

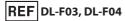


MISURATORE DI PICCO DI FLUSSO
PEAK FLOW METER
SPIROMÈTRE DE CRÊTE
MEDIDOR DE FLUJO ESPIRATORIO MÁXIMO
MEDIDOR DE PICO DE FLUXO
PEAK-FLOW-METER
TOPPFLÖDESMÄTARE
POOMETPO



Taian Dalu Medical Instrument Co., Ltd.

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GIMA 33679 - 33680



Please read all the information in this manual before using the Peak Flow Meter.



- 1. The Peak Flow Meter is recommended for single patient use.
- 2. The Peak Flow Meter should be used under the supervision of a licensed healthcare professional.
- 3. If the PEF is used for longer than its specified life, the accuracy of the device may deteriorate.
- 4. Device use should be limited to exhalation only

Note: Patients symptoms take precedence over Peak Flow Meter readings.

Settina Action Zones

Zone markers may be set with a stylus by the healthcare professional to give personal boundaries for implementing the asthma action plan.

To Use Peak Flow Meter

- 1. Slide pointer to the bottom of the scale.
- 2. Hold device horizontally in front of your mouth.
- 3. Inhale as deeply as possible.
- 4. Seal your lips firmly around the mouthpiece.
- 5. Blow out as HARD and as FAST as possible for a second or longer.
- 6. Take care that tongue or teeth do not obstruct the airflow. A "spitting" action or coughing will give false readings.
- 7. Take note of the reading.
- 8. Repeat steps 1 to 7 three times and record the highest reading.
- 9. Take action according to your personal asthma management plan.

Cleaning

Clean the outer surfaces after use. We recommend using an ordinary alcohol wipe (75%). Pay special attention to the mouth-piece area.

Indications for Use

Device measures peak expiratory flow (PEF) for use on adults and paediatrics, 5 years and older, in primary care, clinics, hospitals and at home, under the supervision of a healthcare professional. PEF can be used to monitor progress in treatment of asthma, determine the severity of the asthma, check response to treatment during an acute asthma episode, detect worsening lung function and avoid a possible severe asthma flare-up.

Contraindications, Warnings, Cautions and Adverse Reactions

- This device is intended to help you assess how well your asthma is under control, by measuring your peak flow which can then be monitored over time.
- Never attempt to dismantle the unit. This can cause faulty Peak Expiratory Flow scores.
- · If you think that the device is not reading correctly, advise your healthcare professional immediately
- Any serious incident that has occurred in relation to the device should be reported to Taian Dalu or its Authorized Representative and the Regulatory Authorities of the country.

Disposal

The peak flow meter and its accessories constitute minimally soiled waste from human healthcare and should be disposed of in line with local requirements.

Shelf Life

3 years

Technical Specifications

Product: Peak Flow Meters Model Number: DL-F03, DL-F04

Material: ABS plastic

Intended use: Measure peak expiratory flow to monitor respiratory condition.

Linearity: The difference between the mean error at any two consecutive test

flowrates shall not exceed 5 % of the larger of the two test flowrates. Under ambient conditions the PEFM reading at any peak flowrate in the Measurement Range shall

not vary by more than 10L/min or 5 % of the mean of the readings, whichever is greater.

Resistance to flow: The resistance to flow across the measurement range of the PEFM shall not exceed PEFM 0.36KPa/(L/s) [0.006kPa/(L/min)].

Error of measurement: The maximum permissible error shall be ± 10 L/min or $\pm 10\%$ of the reading, whichever is greater. **Frequency response:** The difference between the indicated PEF value of A and B shall, for an identical reference PEF, not exceed 15L/min or 12%, whichever is greater.

Highest resistance to flow: DL-F03: 0.20KPa/(L/s) @720L/min; DL-F04: 0.24KPa/(L/s) @200L/min.



Measurement Range: DL-F03: 60~800L/min, DL-F04: 50~400L/min

Storage conditions: store in a clean dry place **Transport conditions Temperature:** 0-50°C

Relative humidity 10%-95%

Peak Flow Meter performance standards: EN ISO 23747:2015

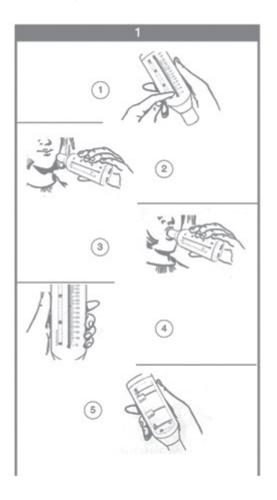
Maximum number of uses: 7000 times

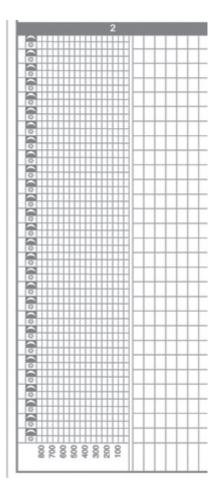
Size/Weight

Model DL-F03: L155mm*W48mm*H28mm/ 55g Model DL-F04: L155mm*W48mm*H28mm/ 55g

Package Contents

Peak Flow Meters, Instructions for Use







Symbols meaning

REF	Product code	类	Keep away from sunlight	[]i	Consult instructions for use
LOT	Lot number	*	Keep in a cool, dry place	<u>~</u>	Date of manufacture
	Manufacturer	CE	Medical device compliant with Regulation (EU) 2017/745	EU REP	Authorized representative
MD	Medical Device	Ŵ	Caution: read instructions (warnings) carefully	UDI	Unique Device Identifier

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.