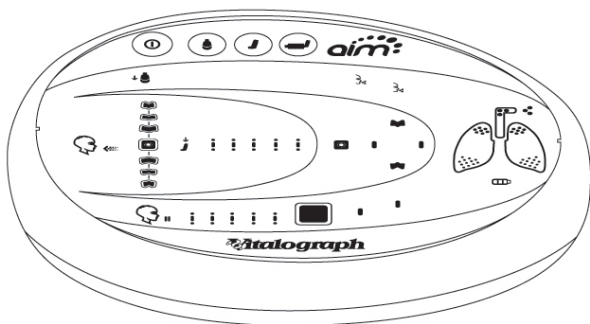




# AIM (Aerosol Inhalation Monitor)

MODEL 4500



Instructions for Use

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 is a registered trademark.

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## 1. Indications for Use

The indications for use of the Vitalograph AIM is in the assessment of inhaler use to guide a subject on good inhaler technique. The device is intended to be operated by the subject, under the supervision of a healthcare provider.

## 2. Contraindications, Warnings, Precautions and Adverse Reactions

1. No modification of this equipment is allowed. Any unauthorised changes to the Vitalograph AIM device may compromise product safety and/or data and as such Vitalograph cannot be held responsible and the device will no longer be supported.
2. The Vitalograph AIM is not designed as a sterile device. Always follow the safety guidelines given by the manufacturer of cleaning and disinfectant chemicals.
3. Vitalograph intends that a new disposable inhaler simulator be used for every subject to prevent cross contamination. The disposable inhaler simulator mouthpiece is for single use only.
4. When using the Vitalograph AIM ensure that the silicone tubing is not pinched or trapped as this may affect results.
5. Take care not to block the mouthpiece with tongue or teeth during testing.
6. Subject fatigue may occur during training depending on the subject's characteristics e.g. age, health status. For safety reasons, training should be preferably done in the sitting position, using a chair with arms and without wheels. Subject may also take a break between inhalation tests.
7. Do not expose the AIM to liquids.
8. The AIM should not be used in the presence of flammable liquids or gases, dust, sand, or any other chemical substances.
9. Service and repairs should be carried out only by the manufacturer or by Service Agents approved by Vitalograph.
10. Only approved accessories from the manufacturer should be used with the device.
11. Take care during battery replacement installation. An AAA battery is a potential choking hazard for a small child. Adult

supervision is required at all times when a child is using the device.

12. Batteries should be removed if the device is intended to be stored or left unused for an extended period of time.
13. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Vitalograph AIM, including cables specified by Vitalograph. Otherwise, degradation of the performance of this equipment could result.
14. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

### 3. Main Components of the Vitalograph AIM

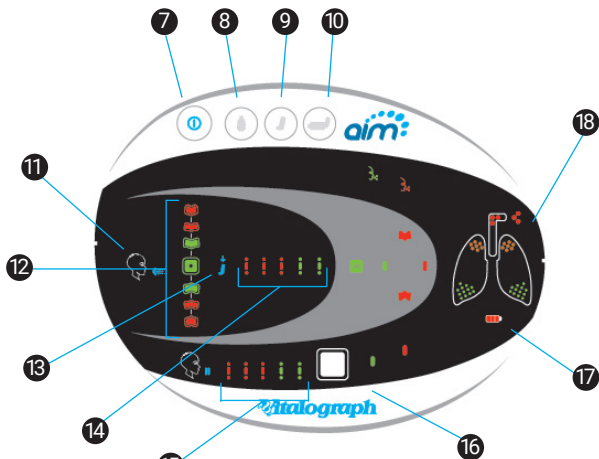
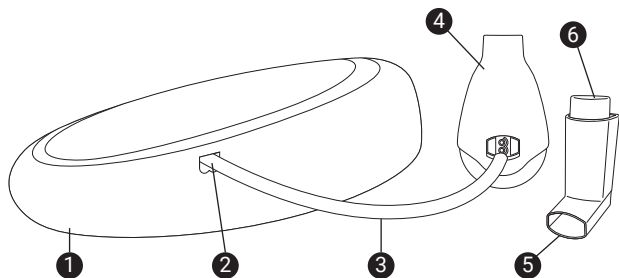


Figure 1: AIM Components

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1	AIM Device
2	Port
3	Silicone tubing
4	Single-use disposable DPI inhaler simulator. (Custom DPI simulator may differ in appearance from illustration)
5	Single-use disposable MDI inhaler simulator (also required for spacer)
6	MDI placebo canister
7	Power button
8	DPI simulator button
9	MDI simulator button
10	MDI Spacer simulator button
11	Ready to inhale indicator
12	Flow lights
13	Canister activation (MDI)
14	Inhalation time lights
15	Breath-hold lights
16	End of breath-hold button
17	Battery low light
18	Inhaler technique summary display

### 3.1. Features of the Vitalograph AIM

- Assists in training subjects to use their inhalers correctly and validates good technique of DPI and MDI inhalers with visual feedback on:
  - Timing of firing cannister activation (MDI)
  - Inspiratory flow rate throughout inspiration
  - Inhalation time within target flow range
  - Breath hold time at the end of inhalation
  - Good/Poor technique summary
- Easy to use.
- Hygienic with disposable MDI and DPI inhaler simulator mouthpieces.
- Clear sounds for audio feedback.

## 4. Setting Up the Vitalograph AIM

1. Remove AIM device from packaging.
2. Remove battery door from rear of the unit. Fit four AAA 1.5V batteries. Replace battery door.
3. Attach the silicone tubing (Figure 1) to the port on the side of the AIM.

## 5. Operating Instructions

**Note:** These operating instructions and results are for the generic AIM device. Some variants with different/custom DPI simulators may differ slightly from what is shown in figure 1. Refer to the supplementary documentation supplied with the device for additional instructions.

### 5.1. Conducting a Test

1. Use the silicone tubing (3) to connect a new MDI or DPI inhaler simulator (Figure 1) mouthpiece to the device.  
**Note:** The inhaler simulators are single patient use.
2. If MDI inhaler simulator mouthpiece is being used, insert the placebo canister (6).  
**Note:** Placebo cannister must be fitted for accurate results.
3. Press power button (7) and select required inhaler simulator option:
  - DPI simulator (8)
  - MDI simulator (9)
  - Spacer simulator (10)
4. Instruct the subject to breathe out fully, but not through the inhaler simulator.
5. Instruct the subject to position inhaler simulator between the lips, and seal lips around the mouthpiece. Ensure teeth and tongue do not block the mouthpiece.  
**Note:** Ensure that the holes/openings on the inhaler simulator next to the tubing connection are not obstructed

### 6. For DPI Simulator

- Instruct subject to take a **forceful deep breath** in until their lungs are full. The flow lights will light up. The objective is to get the flow indicator into the green zone or above as quickly as possible, but not to inhale too fast.



- The initial forced inhalation is important when using a DPI to correctly deposit drug in the patients' lungs.
- Subject should continue to inhale until their lungs are full. Inhalation time lights will light up one second at a time.

#### **For MDI Simulator**

- Instruct subject to take a **slow steady breath** and simultaneously press the placebo canister. Flow lights and the canister activation lights will light up. The objective is to press the canister as the subject starts to inhale, and to continue to inhale for as long as possible, but not too fast, keeping the flow indicator in the green zone.
- The AIM device detects activation of the MDI. The lights on the device indicate when the inhalation rate is correct to deposit drug in the patients' lungs.
- Subject should continue to inhale until their lungs are full (at least 3 seconds). Inhalation time lights will light up one second at a time.

#### **For Spacer Simulator**

**Note:** *The MDI inhaler simulator mouthpiece is used to simulate a spacer. Do not attach a spacer.*

- Instruct subject to press the canister just before or as inhalation starts. Canister activation lights will light up.
- The Spacer Simulator allows subject to take single or multiple breaths.
- Subject should continue until at least 3 seconds of inhalation (in total) is achieved. Inhalation time lights will light up one second at a time.

#### **For all Devices:**

- Subject should hold their breath for as long as comfortable (at least 3 seconds). Breath hold lights will light up one second at a time.
- When subject ceases breath hold, press the end of

breath-hold button (15).

7. Feedback is provided by the individual results lights (Figure 2) and Technique Good/Poor summary (Figure 3 - 5)
8. To repeat, press the appropriate inhaler simulator option button.

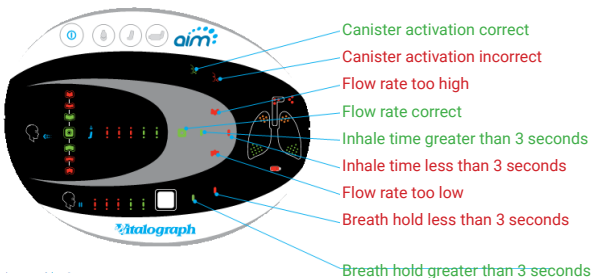
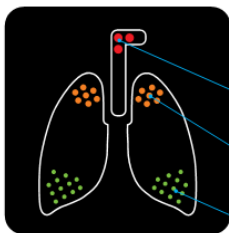


Figure 2 Results Lights

## 5.2. Results Summary



### DPI Simulator Technique Good/Poor Summary

#### Fail (Red):

Inspiratory flow rate was too low or too slow

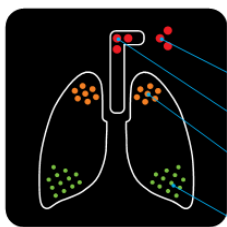
#### Sub-optimal (Orange):

Breath hold too short or inspiratory flow not forceful enough

#### Good (Green):

Forceful inhalation with adequate inspired volume and breath hold time

Figure 3: DPI Simulator Technique Summary



### MDI Simulator

#### Technique Good/Poor Summary

**Fail (Red):**

Canister activated too early or not at all

**Fail (Red):**

Inspiratory flow rate was too fast

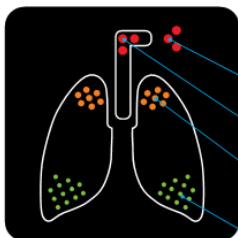
**Sub-optimal (Orange):**

Inhalation time and/or breath hold too short

**Good (Green):**

Correct canister activation, with adequate flow rate, inhale and breath hold time

Figure 4: MDI Simulator Technique Summary



### Spacer Simulator

#### Technique Good/Poor Summary

**Fail (Red):**

No canister activation

**Fail (Red):**

Inspiratory flow rate was too fast

**Sub-optimal (Orange):**

Inhalation time and/or breath hold too short

**Good (Green):**

Correct canister activation, with adequate flow rate, inhale and breath hold time

Figure 5: Spacer Simulator Technique Summary

## 6. Power Management

The AIM requires 4 AAA 1.5V disposable batteries. Batteries should be replaced when the battery light (Figure 1) is ON.

**Note:** Dispose of used batteries safely.

## 7. Cleaning & Hygiene

### 7.1. Preventing Cross-Contamination of Subjects

The AIM is not designed or supplied as a 'sterile' device. Vitalograph intends that a new disposable inhaler simulator be used for every subject to prevent cross contamination. The exterior case, overlay label, white silicone tube and reusable elements of the inhaler simulators such as the MDI canister can be cleaned by wiping with a 70% isopropyl alcohol impregnated cloth. This provides a suitable

form of cleaning and low-level disinfection. This may be preceded by cleaning with an anti-static foam cleaner if necessary.

**Note:** Always follow the safety guidelines given by the manufacturer of cleaning and disinfectant chemicals.

## 7.2. Inspection of the Vitalograph AIM

Visual inspection is recommended on a routine basis; Ensure that the silicone tubing is not pinched or trapped. Also ensure that the silicone tubing is fitted to the AIM device and the disposable inhaler simulator.

## 8. Fault Finding Guide

<b>Problem Fault Symptom:</b>	<ul style="list-style-type: none"> <li>• <b>The flow lights come on but nothing else</b></li> </ul>
Possible Solution:	<ul style="list-style-type: none"> <li>• Press the DPI, MDI, or Spacer simulator button.</li> </ul>
<b>Problem Fault Symptom:</b>	<ul style="list-style-type: none"> <li>• <b>MDI simulator activation light not coming on.</b></li> </ul>
Possible Solutions: (In probable order)	<ul style="list-style-type: none"> <li>• Press the placebo canister at the start of inhalation.</li> <li>• Check Placebo canister is fitted correctly.</li> <li>• Placebo canister may be empty and require replacement.</li> </ul>
<b>Problem Fault Symptom:</b>	<ul style="list-style-type: none"> <li>• <b>Difficulty achieving Good (Green) result with DPI simulator.</b></li> </ul>
Possible Solution:	<ul style="list-style-type: none"> <li>• Ensure patient takes a forceful deep breath at the very start of the inhalation hitting the upper flow band.</li> </ul>
<b>Problem Fault Symptom:</b>	<ul style="list-style-type: none"> <li>• <b>Flow measurement appears low for the MDI simulator.</b></li> </ul>
Possible Solution:	<ul style="list-style-type: none"> <li>• Placebo canister needs to be fitted as it is required for accurate results.</li> </ul>

<b>Problem Fault Symptom:</b>	<ul style="list-style-type: none"> <li>• <b>No flow measurements.</b></li> </ul>
Possible Solutions: (In probable order)	<ul style="list-style-type: none"> <li>• Ensure the silicone tubing is not pinched or trapped.</li> <li>• Ensure the silicone tubing is fitted to AIM device and inhaler simulator.</li> </ul>
<b>Problem Fault Symptoms:</b>	<ul style="list-style-type: none"> <li>• <b>Test begins automatically.</b></li> <li>• <b>Inhalation time accumulates automatically without the subject inhaling.</b></li> </ul>
Possible Solution:	<ul style="list-style-type: none"> <li>• Simulator and/or tubing not stationary at the start of test. Hold both steady until 'Blow Icon' appears.</li> </ul>
<b>Problem Fault Symptoms:</b>	<ul style="list-style-type: none"> <li>• <b>Cannot read user interface.</b></li> <li>• <b>Lights not coming on.</b></li> </ul>
Possible Solutions: (In probable order)	<ul style="list-style-type: none"> <li>• The battery may be low. Replace batteries.</li> <li>• Electronics failure – contact support.</li> </ul>

### 8.1. Software Check

Not applicable.

## 9. Customer Service

Service and repairs should be carried out only by the manufacturer, or by Service Agents approved by Vitalograph. Contact information for approved Vitalograph Service Agents may be found at the start of this manual.

Any serious incident that has occurred in relation to the device should be reported to Vitalograph or its Authorized Representative and the Regulatory Authorities of the country. Refer to the Vitalograph contact information at the start of this manual.

## 10. Consumables and Accessories

Cat. No	Description
45610	Disposable DPI Inhaler Simulator (25)
45611	Disposable MDI Inhaler Simulator (25)
79192	Replacement silicone tubing
45027	HFA Placebo Aerosol (8)

## 11. Disposal








The device must be taken to separate collection at the product end-of-life. Do not dispose of these products as unsorted municipal waste.

- Used inhaler simulators constitute minimally soiled waste from human healthcare.
- Inhaler simulators are made from recyclable material and should be disposed of in line with local requirements.



## 12. Explanation of Symbols

Symbol	Description
k	Type BF equipment
	Class II
VA	Power rating
	Direct current
	Instructions for Use; operating instructions
	Manufacturer
	Date of Manufacture (include date in format yyyy-mm-dd)

	The device must be taken to separate collection at the product end-of-life. Do not dispose of these products as unsorted municipal waste
	Fragile, handle with care
	Keep Dry
	Do not re-use
	Non-sterile
	Recycle
	QR code - matrix bar code. All information in the bar code is included in the text under it

### 13. Description of the Vitalograph AIM

The Vitalograph AIM™ (Aerosol Inhalation Monitor) is designed to enable a healthcare provider to objectively assess in detail how the test subject uses their inhaler. This detailed knowledge allows the medical professional to assess and coach the test subject in perfecting their inhalation technique. Mastery of the correct technique will support more accurate drug delivery and good subject compliance, resulting in better disease management and fewer visits to medical professionals.

## 14. Technical Specification

<b>Product</b>	Vitalograph AIM, Model 4500
<b>Flow Detection Principal</b>	Differential Pressure Sensor
<b>Flow Detection</b>	Flow sampling @ 20Hz
<b>Flow Impedance of Inhaler Simulator</b>	DPI: 0.49 cmH <sub>2</sub> O/L/min at 50 L/min MDI & Spacer: 0.016 cmH <sub>2</sub> O/L/min at 50 L/min
<b>Maximum Flow</b>	100 L/min
<b>Flow Accuracy</b>	Better than $\pm 5\%$ or 5L/min
<b>Power Supply</b>	4 x AAA 1.5V Batteries
<b>Operating Temperature Range</b>	Design limits: 10–40°C
<b>Safety standards</b>	EN ISO 60601
<b>QA/GMP standards</b>	EN ISO 13485, SOR/98-282 & FDA 21 CFR 820
<b>Dimensions</b>	165mm x 133mm (width) x 39.6mm
<b>Weight</b>	260g (including batteries and tubing)

## 15. CE Notice

The Vitalograph Model 4500 AIM is intended for use in a variety of professional healthcare environments, e.g. primary care, hospital wards and occupational health centres, except for near active high frequency surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high. The customer or the user of the Vitalograph AIM should assure that it is not used in such an environment.

The Model 4500 AIM has been tested in accordance with:

*EN60601-1: - Medical electrical equipment. General requirements for basic safety and essential performance*




*EN 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.*

<b>EN 60601-1-2 - Emissions tests</b>		
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
RF emissions CISPR 11	Group 1	The Model 4500 AIM uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Model 4500 AIM is suitable for use in all establishments, including domestic establishments and those connected to the public mains network (e.g. at home and doctor's offices in residential areas)
Harmonic emissions IEC 61000-3-2	Battery Operated	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Battery Operated	

<b>EN 60601-1-2 - Immunity tests</b>			
<b>Immunity test</b>	<b>Test level</b>	<b>Compliance level Reached</b>	<b>Electromagnetic environment - guidance</b>
Electrostatic discharge (ESD) EN 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air.	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1 kV for input/output lines	Battery Operated	
Surge IEC 61000-4-5	±1kV differential mode ±2 kV common mode		
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5 % 100V (>95% dip in 100V) for 0.5 cycle  40 % 100V (60% dip in 100V) for 5 cycles  70 % 100V (30 % dip in 100V) for 25 cycles  <5 % 100V (>95 % dip in 100V) for 5 sec		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not Applicable	Power frequency magnetic fields should be at levels characteristic of a typical location in typical commercial or hospital environment.

<p>Conducted RF. IEC 61000-4-6</p> <p>Radiated RF. IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz in ISM bands</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>Battery operated</p> <p>3V/m from 80MHz top 2.5GHz</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p><math>d = 1.2\sqrt{P}</math></p> <p><math>d = 1.2\sqrt{P} \dots 80\text{MHz to } 800\text{ MHz}</math></p> <p><math>d = 2.3\sqrt{P} \dots 800\text{ MHz to } 2.5\text{GHz}</math></p> <p>Where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following</p> 
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EN

Devices may be affected by mobile RF communications equipment including cellular telephones and other personal or household devices not intended for medical facilities. It is recommended that all equipment used near the Vitalograph product comply with the medical electromagnetic compatibility standard and to check before use that no interference is evident or possible. If interference is suspected or possible, switching off the offending device is the normal solution, as is required in aircraft and medical facilities. Electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided.

## 16. FDA Notice

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

## 17. EU Declaration of Conformity

Product: Model 4500 Vitalograph AIM

Vitalograph hereby ensures and declares that the above product associated with these instructions for use, is designed and manufactured in accordance with the following QMS regulations and standards:

- EU Directive 2001/95/EC General Product Safety Directive
- EU Directive 2014/30/EU EMC Directive
- EU Directive 2014/35/EU Low Voltage Directive

Signed on behalf of Vitalograph (Ireland) Ltd.



Frank Keane.  
CEO, Vitalograph Ltd.

## 18. Guarantee

Subject to the conditions listed below, Vitalograph Ltd. and its associated companies, (hereinafter called the Company) guarantee to repair or at its option replace any component thereof, which, in the opinion of the Company is faulty or below standard as a result of inferior workmanship or materials.

The conditions of this Guarantee are:

1. This Guarantee shall only apply to hardware defects which are notified to the Company or to its accredited distributor within 1 year of the date of purchase of the equipment, unless otherwise agreed in writing by the Company.
2. Software (meaning computer software, or user installable modules) is guaranteed for 90 days from the date of purchase.
3. The Company warrants that the software when correctly used in conjunction with the hardware will perform in the manner described in the Company's literature and user manuals. The Company undertakes to rectify at no expense to the customer any software failure notified within the period stated above, provided that the failure can be recreated and the software has been installed and used in accordance with the user manual. Notwithstanding this clause, the software is not warranted to be free of errors.
4. This Guarantee does not cover any faults caused by accident, misuse, neglect, tampering with the equipment, use of consumable items or parts not approved by the Company, or any attempt at adjustment or repair other than by personnel accredited by the Company, nor does it cover reinstatement of any configuration changes caused by the installation of any software.
5. If a defect occurs please contact the supplier from whom it was purchased for advice. The Company does not authorize any person to create for it any other obligation or liability in connection with Vitalograph® equipment.
6. This Guarantee is not transferable and no person, firm or company has any authority to vary the terms or conditions of

this guarantee.

7. To the maximum extent permitted by law, the Company does not accept liability for any consequential damages arising out of the use of, or inability to use any Vitalograph® equipment.
8. This Guarantee is offered as an additional benefit to the Consumer's statutory rights and does not affect these rights in any way.

