Vitalograph®

# Spirotrac 6

MODEL 7000


## Instructions for Use

EN

## Vitalograph Branch Addresses

**Vitalograph Ltd, UK**
Maids Moreton, Buckingham
MK18 1SW
England
**Tel:** 01280 827110
**Fax:** 01280 823302
**E-mail:** sales@vitalograph.co.uk
www.vitalograph.com
*Technical Support*
**Tel:** 01280 827177
**Email:** technical.support@vitalograph.co.uk

**Vitalograph GmbH**
Rellinger Straße 64a
D-20257 Hamburg
Germany
**Tel:** +49 40 547391-0
**Fax:** +49 40 547391-40
E-mail: info@vitalograph.de
www.vitalograph.com
*Technical Support*
**Telefon:** +49 40 547391-14
**E-mail:** technical.support@vitalograph.de

**Vitalograph (Ireland) Ltd**
Gort Road Business Park
Ennis, Co Clare, V95 HFT4
Ireland
**Tel:** +353 65 6864100
**Fax:** +353 65 6829289
**E-mail:** sales@vitalograph.ie
www.vitalograph.com
*Technical Support*
**Tel:** +353 65 6864111
**Email:** technical.support@vitalograph.ie

**Vitalograph Ltd, International**
Maids Moreton, Buckingham
MK18 1SW
England
**Tel:** +44 1280 827120
**Fax:** +44 1280 823302
**E-mail:** sales@vitalograph.co.uk
www.vitalograph.com
*Technical Support*
**Tel:** +353 65 6864111
**Email:** technical.support@vitalograph.ie

**Vitalograph Inc.**
13310 West 99th Street
Lenexa, Kansas, 66215
USA
**Toll Free:** 800 255 6626
**Tel:** (913) 730 3200
**Fax:** (913) 730 3232
**E-mail:** contact@vitalograph.com
www.vitalograph.com
*Technical Support*
**Tel:** (913) 730-3205
**Email:** technical.support@vitalograph.com


Current Edition (Issue 15, 18-Dec-2023)
Cat. No. 07790

EN

## Contents

EN

EN

# 1. Indications for Use

The Vitalograph Spirotrac Model 7000 is a PC-based software application intended to be used as a spirometer or connect to compatible Vitalograph or third party devices to acquire, view, store and print the device output.
The product is designed for use on adults and paediatrics, 5 years and older, in a variety of professional healthcare environments, e.g. primary care, hospitals and occupational health centres under the supervision of a healthcare provider.

# 2. Contraindications, Warnings, Precautions and Adverse Reactions

1. No modification of this equipment is allowed. Any unauthorised changes to the Vitalograph device may compromise product safety and/or data and as such Vitalograph cannot be held responsible and the device will no longer be supported.
2. The Vitalograph device is not designed as a sterile device. Always follow the safety guidelines given by the manufacturer of cleaning and disinfectant chemicals.
3. For the device to be used as intended, there is no requirement to clean the supporting computer. If cleaning is required to remove any visible soiling, this should be done as per the computer manufacturer's instructions.
4. Vitalograph intends that a new Bacterial Viral Filter (BVF™) be used for every subject to prevent cross contamination. Using a new BVF provides a significant level of protection of the subject, the device and the user against cross contamination during spirometry manoeuvres. A BVF is for single use only. With the BVF fitted, the flowhead can be left on the desk adjacent to the device.
5. Spirometry may support or exclude diagnosis, but it cannot make one.
6. When using the Vitalograph device ensure that the flowhead connecting tube is not pinched or trapped as spirometry results may appear to be inverted.
7. Take care not to block the mouthpiece with tongue or teeth during testing. A 'spitting' action or cough will give false readings.
8. Subject fatigue may occur during spirometry testing depending on the subject's characteristics e.g., age, health status. For safety reasons, testing should be preferably done in the sitting position, using a chair with arms and without wheels. Subject may also take a break between tests.
9. All values displayed are expressed as BTPS values.
10. Time zero is determined using the back-extrapolated method, from the steepest part of the curve.
11. All spirometry standards recommend checking the calibration of lung function measuring devices daily with a 3-L syringe to validate that the instrument is measuring accurately. Vitalograph Spirotrac should never be outside calibration limits. Calibration should be checked after cleaning or disassembling the spirometer for any reason, after adjusting calibration, or if the flowhead or device has been dropped.
12. Service and repairs should be carried out only by the manufacturer or by Service Agents specifically approved by Vitalograph.
13. Maintenance must not be performed while the device is in use by a subject.
14. Use of accessories and cables other than those specified or provided by Vitalograph for this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of the device and result in improper operation.
15. Non-medical equipment must be kept outside the subject environment i.e., any area in which intentional or unintentional contact between the subject and parts of the system, or some other persons touching part of the system, can occur.
16. The applied part is the flowhead. This along with the BVF, are the contact points for the subject during a spirometry session. There are no adverse effects if the subject comes into contact with any other part of the device.

## 2.1. Cybersecurity Considerations

***Note:*** *Vitalograph commits to providing software that is virus-free. Vitalograph assumes no liability for the* security of customer computer systems. Any computer connected to the local area network {LAN} or internet is at risk of the system being compromised. Vitalograph recommends that customers take appropriate measures to mitigate such risk including installation and maintenance of anti-virus software and firewall(s) on ITsystems to prevent intrusion and protect those systems, in line with customer's internal IT policies

### 2.1.1. Specification

The Vitalograph Spirotrac device is a software application and as such provides no physical communication endpoints for data transmission. Each component of the software is reliant on the target system providing the necessary physical communication ports to fulfil any communication requirements. This includes test data transmission over USB and Bluetooth and remote data transmission over WIFI or Ethernet. Responsibility for security controls on the underlying operating system and physical communication infrastructure is outside the scope of the application.
The Spirotrac application itself will lock after 15 minutes of inactivity. If the user enters their password incorrectly 3 times the application will not allow any further attempts for 15 minutes.
Backups are created and stored on the primary system drive. These backups are not encrypted but Personal Identifiable Information (PII) is encrypted within the database and backups are compressed

EN

into a non- readable format for transport or transmission to other media or sites. Control over the security of the media on which backups are stored is the responsibility of the end user and outside the scope of the application.

#### 2.1.2. Security Recommendations

When using Spirotrac on a PC it is recommended that the PC has the following cybersecurity in place:

- Up to date Operating System: ensure that the Operating System is configured for automatic update for security patches and has all the latest patches applied.
- Antivirus/antimalware: ensure that the PC has an antivirus or antimalware application installed and that all virus definitions are in place.
- Secure Login: ensure that the PC is password protected via industry standard user access controls via active directory or other methods.
- Firewall: if the PC is connected to the internet ensure a firewall or equivalent protection is in place to protect against unauthorised external access.

## 3. Main Components of the Vitalograph Spirotrac

The main components are:

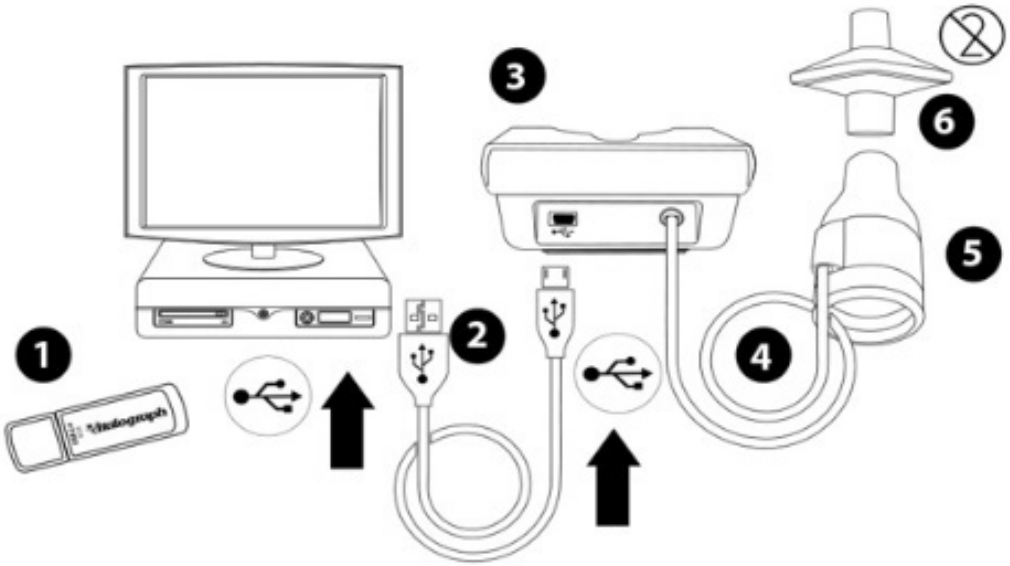



*Figure 1 Main components of Vitalograph Spirotrac System*

Note: Computer not supplied
Note: Both the Vitalograph Compact and Pneumotrac utilize Spirotrac software. All instructions in this IFU for the Pneumotrac device apply also to the Compact device

| | |
|---|---|
| 1 | USB Flash Drive containing Spirotrac, Utilities and manuals |
| 2 | USB Cable |
| 3 | Pneumotrac Base |
| 4 | Flowhead Connection Tubing |
| 5 | Flowhead |
| 6 | Bacterial Viral Filter (BVF) |

### 3.1. Features of Vitalograph Spirotrac

The features are:

- Spirometry test types
  - VC (base and post)
  - FVC (base and post)
  - Challenge Testing (Mannitol and Methacholine Protocols)
- ECG measurement
- Respiratory Muscle Strength test types
  - MIP
  - MEP
  - SNIP
  - PCF
  - MVV
- Oscillometry
- FeNO

- Configurable trend of results including tabular data export option
- ATS/ERS 2019 test quality information, including test session grades, test repeatability and test acceptability
- ATS/ERS 2021 Bronchodilator Response for post testing
- Audit Trail
- Configurable Subject Demographics
- Configurable report templates
- Animated Incentives
- EMR systems integration via HL7 and GDT using Vitalograph Connect
- In-App software updates
- Integration with ArtiQ services
- Integration with Active Directory
- Download results from Vitalograph In2itive device
- Download results from Vitalograph Alpha device
- Database Management – including backup and restore functions and ability to configure current database
- Manual Entry of SpO2 values
- Correct the subject demographics of historic assessments
- Race neutral predicted set (GLI Global)

### 3.2. Compatible Devices

- Pneumotrac
- Pnuemotrac RMS
- BT-12 ECG
- Alpha
- In2itive
- Tremoflo C-100
- Niox Vero

## 4. Setting Up Vitalograph Spirotrac

### 4.1. Installing Spirotrac on a PC

***Note:*** *Spirotrac must be installed by a user with Administrative privileges on the PC refer to Technical Spec for minimum PC requirements.*

To install Spirotrac:

1. Insert USB Flash Drive containing Spirotrac into PC.
2. Browse media contents via File Explorer/This PC and run Setup.
3. Follow onscreen instructions. For first time installation, some pre-requisites (e.g. SQL Server) will install. (This may require a restart)

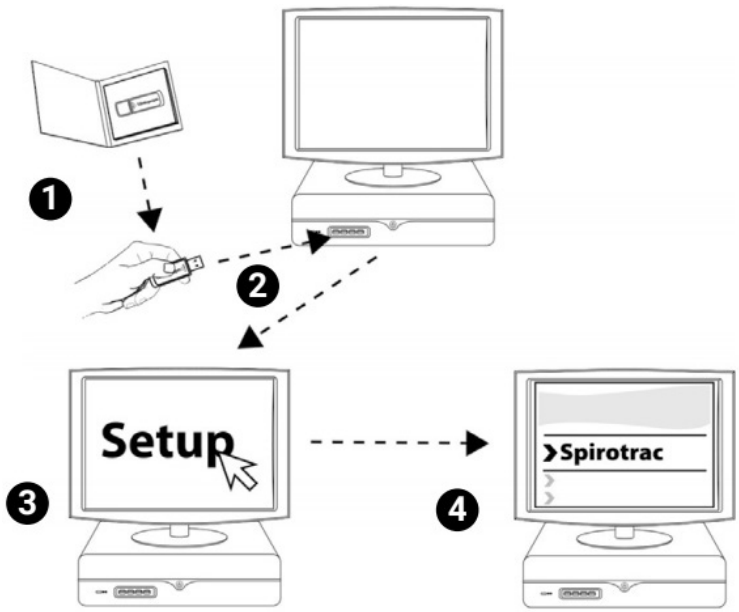



*Figure 2: Setting up Spirotrac*

### 4.2. Starting Spirotrac

Double-click the Spirotrac 6 application shortcut on the desktop *or* select Spirotrac 6 from the Start menu.

EN

#### 4.2.1. Setup

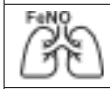
1. When starting Spirotrac for the first time, you must choose a database. To select a different database in the future, refer to Section 8.7
2. For use with a local database, select *Default Database.*
3. For use with a network database:
   ***Note:*** *Consult your SQL Server Database Administrator before setup.*
   a. The network database must already be setup and made available for Spirotrac to use, refer to Section 10.3.1 to create database.
   b. When network database is available, Select *Custom Database.*
   c. Select and enter network server and database connection details. *Note*: Consult the SQL Server Database Administrator for settings.
4. Enter Site information and setup your Administrator user. This account will later be used to setup other Spirotrac users, refer to Section 8.5
5. After Login, the main dashboard displays.

## 5. Operating Instructions

### 5.1. Buttons and Icons used in Vitalograph Spirotrac

Spirotrac buttons/icons

| Icon | Description |
|---|---|
|  | Home |
|  | Settings |
|  | Report Templates e.g., configure the content reported on the FVC Base Report, or configure the batch of sessions to be included in the report |
|  | Access to Logs e.g., Audit Log, Device Calibration Logs |
|  | Instructions for Use (IFU) |
|  | About Box and Session Information |
|  | Lock |
|  | Log Off |
|  | Exit |
|  | Activate Software License |
|  | Search e.g., Subject Search |
|  | Create/Add e.g., create a subject or create new database |
|  | Edit e.g., edit subject |
|  | Notes/Comments e.g., View or Subject Notes, View or Add Session Notes/Comments |
|  | Trend e.g., View and configure Subject Trend |
|  | Test Exit |
|  | Print |

| | |
|---|---|
|  | Filter e.g., filter the tests displayed on the graph |
|  | Enlarge |
|  | Record ECG trace |
|  | Stop ECG trace |
|   | Vital Capacity |
|   | Forced Vital Capacity |
|  | Challenge Testing |
|   | Peak Cough Flow |
|  | Electrocardiogram |
|   | Maximal Inspiratory Pressure |
|   | Maximal Expiratory Pressure |
|   | Sniff Nasal Inspiratory Pressure |
|   | MVV Testing |
|  | Oscillometry |
|  | Pulse Oximetry |
|   | FeNO |
|  | In2itive/Alpha Integration |
|  | Quality parameters in FVC assessment: FET, BEV, FEV/FVC, Text, tRise, tHes, EOTV |
|  | Displays the details of the corresponding field while pressed e.g., password |
|  | ArtiQ Dashboard |

### 5.2. Main Dashboard

The main functions from the dashboard:

| Function | Description |
|---|---|
| Home | Return to main dashboard |
| Settings | Access settings area of Spirotrac |
| Reports | Access and configure report settings |
| Logs | Access to audit trail and calibration log |
| Help | View IFU |

EN

| | |
|---|---|
| About | View software information and contact details |
| Lock | Lock the application via Exit/Lock |
| Log Off | Log off from the application via Exit/Lock |
| Exit | Shut down the application via Exit/Lock |
| License | Allows registration of software to unlock all features |

## 5.3. Subject Management

### 5.3.1. Searching for Subjects

1. On main dashboard, select Search icon  from the toolbar (at top of screen).
2. In Find Subject field, type in subject name or subject ID. To search by additional fields, select the Advanced button.
3. A list of subjects who match the search criteria will display.
4. Double-click the required subject from the list. The subject is now active.

### 5.3.2. Creating Subjects

1. On main dashboard, select Create icon  from the toolbar.
2. Enter subject details. Required subject attributes can be set in Subject Settings, refer to Section 8.1
   ***Note:*** *if spirometry predicted values are required then the following attributes must be set:*
   a. Date of Birth
   b. Height
   c. Sex at Birth
   d. Population Group
3. Select Save. The subject is now saved to the database and is active.
4. To create a new subject, the Subject ID is mandatory. Subject ID can be generated automatically by the software or entered manually. Swedish and Norwegian ID formats are supported in the software. To choose your preferred Subject ID option, refer to Section 8.1

### 5.3.3. Editing Subjects

An active subject may be edited.

1. Select a subject, refer to Section 5.3.1
2. Select *Edit* icon  .
3. Modify the relevant detail.
4. Select *Save*.

### 5.3.4. Subject Notes

Notes may be added to an active subject.

1. Select a subject, refer to Section 5.3.1
2. Select Notes icon 
3. Select Create icon + .
4. Enter note text in the note field.
5. If enabled, an attachment may be added with the note, refer to Section 8.1
6. Select Save.

   Previously saved notes may be edited and/or deleted: Select the note and select Create or Delete button. Follow the on-screen instructions.

### 5.3.5. Subject Trend

Trending of results can be displayed and printed for an active subject.

1. Select a subject, refer to Section 5.3.1
2. Select *Trend* icon  .
3. A trend view of subject's results displays, including both a graph and tabular view
4. Select *Edit* button to configure the trend. The following are configurable: Parameters and Date Range.
5. Select Export icon on the Table tab to export the trend results to csv.
6. To exit Trending, click outside the Subject Trend window.
   ***Note:*** *To unlock this feature, please register your software, refer to Section 10.4*

### 5.3.6. Editing Session Demographics

Historical session demographics can be corrected.

1. Select to edit a subject , refer to Section 5.3.3
2. Modify the relevant information, if required.
3. Select Apply these changes to Previous Assessments and click Save..
4. Find the required assessment and select Update.
5. Select the field(s) to be updated and select Save.
6. When all required assessments have been updated, Select Finish.

EN

#### 5.3.7. Deleting Subjects

A subject along with their testand all associated data may be deleted from the database .

1. Select a subject, refer to Section 5.3.1
2. Select *Edit* icon .
3. Select *Delete Subject*.
4. Select OK to confirm and enter user credentials to complete the deletion of the selected subject.

***Note:*** *Deleting information is permanent and cannot be retrieved.*

## 6. Testing using Spirotrac

### 6.1. Spirometry Testing

Spirotrac supports the following test types:

- VC Test (base and post)
- FVC Test (base and post)
- PCF Test

Before starting a test session:

1. Connect the Vitalograph spirometer device correctly, see relevant device IFU.
2. Ensure that device calibration was checked recently, refer to Section 7.1.1
3. Wash hands (operator and subject).
4. For optimal protection fit a new Bacterial Viral Filter (BVF) to the flowhead for each test subject. The use of a disposable noseclip is recommended.
5. Instruct and demonstrate the test.

#### 6.1.1. Conducting a Spirometry Test

Subject may be tested in either a sitting or standing position. If the standing position is used, an appropriately shaped chair should be placed behind the subject so they can quickly and easily move into a seated position if they become light-headed during manoeuvres.

1. Select a subject and ensure the required demographic information is entered:
   a. To select a subject, refer to Section 5.3.1
   b. To view subject demographics, select *VIEW PROFILE*.
   c. To edit subject demographics, select *Edit* icon.
2. Select *Start Test*.
3. Choose test type. For Post testing, select a baseline test to map against when prompted.
4. If first time use, select your spirometry device from the list of detected devices shown by Spirotrac. Refer to Section 7.2 for switching device.
5. Test screen opens. Select *Start Test*.
6. Carefully instruct and coach the subject. Commence test when *Blow Now* icon appears .
   a. Refer to Section 6.1.1.1 for VC guidelines.
   b. Refer to Section 6.1.1.2 for FVC guidelines.
   c. Refer to Section 6.1.1.3 for PCF guidelines.
7. Test automatically ends when the software detects no flow for 3 seconds. To end the test manually select Test End icon or spacebar.
   ***Note:*** *To disable this automatic end of test for FVC and VC sessions, refer to Section 8.2.1 and 8.2.2*
8. Review test quality information where applicable and choose the appropriate action.
   a. For FVC tests, select Edit to change the acceptability associated with FEV1 and FVC values as required. This can also be changed at any time from the quality tab.
9. If further tests are required in this session, repeat steps 6 – 9 (refer to Section 2 re Subject Fatigue).
10. Test results in the session are available in the information panel. Other information includes:
    a. Session quality: a summary of test quality for each test in the session to date. Refer to Section 6.1.3
    b. Analysis: includes repeatability and reference information depending on the test type and settings. For test settings refer to Section 6.1.4
11. Test graphs in the session are available in the graph panel. To filter graph tests, refer to Section 6.1.6 To attach session notes/comments to the current session. Refer to Section 6.6
12. To end test session, select test exit icon.
    a. To print a report of the session, select *Exit & Print* when prompted.

##### 6.1.1.1. Performing a VC Test

Multi-breath testing:

1. Sit upright, fit nose clip and relax.
2. Place BVF in mouth.
3. Seal lips around the mouthpiece and keep tongue down.
4. Breathe normally- until the end-expiratory lung volume is stable. Stability is defined as having at least three tidal breaths with end expiratory lung volume within 15% of the tidal volume (A notification displays when this is achieved).

EN

5. Inhale completely with a brief pause when lungs are completely full (≤ 2 secs)*.
6. Exhale in a relaxed manner with no hesitation until no more air can be expelled while maintaining an upright posture. It is vital that the operator encourages the subject to keep exhaling to ensure all air is expelled (when a plateau has been reached or expiration time reaches 15 seconds*).
7. A notification message shall be displayed when a satisfactory expiratory flow plateau has been achieved or expiration time > 15 seconds, inhale maximally and then return to normal breathing.
8. The manoeuvre is now complete. Remove BVF from the mouth.
9. The operator should repeat instructions as necessary, coaching vigorously.
10. Repeat for a minimum of three manoeuvres and usually no more than eight for adults.
11. Check VC repeatability and perform more manoeuvres as necessary.
    ***Note:*** *A single-breath VC technique may also be performed on the device.*
    *ATS/ERS 2019 recommendations.

#### 6.1.1.2. Performing an FVC Test

Multi-breath test:

1. Sit upright, fit noseclip and relax.
2. Place BVF in mouth.
3. Seal lips around the mouthpiece and keep tongue down.
4. Breathe normally.
5. Inhale completely and rapidly with a brief pause when lungs are completely full (≤ 2 secs*).
6. Exhale with maximal effort until no more air can be expelled while maintaining an upright posture. It is vital that the operator encourages the subject to keep exhaling to ensure all air is expelled (when a plateau has been reached or forced expiratory time (FET) reaches 15 seconds*).
7. Breathe in with maximal effort until completely full. The manoeuvre is now complete. Remove BVF from the mouth.
8. The operator should repeat instructions as necessary, coaching vigorously.
9. Repeat for a minimum of three manoeuvres, usually no more than eight for adults.
10. Check FEV1 and FVC repeatability and perform more manoeuvres as necessary.
    ***Note*** *A single-breath FVC technique may also be performed on the device.*
    *ATS/ERS 2019 recommendations.

#### 6.1.1.3. Performing a PCF Test

The test is performed with subjects seated.

1. Fit a new Bacterial Viral Filter (BVF) to the flowhead for each test subject.
2. Subjects are instructed to perform a maximal cough after complete inhalation.
3. They should perform 3–6 manoeuvres (<5% variability).
   *Adapted from Reference: Laveneziana P, Albuquerque A, Aliverti A, et al. ERS statement on respi ratorymuscle testing at rest and during exercise. Eur Respir J 2019; 53: 1801214*

### 6.1.2. Test Parameters

Each spirometry test type will have associated test parameters. To set parameters, refer to Section 8.2.

#### 6.1.2.1. VC Parameters

| Parameter | Unit | Description |
|---|---|---|
| VC | L | Vital capacity |
| EVC | L | Expiratory vital capacity. The maximum/highest volume achieved over the expiratory cycle. If the EVC is greater than the VC, the VC will equate to EVC. |
| IVC | L | Inspiratory vital capacity. The maximum/highest volume achieved over the inspiratory cycle.If the IVC is greater than the VC, the VC will equate to IVC. |
| TV | L | Tidal volume. The volume of gas which is inspired or expired during a respiratory cycle. The average value of the last three tidal breaths is used. |
| IC | L | Inspiratory capacity. The maximal volume that can be inspired from functional residual capacity. |
| ERV | L | Expiratory reserve volume. The volume that can be maximally expired from the level of the functional residual capacity. |
| TLC | L | Total lung capacity. The volume of gas in the lung at the end of a full inspiration. |
| RV | L | Residual volume. The volume of gas remaining in the lung at the end of a full expiration. |
| FRC | L | Functional residual capacity. The volume of gas present in the lung and airways at the average end-expiratory level. |

#### 6.1.2.2. FVC Parameters

| Parameter | Unit | Description |
|---|---|---|
| FVC | L | Forced vital capacity. The maximum/highest volume achieved over theexpiratory cycle. |
| $FEV_1$ | L | Expiratory volume achieved after one second taking the Time Zero parameter(TExt) into consideration. It is the volume achieved after Time Zero plus one second. |
| $FEV_1$/VC | ratio | $FEV_1$ divided by the best VC from the visit expressed as a ratio. |
| $FEV_1$/FVC | ratio | $FEV_1$ divided by FVC and expressed as a ratio. |
| FET | s | Forced expiratory time, calculated as (Test Duration – TExt). |
| PEF | L/min | Peak expiratory flow. The maximum/highest flow achieved over the expiratory cycle. |
| $FEF_{25-75}$ | L/s | Average expiratory flow over the middle half of the FVC between 25% and 75% of FVC. |
| FEV6 | L | Expiratory volume achieved after six seconds taking the Time Zero parameter(TExt) into consideration. It is the volume achieved after Time Zero plus six seconds. |
| $FEV_1$/FEV6 | ratio | $FEV_1$ divided by FEV6 and expressed as a ratio. |
| $FEV_1$ Ratio | N/a | $FEV_1$ divided by the largest VC from either the VC or FVC manoeuvre andexpressed as a ratio. |
| PEF | L/s | Peak expiratory flow. The maximum/highest flow achieved over the expiratory cycle. Expressed in L/s. |
| PEF | L/min | Peak expiratory flow. The maximum/highest flow achieved over the expiratory cycle. Expressed in L/min. |
| FIVC | L | Forced inspiratory volume. The maximum/highest volume achieved over the inspiratory cycle. |
| PIF | L/s | Peak inspiratory flow. The maximum/highest flow achieved over the inspiratory cycle. Expressed in L/s. |
| PIF | L/min | Peak inspiratory flow. The maximum/highest flow achieved over the inspiratory cycle. Expressed in L/min. |
| TV | L | Tidal volume. The average volume during tidal breathing. It is calculated from the tidal breaths before the IC cycle. An average of up to a maximum of 3 tidalvolumes is used. |
| IRV | L | The maximal volume that can be inspired from the mean end inspiratory level.It is calculated as (IC - TV). |
| ERV | L | The volume that can be maximally expired from the level of the functionalresidual capacity. It is calculated as the Highest (FVC or FIVC) - IC. |
| IC | L | Inspiratory capacity. The maximal volume that can be inspired from functional residual capacity. It is calculated as the volume from the average tidal line to the bottom of the IC cycle. |
| $FEV_3$ | L | The expiratory volume achieved after 3 seconds taking the Time Zero parameter (TExt) into consideration. It is the volume achieved after Time Zeroplus three seconds. |
| $FEV_{0.5}$ | L | The expiratory volume achieved after 0.5 seconds taking the Time Zero parameter (TExt) into consideration. It is the volume achieved after Time Zeroplus half a second. |
| $FEV_{0.75}$ | L | The expiratory volume achieved after 0.75 seconds taking the Time Zero parameter (TExt) into consideration. It is the volume achieved after Time Zeroplus three-quarters of one second. |
| $FEV_{0.5}$/FVC | ratio | $FEV_{0.5}$ divided by FVC and expressed as a ratio. |
| $FEV_{0.75}$/FVC | ratio | $FEV_{0.75}$ divided by FVC and expressed as a ratio. |

EN

| | | |
|---|---|---|
| $FEV_3$/FVC | ratio | $FEV_3$ divided by FVC and expressed as a ratio. |
| $FEV_6$/FVC | ratio | $FEV_6$ divided by FVC and expressed as a ratio. |
| $FEF_{0.2\text{-}1.2}$ | L/s | The mean forced expiratory flow in the volume interval between 0.2 L and 1.2 L of the test. |
| $FEF_{25\text{-}75}$/FVC | ratio | $FEF_{25\text{-}75}$ divided by FVC and expressed as a ratio. |
| $FEF_{75\text{-}85}$ | L/s | The average forced expiratory flow in the time interval between 75% and 85% of the FVC. |
| FIVC/FVC | ratio | FIVC divided by FVC and expressed as a ratio. |
| $FEF_{25}$ | L/s | The forced expiratory flow at 25% of FVC. |
| $FEF_{50}$ | L/s | The forced expiratory flow at 50% of FVC. |
| $FEF_{75}$ | L/s | The forced expiratory flow at 75% of FVC. |
| $FIF_{25}$ | L/s | The forced inspiratory flow at 25% of FVC or FIVC (whichever is greater). |
| $FIF_{50}$ | L/s | The forced inspiratory flow at 50% of FVC or FIVC (whichever is greater). |
| $FIF_{75}$ | L/s | The forced inspiratory flow at 75% of FVC or FIVC (whichever is greater). |
| $FEV_1$/PEF | L/L/s | $FEV_1$ divided by PEF. |
| $FIF_{50}$/$FEF_{50}$ | ratio | $FIF_{50}$ divided by $FEF_{50}$ and expressed as a ratio. |
| $FIV_1$ | L | The forced inspiratory volume achieved after one second. |
| $FEV_1$/FIVC | ratio | $FEV_1$ divided by FIVC and expressed as a ratio. |
| $FEV_1$/IVC | ratio | $FEV_1$ divided by IVC and expressed as a ratio. |
| $FIV_1$/FIVC | ratio | $FIV_1$ divided by FIVC and expressed as a ratio. |
| $FIV_1$/FVC | ratio | $FIV_1$ divided by FVC and expressed as a ratio. |
| $FEF_{50}$/$FIF_{50}$ | ratio | $FEF_{50}$ divided by $FIF_{50}$ and expressed as a ratio. |
| $MVV_{ind}$ | L/min | Maximum voluntary ventilation. Indirectly calculated from the FEV1. It is themeasured $FEV_1$ value by 37.5. |
| BEV/FVC | percent | BEV divided by FVC and expressed as a percentage to one decimal place. |
| EOTV | L | End of test volume. Calculated by subtracting the volume at a half secondbefore FET from the volume at FET. |
| FMFT | s | Forced mid-expiratory time between 25% and 75% of the FVC. |

| | | |
|---|---|---|
| IVC | L | The maximal volume of air inhaled from the point of maximal exhalation. |
| $FEF_{max}$ | L/s | The maximum flow detected. |
| FEV1/HT2 | $L/m^2$ | $FEV_1$ divided by the subjects' height in metres squared. |
| $RAW_{ind}$ | kPa/L/s | $RAW_{ind}$ is derived indirectly, based on the FEV1% of predicted. |
| $FEV_3/VC$ | ratio | $FEV_3$ divided by the best SVC VC from the visit and expressed as a ratio. |
| TLC | L | Total Lung Capacity. The volume of gas in the lung at the end of a full inspiration. Calculation: TLC = (RV + Highest (FVC or FIVC)) or TLC = (FRC + IC). |
| RV | L | Residual Volume. The volume of gas remaining in the lung at the end of a full expiration. Calculation: RV = (FRC - ERV) or RV = (TLC - Highest (FVC or FIVC)). |
| FRC | L | Functional Residual Capacity. The volume of gas present in the lung and airways at the average end-expiratory level. Calculation: FRC = (RV + ERV). |
| BEV | mL | Volume Expired between 0 seconds and start time according to the back extrapolated volume. Also known as $V_{ext}$. |
| TExt | ms | Time from start of test to back extrapolated time zero. |
| TPef | ms | Time to Peak expiratory flow. Calculation = Volume expired at PEF/PEF. |
| tRISE | ms | Rise Time calculation = (Interpolated Time at 90% PEF) - (Interpolated Time at 10% PEF)<br>PEF should be achieved with a sharp rise and occur close to Time 0 as measured by the rise time from 10% to 90% of peak flow, which should be <150ms but may be greater than this in a manoeuvre in a patient with upper airway obstruction. |
| tHES | s | Start of Test - Hesitation time: The hesitation time, defined as the time from the point of maximal inspiration to Time 0, should be 2 seconds or less. THes =TimeZero - Time at maximal inspiration (prior to TimeZero). |
| $FEV_1Q$ | ratio | Calculated for adults only(>=18 yrs) as follows:<br>For Males: $FEV_1Q$ = (Measured $FEV_1$)/0.5<br>For Females: $FEV_1Q$ = (Measured $FEV_1$)/0.4 |

#### 6.1.2.3. Best Parameters

The best results are determined as follows:

a. All volume based parameters reported (with the exception of FVC and FEV1) are the highest values from acceptable tests.
b. FVC and $FEV_1$ reported are the highest value, excluding values rejected by the user.
c. PEF L/s, PEF L/min, PIF L/s, PIF L/min, FEFmax L/s reported are the highest values from acceptable tests.
d. All flow based parameters reported are from the acceptable test with the highest FVC and $FEV_1$ sum.
e. All time based parameters reported (with the exception of FET) are from the acceptable test with the highest FVC and $FEV_1$ sum.
f. FET is reported from the test with the best FVC.
g. EV (L) and EOTV (L) reported is from the acceptable test with the highest FVC and $FEV_1$ sum.
h. All ratio parameters are re-calculated from their best values.
i. The best IC is the average of the highest 3 acceptable tests. If there are less than 3 acceptable tests, it uses the average of the number of acceptable tests. If no acceptable tests exist, rejected tests are used.
j. The IRV is re-calculated using the best IC parameter minus the best TV parameter.
k. The ERV is re-calculated using the highest parameter from the best FVC and best FIVC minus the best IC parameter.
l. No best values are reported for the following parameters:
    a. Start of Test - Hesitation time.

EN

### 6.1.3. Test Quality

After every test manoeuvre, quality feedback with ATS/ERS acceptability is displayed for that test.

#### 6.1.3.1. FVC Quality Feedback

| Artifact | Description |
|---|---|
| Start of Test | The extrapolated volume must be less than 5% of the FVC or less than 0.100L, whichever is greater.If not, the test is deemed a slow start of test. For a child aged less than or equal to 6 years old, extrapolated volume must be less than 12.5% of the FVC or 0.08L, whichever is greater. If not, the test is deemed a slow start of test and the subject should be encouraged to blast the air out of their lungs without hesitation. |
| Cough Free | Within the first second of exhalation: if there is a 50% drop in flow and a recovery of at least 1L/s the test is deemed to contain a cough. |
| $FEV_1$ | If either a slow start of test occurs or a cough occurs within the first second of exhalation, then $FEV_1$ is deemed to be unusable. Otherwise, if FVC Vs FIVC artefact occurs, then FEV1 is deemednot acceptable but may be usable. |
| Flow Plateau | If there is less than a 0.025L volume increase over 1 second, the test is deemed as having a plateau. When there is any occurrence of flow greater than 200 ml/s over the last 20ml of forced expiratory, the test is deemed as having an abrupt end of test and a plateau has not been achieved. |
| FVC Vs FIVC | If FIVC > FVC and FIVC - FVC > 0.100 L or 5% of FVC, whichever is greater, the FVC Vs FIVC check isdeemed to be unacceptable. This is an indicator that the subject did not start the manoeuvre from TLC. |
| EOFE | When all of the following are true, the test is deemed to contain an unacceptable EOFE:<br>no flow plateau is achieved *and*<br>• FET is <15 seconds and<br>• FVC is not > highest FVC and<br>• FVC is not within the repeatability tolerance of the highest FVC<br>After the first manoeuvre, the EOFE shall be acceptable until another manoeuvre is performed. After each manoeuvre, EOFE shall be re-evaluated and updated as required for all manoeuvres. |
| FVC | If a slow start of test occurs, then FVC is deemed to be unusable.<br>Otherwise, if either of FVC Vs FIVC or EOFE is deemed to be unacceptable, then FVC is deemed notacceptable but may be usable. |

#### 6.1.3.2. VC Quality

| Artefact | Description |
|---|---|
| Flow Plateau | If there is less than a 0.025L volume increase over 1 second, the test is deemed as having a plateau. |

### 6.1.4. Test Analysis

During the test session, an analysis of the session can be accessed by selecting the Analysis button. The content depends on the application settings.

#### 6.1.4.1. VC Analysis Details

| | | |
|---|---|---|
| Repeatability | Number of tests | 3 acceptable tests are required in order to be deemed an acceptable session. |
| | VC | For between-manoeuvre evaluation, the difference in VC between the largestand next largest manoeuvre must be <=smaller of the following:<br>• .0.150 L or 10% VC, for patients older than 6 years of age<br>or<br>• .0.100 L or 10% VC, for those aged 6 years or younger<br>Otherwise, additional trials should be undertaken. |

| | | |
|---|---|---|
| Reference Information | Previous Visit VC | Contains the best VC value from a VC test performed in the previous visit. |

EN

#### 6.1.4.2. FVC Analysis Details

| | | |
|---|---|---|
| Repeatability | Number of tests | 3 acceptable FVC values of which two are repeatable, and 3 acceptable FEV1values of which two are repeatable, are required for a session to be deemed acceptable. |
| | FVC | The difference between the best acceptable FVC and second best acceptableFVC, must be<br>• ≤0.150L for patients older than 6 years of age<br>or<br>• ≤0.100L or 10% of largest value, whichever is greater, for children 6 years or younger. |
| | $FEV_1$ | The difference between the best acceptable $FEV_1$ and second best acceptable $FEV_1$ must be<br>• ≤0.150L, for patients older than 6 years of age<br>or<br>• less than 0.1L or 10% of largest value, whichever is greater, for children 6years or younger. |
| | FVC Grade | The FVC grade determined by the test session results. Refer to Section 6.1.4.3 |
| | $FEV_1$ Grade | The $FEV_1$ grade determined by the test session results. Refer to Section 6.1.4.3 |
| Bronchodilator Response(BDR) | FVC | The change in FVC between base and post as a percentage of the predicted FVC. |
| | $FEV_1$ | The change in $FEV_1$ between base and post as a percentage of the predicted $FEV_1$ |
| Reference Information | Current Visit | Contains the best VC value from VC test performed in the current visit. |
| | Previous VisitFVC | Contains the best FVC value from FVC test performed in the previous visit. |
| | Previous Visit$FEV_1$ | Contains the best $FEV_1$ value from FVC test performed in the previous visit. |
| | Subject Reference Session | An FVC test session may be selected for the current subject in order to act as a baseline, or reference session. This information will be applied to all FVCsessions for this subject. The values in the Reference column in the table of results will be the ATS/ERS best results from that session. The plotted Referencecurve will be the test from that session that has the highest FVC + $FEV_1$ sum. |
| | ReversibilityDrug Info | Drug information can be selected/entered for a Post FVC assessment here. (Ref 8.4 for configuration of selectable drug info) |
| Z-Score Pictogram | Base- Bronchodilator | Contains a graphic for the pictogram display of Z-score values for FVC, $FEV_1$ and $FEV_1$/FVC. Refer to Section 6.1.4.4 |
| | Post- Bronchodilator | If a post test is performed, contains a graphic for the pictogram display of Z-score values for FVC, $FEV_1$ and $FEV_1$/FVC. Refer to Section 6.1.4.4 |
| Interpretation | System Interpretation | Displays the interpretation details from the chosen algorithm. Refer to Section 6.1.4.5 |
| | User Interpretation | The user may use this location to input an interpretation of their own. |

#### 6.1.4.3. Session Grades

From ATS/ERS 2019 Standardization of Spirometry guidelines, session grades for FVC and FEV1 are calculated as follows:

1. For 0-6 year olds:
   a. If there are three or more acceptable tests the following shall apply:
      i. If repeatability is within 0.100L or within 10% of the highest value, whichever is greater, thenthe grade displayed shall be 'A'.
   b. If there are two or more acceptable tests the following shall apply:
      i. If repeatability is within 0.100L or within 10% of the highest value, whichever is greater, thenthe grade displayed shall be 'B'.
      ii. If repeatability is within 0.150L or within 10% of the highest value, whichever is greater, thenthe grade displayed shall be 'C'.
      iii. If repeatability is within 0.200L or within 10% of the highest value, whichever is greater, thenthe grade displayed shall be 'D'.
      iv. If repeatability is not within 0.200L and not within 10% of the highest value, this shall bemarked as "-".
   c. If there is one acceptable test in the session then the grade displayed shall be 'E'.
   d. If there are no acceptable values in the session but one or more usable values, then the grade displayed shall be 'U'.
   e. If there are no acceptable tests in the session, then the grade displayed shall be 'F'.
2. For 7 years and older;
   a. If there are three or more acceptable tests the following shall apply:
      i. If repeatability is within 0.150L then the grade displayed shall be 'A'.
   b. If there are two or more acceptable tests the following shall apply:
      i. If repeatability is within 0.150L then the grade displayed shall be 'B'.
      ii. If repeatability is within 0.200L then the grade displayed shall be 'C'.
      iii. If repeatability is within 0.250L then the grade displayed shall be 'D'.
      iv. If repeatability is not within 0.250L, this shall be marked as "E".
   c. If there is one acceptable test in the session then the grade displayed shall be 'E'.
   d. If there are no acceptable values in the session but one or more usable values, then the grade displayed shall be 'U'.
   e. If there are no acceptable tests in the session then the grade displayed shall be 'F'.

#### 6.1.4.4. Z-Score Pictogram

The Z-score pictogram shows the upper and lower limits of normal (LLN) for FEV1, FVC and FEV1/FVCand highlights any abnormality.

The Z-score pictogram displays Z-score plots from the current session according to the following:

1. The z-score for the best parameter.
2. The reference/predicted value is highlighted at the zero point.
3. The upper limit of normality (ULN) is indicated at + 1.64 standard deviations.
4. The lower limit of normality (LLN) is indicated at - 1.64 standard deviations.
5. The following parameter Z-scores are displayed on the graph:
   a. FVC
   b. FEV1
   c. FEV1/FVC
6. If the z-score value is below -5, it shall be shown at negative edge of the graph.
7. If the z-score value is above +3, it shall be shown at positive edge of the graph.
8. Separate pictograms are available for base and post FVC sessions.

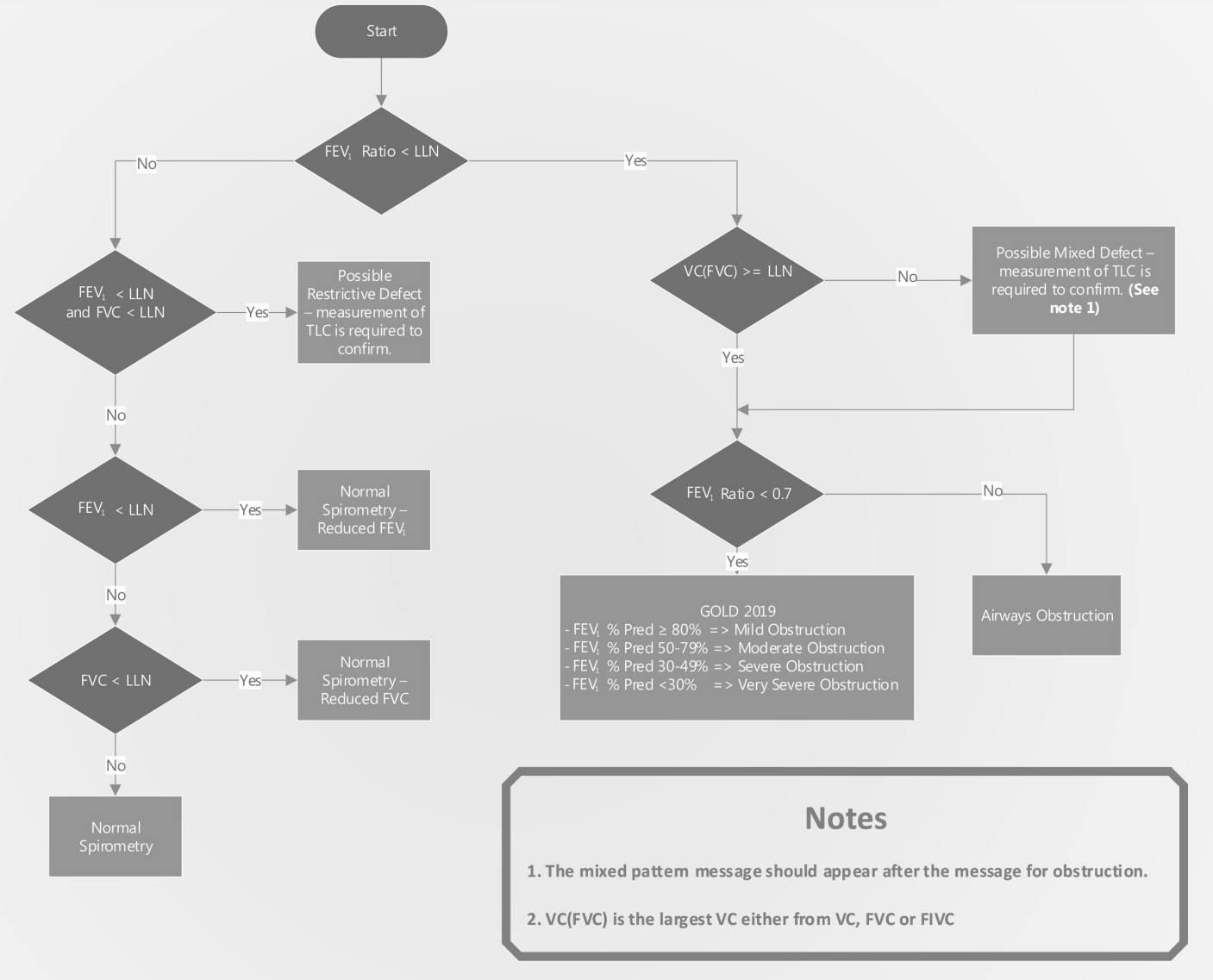
#### 6.1.4.5. System Interpretation

The system interpretation is derived from the selected algorithm refer to Section 8.2.1

##### 6.1.4.5.1. GOLD ATS/ERS Interpretation

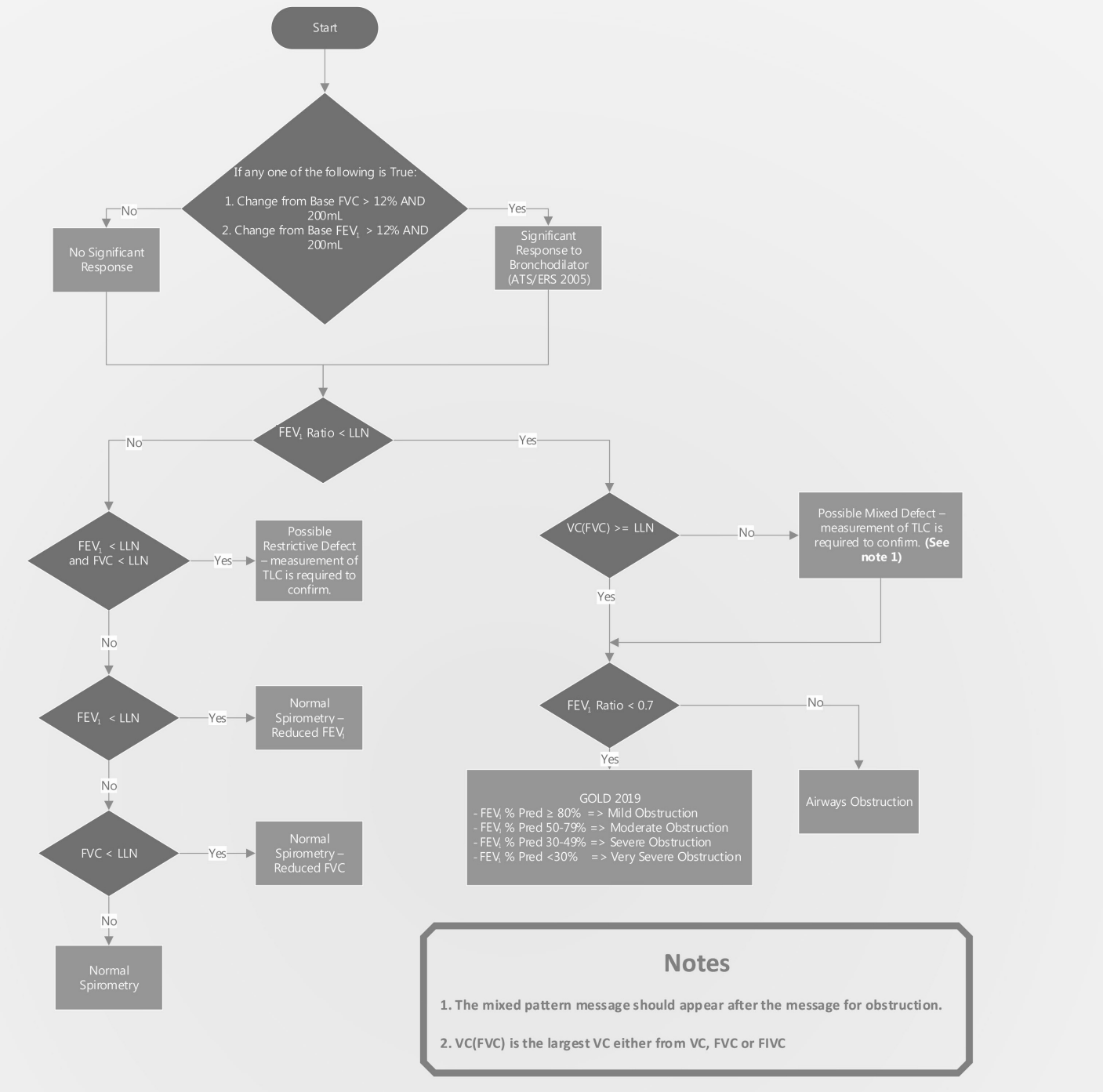
Gold 2019: Global strategy for the diagnosis management and prevention of COPD.Base FVC interpretation algorithm.

Base FVC interpretation algorithm.



EN

Post FVC interpretation algorithm.




### 6.1.5. ArtiQ analysis

As an optional feature, Spirotrac can integrate with ArtiQ services to provide interpretation of pulmonary function tests and automated quality control of Spirometry curves and sessions. This feature is accessed via the ArtiQ dashboard in the FVC test screen.

From the ArtiQ dashboard the user can:

1. Send the session to ArtiQ for PFT interpretation and QC analysis
2. View the interpretation and results provided by ArtiQ
3. Enable and disable this feature, refer to Section 8.2.9

### 6.1.6. Filtering Tests

Tests that are displayed may be filtered by selecting the Filter icon and choosing an appropriate option:

1. Show All
2. Show Best (based on highest FVC+FEV1 sum from acceptable tests)
3. Show Best 3
4. Show Best and Last

#### 6.1.7. Using a reference session for comparison.

Spirotrac allows the user to compare the best test (curve and data) from a user defined previous session. When set, this reference test will appear in both the data and graph results.

1. To enable and disable the Reference Curve functionality and corresponding data, refer to Section 8.2.1
2. To set a session as a reference session, go to the Analysis tab in the FVC test screen, and in Reference Session section, click *Select*.
3. Choose the required session for the subject from the list.
4. Once reference curve/data are enabled, best curve along with best and % change values will display.

### 6.2. 12-Lead ECG Measurements

#### 6.2.1. Performing an ECG Test with the Vitalograph BT12 ECG device

1. Select a subject, refer to Section 5.3.1.
2. Select Start Test button.
3. Choose ECG.
4. Switch on ECG device (BT-12 ECG). Two short signal beeps indicate that the device has completed its self-test. The device display indicates when the device is ready for operation.
5. If first time use, select your ECG device from the list of detected devices presented by Spirotrac. Refer to Section 7.2 for switching device.
6. The ECG test screen opens.
7. Connect the ECG device to the electrodes and then attach ECG electrodes to the subject. Detailed information on preparing the subject and attaching electrodes are in the user manual for the BT-12 ECG device.
8. Select New Recording button.
9. Check torso graphic to ensure a signal is coming from each lead.
10. Select Record ECG Trace icon.
11. Recording automatically ends after the configured time. To stop the recording manually select Stop ECG Trace icon.
12. Review and choose to Save or Discard the recording.
13. If further recordings are required in this session, repeat steps 8 - 12.
14. Recording results in the session are available in the session panel. Choose the recording number to view that recording.
15. Each recording displays basic information along with the following:
    a. Ability to filter the data if interference is suspected from the electricity supply - line filter. This can be set to 50Hz for EU or 60Hz for North America.
    b. Ability to apply a muscle filter (line filter included) to the data.
    c. Tabulated results. Refer to Section 6.2.2.
    d. Suggested Interpretation as derived from the Glasgow Algorithm. Refer to Section 6.2.3.
16. The graph area contains a 10-second ECG strip for a selected channel. The selected channel for the 10-second ECG strip can be changed by selecting the lead symbol above the graph area. Amplitude and Recording Speed for the graph area can be configured by selecting the graph settings above the graph area.
17. Session notes can be attached to the current session. Refer to Section 6.6.
18. Settings for ECG testing can be altered within the session screen. Refer to Section 8.2.5.
19. To end ECG test session, select Close button.

#### 6.2.2. Test Parameters

| Parameter | Unit | Description |
|---|---|---|
| HR | bpm | Heart Rate |
| RR | ms | R-R interval |
| ST | ms | Duration of the ST segment |
| PR | ms | Duration of the PR interval |
| PQ | ms | Duration of the PQ interval |
| QT | ms | Q-T interval |
| P | ms | Duration of the P wave |
| QRS | ms | Duration of the QRS complex |
| QTcH | ms | Q-T interval, corrected by the heart rate (Hodge) |
| QTcB | ms | Q-T interval, corrected by the heart rate (Bazett) |
| QTcF | ms | Q-T interval, corrected by the heart rate (Fridericia) |

| | | |
|---|---|---|
| QTcFra | ms | Q-T interval, corrected by the heart rate (Framingham) |
| P Axis | degrees | Axis of the P wave |
| QRS Axis | degrees | Axis of the QRS complex |
| T Axis | degrees | Axis of the T wave |

#### 6.2.3. Glasgow Interpretation Algorithm

| | |
|---|---|
| VIA VERITAS VITA | The Glasgow Program has been incorporated into Spirotrac and is intended to provide an interpretation of the resting 12 lead ECG in all situations, whether in a hospital or primary care setting. This algorithm has been reviewed against the industry standard, the CSE (Common Standards for Quantitative Electrocardiography) Database. |

***Note:*** *The ECG interpretation is produced pursuant to an agreement with the Glasgow University.*
***Note:*** *If ECG interpretations are required then ensure that the following attributes are set for the subject;*

a. Date of Birth
b. Height
c. Sex at Birth
d. Population Group

### 6.3. Maximal Inspiratory Pressure (MIP) and Maximal Expiratory Pressure (MIP) Testing

Spirotrac includes Maximal Inspiratory Pressure (MIP) and Maximal Expiratory Pressure (MEP) Tests to determine the subject's inspiratory and expiratory muscle strength. These test types require the **Pneumotrac with RMS** (Respiratory Muscle Strength) device with the **relevant MIP flowhead** or **MEP flowhead connected,depending on the test type**.
***Note:*** *The push connector on the connection port should be pushed firmly and squarely against the face of the connector when connecting/disconnecting the tubing.*

#### 6.3.1. Before performing MIP and MEP tests

1. Connect the Vitalograph Pneumotrac with the RMS device, see relevant device IFU.
2. Wash hands (operator and subject).
3. For optimal protection fit a new Bacterial Viral Filter (BVF) to the flowhead for each test subject. The use of a disposable noseclip is preferred.
4. Instruct and demonstrate the test.
5. Select a subject and ensure the required demographic information is entered:
    1. To select a subject, refer to Section 5.3.1.
    2. To view subject demographics, select VIEW PROFILE.
    3. To edit subject demographics, select Edit icon.
    4. Select Start Test.
    5. Choose test type.

#### 6.3.2. Performing MIP testing

Ensure the subject has had an adequate amount of rest prior to beginning the test session.
To perform a MIP test ask the subject to relax, select New Test and wait until the software says 'Begin Test Now!' They should place the nose clip on their nose, mouthpiece in their mouth, then follow the steps below:

1. Instruct the subject to breathe out through the Flowhead until their lungs are completely empty.
2. Once the subjects' lungs are empty, he/she should inhale with as much force as possible for at least 1.5 seconds.
3. When the test is completed the measured value is reported and markers are placed on the graph toindicate the 1 second period for MIP.
4. A maximum of 5 tests can be performed in a session.

Alternatively, if the subject cannot perform a successful MIP test using this method, they should place the nose clip on their nose then follow the steps below:

1. Instruct the subject to breathe out (not through mouthpiece) until their lungs are completely empty.
2. Once the subjects' lungs are empty he/she should place the mouthpiece in their mouth and **inhale with as much force as possible** for at least 1.5 seconds.

***Note:*** *Careful attention must be given to ensure that the subjects' lips are sealed tightly around the mouthpieceto avoid leaks.*

#### 6.3.3. Performing MEP testing

Ensure the subject has had an adequate amount of rest prior to beginning the test session.

To perform the MEP test ask the subject to relax, select New Test and wait until the software says 'Begin Test Now!'. They should place the nose clip over their nose, mouthpiece in their mouth, then follow the steps below:

1. Instruct the subject to breathe in through the Flowhead until their lungs are completely full.
2. Once the subjects' lungs are full, he/she should **exhale with as much force as possible** for at least 1.5 seconds.
3. A maximum of 5 tests can be performed in a session.
4. When the test is completed the measured value is reported and indicators are placed on the graph to indicate the 1 second period for MEP.

Alternatively, if the subject cannot perform a successful MEP test using this method, they should place the nose clip on their nose then follow the steps below:

1. Instruct the subject to breathe in (not through mouthpiece) until their lungs are completely full.
2. Place the mouthpiece in the subjects' mouth, then ask the subject to **exhale with as much force as possible** for at least 1.5 seconds.

***Note:*** *careful attention must be given to ensure that the subjects' lips are sealed tightly around the mouthpieceto avoid leaks*.

#### 6.3.4. MIP and MEP Parameters

To set parameters, refer Section 8.2.6.

| Parameter | Unit | Description |
|---|---|---|
| MIP | $cmH_2O$ | Maximum Inspiratory Pressure. The maximum average inspiratory pressure over a one second period. |
| PIP | $cmH_2O$ | Maximum inspiratory mouth pressure |
| MEP | $cmH_2O$ | Maximum Expiratory Pressure. The maximum average expiratory pressure over a one second period. |
| PEP | $cmH_2O$ | Maximum expiratory mouth pressure |

#### 6.3.5. MIP and MEP Acceptability Criteria

In accordance with the ATS/ERS 2002 Statement on Respiratory Muscle Testing, the following criteria shouldbe used to assess the acceptability of individual MIP/MEP manoeuvres:

1. Consistent pressure sustained for at least 1.5 seconds
2. When the above criteria is met "Good Test" shall be displayed.
3. When the above is not met, the following message shall be displayed:
   a. There was not a consistent pressure sustained for at least 1.5 seconds.'
   b. The test shall be marked as rejected.
   c. The user shall not have the option to accept this type of test manoeuvre.

#### 6.3.6. MIP and MEP Session Repeatability Criteria

1. MIP/MEP repeatability shall be determined as:
   a. A minimum of 3 acceptable tests.
   b. The two largest acceptable MIP/MEP values should agree within a configured % of each other (refer to Section 8.2.6.).
2. When the above criteria are met the following message shall be displayed:
   a. 'Good session'.

#### 6.3.7. MIP and MEP Best Criteria

1. The best test is the test with the highest MIP/MEP from the acceptable repeatable tests.
2. When no acceptable tests exist, the best MIP/MEP comes from rejected tests.

#### 6.3.8. Error Message

1. During testing if the device registers an inhalation or exhalation that lasts <1 second and/or is <20cm/H2O the user shall be asked if they wish to discard the test.

### 6.4. Sniff Nasal Inspiratory Pressure (SNIP) Testing

Spirotrac includes Sniff Nasal Inspiratory Pressure (SNIP) testing to determine the subject's inspiratory muscle strength. This test type requires the **Pneumotrac with RMS** (Respiratory Muscle Strength) **device** with the **relevant SNIP nasal probe consumables.**

#### 6.4.1. Before performing a SNIP test

1. Connect the Vitalograph Pneumotrac with RMS (Respiratory Muscle Strength) device, see relevant device IFU.
2. Wash hands (operator and subject).

3. Find a nasal probe that fits the subject comfortably (a selection of probes is available).
4. Determine the correct nostril to use
   a. One at a time instruct the subject to close each nostril and take an inhale and an exhale to determine which nostril takes in the most air.
5. Attach the nasal probe to the Pneumotrac device using the SNIP connector. Note: The push connector on the connection port should be pushed firmly and squarely against the face of the connector when connecting/disconnecting the tubing.
6. Instruct and demonstrate the test.
7. Select a subject and ensure the required demographic information is entered:
   a. To select a subject, refer to Section 5.3.1.
   b. To view subject demographics, select VIEW PROFILE.
   c. To edit subject demographics, select Edit icon.
8. Select Start Test.
9. Choose test type.
10. Subject Position:

***Note**: Subject position during the test is extremely important.*

   a. Instruct the subject to sit up straight with their back against the chair.
   b. Shoulders should be down.
   c. Eyes should be open.
   d. Both feet should be on the floor.
   e. Legs should be together.

#### 6.4.2. Performing SNIP testing

Ensure the subject has had an adequate amount of rest prior to beginning the test session.
To perform a SNIP test, select *New Test* and wait until the software says 'Begin Test Now!' then follow thesteps below:

1. Put the probe in the nostril that takes in the most air.
2. Instruct the subject to sniff as hard as they can.
3. A maximum of 10 tests can be performed in a session.

#### 6.4.3. SNIP Best Criteria

The best test is the test with the highest value from the acceptable tests.
When no acceptable tests exist, the best value comes from rejected tests.

#### 6.4.4. SNIP Parameters

To set parameters, refer to Section 8.2.6.

| Parameter | Unit | Description |
|---|---|---|
| SNIP | cmH2O | Sniff Nasal Inspiratory Pressure. The maximum inspiratory pressure |

### 6.5. Oscillometry Testing

Spirotrac includes Oscillometry testing which requires the Thorasys Tremoflo device and Tremoflo software. The Tremoflo software application is available to install from the Thorasys USB stick provided with the device.
***Note:** Tremoflo must be installed by a user with Administrative privileges on the PC*
For Tremoflo device and software support please contact technical support:

- For North Americas: techsupport@thorasys.com
- For Europe: techsupporteu@thorasys.com

When installing, ensure that Tremoflo software is installed in the **default folder location**. The Tremoflo software **must be configured before** use with Spirotrac.

#### 6.5.1. Setup Tremoflo for use with Spirotrac 6

1. Run Tremoflo outside of Spirotrac. Follow the Tremoflo setup wizard.
2. Create a user when running setup. ***Note***: The user credentials will have to be re-entered in Spirotrac.
3. Contact TechSupport@Thorasys.com for licensing details.
4. For further details on Tremoflo software and hardware setup, consult the Tremoflo user manual.
5. Close Application.
6. Run Spirotrac, go to Settings.
7. From Testing select Oscillometry, then select Enable Oscillometry.
8. Enter Tremoflo user credentials created on Tremoflo setup, see step 2 above.
9. Select Configure Oscillometry.
10. Select Save.

#### 6.5.2. Before Performing an Oscillometry Test

1. Connect the Thorasys Tremoflo device.

2. Select a subject and ensure the required demographic information is entered and correct:
   - To select a subject, refer to Section 5.3.1
   - To view subject demographics, select VIEW PROFILE.
   - To edit subject demographics, select Edit icon.

EN

#### 6.5.3. Performing Oscillometry

1. Select Start Test.
2. Choose Oscillometry.
3. If first time use, select the Oscillometry device from the list of detected devices. Refer to Section 7.2 for switching device
4. Select New Session.
5. Refer to Tremoflo user manual for details on calibration and on how to perform an oscillometry test.
   ***Note:*** 3 Oscillometry tests are recommended.
6. Select End Test from the Test Tab to exit Tremoflo.
7. When prompted to generate a report, select Yes to exit the application and return to Spirotrac, or select No to continue testing.
8. The Oscillometry report displays in Spirotrac. To end the session, select the Exit icon.
9. To print a report of the session, select Exit & Print when prompted.

#### 6.5.4. Oscillometry Parameters

Refer to Tremoflo user manual for details on parameters.

### 6.6. Session Information

Generic session information can be gathered on the current session.

1. Select *Information* button.
2. Information is available for the following;

a. Date of session
b. Logged in user at time of session
c. Device details
d. Subject demographic details at time of session

### 6.7. Session Notes/Comments

Notes/Comments can be attached to the current session.

1. Select Notes button.
2. Select Add button.
3. Enter the note text in the available note field.
4. For FVC sessions, pre-defined comments can be selected for the session from *Notes* and for each testfrom *Test Acceptability* on the quality tab.
5. Select *Save* button to save the note to the database.
6. Previously saved notes may be edited and/or deleted by selecting that note and selecting the *Create* or *Delete* buttons. Follow the on-screen instructions.

### 6.8. Pulse Oximetry Testing

SpO2 test results can be captured manually within Spirotrac 6 to facilitate trending and/or reporting alongside Spirometry results.

***Note:*** *To print a VC or FVC report containing SpO2 data, first ensure SpO2 section is enabled on the report, refer to section 9.1 and ensure you have performed the VC or FVC session within the same visit as the SpO2 session.*

#### 6.8.1. Capturing Pulse Oximetry data

1. Select Start Test.
2. Choose SpO2.
3. Enter Date, Time, SpO2, Heart Rate and Posture and click Add
4. To end the session, select the Exit icon.

### 6.9. Data Transfer with the Alpha or In2itive device.

Subjects can be uploaded from Spirotrac to the device in order to perform testing on the device and download the results from the device to Spirotrac in order to have all your test results in one central location.

#### 6.9.1. Connecting device to PC/Vitalograph COMPACT

To connect the Vitalograph Alpha or Vitalograph In2itive:

1. Plug one end of USB cable into USB port on PC/COMPACT (usually marked with ⇜ symbol).
2. Plug other end of USB cable into USB port at side of the Vitalograph Alpha/In2itive device (marked with ⇜ symbol).
3. Once switched on, the Vitalograph Alpha/In2itive device is ready for use with Spirotrac.

#### 6.9.2. Uploading subject(s) from Spirotrac to Vitalograph Alpha or In2itive device

***Note:*** *Ensure your device is on the main screen.*

EN

***Note:*** *To ensure subjects are not duplicated, upload the required subject(s) from Spirotrac to the device prior to testing*.

1. Select Download/Upload from left hand menu.
2. The "No device connected" icon displays until a successful connection has been established. Once connection is established, the device name and serial number are displayed.
3. Select Upload Subjects
4. To find the subject you wish to transfer to the device, there is a quick search option and an advanced option. Once found, move subject to right hand list.
   a. Use the quick search option by entering the subject number or name in the search field provided
   b. Use the advanced option to find subjects by any/all of the following: Group, Subject Id, First Name, Last Name, Alternate Id, Date of Birth.
5. On selecting Upload subjects to device the subject(s) are saved to the device.
6. When a subject already exists on the device with the same subject number but was not linked previously the user shall be asked to choose from one of the following options during the upload process:
   a. Update existing subject – this will update the device subject with current demographics from Spirotac
   b. Create new Subject – this will add a new subject to the device
   c. Skip – no subject demographics is transferred to the device

#### 6.9.3. Downloading sessions(s) from Vitalograph Alpha or In2itive device to Spirotrac

***Note:*** *Ensure your device is on the main screen.*

1. Select Download/Upload from left hand menu.
2. The "No device connected" icon displays until a successful connection has been established. Once connection is established, the device name and serial number are displayed.
3. Select Download Sessions
4. To find the sessions you wish to download to Spirotrac, there are 2 quick search options and a custom search option.
   a. Use the quick search option(s) to find sessions performed on the device today or find all sessions
   b. Use the custom search option to find sessions by Date Range, Type or Subject information (First Name, Last Name, Subject Number)
5. All subject(s)/session(s) matching the search criteria are displayed on screen.
6. Select session(s) to be downloaded.
7. On selecting Download Selected the session(s) are saved to Spirotrac. Note: Subject information is downloaded also. All downloaded session(s) are now available to view in the subjects visit list and available for trending.
8. When a subject already exists on Spirotrac but demographics differ the user shall be asked to choose from one of the following options during the download process:
   a. Update existing subject – this will update the Spirotrac subject with current demographics from device
   b. Create new Subject – this will add a new subject to Spirotrac
   c. Skip – no data/session(s) are downloaded for this subject
9. Once download is complete, Spirotrac displays the list of session(s) which have been downloaded and the user can select session(s) to be printed or exported to PDF

### 6.10. Challenge Testing.

Spirotrac includes a Challenge Test module. Challenge testing assesses the severity of reversible broncho-constrictive disease, such as asthma, and is an important part of the diagnosis process as well as defining treatment therapy. A broncho-constrictive agent is given to the subject and the response is monitored by repeated Spirometry.

#### 6.10.1. Conducting a Challenge Test

1. Select a subject and ensure the required demographic information is entered:
   - To select a subject, refer to Section 5.3.1..
   - To view subject demographics, select VIEW PROFILE.
   - To edit subject demographics, select Edit icon.
2. Select the Challenge Test icon from the main screen.
3. On the protocol selection screen:
   - Select the protocol to be used.
   - Select the delivery method to be used.
   - When ready to perform challenge testing, select Confirm.

***Note:*** *The default dose amounts and units of measurement can be configured via the settings icon. Once changed, the new values become the default.*

4. The Challenge test wizard guides the user through the Challenge test procedure.

***Note:*** *Refer to section 8.11 for other Challenge Settings*

#### 6.10.2. Mannitol Challenge Testing

**Pre Challenge Test Phase**: The Challenge test consists of multiple phases. The pre challenge test phase is used to determine the baseline prior to the issuing of a diluent or dose. In this phase the user should perform a spirometry test with a minimum of two blows that meet repeatability criteria of 150 ml. The subjects FEV1 should be >=70% predicted.

**Dosing Steps:** Dosing stage 1 is used to determine the baseline FEV1.When the dose is administered, select the Dose Administered button to start the 60 second countdown timer.
On completion of the timer the subject should perform two repeatable FEV1 measurements. These measurements should be within 150ml variability. If the highest FEV1 is >=10% drop from the pre-challenge FEV1 the challenge test should be discontinued.
Select Next to proceed to the next and subsequent phase(s). Administer the dose for the current phase and select the Dose Administered button. Perform repeatable FEV1 manoeuvres and exit the test screen to move to the next phase.

**Challenge Outcomes:** When a subject achieves a fall in FEV1 of 10% or greater between non-zero dose phases or a 15% fall from the baseline FEV1 a positive result is achieved and the software calculates the PD15. The Challenge test procedure is completed and the user has the option to perform a recovery phase.

**Recovery Phase:** Administer a bronchodilator and monitor the subject to ensure their FEV1 has returned to within 10% of their baseline.

#### 6.10.3. Methacholine ATS 1-min tidal breathing challenge testing

The challenge test consists of multiple phases.

**Pre-Challenge Test Phase:** The Challenge test consists of multiple phases. The pre challenge test phase is used to determine the baseline prior to the issuing of a diluent or dose. In this phase the user should perform a spirometry test with a minimum of two blows that meet repeatability criteria of 150 ml. The subjects FEV1 should be >=60% predicted.

**Baseline Diluent Phase:** This phase must be performed to determine the baseline FEV1 before the user can proceed to the dosing phase. If the FEV1 has increased or decreased by 10 -20 % the option to repeat the diluent step is available.

**Dosing Steps:** When the dose is administered, select the Dose Administered button to start the 60 second countdown timer. On completion of the timer the subject should perform two repeatable FEV1 measurements. These measurements should be within 150ml variability.

**Challenge Outcomes:** When a subject achieves a fall in FEV1 of 20% from the baseline FEV1 a positive result is achieved and the software calculates the PD20. The Challenge test procedure is completed and the user has the option to perform a recovery phase.

**Recovery Phase:** Administer a bronchodilator and monitor the subject to ensure their FEV1 has returned to within 10% of their baseline.

***Note:*** *To choose the FEV1 that you want to use in the analysis you need to reject all other manoeuvres. This is done by toggling the FEV1 acceptability from accepted to rejected for the manoeuvres you do not want to include.*

### 6.11. MVV Testing.

Spirotrac includes a Maximum Voluntary Ventilation (MVV) test to determine the maximum volume of air a subject can breathe over a specified period of time.

#### 6.11.1. Before performing MVV tests

1. Connect the Vitalograph Pneumotrac device, see relevant device IFU.
2. Wash hands (operator and subject).
3. For optimal protection fit a new Bacterial Viral Filter (BVF) to the flowhead for each test subject. The use of a disposable noseclip is preferred.
4. Instruct and demonstrate the test.
5. Select a subject and ensure the required demographic information is entered:
    1. To select a subject, refer to Section 5.3.1.
    2. To view subject demographics, select VIEW PROFILE.
    3. To edit subject demographics, select Edit icon.
    4. Select Start Test.
    5. Choose test type.

EN

### 6.11.2. Performing MVV testing

Ensure the subject has had an adequate amount of rest prior to beginning the test session.
To perform an MVV test ask the subject to relax, select New Test and follow the onscreen instructions. They should sit upright, then follow the steps below:

1. Instruct the subject to seal lips around the mouthpiece and keep tongue down
2. Breathe normally through the Flowhead
3. Once at least 3 resting breaths have been obtained, press the start recording button or spacebar on your keyboard to start the test.
4. Instruct the subject to breathe as deeply and rapidly as possible (for ~12 seconds). The VT (tidal volume) during the manoeuvre should be greater than the subject's resting VT.
5. When the test is completed the measured value is reported.
6. A maximum of 8 tests can be performed in a session.

### 6.11.3. MVV Parameters

To set parameters, refer to Section 8.2.8

| Parameter | Unit | Description |
|---|---|---|
| MVV | Lmin-1 | Maximum volume of air a subject can breath |
| VT | Litres | Maximum volume of air a subject can breath |
| RR | | Respiratory Rate - Number of breaths extrapolated to one minute |
| MVV Time | seconds | Duration of the MVV recording |
| VT/VC | Ratio | Calculated from the most recent VC within the same visit |

### 6.11.4. MVV Acceptability Criteria

In accordance with the ATS 1994 standard
MVV should have

- VT approx. 50% of VC
- RR of approx. 90 breaths per minute
- Should perform 2 acceptable maneuvers

### 6.11.5. MVV Best Criteria

1. The best test is the test with the highest MVV from acceptable tests.
2. When no acceptable test exists, the best MVV comes from rejected tests.

## 6.12. FeNO Testing.

Spirotrac includes FeNO testing using the NIOX VERO® which measures Fractional Exhaled Nitric Oxide (FeNO).
***Note:*** *The FeNO should be measured according to guidelines for NO measurement established by the American Thoracic Society and European Respiratory Society. See device manual for device instructions for use and storage.*

### 6.12.1. Setup NIOX VERO device for use with Spirotrac 6.

If the Biological QC setting is enabled a QC check of the NIOX VERO is enforced. See Section 8.2.11 for details

### 6.12.2. Before performing a FeNO test.

FeNO testing should always be performed before spirometry testing.

1. Plug in the NIOX VERO device using the power cable supplied and connect the NIOX VERO to the PC/ COMPACT using the USB cable provided. Ensure the power supply is connected securely to the NIOX VERO.
2. Turn the device on via the switch on the left-hand side of the NIOX VERO.
3. If enabled, ensure that a QC check has been performed on the NIOX VERO by a qualified biological control.
   ***Note:*** *when QC is not performed all tests shall have a rejected status which the user cannot change.*
4. Lift the breathing handle from the holder and remove the cap.
5. Place a new mouthpiece on the breathing handle.
   a. Make sure to twist the mouthpiece in place.
   b. There is a risk of leakage if the mouthpiece is not correctly attached to the breathing handle which can result in incorrectly measured values.
      ***Note:*** *DO NOT use sharp objects to open the packaging on the mouthpiece or touch the filter membrane.*
   c. Mouthpieces must be used immediately after opening.
6. Select a subject and ensure the required demographic information is entered and correct:
   - To select a subject, refer to Section 5.3.1
   - To view subject demographics, select VIEW PROFILE.
   - To edit subject demographics, select Edit icon.

#### 6.12.3. Performing FeNO Testing

1. Select Start Test and choose FeNO.
2. If first time use, select the FeNO device from the list of detected devices. Refer to Section 7.2 for switching device
3. Instruct the subject on how to perform the manoeuvre and once the subject is ready, select NEW TEST.
4. Instruct the Subject to exhale fully before sealing their lips around the mouthpiece.
5. Coach the Subject to inhale fully but steadily through the mouthpiece.
6. Following full inhalation, instruct the subject to exhale for 10 seconds through the mouthpiece at a constant rate. The aim is to get the device to emit a solid (continuous) tone and once achieved continue blowing at this flow rate.
   a. Getting the correct flow rate of exhalation is essential, and the device will provide feedback to you and the Subject in order for the Subject to achieve a good flow rate.
   b. If the NIOX VERO emits a rapid intermittent beep, the Subject should blow less forcefully.
   c. If the NIOX VERO emits a slow intermittent beep, the Subject should blow more forcefully.
7. 1. In addition to sound feedback, the screen will display an incentive animation.
8. 2. If the flow rate falls too high or too low for a long period of time, the NIOX VERO will stop the test. The test will be discounted and the Subject should repeat the test.
   a. This will be indicated to the Subject by the intermittent high or low tone stopping, followed by a short beep. The device will indicate that the test has been stopped early by displaying one of two screens with an error code (A10 for too forceful and A11 for not forceful enough), and a visual feedback picture. Note: Refer to NIOX VERO user manual for other error codes/alert codes
   b. Once the Subject has achieved a good flow rate for 10 seconds, the NIOX VERO will calculate the FeNO result. A countdown timer will be displayed on the NIOX VERO device while it is analysing the result.
9. The results will automatically transfer into Spirotrac on the PC/COMPACT.
10. Tests which were ended due to error codes A10 or A11 will not be counted.
11. To end the session, select the Exit icon.
12. To print a report of the session, select Exit & Print when prompted.

#### 6.12.4. FeNO Repeatability

- The Subject will need to complete a minimum of 3 FeNO blows in which 2 out of the 3 blows are repeatable.
- A maximum of 6 blows can be performed per session.
- Repeatability can be achieved by 2 blows being within 10% of each other.

## 7. Device Management

### 7.1. Calibration Verification Management in Spirotrac

All spirometry standards (e.g. ATS/ERS/BTS/ANZRS) recommend checking the calibration of lung function measuring devices at least daily with a 3-L syringe, regardless of the flow measuring technology, to validate that the instrument is measuring accurately. The system should never be outside calibration limits unless the measuring device is damaged or faulty. In this event, refer to our fault-finding guide. In normal use, calibration traceability certification is recommended as a part of the routine annual service.
ATS/ERS recommendations require that the difference between the volume measured by the spirometer and the volume pumped into the spirometer from a syringe is within ± 3% (± 2.5% for spirometers plus ±0.5% for calibration syringes).

Routine user calibration verification checking 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 flowhead has been dropped

The equipment used to perform the calibration verification 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 calibration verification can be switched on and off in the Application Settings refer to Section 8.2.4.

***Note:*** *It is recommended that the Vitalograph Precision 3 Litre Syringe is used to perform accuracy checks. This has an accuracy of +/-0.5%.*

EN

#### 7.1.1. Performing a Calibration Verification

To perform a calibration verification:

1. Attach Vitalograph device flowhead to precision syringe.


2. On main dashboard, select the Perform Calibration Verification link.
3. Pump air through flow head as instructed to ensure that the flowhead is at ambient temperature before calibration verification is performed.
4. Enter the mandatory syringe serial number and syringe volume.
   a. Optional information of temperature, ambient humidity, barometric pressure, and altitude can also be entered in the available fields. If temperature is not entered it will be automatically measured by the device.
5. Select *Start* button and follow on-screen instructions.
6. For each stroke, press in and immediately withdraw the syringe with a smooth, firm stroke (not too slowly) maintaining a consistent flow rate to verify both expiratory and inspiratory
7. Three repeatable syringe strokes within 3% of the syringe volume are required, it is recommended to use varying flow rates.
8. Follow on-screen instructions. The software will advise as to whether to adjust the calibration or not. If an adjustment is made, then the calibration verification must be repeated.
9. A faulty equipment or technique message shall be displayed if three consecutive strokes are outside the reproducibility limit of 3% or the percentage difference from the syringe volume is more than 25%. Contact Vitalograph if failure is persistent.

#### 7.1.2. View/Export/Print Calibration Verification History

Spirotrac maintains a Calibration History Log which is updated each time a calibration check is performed with the Pneumotrac in Spirotrac. You may view and export the calibration history log:

1. View the Calibration history by clicking on the main dashboard under *Calibration Verification* andSelect *Verification History. A list of all calibration verifications shall be displayed. To view more information select an individual calibration from the list. Filtering options are available.*
2. Select the *Export* button 
3. Choose your preferred filter option and take note of the export location prior to selecting *Export.* The exported log may be printed using Microsoft Excel.

### 7.2. Select another device

Spirotrac will remember the last device used for each test type. To change the selected device:

1. On selecting *Start Test*, click *Select A Different Device* before selecting the required test type.
2. Select the required test type, Spirotrac shows the list of detected devices.
3. Select the required device and continue testing as per Section 6.

## 8. Application Settings

On the dashboard, select Settings icon from main menu. This allows settings to be adjusted across various functions.

### 8.1. Subject Data Settings.

Allows the user to select which Subject data entry fields are available.

1. Data entry fields can be enabled/disabled. When disabled, the fields do not appear on the subject entry/edit screens.
2. A selection of custom fields may be used to record additional information e.g., record subject occupation.
3. Units of measurements used for Height and Weight can be configured.
4. Subject ID can be entered manually or configured to allow the software auto-generate the ID. Alternatively, Swedish and Norwegian ID can be configured.

#### 8.1.1. Population Groups and Predicted Values

Allows the user to configure the Population groups available. By default, the predicted sets used are those as recommended by the Global Lung Function Initiative (GLI).

1. Population Groups can be adjusted by aligning an appropriate Predicted Set to them while also applying a correction factor.
2. Population Groups can be adjusted by aligning an appropriate race.
3. The Population Group can also be re-labelled.

4. Population Groups can be enabled/disabled as required.
5. To create a New Population Group select Create button and follow the on-screen instructions.

***Note:*** *Predicted sets are named after author/paper and contain a subset of parameters. All other predicted parameters are taken from Vitalograph's background set. For more information on this contact Vitalograph (Refer to contact information at the start of this manual)*

EN

## 8.2. Test Settings

Allows the user to configure general test settings:
Visit Label text
Visit Creation Type: Automatic or Manual. Manual allows advanced users to create a visit and record additional information before testing.

### 8.2.1. FVC Settings

The following FVC settings are available:

1. Parameters: Turn On/Off FVC parameters required for testing, refer to Section 6.1.2.2.
2. Extended Parameter Information:
   a. Columns in test results table can be made visible/hidden.
   b. Information on the Analysis tab can be made visible/hidden.
   c. I-bars/Graph Indicators on the graphs can be made visible/hidden.
3. Interpretations: Configure availability of interpretation information such as System Interpretation.
4. Reference Curve: Set a reference session for a subject to facilitate comparisons between a baseline session and the current session, refer to Section 6.1.7
5. Testing Options:
   a. Select which test(s) are visible on graphs during testing.
   b. Select whether the system will automatically accept/reject each test based on ATS/ERS test quality criteria.
   c. Select whether the system will automatically end the test or enforce the user to end the test manually (useful for COPD subjects).
6. Incentives: Choose from a selection of incentives and configure target values.
   a. Start at % FVC: This represents the percentage of the predicted FVC value which must be reached for the incentive to start during the forced manouevre.
   b. Target Values: This represents the FVC to be achieved for the incentive to play out fully i.e., for candles,this represents volume at which all candles will blow out. The target will use % of predicted for the firstblow and % of the best for all subsequent blows.
   ***Note:*** *To unlock all incentives, please register your software, refer to Section 10.4*

### 8.2.2. VC Settings

The following VC Settings are available:

1. Parameters: Turn On/Off VC parameters required for testing. Refer to Section 6.1.2.1.
2. Extended Parameter Information:
   a. Columns in test results table can be made visible/hidden.
   b. I-bars/Graph Indicators on the graphs can be made visible/hidden.
3. Testing Options:
   a. Select which test(s) are visible on graphs after each test.
   b. Select whether the system will automatically accept/reject each test based on ATS/ERS test quality criteria.
   c. Select whether the system will automatically end the test or enforce the user to end the test manually (useful for COPD subjects).
4. Incentives: Choose from selection of incentives and configure target values. Refer to Section 8.2.1 for more details
   ***Note:*** *To unlock all incentives, please register your software, refer to Sectoin 10.4.*

### 8.2.3. PCF Settings

The following PCF settings are available:

1. Select which test(s) are visible on graphs after each test.

### 8.2.4. Accuracy Settings

The following General Settings are available:

1. Configure whether a daily calibration verification check is required.
2. Environmental Variables can be made visible/hidden.

### 8.2.5. ECG Settings

The following ECG Settings are available:

1. Parameters: Turn On/Off ECG parameters required for testing. Refer to Section 6.2.2.
2. Recording Settings:
   a. Maximum Recordings

3. Recording Duration Analysis Settings:
   a. Analysis QTc Parameter for Glasgow algorithm
4. Filter Settings:
   a. Select appropriate filter required.

#### 8.2.6. MIP, MEP and SNIP Settings

The following settings are available:

1. Parameters: Turn On/Off parameters required for testing.
2. Extended Parameter Information:
   a. Columns in test results table can be made visible/hidden.
3. Testing Options:
   a. Select which test(s) are visible on graphs after each test.
   b. Select repeatability percentage limit to be used (applies to MIP & MEP only).

#### 8.2.7. Oscillometry Settings

The following settings are available:

1. Enable Oscillometry: Turn On/Off the test type and configure Tremoflo for use with Spirotrac.
2. Enter Tremoflo user details, refer to Setcion 6.5
3. Configure Oscillometry: Allows for changes to the Tremoflo application settings to be synched with Spirotrac.

#### 8.2.8. MVV Settings

The following MVV Settings are available:

1. Parameters: Turn On/Off MVV parameters required for testing. Refer to Section 6.11.3
2. Extended Parameter Information:
   a. Columns in test results table can be made visible/hidden.
3. Testing Options:
   a. Select which test(s) are visible on graphs after each test.

#### 8.2.9. ArtiQ Settings

To facilitate communication with ArtiQ services the following must be configured:

1. Enable/disable the ArtiQ functionality.
2. Enter the ArtiQ account credentials to be used and select Save. To create an account, contact ArtiQ at: support@artiq.eu

#### 8.2.10. Challenge Settings

1. To configure Challenge test protocol settings:
   - Configure Dose amounts, units and timer duration.
   - Configure the Recovery timer duration
2. Select the Axis Markers on the Dose Response Curve

#### 8.2.11. Feno Settings

Biological QC: Enabling this setting will enforce a biological QC process. A QC check of the NIOX VERO should be performed by a qualified biological control tester at your site at the start of each testing day. The purpose of this test is to confirm that the instrument is measuring consistently. Refer to NIOX VERO user manual for further details. If the user tests without a valid QC session, the data will have a status of rejected (See Section 6.12.2.3)

### 8.3. Groups Settings

Groups can be created to facilitate assigning subjects into groups such as different healthcare clinics or companies for Occupational Health.

1. To create a new Group select *Create* button and follow on-screen instructions.
2. To allocate a subject to a Group, go to the Subject Add/Edit screen and use drop-down menu to select the required Group.
3. To default the subject search to a specific group, select a Group as the active group via the top menu.

### 8.4. Drugs Settings

1. Drug details can be created to facilitate quick selection of reversibility drug information during post testing.
2. To create new Drug details select *Create* button and enter the information as requested. These shall then be available for selection in the Post FVC test screen, refer to Section 6.1.4.2.

### 8.5. Users Security Settings

1. Enable/disable user login requirements, including enabling use of active directory accounts.
2. Create and manage users of the system, including password reset.
3. Users can manage their own password and security question by selecting the ‘CHANGE MY PASSWORD’ option under User information on the main toolbar.
4. Disable users who should no longer have access to the system.
5. An administrator can trigger a password reset for users who have forgotten their password.

6. To create a new User select *Create* button and follow on-screen instructions.
7. When active directory integration is enabled, only an active directory admin user has the option to import active directory users. This admin user is required to re-enter their active directory password. After selecting the Connect button, select + button to add new active directory users.

***Note:*** *When editing another user, ensure the user is not currently logged in.*
***Note:*** *When active directory integration is enabled, neither the password reset nor the forgot my password features are available.*

### 8.6. Security Settings

1. Enable/disable Audit Annotation to control whether the user is required to enter a reason for changes to data.
2. Set the duration of inactivity after which the application will lock.
3. Manage the user Lockout Policy Settings.

### 8.7. Database Settings

1. Database connections can be created and managed.
2. Users can control which database the application uses by selecting the preferred database as current.
3. To create a new DB connection, select + button and follow on-screen instructions.
4. Database backups can be controlled.
5. A database restore can be performed by selecting button and follow on-screen instructions. Refer to Section 10.3.4

### 8.8. Vitalograph Connect Settings

To facilitate the exchange of data with EMR systems the following must be configured:

1. Enable/disable the Connect functionality.
2. The Connect URL must be provided.
   ***Note:*** *For all other configuration, see Vitalograph Connect IFU.*
3. *Enable/disable Auto Process Orders (for more information ref 10.6.2.1) and select the required default population group to be used.*
   ***Note:*** *For all other configuration, see Vitalograph Connect IFU.*

### 8.9. Language Settings

1. Select the required display language from the drop-down list.
   ***Note:*** *This action will require the software to be re-started.*

## 9. Reporting and Printing

Creating an electronic or paper report of a session:

1. Select a subject, refer to Section 5.3.1
2. Choose the session that you wish to generate a report for.
3. Select *Print* button.
4. The report generator displays a preview.
5. For paper report: Choose destination printer.
   ***or***
   For electronic report: Choose file format (the default is PDF). Select *Export* button. Choose location for the file and select *Save*. ***Note:*** The file name format can be set in report settings (refer to section 9.2)

### 9.1. Combine Multiple Reports into one PDF or printout

To combine multiple reports into one single report, do the following:

1. Select a subject, refer to Section 5.3.1.
2. Select the report icon of the required visit.
3. Select the sessions to be included in the PDF and select Print button.
4. The report generator displays a preview.
5. For paper report: Select Print, choose destination printer and print.

or

For electronic report: Choose file format (the default is PDF). Select Export button. Choose location for the file and select Save.

### 9.2. Report Template Settings

To configure data on a report for a specific session type:

1. Select Reports.
2. Select the report template to be configured, e.g., FVC Base, FVC Post etc.
3. Each report will have a number of sections containing configurable items that can be turned on/off depending on your user preferences e.g.
   - Header Information: to configure report title, header, and logo
   - Subject Information: to enable/disable which subject data is reported
   - Session Information: to enable/disable which session information is reported

EN

- Parameter Information: to enable/disable which parameters, including the order, and which columns are reported in the test results table of the report
- Advanced: to configure which graphs, interpretations and notes are reported
  - Print Options: choose file name format from the drop down list. Options are:
  - Report Type, Assessment Date, Subject Number
  - Report Type, Assessment Date, Subject Name
  - Report Type, Assessment Date, Subject Number, Subject Name

4. Select Save on each section.

# 10. Other functions

## 10.1. Start-up / Logon

***Note:*** *Users who have been added to the Spirotrac software will have their own Username and Password.*

1. The logon screen opens on start-up.
2. Enter Username and password and select Login. When Active Directory is enabled (refer to Section 8.5.) ensure domain information is correct.
   ***Note:*** *Multiple attempts to login can lock the account. The number of attempts and lock duration are set in security settings, refer to Section 8.6*

### 10.1.1. Forgotten Logon Details

To set new login details when a user has forgotten their login details/password:

1. Select Forgot Username or Password on the Login screen.
2. When username is known, enter username and follow the on-screen instructions. The password is now reset and ready to use.
3. When username is unknown for Technician user, contact your local Spirotrac Administrator user to reset your password, refer to Section 8.5.
4. When username is unknown for the Administrator user:
   a. Contact technical support for an unlock code. Contact information is at the start of this manual.
   b. Enter the unlock code as provided by Vitalograph. This will be validated by Spirotrac.
5. Select your username and follow the on-screen instructions. The password is now reset and ready to use.

***Note:*** *This feature is not available when Active Directory integration is enabled.*

## 10.2. Audit Trail

The software records an audit trail of activity. Each event contains the following minimum information:

1. Date/time of event.
2. User logged on.
3. Event description.
4. Event detail including user annotation as appropriate. The enforcement of user annotation can be enabled/disabled, refer to Section 8.6.

To view audit trail, select Audit Log icon from the main menu on the main dashboard. The audit trail can be filtered by user, event type or date range.

## 10.3. Database Management

The Database Studio application is included on the Spirotrac installation media. It provides the following features for Spirotrac:

- Creating a new Spirotrac 6 Database.
- Migrating Spirotrac V Subjects and data to Spirotrac 6.
- Upgrading Spirotrac 6 Database
- Backup and Restore a Spirotrac 6 Database

To install, run *Setup* from the Spirotrac 6 USB flash drive and select to *Install Database Studio*.

### 10.3.1. Create a new Spirotrac 6 Database

Database Studio is used to create a new Spirotrac 6 Database:

- SQL Server 2014 and upwards is supported.

***Note:*** *When using Spirotrac on a SQL instance not provided by Spirotrac, consult with your SQL Server Database Administrator to ensure Filestream is enabled.*

- Ensure the version of Database Studio being used is compatible with Spirotrac 6 by checking the software version number is the same.

To create a new Spirotrac 6 database:

1. Run Database Studio.
2. Select *Create Database*.
3. Select *Instance*. This will list locally available SQL instances.
4. Specify *Database Name.* This must be an alphanumeric value between 3 and 50 characters in length that is also unique compared to other databases that already reside on the given instance.
5. Select *Create.*

### 10.3.2. Migrate Spirotrac V Subjects and data to Spirotrac 6

Database Studio can be used to migrate Subject data from Spirotrac V version 1.19 or later to Spirotrac 6:

- Check Spirotrac V is version 1.19. Upgrade if required.
- Subjects are migrated by Number - where a Subject already exists in Spirotrac 6, ensure the same Number isused in Spirotrac V.
- Delete subjects that are not desired candidates for migration.
- Merge Spirotrac V databases prior to mitigation.
- Backup the Spirotrac 6 database.
- Close all applications connected to Spirotrac V and 6 databases.

To migrate subject data to Spirotrac 6 database:

1. Run Database Studio.
2. Select *New Migration*
3. The following information is mandatory:
   a. *Migration Name* - Enter a name for the migration or use the default – this will appear in the migration log afterwards.
   b. *Source Server*, *Source Destination* and *Authentication* information of the Spirotrac V database.
   c. *Destination Server, Destination Database* and *Authentication* information of the Spirotrac 6 database.
4. Select *START.*

### 10.3.3. Upgrading a Spirotrac 6 Database

Database Studio can be used to upgrade a Spirotrac 6 Database to the current version.Before upgrading:

- Backup the Spirotrac 6 database.
- Close all applications connected to the 6 database.
- Ensure the version of Database Studio being used is compatible with Spirotrac 6 by checking the software version number is the same.

To upgrade a Spirotrac 6 database:

1. Run Database Studio.
2. Select Upgrade Database.
3. Under Authentication, select either SQL or Windows.
4. Select or enter Instance.
5. If SQL authentication is selected, enter Username and Password select CONNECT.
6. Select Database. Only databases requiring an upgrade are listed.
7. Select Upgrade.

### 10.3.4. Performing a backup or restore of a Spirotrac 6 Database

Database Studio can be used to backup or restore a Spirotrac 6 Database (ref 10.3).

Before performing a database backup:

- Close all applications connected to the Spirotrac 6 database.

To backup:

1. Run Database Studio.
2. Select Backup Database.
3. Under Authentication, select either SQL or Windows.
4. Select or enter Instance name.
5. If SQL authentication is selected, enter Username and Password
6. Select CONNECT.
7. Select Database.
8. Select Backup Location and browse to the required location.
9. Select Backup.

Before restoring a database:

- Backup the Spirotrac 6 database.
- Close all applications connected to the Spirotrac 6 database.
- Ensure the SQLservice account has read/write access to the selected location

To restore a Spirotrac 6 database:

1. Run Database Studio.
2. Select Restore Database.
3. Under Authentication, select either SQL or Windows.
4. Select or enter Instance name.
5. If SQL authentication is selected, enter Username and Password select CONNECT.
6. Enter Database name.
7. Select Backup File and browse to the required location. Note: full network location needs to be supplied when restoring a backup file from the network
8. Select Restore.

***Note:*** *When the filestream location of the database backup differs from the filestream location used by the destination server, use the Custom FileStream location option to indicate the custom location to be used.*



#### 10.3.5. Setting/changing the database used by Spirotrac.

Database Studio can be used to set/change the database used by Spirotrac.
Before setting/changing the current database:

- Check Spirotrac 6 is installed on the same system and ensure it is not running.
- Ensure the version of Database Studio being used is compatible with Spirotrac 6 by checking the software version number is the same. The correct version of Database Studio can be installed by choosing About in Spirotrac and selecting Database Studio Installer.

To change the database:

- Run Database Studio.
- Select settings on the left menu.
- Select or enter SQL Server instance name.
- Under Authentication, select either SQL or Windows.
- Select database from the drop down list.
- Enter Database label.
- Click save.

### 10.4. Licensing/Registering the software

When Spirotrac is first installed, certain features of the software are locked by default. Locked features are identified with a To activate your copy of Spirotrac and unlock all features, click on the license icon in the main menu at any time and follow the on-screen instructions to obtain an activation code. If an internet connection is not available on the PC Spirotrac is installed browse to register-spirotrac.vitalograph.com to obtain an activation code. You will need to create a Vitalograph account and register your device serial number first followed by your Spirotrac PIN. Once you have retrieved your activation code, enter it in Spirotrac and select ACTIVATE.

### 10.5. Application Exit

#### 10.5.1. Locking the Application

To lock Spirotrac if leaving the workstation for a period of time:

1. Select *Lock* icon from the main menu on the main dashboard.
2. Spirotrac is now locked and will require the user to login again to unlock.
3. The application will automatically lock after a configurable amount of time, refer to Section 8.6.

#### 10.5.2. Logging Off

To log off the system:

1. Select *Log Off* icon from the main menu on the main dashboard.
2. Following confirmation, you will be logged off Spirotrac. Another user may now log on.

#### 10.5.3. Shutting Down

If you are finished using Spirotrac it should be shut down.

1. Select *Exit* icon from main menu on the main dashboard.
2. Following confirmation, Spirotrac will shut down.

### 10.6. Integration with Vitalograph Connect

Spirotrac integrates with Vitalograph Connect to support the exchange of electronic healthcare information with Electronic Medical Record (EMR) systems. Both Health Level 7(HL7) and GDT protocols are supported.
The Vitalograph Connect application is located on the Spirotrac installation media. To install, browse the media contents, run the *Setup* application, and select to *Install Connect*.

#### 10.6.1. Setup Spirotrac 6 for use with Vitalograph Connect

***Note:*** *For Vitalograph Connect setup and configuration see Vitalograph Connect specific IFU.*
The exchange of data with EMR systems must be setup and enabled from within Spirotrac 6 also, refer to Section 8.8

#### 10.6.2. Performing EMR Requested Test and Return Results

When Spirotrac receives a test request/order for a subject from an EMR system, the count of pending requests is visible on the main dashboard.

1. Click on *New Order(s)* to view the list of requests received and awaiting attention.
2. Identify the EMR request for the subject you wish to process. Select *Start Testing*. This will select the subject associated with the EMR request. **Note**: When race is either not provided on inbound order or does not match an existing population group, you will be prompted to edit the subject.
3. To perform testing, follow instructions as per Section 6
4. When testing is complete, the test session can be returned to the EMR system, select *Return Order* from the main dashboard.

5. Ensure the correct results to be returned are selected.
   a. You may need to scroll through Test Orders where more than one exists for the subject.
6. Select *Return* to transmit the session data for the selected EMR request(s).

#### 10.6.2.1. Allowing Auto Processing of orders

Where clinics require only one request to be submitted at any one time, it is possible to configure Spirotrac to process EMR Test Requests and Results Return more seamlessly.

1. Enable Auto Process Orders via Settings, refer to 8.8.
   When Auto Process Orders is enabled, click on New Order(s) to automatically select the order and associated subject. Note: For EMR systems which do not supply any subject population group information, the default population group to be associated with new subject(s) can be set via settings, refer to Section 8.8
2. To perform testing, follow instructions as per Section 6.
3. When testing is complete, the test session can be returned to the EMR system, select Return Order from
4. the main dashboard to transmit the session data for the EMR request.

### 10.6.3. Returning Unsolicited Results to EMR

Test session data can also be returned for subjects that do not have a pending EMR test request. In this case only an unsolicited message can be returned to the EMR. Note: This is only applicable when enabled in Connect, for details refer to Vitalograph Connect IFU.

1. Ensure Vitalograph Connect is setup and configured, and enabled for Spirotrac, refer to Section 10.6.1
2. If not already selected, select the subject whose test results you intend to transmit back to the EMR system, refer to Section 5.3.1.
3. Select *Send Unsolicited* from the subject screen.
4. Select the results to be returned.
5. Select *Return* to transmit the session data.

### 10.6.4. Viewing EMR Recall orders

When Spirotrac receives a view request/order for a subject or session from an EMR system, it is included in the count of pending requests visible on the main dashboard.

1. Click on New Order(s) to view the list of requests received and awaiting attention.
2. Identify the required EMR request and select View. This will select the subject/session associated with the EMR request.

***Note:*** *The View button is disabled/greyed where a request has been received but the subject or session cannot be found in the database. Please check that the correct subject and session information has been supplied from the EMR system.*

## 10.7. Application Updates

When Spirotrac is opened it automatically checks for any available software updates. If an update is available, the release notes for the update will display, listing new features and changes. Selecting install will begin the process of downloading and installing the update. At any point the download may be cancelled and Spirotrac will check for updates again two weeks later. **Note**: Both the update check and the update itself require an internet connection. When an update for Spirotrac is downloaded, an update for Database Studio is also down loaded (Refer to Section 10.7.2).

### 10.7.1. Manual check for updates

To manually check for updates:

1. Click About on the main menu.
2. Select Check for Updates beside the product version.
3. If an update is available, the release notes will display.
4. Select install and follow the onscreen instructions to complete the update.

### 10.7.2. Database Studio updates

When an update for Spirotrac is downloaded, an update for Database Studio is also included.
To complete the Database Studio update:

1. Click on About in the main menu.
2. Select the Database Studio installer button to view the installer folder (located at C:\ProgramData\Vitalograph\Database Studio\Installer).
3. Click on the installer to complete the process.

***Note:*** *Administrator rights are required to install an update.*

EN

## 11. Cleaning & Hygiene

See relevant device IFU.

## 12. Disposal

See relevant device IFU.

## 13. Fault Finding Guide

### 13.1. Spirometry

| | |
|---|---|
| **Problem Fault Symptoms:** | • **Not measuring flow** |
| Possible Causes/Solutions: (In probable order) | • Ensure tubing is connected correctly. Ribbed side of tubing should be connected toribbed half of connector on the Vitalograph device. |
| **Problem Fault Symptoms:** | • **Incorrect or no volume measurements** |
| Possible Causes/Solutions: (In probable order) | • Ensure tubing is connected correctly. Ribbed side of tubing should be connected toribbed half of connector on the Vitalograph device.<br>• Ensure that connectors are clear of obstruction or dirt and that they are insertedfully.<br>• Ensure tubing is not kinked or squeezed. |
| **Problem Fault Symptoms:** | • **Excessive calibration drift** |
| Possible Causes/Solutions: (In probable order) | • Flowhead may not be clean. Clean flowhead thoroughly.<br>• Contact the nearest dealer for replacement flowhead. |
| **Problem Fault Symptoms:** | • **Test performed but does not show on screen** |
| Possible Causes/Solutions: (In probable order) | • Check device is connected to PC correctly.<br>• Check tubing is connected correctly between flowhead and device (same colour connector at both ends). |
| **Problem Fault Symptoms:** | • **Report does not print all tests**<br>• **Report does not print some parameters** |
| Possible Causes/Solutions: (In probable order) | • Check the correct report settings are set up in the application.<br>• Check the required parameters are selected in settings. |
| **Problem Fault Symptoms:** | • **Communication error message appears when entering the Test screen or the calibration verification screen** |
| Possible Causes/Solutions: (In probable order) | • Ensure the Vitalograph device is attached correctly. |
| **Problem Fault Symptoms:** | • **Calibration Verification variations > +/- 3%** |
| Possible Causes/Solutions: (In probable order) | • Perform a re-verification.<br>• Was the correct syringe volume entered?<br>• Check there is no leak in the connection of the flow head to the syringe and that the correct mouthpiece and adapter are used<br>• Check that the tubing connectors are clear of obstruction or dirt and that they areinserted fully.<br>• Check the tubing is not kinked or squeezed.<br>• Ensure the calibration syringe is emptied and filled in one smooth action duringverification<br>• Was air pumped through the flow head when instructed to ensure no differences between room temperature and that of the calibration syringe and flowhead<br>• Ensure flowhead is clean.<br>• Contact Vitalograph. |
| **Problem Fault Symptoms:** | • **Device does not appear for selection on entrance to test screen** |

| | |
|---|---|
| Possible Causes/Solutions: (In probable order) | • Device is not connected to your PC correctly, see relevant device IFU<br>• Drivers did not successfully install. To install drivers manually, Run *Setup* from USB Flash Drive and Select “Install USB Pneumotrac” |



### 13.2. ECG

| | |
|---|---|
| **Problem Fault Symptoms:** | • **The Bluetooth driver requests the entry of a PIN.** |
| Possible Causes/Solutions: (In probable order) | • The device is no longer paired and is trying to establish a fixed connection.<br>• Enter “1111” and confirm. |
| **Problem Fault Symptoms:** | • **One or several electrode contact points are flashing despite the electrodes being applied.** |
| Possible Causes/Solutions: (In probable order) | • Electrode contact is poor.<br>• Check electrode positioning and skin contact.<br>• Press electrodes firmly on the skin. Shave any hair or clean the skin. Use abrader tape. Replace the electrode.<br>• If the above-mentioned measures show no improvement, the cable might be defective. Please send the device back to the manufacturer for repairs. |
| **Problem Fault Symptoms:** | • **A beep sounds: 2 seconds on, 2 seconds off, for 1 minute.** |
| Possible Causes/Solutions: (In probable order**)** | • Wireless connection is interrupted.<br>• Reduce the distance to the receiver unit or remove any existing obstacle. |
| **Problem Fault Symptoms:** | • **Beep sounds at the same frequency as the flashing electrode contact points.** |
| Possible Causes/Solutions: (In probable order) | • Electrode has possibly come loose during measurement.<br>• Check the electrode contact. Replace the electrode, if necessary. |
| **Problem Fault Symptoms:** | • **“Connection error” message is displayed on the monitor.** |
| Possible Causes/Solutions: (In probable order) | • PIN was not correctly entered. Reconnect with the device and enter PIN “1111”.<br>• ECG device is not switched on. Switch device on.<br>• Bluetooth dongle is not plugged into USB port of the PC. Insert the Bluetoothdongle in free USB port.<br>• Device is paired with another monitor. Unpair the device by pressing the buttonfor 20 seconds. |
| **Problem Fault Symptoms:** | • **When the monitor starts, the error “Bluetooth error, No dongle…” occurs.** |
| Possible Causes/Solutions: (In probable order) | • Bluetooth dongle is not plugged into USB port of the PC. Insert the Bluetooth dongle in free USB port.<br>• Bluetooth driver software is not installed. Install Bluetooth driver software. (Installation instructions included in delivery.) |
| **Problem Fault Symptoms:** | • **The ECG device cannot be found on entrance to test screen.** |
| Possible Causes/Solutions: (In probable order) | • Plug Bluetooth dongle into USB slot on PC. Where PC has integrated Bluetooth capability with the Microsoft Bluetooth stack, a Bluetooth dongle will not be required.<br>• Turn on BT-12 ECG device before initiating an ECG session.<br>• The ECG device is paired. In this state, the device is not visible. Unpair the device by pressing the button for 20 seconds.<br>• Refer to the device IFU |
| **Problem Fault Symptoms:** | • **During recording, red lines are occasionally displayed in the ECG signal.** |
| Possible Causes/Solutions: (In probable order) | • There are transmission errors.<br>• The ECG device is out of range.<br>• One or several electrodes do not have proper contact.<br>• Bring the ECG device back into range of the receiver. Check electrode positioning and skin contact. |

EN

| | |
|---|---|
| **Problem Fault Symptoms:** | • **After the recording, red lines are occasionally displayed in the ECG signal.** |
| Possible Causes/Solutions: (In probable order) | • There were transmission errors during recording.<br>• ECG device was out of range temporarily during recording.<br>• One or several electrodes did not have proper contact during recording.<br>• Check electrode positioning and skin contact. |
| **Problem Fault Symptoms:** | • **During recording, pacemaker pulses were detected (incorrectly) and marked inred.** |
| Possible Causes/Solutions: (In probable order) | • When electrode contact is poor, it can lead to false pacemaker detection.<br>• Check electrode positioning and skin contact or deactivate pacemaker detection for patients without pacemakers. |
| **Problem Fault Symptoms**: | • **ECG device cannot be found after disconnecting and re-connecting the Bluetooth dongle.** |
| Possible Causes/Solutions: (In probable order) | • Bluetooth settings are initialised on application start up.<br>• Restart Spirotrac.<br>• Unpair the device by pressing the button for 20 seconds |

### 13.3. Oscillometry

| | |
|---|---|
| **Problem Fault Symptoms:** | • **Oscillometry Test type is not listed.** |
| Possible Causes/Solutions: (In probable order) | • Oscillometry has not been enabled.<br>• In Spirotrac settings go to Testing – Oscillometry, select enable and save. |
| **Problem Fault Symptoms:** | • **Oscillometry is not configured.** |
| Possible Causes/Solutions: (In probable order) | • Oscillometry testing may be enabled but Tremoflo software was not installed.<br>• Tremoflo software was not installed in the default folder location.<br>• Install Tremoflo from the Spirotrac installation media, ensuring it is installed in the default folder location.<br>• Consult the Tremoflo user manual for further details on software setup. |
| **Problem Fault Symptoms:** | • **Failure to Launch Tremoflo software.** |
| Possible Causes/Solutions: (In probable order) | • Check Tremoflo device is connected to PC correctly.<br>• Check that Tremoflo hardware setup has been completed. Consult the Tremoflo user manual for details on hardware setup. |

### 13.4. FeNO

| | |
|---|---|
| **Problem Fault Symptoms:** | • **DEVICE NOT FOUND displayed on entrance to test screen** |
| Possible Causes/Solutions: (In probable order) | • Ensure device is connected to power supply, connected to PC/COMPACT and is switch on<br>• If the NIOX VERO is in sleep mode, tap the screen to wake it up so that it will connect to the Spirotrac. |
| **Problem Fault Symptoms:** | • **Test was performed on device but no results were saved in Spirotrac** |
| Possible Causes/Solutions: (In probable order) | • The flow rate was incorrect during exhalation or was not maintained for the full 10 seconds. When this happens a Measurement Failed error occurs (e.g. A10=too forceful, A11=not forceful enough). The test should be repeated using the correct flow rate. |
| **Problem Fault Symptoms:** | • **Device temperature outside range** |
| Possible Causes/Solutions: (In probable order) | • leave device idle for 2-3 minutes and wait until the testing is possible |

### 13.5. General

| | |
|---|---|
| **Problem Fault Symptoms:** | • **Account Locked** |

| | |
|---|---|
| Possible Causes/Solutions: (In probable order) | • If you enter your password incorrectly 3 times the account becomes locked fora configurable amount of time, .e.g., 15 minutes. Retry again after this time has lapsed or contact your Spirotrac Admin user. |
| **Problem Fault Symptoms:** | • **Failure to create or connect to default database** |
| Possible Causes/Solutions: (In probable order) | • SQL was not installed during installation.<br>• To use a local database, login to PC as an administrator user and install SQL fromthe Spirotrac setup.hta.<br>• To use a network database, create the database on the network server using DatabaseStudio<br>• Ensure your SQL server is running |
| **Problem Fault Symptoms:** | • **Some features are locked/unavailable** |
| Possible Causes/Solutions: (In probable order) | • Your product may not be registered. For instructions on how to activate your license, see Section 10.4 Licensing/Registering the software |

## 14. Customer Service

Service and repairs should be carried out only by the manufacturer, or by Service Agents specifically approved by Vitalograph.
For the names and addresses of approved Vitalograph Service Agents or to arrange spirometry workshops or training, please refer to the contact information at the start of this manual.
Any serious incident that occurs in relation to the device should be reported to Vitalograph or its Authorized Representative and the Regulatory Authorities of the country. Refer to the Vitalograph contact information at the startof this manual.

## 15. Explanation of Symbols

| Symbol | Description |
|---|---|
|  | Manufacturer |
|  | USB connector |
|  | The device must be taken to separate collection at the product end-of-life. Do not dispose of these products as unsorted municipal waste. |
|  | QR code - matrix bar code. All information in the bar code is included in the text under it. |
| Rx only | **Caution**: Federal Law restricts this device to sale by, or on the order of a physician. |

## 16. Description of the Vitalograph Spirotrac

Vitalograph Spirotrac is a Microsoft Windows based computerized Spirometry system for lung function testing in a variety of professional healthcare environments, e.g., primary care, hospitals and occupational health centres.
In a clinical setting, the measurements obtained from a lung function test form part of the findings of a physician in the detection, diagnosis and control of chest diseases. Spirometry may support or exclude diagnosis, but it cannot make one. Spirometers are also used in non-clinical settings such as occupational health screening where no clinical judgment is made, suspect findings leading to a referral to a clinician. Vitalograph Spirotrac is intended for use by medical professionals trained in respiratory and lung function testing. Apart from this instruction manual, there are no other training requirements for the medical professional

## 17. Technical Specification

| | |
|---|---|
| **Product** | **Vitalograph Spirotrac** |

EN

| | |
|---|---|
| Model | 7000 |
| Processor Speed | 2GHz or greater |
| RAM | 2GB (minimum)<br>8GB (recommended) |
| Disk Space | 1GB or greater<br>If the .Net Framework version 4.8 is not already installed, this will require an additional 1GB (32-bit) or 2GB (64-bit) of hard disk space. If SQL Server Expressis not already installed, this will require an additional 2GB of hard disk space.<br>Supplied with SQL Server 2014 Express SP3 |
| Operating System | • Windows 10 (64-bit)<br>• Windows 11 (64-bit) |
| Monitor Display | 1280 x 800 pixels minimum, higher recommended. |
| Other | • Microsoft .Net Framework 4.8<br>• Mouse<br>• 1 x USB port minimum for Pneumotrac spirometry device and softwareinstallation<br>• Bluetooth support for BT-12 ECG device<br>• 1 x ethernet port minimum for connection to Vitalograph Tremoflo C-100 device to perform Oscillometry |
| Performance standards the Vitalograph Spirotrac meets or exceeds | ATS/ERS 2019, ISO 23747:2015 & ISO 26782:2009 |
| QA/GMP standards | EN ISO 13485, FDA 21 CFR 820 & Japan's PMD Act |

## 18. CE Notice

Marking by the symbol CE 2797 indicates compliance of the Vitalograph Spirotrac Model 7000 to the Medical Devices Directive of the European Community.
The Vitalograph Spirotrac Model 7000 is intended for use in a variety of professional healthcare environments, e.g., primary care, hospital wards and occupational health centres, except for near active high frequency surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high. The customer or the user of Spirotrac and any connected devices should assure that it is not used in such an environment.
Medical Devices may be affected by mobile RF communications equipment including cellular telephones and other personal or household devices not intended for medical facilities. It is recommended that all equipment used near the Vitalograph product comply with the medical electromagnetic compatibility standard and to check before use that no interference is evident or possible. If interference is suspected or possible, switching off the offending device is the normal solution, as is required in aircraft and medical facilities.
Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided.
Portable and mobile RF communications equipment can affect medical electrical equipment.

## 19. FDA Notice

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

## 20. EU Declaration of Conformity

Product: Model 7000, Spirotrac
Vitalograph hereby ensures and declares that the above product associated with these Instructions for Use, is designed

and manufactured in accordance with the following QMS regulations and standards:
European Medical Devices Directive {MDD} 93/42/EEC, as amended.
This device is classified as IIa per Annex IX of the MDD also meets the provisions of the Essential Requirements, Annex I, via compliance with Annex II of the Medical Devices Directive as per Article 11, section 3a, excluding point 4 of Annex II.



- European Medical Devices Directive {MDD} 93/42/EEC, as amended.
  This device is classified as IIa per Annex IX of the MDD also meets the provisions of the Essential Requirements, Annex I, via compliance with Annex II of the Medical Devices Directive as per Article 11, section3a, excluding point 4 of Annex II.

- EN ISO 13485 Medical devices. Quality management systems. Requirements for regulatory purposes.

Certifying Body: British Standards Institute {BSI}.
BSI Notified Body #: 2797
Certificate Nos. CE 00772, MD 82182

Signed on behalf of Vitalograph (Ireland) Ltd.

CE 2797

**Frank Keane.**
CEO, Vitalograph Ltd.

## 21. 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 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.