

**Product Description:****Risk Analysis Report.****General****Specific use:**

The measurement of Oxygen levels in Medical breathing gases.

Gas may contain Oxygen, Nitrogen and Helium. The technology is well known and has been used since 1966.

The instrument includes a galvanic micro fuel cell and a digital voltage readout

**Materials and components used.**

All components to RoHS requirements

The enclosure is ABS

**No substances are supplied or removed from the patient**

The instrument monitors gas passing the sensor

**The product is not Sterile when supplied.****The product is not intended to change the patient environment?****Measuring function**

Measures the PPO<sub>2</sub> of the gas. At 1 Bar this is displayed as a percentage

**Product explanations**

The product is not intended to be the primary or only method for the control of or interaction with medication?

**The product can be sensitive to outside influences;**

The sensor is sensitive to Pressure, temperature and humidity,  
It can also be sensitive to Oxidising gases.

**Routine calibration is necessary:**

By the user prior to use and every 8 hours

**Product does contain software**

The instrument is a basic digital voltmeter

**Product has no known long-term effects**

**Signed J.S.Lamb**

**Date: 11/01/07**