Your Sterilizer Experts

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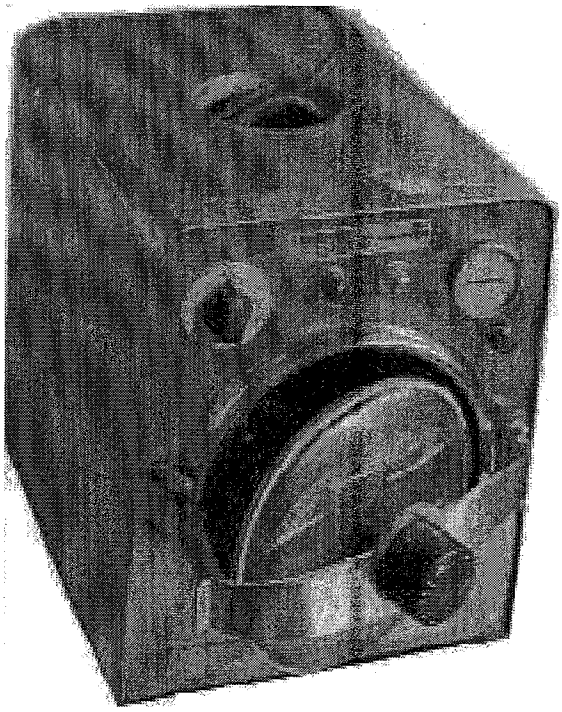
Alfa Medical
59 Madison Ave
Hempstead, NY 11550

1-800-762-1586
516-489-3855
516-489-9364 (fax)
Web site www.sterilizers.com
email info@sterilizers.com

Amsco Sterilizer - Model 613R

Manual & Parts List



WARNING
LIQUID STERILIZATION

TO PREVENT POSSIBLE PERSONAL INJURY OR PROPERTY DAMAGE RESULTING FROM BURSTING BOTTLES AND HOT FLUID, YOU MUST FOLLOW THE RECOMMENDED PROCEDURE LISTED BELOW:

RECOMMENDED PROCEDURE:

- **USE ONLY VENTED CLOSURES — DO NOT USE SCREW CAPS OR RUBBER STOPPERS WITH CRIMPED SEAL.**
- **USE ONLY TYPE I BOROSILICATE (PYREX) GLASS BOTTLES — DO NOT USE ORDINARY GLASS JUGS OR ANY CONTAINER NOT DESIGNED FOR STERILIZATION.**
- **ONLY FOLLOW PROCEDURE FOR STERILIZING FLASKED SOLUTIONS.**
- **DO NOT ALLOW HOT BOTTLES TO BE JOLTED. THIS CAN CAUSE HOT-BOTTLE EXPLOSIONS! DO NOT MOVE BOTTLES IF ANY BOILING OR BUBBLING IS PRESENT.**
- **BOTTLES SHOULD BE COOL TO TOUCH BEFORE ATTEMPTING TO MOVE THEM FROM STERILIZER TO THE STORAGE AREA.**

BEFORE OPERATING THIS EQUIPMENT

1. AT THE BEGINNING OF THE DAY (Refer to Fig. 1).

a. Be sure power cord plug of sterilizer is inserted into properly grounded electric service outlet.

IMPORTANT: Before plugging in sterilizer, check data plate on back of unit for proper voltage.

b. Be sure operating valve handle is in upper position. Remove water-reservoir cover and pour water into reservoir until water level is even with underside of lip (reservoir holds approximately 3½ quarts). Replace cover. Periodically check reservoir when sterilizer is being used: replenish water when necessary.

NOTE: Since excess water will drain from the overflow tube at the rear of the sterilizer, provide a device for either catching the water or directing it to a drain. Tap water may be used but distilled or softened water will minimize scale formation in heating chamber.

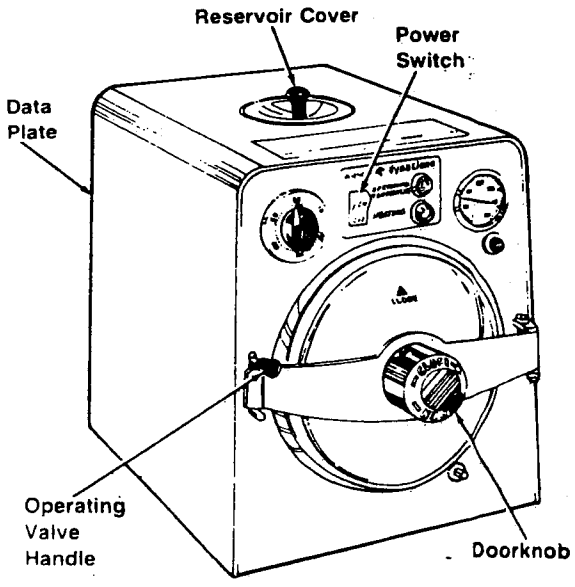


Figure 1. Sterilizer.

2. DOOR OPERATING INSTRUCTIONS (Refer to Figs. 2 and 3).

a. **To open** — Unlock door by turning doorknob counterclockwise until it stops. While firmly holding doorknob pull door forward and to the right. Then pull door and hinge forward and to the left so that left edge of door clears nose of shell before right edge (Fig. 2B).

b. **To close** — Push door and hinge so that right edge of door enters nose of shell before left edge. Then push door forward and to the left. Lock door by turning doorknob clockwise until it stops (Fig. 3).

IMPORTANT: Keep door centered in nose of shell while turning doorknob.

OPERATING INSTRUCTIONS

1. PREPARATION

Open chamber door . . . see door instructions. Pull operating valve handle down; water flows into chamber. When water in chamber reaches the Level Indicator, push operating valve handle up; water stops flowing.

2. LOAD STERILIZER

Prepare load before inserting trays into chamber.

a. **Instruments** — Only use trays supplied with sterilizer. Rinse instruments before placing them in trays.

• Wrapped — Place towel in bottom of tray. Wrap instruments in muslin and place them on tray.

• Unwrapped — Place instruments on tray in any order.

NOTE: Muslin or towel cover facilitates drying and prevents contamination in transit.

b. **Dressings, Small Packs and Rubber Tubes and Gloves** — Wrap them in muslin, and place them loosely in the trays (furnished).

c. **Empty Glassware, Syringes and Utensils** — Place empty containers (wrapped or unwrapped) on their sides or inverted in the sterilizer tray. Cover them with muslin or towel.

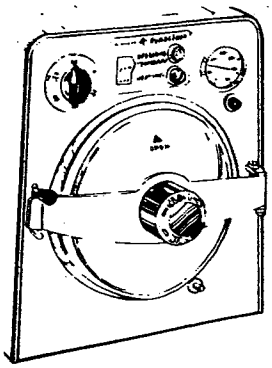


Figure 2A. Unlock Door.

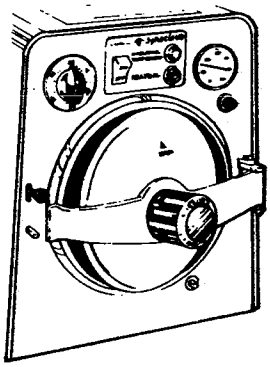


Figure 2B. Partially Open Door.

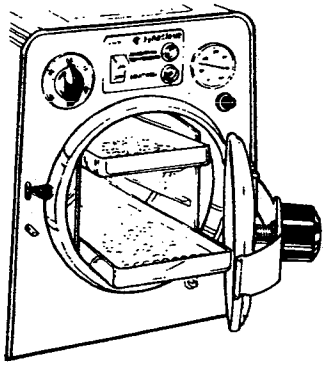


Figure 2C. Completely Open Door.

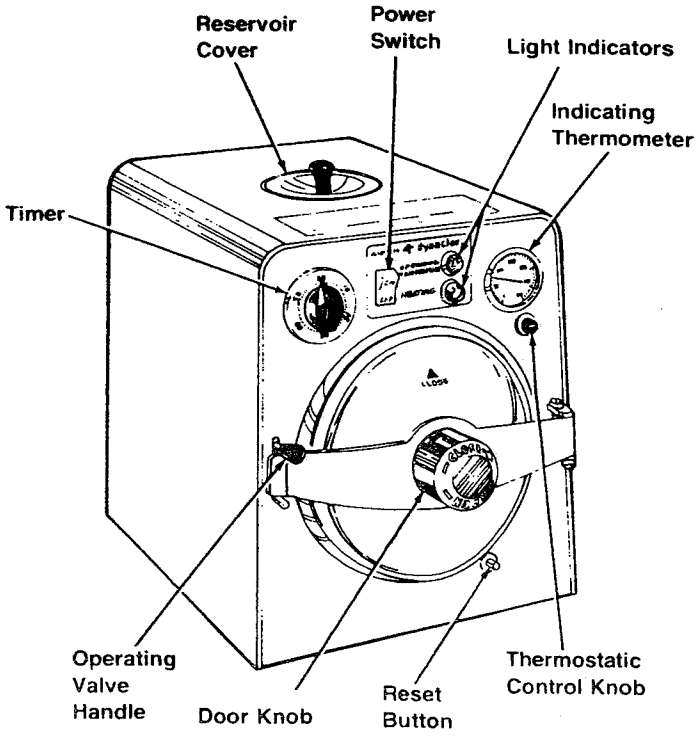


Figure 3. Controls.

WARNING

TO PREVENT POSSIBLE PERSONAL INJURY RESULTING FROM BURSTING BOTTLES AND HOT FLUID, USE ONLY BOROSILICATE (PYREX) FLASKS WITH VENTED CLOSURES FOR STERILIZING LIQUIDS.

• SEE PAGE 6 FOR FURTHER INFORMATION.

d. **Flasked Solutions** — Place 75 ml flasks, filled with solution, on trays in any order desired.

3. OPERATION (Refer to Fig. 3)

a. Close chamber door ... see door instructions. Then lower operating valve handle to top of hinge.

b. Press power switch to ON.

c. Turn thermostatic control knob fully clockwise.

d. Set timer for 60 minutes. Heaters and HEATING light are energized.

RECOMMENDED STERILIZATION EXPOSURE PERIODS

	250 F (121 C) Minutes	270 F (132 C) Minutes
Surgical instruments (unwrapped) without cover	15	3
Surgical instruments (unwrapped) with cover	20	10
Surgical instruments, wrapped	30	15
Dressings and small packs, wrapped	30	15
Utensils, syringes and empty glassware with cover	20	10
Rubber gloves, wrapped	20	
Rubber tubing, wrapped	20	
75 ml Square-Pak flasks filled with solution	20	

NOTE: Steam is generated and temperature will begin to rise. The air inside the chamber will settle to the bottom from where it will be gradually forced out through an air exhaust. The air exhaust is controlled by a thermostatic trap that closes after all the air has passed from the chamber.

e. When indicating thermometer shows desired temperature (usually 250 F or 270 F), turn thermostatic control knob counterclockwise until OPERATING TEMPERATURE light is energized.

NOTE: To regulate temperature, turn thermostatic control knob clockwise to raise temperature, counterclockwise to lower. If the thermometer does not reach the desired temperature when the thermostatic control knob is fully clockwise or the HEATING light **does not** come on, the thermostat must be reset. Turn timer off: wait 10 minutes then press reset button. Do not hold reset button.

CAUTION: Do not set timer if there is no water in chamber. If timer has been set, turn timer off and open door. Wait 10 minutes to allow chamber to cool before adding water or pressing reset button.

f. Set timer for desired exposure period ... see Table on this page.

NOTE: The sterilizer is equipped with a safety valve that will release when chamber pressure reaches approximately 34 psi. If the safety valve releases, excess pressure is being released from the chamber. Safe operation of the sterilizer can be continued if the thermostatic control knob is set at a lower temperature.

IMPORTANT: If the sterilizer shuts off during a cycle, there is insufficient water in the bottom of the chamber. Correct this situation as follows:

(1) turn timer off and lift the operating handle to exhaust chamber pressure;

(2) when chamber temperature is below 212 F, unlock and open chamber door and allow chamber to cool for 10 minutes;

(3) pull operating valve handle down until water in chamber reaches Level Indicator, then push handle up;

(4) close door and lower operating valve handle to top of hinge;

(5) push reset button (do not hold); and

(6) set timer for desired exposure period after temperature is reached.

g. A bell will sound indicating that exposure period is completed.

h. Proceed as applicable:

(1) **Instruments, Dressing and Empty Glassware:**

- Lift operating valve handle.
- When indicating thermometer shows below 212 F, unlock door.
- If drying is desired, leave load in sterilizer for 10-20 minutes.

(2) **Flasked Solutions:**

- When indicating thermometer shows below 212 F, lift operating valve handle.
- Wait 20 minutes, then unlock door.
- After waiting for at least 10 minutes, proceed to step "i".

CAUTION: Do not use heaters for drying.

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i. Open chamber door . . . see door instructions, and remove load.

j. Press power switch to OFF.

CLEANING AND PREVENTIVE AND MINOR MAINTENANCE

CAUTION: Repairs, other than those described in these Instructions, should be attempted ONLY by experienced mechanics fully acquainted with this equipment. Use of inexperienced, unqualified persons to work on the equipment or the installation of unauthorized parts could invalidate the warranty or result in costly damage.

WEEKLY

NOTE: The mineral content of the water will determine the cleaning frequency of the chamber.

Cleaning Chamber. Remove inner metal liner by unscrewing two screws at front of liner and pulling liner forward. Inspect heating surface of outer chamber (steam jacket) for lime and scale deposits; clean if necessary. Replace liner, be sure pin at rear of liner is engaged in fitting at chamber backhead. Replace screws.

QUARTERLY

Lubricating Chamber Door. Place a few drops of machine oil on hinge pins and screw thread of door handle.

AS REQUIRED

1. **Replacing Lamps.** Unscrew lens to expose lamp. Then push in on lamp, turn and pull straight out; replace it. Replace lens.

2. **Replacing Gasket on Chamber Door.** When door fails to close steam-tight under normal closing pressure, replace gasket. (**Note:** Gasket will leak steam at initial operation until temperature reaches approximately 260 F. This is necessary for positive door closure under chamber pressure.) Remove old gasket and clean the groove using a non-ferrous tool or material. (The replacement gasket is cut to provide a tight fit.) Force the new gasket into the groove, a short section at a time; **do not stretch it.** Should the gasket appear too long ... **DO NOT CUT IT** ... start over, compressing short sections into the groove, until the entire length is inserted. Never use sharp tools to push gasket into groove.

NOTE: If door is so corroded that it cannot be cleaned without pitting the surface, replace the door.

REPLACEMENT PARTS

When ordering replacement parts, please include the **part numbers** and **descriptions** listed subsequently.

To hasten service to you, include on your order the model, unit and serial numbers of this equipment.

Send your order directly to the Regional Office which serves your area. Your AMSCO representative will give you the address as well as ordering information regarding other parts.

DESCRIPTION	PART NUMBER
TIMER	P-33115-091
HEATER (120 V)	P-33165-061
HEATER (240 V)	P-33225-042
THERMOSTAT (low water)	P-455086-001
SWITCH, ON-OFF	P-89078-091
BELLOWS	P-33151-091
GASKET, Bellows	P-33150-091
BELLOWS, Air Relief	P-33158-091
GASKET, Door	P-754874-091
THERMOMETER	P-13638-091
LIGHT, Indicator, Red (120 V)	P-41083-091
LIGHT, Indicator, Red (230 V)	P-455050-001
LIGHT, Indicator, White (120 V)	P-41084-091
LIGHT, Indicator, White (230 V)	P-33696-091
LAMP, Pilot	P-23883-091

LIQUID STERILIZATION

Your AMSCO Sterilizer is designed to process liquids when borosilicate (Pyrex) flasks with vented closures are used.

Borosilicate (Pyrex) glass is recommended because it is a superior glass capable of containing higher pressures, of resisting thermal shock (such as cold air striking the hot glass), and of withstanding repeated handling.

Vented closures are recommended because, by design, they will prevent excess pressure by automatically venting a flask!

If other types of glass (such as flint glass) and non-venting (sealed) closures are used to sterilize liquids in your AMSCO Sterilizer; a potential dangerous condition, capable of causing personal injury and property damage, is created. As the liquid and residual air in a sealed flask are heated, they expand and create an internal pressure greater than the external pressure of the steam. With the weaker glass, a greater potential for bursting exists.

After the sterilization exposure, the chamber is exhausted slowly but it still exhausts more rapidly than the pressure within a sealed flask.

This pressure within the flask will exist until the residual air and the liquid have cooled (unlike a flask with a vented closure that prevents this excess pressure). Thus, the potential exists for the flask to burst and cause personal injury or property damage.

LIMITATION OF LIABILITY AND INDEMNITY

In no event, whether as a result of breach of contract, warranty or tort (including negligence and strict liability) shall American Sterilizer Company or its suppliers be liable for any consequential or incidental damages including, but not limited to loss of profits or revenues, loss of use of the Products or any associated equipment, loss of the Buyer's Products, damage to associated equipment, cost of capital, cost of substitute products, facilities, service or replacement power, downtime cost, caused by such Products, or claims of the users for such damages. Buyer and ultimate user hereby agree to indemnify the American Sterilizer Company and to hold the American Sterilizer Company harmless from any and all liability for such consequential or incidental damages. The responsibility of the American Sterilizer Company for damages due to injuries or death or the death of employees of the Buyer or ultimate user of the Product, caused by the Product, shall be limited to that portion of such damages as might be attributable to the negligence or strict liability or other tortious conduct of the American Sterilizer Company. The Buyer and ultimate user agree to indemnify the American Sterilizer Company and hold the American Sterilizer Company harmless from any further damages, indemnity or contribution. If Buyer transfers title to or leases the Products sold hereunder to any third party, Buyer shall obtain from such third party a provision affording American Sterilizer Company and its suppliers the protection of this article relating to Limitations of Liability and Indemnities.

The American Sterilizer Company's liability for any claim of any kind (including negligence and strict liability) for any loss or damage arising out of, or resulting from this agreement, or from the performance or breach thereof, or from the Products or Services furnished hereunder, shall in no case exceed the price of the specified Product, system, component or service which gives rise to the claim. Except as to title, any such liability shall terminate one year from the date of installation of any Product or upon the expiration of the warranty period applicable to each type of Product covered hereby, whichever time period expires first.

DEFECT	REMEDY
(1) Failure of unit to "Start"	Check to insure power at receptacle. Check neon glo tube (panel lights). Remove finishing jacket, check thermostat to insure tha leaf contacts are not severed.
(2) Failure to heat and attain 270° operating temperature	Check to insure that thermostat control knob is 90° t the right. If control knob is loose, turn the thermosta shaft with screwdriver (slot provided) clockwise int the shaft stop. Operate sterilizer, then set control kno so that white index line is horizontal, tighten set scre in control knob. With thermostat control knob into the stop, if situatio still exists, check for excessive escapement of steai through slot in rear of finishing jacket. If steam escape ment is noted, this will indicate a faulty bellows set ting. Remove finishing jacket, reset bellows as pe Paragraph XI of SM-369. If escapement of steam is non-existent, as explained i paragraph above, this is an indication of a faulty therm ostat setting. Adjust thermostat as per Paragraph XI o SM-369.
(3) Leakage below sterilizer base after or during sterilizer operation	Check water level in water pan for over filling. Remov finishing jacket, operate sterilizer. Check visually al connections, tubing, paying particular attention to bush ings, one in sterilizer back head, the other in the botton of the sterilizer shell, to see where leakage occurs dur ing cycle.
(4) Door leakage during sterilizer operation	Check to insure that the chamber is not overfilled in itially. If leakage persists during operation, shut of sterilizer, allow to cool. Renew gasket, taking care that the gasket is uniformly installed in the gasket groove of the door. If after gasket renewal, leakage persists, shut off steri lizer. Check fit of gasket in retaining groove, to insure that it is uniform. Remove finishing jacket. Loosen the two screws holding the hinge to the front panel and saddle. Align the door in the nose of the shell, operate sterilizer. The above procedure will insure positive, unrestricted alignment of the door in the shell. Tighten the screws previously loosened, holding the hinge to the front panel and saddle. Replace finishing jacket.
(5) Lack of thermostat control	If, during operation, heat remains on (red pilot glowing constantly), turn thermostat adjusting knob counter-clockwise. If white pilot light does not come on and red pilot light off indicating heaters are off, the cause may be a faulty thermostat adjustment or the thermostat leaf contacts are sprung or "welded" together. If thermostat

DEFECT	REMEDY
(5) Lack of thermostat control (Continued)	appears faulty, replace and reset thermostat adjustment as per Paragraph XI, SM-369.
(6) "Popping of Safety Valve"	Check to insure that sterilizer is being operated at proper operating temperature. Check to insure that sterilizer is operating correctly, maintaining set temperature, etc. If "popping" persists at operating temperature, replace "O" ring as per Paragraph IX of SM-369. If upon removal of the control housing cover, it is noted that the safety valve seat is of one piece Teflon construction, replace as per Paragraph IX SM-369.
(7) Snap Ring ejected from door post	Remove door as per Paragraph 1 of SM-369. Refer to Drawing SM-187. Clean retaining ring groove of Item 24 "Adapter" to insure that no lubricant is present in the groove. Follow procedure in reverse to reassemble.
(8) Failure of sterilizer to exhaust	Refer to Drawing SM-364. Item 2 Tube Condenser contains an orifice in the tube (at the valve end of the tube). This orifice may become clogged with lint, etc. A thorough cleaning will remedy this situation. If the operating valve handle will not move to the "UP" position (exhaust position), the difficulty is in the operating valve itself. Consult SM-366 for cut away section of valve, replace "O" rings as per Paragraph X of SM-369.
(9) Timer	
(a) Failure of unit to start	(a) Faulty switch in Timer. Remove Timer from front panel, refer to Paragraph V of SM-369. After Timer is removed, remove bell portion by removing hex retaining nut. Spray interior of Timer with silicone spray. Reassemble bell portion, operate timer (manually starting, etc.) to insure that it is functioning properly. Reassemble Timer to sterilizer.
(b) Improper time cycle	(b) This may be checked by the use of a watch or clock and compare known time against the timer.
(c) Failure of Timer bell to ring at end of pre-set time.	(c) Faulty Timer. All or any one of the above conditions will call for replacement of the Timer. No attempt should be made to repair the Timer, direct replacement is recommended.

DIRECTIONS FOR SERVICING
REPLACEMENT OF PARTS

DOOR KNOB

I. TO REPLACE DOOR KNOB, REFERENCE NO. 18 (SEE SM-187).

Holding door firmly, remove Stop Nut, Reference No. 6. Remove Cup Washer, Reference No. 22 and Teflon Washer, Reference No. 26. Remove Door from Screw, Reference No. 16. Release Retaining Ring, Reference No. 5 and Washer, Reference No. 4. Remove knob assembly by pulling knob away from hinge. Remove Washer, Reference No. 4. Remove 3 Screws. Replace knob. To assemble, follow the above procedure in reverse.

CAUTION: Care must be taken to insure that square hole in door, Reference No. 1, is well seated on mating square of Screw, Reference No. 16.

HEATER

II. TO REPLACE HEATER (SEE SM-379 and SM-380 or SM-380A)

Remove plug from receptacle.
Syphon water from reservoir. This may be accomplished by syphoning or the following procedure:

Set machine so that nose of shell (front panel) is over sink or other receptacle. Open door, remove trays. Pull operating handle down, allowing water to flow from reservoir to chamber and out of shell into sink or receptacle. When water flow slows, tilt sterilizer forward to remove water from shell. Remove liner by removing two screws in the front of liner and pulling liner forward and out of shell.

Lay sterilizer on its side (Caution: Lay soft cloths to protect finish of jacket). Remove 4 screws, Reference No. 1 (SM-380 or SM-380A), from bottom and 3 Screws, Reference No. 1, from back of finishing jacket.

Turn sterilizer right side up, remove jacket by pulling straight up.

Remove Nut, Reference No. 5 (SM-379) from heater terminals. Remove Washer, Reference No. 10. Remove wire and nut, Reference 5 from heater terminals. Remove Heater Nut, Reference No. 2 (one per heater leg). Remove Heater through nose of shell.

Refer to Wiring Diagram (SM-191 or P-461639-001) to insure correct location of wires on terminals.

NOTE: In the process of reassembly heater must be held firmly in shell while replacing the Heater Nut, Reference No. 2.

LOW WATER THERMOSTAT REPLACEMENT

III. TO REMOVE AND REPLACE LOW WATER THERMOSTAT (SEE SM-379).

Remove finishing jacket as per Paragraph II.

Remove two wires connected to Thermostat. Remove Screw, Reference No. 7, Lockwasher, Reference No. 12 and Nut, Reference No. 11, which hold Thermostat to bracket. Replace new Thermostat, reassemble following the above procedure in reverse. Regulate thermostat position to ensure free movement of reset rod.

SWITCH REPLACEMENT

IV. TO REMOVE AND REPLACE SWITCH (SEE SM-368 — 380 or 380A — 381 or 381A).

Remove finishing jacket as per Paragraph II. Remove Thermometer, Reference No. 23 (SM-380 or SM-380A), from Control Housing Assembly, Reference No. 16 (SM-381) or Reference No. 15 (SM-381A). Loosen set screw in Switch Adjusting Knob, Reference No. 24 (SM-380 or SM-380A). Remove Knob from shaft, Disconnect Air Vent Tube, Reference No. 10 (SM-381) or Reference No. 9 (SM-381A). Remove Screws, Reference No. 11 (SM-381) or Reference No. 10 (SM-381A), holding control housing assembly to front panel. Disconnect two wires connected (by means of terminal screws) to switch. Remove screw, Reference No. 9 (SM-368), holding switch to Bracket, Reference No. 25 (SM-368).
Install new switch following the above procedure in reverse to reassemble.

To set Switch Adjusting Knob, Reference No. 24 (SM-380 or SM-380A), turn switch shaft (with a screwdriver) clockwise until it hits stop. Replace adjusting knob as follows: With Switch shaft in the extreme clockwise position (into the stop). Replace knob with white line on knob horizontal to the right (3 o'clock on a watch). Tighten set screw.

(For final adjustment of switch, see Paragraph XI.)

TIMER

V. TO REMOVE AND REPLACE TIMER (SEE SM-380 or SM-380A).

Remove finishing jacket as per Paragraph II. Remove two wires connected to Timer, Reference No. 20. Pry off indicator knob on front of timer. Remove retaining nut, holding dial plate. Remove dial plate, timer body. Install new timer following the above procedure in reverse.

NOTE: This timer has the "ON-OFF" Switch incorporated into the timer itself.

THERMOMETER

VI. TO REMOVE AND REPLACE THERMOMETER (SEE SM-380 or SM-380A).

Remove finishing jacket as per Paragraph II.

Remove Thermometer, Reference No. 23, from control housing assembly by means of an open end wrench. Replace new thermometer using pipe compound to insure against leakage.

CAUTION: Do not attempt to tighten thermometer to a point where thermometer dial pulls against front panel, causing front panel to bow and thermometer indicator to be rendered useless.

BELLOWS

VII. TO REMOVE AND REPLACE AIR VENT BELLOWS (SEE SM-368).

Remove finishing jacket as per Paragraph II. Remove 4 Screws, Reference No. 1, holding guard and control housing cover. Remove Guard, Reference No. 32 and Cover, Reference No. 2. Remove Bellows Seal Nut, Reference No. 17, and gasket, Reference No. 16. Remove Bellows Lock Nut, Reference No. 18, and the Seal Washer under the Lock Nut. (This Seal Washer is for shipping purposes and does not need to be replaced. It may be discarded.) Remove Bellows, Reference No. 15 (by means of screwdriver inserted into Bellows shaft which protrudes through the bottom of the control housing). Replace Bellows by starting thread on Bellows shaft into housing by hand being careful not to cross-thread the tapping in the housing.

When a Bellows is replaced it becomes necessary to replace the "O" Ring, Reference No. 26 as follows:

Remove "O" Ring, Reference No. 26, from Air Relief Fitting, Reference No. 14. Replace with new "O" Ring. Examine Gasket, Reference No. 3. Replace if necessary. Reassemble following instructions above in reverse.

See Paragraph XI for final adjustment.

VIII. TO REMOVE AND REPLACE THERMOSTAT BELLOWS (SEE SM-368).

Remove finishing jacket as per Paragraph II. Remove control housing assembly as per Paragraph IV. Remove 2 Screws, Reference No. 7, holding adjusting screw bracket. Remove bracket, remove Bellows, Reference No. 6, clean gasket surface on control housing body. Replace Gasket, Reference No. 5. Replace Bellows, Reference No. 6. Reassemble following instructions above in reverse.

SAFETY VALVE

IX. TO REMOVE AND REPLACE SAFETY VALVE AND SEAT. (SEE SM-368)

Remove finishing jacket as per Paragraph II. Remove 2 Bolts holding safety valve to Control Housing Cover, Reference No. 2. Remove safety valve body. Remove 4 Screws, Reference No. 1, holding guard and cover to control housing. Remove Seat, Reference No. 27, by means of pliers on the exposed edge, on the bottom side of the cover. Replace with new seat being careful not to cross-thread the seat in the cover. Tighten the seat by means of pliers until the flange of the seat is secure against the bottom of the cover. Reassemble guard and cover to control housing following the above instructions in reverse.

OPERATING VALVE

X. TO REPLACE "O" RINGS, OPERATING VALVE (SEE SM-366).

Remove finishing jacket as per Paragraph II.

Remove Operating Valve Handle, Reference No. 11.

CAUTION: Remove water from sterilizer as per Paragraph II.

Push Arm, Reference No. 2, up, thereby releasing Valve, Reference No. 4. Unscrew Nut, Reference No. 5. Remove Valve, Reference No. 4, and Nut, Reference No. 5. Remove "O" Ring, Reference No. 6, Upper Port, Reference No. 7, "O" Ring, Reference No. 6, Lower Port, Reference No. 8 and "O" Ring, Reference No. 6. Difficulty may be experienced in removing the lower "O" Ring. The use of a wire hook to remove this "O" Ring may be necessary.

CAUTION: Care must be taken to avoid scratching inside surface of valve.

For ease in replacement and for assurance of correct alignment, assemble valve components in reverse of above procedure on valve stem. Reassemble shaft to valve body.

CAUTION: Do not attempt to tighten Nut, Reference No. 5, other than is necessary to prevent leakage around valve stem.

FINAL ADJUSTMENT

XI. BELLOWS AND THERMOSTAT ADJUSTMENT. (SEE SM-368)

After servicing or replacing various control housing components, it becomes necessary to adjust the Bellows and Thermostat.

With finishing jacket removed, Bellows seal nut removed, Reference No. 17, start sterilizer as per Operating Instructions, Part No. 38895, or 454697.

At this point, the heaters are energized and the red light on (normal "come up" time is 7-8 minutes from initial starting time).

When thermometer reaches 215° turn Bellows Shaft (with screwdriver) until air ceases to escape through the air relief tube. Tighten Bellows lock nut, Reference No. 18, (on Bellows shaft). Replace Bellows seal nut.

Turn Thermostatic Control Knob clockwise (to the right) into the stop. Check thermostat adjusting screw, Reference No. 22, (behind front Panel, below control housing assembly). Insure that insulated end of adjusting screw is just lightly touching the leaf contact.

When thermometer reaches 275° white light should come on, red light off. If thermometer does not reach 275°, back off on the adjusting screw (closing switch contacts). If thermometer reaches 275° and white light does not come on, tighten adjusting screw, until white light comes on and red goes out.

Points to remember: Red light indicates heater "ON".

White Light indicates heater "OFF".

Adjusting Screw "Out" (Loosen) – Raise Temperature

Adjusting Screw "In" (Tighten) – Lower Temperature

DOOR GASKET REPLACEMENT

XII. TO REPLACE DOOR GASKET (SEE SM-187).

The replacement of the door gasket is quite simple following the procedure below:

It is not necessary to remove the door from the hinge, simply remove the Gasket, Reference No. 2, being careful not to rupture the gasket retaining lip on Door, Reference No. 1. Replace with new gasket. Close door securely (to help seat the new gasket in the retaining lip on the door). Open door, check gasket to insure that it is uniformly pressed into retaining lip.

Start sterilizer as per Operating Instructions, Part No. 33895 or 454697.

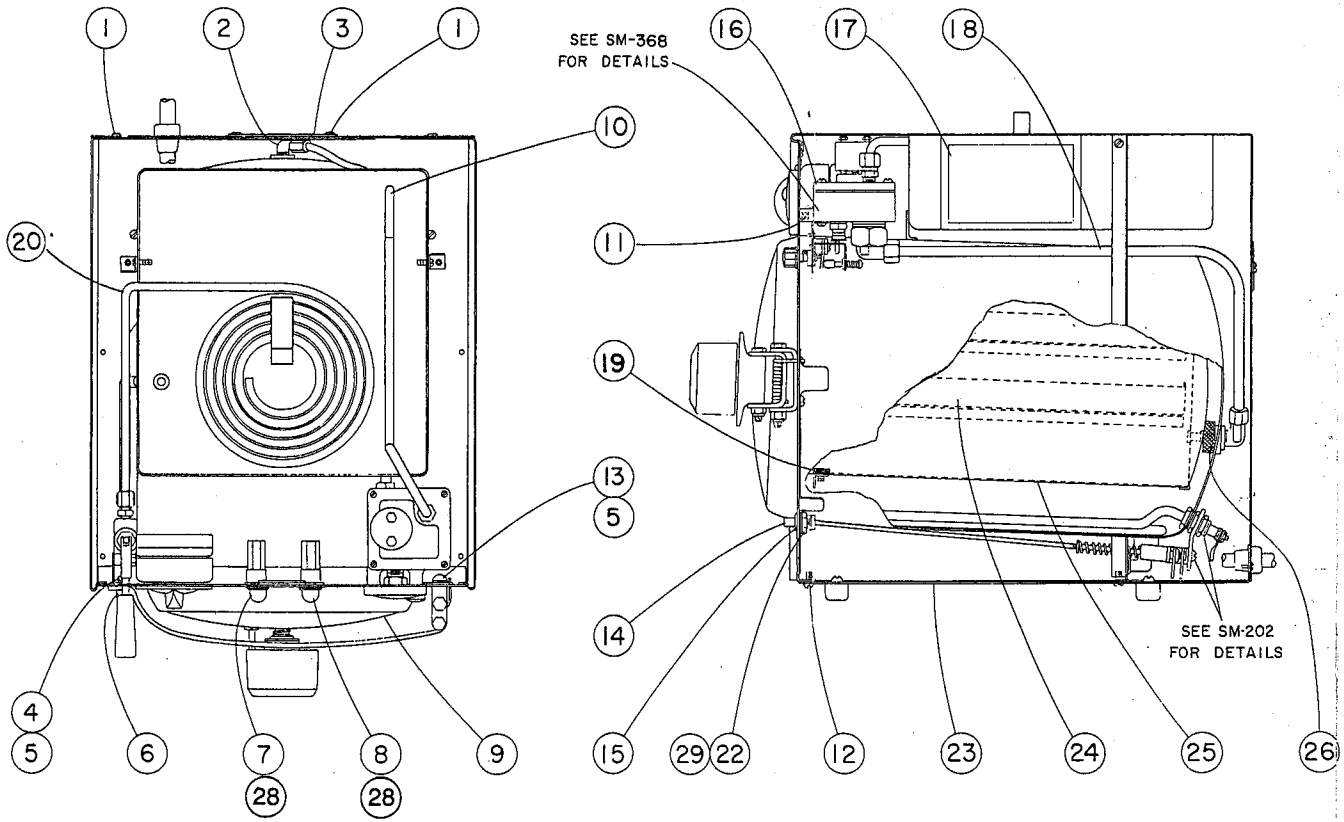
The Sterilizer is so designed and constructed so that internal pressure tends to hold the door closed thus assuring positive locking of the door in the nose of the shell.

Upon the initial cycle after a gasket replacement, steam and water may leak by the door gasket at lower temperature readings. This is normal for this type of door closure until a higher temperature is reached tending to seat the gasket. If gasket leak persists, check door alignment in shell. Check gasket. At least two 20 minute cycles should be run after door gasket replacement or any replacement of parts on the sterilizer.

SPECIAL NOTE:

The 613R sterilizer meets U.L. electrical and pressure requirements. However, it does not bear the ASME stamp. Please contact an AMSCO Regional Office when replacing the following critical components:

Door — P-33128-091
Door Assembly — P-33129-091
Shell Assembly — P-33110-061
Safety Valve — P-33154-091



TOP VIEW

FOR ADDITIONAL DETAILS SEE SM-364

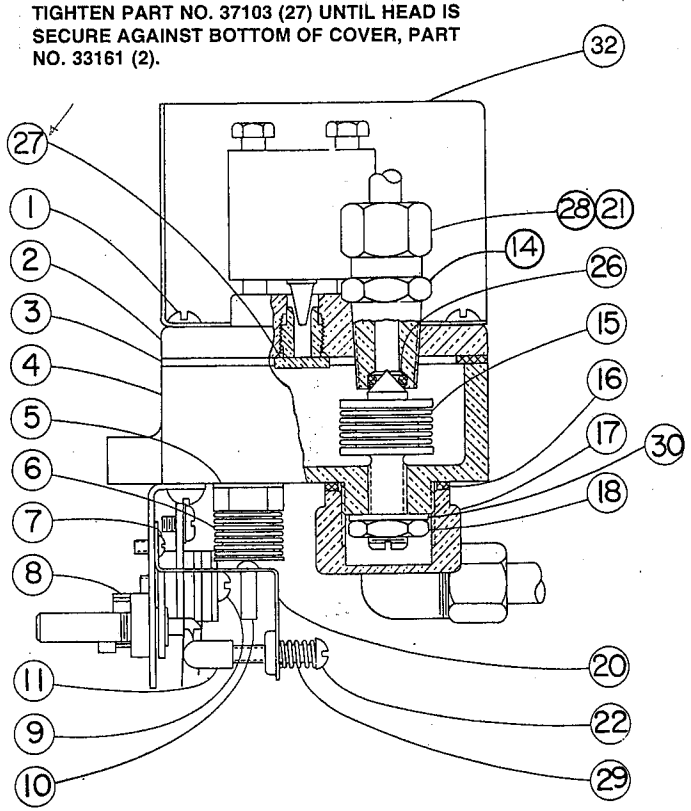
RIGHT SIDE VIEW

BILL OF MATERIAL			
NO.	NAME	PART NO.	RQD.
1	SCREW, #6 SELF TAP.	35544-045	8
2	ELBOW, $\frac{5}{16}$" O.D.T. $\frac{1}{4}$" I.P.S.	7033-091	3
3	PLATE, NAME	27043-091	1
4	NUT, HEX. #10-32	8647-061	1
5	WASHER #10	10863-091	5
6	PIN, HINGE REST	33112-062	1
7	LIGHT, IND. RED 115V. A.C.	24568-091	1
	LIGHT, IND. RED 230VAC	29517-091	1
8	LIGHT, IND. WHT. 115V. A.C.	24571-091	1
	LIGHT, IND. WHT. 230V. A.C.	33696-091	1
9	DOOR ASSEM.	33129-091	1
10	TUBE, VENT $\frac{1}{4}$" O.D.T.	32566-042	1
11	SCREW, FL.HD. #8-32x$\frac{3}{8}$"	4617-041	2
12	SCREW, RD.HD. #8-32x$\frac{1}{4}$"	12534-061	3
13	SCREW, RD.HD. #10-32x$\frac{1}{4}$"	12538-061	2
14	BUTTON, RESET	33145-031	1
15	BUSHING, RESET	33140-051	1
16	CONTROL HOUSING	33164-091	1
17	WIRING DIAGRAM	33282	1
18	TUBE	32711-091	1
19	SCREW-THUMB #8-32	38637-042	2
20	TUBE, CONDENSER	32564-042	1
22	NUT, HALF BRS. $\frac{1}{2}$"-13	33971-091	1
23	BASE	33119-045	1
24	TRAY	33117-044	2
25	LINER ASSEM.	53977-091	1
26	CAP — VENT	47540-091	1
27	WIRING HARNESS NOT SHOWN	53004-091	1
28	LAMP, PILOT	764317-708	Bx. of 10
29	WASHER	33974-091	1

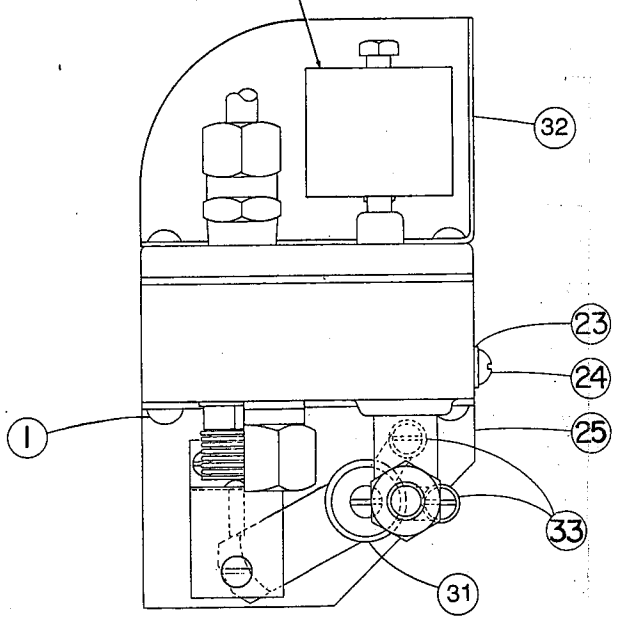
DWG. NO. P-33164-09

NOTE:

TIGHTEN PART NO. 37103 (27) UNTIL HEAD IS SECURE AGAINST BOTTOM OF COVER, PART NO. 33161 (2).



Only Use Safety Valve P-33154-091 In States That Do Not Require ASME Approval



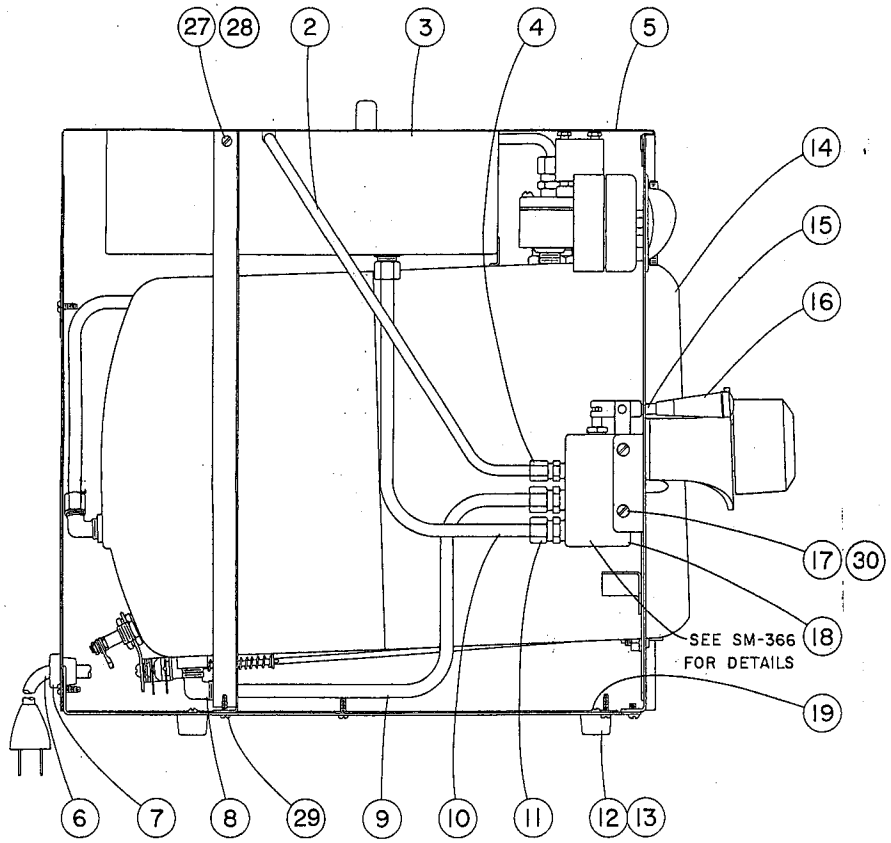
BILL OF MATERIAL

NO.	NAME	PT. NO.	RQD.
1	SCREW, #10-32 x 1/2''	9298-041	6
2	COVER	33161-091	1
3	GASKET /80	33153-091	1
4	HOUSING	33163-091	1
5	GASKET	33150-091	1
6	BELLOWS	33151-091	1
7	SCREW, #4-36x3/16''	3982-041	2
8	THERMOSTAT, TEMP. CONTROL	33149-091	1
9	SCREW	3987-041	1
10	RIVET, 1/8'' DIA.X3/8''	18856-091	1
11	ROD	33228-091	1
12	NOT USED		
13	NOT USED		
14	FITTING, RELIEF	33156-091	1
15	BELLOWS	33158-091	1
16	GASKET	33170-091	1
17	NUT, SEAL	33147-091	1
18	NUT	3045-091	1
19	NOT USED		
20	BRACKET ASSEMBLY	33152-042	1
21	FERRULE	25364-091	1
22	SCREW, #6-32x1/4''	3966-041	1
23	GASKET	33227-091	1
24	SCREW, #8-32x1/4''	3967-041	1
25	BRACKET	33148-061	1
26	"O" RING, TEFLON	33155-091	1
27	SEAT	37103-091	1
28	NUT	30673-091	1
29	SPRING	12461-042	1
30	WASHER	41232-091	1
31	WASHER	30616-091	1
32	GUARD	454196-001	1
33	SCREW	462328-204	2

CONTROL HOUSING ASSEMBLY

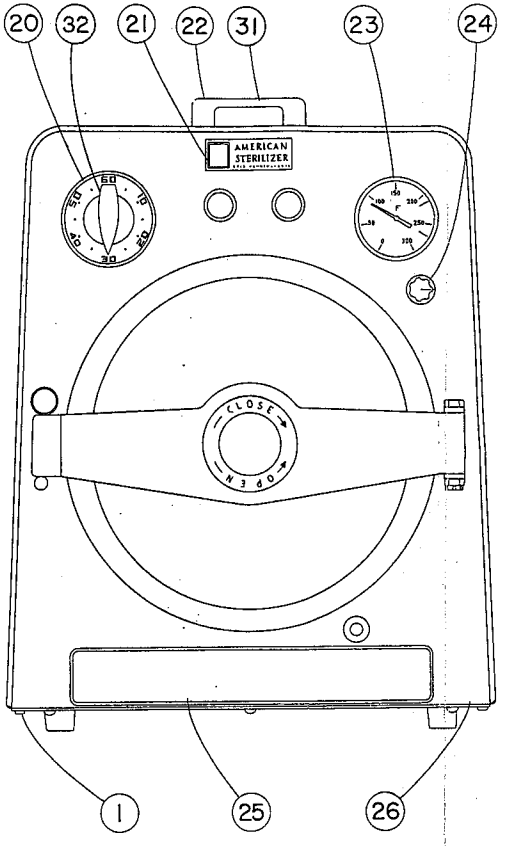
(P-33164-091)

NOVEMBER, 1957 (REV. 3/83)



LEFT SIDE VIEW

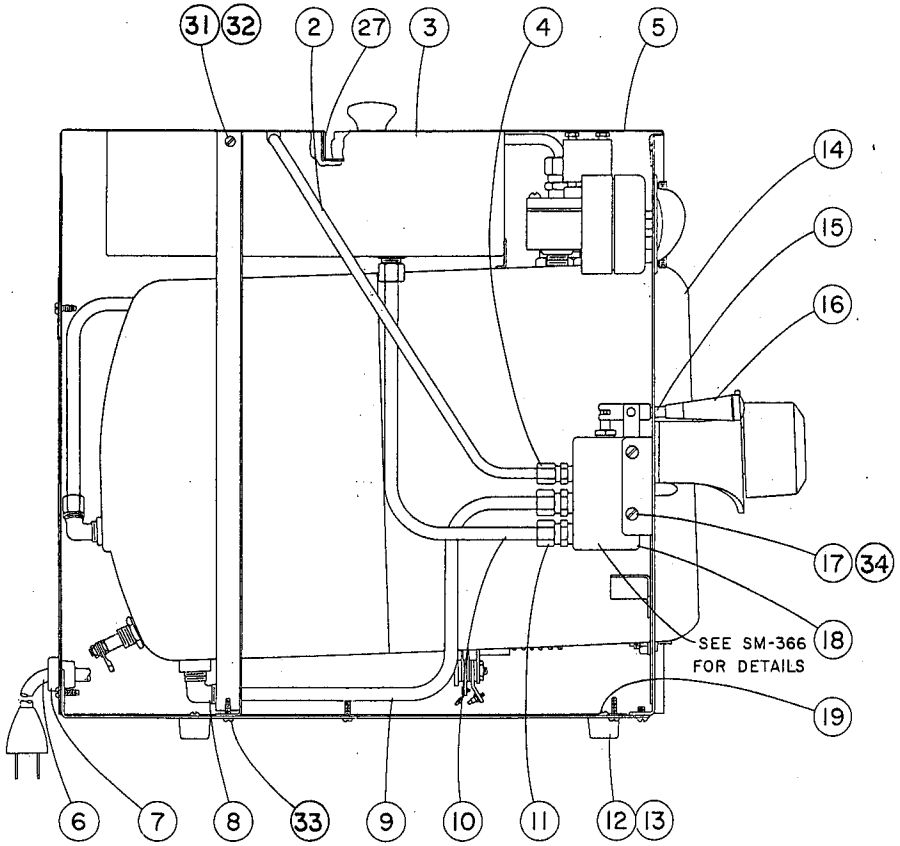
FOR ADDITIONAL DETAILS SEE SM-365



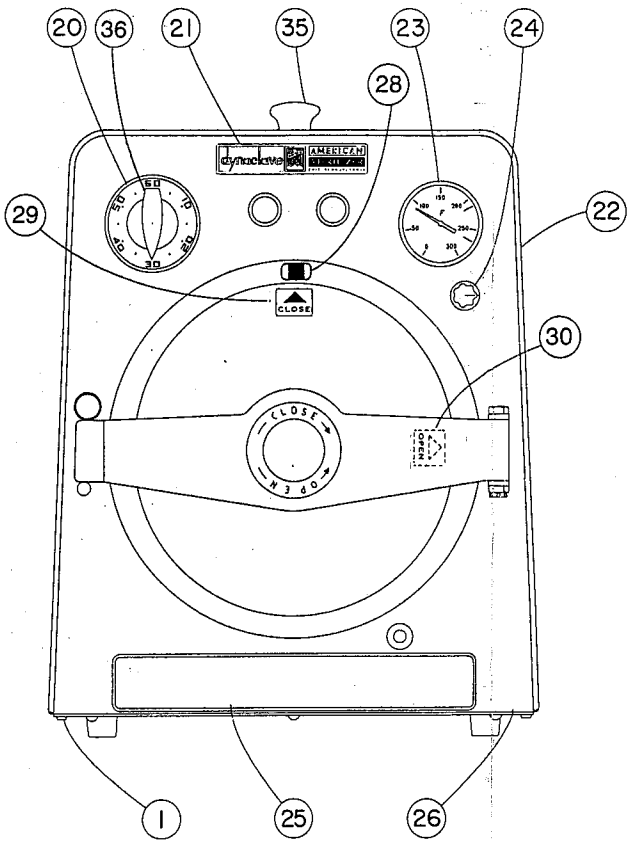
FRONT VIEW

BILL OF MATERIAL

NO.	NAME	PART NO.	RQD.
1	SCREW, #6 SELF TAP	35544-045	8
2	TUBE, COND. 1/4" O.D.T.	32564-042	1
3	WATER PAN	461637-001	1
4	CONN. 1/4" O.D.T. 1/8" I.P.S.	19514-091	1
5	JACKET, FINISHING	33118-091	1
6	CORD, 3W. 115 V. A.C.	56399-004	1
	CORD, 2W. 230 V. A.C.	461641-001	1
	CORD, 3W. 230 V. A.C.	461641-001	1
7	BUSH., 2W. 115 V. A.C. (30622)	NLA	1
	BUSH., 3W. 115 V. A.C.	30627-091	1
	BUSH., 2 W. 3 W. 230 V. A.C.	30636-091	1
8	ELBOW, 5/16" O.D.T. 1/4" I.P.S.	7033-091	1
9	TUBE, FILL 5/16" O.D.T.	32699-091	1
10	TUBE, RES'R 5/16" O.D.T.	32687-091	1
11	CONN. 5/16" O.D.T. 1/4" I.P.S.	22711-042	2
12	BUMPER, RUBBER	33168-091	4
13	NUT, HEX. #8-32	8645-061	10
14	SHELL	33110-061	1
15	STUD, HANDLE	33183-051	1
16	HANDLE, VALVE	33136-091	1
17	SCREW, #10-32 x 1/4" LG.	12538-061	2
18	VALVE, OPERATING	33245-091	1
19	SCREW, #8-32 x 1/2" LG.	3986-041	5
20	TIMER	33115-091	1
21	PLATE, NAME	43540-091	1
22	COVER ASSEMBLY	33428-091	1
23	THERMOMETER	13638-091	1
24	KNOB, CONTROL	33113-091	1
	OPR. INST. METAL CAL (33111)	NLA	1
26	PANEL, FRONT	33493-A	1
27	SCREW, RD. HD.,	13334-091	2
28	NUT, HEX	13794-041	2
29	SCREW, RD. HD.	4672-041	2
30	WASHER	10863-091	5
31	HANDLE ONLY	33137-091	1
32	KNOB, Timer	44654-091	1



LEFT SIDE VIEW



FRONT VIEW

FOR ADDITIONAL DETAILS SEE SM-381

FOR UNITS SHIPPED BEFORE 1/75

NOVEMBER, 1961

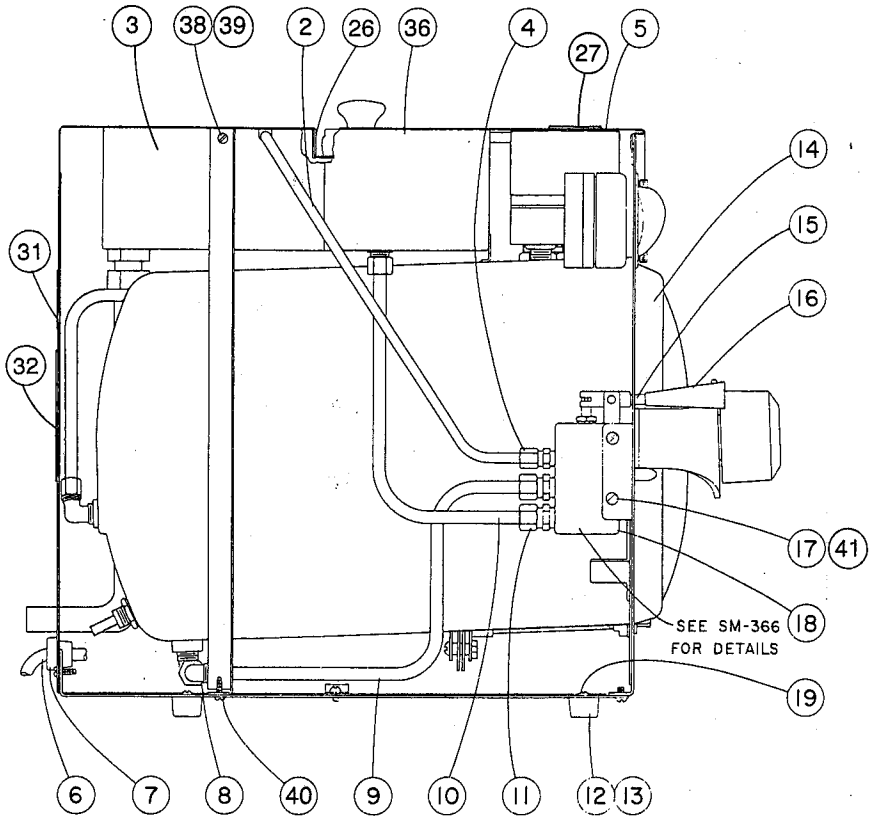
31	SCREW, RD. HD.	13334-091	2
32	NUT, HEX	13794-041	2
33	SCREW, RD. HD.	4672-041	2
34	WASHER	10863-091	5
35	KNOB ONLY	14918-091	1
36	KNOB, Timer	44654-091	1

BILL OF MATERIAL

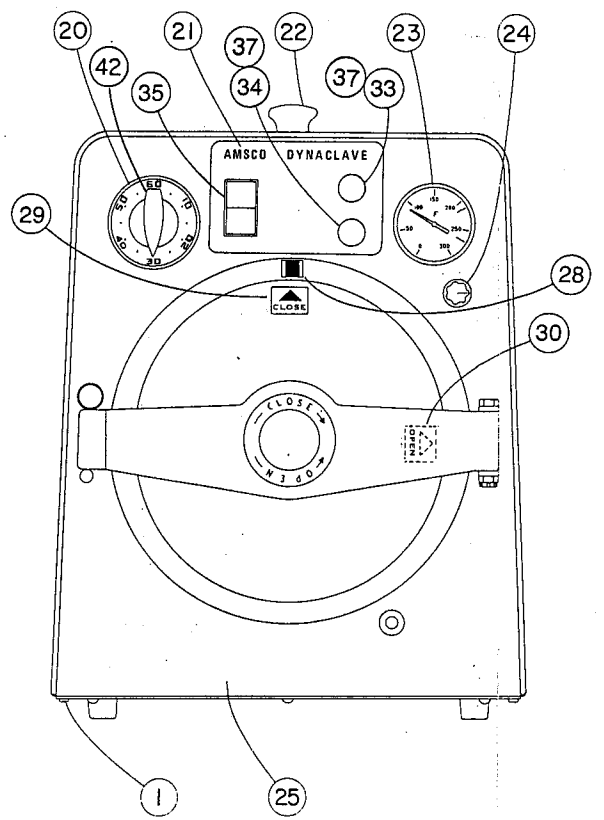
NO.	NAME	PART NO.	RQD.
1	SCREW, #6 SELF TAP.	35544-045	8
2	TUBE, COND. $\frac{1}{4}$" O.D.T.	32564-042	1
3	WATER PAN	461637-001	1
4	CONN. $\frac{1}{4}$" O.D.T. $\frac{1}{8}$" I.P.S.	19514-091	1
5	JACKET, FINISHING	33118-091	1
6			
	CORD, 3W. 115 V. A.C.	56399-004	1
	CORD, 2W. 230V. A.C.	461641-001	1
	CORD, 3W. 230V. A.C.	461641-001	1
7	BUSH, 2W. 115 V. A.C. (30622)	NLA	1
	BUSH, 3W. 115 V. A.C.	30627-091	1
	BUSH, 2 W. 3 W. 230 V. A.C.	30636-091	1
8	ELBOW, $\frac{5}{16}$" O.D.T. $\frac{1}{4}$" I.P.S.	7033-091	3
9	TUBE, FILL $\frac{5}{16}$" O.D.T.	32699-091	1
10	TUBE, RES'R $\frac{5}{16}$" O.D.T.	32687-091	1
11	CONN. $\frac{5}{16}$" O.D.T. $\frac{1}{4}$" I.P.S.	22711-042	2
12	BUMPER, RUBBER	33168-091	4
13	NUT, HEX. #8-32	8645-061	10
14	SHELL	33110-061	1
15	STUD, HANDLE	33183-051	1
16	HANDLE, VALVE	33136-091	1
17	SCREW, #10-32 x $\frac{1}{4}$" LG.	12538-061	4
18	VALVE, OPERATING	33245-091	1
19	SCREW, #8-32 x $\frac{1}{2}$" LG.	3986-041	5
20	TIMER	33115-091	1
21	PLATE, NAME	43540-091	1
22	COVER ASSEMBLY	33428-091	1
23	THERMOMETER	13638-091	1
24	KNOB, CONTROL	33113-091	1
25	OPR. INST. METAL CAL. (33111)	NLA	1
26	PANEL, FRONT	33493-A	1
27	PLATE, INST.	40773	1
28	PLATE, DOOR AREA	35662-091	1
29	"CLOSE" INDICATOR, ALIGNMENT	35663-091	1
30	"OPEN" INDICATOR, ALIGNMENT	35717-091	1

(REV. 7/85)

SM-380



LEFT SIDE VIEW



FRONT VIEW

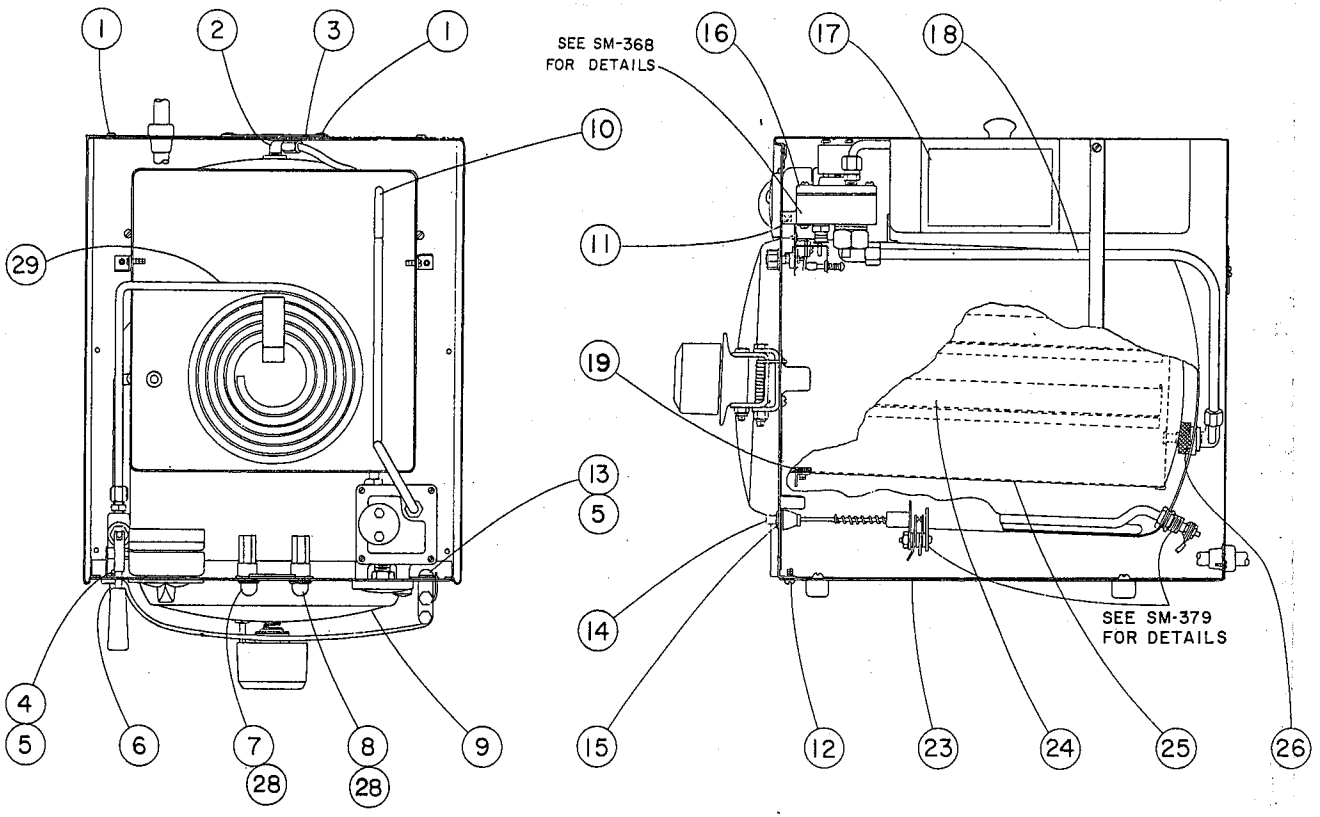
FOR ADDITIONAL DETAILS SEE SM-381A

FOR UNITS SHIPPED AFTER 1/75

BILL OF MATERIAL

NO.	NAME	PART NO.	RQD.
1	Screw, #6 Self Tap.	35544-045	8
2	Tube, Cond. 1/4" O.D.T.	32563-001	1
3	Water Pan Assy.	461637-001	1
4	Conn. 1/4" O.D.T. 1/8" I.P.S.	19514-091	1
5	Jacket, Finishing	33118-091	1
6	Cord, Assy., 15A, 120V	461640-001	1
	Cord, Assy., 15A, 250V	461641-001	1
7	Bushing, Strain Relief	30627-091	1
8	Elbow, 5/16" O.D.T. 1/4" I.P.S.	7033-091	3
9	Tube, Fill. 5/16" O.D.T.	32699-091	1
10	Tube, Res'r. 5/16" O.D.T.	32687	1
11	Conn. 5/16" O.D.T. 1/4" I.P.S.	22711-042	2
12	Bumper, Rubber	33168-091	4
13	Nut, Hex. #8-32	8645-061	10
14	Shell	33110-061	1
15	Stud, Handle	33183-051	1
16	Handle, Valve	33136-091	1
17	Screw, #10-32 x 1/4" Lg.	12538-061	4
18	Valve, Operating	33245-091	1
19	Screw, #8-32 x 1/2" Lg.	3986-041	5
20	Timer	33115-091	1
21	Control Plate	461644-001	1
22	Cover	33428-091	1
23	Thermometer	13638-091	1
24	Knob, Control	33113-091	1
25	Panel, Front	461643-001	1
26	Plate, Inst.	40773	1
27	Decal, Operating Instruction	461645-001	1
28	Plate, Door Area	35662-091	1
29	"Close" Indicator, Alignment	35663-091	1
30	"Open" Indicator, Alignment	35717-091	1
31	Date Plate, 120V	454086	1
	Data Plate, 230V	454024	1
32	Decal, Caution	150369-001	1
33	Light Indicator, White (120V)	41084-091	1
	Light Indicator, White (230V)	33696-091	1
34	Light Indicator, Red (120V)	41083-091	1
	Light Indicator, Red (230V)	455050-001	1
35	Switch	89078-091	1
36	Decal, Wiring Diagram	461639-001	1
37	Lamp, Pilot (Not Shown)	764317-708	Bx of 10
38	Screw, Rd. Hd.	13334-091	2
39	Nut, Hex	13794-041	2
40	Screw, Rd. Hd.	4672-041	2
41	Washer	10863-091	5
42	KNOB, Timer	44654-091	1

(REV. 7/85)



TOP VIEW

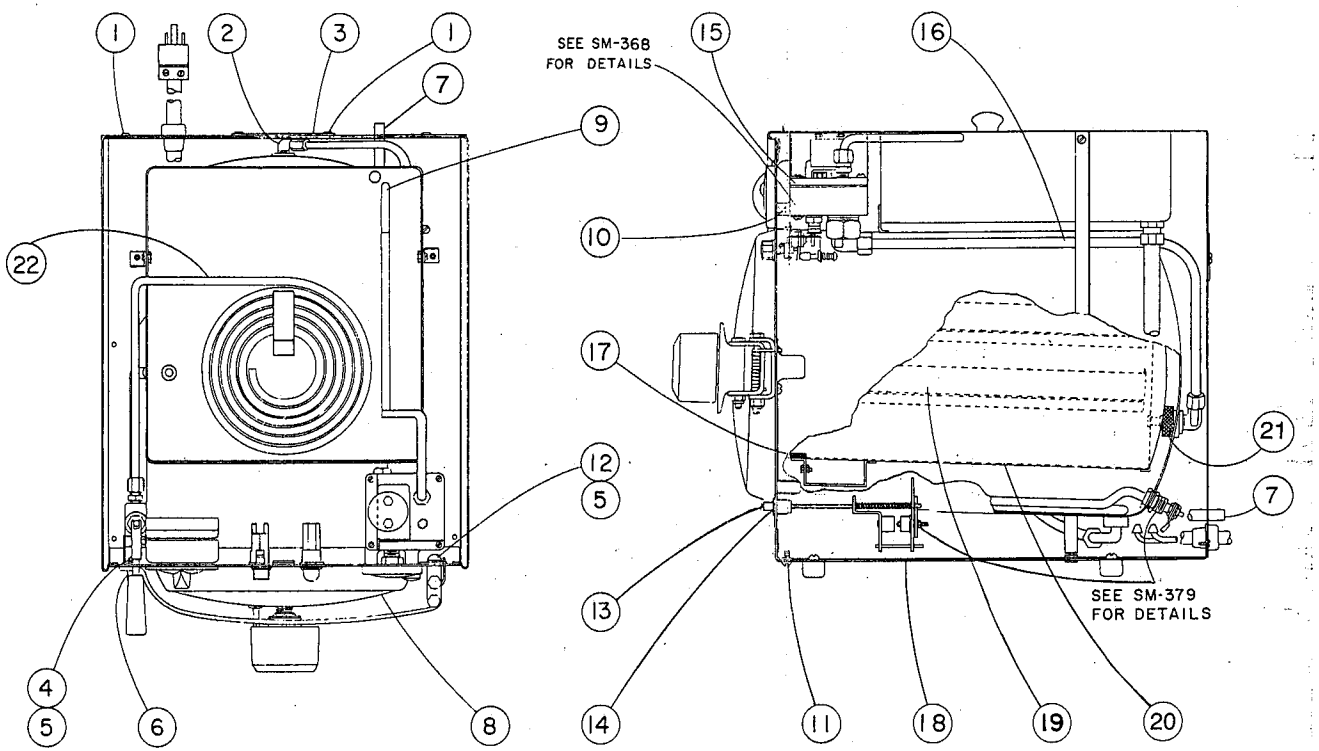
FOR ADDITIONAL DETAILS SEE SM-380

RIGHT SIDE VIEW

BILL OF MATERIAL			
NO.	NAME	PART NO.	RQD.
1	SCREW, #6 SELF TAP.	10695	8
2	ELBOW, $\frac{5}{16}$" O.D.T. $\frac{1}{4}$" I.P.S.	7033-091	3
3	PLATE, NAME	27043-091	1
4	NUT, HEX. #10-32	8647-061	1
5	WASHER #10	10863-091	5
6	PIN, HINGE REST	33112-062	1
7	LIGHT, IND. RED 115V. A.C.	24568-091	1
	LIGHT, IND. RED 230VAC	29517-091	1
8	LIGHT, IND. WHT. 115V. A.C.	24571-091	1
	LIGHT, IND. WHT. 230V. A.C.	33696-091	1
9	DOOR ASSEM.	33129-091	1
10	TUBE, VENT $\frac{1}{4}$" O.D.T.	32566-042	1
11	SCREW, FL.HD. #8-32x$\frac{3}{8}$"	4617-041	2
12	SCREW, RD.HD. #8-32x$\frac{1}{4}$"	12534-061	3
13	SCREW, RD.HD. #10-32x$\frac{1}{4}$"	12538-061	2
14	BUTTON, RESET	33145-031	1
15	BUSHING, RESET	33140-051	1
16	CONTROL HOUSING	33164-091	1
17	WIRING DIAGRAM	33282	1
18	TUBE	32711-091	1
19	SCREW-THUMB #8-32	38637-042	2
20			
21			
22			
23	BASE	33119-045	1
24	TRAY	33117-044	2
25	LINER ASSEM.	53977-091	1
26	CAP — VENT	47540-091	1
27	WIRING HARNESS NOT SHOWN	53004-091	1
28	LAMP, PILOT NOT SHOWN	764317-708	Bx. of 10
29	TUBE, CONDENSER	32563-042	1

FOR UNITS SHIPPED BEFORE 1/75

NOVEMBER, 1971 (REV. 3/83)



TOP VIEW

FOR ADDITIONAL DETAILS SEE SM-380-A

RIGHT SIDE VIEW

BILL OF MATERIAL

NO.	NAME	PART NO.	RQD.
1	Screw, #6 Self Tap.	35544-045	8
2	Elbow, 5/16'' O.D.T. 1/4'' I.P.S.	7033-091	3
3	Plate, Name	27043-091	1
4	Nut, Hex. #10-32	8647-061	1
5	Washer #10	10863-091	5
6	Pin, Hinge Rest	33112-062	1
7	Tube, Overflow	454198-001	1
8	Door Assem.	33129-091	1
9	Tube, Vent 1/4'' O.D.T.	461638-001	1
10	Screw, Fl. Hd. #8-32 x 3/8''	4617-041	2
11	Screw, RD. HD. #8-32 x 1/4''	12534-061	3
12	Screw, RD. HD. #10-32 x 1/4''	12538-061	2
13	Button, Reset	33145-031	1
14	Bushing, Reset	33140-051	1
15	Control Housing	33164-091	1
16	Tube	32711-091	1
17	Screw-Thumb #8-32	38637-042	2
18	Base	33119-045	1
19	Tray	33117-044	2
20	Liner Assem.	53977-091	1
21	Cap — Vent	47540-091	1
	Wiring Harness (Not Shown)	462326-001	1
22	Tube, Condenser	32563-042	1

FOR UNITS SHIPPED AFTER 1/75

Your Sterilizer Experts

Manufacturing – Distribution – Maintenance- Guaranteed!

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Hempstead, NY 11550

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516-489-9364 fax
Web site www.sterilizers.com

Email info@sterilizers.com

To whom it may concern:
Subject: FDA 510K approval for sterilizers manufactured prior to May 28th, 1976

1. There is no need for 510K FDA approvals for "Amsco Autoclaves". This is because according to the FDA rulings, these sterilizers were manufactured and commercially distributed before May 28, 1976 and didn't require Pre Market Approvals.

2. The FDA clause regarding this can be found in **Subpart E- Premarket Notification Procedures Section 807.85 Exemption from pre market notification in Section 1**

3. One of the ways to prove that the sterilizer was manufactured and distributed before May 28th, 1976, is to show catalog pages, promotional material with dates prior to May 28th, 1976

4. Attached you will find two documents:
   a. The FDA documentation explaining that point 2.
   b. Catalog of this sterilizer with dates prior to May 28th, 1976

Please call if you have a need for further help,

Alfa Medical
Customer Service.

from the use of a device; for example, a hearing aid dispenser, optician, clinical laboratory, assembler of diagnostic x-ray systems, and personnel from a hospital, clinic, dental laboratory, orthotic or prosthetic retail facility, whose primary responsibility to the ultimate consumer is to dispense or provide a service through the use of a previously manufactured device.

[42 FR 42526, Aug. 23, 1977, as amended at 58 FR 46523, Sept. 1, 1993; 61 FR 44615, Aug. 28, 1996; 65 FR 17136, Mar. 31, 2000]

Subpart E—Premarket Notification Procedures

§ 807.81 When a premarket notification submission is required.

(a) Except as provided in paragraph (b) of this section, each person who is required to register his establishment pursuant to § 807.20 must submit a premarket notification submission to the Food and Drug Administration at least 90 days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use which meets any of the following criteria:

(1) The device is being introduced into commercial distribution for the first time; that is, the device is not of the same type as, or is not substantially equivalent to, (i) a device in commercial distribution before May 28, 1976, or (ii) a device introduced for commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II.

(2) The device is being introduced into commercial distribution for the first time by a person required to register, whether or not the device meets the criteria in paragraph (a)(1) of this section.

(3) The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification:

(i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.

(ii) A major change or modification in the intended use of the device.

(b) A premarket notification under this subpart is not required for a device for which a premarket approval application under section 515 of the act, or for which a petition to reclassify under section 513(f)(2) of the act, is pending before the Food and Drug Administration.

(c) In addition to complying with the requirements of this part, owners or operators of device establishments that manufacture radiation-emitting electronic products, as defined in § 1000.3 of this chapter, shall comply with the reporting requirements of part 1002 of this chapter.

§ 807.85 Exemption from premarket notification.

(a) A device is exempt from the premarket notification requirements of this subpart if the device intended for introduction into commercial distribution is not generally available in finished form for purchase and is not offered through labeling or advertising by the manufacturer, importer, or distributor thereof for commercial distribution, and the device meets one of the following conditions:

(1) It is intended for use by a patient named in the order of the physician or dentist (or other specially qualified person); or

(2) It is intended solely for use by a physician or dentist (or other specially qualified person) and is not generally available to, or generally used by, other physicians or dentists (or other specially qualified persons).

(b) A distributor who places a device into commercial distribution for the first time under his own name and a repackager who places his own name on a device and does not change any other labeling or otherwise affect the device shall be exempted from the premarket notification requirements of this subpart if:

(1) The device was in commercial distribution before May 28, 1976; or

(2) A premarket notification submission was filed by another person.

§ 807.87 Information required in a premarket notification submission.

Each premarket notification submission shall contain the following information:

(a) The device name, including both the trade or proprietary name and the common or usual name or classification name of the device.

(b) The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission.

(c) The class in which the device has been put under section 513 of the act and, if known, its appropriate panel; or, if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for the person's determination that the device is not so classified.

(d) Action taken by the person required to register to comply with the requirements of the act under section 514 for performance standards.

(e) Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied.

(f) A statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement. This information may include an identification of similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.

(g) Where a person required to register intends to introduce into commercial distribution a device that has undergone a significant change or modification that could significantly affect the safety or effectiveness of the device, or the device is to be marketed for a new or different indication for use, the premarket notification submission must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have the safety and effectiveness of the d vice.

(h) A 510(k) summary as described § 807.92 or a 510(k) statement as d scribed in § 807.93.

(i) A financial certification or disc sure statement or both, as required part 54 of this chapter.

(j) For submissions claiming substa tial equivalence to a device which h been classified into class III under se tion 513(b) of the act:

(1) Which was introduced or deliver for introduction into interstate co merce for commercial distribution b fore December 1, 1990; and

(2) For which no final regulation r quiring premarket approval has be issued under section 515(b) of the act, summary of the types of safety and e fectiveness problems associated wi the type of devices being compared a a citation to the information up which the summary is based (class I summary). The 510(k) submitter sha also certify that a reasonable search all information known or otherwi available about the class III device a other similar legally marketed devic has been conducted (class III certif cation), as described in § 807.94. This i formation does not refer to informa tion that already has been submitte to the Food and Drug Administratio (FDA) under section 519 of the ac FDA may require the submission of th adverse safety and effectiveness dat described in the class III summary d citation.

(k) A statement that the submitte believes, to the best of his or he knowledge, that all data and informa tion submitted in the premarket notifi cation are truthful and accurate an that no material fact has been omitted

(l) Any additional information re garding the device requested by th Commissioner that is necessary for th Commissioner to make a finding as t whether or not the device is substan tially equivalent to a device in com mercial distribution. A request for ad ditional information will advise th owner or operator that there is insuffi cient information contained in th original premarket notification sub mission for the Commissioner to make this determination and that the owne