.

USB port warning label
For connecting the device to a PC.
Only use cables supplied by the manufacturer and observe the IEC 60601-1 safety standards.

SpO2

SpO2 oximetry port warning label

DC IN 12V

Label relating to the method for charging the battery pack
The symbol is screen-printed next to the connector for connecting the battery charger. Only use the charger supplied by the manufacturer. Features of the battery charger: model AC/DC 12W-N1EFM

Technical Specification

FCC certification label
Spirolab complies with section 15 of the FCC standards. Operation of the device is subject to the following conditions:
(1) This device must not cause harmful interference
(2) This device can be subjected to all types of interference, including those which may cause undesired effects

Any modifications made without the express approval of this company may compromise the use of the device by the user.

NOTE: This device has been subjected to tests that confirm it complies with the limits of a class B digital instrument as per section 15 of the FCC Standards. These limits have been set to provide appropriate protection against interference when the device is used in the home. This device generates, uses and can emit radio signals and, if not installed or used as per instructions, can create interference with radio communications.

The absence of interference cannot however be guaranteed for all installations. If this device causes interference to radio or TV reception (that can be determined by turning the device on and off), we recommend the user corrects the interference by adopting one of more of the counter measures listed below:

- Change the angle or position of the antenna.
- Increase the distance between the device and the appliance receiving the signal.
- Connect the device to a different power socket than the one used by the appliance receiving the signal.
- Contact the supplier or radio/TV technician for expert advice.
- The symbols defined may be found on the device ID label.

WEEE label
This symbol applies to European Directive 2002/96/EEC on Waste Electrical and Electronic Equipment. On completion of its useful life, this appliance must not be disposed of as urban waste but must be sent to an authorised WEEE waste disposal centre.

The device can also be sent back to the original supplier free of charge when a new equivalent model is bought. Due to the materials used in its manufacture, disposal of the device as urban waste could harm the environment and/or health. There are legal penalties in place for those who fail to observe the legal requirements mentioned here.

Electrostatic discharge symbol
This symbol, required by the EN 60601-1-2 International Standard, is used near every connector that has been excluded from the electrostatic discharge test.

WARNING
The contacts of connectors identified with the ESD warning symbol should not be touched and connections should not be performed before appropriate precautionary electrostatic discharge (ESD) measures are undertaken.

Technical Specification

Electrostatic discharge symbol (contd.)
Below are examples of such precautionary measures: Environmental procedures: air conditioning, humidification, conductive floor-covering substances, use of non-synthetic clothing

User procedures: discharge using large metal objects; use of an ESD wrist strap. Any staff that uses devices affected by electrostatic discharge should receive adequate explanations concerning the ESD symbol and adequate training on the effects of electrostatic discharge and on the measures to be undertaken to prevent such effects. An electrostatic discharge is defined as an electric charge at rest. It is the sudden flow of electricity between two objects in contact, an electrical short or a dielectric breakdown. ESD may be caused by a build-up of static electricity or by electrostatic induction. At low relative humidity, charge generation will increase significantly due to the dry environment. Common plastics create higher charge levels.

Typical values of voltages caused by electrostatic discharges are shown below:

Walking on a carpet 1500-35000 Volts
Walking on an untreated vinyl floor 250-12000 Volts
Vinyl envelopes used to organise documents 600-7000 Volts
Worker at a table 700-6000 Volts

If two elements have different charge values, their coming into contact could cause an electrostatic discharge spark. This quick and spontaneous transfer of charge can lead to overheating or melting of circuits in electronic components.

A latent defect can occur when an element sensitive to ESD is exposed to an ESD event and is partially damaged by it. The device can continue to function normally and the damage may not be detected by routine checks, but intermittent or persistent damage can occur even after a long time.
With ESD materials, charges go to ground or to another conductive object that the material contacts.

Dissipative materials allow charges to flow to ground more slowly than with conductive materials of equal size. Common plastics and glass can act as insulators. An insulator retains charges and these cannot be transferred to ground. Both conductors and insulators can be charged with electrostatic charges and discharged. Grounding is a very efficient instrument against ESD, but only conductors can be connected to ground.

The fundamental principles of control against ESD are:
- Grounding of all conductors, including people
- Removing insulators and replacing them with ESD-safe versions
- Using ionisers
- Paying attention to areas that are not ESD-safe, e.g. using ESD-safe product packaging

IPX1

Information on protection against ingress of liquids
The label bearing the inscription "IPX1" indicates the degree of protection against ingress of liquids. The device is protected against vertically falling drops of water.

Symbol for devices that include RF transmitters
The symbol is applied in accordance with standard IEC EN 60601-1-2: 2007, section 5.1.1, for products that include RF transmitters.

Symbol for reading the operating instructions
Where applied, the symbol refers the user to this manual for the correct use of the device.

Technical Specification

General specifications

Display	7 inch colour touch screen LCD Display with 800x480 resolution
Dimensions	Main body: 220x210x51 mm
Weight	1450 g (with battery installed)
Storage memory	The memory can store the data from over 2000 spirometric tests. The exact number has not be established as it depends on the configuration set by the user
Keypad	Touch screen
Interface	USB, Bluetooth
Bluetooth interface	Frequency range: 2402-2480 MHz, Output power: 0,001W, Frequency tolerance: 20 ppm Type of antenna: permanently attached, Antenna gain: 0 max dBi
Power supply	Rechargeable battery: NiMH 7.2V battery pack (6 batteries, 1.2V each), 4000 mAh, Charger: AC/DC 12W-N1EFM
Battery pack lifespan	Approx. 10 years of use
Conditions of use	Device for continuous use
Temperature	Storage: MIN -40 °C, MAX + 70 °C - Humidity: MIN 10% RH; MAX 95%RH Transport: MIN -40 °C, MAX + 70 °C - Humidity: MIN 10% RH; MAX 95%RH Operating: MIN + 10 °C, MAX + 40 °C; Humidity: MIN 10% RH; MAX 95%RH
Type of electrical protection	Class II
Degree of electrical protection	BF
Degree of protection against water penetration	IPX1 appliance protected against water leaks
Safety level in the presence of flammable anaesthetic gases, oxygen and nitrogen	Appliance not suitable
Applicable standards	Electrical Safety IEC 60601-1 Electro Magnetic Compatibility IEC 60601-1-2
Key performance (in accordance with EN 60601-1: 2007)	Accuracy in measuring spirometry parameters in accordance with the ATS standard Measurement of oximetry parameters with accuracy as defined in oximetry specifications

Technical Specification

IMPORTANT SAFETY WARNINGS

Spirolab devices have been examined by an independent laboratory that has certified their conformity with EN60601-1 safety standards and guaranteed that their electromagnetic compatibility is within the limits laid out in EN 60601-1-2.

Spirolab devices are subject to continuous checks during production and therefore comply with the safety and quality standards laid down in Council Directive 93/42/EEC for Medical Devices.

Once the device has been removed from its packaging, examine it carefully to make sure there are no signs of damage. In the event of any damage, do not use the device but return it immediately to the manufacturer for possible replacement.

Spirometry specifications

Flow/volume sensor	Bi-directional turbine
Method of detection	Infra-red interruption
Volume measurement	Maximum 10 L
Volume accuracy	± 3% or 50 mL
Flow measurement	± 16 L/s
Flow accuracy	± 5% or 200 mL/s
Dynamic resistance @ 12 L/s	<0.5 cmH2O/L/s
Temperature sensor	Semiconductor (0-45°C)

Technical Specification

Spirometry test parameters

Parameter	Description	Unit
FVC	Forced Vital Capacity	L
FEV1	Volume exhaled in 1st second of the test	L
FEV1/FVC	FEV1/FVC x 100	%
FEV1/VC	FEV1/VC x 100	%
PEF	Peak Expiratory Flow	L/m
FEF25	Maximum flow at 25% of FVC	L/s
FEF50	Maximum flow at 50% of FVC	L/s
FEF75	Maximum flow at 75% of FVC	L/s
FEF25-75	Median flow between 25% and 75% of FVC	L/s
FEF7585	Median flow between 75% and 85% of FVC	L/s
ELA	Estimated Lung Age	
EVOL	Extrapolated Volume	Ml
FET	Forced Exhalation Time	s
PEF Time	Time to achieve 90% of the PEF	s
FEV0.5	Volume exhaled after 0.5 seconds	L
FEV0.5/FVC	FEV0.5/FVC x 100	%
FEV0.75	Volume exhaled after 0.75 seconds	L
FEV0.75/FVC	FEV0.75/FVC x 100	%
FEV2	Volume exhaled in the first 2 seconds of the test	L
FEV2/FVC	FEV2/FVC x 100	%
FEV3	Volume exhaled in the first 3 seconds of the test	L
FEV3/FVC	FEV3/FVC x 100	%
FEV6	Volume exhaled in the first 6 seconds of the test	L

Parameter	Description	Unit
FEV1/FEV6	FEV1/FEV6x100	%
FEV1/PEF	FEV1/PEF (empey's index)	L/L/s
FEV1/FEV0.5	FEV1/FEV0.5	\
FIVC	Forced Inhalation Vital Capacity	L
FIV1	Volume inspired in the 1st second	L
FIV1/FVC	FIV 1 %	%
PIF	Peak Inspiratory Flow	L/s
FIF25	Maximum flow at 25% of FIVC	L/s
FIF50	Maximum flow at 50% of FIVC	L/s
FIF75	Maximum flow at 75% of FIVC	L/s
FEF50/FIF50	FEF50/FIF50 x 100	%
MVVcal	Max. voluntary ventilation calculated based on FEV1	L/s
EVC	Expiratory Vital Capacity	L
IVC	Inspiratory Vital Capacity	L
IC	Inspiratory capacity: (maximum between EVC and IVC) -ERV	L
ERV	Expiratory reserve volume	L
IRV	Inspiratory reserve volume	L
VE	Minute ventilation at rest	L/min
tI	Average inspiratory time at rest	s
tE	Average exhalation time at rest	s
tI/tTOT	tI/(tI+tE)	\
MVV	Maximum voluntary ventilation	L/min

Technical Specification

Oximetry definitions

Desaturation event
Drop in SpO2 >= 4% in a 8- 40 sec period limited and subsequent rise >=2% inside an overall period of 150 sec

Pulse variation event
Rise in Pulse >= 10 BPM in a 8- 40 sec limited period and subsequent drop >=8 BPM inside an overall period of 150 sec.

Oximetry specifications

Method of detection	Red and infra-red light absorption
Measuring range of %SpO2	0 – 99% (with 1% increments)
Resolution of SpO2	1%
Accuracy of %SpO2	2% between 70-99% SpO2
Number of beats for calculating the median SpO2 %	8 beats
Pulse rate measuring range	18 – 300 BPM
Resolution of pulse rate	1 BPM
Pulse rate accuracy	2 BPM or 2% of highest value
Interval for calculating median pulse rate	8 seconds
Signal quality	0 - 8 display segments

Technical Specification

Oximetry test parameters

Parameter	Description	Unit
%SPO2 min	Minimum SPO2 during the test	%
%SPO2 max	Maximum SPO2 during the test	%
BPM min	Minimum BPM during the test	BPM
BPM max	Maximum BPM during the test	BPM
Median %SPO2	Median SPO2	%
Median BPM	Median BPM	BPM
T Total	Duration of the test	hh:mm:ss
Analysis T	Total measuring time (duration of test excluding zeroes)	hh:mm:ss
T<90%	Time with SpO2 less than 90%	%-hh:mm:ss
T<89%	Time with SpO2 less than 89%	%-hh:mm:ss
T5	Time with SpO2 less than 5% of the mean value	%-hh:mm:ss
T<40BPM	Time passed with Pulse rate <40 BPM	%-hh:mm:ss
T>120BPM	Time passed with Pulse rate <120 BPM	%-hh:mm:ss

Troubleshooting

Problem	Message	Possible Cause	Solution
Spirolab doesn't turn on	No Message	Battery pack may be flat	Charge the device using the charger unit
	No Message	The device may have lost internal software	Connect the device to a PC via USB and update the software. For further information contact Intermedical service department.
Problems turning the device on	'Ram error data recovery Please wait'	The data in the device memory has been damaged	If the data has been correctly restored the last standard turning on process will be repeated. If not Contact Intermedical service department.
The device turns itself off then reboots while being used.	No message	There is an internal error	Connect the device to a PC via USB and update the software. For further information contact Intermedical service department.
On completion of spirometry tests, the readings are not credible	No message	The turbine may be dirty	Clean the turbine as described in section 4.1; if necessary, replace the turbine with a new one
	No message	The test was performed in the wrong manner	Repeat the test
On completion of a spirometer test, some parameters are not displayed	No message	Parameters not selected in customise menu. Large number of parameters selected so cannot all be viewed on screen	Check 'Customise', 'Spirometer', 'Indices' for selected parameters and amend accordingly Scroll down on the results to view all parameters
During an oximeter test the readings displayed are irregular, intermittent or wrong	No message	The sensor is wrongly positioned or the patient's perfusion is poor	Reposition the oximeter sensor
	No message	The patient moved	For accurate results, the patient must not make any sudden movements.
The display is not very bright during tests	No message	The brightness level of the display automatically dims 5 minutes after a test starts. This function extends battery life.	None

Troubleshooting

Problem	Message	Possible Cause	Solution
Problems with charging the battery pack	Defective battery	The battery pack is damaged or wrongly positioned	Contact Intermedical service department
Unforeseen memory error	Error in memory	The data stored in the archive have been damaged	Contact Intermedical service department
The device will freeze when unforeseen events occur	No message	/	Press the on button 3 times; wait a few seconds and the device will reset then turn itself on.

Appendix:

Information about the correct use of device in an electromagnetic environment

Manufacturer's recommendations and declarations - electromagnetic emissions		
The SPIROLAB device can be used in the following electromagnetic environments. The SPIROLAB customer or end user must ensure that the device is used in such an environment.		
Emission test	Conformity	Electromagnetic environment - guide
RF emissions CISPR 11	Group 1	SPIROLAB uses RF energy for internal functions only. Its RF emissions are therefore very low and are too weak to cause interference with nearby electronic devices.
RF emissions CISPR 11	RF emissions CISPR 11	SPIROLAB is suitable for use in any environment, including the home and those directly connected to the public low voltage power supply that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000 3-2	Not applicable	
Fluctuations in intermittent voltage/emissions IEC 61000-3-3	Not applicable	

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Information about the correct use of device in an electromagnetic environment

Manufacturer's recommendations and declarations - electromagnetic immunity			
The Spirolab device can be used in the following electromagnetic environments. The Spirolab customer or end user must ensure that the device is used in such an environment.			
Immunity test	Test level IEC 60601	Level of conformity	Electromagnetic environment - guide
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be made of wood, cement or ceramic tiles. If floors are covered with synthetic materials, Relative Humidity must be at least 30%. In the event of an electrostatic discharge occurring during an oximeter test, the device will recover its functionality within 30 seconds (in accordance with ISO 9919)
High speed data transmission lines IEC 61000-4-4	±1 kV per input/output line		The main type of power supply must be that present in commercial or hospital settings.
power surges IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable	The main type of power supply must be that present in commercial or hospital settings.
Drops in voltage, short interruptions and voltage variations in the power supply feed line IEC 61000-4-11	<5 % UT (>95 % gaps in UT) for 0.5 cycles 40 % UT (60 % gaps in UT) for 5 cycles 70 % UT (30 % gaps in UT) for 25 cycles <5 % UT (>95 % gaps in UT) for 5 seconds	Not applicable	
Frequency of magnetic field (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	The magnetic field values must correspond with those present in a commercial or hospital setting.
NOTE: UT is the mains voltage before the application of the test voltage.			

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Information about the correct use of device in an electromagnetic environment

Manufacturer's recommendations and declarations - electromagnetic immunity			
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RF conduit IEC 61000-4-6 RF radiated IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	[3] V [3] V/m	RF and mobile communication items of equipment must not be used any closer the separation distance recommended by SPIROLAB including cables as calculated using the equation applicable to the frequency of the transmitter. **Recommended separation distance:** d=[3.5] √P 3 d=[3.5] √P 80 MHz at 800 GHz 3 d=[7] √P 800 MHz at 2.5 GHz 3 Where P is the maximum nominal distance of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). The intensity of the fixed RF transmitters, as determined by an electromagnetic scan of the site, could be lower than the level of conformity in each frequency interval (b). Interference near the device may be detected from devices marked with the following symbol:
NOTE 1: at 80 MHz and 800 MHz, the highest frequency interval is applied. **NOTE 2:** These guide lines may not apply for all situations. The propagation of electromagnetism is influenced by the absorption and reflection of structures, objects and persons.			
A) The intensities of fixed transmitter fields such a telephone base stations (mobiles and cordless), terrestrial radio equipment, amateur radio appliances, AM and FM radio and TV transmitters cannot be theoretically accurately predicted. To assess an electromagnetic environment generated by fixed RF transmitter, you need to perform an electromagnetic scan of the site. If the intensity of the field where the Spirolab is used exceeds the applicable conformity level mentioned above, you will need to observe how the Spirolab works under normal conditions. If you detect faulty performance, you may need to implement additional measures such as changing the direction or position of the Spirolab. **B)** The intensity of the field in the frequency interval from 150 kHz to 80 MHz should be less than [3] V/m			

Appendix:

Information about the correct use of device in an electromagnetic environment

Recommended separation distance between mobile radio-communication appliances and devices			
Spirolab devices are designed to work in electromagnetic environments in which radiated RF disturbances are controlled. The device customer or end user can contribute towards preventing electromagnetic interference by providing a minimum distance between mobile RF communication devices (transmitters) and the unit as recommended below in relation to the maximum power output of the radio-communication devices.			
Specified maximum power output of the transmitter W	Separation distance at transmitter frequency (m)		
	150 kHz - 80 MHz d=[3.5] √P 3	80 MHz - 800 MHz d=[3.5] √P 3	800 MHz - 2.5 GHz d=[7] √P 3
0.01	0.12	0.24	0.24
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	5.28	5.28	1,056
100	11.66	11.66	23.32
For the specified maximum power output of a transmitter not included above, the recommended separation distance d in metres (m) can be calculated using the equation that applies to transmitter frequency where P is the transmitter's nominal maximum power output in Watts (W) according to the transmitter manufacturer. **NOTE 1:** At 80 MHz and 800 MHz, the separation distance calculated for the highest frequency rage is applied. **NOTE 2:** These guidelines may not apply for all situations. The propagation of electromagnetism is influenced by absorption and reflection caused by structures, objects and persons.			

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