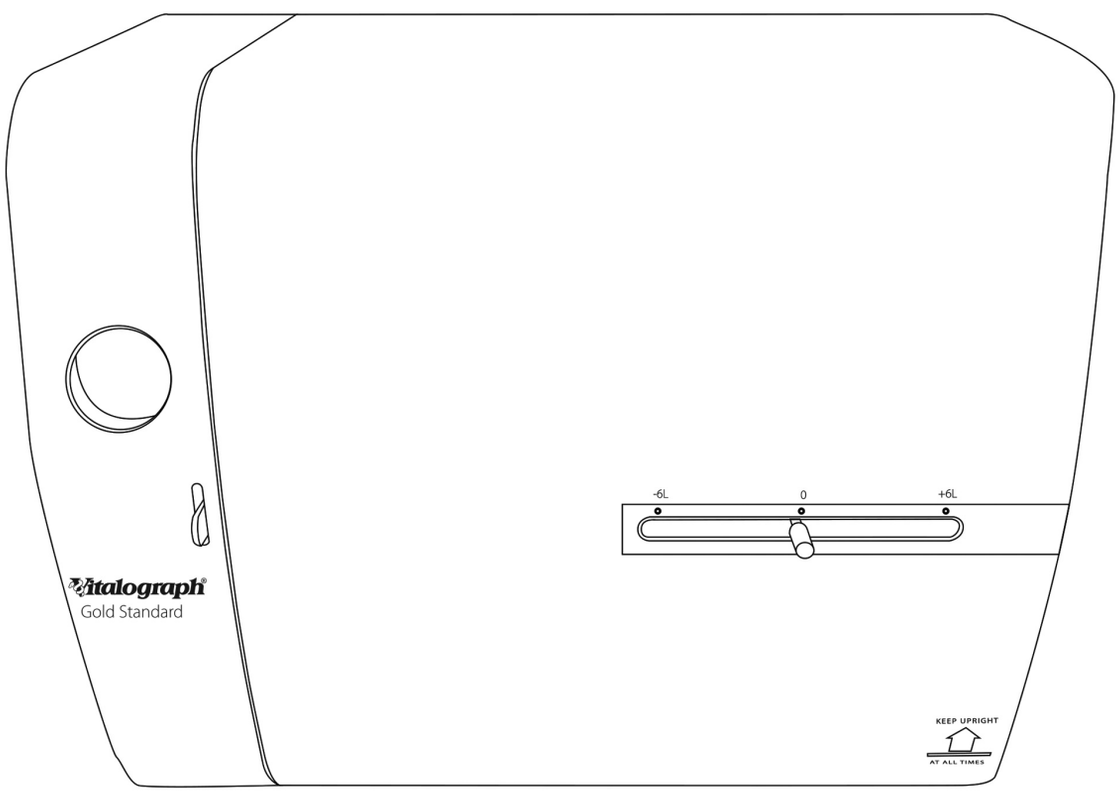
Gold Standard

MODEL 2150



Instructions for Use

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Current Edition (Issue 1, 24-Feb-2020)
Cat. No. 09310

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1. Main Components

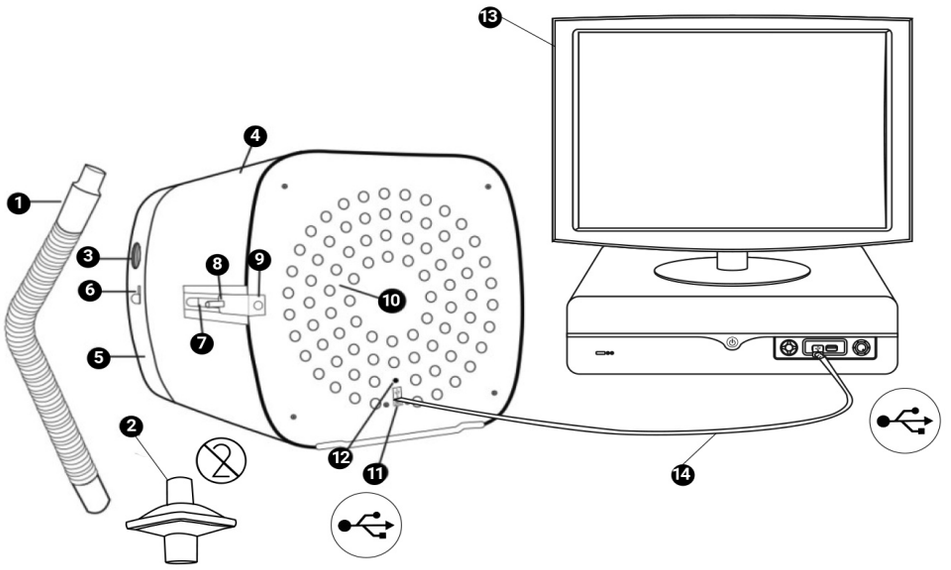

Figure 1 Main components of the Vitalograph Gold Standard

1	Breathing Tube
2	Bacterial Viral Filter (BVF™) - Do not reuse
3	Breathing Tube Socket
4	Outer Case
5	Door
6	Door Latch
7	Scale
8	Volume Scale Adjustment Handle
9	Handle Restraint Strap
10	Ventilation Panel
11	USB Connector (connect to PC with USB Cable)
12	Power LED
13	PC running Vitalograph Spirotrac™ Software (supplied on USB stick, computer not included)
14	USB cable

1.1. Features

- Volumetric design using rolling seal technology
- Ambient temperature sensor
- USB interface for power and communications
- LED to indicate power
- Vitalograph Spirotrac software (to be installed on user's computer)

2. Set Up

To get the Vitalograph Gold Standard ready for use:

1. Install Spirotrac software on the user PC following the instructions supplied with the software.
2. Connect the Vitalograph Gold Standard to the computer using USB cable (via ports marked with the ⇆ symbol).
3. The power LED on the ventilation panel will turn on when power is on.
4. Connect the flexible end of the breathing tube to the breathing tube socket.
5. Fit a bacterial viral filter (BVF) into the other (subject) end of the breathing tube.

Note: *A new BVF should be used for each subject to prevent cross contamination, protecting the subject, the device, and the operator.*

6. To adjust starting volume, unlatch the handle restraint strap from the volume adjustment handle. Set the desired starting position using the volume adjustment handle.

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

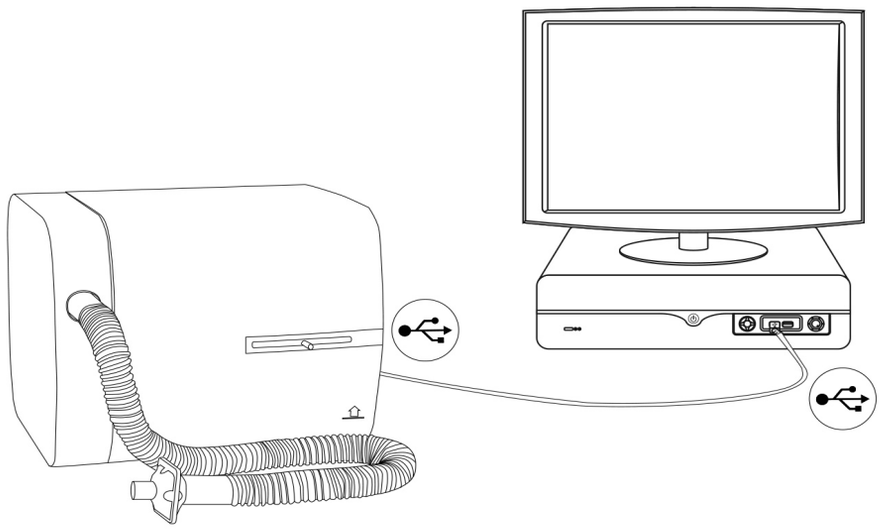

Figure 2: Setting up the Vitalograph Gold Standard

3. Operating Instructions

3.1. Using the Vitalograph Gold Standard with Spirotrac

In order to carry out spirometry testing with the Vitalograph Gold Standard, it must be connected to a PC running Spirotrac software. Refer to the Spirotrac Instructions for Use for details on:

- Installing Spirotrac software
- Connecting the Vitalograph Gold Standard to a PC
- Start-up/logon
- Managing predicted values
- Database management
- Reporting

3.2. Calibration Verification

ATS/ERS Standardisation of Spirometry (2019) recommends that Spirometer calibration verification be undertaken at least daily[1]. To verify the calibration of the Vitalograph Gold Standard:

1. Attach the breathing tube to the 3-L syringe with a BVF fitted as per figure 3.

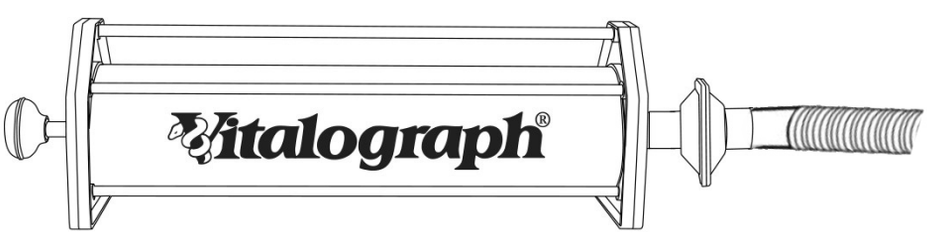

Figure 3: Verifying Calibration

2. Click on Syringe icon on the menu bar in Spirotrac.
3. Follow the on-screen instructions to verify calibration using syringe.

3.3. Spirometry Testing in Spirotrac

For details on spirometry testing using Spirotrac refer to the Spirotrac Instructions for Use.
This includes information on:

- Checks to make before performing a Spirometry test
- Subject management - creating, editing, and deleting a subject
- Different types of testing
- Parameter definitions
- Test quality information
- Setting up incentives

1 Graham, B. L., et al. (2019). "Standardization of Spirometry 2019 Update. An Official American Thoracic Society and European Respiratory Society Technical Statement." Am J Respir Crit Care Med 200(8

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4. Power Management

- The Vitalograph Gold Standard is powered over USB from the user PC.
- When power is applied to the device, the power LED on the ventilation panel will turn on.
- The Vitalograph Gold Standard may be safely powered down by disconnecting the USB cable from the device to the user PC.

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 for the subject, the device and the user against cross contamination during spirometry manoeuvres.

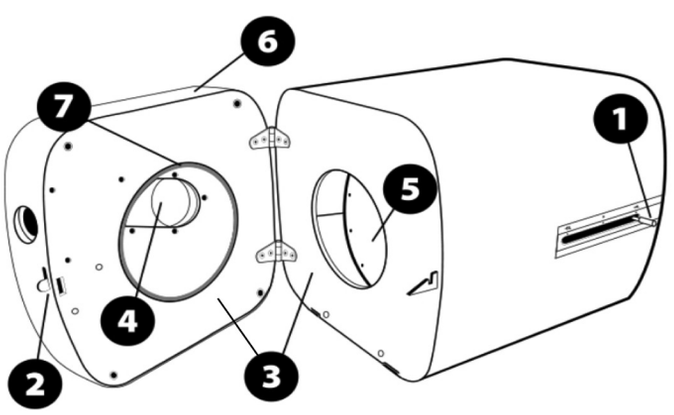
The outside surfaces of the device and breathing tube may be cleaned with a 70% isopropyl alcohol impregnated cloth to remove any visible soiling and for low level disinfection. Internal surfaces should be wiped down and left open to dry at the end of usage for the day; refer to Section 5.2 Cleaning & Inspection of the Vitalograph Gold Standard.
If you suspect the device has become contaminated or where user 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. Cleaning & Inspection of the Vitalograph Gold Standard

A visual inspection is recommended on a routine basis. Remove the breathing tube, and check for damage or contamination. If it is damaged or blocked, discard and replace.
It is recommended that calibration verification be carried out following cleaning and re-assembly as recommended in the ATS/ERS 2019 guidelines[2].
Internal surfaces may be cleaned with a 70% isopropyl alcohol impregnated cloth at the end of usage for the day. Regular air drying of the spirometer interior reduces the potential for growth of micro-organisms, so it is recommended that the door be left open overnight following cleaning and closed the following day before testing recommences.

Accessing Internal surfaces for cleaning:

1. Position volume adjustment handle at maximum position on the volume scale as shown in Figure 3.
2. Lift door latch to open door of the Vitalograph Gold Standard.
3. Wipe both inner plates, including exposed surface of the seal (7).
4. Reach through manifold opening and wipe internal parts of manifold.
5. Reach through inner plates opening and wipe inner tube.
6. Leave door open overnight. Close door prior to recommencing testing.



1	Volume Adjustment Handle
2	Door Latch
3	Inner Plate
4	Manifold
5	Inner Tube
6	Door
7	Door Seal

Figure 3: Surfaces Requiring Cleaning

2 Graham, B. L., et al. (2019). "Standardization of Spirometry 2019 Update. An Official American Thoracic Society and European Respiratory Society Technical Statement." Am J Respir Crit Care Med 200(8)..

6. Fault Finding Guide

Problem Fault Symptoms:	**Accuracy check variations > +/-3%** **False readings suspected**
Possible Solutions: (In probable order)	• Verify calibration with reference to the Spirotrac Instructions for Use. • Ensure correct syringe volume selected. • Cold syringe – ensure the syringe is in its test environment for at least an hour before use. • Calibration verification is required after cleaning the Vitalograph Gold Standard. • Electronics failure – contact support.
Problem Fault Symptoms:	• **Test begins automatically** • **Volume accumulated automatically without the subject blowing** • **Very small VC or FVC test displayed**
Possible Solutions: (In probable order)	• Tubing not stationary at the start of the test. Hold steady until the 'Ready to Blow' prompt appears. • Return to Main Menu and re-enter the test routine.
Problem Fault Symptoms:	**Rocking/unstable Vitalograph Gold Standard**
Possible Solutions: (In probable order)	• Ensure the supporting surface is even and stable. • Check for damaged or missing rubber feet. If any of the rubber feet are damaged or missing contact support.
Problem Fault Symptoms:	**Reserved or no volume measurements.**
Possible Solutions: (In probable order)	• Ensure tubing is connected correctly. • Ensure that the breathing tube is not pinched or trapped.

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

Cat. No	Description
28554	Eco BVF with Bite Lip (75)
28553	Eco BVF with Bite Lip and Disposable Nose Clip (75)
28350	BVF - Bacterial/Viral Filters (50)
36020	3-L Precision Syringe
67252	USB Cable
20301	Breathing Tube

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.

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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
REF	Catalogue Number
LOT	Batch Code
SN	Serial Number
	QR code - matrix bar code. All information in the bar code is included in the text under it

11. Description of the Vitalograph Gold Standard

The Vitalograph Gold Standard is a volume displacement spirometer with a rolling seal design which measures subject respiratory parameters including but not limited to FVC, FEV1, FEV6, Max Flow, MVV and VC. The Vitalograph Gold Standard is designed for desktop use with communications capability to connect with Spirotrac PC based software.
A breathing tube is used for testing, with the starting position of the seal adjusted through the use of the volume adjustment handle.

11.1. Indications for Use

The indication for use of the Vitalograph Gold Standard is in the assessment of lung function through the measurement of static and dynamic lung volumes, i.e. spirometry, in association with Spirotrac PC software.
The Vitalograph Gold Standard is designed to be operated by medical professionals trained in respiratory and lung

function testing on adults and paediatrics, 2.5 years and older, in a variety of professional healthcare environments, e.g. primary care, hospitals and occupational health centres. The measurements obtained from a lung function test provide objective information used in the diagnosis of lung diseases and monitoring lung health.

12. Technical Specification

Product	Vitalograph Gold Standard, Model 2150
Flow Detection Principal	Measuring volume displacement of rolling seal spirometer
Volume detection	Flow integration sampling at 100Hz
Maximum test duration	90s
Maximum displayed volume	9.99L
Volume Accuracy	Better than ±3%
Flow Measurement Range	Flow +/- 10% Max. flow rate ±960 L/min (±16 L/s) Min. flow rate ±1.2 L/min (±0.02 L/s)
PEF Accuracy	±10% or ±10L/min of the reading (ISO 23747:2015)
Back pressure	Less than 0.1kPa/L/sec at 14L/sec (ATS/ERS 2005)
Operating temperature range	ISO 26782: 2009 limits: 17–37°C Design limits: 10–40°C
Operating humidity range	30%–75%
Ambient pressure range	850hPa–1060hPa
Performance standards the Vitalograph Gold Standard meets or exceeds	ATS/ERS 2019, ISO 23747:2015 & ISO 26782:2009
Safety standards	EN 60601-1:2006 + A1:2013
EMC Standards	EN 60601-1-2:2015
QA/GMP standards	BS EN ISO 13485, FDA 21 CFR 820, CMDR SOR/98-282 & JPAL
Dimensions	460mm (length) x 389mm (width) x 376mm (height)
Weight	17.5kg
Communications	USB
Power Supply	5V DC via USB 2.0/3.0
Essential Performance	Measuring volume displacement of rolling seal spirometer
Essential Performance Test Limits	Volume Accuracy better than ±3% or ±0.05L of the reading. (ISO 26782:2009)
Minimum PC System Requirements	Processor Speed: 2GHz or greater RAM: 2GB (Min), 4GB (Recommended) Disk Space: 1GB or greater Operating System: Windows 7 or above Monitor: 1280 x 800 pixel Other: • .Net framework 4.5.1 • USB Port for Vitalograph Gold Standard

Notes:

- All values displayed are expressed as BTPS values.
- Time zero is determined using the back-extrapolated method, from the steepest part of the curve. The operating conditions specified apply to the device plus accessories.
- The breathing tube and BVF are classified as type BF applied parts. The device body or other accessories are not applied parts.
- An applied part is a part of the equipment, which in normal use necessarily comes into physical contact with the subject for equipment or system to perform its function.

13. Contraindications, Warnings, Precautions and Adverse Reactions

1. No modification of this equipment is allowed. Any unauthorised changes to the Vitalograph Gold Standard 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 Vitalograph Gold Standard 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. 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.
5. 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).
6. When using the Vitalograph Gold Standard ensure that the breathing tube is not pinched or trapped as spirometry results may be affected.
7. Take care not to block the mouthpiece with tongue or teeth during testing. A 'spitting' action or cough will give false readings.
8. While cleaning, the door will need to be accessed. The door should only be accessed by trained medical professionals and not by patients using the spirometer.
9. When transporting or storing the Vitalograph Gold Standard, handle the device with care to avoid damage, ensuring to keep the device upright at all times, with reference to the keep upright label on the device body
10. 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 Vitalograph Gold Standard is used with Spirotrac a subject fatigue warning will appear after 8 manoeuvres.
11. Do not expose the Vitalograph Gold Standard to liquids with the exception of the isopropyl impregnated cloth described for cleaning the device.
12. The Vitalograph Gold Standard 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 Vitalograph Gold Standard 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 device has been dropped.
14. Service and repairs should be carried out only by the manufacturer or by Service Agents approved by Vitalograph.
15. Maintenance must not be performed while the device is in use by a subject.
16. 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 Vitalograph Gold Standard and result in improper operation.
17. 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.
18. 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 Vitalograph Gold Standard, including cables specified by Vitalograph. Otherwise, degradation of the performance of this equipment could result.
19. 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.
20. The applied part is the breathing tube. This along with the BVF, are the contact points for the subject during a spirometry session. There are no adverse effects from incidental contact with any other part of the Vitalograph Gold Standard device.
21. Reprocessing of single use devices is not permitted.

14. CE Notice

Marking by the symbol CE 2797 indicates compliance of the Vitalograph Gold Standard Model 2150 to the Medical Devices Directive of the European Community.

The Vitalograph Gold Standard 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 Vitalograph Gold Standard should assure that it is not used in such an environment.

The Vitalograph Gold Standard 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 2150 Vitalograph Gold Standard 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 2150 Vitalograph Gold Standard 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
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.

15. FDA Notice

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

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16. EU Declaration of Conformity

Product: Vitalograph Gold Standard, Model 2150

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.

BS 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 85553

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 who the device was purchased from 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.