

EN Regulatory Notices

Warnings and Advisory Notices

Note: Please read all this information before using this Peak Flow Meter. A full set of instructions, including cleaning instructions, is available at www.vitalograph.co.uk.

- This Vitalograph device is intended to measure how well your asthma is under control, by measuring you peak flow which can then be monitored over time.
- Never attempt to dismantle the unit. This can cause faulty Peak Expiratory Flow scores.
- Take care not to block the mouthpiece with the tongue or teeth. A 'spitting' action or coughing will give false readings.
- If used at home symptoms must take precedence over device measurements*.
- If the device is used for longer than its specified life, the accuracy of the device may deteriorate.
- Store in a clean dry place.
- In Clinic: When used for multiple subjects always use a disposable SafeTway® mouthpiece. The Peak flow meter should be externally disinfected using an IPA wipe between each patient, and should be disposed of after 30 patients or 2 weeks, whichever is the earlier.
- Cleaning & disinfecting: The outer surfaces should be cleaned every week, more often if necessary. The use of an ordinary alcohol wipe (IPA 70-90%) is recommended, with special attention to the mouthpiece area.

* If the patient at home thinks that the device is not reading correctly, they must advise the healthcare professional immediately. Medical facilities may use a spirometer to check the accuracy of this device.

Warranty

Your Vitalograph device is guaranteed for one year*. Replace if it is faulty, otherwise replace the unit every three years.

* Excepting accidental / transit damage or inappropriate use of the device.

CE Notice

Marking by the symbol  indicates compliance of this device to the Medical Devices Directive of the European Community. Such marking is indicative that the Vitalograph device meets or exceeds the referenced technical standards.

FDA Notice

Caution: Federal Law restricts this device to sale by, or on the order of a physician.

Declaration of Conformity

Product: Vitalograph Model 4300

Vitalograph hereby ensures and declares that the above product associated with this user manual, is designed and manufactured in accordance with the following QMS regulations and standards:

- European Medical Devices Directive {MDD} 93/42/EEC. This device, classified as 2a as per Annex IX of MDD 93/42/EEC, meets the following provisions of Annex II of the Medical Devices Directive as per Article 11, section 3a, excluding point 4 of Annex II.
- Canadian Medical Device Regulation {CMDR}
- FDA Quality System Regulation {QSR} 21 CFR 820.
- EN ISO 13485: 2003. Medical devices. Quality management systems. Requirements for regulatory purposes.



Certifying Body {for 93/42/EEC and CMDR}: British Standards Institute {BSI}

Certificate Nos. CE 00772, MD 82182, FM 83550

Technical Specifications

Material:	Recyclable ABS plastic
Accuracy:	± 10 L/min or ± 10% of the reading
Repeatability:	± 5 L/min or ± 5% of the reading
Altitude effects on the Peak Flow Meter (and on the expired air):	Lowers readings by approx. 5% per 1000m, (decreased air density increases PEF by approx 5% per 1000m)
Highest resistance to flow:	0.00384 kPa/L/min @ 720 L/min
Measurement Range:	50-800 L/min BTPS
Storage Conditions:	Temperature: 10-35°C Relative Humidity: 30%-75%
Peak Flow Meter performance standards:	EN ISO 23747:2007; ATS/ ERS; AS/ NZS4237; NHLBI
Frequency response:	Profile A/B difference less than 15 L/min/15% (Annex B, EN ISO 23747:2007)

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