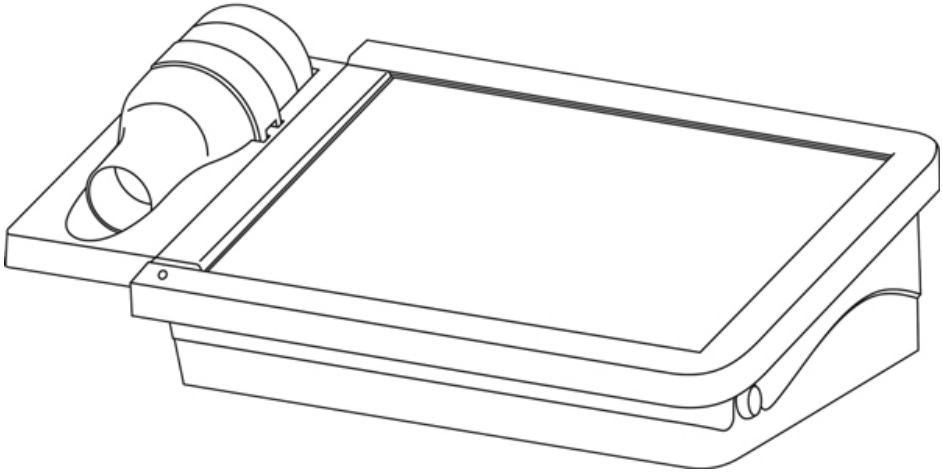
Vitalograph®

COMPACT

MODEL 6600



Instructions for Use

ENG

Vitalograph Branch Addresses

Vitalograph Ltd, UK
Maids Moreton, Buckingham
MK18 1SW
England
Tel: 01280 827110
Fax: 01280 823302
E-mail: sales@vitalograph.co.uk
www.vitalograph.co.uk
Technical Support
Tel: 01280 827177
Email: tech.support@vitalograph.co.uk

Vitalograph Ltd, International
Maids Moreton, Buckingham
MK18 1SW
England
Tel: +44 1280 827120
Fax: +44 1280 823302
E-mail: sales@vitalograph.co.uk
www.vitalograph.eu
Technical Support
Tel: +353 65 6864111
Email: technical.support@vitalograph.ie

Vitalograph GmbH
Rellinger Straße 64a
D-20257 Hamburg
Germany
Tel: +49 40 547391-40
Fax: +49 40 547391-40
E-mail: info@vitalograph.de
www.vitalograph.de
Technical Support
Telefon: +49 40 547391-14
E-mail: support@vitalograph.de

Vitalograph Inc.
13310 West 99th Street
Lenexa, Kansas, 66215
USA
Toll Free: 800 255 6626
Tel: (913) 730 3200
Fax: (913) 730 3232
E-mail: contact@vitalograph.com
www.vitalograph.com
Technical Support
Tel: (913) 730-3205
Email: technical@vitalograph.com

Vitalograph (Ireland) Ltd
Gort Road Business Park
Ennis, Co Clare, V95 HFT4
Ireland
Tel: +353 65 6864100
Fax: +353 65 6829289
E-mail: sales@vitalograph.ie
www.vitalograph.ie
Technical Support
Tel: +353 65 6864111
Email: technical.support@vitalograph.ie

Vitalograph Ltd, Hong Kong/China
P.O. Box 812
Shatin Central Post Office
Hong Kong
E-mail: sales@vitalograph.cn
www.vitalograph.cn
Technical Support
Tel: +353 65 6864111
Email: technical.support@vitalograph.ie

Current Edition (Issue 2, 17-Jun-2020)
Cat. No. 09240

ENG

Contents

ENG

1. Main Components of the Vitalograph COMPACT

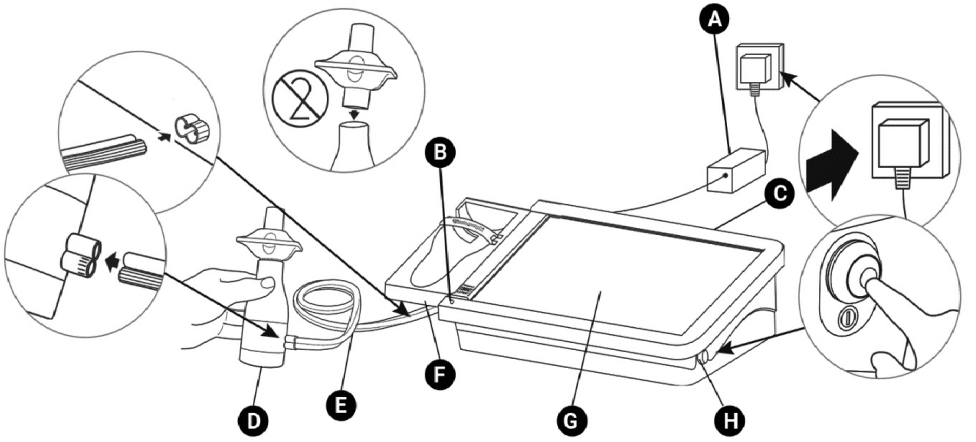


Figure 1 Main components of the COMPACT

A	Power Supply
B	Power LED
C	I/O Ports - 4 x USB, 2 x Ethernet, 2 x Serial, 1 x DVI
D	Flowhead
E	Flowhead Connection Tubing
F	Flowhead Carrier with security strap
G	Colour LCD and Touch Panel Display
H	Power Switch

1.1. Features of the Vitalograph COMPACT

- Touch screen colour display
- Audio feedback
- Auto-recognition of FVC single or multi-breath testing
- VC single or multi-breath testing
- Trending of test results
- Child incentive displays
- Audit Trail log
- Configurable Subject Demographics

- Automatic storage of all test data
- Configurable Spirometry Reports
- Bronchodilator responsiveness testing
- Fully networked database (optional)
- Test QA ATS/ERS 2005 guidelines
- Pulse Oximetry Testing (SpO2)
- PCF (Peak Cough Flow) Test
- Challenge Testing – Mannitol, ATS 5-breath dosimeter, 2-min tidal breathing and Exercise challenge
- Six Minute Walk Testing
- asma-1 Device Downloads/Uploads Module
- Simulation of ATS/ISO waveforms
- 12-Lead ECG module
- Support for the Health Level 7 (HL7) and GDT communication standards
- Maximum Voluntary Ventilation (MVV) Test

2. Setting Up the Vitalograph COMPACT

1. Attach the flowhead to the Vitalograph COMPACT using the dual silicone tubing (Flowhead Connection Tube). Ensure that the ribbed tapping on the flowhead is connected to the ribbed side of the connection in the housing. If tubing is connected the wrong way, spirometry results may appear to be inverted (see Figure 1)
2. Only use the COMPACT with the low voltage power supply provided with the device.
3. Connect the jack plug from the power supply into the socket at rear of the COMPACT. Plug the mains plug into a suitable socket, operate the On/Off button on the side of the instrument. The COMPACT is ready for use.
4. For guidance using Spirotrac software on the COMPACT refer to the Spirotrac Instructions For Use available with the device.
5. To power down COMPACT:
   a. Close the Spirotrac session, this will automatically log-off the current user and power down the device. Or
   b. Press the close button ☒ the main toolbar.

Note: *The device can be powered down by pressing and holding the On/Off button but this is not recommended. Correct power-down is only achieved if one of the two methods listed above are used.*

If the device has just been unpacked or transported, ensure that it is left sitting, fully powered, for at least an hour in order to reach room temperature prior to testing.

ENG

2.1. Vitalograph COMPACT Communications

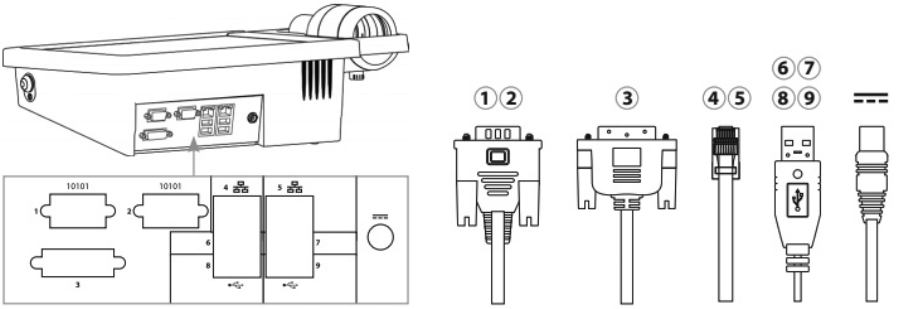


Figure 2 COMPACT Port connections

1,2	Serial Ports x 2
3	DVI video output (Monitor) x 1
4,5	Ethernet x 2
6,7,8,9	USB x 4
⎓	Power

3. Operating Instructions

1. The Vitalograph COMPACT works with Vitalograph Spirotrac software. Refer to *Spirotrac Instructions for Use* for operating instructions and details on:
   - Entering Subject Data
   - Conducting spirometry testing
   - Printing a Report
   - Calibration Verification
2. To enter text, touch the keyboard icon  on the screen and use the onscreen keyboard to enter the relevant details. To close the keyboard, touch the X at the top right hand corner of the onscreen keyboard. Alternatively a USB enabled keyboard may be used.

4. Power Management

The Vitalograph COMPACT must be powered using the 19V low voltage Power Supply unit supplied with the device. When powered and switched ON the LED on the front of the device will be green. The Power Supply unit should be checked regularly and replaced when necessary.

ENG

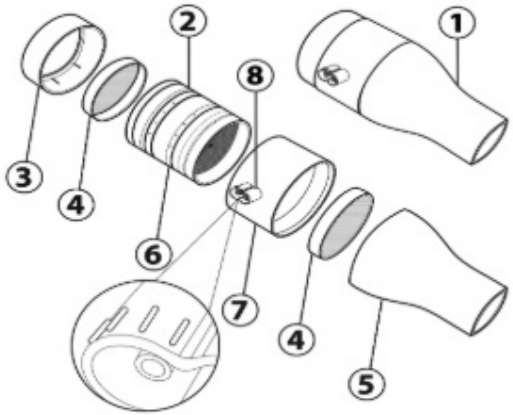
5. Cleaning & Hygiene

5.1. Preventing Cross-Contamination of Subjects

A spirometer is not designed or supplied as a 'sterile' device.
Vitalograph intends that a new Bacterial Viral Filter (BVF) 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.
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 the instructions on 'Cleaning and Hygiene' on the Vitalograph website.

5.2. Inspection of the Vitalograph COMPACT

A visual inspection is recommended on a routine basis: Remove flowhead cone and flowhead end cap from the flowhead. 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-assemble 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 guidelines[1].



1	Flowhead Complete
2	'O' Rings
3	Flow End Cap
4	Flow Conditioning Meshes
5	Flowhead Cone
6	Fleisch Element
7	Flowhead Body
8	Port Pressure Tappings
	Lubrication: Silicone Grease

Figure 3: Flowhead Assembly

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

6. Fault Finding Guide

Problem Fault Symptoms:	• **Not measuring flow**
Possible Solutions: (In probable order)	• Ensure tubing is connected correctly. Ribbed side of tubing should be connected to ribbed half of the connector on the Vitalograph device.
Problem Fault Symptoms:	• **Incorrect or no volume measurements**
Possible Solutions: (In probable order)	• Ensure tubing is connected correctly. Ribbed side of tubing should be connected to the ribbed half of connector on the Vitalograph device. • Ensure that connectors are clear of obstruction or dirt and are inserted fully. • Ensure tubing is not kinked or squeezed.
Problem Fault Symptoms:	• **Excessive calibration drift**
Possible Solutions: (In probable order)	• Clean flowhead thoroughly. • Contact the nearest dealer for replacement.
Problem Fault Symptoms:	• **Test performed but does not show on screen**
Possible Solutions: (In probable order)	• Ensure correct device is selected in *Tools > Device* • Ensure device is connected to PC correctly. • Ensure tubing is connected correctly between flowhead and device (same colour connector at both ends).
Problem Fault Symptoms:	• **Communication error message appears when entering the Test screen, the Accuracy Check screen or the Calibration Update screen**
Possible Solutions: (In probable order)	• Ensure that device is attached correctly.
Problem Fault Symptoms:	• **Accuracy check variations > +/- 3%**
Possible Solutions: (In probable order)	• Recheck Calibration with reference to Spirotrac Instructions for Use • Was correct syringe volume entered? • Ensure tubing connectors are clear of obstruction or dirt and are inserted fully. • Ensure tubing is not kinked or squeezed. • Ensure flowhead is clean.

Problem Fault Symptoms:	• **Test begins automatically** • **Volume accumulates automatically without the subject blowing** • **Very small VC or FVC test displayed**
Possible Solutions: (In probable order)	• Flowhead and/or tubing not stationary at start of test. Hold them steady until the 'Blow Now' prompt appears. • Return to Main Menu and re-enter the test routine.

6.1. Software Check

Information about Spirotrac is available in the 'About' box. This information may be used when contacting Vitalograph or a service agent with queries.
To access the 'About' box:

- Select About from the Help menu.

To launch the Help file:

- Select User Training Manual from the Help menu.

7. 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.

8. Consumables and Accessories

Type	Cat. No	Description
Consumables	28350	BVF Bacterial Viral Filters (50)
	20303	Noseclips (200)
	28501	Eco BVF – Bacterial/Viral Filters (100)
	28572	Eco BVF and Disposable Nose Clip (80)
	28554	2820 Eco BVF with Bite Lip (75)
	28553	2820 Eco BVF with Bite Lip and Disposable Noseclip (75)
Accessories	36020	2040 Precision Syringe 3-L

ENG

	42084	Flow Conditioning Meshes (10)
	67252	USB Cable
	67181	COMPACT 19V Power Supply
	61030	Flowhead Complete
	42029SPR	Flowhead Connection Tube
	41530	Bluetooth Dongle
Compatible Devices	41300	12-Lead BT ECG (IEC)
	41303	12-Lead BT ECG (AHA)
	70453	Pulse Oximetry Finger Probe USB
	79400	2120 Hand Held In2itive™ Spirometer
	40400	4000 Respiratory Monitor asma-1™ USB
Software	70201	7000 Spirotrac Network Licence

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

10. Explanation of Symbols

Symbol	Description
	Type BF equipment
	Class II
VA	Power rating
	Direct current
	Instructions for Use; operating instructions
	Manufacturer

	Year of Manufacture (Date 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

11. Description of the Vitalograph COMPACT

The Vitalograph COMPACT is a desktop medical workstation designed for use by trained medical professionals for physiological measurements in a variety of professional healthcare environments, e.g. primary care, hospitals and occupational health centres. Test data is automatically stored to the relevant subject record. The software running on the COMPACT allows it to be used as a standalone lung function testing device. In a clinical setting, 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. Spirometry may support or exclude diagnosis, but it cannot make one. The COMPACT can also be used with other accessory devices to offer Pulse Oximetry, Six Minute Walk Test, and 12-lead ECG testing.

ENG

11.1. Indications for Use

Vitalograph COMPACT is intended for use by, or on the order of, a physician in a hospital or clinic setting. It is designed for use on both adult and paediatric patients. The device is a desktop based spirometer or may be used to connect to compatible devices to acquire, view, store and print the device output. The device is intended for use by trained medical professionals. Apart from this instruction manual, there are no other training requirements for the medical professional.

12. Technical Specification

Product	Vitalograph COMPACT
Model	6600
Flow Detection Principal	Fleisch type pneumotachograph
Volume detection	Flow integration sampling @ 100Hz
Volume Accuracy	Within ±3%
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
Operating temperature range	ISO26782 limits: 17–35ºC Design limits: 10–40ºC
Performance standards the Vitalograph COMPACT meets or exceeds	ATS/ERS 2005, ISO 23747:2015, ISO 26782:2009,
Safety standards	EN 60601-1:2006 + A1:2013
EMC Standards	EN 60601-1-2:2015
QA/GMP standards	EN ISO 13485, FDA 21 CFR 820, CMDR SOR/98-282 & JPAL MO# 106
Dimensions	375 mm x 235 mm x 110 mm
Weight	2.5 kg net
Communications	USB x minimum 4, Serial x 2, Ethernet x 2, DVI Video output
Power Supply	19V DC Power Supply
Operating System	Windows 7 Embedded
Processor	AMD FT1 Mobile Dual-core T56N

RAM	8GB
Screen	12.1” LCD 1024x768 pixel

13. Contraindications, Warnings, Precautions and Adverse Reactions

1. No modification of this equipment is allowed. Any unauthorised changes to the Vitalograph COMPACT 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 COMPACT is not designed as a sterile device. Always follow the safety guidelines given by the manufacturer of cleaning and disinfectant chemicals.
3. Vitalograph intends that a new Bacterial Viral Filter (BVF™) 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. A BVF is for single use only.
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 COMPACT ensure that the flowhead connecting tube is not pinched or trapped as spirometry results may appear to be inverted.
6. Take care not to block the mouthpiece with tongue or teeth during testing. A ‘spitting’ action or cough will give false readings.
7. Subject fatigue may occur during 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. When the COMPACT device is used a subject fatigue warning will appear after 8 manoeuvres.
8. All values displayed are expressed as BTPS values.
9. Time zero is determined using the back-extrapolated method, from the steepest part of the curve.
10. Do not expose the COMPACT to liquids.
11. The COMPACT should not be used in the presence of flammable liquids or gases, dust, sand or any other chemical substances.
12. 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 COMPACT 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.
13. Service and repairs should be carried out only by the manufacturer or by

Service Agents approved by Vitalograph.

14. Maintenance must not be performed while the device is in use by a subject.
15. 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 COMPACT and result in improper operation.
16. 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.
17. 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 COMPACT, including cables specified by Vitalograph. Otherwise, degradation of the performance of this equipment could result.
18. 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.
19. The applied part is the flowhead. This along with the BVF, 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 COMPACT device.
20. Only use the Vitalograph COMPACT with the power supply provided. Attempted use with other power sources may cause irreparable damage and invalidate the warranty. The output from the power supply is 19 volts DC.
21. The device is susceptible to electrostatic discharge. Occasional flickering of the screen and switching off of the device could occur. To restore function, press the On/Off switch.

14. CE Notice

Marking by the symbol CE 2797 indicates compliance of the Vitalograph Model 6600 COMPACT to the Medical Devices Directive of the European Community. The Vitalograph Model 6600 COMPACT 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 COMPACT should assure that it is not used in such an environment.

The Model 6600 COMPACT has been tested in accordance with:
EN 60601-1:2006 + A1:2013 - Medical electrical equipment – Part 1: 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 6600 COMPACT 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 6600 COMPACT is suitable for use in all establishments, including domestic establishments and those connected to the public mains network (e.g. at home and doctor's offices in residential areas)

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
Electrical fast transient/burst IEC 61000-4-4	±0.5, ±1 & ±2kV 100kHz	±0.5, ±1 & ±2kV 100kHz
Surge IEC 61000-4-5	±1kV differential mode Device is identified as Class II unearthed equipment therefore common mode testing is omitted.	1kV

Voltage dips, short interruptions on power supply input lines IEC 61000-4-11	*>95% drop, 0.5 cycles, 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°* >95% dip, 1 cycle 30% dip, 25 cycles 240V AC, 50Hz	*>95% drop, 0.5 cycles, 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°* >95% dip, 1 cycle 30% dip, 25 cycles 240V AC, 50Hz
Conducted RF EN 61000-4-6	6Vrms 0.15-80MHz 80% AM	6V/m ISM/amateur radios bands 0.15-80MHz 80% AM
Radiated RF EN 61000-4-3	3V/m, 1KHz 80MHz to 2700MHz	3V/m, 1KHz 80MHz to 2700MHz
Power frequency (230V, 50Hz and 120V, 60Hz) magnetic field	30A/m	30A/m

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 (refer to section Contraindications, Warnings, Precautions and Adverse Reactions).

15. FDA Notice

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

16. EU Declaration of Conformity

Product: 6600 Vitalograph Compact
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.

17. 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.