RH-Pro 11 OPERATION MANUAL

High-Velocity Hot Air™ ("HVHA") Sterilizers
Model: RapidHeat™ RH-Pro11

ENVIRONMENTAL SOLUTIONS
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CPAC.com
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CONGRATULATIONS on selecting an RH-Pro11™ High-Velocity Hot Air Sterilizer. The RH-Pro11™ 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 that transfers heat energy to instruments by a combination of convection and conductive processes. Microbial destruction by dry heat results from DNA damage preventing microbial cells to reproduce through the disruption of genetic replication. 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.

The RH-Pro11 has been designed to meet the expanding capacity needs of the dental and healthcare practitioner. Based on the technology ingrained in the Cox RapidHeat Transfer Sterilizer, the RH-Pro11 retains the same pre-set sterilization cycles for unwrapped (6 minutes), wrapped (12 minutes), and dental handpieces (8 minutes) as documented by spore inactivation rate studies. Total treatment time for all HVHA sterilizers is a composite of (1) the time required for instruments to achieve and maintain the temperature necessary to initiate bacterial spore kill (Kill Initiation Temperature) and (2) the holding time necessary at this temperature (or above) to achieve a 12-Log bacterial spore kill. Both time activation and an internal thermal sensor are employed to ensure that instrument Kill Initiation Temperature is achieved for each load. Once bacterial spore kill is initiated, the pre-selected sterilization cycle is initiated and displayed with countdown timer. Cycle times and temperatures are recorded internally with data availability for external downloading or printer access.

Please read this manual carefully, paying particular attention to the requirements for instrument preparation, packaging, and loading of the RH-Pro11™ 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

CUSTOMER WARNING!

PLEASE retain the shipping carton, packing materials and straps in the event this product may need to be returned to the manufacturer for repairs. Failure to retain the carton and materials will result in additional charges for the items in the event a return may be necessary.

IMPORTANT INFORMATION

PLEASE READ THE FOLLOWING INSTRUCTIONS FOR USE PRIOR TO INSTALLATION AND OPERATION OF YOUR RH-PRO11 STERILIZER. BE SURE TO RETAIN A COPY OF THIS USER MANUAL FOR FUTURE REFERENCE.

1.1 Contact Information

Dealer: _____

Authorized Service Representative: _____

1.2 User Reference Information

Date of Purchase: _____

Model Number*: _____

Serial Number*: _____

*Located on the right back side of the sterilizer

1.3 Limited Warranty

CPAC Equipment, Inc. provides a limited three-year warranty for the RH-Pro11 on parts and labor as described in Section 12 of this manual.

1. SAFETY INFORMATION

The RapidHeat RH-Pro11 is designed for easy operation and maintenance. For safe and reliable operation, please read and understand the installation and operating instructions contained in this User Guide. All personnel charged with the operation of the RH-Pro11 should be aware of this User Guide and follow its contents.

2.1 Sterilizer Use

The RH-Pro11 is for the sterilization of medical devices that are not heat-sensitive and that can withstand sterilization at temperatures of 350 degrees F (177 degrees C) wrapped or pouched and 375 degrees F (190 degrees C) unwrapped. **Never use the RH-Pro11 for sterilizing liquids, chemicals or radioactive materials.**

2.1 Safety Symbols

WARNING
INDICATES A POTENTIALLY HAZARDOUS SITUATION THAT COULD LEAD TO INJURY OR EQUIPMENT DAMAGE

ELECTRICAL HAZARD WARNING
INDICATES A POTENTIALLY HAZARDOUS ELECTRICAL SHOCK POTENTIAL THAT COULD LEAD TO INJURY

HOT SURFACE WARNING
INDICATES THAT A SURFACE OR ARTICLE MAY BE HOT ENOUGH TO CAUSE DISCOMFORT OR INJURY

FIRE/EXPLOSION WARNING
INDICATES A SITUATION COULD EXIST THAT COULD LEAD TO A FIRE OR EXPLOSION THAT COULD CAUSE INJURY OR EQUIPMENT DAMAGE

2.2.1 Cautions 

- During operation, the exterior surface of the sterilizer remains comfortable to the touch; however, the tray and the sterilized instruments will be hot. Use only the provided heat-resistant gloves for removing the instrument tray and sterilized instruments. 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 this high temperature environment, but extreme care should be used in sterilizing these materials until compatibility has been confirmed by the manufacturer.
- When sterilizing packaged instruments, use only dry heat packaging material suitable for 375°F (190°C) temperatures.
- Instruments must be dry before being placed into the sterilizer. Water (moisture) interferes with the sterilization process.
- Instruments that have been wiped with alcohol, or any combustible solution, must be rinsed and allowed to thoroughly dry before being placed in the sterilizer. Absolutely no combustible liquids in any quantity are to be placed into the sterilizer.

2.2.2 Temperature Safety Features

- The temperature in the RapidHeat™ Pro11 sterilizer is controlled by computer logic, which is programmed to maintain uniform temperature throughout the sterilizer chamber. The temperature control maintains a uniform temperature of 375°F (190 °C) as indicated on the keypad display with a variability of +/- 2-3°F.
- 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 between cycles. If the temperature drops below 372°F (189°C) at any time, the cycle will not begin or the sterilization cycle will restart after 375°F (190°C) has been reestablished. It is important to note that the displayed temperature is the chamber air temperature and not the temperature of the instrument(s).
- The sterilizer is designed to maintain a temperature of 375°F (190°C) within the chamber during sterilization. The door must be in the "LOCKED" position between cycles to avoid the heating element from shutting off which will result in chamber cool-down and possible re-initiation of the initial chamber heating sequence.

- The door cannot be opened during a sterilization cycle without the operator pressing "Cancel" on the key pad. In the event that 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 will result in a cycle interruption error and notification which will be documented in memory.

2.2.3 General Recommendations

Read the entire instruction manual before installation or operation of the RapidHeat™ Pro11 Sterilizer. It will help you to understand the operation of the system, how various sub-assemblies work in concert, and the operating sequence of the controls.

WARNING:

NEVER ATTEMPT TO PERFORM ANY ELECTRICAL TROUBLESHOOTING, ADJUSTMENT, OR SERVICE UNLESS YOU ARE A FACTORY TRAINED SERVICE TECHNICIAN.

2.3 Important Safeguards

When using your RapidHeat™ Pro11 Sterilizer, follow these basic safety precautions:

- Read and understand all instructions.
- Take care to avoid burns resulting from touching hot parts.
- 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.
- Do not let the power cord hang over sharp edges, the edge of a table or counter, or touch hot surfaces.
- 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 for this unit.
- To protect against electrical shock hazard, do not immerse in water or subject the sterilizer to water or other liquids. Do not place any liquid on the top of the sterilizer or in cabinetry above the unit.
- 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.

- 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 90 pounds and is best lifted by two individuals.

3. ACCESSORIES AND CONSUMMABLES

3.1 Accessories

DESCRIPTION	PART NUMBER
RH-Pro11 Instrument Tray	PR0057
Epson TM-U220B Printer with Auto Cutter	400674
Epson TM-U220A Printer with Journal and Auto Cutter	400675
USB Cable A to B Type, 6' Length	400676
3" 1-Ply Printer Paper/case (50 rolls)	400677
Heat-Resistant Gloves	400672

3.2 Consumables (Contact CPAC Equipment for More Information)

DESCRIPTION
RAPIDHEAT PEEL POUCHES
RAPIDHEAT STERILIZATION WRAP
NYLON (TEAR) POUCHES
CHEMICAL INDICATORS
BIOLOGICAL SPORE TEST INDICATORS
BIOLOGICAL SPORE TEST MONITORING SYSTEM
HANDPIECE LUBICANT
PRINTER PAPER KIT

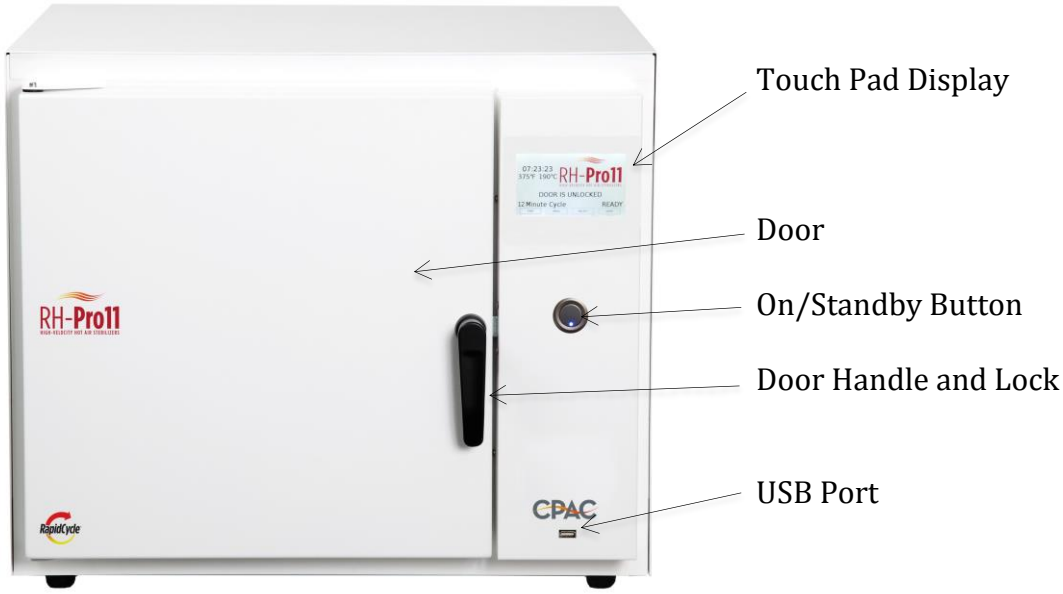
3.3 Included With the Sterilizer

DESCRIPTION
POWER CORD
FOUR (4) LARGE TRAYS
HEAT PROTECTIVE GLOVES (ONE PAIR)
USER MANUAL
OPERATOR QUICK START GUIDE

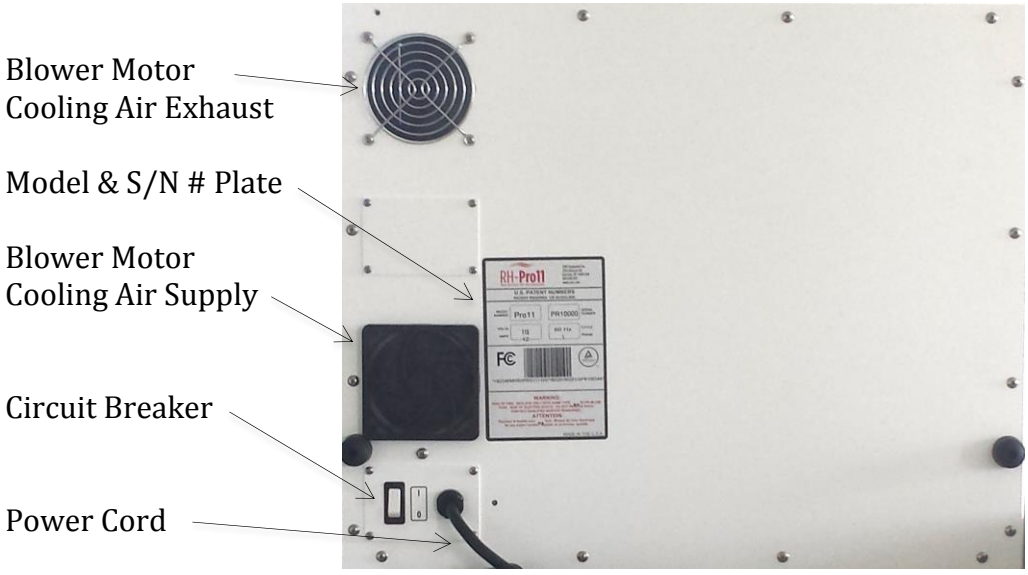
4. COMPONENTS AND CONTROL FUNCTIONS

4.1 Components

FRONT ELEVATION



REAR ELEVATION

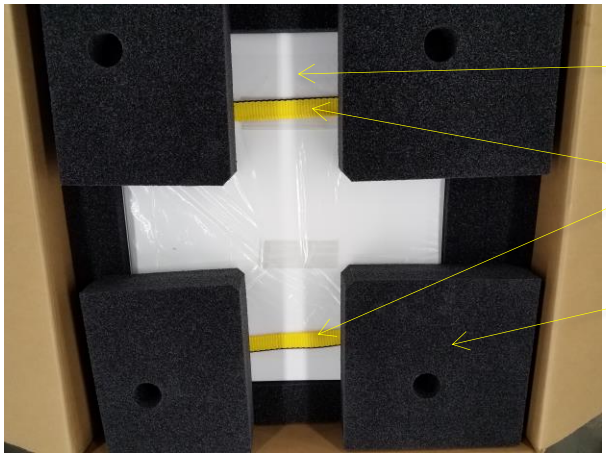


5. INSTALLATION

5.1 Unpacking the Sterilizer

*** DO NOT CUT THE BOX OPEN OR AWAY FROM THE STERILIZER! ***

The RH-Pro11 weighs approximately 95 pounds and with its dimensions, makes the unit difficult to be lifted by one person. To remove from the shipping carton, it is best to remove the top packing cushion and use the (2) two nylon lifting slings (see picture below) encompassing the sterilizer to make lifting the unit out easier. It is recommended that two individuals pair to lift the unit. *Once the unit has been removed from the carton, place the protective cushioning in the carton and store the shipping carton in a safe, dry location should the unit need to be returned for any repairs.*



5.2 Location

- The RH-Pro11 is designed for operation indoors in a protected, relatively dust-free ambient temperature environment at a relative humidity of < 80% up to 88^0F (31^0C).
- Surface Support – Level and of sufficient construction for weight of loaded sterilizer (approximately 100 pounds) and ancillary equipment.

5.3 Sterilizer Dimensions and Required Clearances

- Outer dimension: 22.5" (572mm)W x 25" (625mm)D x 19.5" (492mm)H
- Back of Unit to Back Wall: 3" (75mm)
- Front Support Surface to Front Sterilizer: 1" (25mm)
- Sides of Unit to Side Wall: 3" (75mm) – *See Note below*
- Distance Above the Unit: 3" (75mm)

NOTE: The main power on/off circuit breaker is located at the right rear of the sterilizer. Install the sterilizer with enough clearance to permit reaching past the right side of the sterilizer to operate the switch. This is an infrequent need since there is a front-panel On/Standby button, but the rear panel circuit breaker should remain accessible. About 3.5-4.0 inches of side space is sufficient reach-past for most individuals.

The cooling air supply filter (pictured on page 9) requires occasional rinsing to remove accumulated dust. Installation should include consideration of access to that filter.

5.4 Electrical Requirements

ELECTRICAL WARNING!

For 115 VAC Models: Use 110-120 VAC, 60Hz alternating current only.
For 230 VAC Models: Use 220-240 VAC, 50/60Hz alternating current only.

Failure to do so may result in electrical shock or sterilizer damage.

115 VAC Unit:	110-120 VAC, 12 amp, 60Hz 1400 W warm-up 300 W operating
230 VAC Unit:	220-240 VAC, 6 amp, 50/60Hz 1400 W warm-up 300 W operating
NOTE: The unit must be connected to a properly polarized and grounded receptacle. Always use a power cord with grounding connections that match the receptacles in your location.	

6. OPERATION

6.1 Cautions

WARNING!

HVHA technology is radically different than steam sterilization and conventional practices associated with steam sterilization do not necessarily apply to HVHA technology. Read and employ all safety and operation instructions to maintain employee safety, required treatment efficacy, and equipment efficiency.

WARNING – FIRE OR EXPLOSION HAZARD!

Do not use this sterilizer for sterilizing any liquid, volatile or solid chemical, or radioactive substance. Use this sterilizer only as specified in these user instructions. Ensure that all instruments are dry and free of any organic, chemical, or liquid residue before sterilizing.

WARNING – HOT SURFACES!

The sterilizer's interior, doorway, trays, and the sterilized instruments will be hot. Use heat-protective gloves when touching hot surfaces or objects.

6.2 General Guidelines for Instrument Loading

6.2.1 Instrument and Materials Compatibility

For a high-velocity hot air (HVHA™) sterilizer operating at 375^{0}F, most of today's instruments and their components are constructed of materials that are not subject to damage at this elevated temperature. Standard hand pieces, pliers, and cutters are typically composed of 440-C stainless steel or other high-temperature resistant metals (including solders) and high-temperature materials such as fluoropolymers, polyamide-imides (Torlon), Viton, phenolics, polyimides, and silicones.

WARNING – INSTRUMENT PROTECTION

Before sterilizing instruments in the RH-Pro11, check with the instrument manufacture to ensure material compatibility with the high-temperature process. Always use instrument pouches and wrap compatible with 375^{0}F (191^{0}C).

6.2.2 Cleaning Instruments

- All instruments are to be cleaned, rinsed and dried thoroughly according to manufacturer's instructions. 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.

6.2.3 Loading Instrument Trays 

- The RH-Pro11 is capable of sterilizing unwrapped instruments, unwrapped handpieces, and wrapped instruments.
- Pouches or sterile wrap must be compatible with the higher temperatures used in the RH-Pro11 (375^0F; 190^0C) and must be cleared by the FDA for use in a dry heat environment. It is recommended that the pouches and wrap offered by CPAC Equipment, Inc. be used for assurance of quality.
- Use instrument trays provided with the RH-Pro11 that have been designed to provide required hot airflow from all directions to unwrapped and wrapped/pouched instruments.
- Wrapped or pouched instruments are to be placed flat within the tray, but instruments must not be stacked or have any overlap to provide the airflow necessary for sterilization.
- Instruments or pouches must fit within the tray.
- Trays must be fully inserted into the sterilization chamber to assure full airflow to instruments.

6.2.4 Before Running Your First Sterilization Cycle

- Before turning the sterilizer on, open the door and visually inspect the heating chamber. Clean and wipe as needed with mild soap and a damp cloth or any non-abrasive cleaner. Unit can be externally disinfected with the disinfectant of your choice.
- Check for obstructions to air supply on back panel (clean filter and maintained distance from wall) and interior air exhaust port.
- Check seal around door to ensure it is clean and free of obstructions.
- Close sterilizer door and latch into closed position.
- Start the unit by pressing the on/Standby button and allowing the sterilizer to heat to 375˚F (191˚C) via the “Start-Up” chamber heating sequence. (See 6.3.4.2) The keypad will indicate when the chamber is properly heated (approximately 22 minutes).

6.3 Operation of the RH-Pro11 

6.3.1 High-Velocity Hot Air Sterilization Principles

- The RapidHeat™ Pro11 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 RH-Pro11 sterilizer, airflow moves constantly through the instrument tray from the left to right of the sterilizer chamber.
- Airflow can be restricted by the misplacement of instruments and packaging, which may interfere with the performance of the sterilizer. The three sterilization cycles offered are each unique in their capacity, loading limitations, and restrictions.
- Adherence to these limitations and restrictions is required for assuring performance specifications.
- 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 and pouches that have been demonstrated to be compatible with a temperature of 375˚F can be sterilized in the RH-Pro11 sterilizer.

6.3.2 Pre-set Sterilization Cycles

The RapidHeat™ Pro11 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:

- Unwrapped Instruments;
- Unwrapped Handpieces; and
- Wrapped Instruments.

Note: The conditions presented below for Unwrapped Solid Instruments, Wrapped Handpieces, and Wrapped (Pouched) Solid Instruments have been derived from thermocouple and biological efficacy studies to assure the sterility performance of the sterilizer. It is the responsibility of the operator to adhere to the conditions set below under each cycle setting. Any deviation in the pre-set times, sterilization temperature, maximum

instrument weights per tray or per instrument, or load configuration may jeopardize the efficiency of treatment.

6.3.3 Sterilization Cycles - Capacity Restrictions and Limitations

- **UNWRAPPED INSTRUMENT CYCLE** 

  Unwrapped Instruments Sterilization Instructions

  - To sterilize unwrapped instruments, place them into the instrument tray under the loading and capacity limitations and restrictions noted below for the UNWRAPPED Cycle. Instruments sterilized in the UNWRAPPED Cycle may reach 375˚F by the completion of the cycle.
  - Place the tray into sterilizer by sliding the tray all the way to the rear of the heating chamber using heat-resistant gloves. Close the door ensuring the handle is in the fully closed (vertical) position.
  - Touch Cycle Menu tab on keypad, select UNWRAPPED, and touch to start. Door will lock and sterilization cycle will initiate once the chamber has reached 375˚F.
  - At the end of the cycle, a beep will sound and "Sterilized" will appear on the keypad. The door will unlock for instrument removal.
  - Immediately after opening the door, use heat-resistant gloves to slide the tray out of the chamber. The tray containing the sterilized instruments will remain hot-to-the-touch for approximately 10 minutes.
  - 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.
  - Shut sterilizer door and turn handle to the vertical, or closed position to retain temperature in the sterilizer chamber.

Unwrapped Instruments
• Instrument Weight Limitation Per Tray: 800 g or 1.75 lbs.; Limit 4 Trays
• Single Instrument Weight Should Not Exceed 220 g or 0.5 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

♦ **UNWRAPPED HANDPIECE CYCLE** 

Unwrapped Handpieces Sterilization Instructions

- To sterilize unwrapped handpieces, place them into the instrument tray under the loading and capacity limitations and restrictions noted below for the UNWRAPPED HANDPIECE Cycle. Instruments in the UNWRAPPED HANDPIECE Cycle may reach 375^{0}F by the completion of the cycle.
- Place the tray into sterilizer by sliding the tray all the way to the rear of the heating chamber using heat-resistant gloves. Close the door ensuring the handle is in the fully closed (vertical) position.
- Touch Cycle Menu tab on keypad, select UNWRAPED HANDPIECE, and touch to start. Door will lock and sterilization cycle will initiate once the chamber has reached 375˚F.
- At the end of the cycle, a beep will sound and "Sterilized" will appear on the keypad. The door will unlock for instrument removal.
- Immediately after opening the door, use heat-resistant gloves to slide the tray out of the chamber. The tray containing the sterilized handpieces will remain hot-to-the-touch for approximately 10 minutes.
- 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.
- Shut sterilizer door and turn handle to the CLOSE position to retain chamber temperature.

Unwrapped Handpieces
• Handpiece Weight Limitation Per Tray: 800 g or 1.75 lbs.; Limit 4 Trays
• Single Instrument Weight Should Not Exceed 220 g or 0.5 lbs.
• Handpieces Cannot Overlap or Be Layered, Piled, or Stacked
• Handpieces Must Lay Directly on Tray Bottom

♦ **WRAPPED INSTRUMENT CYCLE** 

Wrapped Instrument Sterilization Instructions

- To sterilize pouched instrument carriers or pouched instruments, place them into the instrument tray under the loading and capacity limitations and restrictions noted below for the WRAPPED INSTRUMENT Cycle. Instruments in the WRAPPED INSTRUMENT Cycle will not exceed 375˚F by the completion of the cycle.
- Place the tray into sterilizer by sliding the tray <u>all the way to the rear</u> of the heating chamber using heat-resistant gloves. Close the door ensuring the handle is in the fully closed (vertical) position.
- Touch Cycle Menu tab on keypad, select WRAPPED INSTRUMENT, and touch to start. Door will lock and sterilization cycle will initiate once the chamber has reached 375˚F.
- At the end of the cycle, a beep will sound and "Sterilized" will appear on the keypad. The door will unlock for instrument removal.
- Immediately after opening the door, use heat-resistant gloves to slide the tray out of the chamber. The tray containing the sterilized instruments will remain hot-to-the-touch for approximately 10 minutes.
- Shut sterilizer door and turn handle to the CLOSE position to retain chamber temperature.

Pouched Instruments Laying Horizontal in Tray
• Instrument Weight Limitation Per Tray: 800 g or 1.75 lbs.; Limit 4 Trays: Limit 160 g (0.35) per Pouch
• Single Instrument Weight Should Not Exceed 140 g or 0.3 lbs.; Limit 4 Trays; Limit 800 g (1.75 lbs.) per Tray
• Pouched Instruments Cannot Overlap or Be Layered, Piled, or Stacked
• Pouched Instruments Must Lay Directly on Tray Bottom

Pouched Handpieces Laying Horizontal in Tray Bottom
• Handpiece Weight Limitation Per Tray: 800 g or 1.75 lbs.; Limit 4 Trays: Limit 160 g (0.35) per Pouch
• Single Instrument Weight Should Not Exceed 140 g or 0.3 lbs.; Limit 4 Trays; Limit 800 g (1.75 lbs.) per Tray
• Pouched Handpieces Cannot Overlap or Be Layered, Piled, or Stacked
• Pouched Handpieces Must Lay Directly on Tray Bottom

Pouched Instruments Carriers Laying Horizontal in Tray
• CPAC 2.5" x 8" Instrument Carrier (With Instruments) Weight Limitation Per Tray: 800 g or 1.75 lbs.; Limit 4 Instrument Carriers per Tray; Limit 4 Trays: Limit 200 g per Pouch
• Single Instrument Weight Should Not Exceed 140 g or 0.3 lbs.; Limit 4 Trays; Limit 800 g (1.75 lbs.) per Tray
• Pouched Instrument Carriers Cannot Overlap or Be Layered, Piled, or Stacked
• Pouched Instrument Carriers Must Lay Directly on Tray Bottom
• Instrument Carriers Must Be Open (No Lid)

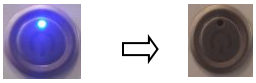
6.3.4 Detailed Cycle Operation

Before turning the sterilizer on, open the door and visually inspect the heating chamber and gasket (Sec. 6.2.4). Close the door, ensuring the handle is in the fully closed (vertical) position.

6.3.4.1 Turning On the RH-Pro11

The On/Standby button will show an illuminated blue LED when electric power is present and the sterilizer is in its "standby" mode.

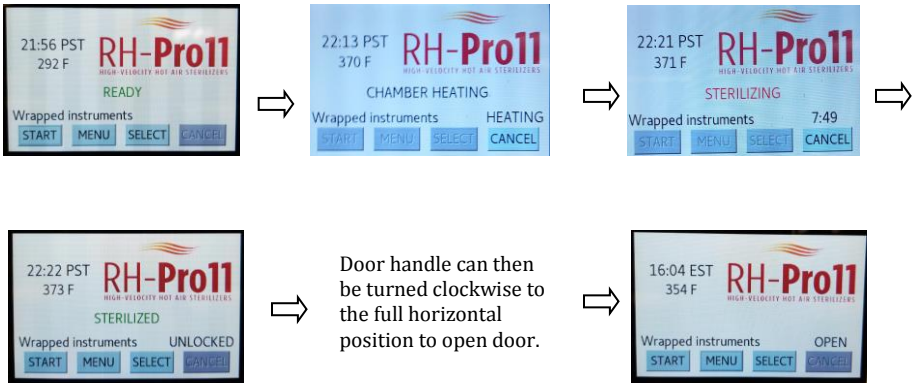
With the door closed and handle in full vertical position, press the On/Standby button to activate the sterilizer. The blue LED in the On/Standby button will go dark after being pressed.



Allowing about 15-20 seconds after pressing the On/Standby button will result in the following screen sequence:

6.3.4.2 "Start-of-Day" Sterilizer Preheating Procedures

At the start of the day the RH-Pro11 will require time to pre-heat the internal metal and insular components that serve as a heat sink to the heated air of the system. "Start-of-Day" sterilizer heating process includes the heating of the chamber to 375°F and holding it through a sterilization cycle (see below). The complete process takes about 22 minutes. Pressing "START" on the "READY" screen initiates the 'cold start' heating sequence as depicted:



Once the "STERILIZED" screen appears, the door is unlocked and is opened by turning the handle clockwise to its full horizontal position. At this point instrument trays may be inserted for sterilization. If no immediate use of the sterilizer is planned, it is best to keep the door closed to minimize temperature loss to the sterilization chamber. The blower and heater will remain on, keeping the sterilization chamber at 350°F. The door may be opened at any time during the "PREHEAT", "STERILIZED-UNLOCKED", or "READY" displays.

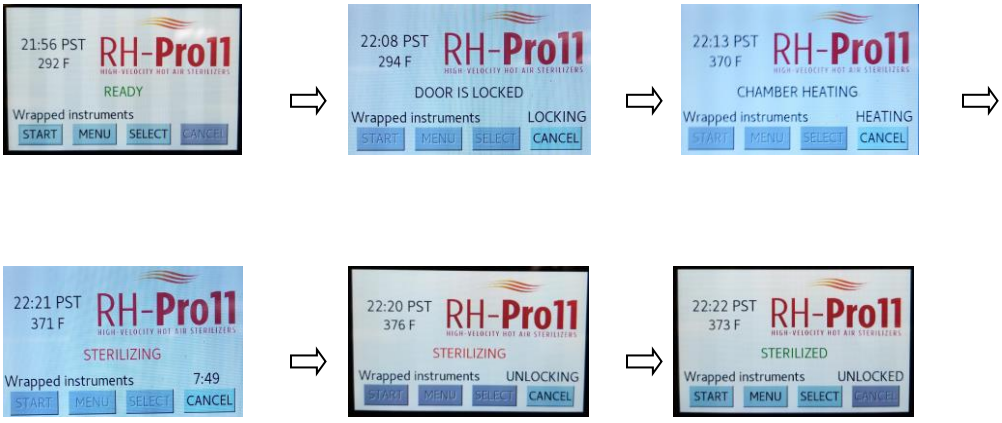
6.3.4.3 Instrument Sterilization Cycle Sequence

Before setting the proper sterilization cycle, see Section 6.3.3 for details in the proper use of each cycle, the load configuration required for each, and instrument packaging and/or loading requirements. The default sterilization cycle is "WRAPPED." To select another cycle press "SELECT" on any screen displaying "READY" or "OPEN" which will give the follow sequence:

Pressing on the selected option or "CANCEL" will return display back to the "READY" screen, which will indicate the sterilization option selected.

Instrument trays may now be loaded into the sterilizer chamber, ensuring that the trays are pushed all the way to the backstop on the tray rails. Once the trays are loaded, close the door and turn handle counterclockwise to its full vertical position. The "READY" screen will be displayed indicating time displayed in 24-hour format and temperature displayed in Fahrenheit or Celsius. The temperature displayed is that of the control thermocouple located at the exhaust screen in the sterilizer chamber. Time and temperature display options appear in the "MENU" descriptions (see below).

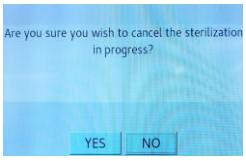
To initiate a sterilization cycle press "START" on the "READY" display will lock the door with the following sequence displayed during the course of chamber heating and instrument sterilization:



The countdown timer is initiated at the start of the sterilization cycle with "UNWRAPPED", "WRAPPED", and "HANDPIECE" cycles of 6, 12, and 8 minutes, respectively once chamber temperature has reached 375°F. At the end of the sterilization cycle, the screen displays "STERILIZED" in green with audible notification and the door is unlocked.

It should be noted that the temperature reading on the display screen is that of the sterilization chamber at the air exhaust port. This temperature reading is the most indicative of the instrument heating process. As air is heated to 375°F by the heaters located in the upper and lower plenums, the air will lose temperature to the instruments as they heat up. The cooling of the chamber is reflective of the "Pre-Heating" process status and is monitored by the thermocouple at the air exhaust port. As the instruments gain heat, they demand less heat from high-velocity air and the temperature of the chamber air gradually increases. At a set maintained temperature the data from the thermocouple initiates the selected pre-set sterilization cycle. This temperature is slightly below 375°F. Readings slightly lower that 375°F are not indicative of the sterilization process and should not be a concern to the operator. This air exhaust port thermocouple also supplies temperature readings to the USB memory and to the printer.

When a "STERILIZING" cycle is in process, the door is in a 'Locked" position and cannot be opened unless "CANCEL" is pressed. "Pressing "CANCEL" results in the following screen sequence:



Pressing 'YES' will unlock the door and terminate the cycle, resulting in the following screen:

The interruption of the sterilization cycle is noted in memory. A new sterilization cycle can be initiated by pressing "START" on the "READY" display.

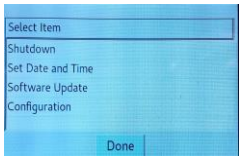
At the completion of sterilization activities the sterilizer may be shutdown by pressing the On/Standby button and holding it for about 5 seconds until the LCD goes dark and the blue LED in the On/Standby button is illuminated.

6.3.5 Menu Set-Up

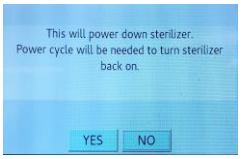
Pressing "MENU" on the "READY"" screen allows the operator to: Shutdown the Sterilizer; Set Time and Date; Upload Software via the USB Port; and Configure Several Settings.

6.3.5.1 Shut Down the Sterilizer Via Menu

As an alternative to shutting down the sterilizer using the On/Standby button or circuit breaker switch, the sterilizer may be turned off via the display screen. Pressing "MENU" on the "READY" screen gives the following display:



Press "Shutdown" ⇨



⇨ Press "YES" to Shut down Sterilizer

Press "YES" to turn off the sterilizer. To restart, press the On/Standby button. The startup sequence in 6.3.4.1 will then initiate.

6.3.5.2 Set Time and Date

To set time and date press "MENU" from "READY" screen to display "SELECT ITEM" screen. Press "SET TIME and DATE" to advance to numerical keypad screen to set time and date.

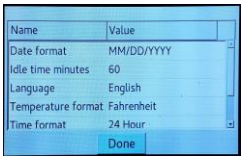
Enter new time and date according to the format at top of screen. Pressing "RST" will restore previous setting. Once new time and date are entered, press "OK" which will lead back to "READY" screen with changes

6.3.5.3 Upload Software Via USB Port

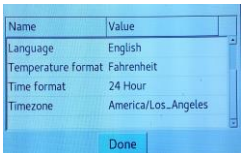
To upload updated software provided CPAC Equipment, Inc. (CEI) via USB flash drive press "MENU" from "READY" screen to display "SELECT ITEM" screen. Press "SOFTWARE UPDATE." Follow loading instructions by CEI-provided with the software.

6.3.5.4 Settings Configuration

To reconfigure several internal settings, press "MENU" from "READY" screen to display "SELECT ITEM, then press "CONFIGURATION." A scrolling menu is provided. A scroll bar on far right of screen will allow advancement through the entirety of the screen as depicted:



and



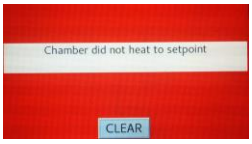
Six formats or operational parameters are presented of which the operator may make changes. Note that none of these operator configurations will affect treatment times and temperatures required of the sterilization process. Press the desired category and follow instructions on the screen for attribute selection. Once the option is selected, the screen reverts to the "CONFIGURATION" listing screen. If no more changes are to be made, press "DONE" to return to "READY" screen.

Of these six all are self-explanatory with the exception of "Idle Time Minutes." Pressing "Idle Time Minutes" allows the operator to set the number of minutes that can elapse between sterilization cycles ("READY" or "STERILIZED" display) before the heater and blowers turn off and the temperature in the sterilization chamber slowly drops from 350°F from to ambient temperature. The screen will remain on and display the following:

Exit from this screen can be accomplished by pressing "START" and initiating a sterilization cycle or by pressing the On/Standby button until the blue light appears, then pressing it again until the light goes off and the sterilizer turns on again.

6.3.6 Error Messages

Error messages are displayed as represented by the following screen for those operations indicating out of conformance with operating specifications:



The following error messages are to assist the operator in diagnosing and correcting any problem that may arise:

Door forced open while locked
Lock failed to operate while locking
Lock failed to operate while unlocking
Power fail during cycle
Ambient too hot 185°F
Ambient too cold 37.4°F
Chamber temperature sensor 1 fail
Chamber temperature sensor 2 fail

Blower temperature sensor failed
Air temperature sensor failed
Return air temperature sensor failed
Chamber too hot 406.4°F
Return air too hot 402.8°F
Return air did not heat to set point
Blower overheat 185.0°F
A/D read failure
Chamber did not heat to set point

7.0 STERILIZATION CYCLE VALIDATION GUIDELINES

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 RH-Pro11.

7.1 Recommended Chemical and Biological Indicators

Biological indicators (i.e. spore test strips) containing *Bacillus atrophaeus* should be used along with the appropriate dry heat chemical indicators to reliably monitor the effectiveness of the RH-Pro-11. Spore test strips and chemical indicators, as well as test services are widely available. CPAC Equipment, Inc. recommends using the following:

- Chemical indicators, supplied by SteriSURE, part. no. 400635
- Spore test strips (*Bacillus atrophaeus*), supplied by SteriSURE, part no. 400634

7.2 Microbial Efficacy Test Protocols

Periodic and routine microbial kill efficacy tests are 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.

1. Prepare a sample test load. The test load should be typical of a normal full load (4 or 6 trays) consisting of instruments normally sterilized during the day.
2. Conduct a pre-check prior to initiation of sterilization cycle (see Appendix I).

3. Prepare the sterilizer, initiate, and trial run the selected sterilization cycle to verify functionality.
4. 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. •For the 6-minute and 8-minute Cycles, layer instruments into the instrument tray with no instrument overlap and place chemical indicator and biological indicator strips under an instrument to secure them in place, taking care not to puncture or tear the outer envelope protecting the biological indicator strip.
   •For the 12-minute Cycle, load the instruments into SteriSURE self-sealing nylon pouches or other CPAC pouches recommended for dry heat and add a chemical indicator and biological indicator strip to the selected test 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.
6. 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.
7. With the sterilizer having already come to operating temperature (375° F; 190° C) via Step 3, place the instrument tray into the sterilizer.
8. Start the sterilization cycle.
9. When the cycle ends, <u>immediately</u> 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 3 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. Indicate that you are using a dry heat process.

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

10. Verify that all chemical indicators changed color. Enter results into the Biological Test Data Manual.
11. 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.
12. Document any other conditions (including any error codes) or observations that may influence results and record them in the Biological Test Data Manual.
13. If conditions occurred during the test trial that have the potential to cause spore test failure, indicate those conditions in the Biological Test Data Manual. Correct those conditions and repeat the test (Steps 3 through 9).

7.3 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. 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" (CDC's *Guideline for Disinfection and Sterilization in Healthcare Facilities,*

2008).

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. Conduct 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.

8.0 MAINTENANCE

- The RH-Pro11 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 a non-bleach disinfectant (preferably quaternary ammonium compound (e.g., Lysol ™).
- At the beginning of each day, check seal around door to ensure it is clean and free of obstructions.
- 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 may be purchased from CPAC Equipment.
- All internal components used in the sterilizer's construction are long life, heavy-duty parts that require no maintenance. See Section 6.3.5 "Error Messages" for a list of potential error messages or see Section 10 "Troubleshooting" for performance symptoms that would indicate the possible need for service. If such an occurrence, call CPAC Equipment at (585) 382-3223 to have the equipment evaluated and shipped back to the factory for repair.

9.0 CYCLE DOCUMENTATION

RH-Pro11 Sterilizer is not designed or capable of Internet/Intranet connectivity, only providing output communication of cycle data to a USB flash drive of 16 Gb or less.

9.1 Data Storage

The RH-Pro11 Sterilizer is capable of downloading cycle data to a POS printer or USB flash drive of 16 Gb or less. The flash drive should be inserted in the USB port located on the lower front side of the sterilizer. While the Pro11 USB jack can provide power for operation of USB memory devices, its design load limit is 200 mA, about 1/10 the output power of a typical USB wall-pluggable charger. The Pro11 USB jack is not intended for use in recharging USB-connectable devices such as cell phones.

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. Although the internal memory of the RH-Pro 11 can store data for

up to 100,000 sterilization cycles, it is recommended that data be downloaded via the USB flash drive daily or weekly and stored on a personal computer or office share drive for easy retrieval, or for printing along with data from the biological and chemical indicator tests.

9.2 Time-Date Setting

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 RH-Pro11 Sterilizer is first used and will need to be updated if the power to the sterilizer is lost for an extended period. Power backup for short power interruptions is provided as part of the timekeeping function. Follow the instructions in Section 6.3.5.2, page 23 “Set Time and Date” to adjust the time settings. The calendar does not handle leap year automatically. The clock does not perform Daylight/Standard time changes automatically.

9.3 Printer

If direct printing is desired, the RH-Pro11has been designed to operate with an Epson TM-U220B having a USB interface and connected by a USB cable. The printer must be connected to the RH-Pro11 USB port, and it must be turned ON, for the printer output to work.

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. Ribbon and paper replacement is detailed in the Epson TM-U220B operating manual.

Epson TM-U220B Printer

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 RH-Pro11 Sterilizer is first used and they will need to be updated if power to the sterilizer is lost. Follow the instructions on page 23, Section 6.3.5.2, “Set

Time and Date", to adjust the time settings. The calendar does not handle Leap Year automatically. The clock does not perform Daylight/Standard time changes automatically.

9.3 STERILIZATION CYCLE LOG FILE

The log file name is mm-dd-yy.TXT, for example, 5.01.19.TXT for a log that is written on May 1, 2019. 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. The printout format is as follows:

```
**********************************
Operator_____________________________
Start Date    - 05/01/2019
Start Time    - 09:53:59PM
Cycle Name - Wrapped
Temp Setting     - 375 F
Time Setting      - 12 min.
Warm-up Delay - 13 min.
Cycle Number    - 083
Serial Number    - 10015

Cycle Phase           Time       Temp (F)
-------------------------------------------------
Warm-up start   09:53:59PM       68
Warm-up end     10:07:05PM     375
 1 min.              10:08:05PM     375
 2 min.              10:09:05PM     375
 3 min.              10:10:05PM     377
 4 min.              10:11:05PM     376
 5 min.              10:12:05PM     376
 6 min.              10:13:05PM     378
 7 min.              10:14:05PM     377
 8 min.              10:15:05PM     377
 9 min.              10:16:05PM     377
 10 min.            10:17:05PM     377
 11 min.            10:18:05PM     377
 12 min.            10:19:05PM     377

 Warm-up time = 13.1 min.
 Exposure time = 12.0 min.
 Total Cycle time = 25.1 min.
 Cycle status = Success
 **********************************
```

10. TROUBLESHOOTING

PROBLEM	POSSIBLE CAUSE	WARN, IND, or ERR	SOLUTIONS
No Power	-Unit unplugged -Breaker Off -No power at outlet -Bad fuse on PCB	IND IND IND IND	-Check outlet -Turn on breaker -Check circuit breaker -Contact Authorized Service Technician
No Display or Grey screen	-Bad LCD -Bad SD Card -Pi PCB not seated	IND IND IND	-Contact Authorized Service Technician
Cycle Interruption	-Power outage -Loss of heat	IND WARN/ERR	-Restart unit -Contact Authorized Service Technician
No Keypad Response	-Bad Pi PCB	IND	-Contact Authorized Service Technician
Door Lock Failure, Locking or Unlocking	-Handle not locked or misaligned	WARN	-Clear Error -Latch handle fully vertical
Chamber Overheating <390^{0}F	-Main PCB or Thermocouple Malfunction	WARN/ERR	-Attempt to Clear -Contact Authorized Service Technician
Chamber Temp not reaching 375^{0}F	-Malfunctioning Heater or Blower	WARN/ERR	-Contact Authorized Service Technician
Temperature Sensor Failure	-Malfunctioning Thermocouple	WARN/ERR	-Contact Authorized Service Technician
Cycle Not Starting	-Temp not reached 375^{0}F -Door not Locked -Heater element malfunction	WARN/ERR IND/WARN WARN/ERR	-See Above -Check seal for debris, Fully latch/Lock door handle -Contact Authorized Service Technician
Circuit Board Overheat	-Clogged Filter -Failed Cooling Fan	IND/WARN WARN/ERR	-Clean or Replace Filter -Contact Authorized Service Technician
Melting Pouches	-Pouches not compatible with 375^{0}F -Pouches Interfering with Chamber Fan -Pouches not Removed Immediately after Cycle Complete	IND/WARN IND/WARN IND/WARN	-Use Steri-Dent Brand Nylon Pouches -Re-align Pouches to Prevent Fan Interference -Promptly Remove Pouches After Cycle Completion
Failing Spore Test	-Improper Instrument Spacing	IND/WARN	-Space Cassettes or Pouches 1” Apart -Do Not Overlap Pouches -See Sec 7.3

	-Torn or Open Biological Indicator Envelope	IND/WARN	-Check Biological Indicator Envelopes for Proper Seals, Cuts, or Tears -See Sec 7.3

11. RH-PRO11 SPECIFICATIONS

SPECIFICATIONS	
Electrical Rating	
RH-Pro11 115 VAC	120 VAC +/- 10%, 60Hz, 12 Amps 1400 Watts warm-up, 300 Watts operating Transient Over-Voltage Category II Applies
RH-Pro11 230 VAC	230 VAC +/- 10%, 50/60Hz, 6 Amps 1400 Watts warm-up, 300 Watts operating Transient Over-Voltage Category II Applies
Dimensions	
Weight (OD)	90 pounds (41 kg)
Width (OD)	22.5" (572mm)
Depth (OD)	22.5" (572mm)
Height (OD)	19.5" (495mm)
Chamber Dimension	11" (279mm) W x 17.75" (433mm) D x 11.75 (299mm) H
Chamber Capacity	2294 cubic inches (10 gal/38 liters)
Instrument Tray (ID)	9" (229mm) W x 15" (381mm) D x 1" (28mm) H
Instrument/Material Compatibility	Check Web Site for List of Compatible Materials and Instruments for RH-PRO11 Sterilization
Sterilization Cycles and Times	
Unwrapped	8 Minute warm-up, 6 Minute cycle; 14 Minutes
Handpieces	8 Minute warm-up, 8 Minute cycle; 16 Minutes
Wrapped/Pouched	9 Minute warm-up, 12 Minute cycle; 21 Minutes
Environmental Operating Conditions (Indoor)	
Temperature Range of 5°C to 40° C (41°F to 104°F)	
Operating Temperature of 375°F (190°C)	
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	
Maximum altitude of 2000 meters (6562 ft.)	
CERTIFICATIONS	
FDA 510(K)	K872643A; K881371
MARKINGS	C US, FC,
PATENTS PENDING	US 62/632,906

12. 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 DISCRETION.

APPENDIX I

STERILIZATION VERIFICATION – MICROBIOLOGICAL INACTIVATION EFFICACY

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, seven to 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]

[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 RH-PRO11 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 left side (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
- ☐ Conduct 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 RH-Pro11 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_____

APPENDIX II

INSTALLATION PROCEDURES AND CONSIDERATIONS FOR CABINET INSTALLS

It is RECOMMENDED that this equipment be countertop installed to obtain the maximum amount of ventilation airflow. A ventilation fan is installed with a user-cleanable filter, described elsewhere in this manual.
The Pro11 has an internal ventilation fan at lower right (viewed from the front) of its rear panel. This fan draws air from the outside, through a ventilation air duct and is discharged through the vent at the upper right of the rear panel. The enclosure ventilation airflow maintains a moderate working temperature of the Pro11's internal blower motor, and helps cool the control panel circuit boards.
The other significant item on the Pro11 rear panel is a switch which controls main power and provides an overcurrent protection circuit breaker for the Pro11.

The main considerations for installation of the Pro11 are:

- Access for inspection and cleaning of the ventilation air filter.
- Access for operation of the main power switch.
- Clearance for entry and exit of Pro11 ventilation air.

If your installation presents a question, please contact us.

CABINET INSTALLATION OPTIONS AND PRECAUTIONS

If considering a cabinet installation, the following options are recommended. Regardless of the option, always maintain 4" or greater clearance at the back of the unit for proper airflow and cooling. The power cord must always be free to extend forward when moving the sterilizer to access the air filter and power breaker.

Recommended clearance dimensions if installed in a cabinet with no pullout:

- Top: 3" inches, for air motion.
- Rear: 4+" inches, for ventilation & airflow into/out of the Pro11 enclosure.
- Left side: No clearance required for airflow. Consider space for the door arc.
- Right side: 4" for air flow, access to filter and main power switch.
- If ventilation is not sufficient, consider removing the shelf back panel and cutting vent holes in right side panel of the alcove shelf
- See Fig. 1

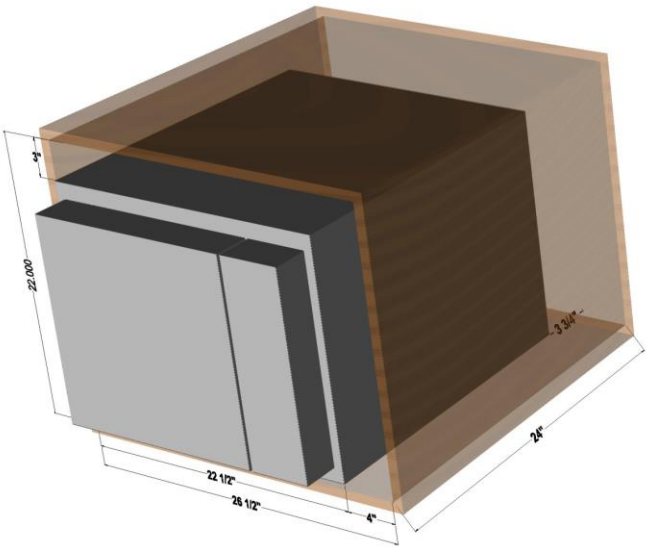


Fig. 1, Alcove installation with no pullout shelf:

Recommended clearance dimensions if installed in a cabinet with a pullout:

- If a closed back, recommend clearance the same as no pullout installation as shown in Fig. 1 above. Simplifies access for filter and switch; still need airflow ventilation
- If open back, ½" clearance needed top & sides; need to access filter and power switch with pullout fully extended.
- Power cord must be free to extend and retract when pullout moved
- See Fig. 2

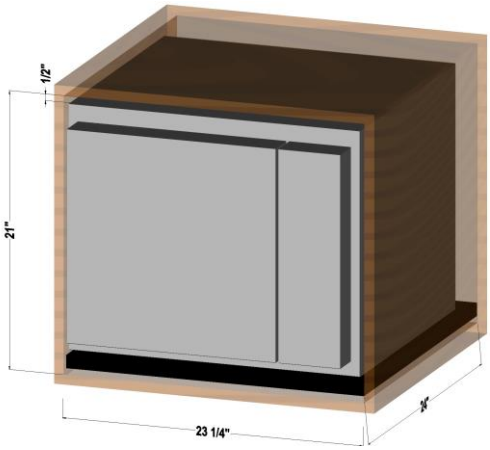


Fig. 2A, Pullout enclosure

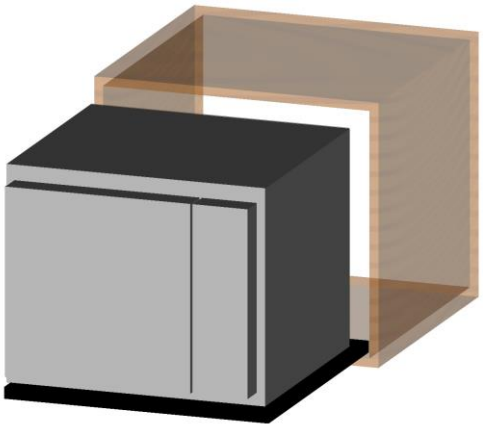


Fig. 2B, Pullout fully Extended