Spirotel®

User guide

Rev. 1.3

Date issued 01.04.2014
Date of approval 01.04.2014

TABLE OF CONTENTS

Thanks you for having chosen a **MIR** product

MEDICAL INTERNATIONAL RESEARCH

⚠WARNING

The nose clip and mouth piece that come supplied with the device are to be treated as single-use disposable items.

Spirotel® products are available in two versions:

- spirometer only
- spirometer with oximeter function

This manual is for the dual function device. Before reading this manual, check which version you have.

Before using your Spirotel®…

- Carefully read the user manual, the labels and all the information supplied with the device
- Configure the device (date, time, assigned values, language etc.) as described in section 2.6

⚠WARNING

Before connecting the Spirotel® to a PC, install the winspiroPRO software supplied with the device.
Once the software has been correctly installed, connect the device to the PC and a message will appear that confirms the recognition of a new peripheral device.

Keep the original packaging!
In the event of a problem with the product, use the original packaging to send it to your local distributor or to the manufacturer.

If the device is being sent for repair, the following rules apply:

- Goods must be sent in their original packaging;
- Costs involved in sending the product are at the sender's expense.

Manufacturer's address

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MIR implements a policy of constant product improvement and the technology we use is in a state of continuous evolution. For this reason, the company reserves the right to up-date these instructions if necessary. If you have any suggestions that you consider useful, please send an e-mail to the following address: mir@spirometry.com. Thank you.
MIR does not accept any responsibility for any harm or damage caused by users failing to follow the instructions or failing to heed the warnings in this manual.

1. INTRODUCTION

1.1 Intended use

The **Spirotel®** spirometer and pulse oximeter is intended to be used by a physician or by a patient under the instruction of a physician or paramedic to test lung function in people of all ages. It is also intended to be used as a single-patient device and can be used in any setting-home, factory, pharmacy, hospital or physician's office.

1.1.1 User type

The **Spirotel®** spirometer + oximeter provides information about 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 technique for using and maintaining the device along with the ability to interpret the results provided calls for a qualified health worker. Before a patient is allowed to operate the device, he or she must be taught how to use it by a qualified health worker.

⚠WARNING

MIR will not be held responsible for any harm or damage of any kind caused by mistakes made by users failing to heed the warnings in this manual.
If Spirotel® user is a person who is incapable of looking after him or herself, the device must be used under the supervision and responsibility of the person who is legally in charge of that person.
When Spirotel® device is used as an oximeter, it is intended for spot checks, bedside sleep oximetry checks during the night and/or monitoring in the presence of a specialist doctor.

1.1.3 Where the device is used

Spirotel® device was designed for use in doctors' surgeries, in hospital wards or by the patient during daily activities to monitor physical conditions. The appendix to this manual contains the information needed for the correct use of the device where electromagnetic factors affect the surrounding environment (as required by EN 60601-1-2).
When used at home, at work, in school or during sporting activities, the device records data and respiratory function parameters every day for a period of weeks or months thus helping the patient better assess his/her physical condition.
The instructions for operating the device at home are given in detail for the type of test that has to be performed; the display provides step-by-step instructions (messages, recommendations etc.) that allow the patient to perform tests properly and to obtain reliable, trustworthy results for the doctor to analyse.
The product is not suitable for use in operating theatres or in the presence of flammable liquids or detergents or where there are anaesthetic gas mixtures that become flammable in the presence of air, oxygen or nitrous oxide.
The product is not suitable for use where it may be exposed to air currents (e.g. the wind), sources of heat or cold, direct sunlight or other sources of light or energy, dust, grit or chemical substances.

It is the responsibility of the user to ensure that the product is used and stored under the proper environmental conditions; for further information, refer to the instructions in section 1.7.3 below.

⚠WARNING

If the device is subjected to climatic conditions different from those shown in section 1.7.3, it is possible that malfunctions may occur and/or that incorrect results may be displayed.

1.1.4 Use at home

If the device is used for carrying out tests at home, it must be configured for such use beforehand by a qualified person. It is the doctor's responsibility to ensure that the device is configured before giving it to the patient for use at home.

1.1.5 Individual patient factors that can affect use of the product

The spirometer can only be used when the patient is resting and is in good health or at least in a state of health that is compatible with the test being carried out. Performing the test actually calls for **collaboration** from the patient who must exhale forcefully to ensure that the parameters measured provide reliable results.

1.1.6 Limitations of use – Contraindications

An analysis of the results of spirometry alone is not sufficient to provide a diagnosis of a patient's clinical condition. A diagnosis can only be made in conjunction with an examination that takes the patient's case history into account as well as the results of other tests recommended by the doctor.
Comments, diagnosis and appropriate therapeutic treatments are made by the doctor.
Any symptoms must be evaluated before spirometry is carried out. The doctor who prescribes use of the device must first ascertain the physical/psychological capacity of the patient to assess his or her suitability for performing tests. The same doctor must subsequently evaluate the data gathered by the device to estimate the degree of **collaboration** for each test carried out.
A correct spirometry test calls for a patient's complete collaboration. The results obtained depend on the patient's ability to inhale and exhale as quickly as possible. If these key conditions cannot be met, the spirometry results will not be reliable or as doctors say, will be "unacceptable".
The **acceptability** of a test is the doctor's responsibility. Extra care must be taken when dealing with elderly patients, children or differently-able persons.
The product must not be used if malfunctions or faults are detected or suspected as these may compromise results.

⚠WARNING

When the Spirotel® device is used as an oximeter, it has a limit alarms system and for this reason the SpO2 and pulse rate shown on the display needs to be checked frequently.

1.2 Important safety warnings

Spirotel® devices have been examined by an independent laboratory that certified their conformity with EN 60601-1 safety standards and guarantee that their electromagnetic compatibility is within the limits laid out in EN60601-1-2.
Spirotel®devices are subject to continuously checks during production and therefore comply with the safety and quality standards laid down in Council Directive 93/42/EEC for Medical Devices**.**
Once the device has been removed from its packaging, examine it carefully to make sure there are no signs of damage. If any damage is found do not use the device but return it immediately to the manufacturer for possible replacement.

⚠WARNING

Patient safety and device performance are only guaranteed if warnings and current safety standards are complied with.
The manufacturers declines all responsibility for harm or damage caused by failure to follow the instructions for using the product.
The product must be used as described in the User Manual especially as regards § Intended Use and only original accessories as specified by the manufacturer are to be used. The use or turbine sensors, oximetry sensors or other non-original accessories might cause erroneous readings or compromise the correct functioning of the device. For this reason, the use of such items is not permitted.
Do not use the product if it has passed its shelf life;. Standard duration of the device is estimated at about 10 years under normal conditions of use.
The battery charge level is constantly monitored by the device itself. The device will display a message warning the user if the battery is flat.
In the event of any incident arising from use of the advise, we strongly advise the user to inform his or her doctor who will then complete the procedure laid down by Article 9 of Legislative Decree N° 46/1997 implementing EC Directive N° 93/42.

1.2.1 Risk of cross contamination

So as to avoid any risk of cross contamination, it is imperative to use a single-use mouthpiece for each individual patient.
Re-usable turbine sensors must be cleaned before being used on a new patient. The use of an anti-bacterial viral filter is left to the doctor's discretion.

1.2.2 Turbine

Re-usable turbine

⚠WARNING

The correct use of a "re-usable" turbine is guaranteed only and exclusively if it is "clean" and free from foreign bodies that alter the motion of the blades. If a re-usable turbine can is not properly cleaned, it can cause cross infection between patients. Periodical cleaning of the device is sufficient only if that device is used exclusively by the same patient. For further details about cleaning, refer to the appropriate section in this User Manual.

Never expose turbine sensors to jets of water or air or allow contact with hot liquids.
To avoid malfunctions or damage, do not introduce dust or foreign bodies into the turbine sensor. The presence of foreign bodies (such as bodily hair, hair, saliva etc.) inside the turbine flow meter can compromise the accuracy of readings.

1.2.3 Mouth piece

The single use mouth piece that comes supplied with the device is provided as a sample to demonstrate the correct type and size. It must be considered clean but not sterile. We recommend that you contact the local distributor where you bought your spirometer to obtain additional mouth pieces. These are usually made of cardboard or plastic and are always for single use only.

⚠WARNING

Use biocompatible mouth pieces to avoid problems for the patient; unsuitable materials might cause the device to malfunction and compromise the accuracy of readings.

It is the responsibility of the user to provide suitable mouth pieces. These items generally have a standard 30 mm external diameter and are commonly used by health workers. They are widely available.

⚠WARNING

To avoid contamination of the environment caused by the disposal of used mouth pieces, the user must comply with all the local regulations in force.

1.2.4 Sensor for oximetry

In addition to the sensor code number 919024_INV supplied with the device, the following specific sensors can also be used for different types of patients:

Manufacturer	Code	Description
BCI	1300	single use sensor for adults
BCI	3026	neonatal wrap sensor
BCI	3043	universal Y sensor
BCI	3078	ear sensor
BCI	3178	re-usable paediatric finger sensor
BCI	3444	re-usable finger sensor for adults (Comfort Clip)
BCI	3044	re-usable finger sensor for adults

These sensors require the use of an extension cable for connection with the **Spirotel®** Two lengths of extension cable are available:

item code 919200_INV 1.5 m in length
item code 919210_INV 0.5 m in length

The prolonged use of a sensor or a patient's condition may mean that the location of the sensor has to be changed periodically. Change the position of sensors every 4 hours and check the condition of the skin, blood flow and that the sensor is properly aligned.

⚠WARNING

The incorrect use of a sensor or faulty sensor cable may compromise the accuracy of readings that could affect the patient's condition. Check every sensor carefully before use.
Do not use sensors that appear to be or are damaged. If you do not have any more working sensors, contact your local distributor who supplied the device.
Only use MIR sensors that have been specifically designed to work with Spirotel®. The use of other sensors may provide faulty readings.
Oximetry results may be faulty if the test is performed under very bright conditions. If necessary, cover the sensor (e.g. with a clean cloth).

⚠WARNING

Any colouring agent present in the blood (e.g. for performing diagnostic tests), such as methylene blue, indocyanine green, indigo carmine, patent blue-V (PBV), can compromise the accuracy of oximetry readings.
Any condition that restricts the flow of blood, e.g. the use of a cuff to measure blood pressure, can compromise the accuracy of readings for SpO2 and pulse rate.
False nails and nail varnish must be removed before using the sensor as they can compromise the accuracy of oximetry readings.
Significant levels of dysfunctional haemoglobin such as carboxyhemoglobin or methemoglobin affect the accuracy of oxygen readings.
If two or more oximetry sensors are positioned near each other, optical interference may occur. Such interference can compromise the accuracy of oxygen readings. To eliminate any such interference, cover the sensors with an opaque material.
Dirt or obstructions that block the red light on the sensor or the detector may provide inaccurate readings or sensor malfunctions. Always make sure that the sensor is clean and free of obstructions.
Never place the sensor in an autoclave. Do not sterilise the sensor.
Before cleaning the sensor, first disconnect it from the Spirotel® unit to prevent damage to the sensor and device and to avoid compromising user safety.

1.2.5 The Spirotel® unit

⚠WARNING

All the maintenance operations described in the User Manual must be carried out with great care. Failure to follow these instructions may lead to incorrect readings or the incorrect interpretation of readings that have been taken.
All modifications, adjustments, repairs and reconfigurations must be performed by the manufacturer or by personnel authorised by the manufacturer. In the event of problems, do not attempt to make repairs. The setting of configurable parameters must be performed by qualified staff. The incorrect setting of parameters however will not compromise a patient's state of health.

The high frequencies emitted by an "electronic" device can interfere with the functioning of the device. For this reason, a minimum distance (of several metres), must be observed if there are other devices in operation in the same area. Examples of such devices include TVs, radios, domestic appliances, mobile phones, cordless phones etc.
The device may provide inaccurate readings in the presence of strong electromagnetic sources such as electrosurgical scalpels or medical devices such as CT equipment.

Do not use the device in the presence of MRI equipment that can generate an induced current in the oximetry sensor and harm the patient.

If the device is used in conjunction with other items of equipment, only equipment that complies with current safety regulations can be used so as meet the safety standards laid down by EN 60601-1-1

As regards the disposal of Spirotel® devices, accessories, plastic consumables (mouth pieces), removable components and items that are subject to ageing (e.g. the battery) only use suitable containers or better, send the materials to the device retailer or an approved disposal centre. Local current legal requirements must be complied with in all cases.
Failure to comply with the above mentioned regulations will relieve MIR of all responsibility from any direct or indirect claim for damages.
Use only the battery specified in § Technical Specifications.
The device can also be powered using a USB cable connected to a computer thus also allowing on-line operation.
Keep the device out of the reach of children and differently able persons.

1.3 Warnings regarding use of the lithium ion battery

The device is powered by a rechargeable lithium ion battery. The power supply is 3.7 V.
For correct use of the device, read the following instructions carefully.

⚠WARNING

Only use batteries supplied by MIR.

Improper use of a battery could lead to an acid leak, the emission of heat and fumes or even explosion or fire.
This could lead to deteriorated performance or damage to the battery or protective device installed in the pack. It could also damage equipment or harm the user.

Pay close attention to the following instructions.

DANGER
Do not open or modify the battery. The pack is fitted with an internal protective device; if the unit is mishandled an acid leak, the emission of fumes or even explosion or fire could follow.

Do not short the positive (+) and negative (-) terminals with metal objects.
Do not place the battery in a pocket or in a bag along with metal objects such as items of jewellery, hairpins, coins or keys.
Do not keep the device near such items.

Do not heat the battery or throw it into the fire.

Do not use or store the battery near a fire or in a car where the temperature can reach over 60°C.

Do not immerse the battery in water or seawater and do not leave it wet. In the event of the battery getting wet, the internal protective device could be damaged leading to a recharge at very high voltages and currents. Chemical reactions might also take place that lead to an acid leak, the emission of fumes or even explosion or fire.

Do not recharge the battery near a fire or in very hot surroundings. High temperatures can activate the internal protective device preventing the battery from recharging or can damage the protective device itself causing a recharge at very high voltages and currents. This could cause chemical reactions that could lead to an acid leak, the emission of fumes, rupture of the device or even explosion and/or fire.
Recharge the battery with a charger that complies with the specifications given in section 1.7.3 A recharge carried out using an unsuitable charger and under non-conforming charging conditions can cause the pack to over-charge or to a recharge at

very high voltages and currents. This could cause chemical reactions that could lead to an acid leak, the emission of fumes, rupture of the device or even explosion and/or fire.

Do not pierce the battery with sharp objects e.g. a nail.
Do not hit the battery with a hammer, stand on it, throw it or subject it to knocks. A damaged or deformed battery may have internal short circuits that can lead to an acid leak, the emission of fumes, rupture of the device or even explosion and/or fire.

Do not use a badly scratched or deformed battery as to an acid leak, the emission of fumes, rupture of the device or even explosion and/or fire could occur.

Do not solder the battery.

Do not fit the battery to the device with the terminals inverted. If it is difficult to connect the battery to the device, do not use force. Check that the terminals are the right way round. Inverting the terminals generates an inverse charge that could lead to an acid leak, the emission of fumes, rupture of the device or even explosion and/or fire.

Do not connect the battery to an electrical socket, a car cigarette lighter etc. If the pack is subjected to a high voltage, over-charging might occur that could lead to an acid leak, the emission of fumes, over-heating, rupture of the device or even explosion and/or fire.

Do not use the battery for purposes other than specified as this may affect its functionality and compromise the life span of the unit. Depending upon the device in which a battery is used, power surges can occur through the battery that can cause an acid leak, the emission of fumes, over-heating, rupture of the device or even explosion and/or fire.

If the battery leaks acid that comes into contact with the eyes, do not rub them but rinse with clean running water and contact a doctor immediately. Failure to do so may result in injury to the eyes.

WARNING
Refer to section 4.4. for instructions about battery charging cycles.

Do not place the battery in a microwave oven or a pressurised container. Rapid heating or a loss of water proofing can lead to an acid leak, the emission of fumes, over-heating, rupture of the device or even explosion and/or fire.

If the battery leaks acid or gives off a bad smell, move it away from any naked flames. Failure to do so may result in the electrolyte catching fire then emitting fumes, rupturing or bursting into flames.

If the battery gives off a smell, generates heat, becomes discoloured or deformed or displays any unusual behaviour during use, recharging or storage, remove it from the device immediately or disconnect the charger and do not use the pack. The use of a faulty battery could lead to an acid leak, the emission of fumes, over-heating, rupture of the device and/or fire.

WARNING
The battery has an in-built safety device. Do not use in an environment where static electricity may be present (in excess of the level specified by the manufacturer). Failure to comply with this may cause damage to the safety device that could result in an acid leak, the emission of fumes, over-heating, rupture of the device and/or fire.

If acid from the battery comes into contact with the skin or clothes, rinse immediately with running water to prevent inflammation of the skin.

Keep batteries out of the reach of children to prevent accidental swallowing.
If a child is to use a battery, an adult must explain the rules governing such use.

Before using the battery, read the User Manual carefully paying particular attention to correct handling procedures.
For information about fitting and removing the battery, refer to the device User Manual.
Read the User Manual carefully before charging the battery.
The battery has a predetermined life span. If the device appears to run for a shorter period of time than usual, replace the battery with a new one.
Remove the battery if it is past its expiry date.
Once the battery has been removed from the device, make sure that the (+) and (-) terminals are isolated with insulating tape; to dispose of the battery, comply with current legal requirements or place the pack in an approved recycling container or send it to an official recycling centre.
If the battery is not going to be used for a long period, remove and store the pack in an environment where the temperature and humidity levels meet specification.
If the battery terminals are dirty, clean them with a dry cloth before use.

The battery can be charged in an environment where the temperature ranges from 0°C to about 40°C.
The battery can be used in an environment where the temperature ranges from -20°C to about 60°C.

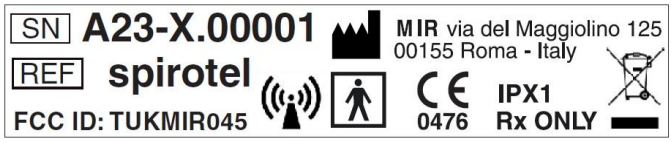
The battery can be stored in an environment where the temperature ranges from -20°C to about 60°C.

1.4 Warnings regarding the GSM module

The GSM module is based in the standard GSM system for mobile communication technology. The GSM standard is used all over the world. This covers Europe, Asia and some parts of America and Asia, it is the most used telecommunication system.
The GSM module used is a low power transmitter and receiver that transmits and receives radio signals. With the GSM application, the system manages calls, controls the radio frequency and power levels in the modem.
To reduce exposure to radio signals, limit the length of calls or use the device efficiently by complying with the following instructions.
Do not use the device if the aerial is damaged, if a damaged aerial comes into contact with the skin, it could cause a second degree burn. A damaged aerial must be replaced immediately by a qualified technician with a unit approved by the manufacturer.
In healthcare environments, some devices are shielded from radio signals and these can have a negative effect on other shielded devices. Consult the manufacturer of each medical device to see if they are suitably shielded against from radio interference.
Turn the device off in any healthcare settings where it is specifically requested to do so. Hospitals and other healthcare settings often employ radio signal monitoring equipment.
Do not use the device on board planes to prevent possible interference with flight equipment.
Keep the device out of the reach of children. The device is not a toy.
Turn the device off in any area that is potentially explosive as it can generate sparks that could set off an explosion or fire.

1.5 Labels and symbols

1.5.1 ID label



The label shows:

- Device serial number (SN)
- Product name (REF)
- Manufacturer's name and address
- WEEE symbol
- Electrical safety symbol
- Antenna symbol for devices whom include RF transmission
- CE mark as per Council Directive 93/42/EEC
- FCC Identification according to FCC standard
- Symbol for FDA regulation (Rx ONLY)
- Index protection against the penetration of external agents (IPX1)

1.5.2 CE mark for medical devices

CE
0476

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

1.5.3 Electrical safety symbol

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

1.5.4 USB port warning label

For connecting the device to a PC.
Only use cables supplied by the manufacturer and observe the **IEC60601-1-1** safety standards

1.5.5 SpO2 oximetry port warning label

SpO2

1.5.6 WEEE label

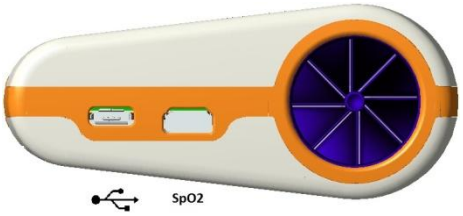
This symbol applies to European Directive 2012/19/EU about Waste Electrical and Electronic Equipment. On completion of its useful life, this appliance must not be disposed of as urban waste but must be sent to an authorised WEEE waste disposal centre.
The device can also be sent back to the original supplier free of charge when a new equivalent model is bought.
Due to the materials used in its manufacture, disposal of the device as urban waste could harm the environment and/or the health.
There are legal penalties in place for those who fail to observe the legal requirements mentioned here.

1.5.7 FCC certification label

Spirotel® complies with part 15 of FCC standards. Operation of the device is subject to the following conditions:
(1) this device must not cause harmful interference
(2) this device can be subjected to all types of interference including those which may cause undesired effects
Any modifications made without the express approval of this company may compromise the use of the device by the user.

WARNING: This device has been subjected to tests that confirm it complies with the limits of a class B digital instrument as per part 15 of the FCC Standards. These limits have been set to provide appropriate protection against interference when the device is used in the home. This device generates, uses and can emit radio signals and, if not installed and used as per instructions, can create interference with radio communications.
The absence of interference cannot however be guaranteed for all installations.
If this device causes interference to radio or TV reception (that can be determined by turning the device on and off), we recommend that the user corrects the interference by adopting one of more of the counter measures listed below:

- Change the angle or position of the aerial
- Increase the distance between the device and the appliance receiving the signal
- Connect the device to a different power socket than the appliance receiving the signal.
- Contact the supplier or radio/TV technician for expert advice.



The symbols mentioned can be found as shown in the illustration shown.

1.5.8 Electrostatic discharge symbol

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

⚠ WARNING

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 vales:

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

1.5.9 Information regarding the protection against the ingress of liquids

The label

IPX1

The symbol describes the protection of the device against the ingress of liquids. The device is protected from the vertical fall of water drop.

1.5.10 Symbol for devices that include RF transmitter

The symbol is required from the standard CEI EN 60601-1-2: 2007 point 5.1.1, for devices that include RF transmitters.

1.6 Product description

Spirotel® is a pocket spirometer that can also features a pulse oximeter function (optional). The device can operate completely autonomously or can be connected to a personal computer or printer by means of various types of connections: USB or Bluetooth.

The device is intended for measuring respiratory parameters and monitoring oxygen saturation and pulse rate. The device carries out a control test on the quality of the readings taken and can save the results of about 10.000 spirometry tests or a maximum of 300 hours of oximetry data.
Spirotel® is intended for use by medical specialists and it provides them with a powerful but compact, portable tool that can process about 30 functional parameters.
A turbine inside the device that uses the interruption of infra-red light as its operating principle, measures volume and flow rate. This operating principle ensures accurate, reproducible results without needing periodic recalibration.
The key features of this type of sensor are as follows:

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

- Unbreakable and shock resistant
- Inexpensive to replace

To keep the turbine working as it should, it must always be disinfected before use on a new patient to ensure the best possible hygiene and safety standards
To properly interpret the results of a spirometry test, it is essential to compare them with the so-called **normal values** that are calculated using standardised patient data or with **personal reference values** associated with that specific patient's clinical history.
An individual patient's clinical history values can vary significantly from normal values that always refer to a "healthy" subject.
Spirotel® can be connected to a computerised system for configuration. The spirometric data from every test is stored in the device and can be transferred to a server and displayed(flow/volume curves, spirometric parameters, oximetric parameters optional).
The device can be connected to a PC via a micro USB port to recharge the battery.

Oximetry function
The oximetry sensor features two light emitting diodes (LED), one emits visible red light and the other infra-red. Both bands of light pass through the finger to reach a light detector. During the passage through the finger, some of the light is absorbed by the blood and soft tissue depending on the concentration of haemoglobin. The amount of each light frequency absorbed depends on how oxygenated the blood is inside the tissue.
This operating principle ensures accurate and reproducible readings without the need to constantly calibrate the device.
The oximetry sensor can be disinfected with Isopropyl alcohol.

The **Spirotel®** eHealth Mini-Lab can also be configured through the Bluetooth connection. A remote hub allows the device to be configured using the options offered by the communication protocol. This protocol allows the user to define the functions to be used, the parameters to be recorded and all of the test settings required.
The device can also be used on the default "factory" settings. The following notes illustrate the base settings and the functions that can be set by the user.

1.7 Technical specifications

Below is a complete description of the specifications for the device, the volume and flow turbine and the oximetry sensor.

1.7.1 Spirometer specifications

Parameters measured:

Symbol	Description	U.M.
FVC	Forced Expiratory Vital Capacity (cL)	cL
FEV1	Forced Expiratory Volume after 1 sec (cL)	cL
PEF	Peak Expiratory Flow (cL/sec)	cL/s
FEF2575	Value of parameter FEF2575 (cL/sec)	cL/s

Flow/volume sensor	Bi-directional turbine
Temperature sensor	semiconductor (0-45°C)
Method of detection	Infra-red interruption
Maximum volume measured	10 L
Flow rate	± 16 L/s
Volume accuracy	± 3% or 50 mL
Flow accuracy	± 5% or 200 mL/s
Dynamic resistance at 12 L/s	<0.5 $cmH_2O/L/s$

1.7.2 Oximeter specifications

Specification:

Method of detection	Red and infra-red light absorption
Measuring range of %SpO_2	0 – 99% (with 1% increments)
Resolution of SpO_2	1%
Accuracy of %SpO_2	± 2% between 70-99% SpO2
Number of beats for calculating the median SpO_2 %	8 beats
Measuring range Pulse rate	18 – 300 BPM
Resolution of pulse rate	1 BPM
Accuracy Pulse rate	± 2 BPM or 2% of highest value
Interval for calculating median pulse rate	8 seconds
Signal quality	0 - 8 display segments

Definitions:

Desaturation event	Drop in SpO2 >= 4% in a 8- 40 sec period limited and subsequent rise >=2% inside an overall period of 150 sec.
Pulse variation event	Rise in Pulse >= 10 BPM in a 8- 40 sec limited period and subsequent drop >=8 BPM inside an overall period of 150 sec.

Oximetry test parameters:

Symbol	Description	u. m.
Median %SPO2	Median SPO2	%
Median BPM	Median BPM	BPM
Analysis T	total measuring time (duration of test excluding zeroes)	hh:mm:ss
T<89%	time with SPO2 less than 89%	%-hh:mm:ss
steps	Estimate of number of steps took during test	/
ODI	Desaturation events per hour of analysis	1/h
m	Estimated distance covered during the test	m

1.7.3 Other features

Memory	The memory can store the data from over 10000 spirometric tests. The exact number cannot be established as it depends on the configuration set by the doctor
Display	LCD black and white touch screen with 160x80 resolution
Keypad	None - touch screen display
Interface	USB, Bluetooth
Duration of 3.7 V Lithium battery	About 500 charge cycles, under normal condition of use
Power supply	Li-ion 3.7 V 1100mAh battery
Battery charger	Voltage = 5VDC Current = 500 mA or more Connector = Type B micro USB
Dimensions	Main body 88x74x38 mm;
Weight	central unit 151 g (including battery)
Bluetooth function	Operating frequency range: 2402 – 2480 MHz Spreading: FHSS Modulations: GFSK, PI/4-DQPSK, 8-PSK Number of channels: 79 hopping channels at all Channel spacing: 1 MHz Number of antennas: 1 Antenna type: Integrated ceramic chip antenna Antenna gain: 0 dBi Output power: 0.1 mW FCC-ID: TUK-MIR045
GSM function	Quad-Band 850/900/1800/1900 MHz. EDGE (E-GPRS) multi-slot class 10. GSM 850/900MHz power class 4 (33dBm). GSM 1800/1900MHz power class 1 (30dBm). Internal antenna (gain 2.42 dBi). SMS MT, MO. SMS CB. SMS storage into SIM card. Internet protocols: TCP/IP, SSMTP, FTP, HTTP, POP3. Secure connection protocol: SSL. Symmetric key encryption: DES, 3DES, RC2,RC4. Asymmetric key encryption: RSA, DSS. Certified R&TTE, FCC, PTCRB.
Type of electrical protection	Class *II*
Degree of electrical protection	BF
Degree of protection against water penetration	IPX1 appliance protected against water leaks
Safety level in the presence of flammable anaesthetic gases, oxygen and nitrogen	Appliance not suitable
Conditions of use	Device for continuous use
Storage conditions	Temperature: MIN -20 °C, MAX + 60 °C Humidity: MIN 10% RH; MAX 95%RH
Operating conditions	Temperature: MIN + 10 °C, MAX + 40 °C; Humidity: Humidity: MIN 10% RH; MAX 95%RH
Applicable standards	Electrical Safety IEC 60601-1

Acoustic signalling:

- Beeps with frequency depending on pulse rate
- Sounds in the event of passing preset threshold values of the $\%SpO_2$ or pulse rate
- Sounds during oximetry if battery low
- Sounds where no signal present (finger not inserted properly, connector not properly attached)
- Sounds the next time the device is turned following an interrupted test due to low battery

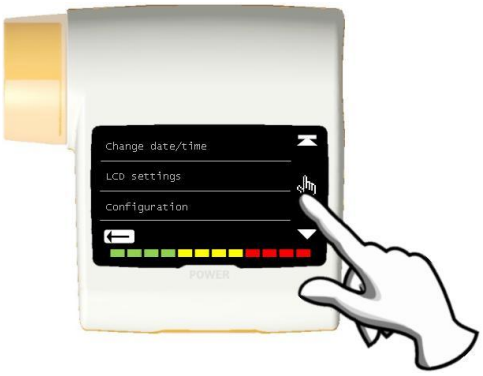
The specifications that apply to oximetry and pulse rate are the same regardless of the sensor used as long as it is one of those mentioned beforehand.

2. USING THE Spirotel®

2.1 Display

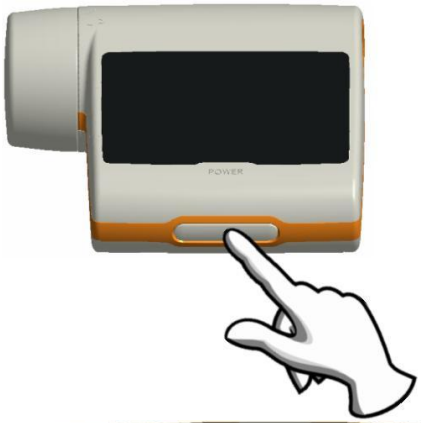
The device does not have a keypad. Simply tapping the touchscreen provides access to all functions.
The touchscreen controls change dynamically in line with the operations performed.
To access a function, press the relevant icon on the display.

To see the list of information, scroll down the right side of the screen.



2.2 Turning the Spirotel® ON and OFF

To turn **Spirotel®** ON, press then release the key on the bottom of the unit



When the device is turned on, the screen shows the manufacturer's name as well as the time and date.
If the screen is not touched, the display will automatically visualise the main menu after a few seconds.

To turn **Spirotel®** OFF, press the key at the bottom of the device then the OK icon at the bottom right of the screen. Keeping the key at the bottom of the device pressed will also turn the unit OFF.
The message alongside, that appears after pressing the key, will guide you through the correct procedure.

2.3 Saving energy

⚠WARNING

When the device is turned on, the display will go into energy saving mode after about 1 minute of inactivity. This automatically lowers the set level of contrast on the screen.
If the device remains inactive for about 5 minutes and is not connected to a PC or battery charger, it emits a beep and turns itself OFF.

The battery charge is displayed when the device is turned on with the following symbol:

This configuration shows that the pack is charged (5 bars). A decreasing number of bars appears as the charge drops.

2.4 Main screen

The following areas can be accessed from the main screen:

 diary area (not enabled in default configuration)

 spirometry area

 oximetry area

 last test results area

 send data area

2.5 Symbols and icons

The following table shows the icons displayed on the various screen and what they mean

ICON	DESCRIPTION
	To go back
	To access oximetry area
	To access spirometry area
	To access the diary area
	To display the last test performed on current patient/display values from a test
	To send data to a phone by e-mail
	To select male patient
	To select female patient
	Change the current set value
	To enter new patient data
	To check the alarms and thresholds set during an oximetry test
	To check the alarms and thresholds set during an oximetry test when at least one parameter is set to OFF
	Alarm warning system enabled during oximetry test/To temporarily disable the alarm
	Alarm warning system disabled during oximetry test/To enable the alarm
	To access the diary area

2.6 Service menu

To access the menu, touch the display on the bottom right and keep it pressed for several seconds.
The service menu will display the following headings

- Change date/time
- LCD settings
- Configuration
- Bluetooth settings
- Info firmware

When you access "Configuration", you can set other options on the device. To access this area, enter the following password:

1 2 2 3 3 3

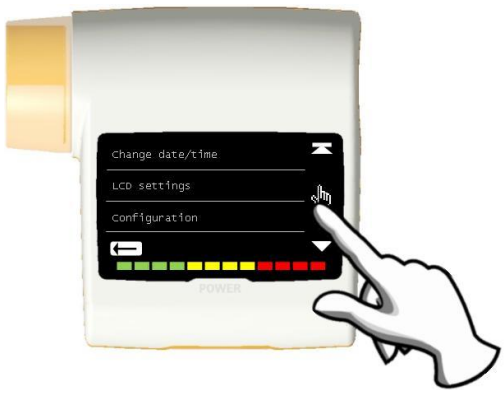
The headings in this sub-menu are as follows:

- Turn ON mode
- Patient data
- Oximetry setup
- Set questions
- Set symptoms
- Personal best
- Select predicted
- Select standard
- Turbine calibration
- Select language
- Date format
- Unit format
- Delete memory
- Email/FTP

Scroll the various headings of the menu as defined in section 2.1; display the heading you want by touching it on the display.
The headings identified with an * are present under the heading "Configuration"; when you touch that heading you will be asked to enter the following password:

1 2 2 3 3 3

Touch OK to access other headings in the menu.



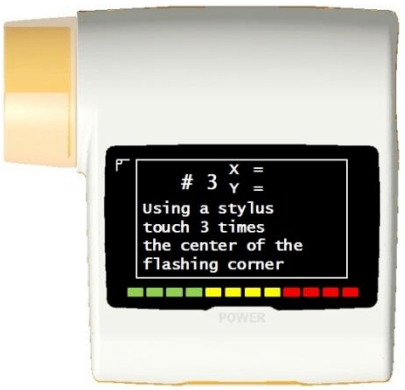
Change date/time
Touch the display to select the heading.
When setting the time and date, the cursor _ indicates the data that will be modified. Use the numbers shown on the screen to modify the date involved, go to the next date with OK. Finally, touch OK per confirm the settings and go back to the service menu; to go back to the service menu without modifying the data, touch ←.

LCD settings
Through this menu you can:

- Set the display brightness and contrast
  There are two ranges that range from 0 to 31 that let you set the display parameters and see the result in real time; once you have found the best combination for your needs, touch OK at the bottom right of the display
- Touch screen function calibration
  This function lets you control correct touchscreen response; when you select the function, a confirmation message appears, touch OK to access calibration.

The procedure is in four stages:

- touch the spot at the top left three times in succession
- touch the spot at the top right three times in succession
- touch the spot at the bottom right three times in succession
- touch the spot at the bottom left three times in succession



The reference point is the one inside the flashing diagram.
This procedure calibrates the touchscreen to match the size of the screen itself.
The procedure must be performed using the tip of a touchscreen stylus from as vertical a position as possible in relation to the screen.

If the calibration procedure is successful, the following message will appear:

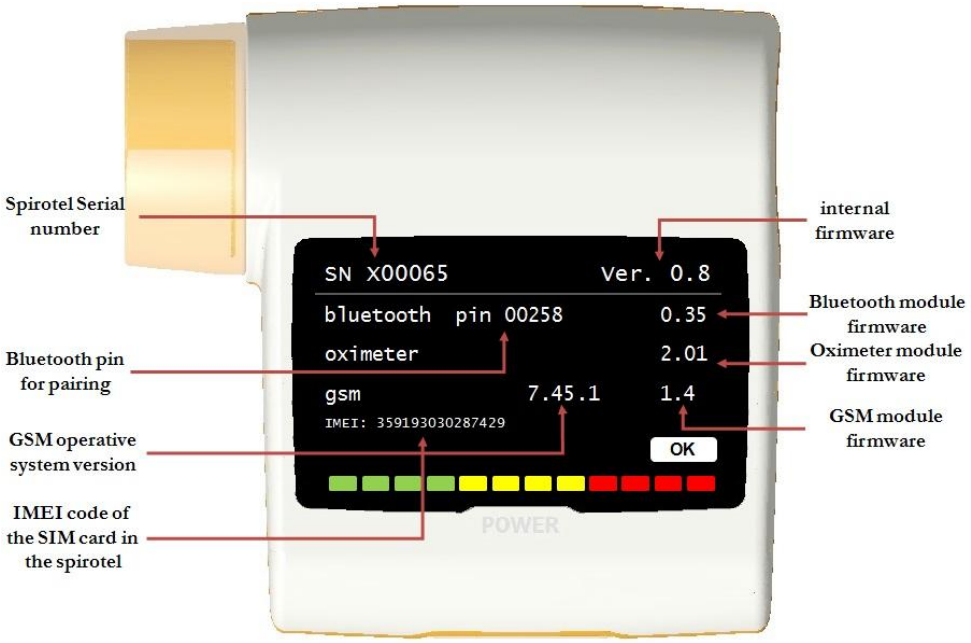
The calibration is OK

If unsuccessful, you will be asked to repeat the procedure.
During calibration, it is not possible to stop the procedure. Carry out the procedure correctly then return to the service menu.

Configuration
This section deals with this menu heading. As mentioned previously, this menu heading allows you to access other function settings, however, these have been set by the doctor who prescribed the device.

Bluetooth settings
The menu lets you choose how you want Bluetooth to be enabled.
Activation: it can be possible to choose between: "On request" and "Always on"; with the former, the function is only enabled when you need it (e.g. to print a test) and otherwise remains off in energy saving mode; with "Always on", the function is always enabled and ready for use (e.g. for transferring data to a mobile phone).
Pairing: lets you automatically connect with a device in such a way that the spirometer acts as a "slave" device.
Search devices: to look for devices that are available for connection. The **Spirotel®** will start searching for nearby Bluetooth devices; On completion, the names of any devices found will be displayed on the screen and simply touching these names will save them to the device. These can include appliances such as a printer, phone or an on-line PC; select one item. If a device has previously been found and connected, an icon will appear that identifies the previous connection (phone, printer or PC).
Option printer, Option phone, Option PC – On line: you can select a device as the default unit by opening the list, touching the display and selecting that device (with which the **Spirotel®** will then automatically connect). Alternatively, you can remove a device from the (in which case you will be asked to confirm the removal by pressing OK).
To exit the screen without making any changes, press ← at the bottom left of the screen.

Info Firmware
This function provides you with information about the revision status of the following components:



To exit the service menu, press OK at the bottom right of the screen.

2.6.1 Configuration menu

Set oximeter
On opening this menu, the following headings will appear:

- Turn ON mode
- Patient data
- Oximetry setup
- Set questions
- Set symptoms
- Personal best
- Select predicted
- Select standard
- Turbine calibration
- Select language
- Date format
- Unit format
- Delete memory
- Update GSM firmware

Tun ON mode
This function lets you set a certain hour at which the device will automatically turn itself on. The device will then start and perform an automatic oximetry test while you are sleeping (this test can also monitor the patient throughout the whole day evaluating rates and VMU).
The device will automatically switch itself off at the preset time.

WARNING

If the device is set to automatically switch on, it is impossible to turn it off during the test. The closed padlock icon to the middle right advises the user about the current setting.

Select the heading you want then choose between the following options:

- Manual
- Automatic

Manual: lets you choose when to turn on the device.
Automatic: lets you programme the frequency and duration of when the device is turned on. Select your preference and press OK.
If you select automatic mode, the following options will appear:

- Once time only
- Once a week
- Monday to Friday
- Saturday - Sunday
- Every day

a menu will appear for each option that lets you set the time and day parameters for switching on/off

Patient data
Through this menu you can:

change current patient data

create a new patient

The  icon lets you change the current patient's data; in this mode patient data are shown on different screens; to change the data, use the alphabetic or numeric keypads that will appear as and when needed.

⚠WARNING

Selecting this function does not create a new patient as described beforehand, but changes the data of the same patient and associates future test data with that patient who is always identified with the same unique ID code.

To go back to the main screen without making any changes, press ←.
Press one of the two options; the steps needed to properly manage patient are as follows:

First screen (name)
Use the keypad to enter the patient's name. On completion, press OK to go to the next screen.
Second screen (surname)
Use the keypad to enter the patient's surname then press OK

Third screen (date of birth, weight, stature and gender)
Use the numbers shown at the bottom of the screen, set the day, month and year of the patient's birth followed by stature and weight; the last item to set is the patient's gender that you can select from the following icons:

 Male  Female

Press OK to move from parameter to the next.

Fourth screen (ethnic group)
Set a correction factor: this value allows adapting test data to the ethic group to which the patient belongs (you can also set "without correction");

ATS/ERS standards		NHANES III standards
Group	**% correction**	
Without correction	100%	Caucasian
Caucasian	100%	Afro-American
Oriental	100%	Mexican-American
Hong Kong Chinese	100%	Others
Japanese	89%	
Polynesian	90%	
North Indian	90%	
South Indian	87%	
Pakistani	90%	
Of African descent	87%	
Aborigine	85%	

In the case of ATS/ERS standards: depending on the ethnic group set, the correction percentage acts on the theoretical values of the following parameters:

FVC, FEV1, FEV3, FEV6, VC

In the case of NHANES III standards: depending on the ethnic group set: different theoretical formulae are taken into account (in accordance with the reference standard).
Once the desired ethnic group has been selected, the device completes defining the patient parameters and returns automatically to the main screen.
Should you need to interrupt entering data, press ← that will take you back to the main screen.

Oximetry setup
Alarms setting
This function lets you set both SpO2 and BPM thresholds; if the readings drop below the minimum or exceeds the maximum levels during oximetry, a warning beep will sound.

The first parameter that can be configured is the beep for which you can choose type and volume; both parameters have two values:

Type 1 kHz 4 kHz
Volume min MAX

as can be seen in the diagram alongside.

Press the corresponding box for the value you want.
Press OK at the bottom right to set the minimum and maximum thresholds. For each parameter, the screen lets you set the alarm for on or off (press ON and OFF) or you can change a threshold setting by pressing  .

The sequence of the values is as follows:

Parameter	Min value that can be set	Max value that can be set
SpO2 min	85	99
SpO2 max	85	99
BPM min	25	235
BPM max	30	240

⚠WARNING

If the maximum value of a parameter is less than or equal to the minimum value, the setting process will not proceed. A beep will sound and the device will automatically return to the screen for setting the minimum value.

Once you have set the maximum BPM value, pressing OK will take you to enabling the alarm beeps for various conditions of use. The sequence is as follows:

- Finger withdrawn
- Sensor deactivated
- Battery flat

The diagram alongside illustrates setting the on-off alarm where the finger is inserted.

SpO2 Sampling rate
This function lets you set the time that passes between saving consecutive oximetry parameter values; press one of the two values shown: 2 seconds or 4 seconds, press OK to set the chosen value and to return to the service menu.

Pulse tone ON/OFF
This function lets you chose whether to have the beep sound with every heart beat during the oximetry test.

Default alarms
This function lets you restore all the settings to preset values. You will be asked to confirm your choice; if you agree, press YES and the settings will be restored to their standard values. The diagram alongside illustrates the factory settings.

After a few seconds, the device will show the oximetry setting menu.

Set questions
This function lets you set the questions that are asked of patients before when device is turned on; the following chart shows the headings that can be set and the reply options that a patient can select:

Question	Possible replies	
Taken drug?	No	Yes
Taken oxygen?	No	Yes
Are you working?	No	Yes
Mood		

Set symptoms
This function lets you set groups of questions that are asked of patients every time a test is performed; the following chart shows the headings that can be set and the reply options that a patient can select:

Symptom	Reply		
Tiredness on walking	NO	MEDIUM	MAX
Daytime drowsiness	NO	MEDIUM	MAX
Breathless on walking	NO	MEDIUM	MAX
Troubled sleep	NO	MEDIUM	MAX
Wheezing	NO	MEDIUM	MAX
Cough score	NO	MEDIUM	MAX
Sputum production	NO	LIGHT	DARK
Sputum increasing	NO		YES
Breathlessness	NO	EFFORT	AT REST
Fatigue	NO	MEDIUM	MAX
Chest tightness	NO	MEDIUM	MAX

Once the symptoms have been enabled by the doctor, the patient can jump the question and go to the next.

Personal best
You can set the reference parameter with which value the spirometry test report will be made You can choose from the following parameters:

FVC FEV1 PEF FEF-2575

Each of the test values can be checked with either a personal value set by the doctor or with a theoretical value by selecting one of the following headings:

- Personal value
- Theoretical value

Select predicted
Touch the display to select the heading.
A list of theoretical authors available will appear; select the desired theoretical value.

Adults	Children
ERS	Knudson
Knudson	Knudson
USA	Knudson
ERS	Zapletal
MC-Barcelona	Zapletal

Select the pair that you want to set then press OK and the device will return to the service menu.

Select standard
Touch the display to select the heading.
Select the standard that you want to use (ATS/ERS or NHANES III) then press OK and the device will return to the service menu.

⚠WARNING

If you select NHANES III, you cannot set or change the theoretical references.

Turbine calibration
Selecting this function gives you a sub-menu with the following headings:

- Show current settings
- Modify calibration
- Factory defaults

The first heading lets you see the current correction percentages.
"Change calibration" lets you enter new values calculated to perform a new calibration; you will be asked for a password before you can change data; the password is as follows:

1 2 2 3 3 3

"Factory settings" lets you delete any entered calibration values and you can also reset the two correction percentages to zero; in this case too, you need to enter the password as above.
Refer to section 2.6.1. for further instructions about the above operation.

Set language
Select the heading that you want to set then press OK. The language will be set and device will return to the service menu.
The languages available are:

- English
- Italian
- French
- French (France)
- Spanish
- German

Date format
Touch the display to select the heading.

dd mm yy
mm dd yy
yy mm dd

Select the format that you want to set then press OK. The format will be set and the device will return to the service menu.

Unit format
Touch the display to select the heading.

Imperial in, lb

Metric cm, kg

Select the format that you want to set then press OK. The format will be set and the device will return to the service menu.

Delete memory
Touch the display to select the heading.
If you really want to erase the device memory, enter the following password:

1 2 2 3 3 3

if you make a mistake entering the password, the following message will appear:

Password ERROR
Press OK to try again

If you fail three times in a row, the device will turn itself off automatically.
If on the other hand you are successful, the following message will appear:

PLEASE WAIT
Erasing memory

After about 30 seconds, the following message will appear:

The memory has been erased

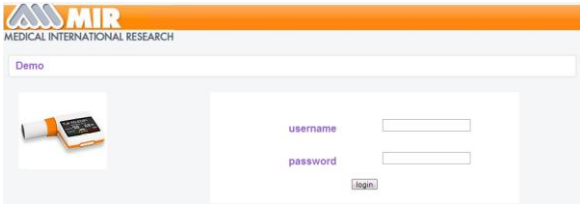
the device will then automatically return to the service menu.

Email/FTP
Select one of the two options and continue as indicated in the points below.

Email

- Select Email and press the icon OK at the bottom

- Use the virtual keyboard which appears to insert the email to which the the report of the tests carried out should be sent; its possible to insert special characters by pressing the icon ALT, which allows numbers and symbols to be selected.
- Once finished press the icon OK in at the bottom right corner.
- When asked the Spirotel will send an email with two files attached to the email address specified one in pdf format which allows of the test to be viewed immediately the other in a file gsm which can be saved on the PC and then opened with the software winspiroPRO.



FTP

- Select FTP and press the icon OK at the bottom

When asked the Spirotel will send the archive to the MIR server.
The user, by connecting to the site www.spirotel.com/demo is able to access the tests done by providing the following credentials:

- user name: mir
- password demo

Then clic on "login"

⚠WARNING

To send the archive it's necessary to visualize the "ADVANCED MENU".

The last icon on the right will be FTP or Email depending on whether the transmission FTP or email is chosen.

After the test go to the main screen and press the icon on the right.
Spirotel will proceed with the connection chosen and at the end it will send back a message "DATA SENT".

It's possible to visualize the email inside the inbox set-up or alternatively at www.spirotel.com/demo.

2.6.2 Turbine calibration

⚠WARNING

Reusable turbine flow meters do not need calibration, just a periodical clean. If however if you really want to carry out a calibration, bear the following in mind.
Calibration can only be carried out on reusable turbines.

Calibration takes place based on the FVC (expiratory) and FIVC (inspiratory) values measured during a test performed with a calibrated syringe.
To start calibration, select "turbine calibration" from the service menu (as described in section 2.6); when you open "Modify" from the sub-menu, you will be asked to enter the password after which you will have access to the area for setting the new calibration parameters shown in the screen alongside:

Before entering the new calibration parameters, make sure that the volume values of the syringe in use match are those shown at the top right; to change the syringe volume value, press ← . Use the cursor to set the correct volume.
Enter the FVC and FIVC values in the FVC and FIVC fields with readings taken from a test carried out with a calibrated syringe using the numbers shown at the bottom of the screen; when the data has been entered for each parameter, press OK.
If the correction coefficients calculated are acceptable (<10%), both the FVC and FIVC values will be shown alongside the FVC and FIVC parameters. Press OK per to set the values as the measurement calibration.
Press ← to return to the previous step.
If the FVC and FIVC values produce a correction coefficient of > 10%, they will not be accepted. This means that the system is unable to correct such a large calibration error. In this case:

- check that the **Spirotel®** is working properly by fitting a new turbine and/or
- clean the turbine in question.

To cancel the calibration in use and restore the factory settings, select "Factory defaults" from the calibration menu.

⚠WARNING

According to the "Standardised Lung Function Testing" publication of the European Respiratory Society (Vol 6, Supplement 16, March 1993), air expelled from the mouth has a temperature of about 33/34°C.
To convert the volumes and air flow rates to BTPS (37 °C) conditions, they must be increased by a factor of 2.6%. The BTPS factor for a temperature of 33°C is 1.026 that is in fact a correction of 2.6%. In practice, the BTPS factor for expiratory volumes and flow rates is constant and equal to 1.026.
The BTPS factor for inspiratory volumes and flow rates depends on ambient temperature as air that is inhaled is at that temperature.
For instance, with an ambient temperature of 20 °C with Relative Humidity of 50%, the BTPS factor is 1.102 that represents a correction of +10.2%.

The correction of inspiratory volumes and flow rates is performed automatically thanks to an ambient temperature sensor that measures the temperature inside the device and allows the BTPS factor to be calculated.
If a 3-litre syringe is used for the test and if the Spirotel® is perfectly calibrated, the FVC (syringe) value measured will be:
3.00 (FVC) x 1.026 (BTPS) = 3.08 L (FVC at BTPS).
If the ambient air temperature is 20 °C, the FIVC (syringe) value measured 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 was converted to BTPS and the "alterations" of the results when compared with expected values do not therefore represent an error.
For example: if you perform the calibration with the data measures:
FVC = 3.08 L and FIVC = 3.31 L at ambient temperature of 20 °C, the correction coefficient will be:

EXPIRATORY	**.00%**
INSPIRATORY	**.00%**

To repeat - this is NOT an error but is the logical consequence of what was explained above.
Calibration can also be performed using the winspiroPRO software that comes supplied with the device. For details about the calibration procedure using this software, refer to the winspiroPRO on-line manual.

2.7 Showing the current patient's last session

To see the results of the last session performed on the current patient, press  on the main screen.
In this section it can be possible choose spirometry or oximetry tests.
The icon on the left is for last spirometry test, the icon on the right is for the last oximetry test.

2.8 On-line mode (connected to a PC)

This function acts like an actual laboratory based real time spirometer connected to a PC.
The PC is connected via a USB connector. **Spirotel®** becomes an intelligent sensor for measuring volume and flow rate while the PC controls the functions including turning on and off.
When connected to a laptop, **Spirotel®** can be used for epidemiological tests in workplaces, schools etc.
In addition to the usual spirometric parameters, this system can also gather more sophisticated information such as ventilatory profiles and extrapolated volume (Vext) data.
The computer software allows the use of more up-dated bronchial provocation protocols and can display FEV1 dose and time-responses.

⚠WARNING

When the device is connected to a PC, it cannot be remotely operated. The settings on the PC are transferred to the device and will remain as its default settings in subsequent remote mode operations.

2.9 Performing spirometry

To perform a correct spirometry test, observe the following instructions to the letter.

- Slide the turbine fully into position then turn it clockwise until it clicks into place.
- Slide the mouthpiece at least 0.5 cm along the groove on the turbine.
- Fit the nose clamp over the patient's nostrils to prevent air from escaping.
- Use both hands to hold the ends of the **Spirotel®**. The screen should be facing to the right.
- Introduce the mouthpiece into the mouth beyond the teeth making sure that air does not escape from the sides of the mouth

⚠WARNING

The proper positioning of the mouthpiece beyond the teeth is essential to eliminate any turbulence that might have a negative effect on the test parameters.

⚠WARNING

We recommend that the patient stays upright during the test and bends forward during exhalation to allow the abdominal muscles to facilitate the expulsion of air.

2.9.1 FVC test

To enter the spirometry test area, press  .
Once a test has been started, the following information will appear on the screen to assist the user to perform the test correctly.
To stop the test, press the on/off button on the bottom of the device.
To perform an FVC test, follow the instructions on the display. These include:

INSPIRE all the air
EXPIRE with force all the air

The test can be started (optional) following the instructions at rest. When you are ready, inhale as quickly as possible (it is easier if you open your arms wide) and expel all the air in your lungs with as much force as you can. The inhalation stage can also be performed before putting the mouthpiece in your mouth.
Following a slow deep intake of breath, the next exhalation should be performed with as much force as possible and as quickly as possible.
After 6 seconds of exhalation, the device will emit a continuous beep that tells you that the minimum exhalation time has passed. This minimum time period standard is required by the main International Pulmonology Associations.

⚠WARNING

Remember that for accurate spirometry results, it is essential that all the air is expelled from the lungs.

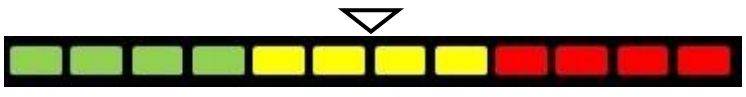
The test can be repeated as often as required without the mouthpiece having to be removed from the mouth. In such event, the **Spirotel®** will automatically recognise the longer cycle (longer FVC+FEV1) and present the relative readings.
On completion of the test, press ON/OFF key.
During the test, the **Spirotel®** emits repeated beeps whose frequency is directly proportional to the speed at which air is being inhaled and exhaled. This helps the doctor understand when the rate of air flow is approaching zero and therefore when the patient has exhausted the volume available in exhalation and inhalation.
The section dedicated to maintenance describes how this feature is also useful for easily checking that the volume and air flow sensors are working properly.
Apart from requiring a deep exhalation of breath for the results of an FVC test to be reliable, the Forced Expiratory Time (FET) must also be long enough to allow the complete expulsion of all the air in the lungs.

2.10 The display and reading of spirometry results

On completion of the test, the device displays a set of readings and an interpretation based on International standards of reference.
Once the FVC test has been completed the spirometry result of the parameter chosen in the "Personal Best" area is displayed.
If the "personal best parameter" chosen is different from FEV1, then the device shows in two lines the "personal best parameter" and FEV1.
If the "personal best parameter" chosen is FEV1, then the device shows in two lines FVC and FEV1.

2.10.1 Interpreting spirometry results

The interpretation of spirometry refers to Forced Vital Capacity (FVC) and is seen in several messages.
Traffic light



The position of the arrow on the traffic light is based on the percentage of the measured parameter compared to the predicted value.
The percentages defining the yellow area can be modified as requied in configuration.
In the device default the start of the yellow zone is 80% of predicted and the end of the yellow zone is 50% of predicted.

Spirotel® also if the test has been made correctly or with errors. The errors detected by the device are:

Vext and PEFT error
If the extrapolated volume (Vext) is greater than 500 mL or greater than 5% of the FVC, or when the PEFT (Peak Tidal Expiratory Flow) is more than 300 ms.
FET error
If the FET is lower than the threshold setting.
FLOW error
If the last point on the F/V curve is more than 200 mL/s, this means that exhalation has not been completed.

If any of these cases are detected then this message is shown:

Exhale with greater effort

Between one test and the next, the **Spirotel®** device evaluates the repeatability of the following parameters:

PEF repeatable when the difference between the two furthest apart PEF values is ≤ 10%;
FEV1 repeatable when the difference between the two furthest apart FEV1 values is ≤ 150mL;
FVC repeatable when the difference between the two furthest apart FVC values is ≤ 150mL;

2.11 Performing oximetry

⚠WARNING

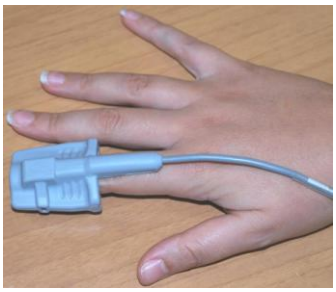
Check that the oximetry function is available on the device you are using as it is optional on several models.

⚠WARNING

The description of the following sensor serves solely as an example. All the sensors described in section 1.2.4 can be used with the Spirotel® device MIR do not recommend any particular sensor; that decision is left to the doctor's discretion. During oximetry tests, the Spirotel® device cannot be turned off . To turn it off, you have to interrupt an on-going test. This system prevents unwanted interruptions that might compromise the reliability of data obtained.

To take a non-invasive reading of oxygen saturation SpO_2 and pulse rate, use the reusable finger sensor. This sensor is recommended for patients weighing over 20 Kg, for those with limited mobility or who remain still during tests; for tests carried out with the patient in motion, other types of sensors that are less affected by movements of the hands are recommended.
To perform an oximetry test, proceed as follows:

Connect the sensor to the device: insert the connector with the arrow facing up
Choose a site with a good blood flow that is suitable for the sensor
Insert the finger all the way into the sensor. Make sure that the under part of the finger completely covers the detector. If you cannot position the finger properly, use a different finger.
Position the sensor so that the cable runs over the back of the hand. This ensures that the light source stays on the same side as the nails while the detector remains under the finger.
Select one of the tests for the **Spirotel®.**



To enter the oximetry area, press  on the main screen.
If the following message appears at start-up:

OXIMETER NOT PRESENT

This means that your device does not have this function.

⚠WARNING

If before starting a test, the power supply is low, the following message will appear:

Low battery

In this case, press ESC to exit the test otherwise the device will start the test a few seconds later.
If a test is interrupted for some unexpected reason, the next time the device is turned on, the following message will appear:

WARNING
the last oximetry test was improperly interrupted

At the same time, the device will beep intermittently for 4 seconds. The Spirotel® will then display the main screen

⚠WARNING

To avoid compromising the reliability of readings and to protect the sensor, do not twist the sensor cable or use excessive force when using, connecting, disconnecting or putting away the oximeter sensor.

The first few seconds of a test are used for finding the strongest signal; once this has been found, the timer resets itself and the **Spirotel®** starts saving data.
For all types of test, if the sensor is not inserted, the following message will appears after a few seconds:

WARNING
Sensor not inserted

At the same time, **Spirotel®** will beep (if set to do so in the service menu).
If the sensor has been inserted but the finger is not properly positioned, the following message will be displayed:

WARNING
FINGER wrongly inserted

At the same time, the **Spirotel®** will beep (if set to do so in the service menu).
If the signal is received properly from the sensor, after a few seconds the device will begin to beep and display readings on the screen.
Alarms can be set for oximetry SpO2 tests as explained in section 2.6.
If during a test, the %SpO2 or BPM rate goes above or below its threshold, the **Spirotel®** emits a beep (if set to do so in the service menu) for as long as this anomaly continues. The BPM alarm can be disabled for tests to be carried out while the patient is asleep.
If all the alarms are enabled during a test, the following icon will be displayed on the screen 
Pressing this icon during a test will display for several seconds all of the alarm settings as can be seen in the image alongside that lets you check the thresholds and alarms enabled in the service menu; after a few seconds, the screen returns to the on-going test screen.

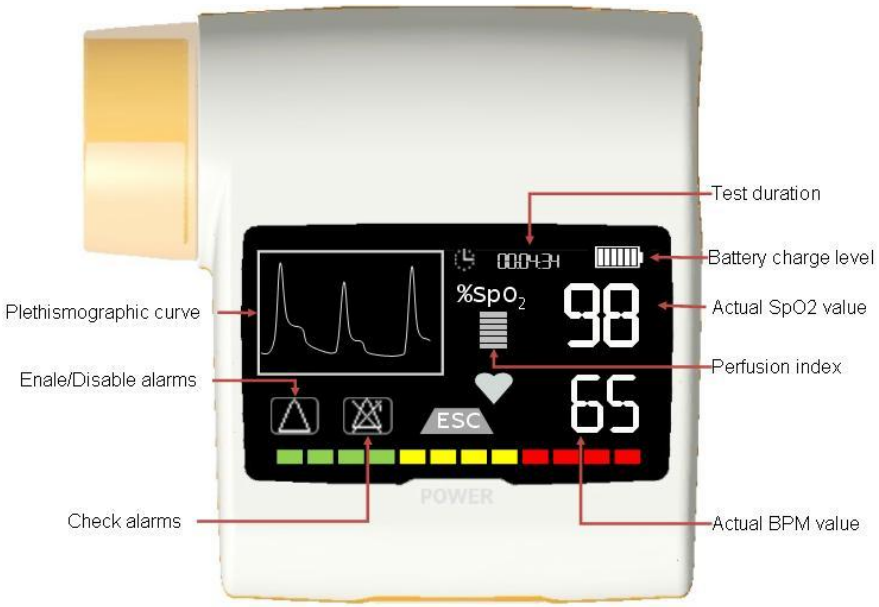
If  appears during a test, this means that at least one of the alarms is set to OFF in the service menu. The configuration can always be checked by pressing the above mentioned icon.

.

When one of the alarms on display is activated,  appears and if you press this icon, the beep will be cancelled for two minutes; in such event, the icon will change to  then back to its previous form once the two minutes are up.
For further information about setting this function correctly, refer to section 2.6.

During oximetry SpO2 tests , the battery level is displayed. This lets you estimate how long the device will run for given the condition in which it is operating (display at maximum or energy saving mode).

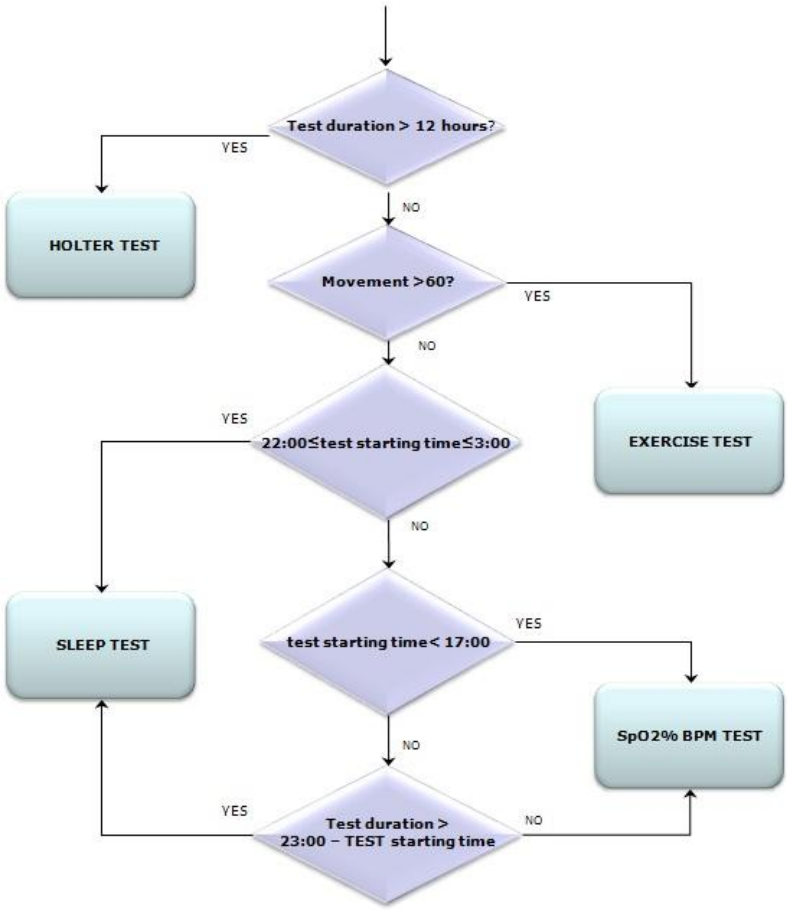
In general, the screen shows the following information during a test:



To end the oximetry test, press the ON/OFF key. If you press ESC, the following message will appear for a few seconds:

2.11.1 Oximetry test classification

Oximetry tests are classified by the device in different ways depending on the values assumed by several parameters; the classification criteria are defined in the following flow chart:



If a test is carried out with the patient in motion or while the patient is asleep, the device must be fastened in place with an appropriate strap.

⚠WARNING

To allow the number of paces a patient takes to be accurately counted during a test, the device must be fitted to the patient's chest as shown in the diagram alongside.

The strap is an optional extra and is only supplied on request.

2.11.2 Instructions for using the sensor on individual adult patients.

⚠WARNING

The description of the following sensor serves solely an as example. Any of the sensors described in §1.2.4 can be used with the Spirotel® device MIR do not recommend any particular sensor; that decision is left to the doctor's discretion.

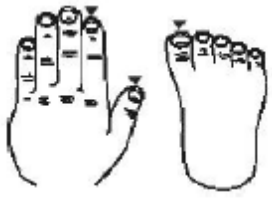
To monitor non-invasive readings of arterial blood oxygen saturation, we recommend the use of "wrap" type reusable sensors.

⚠WARNING

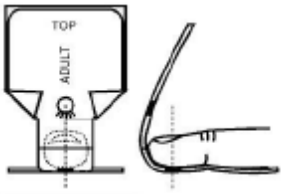
The sensors are made from PROTEIN FREE NATURAL LATEX materials. The materials used in making the sensors have been subjected to stringent biocompatibility tests.

⚠WARNING

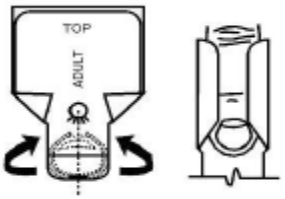
Use of this sensor is recommended for patients weighing over 30 kg and not recommended for use on patients who display allergic reactions to adhesive tape. The sensor is for mono-use for individual patients.



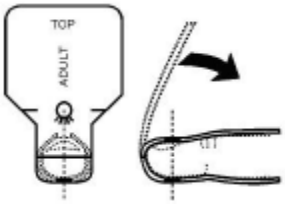
- Choose a suitable site for application on the patient's finger or toe that will allow the light source to line up directly with the detector. The preferred sites are the index finger or thumb.
- Remove any nail polish or false nails.



- Position the patient's finger in the sensor with the nail face up and place the pad of the finger over the detector. An imaginary line through the middle of the sensor should pass through the tip of the finger.



- Apply the adhesive tape to under part of the finger taking care not to cover the nail



- Fold the upper part of the sensor over the finger making sure that the light source is directly in line with the detector below it. Apply the adhesive tape to the upper part of the finger or toe to keep the sensor in place. Run the wire along the palm of the hand or sole of the foot and, if necessary, tape it in place.
- Connect the sensor to the device: insert the connector with the arrow (stamped on the connector) facing up and make sure that everything is working properly as described previously.

⚠WARNING

Do not twist the sensor cable or use excessive force when using, connecting, disconnecting or putting away the oximeter sensor.
If the sensor is fitted too tightly, it may create inaccurate saturation readings. It is therefore very important not to make the adhesive tape too tight.
We recommend using a sticking plaster to fix the sensor wire to the wrist.

3. DATA TRANSMISSION

As well as the Bluetooth connection, **Spirotel®** can use several other connection types for which Bluetooth is not suitable. The following paragraphs describe the various connection types and the activities that can be made.

3.1 Data transmission via Bluetooth to a mobile phone

To enable this function, contact the manufacturer.

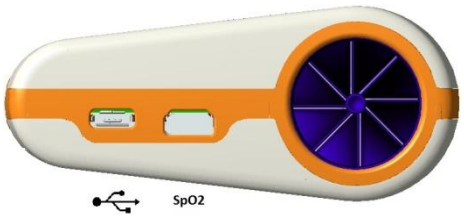
Check that the Bluetooth function is available on the device you are using as it is optional on several models.
Bluetooth communication is considered an additional function. In the event of an interruption in transmission, we recommend the use of a the more reliable USB port technology.

3.2 Connecting with a PC via USB port

⚠WARNING

Before connecting the Spirotel® to the PC via USB, you need to install the software that allows you interface with the device.

To make the connection, insert the micro USB connector supplied with the **Spirotel®** into the USB port on the PC as shown alongside.
When connecting for the first time, the Microsoft certified drivers that are needed will be automatically installed (depending on the OS in use).



3.2.1 Up-dating internal software

When the device is connected to a PC via the USB port, the **Spirotel®** internal software can be up-dated**.** Up-dates can be downloaded on registration from: www.spirometry.com. For further information about downloading up-dates, contact the manufacturer.

3.2.2 Configuration for data transfer via GSM

⚠WARNING

Check that the GSM function is available on the device you are using as it is optional on several models.

To make sure that the GSM function works properly, you need to set the parameters for the server you intend to connect with, for the SIM card in use, for the GSM module firmware up-dating server etc.
The parameters that have to be configured are shown below and are set once the device is connected to the PC via USB:

Network		**SIM**	
APN		PIN	PUK
Surname		PIN2	PUK2
Password			
FTP			
Server			
Username			
Password			
File name			
SMTP		**DATA**	
Server		FTP server	
Username		User name	
Password		Password	
Sender		DWL filename	
Receiver			

Once the data above has been entered, the device can be programmed or can do other activities, contact the manufacturer to know all the functions available.

3.3 Data transfer via GSM

⚠WARNING

Check that the GSM function is available on the device you are using as it is optional on several models.

Press  on the main screen The device will automatically start the procedure for sending data in the archive to the preset server.

- The first stage involves searching for the SIM card's service provider
- This is followed by connection to the server
- This is followed by an authentication process between the device and the server
- After positive authentication, data containing archive material starts to be sent
- On completion of the data transfer, the connection is closed
- If the whole process has happened correctly, the following message will appear: Mail sent

3.3.1 Errors that might occur during the GSM connection

The device can provide information in the form of a numeric code in the event of an error during connection.
The errors that can be traced back to the configuration are as follows:

Error code	Description
10	Impossible to create an FTP connection
12	Impossible to create an FTP data channel
16	Error entering PIN
18	Error entering PIN 2
19	Three PIN entry attempts completed
20	Ten PUK entry attempts completed
21	Error entering PUK
22	Ten PUK 2 entry attempts completed
23	Error entering PUK 2
26	No SIM
30	Three PIN 2 entry attempts completed

If an error code is displayed that does not match any of the above, save the number and contact the manufacturer to explain the fault and the error code displayed by the device.

4. MAINTENANCE

Spirotel® devices need little maintenance. You should periodically:

- Clean and check reusable turbines
- Clean the oximetry sensor (for reusable sensors)
- Replace the adhesive tape on the wrap type oximetry sensor
- Recharge the internal battery

All the maintenance operations described in the User Manual must be carried out with great care. Failure to follow these instructions may lead to incorrect readings or the incorrect interpretation of readings that have been taken.
All modifications, adjustments, repairs and reconfigurations must be performed by the manufacturer or by personnel authorised by the manufacturer.
In the event of problems, do not attempt to make repairs.
The setting of configurable parameters must be performed by qualified staff. In no case does the incorrect setting of the device place a patient at risk.

4.1 Cleaning and checking reusable turbines

The turbine that measures volume and flow rate guarantees great accuracy and has the added benefit of not needing to be periodically calibrated. A simple clean before every use will ensure that the turbine keeps working as it should.

⚠WARNING

It is good practice to periodically check that no impurities or foreign bodies such as skin or even worse, hairs have deposited inside the turbine. Such obstacles could slow or block the turbine blades and compromise the accuracy of readings.

Before every use, perform the test described in section 4.1.1 below that allows you to test the efficiency of the turbine. If the result is negative, act as follows.
To clean the turbine, remove it from its housing in the **Spirotel®** by turning it anti-clockwise and pulling gently. To facilitate removal, you can push the bottom of the turbine gently with a finger.
Soak the turbine in a cold liquid detergent and shake it so as to remove any impurities that have deposited inside; leave to soak for the period of time recommended by the detergent manufacturer that is shown in the instructions for use.

⚠WARNING

To avoid irreparable damage to the turbine, do not use alcohol or oil based detergent solutions and do not soak in water or hot solutions.
Never place the turbine in an autoclave. Do not sterilise the turbine.
Never clean the turbine under running water or spray with other liquids. If no liquid detergents are available, clean the turbine with at least clean water.
MIR recommends the use of Dupont Perasafe that has been tested on all MIR sensors.

Rinse the turbine by immersing it in clean water (**not hot**).
Shake off any excess water off the turbine. Leave the sensor to dry by placing it in an upright position on a dry surface.

Before re-fitting the turbine, check that it is working properly. It is good practice to visually check that the blades are moving freely. Place the turbine on its side and slowly move the blades left and right. They should rotate freely. If this is not the case, the accuracy of readings is no longer guaranteed and the turbine will have to be replaced.

On completion of cleaning, replace the turbine in its housing making sure that it is in the right position as shown by the closed padlock symbol on the **Spirotel®**.
To insert the turbine correctly, push it fully in and turn it clockwise until it clicks into place inside the plastic housing.
To double check that the turbine is working correctly, repeat the checks described in 4.1.1; if the turbine is still problematic, replace it with another.

4.1.1 Checking correct turbine function

- Turn the **Spirotel®** on and act as if you wanted to perform a spirometry test
- Take the **Spirotel®** in one hand and move it slowly from right to left and vice versa so that air passes through the turbine,
- If the blades moves correctly, the device will emit repeated beeps that vary in frequency with the flow of the air passing through
- If no beeps are emitted during this movement, clean the turbine.

4.2 Cleaning the oximetry sensor

Clean the sensor with a damp cloth containing water or a delicate soap solution. To disinfect the sensor, rub it with isopropyl alcohol. After cleaning, allow the sensor to fully dry.
Do not use abrasive or caustic agents to clean the sensor.

⚠WARNING

Do not sterilise by means of radiation, steam or ethylene oxide.
Always disconnect the sensor before cleaning or disinfection.

Spirotel® sensors are latex free.

4.3 Replacing wrap sensor adhesive tape

The adhesive tape is made with latex free materials

- Gently remove and dispose of the adhesive tape from the sensor
- The back of the sensor has pins for lining up the tape. Position the sensor with these pins facing the tape and line up the pins and tape
- Press the sensor firmly to insert the pins into the holes in the tape. Lift both the sensor and the tape to check that the pins are properly lined up

⚠WARNING

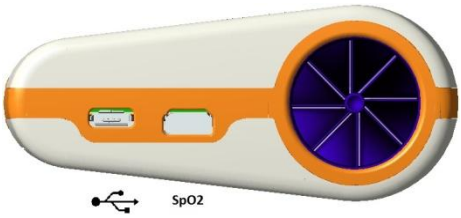
We recommend using new tape for every patient or as required.

4.4 Recharging the battery

When the **Spirotel®** device is turned on, an icon shows the condition of the battery:

A full charge is shown by 5 bars inside the battery.
If there is only one bar or if the device doesn't turn on, you will need to recharge the battery as follows:

- Connect the battery charger to both the micro USB and mains supply, another way is to connect the **Spirotel®** to a PC via USB. During recharging, the device is always turned on
- When recharging is complete, the battery symbol will show 5 bars
- Now disconnect the battery charger from the device and from the mains



⚠WARNING

Do not use the device when it is recharging Always disconnect the charger when recharging has been completed.

5. TROUBLE SHOOTING AND SOLUTIONS

PROBLEM	MESSAGE	POSSIBLE CAUSE	SOLUTION
Spirotel® doesn't turn on	\	Battery may be flat	Charge the device using the charger unit
	\	The battery is not properly fitted in the device	Contact technical services
	\	The device may have lost internal software	Connect the device to a PC via USB and up-date the software; for further information, consult the on-line winspiroPRO User Manual
Problems turning the device on	**Ram error** **Data recovery** **Please wait**	The data in the device memory has been damaged	If the data has been correctly restored, the last standard turning on process will be repeated; if not, contact an authorised service centre or the manufacturer.
The device turns itself off then reboots while being used.	\	There is an internal error	Check www.spirometry.com to see if an up-dated version of the software is available; if this is the case, download the software then up-date the device with the latest software winspiroPRO version. For further information, consult the on-line winspiroPRO User Manual .
On completion of spirometry tests, the readings are not credible	\	The turbine may be dirty	Clean the turbine as described in section 4.1; if necessary, replace the turbine with a new one
	\	The test was performed in the wrong manner	Repeat the test following the instructions shown on the screen
On completion of a spirometer or oximeter test, some parameters are not displayed	\	Parameter settings in the service menu	Check the parameter settings in the "personal best" section of the service menu as described in section 2.6.1
During an oximeter test the readings displayed are irregular, intermittent or wrong	\	The sensor is wrongly positioned or the patient's perfusion is poor	Reposition the oximeter sensor
	\	The patient moved	For accurate results, the patient must not make any sudden movements.
The display is not very bright during tests	\	The brightness level of the display automatically dims a few minutes after a test starts. This function extends battery life	None
Problems with charging the battery	**Defective battery**	The battery is damaged or wrongly positioned	Contact technical services
Unforeseen memory error	**Error in memory**	The data stored in the archive have been damaged	Contact technical services
The device will freeze when unforeseen events occur	\	\	Press the on/off button e times; wait a few seconds and the device will reset then turn itself on,

WARNING

Before contacting the service centre, if possible, transfer data in memory using the Bluetooth connection. This is necessary as the data may be lost during repair activities and also to protect the patient's privacy as neither the manufacturer nor authorised personnel are allowed to see such data.

MEDICAL INTERNATIONAL RESEARCH S.r.l.
Via del Maggiolino 125, 00155 Roma – ITALY

EC Declaration of Conformity
(appendix II excluding para. 4)

We declare that the following device:

Type	**Spirometer/Oximeter**
Make	**MIR Medical International Research**
Name of Device	**Spirotel®**
Class	**IIa**

conforms to the Essential Requirements of Directive 93/42 regarding Medical Devices as amended and to the Law on Enactment in Member States.
This declaration is based on EC Certificate N° MED 9826 issued by Cermet, Notified Body N° 0476.

Rome 01.01.2014

Paolo Sacco Boschetti
President

GUARANTEE CONDITIONS

The **Spirotel®** device and authorised accessories are guaranteed for a period of:

- 12 months in the case of professional use (doctor, hospital, etc.)
- 24 months where the product has been purchased by a patient for private use.

The guarantee takes effect from the date of purchase shown on the invoice or other document.

The guarantee period starts from the date of sale that must be confirmed by an invoice or sales receipt.

The product must be checked at the time of purchase or upon receipt and the manufacturer must be informed immediately of any complaints.

The guarantee covers repair, or (at the manufacturer's discretion) replacement of the product or defective components without any cost for labour or spare parts.

The batteries and components subject to wear and tear (reusable turbine included) are excluded from the terms of this guarantee.

At the manufacturer's discretion, the guarantee does not apply to the following cases:

- Uses that are incorrect, improper or do not conform with the technical or safety standards in force in the country where the product is being used.
- Use of the product for purposes that differ from those in the Instructions for Use or failure to observe such instructions.
- Repair, adaptation, modification or manhandling by personnel who have not been authorised by the manufacturer.
- Damage caused by a lack of or by incorrect maintenance
- Damage caused by physical or abnormal electrical stress
- Damage caused by faults in the electrical systems or in items of equipment to which the device has been connected.
- Series number modified, erased, removed or obliterated.

The repairs and replacements mentioned in the guarantee take place on goods that have been returned to our authorised service centres. For further information about service centres, please contact your local distributor or the manufacturer.

The customer is responsible for the costs incurred for shipping, customs and the delivery of goods.

Every product or component part thereof sent for repair must be accompanied by a clear and detailed explanation of the fault. If the product or component part thereof is to be sent to the manufacturer, this must be authorised in writing or by phone beforehand by the manufacturer.

MIR Medical International Research reserves the right to replace the product or make any changes to it that the company deems necessary.

APPENDIX 3 INFORMATION ABOUT THE CORRECT USE OF DEVICE IN AN ELECTROMAGNETIC ENVIRONMENT

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

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

Manufacturer's recommendations and declarations - electromagnetic immunity			
The **Spirotel®** device can be used in the following electromagnetic environments. The **Spirotel®** customer or end user must ensure that the device is used in such an environment.			
			RF and mobile communication items of equipment must not be used any closer the separation distance recommended by **Spirotel®** including cables as

			calculated using the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d=[\frac{3.5}{3}]\sqrt{P}$ $d=[\frac{3.5}{3}]\sqrt{P}$ 80 MHz at 800 GHz
RF conduit IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	[3] V	$d=[\frac{7}{3}]\sqrt{P}$ 800 MHz at 2.5 GHz
RF radiated IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	[3] V/m	Where P is the maximum nominal distance of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). The intensity of the fixed RF transmitters, as determined by an electromagnetic scan of the site, could be lower than the level of conformity in each frequency interval (b). Interference near the device may be detected from devices marked with the following symbol: 

NOTE 1:At 80 MHz and 800 MHz, the highest frequency interval is applied.

NOTE 2:These guide lines may not apply for all situations. The propagation of electromagnetism is influenced by absorption and reflection caused by structures, objects and persons.

a) The intensities of fixed transmitter fields such a telephone base stations (mobiles and cordless), terrestrial radio equipment, amateur radio appliances, AM and FM radio and TV transmitters cannot be theoretically accurately predicted. To assess an electromagnetic environment generated by fixed RF transmitter, you need to perform an electromagnetic scan of the site. If the intensity of the field where the **Spirotel®** is used exceeds the applicable conformity level mentioned above, you will need to observe how the **Spirotel®** works under normal conditions. If you detect faulty performance, you may need to implement additional measures such as changing the direction or position of the **Spirotel®**.

b) The intensity of the field in the frequency interval from 150 kHz to 80 MHz should be less than [3] V/m

Recommended separation distance between mobile radio-communication appliances and devices

Spirotel® devices are designed to work in electromagnetic environments in which radiated RF disturbances are controlled. The device customer or end user can contribute towards preventing electromagnetic interference by providing a minimum distance between mobile RF communication devices (transmitters) and **Spirotel®** devices as recommended below in relation to the maximum power output of the radio-communication devices.

Specified maximum power output of the transmitter W	**Separation distance at transmitter frequency (m)**		
	150 kHz - 80 MHz $d=[\frac{3.5}{3}]\sqrt{P}$	**80 MHz - 800 MHz** $d=[\frac{3.5}{3}]\sqrt{P}$	**800 MHz - 2.5 GHz** $d=[\frac{7}{3}]\sqrt{P}$
0.01	0.12	0.24	0.24
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	5.28	5.28	1,056
100	11.66	11.66	23.32

For the specified maximum power output of a transmitter not included above, the recommended separation distance d in metres (m) can be calculated using the equation that applies to transmitter frequency where P is the transmitter's nominal maximum power output in Watts (W) according to the transmitter manufacturer.

NOTE 1: at 80 MHz and 800 MHz, the separation distance calculated for the highest frequency rage is applied.

NOTE 2: These guide lines may not apply for all situations. The propagation of electromagnetism is influenced by absorption and reflection caused by structures, objects and persons.