

574-6

1 of 38

|   |  |                  |
|---|--|------------------|
| U.S. ENVIRONMENTAL PROTECTION AGENCY<br>OFFICE OF PESTICIDES PROGRAMS<br>REGISTRATION DIVISION (WH-567)<br>WASHINGTON, D.C. 20460 | EPA REGISTRATION NO.<br>5749-6                                       | DATE OF ISSUANCE |
|   | TERM OF ISSUANCE<br><b>11 FEB 1985</b>                               |                  |
|   | NAME OF PESTICIDE PRODUCT<br>Ampro 100 System Fungicide<br>Sterilant |                  |

**NOTICE OF PESTICIDE:**  REGISTRATION  
 REREGISTRATION  
 (Under the Federal Insecticide, Fungicide,  
 and Rodenticide Act, as amended)

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

American Sterilizer Company  
 2424 West 23rd Street  
 Erie, PA 16514

**NOTE:** Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with Title 40, CFR 155.101(a) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

2. Make the following changes in the label:

- a. Add the phrase "EPA Registration No. 5749-6."
- b. You are reminded that the EPA Establishment Number must appear in a suitable location on the label or on the immediate container.
- c. Delete the number "xxxxxx" from the label. This is your registration number.
- d. Place the word "STERILANT" to appear directly below the product name.

KEEP OUT OF REACH OF CHILDREN

ATTACHMENT IS APPLICABLE

|                                 |      |
|---------------------------------|------|
| SIGNATURE OF APPROVING OFFICIAL | DATE |
|---------------------------------|------|

**BEST AVAILABLE COPY**

e. Change the statement: Eye Protection to read: "Safety goggles or glasses."

f. Move the statements:

IN CASE OF FIRE USE WATER ONLY. IN CASE OF SPILL OR LEAK FLOW AWAY BY FLOODING WITH WATER APPLIED QUICKLY TO THE ENTIRE SPILL OR LEAK.

to the "Physical and Chemical Hazard" section.

g. Add the following statements:

Harmful or fatal if swallowed. Do not get in eyes.

to the precautionary statement section (first paragraph).

3. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 Enclosure for a further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(a). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

John H. Lee  
Product Manager (31)  
Manufacture Branch  
Registration Division (TS-767C)

Enclosures

JOB-90879;Wilson;Kendrick & Co.;898-1270;tax:1/1/85;del.2/11/85;RD-19

BEST AVAILABLE COPY



# hydrogen peroxide sterilant

ACTIVE INGREDIENT  
Hydrogen Peroxide ..... 30%  
INERT INGREDIENTS ..... 70%

**DANGER**  
**KEEP OUT OF REACH OF CHILDREN**

STATEMENT OF PRACTICAL TREATMENT: IN CASE OF CONTACT IMMEDIATELY FLUSH AFFECTED AREA WITH PLENTY OF WATER FOR AT LEAST 15 MINUTES. CALL A PHYSICIAN. REMOVE AND WASH CONTAMINATED CLOTHING AND SHOES PROMPTLY AND THOROUGHLY. IF SWALLOWED DRINK PLENTY OF WATER. IN CASE OF FIRE USE WATER ONLY. IN CASE OF SPILL OR LEAK FLUSH AWAY BY FLOODING WITH WATER APPLIED QUICKLY TO THE ENTIRE SPILL OR LEAK.

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

8.45 FL. OZ. (250 ML) NOT FOR SALE OR USE AFTER

**PRECAUTIONARY STATEMENTS**

HAZARDS TO HUMANS AND DOMESTIC ANIMALS: CORROSIVE. IRRITATION TO EYES, SKIN, NASAL PASSAGES, THROAT, LUNG ORGANS. WEAR RUBBER OR VINYL GLOVES AND EYE PROTECTION.

PHYSICAL AND CHEMICAL HAZARDS: STRONG OXIDIZER. AVOID CONTACT WITH COMBUSTIBLE MATERIALS. DRYING OF THIS PRODUCT ON COMBUSTIBLE MATERIALS MAY CAUSE FIRE. AVOID CONTAMINATION INCLUDING METALS, DUST AND ORGANIC MATERIALS. SUCH CONTACT MAY CAUSE RAPID DECOMPOSITION, GENERATION OF LARGE QUANTITIES OF GAS, AND HIGH PRESSURES.

**DIRECTIONS FOR USE**

GENERAL CLASSIFICATION: IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

THIS PRODUCT IS INTENDED FOR STERILIZATION OF INSTRUMENTS AND LONG NARROW LUMENS, WHEN USED ONLY IN AMSCO HYDROGEN PEROXIDE STERILIZER AS DIRECTED IN THE EQUIPMENT MANUAL. ONLY THE AMSCO STERILIZER MAY USE THIS PRODUCT AS DIRECTED.

**STORAGE AND DISPOSAL**

STORAGE: STORE IN ORIGINAL CONTAINER AT ROOM TEMPERATURE. REFRIGERATED.

DISPOSAL: EMPTY BOTTLE SHOULD BE FLUSHED WITH WATER BEFORE DISPOSAL.

MANUFACTURED BY AMERICAN STERILIZER COMPANY  
EPA REG NO. XXXXXX EPA E

**BEST AVAILABLE COPY**

LABEL: HYDROGEN PEROXIDE SOLUTION

ACC  
with  
EPA  
  
FEB  
Unit -  
Purpos  
as amend  
registered u  
5

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

FEB 11 1985

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.

5749-6

Operator Exposure

PEROXIDE VAPOR CONCENTRATION  
IN AND AROUND THE  
AMSCO HYDROGEN PEROXIDE STERILIZER

INTRODUCTION

Human exposure to hydrogen peroxide vapors might occur in only two situations during operation of the AMSCO Hydrogen Peroxide Sterilizer:

1. At completion of the cycle, when the door is opened and the load removed,
2. If the cycle is interrupted, and the sterilizer opened, after hydrogen peroxide has been injected into the sterilizer.

In practice, the second situation is equivalent to the first, because the automatic controller performs the same peroxide purging steps whether the cycle is interrupted or completes normally.

Other conceivable situations will not result in human exposure to hydrogen peroxide vapors. Leaks in the chamber are not a hazard, because the sterilizer is operated at subatmospheric pressure. Air could leak into the sterilizer, but nothing would leak out of the sterilizer. Peroxide vapors might conceivably pass through the vacuum pump and into the room air. However, our experience has been that most of the water vapor is condensed and collected in the pump. Since hydrogen peroxide is about an order of magnitude less volatile than water, it is hard to imagine that any significant amount of hydrogen peroxide could pass through the pump. Even if some did pass through, it would probably be absorbed in the paper filter element at the pump vent.

To illustrate the range of exposure levels possible, concentrations have been calculated which might exist inside the closed chamber and in a hypothetical 1000 ft<sup>3</sup> unventilated room into which the sterilizer is vented.

THE STERILIZATION CYCLE

The current AMSCO Hydrogen Peroxide Sterilizer has an internal volume of 49 L (1.7 ft<sup>3</sup>) and operates at an internal temperature of about 64 °C (147 °F) and an absolute air pressure of 10 mm Hg. Sterilant injection is controlled by chamber pressure. Injection ceases when the combined partial pressures of peroxide and water vapors, and air, reach 45 mm Hg. The maximum concentration of peroxide vapor inside the closed sterilizer will not exceed 11 mg/L. If air were allowed to fill the chamber to atmospheric pressure, without prior evacuation of the peroxide, the 11 mg/L peroxide vapor would translate to 8,940 ppm (v/v) inside the chamber. The cycle finish includes three air fill and evacuation sequences, which reduce the peroxide vapor concentration in the chamber by a factor of about 0.000225. The evacuation steps draw the peroxide and water vapors out of the chamber and into the vacuum pump, where the vapors condense and mix with the vacuum pump oil. Much of the peroxide harmlessly decomposes to water and

oxygen. The remainder is removed with the water when it is (daily) drained from the pump.

If the load is cooler than 64 °C, some condensation of peroxide vapors may occur, resulting in the injection of additional AMSCO Hydrogen Peroxide Sterilant to reach the required pressure rise. Experience has shown that about 13 mg hydrogen peroxide is injected per liter of chamber volume when a full load is initially at room temperature. For the purpose of worst-case illustration, 15 mg/L will be used.

### EFFECT OF AIR FILL AND EVACUATION STEPS

Filling the chamber with air, then evacuating to a low pressure reduces the peroxide vapor concentration by a factor equal to the ratio of the evacuated and full pressures. Repetition of fill and evacuation sequence reduces the peroxide concentration by the same factor each time. The final concentration is

$$C_f = C_i \cdot d^y$$

- where  $C_f$  = the final peroxide vapor concentration,
- $C_i$  = the initial peroxide vapor concentration,
- $d$  = the dilution factor (evacuated/full),
- $y$  = the number of repeat fill and evacuation steps.

For the AMSCO Hydrogen Peroxide Sterilizer,  $y = 3$  and  $d = 45/740 = 0.0608$  (assuming atmospheric pressure of 740 mm Hg).

### MAXIMUM EXPOSURE LEVELS

The following table provides the maximum vapor concentrations a person might encounter in the sterilizer and in a hypothetical unventilated, 1000 ft<sup>3</sup> room which receives the vapors from an opened 2 ft<sup>3</sup> sterilizer. The minimum and maximum possible injection amounts of hydrogen peroxide are illustrated.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated

FEB 11 1985

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, this pesticide  
registered under EPA Reg. No.

5749-6

8 of 38

MAXIMUM PEROXIDE VAPOR CONCENTRATION IN STERILIZER AND IN CLOSED ROOM

| INJECTION,<br>mg/L | EQUIVALENT<br>CONC. IF<br>IN AIR,<br>ppm | CONC. WHEN DOOR CAN BE OPENED, ppm |                                   |
|--------------------|--|------------------------------------|-----------------------------------|
|                    |  | in 2 ft <sup>3</sup><br>Sterilizer | into 1000 ft <sup>3</sup><br>Room |
| 11                 | 8940                                     | 2.0                                | 0.0040                            |
| 15                 | 12190                                    | 2.7                                | 0.0055                            |

The OSHA permissible exposure level to hydrogen peroxide vapor is 1 ppm, 8 hr TWA, and the short-term exposure level is 2 ppm. The data in the table show that the operator is in no danger of exposure to hazardous levels of peroxide vapors, unless he holds his head in the sterilizer for 10 or 15 minutes after opening the door. There is no reason to expect anyone to do that. In practice, with normal cycles, the concentrations are actually lower than shown in the table, because about half the peroxide vapor decomposes (to water vapor and oxygen) during the five-minute sterilization dwell period.

ALC, 3/14/84

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

FEB 11 1985

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, the pesticide registered under EPA Reg. No.

5749-6

EPHRA  
111111

AMSCO HYDROGEN PEROXIDE  
STERILIZER  
EQUIPMENT MANUAL

ACCEPTED  
with COMMENTS  
EPA Letter Dated:

FEB 11 1965

Under the Federal Insecticide,  
Fungicide, and Fumigant Act  
as amended, for the pesticide  
registered under EPA Reg. No.

5749-10



**CONTENTS**

EPAPR

10 of 38

**1.0 CYCLE DESCRIPTION** . . . . . 1

1.1 General . . . . . 1

1.2 Step by step . . . . . 1

1.3 Safety . . . . . 1

**2.0 INSTALLATION** . . . . . 3

2.1 Summary of Warnings and Cautions . . . . . 3

2.2 Utility and Space Requirements . . . . . 3

2.3 Unpacking . . . . . 3

2.4 Pre-use Checkout . . . . . 4

**3.0 OPERATING INSTRUCTIONS** . . . . . 5

3.1 Before Operating This Equipment . . . . . 5

3.2 AMSCO Hydrogen Peroxide Sterilant . . . . . 5

3.2.1 Precautionary Statements . . . . . 5

3.2.2 First Aid . . . . . 5

3.2.3 Directions for Use . . . . . 6

3.3 Preparation of the Sterilizer . . . . . 6

3.4 Preparation of the Load . . . . . 7

3.4.1 Sterilizable Items . . . . . 7

3.4.2 Wrapping Materials . . . . . 7

3.4.3 Cleaning . . . . . 7

3.4.4 Packages . . . . . 7

3.5 Loading the Sterilizer . . . . . 7

3.6 Sterilization . . . . . 8

3.7 Control Monitoring . . . . . 9

3.7.1 Cycle Status Lights . . . . . 9

3.7.2 Alarm Lights . . . . . 9

3.8 Determining Efficiency of Sterilization Process . . . . . 11

**4.0 PREVENTATIVE MAINTENANCE** . . . . . 12

4.1 Daily . . . . . 12

4.2 Weekly . . . . . 13

4.3 Quarterly . . . . . 13

**5.0 TROUBLESHOOTING** . . . . . 14

**6.0 REPLACEMENT PARTS** . . . . . 15

6.1 Spare Parts List . . . . . 15

6.2 Installing A Chamber Door Gasket . . . . . 15

**7.0 Figures** . . . . . 16

LIST OF ILLUSTRATIONS

11 of 38

- Figure 1. AMSCO Hydrogen Peroxide Cycle . . . . .
- Figure 2. Sterilizer front and left side. . . . .
- Figure 3. Sterilizer Lower Cabinet . . . . .
- Figure 4. Sterilizer, rear view . . . . .
- Figure 5. Vacuum pump . . . . .
- Figure 6. Proper Oil Level . . . . .
- Figure 7. Sterilant Reservoir Bottle in Place . . . . .
- Figure 8. Suggested Wrapping Procedure for Instrument Trays . . . . .
- Figure 9. Manual Vacuum Break Valve . . . . .
- Figure 10. Controls, Status Lights, and Alarm Lights . . . . .
- Figure 11. Bacteria Filter and Prefilter . . . . .
- Figure 12. Door Gasket . . . . .

1.0 CYCLE DESCRIPTION:

FEB 11 1985

Under the Federal Insecticide, Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.

5749-6

1.1 GENERAL

The AMSCO Hydrogen Peroxide Sterilizer is a low temperature, vapor-phase sterilizer for the rapid sterilization of wrapped metal surgical instruments, (such as delicate microsurgical instruments) containing no long narrow lumens. The internal temperature is about 64°C. Cycle completion times are as short as 80 minutes. Extensive testing by AMSCO of the sterilization of these surgical instruments has proven the AMSCO hydrogen peroxide process to be a reliable, noncorrosive, nondulling sterilization method.

The sterilizer is designed to operate automatically, requiring the operator to only load, start, and unload the sterilizer, and to perform a few routine maintenance functions. The sterilization cycle consists of injections of hydrogen peroxide vapors into the evacuated chamber, followed by dwell periods to allow the vapors to penetrate wraps, and to contact and kill any microorganisms. Cycle progress is communicated to the operator by lights indicating ready to begin, currently progressing, and cycle complete. At frequent intervals during operation, internal checks are made of the status of the critical operating parameters: the temperatures of the chamber and the vaporizing unit, the integrity of the chamber vacuum, and the supply of sterilant. If any of these are not correct, a warning light is illuminated, and the cycle is aborted. The load cannot be considered sterile unless the problem is corrected and a new cycle is started, and runs to completion.

1.2 STEP BY STEP

The cycle steps are illustrated in Figure 1 as pressure excursions in time. The cycle starts at atmospheric pressure. The pressure drops as the chamber is evacuated. AMSCO Hydrogen Peroxide Sterilant is then injected, causing a small rise in pressure. The hydrogen peroxide vapor concentration in the sterilizer is approximately 15 mg/L. A dwell period (no change in pressure) allows hydrogen peroxide vapors to penetrate the load. The chamber is again evacuated. Repeated injection, dwell and evacuation sequences are executed. Bacteria-free air is then allowed to fill the chamber. Additional evacuations and air fills follow, flushing peroxide vapors from the system.

1.3 SAFETY

Because it is a vacuum cycle, there is no danger of chamber rupture from over pressurization or of sterilant vapors leaking to the room during the cycle. The door cannot be opened during the cycle, even if it is unlatched. At the completion of a normal cycle, the sterilant vapor concentration in the sterilizer is so low that it presents no hazard to the operator.

The sterilization efficacy of the sterilizer has been proven by standard AOAC sporicidal testing, wherein no surviving spores were found on 720 inoculated

13 838

carriers which were imbedded among surgical instruments in wrapped instrum  
trays and peel pouches.

11 21 04

## 2.0 INSTALLATION

### 2.1 SUMMARY OF WARNINGS AND CAUTIONS

The following is a summary of safety precautions which must be observed when operating or servicing this sterilizer. WARNINGS indicate the potential for danger to personnel, and CAUTIONS indicate the potential for damage to equipment. The precautions are repeated where applicable throughout the manual.

**WARNING: THIS STERILIZER IS DESIGNED FOR USE WITH AMSCO HYDROGEN PEROXIDE STERILANT ONLY. USE OF ANY OTHER MIXTURE COULD CAUSE INEFFECTIVE STERILIZATION OR OTHER HAZARDS.**

**WARNING: AMSCO HYDROGEN PEROXIDE STERILANT IS A STRONG OXIDIZER. USE CARE IN HANDLING. FOLLOW THE PROCEDURES PROVIDED IN "OPERATING INSTRUCTIONS" ON PAGE 5.**

**CAUTION: Use only approved wrapping materials to wrap items to be sterilized. Other materials may reduce the sterilizing effectiveness of this process. (See "Wrapping Materials" on page 7)**

**CAUTION: Never use abrasive cleaning compounds, wire brush, or steel wool on sterilizer surfaces.**

### 2.2 UTILITY AND SPACE REQUIREMENTS

The peroxide sterilizer is a self-contained, transportable device, which requires connection to only one 120 VAC, 60 Hz, 30 amp grounded outlet. Voltage as low as 110 VAC can be used, but momentary voltage excursions below 105 VAC will terminate the automatic operation of the sterilizer, requiring manual restarting.

Space around the sterilizer is needed to permit access to the sterilant reservoir (Figure 2), the vacuum pump (Figure 3), and the manual vacuum break valve (Figure 4) and to allow proper circulation of air to cool the vacuum pump and the controller electronics. Space for proper circulation is generally assured by providing space for human access.

### 2.3 UNPACKING

Upon receiving this equipment:

- Open chamber door and remove packing.
- Be sure chamber shelves are properly positioned on the rack.
- Open the left part of the upper cabinet and remove the packing.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

FEB 11 1985

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.

5749-6

15 9 38

AMSCO

## 2.4 PRE-USE CHECKOUT

1. Open the doors on the right side of the lower cabinet to access the pump (see Figure 3).
2. Check oil level in the vacuum pump. The oil should be just visible at the bottom of the sight glass (see Figure 5). If the level is low, add oil as instructed under "Quarterly" on page 13 of the "PREVENTATIVE MAINTENANCE" section. Use only Marvac Oil No. RO-1000.
3. Rotate the pump pulley by hand one or two turns to make sure the unit is not stuck. If it is impossible to rotate pulley by hand, contact an AMSCO service representative. Do not attempt to run the pump.
4. Check that the manual vacuum break valve (Figure 9) is closed.
5. Insert the plug of the power cord into a 120 volt, 60 Hz, grounded outlet, fused at 30 amp. Turn the power switch on (front panel, see Figure 2). The digital temperature display (front panel) will light up. If it does not, check that the power cord is properly connected, and that the correct power is actually available at the outlet. If the temperature display still does not come on, refer to the "TROUBLESHOOTING" on page 14, under "sterilizer will not operate". If no remedy is found, contact an AMSCO service representative.
6. Wait (about one hour) until the READY light (front panel) comes on. At this time the inside temperature of the sterilizer is about 64 °C.
7. Press the CYCLE START button. The IN PROGRESS light will light and the vacuum pump will start running.
8. Wait (about 10 to 30 minutes) until the NO STERILANT alarm light (front panel) comes on. This will occur after the the vacuum pump has successfully evacuated the sterilizer chamber. (The NO STERILANT light indicates that there is no sterilant in the sterilant reservoir; it is shipped empty.)
9. Stop the cycle and relieve the vacuum as instructed under VACUUM LEAK under "Alarm Lights" on page 9.
10. Turn the POWER switch OFF, and check the (now warm) oil level in the vacuum pump. If it shows an overflow condition (see Figure 6), drain enough oil to return the level to normal. (The draining procedure is given under "Quarterly" on page 13 of the "PREVENTATIVE MAINTENANCE" section.)

15 of 38

### 3.0 OPERATING INSTRUCTIONS

The information in this section, if followed carefully, will provide optimum equipment performance.

#### 3.1 BEFORE OPERATING THIS EQUIPMENT

- Read this equipment manual and become thoroughly familiar with its contents.
- In-service training is required.

#### 3.2 AMSCO HYDROGEN PEROXIDE STERILANT

##### 3.2.1 PRECAUTIONARY STATEMENTS

#### DANGER

##### Hazards to Humans and Domestic Animals:

- Corrosive to eyes. Severe irritant to eyes, skin, nasal passages, throat, lungs, and internal organs.
- Wear rubber, or vinyl gloves and apron, and eye protection when handling.

##### Physical and Chemical Hazards:

- Strong oxidizer.
- Avoid contact with combustible materials. Drying of this product on clothing or combustible materials may cause fire.
- Avoid contamination of AMSCO Hydrogen Peroxide Sterilant from any source, including metals, dust and organic materials. Such contamination may cause rapid decomposition, generation of large quantities of oxygen gas, and high pressures.

Keep out of reach of children.

##### 3.2.2 FIRST AID

- In case of contact with eyes, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician.

- 17 of 38
- In case of contact with skin, flush skin with water. (Skin may temporarily turn white, and a stinging sensation may be felt. Skin will return to normal within 3 hours and stinging will dissipate, if contact time is short.)
  - Remove and wash contaminated clothing and shoes promptly and thoroughly.
  - If swallowed, drink plenty of water

In case of fire use water only.

In case of spill or leak, flush away by flooding with water applied quickly to the entire spill or leak.

### 3.2.3 DIRECTIONS FOR USE

- General Classification. It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
- Use only to sterilize microorganisms on items described under "Sterilizable Items" in the "Preparation of the Load" section of this manual.
- The AMSCO Hydrogen Peroxide Sterilizer automatically dispenses the Sterilant to provide an average dose of 0.2 mL Sterilant per liter of sterilizer volume with each sterilization cycle. Attach the bottle of sterilant to the Sterilizer per instructions under "Daily" in the "Preventative Maintenance" section of this manual.
- Store in original containers at room temperature or refrigerated.
- Spent sterilant containers should be flushed with water before discarding.
- Unused AMSCO Hydrogen Peroxide Sterilant can be flushed down the drain with plenty of water.

### 3.3 PREPARATION OF THE STERILIZER

BEFORE CYCLE STARTING THE FIRST CYCLE OF THE DAY:

Perform daily maintenance, following instructions under "Daily" on page 12 in the "PREVENTATIVE MAINTENANCE" section. This includes:

1. Drain any water from the vacuum pump.
2. Check pump oil level.
3. Clean the inside surfaces and shelves of the sterilizer.
4. Check the level of AMSCO Hydrogen Peroxide Sterilant in the reservoir bottle, and replace with a fresh bottle if needed, as instructed under "Daily" in the "PREVENTATIVE MAINTENANCE" section.



111111

111111

### 3.4 PREPARATION OF THE LOAD

#### 3.4.1 STERILIZABLE ITEMS

The AMSCO Hydrogen Peroxide Sterilizer is designed for the rapid sterilization of wrapped surgical instruments, without dulling or corroding the cutting edges. Typical instruments which can be sterilized include scissors, knives, and burs. Specific examples are microsurgical scissors (iris, corneal, vitreous), cataract knives, tympanum perforators, and forceps. Items with long narrow lumens, such as endoscopes, suction cannula, and aspirating needles, should not be run in this sterilizer.

#### 3.4.2 WRAPPING MATERIALS

**CAUTION:** Use only recommended materials to wrap items to be sterilized. Some absorbent materials (for example, muslin) may reduce the sterilizing effectiveness of this process.

Recommended materials include heat bonded polypropylene sheets (such as Kinguard®, Kimberly-Clark, Neenah, Wisconsin) and spunbonded olefin peel pouches (such as Tyvek®, E. I. duPont, Wilmington, Delaware).

#### 3.4.3 CLEANING

The article to be sterilized must be decontaminated, cleaned, rinsed and dried before placement in the sterilizer. The cleaned article may be dried in ambient air or by towel, but never by heat.

#### 3.4.4 PACKAGES

Items to be sterilized may be loosely grouped in trays and wrapped with recommended wraps. The tray should be perforated at sides, bottom, and top to allow vapors to pass into the tray and contact all surfaces of the load. Wrapping of the tray is required to prevent contamination of the load during storage following sterilization. A suggested wrapping procedure is shown in Figure 8. Items may also be packaged in peel pouches and the peel pouches stacked on edge in a basket.

### 3.5 LOADING THE STERILIZER

- Place packages on the shelves and arrange the load so that the sterilant vapor can circulate freely around each item.

OPERATING INSTRUCTIONS

- Leave an inch or more space between packages.
- Provide at least 2 inches of space between the chamber walls and the packages of the load.

### 3.6 STERILIZATION

Review the preceding sections of this manual before operating the sterilizer.

1. Plug the power cord into a grounded 120 V, 60 Hz, 30 amp outlet.
2. Turn on the power by pressing the POWER switch on the front panel.
3. Check that the manual vacuum break valve (Figure 9) is closed.
4. Allow about two hours for warm-up before loading or using the sterilizer. This time is required to heat the chamber to a uniform operating temperature. Close and latch the door during this warm-up period.
5. After the READY lamp has come on, place the load in the chamber and latch the door.
6. Press the CYCLE START switch. The sterilizer will automatically proceed through its cycle of evacuation, sterilant introduction, and sterilizing dwells. During this period the IN PROGRESS lamp is illuminated.
7. The COMPLETE lamp will light when the cycle is complete and the door may be opened. Open the door and remove the load.
8. A new load may now be placed in the sterilizer. When the door is closed, the controller automatically resets for the start of a new cycle. Proceed as instructed in steps 6 and 7.
9. If subsequent cycles are not going to be run now:
  - a. Press the POWER switch OFF.
  - b. Leave the door slightly open when not in use. This will extend the life of the gasket.

**Note:** The cycle may be interrupted at any time by pressing RESET. The controller will jump to the cycle termination step to flush out any sterilant vapors and prepare the sterilizer to be opened. Reinitiate the cycle by pressing CYCLE START after the READY light is on.

**Note:** If there is a power interruption during a cycle, the IN PROGRESS light will go out and will not go on again when power is restored. The cycle must be restarted, after power is restored, by:

1. Press the POWER switch off, then on again,
2. Wait until the READY light lights,
3. Press the CYCLE START switch.

The controller will return to the beginning of the cycle and run a complete cycle, without regard to the fraction of the cycle that was completed at the time of the power interruption.

### 3.7 CONTROL MONITORING

To ensure the validity of the sterilizing process, the automatic control continually monitors the cycle. The indicating lights on the front panel (see Figure 10) call attention to the "STATUS" of the sterilizer cycle (upper three lights) and to conditions that might prevent successful completion of a sterilization cycle (lower five "ALARM" lights). An explanation of each light follows, along with actions that should be taken, should an alarm condition occur.

#### 3.7.1 CYCLE STATUS LIGHTS

- **READY** -- Chamber is at correct temperature; sterilizer can be loaded and started.
- **IN PROGRESS** -- Controller is operating; sterilizing cycle is progressing.
- **COMPLETE** -- Cycle is complete; sterilizer may be opened and unloaded.

#### 3.7.2 ALARM LIGHTS

##### 1. VACUUM LEAK

Indicates air is leaking into the evacuated chamber.

OPERATOR SHOULD:

- Open the access door on the rear panel (Figure 4) and check that the manual vacuum break valve (Figure 9) is closed tightly.  
IF it was NOT, break the vacuum and restart the cycle:
  - a. Slowly open the manual vacuum break valve. A loud hissing sound will be heard as air rushes through the valve into the evacuated sterilizer.
  - b. When the vacuum in the sterilizer has been relieved (hissing cannot be heard), close the manual vacuum break valve tightly.
  - c. Press the RESET switch, then, when the READY light comes on, press CYCLE START (front panel).

IF the manual vacuum break valve IS CLOSED tightly and the condition occurs, call an AMSCO service representative.

##### 2. SHELL TEMPERATURE OUT OF RANGE

21 of 38

Normally lit during the initial warm-up period, after the POWER switch is turned on, and before the READY light comes on. It is normally off at all other times.

IF this light comes on AFTER a cycle has begun,  
OPERATOR SHOULD:

- a. Press the RESET switch. The controller will jump to the cycle termination step to flush out any sterilant vapors and prepare the sterilizer to be opened.
- b. Wait 30 minutes
- c. If the READY light comes on, press the CYCLE START switch, to restart the sterilization cycle.
- d. If the READY light does NOT come on, press the POWER switch off, and call an AMSCO Service representative.

### 3. VAPORIZER TEMPERATURE OUT OF RANGE

Indicates a malfunction in the vaporizer heater.  
IF this light comes on during a cycle,

OPERATOR SHOULD:

- a. Press the RESET switch. The controller will jump to the cycle termination step to flush out any sterilant vapors and prepare the sterilizer to be opened.
- b. Wait 30 minutes
- c. If the READY light comes on, press the CYCLE START switch, to restart the sterilization cycle.
- d. If the READY light does NOT come on, press the POWER switch off, and call an AMSCO Service representative.

### 4. NO STERILANT

Indicates sterilant is not being delivered to the chamber.

OPERATOR SHOULD:

- Press the RESET switch.
- Check the sterilant reservoir bottle (Figure 7). If empty,
  - a. Replace with a new bottle of AMSCO Hydrogen Peroxide Sterilant per instructions under "Daily" in the "PREVENTATIVE MAINTENANCE" section.
  - b. Restart the cycle, when the READY light comes on, by pressing the CYCLE START switch.
- If the bottle is NOT empty, wait until the READY light comes on, then press the POWER switch off, and call an AMSCO Service Representative.

### 5. SLOW DRAW DOWN

Indicates that evacuation is taking much longer than normal. It could be an indication of a vacuum leak or a pump malfunction.

OPERATOR SHOULD:

- Open the access door on the rear panel (Figure 4) and check that the manual vacuum break valve (Figure 9) is closed tightly. IF it was NOT, break the vacuum and restart the cycle:
  - a. Slowly open the manual vacuum break valve. A loud hissing sound will be heard as air rushes through the valve into the evacuated sterilizer.
  - b. When the vacuum in the sterilizer has been relieved (hissing cannot be heard), close the manual vacuum break valve tightly.
  - c. Press the RESET switch, then, when the READY light comes on, press CYCLE START (front panel).
- IF the manual vacuum break valve IS CLOSED tightly and the alarm condition occurs, break the vacuum as described above, then:
  - Inspect the Door Gasket; replace, if necessary (see "Installing A Chamber Door Gasket" on page 15).
  - Drain some oil from the pump and inspect it. If it is badly oxidized (dark brown or black), or contains water, drain and replace the oil with Marvac Oil No. RO-1000 (the oil changing procedure is given under "Quarterly" on page 13 in the "PREVENTATIVE MAINTENANCE" section.
  - If the oil did not need replacing, check the oil level and add oil as needed.
  - Restart the cycle by pressing RESET, then, when the READY light comes on, press the CYCLE START switch.
  - If the condition recurs, break the vacuum as directed above, and call an AMSCO service representative.

3.8 DETERMINING EFFICIENCY OF STERILIZATION PROCESS

The best procedure to determine the efficacy of a sterilizing process is the biological monitor.

The most reliable form of biological monitor for gas sterilization is one such as AMSCO's Spordi® and Spordex®, which employ dry spores of a hydrogen peroxide resistant species ... Bacillus subtilis (globigii) ... seeded in known populations and standardized so that a known resistance can be demonstrated. It is recommended that 100 µg of catalase be added per milliliter of culture medium to neutralize hydrogen peroxide residuals on the spore strips and allow more efficient recovery of any surviving spores. Spordi, Spordex, and recommendations for preparation of the recovery medium, are available through your local AMSCO representative ... ask for details.

23738

## 4.0 PREVENTATIVE MAINTENANCE

**WARNING: REPAIRS AND ADJUSTMENTS, OTHER THAN THOSE DESCRIBED IN THIS MANUAL, SHOULD BE ATTEMPTED ONLY BY TRAINED SERVICE TECHNICIANS FULLY ACQUAINTED WITH THIS EQUIPMENT. THE USE OF INEXPERIENCED, UNQUALIFIED PERSONS TO WORK ON THE EQUIPMENT OR THE INSTALLATION OF UNAUTHORIZED PARTS COULD CAUSE PERSONAL INJURY, RESULT IN COSTLY DAMAGE, OR REDUCE THE EFFICACY OF THE STERILIZATION PROCESS.**

**CAUTION: Allow chamber to cool to room temperature before performing maintenance in and around the chamber.**

### 4.1 DAILY

Before turning power on (power switch OFF):

1. Drain any water from the vacuum pump at the oil drain plug (see Figure 5). Drain at least 50 mL from the pump. If water appears with the oil, continue to drain until only oil flows from the drain. As much as 100 mL of water may be in the oil chamber, if the unit was in continuous operation the previous day. The water will have settled to the proximity of the drain plug if the pump has been off for more than about 8 hours. THE WATER MAY CONTAIN SOME AMSCO HYDROGEN PEROXIDE STERILANT. Avoid contact. DISCARD THE WATER DOWN A DRAIN, and FLUSH with at least 10 volumes of water.

2. Check the oil level in the vacuum pump. Add oil as needed. Do not overfill. (See oil changing procedure under "Quarterly" on page 14.)

3. Wipe down the inside surfaces of the sterilizer and the shelves with a lint free cloth soaked in distilled or deionized water. Dry with a lint free cloth.

**CAUTION: Never use abrasive cleaning compounds, wire brush, or steel wool on these surfaces.**

4. Check the level of AMSCO Hydrogen Peroxide Sterilant in the reservoir bottle. Replace with a fresh bottle whenever the liquid depth is less than 1 cm. The sterilant bottle is located in a bracket inside the door on the left side of the cabinet (see Figure 2, and Figure 7).

**WARNING: AMSCO HYDROGEN PEROXIDE STERILANT IS A STRONG OXIDIZER. USE CARE IN HANDLING. (SEE "AMSCO HYDROGEN PEROXIDE STERILANT" ON PAGE 5.)**

- a. Open the access door and remove the (empty) bottle from its bracket.
- b. While holding the cap steady, turn the bottle clockwise (as viewed from the top) until it is free from the cap.
- c. Carefully separate the cap and feed tube assembly from the bottle, assuring that the feed tube is not under tension such that it would flip drops of sterilant around as it emerges from the bottle.

- d. Reverse the procedure to install the new bottle in the bracket. Exercise care in handling the feed tube to prevent kinking or stretching.
- e. Flush the used bottle with water before discarding.

### 4.2 WEEKLY

Watch the sterilizer while it goes through a complete sterilizing cycle. Be sure the indicating lights are working properly.

- READY -- Chamber is at correct temperature.
- IN PROGRESS -- Controller is operating.
- COMPLETE -- Cycle is complete.

If the cycle runs properly, but these lights do not light, replace defective light bulbs.

### 4.3 QUARTERLY

- Oil the door hinge: Place a few drops of heavy machine oil (SAE 20 or 30 motor oil) on the chamber door hinge pin. Work oil into the hinge by opening and closing the door several times.
- Inspect the door gasket. Replace it if it becomes deformed, brittle or cracked (see "Installing A Chamber Door Gasket" on page 16).
- Change the pump oil. Drain the oil from the vacuum pump and replace with Marvac Oil No. RO-1000<sup>1</sup>, only. Refer to Figure 5.
  - To drain the oil, hold a receiving tray or bottle under the oil drain plug. Unscrew the plug and allow all the oil to drain. Replace the drain plug.
  - To refill or add oil, remove the exhaust filter housing, and pour oil into the exhaust opening, until the oil level is between the lines on the sight glass (see Figure 6).
- Replace the exhaust filter element of the vacuum pump with a standard toilet paper roll.
- Replace the bacteria-retentive air filter and prefilter located above the pump in the lower cabinet (see Figure 11).

---

<sup>1</sup> Marvac Scientific Manufacturing Co., 1045 Shary Circle, Concord, Calif. 95518.

# 5.0 TROUBLESHOOTING

Lights on the sterilizer front panel provide indications of most trouble conditions. Please refer to "Control Monitoring" on page 9 for corrective actions to take when an alarm light is lit.

Some other conditions which might occur are listed below, along with suggestions for correcting the condition. If you are unable to correct the problem, or a problem occurs which is not described on the chart, please call your AMSCO representative. He will arrange to have your equipment promptly put into working order by a factory-trained representative. NEVER PERMIT UNQUALIFIED PERSONS TO WORK ON THE STERILIZER.

| PROBLEM  | SUGGESTED CORRECTION   |
|--|--|
| Sterilizer will not operate  | <p>Be sure Chamber Door is closed, latched and tightly sealed</p> <p>Be sure the power cord is properly connected at the power outlet.</p> <p>Check that the POWER switch is on (press upper end of switch).</p> <p>Check for power at the outlet; if necessary, correct the cause of power failure, and reset the circuit breaker.</p> <p>Check the voltage at the outlet; a 105 VAC minimum is required.</p> <p>Check the 25 amp fuse, located behind the microprocessor (see Figure 3).</p> |
| Controller does not operate  | <p>Check the voltage at the outlet; a 105 VAC minimum is required. Even short excursions below 105 Volts will cause the controller to fail. When proper voltage is restored, restart the sterilizer.</p>   |
| Neither the IN PROGRESS nor the COMPLETE light is on after a cycle was started | <p>A power interruption has occurred. If power has been restored, either the READY or the CHAMBER TEMPERATURE OUT OF RANGE light will be on. After the READY light comes on, press CYCLE START to reinitiate sterilization.</p>  |



76738

## 6.0 REPLACEMENT PARTS

### 6.1 SPARE PARTS LIST

| DESCRIPTION         | PART NUMBER                    |
|---------------------|--------------------------------|
| Oil for vacuum pump | (Marvac RO-1000 <sup>2</sup> ) |
| Fuse, 25 Amp        |                                |
| Gasket, door        | P-45047-091                    |
| Filter, bacteria    |                                |
| Pre-filter          | P-41285-091                    |

### 6.2 INSTALLING A CHAMBER DOOR GASKET

Refer to Figure 12.

- Remove the old gasket and clean the groove. (The replacement gasket is cut to provide a tight fit.)
- Force the new gasket into the groove, a short section at a time; do not stretch it while doing so. Should the gasket appear too long, DO NOT CUT IT. Start over again, compressing short sections into the groove, until the entire length is inserted. Never use sharp tools to push the gasket into the groove.

<sup>2</sup> Marvac Scientific Manufacturing Co., 1045 Shary Circle, Concord, Calif. 95518.

27938

7.0 FIGURES: 11.21.04

11.21.04

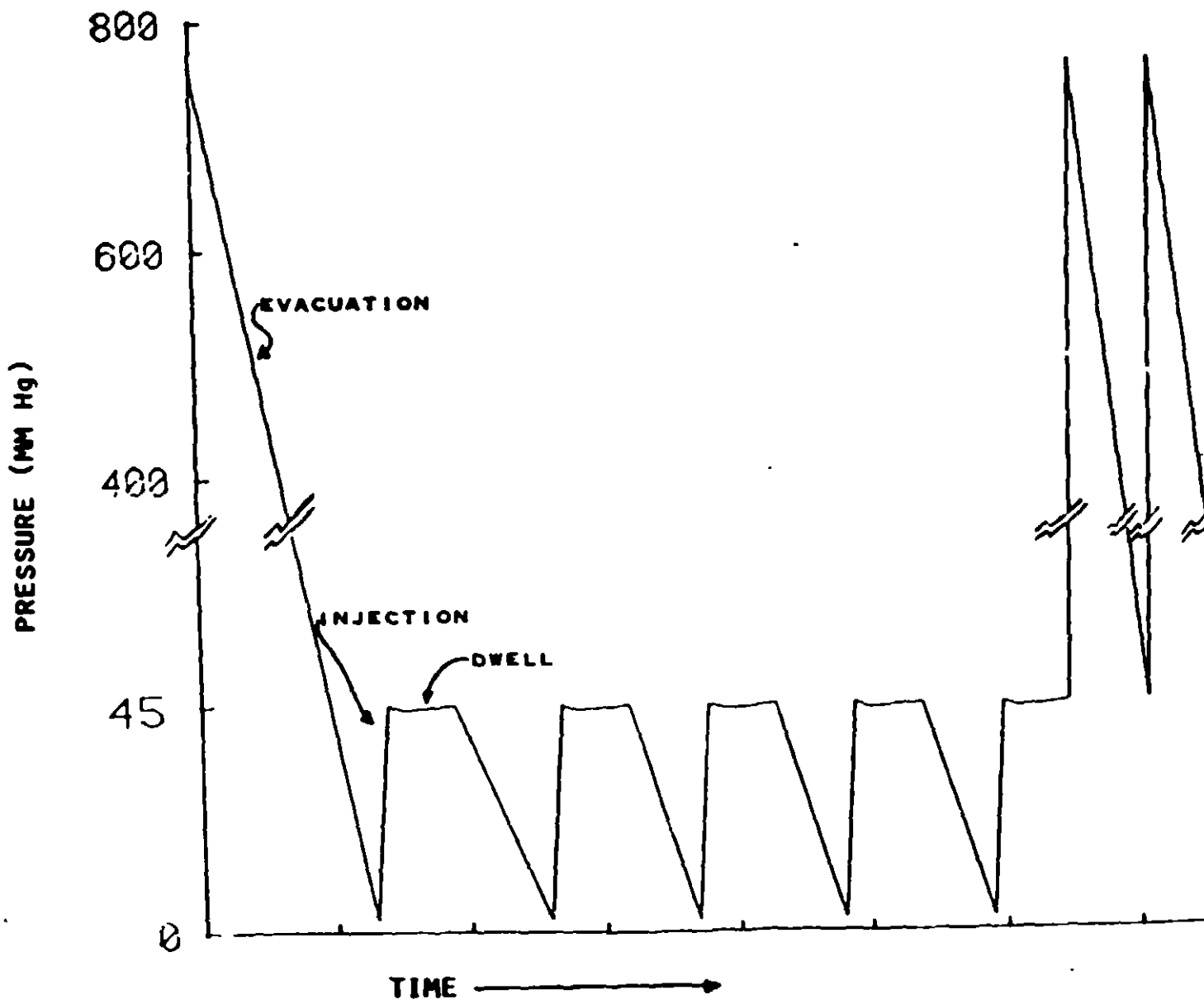
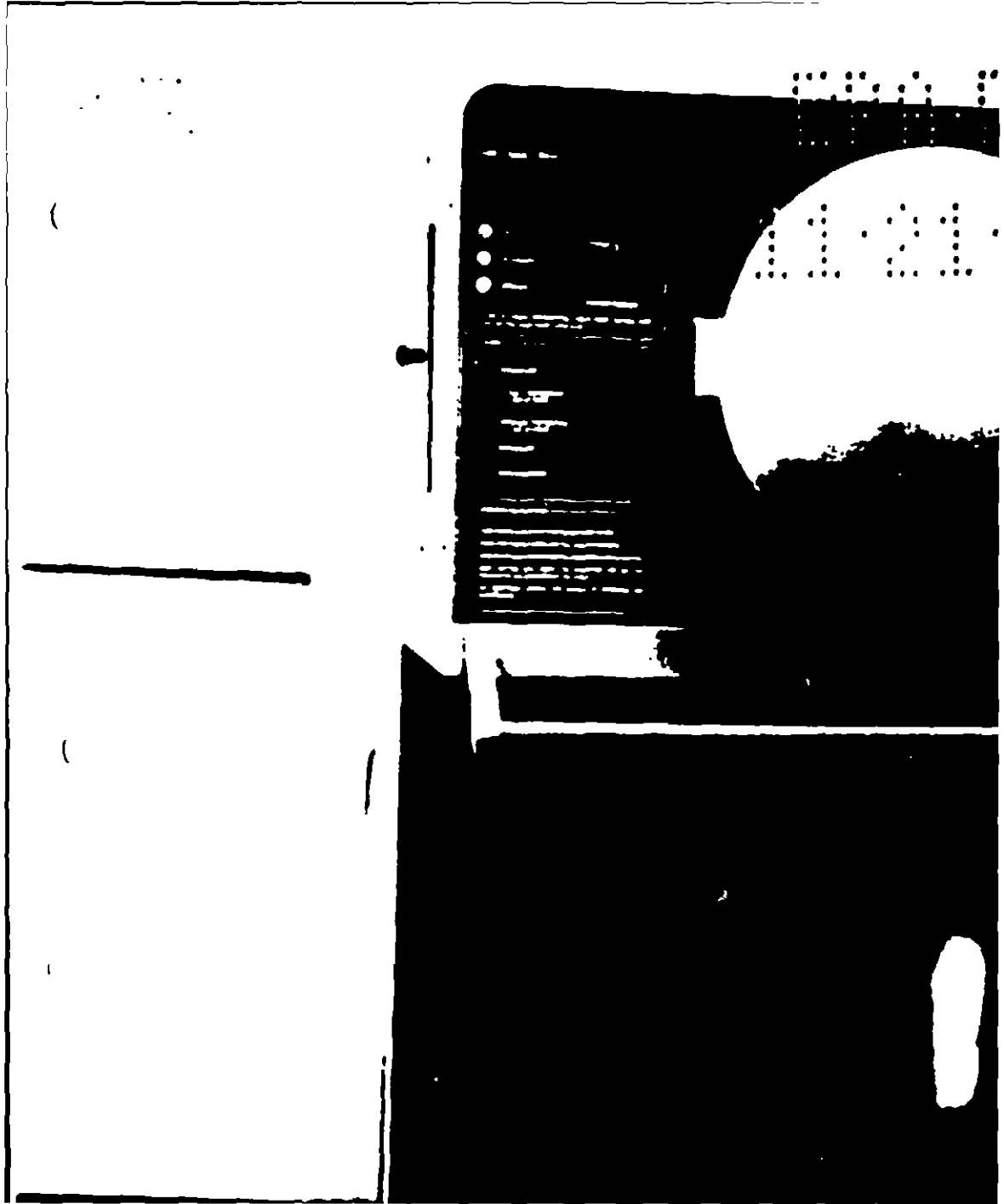
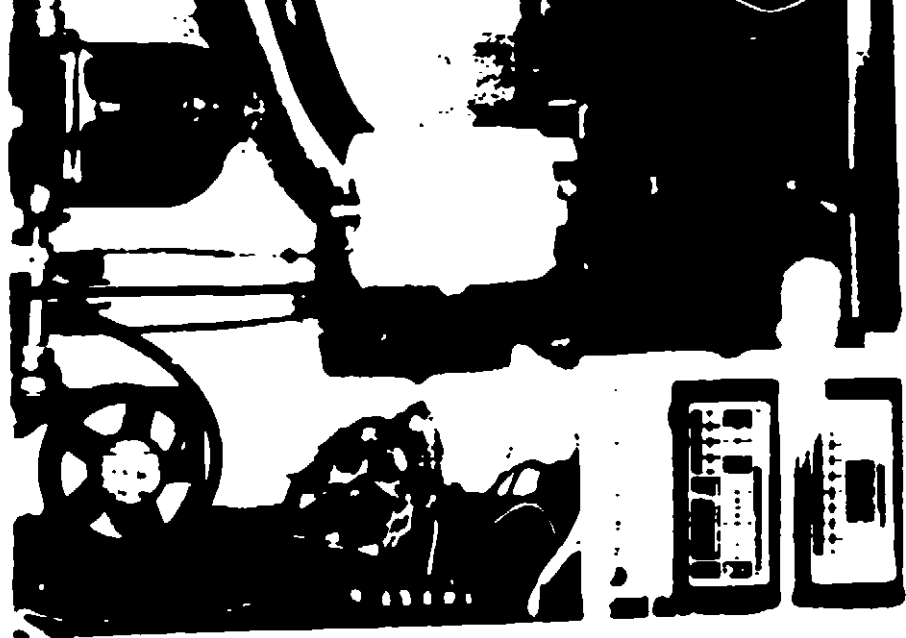


Figure 1. AMSCO Hydrogen Peroxide Cycle

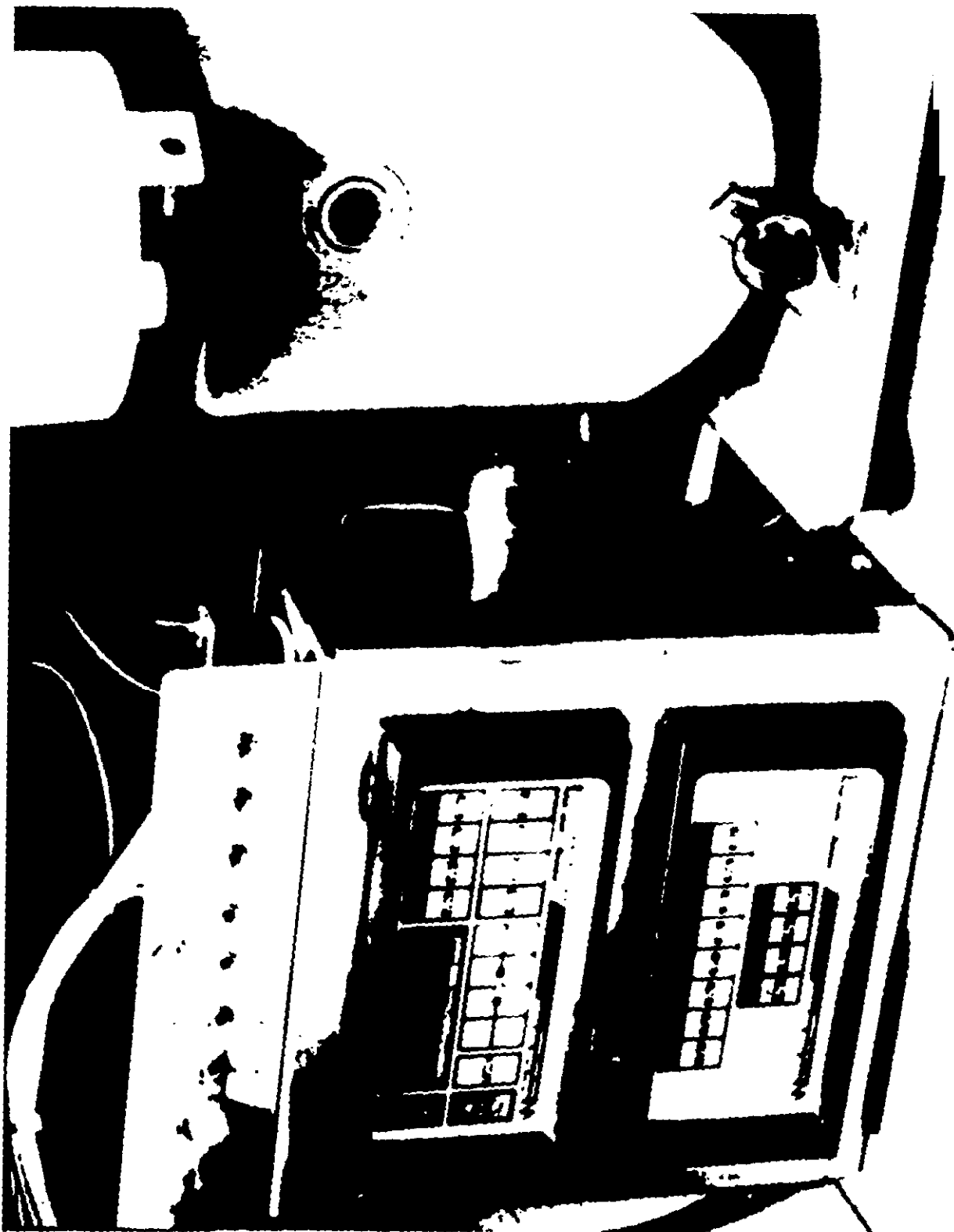




BEST AVAILABLE COPY

Right side view identifying in-cart features (lower cabinet)  
Identify the controller, the vacuum pump and the three

Figure 3. Sterilizer Lower Cabinet



w of vacuum pump. Identify drain and fill points, exhaus  
d oil level sight glass.

Vacuum pump

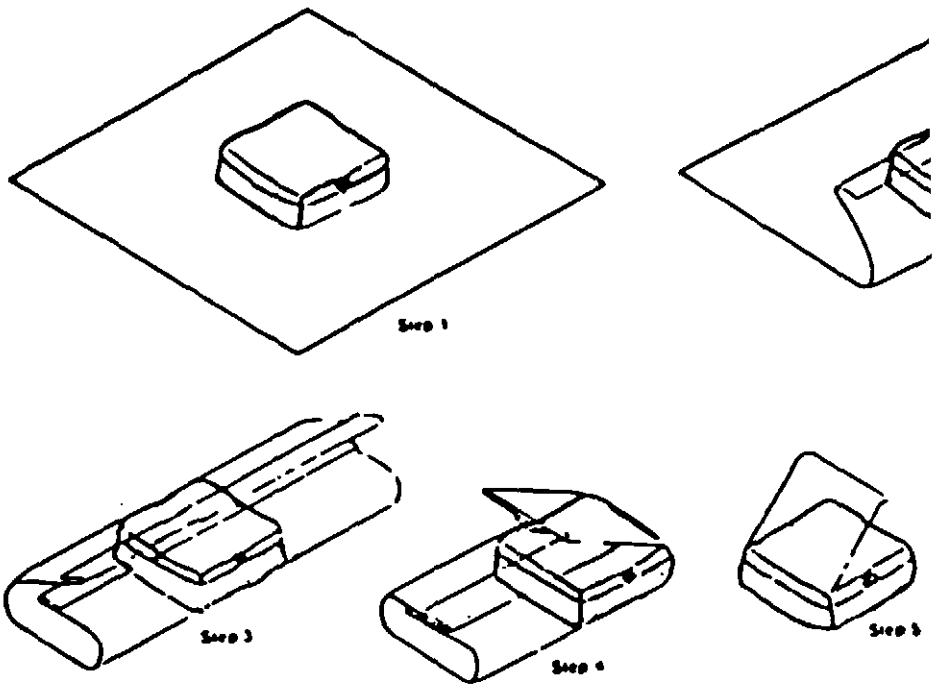
**BEST AVAILABLE COPY**



Close-up of oil level sight glass. Point out ~~correct level~~

Figure 6. Proper Oil Level

**BEST AVAILABLE**



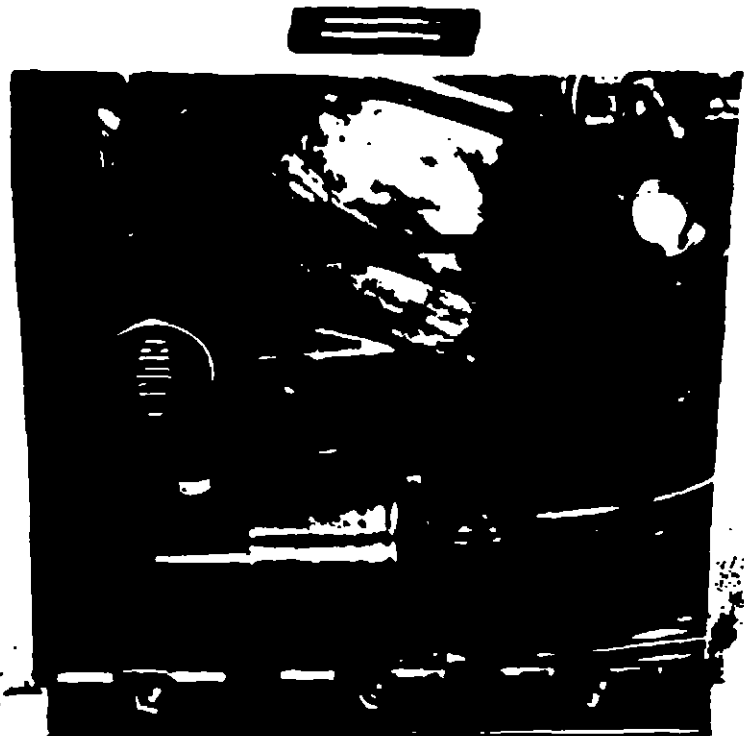
(REPEAT WITH SECOND WRAP)

Figure 8. Suggested Wrapping Procedure for Instrument Trays



35738

074-PA  
112104

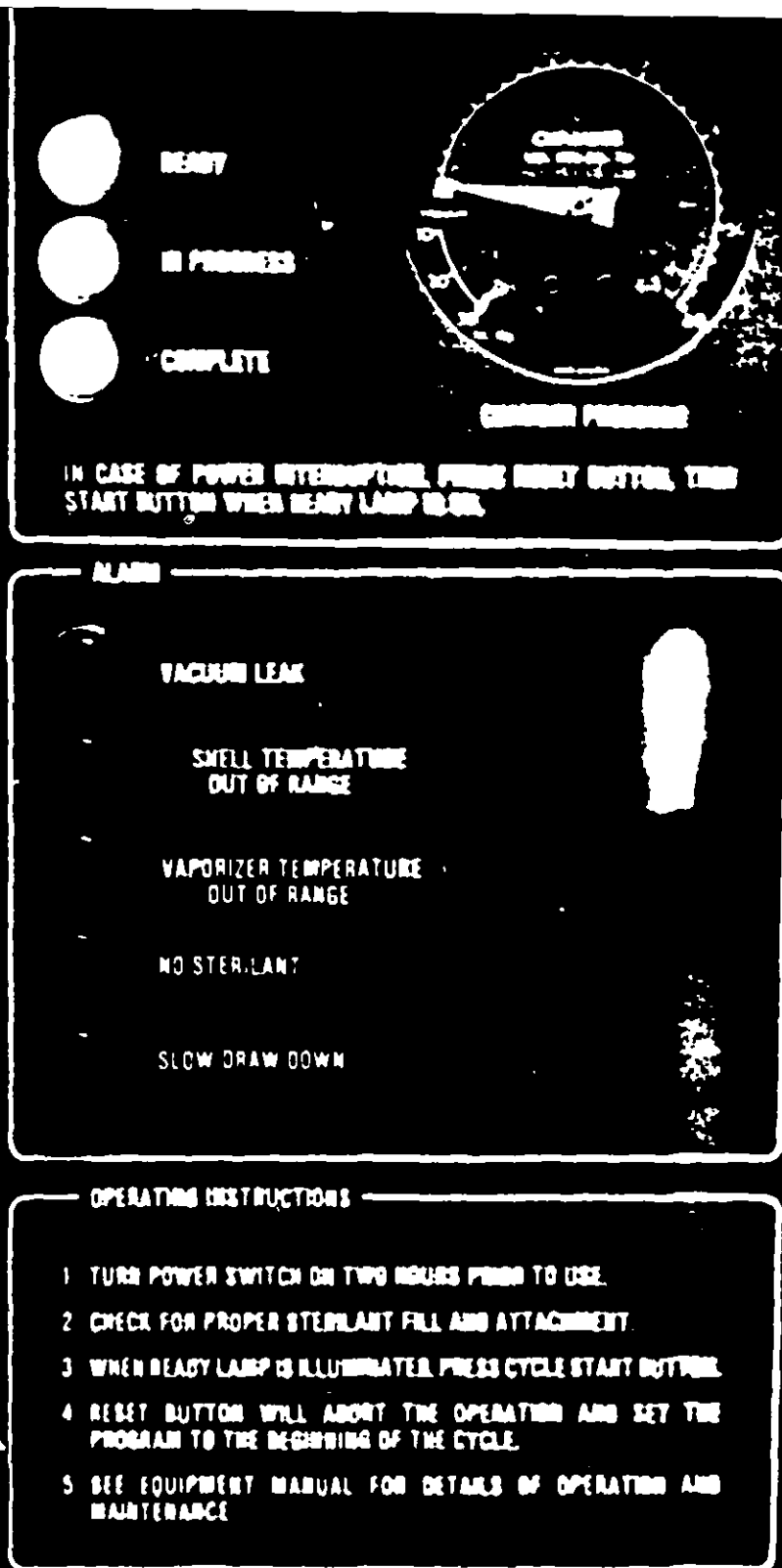


BEST AVAILABLE COPY

View of rear panel with door open. Identify the manual vacuum break valve.

Figure 9 Manual Vacuum Break Valve

BEST AVAILABLE COPY



Close-Up View of front panel showing switches and alarm lights.

Figure 10. Controls, Status Lights, and Alarm Lights



Close-up View of Bacteria retentive air filter and prefilter. Identify them.

Figure 11. Bacteria Filter and Prefilter



ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

FEB 11 1985

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.

5709-6

**BEST AVAILABLE COPY**

Front of sterilizer with door open. Identify the gasket. /

Figure 12. Door Gasket