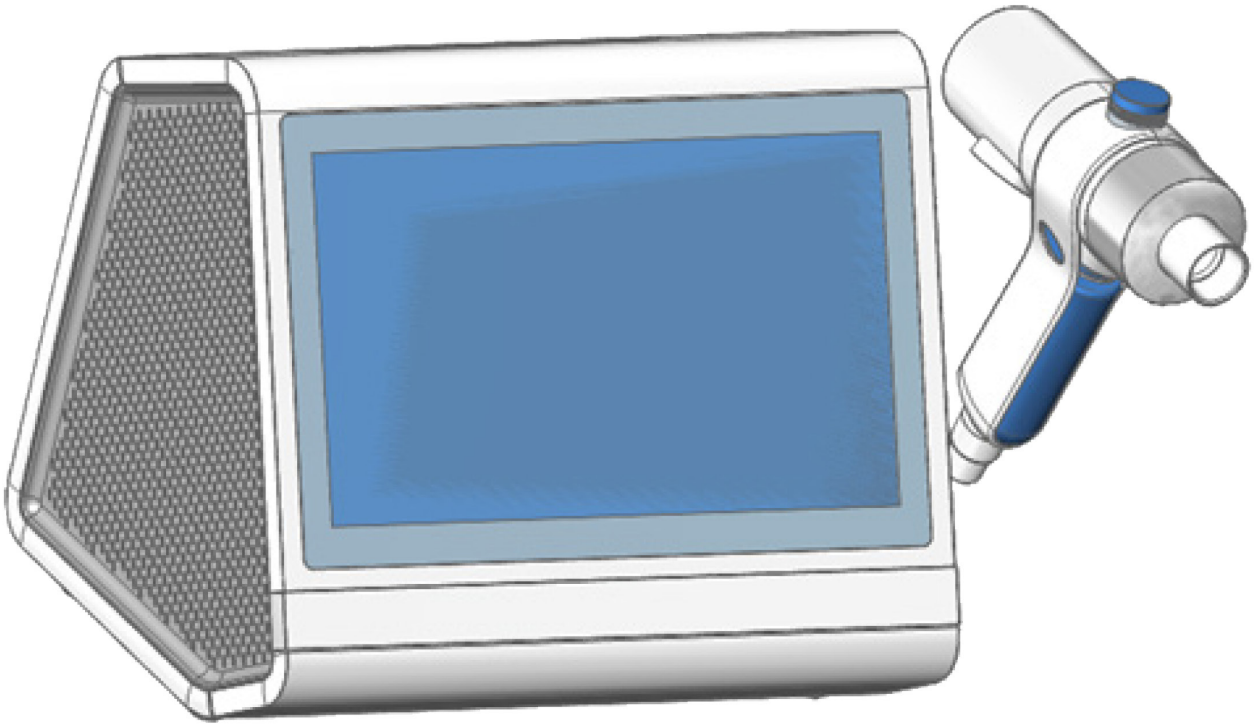
Vitalograph®

VitaloROV®/ROV®+

MODEL 9100



Rx Only

Instructions for Use

Vitalograph Branch Addresses

EN

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@vitalograph.de

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

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
Email: technical.support@vitalograph.ie

Current Edition (Issue 7, 04-Sept-2024)
Cat. No. 09950

EN

Contents

1. Indications for Use 4
2. Contraindications, Warnings, Precautions and Adverse Reactions 4
   - 2.1. Contraindications and Adverse Reactions 4
   - 2.2. Warnings and Precautions 4
3. Main Components of the VitaloROV/ROV+ 6
   - 3.1. Features of the VitaloROV/ROV+ 7
4. Setting Up the VitaloROV/ROV+ 7
5. Operating Instructions 9
   - 5.1. Sensor Calibration 9
   - 5.2. Cybersecurity Considerations 9
6. Power Management 10
   - 6.1. Power Supply Information 10
7. Cleaning & Hygiene 10
   - 7.1. Preventing Cross-Contamination of Subjects 10
   - 7.2. Inspection of the VitaloROV/ROV+ 10
8. Fault Finding Guide 15
9. Customer Service 16
10. Consumables and Accessories 16
11. Disposal 16
12. Explanation of Symbols 17
13. Description of the VitaloROV/ROV+ 18
14. Technical Specification 19
15. CE Notice 20
16. FDA Notice 22
17. EU Declaration of Conformity 23
18. Guarantee 24

EN

1. Indications for Use

The Model 9100 VitaloROV®/ROV+ 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 VitaloROV measures all the above except 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 VitaloROV/ROV+ 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

1. No modification of this equipment is allowed. Any unauthorised changes to the VitaloROV/ROV+ 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 VitaloROV/ROV+ 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™) 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 VitaloROV/ROV+ ready for use:

a. Ensure that gas cylinders are set as follows:
- Calibration Gas outlet pressure 5.0 Bar/ 73psi. (VitaloROV+ Only)
- DLCO Gas outlet pressure 5.0 Bar/73 psi.
- 100% Oxygen outlet pressure, 3.5-5.0 Bar/ 50-73 psi. (VitaloROV+ Only)

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 Section 4 for further details.

c. 6, 8 (VitaloROV+ Only) & 10mm thread to tube push fits must be rated to 14 Bar minimum. See Section 4 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 O.D.) tubing.
ii. Connect the 100% Oxygen to the port labelled "O2" using medium (8mm O.D.) tubing on the VitaloROV+ only.
iii. Connect the O2/CO2 mixed gas to port labelled "CAL" using smallest (6mm O.D.) tubing on the VitaloROV+ Only

e. Ensure that the power supply is securely connected.
Use only the low voltage power supply which is provided by Vitalograph with VitaloROV/ROV+. Attempted use with other power sources may cause damage and invalidate the warranty.

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 Section 4 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 proceeds.*

Note: *The device should not be positioned up against a wall for the following reasons:*
- Ventilation fan inside the device may be restricted.
- Patient Valve may not reach around to the patient.

6. 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 and to negate the possibility of fingers getting trapped due to the movement of the shutter. Alternatively, the Patient Valve can be mounted on the Support Arm.
7. Before disassembling the Patient Valve, the device should be powered off for 5 minutes to allow the internal Heater Assembly to cool down.
8. If a Maximal Inspiratory Pressure (MIP) or Maximal Expiratory Pressure (MEP) test are performed, a MIP/MEP Adaptor must first be attached to Patient Valve , with a BVF then attached to the other end of MIP/MEP Adaptor (Figure 4).
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. 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 VitaloROV/ROV+ 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 VitaloROV/ROV+ 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 VitaloROV/ROV+ to liquids. The VitaloROV/ROV+ is not designed to be waterproof.
16. The VitaloROV/ROV+ should not be used in the presence of flammable liquids or gases, dust, and or any other chemical substances.
17. To isolate the VitaloROV/ROV+ 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 VitaloROV/ROV+ and result in improper operation. Only equipment that has been specified in Section 10 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 VitaloROV/ROV+ device and 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 VitaloROV/ROV+ 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 VitaloROV/ROV+ device.
24. Only use the listed accessories/equipment specified in the Consumables and Accessory section or provided by Vitalograph for this equipment.

EN

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.
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 Section 9 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 VitaloROV/ROV+

The main components are shown below:

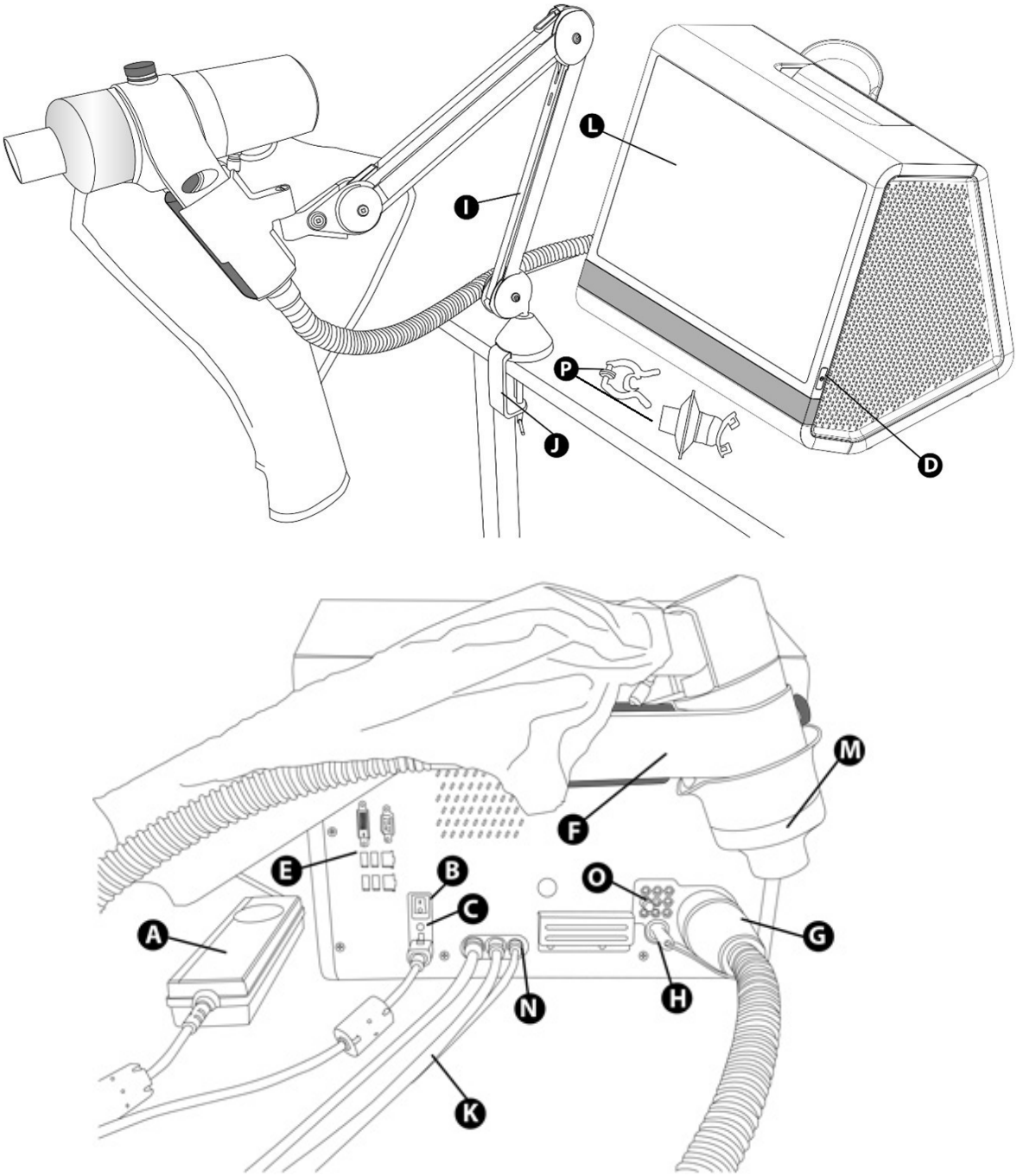


Figure 1: Main Components of VitaloROV/ROV+ (Inspiratory Bag device shown)

A	Medically Approved Power Supply
B	Main Power Switch
C	Power LED
D	Device Power Switch
E	I/O Ports – 5 x USB, 2 x Ethernet, 1 x Serial, 1 x DVI-D, 1 x Display
F	Patient Valve
G	Bulkhead Connector
H	Heater Connector
I	Support Arm
J	Bench Clamp
K	Tubing
L	Colour LCD Touchscreen
M	Patient Valve Holder
N	Tubing Connectors for Test Gases
O	Exhaust Ports
P	Bacterial Viral Filter (BVF) with Bite-On Mouthpiece and Noseclip
Q	MIP/MEP Adaptor (Figure 4)

3.1. Features of the VitaloROV/ROV+

The VitaloROV/ROV+ features include:

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

4. Setting Up the VitaloROV/ROV+

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

1. Attach Patient Valve (F) to VitaloROV/ROV+ device by screwing Patient Valve Bulkhead Connector (G) 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.

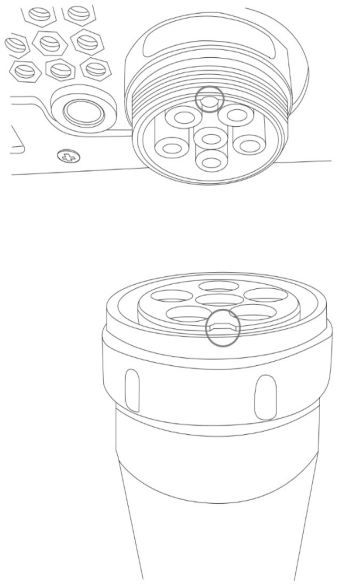


Figure 2: Alignment key on Bulkhead Connector

EN

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

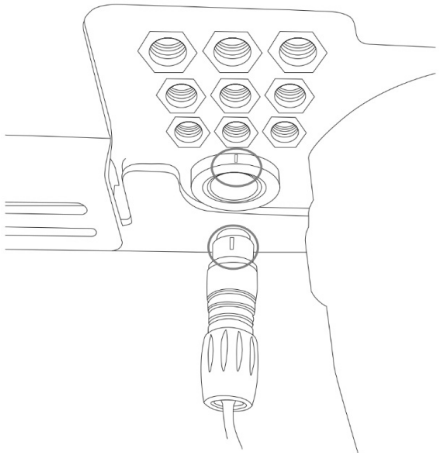


Figure 3: Alignment markings on Heater Connector

3. Slide Patient Valve Holder (M) onto its mount on back of device, with the narrow opening on the Holder pointing downwards.
4. Only use VitaloROV/ROV+ with the low voltage power supply provided by Vitalograph. Attempted use with any other may cause damage and invalidate the warranty.
5. Connect power supply (A) into socket on back of the VitaloROV/ROV+ device. Plug mains plug into a suitable socket. Turn on the MainPower Switch (B). The LED (C) will light to indicate power in the device.
6. Press the white Power Switch (D) to turn on the device. Use the touchscreen (L) to access a touchscreen keyboard to log-in. After logging in, ComPAS2 software will launch automatically.
7. If VitaloROV/ROV+ 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.***
8. Attach Bench Clamp (J) to bench or table by loosening screw until clamp fits, then tightening screw until it is secure.
9. Slot Support Arm (I) into Bench Clamp. Patient Valve (F) sits into the holder on the arm, if required by subject.
10. Connect Gas Tubing (K) into correct Tube Connector (N) on back of device according to label around tube connectors.
    On the VitaloROV+ device, three test gases are used. On the VitaloROV, only one gas is used. 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 (PN32873).
    ii. 100% Medical Oxygen (VitaloROV+ Only). Connect the oxygen to port labelled “O2” using 8mm O.D. tubing (PN 32777).
    iii. Calibration gas: a mix of 13-16% Oxygen, 3-6% Carbon Dioxide, Balance Nitrogen (VitaloROV+ Only). Connect the calibration gas to the port labelled “CAL” using the smallest 6mm O.D. tubing (PN 32778).
11. With gases turned off, reduce outlet pressures for test gas cylinders to zero.
12. Turn on the gases. Ensure that gas cylinders are set as follows:
    - Calibration Gas (VitaloROV+ Only) outlet pressure 5.0 Bar/73psi.
    - DLCO Gas outlet pressure 5.0 Bar/73 psi.
    - 100% Oxygen (VitaloROV+ Only) outlet pressure, 3.5-5.0 Bar/50-73 psi.

    Gas outlet pressure should not exceed 5.0 bar/73 psi.
13. If a Maximal Inspiratory Pressure (MIP) or Maximal Expiratory Pressure (MEP) test are performed, MIP/MEP Adaptor (Q) must be attached to the Patient Valve, with a BVF then attached to the other end of MIP/MEP Adaptor (Figure 4).

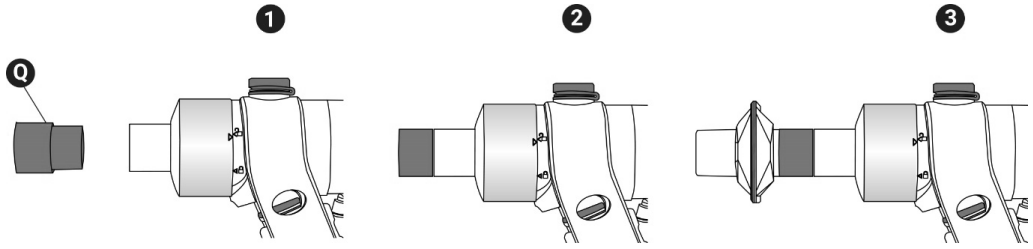


Figure 4: Fitting MIP/MEP Adaptor

14. A printer, monitor, keyboard, mouse and ethernet cable can be connected to the device. Only equipment that has been specified as compatible for use with the system should be used. These are:
    - Printer: HP OfficeJet 6950 Colour Printer
    - Monitor: BenQ BL2405PT 24 Inch HD Monitor

    The above models, along with the keyboard, mouse and ethernet cable, can be ordered using the part numbers in Section 8 Consumables and Accessories.
15. 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 (VitaloROV+ Only): 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 (VitaloROV+ Only): 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) VitaloROV+ Only.
16. Thread to tube push fittings are used to connect the tubing to the gas regulators, these are in sizes 6mm (VitaloROV+ Only), 8mm (VitaloROV+ Only) & 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 the *ComPAS2 Reference Manual (Vitalograph Morgan PFT Range)* 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 VitaloROV/ROV+ 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, refer to the ComPAS2 Reference Manual (Vitalograph Morgan PFT Range) in the ComPAS2 software help menu by choosing Help > View Help.

5.2. Cybersecurity Considerations

5.2.1. Specification

The VitaloROV/ROV+ employs an Operating System (OS) that is not accessible to the end user. When turned on, the device goes directly into the installed ComPAS2 software, which can only be accessed by entering a username and password.
No further controls are required to be applied by users to secure the VitaloROV/ROV+.
ComPAS2 software runs on the OS and is the only user interface on the device. There is no access to Windows. Automatic Windows updates are disabled.
The device will protect against any unauthorized access over the USB, Ethernet, or Serial ports. Only devices with drivers already preloaded on the VitaloROV/ROV+ device can be used. The Basic Input/Output System (BIOS) will not allow the device to boot up any USB flash drives that are plugged into it. The BIOS is also password-protected.
If the VitaloROV/ROV+ becomes inoperable either by fault or compromise, it should be returned to Vitalograph for inspection and repair.
Note: The VitaloROV/ROV+ device should not be used if a tamper evident seal is broken.

EN

5.2.2. Interfaces

USB: The VitaloROV/ROV+ device will only communicate with compatible devices to process and display the data from those devices.

6. Power Management

The VitaloROV/ROV+ 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 turn on the computer, press the white Power Switch on the side of the device.
To shut down the VitaloROV/ROV+ 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
b. Press the power icon on log-on screen.
c. Turn off the Main Power Switch on the back of the device. The LED will turn off.

To move the VitaloROV/ROV+ 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 (BVFTM) 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, the 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 VitaloROV/ROV+

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 as outlined in Section 7.2.1.

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 ‘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 Section 2.2 Warnings and Precautions.

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

7.2.1. Accessing the Lilly Screen

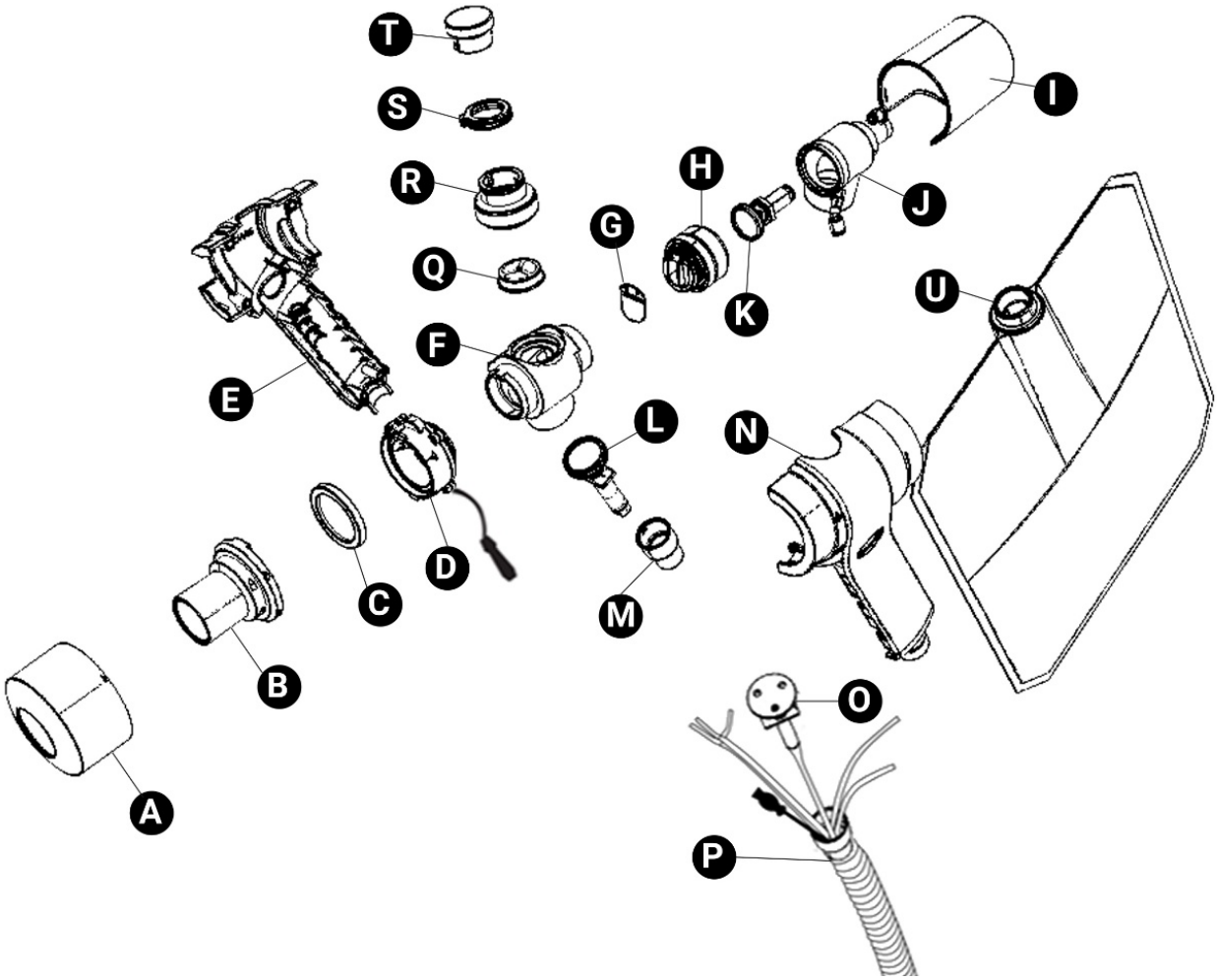


Figure 5: Exploded Assembly for Patient Valve with Inspiratory Bag

A	Front Cap	H	Inspiratory Bag Housing Adaptor	O	Shutter Seal Plate
B	Flowhead Subject End	I	Inspiratory Bag Cap	P	Breathing Tube
C	Lilly Screen	J	Inspiratory Bag Housing	Q	Top One-Way Valve Assembly
D	Heater Assembly	K	Inspiratory Bag Shutter Seal	R	Retainer Cap Housing
E	Left Side Casing	L	Shutter Seal	S	Retainer Cap Loop
F	Main Housing	M	End Cap	T	Retainer Cap
G	One-Way Diaphragm	N	Right Side Casing	U	Inspiratory Bag

Note: *Before disassembling the Patient Valve, the device should be powered off for 5 minutes to allow the internal Heater Assembly to cool down.*
Note: *The Patient Valve must be disassembled in the orientation shown in Figure 6, with the lock/unlock features on the Left Side Casing visible at all times.*

EN

1. Remove Inspiratory Bag from Patient Valve

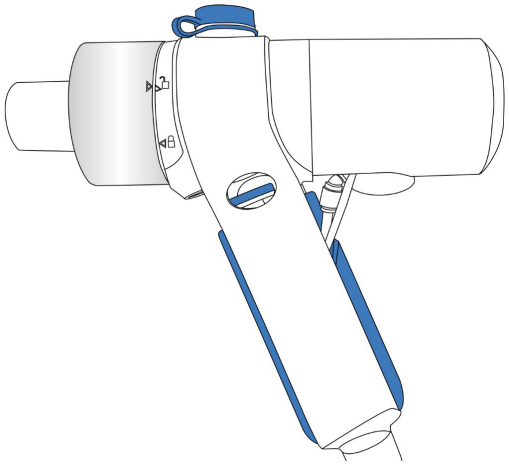


Figure 6- Front Cap in the unlock location.

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

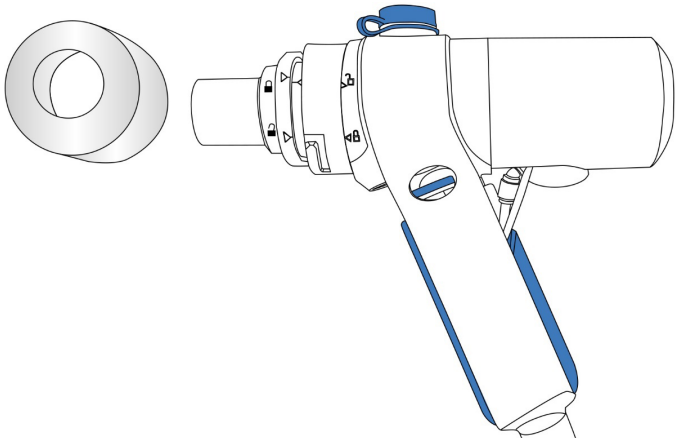


Figure 7 - Flowhead with Front Cap removed.

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

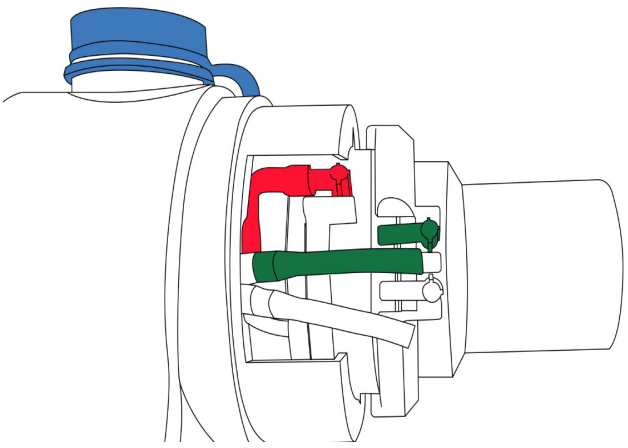


Figure 8 - Green and clear tubing removed from elbows.

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

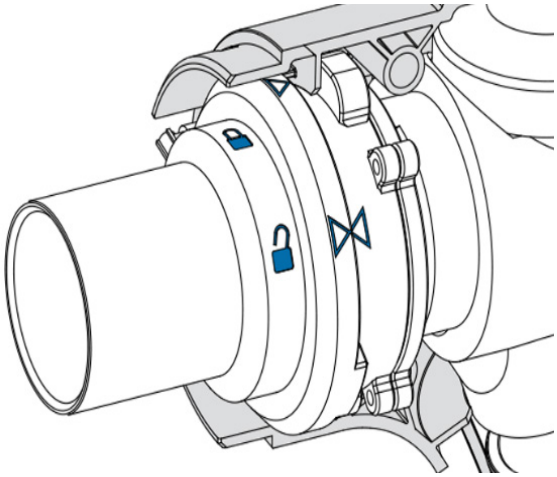


Figure 9 - Flowhead subject end in the unlock position.

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.

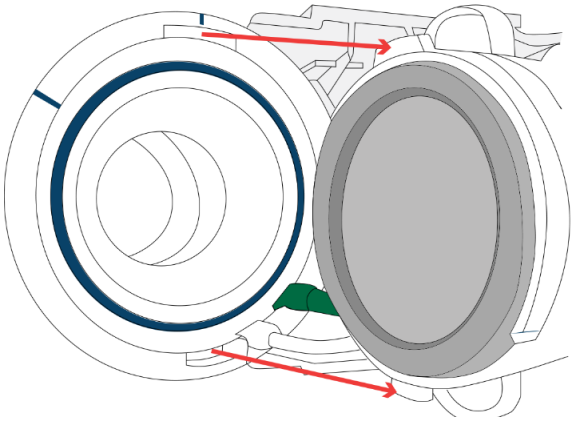


Figure 10 - Alignment of Flowhead Subject End and Heater Assembly

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

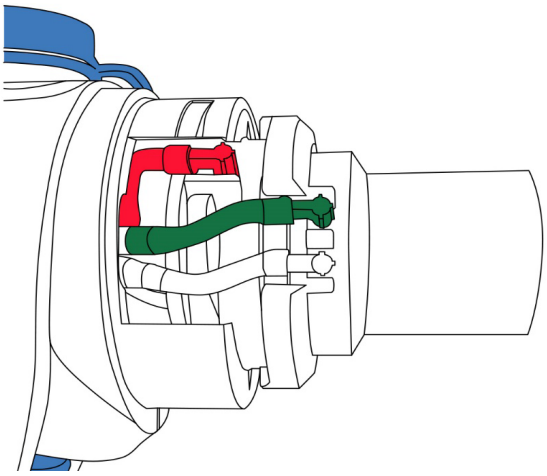


Figure 11 - Tubing re-connected.

EN

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.

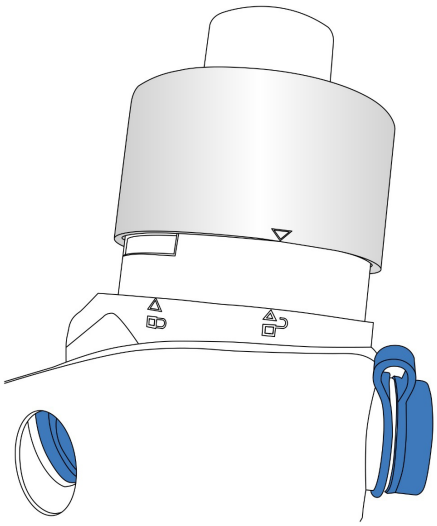


Figure 12 - Front cap aligned in the unlock position.

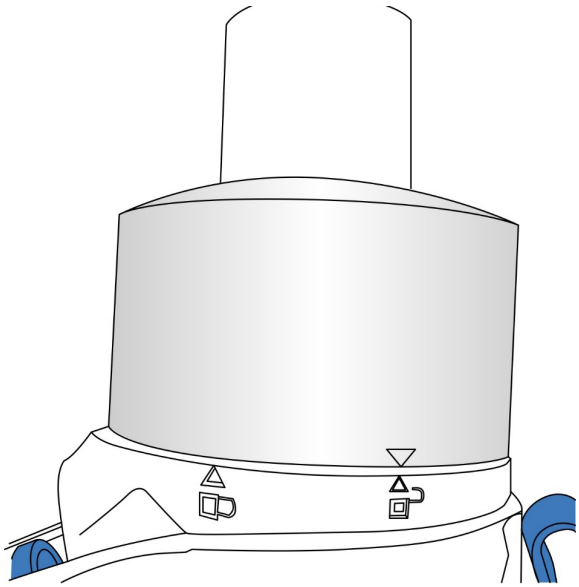


Figure13 - Front cap in the unlock position.

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:	• **Failing flow-volume accuracy check**
Possible Causes: (In probable order)	• Recheck Calibration with reference to flow-volume span and accuracy check (refer Section 4 Setting Up the VitaloROV/ROV+). • Ensure Bulkhead Connector is screwed on fully to back of device. • Cold syringe – ensure syringe is in test environment for at least 1 hour before use. • Check Lilly Screen for any particulate causing a blockage. To clean, refer to Section 7 Cleaning & hygiene. • Ensure tubing is connected correctly. On the Flowhead, red tube should be connected to red elbow and green tubing should be connected to green elbow. • Ensure tubing is pushed onto elbows and securely attached. • Ensure elbows are clear of obstruction or dirt and they are not loose. • Ensure tubing is not kinked or squeezed during reassembly of the Patient Valve. • Internal tubing from Bulkhead Connector is blocked: contact support. • Electronics failure: contact support.
Problem Fault Symptoms:	• **Incorrect or no volume measurements for subjects** • **Not measuring subject flow rates** • **Test performed but does not show on screen**
Possible Causes: (In probable order)	• Recheck Calibration with reference to flow-volume span and accuracy check (refer Section 4 Setting Up the VitaloROV/ROV+). • Ensure Bulkhead Connector is screwed on fully to back of device. • 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. • Check Lilly Screen for any particulate causing a blockage. To clean, refer to Section 7 Cleaning & hygiene. • Ensure tubing is connected correctly. On Flowhead, red tube should be connected to red elbow and green tubing should be connected to green elbow. • Ensure tubing is pushed onto elbows and securely attached. • Ensure elbows are clear of obstruction or dirt and they are not loose. • Ensure tubing is not kinked or squeezed during reassembly of the Patient Valve.
Problem Fault Symptoms:	• **Report does not print all tests** • **Report does not print some parameters**
Possible Causes: (In probable order)	• 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 ComPAS2 help menu by choosing Help > View Help.
Problem Fault Symptoms:	• **Test begins automatically** • **Volume accumulates automatically without the subject blowing** • **Very small VC or FVC test displayed**
Possible Causes: (In probable order)	• Patient Valve and/or Patient Valve. • Tubing Sleeve not stationary at the start of test. Hold both steady until prompted to begin the test. • Return to “Patients” screen then choose “Run Test” to re-enter the test routine.
Problem Fault Symptoms:	• **Gas readings are incorrect**
Possible Causes: (In probable order)	• Ensure the correct gas concentrations have been entered in the Gas Analysers section of the Calibrate page in ComPAS2 software. • Ensure Bulkhead Connector is screwed on fully to back of device. • Ensure tubing is connected correctly. Clear tube should be connected securely to white elbow on Flowhead. • Ensure that white elbow on Flowhead is clear of obstruction or dirt and is not loose. • Ensure tubing is not kinked or squeezed during reassembly of the Patient Valve.

EN

9. Customer Service

Service life of the VitaloROV/ROV+ is 1 year.
The parts on which preventative inspection and maintenance should be performed annually, by Service Agents only, are the Manifold Filters, RTC Batter. The Oxygen Leak sensor is due to be changed every 2 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:
https://vitalograph.com/ifu/Vitalograph_VitaloROV_ROV+_IFU.PDF

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 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 local waste disposal regulations.

EN

12. Explanation of Symbols

Symbol	Description
	Type BF applied part
	Class II
	On (power)
	Off (power)
VA	Power rating (power supply)
	Direct current (power supply)
	UL Component Recognition Mark for Canada and U.S.A. (power supply)
	CE mark (power supply)
Rx Only	Restricted to sale by, or on the order of a physician.
	Certified to applicable Danish standards and requirements by UL International Demko A/S (power supply)
	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)
	Instructions for Use; operating instructions
	Manufacturer
	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
	Fragile, handle with care
	Keep Dry
	Do not re-use
	Non-sterile
	Recycle
	QR code - matrix bar code. All information in the bar code is included in the text under it
PC/ABS	Polycarbonate/Acrylonitrile Butadiene Styrene
	Use by date
	Batch code

EN

	Serial interface
	Refer to instruction manual/booklet
	Computer network
	Serial port
	Transfer of heat in general
SNIP	Sniff nasal inspiratory pressure
DLCO	DLCO gas connection
O_2	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
	Lock location mark
	Unlock location mark
	Location mark
UK CA 0086	UK Conformity Assessment Board
MR	MR Unsafe
MD	Medical Device
IE	Country of Manufacture

13. Description of the VitaloROV/ROV+

The VitaloROV/ROV+, 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 ComPAS2 software running on the VitaloROV/ROV+ allows it to be used as a standalone pulmonary function testing device.

The VitaloROV/ROV+ is designed for desktop use. Each device accommodates an Inspiratory Bag for delivering test gas to the subject.

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 VitaloROV/ROV+ only. 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 measured by the VitaloROV/ROV+ 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 VitaloROV/ROV+. 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 not selectable or measurable on the VitaloROV/ROV+ (though listed in the ComPAS2 Manual) include: FRC (Helium Dilution Testing), VTG (Volume of Thoracic Gas or Plethysmography) and RAW (Airways Resistance Testing).

14. Technical Specification

Products	Model 9100 Vitalograph VitaloROV/ROV+
Model	9100
Essential Performance	Recording the Carbon Monoxide and Methane values from the DLCO Gas Analyser.
Essential Performance Test Limits	Data will be transferred by USB from the device PCBs to the on-board computer. The output from the DLCO Gas Analyser must stay within the predetermined limits (see below) both in normal and single fault conditions. • 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	80-240V; approximately 50/60 Hz
Flow accuracy	Within ±10% over the range of -14 to +14 L/s
Flow Measurement Range	Max. flow rate ±14 L/s Min. flow rate ±0.2 L/s
Operating temperature range	ISO26782 limits: 17–37ºC Design limits: 15–32ºC
Operating humidity range	30%–75%
Ambient pressure range	700hPa–1060hPa
Product Life	10years+ when maintenance and servicing (1 year service life) procedures are adhered to.

EN

Gas Analyser for CO/CH4	Nondispersive infrared (NDIR) sensor. Accuracy: CO ±1 % of Full Scale CH4 ±1 % of Full Scale
Gas Analyser for O2/CO2	Laser diode absorption for O2. Infrared sensor for CO2 Accuracy: O2 ± 0.2% CO2 ± 0.1%
Mouth Pressure	Digital pressure sensor Accuracy: 0.5%
Shutter Valve	Pneumatic spring-return cylinder
Gases required for VitaloROV/ROV+ device	• Mix containing 0.3% Carbon Monoxide, 0.3% Methane, Balance Air • 100% Oxygen • Mix containing 13-16% Oxygen, 3-6% Carbon Dioxide, balance Nitrogen • Only medical grade gases should be used.
Performance standards the VitaloROV/ROV+ meets or exceeds	ISO 23747:2015, ISO 26782:2009, 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, 21CFR Part 820
Size	410 mm x 380 mm x 342 mm
Weight	12.5 kg net
Printer	External
Communications	5 x USB, 2 x Ethernet, 1 x Serial, 1 x DVI-D, 1 x Display, Keyboard and Mouse interface (via a USB adaptor)
Software	Morgan Scientific ComPAS2 Reference Manual (Vitalograph Morgan PFT Range)

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.

15. CE Notice

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

Marking by the symbol UKCA 0086 indicates compliance of the 9100 Vitalograph VitaloROV/ROV+ to the UK Medical Devices Regulations 2002, as amended.

The Vitalograph VitaloROV/ROV+ is intended for use in professional healthcare environments, e.g., 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 VitaloROV/ROV+ should assure that it is used in such an environment.

The 9100 Vitalograph VitaloROV/ROV+ 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 Conducted Emissions CISPR 11 Harmonic Emissions IEC 61000-3-2 Voltage fluctuations/ flicker emissions IEC 61000-3-3	Class A	The Model 9100 is suitable for use in for non-residential/professional environments such as hospitals. If used in residential environment 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.

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

17. EU Declaration of Conformity

Product: 9100 Vitalograph VitaloROV/ROV+
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 Device Regulation as per Article 52.

CE 2797

- 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

UKCA Declaration of Conformity

Product: 9100 Vitalograph VitaloROV/ROV+

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:

- UK Medical Device Regulation 2002, as amended. This device is classified as IIa per EU Directive 93/42 Annex IX, and meets UK MDR 2002 Part II (7), as amended. Devices IIa comply with Annex II, Art 11.

- BS EN ISO 13485 Medical Devices. Quality Management Systems Requirements for Regulatory purposes.

Certifying Body: British Standards Institute (BSI).
BSI Conformity Assessment Body #: 0086
Certificate Nos. TBA

UK CA 0086

Signed on behalf of Vitalograph (Ireland) Ltd.

Frank Keane.
CEO, Vitalograph Ltd.

EN

18. 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 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 for advice. The Company does not authorize 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.

EN