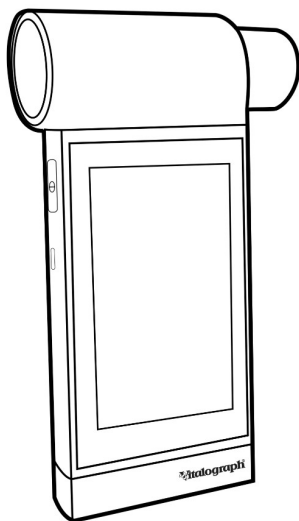


Vitalograph[®]

In2itive

MODEL 2120



Instructions for Use

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1. Indications for Use

The Vitalograph In2itive is a portable device 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, and home visits under direct supervision of a healthcare professional. 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 supports related testing, including field exercise tests.

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 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. It 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 spirometry manoeuvres. A BVF is for single use only.
- Spirometry may support or exclude diagnosis, but it cannot make one (ATS/ERS 2019¹).
 - The device is marked as 'Rx Only' and as such is restricted to sale by, or on the order of a physician.
 - When using the remote flowhead on the device, ensure that the flowhead connecting tube is not pinched or trapped as spirometry results may be affected, or a false reading may be detected.
 - Take care not to block the cone with tongue or teeth during testing. A 'spitting' action or cough will give false readings.
 - Subject fatigue may occur during 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. A max test completed message will appear after eight manoeuvres.
 - All values displayed are expressed as BTPS values.
 - Time zero is determined using the back-extrapolated method, from the steepest part of the curve.
 - Do not expose the device to liquids.
 - The device should not be used in the presence of flammable liquids or gases, dust, sand or any other chemical substances.
 - All spirometry standards recommend completing a calibration verification of lung function measuring devices daily with a 3-L syringe to validate that the instrument is measuring accurately. The device should never be outside accuracy limits. A calibration verification should also be completed after cleaning or disassembling the spirometer for any reason, after adjusting calibration or if the flowhead or device has been dropped.
 - Service and repairs should be carried out only by the manufacturer or by Service Agents approved by Vitalograph.
 - Maintenance must not be performed while the device is in use by a subject.

1 ATS/ERS Standardisation of Spirometry Eur Respir J 2019

- ENG
16. The device contains a Lithium coin cell battery and a Lithium Polymer main battery, neither of which are accessible by the user. Any suspected battery faults should be reported to the manufacturer.
 17. The internal Lithium Polymer battery is not user accessible. In the unlikely event that any issues are noted with the power or battery such as swelling or leaking, stop using the device immediately, do not charge the device and contact the manufacturers' Support. In case of leaking, ensure the electrolyte does not get in the eyes or touch skin as it may cause damage. If electrolyte gets into the eyes flush the area immediately with water for 15 minutes and seek medical attention. If it gets on the skin wash the affected area immediately and seek medical attention. Do not inhale the leaked material, leave the area immediately and allow the battery to cool and any material to dissipate.
 18. Do not disconnect the device or USB cable from the PC running the Software applications during data transfer, firmware upgrades or printing.
 19. If the flowhead is removed from the device (when disassembling for cleaning and/or to attach the remote flowhead adaptor), care should be taken with the exposed edges. During normal use, these edges are covered, are not accessible by the user or subject.
 20. High power USB 2.0 port is required for charging via USB, it must be capable of supplying 500mA or it will not charge the device fully or fast enough.
 21. To isolate the device from the mains supply, remove the 5V Power Supply from the mains wall socket. When charging the device via the 5V Power Supply do not position the Power Supply where it is difficult to unplug from the socket.
 22. 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 device and result in improper operation.
 23. 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.
24. 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 device, including cables specified by Vitalograph. Otherwise, degradation of the performance of this equipment could result.
 25. 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.
 26. 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. 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 section 5.4 of this document for details on completing a calibration verification on the In2itive. If interference is suspected or possible, move the In2itive to a new location and repeat the calibration verification.
 27. The applied part is the flowhead and device body or just the flowhead when using the remote flowhead adaptor. These along with the BVF, are the contact points for the subject during a spirometry session. There are no adverse effects if the subject comes into contact with any other part of the device.

3. Main Components of the Vitalograph In2itive

The main components are:

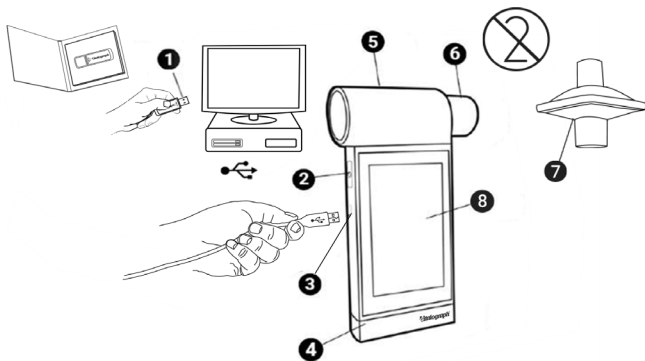


Figure 1: Device Components

1	Software application running on PC/laptop (optional)
2	Power (On/Off) Button
3	Mini USB Port
4	Plinth
5	Flowhead
6	Flowhead Cone
7	BVF
8	LCD/Touch Panel Display

The software applications available for the device are optional and are not required for the device to function. The device is a standalone spirometer.

3.1. Features of the Vitalograph In2itive

The features include:

- ATS/ERS 2019 compliant
- Colour touchscreen display
- Wireless EMR connectivity
- Portable
- Fleisch type Pneumotachograph

4. Setting Up the Vitalograph In2itive

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

Preparing for use:

1. Only use the device with the purpose-built low voltage power supply unit 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 5 volts DC.
2. Connect the power supply into the USB connector on the left side of the device. Plug the mains plug into a suitable socket, press the On/Off switch on the side of the instrument. The device is ready for use.
3. The device is fitted with rechargeable batteries, which allows the device to be used without the power supply connected.
4. On first use the internal battery pack will require a full charge, this will take a minimum of 5 hours.

If the remote flowhead is required (see Figure 2 below):

5. Take care when removing the flowhead and attaching the remote flowhead. Remove the flowhead by holding the device in one hand (screen facing up) and sliding the flowhead to the right with the other hand, off the device.
6. Connect the remote flowhead adaptor (2) to the base of the flowhead (3) by sliding on to the right, as shown. Click into place.
7. Taking care not to press the power button, connect the device cap (1) to the device by sliding on to the left, as shown. Click into place. Remove the rubber cap from tubing connector.

Note: Ensure both the device cap and flowhead adaptor clicks into place

8. Unwrap flowhead connection tubing (5) and connect one end to the device cap (1). The tubing is keyed as shown in Figure 2, match this to the key on the device cap connector to ensure the tubing is in the correct orientation.
9. Connect the other end of flowhead tubing to the flowhead adaptor (2). The tubing is keyed as shown, match this to the key on the adaptor connector to ensure the tubing is in the correct orientation.

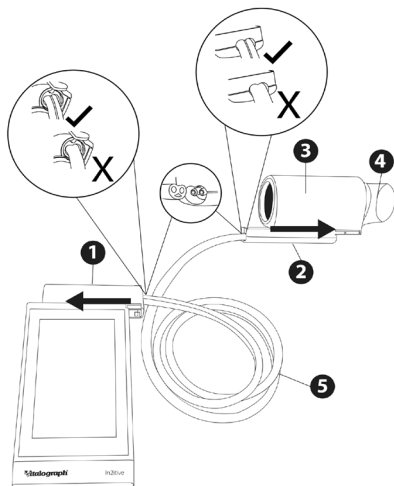




Figure 2: Remote Flowhead Assembly

1	Device cap (with rubber cap)
2	Remote flowhead adaptor
3	Flowhead containing Fleisch
4	Flowhead Cone
5	Tubing

If the device has just been unpacked or transported, ensure that it is left sitting, fully powered and is at room temperature prior to testing. Ensure a calibration verification is completed at least once daily, prior to using the device (see Section 5.4 Calibration Verification).

5. Operating Instructions

On all screens:


the blue arrow  at the top left goes back one step, the green arrow  at the top right moves forward one step.

1. After turning on the device for the first time, the Start-up Wizard opens giving 2 options:

Device Config allows the user to change audio level, haptic feedback, screen brightness, units and language.

Date/Time allows the user to update the Date/Time.

If defaults are acceptable, press the green arrow to move to the main menu.

2. If it is the first power on of the day, the  Calibration Verification option displays in the centre of the screen. To complete a calibration verification, press the green forward button and follow the instructions in Section 5.4. If a verification is not required press the 'X' button.
3. The Main Menu offers three standard options - Subject, Quick Test and Configuration - and a fourth option Connect, if Connect is configured.
4. **Subject** allows the user to select a current subject by ID, forename or surname (see Section 5.2 Conducting a Test) or to add/create a new subject (see Section 5.1 Entering Subject Data).
All subject demographics may be added in the add subject screen.
5. **Quick Test** allows the user to select Spirometry or Reports. Reports will always be blank for the Quick Test as there is no

subject selected.

Spirometry option includes VC, FVC and Post (see Sections 5.2 Conducting a Test).

6. Configuration allows the user to:

- carry out a calibration verification (Section 5.4),
- configure reports (Section 5.3),
- configure parameters for test (Section 5.2),
- configure the device including audio level, hepatic feedback and screen brightness level, setting the date and time, population groups (Section 5.1) and has the About box containing details of the device, including software revision number (Section 9.1).

7. Connect allows the user to connect to an Electronic Medical Records (EMR) system (see Section 5.5).

5.1. Entering Subject Data

1. Select 'Subject' from the Main Menu.
2. Select 'Add Subject'.

Subject information fields are divided into primary and secondary, on 2 separate pages. Enter details in subject information fields:

Primary: ID, Date of Birth, Height, Birth Sex, Population

Secondary: Alternative ID, Forename, Surname, Weight, Smoker and Pack years.

On the comments page, comments may be freeform or selected from a pre-defined list.

3. Press the green forward arrow to save subject details and return to main menu. A warning will appear on screen that no predicted values will be generated if a required field is missed.

5.2. Conducting a Test²



1. Before starting a test session ensure that a calibration verification of the device was completed recently (refer to section 5.4 Calibration Verification).
2. Select a subject and ensure subject details are entered.

2 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

3. Wash hands (operator and subject).
4. Fit a disposable BVF to the flowhead. The use of a disposable nose clip is recommended.
5. Instruct and demonstrate the test.


Note: Vitalograph intends that a new Bacterial Viral Filter (BVF) be used for every subject to prevent cross contamination.

5.2.1. Testing

1. Select 'VC Test' or 'FVC Test' from 'Spirometry' in the Main Menu.
2. Select how the results should be presented by scrolling across the screens or pressing the circles  at the top of the screen:
 - **VC Test** - Volume/Time (V/T) graph or Volume (Bar Chart).
 - **FVC Test** - Volume/Time (V/T) graph or Flow/Volume (F/V) graph.
3. When the 'Blow now' icon appears  the device is ready to accept a blow.
 - Sit upright, fit the nose clip and relax.
 - Place BVF in mouth and close lips around the flowhead cone.
 - Seal lips around the cone and keep the tongue down.
 - Breathe normally.

VC test session


- a. Breathe normally until the end-expiratory lung volume is stable. Stability is defined as having at least three tidal breaths with end expiratory lung volume within 15% of the tidal volume (the device will alert a user when this has been achieved).
- b. Inhale completely, with a brief pause when lungs are completely full (≤ 2 secs).
- c. While maintaining an upright posture, exhale in a

- relaxed manner with no hesitation until no more air can be expelled.
- d. It is vital that the operator encourages the subject to keep exhaling to ensure all air is expelled (when a plateau has been reached or expiration time reaches 15 seconds).
 - e. The operator should repeat instructions as necessary, with enthusiasm.
 - f. When prompted by the device that a satisfactory expiratory flow plateau has been achieved or expiration time >15 seconds, inhale maximally and then return to normal breathing.
 - g. The manoeuvre is now complete. Remove the BVF from the mouth.
 - h. Listen for two beeps and the 'Blow now' icon will reappear. The device is now ready for the next blow.
 - i. Repeat for a minimum of three manoeuvres, up to a maximum of eight.
 - j. Check VC repeatability and perform more manoeuvres as necessary.
 - k. Click on  for quality information and test acceptability.

Note: A single-breath VC technique may also be performed on the device.

FVC test session:

- a. Inhale completely and rapidly, with a brief pause when lungs are completely full (≤ 2 secs).
- b. While maintaining an upright posture, exhale with maximal effort until no more air can be expelled.
- c. It is vital that the operator encourages the subject to keep exhaling to ensure all air is expelled (when a plateau has been reached or forced expiratory time (FET) reaches 15 seconds).
- d. The operator should repeat instructions as

- necessary, with enthusiasm.
- Breathe in with maximal effort until completely full. The manoeuvre is now complete, remove the BVF from the mouth.
 - Listen for two beeps and the 'Blow now' icon will reappear. The device is now ready for the next blow.
 - Repeat for a minimum of three manoeuvres, up to a maximum of eight.
 - Check FEV1 and FVC repeatability and perform more manoeuvres as necessary.
 - Click on  for quality information and test acceptability (see Table 2 below).

Note: A single-breath FVC technique may also be performed on the device.

Results grading for FEV1 and FVC is shown below in Table 1.

Grade	Number of measurements	Repeatability: Age >6yr	Repeatability: Age ≥5yr and ≤6yr
A	≥ 3 acceptable	Within 0.150L	Within 0.100L*
B	2 acceptable	Within 0.150L	Within 0.100L*
C	≥ 2 acceptable	Within 0.200L	Within 0.150L*
D	≥ 2 acceptable	Within 0.250L	Within 0.200L*
E	≥ 2 acceptable OR 1 acceptable	> 0.250L N/A	> 0.200L* N/A
U	0 acceptable AND ≥ 1 usable	N/A	N/A
F	0 acceptable and 0 usable	N/A	N/A

*Or 10% of the highest value, whichever is greater

Table 1: Grades

Artifact	Description
Start of Test	The extrapolated volume must be less than 5% of the FVC or less than 0.100L, whichever is greater. If not, the test is deemed a slow start of test. For a child aged ≥ 5 yr and ≤ 6 yr years old, extrapolated volume must be less than 12.5% of the FVC or 0.08L, whichever is greater. If not, the test is deemed a slow start of test and the subject should be encouraged to blast the air out of their lungs without hesitation.
Cough Free	Within the first second of exhalation: if there is a 50% drop in flow and a recovery of at least 1L/s the test is deemed to contain a cough.
FIVC-FVC	If FIVC > FVC and FIVC - FVC > 0.100 L or 5% of FVC, whichever is greater, the FIVC-FVC check is deemed to be unacceptable. This is an indicator that the subject did not start the manoeuvre from TLC.
EOFE	When all of the following are true, the test is deemed to contain an unacceptable EOFE: no flow plateau is achieved or <ul style="list-style-type: none"> • FET is <15 seconds and • FVC is not > highest FVC and • FVC is not within the repeatability tolerance of the highest FVC After the first manoeuvre, the EOFE shall be acceptable until another manoeuvre is performed. After each manoeuvre, EOFE shall be re-evaluated and updated as required for all manoeuvres.
FVC	If a slow start of test occurs, then FVC is deemed to be unusable. Otherwise, if either of FIVC-FVC or EOFE is deemed to be unacceptable, then FVC is deemed not acceptable but may be usable.
FEV1	If either a slow start of test occurs or a cough occurs within the first second of exhalation, then FEV1 is deemed to be unusable. Otherwise, if FIVC-FVC artefact occurs, then FEV1 is deemed not acceptable but may be usable.

Table 2: FVC Quality Feedback


5.2.2. Bronchodilator Responsiveness Testing

Bronchodilator responsiveness testing can be performed on any pre-test session performed.

1. Select 'Spirometry' from the Menu, then select 'Post'.
2. Select the relevant pre-test from the list and perform the test as outlined in section 5.2.1 Testing.

Note: A Post-test may only be completed if an existing Pre-test is available.

5.2.3. Viewing FVC Test Results


Results may be viewed as either a Volume/time (V/t) or Flow/Volume (F/V) graph by scrolling across the screens or pressing the circles  at the top of the screen. Screens viewed in order: F/V graph, V/t graph, Results screen.



The Results screen displays Best, %Pred, Pred values, z-score, LLN


by pressing the tabs



There are additional options to add comments and information on session quality and session interpretation. The user may add

comments of up to 250 characters to the results by clicking  in the top right corner. Select again to save and close.

The icons  and  in the bottom right corner allow the user to select from pre-defined comments as per ATS/ERS 2019. Select again to save and close.

The icon  in the top right corner displays the session information, quality, and interpretation. Select again to close.

5.2.4. Viewing VC Test Results

VC test results may be viewed as either a Volume/time (V/t) or Volume Bar graph by scrolling across the screens. First screen is the bar graph, second is the V/t graph, third is the Results screen.

5.2.5. Test Parameters

Parameter	Unit	Description
VC	L	Vital capacity
EVC	L	Expiratory vital capacity. The maximum/highest volume achieved over the expiratory cycle. If the EVC is greater than the VC, the VC will equate to EVC.
IVC	L	Inspiratory vital capacity. The maximum/highest volume achieved over the inspiratory cycle. If the IVC is greater than the VC, the VC will equate to IVC.
FRC	L	Functional Residual Capacity (FRC): The volume of gas present in the lung and airways at the average end-expiratory level. This shall be calculated as follows: $FRC = (RV + ERV)$.
TV	L	Tidal volume. The volume of gas, which is inspired or expired during a respiratory cycle. The average value of the last three tidal breaths is used.
RV	L	Residual Volume (RV): The volume of gas remaining in the lung at the end of a full expiration. This shall be calculated as follows: $RV = (FRC - ERV)$ or $RV = (TLC - \text{Highest (FVC or FIVC)})$.
TLC	L	Total Lung Capacity (TLC): The volume of gas in the lung at the end of a full inspiration. This shall be calculated as follows: $TLC = (RV + \text{Highest (FVC or FIVC)})$ or $TLC = (FRC + IC)$.
IRV	L	IRV is the maximal volume that can be inspired from the mean end inspiratory level. It is calculated as $(IC - TV)$.
ERV	L	Expiratory reserve volume. The volume that can be maximally expired from the level of the functional residual capacity.
IC	L	Inspiratory capacity. The maximal volume that can be inspired from functional residual capacity.

Table 3: VC Parameters

Parameter	Unit	Description
VC	L	Vital capacity
FVC	L	Forced Vital Capacity. The maximum/highest volume achieved over the expiratory cycle.
FIVC	L	FIVC is the forced inspiratory volume and is the maximum/highest volume achieved over the inspiratory cycle.
FIVC/FVC	ratio	FIVC divided by the FVC and is expressed as a ratio.
FEV0.5	L	FEV0.5 is the expiratory volume achieved after 0.5 seconds. It takes the Time Zero parameter (TExt) into consideration. Therefore, it is the volume achieved after Time Zero plus half a second.
FEV0.5/ FVC	ratio	FEV0.5 divided by the FVC and is expressed as a ratio.
FEV0.75	L	FEV0.75 is the expiratory volume achieved after 0.75 seconds. It takes the Time Zero parameter (TExt) into consideration. Therefore, it is the volume achieved after Time Zero plus three-quarters of one second.
FEV0.75/ FVC	ratio	FEV0.75 divided by the FVC and is expressed as a ratio.
FEV1	L	The expiratory volume achieved after one second. It takes the Time Zero parameter (TExt) into consideration. Therefore, it is the volume achieved after Time Zero plus one second.
FEV1R	ratio	FEV1 divided by the largest VC from either the VC or FVC manoeuvre and is expressed as a ratio.

FEV1/VC	ratio	FEV1 divided by the best SVC VC from the visit expressed as a ratio.
FEV1/EVC	ratio	FEV1 divided by the EVC and is expressed as a ratio.
FEV1/IVC	ratio	FEV1 divided by the IVC and is expressed as a ratio.
FEV1/FVC	ratio	FEV1 divided by the FVC and is expressed as a ratio.
FEV1/FIVC	ratio	FEV1 divided by the FIVC and is expressed as a ratio.
FEV1/ FEV6	ratio	FEV1 divided by the FEV6 and is expressed as a ratio.
FEV1/PEF	L/L/s	FEV1 divided by PEF.
FEV3	L	FEV3 is the expiratory volume achieved after 3 seconds. It takes the Time Zero parameter (TExt) into consideration. Therefore, it is the volume achieved after Time Zero plus three seconds.
FEV3/VC	ratio	FEV3 divided by the VC and is expressed as a ratio.
FEV3/FVC	ratio	FEV3 divided by the FVC and is expressed as a ratio.
FEV6	L	The expiratory volume achieved after six seconds. It takes the Time Zero parameter (TExt) into consideration. Therefore, it is the volume achieved after Time Zero plus six seconds.
PEF	L/s	PEF is the peak expiratory flow and is the maximum/highest flow achieved over the expiratory cycle.

PEF	L/ min	PEF is the peak expiratory flow and is the maximum/highest flow achieved over the expiratory cycle.
FEF ₂₅	L/s	FEF ₂₅ is the forced expiratory flow at 25% of FVC.
FEF ₅₀	L/s	FEF ₅₀ is the forced expiratory flow at 50% of FVC.
FEF ₇₅	L/s	FEF ₇₅ is the forced expiratory flow at 75% of FVC.
FEF _{0.2-1.2}	L/s	The mean forced expiratory flow in the volume interval between 0.2 L and 1.2 L of the test.
FEF ₂₅₋₇₅	L/s	FEF ₂₅₋₇₅ is the average expiratory flow over the middle half of the FVC.
FEF ₂₅₋₇₅ / FVC	ratio	FEF ₂₅₋₇₅ divided by the FVC and is expressed as a ratio.
FEF ₇₅₋₈₅	L/s	The average forced expiratory flow in the time interval between 75% and 85% of the FVC.
FIV1	L	The forced inspiratory volume achieved after one second. It takes an inspiratory Time Zero parameter into consideration. Therefore, it is the volume achieved after Time Zero plus one second.
FIV1/FVC	ratio	FIV1 divided by the FVC and is expressed as a ratio.
FIV1/FIVC	ratio	FIV1 divided by the FIVC and is expressed as a ratio.
PIF	L/s	PIF is the peak inspiratory flow and is the maximum/highest flow achieved over the inspiratory cycle.

PIF	L/ min	PIF is the peak inspiratory flow and is the maximum/highest flow achieved over the inspiratory cycle.
FIF ₂₅	L/s	FIF ₂₅ is the forced inspiratory flow at 25% of FVC or FIVC (whichever is greater).
FIF ₅₀	L/s	FIF ₅₀ is the forced inspiratory flow at 50% of FVC or FIVC (whichever is greater).
FIF ₇₅	L/s	FIF ₇₅ is the forced inspiratory flow at 75% of FVC or FIVC (whichever is greater).
FIF ₅₀ -FEF ₅₀	ratio	FIF ₅₀ divided by FEF ₅₀ and is expressed as a ratio.
FEF ₅₀ -FIF ₅₀	ratio	FEF ₅₀ divided by FIF ₅₀ and is expressed as a ratio.
MVV _{ind}	L/ min	Maximum voluntary ventilation indirectly calculated from the FEV1. It is the measured FEV1 value by 37.5.
FMFT	s	FMFT is the forced mid-expiratory time between 25% and 75% of the FVC.
FET	s	Forced Expiratory Time, calculated as (Test Duration – TExt).
FRC	L	Functional Residual Capacity (FRC): The volume of gas present in the lung and airways at the average end-expiratory level. This shall be calculated as follows: FRC = (RV + ERV).
TV	L	Tidal volume. The volume of gas, which is inspired or expired during a respiratory cycle. The average volume of the last three expired tidal breaths is used.

RV	L	Residual Volume (RV): The volume of gas remaining in the lung at the end of a full expiration. This shall be calculated as follows: $RV = (FRC - ERV)$ or $RV = (TLC - \text{Highest (FVC or FIVC)})$.
TLC	L	Total Lung Capacity (TLC): The volume of gas in the lung at the end of a full inspiration. This shall be calculated as follows: $TLC = (RV + \text{Highest (FVC or FIVC)})$ or $TLC = (FRC + IC)$.
IRV	L	IRV is the maximal volume that can be inspired from the mean end inspiratory level. It is calculated as $(IC - TV)$.
ERV	L	ERV is the volume that can be maximally expired from the level of the functional residual capacity. It is calculated as the $\text{Highest (FVC or FIVC)} - IC$.
IC	L	The inspiratory capacity is the maximal volume that can be inspired from functional residual capacity. It is calculated as the volume from the average tidal line to the bottom of the IC cycle.
Rind	kPa/ L/s	Rind is derived indirectly, based on the FEV1% of predicted.
ELA	yrs	The estimated lung age.
tPEF	ms	The time it takes to achieve maximum flow. It takes the Time Zero parameter into consideration. Therefore, it is calculated by taking the T0 (TExt) from the time where Peak flow was achieved.
Text	ms	Time from start of test to time zero.
BEV	mL	Volume expired before the start of the forced manoeuvre.

BEV/FVC	ratio	BEV divided by FVC and is expressed as a ratio.
EOTV	mL	End of test volume is the volume expired in the last 0.5 seconds.
tRISE	ms	The time between 10% and 90% of PEF.
tHES	s	The time between end of max inhalation and the start of forced expiratory (time zero).

Table 4: FVC Parameters

5.2.6. Saving and Ending a Test Session

The device has capacity to store at least 20,000 tests, with a maximum of 8 blows allowed for each test session. Stored session information includes subject details and best pre-test if it is a bronchodilator responsiveness test session.

A session ends and is saved when the user exits the test screen by pressing the green arrow on the top right.

A session also ends and is saved if any of the following occur:

- The device is turned off
- A new subject is created
- The device is connected to Device Studio.

5.3. Reporting

The device prints the reports to an external printer using the Device Studio application.

To generate PDF reports from the device:

1. Use the USB cable supplied to connect the device to a computer running Device Studio.
2. Ensure that Device Studio application is open, the device is switched on and in the main screen.
3. When connected the remote mode icon will display on the device screen.
4. Device Studio will search for assessments on the device. Available assessments are shown on screen and may be selected and printed and/or saved.
5. Device Studio may also be used to print/save calibration verification reports, data back-up and restore and to update device firmware.

Additional guidance on using Device Studio can be found in the Instruction for Use supplied on the USB flash drive PN 93002 and in the software help menu of the application.

The settings option allows the user to configure information displayed on the session report.

Note: *The software applications available for the device are optional and are not required for the device to function. The device is a standalone spirometer.*

Report Configuration: Select 'Configuration' option of the Main Menu and then 'Reports Config' to configure reports. Options include enable/disable predicted shading, predicted I-bars, test graphs, report % predicted, session comments, subject comments, environmental data, auto acceptability and posture.

5.4. Calibration Verification

ISO 26782 recommendations require that the difference between the volume measured by the spirometer and the volume pumped into the spirometer from a syringe is within 3% (2.5% for the device with an additional 0.5% allowed for the syringe).

1. Fit a disposable BVF to the flowhead.
2. Attach the flowhead with BVF to the syringe as per figure 3 below.



Figure 3

3. If it is the first power on of the day, the Calibration




Verification option  displays in the centre of the

screen to remind the user to complete a daily Calibration Verification.

To complete a Calibration Verification, press the green forward button and then follow the instructions from step 5 below.

4. To access the option from the main screen menu, select 'Configuration' and then select 'Calibration Verification' option.
5. Enter syringe details: serial number, syringe volume (will default to 3L), pressure, altitude and humidity %. At a minimum the serial number, syringe volume and temperature must be entered. The temperature auto fills from the internal temperature sensor but may be changed if required. If a calibration verification was performed previously this will pre-populate with the details of last syringe used.
6. Press the green forward button to continue.
7. Complete 3 full strokes as per onscreen instructions, pausing between each stroke.
8. If the reproducibility between the 3 consecutive syringe strokes is less than 3% of 3L, the calibration verification has passed, and a green tick displays on the syringe icon and <3% is displayed in the top right corner.

In the unlikely event the result is outside 3% or non-reproducible, an error icon will display.

	Successful verification check, with tick in syringe indicating a pass.
	Non-reproducible syringe strokes (red syringe, after the 5 th Stroke). Repeat calibration verification.
	<p>Outside 3%, 6% or 25% (purple syringe, and shows >3%, >6% or >25% in top right corner of screen). The % it is out by indicates the severity of the issue.</p> <p>Over 3%, repeat calibration verification.</p> <p>Over 6% may indicate the device requires cleaning or maintenance.</p> <p>Over 25%, the user should contact Technical Support.</p>

The following displays after the calibration update:



Calibration update (purple syringe with purple tick in a circle, % shown in top right corner of screen).

A report may be printed or saved for the calibration verification if required, see section 5.3.1 External Printer via Vitalograph Device Studio.

If the procedure was followed correctly and the error icon is showing, the calibration verification may be repeated. If the error continues to show, contact the manufacturer using contact information at the start of this document.

Note: A calibration verification is recommended daily, after the device is stored or transported, the flowhead is dropped or replaced and if EMI (Electromagnetic Interference) is suspected or possible.

5.5. Connection to Electronic Medical Records (EMR) via Vitalograph Connect

Connection to an EMR system may be achieved using the Connect service. This is available on the PN 93002 Flash drive supplied with the device. Refer to the Connect IFU on the USB flash drive for additional information on installing and running Connect.

5.5.1. Connect Configuration




On the main menu select 'Connect Config'

The following information is required:

- Address: URL for the Connect service - `http://{host}[:{port}]/connect`
- Network information: Three options - disabled, wired or wireless.

a. Wireless Network

1. When the wireless tab is selected the device

- searches all available networks.
2. Select the required network and enter passkey. The 'Advanced' option allows the user to add/edit the advanced network details if required. The wireless security measures will be determined by the local IT infrastructure, the available options for the In2itive are None (open network), WPA-PSK, WPA-EAP, IEEE8021X.
 3. Press the green forward button to save.
 4. To test the connection, re-select the 'Connect Config' option and press the 'Test Connection' button at the bottom of the screen.
 5. A pop-up message will confirm if there is a good connection.
 6. When connected, a WiFi symbol  displays in the status bar, top left.

Once Connect is configured, the Main menu offers Subject, Quick Test and Configuration options.

Scroll right to access the Connect option.

The Connect screen has three tabs.

- New Orders
- Open Orders
- Return Orders

5.5.2. New Orders

To process an order, go to the 'New Orders' tab, select the order required and press the 'Start Testing' button. The subject information displays. Review and press the green forward button to proceed with a test. The main test menu displays. Select 'Spirometry' and complete a test (see section 5.2.1 Testing). When complete, select the green forward button to exit and close the session.

5.5.3. Open Orders

The 'Open Orders' tab shows a list of orders allocated to the device which have not yet had a test completed. These remain on the

list until they are processed. To process an open order, select it from the list and follow the same instructions as for new orders in section 5.5.2 above.

5.5.4. Return an Order

To return an order go to the 'Return Orders' tab, select the order required. All available sessions for that order will be shown.

If the order is complete, ensure the required sessions are selected (up to a maximum of 10) and press the 'Return' button. **If additional testing is required** select the 'Start Testing' button first and press the green forward button to proceed with a test (see section 5.5.2 New Orders). When complete, select the green forward button to return and complete the order.

5.5.5. Return Unsolicited

Unsolicited Orders are tests that were not allocated by the EMR. If the EMR is configured for unsolicited orders the user may select the 'Return Unsolicited' button, complete a test, and return it to the EMR.

The 'Return Unsolicited' button does not show if the EMR is not configured for unsolicited orders.

6. Cybersecurity Considerations

6.1. Specification

The device employs an Operating System (OS) that is not accessible under normal use. The application runs on top of the OS and is the only user interface to the device. The OS has a configured firewall to protect against any unauthorised access over the communications ports, only Vitalograph PC based applications can access the device over a secure connection. No further controls are required to be applied by users to secure the device. The device will timeout and auto power down after 5 minutes of inactivity.

6.2. Security Recommendations

When connecting to a PC it is recommended that the PC has the following cybersecurity in place:

- **Up to date Operating System:** the Operating System

should be configured for automatic update for security patches and have all of the latest patches applied.

- **Antivirus/antimalware:** the PC should have a reputable antivirus or antimalware application installed and all updated virus definitions in place.
- **Secure Login:** the PC should be password protected via industry standard user access controls, via active directory or other methods.
- **Firewall:** if the PC is connected to the internet ensure a reputable

6.3. Interfaces

Communications interfaces – USB, WiFi: The device will communicate with Vitalograph PC based applications for:

- Back-ups and restore
- Software updates
- Printing to external printer
- Transfer of test data

SD Card: Only used for encrypted backup of stored data.

7. Power Management

The device can be powered from a PC/Laptop via a USB cable, via the 5V power supply or from the internal battery. The battery power icon in the status bar at the top of the screen shows the power status of the device.

When powered from a power supply or USB, the plug icon displays on the status bar, next to the battery icon.

The device is turned on using the On/Off power button on the side of the device. The device may be switched off by pressing and holding the power button on the left side of the device for 1 to 2 seconds.

The device will auto power down after 5 minutes of inactivity.

Note: *This will end a test session if one is still active.*

7.1. Battery Pack

The device is fitted with a rechargeable Battery Pack. This allows the device to be used without the 5V Power Supply or USB connected. The battery pack may be recharged by plugging in the

5V Power Supply to the mini USB connector on the left side of the device. A full charge takes 5 hours and is sufficient for 6 hours testing.

The battery may also be recharged by connecting the device to a USB port on a PC via the USB cable connected to the mini USB connector located on the left side of the device, however charging may take longer.

A plug icon next to the battery power indicator on the status bar indicates when the device is charging. See battery power indications at Section 7.2.

Note: *With the power supply/USB cable plugged in the device will continue to charge even if it auto powers down after 5 minutes of inactivity.*

The device may be used while charging. If the battery is at less than 5% capacity the device will power down.

Note: *A high power USB port capable of supplying 500mA is required for charging over USB.*

Note: *It is recommended that the device is only charged when the battery low symbol displays.*

The recommended battery pack replacement interval is 3 years or when the user determines it is required based on the product useful life checks outlined in section 9.2. Battery replacement should be carried out only by the manufacturer, the approved importer or by Service Agents approved by Vitalograph.



Note: *When charging the device using the 5V Power Supply, ensure it is plugged into an accessible socket so that it may be easily disconnected from the mains supply if required.*

7.2. Battery Power Indications



Battery is fully charged: a white 'Battery Full' icon displays on the status bar at the top of the screen.

Disconnect the device from an external power source when it is fully charged.

	<p>Battery is at less than 20% capacity: an orange 'Battery Low' icon displays on the status bar at the top of the screen. The device may be used but it is advised to connect to an external power source to continue testing.</p>
	<p>Battery is almost discharged: the red 'Battery Discharged' icon displays on the status bar at the top of the screen. If battery is at less than 5% capacity the device will power down. Connect to an external power source to recharge the battery before use.</p>

7.3. Power Save Mode

When left unused the device will automatically power down after 5 minutes. This will occur whether the power is plugged in or not. Pressing the On/Off button will turn the device back on.

8. Cleaning & Hygiene

8.1. 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) 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. There are no special temperature requirements for cleaning, which may be carried out at room temperature. After cleaning, the device should be inspected for residual soiling and repeat cleaning carried out if required.

Table of Cleaning/Disinfection Methods

Part	Clean/ Low Level Disinfection	Recommended Cleaning/Low Level Disinfection
Case exterior	Clean	Wiping with a 70% isopropyl alcohol impregnated cloth provides a suitable form of cleaning. The exposure time for low level disinfection using 70% IPA wipes is ≥ 1 minute. ³
Screen	Clean	For the screen, lightly wipe the surface with cotton pad or other soft material. NOTE: DO NOT use any chemicals. DO NOT wipe in a circular motion. Strokes should be either up/down or over/back.

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.

8.2. Inspection of the Vitalograph In2itive

No inspection of the device is required by the subject. The device is used under the supervision of a healthcare professional. For the healthcare professional a visual inspection is recommended on a routine basis. Examine cone and flow conditioning mesh filter for damage or contamination.

If it is damaged or blocked, it should be replaced with a new part. Examine the Fleisch element and replace if damaged.

If it is suspected that the flowhead has become contaminated or where user risk assessment identifies a need for higher level of decontamination, then it should be cleaned as per the instructions

³ Rutala, W. A. 2017 "Back to the Basics" accessed from disinfection&sterilization.org, June 2020.

on 'Cleaning and Hygiene' on the Vitalograph website.

It is recommended that a calibration verification is carried out following cleaning and re-assembly as recommended in the ATS/ERS 2019 guidelines⁴.

4 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

9. Fault Finding Guide

Problem Fault Symptoms:	<ul style="list-style-type: none"> • Calibration verification variations > +/-3% • False readings suspected
Possible Cause/ Solution: (In probable order)	<ul style="list-style-type: none"> • The % error indicates the severity of the issue. Over 3%, repeat calibration verification. Over 6% may indicate the device requires cleaning or maintenance. Over 25%, the user should contact Technical Support. • Was the correct syringe volume selected? • Flowhead pressure tapping holes blocked. • Flowhead Fleisch element assembly sealing 'O' rings damaged. • Flowhead Fleisch element assembly blocked. • Cold syringe. Ensure syringe is in its test environment for at least an hour before use. • If using the remote flowhead – ensure both end cap on device and remote flowhead adaptor on flowhead are clicked into place. Ensure the tubing is fitted in the correct orientation and not pinched or trapped. • Internal tubing from pressure ports on device is blocked. Contact Support. • EMI (Electromagnetic Interference) that exceeds EN60601-1-2 EMC standard. Turn off offending device or move the device to another location and repeat. • Electronics failure. Contact Support.
Problem Fault Symptoms:	<ul style="list-style-type: none"> • Cannot print to external printer
Possible Cause/ Solution: (In probable order)	<ul style="list-style-type: none"> • Check USB cable is connected from device to PC and Device studio is installed on PC. • The device is in the main menu screen. • Electronics failure. Contact Support.

Problem Fault Symptoms:	<ul style="list-style-type: none"> • Tests begin automatically • Volume accumulates automatically without the subject blowing • Very small VC or FVC test displayed
Possible Cause/ Solution: (In probable order)	<ul style="list-style-type: none"> • Device (or if using remote flowhead, the flowhead) is not stationary at the start of test. Hold them steady until the 'Ready to Blow' prompt appears. • Return to previous menu and re-enter the test.
Problem Fault Symptoms:	<ul style="list-style-type: none"> • Cannot read screen.
Possible Cause/ Solution: (In probable order)	<ul style="list-style-type: none"> • Ensure the on/off button was pressed. • If running off battery, ensure the device is charged and/or the power supply or USB cable is connected. • Electronics failure. Contact Support.
Problem Fault Symptoms:	<ul style="list-style-type: none"> • Reversed or no volume measurements.
Possible Cause/ Solution: (In probable order)	<ul style="list-style-type: none"> • Ensure the flowhead is properly connected/ seated on device. • If using the remote flowhead adaptor, ensure tubing is connected correctly – there is a key on the tubing and a key on the tubing connectors, ensure these match. • If using the remote flowhead adaptor, ensure both end cap on device and remote flowhead adaptor on flowhead are clicked into place. • If using the remote flowhead adaptor, ensure tubing is not pinched or trapped.

Problem Fault Symptoms:	<ul style="list-style-type: none"> • Cannot connect to EMR over WiFi.
Possible Cause/ Solution: (In probable order)	<ul style="list-style-type: none"> • Check that WiFi symbol is showing on status bar and if it is not, repeat steps in 5.5.1. • Ensure correct WiFi network is selected and pass key is correct. • Check the connection by pressing the 'Test Connection' button in the 'Connect Config' screen. • Electronics failure, contact Support.
Problem Fault Symptoms:	<ul style="list-style-type: none"> • Screen is frozen
Possible Solution: (In probable order)	<ul style="list-style-type: none"> • Requires hard reset – press and hold the power button for 15+ seconds, until it powers down and back on again.

9.1. Software Check

Information about the device can be obtained from the About box. This information can be used if any queries are made to Vitalograph or a service agent.

To access the About box , select 'Configuration' on the Main Menu and go to the second screen of options.

9.2. Product Useful Life Checks

To ascertain whether the device has exceeded its useful life Vitalograph recommends checking the flowhead and the batteries.

The flowhead may be checked with the daily calibration verification, to be completed by the clinician/healthcare professional, and during the periodic inspection of the device. Reference section 5.4 Calibration Verification for details on how to check the device flowhead.

As the main battery pack ages, the required charging frequency will increase, and the battery life will decrease. Vitalograph recommend

changing the battery pack every 3 years or if any issues are noted with the battery.

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.

10. Customer Service

Service 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, 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 Authorised Representative and the Regulatory Authorities of the country. Refer to the Vitalograph contact information at the start of this manual.

11. Consumables and Accessories

Cat number	Description
28501	Eco BVF (100)
28554	Eco BVF with Bite Lip (75)
28553	Eco BVF with Bite Lip + Disposable Nose Clip (75)
20303	Nose Clip (200)
36020	3-L Precision Syringe
69131	Flowhead Cone (5)
41526	USB Cable
41525	Power Supply with Power Input Adaptor Set (EU, AU, US)
83157	Flowhead Spare
42175	Flowhead Connection tube

83200	Remote Flowhead Adaptor Kit
83155	Service Kit
83156	Pouch

12. 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. BVFs are made from recyclable material and should be disposed of in line with local requirements.



13. Explanation of Symbols

Symbol	Description
	Type BF equipment
	Class II
VA	Power rating
	Voltage DC / Batt V for battery / DC for power supply
	Instructions for Use; operating instructions
	Manufacturer
	Date of Manufacture (Date format YYYY-MM-DD)
	USB 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
	Operating Temperature Limits
	Operating Relative Humidity Limits
	Operating Atmospheric Pressure Limits
	Non sterile
	Recycle
	Keep dry
	QR code - matrix bar code. All information in the bar code is included in the text under it
Rx Only	Restricted to sale by, or on the order of a physician.
	MR Unsafe – Do not use this device in an MRI environment.

14. Description of the Vitalograph In2itive

The Vitalograph 2120 In2itive is a spirometer designed for lung function testing in a variety of professional healthcare environments, e.g. primary care, hospitals and occupational health centres. It is a handheld, portable device.

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). And as such, spirometry may support or exclude diagnosis, but it cannot make one.

Spirometers are also used in non-clinical settings such as occupational health screening where no clinical judgment is made, suspect findings leading to a referral to a clinician. The device is intended for use as a spirometer by medical professionals trained in respiratory and lung function testing.

15. Technical Specification

Product	Vitalograph 2120 In2itive
Model	2120
Flow Detection Principal	Fleisch type pneumotachograph
Essential Performance	Flow measurement output
Essential Performance Test Limits	Flow Accuracy $\pm 10\%$ or ± 20 L/min, whichever is greater
Back pressure	Less than 0.15kPa/L/second at 14 L/s
Volume detection	Flow integration sampling at 100Hz
Maximum test duration	90 seconds
Volume accuracy	$\pm 2.5\%$

Voltage/frequency	Power supply: Input 100-240V, 50/60Hz, 0.5A Output 5V, 2A Battery: 3.7V, 2Ahr
Accuracy when operated in operating temperature range conditions	Flow $\pm 10\%$ Max. flow rate ± 16 L/s Min. flow rate ± 0.02 L/s
Operating temperature range	ISO 26782 limits: 17 – 37°C Design limits: 10 – 40°C
Operating humidity range	30% – 75%
Ambient pressure range	850hPa – 1060hPa
Performance standards the device meets or exceeds	ATS/ERS 2019, ISO 23747:2015 & ISO 26782:2009
Safety standards	EN 60601-1:2006 + A1:2013 + A2:2021
EMC Standards	EN 60601-1-2:2015 + A1:2021
Coexistence standards	ANSI C63.27-2017 American National Standard for Evaluation of Wireless Coexistence.
QA/GMP standards	EN ISO 13485, FDA 21 CFR 820, CMDR SOR/98-282 & JPAL, MDSAP
Dimensions	186mm x 81mm x 48mm net
Weight	0.3 kg net
Communications	USB, WiFi

Wireless technology	WiFi 802.11bgn Module: WL1831MOD Wi-Fi Texas Instruments Certified/ approved FCC, IC, ETSI/CE, Japan MIC. FCC ID: Z64-WL18SBMOD IC: 4511-WL18SBMOD MIC (Japan): 201-135370 Frequency 2.4-GHz (2412 – 2484 MHz). Maximum RMS output power measured at 1dB: 17.3dBm
Power Supply	5V, 2A DC power supply 3,7V, 2Ahr Lithium Polymer battery
Service life	The recommended service life of the device is 3 years.
Product life	10years+ when maintenance and servicing (every 3 years or when product useful life checks dictate it is required) procedures are adhered to. Reference section 9.2 'Product useful life checks' for information on how to ascertain whether the device or parts on the device have exceeded their useful life.
Minimum PC System Requirements	Processor Speed: 2GHz or greater RAM: 2GB (Min), 4GB (Recommended) Disk Space: 1GB or greater Operating System: Windows 7 or above Monitor: 1280 x 800 pixel or above. Other: <ul style="list-style-type: none"> • .Net framework 4.5.1 • USB Port

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 and storage conditions specified apply to the device plus accessories.
- The device body and flowhead are classified as type BF applied parts.
- An applied part is a part of the equipment, that in normal use necessarily comes into physical contact with the subject for equipment or system to perform its function.

16. CE Notice



Marking by the symbol ²⁷⁹⁷ indicates compliance of the Vitalograph 2120 In2itive to the Medical Devices Directive of the European Community.

The device is intended for and suitable for use in a variety of professional healthcare environments, e.g. primary care, hospital wards, occupational health centres and clinics, 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 device should assure that it is used in such an environment.

The device was 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.

Coexistence: ANSI C63.27-2017 American National Standard for Evaluation of Wireless Coexistence.

EN 60601-1-2:2015 + A1:2021 - Emissions tests		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The device 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 B	The device is suitable for use in all establishments, including those connected to the public mains network (e.g. doctor's offices in residential areas)

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, ± 8 kV, ± 15 kV	Contact: ± 8 kV Air: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV

Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines	+/- 2kV
Surge IEC 61000-4-5	± 0.5 kV, ±1kV differential mode Device is identified as Class II unearthed equipment therefore common mode testing is omitted.	+/- 0.5 kV, 1kV
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 240V AC, 50Hz 100V AC, 50Hz	100% drop, 0.5 cycles, 0o, 45o, 90o, 135o, 180o, 225o, 270o, 315o 100% dip, 1 cycle 30% dip, 25/30 cycles 240V AC, 50Hz 100V AC, 50Hz
Conducted RF 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
Radiated RF EN 61000-4-3	10V/m (home healthcare) 80MHz to 2700MHz	10V/m (home healthcare) 80MHz to 2700MHz
Proximity fields from RF devices EN 61000-4-3	9 to 28V/m 385 to 5785MHz As per Table 9 EN60601-1-2:2015	9 to 28V/m 385 to 5785MHz As per Table 9 EN60601-1-2:2015

Power frequency (120V, 60Hz) magnetic field	30A/m	30A/m
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. Loss or degraded performance due to EMI that exceeds the test levels in immunity test tables above will result in a failed calibration verification. Reference section 5.4 of this document for details on completing a calibration verification on the In2itive.

If interference is suspected or possible, move the device to a new location and repeat the calibration verification. Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided.

The Model 2120 In2itive is a Spirometer and so the performance deemed to be essential is the output of the flow transducer.

WARNING: *No modification of this equipment is allowed.*

17. FDA Notice

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

18. EU Declaration of Conformity

Product: Vitalograph 2120 In2itive

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.

- Canadian Medical Device Regulation {CMDR SOR/98-282}
- FDA Quality System Regulation {QSR} 21 CFR 820.
- 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.



19. 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 30 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 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.

