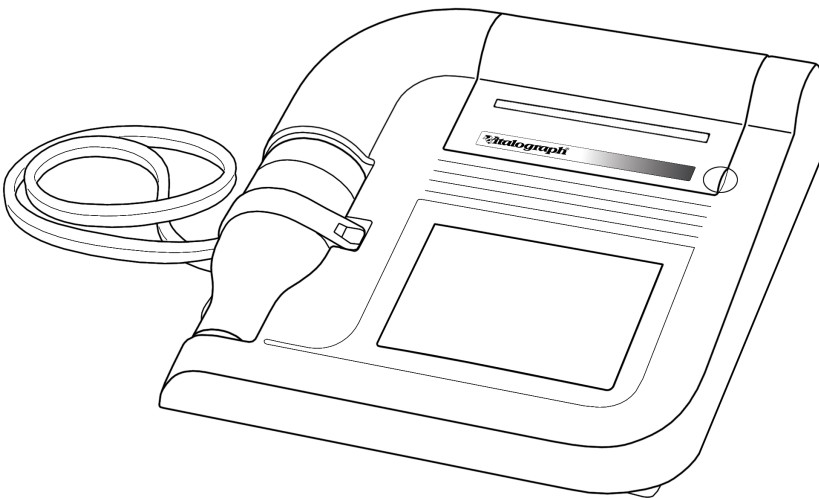


# **Vitalograph<sup>®</sup>** **COMPACT**

MODEL 6600

# **User Manual**



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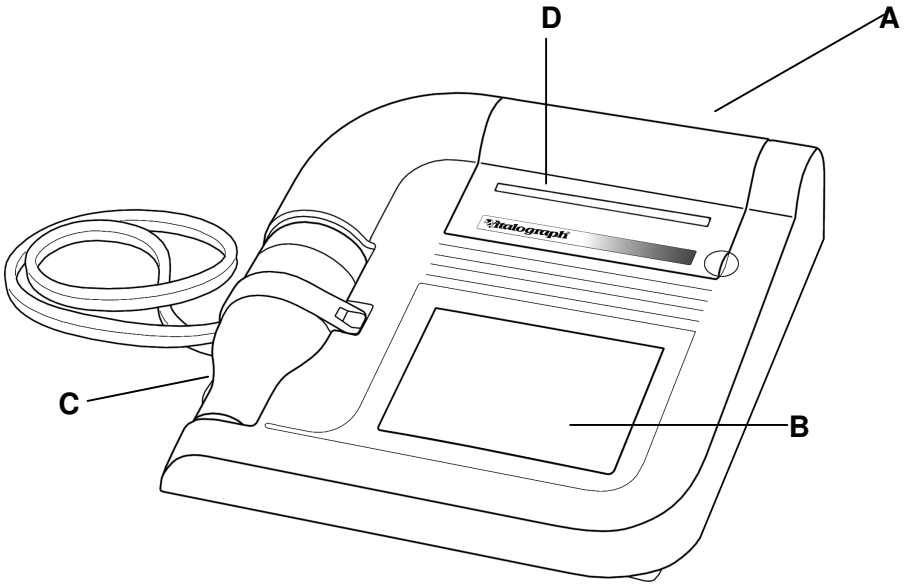
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## DESCRIPTION OF THE VITALOGRAPH COMPACT

The Vitalograph COMPACT is a desktop 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 touchscreen and stored, together with spirometry test data. Current test data and the subject's history 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 **More** button on the Home screen.
2. Press the **About** button.



## MAIN COMPONENTS OF THE VITALOGRAPH COMPACT

- A Vitalograph COMPACT device
- B LCD/Touchscreen
- C Flowhead
- D Printer

## FEATURES OF THE VITALOGRAPH COMPACT

The Vitalograph COMPACT's features include:

- Very high accuracy, linearity and stability
- Automatic trending
- Extremely simple to operate touchscreen with extra-large buttons
- Integral printer for instant results or optional external printing
- Automatic storage of tests and demographic information
- Ability to exchange information with a PC

- Robust, proven fleisch-type flowhead. No moving parts or delicate sensors
- Simple cleaning. The flowhead completely dismantles for washing, disinfecting or even autoclaving.

## GETTING THE VITALOGRAPH COMPACT READY FOR USE

1. Attach the flowhead to the Vitalograph COMPACT by the dual silicone tubing (Flowhead Connection Tube). Ensure that the coloured/ribbed tapping on the flowhead is connected to the ribbed side of the connection in the housing.
2. Open the printer door and remove bubble wrap from each side of paper roll. Feed the paper through the printer (See section [Fitting a New Paper Roll](#))
3. Only use the Vitalograph COMPACT with the purpose-built low voltage power supply unit with which it is supplied. Attempted use with other power sources may cause irreparable damage and invalidate the warranty. The output from the power supply is 10 volts DC.
4. Connect the jackplug from the power supply into the socket on the rear of the Vitalograph COMPACT. The IEC connector on the mains lead plugs into the socket on the power supply. Plug the mains plug into a suitable socket, operate the On/Off switch on the rear of the instrument and the Vitalograph COMPACT is ready for use.
5. A helpful demonstration will automatically start when the COMPACT is powered up for the first time. On subsequent power-up the demonstration will not start automatically. To access the demonstration again press the **Help** button on the Home screen.

*Note: A complete list of the buttons and icons used in this device is available at the back of this Manual.*

# OPERATING THE VITALOGRAPH COMPACT

## Logging In

The COMPACT can be configured so that a user must login during power-up. (See section [User Configurations](#)). If this option is selected, the user is presented on power-up with a login screen showing a list of users stored in the database. There are two options available:

1. Select the required user ID from the list-box and continue to login by pressing the **Return** button.
2. If the required user ID is not on the list, then you can create one by pressing the **New User** button.



Enter the user ID using the on-screen keyboard. When you have entered the user ID you can do one of two things:

- a. Save the user ID to the database and return to the login screen by pressing either the **Home** or **Return** buttons.
- b. Do not save the changes and return to the login screen, by pressing the **Back** button.



or



## Entering or Selecting Subject Information

In order to save test sessions to the database, a current subject must first be created or selected for test.

You can:

- Enter subject information for a new subject as described in the [Creating a New Subject](#) section. This information is stored on the database.

Or

- Recall a previously entered subject from the database as described in the [Selecting a Subject from the Database](#) section.



## Creating a New Subject

There are 2 methods available to the user for creating a New Subject:

- Creating a new subject.
- Creating a new subject field by field.

*Note: Refer to section User Configurations for instructions on how to set the device to enter a subject field by field.*

To access the New Subject screen, select the **New Subject** button from the Home screen.



### Creating a New Subject .

After entering the New Subject screen, you are presented with a series of dialog boxes.

1. Enter data in the fields as required.

a. Enter last name using the on-screen keyboard



(Last Name)

b. Enter first name using the on-screen keyboard



(First Name)

c. Enter the population group from a drop down list



(Population Group)

d. Enter date of birth using the on-screen keyboard



(Date of Birth)

e. Enter gender by selecting the relevant option



(Male/Female)

f. Enter height using the on-screen keyboard



Height

g. Enter weight using the on-screen keyboard



Weight

h. Enter the subject ID using the on-screen keyboard



(Subject ID)

*Note: If you did not enter a subject ID, the unit will automatically create one.*

2. Once you are ready to move onto the next field press Enter on the keyboard.

*Note: The cursor will move on automatically if the maximum information allowed for a field has been entered. Any or all fields can be left blank also.*

3. When you are satisfied with the data you have entered, you can do one of three things:

- a. Save the new subject to the database and return to the Home screen by pressing the **Home** button.
- b. Save the new subject to the database and perform a test session by pressing the **Return** button.
- c. Enter the smoking information screen by pressing the **Forward** button.



4. The smoking information can be modified by selecting the relevant option from the following:

- a. Non-smoker
- b. Current smoker
- c. Ex-smoker



For a Current smoker, you will need to enter the:

- i. Cigs. per day
- ii. Year started



For an Ex-smoker, you will need to enter the:

- i. Cigs. per day
- ii. Year started
- iii. Year quit



- d. If you suspect the subject has COPD, check the COPD check box.

4. Enter subject comments in the field provided using the on-screen keyboard
6. You can return to the New Subject screen by pressing the **Back** button.



### Creating a New Subject field by field.

After entering the New Subject screen, you are presented with a series of dialog boxes in which you can enter information. Once you are ready to move onto the next dialog box, press the Enter key on the keyboard. These dialog boxes appear one at a time.

### Selecting a Subject from the Database

If a subject has previously been created, the details will be stored in the database.

Follow these steps to recall a subject from the database.

1. To access the Recall Subject screen, press the **Recall Subject** button on the Home screen.
2. All subjects are listed. It is possible scroll down through the list by pressing the up/down arrows on the list box.
3. You can list the subject by Name or ID by making the relevant selection.
4. Highlight the subject you require by making a selection in the list box. The subject will now appear in the dialog box beside the list box.



or



You can now do one of three things:

- a. Make the selection the current subject and return to the Home screen by pressing the **Home** button.



*Note: If the selected subject has a name entered it will appear at the status bar on the bottom of the screen. If the selected subject has no name entered the text 'No name entered' will appear on the status bar.*

- b. Cancel the selection and return to the Home screen by pressing the **Back** button.
- c. Make the selection the current subject and edit the subject's information by pressing the **Return** button.



Refer to section [Modifying Subject Information](#) on how to edit subject information. Carry out a test session on the selected subject by pressing the **Return** button again.

## 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 COMPACT unit was checked recently. (Refer to section on [Checking Accuracy](#))
2. Check that the required Save Options, FVC Test Type and Test Indices are selected. (Refer to section on [Test Configuration](#)).
3. Check that a subject is selected and that all the required demographic information is entered for the subject. (Refer to section on [Selecting a Subject from the Database](#)).

*Note: If a name has been entered, then that name will appear in the status bar. If no name has been entered, then 'No name entered' will appear on the status bar.*

### Performing an FVC Test

There are two test types that can be performed using the COMPACT. These are:

- Single Breath Test
- Closed Circuit Spirometry

Refer to section on [Test Configuration](#) for selecting the test type.

### Performing a Single Breath Test

Follow these steps to perform a single breath test:

1. Press the **Perform Test** button on the Home screen.



*Note: If no subject has been selected from the database then you will be presented with a list of all subjects. There are two options here. You can:*

- a. *Select the subject required and press the Enter key. The subject's demographic information will then be displayed. Review this and change if required. Press the Enter key to display the testing screen.*
- b. *Press the Enter key without selecting any subject from the database. The COMPACT unit will automatically create a subject ID before displaying the testing screen.*

Depending on the Test Configuration settings, you may be presented with a testing screen to either perform a VC or an IVC test.

*Note: If neither VC or IVC is selected in the Test Configuration settings, then the testing screen will not be displayed.*

## Perform a VC Test

1. Wait for the **Exhale to Begin** icon to appear.



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

*Note: The test session **Preview** button appears on the top of the test screen. To view a previous test session, press this button.*



2. Read the following instructions to the subject so that testing is performed properly:
  - a. Stand up.
  - b. Keep the flowhead away from your mouth.
  - c. Inhale as deeply as possible and insert the bacterial viral filter into your mouth, clamping it between your teeth.
  - d. Close your lips around the bacterial viral filter.
  - e. Exhale normally for as long as possible.

3. If you are prompted to accept the test, press the **Cancel** button to reject the test or the **Enter** button to accept the test.

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 to perform another VC test if required.

*Note: A maximum of 12 VC tests can be performed in one session.*

5. After performing the VC tests, you can do one of four things:

- a. Return to the Home screen by pressing the **Home** button. This will finish the test session.
- b. Return to the Subject Select screen by pressing the **Back** button. This will end the test session.
- c. Perform a Single Breath Test by pressing the **FVC** button.
- d. Perform a Post test by selecting the **Post** button.



*Note: Refer to the section on [Performing a Post Test Session](#)*

## Perform an IVC Test

1. Wait for the **Exhale to Begin** icon to appear.



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

*Note: The test session **Preview** button appears on the top of the test screen. To view a previous test session, press this button.*



2. Read the following instructions to the subject so that testing is performed properly:

- a. Stand up.
- b. Insert the bacterial viral filter into your mouth and, clamping it between your teeth.
- c. Close your lips around the bacterial viral filter.
- 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. Exhale as deeply as possible.
  - f. Inhale as much as possible (speed is not important) and when fully inhaled
  - g. Return to tidal breathing i.e.: Breathe in and out normally again.
3. If you are prompted to accept the test, press the **Cancel** button to reject the test or the **Enter** button to accept the test.

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

4. Repeat to perform another IVC test if required.

*Note: A maximum of 12 IVC tests can be performed in one session.*

5. After performing the IVC tests, you can do one of four things:

1. Return to the Home screen by pressing the **Home** button. This will end the test session.
2. Return to the Subject Select screen by pressing the **Back** button. This will end the test session.
3. Perform a single breath test by pressing the **FVC** button.
4. Perform a Post test by pressing the **Post** button.



*Note: Refer to the section on [Performing a Post Test Session](#)*

## Performing a Single Breath Test Continued

*Note: If you have not selected either of the VC or IVC check boxes in the Test Indices selection screen, you will be brought directly into the FVC test screen.*

1. Press the **FVC** button in the VC or IVC screens to enter the Single Breath Test screen. To perform a Single Breath Test:

- a. Wait for the **Exhale to Begin** icon to appear.



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

- b. Read the following instructions to the subject so that testing is performed properly:
  - i. Stand up.
  - ii. Keep the flowhead away from your mouth.
  - iii. Inhale as deeply as possible, then inset the bacterial viral filter into your mouth, clamping it between your teeth.
  - iv. Close your lips around the bacterial viral filter.
  - v. Exhale as much and as quickly as possible and try to keep exhaling for at least 6 seconds.
  - vi. If inspiratory indices are selected, then inhale as quickly as possible.
2. If you are prompted to accept the test, press the **Cancel** button to reject the test or the **Enter** button to accept the test.

The FVC and FEV1 values recorded for the blow are tabulated. The best FVC and FEV1 values for the current session and the Lower Limit of Normality (LLN) are also displayed.

3. Repeat to perform another Single Breath Test if required.

*Note: A maximum of 12 Single Breath tests can be performed in one session.*

## Using the Incentive Device

The Incentive Device is used as an aid in the Single Breath Test of children. To access this:



1. Press the **Incentive** button on the top of the screen.



*Note: You must wait for the **Exhale to Begin** icon to appear before a blow can be performed.*



2. To view the results for the individual blows associated with the test session, press the **Results** tab.



The blows are listed in order of ranking. The best blow being listed first. Predicted values are shown for the selected indices. The predicted value will be displayed if the date of birth, height, gender and population group are entered.

3. To view the next ranked blow, press the **Arrow** button.



4. To view the trend graph for the current subject, press the **Trend** tab.



There is an option here to switch between trending.

Trending for all test sessions performed will be shown by default when you select the Trend tab. This is a seventy-year trend of the best FEV1 value. A predicted line is shown from the 25–70<sup>th</sup> year, if the subject's demographic information is entered.

- a. In order to view the trend of the last ten test sessions, press the **Ten Point Trend** button.



- b. To switch back to the full trend, press the **Full Trend** button.



5. Press the **Info** tab to view the quality information and the interpretation of the session results.



The reproducibility information for FVC, FEV1 and PEF is displayed if at least two tests are performed. If the reproducibility criteria are met, then a message saying 'GOOD test session' is displayed. No reproducibility information will be displayed if the manual save option is selected. Refer to the [Test Configuration](#) section.

1. Press the **Interpretation** button to view the suggested interpretation of the results. Interpretation will be displayed if the height, date of birth and population group are entered for the subject. There also needs to be a measured value of FEV1.



2. Press the **COPD Risk** button to view the COPD risk. This calculates a subject's risk of developing COPD within the next 10 years, and also the risk if the subject stopped smoking.



COPD risk will be displayed if the date of birth, gender and current smoking information have been entered. The COPD checkbox must also be selected.

3. Press the **COPD Number** button to view the COPD score.



The COPD number is the measured FEV1 as a percent of the value compared with a reference population of people without lung disease. This is used as a method of categorising the severity of airway obstruction in subjects with COPD. Most lung damage is permanent, so the initial COPD number is unlikely to improve. However, if it remains close to constant, it is a positive sign that the subject's lungs are not suffering further deterioration. The number will be displayed if the date of birth, height and population group have been entered and the COPD check box has been selected for the subject.

4. To print the COPD number, press the **Print COPD** button.



5. In order to view the predicted lung age, press the **Lung Age** button.



6. After performing the Single Breath Tests, you can do one of four things:

a. Return to the Home screen by pressing the **Home** button. This will end the test session.



b. Return to the Subject Select screen by pressing the **Back** button. This will end the test session.



c. Print the test session by pressing the **Print** button. This will end the test session.



d. Perform a Post test by pressing the **Post** button.



*Note: Refer to the section on [Performing a Post Test Session](#)*

## Performing Closed Circuit Spirometry

Follow these steps to perform Closed Circuit Spirometry:

1. Press the **Perform Test** button on the Home screen.



*Note: If no subject has been selected from the database, then you will be presented with a list of all subjects.*

There are two options here. You can:

a. Select the subject required. Press the Enter key and the subject's demographic information will be displayed. Review this and change if required. Press the Enter key to bring you onto the testing screen.

b. Press the Enter key without selecting any subject from the database. The COMPACT unit will

automatically create a subject ID and bring you onto the testing screen.

2. If FRC, RV and TLC are selected as indices (refer to the section [Test Configuration](#)), then a screen asking you to enter a value for FRC, RV or TLC will appear. Enter a value using the on-screen keyboard. If one value is known, the others may be calculated from the closed circuit test.

*Note: If none of the indices FRC, RV or TLC is selected in the Test Configuration screen, then this screen will not appear and you will be brought directly into the Closed Circuit Test screen.*

3. Once you have the required value entered, you can do one of three things:
  - a. Return to the Home screen by pressing the **Home** button. This will finish the test session.
  - b. Return to the Subject Select screen by pressing the **Back** button. This will finish the test session.
  - c. Perform a Closed Circuit Test by pressing the **Return** button.
4. After pressing the Enter key in FRC/RV/TLC value entry screen, you will be brought into the Closed Circuit Test screen.
5. Wait for the **Exhale to Begin** icon to appear. This indicates that the COMPACT unit is ready to accept a blow.



Read the following instructions to the subject to ensure that testing is performed properly:

- a. Clip on the nose clip to seal your nose.
- b. Put the Bacterial Viral Filter into your mouth, biting it lightly.
- c. Seal your lips around the mouthpiece
- 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. Exhale as much and as quickly as possible, and when fully exhaled
  - g. Inhale fully as quickly as possible
  - e. Return to tidal breathing, i.e. breathe in and out normally again.
6. If you are prompted to accept the test, press the **Cancel** button to reject the test or the **Enter** button to accept the test.

The FVC and FEV1 values recorded for the Closed Circuit Test, are tabulated. The best FVC and FEV1 values for the current session and the Lower Limit of Normality (LLN) are also displayed.

7. Repeat to perform another Closed Circuit Test if required.

*Note: A maximum of 12 Closed Circuit Tests can be performed in one session.*

8. You can view the flow data in Volume/Time or Flow/Volume format. To switch between the different formats:

- a. Select the relevant tab  
Volume/Time  
Flow/Time



- b. Press the **Results** tab to view the results for the individual blows associated with the test session. Refer to section on [Single Breath Test](#) for more information.
- c. Press the **Trend** tab to view the trend graph for the current subject. Refer to section on [Single Breath Test](#) for more information.
- d. Press the **Info** tab to view the quality information and the interpretation of the session results. Refer to section on [Single Breath Test](#) for more information.



9. After performing the Closed Circuit tests, you can do one of four things:

- a. Return to the Home screen by pressing the **Home** button. This will end the test session.
- b. Return to the Subject Select screen by pressing the **Back** button. This will end the test session.
- c. Print the test session by pressing the **Print** button. This will end the test session.
- d. Perform a Post test by pressing the **Post** button.



*Note: Refer to the section on [Performing a Post Test Session](#).*

### 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. Press the **More** button on the Home screen.
- 2. Press the **Post Test** button.



- 3. If there is no current subject selected then you will be presented with the list of subjects saved to the database.

Select the required subject and press the **Return** button.



*Note: If there is already a current subject selected, then you will be brought into the pre-session select screen.*

- 4. You will be presented with a list of pre-test sessions performed by the current subject, listed by date and time. Select the pre-test from the list and press the **Return** button.



*Note: If the FVC test type was a closed circuit test, then*

the session will be marked CCS.

5. You will be brought into the test screen. Perform the Post test as normal. Refer to the sections on [Performing a Single Breath Test](#) and [Performing Closed Circuit Spirometry](#).

*Note: You can also access the Post test screen from within the pre-test session screen. Press the **Post** button on the top of the screen. This will end the current session and bring up the list of pre-test sessions performed by the current subject, with the last session highlighted.*

## Printing and Viewing Test Sessions

You can print or view test sessions for any subject.

The COMPACT has an internal printer but can also be connected through the USB A port at the rear of the unit to an external USB printer.

*Note: The internal (thermal) printout will fade over time when exposed to light or heat. If a permanent record is required, photocopy the thermal printout or print to the external USB printer.*

*Note: Refer to the section on [Report Options](#) for information on selecting the internal or external printer. Contact Vitalograph for a list of compatible USB printers.*

To access the print/preview screen, press the **Print Report** button on the Home screen.



*Note: A current subject must first be selected. Refer to the section on [Selecting a Subject from the Database](#) to do this.*

After entering the Session Select screen, you are presented with a log of sessions performed by the current subject. The following information is contained in the log:

- a. Session date
- b. Session time
- c. Pre or Post Test.

*Note: An ‘\*’ will appear in the log if it is a Post test session*

- d. Session type. CCS will appear in the log if closed circuit spirometry was carried out by the subject.

*Note: Pressing the **Home** or **Back** buttons will bring you back to the Home screen.*



or



### Printing a Test Session

To print a particular session, select it and press the **Print** button.



### Viewing a Test Session

1. To view a particular session, select it and press the **Preview** button.



The selected session will be recalled from the database.

2. Review the graphs by selecting the **Graphs** tab.

- a. For a single breath FVC test, press the **Graphs** tab



This will show the Flow/Volume and Volume/Time curves for the test session.

- b. For a closed circuit spirometry FVC test type, press the **Graphs** tab. This will show the Flow/Volume curve for the test session.



*Note: The Volume/Time curve cannot be viewed.*

3. Review the results by selecting the **Results** tab.



*Note: Refer to the section on [Performing a Test Session](#) on the information displayed in this tab.*

4. View the trend graph by selecting the **Trend** tab.





*Note: Refer to the section on [Performing a Test Session](#) on the information displayed in this tab.*

5. Review the quality information by selecting the **Info** tab.



*Note: Refer to the section on [Performing a Test Session](#) on the information displayed in this tab.*

6. After reviewing the test session results, you can do one of four things:

- a. Return to the Home screen by pressing the **Home** button.



- b. Return to the Session Select screen by pressing the **Back** button.



- c. Print the test session by pressing the **Print** button.



- d. Perform a Post test by selecting the **Post** button.




*Note: Refer to the section on [Performing a Post Test Session](#) for information on performing a Post test.*

## **Modifying Subject Information**

It is possible to modify subject information stored on the database.

The subject must first be recalled from the database, as per section on [Selecting a Subject from the Database](#).

Once the subject information is recalled from the database, you can modify the information fields as follows:

1. To change the subject's last name, place the cursor in the last name field () , delete the existing text and type the new text using the on-screen keyboard. You can also modify:

a. First name using the on-screen keyboard



(First name)

b. Population group from a drop-down list



(Population Group)

c. Date of birth using the on-screen keyboard



(Date of birth)

d. Gender by selecting the relevant option



(Male/Female)

e. Height using the on-screen keyboard



(Height)

f. Weight using the on-screen keyboard



*Note: The Subject ID cannot be altered.*



(Subject ID)

2. To modify the smoking information, press the **Forward** button. This will allow you to modify the smoking status by selecting from the following options:



i. Non-smoker




ii. Current Smoker




iii. Ex-smoker





For a Current Smoker you can modify the:


i. Cigs. per day using the on-screen keyboard 

ii. Year Started using the on-screen keyboard 

For an Ex-smoker you can modify the:

i. Cigs. Per day using the on-screen keyboard 

ii. Year Started using the on-screen keyboard 

iii. Year Quit using the on-screen keyboard 

a. You can check/uncheck the COPD check box.

b. Modify subject comments using the on-screen keyboard.

3. Return to the New Subject screen by pressing the **Back** button.



When you have made all the changes required, you can do one of two things:

a. Save the changes to the database and return to the Home screen by pressing the **Home** button.



b. Save the changes to the database and perform a test session by pressing the **Return** button.



## 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 COMPACT 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. Attach the flowhead to the precision syringe

2. Press the **More** button on the Home screen.



3. Press the **Accuracy Check** button.



4. Press the **Accuracy Check** button again.



5. Select the required user ID from the drop-down list.



6. Enter the volume of the syringe



7. Enter the syringe serial number.



8. Press the **Return** button.



9. 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.

10. Press the **Return** button.



Follow the on-screen instructions.

11. If a print out is required, press the **Print** button.



## Viewing/Printing the Accuracy Log

The accuracy check is added to a log. Follow these steps to view the log.

1. Press the **More** button on the Home screen



2. Press the **Accuracy Check** button.



The log contains the following information:

- a. Date of accuracy check
- b. Time of accuracy check
- c. Syringe serial number
- d. Volume of syringe
- e. Volume recorded by COMPACT.

The following \*\*\* will appear beside the log if the calibration was updated on the unit.

It is possible to print the accuracy check log by pressing the **Print** button.

In addition to the above items, the following will be shown on the printout:

- f. User ID
- g. Ambient temperature at time of accuracy check.

The date and time the log was printed and the COMPACT serial number will be shown in the headings.

## 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 has been dropped.

## DELETING SUBJECT INFORMATION AND/OR TEST RESULTS.

There are four choices available for deletion:

1. All tests and all subject information
2. All tests for all subjects but no subject information
3. All tests for a specific subject and his or her subject information
4. All tests for a specific subject but no subject information

Follow these steps to access information for deletion:

1. Press the **More** button on the Home screen



2. Press the **Database** button.



- a. To delete all test and all subject information:
  - i. Check the Select All Subjects check box.
  - ii. Select the Delete Subject option.
  - iii. Press the **Delete** button.



A confirmation message will appear

- iv. To continue with the deletion, press the **Return** button.



- v. To cancel the deletion, press the **Cancel** button.



- b. To delete all tests for all subjects but no subject

information:

- i. Check the Select all Subjects check box.
- ii. Select the Delete Sessions Only option.
- iii. Press the **Delete** button.



A confirmation message will appear

- vi. To continue with the deletion, press the **Return** button.



- vi. To cancel the deletion, press the **Cancel** button.



- c. To delete all tests for a specific subject and his or her subject information:

- i. Do not select the Select all subjects check box
- ii. Select the Delete Subject option
- iii. Select a subject
- iv. Press the **Delete** button.



A confirmation message will appear.

- v. To continue with the deletion, press the **Return** button.



- vi. To cancel the deletion, press the **Cancel** button.



- d. To delete all tests for a specified subject but no subject information:

- i. Do not select the Select all subjects check box
- ii. Select the Delete Sessions Only option
- iii. Select the subject
- iv. Press the **Delete** button.



A confirmation message will appear.

- v. To continue with the deletion, press the **Return** button.



- vi. To cancel the deletion, press the **Cancel** button.



## POPULATION GROUPS AND NORMAL SETS

When entering subject information, you can specify the population group of the subject. (Refer to the section on [Entering or Selecting Subject Information](#)). There are a number of population groups to select from. These population groups have an associated predicted normal set and correction factor. These normal sets are usually based on sex, age and height and are useful when comparing a subject's test results with predicted normal values from a suitable reference population. There is considerable variation in the predicted figures, and most researchers have an individual preference for a particular normal set. It is possible to create custom population groups with associated normal sets and correction factors and save to the database. You can also delete existing population groups from the database.

To access the Population Group screen:

1. Press the **Options** button on the Home screen.



2. Press the **Population** button on the Options screen.



To modify the Normal set and Correction factor for an existing Population:

1. Highlight the population group in the population group list box.
2. Select an alternative normal set from the normal set drop-down list.
3. Enter the correction factor in the correction factor field using the on-screen keyboard. Valid values are between 50–150.



4. You can now do one of three things:

a. Save the changes to the database and return to the Home screen by pressing the **Home** button.



b. Do not save the changes to the database and return to the Options screen by pressing the **Back** button.



c. Save the changes to the database and return to the **Options** screen by pressing the **Return** button



To create a new Population Group:

1. Press the **New Population Group** button.



2. Enter the Population Group name using the on-screen keyboard.

3. Return from screen by pressing the **Back** button.



4. Enter the correction factor using the on-screen keyboard. Valid values are between 50–150.

5. Select a normal set from the drop-down list.

6. You can now do one of three things:

a. Save the new population group to the database and return to the Home screen by pressing the **Home** button.



b. Do not save the new population group to the database and return to the Options screen by pressing the **Back** button.



- c. Save the new population group to the database and return to the Options screen by pressing the **Return** button.



To delete an existing population group:

1. Highlight the population group in the population group list box.
2. Press the **Delete** button.
3. A dialog box will appear asking you to Delete the selected population group?
  - a. If you wish to delete the population group, press the **Return** button.
  - b. If you do not want to delete the population group, press the **Cancel** button.



## TEST CONFIGURATION

There are two basic test types that the COMPACT can record:

- Closed Circuit Spirometry
- Single Breath Test.

These can be selected in the Test Configuration screen. It is also possible to configure the test screen to your own requirements.

To access the Test Configuration screen:

1. Press the **Options** button on the Home screen.
2. Press the **Indices** button on the Options screen.



3. The Default Volume Graph Scale can be modified, by selecting one of the alternative options. This will set the default scale on the graphs (and printouts).
4. The Save Option can be modified by selecting one of the alternative options.
  - a. If the ATS Best 3 option is selected, then the best three tests will be saved to the database based on the highest FVC+FEV1 sum for each test.
  - b. If the ERS Best 3 option is selected, then the best three tests will be saved to the database based on the highest FEV1 for each test.
  - c. If the Manual option is selected then, at the end of the session, you select the test to save to the database. Only one test can be selected for saving.
5. The FVC Test Type can be selected as either Closed Circuit Spirometry or Single Breath Test.
6. The COMPACT will, by default, accept all tests performed during a session and save the tests to the database at the end of the session based on the Save Option selected. You can also configure the COMPACT to ask at the end of each test whether you wish to keep the test. To do this, un-check the Automatically Accept Tests check box.
7. The test Indices can be modified by pressing the **Test Indices** button.



This gives a complete list of the test indices that can be reported (and printed) for a test session. To select/unselect a index check/uncheck the relevant check boxes. Additional indices are available by using the scroll bar on the right of the screen.

The following list supplies definitions of the indices:

<b>Indices</b>	<b>Definition</b>
<b>FVC Test</b>	
IVC	Inspiratory vital capacity (L)
FVC	Forced vital capacity (L)
FEV.5	Forced expiratory volume after 0.5 seconds (L)
FEV.5/FVC% (FEV.5/F%)	Percentage FEV 0.5 of FVC (%)
FEV.75 (F.75)	Forced expiratory volume after 0.75 seconds (L)
FEV.75/FVC% (F.75/F%)	Percentage FEV 0.75 of FVC (%)
FEV1	Forced expiratory volume after 1 second (L)
FEV1%	Percentage FEV1 of VC (%)
FEV1/FVC% (FEV1/F%)	Percentage FEV1 of FVC (%)
FEV1/PEF% (F1/PEF%)	Percentage FEV1 of PEF (%)
FEV3	Forced expiratory volume after 3 seconds (L)
FEV3/VC% (FEV3%)	Percentage FEV3 of VC (%)
FEV 3/FVC% (FEV3/F%)	Percentage FEV3 of FVC (%)
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 (F0.2-1.2)	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 25-75/FVC (F2575/F%)	Percent FEF 25–75 of FVC (%)
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)

## Indices

### FVC Test

FEF 75

Forced expiratory flow at 75% of the FVC (L/sec)

FIVC

Forced inspiratory vital capacity (L)

FIVC/FVC

Percentage FIVC of FVC (%)

(FIVC/F%)

PIF L/s

Peak inspiratory flow (L/sec)

PIF L/min

Peak inspiratory flow (L/min)

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)

FIF50/FEF50

Percentage FIF 50% of FEF 50% (%)

(FIF/FEF%)

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)

Vext/FVC

Percentage extrapolated volume of FVC (%)

(Vext/F%)

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)

### VC Test

VC

Vital capacity (L)

### Body Mass

#### Index

BMI

Body Mass Index (kg/[Height(m)]<sup>2</sup>)

Once you have made your selection, you can do one of three things:

- Save the changes and return to the Home screen by pressing the **Home** button.



- Do not save the changes and return to the previous screen by pressing the **Back** button.



- c. Save the changes and return to the previous screen by pressing the **Return** button.



- 8. The Incentive Device can be configured by pressing the **Incentive** button.



The Incentive Device is used as an aid in the Single Breath Test of children.

- a. To change the incentive device to be used in testing, select an alternative from the Incentive Device list box.

The % of predicted value for the first test can be modified using the on-screen keyboard. The value entered must be between 50–150.

The % of Best Test value for the other tests can be modified using the on-screen keyboard. The value entered must be between 50–150.

- b. Once you have made your selection/changes, you can do one of three things:

- i. Save the changes and return to the Home screen by pressing the **Home** button.



- ii. Do not save the changes and return to the previous screen by pressing the **Back** button.



- iii. Save the changes and return to the previous screen by pressing the **Return** button.



- 9. Once you have made the required changes, you can do one of three things:

- a. Save the changes and return to the Home screen by pressing the **Home** button.



- b. Do not save the changes and return to the previous screen by pressing the **Back** button.



- c. Save the changes and return to the previous screen by pressing the **Return** button.



## VITALOGRAPH COMPACT CONFIGURATION

The COMPACT unit can be configured to suit your requirements.

To access the Unit Configuration screen:

- 1. Press the **Options** button on the Home screen.



- 2. Press the **Configuration** button on the Options screen.



- 3. To access the touch screen calibration, press the **Touch Screen Calibration** button. Calibration is performed by briefly holding the stylus on the centre of the target. Repeat as the target moves around the screen. Once the calibration has been changed you are given 30 seconds to accept the new settings by tapping the screen.



*Note: Touch screen is very responsive and could be damaged if excessive force is used.*

- 4. The LCD contrast can be modified by pressing the **Contrast Adjust** button.



- 5. Move the scroll bar to achieve the desired contrast. Once you are satisfied with the contrast, you can do one of three things:

- a. Save the changes and return to the Home screen by pressing the **Home** button.
  - b. Do not save the changes and return to the previous screen by pressing the **Back** button.
  - c. Save the changes and return to the previous screen by pressing the **Return** button.
6. The date format used can be modified by selecting one of the alternative options. The date format can be either:
- a. DD/MM/YYYY
  - b. MM/DD/YYYY
  - c. YYYY/MM/DD
7. The time format used can be modified by selecting the alternative option. The units used can be either:
- a. 12hr
  - b. 24hr
8. The date and time can be modified by pressing the **Date and Time** button.
9. Enter the date and time using the on-screen keyboard.
10. Once you have made the changes, you can do one of three things:
- a. Save the changes and return to the Home screen by pressing the **Home** button.
  - b. Do not save the changes and return to the previous screen by pressing the **Back** button.
  - c. Save the changes and return to the previous screen by pressing the **Return** button.





11. The units used can be modified by selecting the alternative option. The units used can be either:
  - a. US (Imperial)
  - b. Metric
12. The language used can be selected from the drop-down list. If the language you require is not available contact Vitalograph.
13. The unit Startup screen is configured on by default. It can be switched off by deselecting the check box.
14. The demonstration is configured on by default. It can be switched off by deselecting the check box. Refer to the section on [Getting the Vitalograph COMPACT Ready For Use](#) for running the demonstration.
15. The sound is configured on by default. It can be switched off by deselecting the check box.

16. The sounds can be configured by pressing the **Sounds** button.



17. In order to set a sound for a particular event, select the event in the Events list box and select a sound from the drop-down Sounds list.

18. To play a sound select one from the drop-down Sounds list and press the **Play Sound** button.



19. The volume can be adjusted by pressing the **Volume** button. Adjust the volume by pressing on the arrow buttons.



Once the volume is set, you can do one of three things:

a. Save the changes and return to the Home screen by pressing the **Home** button.



b. Do not save the changes and return to the previous screen by pressing the **Back** button.



c. Save the changes and return to the previous screen by pressing the **Return** button.



20. The sounds can be set to default by selecting an event from the Events list box and pressing the **Set to Default** button.



21. Once the sound is configured, you can do one of three things:

a. Save the changes and return to the Home screen by pressing the **Home** button.



b. Do not save the changes and return to the previous screen by pressing the **Back** button.



c. Save the changes and return to the previous screen by pressing the **Return** button.



22. When you have modified/set the unit configuration, you can do one of three things:

a. Save the changes and return to the Home screen by pressing the **Home** button.



b. Do not save the changes and return to the previous screen by pressing the **Back** button.



c. Save the changes and return to the previous screen by pressing the **Return** button.



## REPORT/PRINTER OPTIONS

The information printed on the session reports can be configured to suit individual requirements. The COMPACT can print to either the internal printer or to a compatible USB printer. Individual report

headings can also be included in the reports. Contact Vitalograph for a list of compatible printers.

To access the Report Options screen:

1. Press the **Options** button on the Home screen.



2. Press the **Report Options** button on the Options screen.



3. The items printed on the session report can be configured by selecting/deselecting the Report Options check boxes. The following are configurable:
  - a. *User ID*: This is printed by default.
  - b. *Name*: The subject's name is printed by default.
  - c. *Weight*: The subject's weight is printed by default.
  - d. *Comments*: This refers to the session comments, which are printed by default
  - e. *Use SDS*: In the session table of results the % of Predicted value will be printed by default. If this check box is selected, the SDS (Standard Deviation Score) will be printed instead.
  - f. *FV Graph*: The FV (Flow vs. Volume) graph is printed by default.
  - g. *VT Graph*: The VT (Volume vs. Time) graph is printed by default.
  - h. *Ref. Population*: The subject's population group is printed by default. This includes the normal set used and the correction factor applied if different than 100%.
  - i. *Three Tests*: By default the printout will show the results of the best test only, rather than the results of the three tests saved to the database. (Refer to the section [Test Configuration](#) on test save options). In order to show the three tests saved to the database, select the check box.

- j. *COPD Number*: If the COPD check box is selected in the Subject Demographics (Refer to the section on [Creating a New Subject](#)), then the subject is suspected of having COPD. If this is the case, the COPD number will be printed on the report by default.
- k. *COPD Risk*: If the COPD check box is selected in the Subject Demographics (Refer to the section on [Creating a New Subject](#)), then the subject is suspected of having COPD. If this is the case, the COPD risk will be printed on the report by default.
- l. *Lung Age*: The subject's lung age is printed by default.

*Note: 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.*

- m. *Interpretation*: The interpretation of the session results is printed by default.
- n. *Smoking Details*: Information on the subject's smoking history is printed by default.

4. The COMPACT can be set to print to either the internal printer or an external USB printer. If the External Print option is selected, there is an option to select the Best Quality print-out and/or Colour.

5. The report heading can be configured. Press the **Edit Text** button to do this.



a. Enter the required text using the on-screen keyboard

b. Return to the previous screen using the **Back** button.



6. To activate the paper feed press the **Paper Feed** button.



7. When you have modified/set the report options and printer configuration, you can do one of three things:

a. Save the changes and return to the Home screen by pressing the **Home** button.



b. Do not save the changes and return to the previous screen by pressing the **Back** button.



c. Save the changes and return to the previous screen by pressing the **Return** button.



## Fitting a New Paper Roll

The COMPACT is supplied with a roll of paper fitted into the printer. *(Note: The outside of the roll will not give a strong print impression due to loss of sensitivity on exposure to light.)* Replacement of the paper roll requires that the COMPACT be switched on.

To replace the paper:

1. Open the printer door using the finger catch on the right side of the door. This will expose the head of the printer and the paper roller mechanism.
2. Take out the empty roll by unclipping the roll support rod from the holder.
3. Put the roll support rod into the new roll of paper and unroll about 15 cm (6 inches) of paper. *(Note: To make fitting easier create a point in the middle of the paper by tearing off the two corners of the leading edge of the paper.)*
4. Lay the paper roll between the back of the COMPACT unit and the inside of the open door, with the paper coming out from the bottom of the roll and pointing toward the printer. This will allow you more access to the printer feed mechanism.

5. Lift the green lever on the printer.
6. Feed the leading edge of the paper into the bottom slot of the printer until the paper appears through the top of the printer. The paper can now be pulled through.
7. Close the green lever and press the **Paper Feed** button on the touchscreen. Press the **Paper Feed** button again once about 10 cm (4 inches) of paper has been fed through the printer.
8. Fit the new paper roll onto the holding clips.
9. Feed the paper through the slot in the printer door and close the door.



*Note: The Vitalograph logo should appear on the right edge of the paper and be facing you.*

*Warning: Paper tear bar contains sharp edges. Users should take care not to cut/scrap their fingers.*

## USER CONFIGURATIONS

The COMPACT can have different users. The unit can be configured so that it requires the users to login during start-up. (Refer to the section on [Logging In](#)).

To access the User Configuration screen:

1. Press the **Options** button on the Home screen.
2. Press the **User Configuration** button on the Options screen.
3. To create a new user, press the **New User** button.  
Enter the new user ID using the on-screen keyboard. When the user ID has been entered, you can do one of three things:
  - a. Save the user ID and return to the Home screen by pressing the **Home** button.



b. Do not save the user ID and return to the previous screen by pressing the **Back** button.



c. Save the user ID and return to the previous screen by pressing the **Return** button.



4. To delete a user, highlight the user in the user list box and press the **Delete** button.



5. A user can be set as the Current User by highlighting the user in the user list box and checking the Log On Current Selection check box. The logged on user ID will appear in the Current User dialog box.

6. The COMPACT can force users to login during start-up. To do this, check the Require User Login check box.

7. When you have modified/set the user configuration, you can do one of three things:

a. Save the changes and return to the Home screen by pressing the **Home** button.



b. Do not save the changes and return to the previous screen by pressing the **Back** button.



c. Save the changes and return to the previous screen by pressing the **Return** button.



## CLEANING INSTRUCTIONS

### Cleaning and Disinfecting the Vitalograph COMPACT

A new mouthpiece (either *SafeWay* 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 conditioning meshes should also be replaced in the event of damage, 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.

Refer to [Figure 2](#) for identification of parts.



## 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	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. <b>Note: Ensure isopropyl alcohol does not come in contact with the touchscreen.</b> <i>Warning: Paper tear bar contains sharp edges. Users should take care not to cut/scrap their fingers.</i>
White Flowhead Tube	Silicone Rubber	Clean	Viable	
Touchscreen	Electrode with Anti-Newton-Ring Treatment	Clean	No	Lightly wipe the surface with cotton pad or other soft material. <b>NOTE: DO NOT use chemicals such as acetone, toluene, ethanol or isopropyl alcohol. DO NOT wipe in a circular motion. Strokes should be either up/down or over/back.</b>
Fleisch Element	Aluminium, Stainless Steel	Clean	Viable	Disinfect by immersion in sodium dichloroisocyanurate solution at 1000 ppm concentration of free chlorine for 15 minutes (see following section for recommended cleaning/disinfection method for the Vitalograph COMPACT Flowhead) The flowhead may also be disinfected by autoclaving at 134°C for 3 minutes or 120°C for 20 minutes.
Flowhead Body	Aluminium & Acetyl	Clean & Disinfect	No	
Flowhead Cone	TPX	Clean & Disinfect	Viable	
Flowhead End Cap	TPX	Clean & Disinfect	Viable	
Flow Conditioning Meshes	Acetyl and Polyester	Dispose	No	

All external parts of the Vitalograph COMPACT require **cleaning**, i.e. the removal of visible particulate contamination. The parts of the Vitalograph COMPACT that make up the flowhead, which comes into

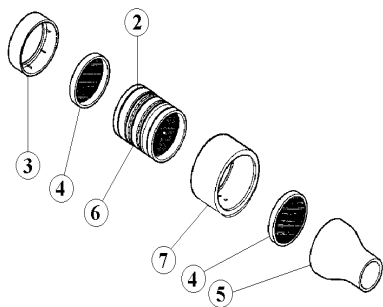
contact with subjects being tested, also require **disinfecting**. A spirometer is not designed as a 'sterile' device.

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".

## Disassembling the Vitalograph COMPACT

1. Remove the cone and the end cap from the flowhead.
2. Remove the flow conditioning meshes from inside the cone and the end cap, and discard them.
3. To remove the flowhead body from the fleisch element, place the fleisch element on a hard, flat surface with the largest diameter at the top. Push down on the flowhead body with thumbs and forefingers until it reaches the flat surface. A final pulling and twisting action will separate the parts.



1. Flowhead Complete – 61030
2. 'O' rings - 2120013
3. Flowhead End Cap -62006SPR
4. Flow Conditioning Meshes - 42084
5. Flowhead Cone - 62019SPR
6. Fleisch Element - 62055SPR
7. Flowhead Body – 61020
8. Lubrication: Silicone Grease – 30961SPR

Figure 2: Flowhead Assembly

4. Clean each separate part of 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.

The flowhead body (7) does not require disinfection, but may be cleaned/disinfected with the rest of the flowhead for convenience.

5. Rinse all parts in clean water.
6. 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.
7. Rinse with very hot water to aid later drying.
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.

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 tappings.
2. Check the 'O' rings for damage and ensure that they are correctly positioned within the grooves.
3. Apply a very small amount of silicone grease to 'O' Rings and inside the surfaces of the flowhead body. Wipe off any visible amounts of grease. Ensure that the tiny annular holes on the outside of the fleisch element are not blocked.
4. When re-assembling the flowhead, ensure that the blue pressure tapping is nearest to the largest diameter of the fleisch element.
5. Ensure that the flowhead body is pushed fully home and rotate it so that the pressure ports are approximately 180° opposite the end of the fleisch element coil.
6. Fit new flow conditioning meshes to both the flowhead cone and the flowhead end cap.
7. Push the flowhead end cap onto the larger diameter of the fleisch element and push the flowhead cone onto the smaller diameter.

8. When attaching the flowhead connection tube ensure that the matching coloured/serrated edge pressure tapings on the flowhead and the Vitalograph COMPACT are connected to each other.
9. It is recommended that an accuracy check is carried out following reassembly to verify correct operation and accuracy.

## FAULT FINDING GUIDE

Problem Fault Symptoms:	<ul style="list-style-type: none"> <li>• Accuracy check variations &gt; +/-3%</li> <li>• False readings suspected</li> </ul>
Possible Causes: (In probable order)	<ul style="list-style-type: none"> <li>• Recheck Calibration with reference to section Checking Accuracy</li> <li>• Was the correct syringe volume selected?</li> <li>• An accuracy check is required after cleaning/disinfecting the flowhead fleisch element assembly.</li> <li>• Flowhead cone fleisch element filter mesh missing or blocked.</li> <li>• Flowhead body pressure port holes blocked.</li> <li>• Flowhead fleisch element assembly sealing 'O' rings damaged.</li> <li>• Flowhead fleisch element assembly not dried thoroughly.</li> <li>• Flowhead fleisch element assembly blocked.</li> <li>• Flowhead body tubing from pressure ports to main PCB blocked – contact support.</li> <li>• Main PCB failure – contact support.</li> </ul>
Problem Fault Symptoms:	<ul style="list-style-type: none"> <li>• Test begins automatically</li> <li>• Volume accumulates automatically without the subject blowing.</li> <li>• Very small VC or FVC test displayed</li> </ul>
Possible Causes: (In probable order)	<ul style="list-style-type: none"> <li>• Flowhead and/or tubing not stationary at the start of test. Hold them steady until the 'Ready to Blow' prompt appears.</li> <li>• Return to Home screen and re-enter the test routine.</li> </ul>

Problem Fault Symptoms:	<ul style="list-style-type: none"> <li>•Rocking device.</li> </ul>
Possible Causes: (In probable order)	<ul style="list-style-type: none"> <li>•Check for damaged or missing rubber feet.</li> <li>•If any of the rubber feet are damaged or missing replace all four rubber feet.</li> </ul>
Problem Fault Symptoms:	<ul style="list-style-type: none"> <li>•Reversed or no volume measurements.</li> </ul>
Possible Causes: (In probable order)	<ul style="list-style-type: none"> <li>•Ensure tubing is connected correctly. Ribbed side of the tubing should be connected to the ribbed half of the connector on the COMPACT device and the blue tapping on the flowhead connector</li> <li>•Ensure that the flowhead connecting tube is not pinched or trapped.</li> </ul>
Problem Fault Symptoms:	<ul style="list-style-type: none"> <li>•Cannot print to internal printer.</li> </ul>
Possible Causes: (In probable order)	<ul style="list-style-type: none"> <li>•Check that internal printer is selected in the Report Options screen.</li> <li>•Check the paper is loaded correctly and not reversed.</li> <li>•Ensure the green flap on the printer is pressed down.</li> <li>•Internal printer failure – contact support.</li> </ul>
Problem Fault Symptoms:	<ul style="list-style-type: none"> <li>•Cannot print to external printer.</li> <li>•Corrupt or missing data on printout.</li> </ul>
Possible Causes: (In probable order)	<ul style="list-style-type: none"> <li>•Check that external printer is selected in the Report Options screen.</li> <li>•Check USB cable is connected between COMPACT and printer.</li> <li>•Check printer as per manufacturers instructions.</li> <li>•Check printer compatibility – contact support.</li> <li>•Main PCB failure – contact support.</li> </ul>
Problem Fault Symptoms:	<ul style="list-style-type: none"> <li>•Cannot read LCD</li> </ul>
Possible Causes: (In probable order)	<ul style="list-style-type: none"> <li>•Ensure the switch on the back of the unit is in the 'On' position.</li> </ul>

order)	<ul style="list-style-type: none"> <li>•Check contrast adjustment in the COMPACT Configuration screen.</li> <li>•LCD failure – contact support.</li> <li>•Main PCB failure – contact support.</li> </ul>
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## 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	<i>SafeTway</i> Mouthpieces (200)
20303	Nose Clips (10)
28350	BVF (50)
20408	1-L Precision Syringe
36020	3-L Precision Syringe
42084	Flow Conditioning Mesh (10)
66149	Thermal Printer Paper (5)
67056	Serial Cable
67252	USB Cable
311204	10V DC Power Supply
31297SPR	3 Pin Mains Power Cable with 5A fuse (UK)
31375SPR	2 Pin Mains Power Cable (USA)
31376SPR	2 Pin Mains Power Cable (International)
67050	Replacement Stylus 'Pen'
61030	Flowhead Complete
42029SPR	Flowhead Connection Tube
67052	CD with User and Service Manual


## EXPLANATION OF SYMBOLS

 Type BF equipment

 Class II


VA Power rating

V  Voltage DC

 Attention (reference relevant section in manual)

## OTHER LABELS

 Serial connector

 Power input connector


 USB connector

## TECHNICAL SPECIFICATIONS

Flow detection principle	Fleisch type pneumotachometer
Back pressure	Better than 0.1kPa/L/second, ATS standard. Highest back pressure occurs at 16L/sec.
Volume measurement	Flow integration
Maximum recorded flow rate	±16L/s
Maximum recorded volume	9.9 L
Measuring accuracy	Better than ±3% or ±0.05L volume, whichever is greater, and ±5% flow (inspiratory: ±5% vol., ±8% flow)
Operating temperature	10–40°C
Safety standards	Conforms to EN60601-1, EN60601-1-2
Certified Spirometry standards	ATS and ERS
Size	343 mm x 244 mm x 116 mm
Weight	2,250 g
Storage Temperature	0–50°C
Storage Humidity	Relative 10%–95%

*Note: All values displayed by the COMPACT are expressed as BTPS values.*

## CE NOTICE

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



Guidance and manufacturer's declaration – electromagnetic emissions		
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment		
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
RF emissions CISPR 11	Group 1	The [equipment or system] uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class [A]	
Harmonic emissions IEC 61000-3-2	Class [A]	
Voltage Fluctuations/Flicker emissions IEC61000-3-3	[Complies]	
The [equipment or system] is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.		

Guidance and manufacturer's declaration – electromagnetic immunity			
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment			
<b>Immunity test</b>	<b>IEC 60601 Test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	Complies	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the

			relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	$\pm 2$ kV for power supply lines $\pm 1$ kV for input/output lines	Complies	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	$\pm 1$ kV differential mode $\pm 2$ kV common mode	Complies	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$< 5\% U_t$ ( $> 95\%$ dip in $U_t$ ) for 0.5 cycle $40\% U_t$ (60% dip in $U_t$ ) for 5 cycles $70\% U_t$ (30% dip in $U_t$ ) for 25 cycles $< 5\% U_t$ ( $> 95\%$ dip in $U_t$ ) for 5 sec	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the system requires continued operation during power mains operation, it is recommended that the system be powered from an uninterruptible power supply or battery
Power frequency (50/60 Hz)	3 A/m		Power frequency magnetic fields should be at

magnetic field IEC 61000-4-8			levels characteristic of a typical location in a typical commercial or hospital environment
Note: Ut is the a.c.mains voltage prior to application of the test level			

Guidance and manufacturer's declaration – electromagnetic immunity			
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system 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	[3]V	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. <b>Recommended separation distance</b> $d = [3.5/3]\sqrt{P}$
Radiated RF	3 V/m	[3]V/m	

IEC 61000-4-3	80 MHz to 2.5 GHz		<p> <math>d = \sqrt[3]{\frac{3.5}{P}}</math> 80MHz to 800 MHz  <math>d = \sqrt[3]{\frac{7}{P}}</math> 800 MHz to 2.5GHz         </p> <p>           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)         </p> <p>           Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup> </p> <p>           Interference may occur in the vicinity of equipment marked with the         </p>
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The system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter  <i>W</i>	Separation distance according to frequency of transmitter  m		
	150 kHz to 80 MHz $d = [3.5/ 3] \sqrt{P}$	80 MHz to 800 MHz $d = [3.5/ 3] \sqrt{P}$	800 MHz to 2.5GHz $d = [7/ 3] \sqrt{P}$
<b>0.01</b>			
<b>0.1</b>			
<b>1</b>			
<b>10</b>			
<b>100</b>			

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.

### **FDA NOTICE**

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

## DECLARATION OF CONFORMITY

Product: **Vitalograph<sup>®</sup>**  
**COMPACT**

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.



- 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

Signed on behalf of Vitalograph (Ireland) Ltd.

A handwritten signature in black ink, appearing to read 'B. R. Garbe', is written over a light grey rectangular background.

B. R. Garbe.  
Group Managing Director



## **GUARANTEE**

Subject to the conditions listed below, Vitalograph Ltd. and its associated companies, (hereinafter called the Company) guarantee to repair or at its opinion 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 authorise 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.

## BUTTONS AND ICONS USED IN COMPACT

The following buttons are used in the COMPACT:



... Return to the home screen



... Access the help files



... Recalls an existing subject from the database



... Enter the details of a new subject



... Perform a test session



... Print or view a test session, calibration log or report



... Access additional COMPACT functions



... Scroll through screens



... Access the configuration options



... Return to the previous screen without saving any changes made



... Brings you onto the next screen or logical step and saves any changes made



... Cancel a selection



... Perform an accuracy check



... Access the database management screen



... Gives information about the COMPACT software



... Perform a Post test



... Access the population group configuration screen



... Access the test configuration screen



... Access the unit configuration screen



... Access the print configuration screen



... Access the user configuration screen



... Perform a Single Breath Test



... Perform a CCS Test



... View the suggested Interpretation of the session results



... View the COPD risk



... View the COPD score



... Print COPD score



... View the lung age



... Trend last ten test sessions for current subject



... Show seventy-year trend for current subject



... Show the results for the next test



... Recalls an existing test session stored in the database



... Delete information from the database



... Create a new population group in the database



... Select test indices to be reported



... Incentive device used in the Single Breath Test of children



... Adjust the screen contrast



... Configure the sounds used



... Play the sound selected



... Adjust the sound volume



... Set sounds used to default



... Calibrate the touch screen



... Configure the date and time



... Enter comments/text



... Feed paper through the internal printer



... Create a new user

The following icons are used in the COMPACT:



Unit is ready to accept a blow



Subject's name



Subject's first name



Subject's last name



Subject I.D.



Population group



Date of birth

(Note: Also in format-  &  )



Male



Female



Height



Weight



Non-smoker



Smoker



Ex-smoker



Cigs. per day



Year started smoking



Year quit smoking



Graph tab when performing Single Breath Test



Graph tab for Closed Circuit test (Flow/Volume)



Graph tab for Closed Circuit test (Volume/Time)



Test session results tab



Subject history trend tab



Test session information tab



User I.D.



Syringe volume



Syringe serial number