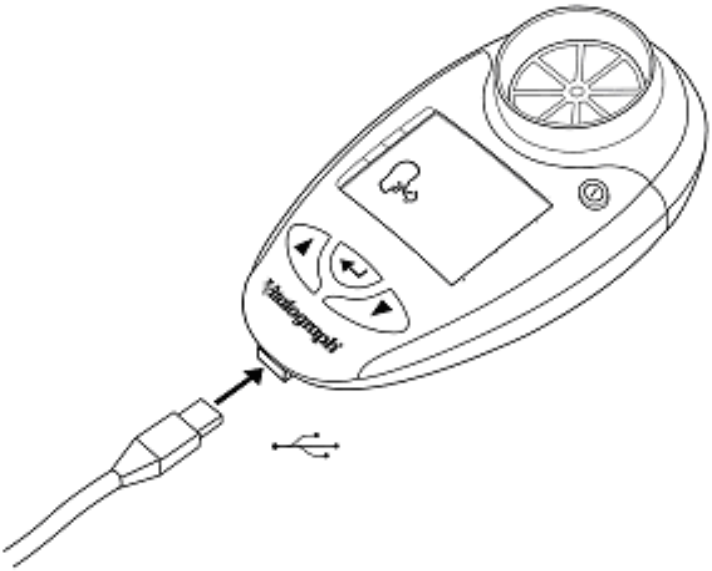
Vitalograph®

4000 Respiratory Monitor

lung monitor **usb**

User Manual



Medical Devices Directive
93/42/EEC L169, Vol. 36.
EN ISO 13485
FDA QSR 21 CFR 820/803

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Current Edition (Issue 2)
Cat. No. 07515

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WARNINGS AND ADVISORY NOTICES

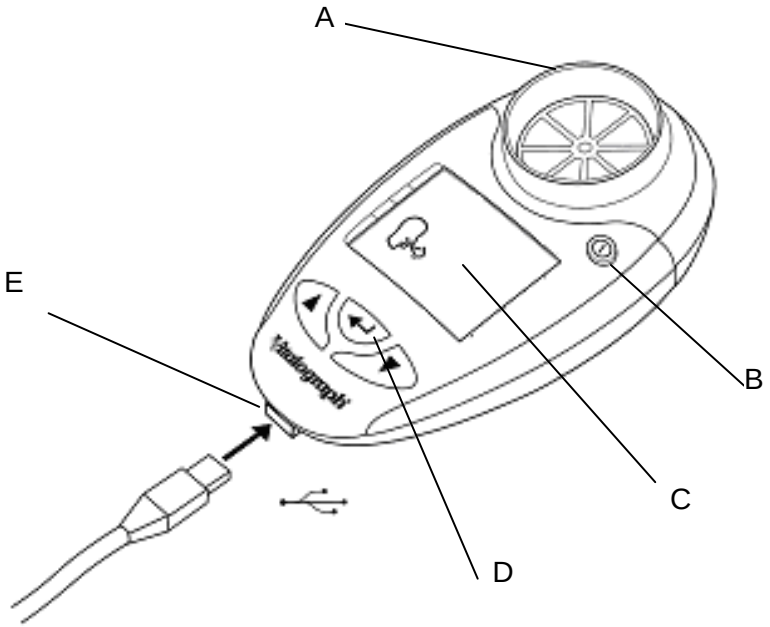
Note: Please read all the information in this manual before using the Vitalograph lung monitor USB device. A full set of instructions, including cleaning instructions, is available at www.vitalograph.co.uk.

- The Vitalograph lung monitor is recommended for single patient use.
- The Vitalograph lung monitor should be only used under the supervision of a healthcare professional.
- Symptoms must take precedence over device measurements*.
- If the device is used for longer than its specified life, the accuracy of the device may deteriorate.
- Before use, ensure that the batteries do not exceed their shelf life, as indicated on the batteries.
- Store in a clean dry place.

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

MAIN COMPONENTS OF THE VITALOGRAPH LUNG MONITOR USB

A Flowhead
B On / off button
C Display
D User buttons
E USB connector



WHAT IS THE VITALOGRAPH LUNG MONITOR USB USED FOR?

The Vitalograph lung monitor USB is an easy to use home monitoring device designed to record key lung function parameters for those with respiratory conditions, including cystic fibrosis and transplant patients. The lung monitor can also be used in primary and secondary care, occupational health and clinical studies.

The primary features of the Vitalograph lung monitor are:

- Measures FEV1, FEV6 and the ratio

- Displays % of personal best FEV1
- Simple to use
- Electronic record, eliminating need for record cards
- Stores 200 test sessions
- Quality of blow indicator
- FEV1 zones can be personalized
- Uses disposable AAA batteries

HOW TO USE THE VITALOGRAPH LUNG MONITOR USB

Setting Personal Best (Reference) Values

Personal Best (reference) values can be set for forced expiratory volume after 1 second (FEV1).

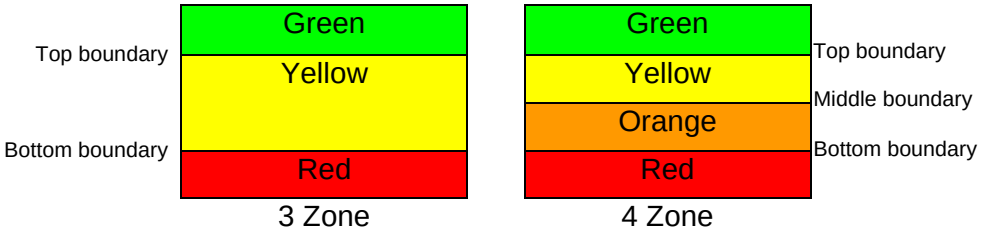
To set the Personal Best (reference) FEV1, follow these steps:

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 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.
4. Press ENTER ↵ to keep this reference FEV1 value. The device will return to the test screen.

Note: to de-activate zones, set the FEV1 reference value to 0.00.

Setting Management Zones

The Vitalograph lung monitor can be set for use with 3 or 4 zone management plans. The zone percentages are factory set to 2 boundaries, 95% & 90%, i.e. 3 Zones (95-100%, 90-95%, 0-90%). 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 10 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.
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.

Performing the Test

1. Sit down when blowing into the device (unless the physician advises otherwise).
2. Turn the device on, ①. 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 lung monitor 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, as FAST and as LONG as possible (the device will stop taking readings after 6 seconds). Be careful not to block the mouthpiece with the tongue or teeth. A 'spitting' action will give false readings.
6. Following each blow and at the end of the test session, the FEV1 value will be displayed and below that, FEV1 % Personal Best results for that blow.
7. Pressing the ▲ button will show the FEV6 result.
8. Pressing the ▲ button again will show the FEV1/FEV6 result.
9. Pressing the ▲ button again will show the FEF25-75 result.
10. With the blow icon showing, blow again (). Usually 3 blows are required.
11. To view the best test in the session (best FEV1 and best FEV6), 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 Vext (extrapolated volume) is > 5% or 150mL of FEV6 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 lung monitor can store up to 200 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 FEV1 result will be displayed for approximately 3 seconds, followed by the best FEV6 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.

Sending Test Results to Vitalograph Reports

The test session may be transmitted to the Vitalograph Reports Utility on your PC where it can be stored as a PDF file and viewed or printed.

Before you can transmit you must first have the Vitalograph Reports Utility installed and running on your PC. If the 'Snake V' icon is showing in your PC System Tray then the utility is running, if not refer to Vitalograph Reports Utility instructions.

1. Connect the Vitalograph lung monitor USB device to the PC using the USB cable supplied.
2. On Vitalograph Reports ensure 'Vitalograph lung monitor' is selected as the device.
3. There are two ways to print the test results from the lung monitor;
    a. When the device is ready for a test (), press the ▲ button for 3 seconds on the device will show the Report icon ().
    b. After completing the test session, press the ▲ or ▼ button until the print () screen is displayed. Press ↵.
4. On the Vitalograph Reports enter the Subject Demographic details and Comments. Select 'Continue' on Vitalograph Reports when you are finished entering the information.
5. Select a location for the test report on your PC as requested by Vitalograph Reports. A PDF of the test results will appear and will also be stored to the PC.

CARE AND CLEANING OF THE VITALOGRAPH LUNG MONITOR USB

Home use cleaning and disinfection of the Vitalograph lung monitor

The Vitalograph lung monitor 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	Cold liquid, e.g. Effervescent Chlorine solution
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 lung monitor 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
Plastic Mouthpiece	ABS	Do not use in clinic	No	Disinfect by immersion in sodium dichloroisocyanurate solution at 1000ppm concentration of free chlorine for 15 minutes
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 lung monitor 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.

CONSUMABLES, ACCESSORIES AND SPARE PARTS

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

Device symbols;

 Type BF equipment

 Class II

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

 Attention (reference relevant section in manual)

 USB connector

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)

 Transmit Report Symbol

TECHNICAL SPECIFICATIONS

Material:	PC/ABS
Accuracy:	Better than ± 3%
Flow Impedance:	Better than 0.15kPa/L/s at 14L/s
Measurement Range:	0 – 9.99 L BTPS
Performance And Safety Standards:	ISO EN 23747:2007 ATS/ERS Guidelines 2005
Electromagnetic emissions:	CISPR 11 Group 1 (battery operated)
Electromagnetic immunity:	IEC 61000-4-2, IEC 61000-4-3 (battery operated)
Sensor	Stator/rotor
Power Supply	2 x AAA batteries
Operating Temperature	17 – 37°C
! Bad Test Criteria	Slow start of test (Vext>5%) or a cough detected in the first second
Auto power down time	Set to 2 minutes as standard
Communications	USB

CE NOTICE

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

Guidance and manufacturer's declaration – electromagnetic emissions		
The 4000 Respiratory Monitor lung monitor is intended for use in the electromagnetic environment specified below. The customer or the user of 4000 Respiratory Monitor lung monitor 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 lung monitor 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 4000 Respiratory Monitor lung monitor 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	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Class A	

Guidance and manufacturer's declaration – electromagnetic immunity			
The 4000 Respiratory Monitor lung monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the 4000 Respiratory Monitor lung monitor 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 device	
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 device	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Performance A	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or

			hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity

The 4000 Respiratory Monitor lung monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the 4000 Respiratory Monitor lung monitor 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 lung monitor 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 device	$d = 0.35\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3V/m from 80MHz to 2.5 GHz	$d = 0.35\sqrt{P}$ 80MHz to 800MHz $d = 0.7\sqrt{P}$ 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 lung monitor			
The 4000 Respiratory Monitor lung monitor 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 lung monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 4000 Respiratory Monitor lung monitor 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: Vitalograph 4000 Respiratory Monitor lung monitor

Vitalograph hereby ensures and declares that the above product associated with this user manual, is designed and manufactured in accordance with the following QMS regulations and standards:
European Medical Devices Directive {MDD} 93/42/EEC.
This device, classified as 2a as per Annex IX of MDD 93/42/EEC, meets the following provisions of Annex II of the Medical Devices Directive as per Article 11, section 3a, excluding point 4 of Annex II.
CE 0086
This device complies with the EMC Directive 89/336/EC, conformance demonstrated by following standard EN60601-1-2:2001. Equipment classification: Residential.
Canadian Medical Device Regulation {CMDR}
FDA Quality System Regulation {QSR} 21 CFR 820.
EN ISO 13485: 2003. Medical devices. Quality management systems. Requirements for regulatory purposes.
Certifying Body {for 93/42/EEC and CMDR}: British Standards Institute {BSI}
Certificate Nos. CE 00772, MD 82182, FM 83550

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