MICRO-FUEL CELL*
CLASS B-1, C-1, & C-2

INSTRUCTION MANUAL

NOTE

The instructions contained herein supersede all previous test and maintenance information, written and verbal. These instructions can only be changed by a Teledyne supersedure notice, dated and signed.

THIS INSTRUCTION MANUAL IS PREPARED SPECIFICALLY FOR: _____

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* U.S. Patent Nos. 3,429,796 and 3,767,552

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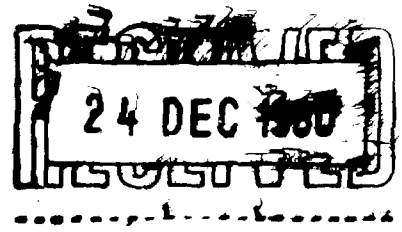

TELEDYNE ANALYTICAL INSTRUMENTS

1. GENERAL

The TAI Micro-Fuel Cell (see Figure 1) is a sealed, disposable electrochemical transducer that provides oxygen sensing capability useful in general hospital applications. The cell has no electrolytes to change or electrodes to clean. It is maintenance-free; when the cell reaches the end of its useful life, it is replaced like the battery in a flashlight. The Micro-Fuel Cell will operate at relative humidities from 0 to 100%, barring excessive condensation.

Oxygen in the gas space surrounding the cell diffuses through a Teflon membrane and is reduced on the surface of the cathode. A corresponding oxidation occurs at the anode. An electrical current that is generated is proportional to the concentration of oxygen. Output is limited only by the rate at which oxygen enters the cell and by the amount of anode material stored within. This linear, current output is sufficient to drive microammeters directly or, after amplification, to perform more complicated analog functions.

The Micro-Fuel Cell is designed to give long-term reliable performance and to respond rapidly to changes in oxygen concentration. Useful life of the cell depends upon the length of time it is exposed to oxygen and the magnitude of the oxygen concentration. In air (20.9% O_2), the cell provides from 3 to 18 months of life, depending upon its class (see para. 2, Specifications). If left in its environmental gas barrier bag, life expectancy of the Micro-Fuel Cell will deteriorate only a small fraction of its "in air life" per year. A shelf life of 1 year and more is common. The 90% response time of the Micro-Fuel Cell is from 7 to 30 seconds and is also dependent upon the class of cell that is utilized.

The Micro-Fuel Cell is designed to withstand shock, vibration and movement. However, excessive G-forces may cause erratic readings and/or damage. Since oxygen sampling is diffusion controlled (through the membrane), the rate at which the sample gas flows over the cell is not critical. Flow rates in the range of 0.1 to 10 liters/minute cause no change in the reading, provided that no significant backpressure is produced.

2. SPECIFICATIONS

Application	Medical*
Analytical Range	0 to 100% O_2
Sensor	Micro-Fuel Cell: Class B-1,C-1,C-2
Response Time	B-1: 90% in 7 sec. C-1: 90% in 30 sec. C-2: 90% in 30 sec.
Warranty	B-1: 6 months C-1: 12 months C-2: 3 months
Output at 25°C (in air) - nominal	B-1: 500 microamp. C-1: 200 microamp. C-2: 200 microamp.
Accuracy**	±1% of full scale, nominal
Oper. Temp. Range	32°F to +131°F (0°C to +50°C)
Temperature Compensation	Dependent upon system utilized (see para. 3)
Weight	30 grams (without shorting clip)

* The C-2 Micro-Fuel Cell is specifically designed for anesthesia applications.

** Statement of accuracy is based upon the capabilities of the TAI supplied components, and is contingent upon the stability and/or accuracy of customer-supplied components and/or circuitry.

3. TEMPERATURE COMPENSATION

To insure operational accuracy of the Micro-Fuel Cell, it is necessary that the output of the cell be completely independent of temperature variations, i.e., temperature compensated. The exact compensation network and its installation is dependent upon the application and configuration of the cell and/or cell holder or probe. When properly located, accuracy of the cell should be ±1% of full scale over the operating temperature range (see para. 2, Specifications). If temperature compensation is to be performed by customer personnel, TAI should be contacted for guidance.

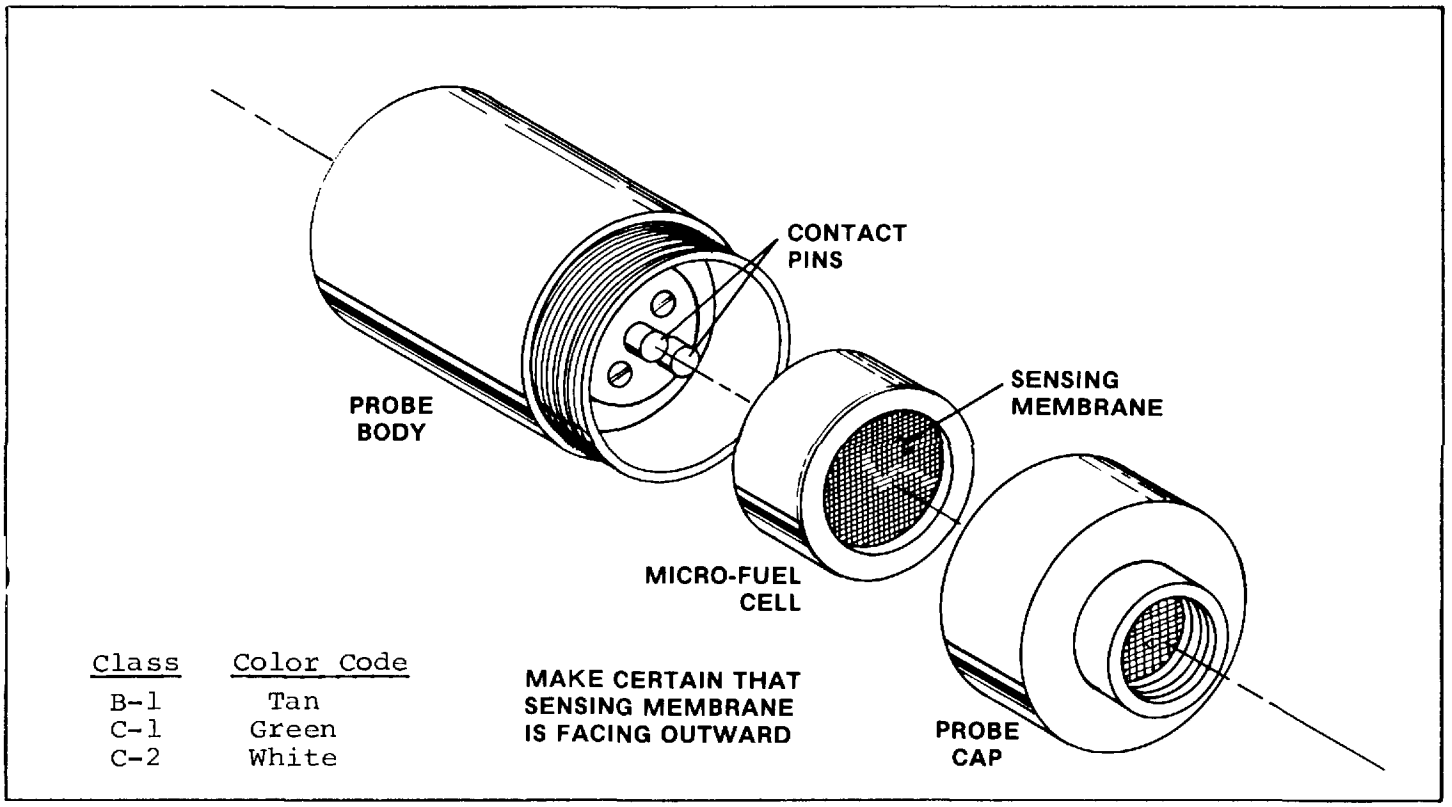

Figure 1. Micro-Fuel Cell

4. RECOMMENDED OUTPUT CIRCUITS

For most applications, the electronic output network is established by the user. A two-stage amplifier circuit is recommended if the user requires a variable-range capability and temperature compensation (see Figure 2).

The first stage is an I-to-E converter whose negative feedback loop is used to facilitate range change. The second amplification stage is used to affect temperature compensation. To complete the amplification circuitry, it is only necessary to provide span (or calibration) and readout capability.

For single-range low-power applications, amplification may be unnecessary or only a single amplification circuit will suffice (see Figure 2).

5. REMOVAL OF SHORTING CLIP

The shorting clip provides a current loop, assuring that the cell is ready for immediate use when placed into an analyzer. If the clip is not installed, oxygen will diffuse into the cell until the electrolyte is saturated. In this condition, it may be necessary to wait a considerable length of time before placing the cell into an operating situation.

NOTE: If the shorting clip has been removed from a cell for some time, placing the cell into service will result in the readout indication being driven off-scale. The user can either remove the cell from his instrument and short its output with a shorting clip, or leave the Micro-Fuel Cell installed in the analyzer with its output shorted (with power "off"). In either case, it will be necessary for the cell to equilibrate to an unsaturated state before placing it into service. For every hour the cell has been unshorted, approximately one hour will be required for stabilization.

To remove the shorting clip, pull it off from the top first, then down and away from the cell body (see Figure 3). If the shorting clip is first pulled off the bottom of the cell, there is a danger that the membrane will be punctured.

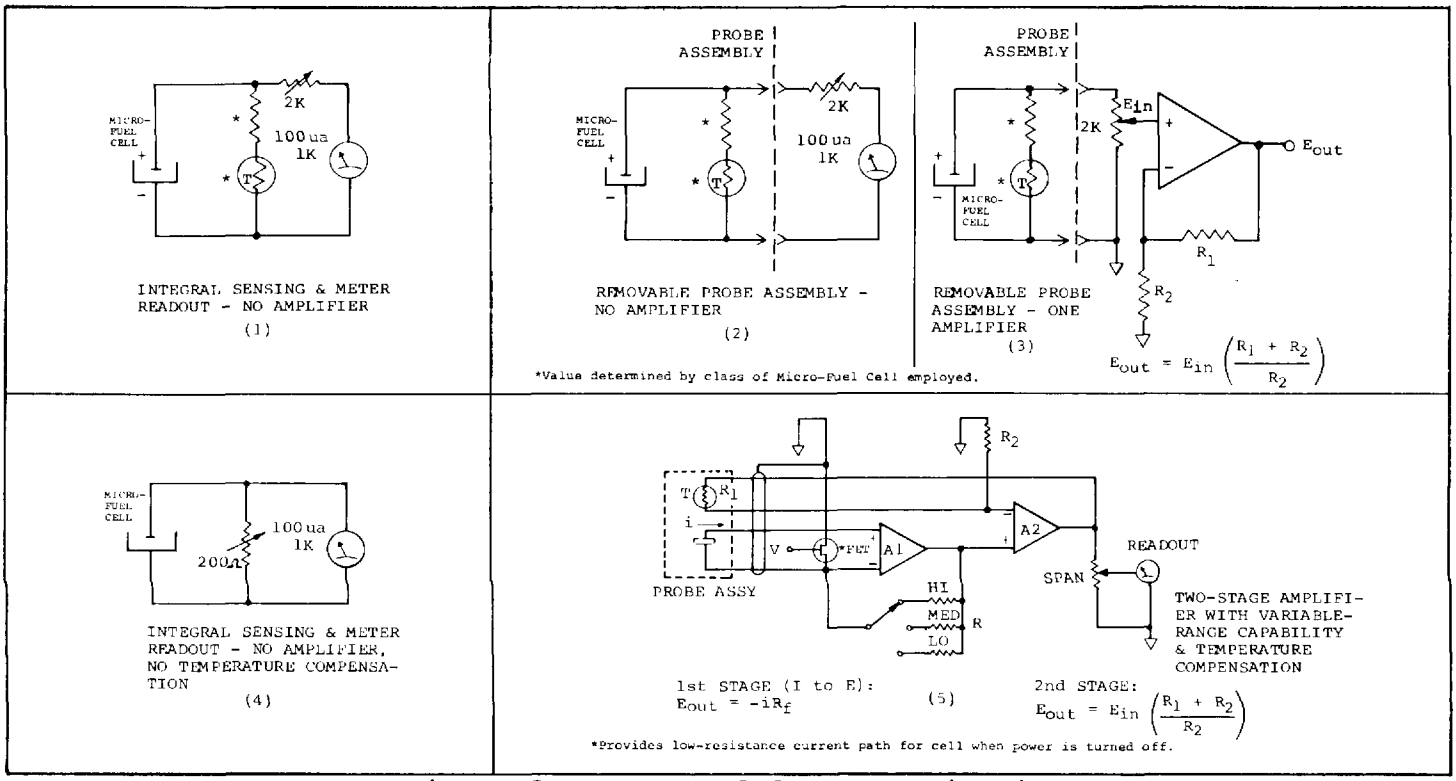

Figure 2. Recommended Output Circuits

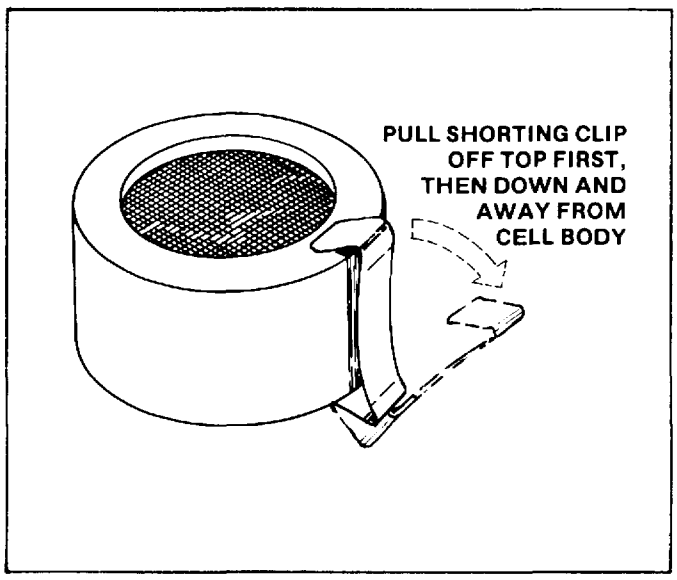

Figure 3. Removal of Shorting Clip

CAUTION: If the membrane is punctured for any reason, lay cell to one side. Then wash hands and any other parts of body or clothing that might have come into contact with the liquid (KOH solution) within the cell. Use copious quantities of water. The cellular liquid is a strong caustic and can cause severe burns.

6. CELL LEAKAGE

Cell leakage is covered by warranty if determination is made during the warranted life of the cell. Certain requirements, however, must be met:

1. Cell leakage determination must be made before the transparent barrier bag housing the cell is opened. Under no circumstance will a cell with a perforated membrane be considered for warranty replacement once the original seal on the barrier bag has been violated.

2. If the electrolyte liquid within the cell is visible anywhere on the cell or within the barrier bag, or if crystal growth is visible anywhere on the sensing membrane of the cell, or if the solder points on the printed circuit contact plate appear blackened, the cell is leaking. It will be replaced upon return to TAI after warranty confirmation.

IMPORTANT: Crystal development around the wire sealing plugs on the circumference of the cell do not in themselves constitute a valid warranty claim for leakage.

7. STORAGE CONSIDERATIONS

Long-term storage of the Micro-Fuel Cell should be avoided. Warranty protection begins from the date of shipment from TAI. Careful adherence to a stock rotation system is absolutely essential. Stock rotation should be based upon a "first in, first out" basis.

Never remove the Micro-Fuel Cell from its barrier bag until ready for use or testing. This will ensure maximum longevity of the cell. Cells should be returned to their barrier bags (with shorting clips installed) and the bags sealed as soon as testing is completed.

In order to reseal the original barrier bag, the bag must be opened by cutting it with scissors close to one of the original sealing seams. There are a number of commercial sealers that can be used; if desired, TAI will recommend specific types and manufacturers.

8. TESTING PROCEDURE

Prior to shipment from TAI, each Micro-Fuel Cell is subjected to a thorough inspection and test program. If the user desires to repeat this program, a Teledyne Model 1020 Micro-Fuel Cell Test Fixture (see Figure 4) must be employed. This fixture will give the user the ability to establish a quality assurance program that meets all testing criteria of Teledyne Analytical Instruments.

Prior to commencing the test, inspect the Micro-Fuel Cell while it is still sealed within the barrier bag. Check for evidence of physical damage and the possible perforation of the sensing membrane. Pay particular attention to the area where the membrane is sealed to the cell body. Leakage of electrolyte is difficult to detect; the liquid is clear, although eventually it will form crystals. If leakage is observed, return Micro-Fuel Cell to Teledyne for warranty replacement (refer to step (7) of procedure following).

Perform test procedure as follows:

(1) Check test fixture batteries by setting the selector switch to the BAT. TEST position. The meter pointer should indicate within the BAT. OK area. If not, replace the batteries.

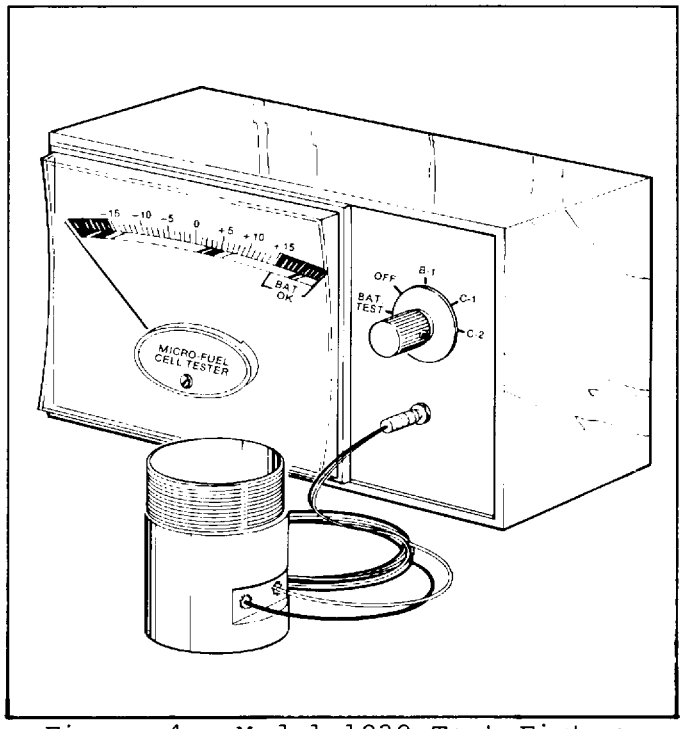

Figure 4. Model 1020 Test Fixture

(2) Remove the Micro-Fuel Cell from its barrier bag (refer to para. 7). Detach shorting clip from the cell (refer to para. 5 and Figure 3).

(3) Place cell to be tested into tester probe. Make certain that the membrane surface is facing out or upward. Do not install the oxygen cell upside down.

(4) Set selector switch to the position that corresponds to the cell class being tested: B-1, C-1 or C-2.

(5) Depress cell in probe so that a good electrical connection is made between the cell contact plate and spring-loaded contacts within the probe.

CAUTION: Observe caution not to scratch or damage the sensing membrane. Always press down on the lip around the membrane, not directly on the membrane.

(6) The meter indicator should indicate within the +15 and -15 "window" area. A satisfactory test result will assure that the cell has a normal output and that response times are within specification. If test results are within

acceptance criteria, remove cell from probe and discontinue testing. If cell fails test, refer to para. 10, Trouble Shooting.

(7) If the cell appears to be undamaged, and all efforts for remedial action still cannot bring about a satisfactory test, return cell to TAI for warranty determination.

IMPORTANT: Those cells that are returned to TAI because tests indicate high, low, or no output, as determined by the test fixture, must be re-equipped with their shorting clips and resealed in their original barrier bag containers. The serial number engraved on the contact plate of the cell must be in agreement with the tag serial number within the bag to qualify for warranty consideration. TAI warranty claims will be disallowed if, upon inspection, it is determined that physical damage to the cell was incurred after initial shipment by TAI.

9. APPLICATION CONSIDERATIONS

High Humidity - The Micro-Fuel Cell is designed to operate in a 100% relative humidity. If reasonable care is taken to keep the sensing surface of the cell out of condensate buildup, high humidity environments pose no special problems. Never install a Micro-Fuel Cell in a breathing circuit so that the sensing surface is immersed in a condensate stream (see Figure 5). However, if the membrane should become immersed in water during test or operation, blot it dry with a cotton swab or soft absorbant tissue.

Pressure Sensitivity - All electrochemical oxygen sensors respond to partial pressure changes of oxygen; thus, they are all pressure sensitive. In any test or operation application, make certain there is a continuous flow of oxygen (or air) past the sensing surface of the Micro-Fuel Cell. Oxygen must flow past the cell and exit freely (see Figure 5). Make certain that any setup allows for proper venting.

Recommended flow rate is 1 to 2 liters/minute, although rates as high as 10 liters/minute can be tolerated as long as backpressure is not created. Excessive flow rates can create backpressure, especially if the test or operational setup is improperly vented.

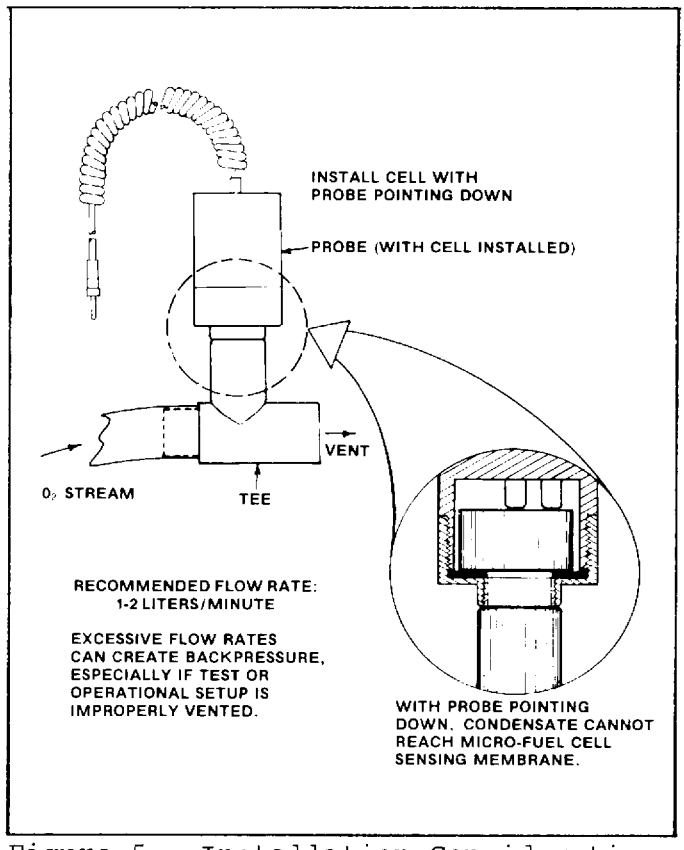

Figure 5. Installation Considerations

Cell-to-Probe Installation - When installing the cell in the probe housing (see Figure 1), make certain that the sensing membrane is facing up (or outward) and the shorting clip is removed. Do not install the oxygen cell upside down as the cell will be damaged. Also, when installing the cell, observe caution not to scratch or damage the sensing membrane. Always press down on the lip around the membrane, not directly on the membrane.

Position Sensitivity - Some cells will exhibit a sensitivity to position or motion. This is normal. This is due to the momentary change in the sensing membrane spacing relative to the sensing electrode. The excursion is nominally ±2 to ±5% of reading, and the reading normally returns to the original reading after the movement of the Micro-Fuel Cell ceases.

Disinfecting - TAI's recommended solutions for disinfecting the Micro-Fuel Cell are either:

(1) Sonacide (potentiated acid glutaraldehyde) - Ayerst Laboratories

(2) Cidex (activated dialdehyde) - Arbrook Inc.

To disinfect the cell, dip it for one (1) minute, minimum, in either of the solutions noted. Then, using a soft absorbant tissue, blot dry the sensing membrane. Place the cell on a paper towel (membrane side up) for 10-15 minutes to allow any solution trapped between the contact plate to drain.

Sterilization - For complete sterilization to destroy various tubercle bacilli and resistant spores, use either Sonacide or Cidex, although Cidex is preferred if time is not a factor (see below).

If Sonacide is used, immerse and maintain the cell at 60°C (+122°F) for 60 minutes.

CAUTION: Do not autoclave or subject the Micro-Fuel Cell to temperatures above 150°F (65°C). Excessive temperatures will damage the cell.

NOTE: After using Sonacide for one (1) hour, a brown ring may be observed under the white hydrophobic sensing membrane. This discoloration will have no effect on performance or cell life.

If Cidex is used as a sterilization agent, immerse the cell for a period of 10 hours (overnight), minimum. Heating is unnecessary when using Cidex.

NOTE: Because heating is unnecessary when using Cidex, this solution is preferred for sterilization. However, the time factor is 10 times greater when using Cidex instead of Sonacide.

Following sterilization of the Micro-Fuel Cell, blot it dry with a cotton swab or soft absorbant tissue. Place the cell on a paper towel (membrane side up) for 10-15 minutes to allow any solution trapped behind the contact plate to drain.

NOTE: Directions for sterilization are plainly and simply described on each solution container. These printed directions should be followed explicitly.

10. TROUBLE SHOOTING

Erratic Readings - Check the following:

(1) Make certain that the cell is properly installed in the probe and that sufficient finger pressure is applied to assure good cell-to-probe electrical contact. (See precautionary note in step (5) of para. 8.)

(2) Check for any physical damage to the Micro-Fuel Cell (see para. 6).

(3) Check contacts on cell contact plate and mating contacts in cell holder (probe) for cleanliness. Clean, if required.

High Output - Check the following:

(1) Verify that cell has been at the proper temperature (25°C)) for a minimum of 8 hours.

(2) Install shorting clip and wait a minimum of 8 hours before retesting. (**NOTE:** Improper installation of the shorting clip may cause high resistance contact and subsequent high output.)

(3) Check that selector switch on test fixture is set to a position corresponding to the cell class.

Low Output - Check the following:

(1) Verify that cell has been at the proper temperature (25°C) for a minimum of 8 hours.

(2) Inspect sensing membrane for damage.

(3) Check that selector switch on test fixture is set to a position corresponding to the cell class.

Output Drifts toward Zero - Check the following:

(1) Micro-Fuel Cell has reached the end of its useful life. Replace cell.

(2) Install shorting clip and wait a minimum of 8 hours before re-testing.

Zero Output - Micro-Fuel Cell has reached the end of its useful life. Replace cell.

11. WARRANTY EVALUATION PROCEDURES

Teledyne Analytical Instruments offers a limited warranty evaluation program. Customers are required to prescreen cells to determine their factory warranty status. Those customers with warranty claims must contact Teledyne Analytical Instruments and obtain a Return Material Authorization Number. When requesting an RMA Number, customers must be prepared to supply the quantity of material being returned, description, reject ticket number, and shipper number. Date of the request will be date used in evaluating a given cell's qualification under warranty. After return authorization is granted and the cell or cells in question have been returned for evaluation, and it is determined that cell failure is due to faulty workmanship or parts, the cell or cells so classified will be reworked or replaced at no cost to the customer. If, upon inspection, there is evidence of tampering or damage through mishandling or misapplication, the warranty will be voided. Unless otherwise specified, all cells found to be out of warranty will be segregated, tagged with Teledyne's findings, and returned, using the document shown in Figure 6.

WARRANTY REPORT

Report No._____ Date _____

Customer _____ Address _____

P. O. No._____ Debit No._____

Shipping Ticket No. _____ Receiving Record No._____

Our Customer Service Department has evaluated the_____sensor(s) returned for warranty evaluation and we have summarized their findings below.

UNDER WARRANTY

Qty_____display no indication of failure and are functional within specifications

Disposition: Return to Customer

Qty_____Out of specification

Disposition: Customer instructions: Replace ___ Credit _____

*Total Credit_____ See Attached _____

OUT OF WARRANTY

Qty_____Display no indication of failure and are functional within specifications. NOTE: useful life remaining in sensors under this category is questionable and cannot be determined without destructive analysis.

Disposition: Return to Customer

Qty _____low or zero output. Useful life has been exhausted.

Disposition: Customer instructions: Return__Destroy__Replace_____

Qty _____ Physically damaged beyond repair and, therefore, no further evaluation is possible.

Disposition: Customer instructions: Return _ Destroy _ Replace_____

If there should be any questions related to this evaluation, please contact the undersigned.

Sincerely,

TELEDYNE ANALYTICAL INSTRUMENTS

* To insure that proper credit is issued please reference this report number on your next order.

Figure 6. Warranty Report (original size: 8½" x 11")

12. ENCAPSULATION OF CELL

If the cell is to be encapsulated or installed in a housing, caution should be taken to ensure that it has sufficient space for thermal expansion. Failure to allow for this phenomenon will result in output drift due to distortion of the sensing membrane.

13. SOLDERING ON CONTACT PLATE

Excessive heat on the contact plate may damage the cell. Any soldering that is done must be accomplished quickly in order to reduce excessive heat buildup.