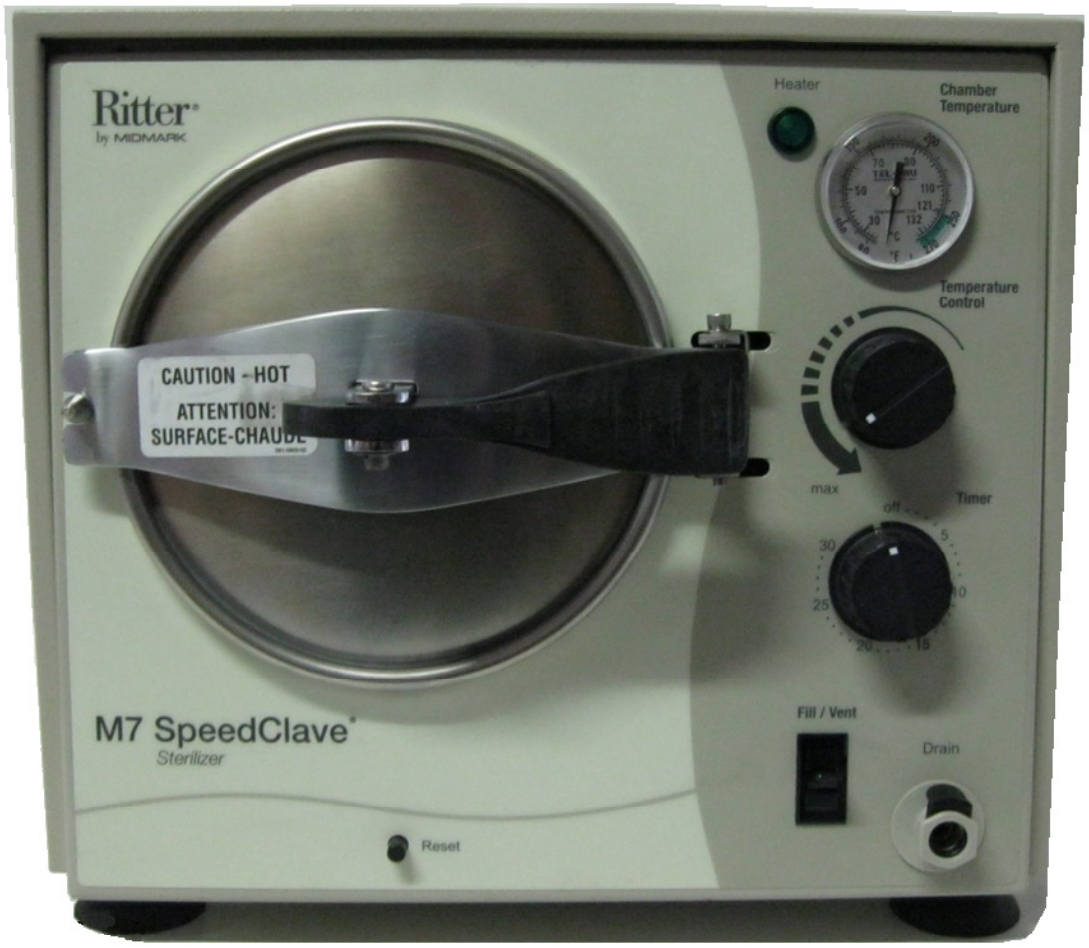
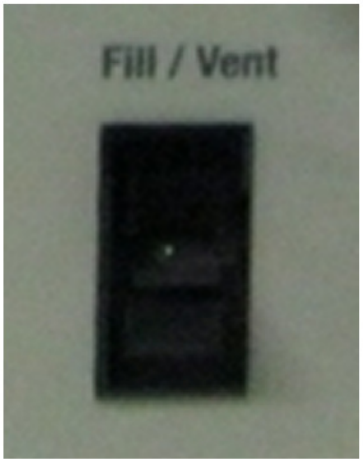


Rocker Switch Used on V Series



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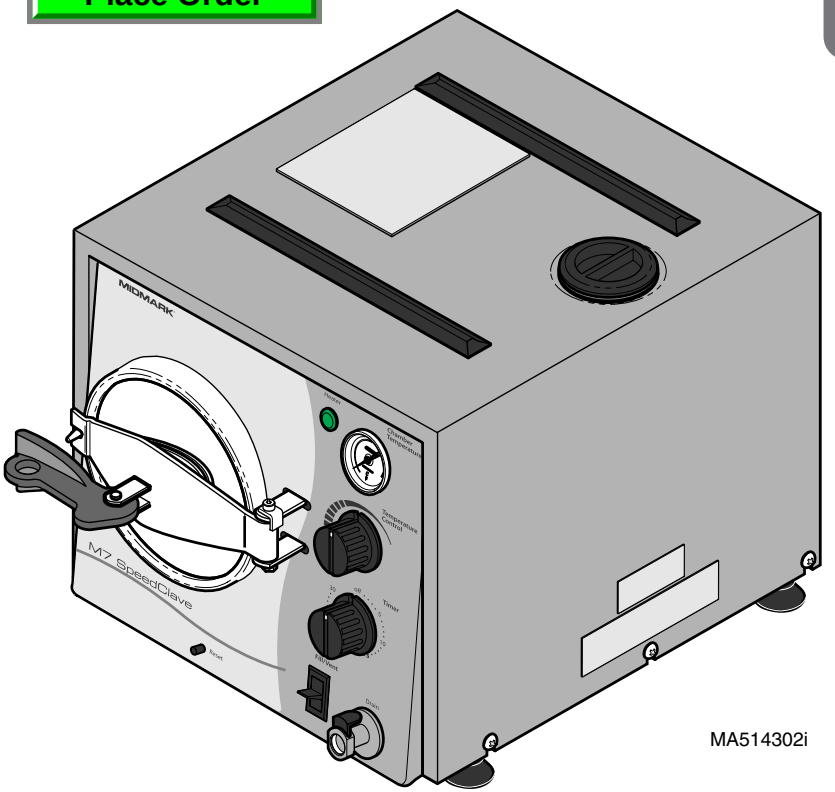
MIDMARK®

M7 SpeedClave® Steam Sterilizer

To purchase a printed copy of this manual, click on the "Place Order" button below.

Place Order

For Models:
M7-020
M7-021
M7-022



MA514302i

User's Guide

SF-1849
003-1417-00 (Rev E)

Style L

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Owner's Product Identification

(The information below is required when calling for service)

Model Number (2):

Serial Number (1):

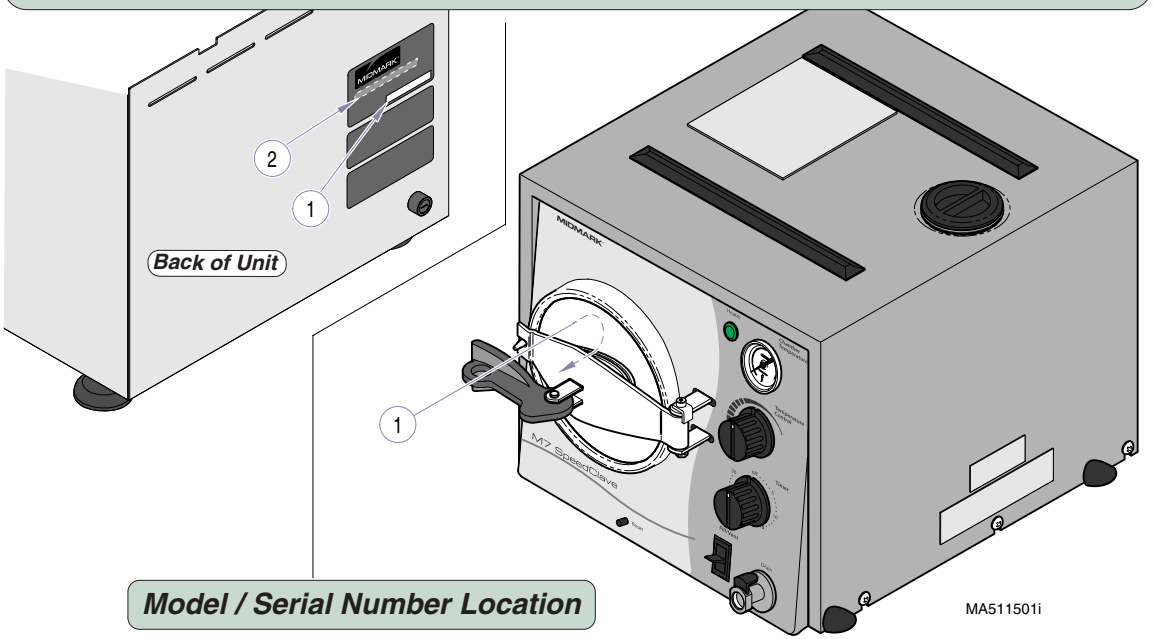
Date of Purchase:

Name of Owner / Facility:

Name of Dealer:

Dealer's Phone Number:

Midmark Authorized Service Company:



Model / Serial Number Location

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Calling For Service

Note
Model / Serial Number information is required when calling for service.

Contact your Midmark Dealer, or log onto www.midmark.com to locate your nearest service provider. To contact Midmark directly:

1-800-Midmark (1-800-643-6275) or 937-526-3662
8:00 am until 5:00 pm. Monday through Friday (EST)
[excluding standard U.S. holidays]

Important Information

Safety Symbols

Warning
Indicates a hazardous situation which could result in serious injury if not avoided. This symbol is used only in the most extreme situations.

Caution
Indicates a potentially hazardous situation which could result in minor injury if not avoided.

Equipment Alert
Indicates a potentially hazardous situation which could result in equipment damage if not avoided.

Note
Amplifies a procedure, practice, or condition.

Consult User Guide for important information.

Proper shipping orientation

Fragile

Protective earth ground

Keep dry

Maximum stacking height (**palletted** units)

Minimum and maximum storage temperature for the unit.

Important Information

Intended Use

This product is intended to be used in medical and dental offices, hospitals, clinics, nursing homes, laboratories, and other facilities to sterilize heat and moisture stable, reusable equipment.

All M7 efficacy testing is exclusive of lumened device sterilization. It is our recommendation that the end-user contact the device manufacturer to determine the recommended sterilization equipment procedures and parameters for the device being sterilized. This is consistent with a Public Health Notice for Reprocessing of Reusable Ultrasound Transducer Assemblies Used for Biopsy Procedures issued by the FDA.

Electromagnetic Interference

This Midmark sterilizer is designed and built to minimize electromagnetic interference with other devices. However, if interference is noticed between another device and this sterilizer, remove interfering device from room and/or plug sterilizer into an isolated circuit.

Transportation / Storage Conditions

EQUIPMENT ALERT
The water must be drained from the unit's reservoir before transporting or storing at 32°F (0°C) or below.

Ambient Temperature Range: ..... -40°C to +70°C (-40°F to 158°F)
Relative Humidity ..... 10% to 90% (non-condensing)
Atmospheric Pressure ..... 500hPa to 1060hPa (0.49atm to 1.05atm)

Safety Instructions

Primary concern of Midmark is that this equipment is operated and maintained with safety of patient and staff in mind. To assure safer and more reliable operation:

- Read and understand this manual before attempting to install or operate sterilizer.
- Assure that appropriate personnel are informed on contents of this manual; this is the responsibility of the purchaser.
- Assure that this manual is located near sterilizer, or if possible, permanently affixed to sterilizer.

Operating Environment Conditions

EQUIPMENT ALERT
Unit should be allowed to reach room temperature before operating. Failure to do so could result in damage to the unit.

- Operating Environment
  Temperature Range: ..... 0° F to 104°F (20°C to 40°C)
- Normal Operating Altitude: ..... Below 9842 ft. (3000 m) above sea level.
- Device approved for *Indoor Use Only.*

- Device to be operated in a relatively dust free environment. An excessive relative humidity environment should in accordance to IEC664).
- Device should be connected to a power source with over-voltage limits less than 1500 volts from mains to ground. (Installation Category II in accordance to IEC 664)

Electrical Requirements

WARNING

Use 207 - 253 VAC, 50 HZ alternating current only for 230 VAC models and 104 - 126 VAC, 60 HZ alternating current only for 115 VAC models. Failure to do so could result in electrical shock to personnel and will result in damage to sterilizer.

Note

Grounding reliability can only be achieved if this unit is connected to a matching three pronged, grounded, isolated, correctly polarized receptacle.

Unit Ratings:

115 VAC Unit: 115 VAC, 60 Hz, 10 Amp
Dedicated branch circuit: 120 VAC, 60 Hz, 15 Amp
Maximum Power Consumption: 1300 Watts

230 VAC Unit: 230 VAC, 50 Hz, 5 Amp
Dedicated Branch Circuit: 230 VAC, 50 Hz, 10 Amp
Maximum Power Consumption: 1300 Watts

Fuse Ratings:

115 VAC Unit: ..... F1, 12 Amp, 250 V, Fast Acting, 1/4" x 1 1/4"

230 VAC Unit: ..... F1, 8 Amp, 250 V, Fast Acting, 5 x 20 mm

Certifications

c UL us LISTED
LABORATORY EQUIPMENT 59FM

This product has been evaluated with respect to electrical shock, fire & mechanical hazards only, in accordance with UL61010A-1, UL61010-2-041, CAN/CSA C22.2 NO. 1010 and CAN/CSA C22.2 NO. 1010.2-041-96.

ISO 9001 Certified

Equipment <u>not</u> suitable for use in the presence of a flammable anesthetic mixture with air, or with oxygen, or nitrous oxide.

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Operation Precautions

WARNING

Do not use **this sterilizer in an explosive or oxygen-rich atmosphere, or where flammable anesthetics are stored. To do so could result in an explosion or fire.**

Do not use **this sterilizer for sterilizing volatile substances or for any purpose other than its intended design. Burns and toxic or explosive conditions could result.**

Clean and dry instruments **before putting them into the sterilizer. Incomplete and improper cleaning of instruments will hinder sterilization. This will result in unsterile instruments which could lead to personal injury or death.**

If the sterilizer malfunctions**, immediately unplug it. If it continues to malfunction, call your nearest factory trained servicer or dealer. Do not attempt to repair the sterilizer yourself or by an untrained person.**

Do not force the door handle **at any time. Chamber pressure may cause the door to open with extreme force. If door handle does not move freely, allow unit to cool and depressurize for 40 minutes before attempting to open the door. Failure to comply to these instructions could result in severe personal injury.**

EQUIPMENT ALERT

Do not use toweling or packaging which may contain chlorine bleach residue. Doing so could result in trays and/or chamber rusting or discoloration. In extreme cases, the life of the chamber may be significantly shortened.

Steam Sterilization Monitoring

EQUIPMENT ALERT

Processing goods using an incorrect sterilization program could result in unsterile goods and may damage instruments. Consult with your supply manufacturer for specific sterilization instructions.

WARNING

Use process monitors with *each sterilization load* rated for use with *Gravity Displacement Steam Sterilizers*. Also, if sterilization cycle terminated prematurely, reprocess instruments to ensure sterility of load.

Process monitors *(Rated for Gravity Displacement Steam Sterilizers)*

- Should be included in each sterilization cycle.
- Detect whether cycle parameters were delivered.
- Cannot establish that a processed item is actually sterile.
- If a failure is detected, the user must determine source of failure. (Failures could result from improper packaging, loading, or sterilizer malfunction).
- Follow process monitor manufacturer's instructions for proper selection, storage, use, and interpretation of their devices.

Steam Sterilization Monitoring

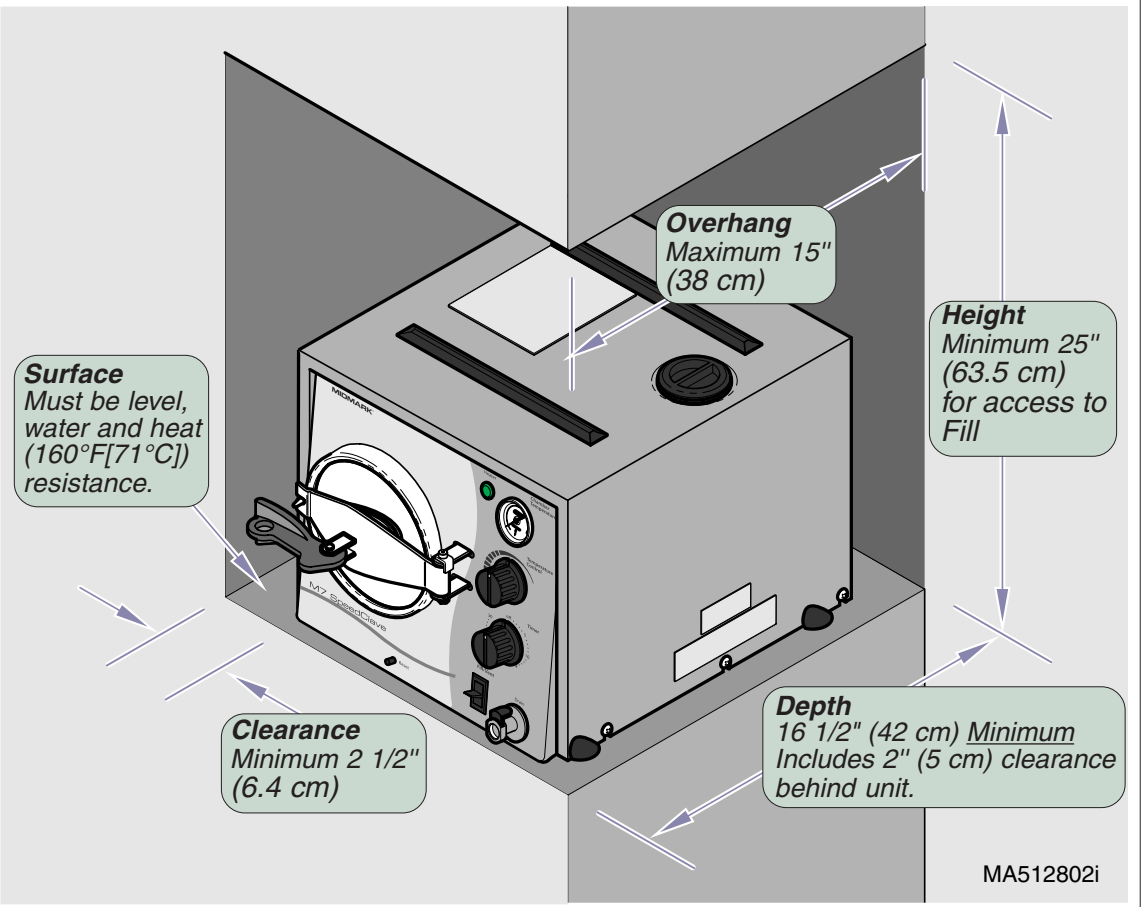
Follow appropriate agency

(state dental or medical board) for sterilization monitoring guidelines for your office. Additional information can also be obtained from CDC, AAMI, OSAP, and ADA regarding monitoring programs or other sterilization issues.

Location Requirements

WARNING

Do not use **this sterilizer in an explosive or oxygen-rich atmosphere, or where flammable anesthetics are stored. To do so could result in an explosion or fire.**



Instrument Cleaning

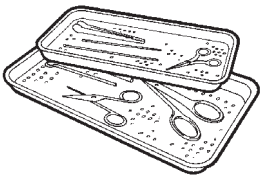
WARNING

Clean and dry instruments before putting them into sterilizer. Incomplete or improper cleaning of instruments will hinder sterilization. This will result in unsterile instruments which could lead to personal injury or death.

- Clean instruments in accordance with the Manufacturer of the instruments and OSHAís recommendations.
- Thoroughly wash instruments to remove gross debris (either manually or using an ultrasonic cleaner).
- Rinse instruments thoroughly and dry.

Loading Trays

- Sterilize jointed instruments in an open position.



- Place all containers so opening allows steam to enter and air to leave. Containers are usually positioned on side with opening tilted slightly down.

- Pouch or wrap items to preserve sterility after processing. Use only coverings designed and recommended for steam sterilization.
- Do not wrap items too tightly. Steam penetration will be affected.
- Do not stack trays on one another. Use Midmarkís tray rack trays provided.
- Position loads on trays with appropriate spacing between items for proper steam flow and drying.
- Place unwrapped items on a towel.

Maximum Capacities			
Load Type	**M7 Large Tray**	**M7 Small Tray**	**Sterilizer Total**
Solid items	21instruments - 1100 grams (2.4 lbs.) ***or***	14 instruments - 700 grams(1.6 lbs.) ***or***	56 instruments - 2.9 kg (6.4 lbs.) ***or***
Packs (**)	1080 cu. cm up to 2.5 cm thick (66 cu. in. up to 1in. thick)	1080 cu. cm up to 2.5 cm thick (66 cu. in. up to 1in. thick)	2940 cu. cm up to 2.5 cm thick (180 cu. in. up to 1 in. thick)

****** Packs to have a minimum of 1/4 in. (6.3 mm) space between each other and away from all sterilizer surfaces.

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Recommended Temperatures & Times

Temp. / Pressure / Exposure Time* (Minimums)	Items To Be Sterilized (Always consult the item manufacturer's recommendation for sterilization).
270°F (132°C) 27 PSI (186 kPa) 3 Minutes Exposure Time*	* Instruments loose on a tray. * Open glass or metal canisters. * Tubing not used in surgical procedures. * Items manufacturer recommends exposure at 270°F (132°C) for 3 minutes. * Sterility of unwrapped items is compromised on exposure to a non-sterile environment.
270°F (132°C) 27 PSI (186 kPa) 15 Minutes Exposure Time*	* Instruments loose on a tray. * Loosely wrapped individual instruments. * Multiply wrapped instruments separated by fabric. * Wrapped trays of loose instruments. * Tubing not used in surgical procedures. * Items manufacturer recommends exposure at 270°F (132°C) for 15 minutes.
250°F (121°C) 15 PSI (104 kPa) 30 Minutes Exposure Time*	* Textiles and surgical packs wrapped for sterilization. * Items, except liquids, manufacturer recommends for exposure at 250° (121°C) for 30 minutes.

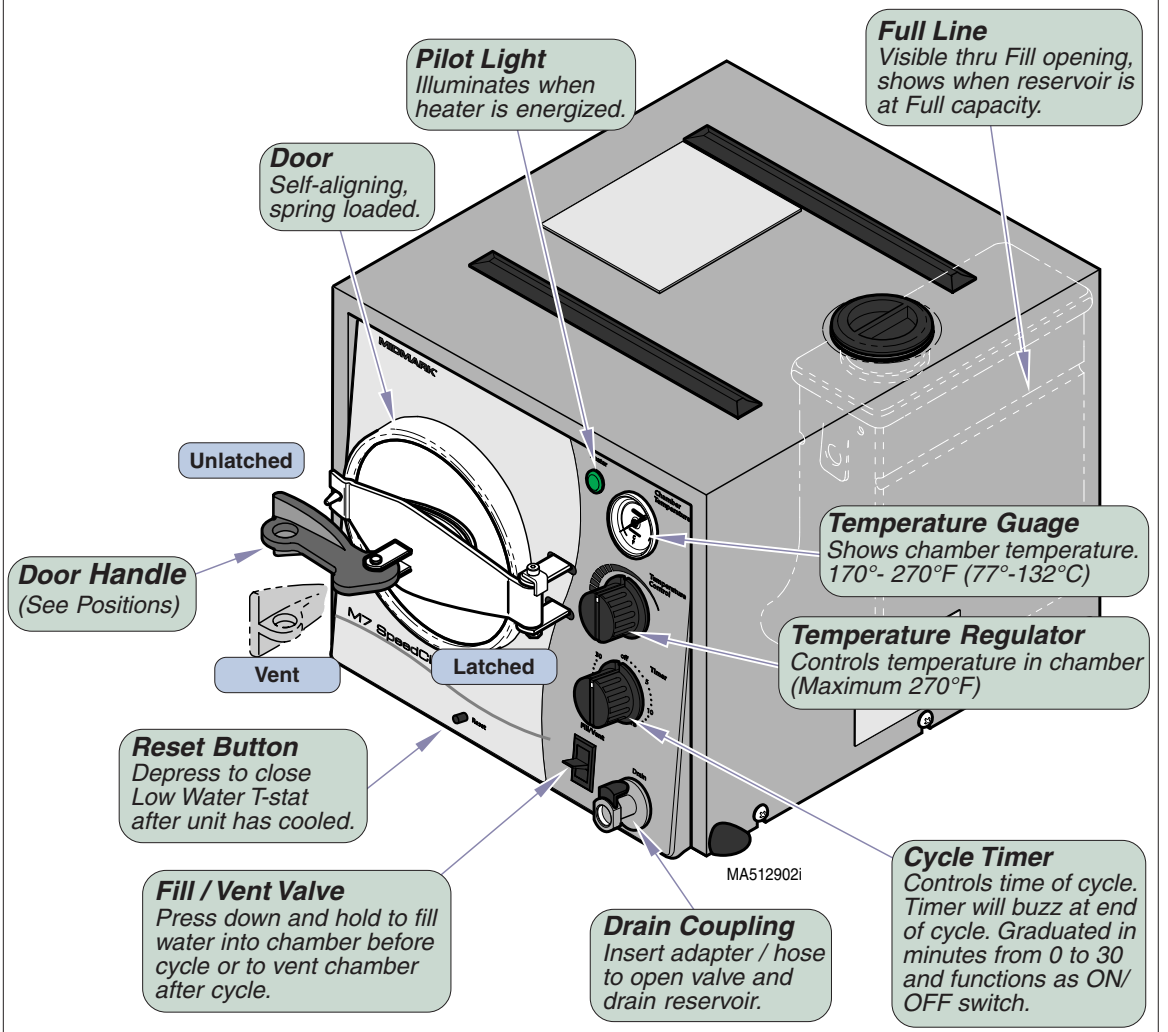
* **Exposure Time** is the total time required for sterilization of the load.
This period *begins* when the sterilizer *reaches* the sterilization temperature.
Sterilization temperature *must be held* for the amount of time as recommended in the above chart.
Not included in Exposure Time are the time it takes to reach sterilization temperature and the time it takes to cool back down.

Suggested Extended Times At Reduced Temperature For Higher Altitudes

Altitudes higher than 1000 ft. (305 m) above sea level, maximum temperature that unit achieves may be less than 270°F (132°C).
Use the following to process items at the higher altitudes:

- **Unwrapped Items** 250°F (121°C) for 15 minutes exposure time*.
- **Wrapped Items** 250°F (121°C) for 20 minutes exposure time*.

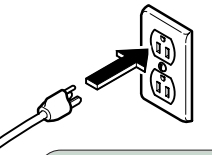
Controls & Indicators



Preparation Before Operation

EQUIPMENT ALERT

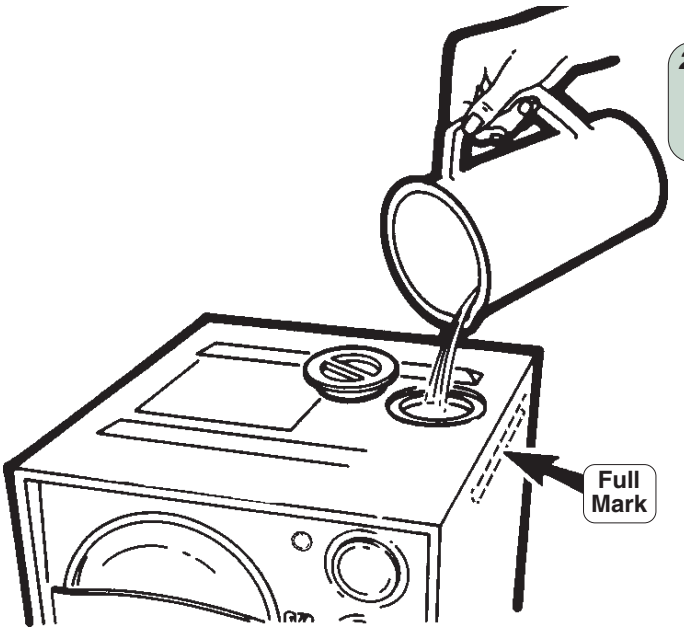
Assure Sterilizer electrical specifications, as shown on Model / Serial Number label, match the electrical supply before plugging unit into outlet.



1. Plug Unit In
Plug Sterilizer into an outlet that has a dedicated circuit.

EQUIPMENT ALERT

Use only distilled or demineralized water.
Do Not use normal tap water as the minerals and chlorides in the water could adversely affect the life and reliability of the Sterilizer and articles being sterilized.



2. Fill Reservoir
Remove cap and fill with distilled / demineralized water to Full mark.

Note
Do *not* overfill reservoir.
Overfilling may cause:
- Water splashing out reservoir.
- Water siphoning back into chamber during venting.
- Sterilized products could remain wet.
- Water could run out bottom of door.

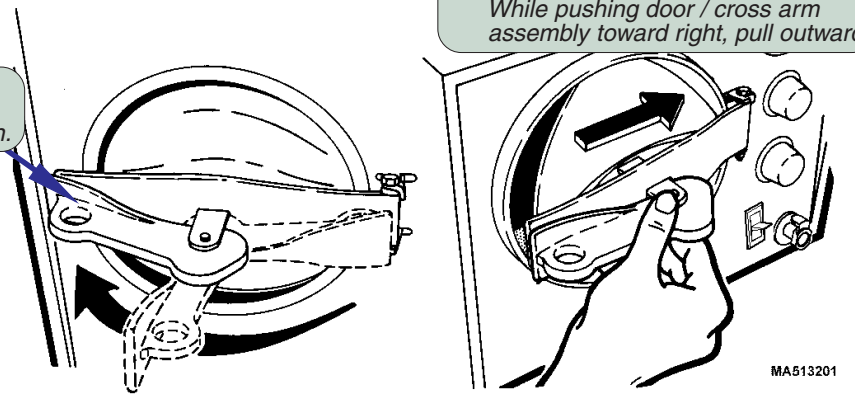
Operation

Opening Door

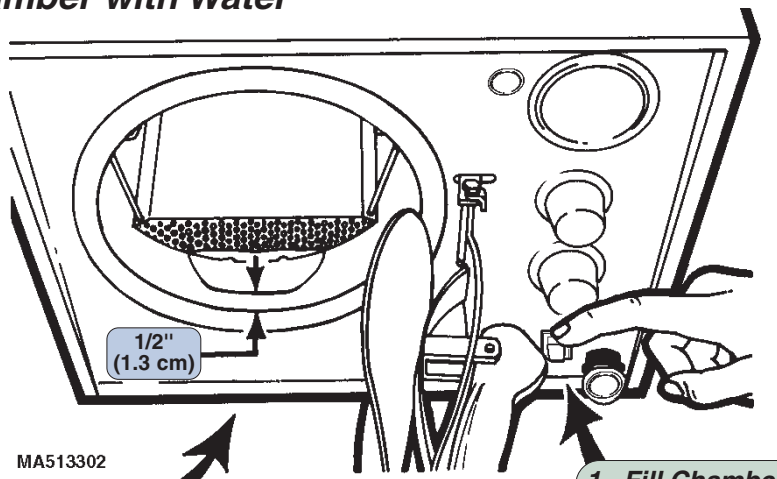
EQUIPMENT ALERT
Never run the Sterilizer without the Tray Rack installed.

1. Unlatch Door
Place handle in Unlatched position.

2. Open Door
While pushing door / cross arm assembly toward right, pull outward.



Filling Chamber with Water

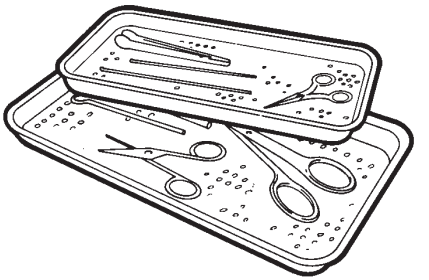


1. Fill Chamber
Press down and hold Fill / Vent Lever until water is within 1/2" (1.3 cm) of rim.

Note
Fill may take between 30 to 40 seconds dependent on water level in reservoir.

Place Trays Into Chamber

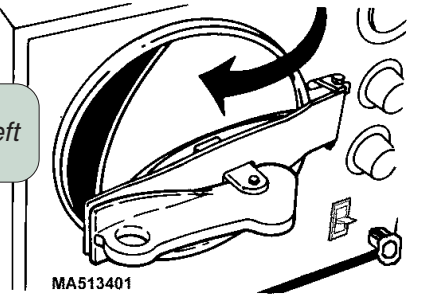
1. ***Pack Trays***
   Pack trays (see Loading Trays) then load into chamber.

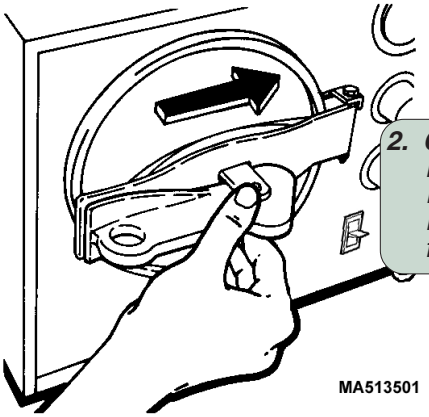


Note
Always include a process monitor strip with each load. Use only *Gravity Displacement Steam Sterilizer* monitor strips.

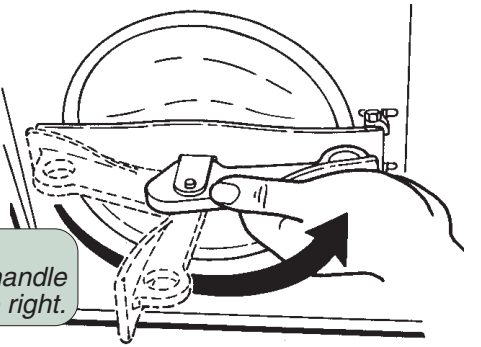
Close and Latch Door

1. ***Close Door***
   Swing door to left until it stops.





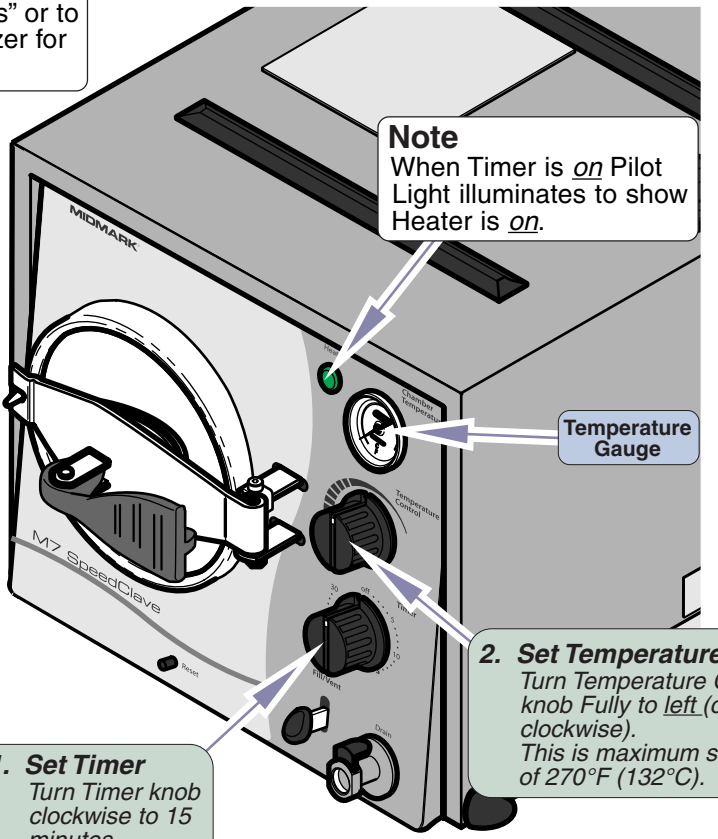
2. ***Close Door***
   Push door to right and swing inside chamber,then release. Door should spring back fitting inside chamber.



3. ***Latch Door***
   Swing door handle all the way to right.

Set Time & Temperature

Note
Refer to "Recommended Temperatures & Times" or to chart on top of Sterilizer for proper settings.



Note
When Timer is *on* Pilot Light illuminates to show Heater is *on*.

1. Set Timer
Turn Timer knob clockwise to 15 minutes.

2. Set Temperature
Turn Temperature Control knob Fully to left (counter-clockwise).
This is maximum setting of 270°F (132°C).

3. Re-Set Temp. Control
When Temperature Gauge reaches desired temperature, immediately turn Temperature knob slowly clockwise until pilot light goes out.

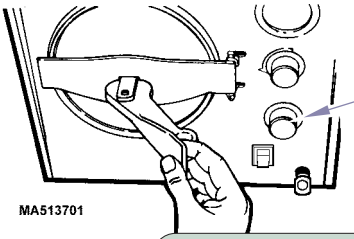
4. Re-Set Timer
After re-setting Temperature Control re-set Timer to desired sterilization time.

CAUTION
Temperatures set below 250°F (121°C) should not be used for sterilization, unless otherwise required by the device manufacturer. Temperatures below 250°F (121°C) are provided for disinfection only.

Note
Place a mark on front face of Temperature Control to mark position of knob for future reference.

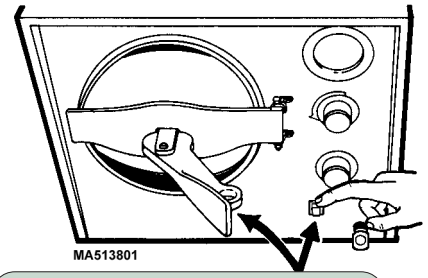
Venting Sterilizer

Note
Allowing Sterilizer to set *without venting* will cause items to come out wet



1. ***Vent***
   Turn Timer off when buzzer sounds.

2. ***Vent***
   Swing door handle to "Vent" position.



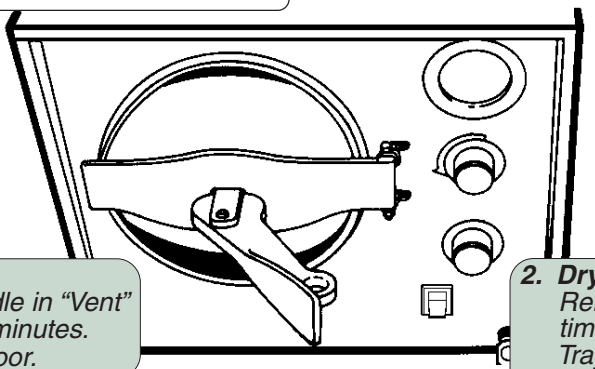
3. ***Vent***
   Hold Fill / Vent lever down until door "pops" inward. Leave door in "Vent" position. Do not open door.

CAUTION
The metal door and surronding metal surfaces are HOT!
Use care when operating door to prevent burns.

Drying

CAUTION
The metal door and surronding metal surfaces are HOT!
Use care when operating door to prevent burns.

EQUIPMENT ALERT
Do NOT turn on heat (Timer) or open door during 15 minute drying period.



1. ***Drying***
   Keep door handle in "Vent" position for 15 minutes. Do NOT open door.

2. ***Drying***
   Remove contents after Dry time has elapsed. Trays may be placed on racks on top of Sterilizer.

Operator Maintenance

CAUTION
Make sure that Sterilizer is cool before attempting to clean to prevent personal injury from burns.

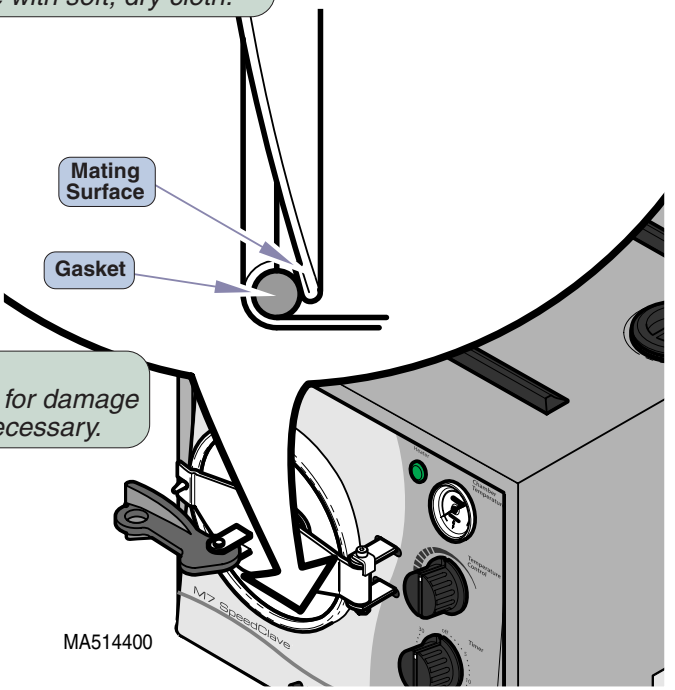
EQUIPMENT ALERT
Never use abrasive or bleaching agents (steel wool, scouring powder, bleach, etc. or a wire brush) to clean chamber. Damage to the chamber or related components could occur.

Daily

1. ***External Surfaces***
   Wash with damp cloth and mild soap solution, then wipe with soft, dry cloth.

2. ***Door Gasket & Surface***
   Wipe door gasket & mating surface with a damp cloth.

3. ***Door Gasket***
   Examine gasket for damage and replace if necessary.



Operator Maintenance

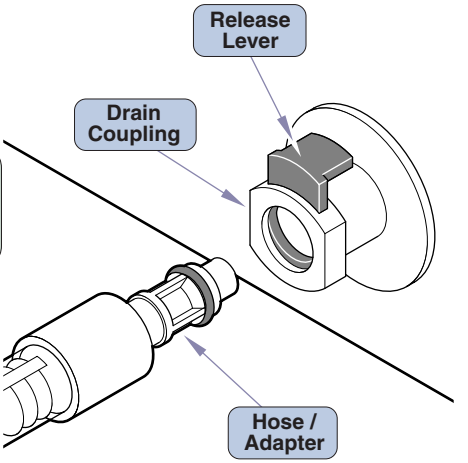
Weekly

Note
Refer to "Tray Rack" for Removal & Installation Instructions

1. ***Trays & Chamber***
   Wash with damp cloth and mild soap solution, then wipe with soft, dry cloth.

2. ***Drain Reservoir***
   Place end of hose in container and connect hose adapter to coupling.

Note
If drain coupling leaks after insertion or removal reinsert adapter / hose several times to clean seals, stopping leak.



MA514001

3. ***Remove Hose***
   Press down on release lever and remove hose assembly.

4. ***Fill Reservoir***
   Use only distilled or demineralized water.

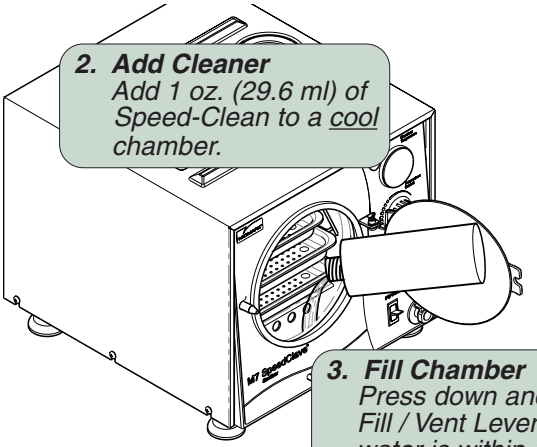
Operator Maintenance

Monthly (Flush The System)

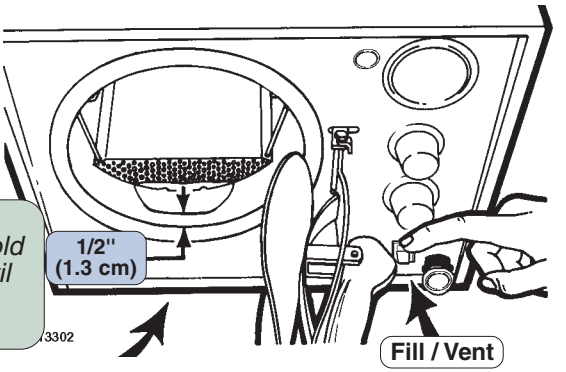
Note
Never sterilize instruments while performing cleaning procedures.

1. Drain & Refill Reservoir
Drain reservoir and refill with clean distilled or demineralized water. (Refer to Weekly Cleaning)

2. Add Cleaner
Add 1 oz. (29.6 ml) of Speed-Clean to a cool chamber.



3. Fill Chamber
Press down and hold Fill / Vent Lever until water is within 1/2" (1.3 cm) of rim.

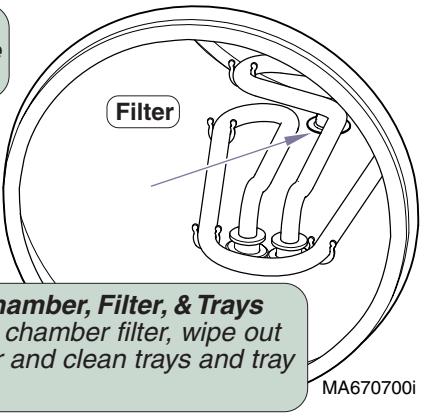


4. Run Cycle
Run one 6 Minute cycle at 270°F (132°C).

5. Drain & Refill Reservoir
Drain chamber and reservoir and refill with clean distilled or demineralized water.
(Refer to Weekly Cleaning)

6. Fill Chamber
Press down and hold Fill / Vent Lever until water is within 1/2" (1.3 cm) of rim.

7. Run Cycle
Run one 3 Minute cycle at 270°F (132°C).



8. Drain & Cool
Drain chamber and reservoir and allow sterilizer to cool, Remove trays and tray rack (Refer to Tray Rack Removal).

9. Clean Chamber, Filter, & Trays
Remove chamber filter, wipe out chamber and clean trays and tray rack.

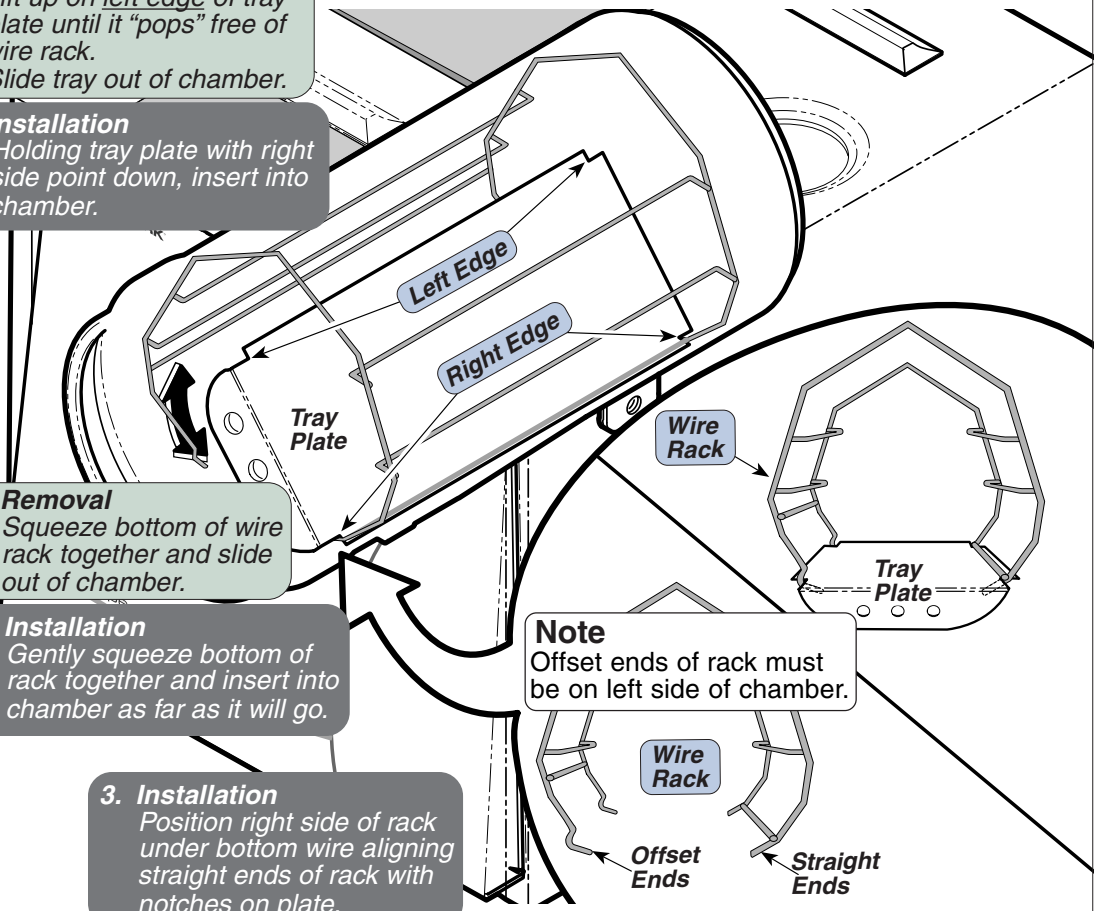
10. Refill Reservoir
Refill reservoir with clean distilled water. Install chamber filter, tray rack and trays.

Tray Rack

WARNING
Make sure unit is cool before attempting to remove or install tray rack and plate.
Use care to prevent injury when handling metal tray rack assembly.
Do NOT run sterilizer without Tray Rack assembly in place.

1. Removal
Lift up on left edge of tray plate until it "pops" free of wire rack.
Slide tray out of chamber.

1. Installation
Holding tray plate with right side point down, insert into chamber.



2. Removal
Squeeze bottom of wire rack together and slide out of chamber.

2. Installation
Gently squeeze bottom of rack together and insert into chamber as far as it will go.

Note
Offset ends of rack must be on left side of chamber.

3. Installation
Position right side of rack under bottom wire aligning straight ends of rack with notches on plate.

4. Installation
Holding right side of plate in position, press down left side of plate until it snaps into offsets of wire rack.

Troubleshooting Guide

Problem	Possible Cause	Solution
• **Timer On** • **No Pilot Light** • **No Heat**	Power cord not plugged into outlet	Plug into outlet.
	Facility circuit breaker to unit tripped.	Reset circuit breaker. If it continues to trip call Service Company.
	Sterilizer Fuse open.	Replace Fuse with same size (see Fuse Ratings).
	Overheat Thermostat(s) tripped.	Allow unit to cool 15 - 20 minutes. Add water to reservoir & chamber if necessary. Press Reset button and run cycle.
Process Monitor(s) show sterilization failure.	Process Monitor(s) out of date, malfunctioned, or is not rated for *Gravity Displacement Steam Sterilizers.*	Use a fresh monitor for *Gravity Displacement Steam Sterilizers*. Follow manufacturer's guidelines.
	Sterilization conditions were not present at location of monitor(s).	Reload Sterilizer per *"Loading Trays"* guidelines. Follow manufacturer's placement of monitor(s). If problem persist take unit out of service & contact Dealer or Servicer.
	Insufficient air removal, low temperature, or low pressure.	Take unit out of service and contact your Dealer or an Authorized Servicer.
Water leaks out door.	Overfilling chamber	Fill chamber until water is within 1/2" (1.3 cm) of front chamber rim.
	Sterilizer not level.	Level Sterilizer.
	Reservoir over FULL mark. Water siphoning into chamber.	Drain reservoir until level is within limits.
	Door gasket dirty or damaged.	Clean and / or replace door gasket.
Packs not dry.	Sterilizer overloaded.	Reload Sterilizer per *"Loading Trays"* guidelines. If problem persist take unit out of service & contact Dealer or Servicer.
	Sterilizer not level.	Level Sterilizer.
	Reservoir over FULL mark. Water siphoning into chamber.	Drain reservoir until level is within limits.
	Door being opened before Dry Cycle complete.	Leave door in "VENT" position for at least 15 minutes after venting unit
	Filter screen clogged in chamber.	Clean or replace filter screen.
	Supply voltage ot sterilizer too low.	Have a qualified electrician connect sterilizer to a separate dedicated circuit with proper voltage level.
Door Handle hard to open.	Dry cam on door handle. (Cam is surface that contacts door when in latched position).	Place a high temperature grease (300°F [149°C]) on cam part of handle.

Accessories

Accessories		
Description	**Part Number**	**Intended Use**
Speed-Clean® 1 (16 oz.) Bottle	002-0396-00	A cleaning solution used in the cleaning process of the Sterilizer.
Speed-Clean® 1 Case (12 [16 oz.] Bottles)	002-0396-01	A cleaning solution used in the cleaning process of the Sterilizer.
Cool Hand Tool	9A307001	Tool used to remove trays from Sterilizer chamber.

Specifications

Physical Dimensions:

Overall Length ..... 48.3 cm (19 in.)
Overall Width ..... 35.6 cm (14 in.)
Overall Height ..... 33 cm (13 in.)
Shipping Carton ..... 61 cm x 40.6 cm x 40.6 cm (24 in. x 16 in. x 16 in.)
Counter Area ..... 42 cm (D) x 39.4 cm (W) (16.5 in. x 15.5 in. includes 5 cm [2"] clearance on one side and back)
Chamber ..... 19.0 cm Diameter x 36.2 cm depth (7.5 in. Diameter x 14.25 in. depth)
Door Opening ..... 16.8 cm (6 5/8 in.)
Large Trays (2) ..... 30.5 cm x 14.3 cm x 22.2 cm (12 in. x 5 5/8 in. x 7/8 in.)
Small Trays (1) ..... 30.5 cm x 10.5 cm x 2.22 cm (12 in. x 4 1/8 in. x 7/8 in.)

Weight:

Empty Reservoir ..... 13.6 kg (30 lb.)
Full Reservoir ..... 19.0 kg (41.8 lb.)
With Shipping Carton ..... 17.7 kg (39 lb.)

Water Reservoir Capacity ..... Approximately 4.96 Liters to full mark (1.31 gallons).
Chamber Safety Valve ..... set at 214 kPa (31 PSI)

Warranty Information

Limited Warranty

SCOPE OF WARRANTY

Midmark Corporation (“Midmark”) warrants to the original purchaser its new Alternate Care products and components (except for components not warranted under “Exclusions”) manufactured by Midmark to be free from defects in material and workmanship under normal use and service. Midmark’s obligation under this warranty is limited to the repair or replacement, at Midmark’s option, of the parts or the products the defects of which are reported to Midmark within the applicable warranty period and which, upon examination by Midmark, prove to be defective.

APPLICABLE WARRANTY PERIOD

The applicable warranty period, measured from the date of delivery to the original user, shall be one (1) year for all warranted products and components.

EXCLUSIONS

This warranty does not cover and Midmark shall not be liable for the following: (1) repairs and replacements because of misuse, abuse, negligence, alteration, accident, freight damage, or tampering; (2) products which are not installed, used, and properly cleaned as required in the Midmark “Installation” and or “Installation / Operation Manual” for this applicable product. (3) products considered to be of a consumable nature; (4) accessories or parts not manufactured by Midmark; (5) charges by anyone for adjustments, repairs, replacement parts, installation, or other work performed upon or in connection with such products which is not expressly authorized in writing in advance by Midmark.

EXCLUSIVE REMEDY

Midmark’s only obligation under this warranty is the repair or replacement of defective parts. Midmark shall not be liable for any direct, special, indirect, incidental, exemplary, or consequential damages or delay, including, but not limited to, damages for loss of profits or loss of use.

NO AUTHORIZATION

No person or firm is authorized to create for Midmark any other obligation or liability in connection with the products.

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