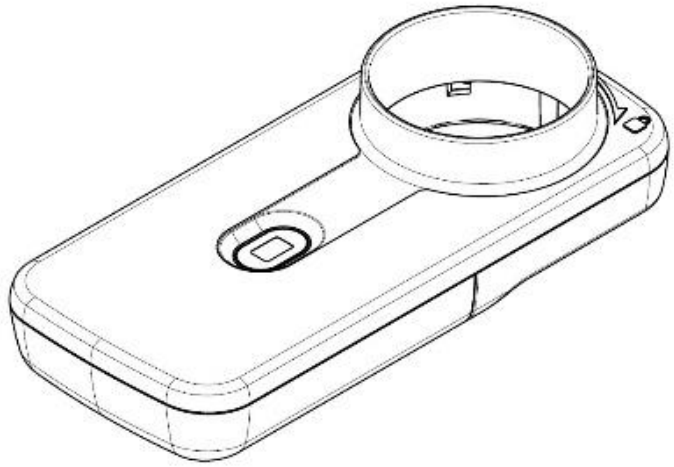
SMARTONE Oxi ®



English (EN)

BEFORE USING THIS DEVICE READ ALL INFORMATION CONTAINED IN THIS USER MANUAL. IF YOU DO NOT UNDERSTAND THESE INSTRUCTIONS OR IF YOU HAVE QUESTIONS ABOUT YOUR SPIROMETER AND ITS USE CONSULT YOUR PHYSICIAN OR OTHER LICENSED HEALTHCARE PROFESSIONAL.
IF THE INSTRUCTIONS ARE NOT CLEAR:

USA:
Call MIR USA Tel + 1 (262) 565 - 6797 ; Fax + 1 (262) 364 - 2030, Monday to Friday 8 AM to 5 PM (central time), or contact us at mirusa@spirometry.com, **or write to us at MIR USA, 5462 S. Westridge Drive, New Berlin, WI 53151 – USA.**

EUROPE and WORLDWIDE:
Call MIR +39 06 22754777, Monday to Friday 8 AM to 5 PM (GMT+1), or contact us at mir@spirometry.com, **or write to us at MIR Via del Maggiolino 125, 00155 Rome, Italy.**

User Manual Rev 2.0.1 Issue Date 14.03.2023

CE 0476

Date	Measurements		Recommendation	Doctor
	PEF	FEV1		

Reserved for the physician or other licensed healthcare professional to write your positive flow rates and to provide specific interventions he/she recommends for ranges of decreased flow rates.

CONTENTS

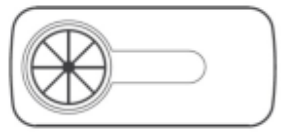
Before connecting **SMART ONE OXI** to a smartphone, install the **MIR SMART ONE** free app, which you can download from the App Store (for iPhone and iPad) or Play Store (for Android devices).

After removing the device from its packaging, check that there is no visible damage. If it looks damaged, do not use the device and return it directly to request replacement.

If there is, do not use the device and send it straight back for replacement.

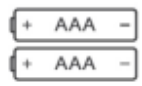
INCLUDES

Spirometer for peak flow and FEV1



Plastic mouthpiece

2 AAA batteries



User Manual

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

MIR USA, INC.
5462 S. Westridge Drive
New Berlin, WI 53151 - USA

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The manufacturer cannot be held responsible for any damage caused by users failing to follow the instructions contained in this manual.

1. INTENDED USE

Smart One Oxi spirometer and pulse oximeter is intended to be used by a physician or by a subject under the instructions of a physician or paramedic to assess lung function. The device is designed for children of over five years of age, adolescents and adults, and can be used at home, in a factory, pharmacy, hospital or medical surgery.

2. IMPORTANT INFORMATION CONCERNING INTENDED USE

PEF is the maximum speed a person can blow air out of the lungs after taking a very deep breath.
FEV1 is the maximum volume of air a person can exhale from the lungs in one second after taking as big a breath as possible.
SpO2 is the percentage of oxygen saturation in the blood.
BPM is the heart rate.

WARNING: WHEN SMART ONE OXI IS USED TO MONITOR LUNG CONDITIONS SUCH AS ASTHMA YOU SHOULD BE UNDER THE CARE OF A PHYSICIAN OR OTHER LICENSED HEALTHCARE PROFESSIONAL.

Medical studies have shown that regularly reviewing accurate measurements of PEF and FEV1 with a physician or other licensed healthcare professional may allow individuals with lung disease to better manage their conditions.

It is very important to watch for **changes** from one measurement to the next, and to follow the actions you have to take according to the **plan of action** provided to you by your physician or other licensed healthcare professional.

If you have respiratory conditions such as asthma your physician or licensed healthcare professional may recommend that you measure PEF/FEV1 to watch your disease and discover if there are changes in your airflow. When you blow into the mouthpiece of the flow meter, the device will display a number. The faster you blow, the higher the reading.

This number tells you how well air is moving through the airways in your lungs. When you use **SMART ONE OXI** regularly, you will be able to detect changes in your measurements, which will tell you and your physician or other licensed healthcare professional what is happening with your lungs.

These changes may require special treatment of your condition according to the action plan given to you by your physician or licensed healthcare professional which will tell you when and how often to use your **SMART ONE OXI** meter. They also will explain how your PEF and FEV1 measurements help them monitor your lung function and how well treatments are working.

3. DETERMINING YOUR PEF BASELINE VALUES

A PEF measure with a high value usually means that your airflow is good.
The best way to determine what is a healthy PEF for you is to discuss this with your physician or other licensed healthcare professional. The importance of any changes in airflow from one measuring to the next depends upon **how much they are different from the baseline value** you should reach when you are in healthy physical condition.

Your physician or other licensed healthcare professional will use one of two possible ways to identify **your baseline value**. The first method adopts the **predicted value** calculated according to the results of epidemiological studies of large groups of healthy subjects of your same age, height, gender and origin. The second method adopts the **personal best value** you can reach when you are in the healthiest physical condition.

The **MIR SMART ONE** app can calculate the PEF **predicted value,** i.e. the expected value for healthy people, depending on age, height, gender, and origin. **MIR SMART ONE** app calculate the predicted value endorsed by ATS (American Thoracic Society): PEF predicted values are calculated according to *Knudson, R. J., Slatin R. C., Lebowitz, M. D., Burrows, B., The Maximal Expiratory Flow-Volume Curve – Normal Standards, Variability, and Effects of Age, AM REV RESPIR DIS, 1976 113;587-600.*

In this case, the predicted value becomes the baseline value for your treatment plan. If your physician or other licensed healthcare professional prefers this method, **MIR SMART ONE** app provides the calculation of the predicted PEF value.

It is important to know that these predicted values are average numbers for large groups of people. You may have a higher PEF measure than the predicted value and you may not be healthy. Or you may have a lower PEF than the average and be healthy.

PEF table Male (L/min)

AGE \ Height (cm)	120	130	140	150	160	170	180	190	200
5	128	175	221	268	315	362	409	455	502
10	178	224	271	318	365	412	458	505	552
15	227	274	321	368	415	461	508	555	602
20	277	324	371	418	464	511	558	605	652
25	265	321	378	434	490	547	603	660	716
30	254	311	367	423	480	536	593	649	705
35	244	300	357	413	469	526	582	639	695
40	233	290	346	402	459	515	572	628	684
45	223	279	336	392	448	505	561	618	674
50	212	269	325	381	438	494	551	607	663
55	202	258	315	371	427	484	540	597	653
60	191	248	304	360	417	473	530	586	642
65	181	237	294	350	406	463	519	576	632
70	170	227	283	339	396	452	509	565	621
75	160	216	273	329	385	442	498	555	611
80	149	206	262	318	375	431	488	544	600
85	139	195	252	308	364	421	477	534	590
90	128	185	241	297	354	410	467	523	579

Female PEF values (l/min)

AGE \ Height (cm)	120	130	140	150	160	170	180	190	200
5	165	194	224	253	283	312	341	371	400
10	212	241	271	300	330	359	388	418	447
15	259	289	318	347	377	406	436	465	494
20	279	308	338	367	396	426	455	485	514
25	271	301	330	359	389	418	448	477	506
30	264	293	323	352	381	411	440	470	499
35	256	286	315	344	374	403	433	462	491
40	249	278	308	337	366	396	425	455	484
45	241	271	300	329	359	388	418	447	476
50	234	263	293	322	351	381	410	440	469
55	226	256	285	314	344	373	403	432	461
60	219	248	278	307	336	366	395	425	454
65	211	241	270	299	329	358	388	417	446
70	204	233	263	292	321	351	380	410	439
75	196	226	255	284	314	343	373	402	431
80	189	218	248	277	306	336	365	395	424
85	181	211	240	269	299	328	358	387	416

WARNING: INDEPENDENTLY OF THE METHOD CHOSEN BY YOUR DOCTOR OR OTHER LICENSED HEALTH PROFESSIONAL, THE PATIENT MUST CLEARLY UNDERSTAND THE MEANING OF THE BASELINE VALUE AND HOW IT INFLUENCES THE TREATMENT PLAN. IF IN DIFFICULTY REGARDING ESTABLISHING YOUR OWN BASELINE VALUE, ASK FOR HELP FROM YOUR PHYSICIAN OR ANOTHER LICENSED HEALTH PROFESSIONAL.

4. WARNINGS AND PRECAUTIONS

⚠ **PLEASE READ ALL THE INFORMATION IN THIS USER MANUAL BEFORE USING THIS DEVICE. IF YOU DO NOT UNDERSTAND THESE INSTRUCTIONS OR IF YOU HAVE QUESTIONS ABOUT YOUR FLOWMETER FOR MEASURING PEF AND FEV1 AND ITS USE CONSULT YOUR PHYSICIAN OR OTHER LICENSED HEALTHCARE PROFESSIONAL.**

⚠ **WHEN SMART ONE IS USED TO MONITOR LUNG CONDITIONS SUCH AS ASTHMA YOU SHOULD BE UNDER THE CARE OF A PHYSICIAN OR OTHER LICENSED HEALTHCARE PROFESSIONAL.**

⚠ **TO INTERPRET THE MEANING AND SIGNIFICANCE OF A MEASUREMENT TAKEN USING SMART ONE OXI AND TO DECIDE ON AN APPROPRIATE PLAN OF ACTION, BE SURE TO CONSULT A HEALTHCARE PROFESSIONAL, ALSO IN VIEW OF THE FACT THAT THE DEVICE IS NOT EQUIPPED WITH ALARMS.**

⚠ **APPROPRIATE DIAGNOSIS AND TREATMENT CAN ONLY BE PROVIDED BY A PHYSICIAN OR OTHER LICENSED HEALTHCARE PROFESSIONAL. THE PLAN OF ACTION WILL INDICATE WHICH ACTION IS TO BE TAKEN WHEN THERE ARE CHANGING MEASUREMENTS.**

⚠ **SELF-MEASUREMENT MEANS CHECKING, NOT DIAGNOSING OR CHOOSING A TREATMENT. IF ANY EVENT OCCURS SHOW YOUR MEASUREMENTS TO YOUR PHYSICIAN OR OTHER LICENSED HEALTHCARE PROFESSIONAL. THEY WILL ALSO EXPLAIN WHICH ARE THE NORMAL VALUES FOR YOU.**

⚠ **INDEPENDENTLY OF YOUR VALUES, IF YOU ARE SHOWING SIGNS AND SYMPTOMS SUCH AS THORACIC CONSTRICTION, SHORT BREATH, COUGH OR DYSPNOEA, CONTACT YOUR PHYSICIAN OR A LICENSED HEALTHCARE PROFESSIONAL.**

⚠ TO OBTAIN ACCURATE MEASUREMENTS, CAREFULLY FOLLOW THE INSTRUCTIONS. IF YOU CANNOT OBTAIN A VALUE, CONTACT YOUR HEALTHCARE PROFESSIONAL.

⚠ ASK YOUR PHYSICIAN OR LICENSED HEALTHCARE PROFESSIONAL TO WATCH YOU USING THE SMART ONE BEFORE RELYING ON ANY MEASUREMENT.

⚠ MODIFYING THE PLAN OF ACTION OR THE BASELINE VALUES MUST BE CARRIED OUT ONLY FOLLOWING INDICATIONS OF YOUR PHYSICIAN OR OTHER LICENSED HEALTHCARE PROFESSIONAL. SPEAK WITH YOUR PHYSICIAN BEFORE PROCEEDING.

⚠ NEVER CHANGE DRUG DOSES WITHOUT FIRST AGREEING THEM WITH YOUR PHYSICIAN.

⚠ THE DEVICE SHOULD NOT BE USED BY MORE THAN ONE PERSON. IF MORE THAN ONE PERSON WISHES TO USE IT, THE MEASUREMENT OF EACH PERSON SHOULD BE ATTRIBUTED CORRECTLY AND BOTH THE TURBINE AND THE MOUTHPIECE MUST BE CLEANED CAREFULLY FOLLOWING EACH USE UNLESS MORE THAN ONE MOUTHPIECE/TURBINE IS AVAILABLE.

⚠ IF ANOTHER PERSON INTENDS TO USE THE DEVICE EXCLUSIVELY, THE PREVIOUSLY SAVED DATA ON THE MIR SMART ONE APP MUST BE DELETEDAND A NEW BASELINE MEASUREMENT WILL HAVE TO BE ESTABLISHED ACCORDING TO WHAT IS ESTABLISHED BY THE PHYSICIAN OR THE LICENSED HEALTHCARE PROFESSIONAL.

5. CONTRAINDICATIONS

The ATS/ERS guideline updated 2019 sets out the relative contraindications of spirometry as follows.

Due to increased myocardial demand or changes in blood pressure: Acute myocardial infarction within 1 week; Systemic hypotension or severe hypertension; Significant atrial/ventricular arrhythmia; Uncompensated heart failure; Uncontrolled pulmonary hypertension; Acute pulmonary heart; Clinically unstable pulmonary embolism; History of syncope related to forced expiration/cough.

Due to increased intracranial/intraocular pressure: Cerebral aneurysm; Brain surgery within 4 weeks; Recent concussion with persistent symptoms; Eye surgery within 1 week.

Due to increased sinus and middle ear pressure: Sinus or middle ear surgery or infection within 1 week.

Due to increased intrathoracic and intraabdominal pressure: Presence of pneumothorax; Thoracic surgery within 4 weeks; Abdominal surgery within 4 weeks; Over term pregnancy.
Due to infection control problems: Active or suspected transmissible respiratory or systemic infection, including tuberculosis; Physical conditions predisposing to transmission of infection, such as haemoptysis, significant discharge or oral injury or oral bleeding.
⚠ The medical professional is obliged to assess the patient's health condition before he or she performs spirometry.

6. HOW TO START TO USE THE MIR SMART ONE APP

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

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

Launch the **MIR SMART ONE OXI** app and proceed with the following steps.
These are one-off steps that do not need to be repeated each time the app is accessed.

a) authorisation for data exchange with the Health app, already installed in the 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.

Authorisation for each parameter can be given or denied.

b) entering your own personal data: date of birth, origins, weight, height, gender.

The **MIR SMART ONE OXI** will use this data to calculate the baseline values of the PEF and to assign a colour indicator to your test (green, yellow or red). Consult the **CALCULATION OF BASELINE VALUES** section for a full detailed explanation of the baseline value. If the data is not entered a warning message appears.

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

7. HOW SMART ONE OXI WORKS

SMART ONE OXI is an electronic device for domestic use which precisely measures your PEF (Peak Expiratory Flow) and the FEV1 (maximal expiratory volume in the 1st second, VEMS). The device also measures the parameters related to the oximetry test in particular the SpO2 and the BPM.

The **PEF** is the **maximal expiratory volume** with which the air can be expelled from the lungs after having drawn breath in deeply, while the **FEV1** is the **maximal expiratory volume** of air a person can exhale from the lungs in one second after taking as big a breath as possible.

WHAT IS THE SCIENTIFIC BASIS FOR MEASUREMENT OF PEF AND FEV1 AT HOME?

The first portable **mechanical measuring instrument** for calculating PEF was introduced by B. Wright in 1959. The wide use made of this device for monitoring children above five years of age and adults made this instrument popular for tracing the respiratory conditions of patients with asthma and other pulmonary dysfunctions.

Electronic measuring instruments, economical, small, portable and easy to use for assessing respiratory dysfunction are now widely available. These offer numerous advantages, including the possibility of recording the **PEF** and **FEV1**, and **recording and transferring the data to a physician** or another licensed healthcare professional.

SMART ONE OXI emits a warning signal if the test is not correctly carried out, for example if instead of blowing as much as possible exhalation is too slow. This is a further objective advantage with respect to a mechanical spirometer which does not provide any such signalling.

The PEF and FEV1 are measured during the same exhalation. When the test is correctly carried out, the PEF is measured for 0.10-0.15 seconds from the start of exhalation, while the FEV1 is measured for 1 second exactly from the start of the exhalation.
According to the best tests of effectiveness, taken from among numerous scientific studies, research documents and expert clinicians, both the PEF and FEV1 are good indicators of the respiratory mechanics in conditions of health and illness and can indicate how the breathing functions and can help to verify whether there have been alterations to the respiratory flow. The constant measurement of PEF and FEV1 provides a proof of progression of an illness.

The **GUIDE FOR MANAGEMENT AND PREVENTION OF ASTHMA**, published in 2016 by GINA Global Strategy for Asthma Management and Prevention) states:

To obtain training for effective self-management of asthma the following is necessary:

- ***Self-monitoring of the symptoms and/or the lung function***
- ***A written plan of action for asthma***
- ***Periodic medical checks***

The above indicates that when self-managing asthma the conditions of your lungs can effectively be monitored on the basis of the plan of action written out by a physician or a licensed healthcare professional.

WARNING: TO INTERPRET THE MEANING AND IMPORTANCE OF A MEASUREMENT OBTAINED USING SMART ONE OXI AND DECIDING AN APPROPRIATE PLAN OF ACTION IT IS NECESSARY TO CONSULT A PHYSICIAN OR OTHER HEALTHCARE PROFESSIONAL.
The SMART ONE OXI connects to a smartphone via Bluetooth SMART technology. Connection is automatic once the MIR SMART ONE OXI application has been installed on the smartphone.

Each PEF and FEV1 measurement is transferred by the device to the smartphone so as to be displayed. The use of the coloured PEF indicator (green, yellow or red) is recommended as indicated by your physician or another licensed healthcare professional. These are the professionals who will help you to accurately run the test and advise you as to the actions to undertake when measuring decreasing values.

WARNING: WHEN SMART ONE OXI IS USED TO MONITOR LUNG CONDITIONS SUCH AS ASTHMA YOU SHOULD BE UNDER THE CARE OF A PHYSICIAN OR OTHER LICENSED HEALTHCARE PROFESSIONAL.

A higher PEF and FEV1 value usually means that the air is easily accessing the lungs. When there is an asthma attack the air can no longer easily circulate in the lungs and lower measurements are the outcome. It is usually recommended to carry out the measurements as indicated by the licensed healthcare professionals.
SMART ONE OXI should be used also when respiratory difficulty symptoms are manifested, to help the person and the physician or licensed healthcare professional to determine the severity of the respiratory symptoms and understand how the treatment is working. Consult your physician or other licensed healthcare professional about the times and frequency of use of the SMART ONE OXI spirometer and pulse oximeter.

7.1 Control of registrations

The **MIR SMART ONE OXI** app keeps a trace of the **higher PEF and FEV1 values read both for the morning and evening session**, complete with date and time of reading. The points between two readings are connected to one another to form a graph of the trend. This recording is destined in future to become an important part of the plan of action for every sufferer's asthma.

The **MIR SMART ONE** can transfer the data measured to the family physician or another licensed healthcare professional. If correctly used, **SMART ONE OXI** helps patients and physicians or licensed health personnel to monitor asthma and other lung pathologies so as to offer the best treatment.

The subsequent revision of the measured data enables patients and healthcare professionals to more precisely check the respiratory complaint present in order to provide the most suitable personalised treatment.

As the smartphone automatically memorises hundreds of readings, the device can be taken along to a meeting with your physician or healthcare professional so that a large quantity of readings can be viewed.

7.2 Self-measurement of PEF and FEV1 values

BEFORE USING THIS DEVICE READ ALL INFORMATION CONTAINED IN THIS USER MANUAL. IF YOU DO NOT UNDERSTAND THESE INSTRUCTIONS OR IF YOU HAVE QUESTIONS ABOUT YOUR SPIROMETER AND ITS USE CONSULT YOUR PHYSICIAN OR OTHER LICENSED HEALTHCARE PROFESSIONAL.
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ASK YOUR PHYSICIAN OR OTHER LICENSED HEALTHCARE PROFESSIONAL TO WATCH YOU USING THE SPIROMETER. THIS HELPS TO ENSURE CORRECT USE OF THE INSTRUMENT.

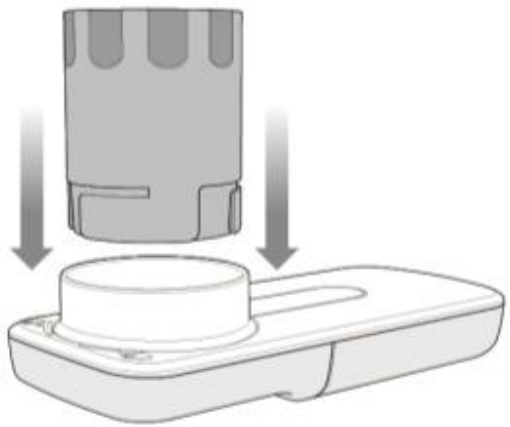
INDEPENDENTLY OF THE MEASUREMENT VALUES ON YOUR SPIROMETER, IF YOU ARE SHOWING SIGNS AND SYMPTOMS SUCH AS THORACIC CONSTRICTION, SHORT BREATH, COUGH OR DYSPNOEA, CONTACT AND FOLLOW THE INDICATIONS OF YOUR PHYSICIAN OR A LICENSED HEALTHCARE PROFESSIONAL.
IF YOU CANNOT OBTAIN A VALUE, CONTACT YOUR PHYSICIAN IMMEDIATELY.

SMART ONE OXI must be cleaned as illustrated in the **MAINTENANCE AND CLEANLINESS** section prior to starting to use it and then periodically.

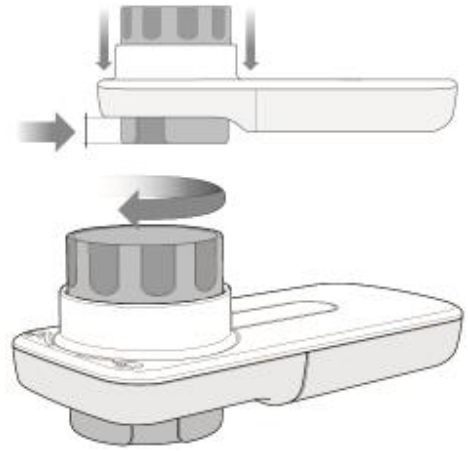
To perform a measurement:

- **Running the MIR SMART ONE app on a smartphone**
- **Press the START icon**
- **Wait for the Bluetooth connection**

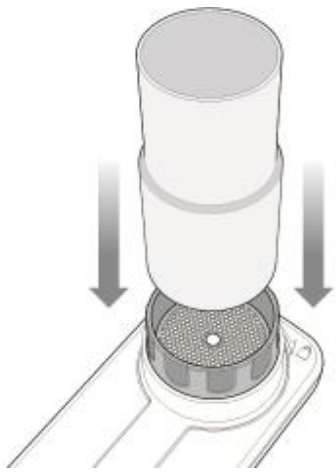
1 Push the turbine into the slot until it stops



2 Turn the turbine clockwise until it stops



3 Insert the mouthpiece at a depth of at least 0.5 cm in the turbine socket.



4 The SMART ONE is ready to use.

Hold SMART ONE OXI in your hand as if it were a mobile telephone and ensure that the turbine is not obstructed by your hand.

5

Insert the mouthpiece between your teeth and close your lips about the mouthpiece. Ensure that your lips grip the mouthpiece forcefully.

To prevent turbulence that might otherwise affect the results do not put your tongue in the mouthpiece. Do not bend your neck.

6

Tap the "Start Test" icon under SPIROMETRY on the MIR SmartOne App.

6

It is best to do the test standing or sitting upright. (it makes no difference to the test results).

7

- Slowly inhale, taking in as much air as possible.
- Blow with maximum force possible until the result appears on the smartphone screen.
- These are your **PEF** and **FEV1** values.

N.B.: Avoid exhaling slowly and at length

As each test must consist of three individual tests, repeat steps from 4 to 7 twice more.

Each session lasts 5 minutes.

SMART ONE OXI will save the highest value of the three individual tests only if the highest in the session presently open.

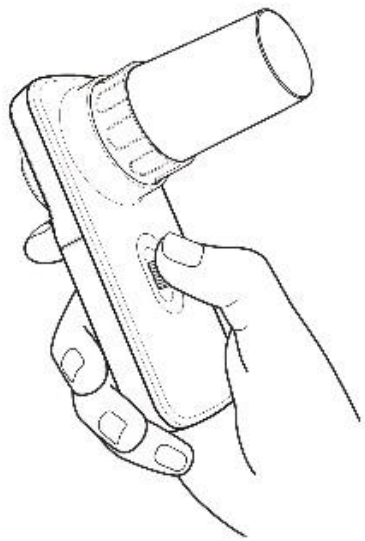
Warning: For monitoring elderly patients and children and differently-able persons, the supervision of an adult is required.

The device shows an error message if the exhalation start-up was not satisfactory and if the exhalation did not finish satisfactorily.

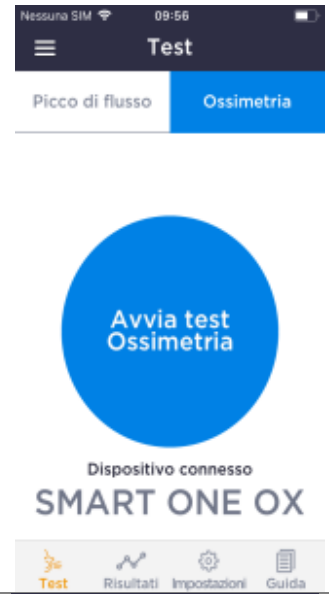
7.3 Performing the oximetry test

To perform the test correctly, follow the instructions below.

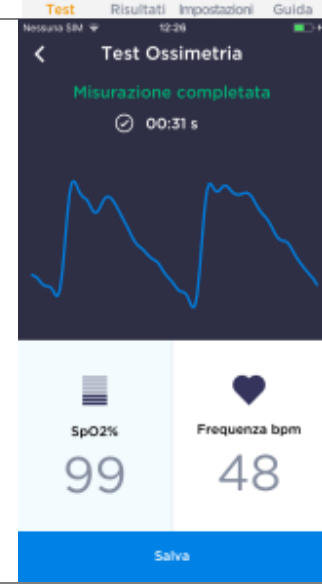
1 Place the thumb of the hand holding the **SMART ONE OXI** on the sensor as in the image



2 Tap the "Start Test" icon under OXIMETRY on the SMART ONE application.



3 During the test the perfusion index is reported with a bar indicator.
Minimum duration of a test is 30 seconds.



The device displays an error message if the sensor is not functioning and if the finger is not positioned on the sensor.
If the signal detected is not of sufficient quality to estimate the oximetry parameters; the parameters are not displayed.

7.4 How to interpret the results

For the spirometry measurements, three individual tests are made in each test, after which the **MIR SMART ONE** app compares the values with all those obtained in the preceding 5 minutes. For the session PEF values it is therefore automatically selected, saved and compared with the baseline value. The app shows a graphic sign (green, yellow or red) which is then displayed as a coloured circle about the PEF value obtained.

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

COLOUR	RESULT	MEANING	ACTION
Green	Above 80% of the baseline	OK	Respiratory conditions seem to be under control. The treatment is working. Process with normal activities.
Yellow	Above 50% and below or identical to 80% of the baseline	Warning	Caution in carrying out the operations Refer to the plan of action set out by your physician or by a licensed healthcare professional to establish which action is to be undertaken.
Red	Below or identical to 50% of the baseline	Danger	Medical alert. Seek immediate medical help. Act as agreed with your physician or other licensed healthcare professional.

For the oximetry measurements, each test saved in the memory appears in the Results section, which contains the value of SpO2, the value of cardiac frequency, the date and time of the test and any notes.

WARNING: ASK YOUR PHYSICIAN OR LICENSED HEALTHCARE PROFESSIONAL TO WATCH YOU USING THE SMART ONE OXI BEFORE RELYING ON ANY MEASUREMENT.

WARNING: WHEN SMART ONE IS USED TO MONITOR LUNG CONDITIONS SUCH AS ASTHMA YOU SHOULD BE UNDER THE CARE OF A PHYSICIAN OR OTHER LICENSED HEALTHCARE PROFESSIONAL.

WARNING: THE PLAN OF ACTION PROVIDED BY YOUR PHYSICIAN OR OTHER LICENSED HEALTHCARE PROFESSIONAL WILL INDICATE WHICH ACTION TO TAKE IN A CASE IN WHICH THERE ARE RELEVANT VARIATIONS IN VALUES.

WARNING: INDEPENDENTLY OF YOUR VALUES, AND EVEN WHERE THE DEVICE IS NOT INDICATING ALARMS, IF YOU ARE SHOWING SIGNS AND SYMPTOMS SUCH AS THORACIC CONSTRICTION, SHORT BREATH, COUGH OR DYSPNOEA, CONTACT YOUR PHYSICIAN OR LICENSED HEALTHCARE PROFESSIONAL.

8. 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.

⚠ For monitoring elderly patients and children above 5 years of age, and differently-able persons, the supervision of an adult is required.

⚠ 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.

⚠ Check that no impurities or foreign bodies, such as skin or hairs, have accumulated inside the turbine. Any modifications not expressly approved by this Company could compromise use of the device by the user.

⚠ Check that there are no elements obstructing the oximetry sensor. Any modifications not expressly approved by this Company could compromise use of the device by the user.

⚠ Do not let the device fall and do not treat it with lack of care. Avoid strong vibrations. 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 exposed to environmental conditions other than those specified, it might 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. If problems arise, do not try to repair the device yourself.

8.1 Data security warnings

The smartphone stores the user's 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 of data in memory by unauthorized persons
- Loss of data in memory
- Inability to use smartphone for communications
- The integrity check of the data is made automatically and in case of transmission error it will create a corruption of the data and the file will be illegible.

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
- Check that the email address you are to send your test results to is the correct one
- After transmitting the data call your physician to confirm that it has been received

8.2 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. This electromagnetic interference could cause the medical device to malfunction, such as an accuracy of measurement that is lower than the declared one, and create a potentially unsafe situation.

SMART ONE OXI complies with EN 60601-1-2:2015 on electromagnetic compatibility (EMC for electro-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 OXI and the smartphone on which the app is installed are no more than 2 metres apart.
- Do not use SMART ONE OXI near other devices (computers, cordless phones, cell phones, etc.) that generate strong electromagnetic fields. Keep the above-described equipment at a distance of at least 30 centimetres. If a use under lower distances is necessary, SMART ONE OXI and the other devices should be kept under observation to verify that they are functioning normally.

8.3 Notes on FCC certification

SMART ONE OXI complies with Part 15 of the FCC Standards. Operation is subject to the following conditions:
(1) this device cannot cause harmful interference
(2) this device must accept interference in reception, including the interference that might cause an undesired functioning.

Any modifications not expressly authorised by this company might compromise the use of the device by the user.

N.B.: This equipment has been tested and conforms to the limits for Class B digital devices in accordance with Part 15 of the FCC Standards. These limits are conceived to provide reasonable protection from damaging interferences when the equipment is used in a residential context. 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. It is not however possible to guarantee that these interferences will not occur. The device causes interference with the reception of radio or tv signals, which can arise by switching the device on or off; the user is advised to try to correct the interference by taking one of the following steps:

- Reorienting or relocating the antenna
- Increasing the distance between the equipment and the receiver
- Connecting the equipment to a socket on a different circuit from the one the receiver is connected to
- Consulting the dealer and/or an radio/tv expert technician.

9. MAINTENANCE AND CLEANLINESS

SMART ONE OXI is a device that requires little maintenance. The following operations must be carried out regularly:

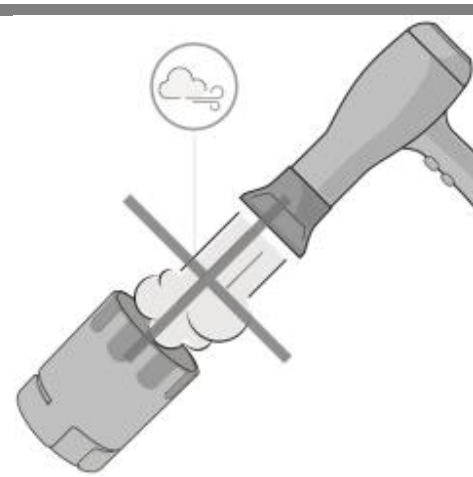
- cleaning of the reusable turbine
- cleaning of the mouthpiece
- Replacing the FlowMir® turbine
- cleaning of the device
- replacing batteries

At each patient change, the reusable turbine must be cleaned if it is used instead of the FlowMir® turbine.

9.1 Cleaning of the reusable turbine

The following instructions only apply if the reusable single-patient turbine is used. If the FlowMir® is used, replace it after each session.

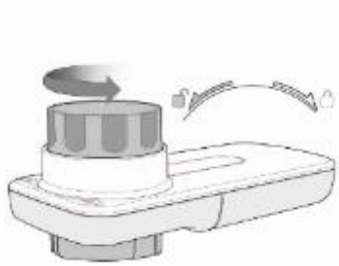
To avoid irreparable damage to the turbine, do not use detergents including alcohol or oily substances and do not immerse the turbine in water or solutions at high temperatures. Never try to sterilise the turbine in boiling water. Never try to clean the turbine under a direct jet of water or other liquids. If you do not have liquid detergents available, the turbine must be washed at least with clean water.



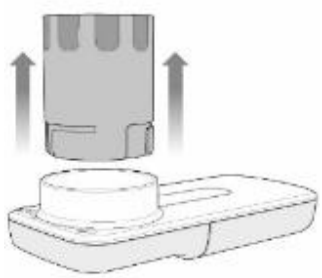
Correct functioning of the turbine is guaranteed only if it is “clean” and free of foreign bodies which interfere with its movement. The presence of dust or foreign bodies (such as hairs,

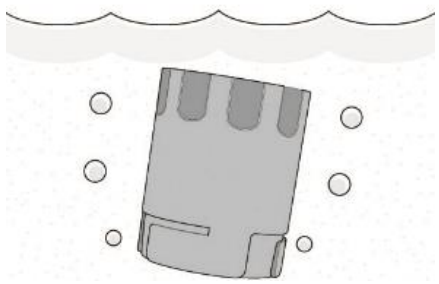
sputum etc.) could slow or block the moving parts of the turbine and make the result less accurate, or damage the turbine itself. After each use, check the cleanliness of the turbine.

To clean the turbine, follow the steps below:

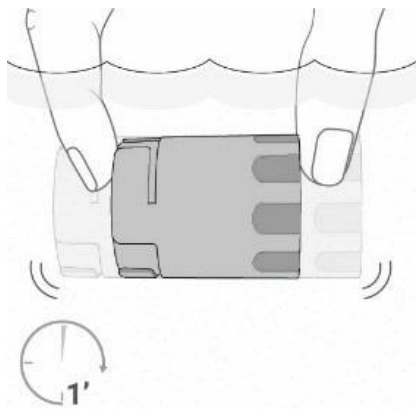


1) Remove the turbine from its housing by turning anti-clockwise and apply light pressure with your fingers from the bottom of the turbine to lift it out of its housing.



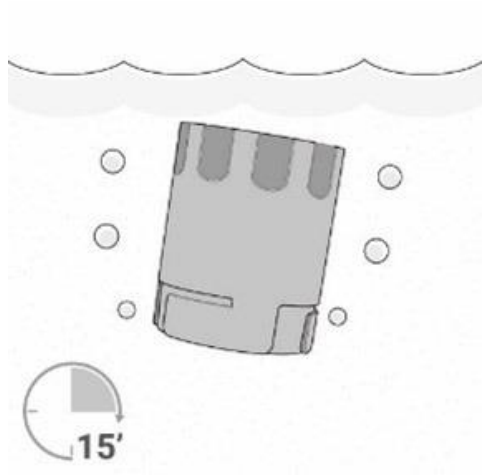


2) Mix ¾ cup of Clorox™ bleach (7.5%) in a quart of water. Place the orange turbine in the solution.

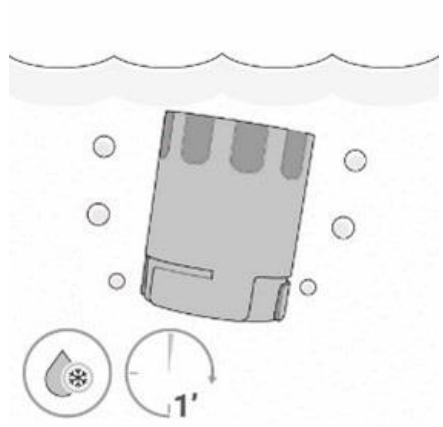


3) Shake the turbine to remove all impurities for at least 1 minute.

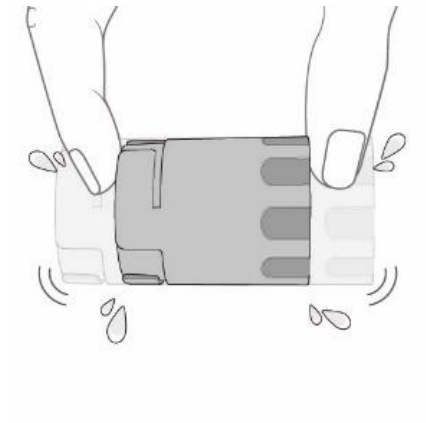
4) Let the turbine soak for 15 minutes.



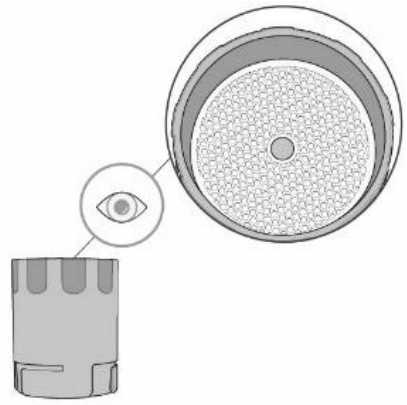
5) Clean the turbine by immersing it in clean (not hot) water for at least 1 minute.



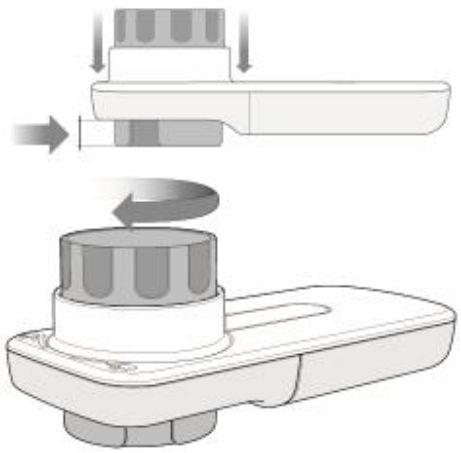
6) Remove excess water from the turbine by shaking it and let it dry by placing it vertically on a dry surface



7) Check that it is clean and free of any foreign bodies.



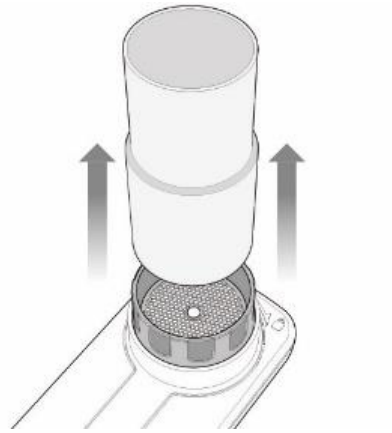
8) Dry it with a cloth.
After cleaning, insert the turbine into the socket in the direction indicated by the closed padlock symbol screen-printed on the SMART ONE OXI device. To insert the turbine correctly, push it down and turn it clockwise until it stops, to make sure it is fully inserted into the plastic housing.



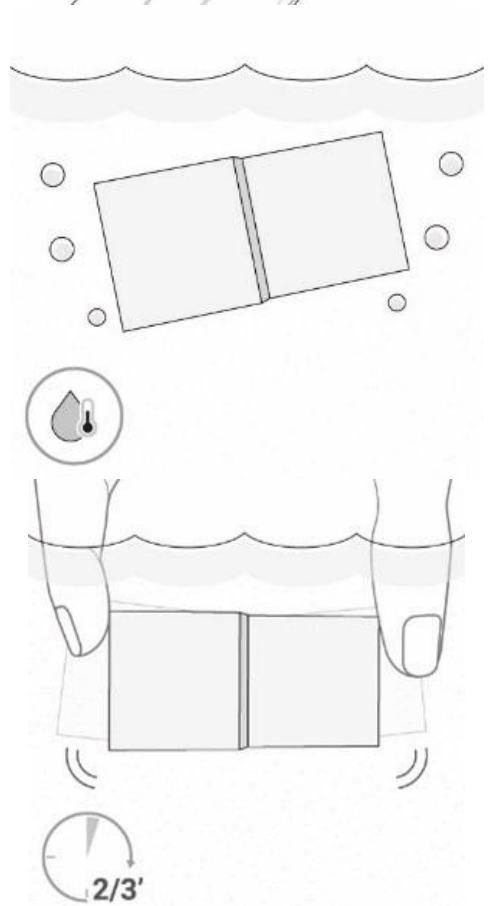
9.2 Cleaning of the mouthpiece

Be sure to clean the mouthpiece after each use, as outlined in the instructions below.

1) To clean the nozzle, simply remove it from the turbine.

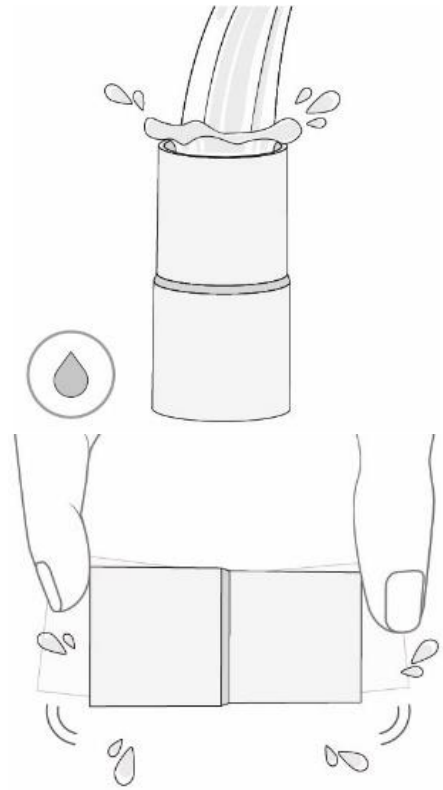


2) Immerse the mouthpiece in warm water.



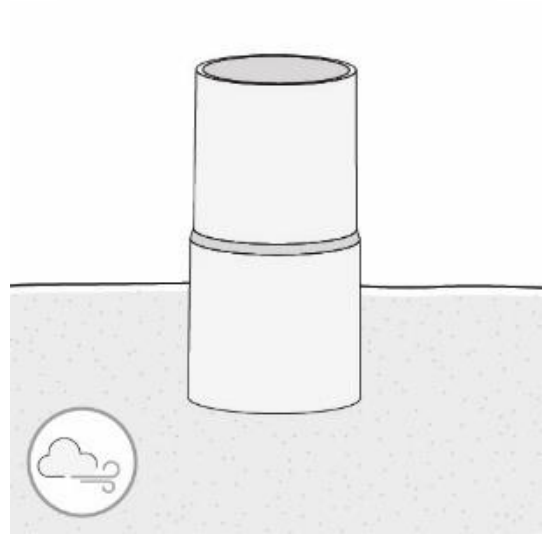
3) Shake the mouthpiece for 2-3 minutes.

4) Rinse it in clean water.



5) Shake it gently to remove any excess water.

6) Let it dry on a cloth.
Afterwards, insert the mouthpiece into the turbine with gentle pressure.



9.3 Cleaning of the device

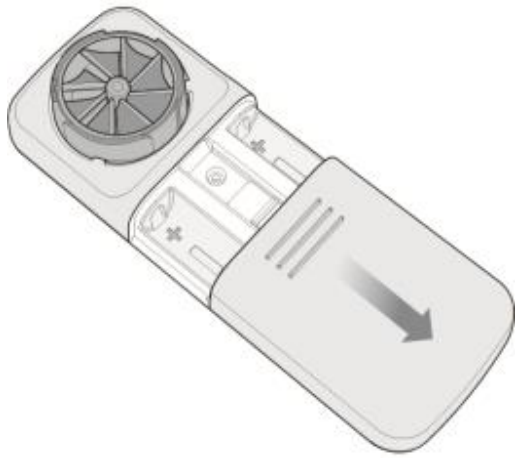
Clean the device once a day using a clean damp cloth. To clean, wipe the device's surfaces with a soft damp cloth. Dry with a soft cloth, or allow to air dry. Ensure that all surfaces are completely dry. Never put the device into water or other fluids
Do not use alcoholic solutions.

9.4 Replacing batteries

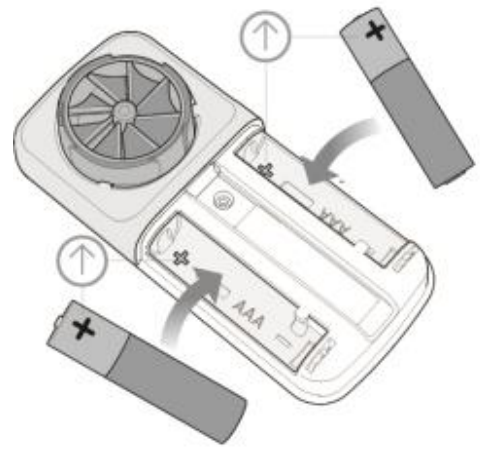
The device continuously monitors the battery level. A message on the smartphone display alerts the user when the device battery is low. When the batteries are completely charged the device has an operational span of five years or 1000 tests, whichever comes first.

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

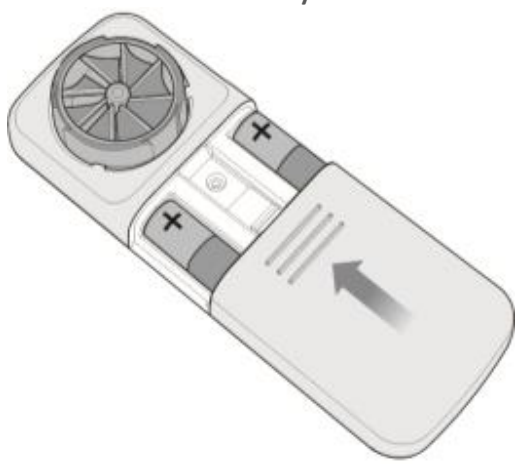
1 Remove the battery cover on the back of the **SMART ONE OXI.**



2 Remove the two batteries and replace them with two new ones, following the polarity as indicated by the symbols in the compartment.



3 Reposition the battery cover.



10. ERROR MESSAGES

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

MESSAGE	Storage conditions	SOLUTION
Bluetooth	Bluetooth is deactivated	To perform measurements with the device, you must activate Bluetooth on the smartphone. Exit the app and activate the Bluetooth from the smartphone settings menu.
Battery low	When the **SMART ONE OXI** batteries are below 15%	Replace the **SMART ONE OXI** batteries
It appears that no email account has been configured.	The user wants to share the results of the tests, but has not configured an e-mail account on their smartphone.	Set an email account from the smartphone settings menu.
The oximetry test has not been stored	The test lasted less than 30 seconds or the average value of the finger pressure was unsatisfactory	Repeat the test following the instructions given on the display and wait at least 30 seconds for the test to complete. The test lasts a maximum of 60 seconds after which it is automatically interrupted

11. TROUBLESHOOTING

If you have an unusually low reading, it could mean that your **SMART ONE OXI** flowmeter is broken, or it could mean that the reading is accurate and your asthma is getting worse.
Check that the flowmeter is not broken. Scrupulously follow the instructions to obtain accurate results. If the flowmeter is not broken, follow the instructions in your plan of action relating to low readings and consult your physician or another licensed healthcare professional.

For any question relating to the use of the device, contact your physician or other licensed healthcare professional, or contact MIR USA, Inc.
Freephone no: 844–464–7872.
USA:
Call MIR USA 1-844-464-7872, Monday to Friday 8 AM to 5 PM (central time), or contact us at mirusa@spirometry.com, or write us at MIR USA**,** 5462 S. Westridge Drive New Berlin, WI 53151 - USA
EUROPE and WORLDWIDE:
Call MIR +39 06 22754777, from Monday to Friday, from 8 am to 5 pm (GMT+1), or contact us at mir@spirometry.com, or write TO us at MIR Via del Maggiolino 125, 00155 Roma, Italy.

If problems occur when using the device, the following points should be checked.

MALFUNCTIONING	Storage conditions	SOLUTION
SMART ONE OXI cannot connect with the smartphone	The Bluetooth connection is not working properly	Look for SMART ONE OXI on the list of recognized devices. For correct use, the smartphone needs Bluetooth version 4.0 or higher
The test results are unreliable	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 contact the manufacturer.
	The test was performed wrongly	Repeat the test, following the directions on the screen. Avoid sudden movements when you finish exhalation. Speak to your physician about the measured values

MALFUNCTIONING	Storage conditions	SOLUTION
	The turbine has not been inserted properly	Insert the turbine from the front part of the device by pushing it downwards until it stops, and then rotating it in a clockwise direction
The oximetry test has not been stored	The test lasted less than 30 seconds or the average value of the finger pressure was unsatisfactory	Repeat the test following the instructions given on the display and wait at least 30 seconds for the test to complete.

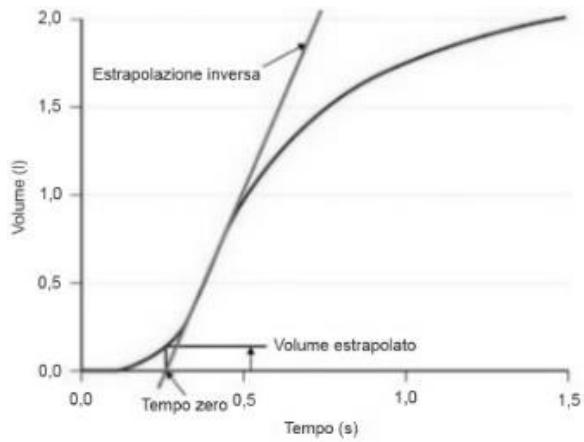
12. ACCURACY AND RELIABILITY

For the spirometry measurements, the device complies with the requisites of the following standards:
Standardisation of the spirometry (ATS 2005, 2019 update)
ISO 23747: 2015
ISO 26782: 2009

Volume max	10 l
Volume accuracy: the higher value between	±2.5% and ±0.05 l (ATS 2019)
Max. peak flow	960 l/min (16 l/s)
Peak flow accuracy: highest value between	±10% and ±20 l/min (±0.33 l/s)

Time zero

At the point of peak expiratory flow (PEF), a tangent is drawn with a slope equal to PEF and its intersection on the abscissa defines TIME ZERO. The back extrapolated volume is the volume of gas that has already been exhaled at the point of TIME ZERO as defined by back extrapolation. The method to determine the time elapsed by TIME ZERO, t0, is given by the following equation:



Time zero = t_{PEF} - (V_{PEF}/PEF)

Where
PEF is the peak expiratory flow;
t_{PEF} is the elapsed time at PEF;
V_{PEF} is the expired volume at PEF

For the oximetry measurements, the device conforms to the requisites of the following standard:
ISO 80601-2-61:2017 Medical electrical equipment – particular requirements for basic safety and essential performance of pulse oximeter equipment

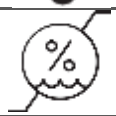
Range (SpO2)	Arms (%)
70-100 %	± 1.90
70-80 %	± 2.32
80-90 %	± 1.71
90-100 %	± 1.43

The Arms (Accuracy Root Mean Square), as mentioned in the above-cited standard, represents the accuracy of the device in terms of mean quadratic error of each SpO2 measurement, obtained by pulse oximetry, in relation to the respective reference value of SaO2, obtained by co-oximetry.
The listed ranges show the different saturation intervals of oxygen for which the accuracy has been calculated.
The accuracy of the device cannot be assessed with a tester.

13. LABELS & SYMBOLS

The symbols are described in the table below

SYMBOL	DESCRIPTION
Model:	Description of product
SN	Series number of the device
	Manufacturer's name and address
CE 0476	The product is a certified Class IIa medical device and meets the requirements of Regulation (EU) 2017/745 for medical devices.
	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 2012/19/EU 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 for collection of waste from electrical and electronic equipment. 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 arranged at up to 15° from the vertical.
	The symbol is used to identify products containing RF transmitters.
FCC ID	Identification showing traceability in compliance with FCC Standards
	Instructions for use symbol. Read this manual carefully before using the medical device
	Production date

SYMBOL	DESCRIPTION
	Temperature limits: indicates the temperature limits to which the medical device can be safely exposed
	Humidity limitation: indicates the range of humidity to which the medical device can be safely exposed
MD	The symbol indicates that the product is a medical device
UDI	The symbol indicates the Unique Device Identification

SMART ONE OXI complies with the Basic Requirements of Regulation (EU) 2017/745 for medical devices.

14. TECHNICAL SPECIFICATIONS

Peak Expiratory Flow	PEF (l/min)
Maximum Expiratory Volume in 1st second	FEV1 (l)
Mean saturation percentage of oxygen in the blood during the test	SpO2 (%)
Average heart rate during the test	BPM (heartbeats per minute)
Measuring system	Bi-directional turbine (rotary blade)
Spirometry principle of measurement	Infrared interruption
Oximetry principle of measurement	Reflective LED sensor, with double wavelength
Max. peak flow	PEF 960 l/min (16 l/s)
Volume max	FEV1 10l
Volume accuracy (ATS 2019)	The greater value between ± 2.5% and ± 0.05 l
Peak flow accuracy	The greater value between ± 10% and ± 20 l/min (± 0.33 l/s)
Dynamic resistance at 12 L/s	<0.5 cm H_2O/L/s
SpO2 measurement range	70%-100%

SpO2 accuracy	±1.9%
Cardiac frequency measurement range	30-200 BPM
BPM accuracy	±3%
Communication interface	Bluetooth SMART (4.0 or higher)
Electrical power supply	2 x 1.5V AAA alkaline batteries
Measurements	Main body 109x49x21 mm
Weight	60.7 g (including batteries)
Type of electrical protection	Internal power supply
Level of electrical protection	BF type part applied
IP protection level	IP22
Applicable standard	ATS/ERS Guidelines: 2005, 2019 update ISO 26782: 2009 ISO 23747: 2015 EN ISO 14971: 2019 ISO 10993-1: 2018 2011/65/UE Directive EN ISO 15223-1:2021 IEC 60601-1:2005 + A1: 2012 EN 60601-1-2: 2015 EN IEC 60601-1-6: 2010+Amd2013 EN 60601-1-11: 2015 ISO 80601-2-61: 2017 IEC 62304:2006/A1:2015 Directive 2014-53-EU-RED
Conditions of use	Device for continuous use
Conservation conditions	Temperature: MIN -25°C, MAX +70°C Humidity: MIN 10% UR; MAX 93% UR
Transport conditions	Temperature: MIN -25°C, MAX +70°C Humidity: MIN 10% UR; MAX 93% UR
Operating conditions	Temperature: MIN +5 °C, MAX +40 °C Humidity: MIN 15% UR; MAX 93% UR
LED sensor wavelengths	Red light: 660 nm** Infrared light: 880 nm**

Mean maximum optical power in output	1.2 mW

** This information can be useful for the physician.

⚠ Warning: Life time - the expected life time (or service life) of the device if properly used and stored is 5 years.

15. INFORMATION ON BLUETOOTH WIRELESS TECHNOLOGY

Bluetooth compliance:	Bluetooth 5-Ready
Operating Frequency:	from 2.4 GHz to 2.4835 GHz
Max Output Power:	TX: 0 dBm; 1 mW
Operating Range:	radius of 10 metres (range of vision)
Network Topology:	Star - bus
Operation:	Server
Antenna type:	Antenna integrated in the module
Modulation Technology:	FHSS
Modulation Type:	GFSK
Data Rate:	1 Mbit/second
Data latency:	7 – 40 ms
Data Integrity:	Adaptive frequency hop, Lazy Acknowledgement, CRC at 24 bit, message integrity check at 32-bit
Format:	Sending data packages every 60 ms. It includes 3 control bytes to enable the host to detect any missing packages and the device to re-transmit them.
Quality of Service:	This device uses Bluetooth Smart technology for wireless communications, so as to provide reliable communication in electrically noisy environments and transmit data packages every 60 ms. It includes 3 control bytes to enable the host to detect any missing packages and the device to re-transmit them. In the event of the connection being interrupted, the app changes status, from connected to not-connected, and becomes immediately available for a connection.
Bluetooth Profiles supported:	Profile based on GATT
Authentication and Encryption:	Supported
Encryption Key Size:	AES 128 bit with Counter Mode CBC-MAC and application level defined by the user

15.1 Communication at radiofrequency (RF)

This device conforms to the FCC standards (United States Federal Communications Commission) and to the international standards on electromagnetic compatibility. The following information is provided in accordance with the FCC (Federal Communications Commission) rules.

The device complies to Part 15 of the FCC Standards. Operation is subject to the following conditions: (1) This device must not cause damaging interference and (2) this device must accept any interference received, including the interference which might cause an undesired functioning.

The device does not interfere with the radiofrequency signals transmitted from external sources. The FCC standards were conceived to provide reasonable protection against excessive radiofrequency interference and to prevent malfunctioning of the device caused by undesired electromagnetic interference.

15.2 Interference in radiofrequency (RF) caused by other wireless devices

The majority of consumer electronic devices on the same frequency band as used by SmartOne can prevent the uploader or the mobile device from receiving the data.

This equipment has been tested and conforms to the limits for Class B digital devices in accordance with Part 15 of the FCC Standards. These limits are conceived to provide reasonable protection from damaging interferences in a residential context. 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. It is not however possible to guarantee that these interferences will not occur in a particular installation. The device causes damaging interference with the reception of radio or tv signals, which can arise by switching the equipment on or off; the user is advised to try to correct the interference by increasing the distance separating the equipment from the receiver.

16. WARRANTY TERMS

SMART ONE OXI is guaranteed for a period of 12 months in the case of professional use (physician, hospital, etc.) or 24 months for other use. 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 flow meter, 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 handling, improper installation, improper operation of the device, or if the installation does not comply with local technical or safety regulations
- Use of the product for purposes other than those provided or failure to follow instructions
- Repair, adaptation, modification or tampering by third party
- Damage caused by lack of or incorrect maintenance
- Damage caused by abnormal physical or electrical stress, or by leaking batteries
- 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 certified service centres authorized by manufacturer. For details of these centres please contact either your local supplier or the manufacturer. Any unauthorized opening of the device invalidates all guarantee claims.

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.

The manufacturer (MIR - MEDICAL INTERNATIONAL RESEARCH S.p.A.) reserves the right to replace the product or make any changes deemed necessary.