

COMPANY OPERATING PROCEDURES

0018780

Invivo

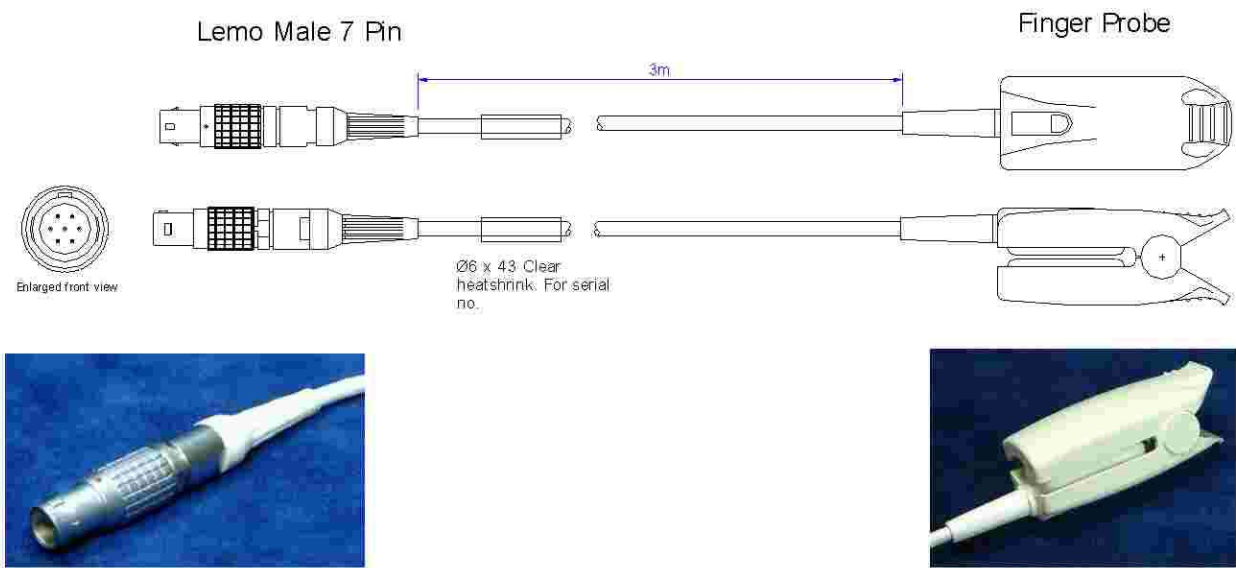
P878RA

VM3/COP/32.23

Date: 15-Dec-01

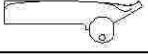
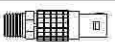
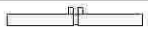
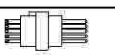
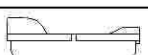


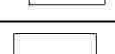
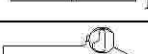

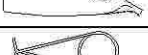
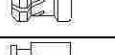




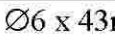

Revision date: 17-May-04

Issue: 3



Equipment required: Soldering iron (0060120), solder (0050012), Wire stripper (0060030), Flush Cutter (0060010), Snipe nose pliers (0060021), ‘helping hand’ (0060145), Heat gun (0060100).

Parts list: Kit and parts required.

Lemo male 7-pin Side			Finger Probe Side		
Qty	Description	Part No.	Qty	Description	Part No.
1	Lemo Male 7-pin kit	0010650	1	 Top Shell (x25)	0010110
(1)	 Housing	Kit	2	 Pad Support (white) (x50)	0010160
(1)	 Connector	Kit	1	 Top Pad (white)(x25)	0010130
(1)	 Upper sleeve	Kit	1	 Bottom Pad (white)(x25)	0010131
(1)	 Lower sleeve	Kit	1	 Bottom Shell (x25)	0010111
(1)	 Collett	Kit	1	 Spring (x25)	0010140
(1)	 Rear Housing	Kit	2	 Button (White) (x50)	0010180
1	 Strain relief (white)	0030654	1	 Detector	0030901
1	Ø6 x 43mm Clear heat shrink	0032331	1	 LED/ I.R.	0030950
1	 R1 39.2k Ω Resistor	0032100	1	 Strain Relief	0010150

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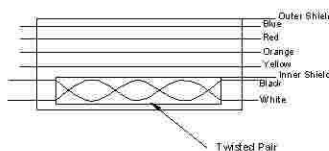
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ASSEMBLY OPERATIONS

1. Pre Heat soldering iron temperature to 240^oc.
2. Collect all required parts and equipment listed above.
3. Cut a 3.1 metre length of standard 6-core cable. (Details shown below).

1.0 Mechanical Specifications

1.1 Cable Schematic



1.2 Cable Cross Section

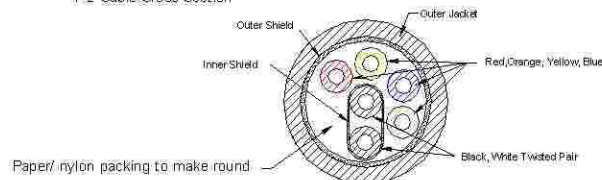


Fig 1.

Lemo 7-pin side:

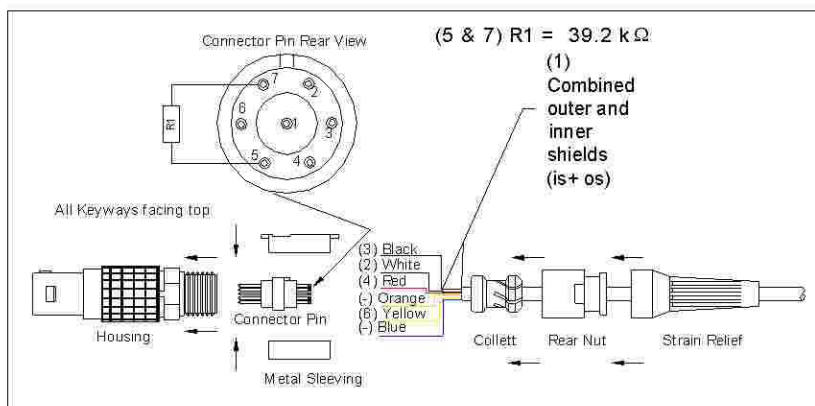


Fig 2.2

1. Feed Ø6 x 43mm (clear) heat shrink, strain relief, rear nut, collett and Ø6 x 25mm (black) heat shrink over end of cable.
2. Strip 20mm off outer jacket of wire to reveal coloured wires, outer shield, and nylon/paper wire packing.
3. Cut all packing, orange and blue wire to the base.
4. Strip 20mm off inner jacket to reveal black and white wires and the inner shield.
5. Twist outer and inner shields together.
6. Trim ends of wires to 13mm long. And resistor legs to 4mm and 15mm.
7. Strip jacket of every wire 2mm to reveal copper core.
8. Heat Ø6 x 25mm (black) heat shrink up to the end of the cable.

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9. Solder ends of every wire, resistor and shields to the correct positions on the rear of the connector.
10. Fit metal sleeves over the connector, and insert into the housing ensuring all keyways lie up.
11. Holding the housing fixed with a spanner, tighten the rear nut over the collett and onto the housing.
12. Push the strain relief onto the rear nut.

Finger Probe side:

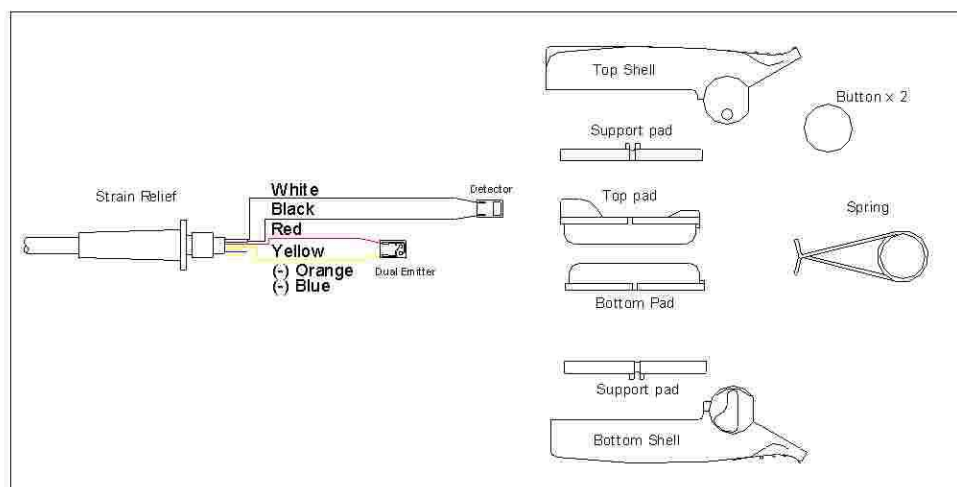


Fig 2.3

1. Apply loctite primer to the cable surface, and slide on the strain relief.
2. Apply a small amount of superglue on to the surface of the cable and push the strain relief over the glue to secure in place leaving approximately 80 mm of cable.
3. Strip outer jacket up to the strain relief and cut packing, outer shield, blue and orange wires.
4. Cut red and yellow wires to 15 mm, strip jackets off 2mm and apply a small amount of solder to the ends.
5. Strip 10 mm off inner jacket and cut off inner shield.
6. Strip jackets 2mm and apply small amount of solder.
7. Solder wires to the detector, LED/I.R as shown in fig 2.3
8. Place the assembly on the drying rack, and apply a small amount of clear silicon to the front of the detector and LED/I.R and mount into the pads (Led/IR in the top pad and Detector in the bottom pad) allowing the sensors to be seen and central, and scrape excess silicon. Then place the drying rack in the drying cabinet and leave to dry overnight.
9. Superglue loose cable to the pads and fill the rears with white silicon.
10. Glue pads onto the pad supports (prime first).
11. Place spring around pads and into place.
12. Clip upper and lower shells (apply a little super glue) into place and glue caps onto the sides.

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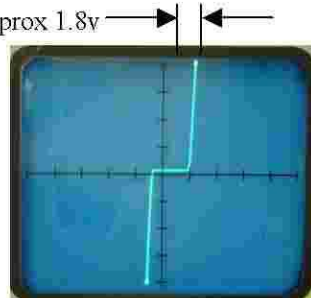
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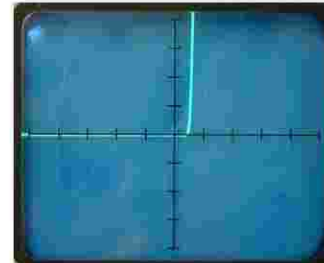
TESTING

1. Attach Lemo 7-pin side to the test box connector marked 'G'.
2. Check display is showing correct characteristics as shown below. (At correct switch positions)

LED should read approx 1.8v



Position 1, IR, LED.

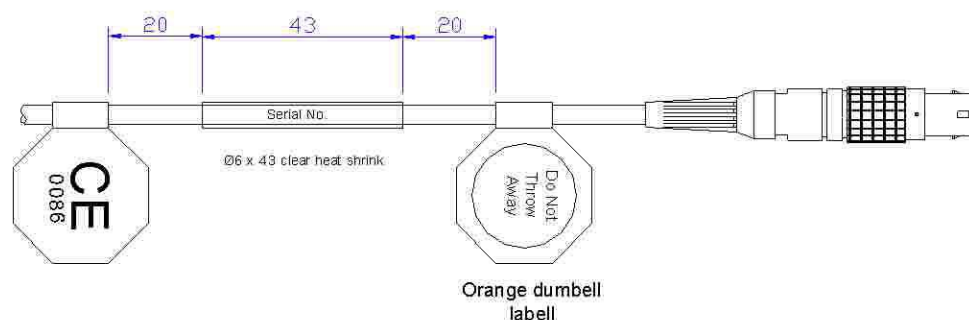


Position 4, Detector

3. If the LED signal is at the bottom then it is wired incorrectly.
4. 'Play' with wire at connections to see if any change in the display (i.e. flickering etc).
5. If there is any movement of signal, the cable must be taken apart and all connections checked and re-soldered. Then tested again until results are satisfactory.
6. Check the cable is of correct quality standard. (See VM/COP/30.11 for details).
7. Attach Lemo 7-pin side to an adapter cable then to a Nellcor monitor and the probe on to the finger simulator to check SpO₂ level. (Ideal reading 95-100.)

Labelling

1. Labels: to be attached facing upwards as looking at the top of the probe.
 - 1 x CE Label
 - 1 x Viamed shell label on probe lower shell.
 - 1 x Serial no. Label
 - 1x Orange 'Do Not Throw Away' Label (correct one of two is dependant of country unit is being sold to).



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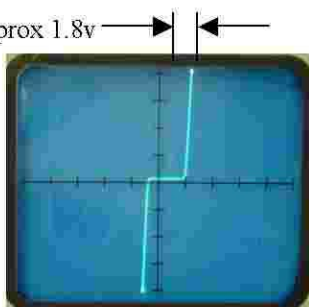
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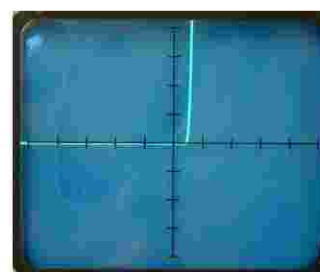
Quality Assurance (QA)

1. Attach Lemo 7-pin side to the test box connector marked 'G'.
2. Check display is showing correct characteristics as shown below. (At correct switch positions)

LED should read approx 1.8v



Position 1. IR, LED.



Position 4. Detector

3. If the LED signal is at the bottom then it is wired incorrectly.
4. 'Play' with wire at connections to see if any change in the display (i.e. flickering etc).
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6. Check the cable is of correct quality standard. (See VM/COP/30.11 for details).
7. Attach Lemo 7-pin side to an adapter cable then to a Nellcor monitor and the probe on to the finger simulator to check SpO₂ level. (Ideal reading 95-100.)
8. Fill and sign attached paperwork.

Packaging

1. Visually check all labels are attached properly
2. Using a twist tie (bunny clip) wrap the cable and place in a small blue Viamed plastic box, ensuring the cable is inserted in a neat and tidy presentable manor.
3. Place a serial number sticker (supplied with the batch) on the front face of the box.
4. Place a packed and tested sticker (also containing initials of the individual who is packing) on the right hand side top left corner of the box. Do not close box.

Final QA

1. Final inspection. Visually ensure cable sit neatly within the box and is in a presentable state.
2. Boxes are ready to stock in stores.