

# VitaloLAB<sup>®</sup>

**MODEL 9100** 



**Rx Only** 

# Instructions for Use

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#### Vitalograph Branch Addresses

#### UK REP Vitalograph Ltd, UK

Maids Moreton, Buckingham MK18 1SW England **Tel:** 01280 827110 **Fax:** 01280 823302 **E-mail:** sales@vitalograph.co.uk www.vitalograph.com *Technical Support* **Tel:** 01280 827177 **Email:** technical.support@vitalograph.co.uk

#### Vitalograph Ltd, International

Maids Moreton, Buckingham MK18 1SW England **Tel:** +44 1280 827120 **Fax:** +44 1280 823302 **E-mail:** sales@vitalograph.co.uk www.vitalograph.com *Technical Support* **Tel:** +353 65 6864111 **Email:** technical.support@vitalograph.ie

#### Vitalograph GmbH

Rellinger Straße 64a D-20257 Hamburg Germany **Tel:** +49 40 547391-0 **Fax:** +49 40 547391-40 **E-mail:** info@vitalograph.de www.vitalograph.com *Technical Support* **Telefon:** +49 40 547391-14 **E-mail:** technical support@vitalo



#### Vitalograph (Ireland) Ltd

Gort Road Business Park Ennis, Co Clare, V95 HFT4 Ireland Tel: +353 65 6864100 Fax: +353 65 6829289 E-mail: sales@vitalograph.ie www.vitalograph.com Technical Support Tel: +353 65 6864111

E-mail: technical.support@vitalograph.de Email: technical.support@vitalograph.ie

#### Vitalograph Inc.

13310 West 99th Street Lenexa, Kansas, 66215 USA **Toll Free:** 1-800 255 6626 **Tel:** (913) 730 3200 **Fax:** (913) 730 3232 **E-mail:** contact@vitalograph.com www.vitalograph.com *Technical Support* **Tel:** (913) 730-3205 **Email:** technical.support@vitalograph.com

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#### 1. Indications for Use

Vitalograph

The Model 9100 VitaloLAB<sup>®</sup> is a pulmonary function testing device which uses Morgan Scientific's ComPAS2 software to measure subject respiratory parameters; FVC, SVC, MVV, CPF, RMS, SNIP, DLCO, MBN2 and SBN2.

The device is PC-based and designed for lung function testing on adults and paediatrics, 6 years and older, in a variety of professional healthcare environments e.g., primary care, hospitals, pharmaceutical research centres and physicians' offices.

The indications for use of the VitaloLAB is in the simple assessment of respiratory function through the measurement of dynamic lung volumes i.e., spirometry and other lung functions i.e., diffusing capacity.

Patients below the age of 6 years can be tested providing they can cooperate with the test instructions from the healthcare professional.

#### 2. Contraindications, Warnings, Precautions and Adverse Reactions

#### 2.1. Contraindications and Adverse Reactions

#### 2.1.1. Contraindications

1. The decision to conduct pulmonary function testing is determined by the ordering healthcare professional on the basis of their evaluation of the risks i.e., subject fatigue, and the benefits of pulmonary function testing for the particular patient. Caution should be used for patients prone to fatigue.

#### 2.1.2. Adverse Reactions

1. Subject fatigue may occur during pulmonary function 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.

#### 2.2. Warnings and Precautions

- No modification of this equipment is allowed. Any unauthorised changes to the VitaloLAB 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 VitaloLAB is not designed as a sterile device. Always follow the safety guidelines given by the manufacturer of cleaning and disinfectant chemicals.
- 3. Vitalograph intends that a new Bacterial Viral Filter (BVF<sup>™</sup>) 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 pulmonary function test manoeuvres. A BVF is for single use only.
- 4. Pulmonary function testing 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. Pulmonary function testing may support or exclude diagnosis, but it cannot make one.
- 5. When getting the VitaloLAB ready for use:
  - a. Ensure that gas cylinders are set as follows:
    - Calibration Gas outlet pressure 5.0 Bar/ 73psi.
    - DLCO Gas outlet pressure 3.5-5.0 Bar/ 50-73 psi
    - 100% Oxygen outlet pressure, 3.5-5.0 Bar/ 50-73 psi.

#### Gas outlet pressure should not exceed 5.0 bar/73 psi.

- b. Gas regulators used must be minimum specification of two stage diaphragm, 0-10 Bar outlet pressure. See <u>Section 4</u> for further details.
- c. 6, 8 & 10mm thread to tube push fits must be rated to 14 Bar minimum. See <u>Section 4</u> for further details.
- d. Ensure that the correct gases are connected to the tubing connectors as labelled on the back of the device. **Only medical grade gases should be used.** 
  - i. Connect DLCO test gas to the port labelled "DLCO" using largest (10mm 0.D.) tubing.
  - ii. Connect the 100% Oxygen to the port labelled "O2" using medium (8mm O.D.) tubing.
  - iii. Connect the O2/CO2 mixed gas to port labelled "CAL" using smallest (6mm O.D.) tubing.
- e. Ensure that the power supply is securely connected. Only use the VitaloLAB with the medically approved low voltage power supply with which it is supplied. Attempted use with other power sources may cause irreparable damage and invalidate the warranty. The output from the power supply is 24 volts DC.
- f. Ensure that the Patient Valve Bulkhead Connector is screwed on fully and the Heater Connector is connected at the back of the device as per the instructions in <u>Section 2</u>. If either connector is not secure, test results may be inaccurate.

Note: The device should be powered on to warm up for 20 minutes before testing.

**Note:** The device should not be positioned up against a wall because:

- Ventilation fan inside the device may be restricted.
- Patient Valve may not reach around to the patient.

- 6. Ensure that the patient holds the Patient Valve by the Handle Grip and avoids putting their fingers into the openings where the Shutter Valve is located. Alternatively, the Patient Valve can be mounted on the Support Arm.
- 7. The device should be powered off 5 minutes before disassembling the Patient Valve, to allow the internal Heater Assembly to cool down first.
- If Maximal Inspiratory Pressure (MIP) or Maximal Expiratory Pressure (MEP) tests are performed, a MIP/MEP Adaptor must first be pushed into Patient Valve (see Figure 5), with a BVF then pushed into the other end of MIP/MEP Adaptor.
- 9. Ensure that the Patient Valve tubing is not pinched or trapped when the Patient Valve is reassembled after accessing the Lilly Screen, as test results may be affected.
- 10. Take care not to block the mouthpiece with tongue or teeth during testing. A 'spitting' action or cough will give false readings.
- 11. The following checks should be performed. If the device fails to pass these checks, contact the manufacturer or Service Agent approved by Vitalograph:
  - a. All pulmonary function standards recommend checking the accuracy of lung function measuring devices daily with a 3 litre Precision Syringe to validate that the instrument is measuring accurately. The VitaloLAB should never be outside accuracy limits. Check accuracy after cleaning or disassembling the Patient Valve for any reason, after adjusting calibration, or if the Patient Valve or device has been dropped.
  - b. If the device or Patient Valve have been dropped it is recommended that a Single Breath Diffusion Quality Control Test is performed to check functionality. For details on the test, see the ComPAS2 Reference Manual (Vitalograph Morgan PFT Range), available in the ComPAS2 software help menu by choosing Help > View Help.
  - c. It is recommended that a DLCO test is performed weekly with a calibrated 3 litre Precision Syringe. For guidelines on how to perform this test, refer to *Single Breath Diffusion Quality Control Test* in the *ComPAS2 Reference Manual (Vitalograph Morgan PFT Range).*
  - d. Each month, gas-analyser linearity should be assessed. The VitaloLAB should never be outside accuracy limits. In normal use, calibration traceability certification is recommended as a part of the routine service.
- 12. Preventative inspection, maintenance and repairs should be carried out only by the manufacturer or by Service Agents approved by Vitalograph.
- 13. Maintenance must not be performed while the device is in use by a subject.
- 14. All values displayed are expressed as BTPS values.
- 15. Do not expose the VitaloLAB to liquids. The VitaloLAB is not designed to be waterproof.
- 16. The VitaloLAB should not be used in the presence of flammable liquids or gases, dust, and or any other chemical substances.
- 17. To isolate the VitaloLAB device from the mains supply, turn off the Main Power Switch on the back of the device. Remove the Power Supply from the mains wall socket. Do not position the device so that the Main Power Switch on the back is inaccessible, or that the Power Supply is difficult to unplug from the socket.
- 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 VitaloLAB and result in improper operation. Only equipment that has been specified in <u>Section 2</u> as compatible for use with the system should be used.
- 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 VitaloLAB device, 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 Patient Valve. This along with the BVF, are the contact points for the subject during a pulmonary function test session. There are no adverse effects if the subject comes into contact with any other part of the VitaloLAB device.
- 23. Ensure that the user does not simultaneously touch the patient and any output connectors (USB ports, Ethernet ports, Serial port, DVI-D port, Display port, power supply socket or Heater Connector) on the VitaloLAB device.
- 24. Only use the listed accessories/equipment specified in the Consumables and Accessory section or provided by Vitalograph for this equipment.
- 25. Avoid exposure to known sources of EMI (electromagnetic interference) such as diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as anti-theft/ electronic article surveillance systems, metal detectors. Note that the presence of RFID devices may not be obvious. If such interference is suspected, reposition the equipment, if possible, to maximize distances. In an extreme EMI event such use as excessive electrical fast transients on the power supply line, communications may be halted, and the device will have to be turned off and then back on again for normal function to resume.
- 26. Caution: Federal Law restricts this device to sale by, or on the order of a physician.

27. If the Patient Valve or device has been dropped, check the device to ensure there are no indications of moving parts sticking or resisting movement or excessive vibration/ separation/ fragmentation/ break/ crack/ fracture/ odor/ smoking. See <u>Section 9</u> Customer Service if a repair is required. All pulmonary function standards recommend checking the accuracy of lung function measuring devices daily with a 3 litre Precision Syringe to validate that the instrument is measuring accurately. The VitaloLAB should never be outside accuracy limits. It is recommended that a Single Breath Diffusion Quality Control Test is performed to check functionality. For details on the test, see the ComPAS2 Reference Manual (Vitalograph Morgan PFT Range), available in the ComPAS2 software help menu by choosing Help > View Help.

#### 3. Main Components of the VitaloLAB

The main components are shown below:



Figure 1: Main Components of VitaloLAB (Inspiratory Bag device shown)

Α	Patient Valve
В	Medically Approved Power Supply
С	Main Power Switch
D	Power LED
E	USB Panel Mount Connector
F	SNIP Test Connector
G	Tubing Connectors for Test Gases
Н	Heater Connector
I	Bulkhead Connector
J	Nose Clip
K	Bacterial Viral Filter (BVF)
L	Bench Clamp
М	Support Arm

#### 3.1. Features of the VitaloLAB

The VitaloLAB features include:

- Lilly screen pneumotachograph to measure flow
- External weather station
- ComPAS2 software
- Choice of child incentive displays
- Customisable report format
- Pre/post bronchodilator comparison
- Choice of predicted values and languages
- Diagnostic interpretation options
- Real-time test quality prompts

# 4. Setting Up the VitaloLAB

Check that the contents of the packaging match the contents label on the inside of the carton.

1. Attach Patient Valve (A) to VitaloLAB device by screwing Patient Valve Bulkhead Connector (I) onto its component on back of device. The Bulkhead Connector alignment key should be in correct alignment to the connector on back of device (Figure 2).

The Bulkhead Connector must be screwed on fully to ensure a leak-tight fit.



Figure 2: Alignment key on Bulkhead Connector

2. Plug in Heater Connector (H), aligning white line on the connector with corresponding white line on connector at back of device (Figure 3).



Figure 3: Alignment markings on Heater Connector

- 3. Only use VitaloLAB with the supplied medically approved low voltage power supply. Attempted use with other power sources may cause irreparable damage and invalidate the warranty.
- 4. Connect power supply (B) into socket on back of the VitaloLAB device. Plug mains plug into a suitable socket. Turn on the Main Power Switch (C) on back of device. The LED (D) light indicates power in the device.
- 5. Install ComPAS2 software onto the PC intended to be used with the device. After logging in, ComPAS2 software will launch automatically.
  - 6. If the VitaloLAB has just been unpacked or transported, ensure it is left sitting, fully powered and is at room temperature prior to testing.

**Note:** The device must be turned on for 20 minutes to allow the Lilly Screen to warm up before testing, calibration or accuracy checks are performed. Always ensure Heater Connector is connected at back of device. **Note:** The device should not be positioned up against a wall because:

- Ventilation fan inside the device may be restricted.
- Patient Valve may not reach around to the patient.
- 7. Attach Bench Clamp (L) to bench or table by loosening screw until clamp fits, then tightening screw until it is secure.
- 8. Slot Support Arm (M) into Bench Clamp. Patient Valve (A) sits into the holder on the arm, if required by subject.
- 9. Connect Gas Tubing (N) into correct Tube Connector (G) on back of device according to label around tube
  - connectors.

#### On VitaloLAB device, three test gases are used and only medical grade gases should be used

- i. DLCO test gas: a gas suitable for human consumption, a mix of 0.3% Carbon Monoxide, 0.3% Methane, Balance Air. Connect this gas to port labelled "DLCO" using largest 10mm O.D. tubing (PN 32873).
- ii. 100% Medical Oxygen. Connect the oxygen to port labelled "O2" using 8mm O.D. tubing (32777).
- iii. Calibration gas: a mix of 13-16% Oxygen, 3-6% Carbon Dioxide, Balance Nitrogen. Connect the calibration gas to the port labelled "CAL" using the smallest 6mm 0.D. tubing (32778).
- 10. With gases turned off, reduce outlet pressures for test gas cylinders to zero.
- 11. Turn on the gases. Ensure that gas cylinders are set as follows:
  - Calibration Gas outlet pressure 5.0 Bar/ 73psi.
  - DLCO Gas outlet pressure 3.5 5.0 Bar/ 50-73 psi.
  - 100% Oxygen outlet pressure, 3.5-5.0 Bar/ 50-73 psi.
  - Gas outlet pressure should not exceed 5.0 bar/73 psi.
- 12. If Maximal Inspiratory Pressure (MIP) or Maximal Expiratory Pressure (MEP) tests are performed, MIP/MEP Adaptor (Q) must first be pushed into Patient Valve as shown in Figure 4, with a BVF then pushed into the other end of MIP/MEP Adaptor.



- 13. A printer, monitor, keyboard, mouse and ethernet cable can be connected to the device. Only the following equipment that has been specified as compatible should be used:
  - Printer: HP OfficeJet 6950 Colour Printer
  - Monitor: Dell 24 Inch HD Monitor

The above models, along with the keyboard, mouse and ethernet cable, can be ordered using the part numbers given in <u>Section 8</u> (Consumables and Accessories).

- 14. Gas regulators are required to set the outlet pressure to the device for each of the three gases. Only equipment that has specifications suitable for use with the system should be used. These are:
  - Cal gas Regulator: Gas Arc Lab Master 6 port 2 stage diaphragm with EPDM seal. Inlet <= 300 bar. Outlet: BS 341
  - No. 3, 0-10 bar ¼ NPT Female thread. (Or equivalent to suit users gas cylinder fitting)
  - DLCO gas Regulator: Gas Arc Lab Master 6 port 2 stage diaphragm with EPDM seal. Inlet <= 300 bar. Outlet: BS 341
  - No. 4, 0-10 bar ¼ NPT Female thread. (Or equivalent to suit users gas cylinder fitting)
  - O2 gas Regulator: Gas Arc 2 stage neoprene diaphragm. Inlet <= 300 bar. Outlet: BS 341 No. 3, 0-10 bar ¼ NPT
  - Female thread. (Or equivalent to suit users gas cylinder fitting)
- 15. Thread to tube push fittings are used to connect the tubing to the gas regulators, these are in sizes 6, 8 & 10mm. Only equipment that has specifications suitable for use with the system should be used. These are:
  - · Festo QS series rated to 14 bar with thread to suit correct regulator.

### 5. Operating Instructions

For guidance on using the ComPAS2 software on the device, refer to *ComPAS2 Reference Manual (Vitalograph Morgan PFT Range)*, available in the software help menu by choosing Help > View Help.

1. On first use:

- a. Enter the exact mixtures of the test gas cylinders in the Calibration screen in ComPAS2. Then perform a gas calibration as per the on-screen instructions. Gas calibration should be performed daily.
- b. Perform a flow-volume span and accuracy check in the Calibration screen in ComPAS2. This should be performed daily.
- c. It is recommended that a *Single Breath Diffusion Quality Control Test* is performed. For details on the test, see *ComPAS2 Reference Manual (Vitalograph Morgan PFT Range)*. This test should be performed weekly.
- 2. Select required subject from ComPAS2 database
- or

Create a new subject.

- 3. Select required test. Instruct subject on the test procedure.
- 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 pulmonary function test manoeuvres. With the BVF fitted the Patient Valve can be left on the Support Arm or on the desk adjacent to the VitaloLAB device.

**Note:** The patient should hold the Patient Valve by the Handle Grip and avoid putting their fingers into the openings where the Shutter Valve is located. Alternatively, the Patient Valve can be mounted on the Support Arm.

#### 5.1. Sensor Calibration

Calibration of all pressure, flow and gas sensors is done using ComPAS2 software. For guidance using the ComPAS2 software on the device, refer to *ComPAS2 Reference Manual (Vitalograph Morgan PFT Range)*, available in the help menu in ComPAS2 software by choosing Help > View.

#### 5.2. Cybersecurity Considerations

#### 5.2.1. Specification

The VitaloLAB requires a user's PC to run ComPAS2 software to operate and therefore will inherit the user's cybersecurity considerations. When connected to a PC, the device goes directly into the installed ComPAS2 software, which can be only accessed by entering a username and password.

No further controls are required to be applied by users to secure the VitaloLAB. ComPAS2 software runs on the user's PC OS and is the only user interface on the device. The device will be protected against any unauthorized access over the USB. The Basic Input/Output System (BIOS) will not allow the device to boot up any USB

Flash Drives that are plugged into it. If the VitaloLAB becomes inoperable either by fault or compromise, the VitaloLAB should be returned for inspection and repair.

**Note:** The VitaloLAB device should not be used if a tamper evident seal is broken.

#### 5.2.2. Interfaces

5.2.3. USB: The VitaloLAB device will only communicate with compatible devices to process and display the datafrom such devices.

#### 6. Power Management

The VitaloLAB is powered by a medically approved low voltage power supply, the combination forming a Medical Electrical (ME) System. Attempted use with other power sources may cause irreparable damage and invalidate the warranty. The output from the power supply is 24 volts DC.

When Main Power Switch on the back of the device is turned on, a blue LED will light to indicate power in the device. To shut down the VitaloLAB device:

- a. Close the ComPAS2 session on screen. A prompt will appear to turn off gas supply. This will automatically log-off the current user.
  - Or

Press the power icon on log-on screen.

b. Turn off the Main Power Switch on the back of the device. The LED will turn off.

To move the VitaloLAB device, ensure that the gas supplies are turned off, the gas tubing is bled free of gas and then disconnected from the "DLCO", "O2" and "CAL" ports on the back of the device before shutdown.

#### 6.1. Power Supply Information

Manufacturer	SL Power Electronics
Manufacturer Part Number	ME150A2451N01
AC Input	100-240Vac (+/- 10%)
Output Voltage	24V
Output Current	6.05A at 100-110V
	6.25A at 110-240V
Output Connector	6 pin Molex Type

#### 7. Cleaning & Hygiene

#### 7.1. Preventing Cross-Contamination of Subjects

Pulmonary function test equipment is not designed or supplied as a 'sterile' device.

Vitalograph intends that a new Bacterial Viral Filter (BVF<sup>™</sup>) 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 pulmonary function test manoeuvres.

The interior of a Vitalograph Patient Valve does not require decontamination where a new BVF is used for each subject. The outside surfaces of the device, Patient Valve and Patient Valve Tubing Sleeve may be cleaned with a 70% isopropyl alcohol impregnated cloth to remove any visible soiling and for low level disinfection.

If you suspect the Patient Valve has become contaminated or where user risk assessment identifies a need for higher level of decontamination, then it should be cleaned by a medical professional as per the 'Cleaning and Hygiene' instructions on the Vitalograph website.

#### 7.2. Inspection of the VitaloLAB

A visual inspection is recommended on a routine basis.

If you suspect the Lilly Screen has particulate which needs to be removed, the Patient Valve can be partly disassembled to aid cleaning. Instructions on accessing the Lilly Screen are given below.

Whilst the Patient Valve is disassembled it is recommended to examine the O-rings, Shutter Seal, One-way Diaphragm, Bag Assembly Diaphragm, Inspiratory Bag Shutter Seal, and Inspiratory Bag in the Patient Valve and replace if damaged.

These parts must be replaced on an annual basis as part of the device service.

For instructions on how to access these parts, refer to the relevant steps in 'Cleaning and Hygiene' on the Vitalograph website.

An accuracy check should be carried out following reassembly to verify correct operation and accuracy. See point 11 in <u>Section 2.2</u> Warnings and Precautions.

Remove any visible soiling from outside surfaces of any connected equipment using a cloth.

#### 7.2.1. Accessing the Lilly Screen



Figure 5: Exploded Assembly for Patient Valve with Inspiratory Bag

A	Front Cap	Н	Inspiratory Bag Housing Adaptor		Shutter Seal Plate
В	Flowhead Subject End	1	Inspiratory Bag Cap		Breathing Tube
С	Lilly Screen	J	Inspiratory Bag Housing Q Top One-Way Valu		Top One-Way Valve Assembly
D	Heater Assembly	K	Inspiratory Bag Shutter Seal R Retainer Cap Hous		Retainer Cap Housing
Ε	Left Side Casing	L	Shutter Seal		Retainer Cap Loop
F	Main Housing	М	End Cap		Retainer Cap
G	One-Way Diaphragm	N	Right Side Casing   U   Inspiratory Bag		Inspiratory Bag

**Note:** The device should be powered off 5 minutes before disassembling the Patient Valve, to allow the internal Heater Assembly to cool down first.

**Note:** The Patient Valve must be disassembled in the orientation shown in Figure 7, with the lock/unlock features on the Left Side Casing visible at all times.

1. Remove Inspiratory Bag from Patient Valve



Figure 6- Front Cap in the unlock location.

2. Turn Front Cap anticlockwise to the unlock position (Figure 6) and remove (Figure 7).



Figure 7 - Flowhead with Front Cap removed.

3. Remove green and clear tubing by sliding them off the green coloured elbow (Figure 8).



Figure 8 - Green and clear tubing removed from elbows.

4. Turn the flowhead subject end anticlockwise to the unlock position and remove, giving access to the Lilly Screen (Figure 9).



Figure 9 - Flowhead subject end in the unlock position.

- 5. Remove the Lilly Screen and clean it.
- 6. Fit Flowhead Subject End to Heater Assembly by lining up large and small alignment keys as in Figure 10 and then turning the parts clockwise to the lock position. This forms the Flowhead.



Figure 10 - Alignment of Flowhead Subject End and Heater Assembly

7. Reconnect the green tubing to the associated elbow ensuring there are no kinks (Figure 12).



Figure 11 - Tubing re-connected.

8. Align the arrow on the front cap with the unlock position on the flowhead body (Figure 12). Carefully push in the front cap fully and turn clockwise until in the locked position.



Figure 12 - Front cap aligned in the unlock position.



Figure13 - Front cap in the unlock position.

9. On the Patient Valve, push round collar of Inspiratory Bag into opening on Inspiratory Bag Housing.

10. Wipe all external surfaces of Patient Valve with a 70% isopropyl alcohol impregnated cloth.

# 8. Fault Finding Guide

Problem Fault Symptoms:	<ul> <li>Failing flow-volume accuracy check</li> </ul>		
Possible Causes: (In probable order)	<ul> <li>Recheck Calibration with reference to flow-volume span and accuracy check in <u>Section 3</u> in this manual.</li> <li>Ensure Bulkhead Connector is screwed on fully to back of device.</li> <li>Cold syringe – ensure syringe is in test environment for at least 1 hour before use.</li> <li>Ensure Patient Valve Heater Connector is connected to back of device. Check that heater plug, and socket are connected in the handle of the Patient Valve</li> <li>Check Lilly Screen for any particulate causing a blockage. To clean, refer to <u>section 5</u> in this manual.</li> <li>Ensure tubing is connected correctly. On the Patient Valve, red tube should be connected to red elbow and green tubing should be connected to green elbow.</li> <li>Ensure tubing is pushed onto elbows and securely attached.</li> <li>Ensure elbows are clear of obstruction or dirt and they are not loose.</li> <li>Internal tubing from Bulkhead Connector is blocked: contact support.</li> <li>Electronics failure: contact support.</li> </ul>		
Problem Fault Symptoms:	<ul> <li>Incorrect or no volume measurements for subjects</li> <li>Not measuring subject flow rates</li> <li>Test performed on subject but does not show on screen</li> </ul>		
Possible Causes: (In probable order)	<ul> <li>Recheck Calibration with reference to flow-volume span and accuracy check in <u>Section</u> in this manual.</li> <li>Ensure Bulkhead Connector is screwed on fully to back of device.</li> <li>Ensure Patient Valve Heater Connector is connected to back of device. Also check that heater plug, and socket are connected in the handle of the Patient Valve.</li> <li>Check Lilly Screen for particulate causing a blockage. To clean, refer to <u>section 5</u> in this manual</li> <li>Ensure tubing is connected correctly. On Patient Valve, red tube should be connected to red elbow and green tubing should be connected to green elbow.</li> <li>Ensure tubing is pushed onto elbows and securely attached.</li> <li>Ensure elbows are clear of obstruction or dirt and they are not loose.</li> <li>Ensure tubing is not kinked or squeezed during reassembly of the Patient Valve.</li> </ul>		
Problem Fault Symptoms:	Report does not print all tests     Report does not print some parameters		
Possible Causes: (In probable order)	<ul> <li>Ensure correct report settings are entered in Reports page in ComPAS2 software. See Reports section of Morgan Scientific ComPAS2 Reference Manual (Vitalograph Morgan PFT Range), available in the help menu in ComPAS2 software by choosing Help &gt; View Help.</li> </ul>		
Problem Fault Symptoms:	<ul> <li>Test begins automatically</li> <li>Volume accumulates automatically without the subject blowing</li> <li>Very small VC or FVC test displayed</li> </ul>		
Possible Causes: (In probable order)	<ul> <li>Patient Valve and/or Patient Valve</li> <li>Tubing Sleeve not stationary at the start of test. Hold them steady until prompted to begin the test.</li> <li>Return to "Patients" screen then choose "Run Test" to re-enter the test routine.</li> </ul>		
Problem Fault Symptoms:	Gas readings are incorrect		
Possible Causes: (In probable order)	<ul> <li>Ensure the correct gas concentrations have been entered in the Gas Analysers section of the Calibrate page in ComPAS2 software.</li> <li>Ensure Bulkhead Connector is screwed on fully to back of device.</li> <li>Ensure tubing is connected correctly. Clear tube should be connected securely to white elbow on Patient Valve.</li> <li>Ensure that white elbow on Patient Valve is clear of obstruction or dirt and is not loose.</li> <li>Ensure tubing is not kinked or squeezed during reassembly of the Patient Valve.</li> </ul>		

#### 9. Customer Service

Service life of the VitaloLAB is 1 year.

Service and repairs should be carried out only by the manufacturer or by Service Agents approved by Vitalograph. Preventative inspection and maintenance should be performed annually by Service Agents only on the following parts: the Manifold Filters, Sample Line Filters, Fuses and Nafion Tubing. The Oxygen Leak Sensor is due to be changed every years. The service manual outlines how preventative inspection and maintenance should be performed. Preventative inspection, maintenance and repairs should be carried out only by the manufacturer or by Service Agents approved by Vitalograph.

For the names and addresses of approved Vitalograph Service Agents or to arrange pulmonary function test workshops, please refer to the contact information 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.

Calibration gas is expected to last up to 20 weeks. Assuming typical device usage and cylinder size AV filled to 137 Bar.

This IFU is available on the Vitalograph website at the following location: <u>https://vitalograph.com/ifu/Vitalograph\_VitaloLab\_IFU.pdf</u>

The ComPAS2 User Manual is available on the Morgan Scientific website at the following location: https://www.morgansci.com/mp-files/compas2-reference-manual-with-model-9100-vitalograph-morgan-pft.pdf/

#### **10. Consumables and Accessories**

Cat. No.	Description
28501	Eco BVF – Bacterial/Viral Filters (100)
28572	Eco BVF and Disposable Nose Clip (80)
28551	Eco BVF with Silicone Bite-On Mouthpiece and Disposable Nose Clip (60)
28554	Eco BVF with Bite Lip (75)
28553	Eco BVF with Bite Lip and Disposable Nose Clip (75)
20392	Silicone Bite-On Mouthpiece (50)
20303	Nose Clips (200)
36020	3 litre Precision Syringe
91977	Power Supply
91342	Lilly Screen (x5)
91279	O-rings for Patient Valve (replacements)
91280	Bag Assembly Diaphragm (replacement)
91333	Shutter Seal (replacement)
91334	Inspiratory Bag Shutter Seal (replacement)
91346	One-way Diaphragm
91945	9L Inspiratory Bag
91947	Krytox Grease
67252	USB A to USB B Cable (to connect printer)
91345	Ethernet Cable

#### 11. 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.

Accessories:

- 1. The 3 litre Precision Syringe should be returned to Vitalograph for disposal at the product's end-of-life.
- 2. Electrical accessories and batteries must be disposed of separately according to the regulations for your country.
- 3. Used BVFs constitute minimally soiled waste from human healthcare and should be disposed of in line with local requirements. BVFs are made from polypropylene.



4. Remaining accessories should be disposed of using their local waste disposal regulations.

# 12. Explanation of Symbols

Symbol	Description
★	Type BF applied part
	Class II
	On (power)
0	Off (power)
VA	Power rating (power supply)
v ====	Direct current (power supply)
c <b>RL</b> us	UL Component Recognition Mark for Canada and U.S.A. (power supply)
CE	CE mark (power supply)
Rx Only	Restricted to sale by, or on the order of a physician.
D	Certified to applicable Danish standards and requirements by UL International Demko A/S (power supply)
Ŵ	United States Department of Energy Level VI (power supply)
IP22	Ingress Protection. Protection against objects greater than 12.5mm and dripping water when tilted at 15o (power supply only)
i	Instructions for Use; operating instructions
	Manufacturer
$\sim$	Date of Manufacture
●	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
Ţ	Fragile, handle with care
Ť	Keep Dry
(	Do not re-use
NON STERILE	Non-sterile
R A	Recycle
	QR code - matrix bar code. All information in the bar code is included in the text under it
PC/ABS	Polycarbonate/Acrylonitrile Butadiene Styrene
$\leq$	Use by date
LOT	Batch code

#### **Witalograph**

	Serial interface	
<b>E</b>	Refer to instruction manual/booklet	
물물	Computer network	
	Serial port	
	Transfer of heat in general	
SNIP	Sniff nasal inspiratory pressure	
DLCO	DLCO gas connection	
02	O2 gas connection (VitaloROV+ Only)	
CAL	Calibration gas connection (VitaloROV+ Only)	
SN	Serial number	
REF	Catalogue number	
MIP/MEP	Maximum inspiratory pressure/Maximum expiratory pressure	
8	Lock location mark	
2	Unlock location mark	
$\triangleright$	Location mark	
	MR Unsafe	
MD	Medical Device	
	Country of Manufacture	

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#### 13. Description of the VitaloLAB

The VitaloLAB, in association with ComPAS2 software, is a pulmonary function testing device designed for use in a variety of professional healthcare environments e.g. primary care, hospitals, pharmaceutical research centres and physicians' offices.

The VitaloLAB is designed for desktop use. Each device accommodates an Inspiratory Bag for delivering test gas to the subject. The VitaloLAB is a pulmonary function testing device only and must be used in conjunction with a desktop PC and ComPAS2 software.

Pulmonary function testing 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. Pulmonary function testing may support or exclude diagnosis, but it cannot make one.

The devices are intended for use by medical professionals trained in respiratory and lung function testing. Apart from this instruction manual, there are no other training requirements for the medical professional.

This Instructions for Use document relates to the hardware of the VitaloLAB only. For guidance on using ComPAS2 software refer to the ComPAS2 Reference Manual (Vitalograph Morgan PFT Range), available in the help menu in ComPAS2 software by choosing Help > View Help.

Tests measured by the VitaloLAB include:

Abbreviation	Test
FVC	Forced Vital Capacity Testing
SCV	Slow Vital Capacity Testing
MVV	Maximum Voluntary Ventilation Testing
CPF	Cough Peak Flow Testing
RMS	Respiratory Muscle Strength (MIP and MEP) Testing
SNIP	Sniff Nasal Inspiratory Pressure Testing
DLCO	Traditional Single Breath Diffusion Testing
MBN2	Multi-Breath Nitrogen Washout LCI Testing (VitaloROV+ Only)
SBN2	Single-Breath Nitrogen Washout Testing (VitaloROV+ Only)

Not all tests listed in ComPAS2 are selectable in the VitaloLAB. Selectable tests will be available to select on the test screen. For guidance on using ComPAS2 software refer to the ComPAS2 Reference Manual (Vitalograph Morgan PFT Range), available in the ComPAS2 software help menu by choosing Help > View Help.

Tests listed in the ComPAS2 Manual but are not selectable or measurable on the VitaloLAB include FRC (Helium Dilution Testing), VTG (Volume of Thoracic Gas or Plethysmography) and RAW (Airways Resistance Testing).

#### 14. Technical Specification

Products	Model 9100 Vitalograph VitaloLAB		
Model	9100		
Essential Performance	Recording the Carbon Monoxide and Methane values from the DLCO Gas Analyser.		
	Data will be transferred by USB from the device PCBs to the desktop computer.		
Essential Performance	The output from the DLCO Gas Analyser must stay within the predetermined limits (see below) both in normal and single fault conditions.		
Test Limits	Carbon Monoxide (CO) values in DLCO Gas Analyser: +/- 30 counts		
	Methane (CH4) values in DLCO Gas Analyser: +/- 75 counts		
Flow detection principle	Heated Lilly type pneumotachograph		
Back pressure	Less than 0.15kPa/L/second @ 14L/s, complies with ISO26782:2009		
Volume detection	Flow integration sampling @ 100Hz		
Volume accuracy	Within ±2.5% or ±75 mL		
Voltage/Frequency	100 - 240V; approximately 50/60 Hz		
Flow accuracy	Within $\pm 10\%$ over the range of -14 to +14 L/s		

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Flow Measurement Range	Max. flow rate ±14 L/s		
	Min. flow rate ±0.2 L/s		
Operating temperature	ISO26782 limits: 17–37°C		
range	Design limits: 15–32°C		
Operating humidity range	nge 30%-75%		
Ambient pressure range700hPa-1060hPa			
	Nondispersive infrared (NDIR) sensor. Accuracy:		
Gas Analyser for CO/CH4	CO ±1 % of Full Scale CH4 ±1 % of Full Scale		
	Laser diode absorption for O2. Infrared sensor for CO2 Accuracy:		
Gas Analyser for 02/C02	02 +/- 0.2%		
	CO2 +/- 0.1%		
Mouth Pressure	Digital pressure sensor Accuracy: 0.5%		
Shutter Valve	Pneumatic spring-return cylinder		
Product Life	10 years+ when maintenance and servicing (1 year service life) procedures are adhered to		
Cases required for Vitalal AP	Mix containing 0.3% Carbon Monoxide, 0.3% Methane, Balance Air		
device	• 100% Oxygen		
	Mix containing 13-16% Oxygen, 3-6% Carbon Dioxide, balance Nitrogen		
Performance standards the	ISO 23747:2015, ISO 26782:2009,		
VitaloLAB meets or exceeds	ATS/ERS: 2019		
Safety standards	EN 60601-1:2006+A1:2013+A2:2021		
EMC standards	EN 60601-1-2:2015 + A1:2021		
QA/GMP standards	EN ISO 13485		
Size	500mm x 395mm x 135mm		
Weight	9 Kg		
Printer	External		
	On device: USB B (x1).		
Communications	USB (x2) for Tech Support access.		
	[User PC spec is called out in the Compas2 user manual; USB (x6) (5 available after Lab is connected), Ethernet (x1), Display Port (x1) & HMDI (x1).] – based on users PC.		
Software Morgan Scientific ComPAS2 Reference Manual (Vitalograph Morgan PFT Rat			

Notes

• The specified operating temperature and humidity ranges apply to the device plus accessories.

- The Patient Valve is a type BF applied part. 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 the
  equipment or system to perform its function.
- Vitalograph will make available any information necessary to assist Service Agents to repair parts, such as circuit diagrams, part lists, descriptions, calibration instructions or other information.

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#### 15. CE Notice



Marking by the symbol 2797 indicates compliance of the 9100 Vitalograph VitaloLAB to the European Medical Device Regulation 2017/745 (EU MDR) as amended.

The Vitalograph VitaloLAB is intended for use in a variety of professional healthcare and home environments, e.g. private domiciles, primary care, hospital wards, occupational health centres, except for near active high frequency surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high. The customer or the user of the Vitalograph VitaloLAB should assure that it is used in such an environment.

The 9100 Vitalograph VitaloLAB has been tested in accordance with:

EN 60601-1:2006+A1:2013+A2:2021 with US deviations - Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

EN 60601-1-2:2015 + A1:2021- Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

EN 60601-1-2:2015 + A1:2021- Emissions tests			
Emissions test	Compliance	Electromagnetic environment - guidance	
RF emissions CISPR 11	Group 1	The Model 9100 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.	
Radiated and Conduct- ed Emissions CISPR 11			
Harmonic Emissions IEC 61000-3-2	Class A	The Model 9100 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)	
Voltage fluctuations/ flicker emissions			
IEC 61000-3-3			

EN 60601-1-2:2015 + A1:2021- Immunity tests			
Immunity test	Test level	Compliance level Reached	
Electrostatic discharge (ESD)	±8 kV contact	±8 kV contact	
EN 61000-4-2	±15 kV air	±15 kV air	
Proximity fields from RF wireless communications equipment	9 to 28V/m	9 to 28V/m	
	385 to 5785MHz	385 to 5785MHz	
EN 61000-4-3	As per Table 9 EN60601-1-2	As per Table 9 EN60601-1-2	
Radiated	3 V/m (professional healthcare)	3 V/m (professional healthcare)	
RF EN	80 MHz to 2.7 GHz	80 MHz to 2.7 GHz	
61000-4-3	80 % amplitude modulated at 1 kHz	80 % amplitude modulated at 1 kHz	
Surge Immunity EN 61000-4-5	±1kV differential mode	±1kV differential mode	
	Device is identified as Class II unearthed equipment therefore common mode testing is not required	Device is identified as Class II unearthed equipment therefore common mode testing is not required	

Conducted RF Immunity EN 61000-4-6	3V/m 0.15-80MHz 6V/m ISM/amateur radios bands 0.15-80MHz 80% AM at 1kHz	3V/m 0.15-80MHz 6V/m ISM/amateur radios bands 0.15-80MHz 80% AM at 1kHz
Power frequency (50/60 Hz) magnetic field Immunity EN 61000-4-8	30 A/m; 60 Hz	30 A/m; 60 Hz
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	100% drop, 0.5 cycles, 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 100% dip, 1 cycle 30% dips, 25/30 cycles	100% drop, 0.5 cycles, 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 100% dip, 1 cycle 30% dips, 25/30 cycles
Proximity magnetic Fields EN 61000-4-39	8A/m 30kHz 65A/m 134.2kHz (2.1 kHz PM) 7.5A/m 13.56MHz (50 kHz PM)	8A/m 30kHz 65A/m 134.2 kHz (2.1 kHz PM) 7.5A/m 13.56 MHz (50 kHz PM)

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.

**Note:** The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

WARNING: No modification of this equipment is allowed.

#### 16. FDA Notice

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

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# 17. EU Declaration of Conformity

#### Product: 9100 Vitalograph - VitaloLAB

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 Device Regulation (MDR) 2017/745, as amended.

This device is classified as IIa per Annex IX of the MDR also meets the provisions of the General Safety and Performance Requirements, Annex I, via compliance with Annex IV of the Medical Devices Regulation as per Article 52.



• EN ISO 13485 Medical devices. Quality management systems. Requirements for regulatory purposes.

Certifying Body: British Standards Institute (BSI). BSI Notified Body #: 2797 Certificate Nos. 772430

Signed on behalf of Vitalograph (Ireland) Ltd.

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Frank Keane. CEO, Vitalograph Ltd.

## 18. Guarantee

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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 2 years 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 2 years 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. The Company does not authorize any person to create for it any other obligation or liability in connection with Vitalograph<sup>®</sup> 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.

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