Clinical Trials & Compatibility Studies on SpO_2 Probes

Objective

1. To ensure that the SpO2 probes perform to the same accuracy claimed by the manufacturer when used with the manufacturers instrument.
2. To validate the claims that the probes are compatible with the original manufacturer's
3. To collect sufficient data to satisfy the CE mark requirements
4. To collect sufficient data to satisfy F.D.A. 510K submission

On-going tests to ensure the quality of the sensors is consistent.

Protocols

Electronic Testing

Prior to testing a proprietry electronic SpO2 simulator has been constructed which can simulate a range of SpO2 values. The simulator has been tested on a number of pulse Oximeter probes to establish accuracy. The simulator is used in conjunction with the manufacturers instrument..
10 Probes are tested in the range 60 -100 %

From each batch 10% of probes are tested.

Clinical Tests

10 probes of each type to be used on patients with arterial lines and with original manufacturers equipment. The values obtained to be recorded against actual Blood gas analysis.
Where the original manufacturers equipment is NOT that normally used in the monitoring system the readings of the monitoring system shouild also be recorded.

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