

OPERATOR MANUAL

**Amsco® Eagle® 3000 Series FLJ
Floorloading Vacumatic Sterilizers**

(10/05/01)

P-150828-805

A WORD FROM STERIS CORPORATION

This manual contains important information on proper use and maintenance of this sterilizer. All operators and department heads are urged to carefully review and become familiar with the warnings, cautions and instructions contained herein. This sterilizer is specifically designed to process goods using only the cycles as specified in this manual. If there is any doubt about a specific material or product, contact the manufacturer of the product for the recommended sterilization technique.

Service Information

A thorough preventive maintenance program is essential to safe and proper sterilizer operation. You are encouraged to contact STERIS Engineering Service concerning our Preventive Maintenance Agreement. Under terms of this agreement, preventive maintenance, adjustments, and replacement of worn parts are done on a scheduled basis to assure equipment performance at peak capability and to help avoid untimely or costly interruptions. STERIS Engineering Service maintains a nationwide staff of well-equipped, factory-trained technicians to provide this service, as well as expert repair services. Contact your STERIS representative for details.

This sterilizer is not designed to process flammable liquids or liquids in containers that are not designed for sterilization. Any alteration of the sterilizer which affects its operation will void the warranty and could violate state and local regulations and jeopardize insurance coverage.

Advisory

A summary of the safety precautions to be observed when operating and servicing this equipment can be found in Section 1 of this manual. Do not operate or service the equipment until you have become familiar with this information.

Any alteration of the sterilizer not authorized or performed by STERIS Engineering Service which could affect its operation will void the warranty, could adversely affect sterilization efficacy, could violate federal, state and local regulations and jeopardize your insurance coverage.

Indications for Use

The Amsco Eagle 3000 Series FLJ Steam Sterilizer is designed for efficient, sterilization of non-porous and porous, heat and moisture-stabile materials used in healthcare facilities. The Eagle 3000 Series FLJ Steam Sterilizer is available in the following configurations:

- 42" Single Door
- 42" Double Door
- 76" Single Door
- 76" Double Door

The Eagle 3000 Series FLJ Steam Sterilizer is equipped with four factory-programmed sterilization cycles. These cycles have been validated to AAMI ST-8 standards using the following loading configurations and cycle values:

PREVACUUM CYCLES

CYCLES	RECOMMENDED LOAD/CAR	STERILIZE TEMP.	STERILIZE TIME	DRY TIME
PREVAC	One fabric pack.	270°F (132°C)	4 minutes	5 minutes
PREVAC	Up to six double wrapped instrument trays, maximum weight, 17 lbs. Up to eighteen fabric packs.	270°F (132°C)	4 minutes	20 minutes

GRAVITY CYCLES

CYCLES	RECOMMENDED LOAD/CAR	STERILIZE TEMP.	STERILIZE TIME	DRY TIME
GRAVITY	Up to eighteen packs	250°F (121°C)	30 minutes ¹	15 minutes

¹A 270°F (132°C) cycle adjusted to 25 minute Sterilize Time can be used for processing Fabric Packs.

LIQUID CYCLE

CYCLES	VALIDATED LOADS	STERILIZE TEMP.	STERILIZE TIME	DRY TIME
LIQUIDS	Three 1000 ml. bottles ²	250°F (121°C)	45 minutes	-

²This is a minimal load and represents the worst case loading condition for sterilization of liquids in this chamber; it is consistent with AAMI ST-8 validation standards.

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LISITNG OF WARNINGS AND CAUTIONS

1

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

WARNING – EXPLOSION HAZARD:



This sterilizer is not designed to process flammable compounds. Do not operate this sterilizer in the presence of flammable compounds.

WARNING – INJURY HAZARD:



Process only vented closures; do not use screw caps or rubber stoppers with crimped seal.



Process only Type 1 borosilicate glass bottles; do not use ordinary glass bottles or any container not designed for sterilization.



Do not allow hot bottles to be jolted; this can cause hot-bottle explosions. Do not move bottles if any boiling or bubbling is present.



Allow containers to cool to touch before attempting to move them from sterilizer cart to the storage area.



Sterilizer repairs and adjustments should be performed only by experienced persons fully acquainted with this equipment. Use of inexperienced, unqualified persons to work on the equipment or the installation of unauthorized parts could cause personal injury or result in costly damage.



Before performing any cleaning or maintenance procedures, lock customer supplied main power disconnect switches in OFF position and allow sterilizer and loading equipment to cool to room temperature.



Sterilizer and loading cart will be HOT after cycle is run. Always wear protective gloves and apron (also face shield if processing liquids) when removing a processed load. Protective gloves and apron should also be worn when reloading sterilizer following previous operation.

WARNING – BURN HAZARD:



When sterilizing liquids, to prevent personal injury or property damage resulting from bursting bottles and hot fluid, you must observe the following procedures:


- Use Liquids cycle only. No other cycle is safe for processing liquids.
- Avoid sudden full opening of door at the end of the cycle. Unlock sterilizer door, but do not open door. Wait at least 10 minutes before unloading the sterilizer.

WARNING – SUFFOCATION AND BURN HAZARD:






When entering sterilizer for any reason, shut POWER and CONTROL switches OFF, lock customer supplied main power disconnect switches in OFF position and always place red door safety stop in a horizontal position to prevent door closure. Never enter sterilizer when door is closing (as indicated by beeping alarm).





WARNING – SLIPPING HAZARD:

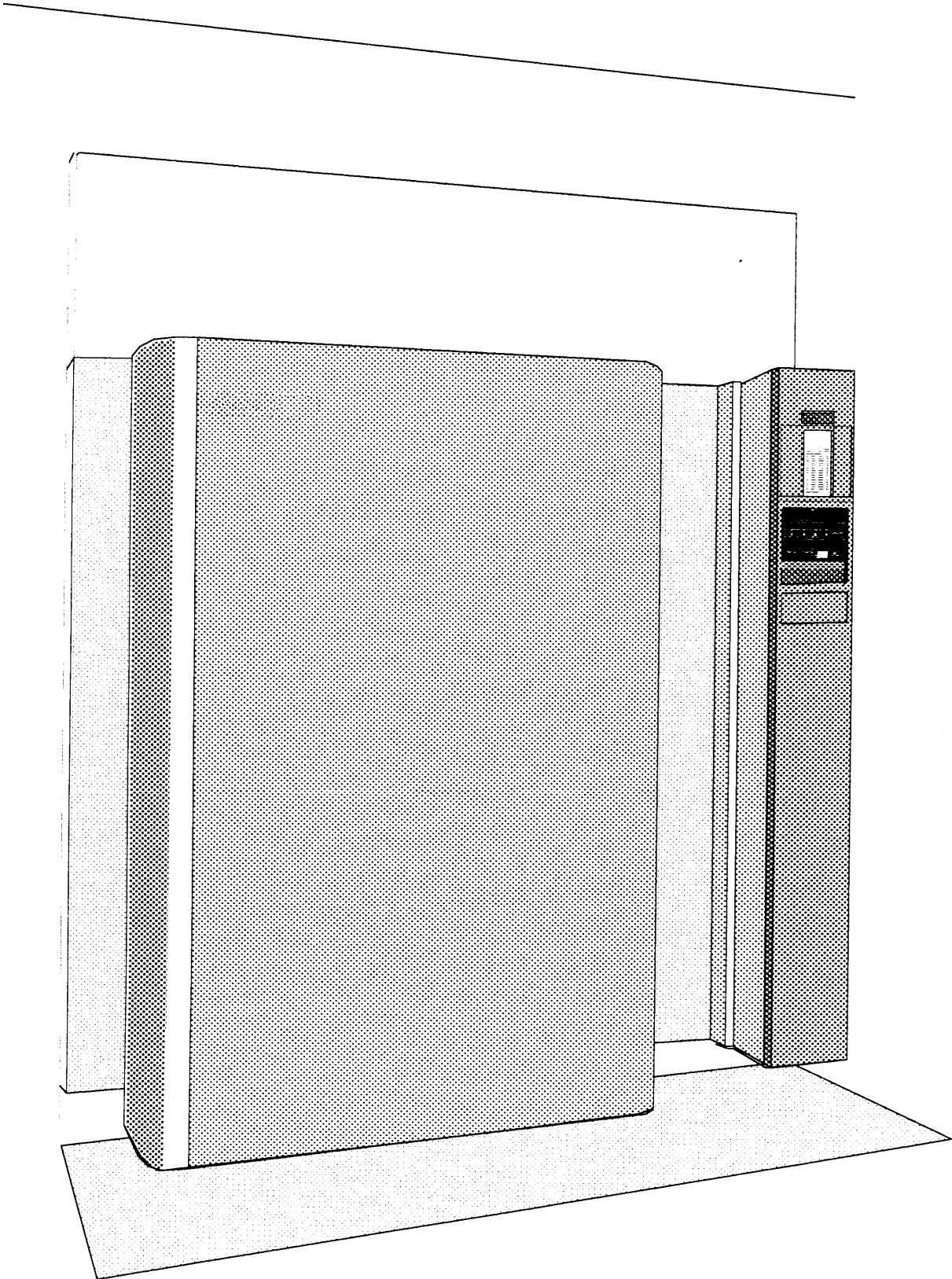
-  To avoid slippery floor conditions, immediately wipe up any spilled liquids or condensation in sterilizer loading area.

WARNING – STERILITY ASSURANCE HAZARD:

-  According to AAMI standards a measured leak rate of one millimeter or greater per minute indicates a problem with the sterilizer. Refer the situation to your supervisor before using the sterilizer further.
-  Load sterility may be compromised if the biological, air removal or air leak tests indicate a potential problem. If these indicators show a potential problem, refer the situation to your supervisor before using the sterilizer further.
-  It is inappropriate for a health care facility to sterilize liquids for direct patient contact.

CAUTION – POSSIBLE EQUIPMENT DAMAGE:

-  Never use a wire brush, abrasive cleaner or steel wool on door, chamber assembly or loading car.
-  Immediately wipe up saline solution spills on loading car, to prevent damage to stainless steel.
-  Do not use cleaners containing chlorides on loading cars. Chloride-based cleaners will deteriorate the loading car metal.
-  Do not overload the loading cart. The STERIS Floor Loader Loading Cart has a maximum total load capacity of 1,000 lbs (453.6 kg). Each loading cart shelf has a maximum load capacity of 200 lbs (90.7 kg). All loads shall be uniformly distributed on the loading car shelves.



Amsco® Eagle® 3000 Vacamatic Floor Loading Sterilizer

Control Locations

(See Figure 2-1)

Become familiar with all control locations and functions before operating the sterilizer.

Controls are located at the top of a vertical column located at the side of the sterilizer. Column is on side opposite door hinge.

- **Sterilizer Control Power Switch** – located behind the printer door. This switch is used to switch the sterilizer control between STANDBY and READY (i.e., operating) conditions.
- **Chamber Pressure/Vacuum Gauge** – This is located above the door behind the hydraulic piston (see Figure 2-1). When the door is closed, the gauge can be read by opening the door's hinged side cover.
- **Jacket Pressure Gauge** – This is located above the door behind the hydraulic piston (see Figure 2-1). When the door is closed, the gauge can be read by opening the door's hinged side cover.

Printer

Printer records all cycle data on 2-1/4 inch wide single ply thermal paper. Refer to Service and Maintenance procedures manual, P-150828-806, for paper ordering information and for paper changing procedure (see Figure 2-1).

- **Printer Function Switch** (located behind printer door) controls two printer functions, print and print values.
 - **Print** – Press top of printer function switch to obtain a complete duplicate printout of the last previous cycle (when unit is not in cycle) or to obtain a printout of current cycle phase and conditions (when unit is in cycle).
 - **Print Values** – Press bottom of printer function switch to obtain a printout of all currently set cycles and cycle values (when unit is not in cycle).

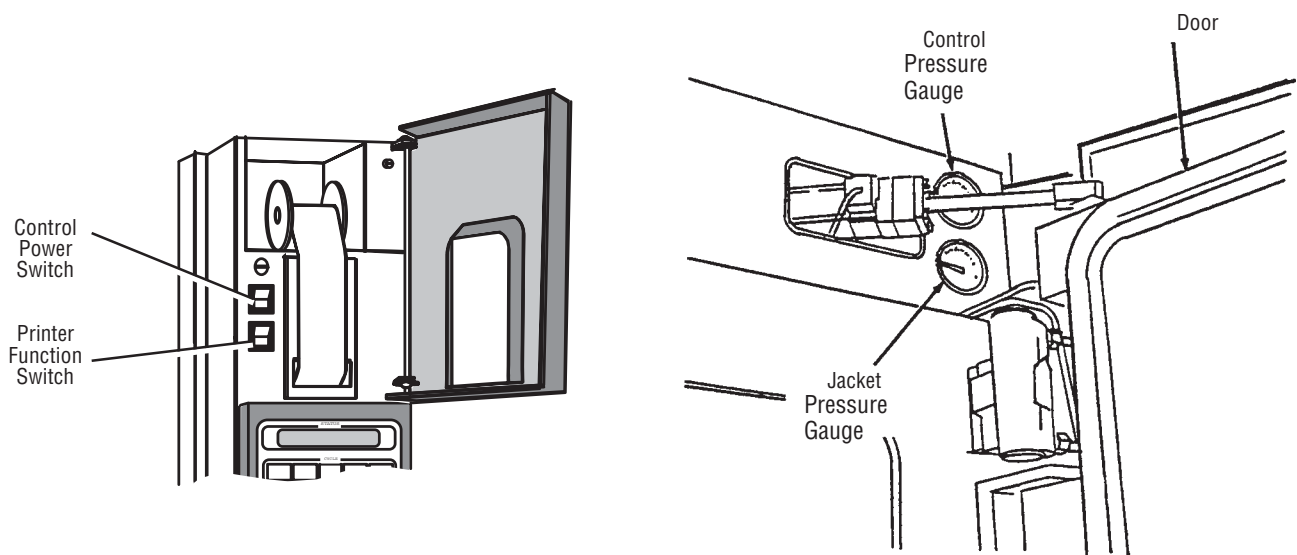


Figure 2-1. Control Locations

Control Panel

The operating end control panel is used to operate the door, start cycles, set cycles and cycle values, and reset the sterilizer.

NOTE: To view cycle values, press and hold the corresponding cycle selector touch pad.

- Cycles and cycle values can be set using the cursor control touch pads accessible when sterilizer is out of cycle.
- Cycles can be started or reset using the numbered touch pads accessible when door is locked.
- Cycle status and control messages are shown on a 2 line x 20 character display.

When not in cycle and sterilizer not displaying time of day, the display shows a brief status of the sterilizer:

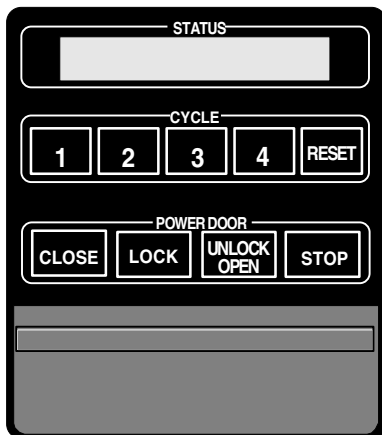
. . . DOOR UNLOCKED or
 . . . NOE DOOR UNLOCKED, or
 . . . BOTH DOORS UNLOCKED, or

Shows the door(s) is locked and some abnormal out-of-cycle condition exists such as:

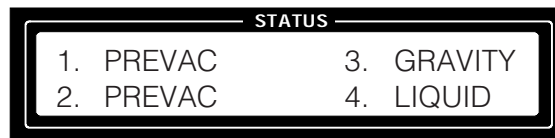
. . . PRESSURE IN CHAMBER
 . . . WARNING: HOT LIQUIDS

NOTE: See *Control Monitoring and Communications* for recommended operator actions if abnormal conditions occur.

When not in cycle and sterilizer displaying time of day, the display alternately shows available cycle selections . . . (example)



Control Panel



and . . . time of day.

When cycle is in progress, display shows cycle status and information. It will also show abnormal conditions such as:

. . . OVERTEMP
 . . . UNDERTEMP

Printer will record above messages and also additional abnormal conditions such as:

. . . ALARM: TOO LONG IN FAST EXHAUST
 . . . ALARM: TOO LONG IN VENT
 . . . ALARM: TOO LONG IN EXHAUST
 . . . ALARM: TOO LONG IN CHARGE

NOTE: The non-operating end control panel is only found on double door sterilizers.

Non-Operating End Control Panel

The non-operating end control panel features door control touch pads, four cycle selector touch pads, and RESET touch pad. Display window concurrently shows the same message as shown in display window on the operating end of the sterilizer.

- Cycles can be started or reset using the four cycle selector and RESET touch pads.
- Cycle status and control messages are concurrently shown on a 2 line x 20 character display.
- The door can be operated.

Reset Function

See Figure 2-2.

The RESET touch pad is used to abort a cycle and put the control into a known condition.

NOTE: *If you push the wrong cycle selector touch pad when starting a cycle, proceed as follows:*

1. Press RESET touch pad to abort cycle. Display shows . . . ABORT. . . and the printer records time RESET was pressed and prints ABORT....(time of day).
2. Wait until display shows . . .time of day.
3. Press touch pad for correct cycle and printer will record cycle selected and proceed through correct cycle.

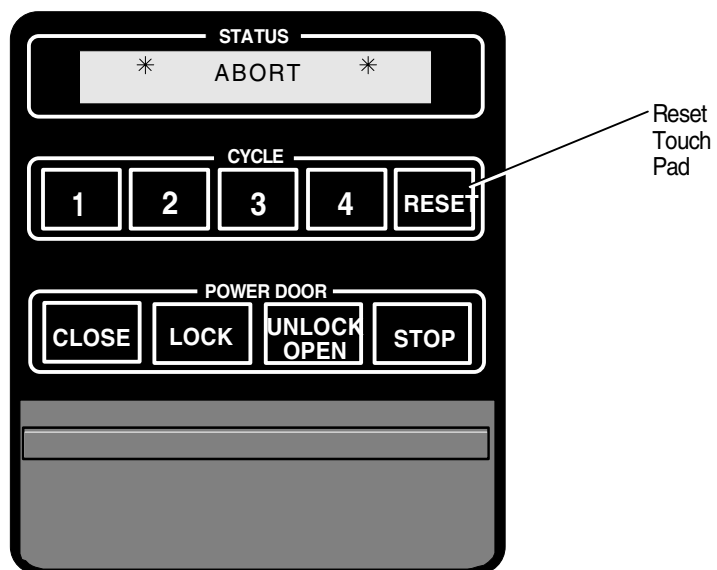


Figure 2-2. Reset Function

Power Door Operation

NOTE: Door(s) should be kept closed when power to unit is on (even if not in cycle).

NOTE: Door motion stops whenever a resistance of 5-15 pounds is encountered and motion resumes when resistance is removed.

NOTE: If more than 2 in Hg vacuum or 2 psig pressure exists in the chamber, the sterilizer control will not allow the door to be opened by power door control.

Refer to Figure 2-3 for touch pad locations.

Door movement on units equipped with power door(s) is controlled by four pushbuttons located on the control column (both ends of double door units).

Touch pads are labeled CLOSE, LOCK, UNLOCK/OPEN, and STOP and perform the following:

- CLOSE - press to swing the door closed.
- LOCK - press to lower and lock the door (from door closed position). Display message changes to "TIME" and time of day. Display alternates with menu of cycle selections.
- UNLOCK/OPEN - To unlock the door from the locked position, press once to unlock and raise door and press again to open the door. Display message changes to time of day display. Display alternates with menu of cycle selections.
- STOP - press to stop movement of door at any time. Press the desired movement pushbutton to resume operation of the door.

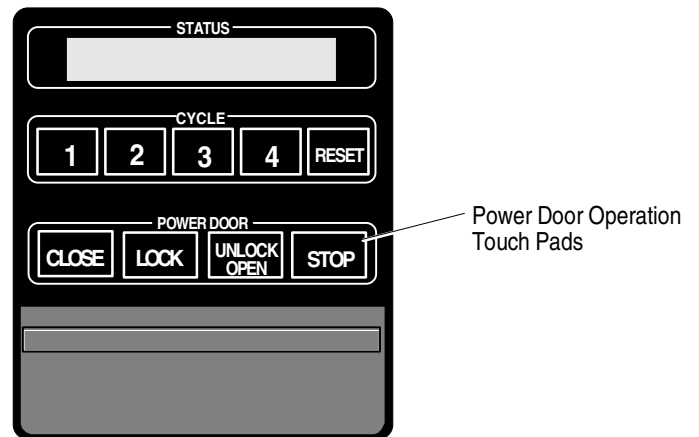


Figure 2-3. Power Door Operation

Emergency Manual Operation of Power Door

Refer to Figure 2-4.

The power hydraulic door can be operated (if, for example, power is lost to the sterilizer) using a hand pump (mounted on the left side of the hydraulic pump motor) and the manifold valve assembly (mounted above and to the right of the motor pump assembly).

1. Turn the power and control power switches to OFF, and wait until chamber pressure reaches 0 psig.
2. Remove the lever (handle) from its storage position and use it to verify the screw release (on hand pump) is fully clockwise and closed.
3. Insert lever into hand pump.
4. One of the manual override buttons listed on the table below must be fully depressed while pumping the hand pump. Each button is located on a different solenoid valve of the manifold assembly.

Door Operation	Depress Manual Override Button	Strokes of Hand Pump (Approx)
Unlock	Located at top of lock-unlock solenoid	25
Raise	Located at top of raise-lower solenoid	25
Open	Located at top of open-close solenoid	30
Close	Located at bottom of open-close solenoid	25
Lower	Located at bottom of open-close solenoid	15
Lock	Located at bottom of lock-unlock solenoid	25

- Turn screw release counter-clockwise after desired door operation has been completed. Doing so is important in order to relieve pressure in line to manifold assemblies. After line pressure has been relieved turn screw release clockwise until closed so that power system will operate correctly.

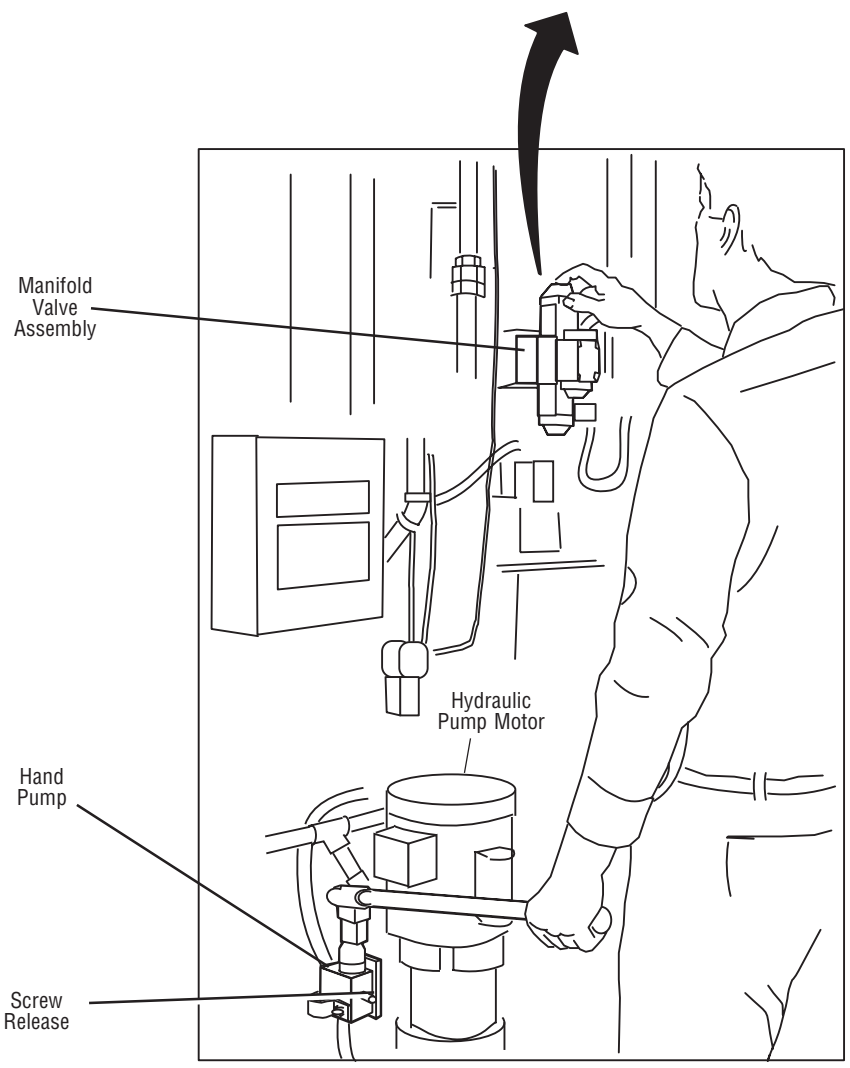
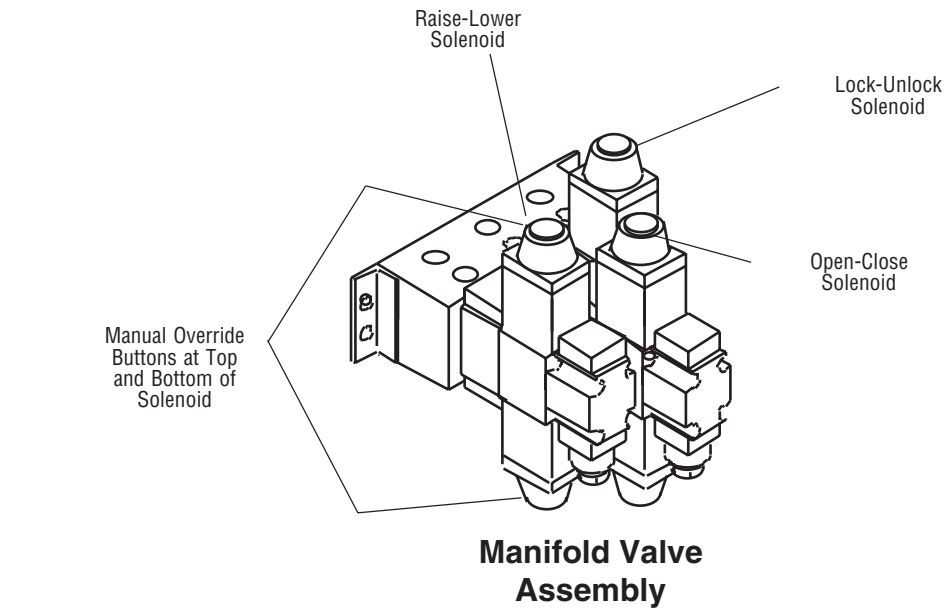


Figure 2-4. Emergency Manual Door Operation

The information in this section is intended as a general guide to steam sterilization techniques. For a more detailed description of this subject, refer to Technique Manual (MK-2085) shipped to you with the sterilizer. Another publication, the Wet Pack Problem Solving Guide (MK-3099), is also available from STERIS education. (Contact STERIS for copies of either publication.) STERIS also refers all supervisors and operators to the Association for the Advancement of Medical Instrumentation (AAMI) standard for Steam Sterilization and Sterility Assurance (SSSA).

The information in this section is intended as a guide to steam sterilization techniques for the most common types of steam sterilizable articles and materials. Preparatory to sterilization, all materials and articles must be thoroughly cleaned. After sterilization, most goods should be stored for no longer than thirty days, depending on wrapping materials. For sterilization of articles or materials not covered in this section, contact the manufacturer of the article for the recommended procedure. Cycle times and temperatures not covered in this section should always be validated for efficacy before processing loads.

For in-depth training, STERIS offers a wide range of education/training programs designed to meet the educational needs of Health-Care Industries. Contact STERIS for details.

Before sterilization, all materials must be thoroughly cleaned.

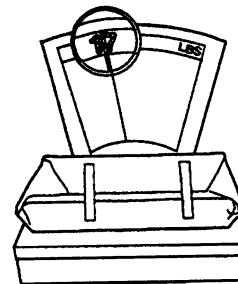
See Figure 3-1.

The Eagle 3000 Series FLJ Floorloading Vacumatic sterilizer chamber holds commonly used wrapped or unwrapped trays and containers.

1. Wrappers may be made of 100% cotton (or equivalent), 140 thread count, two-ply fabric, and freshly laundered.
2. Limit the weight of each pack to approximately 3.3 pounds, and density to 11.3 lb/ft³. STERIS recommends following the AAMI-ST8 recommendations in Section 5.5.1.1.
3. Limit the weight of wrapped instrument sets to 17 pounds in order to assist in minimizing moisture retention. STERIS recommends following the AAMI-ST8 recommendations in Section 5.5.3.1.
4. Use two double-thickness 140 thread count muslin (or equivalent) wrappers for surgical supplies. This provides protection after sterilization.

Preparing Loads for Sterilization Cycles


**Muslin of 140 thread count is the present standard for steam sterilization. The manufacturer of other materials should show data that indicates their product is equivalent to the muslin profile in steam sterilization, drying and sterility maintenance.*




Instrument Sets


Figure 3-1. Loading Parameters

Guidelines for Placement of Various Loads

 **WARNING – BURN HAZARD:** Sterilizer and loading car will be hot after cycle is run. Protective gloves and apron must be worn when reloading sterilizer following the previous operation. (See Section 1 for expanded warning.)

 **WARNING – PERSONAL INJURY HAZARD:** When closing the chamber door, keep hands and arms out of the door opening and make sure opening is clear of any obstructions.

Loading the Sterilizer

 **CAUTION – POSSIBLE EQUIPMENT DAMAGE:** Do not overload the loading cart. The STERIS Floor Loader Loading Cart has a maximum total load capacity of 1,000 lbs (453.6 kg). Each loading cart shelf has a maximum load capacity of 200 lbs (90.7 kg). All loads shall be uniformly distributed on the loading car shelves.

Refer to AAMI ST-46 for load placement guidelines.

1. Open the sterilizer chamber door.

NOTE: If a cycle has been run, sterilizer and loading car may be hot.

2. Place all packs on edge, and arrange load on loading car shelves to allow for maximum exposure, so that there is minimal resistance for steam passage through the load.
3. Place utensils and treatment trays on their edges so that they will be sterilized and properly dried.
4. Place instrument sets in trays that have a perforated bottom (or equivalent). Place flat for sterilization.
5. In mixed loads of fabrics and hard goods, place the hard goods on lower shelf. This prevents wetting of muslin packs from condensate dripping from a hard goods load.
6. **DO NOT OVERLOAD STERILIZER.** Allow for steam penetration between packs. Do not extend load beyond loading car shelves.
7. Materials capable of holding water, such as solid-bottomed pans, basins and trays, should be positioned so that they are oriented in the same direction and so that condensate can be eliminated.
8. After placing load in chamber, close the chamber door. The sterilizer is now ready to run a cycle. Proceed to appropriate cycle description in this section.

1. **STERILIZE LIQUIDS SEPARATELY** from other supplies or materials. See Liquids: Use Liquids Cycle Only, below.
2. Place all fabric packs on edge, and arrange load in chamber to allow for maximum exposure (i.e., minimal resistance for steam passage through the load).
3. Install side support rods on sides of cart to prevent loads from falling off during cart movement.
4. Place jars, canisters, and all other non-porous containers of dry material on sides, with covers ajar or removed. This permits rapid displacement of air and quick contact of steam with all surfaces of containers and contents. Drying is also facilitated.
5. Place utensils and treatment trays on edge so they will be sterilized and dried properly.
6. Place instrument set in tray having perforated bottom (or equivalent). Place flat for sterilization.
7. In mixed loads combining fabrics and hard goods, place the hard goods on lower shelves of loading car. This prevents wetting of muslin packs from condensate dripping from hard goods load.
8. **DO NOT OVERLOAD THE LOADING CART OR THE STERILIZER.** The Floor Loader Loading Cart has a maximum total load capacity of 1,000 lbs (453.6 kg). Each loading cart shelf has a maximum load capacity of 200 lbs (90.7 kg). All loads shall be uniformly distributed on the loading car shelves. Allow for steam penetration between packs. Avoid contact of load components with the walls of the chamber.

Unloading the Sterilizer

⚠ WARNING - INJURY HAZARD: Sterilizer and loading car will be hot after cycle is run. Protective gloves and apron must be worn when reloading sterilizer following the previous operation. (See Section 1 for expanded warning.)

1. Press the UNLOCK/OPEN touchpad once to unlock the sterilizer door and a second time to open the door.
2. Remove loading car(s) from sterilizer and place it where there is no air conditioning or other cold air vents in close proximity. Press the CLOSE touchpad to close the sterilizer door.
3. Visually check outside wrappers for dryness. A pack or instrument tray is considered unacceptable if there are water droplets or visible moisture on the exterior of the package, or on the tape used to secure it.
4. Remove packs or instrument trays from the loading car when they have reached ambient (room) temperature. Depending upon items and environment of area, cooling may take up to one hour.

Liquids: Use LIQUIDS Cycle Only

⚠ WARNING—EXPLOSION HAZARD: This sterilizer is not designed to process flammable compounds. Do not operate this sterilizer in the presence of flammable compounds.

⚠ WARNING - BURN HAZARD: When sterilizing liquids, to prevent personal injury or property damage resulting from bursting containers and hot fluid, you must observe the following precautions:

- Use Liquids cycle only. No other cycle is safe for processing liquids.
- Avoid sudden full opening of door at end of the cycle. Unlock sterilizer door, but do not open door. Wait at least 10 minutes before unloading sterilizer.

IMPORTANT: Please read the following paragraphs before sterilizing any liquids in your sterilizer.

Your STERIS sterilizer is designed to process liquids only when borosilicate containers with vented closures are used.

Borosilicate glass is required because it is a superior glass capable of resisting thermal shock. If glass not as thermally resistant is used, a greater potential for bursting exists.

Do not operate this sterilizer in the presence of flammable compounds.

Vented closures are required because, by design, they release internal pressure build-up by automatically venting the containers, whereas pressure in unvented containers remains until the contents have cooled. Examples of vented closures are shown in Figure 3-2.

Sterilizing liquids in any other type of container or with the use of non-vented closures requires a sterilizer specifically designed for that purpose.

When loading, place small bottles in a separate basket to minimize sliding. Always use side rails on the loading cart to prevent containers or baskets from falling off.

IMPORTANT: It is inappropriate for a health care facility to sterilize liquids intended for direct patient contact.

Biological Monitors

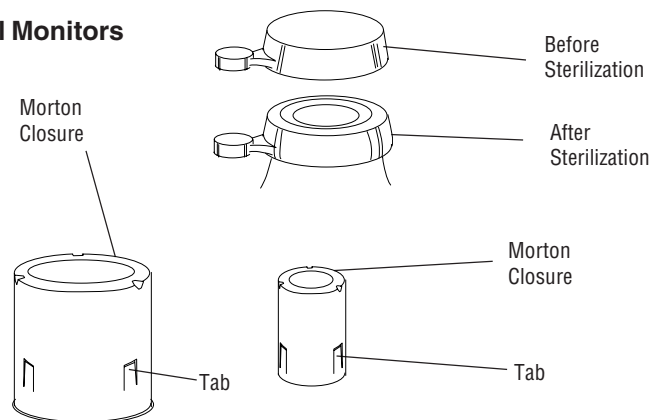


Figure 3-2. Vented Closures

⚠ WARNING—INJURY HAZARD: Process only vented closures; do not use screw caps or rubber stoppers with crimped seal.

⚠ WARNING—INJURY HAZARD: Process only Type 1 borosilicate glass containers; do not use ordinary glass bottles or any container not designed for sterilization.

- Do not allow hot bottles to be jolted; this can cause hot-bottle explosions. Do not move bottles if any boiling or bubbling is present.
- Allow containers to cool to touch before attempting to move them from sterilizer cart to the storage area.

⚠ WARNING—STERILITY ASSURANCE HAZARD: It is inappropriate for a health care facility to sterilize liquids for direct patient contact.

⚠ CAUTION: Immediately wipe up saline solution spills on loading car, to prevent damage to stainless steel.

⚠ CAUTION: Do not use cleaners containing chlorides on loading cars. Chloride-based cleaners will deteriorate the loading car metal.

TABLE 3-1. MINIMUM RECOMMENDED EXPOSURE TIMES FOR FULL LOAD OF AUTOPOUR® FLASKED SOLUTIONS

ASPF Size	Time (Minutes)	Temperature
75 ML	25	250 F (121 C)
250 ML	30	250 F (121 C)
500 ML	40	250 F (121 C)
1000 ML	45	250 F (121 C)
1500 ML	50	250 F (121 C)
2000 ML	55	250 F (121 C)

Control Measures For Verifying Sterilization Process

As part of the operator’s verification of the sterilization process, biological indicators may be used to demonstrate that sterilization conditions have been met. The biological indicators used should consist of spores of *Bacillus stearothermophilus* that comply with the *American National Standard for Biological Indicators for Saturated Steam Sterilization Processes in Health Care Facilities (AAMI ST19, 1986)*.

NOTE: Contact your **STERIS** representative for information on specific biological indicators recommended for use with this sterilizer.

This sterilizer should be biologically monitored during initial installation, after any major repairs, and at least once a week (preferably daily) during normal use. Each type of sterilization cycle used should be monitored. Consult AAMI ST42, “Steam sterilization and sterility assurance in office-based, ambulatory-care medical and dental facilities” for details, including guidelines for loads containing implantable devices.



WARNING – STERILITY ASSURANCE HAZARD:
Load sterility may be compromised if the biological, air removal or air leak tests indicate a potential problem. If these indicators show a potential problem, refer the situation to your supervisor before using the sterilizer further.

The biological test pack used for installation testing or biological monitoring should be representative of the type of package or tray that will routinely be processed in the sterilizer. Of the types of packs or trays most frequently processed in each cycle, the one considered to be the most difficult to sterilize should be selected as the test pack for that cycle. *When selecting challenge packs, you should consider multiple layers of dressing materials, large metal masses, and mixed packs incorporating both.* The pack or tray selected should contain the items normally present during routine sterilization, plus at least one biological indicator. At least one additional biological indicator from the same lot should be left unexposed to the sterilant and should be incubated and processed as a control.

The biological indicator test pack should be placed on its edge if it is a small pack or flat if it is a tray or large pack and should be positioned in the center of the chamber, as close to the chamber door as possible. This is the “cold point” area of the chamber, which presents the greatest challenge to sterilization. The cycle being tested can then be selected and started, after which the biological indicators are to be handled, processed, and interpreted according to the biological indicator manufacturer’s instructions.

Reference ANSI/AAMI ST42-1992, “Steam sterilization and sterility assurance in office-based, ambulatory-care medical and dental facilities.”

Testing for Air Removal Efficiency

The first prevacuum cycle of each day should be used to test the adequacy of air removal from the chamber and load during the prevacuum phase, so that steam can penetrate the load virtually instantaneous. It is not a test for time and temperature exposure levels.

Tests such as the Bowie-Dick or the Amsco Dart* (Daily Air Removal Test) are designed to document the removal of residual air from a sample challenge load.

In the case of these tests, following exposure in a prevacuum sterilizing cycle, the pack is opened, and an indicator strip or chart examined for evidence of residual air, if any, that remained in the pack during the sterilizing cycle. Any indication of a malfunction must be reported to the supervisor, who will determine the disposition of the sterilizer, i.e., whether it should be retested, serviced, or remain in use.

Refer to instruction for running a Dart test given in Section 4 of this manual.

STERIS recommends a Daily Air Removal Test (Dart), or Bowie-Dick test package. Any test package must be constructed in accordance with AAMI standard SSSA. Place the indicator used within the pack in accordance with instructions given in AAMI standard SSSA.

NOTE: *With the Dart (Daily Air Removal Test) product, a simple color change from yellow to black of the six (6) indicator bars verifies that air has been removed from the challenge load area of the Dart product.*

Dart (Bowie-Dick) Test

Vacuum Leak Test



WARNING - STERILITY ASSURANCE HAZARD: According to AAMI standards a measured leak rate of one millimeter or greater per minute indicates a problem with the sterilizer. Refer the situation to your supervisor before using the sterilizer further.

The Vacuum Leak Test Cycle (see appropriate cycle description in Section 4 of this manual) measures the integrity of the sealed pressure vessel and associated piping to assure air is not being admitted to the sterilizer during the vacuum draw downs.

After running a vacuum leak test, a value or leak rate will be printed on the printer tape. This value will help define a trend over a period of time if the integrity of the system begins to deteriorate (i.e., allowing air to enter the system). By running a vacuum leak test cycle daily or weekly, the operator or maintenance personnel can always monitor the air tightness of the system and make repairs or adjustments when necessary. A leak rate of one millimeter or greater per minute indicates a problem with the sterilizer that must be addressed.

Auxiliary Controls

Printed Record and Display Messages

Observe the print records and display messages during and after each cycle to determine if correct time/temperature relationship has been attained and maintained as necessary for a particular sterilizer load. An example of the printed record is shown in Figure 3-3.

Chemical Indicators - Examples are shown in Figure 3-3.

1. Sterilizer Tape - Used for securing wrapper/package and only as an index of exposure to the sterilant system.
2. Chemical Indicator - such as Chemdi Steam Indicator Strips*. Placed in center of pack/package . . . indicates physical conditions of temperature, time, moisture have been reached in that portion of the pack/package.

*Available from your local STERIS representative.

```

=====
===== PRE VAC =====
=====
CYCLE START AT 10:48:55A
                ON 4/05/93

CYCLE COUNT    00000
OPERATOR
STERILIZER     FLJ 00

STER TEMP = 270.0F
CONTROL TEMP = 273.0F
STER TIME = 4 MIN
DRY TIME = 20 MIN

          U=inHg
- TIME    T=F  P=psi
C 10:48:56A  77.0  0P
C 10:49:55A  167.0  0P
C 10:52:56A  158.0  10U
C 10:55:06A  268.0  26P
C 10:57:00A  200.6  12U
C 10:58:41A  268.0  26P
C 11:00:36A  197.9  16U
C 11:02:17A  268.0  26P
C 11:04:10A  194.3  20U
S 11:06:30A  270.1  27P
S 11:08:43A  273.0  29P
E 11:10:45A  273.0  29P
E 11:11:35A  219.0  3P
E 11:30:26A  198.2  28U
Z 11:30:39A  192.8  2U

LOAD          040501

TEMP MAX=273.0F
TEMP MIN=270.1F

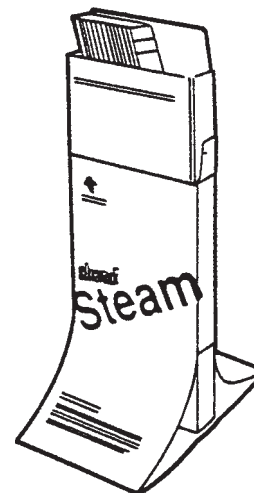
CONDITION    =17:42
STERILIZE    = 4:00
EXHAUST      =21:03
TOTAL CYCLE  =42:52

=====
=  READY TO UNLOAD  =
=====
    
```

Printed Record



Prevacum Test



Chemical Indicators

Figure 3-3. Auxiliary Controls

The information in this section will provide optimum equipment performance if followed carefully. It will not, however, compensate for failure to observe and understand the parameters (time, temperature, and pressure relationships) of the sterilization process. Refer to Section 3 for proper Sterilization Techniques.

Prepare Equipment For Operation

⚠ WARNING – SUFFOCATION AND BURN HAZARD: When entering sterilizer for any reason, shut **POWER** and **CONTROL** switches **OFF**, lock customer supplied main power disconnect switches in **OFF** position and always place red door safety stop in a horizontal position to prevent door closure. Never enter sterilizer when door is closing (as indicated by beeping alarm).

NOTE: Pressure display should read zero when the sterilizer door is open. If it does not, press the RESET button on control panel.

Routine Power-Up of Sterilizer

See Figure 4-1.

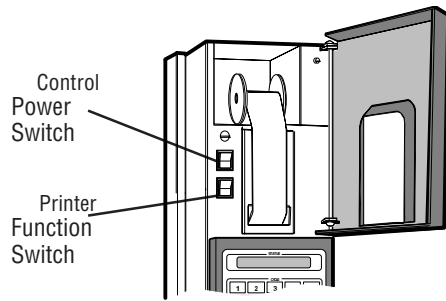
1. Make sure steam and water utilities are supplied to the sterilizer.
2. Unlock and open chamber door (see Section 2: "Power Door Operation").
3. Check that chamber drain strainer is clean and in place, and that chamber interior is clean. If cleaning is necessary refer to Service and Maintenance Procedures manual, P-150828-806.
4. Make sure the main power disconnect switch, located at the service side of the sterilizer behind the control column, is turned ON. Control column display should read "STANDBY".
5. Open the printer door and position the Control Power switch to ON.
 - Display changes from "STANDBY" to "READY" (and time of day).
 - Printer records the time and date that the power is turned ON.
6. Check display for correct time and date.
 - To change time or date, press the Change Values touch pad and adjust displayed time or date following "Set Time and Date" procedure in Service and Maintenance procedures manual, P-150828-806.
7. Check paper roll. A colored warning stripe is visible on the paper when the roll is near its end. If it is necessary to change the paper roll, refer to Service and Maintenance procedures manual, P-150828-806.

This cycle is used for sterilizing double-wrapped instrument trays or fabric packs.

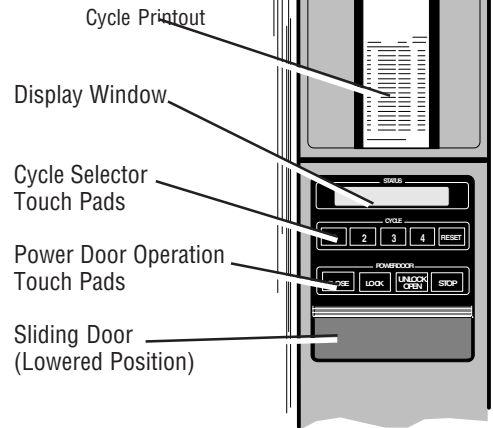
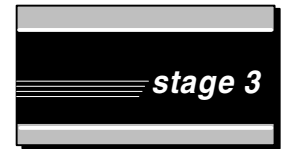
If the sterilizer is in STANDBY, open the printer door and position control power switch to ON.

- Display window shows the following:





**Controls With
Printer Door Open**



Stage 3™ Control

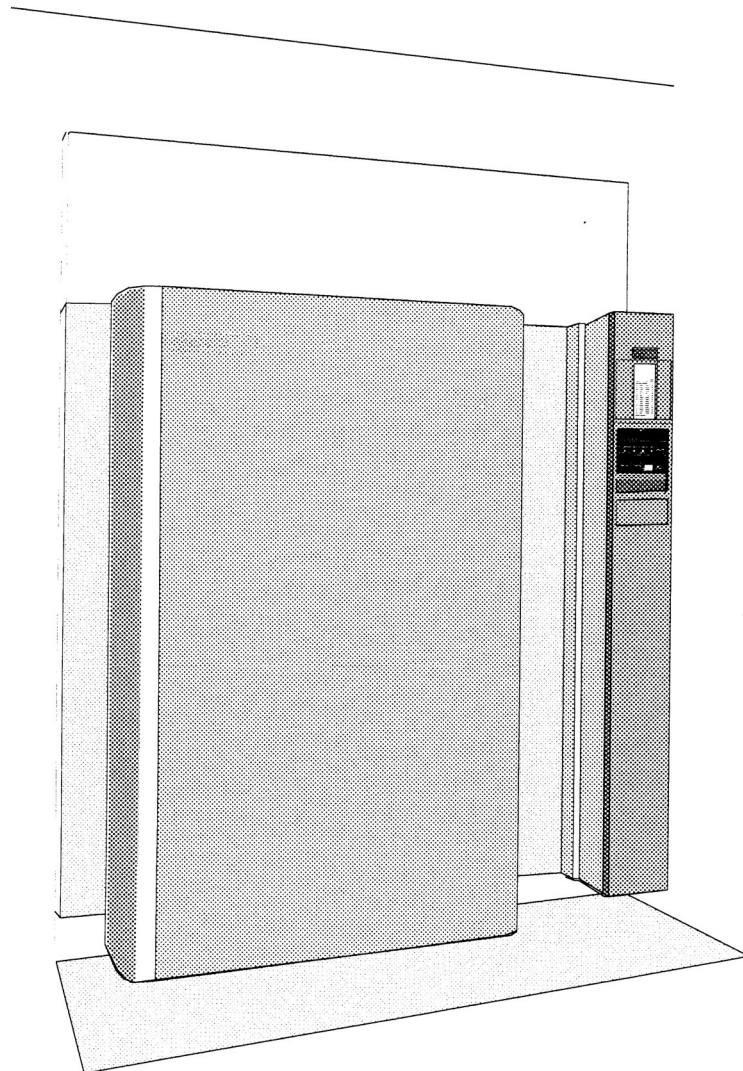
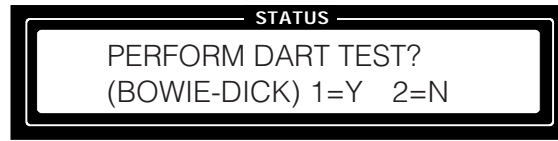


Figure 4-1. VACAMATIC FLOOR LOADING SYSTEM STERILIZER

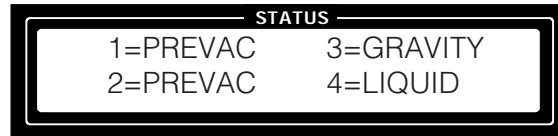
NOTE: 1 and 2 refer to the #1 and #2 touchpads on the control column, located beneath the Display Window.

Press 2 to bypass the Leak Test. Once this test has been bypassed the next message appears on the display:



NOTE: Recommendations for when to use the Leak Test and Dart Test, as well as operating details for both can be found near the end of this Section of the manual.

Press 2 to bypass the DART test. Once these cycles have been bypassed (or, when necessary, run) the display changes to the show Door Status, then changes again to show the main cycle selection menu:



The door may be opened, or unlocked. If open, press the door control touchpad labeled "CLOSE" once. While the door is closing, an intermittent alarm tone sounds. Once the door is closed, press the LOCK touchpad; the door lowers into place and locks. The sterilizer is now ready to run cycles.

Automatic Operation: Prevacuum Cycle

NOTE: Refer to Troubleshooting section in Service and Maintenance Procedures (P-150828-806), to identify the cause of any abnormal condition during a sterilization cycle.

1. Follow instructions in Prepare Equipment For Operation on the first page of this section.
2. Open door of printer and check that CONTROL POWER switch is ON.
3. Unlock and open chamber door (see Section 2: "Power Door Operation").
 - Printer records time door is unlocked and prints NOT READY.
 - Display message is "DOOR UNLOCKED".
4. Load the chamber. (See page 3-2 "Loading the Sterilizer.")
5. Close and lock chamber door (see Section 2: "Power Door Operation"). Display window message is "TIME" plus Time of Day.
6. Press corresponding number touch pad (1,2,3 or 4) for PREVACUUM cycle and release, then press and release touch pad a second time within five seconds to begin cycle. Sterilizer will automatically progress through cycle as shown in Figure 4-2.
7. Unlock and open chamber door (see Section 2: "Power Door Operation").
 - Printer records time door is unlocked and prints NOT READY.
 - DOOR UNLOCKED message is displayed.
8. Unload chamber (See page 3-3 "Unloading the Sterilizer") and, if duplicate printout is requested, tear off duplicate record and place with the completed load.
9. Close chamber door between cycles.

⚠ WARNING – BURN HAZARD: Sterilizer and loading cart will be HOT after cycle is run. Always wear protective gloves and apron (also face shield if processing liquids) when removing a processed load. Protective gloves and apron should also be worn when re-loading sterilizer following previous operation.

⚠ WARNING – SLIPPING HAZARD: To avoid slippery floor conditions, immediately wipe up any spilled liquids or condensation in sterilizer loading area.

```

=====
==== P R E V A C =====
=====
CYCLE START AT 9:38:37A
                   ON 5/19/93

CYCLE COUNT      00015
OPERATOR -----
STERILIZER       FLJ 00

STER TEMP = 270.0F
CONTROL TEMP = 273.0F
STER TIME = 4 MIN
DRY TIME = 5 MIN

                                U=inHg
- TIME          T=F  P=Psi
-----
C 9:38:37A  188.1  0P
C 9:39:36A  247.6  12P
C 9:40:57A  140.4  22U
C 9:42:27A  265.4  26P
C 9:44:02A  151.5  23U
C 9:45:10A  267.4  26P
C 9:46:41A  153.6  23U
C 9:47:48A  268.7  26P
C 9:49:19A  145.2  23U
  
```

```

S 9:50:33A  270.1  27P
S 9:52:34A  273.2  27P
E 9:54:33A  273.4  27P
E 9:55:01A  230.1  3P
E 10:00:00A  95.6  26U
Z 10:02:31A  125.7  1U

LOAD                      051903

TEMP MAX=273.7F
TEMP MIN=270.1F

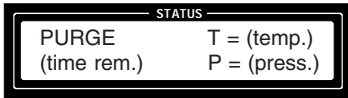
CONDITION  =11:57
STERILIZE  = 4:00
EXHAUST    = 7:58
TOTAL CYCLE =23:55

=====
=  READY TO UNLOAD  =
=====

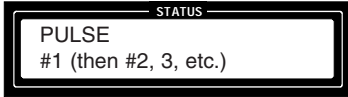
* NOT READY  10:03:19A
DOOR UNLOCKED
  
```

Prevacuum Cycle, Example Printout

**DISPLAY MESSAGE SEQUENCE
FOR PREVAC CYCLES**



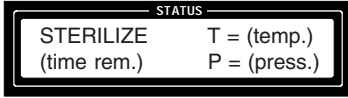
First Message of cycle when cycle starts.



Second Message -- after PURGE completed, will continue for number of pressure/vacuum pulses set for current cycle.



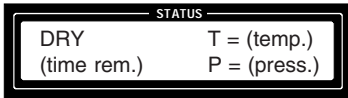
Third Message -- after PULSE sequence completed.



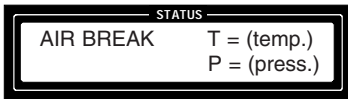
Fourth Message -- after CHARGE completed.



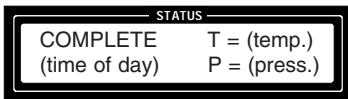
Fifth Message -- after STERILIZE time completed.



Sixth Message -- if DRY set to zero, this display will not appear. AMSCO does not recommend this.



Seventh Message -- after EXHAUST or DRY completed.



Last Message -- after AIR BREAK complete.

**Prevacuum Cycle, Example
Displays**

- PREVACUUM . . . and start of cycle message and cycle parameters are printed.
- Chamber is purged with steam. Start of condition is printed.
- Pressure point is printed and chamber is evacuated.
- Vacuum point is printed and chamber is charged with steam.
- Pressure point is printed and vacuum/pressure pulses are repeated.
- After last vacuum pulse, chamber is charged with steam until set sterilize temperature is reached.
- Start of sterilize phase is printed when the chamber reaches set temperature.
- Chamber temperature is printed at selected print interval control values. Chamber is controlled at set point plus overdrive.
- Start of exhaust is printed and chamber is exhausted to three psig.
- If Selected - Start of dry is printed and display counts down dry time remaining. Vacuum pulled in repeating five minute pulses until phase complete.
- Chamber is vented to atmospheric pressure.
- Complete tone sounds.
- Cycle summary and end of cycle messages are printed.

Figure 4-2. Prevacuum Cycle

Automatic Operation: Gravity Cycle (Wrapped and Unwrapped Goods)

NOTE: Refer to Troubleshooting section in Service and Maintenance Procedures (P-150828-806), to identify the cause of any abnormal condition during a sterilization cycle.

NOTE: Dry time is not required for unwrapped goods, however, a minimum of two minutes dry time will help eliminate excess steam vapor when opening chamber door at end of cycle.

⚠ WARNING – INJURY HAZARD: Sterilizer and loading cart will be HOT after cycle is run. Always wear protective gloves and apron (also face shield if processing liquids) when removing a processed load. Protective gloves and apron should also be worn when reloading sterilizer following previous operation.

⚠ WARNING – SLIPPING HAZARD: To avoid slippery floor conditions, immediately wipe up any spilled liquids or condensation in sterilizer loading area.

250°F (121°C) cycle is used for sterilizing fabric packs.

1. Follow instructions on first page of Section 4: "Prepare Equipment For Operation".
2. Open printer door: Check that CONTROL POWER switch is ON.
3. Unlock and open chamber door (see Section 2: "Power Door Operation").
 - Printer records time door is unlocked and prints NOT READY.
 - Display message is "DOOR UNLOCKED".
4. Load the chamber. (See page 3-2 "Loading the Sterilizer.")
5. Close and lock chamber door (see Section 2: "Power Door Operation"). Display window message is "TIME" plus time of day.
6. Press corresponding number touch pad (1,2,3 or 4) for GRAVITY cycle and release, then press and release touch pad a second time within five seconds to begin cycle. Sterilizer will automatically progress through cycle as shown in Figure 4-3.
7. Unlock and open chamber door (see Section 2: "Power Door Operation").
 - Printer records time door is unlocked and prints NOT READY.
 - DOOR UNLOCKED message is displayed.
8. Unload chamber (See page 3-3 "Unloading the Sterilizer") and, if duplicate printout has been programmed, tear off duplicate record and place with the completed load.
9. Close chamber door between cycles.

```

=====
==== GRAVITY ====
=====
CYCLE START AT 11:08:37A
                ON 5/19/93

CYCLE COUNT    00017
OPERATOR -----
STERILIZER     FLJ 00

STER TEMP = 250.0F
CONTROL TEMP = 253.0F
STER TIME = 30 MIN
DRY TIME = 15 MIN

- TIME          T=F  P=psig  U=inHg
-----
C 11:08:37A    176.2   0P
C 11:09:36A    251.0  13P
S 11:09:36A    251.0  13P
S 11:14:37A    253.1  18P
S 11:19:36A    253.6  17P
S 11:24:36A    253.2  16P
S 11:29:36A    253.4  16P
  
```

```

S 11:34:36A    253.4  16P
E 11:39:36A    253.4  16P
E 11:39:55A    228.7   3P
E 11:44:56A     93.2  26V
E 11:47:18A    125.0   2U
E 11:52:19A    204.0  25U
E 11:54:35A    168.3   2U
E 11:54:55A    211.3   8U
Z 11:55:48A    189.9   1U

LOAD           051905

TEMP MAX=258.4F
TEMP MIN=251.0F

CONDITION     = 1:00
STERILIZE     =30:00
EXHAUST       =16:13
TOTAL CYCLE   =47:14

=====
=  READY TO UNLOAD  =
=====
  
```

Gravity Cycle, Example Printout

DISPLAY MESSAGE SEQUENCE FOR GRAVITY CYCLES

STATUS	
PURGE (time rem.)	T = (temp.) P = (press.)

First Message of cycle when cycle starts.

STATUS	
CHARGE	T = (temp.) P = (press.)

Second Message -- after PURGE completed.

STATUS	
STERILIZE (time rem.)	T = (temp.) P = (press.)

Third Message -- after CHARGE completed.

STATUS	
FAST EXHAUST	T = (temp.) P = (press.)

Fourth Message -- after STERILIZE time completed.

STATUS	
DRY (time rem.)	T = (temp.) P = (press.)

Fifth Message -- only if DRY time selected.

STATUS	
AIR BREAK	T = (temp.) P = (press.)

Sixth Message -- after EXHAUST or DRY completed.

STATUS	
COMPLETE (time of day)	T = (temp.) P = (press.)

Last Message -- after AIR BREAK complete.

Gravity Cycle, Example Displays

- GRAVITY . . . and start of cycle message and cycle parameters are printed.
- Chamber is purged with steam. Start of condition is printed.
- Chamber is charged with steam. Start of steam charge is printed.
- Start of sterilize phase is printed when the chamber reaches set temperature.
- Chamber temperature is printed every five minutes (or selected print interval control value). Chamber is controlled at set point plus overdrive
- Start of exhaust is printed and chamber is exhausted to three psig.
- If Selected - start of dry is printed and display counts down dry time remaining. Vacuum pulled in repeating five minute pulses until phase complete.
- Chamber is vented to atmospheric pressure.
- Complete tone sounds.
- Cycle summary and end of cycle messages are printed.

Figure 4-3. Gravity Cycle

Liquids Cycle

WARNING – EXPLOSION HAZARD: This sterilizer is not designed to process flammable compounds. Do not operate this sterilizer in the presence of flammable compounds.

WARNING – INJURY HAZARD: Process only vented closures; do not use screw caps or rubber stoppers with crimped seal.

WARNING – INJURY HAZARD: Process only Type I borosilicate glass bottles; do not use ordinary glass bottles or any container not designed for sterilization.

WARNING – INJURY HAZARD: Do not allow hot bottles to be jolted; this can cause hot-bottle explosions! Do not move bottles if any boiling or bubbling is present.

WARNING – INJURY HAZARD: Allow containers to cool to touch before attempting to move them from sterilizer cart to the storage area.

WARNING – INJURY HAZARD: Sterilizer and loading cart will be HOT after cycle is run. Always wear protective gloves and apron (also face shield if processing liquids) when removing a processed load. Protective gloves and apron should also be worn when reloading sterilizer following previous operation.

1. Follow instructions on first page of this Section: "Prepare Equipment For Operation".
2. Open printer door: Check that CONTROL POWER switch is ON.
3. Unlock and open chamber door (see Section 2: "Power Door Operation").
 - Printer records time door is unlocked and prints NOT READY.
 - Display message is "DOOR UNLOCKED".
4. Load the chamber.
5. Close and lock chamber door (see Section 2: "Power Door Operation"). Display window message changes to "TIME"; plus time of day.
6. Press corresponding number touch pad (1, 2, 3 or 4) for LIQUIDS cycle and release touch pad a second time within five seconds to begin cycle. Sterilizer will automatically progress through cycle as shown in Figure 4-4.
7. Unlock door, but do not open, and wait at least 10 minutes for all boiling and bubbling of solutions to cease (see Section 2: "Power Door Operation").
 - Display shows . . . NOT READY . . .
 - Printer records the time the door is unlocked and prints "DOOR UNLOCKED".
 - Display begins countdown from 10 minutes and alternately shows . . . UNLOAD IN . . . (time remaining) and . . . WARNING: HOT LIQUIDS
 - Tone sounds at end of 10 minutes and display shows . . . READY TO UNLOAD . . .
8. Unload chamber and, if duplicate printout has been requested, tear off duplicate record and place with completed load.

```

=====
===== L I Q U I D =====
=====
CYCLE START AT 11:07:57A
                ON 4/05/93

CYCLE COUNT    00002
OPERATOR
STERILIZER     FLJ 00

STER TEMP = 250.0F
CONTROL TEMP = 253.0F
STER TIME = 45 MIN

                U=inHg
- TIME          T=F  P=psig
C 11:07:57A    175.0  0P
C 11:08:57A    239.0  11P
S 11:10:15A    250.1  15P
S 11:14:57A    253.0  17P
S 11:19:36A    253.0  17P
S 11:24:15A    253.0  17P
S 11:28:47A    253.0  17P
S 11:33:18A    253.0  17P
S 11:37:59A    253.0  17P
S 11:42:47A    253.0  17P
S 11:47:17A    253.0  17P
E 11:52:00A    253.0  17P
  
```

```

E 11:56:26A    218.8  3P
E 11:57:01A    213.4  1P
Z 11:57:10A    212.5  0P

LOAD          040503

TEMP MAX=253.0F
TEMP MIN=250.1F

CONDITION     = 2:13
STERILIZE     =45:00
EXHAUST       = 5:15
TOTAL CYCLE   =52:35

+++++++
+ WARNING +
+ HOT LIQUIDS! +
+ UNLOCK DOOR +
+ AND UNLOAD IN 10min. +
+++++++
+ DOOR OPEN 11:57:59A +
+++++++

=====
= READY TO UNLOAD =
=====
  
```

Liquid Cycle, Example Printout

⚠ WARNING – BURN HAZARD: When sterilizing liquids, to prevent or property damage resulting from bursting containers and hot fluid, you must observe the following precautions:

- Use Liquids cycle only. No other cycle is safe for processing liquids.
- Avoid sudden full opening of door at the end of the cycle. Unlock sterilizer door, but do not open door. Wait at least 10 minutes before unloading the sterilizer.

⚠ WARNING – STERILITY ASSURANCE HAZARD: It is inappropriate for a health care facility to sterilize liquids for direct patient contact.

⚠ CAUTION: Immediately wipe up saline solution spills on loading car, to prevent damage to stainless steel.

⚠ CAUTION: Do not use cleaners containing chlorides on loading cars. Chloride-based cleaners will deteriorate the loading car metal.

DISPLAY MESSAGE SEQUENCE FOR LIQUIDS CYCLES

STATUS	
PURGE (time rem.)	T = (temp.) P = (press.)

First Message of cycle when cycle starts.

STATUS	
CHARGE	T = (temp.) P = (press.)

Third Message -- after PULSE sequence completed.

STATUS	
STERILIZE (time rem.)	T = (temp.) P = (press.)

Fourth Message -- after CHARGE completed.

STATUS	
SLOW EXHAUST	T = (temp.) P = (press.)

STATUS	
WARNING HOT LIQUIDS	T = (temp.) P = (press.)

Fifth Message -- after STERILIZE time completed (alternate every four seconds).

STATUS	
VENT	T = (temp.) P = (press.)

STATUS	
WARNING HOT LIQUIDS	T = (temp.) P = (press.)

Seventh Message -- after EXHAUST completed (alternate every four seconds).

STATUS	
COMPLETE (time of day)	T = (temp.) P = (press.)

STATUS	
WARNING HOT LIQUIDS	T = (temp.) P = (press.)

Last Message -- after VENT complete (alternate every four seconds).

- LIQUID . . . and start of cycle message and cycle parameters are printed.
- Chamber is purged with steam. Start of condition is printed.
- Chamber is charged with steam. Start of steam charge is printed.
- Start of sterilize phase is printed when the chamber reaches set temperature.
- Chamber temperature is printed every five minutes (or selected print interval control value). Chamber is controlled at set point plus overdrive.
- Start of exhaust is printed and chamber is slow exhausted to three psig (or selected P3 control value).
- Exhaust opens to atmosphere.
- Chamber pulled to slight vacuum to remove steam.
- Complete tone sounds. Cycle summary, end of cycle messages, and WARNING HOT LIQUIDS UNLOCK DOOR AND UNLOAD IN 10 MINUTES, are printed.

Liquid Cycle, Example Displays

Figure 4-4. Liquid Cycle

Vacuum Leak Test Cycle

NOTE: Cycle requires approximately 45 minutes to complete.

NOTE: If vacuum level of 20" Hg (253 mm Hg) is not reached within 30 minutes from cycle start, cycle will time out and automatically abort. This indicates a major leak or equipment malfunction is present. Have qualified technician correct problem.

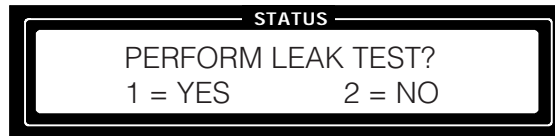
NOTE: Sequential records of tests should be kept to detect if any major changes in leak rates are occurring. Maintenance can then be scheduled to correct any loose fittings, bad gaskets, etc.

See Figure 4-5.

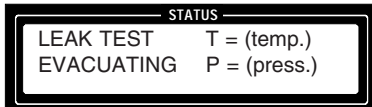
A VACUUM LEAK TEST CYCLE may be run as the first cycle only after positioning power switch to ON. If any cycle has been run after switching power ON, the leak test cycle cannot be started until power is switched OFF, and then ON again. In this cycle the sterilizer automatically checks for vacuum leaks in the piping and door seal.

The measured leak rate (mm Hg per minute) is calculated by the control over a timed period and included in the cycle printout.

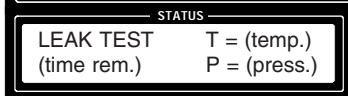
1. Verify that STEAM and WATER utility supplies to the unit are ON.
2. Unlock chamber door and check that chamber is empty, then close and lock chamber door(s).
3. Turn sterilizer CONTROL POWER switch OFF, then ON.
 - Display asks . . .



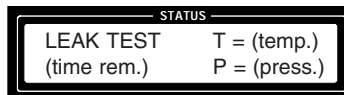
DISPLAY MESSAGE SEQUENCE FOR VACUUM LEAK TEST CYCLE



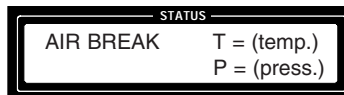
First Message -- shown during 10 minute evacuation (alternates every four seconds).



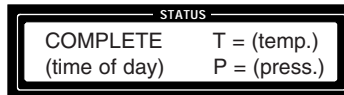
Second Message -- shown during two minute stabilization period.



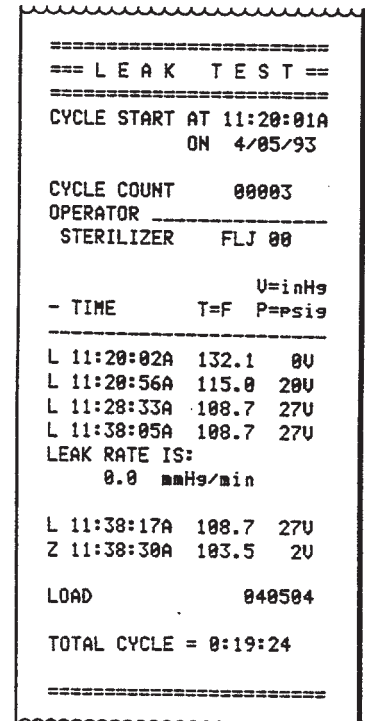
Third Message -- shown during 10 minute measured leak rate time.



Fourth Message -- shown at completion of measured leak rate time.



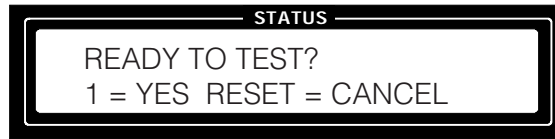
Last Message -- after AIR BREAK complete.



Example Printout

Figure 4-5. Vacuum Leak Test

4. Press cycle selector touch pad "1" to select the cycle.
 - Display asks . . .

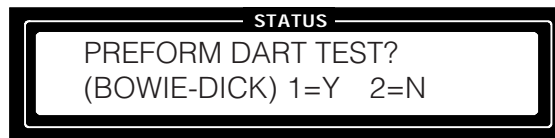


5. Press cycle selector touch pad "1" to start the cycle and sterilizer will automatically progress through Leak Test Cycle as follows:

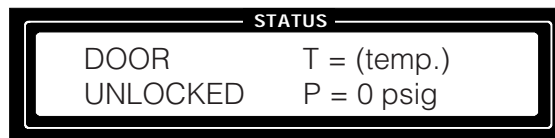
- Printer records cycle start.
- Printer records temperature and vacuum at beginning of evacuation time.
- The sterilizer pulls a vacuum in the chamber, stabilization period begins after evacuation is completed.
- Ten minute leak test period begins after stabilization is completed.
- Printer records calculated leak rate (mm Hg per minute) after ten minute leak time.
- Chamber is returned to atmospheric pressure, complete tone sounds and cycle summary and end of cycle messages are printed.

6. Unlock and open chamber door.

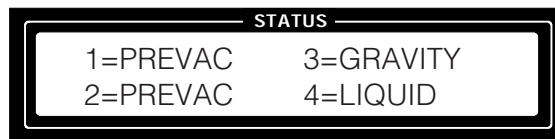
- After the cycle is complete, the display shows the following message:



- Press 1 to run DART test, or 2 to bypass.
- Display alternately shows . . . (example)



and



- Printer records time door is opened and prints "NOT READY" and time of day; display message changes to "DOOR UNLOCKED"

7. File duplicate print in maintenance records.

⚠ WARNING – STERILITY ASSURANCE HAZARD: According to AAMI standards, a measure leak rate of one millimeter or greater per minute indicates a problem with the sterilizer. Refer the situation to your supervisor before using the sterilizer further.

⚠ WARNING – STERILITY ASSURANCE HAZARD: Load sterility may be compromised if the biological, air-removal or air leak tests indicate a potential problem. If these indicators show a potential problem, refer the situation to your supervisor before using the sterilizer further.

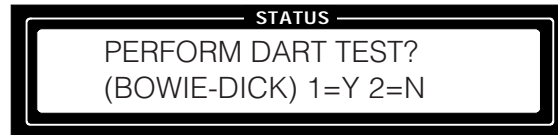
Dart (Bowie-Dick) Test Cycle

A Dart (BOWIE-DICK) TEST CYCLE may be run as the first or second cycle only after positioning the CONTROL POWER switch to ON. Chamber must be at operating temperature when Dart (BOWIE-DICK) TEST is performed. A LEAK TEST cycle should be completed prior to performing Dart (BOWIE-DICK) TEST. Tests such as the Dart or Bowie-Dick are designed to document the removal of residual air from a sample challenge load and should be run before sterilizer use each day (refer to Testing For Air Removal Efficiency in Section 3 and Figure 4-6 on next page).

1. Verify that STEAM and WATER utility supplies to the unit are ON.
2. Unlock chamber door and check that chamber is empty, then close and lock chamber door(s).
3. Turn sterilizer CONTROL POWER switch to OFF, then ON.
 - Display asks . . .



4. Press cycle selector touch pad number "2" for NO, or if a vacuum leak test is desired, refer to the Vacuum Leak Test Cycle section of this manual.
 - The following message will be shown at the completion of Leak Test or after pressing "2".



5. The display then shows the following message:



Press cycle selector touch pad "1" and sterilizer will automatically proceed to run a "short gravity" warm-up cycle with three minute sterilize and one minute dry times. Refer to Service and Maintenance Procedures (Manual P-150828-806) for procedures to change cycle phase times.

! WARNING – STERILITY ASSURANCE HAZARD: According to AAMI standards, a measure leak rate of one millimeter or greater per minute indicates a problem with the sterilizer. Refer the situation to your supervisor before using the sterilizer further.

! WARNING – STERILITY ASSURANCE HAZARD: Load sterility may be compromised if the biological, air-removal or air leak tests indicate a potential problem. If these indicators show a potential problem, refer the situation to your supervisor before using the sterilizer further.


```

=====
===== D A R T =====
=====
CYCLE START AT 11:23:59A
ON 4/05/93

CYCLE COUNT 00004
OPERATOR -----
STERILIZER FLJ 00

STER TEMP = 270.0F
CONTROL TEMP = 273.0F
STER TIME = 3.5 MIN
DRY TIME = 1 MIN

U=inHg
- TIME T=F P=psis
C 11:23:59A 100.0 0P
C 11:24:59A 192.7 0P
C 11:27:59A 183.7 10U
C 11:29:53A 267.6 26P
C 11:31:50A 200.2 12U
C 11:33:29A 267.9 26P
C 11:35:25A 197.8 16U
C 11:37:10A 268.2 26P
C 11:39:06A 194.5 20U
S 11:41:37A 270.1 27P
S 11:42:42A 273.0 29P
S 11:43:43A 273.0 29P
S 11:44:41A 273.0 29P
E 11:45:07A 273.0 29P
E 11:46:00A 219.0 3P
E 11:46:59A 210.9 9U
Z 11:47:11A 209.3 2U

LOAD 040505

TEMP MAX=273.0F
TEMP MIN=270.1F

CONDITION =17:35
STERILIZE = 3:30
EXHAUST = 2:04
TOTAL CYCLE =23:09

=====
= READY TO UNLOAD =
=====

```

Example Printout

DISPLAY MESSAGE SEQUENCE FOR BOWIE-DICK TEST CYCLE

STATUS
PURGE T = (temp.)
(time rem.) P = (press.)

First Message of cycle when cycle starts

STATUS
PULSE
#1 (#2, #3, etc.)

Second Message -- after PURGE completed, will repeat for time for the four vacuum pulses

STATUS
CHARGE T = (temp.)
P = (press.)

Third Message -- after PULSES completed

STATUS
STERILIZE T = (temp.)
P = (press.)

Fourth Message -- after charge completed.

STATUS
FAST T = (temp.)
EXHAUST P = (press.)

Fifth Message -- after STERILIZE phase completed..

STATUS
DRY T = (temp.)
(time rem.) P = (press.)

Sixth Message -- only if DRY time selected.

STATUS
AIR BREAK T = (temp.)
P = (press.)

Seventh Message -- after DRY or EXHAUST time completed.

STATUS
COMPLETE T = (temp.)
(time of day) P = (press.)

Last Message -- after AIR BREAK completed.

- At completion of warm-up cycle, display will show following message:

STATUS
LOAD DART PACK
PRESS 1 TO TEST

If a Warm-Up Cycle is not required . . . Press cycle selector touch pad number 2 for NO if sterilizer is at operating temperature (i.e., Leak Test just performed, unit has been in operation).

- Display will show following message:

STATUS
LOAD DART PACK
PRESS 1 TO TEST

- Load Dart or Bowie-Dick type test pack (see Testing For Air Removal Efficiency in Section 3) and press cycle selector touch pad "1" to perform test cycle. Sterilizer will automatically proceed through a prevacuum test cycle with four pressure/vacuum pulses and three and one half minute sterilize and one minute dry times (see Automatic Operation: Prevacuum Cycle for sequence of cycle events).
- Unlock and open door at end of cycle and check Dart or Bowie-Dick type test pack for results and keep a record of all test results (see Testing For Air Removal Efficiency in Section 3).

Figure 4-6. Bowie-Dick Test Cycle

Cycle Graphs

These cycle graphs provide a visual representation of Eagle 3000 Series FLJ and their phases.

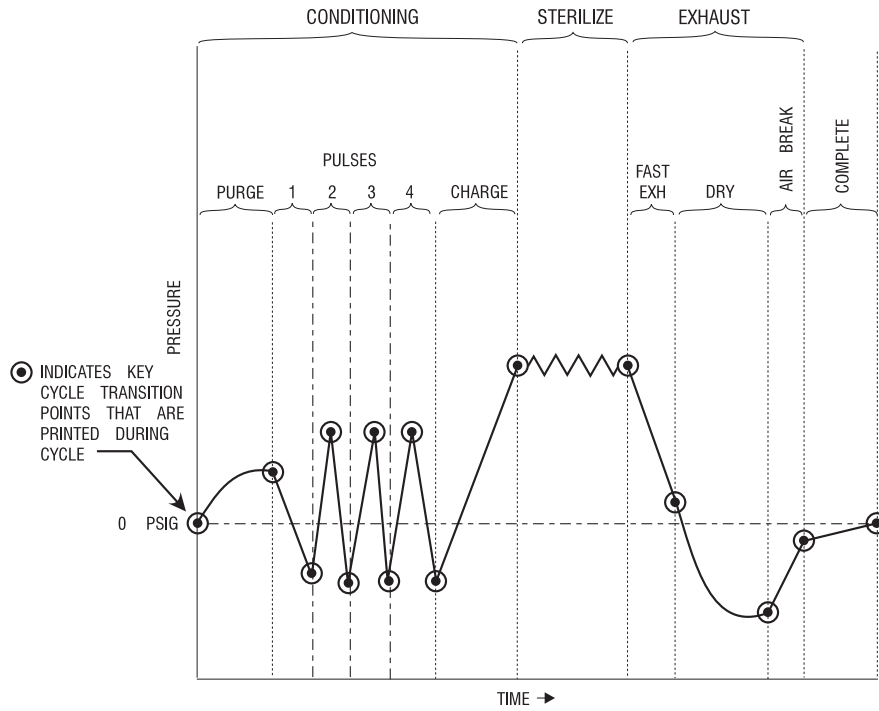


Figure 4-6. Cycle Graph - Prevacuum and Dart Cycles

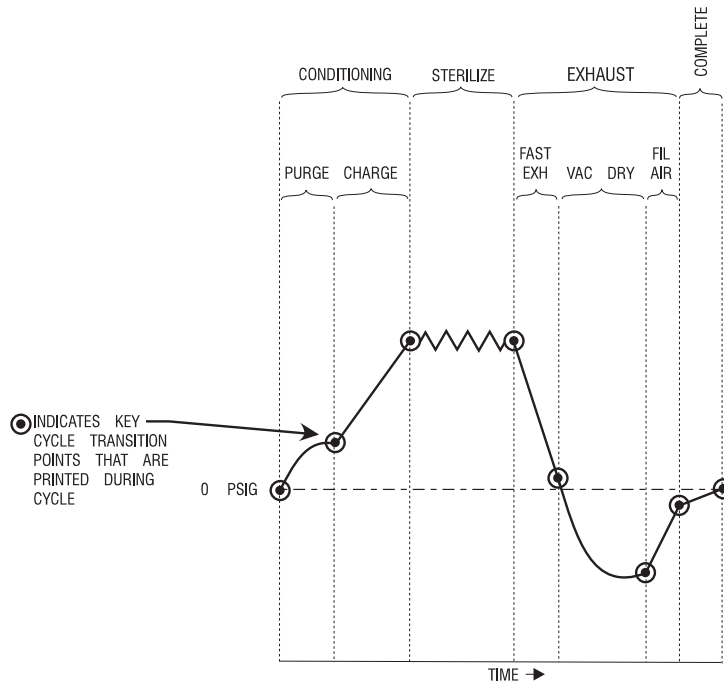


Figure 4-7. Cycle Graph - Gravity Cycle

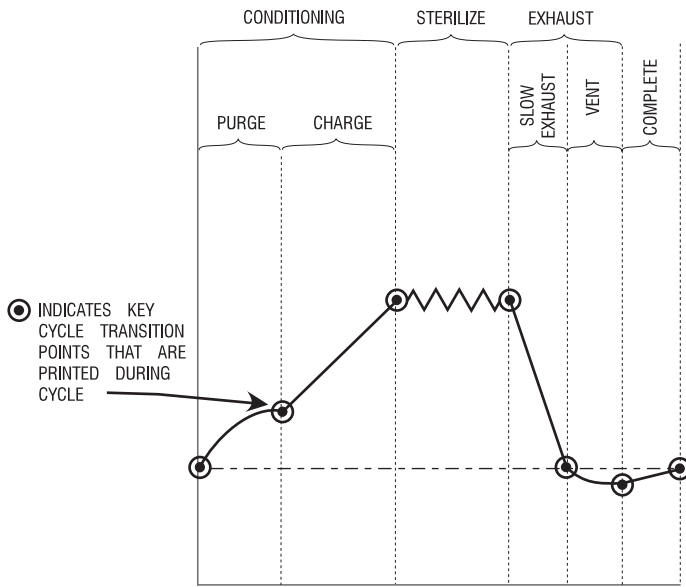


Figure 4-8. Cycle Graph - Liquid Cycle

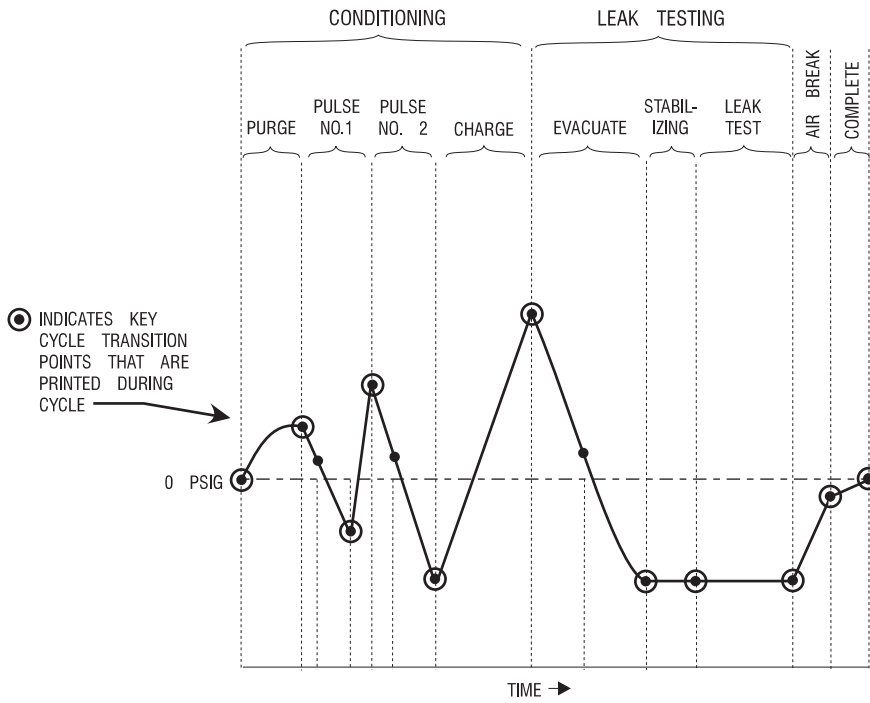


Figure 4-9. Cycle Graph - Leak Test Cycle

STERIS Eagle 3000 Series FLJ sterilizers are shipped with factory-set cycles, cycle values and control values programmed into the control (see Table 5-1). These are the cycles and values to which the control will default should a battery or battery-powered memory failure ever occur. To adjust cycle values, refer to procedures later in this section.

NOTE: If a battery or memory failure should occur, any customer adjusted cycles would be lost. The factory-set cycles, and cycle values would then appear on the display when the sterilizer power is switched ON.

IMPORTANT: The cycles listed in Table 5-1 have been validated using the techniques documented in AAMI ST-8 (see Cycle Validation Standards table, below). If different cycle parameters (sterilize time or dry time) are required, it is the responsibility of the health care facility to validate the cycle. Reference appropriate AAMI guidelines for validating sterilization cycles to assure the proper Sterility Assurance Level (SAL) as well as moisture retention acceptance criteria.

TABLE 5-1. Summary of Cycle Validation Standards

Validated Per AAMI ST-8
250°F Gravity
270°F Gravity
270°F Prevac
250°F Liquid
Dart

Sterilizer (Factory) Cycle Settings

Amsco Eagle 3000 Series FLJ Sterilizers are shipped with the factory-set cycles and cycle values listed in Table 5-2.

TABLE 5-2. Factory-Set Cycles and Cycle Values

PREVACUUM CONFIGURATION					
CYCLES	STERILIZE TEMP.	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD/CAR	VALIDATION STANDARD
PREVAC	270°F (132°C)	4 min.	5 min.	One fabric pack.	ST-8
PREVAC	270°F (132°C)	4 min.	20 min.	Up to six double wrapped instrument trays, maximum weight, 17 lbs. Up to eighteen fabric packs.	ST-8
PREVACUUM TESTING CYCLES	STERILIZE TEMP.	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD/CAR	VALIDATION STANDARD
LEAK Test ¹	270°F (132°C)	N/A	N/A	N/A	ST-8
Dart Test ¹	270°F (132°C)	3-1/2 min.	1 min.	Bowie-Dick Test or Dart	ST-8
Dart Warm-up ¹	270°F (132°C)	3 min.	1 min.	N/A	N/A

¹Not adjustable

NOTE: Prevacuum configuration sterilizers can also be used to run gravity cycles, using the same values as shown for gravity configuration sterilizers.

GRAVITY CONFIGURATION					
CYCLES	STERILIZE TEMP.	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD/CAR	VALIDATION STANDARD
GRAVITY	250°F (121°C)	30 min. ²	15 min.	Up to eighteen packs	ST-8

²A 270°F (132°C) cycle adjusted to 25 minute Sterilize Time can be used for processing Fabric Packs.

GRAVITY CONFIGURATION- LIQUID CYCLE					
CYCLES	STERILIZE TEMP.	STERILIZE TIME	DRY TIME	VALIDATED LOADS	VALIDATION STANDARD
LIQUID	250°F (121°C)	45 min.	—	Three 1000 ml. bottles ³	ST-8

³This is a minimal load and represents the worst case loading condition for sterilization of liquids in this chamber; it is consistent with AAMI ST-8 validation standards.

Troubleshooting

Refer to Service and Maintenance Procedures (150828-806) for Troubleshooting procedures for the Amsco Eagle 3000 Series FLJ Sterilizers .