TED 191 PORTABLE OXYGEN MONITOR

RISK ANALYSIS
(REFERENCE : IEC 601 PART 2.19)

AUTHORISED BY :
DESIGNATION : Director Operations
DATE : February 1997

The monitor gives a visual display, and audible and visual alarms; there are no other outputs from the unit (mechanical, electrical or chemical). Aspects of the environment which could affect the operation of the monitor have been tested (heat, humidity, spillage, electromagnetic radiation), and the results of these tests are given later in this document.

Users of the Oxygen Monitor require no training, other than to be shown how to release the calibration knob. The unit does require calibration once per day, and this calibration procedure would identify any malfunction of the device. The calibration and user instructions are provided on the top of the unit. To prepare the unit for use, it must be switched on, calibrated, placed where required, and the alarm limits set as required. Typically, this preparation can be accomplished in less than 5 minutes. The calibration setting is locked, providing protection against accidental knocks or tampering.

Once in use, the unit will generate an alarm if the oxygen concentration moves out of the pre-defined range. The audible alarm may be silenced for periods of 60 seconds, but the visual alarm continues until the alarm condition is cleared. Note that the alarms may be rendered inactive if the patient or any other person changes the alarm limit settings.

4. IDENTIFICATION OF HAZARDS

4.1 STATEMENT OF SAFETY OF DESIGN, AND TESTS CONDUCTED

The Oxygen Monitor has been designed to comply with IEC 601-1 and IEC601-1-2. It has been tested by the SABS and certified to comply to IEC 601-1 and IEC 601-1-2. Additional tests have been carried out to verify its compliance to EC standards for EMC and EMI, and elements of ISO 7767 (a standard applicable to oxygen monitors). These tests are as follows :

4.1.1	EN 60601-1-2:1993 :	Medical Electrical Equipment Part I. General requirements for safety, Section 1.2 Collateral standard : Electromagnetic Compatibility - Requirements and Tests
4.1.2	IEC 801-3 :	Susceptibility to radiated electromagnetic energy
4.1.3	CISPR 11 :	Radiated emissions
4.1.4	ISO 7767 clause 21 :	Mechanical strength
4.1.5	ISO 7767 clause 43 :	Fire prevention
4.1.6	ISO 7767 clause 50 :	Accuracy of operating data

In all cases, the oxygen monitor complied.

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4.2 USER ERRORS

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, and set the alarm limits appropriately. If the unit is not calibrated for an extended period, the displayed oxygen concentration may drift from the true concentration.

The alarm limits are provided to alert the user to variations in the oxygen concentration of the air supplied to the patient. If the alarm limits are not set appropriately, the monitor will not generate an alarm.

4.3 BATTERY DEPLETION

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 device will continue to operate for 24 hours (constant non-alarming operation) after first indication of a low battery condition.

4.4 ELECTRONIC FAILURE

The device is based on an analogue design, and as it is battery powered, it has been designed to consume a minimal amount of power. Consequently, all the components in the unit are operating well below their maximum ratings, and thus should be highly reliable. There are a total of 110 electronic components - 10 of which are essential for the generation of an alarm in a fault condition. Failure of any one of 10 of these would result in a condition where the device would not give any alarm. Failure of any of the other components would either have no effect, or would result in an alarm (visual and/or audible).

As the unit is calibrated, its functionality is tested, and the possibility of a failure of any component between calibrations is very small. Further, the failure of one of the 10 components which would prevent an alarm signal is smaller still.

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4.5 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 would cease to function. A functional test after damage has occurred would indicate this situation.

The sensor is more resilient than the casing of the monitor, and would require force greater than could be exerted by a user alone to damage its casing. If the casing were punctured, there is a possibility of the contents of the cell leaking. The cell contains small quantities of Lead and KOH (Potassium Hydroxide), neither of which would cause any hazard, unless ingested. If the cell is damaged it should be disposed of as described in the manual.

4.6 END OF SENSOR LIFE

The sensor will require replacement, typically after 12 months of use, but often much longer. It operates by a consumptive electro-chemical process, thus the output voltage from the cell diminishes gradually over time. The indication that the sensor has reached the end of its life is when it is not possible to calibrate the device as specified. Regular calibrations will identify this situation. The sensor is not likely to fail between calibrations.

5 ESTIMATION OF RISKS

For each of the identified hazards detailed above, the risk of occurence (between 0 and 1) has been estimated as shown in the following table. The acceptability of each risk is noted in the third column.

Hazard	Risk	Acceptable ?
User error	0.80	No
Battery depletion	0.01	Yes
Electronic failure	0.05	Yes
Mechanical damage	0.01	Yes
End of sensor life	0.01	Yes

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6 REDUCTION OF RISK

The risk of user error (particularly the failure to calibrate and check the device on a regular basis) has been identified to be unacceptable. This risk is reduced by the presence of strongly worded statements in the manual, as well as detailed calibration instruction sticker 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.

A section of the manual describes the setting of the alarms to make full use of this feature of the device.

Considering the fact that the actions and ommissions of the user are beyond the control of the manufacturer, these warning notices, and instructions in the user manual render the risk acceptable.

Note that abbreviated user instructions are provided on the top of the device.

7 ADEQUACY OF DEVICE SAFETY

Given that the device is designed as a secondary monitor of an independent system which establishes a required oxygen concentration, and that the actions of the user are beyond the control of the manufacturer, the safety of the device is adequate for its intended application.

8 IDENTIFICATION OF PARTY CONDUCTING RISK ANALYSIS

This risk analysis has been conducted by

Brian Goemans Pr Eng (900142(SA)), MSc (Medicine), BSc (Electrical Engineering)

assisted by

Sid Green.