RIGEL
MEDICAL

RIGEL SP-SIM

SP02 simulator

Rigel Medical 24 Month Warranty Statement

Rigel Medical provides a standard 12-month manufacturer's warranty against breakdown during normal use. This warranty can be upgraded to a 24-month warranty (terms and conditions apply*). Problems caused through misuse, damage, fair wear & tear, consumables and accessories are excluded from standard warranty. Such components found to be being used in excess of their manufacturer's operating recommendations are also excluded. Shipping to an authorised service centre is the responsibility of the sender.

*Terms and Conditions of 24 Month Warranty

The Rigel product must be registered with Rigel Medical within 30 days of purchase to be eligible for the extended 24-month warranty. Instruments must be returned to an authorised service centre complete with proof of purchase within 13 months of purchase for calibration at the current rate. Any items returned for calibration outside of the 13 month period stated above may not be eligible for the second 12 month section of warranty. The second 12 month section of the warranty begins at the expiry of the initial 12 month period, not when the unit is calibrated.

Details correct at time of going to print. The manufacturer retains the right to make amendments to the above terms and conditions without prior notice.

Calibration Statement

The Rigel SP-SIM SPO2 Simulator is fully calibrated and found to be within the specified performance and accuracy at the time of production. The Seaward Group provides its products through a variety of channels; therefore it may be possible that the calibration date on the provided certificate may not represent the actual date of first use.

Experience has indicated that the calibration of this instrument in not effected by storage prior to receipt by the user. We therefore recommend that the recalibration period be based on a 12 month interval from the first date the unit is placed in to service.
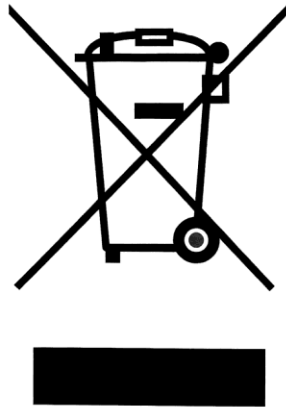

Date received into service;   /   /   .

Disposal of old product

The Rigel SP-SIM SPO2 Simulator has been designed and manufactured with high quality materials and components, which can be recycled and reused.

Please familiarise yourself with the appropriate local separate collection system for electrical and electronic products or contact your local supplier for further information.

Please dispose of this product according to local regulations. Do not dispose of this product along with normal waste material. By offering your old products for recycling, you will help prevent potential negative consequences for the environment and human health.

Statement of Conformity

This product is manufactured by:

Seaward Electronic Ltd, Bracken Hill, South West Industrial Estate, Peterlee, County Durham, SR8 2SW, UK

As the manufacturer of the apparatus listed, we declare under our sole responsibility that the product:

Rigel SP-SIM SPO2 simulator

Conforms with the relevant Directives and conformity is indicated by the symbol $C\epsilon$, i.e. "Conformité Européenne"

Seaward Electronic Ltd. is registered under **BS EN ISO9001** Certificate No.: Q05356.

A copy of the Declaration of Conformity and a copy of our ISO certificate are available in the Support & Resources area of the Seaward website www.seaward.co.uk".

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User Notes

These operating instructions are intended for the use of adequately trained personnel.

The following symbols are used in these operating instructions and on the Rigel SP-SIM.

Warning of electrical danger!
Indicates instructions must be followed to avoid danger to persons.

Important, follow the documentation! This symbol indicates that the operating instructions must be adhered to in order to avoid danger.

If the SP-SIM is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

The SP-SIM is supplied with a mains power supply unit. The use of any other power supply unit may cause damage to the equipment and may result in a hazard to the user.

1. Introduction

Rigel Medical has introduced a new hand held, high performance pulse oximetry simulator for the fast, accurate and efficient testing of SpO2 devices.

The lightweight and battery powered Rigel SP-SiM is the first hand held simulator of its type and utilises new technology to eliminate the inconsistencies that can often be associated with testing using traditional equipment like an optical finger. In addition, the new technology has proven to identify worn SpO2 probes, which are not detected by either the SpO2 monitor nor traditional simulators and probe testers.

Market leaders in oximeters use and specify instruments using electronic simulation for quality assurance purposes as a direct result of the high accuracy and repeatability of direct electrical simulation, yet the optical simulation method is able to take account of optical uncertainties. The SP-SIM is the first SpO2 simulator able to utilise both electronic and optical methods in a single test setup, reducing uncertainties thus improving the test time.

The SP-SiM features pulse volume adjustments, heart rate and manufacturer specific R-curves for maximum flexibility, combined with a large capacity internal memory for the data capture, storage and easy downloading to a PC via Bluetooth of test results for record keeping – details of up to10,000 devices can be stored. Manufacturer specific test programs can be uploaded via the Bluetooth technology while probe and monitor are tested at the same time for improved accuracy and faster results.

The SP-SiM is available as individual simulator or as part of the new Med-eKit portable biomed trolley and is part of a comprehensive range of high performance specialist biomedical test equipment supplied by Rigel Medical.

1.1. Rigel SP-SIM Design Philosophy

The SP-SIM has been designed to address the increasing demand for smaller more comprehensive test equipment within the Healthcare Industry.

The challenge was to combine the benefits of the size and weight of a smaller hand-held SPO2 Simulators with the test versatility and convenience of a larger bench-mounted simulator. Today's industry demands test equipment that can save time and cost, thus offering greater flexibility. These factors have all been taken into account during the development of the SP-SIM.

The test capabilities and functionality exceed that of most common SPO2 simulators yet the instrument is only a fraction of the size and weight.

No other SPO2 simulator on the market offers a hand-held enclosure with the test capabilities equal to most bench marked version interface, large internal memory, Blue Tooth communication, asset management facilities, user configurable Performance Tests and more.

We believe that the new SP-SIM is set to become the new standard in NIBP performance Testing.

1.2. Key Features

- **Portable and Lightweight** - Ideal for field service technicians and in-situ testing of SPO2 performance

- **Battery Operated** - For convenient and fast testing without mains power

- **Manufacturer R-curves** - To ensure accurate simulations across a wide range of different brands of SPO2 probes

- **Prepared for PPM Protocols** - Configured for automatic performance testing of a variety of parameters

- **Full Keyboard** - Easy data capturing and asset management

- **Intuitive User Interface** - Fast and easy navigation using graphics display

- **Graphics Display** - Allowing real-time display of simulation data

- **Bluetooth Communication** - PC download and future field upgrades

- **Web Updates** - Enjoy easy updates through our website to benefit from the latest features

1.3. Rigel SP-SIM includes:

- Battery charger
- Carry case
- Application disc
- Calibration certificate

1.4. Optional Accessories

- PULS-R universal SPO2 simulator finger   (p/n 399A910)
- Med-eBase PC Download software   (p/n 383A910)
- Med-eBase SIM licence   (p/n 383A916)
- Bluetooth Barcode scanner   (p/n 339A923)
- BlueTooth Test 'N' Tag Elite 2 Printer   (p/n 339A989)

1.5. Test 'n Tag Compatible

The Rigel SP-SIM is compatible with the Seaward Test 'n Tag and Elite system. Our Test 'n Tag systems allows you to print customised Thermal PASS / FAIL labels.

The benefits of using the Test 'n Tag printers are:
- Robust and durable labels
- Resistant to most solvents used in the medical sector
- Free opportunity to advertise your logo and company details or emergency telephone number with every item you Test 'n' Tag.
- Automatic barcode generation to provide easy use of the barcode scanner thus speeding up your test time.

The unique Test 'n' Tag label provides test status and retest due date, barcode and asset ID number, and person conducting the test. For more information on using the Test 'n Tag printer, see section 4.

1.6. Interfaces
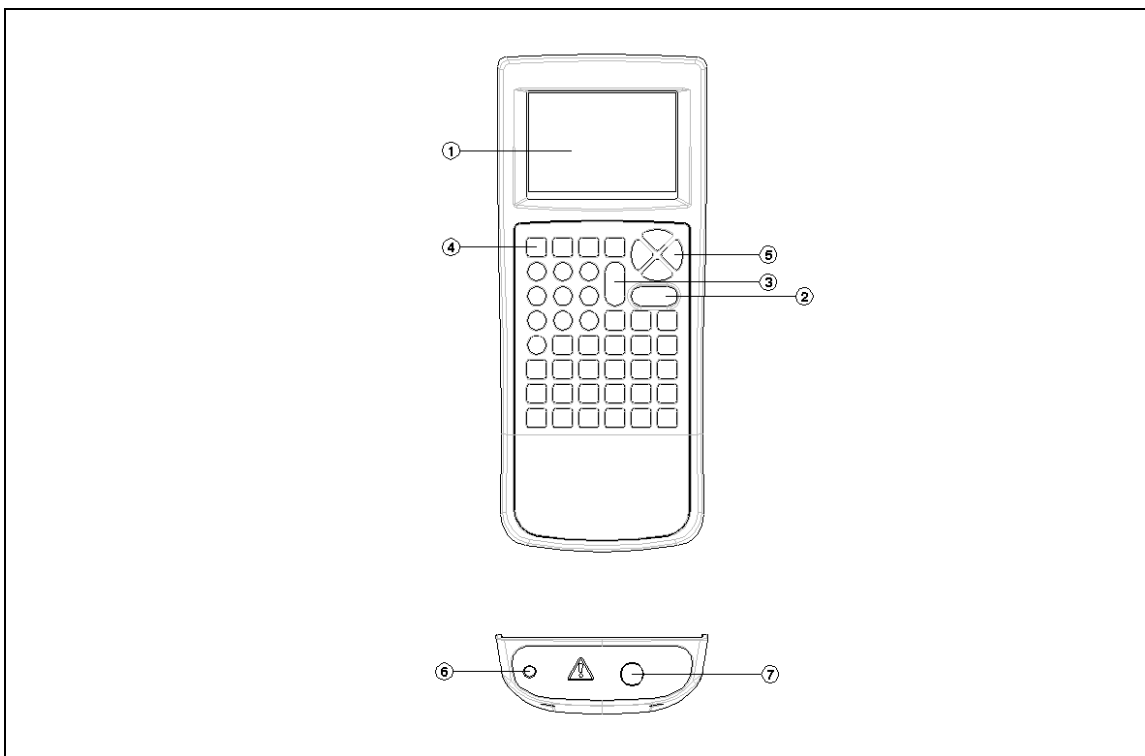
1) Full graphic Monochrone LCD, blue with white backlit, 1/4 VGA
2) Larger Green Start/On key
3) Larger Red key Stop/Off Key
4) 4 Programmable soft keys below display
5) Alpha Numeric keyboard, Up / Down and Left / Right cursor control.
6) Power Supply inlet
7) SPO2 Input/Output connector

2. Using the PULS-R optical finger with the UNI-SIM

The PULS-R optical finger is for use only with Rigel SP-SIM and UNI-SIM products
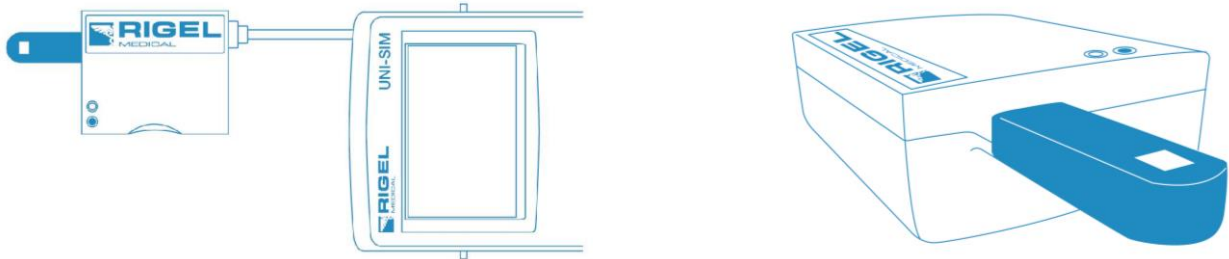
2.1. Accuracy of simulation when used with the corresponding R-curves

Resolution	Range	Repeatability*
1% steps	30 - 60%	±5%**
1% steps	60 - 90%	±3%
1% steps	90 - 100%	±1%

* Based on using the same probe and monitor setup
**Note that some monitor types might not be able to display low range sats

Operating temperature	0-40°C
Dimensions	78 x 68 x 29 mm
Finger shape	40 x 18 mm
Heart Rate	30-300 bpm
Part number	399A910

2.2. Getting started

Turn on your Rigel UNI/SP-SIM by pressing and holding the green start button until you hear a "beep" and the Rigel splash screen appears.

The summary simulation screen appears displaying the settings from the previous simulation for all parameters and can be repeated by simply pressing the green start key

For both the Rigel UNI and SP- SIM the user will need to select.
SPO2 Simulation.

Image 1 of the UNI-SIM shows NIBP, SPO2, ECG, IBP, Respiration and Temperature and Image 2 shows the same for the SP-SIM.
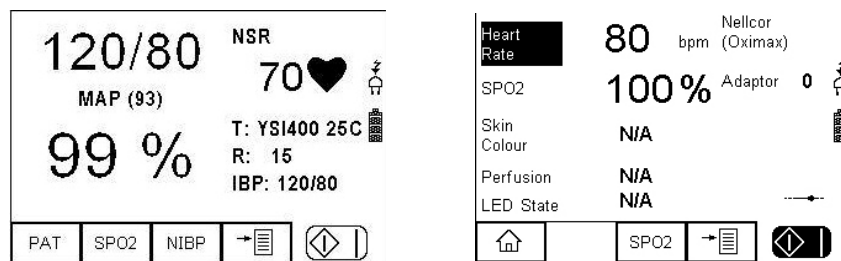
The connection between the PULS-R, the UNI/SP-SIM and the monitor is shown in the diagram using the SP02 connector lead.

2.3. Performing SP02 simulations

The connection between the PULS-R, the UNI/SP-SIM and the monitor is shown in the diagram connected to the SPO2 port on the SP-SIM/UNI-SIM' or similar text.

The correct orientation for probe place is with the LED of the probe on the top side of the PULS-R.
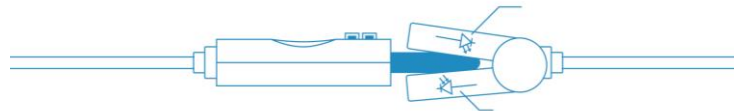
Parameters can be varied to validate the monitor and probe including:
- Technology. E.g.: PULS-R, Masimo, Nellcor....
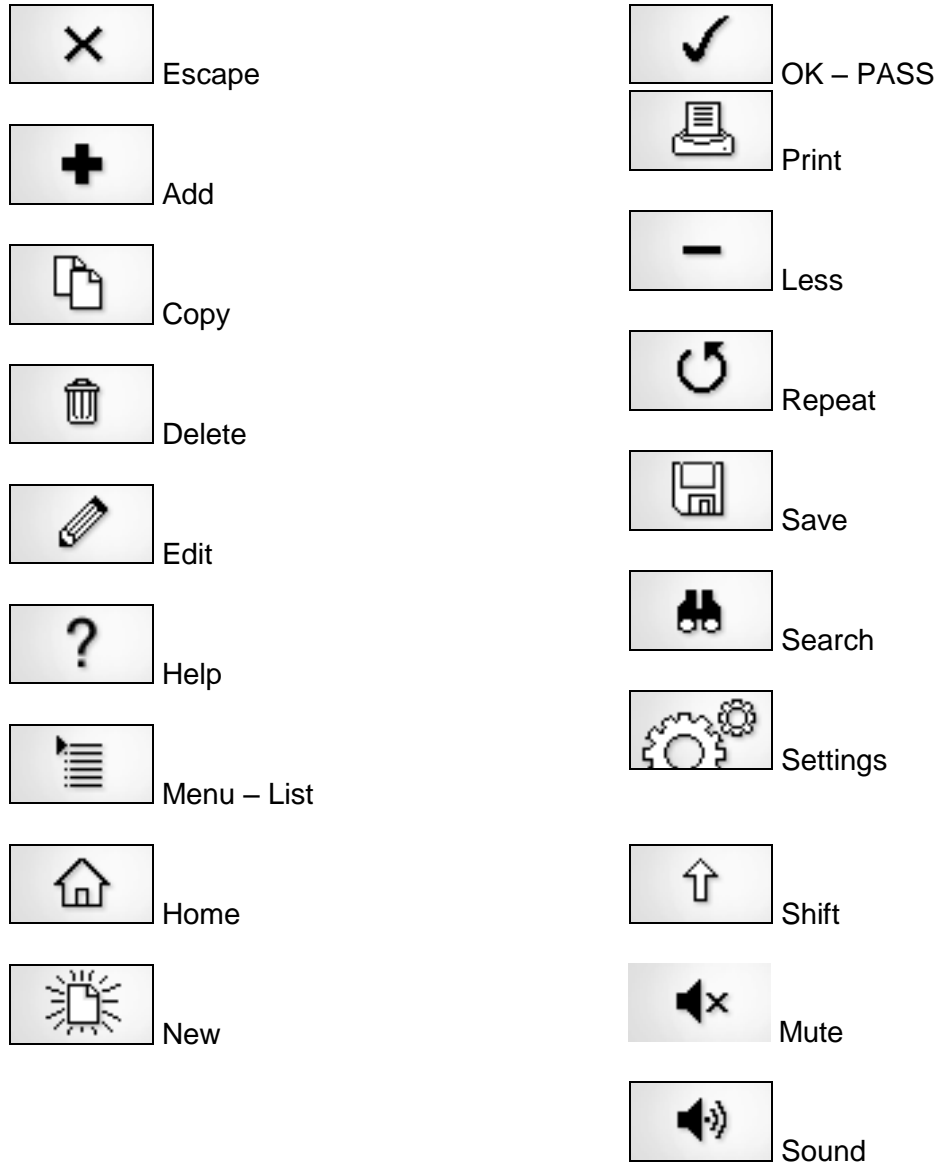- SPO2 (%) simulated
- Heart Rate

Supported Default curves:
- Beijing Choice (PULS-R)
- Criticare (PULS-R)
- GE Ohmeda Tuffsat (PULS-R)
- Masimo (PULS-R)
- Mindray (PULS-R)
- Nellcor (PULS-R)
- Nellcor OxiMax (PULS-R)
- Nihon Kohden (PULS-R)
- Nonin (PULS-R)
- Novametrix (PULS-R)
- Philips/HP (PULS-R)

To customise your own R curves please see application note 0061 Creating and uploading R Curves for UNI-SIM and SP-Sim.

2.4. Unique use of ICONS
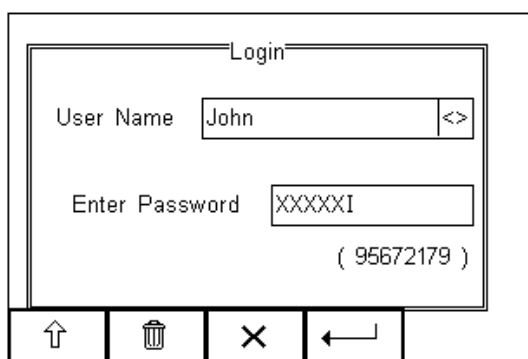
The Rigel SP-SIM features a hi resolution graphic back lit display which not only provides highly visible and easy to follow menu structures but also allows the user to operate the tester using intuitive icons to speed up their test routines.

Below are of some of the icons used in the Rigel SP-SIM:

 Escape

 Add

 Copy

 Delete

 Edit

 Help

 Menu – List

 Home

 New

 OK – PASS

 Print

 Less

 Repeat

 Save

 Search

 Settings

 Shift

 Mute

 Sound

3. Logging on

When switching on the Rigel SP-SIM, the user will be able to log-in to allow for specific default user preferences and to provide traceability of test results. To increase the security and protection of the user, a password can be set prior to using the Rigel SP-SIM. See 4.5.3 for further details. The default password setting is OFF and the login screen will not require a password. In case a user and password are set, the tester will default to the last user / password.

```
┌──────────────────────────────────────────┐
│  ┌────────────────Login─────────────────┐ │
│  │                                       │ │
│  │  User Name  ┌──────────────┬───┐     │ │
│  │             │John          │<> │     │ │
│  │             └──────────────┴───┘     │ │
│  │                                       │ │
│  │  Enter Password ┌──────────────┐     │ │
│  │                 │XXXXXI        │     │ │
│  │                 └──────────────┘     │ │
│  │                    ( 95672179 )       │ │
│  └───────────────────────────────────────┘ │
│  ┌──────┬──────┬──────┬──────┬──────┐     │
│  │  ⇧   │  🗑   │  ✗   │  ←┘  │      │     │
│  └──────┴──────┴──────┴──────┴──────┘     │
└──────────────────────────────────────────┘
```

To change the user, use the drop down menu provided [<>] and select the new user. In case a password is set for the new user, please enter the password (case sensitive).

In case a password is lost and the unit is blocked, please call our helpdesk on:
+44 (0) 191 5878701 or contact your local distributor and quote the 8-digit code (shown below the password field) and the serial number of the tester. A new password will then be created. For security reasons, this new password can only be provided to the email address of the original purchaser of the device.

The Rigel SP-SIM is designed to allow a user to customise test sequences and allow default settings. This customisation can speed up testing by providing the user with default manufacturer lists, model numbers, user text protocols, automatic printing post-text and fault menus.

4. Setting-up your tester

The Rigel SP-SIM is designed to allow the user to customise the device to allow default setting in order to speed up the testing such as, default lists of manufacturers, model numbers, user test protocols, automatic printing following test, fault menu's and so on.

All custom facilities can be found under the SETUP menu. Simply press the ▸☰ [F4] from the home screen and select Setup from the menu.

Hint: The underlined character acts as a short key to allow swift navigation through the menu structure.
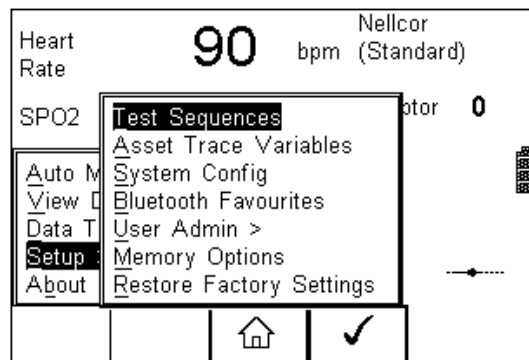
Options available

Test Sequences	Modify or create test sequences (see 4.1)
Asset Trace Variables	Generate default list of variables (see 4.2)
Systems Config	Configure default test options (see 4.3)
Blue Tooth Favourites	Setup your Blue Tooth devices (see 4.4)
User admin	Setup users and preferences (see 4.5)
Memory Options	Manage the tester's memory (see 4.6)
Restore Factory Settings	Defaults the tester to factory settings (see 4.7)

4.1. Test Sequences

The Rigel SP-SIM can be set-up to create new test sequences to meet monitor specific requirements or to modify existing test sequences to meet personal preference.

Preset test sequences cannot be changed by the user, however alterations are possible by producing a copy of the default test sequence setting.

The total number of possible preset test sequences is 50 including 12 default test sequences.

4.1.1. User definable tests

This feature gives the Rigel SP-SIM the capability of recording user defined visual inspections, checks or tests including measurements from SPO2, ECG, NIBP, Defib, Infusion, Ventilation, Pressure etc.

The input is text only as no measurements are performed by the Rigel SP-SIM during these tests. The user can enter questions or instructions followed by either a PASS/FAIL result or alpha numeric input. Preset engineering units e.g. %, Joules, mmHg, PSI, CmH2O etc are available.

4.1.2. View, Delete or Copy an existing Test Routine.

Preset test sequences cannot be deleted or changed by the user however, alterations are possible by producing a copy of the default test sequence.
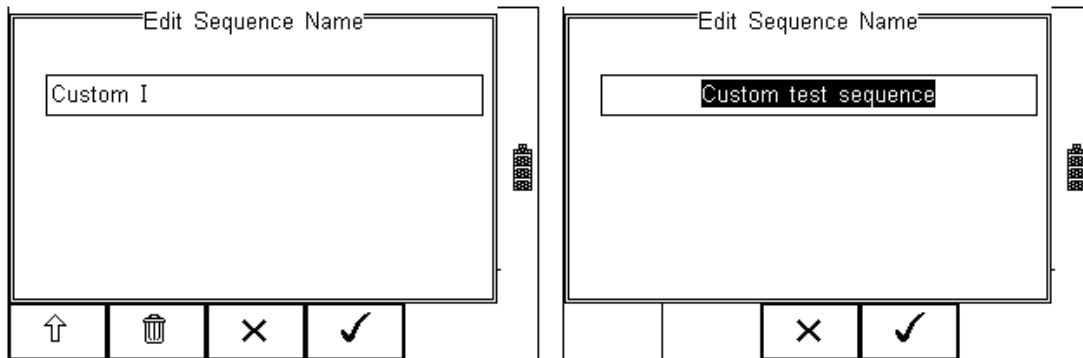
To enter the Test Sequences menu, click on ⭢▤ , followed by Setup. Select the Test Sequences from the list and press ✓ (F4).
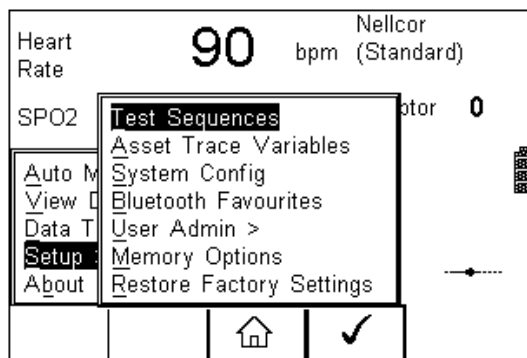
The following overview is provided and shows the list of default and customised test sequences availble. Copied Test Sequences will appear in the list with an *pre-fix.
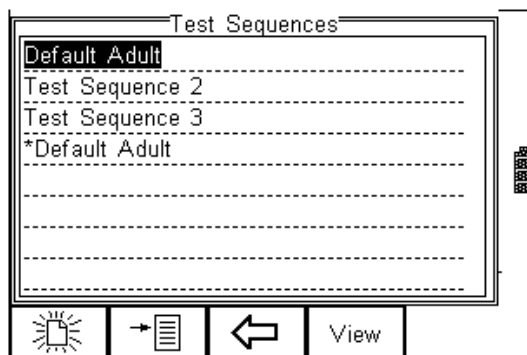
From this menu, the user is able to View a test sequence by pressing the View button (F4). Default test settings cannot be altered at any stage.

To Copy, Delete or Print an existing or default test sequence, use the Up & Down arrow keys to highlight the test sequence and press the ⇥▤ button (F2).
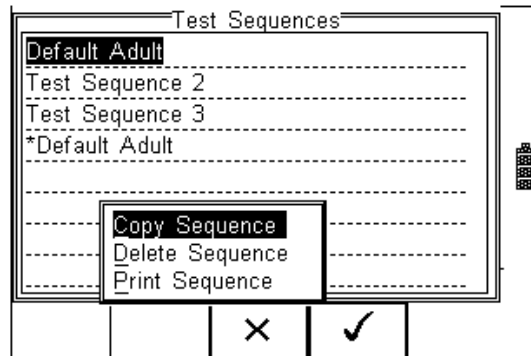
Use the Up & Down Arrow keys to select the required action and press the ✓ (F4) to confirm. Press Escape (F3) to cancel and return to previous screen.

Copied Test Sequences will appear in the list with an *pre-fix. All Copied test Sequences can be edited. See 3.1.3 for more on editing test sequences.

Print Test Sequence will provide an overview of the Test Sequence on the Favourite Blue Tooth Printer. See 4.4 for help on setting up Blue Tooth devices.

Delete Sequence will remove the highlighted test sequence from the memory of the Rigel SP-SIM.

Note: Default Test Sequences cannot be Deleted.

3.1.3   Modifying (Edit) Existing Test Sequences

Preset test sequences cannot be modified by the user, however alterations are possible by producing a copy of the default test setting (see 4.1.2).

Non-default Test Sequences can be modified from the Test Sequences menu. When non-default Test Sequences are highlighted, the ✎ (F4) will appear in the menu screen.
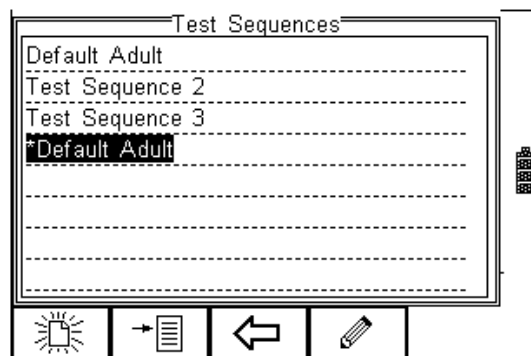
Pessing the ✏ button (F4) will open the Test Sequence for Editing as shown below;

```
┌─────────Edit Sequence─────────┐
│*Default Adult                  ▓│
│                                ▓│
│                                 │
│                                 │
│ - - - - - - - - - - - - - - - - │  🔋
│SPO2 Monitor Type                │
│Default SPO2 monitor             │
│                                 │
└──────────[ ⇦ ][ ✏ ]───────────┘
```
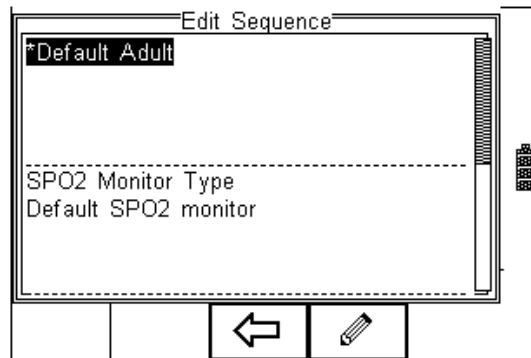
To change the Name and or Class of the Test Sequence, press the ✏ Button (F4) and enter the Name and or Class required.

```
┌──────Edit Sequence Name──────┐    ┌──────Edit Sequence Name──────┐
│                               │    │                               │
│ Custom I                      │    │      Custom test sequence     │
│                               │ 🔋 │                               │ 🔋
│                               │    │                               │
│                               │    │                               │
│[ ⇧ ][ 🗑 ][ ✕ ][ ✓ ]          │    │        [ ✕ ][ ✓ ]            │
└───────────────────────────────┘    └───────────────────────────────┘
```

To change to upper or lower case or use language specific characters, press the ⇧ button (F1) and select the required entry.

To Delete a character, press the 🗑 button (F2)

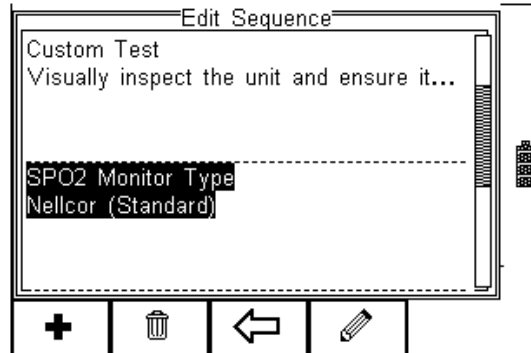To return to the previous menu without changes, press the ✕ button (F3)

Confirm the changes with the ✓ button (F3) or cancel using the ✕ button (F4).

To Insert a new test, highlight the test using the Up & Down arrow keys and press the Insert button (F1)

To Delete an individual test, highlight the test using the Up & Down arrow keys and press the 🗑 button (F2)
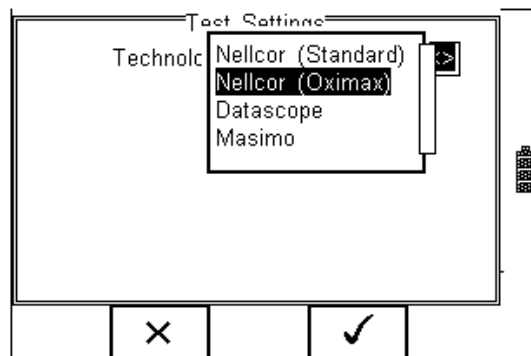
To go back to the previous menu, highlight the test using the Up & Down arrow keys and press the ✕ button (F3)

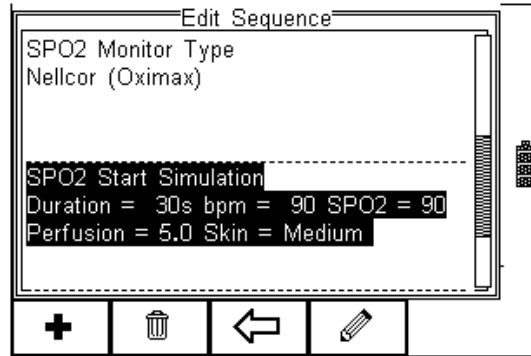To modify an individual test, highlight the test using the Up & Down arrow keys and press the ✎ Button (F4)

```
┌══════════════Edit Sequence══════════════┐
│Custom Test                              ▓│
│Visually inspect the unit and ensure it...▓│
│                                          │
│                                         ▓│
│                                         ▓│
│ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─     │
│SPO2 Monitor Type                        ▒│
│Nellcor (Standard)                        │
│                                          │
│ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─     │
├──────┬──────┬──────┬──────┐              │
│  ✚   │  🗑   │  ⇦   │  ✎   │              │
└──────┴──────┴──────┴──────┘              │
```

4.1.3. Edit individual Test

Press the ✎ button (F4) as shown above. The SPO2 sub menu will allow you to set the SPO2 simulation mode. This is only required once in the whole sequence.

```
┌══════════════Test Settings══════════════┐
│           ┌────────────────────┐         │
│ Technolo  │Nellcor (Standard)  │◇▷       │
│           │Nellcor (Oximax)    │         │
│           │Datascope           │         │
│           │Masimo              │        ▓│
│           └────────────────────┘        ▓│
│                                          │
│        ┌──────┐      ┌──────┐            │
│        │  ✕   │      │  ✓   │            │
│        └──────┘      └──────┘            │
└──────────────────────────────────────────┘
```

Open the drop down box using the arrow keys and select the required SPO2 setting.

When the right settings have been achieved, press the ✓ button (F4) to save the changes or press ✕ (F3) to return to the previous menu without changes.

Now scroll down to the next entry to set the parameters for the simulation by highlighting the "SPO2 Start Simulation" from the screen as shown below;

Press the ✎ button (F4) as shown above to open the various options;

To Delete an individual test, highlight the test using the Up & Down arrow keys and press the 🗑 button (F2)
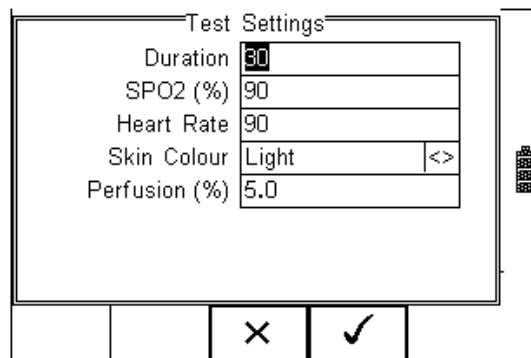
Set the test duration, SPO2 value, Heart rate, Skin Colour and Perfusion by using the arrow keys to navigate and key pad to enter the required data.
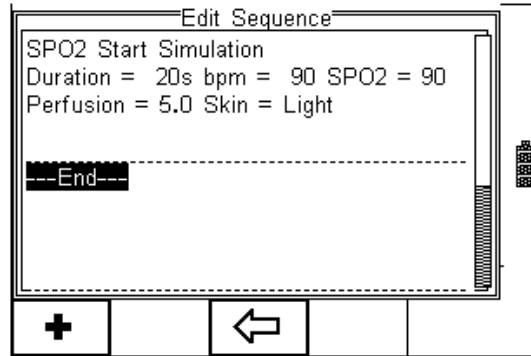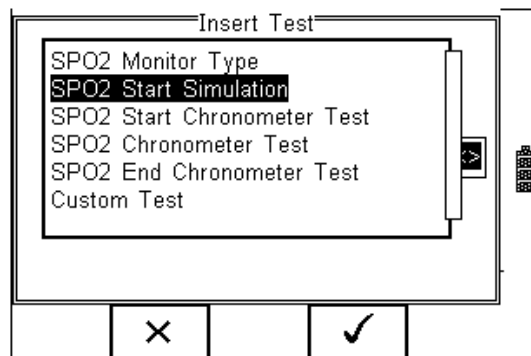
When the right settings have been achieved, press the ✓ button (F4) to save the changes or press ✗ (F3) to return to the previous menu without changes.

4.1.4. Insert additional tests

To insert an additional test, use the up and down keys to highlight the position where a new test needs inserting and press the Insert button (F1) from the menu below.

Note; Tests will be inserted before the highlighted position not after.

To modify a test sequence, please refer to 4.1.3

```
                 ┌──────Edit Sequence──────┐
                 │ SPO2 Start Simulation    │ │
                 │ Duration =  20s bpm =  90 SPO2 = 90 │
                 │ Perfusion = 5.0 Skin = Light │
                 │                          │
                 │ ───End───                │ ▓
                 │                          │ ▓
                 │                          │ ▓
                 └──────────────────────────┘
             ┌──────┐      ┌──────┐
             │  ✚   │      │  ⇦   │
             └──────┘      └──────┘
```

Once the Insert button (F1) has been pressed, a drop down box will appear with all available tests. Activate the drop down box using the left key and or scroll through the available tests using the up and down keys.

```
                 ┌──────Insert Test──────┐
                 │ SPO2 Monitor Type      │
                 │ ▓SPO2 Start Simulation▓ │
                 │ SPO2 Start Chronometer Test │
                 │ SPO2 Chronometer Test   │ ◄►
                 │ SPO2 End Chronometer Test │
                 │ Custom Test             │
                 └─────────────────────────┘
             ┌──────┐      ┌──────┐
             │  ✗   │      │  ✓   │
             └──────┘      └──────┘
```

Once the desired test has been highlighted, confirm using the OK button (F4) and finally

confirm to insert into the test Sequence. Pressing the   ✗   button (F3) will return to the previous screen without changes being made.

The individual test has now been inserted and can be edited as described in 3.1.4

```
                 ┌──────Edit Sequence──────┐
                 │ SPO2 Start Simulation    │ ▓
                 │ Duration =  30s bpm =  90 SPO2 = 90 │
                 │ Perfusion = 5.0 Skin = Medium │
                 │                          │
                 │ ▓SPO2 Start Simulation▓  │ ▓
                 │ ▓Duration =  30s bpm =  90 SPO2 = 90▓ │
                 │ ▓Perfusion = 5.0 Skin = Medium▓ │
                 └──────────────────────────┘
          ┌────┐  ┌────┐  ┌────┐  ┌────┐
          │ ✚  │  │ 🗑  │  │ ⇦  │  │ ✎  │
          └────┘  └────┘  └────┘  └────┘
```
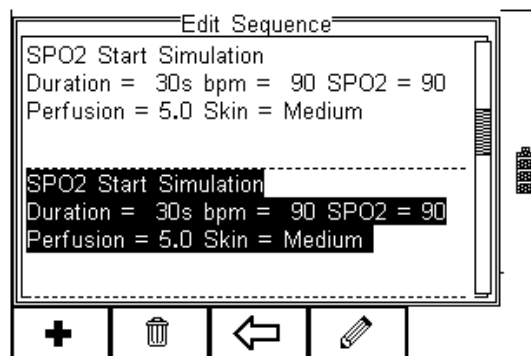
Further tests can be inserted or deleted by following the steps described herein.

4.1.5. Insert chronometer test

The SP-SIM has the ability to perform a chronometer test in order to capture the time taken to respond between different settings. To utilise the chronometer test, SP-SIM must be set to the start settings (Start Chronometer Test), the next settings ((Chronometer Test) and when the final settings have been inserted (a number of next settings can be inserted) the SP-SIM must be set to stop the chronometer test (End chronometer Test)

In an example below, the SP-SIM will simulate from <u>98% to 90%, then down to 85%</u> by inserting the following tests.

Start Chronometer Test:
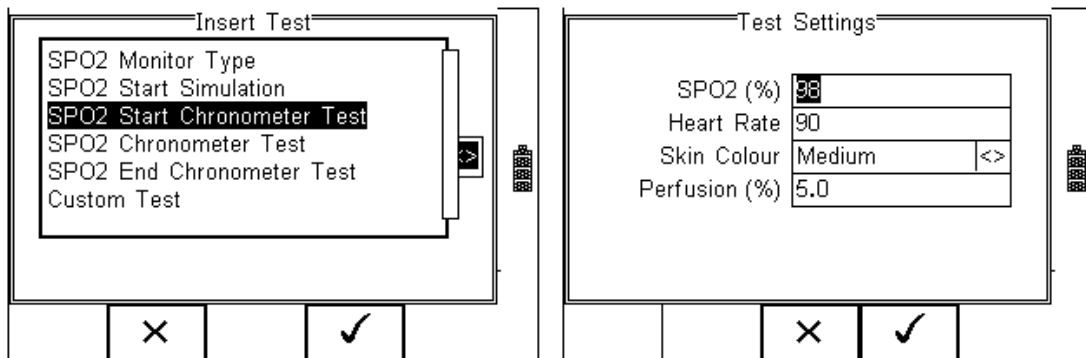
Chronometer Test to 90%
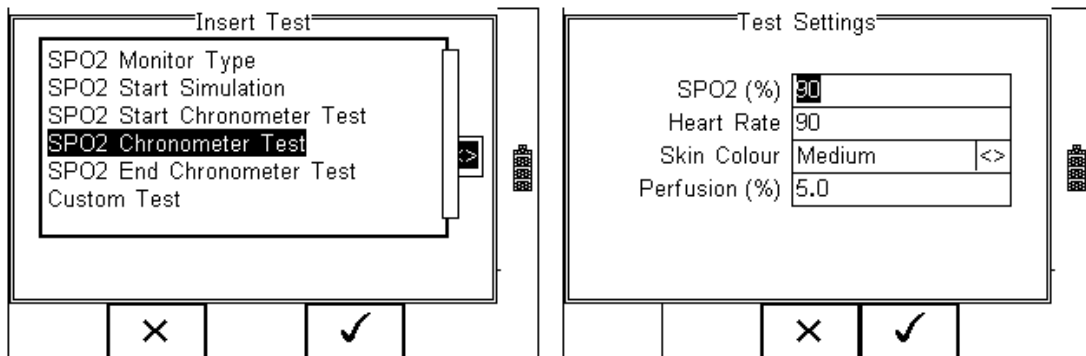
Chronometer Test to 85%
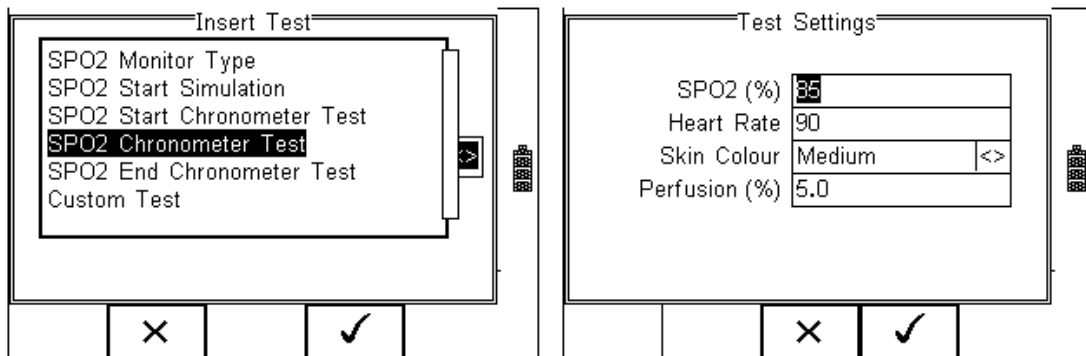
Once the final test settings have been selected, the SP-SIM must be instructed to stop the simulation mode. This is done by inserting the END CHRONOMETER TEST;

```
┌─────────────Insert Test─────────────┐
│ ┌─────────────────────────────────┐ │
│ │ SPO2 Monitor Type               │ │
│ │ SPO2 Start Simulation           │ │
│ │ SPO2 Start Chronometer Test     │ │
│ │ SPO2 Chronometer Test           │ │
│ │ SPO2 End Chronometer Test       │ │
│ │ Custom Test                     │ │
│ │                                 │ │
│ └─────────────────────────────────┘ │
│        ┌─────┐      ┌─────┐          │
│        │  ✗  │      │  ✓  │          │
│        └─────┘      └─────┘          │
└─────────────────────────────────────┘
```
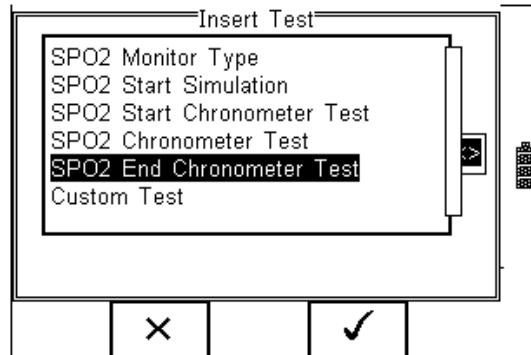
4.1.6. Insert Custom Tests or Instructions

Custom tests or Instructions are intended to allow the user to capture additional information either prior to or after the main SPO2 performance tests. Such information could indicate the condition such as Labels, software version, certain damage or upgrades. To create customised inspections, use the insert Custom Test function using the instructions below and set the engineering units to blank.

Hint: Create a unique range of visual tests or instructions by creating a new test sequence (see 4.1.7) and select Custom Test as the nature of the test. This will create a unique test sequence.

The maximum number of **characters** in the test description or instruction is 255.

To insert a Custom Test, highlight the place where a new test needs inserting using the up and down keys and press the Insert button (F1) from the menu below.

Note; Tests will be inserted before the highlighted position not after.

```
┌────────────Edit Sequence────────────┐
│ ┌─────────────────────────────────┐ │
│ │ SPO2 End Chronometer Test       │ │
│ │                                 │ │
│ │                                 │ │
│ │ ┌───End───┐─ ─ ─ ─ ─ ─ ─ ─ ─ ─  │ │
│ │                                 │ │
│ │                                 │ │
│ └─────────────────────────────────┘ │
│    ┌─────┐      ┌─────┐              │
│    │  ✚  │      │  ⇐  │              │
│    └─────┘      └─────┘              │
└─────────────────────────────────────┘
```
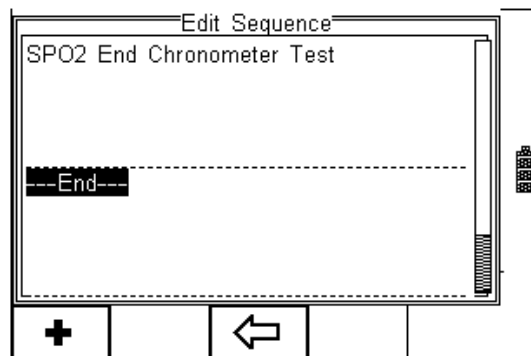
Once the Insert button (F1) has been pressed, a drop down box will appear with all available tests and inspection available. Activate the drop down box using the left key and select the Custom Test option.
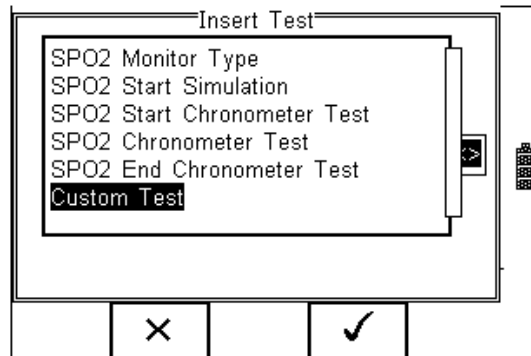
Confirm using the ✓ button (F4). The following menu will define the nature of the test (eg test Instruction prior to leak test)

Use the drop down box to choose a preset instruction and engineering unit or simply type in the boxes provided. Newly entered data will be added to the drop down box on a first come first serve basis.
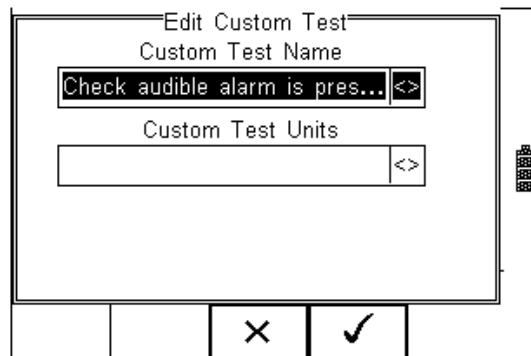
To insert the new Custom Test, press the ✓ button (F4) or exit using the ✗ button (F3) and return to the previous screen without changes being made.
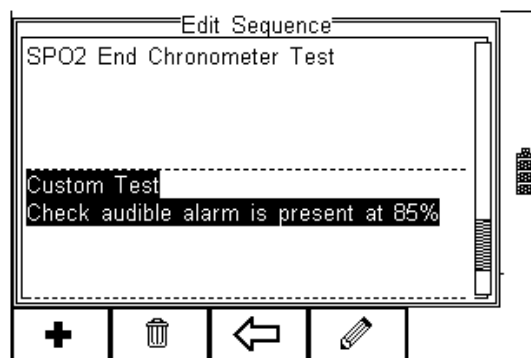
Further tests can be inserted or deleted by following the steps described herein.

To exit and save the changes for future press the ⇦ button followed by pressing the 💾 button. If the Escape button (F3) is pressed, the Rigel SP-SIM will return to the previous meny without changes being made.
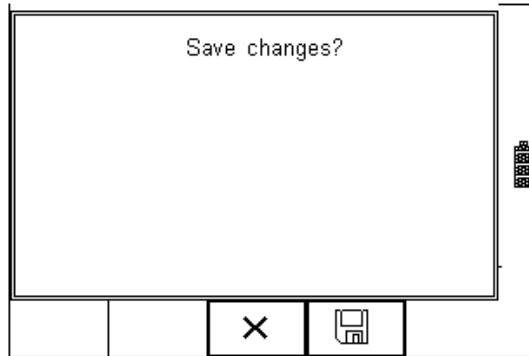
4.1.7. Create a new Test Sequence

To create a new Test Sequence, enter the Menu button (F4) from the home screen, select Setup followed by Test Sequences from the menu.
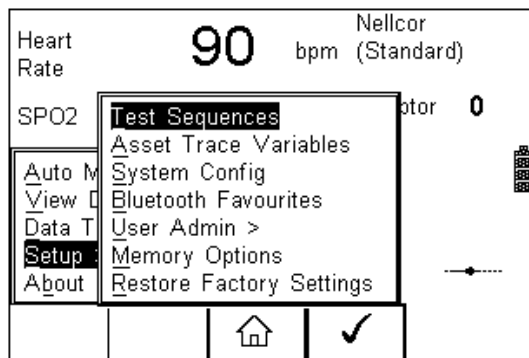
The following screen displays the list of default and customised tests available. Copied Test Sequences will appear in the list with an *pre-fix.
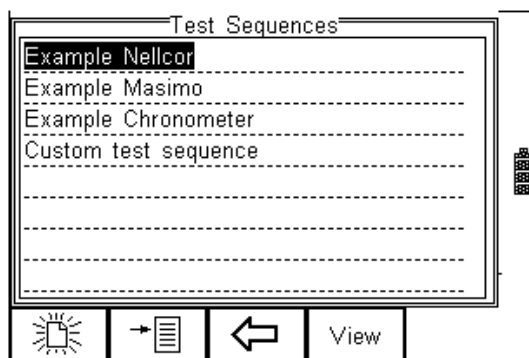
From this menu, the user is able to create a new Test Sequence by pressing the button (F1).

```
┌──────New Test Sequence──────┐
│ ┌─────────────────────────┐ │
│ │Test Sequence 5          │ │
│ └─────────────────────────┘ │
│                          ▓   │
│                          ▓   │
│                          ▓   │
│ ┌──────┬──────┬───┬───┐      │
│ │      │      │ ✕ │ ✓ │      │
└─┴──────┴──────┴───┴───┴──────┘
```
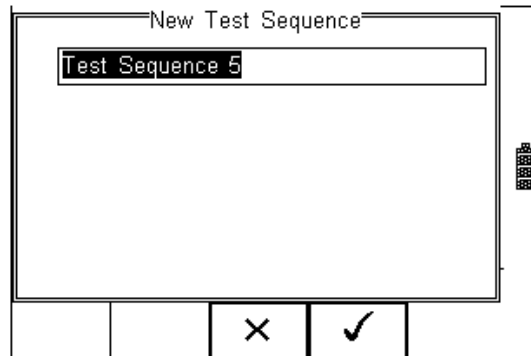
Use the keyboard to activate the text box. When activated, function keys F1 ⇧ and F2 🗑 appear automatically. In this instance 'Customer test 1' has been created as Test Name.
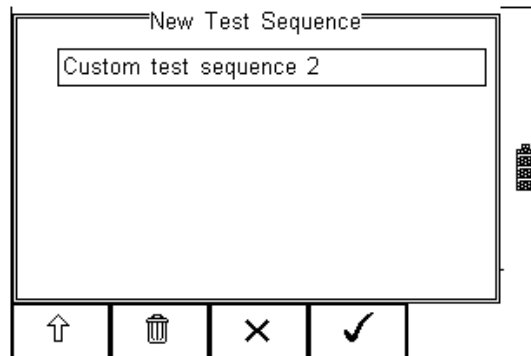
```
┌──────New Test Sequence──────┐
│ ┌─────────────────────────┐ │
│ │Custom test sequence 2   │ │
│ └─────────────────────────┘ │
│                          ▓   │
│                          ▓   │
│                          ▓   │
│ ┌───┬───┬───┬───┐            │
│ │ ⇧ │ 🗑 │ ✕ │ ✓ │            │
└─┴───┴───┴───┴───┴────────────┘
```

To change to upper or lower case or use language specific charaters, press the ⇧ button (F1) and select the required entry.

To Delete a character, press the 🗑 button (F2)

To return to the previous menu without changes, press the ✕ button (F3)

To confirm the entry, press the ←┘ button (F4)

Next step is to save the name of the newly create Test Name, by pressing the OK button (F4). Pressing the ✕ key (F3) would return to the Test Sequence menu without changes.

The newly created Test Name now appears in the Test Sequence menu and can be modified to include the required individual tests. Press the ✐ button (F4) to open the sequence for editing.
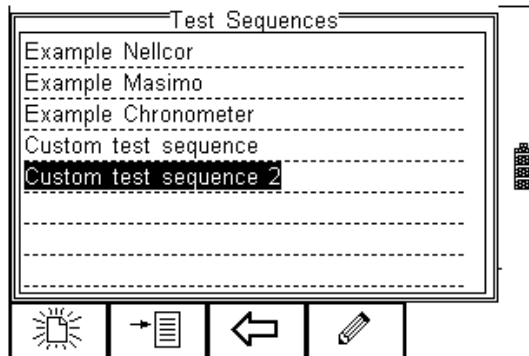
Once the Test Sequence has been opened, individual tests can be inserted by highlighting the place where a new test needs inserting using the up and down keys.

Note; Tests will be inserted before the highlighted position not after.

To modify a test sequence, please refer to 4.1.3

4.2. Asset Trace Variables

The Asset Trace Variables allow the user to include valuable data to the test results to enhance the traceability and to provide increased search criteria when using database software. Asset trace variables may consist of a maximum of 25 characters and can be selected prior to each test when using the Rigel SP-SIM in automatic mode.
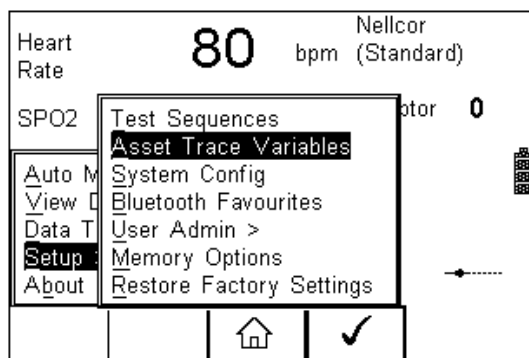
The following variables can be added to the test results:
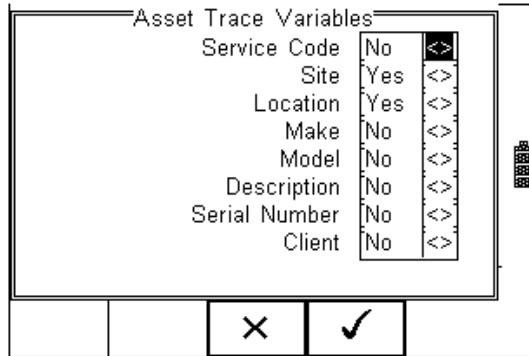
The default settings on the Rigel SP-SIM include the Site and Location variables. Both are activated. The drop down box is set to [Yes].

To activate or de-activate each variable, use the up and down keys to select the variable and the left and right keys to select yes or no.

Once a variable has been activated, the user is given the ability to enter Trace Variables prior to a safety test by selecting from or adding to the list of default items. Each variable entered during the automatic test will automatically be added to the list for future use.

Trace Variables that are de-activated (set to NO) will not appear during the automatic tests.

Note that a maximum of 40 individual entries are available for each Trace Variable. Additional entries will overwrite on a first in first out basis.

4.3. System Config

This feature can setup the Rigel SP-SIM to automatically perform certain features during or after a test as well as allowing the user to set Time and Date preference.

To select System Config, press the button (F4) followed by Setup in the menu and System Config from the list as shown below;
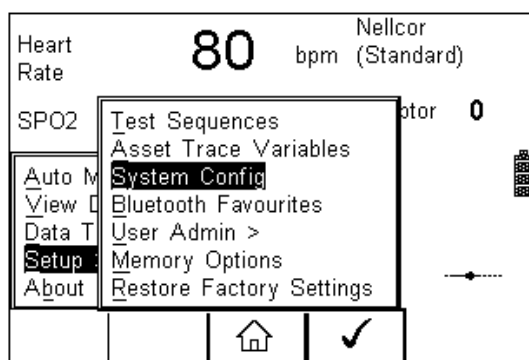
The System Config menu is displayed below;
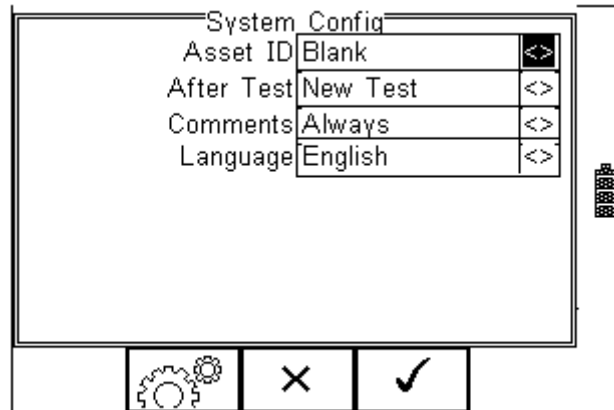
The System Config menu provides the following features:

4.3.1. Asset ID

Provides automatic Asset ID configuration. Use the Left & Right Keys to select between

- Increment - Automatically increments the next Asset ID's least significant number by 1
- Blank – Will leave the next Asset ID field blank
- Repeat Last - Will copy the previous Asset ID into the next Asset ID field

4.3.2. After Test

Provides automatic action after a test is completed. Use the left and right keys to select from the following

- New Test – Automatically brings up the next test screen.
- Download – Automatically down loads the test results to the PC (see 8.1)
- Print Label – Automatically prints the test results or label to a printer (see Appendix B)
- Options Menu – Provides a menu to allow further choices after a test. (see 6.3)

4.3.3. Comments

Provides the ability to enter further comments after successful or failed tests. Use the left and right keys to select from the following

- Always – Comment field is displayed after each passed or failed test.
- On Pass – Comment field is displayed after a passed test only.
- On Failure – Comment field is displayed after failed test only
- Never – Comment field is not displayed.

4.3.4. Language

Provides the ability to change the default language in the Rigel SP-SIM. A number of languages are available and will be updated which ach firmware revision. Use the up, down, left and right keys to select from the available languages. Additional languages (firmware upgrades) can be downloaded from **www.rigelmedical.com** or contact your local Rigel sales office (UK ; +44 (0) 191 5878701)

4.3.5. Date / Time

Allows the user to set the current date / time and preferred formats.

Press the Date / Time button (F2). The following menu will be displayed;

```
┌──────Date / Time──────┐
│   Day    [8]           │
│                        │
│  Month   [Jul  ] [<>]  │
│                        │
│   Year   [2009 ]       │
│                        │
│   Time   [  14:43]     │
│                        │
│         [ ✕ ] [ ✓ ]    │
└────────────────────────┘
```

Day	Enter current day
Month	Use the up, down, left and right keys to select the current month
Year	Enter current year
Time	Enter current time. Use the ':' (F1) to separate hours from minutes to ensure the correct time is entered and saved.

Confirm the settings by pressing the ✓ button (F4)

Ones all System Configurations have been completed, press the ✓ button (F4). Changes are saved automatically.

4.4. Blue Tooth Favourites

In order for the Rigel SP-SIM to automatically connect to the correct Bluetooth accessory, details of that accessory must be entered into the Bluetooth Favourites list.

The Bluetooth Favourites list comprises of three sub-lists (device types), each of which can store up to 3 accessories of the same type. The three sub-lists are shown below:

- Barcode (Scanner)
- Printer
- Computer

To select Bluetooth Favourites, press the ⌐▤ button (F4) followed by Setup in the Menu and Bluetooth Favourites from the list as shown below. Press ✓ (F4) to select;
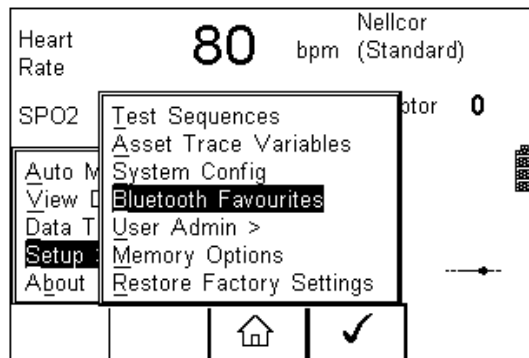
The following shows how to add a Computer to Bluetooth Favourites.
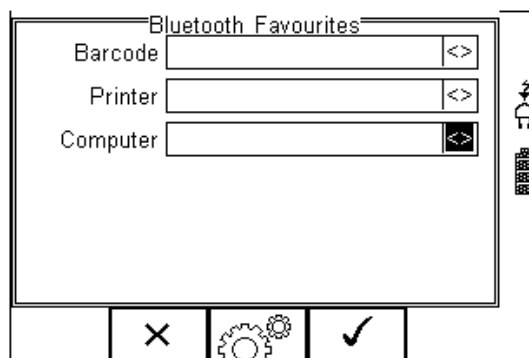
Use the up/down arrow keys to highlight the device type (in this case Computer) then press ⚙ (F3).

Make sure that the device you want to add to your new favourites is switched on.

Press ![binoculars] (F1). The Rigel SP-SIM will search for all discoverable Bluetooth devices within a 10m range. The time taken to perform the search will vary depending on the number of Bluetooth devices in range. A progress bar will show during the search. When the search is completed, the progress bar will disappear.
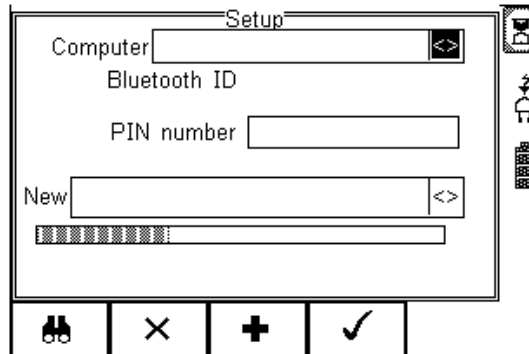
Use the arrow keys to highlight the field labelled "New" and press the left or right keys to open the list of devices which have been found during the search.

Note: *If more than 10 Bluetooth devices have been found the list will show the last 10 devices found.*

In the following example, the search has identified Bluetooth devices named "SELLT023", "SELPC045" and "Elite 36-5011"
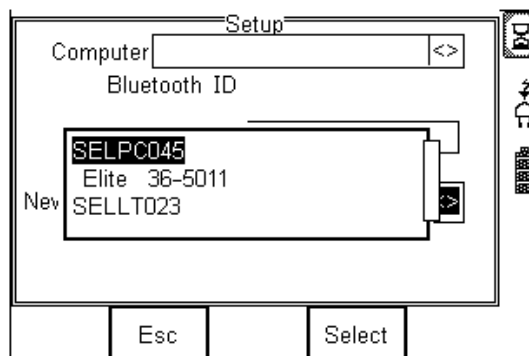
Note: *If the required device is not shown, check that it is powered on with the Bluetooth function active then repeat the search.*

Note: *Some Bluetooth devices do not report a recognisable name and may cause confusion when setting up Favourites. Turn off or disable unused Bluetooth devices when configuring Favourites.*

Use the up/down keys to highlight the required device (in this case SELLT023i) and press the ✔ button (F4). **SELLT023** is now placed in the "New" field as shown below.
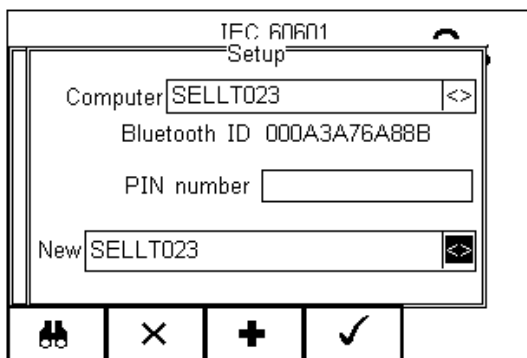
Press ✚ (F3) to add SELLT023 to the Favourite Computer list.

To add further devices to the list of available computers select the new field again, use

the up, down, left and right keys to select the required device and press ✚ (F3) to add the chosen device.

"SELLT023" has been added to the Computer field with **Bluetooth ID.**

Press ✓ (F4) to store the changes and return to the previous screen.

A PIN number can be entered if required for the device to be added to the Favourites list.

Note: *Seaward and Rigel accessories do not require a PIN. For other Bluetooth devices refer to the manufacturer's documentation.*

Note: *Devices that are not required can easily be removed by selecting the Computer field, pressing the left of right keys to open the list, highlighting a device using the up/down keys and pressing 🗑 (F2). Confirm the deletion by pressing the ✓ button (F4). Press the ✓ button (F4) to save Bluetooth Favourites settings.*

All Bluetooth devices have a unique ID. The Bluetooth ID is shown when a device is added to the Favourites list.

Repeat the actions above to select a printer for the SP-SIM;
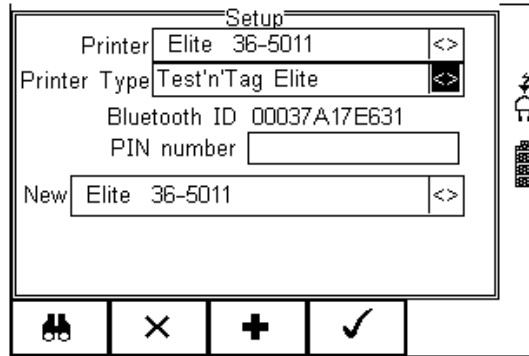
Ensure when selecting the printer, that the Printer type is selected corresponding with the print media:

Printer used	BT ID	Printer type
Test and Tag Elite	Elite 36-xxxx	Test 'n' Tag Elite
Citizen list printer	CITIZEN SYSTEMS	Citizen CMP/10
Test and Tag	SW T'nT (xxx-xxxx)	Test 'n' Tag

Press ✓ (F4) to store the changes and return to the previous screen.
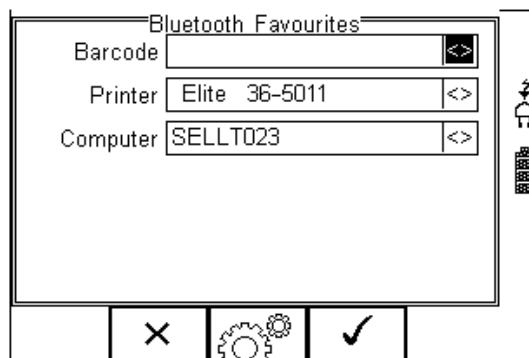
"SELLT023" and "Elite 36-5011" are now a Bluetooth Favourite and the Rigel SP-SIM will automatically establish a connection with "SELLT023" when using functions that communicate with a computer e.g. downloading records to a PC database software package or connect to "Elite 36-5011" when requiring a print-out.

Note: Press ✕ (F2) to exit without saving changes.

Press 🛠 (F3) if necessary, to select another device..

Press ✓ (F4) button to save changes.

When all your favourite devices have been set up, press ✓ (F4) and they will be saved.

4.5. User Admin

The User Admin feature allows the user to personalise the way in which the tester behaves during normal use and include features such as:

- Preferences (see 4.5.1)
- Change User (see 4.5.2)
- Change Password (see 4.5.3)
- User Profile (see 4.5.4)

To enter the User Admin feature, press the ➙🗐 button (F1) from the home screen, select Setup followed be User Admin.

The following menu will appear:
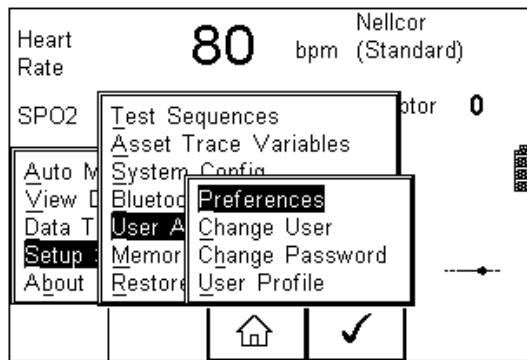
Navigate through this menu using the Up & Down Keys and select by pressing the ✓ button (F4) or the right arrow key.

4.5.1. Preferences

Provides means of configuring the default settings of the tester's behaviour during normal use. All settings are user specific and stored against the logged-in user :
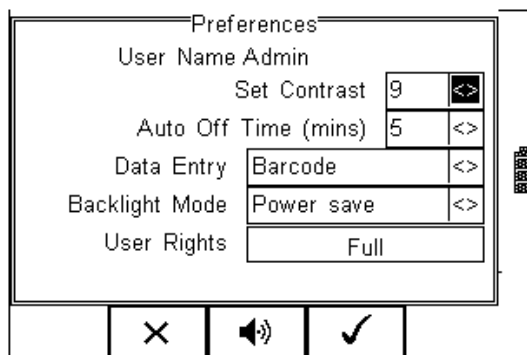
- **Set Contrast** – Use the up, down, left and right keys to set the contrast

- **Auto Off Time (mins)** - Use the up, down, left and right keys to set the power off time on the tester. Settings between 0- 10 minutes. Note 0 minutes will deactivate the AutoSwitch Off feature.

- **Data Entry –** Sets the tester up to take data entry from Barcode or Keypad only. Use the up, down, left and right keys to select Barcode or Keypad only.
  Note: *In data entry mode the unit will automatically try to connect to a barcode scanner via the internal Bluetooth module – if the scanner is available this feature will drain the batteries u-necessarily. In this instance it is recommended that the unit be set to Keypad only.*

- **Backlight Mode –** Chose between Always Off, Always On, Power Save (Back light on for 30 secs after each key press). Use the up, down, left and right keys to select.

- **User Rights** – For information only. To change the user rights, see 4.5.4

The ◀⋅⋅) (F2) button allows the user to set the audible warnings and beep on key presses. See menu below:

```
┌────────Tone preferences────────┐
│   Beep on key press  No  ◄►     │   ⚡
│   Beep on Heartbeat  No  ◄►     │   ⌂
│   Beep on Barcode    Yes ◄►     │
│   Beep on warning    Yes ◄►     │   ▦
│   Beep on data entry No  ◄►     │
│   Beep on Tests      Yes ◄►     │
│                                 │
├──────┬──────┬──────┬──────┐     │
│ Esc  │ Back │  OK  │      │     │
└──────┴──────┴──────┴──────┘─────┘
```
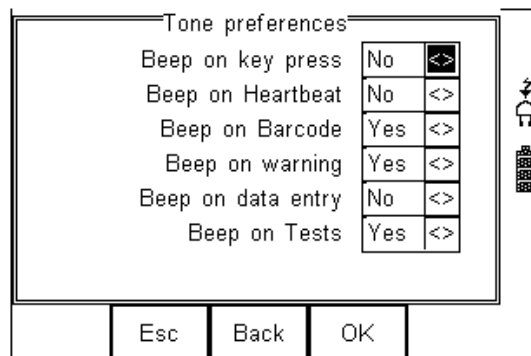
Navigate using the Up & Down Keys and change between Yes / No using the left key.

Confirm the settings using:

- o ✓ *button (F4) this will return to the Home screen*

- o ⇦ *button (F2) will return to previous menu and save data.*

- o ✗ *button (F3) will return to the home screen without changes being saved.*

4.5.2. Change User

This feature allows an operator to default to a different existing user or setup a new user. Admin rights are required for this feature. Alternatively, new users can be created in the User Profile menu, see below.
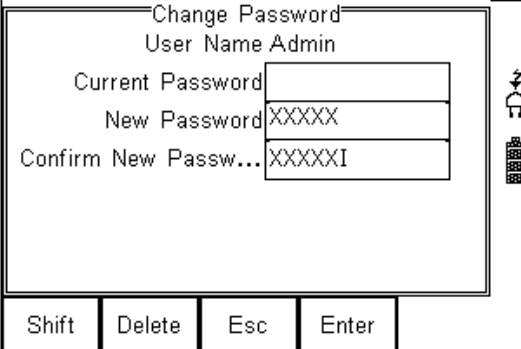
Note A brand new Rigel SP-SIM will automatically default to admin rights so new users can be created.

4.5.3. Change Password

This feature allows a new password to be assigned or changes to an existing password.

To create a new password, highlight the New Password field using the Up & Down Keys and enter a new password followed by confirmation of the new password. Use the ⮐ key (F4) to finish and press the ✓ button (F4) to confirm and save the new password.

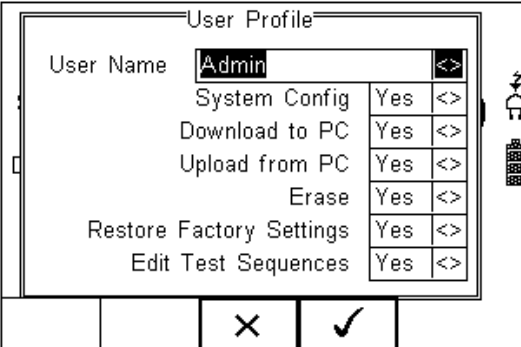To change an existing password, enter current password and repeat the steps above. See menu below for an overview of the Change Password screen.

```
┌──────────────Change Password──────────┐
│              User Name Admin           │
│   Current Password ┌──────────┐      ⚡ │
│      New Password  │XXXXX     │      ⌂ │
│   Confirm New Passw...│XXXXXXI │      ▓ │
│                    └──────────┘        │
│                                        │
│                                        │
├──────┬───────┬───────┬───────┬─────────┤
│ Shift│ Delete│  Esc  │ Enter │         │
└──────┴───────┴───────┴───────┴─────────┘
```

4.5.4. User Profile

This feature allows the administrator to setup new and existing users and inhibit or assign certain feautures to individual users.

Note that the User Profile is only valid when the ADMIN user has been setup with a PASSWORD. See item above. If no ADMIN password has been set, all users have FULL User Rights.

Select the applicable user name, use the Up & Down Keys to navigate through the menu, use the Left & Right Keys to activiate (yes) or de-activate (no) certain features. See menu below.

```
┌──────────────User Profile──────────────┐
│  User Name  │Admin        │    <>│   ⚡ │
│          System Config │Yes│<>│      ⌂ │
│          Download to PC│Yes│<>│      │ │
│          Upload from PC│Yes│<>│      ▓ │
│                   Erase│Yes│<>│        │
│    Restore Factory Settings│Yes│<>│     │
│      Edit Test Sequences│Yes│<>│       │
├───────┬───────┬───────┬───────┬─────────┤
│       │       │   ✕   │   ✓   │         │
└───────┴───────┴───────┴───────┴─────────┘
```
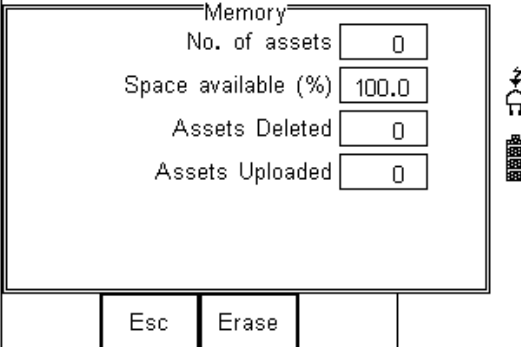
Press the ✓ button (F4) to save user profile.

4.6. Memory options

This feature is used to view information about the Rigel SP-SIM memory status. Press ➔▤ (F4), select setup using the up/down keys and select Memory Options by pressing the press ✓ (F4) to accept.
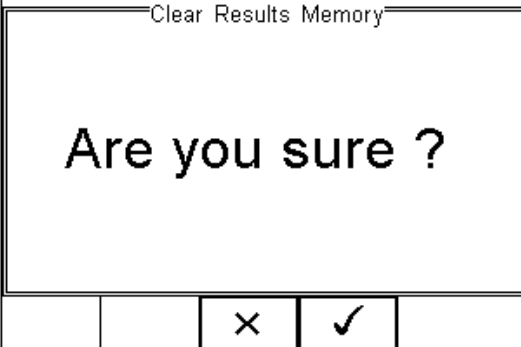
```
┌────────────Memory────────────┐
│        No. of assets  │   0   │    ⚡
│   Space available (%) │ 100.0 │    ⌂
│        Assets Deleted │   0   │
│       Assets Uploaded │   0   │    🔋
│                                │
├──────┬──────┬──────┬──────────┤
│      │ Esc  │Erase │          │
└──────┴──────┴──────┴──────────┘
```

The display shows the number of asset records currently stored, the remaining memory space, number of assets deleted and number of assets in upload memory.

The nature of Flash memory is such that when records are deleted only the reference to the data is removed. The data still remains and will use memory space. The memory must be erased in order to release memory used by deleted records.

If the Erase (F2) key is pressed, a prompt is shown below. To erase the memory press ✓ button (F4).

```
┌───────Clear Results Memory───────┐
│                                  │
│                                  │
│         Are you sure ?           │
│                                  │
│                                  │
├──────┬──────┬──────┬─────────────┤
│      │      │  ✕   │   ✓          │
└──────┴──────┴──────┴─────────────┘
```

4.7. Restore Factory Settings

The factory settings can be restored at any time using this function. Press →▤ button (F4). Select Setup followed by Restore Factory Settings.
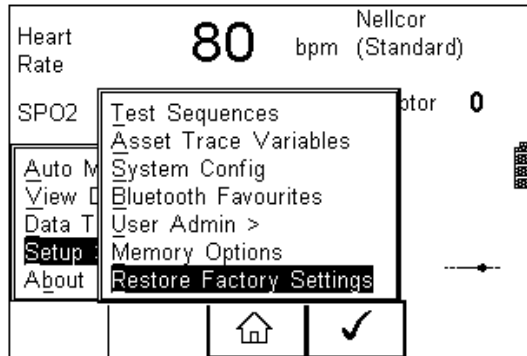
All the settings provided within the Setup menu will default to Factory Settings including; All Asset Trace Variables, Test Sequences, User Admin, Test Codes and System Config.

Warning: Restore Factory Settings cannot be undone and will remove all the customised items described above.

Hint; All customised settings within Setup can be cloned to a PC. We advise that this is done on a regular basis to ensure custom settings are saved for back-up. See 7.4 for further details on Cloning.

5. Manual Mode

The Manual mode provides the user with the features of testing a specific individual test and or test condition for example to test a selection of:

- SPO2 value
- Heart rate
- Manufacturer R-curves
- Skin colour
- Perfusion
- Arrhythmia's (upgrade)
- Artefacts (upgrade)
- Chronometer function
- Checking of LED quality (both Red and InfraRed

Press SPO2 (F3) from the start screen;
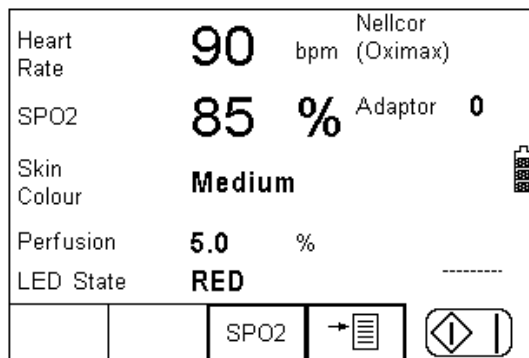
When SPO2 is selected, a number of options will be available;
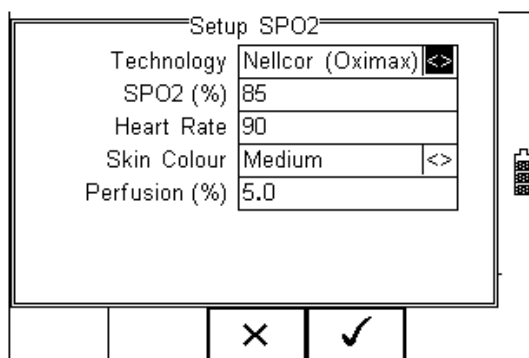
Navigate using the Up & Down Keys and change each setting by using the left key.

Technology;   Select between the various R-curves;
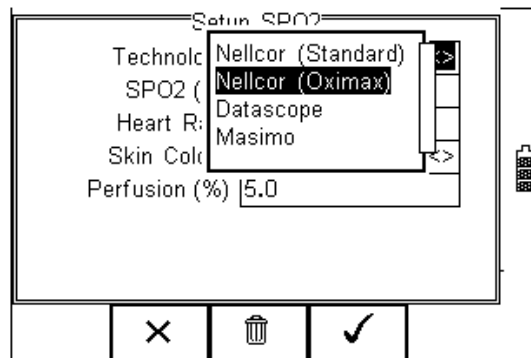
The list of available R-curve data is under constant development. Please monitor our website for new firmware releases. New firmware can be uploaded by the end-user and does not void the calibration of the device. Please go to: http://www.rigelmedical.com/downloads.asp

SPO2; Enter the required simulation value in %
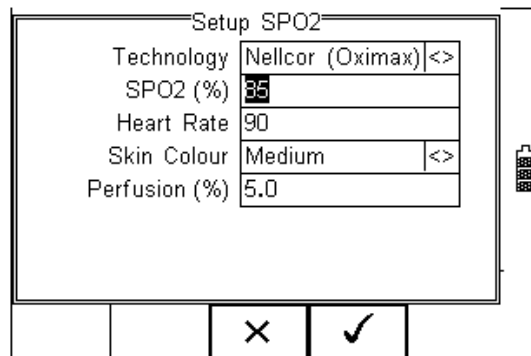
Heart Rate;   Enter the required simulated heart rate;
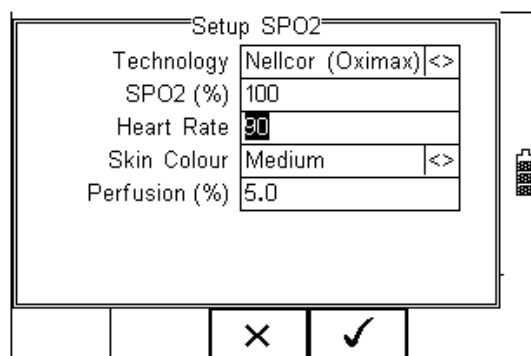
Skin Colour   Select different levels of simulations of different skin colours.
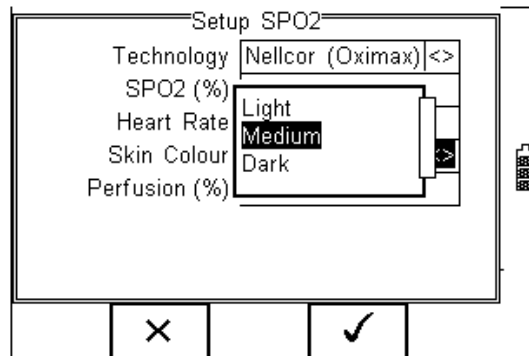
Perfusion: Select the required signal strength to simulate different patient conditions ie infant, obese, average. Enter a value between 0 – 20% in steps of 0.1% where 5% is average perfusion.
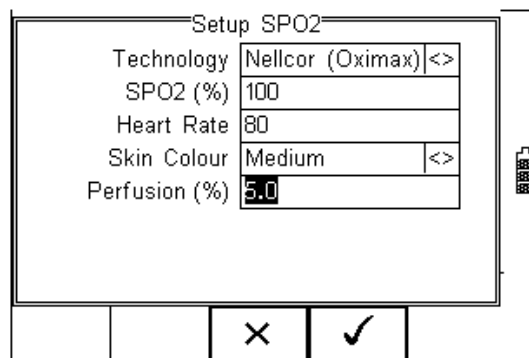
Once the selections are complete, select the ✓ (F4), to confirm the settings;
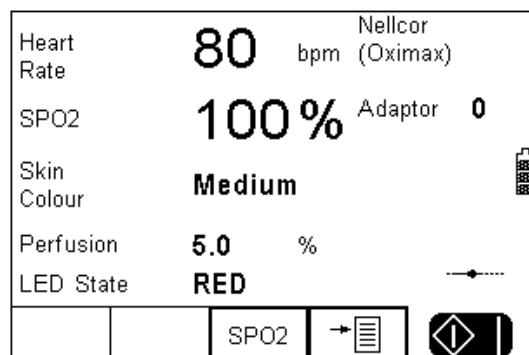
Press the Green Start key to start the simulation.

When the simulation is present (ie the internal SP-SIM valve is closed), a "pulse" symbol will be shown;
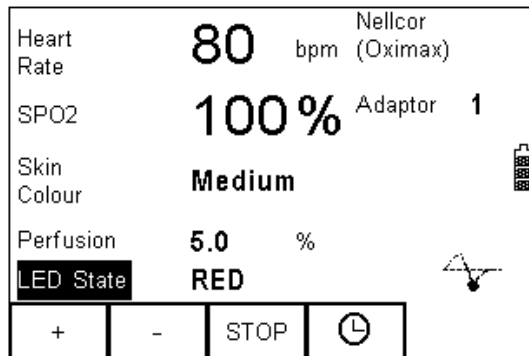
Whilst the simulation is being performed, the SP-SIM can change settings. Use the arrow keys to scroll to the setting and use the "+" and "-" keys to change the values.

Use the timer ⊕ key to start the chronometer function which will record the time taken from one simulation setting to the next.

Note: The SP-SIM simulates both Red and Infrared data through either of the Red or InfraRed LED's at any given time. This allows the user to test the quality of individual probes and circuits. Tests have shown that worn probes might still provide a reading on the monitor though the accuracy or functionality is not guaranteed. By altering the simulation through the Red and Infrared circuits, one can detect anomalies between the two simulations (should be within 1%) which would indicate a potential problem with either one of the circuits.

6. Automatic Mode

The Automatic mode provides the user with the ability to run a preset test sequence and store the data afterwards.

Press ➡️▤ (F4), select Auto Mode using the up/down keys, Select by pressing the press ✓ (F4) to accept.
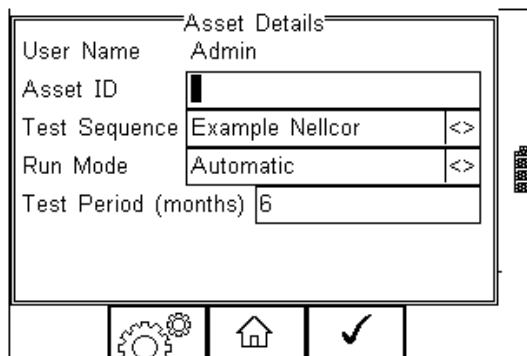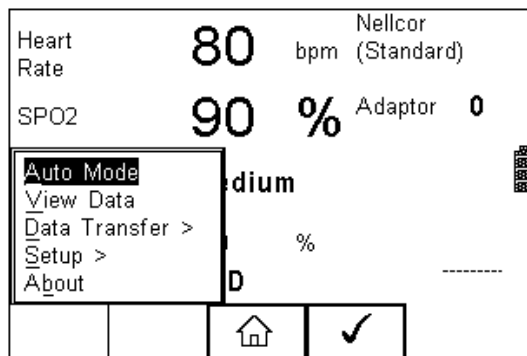
Asset ID

Each test record is stored using the Asset ID number (25 character max) and date / time of test. Multiple entries can be applied using the same Asset ID number. In this case, the memory will hold all entries and differentiate using the test date.

Test Sequence

The Rigel SP-SIM comes standard with preset test routines to meet the requirements of:
- Default Adult Sequence
- Default Pediatric Sequence

In addition, the user can create a total of 50 preset test sequences to meet specific requirements. (See   4.1 more information on creating new test sequences)

Run Mode

- Semi-Automatic allows the user the enter data after each individual test that forms a test sequence.
- Full Automatic will run through the test sequence and provides an opportunity to enter data at the end of the complete sequence.

Test Period

The re-test period allows the user to include the next test date on printed labels and PC downloads that make it easier to schedule future work. More details on printing labels see 6.2)

Trace Variables

To increase the traceability of the safety test, the user can include valuable data with the test record such as Re-test period and Asset variables (see 4.2 for more information). Trace variables can be added once the above data has been entered and confirmed (See next chapters for more details

6.1. Performing an Automatic Test:

The automatic mode provides an option to test all available tests (SPO2 simulations, Chronometer Test) in an automatic sequence.

6.1.1. Failure Menu
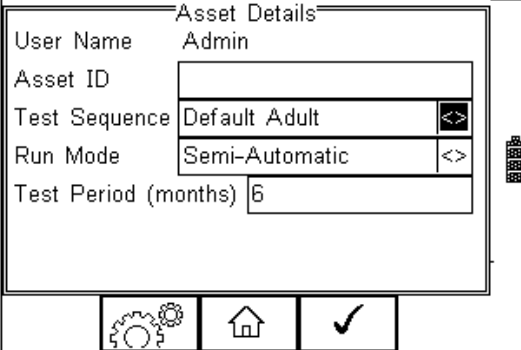
When a specific test fails, the user will be provided with a number of options depending on the nature of the fault. The Failure Menu will enable the user to:
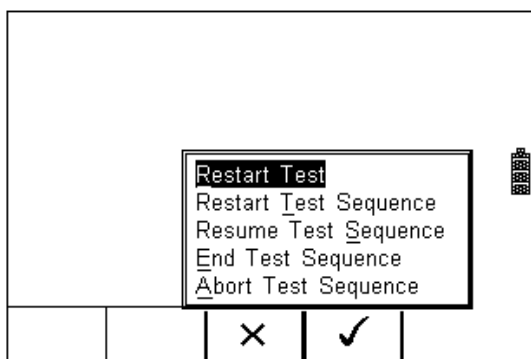
- Restart Test (Individual test)
- Restart Test Sequence (Whole Test sequence)
- Resume Test (Skip the failed test)
- End Test Sequence (store result and follow options. See 6.3)
- Abort Test Sequence (no information stored, return to home screen)
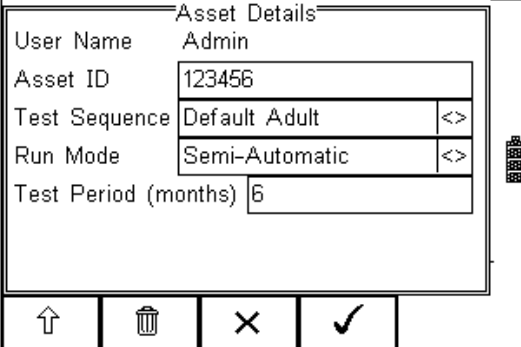
The following procedures describe the setup and completion of an automatic test sequence. The steps are applicable to all available test sequences. As example we describe a default test sequence.

Press the ➜▤ button (F4) from the home screen and select Auto Mode. This will show the Asset Details screen as detailed below;

```
┌─────────────Asset Details─────────────┐
│  User Name    Admin                     │
│  Asset ID     [                    ]    │
│  Test Sequence [Default Adult      ]<>  │
│  Run Mode     [Semi-Automatic      ]<>  │
│  Test Period (months) [6]               │
│                                          │
│        ⚙     ⌂     ✓                    │
└─────────────────────────────────────────┘
```

Select the right criteria for the Test from the Asset Details screen;

1. Enter the Asset ID number using the keypad or barcode scanner.
2. Enter the Test Code if this has been created (see 3.2)
3. Use the up, down, left and right keys to select the required Test Sequence
4. Enter the required test period in months.

```
┌─────────────Asset Details─────────────┐
│  User Name    Admin                     │
│  Asset ID     [123456]                  │
│  Test Sequence [Default Adult      ]<>  │
│  Run Mode     [Semi-Automatic      ]<>  │
│  Test Period (months) [6]               │
│                                          │
│      ⇧     🗑     ✕     ✓               │
└─────────────────────────────────────────┘
```

5. Returning to the Asset Details screen, the ⚙ button (F2) provides the user with the option to modify or create a new Test Sequence from this menu. This feature is identical to that of the Test Sequence feature in the Setup - Test Sequence menu. (See 4.1 for more information)

When all parameters are set, press the ✓ button (4) to enter the Asset Trace Variables screen (when applicable). In this example, all Asset Variables are activated.
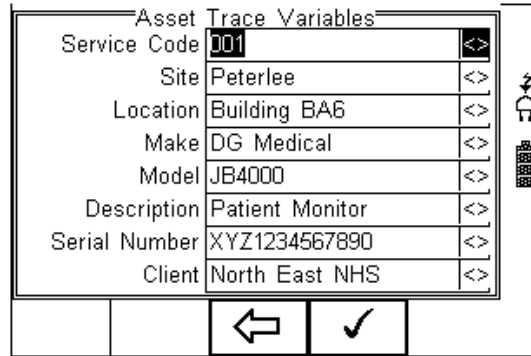
6. Use the Up & Down Keys to navigate the menu and the Left & Right Keys to open the drop down boxes [<>]. Select the required input and confirm with the ✓ button (F4). Each variable entered during the automatic test will automatically be added to the list for future use. Trace Variables that are de-activated (set to NO in the Setup menu, section 4.2) will not appear during the automatic tests.

Note that a maximum of 40 individual entries are available for each Trace Variable. Additional entries will overwrite on a first in first out basis.

When all information is provided, press the ✓ button (F4) to start the safety test.

A default visual inspection is provided at the start of each sequence.
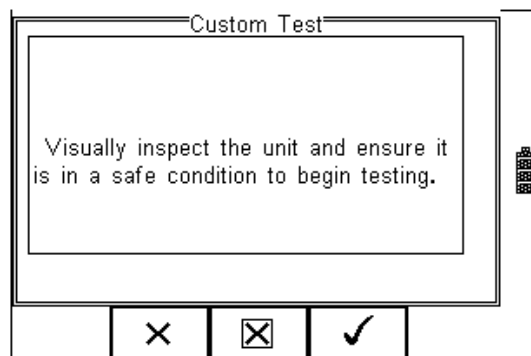
In the following example, a simulation is done in semi automatic mode where the user can enter the results in between each test; An initial simulation is done at 98% foloowed by a chronometer test and capturing of alarm (using a custom test, text input)
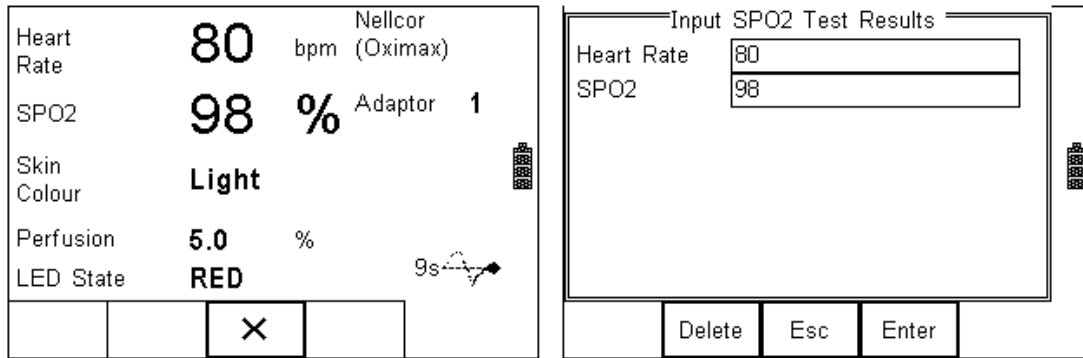
Following the initial simulation at 98%, HR 80 bpm, the tester offers a result screen as shown above. Enter the data from the monitor into the results screen and confirm. The next test in this example is a chronometer test, measuring the time taken for the monitor to establish a reading from 90% to 85% (target) SPO2;
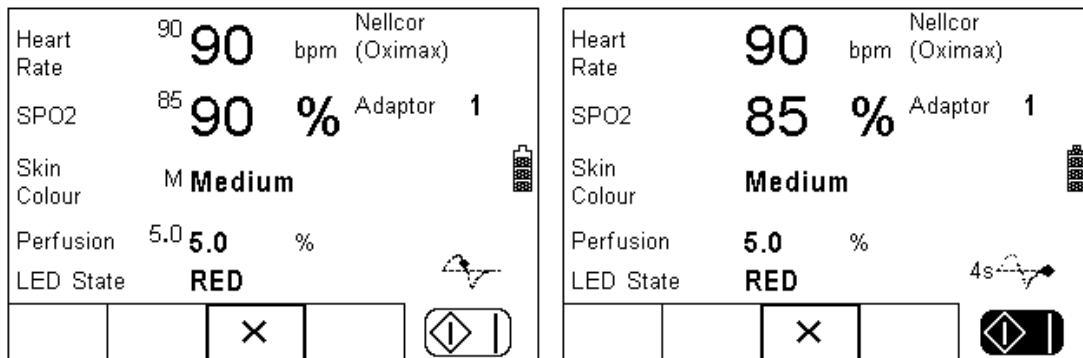
After 6 seconds the SPO2 monitor displayed the required value at which the green

 button is pressed to stop the chronometer. The results screen is then displayed to confirm the reading as shown below;
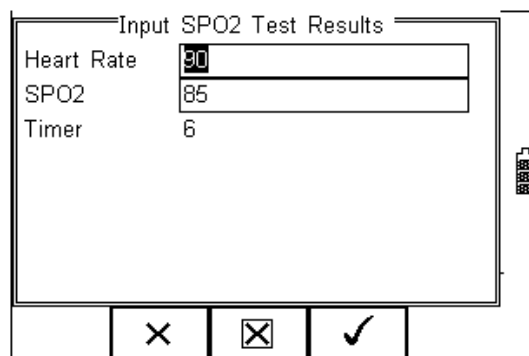
Following this test in this example, the SP-SIM is setup to perform an an alarm check as shown below;

```
┌────────Custom Test────────┐
│ ┌───────────────────────┐ │
│ │                       │ │
│ │                       │ │
│ │ Check audible alarm   │ │   ▯
│ │ is present at 85%     │ │
│ │                       │ │
│ │                       │ │
│ └───────────────────────┘ │
│    ┌───┬───┬───┐          │
│    │ ✗ │ ⊠ │ ✓ │          │
└────┴───┴───┴───┴──────────┘
```
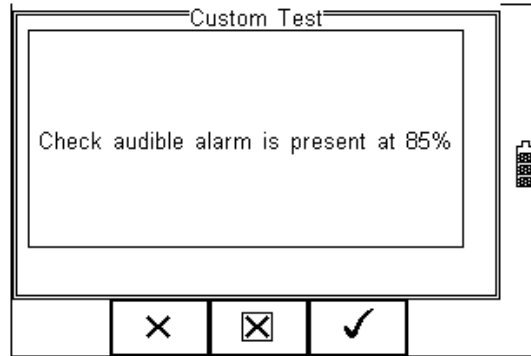
Following the confirmation that the alarm did activate at 85%, press the ✓ (F4) to end the test.

Pressing the ✗ (STOP) button (F3) during any test will bring up the failure menu (see 6.1.1)

At the end of the test, the user has the ability to enter comments. See 4.3.3 for more information on how to activiate comments after a test.


```
┌─────Enter User Comments─────┐
│ ┌─────────────────────┬───┐ │
│ │Accepted for service │<> │ │
│ └─────────────────────┴───┘ │
│ ┌─────────────────────┬───┐ │
│ │                     │<> │ │
│ └─────────────────────┴───┘ │   ▯
│ ┌─────────────────────┬───┐ │
│ │                     │<> │ │
│ └─────────────────────┴───┘ │
│ ┌─────────────────────┬───┐ │
│ │                     │<> │ │
│ └─────────────────────┴───┘ │
│           ┌───┬───┬───┬───┐ │
│           │   │   │   │ 🖫 │ │
└───────────┴───┴───┴───┴───┴─┘
```
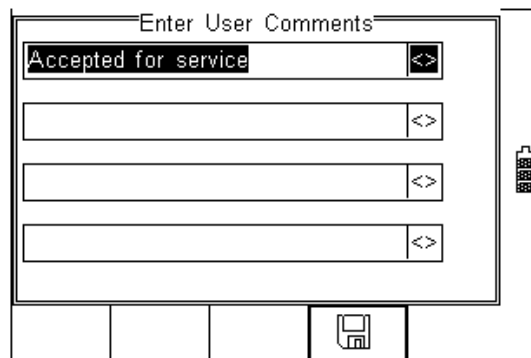
Press the 🖫 button (F4) to store the comments.

Depending on the settings in Menu - Setup - System Config (see 4.3.2) , a number of After Test options are possible;

- **New Test** – Automatically brings up the next test screen.
  No further options or viewing of results available

- **Download** – Automatically down loads the test results to the PC (see 7.1)
  No further options or viewing of results available. The tester will return to the home screen.

- **Print Label** – Automatically prints the test results to a thermal printer.
  No further options or viewing of results available. The tester will return to the home screen.

- **Test 'n Tag** – Automatically prints a Test 'n Tag label. (see 4.2)

No further options or viewing of results available. The tester will return to the home screen.

- **Options Menu** – Provides a menu to allow further choices after a test. (see 4.3)

6.2. Test 'n Tag

The Rigel SP-SIM is compatible with the Seaward Test 'n Tag and Test 'n tag Elite system To use the Test 'n Tag printer, add your T'nT printer to the Bluetooth Favorites. See 4.4

A detailed application note is available from the Rigel website on the used of Test' n Tag printers with the Rigel SP-SIM.

Please visit; http://www.rigelmedical.com/knowledgebase/

6.3. Options Menu

When Options has been selected in the Setup - System Config menu, the Rigel SP-SIM will show a Test Details screen, see below.

```
┌─────────Test Details─────────┐
│  Asset ID │12345           │  │
│  Tested by │Admin          │  │
│  Tested on │ 08 Jul 2009 03:28 PM │ ▓
│       Mode │Semi-Auto...   │  ▓
│     Status │    Pass       │  ▓
│  Test Period (months) │  6 │  │
│                              │  │
│       ⇦    ⇨    →▤          │
└──────────────────────────────┘
```

The test screen provides the following features;

- Go to the home screen (F1)
- Continue with the next test (F2)
- Options (F3)

To view the options menu, select the →▤ button (F4) from the test details screen;
The options menu provides the following sub menu:
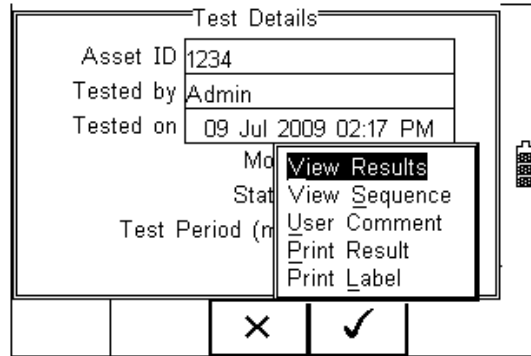
View Results will display the results of the test (see section 6.4)
User Comment will allow the user to enter comments if required
Print Label will print a pass/fail label on the thermal printer (50 mm roll)
Print Result will print the result on the thermal printer (50 mm roll)

6.4. View Results

Press the View result Button to review the data. Use the Up and Down keys to scroll through the screen.
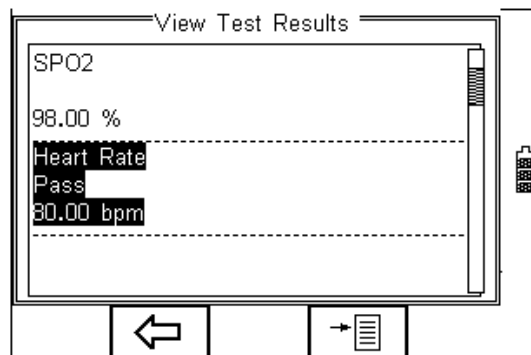
Use the ⇐ button (F2) to return to the Test Details screen.

The ⇥▤ button (F4) provides extra option to print results, label or Test 'n tag

7. View Data

To view the stored data, press the →▤ button (F4) and select View Data from the menu;
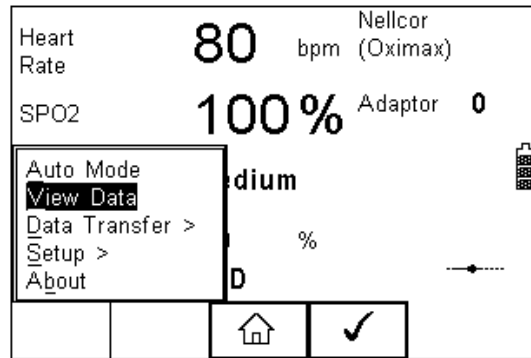
The following screen provides an overview of all available records in the memory, identified by Asset ID, Site and Pass or Fail.
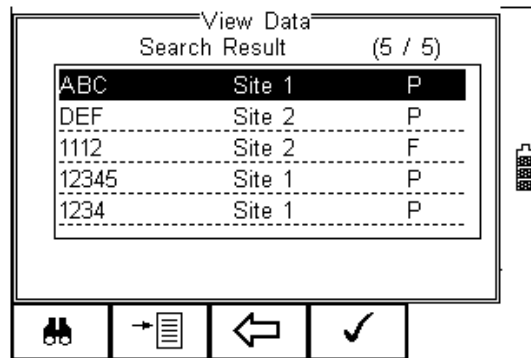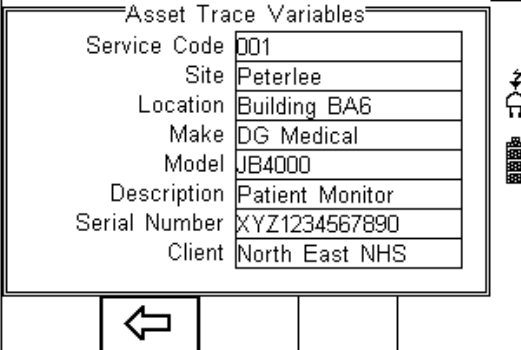
Use the up and down arrow keys to scroll through the database. When the desired record is highlighted, press the ✓ button (F4) to enter the record and view the data.

This will display the Test Details Screen
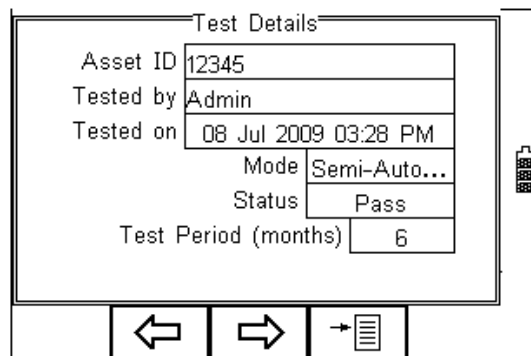
Use the ⇐ button (F2) to return to the main View Data screen.
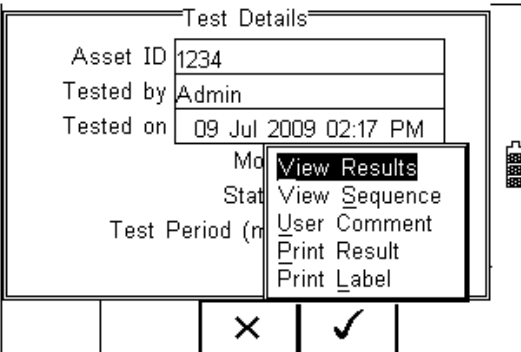
Use the ⇒ button (F3) to view the Trace Variables;

Use the ⇐ button (F2) to return to the main View Data screen.

In the Test Details screen, press the ▯ button (F4) to view the following options:


- **View Results** will display the results of the test (see section 7.1)
- **View Sequence** will display the test Sequence
- **User Comment** will allow the user to enter comments if required
- **Print Result** will print the result on the thermal printer (50 mm roll) (see Appendix B)
- **Print Label** will print a pass/fail label on the thermal printer (50 mm roll) (See Appendix B)

7.1. View Results

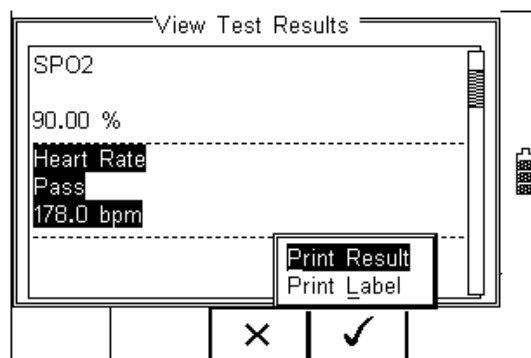From the Test Details screen, select →▤ button (F4).
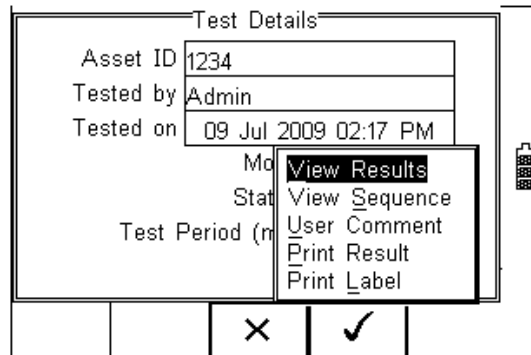
Use the up and down keys to select the view results option. Press the ✓ button (F4) to display the view text results screen (see below).
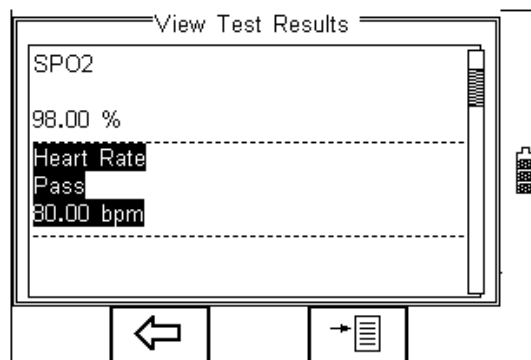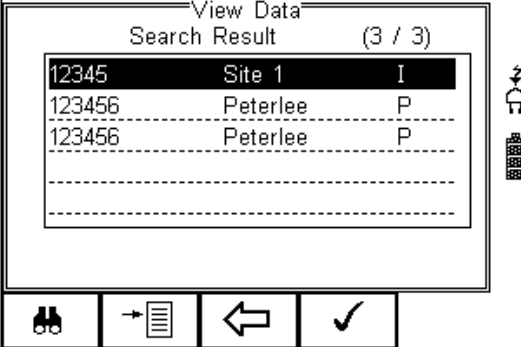

Use the ⇐ button (F2) to return to main menu.

Press the →▤ button (F4) to provide the options to print the results;
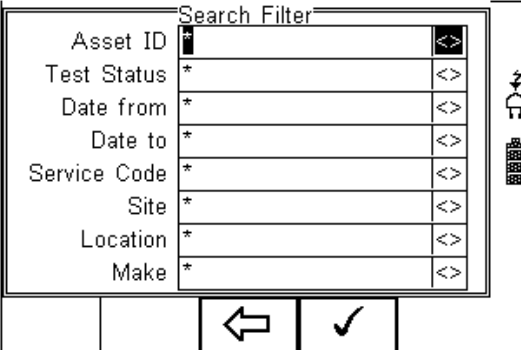
7.2. Search the database

From the main View Data screen, press the ⚏ button (F1).

Use the up, down, left and right keys to navigate this screen.

The default setting is '*' which includes all records that Passed.
To search for more specific criteria, fill in the required fields by either using the keyboard or drop down boxes.

Note   *The entered data must be identical to the data stored with the test. This includes visible and invisible SPACE characters.*
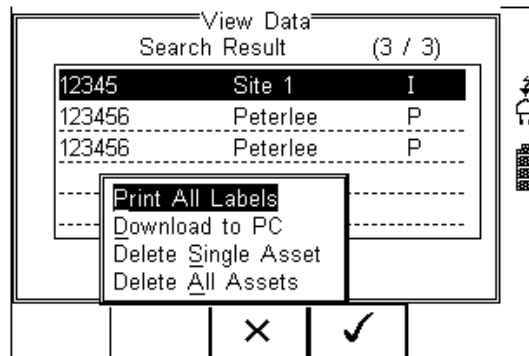
For Date entry use format DDMMYYYY or DD MM YYYY. For example for 31st October 2008 use 31102008.

Test Status Allows the user to select search criteria based on PASSED, FAILED or UPLOADED items.

To start the search, press the ✓ button (F4) or the ⇦ button (F3) to leave this screen.

7.3. View Data Options

From the main View Data screen, press the button (F2).

This will present an options menu to allow the user to:

- **Print All Labels** – Will download all records within the search criteria to the Test 'n Tag printer, setup in Bluetooth favourites.
- **Download to PC** – Will download all records within the search criteria to the PC, setup in Bluetooth favourites.
- **Delete Single Asset** – Will delete the single selected record.
- **Delete All Assets** – Will delete all records from the memory (this action is irreversible).

8. Data Transfer

Data transfer is used to transfer records and configuration data to and from a PC load a logo in bitmap format for use with the Seaward Test 'n' Tag print system, and clone data.

The Data Transfer functions are accessed by pressing the →🗎 button (F4), selecting **Data Transfer** using the up and down keys and pressing the ✓ button (F4).
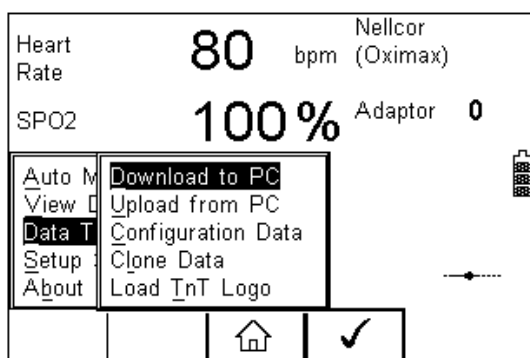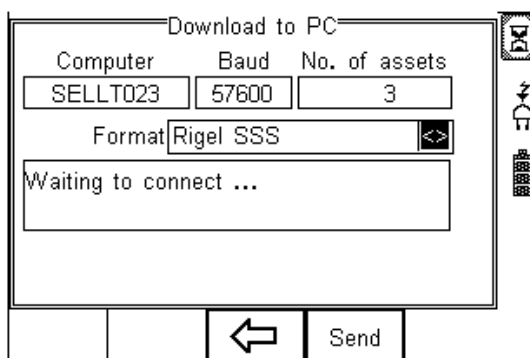

8.1. Download to PC

This feature is used to download records to a PC. Select Download to PC and press the ✓ button (F4) to accept. The Rigel SP-SIM will now attempt to make a Bluetooth connection with the Computer that has been configured in the Bluetooth Favourites.

Initially, the Bluetooth status icon will display the egg timer for a few seconds, as shown on the left, while the connection is established. When the connection is established and ready to communicate the Bluetooth status icon will change to show the Bluetooth icon as shown on the right.
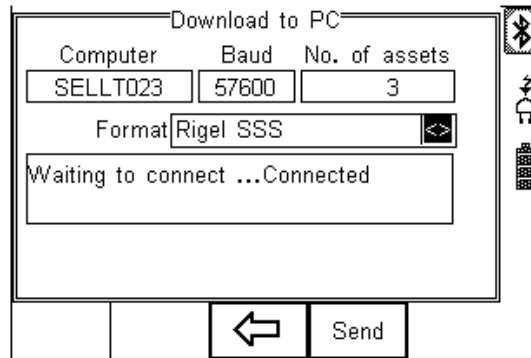
The Rigel SP-SIM is able to download in a number of formats to suit individual requirements. These are;

- CSV Full (Comma Separate Value, download only)
- CSV Summary (Comma Separate Value, download only)
- Rigel SSS (Up and download format)

Toggle between the options by using the left and right arrow keys.

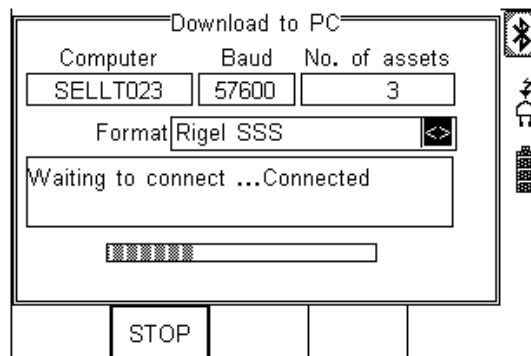The Rigel SP-SIM is now ready to transfer data. The No. of assets field shows the number of records that will be downloaded. Ensure that the PC application is ready to receive data then press the Send button (F4).

A progress bar, as shown below, will now follow the data transfer until download is complete.

Note   **To download a selection of the database, refer to "View Data" (section 6). Search on the required criteria then select "download to pc" from the options menu.**

8.2. Upload from PC

This feature is only available when used in combination with the new Med-eBase PC software and when the SSS format is activated on your device.

Select the Upload from PC option from the Data Transfer menu. The Rigel SP-SIM will now attempt to establish a Bluetooth connection to the PC as previously described in Download to PC. The Rigel SP-SIM is now ready to receive upload data from a PC. Refer to the Instruction manual of MediGuard plus on how to transmit data from the PC.

To activate the .SSS format on your Rigel SP-SIM tester, please download the SSS Application note from our knowledge base.

Please visit; www.rigelmedical.com/knowledgebase/

8.3. Configuration Data

This feature can be used to transfer store or modify the current Trace Variables, User Profiles and Comment lists to/from a PC. It can be used to configure a number of Rigel SP-SIM units with identical Trace Variable, User Profile and Comment lists.
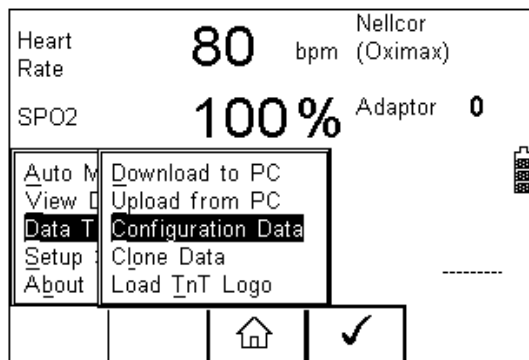
Once the SP-SIM has connected to the PC, the Bluetooth icon will appear. Capture the data using the datatransfer.exe program or Windows hyperterminal.
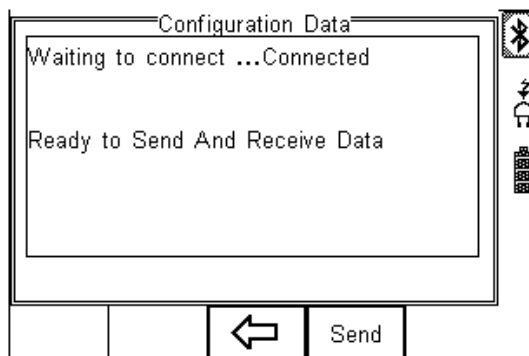
Press the SEND (F4) button to send data to the PC.

The SP-SIM will automatically receive data when the ready message is shown as above.

Press the ⬅ (F3) button to go back to the start screen.

Open the Bluetooth Downloader (Data Transfer.exe) application on your PC and check that the Com Port is correct for the Bluetooth USB adaptor being used with the P.C. The baud rate will default to the correct value of 57600.

In the application, select Start Capture from the Capture menu in the task bar.
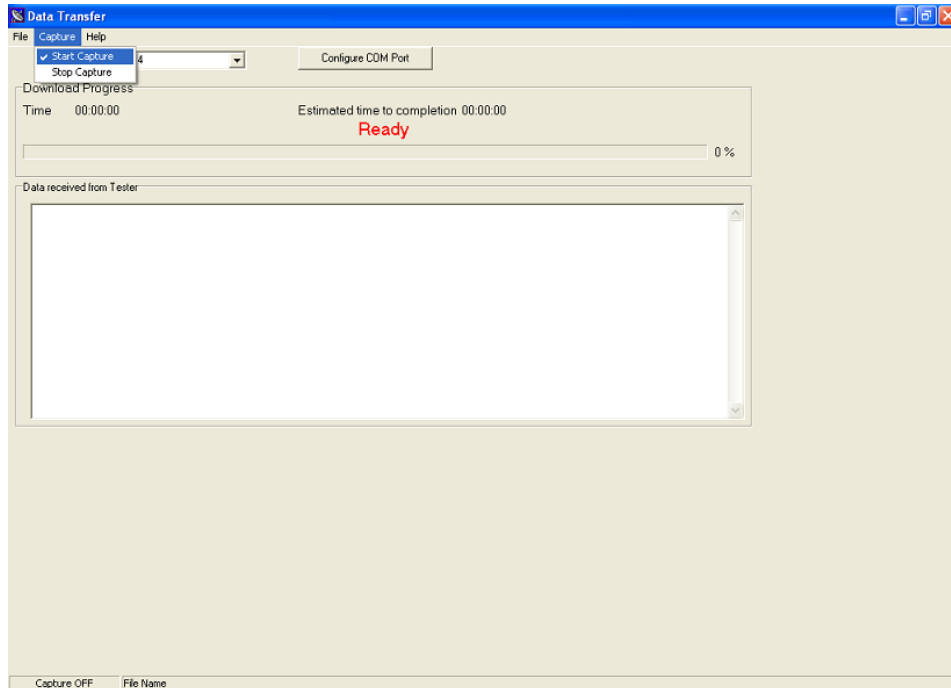
Enter a valid file name for the text file containing the download information; see below.
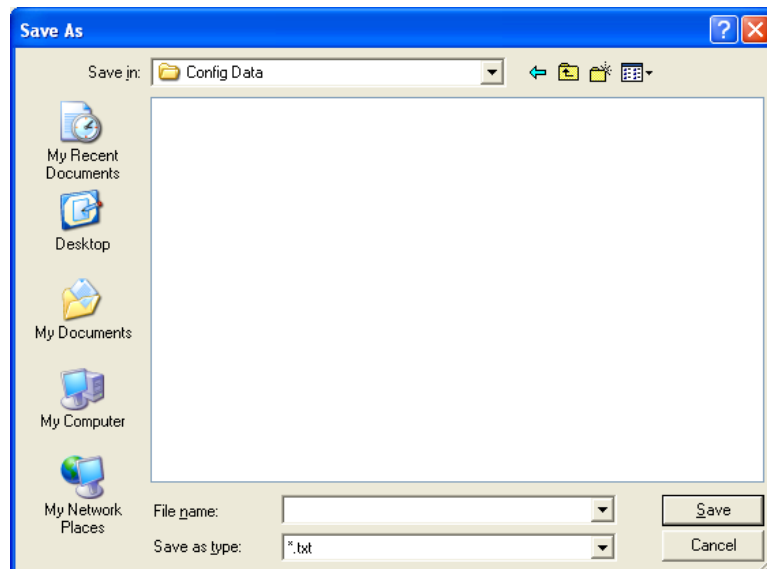
Once the text file has been created, press the Send button (F4) to transfer the Asset Trace variables and User names from the Rigel SP-SIM to the PC.

The downloaded text will appear in the Bluetooth Downloader screen. Select Stop Capture from the Capture menu in the task bar. See below;

Close down the Application and open the text file using word pad or equivalent.

The downloaded information can be used to 'clone' other Rigel SP-SIM's or modified to add additional trace variables. Again these can be uploaded to any Rigel SP-SIM for convenience.
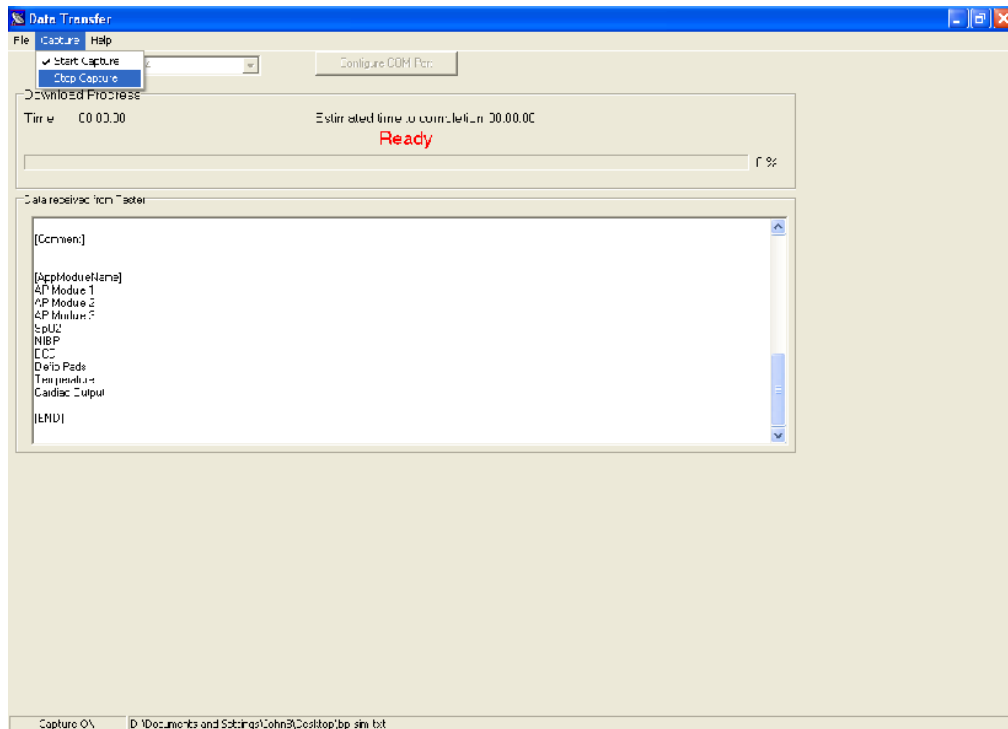
Note: *The file transfer can be made using any suitable PC application such as the Seaward Bluetooth Downloader (Data Transfer.exe) or Hyperterminal capable of sending and receiving a text file.*

Note: *The maximum number of entries for each field is SiteName (40), LocationName (50), UserName (40) and Comment (80).*

8.3.1. Receive Config Data

Follow the steps above in Send Config Data to run the Bluetooth Downloader and connect the Rigel SP-SIM to your PC.

Click on File on the Bluetooth Downloader menu and select Send File. This will open a window allowing you to select the text file containing your Trace Variables, User Profiles

and Comments configuration data. Select the require file and click on Open. The Bluetooth Downloader will now transfer the configuration file to the Rigel SP-SIM.

When the transfer is complete the Rigel SP-SIM screen will display a message as shown below.
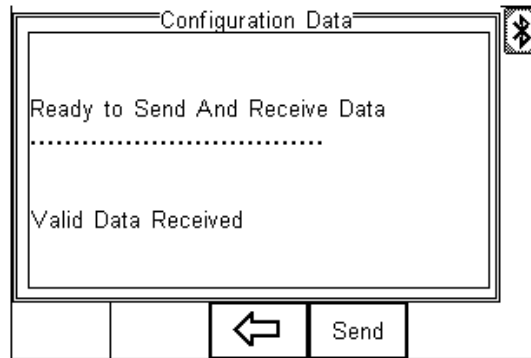
If the transfer is not successful, check that the format of the configuration file exactly matches that specified.

Note: *The Config file must be ASCII text and the last entry must be the [END] statement.*

8.4. Clone Data

This feature can be used to transfer or store the test sequences to/from a PC. It can be used to configure a number of Rigel SP-SIM units with identical sequences.
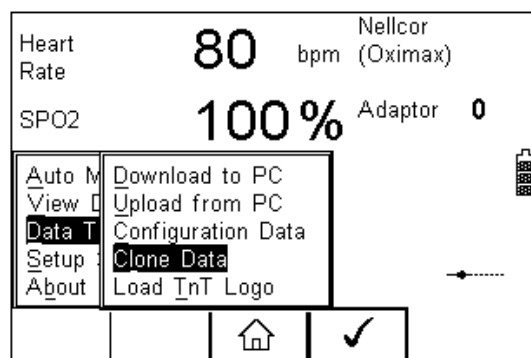
Once the SP-SIM has connected to the PC, the Bluetooth icon will appear. Capture the data using the datatransfer.exe program or Windows hyperterminal.

Using the DATATRANSFER.exe program and following the procedures from paragraph 8.3

Press the SEND (F4) or RECEIVE button to transfer data to the PC.

Press the ⬅ (F3) button to go back to the start screen.

8.5. Load TnT Logo

A bitmap logo can be transferred to the Rigel SP-SIM for use with the Seaward Test 'n' Tag print system.
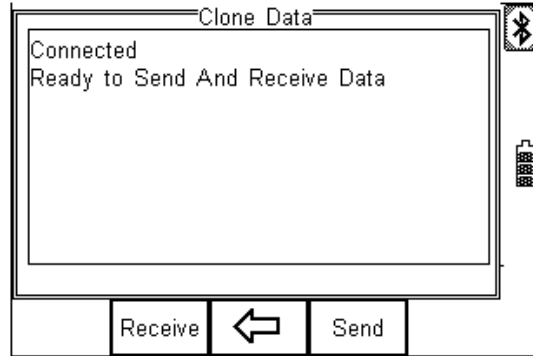
The logo must be in .BMP format with a maximum size of 320 pixels by 240 pixels.

Press ▣ button (F4), select Data Transfer using the up/down keys, select load T 'n' T logo and press the ✓ button (F4);
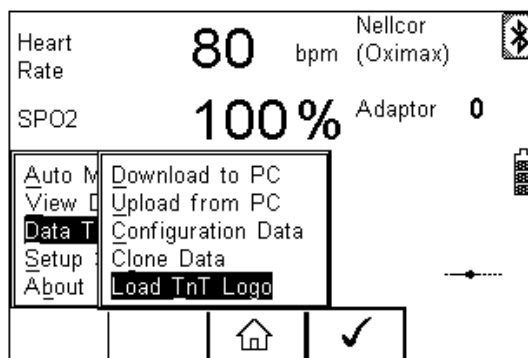
The Rigel SP-SIM will now attempt to connect to the PC, setup in Bluetooth Favourites. When a connection has been established the display will be as shown below.
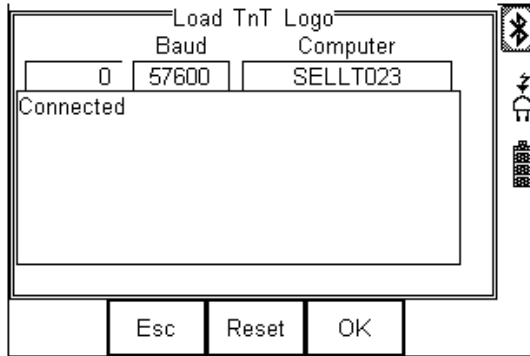
The Rigel SP-SIM is now ready to receive data. The amount of data received is shown numerically on the top left of the display (0 in the screen shot above).

When using the Bluetooth Downloader application, select Send File from the File menu in the task bar. This will open a window allowing you to select the Bitmap file.
Select the required Bitmap and click on Open. The Bluetooth Downloader will now transfer the file to the Rigel SP-SIM.

When the transfer is complete the Rigel SP-SIM screen will display a message as shown below.

Press the ✓ OK button (F4) to save the logo. The logo is now available for printing using the Seaward Test 'nTag printer.

Note: *The file transfer can be made using any suitable PC application such as the Seaward Bluetooth Downloader (data transfer.exe) or Hyperterminal.*

9. About

This screen provides details on the Rigel SP-SIM's;

- Firmware version
- Hardware version
- Calibration status
- Last Calibration Date
- Serial Number
- Blue Tooth ID

Select ABOUT from the menu below;
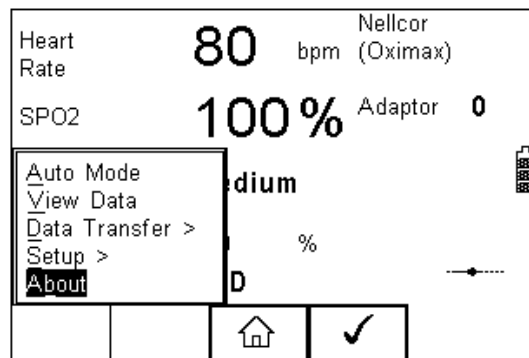
Select using the F4 key and use the scoll keys (F3) to toggle between the different information screens;
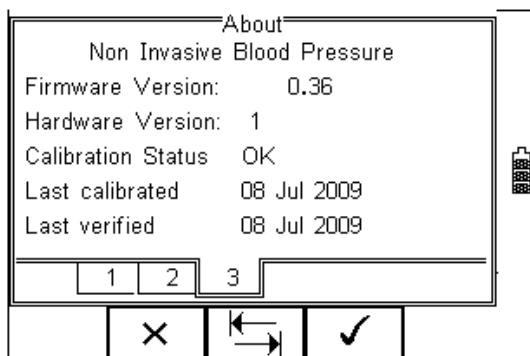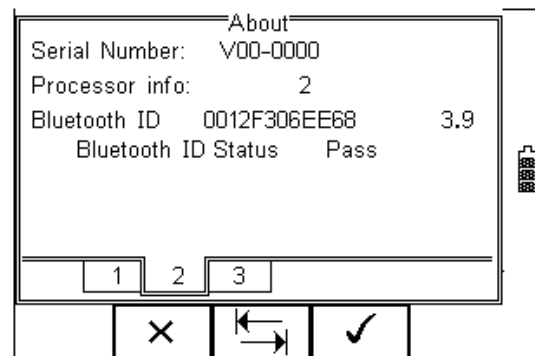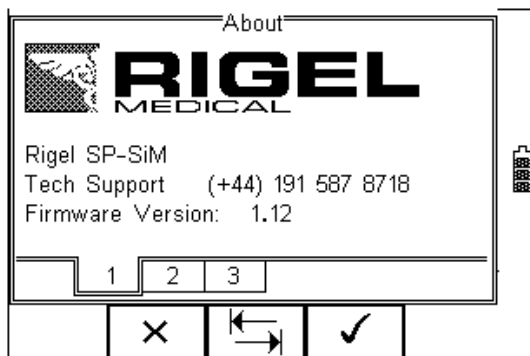
Ensure you have this information available when contacting Rigel Medical for Technical Support or Service. See chapter 9 for more information on Service and Calibration Procedures.

10. Trouble shooting

This part of the manual is dedicated to a FAQ section. Due to the age of this product, this section is limited to information known at the time of completing this revision of the instruction manual.

"I get no or incorrect readings on my oximeter";

We can suggest the following checks can be performed;

1. Check the correct probe adaptor and R-curve settings have been set on the SP-SIM

2. Check that the SPO2 probe used is not damaged or the optics are miss-aligned

3. Check that the SPO2 probe is not placed in an over-lit area ie cover the sensor if required.

4. Remove the power supply from the SP-SIM. The SP-SIM unit can sometimes give an incorrect or noisy simulation when used with certain Pulse Oximeters. If this appears to be the case try removing the SP-SIM power supply to correct this problem.

5. Stop the simulation on the SP-SIM, switching the Oximeter off then on, and then start the simulation again by pressing the green start key. Some Pulse Oximeters will not start up correctly if they are connected to the SP-SIM with the simulation running.

6. Replace the SPO2 probe for a new probe

7. If any of these actions fail to improve the accuracy of the reading, contact us with the monitor type / model and SPO2 technology / probe details and email to:
info@rigelmedical.com

11. Maintaining the Rigel SP-SIM

11.1. Cleaning the SP-SIM

The Rigel SP-SIM case can be cleaned with a damp cloth with, if necessary, a small amount of mild detergent. Prevent excessive moisture around the socket panel or in the lead storage area.

Do not allow liquid inside the Rigel SP-SIM or near the sockets. Do not use abrasives, solvents or alcohol.

If any liquid is spilt into the Rigel SP-SIM case, the simulator should be returned for repair, stating the cause of the defect.

11.2. User Maintenance

The Rigel SP-SIM is a rugged quality instrument. However, care should always be taken when using, transporting and storing this type of equipment. Failure to treat the product with care will reduce both the life of the instrument and its reliability.

If the Rigel SP-SIM is subject to condensation, allow the Analyser to completely dry before use.

- Always check the Rigel SP-SIM and supplied accessories for signs of damage and wear before use.
- Do not open the Rigel SP-SIM under any circumstances.
- Keep the instrument clean and dry.
- Avoid testing in conditions of high electrostatic or electromagnetic fields.
- Maintenance should only be performed by authorised personnel.
- There are no user replaceable parts in the Rigel SP-SIM.
- The unit should be regularly calibrated (at least annually).

11.3. *Return Instructions.*

For repair or calibration return the instrument to:-

Rigel Medical
Service Dept.,
p.a. Seaward Electronic Limited.
Bracken Hill
South West Industrial Estate
Peterlee, Co. Durham
SR8 2SW, England

Tel : +44 (0)191 5878739
Fax: +44 (0)191 586 0227

sales@rigelmedical.com

calibration@seaward.co.uk

www.seaward.co.uk

www.rigelmedical.com

Prior to returning your unit for service, please contact our service department to obtain a Returns Number.

By obtaining a Returns Number, your service request can be booked in advance thus reducing the down time of your equipment.

When asking for a Returns Number, please quote:

- Instruments name and model
- Serial number (see section 8)
- Firmware version (see section 8)

10   Technical Specifications

Oxygen Saturation Simulation (PULS-R)

Range   30 to 100%
Repeatability   ± 5%** of reading between 30-59% SPO2
                             ± 3% of reading between 60-99% SPO2
                             ± 3% of reading between 90-100% SPO2

Accuracy of simulation when used with the corresponding R-curves
*Based on using the same probe and monitor setup
**Note that some monitor types might not be able to display low range sats

Heart rate   30-300 bpm***
Accuracy   ± 1 bpm
Compatibility   Beijing Choice, Criticare, GE Tuffsat, Masimo,
                             Mindray, Nellcor, Nellcor Oximax, Nihon Kohden,
                             Nonin, Novametrix, Philips / HP

***Subject to monitor capability

Operation   Battery cell, in-situ charge
Mains supply   230V/110V AC +/- 10% 50/60Hz
Battery life   Approx. 11 hours testing
Weight   <1 kilo
Dimensions   26 x 10 x 5.5 cm
Operating conditions   10-30'C, 0-90% RH - NC
Storage environment   -15' - +60'C
Environmental Protection   IP 40

Appendix A   Firmware Route Map

Manual Mode	*SPO2 simulation settings*

Auto Mode

View Data

Data Transfer	*Download to PC*
	Upload fro PC
	Configuration Data
	Load T'nT Logo

Setup	*Test Sequences*
	Test Codes
	Asset Trace Variables
	System Config
	Bluetooth Favourites
	User Admin >

Preferences
Chance User
Change Password
User Profile

Memory Options
Restore Factory Settings

About