2120 Vitalograph®
Hand Held Spirometer

In2itive™

User Manual

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Current Edition (Issue 2)
Cat. No. 07514

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DESCRIPTION OF THE VITALOGRAPH DEVICE

The Vitalograph In2itive is a handheld spirometer designed for use by trained professionals in the doctor's office, clinic, hospital department, etc. for measuring and archiving tests on human subjects. Demographic data are uploaded or entered via a keypad and stored, together with spirometry test data. Current test data can be viewed on the LCD and printed and downloaded to a PC. There are a variety of backup and other configuration options.

Information about the software 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:

1. Press the Configuration button from the Main Menu.
2. Press the About button.

The main components for the Vitalograph In2itive are shown in Figure 1.

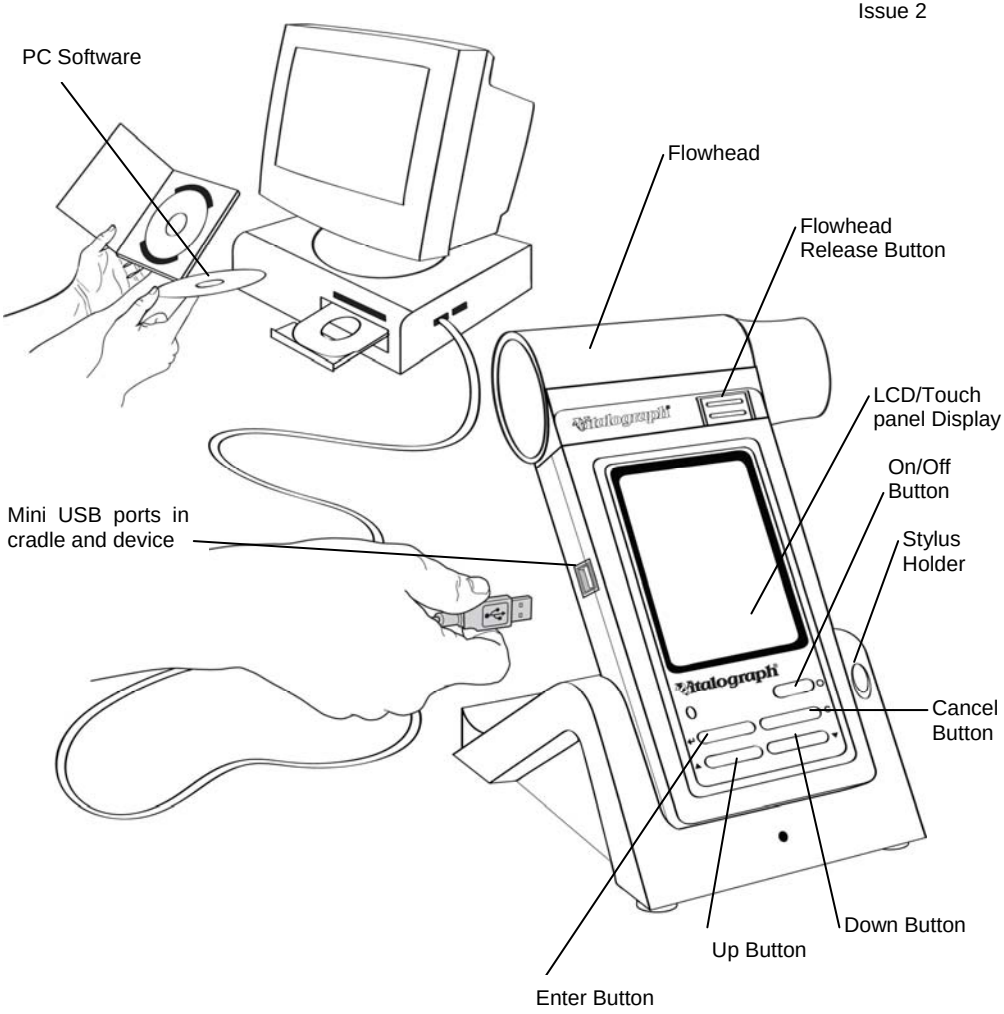

PC Software
Flowhead
Flowhead
Release Button
LCD/Touch
panel Display
On/Off
Button
Mini USB ports in
cradle and device
Stylus
Holder
Cancel
Button
Down Button
Up Button
Enter Button

Figure 1

FEATURES OF THE VITALOGRAPH DEVICE

The Vitalograph In2itive features include:

- Fleisch pneumotachograph
- Integral and removable flowhead
- Touch screen color display or buttons
- Clear sounds for audio feedback
- Choice of child incentive displays
- Fully customizable report format
- Desktop cradle supplied as standard
- Optional cradle for connection to A4 USB printers (PCL compatible)
- Optional communications cradles
- Automatic download of new subjects
- 10,000 subject test memory
- Automatic upload of all test data
- Pre/post bronchodilator comparison
- Choice of predicted values and languages
- Diagnostic interpretation options
- Lung age for adults and adolescents
- Real-time test quality prompts
- Vitalograph PC software included
- Stylus
- Can enter subject details on device

GETTING THE VITALOGRAPH DEVICE READY FOR USE

1. Place the Spirotrac V CD-ROM into the CD drive. The installation program starts automatically after a short period of time and leads you through the installation. The following are the most important points of the installation procedure.
2. If you do not already have Acrobat reader installed then select ‘Install Acrobat Reader’. You will require it to read the User Manual and any Test Reports that you have chosen to ‘Print’ as a PDF document.
3. Spirotrac V can import and export to your practice software, if your practice software supports one of the communications standards in

Spirotrac V. Administration rights on your PC are required. This can also be installed later.

4. For security reasons it is necessary during installation to enter an activation key and licence key. These are available on the CD cover.
5. When installation is complete remove the CD and keep in a safe place.
6. Connect one end of the USB cable into an available USB connection on your computer and the other end into the USB connection on the side of the cradle. The cable can also be connected into the left side of the Vitalograph In2itive device. The device is powered via the USB cable.
7. Place the In2itive device into the cradle.
8. The Vitalograph In2itive device may also be powered using 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. Connect the mini USB connector from the power supply into the USB socket on the side of the unit or into the cradle. Plug the mains plug into a suitable socket.
9. Operate the On/Off switch on the front face of the instrument and the Vitalograph In2itive is ready for use.
10. For portability the Vitalograph In2itive comes fitted with rechargeable batteries, which allows the device to be used for a period of time without the mains connected.

OPERATING THE DEVICE WITH SPIROTRAC V

Refer to the Help Files on Spirotrac V for information on operating the Vitalograph In2itive with Spirotrac V.

CONNECTING THE REMOTE FLOWHEAD

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

1. Hold the device body firmly in your left hand.
2. Hold the flowhead with your right hand, at the same time 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 same position as the flowhead was attached. This is done by sliding the flowhead into the grooves in

the top cover. The Vitalograph font and button on the device cap should be on the same face as the LCD when assembled. Ensure this 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 the two pressure ports on the device cap.
7. Attach the remote flowhead to the Vitalograph In2itive device cap by the dual silicone tubing (Flowhead Connection Tube).
8. A recess is provided on the cradle to hold the remote flowhead when not in use.
9. The remote flowhead can be disconnected by removing the device cap from the Vitalograph In2itive, and removing the remote flowhead adaptor from the flowhead. Then slide the flowhead back onto the Vitalograph In2itive.
10. It is recommended that an accuracy check is carried out after the remote flowhead is fitted or removed to verify correct operation and accuracy.

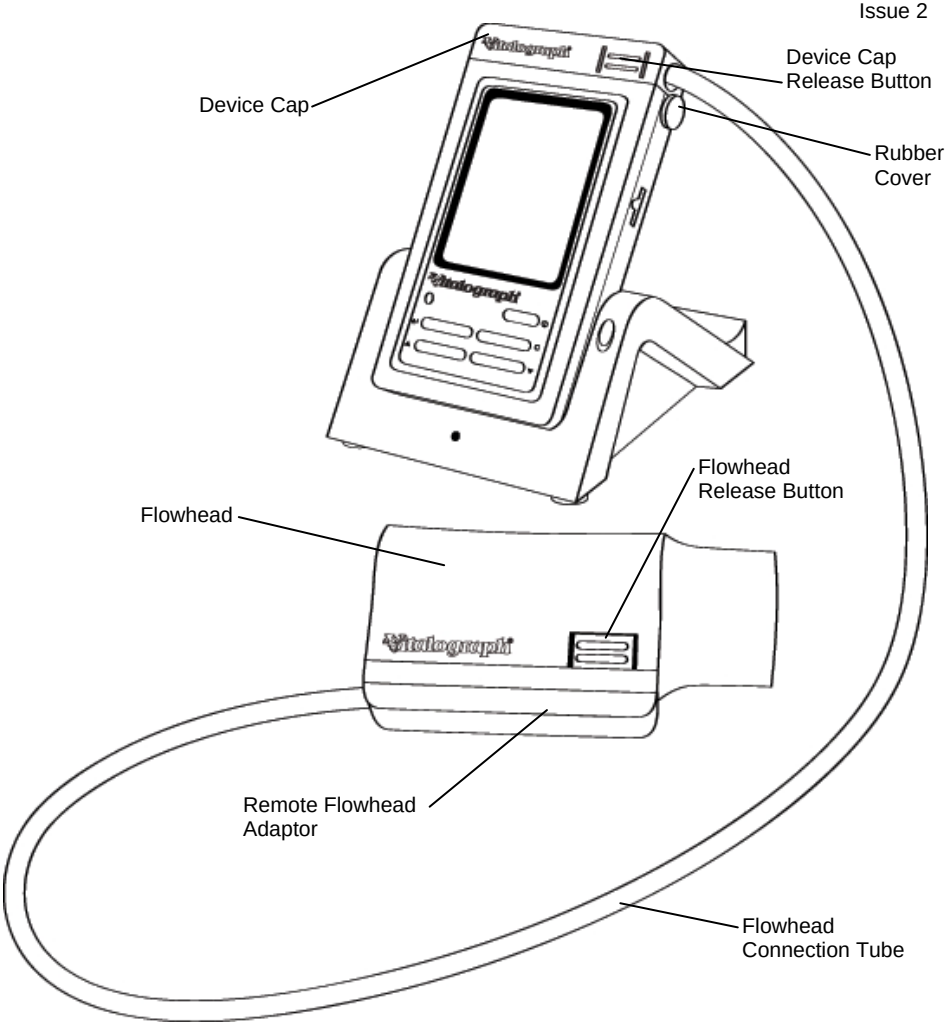


Figure 2

POWER MANAGEMENT IN THE VITALOGRAPH DEVICE

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

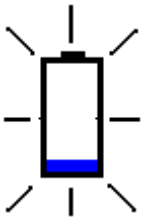
Battery Pack

The Vitalograph 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 Vitalograph In2itive and leave it plugged in over-night.

The battery pack can also be re-charged by connecting the device or cradle to a PC via the USB cable. The USB connector is located on the left side of the device.

Battery Low Detect

The Vitalograph In2itive has a number of battery power detect messages:

	When the Battery Pack starts to run low the *Battery Low* icon will flash on and off on the **Main Menu** screen. You will be allowed to continue to use the device. It is advised that you plug in the 5V Power Supply or attach the device to a PC to re-charge the batteries and continue testing.
	When the Battery Pack is approaching fully discharged the *Battery Discharged* icon will appear continuously on the **Main Menu** screen. Plug in the 5V Power Supply or attach to a PC to re-charge the batteries and continue testing.

OPERATING THE VITALOGRAPH DEVICE

Entering Subject Information

After turning on the device, you are presented with the **Main Menu** screen.

Note: In Smart mode you can configure the device to go directly into the Subject Select screen. See Smart Options.

1. Select the Subject button, to bring you into the Select Subject screen.
2. You can list the subjects saved on the device by selecting either the Name or ID tab.
3. To select a subject from the database, hi-light the subject. This will allow you the view the subject details. Select Enter to make the subject current.
4. To create a new subject, select the New tab. Enter the subject details by hi-lighting the required field and typing in the information using the touch panel keypad. Additional subject information may also be entered by selecting the Optional tab. Press the Enter button to save the subject to the database and return to the Home Menu.

Note: The current subject surname 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.

Performing a Test Session

Checks to Make before Performing a Test Session

Before starting a test session, there are a number of checks which should be made:

1. Ensure that the accuracy of the Vitalograph In2itive unit was checked recently. (Refer to the section on Checking Accuracy)
2. Ensure a subject is selected (subject ID will appear on the status bar at the bottom of the **Main Menu**) and the required demographic information is entered for the subject.
3. Fit a disposable BVF or SafeTway mouthpiece. The use of a disposable noseclip is also recommended.

Performing a VC Test

Perform the VC test as follows:

1. Select the 'VC Test' option from the **Main Menu**.
2. Wait for the 'Exhale to Begin' icon to appear.

This indicates that the Vitalograph In2itive unit is ready to accept a blow.

Note: You can view the results as either a Volume/time graph or a Volume bar graph by selecting the relevant tab.

The VC test can be performed using two methods. Read either of the following instructions to the subject so that testing is performed properly:

Method 1:

a. Sit upright, fit the nose clip and relax.
b. Hold the unit, keeping it away from your mouth.
c. Inhale as deeply as possible, hold your breath, then insert the mouthpiece carefully into your mouth, not like a trumpet, but clamping it gently between your teeth.
d. Seal your lips around the mouthpiece and keep your tongue down.
e. Blow out as long as possible. Keep blowing until all air is expelled. It is vital that the operator encourages to subject to keep blowing to ensure all air is squeezed out.
f. Listen for two beeps. This indicates that Vitalograph In2itive is ready for the next blow.

Method 2:

Note: Method 2 can only be used when the Volume/Time (V/t) graph is selected as the display option. This method cannot be used when the Volume bar graph is selected as the display.

a. Sit upright, fit the noseclip and relax.
b. Insert the mouthpiece carefully into your mouth, not like a trumpet, but clamping it gently between your teeth.
c. Seal your lips around the mouthpiece and keep your tongue down.
d. Breathe in and out normally. This is tidal breathing.

When you are happy that the subject has achieved steady tidal breathing, continue with:

e. Blow out as long as possible. Keep blowing until all air is expelled. It is vital that the operator encourages to subject to keep blowing to ensure all air is squeezed out.
f. Inhale as deeply as possible (speed is not important) and when fully inhaled.
g. Return to tidal breathing, i.e. breathe in and out normally again.

The VC values recorded for the blow are tabulated. The best VC value for the current session and the Lower Limit of Normality (LLN) are also displayed.

4. Repeat the blow three times or more to obtain good test quality.

5. After performing the VC tests press the Cancel button to exit the **VC Test** screen. This brings you back to the **Main Menu.**

Performing an FVC Test

1. Select the 'FVC Test' option from the **Main Menu**.
2. Wait for the 'Exhale to Begin' icon to appear.

This indicates that the Vitalograph In2itive unit is ready to accept a blow.

Note: You can view the results as either a Volume/time (V/t) or a Flow/Volume (F/V) graph by selecting the relevant tab.

3. The FVC test can be performed using 2 methods as follows. Read either of the following instructions to the subject so that testing is performed properly:

Method 1:
a. Sit upright, fit the noseclip and relax.
b. Hold the unit, keeping it away from your mouth.
c. Inhale as deeply as possible, hold your breath, then insert the mouthpiece carefully into your mouth, not like a trumpet, but clamping it gently between your teeth.

d. Seal your lips around the mouthpiece and keep your tongue down.
e. Blow out as long as possible. Keep blowing for at least 6 seconds. (From the very beginning of the blow the operator should encourage the subject to keep going in a lively fashion. Keep eye contact with the subject)
f. If inspiratory indices are selected, then inhale as quickly as possible.
g. Listen for two beeps. This indicates that Vitalograph In2itive is ready for the next blow.

Method 2:

a. Sit upright, fit the noseclip and relax.
b. Insert the mouthpiece carefully into your mouth, not like a trumpet, but clamping it gently between your teeth.
c. Seal your lips around the mouthpiece and keep your tongue down.
d. Breathe in and out normally. This is called tidal breathing.

When you are happy that the subject has achieved steady tidal breathing, continue with:

e. Inhale as deeply as possible
f. Blow out as long as possible. Keep blowing for at least 6 seconds. (From the very beginning of the blow the operator should encourage the subject to keep going in a lively fashion. Keep eye contact with the subject)
g. Inhale fully as quickly as possible
h. Return to tidal breathing, i.e. breathe in and out normally again.

4. The FVC, FEV1 and PEF values recorded for the blow are tabulated. The best FVC, FEV1 and PEF for the current session are displayed.

The test quality (QA) is shown at the bottom of the test screen.

The best 3 tests performed and the Test Grade are shown in the V/t screen. Each test series is graded in relation to its repeatability

between acceptable manoeuvres. The quality Grades are A, B, C, D and F.

The repeatability (Within) of FVC and FEV1 are shown in the Information screen. The repeatability information is displayed if at least two tests are performed. I Bars on the F/V graph are shown for FEF25, FEF 50 and FEF75. An I Bar for FVC is also shown on the Volume axis. The upper mark on the I Bars indicates the predicted value for the subject. The lower mark on the I Bar indicates the LLN value for the subject. The I Bars are based on the predicted sets and will be shown if sufficient subject demographics information is entered.

5. Repeat the blow three times or more to obtain good test quality.

6. To view results select the results tab.

   - You can view the results for each blow by selecting the up/down arrows on the top left of the screen. If any of the parameters are below the Lower Limit of Normality (LLN), then they will be displayed in red, provided the subject age, height and gender are entered.
   - To view the graph of the blow select the graph button on the bottom of the screen.
   - You can choose to manually accept or reject a blow using the drop down list for User Acceptability.
   - You can view the trend graph by selecting the trend button on the bottom left of the screen.

7. After performing the FVC tests press the Cancel button to exit the **FVC Test** screen. This brings you back to the **Main Menu.**

Saving the Test Session.

The test session is automatically saved to the database.

Note: If a micro SD card is inserted into the micro SD connector at the right side of the device, then all test blows and not just the best three will be saved to the micro SD 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.

Performing a Post Test Session

A Post 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 perform a Post test:

1. Select 'Post Mode' from the **Main Menu**.
2. If you want to perform a Post Test on the Pre-test Session just performed select 'Perform Post test on Current Subject'. This will return you to the test screen. The text Post Mode will appear on the graph.
3. If you wish to perform a Post Test on a different subject or Pre-test:
    a. Select 'Select Subject from List'.
    b. 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.
    c. Select the subject you wish to perform the Post test on, and the **Select Test Session** screen will appear. Select the test session.

        Note: The letters P, V or F or a combination of these will appear after the session ID.

        If the letter P appears then a POST test session has already been performed on this pre session.

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

        If F appears then and FVC test has been performed as part of the pre-session.
    d. Press 'Enter' to bring you to the test screen. The text Post Mode will appear on the graph.
4. Perform the Post FVC test as outlined in section Performing a Test Session.

Permanent Storage of Pre-Test Sessions

The **Post Mode** screen also gives you 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 Spirotrac V or printed. To access this option select 'Permanent Storage'.

The **Permanent Storage** screen gives you four options:

1) Save Test to Permanent Storage: When this option is selected a message will appear informing you of the memory location where the test session will be saved. There are nine permanent memory locations on the Vitalograph In2itive.
2) Load Test from Permanent Storage: When this option is selected 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.
3) Delete Test from Permanent Storage: When this option is selected the list of permanent pre-test sessions will appear. Select the Test session you wish to delete and press enter. This location will then be marked as 'Empty'.
4) Delete all Tests from Permanent Storage. When this option is selected a warning message will appear:- 'Do you want to delete all tests stored in permanent storage?'. Press enter to delete all tests.

Printing and Viewing the Test Session

You can print the current test session for the subject by selecting 'Print' from the **FVC Test** screen.

The Vitalograph In2itive can be connected through the USB port at the side of the unit or from the cradle to the Vitalograph Reports Utility, so that the report can be written to a PC. By using the optional Print Cradle the Vitalograph 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 configured to suit individual requirements. Refer to section on Report Options.

You can also select the Report option from the **Main Menu**. If you already have a Current Subject selected the following options are available:

a) Current Test Session: You can select to view and print the current test session. To print the current session, select the print icon at the top of the session results screen.

b) Select Test Session: You can select a test session for the current subject.
c) All Test Sessions: You can print all test sessions for the current subject.

You can also print Test Session(s) from a different subject in the database. This is done by selecting the 'Select' tab in the **View and Report** screen. The following options are available:

a) Select Test Session: You must first 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.
b) All Test Sessions: This will print all test sessions performed on a subject. When you select this option you must first select a subject from the database.
c) All Test Sessions Between…: This will print all sessions stored on the device between specified dates. You must first select the dates.

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.

Clear Results

If you wish to delete the current session you can do this as follows:

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 not save the current test session and return to the **Main Menu**. Select 'C' to cancel the operation and continue with the current test session.

Checking Accuracy

All spirometry standards (e.g. ATS/ERS/BTS/ANZRS) recommend checking the accuracy of lung function measuring devices at least daily with a 3-L syringe to validate that the instrument is measuring accurately. The Vitalograph In2itive should never be outside accuracy limits unless damaged or in a fault 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.

ATS 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%.

Follow these steps to check the accuracy of the unit.

1. Select Accuracy Check from the **Main Menu** using the keypad.
2. Enter the Syringe reference using the touch panel keypad.
3. Depending on how the device is configured you may be prompted 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 keypad.
4. 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.
5. Press the 'Enter' key to bring you into the **Accuracy Check** screen and follow the on-screen instructions.

   *Note: Note: 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 Vitalograph In2itive memory in this case.*

6. If an Accuracy Check report is required select the Report option.

   Note: If the device is outside calibration you will be given the option to update the calibration. If you select this option you will be brought through the accuracy check routine again.

When to Check Accuracy

- In accordance with your own established procedures
- After annual maintenance checks
- After cleaning or disassembling spirometer for any reason
- After adjusting calibration
- If the flowhead or device has been dropped.

Configuration Options

There are a number of Configuration options available on the Vitalograph In2itive device. To access these, select the 'Configuration' option on the **Main Menu**. The options available are:

Test Preferences

This allows you to configure the test screen to your requirements. The following options are available:

d) FVC Display: You can 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.
e) VC Display: You can select to show the Bar Graph or V/T (Volume-Time) Graph by default in the VC test screen.
f) Test Acceptance: This allows you to manually accept the tests performed, or allow the device to determine test acceptability (automatic).
g) Graph Scale: This allows you to select the default graph scale.
h) Post VC Test: If you have done a VC test in a pre test session and then go to do a Post test on that session then the VC test screen will automatically come up. By selecting 'off' in the drop down list you will be brought directly into the FVC test screen.
i) Posture: You can select to no posture selected, standing or sitting.
j) Temperature: By selecting 'on' in the drop down list, the device give the user the option to manually enter the ambient temperature as they go into the FV or FVC test screens.

Database

This allows you to manage the available memory on the device. The Management tab tells you how much subject and test session memory has been used up. As with all memory after a period of time and repeated use the memory becomes fragmented. Because of this the total available memory is not being used. In order to correct this, select the Defragment option. This process may take several minutes to complete.

The Deletion tab allows the user to delete sessions. By selecting the relevant box the session will be deleted from the device after being:

d) Sent to Spirotrac V

e) Printed (Either a print to an external printer or sent to Vitalograph Reports).

The user has the option to select none, one or both of these options. You are also given the option to 'Select Test Sessions' for deletion, or 'Delete All Sessions' from the device by pressing the relevant button using the touch panel LCD.

Calibration

The Vitalograph In2itive should never be outside accuracy limits unless damaged or in a fault 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.

Select the Calibration Options menu. You are presented with three options:

- Precision Syringe
- Linearity
- Calibration

Precision Syringe:

b) Select Precision Syringe from the **Calibration** screen.
c) Select the volume of the calibrated syringe you are using from the drop down list.
d) 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

a) Select Linearity from the **Calibration** screen.
b) 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.
c) Enter the environmental data if prompted to do so.
d) Press the 'Enter' key to bring you into the **Linearity Check** screen.
e) Using a 3L Calibrated syringe pump air into the flowhead at a slow rate of <2L/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.

*Note: Press the 'C' key to exit the **Linearity Check** screen.*

f) Repeat for the slow rate three times in total.
g) Repeat the procedure outlined in step e for a medium rate >2L/s and <6L/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.
h) Repeat for the medium rate three times in total.
i) Repeat the procedure outlined in step e for a fast rate >6L/s. This manoeuvre should show on the graph between outside green lines. If it is a correct manoeuvre the test number and the FVC and FIVC values will be updated in the table.
j) Repeat for the medium rate three times in total.
k) When all the manoeuvres are complete press 'Enter' for the result.
l) If a Linearity Check report is required select the Report option.

Calibration

a) Select Calibration from the **Calibration/Linearity** screen.
b) 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.
c) Press the 'Enter' key to bring you into the **Calibration** screen and follow the on-screen instructions.

*Note: Press the 'C' key to exit the **Calibration** screen.*

d) If a Calibration report is required select the Report option.

Settings

This allows you to adjust the settings of the device. The following options are available in the **Device Settings** screen:

- Date/Time
- Sound Options
- Incentive
- Units
- Power Save Options
- Parameters
- Volume

Date/Time

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

a) In order to change the time, scroll the hours and minutes to the required settings by pressing the arrows on the touch panel LCD.
b) The time format can be changed from 24 hour to 12 hour by switching On/Off the '24 Hour Format' option.
c) In order to change the date, scroll the day, month and year to the required settings by pressing the arrows on the touch panel LCD.
d) To modify the Date Format select the required option from the drop done list. The options available are:
   DD/MM/YYYY
   MM/DD/YYYY
   YYYY/MM/DD

Sound Options

This allows you to turn off and on the Key, Flow, Error and Welcome sounds on the device. Simply select the on/off key for the specific sound.

Incentive

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

a) To change the incentive device to be used in testing, select an alternative for the Incentive Device drop

down list. A preview of the incentive will appear on the screen.

b) The % of predicted can be modified using the on-screen keyboard. The value entered must be between 80-150.
c) The % of Best Test value can be modified using the on-screen keyboard. The value entered must be between 80-150.

Units

The units used can be modified by selecting the alternative option available on the drop down list:

- Metric
- US (Imperial)

Power Save Options

In order to improve battery life the device will auto power down if left unused for a set length of time. You can modify this by selecting an alternative auto power down time from the drop down list. The options available are 2, 4, 6, 8 and 10 minutes. You can also configure the device to dull the display after 3 minutes. This can be switched on or off.

Parameters

This gives a complete list of the test parameters that 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.

The following list supplies definitions of the parameters:

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.

Volume
Adjust the sound level by pressing the '-/+' on the touch panel LCD.

Subject Options

The following options are available in the **Subject Options** screen:

a) Primary View: The default view in which the subjects are listed can be set to either name or ID. Select the required option from the drop down list.
b) The facility to enter Weight, Population Group and Smoking History can be configured on or off when creating a new subject on the device. To change the setting simply select the on/off button on the touch panel keypad.

Smart Options

The **Smart Options** allow you to set up the device to follow a set sequence of operation on power up. In the **Smart Options** screen you can set Smart on or off by selecting from the drop down list. When set to on you are given four options:

a) After Power Up: You can either configure the device to go to the Main Menu or go to the Subject screen after power up. Select the required option from the drop down list.
b) After Subject: You can configure the device to go to VC Test, FVC Test or the Main Menu after selecting a subject. Select the required option from the drop down list.
c) After VC: You can configure the device to go to FVC or the Main Menu after performing a VC test. Select the required option from the drop down list.
d) After FVC: You can configure the device to go to POST mode, Print the test or go to the Main Menu after performing an FVC test. Select the required option from the drop down list.

Report Options

The **Report Options** screen allows you to set the Report Content and the Report Method.

Report Content

The information printed on the session reports can be configured to suit individual requirements. The following can be configured in the report:

a) Table: The device can be configured to show the results for the best test only (Best 1) or the three best tests (Best 3). Select the required option from the drop down list.
b) Normal Compensation: In the session table of results either the % of Predicted value or the SDS (Standard Deviation Score) will be printed. Select the required option from the drop down list.
c) Test QA: The session report can be configured to show the test QA. Select the required option to turn this on or off.
d) Interpretation: The session report can be configured to show the device suggested interpretation. Select the required option to turn this on or off.
e) Comments Header: The session report can be configured to show a Comments Header. Select the required option to turn this on or off.
f) Ambient Conditions: The session report can be configured to show the Ambient Conditions. The ambient conditions (Humidity, Pressure and Altitude) are those entered when performing an accuracy check or calibration update. Select the required option to turn this on or off.

g) V/T Size: The Volume/Time graph can be changed from standard to ATS/ERS 2005 (ATS) requirements. Select the required option from the drop down list.
h) F/V Size: The Flow/Volume graph can be changed from standard to ATS/ERS 2005 (ATS) requirements. Select the required option from the drop down list.
i) V/T Graph: The session report can be configured to show the V/T (Volume vs. Time) graph. Select the required option to turn this on or off.
j) F/V Graph: The session report can be configured to show the F/V (Flow vs. Volume) graph. Select the required option to turn this on or off.
k) Trend Graph: The session report can be configured to show the trend graph. Select the required option to turn this on or off.

Report Method

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

a) Report: Select the option to either Send To PC or External Printer from the drop down list.
b) Content: The report can be set to print a single page report or else multi page report. Select the required option from the drop down list.
c) Auto Print: The report can be printed automatically after finishing a test session. Select the required option to turn this facility on or off.
d) Colour: The printout can be set to Colour or Black & White. Select on for a colour printout, and off for black & white.

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

CLEANING INSTRUCTIONS

Cleaning and Disinfecting the Vitalograph In2itive

A new mouthpiece (either *SafeTway* or *BVF*) should be used for each subject. A delay of at least 5 minutes should be allowed between subjects to allow settling of previously aerosolized particles in the measuring device.

It is recommended that the flowhead be regularly cleaned according to the guidelines of the user's facility.

In the event of visible contamination of the flowhead cones or flowhead element, they should be cleaned or disinfected as described in the accompanying table. The flowhead should also be replaced in the event of damage to the conditioning meshes, or if visibly contaminated.

The frequency of cleaning and disinfecting is dependent on the Facility's Risk Assessment, usage, and test environment, but it should be at least monthly or every 100 subjects (500 blows).

It is recommended that the flowhead—flowhead complete and flowhead connection tube—be replaced annually.

Table of Materials Used & Cleaning/Disinfection Methods

This listing of materials used is given to provide users with information to allow the assessment of other cleaning and disinfecting procedures available in the facility on this device.

Part	Material	Clean/ Disinfect	Autoclave Possible?	Recommended Disinfectants
Case Exterior	PC/ABS	Clean	No	Wiping with a 70% isopropyl alcohol impregnated cloth provides a suitable form of cleaning and low-level disinfection. This may be preceded by cleaning with an anti-static foam cleaner if necessary.
White Flowhead Tube	Silicone Rubber	Clean	Viable	
Remote Flowhead Attachments	PC/ABS, Silicone Rubber	Clean	No	
Cradle Case Exterior	PC/ABS	Clean	No	
Stylus	PC/ABS	Clean	No	
Screen	Electrode with Anti-Newton-Ring Treatment	Clean	No	
Flowhead	PC/ABS, Stainless Steel.	Clean	No	Disinfect by immersion in sodium dichloroisocyanurate solution at 1000 ppm concentration of free chlorine for 15 minutes.
Flowhead Cone	PC/ABS	Clean	No	

Note: Always follow the safety guidelines given by the manufacturer of cleaning and disinfectant chemicals.

All external parts of the Vitalograph In2itive require **cleaning,** i.e. the removal of visible particulate contamination. The parts of the Vitalograph In2itive that make up the flowhead, which comes into contact with subjects being tested, also require **disinfecting**. A spirometer is not designed as a 'sterile' device.

Definitions of cleaning and disinfection are as defined in "Sterilization, Disinfection and Cleaning of Medical Equipment: Guidance on Decontamination from the Microbiology Committee to Department of Health Medical Devices Directorate, 1996".

Recommendations for chemical disinfectants are derived from the PHLS publication "Chemical Disinfection In Hospitals 1993".

Removing the Fleisch Flowhead

1. Hold the device body firmly in your left hand.
2. Hold the flowhead with your right hand, at the same time 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. Remove the flowhead cone from the flowhead, by twisting and pulling it away from the flowhead.
5. Clean the flowhead by washing in a mild detergent and removing particulate contamination. To clean the fleisch element, swill vigorously in water with mild detergent or use an ultrasonic bath. Do not attempt to "rub" or "scrub" at capillaries.
6. Rinse all parts in clean water.
7. Disinfect by immersion in sodium dichloroisocyanurate (NaDCC) solution at 1,000 ppm concentration of free chlorine for 15 minutes. Prepare disinfectant solution as directed in the manufacturer's guidelines.
8. Leave to dry completely before reassembling. Drying the fleisch element components may require placing them in a warm place overnight. A drying cabinet is ideal.

   Note: Always follow the safety guidelines given by the manufacturer of cleaning and disinfectant chemicals.

Reassembling the Fleisch Flowhead

1. Examine the fleisch element to ensure that no liquid or particles remain in the holes, grooves or pressure tapings.
2. Examine the rubber grommets at the top of the device to ensure no liquids or particles remain in the holes. Also ensure the grommets are not damaged.
3. Fit a new flowhead cone to the flowhead.
4. Slide the flowhead into the grooves in the top cover. The Vitalograph logo and button on the flowhead should be on the same face as the LCD when assembled.
5. It is recommended that an accuracy check is carried out following reassembly to verify correct operation and accuracy.

FAULT FINDING GUIDE

Problem Fault Symptoms:	• Accuracy check variations > +/-3% • False readings suspected
Possible Causes: (In probable order)	• Recheck Calibration with reference to section Checking Accuracy • Was the correct syringe volume selected? • An accuracy check is required 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. • Main PCB failure – contact support.
Problem Fault Symptoms:	• Test begins automatically • Volume accumulates automatically without the subject blowing. • Very small VC or FVC test displayed
Possible Causes: (In probable order)	• Flowhead and/or tubing not stationary at 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:	• Rocking cradle
Possible Causes: (In probable order)	• Check for damaged or missing rubber feet. • If any of the rubber feet are damaged or missing replace all rubber feet.
Problem Fault Symptoms:	• Reversed or no volume measurements.
Possible Causes: (In probable order)	• Ensure that the flowhead connecting tube is not pinched or trapped.
Problem Fault Symptoms:	• Cannot print to external printer. • Corrupt or missing data on printout.
Possible Causes: (In probable order)	• 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 manufacturers instructions. • Check printer compatibility – contact support. • Main PCB failure – contact support.
Problem Fault Symptoms:	• Cannot print to PC (Vitalograph Reports Application). • Corrupt or missing data on printout.
Possible Causes: (In probable order)	• Check that Send to PC is selected in the Configuration screen. • Check USB cable is connected between Vitalograph In2itive and the PC. • Check to ensure the Vitalograph Reports Application is correctly installed. • Check to ensure the required software drivers are installed on the PC. • Main PCB failure – contact support.
Problem Fault	• Cannot communicate with Spirotrac V

Symptoms:	• Corrupt or missing data
	• Check USB cable is connected between Vitalograph In2itive and the PC. • Check to ensure the Spirotrac V Application is correctly installed. • Check to ensure the required software drivers are installed on the PC. • Main PCB failure – contact support.
Problem Fault Symptoms:	• Cannot read screen.
Possible Causes: (In probable order)	• The battery may be low. Plug in the USB cable or mains power supply and switch on the device. • LCD failure – contact support. • Main PCB failure – contact support.

CUSTOMER SERVICE

Service and repairs should be carried out only by the manufacturer, the approved importer or by Service Agents specifically approved by Vitalograph.

For the names and addresses of approved Vitalograph Service Agents or to arrange spirometry workshops, please refer to the contact information at the start of this manual.

CONSUMABLES AND ACCESSORIES

Cat. no	Description
20242	*SafeTway* Mouthpieces (200)
20303	Nose Clips (200)
28350	BVF - Bacterial/Viral Filters (50)
20408	1-L Precision Syringe
36020	3-L Precision Syringe
79158	Flow Cone (10)
40079	Mini USB Cable
79159	5V DC PowerSAFE
79160	5V DC Input Module Spare Set.
79161	Flowhead Complete
79162	Flowhead Connection Tube
79163	Remote Flowhead Adaptor Kit
79164	CD with User Manual
79165	Test Data Storage Card
65030SPR	Vitalograph Reports Application
79166	Stylus (2)
70200	Vitalograph Spirotrac V

EXPLANATION OF SYMBOLS

	Type BF equipment
	Class II
VA	Power rating
V	Voltage DC
	Attention (reference relevant section in manual)
	USB connector

TECHNICAL SPECIFICATIONS

Product	Vitalograph In2itive
Model	2120
Flow detection principle	Fleisch type pneumotachograph
Back pressure	Less than 0.1kPa/L/second @ 14L/s, complies with ATS/ERS 2005
Volume detection	Flow integration sampling @ 100Hz
Maximum test duration	90 seconds
Maximum displayed volume	10 L
Volume accuracy	Better than ±3%
Voltage/Frequency	110-250 V; approximately 50/60 Hz
Accuracy when operated in operating temperature range conditions	Flow ±10% Max. flow rate ±16 L/s Min. flow rate ±0.02 L/s
Operating temperature range	ATS/ERS limits: 17–37ºC Design limits: 10–40ºC
Performance standards the Vitalograph In2itive meets or exceeds	ATS/ERS 2005 & BS EN ISO 23747:2007
Safety standards	EN ISO 60601
QA/GMP standards	EN ISO 23747:2007, EN ISO 26782:2009 & FDA 21CFR820
Size	160 mm x 100 mm x 45 mm
Weight	0.23 kg net
Storage Temperature	0–50ºC
Storage Relative Humidity	10%–95%
Printer	PCL compatible USB printer.
Communications	USB, micro SD Card, Cradle

Note: All values displayed by the Vitalograph In2itive are expressed as BTPS values.

CE NOTICE

Marking by the symbol CE 0086 indicates compliance of the Vitalograph In2itive to the Medical Devices Directive of the European Community. Such marking is indicative that the Vitalograph In2itive meets or exceeds the following technical standards:

<table>
<tr><td colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</td></tr>
<tr><td colspan="3">The Model 2120 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 2120 should assure that it is used in such an environment</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The Model 2120 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Battery Operated</td><td rowspan="3">The Model 2120 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Battery Operated</td></tr>
<tr><td>Voltage Fluctuations/Flicker emissions
IEC61000-3-3</td><td>Battery Operated</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity			
The Model 2120 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 2120 should assure that it is used in such an environment			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. See Warning 2 below.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1 kV for input/output lines	500V	See Warning 3 below.
Surge IEC 61000-4-5	±1kV differential mode ±2 kV common mode	±1kV 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	A A A	Unit has a battery installed

	(30 % dip in 100V) for 25 cycles <5 % 100V (>95 % dip in 100V) for 5 sec	A	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not Applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Model 2120 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 2120 should assure that it is used in such an environment			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF. IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz in ISM bands	3Vrms from 150kHz top 80kHz	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**

Radiated RF. IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3V/m from 80MHz top 2.5GHz	d = 1.2√P…80MHz to 800 MHz d = 2.3√P…800 MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

Recommended separation distances between portable and mobile RF communication equipment and the Model 2120

The Model 2120 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model 2120 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model 2120 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5GHz** $d = 2.3\sqrt{P}$
0.01	0.1m	0.1m	0.2m
0.1	0.4m	0.4m	0.7m
1	1.2m	1.2m	2.3m
10	3.7m	3.7m	7.4m
100	11.7m	11.7m	23.3m

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Medical Devices may be affected by 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,

Portable and mobile RF communications equipment can affect medical electrical equipment.

WARNINGS:

1) No modification of this equipment is allowed.

FDA NOTICE

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

DECLARATION OF CONFORMITY

Product: Vitalograph® In2itive

Vitalograph hereby ensures and declares that the above product associated with this user manual, is designed and manufactured in accordance with the following QMS regulations and standards:

- European Medical Devices Directive {MDD} 93/42/EEC.
  This device, classified as 2a as per Annex IX of MDD 93/42/EEC, meets the following provisions of Annex II of the Medical Devices Directive as per Article 11, section 3a, excluding point 4 of Annex II.

CE 0086

- Canadian Medical Device Regulation {CMDR}
- FDA Quality System Regulation {QSR} 21 CFR 820.
- EN ISO 13485: 2003. Medical devices. Quality management systems. Requirements for regulatory purposes.

Certifying Body {for 93/42/EEC and CMDR}: British Standards Institute {BSI}

Certificate Nos. CE 00772, MD 82182, FM 83550

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 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.