

- Device classification: Class Im
- Notified body number: 0086
- Complies with the 93/42/CEE directive



Vitalograph (Ireland) LTD – Gort Road Business Park – Ennis – Clare - Ireland

<i>General description</i>	Meter for mechanically measuring PEF (Peak Expiratory Flow)		
<i>Attachments</i>	Yes	Photo, instructions for use	
<i>Batch Reference</i>	Yes	See "BATCH" on the product label	
<i>Connected device</i>	Yes	Mouthpieces	
<i>Single use device</i>	No	The mouthpieces are single-use	
<i>Sterile device</i>	No		
<i>Sterilisation</i>	No		
<i>Autoclavable</i>	No		
<i>Cleaning</i>	Yes	Weekly cleaning is recommended. With a dry cloth impregnated with 70% alcohol.	
<i>Unsuitable substance</i>	Products that attack ABS (Acrylonitrile butadiene styrene)		
<i>Component parts</i>	No		
<i>Material</i>	ABS (Acrylonitrile butadiene styrene) Plastic Flow Meter with cardboard mouthpieces		
<i>Contains latex</i>	No		
<i>Tube</i>	No		
<i>Labelling</i>	Yes	Name, reference, CE, COMED, address, Batch, Serial no., manufacturer, EC representative	
<i>Packaging</i>	Yes	In a plastic bag and a cardboard box	
<i>Special packaging</i>	Yes	In a place with an ambient temperature between 0-50°C and relative humidity between 10-95%. In a clean, dry place away from sunlight.	
<i>Standards</i>	EN 13826 ; ATS/ERS ; AS/NZS4237 ; NHLBI		
<i>Marking on medical device</i>	Yes	Name, CE, manufacturer, batch.	
<i>References</i>	30 100 00	30 100 22	30 100 30
<i>Designation</i>	PEAK FLOW METER	Mouthpieces children	Mouthpieces adults
<i>Dimensions L x Ø (mm)</i>	150 x 52 x 25	66 x Ø 22	66 x Ø 30
<i>Temperature resistance (°C)</i>	-10 to +50°C	/	/
<i>Storage temperature (°C)</i>	0 to +50°C	/	/
<i>Relative humidity (%)</i>	10 – 95%	/	/
<i>Measurement range</i>	50 – 800L/min	/	/
<i>Accuracy</i>	Above +/- 10 L/min or +/- 10% of the measurement	/	/
<i>Reproducibility</i>	Above +/- 5 L/min or +/- 5% of the measurement	/	/
<i>Leakage resistance</i>	0.00384 kPa/L/min – 720L/min kPa/l/min	/	/
<i>Standard zone</i>	50-800 L/min BTPS	/	/
<i>Frequency response</i>	Difference between A/B profiles below 15 l/min/15%	/	/
<i>Net weight (g)</i>	62	3	5
<i>Colours</i>	Grey and white	White	White
<i>Usage</i>	Meter for mechanically measuring PEF (Peak Expiratory Flow) Can measure the intensity of an asthma attack and reveal a respiratory deficiency. Adjustable zone marker (green - yellow - red). Recommended to patients for self-measurement and to doctor's offices.		

<i>Instruction for use</i>	<ol style="list-style-type: none"> 1. Sit down. Slide the pointer to the bottom of the measurement scale. 2. Hold the the meter so that you are not touching the measurement scale and bring it close to your mouth. 3. Inhale as deeply as possible. Place the mouthpiece in your mouth, biting it lightly, then close your lips around it. 4. Exhale for a second or more, as quickly and powerfully as possible. Ensure the mouthpiece hole is not blocked by your teeth or tongue. 5. Your peak flow can be read on the scale next to the pointer. Write down the result and slide the pointer to the bottom of the measurement scale. 6. Perform the test 3 times and write down the best result in the logbook.
<i>Precautions for use</i>	<p>The mouthpieces are single-use only. Do not reuse them.</p> <p>Ensure the meter is cleaned with a 70% alcohol solution between each patient.</p> <p>After 30 patients, or 2 weeks, whichever is earlier, the equipment must be replaced. The device should be calibrated on an annual basis.</p>
<i>Recycling</i>	No
<i>Recycling/Recovery</i>	Waste bin
<i>WEEE/REACH</i>	No/NC
<i>PVC/PHTHALATES</i>	No/No
<i>Safety data</i>	R-Phrases = None Combination phrases = None