



User Manual Rev. 1.9

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Thank you for choosing a product from **MIR**
MEDICAL INTERNATIONAL RESEARCH

WARNING

The paper mouthpiece, the nose clip and the disposable turbine with mouthpiece in the equipment should be considered disposable products.

Before using your MiniSpir ...

- Read this manual carefully, plus all labels and other product information supplied.
- Set the device configuration (date, time, predicted values, language etc.) as described in the Software WinspiroPro Manual.
- Check PC system requirements for compatibility with the device (RAM: 512 Mb minimum, 1024 Mb preferred; Operating system: Windows 2000 – XP Windows Vista (32bit/64bit)- Windows 7 (32bit/64bit); Windows 10 (32bit/64bit); Minimum disk space: 500 Mb; CPU Pentium IV-class PC 1 GHz; display resolution 1024x768 or higher.
- **MiniSpir** should only be connected to a computer manufactured in compliance with EN 60950/1992.

WARNING

The winspiroPRO PC software supplied with the device MUST be installed correctly to the PC before connecting MiniSpir to the PC. At the end of the installation, connect the device to the PC and the hardware will be "recognised" by the PC. The device can then be used with the winspiroPRO software.

Keep the original packaging!

In the event that your device requires attention then always use the original packaging to return it to the distributor or the manufacturer.

In such an event then please follow these guidelines:

- Return the complete device in the original packaging, and
- The transport (plus any customs or taxes) costs must be prepaid.

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MIR has a policy of continuous product development and improvement, and the manufacturer therefore reserves the right to modify and to update the information contained in this User's Manual as required. Any suggestions and or comments regarding this product should be sent via email to: mir@spirometry.com. Thank you.
MIR accepts no responsibility for any loss or damage caused by the User of the device due to the use of this Manual and/or due to an incorrect use of the product.
Copying this manual in whole or in part is strictly forbidden.

FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

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1. INTRODUCTION

1.1 Intended Use

MiniSpir spirometer and pulse oximeter (optional) is intended to be used either by a physician, respiratory therapist or technician. The device is intended to test lung function and can make:

- spirometry testing in people of all ages, excluding infants and neonates
- oximetry testing in people of all ages.

It can be used in hospital setting, physician's office, factory, pharmacy.

1.1.1 User Category

MiniSpir calculates a series of parameters relating to human respiratory function.

Use of the device is usually "prescribed" by a doctor, who is responsible for analysing and checking the results and the data gathered during the test period .

1.1.2 Ability and experience required

The correct use of the device, the interpretation of the results and the maintenance of the device, with particular attention to disinfection (cross-contamination risk), all require qualified personnel.

WARNING

The manufacturer cannot be held responsible for any damage caused by the user of the device failing to follow the instructions and warnings contained in this manual.

The MiniSpir when used as a pulse oximeter is intended for spot-checking oximetry.

1.1.3 Operating environment

MiniSpir has been designed for use in hospital setting, physician's office, factory, pharmacy.

The instrument is not intended for use in an operating theatre nor in the presence of inflammable liquids or detergents, nor in the presence of inflammable anaesthetic gases, oxygen or nitrogen.

The instrument is not designed to be used in direct air currents (e.g. wind), sources of heat or cold, direct sun rays or other sources of light or energy, dust, sand or any other chemical substances.

The user is responsible for ensuring that the device is stored and used in appropriate environmental conditions as specified in paragraph 1.6.3.

WARNING

If the device is exposed to unsuitable environmental conditions, this could cause the device to malfunction and to give incorrect results.

1.1.4 Who can or must make the installation

The device requires installation by qualified personnel.

1.1.5 Subject effect on the use of the device

A spirometry test should only be carried out when the subject is at rest and in good health, and thus in a suitable condition for the test. A spirometry test requires the **collaboration** of the subject since the subject must make a complete forced expiration, in order to have a meaningful test result.

1.1.6 Limitations of use - Contraindications

An analysis of the results of a spirometry test is not by itself sufficient to make a correct diagnosis of the subject's clinical condition.

A detailed clinical history of the subject is also required together with the results of any other test(s) suggested by a doctor.

Test comments, a test interpretation and suggested courses of treatment must be given by a doctor.

A spirometry test requires the collaboration of the subject. The results depend on the person's capability to inspire and to expire all air completely and as fast as possible. If these fundamental conditions are not respected then the results obtained during spirometry testing will not be considered accurate, and therefore the test results are "not acceptable".

The **acceptability** of a test is the responsibility of the user. Special attention should be given to testing elderly subjects, children and people with disabilities.

The device should never be used when it is possible or probable that the validity of the results may be compromised due to any such external factors.

WARNING

MiniSpir when used as a pulse oximeter has limited alarms, therefore the device requires frequent PC display observation of SpO2 and pulse rate.

1.2 Important safety warnings

MiniSpir has been examined by an independent laboratory which has certified the conformity of the device to the Safety Standards IEC 60601-1 and guarantees the EMC Requirements within the limits laid down in the Standard IEC 60601-1-2.

MiniSpir is thoroughly tested during its production and therefore the product complies with the safety requirements and quality standards laid down by the Council Directive 93/42/EEC for **MEDICAL DEVICES**.

After removing the device from its packaging, check that there is no visible damage. In case of damage do not use the device and return it to the manufacturer for replacement.

WARNING

The safety and the correct performance of the device can only be assured if the user of the device respects all of the relevant safety rules and regulations.

The manufacturer cannot be held responsible for damage caused by the failure of the user to follow these instructions correctly.

The device must be used according with the indications given by the manufacturer in the User Manual with particular attention to § Intended Use utilizing only original spare parts and accessories. Use of non original parts such as the turbine flow sensor and oximetry sensor or other accessories may cause errors in measurement and/or compromise the correct functioning of the device, and is therefore not permitted.

In particular, the use of cables other than those specified by the manufacturer could cause increased emissions or lower electromagnetic immunity from the device and result in improper operation.

In the event of any incident or accident of any kind resulting from the use of the device, the user is required to inform the manufacturer without delay, according with Directive 93/42/EEC on Medical Devices.

1.2.1 Danger of cross-contamination

Two different types of turbine sensors can be used with the device: one is single-patient disposable and one is reusable. A mouthpiece is required in order to connect a subject to the spirometer.

In order to avoid exposing the subject to the hazard of cross-contamination, the reusable flow sensor must always be cleaned before each spirometry test, and a new disposable mouthpiece must always be used for each subject. The use of an anti bacterial filter is at the discretion of the doctor.

If a disposable turbine is used, then a new one must be used for each patient.

1.2.2 Turbine



Disposable turbine



Reusable turbine

If you are going to perform the spirometry test with a disposable turbine, it is important to use a new turbine for every new patient. The characteristics, accuracy and the hygiene of the disposable turbine can only be guaranteed if it has been stored beforehand in its original sealed packaging.

The disposable turbine is made of plastic and its disposal after use should adhere to the local authority guidelines / norms.

The correct functioning of the re-usable turbine can only be guaranteed if it has been cleaned in the correct manner and is free from foreign bodies which could alter its movement. If the turbine has not been cleaned sufficiently this could cause cross contamination from one patient to another.

The cleaning of the turbine should be done following the guidelines in the user manual.

The following informations are valid for both models of turbine.

Do not expose the turbine to a direct jet of water or air, and avoid contact with high temperature liquids.

Do not allow dust or foreign bodies to enter the turbine sensor, in order to avoid incorrect functioning and possible damage. The presence of any impurities (such as hair, sputum, threads etc.) within the body of the turbine sensor may seriously compromise the accuracy of the measurements.

Notes about calibration of reusable turbine

WARNING

The turbine flow sensor does not require calibration but needs only a regular cleaning. If a calibration must be made then the following guidelines should be carefully noted.

Calibration can be made using a siring a calibration syringe and making a FVC test.

In line with the publication "Standardised Lung Function Testing" of the European Respiratory Society (Vol 6, Supplement 16, March 1993), the air expired from the mouth is at a temperature of circa 33/34 °C.

The expired flow and volume, to be converted to BTPS conditions (37 °C) must be increased by 2.6% - this is derived from the BTPS factor of 1.026 at a temperature of 33°C, which represents a correction of 2.6%. In practice the BTPS factor for the expired flow and volumes is therefore constant and equal to 1.026.

For the inspired volumes and flows, the BTPS factor depends upon the ambient temperature as the air inspired is at ambient temperature.

For instance at an ambient temperature of 20°C with relative humidity at 50%, the BTPS factor is 1.102, a correction of +10.2%.

The correction of the inspired volumes and flows is made automatically as the machine has an internal temperature sensor; the BTPS values are thus calculated.

If a 3L syringe is used to make the calibration and if the MiniSpir is calibrated correctly then the FVC (syringe) value will be:

$3.00 \text{ (FVC)} \times 1.026 \text{ (BTPS)} = 3.08 \text{ L (FVC at BTPS)}$.

If the ambient temperature is 20°C, the FIVC (syringe) value will be:

$3.00 \text{ (FIVC)} \times 1.102 \text{ (BTPS)} = 3.31 \text{ L (FIVC at BTPS)}$.

The user must be aware that the volume of the syringe shown by the machine is converted to BTPS conditions, so that the "increase" of the results with respect to the expected values does not constitute an error.

For instance, if the calibration procedure is carried out with measured data:

FVC = 3.08 L and FIVC = 3.31 L at an ambient temperature of 20°C the resulting correction factor becomes:

EXPIRATION	.00%
INSPIRATION	.00%

This does not represent an error, but is a logical consequence of the explanation detailed above.

1.2.3 Mouthpiece

Any disposable mouthpieces included with the device are supplied only as a guide to the correct type and dimensions of the mouthpiece required for this device, they are clean but not sterile. To purchase appropriate mouthpieces, generally either paper or plastic but in any case mono-use/disposable, we suggest that you contact your local distributor who supplied the spirometer.

WARNING

The use of a mouthpiece made from an inappropriate material could modify the bio-compatibility and could be the cause of an incorrect functioning of the device and thus of incorrect test results, and create inconvenience to the patient.

The user is responsible for obtaining the correct type of mouthpieces for the device. Those required are a standard type with an outside diameter of 30 mm, they are commonly used and in general easily procured.

To avoid contamination of the environment, caused by the disposal of used mouthpieces, the user must follow all of the relevant local regulations in force.

1.2.4 Oximetry sensor

The included sensor code 919024_INV and the following oximetry sensors can be used with MiniSpir:

Manufacturer	Code	Description	MIR code
Envitec	RS-3222-12	Reusable small soft sensor (paediatric)	939006
Envitec	RM-3222-12	Reusable medium soft sensor (adults)	939007
Envitec	R-3222-12	Reusable large soft sensor (adults)	939008
BCI	3044	Reusable hard finger sensor (adults)	919020

These sensors, with the exception of the sensor MIR code 919020 which has the MIR connector with orange arrow, require the use of an extension cable to be correctly connected to the device: the extension cables available are:

code 919200_INV lenght 1,5 m
code 919210_INV lenght 0,5 m

Prolonged use and/or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.

WARNING

Incorrectly applied sensors or damaged cables may cause inaccurate readings. Using a damaged sensor may cause inaccurate readings, possibly resulting in patient injury or death. Inspect each sensor before use.

If a sensor appears damaged, do not use it. Use another sensor or contact your authorized repair centre for assistance.

Use only MIR sensors supplied with, or specifically intended for use with the MiniSpir. Use of sensors not intended for use with the MiniSpir may cause inaccurate readings.

Oximetry measurements may be inaccurate in the presence of high ambient light. Shield the sensor area (with a surgical towel, for example) if necessary.

WARNING

Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, patent blue V (PBV), and fluorescein may adversely affect the accuracy of the oximetry reading.

Any condition that restricts blood flow, such as the use of a blood pressure cuff or a device for systemic vascular resistance, may cause an inability to determine accurate pulse rate and SpO2 readings.

Remove fingernail polish and/or false fingernails before applying SpO2 sensors. Both may cause inaccurate oximetry measurement.

Significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin or methemoglobin, may adversely affect the accuracy of the oximetry measurement.

Optical cross-talk can occur when two or more sensors are placed in close proximity. Optical cross-talk may adversely affect the accuracy of the oximetry readings. The danger can be eliminated by covering each site with opaque material. Obstructions or dirt on the sensor's emitter and/or detector may cause a sensor failure or inaccurate readings. Make sure there are no obstructions and the sensor is clean.

Autoclaving, ethylene oxide sterilizing, may cause sensor damage. Do not attempt to sterilize the sensor.

Unplug the sensor from MiniSpir before cleaning or disinfecting to prevent damaging sensor or device, and to prevent safety hazards for the user.

1.2.5 USB Connection Cable

Incorrect use or application of the USB cable may produce inaccurate measurements, which will show very inaccurate values of the patient's condition. Carefully inspect each cable before use.

Do not use cables that appear to be or are damaged. If a new cable is required, contact your local distributor.

Use only cables supplied by MIR, specifically designed to be used with **MiniSpir**. The use of other types of cables can lead to inaccurate measurements.

1.2.6 Device**WARNING**

The maintenance operations detailed in this manual must be carried out to the letter. If these instructions are not followed this can cause measurement errors and/or an incorrect test interpretation.

Any modifications, adjustments, repairs or reconfiguration must be made by the manufacturer or by personnel authorised by the manufacturer. In case of problems, never attempt to make a repair oneself. The set-up of configurable parameters should only be made by qualified personnel. However, an incorrect set up of the parameters does not put the patient at risk.

When connected to other devices to preserve the safety of the system as required in the IEC 60601-1 standard, it is necessary to use exclusively device compliant with the safety rules. So the PC which the MiniSpir is connected must be compliant with IEC 60601-1.

If the PC connected to MiniSpir is used in the area containing the patient, it is necessary that the PC complies with the EN 60601-1 Standard (ref. EN 60601-1 Standard).

For the disposal of the MiniSpir, the accessories, plastic consumable materials (mouthpieces), use only the appropriate containers or return all such parts to the seller of the instrument or to a recycling centre. All applicable local regulations must be followed.

If any of these rules are not followed then MIR will decline all responsibility for any direct or indirect damages, however caused.

1.2.7 Warnings for use in electromagnetic environments

Due to the increasing number of electronic devices (computers, cordless phones, cell phones, etc.) medical devices may be subject to electromagnetic interference caused by other equipment.

Such electromagnetic interference could cause the medical device to malfunction, such as a lower measurement accuracy than stated, and create a potentially dangerous situation.

MiniSpir complies with the EN 60601-1-2:2015 standard on electromagnetic compatibility (EMC for electromedical devices) both in terms of immunity and emissions.

For the correct operation of the device, however, it is necessary not to use MiniSpir near other devices (computers, cordless phones, cell phones, etc.) that generate strong magnetic fields. Keep these devices at a minimum distance of 30 centimeters. If it is necessary to use it at shorter distances, MiniSpir and the other devices must be kept under observation to verify that they work normally.

Do not use the instrument in the presence of MRI equipment, which can generate an induced current in the sensor to measure oximetry, causing injury to the patient.

Note: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (IEC/CISPR 11 Class A). If it is used in a residential environment (for which IEC/CISPR 11 Class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment."

1.3 Unforeseen errors

If any problems should arise with the device, a message indicating the nature of the problem will appear on the screen of the PC, together with a warning "beep".

Errors in measurement or in interpretation can also be caused by:

- use by non-qualified or non-trained personnel, lacking ability or experience
- user error
- use of the instrument outside the guidelines described in this User's Manual
- use of the instrument even when some operational anomalies are encountered
- non-authorized servicing of the instrument.

1.4 Labels and symbols

1.4.1 Identification label



Symbol	Description
Model:	Product name
SN	Device serial number
	Manufacturer symbol
	This product is certified to conform to the Class IIa requirements of the 93/42/EEC medical device directive.
	In accordance with the IEC 60601-1 Standard, this product and its component parts are of type BF and therefore protected against the dangers of direct and indirect contact with electricity.
	Class II equipment symbol: as per IEC60601-1, the product complies safety requirements of Class II equipment
IPX1	Information on protection against ingress of liquids. The label indicates the degree of protection against ingress of liquids (IPX1). The device is protected against vertically falling drops of water
	To connect to other devices such as PC or printer. Use only the USB cable supplied by the manufacturer and observe the safety regulations of IEC 60601-1-1 .
SpO2	Warning symbol for the SpO2 port for oximetry (Oximetry function is on request)
	Warning symbol for the WEEE As laid down in the European Directive 2012/19/EEC requirements regarding the disposal of electrical and electronic devices (WEEE), at the end of its useful life this device must not be thrown away together with normal domestic waste as it contains materials which would cause damage to the environment and/or represent a health risk. Instead it must be delivered to a WEEE authorised collection center, where the device will then be disposed of correctly. An alternative is to return the device without charge to the dealer or distributor, when a new equivalent device is purchased. Due to the materials used in the manufacturing of the device, disposing it as a normal waste product could cause harm to the environment and/or health. Failure to observe these regulations can lead to prosecution.
	The (ESD) symbol required by the international standard is used in the vicinity of any connector which has not undergone electrostatic discharge testing.
Rx ONLY	Symbol for FDA regulation: use the device under the prescription of the physician
	Instruction for use symbol. Refer to instruction manual. Read this manual carefully before using the medical device.
	Manufacturing date of the device
	Temperature limits: indicates the temperature limits to which the medical device can be safely exposed

Symbol	Description
	Humidity limitation: indicates the range of humidity to which the medical device can be safely exposed
	Pressure limitation: indicates the range of pressure to which the medical device can be safely exposed

1.4.2 (ESD) Electrostatic discharge sensitivity symbol

WARNING

Pins of connectors identified with the ESD warning symbol should not be touched and the connections should not be made to these connectors unless ESD precautionary procedures are used.

Precautionary procedures are the following:

- Environmental procedures as: air conditioning, humidification, conductive floor coverings, non-synthetic clothing
- User procedures as: discharging one's body to a large metal object, using wrist strap connected to earth.

It is recommended that all staff involved receive an explanation of the ESD warning symbol and training in ESD precautionary procedures.

the electrostatic discharge is defined as an electric charge at rest. It is the sudden flow of electricity between two objects caused by contact, an electrical short, or dielectric breakdown. ESD can be caused by a buildup of static electricity by tribocharging, or by electrostatic induction. At lower relative humidity, as the environment is drier, charge generation will increase significantly. Common plastics generally will create the greatest static charges.

Typical electrostatic voltage values:

Walking across a carpet	1.500 – 35.000 volts
Walking over untreated vinyl floor	250 – 12.000 volts
Vinyl envelope used for work instructions	600 – 7.000 volts
Worker at a bench	700 – 6.000 volts

If two items are at different electrostatic charge levels, as they approach one another, a spark or Electrostatic Discharge (ESD) can occur. This rapid, spontaneous transfer of electrostatic charge can generate heat and melt circuitry in electronic components. A latent defect can occur when an ESD sensitive item is exposed to an ESD event and is partially degraded. It may continue to perform its intended function, so may not be detected by normal inspection. Intermittent or permanent failures may occur at a later time.

Static dissipative material will allow the transfer of charge to ground or to other conductive objects. The transfer of charge from a static dissipative material will generally take longer than from a conductive material of equivalent size. Some well known insulators are common plastics, and glass. An insulator will hold the charge and cannot be grounded and conduct the charge away.

Both conductors and insulators may become charged with static electricity and discharge. Grounding is a very effective ESD control tool, however, only conductors (conductive or dissipative) can be grounded.

The fundamental ESD control principles are:

- Ground all conductors including people
- Remove insulators, substitute with ESD protective versions
- neutralize with ionizers
- ESDS outside the EPA (ESD protected area) to be in packaging having ESD shielding property

1.5 Product description

MiniSpir is a spirometer spirometer that can also features a pulse oximeter feature (optional), and is connected to a Personal Computer using a USB cable.



The device measures a range of respiratory parameters, and the saturation of oxygen in the blood and the heart beat.

The main features of this multipurpose **MiniSpir** make it is easy to use and versatile.

Spirometry function

MiniSpir calculates up to 30 functional respiratory parameters, as well as the parameter comparison after the administration of a drug (PRE/POST) for a bronchodilator test or for a bronchial challenge test. A comparison of data is made between POST (after-drug) and PRE (before drug administration). The Pre test data relates to percentage variations between the measured results and the predicted values based on the anthropometric data inserted.

The flow and volume measurement sensor is a digital turbine, based on the infrared interruption principal, which ensures accuracy in time as required from a professional device.

The special features of this kind of sensor are listed below:

- Accurate measurement even at very low flow rates (end of expiration)
- Not affected by gas humidity nor density
- Shockproof and unbreakable
- Inexpensive to replace.

The two versions of the turbine flow measurement sensors, used on **MiniSpir** (single-patient disposable or reusable), ensure high precision in measurements and have the great advantage of requiring no periodic calibration (however, the turbines can be calibrated if required by the doctor).



In order to maintain the characteristics of the turbines the following precautions must be closely observed:

- for the single-patient disposable turbine: they must always be substituted between patients.
- for the reusable turbine: always clean the turbine between patients, to ensure the maximum level of hygiene and safety for the patient.

For a correct interpretation of a spirometry test, the measured values must be compared either to the so-called **normal or predicted values** which are calculated from the anthropometric details of the patient or, alternatively, to the personal best values from the clinical history of the subject.

The personal best values can vary considerably from the predicted values, which are taken from “healthy” subjects.

MiniSpir is connected to a PC through a USB port. Data measured by **MiniSpir** are transferred to the PC in real-time. The Windows “winspiroPro” software allows to view the spirometric test results (flow/volume curves, spirometry parameters, oximetric parameters optional) plus the related subject detail.

The data measured by **MiniSpir** and arranged by the software are available for interpretation by specialised personnel.

The software gives an interpretation of each spirometry test by assigning a “traffic light” code and by comparing the previous values of the same subject or the reference values of the subject’s group. For further details see the online manual of the WinSpiroPro Software.

MiniSpir is able to make FVC, VC & IVC, MVV and breathing profile tests, calculates an index of test acceptability (quality control) plus reproducibility of the spirometry tests carried out. The automatic test interpretation follows the latest 11 level ATS (American Thoracic Society) classification. Each test can be repeated as required. The best parameters are always available for review. The normal (predicted) values can be selected from several normal “sets”. For example, within the European Union the majority of doctors use the ERS (European Respiratory Society) predicted values. For the configuration of parameters and storing tests, see the online manual of the WinSpiroPro Software.

Oximetry function (optional)

The oximetry sensor has two light emitting diodes (LEDs), one emits in the visible spectre and one infrared. Both lights then pass through the finger and are “read” by the receiver. As these lights pass through the finger, a proportion of the light is absorbed by the blood and by the soft tissue, in function of the concentration of haemoglobin. The quantity of light absorbed, at each frequency, depends on the degree of oxygenation of the haemoglobin inside the soft tissue.

This measurement principal ensures accuracy and reproducibility, without requiring regular calibration.

1.6 Technical features

There follows a comprehensive description of the main features of the device.

1.6.1 Features of the spirometer

This device meets the requirements of the following standard:

- ATS Standardization of Spirometry 2005
- ISO 23747: 2015
- ISO 26782: 2009

Measured parameters:

SYMBOL	DESCRIPTION	m.u.
FVC	Forced Vital Capacity	L
FEV1	Volume expired in the 1 st second of the test	L
FEV1%	FEV1/FVC x100	%
FEV3	Volume expired in the initial 3 seconds of the test	L
FEV3/FVC	FEV3/FVC x 100	%
FEV6	Volume expired in the initial 6 seconds of the test	L
FEV6%	FEV1/FEV6 x 100	%
PEF	Peak Expiratory Flow	L/min
PEF Time	Time to achieve 90% of the PEF	s
FEF2575	Flow ratio at 25% and at 75%	L/s
FEF7585	Median flow between 75% and 85% of FVC	L/s
FEF25	Forced Expiratory Flow at 25% of FVC	L/s
FEF50	Forced Expiratory Flow at 50% of FVC	L/s
FEF75	Forced Expiratory Flow at 75% of FVC	L/s
FEV05	Volume exhaled after 0.5 seconds	L
FEV05/FVC	FEV05/FVC x 100	%
FEV075	Volume exhaled after 0.75 seconds	L
FEV075/FVC	FEV075/FVC x 100	%
FEV2	Volume exhaled in the first 2 seconds of the test	L
FEV2/FVC	FEV2/FVC x 100	%
FEV1/PEF	FEV1/PEF (empey's index)	L/L/s
FEV1/FEV0.5	FEV1/FEV0.5	\
FET	Forced expiratory time	s
EVOL	Extrapolated volume	mL
FIVC	Forced inspiratory volume	L
FIV1	Volume inspired in the 1 st second of the test	L
FIV1/FIVC	FIV1/FIVC x 100	%
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	%
ELA	Estimated lung age	years
*FVC	Best FVC	L
*FEV1	Best FEV1	L
*PEF	Best PEF	L/s
VC	Slow vital capacity (expiratory)	L
IVC	Slow inspiratory vital capacity	L
IC	Inspiratory capacity (max between EVC and IVC) - ERV	L
ERV	Expiratory reserve volume	L
IRV	Inspiratory reserve volume	L
FEV1/VC	FEV1/VC x 100	%
VT	Tidal volume	L
VE	Ventilation per minute, at rest	L/min
Rf	Respiratory frequency	
t _i	Average time of inspiration, at rest	S
t _E	Average time of expiration, at rest	S
t _i /t _{tot}	Average time of inspiration / total time	min
VT/t _i	Average inspiratory flow, at rest	L/s
MVV(cal)	Maximum voluntary ventilation calculated on FEV1	L/min

*= best values

Flow/volume measurement system	Bi-directional digital turbine
Temperature sensor	semiconductor (0-45°C)
Measurement principle	Infrared interruption
Volume range	10 L
Flow range	± 16 L/s
Volume accuracy (ATS 2019)	± 2.5% or 50 mL
Flow accuracy	± 5% or 200 mL/s
Dynamic resistance at 12 L/s	<0.5 cmH ₂ O

1.6.2 Features of the oximeter

For oximetry measurements, the device complies with the requirements of the following standard:

ISO 80601-2-61:2017 Medical electrical equipment - particular requirements for basic safety and essential performance of pulse oximeter equipment

Reusable hard sensor for adults		Reusable soft sensor for adults		Reusable paediatric soft sensor	
Range (SpO ₂)	Arms (%)	Range (SpO ₂)	Arms (%)	Range (SpO ₂)	Arms (%)
70-100 %	1.19	70-100 %	± 1.470	70-100 %	± 1.390
70-80 %	0.554	70-80 %	± 1.626	70-80 %	± 1.851
80-90 %	1.32	80-90 %	± 1.667	80-90 %	± 1.397
90-100 %	1.45	90-100 %	± 0.941	90-100 %	± 0.652

The Arms (Accuracy Root Mean Square), as recalled in the above mentioned standard, represents the accuracy of the device in terms of the mean square error of each SpO₂ measurement, obtained by pulse oximetry, in relation to the respective SaO₂ reference value, obtained by co-oximetry.

The ranges listed show the different oxygen saturation ranges for which the accuracy has been calculated.

The accuracy of the device can be assessed with a tester.

Measured parameters:

SYMBOL	DESCRIPTION	Units
SpO ₂ Baseline	SpO ₂ Average in first three minutes	%
SpO ₂ Min	SpO ₂ Minimum during analysis period	%
SpO ₂ Max	SpO ₂ Maximum during analysis period	%
SpO ₂ Mean	SpO ₂ Average during analysis period	%
BPM Baseline	Average pulse frequency in the first 3 minutes	BPM
BPM Min	Minimum pulse frequency during the analysis period	BPM
BPM Max	Maximum pulse frequency during the analysis period	BPM
BPM Mean	Average pulse frequency during the analysis period	BPM
Recording time	Total time measure of SpO ₂	hh:mm:ss
Analysis Time	Total time of analysis	hh:mm:ss
T90	Time passed with SpO ₂ < 90 %	% hh:mm:ss
T89	Time passed with SpO ₂ < 89 %	% hh:mm:ss
T88	Time passed with SpO ₂ < 88 %	% hh:mm:ss
T87	Time passed with SpO ₂ < 87 %	% hh:mm:ss
N. SpO ₂ Events < 89%	Fall of SpO ₂ below 89 % for at least 20 seconds	\
Δ Index (12sec)	Index of SpO ₂ fluctuation calculated in intervals of 12 seconds	\
T< 40 BPM	Time passed with pulse frequency < 40 BPM	% hh:mm:ss
T> 120 BPM	Time passed with pulse frequency > 120 BPM	% hh:mm:ss
Bradycar. Events < 40 BPM	Bradycardia events during the entire analysis period	\
Tachycar. Events>120 BPM	Tachycardia events during the entire analysis period	\

Δ=DELTA

Measurement method	Red and infrared absorption
%SpO₂ range	0 – 99% (with 1% increments)
%SpO₂ accuracy	± 2% between 70-99% SpO ₂
Average number of heart beats for %SpO₂ calculation	8 beats
cardiac pulse range	30 – 300 BPM (with 1 BPM increments)
cardiac pulse accuracy	± 2 BPM or 2%
Average interval for the calculation of cardiac pulse	8 seconds
Signal quality indication	0 - 8 segments on display
Wavelengths and maximum optical output power average of the oximetry sensors (919024, 919020)	Red light: 660 nm, 2.0 mW (**) Infrared light: 905 nm, 2.4 mW (**)
Wavelengths and optical output power of oximetry sensors (Envitec sensors)	Red light: 660 nm, 3.5-4.5 mW (**) Infrared light: 905 nm, 3.5-4.5 mW (**)

** This information may be useful to the doctor.

The specifications for both the oximetry and for the cardiac pulse are the same, regardless of which of the above mentioned oximetry sensors is used.

A more detailed specification of oximetry accuracy for some of the oximetry probes is given in Annex 2.

1.6.3 Other features

Interface	USB
Power supply	USB connection
Dimensions	142x49.7x26mm

Weight	65 grams
Storage conditions	Temperature: MIN -40 °C, MAX + 70 °C Humidity: MIN 10% RH; MAX 95%RH
Shipping conditions	Temperature: MIN -40 °C, MAX + 70 °C Humidity: MIN 10% RH; MAX 95%RH
Operating conditions	Temperature: MIN + 10 °C, MAX + 40 °C; Humidity: MIN 10% RH; MAX 95%RH
Compliance with standards	Electrical Safety Standard IEC 60601-1 EMC Standard IEC 60601-1-2
Type of electrical protection	Class II
Grade of electrical protection	BF
Grade of protection against water ingress	IPX1
Level of safety in the presence of inflammable anaesthetic gas, oxygen or nitrogen	Not suitable
Conditions of use	Device for continuous use
Storage conditions	Temperature: MIN -20 °C, MAX + 60 °C Humidity :MIN 10% RH; MAX 95%RH Atmospheric pressure: 50kPa, 106 kPa
Transport condition	Temperature: MIN -20 °C, MAX + 60 °C Humidity :MIN 10% RH; MAX 95%RH Atmospheric pressure: 50kPa, 106 kPa
Operating conditions	Temperature: MIN + 10 °C, MAX + 40 °C; Humidity: MIN 10% RH; MAX 95%RH Atmospheric pressure: 70kPa, 106 kPa
Applied norms	IEC 60601-1:2005 + A1: 2012 (Electrical Safety) IEC 60601-1-2:2015 (EMC) ATS/ERS Guidelines: 2005 ISO 26782: 2009 ISO 23747: 2015 EN ISO 14971: 2012 ISO 10993-1: 2018 2011/65/UE Directive EN ISO 15223:2016 IEC 60601-1-6: 2010+Amd2013
Essential performances (compliant with EN 60601-1:2005 + A1:2012)	Error of displayed numeric value: Flow measurement percentage error < ± 5% Oximetry parameters measuring with accuracy defined in table on §1.6.2
Emission limits	CISPR 11 Group 1 Class B
Electrostatic discharge protection	8kV contact, 15kV air
Magnetic field immunity	30 A/m
Radio Frequency Immunity	3V/m @ 80-2700 MHz

2. FUNCTIONING OF THE MiniSpir

2.1 Connection to PC

WARNING

Before connecting MiniSpir to a PC, the winspiroPro software must be installed on the PC in order to interface it with the device.

To make the connection, attach the other connector to the USB port of the PC.
When initially making a connection, the PC will, either make an automatic driver installation or request some information. To avoid errors in this phase please read the winspiroPRO User Manual very carefully.
To control the proper connection between the device and the PC use the communication check available on winspiroPRO.

2.2 Using the MiniSpir

For correct use of the device and for setup of data required for the interpretation of the results (initial setup, turbine calibration, patient data management, viewing previous data and interpretation of results) see the winspiroPro software manual.

2.3 Spirometry Testing

WARNING

The device must only be used by qualified personnel with complete knowledge of spirometry; this is important for the correct execution of the tests, for the acceptability of measured parameters as well as for the correct interpretation of results.

For correctly carrying out a spirometry test, it is strongly recommended to carefully follow the instructions as described below.

- Insert the mouthpiece supplied into the hollow part of the turbine by at least 0.5 cm.
- Fit the nose clip onto the nose of the subject to ensure that air cannot escape through the nostrils.
- Hold **MiniSpir** in one hand as you would a cell phone. The side with the **ID** label should be in the hand of the user.
- Insert the mouthpiece well into the mouth beyond the teeth, being carefully to ensure that air cannot escape from the sides of the mouth.
- It is suggested to make testing in a standing position and during an expiration lean forward, in order to help the expiratory action with a compression of the abdomen.

WARNING

Do not touch the USB cable during a test to avoid interfering with the transfer of data to the PC or stopping a test too soon.

Please note it is indispensable for an accurate spirometry that all air must be expired from lungs. It is important to stress that the disposable mouthpiece and turbine must be changed at the end of each test.

After 6 seconds from the initial forced expiratory **MiniSpir** emits a continuous beep,. This is useful to the doctor to understand if the patient has reached the minimum expiry time pursuant to the requirements as set forth by the major international associations of pneumology.

2.4 Spirometry test interpretation

The interpretation of these indices %, according to the ATS standards, generates a series of messages which correspond to possible levels of obstruction or restriction plus one level of normal spirometry, as shown in the following table:

- normal
- mild
- moderate
- moderately severe
- severe
- very severe

Through an analysis applied to some of the indices and parameters calculated in the FVC test, **MiniSpir** produces a variety of **quality control comments** useful to understand the reliability of the test made.

This control quality check assigns a letter for the current session as described below:

PRE Test

A = At least two acceptable manoeuvres, with the highest two FEV1 values matching to within 100 mL and the largest two FEV6 values within 100 mL.

B= At least two acceptable manoeuvres, with the FEV1 values matching to within 101 to 150 mL

C= At least two acceptable manoeuvres, with FEV1 values matching to within 151 to 200 mL

D= only one acceptable manoeuvres, or more than one, but the FEV1 values not matching to within 200 mL (with no interpretation).

F= No acceptable manoeuvres (with no interpretation).

POST Test

A = two acceptable (1) FEV1 values matching within 100 mL

B= two acceptable (1) FEV1 values matching within 200 mL

C= two acceptable (1) FEV1 values that do not match within 200 mL

D= only one acceptable (1) FEV1 manoeuvre

F= No acceptable (1) FEV1 manoeuvres

Acceptable manoeuvre means: good start and satisfactory exhalation (duration and flow)

Where several *comments* related to the single test are calculated, **MiniSpir** will only show the most important to facilitate the test interpretation.

ERROR IN Vext and PEF

If the extrapolated volume Vext is greater than 500 mL or greater than 5% of the FVC, or if the PEFT (time to peak flow) is greater than 200 ms, then the following comment is shown:

REPEAT TEST AND BLOW FASTER

FET error

If FET is less than the minimum (6 seconds) the message appears, this message is shown

EXPIRY TIME INSUFFICIENT <6s

FLOW ERROR

If the last flow point of the F/V curve is greater than 200 mL/s, this indicates that the expiration was not complete and thus the following comment is shown:

BLOW OUT ALL AIR IN LUNGS

Between two tests, **MiniSpir** evaluates the repeatability of the following parameters:

If FVC is > 1.0 L then:

FEV1 repeatable when the difference between the two largest FEV1 is ≤ 150 mL;

FVC repeatable when the difference between the two largest FVC is ≤ 150 mL;

if FVC is ≤ 1.0 L then:

FEV1 repeatable when the difference between the two largest FEV1 is ≤ 100 mL;

FVC repeatable when the difference between the two largest FVC is ≤ 100 mL;

2.5 Oximetry testing

WARNING

If MiniSpir as been purchased without the oximetry option, then only spirometry tests can be made

WARNING

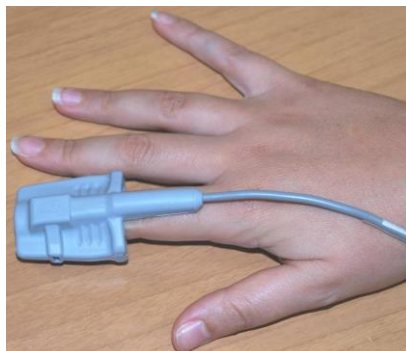
The sensors described below are for illustration purposes only. MiniSpir is enabled for the use of any of the sensors described in the Paragraph 1.2.4. MIR does not recommend the use of a specific type of sensor; any decision in regard is made by the individual doctor.

Re-usable finger sensor

This sensor is recommended for patients weighing > 20 Kg with limited activity.

Carry out an oximetry test as follows:

- Connect the sensor to the instrument: insert the connector with the arrow (printed on the connector) face-up, as shown:
- Choose a high perfusion site, easily adaptable to the sensor
- Insert finger into the sensor until the finger touches the end of the probe. Ensure that the bottom part of the finger completely covers the detector. If the finger is not able to be correctly positioned, use another finger.



- Position the sensor so that the cable is underneath the top of the hand. This enables the light source to remain on the fingernail and the detector on the bottom part of the finger.

WARNING

In order not to compromise the reproducibility of the measurements and the integrity of the sensor, avoid twisting the sensor cable and handle it with care when using, connecting, disconnecting and when placing the finger into it.

During the first few seconds of the test the device searches for the best signal, after which the timer re-sets to zero and **MiniSpir** starts to memorise the data.

If the sensor has not been correctly inserted, the message "Sensor unplugged" will appear on the PC screen.

If the sensor has been inserted but the finger is not inserted correctly, the message "Finger not detected correctly" will appear on the PC screen.

If the sensor correctly receives the signal, after a few seconds the device starts to 'beep' and the values will be displayed on the PC screen.

WARNING

A test is archived using the name of last patient visualised. If this refers to a patient whose data has already been inserted in the past, call up a previous test carried out on the patient in question and proceed as described in the final part of paragraph 2.6.

WARNING

For archiviations method of the tests please see on line manual of winspiroPRO software

Reusable "soft" sensor**WARNING**

The materials used for manufacturing the sensor are NATURAL LATEX PROTEIN free. The materials used for the sensor are subject to biocompatibility tests.

Adult Patient Sensor – Instructions for Use

- Choose an application site on the patient's finger or toe where the light source will be directly over and in-line with the detector. The preferred sites are the forefinger or smaller thumb.
 - Remove nail polish or artificial fingernails
 - Place the patient's digit in the sensor nail-side up, lining up the digit's pad over the detector. The sensor's positioning line runs across the mid axis of the fingertip
- 
- Wrap the bottom adhesive around the digit, being careful not to cover the nail.
 - Fold the sensor's top over the digit, making sure the light source is directly over and in-line with the detector. Route the cable along the palm or the bottom of the foot, and secure with adhesive tape if necessary.
 - Connect the sensor to the instrument: insert the connector with the arrow on the connector face-up and control the correct functioning according to the previous instructions.

WARNING

Do not twist unnecessarily or use excessive force when using, connecting, disconnecting, or storing the sensor. An over-tight sensor can produce inaccurate saturation measurements. It is recommended to fasten the cable to the wrist with a bandage.

3. DATA TRANSMISSION**WARNING**

Read the instructions carefully before starting the transmission of data taking due care in ensuring that all the information has been properly understood.

3.1 Transmission with USB cable

All data in the **MiniSpir** is transferred through a USB cable connection. Refer to Paragraph 2.1 of this Manual to connect the device to a PC. The data measured by **MiniSpir** during a spirometry test are sent to the PC in digital form and managed by the winspiroPro software.

WARNING

Do not disconnect MiniSpir from the PC during a test. Before to disconnect MiniSpir from the PC close winspiroPRO software. To disconnect MiniSpir remove the USB cable from the PC connector. For more details read the winspiroPRO user manual.

3.2 Upgrade Internal software

MiniSpir software can be upgraded when connected to a PC via USB. Upgrades can be downloaded by registering on www.spirometry.com. For further information on upgrading software see the winspiroPro software manual.

4. MAINTENANCE

WARNING

No part can be subjected to maintenance during use.

MiniSpir is an instrument that requires very limited maintenance. The operations to perform periodically are:

- Cleaning and controlling of the reusable turbine
- Changing the single-patient disposable turbine at each test
- Cleaning of the oximetry sensor (for reusable sensors)

The maintenance operations set forth in the User's Manual must be carried out carefully. Failing to observe the instructions contained in the manual may cause errors in measurement or in the interpretation of measured values.

Modifications, adjustments, repairs, and reconfiguration must be carried out by the manufacturer or authorised persons.

In case problems arise do not attempt to personally repair the unit.

The setting of configuration parameters must be carried out by qualified personnel. In any case the risks pertaining to incorrect settings do not constitute a hazard for the patient.

4.1 Cleaning and controlling the reusable turbine

The turbine utilized on MiniSpir belongs to one of two categories: disposable and reusable. Both guarantee precise measurements and have the great advantage of requiring no periodic calibration. In order to maintain the characteristics of the turbine a simple cleaning is required prior to each use (**only for the reusable turbine**).

Cleaning of the **disposable turbine** is not required, as it is supplied clean in a sealed plastic bag. It must be disposed of after use.

It is a good practice to control from time to time that dirt or foreign bodies are not deposited inside the turbine such as threads or hair. Any such deposit could brake or block the rotation of the turbine blade and thus compromise the measurement accuracy.

To clean the **reusable** turbine, remove it from its compartment on the MiniSpir by turning it anti-clockwise and pressing lightly. It can be helpful to push it gently from underneath with one finger.

Immerse the turbine in the recommended cold detergent solution, and move it within the liquid to remove any impurities which may be deposited inside. Leave the turbine immersed for the time specified in the instruction of the solution.

To avoid any kind of damage to the reusable turbine please do not use any alcoholic or oily substances, do not immerge the turbine in hot water or hot solution.

Do not put the turbine under a direct jet of water or other liquid. If no detergent solution is available, clean the turbine in clean water.

MIR suggest the use sodium hypochlorite which has been tested on all MIR sensors.

Rinse the turbine by immersing it in clean water (**not hot**).

Shake off the excess water from the turbine and leave it to dry, standing it vertically on a dry surface.

Once the turbine has been cleaned insert the turbine tube in its place according to the direction as indicated by the closed lock symbol printed on the plastic casing of the MiniSpir.

To correctly insert the turbine push it to the end and turn it clockwise until reaching the wedge which ensures that the tube has been blocked inside the plastic casing.

When using the disposable turbine, do not clean it, but change it after each patient.

4.2 Cleaning the oximetry sensor

The reusable oximetry sensor must be cleaned whenever the patient changes, before to apply the sensor to another patient.

Clean the sensor with a soft cloth moistened with water or a mild soap solution. To disinfect the sensor, rub with isopropyl alcohol. Allow the sensor to dry completely after cleaning.

WARNING

Do not sterilize by irradiation, steam, or, ethylene oxide. Do not immerse in liquids.

Unplug the sensor from the device before cleaning or disinfecting it.

5. PROBLEM SOLVING

PROBLEM	MESSAGE	POSSIBLE CAUSES	REMEDY
MiniSpir does not connect with the PC	\	The USB cable is not correctly connected	Check the correct connection of the USB cable side Pc
	\	The driver doesn't work correctly	Check the presence of the device in the list of USB devices connected. Try to remove and connect the device.
Spirometry data at the end of the test are not acceptable	\	The turbine don't rotate correctly	Clean the turbine and check another time; use a new turbine
	\	The test is performed in a wrong way	Repeat the test following the indications on the screen
During an oximetry test the values are wrong, irregular	\	The sensor is positioned in a wrong way or the perfusion index of the patient is low	Put the sensor in another position.
	\	The patient is moving	To obtain an accurate measurement the patient should not make sudden movements.

6. LIMITED WARRANTY CONDITIONS

MiniSpir, together with its standard accessories is guaranteed for a period of 12 months if intended for professional use (doctors, hospitals, etc.).

The warranty is effective from the date of purchase contained in the relevant sales invoice or proof of purchase.

The instrument must be checked at the time of purchase, or upon delivery, and any claims must be made immediately in writing to the manufacturer.

This warranty covers the repair or the replacement (at the discretion of the manufacturer) of the product or of the defective parts without charge for the parts or for the labour.

All batteries and other consumable parts, reusable turbine included, are specifically excluded from the terms of this guarantee.

This warranty is not valid, at the discretion of the manufacturer, in the following cases:

- If the fault is due to an improper installation or operation of the machine, or if the installation does not conform to the current safety norms in the country of installation.
- If the product is utilised differently from the use described in the Users Manual.
- If any alteration, adjustment, modification or repair has been carried out by personnel not authorised by MIR.
- If the fault is caused by lack of or incorrect routine maintenance of the machine.
- If the machine has been dropped, damaged or subjected to physical or electrical stress.
- If the fault is caused by the mains or by another product to which the instrument has been connected.
- If the serial number of the instrument is missing, tampered with and/or not clearly legible.

The repair or replacement described in this warranty is supplied for goods returned at the customers' expense to our certified service centres. For details of these centres please contact your local supplier of the spirometer or contact the manufacturer directly.

The customer is responsible for the transportation and for all transport and customs charges as well as for delivery charges of the goods both to and from the service centre.

Any instrument or accessory returned must be accompanied by a clear and detailed explanation of the defect or problem found. If units are to be returned to the manufacturer then written or verbal permission must be received before any instruments are returned to MIR.

MIR Medical International Research, reserves the right to modify the instrument if required, and a description of any modification made will be sent along with the returned goods.