

SteriSURE®

PRECISION-CONTROLLED DRY HEAT STERILIZERS

Dry Heat Sterilizers with 60 Minute Sterilization Cycle Times



**MODEL
3100**

**MODEL
2100**



cpac
Equipment Inc.

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RECOMMENDATIONS

Read the entire instruction manual *before* installation or operation of the SteriSURE Dry Heat Transfer Sterilizer. It will help you to understand the operation of the system, how various sub assemblies work together and the operating sequence of the controls.

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 your SteriSURE Dry Heat Transfer Sterilizer, these basic safety precautions should be followed:

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

SteriSURE STERILIZERS

The technology used in the SteriSURE sterilizer utilizes the latest advancements in dry heat sterilization. We are confident you will find it a valuable and cost saving addition to your practice. The SteriSURE sterilizer* is intended for indoor use in hospitals and dental, orthodontic and health care facilities.

ACCESSORIES

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

MATERIALS INTEGRITY

The SteriSURE 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 SteriSURE sterilizer. Caution should be used with plastic and rubber goods. 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.
- 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 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 SteriSURE.**

SAFETY NOTES CONCERNING TEMPERATURE

The temperature in the SteriSURE sterilizer is controlled by computer logic, which precisely maintains temperature throughout the sterilizer chamber. The temperature control is extremely sensitive and maintains 320° F (160°C).

*The SteriSURE Sterilizer is non-patient care equipment.

After room temperature instruments are placed in the sterilizer, the temperature may drop a few degrees depending on the size of the load. The cycle will not begin until 320°F (160°C) has been reestablished.

If the temperature drops below 310°F (154°C) during a sterilization cycle, the timer will stop and an error code will display. See Error Codes section on page 9.

Do not open the door during a sterilization cycle. An E-16 error will occur, the sterilizer cycle time will reset and the instruments will have to be sterilized again.

Instruments Validated for Use in Sterilizer

The Model 2100 and 3100 sterilizers have been validated to sterilize 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 2100 and 3100 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.

Chemical Indicator Use

When using a sterilization bag, the chemical indicator listed below should be placed 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 SteriSURE are recommended, part no. 400635.

OPERATING INSTRUCTIONS

WARM UP - If desired, the sterilizer can be warmed up in preparation for a sterilization cycle. Before turning the sterilizer on, visually inspect the interior heating chamber. Close the door and press the ON (WARM-UP) key. The unit will warm up and maintain 320°F (160°C) for 2 hours or until a cycle is started. The temperature will be displayed during warm-up and the LED will display yellow. The LED will display green when unit has reached sterilization temperature.

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 see Materials Integrity – page 4). Prepare all instruments for sterilization by 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 American Dental Association (ADA) recommends bagging the instruments prior to sterilizing.

In order to ensure sterility, instruments intended to be stored must be sealed in SteriSURE nylon pouches prior to sterilization.

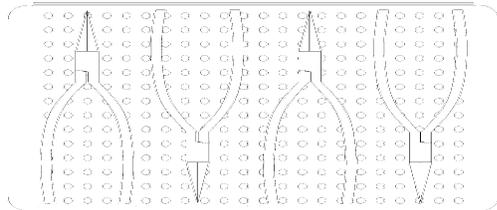
SteriSURE Part No. 400636, NYLON SELF SEAL POUCHES 2" X 10"

SteriSURE Part No. 400651, NYLON SELF SEAL POUCHES 3" X 10"

SteriSURE Part No. 400637, NYLON SELF SEAL POUCHES 4" X 10"

SteriSURE Part No. 400638, NYLON SELF SEAL POUCHES 7" X 10.5"

SteriSURE 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 tray. Instruments should not touch each other. Do not exceed maximum allowable weight indicated below.

MAXIMUM LOADING

Model 2100 Sterilizer – 1.3 pounds per tray (includes the weight of the tray)

Model 3100 Sterilizer – 1.4 pounds per tray (includes the weight of the tray)

Load instruments into sterilizer and press the START CYCLE. Timer will start after unit has reached sterilization temperature. LED will flash green and unit will beep and display will indicate 'CC' when cycle is complete. Remove the trays for cool down.

NOTE: Press the START CYCLE key *after* the instrument trays have been loaded in the sterilizer.

NOTE: When pressing the sterilizer buttons, do not hold them down longer than necessary as this will lead to an Error Code (see Error Codes section on page 9).

TO END THE DAY

Push and release the ON (WARM-UP)/STANDBY button to shut the unit off.

NOTE: The sterilizer will automatically shut down after 2 hours of inactivity (default setting). This time can be adjusted using the SET key (see Default Settings below).

DEFAULT SETTINGS

The following system settings can be changed from their default or viewed. Press the SET key for 3 seconds to enter SET mode and the SET LED will turn yellow. The 4-digit LED display will flash the first setting to be changed. Continue to press the SET key to toggle through all the settings which are listed below. Use the UP and/or DOWN keys to make changes to any of the settings. Press the SET key after the last setting is displayed to exit SET mode and save changes to memory.

STAND-BY MODE: Default - 2 hours

Unit will maintain cycle temperature for 2 hours after last cycle. This time can be adjusted from 2 – 4 hours. Display format example = "Sb-2".

AUDIBLE ALARM: Default – 1(ON)

The unit has an audible alarm that alerts the user when the sterilization temperature has been reached during warm-up and when a cycle has been completed. The alarm can be defeated by changing the value to 0(OFF). Display format example = “AA-1”.

FAHRENHEIT/CELSIUS: Default – F (Fahrenheit)

The temperature measurement can be displayed in units of Fahrenheit (F) or Celsius(C). Display format example = “ F”.

PRINTER OUTPUT COPIES: Default – 1

The number of copies for the printer output can be increased to 2 or 3. Display format example = “PC-1”.

YEAR: Default – year when power turned off to sterilizer.

The year can be updated to current year. Display format example = “2011”.

MONTH: Default – month number when power turned off to sterilizer.

The month can be updated to current month as follows: 1-January, 2-February, 3-March, 4-April, 5- May, 6-June, 7-July, 8-August, 9-September, 10-October, 11-November or 12-December. Display format example = “10”.

DAY of MONTH: Default – day of month when power turned off to sterilizer.

The day of month can be updated to current day. Display format example = “d-18”.

TIME: Default - time when power turned off to sterilizer.

The time can be changed, based on a 24 hour clock.

MODEL: Sterilizer model can only be viewed not changed. Display format example = “2100”.

SERIAL NUMBER – First 4-digits: Serial number can only be viewed not changed. Display format example = “ 1”.

SERIAL NUMBER – Last 4-digits: Serial number can only be viewed not changed. Display format example = “2345”.

CLEANING AND MAINTENANCE

The SteriSURE 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 electronic 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.

The inner door gasket should be replaced if it shows sign of wear or if it comes loose. Order Gasket Kit #211001 for Model 2100 and #311001 for Model 3100.

Contact your authorized service representative or call CPAC at (585) 382-3223.

REPLACEMENT FUSES

Models 2100 & 3100: Slow Blow type, rated 10A, 250V

Models 2100-230V & 3100-230V: Slow Blow type, rated 5A, 250V

The fuse is located in the bottom panel towards the back of the unit, next to the power cord.

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.

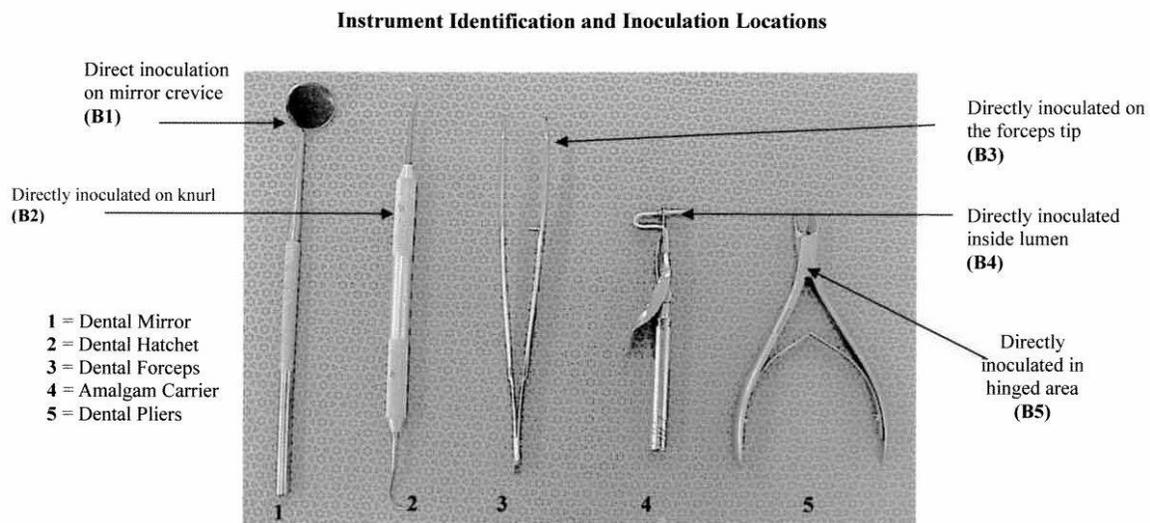
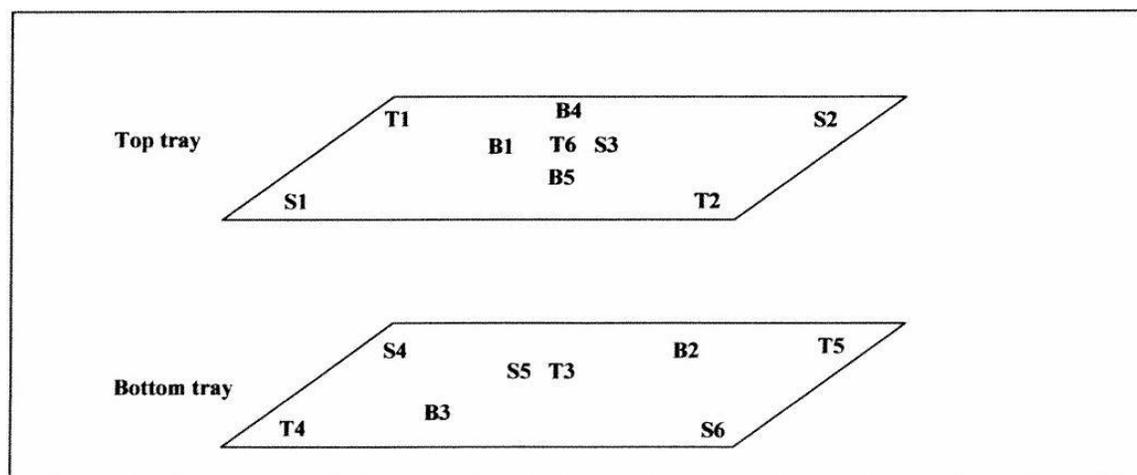
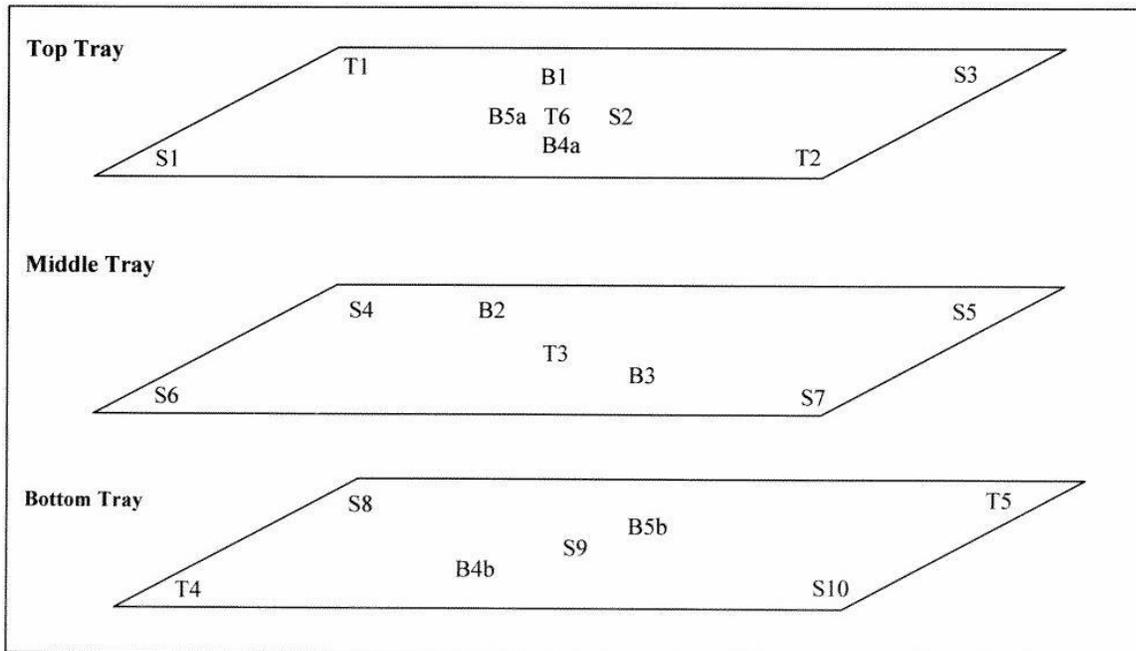


Figure 1



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

ERROR CODES

Any failure in performance will be signaled by an error code.

If one of the following error codes appears, push and release the ON (WARM-UP)/STANDBY button to reset the unit. This will reestablish the error detect logic and will eliminate false error codes that may occur.

If the error code persists, call your authorized service representative or CPAC at **(585) 382-3223**.

Process Failures:

E-12 Key Switch failure
E-14 Board over heat
E-16 Cycle Interruption
E-18 PCB Failure

Temperature Probe:

E-20 Open Probe
E-21 Thermocouple

Heater Drive:

E-30 Over heat
E-31 Under heat

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, Inc. recommends that a biological indicator and the recommended test load of 2.6 lbs for model 2100 and 4.2 lbs for model 3100 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 SteriSURE are recommended, part. no. 400635
- Spore test strips supplied by SteriSURE 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, scalars, 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 2100 tray weighs 0.3 lbs.

Model 3100 tray weighs 0.4 lbs.

- Self Sealing nylon pouches from SteriSURE are required:

SteriSURE Part No. 400636, NYLON SELF SEAL POUCHES 2" X 10"

SteriSURE Part No. 400651, NYLON SELF SEAL POUCHES 3" X 10"

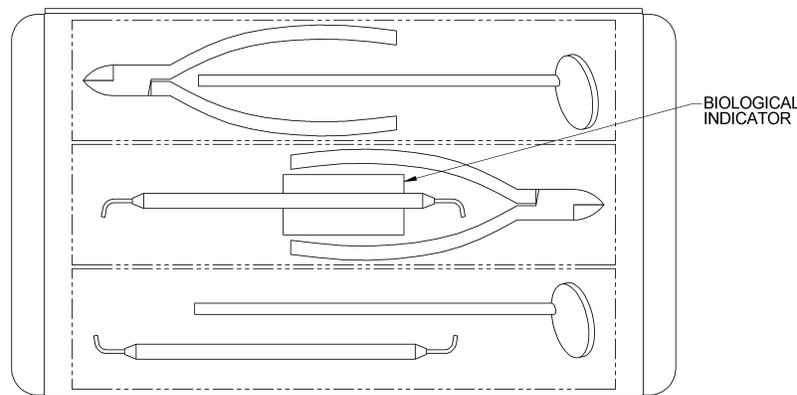
SteriSURE Part No. 400637, NYLON SELF SEAL POUCHES 4" X 10"

SteriSURE Part No. 400638, NYLON SELF SEAL POUCHES 7" X 10.5"

SteriSURE Part No. 400639, NYLON SELF SEAL POUCHES 9.5" X 13"

Procedure:

1. Obtain a full load of instruments as indicated above.
2. Prepare the sterilizer and initiate a cycle to verify functionality.
3. Load the instruments into SteriSURE self sealing nylon pouches.
4. Add a chemical indicator to each pouch.
5. Add a spore test strip to one pouch and seal each pouch.
6. Evenly distribute the load throughout the sterilizer trays assuring that the pouch with the spore test strip is located in the center of the tray.
7. With the sterilizer operating at 320° F (160° C), place the tray containing the spore test strip in the top shelf of the sterilizer. Load the remaining trays into the sterilizer.
8. Start the test cycle by pressing the START CYCLE/COMPLETE key.
9. When the cycle ends, remove the spore test strip for culturing.



**EXAMPLE OF INSTRUMENTS
LOADED IN TOP TRAY**

UNIT ELECTRICAL RATINGS

MODEL 2100
MODEL 3100
MODEL 2100-220V
MODEL 3100-220V

115 VAC, 50/60 Hz, 10 Amps
115 VAC, 50/60 Hz, 10 Amps
230 VAC, 50/60 Hz, 5 Amps
230 VAC, 50/60 Hz, 5 Amps

USB PORT

The Steri-SURE Sterilizer is capable of storing sterilization cycle data on a USB flash drive. The flash drive should be inserted in the provided USB port located on the front of the sterilizer. The sterilizer will record cycle parameters, including start date and time, cycle phase time and temperatures, and the cycle status. The cycle status at the end of the record will indicate whether the sterilization cycle successfully completed or if there was an error. A new text file is automatically created each day and named using the following format: month-day-year.txt (ex: 09-14-12.txt).

The flash drive can be any type formatted for FAT (FAT16) or FAT32.

NOTE: The flash drive must be installed before the cycle ends or the cycle data will not be stored. The drive can be removed anytime after a cycle ends and the data can be downloaded to your computer for archiving or printing.

If direct printing is desired, the following printer can be connected to the USB port:

Printer - Epson TM-U220 with USB interface

Cable – USB printer cable

NOTE: The printer must be connected to the USB port via the above cable and must be turned on for the printer output to work. The number of copies can be changed in order to printout multiple copies (see DEFAULT SETTINGS). Cycle data will not be stored electronically when the printer is used.

The date and time should be set before the Steri-SURE sterilizer is first used

and will need to be updated if power is lost to the sterilizer. Follow the instructions on pages 6-7 to adjust these settings.

SAMPLE PRINTER OUTPUT

Operator _____

Start Date - 03/04/2012
Start Time - 03:16:39PM
Temp Setting - 320 F
Time Setting - 60 min.
Cycle Number - 084
Serial Number - 01234

Cycle Phase	Time	Temp(F)
Warm-up start	03:00:41PM	075
Warm-up end	03:16:39PM	321
5 min.	03:21:39PM	326
10 min.	03:26:39PM	322
15 min.	03:31:39PM	325
20 min.	03:36:39PM	324
25 min.	03:41:39PM	326
30 min.	03:46:39PM	321
35 min.	03:51:39PM	322
40 min.	03:56:39PM	322
45 min.	04:01:39PM	325
50 min.	04:06:39PM	325
55 min.	04:11:39PM	326
60 min.	04:16:39PM	324

Warm-up time = 16.0 min.
Exposure time = 60 min.
Total Cycle time = 76.0 min.

Cycle status = COMPLETE

ENVIRONMENTAL CONDITIONS

The SteriSURE Dry Heat Transfer 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 IEC 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).

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.