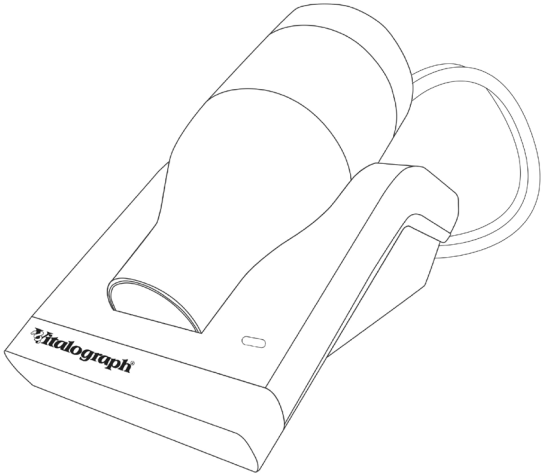
Vitalograph®

Pneumotrac with Respiratory Muscle Strength (RMS)

MODEL 6800



Instructions for Use

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1. Indications for Use

The primary indication for the use of the Pneumotrac is the simple assessment of respiratory function through the measurement of lung function in association with Spirotrac PC software by medical professionals trained in respiratory and lung function testing on adults and paediatrics, 5 years and older, in a variety of professional healthcare environments, e.g. primary care, hospitals and occupational health centres.

Note: *The measurements obtained from a lung function test form part of the various findings of a physician in the detection, diagnosis and control of chest diseases.*

2. Contraindications, Warnings, Precautions and Adverse Reactions

1. No modification of this equipment is allowed. Any unauthorised changes to the Pneumotrac 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 Pneumotrac is not designed as a sterile device. Always follow the safety guidelines given by the manufacturer of cleaning and disinfectant chemicals.
3. For the device to be used as intended, there is no requirement to clean the supporting computer. If cleaning is required to remove any visible soiling, this should be done as per the computer manufacturer's instructions.
4. Spirometry is a valuable tool that provides important information to clinicians which is used together with other physical findings, symptoms, and history to reach a diagnosis (ATS/ERS 2019).
5. When using the Pneumotrac ensure that the flowhead connecting tube is not pinched or trapped as spirometry results may appear to be inverted.
6. Attach the MIP or MEP flowhead to the Vitalograph Pneumotrac using the tubing supplied.
7. Take care not to block the mouthpiece with tongue or teeth during testing. A 'spitting' action or cough will give false readings.

8. Subject fatigue may occur during MIP, MEP or spirometry testing depending on the subject's characteristics e.g. age, health status. For safety reasons, testing should be preferably done in the sitting position, using a chair with arms and without wheels. Subject may also take a break between tests.
9. All values displayed are expressed as BTPS values.
10. Time zero is determined using the back-extrapolated method, from the steepest part of the curve.
11. Do not expose the Pneumotrac to liquids.
12. The Pneumotrac should not be used in the presence of flammable liquids or gases, dust, sand, or any other chemical substances.
13. All spirometry standards recommend checking the accuracy of lung function measuring devices daily with a 3-L syringe to validate that the instrument is measuring accurately. The Pneumotrac should never be outside accuracy limits. Accuracy should be checked after cleaning or disassembling the spirometer for any reason, after adjusting calibration or if the flowhead or device has been dropped.
14. Take care not to block the MIP MEP pressure vent on the flowhead during testing. This pressure vent is intended to prevent glottal closure and prevent the use of cheek muscles as indicated in the ATS/ERS Statement on Respiratory Muscle Testing.
15. The following contraindications apply to MIP/MEP/SNIP testing:
    a. Pathological conditions resulting in relatively large pressure swings in the abdomen or thorax.
    b. Aneurisms
    c. Uncontrolled hypertension
    d. Urinary incontinence
16. If subject cannot form a good seal on the BVF during MIP/MEP test then a bite-on mouthpiece should be fitted to the BVF.
17. Service and repairs should be carried out only by the manufacturer or by Service Agents specifically approved by Vitalograph.

18. Maintenance must not be performed while the device is in use by a subject.
19. Use of accessories and cables other than those specified or provided by Vitalograph for this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of the Pneumotrac and result in improper operation.
20. Non-medical equipment must be kept outside the subject environment i.e. any area in which intentional or unintentional contact between the subject and parts of the system, or some other persons touching part of the system, can occur.
21. 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 Pneumotrac, including cables specified by Vitalograph. Otherwise, degradation of the performance of this equipment could result.
22. 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.
23. The applied parts are the Fleisch flowhead and MIP/MEP flowhead. This along with the BVF and nasal probes, are the contact points for the subject during a spirometry session. There are no adverse effects if the subject comes into contact with any other part of the Pneumotrac device.

3. Main Components of the Vitalograph Pneumotrac RMS

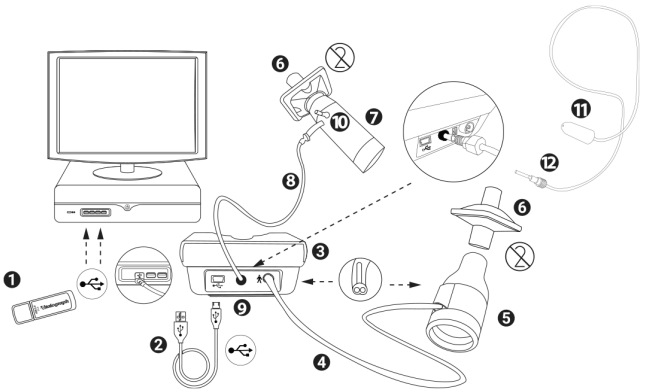

Figure 1

1	USB Flash Drive containing Spirotrac
2	USB Cable
3	Pneumotrac Base
4	Fleisch Flowhead Connection Tubing
5	Fleisch Flowhead
6	Bacterial Viral Filter (BVF)
7	MIP or MEP Flowhead. (Note: Both a MIP and MEP Flowhead are supplied)
8	MIP/MEP Flowhead Connection Tube
9	MIP/MEP/SNIP Connection Port
10	MIP/MEP Pressure Vent
11	SNIP Nasal Probe
12	SNIP Nasal Probe Adaptor

A computer is required to run Spirotrac and to use Vitalograph Pneumotrac RMS. (*Computer not included*)

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3.1. Features of the Vitalograph Pneumotrac RMS

- Fleisch type pneumotachograph to measure flow
- MIP and MEP flowhead to measure inspiratory and expiratory muscle strength
- Sniff nasal inspiratory pressure (SNIP) to measure nasal inspiratory pressure
- Ambient temperature sensor
- USB powered
- LED power indicator
- Soft pouch to store Pneumotrac RMS

4. Setting Up the Vitalograph Pneumotrac RMS

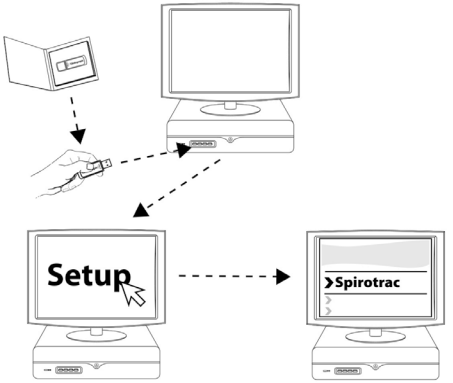

Figure 2

1. Remove Vitalograph® USB drive from packaging.
2. Insert USB drive into USB port on computer.
3. Browse USB Drive and click Setup.
4. Select Install Spirotrac. Follow on-screen instructions to complete installation. Further details are provided in the *Spirotrac Instructions* supplied with the software.
5. Close installation and select the Vitalograph Spirotrac icon from the desktop.

6. Connect Pneumotrac to the computer using the USB cable (via ports marked with the  symbol).
7. The green LED on the front indicates power is on.
8. Connect one end of the Fleisch flowhead connection tubing to the Pneumotrac base. Connect other end of flowhead tubing to the flowhead.
9. Connect the required MIP or MEP flowhead tubing to the MIP/MEP/SNIP connection port on the Pneumotrac base.

Note: *The push in connector on the connection port should be pushed firmly and squarely against the face of the connector when connecting/disconnecting the tubing.* Connect other end of tubing to the flowhead.

10. When SNIP is required attach the nasal probe adaptor to the MIP/MEP/SNIP connection port on the Pneumotrac base. Fasten the SNIP nasal probe to the adaptor.

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If the device has just been unpacked or transported, ensure that it is left sitting, fully powered to reach room temperature before testing.

5. Operating Instructions

The Pneumotrac RMS works with Vitalograph Spirotrac software. Spirotrac must be installed on the PC to begin testing. Refer to Spirotrac Instructions for Use for details on:

- Installing Spirotrac software
- Entering Subject Data
- Conducting spirometry testing
- Conducting MIP MEP testing
- Conducting SNIP testing
- Printing a Report
- Calibration Verification

6. Power Management

1. The Pneumotrac RMS device is powered over USB.
2. The green LED on the front of the device indicates that it is powered.
3. The Pneumotrac RMS may be powered down by disconnecting the USB cable from the device.

7. Cleaning & Hygiene

7.1. Preventing Cross-Contamination of Subjects

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A spirometer is not designed or supplied as a 'sterile' device. Vitalograph intends that a new Bacterial Viral Filter (BVF)/ SNIP nasal probe be used for every subject to prevent cross contamination. Using a new BVF provides a significant level of protection of the subject, the device and the user against cross contamination during spirometry manoeuvres. SNIP nasal probes are single use and disposable.
The interior of a Vitalograph flowhead does not require decontamination where a new BVF is used for each subject. The outside surfaces of the device and flowhead tube may be cleaned with a 70% isopropyl alcohol impregnated cloth to remove any visible soiling and for low level disinfection.
Where the user suspects that the flowhead has become contaminated or where local risk assessment identifies a need for higher level of decontamination, then it should be cleaned as per 'Cleaning and Hygiene' instructions on the Vitalograph website.

7.2. Inspection of the Vitalograph Pneumotrac

Fleisch Flowhead:
Visual inspection is recommended on a routine basis. Remove flowhead cone and flowhead end cap from the Fleisch flowhead (Figure 3). Examine flow conditioning mesh filters for damage or contamination. If they are damaged or blocked, discard and replace with new parts. Examine the O-rings on the Fleisch element and replace if damaged. Re-assembly the cone and end cap.
It is recommended that an accuracy check is carried out following cleaning and re-assembly as recommended in the ATS/ERS 2019 guidelines[1].

1 Derived from terminology and guidance taken from ATS/ERS Standardisation of Spirometry 2019 Update Am J Respir Crit Care Med 2019 Vol 200, Iss 8 pp e70-e88

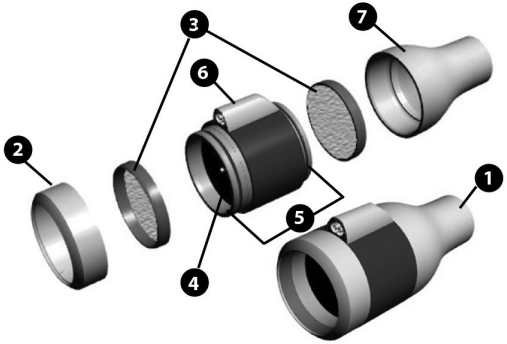

Figure 3: Flowhead Assembly

1	Flowhead Complete
2	Flowhead End Cap
3	Flow Conditioning Mesh
4	Fleisch element Assembly
5	'O' Rings
6	Pressure Tapping
7	Flowhead Cone
	Lubrication: Silicone Grease

MIP/MEP Flowhead:
Visual inspection is recommended on a routine basis. Unscrew the MIP/MEP end cap from the cone. Remove the one-way valve from the cone and examine it for damage. If damaged, discard and replace with a new part (Reference Section 10. Consumables and Accessories). Carefully separate the hard plastic housing from the soft silicone one-way valve, avoiding damage to the one-way valve.

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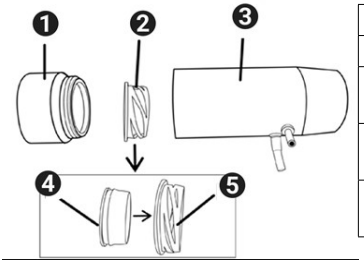

1	MIP/MEP end cap
2	MIP/MEP one way valve
3	MIP/MEP cone
4	One-way valve hard plastic housing
5	Soft silicone one-way valve

Figure 4: MIP/MEP Flowhead Assembly

Carefully re-assemble the silicone one-way valve with the hard plastic housing, taking care not to damage the silicone one-way valve.

Note: *It is important that the one-way valve is fitted to the cone in the correct orientation for the different MIP and MEP flowheads. Refer to the images below for the correct orientations.*

The flowhead version is marked on the end cap. Ensure the one-way valve is fully seated and centered into the groove on the cone.

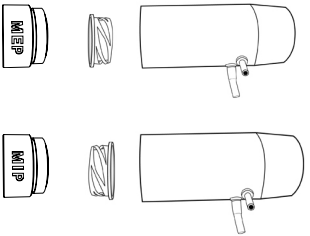

Figure 5: Orientation of one-way valve

Screw the MIP/MEP end cap to the cone. Ensure it is fully screwed home and hand tightened. Attach the white end of the flowhead connection tube to the silver pressure tapping on the MIP/MEP flowhead. The clear end of the flowhead connection tube is connected to the push in connector adjacent to the spirometry connector on the Pneumotrac base.

To check the MIP/MEP flowhead has been correctly re-assembled attach a BVF to the MIP/MEP Flowhead and test as follows:

1. MEP Flowhead: fully inspire though the flowhead. The one-way valve should open, and no resistance should be felt. Then attempt to expire. The one-way valve should close, and a significant resistance should be felt. The only air escaping should be through the MIP/MEP Pressure Vent on the flowhead.
2. MIP Flowhead: fully expire through the flowhead. The one-way valve should open, and no resistance should be felt. Then attempt to inspire. The one-way valve should close, and a significant resistance should be felt. The only air entering should be through the MIP/MEP Pressure Vent on the flowhead.

8. Fault Finding Guide

Problem Fault Symptoms:	• **Accuracy check variations > +/-2.5%** **False readings suspected**
Possible Cause/ Solution: (In probable order)	• Recheck Accuracy (Refer Section 5.Operating Instructions). • Check that the correct syringe volume was selected. • Flowhead conditioning mesh missing or blocked. • Flowhead pressure tapping holes blocked. • Flowhead Fleisch element assembly sealing 'O' rings damaged. • Flowhead Fleisch element assembly blocked • Cold syringe – ensure syringe is in its test environment for at least an hour before use • Internal tubing from pressure ports on device is blocked – contact support. • Electronics failure – contact support.
Problem Fault Symptoms:	• **Test begins automatically** **Volume accumulates automatically without the subject blowing.** **Very small VC or FVC test displayed**

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Possible Cause/ Solution: (In probable order)	• Flowhead and/or tubing not stationary at the start of test. Hold them steady until the 'Blow Now' prompt appears. • Restart the test routine.
Problem Fault Symptoms:	• **Rocking Pneumotrac Base**
Possible Cause/ Solution: (In probable order)	• Check for damaged or missing feet. • Replace both feet if any of the feet are damaged or missing.
Problem Fault Symptoms:	• **Reversed or no volume measurements.**
Possible Cause/ Solution: (In probable order)	• Ensure tubing is connected correctly. • Ensure the flowhead connecting tube is not pinched or trapped.
Problem Fault Symptoms:	• **Incorrect or no pressure measurements during a MIP/MEP/SNIP test.**
Possible Cause/ Solution: (In probable order)	• Ensure tubing is connected correctly to the MIP/MEP flowhead and to the MIP/MEP/SNIP connection port on the Pneumotrac base. • Ensure that the connectors are clear of obstruction or dirt and that they are inserted fully. • Ensure the tubing is not kinked or squeezed • Ensure that the correct flowhead is being used. i.e. a MIP flowhead for a MIP test and a MEP flowhead for a MEP test. SNIP test requires a Nasal probe. • Check that the one-way valve is fitted in the correct orientation to the MIP and MEP flowhead (Reference Figure 5). Test the flowhead following instructions outlined in Section 7.2. • Check the condition of the one-way valve. If damaged, replace with new part.

9. Customer Service

Service and repairs should be carried out only by the manufacturer, or by Service Agents approved by Vitalograph. Contact information for approved Vitalograph Service Agents may be found at the start of this manual. Any serious incident that has occurred in relation to the device should be reported to Vitalograph or its Authorized Representative and the Regulatory Authorities of the country. Refer to the Vitalograph contact information at the start of this manual.

10. Consumables and Accessories

Cat. No	Description
28350	BVF - Bacterial/Viral Filters (50)
28501	Eco BVF – Bacterial/Viral Filters (100)
28572	Eco BVF and Disposable Nose Clip (80)
28554	Eco BVF with Bite Lip (75)
28553	Eco BVF with Bite Lip and Disposable Nose Clip (75)
28551	Eco BVF + Silicone Bite-On Mouthpiece + Disposable Nose Clip (60)
36020	3-L Precision Syringe
77933	Flow Conditioning Mesh (10)
77934	Flowhead Complete
77939	Flowhead Cone
77938	Flowhead End Cap
77973	SNIP Nasal Probe Adaptor
79192	Flowhead Connection Tube
2120013	O-Ring (15)
41543	USB Cable
77652	MIP MEP Flowheads
77651	MIP MEP Connection Tube
77653	Silicone One-way Valve (Pack of 2)
77935	Feet
32254SPR	Silicone Grease Pack

32956	SNIP Nasal Probe (Pack of 30 – Small x 10, Medium x 10, Large x 10)
32981	SNIP Nasal Probe (Pack of 30 – Small)
32982	SNIP Nasal Probe (Pack of 30 – Medium)
32983	SNIP Nasal Probe (Pack of 30 – Large)

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 BVFs and nasal probes constitute minimally soiled waste from human healthcare and should be disposed of in line with local requirements. BVFs are made from polypropylene.

12. Explanation of Symbols

Symbol	Description
	Type B 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

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13. Device Description

The Vitalograph Pneumotrac RMS is a spirometry device which measures subject respiratory parameters as part of lung function testing. It is designed for desktop use. A Fleisch flowhead is used for spirometry testing and has a resting location on the device.

14. Technical Specification

Product	Vitalograph Pneumotrac
Model	6800
Flow Detection Principal	Fleisch type pneumotachograph
Volume Detection	Flow integration sampling @ 100Hz
Volume Accuracy	Within ±2.5%
Flow Measurement Range	Max. flow rate ±960 L/min (±16 L/s) Min. flow rate ±1.2 L/min (±0.02 L/s)
PEF Accuracy	Within ±10%
Back pressure	Less than 0.1kPa/L/sec @ 14L/ sec (ATS/ERS 2005)

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MIP MEP SNIP Measurement Range	0 to 300 cmH20
Operating temperature range	ISO26782 limits: 17–37ºC Design limits: 10–40ºC
Operating humidity range	30%–75%
Ambient pressure range	850hPa–1060hPa
Performance standards the Vitalograph Pneumotrac meets or exceeds	ATS/ERS 2019, ISO 23747:2015 & ISO 26782:2009
Safety standards	EN60601-1:2006 + A1:2013
EMC Standards	EN 60601-1-2:2015
QA/GMP standards	EN ISO 13485, FDA 21 CFR 820, SOR/98-282, JPAL, MDSAP
Dimensions	160mm (length) x 95mm (width) x 63mm (height)
Weight	0.47kg
Communications	USB 2.0/3.0
Power Supply	5V DC via USB

15. CE Notice

Marking by the symbol CE 2797 indicates compliance of the Vitalograph Model 6800 Pneumotrac to the Medical Devices Directive of the European Community.
The Vitalograph Model 6800 Pneumotrac 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 Pneumotrac should assure that it is not used in such an environment.

The Model 6800 Pneumotrac has been tested in accordance with:
EN60601-1:2006 + A1:2013 - Medical electrical equipment. General

requirements for basic safety and essential performance.

EN 60601-1-2:2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

EN 60601-1-2:2015- Emissions tests		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Model 6800 Pneumotrac 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 6800 Pneumotrac is suitable for use in all establishments, including those connected to the public mains network (e.g. at doctor's offices in residential areas).

EN 60601-1-2:2015 - Immunity tests		
Immunity test	**Test level**	**Compliance level Reached**
Electrostatic discharge (ESD) EN 61000-4-2	Contact: ± 8 kV Air: ± 2 kV,± 4 kV, ± 8kV,± 15 kV	Contact: ± 8 kV Air: ± 2 kV,± 4 kV, ± 8kV,± 15 kV
Radiated RF EN 61000-4-3	3 V/m 80MHz to 2700MHz	3 V/m 80MHz to 2700 MHz
Proximity fields from RF devices EN 61000-4-3	9 to 28V/m 385 to 5785MHz As per Table 9 EN60601-1-2:2015	9 to 28V/m 385 to 5785MHz As per Table 9 EN60601-1-2:2015

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.
Medical 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: 6800 Vitalograph Pneumotrac

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

- European Medical Devices Directive {MDD} 93/42/EEC, as amended.

  This device is classified as IIa 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.

- EN ISO 13485 Medical devices. Quality management systems. Requirements for regulatory purposes.

Certifying Body: British Standards Institute {BSI}.
BSI Notified Body #: 2797
Certificate Nos. CE 00772, MD 82182

CE 2797

Signed on behalf of Vitalograph (Ireland) Ltd.

Frank Keane.
CEO, Vitalograph Ltd.

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18. Guarantee & Free Five Year Warranty

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 two years of the date of purchase of the equipment, unless otherwise agreed in writing by the Company. Registration is not required for this base two year guarantee.
2. An extended five year warranty from date of purchase, is available by registering the products serial number at *www.vitalograph.com/warranty* within thirty days of purchase.
3. Software (meaning computer software, or user installable modules) is guaranteed for 90 days from the date of purchase.
4. 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.
5. 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.
6. 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.

7. This Guarantee is not transferable and no person, firm or company has any authority to vary the terms or conditions of this guarantee.
8. 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.
9. This Guarantee is offered as an additional benefit to the Consumer's statutory rights and does not affect these rights in any way.

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