Vitalograph®

AIM

(Aerosol Inhalation Monitor)

Model 4500

User Training Manual

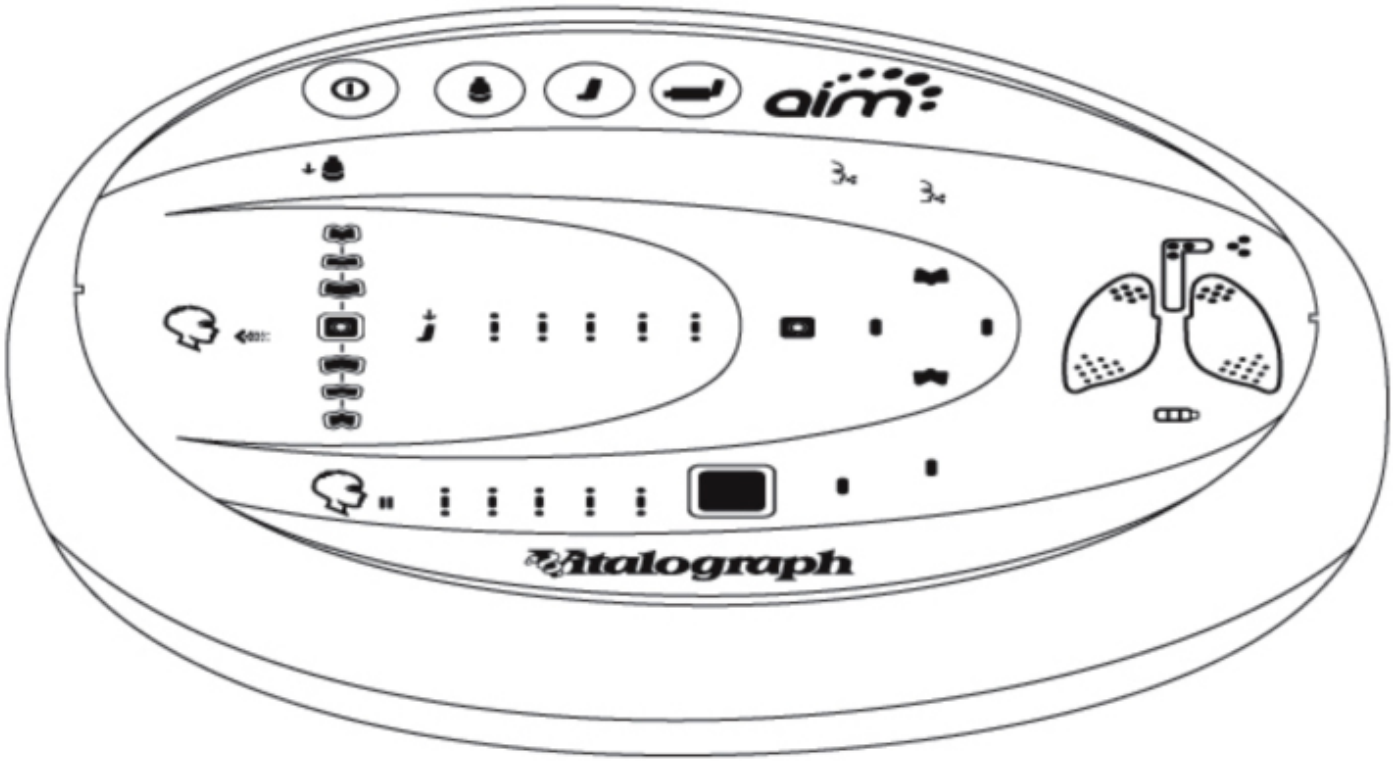

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Table of Contents

1. DESCRIPTION OF THE VITALOGRAPH AIM

The device (Aerosol Inhalation Monitor) is designed to enable a medical professional 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.

The main components for the Vitalograph AIM are shown in Figures 1 and 2.

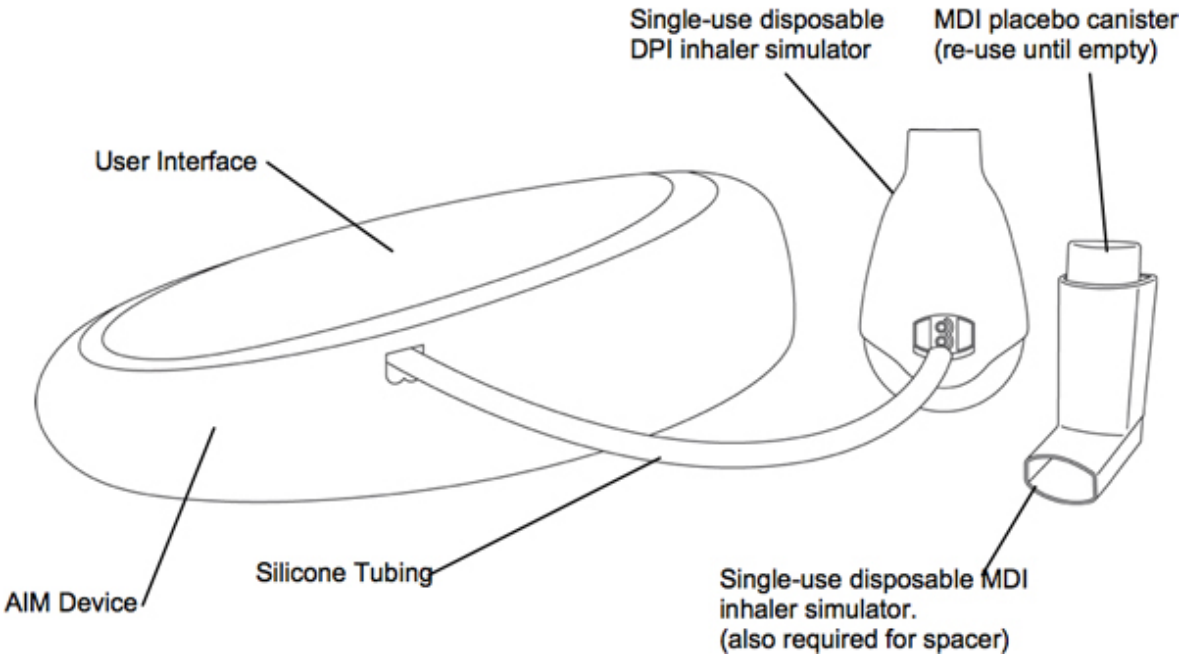

Figure 1: Components of the AIM

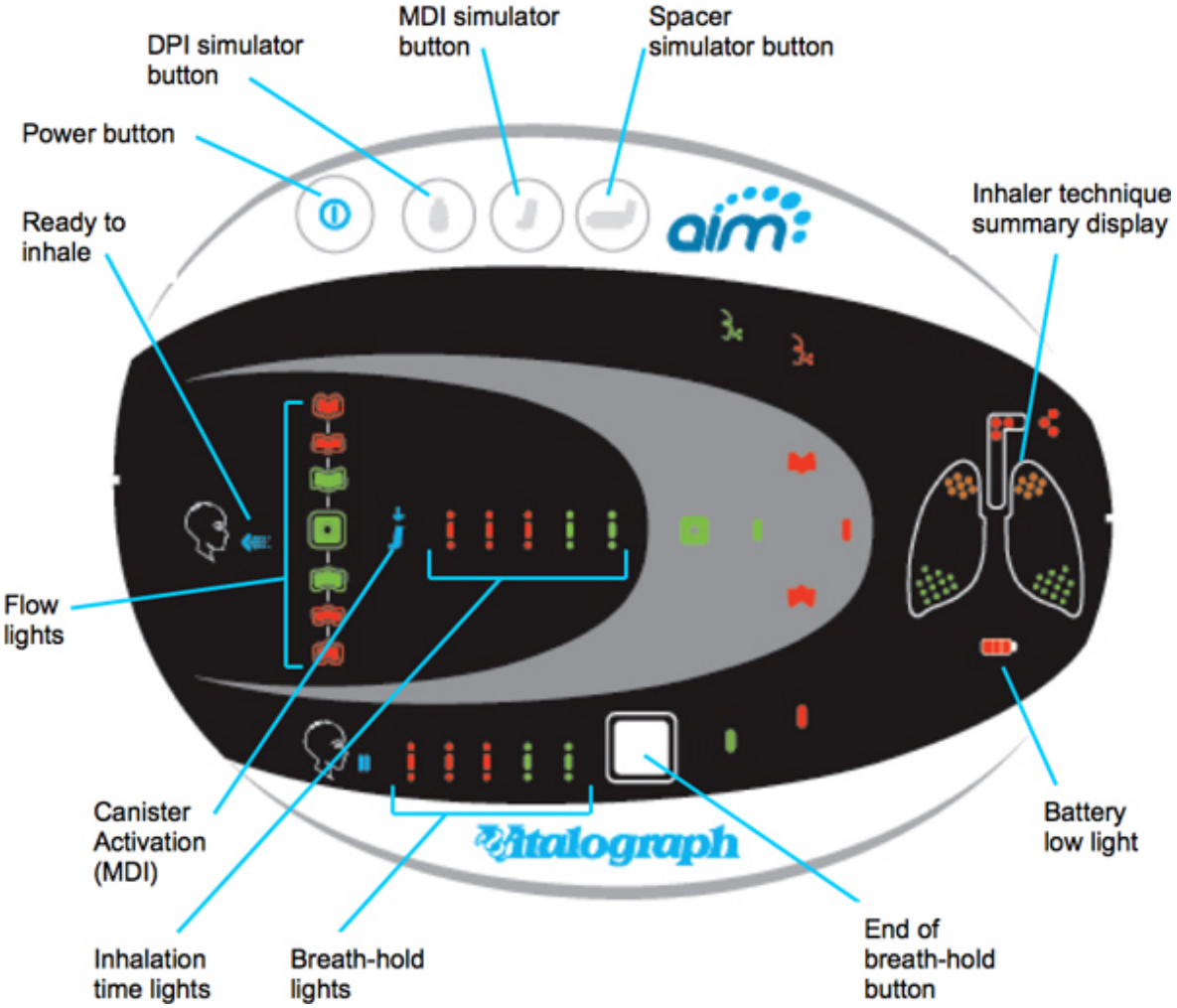

Figure 2: Components of the AIM – User Interface

2. FEATURES OF THE VITALOGRAPH AIM

The Vitalograph AIM features include:

- Assists in training patients to use their inhalers properly
- Inspiratory acceleration at the start of inspiration
- Timing of firing of MDI inhaler simulator
- Inspiratory flow rate throughout inspiration
- Inhalation time within target flow range
- Breath hold time at the end of inhalation
- Identifies and qualifies poor inhaler technique
- Easy to use and hygienic.
- Disposable MDI and DPI inhaler simulator mouthpieces
- Clear sounds for audio feedback
- Device guides the user through use

3. GETTING THE VITALOGRAPH AIM READY FOR USE

1. Remove the battery door from the rear of the unit. Fit four AAA 1.5V batteries, and replace the battery door.
2. Attach the dual silicone tubing (see Figure 1), to the port on the side of the AIM.

4. POWER MANAGEMENT IN THE VITALOGRAPH AIM

The AIM operates with 4 AAA 1.5V disposable batteries. If the battery light (See Figure 2) comes on the batteries need to be replaced. Replace the batteries by removing the battery door on the underside of the device.

Note: *Dispose of used batteries safely.*

5. OPERATING THE VITALOGRAPH AIM

1. Connect a new MDI or DPI inhaler simulator mouthpiece to the device via the silicone tubing.

   Note: *The inhaler simulators are single patient use.*
2. If an MDI inhaler simulator mouthpiece is being used insert the placebo.

   Note: *If a placebo is not fitted then flow measurements will not be correct.*
3. Press the power button and select the inhaler simulator option
   - DPI simulator
   - MDI simulator
   - Spacer simulator
4. Instruct the test subject to breath fully out, but not through the inhaler simulator.
5. Instruct the subject to position the inhaler simulator between the lips sealed around the mouthpiece.

   Note: *Ensure that the holes adjacent to the tubing connection to the inhaler simulator are not obstructed.*
6. Depending on the inhaler simulator option selected the following instructions should be followed:
   a. DPI Simulator
      i. Instruct the subject to take a forceful deep breath in until their lungs are full. The flow lights will light up.
      ii. The aim is to get the flow indicator into the green zone as quickly as possible, but not to inhale too fast.
      iii. The subject should continue to inhale until their lungs are full. The inhalation time lights will light up one second at a time.
      iv. The subject should hold their breath for as long as comfortable (at least 3 seconds). The breath hold lights will light up one second at a time.
      v. When the subject ceases breath hold, press the end of breath-hold button.
   b. MDI Simulator
      i. Instruct the subject to take a slow deep breath and simultaneously press the placebo canister. The flow lights and the canister activation lights will light up.
      ii. The aim 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.

iii. The subject should continue to inhale until their lungs are full (at least 3 seconds). The inhalation time lights will light up one second at a time.

iv. The subject should hold their breath for as long as comfortable (at least 3 seconds). The breath hold lights will light up one second at a time.

v. When the subject ceases breath hold, press the end of breath-hold button.

c. Spacer Simulator

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

i. Instruct the subject to press the canister just before or as inhalation starts. The canister activation lights will light up.

ii. The Spacer Simulator allows the subject to take a single or multiple breaths.

iii. The subject should continue until at least 3 seconds inhalation is achieved. The inhalation time lights will light up one second at a time.

iv. The subject should hold their breath for as long as comfortable (at least 3 seconds). The breath hold lights will light up one second at a time.

v. When the subject ceases breath hold, press the end of breath-hold button.

7. The individual results lights (see Figure 3) and TechniqueGood/Poor summary (see Figure 4 - 6) will then appear.
8. To repeat, press the appropriate inhaler simulator option button.

Note: *The operating instructions and results shown are for the generic AIM device. Some variants will have different operating instructions and results. Please refer to the individual Quick Start Guide for these variants.*

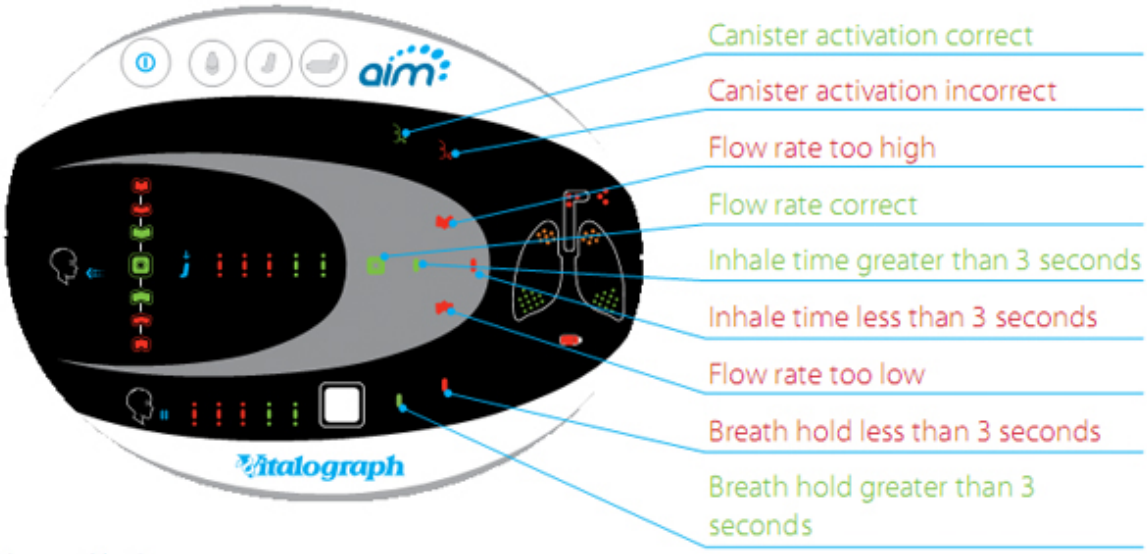

Figure 3: Results lights

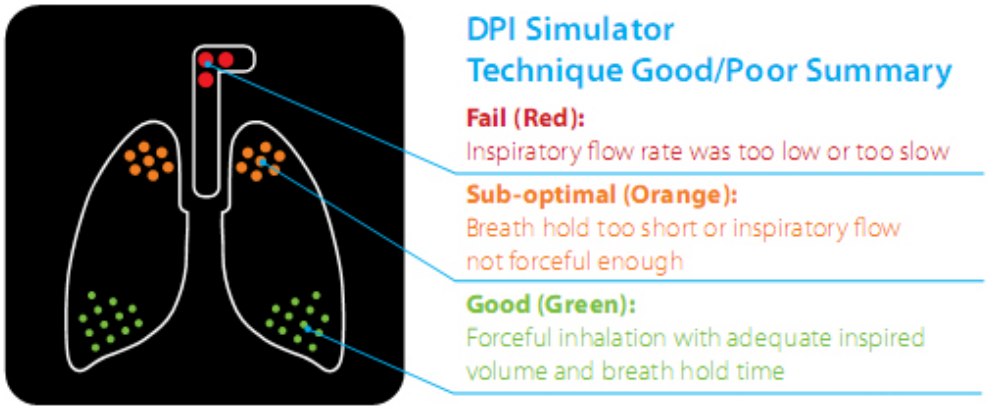

Figure 4: DPI Simulator Technique Summary

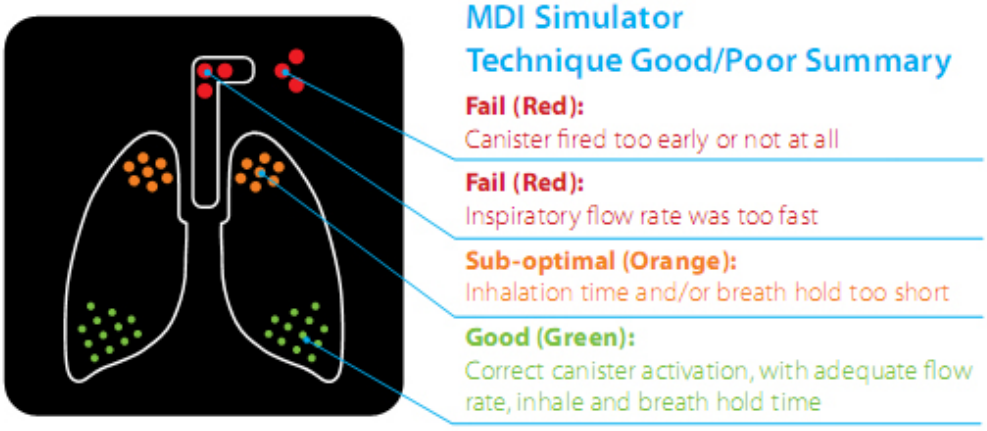

Figure 5: MDI Simulator Technique Summary

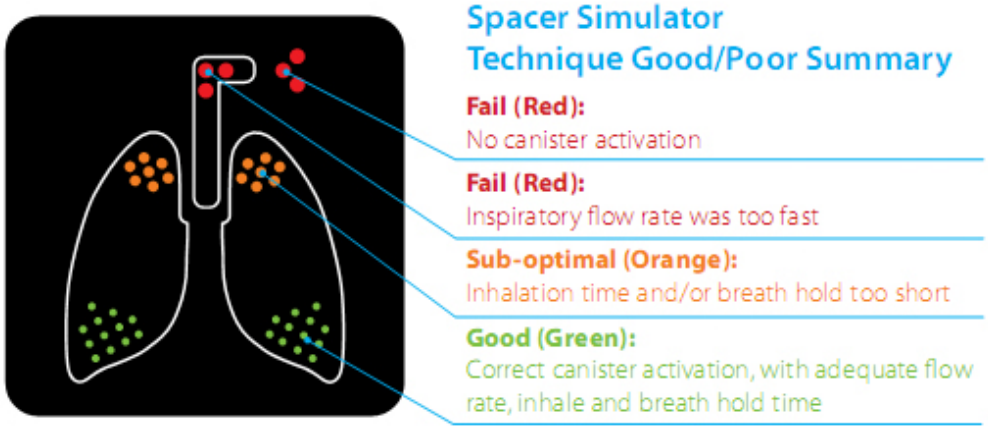

Figure 6: Spacer Simulator Technique Summary

6. CLEANING INSTRUCTIONS

6.1 Cleaning and Disinfecting the Vitalograph AIM

A new disposable inhaler simulator should be used for each subject. The frequency of cleaning and disinfecting is dependent on the Facility's Risk Assessment, usage, and test environment.

Table of Materials Used & Cleaning/Disinfection Methods

This listing of materials used is given to provide users with information to allow the assessment of other cleaning and disinfecting procedures available in the facility on this device.

Part	Material	Clean/ Disinfect	Autoclave	Recommended Disinfectants
Top Case Exterior	ABS	Clean	No	Wiping with a 70% isopropyl alcohol impregnated cloth provides a suitable form of cleaning and low-level disinfection. This may be preceded by cleaning with an anti-static foam cleaner if necessary.
Bottom Case Exterior	AMS	Clean	No	
Overlay label	PET Film	Clean	No	
White Silicone Tubing	Silicone	Clean	Viable	

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

All external parts of the Vitalograph AIM require cleaning, i.e. the removal of visible particulate contamination. The AIM is not designed as a 'sterile' device.

Definitions of cleaning and disinfection are as defined in "Sterilization, Disinfection and Cleaning of Medical Equipment: Guidance on Decontamination from the Microbiology Committee to Department of Health Medical Devices Directorate, 1996".

Recommendations for chemical disinfectants are derived from the PHLS publication "Chemical Disinfection In Hospitals 1993".

7. FAULT FINDING GUIDE

Problem Fault Symptoms:	• Test begins automatically • Inhalation time accumulates automatically without the subject inhaling
Possible Causes: (In probable order)	• Flowhead and/or tubing not stationary at the start of test. Hold them steady until the 'Blow Icon' appears • Press the DPI, MDI or Spacer simulator button
Problem Fault Symptoms:	• Rocking device
Possible Causes: (In probable order)	• Check for damaged or missing rubber feet • If any of the rubber feet are damaged or missing replace all rubber feet
Problem Fault Symptoms:	• No flow measurements
Possible Causes: (In probable order)	• Ensure that the silicone tubing is not pinched or trapped

	• Ensure that the silicone tubing is fitted to the AIM device and the inhaler simulator
Problem Fault Symptoms:	• Cannot read user interface • Lights not coming on
Possible Causes: (In probable order)	• The battery may be low. Replace the batteries • Main PCB failure – contact support
Problem Fault Symptoms:	• MDI simulator activation light not coming on
Possible Causes: (In probable order)	• Placebo canister is not fitted • Placebo canister is empty
Problem Fault Symptoms:	• Flow measurement appears low for the MDI simulator
Possible Causes: (In probable order)	• Placebo canister needs to be fitted. If a placebo is not fitted then flow measurements will not be correct

8. CUSTOMER SERVICE

Service and repairs should be carried out only by the manufacturer, the approved importer or by Service Agents specifically approved by Vitalograph.

For the names and addresses of approved Vitalograph Service Agents or to arrange spirometry workshops, please refer to the contact information at the start of this manual.

9. 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)

10. EXPLANATION OF SYMBOLS

Internally powered ME equipment


Type BF equipment

V ⎓ Voltage DC


Attention (reference relevant section in manual)


Manufacturer


Year of Manufacture


Attention(reference relevant section in manual)


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

11. TECHNICAL SPECIFICATIONS

Product	Vitalograph AIM
Model	4500
Flow detection principle	Differential pressure sensor
Flow impedance of inhaler simulator mouthpiece	DPI: 0.49 cmH2O/L/min at 50 L/min MDI & Spacer: 0.016 cmH2O/L/min at 50 L/min
Flow detection	Flow sampling @ 20Hz
Maximum flow	100 L/min
Flow accuracy when operated in operating temperature range conditions	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 60601:2006 {IEC 60601 -1:2005}
QA/GMP standards	EN ISO 13485:2003, CMDR SOR/98-282 & FDA 21 CFR 820
Size	165 mm x 133 mm x 39.6 mm
Weight	260g (including batteries and tubing)
Storage Temperature	0–50ºC
Storage Relative Humidity	10%–95%

12. CE NOTICE

Marking by the symbol CE indicates compliance of the Vitalograph AIM to the Medical Devices Directive of the European Community. Such marking is indicative that the Vitalograph AIM meets or exceeds the following technical standards:

Guidance and manufacturer's declaration – electromagnetic emissions		
The Model 4500 AIM is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 4500 AIM should assure that it is used in such an environment.		
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 directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Battery Operated	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Battery Operated	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Model 4500 AIM is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 4500 AIM should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 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	Battery Operated	
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 Operated	
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.

Guidance and manufacturer's declaration – electromagnetic immunity

The Model 4500 AIM is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 4500 AIM should assure that it is used in such an environment.

Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
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	Battery operated 3V/m from 80MHz top 2.5GHz	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. **Recommended separation distance** $d = 1.2\sqrt{P}$

			d = 1.2√P…80MHz to 800 MHz d = 2.3√P…800 MHz to 2.5GHz 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 symbol: 

Recommended separation distances between portable and mobile RF communication equipment and the Model 4500 AIM

The Model 4500 AIM is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model 4500 AIM can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model 4500 AIM as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	**Separation Distance According to Frequency of Transmitter M**		
	150 kHz to 80 MHz d = 1.2 √ P	**80 MHz to 800 MHz d = 1.2 √ P**	**800 MHz to 2,5 GHz d = 2.3 √ P**
0,01	0.1m	0.1m	0.12m
0,1	0.4m	0.4m	0.7m
1	1.2m	1.2m	2.3m
10	3.7m	3.7m	7.4m

Recommended separation distances between portable and mobile RF communication equipment and the Model 4500 AIM			
100	11.7m	11.7m	23.3m

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Medical Devices may be affected by 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.

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided.

Portable and mobile RF communications equipment can affect medical electrical equipment.

13. FDA NOTICE

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

14. DECLARATION OF CONFORMITY

Product: Vitalograph Model 4500 AIM

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, as amended.

  This device is classified as 1 with a measuring function per Annex IX of the MDD also meets the provisions of the Essential Requirements, Annex I, via compliance with Annex II of the Medical Devices Directive as per Article 11, section 3a, excluding point 4 of Annex II.

CE 0086

- Canadian Medical Device Regulation {CMDR SOR/98-282}
- 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}

BSI Notified Body #: 0086

Certificate Nos. CE 00772, MD 82182, FM 83550

Signed on behalf of Vitalograph (Ireland) Ltd.

B. R. Garbe.

Group Managing Director

15. GUARANTEE

Terms of 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.