

**SMART ONE**

**Before you use your SMART ONE, please read this user manual, the labels and all the information provided with the product.**

User Manual Rev 2.0

Issue Date

25 June 2015

**CE 0476**

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

**Before you use your SMART ONE, please read this user manual, the labels and all the information provided with the product.**

Before connecting **SMART ONE** to a smartphone, install the **MIR SMART ONE** application which you can download free from the App Store (for iPhone) or Play Store (for Android devices).

The package includes:

- The **SMART ONE** device
- The turbine sensor
- The plastic mouthpiece
- 2 AAA batteries
- The User Manual

After removing the device from its packaging, check that there is no visible damage. If there is, do not use the device and send it straight back to the manufacturer for replacement, where appropriate.

### **Keep the original packaging!**

If your product has a problem, use the original packaging to ship it back to your local distributor or the manufacturer.

The manufacturer's address is as follows:

**MIR SRL**

**VIA DEL MAGGIOLINO, 125 - 00155 ROMA (ITALY)**

**Tel ++ 39 0622754777 - Fax ++ 39 0622754785**

**Website: [www.spirometry.com](http://www.spirometry.com) - Email: [mir@spirometry.com](mailto:mir@spirometry.com)**

**MIR cannot be held responsible for any damage caused by users failing to follow these instructions and/or the warnings contained in this manual.**

## 1. INTRODUCTION

### 1.1 Intended use

**SMART ONE** is intended for home use by patients to monitor PEF (Peak Expiratory Flow) and FEV1 (Forced Expiratory Volume in one second). The device is designed for adult and paediatric subjects.

**SMART ONE** is indicated for monitoring asthma, COPD and other respiratory diseases.

#### 1.1.1 Usage environment

**SMART ONE** is designed to be used in the home.

#### 1.1.2 Restrictions on Use

Analysis of the test results alone will not be enough to diagnose your clinical condition – you will need a medical examination which will take your clinical history into account as well as any other tests recommended by the doctor.

Diagnosis and appropriate treatments are to be given only by a qualified doctor.

The device is intended for use by one person only. If more than one person wishes to use the device, one user's measurements must not be attributed to another. If another person intends to use the device permanently, the previous user data must be erased from the memory and the new user's details data (date of birth, origin, weight, height, sex) must be entered.

If you wish to use the device when it has already been used by another person, make sure to disinfect the mouthpiece and turbine, as explained in the Maintenance section.

## 1.2 Description of product

**SMART ONE** is a pocket-sized system for measuring the following respiratory parameters:

- PEF (Peak Expiratory Flow)
- FEV1 (Forced Expiratory Volume in 1 sec)

The device connects to a smartphone via Bluetooth **SMART** technology. Connection is automatic once the **MIR SMART ONE** application has been installed on the smartphone.

The **MIR SMART ONE** application includes:

- an electronic diary for recording the results. The results can be viewed later
- an incentive displayed on the screen to help improve test performance.

Measurement is performed by a turbine sensor, and is based on the infrared interruption principle. This principle ensures that the measurement is accurate and reproducible.

The advantages of this type of sensor are:

- Unaffected by the humidity and density of the gas
- Shockproof and unbreakable
- Inexpensive to replace

The measurements are transferred in real time from the device to the smartphone. The application compares the parameter measured by the device with the baseline value set during installation, displaying a traffic light health indicator (green, yellow or red) that makes it easy to interpret the test result.



## 1.3 Important information on the parameters measured by SMART ONE

PEF is the maximum speed of the air when you exhale as hard as possible after filling your lungs completely. FEV1 is the volume of air expelled during the first second of the same exhalation. For each of these two parameters, the result is a number shown on the smartphone screen.

A high number (associated with a green light) usually means that the air is moving easily through your lungs. If you have asthma (or another respiratory disease) and have an obstructive episode, the air cannot generally be expelled as forcefully as possible, so your PEF and FEV1 will be lower.

**SMART ONE** thus helps you find out what sort of obstruction you have, if any, at a particular time.

By using the device on a regular basis, you can track any changes that may occur in the parameters. These changes may require appropriate treatment, as prescribed by your doctor.

It is recommended to use the device twice a day, in the morning on waking and at bedtime. If possible, the device should also be used as soon the first signs of respiratory problems occur, so that you can understand how serious your respiratory problem is and/or how well your current therapy is working.

In addition to displaying the PEF (or FEV1) **measurement**, the device also provides a **normal baseline value** (based on your height, age, sex and origin) that is used for **calculating the traffic light**. This value is calculated according to the results of epidemiological studies of large groups of healthy subjects and, as such, a comparison with your measurements is only indicative of your state of health. For example, if your PEF (or FEV1) is higher than the baseline value, you could even be in poor health or if it is lower than the baseline value you could be in good health.

When calculating the traffic light, as an alternative to using the standard baseline value, the best way of finding out your personal PEF (or FEV1) baseline value is to discuss it with your doctor.

This value is normally called the **personal best value**.

## 2. OPERATING THE SMART ONE

### 2.1 Inserting the batteries

Follow the instructions in the Maintenance section for correct battery insertion.

### 2.2 Installing the MIR SMART ONE application

Before measuring the PEF or FEV1, you need to install the **MIR SMART ONE** application on your smartphone.

iPhone devices

From your smart phone (iPhone model 4S or higher running iOS version 7 or higher) access the App Store and install the **MIR SMART ONE** application.

#### 2.2.1 Configuring the MIR SMART ONE application

Launch the MIR SMART ONE application and carry out the following steps. These are one-off operations that do not need to be repeated next time you enter the application.

a) authorize data exchange with the Health application, which is already installed on your smartphone.

The user can decide whether or not to allow

- the following data to be written to the Health application: height, weight, PEF and FEV1
- the following data to be read from the Health application: height, weight, date of birth, gender.

You can allow or deny authorization for each parameter.

b) enter your personal details: date of birth, origin, weight, height, sex.

The **MIR SMART ONE** application will use these data to calculate standard PEF and FEV1 values, and will use them to attribute a traffic light colour to your test.

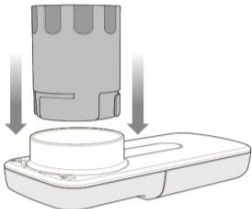
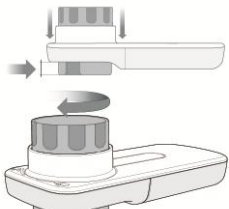
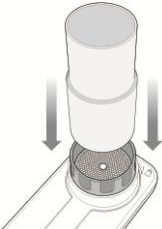

If you don't enter your data, a warning message will be issued.

### 2.3 Connection between SMART ONE and smartphone

Connection between the **SMART ONE** and the smartphone is automatic. To check whether there is a connection, read the messages from the application.

## 2.4 Performing the test

In order to perform the test properly, please follow the instructions below.

<p>1</p> <p>Push the turbine into the slot until it stops</p>  <p>A diagram showing a cylindrical turbine being pushed into a rectangular base. Two downward-pointing arrows indicate the direction of force. The turbine is partially inserted into a slot on the base.</p>	<p>2</p> <p>Turn the turbine clockwise until it stops</p>  <p>A diagram showing the turbine being rotated clockwise. A curved arrow indicates the direction of rotation. The turbine is now fully seated in the slot.</p>
<p>3</p> <p>Insert the mouthpiece at least 0.5 cm into the turbine socket.</p>  <p>A diagram showing a mouthpiece being inserted into the turbine. Two downward-pointing arrows indicate the direction of force. The mouthpiece is partially inserted into the turbine's socket.</p>	<p>4</p> <p>Pick up the <b>SMART ONE</b> either at both ends using both hands or, alternatively, pick it up as if it were a cell phone.</p> <p><b>Make sure not to obstruct the turbine with your hand.</b></p>  <p>A diagram showing a hand holding the SMART ONE device. The hand is positioned to hold the device from the bottom, with the thumb and index finger gripping the sides. The device is held upright, and the turbine is visible at the top.</p>



Insert the mouthpiece in your mouth beyond your teeth, and close your lips tightly over it so that the air you breathe has to pass only through the mouthpiece.

5



**The mouthpiece must be properly located behind the teeth, so as to prevent any turbulence that might otherwise affect the test results.**

Blow out as hard as you can.

**It is best to do the test standing or sitting upright.**

6



7

After exhalation, slowly remove the device from the mouth and check the data on the smartphone.

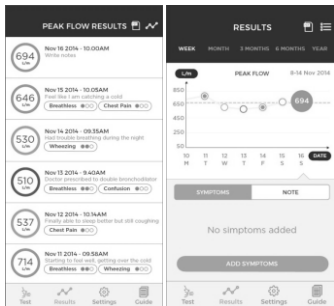
**When SMART ONE is out of your mouth, avoid sudden movements because this will push air into the turbine and a flow value will be measured that may affect the test results.**

Repeat the test three times. **SMART ONE** will save the highest value.

## 2.4.1 Evaluating the test

Three tests are performed per measurement session, after which the **MIR SMART ONE** application automatically selects the highest value and compares it with the baseline value (normal or personal best) set during configuration. The application compares the test result with the baseline value and assigns a traffic light colour (green, yellow or red) to it, which is then displayed around the test result.

The meaning of the traffic lights is displayed in the following table:



Colour	Result	Meaning	Action
Green	above 80% of baseline value	OK	The respiratory problem is under control.
Yellow	above 50% and below or equal to 80% of the baseline value	Warning	In you often get these results, do what your doctor suggested (for example, taking a different dose of the medication you have been prescribed).
Red	below or equal to 50% of baseline value	Danger	Results highlighted in red indicate a red alert! Do what you have previously agreed with your doctor or contact him/her as soon as possible.

## 2.4.2 Results diary

The test results are automatically stored on the smartphone and can be displayed later. Medical studies have shown that if your doctor examines the test results on a regular basis, lung disease can be managed much better.

## 2.5 Important safety warnings



**Warning:** indicates a potentially hazardous situation which, if not prevented, could result in minor or moderate injury to the user or patient or damage the device.



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



Only original accessories as specified by the manufacturer must be used with the device.



Use of an unsuitable turbine flow sensor may cause errors in measurement or compromise the correct functioning of the device.

Use of an unsuitable mouthpiece could also damage the turbine or harm the patient.



In the event of an accident of any kind arising from use of the device, you are strongly recommended to inform your doctor so that he/she can notify the authorities as required by local legislation.



The device 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 chemical substances.



Use and store the device in compliance with the environmental conditions specified in the Technical Specifications. If the device is subjected to environmental conditions other than those specified, it may malfunction and/or display incorrect results.



The maintenance operations set out in the User Manual must be carried out with the utmost care. Failure to follow the instructions may lead to measurement errors or misinterpretation of the measured values.



Do not modify the device without authorization from the manufacturer. All modifications, adjustments, repairs, reconfigurations must be performed by the manufacturer or by authorized personnel.

In case of problems, do not try to repair the device yourself.

## 2.6 Data security warnings

Your smartphone stores your personal data.

Potential threats such as the following:

- Malware installation
- Physical access to the smartphone
- Interception of communications
- Physical damage to the smartphone
- Theft of the smartphone

could have an impact on the integrity or confidentiality of such data, such as:

- Accessing data in memory by unauthorized persons
- Loss of data in memory
- Inability to use smartphone for communications

The following actions help reduce the risk of such events:

- Do not open or install files from suspicious sources
- Use antivirus software
- Back up your data periodically
- Do not leave your smartphone unattended
- Use a password to access the data

## 2.7 Warnings for use in electromagnetic environments

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

Such electromagnetic interference could cause the medical device to malfunction and create a potentially unsafe situation.

**SMART ONE** complies with EN 60601-1-2:2007 on electromagnetic compatibility (EMC for medical devices) for both immunity and emissions.

For the device to function properly, however, the following precautions must be taken:

- Make sure that the SMART ONE and the smartphone on which the MIR SMART ONE application is installed are no more than 2 metres apart.

- Do not use SMART ONE near other devices (computers, cordless phones, cell phones, etc.) that generate strong electromagnetic fields. Keep such equipment at a minimum distance of 7 metres.

## 2.8 Notes on FCC certification

**SMART ONE** complies with Part 15 of the FCC Rules. Operation is subject to the following conditions:

- (1) this device may not cause harmful interference
- (2) this device must accept any interference received, including interference that may cause undesired operation

Any modifications not expressly approved by this company could compromise use of the device by the user.

**N.B.:** 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 when the equipment is operated 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.

If this device does cause interference to radio or television reception, which can be determined by turning the device off and on, the user is encouraged to correct the interference by taking one of the following measures:

- Reorient or relocate the antenna
- Increase the distance 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/television technician for help.

## 3. MAINTENANCE

**SMART ONE** is a device that requires little maintenance. The following operations are to be performed regularly:

- cleaning and disinfection of the turbine
- cleaning and disinfection of the mouthpiece
- cleaning of the device
- replacing batteries

### 3.1 Cleaning and disinfection of the turbine

Correct operation of the turbine is guaranteed only if it is "clean" and free of foreign objects that affect its movement. The presence of dust or foreign bodies (such as hairs, sputum etc.) could slow or block the moving parts of the turbine and make the result less accurate, or damage the turbine itself.

After each use, check the cleanliness of the turbine.

To clean the turbine, pull it out of the **SMART ONE** socket by turning it counterclockwise and simply pulling it out. To make it easier to pull out, push the base of the turbine gently with a finger.

Soak the turbine in a cold detergent solution and shake it to remove any impurities inside it; leave it to soak for the length of time suggested by the cleaning solution manufacturer and shown in the operating instructions.

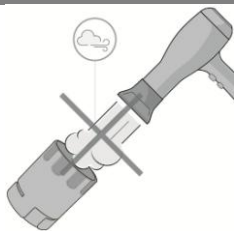
Rinse the turbine by dipping it in clean cold water. Drain the turbine and shake it vigorously. Leave it to dry by laying it with the shaft vertical to the dry support surface.

After cleaning, insert the turbine into the socket in the direction indicated by the screen-printed closed padlock symbol on the **SMART ONE**. To insert the turbine correctly, push it down and turn clockwise until it stops, to make sure it is fully inserted into the plastic container.

To avoid irreparable damage to the turbine, do not use any alcoholic or oily cleaning solutions, and do not immerse in hot water or solutions.

Do not try to sterilize the turbine in boiling water.

Never try to clean the turbine under a direct jet of water or other liquids. If there are no liquid detergents, the turbine must at least be washed in clean water.



### 3.2 Cleaning and disinfection of the mouthpiece

Make sure to clean the mouthpiece after each use. To clean the mouthpiece, simply pull it apart from the turbine.

Just as for the turbine, soak the mouthpiece in a cold detergent solution and shake it to remove any impurities inside it; leave it to soak for the length of time suggested by the cleaning solution manufacturer and shown in the operating instructions.

Rinse the mouthpiece by dipping it in clean cold water.

Drain the mouthpiece and shake it vigorously. Leave it to dry on a dry surface.

After cleaning, reattach the mouthpiece to the turbine, by pressing lightly.

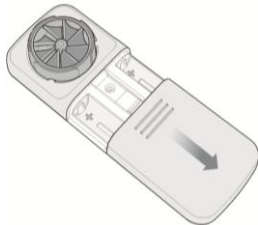
### 3.3 Cleaning of the device

Clean the device once a day using a clean damp cloth. Never put the device into water or other fluids.

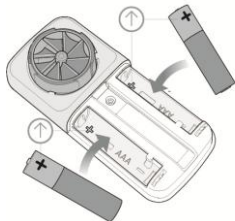
### 3.4 Replacing batteries

The battery charge is continuously monitored by the device. A message on the smartphone display alerts the user when the device battery is low.

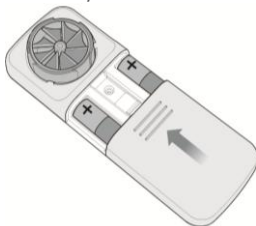
Remove the battery cover on the back of the **SMART ONE**

**1**


Remove the two batteries and replace them with two new ones, making sure they are inserted the right way round as shown in the casing

**2**


Reattach the battery cover

**3**


Used **SMART ONE** batteries should only be disposed of in special containers or preferably returned to the dealer of the device or to a special collection centre. In any case, all applicable local regulations must be complied with.

## 4. ERROR MESSAGES & TROUBLESHOOTING

### 4.1 Error messages

If you encounter any problems when using the **SMART ONE**, a message will appear on the smartphone display to warn of the malfunction.



MESSAGE	POSSIBLE CAUSE	SOLUTION
Bluetooth	Bluetooth is off	To perform measurements with the device, you must activate Bluetooth on the smartphone. Exit the application and activate Bluetooth from the smartphone settings menu.
Battery low	When the <b>SMART ONE</b> batteries are below 15%	Replace the <b>SMART ONE</b> batteries
It seems that you have not configured an e-mail account	The user wants to share the results of the tests, but has not configured an e-mail account on their smartphone	Set up an e-mail account from the smartphone settings menu

## 4.2 Troubleshooting

PROBLEM	POSSIBLE CAUSE	SOLUTION
<b>SMART ONE</b> can't connect with the smartphone	The Bluetooth connection is not working properly	Look for <b>SMART ONE</b> on the list of recognized devices. For correct use, the smart phone needs Bluetooth version 4.0 or higher
	The turbine may be dirty	Clean the turbine as described in the Maintenance section. If necessary, replace the turbine with a new one, if necessary by contacting the manufacturer
The test results are unreliable	The test was performed wrongly	Repeat the test, following the directions on the screen. Avoid sudden movements when you finish exhaling
	The turbine has not been inserted properly	Insert the turbine from the front of the device by pushing it all the way down and turning it clockwise. See the <i>Performing the test</i> section

## 5. LABELS & SYMBOLS

ID label



The label shows:

- Product Name (REF)
- Device serial number (SN)
- Manufacturer's name and address
- Electrical safety symbol
- WEEE Symbol
- CE mark pursuant to Directive 93/42/EEC
- Antenna symbol for devices that include RF transmitters
- FCC ID number
- Degree of protection against penetration by external agents (IP22)

Symbol	Description
	This product is a certified Class IIa medical device, and complies with the requirements of Directive 93/42/EEC
	In accordance with IEC 60601-1 the product and its applied parts are type BF and thus protected against the risks of electrical leakage.
	This symbol is required by European directive 2002/96/EEC on waste 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, disposal as normal waste could cause harm to the environment and/or health. Failure to observe these regulations can lead to prosecution.
<b>IP22</b>	Indicates the degree of resistance to liquids. The device is protected against falling drops of water if it is disposed up to 15° from vertical.



This product is a certified Class IIa medical device, and complies with the requirements of Directive 93/42/EEC



In accordance with IEC 60601-1 the product and its applied parts are type BF and thus protected against the risks of electrical leakage.



This symbol is required by European directive 2002/96/EEC on waste 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, disposal as normal waste could cause harm to the environment and/or health.

Failure to observe these regulations can lead to prosecution.

**IP22** Indicates the degree of resistance to liquids. The device is protected against falling drops of water if it is disposed up to 15° from vertical.

**Symbol Description**


The symbol is used in accordance with IEC EN 60601-1-2: 2007 in section 5.1.1 for products including RF transmitters.

## 6. TECHNICAL SPECIFICATIONS

**Parameters measured:**

FEV1	Expiratory volume in one second of testing	L
PEF	Peak expiratory flow	L/minute

<b>Flow/volume measurement system</b>	Bi-directional turbine
<b>Measurement principle</b>	Infrared interruption
<b>Maximum volume measured</b>	10 L
<b>Flow range</b>	±960 L/minute
<b>Volume accuracy</b>	± 3%
<b>Flow accuracy</b>	± 5%
<b>Dynamic resistance at 12 L/s</b>	<0.5 cm H <sub>2</sub> O/L/s
<b>Communication interface</b>	Bluetooth SMART (4.0 or higher)
<b>Power supply</b>	2 x 1.5V AAA alkaline batteries
<b>Size</b>	main body 109x49x21 mm
<b>Weight</b>	60.7 g (including batteries)
<b>Type of electrical protection</b>	Class II
<b>Electrical protection level</b>	BF
<b>IP protection level</b>	IP22
<b>Regulations applicable</b>	Electrical Safety IEC 60601-1 Electromagnetic Compatibility IEC 60601-1-2 ATS/ERS Standardization of spirometry 2005
<b>Conditions of use</b>	Device for continuous use
<b>Storage conditions</b>	Temperature: MIN -40°C, MAX +70°C Humidity: MIN 10% RH; MAX 95%RH
<b>Transport conditions</b>	Temperature: MIN -40°C, MAX +70°C Humidity: MIN 10% RH; MAX 95%RH
<b>Operating conditions</b>	Temperature: MIN +5°C, MAX +40°C Humidity: MIN 10% RH; MAX 95%RH

## 7. COMPLIANCE WITH EUROPEAN DIRECTIVE 93/42/EEC

**SMART ONE** complies with the Essential Requirements of Directive 93/42/EEC on Medical Devices, as amended and Italian Legislative Decree 46/97 and subsequent amendments and additions thereto.

This statement is made on the basis of CE Certificate no. MED 9826 issued by Cermet, Notified Body no. 0476.

## 8. WARRANTY TERMS

**SMART ONE**, together with any accessories provided, is guaranteed for a period of:

- 12 months in the case of professional use (doctor, hospital, etc.)
- 24 months where the product is purchased directly by the end-user.

The warranty period is effective from the date of purchase, which must be proven by an invoice or sales receipt.

The device 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, including the turbine sensor, are specifically excluded from the terms of this guarantee.

The product warranty shall not apply, at the discretion of the manufacturer, in the following cases:

- Improper installation or operation of the device, or if the installation does not comply with current technical or safety regulations in the country of purchase
- Use of the product for purposes other than those provided or failure to follow instructions
- Repair, adaptation, modification or tampering by personnel not authorised by the manufacturer
- Damage caused by lack of or incorrect maintenance
- Damage caused by abnormal physical or electrical stress
- Damage caused by defects of the mains electricity supply or of equipment to which the product has been connected
- Serial number altered, deleted, removed or rendered illegible

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

The customer shall be responsible for all transport, customs and delivery charges regarding the goods.

Each product, or accessory, sent in for repair must be accompanied by a clear and detailed explanation of the fault. Forwarding to the manufacturer requires the written permission of the manufacturer himself.

MIR Medical International Research reserves the right to replace the product or make any changes deemed necessary.