VN202 Risk Analysis

The VN202 has a digital visual display with a resolution of 0.1 %.There are no outputs from the unit (mechanical, electrical or chemical). Environment changes which could atfect the operation of the VN202 have been addressed and consideration given to the locations of its intended use outside of the Hospital environment. At sea, near water, in the vicinity of water cooling tanks. Electromagnetic Radiation .

The user of the VN202 requires no formal training. The unit does require calibration once per day, or every 8 hours and before use.The calibration procedure identifies malfunctions in the VN202.

Shortform calibration and user instructions are provided on the rear of the unit.
For use in diving a specific diving orientated handbook is suppiled with each VN202. This handbook identifies all the presently known risks.
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SAFETY OF DESIGN, AND TESTS CONDUCTED

The Oxygen Monitor has been designed to comply with 'EC 60 1-1 and IEC6OI-1-2. It has been tested by SGS and certified to comply EN 60601-1-2:1993: Electromagnetic Compatibility -

The monitor does not fully comply with ISO7767 when used with Anaesthetic agents.
However the sensors have been used sucessfully in these environments without ill effects sinct the late 1960's.

It is the responsibility of the user to ensure that the operation and use of the oxygen monitor is clearly understood, particularly the requirement to calibrate the unit,. If the unit is not calibrated for an extended period, the displayed oxygen concentration may drift from the true concentration.

Low Battery

When the batteries need to be replaced, the "LO BAT" indicator is shown. During the calibration procedure, the user would notice this indicator, and should replace the batteries. Should the batteries not be replaced, the unit will cease to function reliably and may show erroneous oxygen concentrations.
The VN202 is based on an analogue design, and it is battery powered, It has been designed to have low current drain .All the components in the unit are operating well below their maximum ratings, and thus should be highly reliable.

Mechanical Damage

Although the device has been tested for resistance to mechanical shocks as would typically be experienced for a device of this nature, mechanical damage could be inflicted by sufficient force. The monitor would most likely suffer damage to its electronic circuits if the casing were damaged and water entered the case. The coiled cable is susceptible to damage which would be displayed in the form of no output or variable unstable output

To conform to EMC regulations the case has been coated with a conductive layer. Damage to the battery leads could cause the battery to be shorted out

If the sensor were punctured, there is a possibility of the contents of the cell leaking. The cell contains small

quantities of Lead and KOH Potassium Hydroxide), In practice unless the sensor was [laced in the proximity of the mouth any leakage of KOH would be evapourated leaving a dry deposit before entering the patient or user.

Sensor

The sensor will require replacement, typically after 18 months of use, but often much longer. The indication that the sensor has reached the end of its life is when it is not possible to calibrate the Vn202 he sensor is not likely to fail between calibrations.

ESTIMATION OF RISKS

For each of the identified hazards detailed above, the risk of occurence (between 0 and 4) has been estimated as shown in the table. The acceptability of each risk is noted in the fith column.

The risk of user error has been reduced by highlighted and repeated statements in the manual, as well as on the case of the unit, to alert the user to the importance of the calibration procedure. This calibration procedure leads the user to test the functionality of the device, achieving not only a calibration, but a basic functionality check as well.

The VN202 is designed as a secondary monitor as stated in the manual.

This risk analysis has been conducted by J.S.Lamb