



COXRAPIDHEAT™

HIGH-VELOCITY HOT AIR STERILIZERS

High Velocity Hot Air Rapid Heat Sterilizers with
6, 8, and 12 Minute Sterilization Cycle Times

USER MANUAL

MODELS:

COX – 115V

COX – 220V



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HVHA STERILIZATION

The Cox RapidHeat™ Transfer Sterilizer employs High-Velocity Hot Air (HVHA) to sterilize medical and dental instruments. Radically different than steam sterilization, HVHA technology uses fluidized hot, dry air to sterilize instruments by a combination of convection and conductive processes. Conventional practices necessary for the sterilization of instruments by steam do not apply to HVHA technology and in many instances are contrary to HVHA protocols provided in this user manual.

Please read this manual carefully, paying particular attention to the requirements for instrument preparation, packaging, and loading of the Cox RapidHeat™ Transfer Sterilizer. Failure to follow the operating instructions in this manual can result in damaged instruments, damage to the sterilizer, user injury, and sterilization efficacy. Following these instructions will result in a worry-free sterilization process that is simple, efficient, and safe, providing long life to your instruments.

CAUTIONS

- During operation, the exterior surface of the sterilizer remains comfortable to the touch; however, the interior of the drawer and the sterilized instruments will be hot. Use only the tray removal tool or heat-resistant gloves to carry the instrument tray. Use caution when handling hot instruments.
- The sterilizer is designed for use with metal instruments. Many plastics (e.g. nylon, polyester), and silicone rubber products can be used in a high temperature environments, but 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 375 °F (190 °C) temperatures.
- Instruments that have been wiped with alcohol, or any combustible solution, must be allowed to dry before being placed in the sterilizer.
- Use only dry heat wraps and pouches suitable for 375 °F (190 °C) temperatures.

SAFETY NOTES CONCERNING TEMPERATURE

The temperature in the Cox RapidHeat™ sterilizer is controlled by computer logic, which precisely maintains temperature throughout the sterilizer chamber. The temperature control maintains 375 °F (190 °C).

After room temperature instruments are placed in the sterilizer, the temperature may drop a few degrees depending on the size of the load and the time during which the door is open. If the temperature drops below 372 °F (189 °C), the cycle will not begin until 375 °F (190 °C) has been reestablished.

The sterilizer is designed to maintain 375 °F (190 °C) at all times. The door must be closed during Operation: Otherwise, the heating element has been programmed to shut off while the door is open resulting in chamber temperature loss from air entering the chamber.

Do not open the door during a sterilization cycle. In the event that the door is opened, the cycle timer will reset and the sterilization cycle will restart after reaching operating temperature.

RECOMMENDATIONS

Read the entire instruction manual before installation or operation of the COX Rapid 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

IMPORTANT SAFEGUARDS

When using your COX Rapid Heat Transfer Sterilizer, follow these basic safety precautions:

1. Read and understand all instructions.
2. Take care to avoid burns resulting 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 the power cord hang over the edge of a table or counter, or touch hot surfaces.
5. DO NOT USE an extension cord 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 door opening in front of unit. Hold securely by the bottom when lifting or moving the sterilizer. The sterilizer weighs approximately 58 pounds.

SAVE THESE INSTRUCTIONS

COX STERILIZERS

The Cox Rapid Heat Transfer Sterilizer was invented by Dr. Keith Cox. The technology used in the Cox Sterilizer represents significant advancement in dry heat sterilization. We are confident you will find it a valuable and cost saving addition to your practice. The Cox RapidHeat™ sterilizer* is intended for indoor use in hospitals, dental clinics, orthodontic and health care facilities.

ACCESSORIES AND CONSUMABLES

The Cox RapidHeat™ sterilizer comes equipped with a removable COX Instrument Tray, COX Instrument Rack for packaged instruments, a tool for changing trays, and a cooling rack upon which to place the tray. Depending on the size of your practice, you may wish to purchase additional sterilizers.

OPTIONAL ACCESSORIES

The following additional sterilizer components are available as a *kit (or individually):

Part No. CX0412	8" COX Instrument Tray
Part No. CX1412	9" COX Instrument Tray
Part No. CX0413	8" COX Instrument Rack
Part No. CX1413	9" COX, 7 or 3 slot Instrument Rack (please specify at time of purchase)**
Part No. CX0403	CPAC Standard Organizer
Part No. CX0405	Organizer Inserts 3-slot
Part No. CX0406	Organizer Inserts 6-slot
Part No. CX0415	SecureSlide™ Instrument Organizer
Part No. CX0031	Mesh Basket (Burr Holder)
*Part No. CX0414	COX Instrument Sterilizer System Kit

Call CPAC at (585) 382-3223 to place an order for these items.

*The complete kit enables the additional preparation and insertion of a tray-ready instrument set into the sterilizer following the removal of a COX Instrument Tray after a completed cycle.

** The 7 slot rack is for individual instrument pouches, the 3 slot instrument rack is configured to accommodate instrument cassettes.

CONSUMABLES

Instrument pouches, biological monitoring supplies, and indicator strips are available from CPAC.

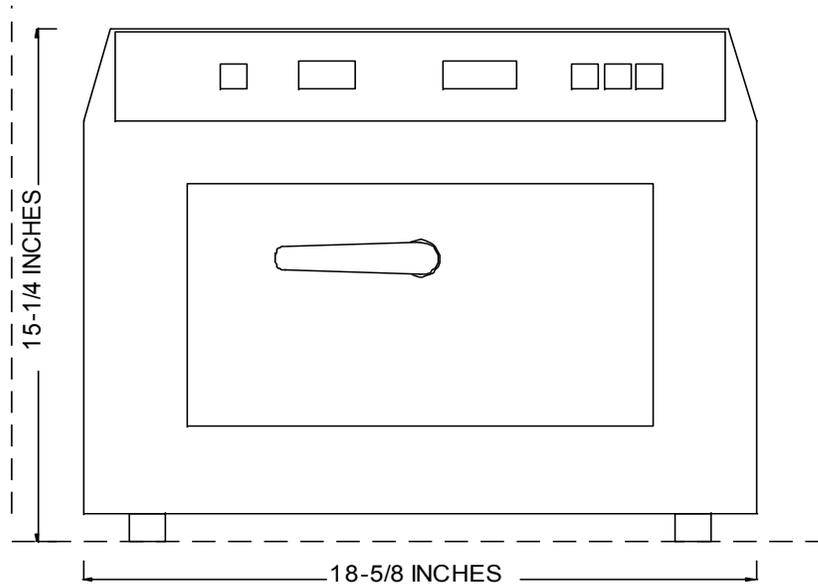
Call CPAC at (585) 382-3223 or visit our website <http://sterisure.com/products.cfm?categoryID=19> for ordering information.

MATERIALS INTEGRITY

Tests have been conducted on various surgical and dental instruments as to compatibility with the 375 °F (190 °C) temperatures used in this system. Generally, all medical and dental stainless and carbon steel hand instruments maintain material integrity in the Cox sterilizer. Caution should be used with plastic and rubber goods. When in doubt, consult the instrument manufacturer.

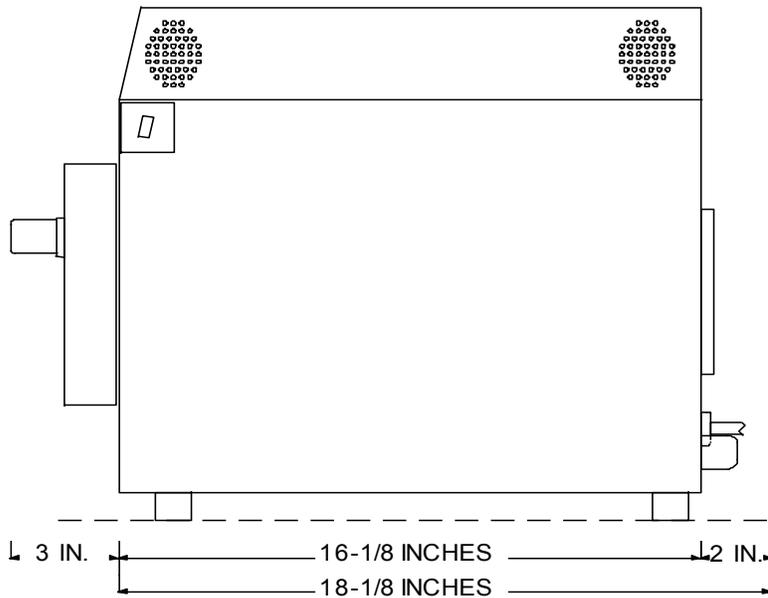
INSTALLATION: DIMENSIONS, CLEARANCES, WEIGHT

Dimensions and clearance requirements are shown below:



FRONT VIEW, PROVIDE 2-INCH CLEARANCE AT EACH SIDE

STERILIZER EMPTY WEIGHT IS 58 POUNDS



SIDE VIEW, INCLUDING 2-INCH REAR CLEARANCE

SUITABLE ELECTRICAL CIRCUIT AND OUTLET

The sterilizer should be plugged into a 120-Volt, grounded outlet. It is best practice to provide an outlet that serves only the sterilizer, or the sterilizer and its optional printer.

OPERATING INSTRUCTIONS

TO START THE DAY

Before turning the sterilizer on, open the door and visually inspect the heating chamber. Close the door, make sure the handle is in the fully closed (horizontal) position, push and release the ON STANDBY/OFF button for 1-2 seconds, and allow the sterilizer to heat to 375 °F (190 °C). This will take about 25 minutes. The ON STANDBY/OFF LED will change color from amber to green when the warm-up to 375 °F (190 °C) is complete.

The sterilizer is very energy efficient and should be left on all day, as its electrical consumption is minimal.

Before beginning a sterilization cycle, be sure instruments are clean, dry, and free of debris (for information about which instruments can be safely sterilized see Materials Integrity – page 5).

PRIOR TO STERILIZATION

All instruments to be sterilized in Cycles I, II, and III **need to be dried** prior to placing them in the sterilizer. Excess water will vaporize at the sterilizer's elevated temperatures and potentially inhibit the sterilization process.

All instruments, including those that have been placed in a holding, ultrasonic, or cold chemical disinfectant solution, must be thoroughly rinsed in water (preferably distilled or de-ionized water to minimize instrument staining or spotting) and thoroughly dried before sterilization.

Any instrument that has been alcohol rinsed must be thoroughly dried before placement in the sterilizer. Any instrument subjected with any other chemical solvent must have that solvent removed before instrument placement into the sterilizer. Failure to remove alcohol or any other chemical solvent may cause a flammable or explosive incident, causing instrument/sterilizer damage or injury to the operator.

Failure to thoroughly remove extraneous agents prior to sterilization could lead to surface staining of instruments.

Units containing a battery will need the date and time set before the Cox sterilizer is first used and will need to be updated if the power is lost to the sterilizer. Follow the instructions on page 16, SETTING THE CLOCK, to adjust these settings.

*Batteries have been installed in units with serial numbers greater than CX18000.

STERILIZATION CYCLES

CYCLE I – 6 MINUTES

Unwrapped Instruments Sterilization Instructions

NOTE: Cycle I to be used only for Non-Critical Care procedures or in limited circumstances in which an emergency situation exists. After the sterilization cycle, cover the unwrapped instrument with a sterile cover to prevent environmental pathogens from causing instrument contamination. Transport for immediate use to patient. Do Not Store Instruments for Future Use.

To sterilize unwrapped instruments, place them in the instrument tray, place the tray into sterilizer sliding the tray into the heating chamber using the tray removal tool. Close the door, make sure the handle is in the fully closed (horizontal) position, push and release the Cycle I button.

NOTE: It is required that only a single layer of instruments be placed in the tray to ensure thorough and complete sterilization. Also, be sure to place burs, diamonds and other small items first in the accessory mesh basket and then into the instrument tray.

At the end of 6 minutes, a beep will sound and a “6 C” will appear in the time window on the face of the sterilizer indicating the cycle has been completed.

Immediately after opening the door, use the instrument tray removal tool to slide the tray out of the chamber and place it on the cooling rack. The tray containing the sterilized instruments will continue to cool on the cooling rack.

CYCLE II – 8 MINUTES

Hand Piece Sterilization Instructions

NOTE: Cycle II to be used only for Non-Critical Care procedures or in limited circumstances in which an emergency situation exists. After the sterilization cycle, cover the unwrapped instrument with a sterile cover to prevent environmental pathogens from causing instrument contamination. Transport for immediate use to patient. Do Not Store Instruments for Future Use.

To sterilize air rotor hand pieces or medical drills with internal tubing, the following protocol should be used:

- Clean the hand piece (flush water lines by running the hand piece for 30 seconds); thoroughly scrub with detergent and water to remove adherent material. Remove old lubricant and debris from turbine head by spraying a hand piece cleaner/solvent into the air drive.
- **DO NOT USE A CLEANER/LUBRICANT.**
- Thoroughly rinse hand pieces with water, preferably distilled or deionized water, to remove solvents or alcohols and to minimize or prevent instrument staining or spotting.
- Place thoroughly clean hand pieces in an instrument tray.

To sterilize hand pieces, select Cycle II. When the beep sounds and an “8 C” appears in the time window at the end of the 8 minutes, promptly remove the instruments and allow to cool, then insert another loaded tray into the sterilizer. Remember to lubricate the hand piece prior to use.

CYCLE III – 12 MINUTES

Wrapped Instruments Sterilization Instructions

NOTE: Cycle III to be used for Critical and Semi-Critical Care procedures.

To sterilize packaged instruments, **thoroughly** dry instruments before packing and place up to 7 packages in the accessory instrument rack.

NOTE: If the instrument rack is not used, do not layer packaged or pouched instruments in the tray. Layering of instrument pouches restricts airflow and can impede the sterilization process. It is also important to ensure that no portion of the pouch extends beyond the lip of the instrument tray. This may result in degraded sterilization efficiency by interfering with the exhaust fan inlet located on the back right panel of the sterilization chamber

It is recommended that the instrument rack be used when sterilizing packaged instruments to ensure thorough and complete sterilization.

Place the rack in the instrument tray, insert the tray in the sterilizer, push and release the Cycle III button. At the end of 12 minutes, a beep will sound and a “12 C” will appear in the window indicating the cycle is complete. Remove and cool the instruments. As a reminder, be sure to use dry heat compatible bagging material suitable for 375 °F (190 °C) temperatures (See “Recommended and Required Accessories” below).

PREPARING TEST LOADS

A sample test load is needed to reliably evaluate the effectiveness of the sterilizer and achieve consistent results. The test load should be a typical full load* consisting of simple metal instruments normally sterilized during the day, particularly those with hinges or mated surfaces, as well as 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.

*NOTE: A full load is characterized as a single layer of instruments filling the instrument tray while ensuring that no instruments overlap each other.

SHUTTING DOWN

Push and release the ON/OFF STANDBY button. The sterilizer will enter standby mode while the cooling fan continues to operate. At the end of ten minutes, the sterilizer will automatically shut off. If the sterilizer is connected to a wall outlet controlled on/off switch, do not turn the switch off, or in any way disrupt the power supply while sterilizer is in cool down mode.

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 monitor and verify the sterilizer's performance. State or local requirements (public health departments) for biological testing may also apply.

CPAC Equipment, Inc. recommends that a test be performed every 25 cycles, or at least once a week, to test the effectiveness of the COX Rapid Heat, model 6000.

Recommended and Required Equipment

Biological indicators (i.e. spore test strips) containing *Bacillus atrophaeus* should be used along with chemical indicators to reliably monitor the effectiveness of the COX Rapid Heat, model 6000. Spore test strips and chemical indicators, as well as test services are widely available through universities and commercial services. CPAC Equipment, Inc. recommends using the following:

- Chemical indicators, supplied by SteriSURE, part. no. 400635
- Spore test strips, supplied by SteriSURE, part no. 400634
- Self Sealing nylon pouches, supplied by SteriSURE are recommended:
 - 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"*

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 510k) 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 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 Cox RapidHeat™ Transfer Sterilizer

I. Cox RapidHeat™ Transfer 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. Strict adherence to the sterilizer's operating instructions is essential, including the retrieval of the biological indicator immediately upon completion of the 12-minute sterilization cycle.

1. Prepare challenge load of instruments according to the Operation Manual, page 9.
2. Prepare the sterilizer and initiate a 12-minute cycle (CYCLE III) to verify functionality.
3. Load the instruments into SteriSURE self-sealing nylon pouches or other CPAC pouches recommended for dry heat.
4. Add a chemical indicator to each pouch.
5. Add a spore test strip to one 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. 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.
6. Evenly distribute the load throughout the instrument tray assuring that the pouch with the spore test strip is located in the center of the instrument tray and the pouches are loaded in a single layer. If a rack is used, ensure that pouch with the spore test strip is located in center of the full load.
7. With the sterilizer having already come to operating temperature (375° F; 190° C), place the instrument tray into the sterilizer.
8. Start a 12-minute cycle.
9. When the cycle ends, immediately and carefully remove the spore test strip for off-site 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, re-run the test.
10. Place biological indicator into the mail-back envelope, following directions provided with the spore test kit.
11. Verify that all chemical indicators changed color. Enter results into the Biological Test Data Manual.
12. Download via USB port the parametric operating conditions (date, times, and temperatures) of 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. If unit does not have a USB data port, record time and temperature throughout 12-minute cycle, recorded every 30 seconds.
13. Document any other conditions (including any error codes) or observations that may influence results and record them in the Biological Test Data Manual.
14. Repeat process (1-13) the same day and submit as a second (backup) test trial for off-site analysis.

In the event of a failed spore test the information recorded in the Biological Test Data Manual will provide the following to assist in determining root cause of the failure. Specifically, this data will provide:

- A second or backup spore test trial of the unit conducted under similar conditions.
- Sterilizer operating parameters (time, temperatures throughout test cycle every 30 seconds).
- 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 the loaded test pouches and loaded racks 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 CPAC Equipment technicians in assisting the customer 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

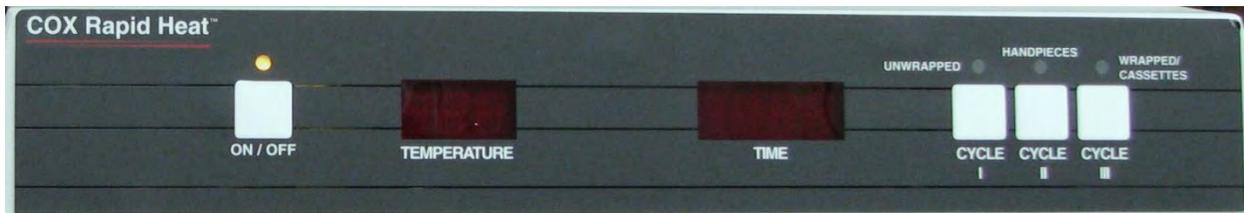
1. Upon notification of a failed spore test(s), collect all data pertinent to the test trial(s) indicated that are archived in the Biological Test Data Manual and review for any outstanding conditions that may indicate cause of spore test failure.
2. Immediately call CPAC Equipment (800-828-6011) and ask for a service technician, indicating the urgency of the situation and its resolution.
3. Provide the technician with information necessary for determination of failure cause and steps 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.

DETAILED OPERATION AND SETUP

Before turning the sterilizer on, open the door and visually inspect the heating chamber. Close the door, making sure the handle is in the fully closed (horizontal) position.

THE STERILIZER CONTROL PANEL

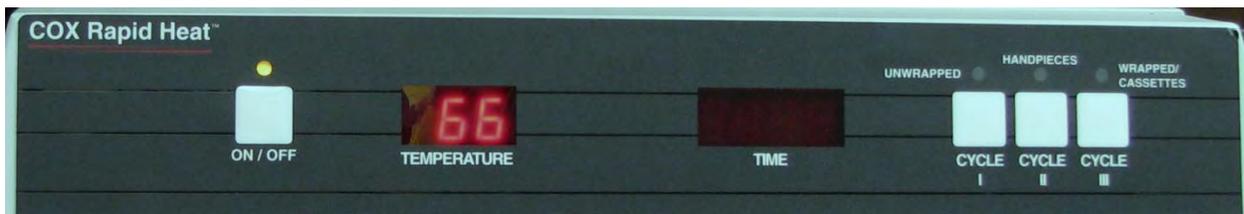


The control panel is shown above. This is the appearance of the panel when the sterilizer is in the STANDBY mode. The light above the ON/OFF button is lit, no heat is produced, and the sterilizer's internal fans are stopped.

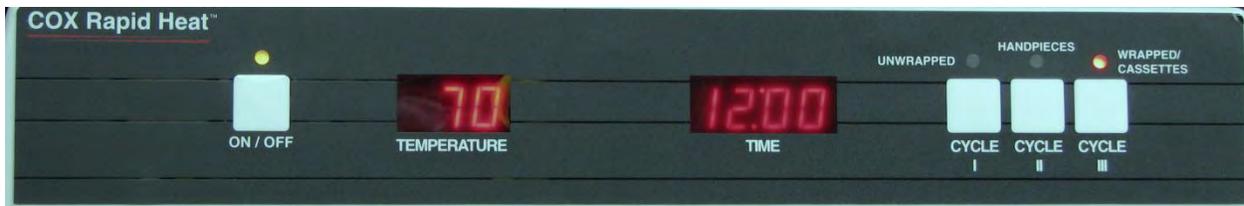
The two windows at right of the ON/OFF button are the TEMPERATURE and TIME windows. The TEMPERATURE window is active during operation of sterilizer's heating function. The TIME window is active to show Date and Time during the setup mode, and it shows remaining time during sterilization cycles.

The CYCLE I, CYCLE II, and CYCLE III buttons are used in combination for entry of sterilizer setup data, such as date and time, and they are used for selection of one of the three alternate sterilization cycles.

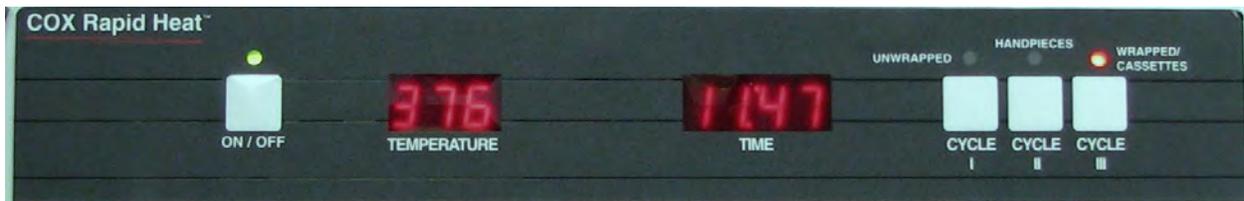
The lights above the CYCLE buttons indicate which cycle is selected. The 12-minute cycle of CYCLE III is the one which is most commonly used.



Above: Press and hold the ON/OFF button, and the sterilizer's fans will start. Temperature of the sterilization chamber is shown in the TEMPERATURE window. Temperature is updated at about five-second intervals. The sterilizer will warm up to an operating temperature of 375 degrees Fahrenheit. Sterilization can be started after operating temperature is reached.



Above: Press the CYCLE III button, and the TIME window will show 12:00 minutes. Twelve minutes is the duration of CYCLE III, which is the cycle for use with wrapped instruments. This picture shows that the sterilizer has not yet warmed up to operating temperature, and the twelve-minute sterilization cycle will not begin until the operating temperature has been reached. If a cycle has been selected, the cycle will begin immediately upon warm-up to 375 F, and the TIME value will begin to count down, seconds and minutes, until the cycle time is completed.



Above: Typical display during time countdown in CYCLE III. TEMPERATURE displays the chamber temperature, and TIME shows the time remaining in the sterilization cycle in minutes and seconds. Small variations above the 375 °F temperature is normal.



Above: Press and hold the ON/OFF button to return the sterilizer to STANDBY mode. A ten-minute cool-down cycle will begin: The heater will be turned off, and the LED displays will be off, as shown above. The fans will continue to operate for ten minutes. After this time, the fans will cease to operate. The sterilizer is then in STANDBY mode. The light above the ON/OFF button will remain lit.

The SETTINGS mode can be entered when the sterilizer is in STANDBY mode or the cool-down interval.

SETTING OPERATOR OPTIONS AND SETTING THE CLOCK

The following system settings can be viewed or changed from their defaults when the sterilizer is in STANDBY mode. Press and hold the CYCLE I key for 5 seconds to enter SET mode. The 4-digit LED display will show the first setting to be changed. Continue to press the CYCLE I key to step through all the settings, which are listed below. Use the CYCLE II key to increase values and the CYCLE III key to decrease the values of the settings. Press the CYCLE I key after the last setting is displayed to exit SET mode and save changes to memory.



STANDBY MODE: Default - 3 hours

Unit will maintain cycle temperature for 3 hours after last cycle. Unit will automatically enter power OFF (Standby) if there is no cycle activity for 3 hours. This time can be adjusted from 2 – 4 hours.

Display format example = “5b-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 silenced 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”.



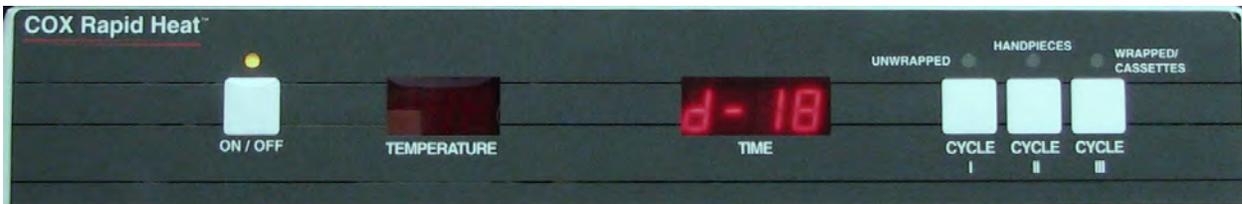
PRINTER OUTPUT COPIES: Default – 1
 This value cannot be changed.



YEAR: Default – Typically the year in which the sterilizer was manufactured or calibrated.
 The year can be updated to current year. Display format example = “2011”.



MONTH: Default – 1.
 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 = “ 1”.



DAY of MONTH: Default – 1.
 The day of month can be updated to current day. Display format example = “d-18”.

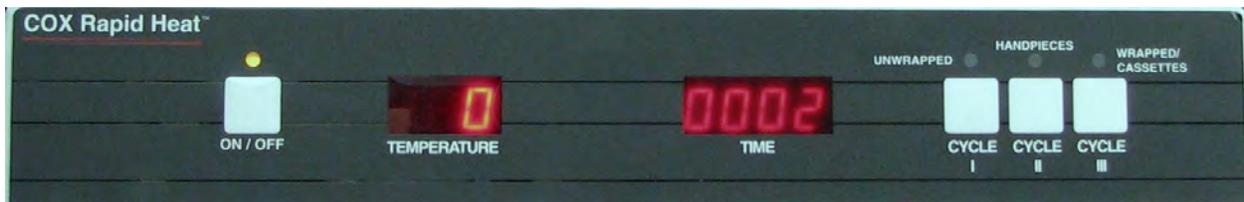


TIME of DAY

Time is set in 24-Hour format, for example 14:05 for 2:05 PM. The hours value flashes to indicate HOURS setting mode. Pressing the CYCLE I button changes to MINUTES setting mode.



MODEL: Sterilizer model can only be viewed, not changed. Display format example = “6000”.



SERIAL NUMBER – Serial number can only be viewed. Display format example = “0 0002”. Note that the TEMPERATURE window shows a 0 in this mode.

USB PORT, AND DATA LOGGING OF OPERATING CYCLE

The COX Rapid Heat Transfer Sterilizer is capable of storing sterilization cycle data on a USB flash drive of 8 Gb or less. The flash drive should be inserted in the USB port located on the upper right side 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 details of the completed sterilization cycle. The flash drive can be any type formatted for FAT (FAT16) or FAT32. FAT32 is the recording format that is most commonly found in these devices.

NOTE: The flash drive must be installed before the cycle ends or the cycle data will not be stored. The flash drive will capture the data information of each cycle while installed. The drive can be removed any time after a cycle ends, and the data can be copied to your computer for archiving or printing.

EXAMPLE: A flash drive is installed at the beginning of the day. Throughout the day a total of 20 cycles are run. Cycle data is captured in a single file on the flash drive for each of the 20 cycles. At the end of the day, the flash drive is removed and the file containing the 20 cycles run that day is transferred to a PC or laptop. Data from a Biologic (spore test) Test is logged in the Biological Test Data manual. The flash drive is returned to the sterilizer for the next day’s recordings.

PRINTER

If direct printing is desired, the following USB isolator and printer should be connected to the USB port:

USB Isolator – SMAKN® USB Isolator USB Digital Isolator Isolation USB to USB Industrial Isolator Available through Amazon.com at: https://www.amazon.com/SMAKN%C2%AE-Isolator-Digital-Isolation-Industrial/dp/B00XXPO4UG/ref=sr_1_1?ie=UTF8&qid=1472685844&sr=8-1&keywords=smaKn+usb+isolator

Printer - Epson TM-U220B with USB interface and USB cable.

NOTE: The isolator and printer must be connected to the COX USB port, and it must be turned ON, for the printer output to work. Only the last set of Cycle data is stored within the sterilizer for retrieval and is cleared when printed or downloaded to a flash drive.



The printer is a point-of-sale receipt-printing device. It prints ink on conventional three-inch receipt paper. Its dimensions are roughly 6 x 6 x 10 inches.

The date and time should be set in the sterilizer, so that information in the data log is correct as to time. These settings should be performed before the Cox sterilizer is first used and they will need to be updated if power to the sterilizer is lost. Follow the instructions on page 14, DETAILED OPERATING INSTRUCTIONS, to adjust the time settings.

The calendar does not handle Leap Year automatically.

The clock does not perform Daylight/Standard time changes automatically.

STERILIZATION CYCLE LOG FILE

The log file name is mm-dd-yy.TXT, for example, 1-11-16.TXT for a log that is written on January 11, 2016. A typical file containing a record of a single 12-minute sterilization cycle is shown below:

(begins with four blank lines, then a line of asterisks)

Operator_____

Start Date - 01/11/2016
Start Time - 04:43:46PM
Temp Setting - 375 F
Time Setting - 12 min.
Cycle Number - 083
Serial Number - 00002

Cycle Phase	Time	Temp(F)

Warm-up		
start	04:42:53PM	368
Warm-up		
end	04:43:46PM	375
1 min.	04:44:46PM	375
2 min.	04:45:46PM	375
3 min.	04:46:46PM	377
4 min.	04:47:46PM	376
5 min.	04:48:46PM	376
6 min.	04:49:46PM	378
7 min.	04:50:46PM	377
8 min.	04:51:46PM	377
9 min.	04:52:46PM	376
10 min.	04:53:46PM	377
11 min.	04:54:46PM	377
12 min.	04:55:46PM	377

Warm-up time = 0.9 min.
Exposure time = 12 min.
Total Cycle time = 12.9 min.

Cycle status = COMPLETE

(ends with a line of asterisks followed by six blank lines)

NOTE: It is important to set the date and time in the sterilizer set-up values, so that the logged date and time will be correct. This example shows a single record captured in the 1-11-16.TXT file. Multiple data cycles will be sequentially captured in the same file as long as the flash drive is plugged into the USB port, e.g. if 10 cycles were run on 1-11-16, 10 sequential cycles would be contained in file 1-11-16.TXT.

BATTERY

The sterilizer may be equipped with a battery to maintain the date and time information*, riding through AC power interruptions. This is recommended, so that power interruptions will not cause a frequent need to reset this information. The battery is a rechargeable lithium type that is maintained by the operation of the electronics within the sterilizer. The battery will normally endure power interruptions of at least 50 Hours. Battery charging is automatic while the unit is plugged into a power source, requiring about 5 Hours to recharge an exhausted battery.

Note: The Lithium battery may drain to its shutoff limit during shipping. It is recommended to plug the unit in upon receipt to allow the lithium battery to recharge. The lithium battery may result in the display of a PF (power fail) code, or the customer seeing the on/off LED lit with no power capability to the unit. See page 23 under ERROR CODES AND SYMPTOMS for clearing. Setting time and date will also be necessary; see page 14, DETAILED OPERATING INSTRUCTIONS.

*If data cycle capture information is not required for your site, the lithium battery can be removed from the unit and stored for future use.

MAINTENANCE – SERVICE

The Cox RapidHeat™ sterilizer is constructed of high quality materials, which may be cleaned with mild soap and a damp cloth or any non-abrasive cleaner. Unit can be externally disinfected with the disinfectant of your choice.

A cooling fan filter is located on the back of the unit to ensure the sterilizer performs reliably for many years. Visually inspect the filter for buildup of dust or contaminants at least once a month. Replace or clean (by rinsing preferably with distilled water and dry) the filter if an excessive amount of dust is evident. Replacement foam filters can be purchased from CPAC.

All internal components used in the sterilizer's construction are long life, heavy-duty parts that require no maintenance. Below is a list of potential error codes or performance symptoms that would indicate the possible need for service. If anything needs to be replaced, an authorized service representative should be called, or call CPAC at (585) 382-3223.

ERROR CODES AND SYMPTOMS

Certain failures in operation will be signaled by an error code. If one of the following error codes appears, press the power ON/OFF key for 1 second. 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.

Change Fan Filter

A 'CFF' indicator will be displayed when the unit is shut off if a clogged filter has not been cleaned or replaced and the performance of the cooling fan is being affected. If the filter is not replaced, an E-14 error code may occur and the sterilizer will require servicing.

Failing spore tests

Possible causes- Instruments stacked on top of each other.

Solution- Place instruments on one level or in divider rack.

Use the 12-minute cycle for items in an organizer or pouch.

Refer to Biological Testing procedures on page 10

Burning pouches

Possible causes - Temperature rising above 380°F.

Not using pouches compatible with sterilizer operating temperature (rated for 375°F).

Instruments not properly processed for sterilization

Solution - Clean cooling fan filter.

Use SteriSure nylon pouches.

Remove pouched instruments promptly after sterilization.

Replace sterilizer temperature sensor.

Timer not counting down during sterilization cycle

Possible causes - Temperature has not reached 375°F.

Door not closed, or faulty door switch.

Solution - Allow temperature to reach 375°F.

Verify that the door is properly closed.

Process Failure Codes:

The following codes are displayed in the event of certain failures

E-12 Key Switch failure: This indicates that a switch is stuck. This calls for replacement of the keypad.

E-14 Board over heat : Indicates excessive temperature within the cabinet, most commonly caused by clogged filter or failed cooling fan.

E-16 Cycle Interruption: Indicates a power interruption, door opening during cycle, or loss of heat

E-18 PCB failure: Indicates circuit board failure requiring service

E-20/21 Open temperature probe: Indicates a bad thermocouple probe, service required.

E-30 Over heat: Sterilization temperature above limit, service required.

E-31 Under heat: Sterilization temperature not reached within time limit, service required for heating Element or blower assembly.

PF - Power Failure indication; press and hold on/off button to clear

Possible causes – Battery has drained to shutoff limit: Press and hold On/Off LED for 2-3 seconds
Local power outage to facility or circuit: check breakers and local power
On/off LED lit, no power to unit, fuse ok: Remove and/or reseal battery

SPECIFICATIONS

UNIT ELECTRICAL RATINGS

MODEL COX-115V 120 VAC, 60Hz, 12 Amperes

MODEL COX-220V 220 VAC, 50Hz, 8 Amperes

DIMENSIONS

HEIGHT 15-1/4 Inches, WIDTH 18-5/8 Inches, DEPTH 17-1/8 Inches

WEIGHT 58 Pounds

ENVIRONMENTAL CONDITIONS

The COX RapidHeat™ 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 meters (6562 ft).

COX 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.

Product Number Description

CX0001	Blower Assembly w/o heater
CX0015	Wire Harness
CX0018	Wire Harness (black and white)
CX0022	Keypad
CX0024	Fuse Holder
CX0025	Fuse 15 Amp 250V (slow blow)
CX0031	Mesh Basket (Burr Holder)
CX0037	Muffin Fan 115V 106 CFM FAN
CX0048	Silicone Mat (6 7/8" x 7 1/2")
CX0051	Rubber Foot
CX0052	Cooling Rack
CX0079	Circuit Board Assembly
CX0082	Heater Assembly Complete
CX0085	Blower Assembly w/Heater
CX0088	Thermocouple
CX0097	Ophthalmology Kit (basket and 2 silicone mats)
CX0190	COX Shipping Box
CX0268	Door Gasket (for new COX design)
CX0273	Tray Removal Tool (new style)
CX0294	Instrument Tray Cooling Rack
CX0315	Cooling Rack, 2 Instrument Trays, Stacked
CX0322	Foam Filter, 4 1/2" Square (5/pack)
CX0412	COX Instrument Tray
CX1412	9" COX Instrument Tray
CX0413	COX Instrument Rack
CX1413	9" COX Instrument Rack: specify 3 or 7 slot configuration
CX0403	CPAC Standard Organizer
CX0405	Organizer Inserts 3-slot
CX0406	Organizer Inserts 6-slot
CX0415	SecureSlide™ Instrument Organizer
CX0414	COX Instrument Sterilizer System Kit

CPAC Equipment, Inc. Limited Warranty

CPAC Equipment, Inc. (CEI) certifies that all equipment manufactured by CEI at its Leicester, New York factory has been produced to exacting standards and has been tested and inspected for proper workmanship and performance.

CEI further warrants that any equipment or components found to be faulty or defective will be repaired or replaced by CEI for a period of 24 months from date of delivery of CEI equipment to Customer by CEI or CEI's authorized agent, (the "Warranty")

During this 24-month Warranty period, CEI will inspect and evaluate CEI equipment or components authorized by CEI for return to CEI's factory to determine if the equipment or components meet CEI's performance standards and specifications. CEI will replace or repair (at CEI's discretion) all CEI Equipment or Components determined faulty or proven to have material defects. Products classified as consumable under ordinary use are excluded under this warranty.

This Limited Warranty does not cover any and all equipment or component failures caused by (or resulting from) improper installation or operation, damage from accidents or casualties, misuse, abuse, tampering, and neglect; nor shall this Warranty extend to equipment that has been repaired or altered outside of CEI's factory without prior authorization from CEI. In addition, CEI assumes no responsibility for any freight damages occurring in transit by a common carrier. Claims for freight damages incurred in transit by a common carrier shall be presented to the carrier by the Customer.

Equipment and/or components to be replaced or repaired under this Warranty must be shipped to CEI, 2364 Leicester Road, Leicester, New York 14481 freight prepaid, or delivered freight prepaid to a facility authorized by CEI to render services provided hereunder. Returned equipment and/or components must be shipped either in their original packaging or in similar packaging that affords an equal degree of protection. All equipment and/or components must have a Return Material Authorization (RMA) code visible on the returned item. RMA's can be obtained by calling CEI at (585) 382-3223. Customer is responsible for all freight charges relating to a Warranty replacement or repair.

This Warranty is expressly in lieu of all other warranties, expressed or implied, including the warranty of merchantability or fitness for a particular purpose. This warranty is limited to the repair or replacement of defective equipment and components manufactured by CEI.

Customer acknowledges that any oral statements about the CEI Products equipment and/or components in any contract made by CEI's representatives, if any such statements are made, do not constitute warranties, shall not be relied upon by Customer and are not a part of the contract for sale for CEI equipment. The entire contract warranty is embodied in this writing, constitutes the final expression of the parties' agreement and is a complete and exclusive statement of the warranty terms.

The parties agree that the Customer's sole and exclusive remedy against CEI shall be for the replacement or repair of CEI equipment and/or components, and that no other remedy (including, but not limited to, incidental or consequential damages for lost sales, lost profits, injury to person or property) shall be available to the Customer.

EVERY EFFORT HAS BEEN MADE TO ENSURE THE ACCURACY OF THE CONTENT 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