Operator's Manual

VALIDATOR®
8″ and 10″

Pelton & Crane
A DCI COMPANY

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WARRANTY

Your Pelton & Crane product is quality equipment that is warranted to the original owner-user against defective parts, materials and workmanship for a period of one (1) year from the date of installation to the original purchaser. Replacement parts and accessories purchased from Pelton & Crane are warranted for a period of 90 days after installation. If within these time limits, your product or any of its components require service, return them through your dealer to our factory for service. The address of our Service Department is: The Pelton & Crane Company, Service Dept., 11727 Fruehauf Drive, Charlotte, North Carolina 28217. Please include an explanation of the problem, the product's model, serial number and finish, if applicable. Transportation charges must be paid both ways by the owner-user. If upon receipt at our factory, our examination reveals faulty or defective original workmanship, parts or materials, we will, at our option, make the necessary repairs or replacements. This warranty does not cover consequential or incidental damages or damage caused by misuse, abuse,accident or neglect. Claims for damage caused during shipment should be made to the carrier. Unauthorized alterations or repairs made outside our factory will cancel this warranty and charges for them will not be allowed. All implied warranties are limited to the duration of this written warranty.

Some states do not allow limitations on the duration of implied warranties so the above limitation may not apply to you. Also, some states do not allow the exclusion of consequential or incidental damages so the above exclusions may not apply to you. This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.

This warranty is valid only when purchaser completes and returns the warranty registration card (attached to each product) within ten (10) days of installation.

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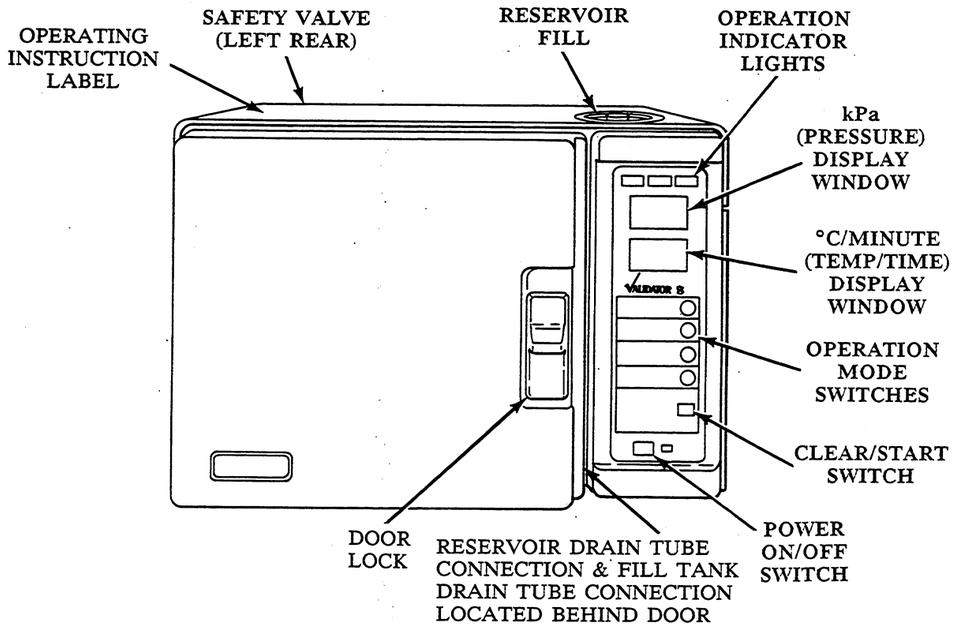
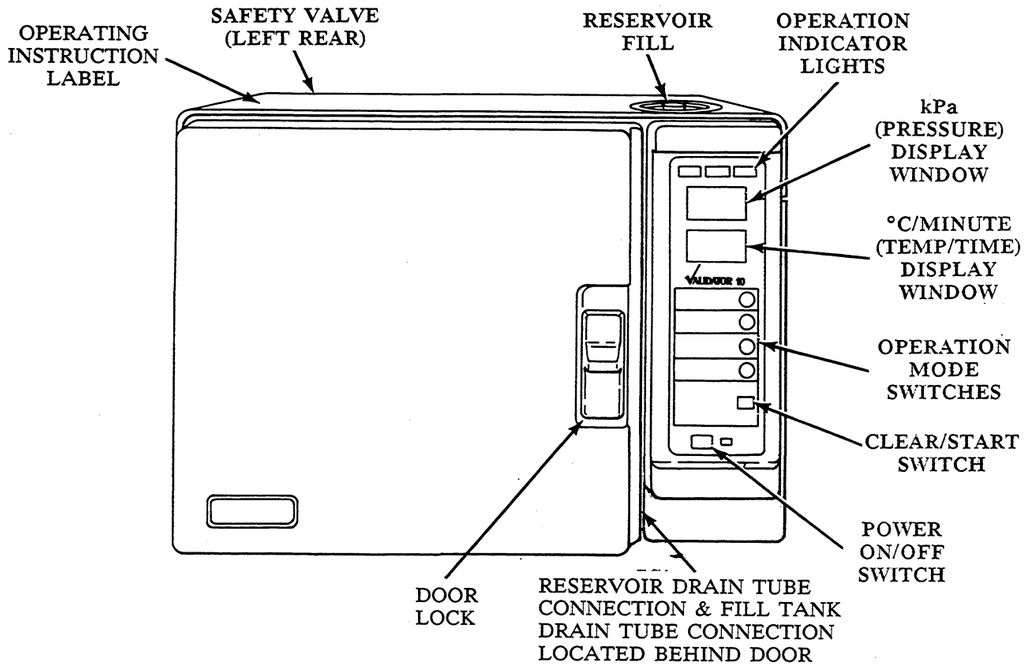


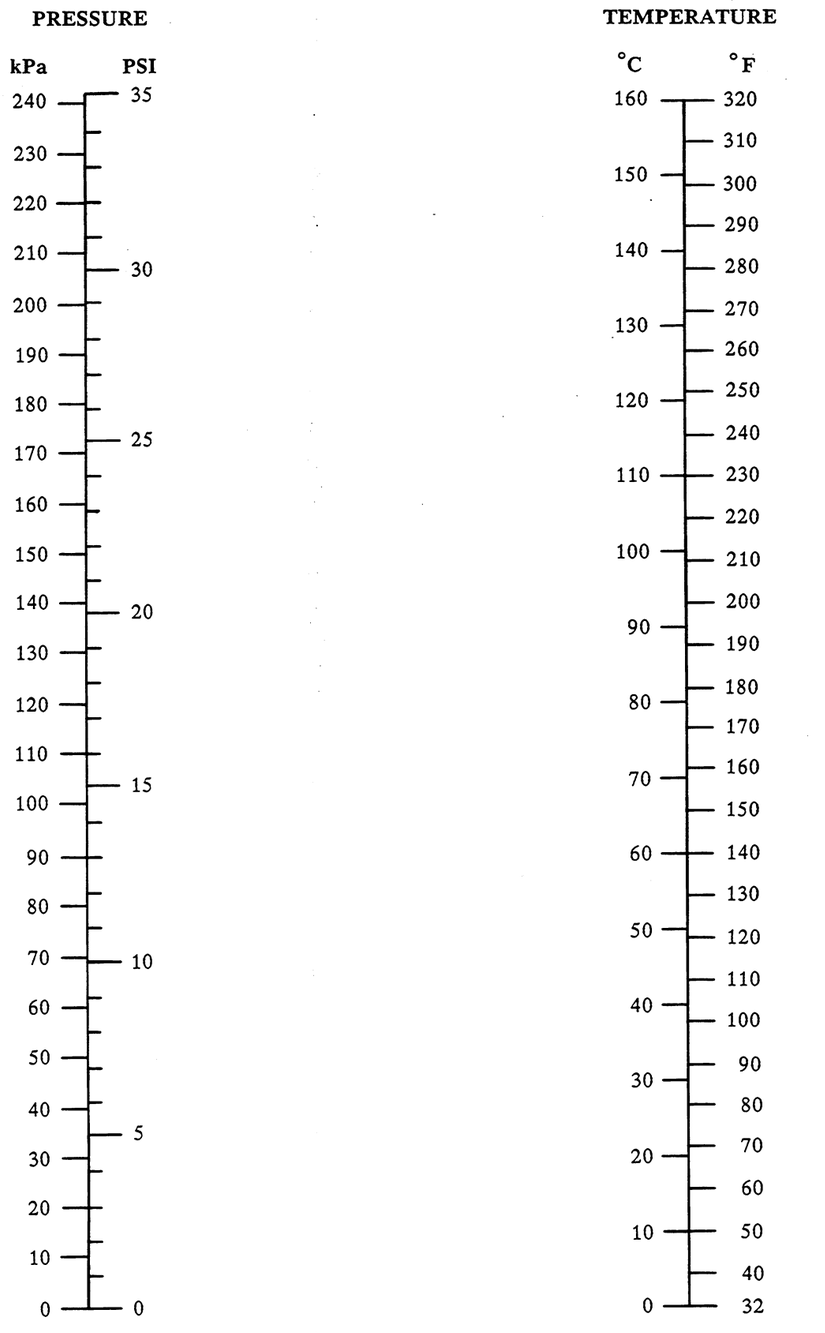
8″ VALIDATOR



10″ VALIDATOR

NOTES:

AUTOCLAVE CONVERSION SCALE



1 PSI = 6.89 kPa

1 kPa = 0.145 PSI

°C = 5/9 (°F–32°)

°F = (9/5 X °C) + 32°

CTION 1 – FAMILIARIZATION

I. SAFETY FEATURES

The design of the Validator autoclave incorporates several safety features for your protection.

A. Door Lock

Chamber can be opened only when internal pressure is at atmospheric pressure.

B. Safety Valve/Vent Valve

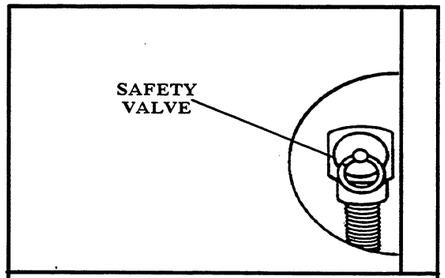


FIGURE 1 – SAFETY VALVE

1. Safety Valve – The safety valve opens as backup protection to reduce chamber pressure in the event pressure exceeds 262 kPa.
2. Vent Valve – If chamber pressure should exceed 225 kPa, the vent valve will open and the PRES alarm will display.

C. Overheat Protection

Chamber temperature is set so as not to exceed 140°C and has an additional overheat protection if temperature reaches 180°C.

D. Electrical Power Interruption

In case of an electrical power failure during the sterilization cycle, pressure in the chamber is automatically vented to the atmosphere.

II. PHYSICAL CHARACTERISTICS

A. Exterior

The overall exterior dimensions of the 8″ model are 12–1/4″ (31.1 cm) high x 19– 3/4″ (50.2 cm) deep, add 1″ (2.54 cm) to include door handle in depth, x 17–1/2″ (44.5 cm) wide. The overall exterior dimensions of the 10″ model are 14″ (35.6 cm) high x 23–5/8″ (60 cm) deep, add 1″ (2.54 cm) to include door handle in depth, x 19–1/4″ (48.9 cm) wide.

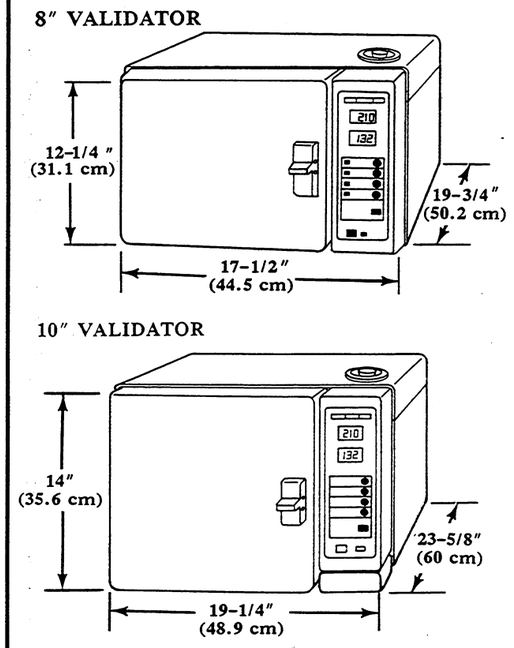


FIGURE 2 – EXTERIOR DIMENSIONS

B. Interior

The overall chamber of the 8″ model shall measure 8–1/4″ (21 cm) inside diameter by 14″ (35.6 cm) deep. The overall chamber of the 10″ model shall measure 9–7/8″ (25.1 cm) inside diameter x 17–1/2″ (44.5 cm) deep.

C. Weight

Without water in the reservoir, the weight is 72 lbs., 32 kgs. (8″ model), 95 lbs., 43 kgs. (10″ model).

III. ELECTRICAL REQUIREMENTS

Three models of the 8″ autoclave are available. One operates on 110–120 volts, 60 hertz alternating current (8.7 amperes nominal). A separate branch circuit, capable of sustaining a 1050 watt load, is recommended. Ensure autoclave is grounded by using the three–wire plug and a grounded receptacle.

One 8″ model operates on 220–240 volts, 50/60 hertz alternating current (4.4 amperes nominal). A separate branch circuit, capable of

sustaining a 1050 watt load, is recommended. Ensure autoclave is grounded using a three–wire plug.

WARNING: Requires dedicated circuit or surge protector such as the Radio Shack Voltage Spike Protector Cat. No. 61–2791.

One 8″ model operates on 90–110 volts, 50/60 hertz alternating current (10.6 amperes nominal). A separate branch circuit, capable of sustaining a 1050 watt load, is recommended. Ensure autoclave is grounded using a three–wire plug.

Two models of the 10″ autoclave are also available. One operates on 110–120 volts, 60 hertz alternating current (10 amperes nominal). A separate branch circuit, capable of sustaining a 1200 watt load, is recommended. Ensure autoclave is grounded by using the three–wire plug and a grounded receptacle.

The other 10″ model operates on 220–240 volts, 50/60 hertz alternating current (5 amperes nominal). A separate branch circuit, capable of sustaining a 1200 watt load, is recommended. Ensure autoclave is grounded using a three–wire plug.

IV. CONTROLS AND INDICATORS

A. Switches

All switches are pressure sensitive push type and located on the front control panel.

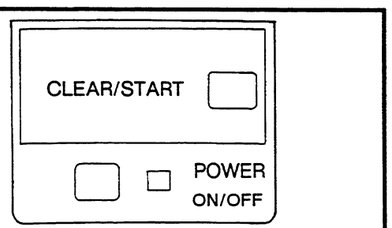


FIGURE 3–POWER/CLEAR/START SWITCHES

1. Power – With the POWER switch in the ON position, the red power light is illuminated and electric power is supplied to the autoclave. The heater elements run at a lower power to preheat the chamber when no cycle is in progress. When in the OFF position, red light out, no electric power is available to the autoclave.

2. Clear/Start – The CLEAR/START switch controls the start of the sterilizing cycle and may be used to clear a cycle. When depressed to start, the cycle selected by the mode switch begins. When depressed to clear, the present program is interrupted and erased.

3. Operational Program Switches

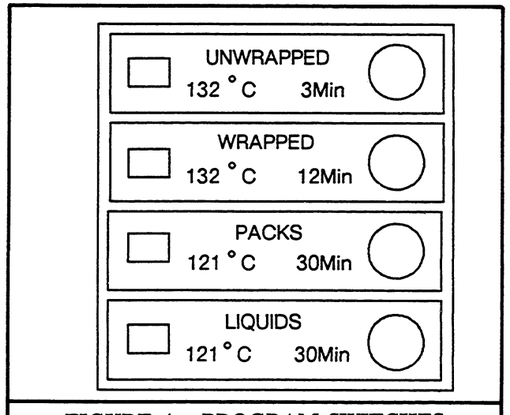


FIGURE 4 – PROGRAM SWITCHES

a. Unwrapped Switch – Depress the UNWRAPPED switch to select a cycle at 132°C/210 kPa for 3 minutes. A red light illuminates to the left of the switch to verify selection of the UNWRAPPED program.

b. Wrapped Switch – Depress the WRAPPED switch to select a cycle at 132°C/210 kPa for 12 minutes. A red light illuminates to the left of the switch to verify selection of the WRAPPED program.

c. Packs Switch – Depress the PACKS switch to select a cycle of 121°C/128 kPa for 30 minutes. A red light illuminates to the left of the switch to verify selection of the PACKS program.

d. Liquids Switch – Depress the LIQUIDS switch to select a cycle of 121°C/128 kPa for 30 minutes followed by a slow vent. A red light illuminates to the left of the switch to verify selection of the LIQUIDS program.

B. Indicator Lights

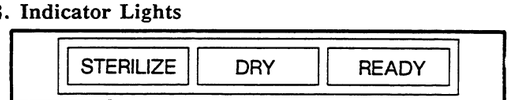


FIGURE 5 – INDICATOR LIGHTS

GLOSSARY

Asepsis:	Freedom from infective microorganisms.
Autoclave:	A container for sterilizing by steam under pressure.
Bioburden:	The level of organisms on a particular item at a specific time.
Biological Monitor or Spore Test:	A preparation of resistant microorganisms which is used to verify sterilization. Usually requires incubation which may be performed by an independent laboratory.
Cold Sterilant:	An agent which sterilizes at room temperature. Usually a chemical such as gluteraldehyde.
Disinfection:	Destruction of bacteria.
Pathogen:	Any microorganism or virus that can cause disease.
Process Monitor:	An indicator which is sensitive to at least one sterilization parameter. Useful to indicate sterilization bypass but does NOT indicate sterilization. Examples: autoclave tape, heat–sensitive bag markings, heat sensitive marked strips, fusible glass melting pellets.
Sanitize:	To make an item surgically clean but not necessarily sterile. Usually accomplished using a low–level disinfectant.
Septic:	Unsterile. Infection caused by introduction of pathogenic microorganisms.
Spores:	The reproductive cell of some microorganisms which is highly resistant.
Sterilization:	Total destruction of all microbial life including bacteria, viruses and spores.
Ultrasound:	A type of cleaner which uses ultrasonic waves at high frequency to agitate contaminants and dirt from items.
Vegetative Bacteria:	A freely multiplying form of bacteria.

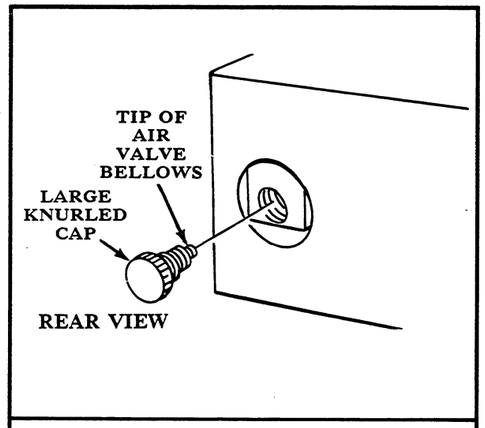


FIGURE 18 – AIR VALVE BELLOWS

1. The air valve is factory set. However, if debris becomes lodged in valve, it may be necessary to remove large knurled cap and clean tip of air valve bellows and seat.

G. Cleaning Exterior Surfaces

1. Clean all exterior surfaces with mild detergent and water using a sponge or cloth.

2. Exterior surfaces may be disinfected using an iodophor (Biocide, Biotrol, Inc., N. Salt Lake City, Utah, or equivalent), glutaraldehyde (Cidex, Surgicos, Dallas, TX, or equivalent) or sodium hypochlorite (household bleach diluted 1:10–1:100).

CAUTION: Do not use any disinfectant on interior stainless steel surface. Damage to the chamber and/or trays may result.

III. STERILIZATION ASSURANCE

A. Clinical Record Keeping

Validate daily and weekly records to substantiate procedures taken to assure sterilization.

B. Techniques for sterilization assurance:

1. Use dated color change indicator closure tapes (3M, St. Paul, MN; Propper, Long Island City, NY,) on all packs or use bags with process indicators.

2. Use internal process indicator strips inside all sterilizer loads to verify gross heat penetration.

3. Use a biological spore test indicator (Attest® Biological Monitoring System, 3M, St. Paul, MN; Propper, Long Island City, NY,) inside a representative sterilizer load weekly.

4. Follow manufacturer's instructions for using all test materials and maintaining good clinical records. Contact dealer to obtain biological test indicators that meet AAMI standards.

5. Follow Preventive Maintenance schedule (see Section 5–I, page 17) to ensure proper operation of the autoclave.

1. Red STERILIZE Light –

   a. At the start of the sterilizing cycle, the red STERILIZE light comes on to indicate that the unit is approaching sterilization temperature and pressure.

   b. When the sterilization temperature and pressure are reached, the red STERILIZE light begins to flash, indicating the sterilization cycle is in progress.

   c. During venting, after the sterilization cycle is complete, the red STERILIZE light is constantly illuminated. This indicates the chamber pressure is being reduced to zero.

   d. Once chamber pressure reaches zero, the red STERILIZE light extinguishes.

2. Yellow DRY Light –

   a. The yellow DRY light indicates the heater is on for the drying cycle.

   b. After the sterilization cycle and vent are completed, the flashing yellow DRY light comes on (flashing green READY light is also on).

   c. The flashing yellow DRY light extinguishes and the heater turns off after 30 minutes.

3. Green READY Light –

   a. When the drying cycle is complete, the green READY light continues to flash, signaling that contents are dry and chamber may be unloaded.

C. Visual Displays

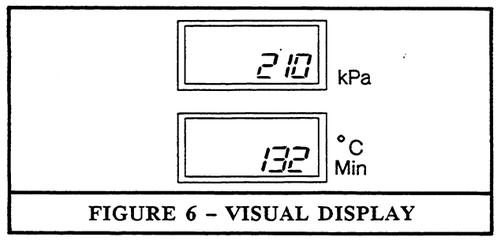


FIGURE 6 – VISUAL DISPLAY

1. kPa Window – The kPa (pressure) window displays the internal pressure of the chamber in kilopascals during the sterilization cycle.

2. °C/Min Window – The °C/MIN window displays several readouts.

   a. Temperature – During the sterilization cycle the temperature of the chamber will be displayed in degrees Celsius.

   b. Time – The sterilization time for each programmed operation counts down to zero. At 0:00 minutes the pressure is vented to the atmosphere. The drying time counts up from zero to 30:00 minutes.

   c. Alpha Messages – This window also displays alpha numeric messages indicating alarm conditions, the end of the cycle, etc.

   NOTE: kPa is a unit of pressure such as PSI. 1 PSI = 6.89 kPa (see Autoclave Conversion Scale, page 21).

D. Audible Signals

1. One beep indicates the beginning of the self diagnostics or the selection of a programmed sterilization cycle.

2. Five Beeps indicate the beginning of drying cycle.

3. Ten beeps indicate drying cycle is complete.

4. Continuous beeps for one minute provide warning of operational difficulty. Depress POWER switch or correct problem to silence beeper.

E. Reservoir Drain Tubes

1. Both 8″ and 10″ models have quick drain connections for the reservoir and fill tank located on the face plate behind the door. Two drain tubes are provided with the unit.

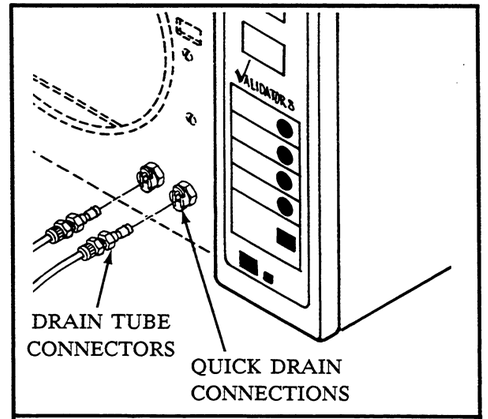


FIGURE 7 – RESERVOIR DRAIN TUBES

2. The earlier 8″ and 10″ models have a reservoir drain tube and a fill tank drain tube that can be extended up to 4″ (10.2 cm) out from under the front of the autoclave. The earliest 8″ models (serial nos. 1001–8570) have only a reservoir drain tube. Both tubes have a knurled closure cap.

F. Leveling Feet

Adjustable feet are provided on the front of the autoclave to compensate for uneven countertops. The unit should be slightly higher in the front than in the rear to ensure proper draining.

II. CLEANING PROCEDURES

A. Drain Reservoir

Quick Connect Drain Tubes

1. With the door open, locate the two quick drain connections at the lower right corner of the face plate. Press each of the two drain tube connectors provided with the unit into the connections on the face plate. This opens the drain lines and draining of the reservoir and fill tank will begin immediately.

Extending Drain Tubes

1. Pull drain tubes out from under the front of the autoclave. Drain tubes will extend 4″ (10.2 cm).

2. Unscrew knurled caps to open tubes and drain reservoir and fill tank.

3. When draining is complete, replace caps and push drain tubes back under the unit.

B. Normal Chamber Cleaning

1. Drain the reservoir and the fill tank using either quick connect drain tubes or extending drain tubes. (To disconnect quick connect drain tubes, push button to release.) For Validators with single drain tube, push CLEAR/START button, then sponge water from inside of chamber.

2. Mix Omni–Cleaner II with distilled water according to the directions on the bottle. Pour into reservoir.

3. Run two consecutive UNWRAPPED cycles. Repeat Step #1. With the drain tube(s) open, pour one to two gallons of tap water into the reservoir until the drained water is clear. This will remove excess suds.

NOTE: Instruments should not be sterilized while cleaning autoclave.

4. Pour half gallon distilled water into reservoir. Run one UNWRAPPED cycle.

5. Repeat Step #1. Wipe the inside of the chamber, the boiler ring and the door gasket. When necessary, clean outside surfaces with mild detergent or disinfectant safe for use on painted surfaces.

6. Fill reservoir with distilled water. Validator is ready for use.

C. Cleaning Deposits and Discoloration on Stainless Steel

1. For deposits not removed by detergent solution, use a non–chlorinated scouring pad containing no metal.

   NOTE: Do not use ordinary steel wool or steel brushes on stainless steel. Pads containing metal will damage chamber.

2. Rub in direction of pattern or grain of the metal.

3. Stainless steel surfaces contaminated with discoloration can be cleaned with a 5% solution of warm oxalic acid.

D. Boiler Ring

1. Clean boiler ring using a non–chlorinated scouring pad containing no metal.

   NOTE: Pads containing metal will damage chamber and cause instruments to be stained with rust.

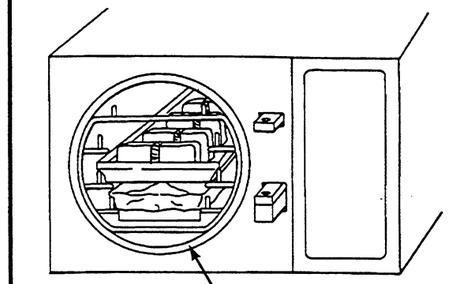


FIGURE 17 – BOILER RING

E. Door Gasket

1. Clean door gasket with Omni–Cleaner II or non–chlorinated detergent and water.

   NOTE: If residue is allowed to accumulate, the seal could be affected and leaks may occur.

F. Air Valve
(User accessible on Validator 8 only)

SECTION 5 – MAINTENANCE

I. PREVENTIVE MAINTENANCE SCHEDULE

CHECK	FREQUENCY	PROCEDURE	ACTION
Clean chamber	After every 25 cycles	4 ozs. Omni–Cleaner Plus to 1/2 gallon of distilled water on WRAPPED program cycle.	See Section 5–II.
Safety valve ring	Every 3 months	Manually pull ring with chamber under pressure. When pressure is relieved, valve automatically retracts. **WARNING:** When ring is pulled on safety valve with unit under pressure, steam is discharged from the chamber straight down the pipe at a high temperature. When you pull ring, steam exits out the bottom. Make sure path is clear and that your hand is out of the way. Use a hot pad or instrument such as pliers to pull ring.	If valve does not open, turn off POWER and call for service.
Door Gasket	Weekly	Inspect and clean using Omni–Cleaner II or mild detergent and distilled water. Check for leaks (have leaking gasket replaced.)	Call authorized service representative for replacement gaskets.
Door Latch	Weekly	Inspect latch mechanism.	Call authorized service representative for improper closure or signs of wear.
Door Switch	Weekly	With door open, attempt to start cycle. If door alarm does not appear on alarm display, door switch is defective or requires adjustment. Do not operate unit.	Call authorized service representative.
Boiler Ring	Weekly	Inspect and clean using non–chlorinated pad which contains no metal.	
Self–diagnostics	Every 3 months or as needed.	See Section 4–II, page 16.	Call authorized service representative if unsatisfactory check is seen.

SECTION 2 – PREPARATION FOR STERILIZATION

I. HANDLING AND CLEANING OF INSTRUMENTS

NOTE: Instruments must be thoroughly cleaned prior to placement in the sterilizer. Debris which remains on instruments impedes sterilization and may damage instruments.

A. Handling

1. Wear heavy rubber gloves while handling instruments. Clean gloved hands with a germicidal cleaner (iodophor surgical scrub). Wash gloved hands well when instrument handling is complete.
2. Transport soiled instruments to cleanup area on a tray. Protect your hands from contact with soiled instruments to prevent any serious infection.
3. Sort out any non–surgical devices or other instruments that cannot withstand immersion without rusting. See Table 2–1.

Table 2–1 ITEMS RECOMMENDED FOR STEAM STERILIZATION

Straight stainless steel instruments.
Surgical stainless steel hinged instruments.
Carbon steel instruments (see special preparation guide II.)
Air powered instruments made to be autoclaved (e.g. handpieces).
Heat resistant plastic items.
Rubber gloves.Rubber tubing.
Glass slabs, beakers and stones.
Gauze.
Liquids.

NOTE: Check manufacturer's recommendations for the individual items before autoclaving.

B. Cleaning

Items must be completely cleaned before sterilizing. Processing instruments with debris or blood contamination may result in staining and/or damage to instruments or sterilizer.

1. Rinse instruments with hard stream of water immediately after use to remove debris. Handle soiled instruments following procedure outlined in Section 2–I–A.
2. Sort instruments by type of metal. Do not mix carbon steel, stainless steel, brass, aluminum, chrome or other types of metals as plating may occur.
3. Wash instruments in an ultrasonic cleaner for five to 10 minutes immersed in a fresh solution of detergent and distilled water or a germicide solution. Follow manufacturer's recommended procedures. Clean all instruments in an open position.

   NOTE: For best results use a detergent specifically designed for use in an ultrasonic cleaner with a neutral ph (7). (Healthsonics, Pleasanton, CA; L&R, Kearny, NJ, or comparable brand). A Germicide, 2% glutaraldehyde or equivalent solution with a neutral ph may also be used. Instrument soaking solutions containing phenols or quaternary ammonium compounds may cause corrosion of the instruments and trays or the stainless steel chamber. Sporicidin®, Lysol® and Omni II® are some disinfectants commonly used in dental practices that contain phenols. Discard and replace ultrasonic cleaning solution daily.
4. After cleaning, rinse instruments very thoroughly for 30 seconds. Inspect instruments to ensure that all debris has been removed. Repeat cycle as necessary.

   NOTE: To prevent staining, instruments should either be rinsed with deionized (distilled) water or dried after rinsing in tap water in areas with hard water (water with a high mineral/salt content).
5. Follow the recommendations by the instrument manufacturer on the use of lubricating products after instruments have been ultrasonicly cleaned. Use a silicon lubricant which will not affect sterilization.

II. SPECIAL PREPARATION GUIDE FOR CARBON STEEL INSTRUMENTS

A. Handle and thoroughly clean instruments as outlined above. (See Section 2–I, Handling and Cleaning of Instruments).

B. Prepare a 2% solution of sodium nitrite (one tablespoon per quart of water). Immerse instruments in the solution and allow them to remain for three minutes.

C. Remove instruments and prepare for sterilization. (See Section 2–III, page 7, Tray Preparation and Loading). Do not rinse or wipe instruments prior to sterilization.

NOTE: Do not place carbon steel instruments directly on the Validator's stainless steel tray. Line the tray with an unbleached towel or paper wrap prior to placing instruments.

D. Instruments which will be wrapped for sterilization should be packaged in a material which promotes drying.

NOTE: Instruments in packages may not dry well and may require use of an atmosphere reducer (Vapor–Phase, Lorvic Corporation, St. Louis, MO) for best results.

III. TRAY PREPARATION AND LOADING

A. General guidelines for tray preparation:

– An internal process indicator strip should be included with each sterilizer load to verify gross heat penetration.

– A biological spore test indicator should be used weekly in a representative sterilizer load for sterilization assurance.

– Date packages and resterilize after one month or according to packaging manufacturers' specifications.

– Sterilization indicators/monitors should be placed in the front bottom area of the sterilizer.

– **DO NOT** mix dissimilar metals in the same package or instrument damage may result.

– Make sure that all instruments are sterilized in an open position. (See AORN guidelines).

– Place all sharps (scissors, knives, skin hooks) so they do not touch during autoclaving. Cotton or gauze may be used to isolate and protect the sharp edges and the smaller instruments.

– Any item which might hold water should be placed so the water will drain out.

– Use small packs to separate larger ones.

– Never stack trays on top of one another. At least one inch should separate trays.

– Wrapped trays and packs must **not** touch the sides of the sterilizer.

– Do not overload trays. Overloading may cause a sterilization failure.

– Use the tray handle provided (Valiator 8's only) to place and remove trays on rack in sterilizer.

B. Unwrapped trays are prepared for sterilization of non–surgical instruments and cannisters to prevent transmitting infectious disease. Always include a process or spore test indicator with every sterilizer load.

1. Loose Instruments

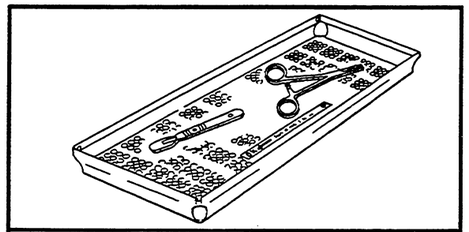


FIGURE 8 – LOOSE INSTRUMENTS

a. Distribute a single layer of instruments in the bottom of a perforated tray. Provide adequate space between instruments for steam circulation. Do not overload. Be sure to include a process or spore test indicator.

b. Place tray on rack in sterilizer.

NOTE: If multiple layers of instruments are to be separated by fabric see instructions for preparing wrapped trays.

c. See Section 3, page 12, for operating instructions.

2. Open Metal or Glass Cannisters

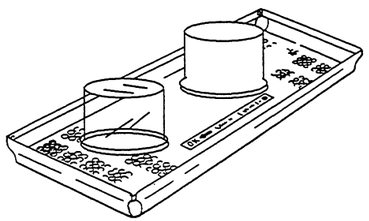


FIGURE 9 – OPEN CONTAINERS

a. Place open metal and glass cannisters on a perforated tray. Tilt the cannister down to provide adequate steam penetration. Be sure to include a process or spore test indicator.

b. Place tray on rack in sterilizer. Do not overload. Inadequate sterilization and drying will result.

Table 4–2 DIAGNOSTIC SEQUENCE NUMBERS

SEQUENCE NUMBER	CHECK DISPLAY	COMPONENTS CHECKED	OPERATIONAL FUNCTION CHECKED
1	GO/NO	Pressure Sensor	Electrical continuity.
*2	GO/NO	Steam Temperature Sensor	Electrical continuity.
3	GO/NO	Chamber Wall Temperature Sensor	Electrical continuity.
4	Blue Display Windows	kPa/°C/Min Displays	All Display segments illuminate for visual inspection. Proper operation is indicated by displays of 8:88 in the kPa window and 8.8:8.8 in the °C/Min window.
5	Other LEDS	Cycle Indicator Lights Program/Power Indicators	All indicator lights illuminate for visual inspection.
6	GO/NO	Vent Solenoid	Solenoid operation and electrical continuity.
7	GO/NO	Fill Solenoid	Solenoid operation and electrical continuity.
8	GO/NO	Exhaust Solenoid	Solenoid operation and electrical continuity.

*No. 2 may indicate a "NO" when unit is cold. Perform the test after unit has been turned on.

SECTION 4 – OPERATIONAL CHECKS

I. OPERATING ALARMS

Five alarms can occur during a sterilization cycle. All alarms are indicated by a "beeping" sound for one minute (or until cause is corrected) and a flashing alarm display in the °C/Min window. The alarm display will remain visible until the problem is corrected or until the CLEAR/START button is depressed. See Table 4–1.

TABLE 4–1 OPERATING ALARMS

DISPLAY	CAUSE	ACTION
door	Chamber door not fully closed.	Shut door properly.
H2O	Not enough water in chamber.	Add distilled water to reservoir.
	Chamber has boiled dry.	Turn off POWER switch and call an authorized service representative.
FAIL	Failure to fill properly.	Turn off POWER switch and call an authorized service representative.
	Failure to seal against pressure.	
	Not enough water in chamber.	Add distilled water to reservoir.
	More than a 3 minute lapse during countdown.	Clear unit. Restart cycle. If problem reoccurs, turn off POWER switch and call an authorized service representative.
	Leak in gasket.	Check door gasket for leakage and clean or replace as needed.
	Chamber overloaded.	Check chamber for proper loading and remove some packages/articles which may be impeding proper steam circulation.
PRES	Overpressure in the system.	Clear unit. Restart cycle. If problem reoccurs, turn off POWER switch and call an authorized service representative.
SENS	Broken circuit in surface temperature sensor.	Turn off POWER switch. Call an authorized service representative.

II. SELF–DIAGNOSTIC CHECK

The autoclave performs a diagnostic self–check on eight key components for operational continuity.

A. Operational Check

1. Depress and hold CLEAR/START switch while depressing then releasing the POWER switch. The autoclave beeps once, signaling the beginning of the self–diagnostic procedure.
2. The °C/Min window displays the self–diagnostic check procedure. See Table 4–2, page 16, for explanation of procedure.

   a. The operational check sequence number with a NO message, or lights and segments visually verified as non–operational, indicate an unsatisfactory check. At the end of the diagnostic check, the highest sequence number with an unsatisfactory check is displayed in the °C/Min window. As each problem is corrected, the next highest number with an unsatisfactory check is displayed until all diagnostic checks are satisfactory.

   b. Call an authorized service representative if an unsatisfactory check is indicated.

   c. Make sure containers are placed so that they will drain. Otherwise, adequate drying will not be possible.

   d. See Section 3, page 12, for operating instructions.

3. Rubber Tubing

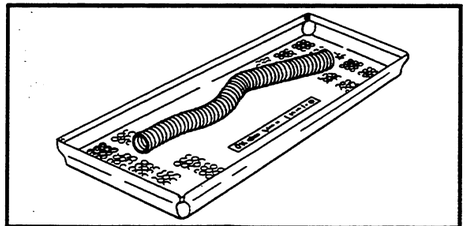


FIGURE 10 – RUBBER TUBING

   a. Clean tubing thoroughly.

   b. Rinse with pyrogen free water and leave wet. Leave both ends open, coil and wrap without kinks or sharp bends.

   c. Place tubing on an autoclave tray. Be sure to include a process or spore test indicator.

   d. Place tray on rack in sterilizer. **Do not** overload. Inadequate sterilization and drying will result.

      CAUTION: Tubing which will come in contact with a surgical wound should be prepared as outlined above and wrapped to maintain sterility.

   e. See Section 3, page 12, for operating instructions.

C. Wrapped Trays and Instruments

There are several ways to prepare wrapped trays. See Table 2–2, page 11, for acceptable wrapping materials.

1. Individually wrapped instruments

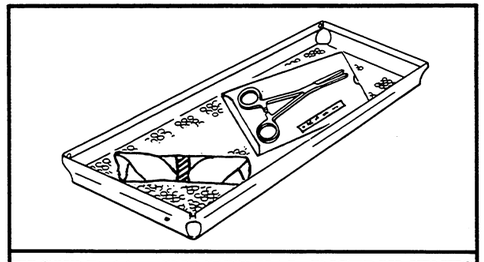


FIGURE 11 – INDIVIDUAL INSTRUMENTS

   a. Individually wrap instruments that have been cleaned according to Section 2–I, page 6 in autoclave bags or paper (3M, St. Paul, MN; Propper, Long Island City, NY). Do not tightly roll instruments in paper.

   b. Seal with autoclave tape or heat sealer (3M, St. Paul, Mn; Propper, Long Island City, NY).

      CAUTION: Do not use staples, pins or other devices which will puncture the packaging material. Otherwise, sterility may be compromised.

   c. Place individually wrapped instruments on perforated trays. Provide adequate space between instruments for steam circulation.

      CAUTION: Do not overload trays or inadequate sterilization may result.

   d. Include a process or spore test indicator. Place the indicator inside an individually wrapped instrument which will be placed in the front of the bottom tray.

   e. Place trays on the rack in the sterilizer. Ensure adequate space is provided between trays to allow steam circulation.

   f. See Section 3, page 12, for operating instructions.

2. Wrapped Instruments

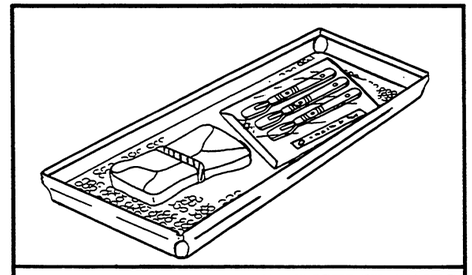


FIGURE 12 – WRAPPED INSTRUMENTS

   a. Collect a group of similar instruments which have been cleaned according to Section 2–I, page 6.

      or

      Collect instruments used for a particular procedure (i.e. amalgam, exam, etc.) which have been cleaned according to Section 2–I, page 6. Do not mix dissimilar metals.

b. Place instruments in autoclave bag (3M, St. Paul, MN; Propper, Long Island City, NY).

or

Loosely wrap instruments in 2–4 layers of muslin towels or autoclave paper (3M, St. Paul, MN; Propper, Long Island City, NY).

CAUTION: Do not wrap instruments too tightly. Inadequate sterilization may result from improper wrapping or placing too many instruments per package. (If a large number of instruments per package are desired, see Section 2–III–D, page 9, for PACKS).

c. Place a process or spore test indicator inside a representative bag.

d. Seal with autoclave tape (3M, St. Paul, MN; Propper, Long Island City, NY) or heat sealer.

CAUTION: Do not use staples, pins or other devices which will puncture the packaging material. Otherwise, sterility may be compromised.

e. Place packages on perforated trays. Ensure adequate space between packages to allow steam circulation.

NOTE: Place the package containing the sterilization monitor in the front of the bottom tray.

f. Load tray in the rack in the sterilizer. Ensure adequate spacing between trays to allow steam circulation.

CAUTION: Do not overload. Inadequate sterilization may result.

g. See Section 3, page 12, for operating instructions.

3. Wrapped Trays

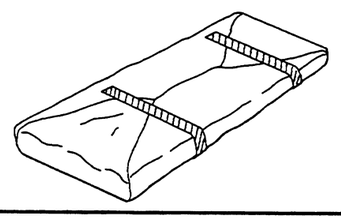


FIGURE 13 – WRAPPED TRAYS

a. Place instruments, cleaned according to Section 2–I, page 6, in a perforated tray. Allow adequate space between instruments for steam circulation.

b. Place a process or spore test indicator in at least one tray to be cycled.

c. Wrap the tray in 2–4 layers of towels or other wrapping material. (See Table 2–2, page 11). Close using autoclave tape.

d. Place wrapped trays on the rack in the sterilizer. Ensure that the wrapping does not touch the sides of the chamber. Allow adequate space between trays for steam circulation.

NOTE: Place the tray containing the sterilization monitor in the bottom of the sterilizer.

CAUTION: Do not overload. Inadequate sterilization will result.

e. See Section 3, page 12, for operating instructions.

D. Packs

Packs are for sterilizing surgical instruments, gloves and textiles.

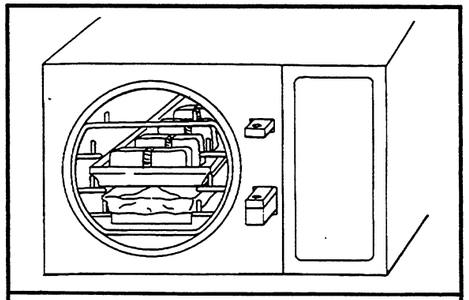


FIGURE 14 – PACKS

1. Instruments and textiles

a. Clean instruments according to Section 2–I, page 6. Textiles should be laundered prior to sterilization.

Table 3–1 PROGRAM PARAMETERS*

PROGRAM	**TEMP/**PRES/TIME	ITEMS TO BE STERILIZED
UNWRAPPED	132° C/210 kPa for 3 minutes	Non–surgical instruments, or other instruments that cannot withstand immersion without rusting, loose on a tray. Open glass or metal canisters. Heat–resistant rubber tubing, which will not be used in surgical application. Any items where 132°C for 3 minutes is appropriate.
WRAPPED	132° C/210 kPa for 12 minutes	Loosely wrapped individual instruments. Multiple layers of instruments separated by fabric. Instruments in paper bags. Wrapped trays of loose instruments. Heat–resistant rubber tubing. Any items where 132°C for 12 minutes is appropriate.
PACKS	121° C/128 kPa for 30 minutes	Groups of instruments and supplies (textiles) wrapped in multiple layers of muslin or equivalent. Common groups of surgical instruments in commercially–prepared packs. Surgical instruments subject to prolonged storage. Surgical gloves wrapped for sterilization. Any items, other than liquids, where 121°C for 30 minutes is appropriate.
LIQUIDS	121° C/128 kPa for 30 minutes	Liquids or gels that could boil over or spill out of the container. At the end of the sterilizing cycle, venting is slowed to allow heat in the liquid to dissipate slowly and eliminate boilovers. Venting occurs at 16 kPa to complete the cycle. There is no drying cycle in the LIQUIDS mode.

* For mixed loads, use the longer or lower temperature program (i.e. for loose instruments and surgical dressings in packs, use PACKS).

** Time and temperature are minimums.

NOTE: When sterilizing handpieces, check manufacturer's recommendations for maximum temperature. Use WRAPPED program only if handpieces are able to withstand 132°C temperature. Otherwise use PACKS program.

The names of the various modes of operation are general categories. Use good judgement when selecting the mode of operation. First, take into consideration the density of the individual load and the ability of the steam to circulate and penetrate wraps. Then determine the correct programmed values to assure sterilization.

F. Ready/Dry

1. At the end of the sterilization cycle, the chamber is automatically vented. When the chamber pressure reaches zero, five beeps sound. The red STERILIZE light extinguishes and the yellow DRY light and green READY light begin to flash. Once the flashing green READY light is on, the autoclave may be unloaded without finishing the dry cycle.

   NOTE: Items should not be removed from sterilizer until completely dry. However, dry articles may be removed from the sterilizer any time the green READY light is illuminated. It is not necessary to wait until completion of the drying cycle to remove articles from the autoclave.

2. The 30 minute drying cycle now begins. The °C/Min window displays 0:00 and then begins to count up to 30:00, indicating the amount of drying time that has elapsed.

NOTE: In the LIQUIDS program, there is no drying cycle.

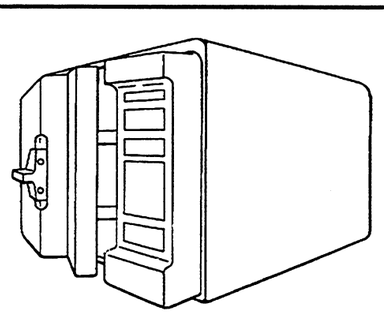


FIGURE 16 – DRYING

NOTE: To speed the drying, it is recommended that the door be cracked open (door open and latch pins against latch bar or open approximately one inch).

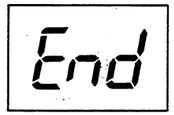
G. Restart

1. If the sterilizer is unloaded before the drying cycle is completed, the program must be cleared by depressing the CLEAR/START button.

2. A new cycle may now begin. See Section 3–II–D, page 12.

H. Unloading

1. The chamber may be unloaded at any time during the drying cycle. At the end of the drying cycle, the °C/Min window displays a flashing END signal and 10 beeps are sounded.



2. The flashing yellow DRY light goes out as the green READY light continues to flash.

   NOTE: When removing sterile instruments from the autoclave, handle with care. They may still be hot.

3. When the END signal is displayed, the heaters automatically shut off. This prevents possible damage if the autoclave is left unattended.

III. END OF DAY

A. Depress the POWER switch OFF. The red POWER light goes out.

B. Wipe and inspect the door gasket.

C. Inspect the filter.

D. Clean any spills from the bottom of the chamber.

CAUTION: Do not use high chlorine or phosphate content detergents or chlorine bleach in laundering items prior to sterilization. Staining of the autoclave and instruments (or more severe damage) may result. The use of chlorides may also result in cracks in the chamber.

b. Loosely package instruments with not more than 10 per pack. Instruments of the same type which are nested should be separated by a layer of absorbent towels and placed so that water will run out. Loosely roll or fold textiles.

   CAUTION: Density should not exceed 1/2 the capacity of the pack and the packs should not exceed 1/2 the capacity of the tray. Otherwise, inadequate sterilization could result.

   or

   Wrap properly cleaned articles in 2–4 layers of muslin towels or other packaging material. (See Table 2–2, page 11).

c. Place a process or spore test indicator inside a representative pack.

d. Seal with autoclave tape or heat sealer (3M, St. Paul, MN; Propper, Long Island City, NY).

   CAUTION: Do not use staples, pins or other devices that could puncture packaging material. Otherwise, sterility could be compromised.

e. Place packs on perforated trays. Leave adequate space between packs to allow steam to circulate. Load packs upright, side–by–side on the tray. Do not stack.

   CAUTION: Adequate drying will not occur unless space is left between packs. Metal and glass containers should not be used to separate packs as these will inhibit drying. Packs should not exceed 1/2 the capacity of the tray. Otherwise, sterilization could be compromised.

f. Load trays onto the racks in the sterilizer. Ensure that packs do not touch the sides of the chamber. Allow adequate space between trays for steam circulation. If packs are large, some trays may be omitted to allow more clearance.

   CAUTION: Do not overload. Inadequate sterilization may result.

g. Place pack containing sterilization monitor in the bottom front of the sterilizer.

h. See Section 3, page 12, for operating instructions.

2. Surgical gloves

NOTE: Disposable gloves should not be sterilized.

a. Clean and dry gloves.

b. Place a square of muslin or other absorbent towel into the glove up to the finger.

c. Place a strip of muslin or other absorbent towel around the cuff and fold it back.

d. Place a process or spore test indicator in one glove. Wrap gloves in muslin or other packaging material. (See Table 2–2, page 11.)

e. Place wrapped packs of gloves on end in a perforated tray. Leave space between packs to allow steam to circulate.

f. Load trays onto rack in the sterilizer. Leave adequate space between trays for steam circulation. Ensure that packs do not touch sides of chamber.

   CAUTION: Do not overload. Inadequate sterilization may result.

g. Place pack with sterilization monitor in the front bottom tray.

h. See Section 3, page 12, for operating instructions.

IV. LIQUIDS PREPARATION

A. Place liquids in a heat proof glass container, filled 2/3 full.

B. Cover container loosely. Do not seal container.

C. Place container on a perforated tray. Include a process or spore test indicator. Load onto the rack in the sterilizer. (See Section 3, page 12, for operating instructions.)

Table 2–2 WRAPPING MATERIALS FOR STEAM STERILIZATION

SUITABLE	UNSUITABLE
Muslin 2 (layers)	Canvas
Nylon bagging material	Aluminum foil
Kraft paper	Steam impermeable plastics
Commercial autoclave paper (must be as permeable as muslin)	Sealed tubes, jars and cannisters
Plastic and paper bags (must be permeable)	Drums not recommended
Cloth or paper covered trays	

SECTION 3 – OPERATIONS

I. START OF DAY

A. Power ON

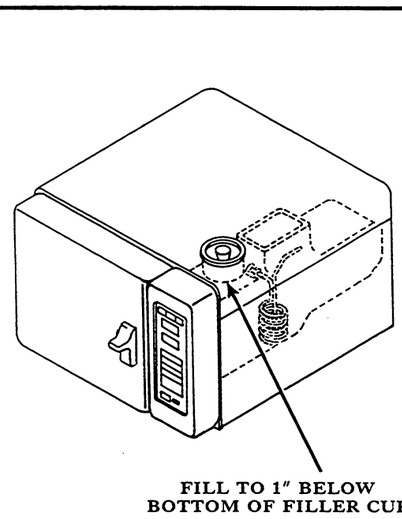
1. Depress POWER switch.
2. Red POWER light verifies that power is being supplied to the unit.

B. Perform optional self–diagnostic check as needed. (See Section 4–2, page 16).

C. Check Reservoir Level

1. Add distilled deionized water to approximately 1″ below bottom of filler cup opening. Unit must have water covering condenser coil to operate properly.

   NOTE: Do not overfill. Filling reservoir too full may cause water to boil over if several cycles are run in rapid succession.



FILL TO 1″ BELOW BOTTOM OF FILLER CUP

FIGURE 15 – RESERVOIR FILL LEVEL

II. STERILIZER OPERATION

A. Power ON

With the POWER switch ON, the red POWER light verifies that power is being supplied to unit.

B. Load

1. Open chamber door.
2. Load autoclave trays as directed in Section 2–III, page 7.
3. Close and latch the chamber door.

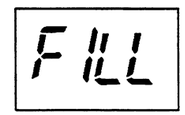
   NOTE: To maintain sterilization when unloading chamber, clean and disinfect chamber door handle if there was a possibility of contamination during loading.

C. Select Program

1. Depress desired program switch.
2. A red light comes on to the left of program switch to verify the selection. See Table 3–1, page 14, for program parameters.

D. Start

1. Depress CLEAR/START switch.
2. Water immediately begins to fill the chamber and the °C/Min window displays the word FILL.



3. Once the fill cycle is complete, the red STERILIZE light comes on.

E. Sterilize

1. As the chamber heats up, the °C/Min window displays the rising temperature in °C and the pressure window displays the building pressure in one kPa increments. Temperature and pressure rise until the programmed values for sterilization are reached. The red STERILIZE light remains illuminated constantly to indicate heat up.
2. Once the required temperature and pressure are reached, the °C/Min window changes and displays the time required for sterilization. Then countdown begins for the remaining time required for sterilization. The red STERILIZE light begins to flash, signaling the start of the sterilization cycle.