BarnsteadInternational

Apogent

Harvey®
Chemiclave EC5500/EC6000 Sterilizers

Owner/Operator Manual

EC5500 Series 1121
EC6000 Series 1122

LT1121X1 • 1/9/03

Table of Contents

Safety Information

Alert Signals

Warning
Warnings alert you to a possibility of personal injury.

Caution
Cautions alert you to a possibility of damage to the equipment.

Note
Notes alert you to pertinent facts and conditions.

Hot Surface
Hot surfaces alert you to a possibility of personal injury if you come in contact with a surface during use or for a period of time after use.

Your Harvey® Chemiclave EC5500/EC6000 sterilizer has been designed with function, reliability and safety in mind. It is your responsibility to install it in conformance with local electrical codes. This manual contains important safety information. You must carefully read and understand the contents of this manual prior to the use of this equipment. For safe operation, please pay attention to the alert signals throughout the manual.

Warnings

This sterilizer employs a chemical vapor process using Harvey Vapo-Steril solution, which contains 0.23% formaldehyde by weight.

Employers should be familiar with any occupational Safety and Health Administration (OSHA) regulations which apply to their workplace. OSHA standards (29 CFR 1910.1048) for Formaldehyde applies to the workplace. For a copy of this standard, contact your nearest OSHA office.

Refer servicing to qualified service personnel.

General Description

The Harvey® Chemiclave sterilizer is a safe, fast and effective sterilizer for use in medical and dental offices, hospitals, clinics and other health care facilities.

To sterilize goods, Chemiclave sterilizers use an unsaturated chemical vapor process. This method is proven for sterilizing instruments without dulling, rusting, corroding or otherwise impairing their properties. Cycles require no drying time—goods come out dry.

The Chemiclave sterilizer is not intended for use with liquids, agars, textiles or heat-sensitive items. Sterilization processes of unique loads not specified in this manual must be validated by the end users.

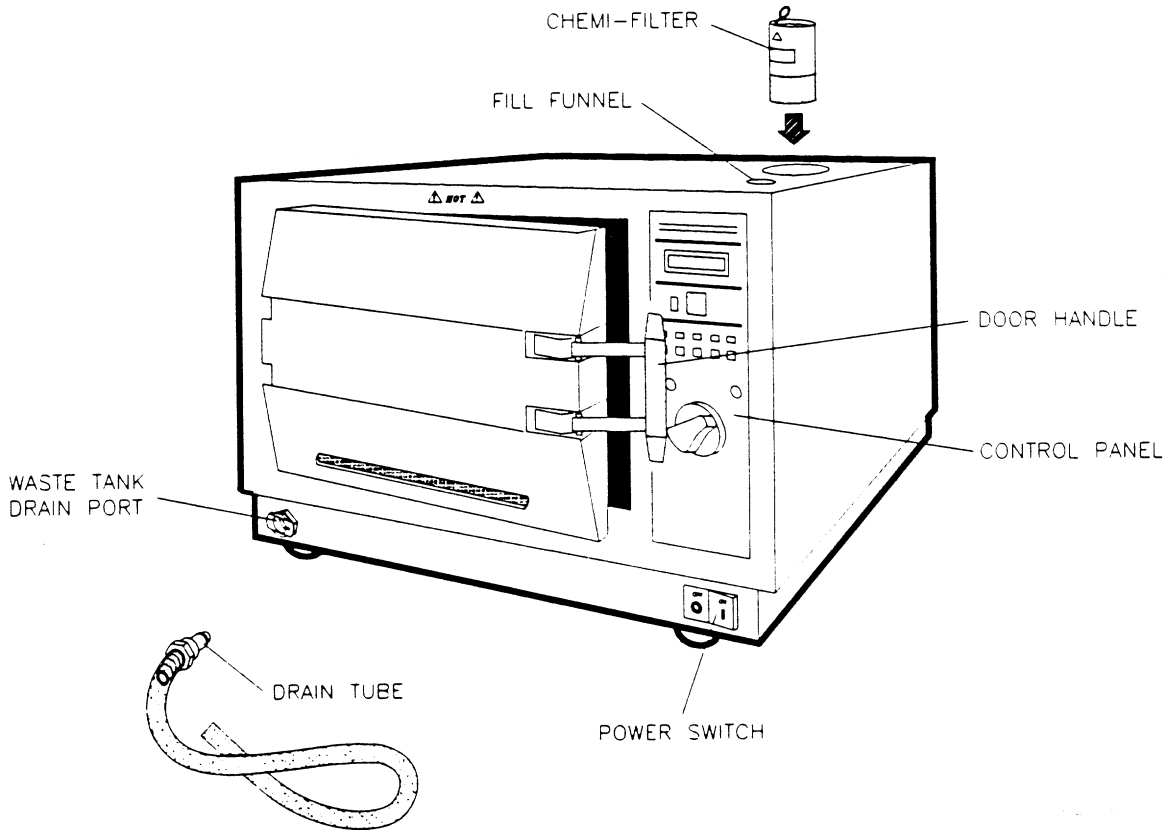
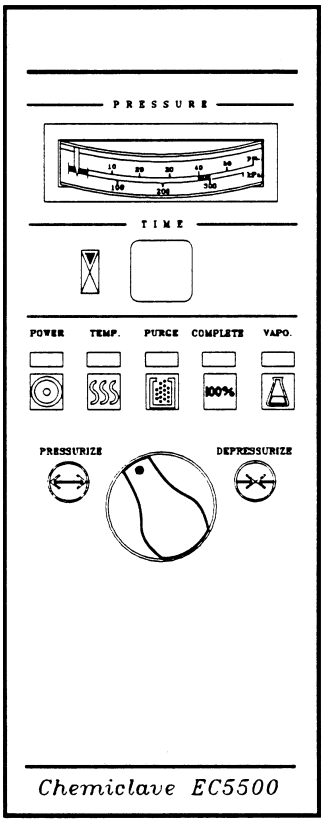


Figure 1: Chemiclave EC5500 (Front View)



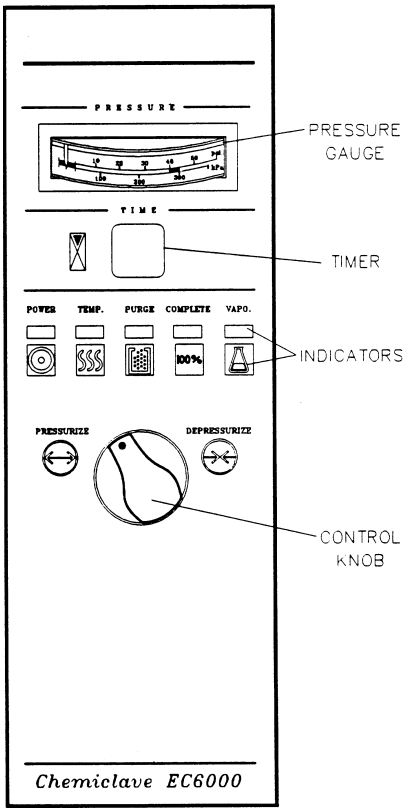


Figure 2: Control Panels

Controls and Features

Power Switch

The power switch on the front of the sterilizer turns power to the sterilizer ON (I) or OFF (O). See Figure 1.

Control Panel

Pressure Gauge

Displays the chamber pressure. See Figure 2.

Timer

Times the 20 minute exposure phase and the purge phase. During the countdown, the decimal point flashes.

Control Knob

When the control knob is turned to PRESSURIZE at the start of a cycle, Vapo-Steril enters the chamber, enabling a cycle to begin. Turning the control knob to DEPRESSURIZE after the exposure phase permits vapors to exhaust from the chamber.

Indicators

POWER: Lights when power to the unit is ON.

TEMP: Turns on and off as the chamber heaters cycle on and off.

PURGE: Flashes when the exposure phase or purge phase is complete. Lights during the purge phase.

COMPLETE: Lights when the exposure phase is complete. Also lights when the purge phase is complete.

VAPO: Lights when the reservoir must be filled with Vapo-Steril solution. The indicator will remain lit until solution is added.

Chemi-Filter®

The Chemi-Filter is a cylindrical filter that is placed in the top of the sterilizer, directly behind the fill funnel. It removes formaldehyde and potentially objectionable odors from the Chemiclave exhaust.

Door Latch

The door latch secures the door. It is opened by the door handle. The handle mechanism prevents the door from being opened while there is pressure in the chamber.

Waste Tank Drain

A quick-disconnect drain port below the sterilizer door is provided to drain used Vapo-Steril solution from the waste tank. A drain hose connects to the port when required.

Pressure Relief Valve

A safety valve on the rear of the sterilizer relieves excess chamber pressure (see Figure 3).

Chemi-Purge

The Chemipurge pumps filtered air into the chamber after a cycle. This forces residual vapors out of the chamber into the condenser and through to the Chemi-Filter.

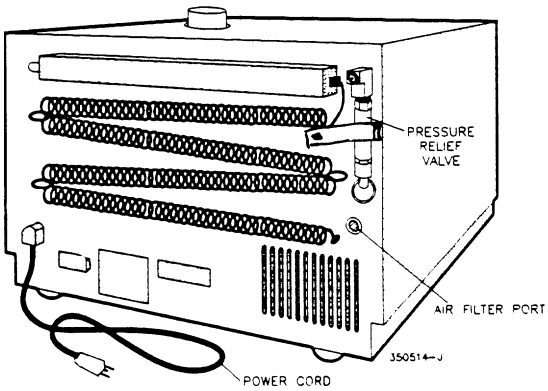


Figure 3: Pressure Relief Valve

Operation

Warning
Do not attempt to open the door until the pressure gauge has returned to 0 psig.

Warning
Do not use this equipment to sterilize volatile substances or for any purpose other than its intended design.

Warning
Do not operate the Chemiclave without a Chemi-Filter in place. Operation without a Chemi-Filter could result in emissions above the permissible exposure levels (PELs) established by OSHA.

Warning
Do not use the equipment to sterilize liquids or solutions. Attempts to process liquids or solutions could result in (1) the liquids boiling over, and/or (2) the containers exploding.

Caution
Replace the door gasket when damage, deterioration or wear prevents a proper seal. A proper seal is essential to safety and performance (see instructions in the “Maintenance” section of this manual.

The Chemiclave sterilizer uses Harvey® Vapo-Steril solution to sterilize instruments without dulling, rusting or corroding. To ensure safe and effective use, follow these precautions:

- Follow the instructions in the Owner/Operator Manual. Do not try to open the door until the chamber is fully depressurized and the pressure gauge reads “o.” Replace the door gasket when damage, deterioration or wear is evident.
- Operate the Chemiclave sterilizer in a well-ventilated area. Ventilation requirements will vary with room size, frequency of use, the number of sterilizers operated within a given area, etc. Ventilation must be adequate to ensure compliance with applicable Occupational Safety and Health Administration (OSHA) standards for levels of exposure to formaldehyde and ethyl alcohol.

Preparing Items for Sterilization

Note
Items placed in the sterilizer must be dry. Moisture on items processed in the sterilizer may cause an incomplete cycle or corrosion of the instruments.

Note
Unwrapped instruments processed in the sterilizer should not be considered sterile when exposed to unsterile environments

1. Thoroughly clean, rinse and dry the items before placing them in the sterilizer, An ultrasonic cleaner is suggested for removal of debris.
2. Clean and lubricate instruments according to the manufacturer's instructions.
3. If processed instruments will be stored, Harvey Chemi-Test indicator bags and pouches are recommended. These permit chemical vapor penetration during processing and maintain integrity after removal from the sterilizer.
4. Open any hinged instruments.
5. Uncover empty containers.
6. Chemical process indicators should be placed in the center of each load. Weekly use of biological indicators is recommended (see "Recommended Sterilization Monitoring Program."

Items not Recommended for Chemical Vapor Sterilization

Caution
Consult the manufacturer of the item that will be placed in the Chemiclave to determine its compatibility with high temperatures. A single unwrapped instrument may be exposed to a possible peak temperature of up to 150°C during the normal cycle.

- Linen, textiles or fabrics— incompatible with the chemical vapor process.
- Liquids and agars— incompatible with high temperature processing (132°C [270°F]).
- Items contained in tightly woven packs or wraps or sealed containers—cause poor vapor penetration. Chemi-Test indicator bags and pouched are recommended.
- Plastics which cannot tolerate temperatures in excess of 132°C (270°F).
- Polycarbonate—chemically incompatible.
- Nylon tubing and bags—inhibit penetration of chemical vapors.

Recommended Sterilization Monitoring Program

All functions of the sterilizer should be monitored to provide maximum sterilization assurance.

The Joint Commission on Accreditation of Hospitals and the American Dental Association recommends that biological indicators be used at least weekly to check the effectiveness of sterilizers. The biological indicator recommended for monitoring chemical vapor sterilization contains Bacillus stearothermophilus. We recommend using Harvey Spor-Test biological indicator.

We also recommend using chemical process indicators such as Harvey Chemi-Test within each package in each cycle. For additional assurance that minimum sterilizing conditions have been achieved, use a biological indicator such as Harvey B/T Sure Biological Monitoring Service at least once a week.

The items below may be ordered from your authorized Harvey dealer, or contact the Customer Service Department at Barnstead International at (800) 553-0039.

DESCRIPTION	PART NO.
PROCESS INDICATORS	
Chemi-Test See-Thru, self-sealing pouches (Box of 200) 2.25" x 5"	ZSX152
Chemi-Test See-Thru, self-sealing pouches (Box of 200) 2.75" x 10"	ZSX153
Chemi-Test All Paper, self-sealing pouches (Box of 250) 2.5" x 10.5"	230301001
Chemi-Test See-Thru, self-sealing pouches (Box of 200) 3.5" x 10"	ZSX155
Chemi-Test See-Thru, self-sealing pouches (Box of 200) 5.25" x 11"	ZSX156
Chemi-Test See-Thru, self-sealing pouches (Box of 150) 5" x 15"	230300001
Chemi-Test See-Thru, Non-self-sealing pouches (Box of 250) 3" x 12" (For steam sterilization only.)	230303001
Chemi-Test See-Thru, Non-self-sealing pouches (Box of 150) 5" x 15"	230302001

Warning
Avoid breathing Vapo-Steril fumes.

Warning
Vapo-Steril solution causes eye damage and may cause skin irritation. Do not get in eyes or on skin or clothing. Wear goggles or face shield when handling. Harmful or fatal if swallowed. Avoid contamination of food.

Warning
Vapo-Steril is flammable. Keep away from heat or flame.

Warning
Never fill the reservoir while a cycle is in progress. Vapo-Steril solution could be forcibly expelled, splashing solution on the operator.

Caution
Always drain the waste tank before filling the reservoir. Otherwise waste could overflow, damage the Chemi-Filter and require cleanup.

Note
Adding Vapo-Steril solution is required only when the VAPO indicator lights on the control panel.

Filling the Vapo-Steril Reservoir

When the VAPO indicator lights, drain the waste tank (a drain fitting and tubing are provided) and fill the Vapo-Steril reservoir. See “Draining the Waste Tank” and “Filling the Reservoir.”

Emergency Treatment

In case of contact with Vapo-Steril solution, immediately flush eyes or skin with water for at least 15 minutes. For eyes, call a physician. Get medical attention if irritation persists.

Warning
Do not drain the waste tank while a cycle is in progress. This could depressurize the chamber and interfere with sterilization.

Warning
Do not reuse Vapo-Steril solution removed from the waste tank. This liquid may be contaminated or chemically altered. It may damage the sterilizer.

Warning
Dispose of Vapo-Steril solution in accordance with all prevailing local jurisdictional requirements.

Warning
Flammable liquid. Treat Vapo-Steril solution as a hazardous waste. Dispose of it properly.

Draining the Waste Tank

1. Insert the open end of the tubing into a container.
2. Lock the drain fitting into the drain port. Waste will begin to exit the drain (see Figure 4).
3. To release the drain fitting, press the release tab.
4. Store the tubing with the drain fitting attached.
5. Dispose of Vapo-Steril solution in accordance with all prevailing federal, state and local regulations.

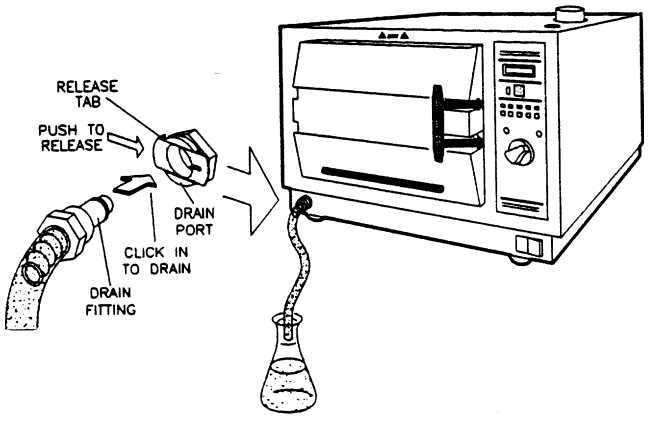


Figure 4: Draining the Waste Tank

Warning
Do not fill the Chemiclave sterilizer without a Chemi-Filter in place. Operation without a Chemi-Filter could result in emission above permissible exposure levels (PELs) established by OSHA.

Note
Use only Harvey Vapo-Steril Solution in the sterilizer. Do not dilute, alter or otherwise change Vapo-Steril solution in any way. Do not use water in the Chemiclave sterilizer. The Harvey Chemiclave sterilizer was designed to use the Vapo-Steril solution. If a solution other than Vapo-Steril is used and damages the Chemiclave sterilizer, the warranty is void.

Caution
Always drain the waste tank before filling the reservoir. If this is not done, excess waste could overflow, damage the Chemi-Filter and require substantial cleanup.

Filling the Reservoir

1. Locate the fill funnel (see Figure 5). Remove cap from the fill funnel.
2. Remove the cap from a bottle of Vapo-Steril solution, and attach the fill spout.
3. Invert the bottle. Insert the fill spout completely into the fill funnel.
4. Empty the bottle into the reservoir. If the reservoir fills before the bottle is empty, the flow will stop automatically. When this occurs, air bubbles will stop entering the bottle.
5. Remove and store the fill spout. Dispose of the bottle properly.

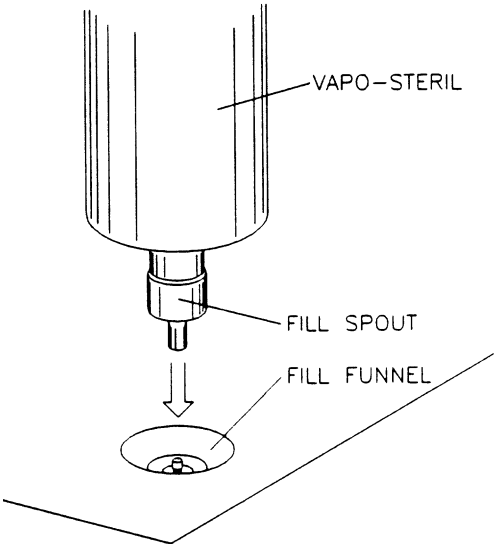


Figure 5: Filling the Vapo-Steril Reservoir

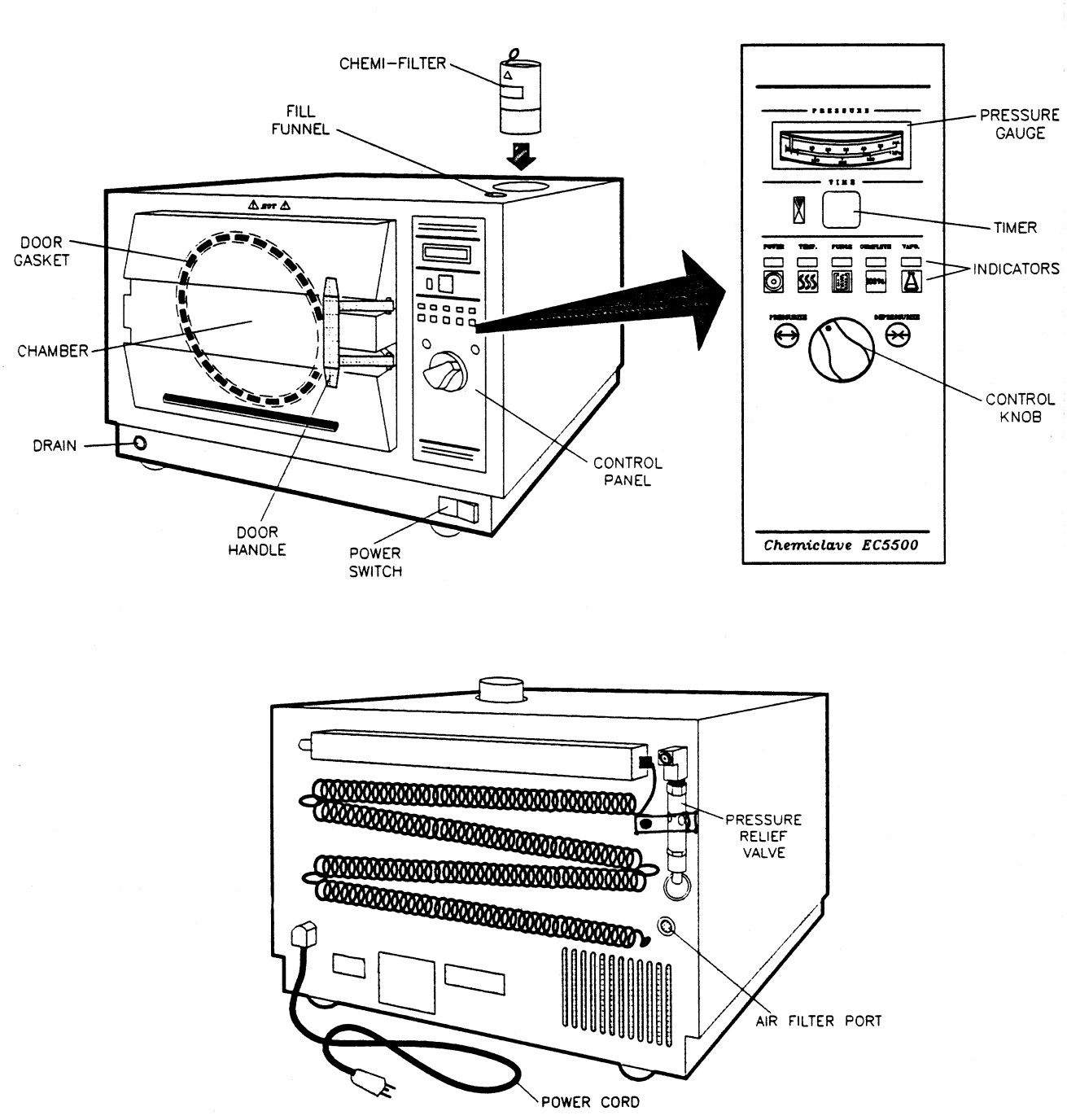


Figure 6: Controls and Features

Caution
Do not operate the Chemiclave sterilizer without a Chemi-Filter in place. Operation without a Chemi-Filter could result in emission above permissible exposure levels (PELs) established by OSHA.

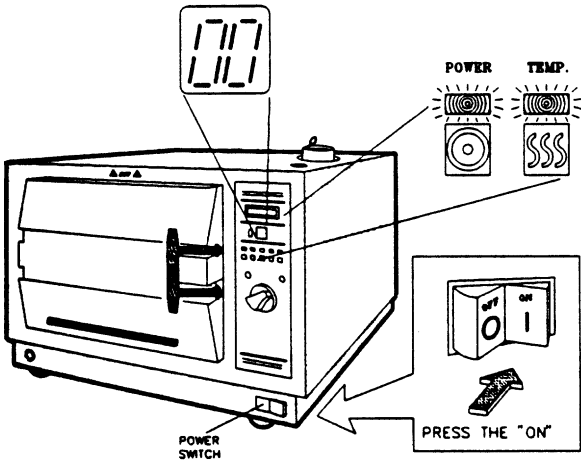


Figure 7: Power Switch

Warning
Do not use this equipment to sterilize volatile substances or for any other purpose than its intended design.

Warning
Do not use this equipment to sterilize liquids or solutions. Attempts to process liquids or solutions in the sterilizer could result in (1) the liquids boiling over and/or (2) the containers exploding.

Running a Cycle

Preparation

1. Set control knob to DEPRESSURIZE. Do this before turning the sterilizer ON (see Figure 5).

2. Check that the Chemi-Filter is in place. If it is not, install it. (See “Chemi-Filter Installation.’)

Power

1. Switch the POWER switch to the ON (I) position. All the indicators (LED’s) should light for approximately two seconds, then extinguish except for the POWER and TEMP indicators which should remain ON.

- The POWER indicator will stay lit as long as the POWER switch is on.

- The TEMP indicator lights whenever the heating elements are on.

- The timer displays “00” during warm-up.

Loading the Chamber

When the TEMP indicator cycles off and on, the chamber is ready to be loaded.

1. Open the door:

2. Check that chamber pressure is less than 2 psi. The door latch cannot be released if pressure in the chamber exceeds approximately 2 psi.

3. Pull the door handle to the right. This releases the door latch (see Figure 8).

4. Swing the door open.

5. Place the items to be processed in the appropriate trays.

   If the door will not open, refer to “If the Door Will Not Open” at the end of this section.

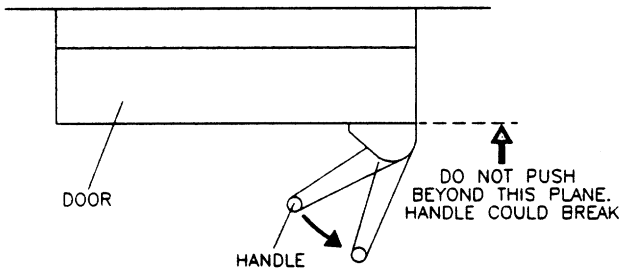


Figure 8: Door Release

Note
Harvey recommends lining each tray with a Harvey Chemi-Test tray liner. Do not use paper towels as tray liners—the chamber will turn black.

Note
Do not use heavy or multiple wraps. These will prevent proper penetration of the VAPO-Steril vapor.

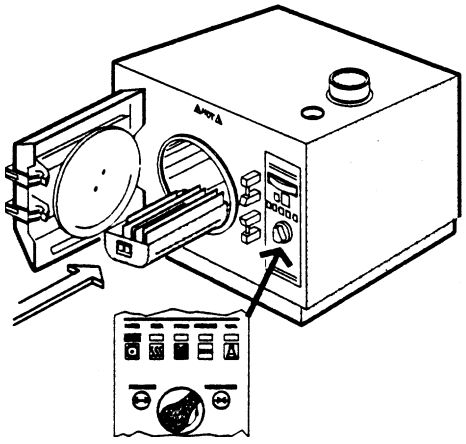


Figure 9: Loading the Chamber

Unwrapped Goods

- Use Harvey Chemi-Test tray liners.
- Be sure instruments are clean and dry.
- Do not overload. Maximum loads: EC5500—3.1 lb. (1400 g); EC6000— 6.2 lb. (2800g).

Wrapped Goods

- Package loads loosely—single wrapped, paper bags or pouches. This permits chemical vapor penetration.
- Arrange pouches on edge, not flat, to permit chemical vapor penetration.
- Do not stack bags or pouches. Do not allow bags or pouches to touch the wall of the chamber.
- Do not overload. Maximum load: EC5500—2.6 lb. (1200 g); EC6000—5.3 lb. (2400 g).

6. Set the trays in the sterilizer chamber (see Figure 9).
7. Close and latch the door.
8. Turn the control knob to PRESSURIZE.

Note
If there is pressure in the chamber, the handle will pivot without releasing the door latch. This safety feature helps prevent opening the door accidentally.

If the Door Will Not Open

1. Swing the door handle 180°.
2. Hook the fingers of your left hand around the door handle and brace your left thumb against the right side of the sterilizer.
3. Squeeze so the handle pulls directly to the right (see Figure 10). This will release the door latch. The door will now open.
4. If the door handle will not engage when chamber pressure is less than 2 psig, adjust the door (See “Door Adjustment” under the “Maintenance” section.

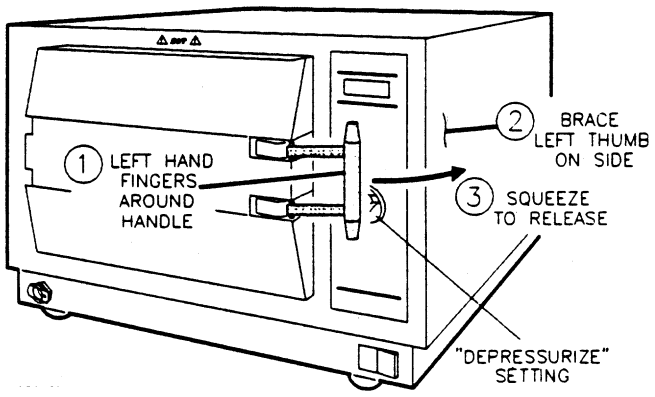


Figure 10: Alternative Door Release

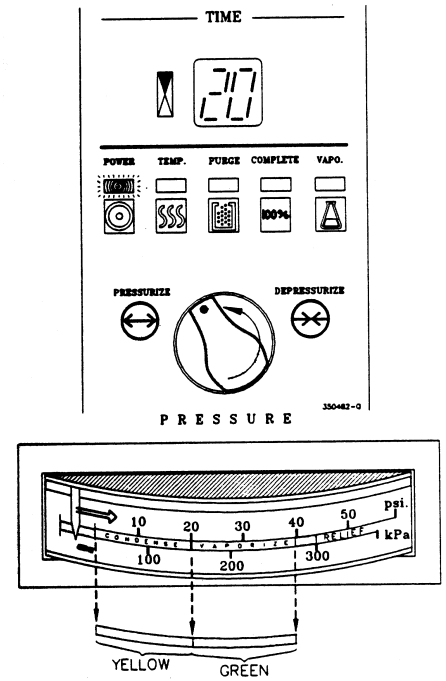


Figure 11: Starting the Cycle

Starting the Cycle

1. Turn the control knob to PRESSURIZE.

- This starts the EXPOSURE phase of the cycle (see Figure 11).
- The timer will display “20.”
- Chamber pressure will increase.

Timed Exposure Begins

- When chamber pressure reaches 20 psi, the timer starts automatically (see Figure 12).
- The timer counts down to zero. During the countdown, the decimal point flashes to show it is in the EXPOSURE phase.
- The decimal point flashes while chamber pressure exceeds 20 psi. If the decimal point stops flashing, chamber pressure has dropped below 20 psi.

Timed Exposure Ends

The tone sounds.

- The timer displays “00.”
- The PURGE indicator flashes.
- The COMPLETE indicator lights.

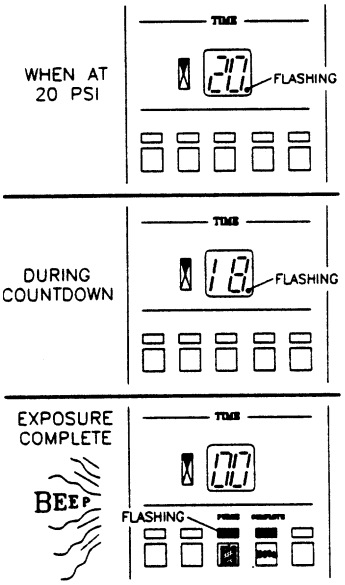


Figure 12: Automatic Timed Exposure Display

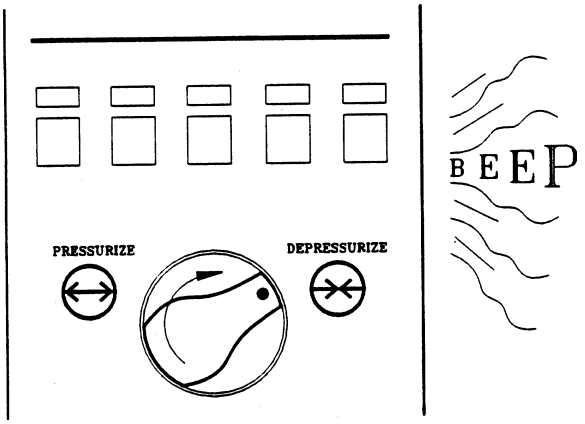


Figure 13: Exposure Complete

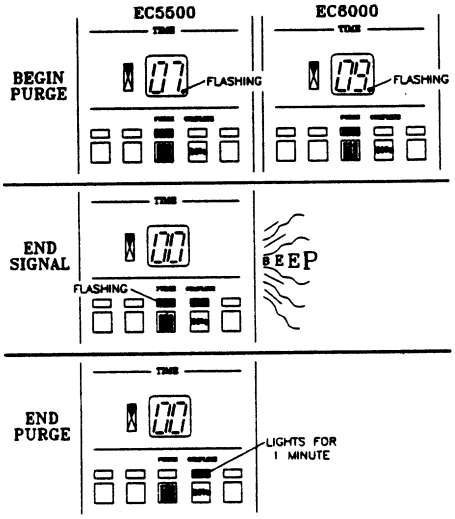


Figure 14: Automatic Purge

Warning
Chemical Hazard: Vapo-Steril solution may be in the chamber. Wear protective goggles and gloves when opening the door.

Completing the Cycle

1. After the tone sounds, turn the control knob to DEPRESSURIZE (see Figure 13).

After 1 minute, the automatic purge phase begins (see Figure 14).

- The PURGE indicator lights.
- The complete indicator goes out.
- The timer displays “07” (EC5500) or “09” (EC6000).
- The decimal point on the timer flashes as the timer counts down to “00.”

When the purge phase ends:

- The tone sounds.
- The PURGE indicator flashes.
- The COMPLETE indicator lights.

When the tone stops, the PURGE indicator goes out. The COMPLETE indicator remains lit for about a minute and then goes out. The timer continues to display “00.”

2. Wait 60 seconds.

This allows chamber pressure to drop and permits the door to open easily.

Removing the Goods

1. Release the door latch. Open the door slightly. Wait 15 seconds for any residual vapors to escape.

If the door will not open:

- Swing the door handle 180°.
- Hook the fingers of your left hand around the door handle and brace your left thumb against the right side of the sterilizer.

Note
If there is pressure in the chamber, the handle will pivot without releasing the door latch. This safety feature helps prevent opening the door accidentally.

Warning
Hot goods! The tray and instruments will be hot after processing. Use the tray handle to remove the tray. DO NOT carry the tray by the handle. Tray must be supported by a gloved hand. Wear heat-protective gloves when handling the tray or goods. Otherwise burns could result.

Note
The tray handle is also the tool to adjust the door (see “Door Adjustment”).

Note
During normal working hours when the sterilizer is not being used, leaving the door closed but unlatched will keep the sterilizer in READY condition.

Caution
Failure to follow the routine cleaning procedures in the “Maintenance” section may cause equipment malfunction and/or void the warranty.

- Squeeze so the handle pulls directly to the right (see Figure 15). This will release the door latch. The door will now open.

2. Open door fully.

3. Use the tray handle to remove the tray from the sterilizer (see Figure 16).

When the unit is not in use, leave the door closed but unlatched. This will prolong the life of the door gasket.

Between cycles, leave the unit ON with the door unlatched and closed. This will give the fastest load turnaround.

Turn the unit OFF only at the end of the working day or when it is not to be used for a long time.

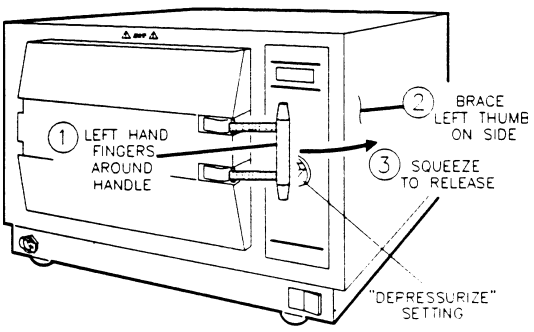


Figure 15: To Release the Door

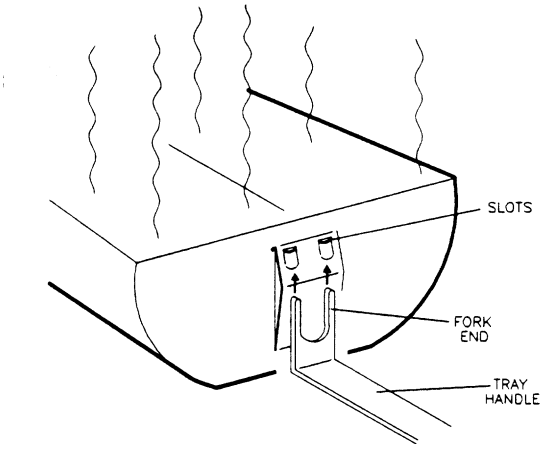


Figure 16: Removing the Tray

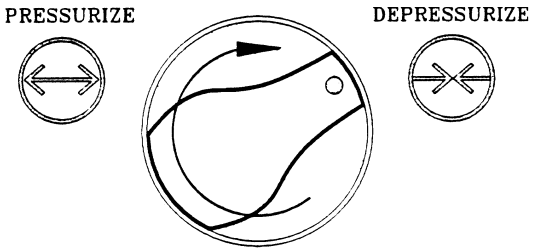


Figure 17: Stopping a Cycle

Warning
Reprocess the load completely. Otherwise the load may not have been subjected to sterilizing conditions.

Caution
Danger of load contamination. Cooling of the chamber may create a partial vacuum in the chamber. If the control knob is set to DEPRESSURIZE, this vacuum could draw back waste Vapo-Steril solution back into the chamber.

Stopping a Cycle

If you must stop a cycle before it is complete, follow the procedure below:

1. Turn the control knob to DEPRESSURIZE.

2. Observe the sterilizer.

a. The timer displays “00.”

b. The tone sounds.

c. The PURGE indicator flashes during the tone.

d. The purge phase will run (refer to “Completing the Cycle”).

- The timer displays “00.”
- The PURGE indicator lights as the timer counts down.

e. The tone sounds.

- The COMPLETE indicator does NOT light.

3. Wait 60 seconds.

4. Remove the load as usual (see “Removing the Goods”).

5. Clean the items in case of contamination. **Process the load again.**

Power Interruption

If the power is interrupted, follow the procedure below:

Power Off

While the power is off:

1. The POWER and TEMP indicators will be off.

2. Do not open the door.

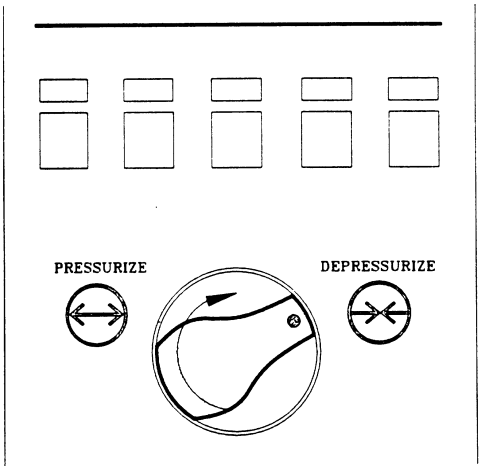


Figure 18: When Power is Restored

Warning
Chemical Hazard: Vapo-Steril solution may be in the chamber. Wear protective goggles and gloves when opening the door.

Warning
Reprocess the load completely. Otherwise the load may not have been subjected to sterilizing conditions.

3. Leave the control knob at PRESSURIZE. This keeps the chamber sealed.

4. Do not remove the load yet. Wait for the power to be restored.

Power Restored

When the power is restored, the sterilizer responds differently depending on (1) the model and (2) where in the cycle it was interrupted. (See table.)

After Prolonged Power Interruption

1. Turn the knob to DEPRESSURIZE.

2. Wait 60 seconds.

3. Remove the load.

4. Clean the items in case of contamination. Process the load again.

If Power is interrupted and Restored (All Models)	**Effect**	**What To Do**
Before cycle starts.	No effect.	Resume normal operation.
During Exposure phase.	Timer displays "20," restarts countdown when pressure reaches 20 psig.	If interruption is momentary, resume normal operation.
	PURGE and COMPLETE indicators go out. Timer displays "20," restarts EXPOSURE phase countdown when pressure reaches 20 psig.	If interruption is prolonged, perform steps 1-4 above.
During 1-minute vent (before purge phase)	Timer displays "00". PURGE phase is cancelled. COMPLETE and PURGE indicators go out.	Wait 60 seconds. Remove the load as usual.
During purge phase.	Timer displays "00." PURGE phase is cancelled. PURGE indicator goes out.	Wait 60 seconds. Remove the load as usual.
After purge phase ends.	Timer displays "00." COMPLETE indicator goes out.	Wait 60 seconds. Remove the load as usual.

Troubleshooting

Problem	Probable Cause	Remedy
Timer stops during EXPOSURE phase.	Pressure has dropped below 20 psi.	When pressure returns to 20 psi, timer will resume. If pressure does not return to 20 psig see "Unit loses pressure" below.
Unit does not pressurize.	Power not ON.	Check that POWER indicator is lit, POWER switch is on and power cord is plugged in. Check fuse.
	Reservoir empty.	Fill reservoir.
	Unit not heating.	Check chamber temperature. Call service technician if not heating.
	Door latch not firmly closed.	Check door. Close and latch door firmly.
	Chamber overloaded.	Check load. Remove items if needed.
	Check valve not seated.	Run purge and try again.
Unit builds pressure slowly.	Chamber overloaded.	Check load. Remove items if needed.
Unit loses pressure.	Door latch not firmly closed.	Check door handle and latch. Close door and latch firmly.
	Door not sealing.	Check that door seal against chamber is snug. Adjust as needed.
	Power not staying ON.	Check that POWER indicator stays lit, POWER switch is ON and power cord is plugged in. Call service technician if needed.
	Check valve not seated.	Run purge and try again.
Unit does not heat.	Power not staying ON.	Check that POWER indicator stays lit, POWER switch is ON and power cord is plugged in. Call service technician if needed.
Temperature and pressure erratic.	Chamber overloaded.	Check load. Remove items if needed.
Debris in chamber and on door.	Loads have not been pre-cleaned and dried.	Check that all loads are pre-cleaned and dried (ultrasonic cleaning is preferred).
	Chamber not being cleaned.	Check that chamber is being cleaned at least weekly.
	Improper wrap materials.	Use Harvey approved wrap materials.
Instruments spot excessively.	Loads have not been pre-cleaned.	Check that all loads are pre-cleaned and thoroughly dried (ultrasonic cleaning is preferred).
Door hard to open when cycle completed.	Pressure still in chamber.	Check that pressure gauge reads "0" before opening door.
	Door needs adjustment.	Check door and readjust if needed.
Load items discolor.	Load left in chamber after cycle is complete.	Check that loads are removed at the end of the cycle.
Wraps are stained.	Residue from wraps due to solvent action of Vapo-Steril where metals touch wraps.	Normal occurrence.

Warning
Avoid burns. Be sure the sterilizer is cool maintaining areas around the chamber and door.

Warning
Failure to follow the routine cleaning instructions in the “Maintenance” section of the Owner/Operator Manual may cause equipment malfunction and/or void warranty.

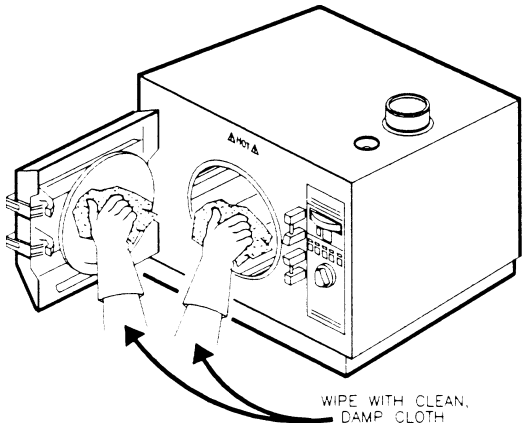


Figure 19: Cleaning the Door Gasket

Daily

Cleaning the Door Gasket

Wipe the door gasket and mating surface each day with a clean, damp cloth (see Figure 19) Do not use abrasive cleaners.

Examine the door gasket for cracks or damage, which could result in a poor pressure seal. If replacement is required, refer to “Door Gasket Replacement.”

Warning
Vapo-Steril solution causes eye damage and may cause skin irritation. Do not get in eyes or on skin or clothing. Wear goggles or face shield when handling. Harmful or fatal if swallowed. Avoid contamination of food.

Warning
Do not drain the waste tank while a cycle is in progress. This could depressurize the chamber and interfere with sterilization.

Warning
Do not reuse Vapo-Steril solution removed from the waste tank. This liquid may be contaminated or chemically altered. It may damage the sterilizer.

Warning
Flammable liquid. Treat Vapo-Steril solution as a hazardous waste. Dispose of it properly.

Warning
Dispose of used Vapo-Steril solution in accordance with all prevailing local jurisdiction requirements.

Caution
Always drain the waste tank before filling the reservoir. If this is done, excess waste could overflow, damage the Chemi-Filter, and require substantial cleanup.

Draining the Waste Tank

Drain the waste tank when the VAPO indicator lights on the control panel (see Figure 20).

If preferred, drain the waste tank daily – but also when the VAPO indicator lights.

Store the tubing with the drain fitting attached.

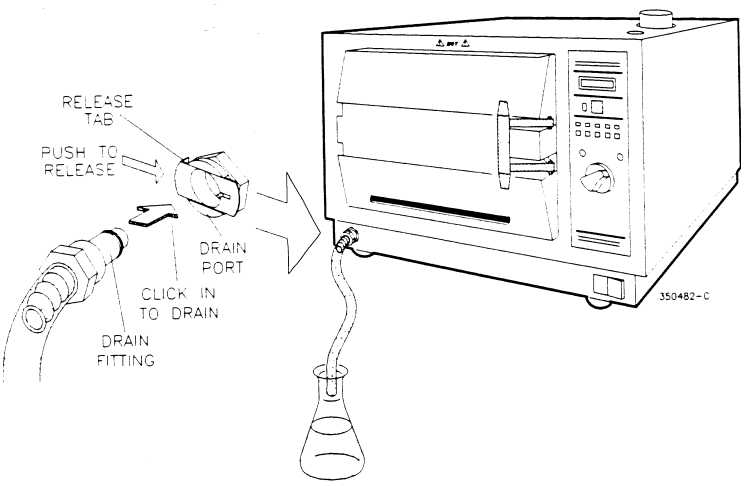


Figure 20: Draining the Waste Tank

Note
Harvey chamber cleaner works best in a warm, dry chamber.

Hot Surface
Wear protective gloves and safety glasses. Chamber and trays may cause burns if touched.

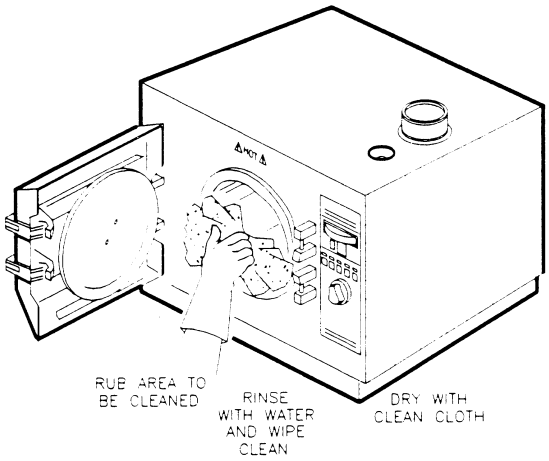


Figure 21: Cleaning the sterilizer chamber

Warning
Exposure Hazard. Do not operate the valve plunger while the sterilizer is in cycle or under pressure. Exposure to chemical vapor could result.

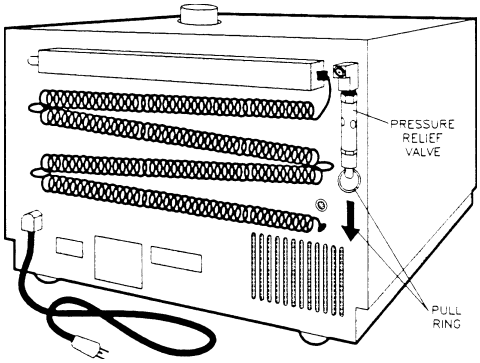


Figure 22: Checking the Pressure Relief Valve

Weekly

Cleaning the Chamber and Trays

1. Close the door.
2. Turn ON the POWER switch. Wait 2 minutes.
3. Turn OFF the POWER switch.
4. Open the door. The chamber should be warm, not hot.
5. Clean the chamber and trays with Harvey Chamber cleaner. Follow the instructions on the container.

Monthly

Checking the Pressure Relief Valve

Manually operate the valve plunger of the pressure relief valve on the back of the sterilizer (see Figure). This is to be sure the plunger will move should the chamber become over-pressurized.

To check the plunger:

1. Pull on the ring several times to ensure free movement.
2. If the plunger does not move freely, contact service personnel to replace the pressure relief valve.

Warning
If the Chemi-Filter cartridge is broken, avoid contact with skin and eyes and avoid breathing dust. For additional information, see the Material Safety Data Sheet.

Warning
Do not attempt to remove the cartridge while the sterilizer is processing.

Warning
Replace only with a Harvey Chemi-Filter.

Warning
To dispose of the used cartridge, consult the Material Safety Data Sheet.

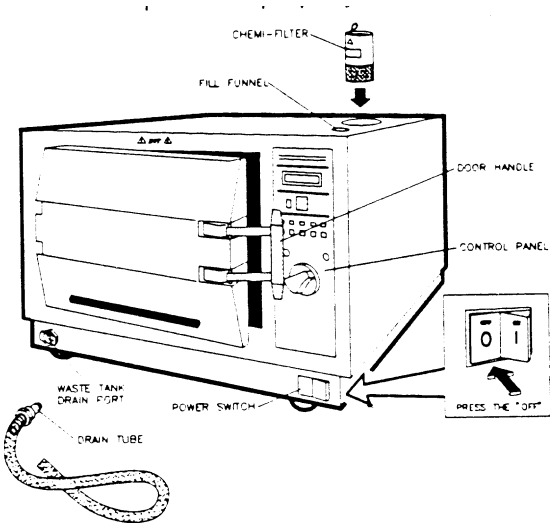


Figure 23: Replacing the Chemi-Filter

When Required

Replacing the Chemi-Filter

1. Be sure the power switch is OFF. (See Figure.)
2. Grasp the pull strap at the top of the used Chemi-Filter. Remove the filter from the filter opening. Dispose of it properly.
3. Remove the new Chemi-Filter from its package.
4. Mark the replacement date in the “Replace By’ box on the Chemi-Filter label. To calculate this date, read the Chemi-Filter label or refer to “Finding the Replacement Date.”
5. Grasp the pull strap at the top of the Chemi-Filter. Insert the filter into the filter opening. Push the filter down as far as possible.

Finding the Replacement Date

Calculate the replacement date by adding the number of months until replacement to the current date. Mark the replacement date in the “Replace By” box on the filter label.

Use the chart on the Chemi-Filter label to find the number of months until replacement.

The chart on the Chemi-Filter label is based on a 5-day work week and an average number of cycles/workday of 2, 4, 6, 8, 10 or 12.

If your usage differs from these values, calculate the months until replacement as shown:

Total Cycles Before Filter Replacement (T)		
Model	**EC550**	**EC6000**
Total Cycles (T)	500	250

Months Until Replacement Calculation

Values Needed:

1. Assign proper values to c, D and T.

   c = no. of cycles/workday (operator defined)

   D = no. of workdays/week (operator defined)

   T = Total no. of cycles before filter needs replacement (see chart)

Calculation:

2. Insert the values for c, D and T into the formula:

   no. of months until replacement = 0.231 x (T/[c x D])

Example:

A. An operator has an EC5500 sterilizer. She intends to run it 7 cycles each day, 4 days/week.

   How soon must she replace the Chemi-Filter?

Solution:

   c = 7, D = 4 and T = 500. Substituting into the formula, we get:

   0.230 x (500/[7 x 4]) = 4.125

Replace the Chemi-Filter after 4 months.

Replacing the Door Gasket

Replace the door gasket at least once a year.

1. Open the door.

2. Remove the gasket from the gasket grove in the rim of the chamber (see Figure).

3. Clean the groove and surrounding area so that it is free of dirt or deposits.

4. Wipe the replacement gasket with a clean, damp cloth. Then insert the gasket into the gasket groove. Follow the instructions packaged with the gasket.

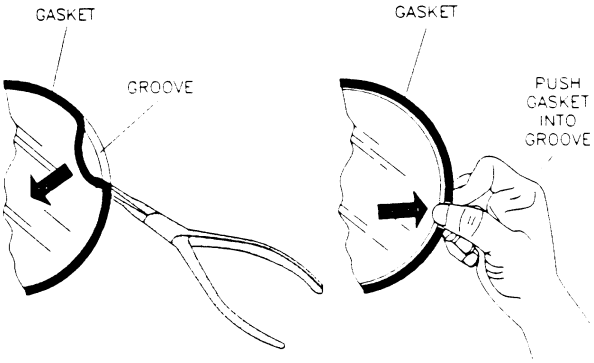


Figure 24: Door Gasket Replacement

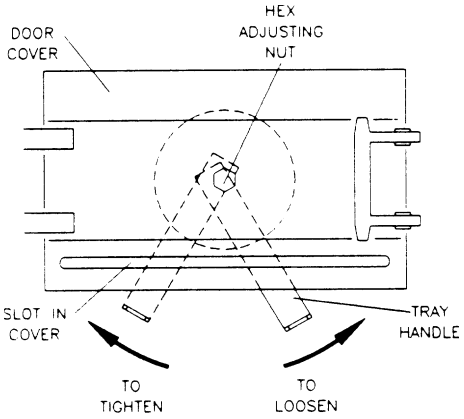


Figure 25: Door Adjustment

Door Adjustment

If chamber pressure is not retained during a cycle, door adjustment may be necessary.

1. Clean or replace the door gasket if necessary.

2. Turn the sterilizer ON. Run a “no load” cycle to heat it to operating temperature. When the cycle is complete and chamber pressure is below 2 psi, open the door.

- If chamber pressure is retained during the cycle, do not adjust the door.

- If chamber pressure is not retained, go to step 3.

3. Hold the tray handle at the fork end so the fork points towards you. Insert the hex end of the tray handle through the slot in the bottom of the door cover (see Figure 25).

4. **To Tighten:** Move the fork end of the tray handle toward the right of the slot. Fit the hex end onto the adjusting nut. Move the tray handle to the left side of the slot, turning the adjusting nut clockwise.

5. Moving the tray handle from one side of the slot to the other should be enough to achieve a seal. If the door is difficult to close, loosen the door slightly.

6. **To Loosen:** Position the fork end of the tray handle to the left of the slot. Then fit the hex end onto the adjusting nut. Move the tray handle toward the right side of the slot, turning the adjusting nut counterclockwise.

Installation

Warning
Locate the sterilizer away from areas where explosive anesthetics are used or stored.

Warning
Ventilation must be adequate to ensure compliance with applicable Occupational Safety and Health Administration (OSHA) standards for exposure levels for formaldehyde and ethyl alcohol.

Warning
Ventilation requirements will vary with room size, frequency of use of the system, the number of systems operated within a given area, etc.

Note
The door must open far enough to permit removal of trays and racks.

To install the sterilizer, complete these steps:

- Position the sterilizer.
- Make the electrical connection.
- Install the Chemi-Filter.
- Perform an operational checkout.

Positioning the Sterilizer

Area of Operation

Operate the system only in a well ventilated area.

Support Surface

Place the sterilizer on a level, heat-resistant surface. Temperatures at the bottom of the sterilizer could reach 55°C (131°F).

Clearance

Allow a minimum of 3 inches clearance around the sterilizer for air circulation (see Figure 26).

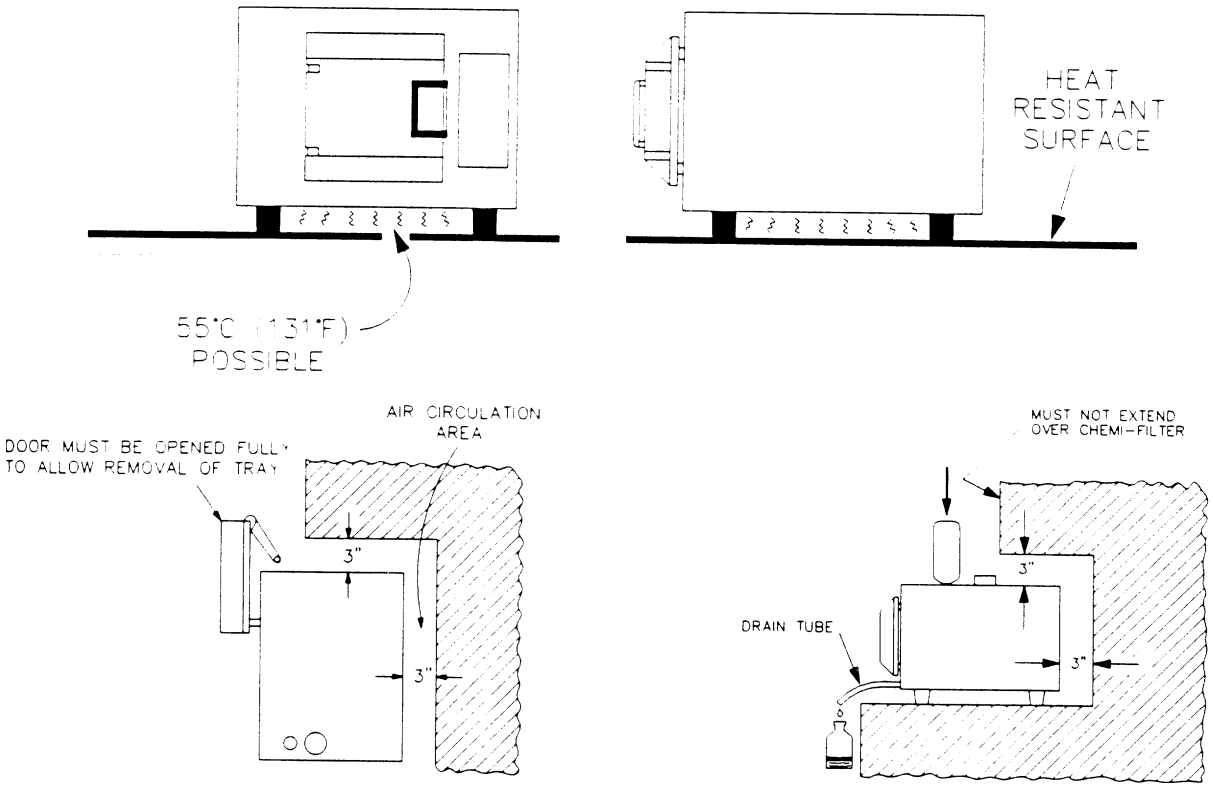


Figure 26: Positioning the Unit

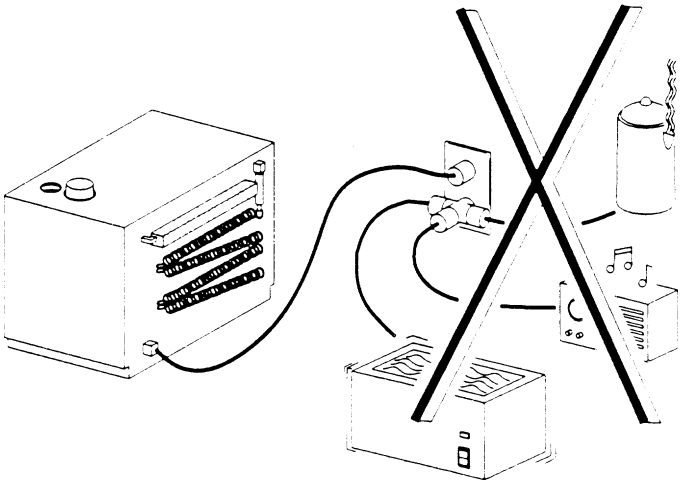


Figure 27: Electrical Connection

Electrical Requirements

a separate electrical circuit is recommended for the electrical power source for the Chemiclave (see Figure 27).

Chemi-Filter Installation

1. Remove the new Chemi-Filter from its package.

2. Mark the replacement date in the “Replace By” box on the Chemi-Filter label or refer to “Finding the Replacement Date” under the “Maintenance” section.

3. Grasp the pull strap at the top of the new Chemi-Filter. Insert the filter into the filter opening. Push the filter down as far as possible (see Figure 28).

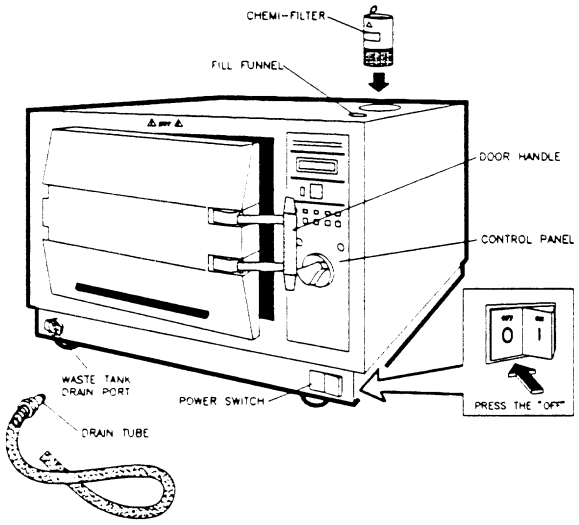


Figure 28: Installing the Chemi-Filter

Operational Check-Out

1. Run a cycle with no load in the chamber (see “Running a Cycle” p.).

2. If operating pressure is not retained throughout the cycle, set the control knob to DEPRESSURIZE. Wait 60 seconds. Then run a second no-load cycle.

3. If pressure drops again, adjust the door. Refer to Door Adjustment.”

4. If operating pressure is retained throughout the cycle, the sterilizer is ready for operation.

Technical Specifications

Technical Data	
Model EC5500	
Cabinet Size	16.75" W x 13" H x 18.5" D (425mm x 330mm x 470mm)
Chamber Size	8" diameter x 13.25" deep (203mm x 337mm)
Weight	59 lbs. (26.8 kg)
Heater Wattage	800 W
Electrical Rating	100 VAC, 60 Hz, 10 Amps 100 VAC, 50 Hz, 10 Amps 115 VAC, 60 Hz, 8 Amps 230 VAC, 50-60 Hz, 4 Amps
Operating Pressure	20-40 psig (138-276 kPa)
Operation Temperature	132°C (270°F)
Pressure Relief Valve	45 psig (310 kPa)
Fluid Capacities	Solution Reservoir: 1.1 liters (37 fl oz.) Waste Tank: 1.1 liters (37 fl. oz.)
Model EC6000	
Cabinet Size	19.25" W x 16.5" H x 20.5" D (489mm x 419mm x 521mm)
Chamber Size	10" diameter x 16" deep (254mm x 406mm)
Weight	120 lbs. (54.4 kg)
Heater Wattage	1200 W
Electrical Rating	100 VAC, 60 Hz, 13 Amps 115 VAC, 60 Hz, 12 Amps 230 VAC, 50-60 Hz, 6 Amps
Operating Pressure	20-40 psig (138-276 kPa)
Operation Temperature	132°C (270°F)
Pressure Relief Valve	45 psig (310 kPa)
Fluid Capacities	Solution Reservoir: 1.1 liters (37 fl oz.) Waste Tank: 1.1 liters (37 fl. oz.)

Declaration of Conformity

Barnstead International hereby declares under its sole responsibility that this product conforms with the technical requirements of the following standards (230 volt models only):

EMC: EN 61326-1

Safety: EN 61010-1
EN 61010-2-010

and meet(s) the requirements of the Medical Device Directive 93/42/EEC, and its relevant transition into the national laws of the member states into which we place the device(s).

The authorized representative located within the European Community is:

Electrothermal Engineering Ltd.
419 Sutton Road
Southend On Sea
Essex SS2 5PH
United Kingdom

Copies of the Declaration of Conformity are available upon request.

Environmental Conditions

Operating:

10° to 40°C; 30% to 70% relative humidity, non-condensing. Installation Category II (over-voltage) in accordance with IEC 664. Pollution Degree 2 in accordance with IEC 664. Altitude limit: 3,650 meters.

Storage:

-25° to 65°C; 10% to 85% relative humidity.

Replacement Parts

Recommended Spare Parts		
Qty.	**Part No.**	**Description**
1	260560	Air Filter (EC5500)
1	261569	Chemi-Filter
1	GSX60	Door gasket, 8" (EC5500) Series 1121
1	280000301	Door gasket, 8" (EC5500) Series 1116
1	260006701	Door gasket, 10" (EC6000)
1	232010301	Harvey Cleaning Kit (6 pack)

Ordering Procedures

Please refer to the Specification Plate for the complete model number, serial number and series number when requesting service, replacement parts or in any correspondence concerning this unit.

All parts listed herein may be ordered from the Barnstead International dealer from whom you purchased this unit or can be obtained promptly from the factory. When service or replacement parts are needed we ask that you check first with your dealer. If the dealer cannot handle your request, contact our Customer Service Department at 563-556-2241 or 800-553-0039.

Glossary

Agar: Semisolid growth medium used in growing microorganisms.

Biological Indicator: A calibrated population of bacterial spores (of high resistance to the mode of sterilization being monitored) in or on a carrier, put up in a package which maintains the integrity of the inoculated carrier and which is of convenience to the ultimate user, that serves to demonstrate whether the contents have been subjected to sterilizing conditions.

Celsius: (Centigrade) Metric scale of temperature.

Chamber: The portion of the sterilizer in which items are processed.

Chemical Indicator: A sterilization process monitoring device designed to respond with a characteristic chemical or physical change to one or more of the physical conditions within the sterilizing chamber. Chemical indicators are intended to detect potential sterilization failures that may result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer. The “pass” response of a chemical indicator does not prove that the item accompanied by the indicator is sterile.

Chemi-Filter: Cartridge used to remove formaldehyde from the exhaust air of the Chemiclave sterilizer.

Chemi-Test Indicator: A chemical indicator strip available from Harvey.

Chemi-Test Indicator Bag: A bag, with an integral chemical indicator, in which an instrument can be processed and stored. Available form Harvey.

Control Panel: The panel on the front of the sterilizer containing the selectors and indicators.

Cycle: The processes and events that take place from when the control knob is turned to PRESSURIZE until the door is opened to remove processed goods.

Dedicated Circuit: Electrical circuit with no other major appliances or equipment connected.

Exposure: Phase of cycle when items in the sterilizer chamber are subjected to sterilizing conditions.

Gasket: Soft ring which seals against the door.

kPa: (kiloPascal) Metric unit of pressure.

No-Load Cycle: A cycle with no items in the chamber.

OSHA: Occupational Safety and Health Administration; a U.S. agency that regulates safety in the workplace.
Phase: a timed portion of a cycle.

Pre-Set: Adjusted in advance or at the factory.

Pressure Relief Valve: A valve that automatically opens at a preset pressure to prevent an overpressure condition in the chamber.

PSI: (pounds per square inch) English unit of pressure.

Purge: Phase of the cycle when vapors are removed from the chamber.

B/T Sure Biological Indicator: A biological indicator strip for monitoring steam and chemical vapor sterilization, available from Harvey.

Sterilant: Chemical solution (Vapo-Steril solution, for example) used as an agent in the sterilization process.

Ultrasonic: A sound vibration above the audible range of the human ear. Ultrasonic vibrations are used in certain instrument cleaners.

Vapo-Steril Solution: The sterilant produced by Harvey for use in the Chemiclave sterilizers.

Volatile Substances: Substances that vaporize or evaporate quickly.

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email@sterilizers.com