Use By Date rationale on Oxygen sensors

Introduction

The sensor is technically a component it is not a stand alone medical device.
It is used in medical devices and can be viewed in the same terms as a battery.
Under the MDD essential requirements it does not fit the definition medical device.
It could be construed as a special component but technically any oxygen sensor with the same physical and electrical attributes can be used to measure oxygen.
The MED suffix is a unique American requirement to differentiate products as medical as opposed to industrial although technically they can be identical.
The sensor reduces oxygen via a lead anode and produces a current directly proportionate to the partial pressure of oxygen.
It is effected by humidity , atmospheric pressure, gas pressure and in some circumstances temperature. This means that the measuring or control equipment needs a method of regular (8 hours is recommended) calibration.
As the lead is continually being reduced by the oxygen the sensor is guaranteed to fail at some future date. The life can only be estimated in % oxygen hours. This can be severely reduced if the sensor is exposed to high temperatures e..g. 37C
Due the mechanical construction there are several reason for unexplained premature failure.
For this reason the sensor is not recommended for use as a single source of oxygen measurement in any circuit. For this reason the designers of equipment and the user must be aware the sensor will fail and the equipment so designed to make the user aware of its continual degradation.
The end users are continually educated about shelf life of sensors.
In the past we have carried out seminars,
Data sheets have been disseminated
All callers are advised on multiple orders.
Book published on Oxygen monitoring for divers
Information in instrument instruction manuals.

Warranty

Micro Fuel Cell has to be viewed like a battery.

Once manufactured its use depends almost entirely on the way it is used. Once the bag is broken the manufacturer has no control. The user is advised that bags should be examined before opening for signs of leakage or damage.

The manufacturer gives a one year limited warranty (usually 15months to distributors & OEM's) on the sensors from the date despatched. This is limited to faulty workmanship or materials but not exhaustion.

Sensors stored for many months may not be covered by warranty when the bag is opened.

The user is advised always to purchase fresh sensors.

All sensors have a serial number, which can be traced to date of manufacture and quality control examinations.

The user is advised never remove the label or deface the serial number.

Sensor life

Sensor life is a series of trade off's. The basic formulae for the life of a sensor is governed by the amount of lead (physical size), the thickness of the membrane (speed of response) the amount of energy taken from the sensor (type of readout), and the amount of Oxygen to which the sensor is exposed .

The sensor life can be calculated as follows: using the equation

Life in months = $\frac{PB \times K \times 70\%}{I}$ in 100% Oxygen

I =output current in Amps

Pb is the weight of Lead in grams

K= 3.59×10^{-4} (This is called the Proportionality constant and is a figure calculated by the designers that allows us to use the simple style of calculation}

70% = Anode efficiency.

Unfortunately it is impossible for the sensor to use up 100% of the lead. 70% is the worst case with most sensors providing 80-90% anode efficiency. NB Some companies work out the estimated life based on 100% giving much larger figures.

The Anodes are specifically designed to provide maximum consumption

As a rule sensors with an expected life in air of 48 months will have an expected life 1/5 of that in 100% oxygen i.e. 10 months.

A sensor has a life expectancy measured in Oxygen % Hours.

e.g. an R-17 has a life expectancy of 700,000 O_2% Hrs

21% Oxygen	48 months
50%	24 months
75%	12 months
100%	10 months

Whilst the sensors are in a sealed gas barrier bag they are consuming very little Oxygen and are not consuming large amounts of lead.

Electrolyte drying out.

The thin layer of electrolyte between the membrane and the anode plays an important part in keeping the anode wet which in turn assures a minimum internal resistance during the oxygen sensing reaction.

Membranes are manufactured in Teflon and are chosen carefully to match the sensor application. Thin membranes speed up the response but also allow water to diffuse more quickly out of the sensor. Thick membranes slow down the response and extend the working life of the sensor.

Due to the long life of the sensors, leakage and electrolyte drying out is as common as lead depletion and care has to be taken concerning the environment surrounding the stored sensor.

Storage

The useful life of the cell depends upon the concentration of oxygen and temperature. If it is left inside the sealed gas barrier bag at ambient temperature its life expectancy should only deteriorate by 1/20 of its in air life per year.

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Whilst in a controlled pre-use environment which can be almost but never 100% oxygen free sensors can react to a depletion of Oxygen by going into a "sleep mode ". It can take 15 minutes for a sensor to wake up when re-introduced to air.

Other sensors show instability for some time on being released from a sealed environment. The T-1 sensors for instance can be left in air without the temperature compensation circuit and will not deteriorate as no current is flowing. However once introduced back into the measuring circuit it can take up to 8 hours for complete stability to be achieved. When manufactured these sensors are supplied in a gas barrier bag with a shorting clip across the output connectors. This is to reduce the time taken to achieve stability once the bag is opened.

R-17 & R-22 type sensors have built in temperature compensation and therefore are never open circuit. This results in a quicker equilibrium when the bag is opened.

Heat in the form of closed cars on hot days will encourage dry-out. Sensors should never be left in sunlight.

It is not recommended that sensors be stored longer than one year. Microscopic leaks similar to flash light batteries may develop which may damage the electronic connections.

Conclusion
This is a component that requires equipment manufacturers to acquire a technical understanding of its properties and typical reaction throughout its life. In itself it is guaranteed to deteriorate and eventually fail so facilities within the equipment should mirror this requirement. The sensosor in itself is not unsafe or in a position to cause harm to a patient or user.
A use by date has proved confusing to the end user.
Sensors have remained usable up to 5 years in the gas barrier bags. Other sensors have failed within the warranty period either due to leakage or poor storage. Export has introduced extra problems as some countries can extend the import time severely. Some users always want the latest use by date. This is not always practical without large increases in cost as the sensors can only be manufactured economically in large batches.

If a use by date is deemed necessary by the definitions of MEDDEV 2.2/3rev3 then it can only by scientific reasoning be the warranty period.

The use by date will therefore be the warranty. The wording in accordance with the definitions and requirements of MEDDEV 2.2/3Rev3 will be added.

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