Part No: 0093101.

DL - 3000
SpO_2 Simulator.

Operating Instructions.

VIAMED

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Calibration of the DL-3000 SpO_2 Simulator.
Module Support : The DL-3000M/ES SpO_2 Probe Analyser Module.

Introduction.

The DL-3000 SpO_2 simulator provides a facility to test and assess Pulse Oximeters and probes from a wide range of manufacturer's.

Pulse Oximetry.

The principle behind SpO_2 measurement is very simple: the colour of blood changes depending on the oxygen saturation of the haemoglobin.

SpO_2 monitoring relies on the fact that oxygenated and deoxygenated haemoglobin absorb varying amounts of different types of light. The amount absorbed varies dependent on the wavelength or colour of light used. Red and infrared light sources are normally selected, giving the greatest difference in absorption levels.

An SpO_2 finger probe contains a red and infrared light source on one side of the clip, normally in the form of a dual LED package. Immediately opposite, lies a detector; a photodiode. The pulse Oximeter activates the two light sources in an alternating sequence. In timing the pulses, the Oximeter can determine the level of red and infrared light absorbed through the patients' tissue. Some pulse Oximeters have a period when both light sources are off which is used to assess the level of ambient light falling on the detector.

The SpO_2 value of interest is that of the arterial blood supply. The pulse of arterial blood during the heartbeat varies the level of light absorption. The detector produces a voltage dependent on the amount of light falling on it. There are two components of its output; an AC signal, due to arterial blood flow and a DC signal, due to tissue, bone and venous blood.

The pulse oximeter then derives the 'R ratio' = $\frac{AC_{RED}}{AC_{INFRARED}} \times \frac{DC_{INFRARED}}{DC_{RED}}$

In many pulse Oximeters, when the calculation for R ratio equals 1.00, the value of SpO_2 is 85%. When the R ratios for all SpO_2 readings are put together, practically from 60% to 100%, the 'R-curve' is formed. The R-curve relates the SpO_2 reading displayed to the value of blood oxygenation obtained by blood gas analysis.

R curve values are dependent on several factors; the LED wavelengths used, the method of calculation or software algorithm employed and the data obtained by the manufacturer.

'Functional' SpO_2 measurement is the oxygenated haemoglobin expressed as a percentage of haemoglobin capable of carrying oxygen. 'Fractional' SpO_2 is the percentage of oxygenated haemoglobin when compared to all types of haemoglobin. Most pulse Oximeters measure functional SpO_2 however some are capable of relating detector returns to fractional SpO_2.

SpO_2 is the percentage haemoglobin saturation with oxygen, either functional orfractional, as measured by a pulse Oximeter and displayed as a percentage.

Introducing the DL-3000 SpO_2 Simulator.

The DL-3000 simulates the levels of returns from the two light sources, in order to test the Oximeter and probe, at SpO_2 values across the clinical range. The simulation facilities provided could be utilised during research & development, production, quality assurance, evaluation / servicing of monitors, hardware / software algorithm generation or training staff.

It is primarily for use with reusable SpO_2 probes, but can also be used with different models and types of probes i.e. multi-site 'Y' probes and disposables. It is compatible with most manufacturers technologies and LED drive configurations. It is easy to use however operation may vary due to model, type, design, materials used, style and performance (specification / possible degradation) of opto-electronics. Some probes may also contain additional active or passive components. In some cases, passive components may be used to identify probe type / model or wavelength of LEDs (red and / or infrared).

The unit operates in conjunction with a unique, physiologically designed test finger, which does not require adapter cables for use with different manufacturer's Oximeters. The test finger functions with most pulse oximeters using transmission of light to measure SpO_2. Correct alignment of the finger probe clip on the test finger is indicated on the DL-3000 facia.
The test finger accepts a wide range of probes types and designs.

All external parts of the DL-3000 should be cleaned using isopropyl-alcohol. The DL-3000 should not be operated, sited or stored in extremes of temperature or humidity.

The DL-3000 uses one of four modes; Simulation, Engineering, Artifact or Evaluation.

It provides a facility to simulate SpO_2 value, heart rate and ECG waveform, and is capable of introducing patient artifact and change in patient characteristics or probe component degradation. The unit is capable of interfacing with a wide selection of pulse Oximeters and probe combinations and those not preprogrammed may be user set through engineering mode. It does not test the wavelength of the probes emitters, only the optical integrity of the probe. When the optional DL-3000M/ES module is used, the emitters' intensities can be quantified.

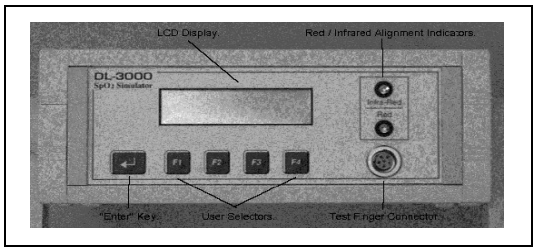
The unit is operated, by a simple to use, scrolling menu, requiring only five selectors. The display has an upper and lower readout line. The upper line shows the current option. The lower line shows labels for selectors F1 to F4 or the next selection option. Selectors labelled 'up' & 'down', allow the user to cycle through the menu options, shown on the upper and lower readout lines. Selectors annotated with upper case labels indicate rapid increase / decrease of the variable, lower case labels indicate single increments. Enter, " ⟵┘ ", selects the option on the upper readout line and progresses to the next menu.

R-curves are pre-installed, matching Oximeter models from leading manufacturers. The unit as supplied, accepts a total of 84 R-curves and could accept further R-curves if necessary.

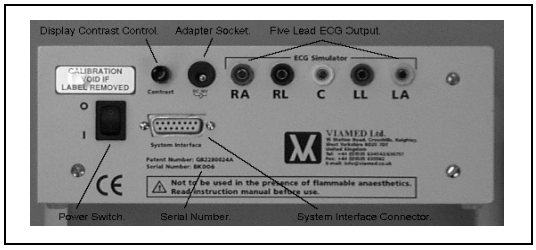
Note. The DL-3000 requires an understanding of pulse Oximetry and experience in Oximeter testing / SpO_2 simulation, to fully benefit from all the facilities provided. Further information or explanation on the DL-3000 operation can be obtained from Viamed Ltd. Unless 'R' curves are verified and authorised by the respective pulse Oximeter manufacturer, the DL-3000 should only be used as a simulator.

Connections and Selectors.

The DL-3000 is a compact, robust unit with integral carrying handle. All connections to the unit are made through the rear panel, except the test finger, which connects on the facia (the red dot on the plug aligns with the red dot on the socket). The unit is portable and can be powered via the internal battery or the supplied mains adapter. The unit has been designed to be simple and uncluttered. The facia consists of the display panel, red & infrared alignment indicators, test finger connector and five tactile user selectors.



The rear of the unit accepts connection of a 5 lead ECG cable, the system interface connector and AC/DC adapter lead. Also located here is the on/off switch & control for display contrast.



The carrying handle may be employed as a stand to elevate the display. To do this, depress the handle locking buttons, rotate the handle to the required position, release the locking buttons and allow the handle to lock into the closest available position.

Simulator, Oximeter and Finger Probe Setup.

The Oximeter manufacturer and model is selected (see overleaf for detailed selection procedure) and with the Oximeter switched on, the finger probe of the Oximeter under test is connected onto the DL-3000's test finger. The finger probe is attached to the test finger with the probe upside down. The lit red LED aids in visually aligning the LED package with the optical window of the test finger. Ensure that the finger probe is transmitting light through the window of the test finger. When the correct location is achieved the red and infrared alignment LED's on the facia of the simulator will be

illuminated. The Oximeter should begin to respond. If the alignment LED's are not lit, reposition the finger probe.

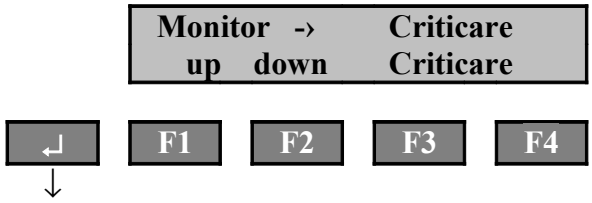
Operating the DL3000.

The DL-3000 can operate using it's internal battery or from the mains supply using the AC/DC adapter. (If necessary connect to the mains outlet using the AC/DC adapter, with the tip polarity converter in "tip >< +" position). Switch on the unit and adjust the display contrast control to obtain a readable display.

Pulse Oximeter Selection.

This is the initial display after switching on.

1. **Select Manufacturer.** Using F1 and F2 keys, scroll through the list until the required manufacturer (or compatible i.e. original equipment manufacturer or licensee) appears on the upper readout line of the display. Press Enter to select.



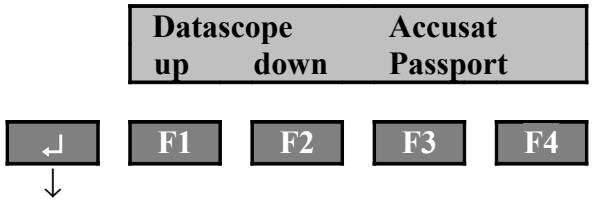
Selections.

F1 & F2: Scroll through the list of Manufacturers.
F3 & F4: No function.

Enter: Selects choice of Manufacturer (See Page 8 for table of manufacturers & models).

Example: Press F1 (up) three times for Datascope followed by Enter.

2. **Select Model.** Using F1 & F2 keys, scroll through the list until the required model (or compatible) appears on the upper readout line of the display. Press Enter to select.



Selections.

F1 & F2: Scroll through the list of Models.
F3 & F4: No function.

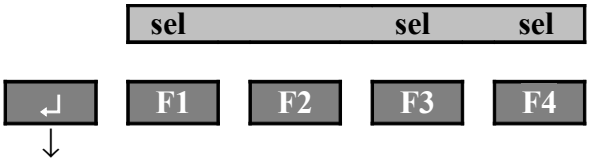
Enter: Selects choice of Model (See Page 8 for table of manufacturers & models).

Example: Press F1 (up) or F2 (down) to select Accusat or Passport followed by Enter.

The DL-3000 begins to simulate at a value of 97% SpO_2 and a heart rate of 80 bpm, based on the selected Manufacturer and Model. (Default values of zero artifact introduction and 100% for pulse / DC levels for light sources apply. See corresponding sections for further details).

3. **Select Function.**

Selections.



F1: Select Simulation Mode.
F2: Select Engineering Mode (no label).
F3: Select Artifact Mode.
F4: Select Evaluation Mode.

Enter: Returns to Select Manufacturer.

Modes of Operation Overview.

1. **Simulation:** **The primary mode for simulation of SpO_2 value, ECG waveform & heart rate. SpO_2 and heart rate can be adjusted using F1 - F4.**

- A simulated ECG output of $1mV_{PEAK}$ is available via the 4mm sockets on the rear panel. This output is synchronized with the SpO_2 pulse. The ECG output is available whenever Simulation Mode is selected. The DL-3000 can be used as a standalone ECG simulator. Automatic switch from ECG derived to SpO_2 derived heart rate can be tested on some patient monitors, when an ECG lead becomes detached.

2. **Engineering :** **A provision to access and alter all parameters for SpO_2 simulation, to create a custom R-curve for a particular oximeter model. (See Appendix A for operation of Engineering Mode).**

- Engineering Mode is accessed from the Select Function menu using F2. This key is purposely not labelled. This mode has been incorporated to provide the ability to access and alter all the parameters for SpO_2 simulation, to create a custom R-curve. The mode should only be used to verify a known calibrated oximeter and probe.

3. **Artifact :** **A facility for 'noise' introduction to assess oximeter sensitivity. SpO_2, bpm and artifact levels can all be adjusted.**

- Artifact Mode allows the introduction of monitorable amounts of noise, representing patient movement etc., into the simulation, at set SpO_2 / heart rate values. The level of noise introduced is user alterable, from 0 to a maximum of 4000.

4. **Evaluation :** **A simulation allowing alteration of light returns, to assess the effect of patient variation and / or probe component degradation.**

- Evaluation Mode allows the level of light present at the detector to be altered, to simulate change in patient characteristics such as skin pigmentation, tissue & bone density, size and perfusion volume. These user-derived variations in light source output also simulate degradation of probe components and evaluates their effects on SpO_2 determination.

Simulation Mode.

This mode is most commonly used and has only one screen display as shown below.

Selections.

spo2 := 97% F1 and F2 : Adjust SpO_2 level.

bpm := 80 F3 and F4 : Adjust bpm rate.

up down

up down

↓

Enter : Returns to Select Manufacturer.

In this mode, the SpO_2 level can be varied using F1 & F2 and likewise bpm rate can be altered using F3 & F4. Pressing Enter exits Simulation Mode and returns to Select Manufacturer.

Table A : Selection of Pulse Oximeter Manufacturers and Models.

DL-3000 Selected Options.		
Manufacturer.	Abbreviated Model.	Actual Model.
Agilent	A1	A1
Criticare.	503. 504. 504DX.	503. 504. 504DX.
Critikon.	Compact TS. Oxyshttl 1. Oxyshttl 2.	Compact TS. Oxyshuttle I. Oxyshuttle II.
Datascope.	Accusat. Passport. Passport2m.	Accusat. Passport. Passport2 using MasimoSET.
Datex.	Cardiocap. Cardiocap2. Satlite tr.	Cardiocap. Cardiocap II. Satlite Trans.
Datex-Ohm	TuffSat	TuffSat
Dolphin	Voyager	Voyager
Drager	Oxipac	Oxipac
Elmed/BCI.	Pso 1000. 71000A2.	PSO 1000. 71000A2.
HME.	LP28.	LP28.
Ivy Biomed(ical).	2000.	2000.
Kontron.	7840. 7850.	7840. 7850.
Marquette.	Eagle 3000. 450SL.	Eagle 3000. Tram Module T450SL.
Masimo.	Masimo(1).	Oximeters using licensed MasimoSET technology.
MDE.	Escort psm.	Escort PSM.
Minolta.	3i. Pulsox-7.	3i. Pulsox-7.
Nascor.	2B.	2B.
Nellcor.	N-20. N-180. N-185. N-200. N-250. N-3000. NBP- 40. NBP-190. NBP-195. NBP-290. NBP-295. NBP-395. NBP-39XX. NBP-4000.	N-20. N-180. N-185. N-200. N-250. N-3000. NBP- 40. NBP-190. NBP-195. NBP-290. NBP-295. NBP-395. NBP-39XX series. NBP-4000.
Nonin.	4600FO. 8500. Onyx.	4600FO. 8500. Onyx.
Novametrix.	Satchk. 515.	Satcheck. 515.

Ohmeda.	3700e V<Q. 3700e V>Q. 3740. 3770. 3775. 3800 Func. 3800 Frac 3900 Func. 3900 Frac.	3700e, software version before Q. 3700e, software version after Q. 3740. 3770. 3775. 3800 set to functional. 3800 set to fractional. 3900 set to functional. 3900 set to fractional.
Palco.	340.	340.
Sensormed(ics).	Sat-Track.	Sat - Trak.
Simed.	S-100e.	S-100e.
Space Labs.	90496.	90496.
S&W.	Athena. Trav 4053. NT 3050.	Athena 9140. Diascope Traveller T4053. Diascope NT 3050.
W(elch) Allyn.	52000.	52000.

Note : Oxyshuttle I oximeters can be alternatively labelled as being manufactured by Critikon or Sensormedics. The R curve for this model is therefore installed under Critikon and under Sensormedics. Both R curves are identical.

Table B : SpO_2 values and heart rates.

% SpO_2 values : 60 - 90% at 5% intervals, Heart rate : 40 - 200 at 20 bpm intervals.
% SpO_2 values : 91 - 100% at 1% intervals, Heart rate : 40 - 200 at 20 bpm intervals.

SpO_2 (%)	Heart Rate (bpm)
100	200
100	180
100	160
100	140
100	120
100	100
100	80
100	60
100	40
99	200
99	180
99	160
99	140
99	120
99	100
99	80
99	60
99	40
98	200
98	180
98	160
98	140
98	120
98	100
98	80
98	60
98	40
97	200
97	180
97	160
97	140
97	120
97	100
97	80
97	60
97	40
96	200
96	180
96	160
96	140
96	120
96	100

SpO_2 (%)	Heart Rate (bpm)
95	200
95	180
95	160
95	140
95	120
95	100
95	80
95	60
95	40
94	200
94	180
94	160
94	140
94	120
94	100
94	80
94	60
94	40
93	200
93	180
93	160
93	140
93	120
93	100
93	80
93	60
93	40
92	200
92	180
92	160
92	140
92	120
92	100
92	80
92	60
92	40
91	200
91	180
91	160
91	140
91	120
91	100

SpO_2 (%)	Heart Rate (bpm)
90	200
90	180
90	160
90	140
90	120
90	100
90	80
90	60
90	40
85	200
85	180
85	160
85	140
85	120
85	100
85	80
85	60
85	40
80	200
80	180
80	160
80	140
80	120
80	100
80	80
80	60
80	40
75	200
75	180
75	160
75	140
75	120
75	100
75	80
75	60
75	40
70	200
70	180
70	160
70	140
70	120
70	100

SpO_2 (%)	Heart Rate (bpm)
65	200
65	180
65	160
65	140
65	120
65	100
65	80
65	60
65	40
60	200
60	180
60	160
60	140
60	120
60	100
60	80
60	60
60	40

96	80
96	60
96	40

91	80
91	60
91	40

70	80
70	60
70	40

Artifact Mode.

Artifact Mode is used to introduce 'noise' into the simulation procedure. The level of noise introduced is controllable using the 'Art Value' variable. This mode can be used to compare monitors from different manufacturers.

The level of noise introduced into the simulation can assist in evaluating the ability of the oximeter under test to select the required signal over the level of noise present. The setting of the artifact level can be adjusted between 0 and 4000.

When tested, a particular oximeter will possess a given threshold to artifact introduction, at which point it will show intermittent display of SpO_2 and pulse. Over time during routine checks, the artifact rejection level can be monitored to verify the ability of the oximeter to maintain similar levels of noise rejection.

The first screen display after selection of Artifact Mode is shown below.

Selections.

spo2 := 97% F1 and F2 : Adjust SpO_2 level.

bpm := 80 F3 and F4 : Adjust bpm rate.

up down

up down

↓

Enter : Selects Artifact adjustment.

Selections.

Set 0

Art Value

F1 & F2 : Rapid change in Artifact level.
F3 & F4 : Fine change in Artifact level.
(Changes do not need confirming).

UP DOWN

up down

↓

Enter : Return to SpO_2 / bpm adjustment.

Selections.

Spo2 / bpm

F1 : Return to SpO_2 / Bpm adjust.
F2, F3 & F4 : No function.

adjust

↓

Enter : Return to Select Manufacturer.

Evaluation Mode.

Oximeters have to be able to cope with varying physical properties from patient to patient. These variables include change in finger diameter and skin pigmentation levels. To cope with these variations, oximeter circuits usually automatically adjust the light source intensity in response to the level of return from the detector. Any degradation of the LED / detector performance may have adverse effects on the accuracy of the oximeter SpO_2 reading.

The Evaluation Mode of the simulator allows the emulation of variation in patient characteristics such as skin colour, tissue and bone density, size and perfusion volume. The mode may also be used to independently assess probe component degradation.

The initial display of the Evaluation Mode is shown below.

	Selections.
mode >	F1 & F2 : Cycle through the menu. F3 & F4 : No function.
Pulse only	
up down	
DC & Pulse	

↓

Enter : Select option on upper readout line.

The options available are :

Pulse off.	No AC component of the detector signal, therefore no patient pulse or SpO_2 reading. The oximeter under test should lose both SpO_2 and pulse with corresponding alarms.
Pulse only.	Allows an increase / decrease in the AC component of the detector signal. Oximeters with graphical / bar displays show a corresponding change in pulse amplitude.
DC.	Allows an increase / decrease in the DC component of the detector signal. This simulates changeable light levels arriving at the detector due to skin pigmentation levels or finger diameter etc.

DC & Pulse. Allows an increase / decrease in both the AC and DC components of the signal. Represents simultaneous changes in skin pigmentation levels, finger diameters and pulse amplitude.

Mon. Returns to the Select Manufacturer menu.

Pulse and DC levels have a default setting of 100% and have a range of between 0 and 200%.

Pulse only.

Selections.

Puls 100%

F1 & F2 : Fine change in Pulse level.
F3 & F4 : No function.

up down

↓

Enter : Return to Evaluation Mode Select.

DC only.

Selections.

DC 100%

F1 & F2 : Fine change in DC level.
F3 & F4 : No function.

up down

↓

Enter : Return to Evaluation Mode Select.

DC & Pulse.

Selections.

DC&P 100%

F1 & F2 : Fine change in DC & pulse.
F3 & F4 : No function.

up down

↓

Enter : Return to Evaluation Mode Select.

Pulse Off.

	Selections.
Pulse off	F1 - F4 : No function.

↓

Enter : Return to Evaluation Mode Select.

Cross Reference Tables.

Ohmeda probes contain a resistor which the pulse oximeter requires to select the correct R-curve and algorithm. Change in software / hardware revision of the oximeter also affects the SpO_2 value derived.

It has proved impractical to incorporate a different R-curve into the DL-3000 to match every combination of probe resistor and oximeter software / hardware revision. The use of an adapter cable, to disconnect the probes resistor and connect a known value, was not felt appropriate, as this would allow a probe with a faulty resistor / wiring to pass a functional test.

R-curves for Ohmeda models are developed using a probe containing a 56.6kΩ resistance.

3700e pulse oximeter.

Known acceptable probe resistances lie in the range of 20.0 to 442.0kΩ. Software / hardware versions run in the alphabetical order of M to T followed by numeric versions of .21 to .24.

3700e pulse oximeters are fitted with either a black or white 'hypertronics' (Ohmeda) socket.

Black socket, rev Q & below oximeters recognise probe resistances from 20.0 - 90.9kΩ. White socket, rev Q & below oximeters recognise probe resistances from 20.0 - 442.0kΩ. White socket, rev T oximeters recognise probe resistances from 20 - 90.9kΩ.
Contact Viamed Ltd for probe resistances recognised by black socket, rev R or T oximeters.

R-curves for the Ohmeda 3700e pulse oximeter, correspond to revisions of Q and below, "V<Q", and revisions Q and above, "V>Q" (including numerics). Probes with resistances other than 56.6kΩ, will cause the oximeter under test to reflect a different SpO_2 reading.

To obtain an absolutely accurate SpO_2 value, use one of the following look up tables. Table 1 for versions of Q and below and Table 2 for versions of Q and above (including numerics).

3740 / 3770 pulse oximeters.

Known acceptable probe resistances lie in the range of 20.0 to 90.9kΩ.
Use Table 3 to obtain an absolute SpO_2 reading in relation to probe resistor value.

3800 / 3900 pulse oximeters.

The 3800/ 3900 pulse oximeters have the ability to relate the returns from the probe to functional or fractional Spo_2, dependent on the selection made to switches on the rear panel.

DL-3000 R-curves for the Ohmeda 3800 / 3900 pulse oximeters, correspond to functional "Func" or fractional "Frac" setting of the oximeter. Any probe used with a resistance other than 56.6kΩ, will cause the oximeter under test to reflect a different SpO_2 reading.

Known acceptable probe resistances lie in the range of 20.0 to 90.9kΩ.
To obtain an absolutely accurate SpO_2 value, use one of the following look up tables. Table 4 for use when testing a functionally set oximeter and Table 5 for a fractionally set oximeter.

Table 1.

3700e, Ver Q and below : SpO_2 value / Probe resistor value.

For revisions Q and below, determine the value of probe resistance and select the preprogrammed R-curve for the 'Ohmeda , 3700e V<Q'.

Select the SpO_2 level on the top row of the table and the probe resistor value in the left hand column. The intersecting square then shows the actual SpO_2 reading to be expected using that probe resistance & software / hardware revision.

SpO_2 value			100	99	98	97	96	95	94	93	92	91	90	85	80	75	70	65	60
(	(	(	20.0	100	100	99	98	97	95	96	94	93	92	90	86	82	77	72	67	63
B	W	P	21.5	100	100	99	98	97	95	96	94	93	92	91	86	81	76	72	67	62
L	H	R	23.2	100	99	99	98	97	95	96	94	93	92	91	86	81	76	71	66	61
A	I	O	24.9	100	99	98	97	96	94	95	93	92	91	90	85	80	76	71	66	61
C	T	B	26.7	100	99	98	97	96	94	95	93	92	91	90	85	80	75	70	65	60
K	E	E	28.7	100	99	98	97	96	94	95	93	92	91	90	85	80	75	70	65	60
			30.9	100	99	98	97	96	93	94	92	91	90	89	84	79	74	69	64	59
S	S	R	33.2	100	99	97	96	95	93	94	92	91	90	89	84	79	74	69	63	58
O	O	E	35.7	99	98	97	96	95	93	94	92	91	90	89	84	78	73	68	63	58
C	C	S	38.3	99	98	97	96	95	93	94	92	91	90	89	83	78	73	68	62	57
K	K	I	41.2	100	100	99	98	97	95	96	94	93	92	91	86	82	77	72	67	63
E	E	S	44.2	100	100	99	98	97	95	96	94	93	92	91	86	81	77	72	67	62

TRANGE	TRANGE																		
		T	47.5	100	99	99	98	97	95	96	94	93	92	91	86	81	76	71	66	62
		O	51.1	100	99	98	97	96	94	95	93	92	91	90	85	80	76	71	66	61
		R	56.6	100	99	98	97	96	95	94	93	92	91	90	85	80	75	70	65	60
			61.9	100	99	98	97	96	94	95	93	92	91	90	85	80	75	70	65	60
		I	68.1	100	99	98	97	96	93	94	92	91	90	89	84	79	74	69	64	59
		N	75.0	100	98	97	96	95	93	94	92	91	90	89	84	79	74	69	63	58
			82.5	99	98	97	96	95	93	94	92	91	90	89	84	78	73	68	63	58
		K	90.9	99	98	97	96	95	93	94	92	91	90	89	83	78	73	68	62	57
		I	113.0	100	100	99	98	97	95	96	94	93	92	91	86	81	76	72	67	62
		L	127.0	100	99	99	98	97	95	96	94	93	92	91	86	81	76	71	66	62
		O	143.0	100	99	98	97	96	94	95	93	92	91	90	85	80	76	71	66	61
			165.0	100	99	98	97	96	94	95	93	92	91	90	85	80	75	70	65	60
		O	191.0	100	99	98	97	96	94	95	93	92	91	90	85	80	75	70	65	60
		H	226.0	100	99	98	97	96	93	94	92	91	90	89	84	79	74	69	64	59
		M	274.0	100	98	97	96	95	93	94	92	91	90	89	84	79	74	69	64	58
		S	340.0	99	98	97	96	95	93	94	92	91	90	89	84	78	73	68	63	58
			442.0	99	98	97	96	95	93	94	92	91	90	88	83	78	73	67	62	57

Table 2.

3700e, Ver Q and above (including numeric versions) : SpO_2 value / Probe resistor value.

For revisions Q and above (including numeric versions), determine the value of probe resistance and select the preprogrammed R-curve for the 'Ohmeda , 3700e V>Q'.

Select the SpO_2 level on the top row of the table and the probe resistor value in the left hand column. The intersecting square then shows the actual SpO_2 reading to be expected using that probe resistance & software / hardware revision.

SpO_2 value		100	99	98	97	96	95	94	93	92	91	90	85	80	75	70	65	60
WHITE SOCK	20.0	100	99	98	98	97	96	95	94	93	92	91	86	82	77	72	68	64
	P 21.5	100	99	98	97	97	96	95	94	93	92	91	86	81	77	72	67	63
	R 23.2	100	99	98	97	96	95	94	93	92	91	91	86	81	77	71	67	63
	O 24.9	100	99	98	97	96	95	94	93	92	91	90	86	81	78	71	66	62
	B 26.7	100	99	98	97	96	95	94	93	92	91	90	85	80	75	70	65	61
	E 28.7	100	99	98	97	96	95	94	93	92	91	90	85	80	75	70	65	60
	30.9	100	99	98	97	96	95	94	93	92	91	90	84	79	74	69	64	60
	R 33.2	100	99	98	97	96	95	94	93	92	91	90	85	79	74	69	64	58
	E 35.7	100	99	98	97	96	95	93	92	91	90	89	84	79	73	67	62	57
	S 38.3	100	99	98	97	95	94	93	92	91	90	89	84	78	73	67	61	56
	I 41.2	100	99	99	98	97	96	95	94	93	92	91	87	82	77	73	68	64

E	S	44.2	100	99	98	98	97	96	95	94	93	92	91	86	81	76	72	67	63
T	T	47.5	100	99	98	97	96	95	94	93	92	91	91	86	81	76	71	68	63
	O	51.1	100	99	98	97	96	95	94	93	92	91	90	86	81	76	71	66	62
R	R	56.6	100	99	98	97	96	95	94	93	92	91	90	85	80	75	70	65	60
A		61.9	100	99	98	97	96	95	94	93	92	91	90	85	80	75	70	65	60
N	I	68.1	100	99	98	97	96	95	94	93	92	91	90	85	80	74	69	64	59
G	N	75.0	100	99	98	97	96	95	93	92	91	90	89	84	79	73	68	63	58
E		82.5	100	99	98	97	96	95	93	92	91	90	89	84	79	73	68	62	57
(	K	90.9	100	99	98	97	95	94	93	92	91	90	89	84	78	73	67	62	56
	I	113.0	)																
	L	127.0	|															
	O	143.0	|															
		165.0	|															
	O	191.0	} Probes not recognised by 3700e oximeter, rev T, white socket.																
	H	226.0	|															
	M	274.0	|															
	S	340.0	|															
	(	442.0	)																

Table 3.

3740 : SpO_2 value / Probe resistor value.

Select the SpO_2 level on the top row of the table and the probe resistor value in the left hand column. The intersecting square then shows the actual SpO_2 reading to be expected using that probe resistance & software / hardware revision.

SpO_2 value		100	99	98	97	96	95	94	93	92	91	90	85	80	75	70	65	60
(	(	20.0	100	99	98	97	96	96	95	94	93	92	91	86	83	77	73	68	63
W	P	21.5	100	99	98	97	97	95	94	94	92	92	91	86	80	77	72	65	62
H	R	23.2	100	99	98	97	96	96	94	93	92	91	91	86	81	76	72	67	62
I	O	24.9	100	99	98	97	96	95	94	93	92	91	90	85	80	76	71	65	62
T	B	26.7	100	99	98	97	96	95	94	93	92	91	90	85	80	75	71	66	60
E	E	28.7	100	99	98	96	96	95	94	93	91	91	90	85	79	74	68	65	60
		30.9	100	99	98	97	96	95	94	93	92	90	90	85	79	74	69	63	59
S	R	33.2	100	99	98	96	95	94	93	92	91	90	90	85	78	74	67	63	57
O	E	35.7	100	99	98	97	95	94	93	92	91	90	89	85	79	74	68	63	57
C	S	38.3	100	99	97	97	95	94	93	92	91	90	89	84	78	73	67	62	57
K	I	41.2	100	99	98	97	96	96	95	94	92	92	91	86	81	77	73	69	64
E	S	44.2	100	99	98	98	97	96	95	94	93	92	91	86	81	76	72	68	63
T	T	47.5	100	99	98	97	96	96	94	93	92	92	90	86	81	76	72	68	63
	O	51.1	100	99	98	97	96	95	94	93	92	91	90	85	80	76	71	66	61

RANGE																			
	R	56.6	100	99	98	97	96	95	94	93	92	91	90	85	80	75	70	65	60
		61.9	100	99	98	97	95	95	94	93	92	90	90	85	79	75	70	64	59
	I	68.1	100	99	98	96	96	95	94	92	92	90	89	85	79	74	69	63	58
	N	75.0	100	99	98	97	95	94	94	93	91	90	89	85	78	74	69	63	58
		82.5	100	99	98	97	96	95	94	92	91	90	89	85	78	72	68	62	57
	K	90.9	100	99	98	96	95	94	93	92	91	90	89	84	77	71	67	61	56
	I	113.0																	
	L	127.0																	
	O	143.0																	
		165.0																	
	O	191.0																	
	H	226.0																	
	M	274.0																	
	S	340.0																	
		442.0																	

Probes not recognised by 3740 oximeter, rev 9, white socket.

Table 4.

Ohmeda 3800 / 3900 'Func' : SpO_2 value / Probe resistor value.

SpO_2		100	99	98	97	96	95	94	93	92	91	90	85	80	75	70	65	60
	20.0	100	100	99	97	96	96	95	94	93	92	91	87	82	78	73	68	65
P	21.5	100	99	98	97	96	95	95	94	93	92	91	87	82	77	73	68	64
R	23.2	100	99	98	97	96	95	95	94	93	92	91	86	81	77	72	67	63
O	24.9	100	99	98	97	96	95	94	93	93	92	91	86	81	76	71	67	62
B	26.7	100	99	98	97	96	95	94	93	92	91	91	86	81	76	71	66	61
E	28.7	100	99	98	97	96	95	94	93	92	91	91	85	80	75	70	65	61
	30.9	100	99	98	97	96	95	94	93	92	91	90	85	80	75	70	65	60
R	33.2	100	99	98	97	96	95	94	92	92	91	90	85	80	74	69	63	59
E	35.7	100	99	98	97	95	95	94	92	92	91	90	84	79	74	68	63	58
S	38.3	100	99	98	96	95	94	93	92	91	91	90	84	78	73	68	62	57
I	41.2	100	100	99	98	97	96	95	93	93	92	91	87	82	78	74	69	64
S	44.2	100	99	98	97	96	95	94	94	93	92	91	87	82	77	73	68	63
T	47.5	100	99	98	97	96	95	94	94	93	92	91	86	81	77	72	67	62
O	51.1	100	99	98	97	96	95	94	93	92	92	91	86	81	76	72	66	62
R	56.6	100	99	98	97	96	95	94	93	92	91	90	85	80	75	70	65	61
	61.9	100	99	98	97	96	95	94	93	92	91	90	85	80	75	70	65	60
I	68.1	100	99	98	97	96	95	94	93	92	91	90	85	80	74	69	64	59
N	75.0	100	99	98	96	95	94	93	92	92	91	90	84	79	74	69	64	58

	82.5	100	99	97	96	95	94	93	92	91	90	89	84	79	73	68	63	57
K	90.9	100	99	97	96	95	94	93	92	91	90	89	84	78	73	67	62	56
I	113.0	⎫																
L	127.0	⎪																
O	143.0	⎪																
	165.0	⎪																
O	191.0	⎬ Probes not recognised by 3800 oximeter, revision 3.000/01.000.																
H	226.0	⎪																
M	274.0	⎪																
S	340.0	⎪																
⎩	442.0	⎭																

Table 5.

Ohmeda 3800 / 3900 'Frac' : SpO_2 value / Probe resistor value.

SpO_2		100	99	98	97	96	95	94	93	92	91	90	85	80	75	70	65	60
⎛	20.0	100	99	98	97	96	95	94	93	92	91	90	86	81	76	72	67	62
P	21.5	100	99	98	97	96	95	94	93	92	91	90	86	81	76	71	67	62
R	23.2	100	99	98	97	96	95	94	93	92	91	90	85	80	76	71	66	61
O	24.9	100	99	98	97	96	95	94	93	92	91	90	85	80	75	70	65	60
B	26.7	100	99	98	97	96	95	94	93	92	91	90	85	80	75	69	64	59
E	28.7	100	99	98	97	96	94	93	92	91	90	89	84	79	74	69	63	58
	30.9	100	99	98	96	95	94	93	92	91	90	89	84	79	73	68	63	57
R	33.2	100	98	97	96	95	94	93	92	91	90	89	84	78	73	68	62	56
E	35.7	100	98	97	96	95	94	93	92	91	90	89	83	78	72	66	61	55
S	38.3	100	98	97	96	95	94	93	92	91	90	89	83	78	72	66	60	55
I	41.2	100	99	98	98	97	95	94	93	92	91	90	86	81	77	72	67	63
S	44.2	100	99	98	97	96	95	94	93	92	91	90	86	81	76	71	66	62
T	47.5	100	99	98	97	96	95	94	93	92	91	90	85	80	76	71	66	61
O	51.1	100	99	98	97	96	95	94	93	92	91	90	85	80	75	70	65	60
R	56.6	100	99	98	97	96	95	94	93	92	91	90	85	80	75	70	64	59
	61.9	100	99	98	97	96	95	93	92	91	90	89	84	79	74	69	63	58
I	68.1	100	99	98	97	96	94	93	92	91	90	89	84	79	74	68	63	57
N	75.0	100	99	98	97	95	94	93	92	91	90	89	84	78	73	68	62	56

	82.5	100	98	97	96	95	94	93	92	91	90	89	84	78	73	67	61	56
K	90.9	100	98	97	96	95	94	93	92	91	90	89	83	77	72	66	60	55
I	113.0																	
L	127.0																	
O	143.0																	
	165.0																	
O	191.0	} Probes not recognised by 3800 oximeter, revision 3.000/01.000.																
H	226.0																	
M	274.0																	
S	340.0																	
	442.0																	

DL-3000 Compatibility : R-Curve Table.

Manufacturer.	Model.	Existing R-Curve to Use.
Kontron.	Microsat 7850-003, (Masimo set).	Kontron 7840.
Nellcor Puritan Bennet.	NPB - 3910.	NPB 4000.

- **These entries are known examples only.**

  Pulse oximeter development is ongoing and there are currently a diverse number of available oximeters. Coupled with modules available from original equipment manufacturers and licensed compatible technologies, the number of different combinations is vast.

DL-3000 Technical Specification.

Modes of operation : Simulation, Engineering, Artifact, Evaluation and Module Support.

% SpO_2 values :	60 - 90% inc. at 5% intervals, 91 - 100% inc. at 1% intervals.
Accuracy :	± 0.3% (worst case, with matched R-curve).
Resolution :	± 0.05% (worst case, i.e. 1/20% at 60% SpO_2).

Pulse rate :

Range :	40 - 200 bpm.
Rate values :	40 - 200 at 20 bpm intervals.
Accuracy :	± 1%.

ECG output (l mV_{PEAK}) synchronization with SpO_2 pulse ± 1%.

R-curves :

Preset monitor R-curves : 84.

Standard R-curve selection covers the following manufacturer's SpO_2 monitors : Criticare, Critikon, Datascope, Datex, Elmed / BCI, HME, Ivy Biomedical, Kontron, Marquette, MDE, Minolta, Nascor, Nellcor, Nonin, Novametrix, Ohmeda, Palco, Sensormedics, Simed, Space Labs, S&W, Welch Allyn.

Plethysmographic amplitude :

Range of Pulse amplitude : 0 - 200% of nominal.
'Tissue perfusion' (AC parameters)

and / or quiescent parameters (DC parameters).

Resolution :	1%.
Accuracy :	± 1%.

Motion artifact :

Amplitude range :	0 - 4000.
Resolution :	0.05%.
Artifact :	Variable.
Rechargeable battery :	12V, 1.2 Ah, (> 90 minutes usage).

Standard AC/DC adapters :

UK Version (P/No. 961014) :- Input : 230V AC, 100mA, 50Hz. Output : Variable.
EU Version (P/No. 961114) :- Input : 230V AC, 100mA, 50Hz. Output : Variable.
US Version (P/No. 954084) :- Input : 115V AC, 200mA, 60Hz. Output : Variable.

General Options :

DL-3OOOM/ES Module.

The SpO_2 probe analyzer module can be used to assess degradation of probes, for fault finding and planned preventative maintenance. The module tests probes passive components and assesses light levels of red and infrared emitters. Standard module designed for use with Nellcor and Ohmeda probes. The DL-3OO0M/ES module connects to DL-3000 via the system interface. Please contact Viamed for availability of other module configurations and adapter cables for other $Sp0_2$ probe / monitor manufacturers.

Electromagnetic Conformity.

The DL-3000 bears a CE mark for Electromagnetic Interference and Susceptibility, EC EMC Directive 89 / 336 / EEC.

The system was also tested and found to meet requirements for Electrostatic Discharge Susceptibility, Radiated Susceptibility and Electrical Fast / Transient / Burst Susceptibility.

The DL-3000 may have its operation affected by strong electromagnetic sources, such as electrosurgery and imaging equipment.

The DL-3000 is a battery-powered device which operates at voltages below 75 volts and is not patient connected.

Glossary of Terms.

AC :	Alternating current.
Bpm :	Beats per minute.
DC :	Direct current.
DVM :	Digital volt meter
ECG :	Electro-cardio-graph.
IDC :	Infrared DC level.
Infrared :	A wavelength of light in the electromagnetic spectrum. For SpO_2 pulse oximeters, currently 880 - 940 nanometers.
ISNS :	Infrared SeNSitivity.
LED :	Light emitting diode.
Pleth / PLT :	Plethysmographic level.

R ratio : The ratio, calculated within the oximeter, of the relative returns of the AC / DC components of Red / Infrared light, on passing through the patients tissue.

R-curve : Relates the SpO_2 reading to blood gas analysis values throughout the entire range.

RDC : Red DC level.

Redac : Red AC level.

RSNS : Red SeNSitivity.

SpO_2 : SpO_2 is the percentage haemoglobin saturation with oxygen, either functional or fractional, as measured by a pulse oximeter and displayed as a percentage.

DL-3000 SpO_2 Simulator. **Product Descriptions and Part Numbers.**		
Part Number	**Model**	**Description**
0013000	DL3000	SpO_2 Simulator. Includes : Test finger. AC-DC adaptor: Model 961014. United Kingdom, 3 pin plug, Input 230VAC, 50Hz, 100mA. Operating instructions.
0013011	DL3000	SpO_2 Simulator. Includes : Test finger. AC-DC adaptor: Model

		961114. Europe, 2 pin plug, Input 230VAC, 50Hz, 100mA. Operating instructions.
0013012	DL3000	SpO_2 Simulator. <u>Includes :</u> Test finger. AC-DC adaptor: Model 954084. North America, 2 pin plug, Input 115VAC, 60Hz, 200mA. Operating instructions.
0013009	DL3000CC	Carrying Case for DL-3000 SpO_2 Simulator.
0013001	DL3000M/ES	SpO_2 Probe Analyser Module. For use with Nellcor and Ohmeda compatible finger probes. <u>Includes :</u> Interface cable to DL-3000. Operating instructions.
0013002	DL3000DAC	Datascope Adapter Cable (9 pin D'sub male to 8 pin Din female) for use with DL3000M/ES SpO_2 probe analysis module.
Maintenance options.		
0013020	DL3000FC	DL-3000 SpO_2 simulator test finger calibrator.
0013021	DL3000LS	Calibrated light source for use with DL-3000 SpO_2 simulator.

Appendix A.

DL - 3000
SpO_2 Simulator.

Engineering Mode.

Appendix A : Engineering Mode.

Warning : This mode should not be used without the user having a detailed understanding of SpO_2 simulation and oximeter circuitry behaviour.

Engineering Mode allows the alteration of all parameters in order to create a new R-curve or to test and assess the hardware / software performance of a given oximeter and probe.

Pressing Enter at each screen display, cycles the variables in the following order :

Screen Display.	Function.
r / syn : i / syn :: monitor.	Enable / Disable Red & Infrared light sources, Exit engineering mode.
RSNS.	Set red sensitivity.
ISNS.	Set infrared sensitivity.
RDC.	Set red DC level.
IDC.	Set infrared DC level.
ART & ECG.	Set artifact level and ECG amplitude.
PLT.	Set pleth level.
Red Weighting.	Set red weighting
Redac.	Set red AC level.

Engineering Mode Menu.

Depressing and releasing F2 at the Select Function menu enters Engineering Mode. The opening screen of the Engineering Mode menu, is shown below.

1. **r / syn : i / syn :: monitor.**

Selections.

r/syn : i/syn

:: monitor

F1 : Enable / Disable red light source.
F2 : Enable / Disable infrared light source.
F3 : No function.
F4 : Exit Engineering Mode.

off off

sel

↓

Enter : Accept and progress to RSNS.

F1 and F2 enable and disable the two components of the SpO_2 simulated signal.

** Note : Depressing & holding F2, from the Select Function menu, reveals the simulator software version as shown below.

Spo2 Simulator

Software Ver10528M1E

2. **RSNS - Red Sensitivity**.

	Selections.
RSNS : 20	F1 & F2 : Rapid change in RSNS. F3 & F4 : Fine change in RSNS.

UP DOWN

up down

↓

Enter : Accept and progress to ISNS.

A value within the range 0 (least sensitive) and 100 (most sensitive), enables the user to attenuate or amplify incoming red light levels, bringing these levels within a band acceptable to the simulator. The ability to adjust detection sensitivities enables the DL-3000 to be used with most pulse oximeters.

3. **ISNS - Infrared Sensitivity**.

Selections.

ISNS : 20

F1 & F2 : Rapid change in ISNS.

F3 & F4 : Fine change in ISNS.

UP DOWN

up down

↓

Enter : Accept and progress to RDC.

ISNS adjustment is made using the same method as RSNS. Control of this variable is equally important as RSNS for correct simulator operation.

4. **RDC - Red DC Level.**

Selections.

RDC : 400

F1 & F2 : Rapid change in RDC.
F3 & F4 : Fine change in RDC.

UP DOWN

up down

↓

Enter : Accept and progress to IDC.

Values set between 0 and 4000 represent DC levels of between 0 and +2.5V. The value entered for this variable is used to bias the simulator probe, providing the oximeter under test with the static red light required by its receiver. This value may

be different for each type of oximeter. The correct value is essential if the monitor is to respond appropriately.

5. **IDC - Infrared DC Level.**

Selections.

IDC : 400

F1 & F2 : Rapid change in IDC.
F3 & F4 : Fine change in IDC.

UP DOWN

up down

↓

Enter : Accept and progress to ART & ECG.

IDC controls the infrared DC level in same manner as RDC. The DC level and hence the infrared light can be biased from 0 to +2.5V. IDC & RDC should be set to the same value.

6. **Artifact & ECG.**

Selections.

F1 & F2 : No function.
F3 : Select Artifact amplitude adjustment.
F4 : Select ECG amplitude adjustment.

ART ECG

sel sel

↓

Enter : Accept and progress to PLETH.

If F3 or F4 are chosen at this point, Artifact or ECG amplitude can be adjusted.

6(i). **Artifact Level.**

Selections.

Set 0

Art Value

F1 & F2 : Rapid change in Artifact level.
F3 & F4 : Fine change in Artifact level.

UP DOWN

up down

↓

Enter : Accept and progress to PLETH.

Artifact allows ‘noise’ to be introduced into the simulation procedure. Please refer to P9.

6(ii). **ECG Level.**

Selections.

ECG : 0

F1 & F2 : Rapid change in ECG level.
F3 & F4 : Fine change in ECG level.

UP DOWN

up down

↓

Enter : Accept and progress to PLETH.

The ECG amplitude can be altered independently of SpO_2 derived pulse. Values can be user selected from 0 to 4000. ECG variable defaults to 0 on selection. A value of 1750 equates to an ECG amplitude of $1mV_{PEAK}$.

7. **Pleth.**

Selections.

PLT : 500

F1 & F2 : Rapid change in PLT.
F3 & F4 : Fine change in PLT.

UP DOWN

up down

↓

Enter : Accept and progress to Red weighting.

The amplitude of Pleth signal provided, is controlled by the PLT setting. A PLT setting of 4000 corresponds to a maximum Pleth signal amplitude of 5V. Change in PLT setting gives a proportional change in Pleth signal, down to a PLT setting of 0, no Pleth signal. Pleth adjustment allows the overall pulse to be set to a level acceptable by the oximeter under test.

8. **Red Weighting.**

Selections.

Red Weighting:
84

F1 & F2 : No function.
F3 & F4 : Fine change in Red Weighting.

up **down**

↓

Enter : Accept and progress to Redac.

The ratio of red to infrared light is controlled by Red Weighting, as some oximeters require the red light received to be a proportion of the infrared. Red weighting is adjustable between 64, a red : infrared light ratio of 0.5:1 and 94, a ratio of 2.0:1. Interim ratios are shown below.

65	0.525 :1	70	0.65: 1	75	0.775 :1	80	0.9:1	85	1.1:1	90	1.6:1
66	0.55: 1	71	0.675 :1	76	0.8:1	81	0.925 :1	86	1.2:1	91	1.7:1
67	0.575 :1	72	0.7:1	77	0.825 :1	82	0.95: 1	87	1.3:1	92	1.8:1
68	0.6:1	73	0.725 :1	78	0.85: 1	83	0.975 :1	88	1.4:1	93	1.9:1
69	0.625 :1	74	0.75: 1	79	0.875 :1	84	1.0:1	89	1.5:1		

9. **Redac - Red AC Level.**

Selections.

Redac 1240

F1 & F2 : Rapid change in Redac.
F3 & F4 : Fine change in Redac.

UP DOWN

up down

↓

Enter : Accept and return to start of menu.

The red AC level is controlled using the Redac setting. A significant change in this variable is often necessary to cause an oximeter to register a change of just 1% SpO_2 reading. During evaluation of a new R-curve, it is necessary that the range of Redac values, corresponding to a single SpO_2 reading are discovered. The median value for this range is then taken to be the value used by the DL-3000 for a known SpO_2 reading.

Appendix B.

DL - 3000
SpO_2 Simulator.

Procedure Change.

Appendix B : Procedure change if oximeter pick up becomes intermittent.

Some oximeters may require experimentation with the alignment of the DL-3000 test finger and the oximeter's probe. The Critikon / Sensormedics Oxyshuttle I / II are known examples whose behaviour is incorporated into the following procedure.

Normal setup for the Critikon / Sensormedics Oxyshuttle I / II would be :-

1. Place the test finger into the monitor finger probe, carefully aligning the transmitters over the test finger window. Allow the finger clip to close over the test finger.

2. Switch on the oximeter and allow it to perform its self test. It will then begin searching for a signal which is indicated by two horizontal bars moving up and down the display.

3. When the oximeter receives a compatible signal, the two horizontal bars lock in to the middle of the display and the oximeter begins to display the target SpO_2 value.

The oximeter may take a few seconds to display a stable SpO_2 value and pulse rate. If the oximeter does not lock on to the simulator, carry out the following procedure :-

1. Place the test finger into the monitor finger probe, this time overshooting the test finger windows. In this position, the oximeter should not respond.

2. In small steps, gradually pull the probe outwards so that an increasing amount of light is allowed to pass from the probe transmitters into the test finger windows.

Improved alignment should be indicated by more consistantly lit DL-3000 alignment LEDs. Allow a short period of time for the oximeter to settle.

3. Repeat step (2), until the probes transmitters are fully aligned with the test finger windows. When the probe transmitters and test finger windows are partially aligned, the oximeter under test may show intermittant pickup or reflect different or drifting SpO_2 values. When full alignment is acheived, the oximeter should have locked to the simulator signal and reflect accurate SpO_2 values and heart rates.

This change in procedure allows the DL-3000 to operate correctly and provide a good and compatible simulation for the Critikon / Sensormedics Oxyshuttle I / II. These are the only known oximeters at this time which can show intermittent pick up of the DL-3000 simulation. It is suspected that any further models encountered by users will require similar experimentation and modification of procedures. Should problems persist, please contact Viamed Ltd.

Some oximeters are difficult to effect a simulation. Whereas some competitive simulators can not function with such oximeters, the DL-3000 has proved that it can adapt to these albeit with a little more time taken during set up.