SteriDENT
DRY HEAT STERILIZERS

cpac Equipment Inc.

Dry Heat Sterilizer models 200 and 300

Operating Instructions

MODEL 200

MODEL 300

cpac Equipment Inc.

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SAVE THESE INSTRUCTIONS

To avoid electrical shock hazard, do not disassemble this appliance unless you are an authorized service technician. Contact a CPAC authorized service technician when service or repair work is required. Incorrect reassembly can cause an electric shock hazard. Unauthorized repair or replacement of parts by non-certified personnel will void of all warranty guarantees.

WARNING: NEVER ATTEMPT TO PERFORM ANY ELECTRICAL TROUBLESHOOTING ADJUSTMENT(S) OR SERVICE(S) UNLESS YOU ARE A QUALIFIED ELECTRICIAN, ELECTRONICS TECHNICIAN OR FACTORY TRAINED SERVICE TECHNICIAN.
The protection provided by the equipment may be impaired if the Sterilizer is used in a manner not specified in this manual.

IMPORTANT SAFEGUARDS

When using the Steri-Dent Dry Heat Sterilizer, follow these basic safety precautions:

1. Read and understand all instructions.

2. Care must be taken to avoid burns from touching hot parts.

3. Do not operate this appliance with a damaged cord or if appliance has been dropped or damaged until it has been examined by a qualified service technician.

4. Do not let power cord hang over edge of table or counter or touch hot surfaces.

5. An extension cord should not be used with this unit. The unit should be plugged directly into a power outlet. Only use a properly grounded fuse/breaker protected outlet (110V, 60 cycles, or a 220/240V, 50 cycles). A separate circuit is recommended.

6. To protect against electrical shock hazard, do not immerse this appliance in water or other liquids.

7. To avoid electrical shock hazard, do not disassemble this appliance. Call a qualified service technician when service or repair work is required. Incorrect reassembly can cause electric shock hazard.

8. Do not lift unit by the handle. Hold securely by the bottom when lifting or moving unit.

SAVE THESE INSTRUCTIONS

OPERATING INSTRUCTIONS

STERILIZER SET UP (First time only)
Before using the sterilizer for the FIRST time, the thermostat setting must be checked to ensure the sterilizer will operate at the proper temperature. For 320°F (160°C), verify the number "7" on the thermostat dial is lined up with the black marking dot located on the right side of the sterilizer. Set the timer to "HOLD" position.

After approximately 45 minutes, check the thermometer. It should read between 320°F (160°C) and 330°F (165°C). If not, adjust the thermostat dial and wait approximately 15 minutes for the temperature to change. NOTE: The thermostat dial is very sensitive. Decreasing the dial by 1 will drop the temperature approximately 15°F. Continue to adjust the thermostat as needed until the thermometer reads between 320 Degrees F (160 Degrees C) and 330 Degrees F (165 Degrees C). Temperatures may vary during initial heat-up period.

STERILIZER PROCEDURES
Steri-Dent Dry Heat Sterilizers* are intended for indoor use in hospitals and dental, orthodontic and health care facilities, veterinary, beauty and body art salons. They come equipped with a mechanical automatic timer, bi-metal thermostat, and thermometer.

Steri-Dent sterilizers are the result of a design that has been in use for many years by dentists, hospitals, and the U.S. Armed Forces. This design has been refined and improved over the years to make it safe and simple to operate, easy to use, and low in cost to operate. It is user friendly and very reliable, but requires the operator to choose the proper loading, temperature, and time settings to ensure complete sterilization.

***The Steri-DENT Sterilizer is non-patient care equipment.**

INSTRUCTIONS FOR OPERATION

MECHANICAL AUTOMATIC TIMER
The timer serves as the ON/OFF switch for the sterilizer. To activate the timer and turn the sterilizer on, turn the knob clockwise (right) past the number "10". The timer can then be set for the desired time as indicated on the calibrated scale dial. If intending to run additional cycles during the workday, turn the knob to the "Hold" position when a cycle is complete.

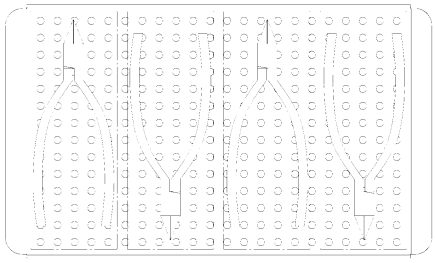
To set the timer for "warm up" or continuous operation, turn the knob counter clockwise (left) to the "HOLD" position. CAUTION: The sterilizer will remain on and in the warm up condition until it has been manually turned off or set for a timed sterilization cycle.

WARM UP - The sterilizer should be warmed up in preparation for a sterilization cycle. Before turning the sterilizer on, visually inspect the interior heating chamber. Close the door and turn the timer to the "HOLD" position. The unit will warm up and maintain 320°F (160°C) until a cycle is started. Do not insert a sterilization load until the unit has reached a temperature of 320°F.

CYCLE START - Before beginning a sterilization cycle, be sure instruments are clean and free of debris (for information about which materials can be safely sterilized refer to instruments validated for use in the sterilizer above). Prepare all instruments for sterilization by rinsing or using an ultrasonic cleaner, as recommended by the Centers for Disease Control (CDC).

Thoroughly rinse the instruments and pat dry with a paper towel. The CDC recommends bagging or pouching the instruments prior to sterilizing. *Sterilization bags specific to dry heat sterilization Must be used. Bags and pouches are available from Steri-Dent.*

In order to ensure sterility, instruments intended to be stored must be sealed in Steri-DENT nylon pouches prior to sterilization.
Steri-DENT Part No. 400597B, Dry Heat Sterilization Bags, 2.5" X 1.5" X 10.5"
Steri-DENT Part No. 400636, NYLON SELF SEAL POUCHES 2" X 10"
Steri-DENT Part No. 400651, NYLON SELF SEAL POUCHES 3" X 10"
Steri-DENT Part No. 400637, NYLON SELF SEAL POUCHES 4" X 10"
Steri-DENT Part No. 400638, NYLON SELF SEAL POUCHES 7" X 10.5"
Steri-DENT Part No. 400639, NYLON SELF SEAL POUCHES 9.5" X 13"



Instruments should be placed in a single layer and distributed evenly on the sterilizer's trays. Instruments should not touch each other. Load instruments into sterilizer and pre-heat to temperature indicated in the TIME/TEMPERATURE chart. Run the sterilization cycle for the length of time indicated.

NOTE: Allow time for instruments to reach operating temperature before starting the time cycle.

TIME/TEMPERATURE CHART

Contents	Preparation	Temperature	Time
Metal instruments, surgical blades, etc	Thoroughly cleaned and spread out on trays.	320 Degrees F 160 Degrees C	60 minutes

MAXIMUM LOADING
Model 200 Sterilizer – 1.3 pounds per tray (includes the weight of the tray)
Model 300 Sterilizer – 1.4 pounds per tray (includes the weight of the tray)

MATERIALS INTEGRITY

The Steri-DENT sterilizer is designed to operate at 320°F (160°C), but could potentially reach temperatures up to 392°F (200°C). Tests have been conducted on various surgical and dental instruments as to compatibility with these temperatures. Generally, medical and dental stainless and carbon steel hand instruments are safe in the Steri-DENT sterilizer. **Caution**: **Instruments containing plastic and rubber goods should not be sterilized in dry heat sterilizers.** When in doubt, consult the instrument manufacturer.

CAUTIONS

- During operation, the door and outer housing as well as the heating coils, trays and sterilized instruments will be hot. Caution should be taken when handling hot instruments and trays. Use tool accessory to change out trays.
- The sterilizer is designed for use with metal instruments. While many new plastics, Teflon and rubber products can be used in a high temperature environment, extreme care should be used in sterilizing these materials until compatibility has been confirmed by the instrument manufacturer.
- When sterilizing packaged instruments, use only dry heat packaging material suitable for 392°F (200°C) temperatures. All items being sterilized and any associated wraps should be able to withstand temperatures up to 200°C (392°F).
- Instruments that have been wiped with alcohol or other flammable liquids **must** be allowed to dry completely before being placed in the sterilizer. Do not allow flammable materials or liquids within 12 inches (30.5 cm) of the sterilizer.

- **Use only dry heat pouches supplied by Steri-DENT.**

Instruments Validated for Use in Sterilizer

The Model 200 and 300 sterilizers have been validated to sterilize the Sirona Dental Systems, Cerex Omnicam sleeve and simple metal instruments such as those with hinges, mated surfaces, and lumens. Examples are cutters, pliers, mirrors, scalers, forceps, brackets, bands, burrs, amalgam plungers (lumens of 11mm maximum length by 2.5 minimum diameter), nippers, clippers, tweezers, and other similar devices.

The Model 200 and 300 sterilizers have not been validated to sterilize complex devices such as those that have power-driven machinery or multiple moving parts. These complex devices should only be sterilized according to the device manufacturer's instructions. A list of instruments compatible for dry heat sterilization can be found on our web site at www.cpac.com.

SAFETY NOTES CONCERNING TEMPERATURE

The temperature in the Steri-DENT sterilizer is controlled by a bi-metal thermostat, which is calibrated during manufacturing to maintain temperature throughout the sterilizer chamber. The temperature control is extremely sensitive and calibrated to maintain 320° F (160°C).

After room temperature instruments are placed in the sterilizer, the temperature may drop a few degrees depending on the size of the load. Leave the timer in the HOLD position and Do Not begin the sterilization cycle until the thermometer temperature has returned to 320°F (160°C).

Do not open the door during a sterilization cycle as this will result in possible spore test failures and incomplete sterilization of instruments.

THERMOMETER & THERMOSTAT

The bi-metal thermostat is used to adjust the temperature of the sterilizer. The glass thermometer on the front of the unit indicates the sterilizer's chamber temperature.

PILOT LIGHTS

The sterilizer has two (2) pilot lights. The left light will be on as long as the timer switch is in the "ON" position indicating the unit has power. The right light is on only while the heating elements are operating and heating the sterilization chamber. Once the chamber has reached sterilization temperature, the light will come on intermittently as current is needed to maintain the chamber temperature.

ACCESSORIES

The Steri-DENT sterilizer comes equipped with two or three instrument trays and a tool for changing trays. Biological indicator test strips, spore testing kits, and Steri-Dent brand nylon pouches are available from your distributor or CPAC. Depending on the size of your practice, you may wish to purchase additional trays.

Chemical Indicator Use

When using a sterilization bag, the chemical indicator listed below may be placed on the outside or inside the bag along with the instruments to provide an indication the instruments have gone through a sterilization cycle before use. The chemical indicator should only be used to prevent the accidental use of a bag of instruments that has not been sterilized. It is not a means of proving the instruments are being sterilized properly. See section on Biological Testing for instructions on periodic testing of the effectiveness of the sterilizer.

Dry Heat Chemical Indicator Strips supplied by Steri-DENT are recommended, part no. 400635.

Spore Test Strips

The Centers for Disease Control (CDC) recommends the sterilizer be tested weekly. For Dry Heat Sterilizers, use Bacillus Atrophaeus spore test strips, CPAC part number, 400664.

CLEANING AND MAINTENANCE

The Steri-DENT sterilizer is designed for minimum and easy service. Clean the inside and outside of the sterilizer with a stainless steel cleaner at least once a month. We recommend Cleaning Kit #201009. When cleaning the inside of the chamber, spray cleaner on cloth first and avoid contact with heating elements. Use a wet cloth to wipe away any cleaner residue and then follow with a dry cloth to wipe dry.

All of the electrical and mechanical components used in the sterilizer's construction are long life, heavy-duty parts that require no maintenance. An authorized service representative or CPAC should be contacted if any of these parts need to be replaced.

Replace the inner door gasket once a year, or sooner if it becomes loose or worn. Order gasket #201108 for Model 200 or #301108 for Model 300. Replace the thermostat if the temperature control becomes erratic or every 3 years. Order part #201032 for Model 200 or part #301032 for Model 300.

POWER SOURCE AND RATINGS

Standard units operate on 115 VAC electrical power. Other voltages are available upon request. Voltage rating is printed on the nameplate located near power cord.

Model 200 Power Rating – 500 Watts Model 300 Power Rating – 735 Watts

SIMULATED USE TESTING

A full load of sample metal instruments depicted in Figure 1 were tested in load configurations depicted in Figures 2 and 3. Performance testing was conducted to validate that the sterilizer cycle parameters are safe and effective.

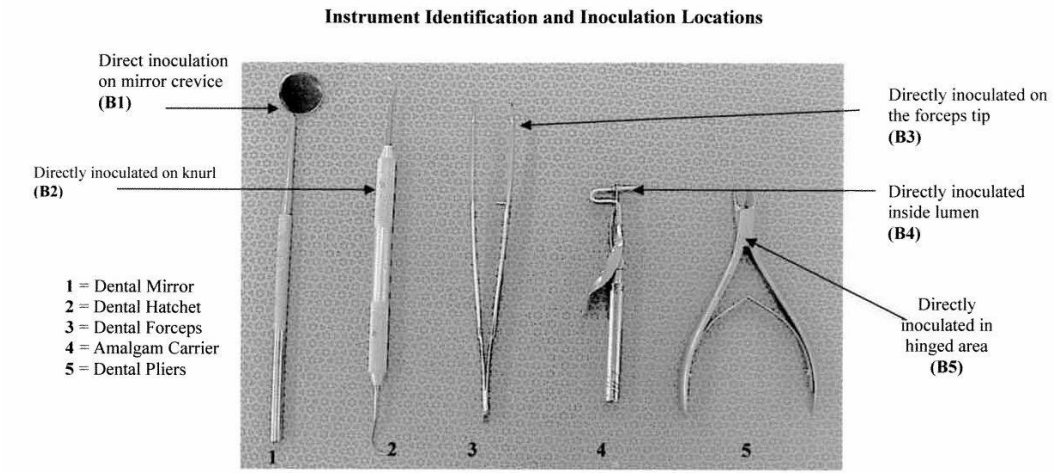
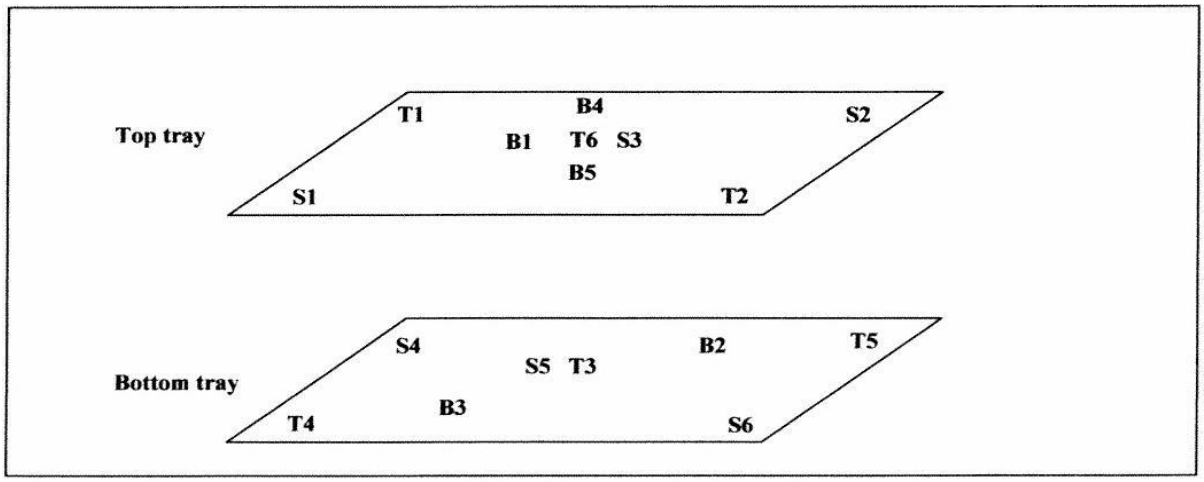
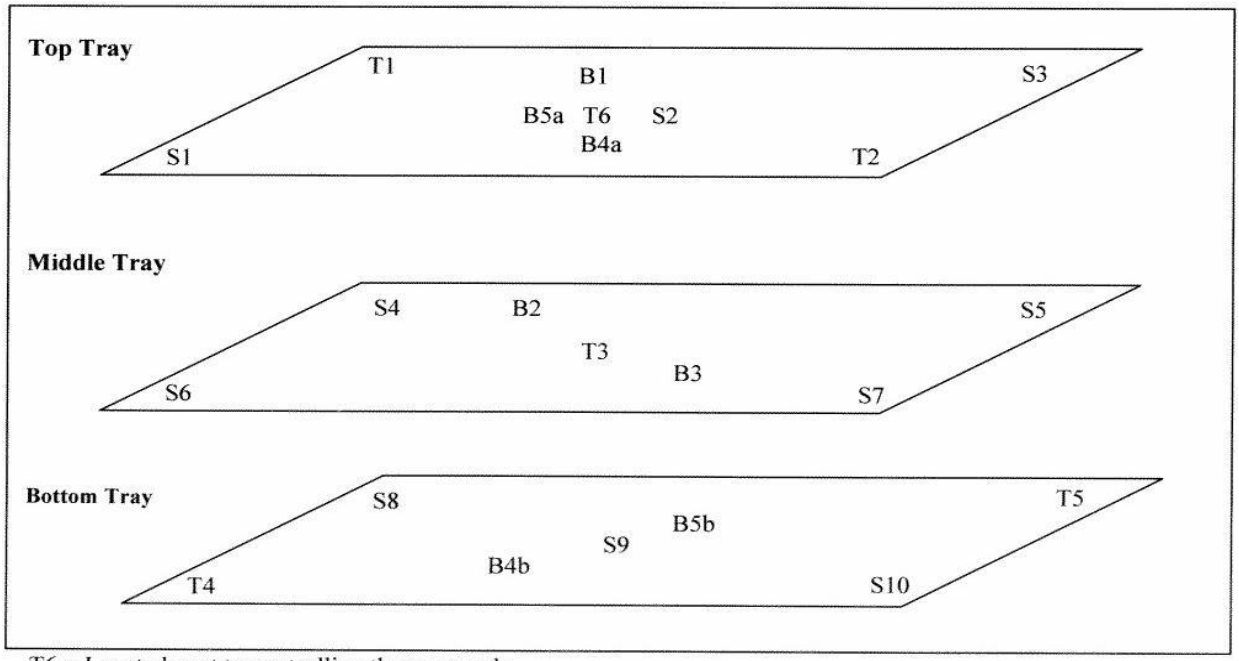


Figure 1



T6 = Located next to controlling thermocouple
S1 thru S6 = BI Strip
B1 thru B5 = Inoculated device

Figure 2: Test Load Configuration for Model 2100



T6 = Located next to controlling thermocouple
S1 thru S10 = BI Strip
B1 thru B5b = Inoculated instrument

Figure 3: Test Load Configuration for Model 3100

ENVIRONMENTAL CONDITIONS

The Steri-Dent sterilizer is designed for indoor use with the following conditions:

- Temperature Range of 5°C to 40°C (41°F to 104°F)
- Maximum Relative Humidity of 80% up to 31°C (88°F). Decreasing linearly to 50% at 40°C (104°F).
- Pollution Degree 2 applies in accordance with IE 664.
- Transient Over-voltage Category II applies.
- Supply voltage not to fluctuate more than 10% (+/-12V at 120V, +/-22V at 220V)
- Maximum altitude of 2000 m (6562 ft).

UNIT ELECTRICAL RATINGS

MODEL 200	115 VAC, 50/60 Hz, 10 Amps
MODEL 300	115 VAC, 50/60 Hz, 10 Amps
MODEL 200-220V	230 VAC, 50/60 Hz, 5 Amps
MODEL 300-220V	230 VAC, 50/60 Hz, 5 Amps

FAILURES SYMPTOMS and TROUBLESHOOTING

The following symptoms or failures listed in **Bold** are followed by steps to help trouble shoot the cause of the symptom or failure. If the information in this technical manual does not help in correcting or repairing the problem, please contact CPAC Technical Service at 585-382-3223.

Burning/Melting bags/pouches – Verify the following:

1) Temperature reads 320-330°F. If temperature too high, check thermostat and adjust/replace.
2) Instruments are clean, free of all cleaning agents or compounds, and DRY.
3) Bags/pouches are labeled for DRY HEAT USE ONLY to be used in the sterilizer.
4) Bags/pouches are not left in sterilizer for more than 15 minutes after cycle is complete.

Failing spore tests – Verify the following:

1) Instruments are DRY, placed in single tier level, not stacked, and trays not overloaded; see maximum load parameters in Operating Instructions.
2) Bags/pouches are labeled for DRY HEAT USE ONLY for use in the sterilizer.
3) Bacillus Atrophaeus (BI) spore strip is sealed in a dry heat bag/pouch for testing.
4) Temperature reads 320-330°F before cycle is started and cycle ran for 60 minutes.
5) Was cycle observation data recorded (temperature readings at 1st and 5 minute intervals)
6) Refer to Biological Testing Protocols section for further guidance

Thermometer not reading 320-330°F – Verify the following:

1) Thermostat knob is set to 7. Adjust knob until thermometer reads 320-330°F. If not able to set proper temperature through knob adjustment (too hot, or too cold), replace thermostat (Model 200–201042 and Model 300-301032).
2) Is there liquid in the thermometer? Remove thermometer bracket on front of unit and pull out thermometer. If thermometer is broken and/or liquid has leaked out/missing, replace thermometer (201024-A).
3) If recently replaced, is thermometer threaded under chamber insulation to allow proper temperature readings?
4) Refer to Steri-Dent Thermometer/Thermostat Replacement Instructions for assistance.

U**nit won't reach or hold temperature –** Verify the following:

1) Unit is plugged in.
2) Fuse in place, thermostat knob set at 7.
3) Thermometer temperature is rising during heating cycle and able to set temperature. If not able to set proper temperature, replace thermostat (Model 200 – 201032 and Model 300 - 301032).
4) Refer to Steri-Dent Thermostat Replacement Instructions for assistance. If thermostat replacement does not work, replace thermostat circuit switch (210042). Refer to Steri-Dent Thermostat Replacement Instructions.

Timer not timing down – Verify the following:

1) Check that timer dial turns properly. Must turn past 10 minutes for timer to work.
2) Empty sterilizer and turn timer to 120 minute setting. If timer does not reach 0 (zero) in 2 hours, replace timer (201042S).
3) Refer to Steri-Dent Timer Replacement Instructions for assistance.

Pilot lights not lit/functioning – Verify the following:

1) Unit plugged in and timer knob set to HOLD position or starting a cycle.
2) Left light illuminates as long as the timer switch is in the ON position. If not lit when in the HOLD position or during any sterilization cycle, replace the light.
3) The right light illuminates only while the heating elements are operating and heating the sterilization chamber. Light should be lit during warmup and to maintain sterilization temperatures. If not lit replace light.
4) Refer to manufacturer replacement instructions.

No power to unit – Verify the following:

1) Unit plugged in.
2) Pull and check the fuse to see if blown.
3) Check office circuit breakers if tripped or there was a recent power outage.
4) Check unit fuse holder, circuit switch and wire connections (requires removal of back panel and insulation).
5) Refer to manufacturer replacement instructions.

STERI-DENT Model 200/300 Troubleshooting Quick Reference Diagnosis and Repair Chart

STERI-DENT	**MODEL 200/300**	
FAILURE/ERROR CODE	**VERIFY**	**Remedy**
Failing spore tests	1) Thermometer reads 320-330°F before cycle is started.	Adjust thermostat to obtain correct thermometer range. Replace thermostat. Refer to Steri-Dent Thermostat Replacement Instructions for assistance.
	2) Instruments are placed on single tier level and not stacked.	Separate instruments into single tier.
	3) Proper spore test strips being used.	If not, replace with Bacillus Atrophaeus spore test strips.
Burning bags/pouches	1) Thermometer reads 320-330°F.	Adjust thermostat to obtain correct thermometer range. Replace thermostat.
	2) Bags/pouches are labeled for use in a dry heat sterilizer.	Use manufacturer recommended dry heat bags/pouches.
	3) Bags/pouches are not left in sterilizer for more than 15 minutes after cycle is done.	Remove bags/pouches when cycle completes.
Thermometer damaged or liquid missing	1) Check thermometer, remove bracket on front of unit and pull out thermometer to check.	If thermometer is broken and/or liquid has leaked out, replace thermometer (201024-A). Refer to Steri-Dent Thermometer Replacement Instructions.
Unit won't reach or hold temperature (320-330°F)	1) Thermostat knob is set to 7.	Adjust knob until thermometer reads 320-330°F. If not able to set proper temperature, replace thermostat.
	2) Thermometer is not damaged.	Replace thermometer and check with thermostat adjustment.

	3) Thermometer too cold	Check thermometer is threaded under chamber insulation.
	4) Knob adjusted too high/low	Set knob to 7 and stabilize temp. If unit won't hold 320-330°F, replace thermostat. Refer to Thermostat replacement instructions
Unit not heating or No Power	1) Unit plugged in.	Plug in unit, set timer, check thermometer reading, adjust thermostat knob to 7.
	2) Pilot lights on, temperature rising, thermostat knob at 7.	Check thermostat circuit switch (210042) for damage. Replace circuit switch.
	3) Check fuse is in place and working.	Replace fuse/fuse holder.
	4) Element tabs not loose, no broken connections	Replace bad element.
Timer not timing down	1) Timer turned past 10 minutes to test function.	If timer does not reach 0 (zero) in 2 hours, or function turned past 10 minutes, replace timer (201042S). Refer to Steri-Dent Timer Replacement Instructions.
	2) Empty sterilizer and turn timer to 120 minute setting to verify function.	
Pilot lights not lit	1) Unit plugged in.	Plug unit in and turn timer knob to HOLD position, check lights, replace bad one. Refer to Steri-Dent Pilot Light Replacement instructions.
	2) Left pilot light lit during cycle operations.	If not lit during operation replace left pilot light.
	3) Right pilot light lit when unit is heating.	If not lit during heating operations, replace right pilot light.

SteriDENT
DRY HEAT STERILIZERS

SPECIFICATIONS:

Sterilization Time:	60 Minutes
Unit Size (Outside Dimensions):	
Model 200	15.5” W x 9.5” D x 10.5” H / 394 x 241 x 267 mm
Model 300	19” W x 11” D x 14.5” H / 483 x 279 x 368 mm
Chamber Size (Inside Dimensions):	
Model 200	11.25” W x 7.5” D x 4.75” H / 286 x 190 x 121 mm
Model 300	13.5” W x 8” D x 6.75” H / 343 x 203 x 171 mm
Weight:	
Model 200	13 lbs (6 kg)
Model 300	20 lbs (9 kg)
Dimensional Shipping Weight/Dimensions:	
Model 200	16 lbs, 20” x 16” x 14”
Model 300	45 lbs, 22” x 18” x 18”
Tray size:	
Model 200 (2 trays)	10” W x 6.25” D, 254 mm x 159 mm
Model 300 (3 trays)	11.75” W x 7.25” D, 298 mm x 184 mm
Electrical:	110V-120V, 60 Hz, or 220V-240V, 50 Hz Model 200 - 500 Watts, Model 300 - 750 Watts
Sterilization Temperature:	320° Fahrenheit (160° Celcius)
Warranty:	Three years (parts and labor)
Models:	200, 300
Approvals:	ETL FDA 510(k) K771070 IEC Safety Standard 61010-2-040 UL 61010-1, CAN/CSA C22.2 No. 61010-1

Intertek Intertek

For additional technical advice, service instructions or parts, contact CPAC Equipment, Inc.
Technical Services: (800) 828-6011 or (585) 382-3223

STERI-DENT STERILIZER SPARE PARTS LIST

Many of the items listed below require installation by an appropriately trained technician. Contact CPAC by telephone at (585) 382-3223 for assistance.

Part Number	**Description**
MODEL 200	**Part Number**
Thermostat, SD 200	201032
Extra Tray for Model 200 – 10 x 6 ¼	201095
Door Gasket Kit, SD 200	201108
Right Side Heating Element	201058
Left Side Heating Element	201059
MODEL 300	
Thermostat, SD 300	301032
Extra Tray for Model 300 – 12 x 7 ¼	301095
Door Gasket Kit, SD 300	301108
Side Heating Elements, SD 300	301058
Bottom Heating Element, SD 300	301059
COMMON PARTS – BOTH MODELS	
Rubber Foot	CX0051
Tray Handle – Both Models	CX0047
Fuse, 10A, 250V slow blow ceramic (115V units)	CX0076
Fuse, 5A, 250V Ceramic (230V units)	PV229
Dry Heat Sterilizer Cleaning Kit	201009
Thermometer Bracket	201021
Thermometer	201024-A
Thermostat Knob	201030
Pilot Light, Red – 230V Power Indicator	201038
Pilot Light, White – 115V only	201039
Pilot Light, White – 230V Heating Indicator	201040
Timer	201042
Door Handle	201073
Needle Tray	201096
Circuit Thermostat	210042
Fuse Holder	302110

BIOLOGICAL TESTING

The American Dental Association, United States Air Force, Joint Commission of Accreditation of Hospitals, and the Centers for Disease Control recommend biological indicator tests to verify the sterilizer's performance.
CPAC Equipment, Inc. recommends that a biological indicator and the recommended test load of 2.6 lbs for model 200 and 4.2 lbs for model 300 be used on a weekly basis or every 25 cycles, whichever comes first, to test the effectiveness of the sterilizer.

Recommended and Required Equipment

For monitoring dry heat, biological indicators containing *Bacillus atrophaeus* should be used along with the recommended test load. Spore test strips, as well as test services are widely available through universities and commercial services.

- Chemical indicators supplied by Steri-DENT are recommended, part. no. 400635
- Spore test strips supplied by Steri-DENT are recommended, part no. 400634
- The test load should be a full load consisting of simple metal instruments such as those with hinges, mated surfaces, and lumens. Examples are cutters, pliers, mirrors, scalers, forceps, brackets, bands, burrs, amalgam plungers (lumens of 11mm maximum length by 2.5 minimum diameter), nippers, clippers, tweezers, and other similar devices. A full load consists of 1 lb. of instruments per tray (plus weight of the tray)
  NOTE: Model 200 tray weighs 0.3 lbs.
  Model 300 tray weighs 0.4 lbs.
  - Self Sealing nylon pouches from Steri-DENT are recommended:

  Steri-DENT Part No. 400636, NYLON SELF SEAL POUCHES 2" X 10"
  Steri-DENT Part No. 400651, NYLON SELF SEAL POUCHES 3" X 10"
  Steri-DENT Part No. 400637, NYLON SELF SEAL POUCHES 4" X 10"
  Steri-DENT Part No. 400638, NYLON SELF SEAL POUCHES 7" X 10.5"
  Steri-DENT Part No. 400639, NYLON SELF SEAL POUCHES 9.5" X 13"

Introduction
Biological indicators are used in healthcare to validate protocols and operational parameters of a sterilization process. Sterilizers are operated under standard operational protocols required of the manufacturer to meet FDA and ANSI/AAMI standards and criteria. For dry heat sterilizers, time and temperature are the parametric criteria demanded of the sterilizer to provide the conditions by which sterilization will occur. To effect instrument sterilization under the prescribed time-temperature sterilization profile, protocols for packaging and loading that are established through national standards (as well as those sterilizer-specific as mandated by FDA 510(k)'s must be followed.

To assure that both the sterilization unit is functioning properly and that operational protocols are efficacious, a surrogate challenge microorganism is used that (1) provides a challenge to the sterilization process; (2) demonstrates that all forms of microorganisms are rendered inactivated by the process, and (3) provides a quantitative reduction of microbial inactivation. To

demonstrate that the thermal process is providing all conditions necessary for sterilization to occur, biological indicator strips containing 6 Logs of *Bacillus atrophaeus* spores are used for periodic process validation. *B. atrophaeus* spores are rated most thermal-resistant in the hierarchy of resistance over all other RNA/DNA-containing microbial categories (i.e., viruses, vegetative bacteria, fungi, parasites, and mycobacterium). Complete inactivation of all spores on the biological indicator strip indicates (1) all other microbial species will be killed at a 6 Log reduction or higher and (2) the required 6 Log microbial kill necessary to meet the definition of sterilization has been achieved.

Biological indicators are used to provide a direct correlation of the sterilizer's parametric indicators and packaging/loading protocols with microbiological kill. Their use is not intended for the everyday monitoring of the sterilizer's performance, but rather to provide another monitoring perspective of typical or challenging operating conditions. Local or state public health departments have jurisdictional oversight for the periodic use of biological indicators, typically mandating weekly or monthly biological monitoring.

Biological indicators were never intended for routine use. The use of biological indicators as routine indicators (daily or per load) is impractical for dry heat sterilization technologies. As a biological, time is required for culturing and assuring all spores are inactivated. Since the quantitative analysis performed is measured by "growth/no growth", spores not fatally injured in the sterilization process are given a week to repair and reproduce. From the time of spore strip submission to a contracted laboratory, eight days are minimally required to obtain results from a biological indicator test. (Note: There are no "rapid read" biological indicators currently for dry heat sterilization as there are for steam and ethylene oxide sterilization.)

In-house culturing is an option from which cultured spore strips can be monitored throughout the seven-day incubation period for growth. Although a full seven days is required for culturing, spore strip failures are usually seen within the first 24-48 hours of culturing as indicated by color change and media turbidity. Although in-house biological monitoring is an option for a more timely indication of a spore strip failure, this culturing process requires the stringent use of proper sterile technique when transferring the spore strip to the culture media to avoid the introduction of an environmental microbial contaminant.

Accordingly, most small clinical and dental practices have preferred the use of a contracted laboratory for spore strip analysis. The absence of a timely turnaround of spore testing results is of concern only when positive growth is reported. A significant amount of time has elapsed since the sterilization cycle was tested and as a result, the cause of the failure may be difficult to trace and to determine since numerous factors can lead to a spore test failure. These protocols are provided to assist the practitioner in performing a proper spore test and in the event of a spore test failure, in determining the cause of a spore test failure through the use of proactive testing documentation. Following these protocols can provide the documentation required of root-cause analysis of why the failure may have occurred or minimally, determining those factors that did not lead to the failure. These protocols are based in part on identified factors that can lead to a spore strip failure as described in CDC's *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008*. [1]

Biological Testing Protocols for the Steri-DENT Sterilizer

I. Steri-DENT Sterilizer and Instrument Load Preparation

These test trials will be conducted for the sole purpose of verifying operating performance. All operating parameters for these tests shall be recorded as detailed below and retained in the Biological Test Data Manual. Biological Indicator testing is a Risk Management function and as such, strict adherence to the sterilizer's operating instructions is essential, including the retrieval of the biological indicator immediately upon completion of the sterilization cycle.

Prepare challenge load of instruments according to the Operating Manual (page 9), conducting pre- and post-evaluation as provided in the "Checklist for Weekly/Monthly Biological Indicator Testing for the **Steri-DENT** Sterilizer" (page 15-16).

Procedure:

1. Prepare the sterilizer per the warmup instructions.

2. Load the instruments into Steri-DENT self-sealing nylon pouches or other CPAC pouches recommended for dry heat. If not pouching, layer instruments in the instrument tray with no instrument overlap.

3. Add a chemical indicator to each pouch, or place chemical indicator strip under an instrument in each tray to secure it in place.

4. Insert a spore test strip into a pouch and seal pouch. Take extreme care not to puncture, tear, or rip the outer envelope protecting the biological indicator strip during insertion into the pouch or by an accompanying instrument.
   (a) Inspect the biological indicator envelope before and after the sterilization cycle to ensure envelope integrity. Failure to detect any defect in the envelope or its sealed fold may result in entry of an environmental contaminant, which may cause positive growth.

5. Evenly distribute the load throughout the instrument tray assuring that the spore test strip is located in the center of the upper instrument tray (model 200), or the top instrument tray (300) and that the pouches or instruments are loaded in a single layer.

6. With the sterilizer at operating temperature (320° F; 160° C) via Step 1, place the instrument trays into the sterilizer, spore test in appropriate location by model.

7. Allow the sterilizer to return to 320° F, then set the timer for 60 minutes to start the sterilization cycle.

8. Record the parametric operating conditions (date, times, and temperatures) of the test cycle in five (5) minute intervals throughout the test and place into the Biological Test Data Manual.

9. When the cycle ends, immediately and carefully remove the spore test strip for culturing. Evaluate test strip envelope for any undue deviations that could lead to a break in the integrity of the envelope, specifically punctures, tears, seals along envelopes perimeter and flap. Verify integrity by documenting in the Biological Test Data Manual. If the envelope shows signs of seal or flap adhesive separation or loss of integrity or if the time-temperature parameters deviate from prescribed conditions, repeat steps 1 through 7.

    (a) If mailing the spore test to an off-site test center, place biological indicator into the mail-back envelope, following directions provided with the spore test kit. This maintains sterile integrity of the spore test envelope and strip during shipment.

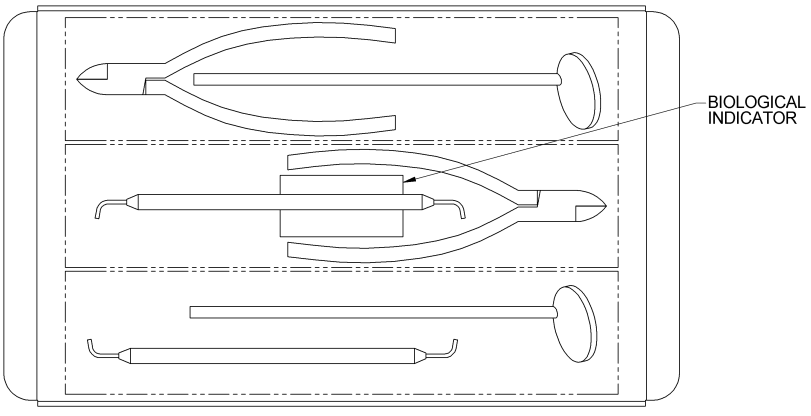
    (b) If conducting in-office testing of the spore strip, use sterile techniques when removing the spore strip from its envelope and transferring the strip to the media tube for incubation. Follow specified incubation times and temperatures. Note any actions that might result in cross contamination to the indicator strip.

10. Verify that all chemical indicators changed color. Enter results into the Biological Test Data Manual.

11. Review the parametric operating conditions data (date, times, and temperatures) from the test cycle and place into the Biological Test Data Manual. Review this data to assure the sterilizer was performing properly during this test cycle. Record time and temperature throughout the sterilization cycle, recorded every 5 minutes.

12. Document any other conditions (including any failure symptoms) or observations that may influence results and record them in the Biological Test Data Manual.

13. If conditions occurred during the test trial that have the potential to cause spore test failure, indicate those conditions in the Biological Test Data Manual. Correct those conditions and repeat the test (Steps 1 through 11).



EXAMPLE OF INSTRUMENTS LOADED IN TOP TRAY

In the event of a failed spore test, the information recorded in the Biological Test Data Manual and the accompanying "Checklist for Weekly/Monthly Biological Indicator Testing for your SteriDENT Sterilizer" will provide the following to assist in determining root cause of the failure. Specifically, this data will provide:

- Sterilizer operating parameters (time, temperatures throughout test cycle every 5 minutes).
- Visual observations of the biological indicator envelope before and after each test trial.
- Chemical indicator results of each test trial.
- Other recorded observations that may assist in determining root cause of failure. Photographs of test loads would be useful in this regard.

II. Procedures to Follow In the Event of a Spore Test Failure.

Occasionally the customer may experience a spore test failure. Although this should only be a rare occurrence, the following protocols should be followed to assure the sterilizer is operating within specifications and to ensure instrument packaging and sterilization loading conditions are followed. These protocols will assist the customer and CPAC Equipment technicians in determining the cause of the spore test failure, and determining whether the sterilizer should be taken out of service and returned to CPAC Equipment for further evaluation.

It should be noted that there are numerous factors that can lead to a failed spore test other than sterilizer failure.[1] It should be further noted that CDC states that the large margin of safety required for sterilization technologies (documented 12 Log spore kill) "that there is minimal infection risk associated with items in a load that show spore growth, especially if the item was properly cleaned and the temperature was achieved (e.g., as shown by acceptable chemical indicator or temperature chart). There are no published studies that document disease transmission via a non-retrieved surgical instrument following a sterilization cycle with a positive biological indicator."[1]

1. Upon notification of a failed spore test(s), collect all data pertinent to the test trial(s) that are archived in the "Biological Test Data Manual" and the "Weekly/Monthly Biological Indicator Checklist." Review for any outstanding conditions that may indicate cause of spore test failure.
2. Specifically review the sterilization cycle data for that biological indicator test to determine if that cycle met all the time and temperature conditions as specified (e.g., temperature is maintained between 320°F and 330°F for the duration of the sterilization cycle). This should have been noted upon completion of the test if the "Weekly/Monthly Biological Indicator Checklist" had been followed.
3. If the time and temperature conditions were met, the sterilizer was not a contributing factor to the spore test failure. Review the "Weekly/Monthly Biological Indicator Checklist" to determine if there were any potential causes as a result of spore strip envelope failure, improper loading conditions, or potential for cross contamination of the spore strip prior to its shipment to the contracted laboratory for analysis or during

its transfer for on-site incubation and analysis.
4. Run another spore test, applying close attention to all elements of the "Weekly/Monthly Biological Indicator Checklist" to ensure the sterilizer has met its performance specifications, to ensure proper loading conditions were met, and to ensure the spore strips are properly sealed to avoid environmental contamination. Submit spore strip to the contracted laboratory for analysis or perform on-site analysis.
5. If the second spore test results in a failure, call CPAC Equipment (800-828-6011) and ask for a service technician to discuss the problem and to determine a cause for failure. Provide the technician with information necessary for determination of failure cause and steps that may be required to remedy the problem. These steps may involve additional analysis on-site by the customer or may involve the sterilizer being returned to CPAC Equipment for further evaluation.

[1] William A. Rutala, Ph.D., M.P.H., David J. Weber, M.D., M.P.H. and the Healthcare Infection Control Practices Advisory Committee (HICPAC); CDC's *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008*; pages 76-79; http://www.cdc.gov/hicpac/pdf/guidelines/disinfection_nov_2008.pdf.

Checklist for Weekly/Monthly Biological Indicator Testing for Steri-DENT Sterilizer
(Upon Completion Place This Form in Biological Test Data Manual)

Date_____ Cycle Start Time _____ Cycle End Time _____
Operator_____
Sterilizer Equipment Model/Serial Number _____

Pre-Check Prior to Initiation of Sterilization Cycle

- ☐ Sterilizer checked for obstructions or foreign debris
- ☐ Interior sterilization chamber is clean; seal around door is clean and free of obstructions
  - ☐ Sterilizer pre-warmed and maintaining 320-330°F in the "HOLD" position
- ☐ Visual inspection of biological indicator envelope to assure integrity of envelope and seals (**Do Not Use** biological indicator if there is any indication of structural or adhesive damage)
- ☐ Challenge load constructed to Operations Manual and clinic office specifications
- ☐ Followed instructions contained in "**Steri-DENT** Sterilizer and Instrument Load Preparation" in Operations Manual for insertion of biological indicator and chemical indicators

Sterilization Cycle Data Collection

- ☐ Sterilizer thermometer readings taken at 5 minutes intervals for the duration of the cycle
- ☐ Sterilizer readings recorded in the test data manual
- ☐ Sterilizer readings throughout the cycle were between 320-330°F

Post-Check After Completion of Sterilization Cycle

- ☐ Evaluated test strip envelope for any undue deviations that could lead to a break in the integrity of the envelope, specifically punctures, tears, seals along envelopes perimeter and flap. Verified integrity by documenting in the Biological Test Data Manual
- ☐ Verified that all chemical indicators changed color and entered results into the Biological Test Data Manual
- ☐ Recorded the parametric operating conditions (date, times, and temperatures) of the test cycle data into the Biological Test Data Manual
- ☐ Reviewed cycle data to assure the sterilizer was performing properly during this test cycle
- ☐ Listed any other conditions (including any failure symptoms) or observations that may influence results and recorded them in the Biological Test Data Manual

Attest:
Upon completion of test cycle, did the sterilizer meet performance standards as stipulated in the Operations Manual?

☐ Yes ☐ No

Signature of Operator _____ Date_____

Note: It is recommended to print out copies of the Checklist for Weekly/Monthly Biological Indicator Testing, pages ~~15~~ 16 and 17 for placement in the Biological Test Data Manual.

STATEMENT OF WARRANTY

All equipment is manufactured to exacting standards and has been tested and inspected for proper workmanship and performance before shipping.

Any parts which are defective will be repaired or replaced within a three-year period after date of shipment, provided the equipment has been used according to the instruction manual and has not been abused or tampered with.

The company will not be responsible for any damage resulting from improper installation, operator carelessness or improper operation of the equipment. The company assumes no responsibility for damage in transit and the customer should present any claim for such damages to the carrier.

This warranty gives you specific legal rights. You may also have additional rights that vary from state to state.

Any unit to be repaired under warranty must be shipped, freight prepaid, or delivered to a facility authorized to render services provided hereunder. Returned unit must be either in its original package or a similar package affording an equal degree of protection. All units must have a Return Material Authorization code (RMA) visible on the returned item. RMA's can be obtained by calling CPAC at **(585) 382-3223**.

EVERY EFFORT HAS BEEN MADE TO ENSURE THE COMPLETE ACCURACY OF THE CONTENTS OF THIS MANUAL. NO LIABILITY ARISING FROM ITS USE, HOWEVER, CAN BE ACCEPTED BY THE COMPANY, WHO RESERVES THE RIGHT, WITHOUT PRIOR NOTICE, TO ALTER THE SPECIFICATIONS, CONSTRUCTION, OR CONTENT OF ITS EQUIPMENT AT THE COMPANY'S OWN DISCRETION.