

SMARTONE®

PEAK FLOW AND FEV1 METER



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 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. 1900 Pewaukee Road, Suite D Waukesha, WI 53188.

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 3.1

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CE 0476

SMARTONE

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| 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.

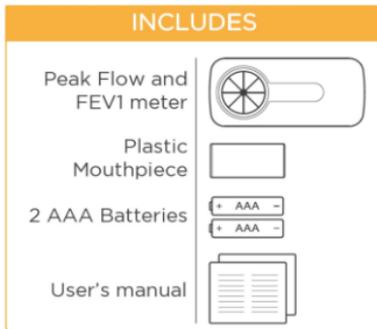
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Before connecting **SMART ONE** to a smartphone, install the **MIR SMART ONE** free app, which you can download from the App Store (for iPhone and iPad) or Play Store (for Android devices).

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.

1900 Pewaukee Road, Suite D

Waukesha, WI 53188

Tel + 1 (262) 565 – 6797

Website: www.spirometry.com

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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. INDICATIONS FOR USE

Smart One is intended for home use by patients to monitor PEF (Peak Expiratory Flow) and FEV1 (Forced Expiratory Volume in one second). The device is designed for children, adolescent and adult subjects.

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 or 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** in your **PEF** or **FEV1** 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 or 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 PEF or FEV1, 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 or FEV1 measurements help them monitor your lung function and how well treatments are working.

3. DETERMINING YOUR PEF OR FEV1 BASELINE VALUE

A PEF or FEV1 measure with a high value usually means that your airflow is good.

The best way to determine what is a healthy PEF or FEV1 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 or FEV1 predicted value, i.e. the expected value for healthy people, depending on age, height, sex, and origin. **MIR SMART ONE** app calculate the PEF or FEV1 predicted value that has been endorsed by ATS (American Thoracic Society): for PEF the 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*; for FEV1 the predicted values are calculated according to *GLI-2012 All-Age Multi-Ethnic Reference Values by Philip H. Quanjer, Sanja Stanojevic, Janet Stocks, Tim J. Cole*.

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 or FEV1 value.

It is important to know that these predicted values are average numbers for large groups of people. You may have a higher PEF or FEV1 measures than the predicted value and you may not be healthy. Or you may have a lower PEF or FEV1 than the average and be healthy.

| | 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)

| | 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 |
| 90 | 174 | 203 | 233 | 262 | 291 | 321 | 350 | 380 | 409 |

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 INCLUDING WHICH PARAMETER TO USE, PEF OR FEV1.

⚠️ 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 PEF OR FEV1 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 PEF OR FEV1 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 PEF OR FEV1 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 OR FEV1 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 THOROUGHLY 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 BASELINE VALUE FOR PEF OR FEV1 MUST BE DEFINED ACCORDING TO A PHYSICIAN OR OTHER LICENSED HEALTHCARE PROFESSIONAL.

5. 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 or FEV1 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 OR FEV1 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.

6. 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 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 or 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 (PEF or FEV1)*
- *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 INCLUDING WHICH PARAMETER TO USE, PEF OR FEV1.

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 or FEV1 is transferred from the device to the smartphone to be displayed. Please use the 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 or FEV1 usually means air is moving easily through the lungs. When asthma attacks occur air cannot move easily through the lungs and lower values of PEF or FEV1 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.

6.1 Diary record

The **MIR SMART ONE APP** keeps a record of your **highest reading of PEF or 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.

6.2 Self-measuring of PEF or FEV1 value

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:

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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.

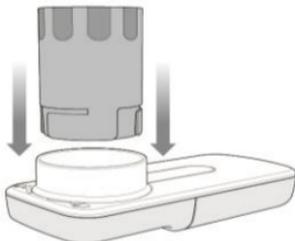
SMART ONE must be cleaned as shown in **CARE AND CLEANING** section before your initial trial and periodically thereafter.

To carry out a measurement:

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

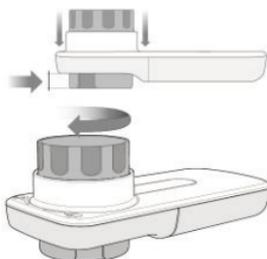
Push the turbine into the slot until it stops

1



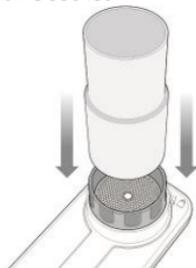
Turn the turbine clockwise until it stops

2



Insert mouthpiece at least 0.5 cm into the turbine socket.

3



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.

4



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.

5



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 result on the screen of your smartphone.
- This is your **PEF** (or **FEV1**) measure.

7 NOTE: Avoid long slow exhalation

Since each test session should consist of three trials, repeat steps 4–7 twice more.

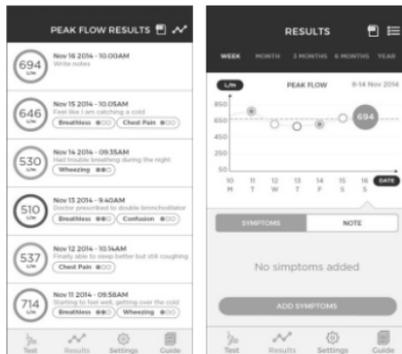
SMART ONE will save the highest value.

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

6.3 Interpreting results

Three tests are performed per each session, after which the **MIR SMART ONE APP** automatically selects and save the highest PEF or FEV1 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 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 PEF OR FEV1 MEASURES.

CAUTION: NO MATTER WHAT YOUR PEF OR FEV1 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.

7. 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-able 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.

7.1 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

7.2 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 and create a potentially unsafe situation.

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

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

- Make sure that the SMART ONE and the smartphone on which the MIR SMART ONE 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 7 metres.

7.3 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.

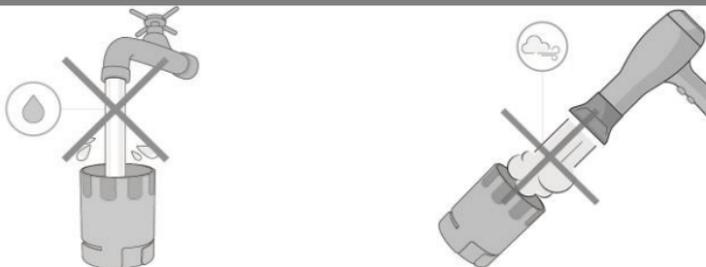
8. CARE AND CLEANING

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

- Cleaning and disinfection of the turbine
- Cleaning and disinfection of the mouthpiece
- Cleaning of the device
- Replacing batteries

8.1 Cleaning and disinfection of the 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, pull it out of the **SMART ONE** socket by turning it counterclockwise and simply pulling it out. To make it easier to pull out, push the base of the turbine gently with a finger. Weekly cleaning is recommended. Immerse the turbine flowmeter in warmy soapy water and agitate the turbine for 2-3 minutes.

The hand dishwashing detergent that was tested includes these ingredients: Aqua, coco glucoside, myristyl glucoside, lauryl glucoside, sodium chloride, sodium gluconate, sodium citrate, allyl caproate, ethylene brassylate, methylidihydrojasmonate).

Rinse in clean water and shake gently to remove any excess water. Allow to air dry on a towel. Store in a clean, dry place in your home.

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

8.2 Cleaning and disinfection of the mouthpiece

Make sure to clean the mouthpiece after each use. To clean the mouthpiece, simply pull it apart from the turbine. Just as for the turbine, Immerse the mouthpiece in warmy soapy water and agitate the mouthpiece for 2-3 minutes . Rinse in clean water and shake gently to remove any excess water. Allow to air dry on a towel. Store in a clean, dry place in your home.

After cleaning, insert the mouthpiece in the turbine, by pressing lightly.

8.3 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.

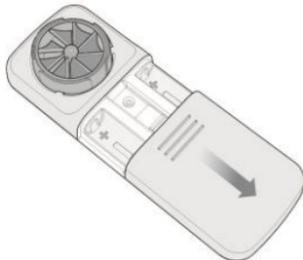
8.4 Replacing batteries

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.

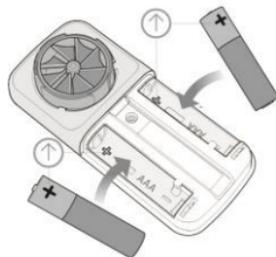
Remove the battery cover on the back of the **SMART ONE**

1



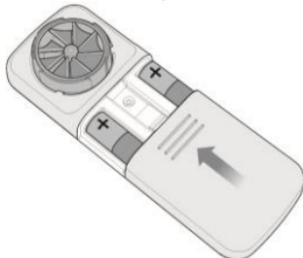
Remove the two batteries and replace them with two new ones, following the polarity as indicated by the symbols in the compartment

2



Reattach the battery cover

3



9. 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 |

10. 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. 1900 Pewaukee Road, Suite D Waukesha, WI 53188.

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 |

11. ACCURACY AND RELIABILITY

This device meets the requirements of the following standard:
 ATS Standardization of Spirometry 2005

| | |
|--------------------|--|
| Volume max | 10 L |
| Volume accuracy | $\pm 3.5\%$ or ± 0.1 L whichever is greater |
| Peak Flow max | 960 L/min (16 L/s) |
| Peak Flow accuracy | $\pm 12\%$ or ± 25 L/min (± 0.42 L/s) whichever is greater |

12. LABELS & SYMBOLS



Symbols are described in the table below

| SYMBOL | DESCRIPTION |
|---|---|
|  | Product Name |
|  | Device serial number |
|  | Manufacturer's name and address |
|  | This product is a certified Class IIa medical device, and complies with the requirements of Directive 93/42/EEC. |
|  | In accordance with IEC 60601–1 the product and its applied parts are type BF and thus protected against the risks of electrical leakage. |
|  | <p>This symbol is required by European directive 2002/96/EEC on waste electrical and electronic equipment (WEEE). At the end of its useful life this device must not be disposed of as normal domestic waste. Instead it must be delivered to a WEEE authorised collection centre. As an alternative, the device may be returned without charge to the dealer or distributor, when it is replaced by another equivalent device.</p> <p>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.</p> |
| IP22 | Indicates the degree of resistance to liquids. The device is protected against falling drops of water if it is disposed up to 15° from vertical. |
|  | The symbol is used in accordance with IEC EN 60601–1–2: 2007 in section 5.1.1 for products including RF transmitters. |
| FCC ID | Identification showing traceability to FCC compliance |

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.

13. 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 | $\pm 3.5\%$ or ± 0.1 L whichever is greater* |
| Peak Flow accuracy | $\pm 12\%$ or ± 25 L/min (± 0.42 L/s) whichever is greater* |
| Dynamic resistance at 12 L/s | <0.5 cm H ₂ O/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 | Class II |
| Electrical protection level | BF |
| IP protection level | IP22 |
| Regulations applicable | Electrical Safety IEC 60601-1 Electromagnetic Compatibility IEC 60601-1-2 ATS Standardization of spirometry 2005 |
| 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 |

*The accuracy limits include the tolerance of the ATS test procedure.

14. BLUETOOTH WIRELESS TECHNOLOGY INFORMATION

| | |
|--------------------------------|---|
| Bluetooth Compliance: | Version 4.0 single mode low energy |
| Operating Frequency: | 2.4 to 2.4835 GHz |
| Max Output Power: | TX: -5.99 dBm; 0.25 mW |
| Operating Range: | 10 meter radius (line of sight) |
| Network Topology: | Star – bus |
| Operation: | Server |
| Antenna Type: | PCB antenna |
| 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: | <p>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.</p> <p>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.</p> |
| 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.

14.1 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.

14.2 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.

15. INFORMATION FOR CORRECT USE IN AN ELECTROMAGNETIC ENVIRONMENT

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

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|--|----------------------|------------------|---|
| <p>The Smart One is intended for use in the electromagnetic environment specified below. The customer or the user of the Smart One should assure that it is used in such an environment.</p> | | | |
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±6 kV contact | ±8 kV contact | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. In the event of disruption due to ESD during oximetry test, the device recovers from any disruption within 30 s. (according to ISO 9919). |
| | ±8 kV air | ±15 kV air | |

| | | | |
|--|---|----------------|---|
| Electrical fast transient/burst IEC 61000-4-4 | ±1 kV for input/output lines | Not applicable | |
| Surge IEC 61000-4-5 | ±1 kV differential mode ±2 kV common mode | Not Applicable | |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles 70 % <i>UT</i> (30 % dip in <i>UT</i>) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 5 sec | Not Applicable | |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |

NOTE *UT* is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The **Smart One** is intended for use in the electromagnetic environment specified below. The customer
or the user of the **Smart One** should assure that it is used in such an environment.

| | | | |
|--|--|--|--|
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the Smart One , |
|--|--|--|--|

| | | | |
|---------------------------------------|---|---------------|---|
| <p>Conducted RF IEC 61000-4-6</p> | <p>3 Vrms 150 kHz to 80 MHz</p> | <p>NA</p> | <p>including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance</p> <p><i>d not applicable</i></p> <p>$d = 0,175 \sqrt{P}$ 80 MHz to 800 GHz</p> |
| <p>Radiated RF IEC 61000-4-3</p> | <p>3 V/m 80 MHz to 2,5 GHz</p> | <p>20 V/m</p> | <p>$d = 0,35 \sqrt{P}$ 800 MHz to 2,5 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |

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

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

- a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **Smart One** is used exceeds the applicable RF compliance level above, the **Smart One** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **Smart One**.
- b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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

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

| Rated maximum output power of transmitter | Separation distance according to frequency of transmitter [m] | | |
|---|---|-------------------|--------------------|
| | 150 kHz to 80 MHz | 80 MHz to 800 MHz | 800 MHz to 2,5 GHz |
| W | <i>d=not applicable</i> | <i>d=0,175 √P</i> | <i>d=0,35 √P</i> |
| 0,01 | not applicable | 0,017 | 0,350 |
| 0,1 | not applicable | 0,055 | 0,110 |
| 1 | not applicable | 0,175 | 0,350 |
| 10 | not applicable | 0,550 | 1,100 |
| 100 | not applicable | 0,750 | 3,500 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

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

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 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.r.l. – reserves the right to replace the product or make any changes deemed necessary.