



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.

This product has not been made (or manufactured) with BPA (Bisphenol A) or Natural Rubber Latex.

Manufactured in the U.S.A. by: monaghan Monaghan Medical Corporation Plattsburgh, NY 12901 Customer Service: 1-800-833-9653 www.monaghanmed.com P/N 96001-12 AWA81-10

INTRODUCTION The TruZone® PFM meets the educational guidelines recommended by the National Asthma Educational Prevention Program (NAEPP) of the National Institutes of Health.

TruZone® PFM is a "one size fits all" peak flow meter, meaning that one model can be used by either children or adults. Best of all, you can personalize TruZone® PFM with our unique color zones as recommended by your physician within a treatment plan to meet your needs.

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. This measurement is useful in detecting changes in airways that could signal a worsening of symptoms or an improvement in breathing function for people with respiratory conditions such as asthma or emphysema.

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.

If you have questions about whether TruZone® PFM is working correctly, or you do not fully understand the user instructions, please contact your physician.

Because your physician's or licensed health care professional's advice is important, their instructions for use must be followed carefully and consistently. They will help you understand the readings and results from your TruZone® PFM. The PEF is normally measured at 8 A.M. and 8 P.M., but always as recommended by a physician or licensed health care professional.

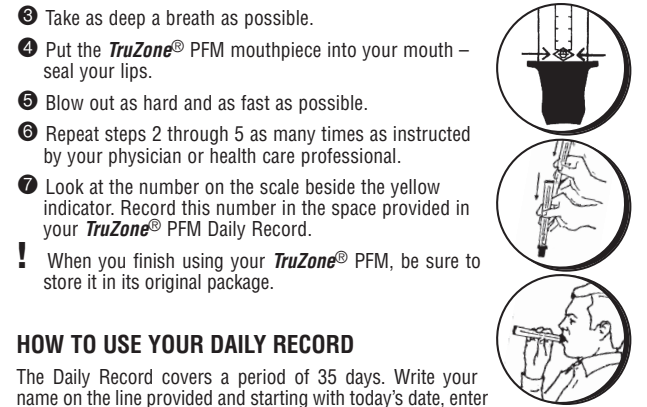
Record your results in the Daily Record each time you use TruZone® PFM to identify changes, trends or patterns in your respiratory symptoms.

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 indicator is positioned directly behind the reset diamond.



- 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. All subsequent results should be entered sequentially to the right.

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. You have a choice of two methods when charting your peak expiratory flow results:

TruZone® PFM METHOD: Because the scales on both your TruZone® PFM and Daily Record are identical, it is easy to record your PEF. Simply lay your TruZone® PFM directly onto the Daily Record. Align the upper and lower limits of the PEF scales of both your TruZone® PFM and Daily Record. Now mark with an "X" below the corresponding Date and Time entry—the point where the yellow indicator rests.

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

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. Rinse gently and thoroughly and allow it to air dry before your next reading.

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. A damaged or problem meter should not be used. 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.

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. Your physician will instruct you on the placement and use of this unique Color Zone® tape 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. To apply, peel the backing from the green zone. Then place the tape in the middle of the scale of the PFM so that the arrows below the word BEST line up with your best PEF as confirmed by your physician or licensed health care professional.

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® tapes are included with this packet. Used Color Zone® tape must be removed before a new one is applied. Do not replace Color Zone® tape before consulting with your physician.

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. This warranty does not cover any defect or damage arising from misuse or lack of proper maintenance.

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PREDICTED AVERAGE PEAK EXPIRATORY FLOW (liters per minute)

Table with 2 columns: Normal Males* (Age, Height) and Normal Females* (Age, Height) showing predicted average peak expiratory flow values.

Table with 2 columns: Normal Children and Adolescents* (Height, Males & Females) showing predicted average peak expiratory flow values.

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

Table with 2 columns: Normal Children and Adolescents* (Height, Males & Females) showing predicted average peak expiratory flow values.

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

DAILY RECORD OF: _____

Daily Record grid with columns for Date and Time (AM, After, PM) and rows for PEF values from 60 to 800.

NOTE: Your Daily Record is identical to your scale on your TruZone® PFM. TRUZONE Peak Flow Meter

MULTI-PATIENT USE

This product has been packaged and labeled to accommodate multi-patient use in a hospital or other clinical setting. Instructions for its use and care when used for screening purposes are supplied below.

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 high level disinfectant OR an active solution of Revital-Ox+ Resert+, a high level disinfectant. 3. Following immersion for 12 minutes in Cidex+ OPA solution OR 8 minutes in Revital-Ox+ Resert+ solution thoroughly rinse the device by immersing it completely in a large volume (e.g., 2 gallons) 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. Revital-Ox+ Resert+ is a product of Stens Corporation

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.

