CoxRAPIDHEAT™
HIGH-VELOCITY HOT AIR STERILIZERS

High Velocity Hot Air Rapid Heat Sterilisers with
6, 8, and 12 Minute Sterilisation Cycle Times

USER MANUAL
MODELS:
COX – 220V

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HVHA STERILISATION

The Cox RapidHeat™ Steriliser employs High-Velocity Hot Air (HVHA) to sterilise medical and dental instruments. Radically different than steam sterilisation, HVHA technology uses fluidised hot, dry air to sterilize instruments by a combination of convection and conductive processes. Conventional practices necessary for the sterilisation 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™ Steriliser. Failure to follow the operating instructions in this manual can result in damaged instruments, damage to the steriliser, user injury, and sterilisation efficacy. Following these instructions will result in a worry-free sterilisation process that is simple, efficient, and safe, providing long life to your instruments.

CAUTIONS

- During operation, the exterior surface of the steriliser remains comfortable to the touch; however, the interior of the drawer and the sterilised 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 steriliser 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 a temperature of 190°C.

- Instruments that have been wiped with alcohol, or any combustible solution, must be allowed to dry before being placed in the steriliser.

- Use only dry heat wraps and pouches suitable for 190°C temperature.

SAFETY NOTES CONCERNING TEMPERATURE

The temperature in the Cox RapidHeat™ steriliser is controlled by computer logic, which is programmed to maintain temperature throughout the steriliser chamber. The temperature control maintains an average temperature of 190 °C indicated on the keypad display. Although the display reads 190 °C, the actual internal chamber temperatures vary between 190°C and 200°C and are averaged across multiple temperature points inside the chamber.

After room temperature instruments are placed in the steriliser, 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 189°C at any time, the cycle will not begin or will restart after 190°C has been re-established.

The steriliser is designed to maintain an average temperature of 190°C within the chamber during sterilisation. 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 sterilisation cycle. In the event that the door is opened or the temperature drops below 189°C, the cycle timer will reset and the sterilisation cycle will restart after reaching the 190°C operating temperature. A temperature drop below 189°C during a sterilisation cycle may result in an E-16 cycle interruption error.

RECOMMENDATIONS

Read the entire instruction manual before installation or operation of the Cox RapidHeat™ Steriliser. 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™ Steriliser, 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.

1. 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 (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 the unit by the door opening in front of unit. Hold securely by the bottom when lifting or moving the steriliser. The steriliser weighs approximately 26 kilograms.

SAVE THESE INSTRUCTIONS

COX RAPIDHEAT STERILISERS

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

ACCESSORIES AND CONSUMABLES

The Cox RapidHeat™ steriliser 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 sterilisers.

OPTIONAL ACCESSORIES

The following additional steriliser 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.metafix.co.uk

Call Metafix (UK) Ltd at 01933 461907 to place an order for these items.

CONSUMABLES

Instrument pouches, biological monitoring supplies, and indicator strips are available from Metafix. Call Metafix (UK) Ltd at 01933 461907 to place an order for these items or visit our website for information www.metafix.co.uk

MATERIALS INTEGRITY

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

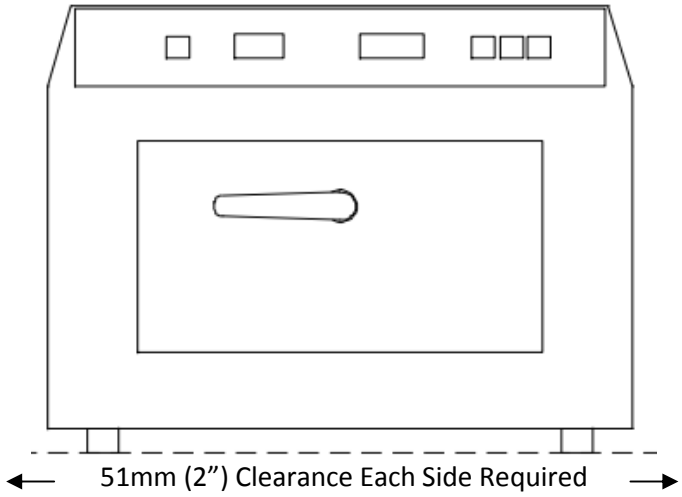
INDEPENDENT VALIDATIONS

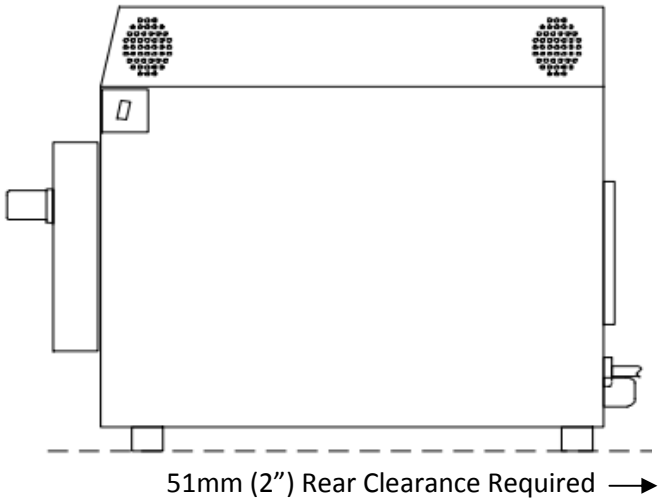
- Sirona Dental Systems has validated the use of the Cox RapidHeat™ Steriliser Cycle I for the sterilisation of the CEREX Omnicam and Bluecam mirror sleeves as provided in "Sirona Dental CAD/CAM System CEREC AC" (11-2016) and "CEREC Camera – Care, Cleaning, Disinfection, and Sterilisation" (7-2016). 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 sterilisation cycle).

- Sirona Dental Systems has validated the use of the Cox RapidHeat™ Steriliser Cycle III for the sterilisation 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 sterilisation cycle).

INSTALLATION: DIMENSIONS, CLEARANCES, WEIGHT

Dimensions and clearance requirements are shown below:





Unit size (OD)	432(W) x 432(D) x 381(H) mm
Chamber size (ID)	244(W) x 197(D) x 102(H) mm
Weight Unit	23Kg
Instrument tray size	241(w) x 197(D) x 48(H) mm
Electrical	220-240V, 1100W warm up, 300W operating

SUITABLE ELECTRICAL CIRCUIT AND OUTLET

The steriliser should be plugged into a 240-Volt, grounded outlet. It is best practice to provide an outlet that serves only the steriliser, or the steriliser and its optional printer.

OPERATING INSTRUCTIONS

TO START THE DAY

Before turning the steriliser 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 steriliser to heat to 190°C. This will take about 25 minutes. The ON STANDBY/OFF LED will change colour from amber to green when the warm-up to 190°C is complete.

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

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

PRIOR TO STERILISATION

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

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

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

Units containing a battery* will need the date and time set before the Cox steriliser is first used and will need to be updated if the power is lost to the steriliser. 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.

STERILISATION CYCLES

CYCLE I – 6 MINUTES
Unwrapped Instruments Sterilisation Instructions

NOTE: After the sterilisation 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 steriliser 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 sterilisation. 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 steriliser 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 sterilised instruments will continue to cool on the cooling rack.

CYCLE II – 8 MINUTES
Handpiece Sterilisation Instructions (Unwrapped)

NOTE: After the sterilisation 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 prepare air rotor handpieces or medical drills with internal tubing for sterilisation, 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 sterilisation process and as with any thermal sterilisation 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), Metafix part number CX0205** should be used. This lubricant has a higher temperature tolerance required for the Cox RapidHeat™ steriliser.

- Place thoroughly clean and dry handpieces into an instrument tray for sterilisation.

To sterilize handpieces, select Cycle II. Upon completion of the cycle a "beep" will sound and an "8 C" appears in the time window. Promptly remove the instruments and allow them to cool. Remember to lubricate the handpiece prior to use if no lubricant was applied prior to the sterilisation cycle. Follow lubrication instructions provided by the manufacturer.

CYCLE III – 12 MINUTES
Wrapped Instruments Sterilisation Instructions

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 sterilisation 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 sterilisation efficiency by interfering with the exhaust fan inlet located on the back right panel of the sterilisation chamber

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

Place the rack in the instrument tray, insert the tray in the steriliser, 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 **(nylon)** pouching material suitable for 190°C temperature (See "Recommended and Required Accessories" below).

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"

PREPARING TEST LOADS

A sample test load is needed to reliably evaluate the effectiveness of the steriliser and achieve consistent results. The test load should be a typical full load* consisting of simple metal instruments normally sterilised 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 steriliser will enter standby mode while the cooling fan continues to operate. At the end of ten minutes, the steriliser will automatically shut off. If the steriliser 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 steriliser is in cool down mode.

BIOLOGICAL TESTING USING COX RAPIDHEAT™ STERILISERS

The American Dental Association, United States Air Force, Joint Commission of Accreditation of Hospitals, and the Centres for Disease Control recommend biological indicator tests to monitor and verify the steriliser'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 **biological spore testing services** are available direct from Metafix:

- Chemical indicators:- Dry Heat Indicator Strips 2 x 250.
- Spore test strips:- Crosstex BG-106 DH B.atrophaeus 1 x 100.
- Steriliser monitoring service:- Biological spore testing service (48hours).

Introduction

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

To assure that both the sterilisation unit is functioning properly and that operational protocols are efficacious, a surrogate challenge microorganism is used that (1) provides a challenge to the sterilisation 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 sterilisation 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 sterilisation has been achieved.

Biological indicators are used to provide a direct correlation of the steriliser's parametric indicators and packaging/loading protocols with microbiological kill. Their use is not intended for the everyday monitoring of the steriliser'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 sterilisation 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 sterilisation process are given 48 hours to repair and reproduce. From the time of spore strip submission to Metafix or another contracted laboratory, three days are minimally required to obtain results from a biological indicator test.

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. 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 Sterilisation in Healthcare Facilities, 2008*. [1]

Biological Testing Protocols for the Cox RapidHeat™ Steriliser

I. Cox RapidHeat™ Steriliser 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 steriliser's operating instructions is essential, including the retrieval of the biological indicator immediately upon completion of the sterilisation cycle.

Prepare challenge load of instruments according to the Operation Manual, (page 9), conducting pre- and post-evaluation as provided in the "Checklist for Weekly/Monthly Biological Indicator Testing for Cox RapidHeat™ Steriliser".

1. Prepare the steriliser, initiate, and trial run the selected sterilisation cycle to verify functionality.

2.
   (a) For Cycle III, load the instruments into SteriSURE self-sealing nylon pouches or other 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 sterilisation 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 centre 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 centre of the full load.

6. With the steriliser having already come to operating temperature 190° C via Step 1, place the instrument tray into the steriliser.

7. Start the sterilisation 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 Metafix, place the 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 colour. Enter results into the Biological Test Data Manual/Logbook.

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/Logbook. Review this data to assure the steriliser was performing properly during this test cycle. If the unit does not have a USB data port, record time and temperature throughout the sterilisation 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/Logbook.

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™ Steriliser" will provide the following to assist in determining root cause of the failure. Specifically, this data will provide:

- Steriliser 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 steriliser is operating within specifications and to ensure instrument packaging and sterilisation loading conditions are followed. These protocols will assist the customer and Metafix technicians in determining the cause of the spore test failure and determining whether the steriliser should be taken out of service and returned to Metafix for further evaluation.

It should be noted that there are numerous factors that can lead to a failed spore test other than steriliser failure. 1 It should be further noted that CDC states that the large margin of safety required for sterilisation 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 sterilisation 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 sterilisation 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 190°C and 195°C for the duration of the sterilisation 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 steriliser 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 steriliser 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 Metafix for analysis or perform on-site analysis.

5. If the second spore test results in a failure, call Metafix on 01933 461907 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 steriliser being returned to Metafix 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 Sterilisation 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™ Steriliser

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

Date_____ Cycle Start Time _____ Cycle End Time _____

Operator_____

Steriliser Equipment ID/Serial Number _____

Pre-Check Prior to Initiation of Sterilisation Cycle

☐ Steriliser checked for obstructions to (1) air supply on back panel (clean filter and maintained distance from wall) and (2) interior air exhaust port

☐ Interior sterilisation chamber is clean; seal around door is clean and free of obstructions

☐ Steriliser pre-warmed and maintaining 190°C

☐ Flash/Thumb drive inserted in USB port

☐ Conducted pre-test to assure sterilisation cycle time and temperature is recorded for correct day, month, year; temperature records as 190°C (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™ Steriliser and Instrument Load Preparation” in Operations Manual for insertion of biological indicator and chemical indicator

Post-Check After Completion of Sterilisation 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 colour 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 steriliser 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 steriliser meet performance standards as stipulated in the Operations Manual?

☐ Yes

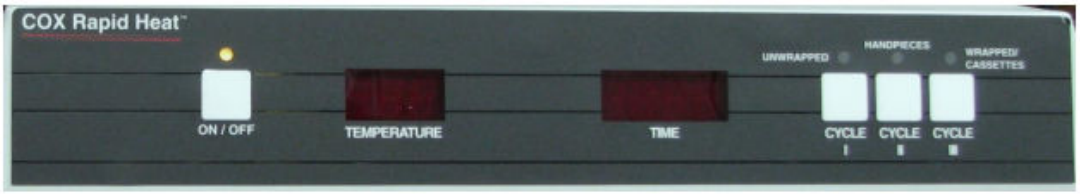
☐ No

Signature of Operator _____ Date_____

DETAILED OPERATION AND SETUP

Before turning the steriliser 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 STERILISER CONTROL PANEL

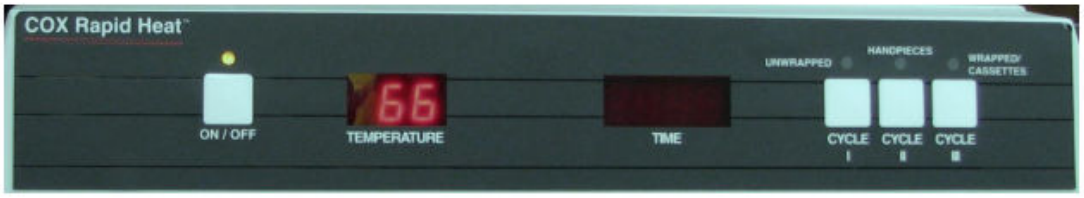


The control panel is shown above. This is the appearance of the panel when the steriliser is in the OFF or STANDBY mode. The light above the ON/OFF button is lit, no heat is produced, and the steriliser's internal fans are stopped.

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

The CYCLE I, CYCLE II, and CYCLE III buttons are used in combination for entry of steriliser setup data, such as date and time, and they are used for selection of one of the three alternate sterilisation 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 steriliser's fans will start. Temperature of the sterilisation chamber is shown in the TEMPERATURE window. Temperature is updated at about five second intervals. The steriliser will warm up to an operating temperature of 190 Degrees Celcius. Sterilisation 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 steriliser has not yet warmed up to operating temperature, and the twelve-minute sterilisation 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 190^{o}C, 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 sterilisation cycle in minutes and seconds. Small variations above the 190^{o}C temperature is normal.

Above: Press and hold the ON/OFF button to return the steriliser 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 steriliser is then in OFF or STANDBY mode. The light above the ON/OFF button remains lit.

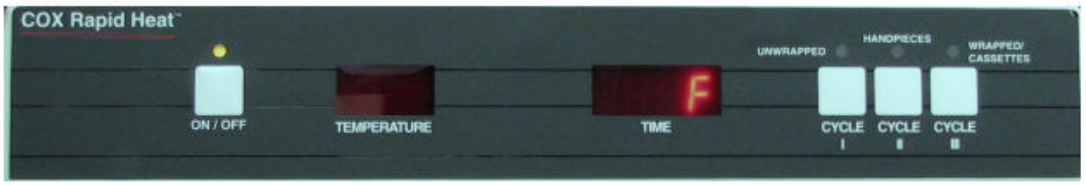
The SETTINGS mode can be entered when the steriliser is in STANDBY mode or the cool-down interval.

SETTING OPERATOR OPTIONS AND SETTING THE CLOCK

The following system settings can be viewed or changed from their defaults when the steriliser 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 = “Sb-2”.

AUDIBLE ALARM: Default – 1(ON)
The unit has an audible alarm that alerts the user when the sterilisation 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 steriliser 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 hour value flashes to indicate HOURS setting mode. Pressing the CYCLE I button changes to MINUTES setting mode.

MODEL: Steriliser 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™ Steriliser 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 steriliser. The steriliser 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 sterilisation 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 steriliser for the next day’s recordings.

PRINTER

NOTE: The Cox RapidHeat™ Steriliser 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-IsolationIndustrial/dp/B00XXPO4UG/ref=sr_1_1?ie=UTF8&qid=1472685844&sr=81&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 steriliser 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 steriliser, so that information in the data log is correct as to time. These settings should be performed before the Cox steriliser is first used and they will need to be updated if power to the steriliser 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.

STERILISATION 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 sterilisation cycle is shown below. It is normal for this cycle data to reflect temperatures ranging from 373°F to382 °F during a sterilisation 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 – 190 C
Time Setting - 12 min.
Cycle Number - 083
Serial Number - 00002

Cycle Phase	Time	Temp(C)
Warm-up start	04:42:53PM	187
Warm-up end	04:43:46PM	190
1 min.	04:44:46PM	190
2 min.	04:45:46PM	190
3 min.	04:46:46PM	191
4 min.	04:47:46PM	190
5 min.	04:48:46PM	190
6 min.	04:49:46PM	190
7 min.	04:50:46PM	191
8 min.	04:51:46PM	190
9 min.	04:52:46PM	190
10 min.	04:53:46PM	190
11 min.	04:54:46PM	190
12 min.	04:55:46PM	190

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 steriliser 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 1-1116.TXT.

BATTERY

The steriliser 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 steriliser. 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™ steriliser 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 steriliser performs reliably for many years. Visually inspect the filter for build-up 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 Metafix.

All internal components used in the steriliser'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 call Metafix on 01933 461907.

ERROR CODES AND SYMPTOMS

Certain failures in operation will be signalled by an error code. If one of the following error codes appears, press the power ON/OFF key for 1 second. This will re-establish the error detect logic and will eliminate false error codes that may occur. If the error code persists, call Metafix on 01933 461907.

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 steriliser 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 190 ^{o}C.
	Not using nylon pouches compatible with the steriliser operating temperature (rated for 190 ^{o}C).
	Instruments not properly processed for sterilisation
Solution:	Clean cooling fan filter.
	Use SteriSure nylon pouches.
	Remove pouched instruments promptly after sterilisation.
	Replace steriliser temperature sensor.

Timer not counting down during sterilisation cycle

Possible causes:	Temperature has not reached 190 ^{o}C.
	Door not closed, or faulty door switch.
Solution:	Allow temperature to reach 190 ^{o}C.
	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: Sterilisation temperature above limit, circuit board service required.

E-31 Under heat: Sterilisation 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-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™ Steriliser 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 STERILISER SPARE PARTS LIST

Many of the items listed below require installation by an appropriately trained technician. Contact Metafix by telephone on 01933 461907 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

Metafix (UK) Ltd.

Limited Warranty

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

Metafix further warrants that any equipment or components found to be faulty or defective will be repaired or replaced by Metafix for a period of 36 months from date of delivery of CEI equipment to Customer by Metafix, (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. Metafix 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 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 by non Metafix appointed engineers.

Equipment and/or components to be replaced or repaired under this Warranty must be notified at the first instance to the Metafix Helpdesk on 01933 461907 or info@metafix.co.uk

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.

The parties agree that the Customer's sole and exclusive remedy against Metafix 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.

END OF LIFE

The EU Waste Electrical and Electronic Equipment (WEEE) Directive In August of 2005, the European Union (EU) implemented the EU WEEE Directive 2002/96/EC and later the WEEE Recast Directive 2012/19/EU requiring Producers of electronic and electrical equipment (EEE) to manage and finance the collection, reuse, recycling and to appropriately treat WEEE that the Producer places on the EU market after August 13, 2005. The goal of this directive is to minimize the volume of electrical and electronic waste disposal and to encourage re-use and recycling at the end of life. If you have purchased CPAC Equipment Inc. HVHA steriliser(s) from Metafix (UK) Ltd and are intending to discard these products at the end of their useful life, please do not dispose of them with your municipal waste. CPAC Equipment Inc. has labelled its branded electronic products with the WEEE Symbol (figure 1) to alert our customers that products bearing this label should not be disposed of with municipal waste in the EU. Instead, please be aware that Metafix (UK) Ltd is making a return and collection system available to you, free of transportation and recycling costs, for discarding these products.

Figure 1: WEEE symbol – crossed out wheeled bin