Vitalograph®

copd-6 BT

MODEL 4000

Instructions for Use

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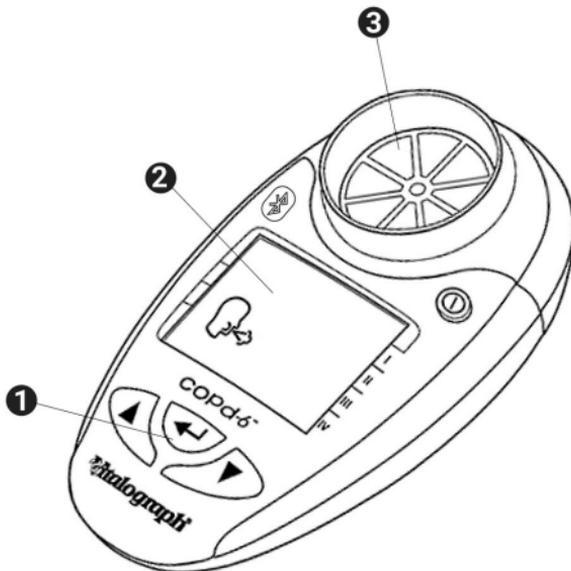
1. Main Components of the Vitalograph COPD-6 BT

Figure 1 Vitalograph COPD-6 BT Components

1	User buttons
2	Display
3	Flowhead
▼	Down Button
▲	Up Button
◄┘	Enter Button

1.1. Features of the Vitalograph COPD-6 BT

- Early detection of COPD.
- Displays FEV1, FEV6, ratio and % predicted, obstructive

index, COPD classification (stage I - IV) and lung age.
- Identifies risk of COPD at pre-symptomatic stage.
- Screens out those with normal FEV1.
- Automatically assesses test quality.
- Large, easy to read display.
- Built-in quality of blow indicator.
- Can be used with SafeTway mouthpiece or Eco BVF.
- Download test results via BlueTooth and export to PDF report using Vitalograph Reports software.

2. Setting Up the Vitalograph COPD-6 BT

To get the COPD-6 BT ready for use:

1. Remove the detachable battery door at rear of unit. Fit two AAA 1.5V batteries. Replace battery door.
2. Turn on via the ⏻ On/Off Button. (The same button is used to power down.)
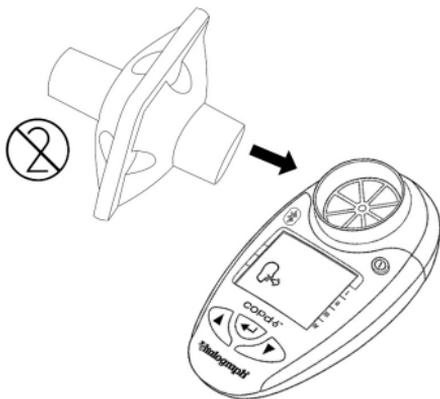3. Attach a mouthpiece to the flowhead, see Figure 2.

Figure 2. Mouthpiece inserted into flowhead

4. Vitalograph intends that a new Eco Bacterial Viral Filter (Eco BVF) be used for every subject to prevent cross contamination. Using a new Eco BVF provides a significant level of protection of the subject, the device and the user

against the risk of cross contamination during spirometry manoeuvres. Eco BVF and SafeTway mouthpieces are single use items and must be disposed of after use.

3. Operating Instructions

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

3.1. Entering Subject Data

The subject's physical data should be entered into the device in order to calculate predicted data. There are default values on the device for age, height, and gender. If default values are used instead of the subject's own information, then the predicted data will not be accurate for the subject being tested.

To enter subject data:

1. Turn device on. $\textcircled{I}$

2. Set subject's age ($\dagger\dagger$) by pressing the $\blacktriangle$ or $\blacktriangledown$ button to reach the correct age. Age increases/decreases in values of 1. If the button is kept depressed, the values scroll faster. Press $\longleftarrow$ to save the age.

3. Set subject's height ($\dagger$) by pressing the $\blacktriangle$ or $\blacktriangledown$ button to reach the correct height. Height increases/decreases in values of 1. If the button is kept depressed, the values scroll faster. Press $\longleftarrow$ to save the height.
   Note: if height values are set below 100, the device assumes height is in inches and that Weight will be in lbs rather than Kg.

4. Set subject's gender ($\female$) by pressing the $\blacktriangle$ or $\blacktriangledown$ button and releasing when appropriate gender shows: Male ($\male$) or Female ($\female$). Press $\longleftarrow$ to save the gender. The device will go to Test Mode showing the Blow Icon. On some variants, an additional data field comes first (see below).

5. (This step may be omitted, depending on the variant. On some variants this is Weight instead.) The Population

Group can be set ($\bigcirc$) by pressing the ▲ or ▼ button and releasing when the desired setting is reached. Press ↵ to save.

Set No.	Population Group
1	NHANES III Caucasian C
2	NHANES III African-American AA
3	NHANES III Hispanic-American HA

3.2. Performing the Test

1. Turn the device on. $\bigcirc$
2. The blow icon shows when the device is ready for a test ( ).
3. Put a SafeTway or Eco BVF filter onto the device.
4. The subject should sit down to blow into the device (unless a physician advises otherwise).
5. Instruct subject to hold their head high and hold the Vitalograph COPD-6 BT ready in front of the mouth, see Figure 3.
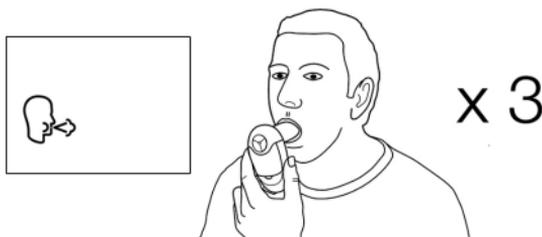

Figure 3. Holding device during test.

6. Instruct subject to
   a. Breathe in as deeply as possible.
   b. Hold the breath.
   c. Place the mouthpiece into the mouth (biting the mouthpiece lightly and sealing the lips firmly around it).
   d. Blow out as HARD and FAST as possible until told to stop (the unit will beep at end of test - after 6 seconds).
   e. Repeat the blow two more times.

7. Instruct the subject not to block the mouthpiece with tongue or teeth. A 'spitting' action will give false readings.
8. To view the result (the best values in the session), press the ◄┘ button.
9. The COPD Classification shows on the right-hand arrow.
   - Green is NORMAL, negative for COPD. No need to refer this subject for spirometry.
   - Any one of the blue zones, I, II, II or IV are not normal. This subject should be referred for spirometry.
10. The Obstructive Index (OI) shows on the left-hand arrow.
    - 0 - Green is NORMAL.
    - 1, 2 or 3 – Yellow, orange or red are not normal. Refer for spirometry, but this is unlikely to be COPD.
    - Note: If the right hand (COPD) arrow is not green, the left hand (OI) arrow will also not be green.
11. This is the end of the test, but if desired some test parameters may be viewed.
12. Following each blow and at the end of the test session, the FEV1 value displays. Below that is the FEV1 % Predicted results for that blow, or for the best in session if the ◄┘ button has been pressed. Pressing ◄┘ again will toggle between best and last blow.
13. Pressing the ▲ button shows the FEV6 and FEV6 % Predicted results.
14. Pressing the ▲ button again shows the FEV1/FEV6 and FEV1/FEV6 % Predicted results.
15. Pressing the ▲ button for a final time shows the estimated Lung Age. (🫁)

Notes on testing:

1. During testing, an exclamation mark (!) indicates a poor-quality blow and the user should blow again. Reasons for poor quality are;
   - Slow Start of test: Vext (extrapolated volume) is > 5% or 150mL of FEV6
   - Cough detected.
2. In the event that a test is < 3 seconds duration and has an

abrupt end (change in volume is > 25ml in the last second of the test), the value FEV will be displayed instead of FEV6.

3. If the subject experiences side effects such as dizziness or fatigue during the test procedure, stop testing until recovered.

3.3. Setting the Obstructive Index and COPD Classification Zones

The device's Obstructive Index and COPD Classification zones are set to the GOLD (Global Initiative for Chronic Obstructive Lung Disease) standard. It is unlikely that a user will need to change this, however if change is required the instructions are outlined below. The colour systems for each zone type are pre-set as follows:

FEV1% Pred.	Obstructive Index		COPD Classification	FEV1/FEV6 Ratio and FEV% Pred.
≥ 80%	0 (Green)		Not COPD	FEV1/FEV6 > 0.7
		Top Boundary	Stage I	FEV1/FEV6 < 0.70 and FEV1 ≥ 80% Pred.
< 80%	1 (Yellow)	Middle Boundary	Stage II	FEV1/FEV6 < 0.70 and FEV1 < 80% Pred.
< 50%	2 (Orange)	Bottom Boundary	Stage III	FEV1/FEV6 < 0.70 and FEV1 < 50% Pred.
< 30%	3 (Red)		Stage IV	FEV1/FEV6 < 0.70 and FEV1 < 30% Pred.

To set the boundary percentage values for both the Obstructive Index and COPD Classification zones together:

1. Turn device on, ⓞ.
2. When the 👤 icon appears, press and hold ◀— and ▲ buttons for approximately 3 seconds.
3. Set the top boundary by pressing the ▲ or ▼ button and releasing when the value is reached. The values increase/decrease in values of 1%. If the button is kept depressed, the values scroll faster.
4. Press ◀— to save the top boundary value.
5. Set the middle boundary by pressing the ▲ or ▼ button and releasing when the value is reached. The values increase/decrease in values of 1%. If the button is kept depressed, the values scroll faster.
6. Press ◀— to save the middle boundary value.
7. Set the bottom boundary by pressing the ▲ or ▼ button and releasing when the value is reached. The values increase/decrease in values of 1%. If the button is kept depressed, the values scroll faster.
8. Press ◀— to save the bottom boundary value.
9. Press ◀—. The device returns to the age entry screen.

3.4. Reviewing Last Session Test Results

The Vitalograph COPD-6 BT always stores the last test session, even after the device has powered itself down or has been switched OFF. To view the last test session:

1. Turn the device on. ⓞ
2. When the device is ready for age entry (👤), press ◀— button for approximately 3 seconds. The last test session (best results) data will show again.
3. When you have reviewed the data, press the OFF button for 3s.
   OR
   Press ◀—. The device returns to the age entry screen.

3.5. Downloading saved results

The test session may be transmitted to Vitalograph Reports on your PC to be stored as a PDF file and viewed or printed.
Vitalograph Reports must be installed and running on the PC before data is transmitted. The software is running if the Vitalograph 'V' icon shows in the PC System Tray. If not, refer to help button of the software for more information. The Bluetooth Adaptor should be plugged in to the host PC to allow communication. Drivers should automatically install.

1. Run Vitalograph Reports.
2. If 'No devices have been detected' message appears, click 'Continue'.
   a. Turn device on, $\mathbb{O}$.
   b. In Vitalograph Reports ensure 'Vitalograph COPD-6' is

      selected via the Device Selection Button
3. To print test results from the COPD-6 BT:
   When the device is ready for age entry, press ◄┘ button

   for 3 seconds for the last saved session. Use the ▲ or

   ▼ buttons to scroll to the Report icon (🗐). Press ◄┘ to print. Click the "Start" button on the main screen of

   Vitalograph Reports.
   OR

   After completing the test session, press the ▼ or ▲

   buttons until the Report icon (🗐) displays Press ◄┘ to print. Click the "Start" button on the main screen of Vitalograph Reports.
4. In Vitalograph Reports enter the Subject Demographic details and Comments. Select 'Continue'.
5. Select a location for the test report on your PC. A PDF of the test results opens and is also stored to the chosen location on the PC.

4. Power Management

The COPD-6 BT operates with 2 AAA 1.5V disposable batteries.
If the battery symbol flashes the batteries should be replaced.
Replace batteries by removing the battery door on the underside of
the device.
Note: *Dispose of used batteries safely.*

5. Cleaning & Hygiene

The COPD-6 BT is not designed or supplied as a 'sterile' device.
Keep the device clean and dust free. If you suspect the device
is damaged or is measuring incorrectly, contact your medical
professional immediately.
The COPD-6 BT should continue to give reliable measurements for
up to three years in home use. It should then be replaced with a new
device.

5.1. Cleaning in Single Patient Environment

For single patient use, the plastic mouthpiece may be used.
Weekly cleaning of the mouthpiece, outside surfaces and flowhead
of the device is recommended. A cloth impregnated with 70%
isopropyl alcohol may be used. The reusable plastic mouthpiece
may be washed in warm soapy water and then rinsed in clean water.
The device should be cleaned before and after an extended period
of storage.

5.2. Preventing Cross-Contamination of Subjects in Clinic use

For multi-patient use in a clinic or telemedicine environment
Vitalograph recommends the use of Eco BVF filters or, if these aren't
available then SafeTway mouthpieces may be used based on the
customer own risk assessment and hygiene controls.
Before use by the next subject, the mouthpiece, outside surfaces
and flowhead of the device should be cleaned with a cloth
impregnated with 70% isopropyl alcohol. The device should be
cleaned before and after an extended period of storage. If you
suspect that a device intended for multi-patient use has become
contaminated, it should be replaced.
When used in the clinic environment, it is recommended that

the device be replaced annually. There is no planned preventive maintenance for this medical device.

6.   Fault Finding Guide

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

7.   Customer Service

For further assistance, setting up, using or maintaining the device or to report unexpected operations or changes in performance, contact Vitalograph, using the contact information at the start of this manual. Also contact the healthcare provider on any changes to the performance of the device, as a precaution.

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
28501	Eco BVF (100)
28572	Eco BVF + Disposable Noseclips (80)
20242	SafeTway Mouthpieces (200)
20303	Disposable Noseclips (200)
20980	SafeTway Mouthpieces mini (50)
20991	SafeTway Mouthpieces long (130)
40167	Pouch Spare (x10)
67201	Bluetooth Adaptor

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. The pouch can be disposed of in unsorted municipal waste. Used Eco BVFs and SafeTways, constitute minimally soiled waste from human healthcare and should be disposed of in line with local requirements. Eco BVFs are made from 100% polypropylene.

10. Explanation of Symbols

Symbol	Description
🧍	Type BF equipment
VA	Power rating
v ---	Direct current
📖	Instructions for Use; operating instructions
▙	Manufacturer
⌁	Date of Manufacture (include date in format yyyy-mm-dd)

Symbol	Description
	The device must be taken to separate collection at the product end-of-life. Do not dispose of these products as unsorted municipal waste
SN	Serial Number
REF	Device Order Number
	Use by Date (Date format yyyy-mm-dd)
	Keep Dry
	Do not re-use
NON STERILE	Non sterile
	Recycle
	QR code - matrix bar code. All information in the bar code is included in the text under it
Other Labels	
	Battery status Battery status Full Battery status Half Battery status Quarter Battery status Empty (flashing)
	Blow Now Symbol
!	Bad Test Symbol
kglb	Unit of Weight/Measurement

Symbol	Description
	Lung Age
	Age Icon
	Height Icon
	Gender Icon
	Memory 90% - 100% Full Icon Flashes when memory reaches 100%
	Transmit Report Symbol

11. Description of the Vitalograph COPD-6 BT

The Vitalograph COPD-6 BT is a device intended for measuring lung function. It can be used by healthcare professionals or assistants as a rapid pre-spirometry test to screen-out at-risk individuals who do not have COPD and indicate those who may be at risk of COPD at the presymptomatic stage. This "screening" or "case selection" for full spirometry examinations may result in earlier medical intervention and facilitate better clinical outcomes.

The device displays some key parameters for clinical interpretation:
- FEV1 and FEV1 % Predicted
- FEV6 and FEV6 % Predicted
- FEV1/FEV6 and FEV1/FEV6 % Predicted

If an abnormal result is indicated, arrows on the display show:
- Obstructive Index
- COPD Classification (stages I - IV)

11.1. Indications for Use

The Vitalograph COPD-6 BT is a hand held respiratory monitor which measures subject respiratory parameters FEV1 and FEV6. It

also displays FEV1 %, FEV6 % Predicted and FEV1/FEV6 ratio. It is designed for lung function testing of adults and children, 5 years and older, in the home and professional healthcare environments, e.g. primary care, hospitals and occupational health centres. The device is intended to be operated by the patient, under the supervision of a healthcare provider.

12. Technical Specification

Product	Respiratory Monitor COPD-6 BT
Model	4000
Dimensions	109mm (length) x 63mm (width) x 42mm (height)
Weight	63g (not including batteries)
Flow Detection Principal	Stator/rotor
Accuracy:	Better than ± 3%
Flow Impedance:	Better than 0.15kPa/L/s at 14L/s
Back pressure	Less than 0.15kPa/L/second @ 14L/s
Measurement Range:	0 – 9.99 L BTPS
Power Supply:	3V (2 x 1.5V AAA batteries)
Battery Life	3 months of use, 3 tests per day (Batteries near the end of their shelf life will have reduced capacity.)
Product Life	6 Years for the main device. The Eco BVF, SafeTway & nose clips are single use.
! Bad Test Criteria:	Slow start of test (Vext>5%) or a cough detected in the first second
FEV substituted for FEV6	When FET < 3s and abrupt end of test

Operating temperature range	17 – 37°C
Operating humidity range	30%–75%
Ambient pressure range	850hPa–1060hPa
Performance standards:	ATS/ERS 2019, ISO 23747:2015, ISO 26782:2009
Safety standards	EN 60601-1, EN 60601-1-11
EMC Standards	EN 60601-1-2
QA/GMP standards	EN ISO 13485, FDA 21 CFR 820, CMDR SOR/98-282, JPAL, MDSAP.
Communications	Bluetooth
Bluetooth Adaptor Requirements	USB2.0/3.0
PC Requirements	Windows® 7, Windows® 8 or Windows® 10
Auto power down time	Set to 2 minutes as standard

13. Contraindications, Warnings, Precautions and Adverse Reactions

1. No modification of this equipment is allowed. Any unauthorised changes to the 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 device should only be used under the supervision of a healthcare professional.
3. The device is not designed as a sterile device. Always follow the safety guidelines given by the manufacturer of cleaning and disinfectant chemicals.
4. Vitalograph intends that a new Eco Bacterial Viral Filter (Eco BVF) be used for every subject to prevent cross contamination. Using a new Eco BVF provides a significant level of protection of the subject, the device and the user against the risk of cross contamination during spirometry manoeuvres. An Eco 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). And as such, spirometry may support or exclude diagnosis, but it cannot make one.

6. Take care not to block the mouthpiece with the tongue or teeth during testing. A 'spitting' action or cough will give false readings.

7. Subject fatigue may occur during 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 can also take a break between tests.

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. Symptoms must take precedence over device measurements.

11. Do not expose the device to liquids other than cleaning liquids specified.

12. Keep device dry. If the device gets wet, do not use it, and contact Vitalograph using the contact information at the start of this manual. Do not connect any part of this device to mains power as there is a risk of injury especially if the device is wet.

13. The device is not intended to be used in the presence of flammable liquids or gases, dust, sand or any other chemical substances.

14. Service and repairs should be carried out only by the manufacturer or by Service Agents specifically approved by Vitalograph.

15. RF communications equipment (including peripherals such as antenna cables and external antennas), which emit electromagnetic fields, should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by Vitalograph. Otherwise, degradation of the performance of this equipment could result.

16. The device is a Type BF applied part. The subject comes into contact with the device, mouthpiece, SafeTway or Eco BVF

during use.
17. Take care during battery replacement or during Bluetooth adaptor installation. An AAA battery and Bluetooth adaptor are potential choking hazards for a small child. Adult supervision is required at all times, when a child is using the device. The battery door, when removed, has pointed corners which may present a risk of injury.
18. The batteries should be removed if the device is intended to be stored or left unused for an extended period of time.
19. Only approved accessories from the manufacturer should be used with the device. It is may be unsafe to use accessories, detachable parts and materials not described in this document.
20. Non-Medical Electrical equipment used with the device, should comply with its relevant IEC or ISO standard.
21. 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.

14. CE Notice

Marking by the symbol $C\,\epsilon$ 2797 indicates compliance of the Vitalograph Model 4000 COPD-6 to the Medical Devices Directive of the European Community.

The Vitalograph Model 4000 COPD-6 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 COPD-6 should assure that it is not used in such an environment.

The Model 4000 COPD-6 has been tested in accordance with:

EN60601-1:2006 + A1:2013
Medical electrical equipment. General requirements for basic safety and essential performance

EN 60601-1-11: 2015
Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

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 - Emissions tests		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Model 4000 COPD-6 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 4000 COPD-6 is suitable for use in all establishments, including domestic establishments.

EN 60601-1-2 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.

16. EU Declaration of Conformity

Product: Respiratory Monitor 4000, COPD-6
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

$C \epsilon$
2797

Signed on behalf of Vitalograph (Ireland) Ltd.

Frank Keane.
CEO, Vitalograph Ltd.

17. Guarantee

1. 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:-

2. 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.

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.