MiniSpir Light

MEDICAL INTERNATIONAL RESEARCH

User Manual Rev. 2.2.1

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English

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

Before using your MiniSpir Light …

- 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 MIR Spiro 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 Light** should only be connected to a computer manufactured in compliance with EN 60950.

WARNING ⚠

Before connecting MiniSpir Light to a PC, carry out all the necessary steps for the correct installation of the MIR Spiro software that can be downloaded from the MIR website. 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 MIR Spiro 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.

Manufacturer's address

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

CE 0476

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1. INTRODUCTION

1.1 Intended Use

MiniSpir Light spirometer 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

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

1.1.1 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.

1.1.2 Operating environment

MiniSpir Light 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 1.6.2.

WARNING ⚠

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

1.1.3 Who can or must make the installation

The device requires installation by qualified personnel.

1.1.4 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.

1.1.5 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.

Spirometry has relative contraindications, as reported in the 2019 update of the ATS/ERS guideline:
Due to increased myocardial demand or changes in blood pressure

- Acute myocardial infarction within 1 week
- Systemic hypotension or severe hypertension
- Significant atrial/ventricular arrhythmia
- Uncompensated heart failure
- Uncontrolled pulmonary hypertension
- Acute pulmonary heart
- Clinically unstable pulmonary embolism
- History of syncope related to forced expiration/cough

Due to increased intracranial/intraocular pressure

- Brain aneurysm
- Brain surgery within 4 weeks

- Recent concussion with persistent symptoms
- Eye surgery within 1 week

Due to increased sinus and middle ear pressure

- Sinus or middle ear surgery or infection within 1 week

Due to increased intrathoracic and intraabdominal pressure

- Presence of pneumothorax
- Thoracic surgery within 4 weeks
- Abdominal surgery within 4 weeks
- Pregnancy beyond term

Due to infection control problems

- Active or suspected transmissible respiratory or systemic infection, including tuberculosis
- Physical conditions predisposing to transmission of infection, such as haemoptysis, significant discharge or oral lesions or oral bleeding.

1.2 Important safety warnings

MiniSpir Light 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 Light is throughly tested during its production and therefore the product complies with the safety requirements and quality standards laid down by Regulation (EU) 2017/745 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 fom the device and result in improper operation.

The device should not be used beyond the declared life span. In normal conditions the lifespan of the device is estimated to be around 10 years.

Notice
You must report any serious incidents occurring in relation to the device to the manufacturer and the competent authority of the Member State where the user and/or patient is established, in accordance with Regulation 2017/745.

1.2.1 Danger of cross-contamination

One type of turbine sensor can be used with the device: the single-patient disposable. 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 disposable flow sensor must always be changed before each subject,. The use of an anti bacterial filter is at the discretion of the doctor.

1.2.2 Turbine

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.

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 turbine

WARNING ⚠

The turbine flow sensor does not require calibration. If a calibration must be made then the following guidelines should be carefully noted.
Calibration can be made using a siring a calibration syringe ad 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 Light is calibrated correctly then the FVC (syringe) value will be:
3.00 (FVC) x 1.026 (BTPS) = 3.08 L (FVC at BTPS).
If the ambient temperature is 20°C, the FIVC (syringe) value will be:
3.00 (FIVC) x 1.102 (BTPS) = 3.31 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 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 Light**. The use of other types of cables can lead to inaccurate measurements.

1.2.4 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.

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

1.2.5 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 Light 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 Light 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 Light 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 for measuring 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.

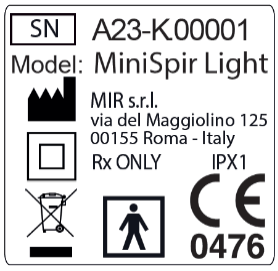
1.3 Unforeseen errors

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-authorised 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
CE 0476	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
	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
	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
MD	The symbol indicates that the product is a medical device
UDI	The symbol indicates the Unique Device Identification
	The symbol indicates that the device must not be exposed to direct sunlight
	The symbol indicates that the device must be kept dry

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 Light is a spirometer, and is connected to a Personal Computer using a USB cable.

The device measures a range of respiratory parameters,.
The main features of this multipurpose **MiniSpir Light** make it is easy to use and versatile.

Spirometry function
MiniSpir Light calculates 10 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 POST session is available only on the **MiniSpir Light BD** version.
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 turbine flow measurement sensors, used on **MiniSpir** 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).

DISPOSABLE TURBINE

In order to maintain the characteristics the turbines must always be substituted between patients.

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

The data measured by **MiniSpir Light** 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 MIR Spiro Software.

MiniSpir Light is able to make FVC, VC & IVC tests, calculates an index of test acceptability (quality control) plus reproducibility of the spirometry tests carried out. Automatic functional interpretation involves the levels defined by the 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 MIR Spiro Software.

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, 2019 update
- ISO 23747: 2015
- ISO 26782: 2009

Measured parameters:

SYMBOL	DESCRIPTION	m.u.
FVC	Forced Vital Capacity	L
FEV1	Volume expired in the 1st second of the test	L
FEV6	Volume expired in the initial 6 seconds of the test	L
FEV1%	FEV1/FVC x100	%
PEF	Peak Expiratory Flow	L/s
FEF2575	Flow ratio at 25% and at 75%	L/s
FIVC	Forced inspiratory volume	L
ELA	Estimated lung age	years

SYMBOL	DESCRIPTION	m.u.
EVC	Slow vital capacity (expiratory)	L
IVC	Slow inspiratory vital capacity	L

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_2O

1.6.2 Other features

Interface	USB
Power supply	USB connection
Dimensions	127x52x15 142x49.7x26mm
Weight	65 grams
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 Athmospheric pressure: 50kPa, 106 kPa
Transport condition	Temperature: MIN -20 °C, MAX + 60 °C Humidity :MIN 10% RH; MAX 95%RH Athmospheric pressure: 50kPa, 106 kPa
Operating conditions	Temperature: MIN + 10 °C, MAX + 40 °C; Humidity: MIN 10% RH; MAX 95%RH Athmospheric pressure: 70kPa, 106 kPa
Applied norms	IEC 60601-1:2005 + A1:2012 (Electrical Safety) EN IEC 60601-1-2:2015 (EMC) ATS/ERS Guidelines: 2005, 2019 update ISO 26782: 2009 ISO 23747: 2015 EN ISO 14971: 2019 ISO 10993-1: 2018 2011/65/UE Directive EN ISO 15223-1:2021 IEC 60601-1-6: 2010+Amd2013
Essential performances (compliant with IEC 60601-1:2005+A1:2012)	Error of displayed numeric value: Flow measurement percentage error< ± 5%
Emission limits	CISPR 11 Group 1 Class A
Electrostatic discharge protection	8kV contact, 15kV air
Magnetic field immunity	30 A/m
Radio Frequency Immunity	3V/m @ 80-2700 MHz

MIR will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair those part of the device that are designated by MIR as repairable by service personnel.

2. FUNCTIONING OF THE MiniSpir Light

2.1 Connection to PC

WARNING ⚠

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

To connect the device to the PC, it is sufficient to connect the standard USB socket of the device to one of the USB ports 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 MIR Spiro User Manual very carefully.
To control the proper connection between the device and the PC check that the led on the device is lit.

2.2 Using the MiniSpir Light

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 MIR Spiro 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.

- Fit the nose clip onto the nose of the subject to ensure that air cannot escape through the nostrils.
- Hold **MiniSpir Light** 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 turbine must be changed at the end of each test.

After 6 seconds from the initial forced expiratory **MiniSpir Light** 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 Acceptability, Repeatability and quality messages

Acceptability, usability, and repeatability of FVC and FEV1 parameters for each single test are defined as summarized in Table 7 of the ATS/ERS 2019 guideline:

For FEV1 and FVC	**Required for Acceptability**		**Required for Usability**	
Acceptability and Usability Criterion	**FEV1**	**FVC**	**FEV1**	**FVC**
Must have EVOL (VEXT or BEV) <5% of FVC or 0.100 L, whichever is greater	YES	YES	YES	YES
Must have no cough in the first second of expiration*	YES	NO	YES	NO
Must have no glottic closure in the first second of expiration*	YES	YES	YES	YES
Must have no glottic closure after 1 second of expiration	NO	YES	NO	NO
Must achieve one of these three end of forced expiration (EOFE) indicators: 1. Expiratory plateau (<0.025 L in the last 1 second of expiration) 2. Expiratory time >15 seconds 3. FVC is within the repeatability tolerance of or is greater than the largest prior observed FVC †	NO	YES	NO	NO
Must have no evidence of obstructed mouthpiece or spirometer	YES	YES	NO	NO
Must have no evidence of a leak	YES	YES	NO	NO
If the maximal inspiration after EOFE is greater than FVC, then FIVC - FVC must be <0.100 L or 5% of FVC, whichever is greater‡	YES	YES	NO	NO

Repeatability criteria (applied to acceptable FVC and FEV1 values)

Age > 6 years: The difference between the two largest FVC values must be <0.150 L, and the difference between the two largest FEV1 values must be <0.150 L

Age ≤ 6 years: The difference between the two largest FVC values must be <0.100 L or 10% of the highest value, whichever is greater, and the difference between the two largest FEV1 values must be <0.100 L or 10% of the highest value, whichever is greater

Abbreviations: EVOL (VEXT o BEV) = back-extrapolated volume; EOFE = end of forced expiration; FEV075 = forced expiratory volume in the first 0.75 seconds.

The grading system (above Table 10) will inform the interpreter if values are reported from usable maneuvers not meeting all acceptability criteria.

**For children aged 6 years or younger, must have at least 0.75 seconds of expiration without glottic closure or cough for acceptable or usable measurement of FEV0.75.*

† Occurs when the patient cannot expire long enough to achieve a plateau (e.g., children with high elastic recoil or patients with restrictive lung disease) or when the patient inspires or comes off the mouthpiece before a plateau.

For within-maneuver acceptability, the FVC must be greater than or within the repeatability tolerance of the largest FVC observed before this maneuver within the current prebronchodilator or the current post-bronchodilator testing set.
‡ Although the performance of a maximal forced inspiration is strongly recommended, its absence does not preclude a maneuver from being judged acceptable, unless extrathoracic obstruction is specifically being investigated.
The design of MIR spirometers with turbine is such that they are not subject to faulty zero-flow setting.

For VC test the acceptability criteria according to ATS/ERS 2019 guideline is defined as follows: the VC test is considered acceptable is there is less than a 0.025 L volume increase over 1 second; in this case the test is deemed as having a plateau.

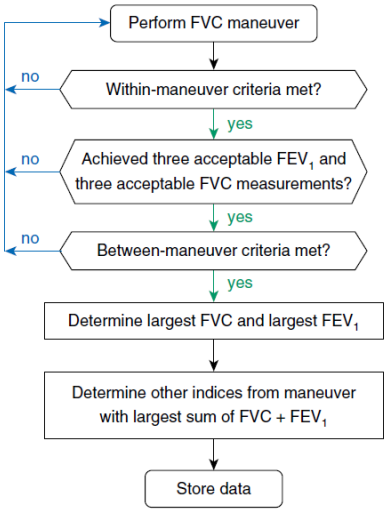
The Repeatability criteria in case of VC test is defined as follows:

Number of tests	3 acceptable tests are required
VC	The difference in VC between the largest and next largest manoeuvre must be ≤ smaller of the following: 0.150 L or 10% VC, for patient older than 6 years of age Or 0.100 L or 10% VC. For those aged 6 years or younger Otherwise, additional trials should be performed.

After each maneuver, ATS/ERS 2019 guideline provides a quality messages based on acceptability criteria define in table 7 of ATS/ERS 2019 guideline, as follows:

Warning message	Warning trigger	Instruction to patient
No plateau	no plateau and expiration < 15 s	keep going until completely empty
Hesitant start	EVOL (VEXT o BEV) exceeds limit	blast out immediately when completely full
Slow start	rise time > 150 ms	blast out immediately when completely full
Abrupt stop	suspected glottis closure	if you feel your throat closing, relax, but keep pushing
Cough in expiration	suspected cough in first second of expiration	try having a sip of water before the next blow
Hesitation at maximum volume	hesitation time > 2 s	blast out when completely full
Slow filling	mean inspiratory flow of the breath just prior to forced expiration is less than 2 L/s	breathe in faster before blasting out
Low final inspiration	FIVC < 90% FVC	after completely emptying your lungs, remember to breathe in - back to the top
Incomplete inspiration	FIVC < FVC	fill your lungs completely before blasting out – take the deepest breath possible

WARNING
The best test meeting the criteria outlined in the 2019 ATS guideline meets its accessibility guidelines, even if it is not necessarily the one with the best FVC+FEV1 sum. Therefore, it is chosen among the tests that do not provide error messages.
The following table outlines the test selection criteria by accessibility and repeatability as outlined in the 2019 ATS guideline.



Further consideration and management of particular cases are detailed in the ATS/ERS 2019 guideline.

The quality grade of a test session is expressed with a letter, which separately refers to FVC and FEV1, as described in Table 10 of the ATS/ERS 2019 guideline:

Grade	Number of Measurements	Repeatability: Age > 6 years	Repeatability: Age <6 years*
A	≥ 3 acceptable	Within0.150 L	Within0.100 L*
B	2 acceptable	Within0.150 L	Within0.100 L*
C	≥ 2 acceptable	Within0.200 L	Within0.150 L*
D	≥ 2 acceptable	Within0.250 L	entro 0.200 L*
E	≥ 2 acceptable or 1 acceptable	> 0.250 L N/A	> 0.200 L* N/A
U	0 acceptable AND ≥ 1 usable	N/A	N/A
F	0 acceptable AND 0 usable	N/A	N/A

The repeatability grade is determined for the set of prebronchodilator maneuvers and the set of post-bronchodilator maneuvers separately. The repeatability criteria are applied to the differences between the two largest FVC values and the two largest FEV1 values. Grade U indicates that only usable but not acceptable measurements were obtained. Although some maneuvers may be acceptable or usable at grading levels lower than A, the overriding goal must be to always achieve the best possible testing quality for each patient. Adapted from *Am. J. Respir. Crit. Care Med. 2017;196:1463–1472*.
*Or 10% of the highest value, whichever is greater; applies for age 6 years or younger only

2.5 Interpreting spirometry results

The interpretation of spirometry refers to Forced Vital Capacity (FVC) and is seen by means of indicator lighting.
This interpretation is calculated on the best manoeuvre according to the ATS /ERS 2019 guideline.
The messages can include the following:

- Normal spirometry
- Light obstruction/restriction
- Moderate obstruction/restriction
- Moderately severe obstruction/restriction
- Severe obstruction/restriction
- Very severe obstruction/restriction

The final interpretation level is "restriction + obstruction", where the indicator light indicates the worst parameter between restriction and obstruction.

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 Light** 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 Light** during a spirometry test are sent to the PC in digital form and managed by the MIR Spiro software.

WARNING ⚠

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

3.2 Upgrade Internal software

MiniSpir Light 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 MIR Spiro software manual.

4. MAINTENANCE

WARNING ⚠

No part can be subjected to maintenance during use.

MiniSpir Light is an instrument that requires very limited maintenance. The only operations to perform periodically is the

- Changing the single-patient disposable turbine at each test

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.

5. PROBLEM SOLVING

PROBLEM	MESSAGE	POSSIBLE CAUSES	REMEDY
MiniSpir Light does not connect with the PC	\	The USB cable is not correctly connected	Check the correct connection of the USB cable side PC and side device.
	\	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	use a new turbine
	\	The test is performed in a wrong way	Repeat the test following the indications on the screen

6. LIMITED WARRANTY CONDITIONS

MiniSpir Light, 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 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 S.p.A. - 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.