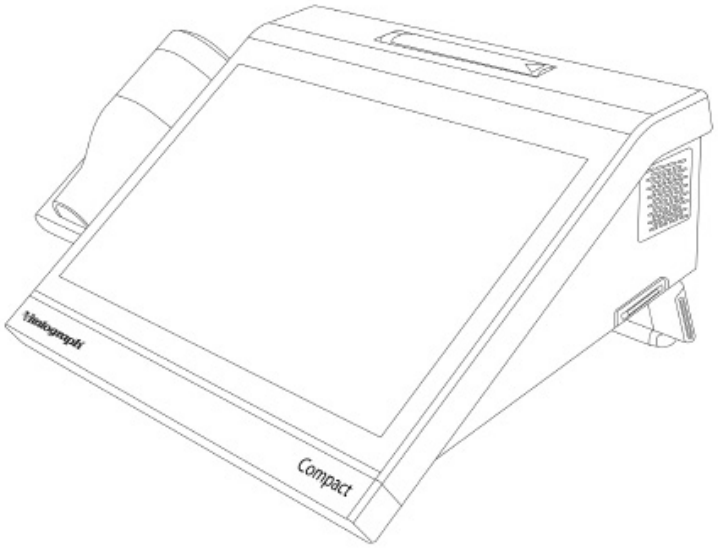
Vitalograph®

Compact

MODEL 6600



Rx Only

Instructions for Use

ENG

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Contents

1. Indications for Use

The Vitalograph Compact is a medical workstation which measures subject respiratory parameters and is capable of centralising data from external cardio-pulmonary related testing devices. It is intended for use by trained healthcare professionals in a variety of professional healthcare environments, e.g. primary care, hospitals, clinics and mobile clinics including occupational health settings. The device is designed for use on adult and paediatric patients from the age of 5 years.

Patients below the age of 5 years can be tested providing they can cooperate with the test instructions from the healthcare professional. The device functionality includes integrated spirometry and related pulmonary function testing including respiratory muscle strength assessments.

Note: *The measurements obtained from a lung function test form part of the various findings of a physician in the detection, diagnosis and control of chest diseases.*

Apart from this instruction manual, there are no other training requirements for the healthcare professional

2. Contraindications, Warnings, Precautions and Adverse Reactions

1. No modification of this equipment is allowed. Any unauthorised changes to the Vitalograph Compact 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. Any changes to the operating system or additional unapproved installations must be validated by the end user.
3. The Compact is not designed as a sterile device. Always follow the safety guidelines given by the manufacturer of cleaning and disinfectant chemicals.
4. Vitalograph intends that a new Bacterial Viral Filter (BVF™) be used for every subject to prevent cross contamination. Using a new BVF provides a significant level of protection of the subject, the device and the user against cross contamination during spirometry manoeuvres. A BVF is for single use only.
5. Spirometry is a valuable tool that provides important information to clinicians which is used together with other physical findings, symptoms, and history to reach a diagnosis (ATS/ERS 2019).
6. When using the Compact ensure that the flowhead connecting tube is not pinched or trapped as spirometry results may appear to be inverted.
7. Take care not to block the mouthpiece with tongue or teeth during testing. A ‘spitting’ action or cough will give false readings.

8. Subject fatigue may occur during RMS or spirometry testing depending on the subject's characteristics e.g. age, health status. For safety reasons, testing should be preferably done in the sitting position, using a chair with arms and without wheels. Subject may also take a break between tests. When the Compact device is used a subject fatigue warning will appear after 8 manoeuvres.
9. All values displayed are expressed as BTPS values.
10. Time zero is determined using the back-extrapolated method, from the steepest part of the curve.
11. Do not expose the Compact to liquids.
12. The Compact should not be used in the presence of flammable liquids or gases, dust, sand or any other chemical substances.
13. All spirometry standards recommend checking the accuracy of lung function measuring devices daily with a 3-L syringe to validate that the instrument is measuring accurately. The Compact should never be outside accuracy limits. Accuracy should be checked daily, after cleaning or disassembling the spirometer for any reason, after adjusting calibration or if the flowhead or device has been dropped.
14. Take care not to block the MIP MEP pressure vent on the flowhead during testing. This pressure vent is intended to prevent glottal closure and prevent the use of cheek muscles as indicated in the ATS/ERS Statement on Respiratory Muscle Testing.
15. The following contraindications apply to MIP/MEP/SNIP testing:
    a. Pathological conditions resulting in relatively large pressure swings in the abdomen or thorax.
    b. Aneurisms
    c. Uncontrolled hypertension
    d. Urinary incontinence
16. If subject cannot form a good seal on the BVF during MIP/MEP test then a bite-on mouthpiece should be fitted to the BVF.
17. Service and repairs should be carried out only by the manufacturer or by Service Agents approved by Vitalograph.
18. Maintenance must not be performed while the device is in use by a subject.
19. 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 Compact and result in improper operation.
20. 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.
21. 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 Compact, including cables specified by Vitalograph. Otherwise, degradation of the performance of this equipment could result.

22. 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.
23. The applied part is the Fleisch flowhead. This along with the BVF, are the contact points for the subject during a spirometry session.
24. Only use the Vitalograph Compact 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 19 volts DC.
25. The device may be susceptible when exposed to high levels of electrostatic discharge. To restore function, press the On/Off switch.
26. To isolate the Model 6600 Compact from the mains supply, remove the 19V Power Supply from the mains wall socket. Do not position the 19V Power Supply where it is difficult to unplug from the socket.
27. 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.
28. Loss or degraded performance due to EMI that exceeds the test levels in immunity test tables below will result in a failed calibration verification. Reference Spirotrac IFU for details on completing a calibration verification on the device. If interference is suspected or possible, move the device to a new location and repeat the calibration verification.

3. Main Components of the Vitalograph Compact

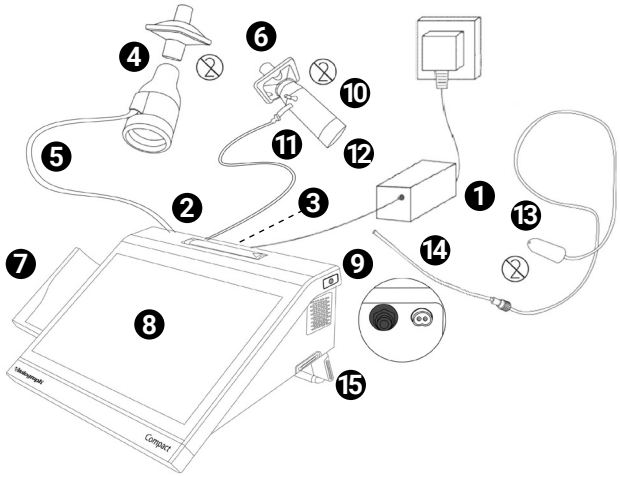


Figure 1. Main components of the COMPACT

1	Power Supply
2	Stylus
3	I/O Ports - 6 x USB, 2 x Ethernet, 2 x Display Port Power connection, RMS port (MIP/MEP/SNIP) and flowhead port
4	Flowhead
5	Flowhead Connection Tubing
6	Bacterial Viral Filter (BVF)
7	Flowhead Carrier
8	Colour LCD and Touch Panel Display
9	Power Switch
10	MIP/MEP Pressure Vent
11	MIP/MEP Flowhead Connection tube
12	MIP/MEP Flowhead
13	SNIP Nasal Probe
14	SNIP Nasal Probe Adaptor
15	Adjustable Leg
16	WiFi dongle (not pictured)
17	USB key with Connect Software (not pictured)

3.1. Features of the Vitalograph Compact

- Medical workstation running Vitalograph Spirotrac Software
- Spirometry flowhead (Fleisch Pneumotachograph)
- Respiratory muscle strength (RMS) flowheads (optional)
- Touch screen colour display
- Audio feedback
- Connectivity for devices integrated with Spirotrac software
- Automatic storage of all test data
- Networked database (optional)
- Sniff nasal inspiratory pressure (SNIP) measurement
- Adjustable leg to change viewing angle of display.

4. Setting Up the Vitalograph Compact

1. Attach the flowhead to the Vitalograph Compact using the silicone tubing (Flowhead Connection Tube). The tubing is keyed so that it may only be inserted in the correct orientation.
2. If required, attach the MIP or MEP flowhead to the Vitalograph Compact by the tubing supplied. Ensure that the clear end of the tube is connected to the RMS Connection port on the Compact, adjacent to the spirometry connector. The white silicone tube on the other end of the tubing is attached to the connector on the MIP or MEP flowhead.
   Note: The push in connector on the connection port should be pushed firmly and squarely against the face of the connector when connecting/ disconnecting the tubing. Connect other end of tubing to the flowhead.
3. If required, attach the SNIP nasal probe adaptor to the RMS connection port on the Compact. Fasten the SNIP nasal probe to the adaptor.
   Note: The push in connector on the connection port should be pushed firmly and squarely against the face of the connector when connecting/ disconnecting the tubing.
4. If required, attach the Wifi dongle (16) into an available USB port on the back of the device (3) (see Figure 1).
5. The leg may be adjusted to change the viewing angle of the display.
6. Connect the jack plug from the power supply into the socket at rear of the Compact. Plug the mains plug into a suitable socket, operate the On/Off button on the side of the instrument. The Compact is ready for use.
   Note: Only use the Compact with the purpose-built low voltage power supply with which it is supplied.
7. Use the Launcher to open the Spirotrac application, add Ethernet, WiFi, printers. Contact Technical Support for approved installation assistance.
8. For guidance using Spirotrac software on the Compact refer to the Spirotrac Instructions For Use available on the device, in the "i' (information) option in the menu on the left side of the Spirotrac application.
9. For guidance installing the Vitalograph Connect Software, please refer to the Connect Instructions for Use on the USB Key. Connect will need to be

installed on a separate networked PC/Network and NOT on the Compact device.

10. To power down Compact close the Spirotrac session by pressing the power button on the menu at the left side, this will automatically log-off the current user and return to the Launcher. In the Launcher the power option is in the menu on the left.

    Note: The device may be powered down by pressing and holding the On/Off button but this is only recommended if there is a malfunction. Correct power-down is only achieved if Spirotrac is closed properly.

If the device has just been unpacked or transported, ensure that it is left sitting, powered on and is at room temperature prior to testing for at least an hour before use.

4.1. Compact Communications

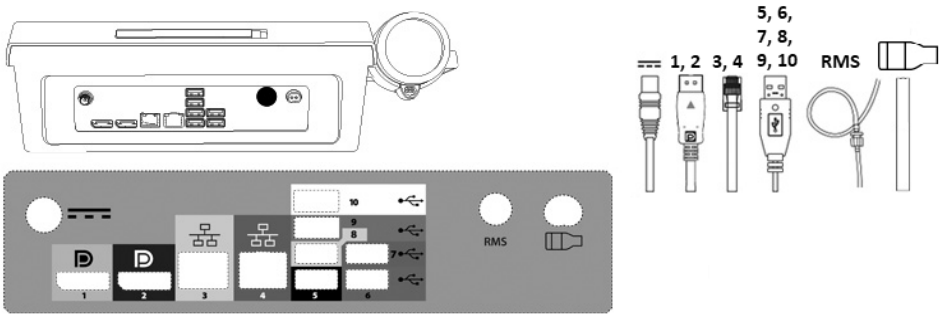


Figure 2. Compact communications/connectors

1,2	Display port x 2
3, 4	Ethernet x 2
5,6,7,8,9,10	USB x 6
⎓	Power
RMS	Connector for MIP/MEP flowheads or Reusable SNIP adaptor.
⊏⊐	Connector for flowhead

5. Operating Instructions

1. The Vitalograph Compact works with Vitalograph Spirotrac software. Refer to Spirotrac Instructions for Use (available on the device) for operating instructions and details on:

- Entering Subject Data
- Conducting spirometry testing

- Conducting testing with accessory or third party integrated devices
- Printing a Report
- Calibration Verification
- Connect set-up for EMR Integration

2. To enter text, touch relevant field on the screen and use the onscreen keyboard to enter the details.
3. Use the Launcher to open the Spirotrac application, add Ethernet, WiFi, printers. Contact Technical Support for approved installation assistance.
4. To install and configure the Connect functionality see Vitalograph Connect IFU.

   Note: Connect Software (17) MUST be installed on an external PC/ Network and NOT on the Compact device.

6. Power Management

The Vitalograph Compact must be powered using the 19V low voltage Power Supply unit supplied with the device.
The Power Supply unit should be checked regularly and replaced when necessary.

7. Cleaning & Hygiene

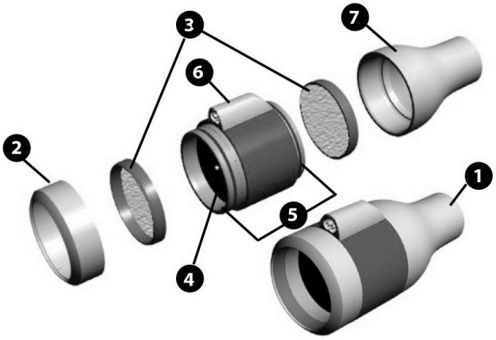
7.1. Preventing Cross-Contamination of Subjects

A spirometer is not designed or supplied as a 'sterile' device.
Vitalograph intends that a new Bacterial Viral Filter (BVF) and where required, SNIP nasal probe, be used for every subject to prevent cross contamination. Using a new BVF provides a significant level of protection of the subject, the device and the user against cross contamination during spirometry manoeuvres.
The interior of a Vitalograph flowhead does not require decontamination where a new BVF is used for each subject. The outside surfaces of the device and flowhead tube may be cleaned with a 70% isopropyl alcohol impregnated cloth to remove any visible soiling and for low level disinfection.
Where the user suspects that the flowhead has become contaminated or where local risk assessment identifies a need for higher level of decontamination, then it should be cleaned as per the instructions on 'Cleaning and Hygiene' on the Vitalograph website.

7.2. Inspection of the Vitalograph Compact

Fleisch Flowhead:
Visual inspection is recommended on a routine basis. Remove flowhead cone and flowhead end cap from the flowhead. Examine flow conditioning mesh filters for damage or contamination. If they are damaged or blocked, discard and replace with new parts. Examine the O-rings on the Fleisch element and replace if damaged. Re-assemble the cone and end cap.
It is recommended that an accuracy check is carried out following cleaning and re-assembly as recommended in the ATS/ERS 2019 guidelines[1].

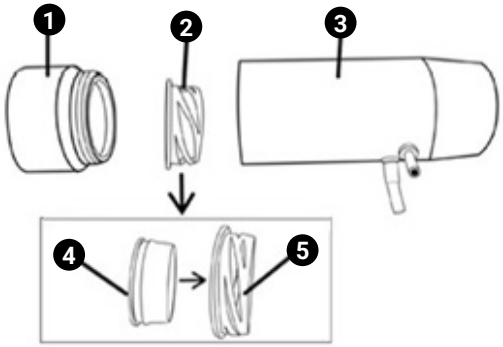
1 Derived from terminology and guidance taken from ATS/ERS Standardisation of Spirometry 2019 Update Am J Respir Crit Care Med 2019 Vol 200, Iss 8 pp e70-e88



1	Flowhead Complete
2	Flowhead End Cap
3	Flow Conditioning Mesh
4	Fleisch element Assembly
5	'O' Rings
6	Pressure Tapping
7	Flowhead Cone

Figure 3: Fleisch Flowhead Assembly

MIP/MEP Flowhead:
Visual inspection is recommended on a routine basis. Unscrew the MIP/MEP end cap from the cone. Remove the one-way valve from the cone and examine it for damage. If damaged, discard and replace with a new part (Reference Section 10. Consumables and Accessories). Carefully separate the hard plastic housing from the soft silicone one-way valve, avoiding damage to the one-way valve.



1	MIP/MEP end cap
2	MIP/MEP one way valve
3	MIP/MEP cone
4	One-way valve hard plastic housing
5	Soft silicone one-way valve

Figure 4: MIP/MEP Flowhead Assembly

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Carefully re-assemble the silicone one-way valve with the hard plastic housing, taking care not to damage the silicone one-way valve.

Note: *It is important that the one-way valve is fitted to the cone in the correct orientation for the different MIP and MEP flowheads. Refer to the images below for the correct orientations. The flowhead version is marked on the end cap. Ensure the one-way valve is fully seated and centered into the groove on the cone.*

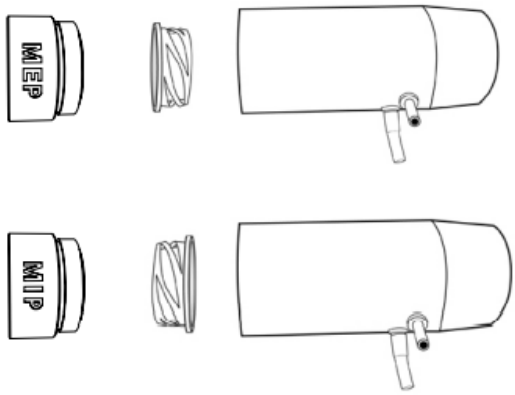

Figure 5: Orientation of one-way valve

Screw the MIP/MEP end cap to the cone. Ensure it is fully screwed home and hand tightened. Attach the white end of the flowhead connection tube to the pressure tapping on the MIP/MEP flowhead. The clear end of the flowhead connection tube is connected to the push in connector adjacent to the spirometry connector on the Compact base.

To check the MIP/MEP flowhead has been correctly re-assembled attach a BVF to the MIP/MEP Flowhead and test as follows:

1. MEP Flowhead: fully inspire though the flowhead. The one-way valve should open, and no resistance should be felt. Then attempt to expire. The one-way valve should close, and a significant resistance should be felt. The only air escaping should be through the MIP/MEP Pressure Vent on the flowhead.
2. MIP Flowhead: fully expire through the flowhead. The one-way valve should open, and no resistance should be felt. Then attempt to inspire. The one-way valve should close, and a significant resistance should be felt. The only air entering should be through the MIP/MEP Pressure Vent on the flowhead.

8. Fault Finding Guide

Problem Fault Symptoms:	• **Incorrect or no volume measurements**
Possible Causes: (In probable order)	• Ensure tubing is connected correctly. • Ensure that connectors are clear of obstruction or dirt and are inserted fully. • Ensure tubing is not kinked or squeezed.
Problem Fault Symptoms:	• **Test performed but does not show on screen**
Possible Causes: (In probable order)	• Ensure tubing is connected correctly between flowhead and device (tubing is keyed so will only fit properly in the correct orientation). • Possible internal PCBA failure – turn off and on the device, repeat test. If problem persists, contact Support.
Problem Fault Symptoms:	• **Communication error message appears when entering the Test screen, the Calibration Verification screen or the Calibration Update screen**
Possible Causes: (In probable order)	• Possible internal PCBA failure – turn off and on the device, repeat test. If problem persists, contact Support.
Problem Fault Symptoms:	• **Accuracy check variations > +/- 2.5%**
Possible Causes: (In probable order)	• Recheck Calibration with reference to Calibration Verification section in the Spirotrac IFU. • Was correct syringe volume entered? • Ensure tubing connectors are clear of obstruction or dirt and are inserted fully. • Ensure tubing is not kinked or squeezed. • Ensure flowhead is clean. • Cold syringe – ensure syringe is in its test environment for at least an hour before use. • Internal tubing from pressure ports on device is blocked – contact Support. • Electronics failure – contact Support.
Problem Fault Symptoms:	• **Test begins automatically** • **Volume accumulates automatically without the subject blowing** • **Very small VC or FVC test displayed**

Possible Causes: (In probable order)	• Flowhead and/or tubing not stationary at start of test. Hold them steady until the 'Blow Now' prompt appears. • Return to Main Menu and re-enter the test routine.
Problem Fault Symptoms:	• **Time and date are incorrect, or device will not hold the time and date once it is powered off.**
Possible Causes: (In probable order)	• RTC may have reset – manually reset the time and date. Power device off and on again to check it is holding the time and date. • Possible RTC battery failure – the coin cell battery may need replacing, contact Support.
Problem Fault Symptoms:	• **Incorrect or no pressure measurements during a MIP/MEP/SNIP test.**
	• Ensure tubing is connected correctly to the MIP/MEP flowhead and to the MIP/MEP/SNIP connection port on the Compact. • Ensure that the connectors are clear of obstruction or dirt and that they are inserted fully. • Ensure the tubing is not kinked or squeezed. • Ensure that the correct flowhead is being used. i.e. a MIP flowhead for a MIP test and a MEP flowhead for a MEP test. SNIP test requires a Nasal probe, ensure that it is the correct size. • Check that the one-way valve is fitted in the correct orientation to the MIP and MEP flowhead (Reference Figure 5). Test the flowhead following instructions outlined in Section 7.2. • Check the condition of the one-way valve. If damaged, replace with new part.

8.1. Software Check

Information about Spirotrac, and the IFU, is available in the "i' (information) option in the menu on the left side of the Spirotrac application. This information may be used when contacting Vitalograph or a service agent with queries.

8.2. Product Useful Life Checks

To ascertain whether the device has exceeded its useful life Vitalograph recommends checking the flowhead and the Real Time Clock battery.

The flowhead may be checked with the recommended daily calibration verification, to be completed by the clinician/healthcare professional, and during the periodic inspection of the device. Reference the calibration verification section in the Spirotrac Instructions for Use, for details on how to check the device flowhead.

The clock may reset to a default time and date on power down if the 3V coin cell battery has depleted. Vitalograph recommend changing the battery during routine service every 5 years.

9. Customer Service

Service and repairs should be carried out only by the manufacturer, or by Service Agents approved by Vitalograph. Contact information for approved Vitalograph Service Agents may be found at the start of this manual.
Any serious incident that has occurred in relation to the device should be reported to Vitalograph or its Authorised Representative and the Regulatory Authorities of the country. Refer to the Vitalograph contact information at the start of this manual.
It is recommended the coin cell battery powering the RTC is changed every 5 years by a trained Vitalograph service agent or the manufacturer.

10. Consumables and Accessories

Type	Cat. No	Description
Consumables	28572	Eco BVF and Disposable Nose Clip (80)
	28370	28350 BV Filter + 20243 Nose Clips - box of 50
Accessories	36020	2040 Precision Syringe 3-L
	67181	COMPACT 19V Power Supply
	77933	Flow Conditioning Mesh (10)
	77934	Flowhead Complete
	77939	Flowhead Cone
	77938	Flowhead End Cap
	79192	Flowhead Connection Tube
	2120013	O-Ring (15)
	77652	MIP MEP Flowheads
	77651	MIP MEP Connection Tube

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	77653	Silicone One-way Valve (Pack of 2)
	77973	SNIP Nasal Probe Adaptor
	67242	Compact Stylus

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.
Used BVFs constitute minimally soiled waste from human healthcare and should be disposed of in line with local requirements. BVFs are made from polypropylene.

12. Explanation of Symbols

Symbol	Description
	Type B equipment
	Class II
VA	Power rating
	Voltage DC
	Instructions for Use; operating instructions
	Manufacturer
	Year of Manufacture (Date format YYYY-MM-DD)
	USB connector
	Ethernet connector
	Flowhead connector
RMS	MIP/MEP/SNIP connector

	On/Off
	The device must be taken to separate collection at the product end-of-life. Do not dispose of these products as unsorted municipal waste
	Non sterile
	Recycle
	Keep dry
	Do not re-use
	QR code - matrix bar code. All information in the bar code is included in the text under it
	MR Unsafe – Do not use this device in an MRI environment.
Rx Only	Restricted to sale by, or on the order of a physician

13. Description of the Vitalograph Compact

The Vitalograph Compact is a desktop medical workstation designed for use by trained medical professionals for physiological measurements in a variety of professional healthcare environments, e.g. primary care, hospitals, clinics and occupational health centres. Test data is automatically stored to the relevant subject record. The software running on the Compact allows it to be used as a standalone lung function testing device. In a clinical setting, the measurements obtained from a lung function test form part of the various findings of a physician in the detection, diagnosis and control of chest diseases. Spirometry may support or exclude diagnosis, but it cannot make one. The Compact can also be used with other accessory devices to offer Pulse Oximetry, Six Minute Walk Test, 12-lead ECG and Audiometry testing.

14. Technical Specification

Product	Vitalograph Compact
Model	6600
Flow Detection Principal	Fleisch type pneumotachograph
Volume detection	Flow integration sampling @ 100Hz
Volume Accuracy	±2.5% or ±0.05L
Flow Measurement Range	Max. flow rate ±960 L/min (±16 L/s) Min. flow rate ±1.2 L/min (±0.02 L/s)
PEF Accuracy	±10% or 0.3 L/s
Back pressure of Fleisch Flowhead	Less than 0.1kPa/L/sec at 14L/sec
Operating Pressure RMS	+/- 300cmH20
Pressure Accuracy RMS	+/- 3%
Pressure Resolution RMS	1 cmH20
Operating temperature range	ISO 26782:2009 Guidelines: 17–35ºC Design limits: 10–40ºC
Operating humidity range	30%–75%
Operating ambient pressure range	850hPa–1060hPa
Performance standards the Vitalograph COMPACT meets or exceeds	ISO 23747:2015, ISO 26782 2009, ATS/ERS 2019
Safety standard	EN60601-1:2006 + A1:2013 + A2:2021 + A2:2021
EMC standard	EN 60601-1-2:2015 + A1:2021
QA/GMP standards	EN ISO 13485:2016, FDA 21 CFR 820, CMDR SOR/98-282 & Japan's PMD Act
Dimensions	296 x 261 x 108 mm
Weight	3 kg net
Communications	USB x 6, Ethernet x 2, Wifi
Power Supply	19V DC Power Supply
Operating System	Windows 10 Embedded
Processor	Intel Quad Core Processor
RAM	4GB
Screen	12.1" LCD 1280*800 pixel with capacitive touch screen

Notes:

- All values displayed are expressed as BTPS values.
- Take care not to block the cone with the tongue or teeth. A 'spitting' action or coughing will give false readings.
- Time zero is determined using the back-extrapolated method, from the steepest part of the curve. The operating conditions specified apply to the device plus accessories.
- The flowhead and BVF are classified as type B applied parts. The device
- body or other accessories are not applied parts. An applied part is a part of the equipment, that in normal use necessarilycomes into physical contact with the subject for equipment or system toperform its function

15. CE Notice

Marking by the symbol CE 2797 indicates compliance of the Vitalograph Model 6600 Compact to the Medical Devices Directive of the European Community. The Vitalograph Compact is intended for use by trained healthcare professionals in a variety of professional healthcare environments, e.g. primary care, hospitals, clinics and mobile clinics including occupational health settings 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 should assure that it is not used in such an environment.
The Model 6600 Compact has been tested in accordance with:

EN60601-1:2006 + A1:2013 + A2:2021 - Medical electrical equipment. 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 6600 Compact uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Model 6600 Compact is suitable for use in professional environments only, such as hospitals, clinics. This device is not suitable for use in home/ residential environments.

EN 60601-1-2:2015 + A1:2021 - Immunity tests		
Immunity test	Test level	Compliance level Reached
Electrostatic discharge (ESD) EN 61000-4-2	Contact: ± 8 kV Air: ± 2 kV,± 4 kV, ± 8kV,± 15 kV	Contact: ± 8 kV Air: ± 2 kV,± 4 kV, ± 8kV,± 15 kV The device may reset/turn off when exposed to higher levels of ESD. To recover press the On/Off button.
Proximity fields from RF wireless	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 IEC 61000-4-4	±0.5, ±1 & ±2kV 100kHz	±0.5, ±1 & ±2kV 100kHz

Surge IEC 61000-4-5	±1kV differential mode Device is identified as Class II unearthed equipment therefore common mode testing is omitted.	±1kV differential mode
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
Voltage dips, short interruptions on power supply input lines IEC 61000-4-11	100% drop, 0.5 cycles, 0o, 45o, 90o, 135o, 180o, 225o, 270o, 315o 100% dip, 1 cycle 30% dips, 25/30 cycles	100% drop, 0.5 cycles, 0o, 45o, 90o, 135o, 180o, 225o, 270o, 315o 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)
Power frequency (230V, 50Hz and 120V, 60Hz) magnetic field	30A/m	30A/m

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 (refer to section 2. Contraindications, Warnings, Precautions and Adverse Reactions).

Note: *The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If 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.*

Note: *The device may be susceptible when exposed to high levels of electrostatic discharge. To restore function, press the On/Off switch.*

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: 6600 Vitalograph Compact

Vitalograph hereby ensures and declares that the above product associated with these instructions for use, is designed and manufactured in accordance with the following QMS regulations and standards:

- European Medical Devices Directive {MDD} 93/42/EEC, as amended.

  This device is classified as IIa per Annex IX of the MDD also meets the provisions of the Essential Requirements, Annex I, via compliance with Annex II of the Medical Devices Directive as per Article 11, section 3a, excluding point 4 of Annex II.

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. CE 00772, MD 82182

Signed on behalf of Vitalograph (Ireland) Ltd.

Frank Keane.
CEO, Vitalograph Ltd.

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 two years of the date of purchase of the equipment, unless otherwise agreed in writing by the Company. Registration is not required for this base two year guarantee.
2. An extended five year warranty from date of purchase, is available by registering the products serial number at www.vitalograph.com/warranty within thirty days of purchase.
3. Software (meaning computer software, or user installable modules) is guaranteed for 90 days from the date of purchase.
4. 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.
5. 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.
6. 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.
7. This Guarantee is not transferable and no person, firm or company has any authority to vary the terms or conditions of this guarantee.
8. 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.
9. This Guarantee is offered as an additional benefit to the Consumer's statutory rights and does not affect these rights in any way