

COMPANY OPERATING PROCEDURES

0018650

Sensormedics

P865RA

VM3/COP/32.12

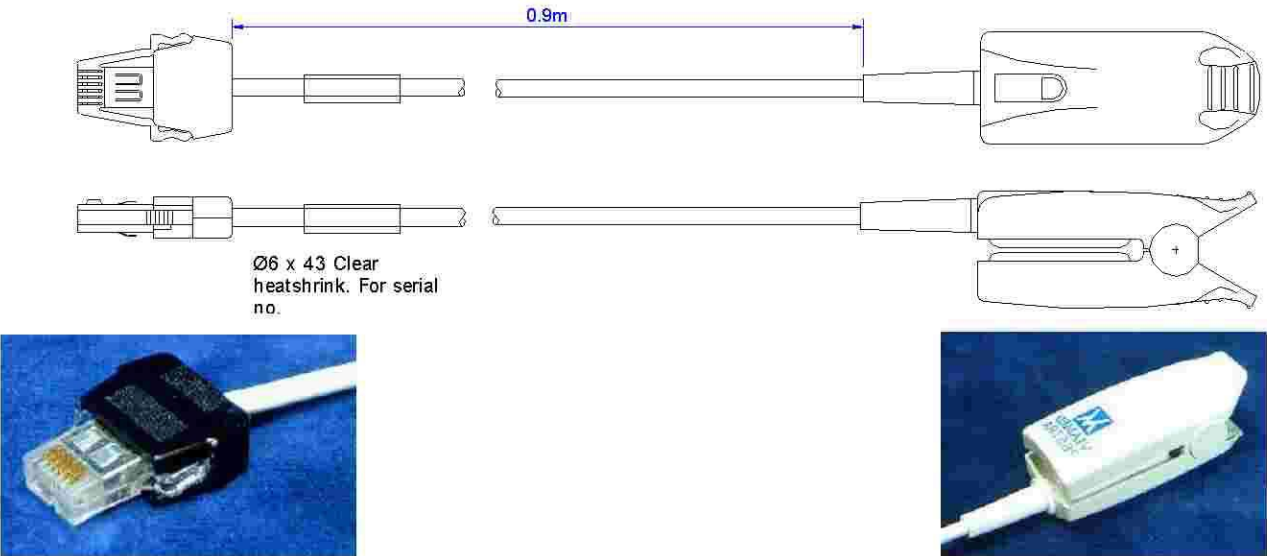
Date: 14-Dec-01

Revision date: 17-May-04

Issue: 3

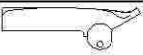
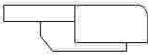
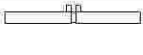

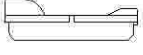
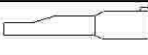

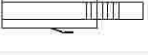




Compushield M-6

Finger Probe



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. (Continued over page)

Compushield male 6-pin side			Finger Probe Side		
Qty	Description	Part No.	Qty	Description	Part No.
1	Compushield male 6-pin kit	0010710	1	 Top Shell (x25)	0010110
(1)	 Upper case	kit	2	 Pad Support (White) (x50)	0010160
(1)	 Lower case	kit	1	 Top Pad (white)(x25)	0010130
(1)	 Wire housing	kit	1	 Bottom Pad (white)(x25)	0010131
(1)	 Connector	kit	1	 Bottom Shell (x25)	0010111
(1)	 Cable Grip	kit	1	 Spring (x25)	0010140
1	Ø6 x 43mm heat shrink (clear)	0032331	2	 Cap (White) (x50)	0010180

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


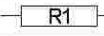
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1	Ø6 x 30mm heat shrink (Clear)	0032331	1		Detector	0030900
	Ø3.2 x 18 heat shrink		1		LED/ I.R.	0030952
			1		Strain Relief	0010150
			1		18.7 kΩ Resistor	0033014

ASSEMBLY OPERATIONS

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

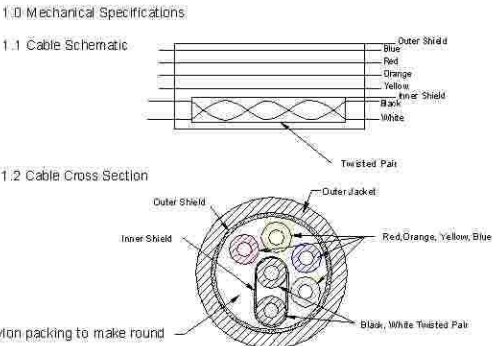


Fig 1.

Compushield male 6-pin side:

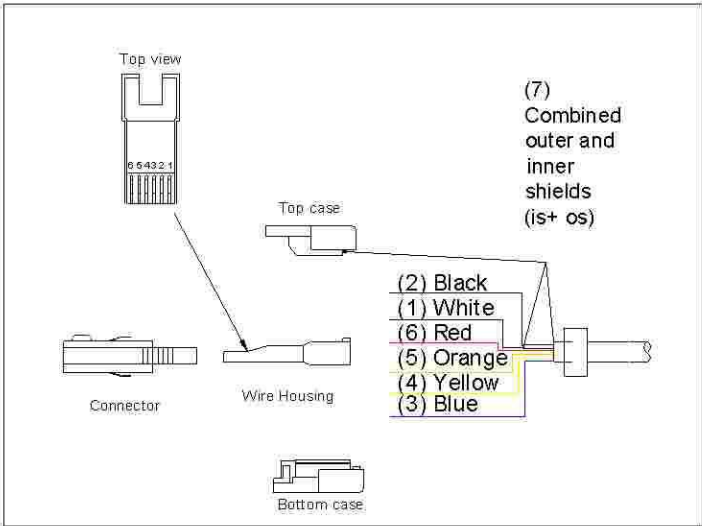


Fig 2.2

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1. Feed Ø6 x 43mm Clear heat shrink, cable grip and Ø6 x 30mm heat shrink (clear) over end of cable.
2. Strip 20mm off outer jacket of cable to reveal coloured wires, outer shield, and nylon/paper wire packing.
3. Cut all packing to the base.
4. Strip 20mm off inner jacket to reveal black and white wires and the inner shield.
5. Twist inner and outer shields together and solder to the top inner metal surface of the upper casing.
6. Clamp cable grip 2mm from the end of the cable outer jacket.
7. Push wires firmly into correct locations. (Apply small amount of glue if necessary).
8. Trim any excess wire 'overhanging' from the front end of the wire housing.
9. Push housing into the connector, and use crimp tool to push pins down through wires.
10. Push upper and lower cases around the connector firmly into place.

Finger Probe side:

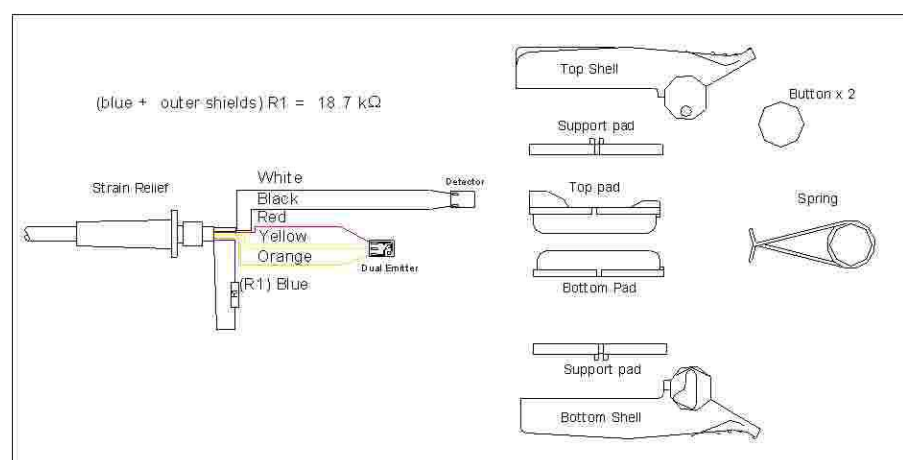


Fig 2.3

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 to the base. Cut outer shield to 10mm and blue wire to 20mm.
4. Cut red, yellow and orange 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 inner shield.
6. Strip jackets 2mm and apply small amount of solder.
7. Cut resistor legs to 4mm and 15mm, and solder one leg to the outer shield and the other to the blue wire. And cover in heat shrink Ø3.2 x18mm.
8. Solder wires to the detector, LED/I.R as shown in fig 2.3

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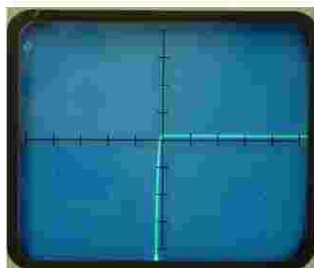
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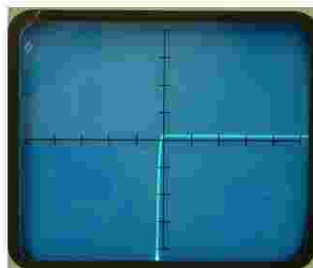
9. Place the assembly on the drying rack, and apply a small amount of clear silicon to the front of the detector and LED/I.R and mount into the pads (Led/IR in the top pad and Detector in the bottom pad) allowing the sensors to be seen and central, and scrape excess silicon. Then place the drying rack in the drying cabinet and leave to dry overnight.
10. Superglue loose cable to the pads and fill the rears with white silicon.
11. Glue pads onto the pad supports (prime first).
12. Place spring around pads and into place.
13. Clip upper and lower shells (use a little super glue) into place and glue buttons onto the sides.

TESTING

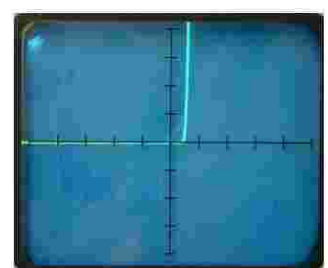
1. Attach Compushield male 6-pin side to a test lead and then to the test box connector marked 'B'.
2. Check display is showing correct characteristics as shown below. (At correct switch positions)



Pos 2. LED



Pos 3. IR



Pos 4. Detector

3. 'Play' with wire at connections to see if any change in the display (i.e. flickering etc).
4. 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.
5. Check the cable is of correct quality standard. (See VM/COP/30.11 for details).
6. Connect Compushield male 6-pin side to a sensormedics oxyshuttle monitor and attach probe on finger 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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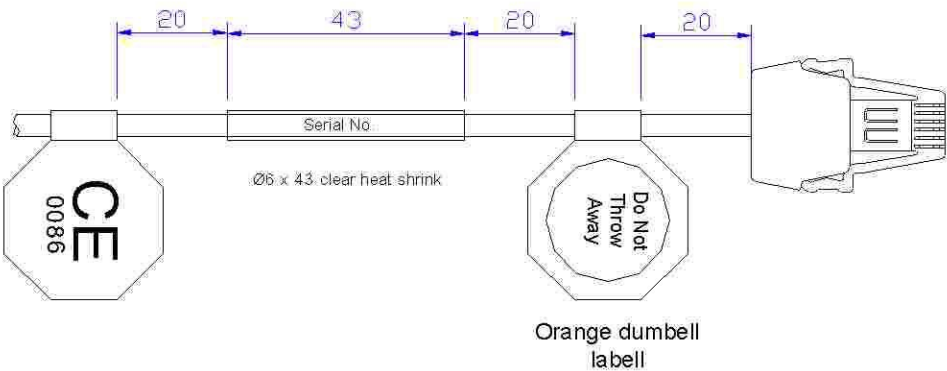
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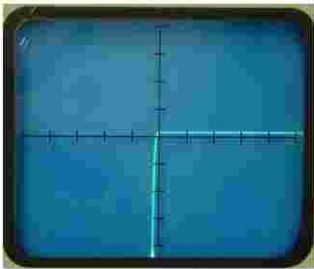
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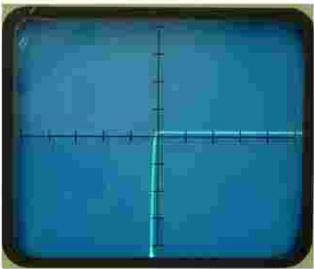


Quality Assurance (QA)

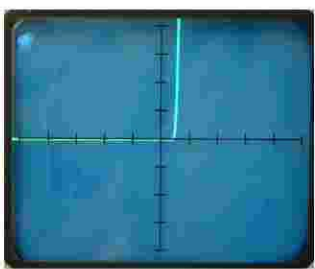
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2. Check display is showing correct characteristics as shown below. (At correct switch positions)



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Pos 4. Detector

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5. Check the cable is of correct quality standard. (See VM/COP/30.11 for details).
6. Connect Compushield male 6-pin side to a sensormedics oxyshuttle monitor and attach probe on finger to check SpO₂ level. (Ideal reading 95-100.)
7. Fill and sign attached paperwork.
8. Test 10 % of batch on DL3000 simulator.
9. Log all results on compatibility sheet.

Packaging

1. Visually check all labels are attached properly

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- 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.