REPORT ON DATA
TELEDYNE ANALYTICAL INSTRUMENTS
MEDICAL OXYGEN SENSORS
FOR 510K COMPLIANCE

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I

PERFORMANCE TESTS
(R17MED, R22MED, R13, R15, T1, T2, T4, and T7)

INTRODUCTION:

Groups of R17MED, R22MED, R13, R15, T1, T2, T4, and T7 sensors were subjected to the following tests: output in air, 90% response time, and accuracy. The sensors (less the T7 sensor) were tested for accuracy during operational and for accuracy after storage temperatures.

EQUIVALENCY:

The C1R and C2R sensors are essentially the same as the T1 and T2 sensors. The only difference is that the C1R and C2R have two wire pin-connectors attached to the back-plate. The T1 and T2 do not have the pin-connectors. The C1R sensors utilize the same sensing membrane, cathode, electrolyte, and anode as the T1 sensors. The C2R sensors utilize the same sensing membrane, cathode, electrolyte, and anode as the T2 sensors. Therefore, the data for the T1 and T2 sensors can be considered equivalent for the C1R and C2R sensors.

METHODS:

The output in each test gas was measured using a digital multimeter capable of resolving 0.01 millivolts (mV). Response was measured by producing a step change in the flow of the sample gas between nitrogen or air (20.9% oxygen) and 100% oxygen. The sensors were connected to flow-adaptors (in series) inside an environmental chamber and then flowing test gas at 3 SCFH. During the response, the chamber was set at 25 deg. C and the measuring intervals of the chart recorders was set at a chart speed of 30 cm/min (equivalent to 2 seconds per cm). The remainder of time a chart speed of 6 cm/hr (equivalent to 10 minutes per cm) was used. Output readings were measured by flowing each test gas over the sensing surface of the test sensors and noting the mV output after stable readings were obtained (usually 10-15 minutes). The accuracy errors were determined by noting the 100% oxygen reading (the reference reading) and then switching to 60%, 40%, 20.9% oxygen and nitrogen gas. For air (20.9% oxygen), a gas sampling pump was used to pass room ambient air over the test sensors at a flow rate of 3 SCFH. The rest of the test gases came from certified gas cylinders. The test sensors were allowed to stabilize with each test gas before the mV outputs were recorded. To eliminate back pressure from an incoming test gas, a four-way switching valve was used in order to keep the gas flow constant: one direction to the cells and the other direction to by-pass vent.

To demonstrate that the sensor meets the operation temperature requirements, the sensors were tested for accuracy by calibrating with 100% oxygen at 25 deg. C. Then, the sensor was checked with other test gases (i.e. various oxygen concentrations). Compressed air was allowed to flow through at a flow of 3.0 scfh for 10-15 minutes. Then, the chamber was set to 0, 10, 15, and 40 deg. C. After a stabilization time of 1.0-1.5 hours at each temperature, the sensor accuracy was checked again by the same procedure that was done before introduced into chamber.

To demonstrate that the sensor meets the storage temperature requirements, the sensor was stored inside the environmental chamber at 0 deg. C for 12 hours tested and then at 50 deg. C for another 12 hours. The chamber was returned to 25 deg. C and then the sensor was tested for accuracy by calibrating with 100% oxygen at 25 deg. C. Next, the sensor was checked with other calibration gases.

Sensor measurement accuracy (percentage of full scale) at each temperature was determined by calculating the deviation between the 100% oxygen readings (the reference readings) and the other test gas readings one by one. The test sensor was allowed to stabilize in each test gas before the mV output was recorded.

EQUIPMENT AND MATERIAL:

3 R17MED SENSORS (SN 415210, 415211, and 415212)
3 R22MED SENSORS (SN 397854, 397855, and 397856)
3 R15 SENSORS (SN 393313, 393314, and 393315)
3 R13 SENSORS (SN 423430, 423432, and 423433)
3 T1 SENSORS (SN 416183, 416184, and 416185)
2 T2 SENSORS (SN 324320 and 324321)
4 T4 SENSORS (SN 412522, 412523, 412524 and 412525)
2 T4 TEST UNITS (SEN 111 - TED 80 and SEN 112 - TED 100)
1 R13 TEST UNITS (SEN 110 - TED80)
1 CAL GAS #1, 100% OXYGEN (EXTRA-DRY GRADE)
1 TEST GAS #2, 59.9% OXYGEN IN NITROGEN (certified)
1 TEST GAS #3, 40.1% OXYGEN IN NITROGEN (certified)
1 TEST GAS #4, COMPRESSED AIR, 20.9% OXYGEN
1 TEST GAS #5, 100% NITROGEN (ULTRA-HIGH PURITY)
1 TENNEY JR. ENVIRONMENTAL CHAMBER (MODEL TJR-17 SN 25529-16)
1 DIGITAL MULTIMETERs, FLUKE, MDL. 8020A SN CC23741and 8060A SN CC05832

RESULTS:

The following tables summarize the results of all tests. Attached pages contain total test results.

Table 1: Summary of the average Air Output and 90% Response Time Test Data at 25 °C:

Sensor	Output in Air, 25 °C Specification	Average Output in Air, Test Results	90% Response Specification	Average 90% Response Test Results
R17MED	10 +/-3 mV	9.9 mV	< 6 seconds	3
R22MED	10 +/-3 mV	9.9 mV	< 6 seconds	3
R13	0.4 +/-0.1 uA	Test unit 0-100% O2	< 6 seconds	3
R15	59 +/-11 uA	51 uA	< 15 seconds	9
T1	200 +/-40 uA	213 uA	< 30 seconds	22
T2	200 +/-40 uA	235 uA	< 30 seconds	20
T4	0.4 +/-0.2 uA	Test unit 0-100% O2	< 6 seconds	4
T7	0.4 +/-0.1 uA	Test unit 0-100% O2	< 6 seconds	4

NOTE: See next page for individual test performance results.

Table 2: Summary of the average Operational Temperature and Accuracy Test Data at 0-40 deg. C:

Sensor	Accuracy Specification	Accuracy Test Results
R17MED	+/- 1%	Passed within +/- 1%
R22MED	+/- 1%	Passed within +/- 1%
R13	+/- 2%	Passed within +/- 2%
R15	+/- 1%	Passed within +/- 1%
T1	+/- 1%	Passed within +/- 1%
T2	+/- 1%	Passed within +/- 1%
T4	+/- 2%	Passed within +/- 2%

Output and Response Time (air to 100% O2) Testing:

Gases: Compressor Air and 100% O2 flows @ 3 scfh

A. R17MED Sensor:

S/N	Air, mV @25 deg. C	Response 90%, sec.
415210	10.0	3
415211	9.6	3
415212	10.1	3
Avg.=	9.9	3
Spec. =	10 +/-3 mV	< 6 sec.

B. R22MED Sensor:

S/N	Air, mV @25 deg. C	Response 90%, sec.
415210	10.0	3
415211	9.6	3
415212	10.1	3
Avg.=	9.9	3
Spec. =	10 +/-3 mV	< 6 sec.

C. R13 Sensor:

S/N	Reading Air @25 deg. C	Response 90%, sec.
423430	100	4
423432	100	3
423433	100	3
Avg.=	100	3
Spec. =	100	< 6 sec.

D. R15 Sensor:

S/N	Air, uA @25 deg. C	Response 90%, sec.
393313	51.1	10
393314	50.8	9
393315	51.8	9
Avg.=	51.2	9
Spec. =	59 +/-11 uA	< 15 sec.

E. T1 Sensor:

S/N	Air, uA @25 deg. C	Response 90%, sec.
416183.0	217	21
416184	222	20
416185	200	24
Avg.=	213	22
Spec. =	200 +/-40 uA	< 30 sec.

F. T2 Sensor:

S/N	Air, mV @25 deg. C	Response 90%, sec.
324320	239	19
324321	230	20
Avg.=	235	20
Spec. =	200 +/-40 uA	< 30 sec.

G. T4 Sensor:

S/N	Reading 100%O2 @25 deg. C	Response 90%, sec.
412522	100	4
412523	100	3
Avg.=	100	4
Spec. =	100	< 6 sec.

H. T7 Sensor:

S/N	Reading 100%O2 @25 deg. C	Response 90%, sec.
171841	100	4
Spec. =	100	< 6 sec.

Table 3: Summary of the average Accuracy Test Data after Storage Temperature of 0-50 deg. C:

Sensor	Accuracy Specification	Accuracy Test Results
R17MED	+/- 1%	Passed within +/- 1%
R22MED	+/- 1%	Passed within +/- 1%
R13	+/- 2%	Passed within +/- 2%
R15	+/- 1%	Passed within +/- 1%
T1	+/- 1%	Passed within +/- 1%
T2	+/- 1%	Passed within +/- 1%
T4	+/- 2%	Passed within +/- 2%

CONCLUSIONS:

Output in air- All oxygen sensors/cells passed and had outputs within the specification range.

90% response- All sensors/cells passed and had 90% response within the specification range.

Accuracy- Accuracy is specified as accuracy within ±1% or ±2% of full scale at constant temperature and pressure. All sensors/cells passed and were within the ±1% or ±2% of full scale specification range.

II

TEMPERATURE TESTS
T7 SENSORS

INTRODUCTION:

The objective of this test is to demonstrate that the T7 sensor will meet the operation temperature requirements of 0 to +40 degrees Centigrade and the storage requirement for the T7 sensor is 0 to +50 Centigrade degrees. The storage temperature of the TED200-T7 unit requirement is -40 to +70 degrees Centigrade. Since both the unit and the sensor were tested together to the TED200-T7 unit requirement, this extreme temperature range should also covers the sensor temperature requirement.

METHOD:

To demonstrate that the T7 sensor meets the operation temperature requirements, a TED200-T7 unit with a T7 sensor was taken out of stock and tested for accuracy. The sensor was mounted onto a flow adaptor inside an environmental chamber at 25 deg. C. Calibration gas (100% oxygen) was allowed to flow through at a rate of 1.0 scfh. After the reading was stable in 100%, the TED200-T7 unit and chart recorder were calibrated to 100% full scale. Next, the sensor was checked with other calibration gases (60%, 20.9%, and 100% nitrogen) for accuracy.

Then, the chamber was set to +40 deg. C. After 4 hours at this temperature, the sensor accuracy was checked again by the same procedure that was done before by calibrating with 100% oxygen and then checking the other calibration gases. Next, the chamber was set to 0 deg. C. After 4 hours at this temperature, the sensor accuracy was checked again by the same procedure that was done before.

To demonstrate that the sensor meets the storage temperature requirements, the TED200-T7 unit with T7 sensor was tested for accuracy by calibrating with compressed air (20.9% oxygen) at 25 deg. C. Then, the sensor was checked with other calibration gases for accuracy. The unit and sensor were package in its storage box in the same manner as if it was going to be stored or shipped.

Then, the storage box was placed inside the environmental chamber and the chamber was set to -40 deg. C. After 12 hours at this temperature, the chamber was allowed to return to room temperature to 23.0 deg. C. After removing the storage box from the chamber, the sensor was re-connected to the test unit. The sensor accuracy was checked again by the same procedure that was done before introduced into chamber. The sensor was re-bagged and package with the unit in its storage box in the same manner as if it was going to be stored or shipped.

Next, the storage box was placed inside the chamber and the chamber was set to +70 deg. C. After 12 hours at this temperature, the chamber was allowed to return to room temperature to 23.8 deg. C. After removing the storage box from the chamber, the sensor was re-connected to the test unit. The sensor accuracy was checked again by the same procedure that was done before introduced into chamber.

EQUIPMENT AND MATERIAL:

1 TED200-T7 OXYGEN MONITOR (SN 171841)
1 T7 OXYGEN SENSOR (SN 209959)
1 COMPRESSED AIR, 20.9% OXYGEN
2 BOTTLE OF CAL GAS 100% OXYGEN
2 BOTTLE OF CAL GAS 60% OXYGEN IN NITROGEN

1 ZERO GAS, 100% NITROGEN
1 TENNEY JR. ENVIRONMENTAL CHAMBER (MODEL TJR-17 SN 25529-16)

RESULTS:

After initial 100% Oxygen calibration at room temperature, the sensor was exposed to calibration gases of air, 60% Oxygen in Nitrogen, and Nitrogen. After exposure to +40 deg. C (Test #1) and then to +0 deg. C (Test #2), the sensor was exposed to the calibration gases again. The accuracy test results were ± 1% Oxygen for Test #1 and ±2% Oxygen for Test #2. The results met the ±2% Oxygen accuracy requirements of the TED200-T7 Oxygen Monitor.

A. Operational Temperature: The test results are summarized in the table below.

After initial 100% Oxygen calibration at room temperature, the sensor was exposed to calibration gases of air, 60% Oxygen in Nitrogen, and Nitrogen. After exposure to +40 deg. C (Test #1) and then to +0 deg. C (Test #2), the sensor was exposed to the calibration gases again. The accuracy test results were ± 1% Oxygen for Test #1 and ±2% Oxygen for Test #2. The results met the ±2% Oxygen accuracy requirements of the TED200-T7 Oxygen Monitor.

Table 1:

Test No.	Accuracy Test before temperature cycling				Accuracy Test, after exposure to +40 deg. C for 4 hrs.		Accuracy Test, after exposure to 0 deg. C for 4 hours	
	Cal with 100% O2	60% O2 Reading	20.9% O2 Reading	100% N2 Reading	60% O2 Reading	100% O2 Reading	60% O2 Reading	100% O2 Reading
1	100	60	21	0.0	61	101	-	-
2	100	60	21	0.0	-	-	59	102

B. Storage Temperature: The test results are summarized in the table below.

After each air calibration, the sensor was exposed to calibration gases of 100% Oxygen, 60% Oxygen in Nitrogen and 100% Nitrogen. After exposure to –40 deg. C (Test #1) and then to +70 deg. C (Test #2), the accuracy test results were ±1% Oxygen for both tests. The results met the ±2% Oxygen accuracy requirements of the TED200-T7 Oxygen Monitor.

Table 2:

Test No.	Accuracy Test before temperature cycling				Accuracy Test, after exposure to –40 deg. C for 12 hrs.		Accuracy Test, after exposure to +70 deg. C for 12 hours	
	Cal with 21% O2	60% O2 Reading	100% O2 Reading	100% N2 Reading	60% O2 Reading	100% O2 Reading	60% O2 Reading	100% O2 Reading
1	21	60	101	0.0	61	101	-	-
2	21	60	101	0.0	-	-	60	101

CONCLUSION:

The sensor met the ± 2% Oxygen accuracy requirements after being subjected to the extreme operation temperature conditions of 0 to +40 degrees Centigrade. In addition, the sensor met the ±2% Oxygen accuracy requirements after being subjected to the extreme storage temperature conditions of –40 and +70 deg. C.

III

PERFORMANCE TESTS
R24MED SENSORS

INTRODUCTION:

A group of 92 R-24s was made using final configuration molded parts and A58446 clamp rings and woven mesh membrane clamps (A55791). A randomly selected group of 22 cells was subjected to the following tests: output in air, 90% response time, 90% recovery time, offset in nitrogen, linearity, and vacuum linearity error. The remaining 71 cells were labeled for shipment to selected customers and tested for output in air and vacuum linearity only. Five cells from the group of 22 were tested for temperature compensation error.

METHODS:

The output in air was measured using a digital multimeter capable of resolving 0.01 millivolts; the readings were rounded to the nearest 0.1 millivolt. Response and recovery were measured by producing a step change in the flow of the sample gas between oxygen and nitrogen and visa-versa. Three cells were tested at one time by connecting the cells in series and flowing the gases at 2 SCFH. During the response and recovery measuring intervals a chart speed of 12 cm/min was used; the remainder of time a chart speed of 12 cm/hr was used to conserve chart paper. Offsets were measured by flowing nitrogen over the sensing surface of the test cells and noting the reading after 1-2 minutes. The linearity error was determined by noting the reading above 21% in two minutes after switching from 100% oxygen to air. A sampling gas pump was used to pass room air over the test cells at a flow rate of 2 SCFH. Oxygen from a gas cylinder was flown at the same rate so that the back pressure at each cell (again, three sensors in series) remained constant. The vacuum linearity error was determined by noting the output of each cell in air at ambient pressure followed by subjecting the sensing surface to a 10% vacuum. The error was determined by computing the percent additional drop beyond the expected 10% drop:

$$\%\ \text{Error} = \frac{(\text{reading at 10\% vac}) - (\text{expected reading})}{(\text{reading at ambient pressure})} \times 100$$

The temperature compensation error was determined by subjecting the test cells to five temperatures within the range 0-50 deg C (0, 18, 25, 38, and 50). 25 deg C was use used as the reference temperature; the test cells remained at each temperature for 1.5-2.0 hours. Sensor measurement accuracy (percent error of full scale) were determined on the strip chart recording by measuring the deviation of each temperature reading, at the end of the 1.5-2.0 hour equilibration period, from the 25 deg C reading.

RESULTS: The following tables list the results of all tests:

Table 1:

Cell #	Air Output (mv)	90% Resp (sec)	90% Rec (sec)	Offset in N_2 (mv)	Linearity Error (%O_2)	Vac Lin Error (%Read)
1	9.7	5.0	5.0	0.14	0.0	0.0
2	9.5	5.0	5.5	0.13	0.3	0.0
3	9.8	5.0	6.0	0.15	0.5	0.0
4	9.2	4.5	4.5	0.15	0.2	-1.2
5	9.4	6.0	6.0	0.14	0.5	0.0
6	9.1	5.5	6.0	0.13	0.4	0.0
7	9.4	5.0	4.5	0.13	0.2	0.0
8	9.5	5.5	5.0	0.13	0.7	-1.7
9	9.7	5.0	5.5	0.14	0.7	0.0
10	9.7	4.5	4.0	0.15	0.4	0.0
11	9.3	5.0	6.0	0.13	0.4	0.0
12	8.8	6.5	7.0	0.14	0.7	0.0
13	8.9	4.5	4.5	0.13	0.7	0.0
14	9.9	5.0	5.0	0.13	0.3	0.0
15	9.7	5.0	5.0	0.11	0.4	0.0
16	9.4	4.0	4.0	0.12	0.5	0.0
17	9.5	5.5	5.5	0.13	0.3	0.0
18	9.1	5.0	5.5	0.13	0.7	-6.1
19	9.6	5.0	4.0	0.11	0.2	0.0
20	9.6	5.5	5.5	0.15	0.4	0.0
21	9.2	5.0	5.5	0.12	0.5	0.0
22	9.9	4.0	4.5	0.14	0.4	0.0

Table 2:

Temperature Compensation Error (% Full Scale)					
Cell #	25 deg C (reference)	0 deg C	18 deg C	38 deg C	50 deg C
1	0.0	0.0	-3.0	-2.5	1.0
2	0.0	0.0	-2.5	-1.5	1.5
3	0.0	-0.5	-3.0	-1.5	1.0
19	0.0	1.0	-2.5	-2.5	1.0
20	0.0	0.0	-2.5	-2.0	1.5

Table 3:

Cell #	Air Output (mv)	Vac Lin Error (% read)	Cell #	Air Output (mv)	Vac Lin Error (% read)	Cell #	Air Output (mv)	Vac Lin Error (% read)
469009	9.8	0.0	469032	10.2	0.0	468960	10.2	0.0
10	9.6	0.0	33	9.5	-0.5	61	10.0	-0.6
11	9.5	-0.5	34	9.4	0.0	62	9.3	-0.7
12	9.9	0.0	35	9.7	0.0	63	9.7	-0.1
13	9.6	0.0	36	9.2	-0.5	64	9.8	-0.3
14	9.5	0.0	37	9.5	0.0	65	9.6	-0.7
15	10.1	0.0	38	9.6	-0.5	66	9.3	-0.7
16	9.6	0.0	39	9.4	0.0	67	9.6	-1.2
17	9.4	0.0	40	8.8	-0.6	68	9.9	0.0
18	9.7	0.0	41	9.5	-0.4	69	9.1	0.0
19	9.2	0.0	42	10.2	-0.4	70	9.7	0.0
20	9.6	0.0	43	9.5	0.0	71	9.4	-0.4
21	9.3	0.0	44	9.5	0.0	72	9.2	-0.5
22	9.3	0.0	45	8.9	0.0	73	9.8	0.0
23	10.0	0.0	46	9.6	0.0	74	9.6	0.0
24	9.4	0.0	47	9.5	-0.6	75	9.1	-0.4
25	9.7	0.0	48	8.7	-0.4	76	9.4	-0.5
26	10.1	0.0	49	8.6	-1.2	77	9.4	-0.6
27	9.6	0.0	50	9.3	-0.4	78	9.1	-0.1
28	9.9	0.0	51	8.9	0.0	79	9.6	0.0
29	8.9	0.0	52	9.3	-0.1	80	9.0	-0.4
30	9.1	-0.4	53	10.0	-0.2	81	9.1	-0.2
31	9.1	-0.5	468959	9.6	0.0	82	9.6	-0.5

CONCLUSIONS:

Output in air- The specification for the output in air of the R24 at sea level is 7-13 mv. All 92 cells had outputs within this specified range. (8.6- 10.2 mv)

90% response and recovery- The specification for 90% response time is less than 10 seconds. The group of 22 cells that were tested for response and recovery time showed a range of 4.0-6.0 seconds for 90% response and a range of 4.0-7.0 seconds for 90% recovery.

Offset voltage- The specified offset voltage is less than 200 microvolts (0.200 millivolts). The offset in nitrogen after 2 minutes for the 22 cells tested ranged from 0.11-0.15 millivolts, all less then the specified 0.200 millivolts.

Linearity- Linearity is specified as accuracy which should be within ±1% of full scale at constant temperature and pressure. The 22 test cells ranged in error from 0.0-0.7 $\%O_2$(same as % full scale since full scale is 100%O_2.

Vacuum linearity error- Vacuum linearity is not specified for the R24 (or any other cell except the R22cc). In this case it was used as a research tool to determine when the clamping grid was dimensioned properly. All 92 cells were tested for this parameter. Errors ranged from 0.0 to -1.7% with the exception of Cell #18; which had a vacuum linearity error of -6.1%. Even this cell would have passed the R22cc test which allows a -10% vacuum linearity error.

Temperature compensation error- The temperature compensation error is specified at ±5% full scale. For the five cells tested, the errors ranged from-3.0 to 1.5% full scale, well within the specified range.

It is important to note that of those cells made for this production test run (92 pieces), no leaks were found at any of the three sealing areas: the sensing membrane (square o-ring seal), the expansion membrane (conventional o-ring seal) and the epoxy seals around the anode and cathode wires. During the development phase where the clamping ring was being optimized, the clamp ring was in direct contact with the sensing membrane and sometimes the membrane was cut during installation. In the final configuration, the clamp ring does not directly touch the sensing membrane and no potential for cutting exists.

IV

PERFORMANCE TESTS
UFO130 OXYGEN SENSOR

INTRODUCTION:

The objective of this test is to demonstrate that the UFO130 oxygen sensor will meet the operation temperature requirements of 10 to +50 degrees Centigrade and storage temperature requirements of 0 to +50 degrees Centigrade. The storage requirement for the UFO sensor is 0 to +50 degrees.

METHOD:

Different oxygen concentrations were generated by mixing compressed nitrogen and oxygen with two 0 - 300 ml/min mass flow controllers (Teledyne Hasting-Raydist, Model HFC-202E). Both mass flow controllers were one-point calibrated with a bubble flow meter at 500 setting before use. The total flow rate of the mixed gases was constant through the test at about 290 ml/min.

Eight prototype sensors without sampling cap were assemble in R24-MED contact and divert caps (P/N: C60395, C60396). By using a flow adapter, the sensors were connected in series in the gas flow with a 1/32 inch ID PE/PVC sampling tubing. To control the operation temperature, a modified Aqua ZT-1 constant temperature chamber was used. Sensor output was taken 5 minutes after concentration change.

For the linearity test, if the sensor is a pure diffusion controlled device, the sensor output should have a linear relationship with the oxygen partial pressure. However, due to the electrochemical process included in the sensor, the actual output could deviate from this linear relationship.

RESULTS:

1. For the Linearity Test:

Figures 1 and 2 show the calibration curves of the sensors at 26ºC and 50ºC, respectively. By using these data, percentage error of full scale due to nonlinearity when calibrated with air and 100% oxygen can be calculated by:

$$\% \text{ Error} = \frac{C - C_R}{100} \times 100$$

$$C_R = \frac{79}{R_{100} - R_{21}} \cdot \times (R - R_{100}) + 100$$

where R is the output of a sensor, R_{21} the output at 21% oxygen, and R_{100} the output at 100% oxygen. Results of the calculation are listed in Table 2.1.

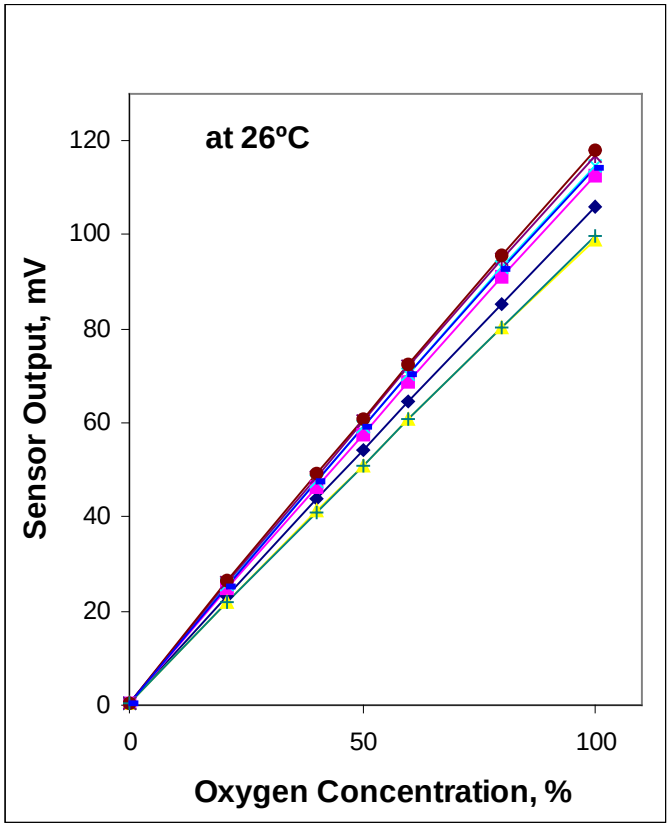


Fig. 1. Sensor calibration curves at 26ºC.

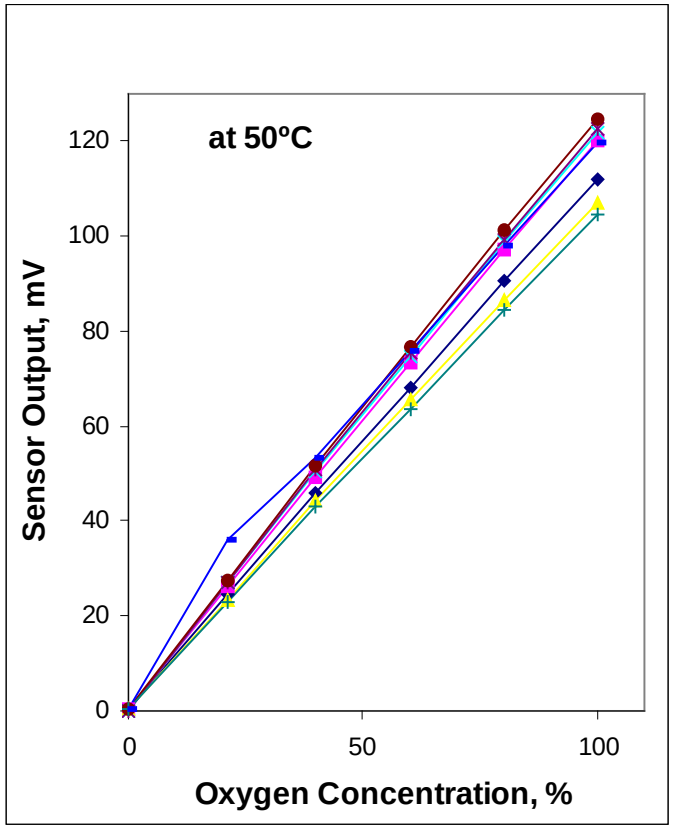


Fig. 2. Sensor calibration curves at 50ºC.

Table 1. Full scale percentage error of sensors when calibrated with air and 100% oxygen at the operation temperatures of 26ºC and 50ºC.

At 26ºC

Sensor ID	P14	P15	P16	P4	P5	P7	P8	P9
Oxygen %				Error%				
21	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
40	0.56	0.45	0.62	0.57	0.65	0.58	0.42	0.68
50	0.54	0.50	0.68	0.65	0.79	0.69	0.41	0.82
60	0.54	0.45	0.78	0.78	0.89	0.80	0.41	0.85
80	0.44	0.53	0.70	0.76	0.82	0.79	0.41	0.73
100	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

At 50ºC

Sensor ID	P14	P15	P16	P4	P5	P7	P8	P9
Oxygen %				Error%				
21	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
40	0.40	0.49	0.47	0.62	0.76	0.68	0.45	-2.66
60	0.34	0.57	0.67	0.85	0.97	0.97	0.45	-1.48
80	0.62	0.70	0.70	0.92	0.85	0.99	0.54	-0.36
100	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

As shown in table 2.1, when calibrated with air and oxygen, the biggest error shows at 60% oxygen and is less than 1%. However, when one-point calibration is used at 100% oxygen, the full scale percentage error can then be calculated as:

$$\% \text{ Error} = \frac{C - C_R}{100} \times 100$$

$$C_R = \frac{100}{R_{100}} \times R$$

As shown in Table 2, with one point calibration at 100% oxygen, the biggest error happens at 50% oxygen and is as high as 1.6%.

Table 2. Full scale percentage error of sensors when one-point calibrated with 100% oxygen at the operation temperatures of 26ºC and 50ºC.

At 26ºC

Sensor ID	P14	P15	P16	P4	P5	P7	P8	P9
Oxygen %	Error%							
0	0.24	0.21	0.24	0.21	0.23	0.21	0.28	0.22
21	0.96	1.04	1.27	1.25	1.32	1.36	1.09	1.23
40	1.28	1.24	1.58	1.50	1.64	1.61	1.24	1.61
50	1.14	1.15	1.47	1.43	1.61	1.54	1.10	1.59
60	1.02	0.97	1.41	1.40	1.54	1.48	0.96	1.46
80	0.67	0.79	1.01	1.06	1.14	1.12	0.68	1.03
100	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

At 50ºC

Sensor ID	P14	P15	P16	P4	P5	P7	P8	P9
Oxygen %	Error%							
0	0.22	0.20	0.23	0.00	0.00	0.20	0.23	0.20
21	0.85	0.84	0.95	1.06	1.09	1.11	0.81	8.99
40	1.04	1.12	1.19	1.42	1.58	1.51	1.06	4.47
60	0.76	0.99	1.15	1.37	1.51	1.52	0.85	3.24
80	0.83	0.90	0.94	1.18	1.12	1.26	0.74	1.96
100	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

2. For the 10 - 90% Response Time Test:

Fick's first law can only provide us information of diffusion at static state. To study the transient behavior of the diffusion, we have to depend on Fick's second law

$$\frac{\partial C}{\partial t} = D\frac{\partial^2 C}{\partial x^2} \qquad (1)$$

By setting the boundary condition of C(x, t=0)=0 and C(0, t=0$^+$)=C_0, equation (2.4) can be solved as:

$$J(d,t) = \frac{DC_0}{d}\left[1 + \sum 2(-1)^n e^{-\frac{n^2\pi^2 Dt}{d^2}}\right] \qquad (2)$$

Equation (2) describes the relationship between the sensor output and time when oxygen concentration changes from zero to C_0. Figure 3.1 shows the plot of J(d, t) in normalized units of DC_0/d versus t in normalized units of d^2/D.

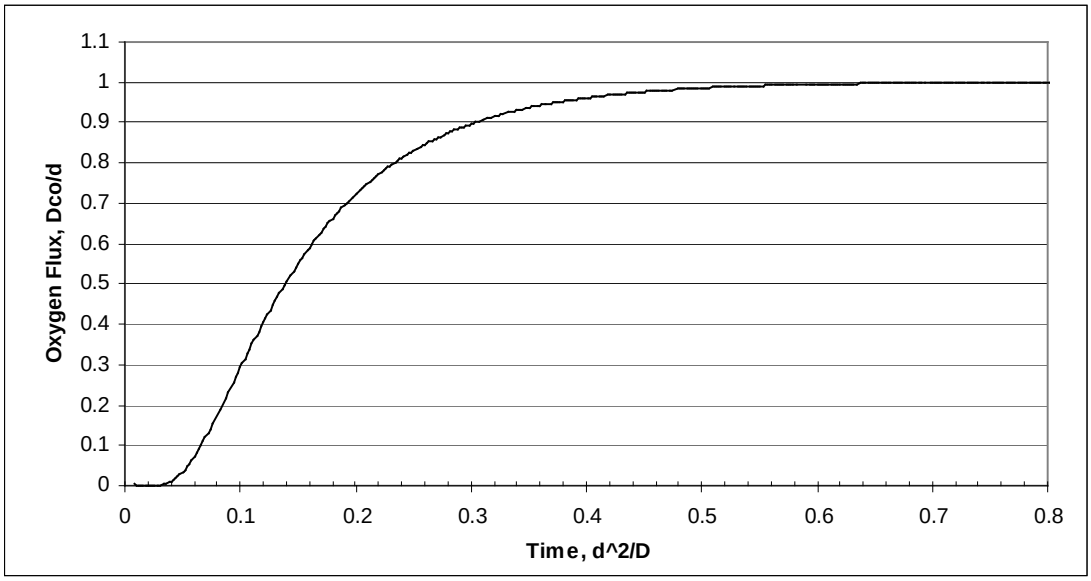


Fig. 3. Response curve at the the boundary condition of C(x, t=0)=0 and $C(0, t=0^{+})=C_0$ with Fick's second law.

As shown in equation (2) and figure 3, the response time T of a sensor in only the function of the diffusion coefficient and the membrane thickness which can be described as:

$$T = C\frac{d^2}{D} \qquad (3)$$

Where C is a constant. From equation (3),it is clear that with the same sensing membrane material, the thinner the sensing membrane, the shorter the response time. From the supplier of our oxygen sensing membrane, the thinnest membrane available is 0.17 mil in thickness.

Our current product R24-MED uses 0.5mil sensing membrane, and it's 10% to 90% response time $T_{10\text{-}90}$ were measure to be 1.35 second. The thickness of the 0.17 mil membrane was measured to be 0.20 mil. With these testing data and the relation shown in equation (3), a sensor with a $T_{10\text{-}90}$ at several hundreds millisecond range can be achieved.

The response speed of the micro-fuel cell oxygen sensor can also be represented by the frequency response of the sensor. Figure 4. shows a typical response curve of a UFO130 sensor at different frequency of oxygen concentration change from 21% to 10%.

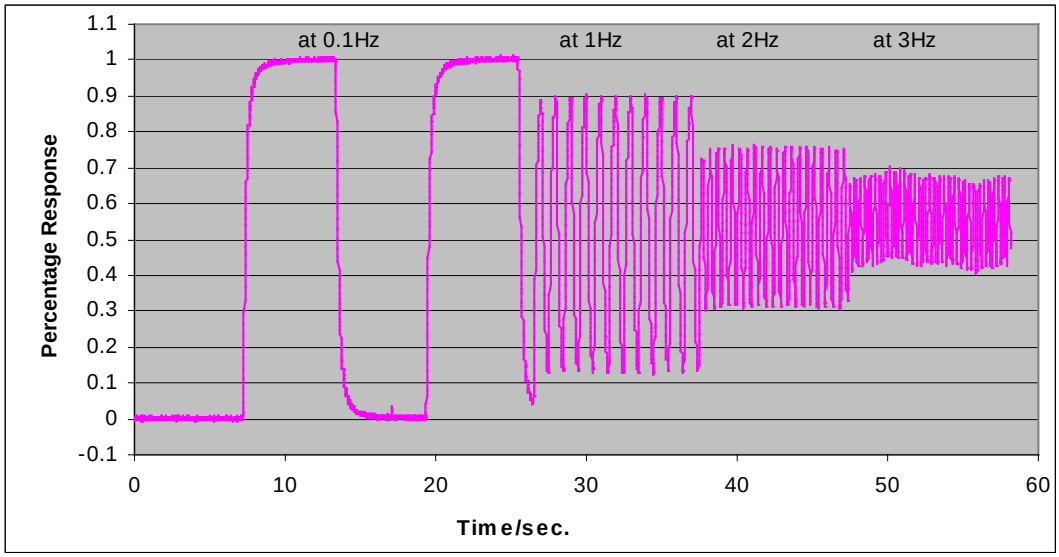


Fig. 2.2. Response of a prototype UFO130 sensor at different oxygen switching frequencies.

As we can see, at low frequency, the sensor exhibits a full response to the oxygen concentration changes. However, when the frequency get closer to and higher than $1/T_{10\text{-}90\%}$, the sensor response starts to attenuate. If we plot the amplitude of the sensor response versus the frequency, we'll get a curve somewhat like the one shown in Figure 2.3. Because the sensor response is controlled by a well-defined process, the attenuation of the response can be compensated electronically. In other word, the response speed of the sensor can be electronically enhanced. The frequency compensation is a well

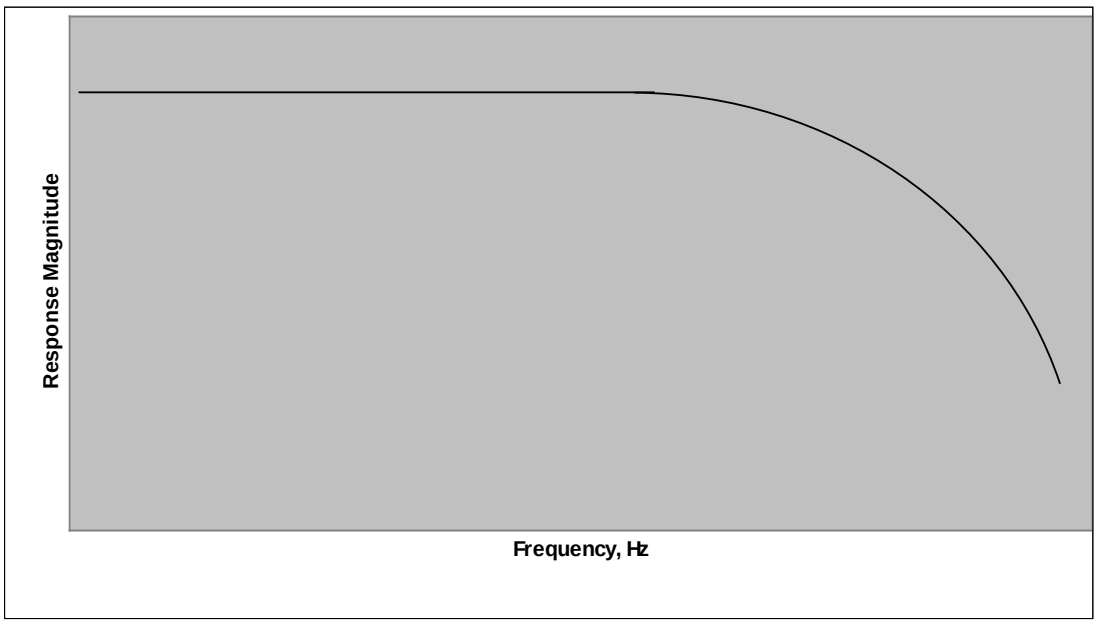


Fig. 2.3. Frequency response curve of a micro-fuel oxygen sensor.

developed technology. The combination of this technology with the micro-fuel cell oxygen sensor is a novel approach in this product development.

A good way to visualize the concept is to view the actual micro fuel cell sensor as series combination of an ideal sensor (one with unlimited high frequency response) and a sensor low pass filter which matches the high frequency attenuation of the actual micro-fuel cell sensor.

Viewing the frequency domain, the ideal sensor would have a flat frequency response. That is its output amplitude for a sinusoidal input oxygen concentration would be the same for any frequency of input oxygen concentration. Viewing the time domain, an ideal step of oxygen concentration into the ideal sensor would yield an ideal step output (zero rise time with no overshoot or ringing).

On the other hand, in the frequency domain, the sensor low pass filter would attenuate the high frequency components of the ideal sensor output. In the time domain, the sensor low pass output would be a step response with a finite rise time when its input had zero rise time.

This visualization is shown in Figure 2.4 below:

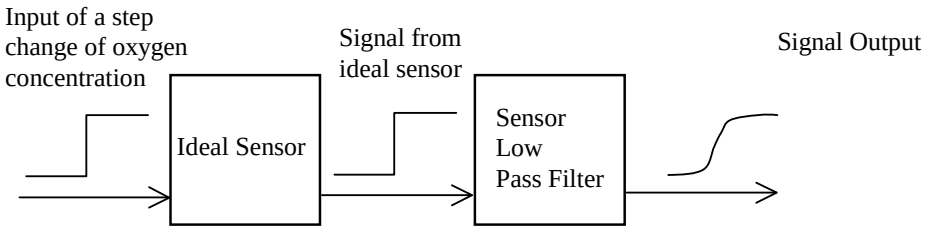


Fig. 2.4. Schematic view of the operation of a micro-fuel sensor at a step change of oxygen concentration.

Ideally, the electronic compensation circuit would be the exact inverse of the sensor low pass filter and thus cancel the effect of the sensor low pass filter and yield a product with perfectly flat frequency response to infinitely high frequency.

The system transfer function (in the "s" plane) is the product of the transfer function of the cell low pass filter and the electronic compensation circuit. If the transfer function of the cell low pass filter were a simple single pole factor, for this idealized case the transfer function of the electronic compensation circuit would be a simple single zero factor, which would cancel the pole and yield an ideal transfer function of "1". This is shown below:

system transfer function =

(cell low pass filter transfer function) x (electronic compensation circuit transfer function)

$Gsys(s) = Gcell(s) \times Gcomp(s)$

$Gsys(s) = \left(1 / (1 + sT1) \right) \times \left((1 + sT1) \right) = 1$

Now an electronic compensation circuit transfer function of "(1 + sT1)" can not be implemented because of finite amplifier gain and finite operational amplifier bandwidth. Also it would not be desirable to implement because it would greatly amplify noise voltages.

However: $Gcomp(s) = \left((1 + sT1) / \left((1 + sT2) \times (1+sT3) \right) \right)$ can be implemented.

Let $T2 = T1 / N$ (where $N > 1$) and $T3 < T2 / 5$

Now:

$Gsys(s) = \left(1 / (1 + sT1) \right) \times \left((1 + sT1) / \left((1 + sT2) \times (1+sT3) \right) \right)$

$Gsys(s) = \left(1 / \left((1 + sT2) \times (1+sT3) \right) \right)$

Since $T3 < T2 / 5$, $Gsys(s) \approx (1 / (1 + sT2)) = (1 / (1 + s(T1 / N)))$ [for the frequencies of interest]

The net result is that the rise time of the system is "N" times smaller than the cell alone!

The actual sensor low pass filter transfer function is more complicated than a simple single pole and it varies with temperature and from one cell to another, however, the basic compensation procedure is the same: for the frequencies of interest, make the electronic compensation circuit transfer function close to the inverse of the sensor low pass filter.

1.2. Validation.

3.2.1. Experiment setup.

The sensor response time was measured by using a gas switching device made in house. Figure 3.1 shows a schematic drawing and working mode of the gas switching device.

↑ Gas outlet delivering to sensor

↑ Gas outlet delivering to sensor

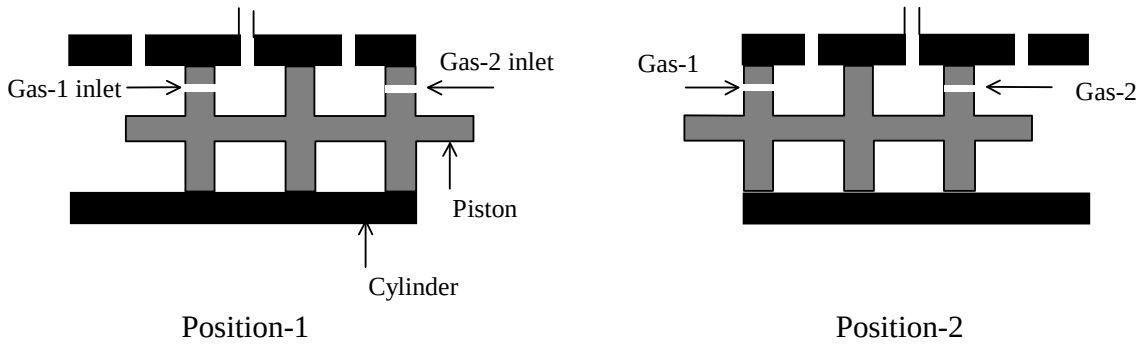
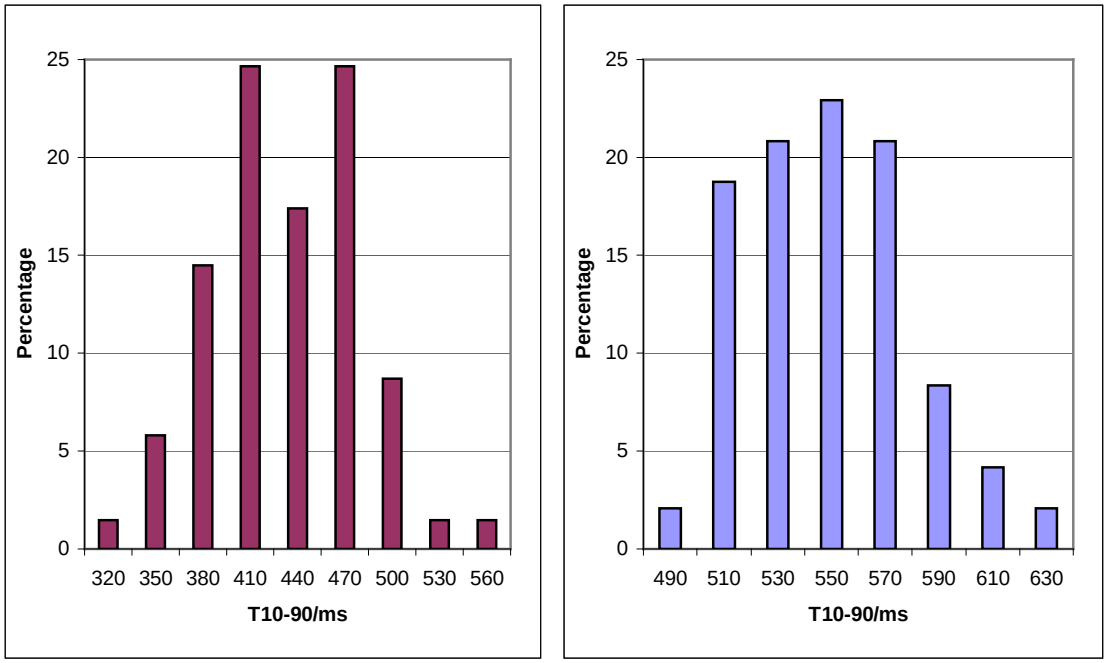


Fig. 3.1. Schematic drawing and working mode of the gas switching device. At position-1, the device is delivering gas-1, while at position-2, the device is delivering gas-2.

The full travel length of the piston from position-1 to position -2 was about 1/4 inch. The opening for gas delivering was about 1/32 inch. Two pull type tubular solenoid (series S-15-75, Magnetic Sensor System, Van Nuys, CA) were used to drive the piston. Transient current change of the solenoid during operation showed that the travel time of the piston from position-1 to position-2 was about 7 milliseconds.

To measure the sensor response time, sensor sampling cap was attached to the sensor. A PE/PVA, 1/16 inch in OD and 2 inch in length, was used to connect the sampling cap and the gas switch outlet. By switching the gas from gas-1 to gas-2, sensor response curve was recorded through a data acquisition system. Unless it is specified, gas-1 is compressed air and gas-2 is compressed oxygen. Response time $T_{10\text{-}90}$ is defined as the time taken from 10% to 90% of the full output change.

3.2.2. Results.



(a) (b)

Fig. 3.2. Response time distribution of (a) sensor S-XX + P-XX, and (b) sensor PT-XX at room temperature.

Figure 3.2 shows the response time distribution of different batches of sensors. The sensor response time varies from 320 to 630 milliseconds. By comparing Figure 4.4. (a) and (b), it is clear that the distribution range also changes from batch to batch. The reason for this variation is not clear yet.

DISCUSSION: According to equations (2.3) and (2.6), both sensor output and sensor response time is related to the properties of the sensing film. So, any variation of the output should be reflected by the variation of the response time. Assuming the diffusion coefficient more constant from sensor to sensor, then we should expect that the higher the sensor output, the shorter the response time. In reality, this relationship was not strictly followed. Figure 3.3 shows a typical scattered relationship between sensor output and response time at room temperature. This scattered relationship also changes from sensors batch to batch.

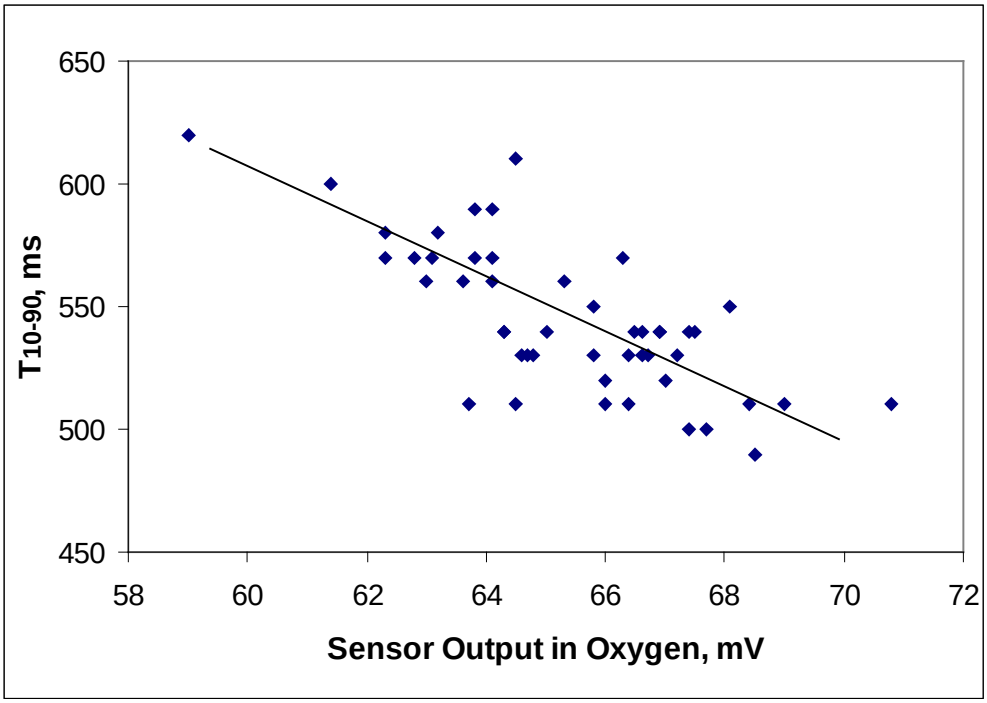


Fig. 3.3. Relationship between output and response time of P-XX sensors at room temperature.

Test results of the prototype sensors after frequency compensation at room temeprature and 100 ml/min gas flow rate are shown in the following table.

Table. 3.1. Test results of prototype UFO130 unit.

Sensor S/N	$T_{10\text{-}90}$, ms	Output in Oxygen, V	Sensor $T_{10\text{-}90}$ Range
PT2	100	3.73	3
PT3	100	3.54	3
PT4	80	3.66	3
PT5	90	3.67	3
PT6	100	3.62	3
PT7	100	3.81	2
PT8	105	3.67	3
PT9	100	3.43	3
PT10	90	3.63	3
PT11	140	3.49	3
PT12	90	3.52	3
PT13	100	3.52	3
PT14	100	3.53	3
PT15	100	3.73	2
PT16	100	3.88	2

PT17	100	3.78	3
PT18	100	3.46	3
PT19	120	3.48	3
PT20	100	3.66	3
PT21	110	3.52	3
PT22	130	3.54	3
PT23	100	3.69	3
PT24	150	3.48	3
PT25	120	3.55	3
PT26	110	3.67	3
PT27	130	3.60	3
PT28	120	3.60	3
PT29	110	3.83	3
PT30	120	3.34	3
PT31	110	3.51	3
PT32	100	3.62	3
PT33	100	3.62	3
PT34	110	3.75	3
PT35	90	3.67	3
PT36	140	3.42	3
PT37	100	3.66	3
PT38	80	3.71	3
PT39	105	3.67	3
PT40	115	3.12	3
PT41	100	3.74	3
PT42	100	3.67	3
PT43	95	3.77	3
PT44	100	3.66	3
PT45	90	3.71	3
PT46	90	3.47	3
PT47	160	3.10	3
PT48	100	3.75	3

4. Cross Interference.

4.1. Verification. None

1.3. Validation.

4.2.1. Experiment Setup.
4.2.1.a. Gas Mixture. Table 4.1 summarizes information of the gas mixtures used for this test.

Table 4.1. Concentration of the Test Gas Mixtures

Gas Mixture	Certified concentration	Manufacturer
Halothane/oxygen	5.42	Scott Medical Product
Enflurane/oxygen	5.00	Scott Medical Product
Isoflurane/oxygen	4.96	Scott Medical Product
N_2O/oxygen	80.12%	Mathson
Helium/oxygen	79.4%	Mathson
CO_2/oxygen	10.09%	Mathson

The concentration of halothane from ISO7767 is required to be 6%. However, Technical staff from Scott informed us that 6% of halothane in oxygen is over the low explosion limit and unsafe. The highest concentration of halothane in oxygen is 5.5%.

4.2.1.b. Sensor and Gas Flow System. Eight prototype sensors, P1, P2, P3, P4, P5, P7, P8, and P9, were used for the test. The gas flow connection was the same as described in section 4.2. The gas flow rate is controlled by using tube flow meters. Tubing used were 1/4 inch OD poly flo (Imperial Eastman^{TM}) and 1/16 inch OD PE/PVA tubing. No other material tubing should be used because of the corrosive property of the anaesthetic agent.

4.2.1.c. Temperature Control. Except for that the CO_2 test was done at room temperature, all the other tests were done at controlled temperature. When tested at controlled temperature, the sensors were placed in a modified Aqua ZT-1 chamber with temperature controlled by an RTD and Omron temperature controller.

4.2.1.d. Test Procedure. Set the temperature of the chamber and flow the blank gas (100% oxygen or compressed air) through the sensors. Let the sensor reach equilibrium with the chamber. Start data recording when the sensor gives a steady output, and switch the gas to the anesthesia gas mixture and hold it for two hours. Switch the gas back to the blank gas. Stop data record when the sensors give a stable output. The error is calculated by calibrate the sensor at the beginning of the test with the blank gas, then substrate the oxygen concentration the sensor reads with the real oxygen concentration during the test. Figure 4.1 shows the typical data of this test.

Fig. 4.1. Test data during a isoflurane interference test at 40ºC.

4.2.2. Results

Table 4.2 summarizes the test results of errors caused by the interfering gases at different temperatures. As shown in table 4.2, at 34ºC for halothane, all the sensors still could not meet the 2% error requirement. At 37ºC for halothane, some sensor met and some did not meet the requirement. At 40ºC, all the sensors met the 2% requirement for halothane, and enflurane gases. For Isoflurane at 40ºC, two sensors showed 2.2% error at the worst case.

Table 4.2. Errors caused by anesthesia gases at different temperatures.

Interfering gases	Error at different temperatures, %			
	23ºC	34ºC	37ºC	40ºC
Halothane		2.0 - 2.7	1.9 - 2.4	1.5 - 1.9
Enflurane				1.2 - 1.9
Isoflurane				1.6 - 2.2
Helium				0.5 - 0.8
Nitrous oxide				0.3 - 0.5
Carbon dioxide	1.3 - 1.5			

5. Storage Tempaerature.

5.1. Verification. Refer to the storage temperature of standard Teledyne oxygen sensors.

5.1. Validation. Refer to the next section (operation temperature).

6. Operating Temeprature.

6.1. Verification. Refer to the operating temperature of standard Teledyne oxygen sensors.

6.2. Validation.

6.2.1. Experiment setup. The test was done by placing the UFO130 unit in a environmental chamber and use the test setup of section 3.

6.2.2. Results. Table 6.1 shows the response speed and output of 4 prototype sensors tested at 10, 23, and 50ºC.

Table 6.1. Sensor performance at different operating temperatures.

Sensor	T10-90 Response Time, ms			Output in air			Output in O_2		
	10ºC	23ºC	50ºC	10ºC	23ºC	50ºC	10ºC	23ºC	50ºC
PT35	110	100	100	0.76	0.77	0.79	3.54	3.60	3.69
PT36	120	120	80	0.69	0.69	7.51	3.24	3.26	3.5
PT41	110	90	70	0.75	0.75	0.79	3.50	3.50	3.69
PT42	110	100	80	0.72	0.74	0.77	3.34	3.45	3.58

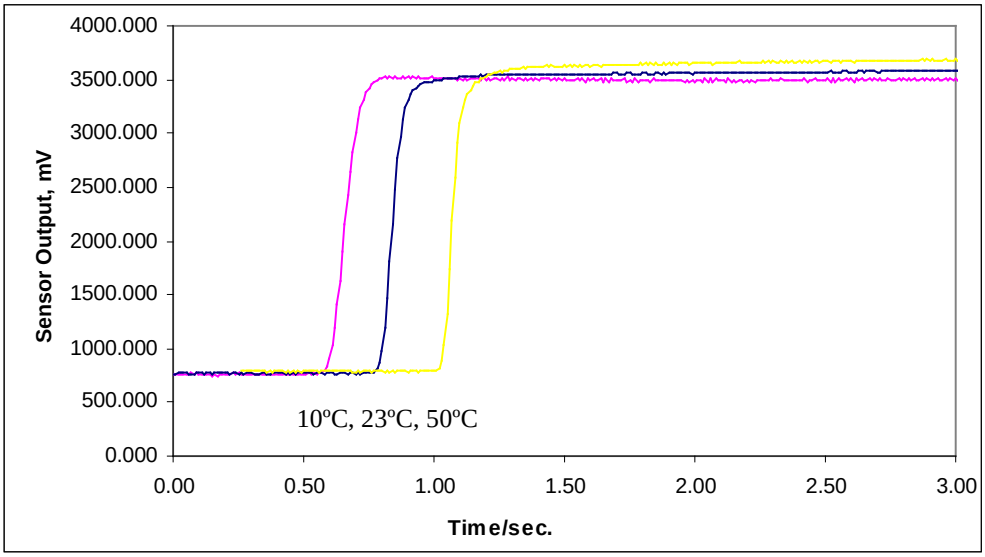


Fig. 6.1. Response curves of PT35 unit at different temperatures.

Figure 6.1 shows the response curves of the PT35 unit at different operation temperatures. The results demonstrate that the UFO130 is operatable at the temperature range of 10 - 50ºC.

7. Operating Humidity.

7.1. Verification. Refer to R24-MED ISO test results.
7.2. Validation. Refer to R24-MED ISO test results.

8. Temperature Compensation Error

8.1. Verification.

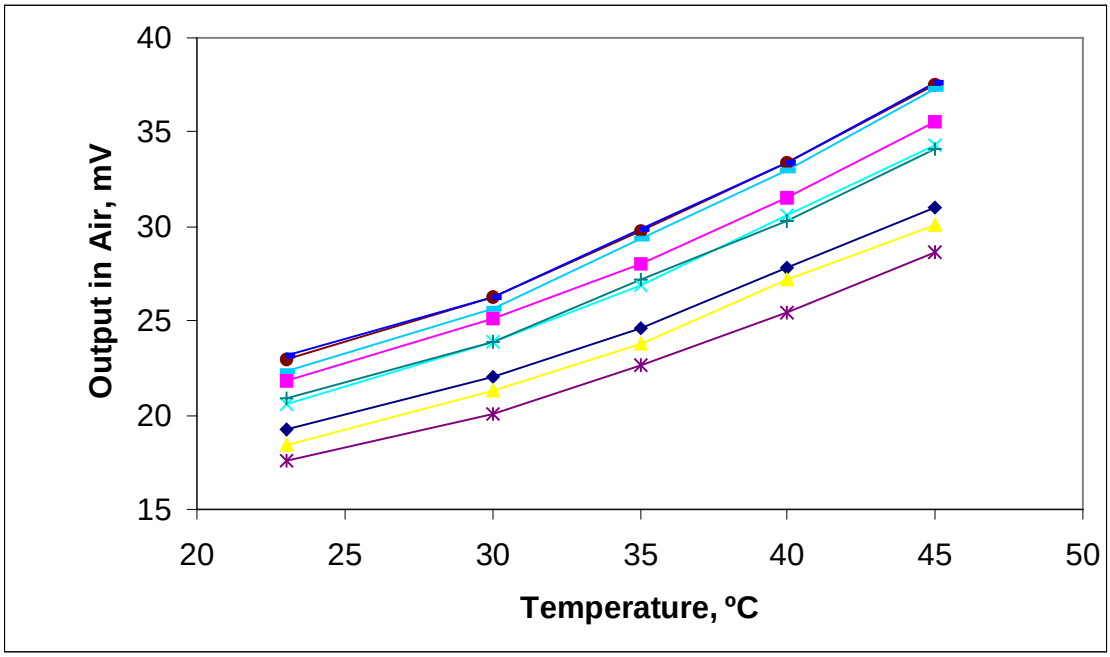


Fig. 8.1. Temperature effect on the output of nine prototype sensors.

Ten sensors were built with R24 bodies. By connecting the sensor output leads with a 100±1% ohm resistor, sensor output at different temperature in air were measured. Figure 3.4 shows the temperature effect on the output of the nine prototype sensors at the temperature range from 23ºC to 45ºC. In this temperature range, test showed that the change of the resistor value was less than 0.2%. The following formula was used to calculate the percentage change per degree centigrade:

$$\frac{(S - S')}{(T - T')S_{23}} \qquad (3.4)$$

where S_{23} represents the sensor output AT 23ºC, S' represents the output at T', and S represents the output at temperature T. This percentage change per degree centigrade actually represents the slop of the plots shown in Figure 3.4. The calculated results are listed in table 8.1.

Table 8.1. Percentage output change per degree centigrade at the temperature range From 23 to 45ºC.

Sensor ID	S11	S12	S13	S14	S15	S16	S17	S18	S19
23 - 30 ºC	2.1	2.2	2.3	2.3	2.0	2.1	2.0	2.0	2.1
30 - 35 ºC	2.6	2.7	2.7	2.8	2.9	3.1	3.1	3.1	3.3
35 - 40 ºC	3.3	3.2	3.7	3.7	3.2	3.1	3.0	3.0	3.2
40 - 45 ºC	3.3	3.7	3.1	3.5	3.6	3.6	3.6	3.6	3.9

As being discussed in concept section, temperature dependence of the sensor output results from temperature effects on the diffusion coefficient. All sensor with the cast-Teflon sensing membrane should have the same temperature dependence.

The data showed in Table 8.1 agrees with the behavior of R24 MED sensors. So, the temperature compensation network (P/N B65388) design for R24-MED sensor were used in this project.

8.2. Validation. Typical temperature compensation effect is shown in Figure 8.2.

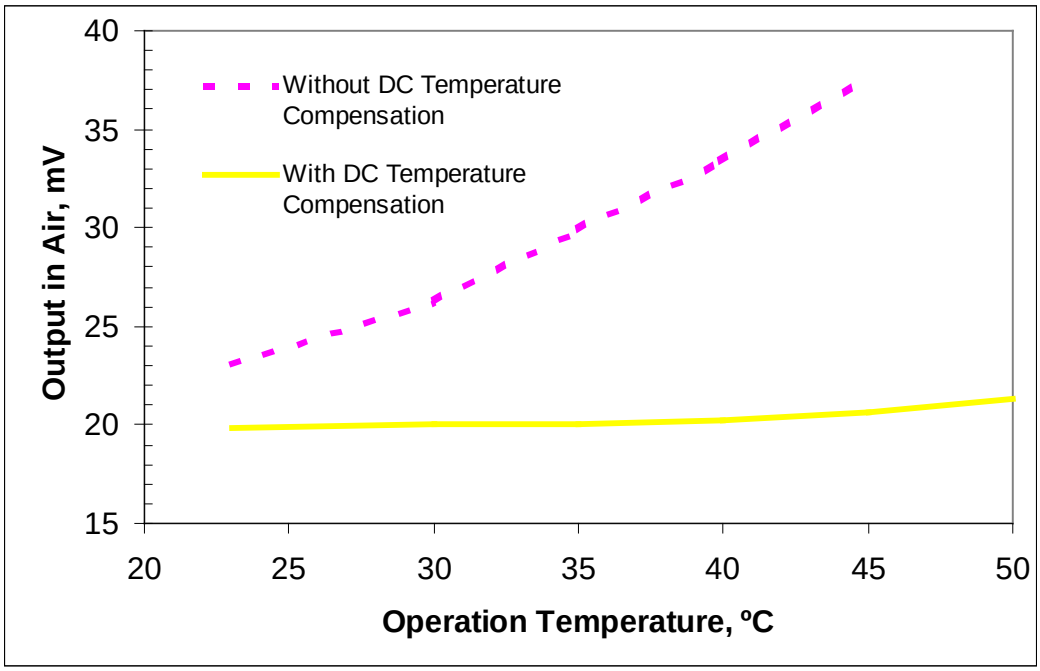


Fig. 3.5. Output of S18 sensor in air at different temperature with and without the temperature compensation.

Based on the test data shown in table 6.1, the temperature compensation error in the operation temperature range is calculated and listed in table 8.2.

Table 8.2. DC temperature compensation error (percentage of reading) in the 10 - 50ºC range.

Sensor Unit	PT35	PT36	PT41	PT42
Total error, %	4.0	8.0	5.4	6.9

As shown in table 8.2, the total error from 10ºC to 50ºC is less than 10%. So when calibrated at certain temperature within the temperature range, the temperature compensation will meet ±5%.

9. Flow Rate of Gas Sampling.

9.1. Verification.

In this project, gas sampling system was called sampling cap. Three gas sampling systems were developed and tested. Figure 9.1 shows the schematic view of the caps.

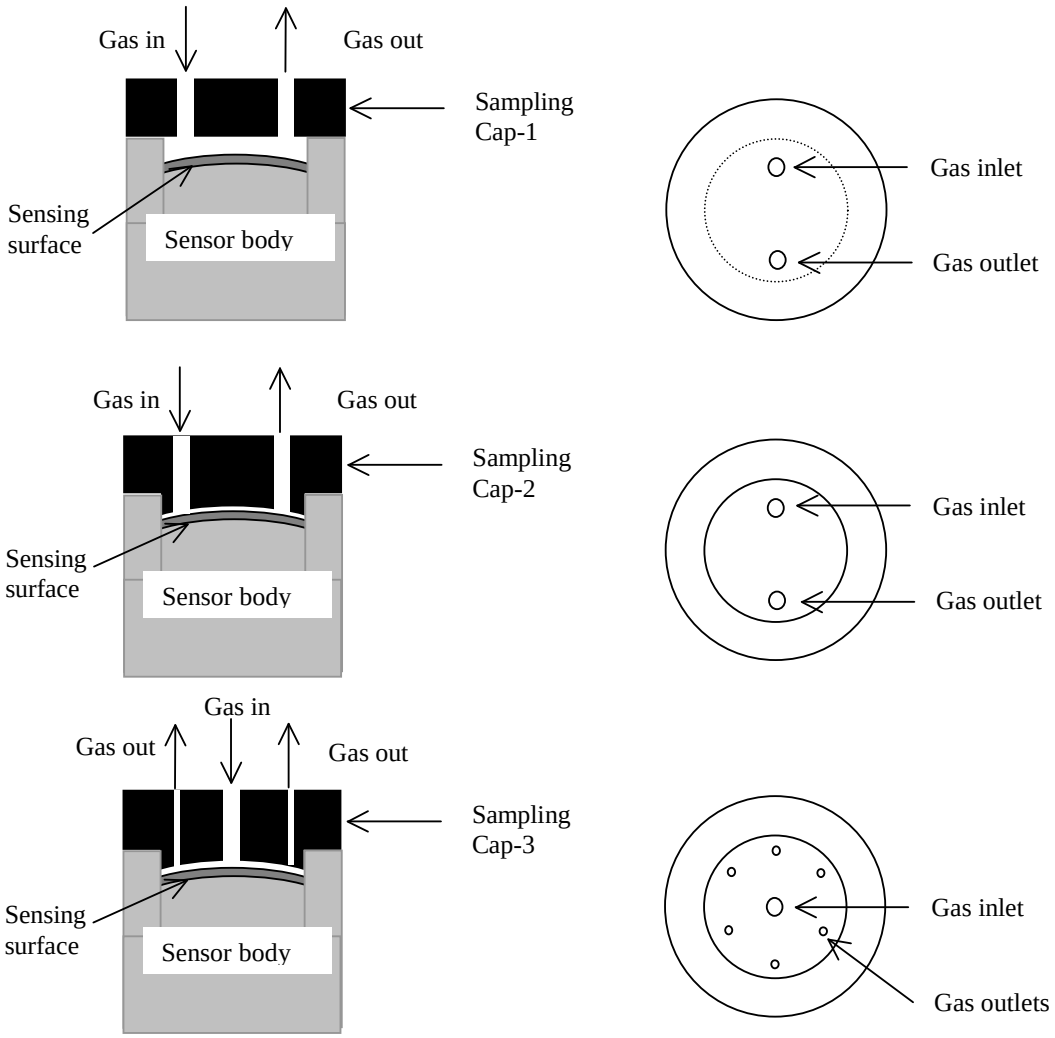


Fig. 9.1. Schematic view of the sampling caps.

Cap-1 was the original design. It forms a big dead volume above the sensing surface and introduces an assymmetric gas flow between the cap and sensing surface. Cap-2 reduces the dead volume but still introduces an assymmetric gas flow. Cap-3 reduces the dead volume and also introduces an symmetric gas flow. Figure 9.2 shows the flow rate dependence of a prototype sensor $T_{10\text{-}90}$ response time with the three sampling caps.

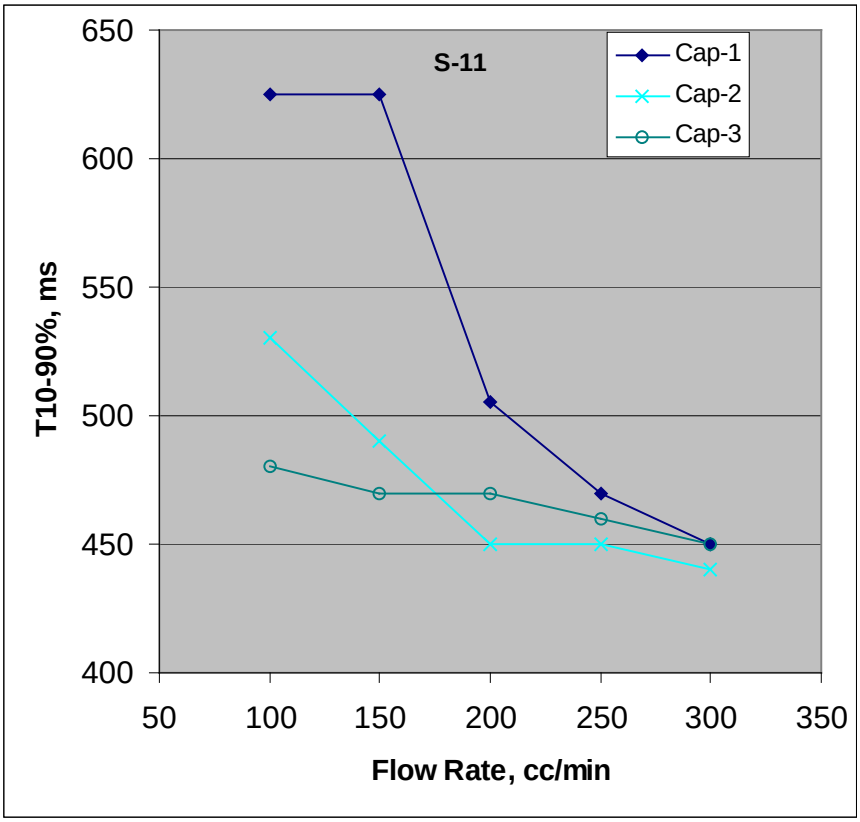


Fig. 9.2. Flow rate dependence of a prototype sensor (S-11) response time with three different sampling caps.

As shown in Figure 3.6, both the reduction of the dead volume and the distribution of a symmetrical gas flow improved the flow rate dependence of the sensor response time. The sensor showed the least flow rate dependence with cap-3.

For the final unit design, the flow rate dependence of the response time is critical because the frequency compensation circuit can only be optimized at one flow rate, but in real application the unit can be used at any flow rate from 100 to 300 ml/min.

9.2. Validation.

The test results shown in Table 3.1 in section 3 demonstrated that the UFO130 unit can be operated at the flow rate as low as 100ml/min and still meet the 130ms response time requirement.

10. Range of Output.

The output range required by SpaceLabs is 3.0 - 3.8 V. Test results shown in Table 3.1 demonstrated that the UFO130 unit meet this requirement.

11. Power Supply of Unit.

The unit requires a +12V, -12V power supply. The tolerance is ±2V.

12. Weight of Unit.

Typical weight of the unit is 50 ± 10 g.

13. Volume of unit.

Dimension of the unit is 4"(L) x 1.8"(W) x 1"(H).

14. Mounting Kit.

A mounting bracket was designed for SpaceLab. (DWG# B68831)

15. Sensor Life Time.

15.1.Verification.

Sensor life are limited by both the effective lead amount and effective volume inside the sensor. The effective volume is defined as the volume change allowed without building significant pressure inside the sensor or the volume change allowed by the back expansion membrane.

15.1.1. Experiment setup.
Four model sensor with not lead inside were assembled together with PT-XX sensors. After assembly, the sensors passed standard production leaking tests. The sensors were then place in ambient air at room temperature or in a oven at 40ºC. For every 24 hours or more, the weight of the sensor was measured with a high sensitive balance (0.1mg).

Drill a hole through the wall of a standard R24-MED sensor, and attach a syringe through the hole sealed with epoxy. By plunging or sucking electrolyte with the syringe, effective volume was measured.

15.1.2. Results

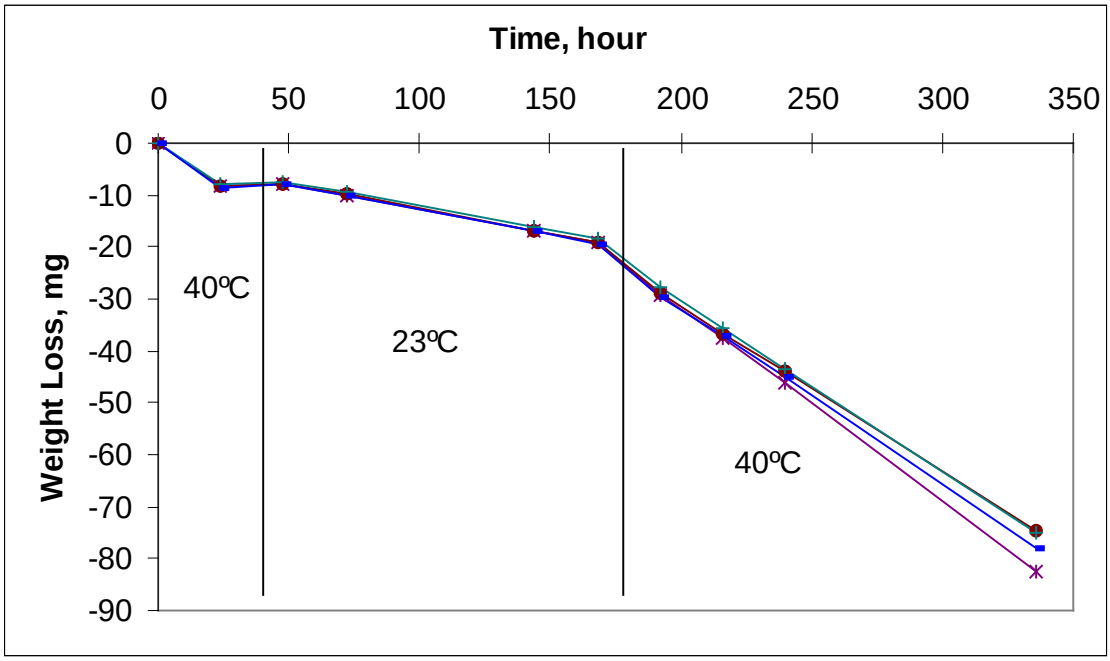


Fig. 15.1. The weight change of the four model sensors during the water lost test at different temperatures.

The effective volume was measured to be 0.57 ml. Figure 15.1 shows the weight change of the four model sensors. The ambient temperature during the test was about 23ºC, and relative humidity varied from 30% to 50%.

From the data, the water loss rate can be calculated and summarized in Table 15.1. Dividing the effective volume, sensor life due to water loss is also calculated.

Table 15.1. Water loss rate of the sensor and sensor life due to water loss at different temperatures.

	Water Loss Rate, mg/day				Sensor life due to water loss, day			
Sensor No.	1	2	3	4	1	2	3	4
23ºC	-2.26	-2.26	-2.16	-2.28	252	252	263	250
40ºC	-8.97	-8.33	-8.4	-8.57	63	68	68	66

Based on Jay Lauer's study, approximately 80% lead in the sensor is effective. The lead amount in the sensor is approximately 10g. A sensor output about 250 µA in air at 23ºC and about 330 µA in air at 40ºC. According to equation (3.1), the life time due to lead consumption at different condition can be calculated and is listed in Table 15.2.

Table 15.2. Calculated life time due to lead consumption at different conditions.

Conditions	Calculated sensor life due to lead consumption, day
At 23ºC in 21% oxygen	375
At 23ºC in 50% oxygen	160
At 40ºC in 21% oxygen	288
At 40ºC in 50% oxygen	122

Tables 15.1 and 15.2 show the estimated life of the sensor. In real application, both water loss and lead consumption can limit the sensor life. Whichever come first will end the sensor's normal operation.

V

EFFECTS OF ANESTHETICS AGENTS on TELEDYNE ANALYTICAL SENSORS

Compliance with ISO 7767 (1997),
Anesthetic Agents (Section 11.1)

HISTORY-

The effect of anesthetic agents on electrochemical sensors has been known for some time. Standards have been written defining the permissible errors since l979, ANSI A79. 10-1979. This standard was withdrawn and replaced with ISO 7767 (dated Dec 1988). ISO 7767 was revised in May of 1997. It was not until this last standard change, that the testing was modified to change the carrier gas for testing, from 100% oxygen to a mixture of 30% oxygen/70% nitrous oxide.

It was found early on that the errors, due to the presence of anesthetic agents, were significantly less in 30% oxygen than in 100% oxygen (this is the normal gas mixture into which the various anesthetic agents are vaporized). The T4 data was obtained in 1983, the R15 and C1(R) data in 1985 and the UFO130 data in September of 1997. All of these data were collected using 100% oxygen as the background gas. Only the R-24 data (which was taken in mid 1995) was run using the 30% oxygen/70% nitrous oxide mixture (anticipating the release of the revised ISO standard).

The concentration of the various agents used in the tests varied considerably. This was due to the fact that earlier drafts and standards used concentrations that were less, due to the opinions of individuals on the writing committees at the time. There was also debate as to whether to use induction or maintenance levels in the testing.

ANALYSIS OF THE DATA (Refer to attached Table)-

For purposes of comparison, since the most current standard uses 30% oxygen/70% nitrous oxide as the background mixture, those data taken in 100% oxygen were factored down by 50% (worst case). In those few instances where data was taken in both backgrounds (see R-24 data), the factors ranged from 10.5% (in 20% Desflurane) to 50% (in 6% Enflurane).

The following relationships were observed:

1) The errors are not directly proportional to the oxygen concentration, but the errors are less at 30% oxygen than 100% by the above observed factors.

2) The error vs agent concentration is not linear (e.g. in the case of R-24s in Halothane, the errors at 4 % are greater than those at 6%).
3) All agents produce negative errors, implying the same or similar mechanism.
4) All exposure vs time charts for all agents show a slow increase in error over the 2 hour test period, followed by a similar or longer recovery period. (Further evidence of a similar mechanism).
5) All errors in the 30% oxygen/70% nitrous oxide background (actual and worst case calculated) are less than the ±2% oxygen allowed by the ISO 7767 (1997) Standard.

EQUIVALENCY-

Data from the above agent tests can be extrapolated to medical sensors that are essentially identical to those actually tested. The differing feature(s) is specified in the "Same as Except" column of following table:

Oxygen Sensor	Equivalent to	Same as Except
C1R	C1	Has wires attached to contact plate.
C2R	C1	Same as above, plus internal diffusion barrier for improved life in nitrous oxide.
R13	T4	Galvanically driven rather than polarographically, KCl electrolyte rather than KOH. Has identical cathode structure and temperature compensation method.
R15	N/A	Actually tested
R17MED	R24	Proportionally larger (same cathode size and sensing membrane), different connector.
R22MED	R24	Proportionally larger (same cathode size and sensing membrane),
R23*	R15	Dual Cathode (two semi circles) in place of single cathode
R24MED	R24	No difference. Actually tested.
R29MED*	N/A	N/A
T1	C1	Label
T2	C1	Same as C1 except has internal diffusion barrier.
T4	N/A	Actually tested
T7	R24	Proportionally larger (same cathode size and sensing membrane), different connector.
UFO130	N/A	Actually tested

*Purchased Part/Private Labeling

Reading Errors Observed in TAI Medical Electrochemical Oxygen Sensors in Various Anesthetic Agents

Sensor	Agent	Conc (%)	Error In 100% O2 (-% O2)	In 30% O2, 70% N2O (-%O2)	In 30% O2, 70% N2O (calculated)*	Sens Memb Thickness (mils)
T-4	Halothane	1.5	3.5		**1.75**	0.6
	Isoflurane	3	3		**1.5**	0.6
	Enflurane	3	2.7		**1.35**	0.6
R-24MED	Halothane	6	3.4 - 3.6	**0.9 - 1**		0.5
	Halothane	4		**1 - 1.2**		0.5
	Halothane	3		**0.6 - 0.7**		0.5
	Isoflurane	6		**0.9 - 1.3**		0.5
	Isoflurane	5	2.6 - 3.6	**1 - 1.1**		0.5
	Enflurane	6	1 - 1.8	**0.5 - 0.7**		0.5
	Sevoflurane	7		**1.1 - 1.3**		0.5
	Sevoflurane	6		**1.1 - 1.3**		0.5
	Sevoflurane	5		**1.1 - 1.3**		0.5
	Desflurane	20	1.9 - 2.2	**0.2 - 0.5**		0.5
	Desflurane	15		**1.1**		0.5
R-15	Halothane	3	2.3		**1.2**	0.75
	Isoflurane	1.4	0.7		**0.4**	0.75
	Enflurane	2.8	1.5		**0.8**	0.75
C-1(R)	Halothane	5	2		**1.0**	1.5
	Isoflurane	5	2		**1.0**	1.5
	Enflurane	3	1		**0.5**	1.5
UFO 130	Halothane	5.42	2.0-2.7		**1.4**	0.2
	Isoflurane	4.96	1.6 - 2.2		**1.1**	0.2
	Enflurane	5	1.2 - 1.9		**1**	0.2

*Error in 100% O2/2

VI

SENSOR LIFE FOR THE MEDICAL OXYGEN SENSORS

The medical oxygen sensor is based on an electro-chemical system with a noble metal such as rhodium as the cathode, lead as the anode, and an aqueous solution of potassium hydroxide as electrolyte. Figure 1 is a schematic showing a cross-sectional view of the sensor.

In the presence of oxygen, the sensor creates a current that flows from cathode to the anode as a result of the following electro-chemical reactions:

Cathode: $O_2 + 2H_2O + 4e^- \rightarrow 4OH^-$

Anode: $2Pb \rightarrow 2Pb^{2+} + 4e^-$

Water and lead are two consumables inside a sensor. The medical oxygen sensor is designed to have enough water to last. The amount of lead is the limit of sensor life. Therefore, the sensor life can be calculated according to the following equation:

$L = 3.59 \times 10^{-4} W_{Pb}/i$ *

Here, L is the life time of a sensor in the unit of month; 3.59x10-4 is a constant deduced from Faraday law (see appendix); W_{Pb} is the amount of lead inside the sensor in the unit of grams; i is the current through the sensor in the unit of ampere. The higher the current i, the shorter the sensor life L. When substitute i with the sensor current in air, the equation give the sensor life time in month/air; when substitute in I with the sensor current in 100% oxygen, the equation give the sensor life time in month/100%oxygen.

Appendix

* Faraday law: Q = nFM

Q is the charge in coulomb; n is the number of electron transfer per molecule, for the lead electrode n=2; F is the Faraday constant, 96500; M is the quantity of material in unit of mole; For the lead electrode $M = W_{Pb}/207$; W_{Pb} is the weight of lead in grams.

On the other hand, Q = i x L. i and L is the current and time, respectively.

Therefore, $L = 2 \times 96500/207\ W_{Pb}/i = 932\ W_{Pb}/i$ (seconds)

Or $L = 3.59 \times 10^{-4}\ W_{Pb}/i$ (months)

NOTE: The above equation assumes one hundred percent usage of the lead electrode. For conservative consideration, 70% anode efficiency should be used to estimate the sensor life.

Table: Expected Life Calculation assuming 70% lead anode efficiency and 25 deg. C

Sensor	Amount of Lead, in grams	Air Current, in microamps	Expected life in Air, in months
C1R	15	240	18
C2R	8	240	10
R13 *	NA	0.4	12
R15	14	70	36
R17MED	14	127	40
R22MED	14	127	40
R23	NA	30	33
R24MED	10	118	24
R29MED	NA	NA	24
T1	15	240	18
T2	8	240	10
T4 **	NA	0.4	NA
T7	14	157	29
UFO130	10	340	6

* Galvanically driven rather than polarographically, KCl electrolyte rather than KOH.
** Polarographically driven rather than Galvanically, KCl electrolyte rather than KOH. Life is determined by the amount of water loss from the KCl electrolyte.

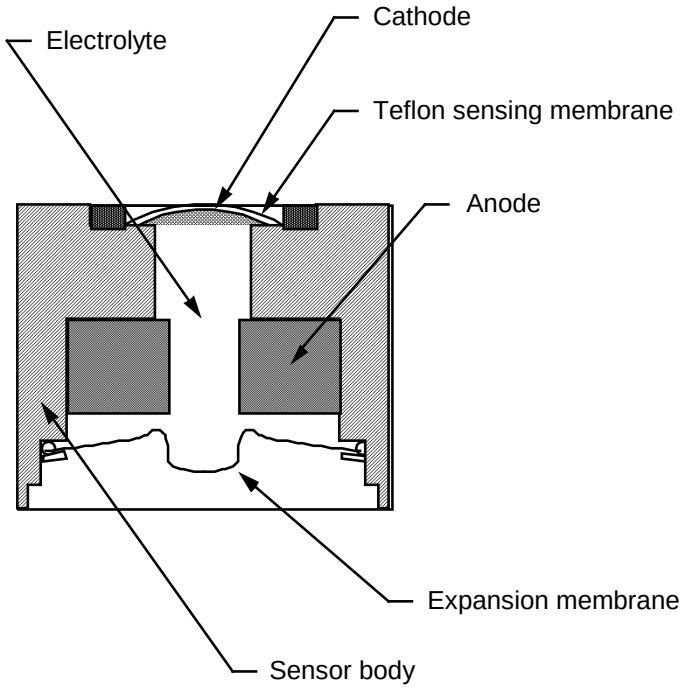


Figure 1