COMPANY OPERATING PROCEDURES

DL3000 SpO_2 Simulator

VM3/COP/45.01

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Equipment required:

Soldering Iron, Hacksaw, Flat File, Small Reamer, Side Snips, Wire Strippers, 12" Rule, Knife, 3mm Metal Drill, Hand Drill, Heat gun, Needle Nosed Pliers, Hot Glue Gun, Flat Blade Screwdriver, Philips Screwdriver, Superglue, Thread-lock.

TEST FINGER:

Parts list: Kit and parts required for the **Test Finger** (DL3100).

Qty	Description	Part No.
2	Finger PCB's	
1	Red Detector	
1	IR Detector	
1	IR Transmitter	
1	6-Core Shielded cable, 130mm	0030513
2	∅6 x 110 mm Heat Shrink (black)	0032321
1	∅9x 150mm Heat Shrink (black)	
1	Lemo 6-pin plug	0033364
1	1 k 8Ω resistor	

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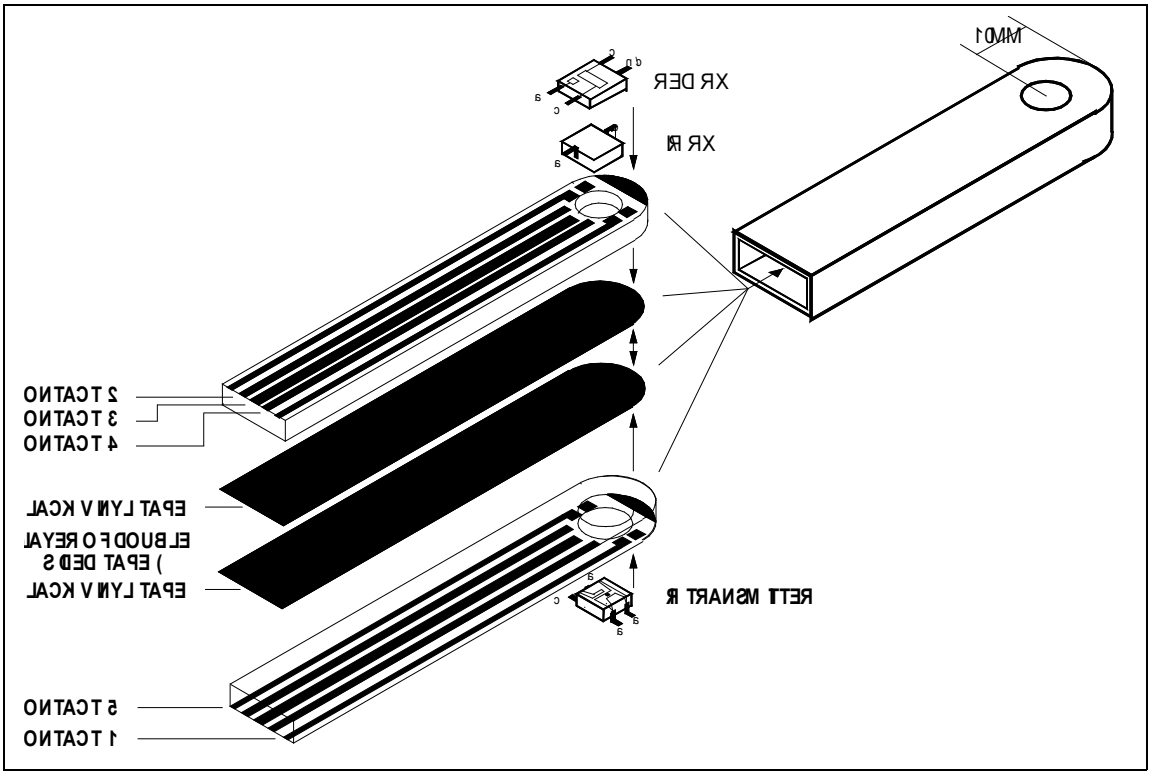
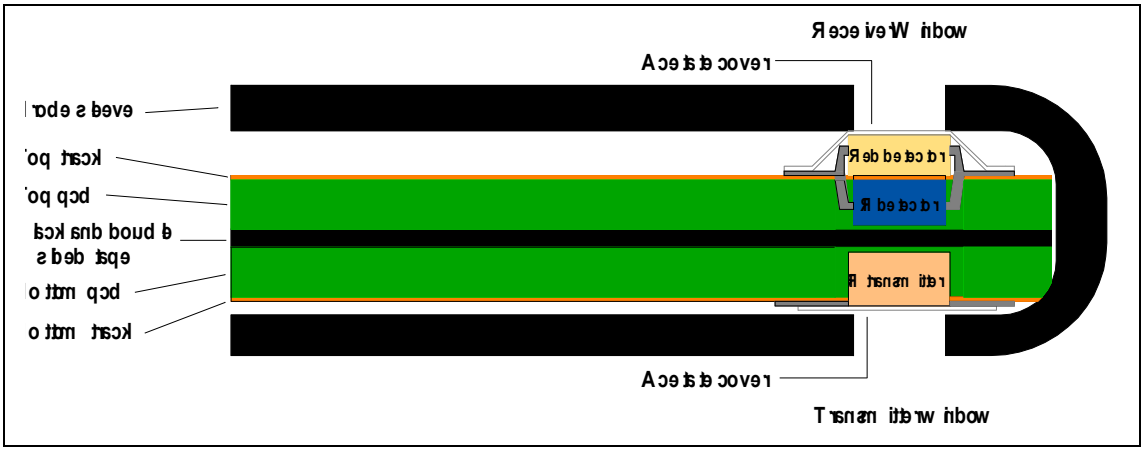
1	Lemo Strain Relief	0033366
1	Strain Relief (5 pin DIN plug)	
1	Probe Sleeve	0033370
1	Double Sided Tape	0033355
1	Black PVC Tape	0033354

ASSEMBLY OPERATIONS





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1. Clean the trackside of both finger PCB's using an abrasive rubber or nylon pen.

2. Enlarge the hole in the tip of one of the finger PCB's and insert the IR detector. Connect the notched cathode to radius end and the anode to contact 3.

3. Connect the red detector such that it sits exactly on top of the IR detector. The cathode connects to the radius end of the PCB with the IR detector cathode. The anode connects to contact 2 of the PCB, whilst the second cathode is connected to contact 4. This leaves a spare anode pin, which can be cut from the detector.

4. Enlarge the hole in the second finger PCB and insert the infrared transmitter. This diode has a dual anode on one side, which should be connected to the two leftmost contacts. Connect the right hand side contacts. Check the orientation of the diode; the exact center of it should look depressed, rather than raised.

5. Attach a strip of PVC tape to underside of each PCB and trim to suit. Stick the PCBs back to back with double sided tape. The black vinyl tape is vital to the probe's operation; should any light be able to leak through from one side to the other, the accuracy of the observed SpO_2 readings on an oximeter will be compromised.

6. Trim 10 mm of sleeve off the 6-core screened cable. Snipe off both the shields and the blue wire. Expose & tin the tips of the remaining conductors.

7. With the receiver side of the PCBs facing up, connect:

   - Red to contact 2 (2nd from left).
   - Orange to contact 3 (3rd from left).
   - Yellow to contact 4 (4th from left).

8. With the infrared transmitter side of the PCBs facing up, connect:

   - White to contact 1 (far left).
   - Black to contact 5 (far right).

9. Cover the diodes with masking tape and spray the copper areas of both boards with acrylic coating. This takes a few minutes to dry. Remove the masking tape.

10. Take the two lengths of ∅6mm x 110mm heat shrink (black), thread each piece over the cable up to the exposed wires and gently heat until tight.

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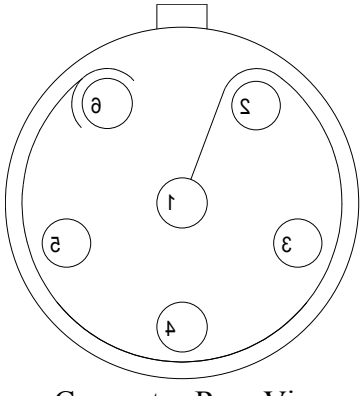
11. Melt hot glue around the wire connections so that the exposed wires between the cable and PCBs are embedded.

12. Thread & reduce a 9mm x 20mm length of heat shrink (black) onto the sleeved cable and over connections on the PCB.

13. Add the rubber strain relief, the Lemo strain relief, the Lemo nut and the collett nut onto the sleeved cable.

14. Trim 10mm of sleeve off the 6-core cable and snip off the blue wire. Expose & tin the tips of the conductors. Solder each of the wires to the Lemo bucket contacts as follows:

Pin 1 - red.
Pin 2 - orange.
Pin 3 - yellow.
Pin 4 - resistor.
Pin 5 - black & resistor
Pin 6 - white.



Connector Rear View

15. Assemble the Lemo connector, ensuring that the side of the finger PCBs corresponding to LED package faces uppermost when the test finger is plugged into the DL3000 fascia.

16. Punch a 4mm hole in either side of the probe sleeve, 10mm from the radius end.

17. Insert of finger probe PCBs into the probe sleeve and glue the strain relief to the sleeve using the superglue.

18. The probe should then be evaluated to ensure that the 1K8 resistor fitted is sufficient. Evaluation is performed using the Test Finger Calibrator, DL3000FC.

SIMULATOR FRONT PANEL:

Parts list: Kit and parts required for the **DL3000 Simulator Front Panel:**

Qty	Description	Part No.

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1	Front panel & tactile keyboard	0033300
1	Lemo 6-pin Socket	0033304
1	8 x 2 way DIL header	
1	LCD module (WMC2002M)	0033301
7	6BA Shake proof washers	
8	6BA full nuts	
1	Molex Housing (8 way)	0033252
1	Molex Housing (3 way)	0033250
9	Molex Inserts	
2	Red LEDs	0033302
2	LED holders	0033303
1	M3 x 6mm Spacers	
1	20-way ribbon cable (100mm):	709-906
1	Ribbon Cable, 3way (white, grey, purple), 70mm.	"
1	Ribbon Cable, 6 way (black, brown, red, orange, yellow, green), 50 mm.	"
1	Ribbon cable 1 way (white) 40mm.	"
1	IDC cable 20-way (16 way x 100mm)	
2	IDC plugs, 16-way, keyed.	0033254
10	∅ 3 x 12mm Heat shrink (black)	0032312

ASSEMBLY OPERATIONS

FRONT PANEL:

1. Place one 6mm spacer on each LCD retaining bolt on the rear of the front panel. Secure each spacer with a 6BA shake-proof washer and 6BA nut.

2. Solder two 8 x 2-way DIL headers to the rear of the LCD module (header facing rearmost). Make connections J1, J3 & J6 on the LCD with solder bridges.

3. Remove the protective film from the LCD module glass and locate the module on the four bolts (DIL header should be on the opposite side to the LED holes). Secure with 6BA shake proof washers on the lower two bolts and upper left, then 6BA nuts.

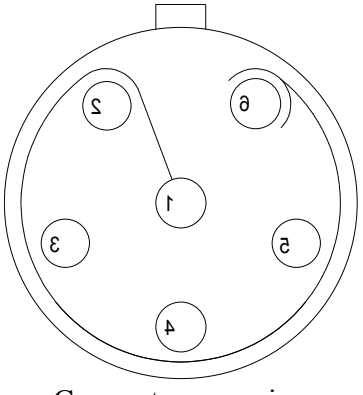
4. Insert the LED holders and tighten the nuts. Insert the two red LEDs and tighten the LED retainers. Trim the LED electrodes to 5mm above the LED retainers. Using the 20-way multi colored Ribbon cable, (separate off a 3-way (white, grey, purple) strip x 100mm long & a single white strip of ribbon cable x 40mm long), molex inserts and 3-way molex housing, make the following connections: (Insulate bare terminations with ∅3 x 12mm black heat shrink tubing).

(i). IR indicator LED, anode, to Molex pin 1 - white,
(ii). IR indicator LED cathode, to Molex pin 3 - purple,
(iii). Red indicator LED anode, to IR indicator LED anode, - white,
(iv). Red LED indicator cathode, to Molex pin 2 - grey.

5. Insert the Lemo socket into the front panel - it should be orientated so that the red mark is uppermost. Secure the Lemo socket with the shake proof washer and nut provided using the thread-lock.

6. Using the Ribbon Cable, (separate off a 6 way (black, brown, red, orange, yellow, green) length x 50 mm), molex inserts and 6-way molex housing, make the following connections: (Insulate terminations with ∅3 x 12mm black heat shrink tubing).

Molex, pin 1 (black) to Lemo socket, pin 2.
Molex, pin 2 (brown) to Lemo socket, pin 3.
Molex, pin 3 (red) to Lemo socket, pin 5.
Molex, pin 4 (orange) to Lemo socket, pin 4.
Molex, pin 5 (yellow) to Lemo socket, pin 6.
Molex, pin 6 (green) to Lemo socket, pin 1.



Connector rear view

7. Construct the LCD module to motherboard connector using the two 16-pin IDC connectors and 16-way IDC ribbon cable: pin 1 - pin 1, pin 16 to pin 16. Slightly trim one IDC plug to suit and connect to the LCD module header (IDC plug keys facing innermost red edge of the cable is pin1).

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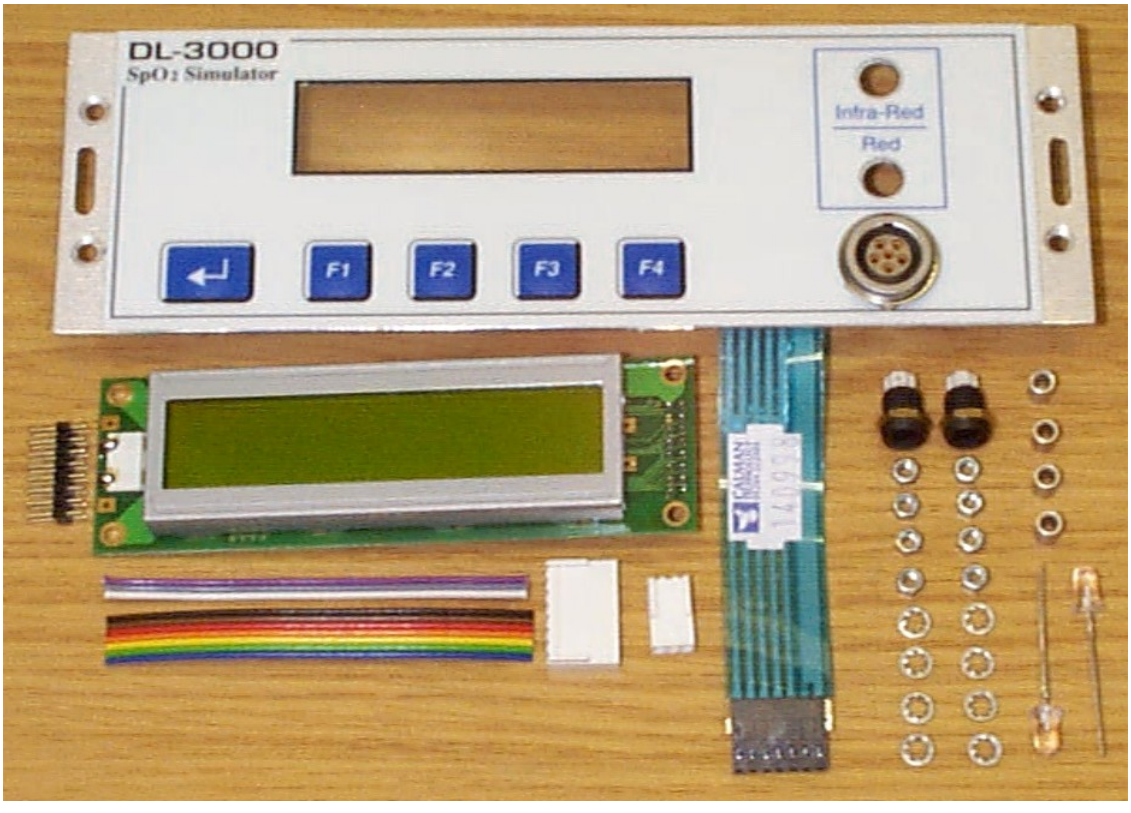

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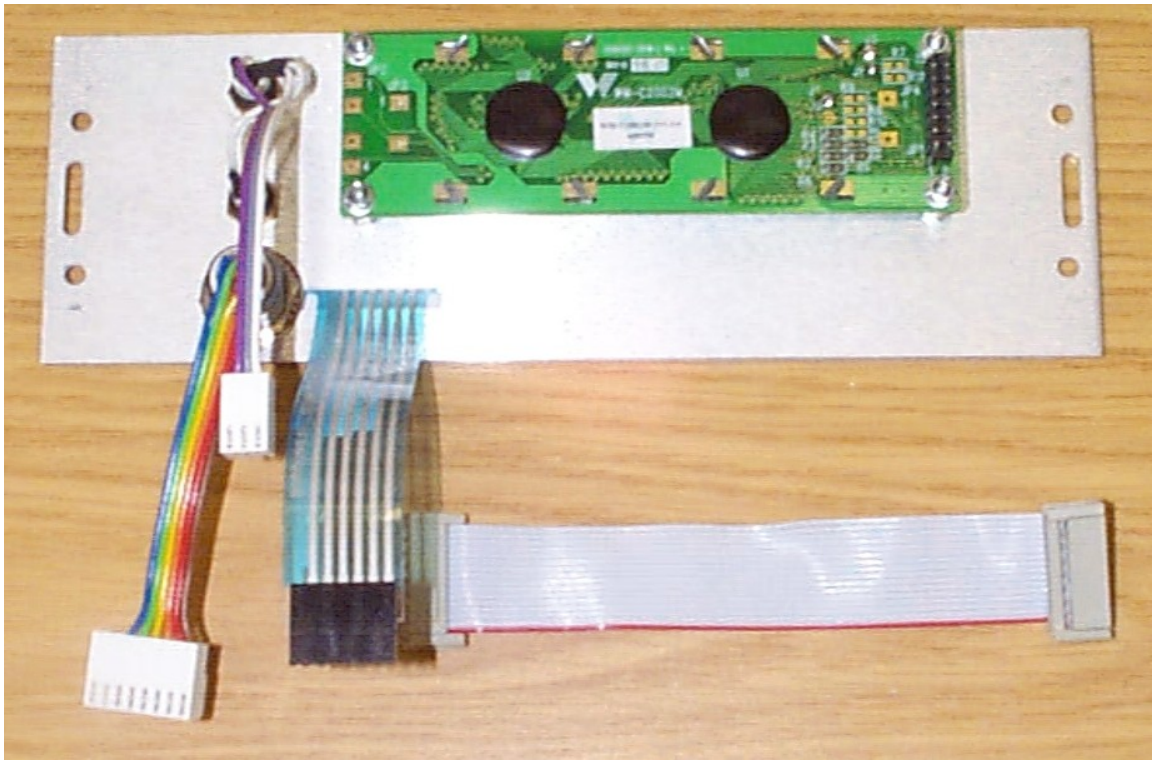

SIMULATOR REAR PANEL:

Parts list: Kit and parts required for the **DL3000 Simulator Rear Panel:**

Qty	Description	Part No.
1	Pre-cut, labelled & finished rear panel.	
1	Visirocker toggle switch (black, red detailing).	0033369
1	1kΩ, rotary potentiometer.	0033371
1	Socket, chassis, DC power, 2.1mm	
1	4 mm socket (Red)	0033356
1	4 mm socket (black)	0033357
1	4 mm socket (white)	0033358
1	4 mm socket (green)	0033359
1	4 mm socket (yellow)	0033360
1	Ferrite bead.	0033363
1	D socket, 15-way. Male	0033256
1	IDC ribbon cable, 20-way (14 way x 200mm).	
1	Molex housing (3 way).	0033250

1	Molex housing (6 way).	0033251
1	Molex housing (8 way).	0033252
14	Molex inserts.	
1	20-way ribbon cable (150mm):	709-906
1	Ribbon cable (5 way: black, brown, red, orange, yellow), 130mm.	"
1	Ribbon cable (5 way: white, grey, purple, blue, green). 130mm	"
1	Ribbon cable, 1 way (black) 20 mm	"
1	Ribbon cable (2 way: black, white) 120mm	"
1	IDC plug, 14-way, keyed, female	0033253
2	M3 x 6mm pan head, cross point screws.	
2	M3 mm full nuts.	
2	M3 shake proof washers.	
19	∅ 3 x 12mm Heat shrink (black)	0032312
2	∅ 6 x 12mm Heat shrink (black)	0032321
5	∅ 6 x 20mm Heat shrink (black)	0032321
2	Cable ties (small)	

ASSEMBLY OPERATIONS

REAR PANEL:

1. Secure the 1kΩ pot in the rear panel using the shake proof washer and nut provided. (The hole may need to be enlarged).

2. Insert the visi-rocker toggle switch into the rear panel (0 up, 1 down).
Using the 8-way molex housing, molex inserts and ribbon cable (separate off a 5 way (black, brown, red, orange, yellow) length x 130 mm and separate off a 20mm length of black wire), make the following connections: (Insulate bare terminations with ∅3 x 10mm black heat shrink tubing).

   (i). Molex Pin 1 (black) to toggle switch, upper spade connector.
   (ii). Molex Pin 2 (brown) to toggle switch, lower spade connector.
   (iii). Molex Pin 3 (red) to 1kΩ pot left hand terminal.
   (iv). Molex Pin 4 (orange) to 1kΩ pot center terminal.
   (v). Molex Pin 5 (yellow) to 1kΩ pot right hand terminal.
   (vi). Molex Pin 6 (black) to pin 7.

   Secure a cable tie just beneath the point where wiring harness divides for support.

3. Insert the DC power socket into the rear panel and secure using the nut provided (hole of DC power plug in the 6 o'clock position). Thread the 2-way ribbon cable (separate off a 2-way (black & white) length x 120mm) through the ferrite bead, forming a loop of cable around the bead. Terminate this cable using a 3-way molex housing & molex inserts as follows: (Insulate terminations with ∅3 x 10mm black heat shrink tubing).

   (i). Pin 1 (Black) to DC power socket, lower left terminal.
   (ii). Pin 2 (White) to DC power socket, upper terminal.

4. Insert the 4mm sockets into the rear panel and secure using the nuts provided: Red (RA), Black (RL), White (C), Green (LL) & Yellow (LA). Using the 6-way molex housing, molex inserts & ribbon cable (strip a 5-way (white, grey, purple, blue, green) length to 130 mm), make the following connections: (Insulate terminations with ∅3 x 10mm black heat shrink tubing).

   (i). Molex pin 1 (white) to ECG "C".
   (ii) Molex pin 2 (grey) to ECG "RL".
   (iii). Molex pin 3 (purple) to ECG "LL".
   (iv). Molex pin 4 (blue) to ECG "LA".
   (v). Molex pin 5 (green) to ECG "RA".

   Insulate ECG terminations with 20mm lengths of heat shrink (black) up to the threads.

5. Using the 16-way IDC ribbon cable (separate to make 14 way), 15 way D socket & 14 way IDC plugs, construct the system interface connector, pin 1 to pin 1 through to pin 14 to pin 14 inc. Insulate each termination at the D type with ∅3 x 10mm heat shrink tubing (black). (Pin 15 not used at D type). Secure the D type plug on the inside of the panel using 2off M3x6mm cross point screws, shake proof washers and nuts. Secure a cable tie just below the point where the wiring harness divides into single conductors for support.

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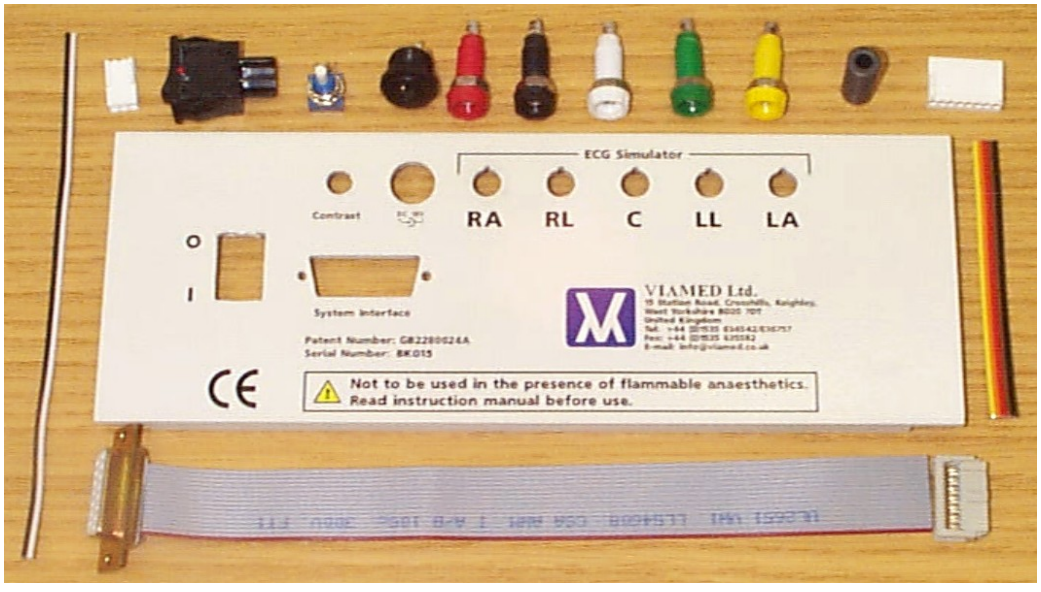

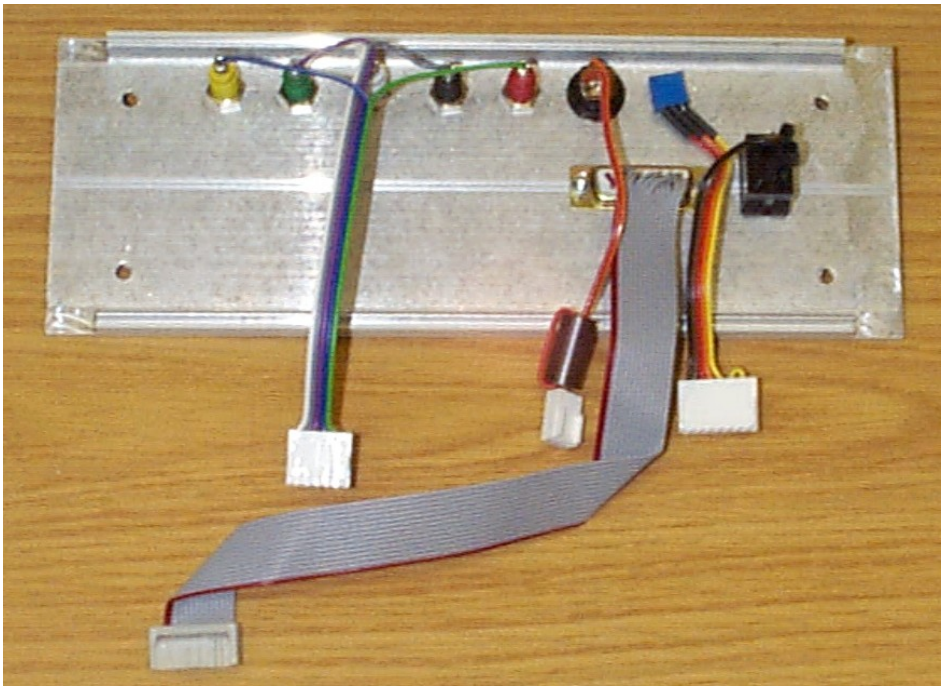

SIMULATOR ASSEMBLY:

Sub assemblies required:

1 x Completed front panel.
1 x Completed rear panel.

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Parts list: Kit and parts required for the **DL3000 Assembly:**

Qty	Description	Part No.
1	315mA, quick blow 20mm fuse	0033427
1	Mettec desk case, 120mm series, off white (With 4off, self-adhesive rubber feet).	0033350
2	Front panel trims (grey).	
1	Fully populated PCB (bar processor).	0033000
1	Pre-blown processor (ST90T40C4).	0033351
1	12V battery.	0033429
1	Battery retaining strap.	
1	M3 8mm spacer.	
2	M3 nuts.	
2	M3 shake proof washers.	
1	M3 x 20 bolt.	
1	Molex housing (2 way).	0033249
2	Molex inserts.	
1	20-way Ribbon cable (175mm)	709-906
2	∅ 9 x 20 mm Heat shrink (black)	
4	Double sided foam pads	

ASSEMBLY OPERATIONS

SIMULATOR ASSEMBLY:

Note: For this section ANTI STATIC PROTECTION IS ESSENTIAL.

1. Fit self-adhesive rubber feet to the Mettec case underside, on the side rails front & rear.

2. Drill a 3 mm hole into the bottom case plate through which the PCB will be secured. To determine the position of this hole, fit the PCB into the bottom case runners, (battery cut out to the rear), and punch a mark into the case through the PCB mounting hole. (The position is 127 mm from left edge and 4 mm from rear panel with the case upside down).

3. Insert the PCB into the bottom runners of the case. Position the M3 x 8mm spacer under the PCB and thread the M3x20mm screw upwards through the drilled case hole, spacer and PCB. Secure with a M3 shake proof washer and nut.

4. Secure the battery to the bottom of the case, within the battery cutout area, using double sided foam pads (only in the recessed, center section of the underside of the battery). Fit the battery-retaining strap and secure to the PCB retaining bolt using an M3 shake proof washer and nut.

5. Fit the ST90 processor into the PLCC socket on the motherboard marked IC1, using the insertion/extraction tool. The top left of the chip and the socket are keyed to prevent incorrect insertion. The processor must have the latest version of the software installed. Mark the processor with its respective software version.

6. Using ribbon cable (separate a 2-way (red, brown) length to 175mm), 2-way molex housing & inserts, make the connection between battery and PCB, molex 3. Battery positive terminal to pin 2 (red), negative terminal to pin 1 (brown). Damage will occur if these terminations are made the wrong way around. Completely insulate battery terminals with ∅ 9 x 20 mm heat shrink (black).

7. Secure the front panel with 4 M3 x 6mm pan head screws. Fit the grey fascia covers.

8. The front panel cable assemblies are wired to the PCB as follows:

- Keypad membrane to PCB molex 7, pins 1 to 7. Pin 8 is not used.
- Lemo socket to PCB molex 6.
- Alignment LED connector to PCB molex 8.
- LCD module to PCB IDC1.

9. The rear panel should then be connected.

- System interface D type connector to IDC2, routing around the battery. Fold the cable once at a 45-degree angle at the IDC plug end.
- The ECG wiring passes over the battery and down to Molex 5, ensuring that it passes over the system interface IDC cable thereby holding it secure against the battery.
- Toggle switch / contrast pot to PCB molex 2.
- DC power socket to PCB molex 1.

10. Check that all internal connections are made & secure, the battery is secure and that there are no loose items within the unit. Ensure all IC's are firmly seated in their sockets. All bare soldered connections should be insulated with heat shrink.

11. Fit 315mA fuse in the motherboard FS1.

12. Do not fit the top cover. Lightly secure the rear panel using 2 M3 x 6 countersink screws.

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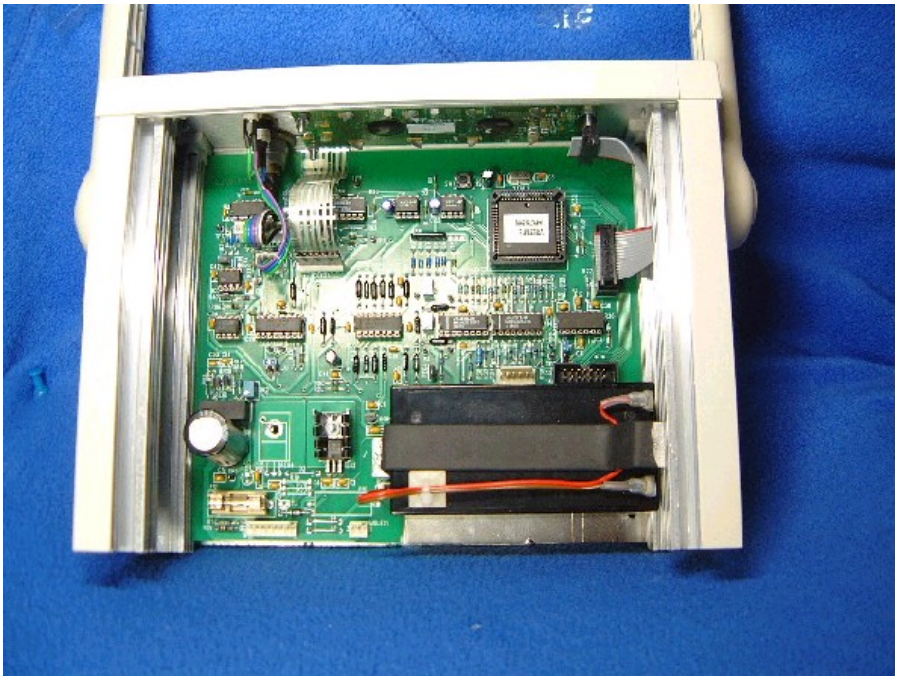

TESTING

Before commencing testing, read the following:

Do ensure that the battery has enough charge. If the voltage is low (less than 5V), the DL-3000 will not function. Charge the battery or replace if necessary.

Do ensure the power supply adapter connector is fitted in the **tip positive ("tip >< +")** position. Damage will be caused to the PCB if incorrectly fitted.

Do not apply power, either via the internal battery or mains adapter, when the processor is not fitted. If the processor is absent, the LCD panel will still illuminate but damage will be caused to other components on the PCB.

1. Test & record the battery terminal voltage.

2. Test the mains adapter and ensure it provides approx. 11.5 – 12.5Vdc under no load.

3. Connect the DL-3000 to the wall mains outlet using the mains adapter.

4. Switch on.

5. Ensure the DL-3000 displays it's software version and after a delay enters 'Select Manufacturer'.

6. Ensure the LCD backlight is illuminated.

7. Adjust the contrast control to obtain a readable display.

8. Ensure character presentation, orientation and display readability is good.

9. Manipulate the menu system ensuring that each user selector is functioning correctly.

10. Switch off.

11. Carry out the DL-3000 calibration procedure.

12. Attach completed 'In-house calibrated' sticker on the PCB, top right hand corner.

13. Test & record the battery terminal voltage. Ensure a greater measured voltage at step 1.

14. Record the DL-3000 software version no., PCB issue no. & unit serial no.

15. Detach rear panel and fit upper case cover.

16. Ensure checks detailed in 'Assembly Instructions, paragraph 10' are carried out.

17. Fit rear panel, securing with 3off M3 x 20 equipment screws in lower positions and upper right. Secure upper left hand position with M3 x 6 counter-sunk screw. Place a 'Calibration void if label removed' sticker over this fastener.

18. <u>Functional Test</u>.

- Ensure no damage to DL-3000 casing, finish, front panel, handle, controls, indicators, sockets and plugs. Handle mechanism operates correctly. Rubber feet fitted. All parts externally visible are secure (especially Lemo socket).

- Test the DL-3000 on the supplied oximeter(s) ensuring that the displayed SpO_2 is ±1% of simulated SpO_2 for benchmarks of 97, 90 & 80%. Record the displayed values.

- Verify correct manipulation of heart rate and tolerance of ±1%.

- Ensure alignment LEDs operate correctly.

- Ensure correct ECG simulation using the Mennen Mercury.
- Verify the correct resistance in the DL-3000 test finger with DL-3000 test finger calibrator.
- Ensure the DL-3000 interfaces with the supplied module.
- Complete all the paperwork.

Quality Assurance (QA)

- Ensure no damage to DL-3000 casing, finish, fascia, handle, controls, indicators, sockets and plugs. Handle mechanism operates correctly. Rubber feet fitted. Contrast knob fitted. All parts externally visible are secure (especially Lemo socket).
- Check for internal rattles.
- Test finger OK - sleeve glued on, window covers in?
- Test the DL-3000 on one supplied oximeter ensuring that the displayed SpO_2 is ±1% of simulated SpO_2 for benchmarks of 97, 95, 90 & 80%. Record the displayed values.
- Displayed heart rate should be ±1% at all values.
- Verify correct manipulation of heart rate.
- Ensure alignment LED's operate correctly.
- Ensure the DL-3000 interfaces correctly with the supplied module.
- Complete all the paperwork.

Trouble Shooting

<u>The machine does not function, using power from the battery or the mains adapter.</u>

Check the fuse FS1 has not blown.
Check battery is charged.
Check all the interconnections.

The machine functions only when powered from the mains adapter and not from the battery.

Check battery is charged.
Check all the interconnections.

The machine functions only when powered from the battery and not from the mains adapter.

Check the fuse FS1 has not blown.
Check all the interconnections.

The machine functions correctly except it fails to simulate.

Check “Cal / Run” link in the “Run” position.