Vitalograph
asma-1™

MODEL 4000

User Manual

CE
0086

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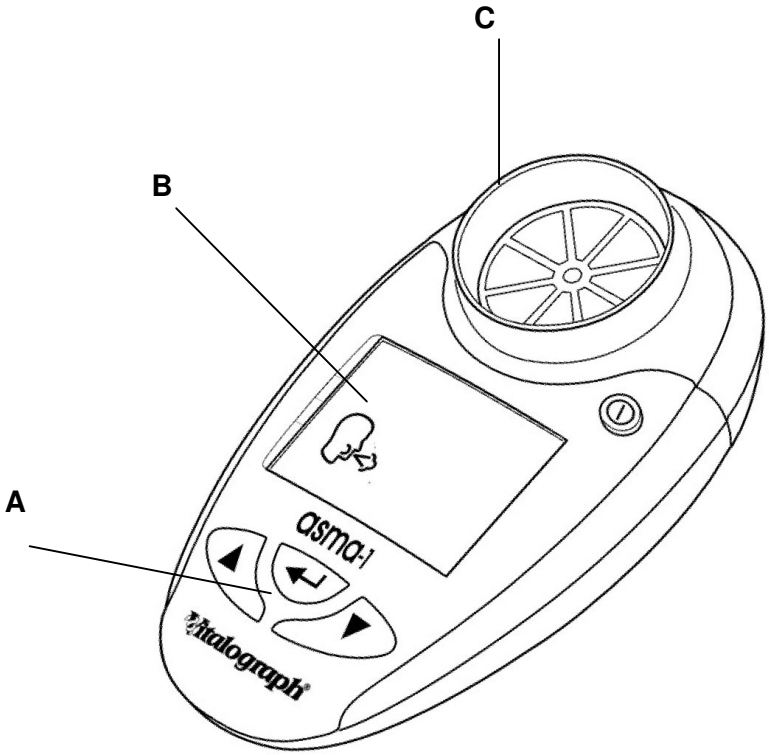


Figure 1: Identification of parts (See Table 1 for description of parts)

DESCRIPTION OF THE VITALOGRAPH ASMA-1

The Vitalograph asma-1 is a medical device intended to give objective measures of lung function for help in managing asthma. The device measures airflow out of the lungs when blown into as hard and fast as possible. The Vitalograph asma-1 can reveal narrowing of the airways well in advance of an asthma attack being felt by the asthmatic. Used mainly by persons with moderate to severe and persistent asthma, the Vitalograph asma-1 can help determine:

- when to seek emergency medical care.
- the effectiveness of a person's asthma management and treatment plan.
- when to stop or add medication, as directed by the physician.
- what triggers the asthma attack (such as exercise-induced asthma).

With asthma, sometimes the sufferer may feel their breathing is fine, but when the sufferer measures it with the Vitalograph asma-1, lung function may be decreased. The Vitalograph asma-1 can help the sufferer determine airway changes and better manage the asthma.

The primary healthcare professional needs to educate the sufferer in Self-Management of asthma. This will start upon diagnosis and continue with all members of the healthcare team. The Action Plan should be tailored to individual needs, but will include: basic facts about asthma; roles of medication; skills required for devices and medication, environmental control measures; when and how to take rescue actions.

The Asthma Sufferer

Most people with asthma need to monitor their asthma at least twice a day and to have a plan of action to keep it under control. Although how the sufferer feels and what the sufferer can do is important, PEF or FEV1 scores may accurately show how the breathing is changing. Modern asthma medicines aim to give the sufferer the best possible score, keeping the sufferer in the green zone. It is also important to aim for stable PEF/FEV1, i.e. little difference between morning and evening scores and from day to day.

Many people over the ages of five will benefit from monitoring their asthma with the Vitalograph asma-1, indicating when and how much to use their reliever medication. It will also help the doctor because scores make it easier to see how well the asthma is controlled and when treatment needs changing.

Only the doctor can determine the best Action Plan for the sufferer. This is likely to be preceded by an initial assessment followed by a diagnostic phase. The Vitalograph asma-1 records many test sessions for subsequent review by the healthcare professional. The Action Plan is then assessed against the scores over several days. The treatment and/or Action Plan may be changed following the diagnostic phase. This procedure may be repeated until the optimum Action Plan is proven.

The 'Personal Best' is the best PEF or FEV1 value that the sufferer can achieve - this is the '100%' or 'reference' value. Population normative standards are not clinically useful in ongoing serial monitoring of the asthma.

MAIN COMPONENTS OF THE VITALOGRAPH ASMA-1

Refer to Figure 1 for identification of parts for the VitaloJAK device.

A	Keypad
B	LCD
C	Flowhead
⏻	On/Off button.
▼	Down button
▲	Up button
↵	Enter button

Table 1: Identification of parts for the asma-1 device

FEATURES OF THE VITALOGRAPH ASMA-1

The Vitalograph asma-1 features include:

- Electronic record – no need for record cards
- Stores 600 test sessions
- Automatically assesses test quality
- High accuracy

- Measures PEF and FEV1 and % of personal best
- PEF and FEV1 zones can be personalized
- Automatically stores best values
- Easy to clean mouthpiece and flowhead.

GETTING THE VITALOGRAPH ASMA-1 READY FOR USE

1. Remove the battery door from the rear of the unit. Fit two AAA 1.5V batteries, and replace the battery door.
2. Insert the mouthpiece and turn on the device.

POWER MANAGEMENT IN THE VITALOGRAPH ASMA-1

The asma-1 operates with 2 AAA 1.5V disposable batteries. If the battery symbol flashes 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.

OPERATING THE VITALOGRAPH *ASMA-1*

Setting Personal Best (Reference) Values

Personal Best (reference) values can be set for peak flow (PEF) and/or forced expiratory volume after 1 second (FEV1).

To set the Personal Best (reference) PEF, follow these steps:

1. Turn the device on, ⏻.
2. When the device is ready for a test (), press the ▼ and ▲ buttons together for 3 seconds.
3. The reference PEF value can now be set. This is done by pressing the ▲ button and releasing when the value is reached. Press the ▼ to roll back.
   The values will increase/decrease in values of 10. If the button is kept depressed, the values will scroll faster.
4. Press ENTER ↵ to keep this reference PEF value.

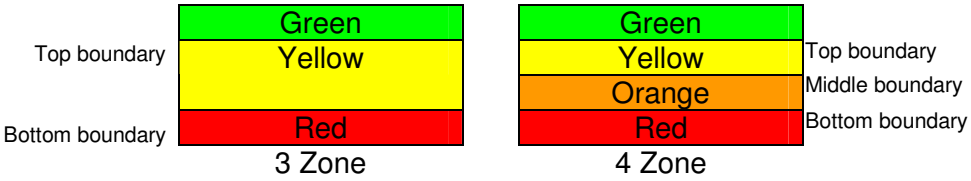
Press ↵ again to exit, or to set the Best Test (reference) FEV1:

1. The reference FEV1 value is set by pressing the ▲ button and releasing when the value is reached. Press the ▼ to roll back. The values will increase/decrease in values of 0.10. If the button is kept depressed, the values will scroll faster.
2. Press ENTER ↵ to keep this reference FEV1 value. The device will return to the test screen.

Note: to de-activate zones, set both the PEF and FEV1 reference values to 000/0.00.

Setting Management Zones

The Vitalograph asma-1 can be set for use with 3 or 4 zone management plans. The zone percentages are factory set to 2 boundaries, 80% & 50%, i.e. 3 Zones (80-100%, 50-80%, 0-50%). For 4 zones the middle boundary is set last. The colour systems for each zone type are as follows;



To set the boundary percentage values for 3 zones, follow these steps;

1. Turn the device on, ⏻.
2. When the device is ready for a test (), press the ▲ and ↵ buttons together for approximately 3 seconds.
3. The top (Green/Yellow) boundary can now be set. This is done by pressing the ▲ or ▼ button and releasing when the value is reached.
   The values will increase/decrease in values of 1%. If the button is kept depressed, the values will scroll faster.
4. Press ENTER ↵ to set the top (Green/Yellow) boundary value.
5. The bottom (Yellow/Red) boundary can now be set. This is done by pressing the ▲ or ▼ button and releasing when the value is

reached.
Press ↵ to set the bottom(Yellow/Red) boundary value.

6. Only 2 boundaries are required for the 3 zone system, so the next value should be selected as 0% (default). Press ↵. The device will return to the test screen.

To set the boundary percentage values for 4 zones, follow these steps;

1. First, set the top and bottom boundaries – see above procedure (steps 1 - 6).
2. The middle (Yellow/Orange) boundary can now be set. This is done by pressing the ▲ button and releasing when the middle boundary value is reached.
   The values will increase/decrease in values of 1% after an initial jump to the lower boundary value. If the button is kept depressed, the values will scroll faster. This boundary value cannot be set at a value that is greater than the top boundary value or less than the bottom boundary value.
3. Press ↵ to set the middle (Yellow/Orange) boundary value. The device will return to the test screen.

How to Use the Vitalograph asma-1

1. Sit down when blowing into the device (unless the physician advises otherwise).
2. Turn the device on, ⏻ with the mouthpiece inserted. (Use a disposable SafeTway mouthpiece in clinic.)
3. When the device is ready for a test (), holding the head high, breathe in as deeply as possible, hold the Vitalograph asma-1 ready in front of the mouth.
4. Holding the breath, place the mouthpiece into the mouth, biting the mouthpiece lightly, and with the lips firmly sealed around it.
5. Blow out as HARD and as FAST as possible for a second or more. Be careful not to block the mouthpiece with the tongue or teeth. A ‘spitting’ action will give false readings.

6. The PEF result for this blow will be displayed, followed by the FEV1 result after approximately 3 seconds and an arrow will indicate which colour management zone this relates to, if the Personal Best has been set.
7. With the blow icon showing, blow again ( ). Usually 3 blows are required.
8. To view the best test in the session (best PEF and best FEV1), press the ↵ button. This is the value that is recorded for the session in the device history.

Note: if an exclamation mark **!** appears, this means it was not a good quality blow and the subject should blow again. **!** appears when: The time to Peak Flow >120ms or a cough is detected in the 1st second.

If the subject experiences dizziness or fatigue during the test session, wait until this passes before blowing again or terminate the session.

Reviewing Previous Results

The Vitalograph asma-1 can store up to 600 test sessions. In order to view previously performed test sessions, follow these steps:

1. Turn the device on, ⏻.
2. When the device is ready for a test ( ), press the ↵ button for approximately 3 seconds.
3. The most recent test session will now be displayed. The best PEF result will be displayed for approximately 3 seconds, followed by the best FEV1 result. The session number '1' is also displayed, this is the latest session.
4. Earlier test sessions can also be viewed. Pressing the ▲ button once will show '2' the previous test, and so on.
5. Press ↵. The device will return to the test screen.

Deleting All Results History

Caution: Once the history has been deleted it cannot be recovered.

To delete the history entirely, i.e. all previously stored session results, follow these steps:

1. Turn the device on, ⏻.
2. When the device is ready for a test (), press the ▼ and ↵ buttons simultaneously for approximately 10 seconds.
3. A long beep will indicate success and the device will return to the test screen.

CLEANING INSTRUCTIONS

Home use cleaning and disinfection of the Vitalograph asma-1

The Vitalograph asma-1 should continue to give reliable measurements for up to three years in home use. Then replace it with a new device.
Keep it clean and dust free. If you suspect the device is damaged or is measuring incorrectly, contact the doctor immediately.
The mouthpiece is the only part of the device, which needs to be routinely cleaned in home use.
The outer surfaces should be thoroughly cleaned every week, more often if necessary. We recommend the use of an ordinary alcohol wipe, paying special attention to the mouthpiece area.

Part	Material	Cleaning Recommendation	Disinfection Recommendation
Plastic Mouthpiece	ABS	Wash in warm soapy water. Rinse in clean water	Alcohol wipe (IPA 70-90%)
Body	ABS	Wipe with a damp cloth	Alcohol wipe (IPA 70-90%)
Fascia	PMMA/ PET	Wipe with a damp cloth	Alcohol wipe (IPA 70-90%)
Buttons	Synthetic Rubber	Wipe with a damp cloth	Alcohol wipe (IPA 70-90%)

Cleaning and Disinfecting the Vitalograph asma-1 In Clinic Use

A new mouthpiece (either *SafeTway* or *BVF*) should be used for each subject. A delay of at least 5 minutes should be allowed between subjects to allow settling of previously aerosolized particles in the measuring device.

It is recommended that the device be regularly cleaned according to the guidelines of the user's facility. The disinfection materials and procedures applied in the users' facility may be more appropriate than the methods outlined below.

In the event of visible contamination of the flowhead element, it should be cleaned or disinfected as described in the accompanying table. The device should be replaced in the event of damage, or if visibly contaminated.

The frequency of cleaning and disinfecting is dependent on the facility's risk assessment, usage, and test environment, but it should be at least monthly or every 100 subjects (300 blows).

It is recommended that the device be replaced annually or test and calibration serviced at least annually. There is no planned preventive maintenance for this medical device.

Table of Materials Used & Cleaning/Disinfection Methods

This listing of materials used is given to provide clinical 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 Possible?	Recommended Disinfectants
SafeTway mouthpiece or BVF	Cardboard/ ABS	Dispose – single use	No	Dispose – single use
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.
Fascia	PMMA/ PET	Clean	No	

Removable flowhead	ABS, Stainless Steel	Clean	No	Disinfect by immersion in sodium dichloroisocyanurate solution at 1000 ppm concentration of free chlorine for 15 minutes (see following section for recommended cleaning/disinfection method for the Vitalograph COMPACT Flowhead) The flowhead may also be disinfected by autoclaving at 134°C for 3 minutes or 120°C for 20 minutes.

All external parts of the Vitalograph asma-1 require **cleaning,** i.e. the removal of visible particulate contamination. The parts of the device that make up the flowhead, which comes into contact with the breath of the subjects being tested, also require **disinfecting**. This device is not designated 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.

Removing the Flowhead for Cleaning and Disinfecting

1. Remove the flowhead from the body with a sharp pulling motion.
2. Clean the flowhead by washing in a mild detergent to remove particulate contamination, taking care not to touch the moving vanes. Swill vigorously in water with mild detergent. Do not attempt to "rub" or "scrub" in the area of the vanes. Rinse with clean water.
3. Disinfect by immersion in sodium dichloroisocyanurate solution at 1000 ppm concentration of free chlorine for 15 minutes. Prepare disinfectant solution as directed in the manufacturer's guidelines. Rinse with warm water for faster drying.
4. Leave it to dry completely before reassembling. Drying the flowhead may require placing it in a warm place overnight. A drying cabinet is ideal.

Wiping with a 70% Isopropyl Alcohol impregnated cloth provides a suitable form of cleaning and low-level disinfection for the case exterior, display, screen surround and keys. Repeat this at least weekly to prevent a build-up of grime from normal handling and use.
Always follow the safety guidelines given by the manufacturer of cleaning and disinfectant chemicals or equipment.
Reassemble the flowhead by pushing back on until it 'clicks' into position. Ensure that the flowhead is pushed fully home.

When the flowhead is reassembled, it is good practice with any respiratory measuring device for an accuracy check be performed using a Precision Syringe, with the volume delivered in less than one second. An accuracy of +/- 3% should be achieved.

FAULT FINDING GUIDE

Problem Fault Symptoms:	•No flow measurements.
Possible Causes: (In probable order)	•The battery may be low. Replace the batteries. •The flowhead may be damaged. Check that the rotating vane is spinning freely.
Problem Fault Symptoms:	• Cannot read user interface.
Possible Causes: (In probable order)	•The battery may be low. Replace the batteries.

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.

CONSUMABLES AND ACCESSORIES

Cat. No	Description
40168	Mouthpiece (20)
20242	SafeTway Mouthpieces (200)
20303	Disposable Noseclips (200)
20980	Mini SafeTway® mouthpieces (50)
20991	Long SafeTway® mouthpieces (130)
28350	BVF® Bacterial/Viral Filters (50)
40167	Pouch Spare (x10)

EXPLANATION OF SYMBOLS

Type BF equipment

Class II

Voltage DC

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.

User Interface Symbols;

Battery status
Battery status Full
Battery status Half
Battery status Quarter
Battery status Empty (flashing)

Blow Now Symbol

Bad Test Symbol (Slow start or Cough)

TECHNICAL SPECIFICATIONS

Product	Respiratory Monitor asma-1
Model	4000
Flow detection principle	Stator/rotor
Back pressure	Better than 0.15kPa/L/s at 14L/s
Measurement Range:	PEF: 25 – 840 L/min BTPS FEV1: 0 – 9.99 L BTPS
Maximum test duration	1 second
Accuracy when operated in operating temperature range conditions	Better than ± 3% (FEV1), ± 10% (PEF)
Power Supply	2 AAA batteries
Operating temperature range	17 – 37°C
Performance standards the Vitalograph asma-1 meets or exceeds	EN ISO 23747:2007 ATS/ERS Guidelines 2005
Electromagnetic immunity:	IEC 61000-4-2, IEC 61000-4-3 (battery operated)
Storage Temperature	0–50ºC
Storage Relative Humidity	10%–95%
Auto power down time	2 minutes

Note:

- *All values displayed by the Vitalograph asma-1 are expressed as BTPS values.*
- *Take care not to block the mouthpiece with the tongue or teeth. A 'spitting' action or coughing will give false readings.*

CE NOTICE

Marking by the symbol CE 0086 indicates compliance of the Vitalograph 4000 Respiratory Monitor asma-1 device to the Medical Devices Directive of the European Community. Such marking is indicative that the Vitalograph 4000 Respiratory Monitor asma-1 device meets or exceeds the following technical standards:

Guidance and manufacturer's declaration – electromagnetic emissions		
The 4000 Respiratory Monitor asma-1 is intended for use in the electromagnetic environment specified below. The customer or the user of 4000 Respiratory Monitor asma-1 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The 4000 Respiratory Monitor asma-1 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	Battery Operated	The 4000 Respiratory Monitor asma-1 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 4000 Respiratory Monitor asma-1 is intended for use in the electromagnetic environment specified below. The customer or the user of the 4000 Respiratory Monitor asma-1 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	±2 kV for power supply lines ±1 kV for input/ output lines	Battery operated	
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	Battery operated device	
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*) for25 cycles <5% *100V* (>95% dip in *100V*) for 5 sec	Battery operated Battery operated Battery operated Battery operated	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The 4000 Respiratory Monitor asma-1 is intended for use in the electromagnetic environment specified below. The customer or the user of the 4000 Respiratory Monitor asma-1 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the 4000 Respiratory Monitor asma-1 including cables, than the recommended separation distance calculated form the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	10 Vrms 150kHz to 80 MHz in ISM bands	Battery operated	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3V/m from 80MHz to 2.5 GHz	$d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz 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 4000 Respiratory Monitor asma-1

The 4000 Respiratory Monitor asma-1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 4000 Respiratory Monitor asma-1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 4000 Respiratory Monitor asma-1 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 **$d = 1.2\sqrt{P}$**	**80 MHz to 800 MHz** **$d = 1.2\sqrt{P}$**	**800 MHz to 2.5GHz** **$d = 2.3\sqrt{P}$**
0.01	0.1m	0.1m	0.2m
0.1	0.4m	0.4m	0.7m
1	1.2m	1.2m	2.3m
10	3.7m	3.7m	7.4m
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.

FDA NOTICE

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

Declaration of Conformity

Product: **4000 Respiratory Monitor asma-1**

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 2a 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: British Standards Institute {BSI}.
{For 93/42/EEC and CMDR}.

BSI Notified Body #: 0086

Certificate Nos. CE 00772, CE 85553, MD 82182, FM 83550

Signed on behalf of Vitalograph (Ireland) Ltd.

B. R. Garbe.
Group Managing Director

GUARANTEE

Subject to the conditions listed below, Vitalograph Ltd. and its associated companies, (hereinafter called the Company) guarantee to repair or at its opinion 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 authorise 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.

This Guarantee is offered as an additional benefit to the Consumer's statutory rights and does not affect these rights in any way.

