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SAFETY REQUIREMENTS FOR ELECTRONIC SENSORS IN OXYGEN ENRICHED ATMOSPHERE AT PRESSURES UP TO 4 ATM (3 BAR)

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RADIOMETER COPENHAGEN

918-525 · 9712B

ISBN 87-88138-31-3
ISSN 0905-8265

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Electronic Sensors in Oxygen Enriched Atmosphere

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ABSTRACT

This paper describes the general safety requirements for patient monitors used in oxygen enriched atmosphere. A test chamber is described where cotton wool can be ignited in pure oxygen at different pressures. The voltage-current curves causing ignition which can be derived from this test, can be used to dimension the monitor circuit so that any failures in the sensor circuit causing sparks are well within the safe level. Some practical design rules are given in connection with the description of Radiometer's Transcutaneous Monitor.

Introduction

The main object of this paper is to present a test chamber where the voltage-current limits for igniting cotton wool in pure oxygen can be determined.

On the basis of a test method originally presented by Underwriters Laboratories, the author has made an improved version of the test chamber so that the ignition curves can also be found under increased pressure.

Safety with Respect to Electric Shock

Before presenting the test chamber and the ignition curves, there will be given a brief description of the safety requirements for monitors for patient use, especially when used in oxygen enriched atmosphere.

Monitors used in connection with patients must comply with IEC 601, UL 544, CSA 125, or other well-known standards.

The main purpose of these standards is to prevent electrical shock, although other hazards are dealt with also.

An important requirement in these standards is the maximum leakage current which can flow through a patient who is grounded, and where the ground circuit of the monitor itself is interrupted.

Here UL 544 specifies a value of max. 10 µA (20 µA with sensor) even when the connection to the patient is a non-cardial contact.

This very low leakage current can be achieved only if the monitor circuit has a very low capacitance to ground.

The best solution is to make an independent circuit to which the transducers are connected, and which transmit the amplified signals through isolation transformers and optocouplers.

As it will be seen, an independent isolated instrumentation amplifier is also the best solution when constructing circuits where a flame hazard is to be avoided.

Transducers in Oxygen Enriched Atmosphere

The main concern when using transducers in oxygen enriched atmosphere is that a failure in the system could create a fire.

It is natural to look upon the standards used for equipment in explosive gas atmosphere, such as IEC 79 and UL 913. However, since oxygen in itself is not an explosive gas, the test methods do not directly apply.

However, since the hazard in the case of a fire is the same, it is proposed to construct the systems according to these standards as far as they apply, and to make special test equipment for the spark test.

This approach was taken by Underwriters Laboratories several years ago; UL designed spark-testing equipment where the criteria was that pure, dry cotton wool should not ignite in oxygen enriched atmosphere when the failure modes according to the standard for intrinsically safe equipment were introduced.

No voltage-current limits were given by UL, and the setup could be used only under normal atmospheric pressure. There were also a few other practical limitations, but the principle of igniting cotton wool has been retained in the test equipment described in this paper.

The main safety requirement of intrinsically safe systems is that a system must not present any fire hazard even after the introduction of two randomly chosen failures. Only the so-called "Protective Components" are not considered to fail during a failure analysis. A "Protective Component" is constructed in a way so that it is "unlikely to become defective in a manner that will lower the intrinsic safety of the circuit" (UL 913, par. 3.9).

Introducing two failures in a recorder connected to the monitor could result in mains voltage appearing on the analog outputs of the monitor. So, as an example, a monitor should not present a fire hazard even when mains voltage is applied to all of the outputs of the monitor.

Defining the Test Conditions

Oxygen is not in itself a flammable gas, but it will nourish a fire, and all the more so the higher the concentration of oxygen.

In order to create a fire in a combustible material in oxygen, the material must either:

1) Reach a temperture beyond the flame point.
2) Be ignited by a flame, spark or the like.

It should be noted, that if a transducer is heated much beyond normal room temperature the combustible material will more easily be ignited. The test should therefore be carried out at the actual transducer temperature.

The most combustible material (apart from flammable gases) which is likely to be found close to a transducer is probably pure, dry cotton wool. Therefore this material has been used for the ignition test, although the material may not actually be present under normal use.

The most likely failure in a transducer is a breaking of wire or a short-circuit between two wires. In those instances the connection or the breaking of the wires will create a spark which could ignite a combustible material.

It should be noted that breaking or short-circuiting of the transducer wires is not considered to be a failure. It could occur due to simple wear and should not be included as one of the two failures in the failure mode analyses.

It is furthermore assumed that the wires in the transducer circuit are made of copper, silver or something similar. If a more flammable material is used, such as magnesium, the wiper in the test-chamber must be of that material.

Finally, it should be stressed, that we are considering only the transducer and the connecting cable to be exposed to the oxygen enriched atmosphere. The monitor itself is assumed to be in a normal in-door environment.

Test Chamber

In the following, the details of the test chamber will be explained in more detail.

As can be seen in Figs. 1 to 3, the outer chamber consists of a brass cylinder with a solid bottom and a lid with a glass window. The window is 30 x 30 x 5 mm, and securely fastened, so that the ignition can be safely observed. The lid is fastened by 4 ø4 mm screws fitting into key-hole slots.

An electrically insulated shaft is connected to a motor so that it can rotate. The shaft bears a copper-wire ø0.8 mm, and this wire acts as one pole of the ignition circuit.

Inside the chamber a double ring of brass is placed where stainless steel wires ø1 mm are secured like the spokes in a wheel half way round the circumference. The steel wires act as the other pole in the circuit.

The ring can be taken out of the chamber so that dry cotton wool can be pressed between the wires from behind. This makes it easy to replace the cotton wool when an ignition has occurred. The reason for having the wires covering only half of the ring is to give any capacitor in the circuit time to be charged. A spring mechanism in the ring (not shown) ensures a good electrical contact to the chamber.

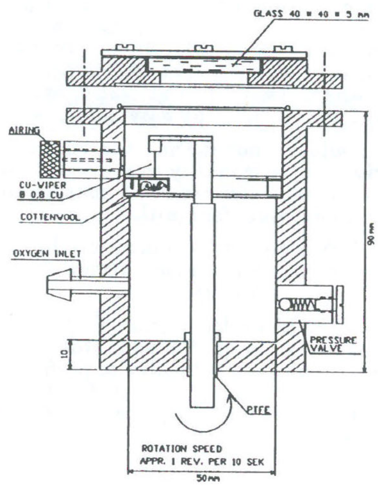


FIG. 1 Schematic drawing of the test chamber.

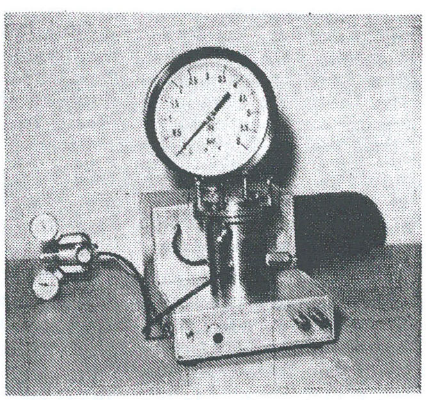


FIG. 2 Test apparatus for determining the ignition level.

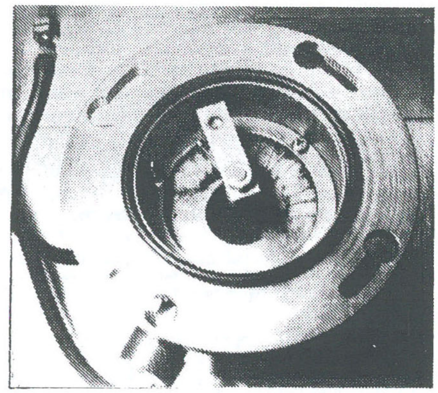


FIG. 3 Cotton wool placed in the test chamber.

The oxygen inlet is connected to the pressure gage meter and the chamber is equipped with a valve with a screw, enabling the chamber to be ventilated when filling it with pure oxygen.

Furthermore, the chamber has a spring-loaded pressure valve which can be set to a value a little higher than the specified oxygen pressure. This valve maintains the correct pressure, and constantly letting a little oxygen out ensures that the chamber contains only pure oxygen. The valve also reacts as a pressure relief every time the ignition occurs.

In order to obtain a good reproducibility, the clean cotton wool is dried overnight in an oven at about 100 °C. Before each exposure, the stainless steel wires are cleaned, and the copper wire must be bright and still have some elasticity to act as a wiper. The heat from the flame sometimes softens the copper.

During the test, the cotton wool is placed close to the wiper with some loose threads extending out, however not so much that the threads prevent the wiper from coming into electrical contact with the wires.

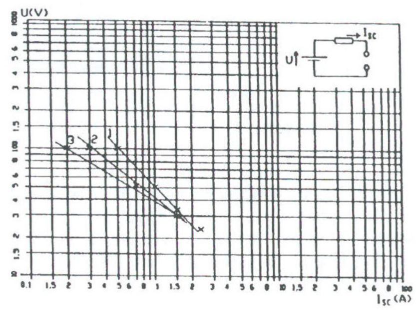
The shaft should rotate quite slowly, i.e. one revolution in about 10 sec., and a test should run for about one minute before deciding that no ignition will occur. Plotting a few points of an ignition curve is a good way of checking the test setup.

After each ignition, the chamber and wires should be dried so that the humidity developed during the burning of the cotton wool is removed.

Ignition Curves

The ignition curves for resistive and capacitive circuits are shown in Figs. 4 and 5 respectively. The curves show the ignition curves for 1, 2 and 4 atm. pressure.

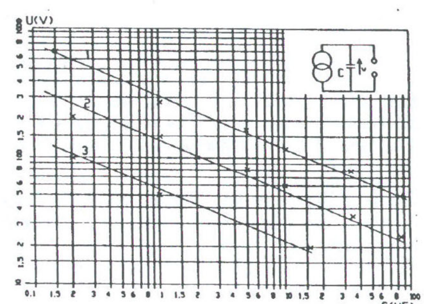
UL has not published data for the maximum energy required to ignite the cotton wool. Independent research at RADIOMETER resulted in the ignition curves described in Figures 3 and 4 below



Curve 1: 1 atm
Curve 2: 2 atm
Curve 3: 4 atm

Barometric pressure: 750 - 760 mmHg
Ambient temperature: 22 - 24 °C
X: indicates ignition

FIG. 4 Ignition curves for hydroscopic cotton in pure oxygen at different pressures. Resistive circuits.



Curve 1: 1 atm
Curve 2: 2 atm
Curve 3: 4 atm

Barometric pressure: 750 - 760 mmHg
Ambient temperature: 22 - 24 °C
Capacitors: Metallized paper type
X: indicates ignition

FIG. 5 Ignition curves for hydroscopic cotton in pure oxygen at different pressures. Capacitive circuits.

In resistive circuits it requires about 2 amp at 24 V to ignite the cotton wool. It is interesting that this value is close to the values for ignition of hydrogen found in IEC 79 (UL 913).

For capacitive loads there is a marked difference between the curves at different pressures. Here, however, there is no resemblance to the hydrogen ignition curves. Oxygen at 4 atm. will at 24 V ignite with 8 µF, whereas hydrogen at 1 atm. and 24 V will ignite with 0.5 µF only.

It should be noted that the curves are derived experimentally from several series of tests, and they are to be considered as minimum values for ignition.

The curves are used to dimension the monitor circuits both under normal use and when failures are introduced.

Even if it can be documented that the max. energy-level is on the safe side, it may sometimes be a good policy to perform the ignition test as a final proof. For this test the described test-equipment is of course well-suited.

Practical Design of Radiometer's Transcutaneous Monitor

The following considerations deal with the safety aspect only, and except when discussing the linearity of the pO_2-electrode with higher pressure, the performance aspects will not be dealt with.

An electrical circuit connected to a patient must have low capacity to ground in order to comply with the leakage-requirements given in IEC 601 and especially UL 544. It was therefore decided to isolate the monitor-circuit by means of a ferrite transformer and high-voltage optocouplers.

In this way very little energy will be transformed to the patient-circuit even when introducing two random failures in the primary and secondary circuits.

Since a double failure can result in mains voltage on the primary of the ferrite transformer, the primary and secondary windings are wound on two separate bobbins with a min. 2 x 0.4 mm insulation.

The bobbin leading to the patient side is provided with a special cover so that the transformer can withstand 4 kV ac, and thus be accepted as an intrinsically safe component, see Fig. 6.

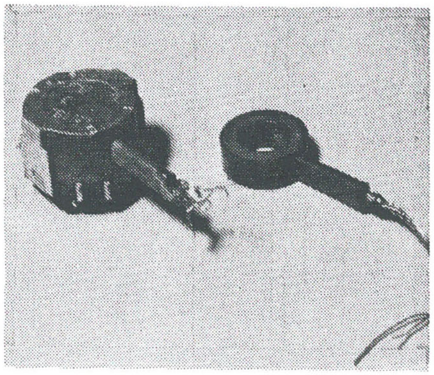


FIG. 6 Safety transformer, separating patient circuits from all other circuits.

The application of an insulated monitor circuit has more advantages than low leakage and protection from faults in other circuits:

- if a defibrillator pulse of up to 5 kV peak is applied during the oxygen monitoring, it will not result in damage of the instrument.
- by means of suitable shielding in the transformer, the monitor reading will only be slightly affected when using a HF surgery knife.
- The circuit will make it easier to meet the legal requirements for low EMC-radiation. Also the pO_2-electrode and its cable will be considerably less sensitive to external fields.

A failure analysis has been performed on the printed circuit board connected directly to the transducer. Even when introducing two random failures the energy level in the Radiometer Monitor type TCM3 is more than a decade below the ignition level.

Furthermore, an independent watch-dog circuit has been introduced so that the energy to the heater is automatically switched off if the wires are either opened or short-circuited.

Linearity at Higher Pressures

The monitor described in the previous section uses a transcutaneous electrode to measure the oxygen pressure. One important application is to measure on premature babies, as they are sometimes exposed to enriched oxygen atmosphere for various periods of time.

The electrode is also used in hyperbaric chambers, where the oxygen pressure under the skin is monitored.

In order to verify the pO_2-reading as a function of the pressure, the ignition chamber can also be used. The lid with the window is replaced by another lid into which the electrode holder is securely fastened (see Fig. 7). The rigidity of the fixture (with electrode) should be checked.

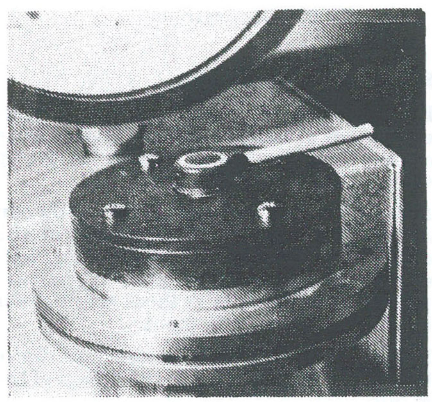


FIG. 7 Test of pO_2 linearity with pressure.

The only reason for using the ignition chamber is that it has the manometer, airing valve and pressure valve, so that a stable O_2-pressure could be maintained.

A typical linearity curve for the electrode type E5247 is shown in Fig. 8. The linearity of the latest electrode, type E5280 is also shown.

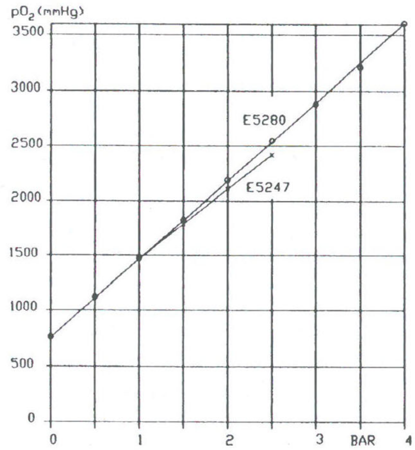


FIG. 8 Monitor reading as a function of pressure for the Radiometer Transcutaneous Electrodes.

Summary

It has been proposed to use special test-equipment to test the ignition level of pure cotton wool in oxygen at pressure levels up to 4 atm (3 Bar).

Ignition curves found experimentally can be used to dimension the circuit of the monitors. It is proposed that monitors connected to transducers in pure oxygen use similar requirements as those specified for intrinsically safe equipment.

Some practical recommendations have been given with respect to the design of the monitor.

Finally, it is shown how the ignition chamber, with a slight modification, can be used to measure the linearity of O_2-electrodes with respect to pressure.