

alpha III

Model 6000

User Instructions

 **Vitalograph[®]**

CE
0086

Vitalograph Ltd., Maids Moreton, Buckingham, MK18 1SW, England
Phone: (01280) 827110 Fax: (01280) 823302
e-mail: sales@vitalograph.co.uk

Vitalograph GmbH, Jacobsenweg 12, 22525 Hamburg, Germany
Phone: (040) 54 73 91-0 Fax: (040) 547 391 40
e-mail: info@vitalograph.de

Vitalograph Inc., 13310 West 99th Street, Lenexa, Kansas 66215, U.S.A.
Phone: (913) 888-4221 Fax: (913) 888-4259
e-mail: vitcs@vitalograph.com


Vitalograph (Irl.) Ltd., Gort Road Business Park, Ennis, Co. Clare, Ireland
Phone: (065) 6864100 Fax: (065) 6829289
e-mail: sales@vitalograph.ie

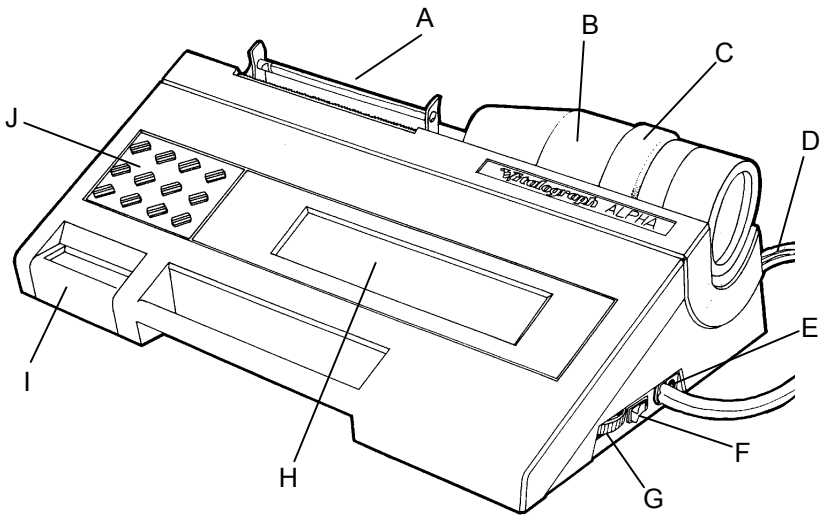
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DESCRIPTION OF THE VITALOGRAPH ALPHA

The **Vitalograph alpha** is a portable office spirometer with an integral graphics screen and thermal printer. It utilises the proven extremely accurate and stable Fleisch type pneumotachograph measuring system.

Operation of the device is as far as possible intuitive, but it is recommended that the following instructions are read thoroughly before using the instrument.

MAIN COMPONENTS OF THE VITALOGRAPH ALPHA

A	Thermal Printer
B	Flowhead
C	Transport Strap
D	Flowhead Tubing
E	Power Inlet Socket
F	On/off Switch
G	Contrast Adjuster
H	LCD Display
I	Program Cartridge
J	Keypad

FEATURES OF THE VITALOGRAPH ALPHA

The **Vitalograph alpha** features include; -

- Portable and easy to carry
- On-screen prompts and menu display
- Test data printed on a wide, fast printer
- Simple checking
- Predicted normal values and computer interpretation
- Provides a hard copy of results
- Automatically selects best tests
- Robust and proven reliability

GETTING THE VITALOGRAPH ALPHA READY FOR USE

First check that the contents of the packaging correlate with what is outlined on the contents label on the inside of the packaging carton.

Environmental Conditions

The **Vitalograph alpha** spirometer must NEVER be used in atmospheres that are potentially explosive, such as in the presence of ignitable or inflammable anaesthetic gases or vapours.

Medical Devices may be affected by 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.

Program Cartridge

The **Vitalograph alpha** program is contained in a cartridge, which must be correctly inserted for normal operation. Removal of the cartridge is not recommended when the unit is powered as this will result in loss of data or cause operational problems, however the printer will not be damaged. If the **Vitalograph alpha** does not work when it is switched on, switch it off and check the cartridge is correctly fitted and pushed fully home. Then switch the **Vitalograph alpha** on again. Also ensure that there is paper in the printer.

Power Supply

The **Vitalograph alpha** spirometer MUST be used with the purpose built low DC voltage PowerSAFE unit (Cat No. 21001204) with which it is supplied, attempted use with other devices may cause irreparable damage.

Connecting the PowerSAFE

The low voltage output cable from the PowerSAFE connects into a socket on the right hand side of the **Vitalograph alpha**. Attach to the **Vitalograph alpha** before plugging it into a mains supply. Plug in the mains plug to a suitable socket, operate the ON/OFF switch on the right hand side of the instrument, and the **Vitalograph alpha** is ready for use and will prompt the operator to verify/adjust the date.

Flowhead and Tubing

The silicone rubber twin-tubing used to connect the flowhead to the instrument may be loosely coiled around the storage lugs located at the rear of the instrument, during transport. Care must be taken that the tubing does not become damaged as this may result in erroneous test results. It is recommended that the retaining strap be completely removed unless transporting the instrument.

When this product is used for specialist rapid testing applications, i.e. hundreds of tests in a day, special precautions need to be taken with the flowhead.

Aerosolised droplets of water vapour reside in spirometry equipment for up to 10 minutes following a test (ref: Hiebert et al, Contaminated Aerosol Recovery from Pulmonary Function Testing Equipment, Am J Respir Crit Care Med 1999, 159, 610-612.).

For this reason, two precautions are recommended:

1. Use a new BVF for each subject. Also change the BVF every 10 expirations, if conducting multiple tests on the same subject.

2. Replace the flowhead every 2 hours or 100 expirations whichever the sooner. Clean and disinfect the flowhead as directed in the User Manual before re-use on the device.

Printout Records

Please be advised that all thermal paper fades with time. *We strongly recommend that all records be photocopied to ensure no loss of data* and to maintain the subject's spirometry history file with summary test results.

Fitting a new roll of paper

The **Vitalograph alpha** is supplied with a roll of paper fitted into the printer. Note that the outside of a roll will not give a strong print impression due to loss of sensitivity on exposure to light. If the printer is used without paper, although not recommended, the printer head will not be damaged.

Replacement of the paper requires the instrument to be "ON", and can be carried out even during a sequence of tests if necessary.

Press the ENT key when either of the screens of data displayed below is shown:

VITALOGRAPH- ALPHA

TODAY'S DATE: 11/01/02

IS THIS CORRECT? PRESS <Y> OR <N>

OR

VITALOGRAPH- ALPHA : MAIN MENU

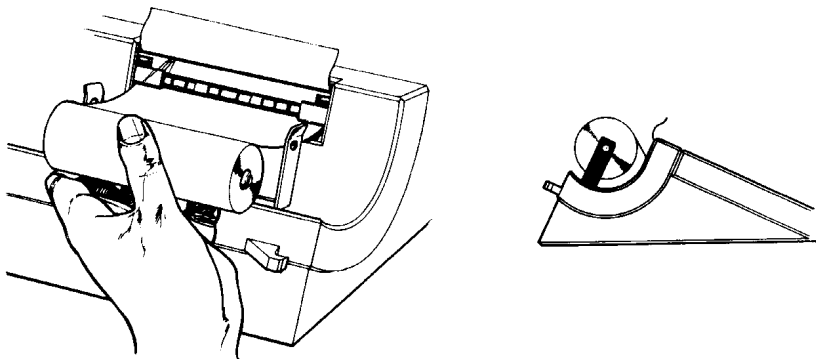
1 : VC TEST	5 : NEW SUBJECT
2 : FVC TEST	6 : ACCURACY CHECK
3 : PRINT	7 : POST MODE
4 : CLEAR RESULTS	

Unclip the paper roll support rod from the holder on the rear of the instrument and discard the old paper roll centre. Use only Vitalograph Cat No 44058 paper – damage caused by incorrect paper will invalidate the Warranty.

Fit the new roll of paper onto the paper rod as shown in the diagram below. Press the ENT key, the printer will now operate, feed the paper into the slot below the

roller in the rear of the printer. Note that the coated side of the paper is inside the roll.

The paper will then be pulled into the printer and appear out of the top. When this occurs press the ENT key again to stop the printer. The paper rod may now be replaced in the holder.



Important: Printer paper must unroll as shown.

Paper should not be pulled through the printer manually. The paper feed On/Off mechanism using the Vitalograph alpha keypad 'ENT' button should be used.

OPERATING INSTRUCTIONS

Keypad

The instrument is controlled by the 12 keys on the front panel. There are ten numeric keys (0-9) two of which have dual functions. Key No. 9 doubles as Y (Yes) and Key No. 0 doubles as N (No). The two remaining keys are ENT (Enter) and DEL (Delete).

The numeric keys are used to enter data and the ENT key to indicate that data entry is complete. The DEL key is used to delete a character that has been entered in error.

The **Vitalograph alpha** is easy to use by following the instructions displayed on the screen.

Date Entry

VITALOGRAPH - ALPHA

TODAY'S DATE: 11/01/02

IS THIS CORRECT? PRESS <Y> OR <N>

The above message will be displayed on the screen immediately the **Vitalograph alpha** is switched on.

If the date is correct press the (Y) key. If incorrect then press (N). The date may now be entered.

N.B. The day, month and year must have two digits for a successful entry e.g. 01/01/01. Failure to enter the date fully will result in the incorrect digits being erased, and the date will be requested again.

Subject Data Entry

Subject information is required to enable the instrument to calculate predicted test result values. If these are not required press the ENT key when the subjects age is requested. After each data entry is complete the ENT key must be pressed.

Reference Number

This may be any combination of numbers up to a maximum of 15 entries.

Subject Age

Enter subject's age in years.

Subject height

The height may be entered in Inches or Centimetres – entries below 85 will automatically be taken as inches.

N.B. On some versions only Centimetres may be entered.

Subject Sex

The spirometer assumes the subject to be MALE and shows the following display. Use the Y and N keys accordingly to make the correct choice.

```
REFERENCE NUMBER : 1234
                   AGE : 46
                   HEIGHT : 170 CM
                   SEX : MALE ?
```

```
IS MALE CORRECT ? PRESS (Y) OR (N)
```

Subject Smoking Status

Some cartridges have an option to enter smoking status – smoker or non-smoker. This will be used in the calculation of Lung Age.

After the subject demographics have been entered the printer immediately starts, which confirms that the subject is now entered as 'current' in the **Vitalograph alpha**.

Instruction of the Subject may now commence.

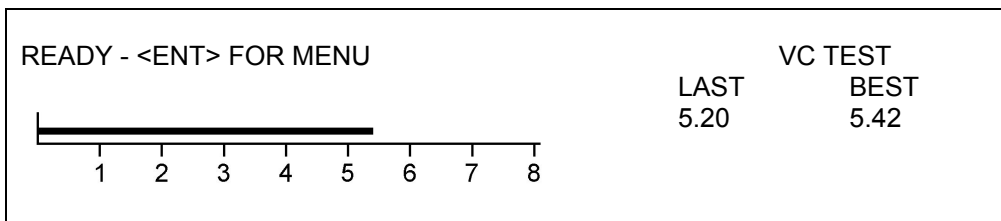
Main Menu

Each item is selected by pressing the key with the corresponding number. The ENT key enables a new roll of paper to be loaded into the printer mechanism.

VC Test (Static or Slow Vital Capacity)

This test may also be repeated as often required to get a valid result. The current test volume (LAST) and highest volume achieved (BEST) being displayed numerically on the screen.

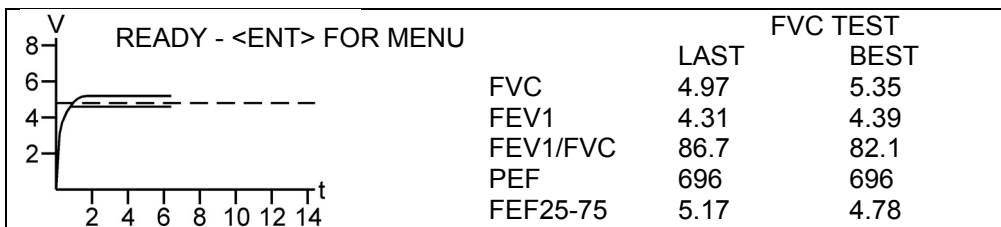
A small vertical line on the graph also gives an indication of the highest volume achieved in the series.



FVC Test (Forced Exhalation Test)

This test may be repeated as many times as required to get a good result. Minimum of three attempts is recommended. Commence each FVC test only when the READY prompt is displayed. If inspiratory testing is available on your cartridge, the FVC will continue for 20 seconds, if the inspiratory manoeuvre is not performed. In this case, press ESC to end the test.

Curves for each test will be superimposed on the screen. The "best" test will be stored for output on the printed test report. (The "best" test has the highest FVC + FEV1 sum).



Print

The printer provides a report of subject data, test results and graphs. To stop the printer, press the ENT key during printing.

Clear Results

Press "Y" to clear both VC and FVC test results. Subject data is retained so that further testing may be performed.

VITALOGRAPH - ALPHA

ALL RESULTS WILL BE CLEARED

PRESS (Y) OR (N)

New Subject

The existing subject data and test results are cleared and the instrument prompts for data from the next subject.

Post Mode (Pre/Post Drug Administration Testing)

The "best Pre" are saved and the "Post Test" mode is selected. A further series of tests may then be performed after drug administration. The results of these tests are compared with the results from the "Pre" test, the details are available on the printed report as selected by menu option three above.

The display shows 'POST' to advise that this mode is switched on. To clear, select 'NEW SUBJECT'.

Performing The Tests

HYGIENE: It is vital for the user to set guidelines for protective hygiene measures whilst performing spirometry testing. There are three main potential sources of cross contamination, skin contact; aerosolised particles and saliva/body fluids. By far the most significant is the last item – a minimum requirement is to use a new disposable mouthpiece for each subject tested. We recommend using the SafeTway mouthpiece for expiratory tests or the Bacterial/Viral Filter for testing involving inspiratory and expiratory manoeuvres. We also recommend that a delay of at least 5 minutes be allowed between subjects. This allows aerosolised organisms to be removed by gravitational sedimentation between tests. (Am J Respir Crit Care Med Vol 159. pp 610-612, 1999).

SUBJECT INSTRUCTION: It is essential that the subject performing the test is clearly instructed in the procedure before the start of each test. The Operator must demonstrate each manoeuvre, using a mouthpiece, prior to instructing the subject.

A very enthusiastic performance by the operator is required so that a maximum effort is made when carrying out the forced expiratory test. A subject who has not previously had a spirometry test should make two or more practice attempts until it appears that a maximum effort is being obtained.

IMPORTANT NOTE: *It is vital that the operator ensures the subject keeps their fingers clear of the outer end of flowhead during testing.*

Testing may be done either in the sitting or standing position. Indication of position is necessary on the report. The Standing position may not be appropriate in some circumstances, such as in hospitals where many patients may not be able to tolerate the standing position, especially when making forced manoeuvres. The selection of the position for testing is, therefore, an individual one. If the standing position is used, an appropriately shaped chair should be placed behind the patient/subject so he/she can quickly and easily be eased into a sitting position if he/she becomes light-headed during the manoeuvre.

Read the following instructions to the subject so that testing is performed properly.
VC test: -

- Stand up.
- Take hold of the unit, keeping it a vertical position and away from your mouth (ensure that the device is not jerked while handing it to the subject).
- Inhale as deeply as possible and insert the mouthpiece into your mouth, clamping it between your teeth.
- Close your lips round the mouthpiece.
- Exhale normally for as long as possible.

FVC test: -

- Stand up.
- Take hold of the unit, keeping it in a vertical position and away from your mouth (ensure that the device is not jerked while handing it to the subject).
- Inhale as deeply as possible and insert the mouthpiece into your mouth, clamping it between your teeth.
- Close your lips round the mouthpiece.
- Exhale as quickly as possible and try to keep exhaling for at least 6 seconds.

The patient's best test can be recorded on a Serial Spirometry Record sheet along with a plot of the FEV1 value. Pads of 50 can be ordered from Vitalograph (Cat. No. 63054).

Where the ALPHA III recognises errors in the test technique, error messages may be displayed, e.g. SLOW START will be displayed if the back extrapolated time zero point exceeds 10% of FVC (This could be due to the subject not biting the mouthpiece giving rise to tongue obstruction, or simply not blowing out hard enough at the start of test).

CHECKING ACCURACY OF THE VITALOGRAPH ALPHA

The **Vitalograph alpha** has an extremely stable measuring system. Although spirometry standards recommend that the device accuracy be checked on a daily basis, the need to adjust the calibration is very infrequent and normally is indicative of a fault or procedural error. Although it is not a specified requirement,

a routine annual service on this equipment is strongly recommended. The equipment used to perform the accuracy check should itself be certified and traceable to national or international standards.

Accuracy Checking Procedure

The Accuracy Checking routine allows the user to simply check if the accuracy of the instrument is within the required tolerance. To perform the accuracy check a precision syringe is required, such as the 1-L Precision Syringe available from Vitalograph (Cat. No. 20408). Before attempting to check the accuracy it is essential that the flowhead and syringe are at the same temperature. Breathing through the flowhead raises its temperature. If the flowhead has recently been used for testing prior to accuracy checking, then the temperature must be lowered to ambient by repeatedly pumping room air through it using the syringe.

The operator is requested to enter the ambient temperature, meaning the temperature of the syringe. **THIS MUST BE MEASURED ACCURATELY.** A precise volume of air must be pumped through the flowhead when requested on the screen. Do not pump too fast or too slowly, a smooth continuous pump will deliver the correct volume. Pumps lasting less than a second will be ignored by the device. Follow the instructions on the screen. When entering the volume of the syringe, please note that this is the stroke volume of the syringe and is unrelated to the number of pumps of the syringe. *If the error is less than, 3%*, then the device is accurate within tolerance and the calibration setting does not need to be adjusted.

Calibration Updating Procedure

This is only necessary *if the error is greater than 3%* when performing an accuracy check. Before considering adjusting the calibration, re-check the accuracy and attempt to locate the fault/cause of error. Adjusting the calibration is carried out totally by control from the keyboard and no mechanical adjustment is necessary. The revised calibration is retained until altered again, even when the spirometer is switched off.

When the accuracy has been checked or the calibration changed there is a choice of either ending the routine or of double checking the result by re-entering the accuracy checking procedure as described above. If the calibration has been adjusted, it is strongly recommended that the accuracy be checked again. Out of limits results is indicative of a fault in the device or the checking procedure.

When the accuracy checking has been completed a printed record of the calibration may be obtained. A calibration REPORT will be printed if the calibration has been updated, a calibration CHECK will be printed if the calibration remains unaltered.

CLEANING INSTRUCTIONS

All parts of the Vitalograph Alpha require regular cleaning, i.e. the removal of visible particulate contamination. The parts of the Vitalograph Alpha that make up the flowhead also require disinfecting. Vitalograph recommends that cleaning and disinfecting should normally be carried out on a weekly basis. In addition to a weekly cleaning and disinfection cycle, Vitalograph recommends cleaning and disinfection of equipment to be carried out after use on infected subjects or prior to use on immuno-compromised subjects. The user must determine what level of disinfection is appropriate and acceptable in any particular circumstance.

Routine Practice

It is recommended that the Flowhead Assembly be regularly cleaned and disinfected. In the event of visible contamination to the FLOWHEAD CONES or FLOWHEAD ELEMENT - these should be cleaned and disinfected.

The FLOW CONDITIONING MESHES should be replaced regularly. The frequency of this is dependent on the Facilities' Risk Assessment, usage, and test environment, but should be at least monthly or every 100 subjects (500 blows). They should also be replaced in the event of damage, or if visibly contaminated.

It is recommended to replace the complete Flowhead Assembly: FLOWHEAD COMPLETE and FLOWHEAD CONNECTION TUBE, at least annually.

Cleaning/Disinfecting- Recommendations Chart

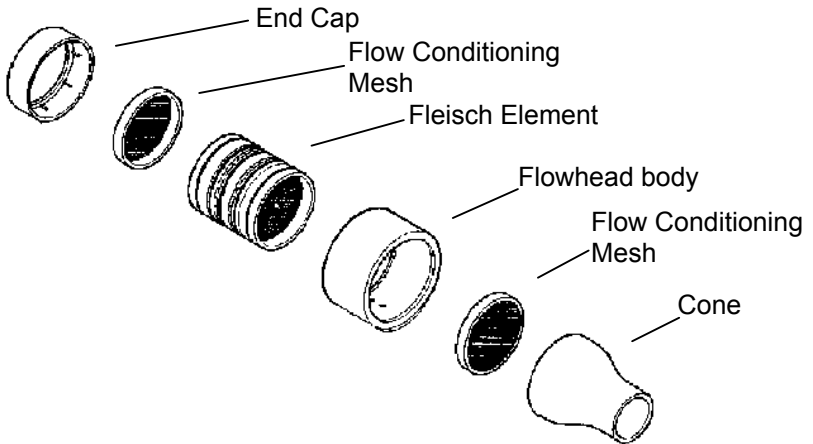
Part	Material	Clean/ Disinfect	Autoclave	Recommended Disinfectants
Case Exterior	Polystyrene high density foam with epoxy paint	Clean	No	Wiping with a 70% Isopropyl Alcohol impregnated cloth provides a suitable form of cleaning and low-level disinfection.
Display	Glass	Clean	No	
Screen Surround	ABS	Clean	No	
Keypads	ABS	Clean	No	
Flowhead Tubing	Silicone Rubber	Clean	Viable	
Flowhead Body	Aluminium	Clean	Viable	
Fleisch Element Assembly	Aluminium, Stainless Steel, Acetal	Clean & Disinfect	Viable	Disinfect by immersion in sodium dichloroisocyanurate solution at 1000 ppm concentration of free chlorine for 15 minutes. (see recommended cleaning/disinfection method for the Vitalograph Alpha Flowhead)
Flowhead Cone	TPX	Clean & Disinfect	Viable	
Flowhead Mesh Housing	Anodised Aluminium	Clean & Disinfect	Viable	
Flowhead Conditioning Mesh	Acetal and Polyester	Disinfect /Dispose	No	
Flowhead End Cap	TPX	Clean & Disinfect	Viable	
				The flowhead will also withstand autoclaving at 134°C for 3 minutes.

Definitions of cleaning and disinfection are as defined in “Sterilization, Disinfection and Cleaning of Medical Equipment: Guidance on Decontamination from the Microbiology Committee to Department of Health Medical Devices Directorate, 1996”

Recommendations for chemical disinfectants are derived from the PHLS publication “Chemical Disinfection In Hospitals” 1993.

Disassembling the Flowhead for Cleaning and Disinfecting

1. Remove the cone and the end cap from the flowhead.
2. Remove the flow conditioning meshes from inside the cone and the end cap, and either clean or discard them.
3. Hold the unit case with one hand and the exposed part of the Fleisch element with the other. Pull and twist the Fleisch element to remove it entirely from the case.



- Clean each separate part of the flowhead by washing in a mild detergent to remove particulate contamination. To clean the Fleisch element, swill vigorously in water with mild detergent. Do not attempt to “rub” or “scrub” at capillaries. If the flow conditioning meshes appear dirty or blocked they should be thrown away and replaced. The flowhead body does not require disinfection, but may be disinfected with the rest of the flowhead for convenience.
- Rinse with clean water.
- Disinfect by immersion in sodium dichloroisocyanurate solution at 1000 ppm concentration of free chlorine for 15 minutes. Prepare disinfectant solution as directed in the manufacturer’s guidelines.
- Rinse with hot water to aid drying.
- Leave to dry completely before reassembling. Drying the Fleisch element assembly may require placing it in a warm place overnight. A drying cabinet is ideal; alternatively another heat source could be used.
- Wiping with a 70% Isopropyl Alcohol impregnated cloth provides a suitable form of cleaning and low-level disinfection for the case exterior, display, screen surround, flowhead tubing, flowhead body and keypads. Repeat at least weekly to prevent build-up of grime from normal handling and use.
- Always follow the safety guidelines given by the manufacturer of cleaning and disinfectant chemicals or equipment.

Reassembling the Fleisch Flowhead

1. Ensure that no liquid remains in the holes, grooves or pressure tapplings of the Fleisch element assembly.
2. If replacing the sealing rings, check for damage and very lightly grease each ring before replacing them in the housing grooves. (Molycote 55 silicone grease or its equivalent is recommended.)
Make sure you remove excess grease as it can cause blockage of the holes in the flowhead body, resulting in false readings.
3. Place cleaned or new flow conditioning meshes into the cone and the end cap.
4. When re-assembling ensure that the BLUE PRESSURE TAPPING is closest to the wider end of the element assembly. Also ensure that the flowhead body is pushed fully home.
5. When attaching the FLOWHEAD CONNECTION tubing ensure that the matching coloured pressure tapplings on the FLOWHEAD and the **Vitalograph alpha** are connected to each other. When connecting the double tubing from the flowhead to the ports on the side of the unit it is very important that the tubing is pushed fully home over the ports. This is critical to obtain accurate results from the unit.
6. When the flowhead is reassembled, an accuracy check must be performed.

CONSUMABLES AND SPARE PARTS

Cat. No.	Description
20242	<i>SafeWay</i> Mouthpieces (200)
20303	Noseclips (10)
20408	1-L Calibration Syringe
28350	Bacteria/Viral Filters (50)
42084	Flow Conditioning Meshes (10)
44058	Thermal Printer Paper (5)
31297SPR	Mains Power Cable - UK
31375SPR	Mains Power Cable - USA
31376SPR	Mains Power Cable - Euro
62019SPR	Flowhead Cone
62006SPR	Flowhead End Cap
21001204	PowerSAFE

EXPLANATION OF SYMBOLS



Type BF equipment



Class II

VA

Power rating

V

Voltage DC




Attention (reference relevant section in manual)

Power input connector

On (I) / Off (O) switch

CE Notice

Marking by the symbol  indicates compliance of the **Vitalograph alpha** to the Medical Devices directive of the European Community. Such marking is indicative that the Vitalograph 2120 meets or exceeds the following technical standards:

- EN60601-1 - “General requirements for safety”
- EN55011 - “Radiated and mains conducted emissions for industrial, scientific and medical (ISM) radio-frequency equipment”
- IEC801-2 - “Electromagnetic compatibility for industrial-process measurement and control equipment Part 2: Electrostatic discharge requirements.”
- IEC801-3 - “Electromagnetic compatibility for industrial-process measurement and control equipment Part 3: Radiated electromagnetic field requirements.”

FDA Notice

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

DECLARATION OF CONFORMITY

(To the requirements of 93/42 EEC 169, volume 36)

Product: Vitalograph Alpha

Vitalograph hereby ensures and declares that the above product associated with this user manual, bearing the CE Mark, which is classified as 2a, meet the following provisions of Annex II of the Medical Devices Directive as per Article 11, section 3a, excluding point 4 of Annex II.



Vitalograph design and manufacture in accordance with the following standards:

- European Medical Devices Directive 93/42/EEC L169 Vol. 36
- BS EN ISO 9001:1994 : Quality Systems - Model for Quality Assurance in Design, Development, Production, Installation and Servicing.
- EN 46001:1996 : Specification for application of EN ISO 9001 to the manufacture of medical devices.

Certifying Body: British Standards Institute - Certificate Nos. Q5460 & CE 00772

FDA Quality System Regulation: 21 CFR Sections 820 & 803.

Signed on behalf of Vitalograph (Ireland) Ltd. / Vitalograph Ltd.

A handwritten signature in black ink, appearing to read 'B. R. Garbe', is shown on a light-colored background.

B. R. Garbe.
Group Managing Director.

TECHNICAL SPECIFICATIONS

Operating Voltage Range:	100 to 250 VAC
Operating Frequency:	50 or 60 Hz
Power Supply Output:	Nominal 10 Volts D.C. at 1.2 Amp
Flow Detection Principle:	Fleisch Pneumotachograph. Back pressure <0.1 kPa/L/s @ 14 L/s
Maximum Flow rate:	16 L/s
Maximum Recording Time:	VC 30 s FVC 20 s
Data Sampling Rate:	100 Hz
Operating Temperature Range:	10°C to 40°C
Measuring Accuracy:	Volumes ± 3% Flowrates ± 3%
System Resolution:	Volume 0.01 L Peak Flowrate 1 L/m All other Flowrates 0.01 L/s.
Dimensions:	300X250X130 (Width, Depth, Height).
Standards and Approvals:	EN 60601-1:1990 EN46001
Storage Conditions	Store between 0-50°C and 10-95% Relative Humidity

CUSTOMER SERVICE

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

For the names and addresses of approved Vitalograph Service Agents or to arrange spirometry workshops, please contact any of the offices at the start of this manual or your local Vitalograph distributor.

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.