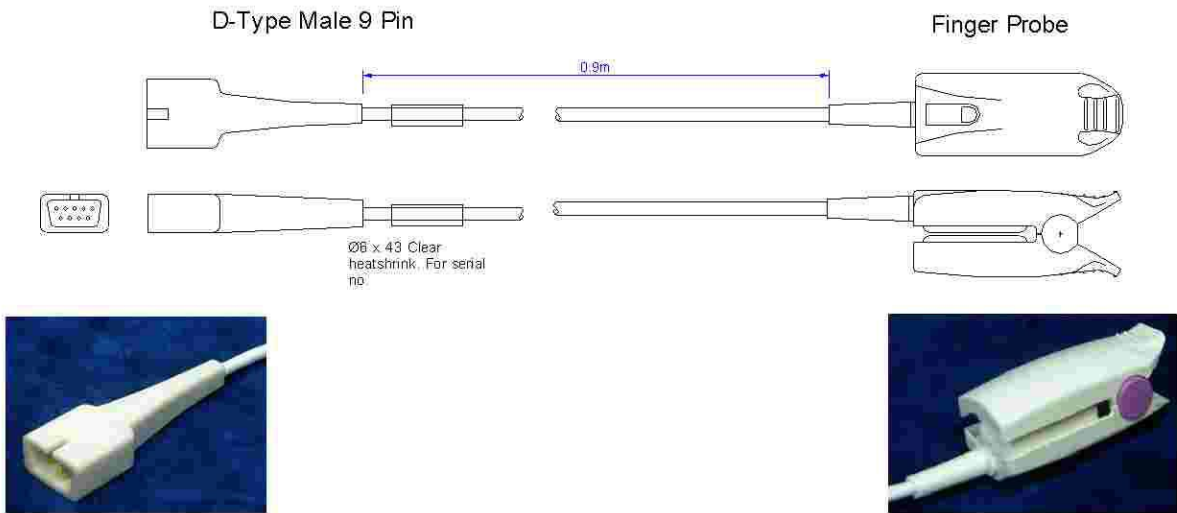


COMPANY OPERATING PROCEDURES

0018690 Criticare P869RA

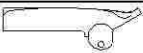
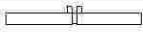
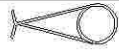
VM3/COP/32.15

Date: 14-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. (Continued over page)

D-Type male 9-pin Side			Finger Probe Side		
Qty	Description	Part No.	Qty	Description	Part No.
1	D-Type male 9-pin kit	0010759	1	 Top Shell (x25)	0010110
(1)	 Outer Casing	kit	2	 Pad Support (purple) (x50)	0010164
(1)	 Cable grip	kit	1	 Top Pad (white)(x25)	0010130
(1)	 Connector	kit	1	 Bottom Pad (white)(x25)	0010131
1	Ø 6 x 43mm Clear heat shrink	0032331	1	 Bottom Shell (x25)	0010111
1	Ø 1.6 x 17mm heat shrink	0032310	1	 Spring (x25)	0010140
1	Ø 6 x 10mm heat shrink	0032321	2	 Button (purple) (x50)	0010184
			1	 Detector	0030901
			1	 LED/ I.R.	0030952
			1	 Strain Relief	0010150

COMPANY OPERATING PROCEDURES

0018690

Criticare

P869RA

VM3/COP/32.15

Date: 14-Dec-01

Revision date: 17-May-04

Issue: 3

ASSEMBLY OPERATIONS

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

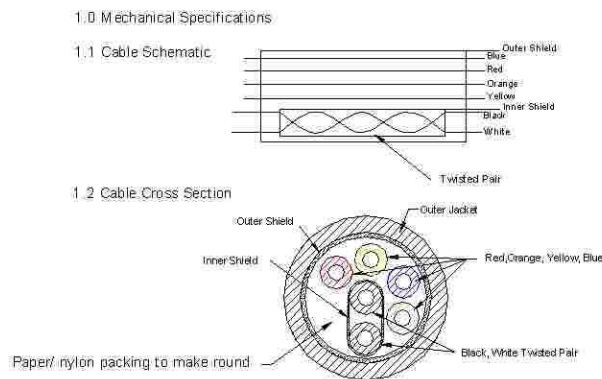


Fig 1.

D-Type male 9-pin side:

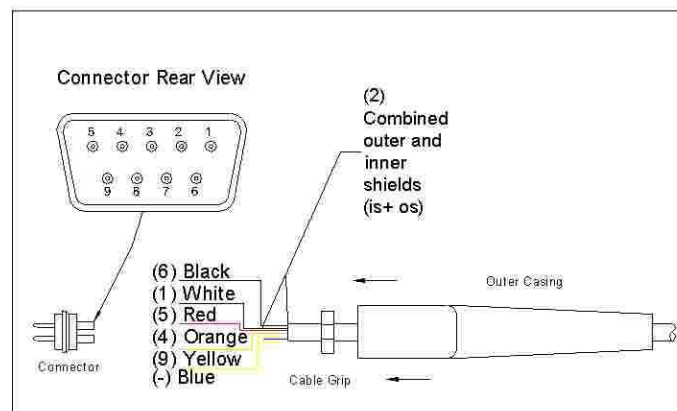


Fig 2.2

1. Feed Ø6 x 43mm (clear) heat shrink, outer casing, cable grip and Ø6 x 10mm heat shrink (black) over end of wire.
2. Strip 20mm off outer jacket of wire 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 outer and inner shields together.
6. Trim ends of wires and shields to the same length.
7. Strip jacket of every wire 2mm to reveal copper core.
8. Heat Ø1.6 x 17mm heat shrink over twisted inner and outer shields to cover naked wire.
9. Apply small amount of solder to ends of each wire and shields.
10. Solder ends of every wire and shields to the correct positions on the rear of the connector.

COMPANY OPERATING PROCEDURES

0018690

Criticare

P869RA

VM3/COP/32.15

Date: 14-Dec-01

Revision date: 17-May-04

Issue: 3

11. Clamp cable grip approximately 2mm from end of outer jacket.
12. Place Ø6 x 10mm heat shrink over cable grip and beginning of wires and heat to shrink firmly over.
13. Push outer casing over cable grip and wires to fit around the pin housing.

Finger Probe side:

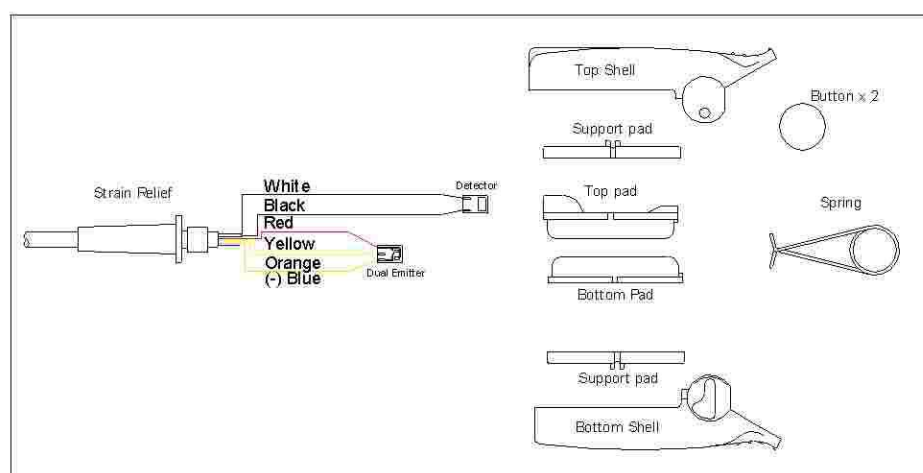


Fig 2.3

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 and blue wire to the base.
4. Cut red, orange 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 (use a little super glue) into place and glue buttons onto the sides.

TESTING

1. Attach D-Type male 9-pin side to a CSI extension cable then to the test box connector marked 'J'.

COMPANY OPERATING PROCEDURES

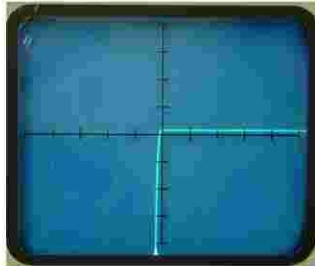
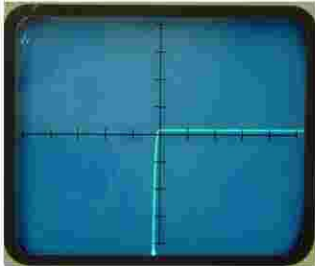
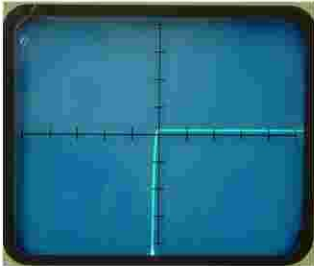
0018690

Criticare

P869RA

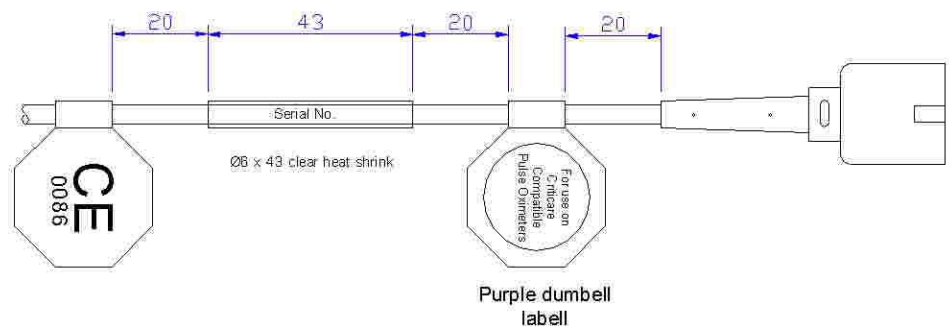
VM3/COP/32.15

Date: 14-Dec-01 Revision date: 17-May-04 Issue: 3

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. Attach D-Type male 9-pin side to a CSI 504 monitor and the probe on to the 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
 - 1 x Purple Criticare Label



Quality Assurance (QA)

1. Attach D-Type male 9-pin side to a CSI extension cable then to the test box connector marked ‘J’.
2. Check display is showing correct characteristics as shown below. (At correct switch positions)

COMPANY OPERATING PROCEDURES

0018690

Criticare

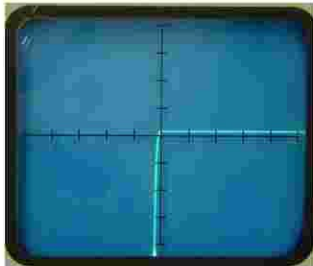
P869RA

VM3/COP/32.15

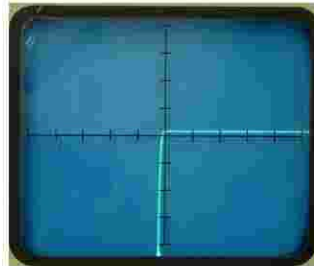
Date: 14-Dec-01

Revision date: 17-May-04

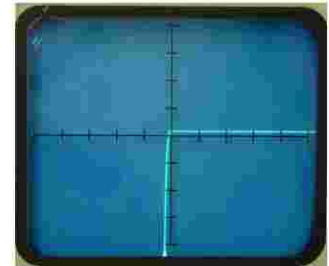
Issue: 3



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. Attach D-Type male 9-pin side to a CSI 504 monitor and the probe on to the 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
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.