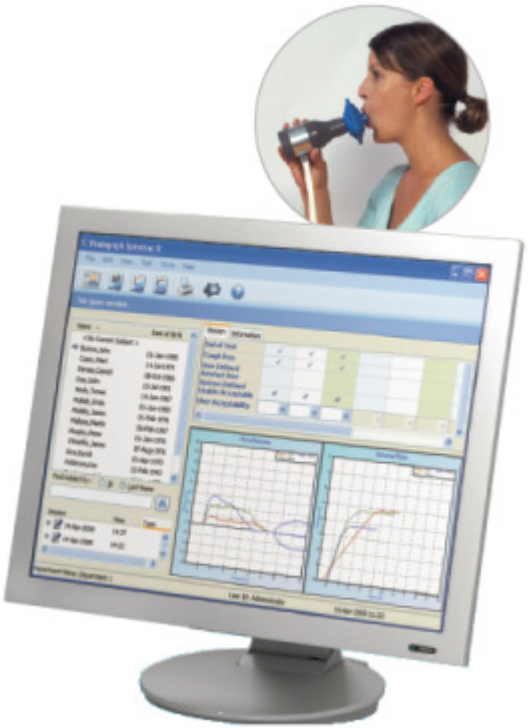
Vitalograph®
Spirotrac®

MODEL **7000**

User Manual



CE
0086

Vitalograph Ltd. Maids Moreton Buckingham MK18 1SW England Tel: +44 (0) 1280 827110 Fax: +44 (0) 1280 823302 e- mail: sales@vitalograph.co.uk	Vitalograph GmbH Jacobsenweg 12 22525 Hamburg Germany Tel: (040) 547391-0 Fax: (040) 547391-40 e-mail: info@vitalograph.de
Vitalograph Inc. 13310 West 99th Street Lenexa Kansas 66215 USA Tel: (913) 888 4221 Fax: (913) 888 4259 e-mail: vitcs@vitalograph.com	Vitalograph (Ireland) Ltd. Gort Road Business Park Ennis Co Clare Ireland Tel: (065) 6864100 Fax: (065) 6829289. e-mail: sales@vitalograph.ie

Internet: www.vitalograph.co.uk

Current Edition (Issue 3)
Cat. No. 07402

Table of Contents

DESCRIPTION OF THE VITALOGRAPH SPIROTRAC

Spirotrac is a Microsoft windows based computerized spirometry system designed for lung function testing in a variety of environments, e.g. occupational health centres, hospitals, pharmaceutical research centres, physicians' and GPs' offices, and wherever else advanced PC-based spirometry is required.

The application will interface with the Vitalograph Pneumotrac hardware. Spirotrac shall provide a system for adding and recalling subjects, testing their lung function, saving the results to its own database and printing reports.

To obtain help on a specific function within the application select a topic in the left panel, type a keyword in the index tab or search for a word in the search tab.

To launch the Help file:

1. Select **Contents** from the **Help** menu

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. Select **About** from the **Help** menu

Buttons and Icons Used in Spirotrac

The following buttons are visible on the main toolbar:

Create a New Subject

Perform VC Testing

Perform FVC Testing

Select Post Mode Testing

Print test reports

Send sessions to over-read

Perform an Accuracy Check on the Vitalograph Pneumotrac

Launch the Help file

FEATURES OF THE VITALOGRAPH SPIROTRAC

Vitalograph Spirotrac V offers a number of sophisticated features that further enhance the functionality of the acclaimed Spirotrac software. These features include:

- New intuitive user interface
- Automatic FEV_1 trending
- FVC single or multi-breath testing with auto-recognition
- New child incentive displays (optional)
- Improved test quality information, including test session grades, test repeatability and test acceptability
- Choice of interpretations (optional)
- Enforceable accuracy check facility
- Individual user logon by password
- Audit trail (optional)
- Configurable subject demographics
- Plug-in regression set architecture
- New spirometry report layouts
- Print preview facility
- Ability to change test acceptability
- Ability to add comments to any test session
- Communications port auto-detect feature for connected Vitalograph devices
- Data storage in Microsoft SQL Server 2005 Express edition
- Ability to view/print previous accuracy check/calibration update sessions
- Facility to print audit trail logs and accuracy logs
- Option to access database over a network
- Sending session information to over-read
- Compatibility with Windows operating systems
- Comprehensive subject demographic information
- Automatic storage of all test data
- Configurable spirometry reports
- Accuracy checking for Vitalograph Pneumotrac hardware
- Configured and printed spirometry reports
- ATS24 Waveforms
- GDT data interchange standard
- VC testing

- Post mode for bronchodilation testing

The new features offered by SpirotracV are in addition to the standard features offered by earlier versions of Spirotrac:

- Full Networked Database / Multi User support (via Microsoft SQL Server 2005)
- Comprehensive Network Database Management (for DB Admins)
- Subject Data Migration from Spirotrac 4
- Improved user interface(s)
- Improved testing functionality

GETTING THE VITALOGRAPH SPIROTRAC READY FOR USE

Loading the Spirotrac Software

NOTE:

- **Spirotrac must be installed by a User with Administrative privileges.**
- **To install a network version, install on the server first, then install on the client pc(s).**

To install Spirotrac, do the following:

1. Place the Spirotrac CD in the DVD/CD-ROM disk drive. After a moment, the installer application will automatically run.
2. When the installer starts click "**Install Spirotrac V**" to start the installation of Spirotrac.
3. Read the Licence Agreement and if you are satisfied with the terms agree to it. If you do not, the installation will not continue.
4. The Spirotrac set-up is displayed – click the **Next** button.
5. If necessary, make changes to the install location by selecting the Browse button. Click the **Next** button when finished.
6. The files are copied to the selected drive and directory. An error message is displayed if there is insufficient space on the drive. If this occurs, you should click on the **OK** button. Create space by deleting or backing up files and then start installing again from step 1.

7. A virtual PDF printer driver is installed onto the system. This allows the user to select this printer when printing, which allows the user to print to an Adobe Acrobat compatible PDF file.
8. A message is displayed on the screen when installation is completed. Click on the **Finish** button.
9. When the installation is complete, the program name appears in the 'START' menu under Start-> Programs menu -> Vitalograph ->Spirotrac V along with a Shortcut icon which is placed on the desktop.
10. Start the Spirotrac application and do the following:
    - Enter the licence key when prompted
    - Setup the database location as follows:
        - To set-up Spirotrac as a stand-alone application, select the option to create the database locally
        - To set-up Spirotrac using a network database, do the following:
            - (If current pc is database server pc) select the option to create the database locally
            - (If current pc is client pc) select the option to use an existing database, and enter the server name/instance of the database
    - Setup the Spirotrac System Administrator user when prompted. The id for this user will be 'Administrator' and the password which is case sensitive must be at least 6 characters in length.
    - You will have the option to set-up other users at this stage. To set-up another user, select the 'Add User' button or users can be added later from within the application if you wish, so select the 'Finish' button.
    - Next, you are prompted to log on to the SpirotracV application. (See Starting Spriotrac for the first time for next steps)

Note: Additional documentation is available on the CD as support. These can be found under the following headings on the installer: 'Release Notes', 'Spirometry Guidelines' and 'Other Manuals'.

Installing the Vitalograph Pneumotrac USB drivers

1. Make sure the Spirotrac CD is inserted in the CD/DVD drive of the PC. If not, insert it now. (**Note**: When the CD is inserted, the installation wizard will start. You can cancel this)

2. Connect one end of the USB cable into an available USB port on the PC
3. Connect to the other end of the USB cable into the Vitalograph Pneumotrac device
4. The PC will detect that new hardware has been connected and “New Hardware” installation wizard shall be displayed
5. Follow the default options on the screen until you are asked where to install your hardware from and choose “install the software automatically”
6. You may be presented with an information dialog in relation to Windows Logo checks. Choose “Continue Anyway” on this screen.
7. The USB Pneumotrac drivers will be installed at this point and you will be presented with a “Finish” screen. Click this button.
8. When you have clicked the “Finish” button, you will once again be presented with the same screen stating that “New Hardware” has been detected. This is because the USB Pneumotrac Device requires two hardware drivers. Follow steps 4 through 7 again. When you complete these steps, your USB Pneumotrac will be ready to use

Connecting the USB Vitalograph Pneumotrac to your PC

The following simple steps need to be carried out to get the Vitalograph Pneumotrac ready for use.

For safety, it is recommended that the PC is fully powered off before you start this procedure.

1. Plug one end of the USB cable into an available USB port at the back of the PC (usually marked with the  symbol).

2. Plug the other end of the USB cable into the USB port at the side of the Vitalograph Pneumotrac (marked with the  symbol).

If you connect additional equipment (not produced by Vitalograph) to the USB interface port, it must conform to VDE0750 Part 1-1 regulations and to your EN specifications, e.g. EN60950 for data equipment, EN60601 for medical equipment. Non medical equipment must be kept outside the patient environment i.e. any area in which intentional or unintentional contact between the patient and parts of the system, or some other persons touching parts of the system can occur. (Contact your distributor if you have any queries.)

3. Unwrap the white twin tubing from its packaging and connect one end to the Vitalograph Pneumotrac device. Ensure that the ribbed side of the tubing is connected to the ribbed half of the connector.

4. Unwrap the flowhead from its packaging and connect the other end of the twin tubing to it. Ensure that the ribbed side of the tubing is

connected to the blue tapping on the flowhead connector.

5. Take one of the flowhead filters from its packaging and place in the flowhead holder on the Vitalograph Pneumotrac device.

6. The Vitalograph Pneumotrac device is now ready for use.

7. The USB driver must be installed on the PC to begin testing. Refer to the USB driver instructions for details.

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 Pneumotrac 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.

Connecting the Serial Vitalograph Pneumotrac to your PC

The following simple steps need to be carried out to get the Vitalograph Pneumotrac ready for use.

For safety, it is recommended that the PC is fully powered off before you start this procedure.

1. Plug one end of the serial cable into an available serial port at the back of the PC (usually marked with the **10101** symbol). If the PC has a 25 pin serial port connector use a 9 pin to 25 pin port adapter.

2. Plug the other end of the serial cable into the serial port at the side of the Vitalograph Pneumotrac (marked with the 10101 symbol).

If you connect additional equipment (not produced by Vitalograph) to the serial interface port, it must conform to VDE0750 Part 1-1 regulations and to your EN specifications, e.g. EN60950 for data equipment, EN60601 for medical equipment. Non medical equipment must be kept outside the patient environment i.e. any area in which intentional or unintentional contact between the patient and parts of the system, or some other persons touching parts of the system can occur. (Contact your distributor if you have any queries.)

3. Unwrap the white twin tubing from its packaging and connect one end to the Vitalograph Pneumotrac device. Ensure that the ribbed side of the tubing is connected to the ribbed half of the connector.

4. Unwrap the flowhead from its packaging and connect the other end of the twin tubing to it. Ensure that the ribbed side of the tubing is connected to the blue tapping on the flowhead connector.

5. Take one of the flowhead filters from its packaging and place in the flowhead holder on the Vitalograph Pneumotrac device.

6. The Vitalograph Pneumotrac device is now ready for use.

Note*: This equipment may be affected by electromagnetic interference. Also other electrical equipment in the close vicinity may be affected by the Pneumotrac. If such effects are suspected either switch off the offending equipment or increase the distance between the affected equipment and that suspected of causing the interference, or shorten connecting leads.*

Starting Spirotrac for the first time

During the installation process an administrator user and password was set-up for the Spirotrac application. Once Spirotrac has been launched, further users may be created and added to the system. For details on how to add additional users, reference the Users section.
The application will prompt for the following details:
Institution details.
Department details.

Note: The user may select to cancel out of the set-up at any time. However, as the above details are required prior to launching the application, the application will not be launched until all the details are provided. Only then will the application actually launch.
Once, the application is launched, checking the configuration settings is recommended, to ensure that user preferences are set-up as required.

OPERATING THE VITALOGRAPH SPIROTRAC

Network Database Installation

- When SpirotracV version 1.02 is run for the 1st time the **Spirotrac V Setup Wizard** will launch. The wizard will prompt the User to supply Licence Key, Server & Database, User, Institution and Department details.
- The SpirotracV version 1.02 Licence Key must be entered on first use. You will find the Key printed on the back cover of the CD casing.
- Initially the user will be asked to select either a **Local Database** Installation or a **Networked Database** Installation.
- For a Local Installation, leave the default values present (localhost) and click 'Continue'.
- For a Networked Installation, select the 'Use a Networked Database' option. Enter the name or I.P. address of the SQL Server 2005 host. Enter the SQL Server 2005 Instance name if required (default SQLEXPRESS). ***Consult with your SQL Server Database Administrator for these settings***.
- If the Database already exists Spirotrac will simply connect to and use this Database.

- If the Database does not exist Spirotrac will create this Database automatically. The User must have the appropriate privileges to perform this action. ***Consult with your SQL Server Database Administrator for these privileges***.
- If a Database from Spirotrac version 1.01 exists, Spirotrac will automatically migrate the data to a new version 1.02 Database.
- The user will be prompted to supply the 'Administrator' password. This account should later be used to setup other SpirotracV users.
- The user will be prompted to add other users to SpirotracV (optional).
- The user will be prompted to supply details of the Institution.
- The user will be prompted to supply details of the Department.
- **Note: At any point during the Spirotrac V Setup Wizard the User may click the 'Setup Later' button. The Wizard will pick up from where it left off during next run.**

Start-up / Logon

Note: In order to use the application, Spirotrac V requires that the PC user adhere to one of the following:

- User must have full administrative rights on the PC, or
- User must be added to the SQLServer2005MSSQLUser group, or
- User must be added to the SQLServer's Security-Login with full read/write access to the SpirotracV database (for upgrades) and SpVDefault for Spirotrac Version 1.02.

Logging into Spirotrac

1. Users who have been successfully added to the Spirotrac software (reference the Users section) will have their own User ID and Password.
2. The logon screen will be presented on start-up, prompting for User ID and Password to be entered. For Network installations the Database field will be enabled allowing the user to select the server database.
3. The User ID will be pre-populated with the User ID of the last person who logged into the Spirotrac software application. If appropriate, enter your own User ID.

4. Enter your password and click the **OK** button, or press **Enter** on your keyboard.
5. If the login is successful (your user criteria is accepted by the system), you will be presented with the application desktop.
6. If the login is not successful (your user criteria is rejected by the system), you will be presented with the Login screen again.
7. If you wish to abort the login process at this stage, click on the **Cancel** button.

Application Lock (Autolock) / Unlock

Spirotrac will automatically lock after defined periods of inactivity (The default is 45 minutes). Only the currently logged on user, or the Administrator user can unlock Spirotrac.

1. Automatic application locking can be configured to different time intervals (see Configure Application Lock Timeout)
2. While the application is locked all active windows & dialogs will be hidden, they will be restored to their current state upon unlock.
3. To unlock the application enter User ID and Password in the Unlock screen and click **OK**.

Subject Management

Creating a Subject

1. Select **New-> Subject** in the File menu or click the new subject button on the main toolbar.
2. Enter details for each field as follows: -
   a) **Subject ID** - a unique number for each subject, this will be generated automatically but the user may change this ID if required. This field is mandatory. **Note**: To create a new subject, the Subject ID is mandatory. All other details are optional
   b) **Alternative Subject ID** - an alternative identifier for the subject. It is configurable as to whether this field is displayed or not (see Subject Data Configuration)
   c) **First Name** - the Subject's first name, can be up to 20 characters in length
   d) **Middle Name** - the Subject's middle name

e) **Last Name** - the Subject's last name, can be up to 20 characters in length
f) **Subject date of birth** (DD-MMM-YYYY)
g) **Gender** – the gender of the subject, can be male or female (drop down list)
h) **Height** – the height of the subject in either cm or inches, can be 3 numeric characters. Unit of measurement is user configurable (see Subject Data Configuration)
i) **Weight** - the weight of the subject in either kg or lbs. Unit of measurement is user configurable and also whether this field can be entered for Subject or not (see Subject Data Configuration)
j) **Population group** – drop down list with predicted values associated with each group. It is user configurable whether this field is entered for Subject's or not (see Subject Data Configuration)
k) **Smoking Information** - the Smoking status of the subject. This can be Smoker, Non-smoker or Ex-smoker via a drop down list
l) **Notes** – notes/comments can be entered for the subject

3. Click on the **OK** button to save this subject to the database.
4. Click on the **Cancel** button to discard new subject and return to the application desktop.

Editing a Subject

1. In order to edit a subject a user may: -
   a) Right click on the subject in the subject list on the left panel and select edit subject
   b) Select the subject from the subject list on the left panel and select the edit button in the subject demographics panel
   c) Select the subject in the subject list on the left panel and select the Subject Details from the Edit menu
2. The subject information is displayed. (See Creating a Subject for details on fields)
3. Click on the **OK** button to save the changes.
4. Click on the **Cancel** button to undo the changes and return to the application desktop.

Note: If the date of birth, gender, height or population group of the subject is changed, the predicted values for the subject shall be re-calculated.

Selecting/Viewing a Subject

1. Select the subject in the subject list on the left panel. The subject becomes the current subject. You may perform a Spirometry test on this subject, view his/her sessions, select a session for print and/or view his/her trend data.
2. The corresponding subject demographics appear for that subject, with any previously modified data appearing in green, and with all his/her sessions appearing in the lower left panel. **Note**: Click on  to expand tree and view sessions.
3. A trend of all the best FEV1 values from subject's sessions is displayed on the lower main panel.

Finding a Subject

A search facility is available on the main desktop for finding subjects.

1. Using the radio buttons, select to search for a subject by either ID or Last name
2. Enter the relevant search information in the space provided
3. Select the search button to begin the search.

Note*:* When searching by ID if subject with matching Subject ID is not found the application will search for a subject with a matching Alternative ID

Deleting a Subject

1. Select the Subject to be deleted from subject list.
2. Right-click this Subject and select **Delete Subject**
3. Select **Yes** to delete the subject or **No** to cancel.

Subject Data Setup

1. Select **Tools -> Options** from Main Menu and then select '**Subject Entry**'.
2. The user can configure the following: -

   a) **Unit of Height**: the user can select to enter height in cm or inches

   b) Enter **subject's weight**: the user can select to enter weight as part of subject demographics or not. When checkbox is ticked, weight can be entered/displayed/printed for subjects.

   c) **Unit of Weight**: the user can select to enter weight in kg or lbs

d) **Alternative Subject ID**: the user can select to enter an alternative subject number as part of subject demographics. When '*Display/Report On'*, this alternative number will be displayed/printed for the subject.

e) **Population Group**: the user can select to enter Population Group as part of subject demographics. When **Select Population Group for Subject** is ticked, then a Population Group can be selected for a subject, and therefore, displayed and printed. When it is not ticked, it will not be possible to select a population group for a subject.

3. Click on the **OK** button to save the settings or **Cancel** to ignore.
4. The user can choose to reset the Subject Data entry settings by selecting the **Reset Subject Settings** button.

Predicted Values

Population Group Setup

1. Select **Tools -> Options** from Main Menu and select **General**.
2. In the **Population Groups & Regression Sets** section, select the **Manage** button.
3. To add a new population group, do the following:
   - Select the **New** button, Enter the name and click OK
   - Select the corresponding Regression Set from the drop down list
   - Enter the correction factor (the % to multiply the predicted value by)
   - Select **OK** to save the new population group or **Cancel** to cancel.
4. To rename a population group, do the following:
   - Select the **Rename** button
   - Enter the new name
   - Select **OK** to save changes or **Cancel** to ignore
5. To Edit a population group, do the following:
   - Select the Population Group from the list
   - Select the new Regression Set from the drop down list
   - Enter the new correction factor
   - Select **OK** to save changes or **Cancel** to ignore
6. To Delete a population group, do the following:
   - Select the Population Group from the list

- Select the **Delete** button
- Select **Yes** to delete the population group or **No** to cancel

Spirometry Testing

Checks to Make before Performing VC, FVC and Post Tests

Before commencing a test routine, check that the options for testing are set up correctly as follows:

1. Check that the Pneumotrac device is connected correctly. (see Connecting the Vitalograph Pneumotrac to your PC)
2. Check that the correct device is selected:
   - Select **Tools** -> **Device**
   - Select the appropriate device from the list
3. Check that the accuracy of the device was checked recently.
4. Check that the parameters to be measured are selected as required:
   - Select **Tools** -> **Options** and then choose Parameters.
   - Select the parameters to be displayed/printed and click **OK**

   Note: All the results of tests are calculated and stored automatically so that the user can later recall a test and display any additional parameters which have been selected from this window.

   Note: The user can reset the parameter selection at any time by selecting the 'Reset Parameter List' button.
5. Check that the correct subject is selected.
6. Check that the correct posture is selected:
   - Select **Tools** -> **Options** from Main Menu and then select **General**.
   - Select the appropriate Posture from the drop down list and click **OK**

Note: When performing Spirometry testing, it is recommended by the joint International ATS/ERS standard on Spirometry that the subject be in a seated position for the duration of the test(s)

VC Testing

1. Select a subject by clicking on the Subject in the subject list on left hand side of main screen.
2. Once the required subject has been selected from the list, select **VC** from the **Test** menu or click on the VC test button
3. Wait for the **BLOW NOW** message to appear on screen
4. Read the following instructions to the patient so that testing is performed properly
    - Keep the flow-head away from your mouth.
    - Inhale as deeply as possible and insert the mouthpiece into your mouth, clamping it between your teeth.
    - Close your lips round the mouthpiece.
    - Exhale normally for as long as possible.
5. Again, wait for the 'BLOW NOW' message to appear on screen, before performing the next blow.
6. When all blows are complete, click on the **Return** button to return to the previous screen.

Performing FVC Testing

Testing may be done either in the sitting or standing position. The standing position may not be appropriate in some circumstances, such as in hospitals where many subjects may not be able to tolerate the standing position, especially when making forced manoeuvres. If the standing position is used, an appropriately shaped chair should be placed behind the subject so he/she can quickly and easily be eased into a sitting position if he/she becomes light-headed during the manoeuvres. The posture type must be selected prior to testing (see Checks to Make before Performing VC, FVC and Post Tests)

1. Select a subject by clicking on the Subject in the subject list on left hand side of main screen.
2. Once the required subject has been selected from the list, select FVC from the Test menu or click on the FVC test button
3. If the Pneumotrac is connected correctly, the correct COM port is selected, and the device is within temperature operating limits, the FVC test screen shall be displayed.
4. If the device is not within temperature, testing may still continue but results may not be valid. This will be indicated by displaying a warning message to the user.

5. If the test screen is left idle for two minutes or more, Spirotrac will suspend the test.
6. Wait for the 'BLOW NOW' message to appear on screen before beginning the test.
7. After each blow a quality summary window is displayed. The test acceptability and session quality for the test performed is displayed to the user (see Test Quality Information).
8. It is possible for the user to Accept or Reject the test at any time using the User Acceptability drop down list. Changing the acceptability of a test will automatically update the best test, reproducibility and quality information.
9. Session information, Quality information, Acceptability and Usability information can be viewed at any time during testing by selecting the relevant tab on the test screen. The Parameters tab contains the parameter values and also includes System Acceptability information and User Acceptability information. The Test QA tab contains information on the status of all test acceptability criteria for each test. The Info tab contains information about the overall session such as Session Grade information, Repeatability information, Session Comments and Interpretations.
10. The next test can be performed once the 'BLOW NOW' message re-appears on screen.
11. The maximum number of blows that a subject should perform in any one session is eight.
12. You may leave the test screen at any time by selecting **Return**. This brings you back to the main screen, but the test session remains open. Selecting the test button again returns you to the test screen, and testing can continue.
13. A test session will remain open until one of the following occurs, and at that point you will be prompted whether or not you wish to close the session:
    - Select a different subject
    - Select the Post mode button
    - Close Spirotrac

- Select to Edit Subject information
- Perform a calibration update
- Sending session(s) to over-read

Post Testing

1. Select a subject by clicking on the Subject in the subject list on left hand side of main screen.
2. Once the required subject has been selected from the list, select **Post** from the **Test** menu or click on the Post button.
3. A list of all previous FVC test sessions for that subject will be displayed.
4. Select the appropriate test session from the list and click **Select**. The post test session will be associated with this selected test session and the FVC test screen is displayed (see Performing FVC Testing)
5. Alternatively, when the list of all previous FVC test sessions is displayed, select **Cancel** to cancel Post testing and return to the main screen.

ATS Waveforms

ATS waveforms may be displayed to simulate the results of FVC testing by selecting values on the screen instead of performing physiological tests.

1. Check that the device is set at ATS Waveforms (**Tools** -> **Device** -> **ATS Waveforms**)
2. Select subject from the subject list.
3. Select **FVC** from the **Test** menu or click on the FVC test button.
4. Once the test screen is displayed, the user can select which ATS wave/curve to run from **ATS 24 Waveforms** menu item in test screen.
5. Click on the waveform number required for the test and the ATS test is performed.

Parameter Definition

VC	Slow Vital capacity (L)
FVC	Forced Vital capacity (L)
FEVn	Forced expiratory volume after n second(s) (L)
FEVn/FVC	Percentage FEVn of FVC (%)
FEV1 Ratio	Ratio of FEV1 versus the largest VC from either VC or FVC manoeuvre
PEF	Peak expiratory flow (L/sec or L/min)
FEF25-75	Maximal mid expiratory flow: the mean FEF in the time interval between 25% and

	75% of the FVC (L/sec)
FEF75-85	Forced late expiratory flow: the mean FEF in the time interval between 75% and 85% of the FVC (L/sec)
FIVC	Forced inspiratory vital capacity (L)
PIF	Peak inspiratory flow (L/sec or L/min)
FET	Forced expiratory time (s)
TV	Tidal Volume (L)
IC	Inspiratory Capacity (L)

Test Quality Information

After every test manoeuvre, a quality control window is displayed which is intended to increase or maintain maximum performance throughout a session. Two types of information will be displayed - acceptability information for that test and session reproducibility information for the session to date, as follows:

Test Acceptability

This section contains information on the acceptability of this single blow. The messages which may appear in this section and what they mean are outlined in the table below.

Message displayed	**Reason**
Slow start of Test	Looking at the measured value of either FEV6 (for blows at least 6 seconds long) or FVC (for blows less than 6 seconds long), the following is true, Either the measured value is greater than 0.15L and the extrapolated volume is greater than 5% of the measured value Or the measured value is less than or equal 0.15L and the extrapolated volume is greater than 0.15L
Min exhalation time not met	A longer test manoeuvre was expected, Either the subject is greater than 10 years of age and the test manoeuvre was less than 6 seconds long Or the subject is less than or equal to 10 years of age and that test manoeuvre was less than 3 seconds

	long
No expiratory flow plateau	The cumulative change in volume over any 1 second of the test manoeuvre was not less than 0.025L
Avoid coughing	After PEF was reached, a drop in the flow value of at least 50% and a recovery of at least 1L/s occurred within the first second of exhalation.

During FVC testing the test quality criteria information can be viewed by selecting the Test QA tab, as follows:

- A ✓ marks that the test passed the specific acceptability criteria.
- An ✗ indicates that the acceptability did not pass for this criteria.

Note: 'User Defined Artefact free' will remain blank until the User Acceptability on the Parameters tab is selected, it will be populated with a ✓ if 'Accept' is selected, or a ✗ if 'Reject' is selected.

Session Quality/Reproducability Information

This section contains information on the quality of the session so far. The messages which may appear in this section and what they mean are outlined in the table below.

Message displayed	Reason
FVC is not repeatable	The largest FVC and second largest FVC (or FEV6) from the acceptable blows in the current session vary by more than 0.15 L.
FEV1 is not repeatable	The largest FEV1 and the second largest FEV1 from the acceptable blows in the current session vary by more than 0.15L.

System Acceptability

The 'System Defined Usable/Acceptable' results are defined as follows:

- represents a curve which passed all test acceptability criteria
- represents a curve which passed 'Start of Test' and 'Artefact free' acceptability criteria only
- represents a curve which did not pass both the 'Start of Test' and 'Artefact free' acceptability criteria

A 'Usable' curve is any curve which passes the 'Start of Test' acceptability criteria and which is artefact free, i.e. no cough detected by system.

Note: If the user rejects a curve then that curve is no longer considered as a usable curve.

Best Test Criteria

All tests in a test session will be saved (including unacceptable tests).

The best test criteria is as follows: -

The highest FVC, FEV1 and PEF from acceptable tests. All other parameters shall be taken from the acceptable test with the largest FVC+FEV1 sum. If there are no acceptable tests unacceptable tests shall be used.

When performing a Post-test session, the best pre test is associated

with the Post test session.

Session Grades

Each test series can be graded in relation to its reproducibility between system usable manoeuvres. Grades are displayed in the session information tab. The following table describes each grade and its associated criteria:

Quality Grade	Criteria
A	At least 2 usable blows with the largest 2 FEV1 values within 100mL and largest 2 FVC/FEV6 values within 100mL Or At least 3 usable blows with the largest 2 FEV1 values within 150mL and largest 2 FVC/FEV6 values within 150mL
B	At least 2 usable manoeuvres, with the highest two of the FEV1 values matching between 101mL and 150mL
C	At least 2 usable manoeuvres, with the highest two FEV1 values matching between 151mL and 200mL
D	Only one usable manoeuvre, or more than one, but the FEV1 values match > 200mL
F	No usable manoeuvres

Incentive Device Setup

Spirotrac can be set to show a graphical incentive during FVC and VC testing. To setup the incentive device follow these steps:

1. Select **Tools -> Options -> Incentive**. The Incentive Device configuration screen is displayed.
2. To switch on the Incentive device ensure the **Show Incentives** check box is checked.
3. Likewise, to switch off the Incentive device un-check this.
4. Select the incentive device to be displayed from the **Current Incentive** drop down list.
5. Enter the **Target % of Predicted**. Valid values are 80% - 150%. This represents the percentage of the predicted volume of the lungs which must be reached for the incentive to play out

fully i.e. for birthday cake, this represents volume at which all candles will blow out.

6. Next, enter the **Target % of Best Test**. Valid values are 80% - 150%. This represents a percentage of the best FVC value of the tests done which must be reached for the incentive to play out fully. This may be used to encourage the child to try harder.
7. The user can change the opacity of the Incentive display window by editing the **Window Opacity** value. Valid values are 50%-100%.
8. The user can also re-set the incentive settings to the default installation at any stage by selecting the **Reset Incentive Device Settings** button.
9. Click on the **OK** button to save settings.
10. Click on the **Cancel** button to cancel.

Note: If the required subject information is not entered to calculate the predicted values, the incentive device will not be displayed.

Sending Sessions

Sending sessions to Over-Read

Spirotrac provides the ability to send FVC session data to an Over-Reader through two options:-

a) Send Sessions – which allows the user to select which sessions are to be sent
b) Send All Unsent – which sends all session data which have never been sent to any over-reader

To select sessions to send to over-read do the following:-

1. Select the subject whose session(s) are to be sent to over-read.
2. Select Send – Send Session(s) from the File Menu or click the Send Sessions to Over-Read button on the main toolbar
3. All FVC session(s) for the currently selected subject are listed, however, a different subject may be selected from the drop down list if required.
4. Select the session(s) to be sent from the list and then select the **Add selected session(s) to send list** button  .
5. To remove any session(s) from the send list, select the relevant session and then select the **Remove selected pending session(s) from send list** button  .

6. Once all session(s) for the subject(s) have been added to the send list, select the **Send** button to send the sessions or select the **Cancel** button to cancel.

To send all unsent sessions to over-read do the following:-

1. Select **Send** – **Send All Unsent…** from the File menu or click the **Send All Unsent Sessions** option from the send button on the main toolbar.
2. All unsent session(s) will be sent to over-read.

Viewing sent sessions

1. Select the subject whose sent session(s) are to be viewed.
2. Select **View** – **Sent Session(s)…** from the main menu.
3. All sent FVC sessions for that subject will be displayed.
4. To view sent sessions for another subject, select that subject from the drop down list.
5. Select the **Close** button to return.

Setup mail settings

In order to Send data to an Over-Reader, Spirotrac needs to be setup with a suitable mail server.

1. Select **Tools** – **Options** from the main menu and then select **Mail Setup**.
2. Enter the details required as follows:-
    a. **SMTP Server** – this is the mail server name with your Internet Service Provider (ISP).
    b. **SMTP Port** – this is the mail server port number with your Internet Service Provider (ISP), typically port 25, however this can be different.
    c. **Connection** – this is the dialup connection to establish during transmission, if required.
    d. **SMTP Username** – this is the user ID of your account with the ISP, if a login is required.
    e. **SMTP Password** – this is the user password of your account with the ISP, if a login is required.
    f. **Over-Read E-Mail Address** – this is the email address of the over-reader to which any session data is to be sent
3. A connections button is provided which will take the user to the System Dial-up connection manager.
4. A test button is provided to check your settings.

Accuracy Checking

Accuracy Checking in Spirotrac

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 system should never be outside accuracy limits unless the measuring device is damaged or in a fault condition. In this event, see the corresponding faultfinding 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%.

Routine user accuracy checking on the measuring equipment should be performed

- before the instrument has been dismantled
- after the instrument has been dismantled
- after cleaning
- if damage is suspected
- after annual maintenance checks
- after adjusting calibration
- if the flow-head has been dropped

The equipment used to perform the accuracy check should itself be certified and traceable to national or international standards. All measuring equipment should be checked for accuracy on an annual basis. Although it is not a specified requirement, a routine annual service on this equipment is strongly recommended.

Mandatory daily accuracy checking can be switched on and off as follows:

- In the **Tools** -> **Options** -> **General** tab.

- When this option is on, the user will not be able to proceed to testing until an accuracy check has been performed for that day.

Note:

- If it is the first time the Pneumotrac device has been used in the system the user must perform a check with this device before proceeding to FVC testing.
- It is recommended that the Vitalograph 3 Litre Syringe be used. This has an accuracy of +/-0.5%.

Checking Accuracy

Follow these steps to perform an accuracy check.

1. Attach the Vitalograph Pneumotrac device flow head to the precision syringe.
2. Select the **Accuracy Check** from the **Tools** menu. Alternatively select the **Accuracy Check button** on the main toolbar.
3. Enter the syringe reference and the syringe volume in L (1-9) in the dialog displayed.
4. Click on the **Check** button and a message shall appear prompting you to pump air through the flow head in order to ensure that the flowhead is at ambient temperature before an accuracy check is performed. Once you have pumped air through the flow head click **OK**.
5. Follow the instructions on the screen. Make sure the plunger is out fully and inject the syringe when prompted.
6. Press in the syringe with a smooth, firm stroke (not too slowly).
7. Follow the instructions on the screen and repeat step 5 and 6. Three repeatable syringe strokes are required.
8. If the accuracy is outside the limits it is suggested that you perform another check before updating the device.
9. If three consecutive strokes are not reproducible within 3%, an error message is displayed.
10. It is possible for the user to enter comments for an accuracy check on the results pop-up dialog.

11. It is possible to view and print the Accuracy Check results at the end of the procedure. To re-check the accuracy select the **Re-Check** button.

Calibration update

Follow these steps to perform a Calibration Update.

1. Attach the flowhead to the precision syringe.
2. Select the **Calibration Adjustment** from the **Tools** menu.
3. Perform steps 3-9 as per 'Checking Accuracy'.
4. If the accuracy is outside the limits the user is presented with the option to Adjust the calibration or not. Select ***Yes*** to adjust the calibration, Select ***No*** to go back to result screen where a re-check can be performed if desired.
5. If user selects to perform a Re-Check, step 3 (3-9 as per 'Checking Accuracy') will be performed again but this time the user will not be prompted to re-check if a calibration adjustment is recommended.
6. If three consecutive strokes are reproducible within 3%, but the overall % difference is greater than 25% the user shall not be allowed adjust the calibration. This may be as a result of the following:
   - Faulty equipment
   - Faulty technique
7. Is it possible for the user to enter comments on the results pop-up dialog.
8. The user may view and print the results at the end of the procedure.

Viewing/Printing accuracy log

1. Spirotrac maintains an accuracy check log.
2. The accuracy check Log is updated each time that an accuracy check is performed with the Pneumotrac in Spirotrac.
3. Select the Accuracy Check Log from the View menu.
4. You will be prompted to select the device ID from a drop down list, or alternatively, select **All Devices** to view the entire accuracy log.
5. A screen is displayed with the following information:
   - Date/Time.
   - Volume that the device measured.
   - Percentage difference from syringe volume.

- If the accuracy was updated or not.
- User ID – the user who performed the check.
- Temperature that accuracy check was performed.

6. The following extra information is shown when the individual accuracy check is selected.
    - User ID – as above.
    - Device ID – the serial number of the device.
    - The device type
    - Syringe volume
    - Syringe reference
    - User comment if the device was updated.
7. The log may be filtered by User, device serial number, the date/ time of the accuracy check. To remove all filters and show all entries click the **Show All** entries button.
8. Select the Report icon to print the accuracy log.
9. You may view an individual accuracy check and flow volume curves by double clicking on an individual check or selecting one in the list and clicking on the **View** button. The following window shall be displayed. The accuracy check results may be printed by selecting the **Report** button.

Institute and Department

Viewing Institution or Department Details

1. Select **Institution Details** or **Current Department** in the **View** menu.
2. The institution or department information will be displayed.
3. Modifications will not be allowed here.
4. Click on the **OK** button when finished.

Editing Institution or Department Details

1. In order to edit institution or department details, select **Institution Details** or **Department Details** in the **Edit** menu.
2. The institution or department information will be displayed.
3. Make the changes required. (any non-editable fields will be greyed out)
4. Select **OK** to save changes or **Cancel** to ignore changes.

Department Management

The Institute can have multiple Departments, which are managed through the 'Department Management' screen.

1. Select **Tools** -> **Department Management**.
2. To add a new department, select **New,** enter department details and then press the **OK** button
3. To switch to another department, select the department name from list and then press **Select** button. When prompted for confirmation, select **Yes** to switch departments or **No** to keep the current department active.
4. Click on the **Close** button to return to the main screen.

Audit Trail

Audit Trail Codes

Note: The user will only be prompted to enter a reason for a change on versions of the software which include audit trail activities and where 'User Annotation' below is indicated with a 'Yes'

Activity Code	Activity Description	System Annotation	User Annotation
AC01	User Logon		No
AC02	User Logoff /Application exit	Switch User *only when user is logged off due to a switch in user*	No
AC03	Institute Create	*Institute ID*	No
AC04	Institute Edit	*Institute Name*, *Field modified*: From<*previous value*> To <*updated value*>	No
AC05	Department Create	*Department Name*	No
AC06	Department Edit	*Department Name*, *Field name modified*: From<*previous value*> To <*updated value*>	Yes
AC07	Subject Create	Subject ID *Subject ID*	No
AC08	Subject Edit	*Subject ID,* *Field name modified*: From<*previous value*> To	Yes

		<updated value>	
AC09	Subject Delete	Subject Number*: Subject ID*	Yes
AC10	User Create	User ID=*ID of new user*	No
AC11	User Edit	*User ID*, <Password Change>	Yes
AC12	User Delete	User ID=*ID of deleted user*	Yes
AC14	Session Create	Subject ID=*Subject ID, Session Type*	No
AC15	Session Edit.	Subject ID=*Subject ID,* Session=*Session Date/Time Field modified* From<*previous value*> To <*updated value*>	Yes
AC16	Calibration Update	*Device Name* Device ID=*device serial number*	Yes
AC17	Add Population Group	<Regression Set Map, Population Group Name: *New Population Groups Name*, Regression Set: *Regression Set Name*, Correction Factor: *Correction Factor*>	No
AC18	Edit Population Group	*Field modified* From <*previous value*> To <*updated value*>	Yes
AC19	Delete Population Group	<Regression Set Map*,* Population Group Name*: name of the deleted population group,* Regression Set*: name of the regression set the deleted population group was mapped to,* Correction Factor*: the correction factor of the deleted population group*>	Yes
AC21	Date/Time Change		No
AC20	Software Update		No

AC22	Test Performed Outside Temp	Subject ID=*Subject ID,* Session=*Session Date/Time*	No
AC23	Calibration Update Outside Temp	Pneumotrac Device ID=*device serial number*	Yes
AC24	Manual Test Temperature Update	Temperature modified From <previous value> To <updated value>	No
AC25	Manual Cal/Acc Temperature Update	Temperature modified From <previous value> To <updated value>	No

Viewing/Printing The Audit Trail

Spirotrac records an entry in an audit trail each time certain events occur within the application. For a list of these events see Audit Trail Codes. All Users can view and print reports of the Audit Trail. **Note**: This only applies to versions of the software that include this functionality.

1. Select **Audit Trail** from the **View** menu.
2. All entries are sorted by date/time initially. The User can change the sort order by clicking any of the column headers.
3. The following information is shown:
   a. User ID – the user who performed this action.
   b. Date/Time - when the action was performed.
   c. Annotation Code – the type of action performed. (AC code)
   d. System Annotation – details of the change will be recorded by Spirotrac e.g. previous and new values etc.
   e. User Annotation – the comment the user entered at the time of the change if required.
4. The following extra information is shown for individually selected audit entries:

a. Annotation Type – a description of this type of annotation record, e.g. User Logon etc.
b. System Annotation – as above.
c. User Annotation – as above.

5. The Entries can be filtered by User  , Date  and/or Annotation Type  . Click any of the corresponding filter buttons and enter your criteria. The matching records will automatically be shown. To remove all filters and show all entries click the **Show All** entries button  .
6. The current entries can be printed by clicking the **Report** button  . **Note**: Only the entries displayed on screen will be printed i.e. if data is filtered by a user ID, then only the entries belonging to that user id will be printed on the report.

Printing

Printer Setup

Spirotrac offers a facility for printing various reports such as audit trail reports, accuracy log reports, trend reports and test session reports. Spirotrac shall save the current selected printer and it shall be possible to change printer setup from within the application.

1. Select **Printer Setup** from the **File** menu.
2. Select the desired printer and click **OK**

Report configuration

Spirotrac provides the user with the option to configure reports as follows:

1. Select ***Tools -> Options*** and then ***Reports***.
2. The user can enter/change the headings to appear on VC/FVC reports (Report Header) and Post Test Reports (Post Report Header)
3. The user can select whether the application will print spirometry reports in full, **Full Report** format, or limit them to one page, **One Page Report** format.

4. When the **Full Report** is selected, the user can configure which tests will be printed on the report. The following print options are available:
   a. **Best Test Only** - Print the ATS/ERS Best Test only
   b. **Best 3 Tests** - Print the best three tests from the session
   c. **All Tests** - Print all tests from the session
5. An Economode option is available for selection. When selected, all test session reports printed will have any shaded areas removed.
6. The user can choose to reset the Report configuration settings by selecting the **Reset Report Settings** button.
7. Select **OK** to save change or **Cancel** to discard.

Note: When the **One Page Report** is printed, a default list of parameters is printed regardless of the parameters selected.

Printing a Test Report.

To print a test report for any test session do the following:

1. Select the Subject to which the test session belongs.
2. Select the session to be printed
3. Select **File** -> **Report** -> **Test Report** OR alternatively select the Print button

Printing a Trend Report.

To print a Trend Report for a subject do the following:

1. Select the Subject to view the Trend Graph.
2. Select **File** -> **Report** -> **Trend Report**

Users

User Management

Spirotrac can have multiple Users that are managed through the 'User Management' screen.

1. Select **Tools** -> **User Management**.
2. A dialog is displayed, listing all the users available on the system, with the current user highlighted in Bold
3. The following actions are available:
   a. Add a new user
   b. Edit user password
   c. Delete an existing user
4. Click on the **Close** button to return to the main screen.

User Preferences

The following information is available to the user for configuration by selecting **Options** from the Tools menu:

1. Subject data information settings
    - i Data to be entered for a subject (see Subject Data Setup)
    - ii Population Group configuration (see Population Group Setup)
2. Spirometry Testing settings (see Checks to Make before Performing VC, FVC and Post Tests)
    - i Parameter Selection Subject posture during testing
    - ii Session comment settings
    - iii Incentive Device settings (see Incentive Device Setup)
    - iv Device Selection
3. Accuracy Check settings. (Check the 'Perform Accuracy Check Daily' checkbox to enforce an accuracy check each day before testing can be performed)
4. Security settings
    - i Automatic Application Lock settings (For 'Lock application after', select the number of minutes from the drop down list)
    - ii Password expiration settings (For 'Expire passwords after', select the number of minutes from the drop down list)

Fault Finding Guide

Problem Fault Symptoms:	• Not measuring flow
Possible Causes: (In probable order)	• Ensure tubing is connected correctly. Ribbed side of the tubing should be connected to the ribbed half of the connector on the Vitalograph Pneumotrac

Problem Fault Symptoms:	• Incorrect or no volume measurements
Possible Causes: (In probable order)	• Ensure tubing is connected correctly. Ribbed side of the tubing should be connected to the ribbed half of the connector on the Vitalograph Pneumotrac • Ensure that the connectors are clear of

	obstruction or dirt and that they are inserted fully • Ensure the tubing is not kinked or squeezed

Problem Fault Symptoms:	• Excessive calibration drift
Possible Causes: (In probable order)	• Clean the flow head thoroughly • Contact the nearest dealer for replacement

Problem Fault Symptoms:	• Test performed but does not show on screen
Possible Causes: (In probable order)	• Ensure correct device is selected from Tools->Device • Ensure device is connected to PC correctly • Ensure tubing is connected between flow-head and device correctly (same colour connector at both ends).

Problem Fault Symptoms:	• Report does not print all tests • Report does not print some parameters
Possible Causes: (In probable order)	• Ensure the correct report settings are set-up in Tools-Options-Reports • Ensure the parameters you require are selected from Tools-Options-Parameters NOTE: If a particular parameter is selected but has no measurement for any test then it will not appear on the printout

Problem Fault Symptoms:	• Communication error message appears when entering the Test screen, the Accuracy Check screen or the Calibration Update screen
Possible Causes: (In probable order)	• Ensure that the Vitalograph Pneumotrac device is attached correctly

Problem Fault Symptoms:	• Accuracy check variations > +/- 3%

Possible Causes: (In probable order)	• Recheck Calibration with reference to section Checking Accuracy • Was the correct syringe volume entered? • Ensure that the tubing connectors are clear of obstruction or dirt and that they are inserted fully • Ensure the tubing is not kinked or squeezed • Ensure flow-head is clean

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 Now' prompt appears. • Return to Main Menu and re-enter the test routine

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.

TECHNICAL SPECIFICATIONS

Product	Vitalograph Spirotrac
Model	7000
Flow detection principle	Fleisch type pneumotachograph
Maximum test duration	45 seconds
Maximum displayed volume	10L
Volume accuracy	*±3%*
Flow accuracy when operated in operating	*±10%*

temperature range conditions	
Operating temperature range	ATS/ERS limits: 17–37ºC Design limits: 10–40ºC
Parameters measured	Varies by country
Note: All values displayed by the Vitalograph Spirotrac are expressed as BTPS values.	

FDA NOTICE

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

GUARANTEE

Vitalograph® Guarantee

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

The conditions of this guarantee are:-

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

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