SmartOne

User manual rev. 0.1

Issue date 05.01.2015
Approval date 05.01.2015

DRAFT VERSION

INDEX

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

⚠ WARNING

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

Before using your Smart One® …

- Read this manual carefully, plus all labels and other product information supplied.
- **Smart One®** should only be connected to a computer manufactured in compliance with EN 60950/1992.

⚠ WARNING

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

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

In such an event then please follow these guidelines:

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

Manufacturer's address

MIR SRL: VIA DEL MAGGIOLINO, 125
00155 ROME (ITALY)

Tel ++ 39 0622754777
Fax ++ 39 0622754785
Web site: www.spirometry.com
Email: mir@spirometry.com

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

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

1. INTRODUCTION

1.1 Intended Use

Smart One® spirometer is intended to be used either by a physician, respiratory therapist or technician.
The device is intended to test lung function and can make spirometry testing in people of all ages, excluding infants and neonates
It can be used in any setting.

1.1.1 User Category

Smart One® calculates a series of parameters relating to human respiratory function.
The product is therefore intended for use by a doctor or by a trained paramedic or technician under the supervision of a doctor.

1.1.2 Ability and experience required

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

⚠ WARNING

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

The Smart One® when used as a pulse oximeter is intended for spot-checking oximetry.

1.1.3 Operating environment

Smart One® has been designed for use in a doctor's office or in a hospital setting.
All information necessary for the proper use of the device in surrounding electromagnetic environments (as required by the EN 60601-1-2) is specified in Annex I.
The instrument is not intended for use in an operating theatre nor in the presence of inflammable liquids or detergents, nor in the presence of inflammable anaesthetic gases, oxygen or nitrogen.
The instrument is not designed to be used in direct air currents (e.g. wind), sources of heat or cold, direct sun rays or other sources of light or energy, dust, sand or any other chemical substances.
The user is responsible for ensuring that the device is stored and used in appropriate environmental conditions as specified in paragraph 1.7.3.

⚠ WARNING

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

1.1.4 Subject effect on the use of the device

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

1.1.5 Limitations of use - Contraindications

An analysis of the results of a spirometry test is not by itself sufficient to make a correct diagnosis of the subject's clinical condition.
A detailed clinical history of the subject is also required together with the results of any other test(s) suggested by a doctor.
Test comments, a test interpretation and suggested courses of treatment must be given by a doctor.
A spirometry test requires the collaboration of the subject. The results depend on the person's capability to inspire and to expire all air completely and as fast as possible. If these fundamental conditions are not respected then the results obtained during spirometry testing will not be considered accurate, and therefore the test results are "not acceptable".
The ***acceptability*** of a test is the responsibility of the user. Special attention should be given to testing elderly subjects, children and handicapped people.
The device should never be used when it is possible or probable that the validity of the results may be compromised due to any such external factors.

1.2 Important safety warnings

Smart One® has been examined by an independent laboratory which has certified the conformity of the device to the Safety Standards **IEC 60601-1** and guarantees the EMC Requirements within the limits laid down in the Standard **IEC 60601-1-2**.
Smart One® is throughly tested during its production and therefore the product complies with the safety requirements and quality standards laid down by the Council Directive 93/42/EEC for **MEDICAL DEVICES.**
After removing the device from its packaging, check that there is no visible damage. In case of damage do not use the device and return it to the manufacturer for replacement.

⚠ WARNING

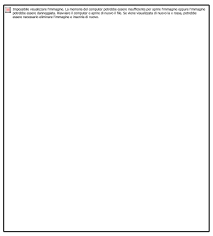
The safety and the correct performance of the device can only be assured if the user of the device respects all of the relevant safety rules and regulations.
The manufacturer cannot be held responsible for damage caused by the failure of the user to follow these instructions correctly.
The device must be used according with the indications given by the manufacturer in the User Manual with particular attention to § Intended Use utilizing only original spare parts and accessories. Use of non original parts such as the

turbine flow sensor and oximetry sensor or other accessories may cause errors in measurement and/or compromise the correct functioning of the device, and is therefore not permitted.
In the event of any incident or accident of any kind resulting from the use of the device, the user is required to inform the manufacturer without delay, according with Directive 93/42/EEC on Medical Devices.

1.2.1 Danger of cross-contamination

Two different types of turbine sensors can be used with the device: one is single-patient disposable and one is reusable. A mouthpiece is required in order to connect a subject to the spirometer.
In order to avoid exposing the subject to the hazard of cross-contamination, the reusable flow sensor must always be cleaned before each spirometry test, and a new disposable mouthpiece must always be used for each subject. The use of an anti bacterial filter is at the discretion of the doctor.
If a disposable turbine is used, then a new one must be used for each patient.

1.2.2 Turbine



The correct functioning of the re-usable turbine can only be guaranteed if it has been cleaned in the correct manner and is free from foreign bodies which could alter its movement. If the turbine has not been cleaned sufficiently this could cause cross-contamination from one patient to another. Periodic cleaning should only be done when the device is for personal use and will only be used by one patient. The cleaning of the turbine should be performed according to the instructions contained in the User's Manual.

Do not expose the turbine to a direct jet of water or air, and avoid contact with high temperature liquids.
Do not allow dust or foreign bodies to enter the turbine sensor, in order to avoid incorrect functioning and possible damage. The presence of any impurities (such as hair, sputum, threads etc.) within the body of the turbine sensor may seriously compromise the accuracy of the measurements.

Notes about calibration of reusable turbine

⚠ WARNING

The turbine flow sensor does not require calibration but needs only a regular cleaning. If a calibration must be made then the following guidelines should be carefully noted.
Calibration can be made using a siring a calibration syringe ad making a FVC test.

In line with the publication "Standardised Lung Function Testing" of the European Respiratory Society (Vol 6, Supplement 16, March 1993), the air expired from the mouth is at a temperature of circa 33/34 °C.
The expired flow and volume, to be converted to BTPS conditions (37 °C) must be increased by 2.6% - this is derived from the BTPS factor of 1.026 at a temperature of 33°C, which represents a correction of 2.6%. In practice the BTPS factor for the expired flow and volumes is therefore constant and equal to 1.026.
For the inspired volumes and flows, the BTPS factor depends upon the ambient temperature as the air inspired is at ambient temperature.
For instance at an ambient temperature of 20°C with relative humidity at 50%, the BTPS factor is 1.102, a correction of +10.2%.
The correction of the inspired volumes and flows is made automatically as the machine has an internal temperature sensor; the BTPS values are thus calculated.
If a 3L syringe is used to make the calibration and if the Smart One® is calibrated correctly then the FVC (syringe) value will be:
3.00 (FVC) x 1.026 (BTPS) = 3.08 L (FVC at BTPS).
If the ambient temperature is 20°C, the FIVC (syringe) value will be:
3.00 (FIVC) x 1.102 (BTPS) = 3.31 L (FIVC at BTPS).
The user must be aware that the volume of the syringe shown by the machine is converted to BTPS conditions, so that the "increase" of the results with respect to the expected values does not constitute an error.
For instance, if the calibration procedure is carried out with measured data:
FVC = 3.08 L and FIVC = 3.31 L at an ambient temperature of 20°C the resulting correction factor becomes:

EXPIRATION	**.00%**
INSPIRATION	**.00%**

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

1.2.3 Mouthpiece

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

⚠ WARNING

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

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

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

1.2.4 Device

⚠ WARNING

The maintenance operations detailed in this manual must be carried out to the letter. If these instructions are not followed this can cause measurement errors and/or an incorrect test interpretation.
Any modifications, adjustments, repairs or reconfiguration must be made by the manufacturer or by personnel authorised by the manufacturer. In case of problems, never attempt to make a repair oneself. The set-up of configurable parameters should only be made by qualified personnel. However, an incorrect set up of the parameters does not put the patient at risk.
High-frequency emissions from "electronic" devices may interfere with the correct operation of the instrument. For this reason, certain minimum clearances (a few metres) should be observed when high-frequency appliances such as a TV, radio, portable phone, etc. and other electronic units are operated at the same time in the same room.
The instrument may give inaccurate readings if operated in the presence of strong electromagnetic sources or in the presence of other medical devices such as echographies.
When connected to other devices to preserve the safety oft he system as required in the IEC 60601-1 standard, it is necessary to use exclusively device compliants with the safety rules. So the PC or the printer which the Smart One® is connected must be compliant with IEC 60601-1.
If the PC connected to Smart One® is used in the area containing the patient, it is necessary that the PC complies with the EN 60601-1 Standard (ref. EN 60601-1-1 Standard).
For the disposal of the Smart One®, the accessories, plastic consumable materials (mouthpieces) plus the battery, use only the appropriate containers or return all such parts to the seller of the instrument or to a recycling centre. All applicable local regulations must be followed.

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

1.3 Unforeseen errors

If any problems should arise with the device, a message indicating the nature of the problem will appear on the screen of the PC, together with a warning "beep".
Errors in measurement or in interpretation can also be caused by:

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

1.4 Labels and symbols

1.4.1 Identification label

The label shows:

- Serial number of the device
- Product name
- Name and address of the manufacturer
- Electrical safety symbol
- Warning symbol for the WEEE Directive
- Mark of conformity with the Medical Device Directive

1.4.2 Electrical safety symbol

In accordance with **IEC 60601-1** this product and its component parts are of **type BF** and therefore protected against the hazards of direct and indirect contact with electricity.

1.4.3 Warning symbol for the WEEE Directive

This symbol is laid down in the 2002/96/EEC regarding the waste of electrical and electronic equipment (WEEE). At the end of its useful life this device must not be disposed of as normal domestic waste. Instead it must be delivered to a WEEE authorised collection centre.
As an alternative, the device may be returned without charge to the dealer or distributor, when it is replaced by another equivalent device.
Due to the construction materials used for the device, disposing it as a normal waste product could cause harm to the environment and/or health.
Failure to observe these regulations can lead to prosecution.

1.4.4 Mark of conformity with the Medical Device Directive

CE 0476

This product is certified to conform to the Class IIa requirements of the 93/42/EEC Medical Devices Directive.

1.5 Product description

Smart One® is a spirometer and pulse oximeter, and is connected to a Personal Computer using a USB cable.

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

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

Spirometry function
Smart One® calculates up to 30 functional respiratory parameters, as well as the parameter comparison after the administration of a drug (PRE/POST) for a bronchodilator test or for a bronchial challenge test. A comparison of data is made between POST (after-drug) and PRE (before drug administration). The Pre test data relates to percentage variations between the measured results and the predicted values based on the anthropometric data inserted.
The flow and volume measurement sensor is a digital turbine, based on the infrared interruption principal, which ensures accuracy in time as required from a professional device.

The special features of this kind of sensor are listed below:
- Accurate measurement even at very low flow rates (end of expiration)
- Not affected by gas humidity nor density
- Shockproof and unbreakable
- Inexpensive to replace.

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

REUSEABLE TURBINE

In order to maintain the characteristics of the turbines the following precautions must be closely observed:
- for the single-patient disposable turbine: they must always be substituted between patients.
- for the reusable turbine: always clean the turbine between patients, to ensure the maximum level of hygiene and safety for the patient.

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

Smart One® is connected to a PC trough a USB port. Data measured by **Smart One®** are transferred to the PC in real-time. The Windows "winspiroPro" software allows to view the spirometric test results (flow/volume curves, spirometry parameters) plus the related subject detail.

The data measured by **Smart One®** and arranged by the software are available for interpretation by specialised personnel.
The software gives an interpretation of each spirometry test by assigning a "traffic light" code and by comparing the previous values of the same subject or the reference values of the subject's group. For further details see the online manual of the WinSpiroPro Software.

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

1.6 Technical features

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

1.6.1 Features of the spirometer

Measured parameters:

SYMBOL	DESCRIPTION	m.u.
FVC	Forced Vital Capacity	L
FEV1	Volume expired in the 1st second of the test	L
FEV1%	FEV1/FVC x100	%
FEV3	Volume expired in the initial 3 seconds of the test	L
FEV3/FVC	FEV3/FVC x 100	%
FEV6	Volume expired in the initial 6 seconds of the test	L
FEV6%	FEV1/FEV6 x 100	%
PEF	Peak Expiratory Flow	L/min
FEF25	Forced Expiratory Flow at 25% of FVC	L/s
FEF50	Forced Expiratory Flow at 50% of FVC	L/s
FEF75	Forced Expiratory Flow at 75% of FVC	L/s
FEF2575	Flow ratio at 25% and at 75%	%
FET	Forced expiratory time	S
Vext	Extrapolated volume	mL
FIVC	Forced inspiratory volume	L
FIV1	Volume inspired in the 1st second of the test	L
FIV1/FIVC	FIV1/FIVC x 100	%
PIF	Peak inspiratory flow	L/s
ELA	Estimated lung age	years
*FVC	Best FVC	L
*FEV1	Best FEV1	L
*PEF	Best PEF	L/s
VC	Slow vital capacity (expiratory)	L
IVC	Slow inspiratory vital capacity	L
IC	Inspiratory capacity (max between EVC and IVC) - ERV	L
ERV	Expiratory reserve volume	L
FEV1/VC	FEV1/VC x 100	%
VT	Tidal volume	L
VE	Ventilation per minute, at rest	L/min
Rf	Respiratory frequency	
ti	Average time of inspiration, at rest	S
te	Average time of expiration, at rest	S
ti/t-tot	Average time of inspiration / total time	min
VT/ti	Average inspiratory flow, at rest	L/s
MVV(cal)	Maximum voluntary ventilation calculated on FEV1	L/min

*= best values

Flow/volume measurement system	Bi-directional digital turbine
Temperature sensor	semiconductor (0-45°C)
Measurement principle	Infrared interruption
Volume range	10 L
Flow range	± 16 L/s
Volume accuracy	± 3% or 50 mL
Flow accuracy	± 5% or 200 mL/s
Dynamic resistance at 12 L/s	<0.5 cmH_2O

1.6.2 Other features

Interface	Bluetooth low energy (4.0 or higher)
Power supply	2 x 1.5 V AAA type alkaline battery
Dimensions	142x49.7x26mm
Weight	65 grams
Storage conditions	Temperature: MIN -40 °C, MAX + 70 °C Humidity: MIN 10% RH; MAX 95%RH
Shipping conditions	Temperature: MIN -40 °C, MAX + 70 °C Humidity: MIN 10% RH; MAX 95%RH
Operating conditions	Temperature: MIN + 10 °C, MAX + 40 °C;

	Humidity: MIN 10% RH; MAX 95%RH
Compliance with standards	Electrical Safety Standard IEC 60601-1 EMC Standard IEC 60601-1-2
Type of electrical protection	Class II
Grade of electrical protection	BF
Grade of protection against water ingress	IPX0
Level of safety in the presence of inflammable anaesthetic gas, oxygen or nitrogen	Not suitable
Conditions of use	Device for continuous use
Essential performances (compliant with EN 60601-1: 2007)	Accuracy in spirometry parameters measuring, compliant with standard ATS

2. FUNCTIONING OF THE Smart One®

2.1 Connection to PC

⚠ **WARNING**

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

To make the connection, performe a Bluetooth pairing between device and PC.
To control the proper connection between the device and the PC check that the led on the device is lit.

2.2 Using the Smart One®

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

2.3 Spirometry Testing

⚠ **WARNING**

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

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

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

⚠ **WARNING**

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

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

2.4 Spirometry test interpretation

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

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

Through an analysis applied to some of the indices and parameters calculated in the FVC test, **Smart One®** produces a variety of **quality control** *comments* useful to understand the reliability of the test made.
This control quality check assigns a letter for the current session as described below:

PRE Test
A = At least two acceptable manoeuvres, with the highest two FEV1 values matching to within 100 mL and the largest two FEV6 values within 100 mL.
B= At least two acceptable manoeuvres, with the FEV1 values matching to within 101 to 150 mL
C= At least two acceptable manoeuvres, with FEV1 values matching to within 151 to 200 mL
D= only one acceptable manoeuvres, or more than one, but the FEV1 values not matching to within 200 mL (with no interpretation).
F= No acceptable manoeuvres (with no interpretation).

POST Test
A = two acceptable (1) FEV1 values matching within 100 mL
B= two acceptable (1) FEV1 values matching within 200 mL
C= two acceptable (1) FEV1 values that do not match within 200 mL
D= only one acceptable (1) FEV1 manoeuvre
F= No acceptable (1) FEV1 manoeuvres

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

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

ERROR IN Vext and PEF
If the extrapolated volume Vext is greater than 500 mL or greater than 5% of the FVC, or if the PEFT (time to peak flow) is greater than 300 ms, then the following comment is shown:

INITIAL EXPIRATION TOO SLOW

FET error
If FET is under the predicted threshold the following message appears:

EXPIRY TIME INSUFFICENT <6s

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

BLOW OUT ALL AIR IN LUNGS

Between two tests, **Smart One®** evaluates the repeatability of the following parameters:

PEF repeatable when the difference between the two largest PEF is ≤ 0.67 L/s;
VC repeatable when the difference between the two largest VC is ≤ 150 mL;

If FVC is > 1.0 L then:
FEV1 repeatable when the difference between the two largest FEV1 is ≤ 150 mL;
FVC repeatable when the difference between the two largest FVC is ≤ 150 mL;

if FVC is ≤ 1.0 L then:
FEV1 repeatable when the difference between the two largest FEV1 is ≤ 100 mL;
FVC repeatable when the difference between the two largest FVC is ≤ 100 mL;

3. MAINTENANCE

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

- Cleaning and controlling of the reusable turbine

The maintenance operations set forth in the User's Manual must be carried out carefully. Failing to observe the instructions contained in the manual may cause errors in measurement or in the interpretation of measured values.
Modifications, adjustments, repairs, and reconfiguration must be carried out by the manufacturer or authorised persons.
In case problems arise do not attempt to personally repair the unit.
The setting of configuration parameters must be carried out by qualified personnel. In any case the risks pertaining to incorrect settings do not constitute a hazard for the patient.

3.1 Cleaning and controlling the reusable turbine

The turbine utilized on **Smart One®** belongs to one of two categories: disposable and reusable. Both guarantee precise measurements and have the great advantage of requiring no periodic calibration. In order to maintain the characteristics of the turbine a simple cleaning is required prior to each use (**only for the reusable turbine**).
Cleaning of the **disposable turbine** is not required, as it is supplied clean in a sealed plastic bag. It must be disposed of after use.

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

To clean the **reusable** turbine, remove it from its compartment on the **Smart One®** by turning it anti-clockwise and pressing lightly. It can be helpful to push it gently from underneath with one finger.
Immerse the turbine in the recommended cold detergent solution, and move it within the liquid to remove any impurities which may be deposited inside. Leave the turbine immersed for the time specified in the instruction of the solution.

To avoid any kind of damage to the reusable turbine please do not use any alcoholic or oily substances, do not immerge the turbine in hot water or hot solution.
Do not put the turbine under a direct jet of water or other liquid. If no detergent solution is available, clean the turbine in clean water.
MIR suggest the use of Perasafe, manufactured by Dupont, which has been tested with positive results on all MIR sensors.

Rinse the turbine by immerging it in clean water (**not hot**).
Shake off the excess water from the turbine and leave it to dry, standing it vertically on a dry surface.

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

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

4. PROBLEM SOLVING

PROBLEM	MESSAGE	POSSIBLE CAUSES	REMEDY
Smart One® does not connect with the PC	\	Thew bluetooth connection is not correct	Check the device in the list of Bluetooth devices recognized
Spirometry data at the end of the test are not acceptable	\	The turbine don't rotate correctly	Clean the turbine and check another time; use a new turbine
	\	The test is performed in a wrong way	Repeat the test following the indications on the screen
	\	The patient is moving	To obtain an accurate measurement the patient should not make sudden movements.

MEDICAL INTERNATIONAL RESEARCH
Via del Maggiolino, 125 00155 - Roma - ITALY

DECLARATION OF CONFORMITY CE

(annex II excluding par.4)

We hereby declare that the following device:

Type	**Spirometer**
Brandname	**MIR Medical International Research**
Device name	**Smart One®**
Class	**IIa**

Complies with the Essential Requirements of directive 93/42/EC concerning Medical Devices, and its amendments, and its transposition in the Member States.
This statement is made on the basis of the CE Certificate n. MED 9826 issued by Cermet, Notified Body n. 0476.

Rome ……

Paolo Sacco Boschetti
The Chairman

LIMITED WARRANTY CONDITIONS

Smart One®, together with its standard accessories is guaranteed for a period of 12 months if intended for professional use (doctors, hospitals, etc.).
The warranty is effective from the date of purchase contained in the relevant sales invoice or proof of purchase.

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

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

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

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

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

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

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

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

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

ANNEX 1 INFORMATION FOR CORRECT USE IN ELECTROMAGNETIC ENVIRONMENTS

Guidance and manufacturer's declaration – electromagnetic emissions		
The Smart One® is intended for use in the electromagnetic environment specified below. The customer or the user of the Smart One® should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Smart One® uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The (equipment or system) is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Smart One® is intended for use in the electromagnetic environment specified below. The customer or the user of the Smart One® should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment –guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±1 kV for input/output lines	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV differential mode	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the (equipment or system) requires continued operation during power mains interruptions, it is recommended that the (equipment or system) be powered from an uninterruptible powe
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Smart One® is intended for use in the electromagnetic environment specified below. The customer or the user of the Smart One® should assure that it is used in such an environment.			
			Portable and mobile RF communications equipment should be used no closer to any part of the Smart One®, including cables, than the recommended separation distance calculated from 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 to 800 GHz $d=[\frac{7}{3}]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	[3] V	
Radiated RF	3 V/m	[3] V/m	

IEC 61000-4-3	80 MHz to 2,5 GHz		should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Smart One® is used exceeds the applicable RF compliance level above, the Smart One® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Smart One®.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Smart One®

The Smart One® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Smart One® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Smart One® as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m **150 kHz to 80 MHz** $d=[\frac{3.5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d=[\frac{3.5}{E_1}]\sqrt{P}$	**800 MHz to 2,5 GHz** $d=[\frac{7}{E_1}]\sqrt{P}$
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 transmitters rated at a maximum output power not listed above, the recommended separation distance ***d*** inmetres (m) can be estimated using the equation applicable to the frequency of the transmitter, where ***P*** is themaximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

FCC RF Exposure Information and Statement
This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment.

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions:
(1) this device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.

NOTE: The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
-Reorient or relocate the receiving antenna.
-Increase the separation between the equipment and receiver.
-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
-Consult the dealer or an experienced radio/TV technician for help
-This device and its antenna(s) must not be co-located or operating in conjunction with any other antenna or transmitter.