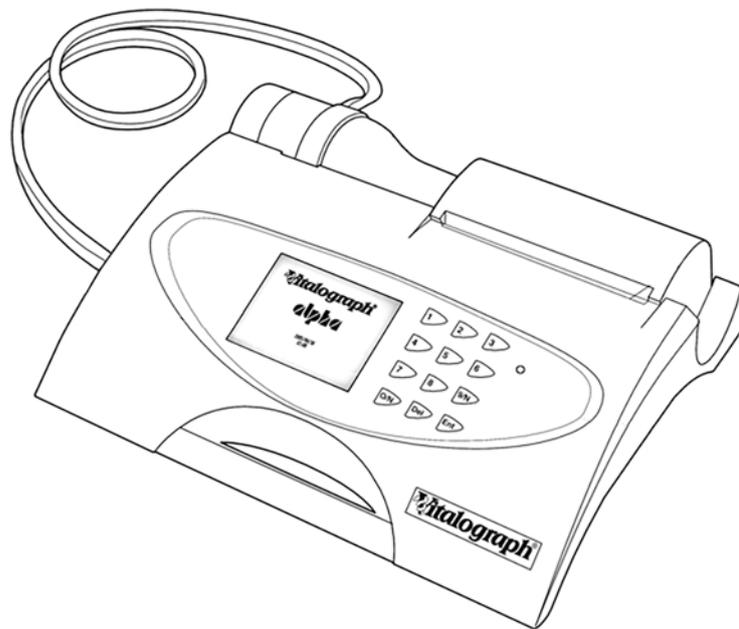# *Vitalograph*®
ALPHA
MODEL 6000
Instructions for Use

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2797

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Table of Contents

1. Main Components of the Vitalograph ALPHA

The main components for the Vitalograph ALPHA are shown below.
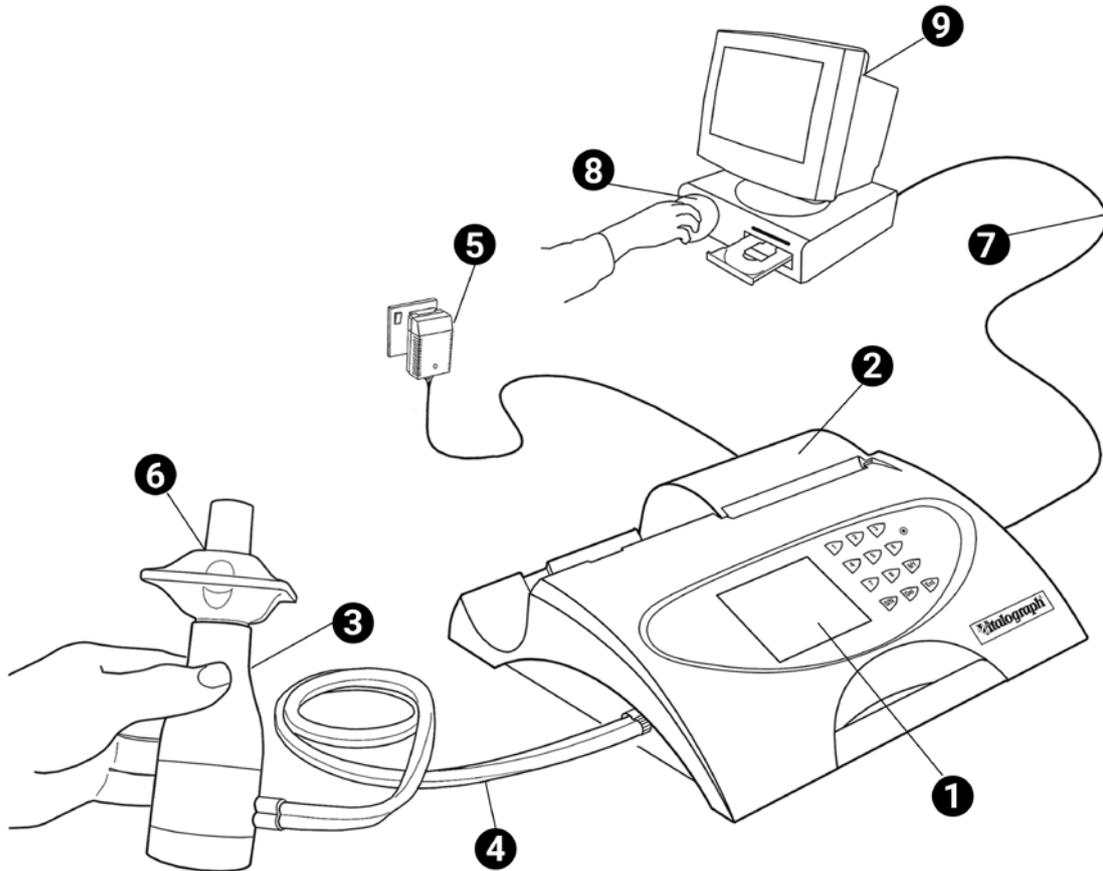
Figure 1 Main components of ALPHA

Note: Computer not supplied

1.	Display
2.	Internal Thermal Printer
3.	Flowhead
4.	Flowhead Connection Tubing
5.	Approved Power Supply
6.	BVF^{TM} Disposable Mouthpiece
7.	USB Cable
8.	Vitalograph Reports Software (Optional)
9.	User's PC

1.1. Features of the Vitalograph ALPHA

The Vitalograph ALPHA features include:
- Fleisch type pneumotachograph to measure flow
- Ambient temperature sensor
- Keypad with extra-large buttons
- Integral printer
- Storage of tests and demographic information
- Ability to exchange information with a computer

2. Setting Up the Vitalograph ALPHA

To get the Vitalograph ALPHA ready for use:

1. Unwrap silicone twin tubing and connect one end to the ALPHA base. The tubing is ribbed on one side. Ensure that the coloured/ribbed tapping on the flowhead is connected to the ribbed side of the connection in the housing.
2. Connect other end of flowhead tubing to the flowhead.
3. Connect the power supply into the rear of the ALPHA. Plug the mains plug into a suitable socket. Switch the ALPHA on (switch at rear) and it is ready for use.

Note: Only use the ALPHA with the purpose-built low voltage power supply unit with which it is supplied. Attempted use with other power sources may cause irreparable damage and invalidate the warranty.
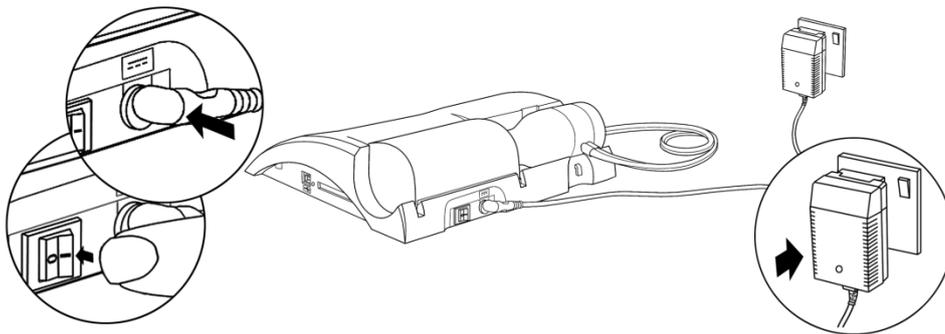

4. The ALPHA comes fitted with a rechargeable battery pack, which allows the device to be used as a portable device without the mains connected.
5. The ALPHA can be connected through the USB port at the side of the unit to the user's computer, so that the report can be written to the Vitalograph Reports Utility (refer to the Vitalograph Reports Instructions for Use)
6. The Vitalograph ALPHA may be used as a flowhead for testing with Spirotrac® software (purchased separately, see Spirotrac IFU for how to do this).

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.

2.1. Fitting a New Paper Roll

The ALPHA is supplied with a roll of paper fitted into the printer. *Note: Paper is light sensitive so the outside of the roll of paper will not give a strong print impression.*
To replace the paper (see Figure 3 below):

1. Open printer door to expose the head of the printer and the paper cartridge.
2. Take out the cartridge that holds the empty paper roll and remove the empty roll.
3. Put new roll of paper into the paper cartridge and unroll about 12cm (6 inches) of paper. Note: To make fitting easier, create a point in the middle of the paper by tearing or cutting the two corners of the leading edge of the paper.
   Note: The Vitalograph logo should be facing you on the right edge of the paper.
4. Clip the paper cartridge back into place between the back of the ALPHA and the inside of the open door. The paper should come out from the bottom of the roll and point towards the printer. This allows more access to the printer feed mechanism.
5. In the home screen, lift the green lever on the printer.
6. Feed the leading edge of the paper into the bottom slot of the printer until the paper appears through the top of the printer. The paper can now be pulled through. To

feed the paper through the printer, press the "Enter" key on the keypad. This will feed a short length of paper through the printer.

7. Close the green lever.
8. Hold the paper over the paper tear bar and close the door.
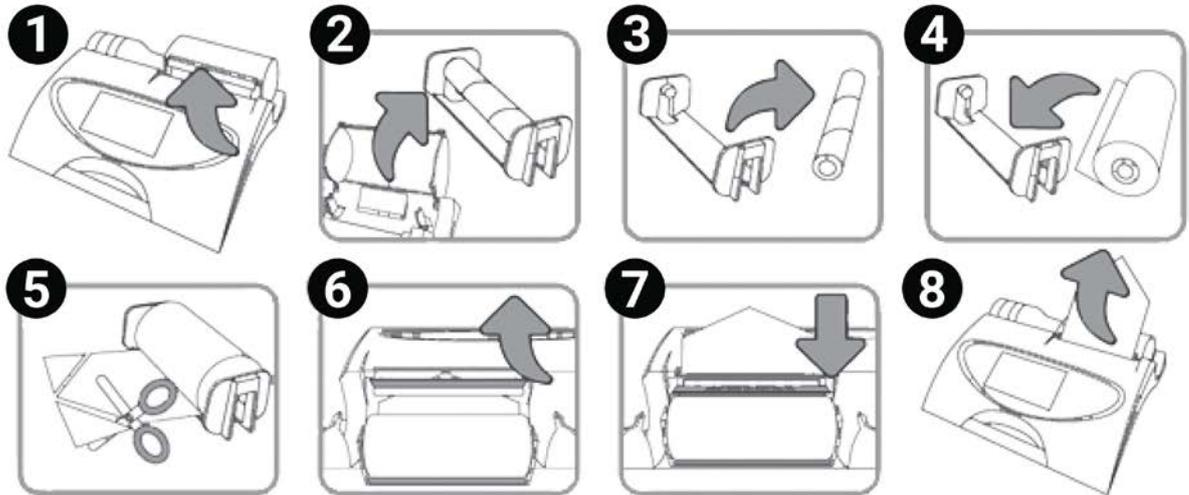
Figure 4 – Fitting a new paper roll.

Warning: *The paper tear bar has sharp edges. Take care not to cut fingers.*

3. Operating Instructions

Turn on the ALPHA (the On/Off switch is at the back of the device).
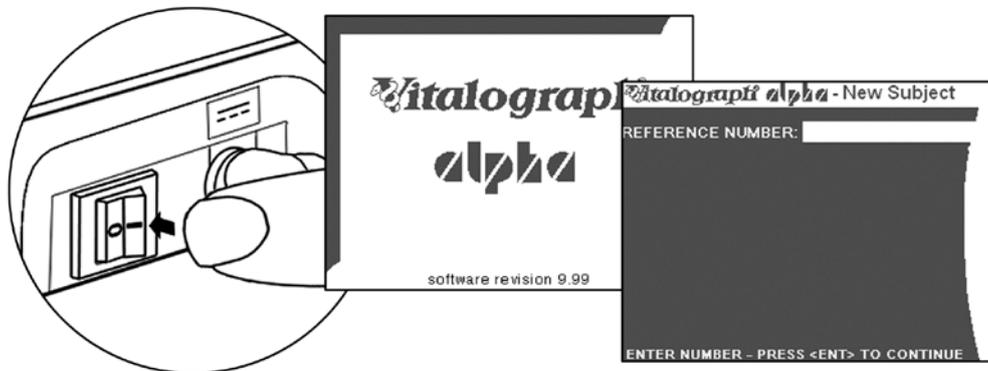
3.1. Entering Subject Data

After a short delay, the 'Welcome' screen displays briefly. This is followed by a screen for entering a new subject's detail showing the first field to be entered. Enter a number for the SUBJECT ID, then press the *Enter* key. Enter number for AGE, then press the *Enter* key. Repeat for all fields. Dialog boxes appear one at a time in the following order:
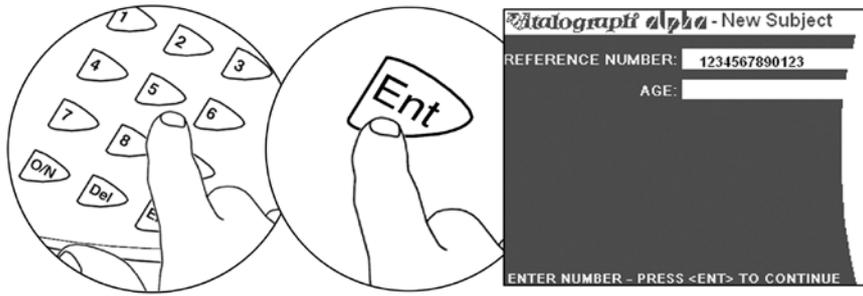
1. Reference Number
2. Age
3. Height
4. Gender
5. Ethnicity
6. Weight
7. Smoking History

Use the *Delete* key to remove data, then enter new information. Press the *Delete* key repeatedly to step back through the dialog boxes. When subject information is complete and correct, press the *Enter* key twice to return to the **Main Menu.** The Subject Information will be printed to the internal printer unless printing is deselected.

This screen may be by-passed to access the Main Menu screen directly by pressing the Enter key 3 times (e.g. for calibration verification before patients arrive).

***Note:** Ethnicity categories may differ between device variants. Weight and Smoking History fields are not available in all variants of the ALPHA.*

To enter another subject's details, select the 'New Subject' option from the **Main Menu** using the keypad. A dialog box will appear to confirm whether to clear current subject details.

- Press *Yes* to open New Subject screen and enter the **New Subject** details.
- Press *No* to return to Main Menu.

3.2. Conducting a Test[1]
Before starting a test session:
1. Ensure that the accuracy of the device was checked recently. (Refer to section: "Calibration Verification").
2. Select a subject and ensure the required demographic information is entered.
3. Wash hands (operator and subject).
4. Fit a new Bacterial Viral Filter (BVF) to the flowhead for each test subject. The use of a disposable noseclip is recommended.
5. Instruct and demonstrate the test.

3.2.1 Testing
1. Select either the 'VC Test' or 'FVC Test' option from the Main Menu.
2. Select how the results should be presented:

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[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

- **VC Test** – Press key 1 for Volume/Time (V/T) graph and key 2 for Volume (Bar Chart).
- **FVC Test** - Press key 1 for Volume/Time (V/T) graph and key 2 for Flow/Volume (F/V) graph.
3. Wait for the 'Exhale to Begin' icon to appear.

The device is now ready to accept a blow.

Example script:
- Sit upright, fit the nose clip and relax.
- Place BVF in mouth and close lips around the mouthpiece.
- Seal your lips around the mouthpiece and keep your tongue down.
- Breathe normally

VC test session:
a. Inhale completely with a brief pause when your lungs are completely full (≤ 2 secs).
b. Exhale with no hesitation until no more air can be expelled while maintaining an upright posture. *It is vital that the operator encourages the subject to keep exhaling to ensure all air is expelled (when a plateau has been reached or forced expiratory time (FET) reaches 15 seconds).*
   The operator should repeat instructions as necessary, coaching vigorously
c. Listen for two beeps. This indicates that device is ready for the next blow.
d. Repeat for a minimum of three manoeuvres, usually no more than eight for adults.
e. Check VC repeatability and perform more manoeuvres as necessary.

NOTE: A single-breath VC technique may also be performed on the device.

FVC test session:
f. Inhale completely and rapidly with a brief pause when your lungs are completely full (≤ 2 secs).
g. Exhale with maximal effort until no more air can be expelled while maintaining an upright posture. *It is vital that the operator encourages the subject to keep exhaling to ensure all air is expelled (when a plateau has been reached or forced expiratory time (FET) reaches 15 seconds).*
   The operator should repeat instructions as necessary, coaching vigorously
h. Breathe in with maximal effort until completely full. The manoeuvre is now complete and the BVF is removed from the mouth.
i. Listen for two beeps. This indicates that device is ready for the next blow.
j. Repeat for a minimum of three manoeuvres, usually no more than eight for adults.
k. Check FEV1 and FVC repeatability and perform more manoeuvres as necessary.

NOTE: A single-breath FVC technique may also be performed on the device.

3.2.2 Saving the Test Session

1. Select *Post Mode* from the Main Menu using the keypad.
2. Select *Save Current Subject Pre Test* from the Post Mode screen using the keypad. An information dialog box will appear showing the memory location where the test session will be saved. There are nine memory locations on the ALPHA. The best three tests will be saved.

Note: If a Compact Flash card is inserted into the Compact Flash connector at the right side of the device, then all test blows and not just the best three will be saved to

the compact flash card. Results are saved as per the format outlined in the ERS/ATS Task Force Report on Standardisation of Lung Function Testing (2005)[2].

3.2.3 Bronchodilator Responsiveness Testing
A Bronchodilator Responsiveness Test session can be performed on an FVC test session following the administration of drugs. Post drug delivery performance is measured versus pre delivery.

To perform a Bronchodilator Responsiveness Test Select *Post Mode* from the Main Menu using the keypad:

1. To perform a Bronchodilator Responsiveness Test on the Pre-test Session just performed, select *Set Post Mode for Current Subject*. The device will return to the Main Menu screen with the text *Post Mode* in the top right-hand corner of the screen.
2. To perform a Bronchodilator Responsiveness Test on a different subject or Pre-test:
   a. Select, '*Select a Subject' from the Pre-Store*.
   b. A message *'Warning! Current Results will be cleared'* will appear. Select *Yes* and the Select Subject screen opens.
   c. Select the number of the Pre-test for which Bronchodilator Responsiveness Testing is required. The device will return to the Post Mode screen.
   d. Press *Enter* to return to the Main Menu screen.

Perform the Post VC and/or Post FVC test as outlined in section, Performing a Test Session.

Note: *If there is no Pre-Test saved, the message No FVC Tests Performed will appear.*

3.2.4 Viewing Current Subject Details
To view the Current Subject details:

1. Select *Post Mode* from the Main Menu using the keypad.
2. Select *View Current Subject* from the Post Mode screen.
3. The Current Subject screen displays.

Note: *It is not possible to modify any of the subject details.*

3.2.5 Deleting a Test Session
To delete the current session:

1. Select the *Clear Results* option from the Main Menu using the Keypad.
2. A message will appear *'Warning! Current Results will be Cleared. Do you wish to proceed?* Select *Yes* to delete the current results *or No* to cancel the delete. Screen returns to the Main Menu.

3.3. Reporting

Select *Print* from the Main Menu to print the current test session.

The information printed on the session report can be configured to suit user requirements. Refer to the section on Report Options.

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[2] ATS/ERS Standardisation of Spirometry Eur Respir J 2005; 26: 319–338

Note: The internal (thermal) printout will fade over time when exposed to light or heat. If a permanent record is required, photocopy the thermal printout or send the report to the Vitalograph Reports Utility. Refer to the section on <u>Configuration</u> for information on selecting the internal or Vitalograph Reports Option.

3.4. Deleting Stored Subjects/Test Results

To delete individual Stored Subjects/Test results:
1. Select *Post Mode* from the Main Menu using the keypad.
2. Select *Delete Stored Tests* from the Post Mode screen. A list of Subjects and their associated stored test is presented. A maximum of nine Subject/Tests can be stored on the device in locations 1-9 as indicated in the Delete Subject screen.
3. Use the keypad to select the number of the Subject/Test to be deleted. This location will then be marked as '*Empty*'.
4. Continue to delete tests as required.
5. Press *Enter* to return to the Post Mode screen.

To delete all Stored Subjects/Test results:
1. Select *Post Mode* from the Main Menu using the keypad.
2. Select *Clear Pre Store* from the Post Mode screen.
3. A message *'Warning! All data in pre store will be cleared. Do you wish to proceed?'* will appear in the Clear Results screen.
4. Select *Yes* to delete the all data and return to the Post Mode screen. Select *No* to cancel the delete and return to the Post Mode screen.

3.5. Calibration Verification
1. Attach flowhead to the syringe with a BVF fitted as per figure 2.

Figure 2: Accuracy Check

2. Select *Accuracy Check* from the Main Menu using the keypad.
3. Pump air through the flowhead to bring it to ambient temperature.
4. If the flowhead has very recently been used for testing or has come from a cold environment, its temperature should be equilibrated by pumping air through it from the syringe several times.
5. Press the *Enter* key to open the Accuracy Check screen and follow the on-screen instructions.
Note: Press the 'Del' key to exit the Accuracy Check screen and return to the Main Menu. The accuracy check will not be logged in this case.

6. If an Accuracy Check report is required select the <Y> PRINT option.

Note: If the device is outside calibration, the user is offered the option to update calibration. Selecting this option repeats the accuracy check routine on the device.

3.6. Configuration Options

There are a number of Configuration options available on the ALPHA through the *Configuration* option on the Main Menu. When updating configuration settings, press *Enter* to save changes *or* press Del to cancel changes. Screen returns to the Configuration screen.

The options available are:

3.6.1 Preferences

Set user requirements on the following options:

Printer – Select whether to print the test report to the Internal Printer or send to the Vitalograph Reports Utility on a PC. Press key '1' on the keypad to switch between the two options.

Note: In order to send the report to the Vitalograph Reports Utility it is necessary to have the Reports Utility installed on a PC and the ALPHA connected to the PC via a USB cable.

Units - Select units as either Metric or Imperial (US). Press key '2' on the keypad to switch between the two options.

Graph Type - Select default graph type to be shown in the FVC test screen. Press key '3' on the keypad to switch between the Volume/Time (V/T) and Flow/Volume (F/V) graphs.

Test Acceptability – Select whether to manually accept the tests performed, or for the device to determine test acceptability (automatic). Press key '4' to switch between Manual and Automatic.

VC Test Type - Select graph type to be shown as default in the VC test screen. Press key '5' on the keypad to switch between Volume/Time (V/T) and Volume Bar graphs.

3.6.2 Date/Time

1. Select 'Date/Time' from the Configuration screen using the keypad.
2. In Date/Time screen press key '1' to change the year. Enter the revised year and press *Enter* to save changes. The Month, Day, Hour and minute fields are modified in the same way by selecting the corresponding key.
3. To modify the Date Format press key '6' repeatedly to switch between different date formats: **DD/MM/YYYY   MM/DD/YYYY   YYYY/MM/DD**
   Press *Enter* to save changes.
4. To modify the Time Format press key '7' to switch between 24 hour and 12 hour. Press *Enter* to save changes.

3.6.3 Report Options

The information printed on the session reports is configurable. To configure reports:

Use the keypad to select *Report Options* from the **Configuration** screen. This lists items that can be configured on the test reports:

- Press key '1' to switch the Volume/time (V/t) graph on or off.
- Press key '2' to switch the Flow/Volume (F/V) graph on or off.
- Press Key '3' to switch the Comments on or off.
- Press key '4' to switch the Test QA messages on or off.
- Press key '5' to switch the Interpretation of the test results on or off.

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- Press key '6' to switch between showing SDS (Standard Deviation Score) or %Predicted to be printed in the session table of results. (% Predicted is default).
- Press key '7' to switch between showing 'Best Test' only or the 'Best 3 Tests' (as saved to the database) on report printout.
- Press key '8' to switch colour on or off. *Option not available for internal printer.*

3.6.4 Syringe/Calibration

Select the Syringe/Calibration menu using the keypad. There are three options:

Set Syringe Volume - Select Precision Syringe using the keypad, then enter the volume of the calibrated syringe you are using. Press *Enter* to save the new volume entered *or* press Del to undo. Screen returns to the Syringe/Calibration screen.

Linearity Check - Select Linearity Check using the keypad, then complete the check as follows:

a. Using a 3L calibrated syringe, pump air through the flowhead to bring it to ambient temperature. If the flowhead has very recently been used for testing or has come from a cold environment, its temperature should be equilibrated by pumping air through it from the syringe several times.

b. Press the *Enter* key to open the Linearity Check screen.

c. Pump air into the flowhead at a slow rate of <2L/s. Immediately withdraw the syringe at a slow rate. This manoeuvre should show on the graph between the two red lines. If it is a correct manoeuvre the table on the screen will show 'Test 1', and the FVC and FIVC values will be updated. Repeat for the slow rate three times in total.
    Note: *Press the Del key to exit the **Linearity Check** screen.*

d. Repeat the procedure for a medium rate >2L/s and <6L/s. This manoeuvre should show on the graph between the red and green lines. If it is a correct manoeuvre the test number and the FVC and FIVC values will be updated in the table. Repeat for the medium rate three times in total.

e. Repeat the procedure for a fast rate >6L/s. This manoeuvre should show on the graph between the outside green lines. If it is a correct manoeuvre the test number and the FVC and FIVC values will be updated in the table. Repeat for the fast rate three times in total.

f. When all manoeuvres are complete press *Enter* for the result.

g. If a Linearity Check report is required select the *Report* option.

3.6.5 Calibration

Calibration is not required for normal use. Calibration should only be conducted by, or under the guidance of Vitalograph Service Agents. See contact details on p. 2.

Select Calibration using the keypad, then calibrate by the following steps:

a. Pump air through the flowhead to bring it to ambient temperature. If the flowhead has very recently been used for testing or has come from a cold environment, its temperature should be equilibrated with ambient by pumping air through it from the syringe several times.

b. Press the 'Enter' key to open the Calibration screen and follow the on-screen instructions.

Note: Pressing the 'Del' key will exit the Calibration screen.

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    c. If a Calibration report is required select the Report option.

3.6.6 Sound Volume

Select *Sound Volume* from the Configuration screen using the keypad.

1. Adjust the sound level up by pressing key '2'.
2. Adjust the sound level down by pressing key '8'.

4. Power Management

The ALPHA can be powered using the purpose-built low voltage Power Supply unit with which it is supplied or from the internal Battery Pack.

The Power Supply unit should be checked regularly and replaced when necessary.
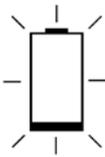
4.1. Battery Pack

The ALPHA is fitted with a rechargeable Battery Pack. This allows the device to be used without the 12V Power Supply connected. The battery pack can be re-charged by plugging in the 12V Power Supply. To fully re-charge, switch off the ALPHA and leave it plugged in overnight.

The battery pack should be replaced after 3 years. Battery replacement should be carried out only by the manufacturer, the approved importer or by Service Agents specifically approved by Vitalograph.

Note: It is not possible to power the device or charge the batteries from the USB.

4.2. Battery Low Detect

The battery power detect messages are:

	Battery Low: The icon flashes on and off on the **Main Menu** screen. The Battery Pack is running low. You may continue to use the device. As a precaution, plug in the 12V Power Supply to re-charge the batteries and continue testing.
	Battery Discharged: The icon appears continuously on the **Main Menu** screen. The Battery Pack is out of power. If you press any key a warning message appears and you will not be allowed to proceed further. Plug in the 12V Power Supply to re-charge batteries and continue testing.

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 for 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 ALPHA

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-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[3].

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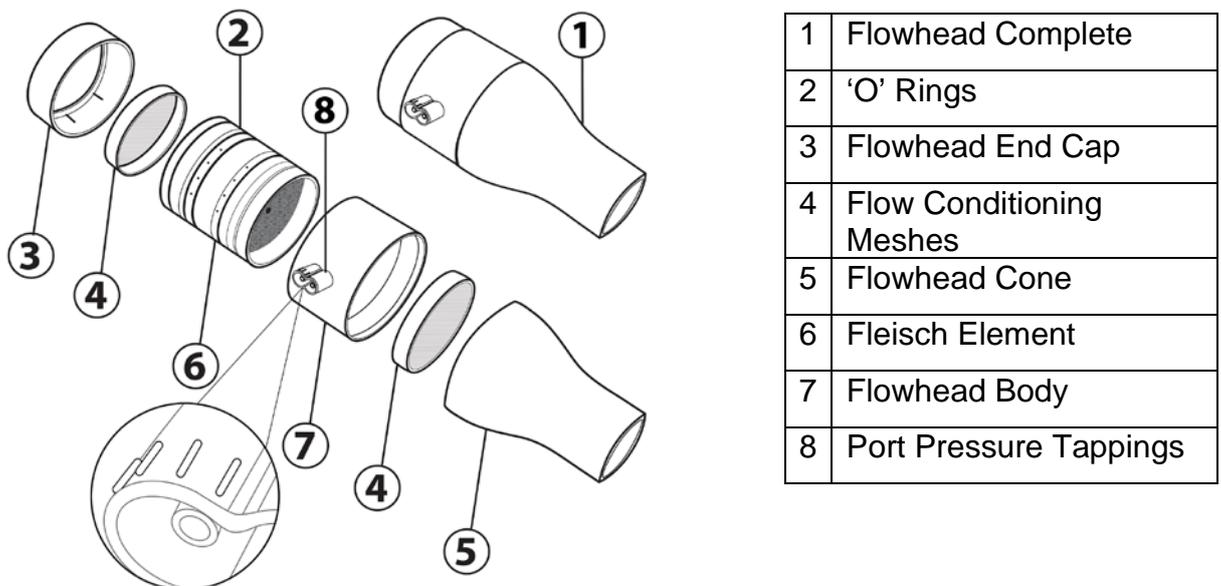
Figure 3: Flowhead Assembly

6. Fault Finding Guide

Problem Fault Symptoms:	• **Accuracy check variations > +/-3%** • **False readings suspected**
Possible Causes: (In probable order)	• Recheck Calibration with reference to section Checking Accuracy • Was the correct syringe volume selected? • An accuracy check is required after cleaning/disinfecting the flowhead Fleisch element assembly. • Flowhead cone Fleisch element filter mesh missing or blocked. • Flowhead body pressure port holes blocked. • Flowhead Fleisch element assembly sealing 'O' rings damaged. • Flowhead Fleisch element assembly not dried thoroughly.

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[3] 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

	• Flowhead Fleisch element assembly blocked. • Flowhead body tubing from pressure ports 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.**
Possible Causes: (In probable order)	• Flowhead and/or tubing not stationary at the start of test. Hold them steady until the 'Ready to Blow' prompt appears. • Return to Main Menu and re-enter the test routine.
Problem Fault Symptoms:	• **Rocking device.**
Possible Causes: (In probable order)	• Check for damaged or missing rubber feet. • If any of the rubber feet are damaged or missing replace all six rubber feet.
Problem Fault Symptoms:	• **Reversed or no volume measurements.**
Possible Causes: (In probable order)	• Ensure tubing is connected correctly. Ribbed side of tubing should be connected to the ribbed half of the connector on the ALPHA and the blue tapping on the flowhead connector. • Ensure that the flowhead connecting tube is not pinched or trapped.
Problem Fault Symptoms:	• **Cannot print to internal printer.**
Possible Causes: (In probable order)	• Check that internal printer is selected in Configuration screen. • Check the paper is loaded correctly and not reversed. • Ensure the green flap on the printer is pressed down. • Internal printer failure – contact support.
Problem Fault Symptoms:	• **Cannot print to PC (Vitalograph Reports Utility).** • **Corrupt or missing data on printout.**
Possible Causes: (In probable order)	• Check that external printer is selected in Configuration screen. • Check USB cable is connected to the ALPHA and the PC. • Check that Vitalograph Reports Utility is correctly installed. • Check the required software drivers are installed on the PC. • Electronics failure – contact support.
Problem Fault Symptoms:	• **Cannot read screen.**
Possible Causes: (In probable order)	• Ensure the switch on the back of the unit is in the *On* position. • LCD failure – contact support. • Electronics failure – contact support.

6.1. Software Check

The software version and issue are shown on the About screen. Please quote this, and the serial number of the ALPHA, to an approved support desk when requesting further advice or assistance.

7. Customer Service

Service and repairs should be carried out only by the manufacturer, or by Service Agents specifically 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
28350	BVF - Bacterial/Viral Filters (50)
28501	Eco BVF – Bacterial/Viral Filters (100)
28572	Eco BVF and Disposable Nose Clip (80)
20303	Nose Clips (200)
36020	3-L Precision Syringe
66149	Thermal Printer Paper (5)
42084	Flow Conditioning Mesh (10)
67252	USB Cable
65054	Alpha 12V PowerSAFE Spare UK
65055	Alpha 12V PowerSAFE Spare EU, AU, US
61030	Flowhead Complete
42029SPR	Flowhead Connection Tube
77939	Flowhead Cone
77938	Flowhead End Cap
2120013	O-Ring (15)
65354	CD with User Manual
65049	Test Data Storage Card
65030SPR	Vitalograph Reports Utility

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
V	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
	Storage Temperature Limit
	Storage Relative Humidity Limits
	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 ALPHA

The Vitalograph ALPHA is a spirometer which measures subject respiratory parameters including but not limited to VC, FVC, FEV1, PEF and MVV. The Vitalograph ALPHA is designed for desktop use. The Fleisch flowhead is used for testing and has a resting location on the device.

11.1. Indications for Use

The indications for use of the Vitalograph ALPHA is in the simple assessment of respiratory function through the measurement of dynamic lung volumes.

The Vitalograph ALPHA 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

form part of the various findings of a physician in the detection, diagnosis and control of chest diseases.

12. Technical Specification

Product	Vitalograph ALPHA, model 6000
Flow Detection Principal	Fleisch type pneumotachograph
Essential Performance	Flow measurement output
Essential Performance Test Limits	Flow Accuracy ±10% or ±20 L/min, whichever is greater
Back pressure	Less than 0.1kPa/L/second @ 14L/s, complies with ATS/ERS 2019
Volume detection	Flow integration sampling @ 100Hz
Maximum test duration	90 seconds
Maximum displayed volume	10 L
Volume accuracy	Better than ±3%
Voltage/frequency	5V USB power
Accuracy when operated in operating temperature range conditions	Flow ±10% Max. flow rate ±16 L/s Min. flow rate ±0.02 L/s
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 ALPHA meets or exceeds	ATS/ERS 2019, ISO 23747:2007 & ISO 26782:2009
Safety standards	EN 60601-1
EMC Standards	EN 60601-1-2
QA/GMP standards	EN ISO 23747:2007, EN ISO 26782:2009 & FDA 21CFR820
Dimensions	300 mm (length) x 250 mm (depth) x 75 mm (height)
Weight	2 kg net
Storage Temperature	0–50°C
Storage Relative Humidity	10%–95%
Printer	Thermal
Communications	USB and Compact Flash
Power Supply	12V, 1.5A DC power supply 7.2V, 1.8Ahr NiMH battery
Minimum PC System Requirements to run Vitalograph Reports	Processor: Pentium, Celeron CPU, 1.73 GHz or better Operating Systems: Windows® 7, Windows® 8 or Windows® 10 Memory: 128 MB of RAM, 256 MB recommended Hard Disk: 40MB for the Vitalograph Reports application 280MB for the .NET framework Display: A display supporting a resolution of 1280 x 800 pixels, higher recommended. Other:

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	• Installation of the .NET Framework 3.5
	• CD-ROM drive
	• USB Port
	Install the application as System Administrator and provide full read/write access rights to the folder and sub-folders where the application has been installed, for all applicable users.
	• Internet Explorer 8.0 or above required.

Notes:
o *All values displayed are expressed as BTPS values.*
o *Take care not to block the mouthpiece with the tongue or teeth. A 'spitting' action or coughing will give false readings.*
o *Time zero is determined using the back-extrapolated method, from the steepest part of the curve. The operating and storage conditions specified apply to the device plus accessories.*
o *The flowhead 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, that 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 ALPHA 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 ALPHA 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 any 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 ALPHA ensure that the flowhead connecting tube is not pinched or trapped as spirometry results may appear to be inverted.

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 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 ALPHA device is used with Spirotrac a subject fatigue warning will appear after 8 manoeuvres.

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 ALPHA to liquids, with the exception of the isopropyl alcohol impregnated cloth described in section 5.1.

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

15. Maintenance must not be performed while the device is in use by a subject.

16. The device contains a Lithium coin cell battery and a Nickle-metal hydride (NiMH) main battery which are not accessible by the user. Any suspected battery faults should be reported to the manufacturer.

17. The internal NiMH battery is not user accessible or user replaceable. In the unlikely event that any issues are noted with the power or battery such as swelling or leaking, stop using the device immediately, do not charge the device and contact Vitalograph support. In case of leaking ensure the electrolyte does not get in the eyes or touch skin. If electrolyte contacts the eyes flush the area immediately with water for 15 minutes and seek medical attention. If electrolyte contacts the skin wash the affected area immediately and seek medical attention. Do not inhale the leaked material, leave the area immediately and allow the battery to cool and any material to dissipate.

18. 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 ALPHA and result in improper operation.

19. 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.

20. 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 ALPHA, including cables specified by Vitalograph. Otherwise, degradation of the performance of this equipment could result.

21. 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.

22. 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 ALPHA device.

14. CE Notice

Marking by the symbol CE 2797 indicates compliance of the Vitalograph Model 6000 ALPHA to the Medical Devices Directive of the European Community.

The Vitalograph Model 6000 ALPHA 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 ALPHA should assure that it is not used in such an environment.

The Model 6000 ALPHA has been tested in accordance with:

EN60601-1: 2006 - Medical electrical equipment. General requirements for basic safety and essential performance
EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

EN 60601-1-2:2007- Emissions tests		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Model 6000 Vitalograph ALPHA 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 6000 Vitalograph ALPHA 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)
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Class A	
Immunity test	**IEC 60601 Test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines
Surge IEC 61000-4-5	±1kV differential mode ±2kV	±1 kV differential mode

	common mode	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% 100V (>95% dip in 100V) for 0,5 cycle	Performance A
	40 % 100V (60% dip in 100V) for 5 cycles	Performance A
	70 % 100V (30% dip in 100V) for 25 cycles	Performance A
	<5% 100V (>95% dip in 100V) for 5 sec	Performance A
Conducted RF IEC61000-4-6	3 Vrms 150kHz to 80 MHz in ISM bands	3 Vrms 150kHz to 80 MHz in ISM bands
Radiated RF EN 61000-4-3	3 V/m 80MHz to 2700MHz	3 V/m 80MHz to 2700 MHz
Warning: In the unlikely event of an electrostatic discharge causing the Alpha to switch off, the device should be turned off and then on again using the power switch.		

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: Model 6000 Vitalograph ALPHA

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.

- Canadian Medical Device Regulation {CMDR SOR/98-282}

- FDA Quality System Regulation {QSR} 21 CFR 820.

- 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, CE 85553, MD 82182, FM 83550

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 opinion replace any component thereof, which, in the opinion of the Company is faulty or below standard as a result of inferior workmanship or materials.
The conditions of this Guarantee are:

1. This Guarantee shall only apply to hardware defects which are notified to the Company or to its accredited distributor within 1 year of the date of purchase of the equipment, unless otherwise agreed in writing by the Company

2. Software (meaning computer software, or user installable modules) is guaranteed for 90 days from the date of purchase.

3. The Company warrants that the software when correctly used in conjunction with the hardware will perform in the manner described in the Company's literature and user manuals. The Company undertakes to rectify at no expense to the customer any software failure notified within the period stated above, provided that the failure can be recreated and the software has been installed and used in accordance with the user manual. Notwithstanding this clause, the software is not warranted to be free of errors.

4. This Guarantee does not cover any faults caused by accident, misuse, neglect, tampering with the equipment, use of consumable items or parts not approved by the Company, or any attempt at adjustment or repair other than by personnel accredited by the Company, nor does it cover reinstatement of any configuration changes caused by the installation of any software.

5. If a defect occurs, please contact the supplier from whom it was purchased for advice. The Company does not authorise any person to create for it any other obligation or liability in connection with Vitalograph® equipment

6. This Guarantee is not transferable and no person, firm or company has any authority to vary the terms or conditions of this Guarantee.

7. To the maximum extent permitted by law, the Company does not accept liability for any consequential damages arising out of the use of, or inability to use any Vitalograph® equipment.

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