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

CPAC
ENVIRONMENTAL SOLUTIONS
2364 Leicester Road, P.O. Box 175, Leicester, NY 14481
Phone (585) 382-3223 ● Fax (585) 382-9481 ● www.cpac.com

CX0073, Rev 7 February 9, 2018

TABLE OF CONTENTS

HVHA STERILIZATION

The Cox RapidHeat™ 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™ 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 is programmed to maintain temperature throughout the sterilizer chamber. The temperature control maintains an average temperature of 375°F (190 °C) indicated on the keypad display and can vary +/- 2-3°F. Although the display reads 375°F (190 °C), the actual internal chamber temperatures vary between 375°F and 395°F and are averaged across multiple temperature points inside the chamber.

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) at any time, the cycle will not begin or will restart after 375°F (190°C) has been reestablished.

The sterilizer is designed to maintain an average temperature of 375°F (190°C) within the chamber during sterilization. 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 or the temperature drops below 372°F, the cycle timer will reset and the sterilization cycle will restart after reaching the 375°F operating temperature. A temperature drop below 372°F during a sterilization cycle may result in an E-16 cycle interruption error.

RECOMMENDATIONS

Read the entire instruction manual before installation or operation of the Cox RapidHeat™ 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 RapidHeat™ 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 RAPIDHEAT STERILIZERS

The Cox RapidHeat™ Sterilizer was invented by Dr. Keith Cox. The technology used in the Cox RapidHeat™ 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 Racks 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:

Part No. CX0031	Mesh Basket (Burr Holder)
Part No. CX0412	8” COX Instrument Tray
Part No. CX1412	9” COX Instrument Tray
Part No. CX0413	9” COX Instrument Rack, 7 slot configuration for pouches
Part No. CX1413	9” COX Instrument Rack, 3 slot configuration for cassettes

Biological Testing, Risk management Procedures and checklist available at www.cpac.com

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

CONSUMABLES

Instrument pouches, biological monitoring supplies, and indicator strips are available from CPAC. Call CPAC at (585) 382-3223 or visit our website https://www.cpac.com/accessories/ 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 RapidHeat™ sterilizer. Caution should be used with plastic and rubber goods. When in doubt, consult the instrument manufacturer.

INDEPENDENT VALIDATIONS

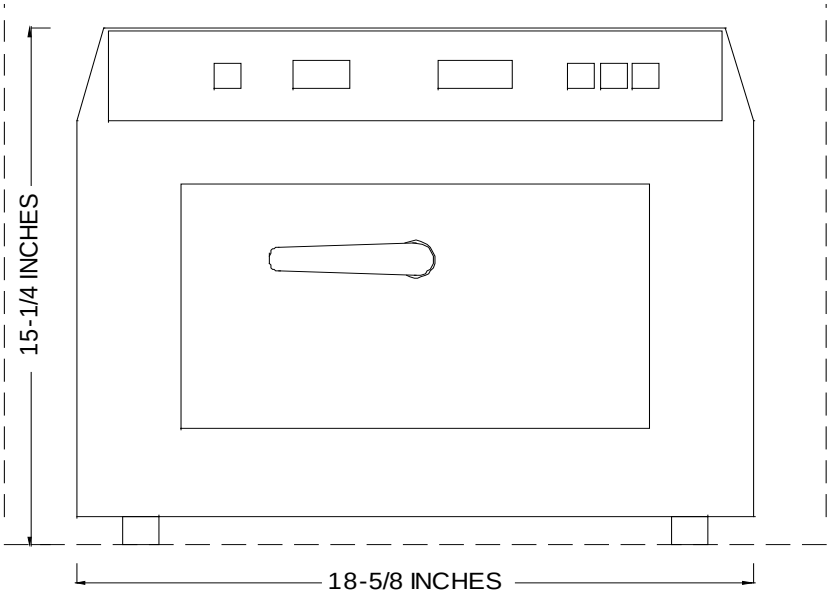
- Sirona Dental Systems has validated the use of the Cox RapidHeat™ Sterilizer Cycle I for the sterilization of the CEREX Omnicam and Bluecam mirror sleeves as provided in “Sirona Dental CAD/CAM System CEREC AC” (11-2016) and “CEREC Camera – Care, Cleaning, Disinfection, and Sterilization” (7-2016). These validations demonstrated that an Assured Sterility Level (SEL) representing a 12-Log microbial reduction is achieved with unwrapped Omnicam and Bluecam mirror sleeves using Cycle I (6-minute sterilization cycle). Use of High-Level Disinfection for the

Omnicam and Bluecam mirror sleeves is not permitted by the FDA in the United States although validated by Sirona for Europe.

- Sirona Dental Systems has validated the use of the Cox RapidHeat™ Sterilizer Cycle III for the sterilization of the CEREX Omnicam mirror sleeve as provided in “Sirona Dental CAD/CAM System CEREC AC” (11-2016). This validation demonstrated that an Assured Sterility Level (SEL) representing a 12-Log microbial reduction is achieved with pouched mirror sleeves using Cycle III (12-minute sterilization cycle). Use of High-Level Disinfection for the Omnicam mirror sleeve is not permitted by the FDA in the United States although validated by Sirona for Europe.

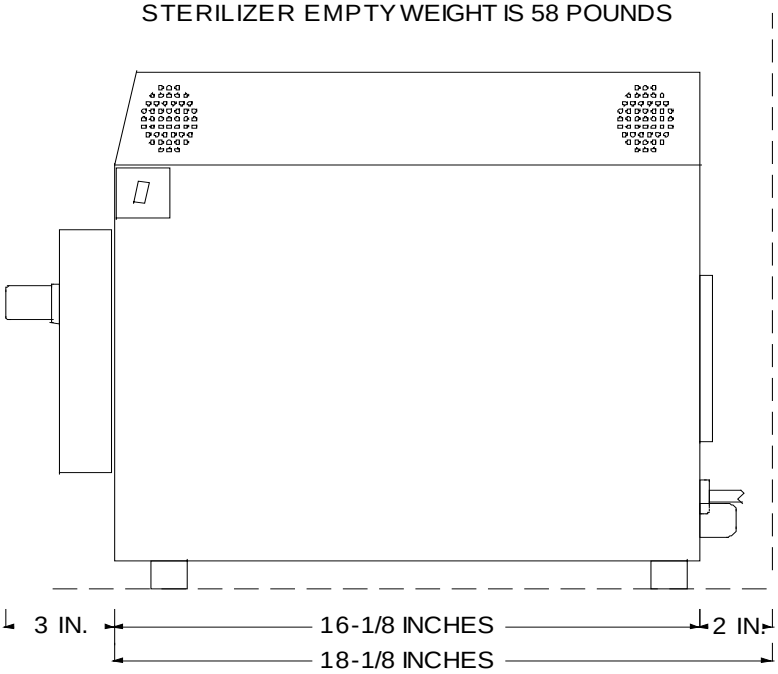
INSTALLATION: DIMENSIONS, CLEARANCES, WEIGHT

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 of 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 CX18130 through CX18591.

GUIDELINES FOR LOADING THE COX RAPIDHEAT™ STERILIZER

The Cox RapidHeat™ sterilizer is equipped with three pre-programmed sterilization cycles, each representing the time required to achieve a 6-Log reduction of bacterial spores plus a Sterility Assurance Level (SAL) of 6 additional Logs for (1) Unwrapped Instruments, (2) Unwrapped Handpieces; and (3) Wrapped Instruments.

The Cox RapidHeat™ sterilizer utilizes dry, rapidly flowing air to sterilize instruments. This process is both a heat conduction and heat convection process and requires that all instruments be directly subjected to the hot, high-velocity moving air. In the Cox RapidHeat™ sterilizer, airflow moves constantly through the instrument tray from the bottom to the top of the sterilizer chamber. This airflow can be restricted by the misplacement of instruments and packaging which may interfere with the performance of the sterilizer. Each of these three sterilization cycles is unique in its capacity and loading limitations and restrictions. Adherence to these limitations and restrictions is required for assuring performance specifications. And as with any sterilization technology, it is imperative that all instruments be clean, dry, and free of any organic or chemical residues. Only those instruments, cassettes, and pouches that have been demonstrated to be compatible with a temperature of 375^0F (190°C) can be sterilized in the Cox RapidHeat™ sterilizer.

CAPACITY LIMITATIONS AND RESTRICTIONS

Cycle I – Unwrapped Instruments

• **Instrument Weight Limitation Per Tray: 900 g or 2 lbs.**
• **Single Instrument Weight Should Not Exceed 250 g or 0.55 lbs.**
• **Instruments Cannot Overlap or Be Layered, Piled, or Stacked**
• **Instruments Must Lay Directly on Tray Bottom**
• **Burs, Diamonds And Other Small Items May Be Placed In an Accessory Mesh Basket**

Cycle II – Unwrapped Handpieces

• **Handpiece Weight Limitation Per Tray: 900 g or 2 lbs.**
• **Single Instrument Weight Should Not Exceed 250 g or 0.55 lbs.**
• **Handpieces Cannot Overlap or Be Layered, Piled, or Stacked**
• **Handpieces Must Lay Directly on Tray Bottom**

Cycle III – Wrapped Instruments

Option I: Wrapped or Pouched Instruments Laying Horizontal on Tray Bottom

• **Instrument Weight Limitation Per Tray: 750 g or 1.65 lbs.**
• **Instrument Weight Limitation Per Pouch: 150 g or 0.33 lbs.**
• **Pouched Instruments Cannot Overlap or Be Layered, Piled, or Stacked**
• **Pouched Instruments Must Lay Directly on Tray Bottom**

Option II: Wrapped or Pouched Instruments Placed Vertically in Instrument Rack

• **Instrument Weight Limitation Per Tray: 600 g or 1.32 lbs.**
• **Instrument Weight Limitation Per Pouch: 150 g or 0.33 lbs.**
• **Pouched Instruments Must Be Spaced 1" to Maintain Airflow to Both Sides of Pouch**

Option III: Wrapped or Pouched Instrument Cassettes Placed Vertically in Rack

• **Cassette/Instrument Weight Limitation Per Tray: 1500 g or 3.3 lbs**
• **Cassette/Instrument Weight Limitation Per Pouch: 500 g or 1.1 lbs**
• **Pouched/Wrapped Cassettes Must Be Spaced 1" to Maintain Airflow to Both Sides of the Cassette**

STERILIZATION CYCLES

CYCLE I – 6 MINUTES

Unwrapped Instruments Sterilization Instructions

To sterilize unwrapped instruments, place them into the instrument tray under the loading and capacity limitations and restrictions noted above for Cycle I. Place the tray into sterilizer by sliding the tray all the way to the rear of the heating chamber using the tray removal tool. Close the door, ensuring the handle is in the fully closed (horizontal) position, push and release the Cycle I button.

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.

After the sterilization cycle, immediately cover the unwrapped instrument(s) with a sterile cover to prevent environmental pathogens from causing instrument contamination. After cooling, retain sterile covering while transporting for immediate use to patient. Do Not Store Instruments for Future Use.

CYCLE II – 8 MINUTES
Handpiece Sterilization Instructions (Unwrapped)

To prepare air rotor handpieces or medical drills with internal tubing for sterilization, the following cleaning, rinsing, and drying protocols should be used:

- Clean the handpiece (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 handpiece cleaner or recommended solvent into the air drive.
- Thoroughly rinse and flush handpieces with water, preferably distilled or deionized water, to remove solvents or alcohols and to minimize or prevent instrument staining or spotting. To expedite solvent and water removal, rinse with alcohol and let dry. Water inhibits the sterilization process and as with any thermal sterilization process (steam or dry), residual solvents may cause a flammable or explosive incident.
- If a lubricant is required for the handpiece, **only Super-Lube Multi-Purpose Synthetic Lubricant with Syncolon (PTFE), CPAC part number CX0205** should be used or equivalent. This lubricant has a higher temperature tolerance required for the Cox RapidHeat™ sterilizer.
- Place thoroughly clean and dry handpieces into an instrument tray for sterilization.

To sterilize handpieces, select Cycle II. Place handpieces into the instrument tray according to the capacity and loading limitations and restrictions noted above for Cycle II. Slide the tray into sterilizer all the way to the rear of the heating chamber using the tray removal tool. Close the door, ensuring the handle is in the fully closed (horizontal) position, push and release the Cycle II button.

Upon completion of the cycle a “beep” will sound and an “8 C” appears in the time window. Promptly remove the handpiece(s) and allow them to cool. Remember to lubricate the handpiece prior to use if no lubricant was applied prior to the sterilization cycle. Follow lubrication instructions provided by the manufacturer.

After the sterilization cycle, immediately cover the unwrapped handpiece(s) with a sterile cover to prevent environmental pathogens from causing instrument contamination. After cooling, retain sterile covering while transporting for immediate use to patient. <u>Do Not Store Instruments for Future Use.</u>

CYCLE III – 12 MINUTES
Wrapped Instruments Sterilization Instructions
The material used for wrapping or pouching instruments and cassettes must be dry heat compatible, suitable for 375°F (190°C) temperatures (See “Recommended and Required Accessories” below).

Place the wrapped or pouched instruments into the instrument tray according to the capacity and loading limitations and restrictions noted above for Cycle III (dependent on wrapped option used). Slide the tray all the way to the rear of the heating chamber using the tray removal tool. Close the door, ensuring the handle is in the fully closed (horizontal) position, 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 time window on the face of the sterilizer indicating the cycle has been completed.

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 USING COX RAPIDHEAT™ STERILIZERS

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 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 Cox RapidHeat™ Sterilizer

I. Cox RapidHeat™ 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 Operation Manual~~,~~ (page 10), conducting pre- and post-evaluation as provided in the "Checklist for Weekly/Monthly Biological Indicator Testing for Cox RapidHeat™ Sterilizer".

1. Prepare the sterilizer, initiate, and trial run the selected sterilization cycle to verify functionality.
2. (a) For Cycle III, load the instruments into SteriSURE self-sealing nylon pouches or other CPAC pouches recommended for dry heat.
   (b) For Cycle I and Cycle II, layer instruments into the instrument tray with no instrument overlap.
3. (a) For Cycle III, add a chemical indicator to each pouch.
   (b) For Cycle I and Cycle II, place chemical indicator strip under an instrument to secure it in place.
4. (a) For Cycle III, 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.
   (b) For Cycle I and Cycle II, place spore strip under an instrument to secure it in place.
   (c) 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 instrument tray and that the pouches or instruments 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.

6. With the sterilizer having already come to operating temperature (375° F; 190° C) via Step 1, place the instrument tray into the sterilizer.
7. Start the sterilization cycle.
8. 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 9.

    (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 technique 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.
9. Verify that all chemical indicators changed color. Enter results into the Biological Test Data Manual.
10. Via printer or via download through the USB port, document 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 the unit does not have a USB data port, record time and temperature throughout the sterilization cycle, recorded every 60 seconds.
11. Document any other conditions (including any error codes) or observations that may influence results and record them in the Biological Test Data Manual.
12. 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 9).

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 Cox RapidHeat™ 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 60 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 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 373°F and 380°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 Cox RapidHeat™ Sterilizer

(Upon Completion Place This Form in Biological Test Data Manual)

Date_____ Cycle Start Time _____ Cycle End Time _____

Operator_____

Sterilizer Equipment ID/Serial Number _____

Pre-Check Prior to Initiation of Sterilization Cycle

- ☐ Sterilizer checked for obstructions to (1) air supply on back panel (clean filter and maintained distance from wall) and (2) interior air exhaust port
- ☐ Interior sterilization chamber is clean; seal around door is clean and free of obstructions
- ☐ Sterilizer pre-warmed and maintaining 375°F
- ☐ Flash/Thumb drive inserted in USB port
- ☐ Conducted pre-test to assure sterilization cycle time and temperature is recorded for correct day, month, year; temperature records as 375°F (373 – 380°F) is within tolerance throughout test cycle
- ☐ 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 "Cox RapidHeat™ Sterilizer and Instrument Load Preparation" in Operations Manual for insertion of biological indicator and chemical indicator

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
- ☐ Downloaded via USB port or via printer the parametric operating conditions (date, times, and temperatures) of the test cycle and place 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 error codes) 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

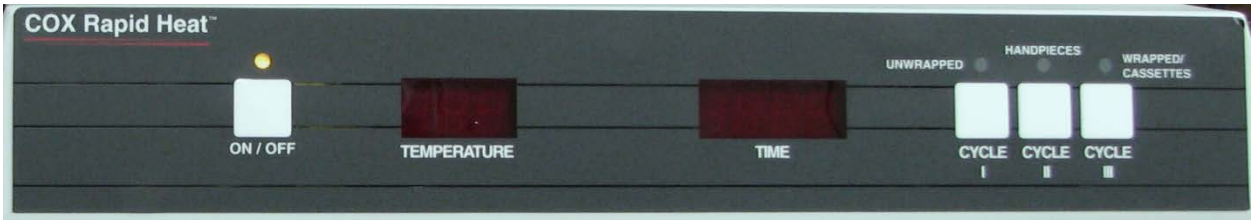
☐ No

Signature of Operator _____ Date_____

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

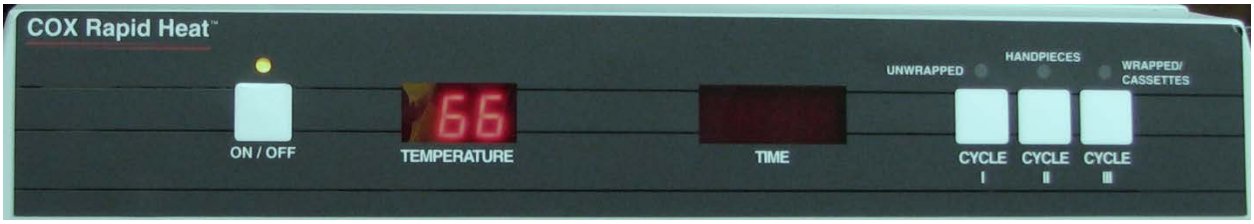


The control panel is shown above. This is the appearance of the panel when the sterilizer is in the OFF or STANDBY mode. The light above the ON/OFF button is lit, no heat is produced, and the sterilizer's internal fans are stopped.

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.

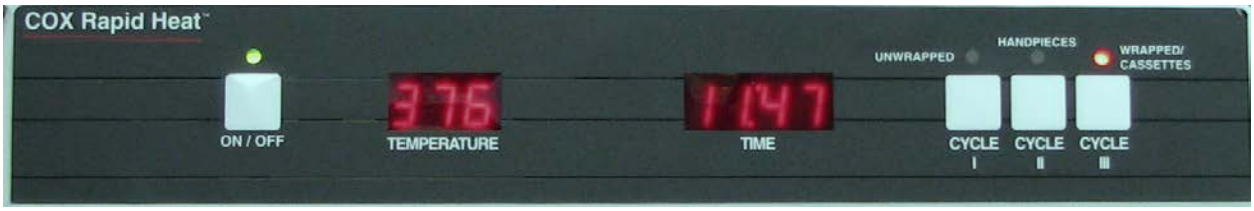
The CYCLE I, CYCLE II, and CYCLE III buttons are used in combination for entry of sterilizer setup data, such as date and time, and they are used for selection of one of the three alternate sterilization cycles.

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.

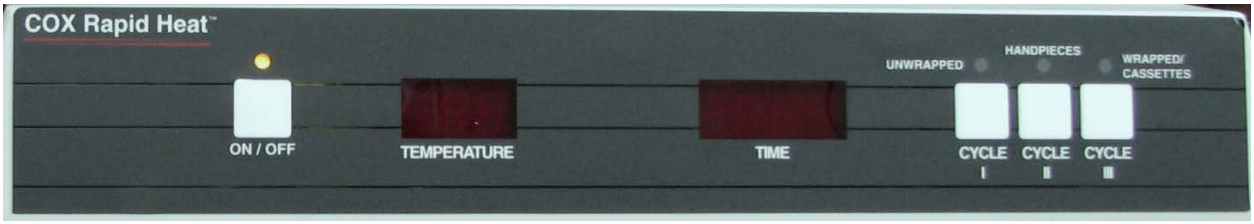


Above: Press and hold the ON/OFF button, and the sterilizer's fans will start. Temperature of the sterilization chamber is shown in the TEMPERATURE window. Temperature is updated at about five-second intervals. The sterilizer will warm up to an operating temperature of 375 degrees Fahrenheit. Sterilization 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 OFF or 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 OFF or STANDBY mode. The light above the ON/OFF button remains lit.

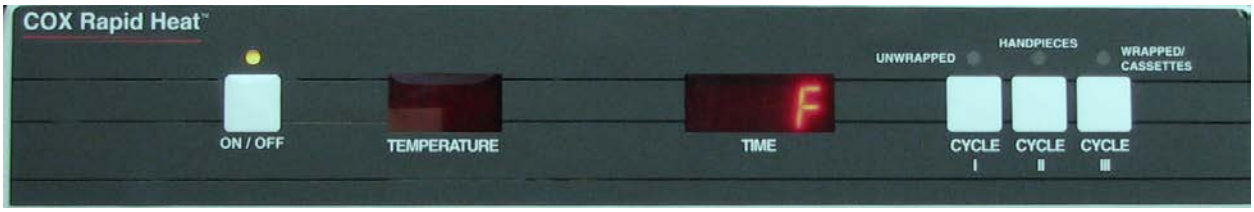
The SETTINGS mode can be entered when the sterilizer is in STANDBY mode or the cool-down interval.

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 - 1 hour
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 1 – 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 silenced by changing the value to 0(OFF). Display format example = “AA-1”.



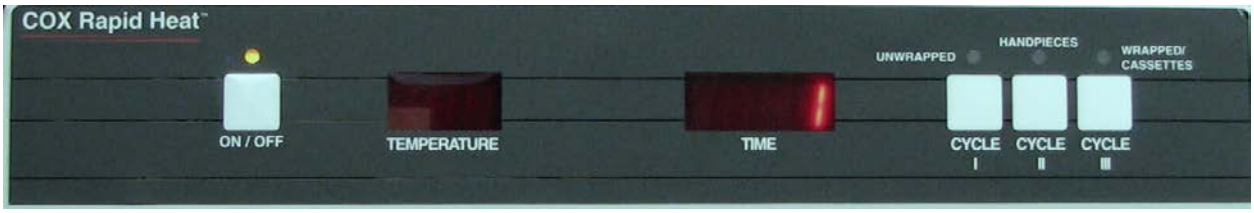
FAHRENHEIT/CELSIUS: Default – F (Fahrenheit)
The temperature measurement can be displayed in units of Fahrenheit (F) or Celsius (C).
Display format example = “ F”.

PRINTER OUTPUT COPIES: Default – 1

This value cannot be changed.

YEAR: Default - Typically the year in which the sterilizer was manufactured or calibrated.

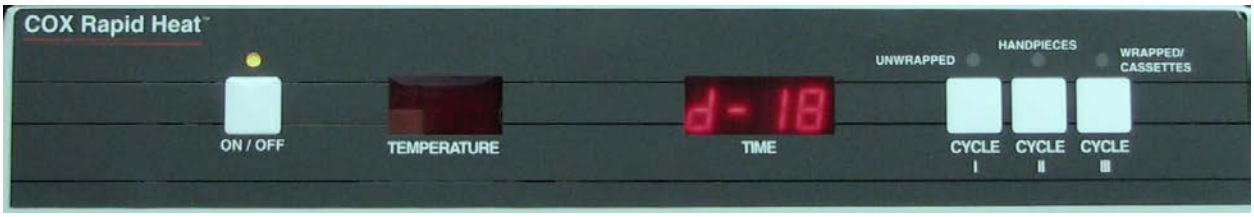
The year can be updated to current year. Display format example = “2016”.



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”.

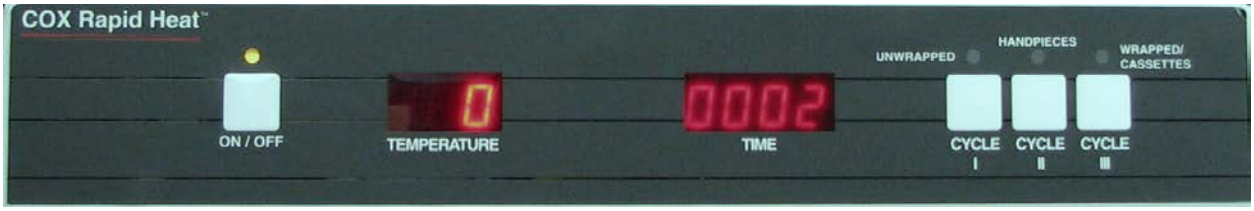


DAY of MONTH: Default – 1.

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 hour 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 RapidHeat™ Sterilizer is capable of downloading cycle data to a POS printer or 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 start of the day. Through 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

NOTE: The Cox RapidHeat™ Sterilizer is not designed or capable of Internet/Intranet connectivity only providing output communication of cycle data to a POS printer or USB flash drive of 8 Gb or less.

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. It is normal for this cycle data to reflect temperatures ranging from 373°F to382 °F during a sterilization cycle as the data is representative of the average chamber temperature under normal operating cycle conditions.

(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	375
11 min.	04:54:46PM	374
12 min.	04:55:46PM	376

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)

NOTES: 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.

Note: Batteries have been installed in units with serial numbers CX18130 through CX18591.

*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

CFF – Indicates a clogged fan filter needs to be cleaned or replaced affecting the performance of the cooling fan. Clean or replace the filter.

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, circuit board service required.

E-31 Under heat: Sterilization temperature not reached within time limit.
Possible causes - Service required for heating element or blower assembly.
Door switch cable loose

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
Circuit breaker tripped or local power outage occurred

On/off LED lit, no power to unit, fuse ok: Remove and/or reseat battery if installed

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™ 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 RAPIDHEAT 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
CX0014	Power Cord
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
CX0079	Circuit Board Assembly
CX0082	Heater Assembly Complete
CX0085	Blower Assembly w/Heater
CX0088	Thermocouple
CX0190	COX Shipping Box
CX0205	Super-Lube Multi-purpose Synthetic Lubricant with Syncolon (PTFE) (for handpieces)
CX0273	Tray Removal Tool (new style)
CX0294	Instrument Tray Cooling Rack (for new Cox design)
CX0315	Cooling Rack, 2 Instrument Trays, Stacked
CX0322	Foam Filter, 4 1/2" Square (5/pack)
CX0326	Door Gasket (for new Cox design)
CX0412	8” COX Instrument Tray
CX1412	9” COX Instrument Tray
CX0413	9” COX Instrument Rack, 7 slot configuration for pouches
CX1413	9” COX Instrument Rack, 3 slot configuration for cassettes

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 36 months from date of delivery of CEI equipment to Customer by CEI or CEI's authorized agent, (the "Warranty")

During this 36-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 14481freight 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