The following statement was issued by Mr Jim Lefever of the MHRA on 23rd February 2006 with regards to the validity of tests conducted using the 'Lightman' SpO2 sensor tester.

"Report of 18 pulse oximeter probes being found to be outside the "usual stated" accuracy of ±2% when tested with a Lightman probe tester.

Clause 50.101.1 of BS EN ISO 99190:2005 (the particular standard for the basic safety and essential performance of pulse oximeter equipment for medical use) requires the accuracy of pulse oximeters to be " a root mean square difference of less than or equal to 4% of SpO2 in the range 70% to 100% SaO2". Therefore the test results show the predicted error for 4 out of the 18 tested may not meet the standard. And in the 90% plus range, the most common range, there is only one predicted failure.

Comment received from a number of the pulse oximeter manufacturers whose probes were tested do not endorse the Lightman SpO2 tester.

The tester predicts the probes accuracy by measuring the spread of IR wavelengths. Annex AA.50.101.2.1 of BS EN ISO 99190:2005 states the accuracy of pulse oximeters cannot be characterized or validated by this type of tester.

As we have no other reports of similar tests we cannot determine if the results are typical of the condition of the pulse oximeter probe population in the UK. Therefore no MHRA action."