

Work Instructions & Test Methods.

The correct information should be supplied with the Customer Order as a reference for the manufacture of the SpO2 Probes and Extension Cables. If the information has not been supplied, the Customer should be contacted, and a Data sheet should then be filled in and a copy filed with the original order.

- Using the information supplied, parts are collected, and booked out, from stock
- The parts are assembled as per the relevant, approved, operating procedure,
- The part assembled unit should now be tested in line with the calibrated test equipment
- When the unit passes the calibrated test, it is then fully assembled
- The fully assembled unit should now be tested on the calibrated test equipment (see the relevant operating procedure).
- The unit should now have a visual Quality Assurance / Control check performed, to ensure that all labels are in position and that the unit is to the same specifications as required by the Customer.
- The completed unit should now be presented to the Q.A. department for assessment.

10% random sample of each manufactured batch are fully tested for the "R" Curve, on a DL3000 and an Original Manufacturers monitor.

The basic probes can have the instrument connector changed, in line with the repair facilities procedure, so that they can be used on other types of equipment.

SpO2 Probes are manufactured as 3 variants:

Part No.	Description.	Procedure
0018540 to 0018960	Finger Probes	VM3COP 32.01 to VM3COP 32.34
0018562 to 0018882	"Y" Probes	VM3COP 35.03 to VM3COP 35.28
0019248 to 0019698	Extension Cables	VM3COP 33.00 to VM3COP 33.29

A sample procedure is attached in the CE File.



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Final Quality Assurance is carried out in Viamed.

All probes

1. visually inspected
2. diodes and resistors checked.
3. Boxed
4. labelled
5. Insert added

One sample of each type and each batch are fully tested for "R" curve on DL3000 and the original manufacturers instrument.

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For Latest Viamed Work Instructions & procedures See
Procedure Files ISO9001/EN46001

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