

Vitalograph[®] micro

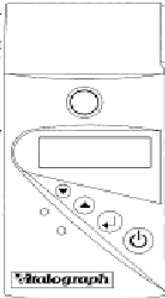
Vitalograph micro

Name _____
 Age: 24 Sex: Male kg
 Predicted Values Set: E 100%
 Accuracy Check: 01/01/2 Adjusted: 01/01/2005
 Micro Serial #: 10529

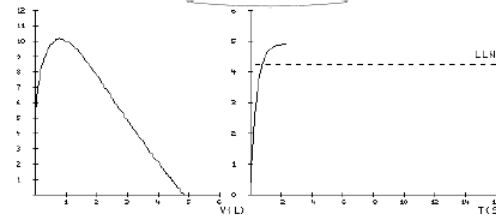
Test Information:
 Test Date: 01/01/2005
 Number Of Tests: 1
 FVC Rep.: - FEV1 Rep.:

Index

FVC	L
FEV1	L
FEV1%	%
FEV6	L
PEF	L/min
PEF25	L/s
PEF75	L/s
PEF25-75	L/s



F(L/S)

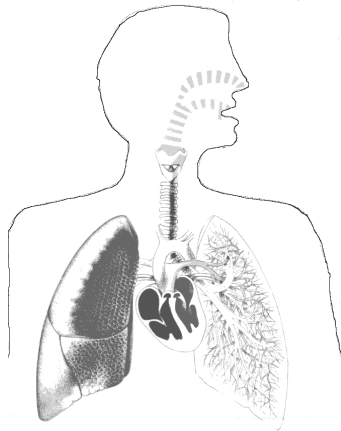


Comments:

Computer Suggested Interpretation: Normal Ventilatory Function
 Signature: _____ Software Reference: 63130 v2.00

USER MANUAL

MODEL 6300



CE
0086

CERTIFIED UNDER THE
 MEDICAL DEVICES DIRECTIVE



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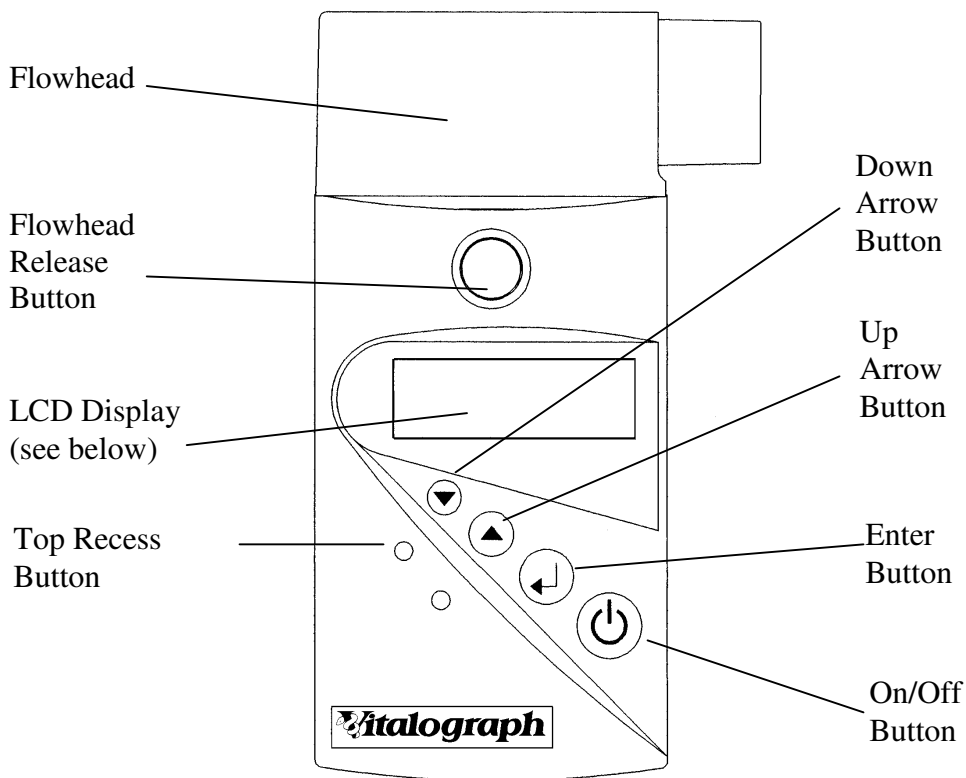
 is a registered trademark

The **Vitalograph micro** is a portable and easy to use precision spirometer. It offers total confidence in rapid spirometry tests as a part of the routine physical examination of your subjects.

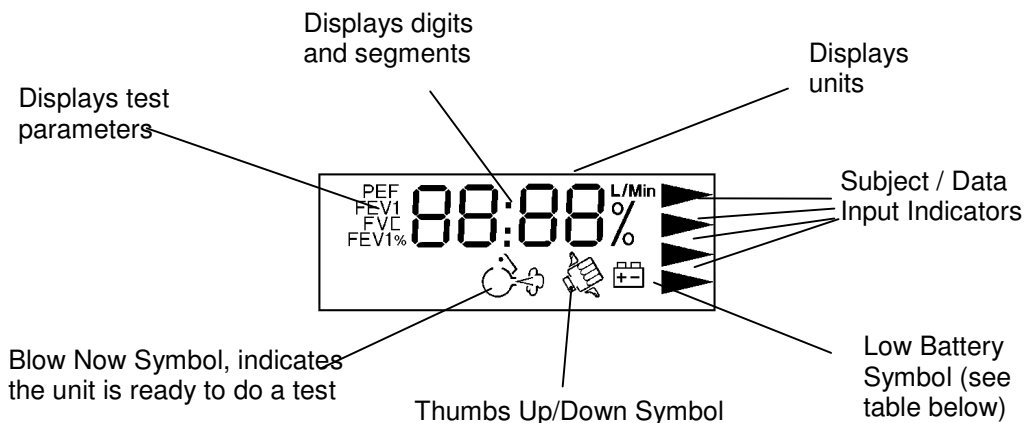
The **Vitalograph micro** features include:

- easy to use
- automatically calculates 'best test' in a series
- single breath calculation of a range of respiratory parameters
- displays FVC, FEV1, FEV1% and PEF after each manoeuvre
- prints predicted values, results and graphs
- prints computer suggested interpretation
- small, pocket size and light weight
- simple, clear display
- on screen battery-low indicator
- auto switch off after 2 minutes of no use
- long term stability with no moving parts
- flowhead, clips in and out for easy cleaning / replacement
- accuracy checking facility with 3-L Precision Syringe
- patented *Safeway*[®] mouthpiece for complete hygiene
- retains last best-test even when switched off (not overwritten until a blow occurs after switch-on)

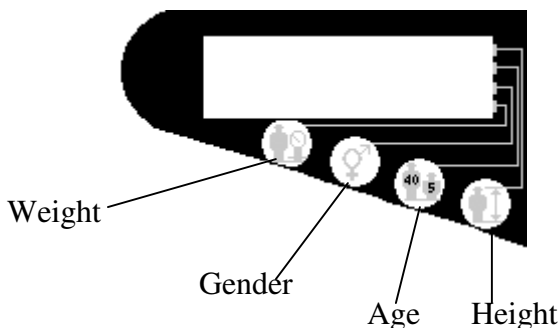
Vitalograph micro





Vitalograph micro Display



Vitalograph micro Label



Symbol (on or flashing)	Condition	Result	Action
	Battery Low	You can perform test	Replace PP3 battery
	Battery Nearly Dead	You cannot perform test	Replace PP3 battery

Preparing For Use

The contents of the **Vitalograph micro** package are:

- The spirometer device
- User Instructions
- Firmware Description
- *Safeway* Mouthpiece samples
- Adaptor for fitting Precision Syringe or BVF
- Serial Spirometry Record Card samples
- Vitalograph micro – Serial Cable
- Vitalograph Print Utility (Windows PC application)

A 9-V (e.g. PP3) alkaline battery (not provided) must be installed before the **Vitalograph micro** is used for the first time.

Open the door at the back of the unit to insert the battery. Make sure the the battery.

Note that it is recommended to remove the battery if you do not intend using the **Vitalograph micro** for several weeks.

Installing the Print Utility software on your PC

Once installed, the Vitalograph Print Utility automatically runs in the background, printing to your PC or network printer or simply creating PDF spirometry reports for you to file, transmit or archive in your PMS software. You need not even be aware of it's presence.

The Print Utility must be installed before the Vitalograph micro will print a PDF document or a paper spirometry report on your PC's printer. You must be running Windows 2000 or XP Pro to use this utility.

Insert the CD into your CD drive, it should auto-run. Read and answer the questions as they appear in the Install Shield. Think carefully about where to send the PDF files on your computer. If you are trying out the Print

Utility for the first time you might like to point them to your desktop initially.

It is recommended to create the PDF files as an electronic archive. You may also wish to set the 'print' setting, but note that the PDF files may be printed at any time without using the 'print' setting.

Connecting the Serial Cable

If your PC has a Serial Port, simply plug the 'D' plug into the Serial socket. Bring the jack plug end of the cable to the front of the PC ready to plug in the Vitalograph micro after a test has been performed.

If you only have USB Ports (such as on a Laptop PC, you will need to buy and install a USB to Serial converter, such as Vitalograph Cat No 77051. Follow the install instructions on the CD.

IMPORTANT: If you use a USB/Serial converter, you will need to change the setting of the Com Port in the Print Utility Application. Open this by right clicking on the blue 'V' Icon at the bottom right-hand side of your taskbar. If you do not know how to find which Com Port is being used by the converter, seek help from your network administrator.


Setting Up the Units, Time and Date

Follow these instructions in sequence to set up the Vitalograph micro before you use it for the first time, or to change settings later.

Step1: Entering configuration mode

1. Press .

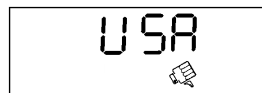
Note that the Vitalograph micro turns itself off if not used within two minutes.

2. Press  repeatedly until the time is displayed...



3. Press the top recess button and ▼ at the same time.

Step 2: Set Units



1. Press ▼ to change Thumbs Up/Down symbol.
👍 means US format for date, 👉 means European format
2. Press ⏪ to continue




Step 3: Set the Time

1. To select the correct hour press ▲ or ▼. Note that pressing down continuously on the button changes the number quickly.
2. Press ⏪
3. To select the correct minute press ▲ or ▼.
4. Press ⏪




Step 4: Set the Date

1. To select the correct year press ▲ or ▼.
2. Press ⏪
3. To select the correct month press ▲ or ▼.
4. Press ⏪
5. To select the correct day press ▲ or ▼.
6. Press ⏪ to finish.

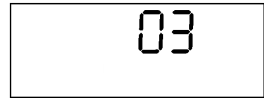
Step 5: Accuracy Check Using A Precision Syringe

1. Press  when  is displayed, if you do not wish to perform an accuracy check. If you do not have a Precision Syringe press .



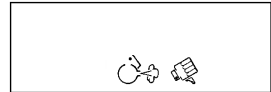
2. Select  if you wish to perform an accuracy check on the Vitalograph micro at this time. (Press  to change the Thumbs Up/Down symbol)
3. Press 

4. The display will look like...



5. **This represents the stroke volume of your 3-L Precision Syringe, not the total volume that will be delivered.** It is very important to adjust this if you are using a syringe with a different stroke volume; otherwise, the accuracy check will be incorrect.

Press . The display will look like ...

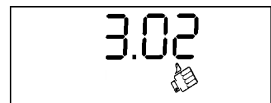



6. Ensure the syringe piston is fully withdrawn. At this point, connect the unit to the syringe and leave it in a stable position - do not move the unit during this procedure.

7. With an even stroke, pump the air from the syringe through the device. The stroke must be at least one second in duration.

8. Wait for a double beep, then withdraw the syringe piston fully and repeat this procedure of injecting the full syringe volume until five beeps sound. **It is very important to wait for the double beep before withdrawing the piston each time.**

If there is a **Thumbs Up** on the LCD, then the unit is within the +/- 3% accuracy tolerance¹.



9. Turn the unit off by pressing . The device will automatically switch off after 2 minutes.


¹The user will be prompted (by means of a double beep) for another stroke of the syringe when the volume difference of the present stroke is not within 3% of the previous stroke. If the maximum of five strokes is executed, then the five beeps will occur, signifying the end of the accuracy check. If there is a thumbs down icon on the LCD, the unit is outside the 3% accuracy tolerance. Check for faulty assembly of the flowhead and your accuracy check procedure. Recheck the accuracy. If still outside tolerance seek technical assistance.

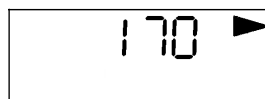
Performing a Test

To obtain accurate and meaningful spirometry test results it is essential that the operator is properly trained.






It is vital to conduct the test properly to ensure that there is proper use of the device and interpretation of the test data during testing. There are many types of training courses available. Please contact Vitalograph, your distributor or your national lung association for more details.



Follow these steps to perform the FVC test.







1. Press . After several seconds, the display will look something like...




*Note: This time delay should be used to give a new **Safeway**[®] mouthpiece to the test subject. The **Vitalograph micro** will turn itself off if you do not blow into it within two minutes.*


2. Height in cm. Press  or  to enter in subject's height between 0 and 250cm (or between 0 and 99 inches if in USA mode).
3. Press . The next data to enter is age. Press  or  to enter in subject's age between 0 and 99.

Note: If a value of 0 is entered for either height or age the rest of the demographic entry will be skipped and will continue from step 6, also no predicted parameters will appear on the printouts. To return to the previous screen, press  and  together.

4. Press . The next data to enter is gender. Press  or  to enter in subject's gender (0 for male, 1 for female).
5. Press . The next data to enter is weight. Press  or  to enter in subject's weight between 0 kg and 250 kg (or between 0 and 550 lbs if in USA mode).

6. Press . After several seconds, the display will look like...




7. It is only possible to perform a test when the 'blow icon'  is displayed. Always watch for this to be displayed. It will be accompanied by two beeps.
8. Fit a disposable *SafeTway*[®] mouthpiece (single use only). The use of a nose-clip is also recommended. Give the following instructions to the subject so that testing is performed properly.
 - a) Sit upright and fit the noseclip.
 - b) Hold the unit, keeping it away from your mouth. Do not jerk the unit (this can de-stabilize the unit).
 - c) Inhale as deeply as possible, then insert the mouthpiece carefully into your mouth, not like a trumpet, but clamping it gently between your teeth.
 - d) Seal your lips round the mouthpiece.
 - e) Exhale as fast and as long as possible. Try to keep exhaling for at least 6 seconds. (During exhalation the operator should encourage the subject to keep going in an animated fashion. Keep eye contact with the subject).
9. At the end of the blow the subject must remove the spirometer from their mouth.
10. Wait for two beeps to indicate that the Vitalograph micro is ready for the next blow. Repeat 3 times or more to ensure a good test.
11. After testing / session is completed, take the Vitalograph micro from the subject and thank them for their co-operation.
12. The operator may view some parameters on the display. The first parameter ...
13. Press ▲ and ▼ to scroll through the spirometric parameters, FEV1, FEV1%, PEF.
14. Make a provisional note of the result after each blow (remember, only the last and not the best is displayed).



Printing To The PC Utility

The PC Utility enables printing of a PDF file and/or to your PC Printer, follow the steps below:

- 1) Immediately after a test session is completed, plug the jack plug into the Vitalograph micro jack socket, which is located on the side of the device.
- 2) Press ▲ or ▼ on the Vitalograph micro until the following screen is displayed. 
- 3) Press ⏪ . The screen should immediately go blank. Put the unit down carefully and talk to your test subject. The Vitalograph micro will take about two minutes to download all the test data during which time it should not be interfered with.
- 4) After two minutes transmission, the device will ‘beep’ and briefly display ‘PRN’ again.
- 5) At this time the creation of the spirometry report begins in the PC Print Utility.
- 6) Depending on your settings, a PDF will be created and/or a print command will be sent to your designated printer².

Note: The best test in the session is printed, not necessarily the last test which is still showing on the LCD screen.

- 7) To cancel at any time press and hold the ⏻ switch for 15 seconds approx.
- 8) Another test can be performed as long as ⏪ is displayed.

² If you installed the Print Utility with default settings, no print command will be sent but a PDF file will be created in the following location:
C:\Program Files\Vitalograph\VitalPrint\Data

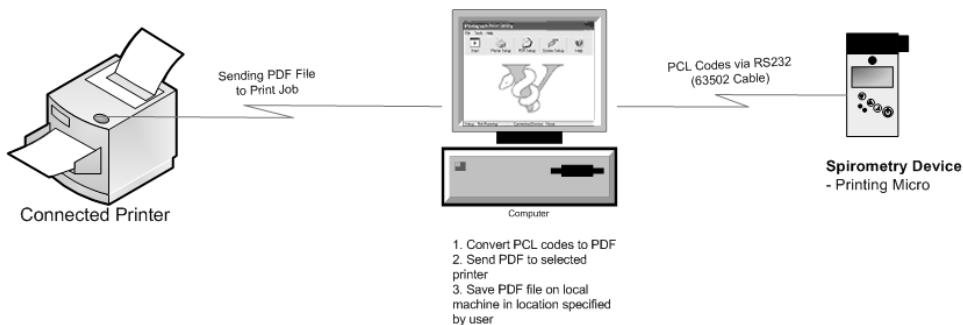


Figure 1 – Vitalograph Print Utility Product Perspective

Note: When the Vitalograph micro switches itself off, the best test from the last session is retained until the next blow. This stored test may be printed at any time as long as no new blow is detected by the device. Switch ON, press Enter repeatedly until the Blow Icon and time are displayed, then press ▲ and ▼ together to print.

Serial Spirometry Record

The subject's session best test should be recorded on a Serial Spirometry Record sheet to plot the FEV1 value against Lower Limit of Normality (LLN). Pads can be ordered from Vitalograph (Cat. No. 63054).



Printing Directly To A Parallel Printer

If you have purchased the optional parallel printer/intelligent cable and parallel printer, follow the steps below:

- 1) Ensure that the cable is correctly connected at both ends.
- 2) Press ▲ or ▼ until the following screen is displayed.
- 3) Make sure the printer is online and paper is installed.
- 4) Press ↻ and walk away.



Note: Because of the serial data transmission, converted to parallel in the cable, and the large amount of data, the printing speed is very slow using this method of printing.

- 5) Only the best test in the session is printed. To cancel at any time press and hold the  switch for 15 seconds approx.
- 6) After the data is sent, the device displays PRN on screen again. Another test can be performed as long as  is displayed.

Care of the Vitalograph micro

Vitalograph recommends that you return this unit to your local service centre for annual PPM servicing, which includes checks for function, safety, performance, hygiene procedures, routine maintenance and calibration certification.

Flowhead

It is recommended that the flowhead be removed for cleaning and disinfecting at least monthly or every 50 tests. See below.

Hydrophilic Filters

You can see two small white cylindrical filters on the top of the unit after the flowhead is removed. These are designed to prevent ingress of water and should be replaced if they get accidentally immersed in water. Otherwise, they are replaced once a year, as a part of the annual service.

SAFETY PRECAUTIONS

The Vitalograph micro does not offer protection against ingress of liquids and must not be used in the presence of flammable agents.

The Vitalograph micro complies with EN60601-1-2: 1993 but does not guarantee that other equipment in the vicinity will not be affected by electromagnetic emissions from the Vitalograph micro. Similarly, other equipment in the vicinity may affect the operation of the Vitalograph micro.

It is recommended that all equipment used near the Vitalograph micro complies with the relevant electromagnetic compatibility requirements for that equipment and to check before use that no interference is evident or disruptive. Increasing the distance between offending devices, and keeping interconnecting leads as short as possible will help reduce the effect.

CLEANING AND DISINFECTING

General Recommendation

To reduce the risk of cross infection the use of **SafeTway**[®] mouthpieces is recommended. A Risk Assessment should be carried out to assess the risks presented to both operator and subject, and an action plan devised by the facility to minimise the chance of cross infection occurring, particularly where known-infectious or immuno-deficient subjects are being tested.

An assessment should be made of methods of decontamination available to the operator, and their effectiveness against potential risks - a table of materials used in the **Vitalograph micro** is provided below to assist in this.

It is recommended that in cases of high risk with no effective disinfection methods available, that the contaminated parts are disposed of. For this device, the Flowhead Assembly: FLOWHEAD COMPLETE.

Routine Practice

A new mouthpiece (SafeTway mouthpiece) should be used for each subject. A period of at least 5 minutes should be allowed between subjects to allow settling of aerosolised particles.

It is recommended that the Flowhead Assembly be regularly cleaned according to the guidelines of the user's facility and replaced as a part of the routine annual service.

In the event of visible contamination to the FLOWHEAD - it should be cleaned and disinfected or replaced. It should also be replaced in the event of damage.

All parts of the Vitalograph micro require **cleaning**, i.e. the removal of visible particulate contamination. The parts of the Vitalograph micro that make up the flowhead also require **disinfecting**.

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 important is the last item – a minimum requirement is to use a new disposable mouthpiece for each subject tested. We recommend using the SafeTway mouthpiece. We also recommend that a period 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)

Cleaning Instructions

All parts of the Vitalograph micro require regular **cleaning**, i.e. the removal of visible particulate contamination. The parts of the Vitalograph micro 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.

Cleaning/Disinfecting- Recommendations Chart

Part	Material	Clean/ Disinfect	Autoclave Possible?	Recommended Disinfectants
Case Exterior	ABS	Clean	No	Wiping with a 70% Isopropyl Alcohol impregnated cloth provides a suitable form of cleaning and low-level disinfection. Do not immerse in liquid.
Display	Glass	Clean	No	
Keypad	Rubber	Clean	No	
Fleisch No2 Flowhead	Aluminium, Stainless Steel, ABS	Clean & Disinfect	Yes	Disinfect by immersion in sodium dichloroisocyanurate solution at 1000 ppm concentration of free chlorine for 15 minutes.
Hydrophilic filters	Polyethylene	Replace every year or after water ingress.	No	Dispose

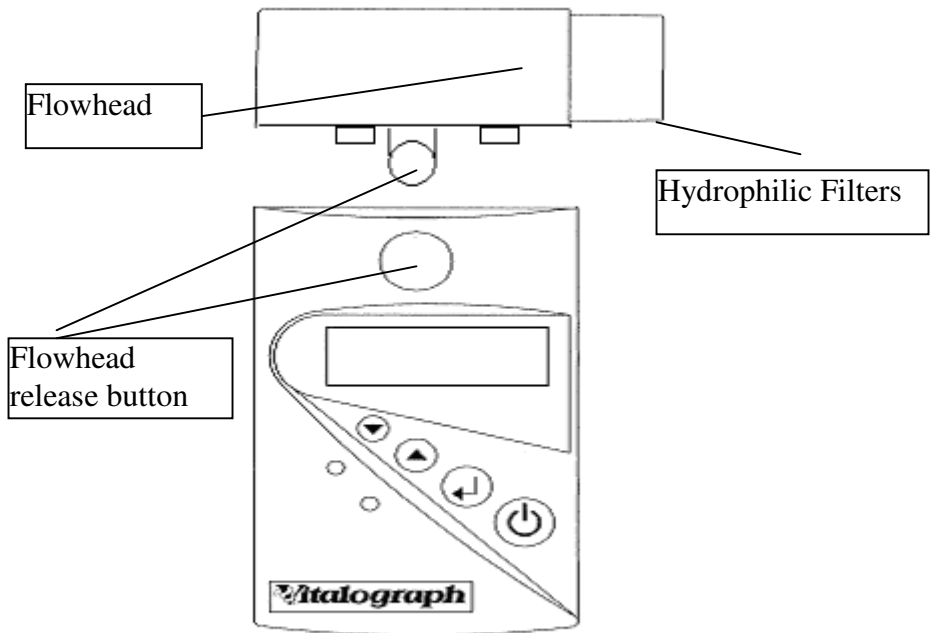
Definitions of cleaning and disinfection are as defined in “Sterilization, Disinfection and Cleaning of Medical Equipment: Guidance on Decontamination from the Microbiology Committee to Department of Health Medical Devices Directorate, 1996”

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

Disassembling for Cleaning and Disinfecting

1. Press in the two round ‘flowhead release buttons’.
2. Lift off the flowhead.
 - ▶ Clean 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 the flowhead should be replaced.
 - ▶ 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, and keypad. 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 the hydrophilic filters are undamaged and dry.
2. Orient the two circular holes under the flowhead with the hydrophilic filters in the body.
3. Push the flowhead onto the body, making sure that the two buttons click into place.
4. It is advisable to check accuracy and perform a functional check after cleaning and disinfecting.



Consumables and Accessories

Only the approved consumables and accessories below should be used. Complying with this will be more cost effective and ensure safety, hygiene and accuracy. Your Warranty may be invalidated by the use of inappropriate disposables.

Cat. No.	Description
20242	SafeTway™ mouthpieces (200)
20303	Nose-clips (10)
63052	Small Carry Case
36020	3-L Precision Syringe
63054	Serial Spirometry Records (6x50)
63053	Flowhead for Vitalograph micro (10)
28200	BVF (50)
63051	Adaptor for Syringe and BVF
2110201	Hydrophilic Filters (20)
2100666	Inkjet Printer – Parallel Connector
63505	Intelligent Parallel Printer Cable for micro
63502	Serial Cable for PC Connection
65030	PC Print / PDF Utility
07064	User Manual
07060	Service Manual

There are no user serviceable components inside the Vitalograph micro.


Technical Specifications

Symbols	 Class II Equipment  Type BF Equipment
Flow detection principle	9V, PP3 Battery type - 9V PP3
Flow impedance	Fleisch No2 type pneumotachometer
Volume measurement	Meets ATS/ERS guidelines
Maximum recorded flow rate	Flow integration
Maximum recorded volume	999 L/min
Measuring accuracy	9.99 L
	+/- 3% or +/-0.05L volume whichever is greater and +/-10% flow or +/-20L/min whichever is greater
Test duration	30 seconds
Operating temperature	15-37°C
Safety standards	Certified to conform to EN60601-1
Spirometric standards	ATS / ERS 2005 Guidelines
Power supply	Alkaline battery, 9V, PP3 (Recommended battery capacity = 550 mAh or greater)
Dimensions	145mm x 70mm x 87mm
Weight	165g (without PP3 battery)
Storage	Temperature : 0-50°C Relative Humidity : 10%-95%

Regulatory Notices

The **Vitalograph micro** is manufactured in Ennis, Ireland under ISO 13485:2003.

CE Certificate of Conformance

Marking by the symbol  indicates compliance of the **Vitalograph micro** to the Medical Devices directive of the European Community. Such marking is indicative that the **Vitalograph micro** 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

Indications for Use: The Vitalograph micro is intended to measure FVC, FEV1 PEF and FEV1% in subjects with respiratory conditions such as Asthma, COPD etc.

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

Customer Service

Only the manufacturer or service personnel specifically trained and approved by Vitalograph Ltd. or its associated companies should carry out SERVICE and REPAIRS.

Guarantee

Terms of Guarantee

Subject to the conditions listed below, Vitalograph Ltd. and its associated companies, (hereinafter called the Company) guarantee to repair or at its option replace any component thereof, which, in the opinion of the Company is faulty or below standard as a result of inferior workmanship or materials.

The conditions of this Guarantee are:

1. This Guarantee shall only apply to hardware defects which are notified to the Company or to its accredited distributor within 1 year of the date of purchase of the equipment, unless otherwise agreed in writing by the company.
2. Software (meaning computer software, or user installable modules) is guaranteed for 90 days from the date of purchase.
3. The company warrants that the software when correctly used in conjunction with the hardware will perform in the manner described in the Company's literature and user manuals. The company undertakes to rectify at no expense to the customer any software failure notified within the period stated above, provided that the failure can be recreated and the software has been installed and used in accordance with the user manual. Notwithstanding this clause, the software is not warranted to be free of errors.
4. This Guarantee does not cover any faults caused by accident, misuse, neglect, tampering with the equipment, use of consumable items or parts not approved by the Company, or any attempt at adjustment or repair other than by personnel accredited by the Company, nor does it cover reinstatement of any configuration changes caused by the installation of any software.

5. If a defect occurs please contact the supplier from whom it was purchased for advice. The Company does not 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.