



Your Sterilizer Experts

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Market Forge Sterilmatic Manual

STM-E & STM-EL



The attached manual is for your records.
Go to the below web site to look for parts
<http://bit.ly/market-forge-sterilmatic-parts>

SECTION 1 INSTALLATION INSTRUCTIONS

AUTOMATIC STERILMATIC STEAM PRESSURE STERILIZER

INSTALLATION

Set sterilizer on counter, using the 4" (102mm) legs provided or assemble the an optional stainless steel stand with under-shelf. If your Sterilmatic includes a water-cooled exhaust condenser, we recommend the use of the Sterilmatic stand, part number [MZZ100704](#). First, level unit in place, then adjust front legs to pitch the unit forward 1/4" (6mm) to insure positive drainage of the cylinder.

ELECTRICAL

Connect to proper electrical supply box and disconnect switch as shown on one of the following schematic diagrams-208 or 240 volts, single or three phase. Connection is located behind the terminal box cover at the lower left side of unit. Whether the supply current is 208 volt or 240 volt, single or three phase, all control circuits are 120 volts. In order to accomplish this connection, a current-carrying grounded neutral must be provided. Thus, a three phase system must be 4-wires and a single phase system must be 3-wires. If a current-carrying grounded neutral is not available from the power source, a separate 120 volt circuit must be run. Most electrical codes require, and we recommend, that a separate disconnect switch be located within sight of the sterilizer. When separate 120 volt control circuit must be run, this must also be part of the disconnect box assembly.

OUTSIDE VENTING

Connect 1/2" (13mm) nominal tubing exhaust to outside vent connection located on the top of the control housing. **IMPORTANT:** Exhaust line must be vented to the outside to eliminate the exhausted steam and the accompanying noise from entering the room. Use 1/2" (13mm) copper tubing or suitable alternate. Length of the line should not exceed 15 feet (4.5 meters) and should have a minimum of bends. The line should slope downward after leaving the sterilizer in order to insure condensate drainage.

WATER-COOLED EXHAUST CONDENSER

If outside venting is not possible, an optional water-cooled condenser is available for connection to an open drain. If required order part number [MZZ100705 Kit](#)

RECORDING THERMOMETER

If a recording thermometer is provided, refer to installation guide provided with recorder.

SECTION 1 INSTALLATION INSTRUCTIONS

TRAY SUPPORTS

Install side tray supports. Tray supports are attached by means of key-hole clearance slots which are slipped over studs located on the sides of the Sterilmatic chamber.

BAFFLE INSTALLATION

To insure maximum drying of packs, a baffle is supplied with your STM-E Sterilmatic. Place perforated splash baffle in bottom of the sterilizing chamber. Install small baffle with no perforation at the rear of the upper tray support channel.

OPERATION CHECK

To check for proper operation of unit:

1. Close drain valve by turning handle clockwise.

WARNING:

**DO NOT OPEN DRAIN VALVE WHILE UNIT IS OPERATING. PREMATURE OPENING
MAY RESULT IN SCALDING OF OPERATOR.**

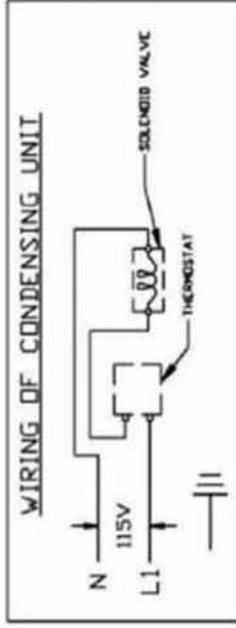
2. Fill chamber with 4 to 6 quarts (3.7 to 5.6 liters) of ordinary tap water. DO NOT USE DISTILLED OR DIONIZED WATER.
3. Close chamber door.
4. Set exhaust selector to INSTRUMENTS AND PACKS (fast exhaust) or LIQUIDS (slow exhaust).
5. Set timer to 15 minutes. Cycle will go to completion automatically.

NOTE: Cycle timer will not start until sterilizing temperature is obtained.

ITEM	PART #	DESCRIPTION	QTY
5	M100224	COPPER TUBING, 3/8 O.D.	22 1/4"
6	M100225	RD HD MACH SCREW, 1/4-20	2
7	M100226	LOCKWASHER, 1/4	2
8	M100227	HEX NUT, 1/4-20	2
9	M100228	RD HD MACH SCREW, 10-32	2
10	M100229	LOCKWASHER, 10	2
11	M100230	HEX NUT, 10-32	2
12	M100231	FRONT TEMPLATE (7" LONG)	1
13	M100232	BACK TEMPLATE (11" LONG)	1

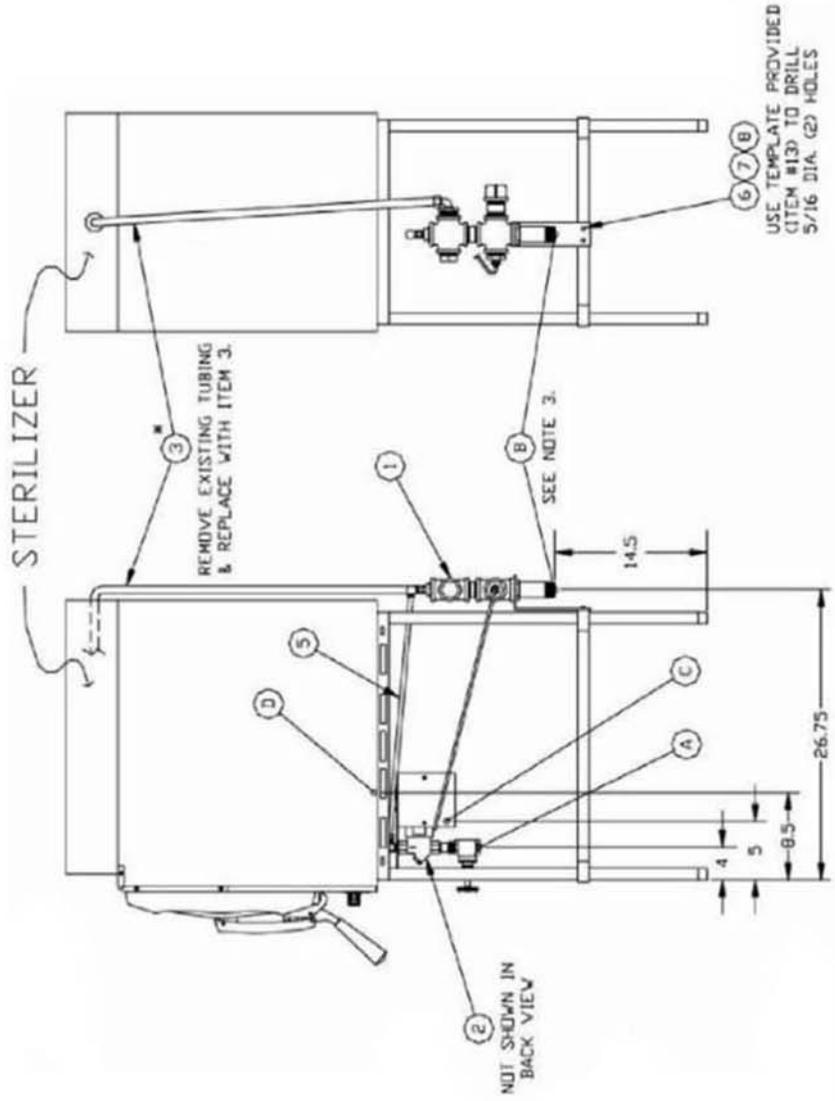
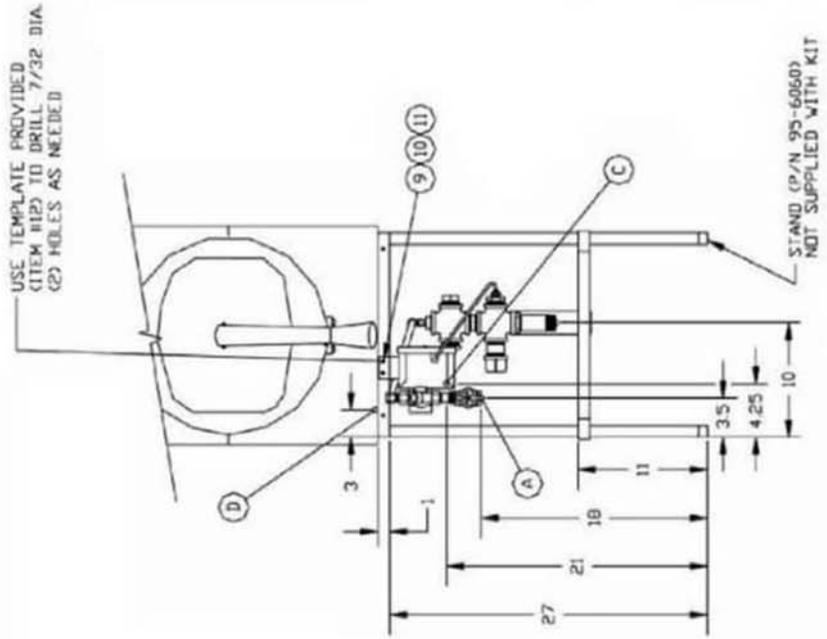
SERVICE CONNECTIONS REQUIRED	
A	1/2" I.P.S. COLD WATER CONNECTION
B	1" I.P.S. DRAIN CONNECTION (SEE NOTE 3.)
C	115V ELEC. CONN. - 7/8 DIA. KNOCKOUT (COND. UNIT)
D	ELECTRICAL CONNECTION

- NOTES:
- UNIT MUST BE GROUNDED AND ALL WIRING TO COMPLY WITH LOCAL CODES.
 - PIPE TO OPEN DRAIN, DO NOT MAKE SOLID CONNECTION TO SEWER.
 - CONDENSING UNIT TO BE INSTALLED AS TO HAVE A BACK TO FRONT PITCH.



NOM. AMPS PER WIRE	STERILIZER	
PHASE	3 PHASE	1 PHASE
VOLTS	208	208
AMPS	34	53

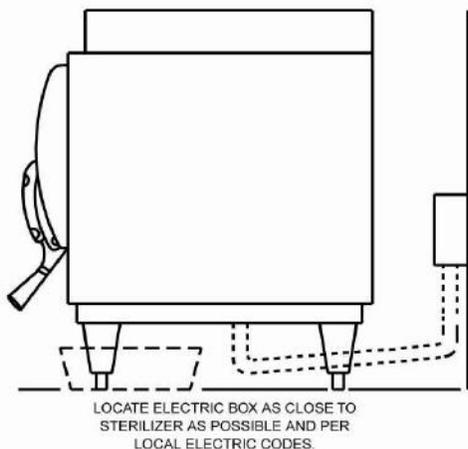
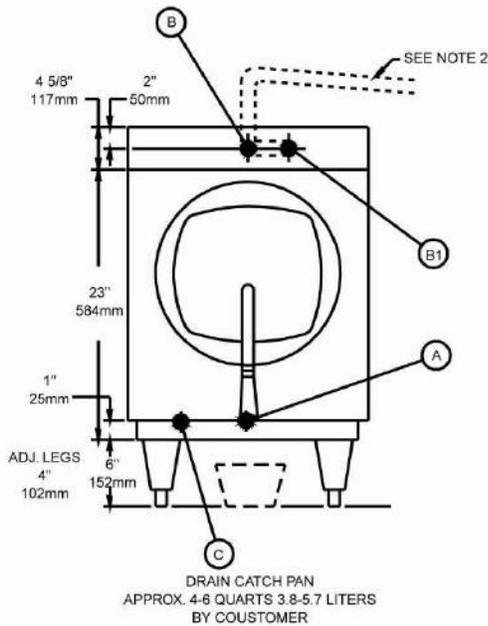
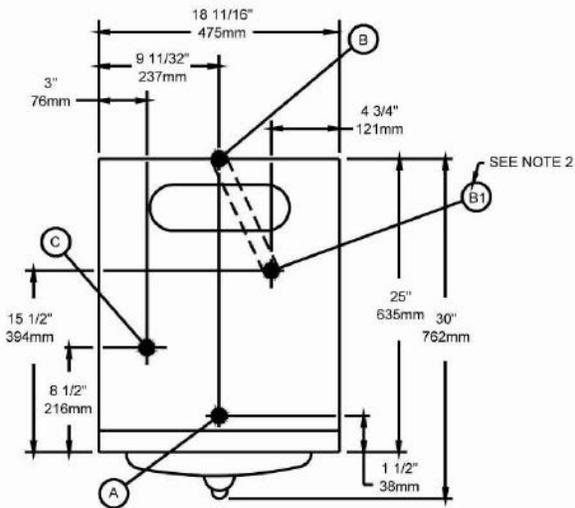
NOM. AMPS PER WIRE	STEAM-IT	
PHASE	3 PHASE	1 PHASE
VOLTS	208	240
AMPS	25	16



INSTALLATION INSTRUCTIONS - COLD WATER CONDENSER

PART NO. [MZZ100705](#)

SECTION 1 INSTALLATION INSTRUCTIONS



REQUIRED CONNECTIONS

A	Drain - 1/2" 13mm FPT of 5/8" 16mm O.D. Copper (See Note No. 1)														
B	Steam Exhaust Connection - 3/8" 10mm I.P.S. (See Note No. 2)														
C	Electrical Connection - (See Note No. 3)														
<p>Nominal amps per wire:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">3 Phase</td> <td style="width: 50%;">4 Wire</td> </tr> <tr> <td>208V</td> <td>240V</td> </tr> <tr> <td>26</td> <td>30</td> </tr> <tr> <td colspan="2"> </td> </tr> <tr> <td>1 Phase</td> <td>3 Wire</td> </tr> <tr> <td>208V</td> <td>240V</td> </tr> <tr> <td>44</td> <td>50</td> </tr> </table> <p style="text-align: center;">208 V (197-219) or 240 V (220-240)</p>		3 Phase	4 Wire	208V	240V	26	30			1 Phase	3 Wire	208V	240V	44	50
3 Phase	4 Wire														
208V	240V														
26	30														
1 Phase	3 Wire														
208V	240V														
44	50														

UNIT MUST BE GROUNDED

NOTES:

1. An air break must be provided if a unit drain line is run.
2. Vent exhaust to atmosphere (1/2 nominal line 15 feet 4.6 meters long maximum with minimum of bends.) B1 is actual connection, but must exit casing at B. Slope exhaust away from unit to avoid condensate re-entering.
3. The timer and exhaust solenoid valve are on 120V while the heaters run on 230V or 208V. Thus, if a neutral to the power circuit is not available, a separate 120V line must be run or a transformer provided where local codes prohibit separate electrical sources.

* When an exhaust condenser is supplied; the following services must be provided: 1/2" 13mm I.P.S. cold water: 1" 25mm I.P.S. waste.

* When recording thermometer is supplied; mount recorder on a solid wall within 4 feet 1.2meters of sterilizer and make electrical connection to unit junction box of 120V, 1 Phase, 60 Cycle.

SECTION 1 INSTALLATION INSTRUCTIONS

INSTRUCTIONS FOR INSTALLING PAN SUPPORTS AND BAFFLES

1. Locate the mounting studs on the inside of the chamber. There are two rack mounting studs on each side.
2. Taking one pan support and positioning rack so that the pan stop is facing the rear of the unit and the wires are facing toward the center of the unit. The pan stop is a piece of sheet metal welded to the rack with a 65° bend.
3. Begin to hang the pan support by placing the rear key-way slot onto the rear mounting stud and slide the rack until the slot sits on the mounting stud. When this is done correctly the front mounting stud will be in position to place the front key-way slot. Slide the rack down into its correct position. See Fig. 1.

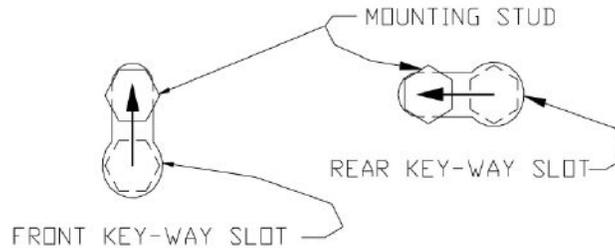


Fig. 1.

4. After installing one pan support rack correctly, you can install the baffle. Position the baffle so that the 45° bend is facing up and towards the front of the unit. Slide the mounting tab onto the flat bend on the pan stop bracket. The baffle should now stay in place by itself, but in a tilted state. See Fig. 2.

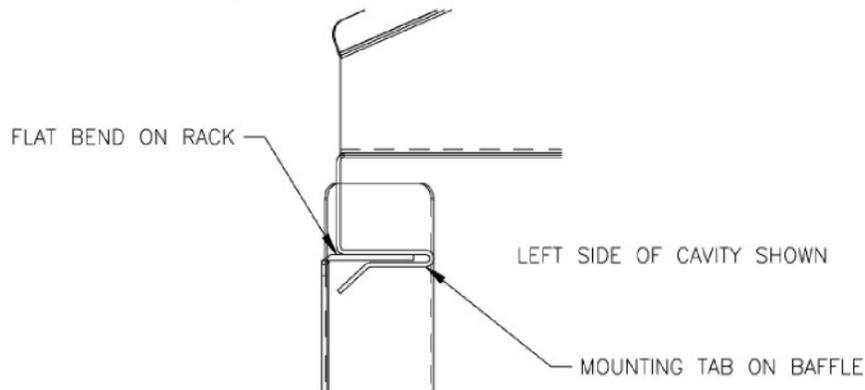


Fig. 2.

5. Position the second pan support rack into the cavity and slide the other mounting tab onto the rack flat bend while the pan support rack is not on the mounting studs. Hang the pan support by placing the rear key-way slot support onto the rear mounting stud and slide the rack until the slot sits on the mounting stud. When this is done correctly the front mounting stud will be in position to place the front key-way slot. Slide the rack down into its correct position. See Fig. 3.

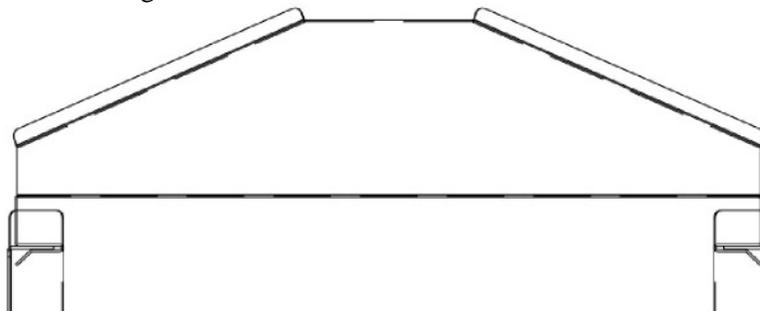


Fig. 3.

SECTION 1 INSTALLATION INSTRUCTIONS

THE ELECTRIC SUPPLY CONNECTIONS FOR STM-E AND STM-EL

Connect to proper electrical supply as indicated on nameplate on top of unit. Connection is located behind the terminal box cover at the lower left side of unit. Whether the supply current is 208 or 240 volt, single phase or three phase, all control circuits are 120 volts. In order to accomplish this, a current-carrying grounded neutral must be provided.

Thus, a three phase system must be 4-wires and a single phase system must be 3-wires. If a current-carrying grounded neutral is not available from the power source, a separate 120 volt circuit must be run. Most electrical codes require, and we recommend, that a separate disconnect switch be located within sight of the sterilizer. When a separate 120 volt control circuit must be run, this must also be part of the disconnect box assembly.

THE ELECTRIC SUPPLY CONNECTIONS FOR STM-EX AND STM-ELX EXPORT

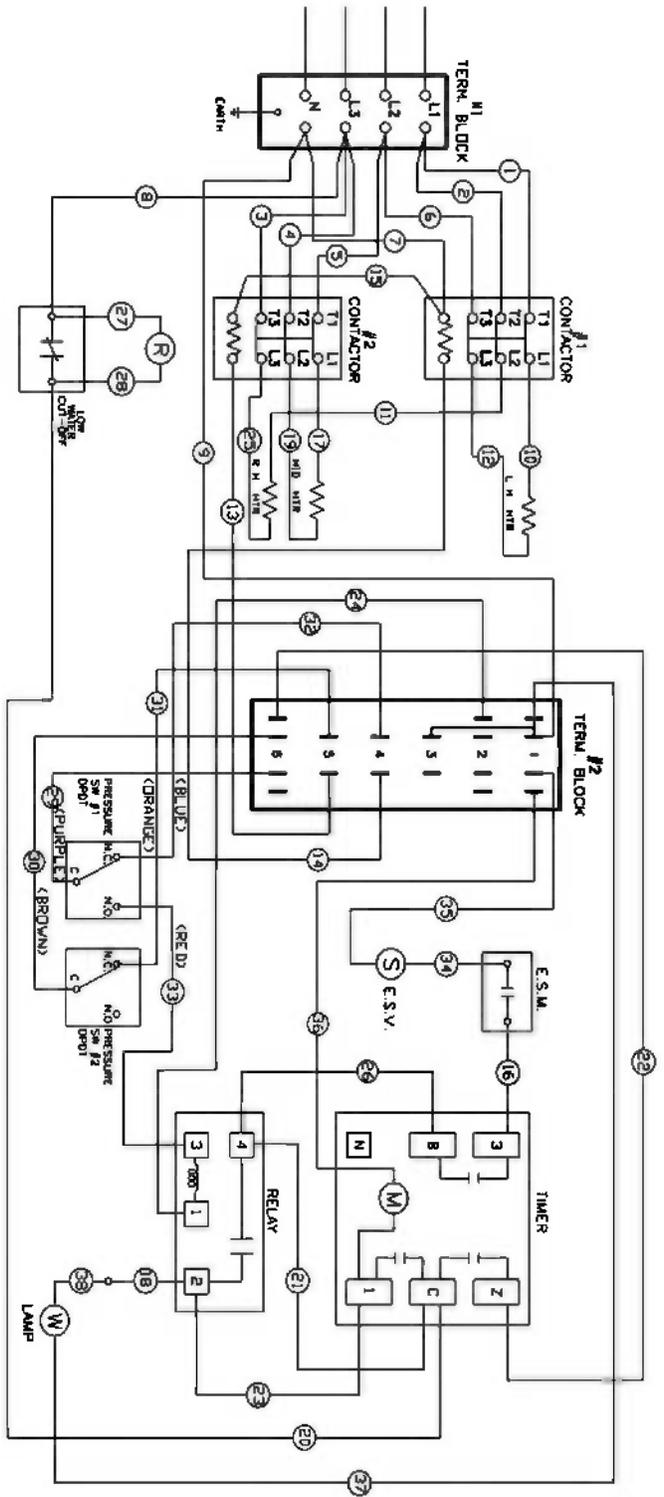
Connect to proper electrical supply as indicated on nameplate on top of unit. Connection is located behind the terminal box cover at the lower left side of the unit. All control circuits are 220 volts.

In order to accomplish this, a current-carrying grounded neutral must be provided.

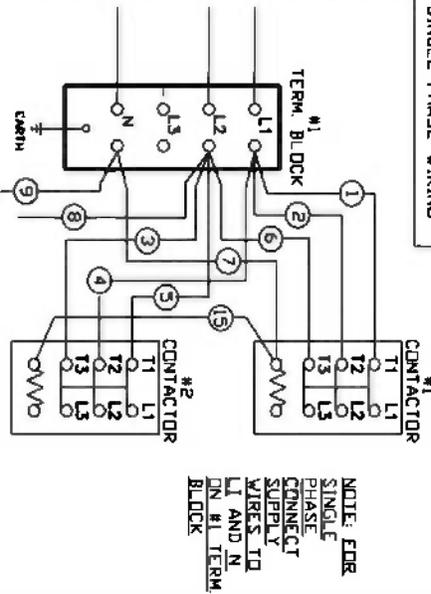
Thus, a three phase system must be 4-wires. Most electrical codes require, and we recommend, that a separate switch be located within sight of the sterilizer.

SECTION 1 INSTALLATION INSTRUCTIONS

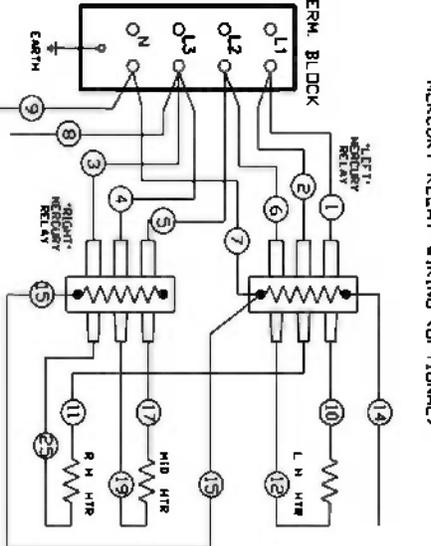
STM-E & STM-EL STERILIZER 208 Volt - 240 Volt / 120 Volt 3Ø - 4 Wire



SINGLE PHASE WIRING



MERCURY RELAY WIRING (OPTIONAL)



E.S.V. = EXHAUST SOLENOID VALVE SELECTOR MANUAL SWITCH

NOTE SEE WIRE LEAD SCHEDULE C95-3550.

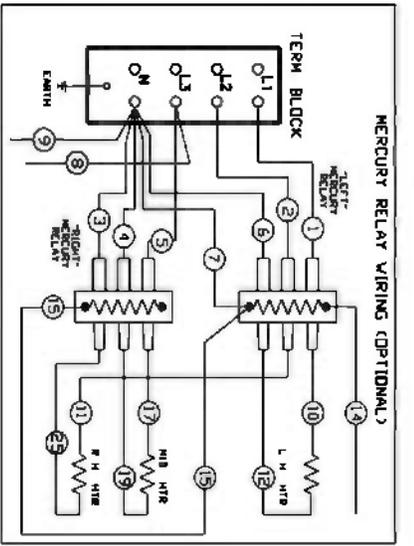
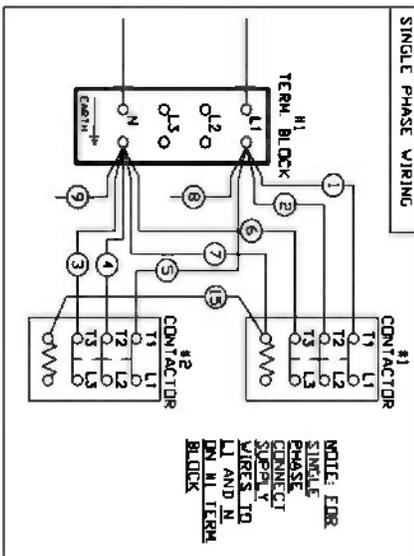
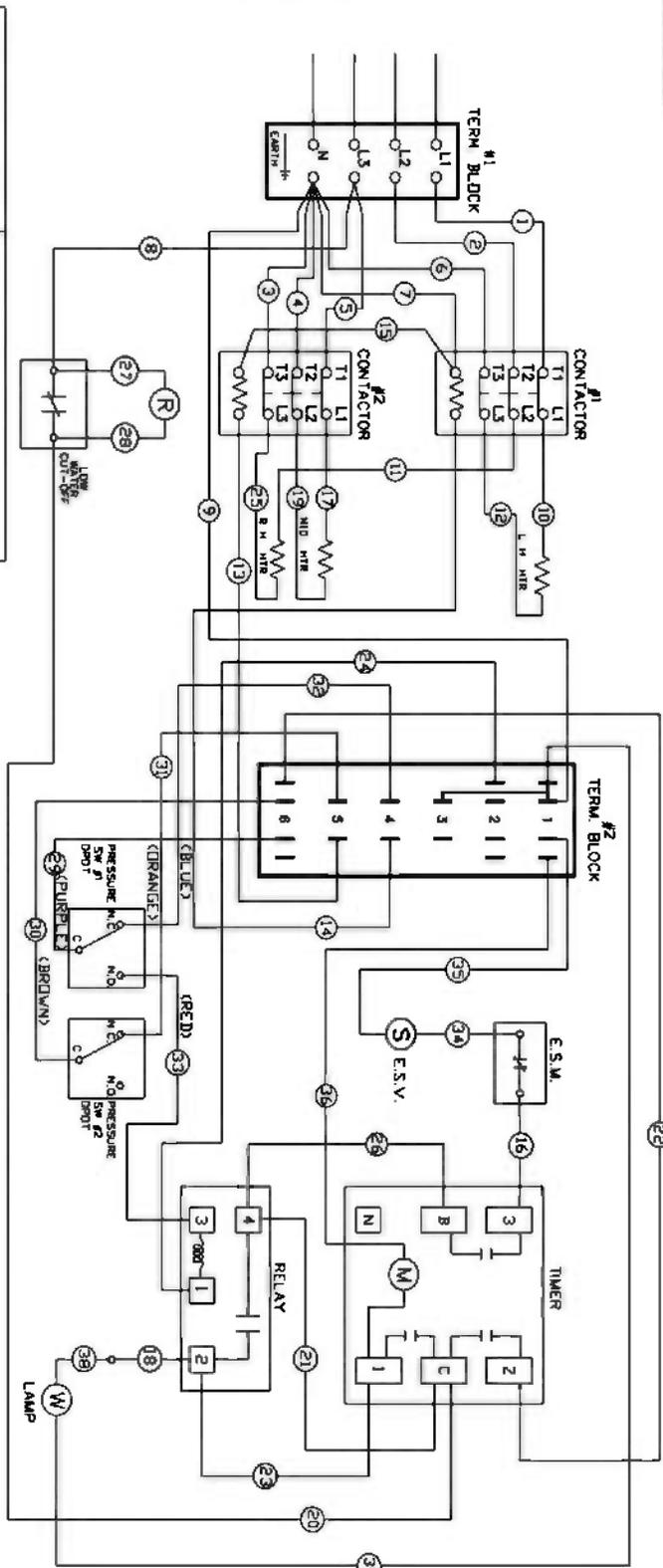
KW	VOLTS	AMP
12	240 V. 3 PH - 4 WIRE 60 HZ.	30
12	240 V. 1 PH - 3 WIRE 60 HZ.	50
9	208 V. 3PH - 4 WIRE 60 HZ.	26
9	208 V. 1PH - 3 WIRE 60 HZ.	44

95-2556 REV. F

SECTION 1 INSTALLATION INSTRUCTIONS

EXPORT STM-EX & STM-ELX STERILIZER 220 Volt / 380 Volt 3Ø - 4 Wire - 50 Cycle

C 95-2748



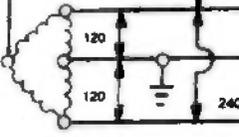
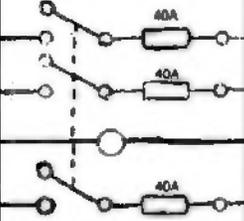
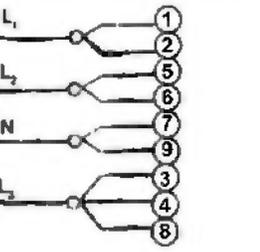
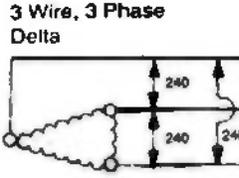
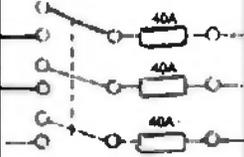
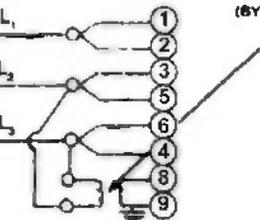
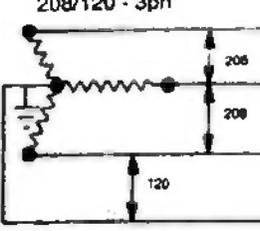
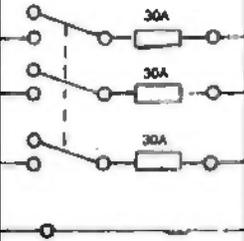
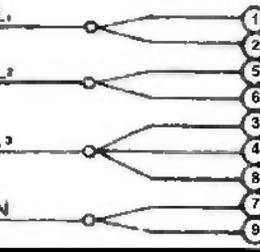
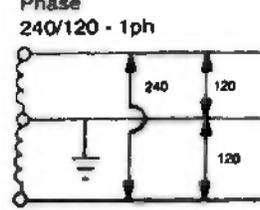
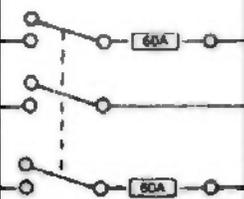
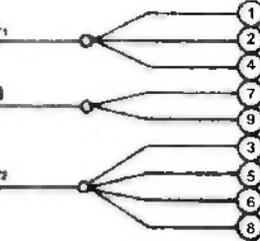
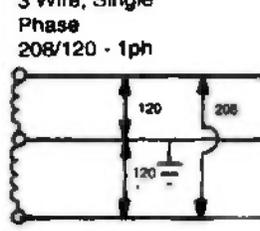
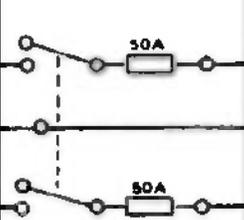
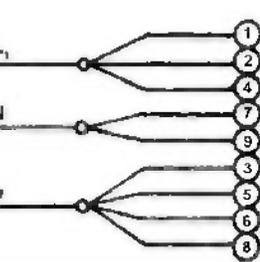
E.S.V. = EXHAUST SOLENOID VALVE
E.S.M. = EXHAUST SELECTOR MANUAL SWITCH

KV	VOLTS	AMP
12	240/415, 3 PH-4 WIRE, 50 HZ	29
10	260/380, 3 PH-4 WIRE, 50 HZ	26
12	240, 1 PH, 50 HZ	50

NOTE: SEE WIRE LEAD SCHEDULE C95-305A. REDUCED WIRING DIAGRAM P/N A17-0235.

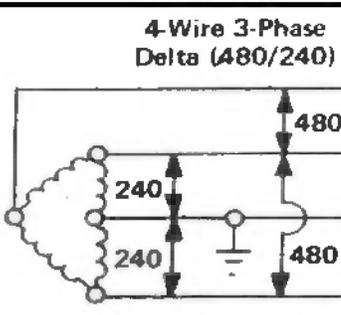
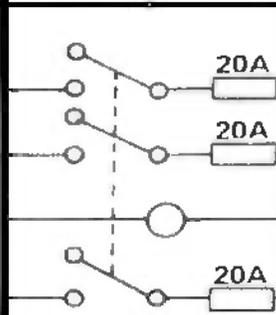
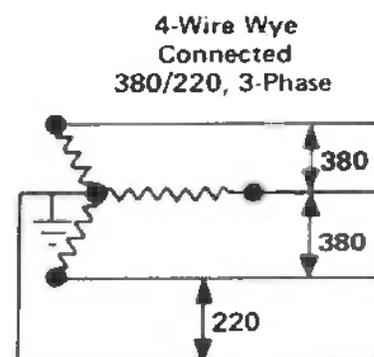
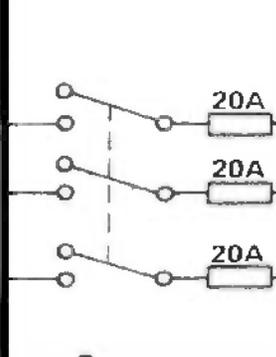
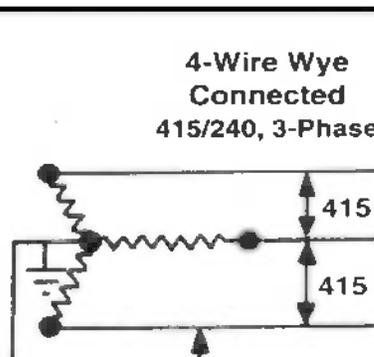
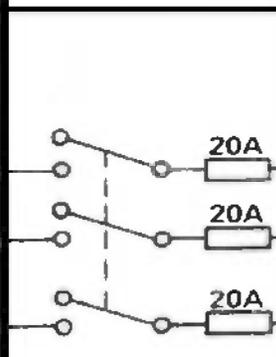
SECTION 1 INSTALLATION INSTRUCTIONS

TYPICAL CIRCUIT CONNECTION FOR STM-E AND STM-EL

ELECTRICAL SOURCE	FUSE & DISCONNECTED MEANS	UNIT WIRING
<p>4 Wire 3 Phase Delta (240/120)</p> 		<p style="text-align: center;">Unit Lead Numbers</p> 
<p>3 Wire, 3 Phase Delta</p> 		 <p style="text-align: right; font-size: small;">2:1 STEP DOWN TRANSFORMER 240/120, 100 WATTS 60/60 CY (BY CUSTOMER)</p>
<p>4 Wire, Wye Connected 208/120 - 3ph</p> 		<p style="text-align: center;">Unit Lead Numbers</p> 
<p>3 Wire, Single Phase 240/120 - 1ph</p> 		
<p>3 Wire, Single Phase 208/120 - 1ph</p> 		

SECTION 1 INSTALLATION INSTRUCTIONS

TYPICAL CIRCUIT CONNECTION FOR STM-EX AND STM-ELX EXPORT MODELS

ELECTRICAL SOURCE	FUSE & DISCONNECTED MEANS	UNIT WIRING
<p>4-Wire 3-Phase Delta (480/240)</p> 		<p>Unit-Lead Numbers</p> <p>L1 — (1)</p> <p>L2 — (2)</p> <p>N — (3), (4), (6), (7), (9)</p> <p>L3 — (5), (8)</p>
<p>4-Wire Wye Connected 380/220, 3-Phase</p> 		<p>Unit Lead Numbers</p> <p>L1 — (1)</p> <p>L2 — (2)</p> <p>L3 — (5), (8)</p> <p>N — (3), (4), (6), (7), (9)</p>
<p>4-Wire Wye Connected 415/240, 3-Phase</p> 		<p>Unit Lead Numbers</p> <p>L1 — (1)</p> <p>L2 — (2)</p> <p>L3 — (5), (8)</p> <p>N — (3), (4), (6), (7), (9)</p>

SECTION 1 INSTALLATION INSTRUCTIONS

INSTALLATION FOR OPTIONAL RECORDING THERMOMETER

The Optional Recording Thermometer may be surface or panel mounted as best accommodates the layout of the sterilization area.

1. Remove the top cover. Remove the pipe plug located in the Y-fitting that also accommodates the safety relief valve and which is connected directly to the sterilizing chamber.
2. Insert the thermometer bulb of the temperature recorder into the pipe, from which the plug was removed.
3. Tighten the fittings. Bend that portion of the Thermometer bulb coil that extends inside the shell toward the rear of the cylinder and at an angle of 45° so that it does not interfere with mounting the overhead baffle plate (Item #20 Master Illustration).
4. For mounting the recorder on a wall or on the unit itself, the 3/16" diameter tapped holes in the angles which are attached to the recorder must be drilled out. This allows for the use of wood or sheet metal screws on walls or panels, and nuts and bolts on the unit itself.*
- 5A. Electrical connections to the recorder are made by running a line from the recorder to any 120 volt supply. Connection can also be made at the supply connection for the unit by utilizing the proper wires to gain 120 volts. Connect either L 1, L2, or L3 for power lead (black wire and the neutral white wire) line for the other side of the 120 volt line.
- 5B. Electrical connections to the recorder are made by running a line from the recorder to any 220 volt supply. Connection can also be made at the supply connection for the unit by utilizing the proper wires to gain 220 volts. Connect either L 1, L2, L3 for power lead (black wire and the neutral white wire) line for the other side of the 220 volt line.
6. The United Electric Recording Thermometer is a 24 hour clock and should be run continuously. Charts should be changed every 24 hours.

"For further mounting instructions. see the Manufacturers Instruction and Maintenance Instructions, Form #17-0099."

TO REMOVE THE CHART

1. Unscrew and remove the chart knob and lift the pen by depressing the pen lifter.
2. Grasp edge of the chart, lift off the chart hub and slide downward and out without permitting the paper to touch the pen.

TO INSTALL NEW CHART

1. Slide edge of the chart under the pen and over the hub, insert the upper edge under the nameplate chart guide and seat the chart hole on the hub.
2. Set correct chart time to the chart plate time index line and replace the knob.

PEN ADJUSTMENT - If the pen point is not aligned properly with the temperature to be recorded (*as checked by an ordinary thermometer*), it may be corrected in the following manner:

1. Locate the small fillister head screw on the right side of the extreme upper end of the Pen Assembly.
2. Turn the screw clockwise for pen movement toward the hub (or counter-clockwise for pen movement away from the hub) until the temperature value of the ink line has been adjusted to its proper position.

PART NO. MZZ100706	REPLACEMENT 24 HOUR THERMOMETER CHART FAHRENHEIT
PART NO. MZZ100707	REPLACEMENT 24 HOUR THERMOMETER CHART CELSIUS

SECTION 2 WATER CONDITIONS

Market Forge from time to time is asked the question about using ***distilled*** or ***dionized*** water for use with our Sterilizer models **STM-E** and **STM-EL**. We are always asked why these water choices are not allowed for use with our units and what would be recommended. To address this situation, we have compiled the following as a means of satisfying these questions:

1. We have found that the use of ***distilled*** or ***dionized*** water will aggressively attack the pure coat of Aluminum Alclad, which protects the bottom surface from oxidizing and then eventually pitting (reference: Operating and Maintenance Instructions).
2. In addition pitting can also be caused by several other external environmental factors. Few examples are as follows. These conditions have been highlighted in our documentation.
 - Grains of hardness in the water supply should be as follows (**.25 to 2**).
 - a pH imbalance in the water supply can greatly affect the life to the aluminum cylinder. The pH range that would be recommended is between **7.0-8.5**.
 - The lack of a positive electrical ground can cause an electrolytic reaction that will accelerate pitting.
 - Another contribution to accelerate pitting is the type of cleaning solutions used or the abrasive scrubbing pads. If a low pH is present with the detergents being used or an abrasive pad, the protective Alclad coating will be removed during the cleaning process.
 - Spillage of media being sterilized can also contribute to the accelerated pitting if it is corrosive.

IMPORTANT NOTE:

Market Forge will not be responsible for damage resulting from the use of hard or corrosive water, from failure to drain the unit daily, or from inadequate cleaning procedures.

SECTION 3 OPERATING INSTRUCTIONS

OPERATING INSTRUCTIONS:

1. **IMPORTANT:** Make sure the drain valve is closed. Fill bottom of the sterilizer chamber with approximately six quarts of water of just bellow ledge at bottom of door opening. (*If water supply is known to be hard or corrosive, a source of treated water should be used.*) DO NOT USE DISTILLED WATER. (*See page 13*)
2. **LOAD STERILIZER:** Use proper sterilizer loading procedures when placing materials in sterilizer chamber. All solid containers or instruments must be placed so that water or air will not be trapped in them.
3. **CLOSE DOOR:** Grasp handle, and holding it in vertical position, pull door down until bottom of door rests in the bottom of door opening. Then rotate handle forward, engaging the lower curved portion under the horizontal rod in the casting at the bottom of the door opening. Push handle all the way down and back until door is locked securely in position.
4. **SET EXHAUST SELECTOR:** Located at center of the control housing mounted on top of the unit, to correct position. Unit is now ready to start. All items, other than solutions, may be sterilized with selector at "Instruments". Solutions require a low exhaust. Place selector at "Liquids".
5. **DETERMINE CORRECT STERILIZATION TIMES:** (*Referring to pages 15 & 16 for minimum required times in the sterilization guide and times table.*) NOTE: In no case should the timer be set to less than 15 minutes. Sterilization will not be accomplished in less than 15 minutes exposure time.
6. **TURN TIMER:** Located at upper right front of sterilizer. Select desired length of sterilizing period. This turns power supply on and starts the cycle after pressure-temperature combination has been reached. Amber pilot light indicates that the timer is running.
7. When the sterilizer chamber reaches the selected temperature, the timed exposure cycle will begin. When the exposure cycle is completed, the electric supply will be opened automatically. When the chamber pressure gauge located at the top of the control housing reads "0", the door may be opened. (Release handle and let go to avoid possible contact with remaining steam.) When opening the door, allow a few seconds for steam to escape from chamber before opening completely.
8. To assist in drying racks, release door handle after pressure has been attained at start of cycle. Pressure in chamber will keep door closed. The use of a wire basket will provide better drying for dressings. At end of sterilizing cycle, release door handle and open slightly. Do not lift door to open position. This will allow steam and moisture to escape. Allow door to remain in this position for 15 to 20 minutes before removing load. Small packs can be dried successfully with this procedure. We do not recommend the sterilization of large packs, such as linens. Be sure condensate baffles are in position in the chamber.
9. Remove load and check water level for next operation.

SECTION 3 OPERATING INSTRUCTIONS

STERILIZATION GUIDE

PACKS (*Linens, gloves, etc.*) – Use wire basket to facilitate drying. Be sure condensate baffles are in place. Place packs on edge and arrange load in chamber, so that only minimal resistant to passage of steam through the load will exist. *NOTE: Place gloves in upper two-thirds of chamber.*

JARS, CANISTERS (*etc.*) – Place containers on side to allow for displacement of air and complete contact of steam to surfaces. Drying is also facilitated.

PETRI DISHES, PIPETTES, DESICCATORS (*etc.*) – Should be inverted.

UTENSILS, TREATMENT TRAYS – Placed on edges to facilitate drying.

INSTRUMENT SETS – Place instruments set in trays having mesh or perforated bottoms. Place trays flat on shelves.

COMBINING FABRICS & HARD GOODS – Place hard goods on lowest shelves.

PLASTIC UTENSILS – DO NOT stack or nest plastic items.

LIQUIDS – Sterilize medium liquids separately from other supplies or materials. Set exhaust selector to proper position (*liquids*).

SMALL ITEMS – Sterilize small items in baskets, or trays.

SECTION 3 OPERATING INSTRUCTIONS

MINIMUM STERILIZATION TIMES

TIME (Minutes)	ARTICLES
15	<ul style="list-style-type: none">- Glassware, empty, inverted.- Instruments, metal in covered or open tray, padded or unpadded.- Needles, unwrapped.- Pipettes, blood diluting, serological, volumetric, etc- Tubing glass (6mm), (10mm) inverted
20	<ul style="list-style-type: none">- Flasked solutions 75-250 ml.- Instruments, metal combined with other materials in covered and/or padded tray.- Instruments wrapped in double thickness muslin.- Rubber gloves, catheters, drains, tubing, etc. Unwrapped or wrapped in muslin or paper.
30	<ul style="list-style-type: none">- Brushes in dispensers, in cans of individually wrapped.- Dressings, wrapped in paper or muslin, small packs only.- Flasked solutions 500-1000 ml.- Needles, luer, individually packaged in glass tubes or paper.- Syringes, unassembled, individually packaged in muslin or paper.
45	<ul style="list-style-type: none">- Flasked solutions 1500-2000 ml.

SECTION 4 DAILY CLEANING

DAILY CLEANING PROCEDURE: (AT THE END OF THE DAY)

- Remove bottom splash baffle

NOTE: IMPORTANT!

STERILIZING CHAMBER MUST BE CLEANED AND DRAINED DAILY USING THE FOLLOWING PROCEDURE. WASH WETTED PORTION OF THE CYLINDER THOROUGHLY BY ADDING A MILD DETERGENT TO WATER IN CYLINDER.

- If a soft cloth or brush is used with the detergent and does not completely remove the surface film, a nylon soap pad should be used. After washing thoroughly rinse with clean water. Dry cylinder* and leave door open overnight.

* The Sterilmatic cylinder is constructed of corrosion resistant Alclad aluminum alloy. The protective properties of this material afforded to the interior portion of the cylinder which is exposed to water may be destroyed by allowing a film to form. Such a film can be caused by salts or other contaminants in the water. Corrosion may also occur if water is not drained daily.

SECTION 5 ASSEMBLY



STERILMATIC OPEN STAND

Market Forge Sterilmatic Stand can be supplemented with an Optional Stand for utility use where maximum compactness is desired.

The sturdy, stainless steel unit is equipped with adjustable leg extensions which allow the unit to be installed and leveled over existing contours in the floor .

The open design lends itself to maximum sanitary conditions because of the ease with which periodic cleaning can be done.

Though simple in design and appearance, the sterilmatic stand is the ideal arrangement for mounting in that it allows secondary air to circulate

STERILMATIC OPEN STAND WITH CONDENSER

Market Forge provides the open stand with a built-in steam condenser system for use where steam exhaustion into the room is undesirable.

The condenser is automatically controlled by the thermostat. The normal factory thermostat setting is 130° (54° C). The open under-shelf of the stand gives added utility. providing a handy tabouret for utensils and access for drainage of water from the sterilizing chamber.

PARTS LIST FOR CONDENSER WITH OPTIONAL STAND

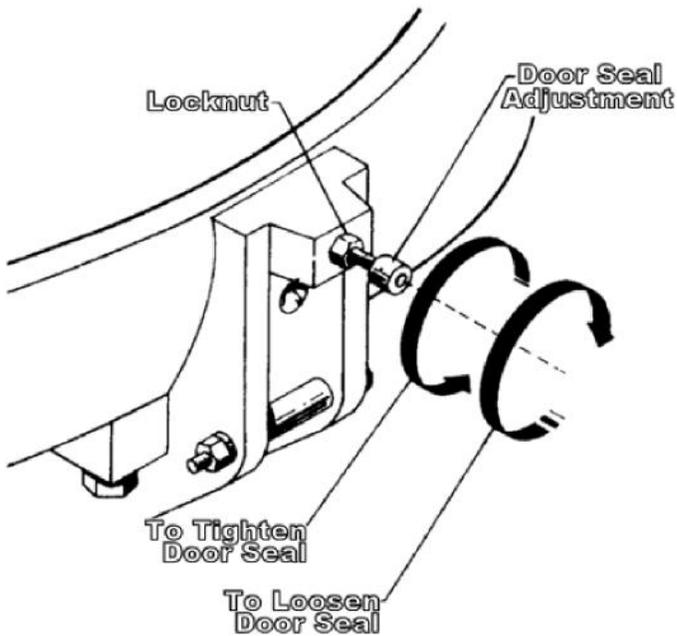
ITEM	PART NO.	50 Hz	DESCRIPTION
1	M100233	M100233	Thermostat
2	M100234	M100234	3/8" Solenoid
3	M100235	M100235	1/2" Water Stop Valve
4	M100236	M100236	Water Injection Assembly
5	M100237	M100237	Shelf

STERILMATIC DOOR ASSEMBLY

The Door of the Sterilmatic has been engineered to establish a positive method of sealing the steam pressure within the sterilizing cylinder. As steam pressure builds up within the cylinder, the door seal will tend to become more positive.

However, the door should be adjusted to make a good initial seal between the door gasket and the door opening without the added assistance of internal cylinder steam pressure with the simple action of securing the door handle down in a locked position, the door gasket should be sufficiently compressed against the door opening, all the way around to prevent any steam leakage from occurring.

SECTION 5 ASSEMBLY



DOOR ADJUSTMENT

The Door Adjustment is Located in the Fulcrum Casting at the base of the door opening. This adjustment employs the use of a screw and locknut In order to adjust the Sterilmatic Door to a tighter closed position (to prevent steam from leaking by the door gasket as pressure builds up), it is necessary to loosen the locknut and back off the screw at least one-quarter of a turn and re-tighten the locknut.

THE DOOR GASKET

Keep the gasket clean. With normal closing and locking of the door assembly, a steam-tight seal should be made

between the door gasket and the door opening. This seal cannot be maintained if particles of foreign matter are allowed to accumulate upon either of the contacting surfaces.

If there is leakage by the door gasket before a steam build-up within the cooking chamber causes it to stop, regard the door assembly as improperly adjusted. A re-adjustment must then be made of the door screw.

To change the door gasket, remove the entire door assembly as a unit. Discard the old gasket, replace it with a new one (no cement is required), and reinstall the door assembly. Make an operational check for leakage and adjust the door, if necessary.

DOOR LIFT SPRING

Market Forge supplies door lift springs in sets only. This policy has been found to be in the best interest of the customer. Through continuous use, some of the original qualities of the springs are lost and it becomes advantageous to make replacements to both the left and right door lift springs in the event that one becomes damaged or broken.

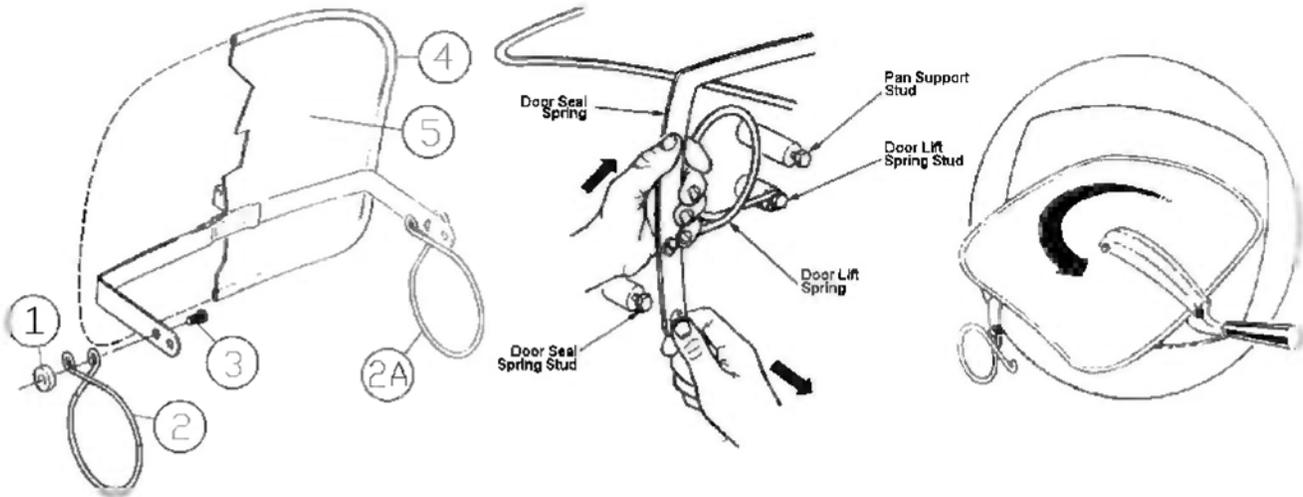
Replacement door lift springs are marked with tabs at the factory prior to shipment to identify a right from a left spring. These springs must be installed with the right door lift spring on the right of the door and the left door lift spring on the left of the door as viewed from the front of the sterilizer.

SECTION 5 ASSEMBLY

TO REMOVE THE DOOR ASSEMBLY

The Door Assembly can be removed from the inner sterilizing chamber as a unit without the use of any special tools or equipment. However, a systematic approach to this is warranted as the clearances through the portal are close, and much confusion can result if not removed in the sequence described below:

1. First, lift off and remove the two pan supports to expose the door linkage on either side of the inner sterilizing chamber .
2. Raise the door to a fully opened position, and disengage the door spring from each of the door spring studs. Accomplish this by counteracting the force of the door lift spring with one hand while working the end of the door spring off the spring stud with the free hand. Do this on both sides of the door assembly.
3. When the end of the door springs have been completely freed from their respective door spring studs, the door springs on either side of the door assembly can easily be slipped off their studs.
4. Rotate the entire door assembly out through the door opening, passing the door handle through the opening first, and then one end of the door spring as shown in the illustration. The remainder of the door assembly will then pass through the door opening quite easily.
5. To replace the door assembly, reverse the step-by-step procedure described above.



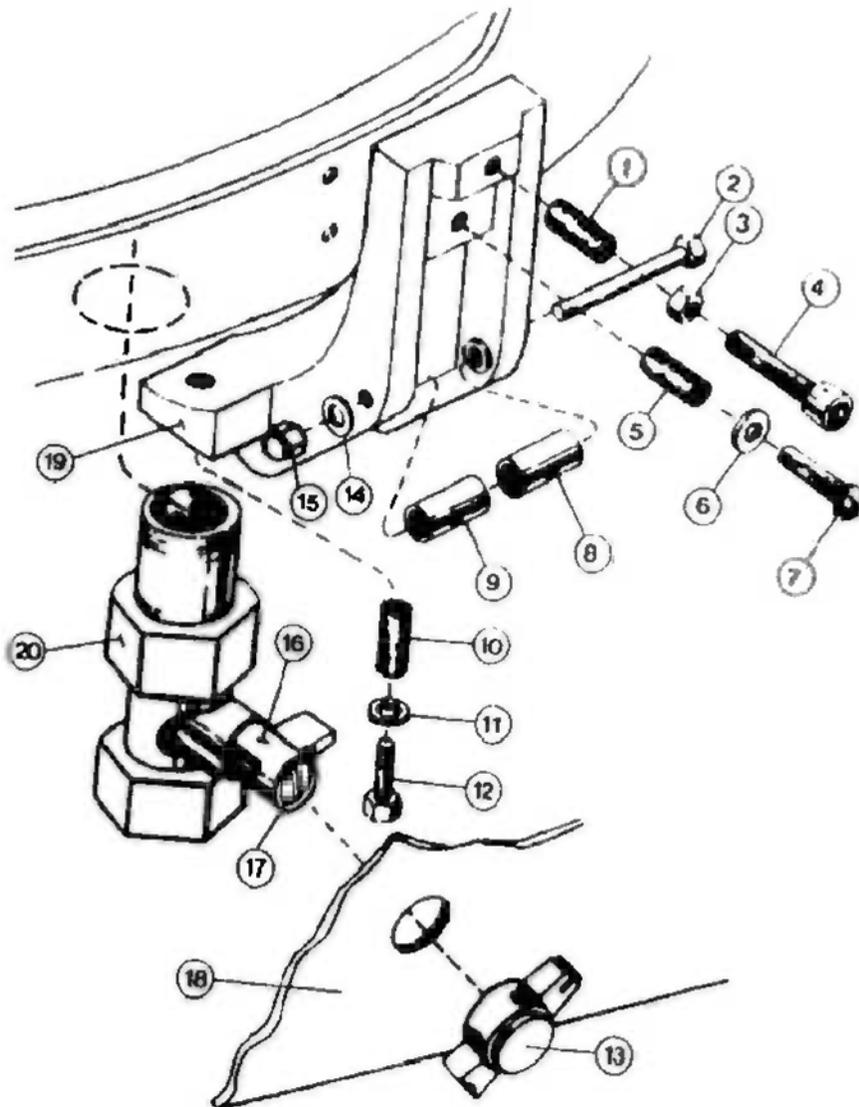
ITEM	PART NO.	DESCRIPTION
1	M100238	Pivot Spring Bearing
2	M100239	Right and Left Door Spring (1 EACH)
3	M100240	10-32 Machine Screw 1/2" Long
4	M100241	Door Gasket
5	M100242	Door & Door Spring Assembly
	M100243	ITEMS 1 THROUGH 6

SECTION 5 ASSEMBLY

Item	Part No.	Description
1	M100244	1/4" - 20 x 5/8 Helicoil
2	M100245	10-32 Machine Screw, 1 5/8" Long
3	M100246	1/4 - 20 Fulcrum Nut
4	M100247	1/4 - 20 Allen Set Screw
5	M100248	1/4 - 20 x 3/8 Helicoil
6	M100249	1/4" Shakeproof Washer
7	M100250	1/4" - 20 Machine Screw 3/4" Long
8	M100251	Bearing Spacer
9	M100252	Bronze Bearing
10	M100253	1/4-20 x 3/8 Helicoil
11	M100254	1/4" Shakeproof Washer
12	M100255	1/4" - 20 Cap Screw, 7/8" Long
13	M100202	Drain Valve Knob
14	M100256	#10 Shakeproof Lockwasher
15	M100257	10-32 Acom Nut
16	M100287	Adapter-Steinball Valve
17	M100259	Screw Round Head 6-32 (1 5/8" Long)
18	M100203	Front Outer Case Lower
19	M100260	Fulcrum and Drain Casting
20	M100261	Nipple 1/2" IPS 2 1/4" Long Stainless Steel
21	M100199	Ball Valve Stein
	M100197	Fulcrum & Drain Assy. (Items 1 to 12,14,15,19)

THE FULCRUM & DRAIN ASSEMBLY

The fulcrum and drain assembly is located at the lower front of the sterilizing chamber and furnishes a sturdy anchorage for the door locking system of the door handle. Also provided in this assembly is a means for adjustment of the door seal. The drain port and drain valve provide a means of discharging accumulations of water from within the sterilizing chamber.



SECTION 5 ASSEMBLY

ROLLER ASSEMBLY (Items 8 & 9)

The Roller Assembly must be kept free-rolling at all times. Should this assembly be allowed to become frozen due to lack of lubrication, undue strain will be put on the door handle and the fulcrum casting while the door is being locked. Use only a dry lubricant such as graphite; as oil or grease will tend to attract dirt to this area.

DOMESTIC

THE PRESSURE ACTUATED TEMPERATURE CONTROL, STM-E AND STM-EL

The pressure actuated temperature control, located behind the control panel assembly, governs the manufacture of steam by controlling the input of electric current to the heating elements.

HOW IT WORKS

When the Timer is set, rear and front contactors will become energized allowing input of current to the temperature control, thus closing the contacts completing the current to the heating elements. Steam will then be generated within the sterilizing chamber.

The steam pressure within the sterilizing chamber is transmitted by means of a tube to the bellows of the temperature control; as the steam pressure increases, its compression action on the bellows causes the Switch #1 on the control is set to cut out on rising pressure at 13.5 PSI and to cut in on falling pressure at 13 PSI. (controlling the two outer banks of heating elements). Switch #2 is set to cut out on rising pressure at 15.5 PSI. and cut in on falling pressure at approximately 15 PSI (controlling center heater element only).

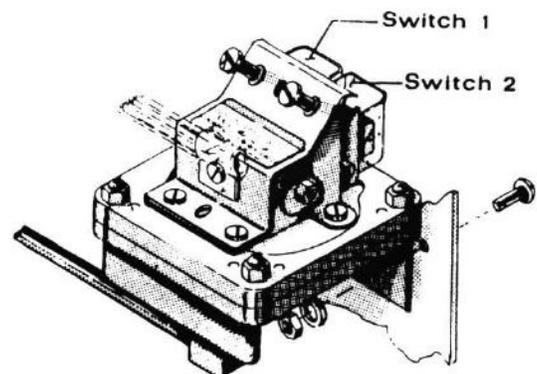
Thus, a balancing effect of steam pressure build-up and heater element current is constantly maintained during the sterilizing cycle. When the Timer signifies the end of the cycle, the electric current to the contactors will automatically be broken; the temperature control contacts will be broken; and steam generation will stop.

ADJUSTING THE RANGE OF OPERATION, STM-E

The operational range of the temperature control is factory set as follows: Outer bank of elements OFF at 13.0- 13.5 PSI; Center bank of elements OFF at 15.5- 15.0 PSI; minor compensating adjustments can be made by turning the adjusting screws counter-clockwise to increase pressure and clockwise to decrease pressure. Both screws should be turned the same amount when making an adjustment.

NOTE: When resetting this control for elevations above sea Level a correction of 6/10 lb. per thousand feet is necessary.

1. Before making adjustments, shut all electrical current to the sterilizer OFF to eliminate shock hazard.
2. Remove the Flue Cover.
3. Make sure that all exposed wires are not in a hazardous position, and then turn on electrical power.
4. Run unit through cycle, observing pressure and temperature gauges, turn adjusting screws as required



SECTION 5 ASSEMBLY

EXPORT

THE PRESSURE ACTUATED TEMPERATURE CONTROL. STM-EX AND STM-ELX

The pressure actuated temperature control, located behind the control panel assembly, governs the manufacture of steam by controlling the input of electric current to the heating elements.

HOW IT WORKS

When the timer is set, rear and front contactors will become energized allowing input of current to the temperature control, thus closing the contacts completing the current to the heating elements. Steam will then be generated within the sterilizing chamber.

The steam pressure within the sterilizing chamber is transmitted by means of a tube to the bellows of the temperature control; as the steam pressure increases, its compression action on the bellows causes the contacts to make or break according to the condition of the pressure at that time (rising or falling).

Switch #1 on the control is set to cut out on rising pressure at 0.89 kg/cm^2 and to cut in on falling pressure at 0.84 kg/cm^2 (controlling the two outer banks of heating elements). Switch #2 is set to cut out on rising pressure at 0.89 kg/cm^2 and cut in on falling pressure at approximately 1.05 kg/cm^2 (controlling center heater element only) .

Thus, a balancing effect of steam pressure build-up and heater element current is constantly maintained during the sterilizing cycle. When the Timer signifies the end of the cycle, the electric current to the contactors will automatically be broken.

CHECKING THE 110°C. SETTING. STM-ELX

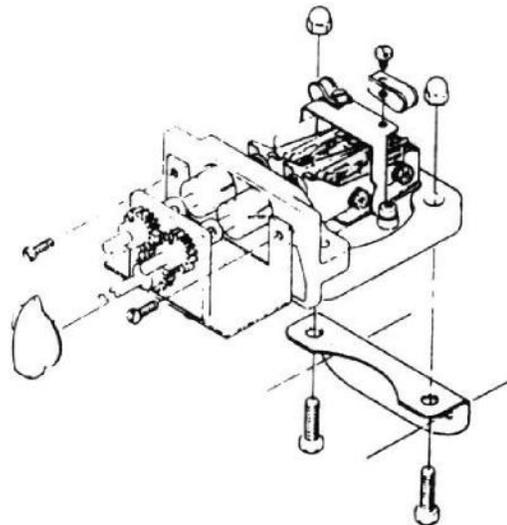
The Unit should be completely evacuated then temperature selector dial turned to 121°C Centigrade. Observe the current until it takes a sharp drop to approximately one-third of the full load; at this instant, there should be a corresponding chamber pressure of 0.14 kg/cm^2 .

Observing the current further will show another sharp drop to approximately 1 Amp; at this instant, there should be corresponding chamber pressure of 0.43 kg/cm^2 and a temperature reading of 121°C Centigrade, on the temperature gauge.

ADJUSTING THE RANGE OF OPERATION. STM-ELX

The range of operation of Model STM-ELX is adjusted by simply turning the adjusting knob on the outside of the Control Panel. A counter-clockwise turn decreases the pressure while a clockwise turn increases the pressure. Observe pressure and temperature gauges and adjust knob as required.

NOTE: When resetting this control for elevations above sea level, a correction of 0.13 kg/cm^2 per kilometer elevation is necessary.



SECTION 5 ASSEMBLY

DOMESTIC

CHECKING THE 230° SETTING, STM-EL

The Unit should be completely evacuated then temperature selector dial should be turned on 230° Fahrenheit, Observe the current until it takes a sharp drop to approximately one-third of the full load; at this instant, there should be a corresponding chamber pressure of 2 PSI

Observing the current further will show another sharp drop to approximately 2 Amps; at this instant, there should be a corresponding chamber pressure of 6.1 PSI and a temperature reading of 22.8° to 232° Fahrenheit, on the temperature gauge.

ADJUSTING THE RANGE OF OPERATION, STM-EL

The range of operation of Model STM-EL is adjusted by simply turning the adjusting knob on the outside of the Control Panel. A counter-clockwise turn decreases the pressure while a clockwise turn increases the pressure. Observe pressure and temperature gauges and adjust knob as required.

NOTE: When resetting this control for elevations above sea level, a correction of 6/10 lbs. per thousand feet is necessary.

CAST-IN HEATING ELEMENTS

Located under the sterilizing cylinder is a bank of (3) U-shaped heating elements. These elements are welded in place in a protective aluminum shield. The elements cannot be removed, and in the unlikely event that one or all fail, the complete cylinder must be replaced.

THE LOW WATER CUT -OFF (MANUAL RESET)

Fastened to a special mounting brace behind the front panel, the Low Water Cut-Off acts to shut off the complete unit, should the water run dry. The Low Water Cut Off is factory set, to shut the unit off when the cylinder temperature rises between 380 and 440° Fahrenheit.

When the Sterilmatic is turned on without water or the water has been evaporated away, the temperature of the aluminum sterilizing cylinder will rise and by heat induction effect the Low Water Cut-Off. Its inner electrical contacts will be forced open from heat expansion, thus cutting off the flow of electric current to the heating elements. With the replacement of water into the cylinder. The cylinder temperature will drop and the contacts of the Low Water Cut-Off can be again closed. The unit will only restart after the manual button has been re-set.

THE ELECTRIC CONTACTORS

The Electric Contactors are located behind the removable lower front panel. These important components receive an electrical impulse when the Timer is turned on. When the unit reaches a pre-set pressure of 1.3-13.5 PSI the #1 switch will cut out causing the front contactor to become de-energized. This, in turn, will disconnect the left and right bank of heaters and the timer motor will start.

SECTION 5 ASSEMBLY

THE TIMER

The Sterilmatic is put into operation with the manual setting of the timer. With the setting of the timer, an electrical current is directed to the pressure control. The current energizes the pressure control, which activates the contactor coils to cause a current flow to the heating elements. When the cylinder pressure reaches 13 to 13.5 PSI, the timer motor and pilot light are energized. At the end of the cycle the timer will cut off the flow of electricity to all the components except the exhaust, the exhaust solenoid and the timer motor. They will revert back to their original deactivated state. The timer motor and pilot light will continue to be energized after the timed sterilizer cycle has been completed and for two additional minutes. Only after this will the timer and white pilot light is de-energized. If the timer fails to operate the Sterilmatic, replace it. The timer is replaceable only as a complete unit as factory repairs to it would not be practical in the economical interests of the customer.

THE STEAM PRESSURE GAUGE

The Steam Pressure Gauge registers the pressure of steam, which is within the sterilmatic sterilizing chamber. To replace this unit, it is necessary to disconnect the copper tubing and to remove the two nuts holding the gauge framework in place

THE SAFETY VALVE

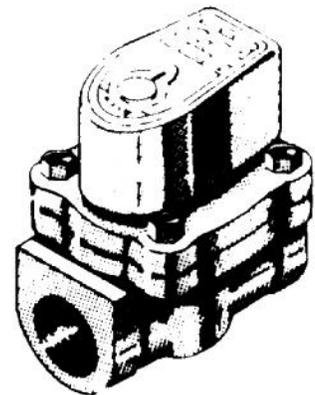
The Safety Valve is factory set to automatically open and exhaust excess steam from within the sterilizing cylinder, thereby assuring that operating pressures remain within safe limits. The lever action of the safety valve 'must be free to operate unrestricted at all times. If the Safety Valve should leak continually with a pressure build-up or should it cause an interruption on a sterilizing cycle prematurely (below 124° Centigrade on the temperature gauge), it must be re- placed. However, the temperature gauge should first be checked for accuracy.

THE FLUE

The Flue serves as a protective shield for the steam trap safety valve, exhaust valve, as well as a mounting base for the control panel. The pressure gauge, dial thermometer, exhaust valve switch and timer, protrude through the control panel. The Flue cover may be removed to allow more room for servicing the control components. The control panel face may then be removed by unscrewing the sheet metal screws, which mount it to the Flue.

THE EXHAUST SOLENOID VALVE

The exhaust solenoid is normally closed and only opens at the end of the cycle when it is energized.



SECTION 5 ASSEMBLY

TO REPLACE A THERMOSTATIC ELEMENT



1. Remove the cap of the steam trap (*turn it counter-clockwise*).
2. Unscrew the diaphragm and seat and discard.
3. Wipe all dirt and scale from the inside of the steam trap.
4. Place a new diaphragm and seat securely into the steam trap and replace the cap (*New Style - Part No. [MZZ100708](#)*).

THE STEAM TRAP

The Steam Trap has the very important automatic, dual function of exhausting all air from the sterilizing compartment, and of making a suitable seal to allow a pressure build-up of live steam during a cycle of sterilization. Also, a slot is milled at an angle through the seat to allow a constant bleed-off of a slight amount of steam during the cycle to completely eliminate any air pockets in the cylinder (see 'A' in figure) Failure of the trap to operate properly will result in an uneven distribution of live steam within the compartment.

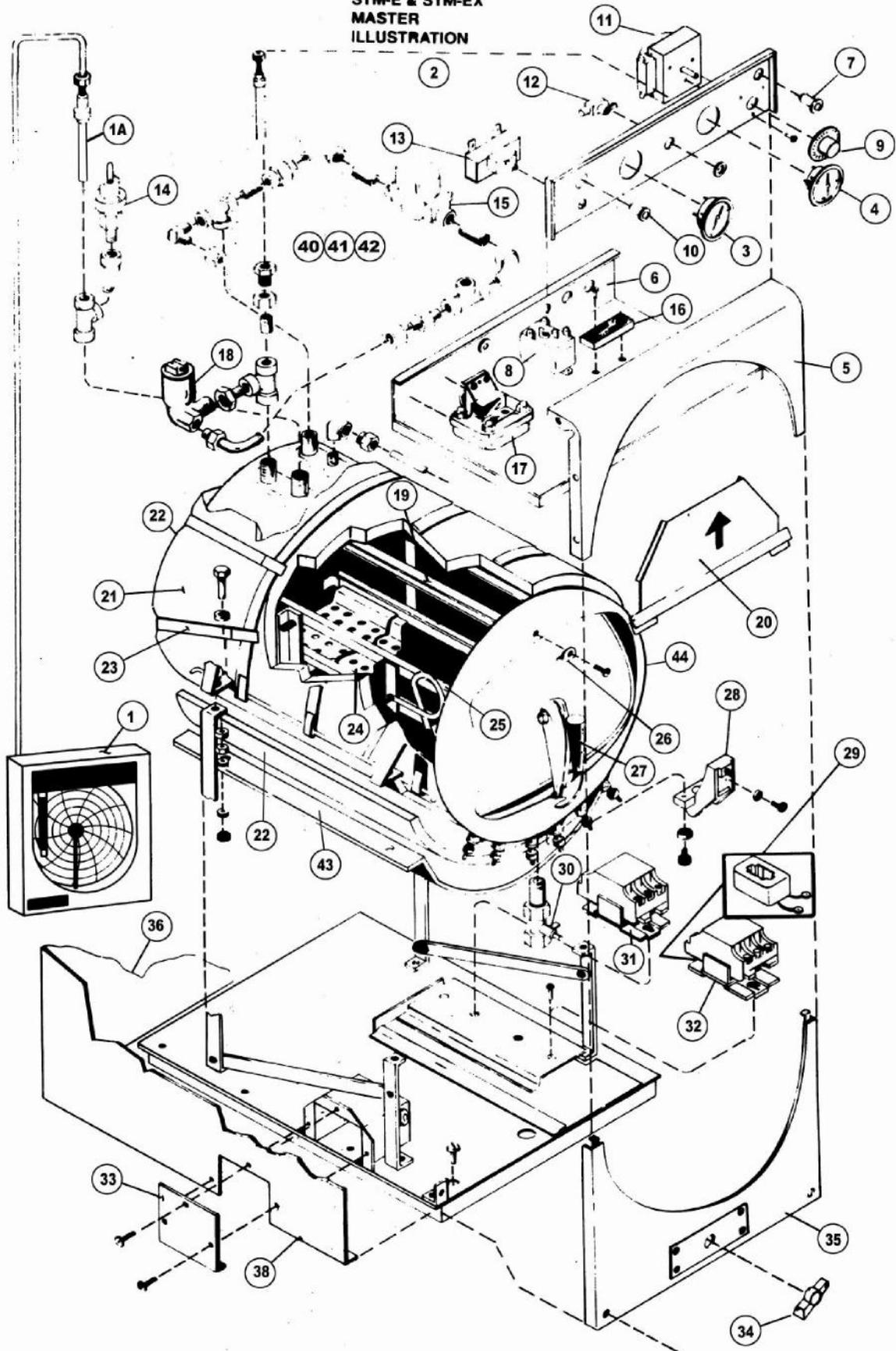


HOW IT WORKS

With the introduction of steam into the sterilizing compartment, cold air will escape. When sufficient generated steam displaces the cold air, it will then start to exhaust through the steam trap to heat the thermostatic element. The expansion of the thermostatic element will make a seal against the seat to enclose the live steam within the sterilizing compartment and a steam pressure build-up will occur.

SECTION 6 ILLUSTRATED PARTS

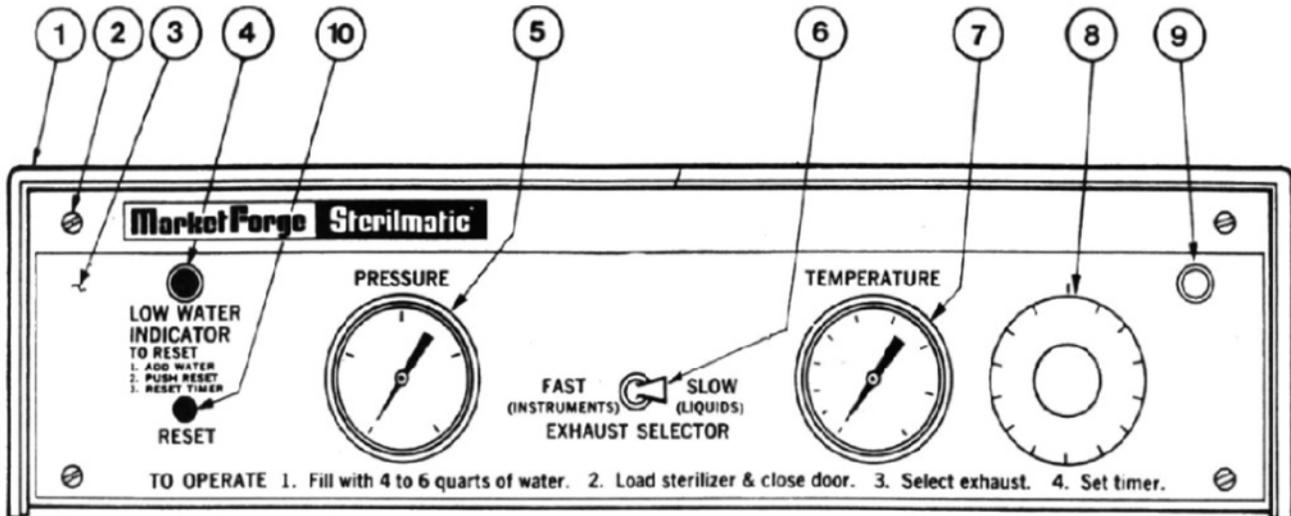
STM-E & STM-EX
MASTER
ILLUSTRATION



SECTION 6 ILLUSTRATED PARTS

STM-E				STM-EX* (Export *)		
Item	Qty.	Part No.	Description	Item	Qty.	Part No.
1	1	M100170	Temperature Recorder 120V (optional)			
			Temperature Recorder 240V (optional)	1	1	M100214
1A	1	M100171	Replacement Probe			
2	1	M100172	Flue Cover	2		
3	1	M100173	Pressure Gauge	3		
4	1	M100174	Temperature Gauge	4		
5	1	M100175	Upper Case Front	5		
6	1	M100288	Upper Mounting Plate	6		
7	1	M100176	Pilot Light (White) 120V			
			Pilot Light (White) 240V	7		M100215
8	1	M100177	Relay 120V			
			Relay 240V	8		M100216
9	1	M100178	Timer Knob	9		
10	1	M100179	Pilot Light (Red) 120V			
			Pilot Light (Red) 240V	10		M100217
11	1	M100180	Timer 120V			
			Timer 240V	11		M100218
12	1	M100181	Exhaust Selector Switch			
13	1	M100182	Low Water Cut-Off			
14	1	M100183	Safety Valve, 17 Lbs.			
15	1	M100184	Exhaust Valve 120V			
			Exhaust Valve 240V	15		M100219
16	1	M100185	Terminal Block			
17	1	M100186	Barksdale Pressure Switch			
18	1	M100187	Steam Trap			
19	1	M100188	Pan Rack Assembly (Right Side)			
20	1	M100189	Condensate Baffle Plate Assembly			
21	1	M100190	Insulation Body			
22	1	M100191	Insulation Bottom			
23	1	M100192	Insulation Back			
24	1	M100193	Perforated Water Baffle			
	4		Wear Strips			
25	1	M100194	Pan Rack Assembly (Left Side)			
26	1	M100195	Handle Bumper			
27	1	M100196	Door Handle Assembly			
28	1	M100197	Fulcrum & Drain Casting Assembly			
29	1	M100198	120 volt, 50/60 Cycle Coil			
30	1	M100199	Drain Valve			
31		M100200	Contactor 120V Coil			
32		M100200	Contactor 120V Coil			
			Contactor 240V Coil	31		M100220
			Contactor 240V Coil	32		M100220
33	1	M100201	Terminal Box Cover			
34	1	M100202	Drain Valve Knob			
35	1	M100203	Lower Front Outer Case			
36	1	M100204	Case, Back			
37	1	M100205	Case, Right Side (not shown)			
38	1	M100206	Case, Left Side			
39	1	M100207	Anode Rod Kit (not shown) OBS / NLA			
40	1	M100208	Wire Harness, Flue Assy (not shown)			
41	1	M100209	Wire Harness, Contactors (not shown)			
42	1	M100210	Flue Assy Wrap (not shown)			
43	1	M100211	Top Cover for Flue (not shown)			
44	1	M100212	Bottom Cover for Elements			
45	1	M100213	Cylinder (208-240V)			

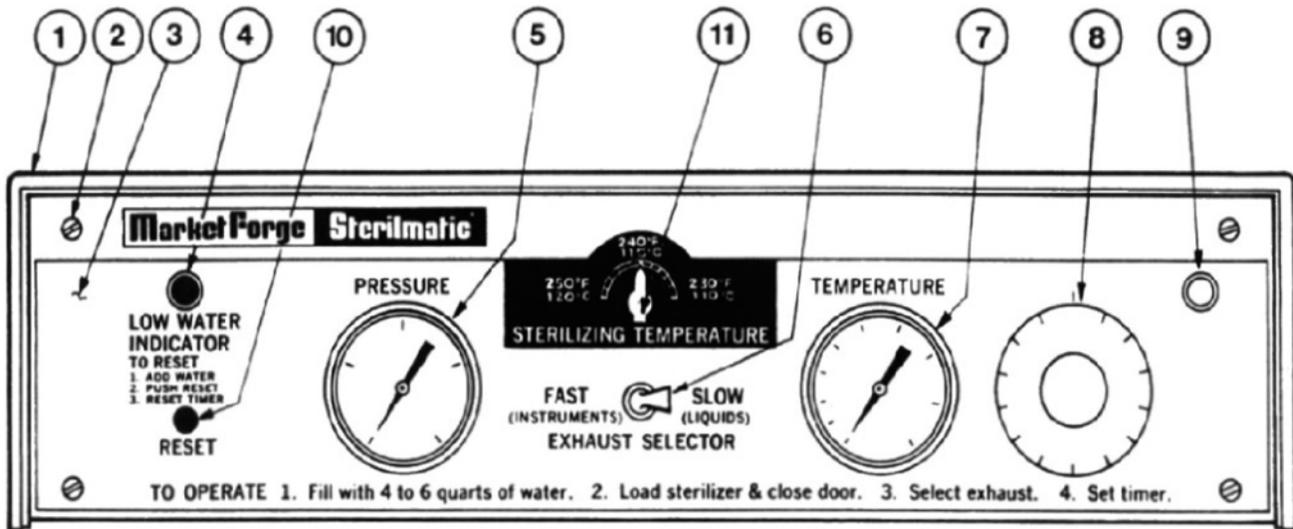
SECTION 6 ILLUSTRATED PARTS



CONTROL PANEL STM-E AND STM-EX

ITEM	STM-E	STM-EX	DESCRIPTION
1	M100262		Bezel
2	M100263		Round Head Machine Screw 6-32
3	M100264		Control Panel
4	M100179	M100217	Pilot Light (Red)
5	M100173	M100266	Pressure Gauge
6	M100181	M100266	Switch
7	M100174		Temperature Gauge
8	M100180	M100218	Timer
9	M100176	M100215	Pilot Light (White)
10	M100182		Low Water Cut-Off

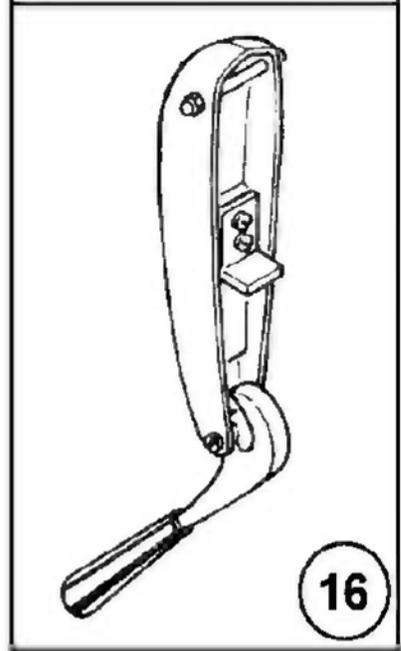
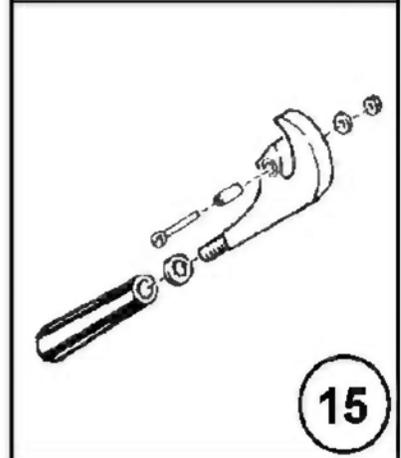
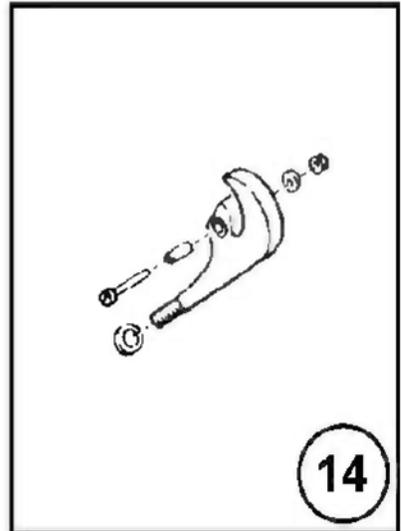
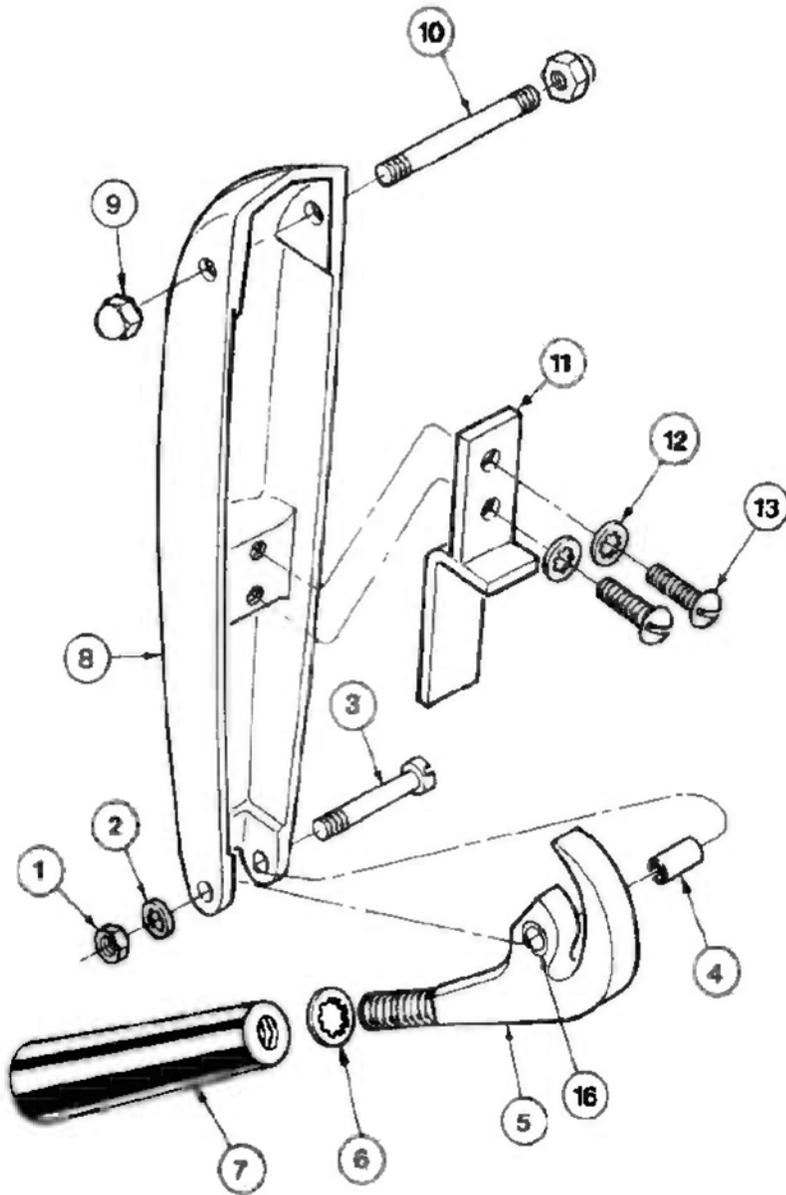
SECTION 6 ILLUSTRATED PARTS



CONTROL PANEL STM-EL AND STM-ELX

ITEM	STM-EL	STM-ELX	DESCRIPTION
1	M100262		Bezel
2	M100263		Round Head Machine Screw 6-32
3	M100269		Control Panel
4	M100179	M100217	Pilot Light (Red)
5	M100173		Pressure Gauge
6	M100181		Switch
7	M100174		Temperature Gauge
8	M100180	M100218	Timer
9	M100176	M100268	Pilot Light (White)
10	M100182		Low Water Cut-Off

SECTION 6 ILLUSTRATED PARTS



Item	Part No.	Description
1	M100270	10-32 Acorn Nut
2	M100271	# 10 Shakeproof Lockwasher
3	M100272	10-32 Machine Screw 1-3/8" Long
4	M100273	Bearing Spacer
5	M100274	Door Lock Casting
6	M100275	3/8" Shakeproof Lockwasher
7	M100276	Door Lock Knob
8	M10277	Door Handle Casting
9	M100278	1/4" - 20 Acorn Nut
10	M100279	Door Handle Bearing Stud
11	M100280	Door Handle Bearing Plate
12	M100281	1/4" Shakeproof Lockwasher
13	M100282	1/4" - 20 Machine Screw 5/8" Long
14	M100283	Door Lock Casting Assembly (Items 1 to 6)
15	M100284	Door Lock Knob Assembly (Items 1 to 7)
16	M100285	Complete Door Handle Assembly (Items 1 to 13)
17	M100286	Handle Bushing

SECTION 7 TROUBLE-SHOOTING

STEAM TRAP TROUBLE-SHOOTING

Trouble can only occur either through the premature closing of the steam trap before all the cold air has been exhausted, or by its failure to close sufficiently to enable a proper steam pressure build-up. Either case warrants a replacement of the thermostatic element.

STERILIZER TROUBLE SHOOTING GUIDE

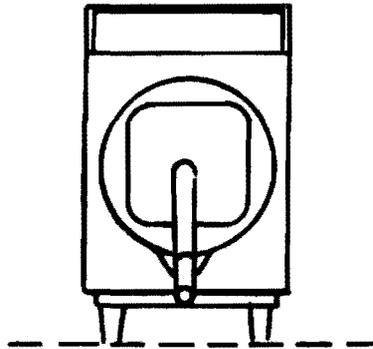
POSSIBLE CAUSE	CORRECTION	P/N
1) Electrical installation incorrect 1a) No 120v supply 2) Blown fuse or tripped breaker 3) Contactor not functioning 4) Loose wire 5) Defective low water cut-off	1) Verify incoming power supply 1a) Supply 120volts for control circuit 2) Change fuse or reset breaker 3) Replace contactor -----> 4) Check all wiring 5) Replace low water cut-off ----->	M100289/M100290 Oct-90
1) Heating element failure 2) Steam trap not closing 3) Malfunction of pressure switch 4) Exhaust valve leaking steam 5) Safety valve leaking steam 6) Steam leak around door	1) Replace cylinder -----> 2) Clean or replace thermo-element in trap ---> 3) Adjust or replace pressure switch -----> 4) Replace exhaust valve -----> 5) Replace safety valve -----> 6) Adjust door and or replace gasket ----->	M100213 M100291 M100292 (STM-E) M100293 (STM-EL) M100184 M100294 (3/4") Oct-66
1) Low water cut-off tripped 2) Safety valve lifting	1a) Verify proper water level in chamber, if not add water and reset lwco 1b) If sufficient water then replace low water cut-off -----> 2) Replace safety valve ----->	 Oct-90 M100294 (3/4")
1) Loose or broken wire to timer 2) Defective timer 3) Defective relay	1) Re-connect or replace wiring to timer 2) Replace timer -----> 3) Replace relay ----->	 M100180/M100218 M100177
1) Steam trap not venting properly 2) Temperature gauge not reading properly	1) Clean or replace thermo-element in trap ---> 2) Replace temperature gauge ----->	M100291 M100174
1) Pressure control contacts remain closed	1) Replace defective switch(es) ----->	M100292 (STM-E) M100293 (STM-EL)
1) Condensate or water baffle missing 2) Steam trap is closing prematurely, trapping air in chamber	1) Verify both interior baffles are in place, if not then install as per (pg. 6) inst. instr. 2) Clean or replace thermo-element in steam trap ----->	 M100291

* Indicates different part numbers for export units.

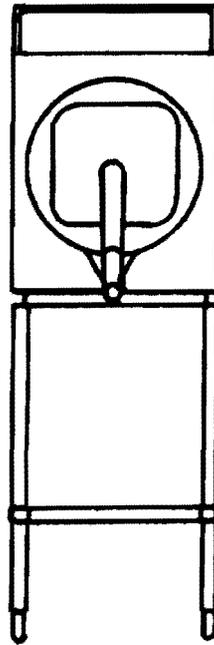
Installation Instructions

STERILMATIC

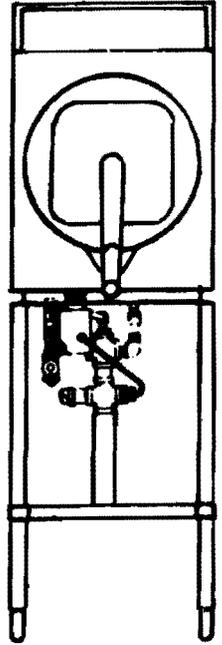
MODEL STM-E & STM-EL



Standard leg



Open Stand



Open Stand
With Cond.

**Market
Forge**

HEALTHCARE EQUIPMENT
EVERETT, MA. 02149



Your Sterilizer Experts

Manufacturing – Distribution – Maintenance- Guaranteed!

Alfa Medical
265 Post Ave
Westbury, NY 11590

1-800-762-1586
516-280-7822
516-997-7434 (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 Market forge sterilmatic model STME & STMEL 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.

act, or because the Commissioner has found, under section 510(g)(4) of the act, that such registration is not necessary for the protection of the public health:

(a) A manufacturer of raw materials or components to be used in the manufacture or assembly of a device who would otherwise not be required to register under the provisions of this part.

(b) A manufacturer of devices to be used solely for veterinary purposes.

(c) A manufacturer of general purpose articles such as chemical reagents or laboratory equipment whose uses are generally known by persons trained in their use and which are not labeled or promoted for medical uses.

(d) Licensed practitioners, including physicians, dentists, and optometrists, who manufacture or otherwise alter devices solely for use in their practice.

(e) Pharmacies, surgical supply outlets, or other similar retail establishments making final delivery or sale to the ultimate user. This exemption also applies to a pharmacy or other similar retail establishment that purchases a device for subsequent distribution under its own name, e.g., a properly labeled health aid such as an elastic bandage or crutch, indicating "distributed by" or "manufactured for" followed by the name of the pharmacy.

(f) Persons who manufacture, prepare, propagate, compound, or process devices solely for use in research, teaching, or analysis and do not introduce such devices into commercial distribution.

(g) [Reserved]

(h) Carriers by reason of their receipt, carriage, holding or delivery of devices in the usual course of business as carriers.

(i) Persons who dispense devices to the ultimate consumer or whose major responsibility is to render a service necessary to provide the consumer (i.e., patient, physician, layman, etc.) with a device or the benefits to be derived 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 pro-

vide a service through the use of a previously manufactured device.

[42 FR 4222, Aug. 22, 1977, as amended at 52 FR 46523, Sept. 1, 1987]

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, 1978, or (ii) a device introduced for commercial distribution after May 28, 1978, 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, 1978; 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 on the safety and effectiveness of the device.

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

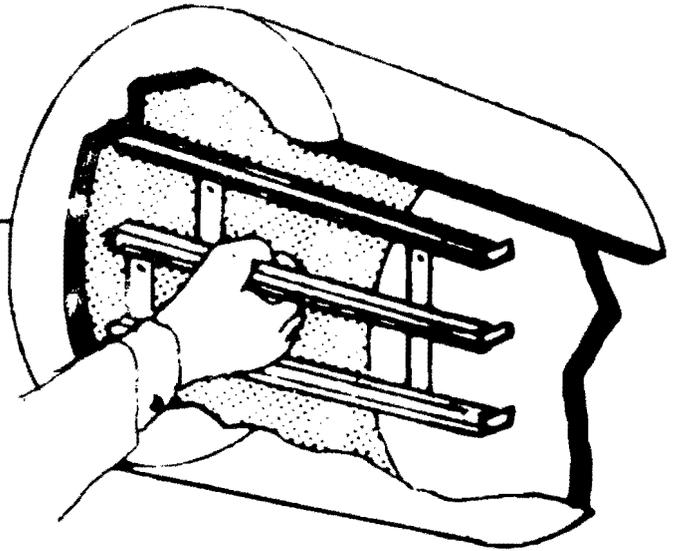
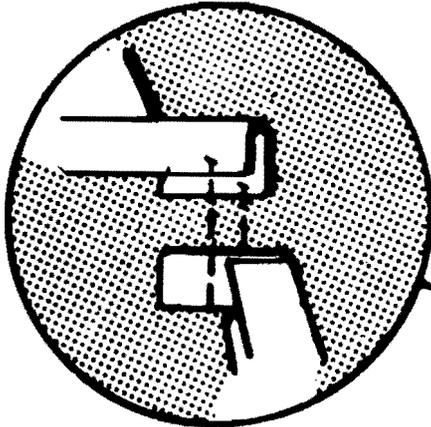
(i) For submissions claiming substantial equivalence to a device which has been classified into class III under section 513(b) of the act:

Instructions for Installing Pan Supports and Baffles

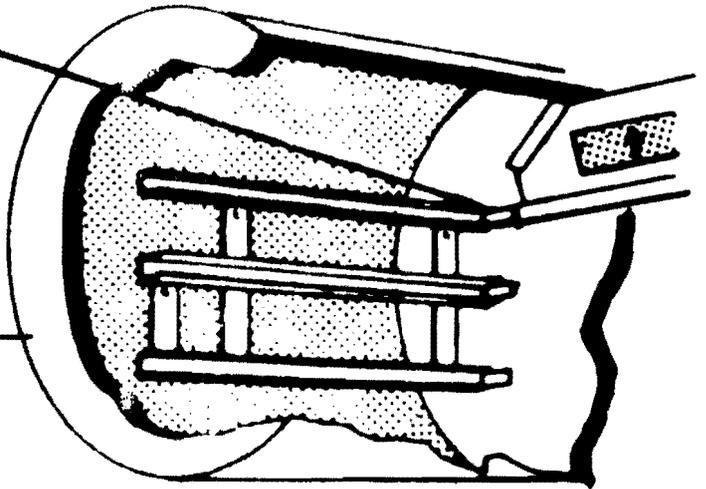
Sterilmatic—ELECTRICALLY OPERATED

1. Hang pan supports on studs in chamber.

Note: the longest of the three channels must be on the top.

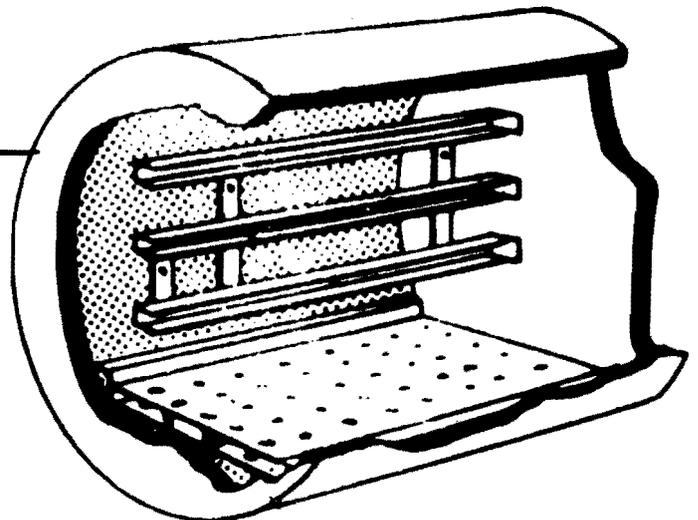


2. Install baffle at the end of the upper channel. Hook clip on baffle over 90 degree end projection of pan support.

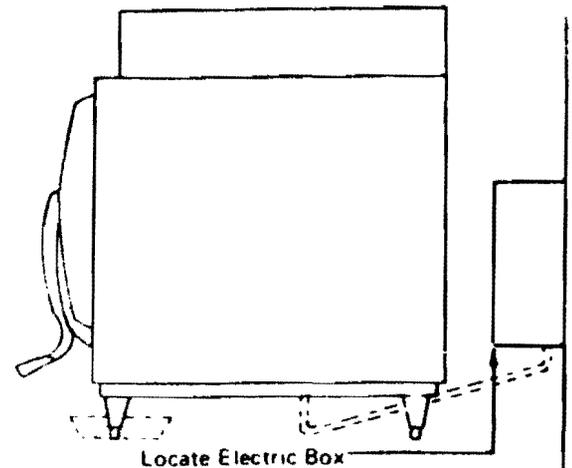
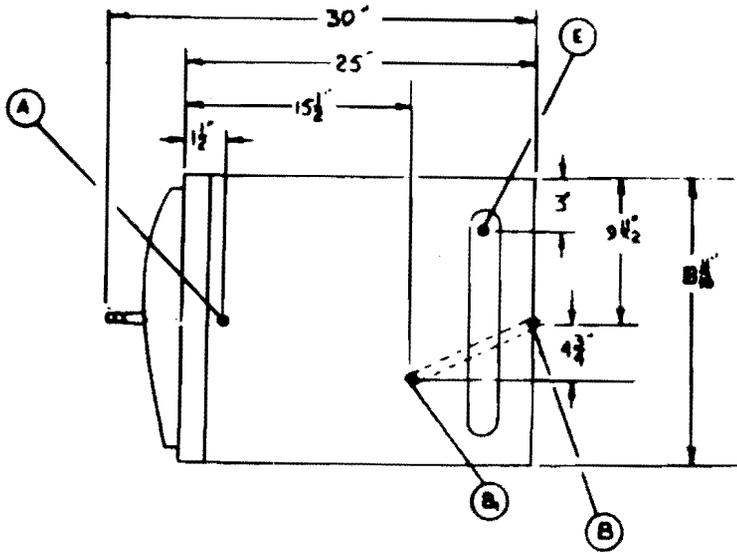


3. Place the two perforated bottom pans together so that they interlock.

Note: that the holes in the top pan do not line up with the holes in the bottom pan, thus preventing the water from boiling through. Set this assembly on the floor of the chamber.



ELECTRIC STERILMATIC STM-E TYPE 'C' W/TEMPERATURE RECORDER

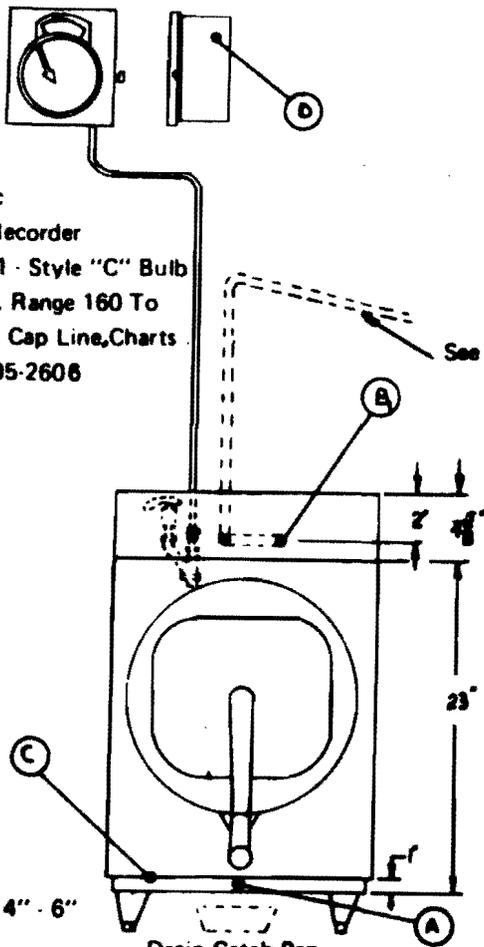


Locate Electric Box
As Close To Sterilizer
As Possible And Per Local
Electrical Codes.

REQUIRED CONNECTIONS			
A	Drain 1/2 FPT or 5/8 Copper (See Note 1)		
B	Steam Exhaust Connections 3/8 I.P.S. (Note 2)		
C	Electrical Connections (See Note 3)		
Nominal Amps Per Wire			
3 Phase - 4 Wire 1 Phase - 3 Wire			
208V	240V	208V	240V
27	34	47	58
208	(197-219) or 240V		(220-240)
D	115V - 60-CY - 1PH - 2.7 Watts		
Units must be grounded			

See Note 5

United Electric
Temperature Recorder
No. 6D01-6531 - Style "C" Bulb
(Coiled) Temp. Range 160 To
280° F W/6Ft. Cap Line, Charts
& Ink Pt. No. 95-2608



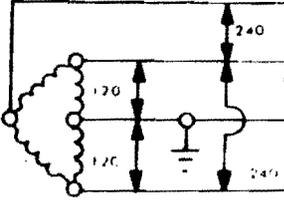
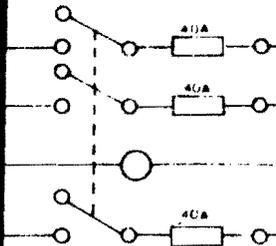
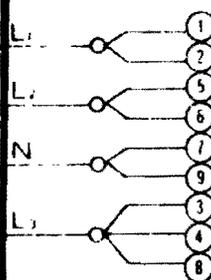
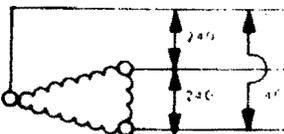
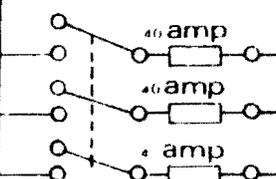
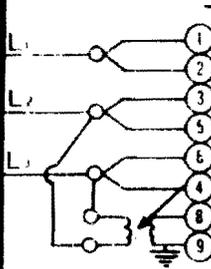
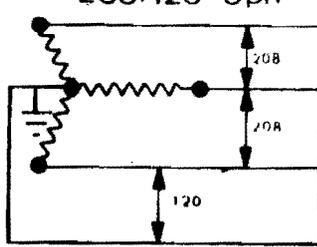
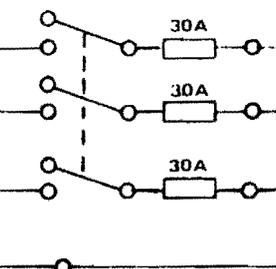
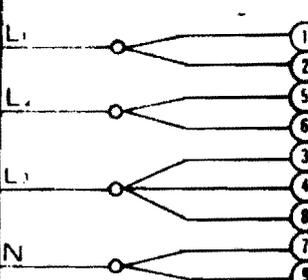
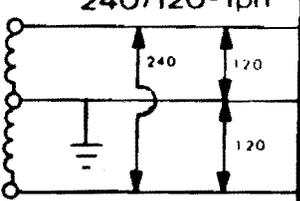
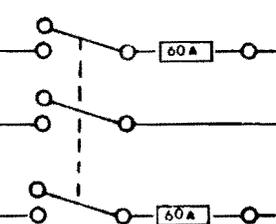
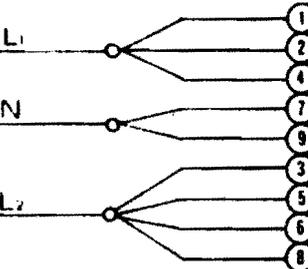
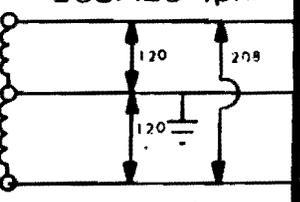
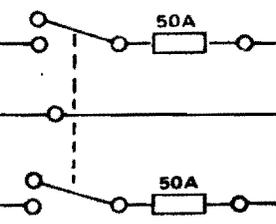
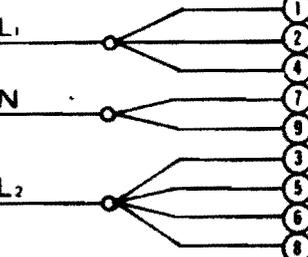
Adj. legs 4" - 6"

Drain Catch Pan
Approx. 4-6 Quarts
By Customer.

NOTES:

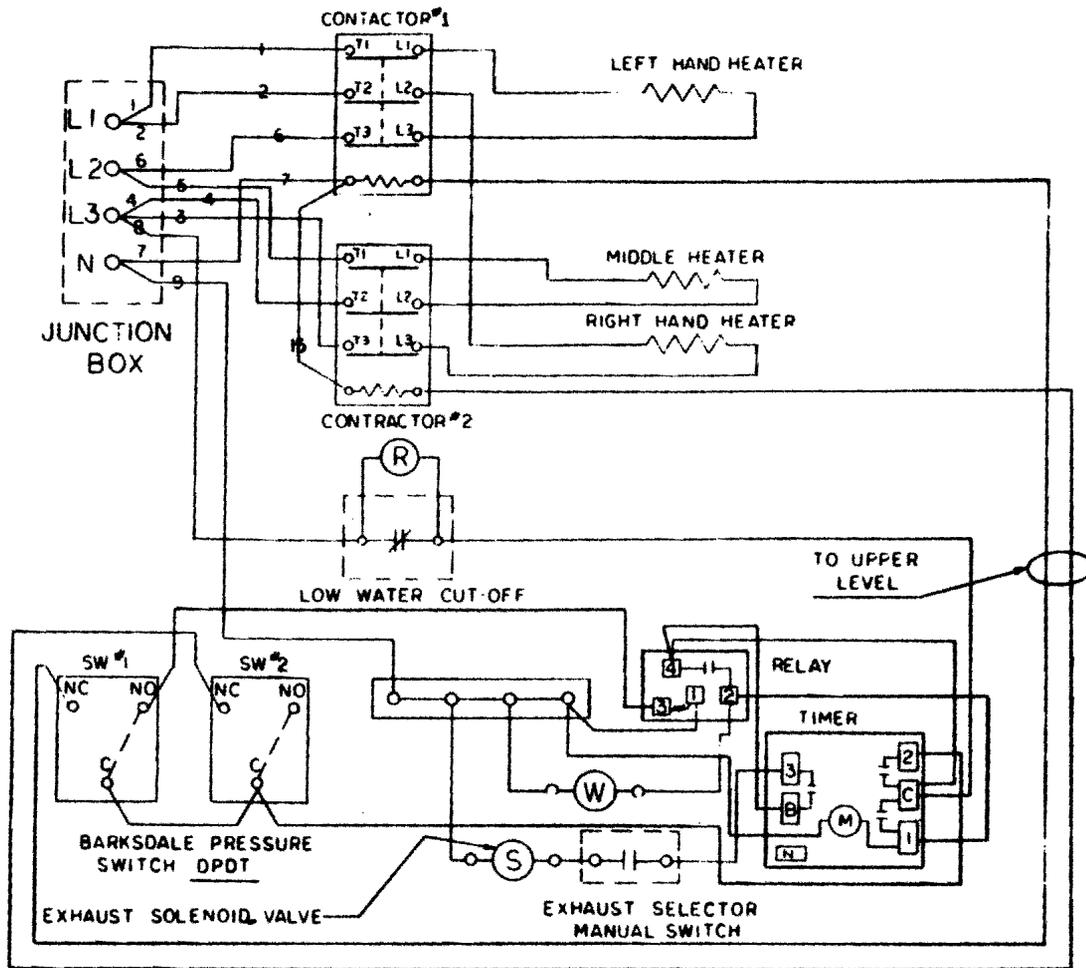
1. An air break must be provided if a unit drain line is run.
2. Vent exhaust to atmosphere (1/2" nominal line 15'0" lg. max. with min. of bends). B₁ is actual connection, but must exit casing at B slope exhaust away from unit to avoid condensate re-entering.
3. The timer & exhaust solenoid valve are on 120V. The heaters run on 230V or 208V. Thus if a neutral to the power circuit if not available a separate 120V line must be run.
4. A 115V line may be run separately into 'D' for the recording thermometer, or the line can be run from 'D' to 'C' by connecting to proper leads.
5. The recorder must be located within 4 feet of the sterilizer preferably on a solid wall but can be mounted on the side of the sterilizer.

Typical Circuit Connections for Sterilmatic MODEL STM-E & STM-EL Style C

Electrical Source	Fuse & Disconnect Means	Unit Wiring
<p>4 Wire 3 Phase Delta (240/120)</p> 		<p>Unit Lead Numbers</p> 
<p>3 Wire, 3 Phase Delta</p> 		<p>Unit Lead Numbers</p>  <p style="text-align: right;">2:1 STEP DOWN TRANSFORMER 240/120, 100 WATTS 50/60 CY. (BY CUSTOMER)</p>
<p>4 Wire Wye Connected 208/120-3ph</p> 		<p>Unit Lead Numbers</p> 
<p>3 Wire, Single Phase 240/120-1ph</p> 		
<p>3 Wire, Single Phase 208/120-1ph.</p> 		

Wiring Diagram for STM-E & STME-EL Sterilizer

208V-240V/120V-3 ϕ -4 WIRE



208V-240V/120V-1 ϕ -3 WIRE CONNECTIONS:	
L1	①②④
L2	③⑤⑥⑧
N	⑨⑦

NOTE: THIS UNIT MUST BE GROUNDED WITH NOT LESS THAN A #16 AWG COPPER CONDUCTOR

POWER REQUIREMENTS			
NOMINAL AMPS PER WIRE			
3-PHASE		1-PHASE	
208V	240V	208V	240V
32	37	47	54

MARKET FORGE CO.
EVERETT, MASS.

17-0233

The Electrical Supply Connections

Connect to proper electrical supply as indicated on nameplate on top of unit. Connection is located behind the terminal box cover at the lower left side of unit. Whether the supply current is 208 or 240 volt, single phase or three phase, all control circuits are 120 volts.

In order to accomplish this, a current-carrying grounded neutral must be provided.

Thus, a three phase system must be 4-wires and a single phase system must be 3-wires. If a current-carrying ground neutral is not available from the power source, a separate 120 volt circuit must be run. Most electrical codes require, and we recommend, that a separate disconnect switch be located within sight of the sterilizer. When a separate 120 volt circuit must be run, this must also be part of the disconnect box assembly.

AUTOMATIC STERILMATIC STEAM PRESSURE STERILIZER

MODEL STM-E ELECTRICALLY OPERATED, TYPE C

Your Sterilmatic Sterilizer has been developed to answer the need for a compact, automatic, low-cost steam pressure sterilizer. The following instructions cover installation. Should service be required, it is readily available by contacting our authorized service agency located nearest to you.

The name of your local service company can be obtained from your Market Forge Representative in your area or by contacting the Hospital Division Service Department, Market Forge, Industrial Way, Wilmington, Massachusetts 01887, telephone A.C. 617-658-5196.

INSTALLATION

Set sterilizer on counter, using 4" legs provided with unit or an optional stainless steel stand with under-shelf and adjustable feet. If your Sterilmatic includes a water-cooled exhaust condenser, we recommend the use of the sterilmatic stand, part number 95-0300. First level unit in place, then by adjusting front legs pitch the unit forward 1/4" to insure positive drainage of the cylinder.

ELECTRICAL

Connect to proper electrical supply box and disconnect switch as shown on one of the following schematic diagrams. (208 volt or 230 volt, single or three phase). Connection is located behind the terminal box cover at the lower left side of unit. Whether the supply current is 208 volt or 240 volt, single phase or three phase, all control circuits are 120 volts.

In order to accomplish this, a current-carrying grounded neutral must be provided. Thus, a three phase system must be 4-wires and a single phase system must be 3-wires. If a current-carrying grounded neutral is not available from the power source, a separate 120 volt circuit must be run. Most electrical codes require, and we recommend, that a separate disconnect switch be located, within sight of the sterilizer. When a separate 120 volt control circuit must be run, this must also be part of the disconnect box assembly.

OUTSIDE VENTING

Connect 1/2 inch I.P.S. exhaust to outside vent connection located on the top of the control housing. **IMPORTANT:** Exhaust line must be vented to the outside to eliminate the exhausted steam and the accompanying noise from entering the room. 1/2 inch copper tubing may be used alternately. Length of the line should not exceed 15 feet and should have a minimum of bends. The line should slope downward after leaving the sterilizer in order to insure a condensate drainage.

WATER-COOLED EXHAUST CONDENSER

If outside venting is not possible, an optional water-cooled condenser is available for connection to an open drain. For details of the installation on the STM-E Sterilizer, see drawing #17-0072, covering both electrical and plumbing connections

RECORDING THERMOMETER

If a recording thermometer is provided, see instructions with the thermometer for installation.

TRAY SUPPORTS

Install side tray supports. Tray supports are attached by means of key-hole clearance slots which are slipped over studs located on the sides of the Sterilmatic chamber. Install so that open end of the channel sides faces the sides of the sterilizer.

BAFFLE INSTALLATION

To insure maximum drying of packs, a baffle is supplied with your STM-E Sterilmatic. Place perforated splash baffle in the bottom of the sterilizing chamber. Install small baffle with no perforation at the rear of the upper tray support channel. (Install as shown on form H-1718.)

OPERATION CHECK

To check for proper operation of unit:

1. Fill chamber with 4 to 6 quarts of ordinary tap water.
2. Close chamber door.
3. Set exhaust selector to 'Instruments and Packs' (Fast Exhaust) or 'Liquids' (Slow Exhaust).
4. Set Timer to 15 minutes. Cycle will go to completion automatically.

NOTE: CYCLE TIMER WILL NOT START UNTIL STERILIZING TEMPERATURE IS OBTAINED.