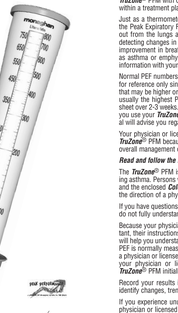
Peak Flow Meter

TRUZONE®

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 is BPA FREE

Manufactured in the U.S.A. by:

monaghan

Monaghan Medical Corporation
5 Latour Ave., Suite 1600
Plattsburgh, NY 12901
Customer Service: 1-800-833-9653
www.monaghanmed.com

P/N #96001-07 AWA81-05 03/11

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. 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. Use the Daily Record as instructed and share this information with your physician or licensed health care professional at each visit.

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 personal best PEF number is usually the highest PEF number that you have recorded on your Daily Record sheet over 2-3 weeks. Your personal best PEF number is your goal to reach when you use your *TruZone*® PFM. Your physician or licensed health care professional will advise you regarding your personal best.

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*® tape 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. To insure proper technique, ask your physician or licensed health care professional to watch you use the *TruZone*® PFM initially.

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

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

❷ To reset, gently shake the *TruZone*® PFM vertically until the yellow indicator is positioned directly behind the reset diamond.

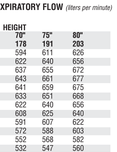
❸ Take as deep a breath as possible.

❹ Put the *TruZone*® PFM mouthpiece into your mouth – seal your lips.

❺ Blow out as hard and as fast as possible.

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

❼ 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. Do not try to clean the inside with a brush. You can also safely clean *TruZone*® PFM using the normal cycle of your dishwasher.

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. As with any pressure/flow rate monitor, 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). All measurements of the *TruZone*® PFM have been validated at Body Temperature and Pressure Saturated with water vapors (BTPS).

**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. These standards reflect the use of 26 flow-time waveforms specifically selected to evaluate peak flow meters. Accuracy is ±12% or 25 l/m, whichever is greater.

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*® tape 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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U.S. Patent No. 5,827,204. Foreign patents issued and pending.

PREDICTED AVERAGE PEAK EXPIRATORY FLOW *(liters per minute)*

Normal Males*

Age (Years)	(in.) (cm)	HEIGHT 60" 152	65" 165	70" 178	75" 191	80" 203
20		554	575	594	611	626
25		580	603	622	640	656
30		594	617	637	655	672
35		599	622	643	661	677
40		597	620	641	659	675
45		591	613	633	651	668
50		580	602	622	640	656
55		566	588	608	625	640
60		551	572	591	607	622
65		533	554	572	588	603
70		515	535	552	568	582
75		496	515	532	547	560

Normal Females*

Age (Years)	(in.) (cm)	HEIGHT 55" 140	60" 152	65" 165	70" 178	75" 191
20		444	460	474	486	497
25		455	471	485	497	509
30		458	475	489	502	513
35		458	474	488	501	512
40		453	469	483	496	507
45		446	462	476	488	499
50		437	453	466	478	489
55		427	442	455	467	477
60		415	430	443	454	464
65		403	417	430	441	451
70		390	404	416	427	436
75		377	391	402	413	422

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

Normal Children and Adolescents**

Height (in.)	(cm)	Males & Females	Height (in.)	(cm)	Males & Females
43"	109	147	**55"**	140	307
44"	112	160	**56"**	142	320
45"	114	173	**57"**	145	334
46"	117	187	**58"**	147	347
47"	119	200	**59"**	150	360
48"	122	214	**60"**	152	373
49"	124	227	**61"**	155	387
50"	127	240	**62"**	157	400
51"	130	254	**63"**	160	413
52"	132	267	**64"**	163	427
53"	135	280	**65"**	165	440
54"	137	293	**66"**	168	454

**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

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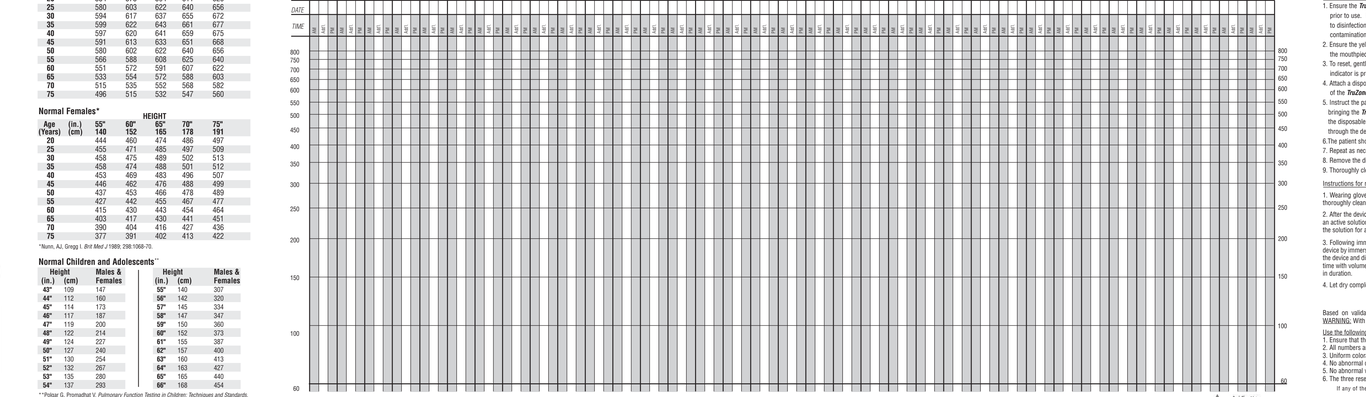
TRUZONE®

DAILY RECORD OF: _____

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



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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. Exhaled sputum, saliva, or blood should be removed prior to disinfection to minimize impact on device accuracy and to prevent cross-contamination of patients.
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. (Patients should be instructed not to inhale through the device.)
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 cold high level disinfectant. Leave the device in the solution for a minimum of 12 minutes at room temperature (20°C or higher).

3. Following immersion for 12 minutes in Cidex® OPA solution, thoroughly rinse the device by immersing it completely in a large volume (e.g., 2 gallons) of water. Remove the device and discard the rinse water. Repeat this process for a total of 3 times, each time with volumes of fresh rinse water. Each rinse should be a minimum of 1 minute in duration.

4. Let dry completely. The *TruZone*® PFM is now ready for use.

Cidex OPA is a product of Advanced Sterilization Products, a division of 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 colorization 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 is presented, the meter should be discarded.

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