



For use in measuring and monitoring Peak Expiratory Flow rates.

Please read the instructions carefully before using.

TruZone® PFM Reorder: PN 96510

This package contains:

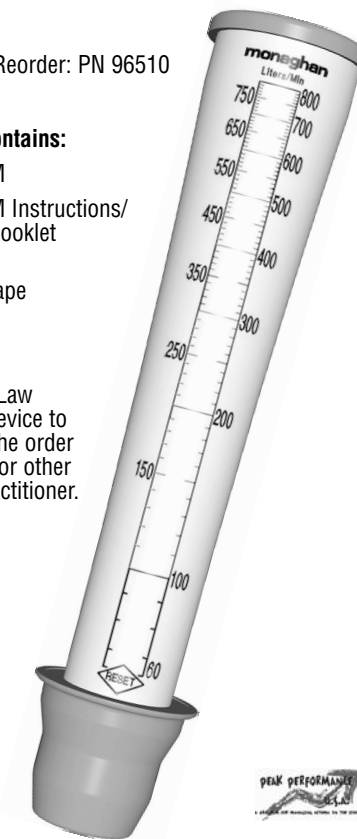
1-TruZone® PFM

1-TruZone® PFM Instructions/ Daily Record Booklet

1-Sheet of Color Zone® Tape

Caution:

Federal (USA) Law restricts this device to sale by or on the order of a physician or other health care practitioner.



Manufactured in the U.S.A. by:



Monaghan Medical Corporation 5 Latour Ave., Suite 1600 Plattsburgh, NY 12901

Customer Service: 1-800-833-9653 www.monaghanmed.com

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INTRODUCTION

TruZone® Peak Flow Meter ("PFM") and its accompanying literature meet the most recent technical Standards of Spirometry for portable peak flow meters established by the American Thoracic Society.

TruZone® PFM is a "one size fits all" peak flow meter, meaning that one model can be used by either children or adults.

Just as a thermometer measures body temperature, TruZone® PFM measures the Peak Expiratory Flow (PEF). PEF is the fastest speed at which air is forced out from the lungs after taking a deep breath.

Normal PEF numbers vary based on gender, age and height. These numbers are for reference only since each individual could have a personal best PEF number that may be higher or lower than the average.

Your physician or licensed health care professional has suggested that you use TruZone® PFM because it is important to measure your PEF daily as part of the overall management of your respiratory condition.

Read and follow the instructions to obtain accurate results.

The TruZone® PFM is intended for persons with respiratory conditions including asthma. Persons with these conditions should only use the TruZone® PFM and the enclosed Color Zone® tapes in conjunction with a treatment plan under the direction of a physician or other licensed practitioner.

Because your physician's or licensed health care professional's advice is important, their instructions for use must be followed carefully and consistently.

Record your results in the Daily Record each time you use TruZone® PFM to identify changes, trends or patterns in your respiratory symptoms.

If you experience unusual symptoms, follow the instructions provided by your physician or licensed health care professional and/or contact them immediately regardless of your PEF.

Your physician or licensed health care professional should always be contacted when changes in your PEF indicate a worsening of your condition.

HOW TO USE YOUR TRUZONE® PFM

1 Prior to using your new TruZone® PFM make sure the yellow indicator has been reset, resting within the diamond near the mouthpiece.

2 To reset, gently shake the TruZone® PFM vertically until the yellow indi-

cator is positioned directly behind the reset diamond.

3 Take as deep a breath as possible.

4 Put the TruZone® PFM mouthpiece into your mouth - seal your lips.

5 Blow out as hard and as fast as possible.

6 Repeat steps 2 through 5 as many times as instructed by your physician or health care professional.

7 Look at the number on the scale beside the yellow indicator. Record this number in the space provided in your TruZone® PFM Daily Record.

When you finish using your TruZone® PFM, be sure to store it in its original package.

HOW TO USE YOUR DAILY RECORD

The Daily Record covers a period of 35 days. Write your name on the line provided and starting with today's date, enter the dates of the next 35 days across the top of the record, in the spaces provided.

Under each date is a graph for charting PEF up to three times a day (AM, PM and one additional). This graph matches the numbers on the TruZone® PFM. Begin entering results in your Daily Record in the left hand column of the chart.

Once the yellow indicator comes to rest at your final PEF, make an "X" to record the measurement under the appropriate Date and Time heading.

TruZone® PFM METHOD: Because the scales on both your TruZone® PFM and Daily Record are identical, it is easy to record your PEF.

GREEN: 80-100 percent of personal best

HIGH YELLOW: 65-80 percent of personal best

LOW YELLOW: 50-65 percent of personal best

RED: below 50 percent of personal best

CONVENTIONAL METHOD: Simply locate the point on the Daily Record, below the Date and Time, that corresponds to the PEF you wish to record.

Always keep your Daily Record up-to-date.

CLEANING YOUR TRUZONE® PFM

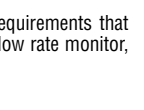
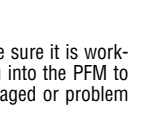
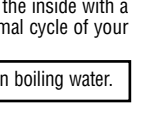
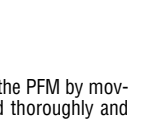
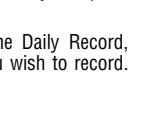
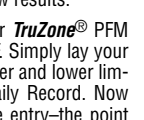
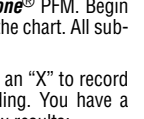
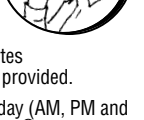
Your TruZone® PFM need only be cleaned once a week. Wash the PFM by moving gently through warm, mild, soapy water.

CAUTION: Never disassemble your TruZone® PFM or place it in boiling water.

QUALITY CHECK

Always visually inspect your TruZone® PFM for damage. Make sure it is working properly before using. This can be done by lightly blowing into the PFM to see if the indicator moves, then resetting the indicator.

Note: The TruZone® PFM meets all accuracy and precision requirements that may be encountered under typical use.



the TruZone® PFM may be affected by extreme altitude variations or temperatures. The meter is not significantly affected by relative humidity and should be used within a normal temperature range (20 to 35 degrees Celsius/68 to 95 degrees Fahrenheit).

**Gardner, RM, et al, Evaluation of Accuracy and Reproducibility of Peak Flow Meter at 1,400m. Chest, 1992; 101:948-952.

STANDARDS

Your TruZone® PFM is designed and manufactured to meet the most recent American Thoracic Society Standards for peak flow measurements.

OPTIONAL COLOR ZONE® TAPE

Our Color Zone® tape system makes the use of your TruZone® PFM easy. These zones are based on a simple traffic light system.

Color Zone® crack-and-peel tape are enclosed that may help to define your individual PEF zones. Remove one piece of multicolored tape from the sheet by cutting along the dotted lines.

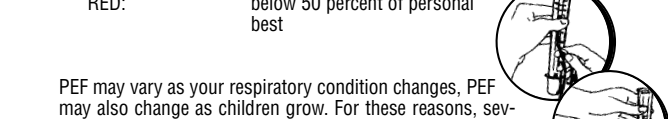
Press the green zone into place. Cut the red zone just above the reset diamond (see illustration), peel off the remaining backing and press into place.

GREEN: 80-100 percent of personal best

HIGH YELLOW: 65-80 percent of personal best

LOW YELLOW: 50-65 percent of personal best

RED: below 50 percent of personal best



PEF may vary as your respiratory condition changes. PEF may also change as children grow. For these reasons, several Color Zone® tape are included with this packet.

MONAGHAN WARRANTY

The TruZone® Peak Flow Meter comes with a one year warranty from the date of purchase. If your TruZone® Peak Flow Meter does not function properly within the warranty period, please return to point of sale with proof of purchase and it will be replaced free of charge.

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† trademarks and registered trademarks of the respective companies. U.S. Patent No. 5,627,324. Foreign patents issued and pending.

PREDICTED AVERAGE PEAK EXPIRATORY FLOW (liters per minute)

Table with columns for Normal Males* (Age, Height, PEF) and Normal Females* (Age, Height, PEF)

Table with columns for Normal Children and Adolescents* (Height, Males & Females, PEF)

*Nunn, AJ, Gregg I. Brit Med J 1989; 298:1068-70.

Table with columns for Normal Children and Adolescents* (Height, Males & Females, PEF)

**Polgar G, Promadhat V. Pulmonary Function Testing in Children: Techniques and Standards. Philadelphia, W.B. Saunders Company, 1971.

DAILY RECORD • DAILY RECORD • DAILY RECORD • DAILY RECORD • DAILY RECORD • DAILY RECORD • DAILY RECORD • DAILY RECORD • DAILY RECORD • DAILY RECORD



DAILY RECORD OF: _____

Daily Record grid with columns for DATE and TIME (AM, AFT, PM) and rows for PEF values from 60 to 800.

NOTE: Your Daily Record is identical to your scale on your TruZone® PFM.



MULTI-PATIENT USE

This product has been packaged and labeled to accommodate multi-patient use in a hospital or other clinical setting.

Instructions for multi-patient use of the TruZone® PFM:

- 1. Ensure the TruZone® PFM has been thoroughly cleaned and disinfected prior to use.
2. Ensure the yellow indicator has been reset, resting within the diamond near the mouthpiece.
3. To reset, gently shake the TruZone® PFM vertically until the yellow indicator is properly positioned as specified above.
4. Attach a disposable one-way valve mouthpiece to the green mouthpiece of the TruZone® PFM.
5. Instruct the patient first to take as deep a breath as possible before bringing the TruZone® PFM to their mouth and sealing their lips around the disposable mouthpiece.
6. The patient should now blow out as hard and as fast as possible.
7. Repeat as necessary for patient response.
8. Remove the disposable mouthpiece and discard.
9. Thoroughly clean and disinfect the TruZone® PFM as instructed.

Instructions for reprocessing the TruZone® PFM:

- 1. Wearing gloves and in a well-ventilated area, ensure the TruZone® PFM has been thoroughly cleaned prior to reprocessing.
2. After the device has completely dried, immerse the TruZone® PFM completely in an active solution of Cidex® OPA, a rapid high level disinfectant.
3. Following immersion for 12 minutes in Cidex® OPA solution, thoroughly rinse the device by immersing it completely in a large volume of water.
4. Let dry completely. The TruZone® PFM is now ready for use.

Cidex® OPA is a product of Advanced Sterilization Products, A Johnson & Johnson company.

Based on validation testing, the TruZone® PFM can be reused up to 10 times. WARNING: With cold sterilants, high-level disinfection cannot be assured.

- Use the following guidelines to inspect the meter after reprocessing:
1. Ensure that there is no crazing of the transparent body of the meter.
2. All numbers and lettering are clearly visible on the transparent body.
3. Uniform coloration of the green mouthpiece, green end cap and yellow indicator.
4. No abnormal discoloration of the metal parts.
5. No abnormal warping or distortion of the piston that pushes the yellow indicator.
6. The three reset balls move freely within the slotted tube.

If any of the above conditions are presented, the meter should be discarded.

