

Vitalograph[®]

In2itive

MODEL 2120



Instructions for Use

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1. Main Components of the Vitalograph In2itive

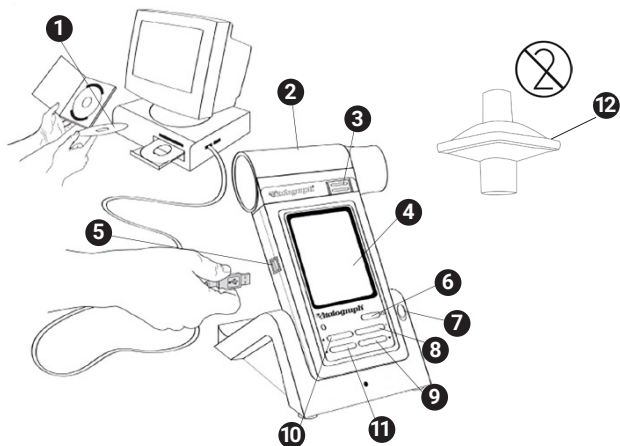


Figure 1 Main components of the In2itive

Note: Computer not supplied

1	PC Software
2	Flowhead
3	Flowhead Release Button
4	LCD/Touch Panel Display
5	Mini USB Ports
6	On/Off Button
7	Stylus Holder in device cradle
8	Cancel Button
9	Enter Button
10	Up Button
11	Down Button
12	BVF™

1.1. Features of the Vitalograph In2itive

- Fleisch Pneumotachograph
- Integral flowhead + remote flowhead adaptor kit
- Colour touch screen with stylus
- Feedback sounds
- Real-time curves and quality prompts
- Incentive display options
- Single and multi-breath testing
- 50+ parameter options
- Bronchodilator responsiveness testing
- Customizable report format
- Long battery life
- 10,000 subject test memory
- Choice of predicted values and languages

2. Setting Up the Vitalograph In2itive

1. Connect the mini USB connector from the power supply into the USB port on the side of the unit or into the cradle. Plug the mains plug into a suitable socket. Attempted use with other power sources may cause irreparable damage and invalidate the warranty. The In2itive™ may be powered directly via the USB cable or using the purpose-built low voltage power supply unit with which it is supplied. The output from the power supply is 5 volts DC.
2. Place the In2itive device into the cradle.
3. Switch on the In2itive using the On/Off switch on the device. The In2itive is ready for use.
4. The In2itive comes fitted with a rechargeable battery, which allows the device to be used for a time without the mains power supply connected.
5. Install the PC software supplied with the device following the software installation instructions (this may be Spirotrac® or Vitalograph® Reports, either as USB or DVD dependent on the version purchased). Where there is a requirement for data to be imported/exported to primary care practice software, guidance is included in the Spirotrac instructions for use.
6. During software installation the user must enter the activation

key and licence key which are supplied with the software.

7. For reporting from the In2itive or to use with Spirotrac, connect one end of the USB cable into an available USB port on the PC and the other end into the USB port on the side of the cradle.

The cable can also be connected into the port on the left side of the In2itive.

If the device has just been unpacked or transported, ensure that it is left sitting, fully powered so that it is at room temperature prior to testing.

2.1. Connecting the Remote Flowhead

The In2itive flowhead can be set up to work remotely from the device as follows (see figure 2):

1. Hold the device body firmly in one hand.
2. With the other hand, hold the flowhead. Press and hold the button firmly on the front of the Fleisch flowhead.
3. Slide the flowhead away from the device from left to right.
4. Attach the device cap in the space which was occupied by the flowhead. This is done by sliding the device cap into the grooves in the top cover of the device body. When assembled, the Vitalograph logo and button on the device cap should be on the same face as the LCD screen. Ensure the cap is fully pushed in.
5. Attach the remote flowhead adaptor to the flowhead. This is done by sliding the flowhead into the grooves in the remote flowhead adaptor. Ensure this is fully pushed in.
6. Open the rubber cover on the left side of the device cap. This will expose two pressure ports on the device cap.
7. Attach the remote flowhead to the port on the In2itive device cap using the Flowhead Connection Tube as shown in Figure 2.
8. A recess is provided on the cradle to hold the remote flowhead when not in use.
9. The flowhead can be refitted to the In2itive body by removing the device cap from the In2itive, and removing the remote flowhead adaptor from the flowhead, then sliding the flowhead back onto the In2itive.
10. It is recommended that an accuracy check is carried out after the flowhead is used remotely or refitted to verify correct operation and accuracy.

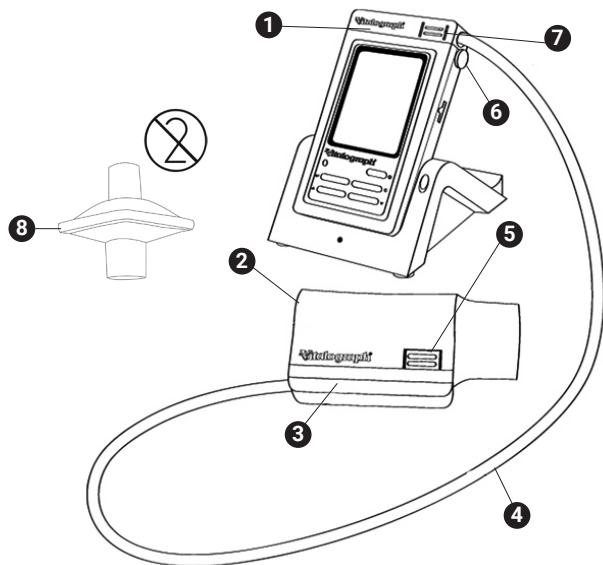


Figure 2: Setting up the In2itive remote flowhead

1	Device Cap
2	Flowhead
3	Remote Flowhead Adaptor
4	Flowhead Connection Tube
5	Flowhead Release Button
6	Rubber Cover
7	Device Cap Release Button
8	BVF™

3. Operating Instructions

3.1. Entering Subject Data

When the device is turned on, the Main Menu screen opens.

1. Select a subject by tapping the Subject button.
2. The subjects saved on the device may be listed using either the Name or ID tab.
3. Select and view the subject details by tapping the subject onscreen. Select 'Enter' to make this the current subject.
4. To create a new subject, select the New tab. Touch the required field onscreen to highlight, then enter subject details using the touch panel keypad. Press Enter to save the subject to the database and return to the Home Menu.

Note: *The current subject surname and forename will be displayed on the bottom left hand corner of the screen.*

- If the subject name is not entered then the subject ID will be displayed.
- If the subject has test session results associated with it then the subject name and ID will appear in black.
- If there are no test session results then the subject name and ID will appear in grey.

3.2. Conducting a Test¹

Before starting a test session:

1. Ensure that the device accuracy was checked recently. (Refer to section on Checking Accuracy).
2. Select a subject and ensure the required demographic information is entered.
3. Wash hands (operator and subject).
4. Fit a new Bacterial Viral Filter (BVF) to the flowhead for each test subject. The use of a disposable noseclip is recommended.
5. Instruct and demonstrate the test.

3.2.1. Testing

1. Select either 'VC Test' or 'FVC Test' option from the Main Menu.

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

2. Select how the results should be presented:
 - VC Test – Select from Volume/Time (V/T) graph and Volume (Bar Chart).
 - FVC Test – Select from Volume/Time (V/T) graph and Flow/Volume (F/V) graph.
3. Wait for the 'Exhale to Begin' icon to appear. The device is now ready to accept a blow.

Example script:

- Sit upright, fit the nose clip and relax.
- Place BVF in mouth and close lips around the mouthpiece.
- Seal your lips around the mouthpiece and keep your tongue down.
- Breathe normally.

VC test session

- a. Inhale completely with a brief pause when your lungs are completely full (≤ 2 secs).
- b. Exhale with no hesitation until no more air can be expelled while maintaining an upright posture. 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). The operator should repeat instructions as necessary, coaching vigorously.
- c. Listen for two beeps. The device is now ready for the next blow.
- d. Repeat for a minimum of three manoeuvres, usually no more than eight for adults.
- e. Check VC repeatability and perform more manoeuvres as necessary.

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 your lungs are completely full (≤ 2 secs).
- b. Exhale with maximal effort until no more air can be

- expelled while maintaining an upright posture. 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). The operator should repeat instructions as necessary, coaching vigorously.
- Breathe in with maximal effort until completely full. The manoeuvre is now complete and the BVF is removed from the mouth.
 - Listen for two beeps. The device is now ready for the next blow.
 - Repeat for a minimum of three manoeuvres, usually no more than eight for adults.
 - Check FEV1 and FVC repeatability and perform more manoeuvres as necessary.

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

3.2.2. Saving the Test Session

The test session is saved to the database by default, by following the on-screen messages.

Note: If a compact flash card is inserted into the compact flash card connector at the right side of the device, then all test blows and not just the best three will be saved to the compact flash card. Results are saved as per the format outlined in the *European Respiratory Journal*, 2005; 26: Pages 319-338: ATS/ERS Task Force: *Standardisation of Lung Function Testing*.

The Post Mode screen also offers the option to save and recall test sessions to and from a permanent storage location on the device. This permanent storage does not get deleted when test sessions are sent to Vitalograph Reports or Spirotrac. To access this option select 'Permanent Storage'.

The Permanent Storage screen gives you four options:

- **Save Test to Permanent Storage:** An information message will state the memory location where the test session will be saved. There are nine permanent memory locations on the Vitalograph In2itive.

- **Load Test from Permanent Storage:** The list of permanent pre-test sessions will appear. Select the required pre-test session from the list and select enter to bring you into the Post Mode screen.
- **Delete Test from Permanent Storage:** A list of stored pre-test sessions will appear. Select the Test session to delete and press enter. This location will then be marked as 'Empty'.
- **Delete all Tests from Permanent Storage:** A warning message will appear:- 'Do you want to delete all tests stored in permanent storage?'. Select 'Enter' to delete all tests.

3.2.3. Bronchodilator Responsiveness Testing

A Bronchodilator Responsiveness Test session can be performed on an FVC test session following the administration of drugs. Post drug delivery performance is measured versus pre delivery.

- To start bronchodilator responsiveness testing select 'Post Mode' from the Main Menu.
- To perform a bronchodilator responsiveness test on the Pre-test Session just performed, select 'Perform Post test on Current Subject'. This will bring up the test screen. The text 'Post Mode' will appear on the graph.
- To perform a bronchodilator responsiveness test on a different subject or Pre-test:
 1. Select 'Select Subject from List'.
 2. A message 'Warning! Current test session will end. Do you want to save the test session?' will appear. Select Yes and the Select Subject screen will appear.
 3. Select the subject for bronchodilator responsiveness testing.
 4. Select the test session from the Select Test Session screen.

Note: The words Pre, VC or FVC or a combination of these will appear after the session ID.

If the word Pre appears then a bronchodilator responsiveness test session has already been performed on this pre session.

If the word VC appears then a VC test has been done as part of the pre-session.

If the word FVC appears then an FVC test has been performed as part of the pre-session.

5. Press 'Enter' to open the test screen. The text Post Mode will appear on the graph.
6. Perform an FVC test post drug delivery as outlined in section 3.2.1. Testing, to assess bronchodilator responsiveness.

3.2.4. Deleting a Test Session

To delete the current session:

1. Select the 'Clear' option from the Main Menu.
2. A message will appear 'Warning! Current Test Session Will End. Do you want to save the test session?'
 - Select 'Yes' to save the current test session and return to the Main Menu.
 - Select 'No' to clear the current test session and return to the Main Menu.
 - Select 'C' to cancel the operation and continue with the current test session.

3.3. Reporting

The In2itive can be connected to a PC by USB through the port at the side of the device or from the cradle so that reports can be written to the Vitalograph Reports Application or generated through Spirotrac. By using the optional Print Cradle the In2itive can also be connected to an external PCL compatible printer.

The information printed on the session report and also the reports method (Vitalograph Reports or External Printer) can be set to individual requirements. Refer to section on Report Options.

To produce a report for the Current Subject via the Report option in the In2itive Main Menu, the options are:

- **Current Session:** Select the print icon on the session results screen.
- **Saved Test Session for Current Subject:** Select the required session then the print icon on the session results screen.

- **All Test Sessions:** It is possible to select to print all test sessions for the current subject via a PC using Vitalograph Reports software.

To print Test Session(s) from a different subject in the database. Click the 'Select' tab in the View and Report screen. The following options are available:

- **Select Test Session:** Select a subject from the database, and then select a test session for that subject. To print the selected session, select the print icon at the top of the session results screen.
- **All Test Sessions:** To print all test sessions for a selected subject via a PC using Vitalograph Reports software
- **All Test Sessions Between...:** This will print all sessions stored on the device between specified dates using Vitalograph Reports software via a PC.

The default test parameters on the report will vary according to regional requirements. Test parameters can be configured to suit individual requirements. Refer to section on Parameters.

3.4. Deleting Stored Subjects/Test Results

Instructions on deleting subjects/test results that have been stored permanently on the device may be found in section 3.2.2. Saving the Test Session.

Instructions on deleting sessions from the device database may be found in section 3.6.2. Database

3.5. Calibration Verification

- Attach flowhead to the syringe with a BVF fitted as per figure 3.



Figure 3: Verifying Calibration

- Select Accuracy Check from the Main Menu using the keypad.
- Enter the Syringe volume and reference using the touch panel keypad.
- Depending on how the device is configured, follow prompts to enter the ambient temperature, humidity (0-99%), pressure (25-31 inHg or 850-1060 hPa-mbar) and altitude (1-8500m). Enter these values using the touch panel or keypad.
- Pump air through the flowhead to bring it to ambient temperature.
- If the flowhead has very recently been used for testing or has come from a cold environment, its temperature should be equilibrated with ambient by pumping air through it from the syringe several times.
- Press the 'Enter' key to open Accuracy Check screen and follow on-screen instructions.
- If an Accuracy Check report is required, select the Report option.
- Press the 'C' key to exit the Accuracy Check screen and return to the Main Menu. The accuracy check will not be logged to the In2itive memory in this case.

Note: If the device is outside calibration, the user is offered the option to update calibration. Selecting to update calibration repeats the accuracy check routine on the device.

3.6. Configuration Options

To access configuration options available on the In2itive, select 'Configuration' on the Main Menu. The options are:

3.6.1. Test Preferences

The following options are available to configure the test screen to your requirements:

- **FVC Display:** Select to show F/V (Flow-Volume) or V/T (Volume-Time) Graph by default in the FVC test screen. Select the required option from the drop down menu.
- **VC Display:** Select to show the Bar Graph or V/T (Volume-Time) Graph by default in the VC test screen.
- **Test Acceptance:** Select whether to manually accept the tests performed, or allow the device to determine test acceptability (automatic).
- **Graph Scale:** Select the default graph scale.
- **Posture:** Select from 'no posture selected', 'standing' or 'sitting'.
- **Post VC Test:** Selecting 'off' here means that selecting Post testing brings the user directly to the FVC test screen. Post VC testing is 'on' by default where VC testing has been done in a pre-test session.
- **Temperature:** By selecting 'on' in the drop down list, the user is offered the option to manually enter the ambient temperature as they go into the VC or FVC test screens.

3.6.2. Database

To manage the available memory on the device, the Management tab tells you how much subject and test session memory has been used up.

- **Defragment:** Device memory may become fragmented through long use. To maximise available memory, select the defragment option. Defragmentation may take several minutes to complete.
- **Deletion:** To delete a session, select the relevant box. The session will be deleted from the device after being printed. (Either print to an internal printer or sent to Vitalograph Reports). It is also possible to 'Select Test Session(s)' for

deletion, or 'Delete Subject(s)' from the device by pressing the relevant button using the touch panel LCD.

3.6.3. Calibration

The In2itive should never be outside accuracy limits unless damaged or in a faulty condition. In this event, see the fault-finding guide. In normal use, calibration traceability certification is recommended as a part of the routine annual service.

The Calibration Options menu offers:

- Calibration: To calibrate the device
- Precision Syringe: To select the volume of syringe used for calibration
- Linearity: To check linearity
- Accuracy Log: To view and print the accuracy log

Calibration

Calibration is not required for normal use. Calibration should only be conducted by, or under the guidance of Vitalograph Service Agents. See contact details on p. 2.

1. Select 'Calibration' from the Calibration screen.
2. Pump air through the flowhead to bring it to ambient temperature. If the flowhead has very recently been used for testing or has come from a cold environment, its temperature should be equilibrated with ambient by pumping air through it from the syringe several times.
3. Press the 'Enter' key to bring you into the Calibration screen and follow the on-screen instructions.
4. If a Calibration report is required select the Report option.

Press the 'C' key to exit the Calibration screen.

Note: An Accuracy check must be done on the same day as the device is calibrated.

Precision Syringe

1. Select 'Precision Syringe' from the Calibration screen.
2. Select the volume of the calibrated syringe from the drop down list.
3. Enter the syringe reference number using the touch panel keypad.

4. Press Enter to save the new volume entered and return to the Calibration screen. Press C to cancel the changes made and return to the Calibration screen.

Linearity Check

1. Select 'Linearity' from the Calibration screen. (Note: Pressing the C key will exit the Linearity Check screen.)
2. Using a 3L calibrated syringe, pump air through the flowhead to bring it to ambient temperature.
3. If the flowhead has very recently been used for testing or has come from a cold environment, its temperature should be equilibrated with ambient by pumping air.
4. Enter environmental data if prompted to do so.
5. Press Enter to open the Linearity Check screen.
6. Pump air into the flowhead at a slow rate of $< 2\text{L/s}$. Immediately withdraw the syringe at a slow rate. This manoeuvre should show on the graph between the two red lines. If it is a correct manoeuvre the table on the screen will show 'Test 1', and the FVC and FIVC values will be updated. Repeat for the slow rate three times.
7. Repeat the procedure for a medium rate $>2\text{L/s}$ and $< 6\text{L/s}$. This manoeuvre should show on the graph between the red and green lines. If it is a correct manoeuvre the test number and the FVC and FIVC values will be updated in the table. Repeat for the medium rate three times.
8. Repeat the procedure for a fast rate $>6\text{L/s}$. This manoeuvre should show on the graph between the outside green lines. If it is a correct manoeuvre the test number and the FVC and FIVC values will be updated in the table. Repeat for the fast rate three times.
9. When all the manoeuvres are complete press Enter for the result.
10. If a Linearity Check report is required select the 'Report' option.

Accuracy Log

1. Select 'Accuracy Log' from the Calibration screen. The accuracy log contains a record of all the accuracy checks done on the device.

2. There are three options:
 - a. To print the complete accuracy log press 'Print All'.
 - b. To print a log of the last 30 accuracy tests done, press 'Print Last 30'.
 - c. To view the accuracy log, press 'View'.
3. Press C to return to the Calibration screen.

3.6.4. Settings

The following options are available in the Device Settings screen:

- **Date/Time:** Update the date and time including format
- **Units:** Metric/Imperial
- **Sound Options:** On/Off/Volume
- **Power Save Options:** Display dulls after 3 minutes
- **Incentive:** Select incentive, % predicted and % best test
- **Parameters:** Select parameters for report/printing

Date/Time

There are two tabs in this screen for the time and date.

1. Change the time by scrolling the hours and minutes to the required settings by pressing the arrows on the touch panel LCD.
2. Change the time format from 24 hour to 12 hour by switching the '24 Hour Format' option off or on.
3. Change the date by scrolling the day, month and year to the required settings by pressing the arrows on the touch panel LCD.

Units

Modify the units by selecting between Metric and US (Imperial) in the drop down list.

Sound Options

- Select Off/On options for Key, Flow, Error and Welcome sounds on the device.
- Adjust the volume by pressing the '-/+ ' on the touch panel LCD.

Power Save Options

In order to improve battery life the device can be configured to dull the display after 3 minutes. This can be switched on or off.

Incentive

The Incentive Device is used as an aid in testing of children.

4. Select the incentive device to be used in testing using the drop down list. A preview of the incentive will appear on the screen.
5. Modify the % of predicted using the on-screen keyboard. The value entered must be between 80-150.
6. Modify the % of Best Test value using the on-screen keyboard. The value entered must be between 80-150.

Parameters

The following parameters can be reported and printed for a test session. To select/unselect a parameter check/uncheck the relevant check boxes. Additional parameters are available by selecting the additional index tabs.

Parameter	Definition
VC	Vital capacity (L)
IVC	Inspiratory vital capacity (L)
FIVC	Forced inspiratory vital capacity (L)
FVC	Forced vital capacity (L)
FEV.5	Forced expiratory volume after 0.5 seconds (L)
FEV.75	Forced expiratory volume after 0.75 seconds (L)
FEV1	Forced expiratory volume after 1 second (L)
FEV3	Forced expiratory volume after 3 seconds (L)
FEV6	Forced expiratory volume after 6 seconds (L)
PEF L/s	Peak expiratory flow (L/sec)
PEF L/min	Peak expiratory flow (L/min)
FEF0.2-1.2 (F02-12)	Mean forced expiratory flow in the volume interval between 0.2 and 1.2 L of the test (L/sec)
FEF 25-75 (F2575)	Maximal mid expiratory flow: the mean FEF in the time interval between 25% and 75% of the FVC (L/sec)

FEF 75-85 (F7585)	Forced late expiratory flow: the mean FEF in the time interval between 75% and 85% of the FVC (L/sec)
FEF 25	Forced expiratory flow at 25% of the FVC (L/sec)
FEF 50	Forced expiratory flow at 50% of the FVC (L/sec)
FEF 75	Forced expiratory flow at 75% of the FVC (L/sec)
FIV1	Forced inspiratory volume after 1 second (L)
PIF L/s	Peak inspiratory flow (L/sec)
FIF 25	Forced inspiratory flow at 25% of the FVC (L/sec)
FIF 50	Forced inspiratory flow at 50% of the FVC (L/sec)
FIF 75	Forced inspiratory flow at 75% of the FVC (L/sec)
MVVind	Maximum voluntary ventilation indirectly calculated from the FEV1 (L/min)
FMFT	Forced mid-expiratory flow time (sec)
FET	Forced expiratory time (sec)
Vext	Extrapolated volume (L)
FRC	Functional residual capacity (L)
TV	Tidal volume (L)
RV	Residual volume (L)
TLC	Total lung capacity (L)
IRV	Inspiratory reserve volume (L)
ERV	Expiratory reserve volume (L)
IC	Inspiratory capacity (L)
Rind	Airways Resistance Indirect measurement.
FIVC/FVC	Ratio FIVC of FVC
FEV.5/FVC	Ratio FEV 0.5 of FVC
FEV1/FEV6	Ratio FEV1 of FEV6
FEV1/FVC	Ratio FEV1 of FVC
FEV1/VC	Ratio FEV1 of VC
FEV1/PEF	FEV1 divided by PEF (L/L/s)
FEV3/VC	Ratio FEV3 of VC

FEV3/FVC	Ratio FEV3 of FVC
FEF 25-75/FVC (F2575/F)	Ratio FEF 25–75 of FVC
FIV1/FVC	Ratio FIV1 of FVC
FIV1/FIVC	Ratio FIV1 of FIVC
FIF50FEF50	Ratio FIF 50% of FEF 50%
FEV75/FVC	Ratio FEV 0.75 of FVC
FEV1/FIVC	Ratio FEV1 of FIVC
FEV1/IVC	Ratio FEV1 of IVC
FEV1R	FEV1 divided by the largest VC from the VC or FVC manoeuvre.
Vext/FVC	Ratio extrapolated volume of FVC
PIF L/min	Peak inspiratory flow (L/min)
Lung Age	Lung age will be displayed if the date of birth, height, population group and smoking information have been entered. Lung age will only be shown if the measured FEV1 value is less than the lower limit of the predicted normal value for FEV1.

3.6.5. Subject Options

The following options are available in the Subject Options screen:

- **Primary View:** Set the default subject list view to either name or ID using the drop down list.
- **Password protection:** Select to turn password protection on/off. Change the password using the touch panel keypad.
- **Smoking History, Population Group and Weight:** Select whether to include these fields when creating a new subject on the device. To change the setting select the on/off button on the touch panel keypad.

3.6.6. Smart Options

Configure the device to follow a set sequence of operation on power up using the Smart Options. Turn Smart Options Off/On using the drop down menu. When turned on there are four areas that may be configured by selecting from a drop down list:

- **After Power Up:** Configure the device to go to the Main Menu or the Subject screen after power up.
- **After Subject:** Configure the device to go to VC Test, FVC Test or Main Menu after selecting a subject.
- **After VC:** Configure the device to go to FVC or Main Menu after performing a VC test.
- **After FVC:** Configure the device to go to POST mode, Print the test or go to the Main Menu after performing an FVC test.

3.6.7. Report Options

Use the Report Options screen to set the Report Content and Report Method.

The In2itive can print to a compatible USB PCL printer or Vitalograph Reports. The following options are available:

- **Report:** Select either 'Send to PC' or 'External Printer'.
- **Content:** Set to print either a single page report or multi-page report.
- **Auto Print:** The report will print automatically after finishing a test session. This facility may be switched on or off.
- **Colour:** Choose to print in Colour or Black & White. Select on for a colour printout (PC option only), and off for black & white.

Note: In order to send the report to the Vitalograph Reports Utility it is necessary to have Vitalograph Reports installed on the user's PC and the In2itive connected to the PC via a USB cable.

Report Content

The following information printed on the session reports may be configured by selecting from a drop down list:

- **Table:** Configure the device to show the results for the best test only (Best 1) or the three best tests (Best 3).
- **Normal Comparison:** Configure the device to print either

- the % of Predicted value or the SDS (Standard Deviation Score) in the session table of results.
- **Test QA:** Configure the session report to show the test QA. Select to turn this on or off.
 - **Interpretation:** Configure the session report to show the device suggested interpretation. Select to turn this on or off.
 - **Comments Header:** Configure the session report to show a Comments Header. Select to turn this on or off.
 - **Ambient Conditions:** Configure the session report to show the Ambient Conditions. The ambient conditions (Humidity, Pressure and Altitude) are those entered when performing an accuracy check or calibration update. Select to turn this on or off.
 - **V/T Size:** Configure the Volume/Time graph displayed to either standard or ATS/ERS 2005 (ATS) requirements.
 - **F/V Size:** Configure the Flow/Volume graph to either standard or ATS/ERS 2005 (ATS) requirements.
 - **V/T Graph:** Configure the session report to show the V/T (Volume vs. Time) graph. Select to turn this on or off.
 - **F/V Graph:** Configure the session report to show the F/V (Flow vs. Volume) graph. Select to turn this on or off.
 - **Trend Graph:** Configure the session report to show the trend graph. Select to turn this on or off. The trend graph can only be printed when the trend graph option and the configurable report option are selected.

4. Power Management

The In2itive can be powered using the purpose-built low voltage Power Supply unit with which it is supplied, from a PC via the USB cable, or from the internal Battery Pack. When powered from the low voltage Power Supply or a PC, the LED on the front of the device shows orange. The LED shows green when the device is powered from the Battery Pack.

4.1. Battery Pack

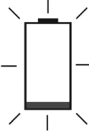

The In2itive is fitted with a rechargeable Battery Pack. This allows the device to be used without the 5V Power Supply connected. The

battery pack can be re-charged by plugging in the 5 V Power Supply. To fully re-charge switch off the In2itive and leave it plugged in overnight.

The battery pack can also be re-charged by connecting the device or cradle to a PC via the USB cable.

4.2. Battery Low Detect

The battery power messages are:

	<p>Battery Low: The icon flashes on and off on the Main Menu screen.</p> <p>The Battery Pack is running low. You may continue to use the device.</p> <p>As a precaution, plug in the 12V Power Supply to re-charge the batteries and continue testing.</p>
	<p>Battery Discharged: The icon appears continuously on the Main Menu screen. The Battery Pack is out of power. If you press any key a warning message appears and you will not be allowed to proceed further.</p> <p>Plug in the 12V Power Supply to re-charge batteries and continue testing.</p>

5. Cleaning & Hygiene

5.1. 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 for 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.

5.2. Inspection of the Vitalograph In2itive

Visual inspection is recommended on a routine basis; Remove flowhead cone from the flowhead. Examine flow conditioning mesh filters for damage or contamination. If they are damaged or blocked, discard and replace with new parts. 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 guidelines².

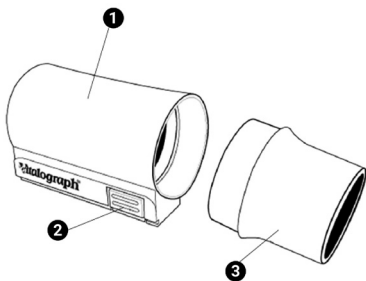


Figure 4: Flowhead Assembly

1	Flowhead body containing Fleisch
2	Flowhead Release Button
3	Flowhead Cone

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

6. Fault Finding Guide

Problem Fault Symptoms:	<ul style="list-style-type: none"> • Accuracy check variations > +/-3% • False readings suspected
<p>Possible Solutions: (In probable order)</p>	<ul style="list-style-type: none"> • Recheck Calibration with reference to section Checking Accuracy. • Was correct syringe volume selected? • Was accuracy check carried out after cleaning/disinfecting the flowhead assembly? • Flowhead cone Fleisch element filter mesh missing or blocked. • Flowhead body pressure port holes blocked. • Flowhead Fleisch element not dried thoroughly. • Flowhead Fleisch element assembly blocked. • Flowhead body tubing from pressure ports to main PCB blocked – contact support. • Electronics failure – contact support.
Problem Fault Symptoms:	<ul style="list-style-type: none"> • Test begins automatically • Volume accumulates automatically without the subject blowing. • Very small VC or FVC test displayed
<p>Possible Solutions: (In probable order)</p>	<ul style="list-style-type: none"> • Flowhead and/or tubing not stationary at the start of test. Hold them steady until the 'Blow Icon' appears. • Return to Main Menu and re-enter the test routine.
Problem Fault Symptoms:	<ul style="list-style-type: none"> • Rocking cradle

Possible Solutions: (In probable order)	<ul style="list-style-type: none"> • Check for damaged or missing rubber feet. • If any of the rubber feet are damaged or missing replace all rubber feet.
Problem Fault Symptoms:	<ul style="list-style-type: none"> • Reversed or no volume measurements.
Possible Solutions: (In probable order)	<ul style="list-style-type: none"> • Ensure that the flowhead connecting tube is not pinched or trapped.
Problem Fault Symptoms:	<ul style="list-style-type: none"> • Cannot print to external printer. • Corrupt or missing data on printout.
Possible Solutions: (In probable order)	<ul style="list-style-type: none"> • Check that external printer is selected in the Report Options screen. • Check USB cable is connected between In2itive Cradle and printer. • Check printer as per manufacturer's instructions. • Check printer compatibility – contact support. • Electronics failure – contact support.
Problem Fault Symptoms:	<ul style="list-style-type: none"> • Cannot print to PC (Vitalograph Reports Application). • Corrupt or missing data on printout.

Possible Solutions: (In probable order)	<ul style="list-style-type: none"> • Check that Send to PC is selected in the Configuration screen. • Check USB cable is connected between In2itive and the PC. • Check the Vitalograph Reports Application is correctly installed. • Check the required software drivers are installed on the PC. • Electronics failure – contact support.
Problem Fault Symptoms:	<ul style="list-style-type: none"> • Cannot communicate with Spirotrac V • Corrupt or missing data
Possible Solutions: (In probable order)	<ul style="list-style-type: none"> • Check USB cable is connected between In2itive and the PC. • Check Spirotrac V Application is correctly installed. • Check the required software drivers are installed on the PC. • Electronics failure – contact support.
Problem Fault Symptoms:	<ul style="list-style-type: none"> • Cannot read screen.
Possible Solutions: (In probable order)	<ul style="list-style-type: none"> • The battery may be low. Plug in the USB cable or mains power supply and switch on the device. • LCD failure – contact support. • Electronics failure – contact support.

6.1. Software Check

The software version and issue are shown on the About screen. Please quote this, and the serial number of the In2itive, to an approved support desk when requesting further advice or assistance.

7. 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 Authorized Representative and the Regulatory Authorities of the country. Refer to the Vitalograph contact information at the start of this manual.

8. Consumables and Accessories











Cat. No	Description
28350	BVF - Bacterial/Viral Filters (50)
28501	Eco BVF – Bacterial/Viral Filters (100)
28572	Eco BVF and Disposable Nose Clip (80)
28554	Eco BVF with Bite Lip (75)
28553	Eco BVF with Bite Lip and Disposable Nose Clip (75)
36020	3-L Precision Syringe
79158	Flow Cone (10)
40079	Mini USB Cable
79159	5V DC PowerSAFE
79191	Flowhead Complete
79192	Flowhead Connection Tube
79163	Remote Flowhead Adaptor Kit
79165	Test Data Storage Card
79166	Stylus (2)
70200	Spirotrac V Software







9. 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.

10. Explanation of Symbols

Symbol	Description
	Type BF equipment
	Class II
VA	Power rating
	Direct current
	Instructions for Use; operating instructions
	Manufacturer
	Date of Manufacture (include date in format yyyy-mm-dd)
	USB connector
	The device must be taken to separate collection at the product end-of-life. Do not dispose of these products as unsorted municipal waste
	Fragile, handle with care
	Keep Dry

	Storage Temperature Limit
	Storage Relative Humidity Limits
	Do not re-use
	Non sterile
	Recycle
	QR code - matrix bar code. All information in the bar code is included in the text under it

11. Description of the Vitalograph In2itive

The Vitalograph In2itive is a handheld spirometer which measures subject respiratory parameters including but not limited to VC, FVC, FEV1, PEF and MVV. The integral Fleisch flowhead is used for testing and by utilising the remote flowhead adaptor kit, can be detached for ease of use.

11.1. Indications for Use

The indications for use of the Vitalograph In2itive is in the assessment of lung function through the measurement of dynamic lung volumes, i.e. spirometry.

The In2itive is designed to be operated by medical professionals trained in respiratory and lung function testing on adults and paediatrics, 2.5 years and older, in a variety of professional healthcare environments, e.g. primary care, hospitals and occupational health centres. The measurements obtained from a lung function test provide objective information used in the diagnosis of lung diseases and monitoring lung health.

12. Technical Specification

Product	Vitalograph In2itive, Model 2120
Flow Detection Principal	Fleisch type pneumotachograph
Volume detection	Flow integration sampling @ 100Hz
Maximum test duration	90 seconds
Maximum displayed volume	10 L
Volume Accuracy	Better than $\pm 3\%$ or $\pm 0.05\text{L}$ of the reading. (ISO 26782:2009)
Flow Measurement Range	Max. flow rate $\pm 960\text{ L/min}$ ($\pm 16\text{ L/s}$) Min. flow rate $\pm 1.2\text{ L/min}$ ($\pm 20\text{ L/s}$)
PEF Accuracy	$\pm 10\%$ or $\pm 10\text{L/min}$ of the reading (ISO 23747:2015)
Back pressure	Less than 0.1kPa/L/sec @ 14L/sec (ATS/ERS 2005)
Operating temperature range	ISO 26782 limits: $17\text{--}35^\circ\text{C}$; Design limits: $10\text{--}40^\circ\text{C}$
Operating humidity range	$30\%\text{--}75\%$
Ambient pressure range	$850\text{hPa}\text{--}1060\text{hPa}$
Performance standards the Vitalograph In2itive meets or exceeds	ATS/ERS 2019, ISO 23747:2015 & ISO 26782:2009
Safety standards	EN 60601-1:2006
EMC Standards	EN 60601-1-2:2007
QA/GMP standards	EN ISO 13485, FDA 21 CFR 820, EN ISO 23747:2007, EN ISO 26782:2009
Dimensions	$160\text{ mm} \times 100\text{ mm} \times 45\text{ mm}$

Weight	0.23 kg net
Storage Temperature	0–50°C
Storage Relative Humidity	10%–95%
Communications	USB, micro SD card
Power Supply	5V DC via USB 2.0/3.0
Essential Performance	Flow measurement output
Essential Performance Test Limits	Flow Accuracy $\pm 10\%$ or ± 20 L/min (ATS/ERS 2005)
Minimum PC System Requirements for Spirotrac or Vitalograph Reports software	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 Other: .Net framework 4.5.1, USB Port for In2itive

Notes:

- All values displayed are expressed as BTPS values.
- Take care not to block the mouthpiece with 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 flowhead and BVF are classified as type BF applied parts. The device body or other accessories are not applied parts.
- An applied part is a part of the equipment, which in normal use necessarily comes into physical contact with the subject for equipment or system to perform its function.


13. Contraindications, Warnings, Precautions and Adverse Reactions

1. No modification of this equipment is allowed. Any unauthorised changes to the Vitalograph In2itive device may compromise product safety and/or data and as such Vitalograph cannot be held responsible and the device will no longer be supported.
2. The In2itive is not designed as a sterile device. Always follow the safety guidelines given by the manufacturer of cleaning and disinfectant chemicals.
3. For the device to be used as intended, there is no requirement to clean the supporting computer. If cleaning is required to remove any visible soiling, this should be done as per the computer manufacturer's instructions.
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 In2itive 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 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.
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 In2itive to liquids.

12. The In2itive 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 In2itive should never be outside accuracy limits. Accuracy should be checked after cleaning or disassembling the spirometer for any reason, after adjusting calibration or if the flowhead or device has been dropped.
14. Service and repairs should be carried out only by the manufacturer or by Service Agents approved by Vitalograph.
15. Maintenance must not be performed while the device is in use by a subject.
16. The device contains a Lithium coin cell battery and a Lithium Polymer main battery which are not accessible by the user and are not serviceable parts. Any suspected battery faults should be reported to the manufacturer.
17. The internal Lithium Polymer battery is not user accessible, replaceable or serviceable. 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 site administrator or support. In case of leaking ensure the electrolyte does not get in the eyes or touch skin. If electrolyte contacts the eyes flush the area immediately with water for 15 minutes and seek medical attention. If it contacts 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. 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 In2itive and result in improper operation.
19. Non-medical equipment must be kept outside the subject environment i.e. any area in which intentional or unintentional contact between the subject and parts of the system, or some other persons touching part of the system, can occur.

20. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the In2itive, including cables specified by Vitalograph. Otherwise, degradation of the performance of this equipment could result.
21. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
22. The applied part is the Flowhead. This 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 In2itive device.
23. Warning: In the unlikely event of an electrostatic discharge causing the In2itive to switch off, the device should be turned off and then on again using the power switch.

14. CE Notice

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

The Vitalograph Model 2120 In2itive is intended for use in a variety of professional healthcare environments, e.g. primary care, hospital wards and occupational health centres, except for near active high frequency surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high. The customer or the user of the In2itive should assure that it is not used in such an environment. The 2120 In2itive has been tested in accordance with:

EN60601-1: 2006 - Medical electrical equipment. General requirements for basic safety and essential performance

EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

EN 60601-1-2:2007- Emissions tests

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The In2itive 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 In2itive is suitable for use in all establishments, including domestic establishments and those connected to the public mains network (e.g. at home and doctor's offices in residential areas)
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Class A	

EN 60601-1-2:2007 - Immunity tests

Immunity test	Test level	Compliance level Reached
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1 kV differential mode

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% 100V (>95% dip in 100V) for 0,5 cycle 40 % 100V (60% dip in 100V) for 5 cycles 70 % 100V (30% dip in 100V) for 25 cycles <5% 100V (>95% dip in 100V) for 5 sec	Performance A Performance A Performance A Performance A
Conducted RF IEC61000-4-6	3 Vrms 150kHz to 80 MHz in ISM bands	3 Vrms 150kHz to 80 MHz in ISM bands
Radiated RF EN 61000-4-3	3 V/m 80MHz to 2700MHz	3 V/m 80MHz to 2700 MHz

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.

15. FDA Notice

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

16. 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 {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, CE 85553, MD 82182.



Signed on behalf of Vitalograph (Ireland) Ltd.

A handwritten signature in black ink that reads 'Frank Keane'. The signature is written in a cursive style.

Frank Keane.
CEO, Vitalograph Ltd.

17. Guarantee

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

The conditions of this Guarantee are:

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

7. To the maximum extent permitted by law, the Company does not accept liability for any consequential damages arising out of the use of, or inability to use any Vitalograph® equipment.
8. This Guarantee is offered as an additional benefit to the Consumer's statutory rights and does not affect these rights in any way.

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