SMARTONE®

PEAK FLOW AND FEV1 METER

ENGLISH (EN)

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 PEAK FLOW AND FEV1 METER AND ITS USE CONSULT YOUR PHYSICIAN OR OTHER LICENSED HEALTHCARE PROFESSIONAL.
IF YOU DO NOT UNDERSTAND THE INSTRUCTIONS:

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 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 US AT MIR Via del Maggiolino 125, 00155 Roma, Italy.

User Manual Rev 4.0.1

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CE 0476

Date	Measurements		Recommendation	Physician
	PEF	FEV1		

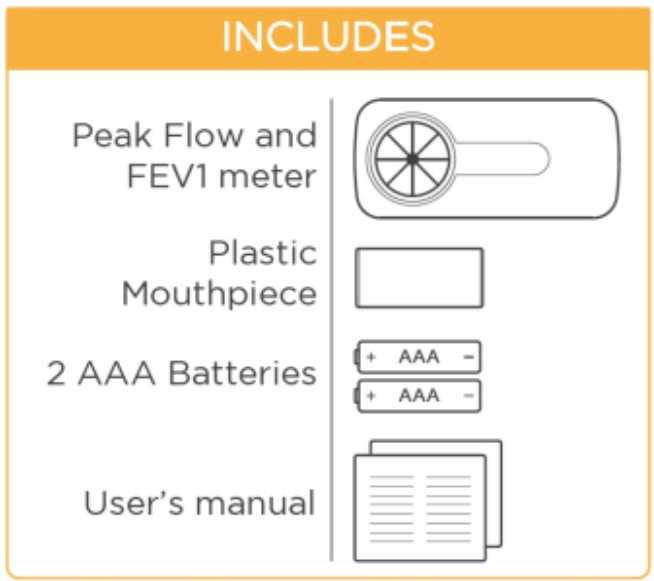
Reserved for the physician or other licensed health care professional to write your good flow rates and to provide specific interventions he/she recommends for ranges of decreased flow rates.

CONTENTS

Before connecting **SMART ONE** 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 there is, do not use the device and send it straight back for replacement.

Check if the packaging contains all the items shown below.



Keep the original packaging! If your product has a problem, use the original packaging to ship it back to your local distributor:

MIR USA, Inc.
5462 S. Westridge Drive
New Berlin, WI 53151 - USA
Tel + 1 (262) 565 – 6797 ; Fax + 1 (262) 364 – 2030
Website: www.spirometry.com ; Email: mirusa@spirometry.com

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 US AT MIR Via del Maggiolino 125, 00155 Roma, Italy.

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 is intended for home use by patients to monitor PEF (Peak Expiratory Flow) and FEV1 (Forced Expiratory Volume in 1st second, VEMS). The device is intended for adult patients, adolescents and children over five years of age.

2. IMPORTANT INFORMATION CONCERNING INTENDED USE

PEF is the maximum speed a person can blow air out of the lungs after taking as big a breath as possible.
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.

CAUTION: 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.

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

If you have breathing 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** 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** 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 VALUE

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. In fact the importance of any changes in airflow from one measuring to the next depends upon how much they are different from **your 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, sex, 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, sex, and origin. **MIR SMART ONE** app calculate the PEF predicted value that has been 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

PEF table female (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

CAUTION: NO MATTER WHICH METHOD YOUR PHYSICIAN OR OTHER LICENSED HEALTHCARE PROFESSIONAL PREFERS TO USE, IT IS IMPORTANT THAT YOU CLEARLY UNDERSTAND THE MEANING OF YOUR BASELINE VALUE AND HOW IT RELATES TO YOUR TREATMENT PLAN. IF YOU HAVE TROUBLE DETERMINING YOUR BASELINE VALUE, ASK YOUR PHYSICIAN OR OTHER LICENSED HEALTHCARE PROFESSIONAL FOR ASSISTANCE.

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 PEF AND FEV1 METER 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.**

⚠ **A HEALTHCARE PROFESSIONAL'S ADVICE IS REQUIRED TO INTERPRET THE MEANING AND IMPORTANCE OF THE MEASUREMENTS REPORTED BY SMART ONE AND HOW TO DECIDE ON AN APPROPRIATE ACTION PLAN**

⚠ **DIAGNOSIS AND APPROPRIATE TREATMENTS ARE TO BE GIVEN ONLY BY A PHYSICIAN OR OTHER LICENSED HEALTHCARE PROFESSIONAL. THE ACTION PLAN WILL TELL YOU WHAT ACTION TO TAKE WHEN THERE ARE CHANGES IN YOUR MEASURES.**

⚠ **SELF–MEASUREMENT MEANS CONTROL, NOT DIAGNOSIS OR TREATMENT. IN ANY EVENT PLEASE BE SURE TO DISCUSS YOUR MEASURED VALUES WITH YOUR PHYSICIAN OR OTHER LICENSED HEALTHCARE PROFESSIONAL. THEY WILL ALSO EXPLAIN WHICH VALUES ARE NORMAL FOR YOU.**

⚠ **NO MATTER WHAT YOUR MEASURES ARE, IF YOU HAVE SIGNS AND SYMPTOMS SUCH AS CHEST TIGHTNESS, SHORTNESS OF BREATH, COUGHING OR WHEEZING YOU SHOULD CONTACT YOUR PHYSICIAN OR LICENSED HEALTH CARE PROFESSIONAL.**

⚠ **FOLLOW INSTRUCTIONS CAREFULLY IN ORDER TO GET AN ACCURATE READING OF YOUR MEASURES. IF YOU ARE UNABLE TO OBTAIN A READING, CONTACT YOUR HEALTHCARE PROFESSIONAL.**

⚠ ASK YOUR PHYSICIAN OR OTHER LICENSED HEALTH CARE PROFESSIONAL TO WATCH YOU USE YOUR SMART ONE BEFORE YOU RELY ON ANY MEASUREMENTS.

⚠ MODIFYING YOUR ACTION PLAN OR MODIFYING YOUR BASELINE VALUE FOR YOUR PEF MEASUREMENT SHOULD ONLY BE DONE WITH DIRECTION FROM YOUR PHYSICIAN OR OTHER LICENSED HEALTHCARE PROFESSIONAL. DISCUSS WITH YOUR PHYSICIAN BEFORE PROCEEDING.

⚠ YOU SHOULD NEVER ALTER THE DOSAGE OF ANY MEDICATION WITHOUT TALKING TO YOUR PHYSICIAN.

⚠ THE DEVICE SHOULD NOT BE USED BY MORE THAN ONE PERSON. IF MORE THAN ONE PERSON WISHES TO USE THE DEVICE, ONE USER'S MEASUREMENTS MUST NOT BE ATTRIBUTED TO ANOTHER AND BOTH TURBINE AND MOUTHPIECE MUST BE CLEANED THROUGHLY AFTER EACH USE UNLESS MULTIPLE TURBINE AND MOUTHPIECE ARE AVAILABLE.

⚠ IF ANOTHER PERSON INTENDS TO USE THE DEVICE PERMANENTLY, THE PREVIOUS DATA STORED BY THE MIR SMART ONE APP MUST BE REMOVED AND THE NEW PEF BASELINE VALUE MUST BE DEFINED ACCORDING TO A PHYSICIAN OR OTHER LICENSED HEALTHCARE PROFESSIONAL.

⚠ ANY SERIOUS INCIDENTS OCCURRING WITH THE DEVICE MUST BE REPORTED TO THE MANUFACTURER AND THE COMPETENT AUTHORITY OF THE MEMBER STATE WHERE THE USER AND/OR PATIENT IS ESTABLISHED, IN ACCORDANCE WITH REGULATION (EU) 2017/745.

5. CONTRAINDICATIONS

The ATS/ERS guideline updated 2019 sets out the relative contraindications of spirometry as follows: 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 exhalation/cough. 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. Presence of pneumothorax; Thoracic surgery within 4 weeks; Abdominal surgery within 4 weeks; Pregnancy beyond term. Active or suspected transmissible respiratory or systemic infection, including tuberculosis; Physical conditions predisposing to transmission of infection, such as haemoptysis, significant discharge or oral lesions or oral bleeding.

⚠ If at least one of these conditions affects you, consult your doctor or a health care professional before using the device.

6. HOW TO START USING THE MIR SMART ONE APP

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

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

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

a) Authorize data exchange with the Health app, 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 app: height, weight, PEF and FEV1
- the following data to be read from the Health app: 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 APP** will use these data to calculate PEF baseline value, and will use it to assign a colored marker to your test (green, yellow, red). Please refer to the section **DETERMINING YOUR PEF BASELINE VALUE** for a clear understanding of the baseline value. If you don’t enter your data, a warning message will be issued.

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

7. HOW SMART ONE WORKS

SMART ONE is an electronic device for home use that accurately measures your PEF (Peak Expiratory Flow) and FEV1 (Forced Expiratory Volume in 1 sec).

PEF is the **maximum speed** a person can blow air out of the lungs after taking as big a breath as possible while **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.

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

The first portable **mechanical meter** to measure PEF was introduced in 1959 by B. Wright. The widespread use of this device to monitor children greater than five years of age and adults has made it a popular means of tracking the degree of respiratory conditions in patients with asthma and other pulmonary conditions.

Inexpensive, small, portable, and easy to use **electronic meters** for evaluating respiratory conditions are now widely available. They offer several advantages including the ability to record **PEF** and **FEV1**, and to **store and transfer data to a physician** or other licensed healthcare professional.

SMART ONE provides a warning message if a test is not correctly performed, for example if instead of blowing out as hard and fast as you can, you exhale too slowly. This is another clear advantage compared to a mechanical peak flow meter that does not provide any message.

PEF and FEV1 are measured during the same exhalation. When the test is correctly performed, PEF is measured 0.10–0.15 seconds after the blow start, while FEV1 is measured exactly 1.0 second after the blow start.
According to best current evidence from several scientific studies, research paper topics and clinical expertise, both PEF and FEV1 have proven to be good indicators of airflow function in health and illness that can indicate how well you are breathing, and can help you determine if there are changes in your airflow. Regular measurements of PEF and FEV1 provide evidence of disease progression.

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

Effective asthma self–management education requires:

- ***Self–monitoring of symptoms and/or lung function***
- ***Written asthma action plan***
- ***Regular medical review***

The above indicates that when engaged in self–management of asthma, your lung conditions can be effectively monitored according with the written action plan prepared by a physician or a licensed healthcare professional.

CAUTION: A PHYSICIAN'S OR OTHER HEALTHCARE PROFESSIONAL'S ADVICE IS REQUIRED TO INTERPRET THE MEANING AND IMPORTANCE OF THE MEASUREMENTS REPORTED BY SMART ONE AND HOW TO DECIDE ON AN APPROPRIATE ACTION PLAN
SMART ONE connects to a smartphone via Bluetooth SMART technology. Connection is automatic once the MIR SMART ONE APP has been installed on your smartphone.

Each measure of PEF and FEV1 is transferred from the device to the smartphone to be displayed. Please use the PEF colored indicator (green, yellow or red) following your physician's or other licensed health care professional's advice. They will help you determine how to perform the test accurately and recommend actions when decreased values are measured.

CAUTION: 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.

A higher value of PEF and FEV1 usually means air is moving easily through the lungs. When asthma attacks occur air cannot move easily through the lungs and lower values will be measured. It is generally recommended to take measurements as directed by the licensed healthcare professionals.
SMART ONE should also be used when you are feeling symptoms of breathing problems in order to help you and your physician or other licensed healthcare professional determine how serious the breathing problem is and how well your treatment is working. Discuss with your physician or other licensed healthcare professional when and how often to use your SMART ONE meter.

7.1 Diary record

The **MIR SMART ONE APP** keeps a record of your **highest reading of PEF and FEV1 for both morning and evening session**, complete with date and time. Dots between consecutively

recorded readings are connected in order to form a trend graph. This on–going record is an important part of your asthma action plan.

The **MIR SMART ONE APP** can transfer the measured data to your physician or other licensed healthcare professional. When used properly, **SMART ONE** will help you and your physician or licensed healthcare professional monitor your asthma or other lung disease to provide the best treatment.

Reviewing the measured data can help you and your physician or other licensed healthcare professional check closely on your respiratory disease to provide the best treatment for you.

Because your smartphone has an automatic memory of hundreds of readings, you can take the device with you the next time you visit your physician or other licensed healthcare professional for a review of many readings.

7.2 Self–measuring of PEF and FEV1 value

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IF YOU DO NOT UNDERSTAND THE INSTRUCTIONS :

USA:
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ASK YOUR PHYSICIAN OR OTHER LICENSED HEALTH CARE PROFESSIONAL TO WATCH YOU USE THE PEAK FLOW METER. THIS WILL HELP ASSURE YOU ARE USING IT CORRECTLY.

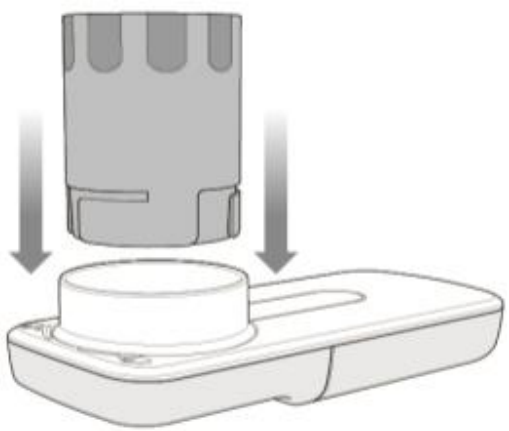
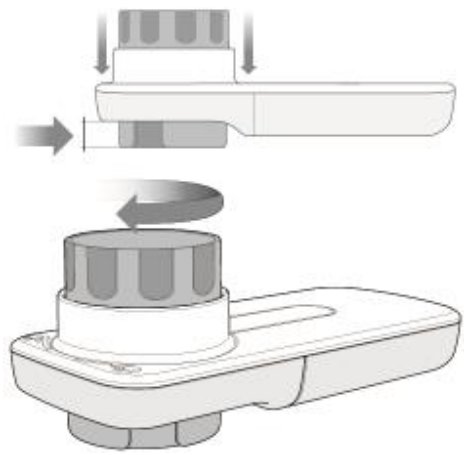
NO MATTER WHAT YOUR PEAK FLOW MEASURES ARE, IF YOU HAVE SIGNS AND SYMPTOMS SUCH AS CHEST TIGHTNESS, SHORTNESS OF BREATH, COUGHING OR

WHEEZING YOU SHOULD FOLLOW YOUR LICENSED HEALTH CARE PROFESSIONAL'S ADVICE FOR CONTACTING HIM OR HER.
IF YOU ARE UNABLE TO OBTAIN A READING YOU SHOULD CONTACT YOUR PHYSICIAN IMMEDIATELY.

SMART ONE must be cleaned as shown in **CARE AND CEANING** section before your initial trial and periodically thereafter.

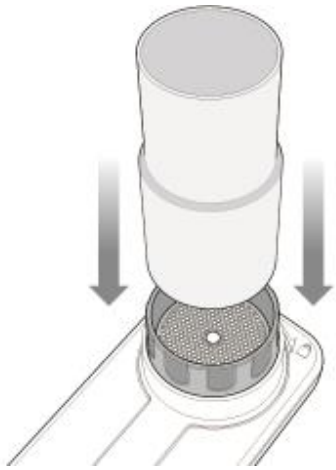
To carry out a measurement:

- **Run the MIR SMART ONE APP on your smartphone**
- **Press the START icon**
- **Wait for Bluetooth connection**

1 Push the turbine into the slot until it stops 	**2** Turn the turbine clockwise until it stops 

3

Insert mouthpiece at least 0.5 cm into the turbine socket.



4

Your SMART ONE is now ready.

Hold SMART ONE with your hand as if it were a cell phone and make sure not to obstruct the turbine with your hand.

5

Insert the mouthpiece end into your mouth beyond your teeth, and close lips around the mouthpiece. Make sure your lips form a tight seal around the mouthpiece.

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

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

6

- Take a slow deep breath as deep as you can.
- Blow out as hard and fast as you can until you can read the results on the screen of your smartphone.
- This is your **PEF** and **FEV1** measure.

7 NOTE: Avoid long slow exhalation

Since each test session should consist of three trials, repeat steps 4–7 twice more.
SMART ONE will save the highest value.

Warning: Supervision of an adult is required for testing elderly subjects, children and differently-able persons

7.3 Interpreting results

Three tests are performed per each session, after which the **MIR SMART ONE APP** automatically selects and save the highest PEF value and compares it with the baseline value. The app shows a graphic marker (green, yellow or red), which is then displayed as a colored circle around the PEF test result.

The meaning of the graphic marker is displayed in the following table.

COLOR	RESULT	MEANING	ACTION
Green	Above 80% of the baseline	OK	Your breathing condition appears under control. Your medication is

			working. Go ahead with your normal activities.
Yellow	Above 50% and below or equal to 80% of the baseline	Warning	Use caution in your activity. Refer to your action plan made by your physician or other licensed healthcare professional for action to be taken.
Red	Below or equal to 50% of the baseline	Danger	Medical alert. You should get immediate medical attention. Act as discussed with your physician or other licensed healthcare professional.

CAUTION: ASK YOUR PHYSICIAN OR OTHER LICENSED HEALTHCARE PROFESSIONAL TO WATCH YOU USE YOUR SMART ONE BEFORE YOU RELY ON ANY MEASUREMENTS.

CAUTION: 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.

CAUTION: THE ACTION PLAN GIVEN TO YOU BY YOUR PHYSICIAN OR OTHER LICENSED HEALTH CARE PROFESSIONAL WILL TELL YOU WHAT ACTION TO TAKE WHEN THERE ARE CHANGES IN YOUR MEASURES.

CAUTION: NO MATTER WHAT YOUR MEASURES ARE, IF YOU HAVE SIGNS AND SYMPTOMS SUCH AS CHEST TIGHTNESS, SHORTNESS OF BREATH, COUGHING OR WHEEZING YOU SHOULD CONTACT YOUR PHYSICIAN OR LICENSED HEALTH CARE 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.

⚠ Supervision of an adult is required for testing elderly subjects, children and differently abled persons

⚠ 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.

⚠ Periodically check that no impurities or foreign bodies, such as skin, hairs have deposited inside the turbine. This may cause errors in measurement or compromise the correct functioning of the device.

⚠ Do not drop the device or treat it roughly in any way. Avoid strong vibration. Do not expose the device to extreme temperature, humidity, dust, sand, or chemical substances, or direct air currents (e.g. wind), sources of heat or cold, direct sunrays or other sources of light or energy.

⚠ 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.

8.1 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 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
- Verify the correct Email address where to send the test results
- When data are transmitted call the physician to ask for confirmation of receipt

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. Such electromagnetic interference could cause the medical device to malfunction, as well as a measurement accuracy lower than the one stated in paragraph 11, and create a potentially unsafe situation.

SMART ONE complies with EN 60601–1–2:2015 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 APP 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 30 cm. If a use under lower distances is necessary, SMART ONE and the other devices should be kept under observation to verify their normal function.

8.3 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.

9. CARE AND CLEANING

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

- Cleaning of the reusable turbine
- Cleaning of the mouthpiece
- Cleaning of the device
- Replacing batteries

9.1 Cleaning of the reusable turbine

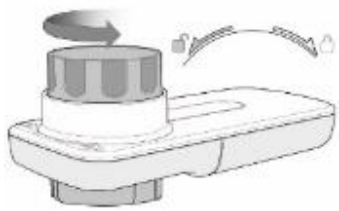
To avoid irreparable damage to the turbine, do not use any alcoholic or oily cleaning solutions, and do not immerse in hot water or solutions. Do not try to sterilize the turbine in boiling water. Never try to clean the turbine under a direct jet of water or

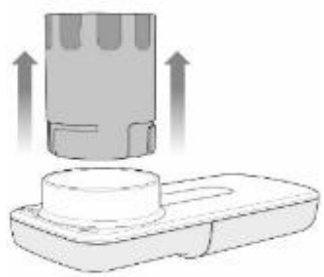
other liquids. If there are no liquid detergents, the turbine must at least be washed in clean water.

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.

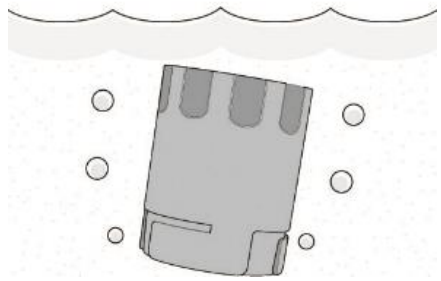
To clean the turbine, follow the steps below:

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.

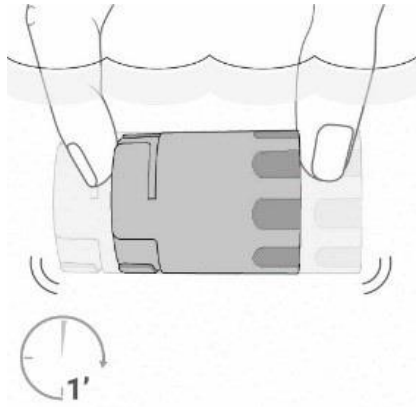




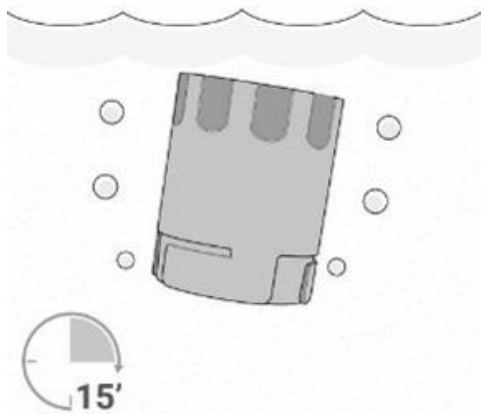
2) Mix ¾ cup of Clorox™ bleach (7.5%) in one quart of water. Place orange turbine in solution.



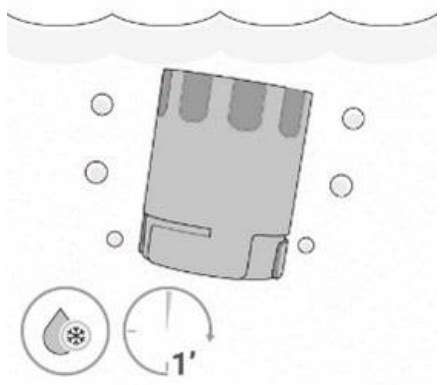
3) Shake the turbine to remove all impurities for at least 1 minute.



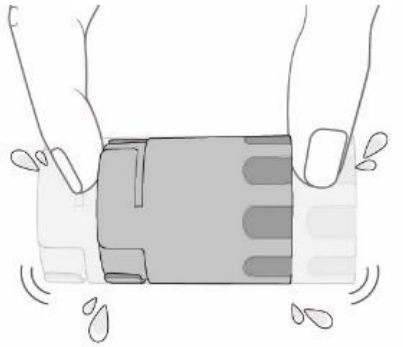
4) Let the turbine soak for 15 minutes.



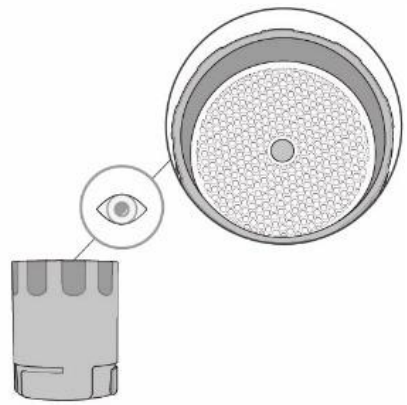
5) Clean the turbine by immersing it in clean (not hot) water for at least 1 minute.



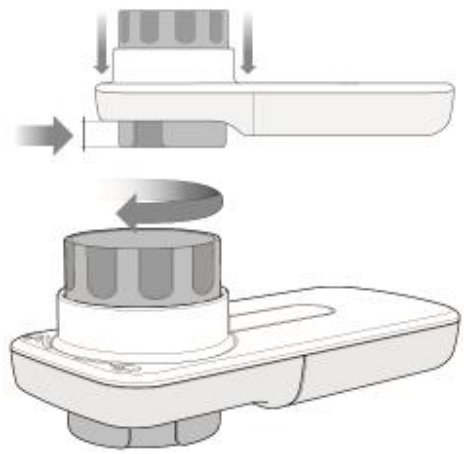
6) Remove excess water from the turbine by shaking it and let it dry by placing it vertically on a dry surface



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



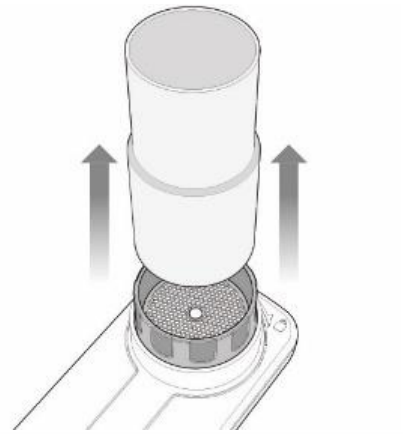
8) After cleaning, insert the turbine into the socket in the direction indicated by the closed padlock symbol screen-printed on the SMART ONE device. To insert the turbine correctly, push it down and turn it clockwise until it stops, to ensure that it is fully inserted into the plastic housing.



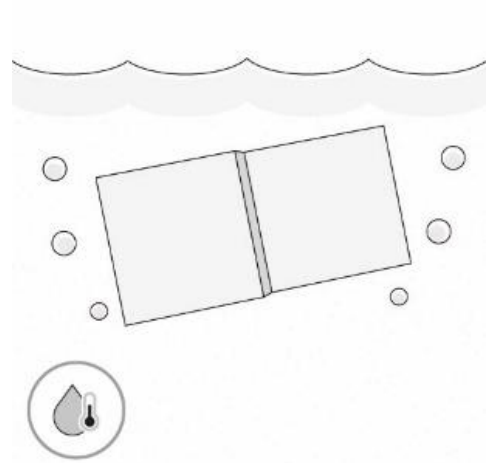
9.2 Cleaning of the mouthpiece

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

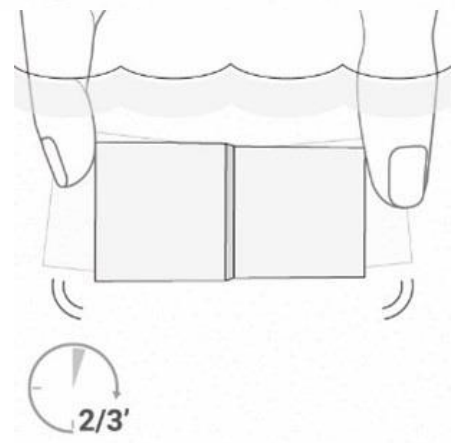
1) To clean the nozzle, simply remove it from the turbine.



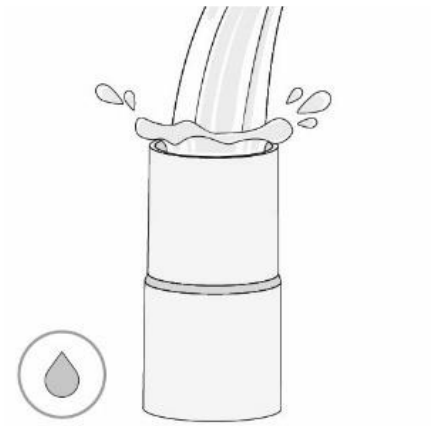
2) Immerse the mouthpiece in warm water



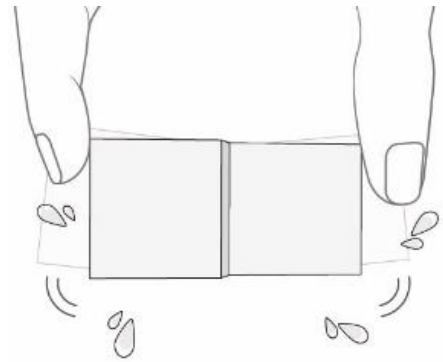
3) Shake the mouthpiece for 2-3 minutes.



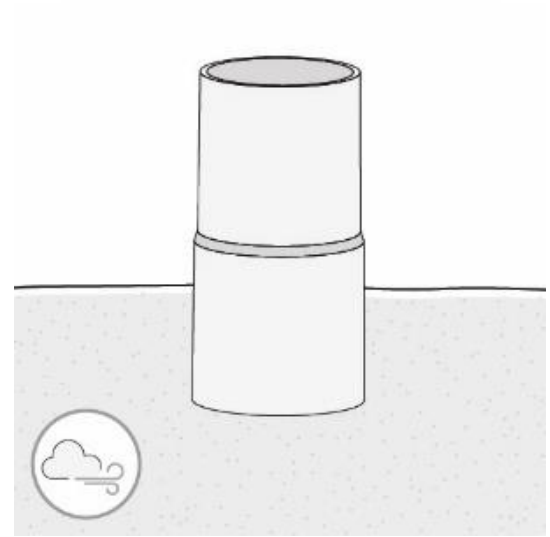
4) Rinse it in clean water.



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

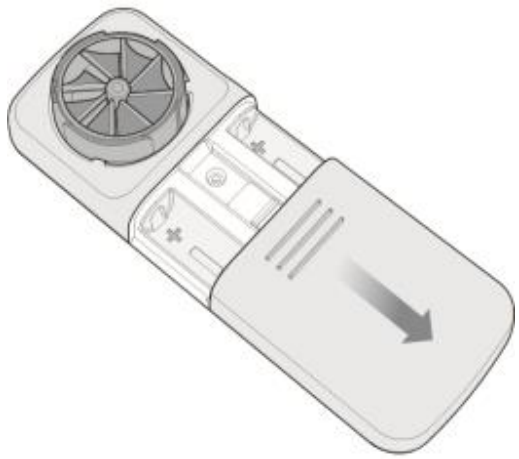
Clean the device once a day. To clean, wipe the device's surfaces with a soft damp cloth. Dry with a soft cloth, or allow to air dry. Ensure that all surfaces are completely dry.
Never put the device into water or other fluids.

9.4 Replacing batteries

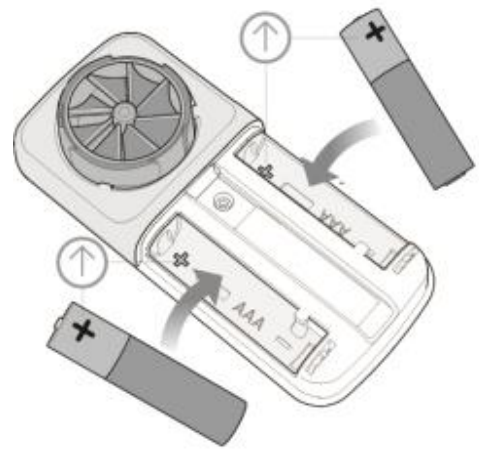
The device continuously monitors the battery level. A message on the smartphone display alerts the user when the device battery is low. On fully charged batteries, the device is expected to work for 5 years or 1000 tests whichever comes first.

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.

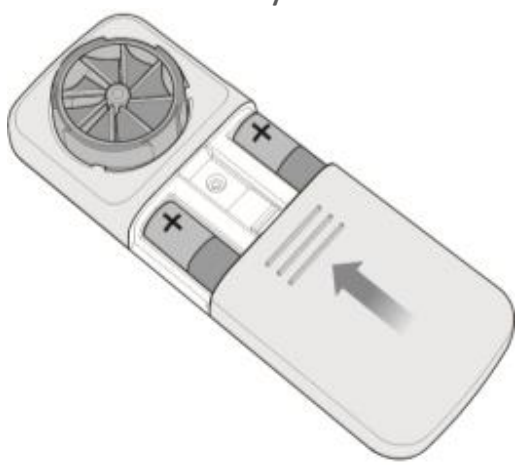
1 Remove the battery cover on the back of the **SMART ONE**



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



3 Reattach the battery cover



10. 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	REMEDY
Bluetooth	Bluetooth is off	To perform measurements with the device, you must activate Bluetooth on the smartphone. Exit the app and activate Bluetooth from the smartphone settings menu
Battery low	When the **SMART ONE** batteries are below 15%	Replace the **SMART ONE** batteries
It seems that you have not configured an Email account	The user wants to share the results of the tests, but has not configured an Email account on the smartphone	Set up an Email account from the smartphone settings menu

11. TROUBLESHOOTING

If you receive an unusually low reading, it could mean that your **SMART ONE** meter is broken, or it could mean that the reading is accurate and your asthma is getting worse.
Check to make sure that the meter is not broken. You must follow directions exactly as instructed to obtain accurate results. If your meter is not broken, follow the instructions in your action plan for low readings and contact your physician or other licensed healthcare professional.

If you have any questions regarding the use of this device, please ask your physician or other licensed healthcare professional, or contact MIR USA, Inc.
Toll free number: 844–464–7872.
USA:
Call MIR USA 1-844-4MIRUSA (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, Inc. 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 US AT MIR Via del Maggiolino 125, 00155 Roma, Italy.

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

MALFUNCTION	POSSIBLE CAUSE	REMEDY
SMART ONE can't connect with the smartphone	The Bluetooth connection is not working properly	Look for SMART ONE 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 smartphone screen. Avoid sudden movements when you finish exhaling. Discuss the value with your physician
	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

12. ACCURACY AND RELIABILITY

This device meets the requirements of the following standard:

- ATS Standardization of Spirometry 2005, 2019 update
- ISO 23747: 2015
- ISO 26782: 2009

Volume max	10 L
Volume accuracy	± 2.5% or ± 0.05 L whichever is greater
Peak Flow max	960 L/min (16 L/s)

Peak Flow accuracy	±10% or ±20 L/min (±0.33 L/s) whichever is greater

13. LABELS & SYMBOLS

Symbols are described in the table below

SYMBOL	DESCRIPTION
Model:	Product Name
SN	Device serial number
	Manufacturer's name and address
CE 0476	This product is a certified Class IIa medical device, and complies with 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/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 with a maximum inclination of 15° from vertical.
	The symbol is used for products including RF transmitters.
FCC ID	Identification showing traceability to FCC compliance
	Instruction for use symbol. Read this manual carefully before using the medical device
	Manufacturing 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 complies with the Essential Requirements of Directive 93/42/EEC on Medical Devices. This statement is made on the basis of CE Certificate no. MED 9826 issued by Kiwa Cermet, Notified Body no. 0476.

14. TECHNICAL SPECIFICATIONS

Peak Expiratory Flow	PEF (L/min)
Forced Expiratory Volume in 1 second	FEV1 (L)
Measurement system	Bi–directional turbine (rotating blade)
Measurement principle	Infrared interruption
Peak Flow max	PEF 960 L/min (16 L/s)
Volume max	FEV1 10 L
Volume accuracy (ATS 2019)	± 2.5% or ± 0.05 L whichever is greater
Peak Flow accuracy	± 10% or ± 20 L/min (± 0.33 L/s) whichever is greater
Dynamic resistance at 12 L/s	<0.5 cm H2O/L/s
Communication interface	Bluetooth SMART (4.0 or higher)
Power supply	2 x 1.5V AAA alkaline batteries
Size	Main body 109x49x21 mm
Weight	60.7 g (including batteries)
Type of electrical protection	Internally powered
Electrical protection level	BF
IP protection level	IP22
Regulations applicable	ATS/ERS Guidelines: 2005, 2019 *update*

	ISO 26782: 2009 ISO 23747: 2015 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 IEC 62304:2006/A1:2015 Directive 2014-53-EU-RED
Conditions of use	Device for continuous use
Storage conditions	Temperature: MIN –25°C, MAX +70°C Humidity: MIN 10% RH; MAX 93%RH
Transport conditions	Temperature: MIN –25°C, MAX +70°C Humidity: MIN 10% RH; MAX 93%RH
Operating conditions	Temperature: MIN +5°C, MAX +40°C Humidity: MIN 15% RH; MAX 93%RH

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

15. BLUETOOTH WIRELESS TECHNOLOGY INFORMATION

Bluetooth Compliance:	Bluetooth 5-Ready
Operating Frequency:	2.4 to 2.4835 GHz
Max Output Power:	TX: 0 dBm; 1 mW
Operating Range:	10 meter radius (line of sight)
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 hopping, Lazy Acknowledgement, 24-bit CRC, 32-bit Message Integrity Check Data
Format:	Sends data packets once per 60 ms. Includes 3 control bytes that allows the host to detect if packets are missing and the device to retransmit.
Quality of Service:	This device uses Bluetooth Smart technology for wireless communications, which allows for reliable communications in electrically noisy environments and transmits packets once per 60 ms. It includes 3 control bytes that allows the host to detect if packets are missing and the device to re-transmit. If the connection is lost, the App changes the connected status from connected to disconnected and become available for a connection immediately.
Bluetooth Profiles Supported:	GATT-based profile
Authentication and Encryption:	Supported
Encryption Key Size:	128-bit AES with Counter Mode CBC-MAC and application layer user defined

The Bluetooth® word mark and logo are registered trademarks owned by Bluetooth SIG, Inc.

15.1 Radio frequency (rf) communication

This device complies with the United States Federal Communications Commission (FCC) and international standards for electromagnetic compatibility. The following information is provided in accordance with Federal Communications Commission (FCC) regulations.

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 undesirable operation. This device does not interfere with any radio frequency signals transmitted from outside sources. These FCC standards are designed to provide reasonable protection against excessive radio frequency interference and prevent undesirable operation of the device from unwanted electromagnetic interference.

15.2 Radio frequency (rf) interference from other wireless devices

Common consumer electronic devices that transmit in the same frequency bands used by the Smartone may prevent the uploader or mobile device from receiving data.
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 increasing the separation between the equipment and receiver.

16. WARRANTY TERMS

SMART ONE 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 unautorized 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.