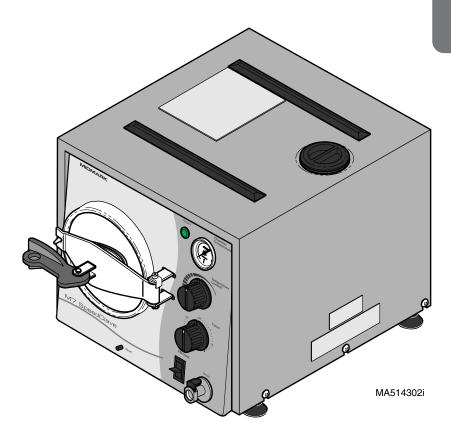


# M7 SpeedClave® Steam Sterilizer

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



User's Guide

## **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: Back of Unit Model / Serial Number Location MA511501i

## **Table of Contents**

Owner's Product Identification	
Calling For Service	2
Important Information	
Safety Symbols	3
Intended Use	4
Electromagnetic Interference	4
Transportation / Storage Conditions	4
Safety Instructions	4
Operating Environment Conditions	4
Electrical Requirements	5
Certifications	5
Operation Precautions	6
Steam Sterilization Monitoring	6
Location Requirements	7
Operation	
Instrument Cleaning	8
Loading Trays	8
Recommended Temperature & Times	9
Controls & Indicators	10
Preparation Before Operation	11
Operation	
Opening Door	12
Filling Chamber	12
Place Trays Into Chamber	13
Close & Latch Door	13
Set Time & Temperature	14
Venting	15
Drying	15
Operator Maintenance	
Cleaning	16
Daily	16
Weekly	17
Monthly	18
Tray Rack	
Removal	19
Installation	19
Troubleshooting	20
Accessories	
List of Authorized Accessories	
Specifications	21
Warranty Information	
Limited Warranty	22

## 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.

- 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



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.

## 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.

<u>Do not use</u> 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.



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

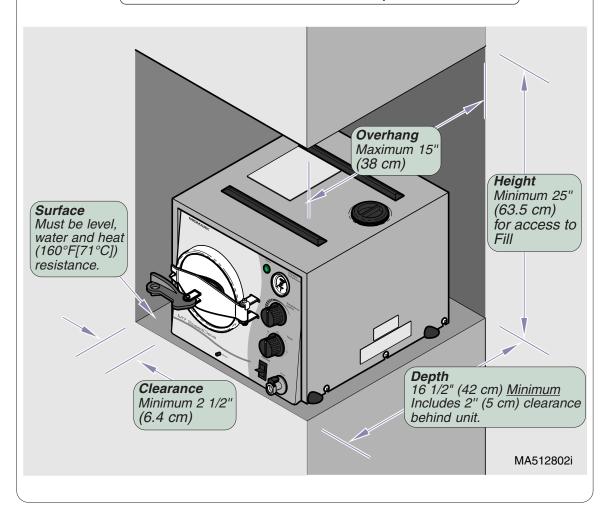
#### Follow appropriate agency

(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

<u>Do not use</u> this sterilizer in an explosive or oxygenrich 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.

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

## **Loading Trays**

Sterilize jointed instruments in an open position.









- I 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.
- Ü Do not wrap items too tightly.
  Steam penetration will be affected.
- Ü 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.
- Ï 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.) <i>or</i>
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)

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

## 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 <u>Exposure Time</u> *	* 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 <u>Exposure Time</u> *	* Instruments loose on a tray.  * Loosely wrapped individual instruments.  * Multiple 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 <u>Exposure Time</u> *	* 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 <u>begins</u> when the sterilizer <u>reaches</u> the sterilization temperature. Sterilization temperature <u>must be held</u> for the amount of time as recommended in the above chart.

<u>Not included</u> in Exposure Time are the time it takes to reach sterilization temperature and the time it takes to cool back down.

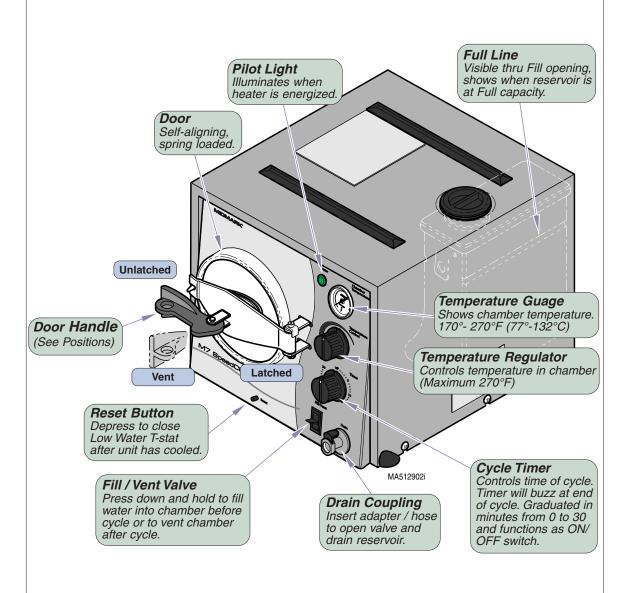
#### Suggested Extended Times At Reduced Temperature For Higher Altitudes

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:

- <u>Unwrapped Items</u> 250°F (121°C) for 15 minutes <u>exposure time</u>\*.
- Wrapped Items 250°F (121°C) for 20 minutes exposure time\*.

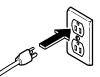
## **Controls & Indicators**



## 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.

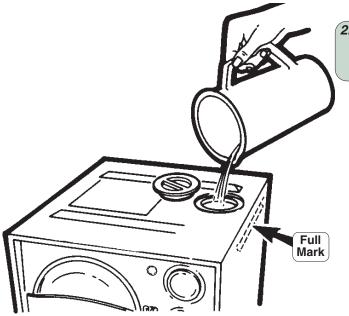


1. Plug Unit In
Plug Sterilizer into
an outlet that has a
dedicated circuit.

#### **EQUIPMENT ALERT**

Use only distilled or demineralized water.

Do <u>Not</u> 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.

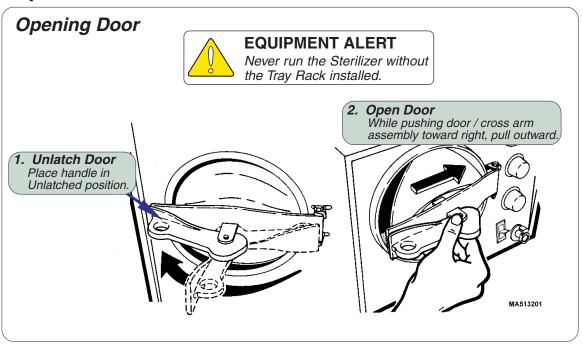
#### Note

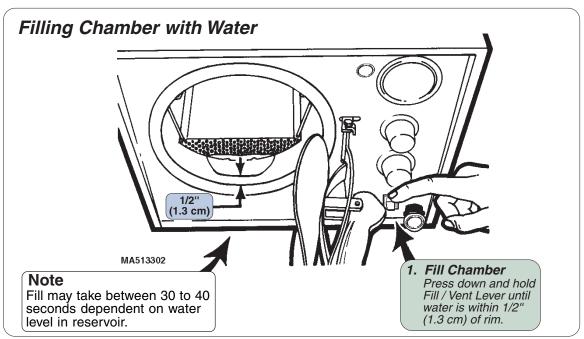
#### Do not overfill reservoir.

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**





## Place Trays Into Chamber

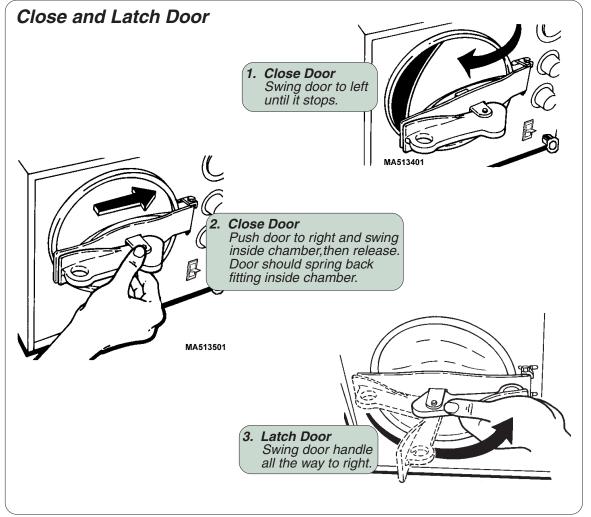
1. Pack Trays

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.

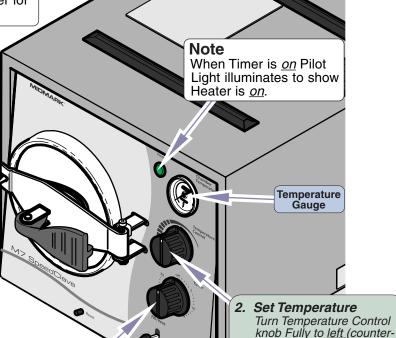




#### Set Time & Temperature

#### Note

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



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

#### 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.

3. Re-Set Temp. Control

This is maximum setting

of 270°F (132°C).

clockwise).

When Temperature Gauge reaches desired temperature, immediately turn Temperature knob slowly clockwise until pilot light goes out.

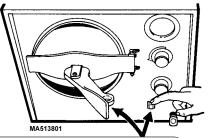
#### Note

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

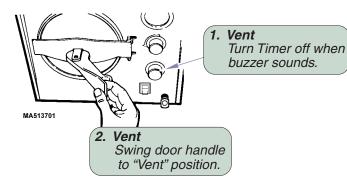
## Venting Sterilizer

#### **Note**

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



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 <u>HOT</u>! re when operating door to

Use care when operating door to prevent burns.

## **Drying**



#### **CAUTION**

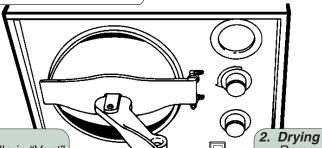
The metal door and surronding metal surfaces are HOT!

Use care when operating door to prevent burns.



#### **EQUIPMENT ALERT**

Do <u>NOT</u> turn on heat (Timer) or open door during 15 minute drying period.



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

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

## Operator Maintenance



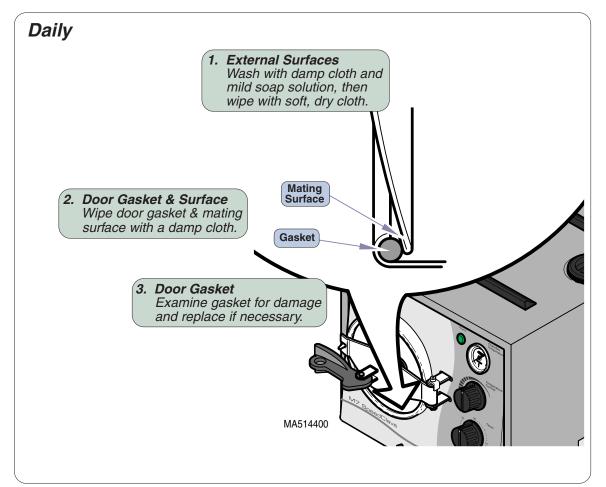
#### **CAUTION**

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.



## Operator Maintenance

## Weekly

#### **Note**

Refer to "<u>Tray Rack</u>" 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.

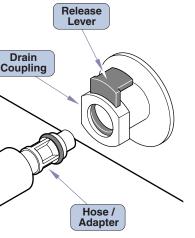
#### Note

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

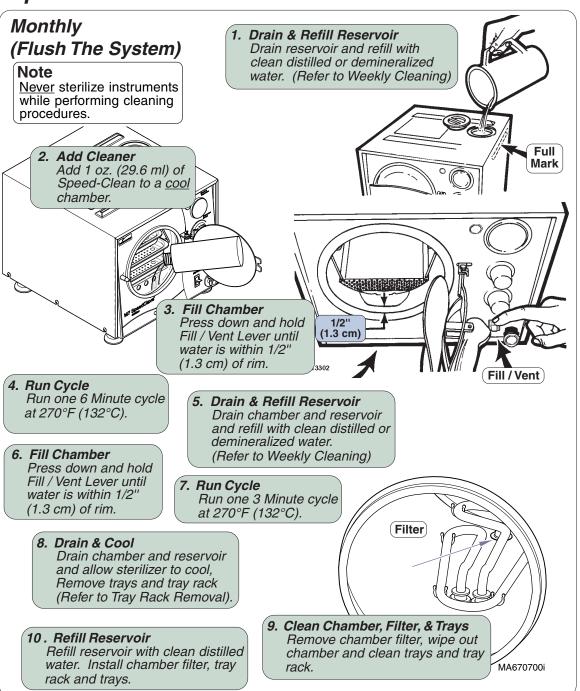
3. Remove Hose
Press down on release lever
and remove hose assembly.

MA514001

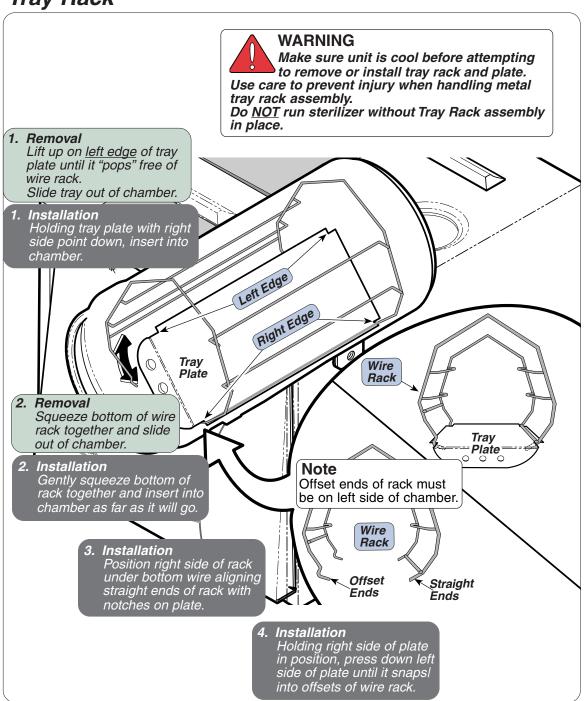
**4. Fill Reservoir**Use only distilled or demineralized water.



## **Operator Maintenance**



## Tray 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 <i>Gravity Displacement Steam Sterilizers</i> . 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 campart 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. <u>includes</u> 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	
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	- · · · · · · · · · · · · · · · · · · ·
Full Reservoir	<del>-</del> , , ,
With Shipping Carton	17.7 kg (39 lb.)
Water Becomedit Consolity	Ammunimentals, 4.00 Litera
Water Reservoir Capacity	• • • • • • • • • • • • • • • • • • • •
Chambay Cafaty Valva	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.

THIS WARRANTY IS MIDMARK'S ONLY WARRANTY AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED. MIDMARK MAKES NO IMPLIED WARRANTIES OF ANY KIND INCLUDING ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE. THIS WARRANTY IS LIMITED TO THE REPAIR OR REPLACE MENT OF DEFECTIVE PARTS.

SF-1487 REV. A1

