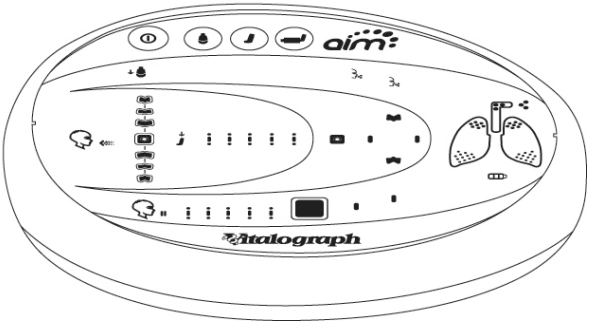
AIM (Aerosol Inhalation Monitor)

MODEL 4500



CE

Rx Only

Instructions for Use

EN

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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 AIM is intended to be operated by the subject, under the supervision of a healthcare provider.

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2. Contraindications, Warnings, Precautions and Adverse Reactions

2.1. Contraindications and Adverse Reactions

2.1.1. Contraindications

N/A

2.1.2. Adverse Reactions

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.

2.2. Warnings and Precautions

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. Maintenance must not be performed while the device is in use by a subject.
11. Only approved accessories from the manufacturer should be used with the device.
12. 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.
13. Batteries should be removed if the device is intended to be stored or left unused for an extended period of time
14. 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 AIM, including cables specified by Vitalograph. Otherwise, degradation of the performance of this equipment could result.
15. 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.
16. 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.

17. The USB cable supplied with the device has the potential to be a strangulation hazard and therefore should be kept out of the reach of children and pets.

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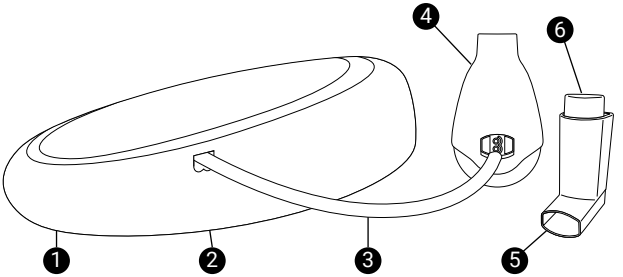
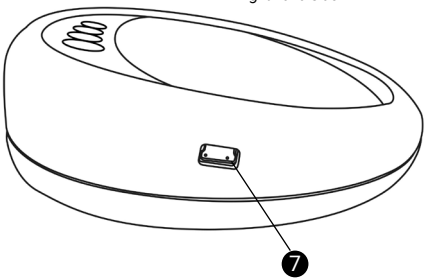
3. Main Components of the Vitalograph AIM

The main components are:



Right hand side



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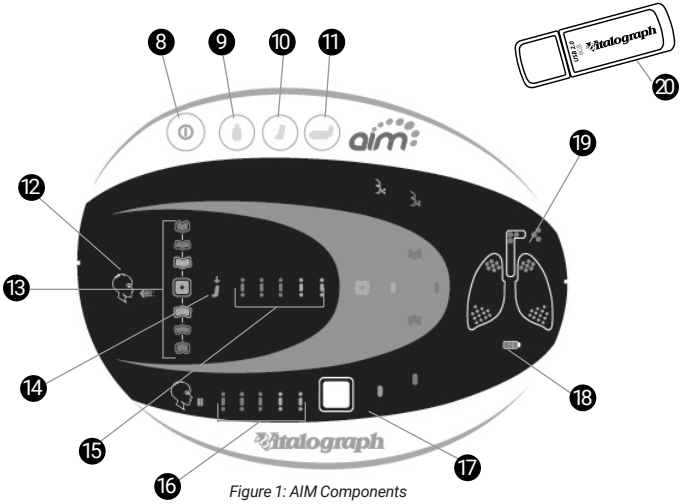

Figure 1: AIM Components

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	USB Port
8	Power button
9	DPI simulator button

10	MDI simulator button
11	MDI Spacer simulator button
12	Ready to inhale indicator
13	Flow lights
14	Canister activation (MDI)
15	Inhalation time lights
16	Breath-hold lights
17	End of breath-hold button
18	Battery low light
19	Inhaler technique summary display
20	USB key with Vitalograph Device Studio Software

3.1. Features of the Vitalograph AIM

The features include:

- 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
- Connects to Device Studio software to provide report on training effort
- 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. Attach the other end of the tubing to the required inhaler simulator.
4. If a printed report of training effort is required, the AIM device must be connected to Device Studio application before training begins.
    1. Use the USB cable supplied to connect the AIM device to a computer running Device Studio.
    2. Ensure that Device Studio application is open, and the device is switched on. The device will automatically connect to Device Studio.

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Additional guidance on using Device Studio can be found in the Instruction for Use PN 09550 supplied on the USB flash drive PN 93002 and in the software help menu of the application. A dialogue box as well as a 'Subject name' prompt allows the user to configure information displayed on the session report.

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, remove the white plastic protective cover from the top of the canister and 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 at the start of the test and to inhale until all 5 inhalation time lights light up.
   - 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 until all 5 are lit.

   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)
   Note: *If using Device Studio application to save/print test result, the test must be saved/printed straight after the test, before proceeding to next test.*
8. To repeat, press the appropriate inhaler simulator option button.

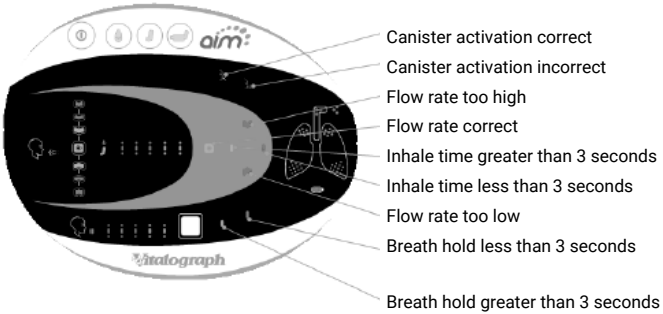

Figure 2 - Results Lights

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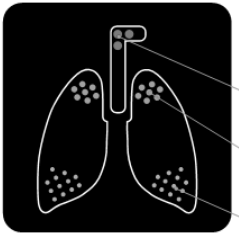
5.2. Results Summary



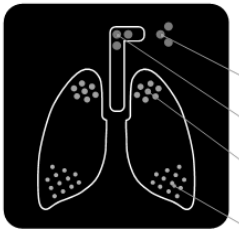
DPI Simulator
Technique Good/Poor Summary

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

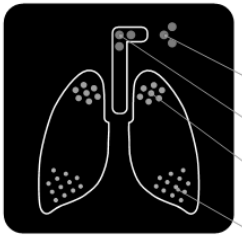
Fail (Red):
Canister activated too early or not at all

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

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5.3. Reporting

To print a summary report:

1. Connect the AIM device to a computer running Device Studio via the USB Cable provided.
2. Turn on the device. The device will automatically connect to device studio.
3. Set up the device to conduct a test as described in section 5.1. Before the test is performed, the user must select the 'Perform Test' button (figure 6).

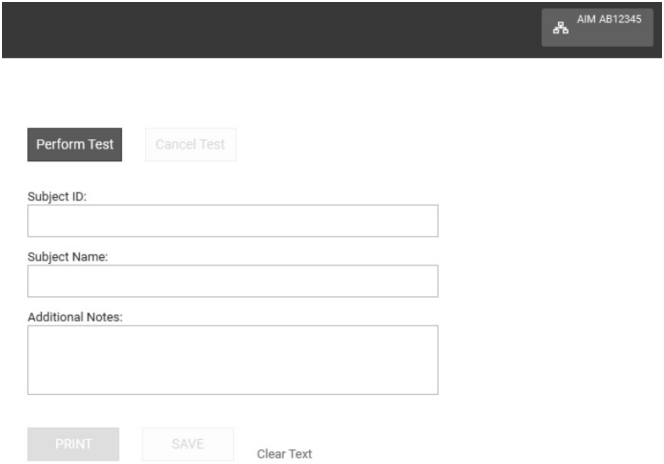

Figure 6: Device Studio initial screen when connected to AIM

4. The user may begin the test when the 8 circles (shown in figure 7) begins to rotate after the 'Perform Test' button is pressed.

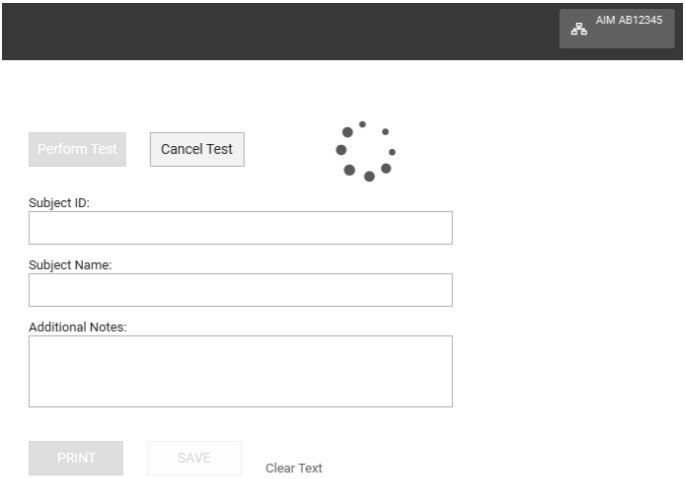

Figure 7: Test may begin once the 8 circles begin to rotate

5. When the test is performed and the Breath hold button is pressed, 'Report Ready' will be displayed. The user can now select 'Print' to print a summary report, or the user can select 'SAVE' to save a PDF of the summary report.

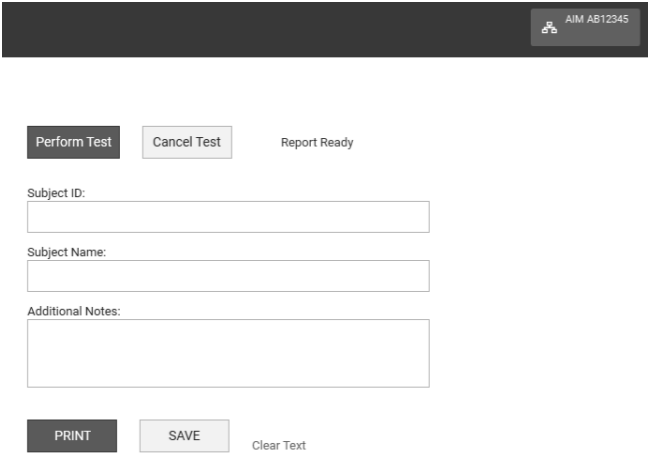

Figure 8: Device studio following Inhale test completed

Note: *Do not disconnect the device or USB cable from the computer during test.*

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.*

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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

Problem Fault Symptom:	• **The flow lights come on but nothing else**
Possible Solution:	• Press the DPI, MDI, or Spacer simulator button.
Problem Fault Symptom:	• **MDI simulator activation light not coming on.**
Possible Solutions: (In probable order)	• Press the placebo canister at the start of inhalation. • Check Placebo canister is fitted correctly. • Placebo canister may be empty and require replacement.
Problem Fault Symptom:	• **Difficulty achieving Good (Green) result with DPI simulator.**
Possible Solution:	• Ensure patient takes a forceful deep breath at the very start of the inhalation hitting the upper flow band.

Problem Fault Symptom:	• **Flow measurement appears low for the MDI simulator.**
Possible Solution:	• Placebo canister needs to be fitted as it is required for accurate results.
Problem Fault Symptom:	• **No flow measurements.**
Possible Solutions: (In probable order)	• Ensure the silicone tubing is not pinched or trapped. • Ensure the silicone tubing is fitted to AIM device and inhaler simulator.
Problem Fault Symptoms:	• **Test begins automatically.** • **Inhalation time accumulates automatically without the subject inhaling.**
Possible Solution:	• Simulator and/or tubing not stationary at the start of test. Hold both steady until 'Blow Icon' appears.
Problem Fault Symptoms:	• **Cannot read user interface.** • **Lights not coming on.**
Possible Solutions: (In probable order)	• The battery may be low. Replace batteries. • Electronics failure – contact support.
Problem Fault Symptoms:	• **AIM device is not connected on Device Studio Application**
Possible Solution:	• USB cable not connected properly to device or laptop

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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.
This IFU is available on the Vitalograph website at the following location: https://www.vitalograph.com/ifu/vitalograph_aerosol_inhalation_ monitor_ifu

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
	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)
	USB connector
	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.
CE	European Conformity marking
Rx Only	Restricted to sale by, or on the order of a physician.

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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

Product	Vitalograph AIM, Model 4500
Flow Detection Principal	Differential Pressure Sensor
Flow Detection	Flow sampling @ 20Hz
Flow Impedance of Inhaler Simulator	DPI: 0.49 cmH2O/L/min at 50 L/min MDI & Spacer: 0.016 cmH2O/L/min at 50 L/min
Maximum Flow	100 L/min
Flow Accuracy	Better than ±5% or 5L/min
Power Supply	4 x AAA 1.5V Batteries
Operating Temperature Range	Design limits: 10–40ºC
Safety standards	EN ISO 60601

Dimensions	165mm x 133mm (width) x 39.6mm
Weight	260g (including batteries and tubing)

15. Electromagnetic Compatibility (EMC) Standards

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.

EN 60601-1-2:2014 - Emissions tests		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
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	

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EN 60601-1-2:2014 - Immunity tests		
Immunity test	Test level	Compliance level Reached
Electrostatic discharge (ESD) EN 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1 kV for input/output lines	
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	Battery
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not Applicable
Conducted RF. IEC 61000-4-6 Radiated RF. IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz in ISM bands 3 V/m 80 MHz to 2.5 GHz	

Medical 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 EU directives:

- 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.

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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.